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DELEGATURA DE NUEVAS CREACIONES

SOLICITUD FASE NACIONAL -PCT

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71. SOLICITANTE: BAYER ESSURE, INC

DOMICILIO: 1011 McCARTHY BLVB, Milpitas
ESTADOS UNIDOS DE AMERICA

74. APODERADO: HELENA CAMARGO WILLIAMSON

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DIRECCIÓN DE NUEVAS CREACIONES
SOLICITUD FASE NACIONAL –PCT

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SOLICITANTE (S) Esta persona también es inventor. Para datos adicionales utilizar hoja de información complementaria			
APELLIDOS O RAZÓN SOCIAL		NOMBRE	IDENTIFICACIÓN
BAYER ESSURE, INC			
6	DATOS DEL SOLICITANTE		
DIRECCIÓN		1011 McCARTHY BLVB	
CIUDAD		Milpitas	
DEPARTAMENTO/ESTADO			
PAÍS DE RESIDENCIA		ESTADOS UNIDOS DE AMERICA	
		No. TELÉFONO	
		CORREO ELECTRÓNICO	
		NACIONALIDAD O LUGAR DE CONSTITUCIÓN	ESTADOS UNIDOS DE AMERICA
7	INVENTOR (ES) Para datos adicionales utilizar hoja de información complementaria		
APELLIDOS		NOMBRES	NACIONALIDAD
1. STOUT		Christopher, A.	ESTADOS UNIDOS DE AMERICA
2. SWANN		Betsy	ESTADOS UNIDOS DE AMERICA
3. CRUZADA		Julian	ESTADOS UNIDOS DE AMERICA
4. SEPE		Chris	ESTADOS UNIDOS DE AMERICA
5. SLOAN		Robert, Todd	ESTADOS UNIDOS DE AMERICA
DIRECCIÓN DE CORREO ELECTRÓNICO:			
8	DATOS INVENTOR (ES)		
PAÍS RESIDENCIA	DEPARTAMENTO/ESTADO	CIUDAD	DIRECCIÓN
1. Estados Unidos de América		1. San Bruno	1. Cherry Avenue
2. Estados Unidos de América		2. Grass Valley	2. 135 Winchester Street
3. Estados Unidos de América		3. San Jose	3. Auzerais Avenue, Unit 358
4. Estados Unidos de América		4. Campbell	4. West Rincon Avenue, Unit A
5. Estados Unidos de América		5. Oak Place	5. Saratoga
OTRO(S) SOLICITANTE(S) Y/O (OTRO(S)) INVENTOR(ES)			
☐ Los demás solicitantes y/o (demás) inventores se indican en una hoja a continuación.			
9	☐ REPRESENTANTE LEGAL ☒ APODERADO		
APELLIDOS		NOMBRES	IDENTIFICACIÓN
CAMARGO WILLIAMSON		HELENA	C.C 35.455.268 T.P 76985
DIRECCIÓN	CARRERA 7 N° 71 – 52, TORRE A, PISO 5		No. TELÉFONO 3257300
CIUDAD	BOGOTÁ		CORREO ELECTRÓNICO helena.camargo@phrlegal.com
PAÍS	COLOMBIA		No. RADICACIÓN DE PROTOCOLO DE PODER GENERAL

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1. ESTADOS UNIDOS DE AMERICA			13/149,631	31/05/2011
11	DECLARACIÓN SOBRE USO DE RECURSOS GENÉTICOS O BIOLÓGICOS			
Declaro que el objeto de la presente solicitud de patente fue obtenido a partir de recursos genéticos o biológicos de los que cualquiera de los países miembros de la Comunidad Andina es país de origen.				
☐ SI ☒ NO				
12	DECLARACIÓN SOBRE USO DE CONOCIMIENTOS TRADICIONALES			
Declaro que el objeto de la presente solicitud de patente fue obtenido a partir de conocimientos tradicionales de comunidades indígenas, afroamericanas o locales de países miembros de la Comunidad Andina.				
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13	REDUCCIÓN DE TASAS			
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☐ SI ☒ NO				
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Entidades sin ánimo de lucro ☐				
Debe aportar los documentos que se indican en el numeral 17 de anexos				
14	AUTORIZACIÓN DE NOTIFICACIÓN EN LÍNEA ☒ SI ☐ NO			
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15	COMPROBANTE DE PAGO O PAGO ELECTRÓNICO	N°	Fecha	
16	FIRMA DEL SOLICITANTE, DEL APODERADO O DEL REPRESENTANTE LEGAL			
Junto a cada firma, indicar el nombre del firmante y su calidad (si tal calidad no es obvia a leer el petitorio)				
HELENA CAMARGO WILLIAMSON				
17	ANEXOS			
Documentación Técnica		Documentación Jurídica		
Solicitud Internacional en castellano				
1. ☒ Descripción N° de folios:		9. ☐ Poderes, si fuera el caso,		
2. ☒ Reivindicaciones N° Reivindicaciones:		10. ☐ Documento que legalmente pruebe la cesión del inventor al solicitante o a su causante.		
3. ☒ Dibujos y/o figuras N° folios:		11. ☐ Copia del contrato de acceso de recursos genéticos o productos derivados, certificado o número de registro, si fuera el caso.		
4. ☒ Resumen.		12. ☐ Copia de la licencia o autorización de Conocimientos Tradicionales, certificado o número de registro, si fuera el caso.		
5. ☐ Certificado de depósito de material biológico si fuera el caso.		13. Reducción de tasas		
6. ☐ Listado de secuencias de nucleótidos y/o aminoácidos en forma digital si fuera el caso.		Micro, pequeñas o medianas empresas		
7. ☒ Arte final 12 x 12.		☐ Copia simple de la declaración de renta del año inmediatamente anterior, o en su defecto prueba documental idónea.		
8. ☐ Anexo formato digital.		☐ Documento de constancia de cumplimiento con lo establecido en la ley 905 de 2004.		
		Universidades públicas o privadas		
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		☐ Hoja de información complementaria.		
		☐ Otros, especificar		
		14. ☒ Comprobante de pago de la tasa de presentación de la solicitud.		
		15. ☐ Comprobante de pago por reivindicación de prioridad.		
		16. ☒ Comprobante de pago de la tasa por concepto de excedente de palabras en la publicación.		
		17. ☒ Comprobante de pago por reivindicación adicional a 10.		

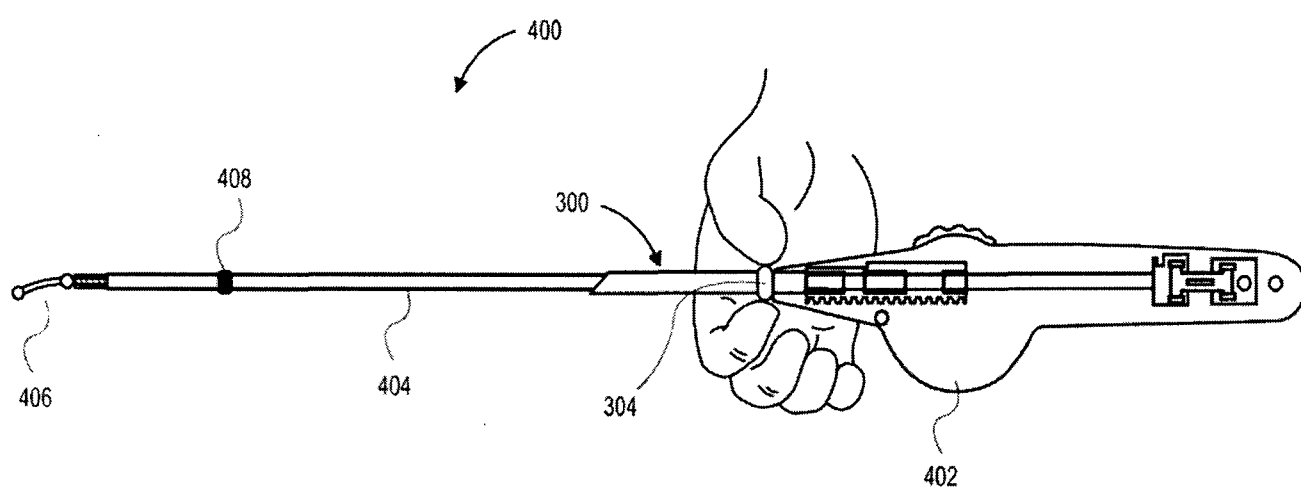


FIG. 5A

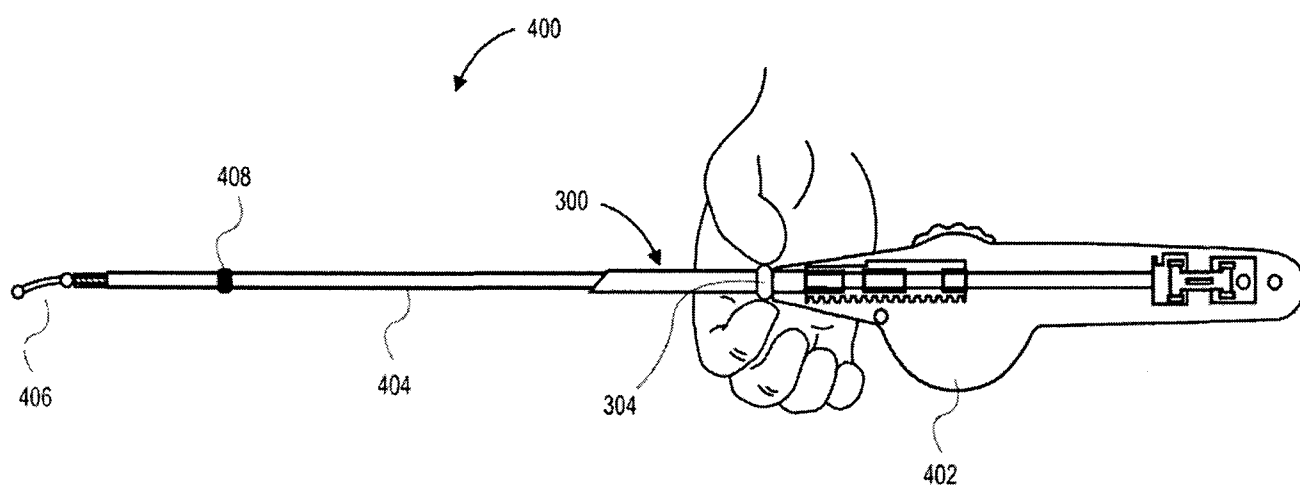


FIG. 5A

DESCRIPCIÓN

Manguito protector de punta

5 **Antecedentes**

Las realizaciones de la presente invención se refieren al campo de los dispositivos médicos quirúrgicos y a procedimientos médicos mínimamente invasivos. Más específicamente, las realizaciones de la presente invención se refieren a dispositivos y procedimientos utilizados para procedimientos ginecológicos transcervicales.

La anticoncepción y la esterilización femenina pueden verse afectadas por la introducción de manera transcervical de un objeto en una trompa de Falopio para impedir la concepción. Dispositivos, sistemas y procedimientos para un enfoque anticonceptivo de este tipo se han descrito en varias patentes y solicitudes de patentes asignadas al presente cesionario. Por ejemplo, la patente US N° 6.526.979, la patente US N° 6.634.361, la solicitud de patente US N° 11/165,733 publicada como publicación US N° 2006/0293560 y la solicitud de patente US N° 12/605,304 describen la inserción transcervical de un inserto (también denominada como implante y dispositivo) en una abertura de una trompa de Falopio y el anclaje mecánico del inserto dentro de la trompa de Falopio. Un ejemplo de un conjunto de este tipo se conoce como "Essure"® de Conceptus, Inc., de Mountain View, California. El crecimiento del tejido en el inserto "Essure"® proporciona anticoncepción a largo plazo y/o esterilización permanente sin la necesidad de procedimientos quirúrgicos.

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El inserto puede colocarse en la trompa de Falopio con un conjunto de catéter de suministro tal como la que se ilustra en la figura 1. El conjunto de catéter de suministro 100 está formado de un dispositivo de control 102, tal como un mango, una funda alargada 104, y un inserto 106. El conjunto de catéter de suministro 100 puede colocarse

de manera transcervical en el útero y las trompas de Falopio a través de un sistema de histeroscopia.

Haciendo referencia a la figura 2 el sistema de histeroscopia 200 puede incluir un canal de trabajo 202 en el que se inserta el conjunto de catéter de suministro. El avance del sistema de catéter de suministro dentro del útero y las trompas de Falopio se suele facilitar mediante la distensión del útero con un fluido de distensión, tal como solución salina, y la visualización de la colocación con el sistema de histeroscopia. Una abrazadera 208 de válvula, tal como una abrazadera de válvula de bola, y un puerto de acceso 206 se colocan en la punta del canal de trabajo 202. El cierre de la abrazadera 208 de la válvula puede sellar la entrada del canal de trabajo 202 para evitar que un fluido de distensión se escape del puerto de acceso 206. Un tapón de sellado 230 que incluye un extremo perforable 232 se puede colocar sobre el puerto de acceso 206 para evitar que el fluido de distensión se escape del sistema de histeroscopia cuando un conjunto de catéter de suministro ocupa el canal de trabajo del sistema de histeroscopia.

Un introductor 220 puede ser utilizado para evitar daños en la punta de la funda alargada 104 o el inserto 106 del conjunto de catéter de suministro 100 durante la inserción a través del extremo perforable 232 de la tapa de cierre 230 y el puerto de acceso 206, y en el canal de trabajo 202 del sistema de histeroscopia 200. El introductor 220 incluye una porción de funda 222 y abertura de hendidura 224 para ayudar en el agarre y en la retirada del introductor 220. El introductor 220 se inserta a través del extremo perforable 232 de la tapa de cierre 230 y en el canal de trabajo 202 antes de insertar el conjunto de catéter de suministro 100. Cuando el introductor 220 se inserta a través de la tapa de cierre 230, el fluido puede pulverizarse fuera del introductor 220 y sobre el médico o el asistente del médico. La cantidad de fluido que salpica hacia atrás puede ser significativa en función de la presión del fluido de distensión durante el procedimiento.

Haciendo referencia a la figura 3, después de colocar el introductor 220 en el canal de

trabajo 202, la punta del conjunto de catéter de suministro 100 se inserta en la abertura de hendidura 224 y a través de la funda 222 del introductor 220 para avanzar en el conjunto de catéter de suministro 100 en el canal de trabajo 202 del sistema de histeroscopia. Esto se realiza típicamente tan pronto como sea posible después de la colocación del introductor 220 en el canal de trabajo 202 para minimizar la cantidad de fluido que se salpica hacia atrás desde el introductor. El introductor 220 puede entonces retirarse o se puede mantener en su lugar durante todo el procedimiento. Después de la inserción del conjunto de catéter de suministro 100 en el introductor 200, una cantidad de fluido de distensión todavía puede gotear entre el introductor y la funda alargada 104 del conjunto de catéter de suministro 100.

Sumario

Las realizaciones de la presente invención generalmente proporcionan conjuntos y procedimientos de inserción de un catéter de suministro en un canal de trabajo de un endoscopio, tal como un sistema de histeroscopia para acceder a un sistema reproductivo femenino. Aunque las realizaciones de la invención se describen con referencia a un sistema de histeroscopia, se entiende que las realizaciones no se limitan al mismo, y también pueden ser compatibles con otros dispositivos quirúrgicos ópticos. En un aspecto, las realizaciones de la invención describen un manguito protector de punta que funciona como un introductor y protege la punta de un conjunto de catéter de suministro al perforar un tapón de cierre, así como durante la inserción a través de un puerto de acceso, en el canal de trabajo y más allá de un abrazadera de válvula de un sistema de histeroscopia. En otro aspecto, las realizaciones de la invención describen un procedimiento y un sistema que puede reducir la cantidad de fluido que salpica hacia atrás y fugas asociadas con la inserción de un conjunto de catéter de suministro en el canal de trabajo de un sistema de histeroscopia.

Una realización de la presente invención se refiere a un conjunto de catéter de suministro

que puede ser utilizado para suministrar un inserto en una vía ovárica (por ejemplo, un tubo de Falopio) de un cuerpo femenino. El conjunto de catéter de suministro puede incluir un dispositivo de control, una funda de catéter alargada que tiene un extremo distal y un extremo proximal conectado al dispositivo de control, y un manguito protector de la punta.

- 5 El manguito protector de la punta puede bloquearse sobre la funda de catéter alargada y ser deslizable sobre una longitud de la funda de catéter alargada entre una posición de tope proximal y una posición de tope distal a lo largo de la funda de catéter alargada. El conjunto de catéter de suministro puede incluir, además, una tope de interferencia que determina la posición de tope distal e impide que el manguito protector de la punta se deslice fuera del extremo distal de la funda de catéter alargada. Por ejemplo, el tope de interferencia puede incluir una parte de interferencia macho que interfiere con el desplazamiento de una parte de interferencia hembra sobre la funda de catéter alargada. La parte interferencia macho puede fijarse a la funda de catéter alargada, y el manguito protector de la punta puede comprender la parte de interferencia hembra. El manguito protector de la punta puede incorporar adicionalmente una válvula de sellado para reducir la cantidad de fluido que salpica hacia atrás y fugas asociadas con la inserción del conjunto de catéter de suministro en el canal de trabajo de un sistema de histeroscopia.

- 20 Otra realización de la presente invención se refiere a un procedimiento de formación de un conjunto de catéter de suministro que incluye el deslizamiento de un manguito protector de la punta sobre un extremo distal de una funda de catéter alargada y hacia un dispositivo de control, y a continuación fijar una protuberancia sobre una región distal de la funda de catéter alargada. Alternativamente, la protuberancia puede fijarse en la región distal de la funda de catéter alargada, y luego el manguito protector de la punta se desliza sobre un extremo proximal de la funda de catéter alargada hacia la protuberancia antes de unir el dispositivo de control a la funda de catéter alargada. El dispositivo de control puede evitar que el manguito protector de la punta se deslice fuera de un extremo proximal de la funda alargada y definir, en parte, una posición de tope proximal. La protuberancia puede evitar que el manguito protector de la punta se deslice fuera de un

extremo distal de la funda de catéter alargada y definir, en parte, una posición de tope distal. En una realización, la protuberancia puede fijarse en una región distal de la funda de catéter alargada mediante la sujeción de una banda sobre la funda de catéter alargada. No es necesario sujetar toda la longitud de la banda, y sólo un extremo proximal de la banda se sujeta en el árbol del catéter alargado en una realización.

Otra realización de la presente invención se refiere a un procedimiento de suministro de un inserto en un lumen de cuerpo, tal como una vía ovárica (por ejemplo, un tubo de Falopio) de un cuerpo femenino. Utilizando un conjunto de catéter de suministro, de acuerdo con las realizaciones de la invención, el manguito protector de la punta se coloca en la posición de tope distal, y el manguito protector de la punta se inserta a través de un extremo perforable de un tapón de cierre, a través de un puerto de acceso de un sistema de histeroscopia y en un canal de trabajo del sistema de histeroscopia. De acuerdo con realizaciones de la invención, el extremo distal de la funda de catéter alargada y el inserto se insertan a través del extremo perforable de la tapa de cierre, a través del puerto de acceso y en el canal de trabajo del sistema de histeroscopia simultáneamente con el manguito protector de la punta en la posición de tope distal. El extremo distal de la funda de catéter alargada y el inserto pueden entonces avanzar a través del manguito protector de la punta y más allá del sistema de histeroscopia a una posición objetivo dentro del lumen del cuerpo en el que el inserto se despliega dentro del lumen del cuerpo. En una realización, el manguito protector de la punta se hace avanzar a través de la tapa de cierre en el canal de trabajo hasta un tope mecánico rebordeado, tal como un talón o porción acampanada, topa con la tapa de cierre (o puerto de acceso si no se utiliza una tapa de cierre) antes de avanzar la funda alargada y el inserto a la posición objetivo.

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Breve descripción de los dibujos

La figura 1 es una vista lateral en sección transversal de un conjunto de catéter de suministro.

La figura 2 es una vista isométrica de un sistema de histeroscopia y un introductor.

La figura 3 es una vista isométrica de un conjunto de catéter de suministro insertado en un
5 introductor y un canal de trabajo de un sistema de histeroscopia.

La figura 4 es una vista lateral de un manguito protector de la punta de acuerdo con una realización de la invención.

10 La figura 5A es una vista lateral de un conjunto de catéter de suministro con un manguito protector de la punta en una posición de tope proximal de acuerdo con una realización de la invención.

La figura 5B es una vista lateral de un conjunto de catéter de suministro con un tope
15 mecánico rebordado de un manguito protector de la punta en una cavidad de un dispositivo de control de acuerdo con una realización de la invención.

La figura 5C es una vista lateral de un conjunto de catéter de suministro con un manguito protector de la punta fijado en la posición de tope proximal mediante un ajuste por fricción
20 de acuerdo con una realización de la invención.

La figura 5D es una vista lateral de un conjunto de catéter de suministro con un manguito protector de la punta enroscado en la posición de tope proximal de acuerdo con una realización de la invención.

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La figura 6 es una vista lateral de un conjunto de catéter de suministro con un manguito protector de la punta en una posición de tope distal de acuerdo con una realización de la invención.

La figura 7 es una vista lateral cercana del extremo proximal de un manguito protector de la punta a través de una funda de catéter alargada de acuerdo con una realización de la invención.

- 5 La figura 8 es una vista lateral en sección transversal cercana del extremo proximal de un manguito protector de la punta a través de una funda de catéter alargada de acuerdo con una realización de la invención

- 10 La figura 9 es una vista lateral en sección transversal de un manguito protector de la punta de acuerdo con una realización de la invención.

La figura 10 es una vista lateral en sección transversal de un manguito protector de la punta de acuerdo con una realización de la invención.

- 15 Las figuras 11A a 11C son vistas en sección transversal lateral de manguitos protectores de la punta que incorporan diversas válvulas de sellado de acuerdo con realizaciones de la invención.

- 20 Las figuras 12A a 12C son vistas isométricas de la inserción de un conjunto de catéter de suministro en un canal de trabajo de un sistema de histeroscopia de acuerdo con una realización de la invención.

Descripción detallada

- 25 Las realizaciones de la presente invención proporcionan en general conjuntos y procedimientos de inserción de un catéter de suministro en un canal de trabajo de un endoscopio, tal como un sistema de histeroscopia u otro dispositivo quirúrgico óptico para acceder a un sistema reproductor femenino. Diversas realizaciones y aspectos se describirán con referencia a los detalles que se mencionan a continuación y los dibujos adjuntos ilustrarán las diversas realizaciones. La siguiente descripción y los dibujos son

ilustrativos de la invención y no deben interpretarse como limitativos de la invención. Numerosos detalles específicos se describen para proporcionar una comprensión completa de diversas realizaciones de la presente invención. Sin embargo, en ciertos casos, detalles bien conocidos o convencionales no se describen para proporcionar una descripción concisa de realizaciones de la presente invención.

En una realización, un conjunto de catéter de suministro incluye un dispositivo de control, una funda de catéter alargada que tiene un extremo distal y un extremo proximal conectado al dispositivo de control, y un manguito protector de la punta. Haciendo referencia a la figura 4, el manguito protector de la punta 300 puede incluir un árbol alargado 302, un tope mecánico rebordeado 304 en un extremo proximal, y un extremo distal 306. El extremo distal 306 puede ser plano o inclinado para ayudar con la perforación de un tapón de cierre. En una realización, el extremo distal 306 tiene una punta en ángulo de aproximadamente 45 grados. El árbol alargado 302 puede estar formado de un material y de un espesor que puede moldearse y no se dobla al perforar un tapón de cierre. Por ejemplo, el árbol alargado 302 puede estar formado de un material tal como poliéter éter cetona (PEEK).

El tope mecánico rebordeado 304 puede proporcionar una variedad de funciones, puede estar formado de una variedad de materiales y puede tener una variedad de formas y tamaños como se explicará con más detalle respecto a las figuras 5A a 12C. Por ejemplo, el tope mecánico rebordeado 304 puede estar formado de un material moldeable, tal como policarbonato, o del mismo material que el árbol alargado 302. El tope mecánico rebordeado 304 puede ser de tamaño y forma más grande que el diámetro interior (ID) de una abertura de puerto de acceso correspondiente a un canal de trabajo o extremo perforable de un tapón de cierre si está presente para actuar como un mecanismo de tope que controla la profundidad de inserción del manguito protector de la punta 300 en el canal de trabajo. El tope mecánico rebordeado 304 también puede estar dimensionado y conformado para sujetarse por la mano de un operador para ayudar con el desplazamiento del manguito protector de la punta 300 en una longitud de la funda de

catéter alargada 404 de un conjunto de catéter. A este respecto, una de las funciones puede ser como mango en el extremo proximal del manguito protector de la punta 300. El tope mecánico rebordeado 304 también puede incorporar una válvula de sellado para reducir la cantidad de fluido que salpica hacia atrás y fugas asociadas con la inserción del conjunto del catéter de suministro en un canal de trabajo.

Haciendo referencia a las figuras 5A a 6, se ilustra un conjunto de catéter de suministro 400 de acuerdo con realizaciones de la invención, en el que el manguito protector de la punta 300 está bloqueado y es deslizable sobre una longitud de la funda de catéter alargada 404. El conjunto de catéter de suministro 400 puede estar formado mediante el deslizamiento de un manguito protector de la punta 300 sobre un extremo distal de una funda de catéter alargada 404 y hacia un dispositivo de control 402, y a continuación, se fija una protuberancia 408 sobre una región distal de la funda de catéter alargada 402. Alternativamente, la protuberancia 408 puede fijarse en la región distal de la funda de catéter alargada 402, y luego el manguito protector de la punta 300 se desliza sobre un extremo proximal de la funda de catéter alargada 402 hacia la protuberancia 408 antes de unir el dispositivo de control 402 a la funda de catéter alargada 402. El dispositivo de control 402 puede impedir que el manguito protector de la punta 300 se deslice fuera de un extremo proximal de la funda alargada 402 y definir, en parte, una posición de tope proximal. La protuberancia 408 puede impedir que el manguito protector de la punta 300 se deslice fuera de un extremo distal de la funda de catéter alargada 402 y definir, en parte, una posición de tope distal. Un operador puede sujetar el tope mecánico rebordeado 304 con la mano, por ejemplo, entre el pulgar y el dedo índice, y desliza el manguito protector de la punta sobre la funda de catéter alargada 404 entre las posiciones de tope proximal y de tope distal.

La figura 5A es una ilustración del manguito protector de la punta 300 colocado en una posición de tope proximal. En la realización ilustrada en la figura 5A, el tope mecánico rebordeado 304 se apoya en un extremo distal del dispositivo de control 402, aunque

otras posiciones de tope proximal a lo largo de la funda de catéter alargada 404 se contemplan de acuerdo con realizaciones de la invención. Por ejemplo, las figuras 5B a 5D son ilustraciones de realizaciones en las que el dispositivo de control 402 está configurado para permitir que el tope mecánico rebordeado 304 se deslice dentro de una

5 cavidad 420 situada en una porción distal del dispositivo de control 402. Tales realizaciones pueden ser útiles durante el funcionamiento para utilizar la longitud de trabajo completa de la funda de catéter alargada 404. De esta manera, el extremo distal del dispositivo de control 402 puede avanzarse para topar con el puerto de acceso 206 del sistema de histeroscopia o el extremo perforable 232 de una tapa de cierre 230, si se

10 desea, durante el funcionamiento. Alternativamente, el extremo distal del dispositivo de control 402 se puede avanzar sobre el puerto de acceso 206 del sistema de histeroscopia o sobre la tapa de cierre 230 y el tope mecánico rebordeado 304 puede topar con el puerto de acceso 206 o el extremo perforable 232 de la tapa de cierre 230. Como se ilustra en la figura 5B, el tope mecánico rebordeado 304 puede deslizarse dentro de la

15 cavidad 420 para topar con una pared trasera 422 de la cavidad en la posición de tope proximal. El tope mecánico rebordeado 304 también puede configurarse para sujetar en el mango 402 en la posición de tope proximal. Por ejemplo, la figura 5C es una ilustración de una realización en la que el tope mecánico rebordeado 304 se puede deslizar dentro de la cavidad 420 y fijarse en la posición de tope proximal mediante un ajuste por fricción con

20 las paredes inclinadas 424 de la cavidad. La figura 5D es una ilustración de una realización en la que el tope mecánico rebordeado 304 puede enroscarse en la cavidad 420 en la que las roscas 330 en el tope mecánico rebordeado 304 se acoplan con unas roscas 430 en el interior de la cavidad 420 para sujetar el manguito protector de la punta 300 en la posición de tope proximal. En una realización, un mecanismo de fijación

25 adecuado para la fijación del manguito protector de la punta 300 en el dispositivo de control 402 es capaz de mantener el manguito protector de la punta 300 en la posición de tope proximal durante la retirada del conjunto de catéter de suministro 400 del canal de trabajo del sistema de histeroscopia.

Haciendo referencia ahora a la figura 6, un operador puede deslizar el manguito protector de la punta sobre la funda de catéter alargada 404 entre la posición de tope proximal y la posición de tope distal que se ilustra en la figura 6. Como se ilustra, el extremo distal 306 del manguito protector de la punta 300 se puede extender distalmente más allá de un extremo distal de la funda de catéter alargada 404 y el inserto 406 cuando está en la posición de tope distal. De esta manera, el manguito protector de la punta 300 puede proteger los extremos distales de la funda de catéter alargada 404 y el inserto 406 durante la perforación de una tapa de cierre y durante la inserción en el canal de trabajo y más allá de una abrazadera de válvula del sistema de histeroscopia.

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Un tope de interferencia puede determinar la posición de tope distal e impedir que el manguito protector de la punta 300 se deslice fuera del extremo distal de la funda de catéter alargada 404. En una realización, el tope de interferencia incluye una parte de interferencia macho que interfiere con el desplazamiento de una parte de interferencia hembra sobre la funda de catéter alargada. Haciendo referencia de nuevo a la figura 5A, la parte de interferencia macho puede comprender una protuberancia 408 fijada a la funda de catéter alargada 404. La protuberancia 408 puede formarse a lo largo de sólo una parte de la circunferencia de la funda alargada, o puede rodear la circunferencia de la funda alargada. En una realización, la protuberancia 408 es una banda fija y que rodea la circunferencia de la funda de catéter alargada. En una realización, la protuberancia 408 está fijada a la funda de catéter alargada 404 con una resistencia a la cizalladura suficiente para asegurar que el manguito protector de la punta puede retirarse de un canal de trabajo de un sistema de histeroscopia junto con la retirada de la funda de catéter alargada 404.

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La figura 7 es una vista lateral de la ilustración cercana del extremo proximal de un manguito protector de la punta a través de una funda de catéter alargada de acuerdo con una realización de la invención. La figura 8 es una vista lateral en sección transversal de la ilustración cercana del extremo proximal de un manguito protector de la punta a través

de una funda de catéter alargada de acuerdo con una realización de la invención. Como se ilustra en las figuras 7 y 8, el tope mecánico rebordeado puede ser un talón 304A que tiene una forma de barril, aunque realizaciones de la invención no se limitan a esta forma. En una realización, el talón 304A se fija al árbol 302 con un adhesivo.

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Haciendo referencia a la figura 8, en una realización el talón 304A puede fijarse a un extremo proximal del árbol alargado 302. El talón 304A puede incluir una porción distal 308 que rodea el extremo proximal del árbol alargado 302, una porción de resalte 310 que se extiende de manera proximal desde el árbol alargado 302, y un tope de retención 312.

10 La porción distal 308 puede fijarse al árbol alargado 302 con un adhesivo. En una realización, el tope de retención 312 topa con el extremo proximal del árbol alargado 302. El tope de retención 312 también puede tener una altura que sea mayor que un espesor del árbol alargado 302. Por ejemplo, la altura puede definirse como la distancia entre un diámetro interior (ID) del tope de retención y un diámetro interior de la porción distal 308

15 del talón 304A. De acuerdo con diversas realizaciones de la invención, las dimensiones y la posición del tope de retención 312 en lo que se refieren a las dimensiones y a la posición de la protuberancia 410 crean una tope de interferencia que determina la posición de tope distal e impide que el manguito protector de la punta se deslice fuera del extremo distal de la funda de catéter alargada 404.

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En una realización, el manguito protector de la punta 300 está bloqueado en un conjunto de catéter de suministro "Essure"®. En dicha realización, el diámetro interior de la funda de catéter alargada 404 puede ser de entre 0,0405 y 0,0420 pulgadas y el diámetro exterior (OD) de la funda de catéter alargada 404 puede ser de entre 0,0538 y 0,0560

25 pulgadas. La funda de catéter alargada 404 puede estar formada de una amida de bloque de poliéter, también conocida bajo el nombre comercial de PEBAX. El diámetro exterior de la funda de catéter alargada 404 puede utilizarse para determinar el diámetro interior de la protuberancia 408. En una realización, la protuberancia 408 puede tener un diámetro interior entre 0,0545 y 0,0555 pulgadas y un diámetro exterior entre 0,0575 y 0,0580

pulgadas. En una realización, el diámetro interior de la protuberancia 408 puede ser menor que el diámetro exterior de la funda de catéter alargada 404. En otra realización, el diámetro exterior de la funda de catéter alargada 404 es más pequeño que el diámetro interior de la protuberancia 408. Por ejemplo, el diámetro exterior de la funda de catéter
5 alargada 404 puede ser de entre 0,0538 y 0,0542 pulgadas.

La protuberancia 408 puede ser una banda que se fija a y rodea la funda de catéter alargada. La protuberancia puede fijarse a la funda de catéter alargada 404 mediante una variedad de mecanismos incluyendo adhesivo y engaste. En una realización, la
10 protuberancia 408 está formada de un material que es lo suficientemente fuerte para resistir la deformación durante el funcionamiento del conjunto de catéter de suministro, pero lo suficientemente maleable para ser adecuada para su sujeción. Por ejemplo, el acero inoxidable posee una resistencia y una maleabilidad adecuadas. En una realización, sólo un extremo distal 410 de la banda se sujeta sobre la funda de catéter alargada, como
15 se ilustra en la figura 8. Esto deja el extremo proximal, con el diámetro exterior original entre 0,0575 y 0,0580 pulgadas, para actuar como la parte de interferencia macho que interfiere con el diámetro interior de tope de retención 312, que funciona como una parte de la parte de interferencia hembra. Aunque una realización de protuberancia 408 se describe en detalle en la figura 8 en relación operable con el talón 304A, se entiende que
20 la protuberancia 408 puede estar en relación operable con otros topes mecánicos rebordeados, tales como los ilustrados en las figuras 9 a 11C.

Todavía con referencia a la figura 8, el talón 304A puede estar formado de una variedad de materiales y tener una variedad de formas y tamaños para realizar una variedad de
25 funciones. En un aspecto, el talón 304A puede ser de tamaño y forma más grande que el diámetro interior (ID) de una abertura de puerto de acceso correspondiente a un canal de trabajo o extremo perforable de una tapa de sellado si está presente para actuar como un mecanismo de tope que controla la profundidad de inserción del manguito protector de la punta 300 en el canal de trabajo. En un aspecto, el talón 304A puede realizar la función

como un asa para la sujeción por parte del operador. En otro aspecto, el talón 304A puede incluir un tope de retención 312 que funciona como parte de la parte de interferencia hembra. En una realización, el talón 304A tiene un diámetro exterior de aproximadamente 0,112 pulgadas. La porción distal 308 del talón 304A puede tener un diámetro interior de aproximadamente 0,070 y puede estar unido al diámetro exterior del árbol alargado 302. El tope de retención 312 puede tener un diámetro interior que es menor que un diámetro exterior del extremo proximal de la protuberancia 408. Por ejemplo, el tope de retención 312 puede tener un diámetro interior de entre 0,0565 y 0,0575 pulgadas. En tal realización, el tope de retención 312 tiene una altura que se extiende desde el diámetro interior del tope de retención 312 al diámetro interior de la porción distal 308 del talón 304, o aproximadamente 0,013 pulgadas.

De acuerdo con realizaciones de la invención, el manguito protector de la punta 300 puede bloquearse en el conjunto de catéter de suministro 400. El árbol 302 puede ser utilizado para perforar una tapa de cierre y proteger la punta del inserto 406, la funda de catéter alargada 404 o el alambre de guía durante la inserción en el canal de trabajo y más allá de una abrazadera de la válvula de un sistema de histeroscopia. En una realización, el árbol 302 y la funda de catéter alargada 404 pueden ser avanzadas en un canal de trabajo de un sistema de histeroscopia sin permitir que una cantidad significativa de fluido (por ejemplo solución salina) salpique hacia atrás o se escape del conjunto de catéter de suministro. La funda de catéter alargada 404 puede, además, deslizarse a través del árbol 302 para suministrar el inserto 406 a un lumen del cuerpo, mientras que el conjunto de catéter de suministro 400 no permite una cantidad significativa de fugas de fluido. Haciendo referencia ahora a la figura 12A, el árbol 302 puede perforar el extremo perforable 232 de una tapa de cierre 230 con la punta del árbol 306. El diámetro exterior del árbol 302 puede encajar de manera ajustada en el extremo perforable 232, creando de manera efectiva un sello estanco al agua entre la tapa de cierre 230 y el manguito protector de la punta 300.

La reducción del fluido que salpica hacia atrás y de las fugas también se puede lograr mediante el control de la forma y de las dimensiones del manguito protector de la punta 300, ya que interactúa con la funda de catéter alargada 404 y la protuberancia 408. En una realización, el árbol 302 puede ser de aproximadamente 2,82 pulgadas de largo desde el extremo proximal al extremo distal de la punta 306, que pueden estar en ángulo. El árbol 302 puede tener un diámetro interior entre 0,0585 y 0,0605 pulgadas y un diámetro exterior entre 0,0690 y 0,0710 pulgadas. El diámetro interior del árbol 302 se puede seleccionar para no permitir que el fluido fluya en dirección proximal entre el árbol 302 y la funda de catéter alargada 404 (y la protuberancia 408), mientras que todavía permite para la funda de catéter alargada 404 se deslice y avance a través del árbol 302. En tal realización, un espacio libre mínimo entre el diámetro interior del árbol alargado 302 (por ejemplo, 0,059 pulgadas) y el diámetro exterior de la funda del catéter alargado 404 (por ejemplo, 0,055 pulgadas) proporciona una resistencia suficiente a las salpicaduras hacia atrás y las fugas. Este espacio libre mínimo puede ser eficaz para la superposición de diámetros constantes del árbol alargado 302 y la funda de catéter alargada 404.

