A microcatheter having an active segment reperfuses occluded blood vessels above the junction of the subclavian artery and common carotid artery. The microcatheter is used to penetrate emboli. Once an embolus is penetrated, the active segment of the microcatheter is activated, causing it to expand radially and thereby open a channel in the embolus. Thus, a channel for restored blood flow is created. The blood’s natural lytic action further degraded the embolus in some cases. Therapeutic agents may be administered through the microcatheter to aid in the reperfusion process.
RAPID PERFUSION DEVICES AND METHODS

RELATED APPLICATIONS

[0001] This application claims the full Paris Convention benefit of, claims priority to, and is a continuation of each of U.S. patent application Ser. No. 12/123,390, filed May 19, 2008; U.S. patent application Ser. No. 12/136,737, filed Jun. 10, 2008; U.S. patent application Ser. No. 12/182,370, filed Jul. 30, 2008; each of which claims priority to and incorporates by reference U.S. Provisional Patent Application Ser. No. 60/987,384, filed Nov. 12, 2007, the contents of each of the above being incorporated by reference herein in its entirety, as if fully set forth herein.

BACKGROUND

[0002] The present disclosure relates to minimally invasive and catheter delivered reperfusion systems for use in the vasculature.

SUMMARY

[0003] A microcatheter having an active segment reperfuses occluded blood vessels above the junction of the subclavian artery and common carotid artery. The microcatheter is used to penetrate emboli. Once an embolus is penetrated, the active segment of the microcatheter is activated, causing it to expand radially and thereby open a channel for restored blood flow in the embolus. The blood's natural lytic action further degrades the embolus in some cases. Therapeutic agents may be administered through the microcatheter to aid in the reperfusion process. Active and passive reperfusion are thus both enabled.

[0004] According to a feature of the present disclosure, a device is disclosed comprising a distal segment having attached thereto a radially expandable active segment, a proximal segment comprising an active segment activator for radially expanding or retracting the active segment, an activation member connecting the active segment activator to the active segment. The distal segment is of a suitable diameter for use above the juncture of the subclavian artery and common carotid artery.

[0005] According to a feature of the present disclosure, a method is disclosed comprising providing a microcatheter having at least a distal segment, proximal segment, and active segment for use above the subclavian artery and common carotid artery, wherein the active segment is radially expandable.

DRAWINGS

[0006] The above-mentioned features and objects of the present disclosure will become more apparent with reference to the following description taken in conjunction with the accompanying drawings wherein like reference numerals denote like elements and in which:

[0007] FIG. 1 shows a perspective view of an embodiment of a rapid reperfusion device in an unexpanded state;
[0008] FIG. 2 shows a perspective view of an embodiment of a rapid reperfusion device in an expanded state;
[0009] FIG. 3A shows a side view of an embodiment of a rapid reperfusion device;
[0010] FIG. 3B shows a sectional view of an embodiment of a rapid reperfusion device;
[0011] FIG. 3C shows a sectional view of an embodiment of a rapid reperfusion device;
[0012] FIG. 4A shows a side view of an embodiment of a rapid reperfusion device;
[0013] FIG. 4B shows a sectional view of an embodiment of a rapid reperfusion device;
[0014] FIG. 4C shows a sectional view of an embodiment of a rapid reperfusion device;
[0015] FIG. 5 shows a side view of an embodiment of a rapid reperfusion device in an unexpanded state;
[0016] FIG. 6 shows a side view of an embodiment of a rapid reperfusion device in an expanded state;
[0017] FIG. 7 shows a perspective view of an embodiment of a rapid reperfusion device in an unexpanded state;
[0018] FIG. 8 shows a perspective view of an embodiment of a rapid reperfusion device in an expanded state;
[0019] FIG. 9 shows a side view of an embodiment of a rapid reperfusion device in an unexpanded state;
[0020] FIG. 10 shows a side view of an embodiment of a rapid reperfusion device in an expanded state;
[0021] FIG. 11A shows a view of a rapid reperfusion device near a target embolus;
[0022] FIG. 11B shows a view of a rapid reperfusion device across a target embolus;
[0023] FIG. 11C shows a view of a rapid reperfusion device deployed against a target embolus;
[0024] FIG. 12A shows a view of a rapid reperfusion device near a target embolus;
[0025] FIG. 12B shows a view of a rapid reperfusion device across a target embolus; and
[0026] FIG. 12C shows a view of a rapid reperfusion device deployed against a target embolus.

