

SYSTEMS AND METHODS FOR FLUSHING EXTERNAL VENTRICULAR DRAINS

BACKGROUND

5 Field

[0001] Systems and methods for flushing external ventricular drains.

Background

[0002] External ventricular drains (EVDs) are used to transport body fluids from one region of the body to an external reservoir. Such systems are used, for example, in the treatment of hydrocephalus use tubes to drain excess cerebrospinal fluid from a patient tissue site, such as the ventricles of the brain, to an external reservoir, such as a drainage bag, to relieve fluid pressure on the brain. Common EVD systems have components that connect to ventricular catheters that have been implanted in the brain to drain fluid out of the brain via patient line. However, after a period of use, solids, and components within the fluid, such as blood (including coagulated blood), cellular, and proteinaceous components, can adhere to the tubes and accumulate, thereby restricting or obstructing flow of fluid into and through the catheter member, necessitating removal and replacement of the EVD, exposing the patient to unnecessary risks associated with such surgery, and increasing the cost of treatments using EVDs.

SUMMARY

[0003] In general, the present disclosure provides a flush assembly for an external ventricular drain (EVD) system comprising a collapsible upper body and a base, the flush assembly connected to the EVD using a connector, a bonding tube surrounding the connector, wherein the connector intersects the collapsible upper body and/or base, and wherein the flush assembly stores a fluid in an internal fluid

reservoir and when the flush assembly is activated, the collapsible upper body pushes the fluid from the internal fluid reservoir to a flushing site to perform a flush of the EVD. The flushing site includes either a tissue site and/or a drain site allowing the fluid to be forced from the flush assembly to remove blockages in a catheter or patient line.

5 [0004] The flush assembly may comprise a stop cock valve, wherein the flush assembly can be turned on and off depending on an orientation of the stop cock valve. The stop cock valve may also allow the introduction of a sterile saline or various thrombolytics such as a tissue plasminogen activator (tPA). The flush assembly connector may be manufactured from a plastic or urethane and may be attached with
10 a luer lock connector.

[0005] The bonding tube may be manufactured from a flexible polymer material and provide a surface for chemical bonding to other similar materials.

[0006] The fluid flow through the flush assembly may be bidirectional and may be expelled in even amounts or non-even amounts in each direction. The fluid flow
15 through the flush assembly may be adjustable.

[0007] The flush assembly may comprise a tactile feature.

[0008] The present disclosure may also provide a flush assembly for an EVD system comprising a hemi-spherical structure having a flat top, a connector located on a side, the connector having a bonding tube surrounding the connector, a drainage
20 tube located on an opposite side, and wherein the flush assembly is connected to the EVD system in-line, and wherein the connector is connected to an externalized ventricular catheter while drainage tube is connected to the EVD system. The flush assembly stores a fluid in an internal fluid reservoir and, when the flush assembly is activated, the flush assembly pushes the fluid from the internal fluid reservoir to a
25 flushing site to perform a flush of the EVD or drainage line. The flush assembly may

also comprise a flat top having a tactile feature.

[0009] The present disclosure may also provide a flush assembly for an EVD system comprising two hemi-spherical structures, a connector located on a side, the connector have a bonding tube surrounding the connector, a drainage tube located
5 near the top of one hemisphere and following the contour of that hemisphere until reaching the side opposite the connector, wherein the flush assembly is connected to the EVD system in-line, and wherein the connector is connected to an externalized ventricular catheter while the drainage tube is connected to the EVD system. The flush assembly stores a fluid in an internal fluid reservoir and, when the flush assembly is
10 activated, the flush assembly pushes the fluid from the internal fluid reservoir to a flushing site to perform a flush of the EVD or drainage line. The flush assembly may also comprise one or both hemispheres having a tactile features.

BRIEF DESCRIPTION OF THE DRAWINGS

15 [0010] The accompanying drawings are included to provide a further understanding of the disclosure and are incorporated in and constitute a part of this specification, illustrate embodiments of the disclosure, and together with the description serve to explain the principles of the disclosure, wherein:

[0011] FIG. 1 is a planar sideview of a flush assembly according to the disclosed
20 subject matter.

[0012] FIG. 2 is a bottom isometric view of a flush assembly according to the disclosed subject matter.

[0013] FIG. 3 is a cross-section of the flush assembly of FIGS. 1 and 2.

[0014] FIG. 4 is a bottom isometric view of a flush assembly according to the
25 disclosed subject matter.

[0015] FIG. 5 is a planar sideview of a flush assembly according to the disclosed subject matter.

[0016] FIG. 6 is a cross-section of the flush assembly of FIGS. 4 and 5.

[0017] FIG. 7 is a planar sideview of a flush assembly according to the disclosed
5 subject matter.

[0018] FIG. 8 is a cross-section of the flush assembly of FIG 7.

[0019] FIG. 9 is a bottom isometric view of a flush assembly according to the disclosed subject matter.

