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ESCOBAR - URIBE ASOCIADOS

ABOGADOS

Carrera 11A No. 94-76 Of. 305 - P.O. Box 94948, Bogotá, Colombia, S.A.
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2579/P

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISION DE NUEVAS CREACIONES

E. S. D.

SUPERINDUSTRIA Y COMERCIO

Radicación: 03058351 00000003

Folios: 77

Fecha (AMD): 2003-11-06 14:12:44

Trámite: 002 PATENTES D 1 REGISTRA/ 329 COMPLEMEN

Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Ref.: Expediente No. 03.058.351
Solicitud de Patente a nombre de
Codman & Shurtleff, Inc.

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 A No. 94-76, of. 305-306, obrando como apoderada de la sociedad Codman & Shurtleff, Inc, domiciliada en Raynham, Massachussets, Estados Unidos de América, solicitante de la patente de la referencia, me permito presentar los siguientes documentos:

1. Documento de cesión suscrito por los inventores a favor de mi mandante.

Sobre el particular, es importante anotar que de conformidad con las normas legales vigentes, artículo 1 de la Resolución 210 de 2001, expedida por el Superintendente de Industria y Comercio y artículo 2 de la Convención de la Haya, los documentos en inglés que se pretendan aportar como parte de los trámites de propiedad industrial ante la Superintendencia de Industria y Comercio no requieren traducción. Por otro lado, la legalización consular y/o diplomática de los documentos expedidos en el extranjero no es necesaria. Por lo tanto, el documento de cesión anexo a este memorial es válidamente presentado en idioma inglés y con la correspondiente Apostilla.

2. Dibujos formales (los cuales fueron anunciados en el capítulo descriptivo) de acuerdo con lo establecido en el artículo 4-d del Decreto 117 de 1994.
3. Artes finales en tamaño 12 x 12 centímetros (por duplicado) y una copia tamaño 6 x 6 centímetros de la figura característica.

4. Copia certificada de la solicitud de Patente número 10/192,394 presentada en los Estados Unidos de América el día 10 de julio de 2002, con la debida traducción de lo pertinente, incluyendo el capítulo reivindicatorio.

Señor Superintendente,


JIMENA ESCOBAR URIBE
C.C.39.779.452 de Usaquén
T.P. 68228
Cód. 5376

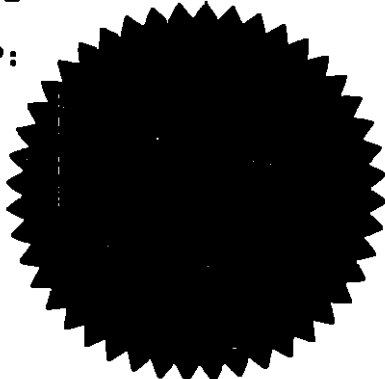
APOSTILLE

(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961)

1. COUNTRY: UNITED STATES OF AMERICA
2. THIS PUBLIC DOCUMENT HAS BEEN SIGNED BY:
CHRISTINA A CLICKNER
3. ACTING IN THE CAPACITY OF:
NOTARY PUBLIC OF NEW JERSEY
4. BEARS THE SEAL/STAMP OF:
CHRISTINA A CLICKNER, NOTARY

CERTIFIED

5. AT TRENTON, NEW JERSEY
6. THE 22ND DAY OF JULY 2003
7. BY: John E McCormac, CPA, NEW JERSEY TREASURER
8. NO. A177352
9. SEAL/STAMP:
10. SIGNATURE



Handwritten signature of John E McCormac.

55 ✓
COD 146 COL(L)

CERTIFICATION

I hereby certify that I have compared the attached document with the original, and that such said document is a true copy of the original Assignment document as filed and recorded in the U.S. Patent Office in connection with USSN 10/192,394 filed JULY 10, 2002.



**Christina A. Clickner
(Notary Public of New Jersey)
My Commission Expires:
March 2, 2005**

SEPTEMBER 19, 2002

PTAS

Under Secretary of Commerce For Intellectual Property and
Director of the United States Patent and Trademark Office
Washington, DC 20231
www.uspto.gov

NUTTER MCLENNEN & FISH LLP
WILLIAM C. GEARY III
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2699



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PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 07/10/2002

REEL/FRAME: 013098/0858
NUMBER OF PAGES: 4

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS).

ASSIGNOR:
MCCUSKER, DANIEL

DOC DATE: 07/09/2002

ASSIGNOR:
DEXTRADEUR, ALAN

DOC DATE: 07/09/2002

ASSIGNOR:
GUPTA, RAINUKA

DOC DATE: 07/09/2002

ASSIGNEE:
CODMAN & SHURTLEFF, INC.
325 PARAMOUNT DRIVE
RAYNHAM, MASSACHUSETTS 02767-0350

SERIAL NUMBER: 10192394
PATENT NUMBER:

FILING DATE: 07/10/2002
ISSUE DATE:

10/192394

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013098/0858 PAGE 2

SAUNDRA BALLENGER, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

07-23-2002



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 JC971 U.S. PTO
 10/192394
 07/16/82

Form PTO-1595 (Rev. 03/01) OMB No. 0551-0027 (exp. 5/31/2002)	RECORDATION FORM COVER SHEET PATENTS ONLY	U.S. DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office
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To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof

1. Name of conveying party(ies): Daniel McCusker, Alan Dextreleur and Rainuka Gupta Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No	2. Name and address of receiving party(ies) Name: <u>CODMAN & SHURTLEFF, INC.</u> Internal Address: _____ Street Address: <u>326 Paramount Drive</u> City: <u>Raynham</u> State: <u>MA</u> Zip: <u>02767-0350</u> Additional name(s) & address(es) attached: ☐ Yes ☒ No
3. Nature of Conveyance: ☒ Assignment ☐ Merger ☐ Security Agreement ☐ Change of Name ☐ Other _____ Execution Date: _____	

4. Application number(s) or patent number(s): If this document is being filed together with a new application, the execution date of the new application is: <u>July 10, 2002</u>	
A. Patent Application No.(s): <u>10/192394</u> Additional numbers attached? ☐ Yes ☒ No	B. Patent No.(s): _____

5. Name and address of party to whom correspondence concerning document should be mailed: Name: <u>William C. Geary III</u> <u>NUTTER MCCLENNEN & FISH LLP</u> Internal Address: <u>Atty. Dkt.: 022719-0032</u> Street Address: <u>One International Place</u> City: <u>Boston</u> State: <u>MA</u> Zip: <u>02110-2699</u>	6. Total number of applications and patents involved: <u>1</u> 7. Total fee (37 CFR 3.41) \$ <u>40.00</u> ☒ Enclosed ☐ Authorized to be charged to deposit account ☐ Authorized to be charged to credit card (Form 2036 enclosed) 8. Deposit account number: <u>141449</u> (Attach duplicate copy of this page if paying by deposit account)
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9. Statement and signature. To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.	
William C. Geary III 00000052 Person Signing	Signature: <u>[Signature]</u> Date: <u>July 10, 2002</u>
Total # of pages including cover sheet, attachments, and documents: <u>4</u>	

Recordation Form Cover Sheet	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: U.S. Patent and Trademark Office, Office of Public Records, Crystal Gateway 4, Arlington, VA 22202, on the date shown below.	
Dated: July 10, 2002	Signature: <u>[Signature]</u> (William C. Geary III)

 2002 BYTBE
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ASSIGNMENT

We, Daniel McCusker, of Bridgewater, Massachusetts, Alan J. Dextrateur, of Franklin, Massachusetts, and Rainuka Gupta, of Cambridge, Massachusetts, in consideration of One Dollar and other valuable consideration paid to us by

CODMAN & SHURTLEFF, INC.

a New Jersey corporation having a place of business at 325 Paramount Drive, Raynham, Massachusetts 02767-0350, the receipt of which is hereby acknowledged, do hereby sell, assign and transfer unto said

CODMAN & SHURTLEFF, INC.

its successors and assigns, the entire interest for the United States of America and all foreign countries including all rights of priority under the International Convention for the Protection of Industrial Property in a certain invention or improvement in

SHUNT VALVE LOCKING MECHANISM

described in an application

X executed by me on even date herewith and about to be filed

in the United States Patent and Trademark Office, and in all Letters Patent of the United States and all foreign countries which may or shall be granted on said invention, or any parts thereof, or on said application, or any divisional, continuing, reissue or other applications based in whole or in part thereon. And we agree, for ourselves and our executors and administrators, with said corporation and its successors and assigns but at its or their expense and charges, hereafter to execute all applications, amended specifications, deed or other instrument, and to do all acts necessary or proper to secure the grant of Letters Patent in the United States and in all other countries to said corporation, with specifications and claims in such form as shall be approved by the counsel of said corporation and to vest and confirm in said corporation, its successors and assigns, the legal title to all such patents.

And we do hereby authorize and request the Commissioner of Patents and Trademarks of the United States to issue such Letters Patent as shall be granted upon said application or applications based thereon to said corporation, its successors and assigns.

09

WITNESS my hand and seal this 9th day of July, 2002.

By: Daniel McCusker
Daniel McCusker

Then personally appeared the above named Daniel McCusker and acknowledged the foregoing instrument to be her free act and deed, before me, this 9th day of July, 2002.

[SEAL]

Maria C. Furtado
Notary Public

My commission expires: 10-11-07

WITNESS my hand and seal this 9 day of July, 2002.

By: Alan J. Dextradeur
Alan J. Dextradeur

Then personally appeared the above named Alan J. Dextradeur and acknowledged the foregoing instrument to be her free act and deed, before me, this 9th day of July, 2002.

[SEAL]

Maria C. Furtado
Notary Public

My commission expires: 10-11-07

61 15

WITNESS my hand and seal this 9 day of July, 2002.

By: Rainuka Gupta
Rainuka Gupta

Then personally appeared the above named Rainuka Gupta and acknowledged the foregoing instrument to be her free act and deed, before me, this 9th day of July, 2002.

[SEAL]

[Signature]
Notary Public

My commission expires: 10-11-07

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BOGOTA D.C. AGOSTO 20, 2003

TRADUCCIÓN POR TRADUCTOR OFICIAL FOTOCOPIA CERTIFICADO

ESTADOS UNIDOS DE AMERICA

A QUIEN CONOZCA DE ESTE DOCUMENTO

DEPARTAMENTO DE COMERCIO DE ESTADOS UNIDOS

Oficina de Patentes y Marca Registrada

Julio 17, 2003

CON EL PRESENTE SE CERTIFICA QUE EN DOCUMENTO ANEXO AQUÍ ES FIEL COPIA DE LOS REGISTROS DE LA OFICINA DE PATENTES Y MARCA REGISTRADA DE ESOS DOCUMENTOS DE LA SOLICITUD DE PATENTE IDENTIFICADA ADELANTE QUE CUMPLIERON CON LOS REQUERIMIENTOS PARA OTORGARLES UNA FECHA DE RADICACIÓN BAJO 35 USC 111.

NUMERO DE SOLICITUD: 10/192,394
FECHA DE RADICACIÓN: JULIO 10, 2002

Por Autoridad de
COMISIONADO DE PATENTES Y MARCAS REGISTRADAS

(HAY FIRMA)
L. EDELEN
Oficial Certificador

Fidel Murcia
FIDEL ANTONIO MURCIA MURCIA
Traductor e Interprete Oficial
Resolución Nr. 488/94 Ministerio de Justicia



REIVINDICACIONES

1. Un sistema de válvula de derivación, que comprende:

un alojamiento que tiene dentro del mismo una cámara que incluye una abertura de admisión para recibir fluido, una abertura de salida para liberación de fluido, y un mecanismo de válvula que incluye un conjunto rotor para regular el flujo de fluido a través del mismo, cuando un diferencial de presión de fluido entre la abertura de admisión y la abertura de salida excede una presión de abertura de válvula seleccionada; y

un conjunto de fijación selectivamente acoplable para evitar rotación del conjunto rotor, teniendo el conjunto de fijación al menos un brazo de agarre que tiene al menos una superficie de contacto que es adecuada para acoplar friccionalmente el conjunto rotor para mantener de manera selectiva el conjunto rotor en una posición deseada.