Haciendo referencia ahora a la figura 9, se ilustra una realización del manguito protector de la punta 300B. Como se ilustra en la figura 9, el manguito protector de la punta 300B incluye un árbol alargado 302, un talón 304B y un árbol interior 320. El manguito protector de la punta 300B opera de manera similar como el manguito protector de la punta 300, con una diferencia que el tope de retención 322 es el extremo distal del árbol interior 320. En una realización de este tipo, la forma y las dimensiones del manguito protector de la punta 300B se controlan de modo que la protuberancia 408 interfiere con el movimiento del extremo distal, el tope de retención 322 del árbol interior 320. En tal realización, el talón 304B puede dimensionarse y conformarse para actuar como un mecanismo de tope que controla la profundidad de inserción del manguito protector de la punta 300B en el canal de trabajo y puede realizar la función como un asa para la sujeción por parte del operador.

Haciendo referencia ahora a la figura 10, se ilustra otra realización del manguito protector de la punta 300C. Como se ilustra en la figura 10, el manguito protector de la punta 300C incluye un árbol alargado 302, una porción de cuello 332, y una porción abombada 304C. El manguito protector de la punta 300C opera de manera similar como los manguitos protectores de la punta 300 y 300B. Una diferencia es que la parte de cuello 332 funciona como tope de retención para la protuberancia 408. La parte de cuello 332 puede estar formada integralmente con el árbol alargado 302 o ser un elemento separado unido al diámetro interior del árbol alargado 302. Asimismo, la parte abombada 304C puede estar formada integralmente con el árbol alargado 302 o ser un elemento separado unido al diámetro exterior del árbol alargado 302. En dicha realización, la parte abombada 304C puede dimensionarse y conformarse para actuar como un tope mecánico rebordeado que controla la profundidad de inserción del manguito protector de la punta 300C en el canal de trabajo y puede realizar la función como un asa para su sujeción por parte del operador.

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También se contemplan realizaciones de la invención en las que la funda de catéter alargado 404 no tiene un diámetro exterior constante a lo largo de su longitud. De acuerdo con algunas realizaciones, el manguito protector de la punta 300 puede incluir un cambio en el diámetro interior o una válvula para acomodar las variaciones en el diámetro exterior de la funda de catéter alargada 404, o para sellar de manera más eficaz una funda de catéter alargada 404 con un diámetro exterior constante. Haciendo referencia de nuevo a la figura 9, el árbol interior 320 se ilustra como que tiene un diámetro más pequeño que el diámetro interior de árbol alargado 302. Además de funcionar como una parte de interferencia, el diámetro interior del árbol interior 320 puede acomodar más eficazmente una reducción en el diámetro exterior de la funda de catéter alargado 404. Haciendo referencia de nuevo a la figura 10, el diámetro interior de la porción de cuello 332 también puede acomodar de manera más efectiva una reducción de diámetro exterior de la funda de catéter alargada 404 además de funcionar como una parte de interferencia. Por lo tanto, un espacio libre mínimo entre el diámetro interior de árbol interior 320 o el diámetro

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interior de la porción de cuello 332 y el diámetro exterior del árbol de catéter alargado 404 puede proporcionar una resistencia mejorada a que el fluido salpique hacia atrás.

Las figuras 11A a 11C son ilustraciones de realizaciones de un manguito protector de la punta que incorpora diversas válvulas de sellado para reducir la cantidad de fluido que salpica hacia atrás y las fugas entre el manguito protector de la punta y la funda alargada del conjunto del catéter de suministro. Si bien se ilustra por separado, se entiende que las realizaciones ilustradas en las figuras 11A a 11C se pueden combinar con otras realizaciones de la invención. Más específicamente, cualquiera de las válvulas de sellado descritas en referencia a las ilustraciones en las figuras 11A a 11C se puede combinar con cualquiera de las realizaciones que describen también las posiciones de tope proximal y de tope distal.

La figura 11A es una ilustración de un manguito protector de la punta 300D que incluye un árbol alargado 302, un alojamiento 304D, y una válvula 340. El alojamiento 304D puede funcionar como un mecanismo de tope que controla la profundidad de inserción del manguito protector de la punta 300D en el canal de trabajo y puede realizar la función como un asa para su sujeción por parte del operador. El árbol alargado 302 puede estar acoplado a una punta distal 342 del alojamiento 304D, que puede funcionar como un tope de retención para la interferencia con una protuberancia 408 fijada en la funda de catéter alargada 404 en la posición de tope distal. El alojamiento 304D adicionalmente aloja la válvula 340 que es capaz de acomodar múltiples variaciones de diámetro exterior de la funda del catéter alargada 404. Por ejemplo, la válvula 340 puede ser una válvula de silicona que contiene una hendidura en el extremo distal, que permite que un árbol de catéter pase a través de la misma. El material de silicona puede permitir que la hendidura se adapte a diferentes formas o diámetros mientras proporciona un sello. Debido a la geometría en el extremo distal de la válvula de silicona, cuando el fluido intenta pasar desde el extremo distal al proximal, el extremo de la válvula puede ser empujada para cerrarse debido a un chafán en el extremo de la válvula.

La figura 11B es una ilustración de un manguito protector de la punta 300E que incluye un árbol alargado 302, un alojamiento 304E, y una válvula de compresión 350 que incluye una tapa roscada 354 que se puede enroscar hacia sobre una junta 352 para comprimirla
5 contra la funda de catéter alargada 404. El alojamiento 304E puede funcionar como un mecanismo de tope que controla la profundidad de inserción del manguito protector de la punta 300E en el canal de trabajo y puede realizar la función como un asa para su sujeción por parte del operador. El árbol alargado 302 puede estar acoplado a una punta distal 342 del alojamiento 304E, que puede funcionar como un tope de retención para la
10 interferencia con una protuberancia fija en la funda de catéter alargada en la posición de tope distal.

La figura 11C es una ilustración de un manguito protector de la punta 300F que incluye un árbol alargado 302, un alojamiento 304F, y una válvula de compresión 360 que incluye
15 una tapa 362, un muelle de compresión 364 y un tubo de pared delgada (no ilustrado) dentro del alojamiento. Por ejemplo, el tubo de pared delgada puede estar hecho de un material tal como silicona. Las roscas entre la tapa 362 y el alojamiento 304F aplican un movimiento de giro al tubo. Cuando se gira el tubo, un diámetro interior del tubo se aprieta como un iris. El muelle de compresión 364 mantiene la tapa 362 extendida y las roscas
20 mantienen el giro o mantienen el iris cerrado. Cuando la tapa 362 se empuja hacia el alojamiento 304F (muelle comprimido), la tapa 362 se desenrolla y el iris se abre. De esta manera, la apertura del iris se puede ajustar sobre la base del diámetro exterior de la funda de catéter alargada 404. De manera similar a los manguitos protectores de la punta 300D y 300E, el alojamiento 304F puede funcionar como un mecanismo de tope que
25 controla la profundidad de inserción del manguito protector de la punta 300F en el canal de trabajo y puede realizar la función como un asa para su sujeción por parte del operador. El árbol alargado 302 puede estar acoplado a una punta distal 342 del alojamiento 304F que puede funcionar como un tope de retención para la interferencia con una protuberancia fija en la funda de catéter alargada en la posición de tope distal.

Un conjunto de catéter de suministro, de acuerdo con realizaciones de la invención, se puede utilizar para suministrar un inserto en una vía ovárica (por ejemplo, una trompa de Falopio) de un cuerpo femenino. El conjunto de catéter de suministro puede proteger la

5 punta de una funda de catéter alargada, alambre de guía, o insertarse durante la perforación de una tapa de cierre y insertarse en el canal de trabajo y más allá de una abrazadera de la válvula de un sistema de histeroscopia y reducir la cantidad de fluido que salpica hacia atrás y fugas asociadas con la inserción de un conjunto de catéter de suministro en el canal de trabajo de un sistema de histeroscopia. En una realización, el

10 conjunto de catéter de suministro incluye un dispositivo de control, una funda de catéter alargada que tiene un extremo distal y un extremo proximal conectado al dispositivo de control, y un manguito protector de la punta de bloqueo sobre la funda de catéter alargada y deslizable sobre una longitud de la funda de catéter alargada entre una posición de tope proximal y una posición de tope distal a lo largo de la funda de catéter alargada. El

15 conjunto de catéter de suministro puede incluir además un inserto dispuesto de forma liberable dentro de la funda de catéter alargada. En una realización, el inserto se extiende distalmente más allá de la funda de catéter alargada. En una realización, el inserto incluye una curva preformada, como se ilustra en la figura 5, que puede ser utilizada para ayudar en la navegación a través de una porción curvada de una trompa de Falopio. Después de

20 proporcionar el conjunto de catéter de suministro, el operador puede sujetar un tope mecánico rebordeado 304 u otra parte adecuada del manguito protector de la punta 300 para colocar el manguito protector de la punta en la posición de tope distal que se ilustra en la figura 6. Si una válvula de sellado está presente en el manguito protector de la punta 300, la válvula de sellado a continuación puede apretarse sobre la funda de catéter

25 alargada 404 si es necesario para proporcionar un cierre hermético óptimo para proteger contra el fluido que salpica hacia atrás y fugas.

Haciendo referencia ahora a las figuras 12A a 12C, el operador puede entonces perforar un extremo perforable 232 de una tapa de cierre 230 con el manguito protector de la

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punta 300 e insertar el manguito protector de la punta 300 a través de un puerto de acceso 206 de un sistema de histeroscopia 200 y en el canal de trabajo 202 del sistema de histeroscopia. Durante la inserción, el manguito protector de la punta 300 se puede avanzar más allá de una abrazadera de la válvula 208 del sistema de histeroscopia. El manguito protector de la punta protege contra la posibilidad de que la parte expuesta del inserto 406 se capture sobre la abrazadera 208 de la válvula y comprometer la integridad del inserto. De acuerdo con realizaciones de la invención, el extremo distal 410 de la funda de catéter alargada 404 y el inserto 406 se insertan a través de la tapa de cierre 230 y el puerto de acceso 206, y en el canal de trabajo 202 del sistema de histeroscopia simultáneamente con el manguito protector de la punta 300 en la posición de tope distal. La inserción simultánea del manguito protector de la punta 300 y la funda de catéter alargada 404 puede evitar un problema de que el fluido salpique hacia atrás asociado con la inserción secuencial de un introductor seguido por una funda de catéter alargada. En una realización, el manguito protector de la punta 300 puede ser avanzado en el canal de trabajo simultáneamente con la funda de catéter alargada y el inserto 406 hasta que el tope mecánico rebordeado 304 se apoya contra el puerto de acceso 206 o la tapa de cierre 230, si está presente, como se ilustra en la figura 12B.

El extremo distal 410 de la funda de catéter alargada 404 puede entonces ser avanzada más allá del sistema de histeroscopia 200 como se ilustra en la figura 12C, y en una posición objetivo con el lumen del cuerpo. El inserto 406 puede entonces desplegarse en el lumen del cuerpo. Dependiendo de las preferencias del operador, el manguito protector de la punta 300 puede permanecer insertado en el canal de trabajo 202 durante los procedimientos de avance de la funda de catéter alargada 404 y de despliegue o retirada del inserto 406 del canal de trabajo 202. De acuerdo con muchas realizaciones de la invención se entiende que el manguito protector de la punta 300 está bloqueado de forma permanente sobre la funda de catéter alargada. También se contempla que el manguito protector de la punta 300 podría eliminarse del conjunto de catéter después de avanzar inicialmente el conjunto de catéter en el canal de trabajo, por ejemplo, mediante la

inclusión de una junta de desgarro en el manguito protector de la punta, en la que el manguito protector de la punta puede separarse manualmente de la funda de catéter alargada por parte del operador.

5 En una realización, el inserto 406 y el extremo distal 410 de la funda de catéter alargada 404 se hacen avanzar a la posición objetivo dentro del lumen del cuerpo mientras el tope mecánico rebordeado 304 en el manguito protector de la punta 300 topa con el puerto de acceso 206 o la tapa de cierre 320, si está presente. La cantidad de la funda de catéter alargada 404 que se extiende entre el tope mecánico rebordeado 304 y el dispositivo de control 402 puede depender del procedimiento y de la anatomía del paciente. Se prevé que se produzcan circunstancias donde el operador pueda desear insertar toda la longitud de trabajo disponible de la funda de catéter alargada 404 en el paciente y avanzar el dispositivo de control 402 completamente hasta el puerto de acceso o la tapa de cierre, si está presente. De acuerdo con realizaciones de la invención ilustradas en las figuras 5B a 10 5D, esto puede ser posible mediante la inclusión de una cavidad 420 en el dispositivo de control 402 para acomodar el tope mecánico rebordeado 304. 15

Una vez que el inserto 406 se despliega en el lumen del cuerpo, el conjunto de catéter de suministro puede ser retirado del canal de trabajo del sistema de histeroscopia. En una 20 realización, durante la retirada del conjunto de catéter de suministro 400 del canal de trabajo, la protuberancia 408 en la funda de catéter alargada 404 puede retirarse proximalmente contra el tope de retención del manguito protector de la punta 300 y hacer que el manguito protector de la punta 300 se retire del canal de trabajo 202 del sistema de histeroscopia 200. En otra realización, el tope mecánico rebordeado 304 en el manguito protector de la punta 300 se puede fijar al dispositivo de control 402. De esta manera, 25 durante la retirada del conjunto de catéter de suministro 400 del canal de trabajo, el manguito protector de la punta 300 queda sujetado al dispositivo de control 402.

En la memoria anterior se han descrito diversas realizaciones de la invención. Sin

embargo, será evidente que varias modificaciones y cambios se pueden hacer en la misma sin apartarse del espíritu y del alcance más amplio de la invención como se expone en las reivindicaciones adjuntas. La memoria y los dibujos, en consecuencia, deben considerarse en un sentido ilustrativo en lugar de en un sentido restrictivo. Por lo

5 tanto, el alcance de la presente invención está limitado únicamente por las siguientes reivindicaciones.

REIVINDICACIONES

1. Conjunto de catéter de suministro que comprende:
un dispositivo de control;
- 5 una funda de catéter alargada que tiene un extremo distal y un extremo proximal conectado al dispositivo de control; y
un manguito protector de la punta bloqueado sobre la funda de catéter alargada y deslizable sobre una longitud de la funda de catéter alargada entre una posición de tope proximal y una posición de tope distal a lo largo de la funda de catéter alargada.
- 10 2. Conjunto de catéter de suministro de acuerdo con la reivindicación 1, que comprende además un tope de interferencia que determina la posición de tope distal e impide que el manguito protector de la punta se deslice fuera del extremo distal de la funda de catéter alargada.
- 15 3. Conjunto de catéter de suministro de acuerdo con la reivindicación 2, en el que el tope de interferencia comprende una parte de interferencia macho que interfiere con el deslizamiento de una parte de interferencia hembra sobre la funda de catéter alargada.
- 20 4. Conjunto de catéter de suministro de acuerdo con la reivindicación 3, en el que el manguito protector de la punta comprende un árbol alargado y un tope de retención que funcionan juntos como la parte de interferencia hembra, y la parte de interferencia macho está fijada a la funda de catéter alargada.
- 25 5. Conjunto de catéter de suministro de acuerdo con la reivindicación 4, en el que la parte de interferencia macho comprende una protuberancia fijada a la funda de catéter alargada.
6. Conjunto de catéter de suministro de acuerdo con la reivindicación 5, en el que la

protuberancia comprende una banda fijada a, y que rodea, la funda de catéter alargada.

7. Conjunto de catéter de suministro de acuerdo con la reivindicación 6, en el que un extremo distal de la banda está engarzada sobre la funda de catéter alargada, y un extremo proximal de la banda no está engarzada sobre el árbol alargado.

8. Conjunto de catéter de suministro de acuerdo con la reivindicación 4, en el que el tope de retención tiene un diámetro interior que es menor que un diámetro exterior de la parte de interferencia macho.

9. Conjunto de catéter de suministro de acuerdo con la reivindicación 8, que también comprende un talón moldeado fijado a un extremo proximal del árbol alargado.

10. Catéter de suministro de acuerdo con la reivindicación 9, en el que el talón moldeado comprende:
una porción distal que rodea el extremo proximal del árbol alargado;
una porción de resalte que se extiende proximalmente del árbol alargado; y
el tope de retención, en el que el tope de retención topa con el extremo proximal del árbol alargado.

11. Conjunto de catéter de suministro de acuerdo con la reivindicación 8, en el que el manguito protector de la punta también comprende un árbol interior fijado a un extremo proximal del árbol alargado, y el tope de retención es un extremo distal del árbol interior.

12. Conjunto de catéter de suministro de acuerdo con la reivindicación 4, en el que la parte de interferencia macho está fijada a la funda de catéter alargada a una primera distancia desde el extremo distal de la funda de catéter alargada, y en el que el manguito protector de la punta es más largo que la primera distancia, de manera que el manguito protector de la punta se extiende distalmente más allá de la funda de catéter alargada

cuando está en la posición de tope distal.

13. Conjunto de catéter de suministro de acuerdo con la reivindicación 12, que también comprende un inserto dispuesto en el interior y que se extiende distalmente más allá de un extremo distal de la funda de catéter alargada, en el que el manguito protector de la punta se extiende distalmente más allá del inserto cuando está en la posición de tope distal.

14. Conjunto de catéter de suministro de acuerdo con la reivindicación 3, en el que el manguito protector de la punta también comprende una válvula de sellado.

15. Procedimiento de formación de un conjunto de catéter de suministro, que comprende: deslizar un manguito protector de la punta sobre un extremo distal de una funda de catéter alargada y hacia un dispositivo de control; fijar una protuberancia en una región distal de la funda de catéter alargada, en el que la protuberancia impide que el manguito protector de la punta se deslice fuera de un extremo distal de la funda de catéter alargada.

16. Procedimiento de acuerdo con la reivindicación 15, en el que la fijación de una protuberancia en una región distal de la funda del catéter alargada comprende un engaste.

17. Procedimiento de acuerdo con la reivindicación 16, en el que el engaste comprende engastar un extremo distal de una banda sobre la funda de catéter alargada.

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18. Procedimiento de acuerdo con la reivindicación 17, que también comprende no engastar un extremo proximal de la banda en el árbol de catéter alargado.

19. Procedimiento de suministro de un inserto, que comprende:

proporcionar un conjunto de catéter de suministro que comprende:

un dispositivo de control;

una funda de catéter alargada que tiene un extremo distal y un extremo proximal conectado al dispositivo de control;

- 5 un inserto dispuesto de forma liberable dentro de la funda de catéter alargada; y
- un manguito protector de la punta bloqueado sobre la funda de catéter alargada y deslizable sobre una longitud de la funda de catéter alargada entre una posición de tope proximal y una posición de tope distal a lo largo de la funda de catéter alargada;
- colocar el manguito protector de la punta en la posición de tope distal;
- 10 introducir el manguito protector de la punta a través de un puerto de acceso de un sistema de histeroscopia y en un canal de trabajo del sistema de histeroscopia;
- avanzar el extremo distal de la funda de catéter alargada a una posición objetivo dentro de un lumen del cuerpo; y
- desplegar el inserto en el interior del lumen del cuerpo.

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20. Procedimiento de acuerdo con la reivindicación 19, en el que la inserción del manguito protector de la punta comprende, además, avanzar un extremo distal del manguito protector de la punta más allá de una abrazadera de válvula del sistema de histeroscopia.

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21. Procedimiento de acuerdo con la reivindicación 20, en el que la inserción del manguito protector de la punta comprende hacer avanzar el manguito protector de la punta en el canal de trabajo hasta que un tope mecánico rebordeado en el manguito protector de la punta haga tope con el puerto de acceso o una tapa de cierre acoplada al puerto de acceso.

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22. Procedimiento de acuerdo con la reivindicación 21, en el que el extremo distal de la funda de catéter alargada se hace avanzar a la posición objetivo dentro del lumen del cuerpo mientras el tope mecánico rebordeado en el manguito protector de la punta haga tope con el puerto de acceso o la tapa de cierre.

23. Procedimiento de acuerdo con la reivindicación 19, que comprende además retirar el conjunto de catéter de suministro del canal de trabajo después de desplegar el inserto en el interior del lumen del cuerpo.

5

24. Procedimiento de acuerdo con la reivindicación 19, en el que la retirada del conjunto de catéter de suministro del canal de trabajo comprende la retirada de una protuberancia en la funda de catéter alargada de manera proximal contra un tope de retención del manguito protector de la punta para provocar que el manguito protector de la punta se retire del canal de trabajo.

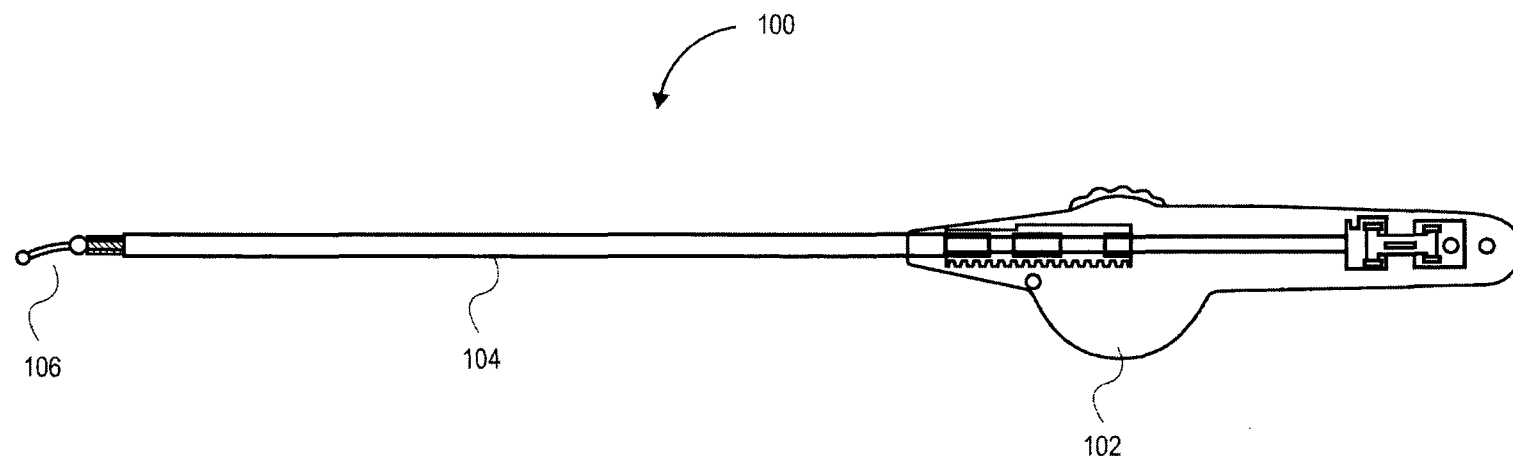
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25. Procedimiento de acuerdo con la reivindicación 19, que comprende además el apriete de una válvula de sellado del manguito protector de la punta sobre la funda de catéter alargada después de colocar el manguito protector de la punta en la posición de tope distal, y antes de insertar el manguito protector de la punta a través del puerto de acceso del sistema de histeroscopia.

15

RESUMEN

Se divulgan conjuntos y procedimientos para insertar un conjunto de catéter de suministro en un canal de trabajo. De acuerdo con algunas realizaciones, se divulga un conjunto de
5 catéter de suministro en el que un manguito protector de la punta está bloqueado en una funda de catéter alargada y es deslizable sobre una longitud de la funda de catéter alargada entre una posición de tope proximal y una posición de tope distal a lo largo de la funda de catéter alargada.



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FIG. 1
(TÉCNICA ANTERIOR)

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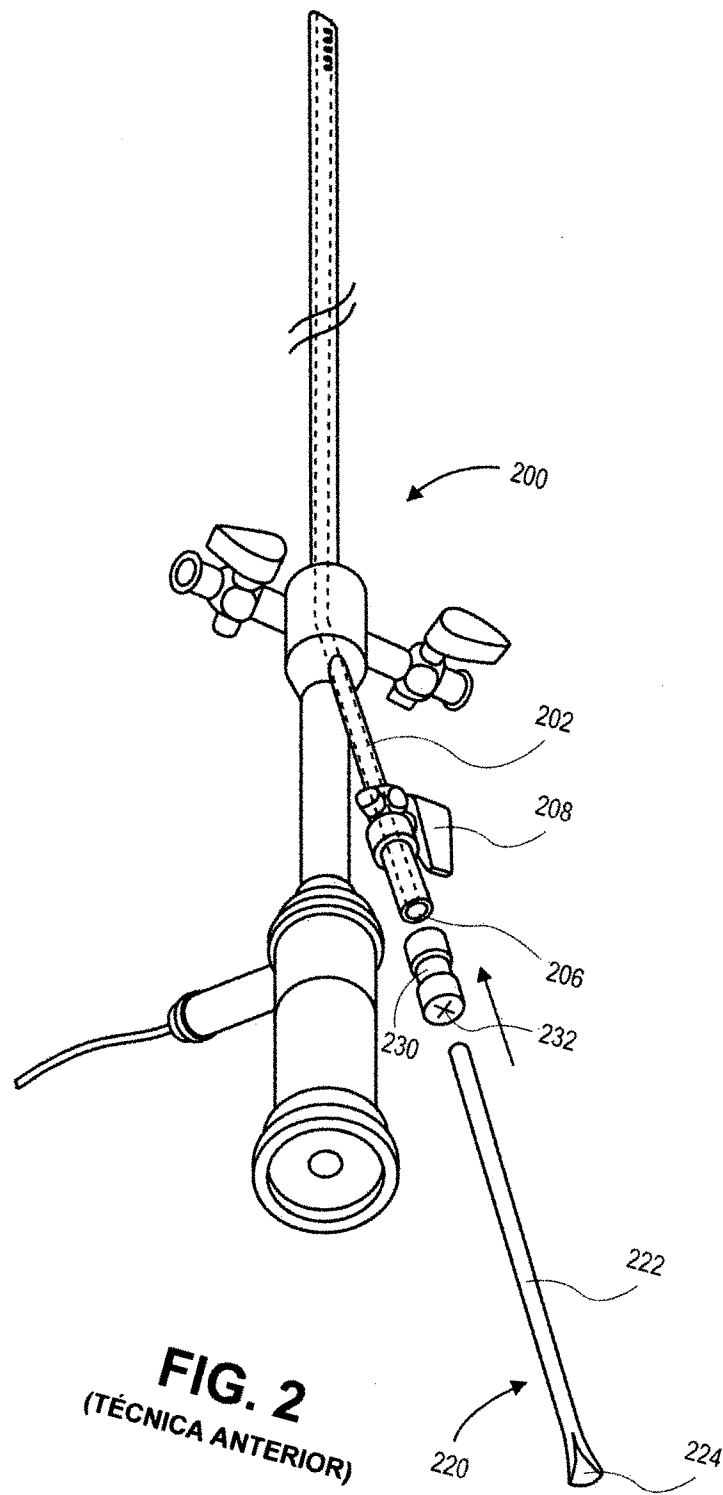
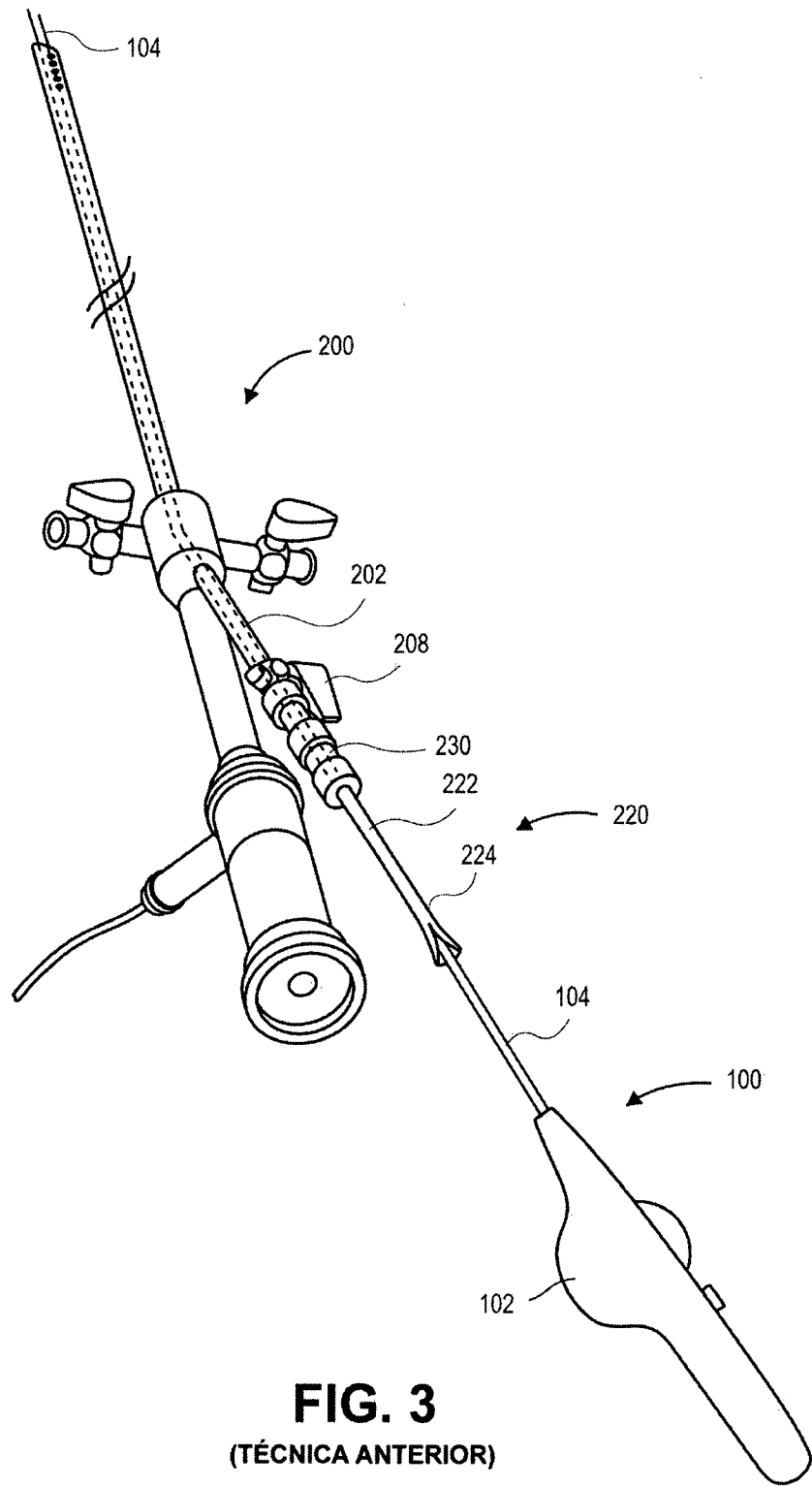


FIG. 2
(TÉCNICA ANTERIOR)

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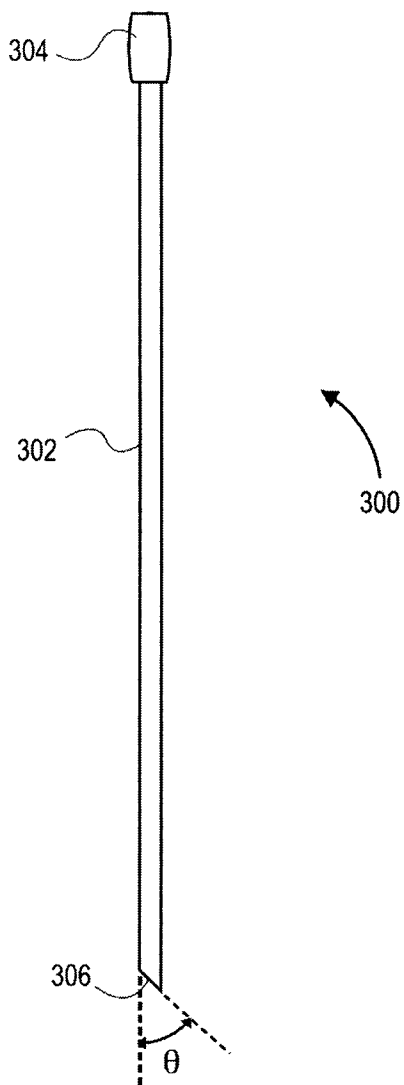


FIG. 4

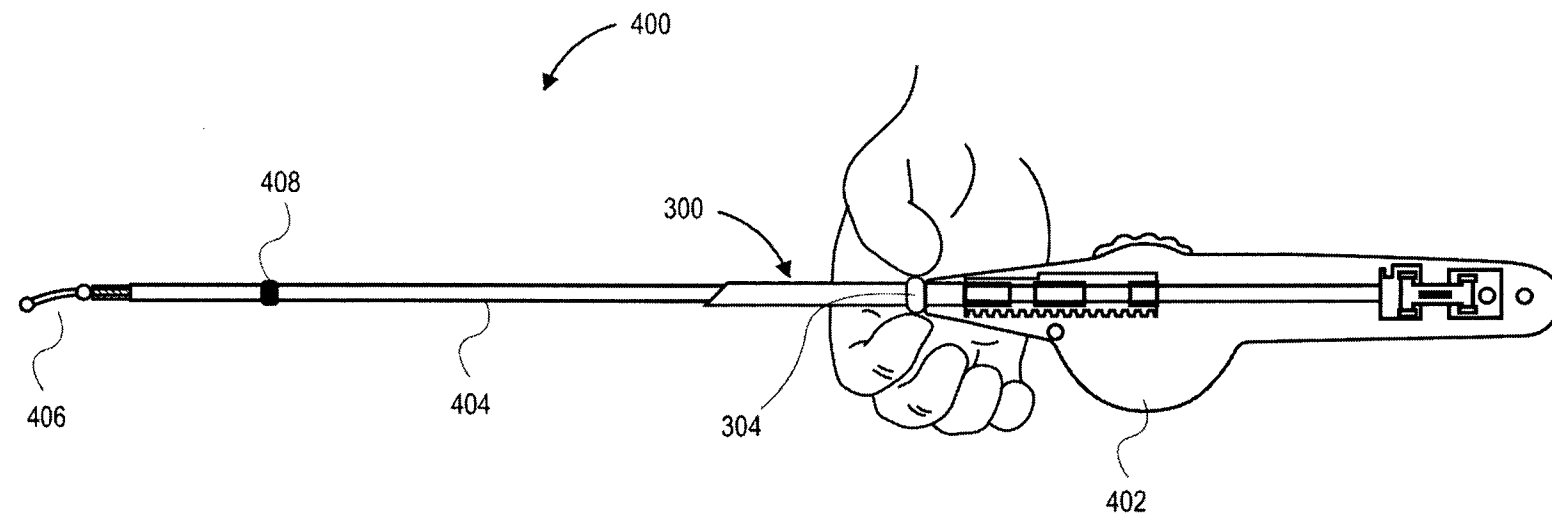


FIG. 5A

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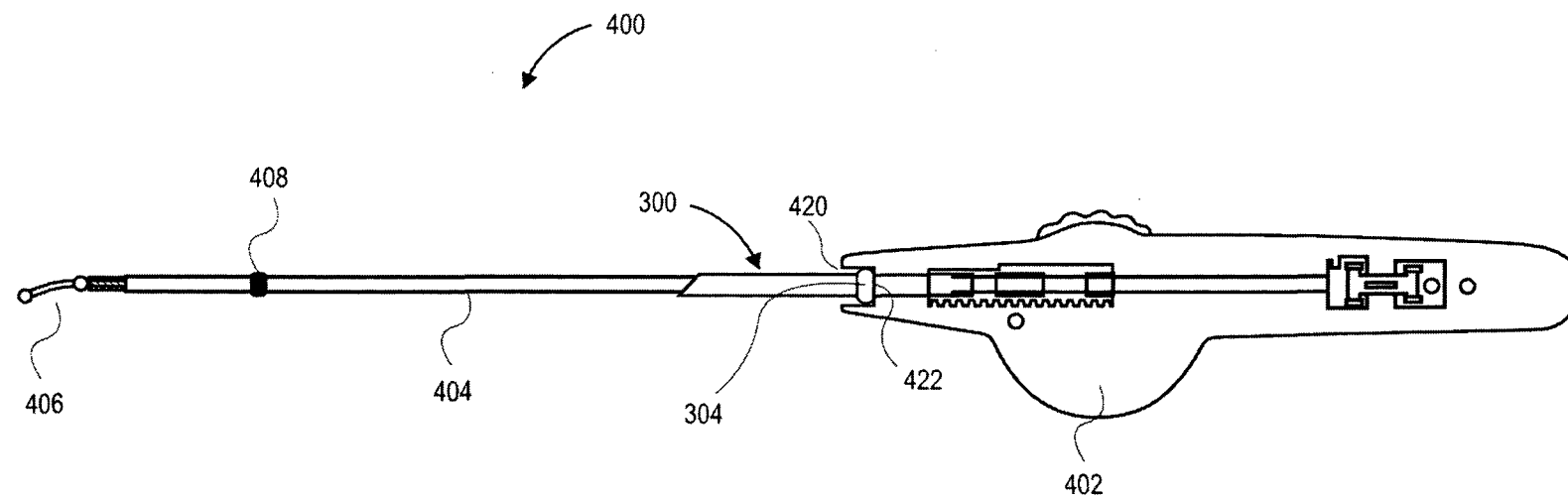