[0020] FIG. 10 is a cross-section of the flush assembly of FIG 9.

10 [0021] FIG. 11 is a top isometric view of a flush assembly according to the disclosed subject matter.

[0022] FIG. 12 is a cross-section of the flush assembly of FIG 11.

[0023] FIG. 13 is a top isometric view of a flush assembly according to the disclosed subject matter.

15 [0024] FIG. 14 is a cross-section of the flush assembly of FIG. 13.

[0025] FIG. 15 is a cross-section of another embodiment of a flush assembly according to the disclosed subject matter.

[0026] FIG. 16 is a top planar view of the flush assembly of the flush assembly of FIG 15.

20 [0027] FIG. 17 is a top isometric view of a flush assembly according to the disclosed subject matter.

[0028] FIG. 18 is a bottom isometric view of a flush assembly according to the disclosed subject matter.

[0029] FIG. 19 is a cross-section of the flush assembly of FIGS. 17 and 18.

25 [0030] FIG. 20 is a bottom view of the flush assembly with the base removed.

[0031] FIG. 21 is a bottom view of the upper body.

[0032] FIG. 22 is an isometric view of FIG. 18.

[0033] FIG. 23 is an isometric view of the valve and channel member.

[0034] FIG. 24 is an isometric view of the channel member.

5 [0035] FIG. 25 is a bottom isometric view of the valve.

[0036] FIG. 26 is an elevation view of a flush assembly according to the disclosed subject matter.

[0037] FIG. 27 is a cross-section of an embodiment of a flush assembly according to the disclosed subject matter, with an enlarged cross-section A-A.

10 [0038] FIG. 28 is a cross-section of an embodiment of a flush assembly according to the disclosed subject matter.

[0039] FIG. 29 is an enlarged view of FIG. 28.

[0040] FIG. 30 is a bottom view of an embodiment of the flush assembly of FIG. 27 with the base removed.

15 [0041] FIG. 31 is an isometric view from above of an embodiment of a flushing assembly according to the disclosed subject matter.

[0042] FIG. 32 is an elevation view of the flushing assembly of FIG. 31.

[0043] FIG. 33 is an isometric view from above of an embodiment of a flushing assembly according to the disclosed subject matter.

20 [0044] FIG. 34 is an end view of the flushing assembly of FIG. 33.

[0045] FIG. 35 is a plan view of an embodiment of a drain catheter according to the disclosed subject matter.

DETAILED DESCRIPTION

25 [0046] Persons skilled in the art will readily appreciate that various aspects of

the present disclosure can be realized by any number of methods and systems configured to perform the intended functions. Stated differently, other methods and systems can be incorporated herein to perform the intended functions. It should also be noted that the accompanying drawing figures referred to herein are not all drawn
5 to scale but may be exaggerated to illustrate various aspects of the present disclosure, and in that regard, the drawing figures should not be construed as limiting. Finally, although the present disclosure can be described in connection with various principles and beliefs, the present disclosure should not be bound by theory.

[0047] This being noted, and with reference to FIGS. 1-3, an embodiment of a
10 flush assembly 100 according to the disclosed subject matter is shown and described. For example, the flush assembly 100 forms an upper body 101 and a base 102, with a connector 103 at a bottom end, and a bonding tube 104 surrounding the connector 103. In an embodiment, the flush assembly 100 is connected to an EVD system of a patient. During use, the flush assembly 100 is used as a component of the EVD system
15 to store and transfer fluid from and internal fluid reservoir 105, to an upstream location such as a tissue site, or to a downstream location, such as a drain site, and thus perform retrograde prophylactic and/or emergency flushing by allowing fluid to be forced from the flush assembly 100 to either location to remove blockages in a catheter due to the accumulation of debris found in the fluid or from tissue infiltration.

20 [0048] In an accordance with an aspect of the present disclosure, the flush assembly 100 is connected to the EVD system by a connector 103 using a standard luer lock connector. In some implementations, fluid communication to flush assembly 100 can be turned on or off depending on the orientation of a stop cock valve of the EVD system. The stop cock valve may also allow the introduction of a sterile saline
25 or various thrombolytics such as a tissue plasminogen activator (tPA).

[0049] In an accordance with various aspects of the present disclosure, the upper body 101 is manufactured from a flexible material, such as silicone, or other thermoplastic elastomer and is therefore a collapsible upper body 101. The collapsible upper body 101 forms an internal fluid reservoir 105 above the base 102.

5 [0050] In an accordance with various aspects of the present disclosure, the base 102 is manufactured from a flexible material such as silicone, or other thermoplastic elastomer or a hard material such as a plastic (e.g., ABS, polycarbonate, PEEK, polyurethane, or the like). The base 102 is intersected by the connector 103, which is in turn surrounded by a bonding tube 104. This creates a fluid pathway from
10 the internal fluid reservoir 105 to the EVD system, for example, by a standard luer lock connection (among others).