2. El sistema de la reivindicación 1, en donde el conjunto rotor incluye adicionalmente una pared exterior, al menos una superficie de contacto de al menos un brazo de agarre que es adecuado para entrar en acción friccionalmente con la pared exterior del conjunto rotor.

contacto de al menos un brazo de agarre siendo adecuada para acoplarse friccionalmente con la pared interior del conjunto rotor.

4. El sistema de la reivindicación 1, en donde el conjunto de fijación
5 incluye adicionalmente un mecanismo de accionamiento para liberar y desplegar el al menos un brazo de agarre.
5. El sistema de la reivindicación 4, en donde el mecanismo de accionamiento comprende una membrana deformable
10 DISPUESTA sobre el alojamiento que está configurado para transferir una fuerza aplicada a la membrana deformable a través del alojamiento y a al menos un brazo de agarre suficiente para mover el al menos un brazo de agarre entre un primer estado en el cual el al menos un brazo de agarre acopla principalmente el conjunto rotor y
15 un segundo estado en el cual el al menos un brazo de agarre es desacoplado desde el conjunto rotor.
6. El sistema de la reivindicación 5, en donde la membrana deformable está formada a partir de un material elastomérico seleccionado entre
20 el grupo formado por un elastómero de silicona, poliuretano, nylon, y sus combinaciones.
7. El sistema de la reivindicación 5, en donde la membrana deformable

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8. El sistema de la reivindicación 7, en donde el material de memoria de forma incluido en el mecanismo de accionamiento es un alambre resortado embebido dentro de la membrana deformable.
- 5 9. El sistema de la reivindicación 1, en donde el mecanismo de fijación contiene brazos de agarre opuestos, bilaterales.
- 10.El sistema de la reivindicación 1, en donde el mecanismo de fijación contiene al menos un brazo de agarre formado como una vejiga inflable.
- 10 11.El sistema de la reivindicación 2, en donde la pared exterior del conjunto rotor contiene características superficiales que aumentan la fricción seleccionadas entre el grupo formado por acanaladuras, retenes, nervaduras, corrugaciones, superficies con asperezas y combinaciones de las mismas.
- 15 12.El sistema de la reivindicación 3, en donde la pared interior del conjunto rotor contiene características superficiales que incrementan la fricción seleccionadas entre el grupo formado por acanaladuras, retenes, nervaduras, corrugaciones, superficies con asperezas y combinaciones de las mismas.
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superficiales que incrementan la fricción seleccionadas entre el grupo formado por acanaladuras, retenes, nervaduras, corrugaciones, superficies con asperezas y combinaciones de las mismas.

- 5 14. Un conjunto de fijación para impedir rotación de un conjunto rotor de un sistema de válvulas de derivación, comprendiendo el conjunto de fijación:
- 10 al menos un brazo de agarre para acoplar friccionalmente el conjunto rotor, teniendo el al menos un brazo de agarre por lo menos una superficie que entra en contacto con el rotor, y
- 15 un mecanismo de accionamiento articulado mecánicamente al brazo de agarre en donde el mecanismo de accionamiento es efectivo para mover el al menos un brazo de agarre entre una posición trabada en la cual el al menos un brazo de agarre acopla friccionalmente el conjunto rotor y una posición destrabada en la cual el al menos un brazo de agarre es desacoplado del conjunto rotor.
- 20 15. El sistema de la reivindicación 14, en el cual el conjunto rotor incluye adicionalmente una pared exterior, al menos una superficie de contacto de al menos un brazo de agarre que es adecuado para entrar en acción friccionalmente con la pared exterior del conjunto rotor.

- 16.El sistema de la reivindicación 14, en donde el conjunto rotor incluye adicionalmente una pared interior, la al menos una superficie de contacto de giro de al menos un brazo de agarre siendo adecuada para acoplarse friccionalmente con la pared interior del conjunto rotor.
- 5 17.El conjunto de fijación de la reivindicación 14, en donde el mecanismo de accionamiento comprende una membrana deformable configurada para transferir una fuerza aplicada a la membrana deformable a al menos un brazo de agarre suficiente para mover el al menos un brazo de agarre entre la posición entrabada y la posición no entrabada.
- 10 18.El conjunto de fijación de la reivindicación 17, en donde la membrana deformable del mecanismo de accionamiento incluye un material de memoria de forma.
- 15 19.El conjunto de fijación de la reivindicación 18, en donde el material de memoria de forma incluido en el mecanismo de accionamiento es un alambre resortado embebido dentro de la membrana deformable.
- 20 20.El conjunto de fijación de la reivindicación 14, que contiene adicionalmente brazos de agarre opuestos, bilaterales.
- 21.El conjunto de fijación de la reivindicación 14, que contiene

22. El 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 flujo de fluido a través del mismo, comprendiendo el conjunto de fijación:

5 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

10 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

15 segunda a las otras de la primera o la segunda posiciones.

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PA 2848206

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

July 17, 2003

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 10/192,394

FILING DATE: July 10, 2002

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS



L. Edelen

L. EDELEN
Certifying Officer

101.92374 .071002
07-11-02
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11054 U.S. PTO
07/10/02

Please type a plus sign (+) inside this box: ☒ Approved for use through 10/31/2002. OMB 0881-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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UTILITY PATENT APPLICATION TRANSMITTAL (Only for new nonprovisional applications under 37 CFR 1.63(d))	
Attorney Docket No.	022719-0032
First Inventor	Daniel McCusker
Title	SHUNT VALVE LOCKING MECHANISM
Express Mail Label No.	EV079189623

APPLICATION ELEMENTS See MPEP chapter 600 concerning utility patent application contents	ADDRESS TO: Box Patent Application Commissioner for Patents Washington, DC 20231
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1. ☒ Fee Transmittal Form (e.g., PTO/88/17) (Submit an original, and a duplicate for fee processing)	7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
2. ☐ Applicant claims small entity status. See 37 CFR 1.27.	8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
3. ☒ Specification [Total Pages: 25] (preferred arrangement set forth below) - Description of the invention - Cross Reference to Related Applications - Statement Regarding Prior art sponsored R & D - Reference to sequence listing, a table, or a computer program listing appendix - Background of the invention - Brief Summary of the invention - Brief Description of the Drawings (if filed) - Detailed Description - Claims - Abstract of the Disclosure	a. ☐ Computer Readable Form (CRF)
4. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets: 7]	b. Specification Sequence Listing on ☐ CD-ROM or CD-R (2 copies); or ☐ paper
5. Oath or Declaration [Total Pages: 5] a. ☒ Newly executed Declaration Power of Attorney b. ☐ Copy from a prior application (37 CFR 1.63(d)) (for continuation/divisional with Box 18 completed) c. ☐ DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.53(b)	c. ☐ Statements verifying identity of above copies
6. ☒ Application Data Sheet See 37 CFR 1.76	

ACCOMPANYING APPLICATIONS PARTS	
9. ☒ Assignment Papers (cover sheet & document(s))	
10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney (when there is an assignee)	
11. ☐ English Translation Document (if applicable)	
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations	
13. ☐ Preliminary Amendment	
14. ☒ Return Receipt Postcard (MPEP 603) (Should be specifically itemized)	
15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)	
16. ☐ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i) Applicant must attach form PTO/SB/35 or its equivalent.	
17. ☒ Other	Check in the amount of \$778.00; and Return Postcard

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No. _____

Prior application information: Examiner _____ Group / Art Unit _____

For CONTINUATION or DIVISIONAL APPS only. The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5a, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS					
☒ Customer Number or Bar Code Label		021125		or ☐ Correspondence address below	
Name	NUTTER MCCLENNEN & FISH LLP William C. Geary III				
Address	One International Place				
City	Boston	State	MA	Zip Code	02110-2899
Country	US	Telephone	(617) 439-2000	Fax	(617) 310-9000
Name (Print/Type)	William C. Geary III		Registration No. (Attorney/Agent)	31,359	
Signature			Date	July 10, 2002	

Transmitted-New Utility Patent Application	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV079189623, in an envelope addressed to: Box Patent Application Commissioner for Patents, Washington, DC 20231, on the date shown below.	
Dated: July 10, 2002	Signature: (William C. Geary III)

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)		Application Number	Not Yet Assigned
		Filing Date	July 10, 2002
		First Named Inventor	Daniel McCusker
		Group Art Unit	N/A
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission		Attorney Docket Number	022718-0032

ENCLOSURES (check all that apply)		
☒ Fee Transmittal Form ☒ Fee Attached ☐ Amendment/Reply ☐ After Final ☐ Affidavit/declaration(s) ☐ Extension of Time Request ☐ Express Abandonment Request ☐ Information Disclosure Statement ☐ Certified Copy of Priority Document(s) ☐ Response to Missing Parts/Incomplete Application ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53	☒ Assignment Papers (for an Application) ☐ Drawing(s) ☐ Licensing-related Papers ☐ Petition ☐ Petition to Convert to a Provisional Application ☐ Power of Attorney, Revocation Change of Correspondence Address ☐ Terminal Disclaimer ☐ Request for Refund ☐ CD, Number of CD(s) _____	☐ After Allowance Communication to Group ☐ Appeal Communication to Board of Appeals and Interferences ☐ Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) ☐ Proprietary Information ☐ Status Letter ☒ Other Enclosure(s) (please identify below) Check in the amount of \$40.00 Return Postcard
Remarks: _____		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual Name	NUTTER MCLENNEN & FISH LLP William C. Geary III
Signature	
Date	July 10, 2002

Transmitted	
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Date: July 10, 2002	Signature:  (William C. Geary III)

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**FEE TRANSMITTAL
for FY 2002**

Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT (\$)** 40.00**Complete If Known**

Application Number	Not Yet Assigned
Filing Date	July 10, 2002
First Named Inventor	Daniel McCusker
Examiner Name	Not Yet Assigned
Group Art Unit	N/A
Attorney Docket No.	022719-0032

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None☐ Deposit AccountDeposit
Account
Number

141448

Deposit
Account
Name

Nutter McClennen & Fish LLP

The Commissioner is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☒ Credit any overpayments☐ Charge any additional fee(s) during the pendency of the application☐ Charge fee(s) indicated below, except for the filing fee

to the above-identified deposit account.

FEE CALCULATION**1. BASIC FILING FEE**

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
101 740	281 370	Utility filing fee	
108 330	208 185	Design filing fee	
107 510	287 285	Plant filing fee	
108 740	208 370	Release filing fee	
114 180	214 80	Provisional filing fee	

SUBTOTAL (1) (\$) 0.00**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

Total Claims	Extra Claims	Fee from Extra Claims	Fee Paid
Independent Claims			
Multiple Dependent			

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
103 18	203 0	Claims in excess of 20	
102 84	202 42	Independent claims in excess of 3	
104 280	204 140	Multiple dependent claims, if not paid	
108 84	208 42	** Release independent claims over original patent	
110 18	210 0	** Release claims in excess of 20 and over original patent	

SUBTOTAL (2) (\$) 0.00

**or number previously paid, if greater; For Release, see above

FEE CALCULATION (continued)**3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
105 130	205 85			Surcharge - late filing fee or oath	
127 80	227 25			Surcharge - late provisional filing fee or cover sheet	
130 130	130 130			Non-English specification	
147 2,520	147 2,520			For filing a request for or posts reexamination	
112 820*	112 820*			Requesting publication of BIR prior to Examiner action	
113 1,840*	113 1,840*			Requesting publication of BIR after Examiner action	
116 110	216 85			Extension for reply within first month	
118 400	218 200			Extension for reply within second month	
117 820	217 480			Extension for reply within third month	
118 1,440	218 720			Extension for reply within fourth month	
125 1,880	225 880			Extension for reply within fifth month	
119 320	219 180			Notice of Appeal	
120 320	220 180			Filing a brief in support of an appeal	
121 280	221 140			Request for oral hearing	
138 1,510	138 1,510			Petition to institute a public use proceeding	
140 110	240 85			Petition to revive - unavoidable	
141 1,285	241 840			Petition to revive - unintentional	
142 1,380	242 840			Utility issue fee (for release)	
143 480	243 230			Design issue fee	
144 620	244 210			Plant issue fee	
122 130	122 130			Petitions to the Commissioner	
123 80	123 80			Processing fee under 37 CFR 1.17(c)	
128 180	128 180			Submission of Information Disclosure Sheet	
501 40	501 40			Recording each patent assignment per property (series number of properties)	40.00
145 740	245 370			Filing a submission after final rejection (37 CFR 1.128(a))	
146 740	246 370			For each additional invention to be examined (37 CFR 1.128(b))	
179 740	279 370			Request for Continued Examination (RCE)	
180 920	180 920			Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 40.00**SUBMITTED BY**

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July 10, 2002

Fee Transmittal

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: U.S. Patent and Trademark Office, Office of Public Records, Crystal Gateway 4, Arlington, VA 22202, on the date shown below.

