

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogada
Jimena Escobar U.
(Apoderado)

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Act. 519 TRASLADOINFORME Folios: 1

ASUNTO	Radicación	03-58351
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	Nº 1 5 3 5 4
	Folios	036 -

Patente de Invención	☒	Patente de Modelo de Utilidad	☐
Vía Nacional	☐		
Vía PCT (fase nacional)	☐	Cap. I	☐
		Cap. II	☐
Solicitud Internacional n.º	_____		
Fecha de Presentación Intrnl.	_____		

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

1. Documentos estudiados

- | | |
|-----------------------|--|
| 1.1 Descripción: | Folios 6 a 40 como se radicó inicialmente |
| 1.2 Reivindicaciones: | Folios 41 a 46 como se radicó inicialmente |
| 1.3 Dibujos: | Folios 113 a 119, con copia en los folios 120 a 126, como se radicó inicialmente |
| 1.4 Prioridad: | Folios 62 a 112; 2002-07-10, US, 10/192 394 |

2. Objeto de la invención

- Título de la solicitud: *Mecanismo de sujeción de válvula de derivación*, folio 1.
- El objeto de la presente solicitud de patente de invención consiste en suministrar un dispositivo que aloja a una válvula de derivación de flujo

variable y que tiene medios para evitar que se cambie la configuración de la válvula de tal manera que se impida el cambio involuntario en el flujo.

Reivindicaciones 1 a 13: Un sistema de válvula de derivación, que comprende: un alojamiento; en cuyo interior se encuentra una cámara que incluye una abertura de admisión, para recibir un fluido, una abertura de salida, para la liberación del fluido, y, un mecanismo de válvula que incluye un conjunto rotor para regular el flujo del fluido a través de la misma, cuando haya un diferencial de presión entre la abertura de admisión y la de salida que exceda una presión preseleccionada de abertura de válvula; y, un conjunto de fijación selectivamente acoplable, para evitar la rotación del conjunto rotor, que tiene al menos un brazo de agarre con al menos una superficie de contacto adecuada para acoplarse friccionalmente con el conjunto rotor, para mantener, de manera selectiva, al conjunto rotor en una posición deseada.

Reivindicaciones 14 a 21: Un conjunto de fijación, para evitar la rotación de un conjunto rotor de un sistema de válvula de derivación, que comprende: al menos un brazo de agarre, para acoplarse friccionalmente con el conjunto rotor, con al menos una superficie que entra en contacto con el rotor; y, un mecanismo de accionamiento articulado mecánicamente al brazo de agarre. En donde el mecanismo de accionamiento es efectivo para mover el brazo de agarre entre una posición trabada, en la cual el brazo de agarre acopla friccionalmente al conjunto rotor, y una posición destrabada, en la cual el brazo de agarre es desacoplado del conjunto rotor.

Reivindicación 22: Un conjunto de fijación, para acoplar de manera selectiva un dispositivo de uso médico que tiene un canal de fluido y un regulador de fluido para evitar el flujo de fluido a través del mismo, que comprende: Un mecanismo de accionamiento que tiene una membrana deformable conectada a un brazo de agarre, siendo el brazo de agarre movable selectivamente entre una primera posición, en la cual el brazo acopla friccionalmente el regulador de fluido, y una segunda posición, en la cual el brazo no se acopla con el regulador de fluido. En donde la membrana deformable está configurada para transferir una fuerza, aplicada a la misma al brazo de agarre, suficiente para hacer que el brazo se mueva desde una de las posiciones, primera o segunda, a la otra posición.

El problema planteado en esta solicitud es satisfacer la necesidad de evitar que se active una válvula de derivación cuando se produzcan cambios en el campo magnético que la rodea, por ejemplo, cuando el paciente portador de la válvula se realiza un examen por medio de imagenología por resonancia magnética.

Para solucionar este problema técnico la solicitud en estudio proporciona un dispositivo que aloja a la válvula de derivación y que, por medios mecánicos fija la posición del regulador de la válvula de derivación.

- Clasificación Internacional de Patentes (IPC) asignada:
\ F16K 35/02, A61M 27/00

3. De la solicitud de Patente

3.1 Descripción (artículo 28 D. 486)

- Durante el análisis del texto de la descripción y de las ilustraciones anexadas, se observaron los siguientes defectos:
 - 1) El título o nombre de la invención no concuerda exactamente con lo que se reclama en las reivindicaciones independientes (la 1, la 14 y la 22), porque en ninguna de ellas se reclama *un mecanismo*. Debe haber una concordancia cercana entre uno y otras.
 - 2) En la página 5, folio 10, aparece por primera vez la expresión *MRI* cuyo significado se desconoce (aparentemente, se trata de imagen por resonancia magnética). El solicitante debe hacer la aclaración respectiva dentro del texto de la descripción.
 - 3) En la página 10, folio 15, aparece por primera vez una expresión en la cual se quiere establecer un intervalo: *0,5 a 1,0 mm*. En los intervalos, cada una de las cifras debe tener sus unidades correspondientes: *0,5 mm a 1,0 mm*.
 - 4) En la página 12, folio 17, aparece la expresión *bola dentro del cono 32* cuyo significado no concuerda con el contexto.
 - 5) En la misma página 12, aparece por primera vez el término *cantilever* que es una palabra inglesa cuya traducción es *voladizo*.
 - 6) En la página 14, folio 19, aparece la expresión *incluye 40 brazos* en donde, según el contexto, debería ser *incluye brazos (40)*. Incidentalmente, se le sugiere al solicitante que utilice los paréntesis para encerrar los números de referencia que se encuentran a lo largo del texto de la solicitud.
 - 7) En la página 21, folio 26, aparece por primera vez el término *nylon* que debe ser sustituido por una expresión en español.
 - 8) En la página 22, folio 27, aparece por primera vez la expresión *en forma de memoria* en donde, según el contexto, debería ser *con memoria de forma* u otra expresión que se ajuste mejor a lo que se quiere decir. En la página 23, folio 28, aparece dos veces, una manera aceptable de decir lo mismo: *de memoria de forma*.
- La descripción no cumple con los requisitos de claridad y divulgación completa, lo que dificulta o impide su comprensión y ejecución de acuerdo al art. 28 de la Decisión 486

3.2 Reivindicaciones (artículo 30 D 486)

- Durante el análisis del texto de las reivindicaciones se observaron los siguientes defectos:
 - 1) Se señala la falta de concordancia entre lo reclamado en las reivindicaciones y el título o nombre de la invención.
 - 2) En la reivindicación 1, folio 41, aparece la expresión (...) *un mecanismo de válvula que incluye un conjunto rotor para regular el flujo de fluido a través del mismo*. En este caso, *mismo* sustituye a *conjunto rotor* por lo que se desdibuja el sentido de la frase.
 - 3) En la reivindicación 6, folio 42, aparece el término *nylon* que fue objetado arriba, con relación a la descripción.
 - 4) En la reivindicación 15, folio 44, se reclama *el sistema de la reivindicación 14* pero, en la reivindicación 14 no se reclama un sistema, por lo que la reivindicación 15 no tiene definición. Lo mismo es aplicable a la reivindicación 16, folio 45.

5) Se observó falta de concisión en el capítulo reivindicatorio. Se le sugiere al solicitante que lo modifique en el sentido del capítulo admitido por la Oficina Europea.

- Las reivindicaciones no cumplen con los requisitos de definición, claridad y concisión de acuerdo al art. 30 de la Decisión 486. Debe entenderse que las reivindicaciones dependientes de las reivindicaciones objetadas son, asimismo, objetadas, por razones análogas.

Se deben presentar, entonces, nuevos capítulos descriptivo y reivindicatorio, ambos completos, junto con un nuevo juego de dibujos, donde se hayan corregido todas las objeciones que se han hecho arriba. Esto con el fin de evitar -cuando solo se presentan algunas páginas sueltas corregidas- que el lector tenga que desplazarse desde un sitio a otro de la solicitud y luego regresar a donde estaba antes sin perder la ilación de la lectura, porque esto produce confusión y afecta negativamente la claridad de dichos capítulos.

4. Unidad de invención (artículo 25 D 486)

- Se observa que existen tres reivindicaciones independientes: la 1, la 14 y la 22. La 1 y la 14 tienen, cada una, un grupo de reivindicaciones dependientes.

La reivindicación 1 reclama, esquemáticamente, un sistema de válvula de derivación, que comprende: un alojamiento; un mecanismo de válvula; y, un conjunto de fijación que tiene al menos un brazo de agarre.

La reivindicación 14 reclama, esquemáticamente, un conjunto de fijación que comprende: un brazo de agarre; y, un mecanismo de accionamiento articulado mecánicamente al brazo de agarre.

La reivindicación 22, reclama, por su parte, esquemáticamente, un conjunto de fijación que comprende: un mecanismo de accionamiento que tiene una membrana deformable conectada a un brazo de agarre.

De lo anterior se deduce que existen tres grupos de invenciones que son independientes entre sí y que, además, son mutuamente excluyentes. Por lo tanto, en el capítulo reivindicatorio no existe unidad de concepto inventivo.

Se le requiere al solicitante que: desista de ciertas reivindicaciones, o que divida la solicitud en dos o tres solicitudes fraccionarias; esto, porque el examinador no tiene facultades para hacerlo.

Cualquiera que sea la determinación que tome el solicitante, la modificación deberá cumplir con el requisito de unidad de concepto inventivo y, además deberá tener en cuenta la concordancia de lo reclamado con el título o nombre de la invención.

Se le sugiere al solicitante que adapte el capítulo reivindicatorio de acuerdo con el admitido por la Oficina Europea para la patente EP 1 380 317 B1 -que pertenece a la familia de patentes de la presente solicitud-; en cambio, no se le recomiendan las reivindicaciones admitidas por la USPTO para la patente US 7 390 310 B2, que también es de la misma familia.

5. Determinación del Estado de la Técnica

- La fecha que se ha tenido en cuenta para determinar el Estado de la Técnica es la

Fecha de presentación de la solicitud prioritaria 2003-07-10

- Se realizó la búsqueda en el estado de la técnica de documentos relacionados con la solicitud teniendo en cuenta la fecha indicada; y durante la búsqueda de anterioridades se encontraron los siguientes documentos, que forman parte de la familia de patentes de la presente solicitud: Publicación US 2004/0010219 A1 del 04-01-15; Publicación US 2008/0127689 A1 del 08-06-05; Patente US 7 390 310 B2 del 08-06-24; publicación EP 1 380 317 A1 del 03-07-09; y patente EP 1 380 317 B1 del 07-08-29. Se anexa la copia de las primeras páginas de estos documentos junto con: la copia de una negación final de la USPTO; una segunda (¿?) negación final de la USPTO; la copia del Informe de Búsqueda Europeo; la copia del capítulo reivindicatorio admitido por la USPTO y la copia del capítulo reivindicatorio admitido por la Oficina Europea, en su versión en inglés. También se encontró el siguiente documento que forma parte del estado de la técnica más cercano al objeto de la solicitud:

Documento	Título	Fecha de publicación
Patente US 5 637 083, cuyos inventores son William J. Bertrand y David A. Watson, quienes le cedieron sus derechos a la Pudenz-Schulte Medical Research Corporation	«Implantable adjustable fluid flow control-valve»(Una válvula de control de flujo de fluidos que es implantable y ajustable)	1997-06-10

Se anexa la copia de las páginas pertinentes de este documento.

NOTAS: No se realizaron las evaluaciones de los demás requisitos de patentabilidad, porque se hicieron algunas objeciones respecto a la definición, la claridad y la concisión, así como respecto a la falta de unidad de concepto inventivo de las reivindicaciones.