[0051] In an accordance with various aspects of the present disclosure, the connector 103 may be manufactured from a hard material such as plastic or urethane. The bonding tube 104 may be manufactured from flexible materials, such as silicone
15 or a thermoplastic elastomer, and may provide a surface for chemical bonding to other similar materials, such as those of the base 102. In an accordance with various aspects of the present disclosure, the bonding tube 104 may also create a mechanical bond to connector 103 in the case that a chemical bond cannot otherwise be established. In some implementations, a thread 106 may be tied around the bonding
20 tube 104 to create a stronger mechanical lock. This effect could also be achieved through the use of laser welding, thermal welding, press fitting or the like.

[0052] When flushing is necessary, the flush assembly 100 is in fluid communication with the flushing site (i.e., the tissue site or drainage site). When the flush assembly 100 is activated, the collapsible upper body 101 pushes fluid from the
25 internal fluid reservoir 105 to the flushing site to perform a flush. In some

implementations, the flush can be performed bidirectionally and push fluid to both sites at once. The amount of fluid expelled in both directions can be evenly split or engineered to direct volumes in non-even amounts in either direction. In accordance with some aspects, the fluid flow through the flush assembly may be adjustable.

5 [0053] In an accordance with various aspects of the present disclosure, the upper body 101 and/or the base 102 of the flush assembly 100 may comprise tactile features to aid in the gripping and use of the flush assembly 100. The tactile features may comprise, among other structure, a continuous ring, interrupted ring, full surface scoring, partial surface scoring, raised wave like patterns and the like. These tactile
10 features may improve use of the device by allowing for proper finger placement and minimize movement to the EVD system helping to ensure patient safety.

[0054] In an accordance with various aspects of the present disclosure, the flush assembly 100 may comprise a material that is resealable after being punctured by a needle. This allows the flush assembly 100 to serve as a delivery system for
15 various therapeutics, such as, for example, tissue plasminogen activator (tPA), other lytic drugs (e.g., Streptokinase, Alteplase, Reteplase, Tenecteplase, Urokinase, Prourokinase, Anistreplase, etc.), heparinized saline, and the like. The therapeutics may be injected into the flush assembly 100. Upon actuation of the flush assembly 100, the therapeutic is pushed into a catheter obstruction eroding the obstruction. The
20 therapeutic may then be sucked back after actuation of the flush assembly 100 has occurred.

[0055] Referring now to FIGS. 4-6, an embodiment of a flush assembly 200 according to the disclosed subject matter is shown and described. The flush assembly 200 forms an upper body 201 and a lower body 203, with a luer connector 204 at the
25 lower body 203. In an accordance with various aspects of the present disclosure, the

flush assembly 200 is connected to the EVD system of a patient. During use, the flush assembly 200 is used as a component of an EVD system to store and transfer fluid from an internal fluid reservoir 207, to an upstream location such as a tissue site, or to a downstream location, such as a drain site, and thus perform retrograde prophylactic and/or emergency flushing by allowing fluid to be forced from the flush assembly 200 to either location to remove blockages in a catheter due to the accumulation of debris found in the fluid or from tissue infiltration. In an accordance with various aspects of the present disclosure, the upper body 201 is depressed into the lower body 203, compressing a spring 208 and expelling fluid from the internal fluid reservoir 207. The spring 208 then acts on the upper body 201 extending it back to its starting position.

[0056] In an accordance with various aspects of the present disclosure, the upper body 201 comprises an outer casing 209 and an inner plunger 205. The inner plunger 205 has a gasket 206, for example, comprised of rubber, on the end. The gasket 206 fits within a flush body inner casing 210 with a geometry that conforms with the interior surfaces of the flush body inner casing 210. The outer casing 209 fits within lower body 203. The gasket 206 may comprise a silicone or urethane to create a mechanical seal within the flush body inner casing 210. The upper body 201, outer casing 209, inner plunger 205, lower body 203, and the flush body inner cavity may comprise a rigid plastic such as PET, PE, PP, PC, or other suitable material.

[0057] In an accordance with various aspects of the present disclosure, the lower body 203 consists of an outer surface 211 and a flush body inner casing 210. On a top outer ring of the lower body 203, finger handles 202 protrude outwardly to allow for gripping of the lower body 203. In an accordance with various aspects of the present disclosure, there may be space between the outer surface 211 and the flush body inner casing 210 that allows for a spring 208. The outer casing 209 engages the

spring 208 with the walls of the flush body inner casing 210 and the outer surface 211 surrounding the outer casing 209 and the spring 208.

[0058] In an accordance with various aspects of the present disclosure, the spring 208 comprises materials typically used for spring construction such as, for example, spring steel, stainless steel or and the like. The flush body inner casing 210 and the gasket 206 form an internal fluid reservoir 207. The internal fluid reservoir 207 contains fluid used for flushing.