DETAILED DESCRIPTION

[0027] In the following detailed description of embodiments of the invention, reference is made to the accompanying drawings in which like references indicate similar elements, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that logical, mechanical, biological, electrical, functional, and other changes may be made without departing from the scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims. As used in the present disclosure, the term "or" shall be understood to be defined as a logical disjunction and shall not indicate an exclusive disjunction unless expressly indicated as such or noted as "xor."

[0028] According to embodiments, a catheter system for use above the juncture of the subclavian artery and common carotid artery, for example, as well as other uses as determined appropriate by qualified medical personnel, may be introduced via a guidewire. The device operates as a microcatheter during introduction into a patient. An active segment of the device or system may expand radially to reperfuse, lyse, or macerate emboli, thrombi, clots, occlusion, blockage, or other matter in a vessel (which terms may be used interchangeably according to embodiments of the present disclosure). After reperfusion is achieved, the active segment may be returned to its configuration maintained prior to expansion, and the catheter system may be removed.
0029. According to embodiments, and as illustrated by an exemplary embodiment in FIG. 1, there is shown microcatheter 100 with active segment 110 in an unexpanded state. Microcatheter 100 comprises proximal segment 102 and distal segment 104. Proximal segment 102 or portions thereof may remain accessible outside of the patient and may be used to insert and retract microcatheter 100, as well as to deploy active segment 110 during operation. As illustrated by an exemplary embodiment in FIG. 2, active segment 110 may be deployed to an expanded state, at least a portion thereof having a radius greater than in an unexpanded state.

0030. According to embodiments, catheter length and diameter are suitable for inserting into a human patient and capable of reaching a target embolus, for example, in the region above the subclavian and common carotid arteries. For example, microcatheter 100 may be about 150 cm long; proximal segment 102 may be about 115 cm with an outer diameter of about 4 French and distal segment 104 is about 35 cm with an outer diameter of about 2.7 French. According to embodiments, a gradual decrease (e.g., stepwise, tapered, etc.) in the outer diameter dimension may be provided as a function of the distance along proximal segment 102. For example, proximal segment 102 may be 4 French at the most proximal end and distal segment 104 may be 2.7 French at the most distal end. Disposed between may be at least one segment having one or more intermediate outer diameters between 4 French and 2.7 French (e.g., 3.4 French, 3.0 French, etc. (see FIGS. 1, 2, 5, and 6). Microcatheter 100 may have at least one lumen having an inner diameter of about 0.012 to about 0.021 inches, which allows microcatheter to be inserted along a preinserted guidewire or used to infuse therapeutic agents. According to embodiments, the performance of microcatheter 100 is compatible with various microcatheters and is designed to track over guidewire 300 or other guidance structures through the neuro-vasculature. Those having ordinary skill in the art will recognize yet other ranges of measurements, dimensions, or attributes that may be varied based on the needs and specification of the vasculature provided.

0031. According to embodiments, activation member 120 may be provided to selectively radially expand and retract active segment 110. Activation member 120 may be a structure that connects distal segment 104 to proximal segment 102 or another component of microcatheter 100. According to embodiments, activation member 120, components thereof, devices attached thereto, or devices capable of acting upon activation member 120 may be directly accessible by a user, for example, at a proximal end of microcatheter 100 (via hub, luer, fitting, etc.). Activation member 120 may allow a user of microcatheter 100 to deploy active segment 110.

0032. According to embodiments, activation member 120 may be made from various materials, including stainless steel wire or braid, composites polymers and metal braids, ribbon or wire coils. As illustrated by an exemplary embodiment in FIG. 3A, 3B, and 3C, activation member 120 may extend through a lumen of microcatheter 100. For example, as shown in FIG. 3B, activation member 120 may be a wire extending through at least a portion of proximal segment 102. Likewise, guidewire 300 may be provided in the same or another lumen of microcatheter 100. By further example, activation member 120 may attach to at least a portion of distal segment 104, such that distal or proximal travel of activation member 120 relative to proximal segment 102 causes corresponding distal or proximal travel of distal segment 104 relative to proximal segment 102.