Dated: July 10, 2002

Signature:

(William C. Geary III)

Application Data Sheet**Application Information**

Application number::	Not Yet Assigned
Application Type::	Regular
Subject Matter::	Utility
Suggested Group Art Unit::	N/A
CD-ROM or CD-R?::	None
Sequence submission?::	Paper
Computer Readable Form (CRF)?::	No
Title::	SHUNT VALVE LOCKING MECHANISM
Attorney Docket Number::	022719-0032
Request for Early Publication?::	No
Request for Non-Publication?::	No
Small Entity?::	No
Petition Included?::	No
Secrecy Order In Parent Appl.?::	No

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APPLICATION
FOR
UNITED STATES PATENT

SHUNT VALVE LOCKING MECHANISM

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EXPRESS MAIL NO.: EV079189623US

SHUNT VALVE LOCKING MECHANISM

CROSS-REFERENCE TO RELATED APPLICATIONS

Not applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

5 Not applicable

FIELD OF THE INVENTION

The present invention relates generally to medical devices for directing bodily fluids from one region of a patient to another region. More specifically, this invention relates to shunt systems having an adjustable shunt valve to control the flow of fluid through the system and, even more specifically, a locking mechanism to control the adjustment of the shunt valve.

BACKGROUND OF THE INVENTION

Hydrocephalus is a neurological condition caused by the abnormal accumulation of cerebrospinal fluid (CSF) within the ventricles, or cavities, of the brain. Hydrocephalus, which can affect infants, children and adults, arises when the normal drainage of CSF in the brain is blocked in some way. Such blockage can be caused by a number of factors, including, for example, genetic predisposition, intraventricular or intracranial hemorrhage, infections such as meningitis, or head trauma. Blockage of the flow of CSF consequently creates an imbalance between the rate at which CSF is produced by the ventricular system and the rate at which CSF is absorbed into the bloodstream. This imbalance increases pressure on the brain and causes the ventricles to enlarge. Left untreated, hydrocephalus can result in serious medical conditions, including subdural hematoma, compression of the brain tissue, and impaired blood flow.

Hydrocephalus is most often treated by surgically inserting a shunt system to divert the flow of CSF from the ventricle to another area of the body, such as the right atrium, the peritoneum, or other locations in the body where CSF can be absorbed as part of the circulatory system. Various shunt systems have been developed for the treatment of hydrocephalus. Typically, shunt systems include a ventricular catheter, a shunt valve and a drainage catheter. At

one end of the shunt system, the ventricular catheter can have a first end that is inserted through a hole in the skull of a patient, such that the first end resides within the ventricle of a patient, and a second end of the ventricular catheter that is typically coupled to the inlet portion of the shunt valve. The first end of the ventricular catheter can contain multiple holes or pores to allow CSF to enter the shunt system. At the other end of the shunt system, the drainage catheter has a first end that is attached to the outlet portion of the shunt valve and a second end that is configured to allow CSF to exit the shunt system for reabsorption into the bloodstream.

Generally, the shunt valve, which can have a variety of configurations, is effective to regulate the flow rate of fluid through the shunt system. In some shunt valve mechanisms, the fluid flow rate can be proportional to the pressure difference at the valve mechanism. These shunt valve mechanisms permit fluid flow only after the fluid pressure has reached a certain threshold level. Thus, when the fluid pressure is slightly greater than the threshold pressure level, the fluid flow rate is relatively low, but as the pressure increases, the fluid flow rate simultaneously increases. Typically, the shunt valve will allow fluid to flow normally until the intracranial pressure has been reduced to a level that is less than the threshold pressure of the shunt valve, subject to any hysteresis of the device.

Shunt valves can be designed to allow adjustment of the threshold pressure level at which fluid flow will commence. It is generally preferred to allow external adjustment of the pressure threshold to avoid invasive surgical procedures. In some shunt systems, the shunt valve contains a magnetized rotor to control the pressure threshold of the valve. Physicians can then use an external adjustment mechanism, such as a magnetic programmer, to adjust the pressure threshold of the shunt valve. However, these magnetized rotors can be unintentionally adjusted in the presence of a strong external magnetic field, such as during an MRI procedure. Unintentional adjustment of the pressure threshold could lead to either the overdrainage or underdrainage of CSF, which can result in dangerous conditions, such as subdural hematoma.

Attempts have been made to provide a locking mechanism that prevents unintentional valve adjustment, even in the presence of a strong external magnetic field, while simultaneously allowing intentional adjustment of the pressure threshold. One such approach has been detailed in U.S. Patent No. 5,643,194, in which Negre discloses a locking means having two opposed

micro-magnets mounted on the rotor. In the presence of a bi-directional magnetic field, these micro-magnets move linearly in the rotor, in a substantially radial direction, to activate the locking means. However, the Negre locking means does not eliminate the risk of inadvertent valve adjustment in the presence of a strong external magnetic field.

5 Another approach has been described in U.S. Patent No. 5,637,083, in which Bertrand *et al.* disclose a valve that includes means for locking the rotor assembly in a desired position. This locking means uses a pin having a first end adapted to engage a series of detents in an outer peripheral surface of the rotor assembly, thereby preventing the rotor assembly from rotating. The locking means is disengaged by a pin-actuating means having two levers that move the pin
10 from a first, extended position, *i.e.*, within the detent(s) in the outer peripheral surface, to a second, retracted position. The first lever is a pivotable lever having a shaft adapted to engage a second end of the pin, while the second lever is a manually actuated lever that is biased to urge the pin into the first, extended position. This manually actuated lever, however, is located within the valve chamber that is used to pump, or flush, fluid from the shunt valve. Thus, by virtue of
15 its location within the pumping chamber, the manually actuated lever, and consequently the pin-actuating means, can impair or inhibit the function of the pumping chamber.

Accordingly, there exists a need for a shunt valve having an improved locking mechanism that simply and effectively prevents unintentional adjustment of the valve pressure threshold, yet still allows simple, non-invasive adjustment of the pressure threshold of the valve.
20 There is also a need for a locking mechanism that does not compromise or inhibit normal operation of the shunt valve. Furthermore, there exists a need for a locking mechanism that has been designed to allow a physician to easily determine the location of the locking mechanism. Finally, there exists a need for a locking mechanism that has little or no artifact, or extraneous signal, during various radiological imaging techniques, including X-Ray or MRI, and therefore,
25 will not interfere with, or compromise necessary medical procedures.

SUMMARY OF THE INVENTION

The present invention overcomes the disadvantages that are inherent in prior art fluid management systems by providing a locking assembly that simply and effectively prevents any

unintentional adjustment of an adjustable valve mechanism in a fluid flow control device, without compromising the function of the fluid flow control device. The locking assembly of the present invention 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 at least one gripping arm. The locking assembly prevents unintentional adjustments that can adversely affect the pressure settings of the fluid flow controlling medical device. In particular, the locking assembly prevents unintentional adjustment in the presence of a strong external magnetic field, such as for example, the strong unidirectional magnetic field in an MRI procedure. The provided locking assembly allows a clinician to easily disengage the locking assembly, such as through the application or removal of an external mechanical force, thereby allowing the clinician to adjust the pressure settings of the fluid flow control device as necessary.

Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the drawings and the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a perspective view illustrating the housing with the locking assembly according to one embodiment of the present invention;

FIG. 1B is a perspective view illustrating the valve mechanism according to one embodiment of the present invention;

FIG. 2 is a perspective view illustrating the valve mechanism of FIG. 1B with the housing of FIG. 1A according to one embodiment of the present invention;

FIG. 3A is a cross-sectional view through lines A – A of the locking assembly of FIG. 2 in an engaged state according to one embodiment of the present invention;

FIG. 3B is a cross-sectional view through lines A – A of the locking assembly of FIG. 2 in a disengaged state according to one embodiment of the present invention;

FIG. 4 is an unassembled perspective view illustrating a locking assembly according to another embodiment of the present invention;

FIG. 5A is a cut-away view of the locking assembly of FIG. 4 in a disengaged state according to another embodiment of the present invention; and

5 FIG. 5B is a cut-away view of the locking assembly of FIG. 4 in an engaged state according to another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION.

The locking assembly of the present invention stably maintains an adjustable valve mechanism of an adjustable fluid flow control device in a desired position, thereby preventing
10 any unintentional adjustments of the fluid flow control device. Generally, the locking assembly of the present invention includes at least one gripping arm that is operatively joined to an actuating mechanism and can control the deployment and release of the at least one gripping arm. The locking assembly prevents unintentional adjustments that can adversely affect the pressure settings of the fluid flow controlling medical device. In particular, the locking assembly
15 prevents unintentional adjustment in the presence of a strong external magnetic field, such as for example, the strong unidirectional magnetic field encountered in an MRI procedure. The locking assembly can be easily disengaged, through the application or removal of an external mechanical force, thereby allowing a clinician to adjust the pressure settings of the fluid flow control device.

In a first embodiment, shown in FIGS. 1A-3B, the locking assembly of the present
20 invention can be used in conjunction with a shunt valve system, such as the shunt valve system 10 illustrated in FIG. 2. The locking assembly of the present invention can be used with a variety of shunt valve systems designed to drain excess fluid from one area of the body and direct it to another site in a patient's body. An exemplary shunt valve system for use with the locking assembly of the present invention is a shunt valve system used in a shunt system
25 designed to treat hydrocephalus. In a hydrocephalus shunt system, the shunt valve system 10 is attached to a ventricular catheter (not shown), which is placed within a ventricle of a patient's brain, and a drainage catheter (not shown), which is placed within another area of the patient's

body, such as for example, the right atrium of the heart or the peritoneum, where the cerebrospinal fluid (CSF) can be absorbed into the patient's bloodstream. The shunt valve system 10, therefore, controls the flow of excess CSF from the ventricle of the brain to another area of the patient's body.

5 As shown in FIG. 1A, the shunt valve system 10 used in conjunction with the locking assembly of this first embodiment includes a housing 12 having an outer surface 14 that contacts the target site of implantation and an inner surface 16 that defines a chamber 18. The chamber 18 is adapted to allow fluid to flow through the shunt valve system 10. The chamber 18 of the shunt valve system 10 includes an inlet port (not shown) for receiving fluid into the shunt valve system 10, and an outlet port (not shown) for releasing fluid from the shunt valve system 10. In a typical hydrocephalus shunt system, the inlet port is in fluid communication with the ventricular catheter, while the outlet port is in fluid communication with the drainage catheter.

15 Referring now to FIG. 1A, the distance between the outer surface 14 and the inner surface 16 defines a thickness of the housing 12. This thickness can vary, but preferably, the thickness of the housing 12 is in the range of about 0.5 to 1.0 mm. The housing 12 of the shunt valve system 10 also includes a first end 20, a second end 22, and a length extending therebetween. The length of the housing 12 can vary, but preferably, the length of the housing 12 is determined according to the dimensions of the target site of implantation. More preferably, the housing 12 has a length in the range of about 2.5 to 5.0 cm.

