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(71) Applicant (for all designated States except US): BOSTON SCIENTIFIC SCIMED, INC. [US/US]; One Scimed Place, Maple Grove, Minnesota 55311-1566 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): CHENG, Eric [US/US]; 4275 West Beech Lane, Bloomington, Indiana 47404 (US).

(74) Agent: GARRETT, Arthur, S.; Finnegan, Henderson, Farabow, Garrett & Dunner LLP, 901 New York Avenue, NW., Washington, DC 20001-4413 (US).

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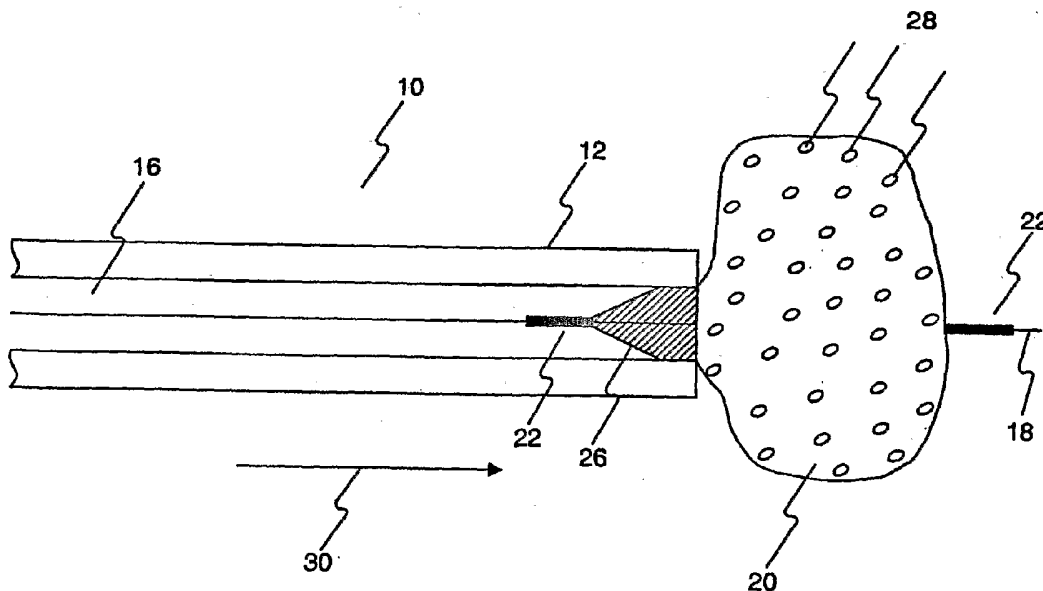
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(54) Title: EXPANDABLE MEDICAL RETRIEVAL DEVICE



(57) Abstract: Embodiments of the invention are directed to a medical device and methods for immobilizing and retrieving material from a patient's body. The device may include a sheath having a lumen, a distal end, and a proximal end. An elongate member is provided including an expansible member connected to a distal portion of the elongate member. The elongate member and expansible member are movable relative to the sheath to achieve a first state of the expansible member when the expansible member is within the lumen of the sheath and an expanded state when the expansible member extends from the distal end of the sheath. The expansible member comprises a material that expands to the expanded state due to the presence of fluid.

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## EXPANDABLE MEDICAL RETRIEVAL DEVICE

**DESCRIPTION OF THE INVENTION**

[001] This international application claims the priority of earlier filed United States Patent Application No. 11/098,518, filed April 5, 2005.

**Field of the Invention**

[002] This invention relates to medical devices and methods for retrieving objects within anatomical lumens of the body. More particularly, the invention relates to methods, and devices, for retrieving and preventing undesired migration of stones, such as urinary tract stones, gall stones, and other objects within anatomical lumens of the body, during a medical procedure.

**Background of the Invention**

[003] Medical immobilization and retrieval devices may include devices for stabilizing and/or removing organic material (e.g., blood clots, tissue, and biological concretions such as urinary, biliary, and pancreatic stones) and inorganic material (e.g., components of a medical device or other foreign matter), which may obstruct or otherwise be present within a body's anatomical lumens. For example, concretions can develop in certain parts of the body, such as in the kidneys, pancreas, and gallbladder. Minimally invasive medical procedures generally involve causing limited trauma to the tissues of a patient, and can be used to dispose of problematic concretions. Lithotripsy and ureteroscopy, for example, are used to treat urinary calculi (e.g., kidney stones) in the ureter of patients.

