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A B O G A D O S

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2723/P.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISION DE NUEVAS CREACIONES

E.

S.

D.

SUPERINTENDENCIA Y COMERCIO

Radicación: 04086715 ESCOBUR

Folios: 41

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Trámite: 002 PATENTES D 1 REGISTRO/ 444 REPUESTA

Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Ref.: Expediente No. 04.086.715
Solicitud de Patente a nombre de
Codman & Shurtleff, Inc.

Y, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 A No. 94-76, of. 305, obrando como apoderada de la sociedad Codman & Shurtleff, Inc., domiciliada en Raynham, Massachusetts, Estados Unidos de América, solicitante de la patente de la referencia, en respuesta su oficio No. 8780 notificado por fijación en lista el día 23 de septiembre de 2004, me permito manifestar lo siguiente:

1. Anexo el documento de cesión suscrito por el inventor a favor de mi mandante.

Sobre el particular, es importante resaltar 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, el documento en inglés que se pretenda 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. Acompaño al presente memorial la copia certificada de la solicitud de Patente Número 10/656,973 presentada en los Estados Unidos de América el día 5 de septiembre de 2003, respectivamente, con la debida traducción de l pertinente, incluyendo el capítulo reivindicatorio.

Espero con esto haber dado cabal cumplimiento a lo solicitado por ese despacho y de conformidad con lo indicado en los artículos 3º., inciso 3, 35 inciso 2 y 59 inciso 2 del CCA, al analizar este memorial, atentamente ruego se traten todas las cuestiones planteadas con motivo del mismo.

Señor Superintendente,


JIMENA ESCOBAR URIBE

C.C.39.779.452 de usaquén

T.P. 68228

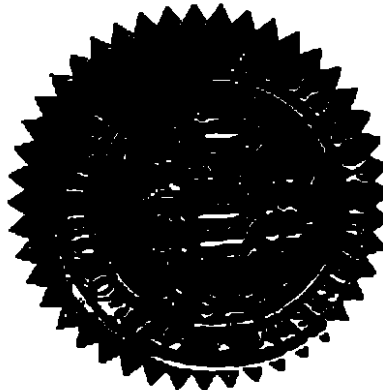
APOSTILLE

(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 7TH DAY OF SEPTEMBER 2004
7. BY: John E McCormac, CPA, NEW JERSEY TREASURER
8. NO. A207429
9. SEAL/STAMP:
10. SIGNATURE



John E McCormac

COD 5023 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 10/656,973 filed SEPTEMBER 5, 2003.

A handwritten signature in cursive script, appearing to read "Christina A. Clickner", is written over a horizontal line.

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



COD 5023

UNITED STATES PATENT AND TRADEMARK OFFICEUNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

APRIL 02, 2004

PTAS



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NUTTER MCCLENNEN & FISH LLP
TRAM ANH T. NGUYEN
WORLD TRADE CENTER WEST
155 SEAPORT BLVD.
BOSTON, MA 02210-2604**UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT**

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

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: 09/05/2003

REEL/FRAME: 014472/0443
NUMBER OF PAGES: 2

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

ASSIGNOR:

ROSENBERG, MEIR

DOC DATE: 09/03/2003

ASSIGNEE:

CODMAN & SHURTLEFF, INC.
325 PARAMOUNT DRIVE
RAYNHAM, MASSACHUSETTS 02767-0350SERIAL NUMBER: 10656973
PATENT NUMBER:FILING DATE: 09/05/2003
ISSUE DATE:SHARON BROOKS, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

ASSIGNMENT

I, Meir Rosenberg, of Newton, Massachusetts, in consideration of One Dollar and other valuable consideration paid to me 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

METHOD AND APPARATUS FOR MANAGING NORMAL PRESSURE HYDROCEPHALUS

described in an application filed on even date herewith 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 I agree, for myself and my 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 I 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.

WITNESS my hand and seal this 3rd day of September, 2003.

By: M. Rosenberg
Meir Rosenberg

Commonwealth of Massachusetts

County of Bristol

Then personally appeared the above named Meir Rosenberg and acknowledged the foregoing instrument to be his free act and deed, before me, this 3rd day of September, 2003.

[SEAL]

Maria O'Connell
Notary Public

My commission expires: 10-11-07

58

**ESTADOS UNIDOS DE AMERICA
A TODOS AQUELLOS A QUIENES EL PRESENTE LLEGUE:**

**DEPARTAMENTO DE COMERCIO DE LOS ESTADOS
UNIDOS
Oficina de Patentes y Marcas de los Estados Unidos**

Septiembre 27 de 2004

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada más adelante, que cumplieron con los requerimientos para concederse una fecha de presentación de acuerdo con 35 USC 111.

Número de Solicitud: 10/656,973

Fecha de Presentación: Septiembre 5 de 2003

**Por la autoridad del
Comisionado de Patentes y Marca**

**(fdo) M.K. HAWKINS
Oficial Certificador
Sello oficial de la Oficina de Patentes y Marcas de los
Estados Unidos de América**

REIVINDICACIONES

1. Un método de regulación del flujo del líquido cerebroespinal en pacientes con hidrocefalia, que comprende:

Proporcionar un sistema de desviación implantable que tiene una válvula de resistencia ajustable para regular el flujo del líquido cerebroespinal dentro y fuera de la cavidad ventricular del paciente y que incluye un elemento sensor para medir una característica fisiológica de la cavidad ventricular y un dispositivo externo controlador del sistema para comunicación con el sistema de desviación implantable, el dispositivo controlador del sistema se ha configurado para efectuar un ajuste de la resistencia de la válvula cuando el dispositivo se aplica al paciente;

Energizar el sistema de desviación implantable con el dispositivo controlador del sistema;

Detectar un valor de la característica fisiológica de la cavidad ventricular medido por el elemento sensor;

Comparar el valor medido con un valor de referencia predeterminado para esa característica fisiológica;

Determinar una resistencia deseada para alcanzar el valor de referencia predeterminado para esa característica fisiológica; y

Ajustar la resistencia actual de la válvula para alcanzar la resistencia deseada.

2. El método de la reivindicación 1, en donde la etapa de detectar un valor de la característica fisiológica comprende comunicar los datos representativos del valor medido de la característica fisiológica desde el elemento sensor hasta el dispositivo controlador del sistema.
3. El método de la reivindicación 2, en donde la etapa de comunicar incluye recibir una señal de entrada generada desde el elemento sensor, en el dispositivo controlador del sistema.
4. El método de la reivindicación 1, en donde la etapa de ajustar una resistencia actual comprende comunicar un comando para ajustar la resistencia, desde el dispositivo controlador del sistema a la válvula.
5. El método de la reivindicación 1, en donde la etapa de ajustar una resistencia actual se repite hasta alcanzar el valor de referencia predeterminado.
6. El método de la reivindicación 4, en donde la etapa de determinar una resistencia deseada incluye transmitir una señal de control de salida generada desde el dispositivo controlador del sistema a la válvula.
7. El método de la reivindicación 1, en donde la etapa de determinar una resistencia deseada incluye determinar si se necesita un incremento o una

disminución en la resistencia actual para alcanzar el valor de referencia predeterminado.

8. El método de la reivindicación 5, en donde la etapa de ajustar una resistencia actual se repite después de que haya transcurrido un período de tiempo suficiente para que el paciente responda a la resistencia actual de la válvula.

9. El método de la reivindicación 1, en donde la característica fisiológica es el volumen, y el elemento sensor está configurado para medir un volumen de la cavidad ventricular.

10. El método de la reivindicación 1, que además incluye la etapa de detectar el valor de una característica fisiológica adicional de la cavidad ventricular.

11. El método de la reivindicación 12 (¿2?), en donde el sistema de desviación implantable incluye un segundo elemento sensor para medir la característica fisiológica adicional.

12. El método de la reivindicación 11, en donde el segundo elemento sensor es un sensor de presión, y característica fisiológica adicional es la presión ventricular.

13. El método de la reivindicación 1, en donde el método se utiliza para manejar el flujo del líquido cerebroespinal en un paciente que sufre de hidrocefalia con presión normal.

14. El método de la reivindicación 13, en donde la etapa de energizar el sistema de desviación implantable ocurre después que el paciente este sintomático de hidrocefalia con presión normal.