0033. As illustrated by an exemplary embodiment in FIGS. 4A, 4B, and 4C, activation member 120 may have a hollow lumen and extend through a lumen of microcatheter 100. Guidewire 300 may be disposed within the hollow lumen of activation member 120, as shown in FIG. 4B. Activation member 120 may slidably move over guidewire 300 to reach distal segment 104. Other devices operable during a procedure may be delivered via a hollow lumen of activation member 120.

0034. According to embodiments, activation member 120 may be a braid (stainless steel, nitinol, composite, polymer, metal, etc.) structure or a ribbon or wire coil. Accordingly, activation member 120 may be longitudinally or radially compressible, extendable, distensible, or otherwise responsive to forces applied thereto. For example, activation member 120 may cause distal segment 104 to move relative to proximal segment 102 by causing activation member 120 to compress or extend longitudinally. By further example, the longitudinal compression or extension of activation member 120 may result in adjustment of the relative position of proximal segment 102 and distal segment 104 where activation member 120 is attached to at least a portion of each of proximal segment 102 and distal segment 104. Another device (guidewire 300, etc.) may be provided to activation member 120 to effect its compression, extension, etc. According to embodiments, deployment of active segment 110 may be achieved by shortening of activation member 120, whereby the distance between proximal segment 102 and distal segment 104 is decreased.

0035. According to embodiments, when active segment 110 is expanded in a vessel, the radial expansion causes a channel to be formed in a thrombus for restored blood flow past the occlusion and thereby reperfuse the vessel. Activation of active segment may be accomplished by mechanical methods, such as with activation member 120 or by using a liner of microcatheter 100. Use of the liner is accomplished by leaving the liner unfused with active segment 110, such that the liner may be independently operable to deploy active segment 110.

0036. According to embodiments, activation member 120 may be fused to the distal-most portion of active segment 110 or the proximal-most portion of distal segment 104. Activation member 120 may further be fused to the proximal-most portion of active segment 110 or the distal-most portion of proximal segment 102.

0037. According to embodiments, active segment 110 and activation member 120 may provide opposing forces. For example, active segment 110 may be heat set into a native configuration in an expanded state. When activation member 120 tensions active segment 110, its state changes from an expanded state into a deliverable state. Such tension may be provided by longitudinal extension of activation member 120 or travel thereof causing proximal segment 102 to distance itself from distal segment 104. Once delivered to the site of an embolus, activation member 120 is adjusted to allow active segment 110 to relax and thereby expand. Such adjustment may be achieved by shortening the longitudinal length of activation member 120 or travel thereof causing proximal segment 102 to approach distal segment 104.

0038. By further example, active segment 110 may be heat set into a native configuration in an expanded state. Activation member 120 may be used to tension active segment 110 when delivered to the site of an embolus, thereby expanding it. Such tension may be provided by shortening the longitu-
dinal length of activation member 120 or travel thereof causing proximal segment 102 to approach distal segment 104. Shortening of activation member 120 may be achieved in a variety of ways, as recognized by those having ordinary skill in the art. For example, activation member 120 may be radially expanded, whereby its longitudinal length is decreased. By further example, activation member 120 may be transitioned from a substantially straight shape to serpentine shape, whereby its longitudinal length is decreased. Guidewire 300 may act upon or within activation member 120 to effect such transitions.

[0039] Other activation methods include electrical, chemical, and thermal activators, as is known and understood by those having ordinary skill in the art. Hydraulic activation may be accomplished with activation member 120 as a balloon in the interior of the catheter that is filled with a fluid, thereby expanding the balloon, which expands active segment 110. Fluids, devices, or other materials may be provided to activation member 120 to effect a change in the shape, geometry, size, orientation, or position thereof, thereby deploying active segment 110.

[0040] According to embodiments, active segment 110 comprises a radially expandable material. For example, as shown in FIGS. 1, 2, 5 and 6, active segment 110 may include a woven mesh. A mesh may be made from materials well known and understood by artisans, including polymers, fluoropolymers, nitinol, stainless steel, vetchan, or kevlar. Other biocompatible materials that may be woven or coiled are similarly contemplated. Active segment 110 is, according to embodiments, about 5 mm to about 50 mm in length when expanded and is designed to substantially return to its pre-expansion configuration for removal of microcatheter 100 after reperfusion.