[004] Lithotripsy is a medical procedure that uses energy in various forms such as acoustic shock waves, pneumatic pulsation, electrical hydraulic shock waves, or laser beams to break up biological concretions such as urinary calculi (e.g., kidney stones). The force of the energy, when applied either extracorporeally or intracorporeally, usually in focused and continuous or successive bursts, divides a kidney stone into smaller fragments that may be extracted from the body or allowed to pass through urination.

[005] When stones are fragmented within a body tract by a lithotripter, the stone must first be stabilized. Typically, a medical retrieval device, such as a surgical grasper or a metal wire basket, is used to capture a stone in the retrieval assembly. With the stone held in position within the retrieval assembly, a lithotripter, such as a laser lithotripter, comes into proximity with the stone and the stone is fragmented by the lithotripter. After the stone is fragmented, the stone fragments can be removed by the same or a different medical retrieval device, or the fragments can be left in the body to be eliminated naturally. With the help of imaging tools such as transureteroscopic video technology and fluoroscopic imaging, the operator of the lithotripter device can monitor the progress of the medical procedure and terminate treatment when residual fragments are small enough to be voided or removed.

[006] Intracorporeal fragmentation of urinary calculi can prove problematic in that stones and/or stone fragments in the ureter may become repositioned closer to and possibly migrate back toward the kidney, thereby requiring further medical intervention to prevent the aggravation of the patient's condition. Existing practices to control migration of stones during lithotripsy include reducing the energy or frequency of the lithotripsy, or reducing the amount or frequency of irrigation used during the procedure. Another known practice includes pushing the stone into the renal pelvis and undertaking another future procedure for its removal.

[007] Various devices may be deployed to control migration and aid in retrieval of fragmented stones. For example, combined immobilization and retrieval devices may be deployed within a patient's body, independently, or through the working channel of an endoscope. Once deployed past the stone, the immobilization device can act as a backstop to prevent upward migration of fragments resulting from a lithotripsy procedure.

[008] Laser lithotriptors, for example, are effective in fragmenting stones that are captured in a retrieval assembly of a medical retrieval device. One drawback of the combined use of a laser lithotripter and a backstop and/or retrieval assembly is the susceptibility of the assembly, or parts of the assembly, to laser energy-induced damage. Damage may be caused by misfiring, misdirection, or unavoidable misalignment of the laser lithotripter with the stone. Laser energy-induced retrieval assembly damage may cause components of the backstop and/or retrieval assembly, such as portions of a traditional metal basket, to become roughened or broken.

Broken or roughened portions of the device expose sharp ends or surfaces that can traumatize the delicate internal lining of the ureter.

[009] Known medical devices for preventing the migration of stones and fragments are often deployed beyond a stone in a configuration that partially occludes the lumen or acts as a barrier to prevent the passage of unwanted material beyond a treatment site. The occluding elements are often made of materials formed at least partially of shape-memory materials, such as, stainless steel, nitinol, copper, cobalt, vanadium, chromium, iron, or the like. The continued deployment, repositioning, and movement of these metallic materials within a patient's body lumen can often cause undesired irritation and unnecessary trauma to the patient's body tract.

[010] Thus, it is desirable to have alternative methods and devices for preventing upward migration of fragments, and extracting such fragments while limiting trauma to the patient.

### **SUMMARY OF THE INVENTION**

[011] Embodiments of the present invention are directed to medical devices for immobilization and/or retrieval of objects within anatomical lumens of the body that obviate one or more of the limitations and disadvantages of prior immobilization and retrieval devices.

[012] In one embodiment, the medical device includes a sheath having a lumen, a distal end, and a proximal end. An elongate member is provided including an expansible member connected to a distal portion of the elongate member. The elongate member and expansible member are movable relative to the sheath to achieve a first state of the expansible member when the expansible member is within the lumen of the sheath and an expanded state when the expansible member extends from the distal end of the sheath. The expansible member comprises a material that expands to the expanded state due to the presence of fluid.

[013] In various embodiments, the medical device may include one or more of the following additional features: a medical device wherein the first state is a compressed state; wherein the elongate member is a flexible wire; a handle at a proximal end of the medical device configured to control axial movement of the expansible member relative to the sheath; wherein the expansible member has a proximal end and a distal end, and markers are positioned along the elongate member

proximate the distal and proximal ends of the expansible member; wherein the expansible member has a tapered proximal end to facilitate movement of the expansible member into the lumen of the sheath; wherein the expansible member has a tapered distal end to facilitate movement of the expansible member out of the lumen of the sheath; wherein the expansible member comprises a material that exhibits an expansion/compression size ratio of approximately 10:1; wherein the expansible member comprises Poly-vinyl Alcohol (PVA); wherein the expansible member comprises a sponge; wherein the expansible member defines holes formed therein for passing irrigation therethrough in the expanded state; wherein the expansible member comprises a material less susceptible to laser-energy induced damage than alloys of nickel/titanium, copper, cobalt, vanadium, chromium, and iron; wherein the sheath includes a longitudinal split along the length such that the sheath can be separated from the expansible member and elongate member by separation along the split; an second sheath for tracking over a proximal end of the elongate member after removal of the first sheath; wherein the second sheath has a lumen larger than the lumen of the first sheath and distal end for receiving the expansible member; wherein the additional sheath includes a tapered distal end extending to an enlarged distal opening.