FIG. 5B

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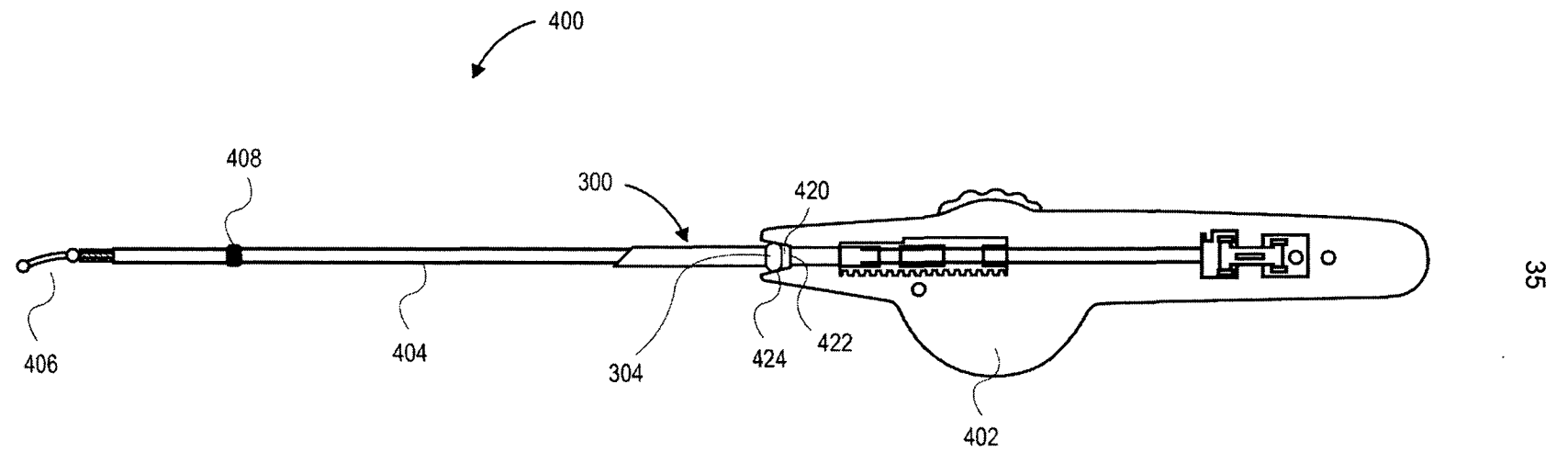
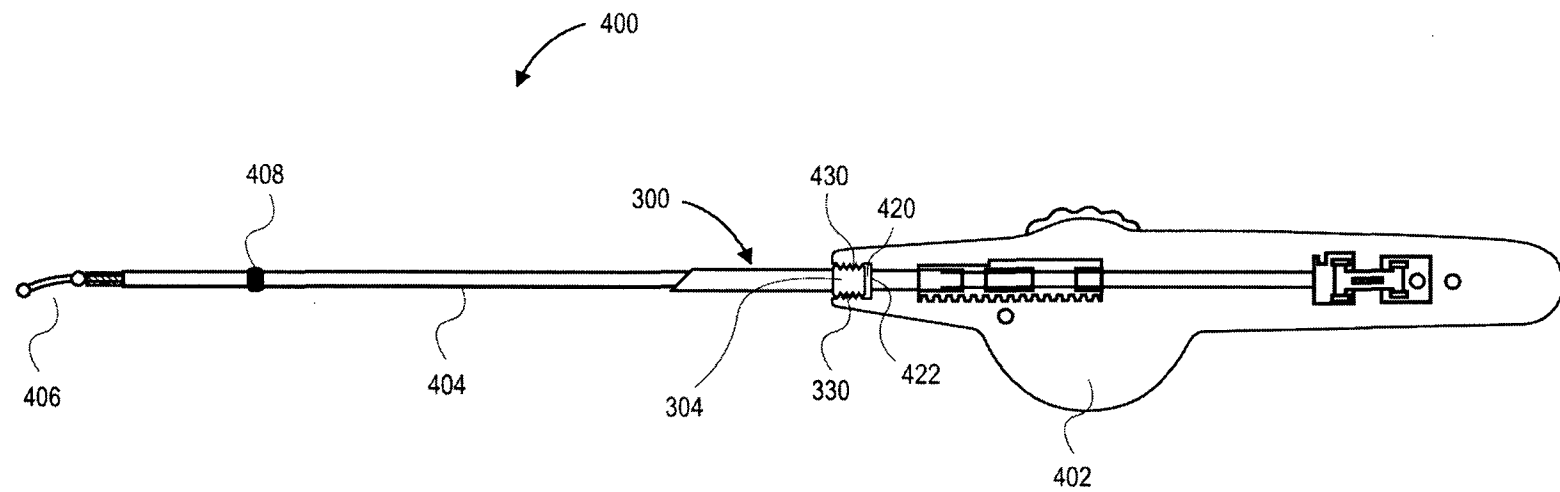


FIG. 5C

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FIG. 5D

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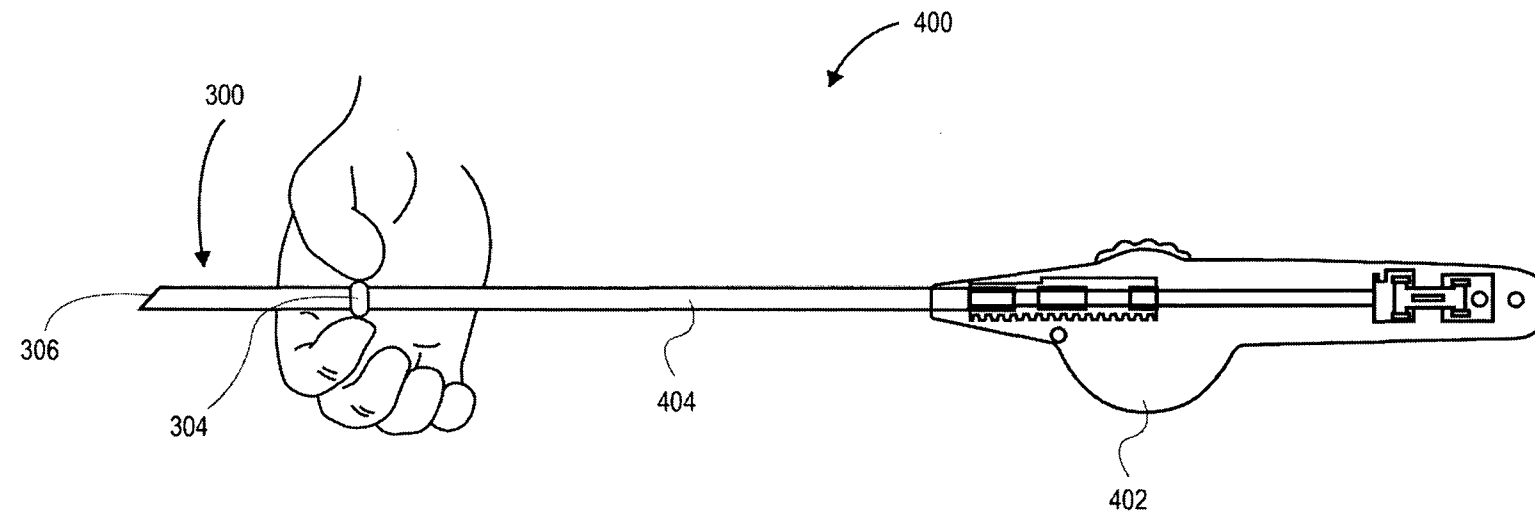


FIG. 6

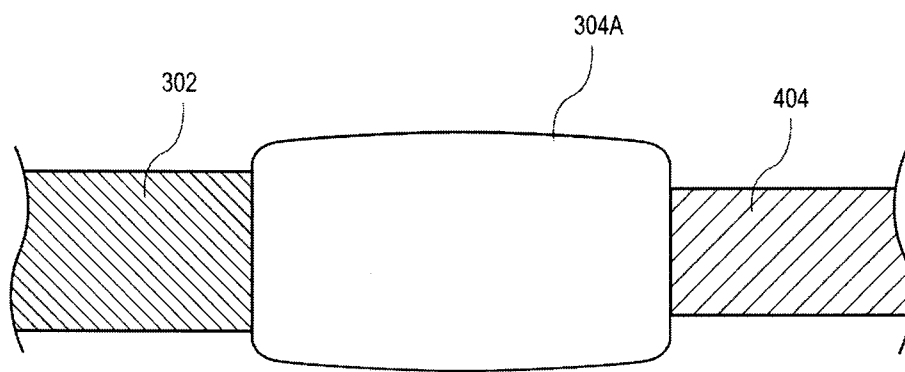


FIG. 7

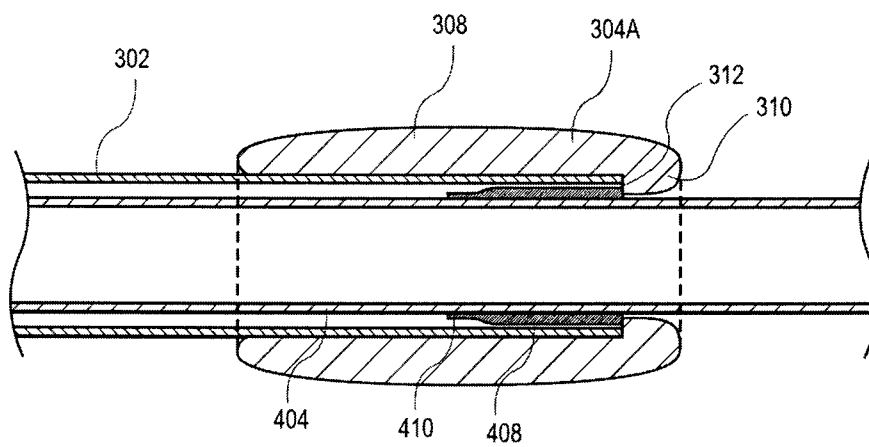


FIG. 8

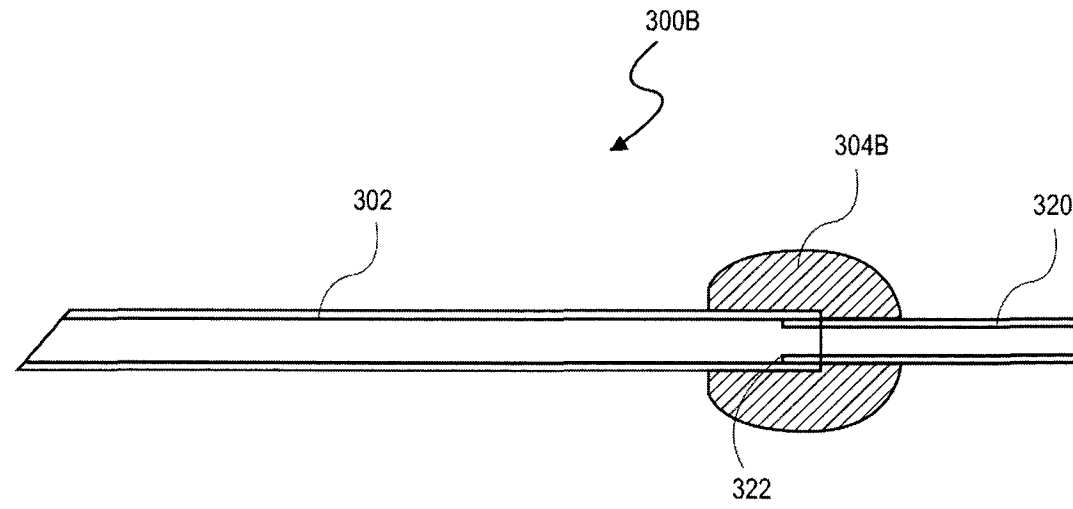


FIG. 9

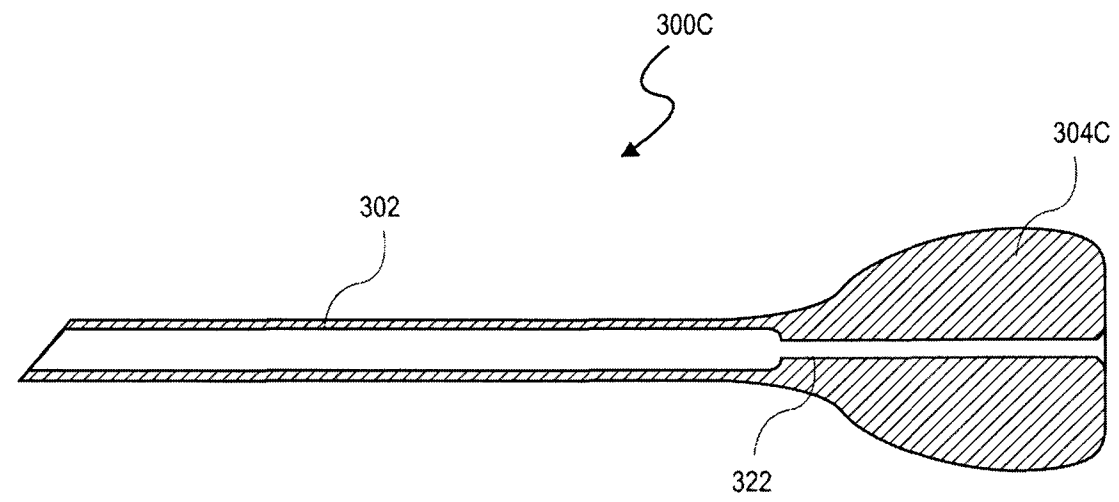


FIG. 10

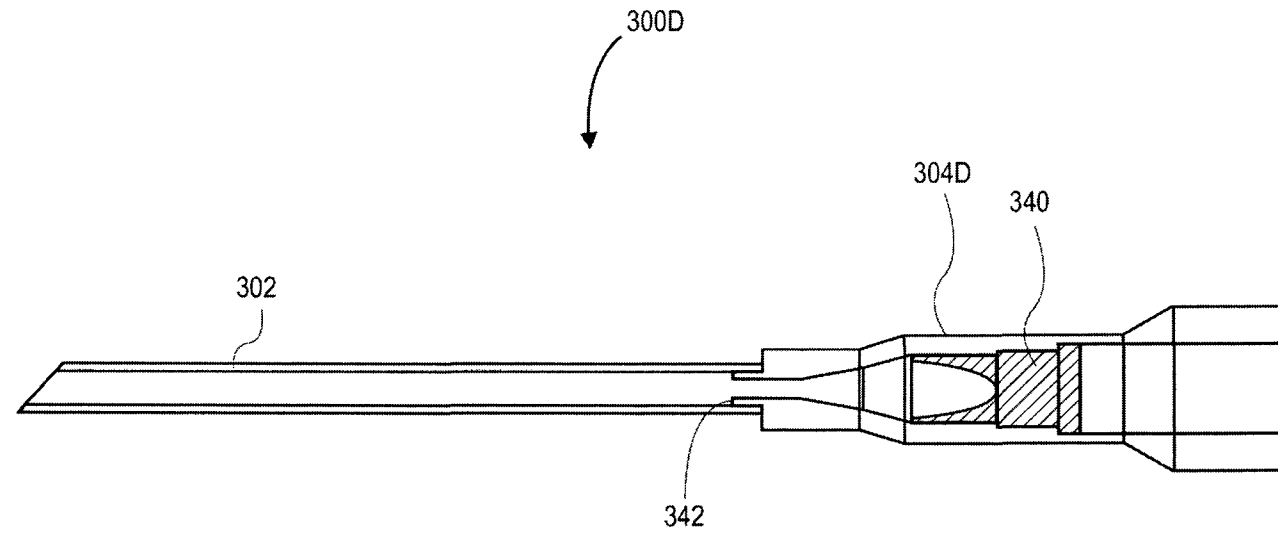


FIG. 11A

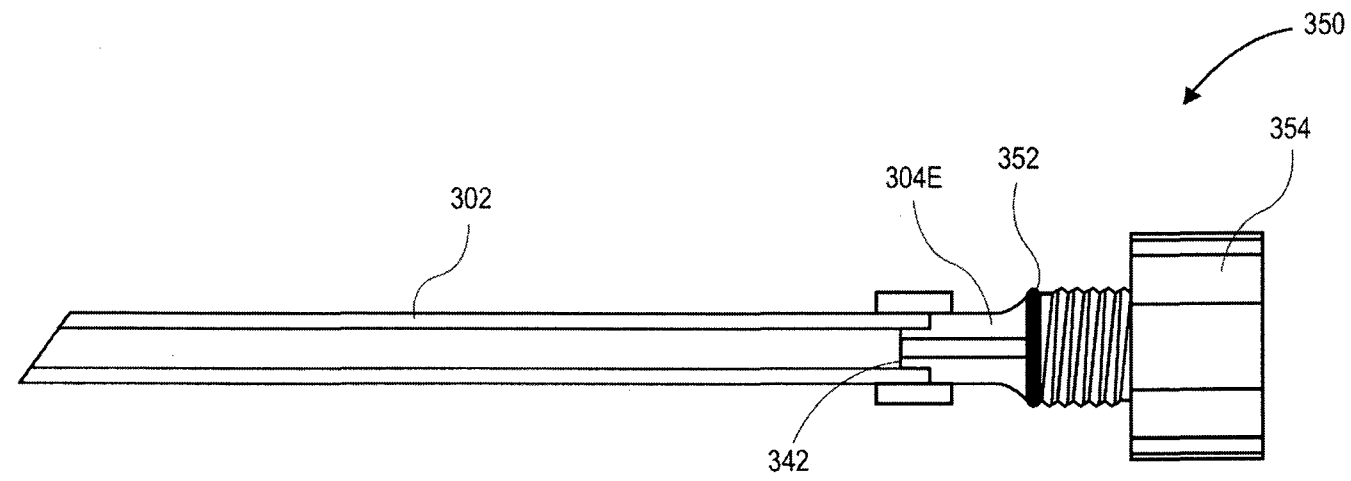


FIG. 11B

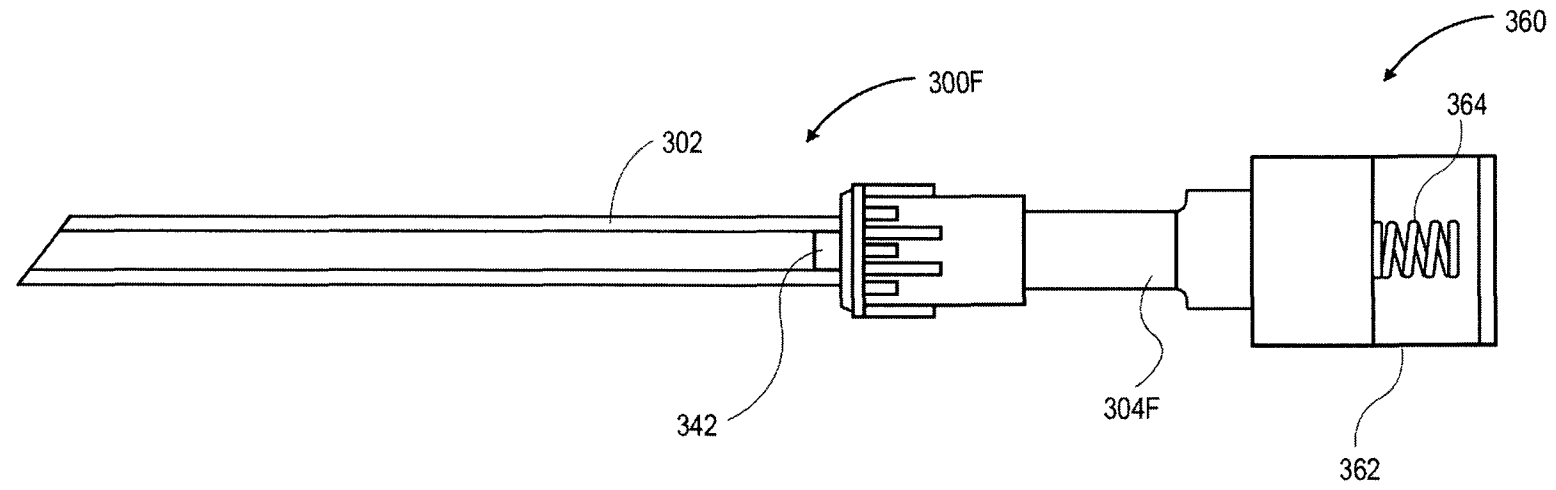


FIG. 11C

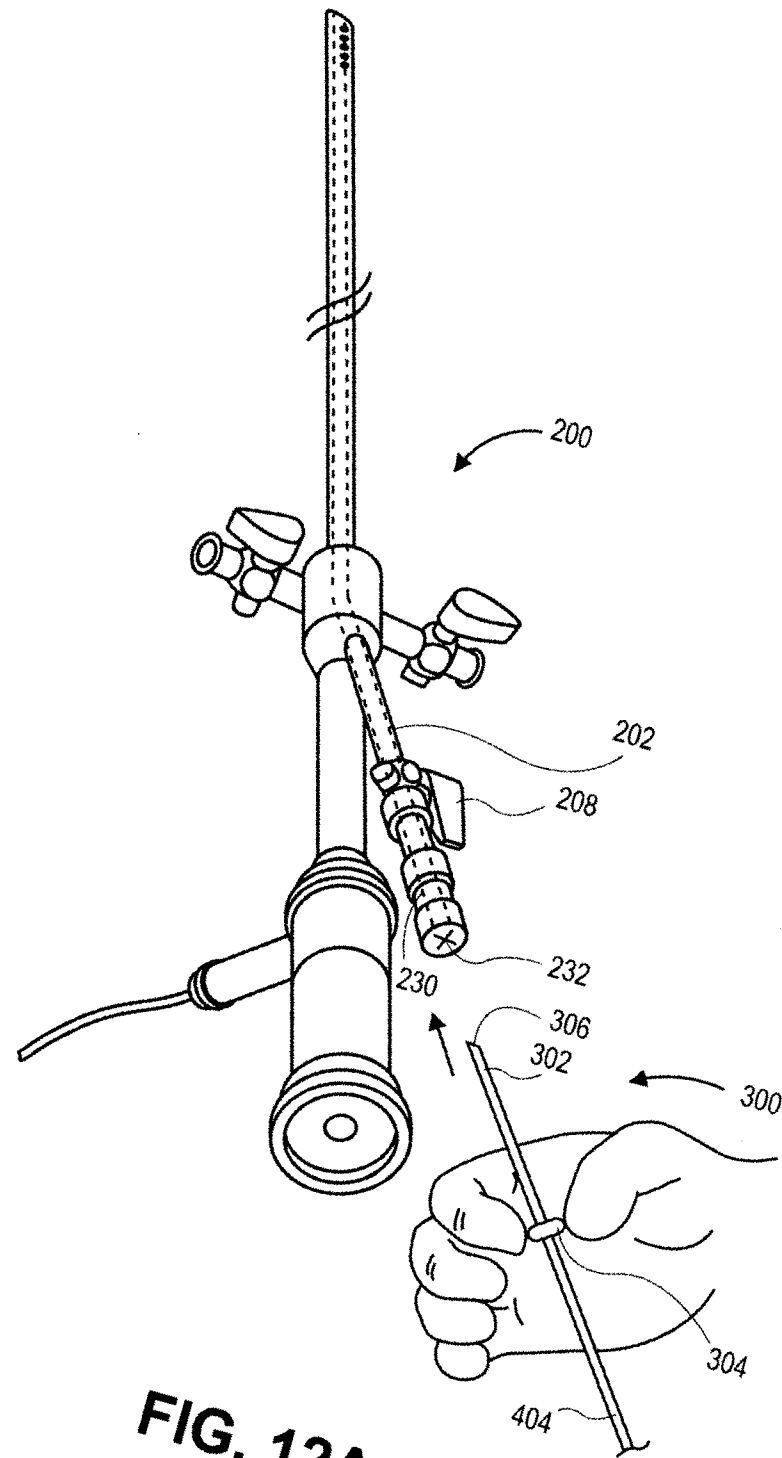
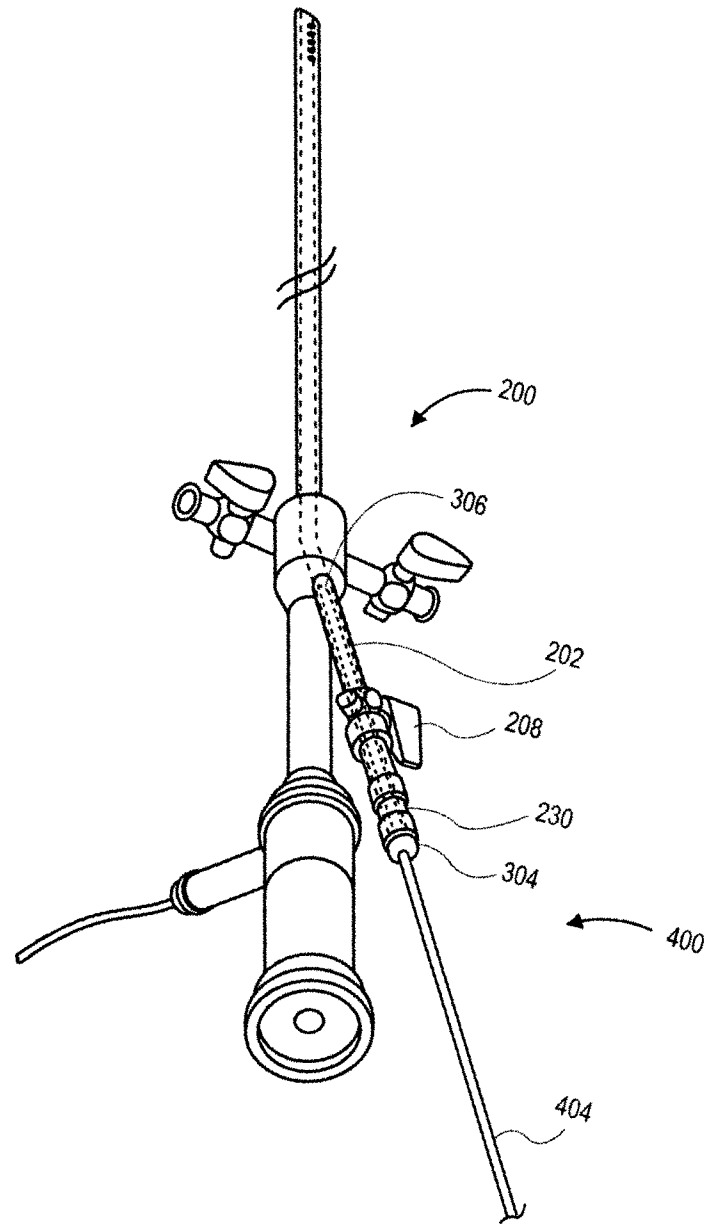
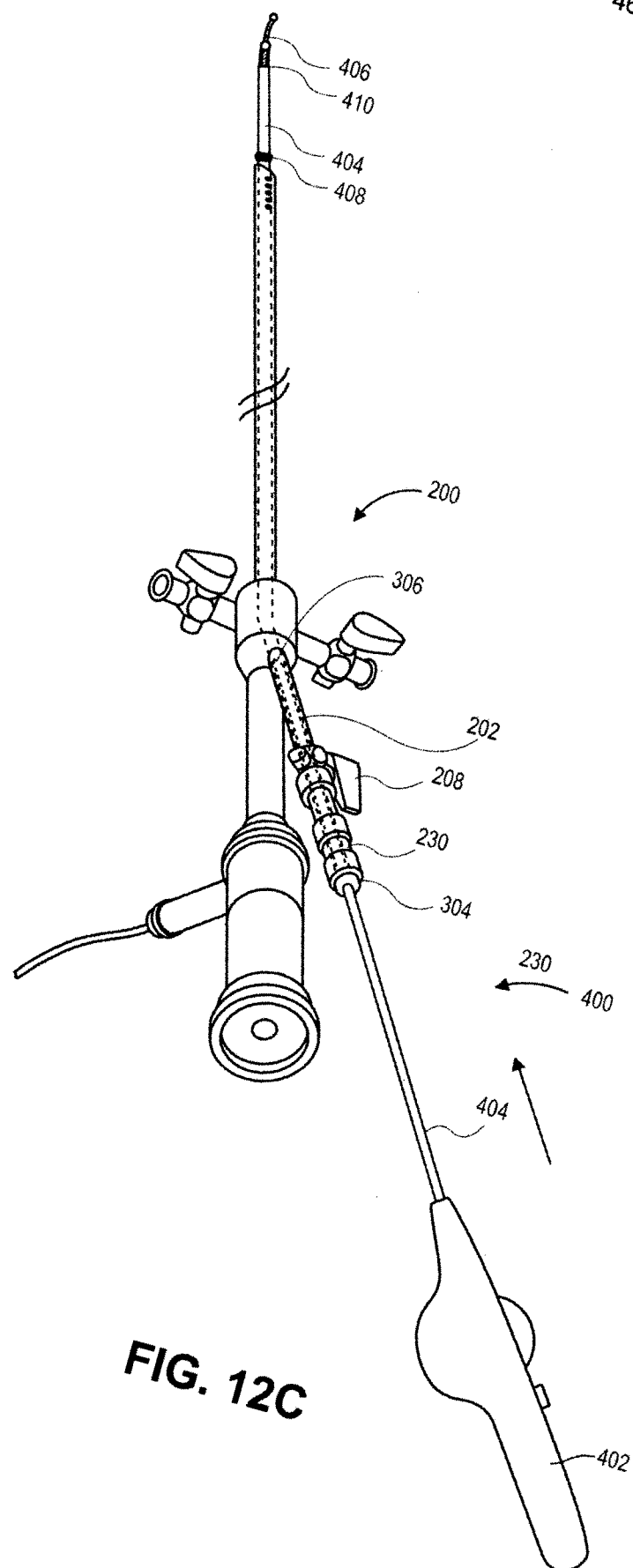


FIG. 12A

**FIG. 12B**

SG



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(71) Applicant (for all designated States except US): **CONCEPTUS, INC.** [US/US]; 331 East Evelyn Avenue, Mountain View, CA 94041 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **STOUT, Christopher, A.** [US/US]; 514 Cherry Avenue, San Bruno, CA 94066 (US). **SWANN, Betsy** [US/US]; 135 Winchester Street, Grass Valley, CA 95945 (US). **CRUZADA, Julian** [US/US]; 809 Auzerais Avenue, Unit 358, San Jose, CA 95126 (US). **SEPE, Chris** [US/US]; 351 West Rincon Avenue, Unit A, Campbell, CA 95008 (US). **SLOAN, Robert, Todd** [US/US]; 14470 Oak Place, Saratoga, CA 95070 (US).
- (74) Agents: **BERNADICOU, Michael, A.** et al.; Blakely, Sokoloff, Taylor & Zafman LLP, 1279 Oakmead Parkway, Sunnyvale, CA 94085-4040 (US).

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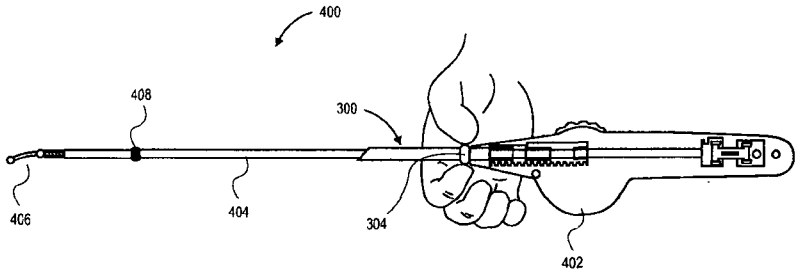


FIG. 5A

(57) Abstract: In accordance with some embodiments, a delivery catheter assembly (400) is disclosed in which a tip protector sleeve (300) is locked onto an elongated catheter sheath (404) and slideable over a length of the elongated catheter sheath between a proximal - stop position (402) and a distal -stop position (408) along the elongated catheter sheath.

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TIP PROTECTOR SLEEVE

BACKGROUND

[0001] Embodiments of the present invention relate to the field minimally invasive surgical medical devices and medical procedures. More specifically, embodiments of the present invention relate to devices and methods used for transcervical gynecological procedures.

[0002] Female contraception and sterilization may be affected by transervically introducing an object into a fallopian tube to inhibit conception. Devices, systems and methods for such a contraceptive approach have been described in various patents and patent applications assigned to the present assignee. For example, U.S. Patent No. 6,526,979, U.S. Patent No. 6,634,361, U.S. Patent Application No. 11/165,733 published as U.S. Publication No. 2006/0293560 and U.S. Patent Application No. 12/605,304 describe transcervically inserting an insert (also referred to as implant and device) into an ostium of a fallopian tube and mechanically anchoring the insert within the fallopian tube. One example of such an assembly is known as "Essure" ® from Conceptus, Inc. of Mountain View, California. Tissue in-growth into the "Essure" ® insert provides long-term contraception and/or permanent sterilization without the need for surgical procedures.

[0003] The insert may be delivered to the fallopian tube with a delivery catheter assembly such as the one illustrated in FIG. 1. The delivery catheter assembly 100 is formed of a control device 102 such as a handle, an elongated sheath 104, and an insert 106. The delivery catheter assembly 100 may be transcervically positioned into the uterus and the fallopian tubes via a hysteroscope system.

[0004] Referring to FIG. 2 the hysteroscope system 200 may include a working channel 202 into which the delivery catheter assembly is inserted. Advancement of the delivery catheter system within the uterus and the fallopian tubes is usually facilitated by distending the uterus with a distention fluid, such as saline, and viewing the placement with the hysteroscope system. A valve clamp 208, such as a ball valve clamp, and an access port 206 are positioned at the tip of the working channel 202. Closing the valve clamp 208 may seal the entrance of the working

channel 202 to prevent a distention fluid from leaking out of the access port 206. A sealing cap 230 including a pierceable end 232 can be placed over the access port 206 to prevent distention fluid from leaking out of the hysteroscope system when a delivery catheter assembly occupies the working channel of the hysteroscope system.

[0005] An introducer 220 may be used in order to prevent damaging the tip the elongated sheath 104 or insert 106 of the delivery catheter assembly 100 during insertion through the pierceable end 232 of the sealing cap 230 and access port 206, and into the working channel 202 of the hysteroscope system 200. Introducer 220 includes a sheath portion 222 and slit opening 224 to aid in grasping and in the removal of the introducer 220. The introducer 220 is inserted through the pierceable end 232 of the sealing cap 230 and into the working channel 202 prior to inserting the delivery catheter assembly 100. When the introducer 220 is inserted through the sealing cap 230, fluid can spray out of the introducer 220 and onto the physician or physician's assistant. The amount of fluid spray-back can be significant depending on the distention fluid pressure during the procedure.

[0006] Referring to FIG. 3, after placing the introducer 220 into the working channel 202, the tip of delivery catheter assembly 100 is inserted into the slit opening 224 and through the sheath 222 of the introducer 220 in order to advance the delivery catheter assembly 100 into the working channel 202 of the hysteroscope system. This is typically performed as soon as possible after placement of the introducer 220 into the working channel 202 in order to minimize the amount of fluid spray-back from the introducer. The introducer 220 may then be removed or may be kept in place throughout the procedure. After insertion of the delivery catheter assembly 100 into the introducer 200, an amount of distention fluid may still leak from between the introducer and elongated sheath 104 of the delivery catheter assembly 100.

SUMMARY

[0007] Embodiments of the present invention generally provide assemblies and methods of inserting a delivery catheter into a working channel of an endoscope, such as a hysteroscope system for accessing a female reproductive system. While

embodiments of the invention are described with reference to a hysteroscope system, it is understood that the embodiments are not limited to such and may also be compatible with other optical surgical devices. In one aspect, embodiments of the invention describe a tip protector sleeve which functions as an introducer and protects the tip of a delivery catheter assembly when piercing a sealing cap, as well as during insertion through an access port, into the working channel and past a valve clamp of a hysteroscope system. In another aspect, embodiments of the invention describe a method and system which may reduce the amount of fluid spray-back and leakage associated with inserting a delivery catheter assembly into the working channel of a hysteroscope system.

[0008] One embodiment of the present invention relates to a delivery catheter assembly which may be used to deliver an insert to an ovarian pathway (e.g. a fallopian tube) of a female body. The delivery catheter assembly may include a control device, an elongated catheter sheath having a distal end and a proximal end connected to the control device, and a tip protector sleeve. The tip protector sleeve may be locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath. The delivery catheter assembly may further include an interference stop which determines the distal-stop position and prevents the tip protector sleeve from sliding off of the distal end of the elongated catheter sheath. For example, the interference stop may include a male interference part which interferes with sliding of a female interference part over the elongated catheter sheath. The male interference part may be fixed to the elongated catheter sheath, and the tip protector sleeve may comprise the female interference part. The tip protector sleeve may additionally incorporate a sealing valve to reduce the amount of fluid spray-back and leakage associated with inserting the delivery catheter assembly into the working channel of a hysteroscope system.

[0009] Another embodiment of the present invention relates to a method of forming a delivery catheter assembly which includes sliding a tip protector sleeve over a distal end of an elongated catheter sheath and toward a control device, and then fixing a bump onto a distal region of the elongated catheter sheath. Alternatively, the bump may be fixed onto the distal region of the elongated catheter sheath, and

then the tip protector sleeve is slid over a proximal end of the elongated catheter sheath toward the bump prior to attaching the control device to the elongated catheter sheath. The control device may prevent the tip protector sleeve from sliding off a proximal end of the elongated sheath and define, in part, a proximal-stop position. The bump may prevent the tip protector sleeve from sliding off of a distal end of the elongated catheter sheath and define, in part, a distal-stop position. In an embodiment, the bump may be fixed onto a distal region of the elongated catheter sheath by crimping a band onto the elongated catheter sheath. It is not necessary to crimp the entire length of the band, and only a proximal end of the band is crimped onto the elongated catheter shaft in an embodiment.

[0010] Another embodiment of the present invention relates to a method of delivering an insert into a body lumen such as an ovarian pathway (e.g. a fallopian tube) of a female body. Utilizing a delivery catheter assembly in accordance with embodiments of the invention the tip protector sleeve is positioned at the distal-stop position, and the tip protector sleeve is inserted through a pierceable end of a sealing cap, through an access port of a hysteroscope system and into a working channel of the hysteroscope system. In accordance with embodiments of the invention, the distal end of the elongated catheter sheath and insert are inserted through the pierceable end of the sealing cap, through the access port and into the working channel of the hysteroscope system simultaneously with the tip protector sleeve in the distal-stop position. The distal end of the elongated catheter sheath and insert may then be advanced through the tip protector sleeve and beyond the hysteroscope system to a target location within the body lumen where the insert is deployed within the body lumen. In an embodiment, the tip protector sleeve is advanced through the sealing cap into the working channel until a flanged mechanical stop, such as a bead or flared portion, abuts the sealing cap (or access port if a sealing cap is not utilized) prior to advancing the elongated sheath and insert to the target location.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 is a cross-sectional side view illustration of a delivery catheter assembly.

- [0012] FIG. 2 is an isometric view illustration of a hysteroscope system and an introducer.
- [0013] FIG. 3 is an isometric view illustration of a delivery catheter assembly inserted into an introducer and working channel of a hysteroscope system.
- [0014] FIG. 4 is a side view illustration of a tip protector sleeve in accordance with an embodiment of the invention.
- [0015] FIG. 5A is a side view illustration of a delivery catheter assembly with a tip protector sleeve at a proximal-stop position in accordance with an embodiment of the invention.
- [0016] FIG. 5B is a side view illustration of a delivery catheter assembly with a flanged mechanical stop of a tip protector sleeve in a cavity of a control device in accordance with an embodiment of the invention.
- [0017] FIG. 5C is a side view illustration of a delivery catheter assembly with a tip protector sleeve fastened into the proximal-stop position by a friction fitting in accordance with an embodiment of the invention.
- [0018] FIG. 5D is a side view illustration of a delivery catheter assembly with a tip protector sleeve screwed into the proximal-stop position in accordance with an embodiment of the invention.
- [0019] FIG. 6 is a side view illustration of a delivery catheter assembly with a tip protector sleeve at a distal-stop position in accordance with an embodiment of the invention.
- [0020] FIG. 7 is a close-up side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention
- [0021] FIG. 8 is a close-up cross-sectional side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention
- [0022] FIG. 9 is a cross-sectional side view illustration of a tip protector sleeve in accordance with an embodiment of the invention.
- [0023] FIG.10 is a cross-sectional side view illustration of a tip protector sleeve in accordance with an embodiment of the invention.