[0059] In an accordance with various aspects of the present disclosure, and referring now to FIGS. 7 and 8, an embodiment of a flush assembly 300 according to the disclosed subject matter is shown and described. In this embodiment, the flush assembly 300 forms a sphere 301, comprising a connector 304 on one side, and a bonding tube 305 surrounding the connector 304. Ridges 302 may be provided to denote finger placement on either side of sphere 301. In an accordance with various aspects of the present disclosure, the flush assembly 300 is connected to the EVD system of a patient. During use, the flush assembly 300 is used as a component of an EVD system to store and transfer fluid from and internal fluid reservoir 303, to an upstream location such as a tissue site, or to a downstream location, such as a drain site, and thus perform retrograde prophylactic and/or emergency flushing by allowing fluid to be forced from the flush assembly 300 to either location to remove blockages in a catheter due to the accumulation of debris found in the fluid or from tissue infiltration.

[0060] In an accordance with various aspects of the present disclosure, and referring now to FIGS. 9 and 10, an embodiment of a flush assembly 400 according to the disclosed subject matter is shown and described. In this embodiment, the flush assembly 400 forms a hemi-sphere 402 having a flat top 401 with a cross mark 403

(or similar tactile feature), a connector 404 on one side, and a bonding tube 406 surrounding the connector 404. In an accordance with various aspects of the present disclosure, the flush assembly 400 is connected to the EVD system of a patient. During use, the flush assembly 400 is used as a component of an EVD system to store
5 and transfer fluid from and internal fluid reservoir 405, to an upstream location such as a tissue site, or to a downstream location, such as a drain site, and thus perform retrograde prophylactic and/or emergency flushing by allowing fluid to be forced from the flush assembly 400 to either location to remove blockages in a catheter due to the accumulation of debris found in the fluid or from tissue infiltration.

10 [0061] In an accordance with various aspects of the present disclosure, and with reference to FIGS. 11 and 12, an embodiment of a flush assembly 500 according to the disclosed subject matter is shown and described. In this embodiment, the flush assembly 500 forms a hemi-sphere 502 having a flat top 501 with a cross mark 506 (or some other tactile or visual feature), a connector 503 on one side, and a bonding
15 tube 505 surrounding the connector 503. In an accordance with various aspects of the present disclosure, the flush assembly 500 is connected to the EVD system of a patient. During use, the flush assembly 500 is used as a component of an EVD system to store and transfer fluid from and internal fluid reservoir 504, to an upstream location such as a tissue site, or to a downstream location, such as a drain site, and thus
20 perform retrograde prophylactic and/or emergency flushing by allowing fluid to be forced from the flush assembly 500 to either location to remove blockages in a catheter due to the accumulation of debris found in the fluid or from tissue infiltration.

[0062] In an accordance with various aspects of the present disclosure, and referring now to FIGS. 13-16, an embodiment of a flush assembly 600 according to
25 the disclosed subject matter is shown and described. In this embodiment, the flush

assembly 600 forms one or two hemi-spherical structures 602 which may have a flat top 601 (in the case of one hemisphere) or a rounded top (in the case of two hemi-spheres).

[0063] In accordance with flat top embodiments (FIGS. 13 and 14), a cross
5 mark 603 (or other tactile feature), a connector 605 on one side, a bonding tube 606 surrounding the connector 605, and a drainage tube 607 opposite the connector 605. In an accordance with various aspects of the present disclosure, the flush assembly 600 is connected to the EVD system of a patient in-line. The connector 605 is attached to an externalized ventricular catheter (see FIG. 35) while the drainage tube 607 is
10 connected to the EVD system. During use, the flush assembly 600 is used as a component of an EVD system to store and transfer fluid from and internal fluid reservoir 604, to an upstream location such as a tissue site, or to a downstream location, such as a drain site, and thus perform retrograde prophylactic and/or emergency flushing by allowing fluid to be forced from the flush assembly 600 to either
15 location to remove blockages in a catheter due to the accumulation of debris found in the fluid or from tissue infiltration.

[0064] In an accordance with various aspects of the present disclosure, and referring now to FIGS. 17-20, an embodiment of a flush assembly 100 according to the disclosed subject matter is shown and described. The flush assembly 100 forms
20 an upper body 802 and a base 882, with a connector 860 at a proximal end 884, and a drain tube 888 at a distal end 886. In this embodiment, the flush assembly 100 is disposed beneath the skin of a patient or externally connected. During use, the flush assembly 100 is used as a component of an EVD system to transport fluid from an upstream location, such as a tissue site to a downstream location, such as a drain site,
25 and to perform retrograde prophylactic flushing by allowing fluid to be forced from the

flush assembly 100 to the upstream location to remove blockages in an upstream catheter due to the accumulation of debris found in the fluid or from tissue infiltration into the upstream catheter.