A pesar de lo anterior, con base en las negaciones finales de la USPTO y en las enseñanzas del documento señalado arriba, se prevén objeciones respecto al nivel inventivo del objeto de la solicitud.

6. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados negativamente por la falta de claridad de la descripción y las reivindicaciones y por la falta de definición y de unidad de concepto inventivo de estas últimas.

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

Notifíquese el presente oficio conforme a lo dispuesto en el número 5.2, letra e), del capítulo quinto del título primero de la Circular Única n.º 10 de 2001.



ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista, de fecha
04 DIC. 2008

CONCEPTO TÉCNICO n.º 3417

EXAMINADOR TÉCNICO
Código n.º 202009



US 20040010219A1

(19) **United States**

(12) **Patent Application Publication**

McCusker et al.

(10) **Pub. No.: US 2004/0010219 A1**

(43) **Pub. Date: Jan. 15, 2004**

(54) **SHUNT VALVE LOCKING MECHANISM**

(57)

ABSTRACT

(76) Inventors: **Daniel McCusker**, Bridgewater, MA (US); **Alan J. Dextrateur**, Franklin, MA (US); **Rainuka Gupta**, Cambridge, MA (US)

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(21) Appl. No.: **10/192,394**

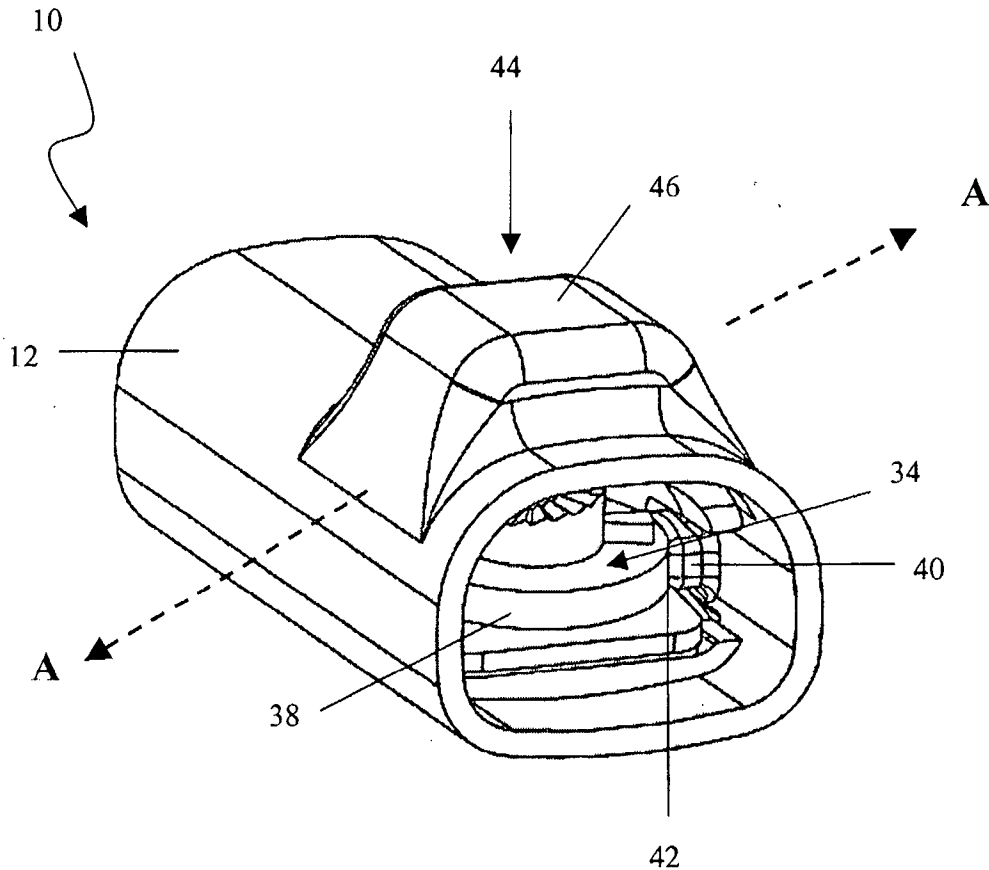
(22) Filed: **Jul. 10, 2002**

Publication Classification

(51) **Int. Cl.⁷ A61M 5/00**

(52) **U.S. Cl. 604/9**

A locking assembly is provided to simply and effectively prevent any unintentional adjustment of the adjustable valve mechanism in a fluid flow control device, without compromising the function of the device. The locking assembly generally includes at least one gripping arm for frictionally engaging at least a portion of the adjustable valve mechanism, and an actuating mechanism for controlling the deployment and release of the gripping arm. The locking assembly prevents unintentional adjustments that can adversely affect the pressure settings of the fluid flow control device. In particular, the locking assembly prevents unintentional adjustment, such as may be caused by the presence of a strong external magnetic field. The locking assembly can be easily disengaged, such as through the application or removal of an external mechanical force, to allow a clinician to adjust the pressure settings of the fluid flow control device as necessary.



Office Action Summary	Application No. 10/192,394	Applicant(s) MCCUSKER ET AL.	
	Examiner Patricia M. Bianco	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

Application/Control Number: 10/192,394
Art Unit: 3761

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DETAILED ACTION

Election/Restrictions

Claims 14-22 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse during a telephone conversation with Lisa Michaud on 9/6/05 (see paper 091909). An affirmation of this election was made by applicant in replying to this Office action in the amendment filed 12/19/05.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, & 11-13 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Bertrand et al. (5,637,083). Bertrand et al. disclose an implantable flow control device having a shunt and valve. The system has a housing defining an inner chamber, an inlet port, an outlet port, and a valve mechanism for regulating fluid flow based on a pressure differential. The valve mechanism includes a rotor assembly. The device also includes a locking assembly for preventing the rotation of the rotor. A pin and detent locking system is seen to be equivalent to applicant's gripping arm, since no definitive structure is set forth with respect to the arm, and both comprise a surface for

frictionally engaging the rotor assembly to selectively maintain the assembly in a particular position. The rotor assembly includes multiple surfaces, or walls, which are engaged by the pin and detent system. The device further includes a lever assembly, or an actuating mechanism for releasing and activating the pin and detent mechanism. With respect to claims 5-7, the actuating mechanism is activated by pressing downwardly on the dome of the housing, which is a flexible or deformable material, to cause the pin and detent system to either engage or disengage the rotor. The dome is made of silicone elastomer, which will retain its shape. (See entire document, namely col. 6-10)

Allowable Subject Matter

Claims 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. With respect to claim 8, the subject matter not found was the deformable member comprising a spring wire in combination with the other elements (or steps) in the claims.

Claim 23 is allowed.

Newly added claim 23 includes the incorporated the objected to as allowable claim language of original claim 10 into an independent form. With respect to claim 23, the subject matter not found was the gripping arm comprising an inflatable bladder in combination with the other elements (or steps) in the claims.

Response to Arguments

Applicant's arguments filed 12/19/05 have been fully considered but they are not persuasive. Applicant argues that the claimed invention requires at least one gripping arm having at least one contacting surface that is adapted to frictionally engage the rotor assembly to selectively maintain the rotor assembly in a desired position and that the use of frictional engagement is not disclosed or suggested by the cited reference. The recitation that the gripping arm is "adapted to frictionally engage the rotor" has not been considered since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Application/Control Number: 10/192,394

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Art Unit: 3761

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571) 272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 3rd, 2006

PATRICIA BIANCO
PRIMARY EXAMINER



Patricia M Bianco
Primary Examiner
Art Unit 3761

Office Action Summary	Application No.		Applicant(s)	
	10/192,394		MCCUSKER ET AL.	
	Examiner		Art Unit	
	Phil Wiest		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

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- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 28 June 2007.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-7,9 and 11-24 is/are pending in the application.

4a) Of the above claim(s) 14-22 is/are withdrawn from consideration.

5) ☒ Claim(s) 23 is/are allowed.

6) ☒ Claim(s) 1-7,9 and 11-13 is/are rejected.

7) ☒ Claim(s) 24 is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 10 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____	6) ☐ Other: _____

Application/Control Number: 10/192,394
Art Unit: 3761

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DETAILED ACTION

Response to Amendment

1. In the amendment filed 5/5/2006, Applicant amended Claim 1, cancelled Claim 8, and added Claim 24. Claims 14-22 remain withdrawn. As a result, Claims 1-7, 9, and 11-24 are currently pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-7, 9, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand et al. (US 5,637,083). Bertrand et al. disclose an implantable flow control device having a shunt and valve. The system has a housing defining an inner chamber, an inlet port, an outlet port, and a valve mechanism for

regulating fluid flow based on a pressure differential. The valve mechanism includes a rotor assembly. The device also includes a locking assembly for preventing the rotation of the rotor. A pin and detent locking system is seen to be equivalent to applicant's gripping arm, and both comprise a surface for frictionally engaging the rotor assembly to selectively maintain the assembly in a particular position. Furthermore, the pin 142 and locking system extend from the housing in order to prevent or permit rotation of the rotor assembly with respect to the housing (Column 3, Lines 49-65). The rotor assembly includes multiple surfaces, or walls, which are engaged by the pin and detent system. The device further includes a lever assembly, or an actuating mechanism for releasing and activating the pin and detent mechanism. With respect to claims 5-7, the actuating mechanism is activated by pressing downwardly on the dome of the housing, which is a flexible or deformable material, to cause the pin and detent system to either engage or disengage the rotor. The dome is made of silicone elastomer, which will retain its shape. (See entire document, namely col. 6-10).

4. Bertrand et al., however, does not disclose that the locking assembly is formed integrally with the housing. It would have been obvious to one of ordinary skill in the art at the time of invention to form the selectively engageable locking assembly integrally with the housing because one of ordinary skill in the art at the time of invention would have recognized that doing so would have been an obvious matter of engineering choice. See MPEP § 2144.04, *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349.

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Allowable Subject Matter

5. Claim 23 is allowed.

Claim 23 includes the incorporated the objected to as allowable claim language of original claim 10 into an independent form. With respect to claim 23, the subject matter not found was the gripping arm comprising an inflatable bladder in combination with the other elements (or steps) in the claims.

Claim 24 will be allowable if corrected to overcome the objection.

Newly added claim 24 includes the incorporated the objected to as allowable claim language of original claim 8 into an independent form. With respect to claim 24, the subject matter not found was the gripping arm comprising a deformable membrane disposed on the housing wherein the deformable membrane of the actuating mechanism includes a shape memory material. The shape memory material is a spring wire embedded within the deformable membrane.

Response to Arguments

6. Applicant's arguments with respect to claims 1-7, 9, and 11-13 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
7/13/07



LOAN H. THANH
PRIMARY EXAMINER

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(19) **United States**

(12) **Patent Application Publication**
McCusker et al.

(10) **Pub. No.: US 2008/0127689 A1**

(43) **Pub. Date: Jun. 5, 2008**

(54) **SHUNT VALVE LOCKING MECHANISM**

Publication Classification

(75) **Inventors:** **Daniel McCusker**, Bridgewater, MA (US); **Alan J. Dextrateur**, Franklin, MA (US); **Rainuka Gupta**, Cambridge, MA (US); **Carleton Bryan Southworth**, Warsaw, IN (US)

(51) **Int. Cl.**
F16K 35/00 (2006.01)
A61M 27/00 (2006.01)

(52) **U.S. Cl.** **70/175; 604/9**

(57) **ABSTRACT**

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BOSTON, MA 02210-2604

A locking assembly is provided to simply and effectively prevent any unintentional adjustment of the adjustable valve mechanism in a fluid flow control device, without compromising the function of the device. The locking assembly generally includes at least one gripping arm for frictionally engaging at least a portion of the adjustable valve mechanism, and an actuating mechanism for controlling the deployment and release of the gripping arm. The locking assembly prevents unintentional adjustments that can adversely affect the pressure settings of the fluid flow control device. In particular, the locking assembly prevents unintentional adjustment, such as may be caused by the presence of a strong external magnetic field. The locking assembly can be easily disengaged, such as through the application or removal of an external mechanical force, to allow a clinician to adjust the pressure settings of the fluid flow control device as necessary.