15. El método de la reivindicación 14, en donde el método se repite cuando el paciente este sintomático de hidrocefalia con presión normal.

16. El método de la reivindicación 15, en donde el método se repite después de que haya transcurrido un periodo de tiempo suficiente para que el paciente responda a la resistencia actual de la válvula.

17. Un aparato para regular el flujo del líquido cerebroespinal en un paciente con hidrocefalia, que comprende:

Un sistema de desviación implantable que tiene una válvula de resistencia ajustable para regular el flujo del líquido cerebroespinal dentro y fuera de la cavidad ventricular del paciente, y que incluye un elemento sensor para medir una característica fisiológica del paciente; y

Un dispositivo externo controlador del sistema que opera selectivamente para comunicar con el sistema de desviación implantable, estando configurado el

dispositivo controlador del sistema para efectuar un ajuste de la resistencia de la válvula cuando el dispositivo se aplica al paciente;

En donde el elemento sensor es un sensor de volumen que detecta las variaciones volumétricas dentro de la cavidad ventricular.

18. El aparato de la reivindicación 17, en donde el elemento sensor esta acoplado a la válvula.

19. El aparato de la reivindicación 17, en donde el dispositivo controlador del sistema esta configurado para recibir una señal de entrada generada desde el elemento sensor durante la operación, señal de entrada que es representativa de un volumen medido de la cavidad ventricular.

20. El aparato de la reivindicación 19, en donde el dispositivo controlador del sistema además esta configurado para transmitir a la válvula una señal de control de salida que comanda a la válvula para ajustar la resistencia durante la operación.

21. El aparato de la reivindicación 20, en donde el dispositivo controlador del sistema incluye un microprocesador que compara el volumen medido detectado por el sensor de volumen con un volumen de referencia predeterminado para el paciente.

22. El aparato de la reivindicación 21, en donde el volumen de referencia se determina a través de análisis clínico del paciente y el microprocesador se programa con el volumen de referencia antes de la aplicación el dispositivo al paciente.

23. El aparato de la reivindicación 21, en donde el microprocesador se programa para calcular una resistencia deseada de la válvula para alcanzar el volumen de referencia.

24. El aparato de la reivindicación 23, en donde el sistema de desviación implantable incluye además un segundo elemento sensor para medir una característica fisiológica adicional del paciente, estando configurado el segundo elemento sensor para transmitir los datos que representan el valor medido de la característica fisiológica adicional al dispositivo controlador del sistema.

25. El aparato de la reivindicación 24, en donde el segundo elemento sensor es un sensor de presión y la característica fisiológica adicional es la presión ventricular.

26. El aparato de la reivindicación 17, en donde la válvula de resistencia ajustable esta configurada para implantar en una cavidad peritoneal del paciente.

27. El aparato de la reivindicación 20, en donde el dispositivo controlador del sistema además incluye un mecanismo sincronizado de cierre.

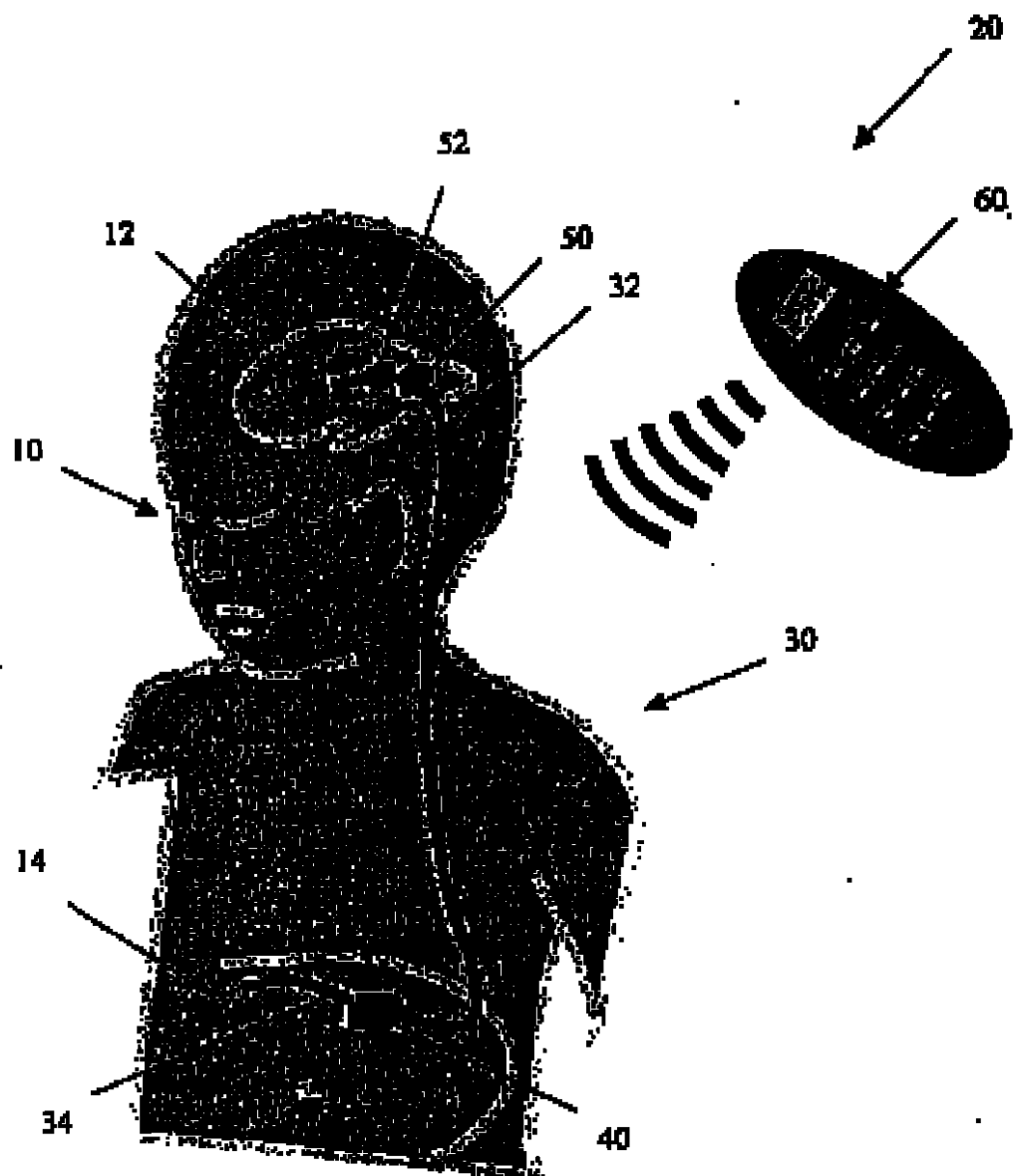


FIG. 1

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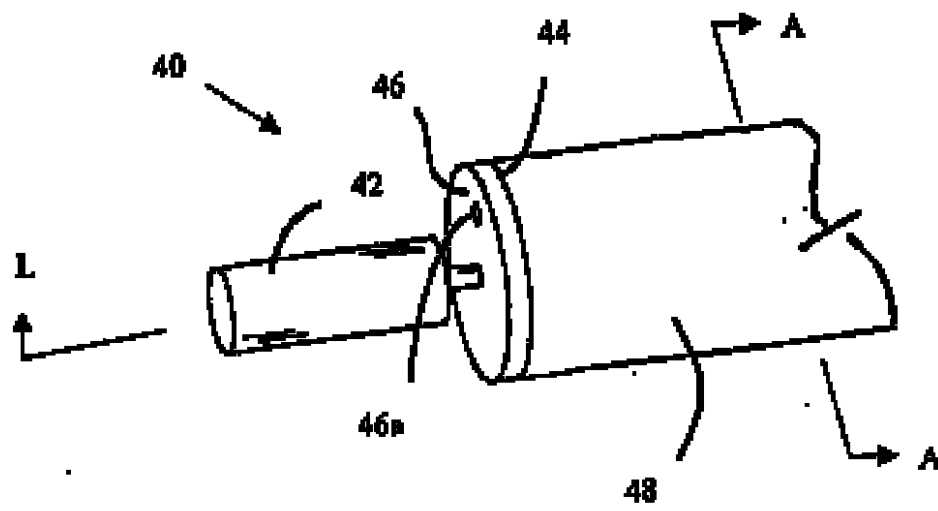