[0041] According to embodiments, active segment 110 comprises a mesh. The mesh comprises a plurality of individual units, having a uniform size or spacing geometry or a variable size or spacing geometry. According to embodiments where the size or spacing geometry is variable, smaller size or spacing geometry is used to provide a tight mesh for expanding a channel through the thrombus. Larger size or spacing geometry units allow for blood flow through active segment 110.

[0042] According to embodiments, as shown in FIG. 6, active segment 110 may comprise both mesh 110A and tethers 1103. According to embodiments, mesh 110A comprises an open braid, a covered braid, or other supporting structure which may provide at least some porosity. The covering may comprise a distal protection mechanism and may be a polymer, such as polyurethane, or other biocompatible cover materials such as ePTFE or related thin film. Tethers 1103 may serve to provide structure and support for mesh 110A as well as attachment to at least one of proximal segment 102 and distal segment 104. Tethers 1103 may further provide openings whereby blood may freely flow from the proximal to distal end of active segment 110 through a lumen formed therein. Tethers 1103 may include braids, wires, coils, etc. Those skilled in the art will readily understand that materials for tethers 1103 and mesh 110A may be the same, different, or interchangeable, as needed.

[0043] According to embodiments, as shown in FIGS. 7, 8, 9, and 10, active segment 10 may comprise expandable coiled wires. The coiled wires may be made from stainless steel wire or braid, composite metal polymers, memory shape alloys such as nitinol, etc., wherein the coil is able to stably expand and return to an original state. As illustrated in FIG. 9, the diameter of coil may be substantially the same as that of microcatheter 100 when in a non-expanded state. However, when expanded (as illustrated in FIG. 10) the coiled wires expand radially according to the reperfusion principles disclosed herein. Such radial expansion may be achieved by a variety of methods, including shortening of the longitudinal length of active segment 110, travel of distal segment 104 relative to proximal segment 102, rotation of distal segment 104 relative to proximal segment 102. Other methods include mechanical, electrical, heat, chemical, etc.

[0044] According to embodiments, as shown in FIGS. 5, 6, 9, and 10, revascularization ports 112 may provide increased blood flow through the lumen of microcatheter 100, as disclosed further herein.

[0045] According to embodiments, variable cell size or spacing geometry may be accomplished with points where the braid crosses over fixed filaments (PCS). Thus, the cell size or spacing geometry varies by varying the density of the braid. Where high radial force is needed to open a channel in an embolus, for example, the filaments of the mesh are denser and therefore cross each other more often, yielding small cell size or spacing geometry that leads to the application of greater radial force when the mesh expands. Where reperfusion is desired, the PCS may be less dense and the resulting cell size or spacing geometry is increased. Additionally, drug delivery through microcatheter 100 will be more effective in mesh configurations having a large size or spacing geometry.

[0046] Active segment 110 may be coated or covered with substances, such as lubricious agents or pharmacologically active agents, according to embodiments. For example, active segment 110 may be covered with heparin or other agents that are used in clot therapy, such as those that aid in dissolving clots or mitigating vasospasms.

[0047] According to embodiments, microcatheter 100 is designed to follow a path of least resistance through a thrombus. Guidewire 300 inserted through a thrombus tends to follow the path of least resistance through the softest parts of the thrombus. When microcatheter 100 crosses the thrombus, it likewise follows this path of least resistance. As blood flow is restored, a natural lytic action further helps to break up the thrombus.

[0048] According to similar embodiments, therapeutic agents are deployable through the lumen of microcatheter 100, thereby allowing users of microcatheter 100 to determine on a case-by-case basis whether to administer an agent. Accordingly, the braid/geometry of active segment 110 is porous to allow the agent to pass from lumen of microcatheter 100 into the blood vessel at the site of an embolus, for example.