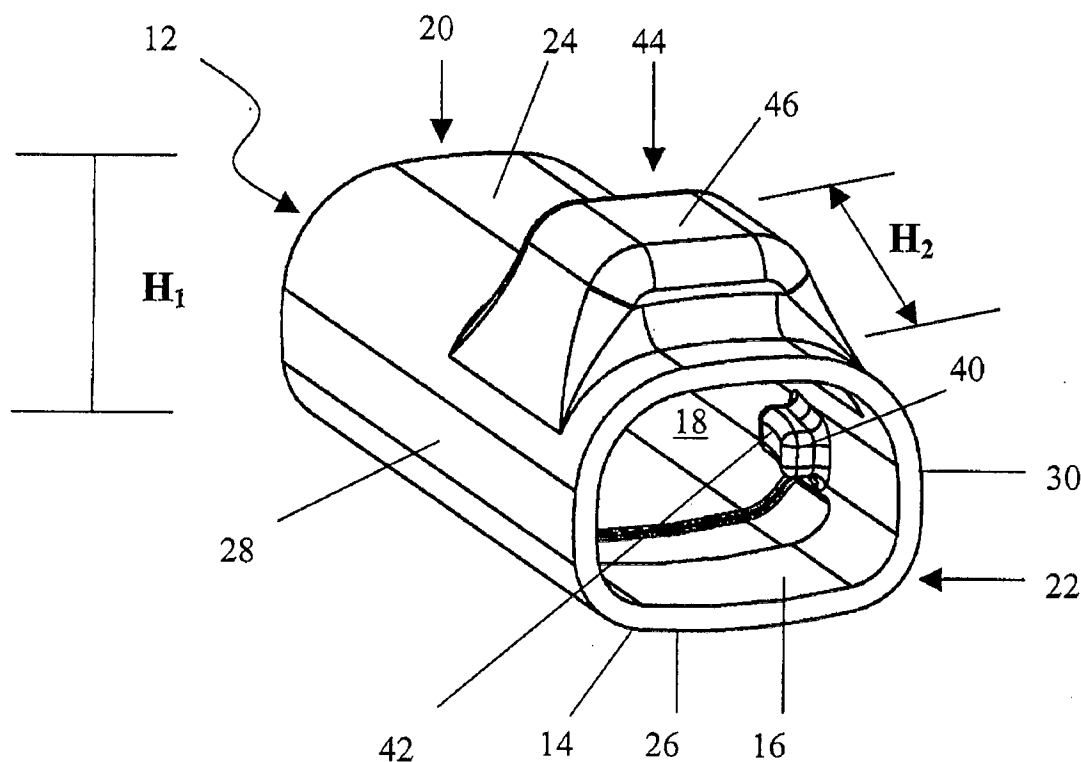
(73) **Assignee:** **Codman & Shurtleff, Inc.**, Raynham, MA (US)

(21) **Appl. No.:** **12/029,818**

(22) **Filed:** **Feb. 12, 2008**

Related U.S. Application Data

(62) Division of application No. 10/192,394, filed on Jul. 10, 2002.





US007390310B2

(12) **United States Patent**
McCusker et al.

(10) **Patent No.:** **US 7,390,310 B2**

(45) **Date of Patent:** **Jun. 24, 2008**

(54) **SHUNT VALVE LOCKING MECHANISM**

(56) **References Cited**

(75) **Inventors:** Daniel McCusker, Bridgewater, MA (US); Alan J. Dextrateur, Franklin, MA (US); Rainuka Gupta, Cambridge, MA (US); Carleton Bryan Southworth, Warsaw, IN (US)

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(73) **Assignee:** Codman & Shurtleff, Inc., Raynham, MA (US)

* cited by examiner

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 882 days.

Primary Examiner—Tatyana Zalukaeva

Assistant Examiner—Phil Wiest

(74) *Attorney, Agent, or Firm*—Nutter McClennen & Fish LLP

(21) **Appl. No.:** 10/192,394

(57) **ABSTRACT**

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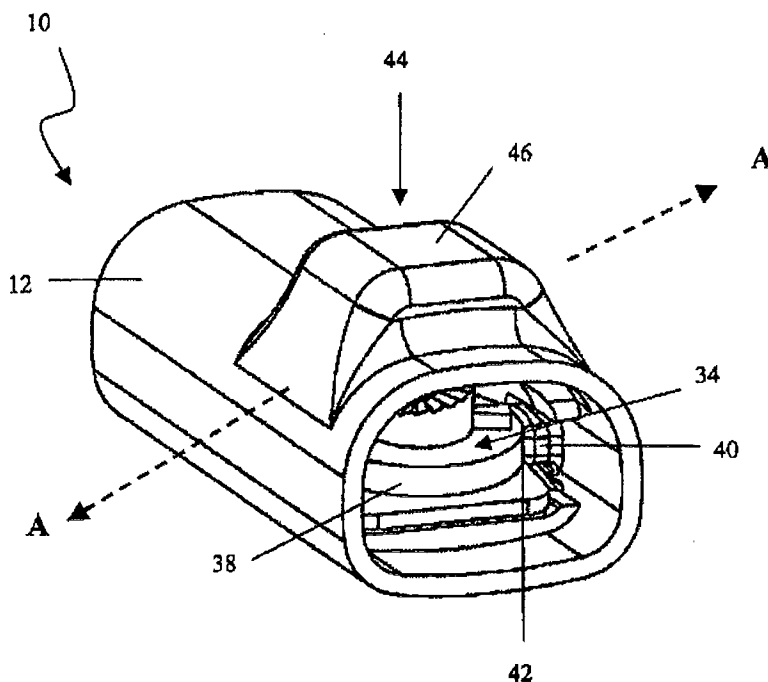
(52) **U.S. Cl.** 604/9; 604/8; 604/247; 251/12; 251/58; 251/59; 251/213; 137/383; 137/384.8; 137/385

(58) **Field of Classification Search** 604/8-10, 604/19, 27, 28, 30-34, 48, 93.01, 183, 186, 604/207, 256, 211-212, 167.01, 167.02, 604/167.03, 167.05, 246-250, 264, 523, 604/537; 251/4, 12, 59, 58, 56

See application file for complete search history.

A locking assembly is provided to simply and effectively prevent any unintentional adjustment of the adjustable valve mechanism in a fluid flow control device, without compromising the function of the device. The locking assembly generally includes at least one gripping arm for frictionally engaging at least a portion of the adjustable valve mechanism, and an actuating mechanism for controlling the deployment and release of the gripping arm. The locking assembly prevents unintentional adjustments that can adversely affect the pressure settings of the fluid flow control device. In particular, the locking assembly prevents unintentional adjustment, such as may be caused by the presence of a strong external magnetic field. The locking assembly can be easily disengaged, such as through the application or removal of an external mechanical force, to allow a clinician to adjust the pressure settings of the fluid flow control device as necessary.

13 Claims, 7 Drawing Sheets



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change in temperature, a change in pH, an ionic change, the presence of light, the presence of an electric field, the presence of a magnetic field, the presence of ultrasound, or any combination of these external stimuli.

In use, upon the application of an external mechanical force to the actuating mechanism 88, such as the application of force by the clinician on the deformable membrane 90, the fluid, gaseous or gel medium within actuating mechanism 88 is transferred to the inflatable bladder 84 of the gripping arm 82, whereupon the gripping arm 82 bellows out, i.e., becomes enlarged with the additional fluid medium transferred thereto. The expanded gripping arm 82 exerts the additional force upon the stair array 80 of the rotor assembly 78 of the shunt valve mechanism 32 of the shunt valve system 50, as shown in FIG. 5B. The expanded gripping arm 82 thus contacts the stair array 80 of the rotor assembly 78 and applies a compressive force to a portion of the stair array 80 to prevent the rotor assembly 78 from rotating. In one embodiment, the gripping arm 82 and the deformable membrane 90 are resilient, and upon release of the external mechanical force, the fluid media within the gripping arm 82 and the deformable membrane 90 will reach equilibrium and the gripping arm 82 will no longer be expanded. Optionally, the channel 72 can include a bleeder valve (not shown) that can initially prevent the flow of the gaseous, fluid or gel medium from the gripping arm 82 to the actuating mechanism 88, but can, over time, allow the fluid, gaseous or gel medium to seep into the actuating mechanism 88. As the gripping arm 82 deflates and resumes its resting state, the rotor assembly 78 will no longer be constrained by the gripping arm 82 pressing against it. Accordingly, as shown in FIG. 5B, the rotor assembly 78 is free to rotate without encumbrances.

It is contemplated that the gripping arm 82, which is intended to contact the stair array 80 of the rotor assembly 78 upon expansion, can also include friction-increasing surface features upon its outer surface. Suitable friction-increasing surface features include, but are not limited to, grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof. These friction-increasing surface features can cooperatively mate with the stair array 80 of the rotor assembly 78 to provide a further means of preventing the rotation of the rotor assembly 78.

One of ordinary skill in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

1. A shunt valve system, comprising:

- a housing having therein a chamber including an inlet port for receiving fluid, an outlet port for fluid release, and a valve mechanism including a rotor assembly for regulating fluid flow therethrough, when a fluid pressure differential between the inlet port and the outlet port exceeds a selected valve opening pressure; and
- a selectively engageable locking assembly formed integrally with a wall of the housing and effective to prevent rotation of the rotor assembly, the locking assembly having at least one protrusion extending from a wall of the housing, the protrusion having at least one contacting surface that is configured to selectively frictionally engage the rotor assembly to selectively maintain the rotor assembly in a desired position.

2. The system of claim 1, wherein the rotor assembly further includes an outer wall, the at least one contacting

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surface of the at least one protrusion being adapted to frictionally engage the outer wall of the rotor assembly.

3. The system of claim 1, wherein the rotor assembly further includes an inner wall, the at least one contacting surface of the at least one protrusion being adapted to frictionally engage the inner wall of the rotor assembly.

4. The system of claim 1, wherein the locking assembly further includes an actuating mechanism for releasing and deploying the at least one protrusion.

5. The system of claim 4, wherein the actuating mechanism comprises a deformable membrane disposed on the housing that is configured to transfer a force applied to the deformable membrane through the housing and to the at least one protrusion sufficient to move the at least one protrusion between a first state in which the at least one protrusion frictionally engages the rotor assembly and a second state in which the at least one protrusion is disengaged from the rotor assembly.

6. The system of claim 5, wherein the deformable membrane is formed from an elastomeric material selected from the group consisting of a silicone elastomer, polyurethane, nylon, and combinations thereof.

7. The system of claim 5, wherein the deformable membrane of the actuating mechanism includes a shape memory material.

8. The system of claim 1, wherein the locking mechanism contains opposed, bilateral protrusions.

9. The system of claim 2, wherein the outer wall of the rotor assembly contains friction-increasing surface features selected from the group consisting of grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof.

10. The system of claim 3, wherein the inner wall of the rotor assembly contains friction-increasing surface features selected from the group consisting of grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof.

11. The system of claim 1, wherein the at least one protrusion has an outer surface containing friction-increasing surface features selected from the group consisting of grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof.

