SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

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DEP: 2020 DIRECCION DE NUEVAS CREACIONES **EVE:** 378 FASE NACIONAL INCLUIDO CAPITULO I
TRA: 11 PCT-PATENTE DE INVENCION CAPITULOS I Y II **FOLIOS**: 13
ACT: 519 TRASLADOINFORME

DIRECCIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogado(a)/Señor(a)
SILVANA MARÍA LÓPEZ DÍAZ

Asunto: Radicación: 14-94083- -4
Trámite: 11
Evento: 378
Actuación: 519
Oficio: 7300
Folios: 13

Patente de Invención	**X**			Patente de Modelo de Utilidad	
Vía Nacional					
Vía PCT (Fase Nacional)	**X**	Capítulo I	**X**	Capítulo II	
No. Solicitud Internacional	PCT/US2012/062078				
Fecha de Presentación Internacional	26/10/2012				

Como resultado del examen de fondo realizado, con fundamento en el Artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se comunica:

1. Documentos estudiados

Descripción:	Rad. N° 14-094083-00000-0000	02Mayo/2015
Reivindicaciones:	Rad. N° 14-094083-00000-0000	02/Mayo/2015
Dibujos:	Rad. N° 14-094083-00000-0000	02/Mayo/2015
Prioridades:	US 13/288,529	03/Noviembre/2011
	US 13/547,650	12/Julio/2012

2. Análisis de la Prioridad

Se acepta la reivindicación de prioridad porque ésta solicitud fue presentada dentro del plazo establecido (Art. 9 D 486) y su contenido técnico corresponde con el de la prioridad reivindicada.

3. Objeto de la invención

De acuerdo con lo establecido en el numeral 1.2.2.2 del Capítulo Primero del Título X de la Circular Única para efectos del examen de patentabilidad, se tendrá en cuenta la tasa pagada por el solicitante al momento de comenzar el examen para las reivindicaciones

adicionales; esto es que cuando la solicitud contenga más de diez (10) reivindicaciones y no se haya pagado la tasa complementaria, sólo se estudiarán las cubiertas por la tasa pagada. Por lo tanto, se estudiaran las reivindicaciones 1 a 45.

Título de la solicitud: “Jeringa Equipada con tapa antiséptica” (Fl. 1).

El problema planteado en esta solicitud, consiste en una jeringa que permita mejorar la seguridad y eficacia de los procedimientos de bloqueo de catéter y de atención general a los pacientes, reduciendo la incidencia de infecciones.

Para resolver este problema técnico, la solicitud en estudio propone una combinación de tapa y jeringa antiséptica que comprende un montaje de soporte de tapa y un embolo de jeringa.

El objeto de la presente solicitud se relaciona con la Clasificación Internacional de Patentes (CIP): A 61 M 5/178.

4. Reivindicaciones relativas a un uso o a un segundo uso (Art 14 y 21 D 486)

Las reivindicaciones 17, 20, 30, 31 y 33 mencionan que un material absorbente sostiene un líquido antiséptico y que la tapa incluye un recubrimiento antiséptico, lo cual hace referencia a la forma de utilizar el producto reclamado, toda vez que el líquido y el recubrimiento no hacen parte estructural integral de la tapa antiséptica. Por lo tanto, esta oficina considera que dicho líquido y dicho recubrimiento son un objeto ajeno al objeto que en la solicitud actualmente estudiada se quiere reclamar.

Adicionalmente, el líquido antiséptico y el recubrimiento antiséptico son compuestos químico y solo podrían reclamarse si están caracterizados por su fórmula estructural o IUPAC, junto con la definición de sus sustituyentes.

De acuerdo con todo lo anterior, se sugiere al solicitante eliminar el líquido y el recubrimiento en mención de las reivindicaciones.

5. De la solicitud de patente

Reivindicaciones (Art 30 D 486, Art 22 PCT)

Las reivindicaciones no son claras porque:

- Las expresiones: *“…que proporciona acceso a la cámara.”* (reivindicación 1), *“…para utilizar el montaje de soporte de tapa al eliminar la cubierta del montaje de soporte de tapa.”* (reivindicación 8), *“…para ubicar la tapa antiséptica sobre el sitio de acceso...”*, *“…para retirar la tapa antiséptica desde el soporte de tapa.”* (reivindicación 9), *“…para mover una protuberancia del soporte de tapa fuera de una primera ranura en nervaduras separadas circunferencialmente en la cámara de embolo.”* (reivindicación 10), *“…para actuar en conjunto con una pluralidad de nervaduras (…) y la tapa antiséptica.”* (reivindicación 13), *“…que sostiene un líquido antiséptico.” (reivindicación 17), “…para recibir de forma liberable la conexión de punto de acceso de la jeringa…”, “…para recibir de forma removible un segundo montaje de la tapa antiséptica.”*

(reivindicación 27), *"…para actuar en conjunto con una pluralidad de nervaduras sobre el segundo montaje de tapa antiséptica para evitar el movimiento rotacional relativo entre la cámara distal y el segundo montaje de tapa antiséptica."* (reivindicación 28), *"…que sostiene una sustancia antiséptica…"* (reivindicación 30), *"…para enganchar el punto de acceso…", "…para recibir de forma removible una tapa antiséptica."* (reivindicación 32), *"…para recibir la proyección distal de la tapa de punta en un extremo y la tapa antiséptica en el otro extremo."* (reivindicación 34), *"…para enganchar de forma removible la tapa de punta."* (reivindicación 36); describen funciones, efectos, ventajas o resultados a alcanzar, los cuales no son aspectos susceptibles de patente. Para mayor claridad, el producto reclamado se debe definir técnicamente mediante sus características estructurales. Se sugiere al solicitante eliminar la reivindicación y las expresiones citadas.

- Los términos: *"por lo menos", "pluralidad"* y *"sustancialmente"* (reivindicaciones 1, 2, 3, 4, 5, 13, 16, 22, 23 y 28), son imprecisos, por lo cual no permiten distinguir la invención del estado de la técnica. Se sugiere al solicitante eliminarlos de las reivindicaciones.

- A pesar de que los materiales absorbentes a base de fibra son ampliamente conocidos en el estado de la técnica[1]. No es claro el término de *"fibra unida"*. En consecuencia, se considera que la reivindicación 18 es de carácter general y no contiene información suficiente como para comprender la invención.

- Las reivindicaciones 35 y 37 no son claras ya que mencionan un ala, pero no se especifica donde, como es dispuesta dicha ala, o como ésta interactuar con los demás elementos de la invención, en ningún aparte de la solicitud (descripción y dibujos).

- Las expresiones: *"primera geometría"* y *"segunda geometría"* de la reivindicación 39 se consideran de carácter general, ya que no se especifica cómo están configuradas estas geometrías. En otras palabras, las expresiones citadas no permiten comprender la configuración del dispositivo reclamado. Se sugiere al solicitante eliminar esta reivindicación.

6. Determinación del Estado de la Técnica

El estado de la técnica se determinó con base en la fecha de presentación de la solicitud de prioridad: noviembre 03 de 2011, y se encontraron los siguientes documentos que anticipan el objeto de esta solicitud:

Ítem	Documento	Título	Fecha de Publicación
D1	WO 2009/002474	'Antiseptic cap with thread cover'	31/Diciembre/2008
D2	US 5'624.402	'Syringe tip cap'	29/Abril/1997
D3	US 2009/0062766	'Sterility – Protecting caps with fluid reservoir for separated connectors'	05/Marzo/2009
D4	US 5'059.172	'Syringe with two part mastitis cannula cap'	22/Octubre/1991
D5	US 8'038.656	'Detachable plunger rod syringe'	18/Octubre/2011

1 http://tecnologiadelosplasticos.blogspot.com/2013/01/polimeros-super-absorbentes.html

El documento D1[2] divulga un ensamble de jeringa (10) que incluye un barril de jeringa (14) que define una cámara (18), un embolo (12) montado en la cámara (18) y movible respecto al barril y un montaje de tapa (80) que contiene una tapa (82) (resumen).

El documento D2[3] divulga una tapa de punta para sellar la punta del barril de una jeringa (resumen).

El documento D3[4] divulga un par de tapas encajables, cada uno estando dimensionada y conformada para proveer una unión de protección en un conector medico (resumen).

El documento D4[5] divulga una tapa para jeringa de dos partes que comprende una tapa exterior y una capa interior (resumen).

El documento D5[6] divulga una varilla de embolo para su uso en un barril de jeringa que incluye una varilla deslizable y que se dispone dentro del barril de la jeringa (resumen).

7. **Examen de Patentabilidad** (Art 14 D486)

Novedad (Art 16 D486)

La reivindicación 1 consiste en: "*Una combinación de tapa y jeringa antiséptica que comprende: un montaje de soporte de tapa que comprende una tapa antiséptica...*" (Ver página 96 del radicado Nº 14-094083-00000-0000).

Comparación de las características técnicas esenciales, con las del estado de la técnica:

Características esenciales	D1
Combinación de tapa y jeringa que comprende:	Combinación de tapa y jeringa que comprende:
Un montaje de soporte de tapa que comprende una tapa antiséptica dispuesta en un soporte de tapa y encerrada allí por una cubierta.	Un montaje de soporte de tapa que comprende una tapa antiséptica (404) dispuesta en un soporte de tapa (402) y encerrada allí por una cubierta (Figs. 53 a 61).
Un embolo de jeringa que tiene una cámara en un extremo próximo.	Un ensamble de embolo (12) que comprende un cámara (60) (Fig. 53; Pág. 10, líneas 9 a 13).
La cámara definida por una pared lateral que tiene un extremo próximo periférico que define una abertura, y un fondo distal, y en donde un borde interior en la pared lateral y el fondo define una	La cámara (60) está localizada en el extremo proximal (42) del embolo (12) y tiene una pared (62) definiendo una cámara (64) teniendo un extremo abierto (66). Un borde interior en la pared

2 https://www.google.ca/patents/WO2009002474A1?cl=en&dq=wo2009002474&hl=es&sa=X&ved=0CB0Q6AEwAGoVChMIjcrMn4aVxgIVhkCMCh20SQGY

3 https://docs.google.com/viewer?url=patentimages.storage.googleapis.com/pdfs/US5624402.pdf

4 https://docs.google.com/viewer?url=patentimages.storage.googleapis.com/pdfs/US20090062766.pdf

5 https://www.google.ca/patents/US5059172?dq=5059172&hl=es&sa=X&ved=0CBwQ6AEwAGoVChMIoY_2je2WxgIVBC2MCh0DFASG

6 https://www.google.ca/patents/US8038656?dq=8038656&hl=es&sa=X&ei=D4KBVZnmIoiAsQS574DYDw&ved=0CB0Q6AEwAA

abertura.	lateral y el fondo define una abertura (Fig. 53; Pág. 10, líneas 9 a 13).

De acuerdo con la tabla anterior, las características esenciales de la composición de la reivindicación 1 habían sido divulgadas previamente en el documento D1, por lo tanto, la materia reivindicada no es nueva.

Asimismo, el documento D1 divulga las características de las reivindicaciones dependientes así:

- Reivindicación 2: Una pluralidad de nervaduras (100) en la superficie interior (63) de la pared lateral de la carcasa (62) (Pág. 12, líneas 5 a 11).

- Reivindicación 3: el soporte de tapa comprende una protuberancia (440) en una superficie externa del soporte de tapa, y la pluralidad de nervaduras separadas circunferencialmente comprenden por lo menos una ranura para recibir de forma removible la protuberancia (Fig. 53).

La reivindicación 12 consiste en: "*Una combinación de tapa y jeringa antiséptica que comprende: un barril de jeringa que tiene una conexión de punto de acceso...*" (Ver página 99 del radicado Nº 14-094083-00000-0000).

Comparación de las características técnicas esenciales, con las del estado de la técnica:

Características esenciales	**D2**	**D3**
Combinación de tapa y jeringa que comprende:	Tapa de punta de jeringa caracterizada por:	Tapa de esterilización con reservorio de fluido para conectores separados caracterizada por:
Un barril de jeringa que tiene una conexión de punto de acceso.	Un barril de jeringa (12) que tiene una conexión de punto de acceso (22) (Fig. 1).	Un barril de jeringa que tiene una conexión de punto de acceso (278) (Fig. 15).
Una tapa de punta que tiene una cámara próxima y una cámara distal, la cámara próxima que recibe y engancha de forma removible la conexión de punto de acceso de la jeringa, la cámara distal recibe y engancha de forma removible una tapa antiséptica.	Una tapa de punta (54) que tiene una cámara próxima (44) y una cámara distal (58), la cámara próxima que recibe y engancha de forma removible la conexión de punto de acceso de la jeringa, la cámara distal recibe y engancha de forma removible una tapa antiséptica (56) (Fig. 1).	Una tapa de punta (216) que tiene una cámara próxima y una cámara distal, la cámara próxima que recibe y engancha de forma removible la conexión de punto de acceso de la jeringa, la cámara distal recibe y engancha de forma removible una tapa antiséptica (264) (Figs. 14 y 15).

De acuerdo con la tabla anterior, las características esenciales de la composición de la reivindicación 12 habían sido divulgadas previamente en los documentos D2 y D3, por lo tanto, la materia reivindicada no es nueva.

Asimismo, los documentos antecedentes divulgan las características de las reivindicaciones dependientes así:

- Reivindicación 13: Nervaduras anti-rotación (68) y (78) (D1: Col. 6, líneas 18 y 19).
- Reivindicación 14: Medios de agarre sobre la pared lateral externa de la tapa de punta (D1: Figs. 1 y 2).
- Reivindicación 15: La tapa de punta incluye una pared lateral cónica - cilíndrica (D1: Fig. 1).
- Reivindicación 16: La cámara distal de la tapa de punta incluye un extremo abierto y una pared de base sustancialmente plana que cierra el extremo abierto (D2: Fig. 14).
- Reivindicación 17: La tapa puede contener material absorbente (D2: Párr. [0014]).
- Reivindicación 20: la cámara distal y la tapa antiséptica tienen una geometría coincidente (D1: Figs. 1 y 2; D2: Fig. 14).

La reivindicación 21 consiste en: "*Una combinación de tapa de punta y tapa antiséptica de jeringa que comprende: una primera cámara que tiene medios para enganchar...*" (Ver página 100 del radicado Nº 14-094083-00000-0000).

Comparación de las características técnicas esenciales, con las del estado de la técnica:

Características esenciales	**D2**	**D3**
Combinación de tapa de punta y tapa antiséptica caracterizada por:	Tapa de punta de jeringa caracterizada por:	Tapa de esterilización con reservorio de fluido para conectores separados caracterizada por:
Una primera cámara que tiene medios para enganchar de forma liberable una conexión de punto de acceso en una jeringa.	Una primera cámara que tiene medios para enganchar de forma liberable una conexión de punto de acceso en una jeringa (Fig. 8).	Una primera cámara que tiene medios para enganchar de forma liberable una conexión de punto de acceso en una jeringa (Figs. 14 y 15).
Una segunda cámara formada integralmente con la primera cámara.	Una segunda cámara formada integralmente con la primera cámara (Fig. 8).	Una segunda cámara formada integralmente con la primera cámara (Fig. 14).
Una tapa antiséptica ubicada dentro de la segunda cámara.	Una tapa antiséptica (56) ubicada dentro de la segunda cámara (Fig. 8)	Una tapa antiséptica ubicada dentro de la segunda cámara (Fig. 14)
Medios para enganchar de forma liberable la tapa antiséptica en la segunda cámara.	Medios para enganchar de forma liberable la tapa antiséptica (56) en la segunda cámara (Fig. 8).	Medios para enganchar de forma liberable la tapa antiséptica en la segunda cámara (Fig. 14).

De acuerdo con la tabla anterior, las características esenciales de la composición de la reivindicación 21 habían sido divulgadas previamente en los documentos D2 y D3, por lo tanto, la materia reivindicada no es nueva.

Asimismo, los documentos antecedentes divulgan las características de las reivindicaciones dependientes así:

- Reivindicación 22: los medios para enganchar de forma liberable una conexión de punto de acceso en una jeringa comprenden una pared lateral generalmente cilíndrica que tiene un extremo abierto y una pared de base plana que cierra el extremo abierto (D2: Fig. 8; D3: Fig. 14).

- Reivindicación 23: Nervaduras anti-rotación (68) y (78) (D2: Col. 6, líneas 18 y 19).

- Reivindicación 24: La primera cámara y la segunda cámara comparten una pared lateral generalmente cilíndrica (D2: Fig. 8; D3: Fig. 14).

Nivel inventivo (Art18 D486)

La reivindicación 27 consiste en: *"Una combinación de tapa y jeringa antiséptica que comprende: un barril de jeringa que tiene una conexión de punto de acceso..."* (Ver página 102 del radicado Nº 14-094083-00000-0000).

Comparación de las características técnicas esenciales, con las del estado de la técnica:

Características esenciales	D1	D2
Una combinación de tapa y jeringa antiséptica que comprende:	Una combinación de tapa y jeringa antiséptica que comprende:	Tapa de punta de jeringa caracterizada por:
Un barril de jeringa que tiene una conexión de punto de acceso.	Un barril de jeringa (14) que tiene una conexión de punto de acceso (Fig. 1).	Un barril de jeringa (12) que tiene una conexión de punto de acceso (22) (Fig. 1).
Un embolo recibido en un extremo por el barril, el embolo tiene una cámara que se recibe de forma removible a un primer montaje de tapa antiséptica en un segundo extremo.	Un ensamble de embolo (12) que comprende un cámara (60) La cámara (60) está localizada en el extremo proximal (42) del embolo (12) y tiene una pared (62) definiendo una cámara (64) teniendo un extremo abierto (66). Un borde interior en la pared lateral y el fondo define una abertura. Un ensamble de tapa (80) en la cámara (64) (Fig. 53; Pág. 10, líneas 9 a 15).	No menciona.
Una tapa de punta que tiene una cámara próxima para recibir de forma liberable la conexión de punto de acceso de la jeringa, y una cámara distal para recibir de forma removible un segundo montaje de tapa antiséptica.	No menciona.	Una tapa de punta (54) que tiene una cámara próxima (44) y una cámara distal (58), la cámara próxima que recibe y engancha de forma removible la conexión de punto de acceso de la jeringa, la cámara distal recibe y engancha de forma removible una tapa antiséptica (56) (Fig. 1).

Los documentos D1 y D2 se consideran el estado de la técnica cercano a la invención definida en la reivindicación 27 porque divulgan una combinación de tapa y jeringa antiséptica y una tapa de punta de jeringa.

La diferencia entre la invención, definida en la reivindicación 27 y la combinación de tapa y jeringa de D1 consiste en una tapa de punta que tiene una cámara próxima para recibir de forma liberable la conexión de punto de acceso de la jeringa, y una cámara distal para recibir de forma removible un segundo montaje de tapa antiséptica.

La diferencia entre la invención, definida en la reivindicación 27 y la tapa de punta de jeringa de D2 consiste en una cámara en el embolo que se recibe de forma removible a un primer montaje de tapa antiséptica en un segundo extremo.

El efecto que logra el incluir una tapa de punta que tiene una cámara próxima para recibir de forma liberable la conexión de punto de acceso de la jeringa, y una cámara distal para recibir de forma removible un segundo montaje de tapa antiséptica es que previene la contaminación del contenido de la jeringa, así como también la jeringa como tal.

Por lo tanto, el problema técnico objetivo que pretende resolver esta invención se puede formular así: “cómo modificar la combinación de tapa y jeringa conocida en D1 prevenir la contaminación del contenido de la jeringa, así como también la jeringa como tal”.

Sin embargo, una tapa de punta que tiene una cámara próxima para recibir de forma liberable la conexión de punto de acceso de la jeringa, y una cámara distal para recibir de forma removible un segundo montaje de tapa antiséptica para prevenir la contaminación del contenido de la jeringa, así como también la jeringa como tal, ya está divulgada en el documento D2 que se refiere a una tapa de punta (54) que tiene una cámara próxima (44) y una cámara distal (58), la cámara próxima que recibe y engancha de forma removible la conexión de punto de acceso de la jeringa, la cámara distal recibe y engancha de forma removible una tapa antiséptica (56) (Fig. 1).

En consecuencia, la persona del oficio normalmente versada en la materia, incluiría una tapa de punta (54) que tiene una cámara próxima (44) y una cámara distal (58), la cámara próxima que recibe y engancha de forma removible la conexión de punto de acceso de la jeringa, la cámara distal recibe y engancha de forma removible una tapa antiséptica (56) del documento D2 en la combinación divulgada en el documento D1 para llegar así al objeto de la reivindicación 27 de la solicitud. Por lo cual se considera obvia.

Asimismo, los documentos antecedentes divulgan las características de las reivindicaciones dependientes así:

- Reivindicación 28: Una pluralidad de nervaduras (100) en la superficie interior (63) de la pared lateral de la carcasa (62) (D1: Pág. 12, líneas 5 a 11). Nervaduras anti-rotación (68) y (78) (D2: Col. 6, líneas 18 y 19).

- Reivindicación 29: Un embolo que comprende una cámara (64), un ensamble de tapa (80) en la cámara (64) (D1:Fig. 53; Pág. 10, líneas 9 a 15). Una tapa de punta (54) que tiene una cámara distal (58), que recibe y engancha de forma removible una tapa antiséptica (56) (D2: Fig. 1).

- Reivindicación 30: Una tapa (80) que comprende una cámara (84) que contiene una esponja 86 (D1: Pág. 10, líneas 14 a 20).

La reivindicación 32 consiste en: *"Una combinación de tapa y jeringa antiséptica que comprende: un barril de jeringa que tiene una conexión de punto de acceso..."* (Ver página 103 del radicado Nº 14-094083-00000-0000).

Comparación de las características técnicas esenciales, con las del estado de la técnica:

Características esenciales	**D2**	**D4**
Una combinación de tapa y jeringa antiséptica que comprende:	Tapa de punta de jeringa caracterizada por:	Jeringa con tapa de dos partes caracterizada por:
Un barril de jeringa que tiene una conexión de punto de acceso.	Un barril de jeringa (12) que tiene una conexión de punto de acceso (22) (Fig. 1).	Un barril de jeringa (16) que tiene una conexión de punto de acceso (22) (Fig. 1).
Un anillo flexible para enganchar el punto de acceso.	No menciona.	Un anillo flexible (54) para enganchar el punto de acceso (Col. 6, líneas 5 a 7).
Una cámara interconectada con el anillo flexible para recibir de forma removible una tapa antiséptica.	Una tapa de punta (54) que tiene una cámara próxima (44) y una cámara distal (58), la cámara próxima que recibe y engancha de forma removible la conexión de punto de acceso de la jeringa, la cámara distal recibe y engancha de forma removible una tapa antiséptica (56) (Fig. 1).	No menciona.

Los documentos D2 y D4 se consideran el estado de la técnica cercano a la invención definida en la reivindicación 32 porque divulgan una tapa de punta de jeringa y una jeringa con tapa de dos partes.

La diferencia entre la invención, definida en la reivindicación 32 y la tapa de punta de D1 consiste en un anillo flexible para enganchar el punto de acceso.

La diferencia entre la invención, definida en la reivindicación 32 y la jeringa de D4 consiste en una cámara interconectada con el anillo flexible para recibir de forma removible una tapa antiséptica.

El efecto que logra el incluir un anillo flexible para enganchar el punto de acceso es que permite un fácil enganche y un desenganche de la tapa del barril de la jeringa.

Por lo tanto, el problema técnico objetivo que pretende resolver esta invención se puede formular así: "cómo modificar la tapa de punta conocida en D2 para permitir un fácil enganche y un desenganche de la tapa del barril de la jeringa".

Sin embargo, un anillo flexible para enganchar el punto de acceso para permitir un fácil enganche y un desenganche de la tapa del barril de la jeringa, ya está divulgada en el documento D4 que se refiere a Un anillo flexible (54) para enganchar el punto de acceso (Col. 6, líneas 5 a 7).

En consecuencia, la persona del oficio normalmente versada en la materia, incluiría un anillo flexible (54) para enganchar el punto de acceso del documento D4 en la tapa de punta divulgada en el documento D2 para llegar así al objeto de la reivindicación 32 de la solicitud. Por lo cual se considera obvia.

Asimismo, los documentos antecedentes divulgan las características de las reivindicaciones dependientes así:

- Reivindicación 28: Una pluralidad de nervaduras (100) en la superficie interior (63) de la pared lateral de la carcasa (62) (D2: Pág. 12, líneas 5 a 11). Nervaduras anti-rotación (68) y (78) (D4: Col. 6, líneas 18 y 19).

- Reivindicación 29: Un embolo que comprende una cámara (64), un ensamble de tapa (80) en la cámara (64) (D2: Fig. 53; Pág. 10, líneas 9 a 15). Una tapa de punta (54) que tiene una cámara distal (58), que recibe y engancha de forma removible una tapa antiséptica (56) (D4: Fig. 1).

- Reivindicación 30: Una tapa (80) que comprende una cámara (84) que contiene una esponja 86 (D1: Pág. 10, líneas 14 a 20).

En cuanto a las reivindicaciones dependientes 5 y 6 se tiene:

Reivindicaciones	Características esenciales	D1	D5
Reivindicación 1	Combinación de tapa y jeringa que comprende:	Combinación de tapa y jeringa que comprende:	Varilla de embolo des-ensamblable de jeringa caracterizada por:
	Un montaje de soporte de tapa que comprende una tapa antiséptica dispuesta en un soporte de tapa y encerrada allí por una cubierta.	Un montaje de soporte de tapa que comprende una tapa antiséptica (404) dispuesta en un soporte de tapa (402) y encerrada allí por una cubierta (Figs. 53 a 61).	No menciona.
	Un embolo de jeringa que tiene una cámara en un extremo próximo.	Un ensamble de embolo (12) que comprende un cámara (60) (Fig. 53; Pág. 10, líneas 9 a 13).	
	La cámara definida por una pared lateral que tiene un extremo próximo periférico que define una abertura, y un fondo distal, y en donde un borde interior en la pared lateral y el fondo define una abertura.	La cámara (60) está localizada en el extremo proximal (42) del embolo (12) y tiene una pared (62) definiendo una cámara (64) teniendo un extremo abierto (66). Un borde interior en la pared lateral y el fondo define una abertura (Fig. 53; Pág. 10, líneas 9 a 13).	
Reivindicación 5.	Embolo con una pluralidad	Embolo con una pluralidad de	Embolo con una pluralidad

	de paredes de soporte que se extienden longitudinalmente.	paredes de soporte que se extienden longitudinalmente (Fig. 5).	de paredes de soporte que se extienden longitudinalmente (Fig. 1).
	Una o más paredes de soporte tienen un área con cavidad que se extiende longitudinalmente a lo largo de un borde periférico de la misma.	No menciona.	Una o más paredes de soporte tienen un área con cavidad que se extiende longitudinalmente a lo largo de un borde periférico de la misma (Fig. 14)
Reivindicación 6.	Un primer grupo de paredes de soporte en una porción distal del émbolo, y un segundo grupo de paredes de soporte en una porción próximo del embolo.		Un primer grupo de paredes de soporte en una porción distal del émbolo, y un segundo grupo de paredes de soporte en una porción próximo del embolo (Fig. 14).

Los documentos D1 y Dr5se consideran el estado de la técnica cercano a la invención definida en las reivindicaciones 1, 5 y 6 porque divulgan una combinación de tapa y jeringa y una varilla de embolo des-ensamblable de jeringa.

La diferencia entre la invención, definida en las reivindicaciones 1, 5 y 6 y la combinación de tapa y jeringa de D1 consiste en una o más paredes de soporte tienen un área con cavidad que se extiende longitudinalmente a lo largo de un borde periférico de la misma. Un primer grupo de paredes de soporte en una porción distal del émbolo, y un segundo grupo de paredes de soporte en una porción próximo del embolo.

La diferencia entre la invención, definida en las reivindicaciones 1, 5 y 6 y la varilla de jeringa de D5 consiste en el montaje de tapa y la cámara del embolo para recibir dicho montaje.

El efecto que logra el incluir las paredes soportes con su cavidad y los dos grupos de las paredes soporte es que proporciona rigidez al émbolo.

Por lo tanto, el problema técnico objetivo que pretende resolver esta invención se puede formular así: “cómo modificar la combinación de tapa y jeringa de punta conocida en D1 para proporcionar rigidez al émbolo”.

Sin embargo, las paredes soportes con su cavidad y los dos grupos de las paredes soporte, ya está divulgada en el documento D5 que se refiere a un primer grupo de paredes de soporte en una porción distal del émbolo, y un segundo grupo de paredes de soporte en una porción próximo del embolo (Fig. 14).

En consecuencia, la persona del oficio normalmente versada en la materia, incluiría Un primer grupo de paredes de soporte en una porción distal del émbolo, y un segundo grupo de paredes de soporte en una porción próximo del embolo del documento D5 en la combinación de tapa y jeringa divulgada en el documento D1 para llegar así al objeto de las reivindicaciones 1, 5 y 6 de la solicitud. Por lo cual se consideran obvias.

Las reivindicaciones 18, 35, 37 y 39 fueron afectadas los numerales 4 y 5 de la presente comunicación.

8. Conclusión

Los requisitos de Patentabilidad de la presente solicitud están afectados así:

Ítem	Documento	Reivindicaciones afectadas	Requisito que afecta
D1	WO 2009/002474	1, 2, 3, 12, 13, 14, 15, 16, 17, 20, 27, 28, 29, 30.	Novedad/Nivel Inventivo
D2	US 5'624.402	16, 17, 20, 21, 22, 23, 24, 27, 28, 29, 32.	Novedad/Nivel Inventivo
D3	US 2009/0062766	21, 22, 24.	Novedad/Nivel Inventivo
D4	US 5'059.172	32, 28, 29.	Novedad/Nivel Inventivo
D5	US 8'038.656	5 y 6.	Novedad/Nivel Inventivo

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta (60) días contados a partir del día siguiente de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Se invita al solicitante se sirva indicar, si así lo considera, su renuncia al término faltante de sesenta (60) días para dar respuesta a este requerimiento y presentarla por escrito.

Finalmente, se le recuerda al solicitante que si como respuesta a este requerimiento llegara a modificar el capítulo reivindicatorio y éste contenga más de diez (10) reivindicaciones, no pagará la tasa de modificación voluntaria pero sí la correspondiente al pago por reivindicación adicional.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la Circular Única No. 10 de 2001.

JOSÉ LUIS SALAZAR LÓPEZ
Director de Nuevas Creaciones (c)

El anterior requerimiento fue notificado por fijación en lista, de fecha 2015-06-30

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(54) **Title:** ANTISEPTIC CAP WITH THREAD COVER

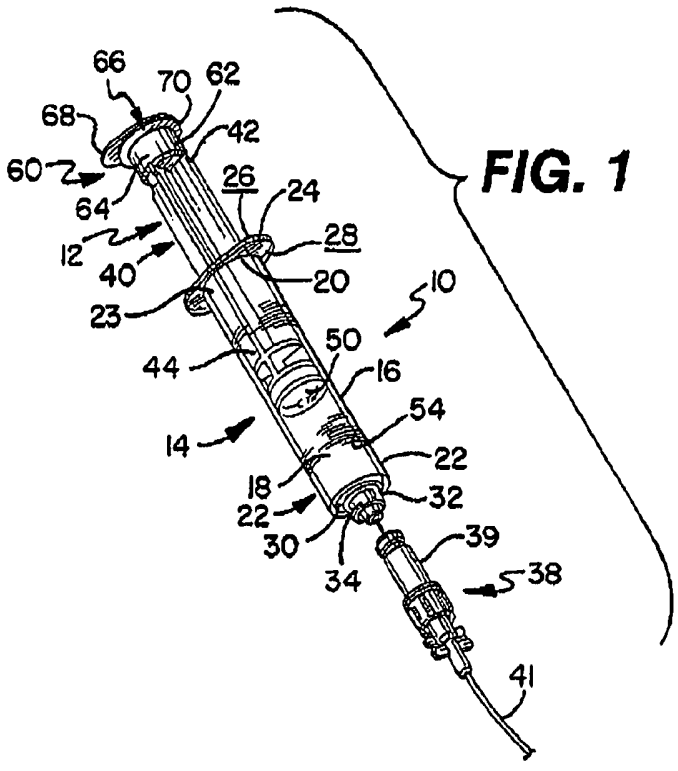


FIG. 1

(57) **Abstract:** A syringe assembly (10) including: (1) a syringe barrel (14) defining a chamber (18); (2) a plunger (12) mounted in the chamber (18) and moveable with respect to the barrel (14); and (3) a cap assembly (80) containing a cap (82) and an absorbent material (86) is removably attached to the plunger.

WO 2009/002474 A1

ANTISEPTIC CAP WITH THREAD COVER

CROSS-REFERENCE TO RELATED APPLICATION:

This application is a continuation-in-part of United States Utility Patent Application No. 11/821,190 filed on June 22, 2007, which is incorporated herein in its entirety by reference and made a part hereof.

BACKGROUND OF THE INVENTION:

Technical Field

The present invention relates to an antiseptic cap having a thread cover to enhance a seal between the cap and an access site to a body of a mammal. More particularly the invention relates to an antiseptic cap for attaching to an access site of an indwelling, central venous catheter and having a thread cover to enhance a seal between the cap and the access site.

Background Art

Catheters are widely used to treat patients requiring a variety of medical procedures. Catheters can either be acute, or temporary, for short-term use or chronic for long-term treatment. Catheters are commonly inserted into central veins (such as the vena cava) from peripheral vein sites to provide access to a patient's vascular system. Catheters offer many advantages for patients; for example, chronic catheters provide ready access without repeated punctures or repeated vessel cannulation for administration of large volumes of fluids, nutrients and medications and for withdrawal of blood on an intermittent basis. With respect to the use of catheters for infusion of fluids, examples include the infusion of drugs, electrolytes or fluids used in chemotherapy. In chemotherapy, catheters are used for infusion of drugs on an intermittent basis, ranging from daily to weekly. Another example includes the use of catheters in hyperalimentation treatment, wherein the catheters are usually used for infusion of large volumes of fluids.

For hemodialysis, catheters are commonly used--usually three times per week--for aspiration of blood for dialysis treatment and rapid return of the blood to circulation after treatment. Although a preferred mode of vascular access for a hemodialysis patient involves using an arteriovenous (AV) fistula of either the upper or lower extremities or an arteriovenous "bridge" graft (typically utilizing PTFE), use of these access devices is not always possible or desirable. When either of these modes of vascular access is not available, for example, due to a paucity of adequate blood vessels for creation of AV "shunts" or due to nonoptimally functioning established AV shunts, a large bore venous line catheter is typically required for hemodialysis. Catheters used for hemodialysis usually include two relatively large diameter lumens (usually molded as one catheter) for aspiration and rapid return of blood required during the hemodialysis procedure. One lumen of such a catheter is used for aspiration, or removal, of blood, while the other lumen is used for returning the blood to the patient's bloodstream.

Catheter connections, such as, for example, connections of catheters to dialysis machine tubing, to IV line tubing, to infusion ports and to catheter caps, which are used to seal the end of a catheter to protect the sterility of the catheter and prevent fluid loss and/or particle contamination, are most often made utilizing the medical industry's standardized Luer taper fittings. These fittings, which may either be male couplings or female couplings, include a tapered end of standardized dimensions. Coupling is made by the press-fit of mating parts. A threaded lock-fit or other type of securing mechanism is commonly utilized to ensure the integrity of the pressure fit of the Luer fittings.

Catheters, especially chronic venous catheters, provide challenges in their use. One such challenge is that such catheters can become occluded by a thrombus. In order to prevent clotting of catheters in blood vessels between uses, such as, for example, between dialysis treatments when the catheter is essentially nonfunctioning and dwells inside a "central" vein (i.e. superior vena cava, inferior vena cava, iliac, etc), the lumens of the catheter are often filled with a lock solution of a concentrated solution of the commonly used anticoagulant, heparin (up to 10,000 units of heparin per catheter lumen).

As used herein, the terms "lock solution" or "locking solution" refer to a solution that is injected or otherwise infused into a lumen of a catheter with the intention of allowing a substantial portion of the lock solution to remain in the lumen and not in the systemic blood circulation until it is desired or required to access that particular lumen again, typically for additional treatment, i.e., infusion or withdrawal of fluid. In addition, attention has been given to the development of alternative lock solutions with the goal of improving the patency rates of vascular catheters. For example, lower-alcohol containing locking solutions are under development wherein the lower alcohols include ethanol, propanol and butanol. Anti-microbial and or anticoagulant additives can optionally be added to the lower-alcohol containing locking solution. Preferably the lock solution can remain in the lumen for a desired amount of time lasting from about 1 hour to 3 or 4 days or longer.

For the reasons set forth above, significant care must be taken when infusing medications, nutrients and the like into a catheter, and when "locking" a catheter between uses, to minimize the risks associated with an indwelling catheter, including the risk of thrombosis or clotting, the risk of excessive anticoagulating and the risk of infection. Syringes are typically used to administer the required amount of catheter lock solution (determined by the catheter manufacturer) into an indwelling catheter after a given use. Flush procedures also require that care be taken to prevent blood reflux into the catheter. Reflux in I.V. therapy is the term commonly used to describe the fluid that is drawn back into the catheter after a flush procedure. The concern is that the reflux fluid contains blood or solution that could cause the catheter to occlude. To ensure that reflux does not occur, flush procedures suggest two techniques: 1) at the end of the flush solution delivery, the user maintains pressure on the syringe plunger while clamping the I.V. line; or 2) while delivering the last 0.5 ml of flush solution disconnect the syringe from the I.V. port or clamp the I.V. line. Either technique maintains positive pressure on the fluid in the catheter to prevent reflux of fluid and blood.

In light of the above-described problems, there is a continuing need for advancements in catheter lock techniques, devices and procedures to improve the safety and efficacy of catheter locking procedures and of overall patient care.

BRIEF DESCRIPTION OF THE DRAWINGS:

FIG. 1 is a perspective view of an antiseptic cap equipped plunger and syringe barrel assembly prior to connection of a syringe tip to an access point to a central venous catheter;

FIG. 2 is a perspective view of an antiseptic cap equipped plunger and syringe barrel assembly with the syringe tip connected to an access point to a central venous catheter;

FIG. 3 is a perspective view of an antiseptic cap equipped plunger and syringe barrel assembly prior to connection of the antiseptic cap to an access point to a central venous catheter;

FIG. 4 is a perspective view of an antiseptic cap equipped plunger and syringe barrel assembly after connection of the antiseptic cap to an access point to a central venous catheter;

FIG. 5 is a perspective view assembly drawing of an antiseptic cap equipped plunger;

FIG. 6 is a perspective view of an antiseptic cap equipped plunger in a partially assembled state;

FIG. 7 is a perspective view of the antiseptic cap equipped plunger of FIG. 6 with a top seal;

FIG. 8 is a perspective view of an antiseptic cap equipped plunger of FIG. 7 mounted in a lumen of a syringe barrell;

FIG. 9 is a side view in cutaway of a an antiseptic cap equipped plunger and syringe barrel assembly;

FIG. 10 shows an exploded view of a detail of FIG. 9 of one embodiment of the antiseptic cap equipped plunger and syringe barrel assembly;

FIG. 11 shows an exploded view of a detail of FIG. 9 of another embodiment of the antiseptic cap equipped plunger and syringe barrel assembly;

FIGS. 12-14 show various embodiments of grips of the antiseptic cap equipped plunger assembly;

FIGS. 15-17 show various views of one embodiment antiseptic cap equipped plunger and syringe barrel assembly with a barrel lock to resist rotation of the plunger assembly with respect to the syringe barrel;

FIG. 18 shows another embodiment of a barrel lock to resist rotation of the plunger assembly with respect to the syringe barrel;

FIGS. 19-20 show various views of another embodiment antiseptic cap equipped plunger and anti-reflux syringe barrel assembly with a barrel lock to resist rotation of the plunger assembly with respect to the syringe barrel;

FIG. 21 shows a perspective view another embodiment antiseptic cap equipped plunger and syringe barrel assembly with a barrel lock to resist rotation of the plunger assembly with respect to the syringe barrel;

FIG. 22a, b are respectively a perspective view of a antiseptic cap without a sponge and with a sponge;

FIGS. 23 and 24 are different embodiments of the antiseptic cap with varying gripping features;

FIG. 25 is a perspective view of the antiseptic cap of FIG. 22b prior to docking with a valve;

FIG. 26 is a perspective view of the antiseptic cap of FIG. 22b docked with a valve;

FIG. 27 is a side view in cutaway of the antiseptic cap and valve assembly shown in FIG. 26;

FIGS. 28-30 are side views in cutaway of two different embodiments of the antiseptic cap;

FIGS. 31a,b are, respectively, side views in cutaway showing an antiseptic cap with a centrally disposed actuation post mounted on a valve with the valve in the unactivated and activated positions;

FIGS. 32 and 33 are side views in cutaway showing two different embodiments of an antiseptic cap having a molded sponge;

FIG. 34 is a side view in cutaway showing another embodiment of an antiseptic cap having a molded sponge docked to a valve;

FIG. 35 is a side view in cutaway showing a step of attaching a molded sponge to an antiseptic cap;

FIG. 36 is a side view in cutaway showing a step of delivering an antiseptic compound to a molded sponge positioned within a cap;

FIG. 37 shows a side view in cutaway of a antiseptic cap docking to a valve with the antiseptic cap having an antiseptic coating;

FIG. 38 shows a perspective view of an antiseptic cap in a blister package;

FIG. 39 is a side cross-sectional view of an antiseptic cap with a thread cover;

FIG. 40 is a side cross-sectional view of an antiseptic cap with a thread cover;

FIG. 41 is a side cross-sectional view of an antiseptic cap with a thread cover;

FIGS. 42a,b are perspective front and back views of an antiseptic cap with a thread cover connected to a Cardinal SMART SITE access site;

FIGS. 43 a,b are perspective front and back views of an antiseptic cap without a thread cover connected to a Cardinal SMART SITE access site;

FIGS. 44 a,b are perspective front and back views of an antiseptic cap with a thread cover connected to a Hospira (ICU) C1000 Clave access device;

FIGS. 45 a,b are perspective front and back views of an antiseptic cap without a thread cover connected to a Hospira (ICU) C1000 Clave access device;

FIGS. 46 a,b are perspective front and back views of an antiseptic cap with a thread cover connected to a B. Braun ULTRASITE access device;

FIGS. 47 a,b are perspective front and back views of an antiseptic cap without a thread cover connected to a B. Braun ULTRASITE access device;

FIGS. 48 a,b are perspective front and back views of an antiseptic cap with a thread cover connected to a Rymed INVISION PLUS access device;

FIGS. 49 a,b are perspective front and back views of an antiseptic cap without a thread cover connected to a Rymed INVISION PLUS access device;

FIG. 50 is a is a side cross-sectional view of an antiseptic cap with a thread cover connected to a Cardinal SMARTSITE PLUS access device;

FIG. 51 is a is a side cross-sectional view of an antiseptic cap with a thread cover connected to a Cardinal SMARTSITE PLUS access device and the thread cover having a reduced diameter when compared to the thread cover shown in FIG. 50;

FIG. 52 is a is a side cross-sectional view of an antiseptic cap with a thread cover connected to a Hospira (ICU) C1000 Clave access device having a thread cover with an alternative profile;

FIG. 53 is an assembly view of an antiseptic cap and cup holder equipped plunger and syringe barrel system;

FIG. 54 is an assembly view of a cup-holder-antiseptic cap assembly adjacent a plunger and syringe barrel system;

FIG. 55 is a side view in cross-section of an antiseptic cap and cup holder equipped plunger and syringe barrel assembly;

FIG. 56a is a perspective view of a medical access device adjacent an antiseptic cap equipped plunger and syringe barrel assembly with a lid stock peeled back in preparation for docking;

FIG. 56b is a perspective view of a medical access device docked to an antiseptic cap equipped plunger and syringe barrel assembly;

FIG. 56c is a perspective view of a medical access device docked to an antiseptic cap adjacent a plunger and syringe barrel assembly;

FIG. 57 is an enlarged view of a cup holder and antiseptic cap assembly adjacent an open and empty chamber of a syringe plunger;

FIG. 58 is an enlarged view of a cup holder and antiseptic cap assembly positioned within a chamber of a syringe plunger;

FIG. 59 is a perspective view of an alternative embodiment of an antiseptic cap assembly adjacent a syringe plunger and barrel assembly;

FIG. 60 is a perspective view of an alternative embodiment of an antiseptic cap assembly docked to a syringe plunger and barrel assembly; and

FIG. 61 is a perspective view of an alternative embodiment of an antiseptic cap assembly docked to a syringe plunger and barrel assembly with an outer wall being transparent to reveal interior portions of the assembly.