20 The housing 12 of the shunt valve system 10 can have virtually any geometry, but preferably, the housing 12 has a generally rectangular shape, as illustrated in FIG. 1A. In this embodiment, the housing 12 includes a top surface 24, a bottom surface 26, and opposed side surfaces 28, 30, as seen in FIG. 1A. The distance between the top surface 24 and bottom surface 26 defines a height H_1 of the housing 12, which can vary, but is preferably in the range of about 4.5 to 6.0 mm. Similarly, the distance between the opposed side surfaces 28, 30 defines a width of the housing 12. This width can vary, but preferably, the width of the housing 12 is in the range of about 7.0 to 10.0 mm. Preferably, the geometry and dimensions of the housing 12 of

the shunt valve system 10, and in particular, the height, width, and length of the housing 12, are determined according to the proportions of the target site of implantation.

Referring now to FIGS. 1B and 2, the housing 12 of the shunt valve system 10 is designed to surround a fluid regulator, such as for example, the shunt valve mechanism 32 illustrated in FIG. 1B, which is effective to control fluid flow through the shunt valve system 10. The locking assembly of the present invention can be used in conjunction with virtually any shunt valve mechanism 32 that is effective to control fluid flow, but preferably, the shunt valve mechanism 32 includes a differential pressure valve, which regulates the flow of fluid according to a pressure differential created between the inlet and outlet ports of the shunt valve system 10. Thus, a pressure differential valve establishes a pressure threshold, which must be met before fluid begins to flow through the shunt valve system 10. Preferably, the shunt valve mechanism 32 is also adapted to allow a clinician to non-invasively adjust the pressure threshold at which fluid begins to flow through the shunt valve system 10.

An exemplary embodiment of the shunt valve mechanism 32, illustrated in FIGS. 1B-3B, is commonly referred to as a ball-in-cone mechanism, such as for example, the Hakim shunt valve mechanism disclosed by U.S. Patent No. 4,615,691, the contents of which are hereby incorporated in their entirety by reference. In a typical ball-in-cone shunt valve mechanism 32, the pressure threshold at which fluid begins to flow through the shunt valve system 10 is regulated by a sphere, which is seated in a circular orifice and is effective to block fluid flow through the orifice until the established pressure threshold has been met. The sphere is operatively joined to a first end of a cantilevered spring, while the second end of the spring is operatively joined to a rotor assembly 34, such as the rotor assembly 34 shown in FIGS. 1B-3B. The rotor assembly 34 typically includes a stair-step array, generally in the shape of a spiral staircase, for engaging the second end of the spring. As the rotor assembly 34 is rotated, the second end of the spring moves up or down each stair of the spiral stair array, which results in a corresponding change in the deflection of the cantilevered spring. The change in the angle of deflection of the spring, in turn, alters the force that is exerted by the spring on the sphere. A change in the force applied by the spring to the sphere results in a corresponding increase or

decrease of the established pressure threshold at which fluid begins to flow through the shunt valve system 10.

Preferably, the ball-in-cone shunt valve mechanism 32 used in the present invention is adapted to allow a clinician to adjust the pressure threshold by rotating the rotor assembly 34 in a non-invasive manner. The rotor assembly 34 of the shunt valve mechanism 32 includes at least one magnet carried in a housing 36 having an outer wall 38 (FIGS. 1B-3B), and optionally, an opposed, inner wall (not shown). This magnet allows the clinician to non-invasively adjust the rotor assembly 34 by applying a strong external magnetic field to the shunt valve system 10, and then rapidly switching the field, which causes the rotor assembly 34 to turn. As described above, when the rotor assembly 34 is turned, the second end of the spring is moved up or down the stair-step array, which ultimately results in a change in the pressure threshold of the shunt valve mechanism 32.

In one aspect of the present invention, the locking assembly can effectively prevent the rotor assembly 34 of the shunt valve mechanism 32 from rotating. Such a locking feature can be advantageous to prevent the rotor assembly 34 from inadvertent and undesirable rotation due to environmental magnetic forces. For example, when the shunt valve mechanism 32 is subjected to strong external magnetic forces, such as during MRI procedures, these magnetic forces can cause unanticipated rotation of the rotor assembly 34. The present invention overcomes this problem by providing a locking assembly that is not affected by magnetic forces.

The locking assembly of the present invention includes at least one gripping arm 40, which can frictionally engage at least a portion of the rotor assembly 34 to prevent the rotor assembly 34 from rotating, even in the presence of strong external magnetic forces. The locking assembly can include virtually any number of gripping arms 40, but preferably, the locking assembly includes opposed, bilateral gripping arms 40, as shown in FIGS. 3A and 3B. To prevent the rotor assembly 34 from rotating, these gripping arms 40 can frictionally engage at least a portion of the rotor assembly 34 and can apply compressive forces to at least a portion of the rotor assembly 34.

Each gripping arm 40 can protrude from the inner surface 16 of the housing 12 of the shunt valve system 10, as shown in FIGS. 1A and 2-3B. The gripping arms 40 of the locking assembly and the housing 12 of the shunt valve system 10 may be integrally formed, or alternatively, the gripping arms 40 and the housing 12 may comprise separate members that have been mated together. A variety of mating techniques known to those having ordinary skill in the art can be used to couple the housing 12 and the gripping arms 40. By way of non-limiting example, the gripping arms 40 can be welded, ultrasonically bonded, adhesively attached or mechanically mated to the housing 12 of the shunt valve system 10.

As shown in FIG. 1A, each gripping arm 40 has at least one rotor contacting surface 42 that is designed to frictionally engage at least a portion of the rotor assembly 34. The dimensions and geometry of each rotor contacting surface 42 can vary. Preferably, each rotor contacting surface 42 is sufficiently sized and configured to mate with a portion of the rotor assembly 34. The contacting surface 42 should be able to maintain the rotor assembly 34 in a static position and counteract any external force urging the rotation of the rotor assembly 34, i.e., provide a braking force which holds the rotor assembly 34 stationary. In one embodiment, the rotor contacting surface 42 can mate with and frictionally engage the outer wall 38 of the rotor assembly 34, as shown in FIG. 3A to stably maintain the rotor assembly 34 in a desired, stationary position. In another embodiment, not shown in the accompanying figures, the rotor contacting surface 42 can mate with and frictionally engage the inner wall (not shown) of the rotor assembly 34, and in yet another embodiment, also not shown in the accompanying figures, the rotor contacting surface 42 can mate with and frictionally engage both the outer wall 38 and the opposed, inner wall (not shown) of the rotor assembly 34.

In an embodiment where the rotor contacting surface 42 frictionally engages the outer wall 38 of the rotor assembly 34, the outer wall 38 may be smooth, as shown in FIGS. 1B-3B, or alternatively, it can include friction-increasing surface features (not shown). The outer wall 38 can include virtually any surface feature that can increase the friction of the outer wall 38. By way of non-limiting example, suitable friction-increasing surface features include grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof. In an embodiment where the rotor contacting surface 42 frictionally engages the inner wall (not shown) of the rotor

assembly 34, either alone or in conjunction with the outer wall 38, the inner wall can be smooth, or alternatively, it can include virtually any surface feature that can increase the friction of the inner wall. Suitable friction-increasing surface features include, but are not limited to grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof. In either of these
5 embodiments, the rotor contacting surface 42 can be smooth, or alternatively, it can include friction-increasing surface features (not shown), such as the friction-increasing surface features described above. Preferably, the friction-increasing surface features of the rotor contacting surface 42 are designed to mate with corresponding surface features located on the outer wall 38 of the rotor assembly 34, the inner wall of the rotor assembly, or both walls of the rotor assembly
10 34.

Actuation of the gripping arms 40 can be achieved by applying an external pressure force to an actuating mechanism 44. The actuating mechanism 44 is configured so that the force applied thereto travels through the housing 12 of the shunt valve system 10 and to the gripping arms 40, deforming the housing 12 and enabling the release of the arms 40 from the rotor
15 assembly 34. Alternatively, the force applied to the actuating mechanism 44 can enable the arms 40 to engage the rotor assembly 34. The actuating mechanism 44 of the locking assembly can have a variety of configurations, but preferably, the actuating mechanism 44 is disposed on the housing 12 of the shunt valve system 10. The actuating mechanism 44 and the housing 12 may be integrally formed, or alternatively, the actuating mechanism 44 and the housing 12 may
20 comprise two separate members that have been mated together. A variety of mating techniques known to those having ordinary skill in the art can be used to couple the housing 12 and the actuating mechanism 44 such that forces exerted on the actuating mechanism 44 can be transferred to the housing 12 and gripping arms 40. By way of non-limiting example, the actuating mechanism 44 can be welded, ultrasonically bonded, adhesively attached or
25 mechanically mated to the housing 12.

As previously described, the actuating mechanism 44 controls movement of the gripping arm 40 by transferring a force from the actuating mechanism 44 through the housing 12 and to the gripping arm 40, which is integral with, or mated to, the housing 12, as described above. In one embodiment, the system is configured such that the gripping arms 40 are biased to the

engaged position. The force applied to the actuating mechanism 44 is sufficient to move the housing 12 from the biased, first state to a deformed, second state, in which the gripping arms 40 are disengaged from contact with any portion of the rotor assembly 34. As the force is applied to the actuating mechanism 44, the width of the housing 12 increases, *i.e.*, buckles, which, in turn, causes the gripping arms 40 to bulge outwardly, as shown in FIG. 3B. As the housing 12 is moved into its second, deformed state, the gripping arms 40 no longer frictionally engage any portion of the rotor assembly 34, and a clinician can adjust the pressure threshold of the shunt valve mechanism 32 by rotating the rotor assembly 34. Upon removal of the force applied to the actuating mechanism 44, the housing 12 returns to the first state in which the gripping arms 40 are biased toward the center of the housing 12 to frictionally engage at least a portion of the rotor assembly 34.

In an alternative embodiment, the system is biased to a disengaged state, in which the rotor contacting surface 42 does not frictionally engage any portion of the rotor assembly 34. Upon application of a force to the actuating mechanism 44, the rotor contacting surface 42 of the gripping arms 40 frictionally engages a portion of the rotor assembly 34. By way of example, in this embodiment, application of a force on the actuating mechanism 44 causes the width of the housing 12 to decrease, which, in turn, causes the gripping arms 40 to contract inwardly, *i.e.*, pinch together, and frictionally engage the rotor assembly 34. As the housing is moved into its second, deformed state, the gripping arms 40 frictionally engage a portion of the rotor assembly 34 to prevent any intentional or unintentional adjustment of the shunt valve mechanism 32. Upon removal of the force applied to the actuating mechanism 44, the housing 12 returns to its biased, first position in which the gripping arms 40 do not frictionally engage any portion of the rotor assembly 34, *i.e.*, the gripping arms 40 buckle away from the center of the housing 12.

In a preferred embodiment, the actuating mechanism 44 is a deformable membrane 46 disposed on the housing 12 of the shunt valve system 10, as illustrated in FIGS. 1A and 2. The deformable membrane 46 can have virtually any size and shape, but preferably, the deformable membrane 46 is generally shaped as a button, as shown in FIGS. 1A and 2-3B. The deformable membrane 46 of the actuating mechanism 44 and the housing 12 of the shunt valve system 10 may be integrally formed, or alternatively, the deformable membrane 46 and the housing 12 may

comprise two separate members that have been mated together using any of the various mating techniques known by those having ordinary skill in the art, as described above.

Preferably, the deformable membrane 46 of the actuating mechanism 44 is sized and shaped to provide at least a tactile cue of the location of the shunt valve system 10 after implantation within a patient. To provide a tactile cue, the deformable membrane 46 preferably protrudes above the housing 12 by a height H_2 , as seen in FIG. 1. In this embodiment, the height H_2 of the deformable membrane 46 is preferably in the range of about 1.0 to 3.0 mm. In other embodiments, the deformable membrane 46 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 10 within a patient. Additionally, the deformable membrane 46 of the actuating mechanism 44 can be adapted to include an audible cue that can indicate when the gripping arms 40 of the locking assembly are in an engaged state, *i.e.*, when gripping arms 40 frictionally engage a portion of the rotor assembly 34. For example, the deformable membrane 46 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 44 to deploy the gripping arm 40.