12. A shunt valve system, comprising:

a housing having therein a chamber including an inlet port for receiving fluid, an outlet port for fluid release, and a valve mechanism including a rotor assembly for regulating fluid flow therethrough, when a fluid pressure differential between the inlet port and the outlet port exceeds a selected valve opening pressure; and

a selectively engageable locking assembly for preventing rotation of the rotor assembly, the locking assembly having at least one protrusion having at least one contacting surface that is adapted to frictionally engage the rotor assembly to selectively maintain the rotor assembly in a desired position, the protrusion formed as an inflatable bladder.

13. A shunt valve system, comprising:

a housing having therein a chamber including an inlet port for receiving fluid, an outlet port for fluid release, and a valve mechanism including a rotor assembly for regulating fluid flow therethrough, when a fluid pressure differential between the inlet port and the outlet port exceeds a selected valve opening pressure; and

a selectively engageable locking assembly for preventing rotation of the rotor assembly, the locking assembly having at least one protrusion having at least one contacting surface that is adapted to frictionally engage the rotor assembly to selectively maintain the rotor assembly in a desired position,

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wherein the locking assembly further includes an actuating mechanism for releasing and deploying the at least one protrusion, the actuating mechanism comprising a deformable membrane disposed on the housing that is configured to transfer a force applied to the deformable membrane through the housing and to the at least one protrusion sufficient to move the at least one protrusion between a first state in which the at least one protrusion

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frictionally engages the rotor assembly and a second state in which the at least one protrusion is disengaged from the rotor assembly, the deformable membrane of the actuating mechanism including a shape memory material, wherein the shape memory material is a spring wire embedded within the deformable membrane.

* * * * *

(12)

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(51)

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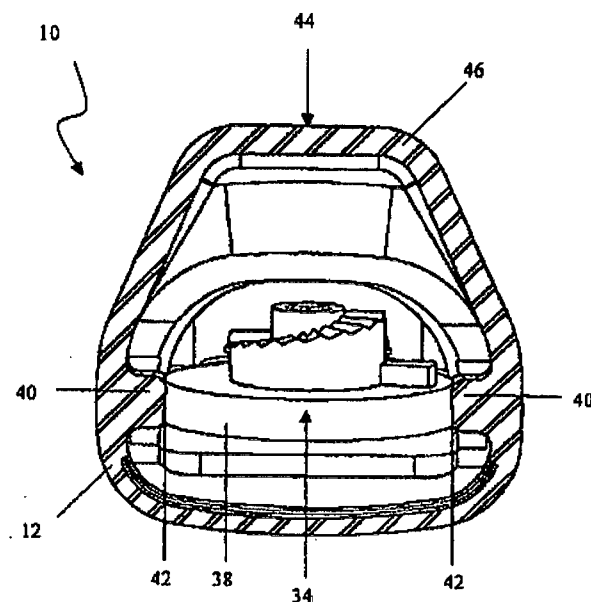
Shunt valve locking mechanism

(57)

A locking assembly is provided to simply and effectively prevent any unintentional adjustment of the adjustable valve mechanism in a fluid flow control device, without compromising the function of the device. The locking assembly generally includes at least one gripping arm for frictionally engaging at least a portion of the adjustable valve mechanism, and an actuating mechanism for controlling the deployment and release of the gripping arm. The locking assembly prevents un-

intentional adjustments that can adversely affect the pressure settings of the fluid flow control device. In particular, the locking assembly prevents unintentional adjustment, such as may be caused by the presence of a strong external magnetic field. The locking assembly can be easily disengaged, such as through the application or removal of an external mechanical force, to allow a clinician to adjust the pressure settings of the fluid flow control device as necessary.

FIGURE 3A



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EP 1 380 317 A1



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 03 25 4355

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
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			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61M F16K
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 16 September 2003	Examiner Michels, N
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

EPO FORM 1503 03.82 (P04001)

EP 1 380 317 A1

ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 03 25 4355

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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16-09-2003

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EPO FORM P4459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



(11) **EP 1 380 317 B1**

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(21) Application number: **03254355.5**

(22) Date of filing: **09.07.2003**

(54) **Shunt valve locking mechanism**

Verriegelungsmechanismus für ein Shunt-Ventil

Mécanisme de verrouillage pour une valve de dérivation

(84) Designated Contracting States:
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(30) Priority: **10.07.2002 US 192394**

(43) Date of publication of application:
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(56) References cited:
EP-A- 0 232 454 EP-A- 0 580 384
US-A- 5 637 083 US-A- 6 152 933

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

the deformable membrane 90 can also be configured to provide a visual cue, such as for example a visible bulge that can indicate the location of the shunt valve system 50 within a patient. Additionally, the deformable membrane 90 of the actuating mechanism 88 can be adapted to include an audible cue that can indicate when the gripping arm 82 of the locking assembly is in an engaged state, such that the gripping arm 82 frictionally engages at least a portion of the stair array 80 of the rotor assembly 78. For example, the deformable membrane 90 can include a preformed spring which can be configured to produce an audible sound, such as a clicking noise, as pressure is applied to the actuating mechanism 88 to deploy the gripping arm 82.

[0045] The locking assembly of this second embodiment of the present invention can be constructed from virtually any biocompatible material. Suitable biocompatible materials have been described above in connection with the first embodiment of the locking assembly of the present invention.

[0046] The deformable membrane 90, in particular, can be constructed from a shape memory material, or alternatively, the deformable membrane 90 can include a shape memory material embedded therein. In an embodiment where the deformable membrane 90 includes a shape memory material, the shape memory material is, preferably, a spring wire embedded within the deformable membrane 90. Suitable shape memory materials for use in the present invention include those discussed above in connection with the first embodiment of the shunt valve system 10. The shape memory materials, which can be used in the deformable membrane 90 of the present invention, are effective to change their shape from a first, resting shape to a second, memorized shape in the presence of an external stimulus, or external stimuli. By way of non-limiting example, the shape memory materials of the present invention can change their shape in response to a change in temperature, a change in pH, an ionic change, the presence of light, the presence of an electric field, the presence of a magnetic field, the presence of ultrasound, or any combination of these external stimuli.

[0047] In use, upon the application of an external mechanical force to the actuating mechanism 88, such as the application of force by the clinician on the deformable membrane 90, the fluid, gaseous or gel medium within actuating mechanism 88 is transferred to the inflatable bladder 84 of the gripping arm 82, whereupon the gripping arm 82 bellows out, i.e., becomes enlarged with the additional fluid medium transferred thereto. The expanded gripping arm 82 exerts the additional force upon the stair array 80 of the rotor assembly 78 of the shunt valve mechanism 32 of the shunt valve system 50, as shown in FIG. 5B. The expanded gripping arm 82 thus contacts the stair array 80 of the rotor assembly 78 and applies a compressive force to a portion of the stair array 80 to prevent the rotor assembly 78 from rotating. In one embodiment, the gripping arm 82 and the deformable mem-

brane 90 are resilient, and upon release of the external mechanical force, the fluid media within the gripping arm 82 and the deformable membrane 90 will reach equilibrium and the gripping arm 82 will no longer be expanded. Optionally, the channel 72 can include a bleeder valve (not shown) that can initially prevent the flow of the gaseous, fluid or gel medium from the gripping arm 82 to the actuating mechanism 88, but can, over time, allow the fluid, gaseous or gel medium to seep into the actuating mechanism 88. As the gripping arm 82 deflates and resumes its resting state, the rotor assembly 78 will no longer be constrained by the gripping arm 82 pressing against it. Accordingly, as shown in FIG. 5B, the rotor assembly 78 is free to rotate without encumbrances.

[0048] It is contemplated that the gripping arm 82, which is intended to contact the stair array 80 of the rotor assembly 78 upon expansion, can also include friction-increasing surface features upon its outer surface. Suitable friction-increasing surface features include, but are not limited to, grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof. These friction-increasing surface features can cooperatively mate with the stair array 80 of the rotor assembly 78 to provide a further means of preventing the rotation of the rotor assembly 78.

[0049] One of ordinary skill in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims.

Claims

1. A locking assembly for preventing rotation of a rotor assembly (34) of a shunt valve system (10), characterized by the locking assembly comprising:

at least one gripping arm (40) having at least one contacting surface (42) that is adapted to frictionally engage the rotor assembly (34) to selectively maintain the rotor assembly (34) in a desired position.
2. The assembly of claim 1, wherein the rotor assembly (34) further includes an outer wall (38), the at least one contacting surface (42) of the at least one gripping arm (40) being adapted to frictionally engage the outer wall (38) of the rotor assembly (34).
3. The assembly of claim 1, wherein the rotor assembly further includes an inner wall, the at least one contacting surface (42) of the at least one gripping arm (40) being adapted to frictionally engage the inner wall of the rotor assembly (34).
4. The assembly of claim 2 or claim 3, wherein the outer

(38) or inner wall, respectively, of the rotor assembly (34) contains friction-increasing surface features selected from the group consisting of grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof.

5. The assembly of any one of claims 1 to 4, wherein the locking assembly further includes an actuating mechanism (44) for releasing and deploying the at least one gripping arm (40).
6. The assembly of claim 5, wherein the actuating mechanism (44) comprises a deformable membrane (46) configured to transfer a force applied to the deformable membrane (46) to the at least one gripping arm (40) sufficient to move the at least one gripping arm (40) between the locked position and the unlocked position.
7. The assembly of claim 6, wherein the deformable membrane (46) is formed from an elastomeric material selected from the group consisting of a silicone elastomer, polyurethane, nylon, and combinations thereof.
8. The assembly of claim 6, wherein the deformable membrane (46) of the actuating mechanism (44) includes a shape memory material.
9. The assembly of claim 8, wherein the shape memory material included in the actuating mechanism (44) is a spring wire embedded within the deformable membrane (46).
10. The locking assembly of any one of claims 1 to 9, further containing opposed, bilateral gripping arms.
11. The locking assembly of any one of claims 1 to 9, further containing at least one gripping arm (40) formed as an inflatable bladder.
12. The assembly of any one of claims 1 to 11, wherein the at least one gripping arm (40) has an outer surface containing friction-increasing surface features selected from the group consisting of grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof.
13. The locking assembly of any preceding claim for selectively engaging a medical device having a fluid channel and a fluid regulator for preventing fluid flow therethrough.
14. The locking assembly of claim 13, wherein the gripping arm is selectively moveable between a first position in which the arm frictionally engages the fluid regulator and a second position in which the arm does not engage the fluid regulator, and wherein the

deformable membrane is configured to transfer a force applied thereto to the gripping arm sufficient to cause the arm to move from one of the first or second positions to the other of the first or second positions.

15. A shunt valve system comprising:

a housing (12) having therein a chamber (18) including an inlet port for receiving fluid, an outlet port for fluid release, and a valve mechanism (32) including a rotor assembly (34) for regulating fluid flow therethrough, when a fluid pressure differential between the inlet port and the outlet port exceeds a selected valve opening pressure; and
the locking assembly of any preceding claim for preventing rotation of the rotor assembly (34).