[0065] In an accordance with various aspects of the present disclosure, the
5 flush assembly 100 shunts cerebrospinal fluid from the ventricles of the brain to a drainage site, typically the abdomen, in the treatment of hydrocephalus. The proximal connector 860 can be connected to a fluid collection tube or ventricular catheter 1200 (see FIG. 35) with drain holes 1208 at a terminal end 1202 providing a fluid communication between the tissue site and catheter 1200, and the drain tube 888 can
10 be connected to other distal components of an EVD system that terminate the EVD system at a drain site, or the drain tube 888 can be a drain catheter terminating at the drain site. The flush assembly 100 enables fluid to flow unobstructed from the connector 860 to the drain tube 888 through a collapsible fluid pathway 837 within the depressible dome 804. When the flush assembly 100 is activated, the collapsible fluid
15 pathway 837 is simultaneously obstructed allowing for flushing of the contents of the flush assembly 100 proximally through the connector 860 to clear any debris or tissues from the ventricular catheter 1200. The unique integration of this collapsible fluid pathway within the wall of the dome 804 significantly decreases the potential for skin erosion that may occur with conventional flushing systems.

20 [0066] In an accordance with various aspects of the present disclosure, the dome 804 is manufactured from a flexible material, such as silicone, and forms a flush cavity 852 above the base 882. The collapsible fluid pathway may be hemispherical, though alternatively, the collapsible fluid pathway may have other configurations, such as generally cylindrical, generally rectangular, or generally curvilinear.

25 [0067] In an accordance with various aspects of the present disclosure, the

base 882 is manufactured from a resilient material, such as polyetheretherketone (PEEK), polyethylene (PE), or Acetal.

[0068] In an accordance with various aspects of the present disclosure, and with reference to FIGS. 21 and 22, a flanged connector 854 extends from the base of the dome 804 forming a proximal channel 815 extending from the flush cavity 852 to a proximal opening 814, and a distal channel 817 extending from the flush cavity 852 to a distal opening 816. The connector 860 is located at the proximal channel 815, and the drain tube 888 is located at the distal channel 817. In an implementation, the connector 860 is formed as one piece and is integrated with the base 882. In an implementation, the connector 860 is not used, and the ventricular catheter 1200 fluidly communicates with the flush assembly 100 adjacent to the proximal channel 815, providing a fluid communication between the tissue site and the flush cavity 852.

[0069] In an accordance with various aspects of the present disclosure, the connector 860 forms a tube 862 extending from a proximal end 864 forming a barb 866, to a head 872 at a distal end 870. The barb 866 allows the flush assembly 100 to be connected to a tube or catheter draining a tissue site. A sleeve 876 around the tube 862 positions the connector 860 within the proximal channel 815, and an O-ring 878 circumscribing the sleeve 876 creates a seal between the sleeve 876 and upper body 802. The head 872 is disposed within the flush cavity 852 preventing the connector 860 from being pulled through the proximal end 884 of the flush assembly 100 when being separated from the structure immediately upstream from the assembly 100, and when the dome 804 is depressed during a flushing operation. The head has a convex proximal face 874 conforming to the dome 804 and providing a seal there between.

[0070] In an accordance with various aspects of the present disclosure, the drain tube 888 extends from a proximal end 890 disposed within the distal channel

817 to a distal end 892. The proximal end 890 communicates with a passage 846 formed by the dome 804 and a channel member 836. The passage 846 provides a fluid communication between the drain tube 888 and the flush cavity 852, and allows fluid draining into the flush cavity 852 from a tissue site to exit the flush assembly 100 and travel to a drain site. The passage 846 can be sealed off from the drain tube 888 by depressing the dome 804 against an occluder valve 820 disposed between the dome 804 and channel member 836. The occluder valve 820 is manufactured from a resilient material, such as silicone.

[0071] In an accordance with various aspects of the present disclosure, the first half of the passage 846 is formed by an upper channel 812 at an interior surface 810 of the dome 804 extending from the distal opening 816 to a valve seat 822 formed in the interior surface 810 of the central part of the dome 804. With specific reference to FIGS. 23 and 25, a second half of the passage 846 is formed by a lower channel 840 formed in a concave upper face 838 of the channel member 836 extending from a distal end 844 at the distal opening 816 to a proximal end 842 at the valve 820. The channel member 836 is manufactured from a flexible material, such as silicone, and the distal end 844 creates a sealing relationship with the drain tube 888 proximal end 890, and the concave upper face 838 conforms to the concave interior surface 810 of the dome 804 sealing the passage 846 from the flush cavity 852. In an implementation, the channel member 836 is a flexible tube.