[014] Another embodiment of the invention is directed to a medical device including a sheath having a lumen, a distal end, and a proximal end. An elongate member is provided including an expansible member connected to a distal portion of the elongate member. The elongate member and expansible member are movable relative to the sheath to achieve a first state of the expansible member when the expansible member is within the lumen of the sheath and an expanded state when the expansible member extends from the distal end of the sheath. In addition, the expansible member comprises a sponge.

[015] Another embodiment of the invention is directed to a method for retrieving material in a body. The method includes providing a medical device including a sheath having a lumen, a distal end, and a proximal end. An elongate member is provided including an expansible member connected to a distal portion of the elongate member. The elongate member and expansible member are movable relative to the sheath to achieve a first state of the expansible member when the expansible member is within the lumen of the sheath and an expanded state when the expansible member extends from the distal end of the sheath. The expansible

member comprises a material that expands to the expanded state due to the presence of fluid. The method further comprises inserting the medical device into an anatomical lumen of the body, with the expansible member of the medical device in a collapsed configuration; positioning the distal end of the sheath beyond the material to be immobilized; and moving the sheath relative to the elongate member and expansible member, such that the expansible member is expanded to the expanded second state outside the distal end of the sheath and at least partially occludes the anatomical lumen.

[016] In various embodiments, the method may include one or more of the following additional features: performing a lithotripsy procedure on the material; irrigating the lumen of the body; retrieving the immobilized material by proximally pulling the elongate member through the anatomical lumen with the expansible member in the expanded state; retracting the expansible member by moving the sheath relative to the elongate member and expansible member, such that the expansible member is retracted to a compressed state inside the lumen of the sheath; wherein anatomical lumen includes an interior surface and the expansible member expands to contact the interior surface of the anatomical lumen; wherein the expansible member comprises a material that exhibits an expansion/compression size ratio of approximately 10:1; wherein the expansible member comprises Poly-vinyl Alcohol (PVA); wherein the expansible member comprises a sponge; wherein the expansible member defines holes formed therein for passing irrigation therethrough in the expanded state; wherein the expansible member comprises a material less susceptible to laser-energy induced damage than alloys of nickel/titanium, copper, cobalt, vanadium, chromium, and iron; wherein the expansible member has a proximal end and a distal end, and markers are positioned along the elongate member proximate the distal and proximal ends of the expansible member; wherein the steps of positioning and moving further include visualizing the position of the markers through a medical imaging device; removing the sheath by completely backing off the sheath from the elongate member; providing a second sheath for tracking over a proximal end of the elongate member after removal of the first sheath, the second sheath having a lumen larger than the lumen of the first sheath and a distal end for receiving the expansible member; wherein the second sheath includes a tapered distal end extending to an enlarged distal opening; tracking the second sheath over the proximal

end of the elongate member; retrieving the immobilized material within the lumen of the second sheath by positioning the material between the distal end of the second sheath and the expansible member and then moving the second sheath relative to the elongate member, such that the expansible member is retracted to a compressed state inside the lumen of the second sheath along with the material.

[017] Additional objects and advantages of the invention will be set forth in part in the description which follows, and in part will be obvious from the description, or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

[018] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

[019] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and together with the description, serve to explain the principles of the invention.

[020] FIG. 1A is a partial side cross-sectional view of a medical immobilization/retrieval device in an undeployed position according to an embodiment of the invention.

[021] FIG. 1B is a partial side cross-sectional view of the medical immobilization/retrieval device of FIG. 1A in a partially deployed position.

[022] FIG. 2A illustrates the insertion of a distal portion of the medical immobilization/retrieval device into a ureter containing a kidney stone, according to an embodiment of the invention.

[023] FIG. 2B illustrates the medical immobilization/retrieval device of FIG. 2A having an expansible member deployed beyond a kidney stone in the ureter, according to an embodiment of the invention.

[024] FIG. 2C illustrates the proximal movement of a deployed expansible member of a medical immobilization/retrieval device within the ureter, according to an embodiment of the invention.