FIG. 2A

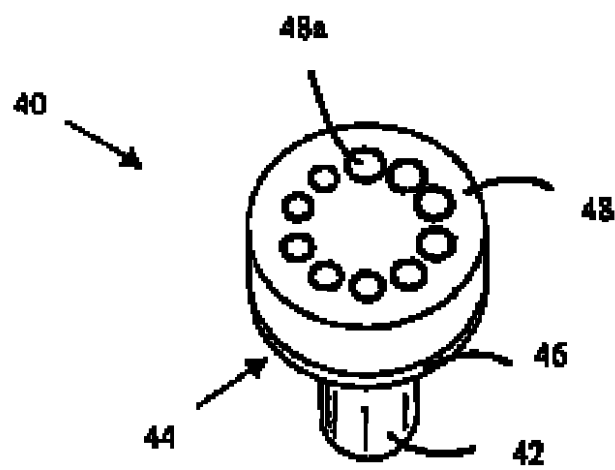


FIG. 2B

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

September 27, 2004

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: 10/636,973

FILING DATE: September 05, 2003

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS




M. K. HAWKINS
Certifying Officer

PTO/SB/08 (2-8-03)
 Approved for use through 07/01/2008. OMB 0451-0002
 U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to supply information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL (Only for new nonprovisional applications under 37 CFR 1.53(a))		Attorney/Dealer No. 022719-0047	
		First Inventor Melr Rosenberg	
		Title METHOD AND APPARATUS FOR MANAGING NORMAL PRESSURE HYDROCEPHALUS	
		Express Mail Label EV324848908US	

APPLICATION ELEMENTS
See MPEP chapter 600 concerning utility patent application contents.

1. ☒ **Fee Transmittal Form** (e.g., PTO/SB/17)
(Attach an original, and a duplicate for fee processing)

2. ☐ **Applicant check** (not entry status).
See 37 CFR 1.27.

3. ☒ **Specification** (Total Pages **21**)
(preferred arrangements per each claim):
 - Claiming the invention
 - Cross References to Related Applications
 - Background Regarding Field of Invention 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 any)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure

4. ☒ **Drawings** (35 U.S.C. 113) (Total Sheets **2**)

5. **Declaration and Power of Attorney** (Total Sheets **2**)
 a. ☒ **Newly executed** (original or copy)
 b. ☐ **Copy from a prior application** (37 CFR 1.53(d))
(For nonprovisional applications with fee 13 corrected)
 c. ☐ **SELECTION OF INVENTORS**
(Sign statement attached during invention)
 signed in the prior application,
 see 37 CFR 1.53(f)(2) and 1.53(g)

6. ☒ **Application Data Sheet** See 37 CFR 1.78

ADDRESS TO:
 M/S Patent Application
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

7. ☐ **CD-ROM or CD-R** in duplicate, large table or
 Computer Program (Appendix)
 8. **Machine-readable form** (e.g., Sequence Listing)
(If applicable, all necessary)
 a. ☐ **Computer Readable Form (CRF)**
 b. **Specification Sequence Listing** on:
 (☐ **CD-ROM or CD-R** (2 copies) or ☐ **Paper**)
 c. ☐ **Statements** verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☒ **Assignment Papers** (cover sheet & document(s))

10. ☐ **37 CFR 1.78(b) Statement**
(when there is an assignment)

11. ☐ **English Translation** (Document) (if applicable)

12. ☐ **Information Disclosure** ☐ **Copies of IDS**
Statement (IDS/PTO-1449) Claims

13. ☐ **Preliminary Amendment**

14. ☒ **Return Receipt Postcard** (MPEP 603)
(Should be specifically described)

15. ☐ **Certified Copy of Priority Document(s)**
(If foreign priority is claimed)

16. ☐ **Recapitulation Request** under 35 U.S.C. 122 (a)(2)(B)(i)
(Applicant must attach form PTO/SB/95 or its equivalent)

17. ☒ **Other:** **Application Title Sheet**
Check in the Amount of \$478.00
Check in the Amount of \$40.00

18. If a **CONTINUING APPLICATION**, check appropriate box, and specify the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.78:

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

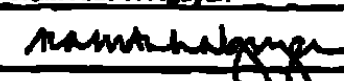
Prior application information: Examiner _____ Act Unit: _____

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

19. CORRESPONDENCE ADDRESS

☒ **Customer Number:** **021125** OR ☐ **Correspondence address below**

Name NUTTER MCCLENNEN & FISH LLP					
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Name (Print/Type)	Tram Anh T. Nguyen	Registration No. (Attorney/Agent)	47,257
Signature		Date	September 5, 2003

1252610.1

Application Data Sheet**Application Information**

Application Type::	Regular
Subject Matter::	Utility
Suggested Group Art Unit::	N/A
CD-ROM or CD-R?::	None
Sequence submission?::	None
Computer Readable Form (CRF)?::	No
Title::	METHOD AND APPARATUS FOR MANAGING NORMAL PRESSURE HYDROCEPHALUS
Attorney Docket Number::	022719-0047
Request for Early Publication?::	No
Request for Non-Publication?::	No
Total Drawing Sheets::	2
Small Entity?::	No
Petition included?::	No
Secrecy Order in Parent Appl.?::	No

Applicant Information

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
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Family Name::	Rosenberg
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State or Province of Residence::	MA
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State or Province of mailing address::	MA

Postal or Zip Code of mailing address:: 02459

Correspondence Information

Correspondence Customer Number:: 021125

Representative Information

Representative Customer Number:: 021125

Assignee Information

Assignee name:: CODMAN & SHURTLEFF, INC.

Street of mailing address:: 325 Paramount Drive

City of mailing address:: Raynham

State or Province of mailing address:: MA

Postal or Zip Code of mailing address:: 02767-0350

73

APPLICATION
FOR
UNITED STATES PATENT

Entitled:

**METHOD AND APPARATUS
FOR
MANAGING NORMAL PRESSURE HYDROCEPHALUS**

Inventor:

MEIR ROSENBERG



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Tel: 617-439-2000
Fax: 617-310-9748

Atty. Docket No. 22719-47

EXPRESS MAIL NO.: EV324848908US

Express Mail No.: EV324848908US
Date of Mailing: September 5, 2003
Atty. Docket No.: 22719-47

METHOD AND APPARATUS FOR MANAGING NORMAL PRESSURE HYDROCEPHALUS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] Not applicable.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

[0002] Not applicable.

FIELD OF THE INVENTION

[0003] The present invention relates to a method and apparatus for managing hydrocephalus in a patient. More particularly, the invention relates to a method and apparatus for draining cerebrospinal fluid in a hydrocephalus patient at a rate responsive to volumetric variations in the patient's ventricular cavity. Even more particularly, the invention relates to a shunt system having an adjustable resistance valve and a volume sensor for regulating the drainage of cerebrospinal fluid in a ventricular cavity undergoing volumetric variations, and a method of using such a shunt system to manage cerebrospinal fluid flow in patients afflicted with normal pressure hydrocephalus.

BACKGROUND OF THE INVENTION

[0004] Hydrocephalus is a condition afflicting patients who are unable to regulate cerebrospinal fluid flow through their body's own natural pathways. Cerebrospinal fluid (CSF) is normally produced by the choroid plexus of the brain and carries essential nutrients, hormones, and other cellular components to various portions of the brain as the fluid circulates through the ventricular system. Along the way, the CSF also helps absorb shock and cushions the brain as the fluid diffuses over the brain and spinal cord. Cerebrospinal fluid that is not recirculated eventually drains into the sagittal sinus where it is naturally absorbed by the body's venous system. In a patient suffering from hydrocephalus, the CSF absorption rate fails to keep up with the production rate, either because of an obstruction along the natural CSF pathway or due to diseased choroid plexus which increases CSF formation. The unabsorbed or excess CSF

accumulates in the ventricles of the patient's brain, leading to an increase in intracranial pressure. If left untreated, the increased intracranial pressure can lead to serious medical conditions such as compression of the brain tissue and impaired blood flow to the brain, with such potential consequences as coma and/or death.