DETAILED DESCRIPTION OF THE INVENTION:

While this invention is susceptible of embodiment in many different forms, there is shown in the drawings, and will be described herein in detail, specific embodiments thereof with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the specific embodiments illustrated.

FIGS. 1 and 2 show an antiseptic cap equipped plunger and syringe barrel assembly **10** having an antiseptic cap equipped plunger assembly **12** and a syringe barrel **14**. The barrel **14** has a side wall **16** defining a chamber **18** and the barrel has a proximal end **20** and a distal end **22**. The proximal end **20** has an opening **23** to the chamber **18** and a flange **24** extending radially outwardly from the wall **16**. The flange **24** has upper and lower surfaces **26**, **28** and provides gripping surfaces for a user of the assembly **10**. The distal end **22** of the barrel **14** has an end wall **30** and an elongate tip **32** extending distally therefrom and having a passageway **34** therethrough and in fluid communication with the chamber **18**. The distal end wall **30**, in one preferred form of the invention, is generally conically shaped and, as is well known in the art, can have a locking luer collar **35** concentrically surrounding the tip **32** and having a set of threads **37** on an inside surface thereof. The luer collar **35** allows for attaching a needle or a cannula to the barrel **14** and for docking the assembly **10** to mating threads located on other devices such as valves, injection sites and other medical access devices well known in the art. FIG. 1 shows the syringe assembly proximate an access site **38** having a valve **39** controlling access to a lumen of a tubing **41**.

In one preferred form of the invention the chamber **18** of the syringe assembly **10** will be filled with a locking solution or a flush solution for use with an indwelling, central venous catheter. The manner of using a locking or flush solution with a catheter is well known in the art. Suitable locking or flushing solutions will be set forth below. The flush or locking solution is injected into a fluid access site of the catheter to clean and disinfect the catheter and can be withdrawn from the catheter or allowed to remain in an end portion of the catheter to serve as a barrier to the ingress of pathogens and contaminants.

The antiseptic cap plunger assembly **12** has an elongate shaft **40**, a proximal end **42** and a distal end **44**. The elongate shaft **40**, in one preferred form of the invention, is generally

cruciform in cross-sectional shape. A stopper or piston **50** is connected to the distal end **44** of the shaft **40**. The piston **50** is dimensioned such that when inserted into the syringe barrel chamber **18** an outer circumferential surface of the piston **50** is in fluid-tight engagement with an inner surface **54** of the syringe barrel. The piston assembly **14** when moved proximally (or when being withdrawn) can draw fluid into the chamber and when moved distally (or when inserted into the syringe chamber) can drive fluid out of the chamber. FIG. 1 shows the piston assembly **14** partially inserted into the syringe chamber and FIG. 2 shows the piston assembly fully inserted into the syringe chamber to deliver fluid to the tubing **41**.

A housing **60** is located at the proximal end **42** of the plunger assembly **12** and has a wall **62** defining a chamber **64** having an open end **66** which can be sealed by any suitable structure or material such as a cap or by a foil material **68**. An optional annular flange **70** extends radially outwardly from the wall **62** and provides a surface upon which the sealing structure can be attached.

FIG. 5 shows a cap assembly **80** proximate the chamber **64** of the housing **60** and FIG. 6 shows the cap assembly **80** positioned within the chamber **64**. In one preferred form of the invention, the cap assembly **80** has a cap **82** having a wall **83** defining a chamber **84** containing an absorbent material **86** such as a sponge. The sponge **86**, in a preferred form of the invention, is wetted or soaked with an agent such as an antiseptic, anticoagulant or antimicrobial ("antiseptic solution") and can be selected from the locking and flushing solutions set forth below or the antiseptic solutions set forth below. The cap **82** has an interior surface **87** with a set of threads **88** for mating with a set of threads on the access site **38**.

FIGS. 7 and 8 show the cap assembly **80** sealed with a foil material or lid stock material **68** which can be attached to the flange **70** by any suitable method such as by adhesives or by conductive or inductive heat sealing techniques. FIG. 7 shows the antiseptic cap piston assembly **12** and FIG. 8 shows the antiseptic cap equipped piston assembly **12** inserted into the chamber of the syringe barrel **14** to define the antiseptic cap equipped piston and syringe barrel assembly **10**.

FIGS. 3 and 4 show one possible method for utilizing the cap assembly **80** by docking with the access device **38**. FIG. 3 shows the lid stock **68** pealed away from the flange **70** and FIG. 4 shows docking the antiseptic cap assembly **80** to the valve **39**. The syringe barrel is rotated clockwise or counterclockwise to engage the threads **88** of the antiseptic cap assembly **80**

with the threads of the access site **38**. After engagement, the syringe barrel **14** will be moved away from the access site **38** and the antiseptic cap assembly **80** will slide outward from the housing **60** and remain docked to the access site **38**. The antiseptic cap assembly **80** can remain docked to the valve **39** of the access site **38** for any suitable period of time from a few minutes to numerous hours. When the antiseptic cap assembly **80** is docked to the valve **39** the tubing or catheter **41** is sealed to block the ingress into the catheter of pathogens and contaminants and a portion of the access site **38** is exposed to the antiseptic material in the sponge **86**.

It is desirable that during the rotation of the syringe barrel that the that the antiseptic cap assembly **80** does not rotate with respect to the housing and/or optionally that the plunger assembly **12** does not rotate with respect to the syringe barrel **14** until the threads **88** of the antiseptic cap have fully engaged the threads of the access site **38**. The present invention provides a mechanism associated with the assembly **10** for preventing the rotation of the antiseptic cap assembly **80** with respect to the plunger assembly **14** and more preferably a mechanism on either the plunger assembly or on the antiseptic cap assembly **80** to prevent relative rotational movement between the antiseptic cap assembly **80** and the plunger assembly **12**. In an even more preferred form of the invention, the mechanism for preventing relative rotation of the antiseptic cap assembly **80** with respect to the plunger assembly **12** has mating portions on both parts that when assembled cooperatively engage one another to prevent relative rotation. It is also contemplated that a separate mechanism, device or member could be used to lock the two parts together to achieve this purpose.

If a user grasps the assembly **10** by the antiseptic cap and plunger assembly **12** than the interlocking structures between the plunger assembly **12** and the syringe barrel **14** would not necessarily be needed. Accordingly, FIGS. 5, 9-11 show exemplary structures for locking the antiseptic cap assembly **80** inside the housing **60** so that these parts rotate together and one part does not rotate in a direction or at a rate different from that of the other part. Further, FIGS. 15-18 show exemplary structures for interlocking the antiseptic cap plunger assembly **12** with the syringe barrel **14**.

In one preferred form of the invention the housing **60** will have a feature or structure that forms an interference fit with an external surface **83** of the antiseptic cap **80**. Even more preferably, an internal surface **63** of the side wall **62** of the housing **60** will have a feature or

structure to form an interference fit with a portion of the antiseptic cap assembly **80**. In another preferred form of the invention the antiseptic cap assembly **80** will have a feature to form an interference fit with the housing **60** and even more preferably the outer surface **83** of the antiseptic cap **80** will have a feature to contact the inner surface **63** of the housing side wall **62**.

In another preferred form of the invention the plunger housing **60** and the cap assembly **80** each will have a feature or structure that cooperatively engage one another to prevent relative rotation of the cap assembly **80** and the housing **60**. FIG. 5 shows one preferred form of the invention having a plurality of circumferentially spaced and axially extending ribs **100** on the internal surface **63** of the housing side wall **62** (internal ribs **100**) for engaging the wall **83** of the antiseptic cap **82** to lock the cap assembly **80** in place to prevent rotation of the cap assembly **80** when positioned inside the housing **60**. In a preferred form of the invention, the internal ribs **100** extend from a bottom wall **102** up to an intermediate height of the housing sidewall **62**. In a preferred form of the invention the internal ribs **100** will have a height roughly equal to a height of the cap **82**. A plurality of internal slots **108** are defined between each set of adjacent internal ribs **100**. The internal ribs **100**, in a preferred form of the invention, will have a width that tapers inwardly from proximate the bottom wall **102** to a top **104** of the internal ribs **100** so that the width of the internal ribs decrease from a bottom **106** of a rib to the top **104** of the rib. Also, it is preferably that the top of the internal ribs **100** have a generally arcuate profile to act as a lead-in during insertion of the antiseptic cap assembly **80** into the housing **60**. In a preferred form of the invention, the internal ribs **100** will terminate short of a top **113** of the housing sidewall **62** to define an annular gap **111** between the top of the rib **104** and the top **113**. Also, extending radially inwardly from the internal surface **63** of the cap **82** is a detent **109** positioned proximate a top portion **113** of the side wall **62**.

The antiseptic cap **82** has a plurality of circumferentially spaced and axially extending ribs **120** extending along an external surface **121** of the wall **83** of cap **82** (external ribs **120**). In one preferred form of the invention the external ribs **120** extend between an annular flange **123** at a proximal end **124** of the cap **82** to a position proximate a distal end **126** of the cap **82**. The external ribs **120** are dimensioned for engaging a portion of the interior wall surface **63** of the housing **62** to prevent relative rotation of the cap assembly **80** and the plunger assembly **12**. Spacing between the external ribs define a plurality of external slots **122** between each adjacent

pair of external ribs **120**. When the cap **82** is positioned within the chamber **64** (FIG. 9 and 11) each of the external ribs **120** are positioned within an internal slot **108** and each of the internal ribs **100** are positioned within an external slot **122** to lock together these parts to assure that the cap rotates in the same direction as the plunger rod assembly **12**. FIGS. 6 and 11 also show that when the cap **82** is positioned within the housing **60**, the detent **109** contacts the annular flange **123** to hold the cap assembly **80** in the plunger housing chamber **64** to prevent or resist inadvertent dropping of the cap assembly **80** from the housing chamber **64** prior to docking of the cap assembly **80** with the access site **38**.

FIGS. 12-14 show several embodiments of gripping surfaces on the housing **60** (with lid stock **68** removed) to facilitate use of the assembly **10** or the plunger assembly **12**. FIG. 12 shows axially extending and circumferentially spaced protuberances **130** on an outer surface of the wall **62**. The protuberances **130** can have numerous different cross-sectional shapes including circular, polygonal, oval and irregular and, in a preferred form of the invention, extend from the flange **70** to a bottom of the housing.

FIG. 13 shows a housing **60** that has no flange **70** and has protuberances **130** on the wall **62** extending substantially the entire height of the housing **60**. FIG. 14 shows a housing **60** where the outer surface of the wall **62** is relatively smooth but as a series of circumferentially spaced and axially extending protuberances **130** on a circumferential edge of the flange **70**.

As with the cap and plunger assembly rotational locking features or structures, the optional plunger assembly **12** and syringe barrel **14** locking feature or structure can be positioned alone on the plunger assembly **12**, or alone on the syringe barrel **14** or have cooperating structures on both the plunger assembly **12** and the syringe barrel **14**. It is also contemplated that a separate mechanism, device or member could be used to lock the two parts together to achieve this purpose.

FIGS. 15-18 show various embodiments for the optional feature of locking the plunger assembly **12** from rotational motion with respect to the syringe barrel **14**. In one embodiment shown in FIGS. 15-17 and 21 a wing **150** extending axially along an outside surface of the housing side wall **62** engages a tooth **152** positioned on an interior surface of the syringe barrel **14** at its proximal end **20**. More preferably, the plunger assembly **12** will have more than one wing **150** with each wing being circumferentially spaced from the other. In an even more

preferred form of the invention the plunger assembly will have four wings **150** spaced 90 degrees from one another. Also, in a more preferred form of the invention, the syringe barrel **14** will have a plurality of circumferentially spaced teeth **152**. When the plunger assembly **12** is nearly fully inserted into the syringe barrel **14** each of the wings **150** will extend into a tooth **152** to prevent rotation of the plunger assembly **12** with respect to the syringe barrel **14**.

FIG. 18 shows another embodiment of a locking feature to prevent rotation of the plunger assembly **12** with respect to the syringe barrel **14** and also prevents relative translational motion of the parts. In this embodiment an annular protuberance **160** positioned on an interior surface of the syringe barrel at is proximal end **20** engages an annular detent **162** on an outside surface of the plunger rod.

FIGS. 19 and 20 show an antiseptic cap equipped plunger assembly **12** and non-refluxing syringe assembly **170**. Non-refluxing syringes are well known in the art and there are numerous methodologies for reducing reflux while accessing the access site of a central venous catheter. In this embodiment the annular flange **70** of the plunger assembly **12** abuts the flange **24** of the syringe barrel prior to the piston **50** contacting an interior surface of the syringe distal end wall **30**.

It is contemplated that the antiseptic cap assembly **80** of the present invention need not be coupled or combined with a plunger or a syringe barrel. FIGS. 22a, b show a stand-alone antiseptic cap assembly **200** having three circumferentially spaced ribs **120** for grasping by the hand of a user of the cap assembly. FIG. 22a shows the cap **82** without an absorbent material **86** and FIG. 22b shows the cap with an absorbent material. The cap **200** can be used for the same purposes of the cap assembly **80** described above but will be used by hand. All other features of the cap **200** are essentially the same as described about with the exception that the cap **200** does not have to be dimensioned to fit within a chamber carried by a syringe plunger. FIGS. 23 and 24 show varying frequency of ribs 120 and varying shapes and sizes.

FIG. 25 shows the cap **200** proximate the access site **38** and FIGS. 26 and 27 show the cap **200** docked to the access site **38**.

A suitable absorbent material **86** includes medical grade materials capable of storing and releasing an antiseptic liquid, or liquid having other medical purposes, and includes materials such as sponges, rupturable capsules and other materials or devices capable of serving this

purpose. Suitable sponges can include any sponge suitable for use for medical purposes and can be naturally occurring or synthetic. The sponges can be die cut into suitable shapes or can be molded into the desired shape. It is desirable that the sponge **86** be attached to the antiseptic cap **82** to prevent the sponge **86** from inadvertently falling out of the cap **82**. FIG. 28 shows the sponge **86** is captured between an annular wall **202** and a disc **204** attached to the cap **82** by any suitable method such as ultrasonic or vibrational welding or other techniques well known in the art.

FIGS. 29 and 30 show a variation on the cap assembly **200** of FIG. 28. In this embodiment, the sponge is retained in the cap **82** with a plastic sheet **206** heat welded to the cap. In one preferred form of the invention the sponge is attached by an adhesive or by other method to form an assembly which is then attached to the cap.

FIGS. 31a, b show the cap **200** having a coaxially disposed and axially extending actuating post **220** circumferentially surrounded by a sponge **86** having a centrally positioned hole to fit over the post **220**. FIG. 31a shows the cap **200** in initial engagement with the access site **38** and FIG. 31b shows the cap threaded onto the access site **38** and the actuating post opens the valve **39** and antiseptic fluid is allowed to flow into the valve.

FIGS. 32-34 show varying shaped sponges that, in one preferred form of the invention, were molded into various desirable shapes. The sponge of FIG. 34 has a central opening **230** to facilitate attaching the sponge to the cap and to filling the sponge with antiseptic, anticoagulant or other suitable fluids set forth above. FIG. 35 shows the cap having a centrally disposed energy director **231**, an ultrasonic welder **232** being brought into cooperative engagement with the sponge on a side of the sponge opposite the energy director **231**. By applying ultrasonic energy the energy director **231** melts and attaches the sponge to the cap. FIG. 36 shows a filling device **240**, having a lumen **242** and a dispensing head **244** in fluid communication with a source of antiseptic, anticoagulant or the like for dispensing a metered amount of such fluid into the interior portion of the sponge.

FIG. 37 shows an alternative embodiment of the antiseptic cap **200** where the sponge is replaced by a antiseptic coating on the actuating post **220**.

FIG. 38 shows the antiseptic cap **200** positioned in a blister pack **233** prior to sealing the blister pack.

FIG. 39 shows an antiseptic cap **300** with a thread cover **302**. The thread cover **302** can be part of any of the antiseptic caps discussed herein. The thread cover **302** is made of a deformable material capable of flexing upon application of moderate force applied by hand. In one preferred form of the invention the thread cover **302** is made from a polymeric containing material and more preferably a polymeric material having a modulus of elasticity of less than 20,000 psi.. In another preferred form of the invention the polymeric material will be an elastomer or plastomer or like material. The thread cover **302** enhances the connection between the antiseptic cap **300** and a device such as a valve or other access devices **38**. The thread cover **302** provides a physical barrier to the ingress of pathogens, dust or other contaminants through the mating threads of the antiseptic cap **300** and the access device or valve to which it is docked. The thread cover **302** also serves to retain antiseptic fluids from the antiseptic cap **300** from leaking out through the threads. The thread cover can be made a part of the antiseptic cap **300** using techniques well known in the art such as overmolding, or by attaching as a separate part using welding techniques such as heat conductive welding, heat induction welding, vibrational welding, stretch or friction fit, or by using a suitable adhesive.

The thread cover **302** can provide a universal fit to most commercially available valves, connectors and access devices, or the thread cover **302** can be customized to dock with a particular access device.

FIG. 39 shows, as is described above, the antiseptic cap **300** has an annular wall **305** having a first end **306** and a second end **320** with the first end having a greater diametrical dimension than the second end. The annular wall defines a central chamber **322** having an open end **323**. In one preferred form of the invention, the chamber **322** will have a sponge **86** positioned therein as shown in FIG. 5 and 6 above, although it is not shown in FIG. 39. The thread cover **302** is shown attached by an optional bonding layer **304** to the first end **306** of the annular wall **305**. The thread cover **302** has a first leg **308** and a second leg **310**. The first leg **308** extends parallel to the annular wall **305** and the second leg **310** extends radially inwardly from the annular wall **305** in a direction transverse to the first leg **308** and across a portion of the open end **323** and defines a central opening **312**, having a reduced diameter when compared to the open end **323**, into the chamber **322**. The second leg **310** terminates at a distal end **330** with a rounded outer surface **332**.

FIG. 40 shows an alternative embodiment of the antiseptic cap **300** having the thread cover **302** having both the first and second legs **308, 310** attached to the first end **306** of the annular wall **305** through bonding layers **304 a,b**. A top surface **340** of the first end **306** is shown having the same thickness or diametrical dimension as the remainder of the first end but it is contemplated the top surface could have a radially extending flange **123** as shown in FIG. 5.

FIG. 41 shows an alternative embodiment of the antiseptic cap **300** that differs from the antiseptic cap shown in FIGS. 39 and 40 by not including a counterbore **336** shown in these figures. The counterbore **336** provides a chamber of reduced diameter and, therefore, will form a tighter fit with access devices with a more narrow outer diameter when compared to the cap shown in FIG. 41 which does not include the counterbore. This is just one example of the modifications that can be made to the geometry of the antiseptic cap to enhance the connection between the cap and an access site.

FIGS. 42a,b show front and back views of the antiseptic cap **300** with the thread cover **302** connected to a Cardinal SMART SITE access site **350**. FIGS. 43 a,b are perspective front and back views of the antiseptic cap without the thread cover **302** connected to the Cardinal SMART SITE access site.

FIGS. 44 a,b are perspective front and back views of the antiseptic cap **300** with the thread cover **302** connected to a Hospira (ICU) C1000 Clave access device **352**. FIGS. 45 a,b are perspective front and back views of the antiseptic cap, without a thread cover **302**, connected to the Hospira (ICU) C1000 Clave access device.

FIGS. 46 a,b are perspective front and back views of the antiseptic cap **300** with the thread cover **302** connected to a B. Braun ULTRASITE access device **354**. FIGS. 47 a,b are perspective front and back views of the antiseptic cap without the thread cover **302** connected to the B. Braun ULTRASITE access device.

FIGS. 48 a,b are perspective front and back views of the antiseptic cap with the thread cover **302** connected to a Rymed INVISION PLUS access device; **356**. FIGS. 49 a,b are perspective front and back views of the antiseptic cap without the thread cover **302** connected to a Rymed INVISION PLUS access device.

FIGS. 50-52 show various embodiments of the thread cover **302**. FIG. 50 differs from FIG. 51 in that the second leg **310** extends farther across the opening of the chamber in FIG. 51

than shown in FIG. 50. FIG. 52 shows another embodiment of the thread cover **302** having a segmented second leg **310 a,b**. This embodiment may be desirable to provide a more effective seal for certain access devices.

FIG. 53 shows an exploded view of an alternative embodiment **400** of the syringe barrel assemblies **10**, discussed above, incorporating a cap holder **402** into the system of parts. Thus, the alternative assembly and system **400** has an antiseptic cap and cap holder equipped plunger assembly **12'**, a syringe barrel **14**, an antiseptic cap **82** (shown with an optional thread cover **302**), an absorbent material **86**, and peelable lid stock **68**. FIG. 54 shows an exploded view of an antiseptic cap holder assembly **404** including the cap holder **402** with the antiseptic cap assembly **80** positioned within a chamber **406** of the cap holder **402**. This embodiment **400** allows for the separate manufacture, assembly, and sterilization of the assembly **400** from the plunger assembly and the syringe barrel.

The cap holder **402** has a proximal and distal ends **408, 410**, and an inner wall surface **412** and an outer wall surface **414**, an opening **416** into the chamber **406**, and a radially outwardly extending flange **418** circumjacent the opening **416** and extending from the proximal end **408** of the cap holder **402**. The cap holder **402** will also have an optional bottom wall **419**.

In a preferred form of the invention, the cap holder **402** or the antiseptic cap **82** will have a structure, element or the like that prevents the relative rotation of the cap holder **402** and the antiseptic cap **82** until the antiseptic cap assembly **80** is securely docked to the access device **38**. Also, in a preferred form of the invention the cap holder **402** or the plunger assembly **12'** will have a structure, element or the like for preventing the relative rotation of the cap holder **402** and the plunger assembly **12'** until the antiseptic cap assembly **80** is securely docked to the access device **38**. Any of the anti-rotation devices discussed above to stop the rotation of the antiseptic cap assembly **80** with the plunger assembly **12** would be suitable for these purposes. Also, it is contemplated the devices discussed above in reference to FIGS. 15-21 to prevent the relative rotation of the plunger assembly **12** and the syringe barrel **14** could be incorporated into this embodiment **400**.

FIG. 53 shows the inner wall surface **412** of the cap holder **402** carries the internal ribs **100** and the internal slots **108** that interact with the external ribs and external slots **120, 122** of the cap **82** as is described above with respect to FIG. 5. These structures prevent or resist the

relative rotation of the cap holder **402** with respect to the antiseptic cap assembly **80**. The term "ribs" referred to herein are structures that are raised or extend outward from a surface. The term "slots" refer to structures that extend below a surface or is defined between two ribs and is at a lower level than the ribs.

FIG. 53 also shows an interlocking structure for preventing the relative rotation of the cap holder **402**, or the cap holder assembly **404**, with respect to the plunger assembly **12'**. The outer wall surface **414** has a plurality of circumferentially spaced and axially extending ribs **420** defining slots **424** between each pair of adjacent ribs. In a preferred form of the invention, the ribs **420** are generally triangular in shape having a base portion **426** and an apex portion **428**. The slots **424** are oppositely-oriented triangularly shaped areas having slot base portions **430** extending between two adjacent rib apex portions **428** and slot apex portions **432** separating adjacent rib base portions **426**. On the internal wall surface **63** of the plunger chamber **64** are similarly shaped plunger ribs **434** and plunger slots **436**. The ribs **420** are dimensioned to fit within the plunger slots **436** and the slots **424** are dimensioned to fit over and receive the plunger ribs **434**. Thus, when the cap holder **402** or the cap holder assembly **404** is inserted in the plunger chamber **64** the cap holder ribs **420** are interdigitated with the plunger ribs **434** to prevent or resist the relative rotation of the cap holder **402**, or cap holder assembly **404**, with respect to the plunger assembly **12'**.

In yet another preferred form of the invention, the cap holder **402**, the cap holder assembly **404** or the plunger assembly **12'** will have a structure, element or the like that resists the relative axial movement of these parts when the cap holder **402** or the cap holder assembly **404** is positioned fully within the plunger assembly **12'**. In one preferred form of the invention the cap holder **402** has an annular protuberance **440** that is dimensioned to fit within an annular groove **442** on the inner wall surface **414** of the cap holder and preferably extends in line with the base portions of the plunger ribs **434**. A second locking structure is provided having a plurality of teeth **450** which extend axially outward from the outer wall surface **414** of the cap holder and are positioned in slots **424**. In a preferred form of the invention the teeth extend axially outwardly to a height beyond the height of the ribs **434**. The teeth **450** can be positioned in one or more of the slots or in each of the slots **424** or in alternating slots or, as is shown, circumferentially spaced 90° from one another. The teeth **450** preferably are positioned at an

intermediate portion, between the base and the apex, of a slot **424**. The teeth **450** are dimensioned to fit within a segmented annular groove **452** that extends circumferentially about the inner surface **412** crossing through the plunger ribs **434** at an intermediate portion, between the base and the apex, of the plunger ribs **434**.

FIGS. 56a,b,c respectively show the assembly **400** in a ready-for-use position, docked position, and used position. The assembly **400** is used in essentially the same fashion as described above with respect to FIGS. 3 and 4 except that when the assembly **400** is in the used position the cap holder **402** remains in the plunger assembly **12'**.

The syringe barrel and plunger can be fabricated from any material suitable for its purpose and includes glass and polymeric material. Suitable polymeric materials include, but are not limited to, homopolymers, copolymers and terpolymers formed from monomers such as olefins, cyclic olefins, amides, esters, and ethers. The polymeric material may be a blend of more than one polymeric material and can be a monolayer structure or a multilayer structure. In one preferred form of the invention the syringe barrel and the plunger are injection molded from a polypropylene material.

FIGS. 59-61 show a third embodiment **500** of an antiseptic cap equipped syringe plunger and barrel assembly with the antiseptic cap assembly **80** and lid stock **68** removed for clarity. The third embodiment **500** provides for retrofitting an antiseptic cap assembly **502** to a standard plunger **504**. The antiseptic cap **502** has a first generally cylindrical outer wall **506** having a proximal end **508** and a distal end **510**. The proximal end **508** is removably or fixedly attached to a button **512** of the plunger **504**. The proximal end has an opening **514** dimensioned to fit about the button **512** and has a member for attaching to the button. In one preferred form of the invention, the attaching member includes a plurality of circumferentially spaced, and axially inwardly directed tabs **516** extending from an inner wall surface **518** and the tabs engage a lower surface of the button **512** to attach the antiseptic cap assembly **502** to the plunger **504**.

The distal end of the antiseptic cap **504** has a top annular flange **520** extending radially inwardly from the first cylindrical wall **506** and defines a generally circular opening **522**. A second cylindrical wall **524** extends axially downwardly from the top annular flange **520** and is coaxially disposed within the first cylindrical wall **506**. When the antiseptic cap **504** is attached

to the plunger button **512** a bottom peripheral edge of the second cylindrical wall **524** will abut a top surface of the plunger button **512** thereby capturing, by oppositely directed axially forces, the plunger button **512** between the tabs **516** and the second cylindrical wall. It is contemplated, however, that a second set of tabs could be provided spaced axially away from the first set of tabs and the piston button **512** could be trapped between the two sets of tabs. Further, it is contemplated other attaching means could be used that are well know in the art and the attaching member shown is merely exemplary.

The second cylindrical wall **524** defines a chamber as is shown in greater detail in FIG. 5 above with the ribs and slots as described for engaging the antiseptic cap assembly **80** to prevent relative rotational movement and to resist relative axial movement of the parts when the antiseptic cap assembly **80** is fully inserted into the chamber. Further, it is contemplated adapting the plunger and syringe as described above to prevent or resist the relative rotational movement of the plunger with respect to the barrel.

The piston **50** can be formed from any suitable material including a polymeric material or a silicone material. The stopper can be selected from a material with a desired durometer so that reflux is reduced when the stopper engages an inner surface of the distal end wall of the syringe barrel.

Suitable locking an flush solutions include a lower alcohol selected from ethanol, propanol and butanol. The locking solution can be a single lower alcohol or a blend of lower alcohols.

Suitable locking solutions can also include a lower alcohol with an antimicrobial and or an anticoagulant. Suitable locking solutions can contain at least one lower alcohol in a range from 1% to 99% by volume and at least one other anti-microbial and/or anti-coagulant compound in a range from 1% to 99% by volume. The lower alcohol will usually be in aqueous solution, typically at 1% to 99% by volume, usually from 5% to 95% by volume. The at least one other anti-microbial is selected from the group consisting of taurolidine and triclosan, and the at least one anti-coagulant is selected from the group consisting of riboflavin, sodium citrate, ethylene diamine tetraacetic acid, and citric acid.

In one preferred form of the invention, the syringe assembly **10** will be pre-filled with one of the locking solutions and will be packaged by a manufacture and shipped to a health care

provider. A cannula or needle will be attached to the distal end of the barrel and placed into fluid communication with the fluid access site of an indwelling central venous catheter. The flush solution will be injected into the catheter to clean or lock the catheter. Afterwards, the cap assembly **80** will be removed from the plunger **17** and the cap will be docked to the fluid access site of the catheter.

Citrate salt containing antiseptic solutions

In one form, the antiseptic is a solution a citrate salt and in another form of the invention the citrate salt solution is a hypertonic solution. The term hypertonic is used herein to refer to a fluid having an osmotic concentration and a density greater than the osmotic concentration and density of the blood of the patient. The antiseptic solution preferably comprises a citrate salt with a concentration range, in weight percent, of from about 1.5% to about 50% with an osmolality of about 300 to about 6400 mOsm. More preferably, the antiseptic solution comprises citrate salt in a concentration range of from about 10% to about 40%, yet more preferably, in a concentration range of from about 20% to about 30%.

In a preferred embodiment, the antiseptic solution is prepared to have a pH lower than that of the pH of the patient's blood. The citrate salt solution may be prepared to have a pH lower than about 6.5, more preferably, from about 4.5 to about 6.5. Also, the citrate salt solution can include pharmaceutically acceptable agents such as sodium chloride and sodium heparin. The citrate salt solution can also include a variety of other antibacterial, antimicrobial and anticoagulant agents such as gentamicin, vancomycin, and mixtures of these agents. Additional anticoagulant agents include, for example heparin, urokinase, tissue plasminogen activation (tPA) and mixtures of these agents.

By "pharmaceutically acceptable," it is meant that the citrate salt solution and the included salts and other additives which are, within the scope of sound medical judgment, suitable for use in contact with tissues of humans and lower animals without undue toxicity, irritation, and allergic response. It is also typically necessary that a composition be sterilized to reduce the risk of infection.

Antibacterial agent containing antiseptic solutions

An antimicrobial agent containing antiseptic solution of the present invention may contain at least one alcohol, at least one antimicrobial agent and at least one chelator and/or anticoagulant. Various antimicrobial substances as disclosed herein and that are well known to one of ordinary skill in the art may be combined with the locking solution in order to inhibit infection. The antimicrobial locking solution of the present invention may be use for filling or flushing a medical device such as an indwelling device such as an implanted catheter. Other medical devices that are contemplated for use in the present invention are disclosed herein.

In another preferred form of the invention, the antiseptic agent can contain antibacterial agents such as those classified as aminoglycosides, beta lactams, quinolones or fluoroquinolones, macrolides, sulfonamides, sulfamethaxozoles, tetracyclines, treptogramins, oxazolidinones (such as linezolid), clindamycins, lincomycins, rifamycins, glycopeptides, polymxins, lipo-peptide antibiotics, as well as pharmacologically acceptable sodium salts, pharmacologically acceptable calcium salts, pharmacologically acceptable potassium salts, lipid formulations, derivatives and/or analogs of the above.

The aminoglycosides are bactericidal antibiotics that bind to the 30S ribosome and inhibit bacterial protein synthesis. They are typically active against aerobic gram-negative *bacilli* and *staphylococci.* Exemplary aminoglycosides that may be used in some specific aspects of the invention include amikacin, kanamycin, gentamicin, tobramycin, or netilmicin.

Suitable beta lactams are selected from a class of antibacterials that inhibit bacterial cell wall synthesis. A majority of the clinically useful beta-lactams belong to either the penicillin group (penam) or cephalosporin (cephem) groups. The beta-lactams also include the carbapenems (e.g., imipenem), and monobactams (e.g., aztreonam). Inhibitors of beta-lactamase such as clavulanic acid and its derivatives are also included in this category.

Non-limiting examples of the penicillin group of antibiotics that may be used in the solutions of the present invention include amoxicillin, ampicillin, benzathine penicillin G, carbenicillin, cloxacillin, dicloxacillin, piperacillin, or ticarcillin, etc. Examples of cephalosporins include ceftiofur, ceftiofur sodium, cefazolin, cefaclor, ceftibuten, ceftizoxime, cefoperazone, cefuroxime, cefprozil, ceftazidime, cefotaxime, cefadroxil, cephalexin,

cefamandole, cefepime, cefdinir, cefriaxone, cefixime, cefpodoximeproxetil, cephapirin, cefoxitin, cefotetan etc. Other examples of beta lactams include mipenem or meropenem which are extremely active parenteral antibiotics with a spectrum against almost all gram-positive and gram-negative organisms, both aerobic and anaerobic and to which *Enterococci, B. fragilis*, and *P. aeruginosa* are particularly susceptible.

Suitable beta lactamase inhibitors include clavulanate, sulbactam, or tazobactam. In some aspects of the present invention, the antibacterial solutions may comprise a combination of at least one beta lactam and at least one beta lactamase inhibitor.

Macrolide antibiotics are another class of bacteriostatic agents that bind to the 50S subunit of ribosomes and inhibit bacterial protein synthesis. These drugs are active against aerobic and anaerobic gram-positive cocci, with the exception of enterococci, and against gram-negative anaerobes. Exemplary macrolides include erythromycin, azithromycin, clarithromycin.

Quinolones and fluoroquinolones typically function by their ability to inhibit the activity of DNA gyrase. Examples include nalidixic acid, cinoxacin, trovafloxacin, ofloxacin, levofloxacin, grepafloxacin, trovafloxacin, sparfloxacin, norfloxacin, ciprofloxacin, moxifloxacin and gatifloxacin.

Sulphonamides are synthetic bacteriostatic antibiotics with a wide spectrum against most gram-positive and many gram-negative organisms. These drugs inhibit multiplication of bacteria by acting as competitive inhibitors of p-aminobenzoic acid in the folic acid metabolism cycle. Examples include mafenide, sulfisoxazole, sulfamethoxazole, and sulfadiazine.

The tetracycline group of antibiotics include tetracycline derivatives such as tigecycline which is an investigational new drug (IND), minocycline, doxycycline or demeclocycline and analogs such as anhydrotetracycline, chlorotetracycline, or epioxytetracycline.

Suitable streptogramin class of antibacterial agents include quinupristin, dalfopristin or the combination of two streptogramins.

Drugs of the rifamycin class typically inhibit DNA-dependent RNA polymerase, leading to suppression of RNA synthesis and have a very broad spectrum of activity against most gram-positive and gram-negative bacteria including *Pseudomonas aeruginosa* and *Mycobacterium* species. An exemplary rifamycin is rifampicin.

Other antibacterial drugs are glycopeptides such as vancomycin, teicoplanin and derivatives thereof. Yet other antibacterial drugs are the polymyxins which are exemplified by colistin.

In addition to these several other antibacterial agents such as prestinomycin, chloramphenicol, trimethoprim, fusidic acid, metronidazole, bacitracin, spectinomycin, nitrofurantion, daptomycin or other leptopeptides, oritavancin, dalbavancin, ramoplamin, ketolide etc. may be used in preparing the antiseptic solutions described herein. Of these, metronidazole is active only against protozoa, such as *Giardia lamblia, Entamoeba histolytica* and *Trichomonas vaginalis*, and strictly anaerobic bacteria. Spectinomycin, is a bacteriostatic antibiotic that binds to the 30S subunit of the ribosome, thus inhibiting bacterial protein synthesis and nitrofurantoin is used orally for the treatment or prophylaxis of UTI as it is active against *Escherichia coli, Klebsiella-Enterobacter* species, *staphylococci,* and *enterococci.*

In other embodiments, the antimicrobial agent is an antifungal agent. Some exemplary classes of antifungal agents include imidazoles or triazoles such as clotrimazole, miconazole, ketoconazole, econazole, butoconazole, omoconazole, oxiconazole, terconazole, itraconazole, fluconazole, voriconazole, posaconazole, ravuconazole or flutrimazole; the polyene antifungals such as amphotericin B, liposomal amphoterecin B, natamycin, nystatin and nystatin lipid formualtions; the cell wall active cyclic lipopeptide antifungals, including the echinocandins such as caspofungin, micafungin, anidulfungin, cilofungin; LY121019; LY303366; the allylamine group of antifungals such as terbinafine. Yet other non-limiting examples of antifungal agents include naftifine, tolnaftate, mediocidin, candicidin, trichomycin, hamycin, aurefungin, ascosin, ayfattin, azacolutin, trichomycin, levorin, heptamycin, candimycin, griseofulvin, BF-796, MTCH 24, BTG-137586, pradimicins (MNS 18184), benanomicin; ambisome; nikkomycin Z; flucytosine, or perimycin.

In another preferred form of the invention, the antimicrobial agent is an antiviral agent. Non-limiting examples of antiviral agents include cidofovir, amantadine, rimantadine, acyclovir, gancyclovir, pencyclovir, famciclovir, foscamet, ribavirin, or valcyclovir. In some forms of the invention the antimicrobial agent is an innate immune peptide or proteins. Some exemplary classes of innate peptides or proteins are transferrins, lactoferrins, defensins, phospholipases,

lysozyme, cathelicidins, serprocidins, bacteriocidal permeability increasing proteins, amphipathic alpha helical peptides, and other synthetic antimicrobial proteins.

In other embodiments of the invention, the antimicrobial agent is an antiseptic agent. Several antiseptic agents are known in the art and these include a taurinamide derivative, a phenol, a quaternary ammonium surfactant, a chlorine-containing agent, a quinaldinium, a lactone, a dye, a thiosemicarbazone, a quinone, a carbamate, urea, salicylamide, carbanilide, a guanide, an amidine, an imidazoline biocide, acetic acid, benzoic acid, sorbic acid, propionic acid, boric acid, dehydroacetic acid, sulfurous acid, vanillic acid, esters of p-hydroxybenzoic acid, isopropanol, propylene glycol, benzyl alcohol, chlorobutanol, phenylethyl alcohol, 2-bromo-2-nitropropan-1,3-diol, formaldehyde, glutaraldehyde, calcium hypochlorite, potassium hypochlorite, sodium hypochlorite, iodine (in various solvents), povidone-iodine, hexamethylenetetramine, noxythiolin, 1-(3-choroallyl)-3,5,7-triazo 1-azoniaadamantane chloride, taurolidine, taurultam, N(5-nitro-2-furfurylidene)-1-amino-hydantoin, 5-nitro-2-furaldehyde semicarbazone, 3,4,4′-trichlorocarbanilide, 3,4′,5-tribromosalicylanilide, 3-trifluoromethyl-4,4′-dichlorocarbanilide, 8-hydroxyquinoline, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid, 1,4-dihydro-1-ethyl-6-fluoro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid, hydrogen peroxide, peracetic acid, phenol, sodium oxychlorosene, parachlorometaxylenol, 2,4,4′-trichloro-2′-hydroxydiphenol, thymol, chlorhexidine, benzalkonium chloride, cetylpyridinium chloride, silver sulfadiazine, or silver nitrate.

In another preferred form of the invention, the antiseptic solution includes a basic reagent and a dye. The basic reagent may be a guanidium compound, a biguanide, a bipyridine, a phenoxide antiseptic, an alkyl oxide, an aryl oxide, a thiol, a halide, an aliphatic amine, or an aromatic amine. In some specific aspects, the basic reagent is a guanidium compound. Non-limiting examples of guanidium compounds include chlorhexidine, alexidine, hexamidine. In other specific embodiments, the basic reagent is a bipyridine. One example of a bipyridine is octenidine. In yet other aspects, the basic reagent is a phenoxide antiseptic.

The dye may be a triarylmethane dye, a monoazo dye, a diazo dye, an indigoid dye, a xanthene dye, an anthraquinone dye, a quinoline dye, an FD&C dye. Non-limiting examples of triarylmethane dye include gentian violet, crystal violet, ethyl violet, or brilliant green.

Exemplary monoazo dyes inlude FD&C Yellow No. 5, or FD&C Yellow No. 6. Other non-limiting examples of FD&C dye include Blue No. 1 or Green No. 3. One non-limiting example of diazo dyes is D&C Red No. 17. An example of an indigoid dye is FD&C Blue No. 2. An example of a xanthene dye is FD&C Red No. 3; of an anthraquinone dye is D&C Green No. 6; and of an quinoline dye is D&C Yellow No. 1.

Other examples of antiseptics that may be used to the solutions of the invention are the phenoxide antiseptics such as clofoctol, chloroxylenol or triclosan. Still other antiseptic agents that may be used to prepare the amntimicrobial solutions of the invention are gendine, genlenol, genlosan, or genfoctol.

One of skill in the art will appreciate that one can use one or more of the antimicrobial agents including one or more antibacterial agent, and/or one or more antifungal agent, and/or one or more antiviral agent, and/or one or more antiseptic agent, and/or combinations thereof.

A wide variety of chelator agents are contemplated as useful in preparing the antiseptic solutions of the invention. This includes chelators such as EDTA free acid, EDTA 2Na, EDTA 3Na, EDTA 4Na, EDTA 2K, EDTA 2Li, EDTA $2NH_4$, EDTA 3K, Ba(II)-EDTA, Ca(II)-EDTA, Co(II)-EDTACu(II)-EDTA, Dy(III)-EDTA, Eu(III)-EDTA, Fe(III)-EDTA, In(III-EDTA, La(III)-EDTA, CyDTA, DHEG, diethylenetriamine penta acetic acid (DTPA), DTPA-OH, EDDA, EDDP, EDDPO, EDTA-OH, EDTPO, EGTA, HBED, HDTA, HIDA, IDA, Methyl-EDTA, NTA, NTP, NTPO, O-Bistren, TTHA, EGTA, DMSA, deferoxamine, dimercaprol, zinc citrate, a combination of bismuth and citrate, penicillamine, succimer or Etidronate. It is contemplated that any chelator which binds barium, calcium, cerium, cobalt, copper, iron, magnesium, manganese, nickel, strontium, or zinc will be acceptable for use in the present invention.

Alternatively, one may use at least one anticoagulant such as heparin, hirudin, EGTA, EDTA, urokinase, streptokinase, hydrogen peroxide etc., in the preparation of the antimicrobial solutions of the invention.

In addition to the alcohols set forth above, a variety of alcohols are contemplated as useful in the preparation of the instant antiseptic solution, and include any antimicrobially active alcohol. Non-limiting examples of alcohols include ethanol, methanol, isopropanol, propylene glycol, benzyl alcohol, chlorobutanol, phenylethyl alcohol, and the like.

One of skill in the art will appreciate that the solutions of the instant invention can comprise various combinations of at least one alcohol, at least one antimicrobial agent, and at least one chelator/anticoagulant. In some specific embodiments, the solution of the invention comprises at least one alcohol, at least one tetracycline and at least one chelator/anticoagulant. In a specific aspect, such an antimicrobial solution comprises ethanol, at least one tetracycline and EDTA or heparin.

In other specific aspects, such a solution comprises ethanol, minocycline and EDTA or heparin. In one embodiment of this aspect, the concentration of minocycline is 0.001 mg/ml to 100 mg/ml. In another embodiment, the concentration of minocycline is about 3 mg/ml. In another aspect, the concentration of EDTA is in the range of 10-100 mg/ml. In one embodiment of this aspect, the concentration of EDTA is about 30 mg/ml.

In another preferred form of the invention, the antiseptic solution includes a pharmacologically acceptable sodium salt, a pharmacologically acceptable calcium salt, a pharmacologically acceptable potassium salt and about one milligram per milliliter polyhexamethylene biguanide hydrochloride in an aqueous admixture. Additionally, the solution of the invention may also contain a pharmacologically acceptable salt of lactic acid.

Salt containing antiseptic solutions

One preferred antiseptic solution includes a pharmacologically acceptable sodium salt such as sodium chloride or the like in a concentration of between about 820 mg to about 900 mg, a pharmacologically acceptable calcium salt, such as calcium chloride dihydrate or the like in a concentration between about 30.0 mg to about 36.0 mg, a pharmacologically acceptable potassium salt, such as potassium chloride or the like in a concentration between about 28.5 to about 31.5 mg and about one milligram per milliliter polyhexamethylene biguanide hydrochloride in an aqueous admixture with one hundred milliliters of water for injection U.S.P. For particular applications, the solution of the invention may also include sodium lactate in a concentration between about 290 mg and about 330 mg in the one hundred milliliter aqueous admixture.