[0072] In an accordance with various aspects of the present disclosure, and referring to FIGS. 23 and 24, the valve 820 is a circular disc forming a centrally located downstream port 828 extending between a top surface 824 and a bottom surface 832 of the disc. A valve channel 830 formed in the bottom surface 832 extends from the downstream port 828 to the edge of the valve 820. An upstream port 826

adjacent the downstream port 828 extends between the top surface 824 and bottom surface 832. The valve seat 822 receives the valve 820 whereby the bottom surface 832 around the downstream port 828 and valve channel 830 sealingly engage the proximal end 842 of the channel member 836, leaving the upstream port freely communicating with an upper chamber 834 and flush cavity 852. The outer edge of the top surface 824 of the valve 820 sealingly engages an upper rim of the valve seat 822 creating a sealing engagement therebetween. The interior surface 810 of the dome 804 is set off from the top surface 824 of the valve 820 creating the upper chamber 834.

10 [0073] In an accordance with various aspects of the present disclosure, the flush assembly 100 can be implanted beneath the skin of a patient using conventional procedures known to persons of ordinary skill in the art, and is used as a component of the EVD system; otherwise, the flush assembly 100 is exterior to the skin.

[0074] When the flush assembly 100 is at rest, the upper chamber 834 allows fluid within the flush cavity 852 to flow unrestricted through the upstream port 826 into the downstream port 828, through the passage 846, exiting the dome through the drain tube 888. When the flush assembly 100 is activated by a single or multi-finger pressure activation depressing the dome 804 toward the base 882, the valve 820 closes and prevents fluid flow to the drain site when a pressure threshold is reached. Before this pressure threshold is reached, fluid can travel both towards the drain site and the tissue site. After the pressure threshold is reached, continued pressure will expel the fluid in the dome 804 to the drain site facilitating a flushing operation.

[0075] In an accordance with various aspects of the present disclosure, the dome 804 material at a palpitation ring 108 forms an upper wall 133 of the upper chamber 834. Depressing the dome 804 causes the upper wall 133 to engage with the

downstream port 828 at the valve 820 top surface 824, sealing the flush cavity 852 from the passage 846 and preventing fluid from exiting the dome 804 via the passage 846. Further depressing the dome 804 toward the base 882 causes the fluid within the flush cavity 852 to be expelled from the cavity through the connector 860 into the
5 upstream structures.

[0076] Upon the release of downward pressure from the dome 804, the elastic nature of the dome 804 allows it to rebound to its original hemispherical configuration to begin receiving fluid within the flush cavity 852 from the tissue site. In an implementation, a rate limiting mechanism within the inlet channel prevents the dome
10 804 from rebounding rapidly by limiting the flow until a sufficient volume of fluid has filled the dome 804, or a sufficient fluid pressure within the dome 804 is achieved. In an implementation, the valve 820 separates the flush cavity 852 into two distinct fluid reservoirs when pressure is applied. Continued pressure expels fluid volume both towards the tissue site catheter and the drainage site catheter for the purpose of
15 dislodging occluding or infiltrating materials.

[0077] In an accordance with various aspects of the present disclosure, when the flushing assembly 100 is activated by depressing the dome 804, fluid is forced into the ventricular catheter 1200, causing movement of the catheter 1200 that dislodge debris from the catheter 1200. The tubular tissue site drain catheters, such as the
20 ventricular catheter 1200, has a terminal end 1202 forming a plurality of drainage holes 1208 and a sealed tip 504. The mass of fluid being flushed from the flush assembly 100 travels orthogonal to catheter tip 1204, creating a force pressing against the tip 1204, expelling fluid from the catheter 1200 through the drainage holes 1208 into the tissue site, and causing the terminal end 1202 to mechanically oscillate at an over
25 molded joint, dislodging debris from the terminal end 1202, and preventing cellular and

protein adhesion of debris to the drainage holes 1208.

[0078] In an accordance with various aspects of the present disclosure, either the patient, or a physician can use the flush assembly 100 to prophylactically flush the shunt to maintain the flush assembly 100 and upstream structures free from
5 blockages, and remove debris that attach to the surfaces of the flush assembly 100 and other upstream EVD components including the ventricular catheter 1200. The prophylactic flushing can occur at any time, such as prior to, or upon, full or partial occlusion of the drainage holes 1208 or catheter 1200.

[0079] The flush assembly 100 can be used for access to the tissue site from
10 outside the patient. In an implementation, the dome 804 is manufactured from a re-sealable material, allowing the flush assembly 100 to be used as an agent delivery pathway to the tissue site. In such an implementation, an agent can be injected into the flush cavity 852 by a needle, and the dome 804 can be depressed in the manner described above causing the agent to flow from the flush cavity 852 to the tissue site.
15 The agents include, among others, pharmaceuticals, hydrogels, drug eluting polymers, pre-loaded bolus, antibiotics, biologics, and gene therapies. In In an accordance with various aspects of the present disclosure, the flush cavity 852 is accessed by a needle inserted through the dome 804.

[0080] In an accordance with various aspects of the present disclosure, the
20 flush assembly 100 can be used with other shunt components, such as catheters, valves, anti-siphoning devices to drain fluid from the tissue site.

