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(54) Title: SYSTEM AND METHOD FOR DRAINING CEREBROSPINAL FLUID

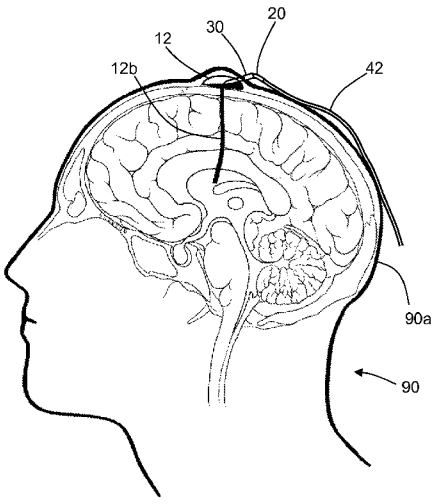


Fig. 2

(57) Abstract: A system and/or a method of evacuating cerebrospinal fluid (CSF) from a CSF reservoir is provided. The system can include a CSF reservoir, a reservoir mating piece, and a securing piece. The reservoir mating piece can have a tip end configured to be insertable into the CSF reservoir and a drainage end configured to be coupled to a drainage tube, the reservoir mating piece forming a drainage passageway for the evacuation of CSF from the CSF reservoir. The securing piece can be configured to be affixed to an individual's skin. In an unlocked position, the securing piece may be configured to slide along the reservoir mating piece, and in a locked position, the securing piece may be configured to be fixed relative to the reservoir mating piece. At least a portion of the drainage passageway is nonlinear between the tip end and the drainage end.

SYSTEM AND METHOD FOR DRAINING CEREBROSPINAL FLUID

Cross-Reference to Related Applications

[0001] This application claims priority to U.S. Provisional Application No. 62/003,068, filed on May 27, 2014, now pending, the disclosure of which is incorporated herein by reference.

Field of the Disclosure

[0002] The present disclosure relates generally to draining cerebrospinal fluid from a body, such as an individual.

Background of the Disclosure

[0003] Individuals with neurosurgical conditions often have a cerebrospinal fluid (CSF) reservoir implanted for drug delivery or as part of a CSF diversion system such as a shunt. Conditions such as hydrocephalus, can cause high intracranial pressures which must often be relieved before continued treatment. This is sometimes accomplished by the shunt built in to the reservoir. However, failure can occur within components of a CSF shunt, for example due to a mechanical disruption/obstruction, and generally requires the replacement of the failed component(s). Valves in CSF reservoirs can fail due to debris build-up (e.g., blood, protein) within the valve, and the outlet of the catheter can fail by fracturing, becoming obstructed, or tethering within scar tissue. These mechanical failures, infections, and other complications cause many implanted CSF shunts to fail within a relatively short period of time.

[0004] Where a shunt has failed or a reservoir does not have a shunt, relief of intracranial pressure, is sometimes performed by externally draining a CSF reservoir by repeatedly tapping the reservoir using a syringe and withdrawing CSF, as shown in Figure 1. Alternatively, an external ventricular drainage system can be placed for the collection of CSF in order to mitigate the high intracranial pressure. However, external ventricular drains require placement of a ventricular catheter and the correspondent risks with such an invasive procedure. CSF can also be drained by directly withdrawing CSF from the ventricles.

[0005] There is a need for alternative methods for relieving intracranial pressure through less invasive techniques.

Summary of the Disclosure

[0006] In one embodiment, the disclosure is embodied as a system for evacuating cerebrospinal fluid (CSF) by way of a CSF reservoir. The system can include a CSF reservoir, a reservoir mating piece, and a securing piece. The reservoir mating piece can have a tip end configured to be insertable into the CSF reservoir and a drainage end configured to be coupled to a drainage tube, the reservoir mating piece forming a drainage passageway for the evacuation of CSF from the CSF reservoir. The securing piece can be configured to be affixed to an individual's skin. In an unlocked position, the securing piece may be configured to slide along the reservoir mating piece, and in a locked position, the securing piece may be configured to be fixed relative to the reservoir mating piece. At least a portion of the drainage passageway is nonlinear between the tip end and the drainage end.