Photo-oxidant solutions

In another preferred form of the present invention, the antiseptic solution contains an anticoagulant and a photo-oxidant. In certain embodiments, a photo-oxidant is selected that has an antiseptic effect. As used herein, the term "photo-oxidant" is intended to refer to a compound (usually an organic dye) that has photo-oxidation properties, in which the compound exhibits an increased oxidizing potential upon exposure to radiant energy such as light. The term "photo-oxidant" also refers to a composition that releases one or more electrons when struck by light.

In one preferred aspect of the invention, the photo-oxidant is methylene blue, which advantageously provides antibiotic and antifungal activity, and also provides a color to make the antiseptic solution clearly identifiable. In addition to methylene blue, other photo-oxidants may include Rose Bengal, hypericin, methylene violet, proflavine, rivanol, acriflavine, toluide blue, trypan blue, neutral red, a variety of other dyes or mixtures thereof. Therefore, in alternate aspects of the invention, one or more alternative photo-oxidants, preferably a colored photo-oxidant is used in accordance with the invention in place of methylene blue.

Enhanced viscosity solutions

In another preferred form of the imvention, the antiseptic solution includes a low viscosity antibacterial agent mixed with a viscosity increasing agent. Examples of antibacterial agents which may be used, in addition to those described above, comprise alcohols, chlorhexidine, Chlorpactin, iodine, tauroline, citric acid, and soluble citric acid salts, particularly sodium citrate, optionally mixed with water.

Suitable viscosity increasing agents include Carbopol, starch, methylcellulose, carboxypolymethylene, carboxymethyl cellulose, hydroxypropylcellulose, or the like.. Carbopol is a cross-linked polyacrylic acid based polymer sold by Noveon, Inc. It is preferably neutralized to about pH 7 with a base material such as tetrahydroxypropyl ethylene diamine, triethanolamine, or sodium hydroxide. Derivatives of starch may also be used, such as hydroxyethylstarch, hydroxypropylstarch, or starch having bonded organic acid ester groups, to improve compatibility with antibacterial agents such as alcohols, for example, ethanol or isopropanol. Such ester groups may be the reaction product of two to twelve carbon organic acids with the starch, for example. Also, the elevated viscosity antiseptic solution may be created

by the use of a fat emulsion, or other dispersions in water/alcohol of glycerol mono or di esters of fatty acids, or fatty acid esters of other polyols such as sugars having one or more bonded fatty acid groups per molecule. Analogous compounds with ether linkages may also be used.

Also, other materials such as alginic acid, with or without calcium citrate may be used, or polyvinyl alcohol, with or without borax, povidone, polyethylene glycol alginate, sodium alginate, and/or tragacanth. If desired, the fluid of this invention may also contain an effective amount of an antithrombogenic agent such as heparin, and a diluent such as water, along with other desired ingredients.

In one preferred form of the invention, the antiseptic solution contains a mixture of isopropyl alcohol and neutralized Carbopol, with other optional ingredients being present such as water, antithrombogenic agents such as heparin, and the like. Preferably, about 0.4 to 2 weight percent of Carbopol is present. Citric acid may also be present as an antibacterial agent, either with or as a substitute for another anti-bacterial agent such as isopropyl alcohol or ethanol.

In another embodiment, the antiseptic solution is a gel of an isopropyl alcohol, optionally with up to about 30 weight percent water, and about 2.2 weight percent hydroxypropylcellulose, to form a high viscosity antiseptic solution.

In yet another preferred form of the invention, the antiseptic solution contains carbohydrates and/or glucose degradation products. Suitable carbohydrates are chosen form the group of glucose and/or fructose. Suitable degradation products include 3-deoxyglucosone (3-DG), acetaldehyde, formaldehyde, acetaldehyde, glyoxal, methylglyoxal, 5-hydroxymethyl-2-furaldehyde (5-HMF), 2-furaldehyde, and 3,4-dideoxyglucosone-3-ene (3,4-DGE).

Other suitable agents to be used in this embodiment of the antiseptic solution includes substances having anticoagulatory properties i.e., inhibitors of the coagulation cascade such as heparin of standard and low molecular weight, fractionated heparin, synthetic inhibitors in the coagulation cascade, Futhan as a broad protease inhibitor, complexing and chelating substances such as citrate, EDTA, EGTA, substances and mixtures used for preservation of blood products (platelets or plasma), CDPA (citrate, sodium phosphate, dextrose, adenine), synthetic or natural thrombin inhibitor substances.

Other suitable additives include fucosidan, riboflavin, vitamin E, alpha-tocopherol, folic acid and amino acids. Furthermore, antiinflammatory compounds and drugs could also be used, e.g. cortison, mycophenolic acid (MPA) and derivates thereof, sirolimus, tacrolimus and cyclosporin, diclofenac, etc.

Inhibitory peptides can also be used in the antiseptic solution such as defensins, (dermacidine), and others. Radicals, such as reactive oxygene species, NO-releasing systems or nitric oxide (NO), and peroxynitrite may also be used. A buffer composition mas also be included in the antiseptic solution, and in one preferred form of the invention, the buffer contains lactate, bicarbonate, pyruvate, ethyl pyruvate and citric acid in combination and mixtures including adjustment of pH by acetic acid, hydrochloric acid or sulphuric acid. Furthermore, viscosity enhancing additives may be added, such as lipids or lipidic substances (also to get water insoluble vitamins or complexes into solution), nutrients in high concentration density gradient e.g. aminoacid containing fluids, polyglucose, Icodextrin, pectine, hydroxyethyl starch (HES), alginate, hyaluronic acid, etc.

Taurolidine antiseptic solutions and gels

The antiseptic solutions of the present invention can include Taurolidine and/or Taurultam to prevent clotting and Biofilm formation or the elements can be combined with other antimicrobial agents. One embodiment of the present invention is a gel with thixotropic properties to keep the solution inside the antiseptic cap and not spill out during the time interval between uses. This is accomplished by making a hydrogel matrix as a drug delivery vehicle containing a biocompatible antimicrobial agent alone or with another active agent, which may be useful for particular purposes. The hydrogel matrix is biocompatible and, biodegradable in the bloodstream. The matrix can be a hydrogel (e.g., pectin, gelatin, etc), a protein (e.g., collagen, hemoglobin, etc), a colloidal substance (e.g., serum albumin etc), an emulsion or other adjuvant. Preferably, the matrix shall have structural integrity and be thixotropic. Thixotropy is a property, which is exhibited by certain gels. It is a property characterized by a solid or semisolid substance that when shaken, stirred or subject to high shear forces becomes fluid like and can flow and then returns to the semisolid state when the forces and/movement are stopped. Alternatively, the gel

could have the properties similar to that of the colloidal dispersion which resists movement, or flow until a high shear force is imparted to the fluid and then it flows easily.

Other ingredients may be added to the gel matrix to provide further functional benefit. The preferred antimicrobial is Taurolidine, which can be added to the matrix as a micro particle powder, or encapsulated in liposomes, microspheres, or nanospheres. It should be appreciated that numerous active agents and drugs can be added to the thixotropic gel including sterileants, lysing agents (such as Urokinase), imaging enhancers, catheter surface modifiers, antibiotics and antimicrobial chemicals.

A hydrogel comprises a three-dimensional molecular network containing large quantities of water giving them good biocompatibility with material consistency that is soft solid—like with high diffusive properties to gases, chemicals and proteins. Suitable hydrogels include natural polymers including serum albumin, collagen, or alginates, polyvinyl alcohol, poly (ethylene oxide) or poly (hydroxyethylene) and polyelectrolytes, such as poly(acrylic acid), poly(styrene sulfonate), and carboxymethylcellulose (CMC).

One preferred form of the antiseptic solution includes Taurolidine with Salicylic acid or Sodium Salicylate in an aqueous solvent. Salicylic Acid and Sodium Salicylate are drugs that have been used with antibiotic locks in catheters to enhance the biocidal action of the antibiotic alone and to inhibit the attachment of microbes to surfaces. This last attribute is especially important because the initiation of a Biofilm expression and growth require that the individual bacteria must first attach themselves to the underlying surface. By stopping attachment, Biofilm formation is blocked.

Sodium salicylate has been demonstrated to have remarkable antibacterial activity, including the ability to enhance the activities of certain antibiotics. This drug inhibits adherence, growth and Biofilm formation.

EDTA containing antiseptic solutions

In one preferred antiseptic solution of the present invention provides antimicrobial, anti-fungal, anti-viral and anti-amoebic properties and may also serve as an anti-coagulant. Specified

salts and compositions of ethylene diamine tetraacetic acid (EDTA) ($C_{10}H_{12}N_2Na_4O_8$) are used at specified concentrations and pH levels.

The EDTA formulations of the present invention are safe for human administration and are biocompatible and non-corrosive. They may also have anticoagulant properties and are thus useful for preventing and/or treating a variety of catheter-related infections. In one embodiment, antiseptic solutions of the present invention have at least four, and preferably at least five, of the following properties: anticoagulant properties; inhibitory and/or bactericidal activity against a broad spectrum of bacteria in a planktonic form; inhibitory and/or fungicidal activity against a spectrum of fungal pathogens; inhibitory and/or bactericidal activity against a broad spectrum of bacteria in a sessile form; inhibitory activity against protozoan infections; inhibitory activity against Acanthamoeba infections; safe and biocompatible, at least in modest volumes, in contact with a patient; safe and biocompatible, at least in modest volumes, in a patient's bloodstream; and safe and compatible with industrial objects and surfaces. The antiseptic solution can have a pH higher than physiological pH such as a pH of >8.0, or at a pH >8.5, or at a pH>9, or at a pH>9.5.

In another preferred form of the invention, the antiseptic solution contain a sodium EDTA salt (or combination of sodium salts) in solution at a pH in the range between 8.5 and 12.5 and, in another embodiment, at a pH of between 9.5 and 11.5 and, in yet another embodiment, at a pH of between 10.5 and 11.5.

When used herein, the term "EDTA salt" may refer to a single salt, such as a di-sodium or tri-sodium or tetra-sodium salt, or another EDTA salt form, or it may refer to a combination of such salts. The composition of EDTA salt(s) depends both on the EDTA salts used to formulate the composition, and on the pH of the composition. For antiseptic solutions of the present invention consisting of sodium EDTA salt(s), and at the desired pH ranges (specified above), the sodium EDTA salts are predominantly present in both the tri-sodium and tetra-sodium salt forms.

In one embodiment, the antiseptic solution contains a combination of at least the tri-sodium and tetra-sodium salts of EDTA, and more preferably solutions containing at least 10% of the EDTA in the composition is present in the tetra-sodium salt form. In yet another embodiment, at least 50% and, more preferably at least 60%, of the EDTA in the composition is present in the tri-sodium salt form.

EDTA solutions of the present invention are preferably provided in a sterile and non-pyrogenic form and may be packaged in any convenient fashion. The compositions may be prepared under sterile, aseptic conditions, or they may be sterilized following preparation and/or packaging using any of a variety of suitable sterilization techniques.

Formulation and production of antiseptic compositions of the present invention is generally straightforward. In one embodiment, desired antiseptic solutions of the present invention are formulated by dissolving one or more EDTA salt(s) in an aqueous solvent, such as purified water, to the desired concentration and adjusting the pH of the EDTA salt solution to the desired pH. The antiseptic solution may then be sterilized using conventional means, such as autoclaving, UV irradiation, filtration and/or ultrafiltration, and other means. The preferred osmolarity range for EDTA solutions is from 240-500 mOsM/Kg, more preferably from 300-420 mOsm/Kg. The solutions are preferably formulated using USP materials.

Antiseptic solutions containing sodium salts of EDTA other than tri- and tetra-sodium salts, such as di-sodium EDTA, is also contemplated. For example di-sodium EDTA solutions can be used but such solutions have a lower pH in solution than the desired pH range of compositions of the present invention but, upon pH adjustment to the desired range using a pH adjustment material, such as sodium hydroxide, sodium acetate, and other well-known pH adjustment agents, EDTA solutions prepared using di-sodium salts are converted to the preferred combination di- and/or tri- and/or tetra-sodium salt EDTA solutions of the present invention. Thus, different forms and combinations of EDTA salts may be used in the preparation of EDTA compositions of the present invention, provided that the pH of the composition is adjusted to the desired pH range prior to use. In one embodiment, antiseptic compositions consisting of a mixture of primarily tri-and tetra-sodium EDTA is provided by dissolving di-sodium EDTA in an aqueous solution, 3%-5% on a weight/volume basis, and adding sodium hydroxide in a volume and/or concentration sufficient to provide the desired pH of >8.5 and <12.0.

Antibacterial enzyme containing antiseptic solutions

"Antibacterial enzyme" refers to any proteolytic, pore-forming, degradative or inhibitory enzyme that kills or damages a bacterial species or particular strain thereof. The result may be achieved by damaging the cell wall of the bacteria, disrupting cell membranes associated with

the cell wall or within the bacteria, inhibiting protein synthesis within the bacteria, disrupting the sugar backbone, or by any other mechanism attributed to a peptide or protein considered by those skilled in the art to be an antibacterial enzyme. The enzyme may be a natural, wild-type enzyme, modified by conventional techniques, conjugated to other molecules, recombinantly expressed, or synthetically constructed.

One example of an antibacterial enzyme is lysostaphin. Lysostaphin is important because it is effective in the treatment of staphylococci and biofilms formed therefrom. "Lysostaphin," and "lysostaphin analogues" are defined as including lysostaphin (wild type), any lysostaphin mutant or variant, any recombinant, or related enzyme (analogue) or any synthetic version or fragment of lysostaphin (whether synthetic or otherwise) that retains the proteolytic ability, in vivo and in vitro, to cleave the cross-linked polyglycine bridges in the cell wall peptidoglycan of staphylococci. The enzymes may be generated by post-translational processing of the protein (either by enzymes present in a producer strain or by means of enzymes or reagents introduced at any stage of the process) or by mutation of the structural gene. Mutations may include site deletion, insertion, domain removal and replacement mutations.

The lysostaphin may be synthetically constructed, expressed in mammalian cells, insects, bacteria, yeast, reptiles or fungi, recombinantly expressed from a cell culture or higher recombinant species such as a mouse, or otherwise. This would include the activity-retaining synthetic construction including synthetic peptides and polypeptides or recombinant expression of portions of the lysostaphin enzyme responsible for its activity against staphylococci as part of a larger protein or peptide, include chimeric proteins, containing the active sites of one or more other antibacterial enzymes that are effective either against staphylococci or other biofilm-forming bacteria species.

The antibacterial enzymes may also be coated on the surface of the devices described herein by immersion of the device in a solution of the enzyme for a length of time sufficient to form a biofilm-formation inhibiting coating of the enzyme on the susceptible surface. Even the most minimal concentration of enzyme will confer some protection. Typically, a concentration of from about 10 μg/ml to about 100 mg/ml can be used. With device surfaces, the coatings may also be formed by covalent attachment of the enzyme thereto.

Antiseptic coatings

It is contemplated that the devices described herein can be coated with an antiseptic coating by any suitable technique such as immersion of the part into an antiseptic solution, by spray coating the part with the antiseptic solution, by blending the antiseptic solution or material into the polymeric material used to fabricate the device.

In one preferred form of the invention, a quantity of physiological, antimicrobial metal compound is added to the resin for direct molding of an article. Physiological, antimicrobial metals are meant to include the precious metals, such as silver, gold and platinum, and copper and zinc. Physiological, antimicrobial metal compounds used herein include oxides and salts of preferably silver and also gold, for example: silver acetate, silver benzoate, silver carbonate, silver citrate, silver chloride, silver iodide, silver nitrate, silver oxide, silver sulfa diazine, silver sulfate, gold chloride and gold oxide. Platinum compounds such as chloroplatinic acid or its salts (e.g., sodium and calcium chloroplatinate) may also be used. Also, compounds of copper and zinc may be used, for example: oxides and salts of copper and zinc such as those indicated above for silver. Single physiological, antimicrobial metal compounds or combinations of physiological, antimicrobial metal compounds may be used.

Preferred physiological, antimicrobial metal compounds used in this invention are silver acetate, silver oxide, silver sulfate, gold chloride and a combination of silver oxide and gold chloride. The particles of the silver compounds are sufficiently able to be extracted to form a zone of inhibition to prevent and kill bacteria growth.

In another preferred form of the invention the devices herein are impregnated with triclosan and silver compounds or triclosan and chlorhexidine.

From the foregoing, it will be observed that numerous variations and modifications may be effected without departing from the spirit and scope of the invention. It is to be understood that no limitation with respect to the specific apparatus illustrated herein is intended or should be inferred. It is, of course, intended to cover by the appended claims all such modifications as fall within the scope of the claims.

CLAIMS

What is claimed is:

1. A syringe assembly comprising:

a syringe barrel defining a chamber;

a plunger mounted in the chamber and moveable with respect to the barrel; and

a cap assembly containing a cap and an absorbent material is removably attached to the plunger.

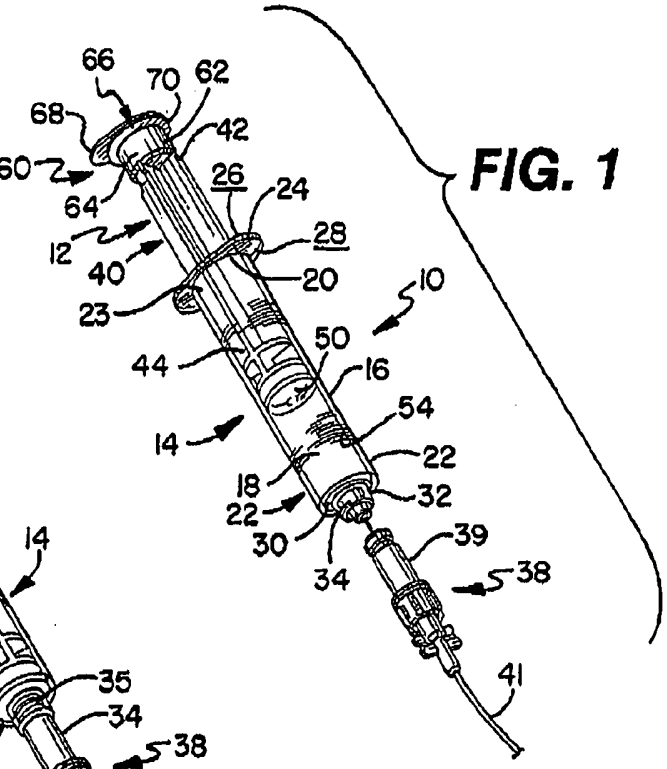


FIG. 1

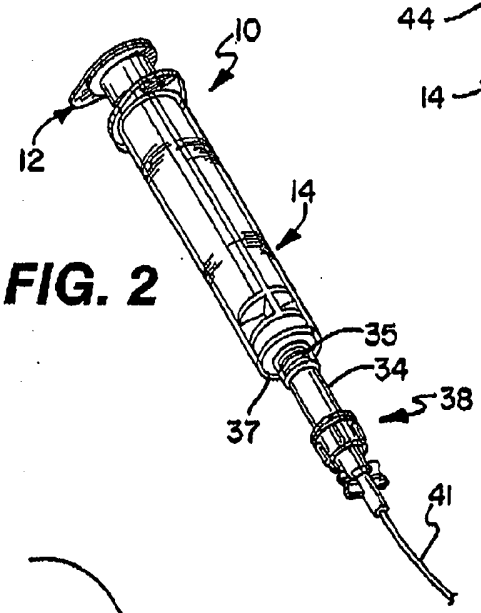


FIG. 2

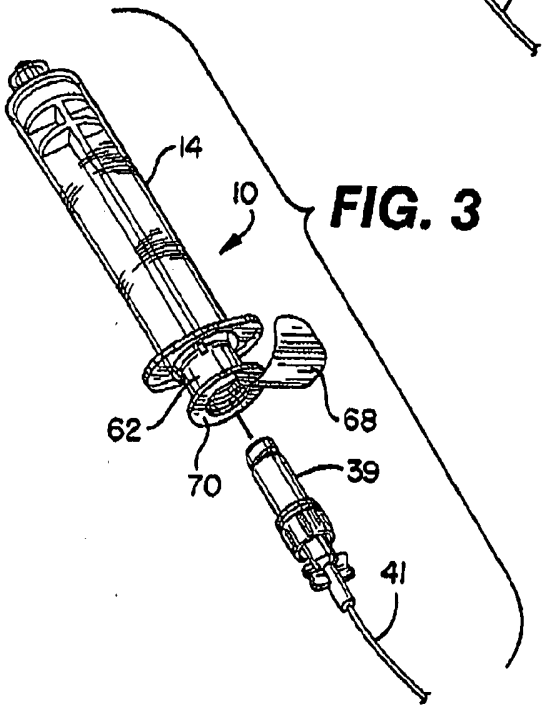


FIG. 3

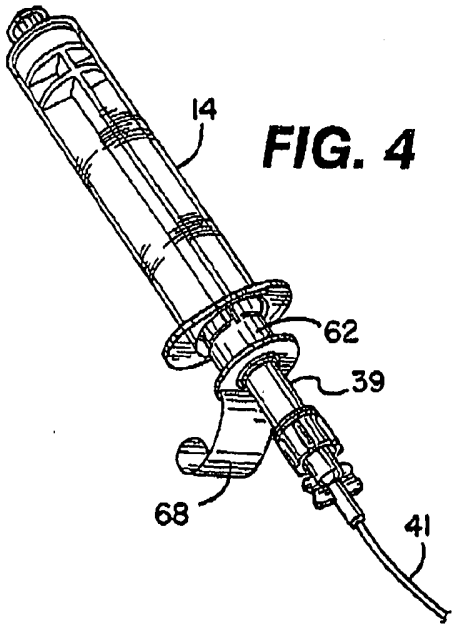


FIG. 4

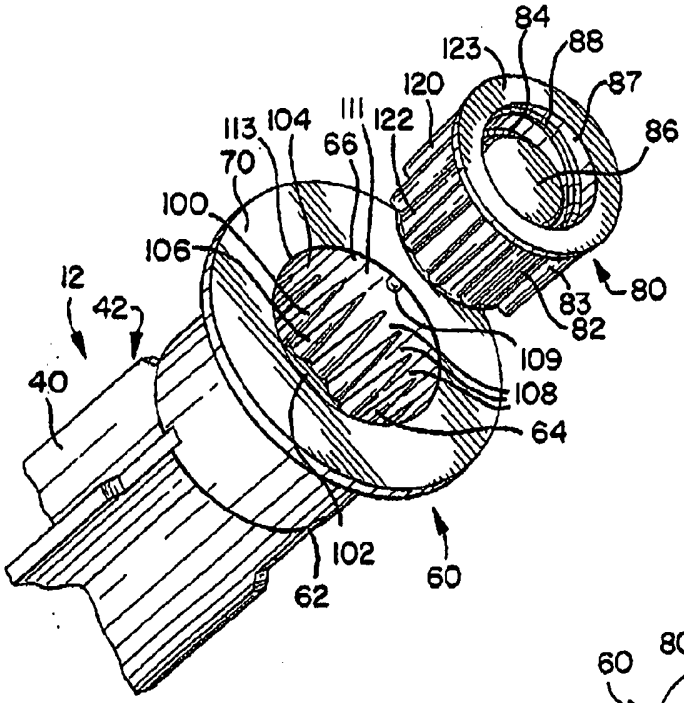


FIG. 5

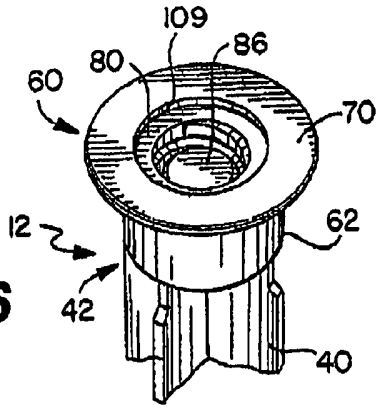


FIG. 6

FIG. 7

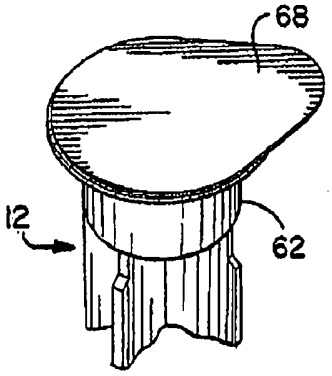


FIG. 8

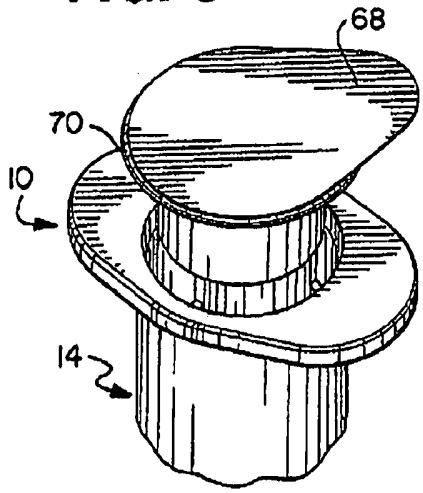


FIG. 9

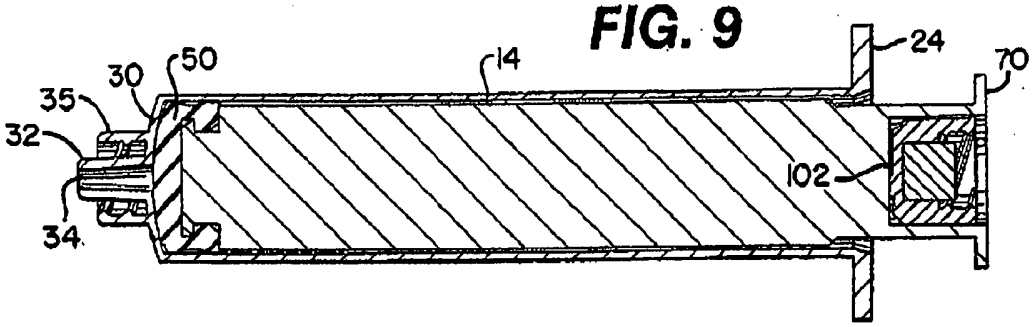


FIG. 10

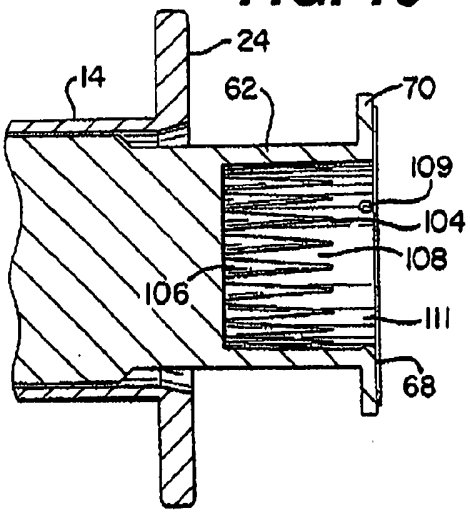


FIG. 11

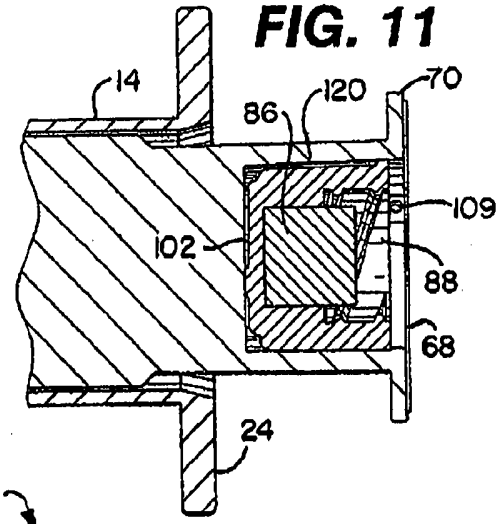


FIG. 12

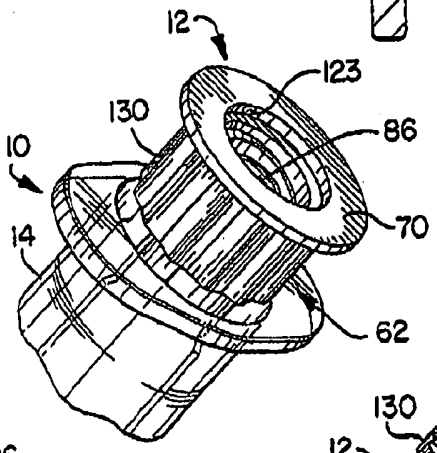


FIG. 13

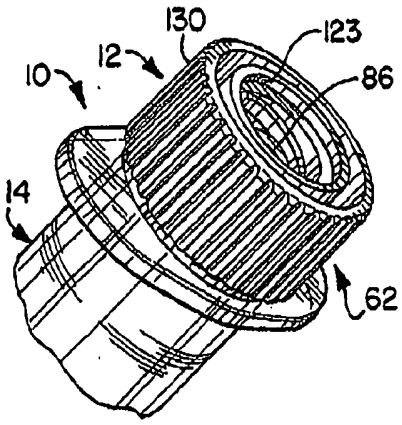


FIG. 14

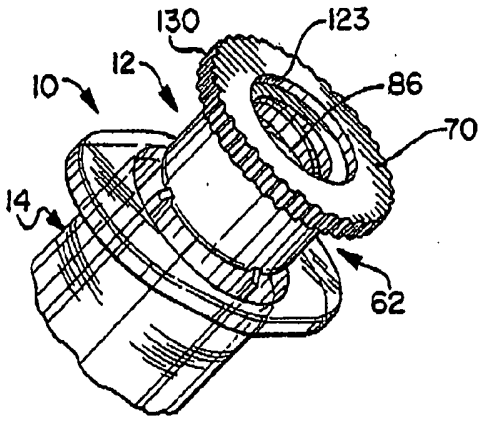


FIG. 15

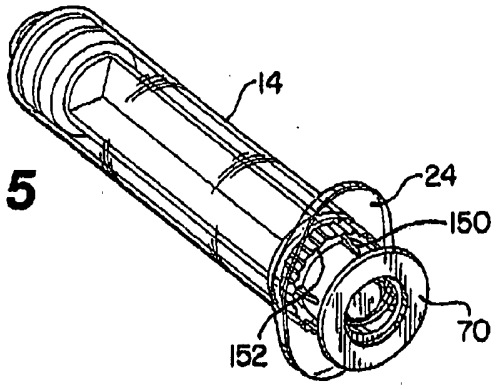


FIG. 16

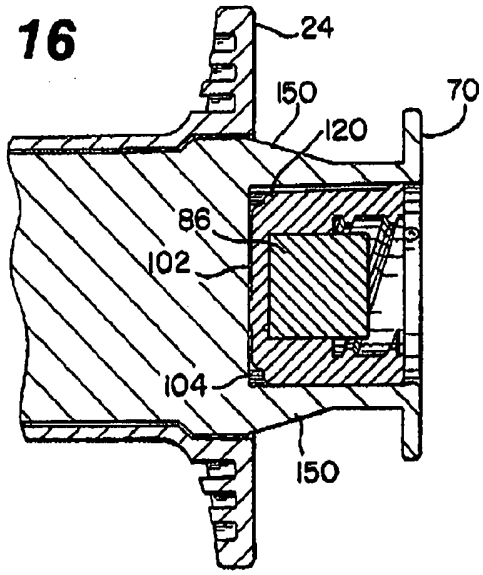


FIG. 17

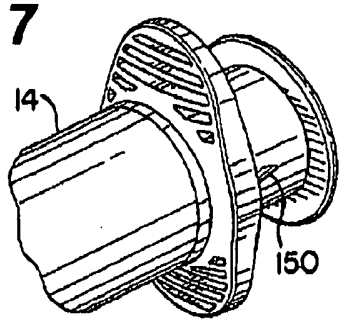


FIG. 18

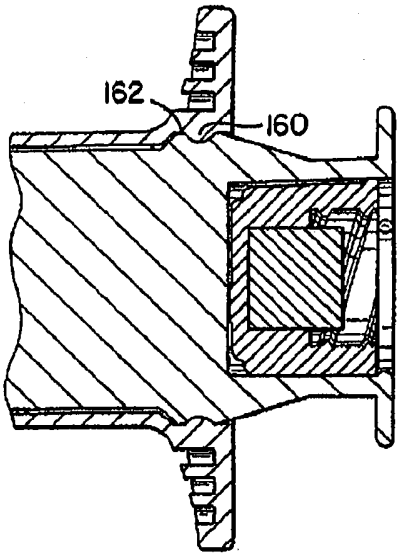


FIG. 19

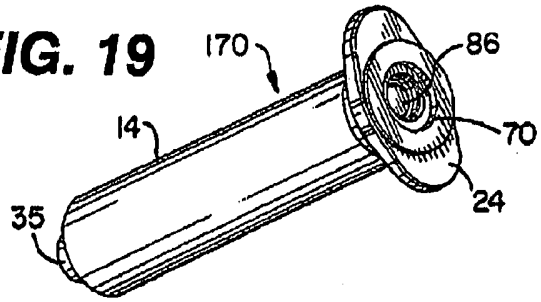
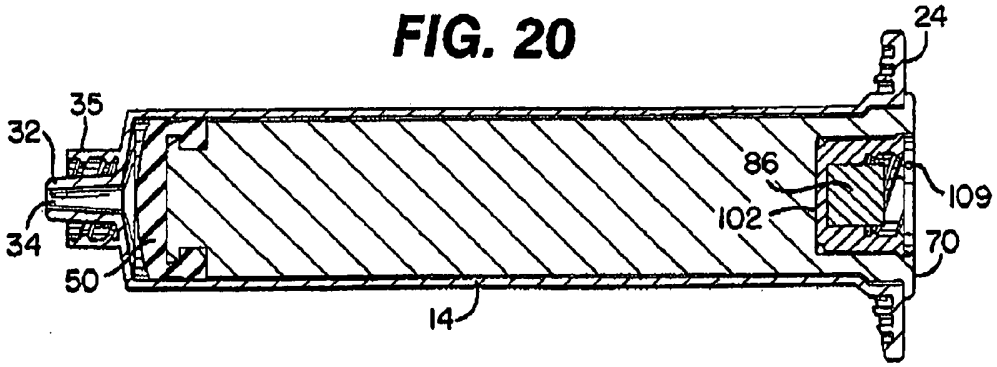


FIG. 20



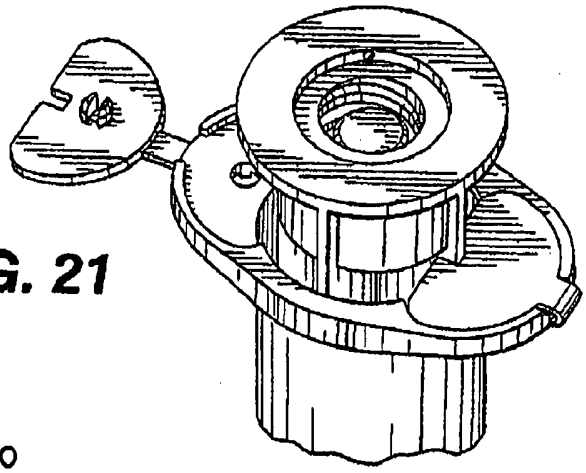


FIG. 21

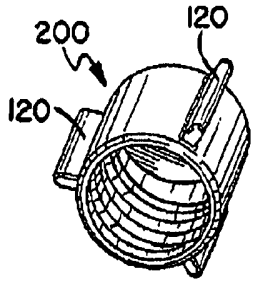


FIG. 22a

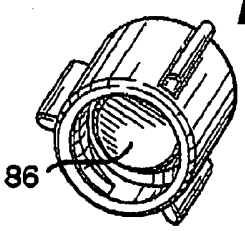


FIG. 22b

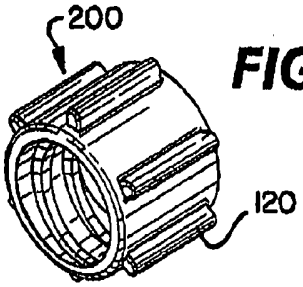


FIG. 23

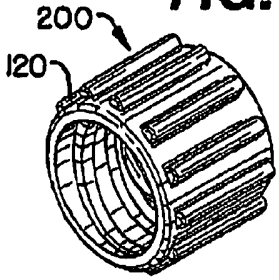


FIG. 24

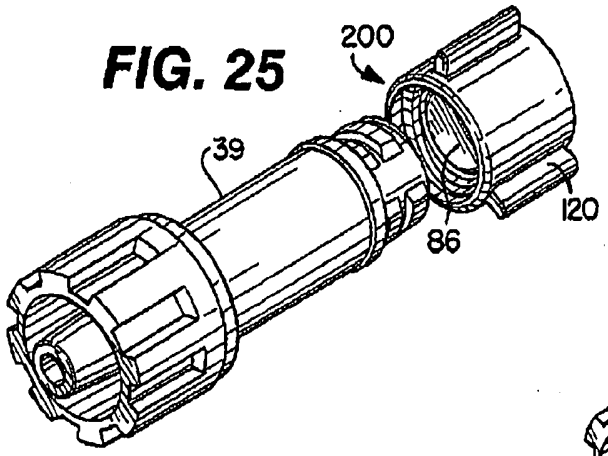


FIG. 25

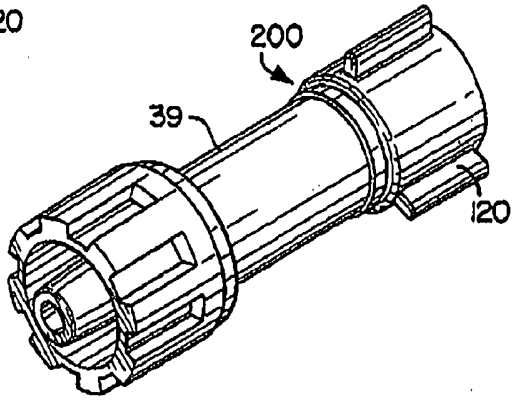
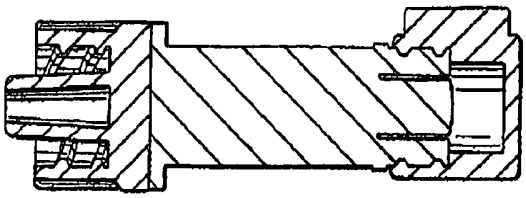


FIG. 26

FIG. 27



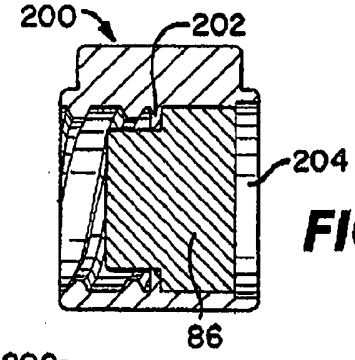


FIG. 28

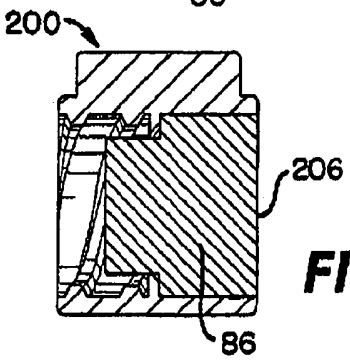


FIG. 29

FIG. 30

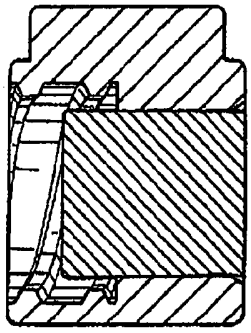


FIG. 31a

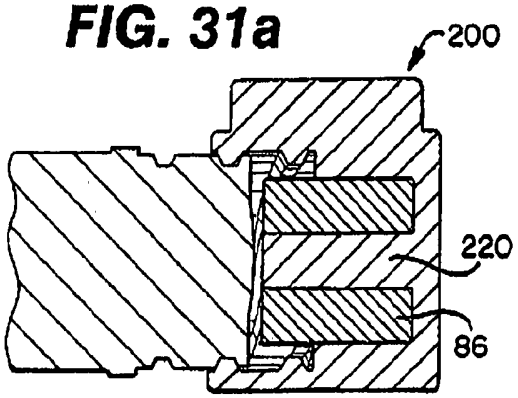


FIG. 31b

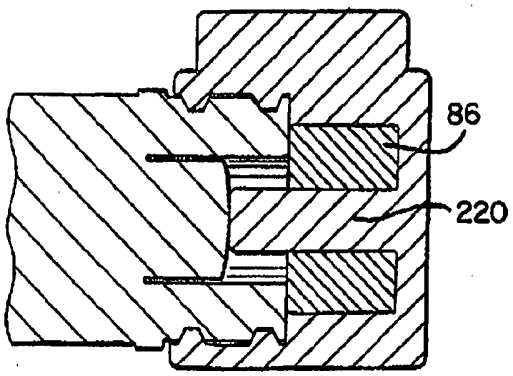


FIG. 32

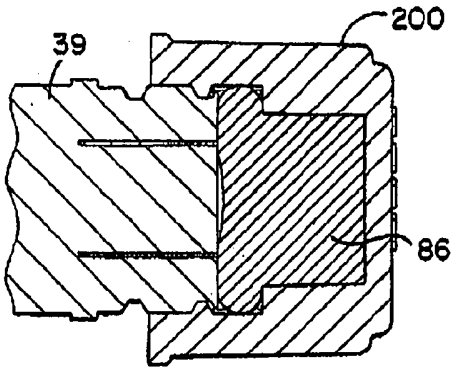
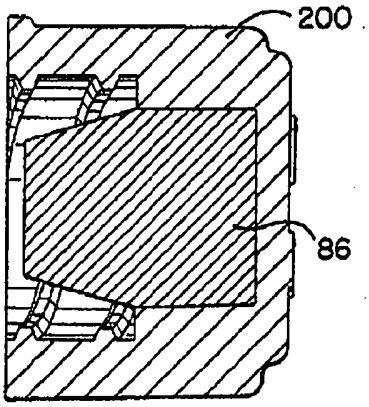


FIG. 33



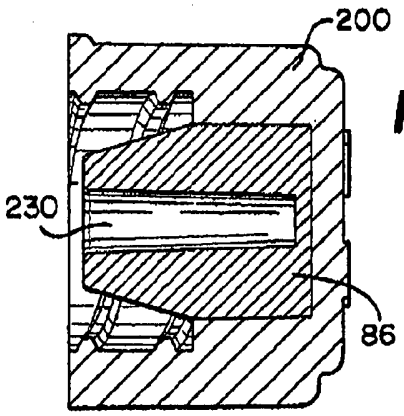
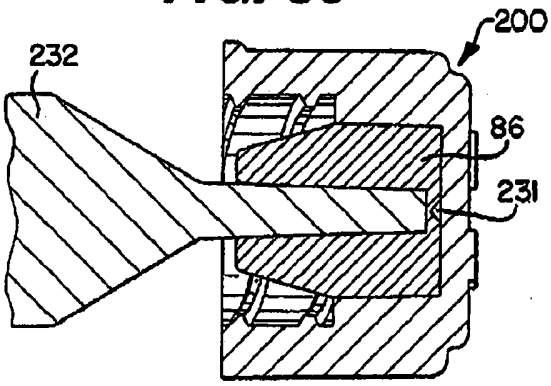