[025] FIG. 2D illustrates a medical immobilization/retrieval device having an expansible member deployed beyond a kidney stone in the ureter and a lithotripsy device positioned proximal to the kidney stone, according to an embodiment of the invention.

[026] FIG. 2E is similar to FIG. 2D except that FIG. 2E shows the kidney stone after being fragmented by a medical lithotripsy device, according to an embodiment of the invention.

[027] FIG. 2F illustrates the partial retraction of an expansible member of the medical immobilization/retrieval device of FIGS. 2A-2E, according to an embodiment of the invention.

[028] FIG. 3A illustrates an alternative medical immobilization/retrieval device, according to an embodiment of the invention.

[029] FIG. 3B illustrates a retrieval procedure for the medical immobilization/retrieval device of FIG. 3A, according to an embodiment of the invention.

### **DESCRIPTION OF THE EMBODIMENTS**

[030] Reference will now be made in detail to the present exemplary embodiments of the invention illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[031] FIG. 1A illustrates a medical device 10 having a sheath 12 and an inner immobilization device 13, according to an embodiment of the invention. Sheath 12 includes a distal opening 14 and an internal sheath lumen 16. The sheath 12 can be manufactured out of materials such as polytetrafluoroethylene (PTFE), polyimide, nylon, or other polymers with column strength and flexibility. In addition, the sheath 12 can be braided to add additional kink resistance.

[032] The immobilization device 13 is initially housed within the sheath lumen 16. The immobilization device 13 includes an elongate member 18 and an expansible member 20 attached along a length of the elongate member 18. The elongate member 18 may be a wire, cable, or other suitable flexible elongate structure movable within the lumen 16 of the sheath 12. Elongate member 18 may include coils attached to improve flexibility and aid in positioning the device within tortuous passages of a

patient's body. Marker bands 22, such as radiopaque markers or other suitable markers, are attached to the elongate member 18 at the distal and proximal ends of the expansible member 20. The expansible member 20 is constrained in a collapsed state by sheath 12 and is movable relative to the sheath 12 within lumen 16. The expansible member 20 may include a tapered distal portion 24 and a tapered proximal portion 26 to facilitate the movement of the expansible member 20 in forward deployment from within the sheath 12 and in retraction back within the lumen 16.

[033] As seen in FIG. 1B, the immobilization device 13 is configured for forward movement relative to the sheath 12, in the direction of arrow 30. The sheath 12 and expansible member 20 are movable relative to each other in order to achieve a first, compressed, collapsed state (FIG. 1A) in which the expansible member 20 is compressed within the internal lumen 16 of the sheath 12 and a second state (FIG. 1B) in which the expansible member extends from the distal opening 14 of the sheath 12 and expands to greater size.

[034] The expansible member 20 may consist of a material that expands in the presence of fluid when unconstrained by the sheath 12. For example, expansible member 20 can be formed of a Poly-vinyl Alcohol (PVA) sponge and may have an expansion ratio of approximately 10:1. A Poly-vinyl Alcohol having other suitable expansion ratios may be used. In addition to Poly-vinyl Alcohol, the expansible member 20 can be formed of any material suitable for placement within an anatomical lumen of a patient's body that exhibits a high expansion/compression ratio. Suitable alternative materials may include, but are not limited to, Soft Polyurethane or Polyethylene Foam. The use of a Poly-vinyl Alcohol material, or the like, is advantageous in that such material is less susceptible to laser-energy induced damage than other immobilization/retrieval device materials, such as traditional metals and alloys thereof.

[035] Figure 1B illustrates a distal portion of expansible member 20 being deployed beyond the distal opening 14 of sheath 12. In the presence of liquid, such as, for example, upon deployment within the ureter of a patient, the unconstrained portion of the expansible member 20 will absorb fluid and expand according to the physical properties of the expansible member. As noted above, the immobilization device 13 is configured for movement relative to the sheath 12. Any such relative movement may be controlled by a user at a proximal end of the medical device 10. In

one configuration, the elongate member 18 and sheath 12 may be coupled to any suitable proximal handle, including those known to one skilled in the art. The proximal end of the elongate member 18 may be connected to a movable internal portion of a handle at the proximal end of device 10, such that movement of the movable internal portion will move the immobilization device 13 relative to sheath 12 between expanded and collapsed states. Alternatively, in another configuration, the proximal end of the sheath 12 may be connected to a movable internal portion of a handle at the proximal end of device 10, such that movement of the movable internal portion will extend the sheath 12 over the immobilization device 13 and thereby collapse the expansible member 20.