[0005] The conventional treatment for hydrocephalus patients has involved draining the excess fluid away from the ventricles and rerouting the excess cerebrospinal fluid to another area of the patient's body, such as the peritoneum or vascular system. An implantable drainage system, commonly referred to as a shunt, is often used to carry out the transfer of fluid and restore the balance between the formation and absorption of CSF in the patient. In order to install the shunt system, a scalp incision is made and a small hole is drilled in the skull. A proximal, or ventricular catheter is installed in the ventricular cavity of the patient's brain, while a distal, or drainage catheter is installed in that portion of the patient's body where the excess fluid is to be reintroduced.

[0006] To regulate the flow of cerebrospinal fluid between the proximal and distal ends of the shunt system, the main body of the shunt usually includes a pump or one-way control valve. Generally, shunt systems include a valve mechanism that operates by permitting fluid flow only once the fluid pressure reaches a certain threshold level. That is, fluid enters the valve only when the fluid pressure overcomes the valve mechanism's resistance to open. Some valve mechanisms permit the non-invasive adjustment, or programming, of the opening pressure level at which fluid flow commences. These passive relief valves can generally be characterized as falling within one of two categories. Differential pressure valves regulate the differential pressure across the shunt, i.e., the difference of the pressures captured at the proximal and distal ends of the shunt system. Variable resistance valves regulate the flow of CSF through the shunt by varying the resistance of the valve, i.e., adjusting the ratio between differential pressure across the valve and the CSF flow through the valve.

[0007] Shunts having valve mechanisms that continuously drain CSF are well known, as are shunts with valves that control and/or adjust the opening pressure and/or drainage rate of the patient's CSF. In congenital hydrocephalus patients (i.e., the hydrocephalus is acquired at birth), and especially in pediatric patients, such current shunt devices have proven to be successful in

regulating CSF flow. However, these same shunt devices have been less effective in patients who suffer from idiopathic normal pressure hydrocephalus, a type of hydrocephalus usually acquired in the later stages of life. Normal pressure hydrocephalus is characterized by enlarged ventricles in the patient's brain, though the ventricles themselves may register as having "normal" pressure. Normal pressure hydrocephalus typically affects middle-aged to elderly adults, as the disease itself is often due to the onset of old age. Classic symptoms include dementia, gait instability, and urinary incontinence. Because the disease produces a "normal" pressure reading, diagnosis is made by correlating the patient symptoms with the size of the ventricles via CT and/or MRI, rather than by detecting the pressure within the ventricular cavities. Presumably in normal pressure hydrocephalus, the pressure in the ventricles was at some time sufficient to cause them to dilate. Once the ventricles expanded, the pressure of the fluid within them returned to "normal" pressure. In older patients, ventricular compliance becomes reduced and so the ventricles are no longer able to contract back to their original size or volume in an appropriate amount of time. As a result, the ventricles remain enlarged, and the patient suffers from neurological dysfunction due to the compression of the neighboring parts of the brain by the overexpanded ventricles.

[0008] Most of the currently available shunt devices are configured to be responsive to changes in proximal, distal and/or atmospheric pressure, i.e., the shunts respond to variations in proximal and distal pressures and/or atmospheric pressure. Whereas these shunts have been effective in regulating cerebrospinal fluid in congenital hydrocephalus patients, these shunts have not proven as effective in patients having normal pressure hydrocephalus because the adjusted opening pressure levels do not account for changes in the volume of the ventricular cavity being drained. Since normal pressure hydrocephalus patients experience more pronounced volumetric variations in their ventricular cavities than ventricular pressure variations, the passive relief valves currently available are less effective in these patients who require drainage rate adjustment based on perceived changes in volume. There is thus a need for a shunt system that can adjust its drainage rate or valve resistance in response to changes in ventricular volume as well as pressure changes in the ventricular cavity, in order to achieve a desirable drainage rate, and a method for managing CSF flow in normal pressure hydrocephalus patients using such a shunt system.

SUMMARY OF THE INVENTION

[0009] The present invention achieves the aforementioned goals by providing an adjustable drainage system for regulating CSF flow in a hydrocephalus patient where the drainage rate is adjusted in response to variations in the ventricular volume of the patient. The system includes an adjustable resistance valve and a volume sensor that can be periodically energized with an external system controller device by the patient or attending physician to determine when, or if, a change in the ventricular volume has occurred. The system enables the user to adjust the valve's resistance in response to changes in the ventricular volume using the controller device so that a target ventricular volume can be achieved. Also provided is a method of regulating the drainage of CSF from the cranial cavity of the patient using the system of the present invention.

[0010] In one exemplary embodiment, the present invention provides a method of regulating CSF flow in a hydrocephalus patient comprising the step of providing an implantable shunt system having an adjustable resistance valve for regulating the flow of CSF into and out of a ventricular cavity of the patient, and including a sensor element for measuring a physiological characteristic of the ventricular cavity. The method also provides an external system controller device that is selectively operable for energizing and communicating with the implantable shunt system. In operation, the system controller device is configured to receive information from the sensor element and also effect an adjustment of the resistance of the valve when the system controller device has been applied to the patient.

[0011] In a hydrocephalus patient having an implanted shunt system of the present invention, either the patient or the attending physician can selectively operate the system controller device by applying the device to the patient to energize the implanted shunt system. The system controller device is configured to detect a value of the physiological characteristic of the ventricular cavity, as measured by the sensor element. The measured value of the physiological characteristic is compared to a predetermined target value for that physiological characteristic. The predetermined target value can be determined through clinical assessment of the patient and is therefore customized for each particular patient. This target value is then preset into the system controller device. When, or if, the system controller device detects a difference between the measured value and the target value (i.e., the measured value is higher or

lower than the target value), the device can be used to command the valve to increase or decrease its resistance accordingly. For instance, the valve's resistance is decreased if the measured volume is higher than the target volume; conversely, resistance is increased if the measured volume is lower than the target volume. If the measured value is within an acceptable range of the target value is detected, then no change is made and the current resistance is maintained. This feedback mechanism serves to maintain the target value of the physiological characteristic over time.

[0012] During the operation of the external system controller device (i.e., when the device is applied to the patient and the implantable shunt system is energized), data is communicated between the device and the implantable shunt system. The sensor element communicates data representative of the measured value of the physiological characteristic to the system controller device. The system controller device compares the measured value to the target value for that patient, and communicates a command to the valve to adjust its resistance accordingly. For example, the system controller device can detect a value of the physiological characteristic measured by the sensor element by receiving an input signal generated from the sensor element that contains data about the measured value of the physiological characteristic. Once received, the system controller device performs a simple algorithm to determine whether the measured value is higher or lower than, or within an acceptable range of the target value for the patient. Based on this determination, the resistance of the valve is either increased, decreased or maintained at the same resistance with no changes made, depending on whether the measured value is higher, lower, or essentially the same as the target value, by generating and transmitting an output control signal from the device to the valve that commands the valve to adjust its resistance accordingly.

[0013] In one aspect of the invention, the physiological characteristic to be measured is ventricular volume, and the sensor element is a volume sensor configured to measure a volume of the ventricular cavity. The method of the present invention is therefore especially useful for managing CSF flow in a patient afflicted with normal pressure hydrocephalus, which is characterized by fluctuations in ventricular volume. It is contemplated that the present method can be performed when the patient becomes symptomatic of normal pressure hydrocephalus, i.e., becomes sick, or experiences discomfort or disorientation. The present method can also be

repeated whenever the patient becomes symptomatic, or ill. Thus, when the patient manifests symptoms of the disease, or becomes ill, the external system controller device can be applied to the patient to detect any variations in the ventricular volume. If the volume has varied from the target volume determined for this patient and which has been preset in the device, then the present method can be carried out to adjust the resistance of the valve in an attempt to restore the ventricular volume back to its target volume.

[0014] In another aspect of the invention, the method also includes the step of detecting the value of another physiological characteristic of the ventricular cavity. For instance, the implantable shunt system can include a second sensor element for measuring an additional physiological characteristic. The second sensor element can be, for example, a pressure sensor, and the second physiological characteristic can be ventricular pressure. Thus, the method of the present invention can involve the detection of either ventricular volume or ventricular pressure, or both, and assessing the variations in either or both of these physiological characteristics when adjusting the resistance of the valve.