Patentansprüche

1. Verriegelungsvorrichtung zum Verhindern einer Rotation einer Rotorvorrichtung (34) eines Shuntventilsystems (10), mit:
wenigstens einem Greifarm (40), welcher wenigstens eine Kontaktoberfläche (42) aufweist, welche angepaßt ist, reibend mit der Rotorvorrichtung (34) zusammenzuwirken, um die Rotorvorrichtung (34) in einer gewünschten Position selektiv zu halten.
2. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Rotorvorrichtung (34) zusätzlich eine äußere Wand (38) aufweist, wobei die wenigstens eine Kontaktoberfläche (42) des wenigstens einen Greifarms (40) angepaßt ist, mit der äußeren Wand (38) der Rotorvorrichtung (34) reibend zusammenzuwirken.
3. Vorrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Rotorvorrichtung (34) zusätzlich eine innere Wand aufweist, wobei die wenigstens eine Kontaktoberfläche (42) des wenigstens einen Greifarms (40) angepaßt ist, mit der inneren Wand der Rotorvorrichtung (34) reibend zusammenzuwirken.
4. Vorrichtung nach Anspruch 2 oder 3, dadurch gekennzeichnet, daß respektive die äußere (38) oder die innere Wand der Rotorvorrichtung (34) Merkmale, welche eine Reibung einer Oberfläche vergrößern, aus der folgenden Gruppe aufweist: Nute, Feststellvorrichtungen, Grate, Rillen, aufgeraute Oberflächen und einer Kombination hiervon.
5. Vorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, daß die Verriegelungsvor-



US005637083A

United States Patent [19]**Bertrand et al.**[11] **Patent Number:** **5,637,083**[45] **Date of Patent:** **Jun. 10, 1997**[54] **IMPLANTABLE ADJUSTABLE FLUID FLOW CONTROL VALVE**[75] Inventors: **William J. Bertrand**, Ventura, Calif.;
David A. Watson, East Greenwich, R.I.[73] Assignee: **Pudenz-Schulte Medical Research Corporation**, Goleta, Calif.

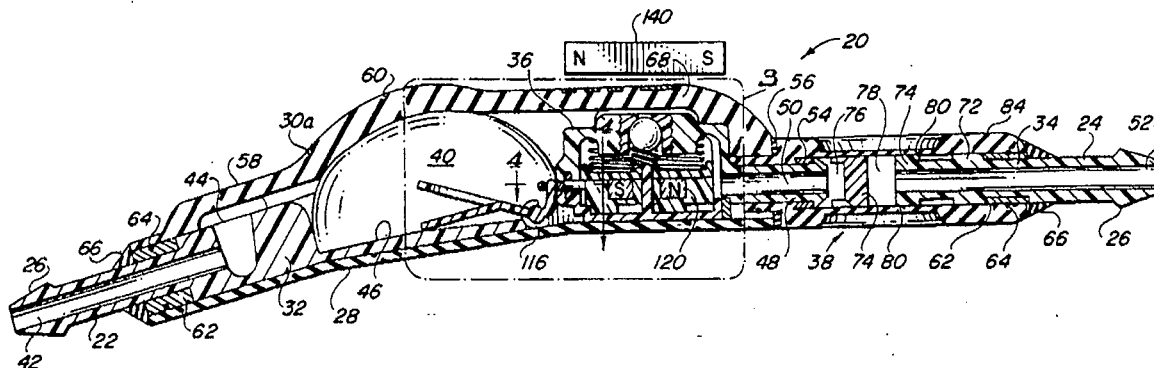
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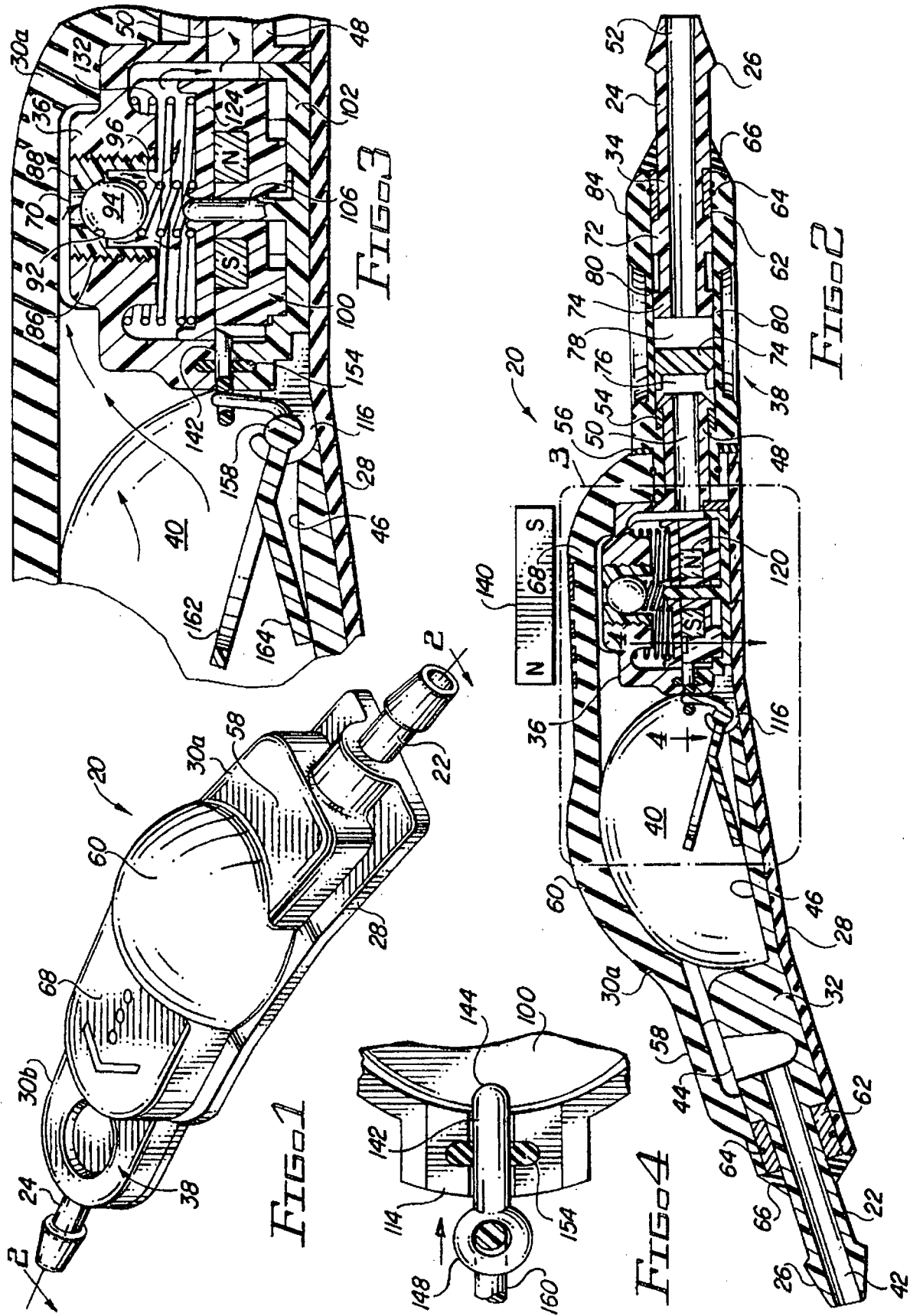
[21] Appl. No.: **588,822**[22] Filed: **Jan. 19, 1996**[51] Int. Cl.⁶ **A61M 5/00**[52] U.S. Cl. **604/9; 604/248**[58] Field of Search **604/8-10, 247, 604/248**[56] **References Cited****U.S. PATENT DOCUMENTS**

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Primary Examiner—John G. Weiss*Assistant Examiner*—Ki Yong O*Attorney, Agent, or Firm*—Kelly, Bauersfeld, Lowry & Kelley[57] **ABSTRACT**

A subcutaneously implantable and percutaneously adjustable fluid flow control device includes a magnetically adjustable valve for controlling fluid flow from an inlet to an outlet. The valve includes a housing having a fluid passageway therethrough, a valve element designed to bear upon a valve seat to close the passageway to fluid flow, and a spring which biases the valve element against the valve seat so as to keep the passageway closed until a fluid pressure differential between the inlet and the outlet exceeds a selected valve opening pressure. A fixed dual concentric stair-step array and an overlying rotor assembly permit the amount of bias applied to the valve element by the spring to be adjusted. The rotor assembly is adapted to rotate in response to an external or percutaneously-applied magnetic field. In one embodiment, the rotor assembly may be locked into one of several possible rotational positions relative to the stair-step array to prevent rotation thereof.