[0081] In an accordance with various aspects of the present disclosure, the flush assembly includes additional components, and the fluid pathway from the tissue site to the drain site is an angular pathway. Referring now to FIG. 26, flush assembly
25 901 is shown connected to a tissue site, such as a ventricle 903 of the brain. The

tissue site is accessed via a burr hole in the skull 905 of a patient. The flush assembly 901 forms a 90-degree fluid pathway from the tissue site to the exterior of the skull 905. The flush assembly 901 includes features found in flush assembly 100, including a collapsible fluid pathway, such as a dome 804, a valve 820, channel member 836, and drain tube 888. Here, a catheter 907 descends from the flush assembly 901 connecting the tissue site to the flush cavity 852. In an implementation, the catheter 907 includes a burr-hole cover 909 providing an attachment point for the base of the flush assembly 901 to the catheter 907.

[0082] In an accordance with various aspects of the present disclosure, and with reference to FIGS. 27-30, an embodiment of the disclosed subject matter is shown where a flush assembly 100 includes an upper body 1002 and a base 1082, with a collapsible fluid pathway 1037 integrally molded into the dome 804 between the exterior surface 806 and interior surface 810. Fluid flows into the flush cavity 852 from the connector 860 and fluid exits the flush cavity 852 through the drain tube 888 via the collapsible fluid pathway 1037. Pushing on the dome 804 from the exterior surface 806 causes the collapsible fluid pathway 1037 to close, and further pressing the upper body 1002 toward the base causes the fluid within the flush cavity 852 to exit the flush assembly 1000 via the connector 860, clearing debris from a ventricular catheter 1200 connected thereto.

[0083] In an accordance with various aspects of the present disclosure, the flush assembly is implanted such a way that when pressed in the manners described above the fluid volume within the flush cavity 852 exits the flush assembly 1000 via the connector 860, clearing debris from the ventricular catheter 1200.

[0084] In an accordance with various aspects of the present disclosure, in acute settings, the treatment of hydrocephalus or head trauma utilizes a drain site that is

either internal or external to the patient. The acute condition results in increased intracranial pressure, requiring use a drainage assembly in fluid communication with a tissue site, such as the ventricles, to drain fluid from the tissue site. The drainage assembly includes one or more of a fluid collection tube in fluid communication with
5 the tissue site. The fluid collection tube can include a drainage catheter connected to one or more ancillary drainage components, such as catheters, and other assemblies used during the treatment of the acute condition, leading to a collection site that is either internal or external to the patient. A flushing assembly can be used to force fluid within the catheters or ancillary drainage components toward the tissue site or the
10 drain site. With reference to FIGS. 31-32, an embodiment of a flushing assembly 1100 according to the disclosed subject matter is shown and described. In an embodiment, the flushing assembly 1100 forms an upper body 1101 forming an occlusion element 1102 and a flushing element 1103.

[0085] In use, In an accordance with various aspects of the present disclosure,
15 the flushing assembly 1100 is placed in engagement with the drainage assembly. First, the occlusion element 1102 engages a fluid collection tube, such as a ventricular catheter, or a drain tube, such as a drain catheter, stopping fluid flow at the occlusion element 1102 by compressing the tube. Next, the flushing element 1103 compresses a component of the drainage assembly. For example, the component may be the
20 collection tube, the drain tube, or a flush assembly fluidly disposed between the collection tube and drain tube, such as flush assemblies 100, 901, 300. The compression of the component by the flushing element 1103 pushes fluid through the drainage assembly in a direction away from the occlusion element 1102. For example, if the flushing element 1103 is upstream from the occlusion element 1102, whereby
25 in-line, the flushing element 1103 is closer to the origin of the fluid collection tube, the

fluid is pushed in the direction of the origin of the fluid collection tube, such as the tissue site. If the flushing element 1103 is downstream from the occlusion element 1102, whereby in-line, the flushing element 1103 is closer to the termination of the drain tube, the fluid is pushed in the direction of the termination of the drain tube, such as the drain site.

[0086] In an accordance with various aspects of the present disclosure and with reference to FIGS. 33 and 34, in an embodiment, a flushing assembly 1110 forms a lower body 1114 that opposes the flushing element 1113 for compressing an ancillary drainage component. The upper body 1111 slidably receives the flushing element 1113, and the lower body 1114 is pivotally attached to the upper body 1111 by a hinge 1116. An occlusion element 1112 at the edge of the upper body 1111 engages a receiver 1118 at the edge of the lower body 1114.