[0007] In another embodiment, the disclosure is embodied as a method of evacuating CSF from a CSF reservoir. The method can include implanting a CSF reservoir into an individual, or the CSF reservoir may have already been implanted in a previous procedure. A tip end of a reservoir mating piece can be inserted into the CSF reservoir. The reservoir mating piece can form a drainage passageway for the evacuation of CSF from the CSF reservoir. A drainage end of the CSF reservoir can be coupled to an evacuation assembly. A securing piece can be moved from a first position relative to the reservoir mating piece to a second position relative to the reservoir mating piece. The securing piece can be locked in the second position such that the securing piece is fixed relative to the reservoir mating piece. The securing piece may be secured to the individual's skin. CSF from the CSF reservoir can be drained through the drainage passageway of the reservoir mating piece and through the evacuation assembly. At least a portion of the drainage passageway is nonlinear between the tip end and the drainage end.

Description of the Drawings

[0008] For a fuller understanding of the nature and objects of the disclosure, reference should be made to the following detailed description taken in conjunction with the accompanying drawings, in which:

Figure 1 depicts a prior art system; and

Figure 2 depicts a system according to an embodiment of the disclosure;

Figure 3 depicts a device according to an embodiment of the disclosure; and

Figure 4 depicts a method according to an embodiment of the disclosure.

Detailed Description of the Disclosure

[0009] Fig. 2 depicts a system **10** for evacuating CSF from a CSF reservoir **12** implanted in an individual **90**. The system **10** can include a reservoir mating piece **20**, a securing piece **30**, and an evacuation assembly **40**.

[0010] A CSF reservoir **12** such as a conventional ventriculostomy reservoir, for example an Ommaya reservoir depicted in Figure 1, may reside in place under the scalp of an individual. The CSF reservoir **12** can be used for the aspiration of CSF or for the delivery of drugs (*e.g.,* chemotherapeutic agents) into the CSF. The CSF reservoir **12** can include a catheter **12b** in a lateral ventricle attached to the reservoir **12b** implanted under the scalp of the individual **90**. The CSF reservoir **12** may include a base having a catheter connector, an integral, upwardly extending cylindrical wall portion, and a flange portion integrally formed with and overlying the wall portion. The base may be manufactured from a metal or other suitable material. A cap, which can be made of a silicone elastomer material or other suitable materials, is typically provided to enclose the upper end of the base and define, with the base, an internal reservoir. A surgeon disposes the catheter into the ventricle through the skull, and attaches the catheter to the connector at the lower end of the base, positioning the reservoir under the scalp. Once the incision is closed, the reservoir can subsequently be accessed through the skin to obtain CSF or deliver medications directly to the CSF.

[0011] In a system **10** of the present disclosure, the reservoir mating piece **20** forms a drainage passageway for the evacuation of CSF from the CSF reservoir **12**. The reservoir mating piece **20** can have a tip end **22** configured to be insertable into the CSF reservoir **12** and a drainage end **24** configured to be coupled to a drainage tube **42** of an evacuation assembly **40**. In this manner, CSF can flow from the CSF reservoir **12**, through the reservoir mating piece **20** and drainage tube **42**, and into an external vessel **44**, such as a bag.

[0012] The tip end **22** of the reservoir mating piece **20** may have, for example, a needle-shape for puncturing an individual's skin **90a**, and/or other tissue, to access an implanted CSF reservoir **12**. The reservoir mating piece **20** can have a curved portion **26** to more closely follow an outer contour of an individual (*e.g.*, the head of the individual). In this way, the reservoir mating piece **20** can be secured closer to the head of the individual for longer-term use (*e.g.*, up to 1-7 days or longer). The reservoir mating piece **20** may be manufactured in multiple sizes and/or curvatures such that a suitable configuration can be selected for a particular individual. Disposition of the reservoir mating portion **20** proximate to the head via the curved portion **26** may also serve to prevent kinking once an appropriate dressing is applied to the entry point. Thus, at least a portion of the drainage passageway in the reservoir mating piece **20** can be nonlinear. At least a portion of the reservoir mating piece **20** may be made of a rigid material, such as a metal. In one embodiment, the entire reservoir mating piece **20** is made of an 18 gauge or 25 gauge stainless steel. The length between the tip end **22** and the curved portion **26** may be approximately 3 cm, but different lengths can be selected according to factors such as patient age, and a patient's scalp thickness. The length between the curved portion **26** and the drainage end **24** can be about 2 cm, but, here again, other lengths may be used according to the application.