The locking assembly of the present invention and the shunt valve system 10 used in conjunction with the locking assembly of the present invention can be constructed from virtually any biocompatible material. For example, the housing 12 of the shunt valve system 10 can be formed from virtually any biocompatible material, but preferably, the housing 12 is constructed from any suitable, flexible biocompatible material, such as for example, silicone, Dow Corning SILASTIC® BioMedical Grade Liquid Silicone Rubber, polyurethane, nylon, polyethersulfone, and combinations thereof. Additionally, the gripping arms 40 of the locking assembly can be formed from virtually any suitable biocompatible material. Suitable biocompatible materials for constructing the gripping arms 40 include, but are not limited to, flexible materials, such as for example, silicone, Dow Corning SILASTIC® BioMedical Grade Liquid Silicone Rubber, polyurethane, nylon, polyethersulfone, and combinations thereof. In one optional embodiment, the gripping arm 40 can be constructed to form a deformable membrane containing a gel medium therein. In this embodiment, the deformable membrane of the gripping arm 40 can be

constructed from virtually any suitable, flexible biocompatible material, such as for example, the flexible materials disclosed above.

The deformable membrane 46 of the actuating mechanism 44 can be constructed from a variety of materials, but preferably, the deformable membrane 46 is constructed from a flexible, biocompatible material. Suitable biocompatible materials include, but are not limited to, a silicone elastomer, polyurethane, nylon, and combinations thereof. In another embodiment, the deformable membrane 46 can be constructed from a shape memory material, or alternatively, the deformable membrane 46 can be constructed to include a shape memory material embedded therein. In an embodiment where the deformable membrane 46 includes a shape memory material, the shape memory material is, preferably, a spring wire embedded within the deformable membrane 46. Suitable shape memory materials for use in the present invention include, but are not limited to, shape memory metal alloys and shape memory polymers. Suitable shape memory metal alloys include, but are not limited to, nickel-titanium alloys such as nitinol (TiNi), copper-base alloys such as CuZnAl and CuAlNi, FeNiAl, and combinations thereof. Suitable shape memory polymers, such as for example, modified polycyclooctene, may include thermoplastic networks, thermoset networks, interpenetrating networks, semi-interpenetrating networks, mixed networks and combinations thereof. The shape memory polymers used in the present invention can be linear or branched thermoplastic elastomers having side chains or other dendritic structural elements.

One of ordinary skill in the art will readily appreciate that the shape memory materials, which can be used in the deformable membrane 46 of the present invention, can 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.

In another embodiment not illustrated in the accompanying figures, in which the actuating mechanism 44, and in particular, the deformable membrane 46, includes a shape

memory material, the actuating mechanism 44 can control the deployment and release of the gripping arm 40, even in the absence of an external force. In this embodiment, the shape memory material of the deformable membrane 46 can change its shape from a first, resting shape to a second, memorized shape in the presence of an external stimulus, or stimuli, as described above. Thus, in this embodiment, the force applied to the actuating mechanism 44 is provided by the change in the shape memory material in the deformable membrane 46. This force travels through the housing 12 and causes the housing 12 to move between a biased, first state and a deformed, second state.

It will be understood that while the above embodiment has been described and shown as having opposed, bilateral arms, the locking assembly according to this first embodiment can include virtually any number of gripping arms 40, provided that the locking assembly 40 includes at least one gripping arm 40.

According to a second embodiment of the locking assembly of the present invention, shown in FIGS. 4-5B, the locking assembly can be used in conjunction with any medical device for regulating the flow of liquid therethrough. For example, the second embodiment of the locking assembly can be used in conjunction with a second embodiment of the shunt valve system described above in connection with the first embodiment of the locking assembly. According to this second embodiment, the shunt valve system 50 includes a housing 52 having an outer surface 54 that contacts the target site of implantation and an inner surface 56 that defines a fluid chamber 58 (FIG. 5A). The fluid chamber 58 is adapted to allow fluid to flow through the shunt valve system 50. The fluid chamber 58 of the shunt valve system 50 includes an inlet port (not shown) for receiving fluid into the shunt valve system 50, and an outlet port (not shown) for releasing fluid from the shunt valve system 50.

Referring now to FIG. 4, the distance between the outer surface 54 and the inner surface 56 defines a thickness of the housing 52. This thickness can vary, but preferably, the thickness of the housing 52 is in the range of about 0.5 to 1.0 mm. The housing 52 of the shunt valve system 50 also includes a first end 60, a second end 62, and a length extending therebetween. The length of the housing 52 can vary, but preferably, the length of the housing 52 is determined

according to the dimensions of the target site of implantation. More preferably, the housing 52 has a length in the range of about 2.5 to 5.0 cm.

The housing 52 of the shunt valve system 50 can have virtually any geometry, but preferably, the housing 52 has a generally rectangular shape, as illustrated in FIG. 4. In this embodiment, the housing 52 includes a top surface 64, a bottom surface 66, and opposed side surfaces 68, 70, as shown in FIG. 4. As seen in FIGS. 5A and 5B, the top surface 64 of the housing 52 can be formed as a base 72. This base 72 can be adapted to slidably engage a corresponding groove on the opposed side surfaces 68, 70 of the housing 52. As seen in FIGS. 5A and 5B, the distance between the top surface 64 (or base 72) and bottom surface 66 defines a height H_3 of the housing 52, which can vary, but is preferably in the range of about 4.5 to 6.0 mm. Similarly, the distance between the opposed side surfaces 68, 70 defines a width of the housing 52. This width can vary, but preferably, the width of the housing 52 is in the range of about 7.0 to 10.0 mm. Preferably, the geometry and dimensions of the housing 52 of the shunt valve system 50, and in particular, the height, width, and length of the housing 52, are determined according to the proportions of the target site of implantation.

As seen in FIGS. 5A and 5B, the housing 52 is designed to surround the shunt valve mechanism 32 described above in connection with the first embodiment of the locking assembly of the present invention. The shunt valve mechanism 32 includes a sphere 74 seated in a circular orifice, a cantilevered spring 76, and a rotor assembly 78. The rotor assembly 78 of the shunt valve mechanism 32 includes a stair-step array 80, generally in the form of a spiral staircase. The stair array 80 of the rotor assembly 78 may be smooth, as shown in FIGS. 5A and 5B, or alternatively, the stair array 80 can include friction-increasing surface features (not shown). The stair array 80 can include virtually any surface feature that can increase the friction of the stair array 80. By way of non-limiting example, suitable friction-increasing surface features include grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof.

In one aspect of the present invention, the locking assembly can effectively prevent the rotor assembly 78 of the shunt valve mechanism 32 from rotating. As discussed above in connection with the first embodiment of the shunt valve system 10, this feature of the locking

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assembly can be advantageous to prevent the rotor assembly 78 from inadvertent and undesirable rotation due to environmental magnetic forces.

Referring now to FIGS. 4-5B, the locking assembly of the present invention includes at least one gripping arm 82, which can protrude from the inner surface 56 of the housing 52 of the shunt valve system 50. The gripping arm 82 can frictionally engage at least a portion of the stair array 80 of the rotor assembly 78 and can apply a compressive force on a portion of the stair array 80 to stably maintain the rotor assembly 78 in a desired, stationary position, even in the presence of external magnetic forces. The gripping arm 82 can have a variety of configurations, but preferably, the locking assembly includes a single gripping arm 82 that can be formed as at least one inflatable bladder 84. Preferably, the inflatable bladder 84 is disposed on the base 72 of the housing 52 and formed as a button that can deform upon contact with the stair array 80 of the rotor assembly 78, as shown in FIG. 5B. In one embodiment of the present invention, the base 72 of the housing 52 and the gripping arm 82 of the locking assembly may be integrally formed, or alternatively, the base 72 and the gripping arm 82 may comprise two separate members that have been mated together by any of the various mating techniques known to those having ordinary skill in the art.

The gripping arm 82 has at least one rotor contacting surface 86, which can frictionally engage and apply a compressive force to at least a portion of the stair array 80 of the rotor assembly 78, as described above. The dimensions and geometry of each rotor contacting surface 86 can vary. Preferably, each rotor contacting surface 86 is sufficiently sized and configured to engage a portion of the stair array 80 of the rotor assembly 78, as shown in FIG. 5B. The contacting surface 86 should be able to maintain the rotor assembly 78 in a static position and counteract any external force urging the rotation of the rotor assembly 78. The rotor contacting surface 86 can be smooth, or in an alternative embodiment, it can include friction-increasing surface features (not shown). Suitable friction-increasing surface features, include, but are not limited to, grooves, detents, ridges, corrugations, roughened surfaces and combinations thereof.

Actuation of the gripping arm 82 can be achieved by applying an external pressure force to an actuating mechanism 88. The actuating mechanism 88 can have a variety of

configurations, but preferably, the actuating mechanism 88 can be formed as a deformable membrane disposed on a base 72, which can be slid into a corresponding groove in the housing 52 of the shunt valve system 50, as seen in FIG. 4. The actuating mechanism 88 can be connected to the gripping arm 82 by a channel 92 to form a closed system, such that the actuating mechanism 88 and the gripping arm 82 are in fluid communication with each other, and application of an amount of force applied to the actuating mechanism 88 transfers an equal amount of force to the gripping arm 82. In the present embodiment illustrated in FIGS. 5A and 5B, the actuating mechanism 88 and the gripping arm 82 can be filled with a gaseous medium such as air, or alternatively, the actuating mechanism 88 and the gripping arm 82 can be filled with a liquid medium that is effective to transfer the applied force from the actuating mechanism 88 to the gripping arm 82. In yet another embodiment, the actuating mechanism 88 and the gripping arm 82 can be filled with a gel medium that can transfer the applied force from the actuating mechanism 88 to the gripping arm 82.

The force transferred from the actuating mechanism 88 to the gripping arm 82 is sufficient to move the gripping arm 82 into and out of a position in which the pressure threshold of the shunt valve mechanism 32 is locked. In one embodiment, the gripping arm 82 is biased to a disengaged condition, shown in FIG. 5A, in which the rotor contacting surface 86 does not frictionally engage any portion of the stair array 80 of the rotor assembly 78. Upon application of a force by the actuating mechanism 88, the gripping arm 82 is moved to an engaged state, shown in FIG. 5B, in which the rotor contacting surface 86 frictionally engages a portion of the stair array 80 of the rotor assembly 78. In this embodiment, application of a force to the actuating mechanism 88 causes the rotor contacting surface 86 of the gripping arm 82 to bulge or expand outwardly from the base 72 of the housing 52. This deformation of the gripping arm 82 is sufficient to cause the rotor contacting surface 86 to frictionally engage the stair array 80 of the rotor assembly, as shown in FIG. 5B. In one embodiment, upon removal of the force applied to the actuating mechanism 88, the gripping arm 82 returns to the first state in which the gripping arm 82 no longer frictionally engages any portion of the rotor assembly 78, as shown in FIG. 5A. In another embodiment, the channel 92 can include a bleeder valve (not shown) that can initially prevent the flow of the fluid, gaseous 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 back into the actuating mechanism 88.

In a preferred embodiment, the actuating mechanism 88 is a deformable membrane 90 disposed on the base 72 of the shunt valve system 50, as illustrated in FIGS. 4-5B. The deformable membrane 90 can have virtually any size and shape, which are, preferably, designed according to the dimensions of the target site of implantation. In a preferred embodiment, the deformable membrane 90 is generally shaped as a button and is bilaterally opposed to the gripping arm 82, as shown in FIGS. 4 and 5A. The deformable membrane 90 of the actuating mechanism 88 and the base 72 of the shunt valve system 50 may be integrally formed, or alternatively, the deformable membrane 90 and the base 72 may comprise two separate members that have been mated together using any of the various mating techniques known by those having ordinary skill in the art, as described above.