[0015] The present invention also provides an apparatus for regulating CSF flow in a hydrocephalus patient which comprises an implantable shunt system having an adjustable resistance valve for regulating the flow of CSF into and out of a ventricular cavity of the patient, and includes a sensor element for measuring a physiological characteristic of the patient. The sensor element can be coupled to the valve, or it can be separate from the valve itself. The apparatus also comprises an external system controller device that is selectively operable for energizing and communicating with the implantable shunt system. In operation, the system controller device is configured to effect an adjustment of the resistance of the valve when the device is applied to the patient (i.e., when the system is energized by the system controller device). In an exemplary embodiment, the sensor element is a volume sensor for detecting volumetric variations within the ventricular cavity of the patient.

[0016] The implantable shunt system and external system controller device of the present apparatus are configured to communicate data between one another during operation (i.e., when the device is applied to the patient and the implanted shunt system is energized). For instance, the system controller device can be configured to energize and receive an input signal generated

from the sensor element that is representative of the measured value of the physiological characteristic. In one aspect, the physiological characteristic is a measured volume of the ventricular cavity of the patient. The system controller device can also be configured to generate and transmit to the valve an output control signal that commands the valve to adjust its resistance.

[0017] In another aspect of the invention, the system controller device can include a processing unit such as a microprocessor which enables the device to compare the measured volume detected by the volume sensor to a predetermined target volume for the patient. The predetermined target value can be ascertained through clinical assessment of the patient and is therefore customized for each particular patient. This target value is then preset or programmed into the system controller device. If, during operation, the system controller device detects a difference between the measured value and the target value, the microprocessor is programmed to increase or decrease the resistance for the valve, depending on whether the measured value is higher or lower than the target value, in order to maintain the target ventricular volume for the patient over time. To adjust the valve, the microprocessor can generate an output control signal to the valve which commands it to adjust its current resistance to the desired resistance. If, however, the measured value is the same as, or falls within an acceptable range of the target value, then the system controller device is programmed to make no changes to the resistance level. To safeguard against repeated or excessive valve adjustments within a short window of time, which could produce deleterious health consequences for the patient, the system controller device can include a timed shutoff mechanism which would limit the user's ability to adjust the valve with the system controller device. For example, the system controller device's valve adjustment features can be configured to deactivate after each use until a preset amount of time (e.g., a day, two days, a week, etc.) has passed whereby the valve adjustment feature can be automatically reactivated.

[0018] In yet another aspect of the invention, the implantable shunt system can further include a second sensor element for measuring an additional physiological characteristic of the patient. Like the first sensor element, the second sensor element can be configured to transmit data representing the measured value of the second physiological characteristic to the system controller device. The second sensor element can be coupled to the valve, or it can be separate

from the valve itself. In an exemplary embodiment, the second sensor element is a pressure sensor and the additional physiological characteristic is ventricular pressure of the patient.

[0019] 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

[0020] The invention can be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

[0021] FIG. 1 is a perspective view of the shunt system and system controller device of the present invention;

[0022] FIG. 2A is a side perspective view of an embodiment of the adjustable resistance valve of the present invention; and

[0023] FIG. 2B is a cross-sectional perspective view of the adjustable resistance valve of FIG. 2A along lines A—A.

DETAILED DESCRIPTION OF THE INVENTION

[0024] Described herein is a method and apparatus for regulating CSF flow in a hydrocephalus patient by adjusting the drainage rate of excess CSF in response to variations in the ventricular volume of the patient. The method and apparatus of the present invention regulates the drainage of CSF from the cranial cavity of a hydrocephalus patient. The apparatus includes an adjustable valve and a volume sensor that can be periodically energized by the patient or attending physician to determine when, or if, a change in the ventricular volume has occurred, and whether corrective adjustment of the valve's resistance should be made.

[0025] Turning now to the drawings and particularly to FIG. 1, an exemplary embodiment of an apparatus 20 in accordance with the present invention is illustrated. The apparatus 20 comprises a shunt system 30 shown herein as being implanted within a hydrocephalus patient 10. The implantable shunt system 30 includes a proximal or ventricular

catheter 32 installed in a ventricular cavity 12 of the patient 10, and a distal or drainage catheter 34 installed in the peritoneum 14 of the patient 10. Extending between the ventricular and drainage catheters 32, 34 is an adjustable resistance valve 40 for regulating the flow of CSF into and out of the ventricular cavity 12 of the patient 10. The valve 40 can be located anywhere along the fluid pathway of the shunt system 30 such as in the patient's cranium. Preferably, the valve 40 is located within the peritoneal cavity 14 of the patient 10 as illustrated, so that size constraints for the valve 40 are minimized (i.e., larger valves 40 can be implanted within the peritoneum than adjacent to the skull).

[0026] Also included with the apparatus 20 is a sensor element 50 for measuring a physiological characteristic of the patient. The sensor element 50 can be coupled to the valve 40, or it can be separate from the valve 40 as shown in FIG. 1. Further, while the sensor element 50 is shown as being positioned within the CSF flow pathway of the shunt system 30, it is understood that sensor element 50 can be located outside of the CSF flow pathway though still residing within the ventricular cavity 12 of the patient 10. In an exemplary embodiment, the sensor element 50 is a volume sensor for detecting volumetric variations within the ventricular cavity 12 of the patient 10. The apparatus 20 also comprises an external system controller device 60 that is selectively operable for energizing and communicating with the implantable shunt system 30. In operation, the system controller device 60 is configured to effect an adjustment of the resistance of the valve 40 when the device 60 is applied to the patient (i.e., when the system 30 is energized by the system controller device 60).

[0027] In the present invention, the implantable shunt system 30 and external system controller device 60 are configured to communicate data between one another when in operation (i.e., when the device 60 is applied to the patient and the implanted shunt system 30 is energized). For example, the system controller device 60 can be configured to energize and receive an input signal generated from the sensor element 50 that is representative of the measured value of the physiological characteristic. In one aspect, the sensor element 50 is a volume sensor and the physiological characteristic is a measured volume of the ventricular cavity 12 of the patient 10. The system controller device 60 can also be configured to generate and transmit to the valve 40 an output control signal that commands the valve 40 to adjust its resistance.

[0028] The implantable shunt system 30 of the present invention can further include a second sensor element 52 for measuring an additional physiological characteristic of the patient. Like the first sensor element 50, the second sensor element 52 can be configured to transmit data representing the measured value of the second physiological characteristic to the system controller device 60. The second sensor element 52 can be coupled to the valve 40, or it can be separate from the valve 40 itself. In an exemplary embodiment, the second sensor element 52 is a pressure sensor and the additional physiological characteristic is ventricular pressure of the patient 10.

[0029] The shunt system 30 and system controller device 60 of the present invention can be equipped with electronic circuitry similar to those for medical telemetry systems that communicate physiological data (e.g., temperature, pressure, etc.) between an implant and a receiver unit. For example, the sensor element 50 can be configured to generate an analog data signal that is then converted electronically to a digital pulse which is then transmitted by radiofrequency (RF) to the system controller device 60. One skilled in the art will recognize that these are merely examples of the forms of remote communication suitable for the present invention, and that other forms of non-invasive communication can be utilized without departing from the scope of the present invention.

[0030] In another aspect of the invention, the system controller device 60 can include a processing unit (e.g., a microprocessor) which enables the device 60 to compare the measured volume detected by the sensor element 50 to a predetermined target volume for the patient 10. The predetermined target value can be ascertained through clinical assessment of the patient 10 and is therefore customized for each particular patient. This target value is then preset or programmed into the system controller device 60. During operation, the system controller device 60 energizes the shunt system 30 and detects the measured value of the physiological characteristic. The device 60 operates according to an algorithm which ascertains whether the measured value is higher than, lower than, or within an acceptable range of the target value. Based on this assessment, the algorithm will then determine whether the resistance should be increased, decreased or maintained accordingly in order to achieve the target ventricular volume for the patient 10. For instance, the valve's resistance is decreased if the measured volume is higher than the target volume; conversely, the resistance of the valve 40 is increased if the

measured volume is lower than the target volume. The microprocessor can then generate an output control signal to the valve 40 which commands it to adjust its current resistance to the desired resistance. If the measured value is essentially the same as, or within an acceptable range of the target value, then the current resistance is maintained and no changes are made.