[0013] The securing piece **30** can include a mating portion **32** and an adjustment mechanism **34**. The mating portion **32** can be configured to affix to an individual's skin **90a**. In one embodiment, the mating portion **32** includes an adhesive for securing the securing piece **30** to an individual's skin **90a**. In another embodiment, the mating portion **32** may be suture compatible, for example, having plastic flanges for securing the securing piece **30** to an individual's skin **90a** with sutures (see, for example, Figure 3). The mating portion **32** is

preferably a pliable material that can form to the contour of the individual's **12** skull. Other forms of attachment to the skin will be apparent in light of the present disclosure and are included within the scope of the present disclosure. In one example, the securing piece **30** can be disc-shaped with a diameter of 5 cm.

[0014] The position of the securing piece **30** can be movable relative to the reservoir mating piece **20** via the adjustment mechanism **34**. In an "unlocked" configuration, the position of the securing piece **30** can be adjusted relative to the reservoir mating piece **20**. In a "locked" configuration, the securing piece **30** is configured to be fixed relative to the reservoir mating piece **20**. Thus, the adjustment mechanism **34** can be a slidably lockable mechanism that slides along the reservoir mating piece **20** for adjustment purposes, and then locks into position for use with an individual. In an embodiment, the adjustment mechanism **34** is a sleeve which can be locked into position by, for example, a suture tied around a circumference of the sleeve. Those skilled in the art will appreciate that various adjustment mechanisms may be used with the reservoir mating piece **20,** including mechanisms having screw-connections or clamping connections.

[0015] In a locked position, the securing piece **30** can be located between the tip end **22** and the curved portion **26** of the reservoir mating piece **20**. As such, the reservoir mating piece **20** may be inserted, through the individual's scalp, into the reservoir **12**, and the securing piece **30** moved to a position proximate to the skin of the individual **90a**. The securing piece **30** can then be secured to the skin **90a** of the individual and locked to a position on the reservoir mating piece **20** to hold the system **10** in place. The adjustability of the system **10** allows for a particular individual's need. For example, the position of the securing piece **30**, relative to the reservoir mating piece **20**, can be adjusted to accommodate a particular type or size of CSF reservoir **12**, location of CSF reservoir **12** in an individual **90**, and size of an individual **90**. A more reliable and comfortable placement of the reservoir mating piece **30** can be thereby be achieved.

[0016] In use, a CSF reservoir **12** can be implanted into an individual **90** according to known methods (or has already been implanted during a previous procedure). The tip end **22**

of the reservoir mating piece **20** can be inserted into the CSF reservoir **12**. The securing piece **30** can be moved from a first position relative to the reservoir mating piece **20** to a second position relative to the reservoir mating piece **20**. The securing piece **30** may be secured to the individual's skin. The securing piece **30** can be locked in the second position such that the securing piece **30** is fixed relative to the reservoir mating piece **20**. A drainage end **24** of the reservoir mating piece **20** can be coupled to an evacuation assembly **40**. The drainage end **24** may have been connected to the drainage assembly **40** before insertion of the reservoir mating piece **20**. An external vessel **44** (which may or may not form a portion of the system **10)** may be attached to the drainage assembly by, for example, a luer connector. CSF from the CSF reservoir **12** can be drained through the drainage passageway of the reservoir mating piece **20**, through the evacuation assembly **40**, into the external vessel **44**. The drainage end **24** may additionally, or alternatively, be connected to an intracranial pressure monitoring device. At least a portion of the drainage passageway may be nonlinear between the tip end and the drainage end.