FIG. 34

FIG. 35



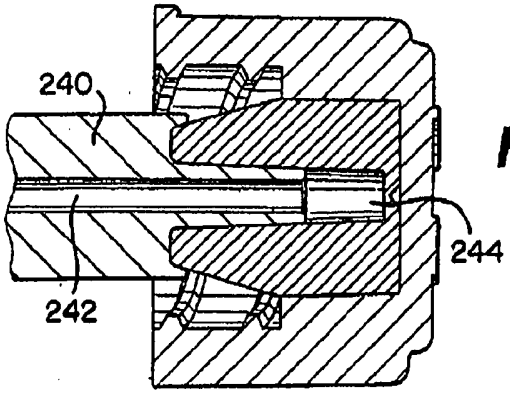


FIG. 36

FIG. 37

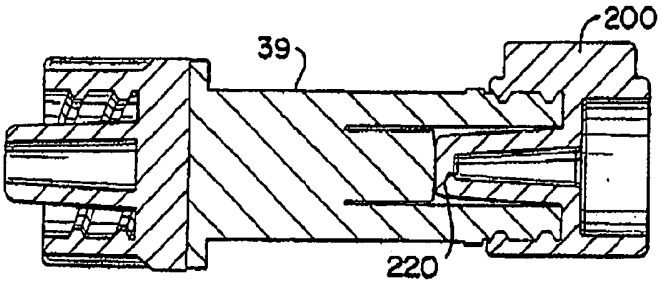


FIG. 38

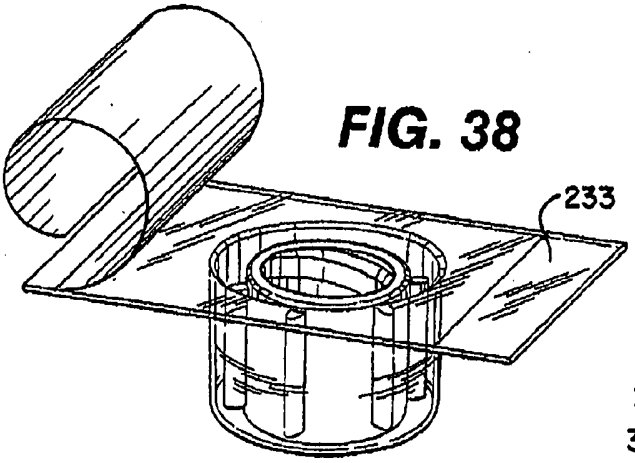


FIG. 39

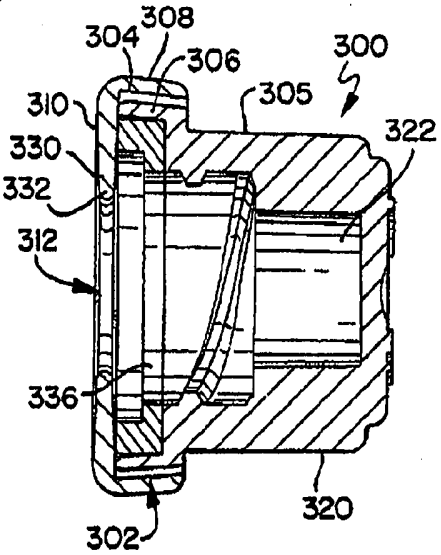


FIG. 40

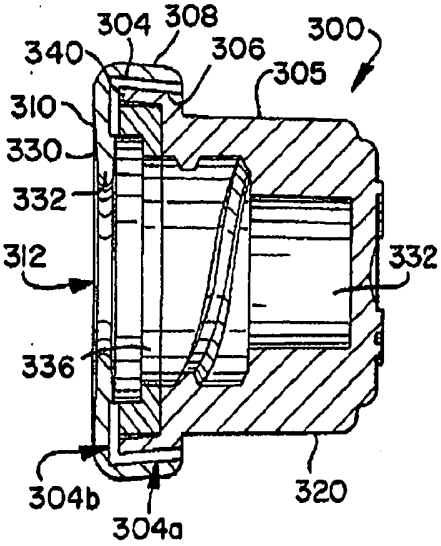


FIG. 41

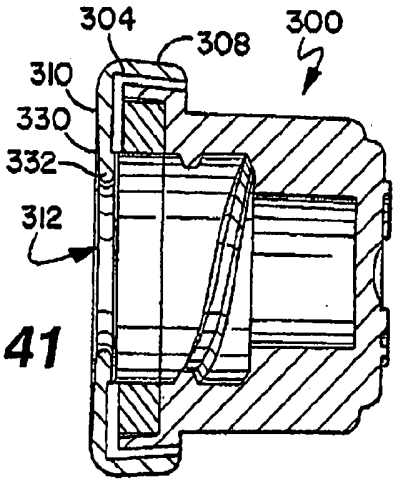


FIG. 42a

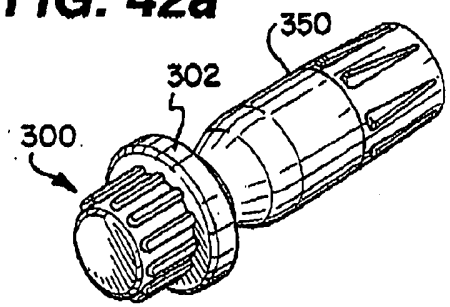


FIG. 42b

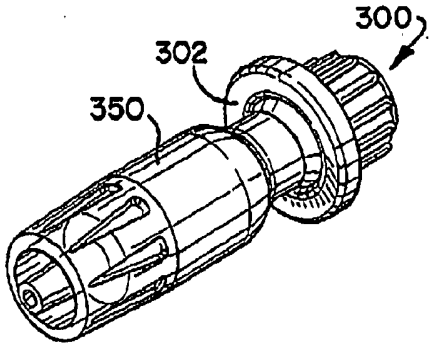


FIG. 43a

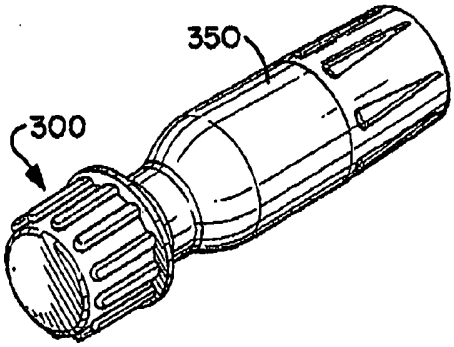


FIG. 43b

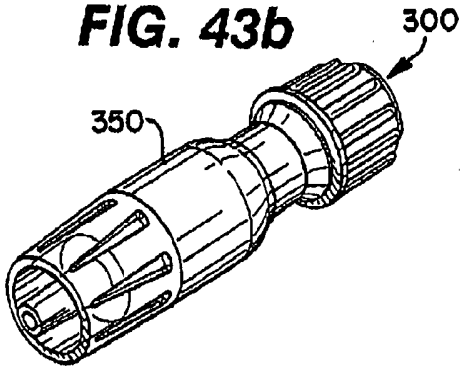


FIG. 44a

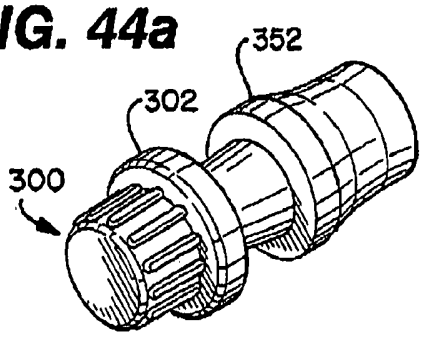


FIG. 44b

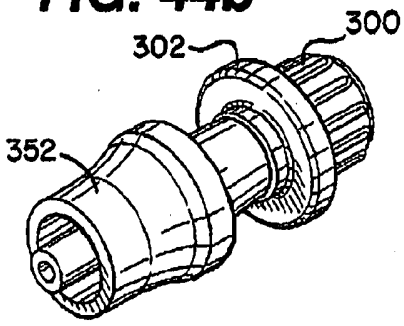


FIG. 45a

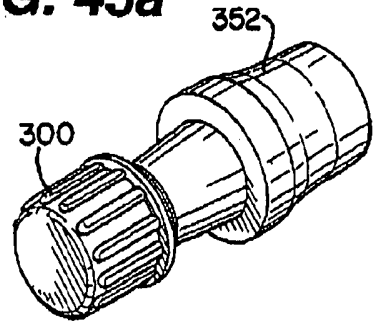


FIG. 45b

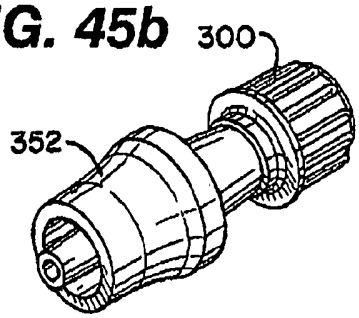


FIG. 46a

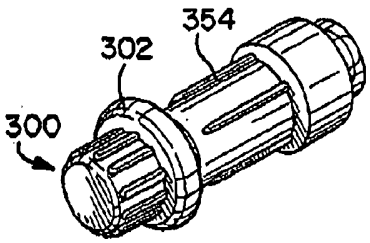


FIG. 46b

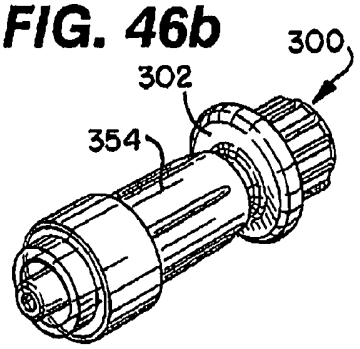


FIG. 47a

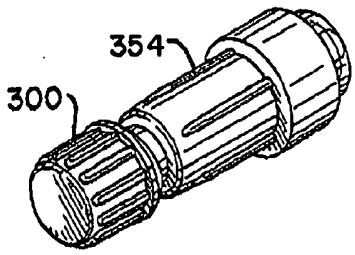


FIG. 47b

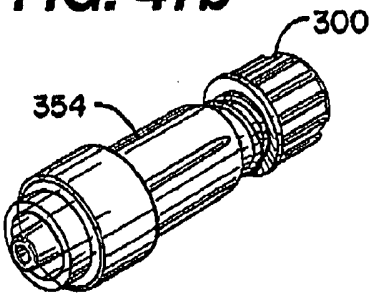


FIG. 48a

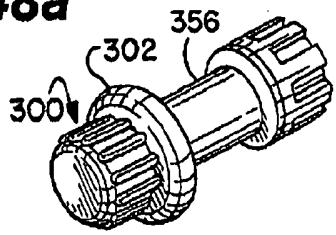


FIG. 48b

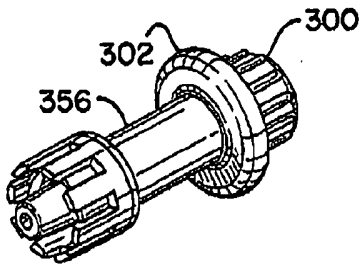


FIG. 49a

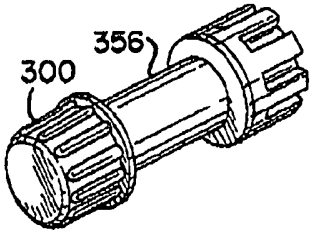
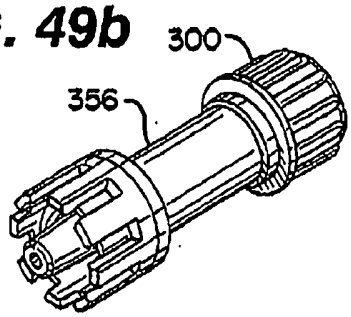


FIG. 49b



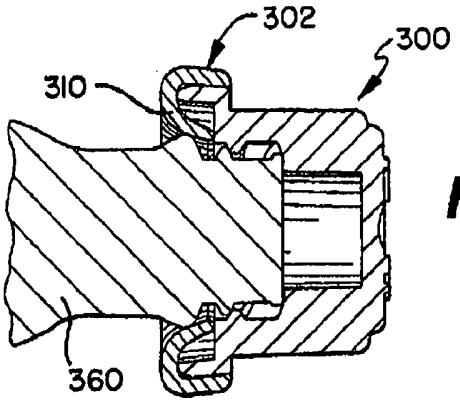


FIG. 50

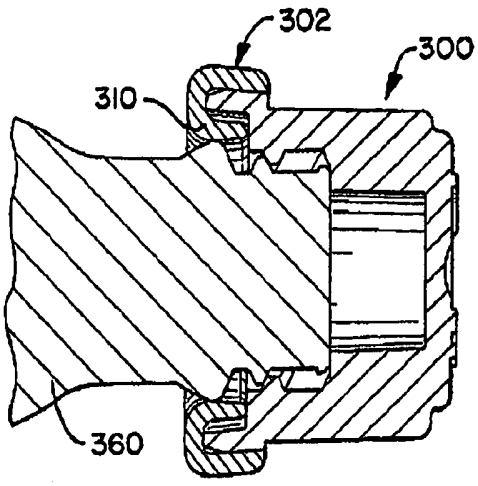


FIG. 51

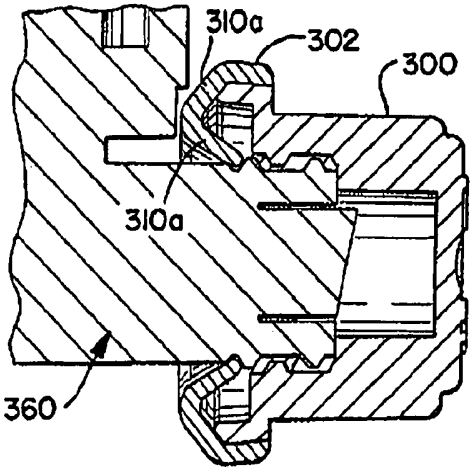
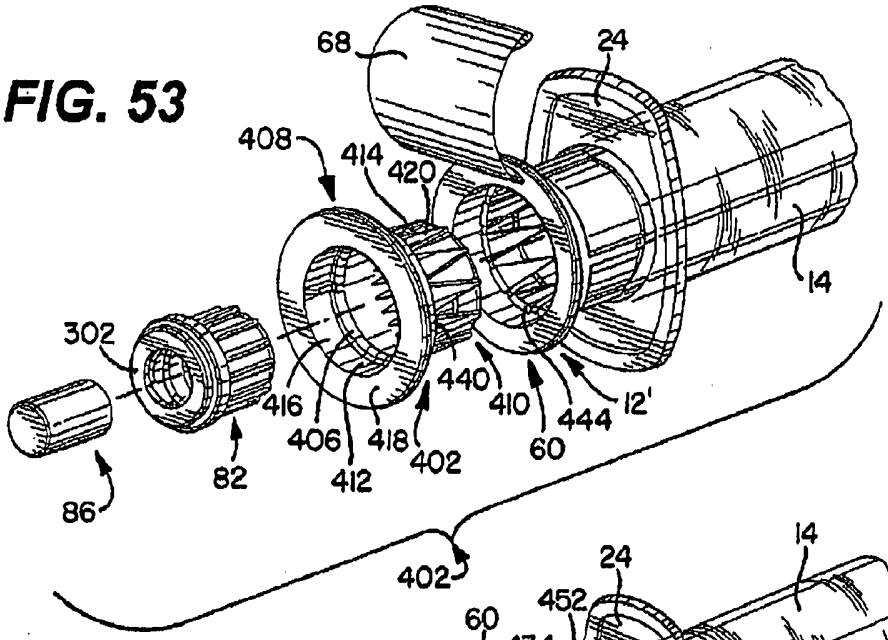


FIG. 52

FIG. 53



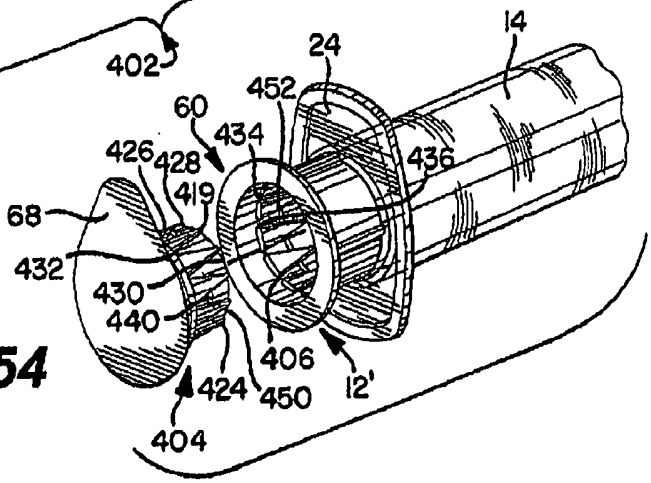


FIG. 54

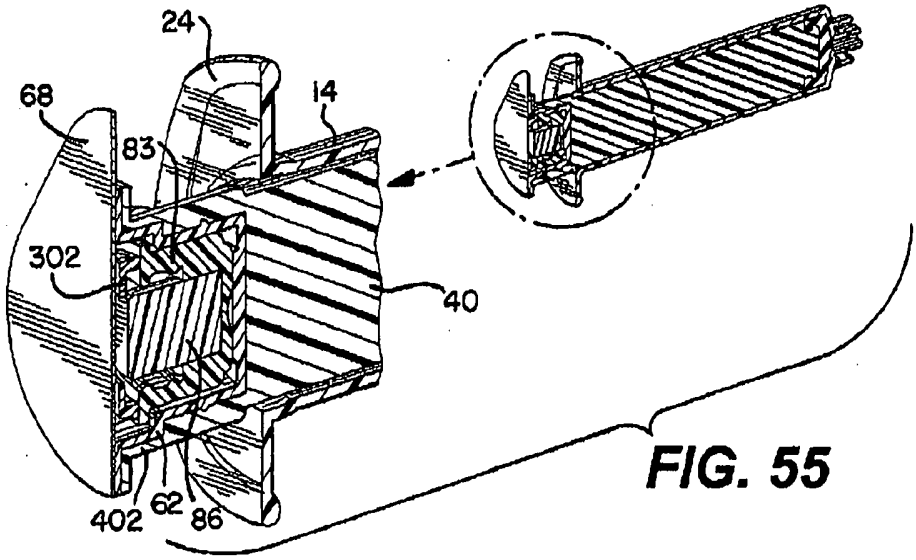


FIG. 55

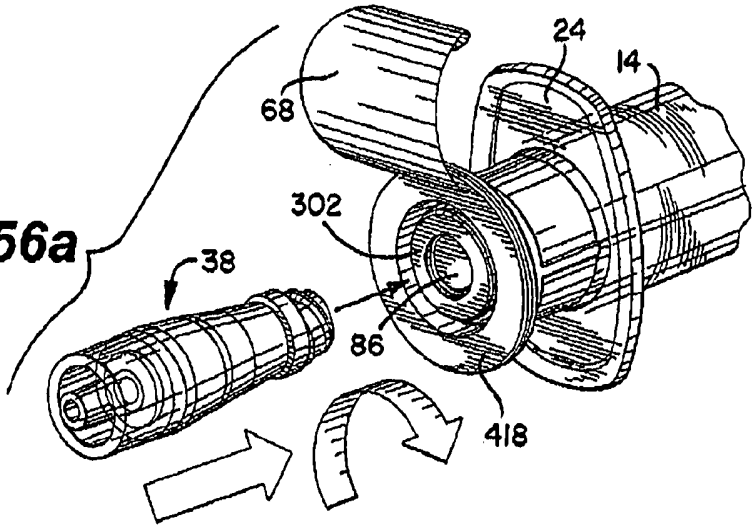


FIG. 56a

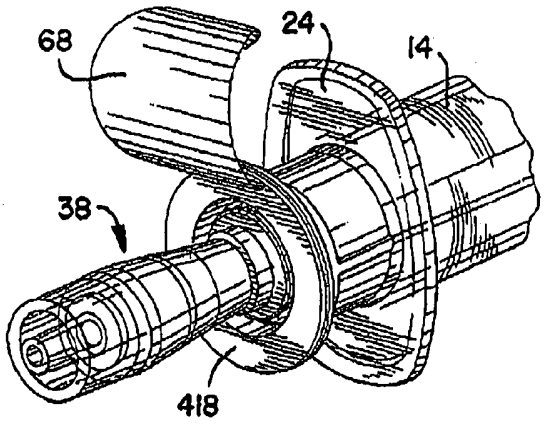


FIG. 56b

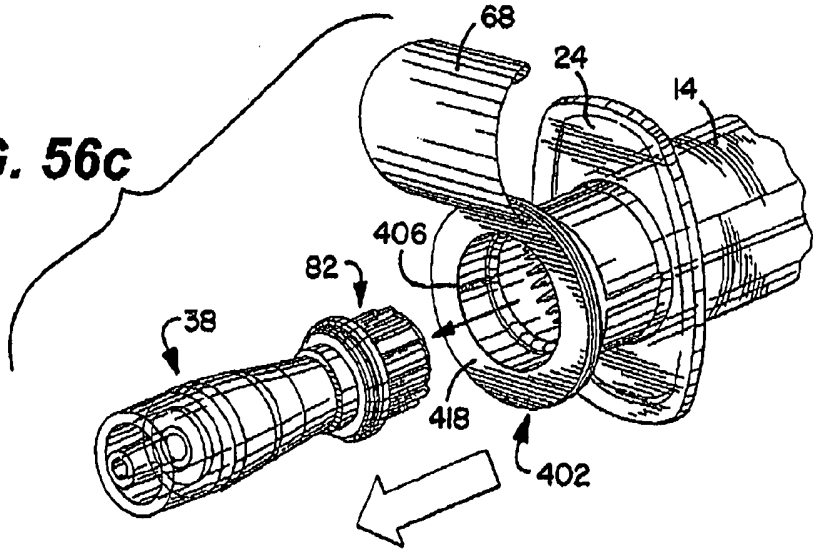


FIG. 56c

FIG. 59

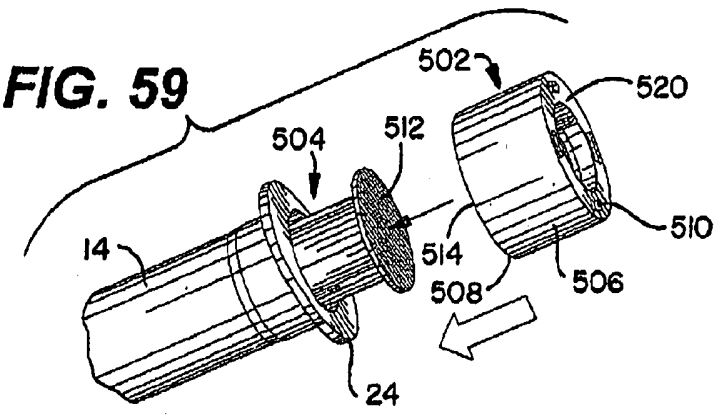


FIG. 60

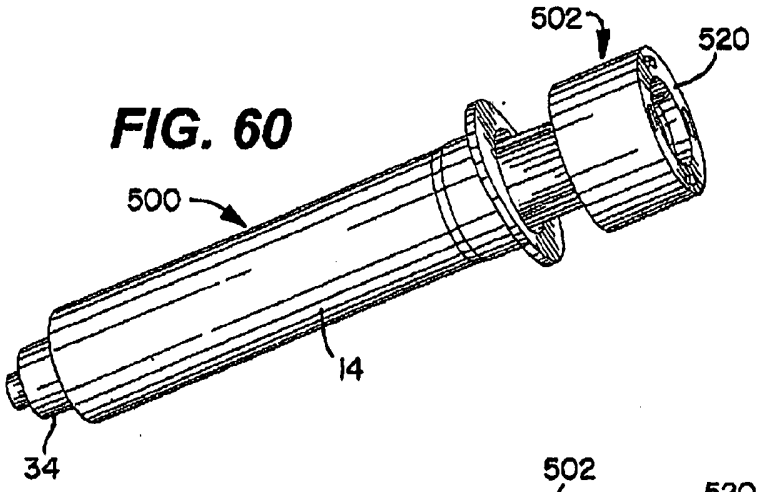
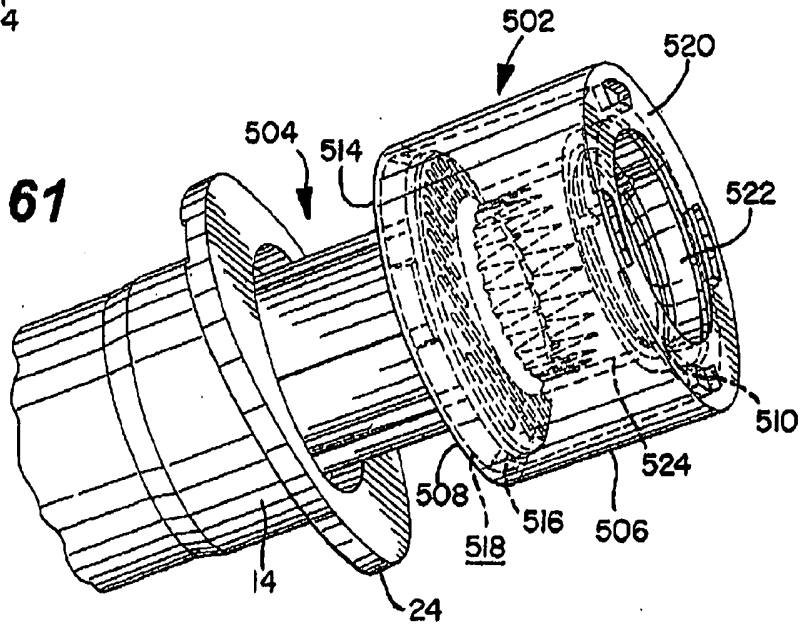


FIG. 61



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/07797

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/00
USPC - 604/256
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 604/256

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 604/241, 256, 268, 523

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST; Google Scholar. Search Terms: plunger, syringe, William, Anderson, cap, absorbent, antiseptic cap, hypodermic, needle, detachable, removable, removably, detach

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,439,184 A (WHEELER). 27 March 1984 (27.03.1984). Column 3, lines 4-24.	1
Y	US 2005/0203460 A1 (KIM). 15 September 2005 (15.09.2005). Paragraph [0005].	1

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
05 September 2008 (05.09.2008)	11 SEP 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

US005624402A

United States Patent [19]

Imbert

[11] Patent Number: 5,624,402

[45] Date of Patent: Apr. 29, 1997

[54] **SYRINGE TIP CAP**

[75] Inventor: **Claude Imbert**, La Tronche, France

[73] Assignee: **Becton, Dickinson and Company**, Franklin Lakes, N.J.

[21] Appl. No.: **355,447**

[22] Filed: **Dec. 12, 1994**

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **604/111**; 604/283; 604/192

[58] **Field of Search** 604/111, 206, 604/240, 241, 242, 243, 256, 283, 192, 905; 215/248, 296, 318, 320

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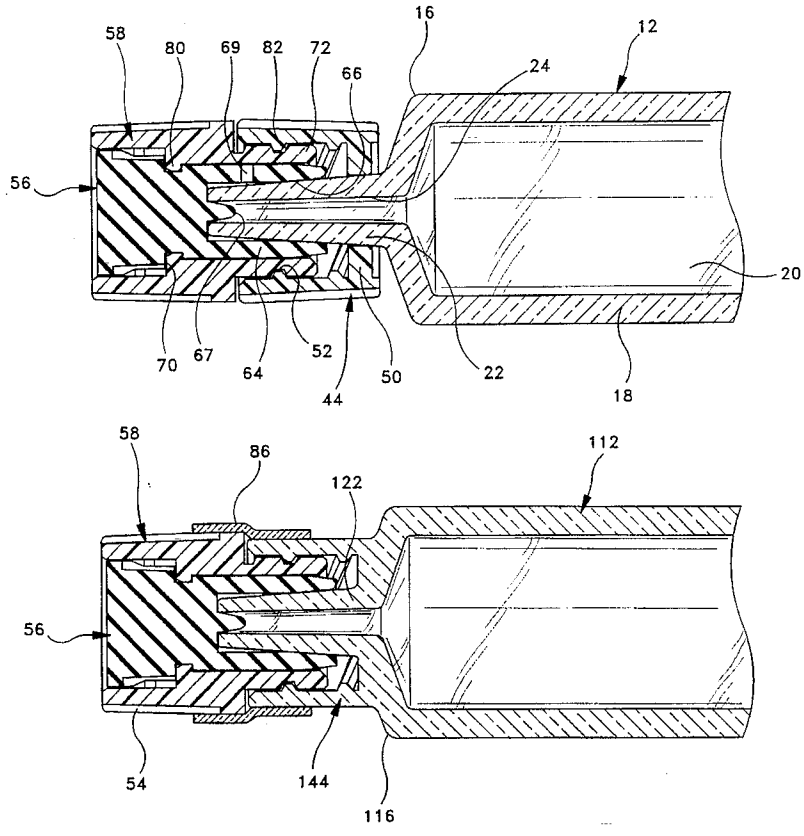
Primary Examiner—Vincent Millin
Assistant Examiner—V. Alexander
Attorney, Agent, or Firm—John L. Voellmicke

[57] **ABSTRACT**

A tip cap is provided for positive sealing engagement with the tip of a syringe barrel. The tip cap includes an inner cap formed from an elastomeric material dimensioned for sealing engagement with the tip of the syringe barrel. The tip cap further includes an outer cap engaged with the inner cap to limit or prevent both axial movement and rotational movement therebetween. The outer cap includes an array of threads for threaded engagement with a luer collar. The luer collar may be a separate component mountable to a syringe barrel or an integral part of the syringe barrel.

2 Claims, 6 Drawing Sheets



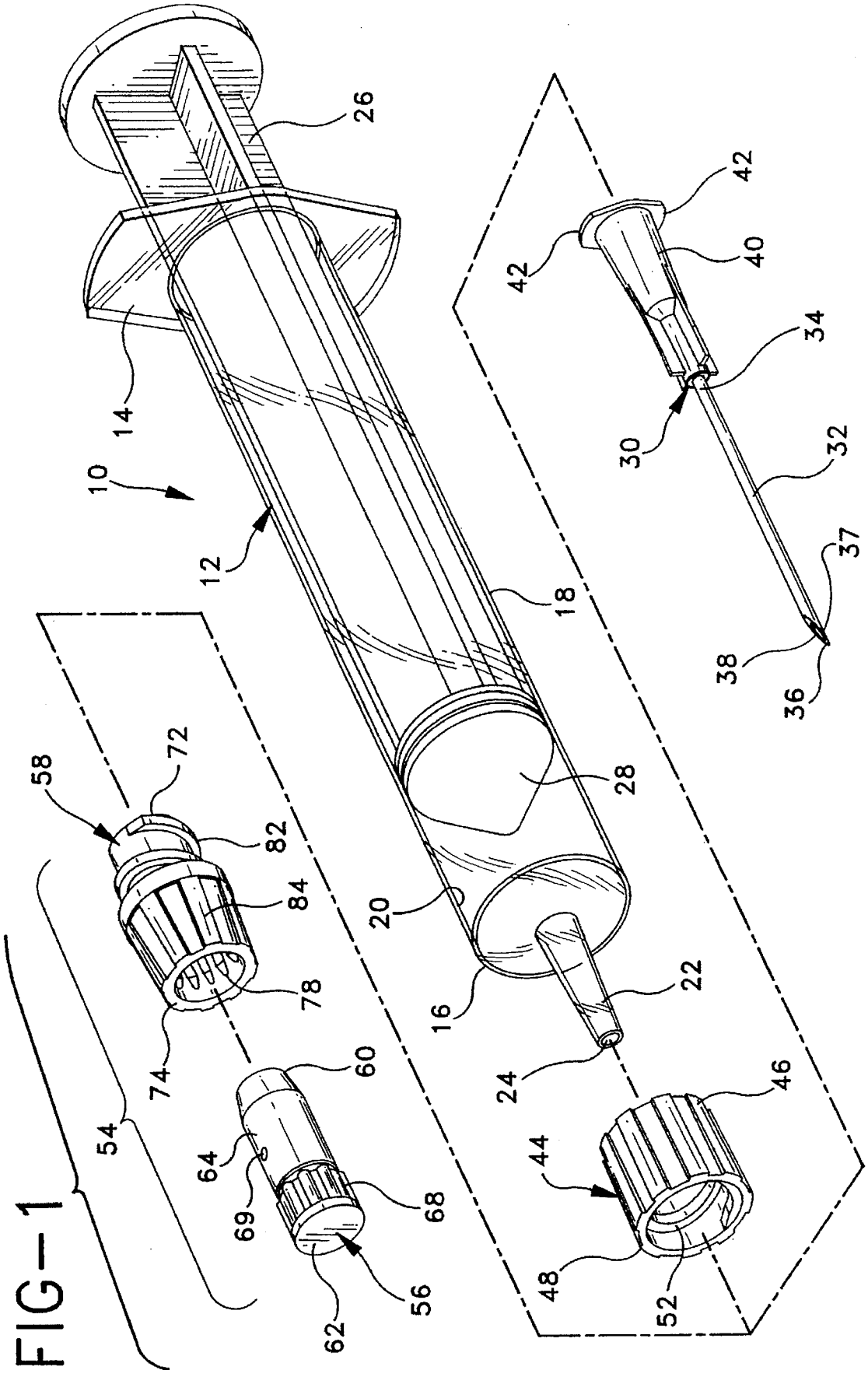

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FIG-1

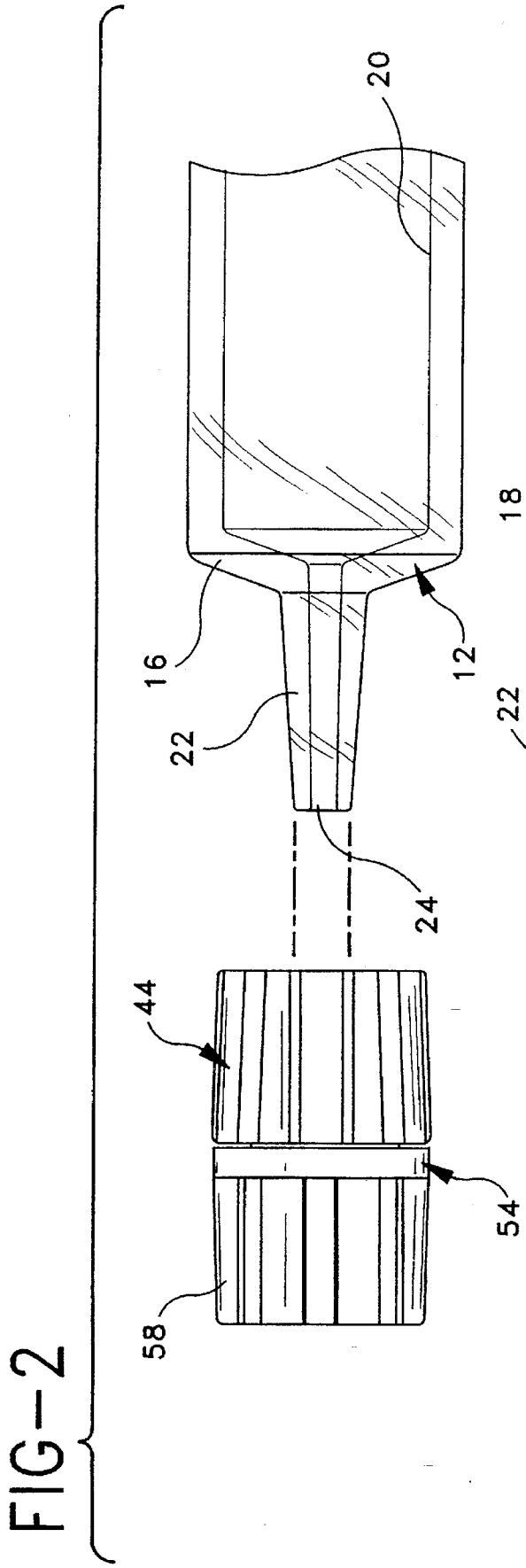


FIG-2

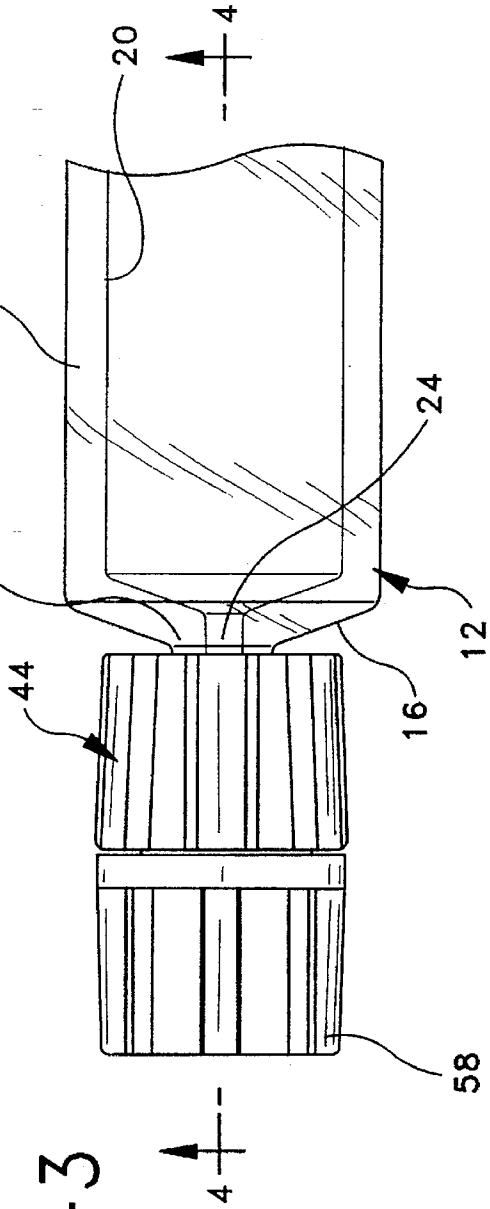


FIG-3

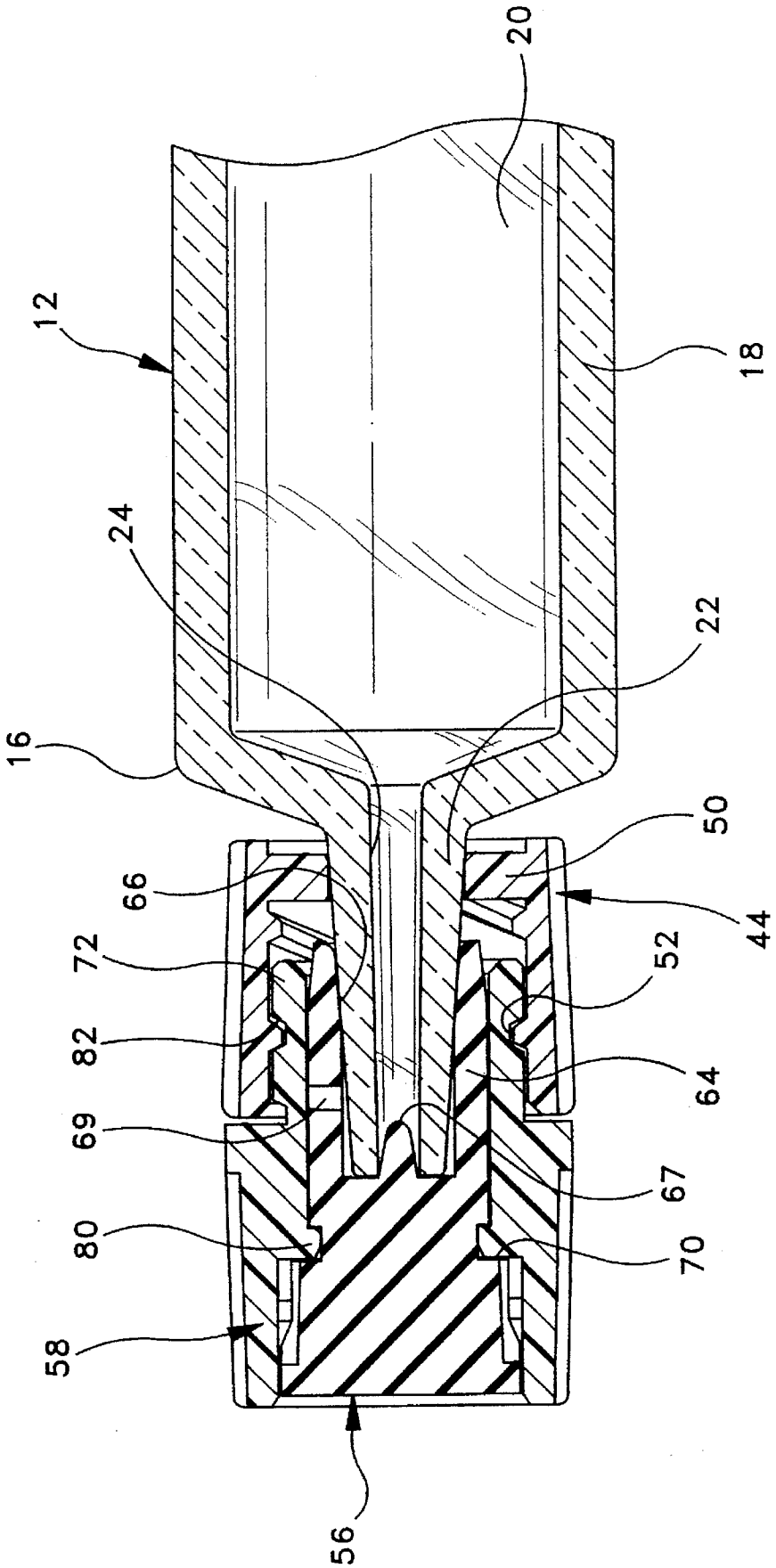
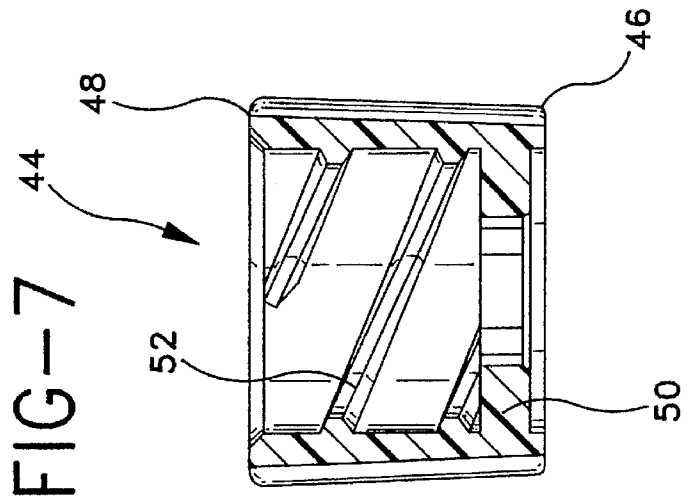
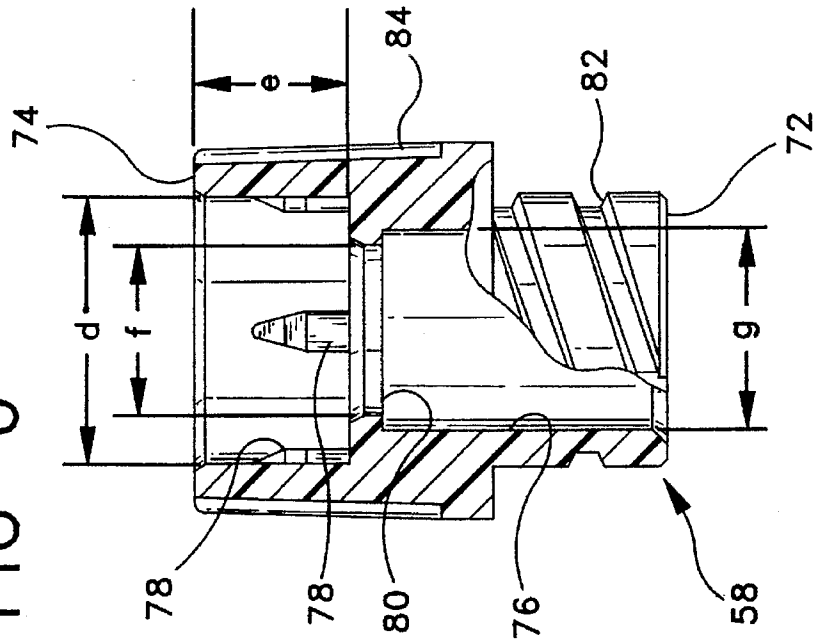


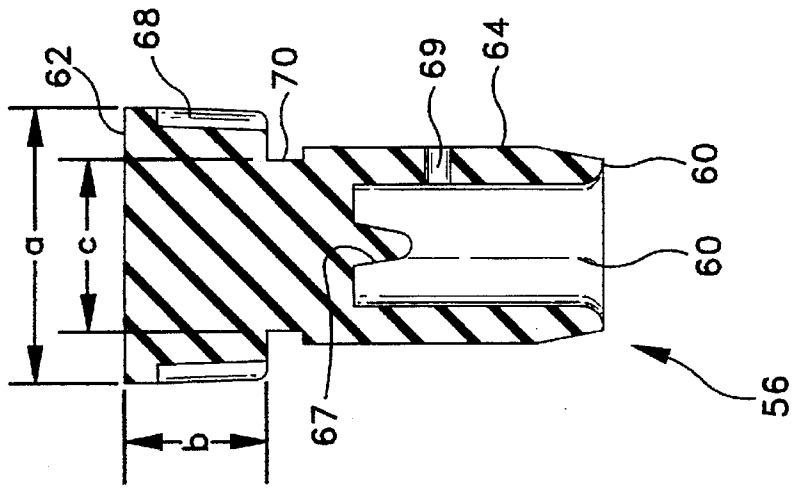
FIG-4



FIG—7



FIG—6



FIG—5

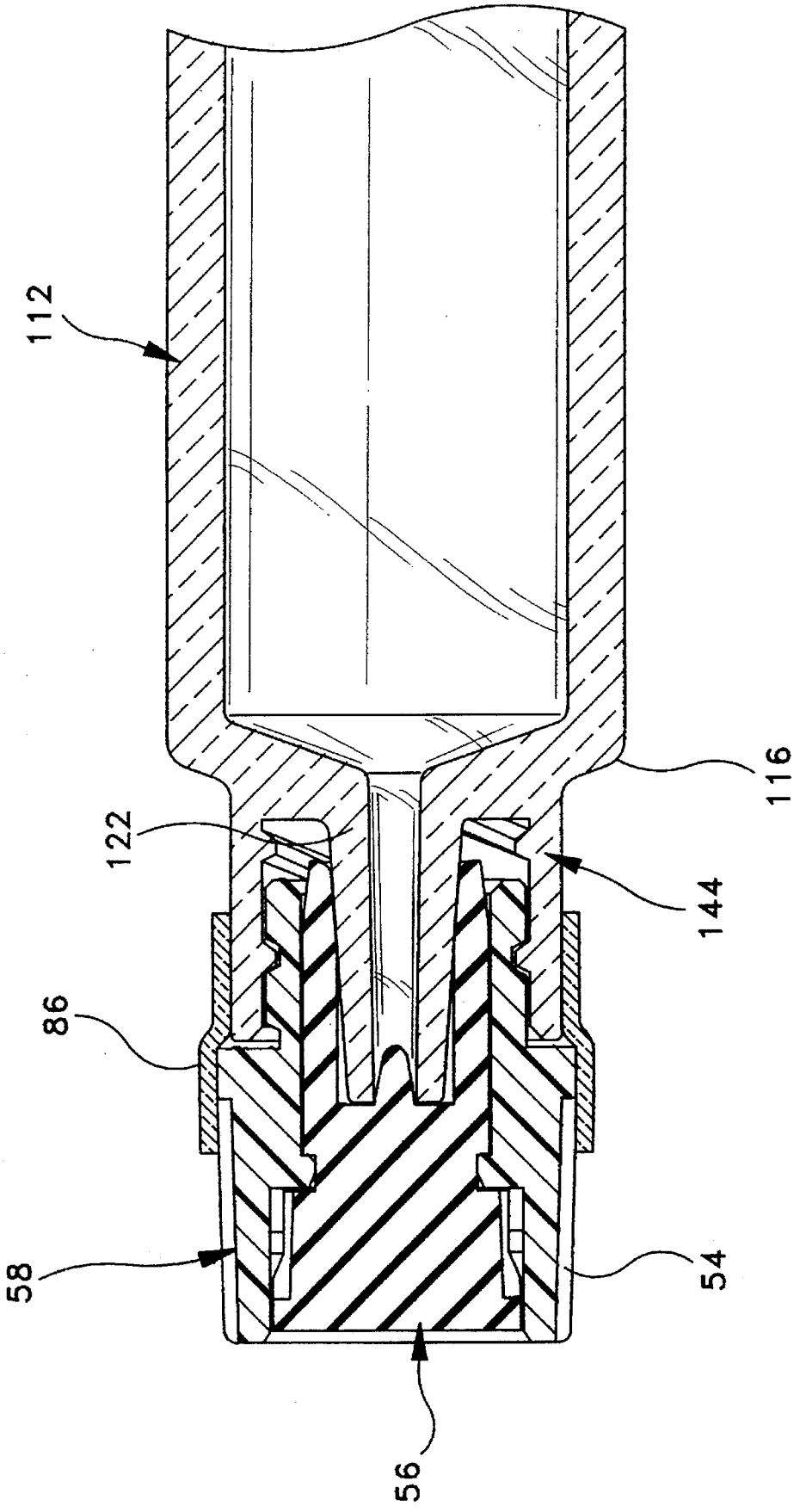


FIG-8

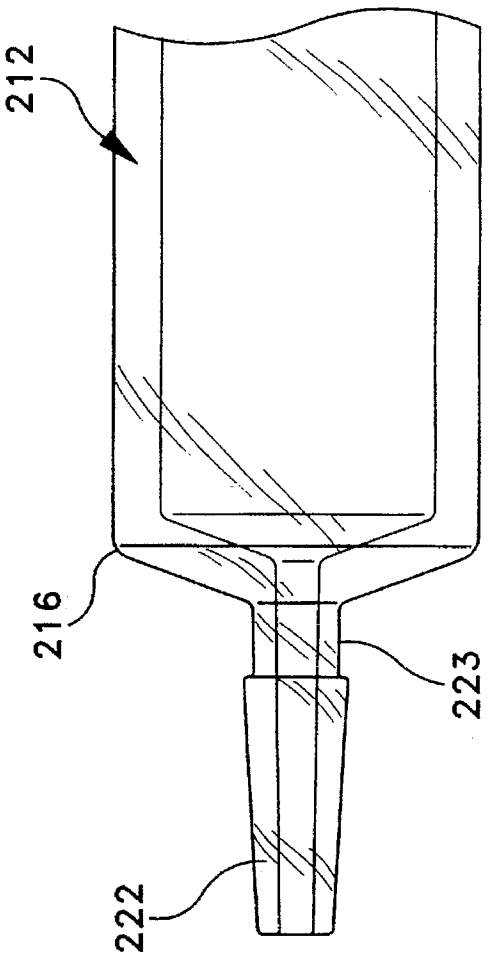


FIG-9

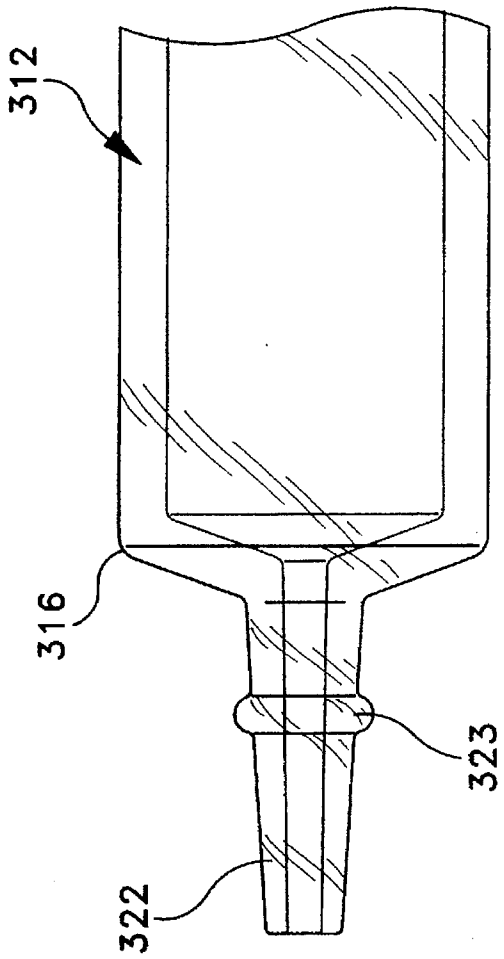


FIG-10

SYRINGE TIP CAP

1. Field of the Invention

The subject invention relates to a tip cap for securely sealing the tip of a hypodermic syringe barrel.