[0031] In accordance with one embodiment of the present invention, the adjustable resistance valve 40 includes an actuator 42 as shown in FIGS. 2A and 2B. The actuator 42 allows the selection of the resistance to flow of the valve 40. The actuator 42 is coupled to a selection mechanism 44 comprising a disc 46 having at least one aperture 46a traversing the disc 46 near its periphery in a direction parallel to its longitudinal axis L. The valve 40 further includes a multi-lumen resistance catheter 48 that is configured to couple to the drainage or distal catheter at one end and the selection mechanism 44 at the other end. The multi-lumen resistance catheter 48 comprising a set of resistors 48a, each resistor 48a defining a different resistance to flow and being configured as a passage or channel that extends parallel to the longitudinal axis L of the disc 46 and catheter 48.

[0032] In general, the resistance of the valve 40 is adjusted by rotating the actuator 42 in order to align the aperture 46a of the disc 46 of the selection mechanism 44 with a resistor 48a. That is, the actuator 42 enables the relative positioning of the selection mechanism 44 with respect to the resistance system 48 by a rotational movement of the disc 46 to axially align the aperture 46a with one of the resistors 48a of the resistance system 48. The disc 46 is positioned so as to allow the flow of CSF to traverse the aperture 46a and resistor 48a and exit through the valve 40. The actuator 42 can comprise a motor connected to the disc 46 in order to drive the rotational movement of the disc 46 with respect to the catheter 48. The size of the aperture 46a should be chosen so as not to limit the resistance of the resistor 48a.

[0033] As illustrated in FIGS. 2A and 2B, the selection mechanism 44 and catheter 48 together form an essentially cylindrical shape. Within the catheter 48, the resistors 48a are disposed so as to form a set of passages parallel to each other and to the longitudinal axis of the catheter 48 and the disc 46. The openings of the resistors 48a face the rotational path of the passage 46a of disc 46. In order to provide a set of resistors 48a having different resistances, the resistors 48a are each configured with the same length and a different internal diameter. The

resistors 48a can be configured with relatively large diameters to reduce their propensity to clog. Since the resistors 48a are contained within a catheter 48 which provides them with structural integrity, the lengths of each of the resistors 48a can be as long as necessary to achieve the desired resistance. The resistors 48a of the catheter 48 are disposed on a circular trajectory so as to face the rotational path of the passage 46a of the disc 46.

[0034] During operation, if the external system controller device 60 detects that the measured value of the physiological characteristic is higher or lower than the preset target value for that characteristic, the device sends a command to the actuator 42 to rotate the disc 46 in order to align the aperture 46a with a selected resistor 48a having a higher or lower resistance than the currently used resistor 48a. For instance, if the measured value is higher than the target value, then the disc 46 is rotated so as to select a resistor 48a having a lower resistance. The selection can be done incrementally, i.e., the disc 46 can be rotated stepwise until the appropriate resistance is attained and the system controller device 60 detects that the measured value is approaching or has approached the target value for that patient. This stepwise adjustment of resistance enables the present invention to operate effectively even when, over time and with use, the resistors 48a become clogged with particulate matter such as blood cells, a potential problem with the resistors 48a having small internal diameters. Since the present invention relies upon the relative resistance or inner diameter of each resistor 48a to operate, rather than the absolute size or resistance level of any particular resistor 48a, the catheter 48 is still effective even when some of the resistors 48a are clogged. This is because the user can bypass (i.e., move incrementally past) any clogged resistors 48a during the adjustment procedure and rotate the catheter 48 until a suitable resistor 48a having either a higher or lower resistance relative to the current resistance is detected. If no difference is detected between the measured value and the target value, then the system controller device 60 is programmed to make no changes and maintain the current resistance of the valve 40.

[0035] In general, the internal diameters of the resistors 48a of the multi-lumen resistance catheter 48 are chosen so as to provide a range of resistance to CSF flow, preferably between about 0 – 50 mm Hg/ml/min. For example, the internal diameters of the resistors 48a can be in the range of approximately 0.30 mm to about 0.60 mm. The valve 40 is configured such that turning the disc 46 adjusts the resistance to CSF flow through the valve 40. The adjustment

process can be done after implantation and non-invasively by means of the actuator 42. As an example, in valve 40 the rotation of the actuator 42 positions the disc 46 to allow the CSF to pass through the desired resistor or passage 48a of the catheter 48 when the resistor 48a is aligned with the aperture 46a of the disc 46. The ability to adjust the resistance to flow of the valve 40 non-invasively after implantation enables the surgeon to optimally fit the patient physiology and provide an optimal treatment of the patient's pathology, in order to match CSF flow rate according to the resorption rate of the drainage site.

[0036] Also provided with the present invention is a method of regulating the drainage of cerebrospinal fluid from the cranial cavity of the patient in response to changes in the patient's ventricular volume. The method involves adjusting a resistance of an implanted shunt system so that the drainage rate is responsive to ventricular pressure and the volume of the patient's ventricular cavity stays constant. In one exemplary embodiment, the method comprises the steps of managing CSF flow in a hydrocephalus patient using the implantable shunt system 30 and external system controller device 60 described herein.

[0037] In a hydrocephalus patient 10 having an implanted shunt system 30 of the present invention, either the patient or the attending physician can selectively operate the system controller device 60 by applying the device 60 to the patient 10 to energize the implanted shunt system 30. The system controller device 60 is configured to detect a value of the physiological characteristic of the ventricular cavity, as measured by the sensor element 50. The measured value of the physiological characteristic is compared to a predetermined target value for that physiological characteristic. The predetermined target value can be determined through clinical assessment of the patient and is therefore customized for each particular patient. This target value is then programmed or preset into the system controller device 60. When, or if, the system controller device 60 detects a difference between the measured value and the target value, the device 60 then determines whether the resistance for the valve should be increased or decreased accordingly in order to achieve the predetermined target value for that physiological characteristic. Using the system controller device 60, the current resistance of the valve 40 is adjusted in order to achieve the desired resistance. If the measured value is essentially the same as, or within an acceptable range of the target value, then no change is made to the resistance of the valve.

[0038] During the operation of the external system controller device 60 (i.e., when the device is applied to the patient 10 and the implantable shunt system 30 is energized), data is communicated between the device 60 and the implantable shunt system 30. The sensor element 50 communicates data representative of the measured value of the physiological characteristic to the system controller device 60, and the system controller device 60 communicates a command to adjust the resistance to the valve 40. For example, the system controller device 60 can detect a value of the physiological characteristic measured by the sensor element 50 by receiving an input signal generated from the sensor element 50 that contains data about the measured value of the physiological characteristic. Similarly, the system controller device 60 can adjust the resistance of the valve 40 by generating and transmitting an output control signal to the valve 40 that commands the valve 40 to adjust its resistance.

[0039] In one aspect of the method, the physiological characteristic to be measured is ventricular volume, and the sensor element 50 is a volume sensor configured to measure a volume of the ventricular cavity 12 of the patient. The method of the present invention is therefore especially useful for managing CSF flow in a patient afflicted with normal pressure hydrocephalus, which is characterized by fluctuations in ventricular volume. It is contemplated that the present method can be performed when the patient 10 becomes symptomatic of normal pressure hydrocephalus, i.e., becomes sick, or experiences discomfort or disorientation. The present method can also be repeated whenever the patient 10 becomes symptomatic, or ill. Thus, when the patient 10 manifests symptoms of the disease, or becomes ill, the external system controller device 60 can be applied to the patient 10 to detect any variations in the ventricular volume. If the volume has varied from the target volume determined for this patient 10 and which has been preset in the device 60, then the present method can be carried out to adjust the resistance of the valve 40 in an attempt to restore the ventricular volume back to its target volume.

[0040] In another aspect of the invention, the value of another physiological characteristic of the ventricular cavity 12 can also be detected. For instance, the implantable shunt system 30 can be provided with a second sensor element for measuring an additional physiological characteristic. The second sensor element 52 can be, for example, a pressure sensor, and the second physiological characteristic can be ventricular pressure. Thus, the method

of the present invention can involve the detection of either ventricular volume or ventricular pressure, or both, and assessing the variations in either or both of these physiological characteristics when adjusting the resistance of the valve 40.