[0017] Once the desired procedure is performed, the tip end **22** of the reservoir mating piece **20** can be removed from the CSF reservoir **12**. The CSF reservoir **12** may be self-sealing, such that once the tip end **22** is removed, the CSF reservoir **12** remains operable.

[0018] In another aspect of the present disclosure, a method **100** for evacuating CSF is provided. The method **100** includes implanting **103** a CSF reservoir into a body. The step of implanting **103** a CSF reservoir may include inserting a catheter into a lateral ventricle of the body. A tip end of a reservoir mating piece is inserted **106** into the CSF reservoir. For example, the tip end may be used to pierce the skin of the body and a wall of the CSF reservoir. In this way, the reservoir mating piece is disposed through the skin and the wall of the CSF reservoir and forms a drainage passageway for the evacuation of CSF from the CSF reservoir.

[0019] A drainage end of the reservoir mating piece is coupled **109** to an evacuation assembly. For example, the drainage end may be configured as a locking luer taper, configured to couple **109** with a corresponding connector of a drain tube of an evacuation

assembly. A securing piece of the reservoir mating piece is moved **112** from a first position relative to the reservoir mating piece to a second position. In an embodiment, the securing piece is configured to slide along a length of the reservoir mating piece from the first position (at a location along the length of the reservoir mating piece) to the second position (at another location along the length of the reservoir mating piece).

[0020] The securing piece is locked **115** in the second positon. In this way, the securing piece is fixed relative to the reservoir mating piece. The securing piece is secured **118** to the body. In this way, the reservoir mating piece can be fixed to the skin by way of the securing piece—thereby reducing the risk that the reservoir mating piece is unintentionally removed from the CSF reservoir. It should be noted that locking the securing piece may be a reversible procedure such that the securing piece can be unlocked for removal or adjustment of the reservoir mating piece.

[0021] The method **100** includes draining **121** CSF from the CSF reservoir through the drainage passageway formed by the reservoir mating piece and into the evacuation assembly.

[0022] Although the present disclosure has been described with respect to one or more particular embodiments, it will be understood that other embodiments of the present disclosure may be made without departing from the spirit and scope of the present disclosure. Hence, the present disclosure is deemed limited only by the appended claims and the reasonable interpretation thereof.

What is claimed is:

1. A system for evacuating cerebrospinal fluid (CSF), comprising:

a CSF reservoir configured to be implanted below the skin of an individual;

a reservoir mating piece having a tip end configured to be insertable into the CSF reservoir and a drainage end configured to be coupled to a drainage tube, the reservoir mating piece forming a drainage passageway for the evacuation of CSF from the CSF reservoir;

a securing piece configured to be affixed to the skin of the individual, wherein in an unlocked position, the securing piece is configured to slide along the reservoir mating piece, and in a locked position, the securing piece is configured to be fixed relative to the reservoir mating piece; and

wherein at least a portion of the drainage passageway is nonlinear between the tip end and the drainage end.

2. The system of claim 1, wherein the securing piece is a disk disposed circumferentially around the reservoir mating piece, the disk having an adhesive side for attachment to the skin.

3. The system of claim 1, wherein the securing piece comprises at least one flange.

4. The system of claim 1, wherein the securing piece is configured to be locked in the locked positon by suture.

5. The system of claim 1, wherein the drainage end of the reservoir mating piece comprises a luer lock configured to correspond to an end of the drainage tube.

6. A device for evacuating CSF from a CSF reservoir, comprising:

a reservoir mating piece having a tip end configured to be insertable into the CSF reservoir and a drainage end configured to be coupled to a drainage tube, the reservoir mating piece forming a drainage passageway for the evacuation of CSF from the CSF reservoir;

a securing piece configured to be affixed to an individual's skin, wherein in an unlocked position, the securing piece is configured to slide along the reservoir

mating piece, and in a locked position, the securing piece is configured to be fixed relative to the reservoir mating piece; and

wherein at least a portion of the drainage passageway is nonlinear between the tip end and the drainage end.

7. The system of claim 6, wherein the securing piece is a disk disposed circumferentially around the reservoir mating piece, the disk having an adhesive side for attachment to the skin.