30 Claims, 4 Drawing Sheets



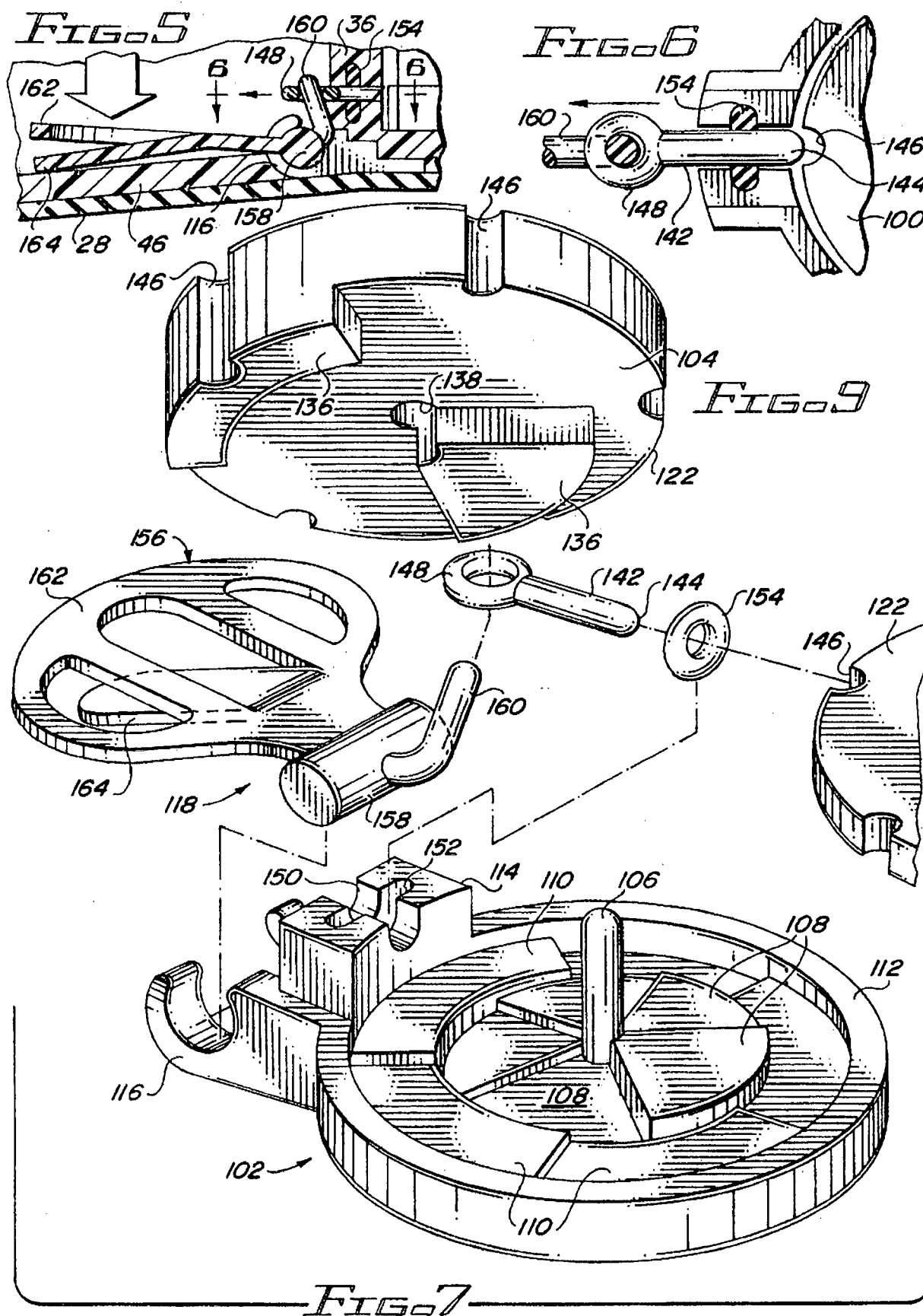


FIG. 8

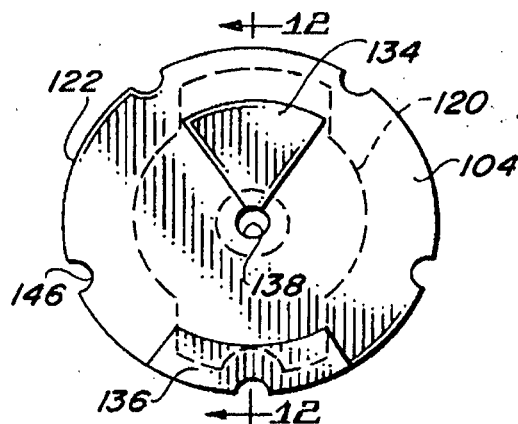
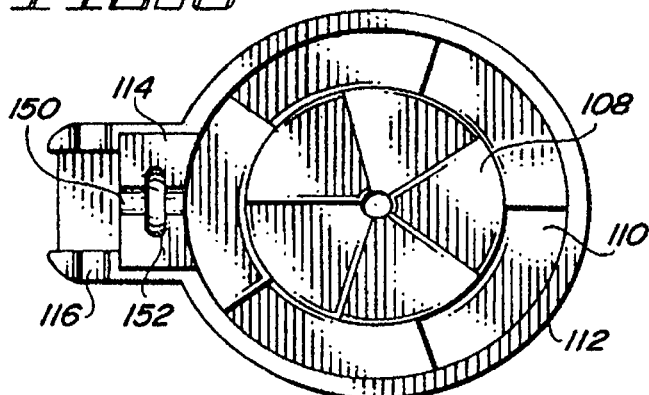


FIG. 10

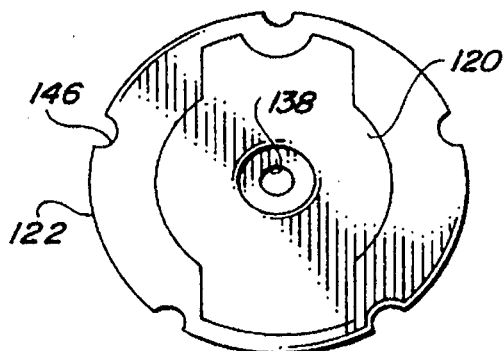


FIG. 11

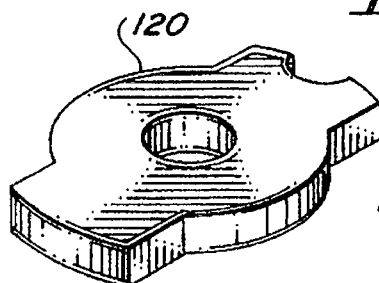


FIG. 13

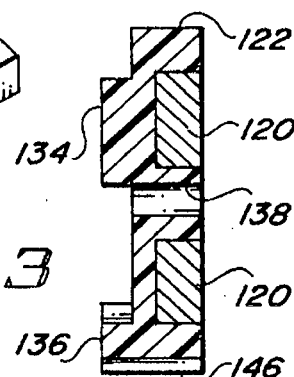


FIG. 12

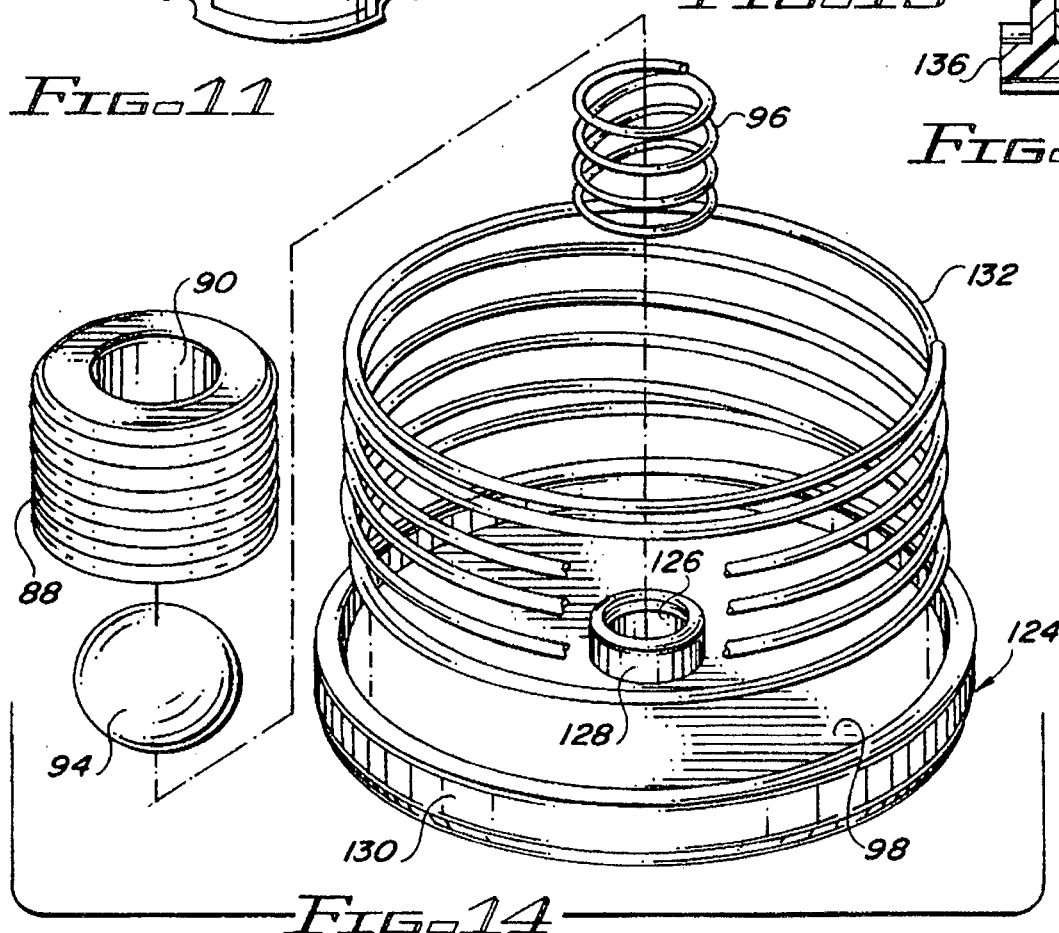
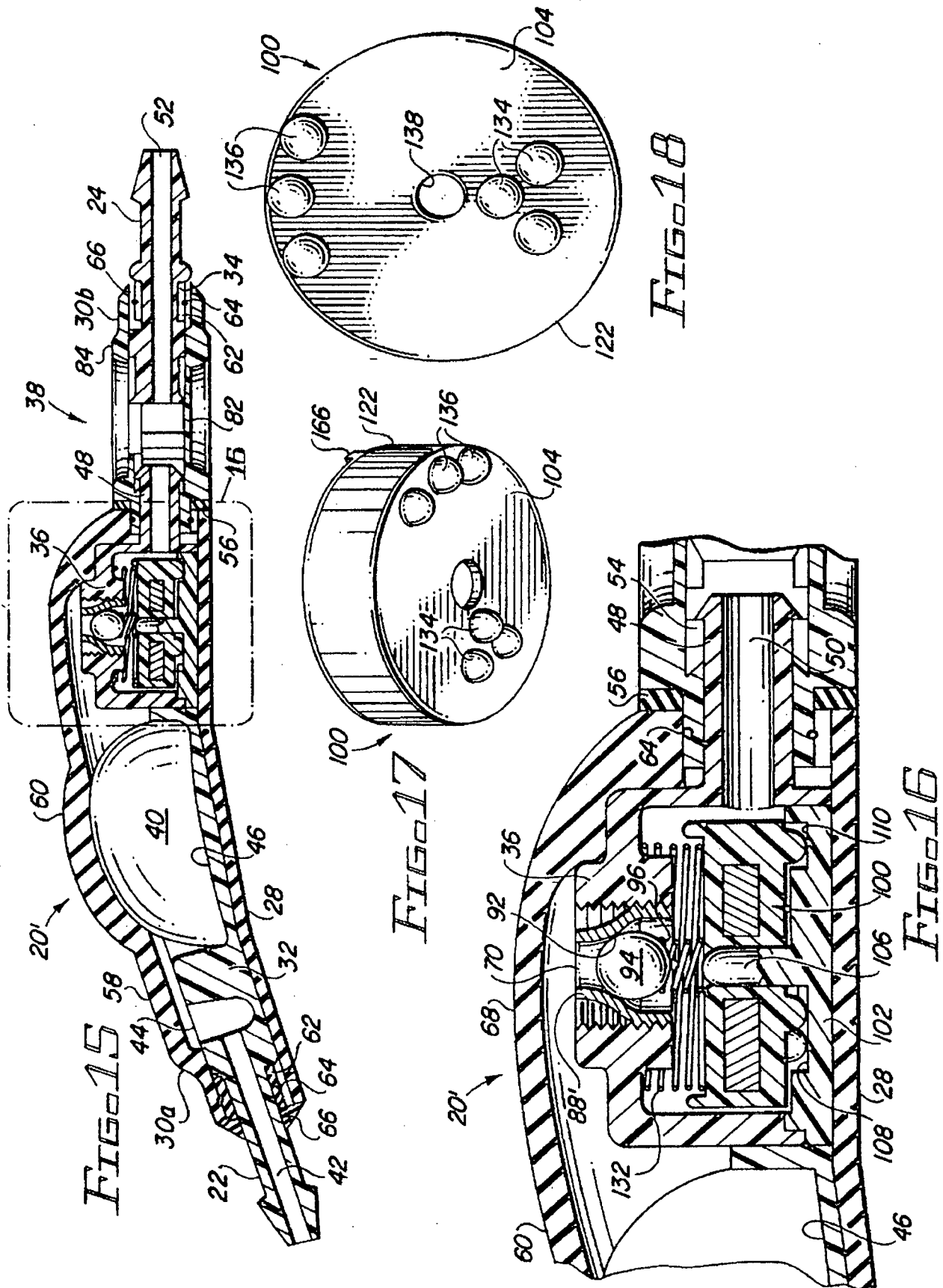


FIG. 14



the inlet and the outlet exceeds a selected valve opening pressure. Further, a pump is situated between the inlet and the valve means. The pump provides means for flushing fluid through the device by the application of percutaneous pressure to the pump.

In one preferred form of the invention, the valve housing includes a threaded aperture and a flow regulator insert which is threaded into the aperture to define the fluid passageway. Means are provided for adjusting the amount of bias applied to the valve element by the biasing means. In particular, the adjusting means includes a fixed dual concentric stair-step array and an overlying rotor assembly having a first surface which supports an end of a valve element-biasing spring, and a second surface which is supported by the stair-step array. The rotor assembly is adapted to rotate in response to an external or percutaneously-applied magnetic field and such rotation of the rotor assembly permits selected seating of the second surface on the stair-step array to raise or lower the rotor assembly with respect to the stair-step array.

The dual concentric stair-step array includes a central rotor pivot, a plurality of inner steps surrounding the rotor pivot, and a plurality of outer steps extending peripherally about the inner steps. The rotor assembly includes a magnet embedded within a base having an inner leg adapted to bear against a selected one of the plurality of inner steps, and outer leg disposed diametrically opposite the inner leg and adapted to bear against a selected one of the plurality of outer steps, a central aperture through which the rotor pivot extends, and a rotor cap fixed to the base on a side thereof opposite the inner and outer legs. The rotor cap provides the first surface of the rotor assembly and includes a central aperture aligned with the central aperture of the base, through which the rotor pivot extends.