[0049] According to embodiments, and as illustrated in FIG. 11A, microcatheter 100 is inserted into a vessel having an occlusion. As previously discussed, microcatheter 100 is insertable along guidewire 300 through a vessel lumen, according to certain embodiments. Microcatheter 100 penetrates embolus 210 in the vessel. As shown in FIG. 11B, active segment 110 is positioned to coincide with the position of embolus 210. According to techniques well known and understood by artisans. As shown in FIG. 11C, active segment 110 is expanded, thereby opening a channel in thrombus 210 and restoring blood flow. According to embodiments illustrated in FIGS. 12A, 12B, and 12C, similar principles may be applied where active segment 110 comprises coiled wires.
Once activated, active segment 110 allows blood to flow around or through microcatheter 100 and active segment 110 to create therapeutic benefits associated with reperfusion. For example and according to embodiments, the portions of proximal segment 102 and distal segment 104 immediately proximal and distal to active segment 110 may have a diameter of about 2.0 French to about 3.0 French.

According to embodiments, portions of proximal segment 102 and distal segment 104 may have installed therein revascularization ports 112, as shown in FIGS. 11A, 11B, 11C, 12A, 12B, and 12C. Revascularization ports 112 comprise openings in microcatheter 100 that allow vascular fluids to flow through portions of microcatheter 100. For example, as shown in FIGS. 11C and 12C, fluid on a proximal side of embolus 210 may enter microcatheter 100 through at least one revascularization port 112 of proximal segment 102. The vascular fluids may travel through portions of microcatheter 100, including active segment 110, and exit through at least one revascularization port 112 of distal segment 104. Additionally, revascularization ports 112 provide additional delivery points for therapeutic agents delivered through microcatheter 100.

According to embodiments, a filter may be placed distal of active segment to prevent embolus pieces detached in the reperfusion process from escaping and causing distal occlusions. Accordingly, active segment 110 may be designed to capture pieces of embolus during the reperfusion processes. These pieces are captured within active segment 110 when active segment 110 is returned to its initial confirmation after expansion.

According to embodiments, a kit of parts is disclosed. The kit may comprise components, devices, and systems disclosed herein, as well as any other compatible with the same, and instructions for use. Likewise, directions for use (“DFU”) are included and the device may be part of a surgical tray or other packaged accessory set for surgeries. The kit may be a sub-component of a surgical tray.

While the apparatus and method have been described in terms of what are presently considered to be the most practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifications and similar structures. The present disclosure includes any and all embodiments of the following claims.

It should also be understood that a variety of changes may be made without departing from the essence of the invention. Such changes are also implicitly included in the description. They still fall within the scope of this invention. It should be understood that this disclosure is intended to yield a patent covering numerous aspects of the invention both independently and as an overall system and in both method and apparatus modes.

Further, each of the various elements of the invention and claims may also be achieved in a variety of manners. This disclosure should be understood to encompass each such variation, be it a variation of an embodiment of any apparatus embodiment, a method or process embodiment, or even merely a variation of any element of these.

Particularly, it should be understood that as the disclosure relates to elements of the invention, the words for each element may be expressed by equivalent apparatus terms or method terms—even if only the function or result is the same.

Such equivalent, broader, or even more generic terms should be considered to be encompassed in the description of each element or action. Such terms can be substituted where desired to make explicit the implicitly broad coverage to which this invention is entitled.

It should be understood that all actions may be expressed as a means for taking that action or as an element which causes that action.

Similarly, each physical element disclosed should be understood to encompass a disclosure of the action which that physical element facilitates.

Any patents, publications, or other references mentioned in this application for patent are hereby incorporated by reference. In addition, any embodiment used it should be understood that unless its utilization in this application is inconsistent with such interpretation, common dictionary definitions should be understood as incorporated for each term and all definitions, alternative terms, and synonyms of at least one of a standard technical dictionary recognized by artisans and the Random House Webster’s Unabridged Dictionary, latest edition are hereby incorporated by reference.

Finally, all referenced listed in the Information Disclosure Statement or other information statement filed with the application are hereby appended and hereby incorporated by reference; however, as to each of the above, to the extent that such information or statements incorporated by reference might be considered inconsistent with the patenting of this/ these invention(s), such statements are expressly not to be considered as made by the applicant(s).

In this regard it should be understood that for practical reasons and so as to avoid adding potentially hundreds of claims, the applicant has presented claims with initial dependencies only.