2. Description of the Prior Art

The prior art hypodermic syringe includes a barrel having an open proximal end and an opposed distal. A cylindrical wall extends between the ends and defines a fluid-receiving chamber. An elongate tip projects from the distal end of the prior art syringe barrel and includes a narrow passage which communicates with the fluid-receiving chamber of the barrel. A plunger may be inserted into the open proximal end of the prior art syringe barrel for sliding fluid-tight engagement with the cylindrical chamber wall. Sliding movement of the plunger in a distal direction urges fluid in the chamber through the passage in the tip. Conversely, sliding movement of the plunger in a proximal direction draws fluid through the passage in the tip and into the chamber of the prior art syringe barrel.

Prior art syringe barrels typically are made of plastic or glass. Glass exhibits lower gas transmissivity than plastic. Thus, glass syringe barrels are used for medications that are particularly susceptible to interaction with ambient gases. Glass syringe barrels also are preferably used for medications that are pre-filled into the syringe barrel and stored for a considerable period of time prior to use.

The prior art hypodermic syringe further includes a needle assembly with a needle cannula having a proximal end, a pointed distal end and a lumen extending axially therethrough. The prior art needle assembly also includes a hub which is engageable with mounting means on the syringe barrel for selectively placing the lumen of the needle cannula in fluid communication with the passage through the tip of the syringe barrel. One prior art mounting means includes a luer collar disposed in spaced concentric relationship around the tip of the syringe barrel. The luer collar includes an array of threads for threaded engagement with corresponding structure on the hub of the needle. For example, the luer collar may include an array of internal threads which are engageable with projections extending outwardly from the hub of the needle cannula. Prior art syringe barrels formed from plastic may have the luer collar unitarily molded therewith. However, glass syringe barrels cannot be formed with a unitary luer collar. Thus, glass syringe barrels and some plastic syringe barrels may have a separately formed luer collar securely mounted to the tip of the syringe barrel. The luer collar may rely upon a slip fit interengagement, a snap fit or other such secure mounting engagement around the tip of the syringe barrel.

Medications that are pre-filled into a syringe barrel must be sealed to prevent contamination or loss of the medication. Seals also prevent health care workers from being needlessly exposed to medications. The prior art has included stoppers mounted over the tip at the distal end of the syringe barrel to prevent leakage and to avoid contamination of the medication. Prior art tip caps have been formed from elastomeric material frictionally and/or resiliently retained in engagement with the tip of the prior art syringe barrel. The prior art tip cap may be removed from the syringe tip shortly prior to usage of the hypodermic syringe. The hub of the needle assembly may then be securely engaged with the luer collar or other mounting means adjacent the exposed tip of the syringe barrel. For example, the needle hub may be threadedly engaged within the luer collar such that the lumen of the prior art needle cannula communicates with the exposed tip of the prior art syringe barrel.

Prior art elastomeric tip caps on the ends of pre-loaded prior art syringe barrels generally perform well. However, the resiliently and/or frictionally engaged prior art tip cap may be accidentally disengaged from the prior art syringe barrel in response to inadvertent forces imposed thereon or due to dimensional changes or instability of the elastomeric seal. Additionally, the vacuum created as the prior art elastomeric tip cap is removed from the tip can lead to the loss of medication and unnecessary personal contact with medication that the tip cap is intended to avoid. Additionally, the prior art elastomeric tip cap provides no evidence of tampering or misuse of a pre-loaded hypodermic syringe.

SUMMARY OF THE INVENTION

The subject invention is directed to an effective tip cap assembly for a hypodermic syringe, and to a hypodermic syringe assembly having a more effectively sealed tip. A hypodermic syringe in accordance with the subject invention includes a barrel having a proximal end, a distal end and a chamber wall extending therebetween. The chamber wall defines a fluid-receiving chamber which may be pre-loaded with a selected dose of medication. The distal end of the syringe barrel includes a tip having a passage extending therethrough. The distal end may further include needle mounting means for selective engagement with mounting structure on a needle cannula. The mounting means may comprise a luer collar that is either unitarily formed with the syringe barrel or that is securely mounted to the syringe barrel in proximity to the tip.

The tip cap of the subject invention includes an elastomeric inner cap frictionally and/or resiliently engaged with portions of the tip for sealing the passage through the tip. The tip cap assembly further includes a substantially rigid outer cap engageable with the needle mounting means of the syringe barrel and protectively enclosing the inner cap. For example, the outer cap may include projections or threads engageable with threads of a luer collar integral with or mounted to the syringe barrel. The outer cap may be frictionally, resiliently and/or mechanically engaged with the inner cap. Thus, disengagement of the outer cap from the needle mounting means of the syringe barrel may simultaneously disengage the inner cap from the tip of the syringe barrel.

The inner cap and the outer cap may be separately manufactured and assembled to one another after manufacture. Alternatively, the inner cap and the outer cap may be integral with one another. In this regard, the inner or outer cap may define an insert in a mold cavity employing insert molding technology. Alternatively, the inner and outer caps may be formed by coinjection of appropriate materials into the mold cavity of an injection molding apparatus. Still further, the inner and outer caps may be formed respectively by sequential injection molding techniques using a single mold cavity.

The inner and outer caps may be assembled or molded together and subsequently attached to a needle mounting structure unitarily formed at the distal end of a plastic syringe barrel. Alternatively, the inner and outer caps may be assembled or formed together and then engaged with a plastic mounting collar for a glass syringe barrel. The assembled inner and outer caps and the mounting collar engaged therewith may then be securely mounted to the tip of a syringe barrel.

The subject invention may further include a tamper evident seal for connecting the outer cap to the needle mounting means of the syringe barrel. The tamper evident seal may

comprise a severable label extending across the interface between the outer cap and the collar. Alternatively, a frangible spot weld may connect the outer cap to the luer collar or other such needle mounting means.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded perspective view of a syringe barrel and a tip cap assembly in accordance with the subject invention.

FIG. **2** is an exploded side elevational view of a syringe barrel and the tip cap assembly of FIG. **1**.

FIG. **3** is a side elevational view of the tip cap assembly and the syringe barrel of FIGS. **1** and **2** in their fully assembled condition.

FIG. **4** is a cross-sectional view taken along line **4—4** in FIG. **3**.

FIG. **5** is a cross-sectional view taken along the longitudinal axis of the inner cap of the tip cap assembly.

FIG. **6** is a side elevational view, partly in section of the outer cap of the tip cap assembly.

FIG. **7** is a cross-sectional view taken along the longitudinal axis of the luer collar of the tip cap assembly.

FIG. **8** is a cross-sectional view similar to FIG. **4** but showing a syringe barrel having a unitary needle mounting collar.

FIG. **9** is a partial side elevational view of an alternative syringe barrel of the subject invention.

FIG. **10** is a partial side elevational view of another alternative syringe barrel of the subject invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Adverting to FIGS. **1–7**, a hypodermic syringe in accordance with the subject invention is identified generally by the numeral **10**. With reference to FIG. **1**, hypodermic syringe **10** includes a syringe barrel **12** unitarily formed from a transparent material, such as glass or plastic. Syringe barrel **12** includes a proximal end **14**, a distal end **16** and a cylindrical wall **18** extending therebetween. Cylindrical wall **18** defines a fluid-receiving chamber **20** in barrel **12**. The distal end of syringe barrel **12** includes a tip **22** having a passageway **24** extending therethrough and communicating with the chamber **20**. A plunger rod assembly **26** extends into proximal end **14** of syringe barrel **12**, and includes a stopper **28**, which is in sliding fluid-tight engagement with cylindrical wall **18** of chamber **20**.

Syringe barrel **12** is used with a needle assembly **30** which includes a needle cannula **32** having a proximal end **34**, a distal end **36** and a lumen **38** extending therebetween. Distal end **36** of the needle cannula preferably includes sharpened tip **37**. A mounting hub **40** is securely affixed to proximal end **34** of needle cannula **32** and includes projections **42** extending therefrom for threaded engagement with a luer collar.

As noted above, syringe barrel **12** may be formed from glass, and hence does not have an integral luer collar for engaging mounting hub **40** of needle assembly **30**. Rather, a thermoplastic luer collar **44** is provided for selective engagement over tip **22** of syringe barrel **30**. More particularly, luer collar **44** is a generally hollow cylindrical structure having opposed proximal and distal ends **46** and **48**, respectively. Proximal end **46** of luer collar **44** includes an array of inwardly directed projections **50** for frictionally engaging tip **22** of syringe barrel **12** and retaining luer collar **44** thereon. Distal end **48** of luer collar **44** includes an array of internal threads **52** dimensioned and pitched for threaded engagement by projections **42** of mounting hub **40** on needle assembly **30**. Thus, proximal end **46** of luer collar **44** can be urged in a proximal direction over tip **22** of syringe barrel **12**. Mounting projections **50** will deflect slightly and frictionally engage tip **22** to resist separation of luer collar **44** from syringe barrel **12**. Mounting hub **40** may then be threadedly engaged with luer collar **44** to place lumen **38** of needle cannula **32** in communication with passage **24** through tip **22**, and further in communication with chamber **20** of syringe barrel **12**.

As noted above, needle assembly **30** may be maintained separate from syringe barrel **12**, and may be mounted to syringe barrel **12** a short time prior to usage of hypodermic syringe **10**. Syringe barrel **12** may be pre-filled with medication, and stored in its pre-filled condition prior to mounting needle assembly **30** thereto. To prevent contamination or leakage of medication stored in syringe barrel **12**, a tip cap assembly is provided.

A tip cap assembly in accordance with the subject invention is identified generally by the numeral **54** in FIGS. **1–4**, and includes an inner cap **56** and an outer cap **58**. Inner cap **56**, as shown most clearly in FIG. **5** is unitarily molded from an elastomeric material and includes opposed proximal and distal ends **60** and **62**, respectively. Portions of inner cap **56** extending proximally from distal end **62** define a tip-engaging portion **64** having a cavity **66** dimensioned to tightly resilient engage tip **22** of syringe barrel **12**. This preferred embodiment preferably includes a stopper **67** projecting proximally from portions of tip engaging portion **64** and defines the inner-most end of cavity **66**. Stopper **67** is disposed and dimensioned to pass into passage **24** of tip **22** for further enhancing the sealing ability of inner cap **56**. Inner cap **56** preferably includes a vent aperture **69** extending through tip engaging portion **64** for reducing the vacuum created as inner cap **56** is being removed from tip **22**. Vent aperture **69** is disposed to be blocked by tip **22** when the inner cap **56** is fully seated. However, vent aperture **69** will permit gas communication to cavity **66** as inner cap **56** is being removed to minimize vacuum as inner cap **56** is being removed from tip **22**.

Portions of inner cap **56** extending proximally from distal end **62** define a plurality of axially extending anti-rotation ribs **68** which are spaced at approximately 45° from one another about the outer circumference of inner cap **56**. Anti-rotation ribs **68** define an outer diameter "a" as illustrated in FIG. **5**.

Inner cap **56** further includes an annular undercut **70** extending around the outer periphery thereof at a location spaced distance "b" from distal end **62** of inner cap **56**. Undercut **70** defines an outside diameter "c".

Outer cap **58**, as illustrated most clearly in FIG. **6**, is a generally tubular member unitarily formed from a rigid thermoplastic material. Outer cap **58** includes opposed proximal and distal ends **72** and **74**, respectively, and a stepped aperture **76** extending entirely therethrough. Portions of aperture **76** adjacent distal end **74** define a major inside diameter "d" which is approximately equal to the outer diameter "a" defined by anti-rotation ribs **68** adjacent distal end **62** of inner cap **56**. However, portions of aperture **76** adjacent distal end **74** of outer cap **58** are characterized by inwardly extending anti-rotation ribs **78**. Distal ends of ribs **78** are generally pointed for urging anti-rotation ribs **68** of inner cap **56** into positions intermediate adjacent ribs **78** during assembly of inner and outer caps **56** and **58**.

Stepped aperture **76** further includes an inwardly extending annular rib **80** disposed and dimensioned to engage in

annular undercut **70** in inner cap **56**. More particularly, annular rib **80** is spaced a distance "e" from distal end **74**, which is approximately equal to or greater than the distance "b" between undercut **70** and distal end **62** of inner cap **54**. Annular rib **80** also defines an inside diameter "f" which is approximately equal to the outside diameter "c" defined by the undercut **70** in inner cap **56**. Distal portions of annular rib **80** are chamfered to facilitate deflection of inner cap **56** during assembly of inner cap **56** and outer cap **58**, as explained further herein.

Portions of stepped aperture **76** extending between annular rib **80** and proximal end **72** of outer cap **58** define an inside diameter "g" which is greater than the outside diameter of tip engaging portion **64** of inner cap **56**, such that tip engaging portion **64** can be loosely engaged therein with room for expansion as the entire tip cap assembly is urged over tip **22**, as explained further below.

Exterior portions of outer cap **58** extending distally from proximal end **72** are characterized by an array of external threads **82**. Threads **82** are disposed and dimensioned to threadedly engage internal threads **52** on luer collar **44** as shown in FIG. **4** above and described in greater detail below. Exterior portions of outer cap **58** extending proximally from distal end **74** are characterized by ribs **84** which are dimensioned and configured to facilitate manual gripping and rotation of outer cap **58**.

Inner and outer caps **56** and **58** are assembled by urging proximal end **60** of inner cap **56** in a proximal direction into distal end **74** of outer cap **58**. Tip engaging portion **64** of inner cap **56** will engage the chaffer of inwardly extending rib **80** on outer cap **58** and will be deflected inwardly. After sufficient distal movement of inner cap **56**, anti-rotation ribs **68** of inner cap **56** may engage anti-rotation ribs **78** of outer cap **58**. The pointed or tapered distal shape of anti-rotation ribs **78** will cause inner cap **56** to rotate slightly, such that anti-rotation ribs **68** of inner cap **56** will align respectively intermediate a pair of adjacent anti-rotation ribs **78** on outer cap **58**. Further advancement of inner cap **56** into outer cap **58** will cause undercut **70** to align with annular rib **80**. Inner cap **56** then will resiliently return toward an undeflected condition, such that annular rib **80** of outer cap **58** is trapped in undercut **70** to substantially prevent further axial movement between inner and outer caps **56** and **58** respectively. In this position, the interdigitation of anti-rotation ribs **68** and **78** will prevent or limit rotation between inner and outer caps **56** and **58**.

Assembly **54** of inner and outer caps **56** and **58** can be threadedly engaged with luer collar **44** as shown in FIG. **2**, and the threadedly engaged cap assembly **54** and luer collar **44** can be urged onto tip **22** of syringe barrel **12** as shown in FIGS. **3** and **4**. Projections **50** on proximal end **46** of luer collar **44** will deflect and engage tip **22** for securely retaining luer collar **44** and the inner and outer caps **56** and **58** threadedly engaged therewith on the tip **22**. Simultaneously, tip engaging portion **64** of inner cap **56** will sealingly engage tip **22**. In this regard, tip engaging portion **64** will resiliently engage outer circumferential portions of tip **22**, while stopper **67** will pass into and sealingly engage passage **24** through tip **22**. In this fully seated position, vent aperture **69** will be blocked by tip **22**.

FIGS. **9** and **10** illustrate alternative syringe barrels having structure for improving the engagement of projections **50** on proximal end **46** of the luer collar with the syringe barrel tip. In particular, alternative syringe barrel **212** includes distal end **216** having tip **222**. Recess **223** is provided at the base of tip **222** for providing a more positive engagement with projection **50** on proximal end **46** of luer collar **44**. Likewise, alternative syringe barrel **312** having distal end **316** and tip **322** includes annular rib **323** for improving the engagement of the luer collar to the barrel. During assembly, projections **50** on proximal end **46** of the luer collar must deflect and snap over annular rib **323** to secure the collar to the barrel tip. Projections **50** can be angled or chamfered to make the engagement force substantially less than the force required to pull the luer collar from the tip. Also, luer collar **44** can be attached to a syringe barrel tip through the use of other means such as adhesives.

The threaded engagement of outer cap **58** with luer collar **44** and the simultaneous engagement of outer cap **58** with inner cap **56** positively prevent inadvertent separation of inner cap **56** from its sealing engagement with tip **22**. However, tip **22** of syringe barrel **12** can be accessed readily by merely rotating outer cap **58** relative to luer collar **44**. Engagement of anti-rotation ribs **68** and **78** ensures that inner cap **56** will rotate with outer cap **58**. Additionally, engagement of annular rib **80** of outer cap **58** with undercut **70** in inner cap **56** ensures that inner cap **56** will move axially in response to the threaded disengagement of outer cap **58** from luer collar **44**.

As illustrated in FIGS. **1–7**, cap assembly **54** is threadedly engaged with a thermoplastic luer collar that is mounted to the tip of a glass syringe barrel. However, cap assembly **54** can be employed with similar advantages to a thermoplastic syringe barrel having a luer collar molded thereto. In this regard, FIG. **8** hows a thermoplastic syringe barrel **112** having a distal end **116** with a tip **122** projecting therefrom. A luer collar **144** projects unitarily from distal end **116** in spaced concentric relationship about tip **122**. Cap assembly **54**, as identified and described above is threadedly engaged with luer collar **144** such that elastomeric inner cap **56** sealingly engages tip **122** of syringe barrel **112**. Unintended separation of inner cap **56** from tip **122** is substantially prevented by the threaded engagement of cap assembly **54** with the luer collar **144** unitarily formed with syringe barrel **112**. However, tip **122** can be accessed readily by rotating outer cap **58** for threaded disengagement from luer collar **144**.

As noted above, misuse of or tampering with medication pre-loaded in a syringe barrel **112** should be guarded against. To provide such tamper evidence, a frangible label **86** is adhesively applied across the interface of the threadedly engaged outer cap **58** and luer collar **144**. Label **86** will serve in response to initial separation of cap assembly **54** from luer collar **44** to provide unmistakable evidence of tampering with syringe barrel **112** and the medication therein.

While the invention has been described with respect to certain preferred embodiments, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims. For example, the inner and outer caps need not be separate parts that are assembled after manufacture. Rather, the inner and outer caps may be simultaneously molded using injection technology or sequential injection technology. Alternatively, the inner cap or the outer cap may define an insert in an injection molding cavity in which the other of the inner and outer caps is molded.

What is claimed is:

1. A tip cap assembly for a glass syringe barrel having a distally projecting tip with a fluid passage extending therethrough, said tip cap assembly comprising:

a luer collar formed from a thermoplastic material and having means for securely locking said luer collar to

said tip, said luer collar having an array of internal threads in spaced concentric relationship around said tip;

a resilient inner cap having opposed proximal and distal ends, said proximal end being configured for sealingly engaging said tip, said proximal end having at least one axially extending projection, portions of said inner cap intermediate said proximal and distal ends defining a locking surface;

a rigid outer cap disposed in generally surrounding relationship to said inner cap, said outer cap including at least one axially extending projection engaged with said rib of said inner cap for controlling relative rotation between said inner and outer caps, said outer cap further comprising at least one surface engaged with said locking surface of said inner cap for preventing relative axial movement therebetween, and said outer cap comprising an array of external threads threadedly engaging said threads of said luer collar, said threads being disposed for urging said inner cap into tight sealing engagement with said tip in response to tightening of said outer cap to said luer collar whereby threaded disengagement of said outer cap from said luer collar disengages said inner cap from said tip; and

vent means in said inner cap for minimizing vacuum during separation of said inner cap from said tip.

2. A tip cap assembly for a glass syringe barrel having a distally projecting tip with a fluid passage extending therethrough, said tip cap assembly comprising:

a luer collar formed from a thermoplastic material and having means for securely locking said luer collar to said tip, said luer collar having an array of internal threads in spaced concentric relationship around said tip;

a resilient inner cap having opposed proximal and distal ends, said proximal end being configured for sealingly engaging said tip, said proximal end having at least one axially extending projection, portions of said inner cap intermediate said proximal and distal ends defining a locking surface;

a rigid outer cap disposed in generally surrounding relationship to said inner cap, said outer cap including at least one axially extending projection engaged with said rib of said inner cap for controlling relative rotation between said inner and outer caps, said outer cap further comprising at least one surface engaged with said locking surface of said inner cap for preventing relative axial movement therebetween, and said outer cap comprising an array of external threads threadedly engaging said threads of said luer collar, said threads being disposed for urging said inner cap into tight sealing engagement with said tip in response to tightening of said outer cap to said luer collar whereby threaded disengagement of said outer cap from said luer collar disengages said inner cap from said tip;

a frangible tamper evident seal extending between and connecting said outer cap and said luer collar.

* * * * *

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Howlett et al.

(54) **STERILITY-PROTECTING CAPS WITH FLUID RESERVOIR FOR SEPARATED CONNECTORS**

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(22) Filed: **Jul. 11, 2008**

Related U.S. Application Data

(63) Continuation-in-part of application No. 12/164,310, filed on Jun. 30, 2008, which is a continuation-in-part of application No. 12/014,388, filed on Jan. 15, 2008.

(60) Provisional application No. 60/880,541, filed on Jan. 16, 2007.

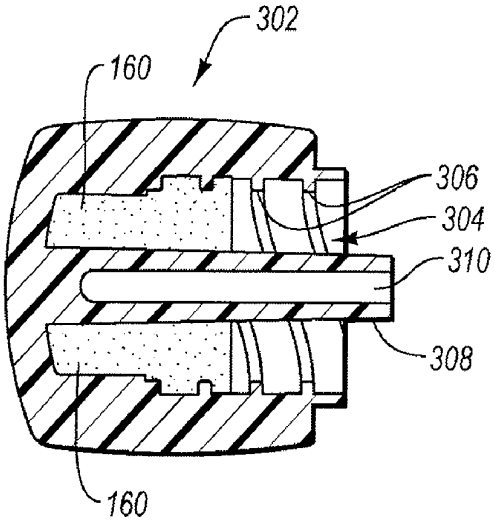
Publication Classification

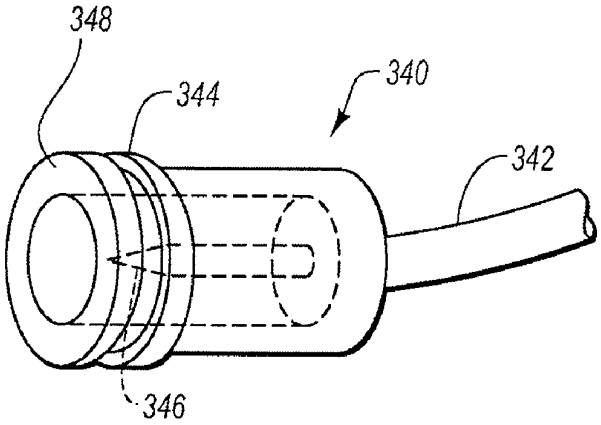
(51) **Int. Cl.**
A61B 19/02 (2006.01)

(52) **U.S. Cl.** **604/411**

(57) **ABSTRACT**

A pair of nestable caps are disclosed, each of the caps being sized and shaped to provide a protective union about a separated medical connector. The pair comprises a male cap and a female cap, each of which is configured to be adjoined to a complimentary cap to form a nested pair. The nested pair is sealed until separated for use, thereby maintaining sterility of the internal surfaces of the nested pair. One of the caps may have a fluid chamber joined thereto filled with medicine or antiseptic. The cap can have a channel extending therethrough to provide fluid communication between the fluid chamber and a fluid pathway. The fluid chamber can be adapted to diffuse the fluid into the fluid pathway over time, or the fluid chamber can be adapted to dispense the fluid out of the fluid chamber without reflux.





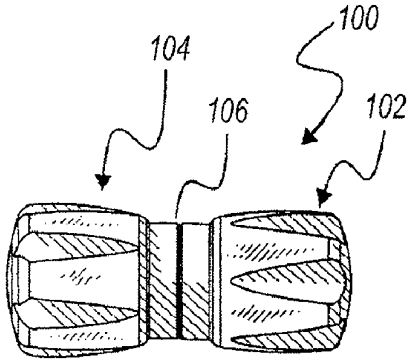
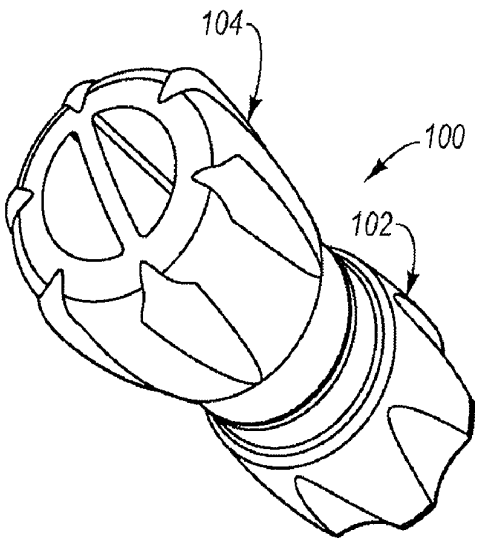


Figure 1



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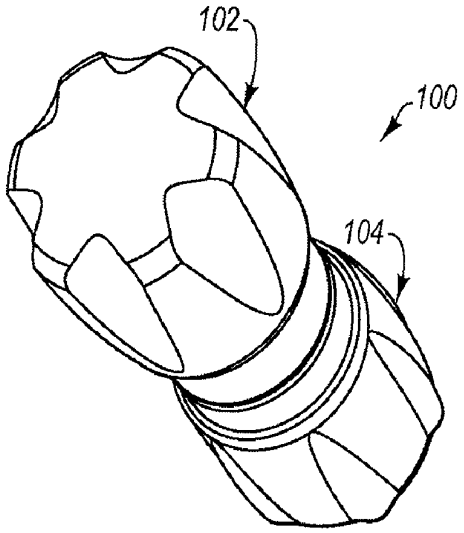


Figure 1B

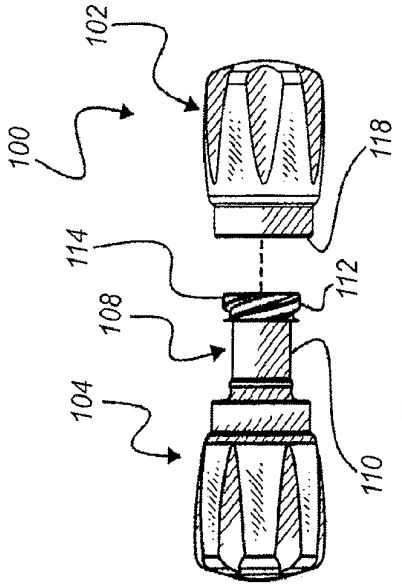
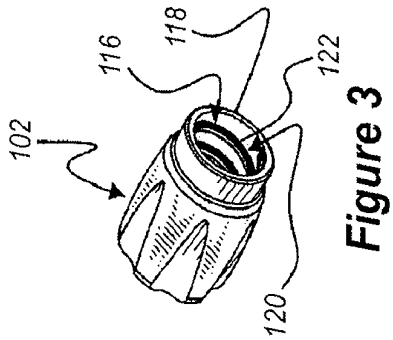


Figure 2



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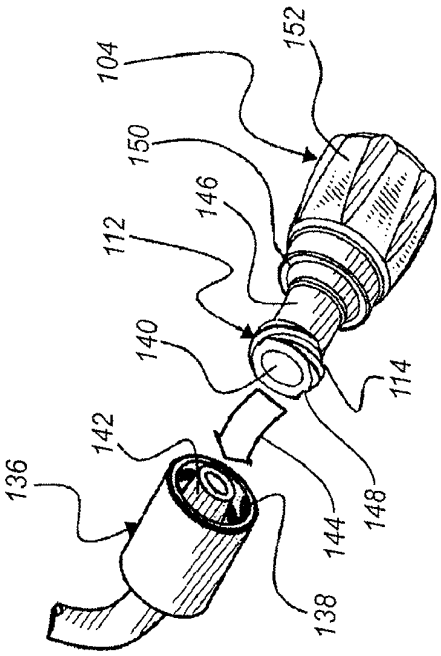

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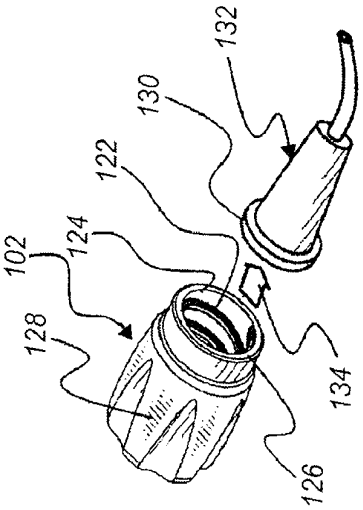

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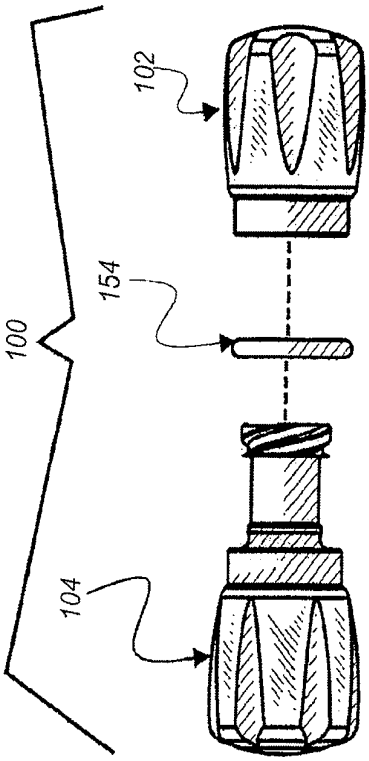

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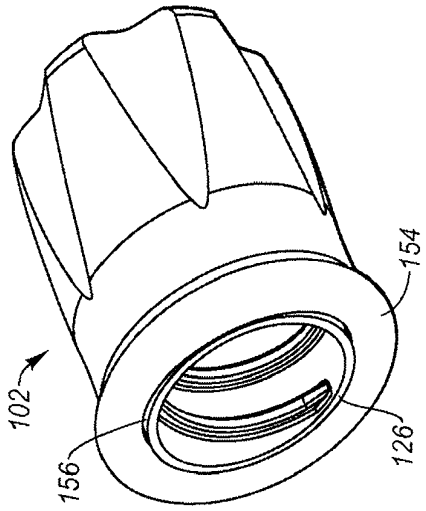

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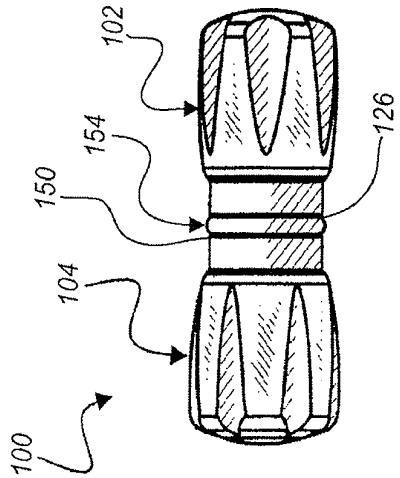

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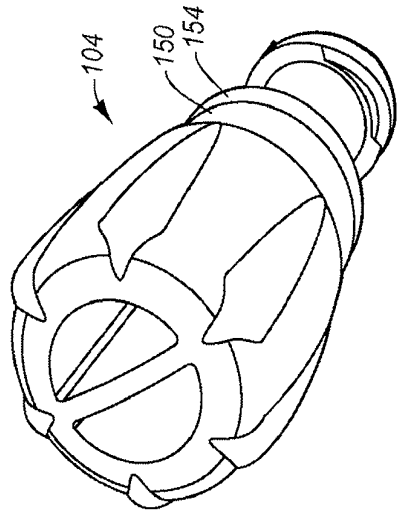


Figure 7A

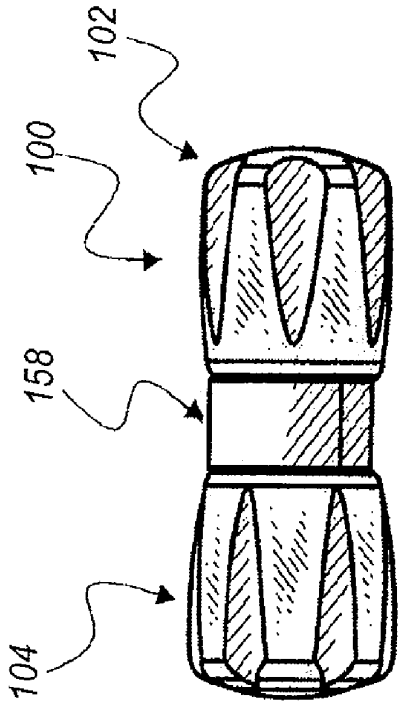


Figure 8B

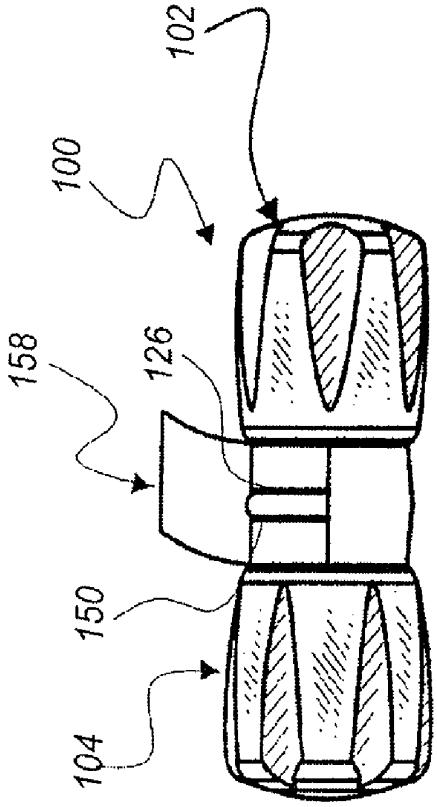


Figure 8A

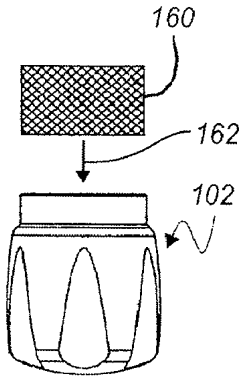


Figure 9A

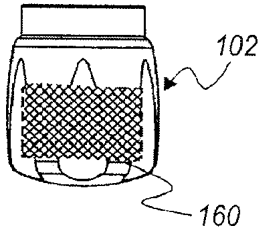


Figure 9B

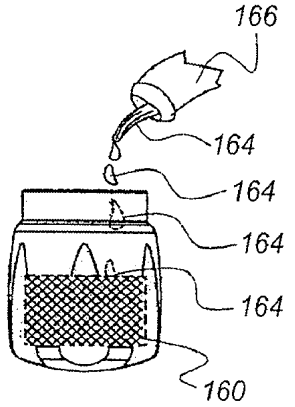
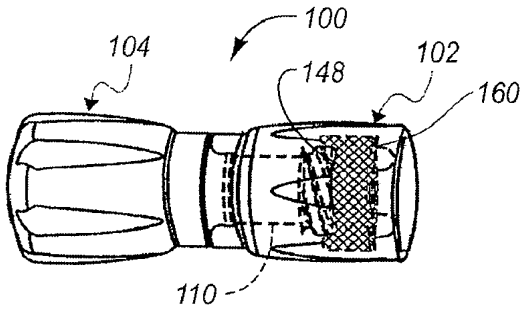


Figure 9C



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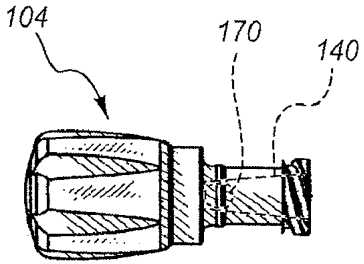
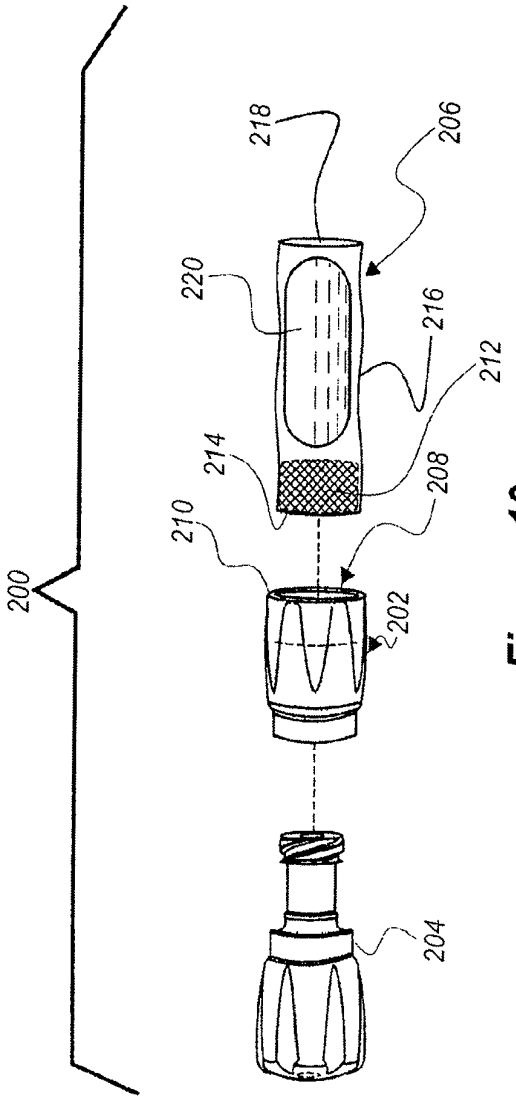


Figure 9E



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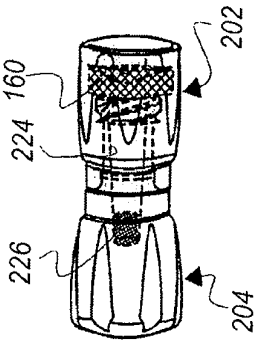

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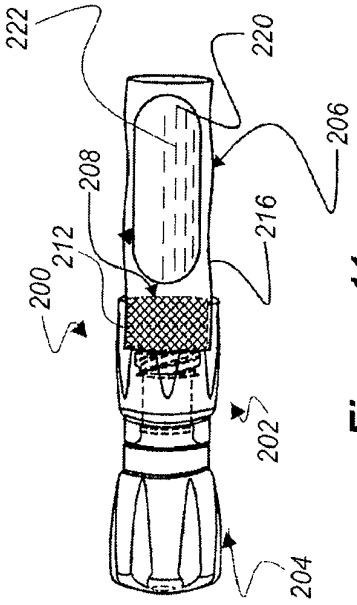