[0087] In use, the flushing assembly 1110 is placed in engagement with a fluid collection tube, such as a ventricular catheter, or a drain tube, such as a drain catheter. The flushing assembly 1110 has engagement surfaces that conform to exterior of the tube. The upper body 1101 then compresses the tube. The occlusion element 1112 contacts the tube compressing it against the receiver 1118, first stopping fluid flow at the compression point. Next, the flushing element 1113 engages the tube, compressing the tube, pushing fluid out of the tube creating a fluid flush. This flush can be directed towards the tissue site or the drainage site. The compression of the tube by the flushing element 1113 pushes fluid through the drainage assembly in a direction away from the occlusion element 1112. For example, if the flushing element 1113 is upstream from the occlusion element 1112, whereby in-line, the flushing element 1113 is closer to the origin of the fluid collection tube, the fluid is pushed in the direction of the origin of the fluid collection tube, such as the tissue site. If the

flushing element 1113 is downstream from the occlusion element 1112, whereby in-line, the flushing element 1113 is closer to the termination of the drain tube, the fluid is pushed in the direction of the termination of the drain tube, such as the drain site. In an embodiment, the occlusion element 1112 is in the center of flushing element 1113
5 whereby compression of the tube by the flushing element 1113 causes a movement of fluid both toward the tissue site and toward the drainage site.

[0088] As required, detailed aspects of the present disclosed subject matter are disclosed herein. However, it is to be understood that the disclosed aspects are merely exemplary of the disclosed subject matter, which may be embodied in various forms.
10 Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present disclosed subject matter in virtually any appropriately detailed structure.

[0089] Likewise, numerous characteristics and advantages have been set forth
15 in the preceding description, including various alternatives together with details of the structure and function of the devices and/or methods. The disclosure is intended as illustrative only and as such is not intended to be exhaustive. It will be evident to those skilled in the art that various modifications may be made, especially in matters of composition, ingredients, structure, materials, elements, components, shape, size,
20 and arrangement of parts including combinations within the principles of the invention, to the full extent indicated by the broad, general meaning of the terms in which the appended claims are expressed. To the extent that these various modifications do not depart from the spirit and scope of the appended claims, they are intended to be encompassed therein.

WHAT IS CLAIMED:

We claim:

1. A flush assembly for an external ventricular drain (EVD) system, comprising:

a collapsible upper body and a base, the flush assembly connected to the EVD using a connector proximate a bottom end of the flush assembly;

a bonding tube surrounding the connector, wherein the base is intersected by the connector; and

wherein the flush assembly stores a fluid in an internal fluid reservoir and when the flush assembly is activated, the collapsible upper body pushes the fluid from the internal fluid reservoir to a flushing site to perform a flush of the EVD.

2. The flush assembly according to claim 1, wherein the flushing site is at least one of a tissue site and a drainage site allowing the fluid to be forced from the flush assembly to remove blockages in a catheter or a drainage line.

3. The flush assembly according to claim 1, further comprising a stop cock valve, wherein the flush assembly can be turned on and off depending on an orientation of the stop cock valve.

4. The flush assembly according to claim 1, wherein the connector is attached with a luer lock connector.

5. The flush assembly according to claim 1, wherein the connector is

manufactured from a plastic or urethane.

6. The flush assembly according to claim 1, wherein the bonding tube is manufactured from a flexible material and provides a surface for chemical bonding to other similar materials.

7. The flush assembly according to claim 1, wherein a fluid flow is bidirectional.

8. The flush assembly according to claim 1, wherein the fluid is expelled in at least one of even amounts and non-even amounts in each direction.

9. The flush assembly according to claim 1, wherein the amount of fluid expelled in in each direction is adjustable.

10. The flush assembly according to claim 1, wherein the collapsible upper body is manufactured from a flexible material and the base is manufactured from at least one of a flexible material and a hard material, and when assembled form the collapsible upper body and the base form the internal fluid reservoir.

11. The flush assembly according to claim 10, wherein the flexible material comprises at least one of silicone or a thermoplastic elastomer and the hard material comprises at least one of ABS, polycarbonate, PEEK, polyurethane and plastic.

12. The flush assembly according to claim 1, further comprising a tactile

feature.

13. A flush assembly for an external ventricular drain (EVD) system, comprising:

at least one a hemi-spherical structure;

a connector located on a side, the connector having a bonding tube surrounding the connector;

a drainage tube located on an opposite side;

wherein the flush assembly is connected to the EVD system in-line, and wherein the connector is connected to an externalized ventricular catheter while drainage tube is connected to the EVD system; and

wherein the flush assembly stores a fluid in an internal fluid reservoir and when the flush assembly is activated, the flush assembly pushes the fluid from the internal fluid reservoir to a flushing site to perform a flush of the EVD.

14. The flush assembly according to claim 13, wherein the hemi-spherical structure has a flat top.

15. The flush assembly according to claim 14, wherein the flat top has a tactile feature.

16. The flush assembly according to claim 13, comprising two hemi-spherical structures.

17. The flush assembly according to claim 13, wherein the flushing site is at

least one of a tissue site and a drainage site allowing the fluid to be forced from the flush assembly to remove blockages in a catheter or a drainage line.