Preferably, the deformable membrane 90 of the actuating mechanism 88 is sized and shaped to provide at least a tactile cue of the location of the shunt valve system 50 implanted within a patient. To provide a tactile cue, the deformable membrane 46 preferably protrudes above the top surface 64 or base 72 of the housing 52, as seen in FIGS. 5A and 5B. In this embodiment, the height of the deformable membrane 90 is preferably in the range of about 1.0 to 3.0 mm. In other embodiments, 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.

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.

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.

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.

5 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
10 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
15 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 engagable locking assembly for preventing rotation of the rotor assembly, the locking assembly having 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.

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

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 gripping arm sufficient to move the at least one gripping arm between a first state in which the at least one gripping arm frictionally engages the rotor assembly and a second state in which the at least one gripping arm 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.

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

8. The system of claim 7, wherein the shape memory material included in the actuating mechanism is a spring wire embedded within the deformable membrane.

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9. The system of claim 1, wherein the locking mechanism contains opposed, bilateral gripping arms.

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10. The system of claim 1, wherein the locking mechanism contains at least one gripping arm formed as an inflatable bladder.

11. 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.

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12. 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.

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

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14. A locking assembly for preventing rotation of a rotor assembly of a shunt valve system, the locking assembly comprising:

at least one gripping arm for frictionally engaging the rotor assembly, the at least one gripping arm having at least one rotor-contacting surface; and

an actuating mechanism mechanically linked to the gripping arm wherein the actuating mechanism is effective to move the at least one gripping arm between a locked position in which the at least one gripping arm frictionally engages the rotor assembly and an unlocked position in which the at least one gripping arm is disengaged from the rotor assembly.

15. The system of claim 14, wherein the rotor assembly further includes an outer wall, the at least one rotor-contacting surface of the at least one gripping arm being adapted to frictionally engage the outer wall of the rotor assembly.

16. The system of claim 14, wherein the rotor assembly further includes an inner wall, the at least one rotor-contacting surface of the at least one gripping arm being adapted to frictionally engage the inner wall of the rotor assembly.

17. The locking assembly of claim 14, wherein the actuating mechanism comprises a deformable membrane configured to transfer a force applied to the deformable membrane to the at least one gripping arm sufficient to move the at least one gripping arm between the locked position and the unlocked position.

18. The locking assembly of claim 17, wherein the deformable membrane of the actuating mechanism includes a shape memory material.

19. The locking assembly of claim 18, wherein the shape memory material included in the actuating mechanism is a spring wire embedded within the deformable membrane.

20. The locking assembly of claim 14, further containing opposed, bilateral gripping arms.

21. The locking assembly of claim 14, further containing at least one gripping arm formed as an inflatable bladder.

22. A locking assembly for selectively engaging a medical device having a fluid channel and a fluid regulator for preventing fluid flow therethrough, the locking assembly comprising:

an actuating mechanism having a deformable membrane connected to a gripping arm, the gripping arm being selectively movable 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,

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.

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ABSTRACT OF THE DISCLOSURE

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.

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**DECLARATION AND POWER OF ATTORNEY FOR
UNITED STATES LETTERS PATENT APPLICATION**

As a below-named inventor, I hereby declare that:

My residence, post-office address and citizenship are as stated below next to my name.

I believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SHUNT VALVE LOCKING MECHANISM

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on:

as Application No.:

and was amended on:

(if applicable).

In the event that the filing date and/or Application No. are not entered above at the time I execute this document, and if such information is deemed necessary, I hereby authorize and request my attorneys/agent(s) at Nutter, McClennen & Fish, LLP, One International Place, Boston, MA 02110-2699, to insert above the filing date and/or Application No. of said application.

I hereby state that I have reviewed and understand the contents of the above-identified application specification, including the claims, as amended by any amendment specifically referred to herein.

I acknowledge the duty to disclose all information known to me that is material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56.

FOREIGN PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code §119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

(check one)

- ☒ no such foreign applications have been filed.
- ☐ such foreign applications have been filed as follows:

**EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

Country	Application Number	Date of Filing (month, day, year)	Priority Claimed Under 35 USC 119
			___ Yes No ___
			___ Yes No ___
			___ Yes No ___
			___ Yes No ___
			___ Yes No ___

**ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS
FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

CLAIM FOR BENEFIT OF EARLIER U.S. PROVISIONAL APPLICATION(s)

I hereby claim priority benefits under Title 35, United States Code §119(e), of any United States provisional patent application(s) listed below:

(check one)

- ☒ no such U.S. provisional applications have been filed.
- ☐ such U.S. provisional applications have been filed as follows:

Application Number	Date of Filing (month, day, year)	Priority Claimed Under 35 USC 119(e)
		___ Yes ___ No ___
		___ Yes ___ No ___
		___ Yes ___ No ___

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(s)

I hereby claim the benefit under Title 35, United States Code §120, of the United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United State Code, §112, I acknowledge the duty to disclose all information that is material to patentability in accordance with Title 37, Code of Federal Regulations, §1.56, and which became available to me between the filing date of the prior application and the national or PCT international filing date of this application:

(check one)

- ☒ no such U.S./PCT applications have been filed.
- ☐ such U.S./PCT applications have been filed as follows:

Application Number	Date of Filing (month, day, year)	Status (Patented/Pending/Abandoned)

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

I hereby appoint:

William C. Geary III	Reg. No. 31,359	Reza Mollaaghababa	Reg. No. 43,810
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all of Nutter, McClennen & Fish, LLP, One International Place, Boston, Massachusetts 02110-2699, jointly, and each of them severally, my attorneys at law/patent agent(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the Patent and Trademark Office connected therewith.

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Inventor's Signature <i>Rainuka Gupta</i>	Date July 9, 2002
Residence 257 Hurley Street #1, Cambridge, Massachusetts 02141	
Country of Citizenship United States of America	
Post Office Address (required) same as above	

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FIGURE 1A

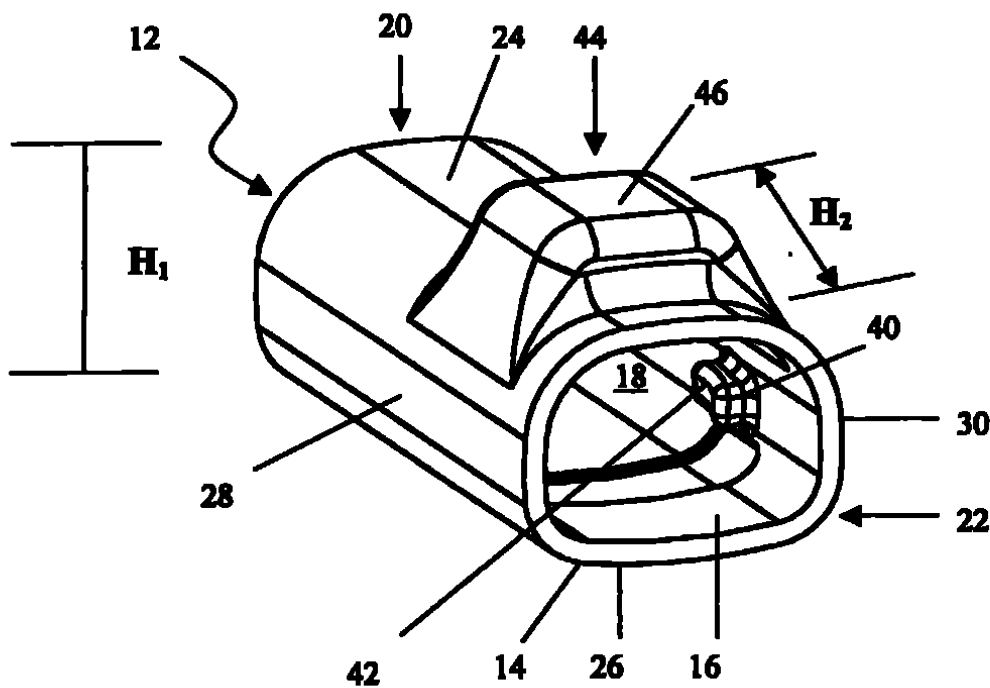


FIGURE 1B

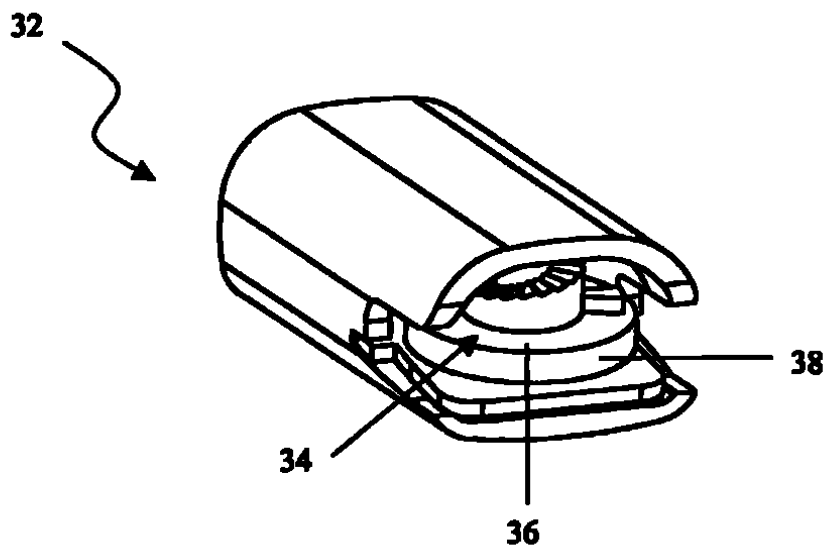
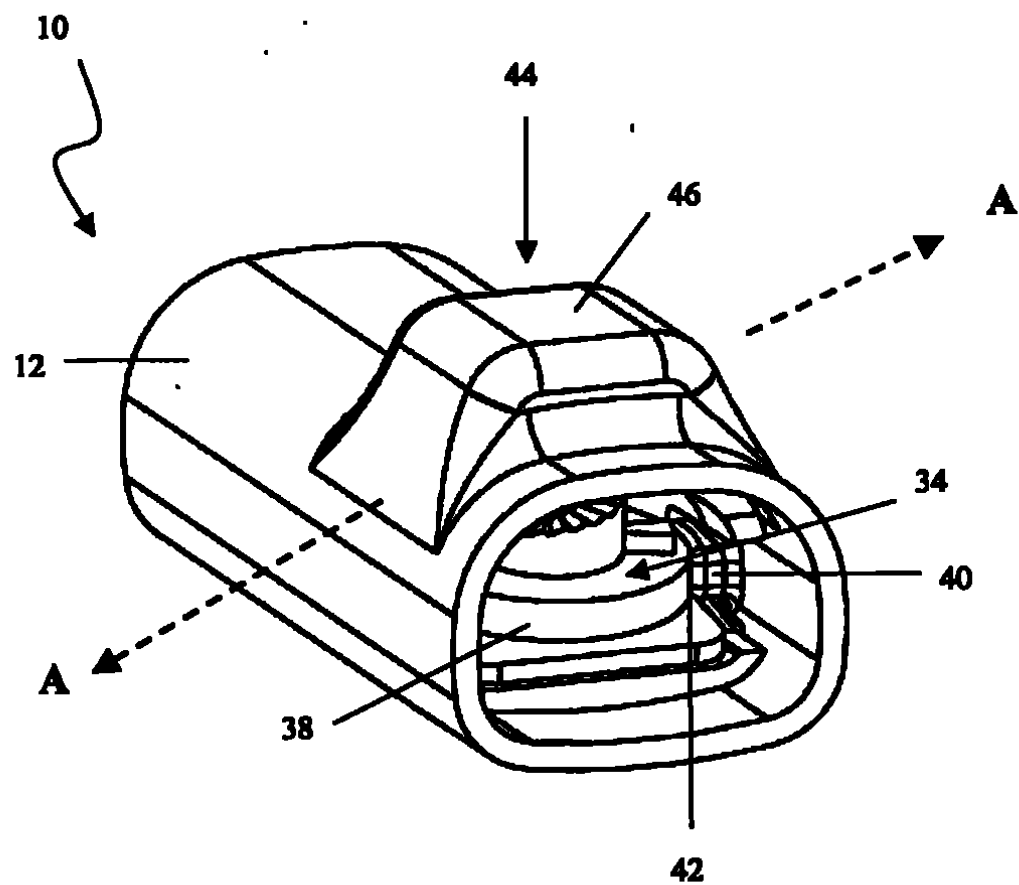
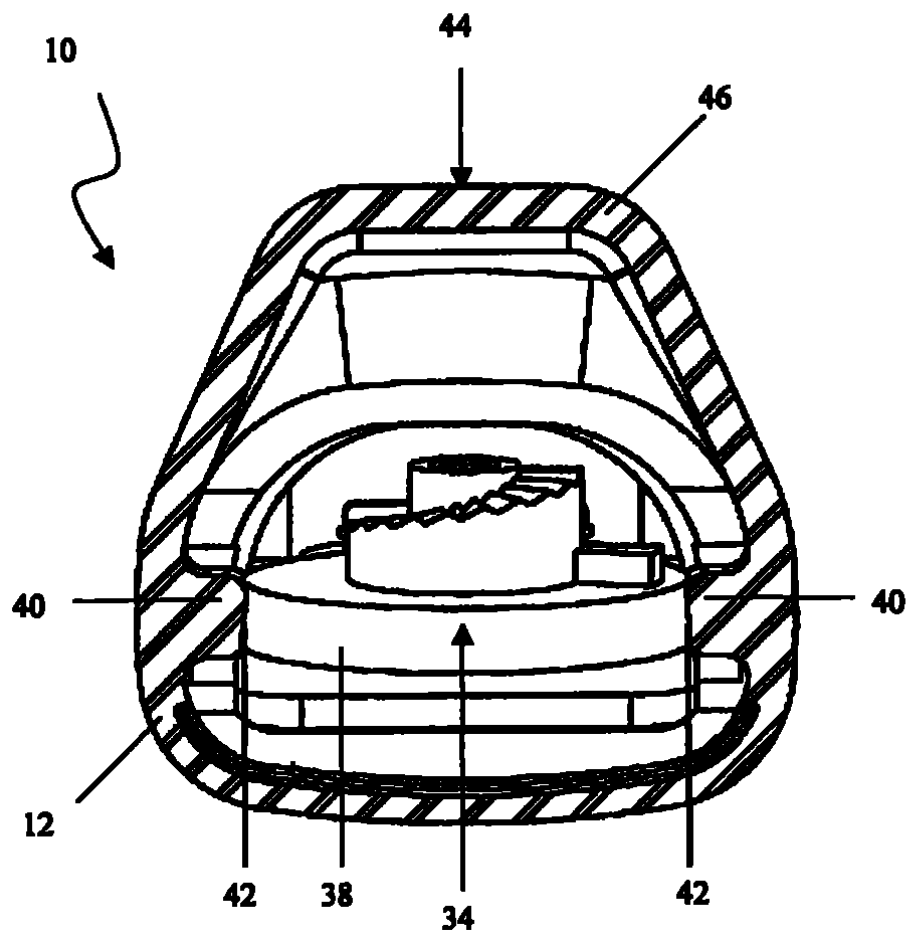