[0024] FIGS. 11A-11C are cross-sectional side view illustrations of tip protector sleeves incorporating various sealing valves in accordance with embodiments of the invention.

[0025] FIGS. 12A-12C are isometric view illustrations of inserting a delivery catheter assembly into a working channel of a hysteroscope system in accordance with an embodiment of the invention.

DETAILED DESCRIPTION

[0026] Embodiments of the present invention generally provide assemblies and methods of inserting a delivery catheter into a working channel of an endoscope, such as a hysteroscope system or other optical surgical device for accessing a female reproductive system. Various embodiments and aspects will be described with reference to details discussed below and the accompanying drawings will illustrate the various embodiments. The following description and drawings are illustrative of the invention and are not to be construed as limiting the invention. Numerous specific details are described to provide a thorough understanding of various embodiments of the present invention. However, in certain instances, well-known or conventional details are not described in order to provide a concise discussion of embodiments of the present invention.

[0027] In an embodiment, a delivery catheter assembly includes a control device, an elongated catheter sheath having a distal end and a proximal end connected to the control device, and a tip protector sleeve. Referring to the FIG. 4 the tip protector sleeve 300 may include an elongated shaft 302, a flanged mechanical stop 304 at a proximal end, and a distal end 306. The distal end 306 can be flat or angled to assist with piercing of a sealing cap. In an embodiment, the distal end 306 has an approximately 45 degree angled tip. Elongated shaft 302 may be formed of a material and to a thickness which can be molded and does not buckle when piercing a sealing cap. For example, elongated shaft 302 may be formed of a material such as polyether ether ketone (PEEK).

[0028] Flanged mechanical stop 304 may provide variety of functions, be formed of a variety of materials and have a variety of shapes and sizes as will be explained in further detail with regard to FIGS. 5A-12C. For example, flanged mechanical stop

304 may be formed of a moldable material such as polycarbonate, or from the same material as the elongated shaft 302. Flanged mechanical stop 304 may be sized and shaped larger than the inside diameter (ID) of a corresponding access port opening to a working channel or pierceable end of a sealing cap if present in order to act as a stop mechanism that controls the insertion depth of the tip protector sleeve 300 into the working channel. Flanged mechanical stop 304 may also be sized and shaped to be gripped by an operator's hand to assist with sliding of the tip protector sleeve 300 over a length of the elongated catheter sheath 404 of a catheter assembly. In this respect, one function may be as a handle at the proximal end of the tip protector sleeve 300. Flanged mechanical stop 304 may also incorporate a sealing valve to reduce the amount of fluid spray-back and leakage associated with inserting the delivery catheter assembly into a working channel.

[0029] Referring to FIGS. 5A-6, a delivery catheter assembly 400 in accordance with embodiments of the invention is illustrated in which the tip protector sleeve 300 is locked onto and slideable over a length of the elongated catheter sheath 404. The delivery catheter assembly 400 may be formed by sliding a tip protector sleeve 300 over a distal end of an elongated catheter sheath 404 and toward a control device 402, and then fixing a bump 408 onto a distal region of the elongated catheter sheath 402. Alternatively, the bump 408 may be fixed onto the distal region of the elongated catheter sheath 402, and then the tip protector sleeve 300 is slid over a proximal end of the elongated catheter sheath 402 toward the bump 408 prior to attaching the control device 402 to the elongated catheter sheath 402. The control device 402 may prevent the tip protector sleeve 300 from sliding off a proximal end of the elongated sheath 402 and define, in part, a proximal-stop position. The bump 408 may prevent the tip protector sleeve 300 from sliding off of a distal end of the elongated catheter sheath 402 and define, in part, a distal-stop position. An operator may grip the flanged mechanical stop 304 by hand, for example between a thumb and index finger, and slide the tip protector sleeve over the elongated catheter sheath 404 between the proximal-stop and distal-stop positions.

[0030] FIG. 5A is an illustration of the tip protector sleeve 300 positioned at a proximal-stop position. In the embodiment illustrated in FIG. 5A, the flanged

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mechanical stop 304 abuts a distal end of the control device 402, though other proximal-stop positions along the elongated catheter sheath 404 are contemplated in accordance with embodiments of the invention. For example, FIGS. 5B-5D are illustrations of embodiments in which the control device 402 is configured to allow flanged mechanical stop 304 to slide within a cavity 420 located at a distal portion of the control device 402. Such embodiments may be useful during operation in order to utilize the full working length of the elongated catheter sheath 404. In this manner, the distal end of the control device 402 can be advanced to abut the access port 206 of the hysteroscope system or the pierceable end 232 of a sealing cap 230 if desired during operation. Alternatively, the distal end of the control device 402 can be advanced over the access port 206 of the hysteroscope system or over sealing cap 230 and the flanged mechanical stop 304 is allowed to abut the access port 206 or the pierceable end 232 of the sealing cap 230. As illustrated in FIG. 5B, flanged mechanical stop 304 may be slid into cavity 420 to abut a back wall 422 of the cavity at the proximal-stop position. Flanged mechanical stop 304 may be also configured to fasten onto the handle 402 at the proximal-stop position. For example, FIG. 5C is an illustration of an embodiment in which flanged mechanical stop 304 may be slid into cavity 420 and fastened into the proximal-stop position by a friction fitting with sloped walls 424 of the cavity. FIG. 5D is an illustration of an embodiment in which flanged mechanical stop 304 may be screwed into cavity 420 in which threads 330 on flanged mechanical stop 304 mate with threads 430 inside cavity 420 to fasten tip protection sleeve 300 in the proximal-stop position. In an embodiment, a suitable fastening mechanism for fastening tip protector sleeve 300 onto control device 402 is able to hold the tip protector sleeve 300 in the proximal-stop position during withdrawal of the delivery catheter assembly 400 from the working channel of the hysteroscope system.

[0031] Referring now to FIG. 6 an operator may slide the tip protector sleeve over the elongated catheter sheath 404 between the proximal-stop position and the distal-stop position illustrated in FIG. 6. As illustrated, the distal end 306 of tip protector sleeve 300 may extend distally beyond a distal end of the elongated catheter sheath 404 and insert 406 when at the distal-stop position. In this manner, the tip protector sleeve 300 may protect the distal ends of the elongated catheter sheath 404 and

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insert 406 during piercing of a sealing cap and during insertion into the working channel and past a valve clamp of the hysteroscope system.

[0032] An interference stop may determine the distal-stop position and prevent the tip protector sleeve 300 from sliding off of the distal end of the elongated catheter sheath 404. In an embodiment, the interference stop includes a male interference part which interferes with sliding of a female interference part over the elongated catheter sheath. Referring again to FIG. 5A, the male interference part may comprise a bump 408 fixed to the elongated catheter sheath 404. Bump 408 may be formed along only a portion of the circumference of the elongated sheath, or may encircle the circumference of the elongated sheath. In an embodiment, bump 408 is a band fixed to and encircling the circumference of the elongated catheter sheath. In an embodiment, bump 408 is fixed to the elongated catheter sheath 404 with a sufficient shear strength to ensure that the tip protector sleeve may be removed from a working channel of a hysteroscope system along with removal of the elongated catheter sheath 404.

[0033] FIG. 7 is a close-up side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention. FIG. 8 is a close-up cross-sectional side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention. As illustrated in FIGS. 7-8, flanged mechanical stop may be a bead 304A having a barrel-like shape, though embodiments of the invention are not limited to such a shape. In an embodiment, bead 304A is fixed to shaft 302 with an adhesive.

[0034] Referring to FIG. 8, in an embodiment bead 304A may be fixed to a proximal end of the elongated shaft 302. Bead 304A may include a distal portion 308 surrounding the proximal end of the elongated shaft 302, a shoulder portion 310 extending proximally of the elongated shaft 302, and a backstop 312. The distal portion 308 may be fixed to the elongated shaft 302 with an adhesive. In an embodiment, the backstop 312 abuts the proximal end of the elongated shaft 302. Backstop 312 may also have a height which is greater than a thickness of the elongated shaft 302. For example, the height may be defined as the distance between an inside diameter (ID) of the backstop and an ID of the distal portion 308

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of the bead 304A. In accordance with various embodiments of the invention, the dimensions and location of the backstop 312 as they relate to the dimensions and location of bump 410 create an interference stop which determines the distal-stop position and prevents the tip protector sleeve from sliding off of the distal end of the elongated catheter sheath 404.

[0035] In an embodiment, the tip protector sleeve 300 is locked onto an “Essure” ® delivery catheter assembly. In such an embodiment, the ID of elongated catheter sheath 404 may be between 0.0405 and 0.0420 inches and the outside diameter (OD) of elongated catheter sheath 404 may be between 0.0538 and 0.0560 inches. Elongated catheter sheath 404 may be formed of a polyether block amide also known under the trade name PEBAX. The OD of elongated catheter sheath 404 may be used to determine the ID of bump 408. In an embodiment, bump 408 may have an ID between 0.0545 and 0.0555 inches and an OD between 0.0575 and 0.0580 inches. In one embodiment, the ID of bump 408 may be smaller than the OD of the elongated catheter sheath 404. In another embodiment, the OD of the elongated catheter sheath 404 is smaller than the ID of bump 408. For example, the OD of the elongated catheter sheath 404 may be between 0.0538 and 0.0542 inches.

[0036] Bump 408 may be a band that is fixed to and encircles the elongated catheter sheath. Bump may be fixed to the elongated catheter sheath 404 by a variety of mechanisms including adhesive and crimping. In an embodiment, bump 408 is formed of a material which is strong enough to resist deformation during operation of the delivery catheter assembly, yet malleable enough to be suitable for crimping. For example, stainless steel possesses suitable strength and malleability. In an embodiment, only a distal end 410 of the band is crimped onto the elongated catheter sheath, as illustrated in FIG. 8. This leaves the proximal end, with the original OD between 0.0575 and 0.0580 inches to act as the male interference part which interferes with the ID of backstop 312 functioning as a part of the female interference part. While an embodiment of bump 408 is described in detail in FIG. 8 in operable relationship with bead 304A, it is understood that bump 408 can be in operable relationship with other flanged mechanical stops, such as those illustrated in FIGS. 9-11C.

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[0037] Still referring to FIG. 8, bead 304A may be formed of a variety of materials and have a variety of shapes and sizes to perform a variety of functions. In one aspect, bead 304A may be sized and shaped larger than the inside diameter (ID) of a corresponding access port opening to a working channel or pierceable end of a sealing cap if present in order to act as a stop mechanism that controls the insertion depth of the tip protector sleeve 300 into the working channel. In one aspect, bead 304A may perform the function as a handle for gripping by the operator. In another aspect, bead 304A may include a backstop 312 which functions as part of the female interference part. In an embodiment, bead 304A has an OD of approximately 0.112 inches. The distal portion 308 of bead 304A may have an ID of approximately 0.070 and may be bonded to the OD of elongated shaft 302. Backstop 312 may have an ID which is smaller than an OD of the proximal end of bump 408. For example, backstop 312 may have an ID between 0.0565 and 0.0575 inches. In such an embodiment, backstop 312 has a height that extends from the ID of back stop 312 to the ID of the distal portion 308 of the bead 304, or approximately 0.013 inches.

[0038] In accordance with embodiments of the invention tip protector sleeve 300 may be locked onto the delivery catheter assembly 400. Shaft 302 may be used to pierce a sealing cap and protect the tip of the insert 406, elongated catheter sheath 404 or guidewire during insertion into the working channel and past a valve clamp of a hysteroscope system. In an embodiment, the shaft 302 and elongated catheter sheath 404 may be advanced into a working channel of a hysteroscope system without allowing a significant amount of fluid (e.g. saline) spray-back or leakage from the delivery catheter assembly. The elongated catheter sheath 404 may additionally be slid through the shaft 302 to deliver the insert 406 to a body lumen, while the delivery catheter assembly 400 does not allow a significant amount of fluid leakage. Referring now to FIG. 12A, the shaft 302 may pierce the pierceable end 232 of a sealing cap 230 with the tip of the shaft 306. The outside diameter of the shaft 302 may fit tightly in the pierceable end 232 effectively creating a water tight seal between the sealing cap 230 and tip protector sleeve 300.

[0039] The reduction of fluid spray-back and leakage may also be achieved by controlling the shape and dimensions of the tip protector sleeve 300 as it interacts

3/3
6/3

with the elongated catheter sheath 404 and bump 408. In an embodiment, shaft 302 may be approximately 2.82 inches long from the proximal end to the distal end of the tip 306, which may be angled. Shaft 302 may have an ID between 0.0585 and 0.0605 inches and an OD between 0.0690 and 0.0710 inches. The shaft 302 ID may be selected to not allow for fluid to flow proximally between the shaft 302 and elongated catheter sheath 404 (and bump 408), while still allowing for the elongated catheter sheath 404 to slide and be advanced through the shaft 302. In such an embodiment, a minimum clearance between the ID of the elongated shaft 302 (e.g. 0.059 inches) and the OD of the elongated catheter sheath 404 (e.g. 0.055 inches) provides sufficient resistance to spray-back and leakage. Such a minimum clearance may be effective for overlapping constant diameters of the elongated shaft 302 and elongated catheter sheath 404.

[0040] Referring now to FIG. 9, an embodiment for tip protector sleeve 300B is illustrated. As illustrated in FIG. 9, tip protector sleeve 300B includes an elongated shaft 302, a bead 304B and inner shaft 320. Tip protector sleeve 300B operates similarly as tip protector sleeve 300 with one difference being that backstop 322 is the distal end of inner shaft 320. In such an embodiment, the shape and dimensions of tip protector sleeve 300B are controlled so that bump 408 interferes with movement of the distal end, backstop 322 of inner shaft 320. In such an embodiment, bead 304B may be sized and shaped to act as a stop mechanism that controls the insertion depth of the tip protector sleeve 300B into the working channel and may perform the function as a handle for gripping by the operator

[0041] Referring now to FIG. 10, another embodiment for tip protector sleeve 300C is illustrated. As illustrated in FIG. 10, tip protector sleeve 300C includes an elongated shaft 302, a neck portion 332, and a flared portion 304C. Tip protector sleeve 300C operates similarly as tip protector sleeves 300 and 300B. One difference is that the neck portion 332 operates as the backstop for bump 408. The neck portion 332 may be integrally formed with the elongated shaft 302 or be a separate member bonded to the inside diameter of elongated shaft 302. Likewise flared portion 304C may be integrally formed with the elongated shaft 302 or be a separate member bonded to the outside diameter of elongated shaft 302. In such an embodiment, flared portion 304C may be sized and shaped to act as a flanged

3A
CA

mechanical stop that controls the insertion depth of the tip protector sleeve 300C into the working channel and may perform the function as a handle for gripping by the operator.

[0042] Embodiments of the invention are also envisioned in which the elongated catheter sheath 404 does not have a constant OD along its length. In accordance with some embodiments, the tip protector sleeve 300 may include a change in ID or a valve to accommodate variations in the OD of the elongated catheter sheath 404, or to more effectively seal an elongated catheter sheath 404 with a constant OD. Referring again to FIG. 9, inner shaft 320 is illustrated as having a smaller ID than the ID of elongated shaft 302. In addition to functioning as an interference part, the ID of inner shaft 320 may more effectively accommodate a reduction in OD of the elongated catheter sheath 404. Referring again to FIG. 10, the ID of neck portion 332 may also more effectively accommodate a reduction in OD of the elongated catheter sheath 404 in addition to functioning as an interference part. Thus, a minimum clearance between the ID of inner shaft 320 or ID of neck portion 332 and the OD of the elongated catheter shaft 404 may provide enhanced resistance to fluid-spray back.

[0043] FIGS. 11A-11C are illustrations embodiments of a tip protector sleeve incorporating various sealing valves to reduce the amount of fluid spray-back and leakage between the tip protector sleeve and elongated sheath of the delivery catheter assembly. While illustrated separately, it is understood that the embodiments illustrated in FIGS. 11A-11C may be combined with other embodiments of the invention. More specifically, any of the sealing valves described in reference to the illustrations in FIGS. 11A-11C may be combined with any of the embodiments further describing the proximal-stop and distal-stop positions.

[0044] FIG. 11A is an illustration of a tip protector sleeve 300D including an elongated shaft 302, a housing 304D, and valve 340. Housing 304D may function as a stop mechanism that controls the insertion depth of the tip protector sleeve 300D into the working channel and may perform the function as a handle for gripping by the operator. The elongated shaft 302 may be coupled to a distal tip 342 of the housing 304D which may function as a backstop for interference with a bump

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408 fixed to the elongated catheter sheath 404 at the distal-stop position. Housing 304D additionally houses valve 340 which is capable of accommodating multiple variations in OD of the elongated catheter sheath 404. For example, valve 340 may be a silicone valve containing a slit at the distal end that allows for a catheter shaft to pass through it. The silicone material may allow for the slit to conform to different shapes or diameters while providing a seal. Due to the geometry on the distal end of the silicone valve, as fluid tries to pass from distal to proximal, the end of the valve may be pushed closed due to a chamfer on the end of the valve.

[0045] FIG. 11B is an illustration of a tip protector sleeve 300E including an elongated shaft 302, a housing 304E, and a compression valve 350 including an screw cap 354 which may be threaded down onto an O-ring 352 to compress it against the elongated catheter sheath 404. Housing 304E may function as a stop mechanism that controls the insertion depth of the tip protector sleeve 300E into the working channel and may perform the function as a handle for gripping by the operator. The elongated shaft 302 may be coupled to a distal tip 342 of the housing 304E which may function as a backstop for interference with a bump fixed to the elongated catheter sheath at the distal-stop position.

[0046] FIG. 11C is an illustration of a tip protector sleeve 300F including an elongated shaft 302, a housing 304F, and a compression valve 360 including a cap 362, a compression spring 364 and a thin walled tube (not illustrated) inside the housing. For example, the thin walled tube may be made of a material such as silicone. Threads between the cap 362 and the housing 304F apply a twist motion to the tube. When the tube is twisted, an inner diameter of the tube tightens like an iris. The compression spring 364 keeps the cap 362 extended and the threads hold the twist or keep the iris closed. When the cap 362 is pushed towards the housing 304F (spring compressed) the cap 362 untwists and the iris opens. In this manner the opening of the iris can be adjusted based upon the OD of the elongated catheter sheath 404. Similar to tip protector sleeves 300D and 300E, housing 304F may function as a stop mechanism that controls the insertion depth of the tip protector sleeve 300F into the working channel and may perform the function as a handle for gripping by the operator. The elongated shaft 302 may be coupled to a distal tip 342

B6
C6

of the housing 304F which may function as a backstop for interference with a bump fixed to the elongated catheter sheath at the distal-stop position.

[0047] A delivery catheter assembly in accordance with embodiments of the invention may be utilized to deliver an insert to an ovarian pathway (e.g. a fallopian tube) of a female body. The delivery catheter assembly may protect the tip of an elongated catheter sheath, guidewire, or insert during piercing of a sealing cap and insertion into the working channel and past a valve clamp of a hysteroscope system and reduce the amount of fluid spray-back and leakage associated with inserting a delivery catheter assembly into the working channel of a hysteroscope system. In an embodiment, the delivery catheter assembly includes a control device, an elongated catheter sheath having a distal end and a proximal end connected to the control device, and a tip protector sleeve locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath. The delivery catheter assembly may further include an insert releasably disposed within the elongated catheter sheath. In an embodiment, the insert extends distally beyond the elongated catheter sheath. In an embodiment, the insert includes a preformed bend, as illustrated in FIG. 5, which may be utilized to assist with navigation through a curved portion of a fallopian tube. Upon providing the delivery catheter assembly the operator may grasp a flanged mechanical stop 304 or other suitable portion of the tip protector sleeve 300 to position the tip protector sleeve at the distal-stop position illustrated in FIG. 6. If a sealing valve is present on the tip protection sleeve 300, the sealing valve may then be tightened onto the elongated catheter sheath 404 if necessary to provide an optimal seal to protect against fluid spray-back and leakage.

[0048] Referring now to FIGS. 12A-12C, the operator may then pierce a pierceable end 232 of a sealing cap 230 with the tip protector sleeve 300 and insert the tip protector sleeve 300 through an access port 206 of a hysteroscope system 200 and into the working channel 202 of the hysteroscope system. During insertion the tip protector sleeve 300 may be advanced past a valve clamp 208 of the hysteroscope system. The tip protector sleeve protects against the possibility of the exposed portion of the insert 406 from catching on the valve clamp 208 and compromising

the insert integrity. In accordance with embodiments of the invention, the distal end 410 of the elongated catheter sheath 404 and insert 406 are inserted through the sealing cap 230 and access port 206, and into the working channel 202 of the hysteroscope system simultaneously with the tip protector sleeve 300 in the distal-stop position. The simultaneous insertion of the tip protector sleeve 300 and elongated catheter sheath 404 may avoid a problem of fluid spray-back associated with sequentially inserting an introducer followed by an elongated catheter sheath. In an embodiment, the tip protector sleeve 300 may be advanced into the working channel simultaneously with the elongated catheter sheath and insert 406 until the flanged mechanical stop 304 abuts against the access port 206 or sealing cap 230, if present, as illustrated in FIG. 12B.

[0049] The distal end 410 of the elongated catheter sheath 404 may then be advanced past the hysteroscope system 200 as illustrated in FIG. 12C, and onto a target location within the body lumen. The insert 406 may then be deployed into the body lumen. Depending upon operator preference, the tip protector sleeve 300 may remain inserted in the working channel 202 during the elongated catheter sheath 404 advancement and insert 406 deployment procedures or removed from the working channel 202. In accordance with many embodiments of the invention it is understood that the tip protector sleeve 300 is permanently locked onto the elongated catheter sheath. It is also contemplated that the tip protector sleeve 300 could be removed from the catheter assembly after initially advancing the catheter assembly into the working channel, for example, by including a tear joint in the tip protector sleeve in which the tip protector sleeve can be manually torn off of the elongated catheter sheath by the operator.

[0050] In an embodiment, the insert 406 and distal end 410 of the elongated catheter sheath 404 are advanced to the target location within the body lumen while the flanged mechanical stop 304 on the tip protector sleeve 300 abuts the access port 206 or sealing cap 320, if present. The amount of elongated catheter sheath 404 spanning between the flanged mechanical stop 304 and control device 402 may depend upon the procedure and patient's anatomy. It is envisioned that circumstances arise where the operator may wish to insert the entire available working length of the elongated catheter sheath 404 into the patient and advance the

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control device 402 all the way to the access port or sealing cap, if present. In accordance with embodiments of the invention illustrated in FIGS. 5B-5D, this can be possible by including a cavity 420 in the control device 402 to accommodate the flanged mechanical stop 304.

[0051] Once the insert 406 is deployed into the body lumen the delivery catheter assembly may be withdrawn from the working channel of the hysteroscope system. In one embodiment, during withdrawal of the delivery catheter assembly 400 from the working channel, the bump 408 on the elongated catheter sheath 404 may be withdrawn proximally against the backstop of the tip protector sleeve 300 and cause the tip protector sleeve 300 to be withdrawn from the working channel 202 of the hysteroscope system 200. In another embodiment, the flanged mechanical stop 304 on the tip protector sleeve 300 can be fastened to the control device 402. In this manner, during withdrawal of the delivery catheter assembly 400 from the working channel, the tip protector sleeve 300 remains fastened to the control device 402.

[0052] In the foregoing specification, various embodiments of the invention have been described. It will, however, be evident that various modifications and changes may be made thereto without departing from the broader spirit and scope of the invention as set forth in the appended claims. The specification and drawings are, accordingly, to be regarded in an illustrative sense rather than a restrictive sense. Hence, the scope of the present invention is limited solely by the following claims.

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69**CLAIMS**

What is claimed is:

1. A delivery catheter assembly comprising:
a control device;
an elongated catheter sheath having a distal end and a proximal end
connected to the control device; and
a tip protector sleeve locked onto the elongated catheter sheath and slideable
over a length of the elongated catheter sheath between a proximal-stop position and
a distal-stop position along the elongated catheter sheath.
2. The delivery catheter assembly of claim 1, further comprising an
interference stop which determines the distal-stop position and prevents the tip
protector sleeve from sliding off of the distal end of the elongated catheter sheath.
3. The delivery catheter assembly of claim 2, wherein the interference stop
comprises a male interference part which interferes with sliding of a female
interference part over the elongated catheter sheath.
4. The delivery catheter assembly of claim 3, wherein the tip protector sleeve
comprises an elongated shaft and a backstop together functioning as the female
interference part, and the male interference part is fixed to the elongated catheter
sheath.
5. The delivery catheter assembly of claim 4, wherein the male interference
part comprises a bump fixed to the elongated catheter sheath.
6. The delivery catheter assembly of claim 5, wherein the bump comprises a
band fixed to and encircling the elongated catheter sheath.

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7. The delivery catheter assembly of claim 6, wherein a distal end of the band is crimped onto the elongated catheter sheath, and a proximal end of the band is not crimped onto the elongated shaft.
8. The delivery catheter assembly of claim 4, wherein the backstop has an ID which is smaller than an OD of the male interference part.
9. The delivery catheter assembly of claim 8, further comprising a molded bead fixed to a proximal end of the elongated shaft.
10. The delivery catheter of claim 9, wherein the molded bead comprises:
a distal portion surrounding the proximal end of the elongated shaft;
a shoulder portion extending proximally of the elongated shaft; and
the backstop, wherein the backstop abuts the proximal end of the elongated shaft.
11. The delivery catheter assembly of claim 8, wherein the tip protector sleeve further comprises an inner shaft fixed to a proximal end of the elongated shaft, and the backstop is a distal end of the inner shaft.
12. The delivery catheter assembly of claim 4, wherein the male interference part is fixed to the elongated catheter sheath a first distance from the distal end of the elongated catheter sheath, and wherein the tip protector sleeve is longer than the first distance such that the tip protector sleeve extends distally beyond the elongated catheter sheath when at the distal-stop position.
13. The delivery catheter assembly of claim 12, further comprising an insert disposed within and extending distally beyond a distal end of the elongated catheter sheath, wherein the tip protector sleeve extends distally beyond the insert when at the distal-stop position.

14. The delivery catheter assembly of claim 3, wherein the tip protector sleeve further comprises a sealing valve.
15. A method of forming a delivery catheter assembly comprising:
sliding a tip protector sleeve over a distal end of an elongated catheter sheath and toward a control device;
fixing a bump onto a distal region of the elongated catheter sheath, wherein the bump prevents the tip protector sleeve from sliding off of a distal end of the elongated catheter sheath.
16. The method of claim 15, wherein fixing a bump onto a distal region of the elongated catheter sheath comprises crimping.
17. The method of claim 16, wherein crimping comprises crimping a distal end of a band onto the elongated catheter sheath.
18. The method of claim 17, further comprising not crimping a proximal end of the band onto the elongated catheter shaft.
19. A method of delivering an insert comprising:
providing a delivery catheter assembly comprising:
a control device;
an elongated catheter sheath having a distal end and a proximal end connected to the control device;
an insert releasably disposed within the elongated catheter sheath;
and
a tip protector sleeve locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath;
positioning the tip protector sleeve at the distal-stop position;

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inserting the tip protector sleeve through an access port of a hysteroscope system and into a working channel of the hysteroscope system;
advancing the distal end of the elongated catheter sheath to a target location within a body lumen; and
deploying the insert inside the body lumen.

20. The method of claim 19, wherein inserting the tip protector sleeve further comprises advancing a distal end of the tip protector sleeve past a valve clamp of the hysteroscope system.

21. The method of claim 20, wherein inserting the tip protector sleeve comprises advancing the tip protector sleeve into the working channel until a flanged mechanical stop on the tip protector sleeve abuts the access port or a sealing cap coupled to the access port.

22. The method of claim 21, wherein the distal end of the elongated catheter sheath is advanced to the target location within the body lumen while the flanged mechanical stop on the tip protector sleeve abuts the access port or the sealing cap.

23. The method of claim 19, further comprising removing the delivery catheter assembly from the working channel after deploying the insert inside the body lumen.

24. The method of claim 19, wherein removing the delivery catheter assembly from the working channel comprises withdrawing a bump on the elongated catheter sheath proximally against a backstop of the tip protector sleeve to cause the tip protector sleeve to be withdrawn from the working channel.

25. The method of claim 19, further comprising tightening a sealing valve of the tip protector sleeve onto the elongated catheter sheath after positioning the tip protector sleeve at the distal-stop position, and prior to inserting the tip protector sleeve through the access port of the hysteroscope system.

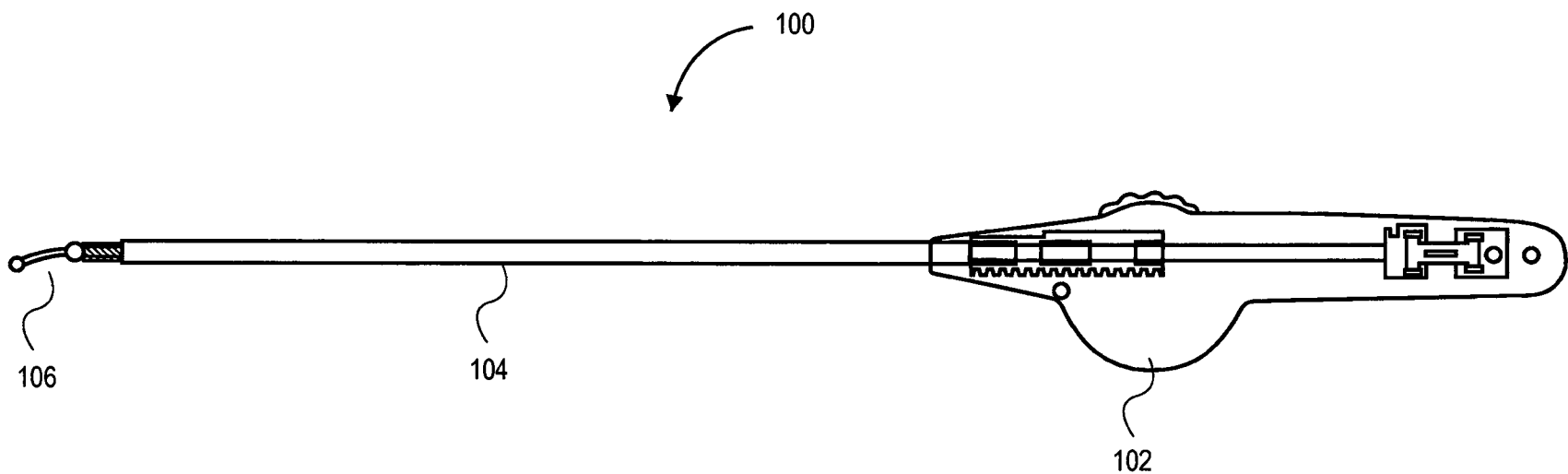


FIG. 1
(PRIOR ART)

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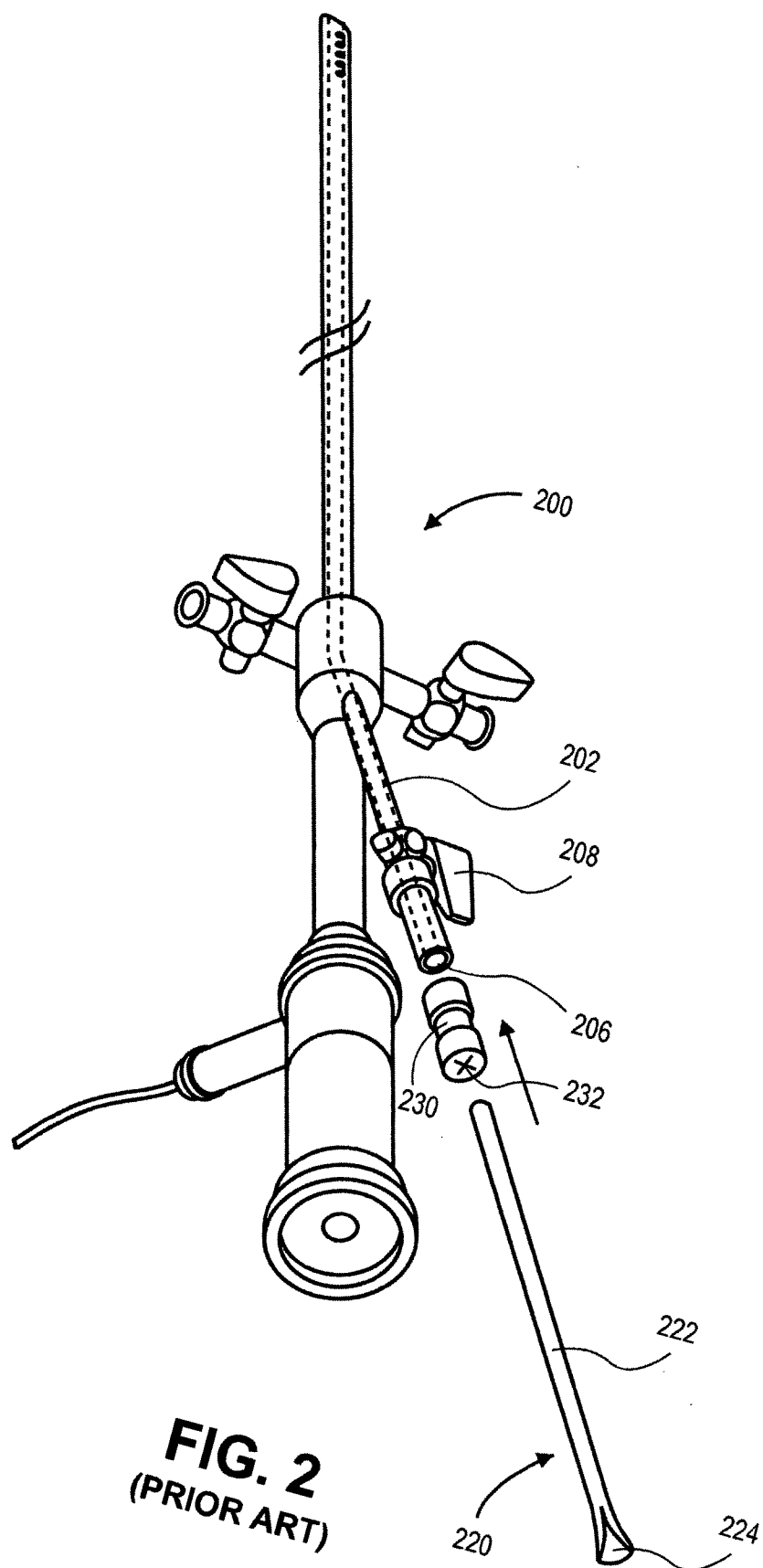
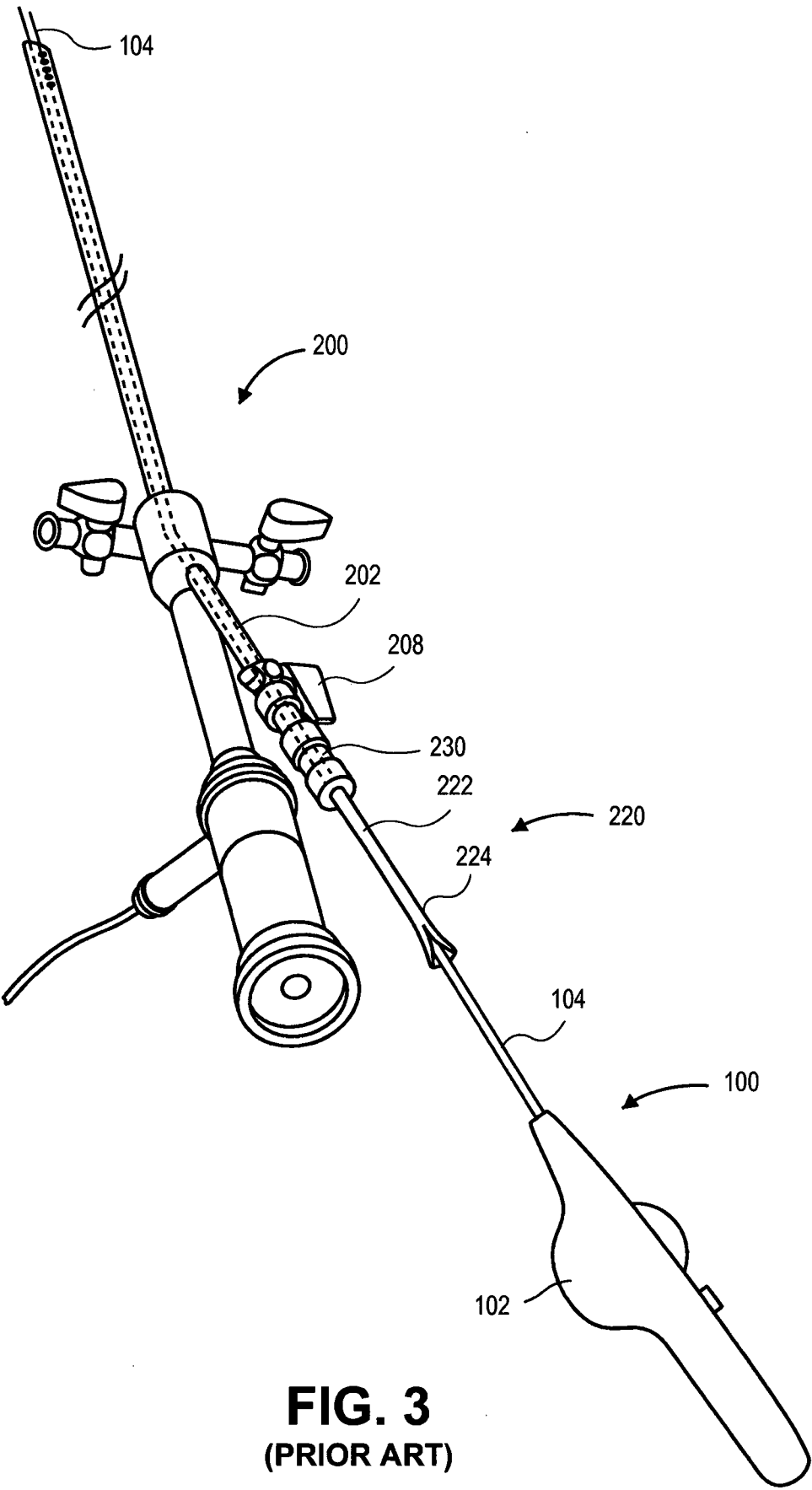