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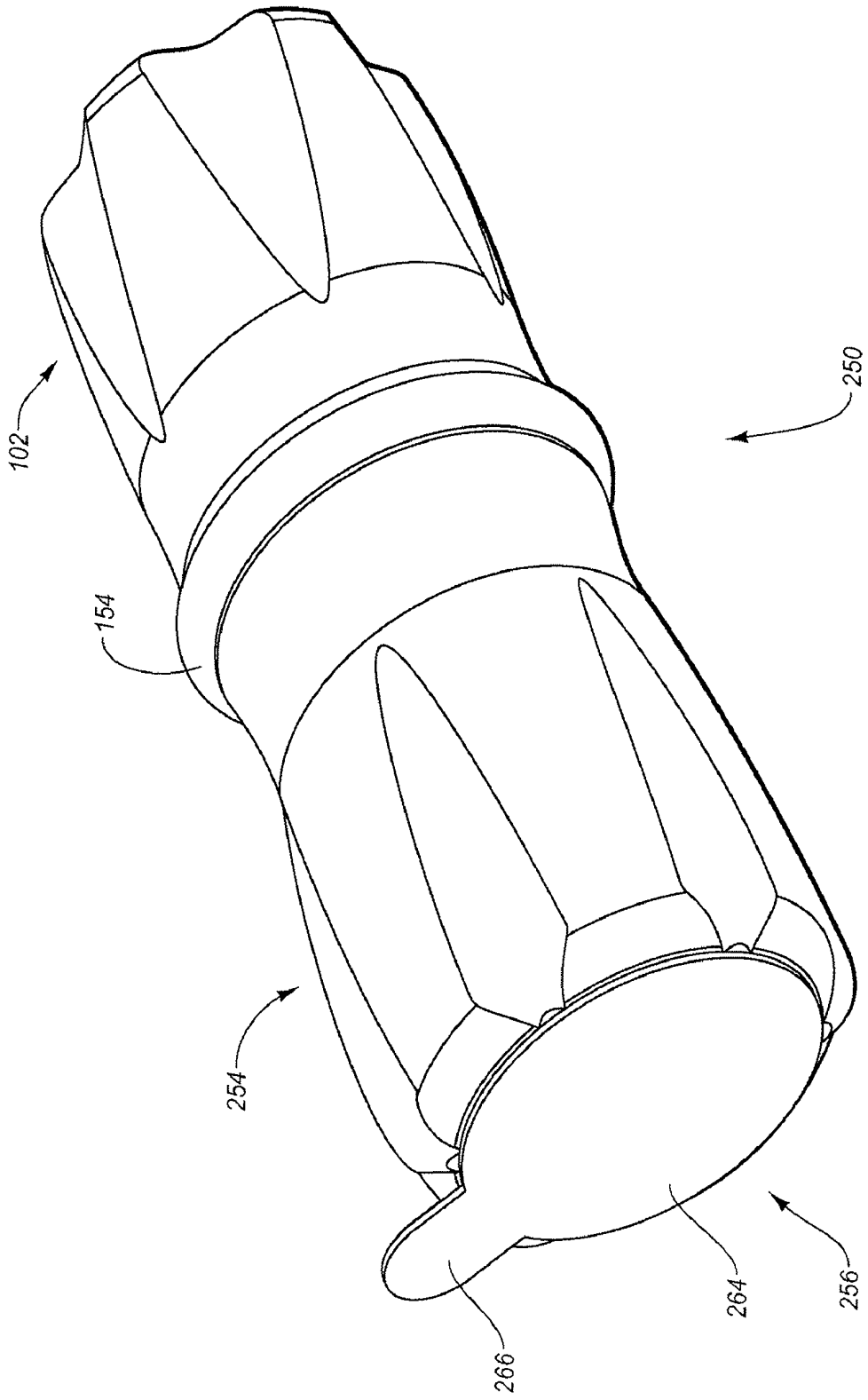

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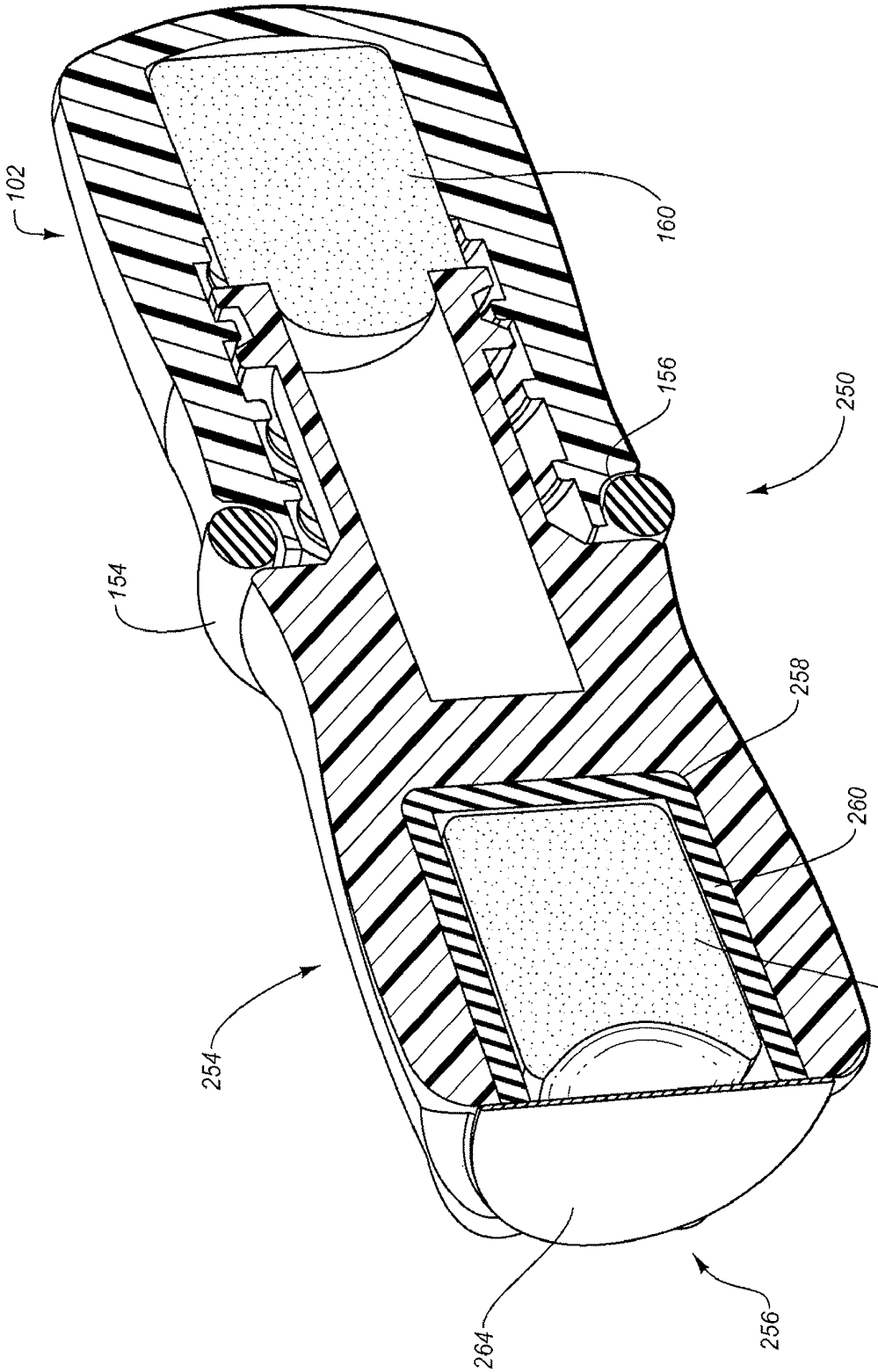

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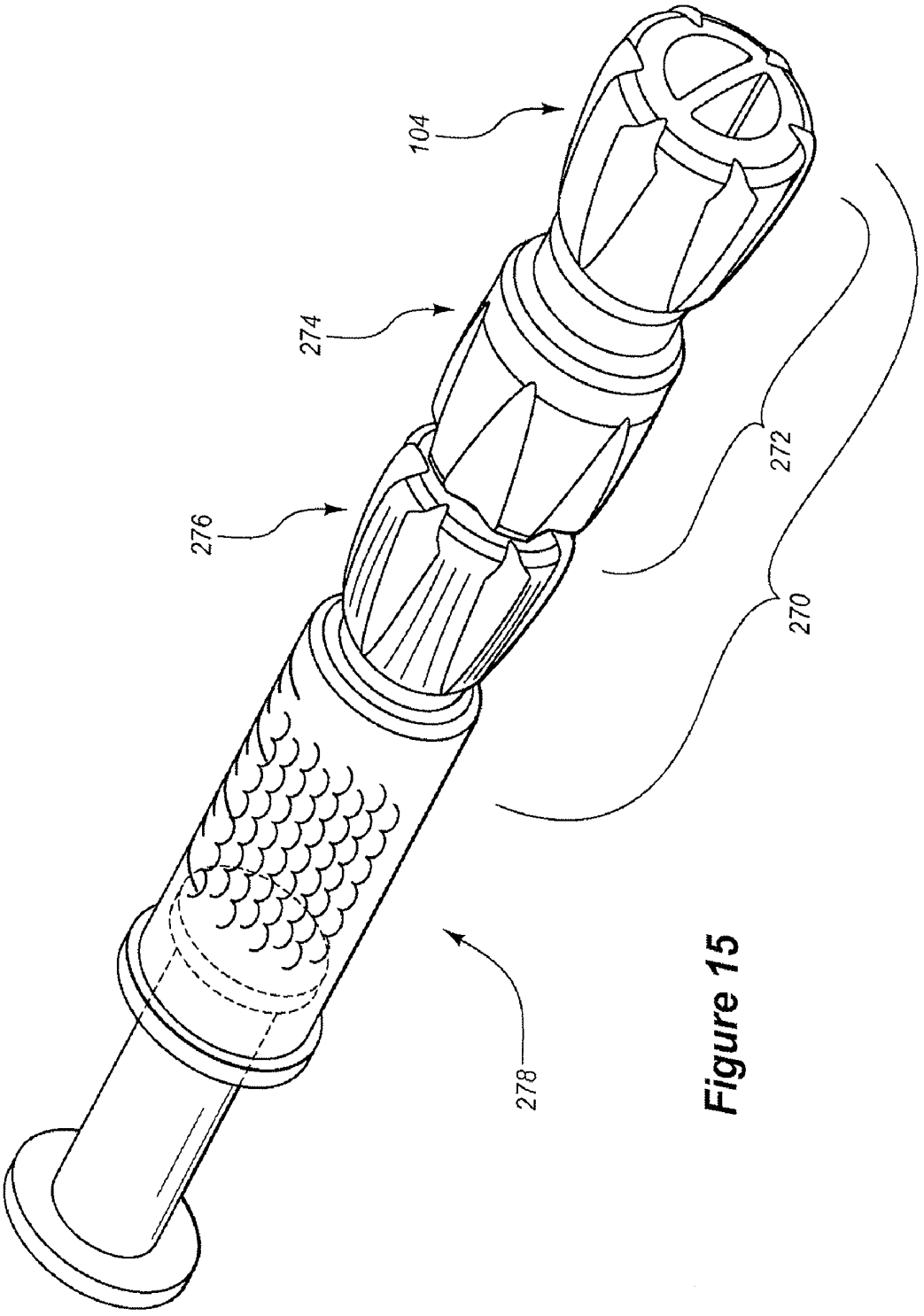

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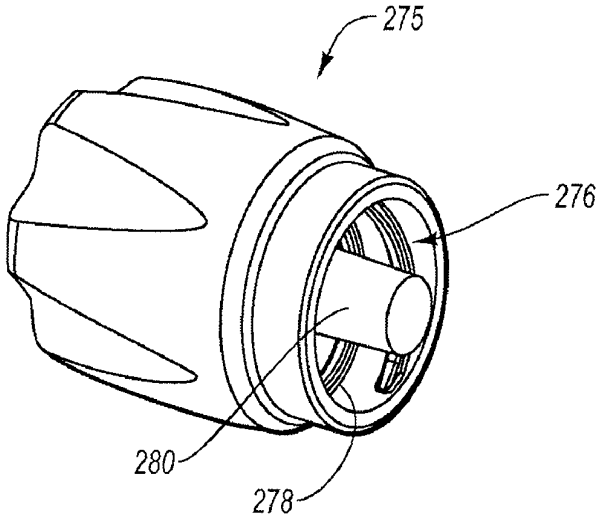

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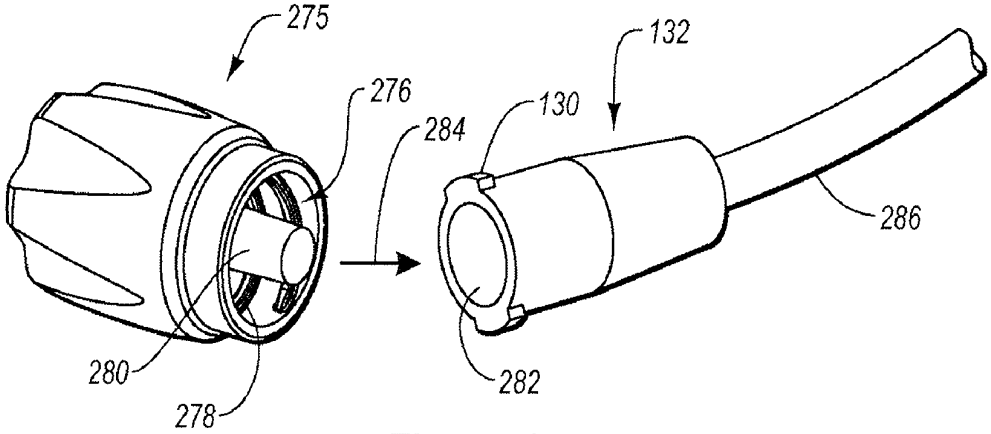

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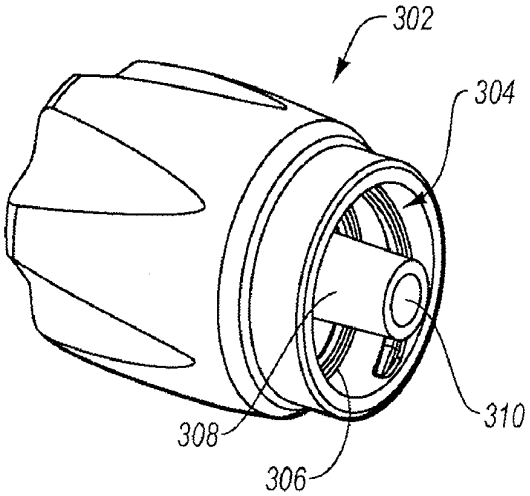

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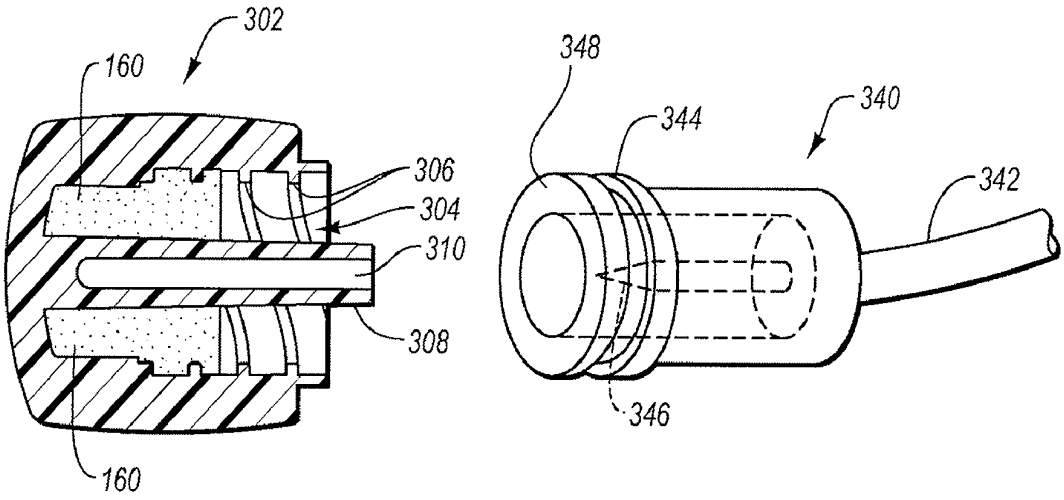

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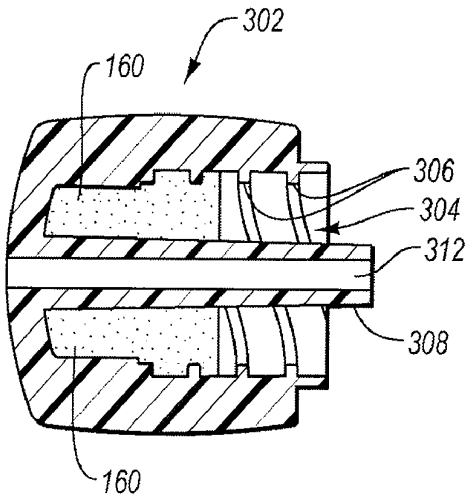

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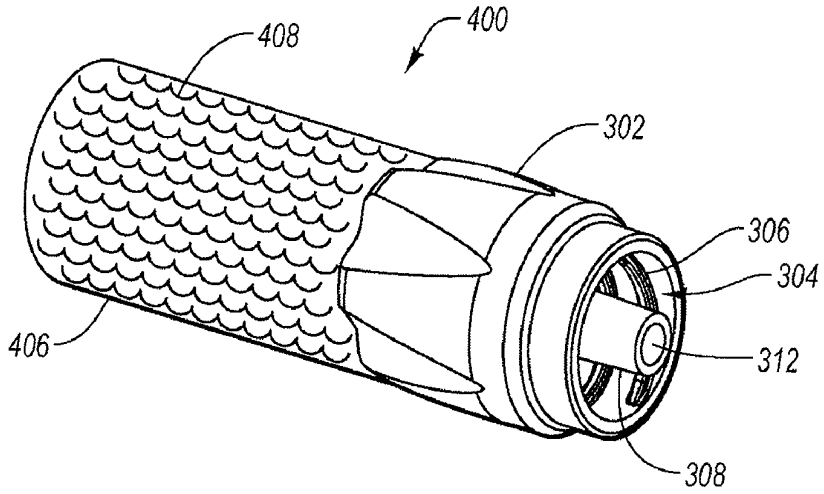

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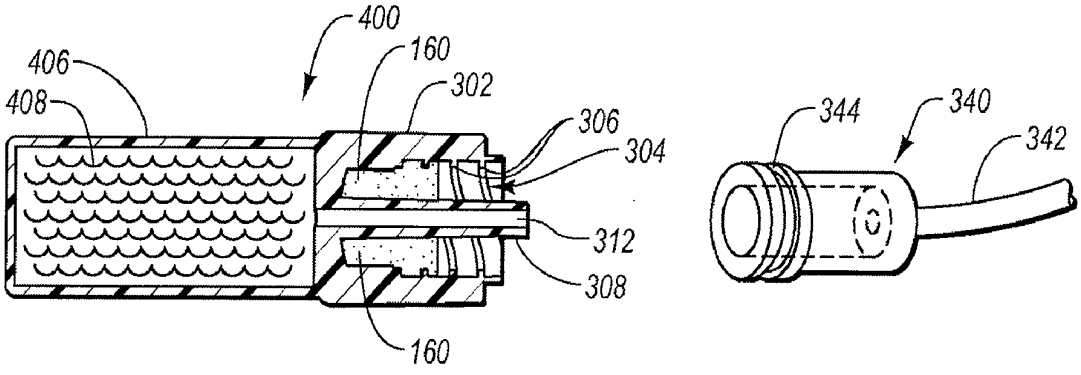

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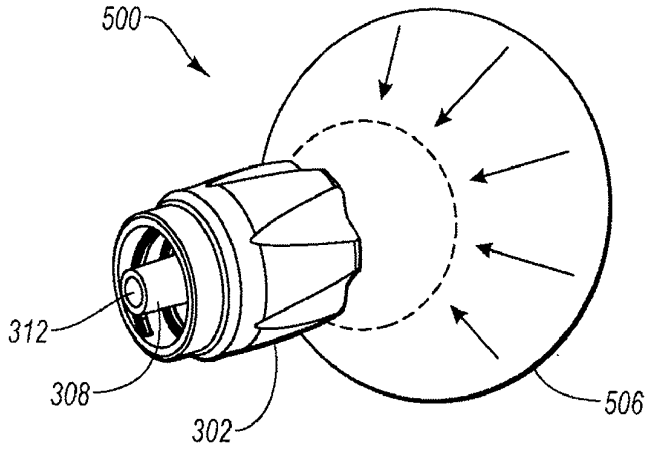

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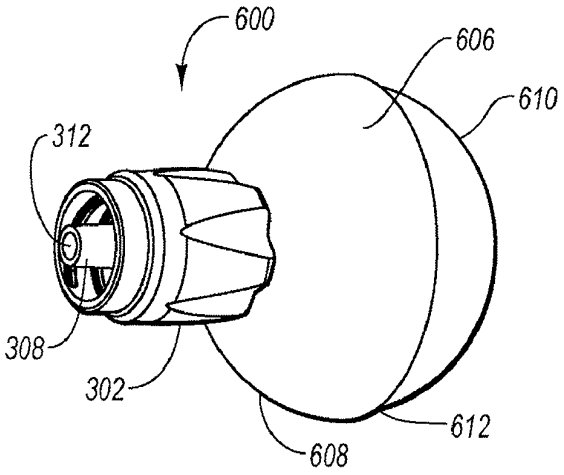

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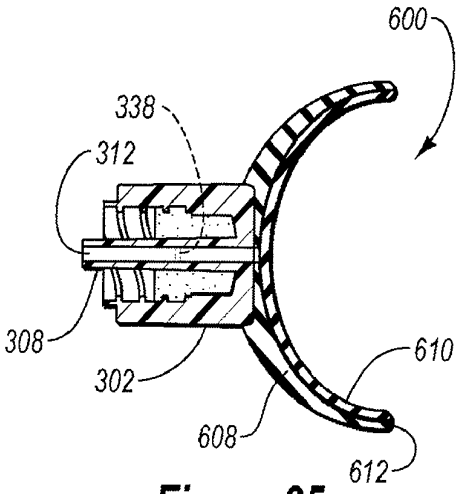

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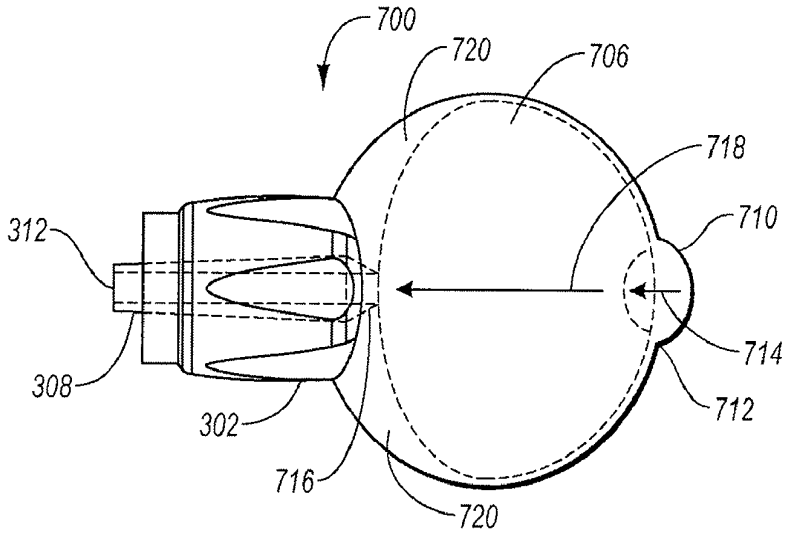

Figure 26

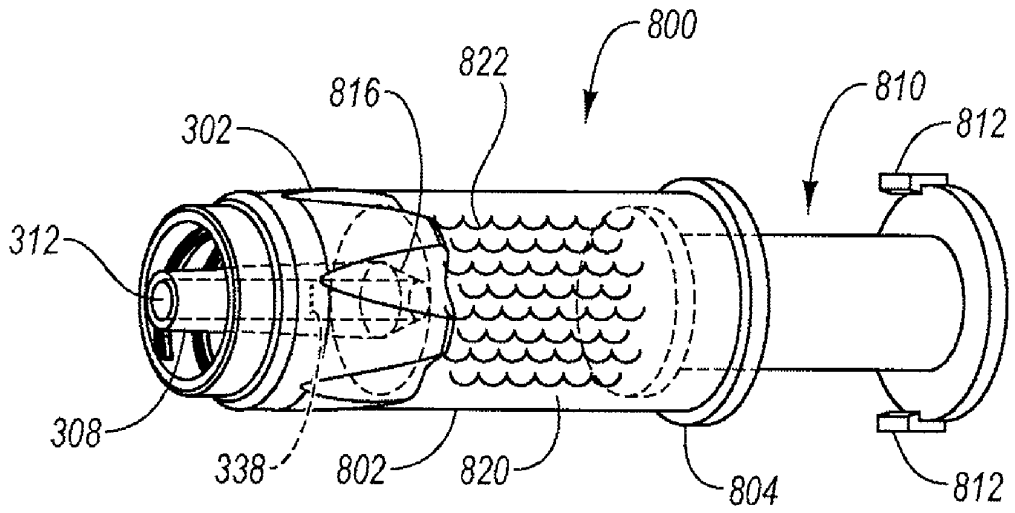

Figure 27

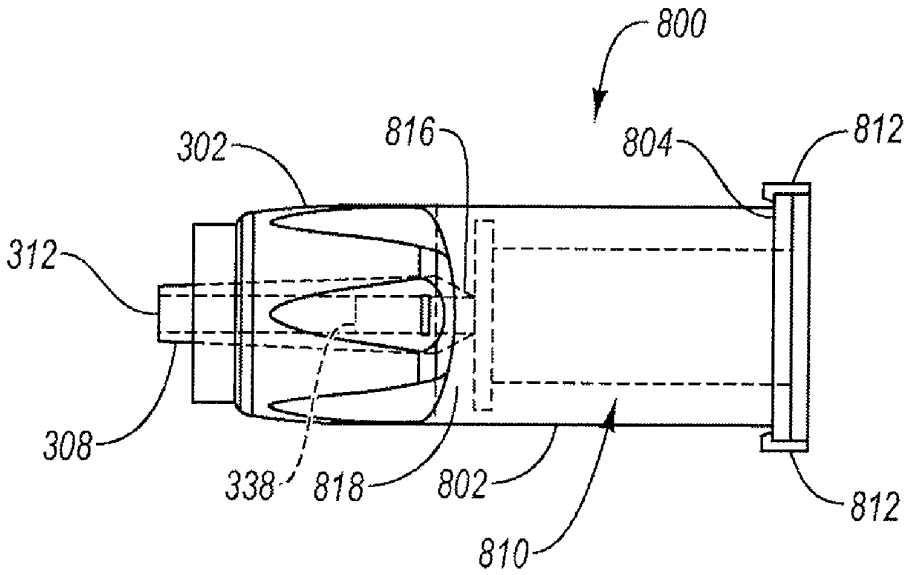

Figure 28

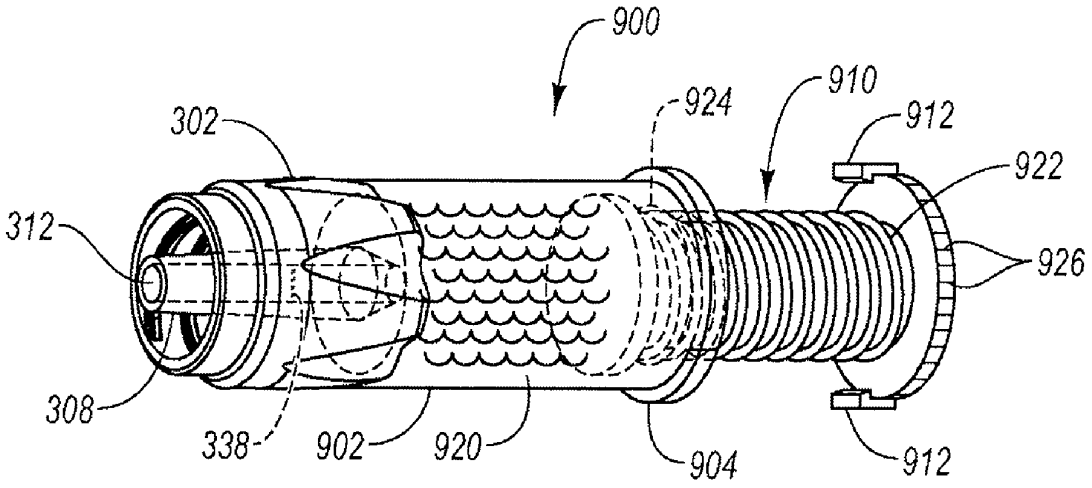

Figure 29

STERILITY-PROTECTING CAPS WITH FLUID RESERVOIR FOR SEPARATED CONNECTORS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 12/164,310, titled NESTABLE STERILITY-PROTECTING CAPS WITH FLUID RESERVOIR FOR SEPARATED CONNECTORS, filed Jun. 30, 2008, which is a continuation-in-part of U.S. patent application Ser. No. 12/014,388, titled NESTABLE STERILITY-PROTECTING CAPS FOR SEPARATED CONNECTORS, filed Jan. 15, 2008, which claims the benefit of U.S. Provisional Application No. 60/880,541, titled ANTISEPTIC PROTECTIVE CAP FOR MALE AND FEMALE SCREW-TOGETHER CONNECTORS, filed Jan. 16, 2007, which are incorporated herein by reference in their entireties.

BACKGROUND

[0002] 1. The Field of the Invention

[0003] This invention is generally related to caps for medical connectors and specifically related to caps used to protect the sterility of separated medical fluid-flow connectors and fluid delivery systems.

[0004] 2. The Relevant Technology

[0005] Catheter-related bloodstream infections are caused by microorganisms in patients with intravascular catheters. These infections are a significant cause of illness and excess medical costs. Approximately 80,000 catheter-related bloodstream infections occur in U.S. intensive care units annually. Additionally, such infections are associated with up to 20,000 deaths per year in the United States alone.

[0006] Guidelines from the Centers for Disease Control and Prevention describe various ways to limit catheter-related bloodstream infections in hospital, outpatient and home care settings. The guidelines address issues such as hand hygiene, catheter site care and admixture preparation. However, despite these guidelines, catheter-related bloodstream infections continue to plague our healthcare system at rates essentially unchanged over the past 10 years.

[0007] Impregnating catheters with various antimicrobial agents is one approach that has been implemented to prevent these infections. These catheters, however, have given less than satisfactory results. Additionally, some microbes have developed resistance to the various antimicrobial agents.

[0008] In another system that is commercially available in Europe, a catheter hub containing an antiseptic chamber is filled with three percent iodinated alcohol. Though it has shown to be effective, the catheter hub is expensive and does not fare as well in a formal cost-benefit analysis.

[0009] Caps used for protecting sterility of medical connectors are well known in the medical art. Commonly, protective tip caps are applied to luer connectors of tubing, IV access devices, stopcocks and syringes. Many examples of such tip caps are commercially available. Most commercially available medical tubing sets are packaged with a cap in place to protect the tubing during handling. Caps for other types of connectors, including catheter injection ports, are less common, though also known in the medical capping art.

[0010] Caps commonly used to cover medical connectors include a cover that is open at one end, closed at the other end and includes a set of spiraling screw threads (for making a secure and sealed luer-type connection) over an associated bared connector, such as an injection port. The inside of the closed end can be equipped with a plastic capsule that can be ruptured when the cover is affixed to the associated connector. Rupturing of the plastic capsule releases antiseptic agents stored in the capsule, thereby applying the antiseptic agents to accessible portions of the connector.

[0011] One of the many examples of medical connectors for which such caps are used are intravascular connectors associated with a fluid pathway, such as a central line. Commonly, a fluid pathway is used to intermittently administer medications to a patient. For example, a fluid pathway, which communicates fluids with a patient's blood stream, may have one or more connectors associated therewith. Each of the fluid pathway connectors can be connected to other connectors, such as a connector associated with an IV bag. In such a situation, the medical connectors, such as luer lock connectors, are connected and disconnected at various times, and may remain disconnected for several minutes or hours. Medical connector caps are used to cover and protect the various medical connectors while the connectors are separated from one another. When the medical connectors are separated from each other, there are two connectors that can require covering by a cap. Therefore, it would be an advantage to have a single connector set that can be used to provide protection for both ends of a separated connection.

[0012] Fluid delivery into medical catheters and other devices is also well known in the art. Various fluid reservoirs including bottles, bags, and syringes are commonly attached to catheters via tubing and connectors for the purpose of delivering fluid therein. Factory pre-fill syringes have become increasingly used to limit the practice of filling syringes in healthcare facilities which may increase the risk of infections and medication/dosing errors. Regulating guidelines including USP 797 and highly publicized incidents of IV medication errors have further underscored the need for safer, low volume fluid delivery devices.

BRIEF SUMMARY

[0013] One embodiment of the present invention comprises a nested pair of protective caps having a male cap and a female cap. Each cap has threads which correspond to connectors generally used in medical apparatuses and which are separated for access thereto. Such medical apparatuses may include, but are not limited to, IV tubing sets, needleless injection sites or ports and vascular access devices. Each cap has threads that connect to a threaded end of an associated cap. As such, a pair of protective caps may be nested together to provide a pair of caps that, before separation, maintain sterile internal surfaces. These caps may subsequently be taken apart and applied to protect and seal both ends of a separated medical connection, such as medical connectors generally used in medical apparatuses, from microbial ingress or other contamination.

[0014] Each protective cap encloses an associated medical apparatus connector and prevents touch contamination that may lead to microbial contamination, colonization, and infection while the medical apparatus connectors are unattached. Further, in some embodiments, the protective caps can contain antiseptic agents that kill microorganisms such as bacteria, viruses, and fungi that may colonize and lead to body-wide infection (e.g. IV catheter related blood stream infections). In such cases, the protective cap may have an absorbent material for applying an antiseptic to an attached

medical apparatus connector. The absorbent material also may provide a friction scrub while the protective cap is being connected. Such scrubbing improves microbial kill.

[0015] The "nesting" geometry of the pair of caps provides both caps as a single unit, sealed against contamination of connecting parts until the nested pair is separated. Generally, the nested pair is connected by the same thread geometries that provide for connecting to associated medical connecting apparatuses. When nested before use, the individual female and male caps are screwed together to form a seal to insure that the sterility of the internal surfaces of each cap is maintained. For this reason, the nested pair unit or device optimally does not require further sterilization before use as the unit is produced and delivered as an inherently self-sealed sterile package.

[0016] For example, the male cap from the device may be generally used to cover the end of an IV tubing set that is disconnected from an IV catheter needleless injection site. Examples of needleless injection sites, sometimes referred to as ports, hubs, and valves, include brands such as Clave (ICU Medical), SmartSite (Cardinal Health), and Q-Site (Becton Dickinson, and Co.). The female cap from the nested pair may then be used to protect the needleless injection site itself. Importantly, once the cap has been applied, the medical apparatus connector need not be re-disinfected (e.g. treated with an alcohol swab) prior to each reconnection, as it will be kept in an uncontaminated state while under the protective cap.

[0017] In an exemplary embodiment, the nested pair of pre-sterilized caps is packaged to protect against contamination by a seal covering about the junction of the two caps. Exemplary embodiments of the nested pair having a female portion and a male portion may also contain a scrubbing material in a closed end of each of the female portion and the male portion. The material can be impregnated with an antiseptic agent. The male portion screws into corresponding threads of the female portion. To assure sterility and prevent fluid loss, the abutting edges of the male and female portions form a seal impermeable to passage of fluid and microbes when tightly affixed together. The abutting edges can be overmolded or co-molded so that the abutting edges can antiseptically seal the interior surfaces of the male and female portions when the male and female portions are coupled together. Alternatively, an O-ring may be affixed about a portion containing internal threads of the male cap. Such a seal reduces or prevents evaporative loss of antiseptic and maintains the sterility of the internal surfaces of the male and female portions. A second, wrap-around seal may also or otherwise be used to provide additional protection for transport and storage. Unscrewing, to separate the two portions, breaks each such seal and prepares the female and male portions for subsequent connection to separated medical connectors. The female portion can then be secured to a male medical connector to protect and seal the male medical connector. Similarly, the male portion can be secured to a female medical connector to protect and seal the female medical connector. As the female portion is secured onto the male medical connector, the scrubbing material disposed in the female portion scrubs the opening edges of the male connector. Likewise, as the male portion is secured onto the female medical connector, the scrubbing material disposed in the male portion scrubs the leading edges of those parts of the female connector that are received within the closed end of the male portion. This, in addition to prevention of contamination, thereby eliminates need for routine swabbing (e.g. by alcohol).

[0018] Other exemplary embodiments provide nested and sealed male and female portions and a fluid reservoir coupled to one of the caps. The fluid reservoir can be adapted to communicate fluid through a channel in the associated cap to a separated medical connector. The fluid within the fluid reservoir can be a medicine or antiseptic agent. In one embodiment, the fluid reservoir is adapted to diffuse the fluid through the associated cap over time. In an alternative embodiment, the fluid reservoir is adapted to dispense the fluid from the fluid reservoir into a fluid pathway. As used herein, a fluid pathway can include, but is not limited to, a central line, a PICC line, a feeding tube, a drain tube, or nearly any type of catheter, including urinary, pulmonary artery, or cardiac catheters. In this embodiment, the fluid reservoir can comprise an elastomeric bulb, a collapsible bulb, a dual-barrel chamber, or a syringe-type barrel-plunger system. The fluid reservoir can be used to administer medicine to a patient through a fluid pathway, or provide an antiseptic to the targeted fluid pathway to maintain catheter patency, or to reduce or eliminate the existence of microbes within the fluid pathway. For example, a specific amount of fluid, such as heparinized saline or other anticlotting medication, could be primed into a central line to maintain catheter patency.

[0019] Additional features and advantages of the present invention will be set forth in the description which follows, and in part will be obvious from the description, or may be learned by the practice of the invention. The features and advantages of the invention may be realized and obtained by means of the instruments and combinations particularly pointed out in the appended claims. These and other features of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. **1** is a side elevation view of an attached pair of medical caps made according to the instant invention;

[0021] FIG. **1**A is a first end perspective view of the caps of FIG. **1**;

[0022] FIG. **1**B is a second end perspective view of the caps of FIG. **1**;

[0023] FIG. **2** is an exploded perspective view of the medical caps of FIG. **1**;

[0024] FIG. **3** is a perspective view of a single cap portion of the attached pair seen in FIG. **2**, with internal threads seen therein;

[0025] FIG. **4** is a perspective view of the cap seen in FIG. **3** with an associated medical connector about to be connected thereto;

[0026] FIG. **5** is a perspective view of a cap, which is complimentary to the cap of FIG. **3**, and a luer lock connector to which the complimentary cap may be affixed;

[0027] FIG. **6** is a side elevation view of an attached pair of medical caps, similar to the caps seen in FIG. **1**, but having an "O" ring disposed about connecting edges of the caps;

[0028] FIG. **7** is an exploded view of the cap assembly seen in FIG. **6**;

[0029] FIG. **7**A is an end perspective view of one of the caps seen in FIG. **7** with a sealing mechanism disposed thereon;

[0030] FIG. **7**B is an end perspective view of the other cap seen in FIG. **7** with a sealing mechanism disposed thereon;

[0031] FIG. **8**A is a side elevation view of the interconnected cap assembly seen in FIG. **6** with a planar or foil seal partially displaced about connecting edges of the cap assembly;

[0032] FIG. **8**B is a side elevation view of the interconnected cap assembly seen in FIG. **8**A with the planar or foil seal fully in place;

[0033] FIG. **9**A is a side elevation view of the cap portion which is seen in FIG. **3** and an absorbent pad being disposed there above;

[0034] FIG. **9**B is a side elevation view of the cap portion and pad seen in FIG. **9**A with the absorbent pad disposed within the cap portion;

[0035] FIG. **9**C is a side elevation view of the cap portion and pad as seen in FIG. **9**B with a quantity of antiseptic material being dispensed into the cap and pad;

[0036] FIG. **9**D is a horizontal perspective view of the cap portion containing the pad as seen in FIGS. **9**B and **9**C affixed to an associated complimentary cap;

[0037] FIG. **9**E is a side elevation view of the cap portion which is seen in FIG. **5** and an absorbent pad disposed there above;

[0038] FIG. **10** is an exploded side elevation view of a pair of complimentary caps, similar to the caps seen in FIG. **1**, but having a tube portion which is sized and shaped to fit through a hole in the female portion of the nested pair, the tube portion having a frangible fluid reservoir therein;

[0039] FIG. **11** is a side elevation view of the complimentary caps seen in FIG. **10** interconnected with the tube portion;

[0040] FIG. **12** is a side elevation view of a pair of complimentary caps, similar to caps seen in FIG. **9**D, with a second absorbent pad disposed therein;

[0041] FIG. **13** a perspective view of a pair of complimentary caps, similar to the caps seen in FIG. **1**, but having an additional scrubbing device disposed in an end of one of the caps;

[0042] FIG. **14** is a cross-sectional perspective view of the pair of caps of FIG. **13**;

[0043] FIG. **15** is a perspective view of an attached pair of medical caps, similar to the caps seen in FIG. **1**, but with one of the caps having a secondary cap portion extending from an end thereof such that the secondary cap portion can be used to cap a pre-filled syringe;

[0044] FIG. **16** is a perspective view of a single medical cap, similar to the cap seen in FIG. **3**, but having a post disposed therein to sealingly engage an interior surface of a medical connector when coupled thereto;

[0045] FIG. **17** is a perspective view of the cap seen in FIG. **16** with an associated medical connector about to be connected thereto;

[0046] FIG. **18** is a perspective view of a single medical cap, similar to the cap seen in FIG. **16**, but having an orifice within the post to receive a spike of a medical connector when coupled thereto;

[0047] FIG. **19** is a cross-sectional view of the cap seen in FIG. **18** with an associated medical connector about to be connected thereto;

[0048] FIG. **20** is a cross-sectional view of a single medical cap, similar to the caps seen in FIG. **16-19**, but having a channel extending entirely through the post to communicate fluid through the cap when the cap is coupled to a separated medical connector;

[0049] FIG. **21** is a perspective view of a cap assembly having a cap, similar to the cap seen in FIG. **20**, and a fluid reservoir coupled thereto;

[0050] FIG. **22** is a cross-sectional view of the cap assembly seen in FIG. **21** with an associated medical connector about to be connected thereto;

[0051] FIG. **23** is a perspective view of an another embodiment of a cap assembly according to the present invention, wherein the fluid reservoir comprises an elastomeric bulb;

[0052] FIG. **24** is a perspective view of yet another embodiment of a cap assembly according to the present invention, wherein the fluid reservoir comprises a deformable fluid bulb;

[0053] FIG. **25** is a cross-sectional view of the cap assembly seen in FIG. **24** with a portion of the fluid bulb inverted to dispense fluid from the fluid reservoir;

[0054] FIG. **26** is a side view of a cap assembly according to the present invention, having a primer bulb and a secondary post to reduce the amount of air introduced into a fluid pathway;

[0055] FIG. **27** is a perspective view of still yet another cap assembly according to the present invention, having an evacuable fluid chamber coupled thereto, the fluid chamber having a barrel and plunger configuration;

[0056] FIG. **28** is a side view of the cap assembly seen in FIG. **26**, with the plunger portion fully compressed;

[0057] FIG. **29** is a perspective view of a cap assembly, similar to the cap assembly seen in FIGS. **27** and **28**, but the plunger and barrel are threadably engaged.

DETAILED DESCRIPTION

[0058] The present invention relates generally to a pair of nestable caps, each of the caps being sized and shaped to provide a protective union about a separated medical connector. The pair comprises a male cap and a female cap, each of which is configured to be adjoined to a complimentary cap to form a nested pair. The nested pair is sealed until separated for use, thereby maintaining sterility of the internal surfaces of the nested pair. One of the caps may have a fluid chamber joined thereto filled with medicine or antiseptic. The cap associated with the fluid chamber can have a channel extending therethrough to provide fluid communication between the fluid chamber and a fluid pathway. The fluid chamber can be adapted to diffuse the fluid into the fluid pathway over time, or the fluid chamber can be adapted to dispense the fluid out of the fluid chamber.