8. The system of claim 6, wherein the securing piece comprises at least one flange.

9. The system of claim 6, wherein the securing piece is configured to be locked in the locked positon by suture.

10. The system of claim 6, wherein the drainage end of the reservoir mating piece comprises a luer lock configured to correspond to an end of the drainage tube.

11. The system of claim 6, further comprising an evacuation assembly.

12. The system of claim 11, wherein the evacuation assembly comprises a drainage tube and a bladder in fluid communication with the drainage tube, wherein the drainage tube is configured to couple with the reservoir mating piece, thereby extending the drainage passageway from the CSF reservoir to the bladder.

13. A method for evacuating CSF, comprising:

implanting a CSF reservoir into a body;

inserting a tip end of a reservoir mating piece into the CSF reservoir, the reservoir mating piece forming a drainage passageway for the evacuation of CSF from the CSF reservoir;

coupling a drainage end of the reservoir mating piece to an evacuation assembly;

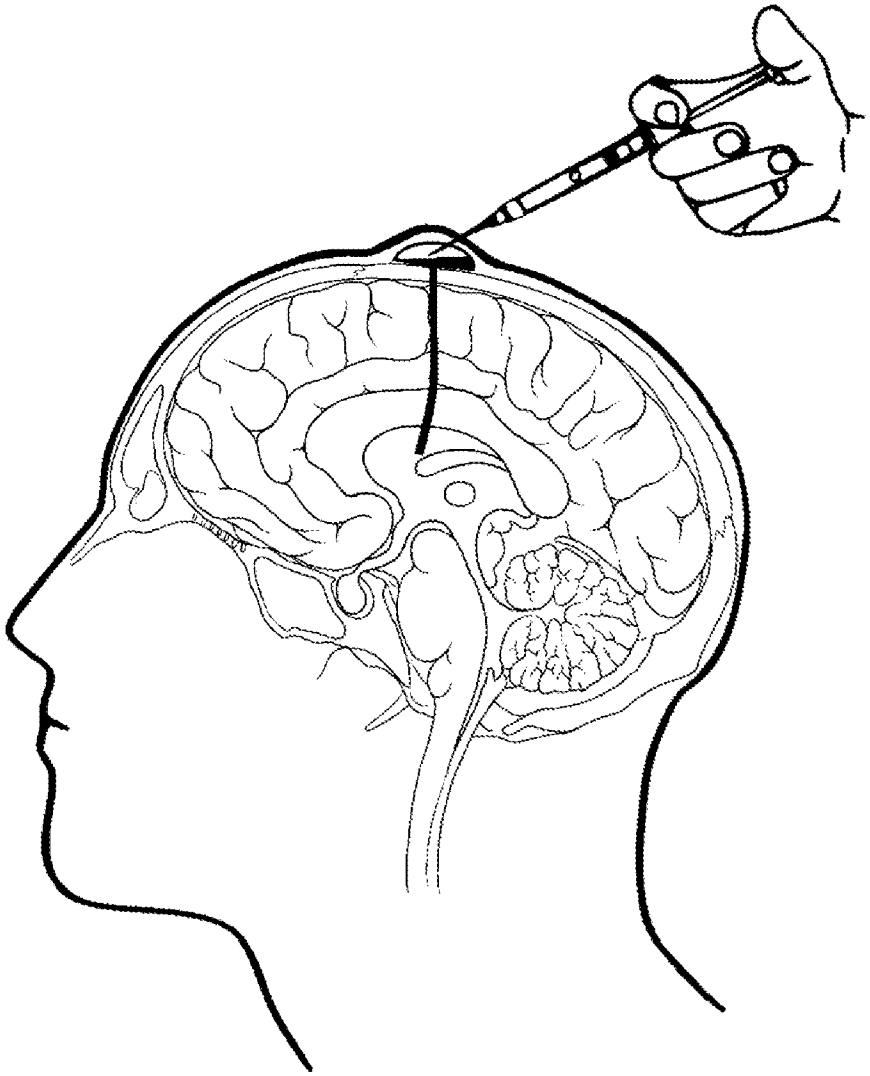
moving a securing piece from a first position relative to the reservoir mating piece to a second position relative to the reservoir mating piece;

locking the securing piece in the second position such that the securing piece is fixed relative to the reservoir mating piece;

securing the securing piece to the body; and

draining CSF from the CSF reservoir through the drainage passageway of the reservoir mating piece and into the evacuation assembly; and

wherein at least a portion of the drainage passageway is nonlinear between the tip end and the drainage end.