[0041] In an application of the method of the present invention, the patient 10 experiences discomfort and pain. The system controller device 60 is applied onto the patient 10 so that the shunt system 30 is energized and data is communicated from the shunt system 30 to the device 60. The device 60 can be applied by either the patient himself or his attending physician. If the measured value is the same as, or falls within an acceptable range of the target value, then the system controller device 60 is programmed to make no changes to the resistance. If, however, the external system controller device 60 detects that the measured ventricular volume is higher or lower than the preset target ventricular volume, the device 60 sends a command to the actuator 42 to rotate the disc 46 in order to align the aperture 46a with a selected resistor 48a having a higher or lower resistance than the currently used resistor 48a. For instance, if the measured ventricular volume is higher than the target ventricular volume, then the device 60 commands the disc 46 to rotate an increment so as to select a resistor 48a having a lower resistance. Then, after some time has elapsed (e.g., a day, two days, a week, etc.) sufficient to allow the patient's physiology to respond to the valve's new resistance setting, and the patient still experiences discomfort or pain, or simply wants to determine the current ventricular volume, the system controller device 60 can again be applied to the patient 10 to measure a current ventricular volume. If the device 60 does not detect a change in the measured ventricular volume from the previous reading, the device 60 sends another command to the valve 40 to decrease the resistance by rotating the disc 46 another increment.

[0042] It is contemplated that the above steps can be repeated until an appropriate resistance is attained and the system controller device 60 detects that the measured ventricular volume is approaching or has approached the target ventricular volume for that patient 10. For example, the above steps can be repeated whenever the patient begins to experience pain or discomfort. However, to safeguard against repeated or excessive valve adjustments within a short window of time, which could produce deleterious health consequences for the patient, the system controller device 60 can include a timed shutoff mechanism which would limit the user's ability to adjust the valve 40 with the system controller device 60 in a given time period. For

example, the system controller device's valve adjustment features can be configured to deactivate after each use until a preset amount of time (e.g., a day, two days, a week, etc.) has passed whereby the valve adjustment feature is automatically reactivated. Such a safeguard ensures that a sufficient amount of time passes between adjustments so that the patient's physiology does not incur rapid CSF flow changes in a short amount of time. Of course, it is contemplated that the system controller device 60 can still be capable of detecting the volume of the patient's ventricular cavity even when the device's valve adjustment features are not active. Hence, the patient can continue to monitor his ventricular volume using the system controller device 60 even between stages of adjusting the valve 40.

[0043] While the present invention has been described and illustrated in relation to the treatment of normal pressure hydrocephalus, the method and apparatus described herein are equally suitable for the treatment of other neurological disorders that result in hydrocephalus. It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. All references cited herein are expressly incorporated by reference in their entirety.

[0044] What is claimed is:

CLAIMS

1. A method of regulating cerebrospinal fluid flow in a hydrocephalus patient, comprising:
providing an implantable shunt system having an adjustable resistance valve for regulating the flow of cerebrospinal fluid into and out of a ventricular cavity of the patient and including a sensor element for measuring a physiological characteristic of the ventricular cavity, and a selectively operable external system controller device for communicating with the implantable shunt system, the system controller device being configured to effect an adjustment of the resistance of the valve when the device is applied to the patient;
energizing the implantable shunt system with the system controller device;
detecting a value of the physiological characteristic of the ventricular cavity measured by the sensor element;
comparing the measured value with a predetermined target value for that physiological characteristic;
determining a desired resistance to achieve the predetermined target value for that physiological characteristic; and
adjusting a current resistance of the valve to achieve the desired resistance.
2. The method of claim 1, wherein the step of detecting a value of the physiological characteristic comprises communicating data representative of the measured value of the physiological characteristic from the sensor element to the system controller device.
3. The method of claim 2, wherein the step of communicating includes receiving an input signal generated from the sensor element with the system controller device.
4. The method of claim 1, wherein the step of adjusting a current resistance comprises communicating a command to adjust the resistance from the system controller device to the valve.
5. The method of claim 1, wherein the step of adjusting a current resistance is repeated until the predetermined target value is reached.

6. The method of claim 4, wherein the step of communicating includes transmitting an output control signal generated from the system controller device to the valve.
7. The method of claim 1, wherein the step of determining a desired resistance includes determining whether an increase or decrease in the current resistance is necessary to achieve the predetermined target value.
8. The method of claim 5, wherein the step of adjusting a current resistance is repeated after a period of time has elapsed sufficient for the patient to respond to the current resistance of the valve.
9. The method of claim 1, wherein the physiological characteristic is volume, and the sensor element is configured to measure a volume of the ventricular cavity.
10. The method of claim 1, further including the step of detecting the value of an additional physiological characteristic of the ventricular cavity.
11. The method of claim 12, wherein the implantable shunt system includes a second sensor element for measuring the additional physiological characteristic.
12. The method of claim 11, wherein the second sensor element is a pressure sensor, and the additional physiological characteristic is ventricular pressure.
13. The method of claim 1, wherein the method is used to manage cerebrospinal fluid flow in a patient afflicted with normal pressure hydrocephalus.
14. The method of claim 13, wherein the step of energizing the implantable shunt system occurs after the patient becomes symptomatic of normal pressure hydrocephalus.
15. The method of claim 14, wherein the method is repeated when the patient becomes symptomatic of normal pressure hydrocephalus.

16. The method of claim 15, wherein the method is repeated after a period of time has elapsed sufficient for the patient to respond to the current resistance of the valve.
17. An apparatus for regulating cerebrospinal fluid flow in a hydrocephalus patient, comprising:
an implantable shunt system having an adjustable resistance valve for regulating the flow of cerebrospinal fluid into and out of a ventricular cavity of the patient, and including a sensor element for measuring a physiological characteristic of the patient; and
a selectively operable external system controller device for communicating with the implantable shunt system, the system controller device being configured to effect an adjustment of the resistance of the valve when the device is applied to the patient;
wherein the sensor element is a volume sensor for detecting volumetric variations within the ventricular cavity.
18. The apparatus of claim 17, wherein the sensor element is coupled to the valve.
19. The apparatus of claim 17, wherein the system controller device is configured to receive an input signal generated from the sensor element during operation, the input signal being representative of a measured volume of the ventricular cavity.
20. The apparatus of claim 19, wherein the system controller device is further configured to transmit to the valve an output control signal that commands the valve to adjust the resistance during operation.
21. The apparatus of claim 20, wherein the system controller device includes a microprocessor for comparing the measured volume detected by the volume sensor to a predetermined target volume for the patient.
22. The apparatus of claim 21, wherein the target volume is determined through clinical assessment of the patient and the microprocessor is preprogrammed with the target volume prior to the application of the device to the patient.

23. The apparatus of claim 21, wherein the microprocessor is programmed to calculate a desired resistance for the valve to achieve the target volume.
24. The apparatus of claim 23, wherein the implantable shunt system further includes a second sensor element for measuring an additional physiological characteristic of the patient, the second sensor element being configured to transmit data representing the measured value of the additional physiological characteristic to the system controller device.
25. The apparatus of claim 24, wherein the second sensor element is a pressure sensor and the additional physiological characteristic is ventricular pressure.
26. The apparatus of claim 17, wherein the adjustable resistance valve is configured for implantation in a peritoneal cavity of the patient.
27. The apparatus of claim 20, wherein the system controller device further includes a timed shutoff mechanism.

ABSTRACT

An adjustable drainage system for regulating cerebrospinal fluid flow in a hydrocephalus patient where the drainage rate is adjusted in response to ventricular volume variations in the patient. The system includes an adjustable valve and a volume sensor that can be periodically energized with an external system controller device by the patient or attending physician to determine when, or if, a change in the ventricular volume has occurred. The system enables the user to adjust the valve's resistance in response to changes in the ventricular volume using the controller device so that a target ventricular volume can be achieved. Also provided is a method of continuously draining cerebrospinal fluid from the cranial cavity of the patient using the system of the present invention.

1245766.1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
DECLARATION AND POWER OF ATTORNEY FOR 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 an original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**METHOD AND APPARATUS FOR MANAGING NORMAL PRESSURE
HYDROCEPHALUS**

the specification of which is attached hereto.