[0059] Seen in FIGS. **1-1**B, is a unit or assembly **100** of a pair of separable caps **102** and **104** securely, but releasably affixed one to the other across a common interface **106**. To serve a meaningful purpose, internal parts and surfaces of assembly **100** must be sterile and, perhaps more important, be able to reduce, prevent, or eliminate contamination of a connector with which each cap becomes associated.

[0060] Caps **102** and **104** are seen apart in FIG. **2**, wherein cap **104** is seen to have an insertable or male section **108**. Section **108** has an elongated portion **110** that ends at an exteriorly disposed threaded segment **112**. Threaded segment **112** comprises threads **114** that are sized and shaped to be inserted and joined by threading into cap **102**.

[0061] Cap **102**, which is better seen in FIG. **3**, has a closed, hollow interior **116** which opens outwardly at a proximal end **118** to expose an interiorly disposed threaded segment **120**. Threads **122** are of a size and pitch to complimentarily engage threads **114** for a screw or push on tight fit with cap **104**.

[0062] As illustrated in FIG. **4**, cap **102** has an interior surface **124**, an opening edge **126** and an exterior surface **128**, opening edge **126** being a common link between interior surface **124** and exterior surface **128**. Further, threads **122** also have a size and pitch to engage a threadable segment **130** of a female connector, such as for example, female luer connector **132**. Such connectors are generally and commonly used as catheter and other fluid tight protective connectors in medical applications. As seen in FIG. **4**, cap **102** provides a protective cover for connector **132** when encased about connector **132** (displaced in direction of arrow **134**) where upon threadable segment **130** engages and is drawn into a secure, but releasable connection with threads **122** of cap **102**.

[0063] Likewise, as seen in FIG. **5**, threads **114** of cap **104** are of a size and pitch to engage threads **138** of a male luer-lock connector **136**. Note that cap **104** has a medially disposed, elongated hole **140**, into which a frustoconical cone shaped luer **142** of connector **136** may be facilely and securely inserted when cap **104** is displaced in direction of arrow **144** to engage connector **136**.

[0064] Cap **104** also has a surface **146** which continues through to a circular edge **148**. Further, distally displaced from circular edge **148**, surface **146** abruptly ends at a circular ring shaped edge **150**, which is therefrom joined to an outside surface **152**. It may be noted that opening edge **126** (see FIG. **4**) and ring shaped edge **150** combine to form common interface **106** (see FIG. **1**) when cap **102** is affixed to cap **104** to construct assembly **100**. It should also be noted that surfaces of assembly **100**, which contact internal surfaces of a connector, such as connector **132** or connector **136**, should be sufficiently sterile to not contaminate the inner surfaces thereof.

[0065] For this reason, internal portions and associated edges of caps **102** and **104** should be pre-sterilized and so maintained until use. Caps **102** and **104** may be injection molded using polypropylene or other material that can be sterilized and which is impervious to contaminating agents while cap **102** is fully nested with cap **104**, before being opened for use. Caps **102** and **104** can also be impregnated or coated with an antimicrobial substance. As an example, each cap **102** and cap **104** may be individually sterilized by ethylene oxide (ETO) before final assembly and aseptically paired, or assembly **100** may be finally consolidated as a single unit and then sterilized, such as by radiation (e.g. gamma). Even so, assembly **100** should be kept intact until time for use, with internal surfaces of nested parts **102** and **104** remaining clean and sterile until assembly **100** is opened for use.

[0066] Reference is now made to FIGS. **6** through **7**B, wherein a seal, such as an "O" ring, is disposed between surfaces **126** and **150** to provide yet another barrier against internal surface contamination of caps **102** and **104**. As seen in FIG. **6**, an "O" ring **154** is disposed between surfaces **126** and **150** to provide a seal thereby. While "O" ring **154** can be displaced from caps **102** and **104** as illustrated in FIG. **7**, it is anticipated that "O" ring **154** can be adapted to remain affixed to one of caps **102** and **104**. For example, as illustrated in FIG. **7**A, "O" ring **154** can remain positioned adjacent surface **150** on cap **104** when caps **102** and **104** are disconnected from one another, rather than being separated when cap **104** is displaced from cap **102**, as seen in FIG. **7**.

[0067] Alternatively, "O" ring **154** can be associated with cap **102**, as seen in FIG. **7**B. In particular, opening edge **126** of cap **102** can have an annular groove **156** for receiving "O" ring **154** therein. Annular groove **156** can be sized and shaped such that "O" ring **154** sealingly engages cap **104** or a medical connector when cap **102** is coupled thereto. It will be appreciated that annular groove **156** can be disposed in opening edge **126** toward the exterior of cap **102** as illustrated in FIG. **7**B, or annular groove **126** can be disposed in opening edge **126** towards the interior of cap **102**. In some exemplary embodiments, opening edge **126** of cap **102** does not have annular groove **126** therein. In such embodiments, "O" ring **154** can be mounted directly to opening edge **126**. "O" ring **154** can be mounted on or to caps **102** or **104** in any suitable manner, including with the use of an adhesive, such as glue, a mechanical fastener, or a friction fitting.

[0068] While the seal between caps **102** and **104** has been described as being an "O" ring mounted on one of caps **102** or **104**, it will be appreciated that other seals are contemplated within the scope of the present invention. For example, each of caps **102** and **104** can have an "O" ring mounted thereon. In such a configuration, the two "O" rings abut each other when caps **102** and **104** are coupled together, thereby forming a seal to antiseptically partition the internal and external surfaces of caps **102** and **104**. Alternatively, one or both of caps **102** and **104** can be formed with a lip, bump, or groove that provides a sealing function when caps **102** and **104** are coupled to each other or to separated medical connectors. In one exemplary embodiment, one of caps **102** and **104** has a ridge extending around its interfacing surface, and the other cap has a corresponding groove in its interfacing surface into which the ridge is received to create the seal. In yet another exemplary embodiment, one or both of caps **102** and **104** can be overmolded or comolded using any known and suitable overmolding or comolding process. For example, one or both of caps **102** and **104**, and associated surfaces **126** and **150**, can be overmolded or comolded. Thus, caps **102** and **104** can be formed of a polymer, and surfaces **126** and **150** can be formed of a softer polymer that is comolded or overmolded to the rest of caps **102** or **104**. Surfaces **126** and **150**, formed of the softer polymer, are thus able to be compressed or deformed sufficiently to create an impermeable seal when caps **102** and **104** are coupled together or coupled to separated medical connectors.

[0069] As noted elsewhere herein, a sealing mechanism, as described herein, can be used to limit or prevent evaporation or loss of an antiseptic agent disposed within caps **102** and **104** when caps **102** and **104** are coupled together. Additionally, a sealing mechanism, as described herein, can also limit or prevent evaporation or loss of an antiseptic agent disposed within caps **102** and **104** when caps **102** and **104** are coupled to separated medical connectors. Further, a sealing mechanism, as described herein, can also limit or prevent microbial ingress within caps **102** and **104** when coupled to each other, or within caps **102** and **104** when caps **102** and **104** are individually coupled to separated medical connectors. Moreover, a sealing mechanism, as described herein, can be adapted to maintain an antiseptic agent within caps **102** and **104** when caps **102** and **3104** are either coupled to one another or to separated medical connectors for a predetermined amount of time. Thus, the seal may be adapted to limit or prevent microbial ingress while also partially or completely preventing evaporation of an antiseptic agent disposed within caps **102** and **104** when caps **102** and **104** are coupled together or when caps **102** and **104** are coupled to separated medical connectors. Similarly, the seal may be adapted to limit or prevent microbial ingress while not preventing evaporation of an antiseptic agent disposed within caps **102** and **104**. In yet other embodiments of the invention, no seal is provided

between caps **102** and **104** when coupled together or between caps **102** and **104** when coupled to separated medical connectors.

[0070] Further safety in sealing against internal surface contamination may be provided by a sealing tape, such as tape **158** seen in FIG. **8**A. Tape **158** is disposed to fully cover exposed edges of surfaces **126** and **150**. Tape **158** may, for example, be of an impervious pliable material, such as a metallized-surface mylar. As seen in FIG. **8**B, tape **158** is wrapped about surfaces **126** and **150** to provide a secure seal. It is preferred that tape **158** frangibly divides when cap **102** is separated from cap **104** to facilitate separation of caps **102** and **104** and provide a visible indication that the seal is broken. Thus tape **158** provides both a seal to prevent microbial ingress and a mechanism for maintaining the secure connection between caps **102** and **104** prior to use. It will be appreciated, however, that any suitable sealing mechanism can be used to maintain the secure connection between caps **102** and **104** prior to use. For example, any sealing mechanism can be used that securely and selectively couples caps **102** and **104** together, requires deliberate action to break the seal, and provides a visual indication of whether the seal has been broken. By way of example and not limitation, a suitable sealing mechanism may include a heat stake, a frictional seal, a barbed seal, a ratchet seal, and the like.

[0071] When capping disconnected medical connectors, it is prudent to do more than just cover those connectors with caps. For this reason, an absorbent pad, such as pad **160**, seen in FIG. **9**A, may be displaced into cap **102** as indicated by arrow **162**. Pad **160** is seen disposed in cap **102** in FIG. **9**B. An antiseptic **164** can also be disposed within cap **102** as illustrated in FIG. **9**C. Antiseptic **164** can be in liquid or solid form. For example, alcohol or another stable liquid antiseptic may be added from a container **166** to saturate pad **160** to a predetermined level. Note that once assembly **100** is fully assembled, pad **160** will substantially remain at the predetermined saturation level due to the exterior seals provided for assembly **100** as described herein. Alternatively, or additionally, pad **160** may be impregnated with a dry antiseptic, such as chlorhexidine gluconate.

[0072] Further note that once cap **104** is securely affixed to cap **102**, as seen in FIG. **9**D, pad **160** is disposed to contact at least circular edge **148** (see also FIG. **5**). (In FIG. **9**D, parts of cap **104** which are internal to assembly **100** are seen with hidden or dashed lines.) Such contact provides a wiping action preferred to make contact with a surface before contact is made with an associated connector. Note also that residual antiseptic on associated internal surfaces of cap **104** may be transferred to related parts of the associated connector for cleaning and/or disinfecting purposes.

[0073] Pad **160** can be formed of a deformable, resilient material such that when cap **104** is coupled to cap **102**, elongated portion **110** can compress pad **160** within cap **102**, as illustrated in FIG. **9**D. Further, pad **160** can expand to its original shape when cap **104** is removed from cap **102**. Similarly, pad **160** can be compressed within cap **102** when cap **102** is coupled to a medical connector, such as medical connector **132**. More specifically, during the connection of cap **102** to a medical connector, cap **102** and pad **160** rotate relative to an opening edge of the medical connector, thereby drawing the medical connector into cap **102**. The rotation of cap **102** causes pad **160** to wipe or scrub the opening edge of the medical connector. Pad **160** and any antiseptic disposed within cap **102** can thus cleanse and disinfect the opening edges of the medical connector. Pad **160** can also be formed such that when a medical connector is coupled to cap **102**, pad **160** is deformed such that pad **160** extends around the opening edges and/or threads of the medical connector. For example, pad **160** can be formed such that as cap **102** is twisted onto medical connector **132**, pad **160** deforms around threads **130** and/or the opening edges of medical connector **132**, thereby scrubbing threads **130** and/or the opening edge of medical connector **132**.

[0074] Pad **160** can also provide additional functionality when a liquid antiseptic is disposed within cap **102**. In particular, pad **160** acts as a sponge to absorb or release the liquid antiseptic within cap **104**. More specifically, when pad **160** is compressed by elongate portion **110** of cap **104** (FIG. **9**D; see also elongate portion **268** compressing pad **160** in FIG. **14**) or the opening edges of a medical connector coupled to cap **102**, pad **160** releases the antiseptic so that the antiseptic can be transferred to elongate portion **110** or the opening edges of the medical connector. Conversely, when cap **102** or a medical connector is disconnected from cap **102**, pad **160** expands and absorbs excess antiseptic so that the antiseptic does not drip or spill out of cap **102**.

[0075] Similar to pad **160** and antiseptic **164** disposed within cap **102**, cap **104** may also have a pad and/or an antiseptic disposed therein. For example, as illustrated in FIG. **9**E, a pad **170** may be disposed within elongate hole **140** of cap **104**. An vantiseptic can also be disposed within cap **104** in a manner similar to antiseptic **164** in cap **102**. Antiseptic can be in liquid or solid form. For example, alcohol or another stable liquid antiseptic may be added from a container to saturate pad **170** to a predetermined level. Alternatively, or additionally, pad **170** may be impregnated with a dry antiseptic, such as chlorhexidine gluconate. Once assembly **100** is fully assembled, an antiseptically saturated pad **170** disposed within cap **104** will substantially remain at the predetermined saturation level due to the exterior seals for assembly **100** as described above. Once caps **102** and **104** are disconnected from each other and connected to individual medical connectors, pad **170** disposed within cap **104** may scrubrelated parts of the associated connector for cleaning and/or disinfecting purposes. It will be appreciated, however, that in some embodiments, pad **170** may not contact a medical connector coupled to cap **104**. Additionally, the antiseptic disposed within cap **104** may be transferred to the related parts of the associated medical connector for cleaning and/or disinfecting purposes.

[0076] Under some conditions, it may be preferable to retain an antiseptic solution within a container prior to separating the nested caps. Reference is now made to FIGS. **10-11** wherein an assembly **200** is seen to comprise a first cap **204**, a second cap **202** and an antiseptic containing vessel **206**.

[0077] As seen in FIG. **10**, geometric features of cap **202** are similar to features of cap **102** except for a through hole **208** in end **210**, providing access into cap **202**. Rather than an absorbent pad **160** (see FIG. **9**D), an absorbent pad **212** is resident at an open end **214** of a hollow pliable tube **216**. Tube **216** is closed at an opposite end **218**. Also, retained in tube **216** by pad **212** and closed end **218** is a frangible capsule **220** which is filled with a predetermined amount of antiseptic solution.

[0078] Note that tube **216** is sized, shaped, and of a material to fill and be securely and sealingly affixed to cap **202** to provide a seal about hole **208**. A commercially available

frangible reservoir tube such as the ChlorPrep Sepp Applicator provided by Enturia may be used for vessel **206**.

[0079] As seen in FIG. **11**, tube **216** is displaced into hole **208** to be adhesively affixed thereat. Resultingly, vessel **206** becomes an integral part of assembly **200**. Prior to separating cap **204** from cap **202**, capsule **220** is manually crushed to cause fluid **222** contained therein to be released into the void of parts of assembly **200** through pad **212**.

[0080] As discussed herein, it is common for a cap, such as caps **104** and **204** to be used to protect a male luer connector. In such a case, a cap **204** seen in FIG. **12** is seen to contain a hollow frustoconically shaped internal connector surface **224**. To further cleanse a male luer connector inserted therein, a second antiseptic filled pad **226** is disposed at the deepest point thereof for contact with the end of the male connector.

[0081] With attention to FIGS. **13** and **14**, another exemplary embodiment of a nestable pair of caps **250** is illustrated having a female cap **102** and a male cap **254**, similar to the caps previously described herein. Disposed between caps **102** and **254** can be a sealing mechanism **154** as described herein. Additionally, one or both of caps **102** and **254** can have a scrubbing chamber **256** disposed within an end thereof. Scrubbing chamber **256** can be adapted to clean, disinfect, and remove particulate from a medical connector prior to connecting the medical connector to another medical connector or to one of caps **102** and **254**.

[0082] In the illustrated embodiment, scrubbing chamber **256** is disposed within cap **254**, however, it will be appreciated that scrubbing chamber **256** can be disposed within the end of cap **102**. Scrubbing chamber **256** comprises a cavity **258** within the end of cap **254**. Positioned within cavity **258** is a liner **260** and a pad **262** disposed within liner **260**. Liner **260** can be removably secured within cavity **258** such that liner **260** can be securely held in place during use of cap **254** and/or scrubbing chamber **256**, and removed after use of scrubbing chamber **256**. Liner **260** can also be adapted to be removed from cavity **258** prior to use of scrubbing chamber **256**, such that scrubbing chamber **256** can be used independently of caps **102** or **254**. Scrubbing chamber **256** may be used to remove potentially hazardous material and particulates, such as blood, body fluids, drug particulate, and the like, from off of a medical connector prior to the medical connector being secured to another medical connector or to one of caps **102** or **254**. After scrubbing chamber **256** has been used, the contents of scrubbing chamber **256**, including liner **260**, pad **262**, and any particulate removed from the medical connector, can be removed from cap **254** and discarded so that the hazardous material does not remain near the medical connector when the cap is coupled thereto.

[0083] As noted above, disposed within liner **260** is pad **262**. Similar to pad **160** described herein, pad **262** can be formed of a deformable material capable of deforming around the opening and threads of a medical connector. Additionally, or alternatively, pad **262** can be formed such that the edges of pad **262** extend closer to the opening of scrubbing chamber **256** than the central portion of pad **262**, as illustrated in FIG. **14**. The extending edges of pad **262** can be adapted to wrap at least partially around the edges of a medical connector so as to enable cleaning, disinfecting, or removal of particulate from outer surfaces and/or threads of a medical connector. Pad **262** can also be formed of an abrasive material that can break up hardened materials that have collected on a medical connector. Additionally, pad **262** can be formed of a material that can be impregnated or saturated with an antiseptic agent, such as alcohol or -chlorhexidine gluconate.

[0084] Scrubbing chamber **256** can also include a removable cover **264** for enclosing liner **260**, pad **262**, and any antiseptic agent within cavity **258**. As illustrated in FIG. **14**, cover **264** extends across the opening to cavity **258** and is secured to cap **254**. Cover **264** can be secured to cap **254** is any manner that sealingly maintains the contents of cavity **258** therein and that allows for ready removal of cover **264** when scrubbing chamber **256** is to be used. Cover **264** can be formed of any suitable material, such as foil, plastic, and the like. Additionally, cover **264** can also include a tab **266** that facilitates quick and convenient removal of cover **264** when scrubbing chamber **256** is to be used.

[0085] In the exemplary embodiment of the present invention illustrated in FIG. **15**, a cap assembly **270** including a nestable pair of caps **272**, having a female cap **274** and a male cap **104**, is provided. Male cap **104** and female cap **274** are similar to the other caps described herein. Specifically, the caps nestably couple together to protect the sterility of their interior surfaces and can be separated and coupled to separated medical connectors to protect the sterility of the separated connectors. Additionally, one of the caps can have a secondary cap portion disposed on an end thereof. For example, in the illustrated embodiment, one end of female cap **274** is formed to receive a portion of and be coupled to male cap **104** or a male medical connector as described herein. Additionally, the other end of female cap **274** is formed with a secondary cap portion **276** such that secondary cap portion **276** can be selectively and securely coupled to a prefilled syringe **278**, for example. It will be appreciated that secondary cap portion **276** could also be formed on an end of cap **104**. Secondary cap portion **276** can be formed to securely and sealingly couple to a fluid coupling interface portion of syringe **278** to as to protect the sterility of the fluid coupling interface portion of syringe **278**. In this configuration, nestable pair of caps **272** can be coupled to prefilled syringe **278** prior to use of prefilled syringe **278**, while maintaining the sterility of the fluid coupling interface portion of syringe **278**. In one embodiment of cap assembly **270**, secondary cap portion **276** can be selectively disconnected from cap **274** either before or after use of syringe **278**. Likewise, secondary cap portion **276** could be disconnected from pair of caps **272** so that pair of caps **272** and syringe **276** can be used independently from one another.

[0086] Coupling pair of caps **272** to secondary cap portion **276** and syringe **278** in the manner described herein provides the convenience of having a pair of caps **272** readily available after a pre-filled syringe is used to dispense a fluid into a fluid pathway. In use, for example, a medical professional could separate a set of medical connectors in order to administer the fluid within syringe **278** to one or both of the fluid pathways associated with the medical connectors. In order to use syringe **278**, cap **276** is removed from syringe **278**. With cap **276** removed, syringe **278** can be coupled to one or both of the separated medical connectors and the fluid within syringe **278** can be dispensed into the fluid pathway. After use of syringe **278** is complete, pair of caps **272** can be separated into individual caps **274** and **104**, which can then be coupled to the separated medical connectors in the same manner as described herein with reference to caps **102** and **104**, for example.

[0087] With attention to FIGS. **16-29**, additional exemplary embodiments of caps according to the present invention will

be described. While the various aspects, features, and characteristics of the exemplary embodiments illustrated in FIGS. **16-29** will be described with specific reference to a female type cap, similar to cap **102**, it will be appreciated that the same aspects, features, and characteristics may be applied to or incorporated within a male type cap, similar to cap **104**. Furthermore, it will be appreciated that the female type caps described with reference to FIGS. **16-29** can be coupled to a male type cap in a manner similar to that described above with reference to caps **102** and **104** in order to create a nested pair of caps. Alternatively, the embodiments described with reference to FIGS. **16-29**, whether in a male or female type cap, can be formed and/or employed without having to be nested or otherwise associated with a complimentary cap.

[0088] With specific reference to FIGS. **16** and **17**, a cap **275** in accordance with an exemplary embodiment of the present invention is illustrated. Cap **275** has an interior portion **276**. Disposed on at least one surface of interior portion **276** are threads **278**, which are of a size and pitch to complimentarily engage threads of another cap, such as cap **104**, or a medical connector to facilitate coupling thereto as discussed herein. Cap **275** further includes a frustoconical cone shaped post **280** positioned in the center of interior portion **276**. Similar to the caps describe elsewhere herein, cap **275** can have a pad, saturated or impregnated with an antiseptic agent, disposed within interior portion **276** and about post **280** to cleanse portions of a medical connector coupled thereto.

[0089] As seen in FIG. **17**, cap **275** provides a protective cover for connector **132** when encased about connector **132** (displaced in direction of arrow **284**) where upon threadable segment **130** engages and is drawn into a secure, but releasable connection with threads **278** of cap **275**. Post **280** is sized and shaped to be received within conduit **282** of connector **132** when cap **275** is secured on connector **132**. Post **280** is further sized and configured to sealingly engage the outer wall of conduit **282** to prevent fluid within fluid pathway **286** from leaking out of connector **132** when cap **275** is secured thereon. Post **280** is also sized and shaped to fit within a medially disposed, elongated hole of a male type cap when cap **275** is coupled thereto. For example, post **280** is adapted to fit within hole **140** of cap **104** (FIG. **5**) when cap **275** is coupled to cap **104**.

[0090] FIGS. **18-20** illustrate exemplary embodiments of a cap **302**, which is similar to cap **275**. In particular, cap **302** has an interior portion **304** with threads **306** disposed on at least one surface thereof. Threads **306** are of a size and pitch to complimentarily engage threads of another cap, such as cap **104**, or a medical connector, such as connector **340**, to facilitate coupling thereto as discussed herein. Furthermore, cap **302** includes a frustoconical cone shaped post **308** positioned in the center of interior portion **304**. Similar to post **280**, post **308** is sized and shaped to be received within and sealingly engage a conduit of connector **340** when cap **302** is secured on connector **340** to prevent fluid within a fluid pathway from leaking out of the connection between connector **340** and cap **302**. Additionally, post **308** is also sized and shaped to fit within a medially disposed, elongated hole of a male type cap when cap **302** is coupled thereto. For example, post **308** is adapted to fit within hole **140** of cap **104** (FIG. **5**) when cap **302** is coupled to cap **104**.

[0091] Additionally, as illustrated in FIG. **19**, disposed within interior portion **304** and about post **308** is a pad **160**, which can be saturated or impregnated with an antiseptic agent, as discussed herein. With either connector **340** or a male type cap, such as cap **104**, connected to cap **302**, pad **160** is disposed to contact at least a portion of connector **340** or cap **140** in a manner similar to that described above with reference to FIG. **9**D. More specifically, pas **160** is disposed to contact at least the opening edge **348** of connector **340** or circular edge **148** of cap **104** to cleanse at least opening edge **348** of connector **340** and circular edge **148**, as discussed herein.

[0092] While post **308** includes many of the same characteristics of post **280**, post **308** further includes an orifice or channel. More specifically, as illustrated in FIGS. **18** and **19**, post **308** includes orifice **310** that extends from an end of post **308** at least partially through the interior thereof. Orifice **310** is sized and shaped to receive a spike **346** of a medical connector **340**, such as a Clave® connector, when cap **302** is coupled to medical connector **340**. Alternatively, post **308** can include a channel **312**, as illustrated in FIG. **20**, which extends entirely through post **308**. Channel **312** can receive a spike **346** of a medical connector **340**. Additionally, channel **312** can provide a fluid passageway through cap **302** for purposes described elsewhere herein.

[0093] Attention is now directed to FIGS. **21-29**, which illustrate various exemplary cap assembly embodiments according to the present invention. Each of the example embodiments includes cap **302** with channel **312** extending therethrough, as described above, and a fluid reservoir joined thereto. The cap assemblies of the present invention can be adapted to communicate fluid from the fluid reservoir, through cap **302**, to a fluid pathway associated with a patient. Such communication of fluid can be to provide medication to a patient, disinfect the fluid pathway, or maintain catheter patency.

[0094] As noted, the various features and characteristics of cap **302** and the cap assemblies described below can be incorporated into a male type cap, such as cap **104**. Additionally, it will be appreciated that the cap assemblies described below, which incorporate cap **302**, can be coupled to a male type cap, such as cap **104**, to create a pair of sterile, nested caps as described above with respect to caps **102** and **104**.

[0095] Attention is now directed to FIGS. **21** and **22** in which an exemplary embodiment of a cap assembly **400** is illustrated. Cap assembly **400** includes cap **302** and a fluid reservoir **406** coupled to one end thereof. As described above, post **308** of cap **302** includes a channel **312** extending therethrough. Channel **312** is sized and shaped to connect to a female luer access device ("LAD") to open the fluid pathway. Channel **312** provides a fluid passageway through cap **302** to enable fluid to flow between fluid reservoir **406** and fluid pathway **342**. For example, cap assembly **400** can be employed to administer a medication to a patient through fluid pathway **342**. Specifically, fluid reservoir **406** can contain a liquid medication that is released into fluid pathway **342** when cap assembly **400** is coupled to connector **340**. Cap assembly **400** can also be employed to cleanse and disinfect fluid pathway **342**. In particular, fluid reservoir **406** can contain an antiseptic agent that is released into fluid pathway **342** when cap assembly **400** is coupled to connector **340**.

[0096] In some embodiments of cap assembly **400**, a seal or valve is disposed within channel **312**. The seal or valve can be adapted to retain fluid **408**, such as an antiseptic solution or medication, within fluid reservoir **406** until cap assembly **400** is securely coupled to a medical connector, such as connector **340**. When cap assembly **400** is coupled to connector **340**, the

seal can be broken or the valve can be opened to allow fluid **408** to flow through channel **312** and into fluid pathway **342**.

[0097] Cap assembly **400** can be configured to diffuse fluid **408** from fluid reservoir **406** into fluid pathway **342** over time as long as fluid **408** has a higher concentration than the fluid within fluid pathway **342**. For example, if fluid **408** has a significantly higher concentration level than the fluid within fluid pathway **342**, fluid **408** will diffuse into fluid pathway **342** more rapidly. In contrast, if fluid **408** has a concentration level only slightly higher than the fluid within fluid pathway **342**, fluid **408** will diffuse into fluid pathway **342** more slowly. Thus, medication can be administered by a physician, or an antiseptic agent can be diffused into fluid pathway **342** over time to reduce or eliminate the existence of microorganisms within fluid pathway **342**.

[0098] Attention is now directed to FIGS. **23-29**, in which alternative embodiments of fluid reservoirs are illustrated for cap assemblies according to the present invention. For example, in FIG. **23** a cap assembly **500** is illustrated, which includes cap **302**, as described above, and fluid bulb **506**. Cap assembly **500** can be employed to administer a medication to a patient through a fluid pathway, such as a central line. Specifically, fluid bulb **506** can contain a liquid medication that is released into a fluid pathway when cap assembly **500** is coupled to a medical connector. Cap assembly **500** can also be employed to cleanse and disinfect the fluid pathway. In particular, fluid bulb **506** can contain an antiseptic agent that is released into a fluid pathway when cap assembly **500** is coupled to a medical connector.

[0099] In the embodiment illustrated in FIG. **23**, fluid bulb **506** is an elastomeric bulb. During manufacture of cap assembly **500**, fluid bulb **506** is filled with a fluid, such as an antiseptic or medicine, so that fluid bulb **506** is expanded to the size illustrated in FIG. **23**. The elastomeric properties of fluid bulb **506** cause fluid bulb **506** to contract in the direction of the illustrated arrows, thereby applying pressure on the fluid within fluid bulb **506**. However, a seal or valve can be disposed within channel **312** of cap **302** to retain the fluid within fluid bulb **506**, thereby preventing fluid bulb **506** from fully contracting back to its normal size (illustrated in dashed lines in FIG. **23**). Nevertheless, once cap assembly **500** is securely coupled to a medical connector, the seal or valve within channel **312** can be activated, allowing fluid bulb **506** to fully contract to its natural size (illustrated in dashed lines in FIG. **23**), thereby forcing the fluid within fluid bulb **506** through channel **312** and into a fluid pathway connected to cap assembly **500**. As discussed elsewhere herein, a valve disposed within channel **312** can also be adapted to prevent fluid from undesirably refluxing into fluid bulb **506**. In particular, the valve can be a one-way valve, a duckbill valve, a back check valve, a pressure activated valve, or the like to prevent fluid from flowing from a fluid pathway into fluid bulb **506**. It will be appreciated however, that in some embodiments, a valve or seal is not disposed within channel **312**.

[0100] FIGS. **24** and **25** depict a cap assembly **600** that is similar to cap assembly **500**. In particular, cap assembly **600** includes cap **302** and a fluid bulb **606** coupled to one end thereof. Fluid bulb **606** includes a fixed, thick wall portion **608**, a collapsible, thin wall portion **610**, and a hinge **612** that joins fixed wall **608** and collapsible wall **610**. In the illustrated embodiment, fixed wall **608** is coupled to cap **302**. It will be appreciated, however, that collapsible wall **610** can be coupled to cap **302** without departing from the scope of the present invention.

[0101] Hinge **612** can be a "living hinge" adapted to enable collapsible wall **610** to be inverted as shown in FIG. **25** in order to dispense fluid from within fluid bulb **606**. In particular, collapsible wall **610** can be pressed toward cap **302**, thereby forcing fluid within fluid bulb **606** to be dispensed through channel **312**. Additionally, thick wall **608** and collapsible wall **610** can be sized and shaped such that collapsible wall **610** nests within thick wall **608** when collapsible wall **610** is inverted as shown in FIG. **25**. Moreover, collapsible wall **610** can be formed such that once collapsible wall **610** is inverted within thick wall **608**, collapsible wall **610** remains inverted within thick wall **608** and does not right itself. Maintaining collapsible wall **610** in the inverted position prevents a vacuum from forming within fluid bulb **606**, in turn preventing fluid from undesirably refluxing into fluid bulb **606**. These features of fluid bulb **606** can be realized by selecting the appropriate dimensions for thick wall **608** and collapsible wall **610**, as well as the material used to manufacture fluid bulb **606**. Fluid bulb **606** can be formed of a polymer material, such as polyethylene or polypropylene, to provide it with the functional characteristics described above.

[0102] In some embodiments of cap assembly **600**, a seal or valve is disposed within channel **312**. The seal or valve can be adapted to retain fluid, such as an antiseptic solution or medication, within fluid reservoir **606** until cap assembly **600** is securely coupled to a medical connector. Once cap assembly **600** is securely coupled to a medical connector, the seal can be broken or the valve can be opened to allow fluid to flow through channel **312** and into fluid pathway. The valve can also be adapted to prevent fluid from undesirably refluxing into fluid reservoir **606**. In particular, the valve can be a one-way valve, a duckbill valve, a back check valve, a pressure activated valve, or the like. While the illustrated embodiment of cap assembly **500** includes a valve **338** disposed within channel **312**, it will be appreciated, however, that in some embodiments, a valve or seal is not disposed within channel **312**.

[0103] As appreciated by one of ordinary skill in the art, it can be undesirable to introduce air into a fluid pathway associated with a patient, such as a central line or catheter. In order to reduce the amount of air introduced into a fluid pathway with a syringe, for example, a medical professional, such as a doctor or nurse, will prime the syringe to remove excess air therefrom. Priming a syringe can be accomplished with three steps. First, the syringe is held with the needle or evacuation channel pointing vertically upward to cause air within the syringe to move toward the needle or evacuation channel. Second, tapping on the side of the syringe helps release air bubbles disposed on the interior surface of the syringe, thereby allowing the air bubbles to move towards the needle or evacuation channel. Finally, compressing the plunger dispenses the air through the needle or evacuation channel prior to injecting the fluid within the syringe into a fluid pathway.

[0104] A similar procedure can be used to prime the cap assemblies of the present invention. Additionally, the cap assemblies of the present invention can also include various features that reduce or eliminate the transfer of air within the fluid bulb into a fluid pathway. While these features will be described with respect to the cap assembly embodiment illus-

trated in FIG. **26**, it will be appreciated that these features can be incorporated into any of the cap assembly embodiments described herein.

[0105] With attention to FIG. **26**, another exemplary embodiment of a cap assembly, generally denoted at **700**, is illustrated. Cap assembly **700** is similar to cap assemblies **400**, **500**, and **600** described herein. In particular, cap assembly **700** includes cap **302** and a fluid bulb **706**. Fluid bulb **706** can be an elastomeric bulb, such as fluid bulb **506**, or a fluid bulb with a "living hinge," such as fluid bulb **606**. Alternatively, fluid bulb **706** can be a fluid reservoir similar to fluid reservoir **406**. Additionally, cap assembly **700** includes a primer bulb **710** to help reduce or eliminate the amount of air transferred from fluid bulb **706** to a fluid pathway. Primer bulb **710** is joined to fluid bulb **706** by a hinge **712**. Hinge **712** can be a "living hinge" adapted to enable primer bulb **710** to be inverted in the direction of arrow **714** in order to evacuate air from within fluid bulb **706** in a manner similar to the compression of a syringe plunger, as described herein. In particular, cap assembly **700** can be held with cap **302** positioned vertically above fluid bulb **706** to cause air within fluid bulb **706** to move toward channel **312**. A medical professional can tap on fluid bulb **706** to cause any air bubbles to be released from the interior surface of fluid bulb **706** and move toward channel **312**. Primer bulb **710** can then be pressed in the direction of arrow **714** toward cap **302**, thereby forcing air within fluid bulb **706** to be evacuated through channel **312**.

[0106] Furthermore, cap assembly **700** includes a secondary post **716** to help reduce or eliminate the amount of air transferred from fluid bulb **706** to a fluid pathway. In the illustrated embodiment, secondary post **716** comprises part of cap **302** and is a shortened mirror image of post **308**. In other words, secondary post **716** is a frustoconical cone shaped post that extends from cap **302** partially into fluid bulb **706**. Channel **312** extends through secondary post **716** so as to create a fluid passageway through cap **302**. Secondary post **716** extends partially into fluid bulb **706** so that when fluid bulb **706** is fully compressed in the direction of arrow **718**, there remains an air entrapment chamber **720** within fluid bulb **706**. As will be appreciated, air bubbles within fluid bulb **706** will be disposed on the interior surface of fluid bulb **706**. As fluid bulb **706** is compressed in the direction of arrow **718**, the air bubbles will be forced along the interior surface of fluid bulb **706** toward secondary post **716**. The air bubbles will accumulate within air entrapment chamber **720**, thereby preventing the air bubbles from being evacuated through channel **312**.

[0107] Similar to fluid bulb **606**, fluid bulb **706** and primer bulb **710** can be formed such that once inverted, primer bulb **710** and fluid bulb **706** remain inverted and do not right themselves. Maintaining primer bulb **710** and fluid bulb **706** in the inverted position prevents a vacuum from forming within fluid bulb **706**, in turn preventing fluid from undesirably refluxing into fluid bulb **706**. These features of primer bulb **710** and fluid bulb **706** can be realized by selecting the appropriate dimensions for primer bulb **710** and fluid bulb **706**, as well as the material used to manufacture primer bulb **710** and fluid bulb **706**. Primer bulb **710** and fluid bulb **706** can be formed of a polymer material, such as polyethylene or polypropylene, to provide the functional characteristics described above.

[0108] FIGS. **27** and **28** illustrate yet another exemplary embodiment of a cap assembly, generally denoted at **800**, according to the present invention. Cap assembly **800** includes cap **302**, barrel **802**, and plunger **810**. Barrel **802** can be joined to cap **302** in any suitable manner, including with the use of an adhesive, such as glue, a mechanical fastener, or a friction fitting. Cap **302** and barrel **802** can be formed as an integral piece. It will be appreciated that barrel **802** can be permanently joined to cap **302**, or barrel **802** can be removably joined to cap **302**. Plunger **810** is movably coupled to barrel **802**. In particular, a first end of plunger **810** is inserted within barrel **802**, and creates a seal between the plunger **810** and the interior surface of barrel **802**.

[0109] In the illustrated embodiment, barrel **802** includes a fluid chamber **820** that is filled with an antiseptic agent or medicine **822**. Fluid chamber **820** is defined by the internal surface of barrel **802**, cap **302**, and the first end of plunger **810**. Plunger **810** can be depressed to force fluid **822** through channel **312** and into a fluid pathway. Continued movement of plunger **810** in the direction of cap **302** decreases the internal volume of fluid chamber **820**, thereby forcing fluid **822** through channel **312** and into a fluid pathway.

[0110] Cap assembly **800** can be equipped with gauges, guides, or other indicator means to assist a medical profession in determining the amount of fluid **822** that has been forced out of cap assembly **800** and into a fluid pathway. For instance, if fluid **822** is a medicine that is administered to a patient incrementally, cap assembly **800** can be equipped with a gauge, guide, or other indicator means that indicates to a medical professional how much of fluid **822** has been administered. For example, barrel **802** can include labels or other markings that correspond to the position of plunger **810** relative to barrel **802** and the internal volume of fluid chamber **820**. Thus, as a medical professional depresses plunger **810**, the leading edge of plunger **810** will be positioned adjacent one of the labels or other markings on barrel **802**, thereby indicating the amount of fluid **822** that has been administered and/or the amount of fluid **822** remaining within fluid chamber **820**. Likewise, fluid chamber **820** can be equipped with audible and/or tactile indicator means that indicate to a medical professional the amount plunger **910** has been depressed, which corresponds to the amount of fluid **822** that has been administered. Thus, cap assembly **800** can be adapted to provide incremental dosages to a patient. Furthermore, cap assembly **800** includes a locking mechanism to prevent reflux of fluid into fluid chamber **820**. The locking mechanism of cap assembly **800** includes a locking ridge **804** and at least one latch **812**. In the illustrated embodiment, latches **812** are formed as part of plunger **810**, and locking ridge extends around the end of barrel **802**. In use, plunger **810** is depressed to dispense fluid **822** from fluid chamber **820**. When plunger **810** is fully depressed, latches **812** engage locking ridge **804** to prevent plunger **810** from being withdrawn from barrel **802**. Because the first end of plunger **810** sealingly engages the interior surface of barrel **802**, withdrawing plunger **810** from within barrel **802** could create a vacuum at within barrel **802**, thereby drawing fluid from a fluid pathway into barrel **802**. To reduce or eliminate such reflux, latches **812** engage locking ridge **804** to prevent the withdrawal of plunger **810** from barrel **802**. Additionally, or alternatively, a valve **338** can be disposed within channel **312** to prevent undesirable reflux of fluid into fluid chamber **820**. In particular, the valve can be a one-way valve, a duckbill valve, a back check valve, a pressure activated valve, or the like. While the illustrated embodiment of cap assembly **800** includes a valve **338** disposed within channel **312**, it will be appreciated, however, that in some embodiments, a valve or seal is not disposed

within channel **312**. Similar to cap assembly **700**, cap assembly **800** can also include a secondary post **816** to help reduce or eliminate the amount of air transferred from fluid chamber **820** to a fluid pathway. In the illustrated embodiment, secondary post **816** comprises part of cap **302** and is a shortened mirror image of post **308**. In other words, secondary post **816** is a frustoconical cone shaped post that extends from cap **302** partially into fluid chamber **820**. Channel **312** extends through secondary post **816** so as to create a fluid passageway through cap **302**. Secondary post **816** extends partially into fluid chamber **820** so that when plunger **810** is fully depressed there remains an air entrapment chamber **818** within fluid chamber **820**. As will be appreciated, air bubbles within fluid chamber **820** will be disposed on the interior surface of fluid chamber **820**. As plunger **810** is depressed, the air bubbles will be forced along the interior surface of fluid chamber **820** toward secondary post **816**. The air bubbles will accumulate within air entrapment chamber **818**, thereby preventing the air bubbles from being dispensed through channel **312**.

[0111] FIG. **29** illustrates a cap assembly **900**, similar to cap assembly **800**. In particular, cap assembly **900** includes cap **302**, barrel **902**, and plunger **910**. Barrel **902** is joined to cap **302** in any suitable manner, including with the use of an adhesive, such as glue, a mechanical fastener, or a friction fitting. Alternatively, cap **302** and barrel **902** can be formed as an integral piece. Plunger **910** is movably coupled to barrel **902**. In particular, a first end of plunger **910** is inserted within barrel **902**, and creates a seal between the plunger **910** and the interior surface of barrel **902**. Further, plunger **910** includes threads **922** disposed on an exterior surface thereof and barrel **902** includes threads **924** disposed on an interior surface thereof. Thread **922** and **924** are adapted to engage one another such that rotation of plunger **910** relative to barrel **902** causes plunger **910** to be drawn into barrel **902**. The end of plunger **910** also includes ridges **926** to facilitate gripping and rotation of plunger **910**.

[0112] In the illustrated embodiment, barrel **902** includes a fluid chamber **920** that is filled with an antiseptic agent or medicine **22**. Fluid chamber **920** is defined by the internal surface of barrel **902**, cap **302**, and the first end of plunger **910**. Plunger **910** can be rotated relative to barrel **902** to force fluid **922** through channel **312** and into a fluid pathway. Continued rotation of plunger **910** decreases the internal volume of fluid chamber **920**, thereby forcing fluid **922** through channel **312** and into a fluid pathway.

[0113] Furthermore, cap assembly **900** includes a locking mechanism to prevent reflux of fluid into fluid chamber **920**. The locking mechanism of cap assembly **900** includes a locking ridge **904** and at least one latch **912**. In the illustrated embodiment, latches **912** are formed as part of plunger **910**, and locking ridge extends around the end of barrel **902**. In use, plunger **910** is rotated relative to barrel **902** to dispense fluid **922** from fluid chamber **920**. When plunger **910** is fully rotated, latches **912** engage locking ridge **904** to prevent plunger **910** from being withdrawn from barrel **902**. Because the first end of plunger **910** sealingly engages the interior surface of barrel **902**, withdrawing plunger **910** from within barrel **902** could create a vacuum within barrel **902**, thereby drawing fluid from a fluid pathway into barrel **902**. To reduce or eliminate such reflux, latches **912** engage locking ridge **904** to prevent the withdrawal of plunger **910** from barrel **902**. Additionally, or alternatively, a valve **338** can be disposed within channel **312** to prevent undesirable reflux of fluid into fluid chamber **920**. In particular, the valve can be a one-way valve, a duckbill valve, a back check valve, a pressure activated valve, or the like. While the illustrated embodiment of cap assembly **900** includes a valve **338** disposed within channel **312**, it will be appreciated, however, that in some embodiments, a valve or seal is not disposed within channel **312**.

[0114] The caps described herein can be formed of, or coated with various colored materials or coatings. In one exemplary embodiment, the caps comprise a single color. Alternatively, each cap can be a separate color. Coloring the caps can provide various advantages, such as ready identification of the type of cap, ready matching of a particularly colored cap with a particular type of medical connector, and the like.

[0115] The inventions disclosed herein may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced within their scope.

What is claimed is:

1. A cap assembly for use in protecting a separated medical connector, comprising:

a cap having an exterior surface, an interior surface, and a post extending from the interior surface, the exterior surface having an opening therein for access to the interior surface, the interior surface having a threaded portion, and the post having a channel extending therethrough, wherein the cap is adapted to be selectively and sealingly secured to a separated medical connector to protect internal surfaces of the medical connector from contamination; and

a fluid reservoir coupled to the cap, the fluid reservoir being adapted to communicate fluid through the channel of the cap to the separated medical connector.

2. A cap assembly according to claim **1**, further comprising a valve disposed within the channel, the valve being adapted to selectively enable fluid to flow from the fluid reservoir to the separated medical connector while preventing fluid from flowing from the separated medical connector to the fluid reservoir.