PRIOR ART

Fig. 1

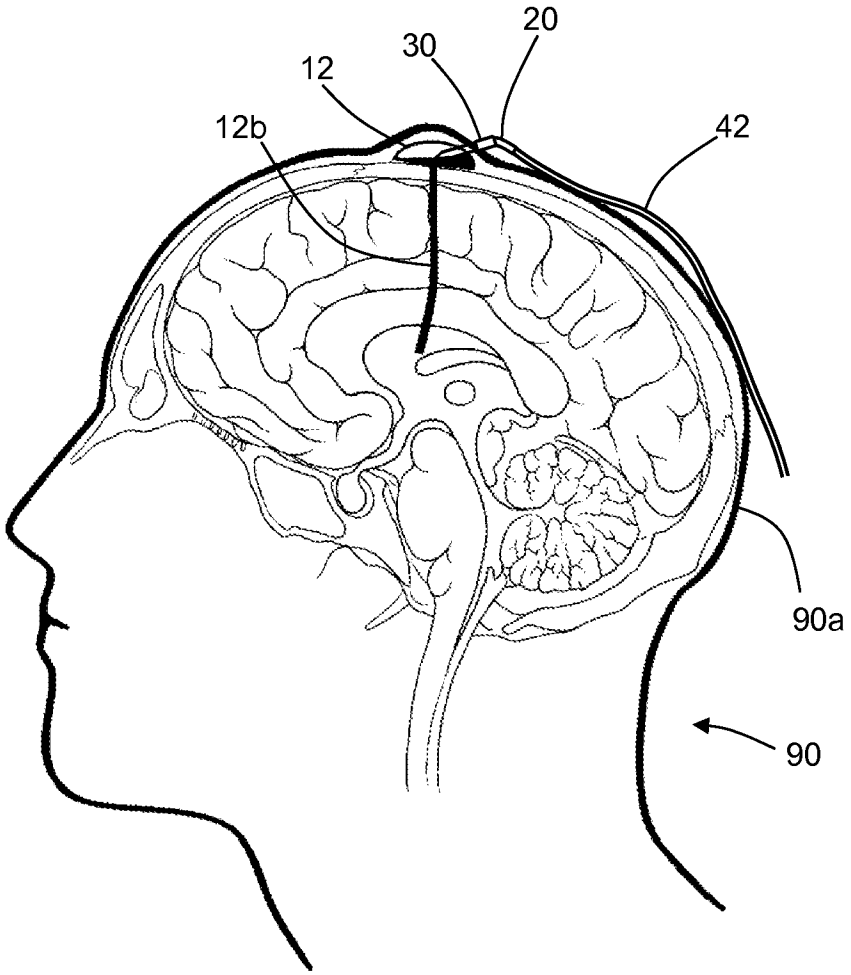


Fig. 2

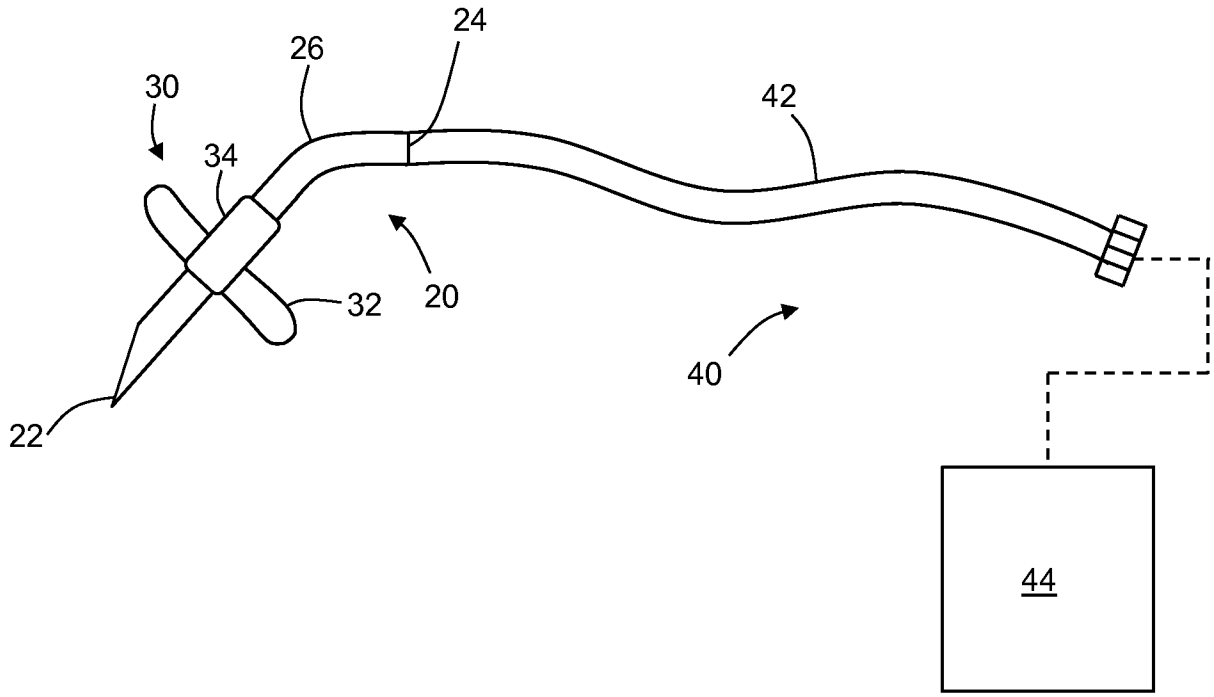


Fig. 3

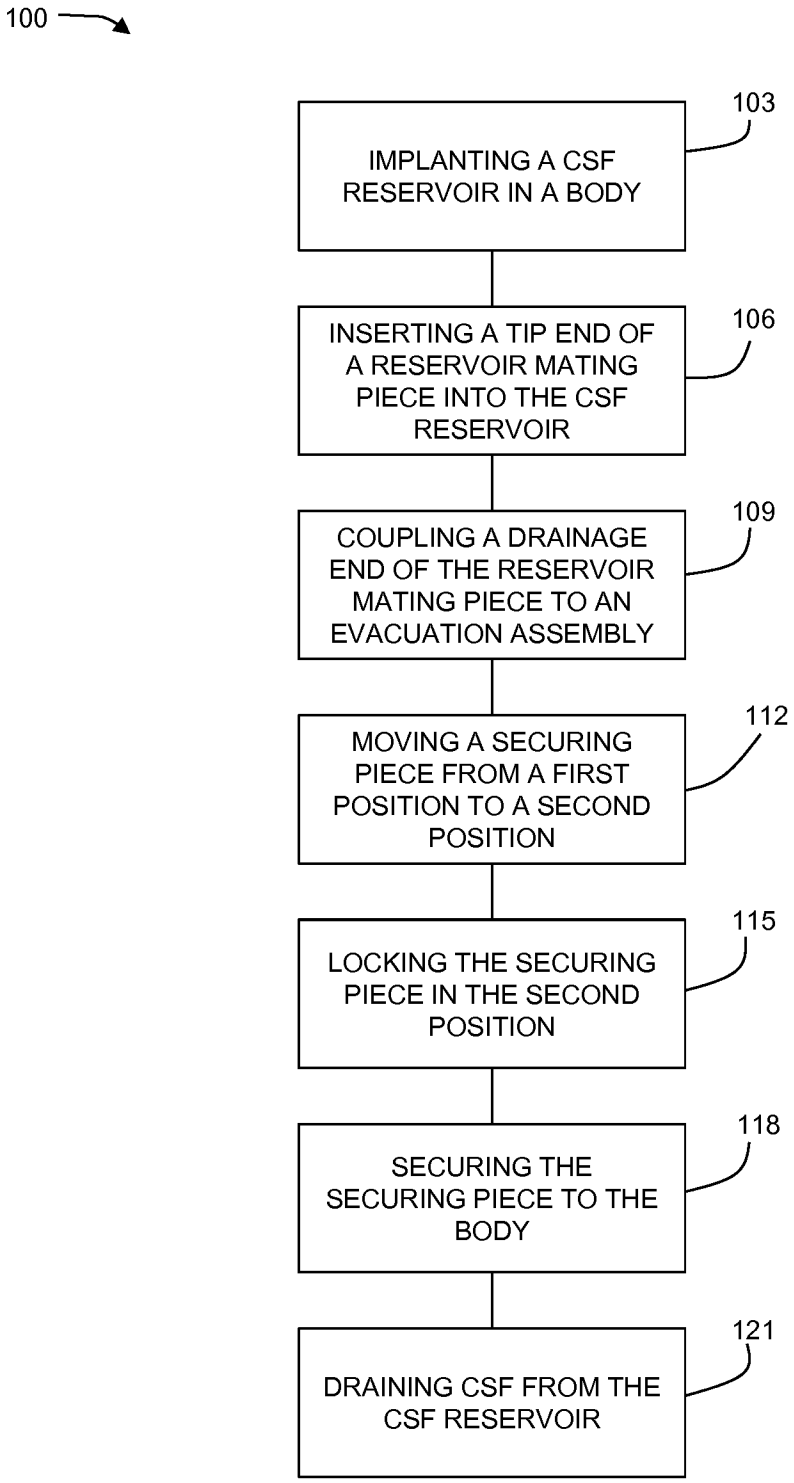

100
103
IMPLANTING A CSF RESERVOIR IN A BODY
106
INSERTING A TIP END OF A RESERVOIR MATING PIECE INTO THE CSF RESERVOIR
109
COUPLING A DRAINAGE END OF THE RESERVOIR MATING PIECE TO AN EVACUATION ASSEMBLY
112
MOVING A SECURING PIECE FROM A FIRST POSITION TO A SECOND POSITION
115
LOCKING THE SECURING PIECE IN THE SECOND POSITION
118
SECURING THE SECURING PIECE TO THE BODY
121
DRAINING CSF FROM THE CSF RESERVOIR

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/32764

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 27/00 (2015.01)
CPC - A61M27/006
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC8 : A61M 27/00 (2015.01)