FIG. 2
(PRIOR ART)



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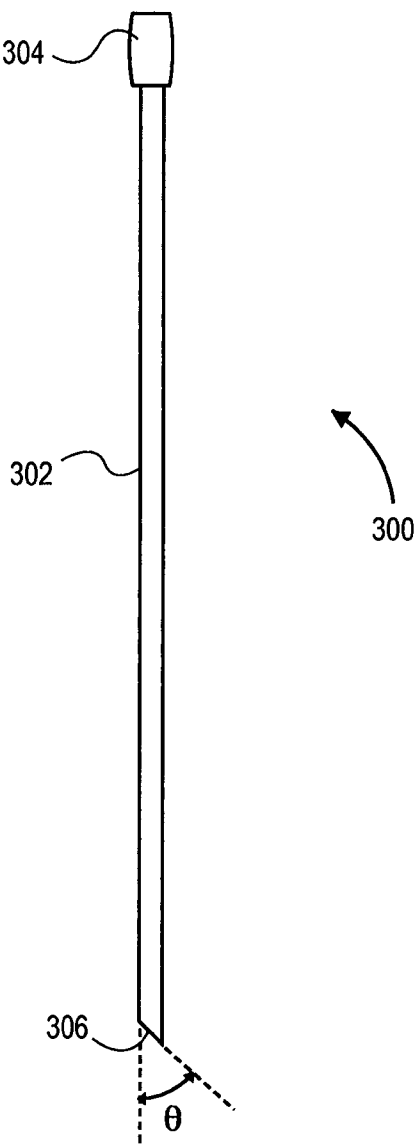


FIG. 4

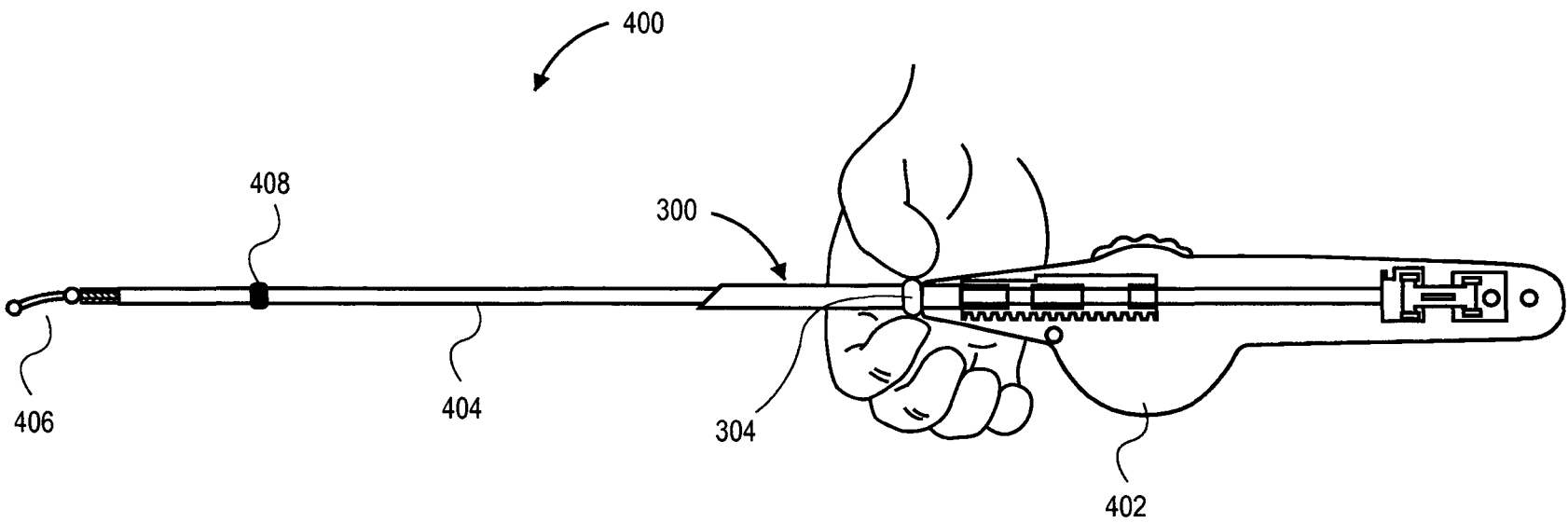


FIG. 5A

Handwritten signature and date: 8/7/17

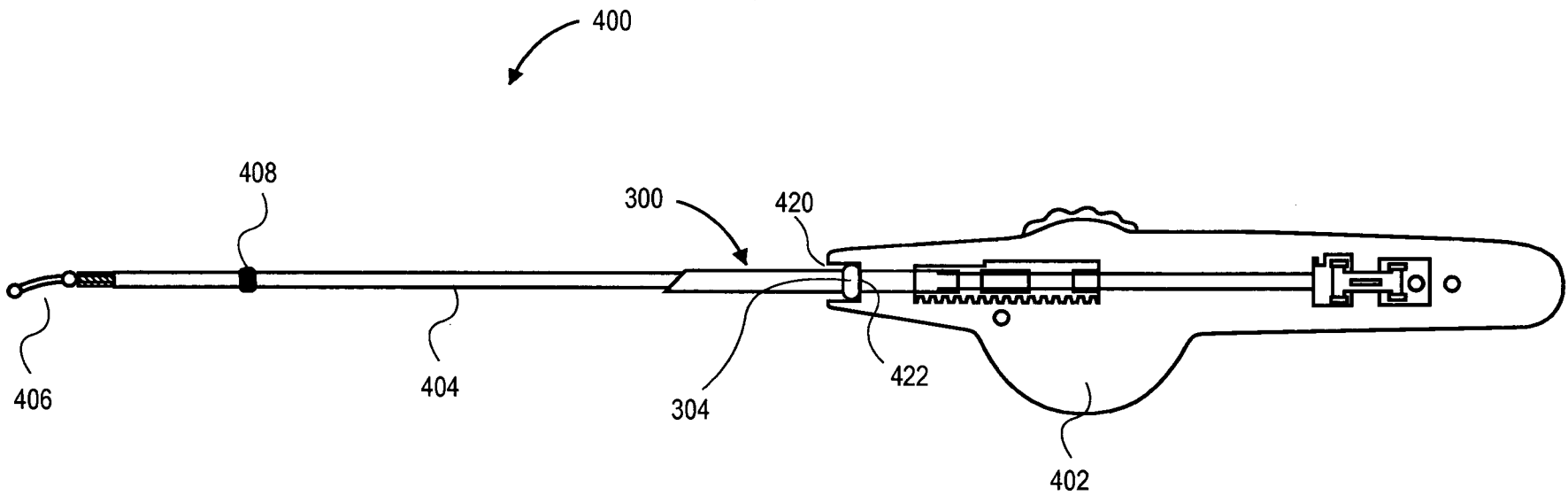


FIG. 5B

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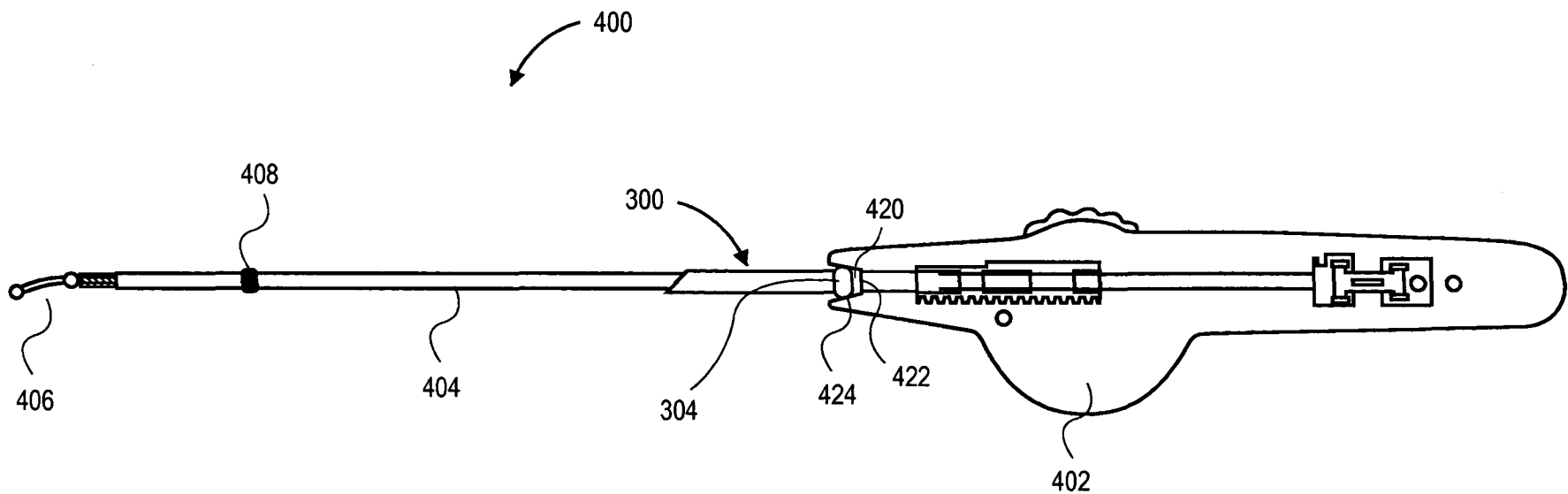


FIG. 5C

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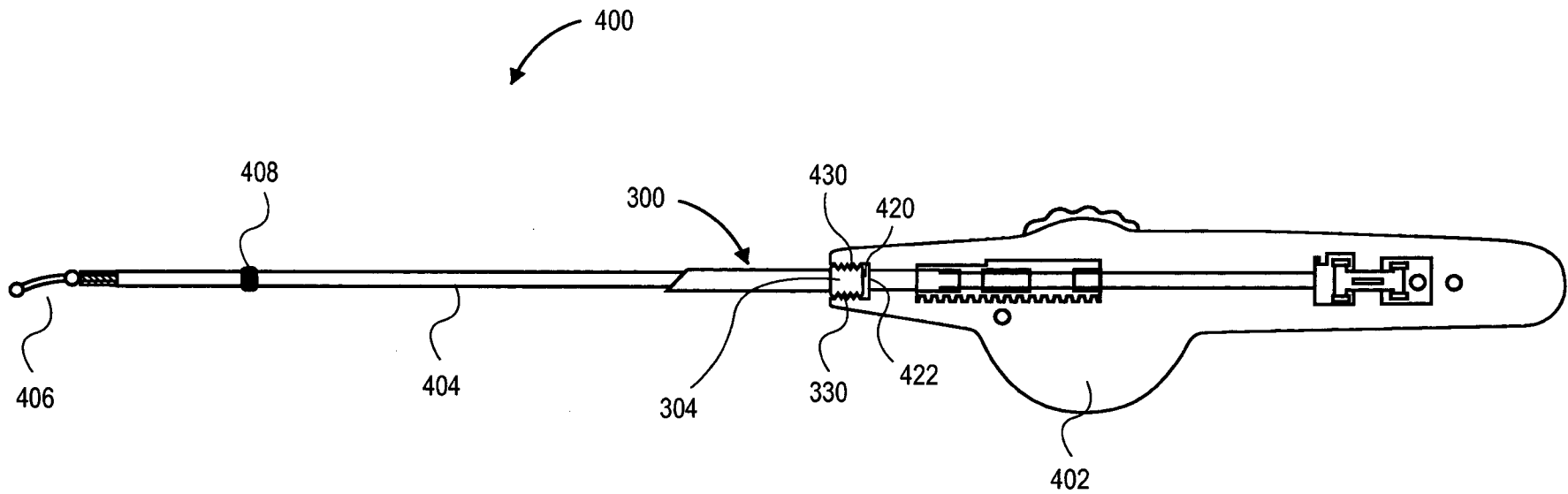


FIG. 5D

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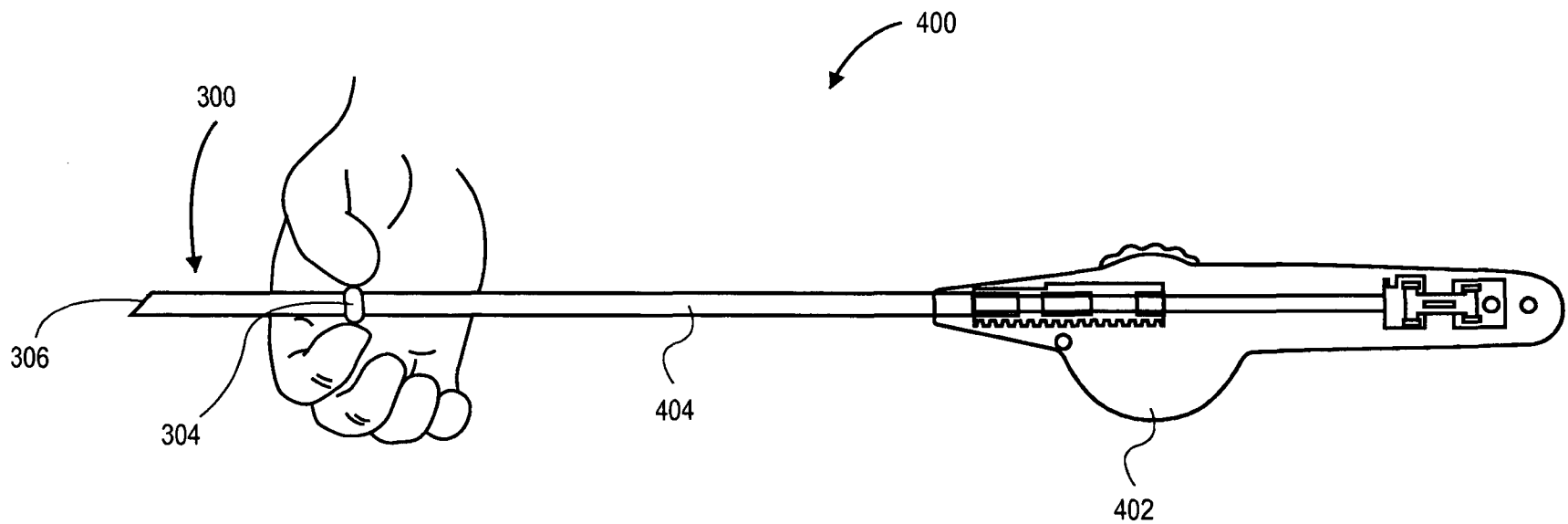


FIG. 6

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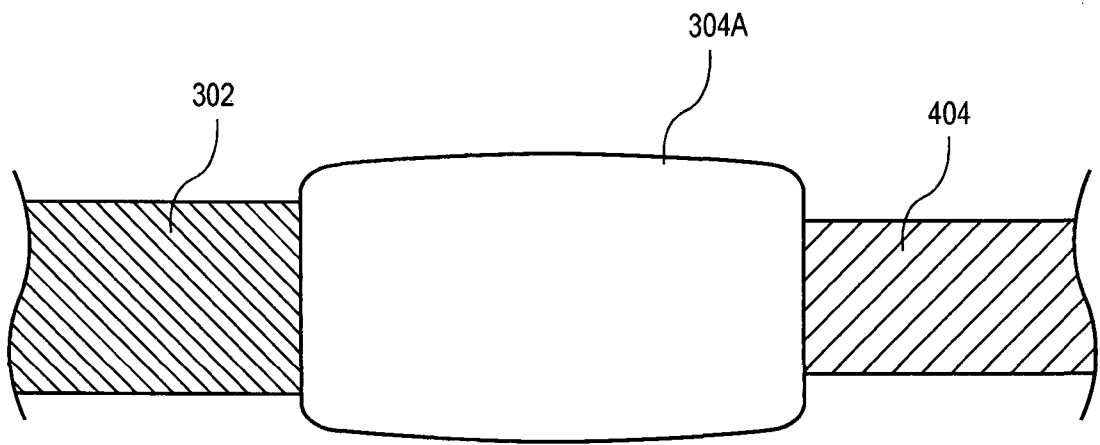


FIG. 7

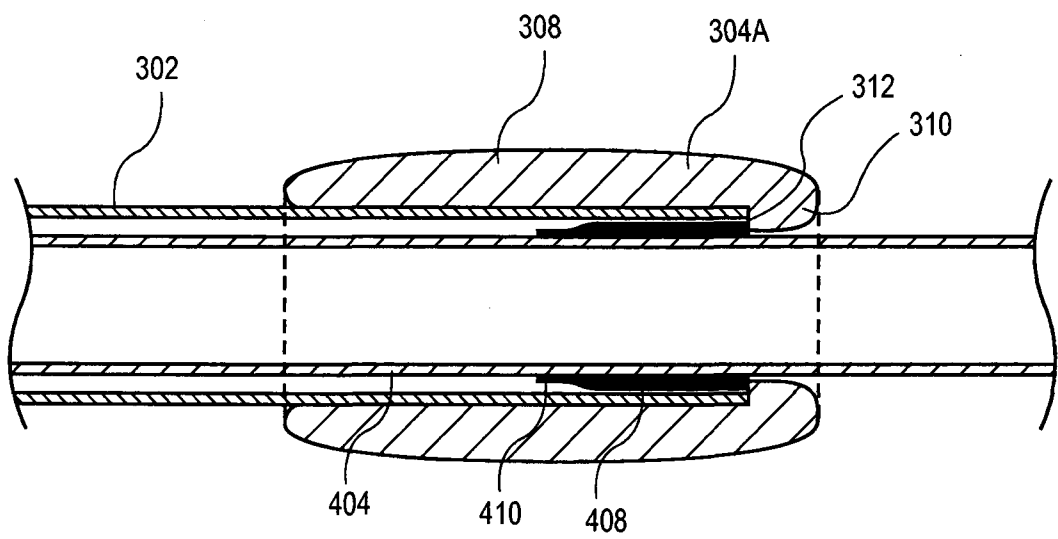


FIG. 8

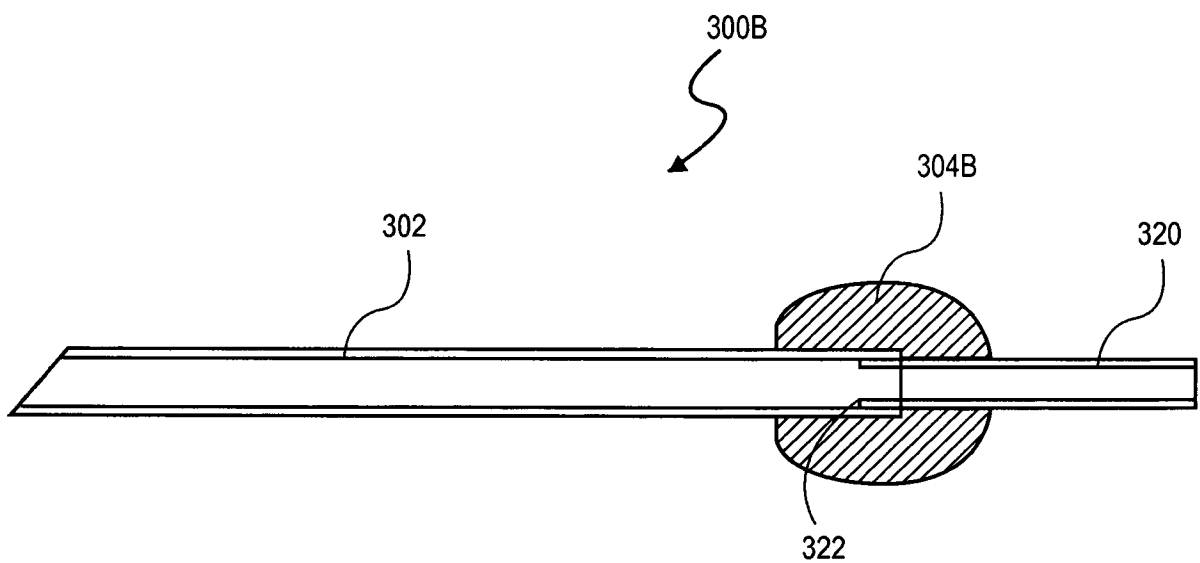


FIG. 9

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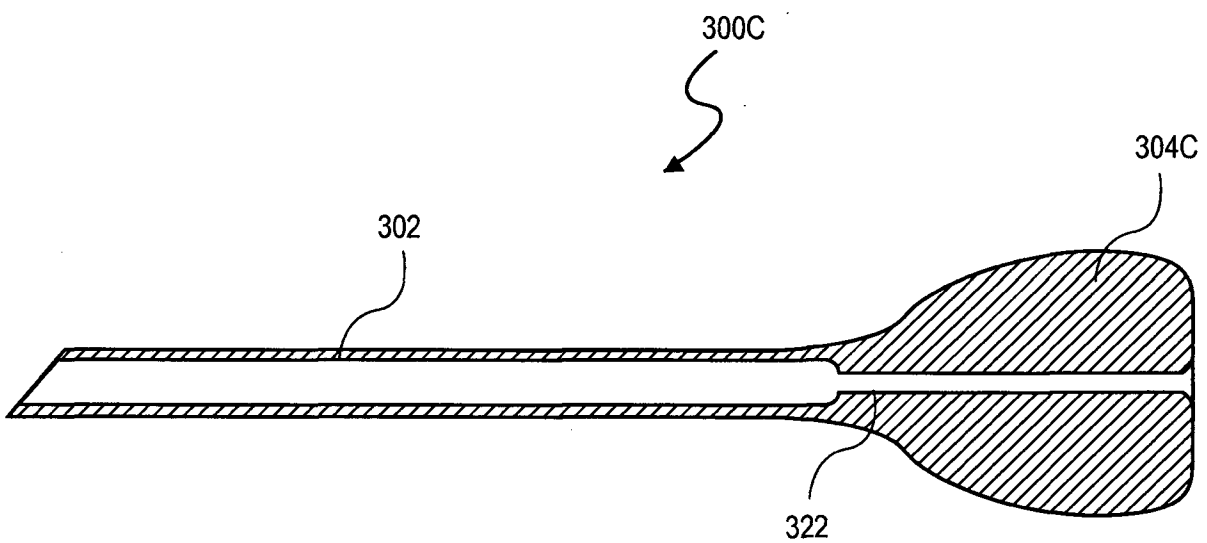


FIG. 10

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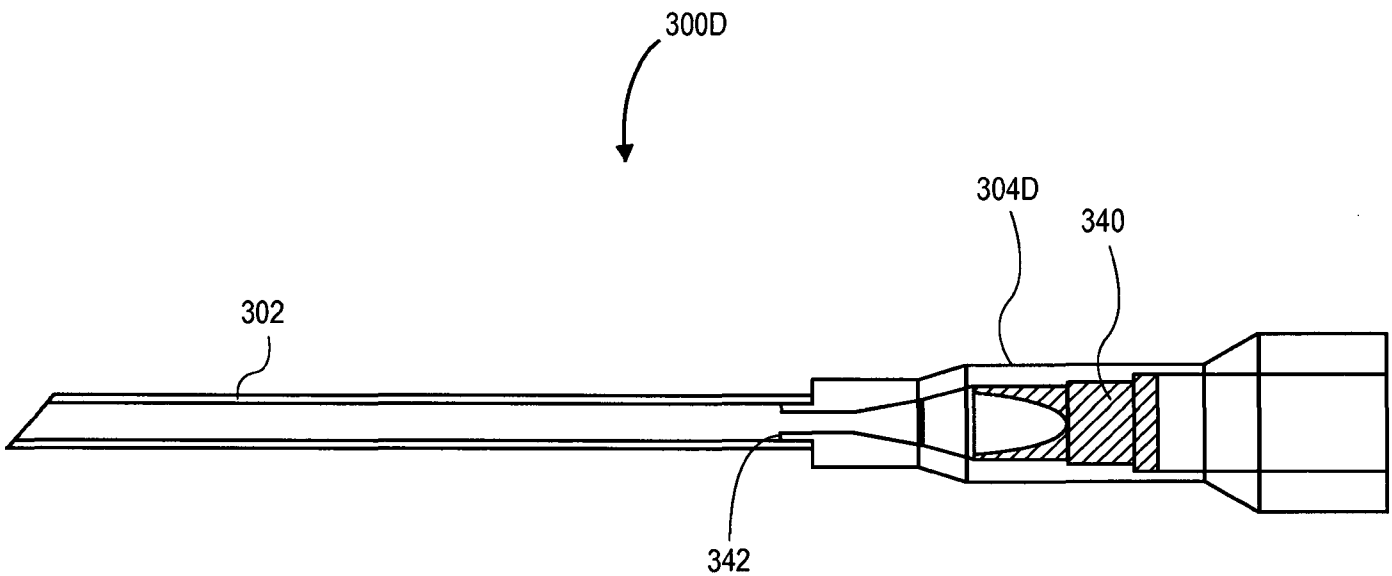


FIG. 11A

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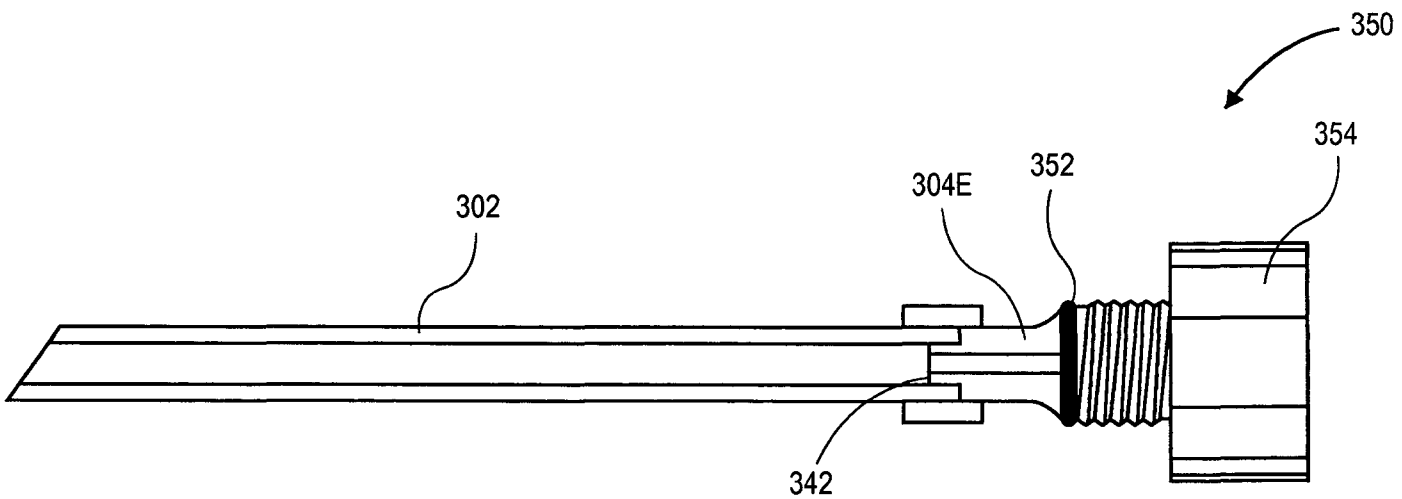


FIG. 11B

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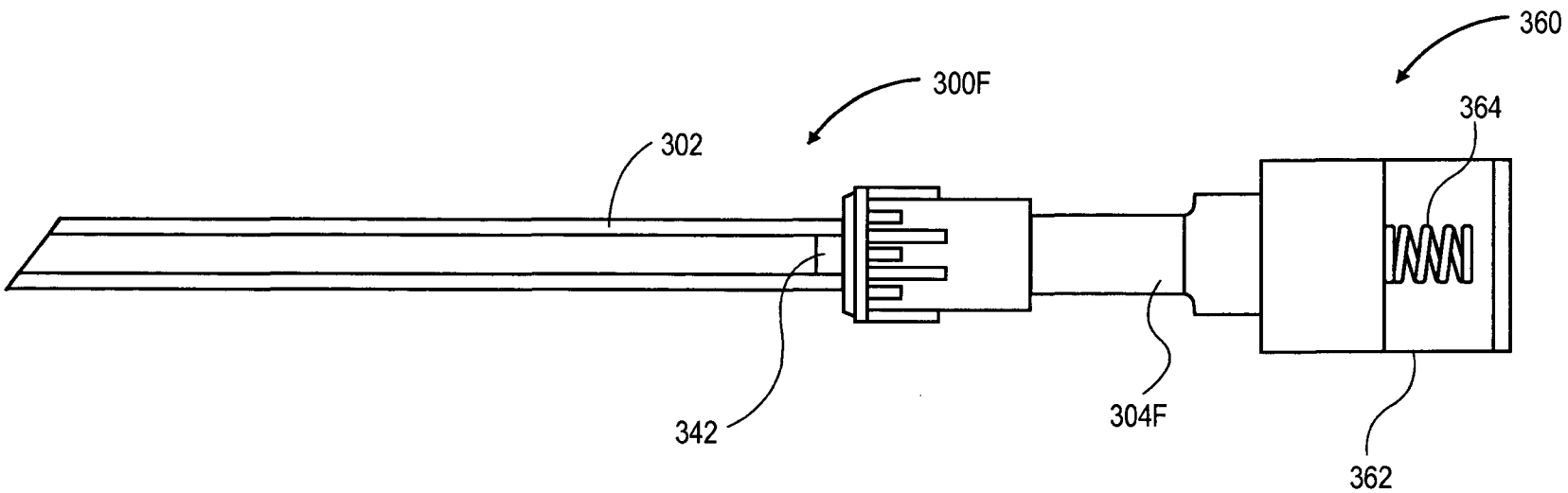


FIG. 11C

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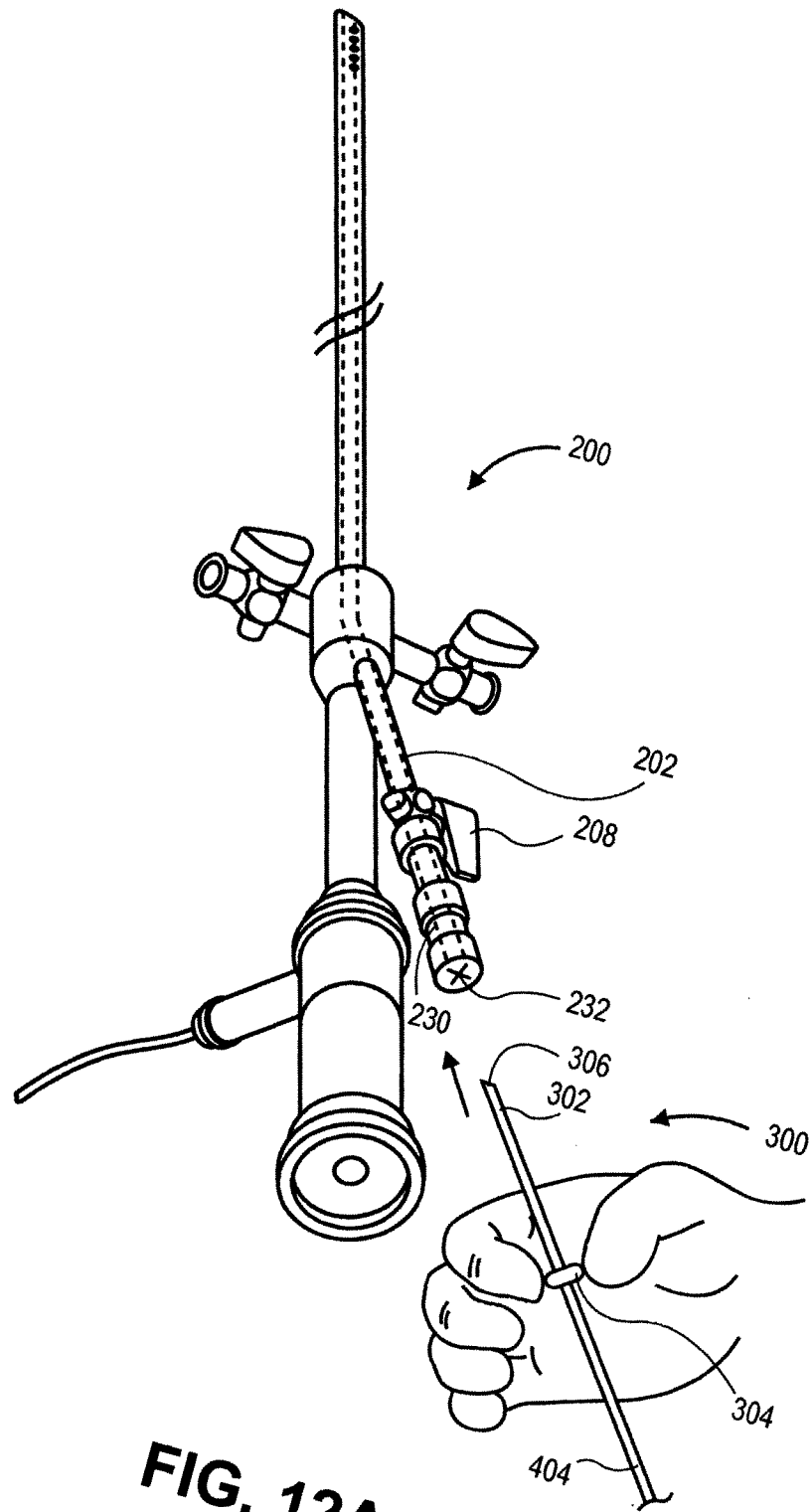


FIG. 12A

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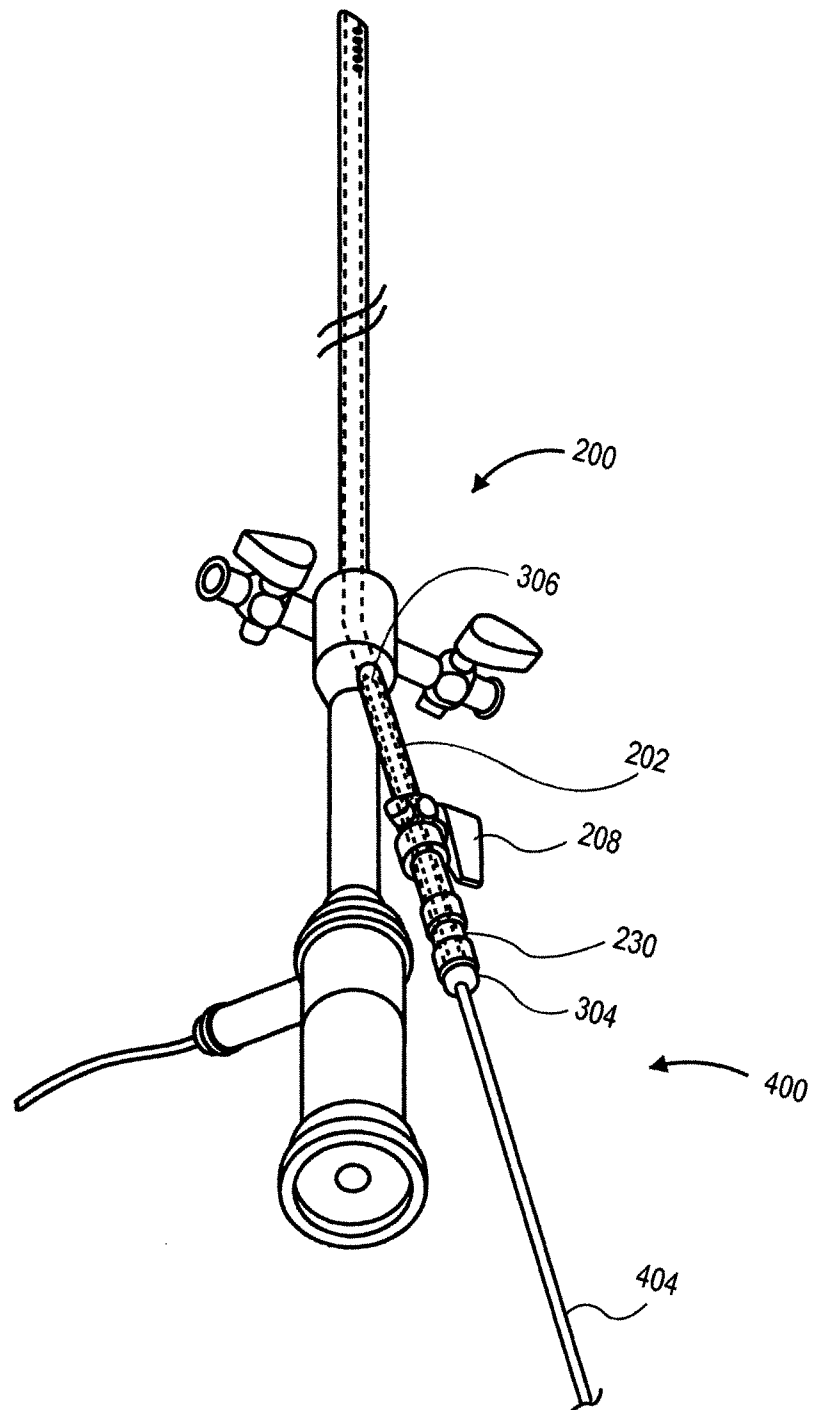


FIG. 12B

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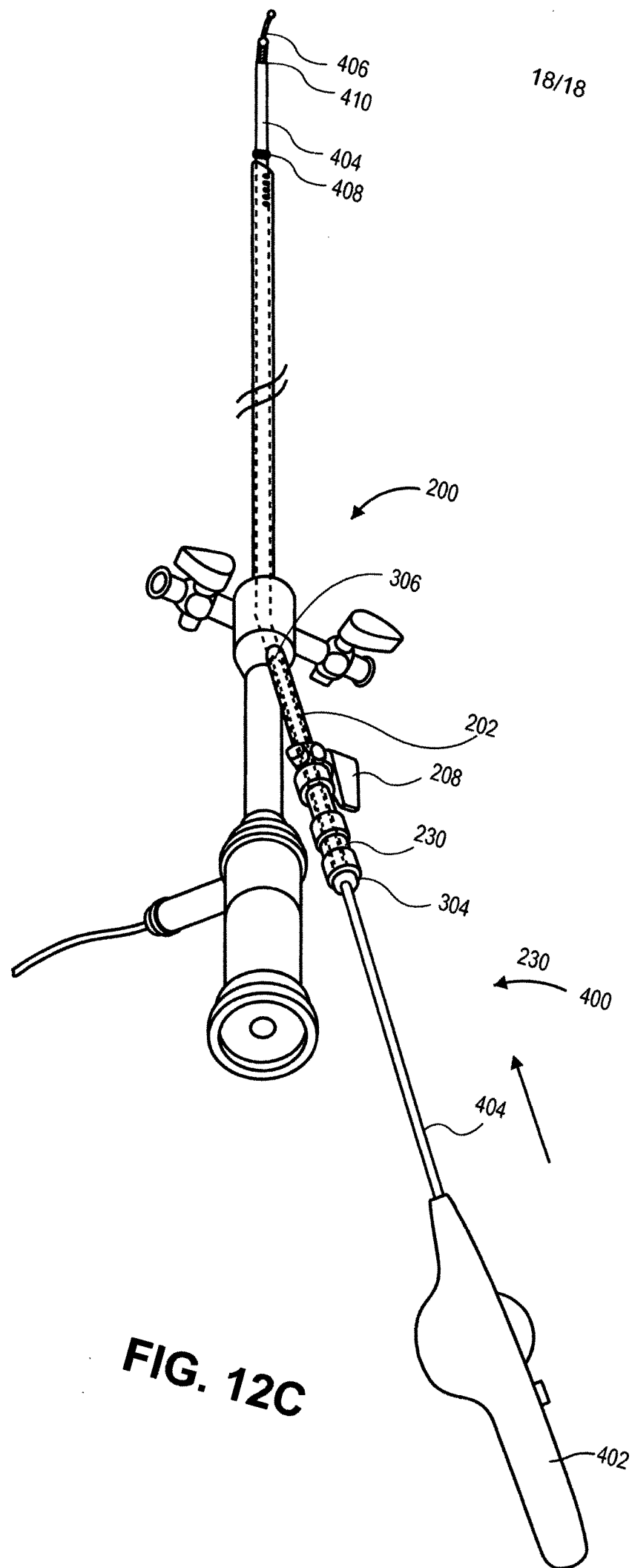


FIG. 12C

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2012/040013

A. CLASSIFICATION OF SUBJECT MATTER INV. A61F6/18 A61F6/22 A61B17/42 ADD.		
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) A61F A61B Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2006/293560 A1 (NGUYEN MIMI [US] ET AL) 28 December 2006 (2006-12-28) cited in the application paragraph [0005] - paragraph [0006] paragraph [0066] - paragraph [0067]; figures 1a-2e -----	1
A	US 6 162 196 A (HART CHARLES C [US] ET AL) 19 December 2000 (2000-12-19) column 11, line 14 - line 34; figure 7 -----	1
A	US 2003/105473 A1 (MILLER ARNOLD [US]) 5 June 2003 (2003-06-05) paragraph [0073]; figures 5a-5f -----	1
☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* 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 28 August 2012		Date of mailing of the international search report 05/09/2012
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Arjona López, G

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/040013

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 19-25
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 19-25

Independent claim 19 defines a method of delivering an insert comprising, inter alia, the step of advancing the distal end of a catheter sheath to a target location within a body lumen and deploying the insert inside the body lumen. Therefore, the subject-matter of independent claim 19 refers to a method of treating the human or animal body by surgery in the sense of Rule 39.1(iv) PCT. Claims 20-25 are dependent on claim 19 and as such also define a surgical method in the sense of Rule 39.1(iv) PCT.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2012/040013

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2006293560	A1	28-12-2006	CA 2613293 A1	04-01-2007
			EP 1909715 A2	16-04-2008
			US 2006293560 A1	28-12-2006
			US 2008041394 A1	21-02-2008
			US 2011112360 A1	12-05-2011
			US 2011112370 A1	12-05-2011
			US 2011224486 A1	15-09-2011
			WO 2007001586 A2	04-01-2007

US 6162196	A	19-12-2000	NONE	

US 2003105473	A1	05-06-2003	AU 9256301 A	13-03-2002
			CA 2441883 A1	07-03-2002
			EP 1317213 A2	11-06-2003
			US 2003105473 A1	05-06-2003
			WO 0217771 A2	07-03-2002

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**DOCUMENT MADE AVAILABLE UNDER THE
PATENT COOPERATION TREATY (PCT)**

International application number:	PCT/US2012/040013
International filing date:	30 May 2012 (30.05.2012)
Document type:	Certified copy of priority document
Document details:	Country/Office: US
	Number: 13/149,631
	Filing date: 31 May 2011 (31.05.2011)
Date of receipt at the International Bureau:	11 June 2012 (11.06.2012)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a),(b) or (b-bis)

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470499

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

June 10, 2012

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: *13/149,631*

FILING DATE: *May 31, 2011*

RELATED PCT APPLICATION NUMBER: *PCT/US12/40013*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US13/149,631*



Certified by

David J. Kappas

Under Secretary of Commerce
for Intellectual Property
and Director of the United States
Patent and Trademark Office

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No. 006701P074
(maximum 12 characters)

First Named Inventor Christopher A. Stout

Title: TIP PROTECTOR SLEEVE

ADDRESS TO: Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☒ **Fee Transmittal Form (e.g., PTO/SB/17)**
(Submit an original and a duplicate for fee processing)
2. ☒ **Applicant Claims Small Entity Status. (37 CFR 1.27)**
3. ☒ **Specification (Total Pages 21)**
(preferred arrangement set forth below)
 - Descriptive Title of the Invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference sequence listing, a table, or a computer program listing appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
4. ☒ **Drawings(s) (35 USC 113) (Total Sheets 18)**
5. ☒ **Oath or Declaration (Total Pages 10)**
 - a. ☒ Newly Executed (Original or Copy)
 - b. ☐ Copy from a Prior Application (37 CFR 1.63(d))
(for Continuation/Divisional with Box 18 completed)
 - i. ☐ DELETIONS OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
 - c. ☐ Unsigned.
6. ☐ **Application Data Sheet. (37 CFR 1.76)**
7. ☐ **CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)**
8. ☐ **Nucleotide and/or Amino Acid Sequence Submission**
(if applicable, all necessary)
 - a. ☐ Computer Readable Form (CRF)
 - b. ☐ Specification Sequence Listing on:
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ paper
 - c. ☐ Statements verifying identity of above copies

Handwritten initials/signature in the top right corner.