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, World Trade Center West, 155 Seaport Boulevard, Boston, Massachusetts 02210-2604, 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 specification, including the claims, as amended by an amendment, if any, 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:

☒ no such foreign applications have been filed

CLAIM FOR BENEFIT OF EARLIER U.S. PROVISIONAL APPLICATIONS

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

☒ no such U.S. provisional applications have been filed.

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 States 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 which became available to me between the filing date of the prior application and the national or PCT international filing date of this application:

☒ no such U.S./PCT applications have been filed.

I hereby appoint all practitioners at Customer Number 021125, all of Nutter McClennen & Fish LLP, World Trade Center West, 155 Seaport Boulevard, Boston, Massachusetts 02210-2604, 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 U. S. Patent and Trademark Office connected therewith.

Please mail all correspondence to William C. Geary at Customer Number 021125 , whose address is:

Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604

Please direct telephone calls to: Tram Anh Nguyen at (617) 439-2734.

Please direct facsimiles to: (617) 310-9734.

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Sole or first inventor's signature	Date
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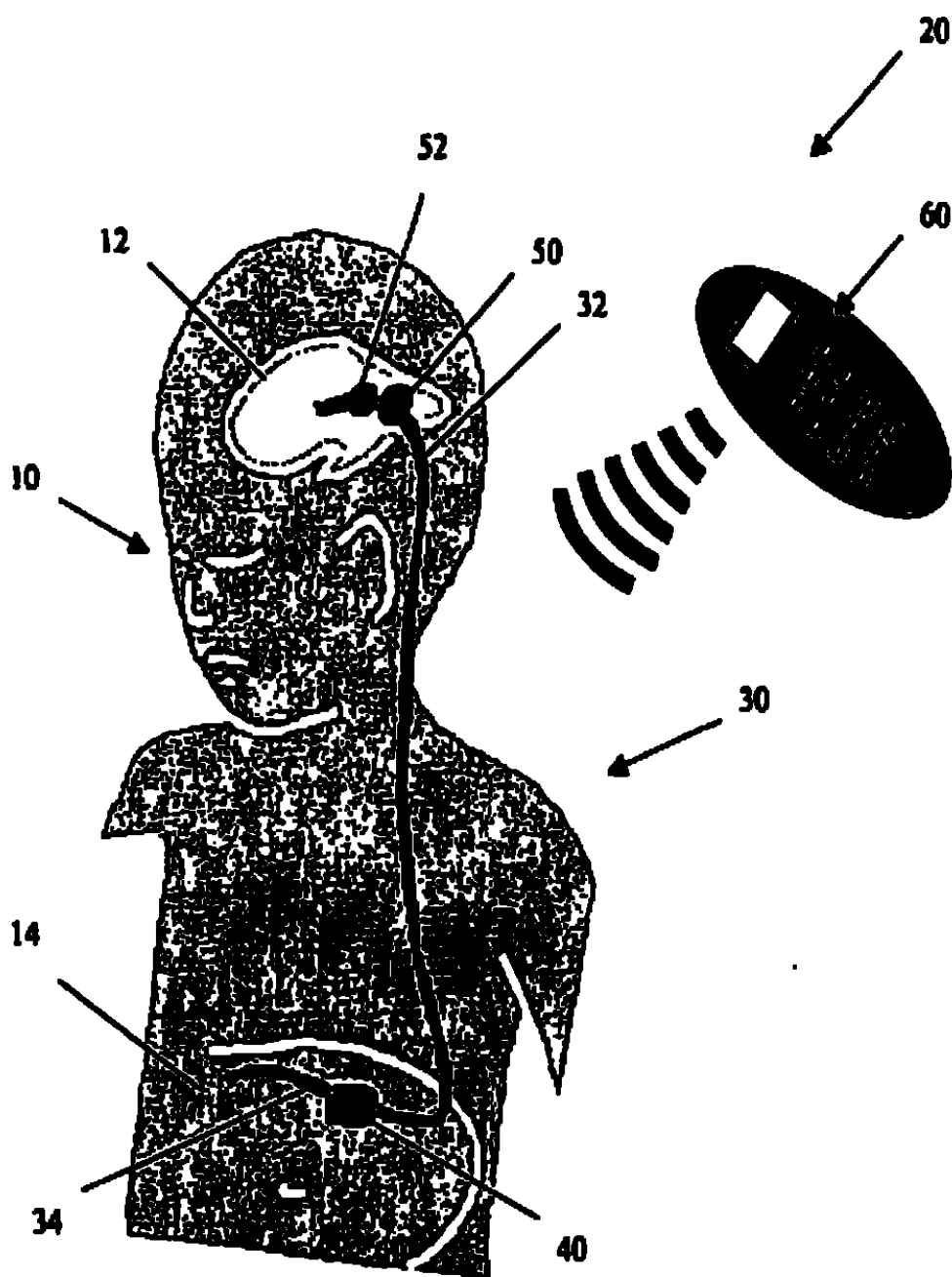


FIG. 1

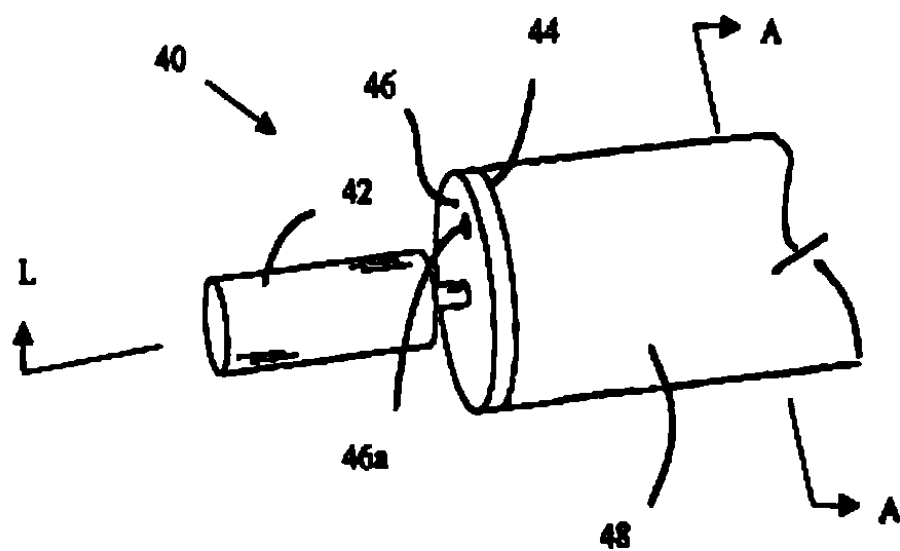


FIG. 2A

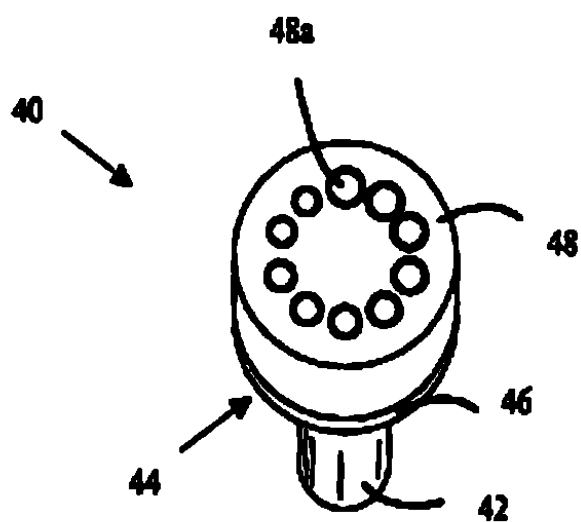


FIG. 2B

2º EXAMEN DE FORMA, PATENTE DE INVENCION

Radicación N° 04-86715

Folio 99

Concepto Técnico N° 702

Clasificación Internacional de Patentes: A61M 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:

- 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 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 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 ☐ Ver hoja(s) anexa(s)

EXAMINADOR TÉCNICO: 202051

Bogotá D C, septiembre 5 de 2005.

2020
Bogotá D C

Doctor(a):
JIMENA ESCOBAR URIBE.
Apoderado (a)

REFERENCIA:	Radicación N°	04-86715
	Trámite	002
	Evento	001
	Actuación	416
	Oficio N°	857
	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 Decisión 486.

Cúmplase
Dado en Bogotá D C,

12 SET. 2005


ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe División de Nuevas Creaciones.

202051