FIGURE 2



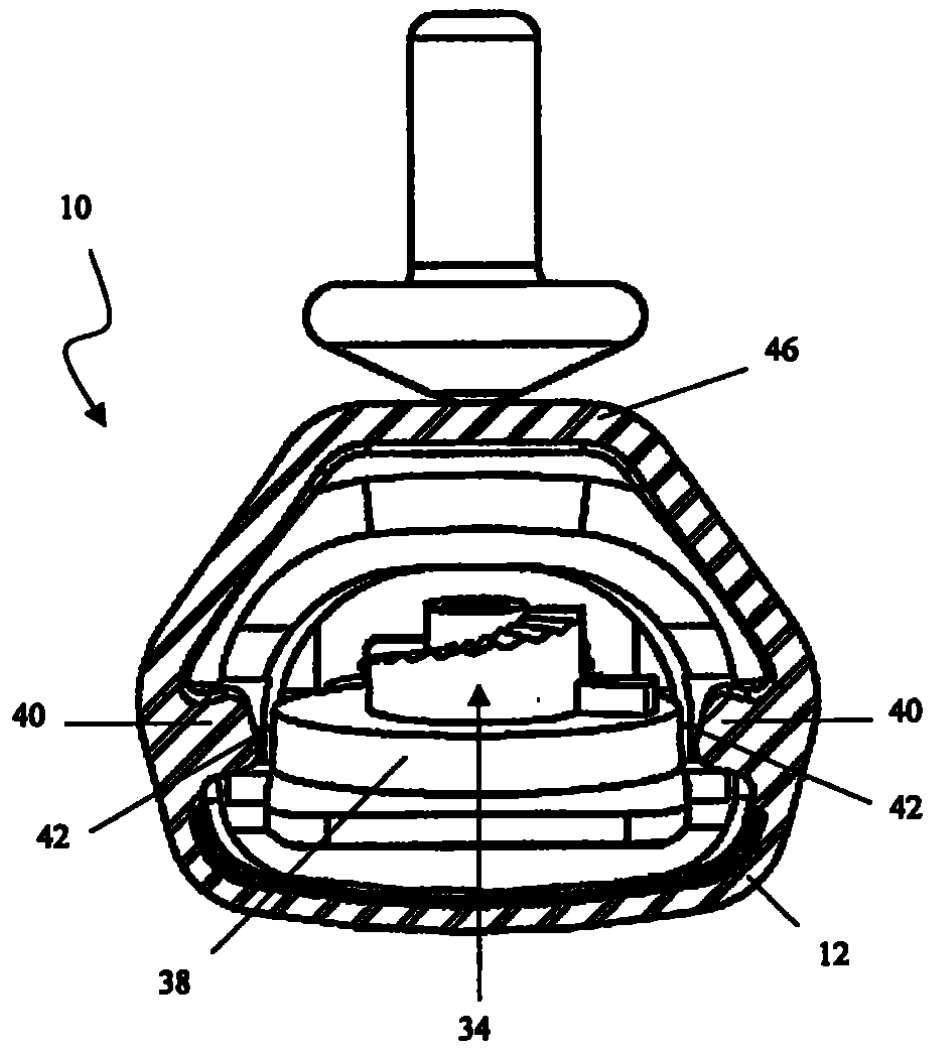
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FIGURE 3A



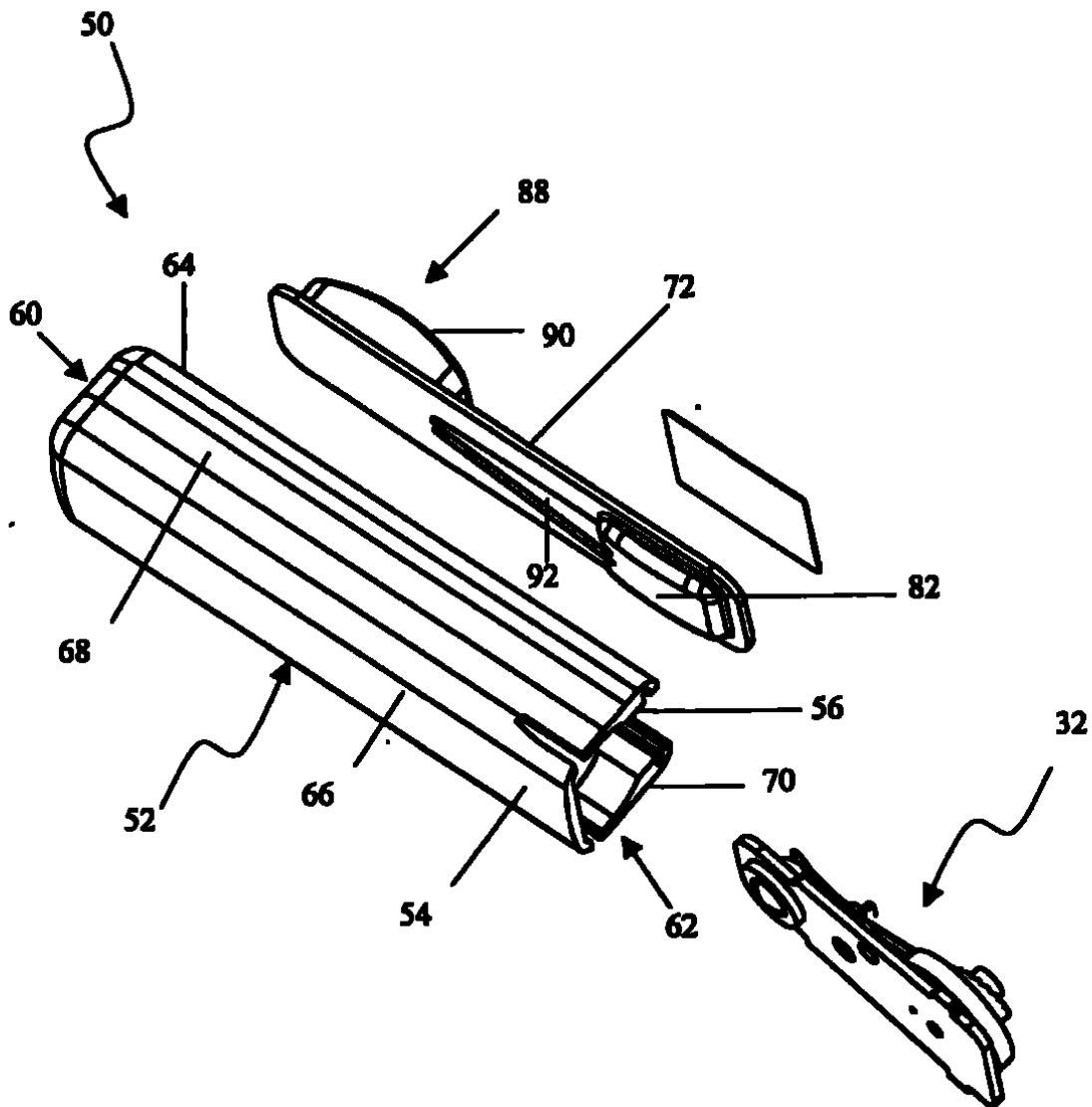
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✓