A compression spring is provided between a portion of the valve housing surrounding the fluid passageway and the first surface of the rotor assembly. The compression spring biases the rotor assembly into contract with the dual concentric stair-step array.

Means are also provided for occluding a portion of the fluid flow control device adjacent to the inlet by application of manual percutaneous pressure to the device. Similarly, means are provided for occluding a portion of the fluid flow control device adjacent to the outlet also by application of manual percutaneous pressure to the device. Moreover, a siphon control device is situated between the valve and the outlet.

In another preferred form of the invention, means are provided for locking the rotor assembly into one of several possible rotational positions relative to the stair-step array to prevent rotation thereof. Further, means are provided for disengaging the locking means to permit rotation of the rotor assembly in response to the external magnetic field. More particularly, the locking means comprises a pin having a first end that engages one of a plurality of detents in an outer peripheral surface of the rotor assembly to prevent rotation thereof. The disengaging means comprises pin actuating means for moving the pin between a first extended position, wherein the end of the pin engages one of the plurality of detents, and a second retracted position. The pin actuating means comprises a pivotable lever including a pin engaging shaft that engages a second end of the pin, and a manually actuated lever disposed within the pump and biased so as to urge the pin into its first position.

Other features and advantages of the present invention will become apparent from the following more detailed

description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate the invention. In such drawings:

FIG. 1 is a perspective view of an adjustable flow control valve embodying the invention;

FIG. 2 is an enlarged elevational section taken generally along the line 2—2 of FIG. 1;

FIG. 3 is an enlarged fragmented sectional view taken of the area designed by the line 3 in FIG. 2;

FIG. 4 is an enlarged, fragmented and partially sectional view taken generally along the line 4—4 of FIG. 2

FIG. 5 is a fragmented vertical section similar to FIG. 3, illustrating the manner in which a lever disposed within a pump reservoir of the device is depressed to disengage a lock;

FIG. 6 is an enlarged, fragmented and partially sectional view taken generally along the line 6—6 of FIG. 5;

FIG. 7 is an exploded perspective view of components of a valve assembly of the fluid flow control device, including a fixed dual concentric stair-step array, a portion of an overlying rotor assembly, a pin reciprocable through an O-ring positioned within a supporting bracket of the stair-step array, and an actuating mechanism pivotable with respect to a lock lever pivot holder attached to the stair-step array, which provides means for reciprocating the pin into and out of detents provided in the outer peripheral surface of the rotor assembly;

FIG. 8 is a top plan view of the fixed dual concentric stair-step array of FIG. 7;

FIG. 9 is a bottom and side perspective view of the rotor assembly base partially shown in FIG. 7;

FIG. 10 is a bottom plan view of the rotor assembly base of FIG. 9;

FIG. 11 is a top plan view of the rotor assembly base of FIGS. 9 and 10;

FIG. 12 is a sectional view of the rotor assembly base taken generally along the line 12—12 of FIG. 10;

FIG. 13 is a top and side perspective view of a magnet embedded within the rotor assembly base of FIGS. 9—12;

FIG. 14 is an exploded perspective view illustrating additional components comprising the valve, in addition to those illustrated in FIG. 7, namely a rotor cap positionable over a top surface of the rotor assembly base, a pressure spring which extends between an upper surface of the rotor cap and a ruby ball valve element, a return compression spring which extends between an upper surface of the rotor cap and a portion of a valve housing, and a threaded flow regulator housing which defines a fluid passageway there-through;

FIG. 15 is a vertical section similar to that shown in FIG. 2, illustrating another embodiment of the invention;

FIG. 16 is an enlarged, fragmented section taken generally of the area indicated by the line 16 in FIG. 15;

FIG. 17 is a bottom and side perspective view of the rotor assembly base partially shown in FIGS. 15 and 16; and

FIG. 18 bottom plan view of the rotor assembly base of FIG. 17.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the present invention is concerned with a subcutaneously

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implantable and percutaneously adjustable fluid flow control device, generally designated in the accompanying drawings by the reference numbers 20 (FIGS. 1-14) and 20' (FIGS. 15-18). The improved fluid flow control devices 20 and 20' are intended for use in a surgically implanted physiological shunt system for draining fluid from one portion of the body to another. In order to connect, for example, the devices 20 or 20' in such a system, the devices include an inlet connector 22 and an outlet connector 24 which each receive one end of a piece of surgical tubing (not shown). The ends of the surgical tubing are placed over the connectors 22 and 24 and secured thereon by a single ligature just inside of an annular ridge 26 formed near the end of each connector.

When the flow control devices 20 and 20' are used in a drainage system intended for the treatment of hydrocephalus, the inlet connector 22 is fluidly connected with a proximal catheter which is inserted through the skull into a brain ventricle containing cerebrospinal fluid under pressure. The outlet connector 24 is fluidly connected to a distal catheter which serves to discharge cerebrospinal fluid to, for example, the atrium portion of a patient's heart. Ordinarily the flow control devices 20 and 20' will be surgically implanted on the patient's skull with a flap of skin overlying the device. To facilitate holding the device in its desired position after implantation, a generally flexible mounting plate 28 can be provided with one or more suture holes.

As will become apparent from the following description, the present invention provides a highly reliable fluid flow control device which has a single flow path therethrough and a valve mechanism which can be percutaneously adjusted when the device is subcutaneously implanted. The present invention is designed to facilitate implantation by eliminating components to be connected or adjusted other than the surgical tubing to the device itself.

In accordance with the present invention, the flow control devices 20 and 20' include a relatively rigid, molded plastic base invested within an elastomeric casing 30 which, together, define a fluid flow path through the fluid flow control devices from the inlet connector 22 to the outlet connector 24. The base comprises an inlet section 32 integrally formed with the inlet connector 22, an outlet section 34 integrally formed with the outlet connector 24, and an intermediate valve housing 36 disposed within the elastomeric casing 30 between the inlet and outlet sections 32 and 34. The valve housing 36 includes a percutaneously adjustable valve mechanism which restricts the flow of fluid through the device 20 or 20'. The casing 30 and the outlet segment 34 of the base cooperate to provide a siphon control device 38 situated between the valve housing 36 and the outlet connector 24, which prevents fluid flow through the devices 20 and 20' in the absence of positive upstream fluid pressure or in response to negative downstream hydrostatic pressure on the device. Further, the casing 30 and the inlet segment 32 of the base cooperate to define a pump or flushing reservoir 40 between the inlet connector 22 and the valve housing 36.

More specifically, and as shown best in FIGS. 1-3, 15 and 16, the inlet segment 32 of the base abuts against a proximal side of the valve housing 36 which, in turn, itself interfits with the outlet segment 34 of the base. The inlet segment 32 defines an inlet flow channel 42 extending through the inlet connector 22 to an upwardly facing inlet occluder port 44. The inlet segment 32 of the base forms a bottom plate 46 for the flushing reservoir 40 and an abutment support for a portion of the valve housing 36.

The valve housing 36 includes a snap-fit interlocking barbed connector 48. The barbed connector 48 extends from

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the valve housing 36 toward the outlet segment 34 of the base, and forms a valve outlet fluid passageway 50 for directing fluids into the siphon control device 38. A pair of splines (not shown) extend from the valve housing 36 adjacent to the connector 48 and, together with the connector 48, interact with corresponding portions of the outlet segment 34 of the base to prevent tensile and torsional movement of the valve housing 36 and the outlet segment 34 of the base with respect to one another.

The outlet segment 34 of the base is integrally formed with the outlet connector 24 which defines an outlet flow channel 52 therethrough. The outlet segment 34 defines a portion of the siphon control device 38. A connector receptacle 54 is provided in the proximal end of the outlet segment 34 for receiving the barbed connector 48 therein. Spline receiving slots (not shown) are provided in the proximal end of the outlet segment 34 to slidably receive and substantially envelope the splines as the connector 48 is inserted into the receptacle 54. A similar base connection arrangement is illustrated in detail in U.S. Pat. No. 5,176,627, the contents of which are incorporated herein.

The elastomeric casing 30 is provided in two parts: a first or inlet casing body 38a into which the inlet segment 32 of the base and the valve housing 36 are invested, and an outlet or second casing 30b which is sealed by a suitable adhesive 56 to the inlet casing 30a in order to provide a continuous elastomeric exterior to the devices 20 and 20', with the exception of the inlet and outlet connectors 22 and 24 which extend therefrom. The inlet casing body 30a is integrally formed with the mounting pad 28 and includes an inlet aperture through which the inlet connector 22 extends, an inlet occluder wing 58 which generally overlies the inlet occluder port 44, and a resiliently flexible dome 60 for the flushing reservoir 40.

In order to provide a fluid-tight seal between the inlet connector 22 and the inlet casing body 30a, a tube 62 is placed over a portion of the inlet connector and secured in place by means of a Mersilene over-suture 64. A silicone adhesive 66 is then injected into any remaining gap between the casing 30 and the inlet connector 22, and is also disposed peripherally about the inlet connector 22 and adjacent the proximal end of the elastomeric casing 30. This same sealing arrangement is utilized between the outlet casing body 30b and the outlet connector 24.

The inlet occluder wing 58 is positioned over the inlet occluder port 44 to facilitate occluding a portion of the fluid flow path through the devices 20 and 20' by pressing the wing 58 downwardly. Depressing the wing 58 and occluding the port 44 prevents proximal fluid flow from the flushing reservoir 40, defined by the dome 60 and the bottom plate 46, when the dome is pressed downwardly by manual percutaneous pressure. The dome 60 is preferably molded of a silicone elastomer material and is designed to permit injection into the fluid flow control devices 20 and 20' by a hypodermic needle through the dome. The inlet segment 32 of the base, as well as the outlet segment 34 and the valve housing 36, is preferably molded of a polypropylene material which provides sufficient rigidity to prevent a needle from inadvertently passing through the devices 20 and 20' if an injection is made into the flushing reservoir 40. The construction of the base segments 32, 34 and 36, and the elastomeric casing 30, helps to guide a physician in manually percutaneously manipulating the devices 20 and 20' when subcutaneously implanted, for purposes of flushing the shunt system and adjusting the valve mechanism, when needed.

A distal occluder wing 68 is positioned over the valve housing 36 to facilitate occluding a valve inlet fluid pas-

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sageway 70. This is accomplished by pressing the wing 68 downwardly, which effectively prevents distal fluid flow from the flushing reservoir 40 when the dome is pressed downwardly by manual percutaneous pressure.

The outlet casing body 30b surrounds a portion of the outlet segment 34 of the base to define the siphon control device 38 which is similar to that shown and described in U.S. Pat. No. 4,795,437, the contents of which are incorporated herein. The siphon control device 38 includes an outer wall 72 and an inner wall 74 which is situated within and encircled about by the outer wall. The valve outlet fluid passageway 50 through the barbed connector 48 directs fluid from the valve housing 36 to a central SCD reservoir 76 defined as the area between the inner wall 74 and the outer wall 72. The outlet flow channel 52 extends through the inner wall 74 to the distal end of the outlet connector 24.

The outer wall 72 is generally circular in shape, and is spaced from and encircles the inner wall 74. The inner wall 74 is also generally circular in shape, and defines an SCD outlet chamber 78 which is adjacent to and in fluid communication with the outlet flow channel 52. The inner wall 74 is constructed to have substantially parallel upper and lower seating surfaces 80, and it effectively forms a barrier separating the SCD reservoir 76 from the SCD outlet chamber 78.