3. A cap assembly according to claim **1**, wherein the fluid reservoir comprises an elastomeric fluid bulb adapted to deliver fluid from the fluid reservoir to the separated medical connector only when the cap is securely coupled to the separated medical connector.

4. A cap assembly according to claim **1**, wherein the fluid reservoir comprises a fluid bulb having a fixed wall, a collapsible wall, and a hinge joining the fixed wall and the collapsible wall.

5. A cap assembly according to claim **4**, wherein the collapsible wall is adapted to be to inverted within the fixed wall to deliver fluid from the fluid reservoir to the separated medical connector.

6. A cap assembly according to claim **5**, wherein the fluid reservoir further comprises a primer bulb adapted to be compressed to remove air from within the fluid reservoir prior to the cap assembly being coupled to the separated medical connector.

7. A cap assembly according to claim **1**, wherein the cap assembly further comprises a secondary post extending partially into the fluid reservoir, the secondary post and an inter-

nal surface of the fluid reservoir cooperating to trap air within the fluid reservoir and substantially prevent air from being introduced into a fluid pathway associated with the separated medical connector.

8. A nestable pair of caps for use in protecting separated medical connectors, comprising:

a male cap having an internal surface, an external surface, an interface, and a connecting geometry whereby the male cap may be selectively and sealingly coupled to a female cap or a separated female medical connector, the male cap further comprising a scrubbing chamber having a removable liner positioned within an end of the male cap, a pad disposed within the liner, and a cover that sealingly encloses the interior the liner; and

the female cap comprising an internal surface, an external surface, an interface, and a connecting geometry whereby the female cap may be selectively and sealingly coupled to the male cap or a separated male medical connector, the female cap also comprising a post extending from the internal surface thereof to be sealingly engaged with an internal surface of a separated male medical connector to substantially reduce fluid leakage from the connection between the female cap and the male medical connector, the post having a channel extending therethrough, the female cap further comprising a fluid reservoir adapted to communicate fluid through the channel to a separated medical connector; and

wherein the interfaces of the male cap and the female cap provide a seal when adjoined together or adjoined individually to separated medical connectors to aseptically partition the internal and external surfaces to insure perpetuated sterility of the internal surfaces.

9. A cap assembly according to claim **8**, wherein the fluid reservoir comprises a barrel and a plunger, the plunger having a first end sealingly disposed within the barrel, the barrel, the plunger, and the cap defining a fluid chamber, wherein the first end of the plunger is adapted to be moved into the barrel to force fluid out the fluid chamber, through the channel, and into the separated medical connector coupled to the cap assembly.

10. A cap assembly according to claim **9**, wherein the plunger and the barrel are threadably engaged such that rotation of the plunger relative to the barrel decreases the volume of the fluid chamber and forces fluid out of the fluid chamber through the channel.

11. A cap assembly according to claim **8**, wherein the fluid reservoir further comprises indicator means for identifying the amount of fluid within the fluid reservoir.

12. A cap assembly according to claim **8**, wherein the cover of the scrubbing chamber is adapted for selective removal to expose the pad, wherein the pad is adapted to clean or disinfect at least one of the separated medical connectors.

13. A cap assembly according to claim **12**, wherein the liner and pad are selectively removable from the male cap

14. A nestable pair of caps for use in providing a protective union about a separated medical connector, the nestable pair comprising:

a male cap having an internal surface and an external surface, the male cap comprising:

means for selectively and sealingly securing the male cap to a female cap or a separated female medical connector; and

means for cleaning or disinfecting a separated medical connector; and

a female cap having an internal surface and an external surface, the female cap comprising:

means for selectively and sealingly securing the female cap to a male cap or a separated male medical connector; and

means for communicating fluid to a fluid pathway associated with the separated male medical connector; and

means for antiseptically partitioning the internal and external surfaces to insure perpetuated sterility of the internal surfaces.

14. A nestable pair of caps according to claim **14**, wherein the means for selectively and sealingly securing the male cap to the female cap or the separated female medical connector comprises an elongated portion adapted to be at least partially inserted within the female cap or the separated female medical connector, wherein the elongated portion comprises a medially disposed hole adapted to receive therein a luer portion of the female cap or the separated female medical connector.

15. A nestable pair of caps according to claim **14**, wherein the means for selectively and sealingly securing the male cap to the female cap or the separated female medical connector comprises a threaded portion adapted to engage a threaded interior portion of the female cap or the separated female medical connector.

16. A nestable pair of caps according to claim **14**, wherein the means for cleaning or disinfecting a separated medical connector comprises a scrubbing chamber having a cavity within the male cap, a liner positioned within the cavity, a pad disposed within the liner, and a cover removably extending across the opening of the liner.

17. A nestable pair of caps according to claim **14**, wherein the means for selectively and sealingly securing the female cap to the male cap or the separated male medical connector comprises a post extending from the internal surface of the female cap, wherein the post is adapted to sealingly engage the internal surface of the male cap or an internal surface of the separated male medical connector to substantially reduce fluid leakage from the connection between the female cap and the male cap or the male medical connector.

18. A nestable pair of caps according to claim **14**, wherein the means for selectively and sealingly securing the female cap to the male cap or the separated male medical connector comprises a threaded portion adapted to engage a threaded exterior portion of the male cap or the separated male medical connector.

19. A nestable pair of caps according to claim **14**, wherein the means for communicating fluid to a fluid pathway associated with the separated male medical connector comprises a fluid reservoir coupled to the female cap, the fluid reservoir being adapted to communicate fluid through the female cap to the separated medical connector.

20. A nestable pair of caps according to claim **19**, wherein the fluid reservoir comprises:

an elastomeric fluid bulb;

a fluid bulb having a fixed wall, a collapsible wall, and a hinges joining the fixed wall and the collapsible wall; or

a barrel and a plunger movably disposed within the barrel.

21. A nestable pair of caps according to claim **14**, wherein the means for antiseptically partitioning the internal and external surfaces comprises a seal disposed about interfacing surfaces of the male and female caps.

22. A nestable pair of caps according to claim **21**, wherein the seal comprises an O-ring, a comolded or overmolded surface, a sealing tape, or a combination thereof.

23. A cap assembly for use in protecting separated medical connectors, comprising:

a fluid delivery device having a fluid coupling interface adapted to be coupled to a separated medical connector to deliver a fluid to a fluid pathway associated with the separated medical connector; and

a nestable pair of caps comprising:

a female cap having an exterior surface and an interior surface, the exterior surface having an opening therein for access to the interior surface, the interior surface having a threaded portion, wherein the female cap is adapted to selectively and sealing couple to a separated medical connector to protect the medical connector from contamination, the female cap further comprising a secondary cap portion coupled thereto, wherein the secondary cap portion is adapted to selectively and sealingly couple to the fluid delivery device to protect the fluid coupling interface from contamination prior to use of the fluid delivery device; and

a male cap having an exterior surface and a frustoconical portion extending from the exterior surface, an outer surface of the frustoconical portion having a threaded portion adapted to engage the threaded interior portion of the female cap to enable the male cap to be selectively secured to and at least partially nested within the female cap, wherein the male cap is also adapted to selectively and sealing couple to a separated medical connector to protect the medical connector from contamination.

24. A cap assembly according to claim **23**, wherein the secondary cap is selectively removable from the female cap.

25. A cap assembly according to claim **23**, further comprising a seal between the female cap and the male cap.

26. A cap assembly according to claim **23**, wherein the seal provides a visual indication of whether the seal has been broken.

* * * * *

United States Patent [19]

Sutherland et al.

[11] **Patent Number: 5,059,172**

[45] **Date of Patent: Oct. 22, 1991**

[54] **SYRINGE WITH TWO PART MASTITIS CANNULA CAP**

[75] Inventors: **Stephen F. Sutherland**, Fort Dodge, Iowa; **Jerome Silverstein**, North Franklin, Conn.

[73] Assignee: **American Home Products**, New York, N.Y.

[21] Appl. No.: **338,893**

[22] Filed: **Apr. 14, 1989**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 212,026, Jun. 23, 1988, Pat. No. 4,850,970, which is a continuation of Ser. No. 30,322, Mar. 26, 1987, abandoned.

[51] **Int. Cl.**[5] **A61M 1/06**

[52] **U.S. Cl.** **604/73**; 604/117; 604/192; 604/278

[58] **Field of Search** 604/54, 73, 117, 192, 604/263, 278, 198

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Primary Examiner—John D. Yasko
Assistant Examiner—Adam J. Cermak
Attorney, Agent, or Firm—Darby & Darby

[57] **ABSTRACT**

A two part mastitis cannula cap includes an outer cap and an inner cap. The inner cap is not as long as the cannula so that a free end of the cannula protrudes beyond an end face of the inner cap. This cannula protrusion is covered by the outer cap which is securable about the free end of the inner cap. Controlled depth partial insertion of the cannula into the teat canal of a dairy cow can be accomplished by removal of only the outer cap. Alternatively, full depth cannula insertion is accomplishable upon removal of the two parts of the cap. In one embodiment, a snap-off outer cap is used. In a second embodiment, a twist-off or breakaway outer cap is utilized.

13 Claims, 2 Drawing Sheets

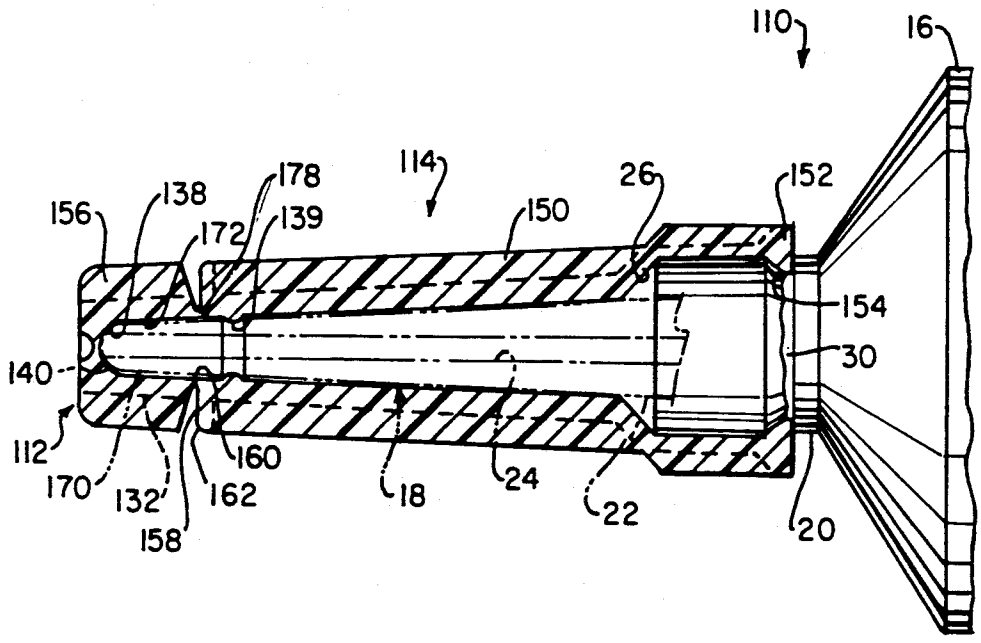


FIG 1

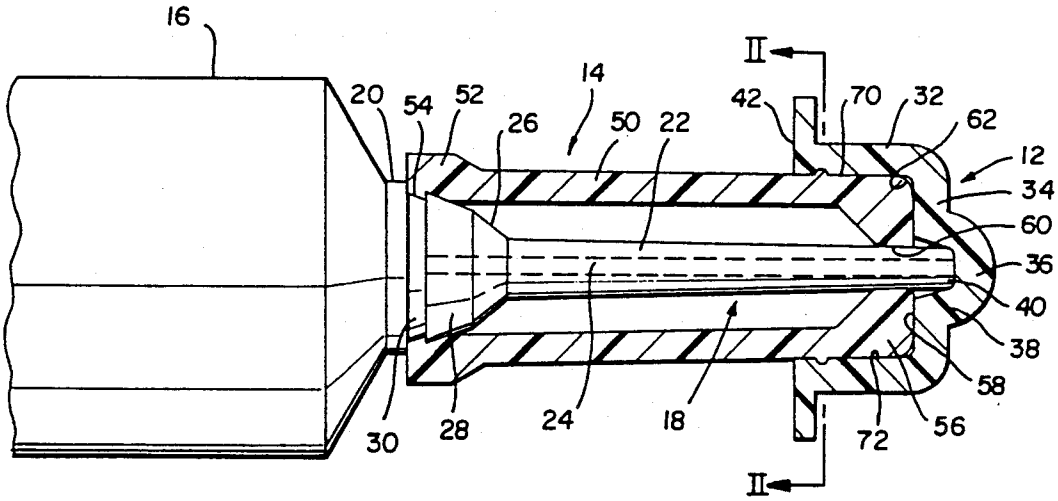
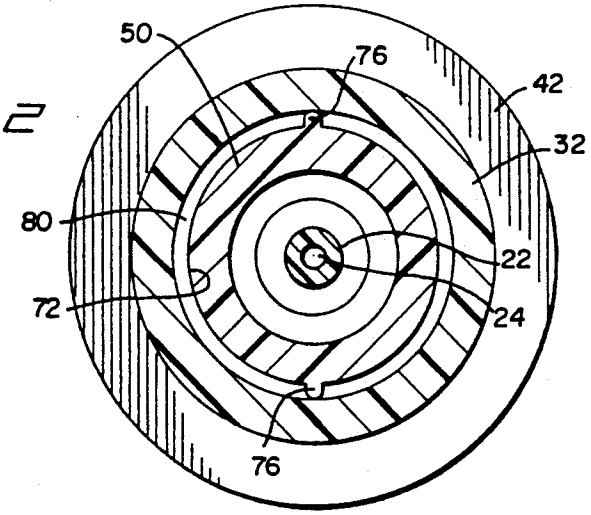


FIG 2



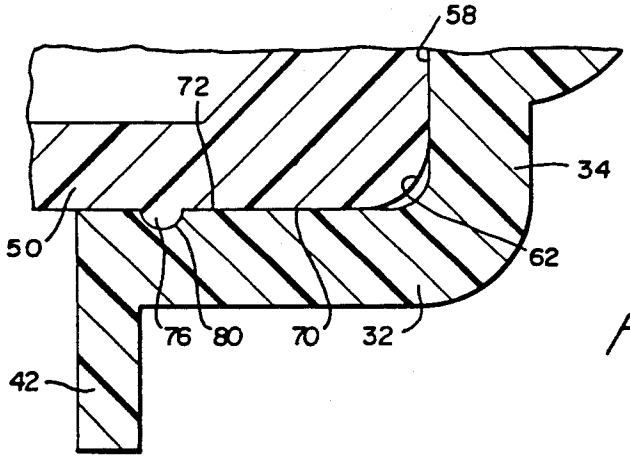
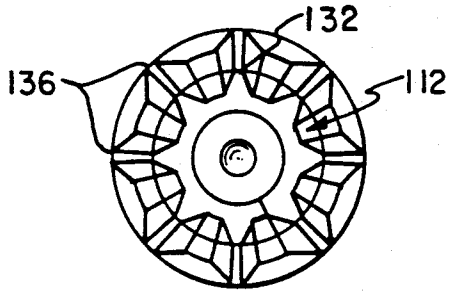


FIG 3

FIG. 4a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136
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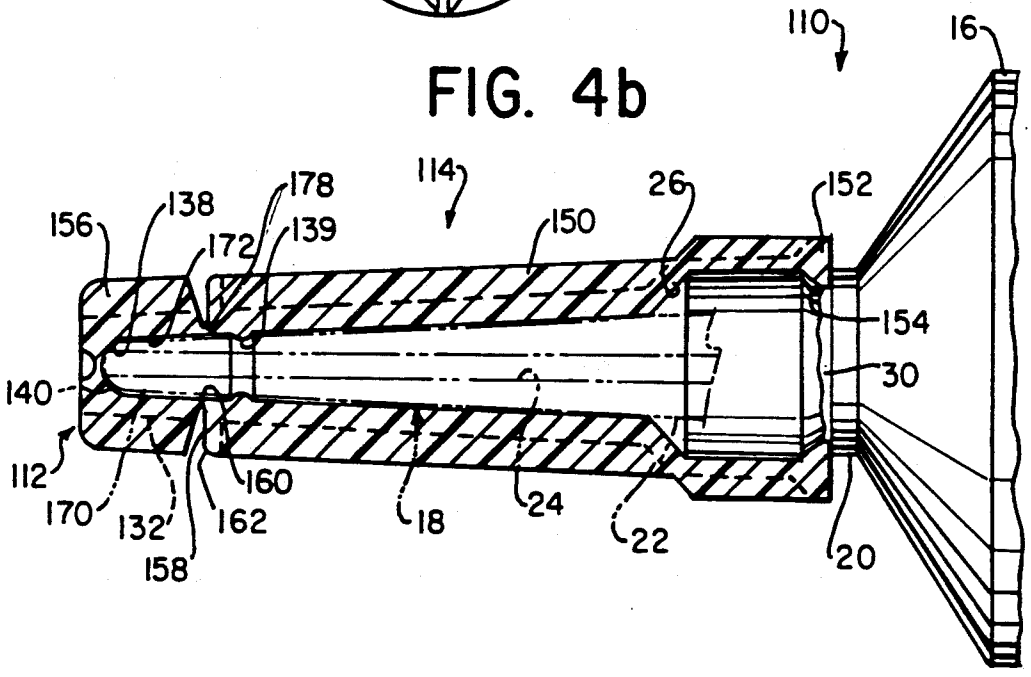
FIG. 4b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SYRINGE WITH TWO PART MASTITIS CANNULA CAP

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. application Ser. No. 212,026 filed June 23, 1988, now U.S. Pat. No. 4,850,970 which, in turn, is a continuation of U.S. application Ser. No. 030,322, filed Mar. 26, 1987, now abandoned.

FIELD OF THE INVENTION

The present invention is directed generally to a two part cap for a cannula. More particularly, the present invention is directed to a two part cap for the cannula of a mastitis infusion syringe. Most specifically, the present invention is directed to a two part, separable, mastitis infusion cannula cap which is usable to limit the cannula's insertion depth into the teat canal of a dairy cow. The two part mastitis cannula cap includes an outer or overcap which is positioned at a free or distal end of an elongated inner cap. The outer cap is dimensioned to expose only a portion of the mastitis syringe cannula when this outer cap is removed from the inner cap. This insures that the cannula's insertion depth can be effectively limited to less than the length of the teat canal when only the outer cap is removed. Bacteria thus cannot be carried into the teat cistern and no damage occurs to the teat canal by the mastitis treatment cannula equipped with the two part cap when only the outer cap is removed.

DESCRIPTION OF THE PRIOR ART

Bovine mastitis is a serious problem which afflicts large numbers of dairy cows. This mastitis, or inflammation of the cow's mammary gland, strikes substantial percentages of cows in dairy herds and has a detrimental effect on milk production and herd profitability. The generally followed method of treatment for bovine mastitis has been the administration of various antibiotic preparations into the cow's udder through the teat canal. A mastitis infusion syringe, which carries the antibiotic preparation, typically is equipped with an insertion cannula having a length of 20 to 30 mm. This cannula and syringe assembly is provided from the antibiotic supplier as a molded plastic, disposable unit which is prefilled with the treatment antibiotic. A single piece plastic cover, which typically snap fits onto the hub of the syringe at the base of the cannula, is used to cover the cannula prior to use. At the time of treatment, the protective cap is removed from the mastitis treatment syringe cannula and the cannula end is inserted into the cow's teat end, passed through the teat canal, and positioned within the teat cistern. Once the cannula has been so positioned, the syringe is utilized to deposit the treatment antibiotic directly into the cow's teat cistern.

Recent studies have suggested that the previously practiced full cannula insertion technique may actually reduce rather than enhance the effectiveness of the treatment. This research has indicated that in some instances bacteria infecting the keratin lining of the teat canal are carried into the teat cistern by the mastitis cannula during full cannula insertion. Once these bacteria enter the teat cistern, they may produce mastitis. The cow's teat canal is approximately 5 to 10 mm in length and has a very narrow lumen (0.4–1.63 mm). This narrow canal helps to prevent bacteria from entering the cow's udder. Some bacteria may survive in the keratin lining and secretions in the distal teat canal but are prevented by the healthy teat canal from traveling the full length of the canal. These bacteria may be aided in their travel up the teat canal by the cannula as it passes through the canal during full cannula insertion. It has also been found that the teat canal or duct keratin layer, which helps control bacterial penetration into the udder, may be damaged by full cannula insertion. This full length cannula insertion may also cause the full length of the teat canal lumen to become dilated thus allowing increased bacterial travel and penetration into the teat cistern and mammary gland. Bacteria which might otherwise exist for months in the distal teat canal keratin without causing mastitis might enter the teat cistern area during full cannula insertion, serving as a source of a mastitis infection.

As a result of these above-discussed studies, there is now being utilized a partial insertion technique wherein the mastitis cannula is inserted into the teat end and up the teat canal only to a depth of generally about 3 to 4 mm. This technique appears to be beneficial in the treatment of mastitis but has made treatment procedures more difficult and time consuming for the dairyman. It is necessary that the cannula insertion depth be limited to generally about 3 to 4 mm to avoid the teat canal keratin damage, to avoid dilating the entire teat canal, and, to prevent the transport of bacteria from the distal teat canal into the teat cistern—all factors which may frequently be related to the full insertion of syringe cannulas and may be prevented by limiting cannula insertion depth to approximately 3 to 4 mm.

There presently exist no commercially available, readily usable yet disposable mastitis infusion syringe assembly which allows the user to quickly and easily control the depth of cannula insertion, thus rendering this partial insertion treatment effective. Individual measurements of each insertion depth are time consuming and are apt to be inaccurate. Mere guessing is even less accurate and may make the treatment of little value. It will thus be seen that a need exists for a mastitis treatment cannula assembly which will accurately, positively, and reproducibly limit the depth of cannula insertion while not increasing treatment time, cost or the risk of contamination. Additionally, there exists a need for a cannula assembly that provides the option of full insertion for those cows in which the 3 to 4 mm depth is impractical. The two part mastitis cannula cap assembly of the present invention provides a very satisfactory solution to these problems.

SUMMARY OF THE INVENTION

It is a primary object of the present invention to provide a cannula cap for use with a mastitis (intramammary) infusion syringe.

A principal object of the present invention is to provide a mastitis (intrammary) cannula cap having the capability of limiting the insertion depth of the syringe cannula into the cows'teat canal.

A further object of the present invention is to provide a mastitis cannula cap that is comprised of two separable parts.

Still another object of the present invention is to provide a removable outer cap that, when detached, will expose a limited portion of the mastitis syringe cannula and provide contact surfaces that will not damage the teat.

Yet another object of the present invention is to provide a two part mastitis cannula cap in which the proximal part of the cap (the inner cap) permits only a portion of the cannula to enter the cow's teat canal.

Still a further object of the present invention is to provide a two part mastitis cannula cap which will allow a herdsman the option of partial insertion of the teat canal, when only the outer cap is removed, or, full cannula insertion when both the inner cap and the outer cap are removed.

Even yet a further object of the present invention is to provide a two part mastitis cannula cap in which the outer cap or the entire two part cap may be readily detached from the mastitis syringe with the aid of only the operator's fingers.

Still yet an additional object of the present invention is to provide a two part mastitis cannula cap which does not leak, prevents contamination of the cannula during storage and will not damage the surface of the mastitis syringe cannula.

A still further object of the present invention is the provision of a two part mastitis cannula cap in a unibody construction prior to use so that no leakage or contamination of the contents of the syringe can occur during storage.

Another object of the present invention is the provision of a breakaway seal between inner and outer cap portions of the cannula cap.

A still further object of the invention is the provision of an internal seal to prevent leakage and contamination of syringe contents.

As will be discussed in greater detail in the description of the preferred embodiments, which is set forth subsequently, the two part mastitis cannula cap assembly in accordance with the present invention includes an inner cap which snaps onto the base of the cannula at the first end, and which has a relatively wide outer or distal end to prevent accidental insertion into a teat orifice and an outer cap which is removably attached or carried on the distal end of the inner cap. The outer cap covers generally about the outer 3 to 4 mm of the mastitis syringe cannula which extends through an aperture at the distal end of the inner cap and, when removed, allows only partial depth insertion of the cannula into the teat canal. This depth of insertion is limited by the relatively large diameter of the distal end of the inner sleeve which also stabilizes the cannula against the teat end and helps to prevent leakage during infusion of the treatment materials during utilization of the partial insertion technique.

One embodiment of this invention includes an outer circumferential rim or flange which is formed as a part of the outer cap and which facilitates easy removal of this first cap.

In another embodiment of the two part cap invention, a twist-off or pull-off outer cap is secured to the inner cap. The outer cap can also be broken off by applying a lateral force, or can be ripped or torn off by, e.g. using the teeth. Raised ridges on the outside surface of the entire cannula cap serve to facilitate the grasping and removal of the outer cap by a herdsman, veterinarian or user. As with the embodiment described above, when the outer cap is removed, approximately 3 to 4 mm of the mastitis syringe cannula is exposed and infusion into the teat canal is limited by the relatively wide diameter of the inner cap.

It is to be understood that the forms of the present invention herein shown and described are to be taken as preferred embodiments. Various changes may be made in size, shape and arrangement of the parts without departing from the scope of the subjoined claims. For example, the method of separation of the cap segments may be made by means other than those illustrated in the drawings. However, these are within the scope of the purpose of the invention, i.e. limiting the depth of penetration into the teat canal.

By use of this invention, the herdsman or the like who is responsible for the treatment of the cattle can readily remove the outer cap, expose only approximately 3 to 4 mm of cannula required for partial insertion, and effect infusion of the treatment material in an efficient, safe, and predictable manner.

In operation, the herdsman or user removes the outer cap using his thumb and forefinger to grasp the relatively wide outer rim or, in another embodiment, the ribbed projections of the outer cap. The cap is taken off by pull, pull combined with rotation or by bending to break off the cap. This exposes approximately 3 to 4 mm of the syringe cannula which is then inserted into the cow's relatively longer (5 to 10 mm) teat canal and the contents of the syringe infused into the cow udder. The depth of insertion into the teat canal is limited to a portion of the cow's teat canal by the relatively wide inner cap; thereby allowing the antibiotic to be infused into the udder without damaging the keratin lining of the teat canal, without dilating the entire length of the teat canal, without transporting bacteria into the teat cistern, and allowing antibiotic to be placed in contact with bacteria within the teat canal. Since the depth of the insertion is controlled by the abutment of the wide diameter of the distal end of the inner cap, there is no chance for insertion beyond the approximately 3 to 4 mm teat canal insertion depth. Thus partial, therapeutic insertion into the teat canal is consistently and readily achieved with this device.

When the outer cap is in place, for example, during storage at the dairy farm, a protective seal is created over the cannula, preventing contamination from the environment while also preventing leakage of the contents of the syringe.

Should a full insertion procedure be desired, the complete cap assembly can be removed from the cannula by separation of the first or proximal end of the inner cap from the base of the cannula generally as has been accomplished in the past. Once the inner cap and outer cap has been removed to expose the full length of the cannula, full insertion can be done in the conventional manner. Thus the two part mastitis cannula cap in accordance with the present invention provides the user with a choice. He can remove only the outer cap and utilize the cannula in a partial insertion treatment procedure, or he can remove both the inner cap and outer cap to expose the full length of the mastitis control cannula for a full insertion procedure.

The two part cap may be sized so as to be usable with existing mastitis treatment cannula and syringe assemblies, is not expensive to manufacture and is thus disposable, and provides treatment flexibility not previously available. The two part mastitis cannula cap of the present invention is a significant advance in the art and is an effective tool in the control of bovine mastitis.

BRIEF DESCRIPTION OF THE DRAWINGS

While the novel features of the two part mastitis cannula cap in accordance with the present invention are set forth with particularity in the appended claims,

a full and complete understanding of the invention may be had by referring to the detailed description of preferred embodiments as is set forth hereinafter and as illustrated in the accompanying drawings in which:

FIG. 1 is a side elevation view, partly in section, of a mastitis treatment syringe and cannula utilizing the two part cap of the present invention;

FIG. 2 is a cross sectional view of the cannula and cap assembly taken along line II—II of FIG. 1; and

FIG. 3 is an enlarged cross sectional side view of a portion of the outer and inner caps of the present invention.

FIG. 4*a* is a cross sectional view and FIG. 4*b* a side elevation view, partly in section, of a mastitis treatment syringe and cannula illustrating a second more preferred embodiment (twist-off version) of the two part cap of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning initially to FIG. 1, a first embodiment of a two part mastitis cannula cap **10**, in accordance with the present invention is presented. Two part cap assembly **10** includes an outer or overcap **12** and an inner cap **14**. This two part mastitis cannula cap is shown in FIG. 1 in conjunction with a typical mastitis infusion syringe **16** that conventionally is a 5 ml or 10 ml disposable plastic syringe which is intended for a one time usage. A proximal or first end of an insertion cannula **18** is integrally molded with a reduced diameter end **20** of syringe **16**. Insertion cannula **18** typically is 20 to 25 mm in length and has a generally cylindrical hollow body **22** with a through bore **24**. A generally conical shaped hub **26** is formed at first or distal end **28** of cannula **18** and this hub **26** is fused to the reduced diameter end **20** of syringe **16**. An annular groove **30** is formed in the end **20** of syringe **16** adjacent cannula hub **26**. This syringe **16** and cannula **18** assembly is a typical configuration in which a bovine mastitis treatment material is supplied. While the two piece mastitis cannula cap in accordance with the present invention will be discussed for use with this syringe and cannula assembly, it will be understood that the size of the syringe, the overall length of the cannula and other similar structural characteristics of this syringe and cannula assembly, which form no part of the subject invention, could be changed or modified.

Two part mastitis cannula cap **10** includes, as was indicated above, an outer cap **12** and an inner cap **14**. As may be seen in FIG. **1**, outer cap or overcap **12** is somewhat capshaped and has a generally cylindrical sidewall **32**. A somewhat planar end wall **34** of outer cap **12** is joined to a first end of cylindrical sidewall **32** and has a central projection **36** which forms an interior concavity **38** that receives a free end or distal tip **40** of the insertion cannula **18**. Concavity **38** has a depth of generally about 3 mm, depending on the length of free end **40** of cannula **22** which extends beyond inner cap **14**, in a manner to be discussed shortly. Concavity **38** and cannula tip **40** are cooperatively sized to form a snug, leak resistant interfit. An enlarged annular outer flange **42** is joined to outer cap **12** at the second end of sidewall **32** opposite planar endwall **34**. This outer flange **42** should be sufficiently large to facilitate grasping of outer cap **12** when this outer **12** is to be removed from inner cap **14**. In this embodiment, this annular outer flange **42** may have a diameter of generally about 10 to 20 mm.

Inner cap **14**, as may be seen most clearly in FIG. **1**, is generally in the shape of an elongated cylindrical sleeve having a tubular sidewall **50**. A snap end **52** of inner cap **14** has a radially inwardly extending lip **54** that is receivable in annular groove **30** formed at the junction of syringe end **20** and hub **26** of cannula **18**. Detachment of the snap end **52** of inner cap **18** from syringe **16** is achieved by bending inner cap **14** to unseat lip **54** from groove **30**.

Inner cap **14** terminates at its distal end **56** in an outer end face **58** that has a central aperture **60** through which the free end **40** of insertion cannula **18** passes. The outer end face **58** of inner cap **14** has a relatively wide diameter, generally in the range of about 3 to 12 mm, preferably about 5 to 7 mm and is smooth and somewhat rounded at its peripheral edges **62**.

Outer cap **12** overlies the distal end **56** of inner cap **14**, as may be seen in FIGS. **1** and **3**. An inner surface **70** of outer cap sidewall **32** slidingly cooperates with an outer surface **72** of tubular sidewall **50** of inner cap **14** to effect retention of outer cap **12** on the distal end **56** of inner cap **14**. Securement of inner cap **14** to outer cap **12** is enhanced by the cooperation of a pair of opposed protrusions **76**, formed on the outer surface **72** of tubular inner cap sidewall **50**, with a circumferential recess **80** cooperatively located in the inner surface **70** of outer cap sidewall **32**. Alternatively, the number of protrusions **76** could be increased or a continuous rim (not shown) could be substituted. These protrusions **76**, or rim, and circumferential recess **80** are sized so that a pulling or pushing force exerted on outer cap annular flange **42** will effect separation of outer cap **12** from inner cap **14** and not separation of inner cap **14** from syringe end **20**. Separation of inner cap **14** from syringe end **20** is more easily accomplished by grasping the tubular sidewall **50** of inner cap **14** and by utilizing a bending force to unseat lip **54** from groove **30**. Thus the two separating forces are of differing types so that separation will occur at the desired point.

Another more preferred embodiment of the two part mastitis cannula cap **110** is illustrated in FIGS. **4***a* and **4***b* where the two part cap is designated and includes, an outer cap **112** and an inner cap **114**. In these figures, elements identical with those in FIGS. **1–3** have the same identifying numbers. As may be seen in FIG. **4***b*, outer cap **112** has a cylindrically shaped sidewall **132** with ridge-like projections **136** that may be visualized on the FIG. **4***a* cross sectional view. Ridge-like projections **136** facilitate grasping of the outer cap. Outer cap **112** is physically joined to inner cap **114** by a thin breakaway seal **178** that completely surrounds but does not contact the distal teat cannula **18**. Approximately 1 mm proximal to the breakaway seal **178** there exists a radial seal **139** that projects from tubular sidewall **150** of the inner sleeve **114**. This radial seal **139** is snugly in contact with and somewhat compresses the insertion cannula **18**, thereby preventing the contents of syringe from leaking out from the cap. Concavity **138** receives the free end or distal tip **140** of insertion cannula **18**. Concavity **138** has a depth of generally about 3 to 4 mm, depending on the length of the free end **140** of cannula **22** which extends beyond inner cap **114** in a manner to be discussed shortly.

Inner cap **114**, as may be seen most clearly in FIG. **4***b*, is generally in the shape of an elongated cylindrical sleeve having a tubular sidewall **150**. The outside of sidewall **150** is embossed with 1/16 inch raised ridges **136** (in a manner similar to the outer cap) which serve to facilitate grasping of the inner cap **114**. A snap end **152** of inner cap **114** has a radially inwardly extending lip

154 that is receivable in annular groove 30 formed at the junction of syringe end 20 and hub 26 of cannula 18. Detachment of the snap end is performed in the same manner as in the first embodiment.

Also as in the first embodiment, inner cap 114 terminates at its distal end in an outer end face 158 that has a central aperture 160 through which the free end 140 of insertion cannula 18 passes. The outer end face 158 of inner cap 114 is planar or slightly convex or bevelled and has a relatively wide diameter, generally in the range of about 3 to 12 mm, preferably about 5 to 7 mm and is smooth and somewhat rounded at its peripheral edges 162.

In FIG. 4*b*, the inner sidewall 170 of the outer cap 112 slidingly cooperates with the outer surface of the distal cannula 172. The inner wall 170 of the outer cap 112 forms the breakaway seal 178 between the inner cap 114 and outer cap 112. The thickness of the breakaway seal 178 is of sufficient strength to maintain a closure between the inner cap 112 and outer cap 114 providing protection against cannula damage or contamination during shipment or storage. The seal 178, however, is thin enough to allow the herdsman to readily separate the outer cap 112 from the inner cap 114 at the junction located at central aperture 160, resulting in a smooth surface on the distal plane 158 of the inner sleeve 114. Separation is facilitated by the traction provided by raised ridges 136 on the outside walls of the entire device 110.

Separation of inner cap from syringe end is effected as in the first embodiment. That is, the tubular sidewall 150 of inner cap 114 is grasped and a bending force to unseat lip 154 from groove 30 is utilized. Thus in both embodiments the two separating forces are of differing types so that separation will occur at the desired point.

As described in a previous section, in use, the two part mastitis cannula cap assembly in accordance with the present invention allows the dairy farmer, veterinarian, herdsman, or the like to practice whichever infusion procedure he feels is appropriate for each teat canal of the udder. Should partial insertion be desired, the outer cap's 12 outer flange 42 in the first embodiment, or the ridges 136 of the outer cap 112 in the second embodiment, are grasped and the outer cap is removed by gently twisting, bending or applying a longitudinal force. This exposes the free or distal end of insertion cannula which is slowly inserted into the teat orifice and passed proximally into the teat canal. In accordance with present procedures, generally about 3 to 4 mm of the cannula free end 40 (or 140) projects beyond the relatively wide diameter smooth end face 58 (or 158) of inner cap 14 (or 114). Since the teat canal of a cow is approximately 5 to 10 mm in length, the 3 to 4 mm projection of cannula free end 40 (or 140) and the wider diameter of the exposed distal end of the inner cap 58 (or 158) limits cannula insertion depth to a point within the teat canal and not into the teat cistern.

Thus partial cannula insertion to the correct depth can be quickly accomplished. The relatively large diameter and slightly bevelled or planar outer end face 58 (or 158) of the inner cap also serves to stabilize the infusion cannula against the teat end while the free end 40 (or 140) of the cannula is inserted partially into the teat canal. This wide planar, or slightly bevelled end face also minimizes leakage of the material being infused. Since removal of the outer cap 12 (or 112) produces a smooth and clean end face 58 (or 158) with gently rounded corners it will not harm the teat end. Additionally, since the teat canal is quite small in diameter, (0.6 to 1.6 mm), there is no possibility of the generally 3–12 mm, preferably 5–7 mm large diameter end face 58 (or 158) of the inner cap being inserted into the teat canal.

If full insertion of the mastitis treatment cannula is desired, this can readily be accomplished by removal of both the outer and inner caps as a single assembly. As discussed previously, this is accomplished by grasping the tubular sidewall 50 (or 150) of the inner cap 14 (or 114) and by exerting sufficient bending force to unseat the lip 54 (or 154) on the snap end or proximal end 52 (or 152) of the inner cap 14 from its cooperating groove 30 at the juncture of the syringe body 16 with the attached cannula 18. This exposes the entire length of cannula 18 so that full insertion of the cannula into the teat cistern through the teat canal can be accomplished.

It should be noted that the juncture of the syringe body with cannula 18 is secure enough that, in removing only the outer cap, the juncture does not break or unseat.

The overall length of the two part mastitis cannula cap of the present invention will be generally in the range of 25 to 40 mm. This dimension is determined by the length of the cannula and is not particularly critical in itself. The length of the inner cap 14 (or 114) with respect to the length of the cannula 18 is important because the difference in lengths between the shorter inner cap 14 (or 114) and the longer cannula 18 determines the length of cannula free end tip 40 (or 140) protrusion beyond the end face 58 (or 158) of inner cap 14 (or 114). As discussed above, a projection of generally about 3 to 4 mm is believed to be proper for optimal infusion of the mastitis treatment antibiotic preparation into the teat canal. The length of cannula tip 40 (or 140) projection, in turn, dictates the depth of interior concavity 38 (or 138) on the end wall 34 (or 156) of the outer cap 12 (or 112). In FIG. 1, the outer end of the distal tip 40 of cannula 18 should bear against the inner surface of this projection 36 to minimize any possible treatment material loss during shipment or handling and before the outer cap 12 is removed, either by itself during partial insertion, or with inner cap 14 during full insertion. With the embodiment described in FIG. 4*b*, leakage of the syringe contents is prevented by the radial seal 139 that projects from the distal inner wall of the inner cap sleeve 150 against the outer wall of the cannula 22 and the break-away seal 178 between the inner and outer caps.

The embodiment of FIGS. 4*a* and 4*b* thus provides several distinct advantages to the dairymen. These features include:

1. The inner and outer caps are sealed together at the junction of the inner cap and the outer cap, forming a unibody cap. This unibody feature provides that an impermeable seal is formed which effectively eliminates the possibility of leakage of the syringe contents or contamination of the syringe cannula during storage.

The plastic seal between the inner and outer cap is designed to break away when sufficient tractional forces are applied by the dairyman. Raised ridges along the outer wall of the entire unibody cap facilitate this process. Thus the outer cap may be easily removed by the dairymen, exposing a portion of the syringe cannula. The resulting 3–4 mm exposed cannula provides the ideal depth of insertion of the mastitis syringe cannula. Additionally, since no additional device needs to be placed on the cannula, the risk of contaminating the cannula is significantly minimized.

2. The two-part cap is secured tightly to the syringe cannula assembly by a snap-lock fit at the hub of the cannula. This tight fit ensures that the entire cap will not snap off while the outer cap is being twisted off. However, should the dairymen choose to remove the entire unibody cap (to expose the full length of the cannula) this may be easily accomplished bending the entire unibody cap. Thus this design allows partial or full insertion to be easily practiced by the dairymen.

3. The radial seal **139** adjacent to the distal end of the inner sleeve serves to compress the syringe cannula just proximal to the breakaway seal. This sealing feature operates in cooperation with the breakaway seal to prevent any possible leakage of the syringe contents.

The two piece mastitis cannula cap in accordance with the present invention provides a safe, easy to use, sterile, accurately controllable and reproducible, disposable, inexpensive means to practice the partial cannula insertion technique which recent studies have suggested may enhance the effectiveness of the treatment of mastitis in dairy cows. At the same time, the two part cap structure affords the user an assembly which can be utilized for conventional full cannula insertion treatment, if desired. Thus, the two part mastitis cannula cap of the present invention provides the freedom to select and use whichever of the two treatment procedures is deemed more desirable without sacrificing ease of use, disposability, and package integrity.

While preferred embodiments of a two part mastitis cannula cap in accordance with the present invention have been set forth fully and completely hereinabove, it will be obvious to one of skill in the art that a number of changes in, for example the size and shape of the syringe, the materials used for the syringe, cannula and cap, the overall length of the cannula and hence the overall length of the two part cap and the like may be made without departing from the true spirit and scope of the present invention which is accordingly to be limited only by the following claims.

What is claimed is:

1. In combination with a mastitis infusion syringe having a blunt-tipped cannula sized in diameter and length to fit the teat canal portion of a teat of a dairy vow, a two part mastitis cannula cap for facilitating controllable length insertion of the mastitis infusion syringe into the teat canal portion of a teat of a dairy cow said cap comprising:

a hollow inner cap including a rear end having means to removably attach said inner cap to the syringe over the cannula and a forward end portion of which has a diameter size to prevent insertion of said inner cap into a teat canal, said forward end having an aperture dimensioned to receive the cannula in sealing engagement therein, means defining an extension of the cannula forward of said forward end, the length of said extension being substantially less than the full length of the cannula, whereby it is less than the length of a teat canal, and means defining a distal end surface closely surrounding said extension for engaging said teat upon insertion of the extension;

an outer cap for covering the cannula extension removably secured in covering relationship with respect to said extension; and

whereby either the outer cap alone can be removed to expose the extension of the cannula for insertion into a teat canal for a distance less than full cannula length, or the outer and inner caps can be removed to expose the cannula for full insertion.

2. A two part mastitis cannula cap in accordance with claim **1**, said cap further comprising:

breakaway means for securing and sealing said outer cap to said inner cap, said breakaway means subject to being broken away by an application of force to said outer cap; and

sealing means in said cannula cap for preventing fluid leakage from said cannula cap.

3. The two part mastitis cannula cap of claim **2** wherein said outer and inner cap are made of plastic and said breakaway means includes a thin strip of plastic between outer cap and inner cap.

4. The two part mastitis cannula cap of claim **2** or **3** including ridges disposed along an outer surface of the outer cap to facilitate removal of said outer cap by twisting or pulling action.

5. The two part mastitis cannula cap of claim **4** including ridges also disposed along an outer surface of said inner cap to enable grasping of said surface during removal of said inner cap or outer cap.

6. A two part mastitis cannula cap in accordance with claim **26**, said cap further comprising:

breakaway means for securing and sealing said outer cap to said inner cap, said means subject to being broken away by force applied to said outer cap.

7. The two part mastitis cannula cap of claim **6** wherein said distal end surface has a diameter of generally between 3 mm and 12 mm.

8. The two part mastitis cannula cap of claim **7** wherein said distal end surface has a diameter of generally between 5 mm and 7 mm.

9. The two part mastitis cannula cap of claim **6** wherein the length of said extension is about 3 to 4 mm.

10. The two part mastitis cannula cap of claim **6** wherein said distal end surface of said inner cap includes a rounded peripheral edge.

11. The two part mastitis cannula cap of claim **6** including ridges disposed along an outer surface of the outer cap to facilitate removal of said outer cap by twisting action.

12. The two part mastitis cannula cap of claim **6** including ridges also disposed along an outer surface of said inner cap to enable grasping of said surface during removal of said inner cap or outer cap.

13. The two part mastitis cannula cap of claim **6** wherein said breakaway means includes a thin ribbon of plastic material between the inner and outer caps.

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