FIGURE 3B



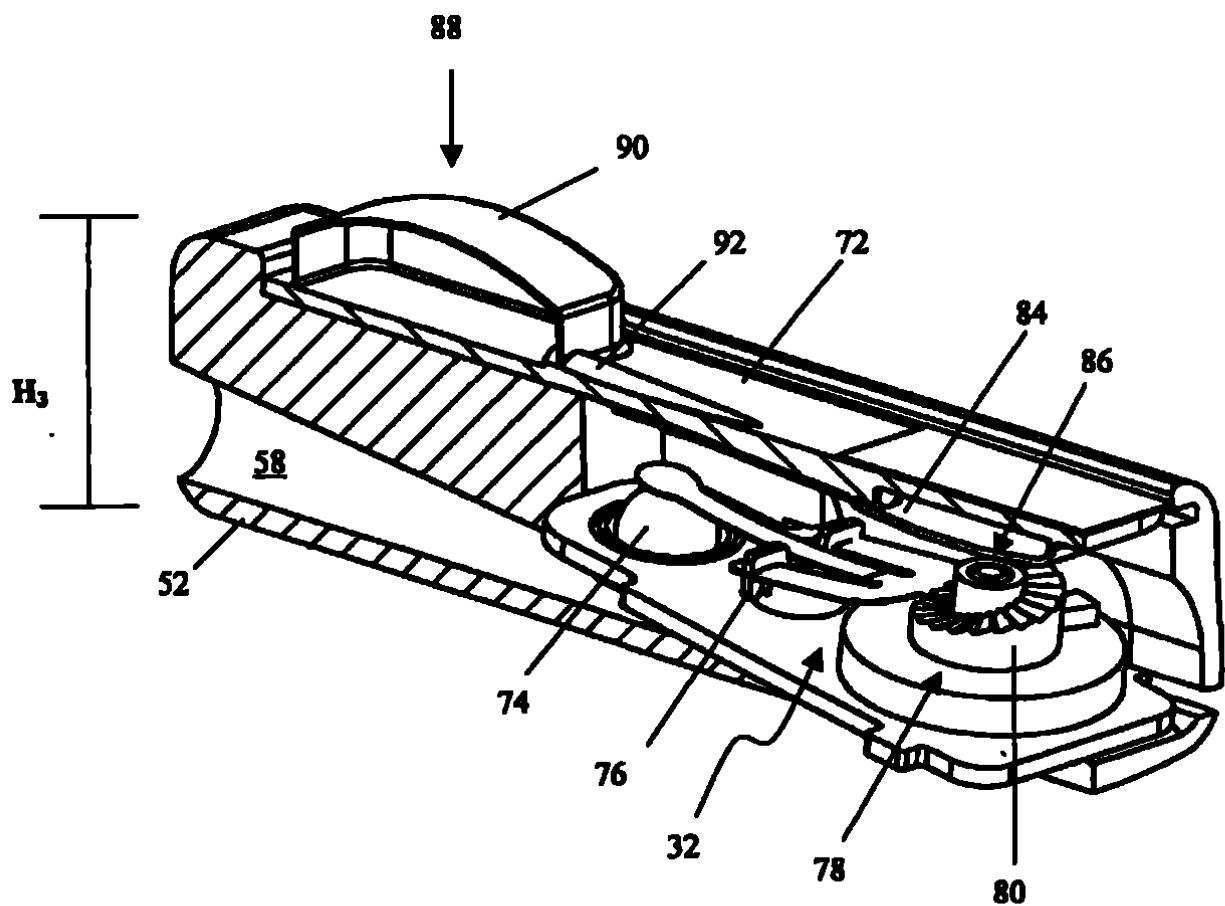
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FIGURE 4



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FIGURE 5A



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FIGURE 5B

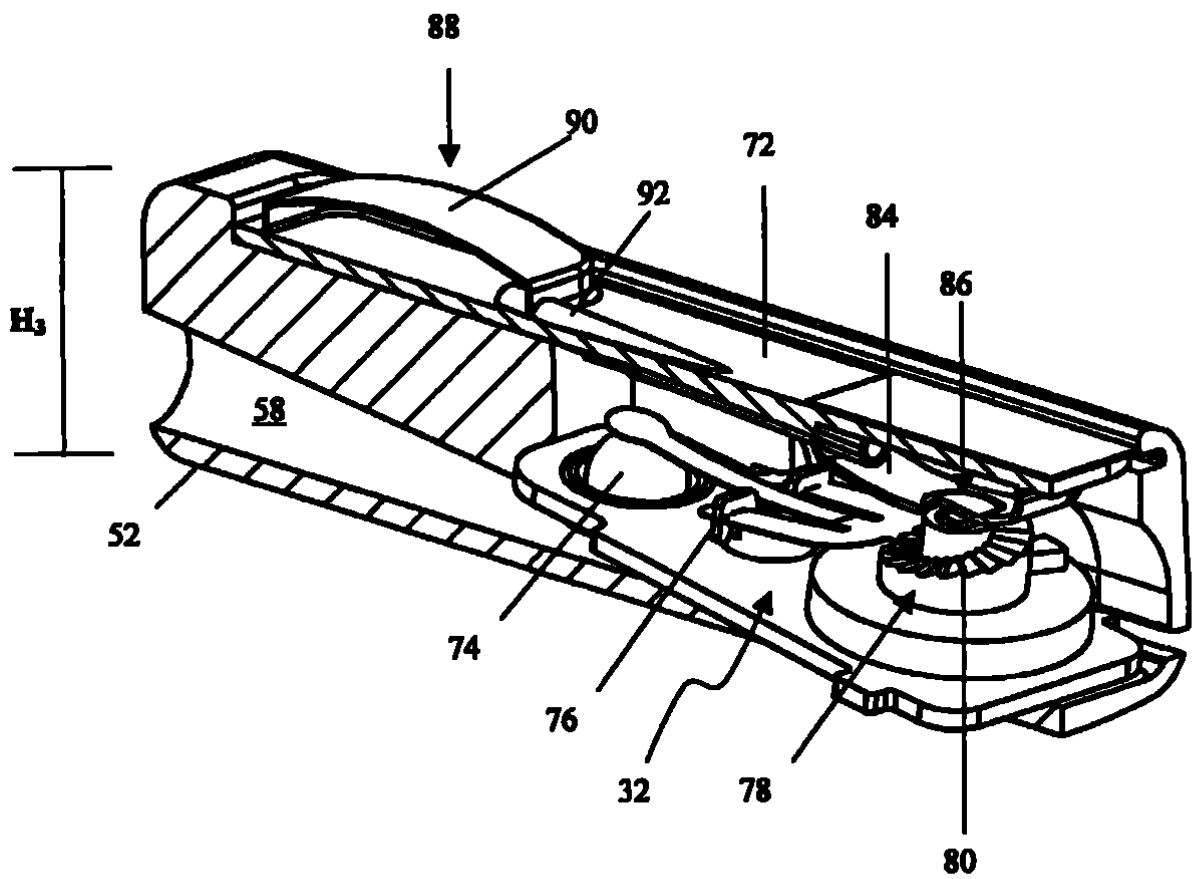
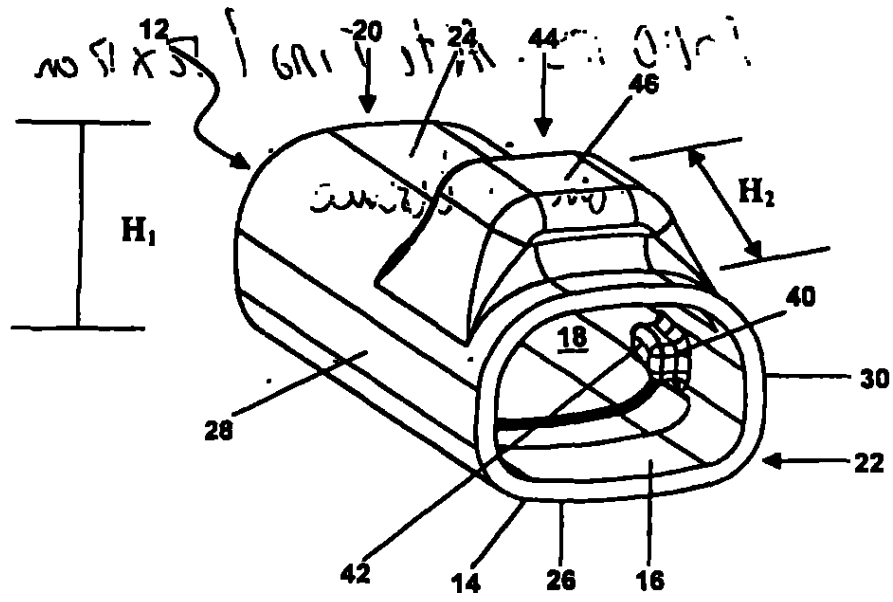


FIGURA 1A

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Folios: 77

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Tramite : 002 PATENTES D 1 REGISTRO/ 329 COMPLETEN

Dependencia: 2000 DIVISION DE NUEVAS CREACIONES

Ref.: Expediente No. 03.058.351
Solicitud de Patente a nombre de
Codman & Shurtleff, Inc.

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 A No. 94-76, of. 305-306, obrando como apoderada de la sociedad Codman & Shurtleff, Inc, domiciliada en Raynham, Massachussets, Estados Unidos de América, solicitante de la patente de la referencia, me permito presentar los siguientes documentos:

1. Documento de cesión suscrito por los inventores a favor de mi mandante.

Sobre el particular, es importante anotar que de conformidad con las normas legales vigentes, artículo 1 de la Resolución 210 de 2001, expedida por el Superintendente de Industria y Comercio y artículo 2 de la Convención de la Haya, los documentos en inglés que se pretendan aportar como parte de los trámites de propiedad industrial ante la Superintendencia de Industria y Comercio no requieren traducción. Por otro lado, la legalización consular y/o diplomática de los documentos expedidos en el extranjero no es necesaria. Por lo tanto, el documento de cesión anexo a este memorial es válidamente presentado en idioma inglés y con la correspondiente Apostilla.

2. Dibujos formales (los cuales fueron anunciados en el capítulo descriptivo) de acuerdo con lo establecido en el artículo 4-d del Decreto 117 de 1994.
3. Artes finales en tamaño 12 x 12 centímetros (por duplicado) y una copia tamaño 6 x 6 centímetros de la figura característica.

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4. Copia certificada de la solicitud de Patente número 10/192,394 presentada en los Estados Unidos de América el día 10 de julio de 2002, con la debida traducción de lo pertinente, incluyendo el capítulo reivindicatorio.

Señor Superintendente,


JIMENA ESCOBAR URIBE
C.C.39.779.452 de Usaquén
T.P. 68228
Cód. 5376



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2do. EXAMEN DE FORMA PATENTE DE INVENCION

Folio 127

Radicación no 03-58351

Concepto Técnico no 271

Clasificación Internacional de Patentes: F15 D 1/00

Practicado el examen de acuerdo a lo establecido en el Art. 38 de la Decisión 486 se determinó que esta solicitud de Patente de Invención:

- SI ☒ NO ☐ Contiene un resumen de la invención (Art.26-e).
- SI ☒ NO ☐ Contiene el título o nombre de la invención (Art.27-d).
- SI ☒ NO ☐ Contiene la descripción de la invención (Art.26-b).
- SI ☒ NO ☐ NO ES APLICABLE ☐ Contiene los dibujos necesarios para comprender la invención (Art.26-d)
- SI ☒ NO ☐ Contiene una o más reivindicaciones. (Art.26-c).
- SI ☐ NO ☐ NO ES APLICABLE ☒ Han sido desarrollados los productos y/o procedimientos a partir de recursos genéticos o de sus productos derivados de los que cualquiera de los Países Miembros es país de origen. (Art. 26- h).
- SI ☐ NO ☐ NO ES APLICABLE ☒ Los productos y/o procedimientos han sido obtenidos o desarrollados a partir de los conocimientos tradicionales de las comunidades indígenas, afro americanas, o locales de los países miembros, de acuerdo a lo establecido en la Decisión 391 y sus modificaciones y reglamentaciones vigentes.(Art.26-i).
- SI ☐ NO ☒ La invención se refiere a un producto relativo a un material biológico. (Art.26-j).
- SI ☒ NO ☐ NO ES APLICABLE ☐ La prioridad coincide con la materia reivindicada.
- SI ☒ NO ☐ CUMPLE LOS REQUISITOS TÉCNICOS**

OBSERVACIONES Y OTROS: SI ☐ NO ☒

EXAMINADOR TÉCNICO
202053

Bogotá D. C., Febrero 20 de 2004.



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Folio 138

2020
Bogotá DC

Doctor(a)
JIMENA ESCOBAR URIBE
Apoderado(a)
CODMAN & SHURTLEFF, INC.

REFERENCIA:	Radicación No.	03-58351
	Trámite	002
	Evento	001
	Actuación	416
	Oficio No.	310
	Folios	001

Teniendo en cuenta que la solicitud de privilegio de patente que se tramita bajo el expediente indicado en la referencia, reúne los requisitos de forma establecidos en los artículos 26 y 27 de la Decisión 486 de la Comisión de la Comunidad Andina, y en las demás disposiciones vigentes sobre la materia, se envía el extracto de la solicitud a la Oficina de Comunicaciones para efecto de su publicación en la Gaceta de Propiedad Industrial, conforme lo establece el artículo 40 de la misma Decisión, y a partir del 10 de enero de 2004.

Cúmplase
Dado en Bogotá DC,

26 FEB 2004

ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones

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