CPC : A61M27/006

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC8 : A61M 1/00 (2015.01)
CPC: A61M 1/00, 27/00, 27/002, 2027/004, 2202/00, 2202/04, 2202/0464, 2210/00, 2210/06, 2210/0693

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Patbase, Google Patent, Google Scholar: csf, cerebrospinal, cerebral, ventriculostomy, cranial, intracranial, implant, subcutaneous, reservoir, chamber, housing, pierce, connect, interconnect, mate, mating, join, drain, tube, lumen, catheter, cannula, shunt, tap, transcutaneous, pecutaneous, transcranial, anchor, tab, disc, disk, cuff, suture

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,795,307 A (KRUEGER) 18 August 1998 (18.08.1998) see especially col 4, ln 13-30, col 5, ln 12-31, col 7, ln 42-57, fig 3, 8	1-13
Y	US 4,645,492 A (WEEKS) 24 February 1987 (24.02.1987) see especially col 3, ln 6-16, col 3, ln 23-51, col 3, ln 67 to col 4, ln 43, fig 1	1-13
A	US 8,152,792 B1 (KORNEL) 10 April 2012 (10.04.2012) see whole document	1-13
A	US 5,352,207 A (NUSSBAUM) 04 October 1994 (04.10.1994) see whole document	1-13
A	US 5,312,357 A (BUIJS et al) 17 May 1994 (17.05.1994) see whole document	1-13
A	US 4,500,311 A (REDMOND et al) 19 February 1985 (19.02.1985) see whole document	1-13
A	US 3,444,861 A (SCHULTE) 20 May 1969 (20.05.1969) see whole document	1-13

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 July 2015 (29.07.2015)	19 AUG 2015
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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