The outlet casing body 30b is provided with a pair of spaced, substantially parallel, flexible elastomeric diaphragms 82 which are fixed about their peripheries adjacent to the outer wall 72. Each diaphragm 82 has an inner surface which defines the upper and lower limits of the SCD reservoir 76 and the SCD outlet chamber 78, and an outer surface which forms an exterior surface of the siphon control device 38. The diaphragms 82 are situated on opposite sides of the inner wall 74 to position a portion of each inner surface thereof in contact with an adjacent one of the seating surfaces 80 to form a seal therebetween which prevents fluid flow between the valve outlet fluid passageway 50 and the outlet flow channel 52.

The second casing body 30b further includes integral offset rings 84 which surround each diaphragm 82 to inhibit overlying tissue from occluding the siphon control device 38 when implanted into a patient. An aperture is provided through the casing body 30b through which the outlet connector 24 extends. A fluid tight seal is effected between the casing outlet aperture and the outlet connector 24 utilizing a tube 62, an over-suture 64 and an adhesive 66 as described above in connection with the inlet casing body 30a and the inlet connector 22.

In use, the diaphragms 82 normally lie against and interact with the seating surfaces 80 of the inner wall 74 to close the devices 20 and 20' to fluid flow. The diaphragms 82 move away from the seating surfaces 80, however, in response to a minimal level of positive fluid pressure within the SCD reservoir 76 to permit passage of fluid from the valve outlet fluid passageway 50 to the outlet flow channel 52. The diaphragms 82 close and seal upon the seating surfaces 80 once again in the absence of such positive upstream fluid pressure, or in response to negative downstream hydrostatic pressure in the SCD outlet chamber 78. The siphon control device 38 thus minimizes the undesirable consequences attendant to excessive overdrainage of fluid due to the siphoning effect of hydrostatic pressure.

With reference now to FIGS. 1-14, the valve mechanism of the first illustrated embodiment of the fluid flow control device 20 will be described in detail.

As illustrated best, initially, in FIGS. 2 and 3, the valve mechanism within the valve housing 36 provides means for

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controlling fluid flow from the inlet connector 22 to the outlet connector 24 and, more particularly, from the flushing reservoir 40 to the valve outlet fluid passageway 50. The valve housing 36 includes a central threaded aperture 86 through an upper section thereof into which is threaded a flow regulator insert 88 (See FIG. 14) which defines a fluid passageway 90 therethrough. The lower end of the flow regulator insert 88 surrounding the fluid passageway 90 forms a valve seat 92 against which a valve element in the form of a ruby ball 94 seats, to control the flow of fluid through the fluid passageway 90. Of course, to accomplish this the diameter of the ruby ball 94 must be larger than the diameter of the valve seat 92.

A pressure spring 96 is disposed immediately below and in contact with the ruby ball 94, to bias the ruby ball against the valve seat 92 to keep the fluid passageway 90 closed until a fluid pressure differential between the inlet and the outlet exceeds a selected valve opening pressure. The pressure spring 96 is supported at an end opposite the ruby ball 94 by a first surface 98 of a rotor assembly 100 which will be described in greater detail below.

The fluid flow control device 20 of the present invention advantageously provides means for adjusting the amount of bias applied to the ruby ball 94 by the pressure spring 96 in order to vary the selected valve opening pressure. Such adjusting means includes a fixed dual concentric stair-step array 102 (see FIGS. 7 and 8) and an overlying rotor assembly 100 (see FIGS. 9-11). A second surface 104 of the rotor assembly 100 is supported by the dual concentric stair-step array 102, and the rotor assembly is rotatable in response to an applied magnetic field to permit magnetic induction adjustments of the valve mechanism.

The dual concentric stair-step array 102 includes a central rotor pivot 106, a plurality of inner steps 108 which surround the rotor pivot, and a corresponding plurality of outer steps 110 which extend peripherally about the inner steps. The inner and outer steps 108 and 110 are constructed so that those steps opposite to one another with respect to the central rotor pivot 106 subtend the same arch and are located at the same level. The stair-step array 102 further includes an outer ring 112 which serves to capture a portion of the rotor assembly 100 therein, a supporting bracket 114 and a lock lever pivot holder 116 which are utilized in connection with a pin actuating mechanism 118 to be described in greater detail below.

The rotor assembly 100, shown best in FIGS. 9-14, includes a magnet 120 embedded within a base 122. A rotor cap 124 is fixed to an upper surface of the base 122 over the magnet 120 to seal the magnet therebetween and to also provide the first surface 98 on which the pressure spring 96 rests. The rotor cap 124 includes a central aperture 126 surrounded by a cylindrical pressure spring-guide flange 128, and a peripheral compression spring-retaining flange 130 which is utilized to help retain a compression spring 132 in a proper position upon the first surface 98. The lower surface of the base 122 defines the second surface 104 of the rotor assembly 100. This portion of the base 122 includes an inner leg 134 which is adapted to bear against a selected one of the plurality of inner steps 108, and an outer leg 136 which is disposed diametrically opposite the inner leg and is adapted to bear against a selected one of the plurality of outer steps 110. The inner and outer legs 134 and 136 extend the same distance downwardly from the base 122. Further, a base central aperture 138 extends centrally through the base 122 and in alignment with the central aperture 126 of the rotor cap, which apertures are configured to permit passage of the central rotor pivot 106 therethrough.

When the rotor assembly 100 is assembled to the stair-step array 102 such that the inner and outer legs 134 and 136 bearing against the diametrically opposite and corresponding inner and outer steps 108 and 110 of the stair-step array, the first surface 98 of the rotor assembly 100, provided by the rotor cap 124, provides a lower seating surface for both the small pressure spring 96 and the much larger compression spring 132. As noted previously, the pressure spring urges the ruby ball 94 into engagement with the valve seat 92 to control the flow of fluid through the fluid passageway 90 of the flow regulator insert 88. The compression spring 132 bears against the rotor cap 124 at one end, and against a portion of the valve housing 36 surrounding the threaded aperture 86 so as to constantly urge the rotor assembly 100 into contact with the stair-step array 102.

The pressure applied by the pressure spring 96 to the ruby ball 92 may be adjusted by rotating the rotor assembly 100 relative to the stair-step array 102. It will be understood that by simply rotating the rotor assembly 100, the vertical height of the rotor assembly relative to the stair-step array 102 may be varied. Positioning the inner and outer legs 134 and 136 on higher inner and outer steps 108 and 110 tends to compress the pressure spring 96, thereby increasing the valve opening pressure in contrast with the positioning of the legs on lower steps.

In order to adjust the rotational position of the rotor assembly 100 relative to the stair-step array 102 when the fluid flow control device 20 is subcutaneously implanted, an external magnetic tool 140 having diametrically opposite north and south magnetic poles (see FIG. 1). When the magnetic tool 140 is placed over the valve housing 136 such that magnetic flux coupling occurs between the magnet 120 and the magnetic tool, the rotor assembly 100 will be lifted vertically upwardly away from the stair-step array 102 against the force of the compression spring 132, thereby disengaging the inner and outer legs 134 and 136 from the inner and outer steps 108 and 110. The rotor assembly 100 may then be freely rotated about the central rotor pivot 106 to place the inner and outer legs 134 and 136 on a desired corresponding pair of inner and outer steps 108 and 110 of the stair-step array 102 to provide the fluid flow control device 20, and specifically the valve mechanism, with a desired valve opening pressure. When the magnetic tool 40 is removed from proximity with the magnet 120, the magnetic flux coupling between the two is broken, thereby allowing the compression spring 132 to again force the rotor assembly 100 downwardly into contact with the stair-step array 102.

It is sometimes desirable to provide a positive locking mechanism which will make it impossible to rotate the rotor assembly 100 relative to the stair-step array 102 even in the presence of magnetic field or flux coupling between the magnet 120 and the magnetic tool 140, unless an additional "unlocking" step is performed. To accomplish this, the pin activating mechanism 118 briefly mentioned above is provided. More specifically, a pin 142 is provided which has a first blunt end designed to engage vertical slots or detents 146 provided in the base 122 of the rotor assembly 100, and a second end 148 which is configured to provide an eyelet. The valve housing 36 and the supporting bracket 114 of the stair-step array 102 cooperate to provide a slot 150 through which the pin 142 may reciprocate, and an internal cavity 152 into which an O-ring 154 is positioned. The O-ring 154 engages the pin 142 and adjacent portions of the valve housing 136 and the supporting bracket 114 to prevent fluid leakage from the flushing reservoir 40 into the valve housing 36. The detents 146 provided in the outer periphery of the

base 122 are arranged such that when any one of such detents is aligned with the first end 144 of the pin 142, the inner and outer legs 134 and 136 of the rotor assembly 100 are properly positioned over a corresponding set of inner and outer steps 108 and 110 of the stair-step array. When the pin 142 extends sufficiently through the slot 150 so that the first end thereof 144 extends into one of the detents 146, the rotor assembly 100 cannot rotate relative to the stair-step array 102.

To control the position of the pin 142, a lever assembly 156 is provided which includes a cylindrical pivot 158, an eyelet-engaging shaft 160 which extends from the pivot 158 to engage the second end 148 of the pin 142, a lock-paddle lever 162 which extends from the pivot 158 into the flushing reservoir 40, and a biasing lever 164 which extends from a portion of the lock-paddle lever angularly downwardly to engage the bottom plate 46 underlying the flushing reservoir. The biasing lever 164 effectively causes the lever assembly to be normally pivoted such that the pin 142 is urged through the slot 150 into engagement with a selected one of the detents 146. However, the pin 142 can be withdrawn through the slot 150 by pressing downwardly on the dome 60 overlying the flushing reservoir 40 so as to also press downwardly on the lock-paddle lever 162, thus overcoming the force of the biasing lever 164. When the lock-paddle lever 162 is pressed downwardly, the lever assembly 156 pivots so that the shaft 160 pulls on the second end 148 of the pin 142 to withdraw the pin partially through the slot 150 a sufficient distance to disengage the first end 144 of the pin from an adjacent detent 146. Of course, when the downward pressure on the lock-paddle lever 162 is removed, the biasing lever 164 automatically pivots the lever assembly 156 to once again cause the first end 144 of the pin 142 to seek to engage a selected detent 146.

Accordingly, once the fluid flow control device 20 has been properly subcutaneously implanted, the valve opening pressure of the valve mechanism can be adjusted utilizing a two-step procedure. First, percutaneous pressure must be applied to the dome 60 sufficiently to press the lock-paddle lever 162 downwardly so as to pivot the lever assembly in a manner causing the first end 144 of the pin 142 to disengage an adjacent detent 146 in the periphery of the base 122 of the rotor assembly 100 (see FIGS. 5 and 6). Next, the external magnetic tool 140 is brought into close proximity with the magnet 120 embedded within the base 122 to permit the rotational position of the rotor assembly 100 to be varied, as desired, relative to the stair-step array 102, through magnetic induction coupling between the external magnetic tool 140 and the magnet 120. When the rotor assembly 100 is properly positioned relative to the stair-step array 102, the percutaneous pressure applied to the dome 60 is removed, thus permitting the biasing lever 164 to urge the lever assembly 156 in a direction causing the first end 144 of the pin 142 to seek to engage an adjacent one of the detents 146 (see FIG. 4). With the pin 142 so positioned, the rotor 100 is incapable of rotating relative to the stair-step array 102, regardless of the presence or absence of the magnetic tool 140 in proximity with the magnet 120. When the magnetic tool 140 is removed from the vicinity of the magnet 120, the compression spring 132 urges the rotor assembly 100 downwardly into positive contact with the stair-step array, thus ensuring proper performance of the fluid flow control device.

FIGS. 15-18 illustrate an alternative embodiment of the fluid flow control device 20', wherein functional equivalent elements of the device 20' similar to those described above in connection with the fluid flow control device 20 having