ACCOMPANYING APPLICATION PARTS	
9.	_____ Assignment Papers (cover sheet & documents(s))
10.	_____ a. Separate 37 CFR 3.73(b) Statement (where there is an assignee)
	_____ b. Power of Attorney
11.	_____ English Translation Document (if applicable)
12.	<u> X </u> a. Information Disclosure Statement (IDS)/PTO-1449 (or PTO/SB/08)
	<u> X </u> b. Copies of IDS Citations
13.	_____ Preliminary Amendment
14.	_____ Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
15.	_____ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16.	_____ Nonpublication Request under 35 U.S.C. 122(b)(2)(B)(i). <u>Applicant must attach form PTO/SB/35 or its equivalent.</u>
17A.	_____ Claim for Foreign Priority
17B.	_____ Other: _____
17C. <u> X </u> Pursuant to 37 C.F.R. 1.136(a)(3), applicant(s) hereby request and authorize the U.S. Patent and Trademark Office to (1) treat any concurrent or future reply that requires a petition for extension of time as incorporating a petition for extension of time for the appropriate length of time and (2) charge all required fees, including extension of time fees and fees under 37 C.F.R. 1.16 and 1.17, to Deposit Account No. 02-2666.	
18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title (e.g., by way of preliminary amendment), or in an Application Data Sheet Under 37 C.F.R. 1.76:	
☐ Continuation Of Prior Application No.: _____ ☐ Divisional Examiner _____ ☐ Continuation-in-part (CIP) Group Art Unit _____ (which is a ☐ continuation/ ☐ divisional/ ☐ CIP of prior application no. _____, which is a ☐ continuation/ ☐ divisional/ ☐ CIP of prior application no. _____) (List entire chain of priority) Applicant(s): Also include a Preliminary Amendment to amend the specification to claim priority. For CONTINUATION AND DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation <u>can only</u> be relied upon when a portion has been inadvertently omitted from the submitted application parts.	
19. Correspondence Address	
<u> X </u>	Customer Number or Bar Code Label <u>08791</u>
	or (Insert Customer No. or Attach Bar Code Label here)
Correspondence Address Below	
NAME _____	
REG. NO. _____	
SIGNATURE _____	
DATE _____	
ADDRESS <u>BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP</u>	
<u>1279 Oakmead Parkway</u>	
CITY <u>Sunnyvale</u> STATE <u>California</u> ZIP CODE <u>94085</u>	
Country <u>U.S.A.</u> TELEPHONE <u>(408) 720-8300</u> FAX <u>(408) 720-8383</u>	
CERTIFICATE OF TRANSMISSION	
I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below.	
Name (PRINT/TYPE): <u>Jacob T. Aikin</u> Registration No.: <u>62,787</u>	
Signature: <u>/Jacob Aikin/</u> Date: <u>May 31, 2011</u>	

Attorney Docket No. 006701P074

PATENT

UNITED STATES PATENT APPLICATION

for

TIP PROTECTOR SLEEVE

INVENTORS:

Christopher A. Stout, Betsy Swann, Julian Cruzada, Chris Sepe

Prepared by:

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN

1279 Oakmead Parkway

Sunnyvale, CA 94085-4040

(408) 720-8300

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TIP PROTECTOR SLEEVE

BACKGROUND

[0001] Embodiments of the present invention relate to the field minimally invasive surgical medical devices and medical procedures. More specifically, embodiments of the present invention relate to devices and methods used for transcervical gynecological procedures.

[0002] Female contraception and sterilization may be affected by transcervically introducing an object into a fallopian tube to inhibit conception. Devices, systems and methods for such a contraceptive approach have been described in various patents and patent applications assigned to the present assignee. For example, U.S. Patent No. 6,526,979, U.S. Patent No. 6,634,361, U.S. Patent Application No. 11/165,733 published as U.S. Publication No. 2006/0293560 and U.S. Patent Application No. 12/605,304 describe transcervically inserting an insert (also referred to as implant and device) into an ostium of a fallopian tube and mechanically anchoring the insert within the fallopian tube. One example of such an assembly is known as "Essure" ® from Conceptus, Inc. of Mountain View, California. Tissue in-growth into the "Essure" ® insert provides long-term contraception and/or permanent sterilization without the need for surgical procedures.

[0003] The insert may be delivered to the fallopian tube with a delivery catheter assembly such as the one illustrated in FIG. 1. The delivery catheter assembly 100 is formed of a control device 102 such as a handle, an elongated sheath 104, and an insert 106. The delivery catheter assembly 100 may be transcervically positioned into the uterus and the fallopian tubes via a hysteroscope system.

[0004] Referring to FIG. 2 the hysteroscope system 200 may include a working channel 202 into which the delivery catheter assembly is inserted. Advancement of the delivery catheter system within the uterus and the fallopian tubes is usually facilitated by distending the uterus with a distention fluid, such as saline, and viewing the placement with the hysteroscope system. A valve clamp 208, such as a ball valve clamp, and an access port 206 are positioned at the tip of the working channel 202. Closing the valve clamp 208 may seal the entrance of the working channel 202 to prevent a distention fluid from leaking out of the access port 206. A sealing cap 230 including a pierceable end 232 can be placed over the access port 206 to prevent distention

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fluid from leaking out of the hysteroscope system when a delivery catheter assembly occupies the working channel of the hysteroscope system.

[0005] An introducer 220 may be used in order to prevent damaging the tip the elongated sheath 104 or insert 106 of the delivery catheter assembly 100 during insertion through the pierceable end 232 of the sealing cap 230 and access port 206, and into the working channel 202 of the hysteroscope system 200. Introducer 220 includes a sheath portion 222 and slit opening 224 to aid in grasping and in the removal of the introducer 220. The introducer 220 is inserted through the pierceable end 232 of the sealing cap 230 and into the working channel 202 prior to inserting the delivery catheter assembly 100. When the introducer 220 is inserted through the sealing cap 230, fluid can spray out of the introducer 220 and onto the physician or physician's assistant. The amount of fluid spray-back can be significant depending on the distention fluid pressure during the procedure.

[0006] Referring to FIG. 3, after placing the introducer 220 into the working channel 202, the tip of delivery catheter assembly 100 is inserted into the slit opening 224 and through the sheath 222 of the introducer 220 in order to advance the delivery catheter assembly 100 into the working channel 202 of the hysteroscope system. This is typically performed as soon as possible after placement of the introducer 220 into the working channel 202 in order to minimize the amount of fluid spray-back from the introducer. The introducer 220 may then be removed or may be kept in place throughout the procedure. After insertion of the delivery catheter assembly 100 into the introducer 200, an amount of distention fluid may still leak from between the introducer and elongated sheath 104 of the delivery catheter assembly 100.

SUMMARY

[0007] Embodiments of the present invention generally provide assemblies and methods of inserting a delivery catheter into a working channel of an endoscope, such as a hysteroscope system for accessing a female reproductive system. While embodiments of the invention are described with reference to a hysteroscope system, it is understood that the embodiments are not limited to such and may also be compatible with other optical surgical devices. In one aspect, embodiments of the invention describe a tip protector sleeve which functions as an introducer and protects the tip of a delivery catheter assembly when piercing a sealing cap, as well as during insertion through an access port, into the working channel and past a valve clamp of a

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hysteroscope system. In another aspect, embodiments of the invention describe a method and system which may reduce the amount of fluid spray-back and leakage associated with inserting a delivery catheter assembly into the working channel of a hysteroscope system.

[0008] One embodiment of the present invention relates to a delivery catheter assembly which may be used to deliver an insert to an ovarian pathway (e.g. a fallopian tube) of a female body. The delivery catheter assembly may include a control device, an elongated catheter sheath having a distal end and a proximal end connected to the control device, and a tip protector sleeve. The tip protector sleeve may be locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath. The delivery catheter assembly may further include an interference stop which determines the distal-stop position and prevents the tip protector sleeve from sliding off of the distal end of the elongated catheter sheath. For example, the interference stop may include a male interference part which interferes with sliding of a female interference part over the elongated catheter sheath. The male interference part may be fixed to the elongated catheter sheath, and the tip protector sleeve may comprise the female interference part. The tip protector sleeve may additionally incorporate a sealing valve to reduce the amount of fluid spray-back and leakage associated with inserting the delivery catheter assembly into the working channel of a hysteroscope system

[0009] Another embodiment of the present invention relates to a method of forming a delivery catheter assembly which includes sliding a tip protector sleeve over a distal end of an elongated catheter sheath and toward a control device, and then fixing a bump onto a distal region of the elongated catheter sheath. Alternatively, the bump may be fixed onto the distal region of the elongated catheter sheath, and then the tip protector sleeve is slid over a proximal end of the elongated catheter sheath toward the bump prior to attaching the control device to the elongated catheter sheath. The control device may prevent the tip protector sleeve from sliding off a proximal end of the elongated sheath and define, in part, a proximal-stop position. The bump may prevent the tip protector sleeve from sliding off of a distal end of the elongated catheter sheath and define, in part, a distal-stop position. In an embodiment, the bump may be fixed onto a distal region of the elongated catheter sheath by crimping a band onto the elongated catheter sheath. It is not necessary to crimp the entire length of the band, and only a proximal end of the band is crimped onto the elongated catheter shaft in an embodiment.

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[0010] Another embodiment of the present invention relates to a method of delivering an insert into a body lumen such as an ovarian pathway (e.g. a fallopian tube) of a female body. Utilizing a delivery catheter assembly in accordance with embodiments of the invention the tip protector sleeve is positioned at the distal-stop position, and the tip protector sleeve is inserted through a pierceable end of a sealing cap, through an access port of a hysteroscope system and into a working channel of the hysteroscope system. In accordance with embodiments of the invention, the distal end of the elongated catheter sheath and insert are inserted through the pierceable end of the sealing cap, through the access port and into the working channel of the hysteroscope system simultaneously with the tip protector sleeve in the distal-stop position. The distal end of the elongated catheter sheath and insert may then be advanced through the tip protector sleeve and beyond the hysteroscope system to a target location within the body lumen where the insert is deployed within the body lumen. In an embodiment, the tip protector sleeve is advanced through the sealing cap into the working channel until a flanged mechanical stop, such as a bead or flared portion, abuts the sealing cap (or access port if a sealing cap is not utilized) prior to advancing the elongated sheath and insert to the target location.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] FIG. 1 is a cross-sectional side view illustration of a delivery catheter assembly.

[0012] FIG. 2 is an isometric view illustration of a hysteroscope system and an introducer.

[0013] FIG. 3 is an isometric view illustration of a delivery catheter assembly inserted into an introducer and working channel of a hysteroscope system.

[0014] FIG. 4 is a side view illustration of a tip protector sleeve in accordance with an embodiment of the invention.

[0015] FIG. 5A is a side view illustration of a delivery catheter assembly with a tip protector sleeve at a proximal-stop position in accordance with an embodiment of the invention.

[0016] FIG. 5B is a side view illustration of a delivery catheter assembly with a flanged mechanical stop of a tip protector sleeve in a cavity of a control device in accordance with an embodiment of the invention.

[0017] FIG. 5C is a side view illustration of a delivery catheter assembly with a tip protector sleeve fastened into the proximal-stop position by a friction fitting in accordance with an embodiment of the invention.

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[0018] FIG. 5D is a side view illustration of a delivery catheter assembly with a tip protector sleeve screwed into the proximal-stop position in accordance with an embodiment of the invention.

[0019] FIG. 6 is a side view illustration of a delivery catheter assembly with a tip protector sleeve at a distal-stop position in accordance with an embodiment of the invention.

[0020] FIG. 7 is a close-up side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention

[0021] FIG. 8 is a close-up cross-sectional side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention

[0022] FIG. 9 is a cross-sectional side view illustration of a tip protector sleeve in accordance with an embodiment of the invention.

[0023] FIG. 10 is a cross-sectional side view illustration of a tip protector sleeve in accordance with an embodiment of the invention.

[0024] FIGS. 11A-11C are cross-sectional side view illustrations of tip protector sleeves incorporating various sealing valves in accordance with embodiments of the invention.

[0025] FIGS. 12A-12C are isometric view illustrations of inserting a delivery catheter assembly into a working channel of a hysteroscope system in accordance with an embodiment of the invention.

DETAILED DESCRIPTION

[0026] Embodiments of the present invention generally provide assemblies and methods of inserting a delivery catheter into a working channel of an endoscope, such as a hysteroscope system or other optical surgical device for accessing a female reproductive system. Various embodiments and aspects will be described with reference to details discussed below and the accompanying drawings will illustrate the various embodiments. The following description and drawings are illustrative of the invention and are not to be construed as limiting the invention. Numerous specific details are described to provide a thorough understanding of various embodiments of the present invention. However, in certain instances, well-known or conventional details are not described in order to provide a concise discussion of embodiments of the present invention.

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[0027] In an embodiment, a delivery catheter assembly includes a control device, an elongated catheter sheath having a distal end and a proximal end connected to the control device, and a tip protector sleeve. Referring to the FIG. 4 the tip protector sleeve 300 may include an elongated shaft 302, a flanged mechanical stop 304 at a proximal end, and a distal end 306. The distal end 306 can be flat or angled to assist with piercing of a sealing cap. In an embodiment, the distal end 306 has an approximately 45 degree angled tip. Elongated shaft 302 may be formed of a material and to a thickness which can be molded and does not buckle when piercing a sealing cap. For example, elongated shaft 302 may be formed of a material such as polyether ether ketone (PEEK).

[0028] Flanged mechanical stop 304 may provide variety of functions, be formed of a variety of materials and have a variety of shapes and sizes as will be explained in further detail with regard to FIGS. 5A-12C. For example, flanged mechanical stop 304 may be formed of a moldable material such as polycarbonate, or from the same material as the elongated shaft 302. Flanged mechanical stop 304 may be sized and shaped larger than the inside diameter (ID) of a corresponding access port opening to a working channel or pierceable end of a sealing cap if present in order to act as a stop mechanism that controls the insertion depth of the tip protector sleeve 300 into the working channel. Flanged mechanical stop 304 may also be sized and shaped to be gripped by an operator's hand to assist with sliding of the tip protector sleeve 300 over a length of the elongated catheter sheath 404 of a catheter assembly. In this respect, one function may be as a handle at the proximal end of the tip protector sleeve 300. Flanged mechanical stop 304 may also incorporate a sealing valve to reduce the amount of fluid spray-back and leakage associated with inserting the delivery catheter assembly into a working channel.

[0029] Referring to FIGS. 5A-6, a delivery catheter assembly 400 in accordance with embodiments of the invention is illustrated in which the tip protector sleeve 300 is locked onto and slideable over a length of the elongated catheter sheath 404. The delivery catheter assembly 400 may be formed by sliding a tip protector sleeve 300 over a distal end of an elongated catheter sheath 404 and toward a control device 402, and then fixing a bump 408 onto a distal region of the elongated catheter sheath 402. Alternatively, the bump 408 may be fixed onto the distal region of the elongated catheter sheath 402, and then the tip protector sleeve 300 is slid over a proximal end of the elongated catheter sheath 402 toward the bump 408 prior to attaching the control device 402 to the elongated catheter sheath 402. The control device 402 may prevent

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the tip protector sleeve 300 from sliding off a proximal end of the elongated sheath 402 and define, in part, a proximal-stop position. The bump 408 may prevent the tip protector sleeve 300 from sliding off of a distal end of the elongated catheter sheath 402 and define, in part, a distal-stop position. An operator may grip the flanged mechanical stop 304 by hand, for example between a thumb and index finger, and slide the tip protector sleeve over the elongated catheter sheath 404 between the proximal-stop and distal-stop positions.

[0030] FIG. 5A is an illustration of the tip protector sleeve 300 positioned at a proximal-stop position. In the embodiment illustrated in FIG. 5A, the flanged mechanical stop 304 abuts a distal end of the control device 402, though other proximal-stop positions along the elongated catheter sheath 404 are contemplated in accordance with embodiments of the invention. For example, FIGS. 5B-5D are illustrations of embodiments in which the control device 402 is configured to allow flanged mechanical stop 304 to slide within a cavity 420 located at a distal portion of the control device 402. Such embodiments may be useful during operation in order to utilize the full working length of the elongated catheter sheath 404. In this manner, the distal end of the control device 402 can be advanced to abut the access port 206 of the hysteroscope system or the pierceable end 232 of a sealing cap 230 if desired during operation. Alternatively, the distal end of the control device 402 can be advanced over the access port 206 of the hysteroscope system or over sealing cap 230 and the flanged mechanical stop 304 is allowed to abut the access port 206 or the pierceable end 232 of the sealing cap 230. As illustrated in FIG. 5B, flanged mechanical stop 304 may be slid into cavity 420 to abut a back wall 422 of the cavity at the proximal-stop position. Flanged mechanical stop 304 may be also configured to fasten onto the handle 402 at the proximal-stop position. For example, FIG. 5C is an illustration of an embodiment in which flanged mechanical stop 304 may be slid into cavity 420 and fastened into the proximal-stop position by a friction fitting with sloped walls 424 of the cavity. FIG. 5D is an illustration of an embodiment in which flanged mechanical stop 304 may be screwed into cavity 420 in which threads 330 on flanged mechanical stop 304 mate with threads 430 inside cavity 420 to fasten tip protection sleeve 300 in the proximal-stop position. In an embodiment, a suitable fastening mechanism for fastening tip protector sleeve 300 onto control device 402 is able to hold the tip protector sleeve 300 in the proximal-stop position during withdrawal of the delivery catheter assembly 400 from the working channel of the hysteroscope system.

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[0031] Referring now to FIG. 6 an operator may slide the tip protector sleeve over the elongated catheter sheath 404 between the proximal-stop position and the distal-stop position illustrated in FIG. 6. As illustrated, the distal end 306 of tip protector sleeve 300 may extend distally beyond a distal end of the elongated catheter sheath 404 and insert 406 when at the distal-stop position. In this manner, the tip protector sleeve 300 may protect the distal ends of the elongated catheter sheath 404 and insert 406 during piercing of a sealing cap and during insertion into the working channel and past a valve clamp of the hysteroscope system.

[0032] An interference stop may determine the distal-stop position and prevent the tip protector sleeve 300 from sliding off of the distal end of the elongated catheter sheath 404. In an embodiment, the interference stop includes a male interference part which interferes with sliding of a female interference part over the elongated catheter sheath. Referring again to FIG. 5A, the male interference part may comprise a bump 408 fixed to the elongated catheter sheath 404. Bump 408 may be formed along only a portion of the circumference of the elongated sheath, or may encircle the circumference of the elongated sheath. In an embodiment, bump 408 is a band fixed to and encircling the circumference of the elongated catheter sheath. In an embodiment, bump 408 is fixed to the elongated catheter sheath 404 with a sufficient shear strength to ensure that the tip protector sleeve may be removed from a working channel of a hysteroscope system along with removal of the elongated catheter sheath 404.

[0033] FIG. 7 is a close-up side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention. FIG. 8 is a close-up cross-sectional side view illustration of the proximal end of a tip protector sleeve over an elongated catheter sheath in accordance with an embodiment of the invention. As illustrated in FIGS. 7-8, flanged mechanical stop may be a bead 304A having a barrel-like shape, though embodiments of the invention are not limited to such a shape. In an embodiment, bead 304A is fixed to shaft 302 with an adhesive.

[0034] Referring to FIG. 8, in an embodiment bead 304A may be fixed to a proximal end of the elongated shaft 302. Bead 304A may include a distal portion 308 surrounding the proximal end of the elongated shaft 302, a shoulder portion 310 extending proximally of the elongated shaft 302, and a backstop 312. The distal portion 308 may be fixed to the elongated shaft 302 with an adhesive. In an embodiment, the backstop 312 abuts the proximal end of the elongated shaft 302. Backstop 312 may also have a height which is greater than a thickness of the elongated

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shaft 302. For example, the height may be defined as the distance between and inside diameter (ID) of the backstop and an ID of the distal portion 308 of the bead 304A. In accordance with various embodiments of the invention, the dimensions and location of the backstop 312 as they relate to the dimensions and location of bump 410 create an interference stop which determines the distal-stop position and prevents the tip protector sleeve from sliding off of the distal end of the elongated catheter sheath 404.

[0035] In an embodiment, the tip protector sleeve 300 is locked onto an “Essure” ® delivery catheter assembly. In such an embodiment, the ID of elongated catheter sheath 404 may be between 0.0405 and 0.0420 inches and the outside diameter (OD) of elongated catheter sheath 404 may be between 0.0538 and 0.0560 inches. Elongated catheter sheath 404 may be formed of a polyether block amide also known under the trade name PEBAX. The OD of elongated catheter sheath 404 may be used to determine the ID of bump 408. In an embodiment, bump 408 may have an ID between 0.0545 and 0.0555 inches and an OD between 0.0575 and 0.0580 inches. In one embodiment, the ID of bump 408 may be smaller than the OD of the elongated catheter sheath 404. In another embodiment, the OD of the elongated catheter sheath 404 is smaller than the ID of bump 408. For example, the OD of the elongated catheter sheath 404 may be between 0.0538 and 0.0542 inches.

[0036] Bump 408 may be a band that is fixed to and encircles the elongated catheter sheath. Bump may be fixed to the elongated catheter sheath 404 by a variety of mechanisms including adhesive and crimping. In an embodiment, bump 408 is formed of a material which is strong enough to resist deformation during operation of the delivery catheter assembly, yet malleable enough to be suitable for crimping. For example, stainless steel possesses suitable strength and malleability. In an embodiment, only a distal end 410 of the band is crimped onto the elongated catheter sheath, as illustrated in FIG. 8. This leaves the proximal end, with the original OD between 0.0575 and 0.0580 inches to act as the male interference part which interferes with the ID of backstop 312 functioning as a part of the female interference part. While an embodiment of bump 408 is described in detail in FIG. 8 in operable relationship with bead 304A, it is understood that bump 408 can be in operable relationship with other flanged mechanical stops, such as those illustrated in FIGS. 9-11C.

[0037] Still referring to FIG. 8, bead 304A may be formed of a variety of materials and have a variety of shapes and sizes to perform a variety of functions. In one aspect, bead 304A may be

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sized and shaped larger than the inside diameter (ID) of a corresponding access port opening to a working channel or pierceable end of a sealing cap if present in order to act as a stop mechanism that controls the insertion depth of the tip protector sleeve 300 into the working channel. In one aspect, bead 304A may perform the function as a handle for gripping by the operator. In another aspect, bead 304A may include a backstop 312 which functions as part of the female interference part. In an embodiment, bead 304A has an OD of approximately 0.112 inches. The distal portion 308 of bead 304A may have an ID of approximately 0.070 and may be bonded to the OD of elongated shaft 302. Backstop 312 may have an ID which is smaller than an OD of the proximal end of bump 408. For example, backstop 312 may have an ID between 0.0565 and 0.0575 inches. In such an embodiment, backstop 312 has a height that extends from the ID of back stop 312 to the ID of the distal portion 308 of the bead 304, or approximately 0.013 inches. [0038] In accordance with embodiments of the invention tip protector sleeve 300 may be locked onto the delivery catheter assembly 400. Shaft 302 may be used to pierce a sealing cap and protect the tip of the insert 406, elongated catheter sheath 404 or guidewire during insertion into the working channel and past a valve clamp of a hysteroscope system. In an embodiment, the shaft 302 and elongated catheter sheath 404 may be advanced into a working channel of a hysteroscope system without allowing a significant amount of fluid (e.g. saline) spray-back or leakage from the delivery catheter assembly. The elongated catheter sheath 404 may additionally be slid through the shaft 302 to deliver the insert 406 to a body lumen, while the delivery catheter assembly 400 does not allow a significant amount of fluid leakage. Referring now to FIG. 12A, the shaft 302 may pierce the pierceable end 232 of a sealing cap 230 with the tip of the shaft 306. The outside diameter of the shaft 302 may fit tightly in the pierceable end 232 effectively creating a water tight seal between the sealing cap 230 and tip protector sleeve 300.

[0039] The reduction of fluid spray-back and leakage may also be achieved by controlling the shape and dimensions of the tip protector sleeve 300 as it interacts with the elongated catheter sheath 404 and bump 408. In an embodiment, shaft 302 may be approximately 2.82 inches long from the proximal end to the distal end of the tip 306, which may be angled. Shaft 302 may have an ID between 0.0585 and 0.0605 inches and an OD between 0.0690 and 0.0710 inches. The shaft 302 ID may be selected to not allow for fluid to flow proximally between the shaft 302 and elongated catheter sheath 404 (and bump 408), while still allowing for the elongated catheter

sheath 404 to slide and be advanced through the shaft 302. In such an embodiment, a minimum clearance between the ID of the elongated shaft 302 (e.g. 0.059 inches) and the OD of the elongated catheter sheath 404 (e.g. 0.055 inches) provides sufficient resistance to spray-back and leakage. Such a minimum clearance may be effective for overlapping constant diameters of the elongated shaft 302 and elongated catheter sheath 404.

[0040] Referring now to FIG. 9, an embodiment for tip protector sleeve 300B is illustrated. As illustrated in FIG. 9, tip protector sleeve 300B includes an elongated shaft 302, a bead 304B and inner shaft 320. Tip protector sleeve 300B operates similarly as tip protector sleeve 300 with one difference being that backstop 322 is the distal end of inner shaft 320. In such an embodiment, the shape and dimensions of tip protector sleeve 300B are controlled so that bump 408 interferes with movement of the distal end, backstop 322 of inner shaft 320. In such an embodiment, bead 304B may be sized and shaped to act as a stop mechanism that controls the insertion depth of the tip protector sleeve 300B into the working channel and may perform the function as a handle for gripping by the operator.

[0041] Referring now to FIG. 10, another embodiment for tip protector sleeve 300C is illustrated. As illustrated in FIG. 10, tip protector sleeve 300C includes an elongated shaft 302, a neck portion 332, and a flared portion 304C. Tip protector sleeve 300C operates similarly as tip protector sleeves 300 and 300B. One difference is that the neck portion 332 operates as the backstop for bump 408. The neck portion 332 may be integrally formed with the elongated shaft 302 or be a separate member bonded to the inside diameter of elongated shaft 302. Likewise flared portion 304C may be integrally formed with the elongated shaft 302 or be a separate member bonded to the outside diameter of elongated shaft 302. In such an embodiment, flared portion 304C may be sized and shaped to act as a flanged mechanical stop that controls the insertion depth of the tip protector sleeve 300C into the working channel and may perform the function as a handle for gripping by the operator.

[0042] Embodiments of the invention are also envisioned in which the elongated catheter sheath 404 does not have a constant OD along its length. In accordance with some embodiments, the tip protector sleeve 300 may include a change in ID or a valve to accommodate variations in the OD of the elongated catheter sheath 404, or to more effectively seal an elongated catheter sheath 404 with a constant OD. Referring again to FIG. 9, inner shaft 320 is illustrated as having a smaller ID than the ID of elongated shaft 302. In addition to functioning as an interference part,

the ID of inner shaft 320 may more effectively accommodate a reduction in OD of the elongated catheter sheath 404. Referring again to FIG. 10, the ID of neck portion 332 may also more effectively accommodate a reduction in OD of the elongated catheter sheath 404 in addition to functioning as an interference part. Thus, a minimum clearance between the ID of inner shaft 320 or ID of neck portion 332 and the OD of the elongated catheter shaft 404 may provide enhanced resistance to fluid-spray back.

[0043] FIGS. 11A-11C are illustrations embodiments of a tip protector sleeve incorporating various sealing valves to reduce the amount of fluid spray-back and leakage between the tip protector sleeve and elongated sheath of the delivery catheter assembly. While illustrated separately, it is understood that the embodiments illustrated in FIGS. 11A-11C may be combined with other embodiments of the invention. More specifically, any of the sealing valves described in reference to the illustrations in FIGS. 11A-11C may be combined with any of the embodiments further describing the proximal-stop and distal-stop positions.

[0044] FIG. 11A is an illustration of a tip protector sleeve 300D including an elongated shaft 302, a housing 304D, and valve 340. Housing 304D may function as a stop mechanism that controls the insertion depth of the tip protector sleeve 300D into the working channel and may perform the function as a handle for gripping by the operator. The elongated shaft 302 may be coupled to a distal tip 342 of the housing 304D which may function as a backstop for interference with a bump 408 fixed to the elongated catheter sheath 404 at the distal-stop position. Housing 304D additionally houses valve 340 which is capable of accommodating multiple variations in OD of the elongated catheter sheath 404. For example, valve 340 may be a silicone valve containing a slit at the distal end that allows for a catheter shaft to pass through it. The silicone material may allow for the slit to conform to different shapes or diameters while providing a seal. Due to the geometry on the distal end of the silicone valve, as fluid tries to pass from distal to proximal, the end of the valve may be pushed closed due to a chamfer on the end of the valve.

[0045] FIG. 11B is an illustration of a tip protector sleeve 300E including an elongated shaft 302, a housing 304E, and a compression valve 350 including an screw cap 354 which may be threaded down onto an O-ring 352 to compress it against the elongated catheter sheath 404. Housing 304E may function as a stop mechanism that controls the insertion depth of the tip protector sleeve 300E into the working channel and may perform the function as a handle for

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gripping by the operator. The elongated shaft 302 may be coupled to a distal tip 342 of the housing 304E which may function as a backstop for interference with a bump fixed to the elongated catheter sheath at the distal-stop position.

[0046] FIG. 11C is an illustration of a tip protector sleeve 300F including an elongated shaft 302, a housing 304F, and a compression valve 360 including a cap 362, a compression spring 364 and a thin walled tube (not illustrated) inside the housing. For example, the thin walled tube may be made of a material such as silicone. Threads between the cap 362 and the housing 304F apply a twist motion to the tube. When the tube is twisted, an inner diameter of the tube tightens like an iris. The compression spring 364 keeps the cap 362 extended and the threads hold the twist or keep the iris closed. When the cap 362 is pushed towards the housing 304F (spring compressed) the cap 362 untwists and the iris opens. In this manner the opening of the iris can be adjusted based upon the OD of the elongated catheter sheath 404. Similar to tip protector sleeves 300D and 300E, housing 304F may function as a stop mechanism that controls the insertion depth of the tip protector sleeve 300F into the working channel and may perform the function as a handle for gripping by the operator. The elongated shaft 302 may be coupled to a distal tip 342 of the housing 304F which may function as a backstop for interference with a bump fixed to the elongated catheter sheath at the distal-stop position.

[0047] A delivery catheter assembly in accordance with embodiments of the invention may be utilized to deliver an insert to an ovarian pathway (e.g. a fallopian tube) of a female body. The delivery catheter assembly may protect the tip of an elongated catheter sheath, guidewire, or insert during piercing of a sealing cap and insertion into the working channel and past a valve clamp of a hysteroscope system and reduce the amount of fluid spray-back and leakage associated with inserting a delivery catheter assembly into the working channel of a hysteroscope system. In an embodiment, the delivery catheter assembly includes a control device, an elongated catheter sheath having a distal end and a proximal end connected to the control device, and a tip protector sleeve locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath. The delivery catheter assembly may further include an insert releasably disposed within the elongated catheter sheath. In an embodiment, the insert extends distally beyond the elongated catheter sheath. In an embodiment, the insert includes a preformed bend, as illustrated in FIG. 5, which may be utilized to assist with navigation through a curved

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portion of a fallopian tube. Upon providing the delivery catheter assembly the operator may grasp a flanged mechanical stop 304 or other suitable portion of the tip protector sleeve 300 to position the tip protector sleeve at the distal-stop position illustrated in FIG. 6. If a sealing valve is present on the tip protection sleeve 300, the sealing valve may then be tightened onto the elongated catheter sheath 404 if necessary to provide an optimal seal to protect against fluid spray-back and leakage.

[0048] Referring now to FIGS. 12A-12C, the operator may then pierce a pierceable end 232 of a sealing cap 230 with the tip protector sleeve 300 and insert the tip protector sleeve 300 through an access port 206 of a hysteroscope system 200 and into the working channel 202 of the hysteroscope system. During insertion the tip protector sleeve 300 may be advanced past a valve clamp 208 of the hysteroscope system. The tip protector sleeve protects against the possibility of the exposed portion of the insert 406 from catching on the valve clamp 208 and compromising the insert integrity. In accordance with embodiments of the invention, the distal end 410 of the elongated catheter sheath 404 and insert 406 are inserted through the sealing cap 230 and access port 206, and into the working channel 202 of the hysteroscope system simultaneously with the tip protector sleeve 300 in the distal-stop position. The simultaneous insertion of the tip protector sleeve 300 and elongated catheter sheath 404 may avoid a problem of fluid spray-back associated with sequentially inserting an introducer followed by an elongated catheter sheath. In an embodiment, the tip protector sleeve 300 may be advanced into the working channel simultaneously with the elongated catheter sheath and insert 406 until the flanged mechanical stop 304 abuts against the access port 206 or sealing cap 230, if present, as illustrated in FIG. 12B.