Support should be understood to exist to the degree required under new matter laws—including but not limited to United States Patent Law 35 USC 132 or other such laws—to permit the addition of any of the various dependencies o other elements presented under one independent claim or concept as dependencies or elements under any other independent claim or concept.

To the extent that insubstantial substitutes are made, to the extent that the applicant did not in fact draft any claim so as to literally encompass any particular embodiment, and to the extent otherwise applicable, the applicant should not be understood to have in any way intended to or actually relinquished such coverage as the applicant simply may not have been able to anticipate all eventualities; one skilled in the art, should not be reasonably expected to have drafted a claim that would have literally encompassed such alternative embodiments.

Further, the use of the transitional phrase “comprising” is used to maintain the “open-end” claims herein, according to traditional claim interpretation. Thus, unless the context requires otherwise, it should be understood that the term “comprise” or variations such as “comprises” or “comprising”, are intended to imply the inclusion of a stated element or step or group of elements or steps but not the exclusion of any other element or step or group of elements or steps.
Such terms should be interpreted in their most expansive forms so as to afford the applicant the broadest coverage legally permissible.

1. A microcatheter device, comprising, in combination:
   a first segment;
   a second segment;
   a radially expandable active segment connecting the first segment to the second segment and having an unexpanded state and an expanded state: an activation member connected to the second segment, wherein the activation member is configured to radially expand and retract the active segment.

2. The microcatheter device of claim 1, wherein the activation member allows a user to deploy the active segment.

3. The microcatheter device of claim 1, wherein the activation member is configured to control the relative distance between the first segment and the second segment.

4. The microcatheter device of claim 1, wherein the activation member comprises a hollow lumen.

5. The microcatheter device of claim 4, wherein the hollow lumen of the activation member is configured to receive a guidewire therein.

6. The microcatheter device of claim 1, wherein the activation member comprises a coil.

7. The microcatheter device of claim 1, wherein the active segment comprises a mesh.

8. The microcatheter device of claim 1, further comprising a plurality of revascularization ports disposed in at least one of the first segment and the second segment.

9. The microcatheter device of claim 1, further comprising a lumen configured to deliver at least one therapeutic agent.

10. A method comprising, in combination:
    providing a microcatheter having at least a proximal segment, a distal segment, an active segment between the proximal segment and the distal segment, an activation member attached to the distal segment, and a guidewire; delivering the guidewire to an embolus; crossing the embolus with the guidewire; advancing the microcatheter along the guidewire, whereby the active segment is aligned with the embolus; radially expanding the active segment.

11. The method of claim 10, further comprising restoring perfusion within a vessel containing the embolus.

12. The method of claim 10, wherein radially expanding the active segment comprises applying tension to the activation member.

13. The method of claim 10, wherein radially expanding the active segment comprises causing a distance between the proximal segment and the distal segment to decrease.

14. The method of claim 10, wherein radially expanding the active segment comprises shortening the longitudinal length of the activation member.

15. The method of claim 10, wherein radially expanding the active segment comprises allowing the activation member to transition from an extended state to a native state, the native state having a shorter longitudinal length than the extended state.

16. The method of claim 10, wherein the embolus is above the juncture of the subclavian artery and common carotid artery.

17. An improved medial device, comprising, in combination:
    a proximal segment;
    a distal segment;
    an active segment having an expanded state and an unexpanded state, wherein the active segment is connected to the proximal segment at a distal end thereof and to the distal segment at a proximal end thereof; an activation member having a shortened state and an extended state, wherein the activation member is connected to the active segment at a proximal end and a distal end thereof and disposed concentrically within the active segment, wherein the activation member is configured to radially expand and retract the active segment.

18. The improved medial device of claim 17, wherein the shortened state of the activation member corresponds to the expanded state of the active segment and wherein the extended state of the activation member corresponds to the unexpanded state of the active segment.

19. The improved medial device of claim 18, wherein the activation member is serpentine in the shortened state and substantially straight in the extended state.

20. The improved medial device of claim 18, wherein the activation member is a coiled wire selectively providing each of the shortened state and the extended state.

21. The improved medial device of claim 18, wherein the activation member comprises a hollow lumen.

22. The improved medial device of claim 21, further comprising a guidewire advanceable within the hollow lumen of the activation member.

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