[0049] The distal end 410 of the elongated catheter sheath 404 may then be advanced past the hysteroscope system 200 as illustrated in FIG. 12C, and onto a target location with the body lumen. The insert 406 may then be deployed into the body lumen. Depending upon operator preference, the tip protector sleeve 300 may remain inserted in the working channel 202 during the elongated catheter sheath 404 advancement and insert 406 deployment procedures or removed from the working channel 202. In accordance with many embodiments of the invention it is understood that the tip protector sleeve 300 is permanently locked onto the elongated catheter sheath. It is also contemplated that the tip protector sleeve 300 could be removed from the catheter assembly after initially advancing the catheter assembly into the working channel,

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for example, by including a tear joint in the tip protector sleeve in which the tip protector sleeve can be manually torn off of the elongated catheter sheath by the operator.

[0050] In an embodiment, the insert 406 and distal end 410 of the elongated catheter sheath 404 are advanced to the target location within the body lumen while the flanged mechanical stop 304 on the tip protector sleeve 300 abuts the access port 206 or sealing cap 320, if present. The amount of elongated catheter sheath 404 spanning between the flanged mechanical stop 304 and control device 402 may depend upon the procedure and patient's anatomy. It is envisioned that circumstances arise where the operator may wish to insert the entire available working length of the elongated catheter sheath 404 into the patient and advance the control device 402 all the way to the access port or sealing cap, if present. In accordance with embodiments of the invention illustrated in FIGS. 5B-5D, this can be possible by including a cavity 420 in the control device 402 to accommodate the flanged mechanical stop 304.

[0051] Once the insert 406 is deployed into the body lumen the delivery catheter assembly may be withdrawn from the working channel of the hysteroscope system. In one embodiment, during withdrawal of the delivery catheter assembly 400 from the working channel, the bump 408 on the elongated catheter sheath 404 may be withdrawn proximally against the backstop of the tip protector sleeve 300 and cause the tip protector sleeve 300 to be withdrawn from the working channel 202 of the hysteroscope system 200. In another embodiment, the flanged mechanical stop 304 on the tip protector sleeve 300 can be fastened to the control device 402. In this manner, during withdrawal of the delivery catheter assembly 400 from the working channel, the tip protector sleeve 300 remains fastened to the control device 402.

[0052] In the foregoing specification, various embodiments of the invention have been described. It will, however, be evident that various modifications and changes may be made thereto without departing from the broader spirit and scope of the invention as set forth in the appended claims. The specification and drawings are, accordingly, to be regarded in an illustrative sense rather than a restrictive sense. Hence, the scope of the present invention is limited solely by the following claims.

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CLAIMS

What is claimed is:

1. A delivery catheter assembly comprising:
a control device;
an elongated catheter sheath having a distal end and a proximal end connected to the control device; and
a tip protector sleeve locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath.
2. The delivery catheter assembly of claim 1, further comprising an interference stop which determines the distal-stop position and prevents the tip protector sleeve from sliding off of the distal end of the elongated catheter sheath.
3. The delivery catheter assembly of claim 2, wherein the interference stop comprises a male interference part which interferes with sliding of a female interference part over the elongated catheter sheath.
4. The delivery catheter assembly of claim 3, wherein the tip protector sleeve comprises an elongated shaft and a backstop together functioning as the female interference part, and the male interference part is fixed to the elongated catheter sheath.
5. The delivery catheter assembly of claim 4, wherein the male interference part comprises a bump fixed to the elongated catheter sheath.
6. The delivery catheter assembly of claim 5, wherein the bump comprises a band fixed to and encircling the elongated catheter sheath.

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7. The delivery catheter assembly of claim 6, wherein a distal end of the band is crimped onto the elongated catheter sheath, and a proximal end of the band is not crimped onto the elongated shaft.
8. The delivery catheter assembly of claim 4, wherein the backstop has an ID which is smaller than an OD of the male interference part.
9. The delivery catheter assembly of claim 8, further comprising a molded bead fixed to a proximal end of the elongated shaft.
10. The delivery catheter of claim 9, wherein the molded bead comprises:
a distal portion surrounding the proximal end of the elongated shaft;
a shoulder portion extending proximally of the elongated shaft; and
the backstop, wherein the backstop abuts the proximal end of the elongated shaft.
11. The delivery catheter assembly of claim 8, wherein the tip protector sleeve further comprises an inner shaft fixed to a proximal end of the elongated shaft, and the backstop is a distal end of the inner shaft.
12. The delivery catheter assembly of claim 4, wherein the male interference part is fixed to the elongated catheter sheath a first distance from the distal end of the elongated catheter sheath, and wherein the tip protector sleeve is longer than the first distance such that the tip protector sleeve extends distally beyond the elongated catheter sheath when at the distal-stop position.
13. The delivery catheter assembly of claim 12, further comprising an insert disposed within and extending distally beyond a distal end of the elongated catheter sheath, wherein the tip protector sleeve extends distally beyond the insert when at the distal-stop position.
14. The delivery catheter assembly of claim 3, wherein the tip protector sleeve further comprises a sealing valve.

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15. A method of forming a delivery catheter assembly comprising:
sliding a tip protector sleeve over a distal end of an elongated catheter sheath and toward a control device;

fixing a bump onto a distal region of the elongated catheter sheath, wherein the bump prevents the tip protector sleeve from sliding off of a distal end of the elongated catheter sheath.

16. The method of claim 15, wherein fixing a bump onto a distal region of the elongated catheter sheath comprises crimping.

17. The method of claim 16, wherein crimping comprises crimping a distal end of a band onto the elongated catheter sheath.

18. The method of claim 17, further comprising not crimping a proximal end of the band onto the elongated catheter shaft.

19. A method of delivering an insert comprising:
providing a delivery catheter assembly comprising:

a control device;

an elongated catheter sheath having a distal end and a proximal end connected to the control device;

an insert releasably disposed within the elongated catheter sheath; and

a tip protector sleeve locked onto the elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath;

positioning the tip protector sleeve at the distal-stop position;

inserting the tip protector sleeve through an access port of a hysteroscope system and into a working channel of the hysteroscope system;

advancing the distal end of the elongated catheter sheath to a target location within a body lumen; and

deploying the insert inside the body lumen.

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20. The method of claim 19, wherein inserting the tip protector sleeve further comprises advancing a distal end of the tip protector sleeve past a valve clamp of the hysteroscope system.

21. The method of claim 20, wherein inserting the tip protector sleeve comprises advancing the tip protector sleeve into the working channel until a flanged mechanical stop on the tip protector sleeve abuts the access port or a sealing cap coupled to the access port.

22. The method of claim 21, wherein the distal end of the elongated catheter sheath is advanced to the target location within the body lumen while the flanged mechanical stop on the tip protector sleeve abuts the access port or the sealing cap.

23. The method of claim 19, further comprising removing the delivery catheter assembly from the working channel after deploying the insert inside the body lumen.

24. The method of claim 19, wherein removing the delivery catheter assembly from the working channel comprises withdrawing a bump on the elongated catheter sheath proximally against a backstop of the tip protector sleeve to cause the tip protector sleeve to be withdrawn from the working channel.

25. The method of claim 19, further comprising tightening a sealing valve of the tip protector sleeve onto the elongated catheter sheath after positioning the tip protector sleeve at the distal-stop position, and prior to inserting the tip protector sleeve through the access port of the hysteroscope system.

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ABSTRACT

Assemblies and methods of inserting a delivery catheter assembly into a working channel are disclosed. In accordance with some embodiments, a delivery catheter assembly is disclosed in which a tip protector sleeve is locked onto an elongated catheter sheath and slideable over a length of the elongated catheter sheath between a proximal-stop position and a distal-stop position along the elongated catheter sheath.

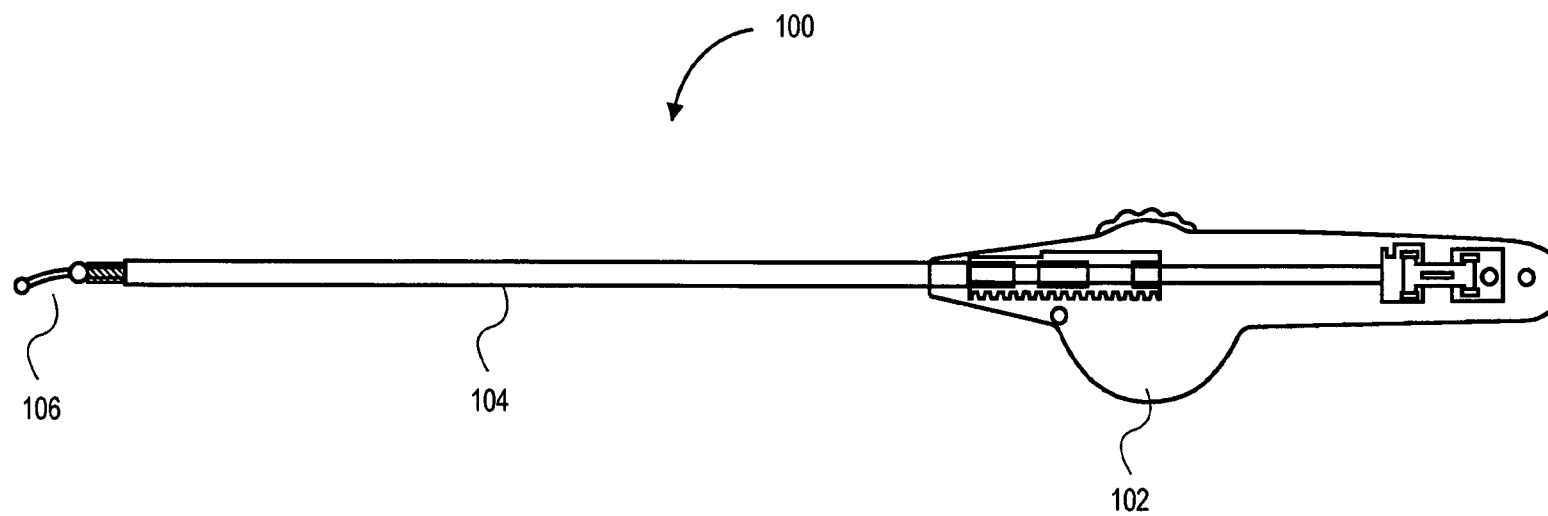
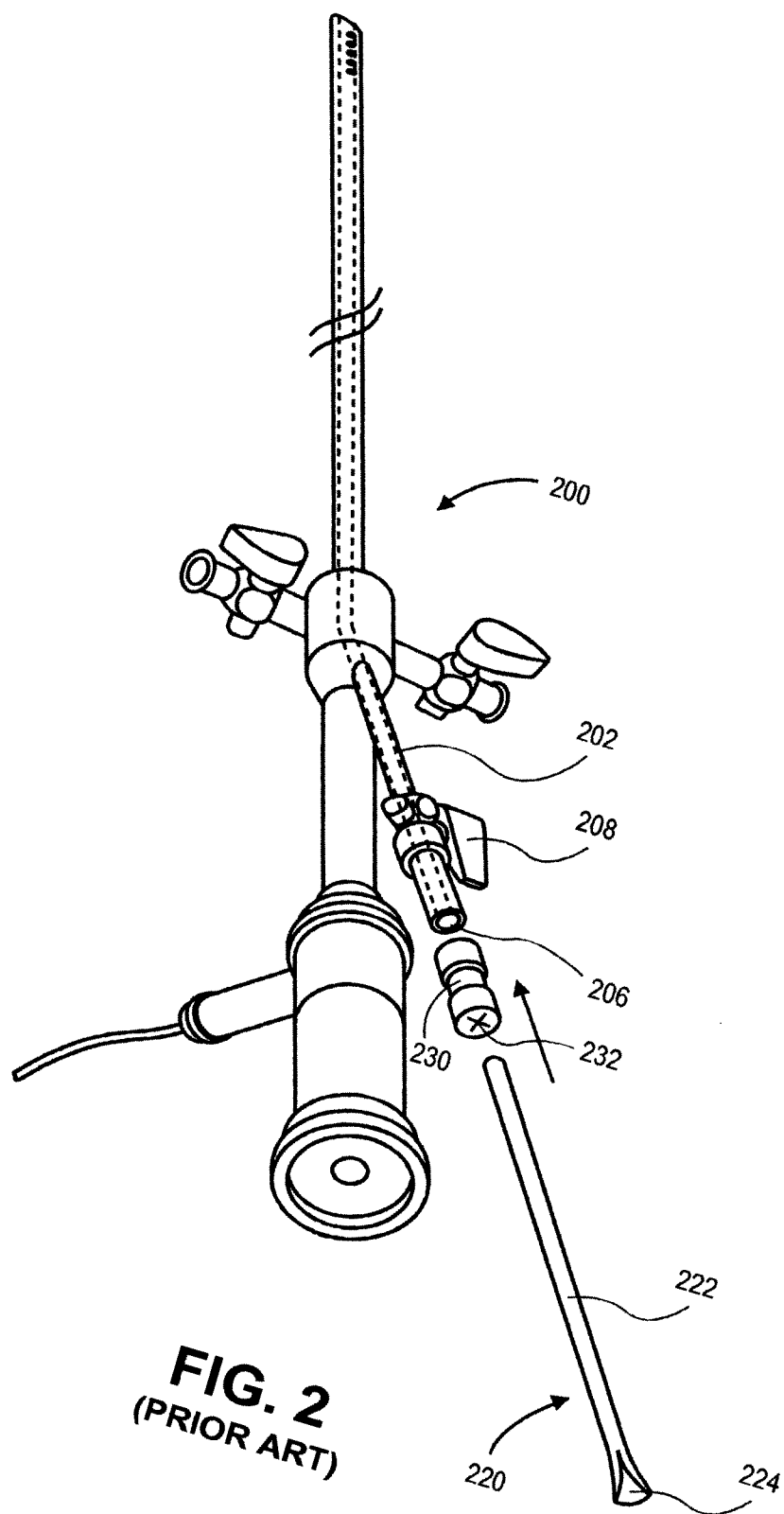


FIG. 1
(PRIOR ART)

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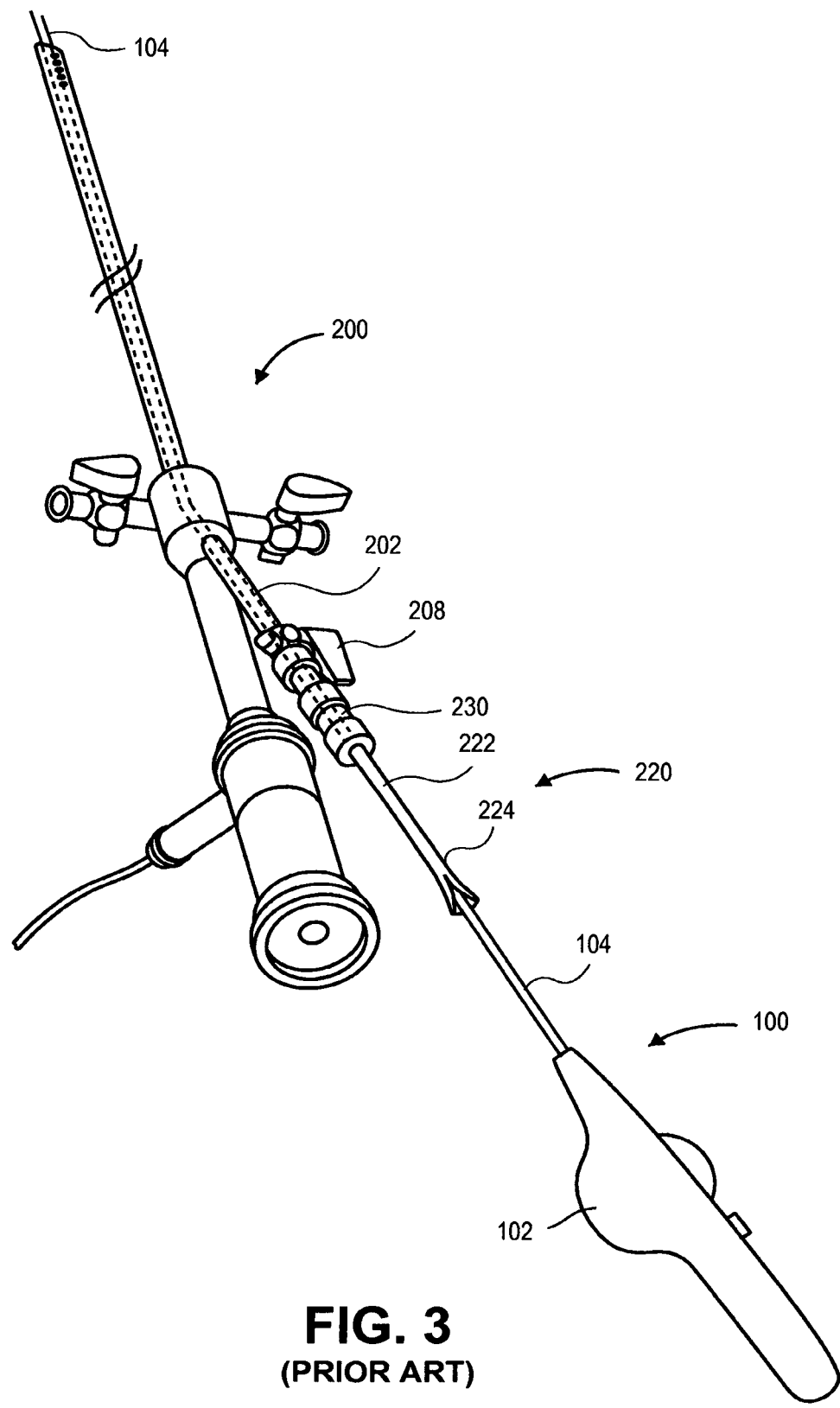


FIG. 3
(PRIOR ART)

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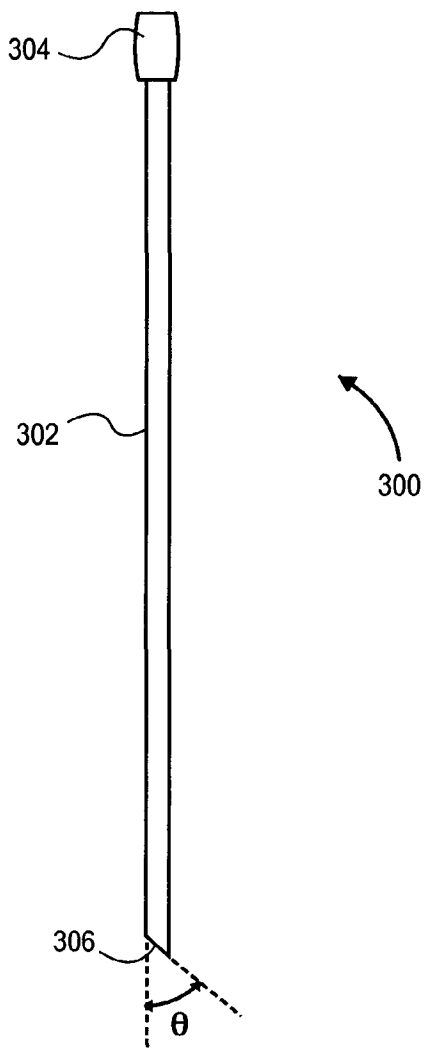


FIG. 4

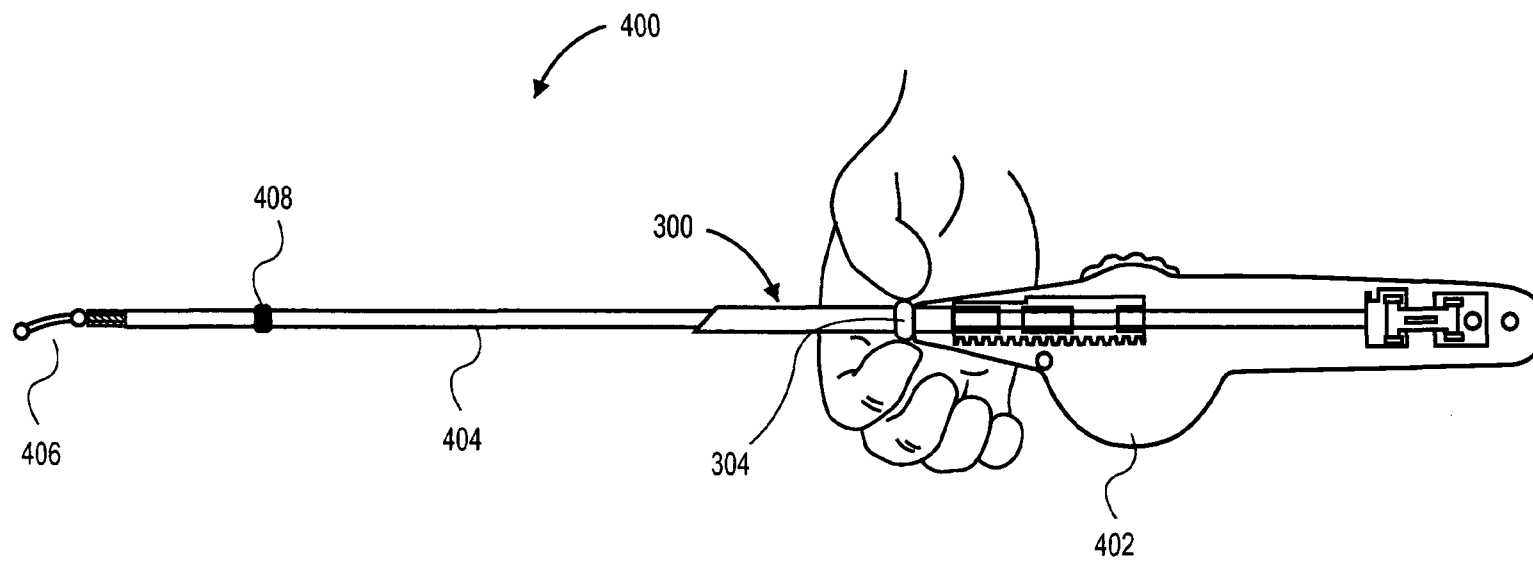


FIG. 5A

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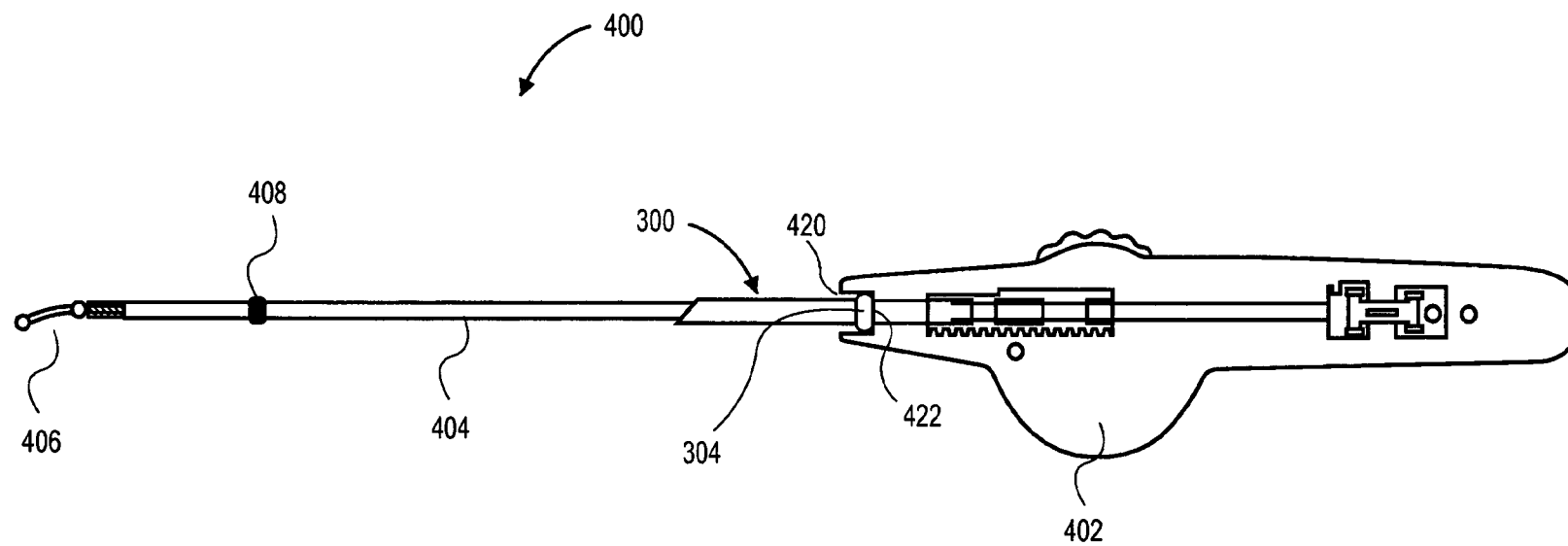


FIG. 5B

125

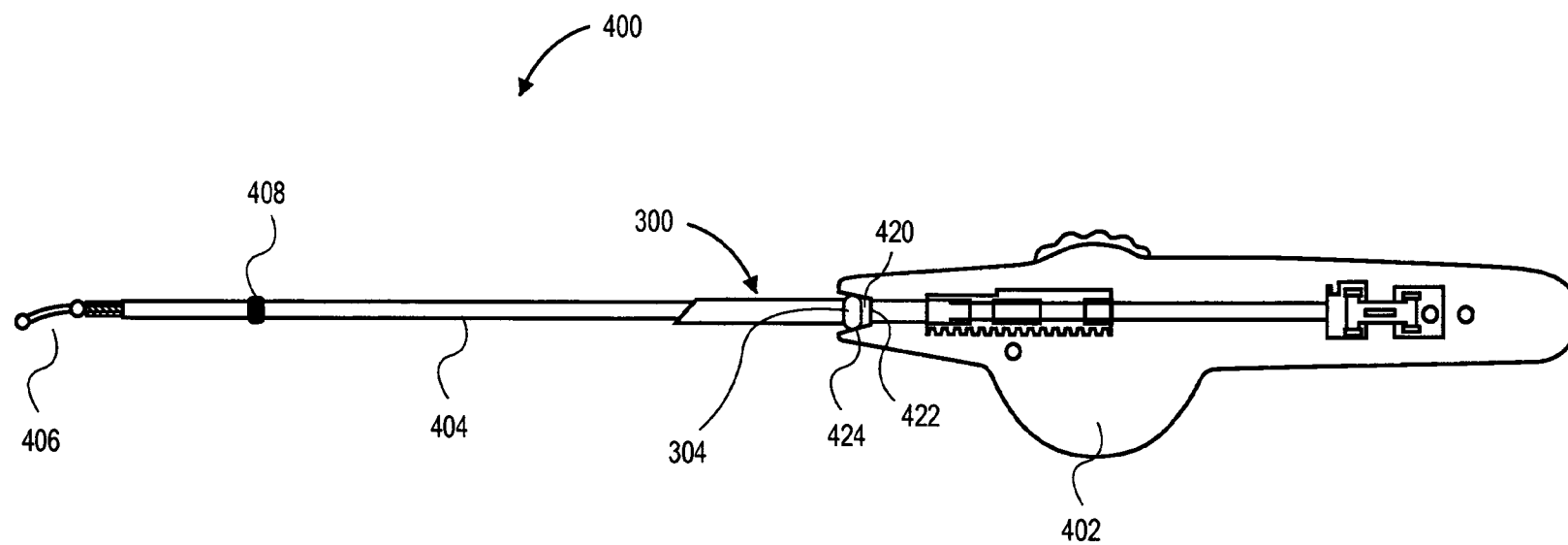


FIG. 5C

22

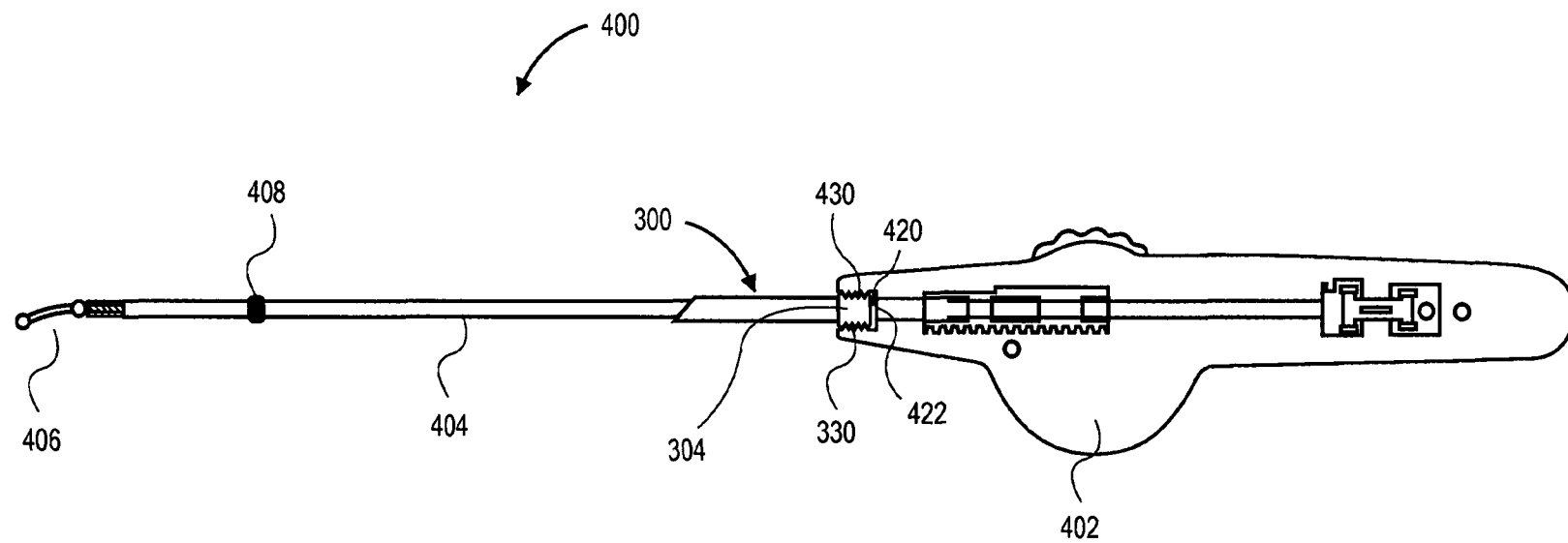


FIG. 5D

12/2/20

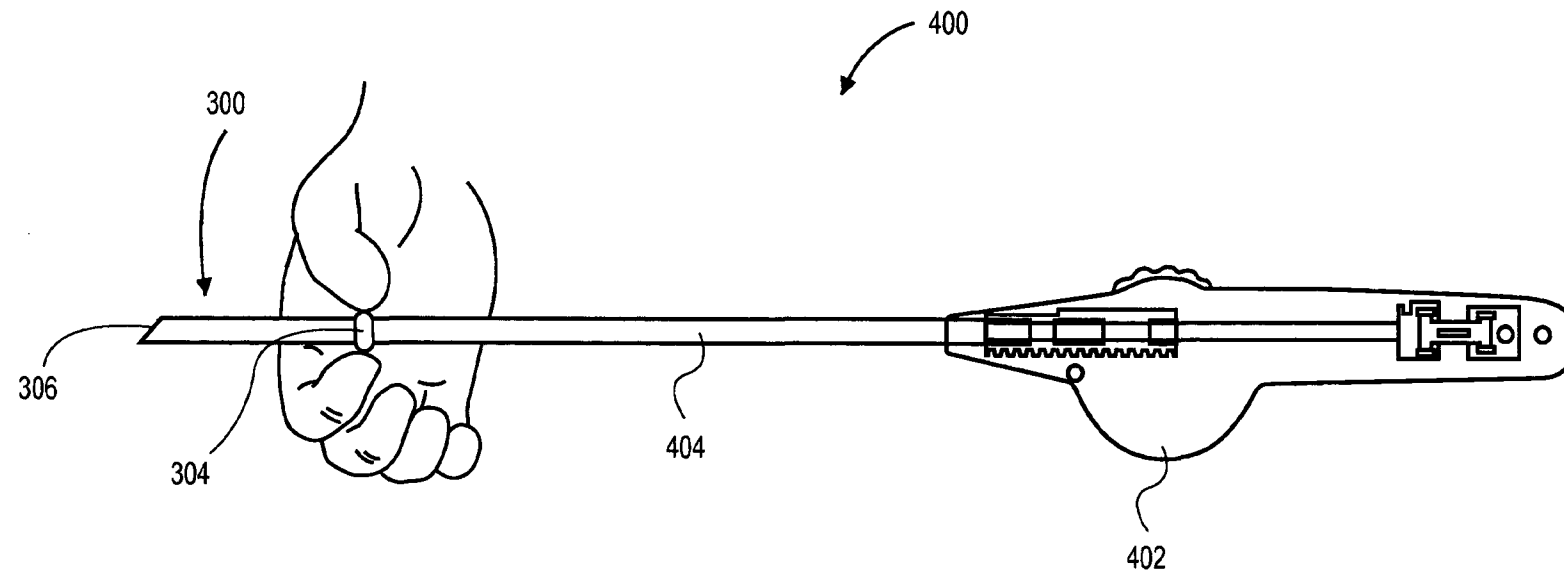


FIG. 6

Handwritten signature or initials.

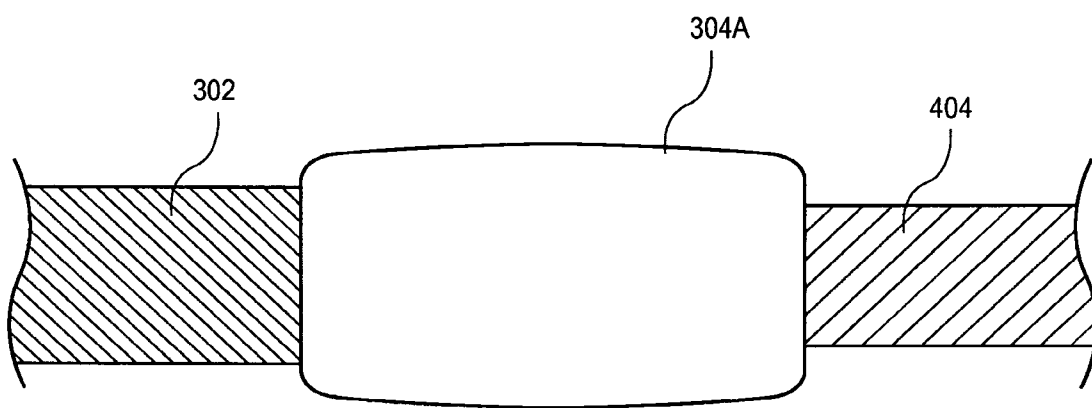


FIG. 7

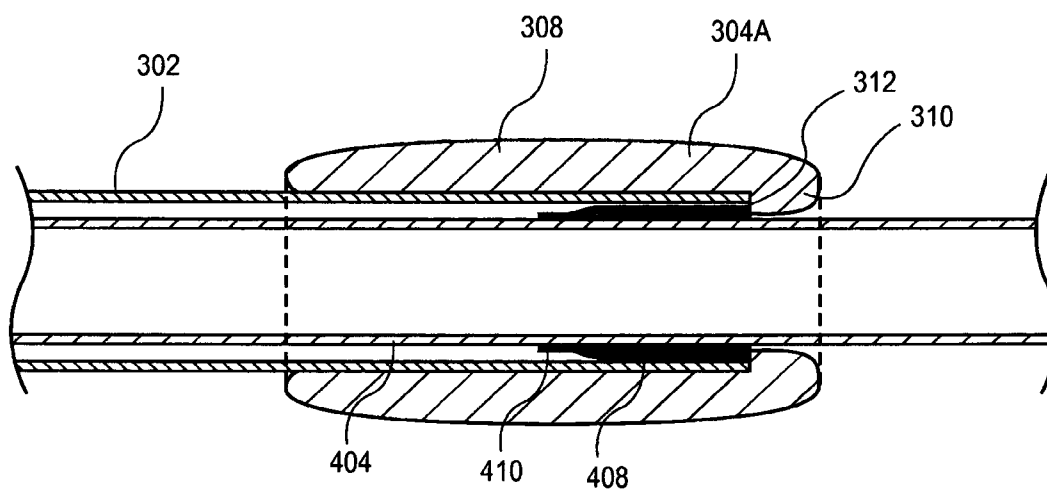


FIG. 8

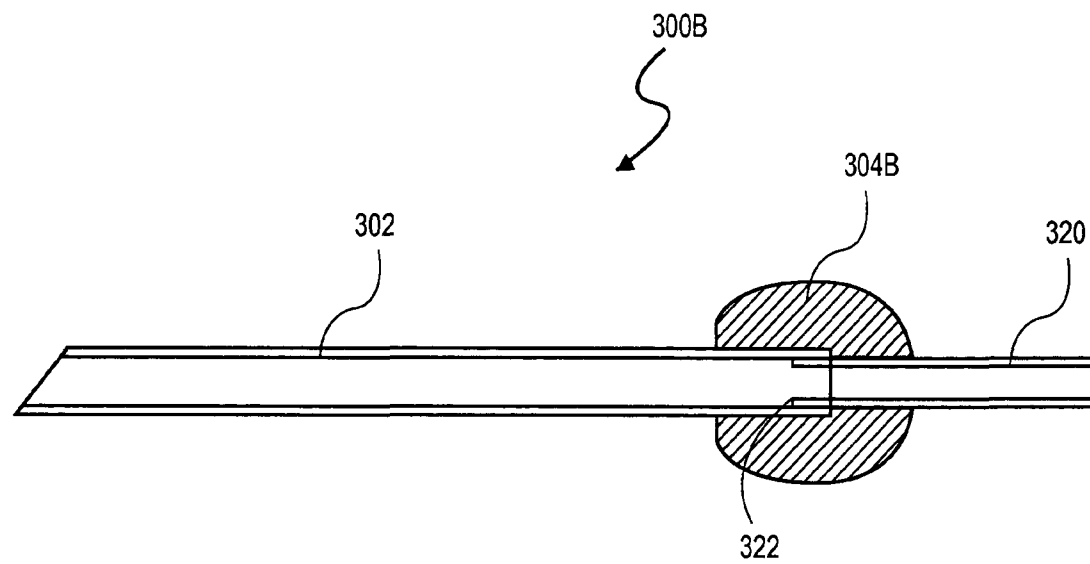


FIG. 9

Handwritten signature or initials.

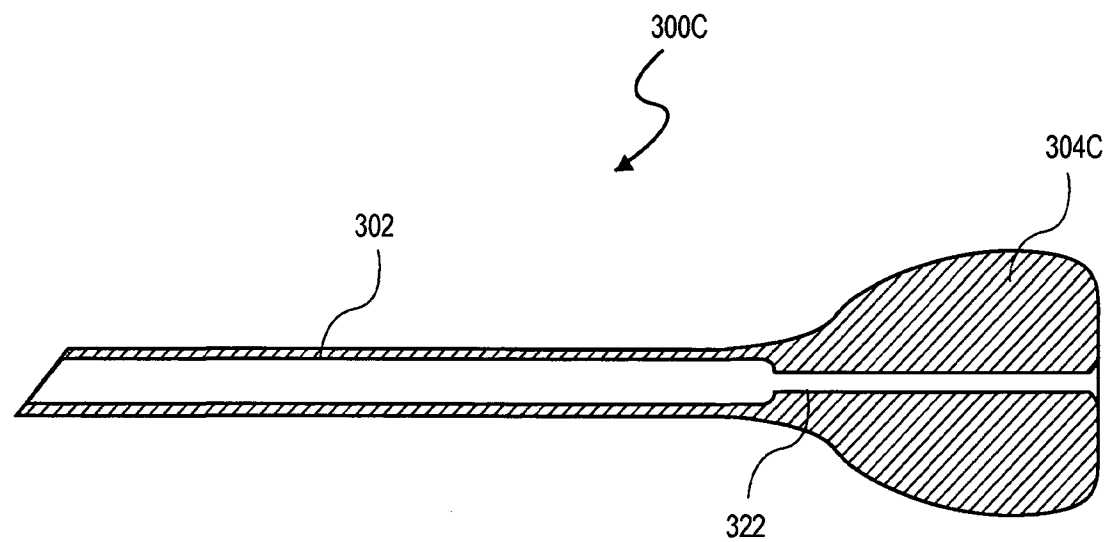


FIG. 10

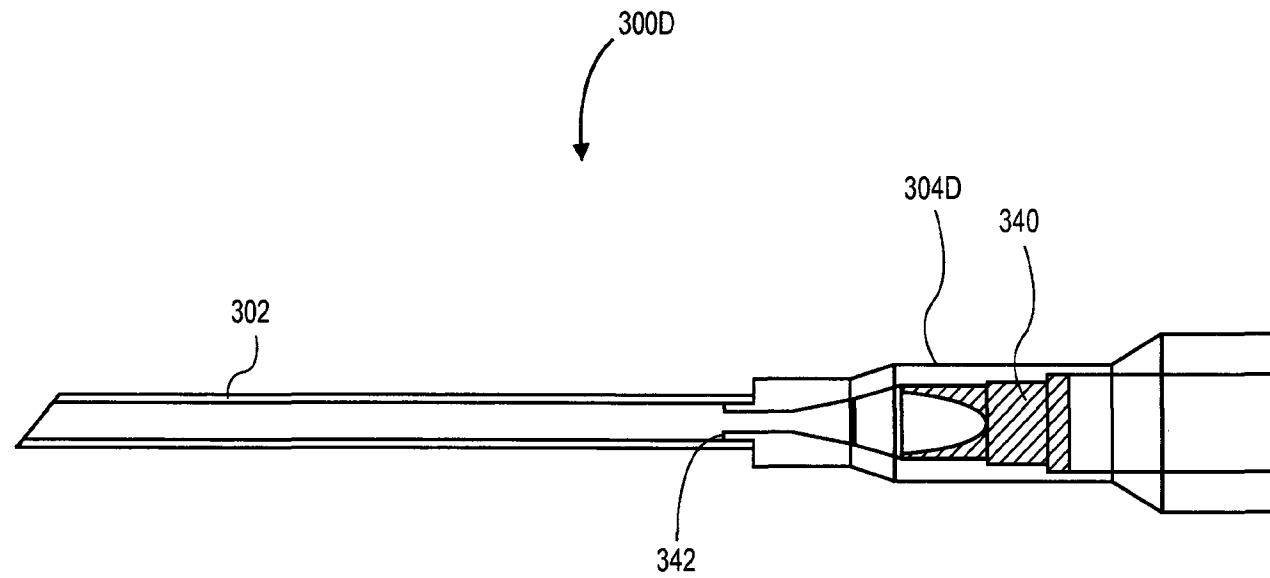


FIG. 11A

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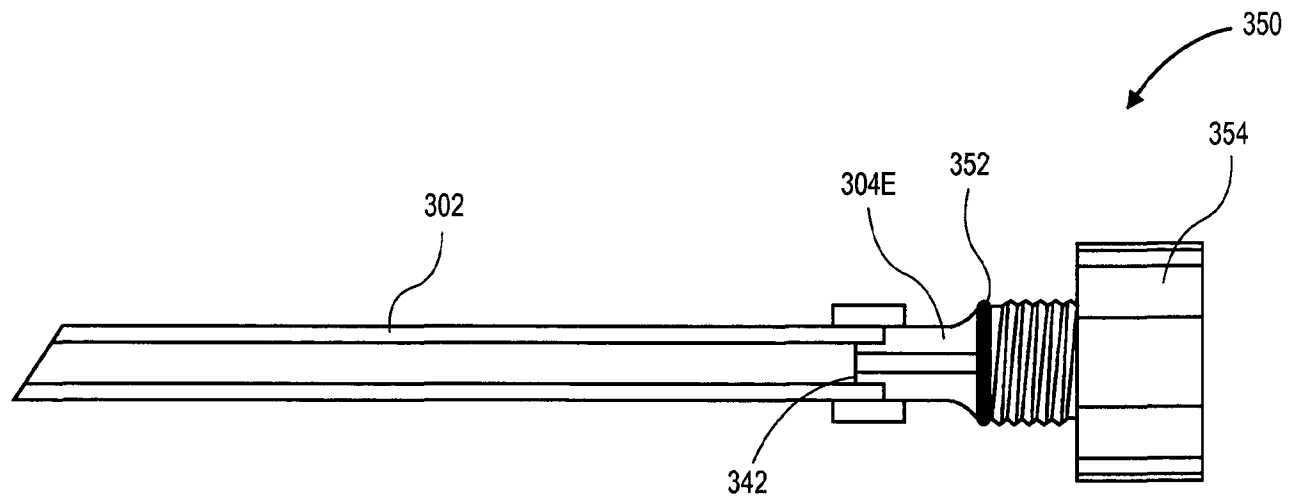


FIG. 11B

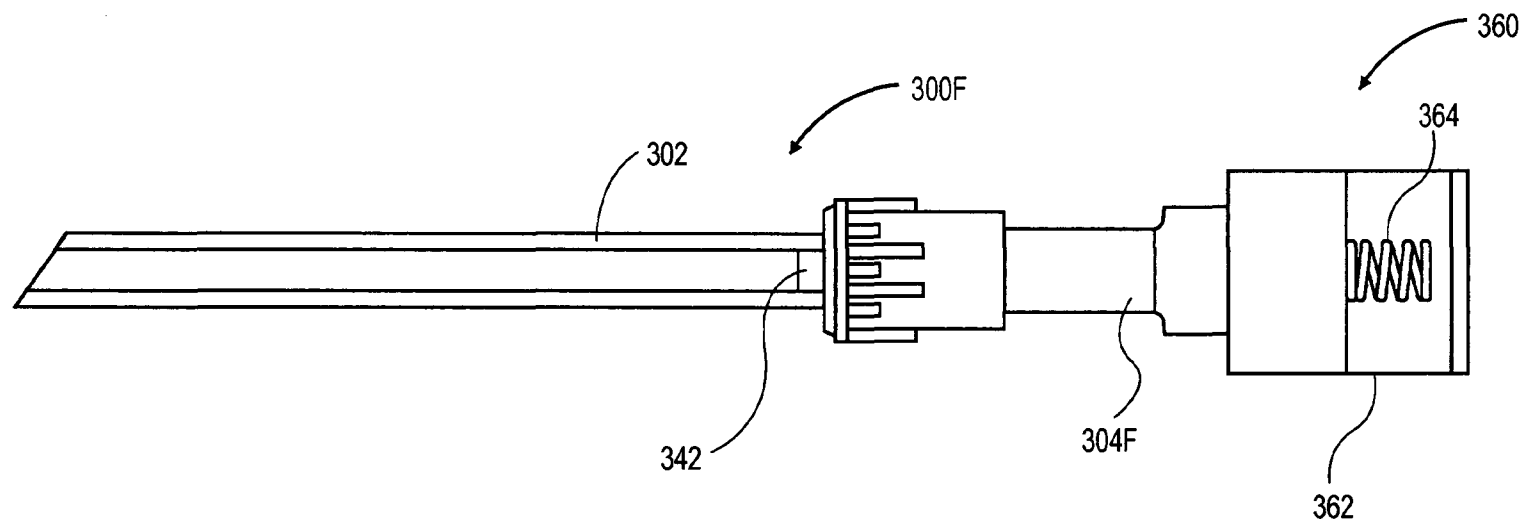


FIG. 11C

Handwritten signature or initials.

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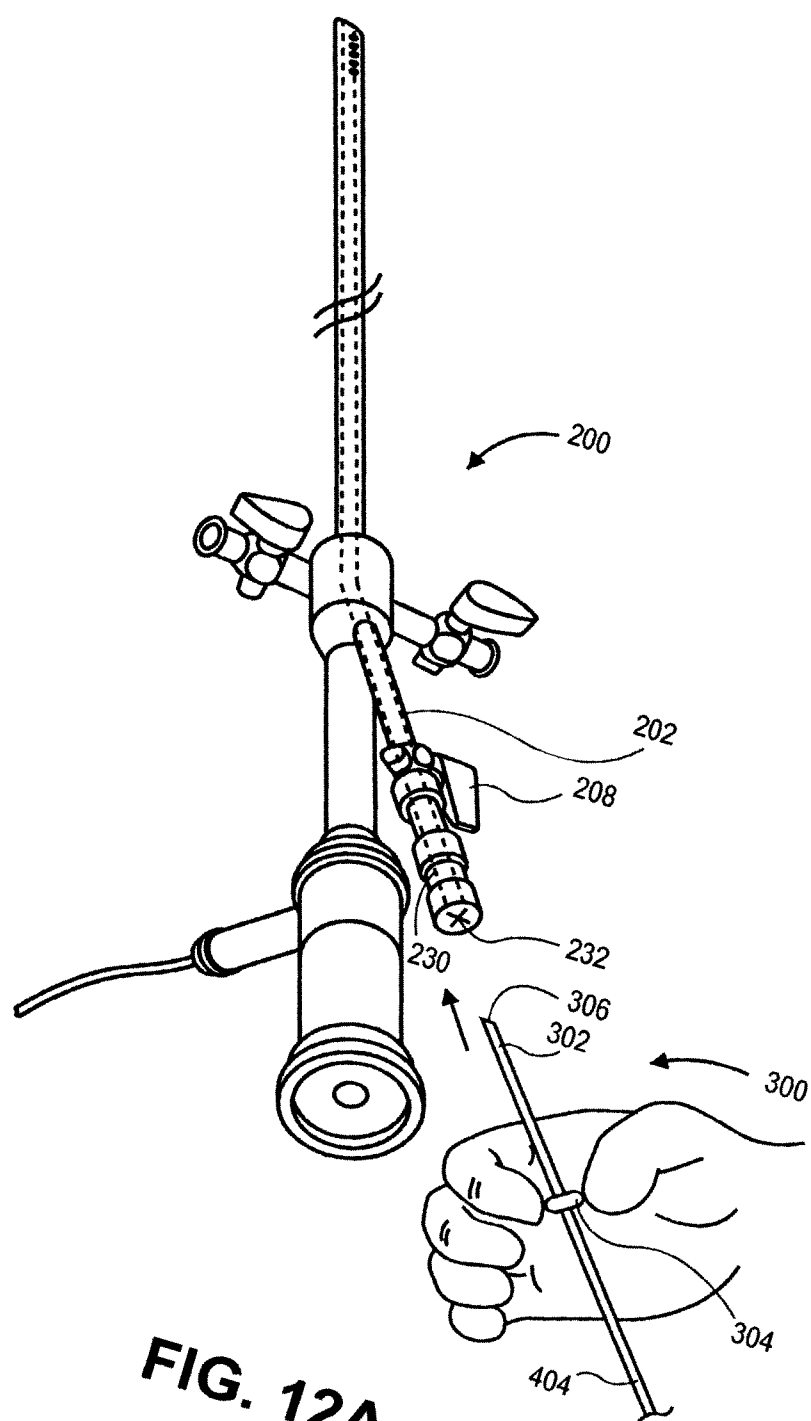


FIG. 12A

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136

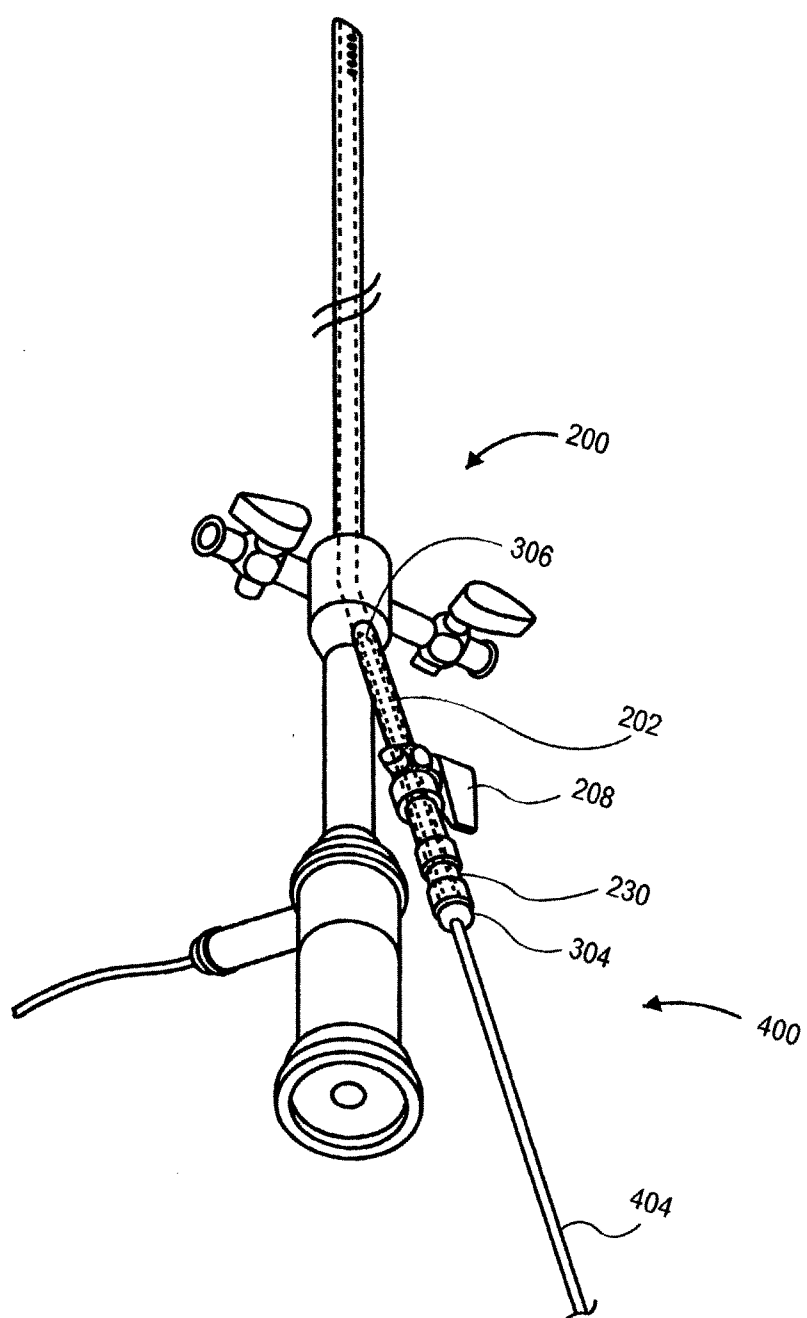


FIG. 12B

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137

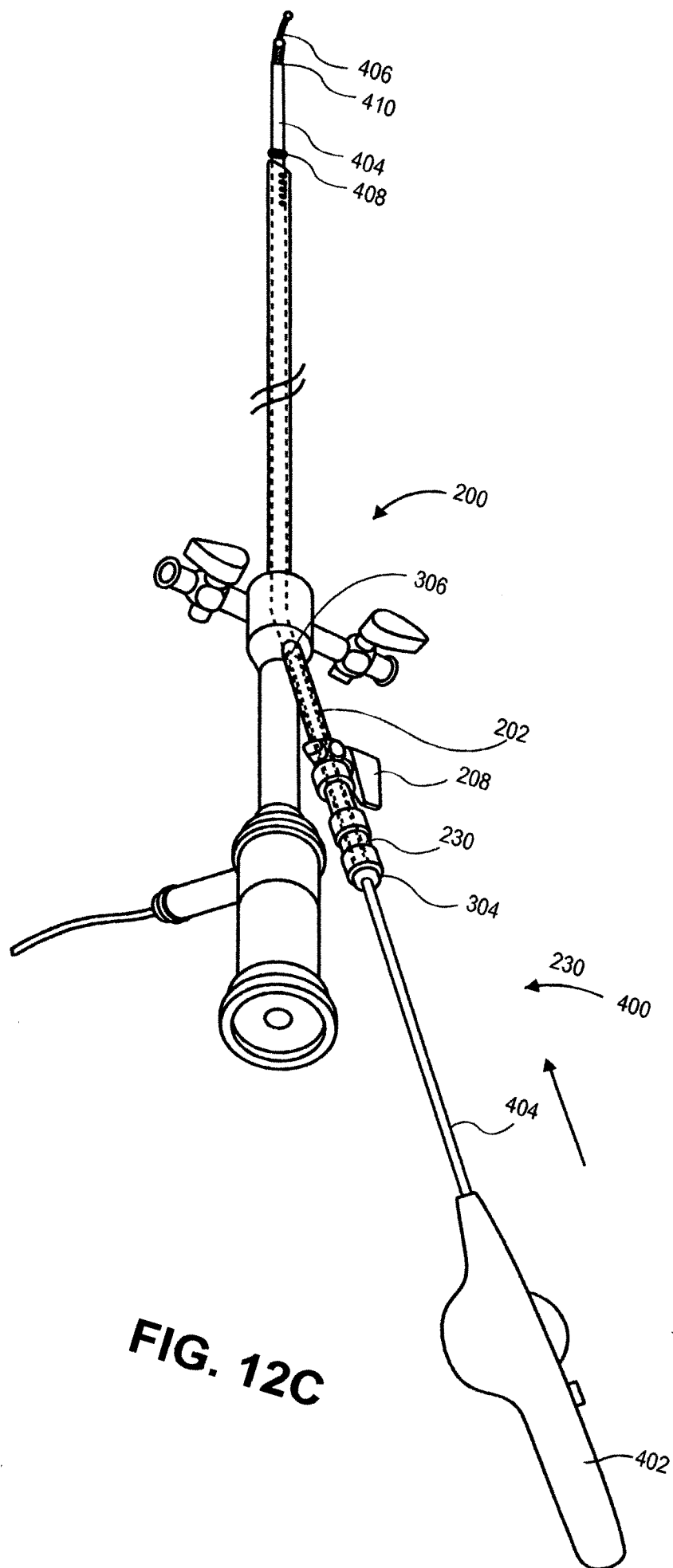


FIG. 12C

108-152

Attorney Docket No.: 6701P074

Patent

First Named Inventor: Christopher A. Stout

Check One:

☒ Declaration Submitted with
Initial Filing OR
☐ Declaration Submitted After
Initial Filing (Surcharge under
37 C.F.R. § 1.16(f) Required).

Complete If Known:

Application No.: _____
Filing Date: _____
Art Unit: _____
Examiner Name: _____

DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION

I hereby declare that:

(1) Each inventor's residence, mailing address, and citizenship are as stated below next to their name; and (2) I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TIP PROTECTOR SLEEVE

(Title of the Invention)

the specification of which

☒ is attached hereto OR
☐ was filed on (MM/DD/YYYY) _____
as United States Application Number _____
or PCT International Application Number _____
and was amended on (MM/DD/YYYY) _____
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment specifically referred to above.

I do not know and do not believe that the claimed invention was ever known or used in the United States of America before my invention thereof, or patented or described in any printed publication in any country before my invention thereof or more than one year prior to this application. I do not know and do not believe that the claimed invention was in public use or on sale in the United States of America more than one year prior to this application, nor do I know or believe that the invention has been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months (for a utility patent application) or six months (for a design patent application) prior to this application.

I acknowledge the duty to disclose all information known to me to be material to patentability as defined in 37 C.F.R. 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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Authorization To Permit Access to Application by Participating Offices

☒ If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), and any other intellectual property offices in which a foreign application claiming priority to the above-identified application is filed access to the above-identified patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, or other intellectual property office in which a foreign application claiming priority to the above-identified application is filed to have access to the application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the application-as-filed with respect to: (1) the above-identified application, (2) any foreign application to which the above-identified application claims priority under 35 USC 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the above-identified US application, and (3) any U.S. application from which benefit is sought in the above-identified application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing the Authorization to Permit Access to Application by Participating Offices.

Claim of Foreign Priority Benefits

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

<u>Prior Foreign Application(s)</u>			Check Box Below		
			Only if Priority Not Claimed:	Certified Copy Attached?	
_____ (Number)	_____ (Country)	_____ (Foreign Filing Date - MM/DD/YYYY)	☐	☐ Yes	☐ No
_____ (Number)	_____ (Country)	_____ (Foreign Filing Date - MM/DD/YYYY)	☐	☐ Yes	☐ No
_____ (Number)	_____ (Country)	_____ (Foreign Filing Date - MM/DD/YYYY)	☐	☐ Yes	☐ No

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

140

Appointment of Patent Practitioners:

I hereby appoint the patent practitioners associated with the **Customer Number 08791** as my respective patent attorneys and patent agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected herewith.

If this patent application is assigned, then the undersigned hereby authorizes the patent attorneys and patent agents named herein to accept and follow instructions from the assignee(s) as to any action to be taken in the United States Patent and Trademark Office regarding this application without direct communication between the patent attorneys and patent agents and the undersigned. In the event of a change in the persons from whom instructions may be taken, at least one patent attorney or patent agent named herein will be so notified by the undersigned.

Direct all correspondence to (check one):

☒ **Customer Number 08791 OR**

☐ **Correspondence Address Below:**

Jacob T. Aikin
(Name of Attorney or Agent)
BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP
1279 Oakmead Parkway
Sunnyvale, California 94085-4040 U.S.A.
Telephone: (408) 720-8300
Fax: (408) 720-8383

WARNING:

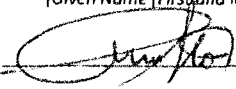
Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioner/applicant should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. Petitioner/applicant is advised that documents which form the record of a patent application (such as the PTO/SB/01) are placed into the Privacy Act system of records DEPARTMENT OF COMMERCE, COMMERCE-PAT-7, System name: *Patent Application Files*. Documents not retained in an application file (such as the PTO-2038) are placed into the Privacy Act system of COMMERCE/PAT-TM-10, System name: *Deposit Accounts and Electronic Funds Transfer Profiles*.

141

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Full Name: Christopher A. Stout
(Given Name (First and Middle (if any)), Family Name (or Surname), and Suffix (if any))

Inventor's Signature  Date 5/4/11

Residence San Bruno, California, U.S.A. Citizenship U.S.A.
(City, State, Country) (Country)

Mailing Address 514 Cherry Avenue
San Bruno, CA 94066

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Full Name: Betsy Swann
(Given Name (First and Middle (if any)), Family Name (or Surname), and Suffix (if any))

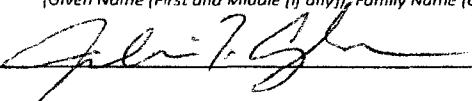
Inventor's Signature _____ Date _____

Residence Grass Valley, California, U.S.A. Citizenship U.S.A.
(City, State, Country) (Country)

Mailing Address 135 Winchester St.
Grass Valley, CA 95945

NAME OF THIRD INVENTOR: ☐ A petition has been filed for this unsigned inventor

Full Name: Julian Cruzada
(Given Name (First and Middle (if any)), Family Name (or Surname), and Suffix (if any))

Inventor's Signature  Date 05/09/11

Residence San Jose, California, U.S.A. Citizenship U.S.A.
(City, State, Country) (Country)

Mailing Address 809 Auzerai Ave. Unit 358
San Jose, CA 95126

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142

NAME OF FOURTH INVENTOR:

☐ A petition has been filed for this unsigned inventor

Full Name: Chris Sepe

(Given Name (First and Middle [if any]), Family Name (or Surname), and Suffix [if any])

Inventor's Signature

[Signature]

Date

05/04/11

Residence Campbell, California, U.S.A.

(City, State, Country)

Citizenship

U.S.A.

(Country)

Mailing Address

351 West Rincon Ave, Unit A
Campbell, CA 95008

143

Attorney Docket No.: 6701P074

Patent

First Named Inventor: Christopher A. Stout

Check One:

- ☒ Declaration Submitted with
Initial Filing OR
☐ Declaration Submitted After
Initial Filing (Surcharge under
37 C.F.R. § 1.16(f) Required).

Complete If Known:

Application No.: _____
Filing Date: _____
Art Unit: _____
Examiner Name: _____

DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION

I hereby declare that:

(1) Each inventor's residence, mailing address, and citizenship are as stated below next to their name; and (2) I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TIP PROTECTOR SLEEVE

(Title of the Invention)

the specification of which

☒ is attached hereto OR
☐ was filed on (MM/DD/YYYY) _____
as United States Application Number _____
or PCT International Application Number _____
and was amended on (MM/DD/YYYY) _____
(if applicable)

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10/24/14

Authorization To Permit Access to Application by Participating Offices

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Prior Foreign Application(s)			Check Box Below	
			Only if Priority Not Claimed:	Certified Copy Attached?
(Number)	(Country)	(Foreign Filing Date - MM/DD/YYYY)	☐	☐ Yes ☐ No
(Number)	(Country)	(Foreign Filing Date - MM/DD/YYYY)	☐	☐ Yes ☐ No
(Number)	(Country)	(Foreign Filing Date - MM/DD/YYYY)	☐	☐ Yes ☐ No

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

HS
AS

Appointment of Patent Practitioners:

I hereby appoint the patent practitioners associated with the **Customer Number 08791** as my respective patent attorneys and patent agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the U.S. Patent and Trademark Office connected herewith.

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Direct all correspondence to (check one):

☒ **Customer Number 08791 OR**

☐ **Correspondence Address Below:**

Jacob T. Aikin
(Name of Attorney or Agent)
BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP
1279 Oakmead Parkway
Sunnyvale, California 94085-4040 U.S.A.
Telephone: (408) 720-8300
Fax: (408) 720-8383

WARNING:

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146

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Full Name: Christopher A. Stout
(Given Name (First and Middle [if any]), Family Name (or Surname), and Suffix [if any])

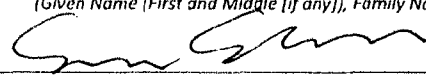
Inventor's Signature _____ Date _____

Residence San Bruno, California, U.S.A. Citizenship U.S.A.
(City, State, Country) (Country)

Mailing Address 514 Cherry Avenue
San Bruno, CA 94066

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Full Name: Betsy Swann
(Given Name (First and Middle [if any]), Family Name (or Surname), and Suffix [if any])

Inventor's Signature  Date 5/19/2011

Residence Grass Valley, California, U.S.A. Citizenship U.S.A.
(City, State, Country) (Country)

Mailing Address 135 Winchester St.
Grass Valley, CA 95945

NAME OF THIRD INVENTOR: ☐ A petition has been filed for this unsigned inventor

Full Name: Julian Cruzada
(Given Name (First and Middle [if any]), Family Name (or Surname), and Suffix [if any])

Inventor's Signature _____ Date _____

Residence San Jose, California, U.S.A. Citizenship U.S.A.
(City, State, Country) (Country)

Mailing Address 809 Auzerals Ave. Unit 358
San Jose, CA 95126

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147

NAME OF FOURTH INVENTOR: ☐ A petition has been filed for this unsigned inventor

Full Name: Chris Sepe
(Given Name (First and Middle (if any)), Family Name (or Surname), and Suffix (if any))

Inventor's Signature _____ Date _____

Residence Campbell, California, U.S.A. Citizenship U.S.A.
(City, State, Country) (Country)

Mailing Address 351 West Rincon Ave, Unit A
Campbell, CA 95008

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Electronic Acknowledgement Receipt	
EFS ID:	10200771
Application Number:	13149631
International Application Number:	
Confirmation Number:	1806
Title of Invention:	TIP PROTECTOR SLEEVE
First Named Inventor/Applicant Name:	Christopher A. Stout
Customer Number:	08791
Filer:	Jacob T. Aikin/Harleen Bains
Filer Authorized By:	Jacob T. Aikin
Attorney Docket Number:	006701P074
Receipt Date:	31-MAY-2011
Filing Date:	
Time Stamp:	19:10:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 592
RAM confirmation Number	6725
Deposit Account	022666
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)	

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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	6701P074_Utility_Transmittal.pdf	56582 c5207ba93de4e34f714c716a5d392bc7e776b120	no	2
Warnings:					
Information:					
2		6701P074_Application_FINAL.pdf	111201 6886b3c4782ad0420e5b3ea5c566fb4347fde50	yes	21
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	16	
	Claims		17	20	
	Abstract		21	21	
Warnings:					
Information:					
3	Drawings-only black and white line drawings	6701P074_FormaL_Figures_FINAL.pdf	175939 893e8a5512c3b1f236afeeb3c2d177e495f7875f2	no	18
Warnings:					
Information:					
4	Oath or Declaration filed	6701P074_Declaration.PDF	739533 584108e0ca84bcd7075fef4ec1be2e8bd59ace31	no	10
Warnings:					
Information:					
5		6701P074_IDS_and_1449.pdf	122921 db9bdfb59f3ba402a597234cfffds576a070a847	yes	3
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Transmittal Letter		1	2	
	Information Disclosure Statement (IDS) Filed (SB/08)		3	3	
Warnings:					
Information:					

70
150

6	NPL Documents	NPL1.pdf	3439001 30cc08e2b79ad242f3c169347091382d3a9e0bee	no	70
Warnings:					
Information:					
7	NPL Documents	NPL2.pdf	1674410 9fe42dc4589834f324fbc699086962db88081b0a	no	7
Warnings:					
Information:					
8	Fee Worksheet (PTO-875)	fee-info.pdf	36472 2d6b59a4836e5404128bd4a770e923f2c29048cf	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			6356059		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

ADVANCE E-MAIL

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

To:

BERNADICOU, Michael, A.
Blakely, Sokoloff, Taylor & Zafman LLP
1279 Oakmead Parkway
Sunnyvale, CA 94085-4040
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

27 November 2013 (27.11.2013)

Applicant's or agent's file reference

6701P074PCT

IMPORTANT NOTIFICATION

International application No.

PCT/US2012/040013

International filing date (day/month/year)

30 May 2012 (30.05.2012)

1. The following indications appeared on record concerning:

☒ the applicant ☐ the inventor ☐ the agent ☐ the common representative

Name and Address

CONCEPTUS, INC.
331 East Evelyn Avenue
Mountain View, CA 94041
United States of America

State of Nationality

US

State of Residence

US

Telephone No.

Facsimile No.

E-mail address

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☒ the person ☐ the name ☐ the address ☐ the nationality ☐ the residence

Name and Address

BAYER ESSURE INC.
1011 McCarthy Blvd.
Milpitas, CA 95035
United States of America

State of Nationality

US

State of Residence

US

Telephone No.

Facsimile No.

E-mail address

☐ Notifications by e-mail authorized

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
☐ the International Searching Authority
☐ the Authority(ies) specified for supplementary search☐ the International Preliminary Examining Authority
☒ the designated Offices concerned
☐ the elected Offices concerned
☐ other:The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Coppolino Sita

Facsimile No. +41 22 338 89 65

e-mail pt02.pct@wipo.int

Telephone No. +41 22 338 74 02

PATENT COOPERATION TREATY

PCT/US2012/040013

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION,
OBTENTION OR TRANSMITTAL
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

BERNADICOU, Michael, A.
Blakely, Sokoloff, Taylor & Zafman LLP
1279 Oakmead Parkway
Sunnyvale, CA 94085-4040
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year) 19 June 2012 (19.06.2012)	
Applicant's or agent's file reference 6701P074PCT	IMPORTANT NOTIFICATION
International application No. PCT/US2012/040013	International filing date (day/month/year) 30 May 2012 (30.05.2012)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 31 May 2011 (31.05.2011)
Applicant CONCEPTUS, INC. et al	

The applicant is hereby notified of the date of receipt (or of obtaining by the International Bureau) of the priority document(s) relating to all earlier application(s) whose priority is claimed. Unless otherwise indicated by the letters "NR", in the right-hand column or by an asterisk appearing next to the date of receipt, **the priority document concerned was submitted to or transmitted to or obtained by the International Bureau in compliance with Rule 17.1(a), (b) or (b-bis)**. This Form replaces any previously issued notification concerning submission, transmittal or obtaining of priority documents.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
31 May 2011 (31.05.2011)	13/149,631	US	11 June 2012 (11.06.2012)

The letters "NR" denote a priority document which, on the date of mailing of this Form, had not yet been received or obtained by the International Bureau in compliance with Rule 17.1(a), (b) or (b-bis). Where the applicant has failed to either submit, request to prepare and transmit or obtain and transmit, or to request the International Bureau to obtain the priority document within the applicable time limit under that Rule, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

An asterisk "*" next to a date of receipt, denotes a priority document submitted or transmitted to or obtained by the International Bureau but not in compliance with Rule 17.1(a), (b) or (b-bis) (the priority document was received after the time limit prescribed in Rule 17.1(a); the request to prepare and transmit the priority document was submitted to the receiving Office after the applicable time limit under Rule 17.1(b) or the request to the receiving Office or the International Bureau to obtain the priority document was made after the applicable time limit under Rule 17.1(b-bis)). Even though the priority document was not furnished in compliance with Rule 17.1(a), (b) or (b-bis), the International Bureau will nevertheless transmit a copy of the document to the designated Offices, for their consideration. In case such a copy is not accepted by the designated Office as the priority document, Rule 17.1(c) provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 89 65	Authorized officer Lingfei Bai e-mail pt02.pct@wipo.int Telephone No. +41 22 338 74 02
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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800.176.089-2

- / -

Industria y Comercio
SUPERINTENDENCIA

RECIBO DE CAJA

No. 13 - 130508

Bogotá D.C., Diciembre 17 de 2013 - 14:27:22

RECIBIDO DE : POSSE HERRERA & RUIZ S.A.

NI 830.022.196

*** Soporte del Pago ***

TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	VR PAGO
CONSIGNACION	BANCO DE BOGOTA	062754387	599246362	17/12/2013	9.209.000.00

*** Conceptos Pagados ***

CANT.	RENTISTICO	CONCEPTO	Vr. UNDITARIO	Vr. CONCEPTO
15	50005-01-01 SOLICITUDES	1607 REIVINDICACION PATENTE UNITARIA ADICIONAL A LAS 10 INIC	30.000.00	450.000.00
				\$450.000.00

SON: **CUATROCIENTOS CINCUENTA MIL PESOS MONEDA CORRIENTE***

Responsable: _____

Recibo de Caja Aplicado al Expediente No. _____

Reivindicaciones

Manguito Protector de Puentes

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 13-295350-00000-0000

Fecha: 2013-12-18 14:53:25 Dep. 2020 DIR.NUEVASCR
Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 411 PRESENTACION Folios: 12/154

Sede Centro: Carrera 13 No. 27 - 00 Pisos 3,4,5 y 10 Bogotá, D.C.- Colombia

Web: www.sic.gov.co e-mai: info@sic.gov.co Conmutador: (571) 5870000 Fax: (571) 5870284 Línea: 018000-910165 Call Center: (571) 6513240

Diciembre 17 de 2013 - 14:27:24

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800.176.089-2

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Industria y Comercio
SUPERINTENDENCIA

RECIBO DE CAJA

No. 13 - 130506

Bogotá D.C., Diciembre 17 de 2013 - 14:27:22

RECIBIDO DE : POSSE HERRERA & RUIZ S.A.

NI 830.022.196

*** Soporte del Pago ***

TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	VR. PAGO
CONSIGNACION	BANCO DE BOGOTA	062754387	599246362	17/12/2013	9.209.000.00

*** Conceptos Pagados ***

CANT.	RENTISTICO	CONCEPTO	Vr. UNDITARIO	Vr. CONCEPTO
1	50005-01-01 SOLICITUDES	1 TRAMITES DE SOL. DE PATENTE DE INVENCIÓN	500.000.00	500.000.00
				\$500.000.00

SON: **QUINIENTOS MIL PESOS MONEDA CORRIENTE***

Responsable: _____

Recibo de Caja Aplicado al Expediente No. _____

Patente

Manguito Protector

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 13-295350-00000-0000

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, Diciembre 17 de 2013 - 14:27:23

PATENTE DE INVENCION ☐

MODELO DE UTILIDAD ☐

Art 33 Decisión 486/00

- ☐ Indicación que se solicita una patente.
 - ☐ Datos de identificación del solicitante o de la persona que presenta la solicitud
 - ☐ Descripción de la invención
 - ☐ Dibujos de ser estos pertinentes
 - ☐ Comprobante de pago de las tasas establecidas (De ser el caso formato de descuento)
- Completa ☐ Incompleta ☐

PATENTE DE INVENCION PCT ☒

MODELO DE UTILIDAD PCT ☐

Art.33 Decisión 486/00, Circular Única

- ☒ Indicación que se solicita una PCT
 - ☒ Copia de la solicitud en español, tal como fue presentada inicialmente (capítulo descriptivo, reivindicatorio, resumen)
 - ☒ Dibujos de ser estos pertinentes
 - ☒ Comprobante de pago de las tasas establecidas (de ser el caso formato de descuento)
- Completa ☒ Incompleta ☐

DISEÑO INDUSTRIAL ☐

(Art. 119 Decisión 486/00)

- ☐ Indicación que se solicita Diseño industrial
 - ☐ Datos de identificación del solicitante o de la persona que presenta la solicitud
 - ☐ Representación gráfica y fotográfica del Diseño industrial o muestra del material que incorpora el diseño
 - ☐ Comprobante de pago de las tasas establecidas
- Completa ☐ Incompleta ☐

ESQUEMA DE TRAZADO ☐

(Art. 92 Decisión 486/00)

- ☐ Indicación que se solicita un esquema de trazado
 - ☐ Datos de identificación del solicitante o de la persona que presenta la solicitud
 - ☐ Representación gráfica de un esquema de trazado
 - ☐ Comprobante de pago de las tasas establecidas
- Completa ☐ Incompleta ☐

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 13-295350- -00000-0000

Fecha: 2013-12-18 14:53:25 Dep. 2020 DIR.NUEVASCR
Tra. 11 PATENTEIYII Eve: 378 FASENACIONALI
Act. 411 PRESENTACION Folios: 124 54.