[036] FIGS. 2A-2F illustrate a system and method for retrieving, immobilizing, and/or preventing migration of objects in anatomical lumens during a medical procedure. Referring to FIG. 2A, medical device 10 may be positioned at an internal treatment site, for example, such as within a patient's ureter 32. The positioning may be performed by any suitable method known in the art, and may include known imaging and viewing techniques. A distal portion 19 of elongate member 18 may extend outside of sheath 12 beyond the distal opening 14 and function as a guidewire for accurate placement of the medical device 10. Accordingly, the distal portion 19 of elongate member 18 may be more flexible than the remaining proximal section of device 13 (including sheath 12 and elongate member 18) to assist in positioning the elongate member 18, while preventing damage to a patient's internal tissues.

[037] As seen in FIG. 2A, the distal portion 19 of elongate member 18 and the distal opening 14 of sheath 12 are positioned within ureter 32, beyond a kidney stone 34. Referring to FIG. 2B, elongate member 18 is then moved forward relative to sheath 12, thereby deploying the expansible member 20 within the ureter 32. For example, FIG. 2B shows that sheath 12 has been moved proximally to deploy member 20. No longer constrained by the sheath 12 and due to the presence of fluid, the expansible member 20 achieves its expanded second state beyond the kidney stone 34. Marker bands 22, attached to the elongate member 18, may comprise bands of radiopaque material for designating the position of the expansible member 20 prior to, during, and/or after positioning, using standard medical imaging technology. FIG. 2B further illustrates that in an expanded state, expansible member 20 fills a portion of

ureter 32 while still adjusting to comply with contours and turns that may exist along the lumen within which the expansible member is deployed.

[038] In embodiments where the expansible member consists of a PVA sponge material, the expansible member 20 is hydrated when deployed within a patient's anatomical body lumen, thereby expanding to expose pores 28. The pore size may be varied as appropriate depending on the desired rigidity of the sponge material. Holes defining apertures (not shown), separate from the pores 28, can be manufactured in the sponge. The holes can be used for the passage of irrigation and to provide a smaller profile of the sponge in the compressed state. The hole diameter would ideally be less than 4 mm to prevent a larger stone from being imbedded in the sponge or migrating past the sponge during deployment.

[039] FIG. 2C illustrates the use of medical device 10 as a tool to move a stone 34 proximally along a ureter 32. In the expanded state of FIG. 2C, expansible member 20 can be moved along the ureter 32, in the direction of arrow 36, to sweep stone 34 proximally along the ureter 32. Upon the continued proximal movement of expansible member 20, stone 34 may be swept and repositioned to a new location more accessible for retrieval and removal, or swept from the ureter altogether. The material of expansible member 20, such as Poly-vinyl Alcohol, for example, is selected to be soft enough when expanded not to damage the surrounding tissue during movement and yet rigid enough to sweep or immobilize a stone 34.

[040] Referring to FIGS. 2D and 2E, an endoscope 38 including a lithotripter 40 may be positioned at an internal treatment site within a patient's ureter 32 along with the deployed medical device 10. Where a concretion, such as kidney stone 34, is too large to be extracted without fragmentation, a lithotripter 40 can be advanced through the working channel of an endoscope 38 in order to perform the fragmentation. Lithotripter 40 may be, for example, a laser fiber for directing laser energy at kidney stone 34 in order to break down the concretion into smaller pieces to facilitate retrieval or normal passage through the bladder.

[041] As seen in FIG. 2E, after a lithotripsy procedure is completed, kidney stone 34 is fragmented into multiple smaller stones 42. During the lithotripsy procedure, the expansible member 20 serves as a backstop to prevent migration of the smaller stones 42 beyond the immobilization device 13, thereby preventing complications resulting from the potential migration of stones 42 back into a patient's

kidneys. After the fragmentation of stone 34, the lithotripter 40 is withdrawn and the expansible member 20 can then be pulled proximally along the ureter 32 to sweep the remaining smaller stones 42 toward the bladder to be voided or repositioned to facilitate retrieval by an additional retrieval device.

[042] If the stone fragments 42 resulting from the lithotripsy procedure are of a size capable of being accommodated within sheath 12, stones 42 may be retrieved within sheath 12 along with the immobilization device 13 upon retraction of the expansible member 20. FIG. 2F illustrates the partial retraction of expansible member 20 back within sheath 12. Upon movement of immobilization device 13 relative to the sheath 12, in the direction of arrow 44, expansible member 20 is retracted in order to achieve a collapsed configuration to facilitate removal from the patient's ureter 32. Tapered proximal portion 26, shown in FIG. 1A, of expansible member 20 facilitates the retraction of immobilization device 13 within sheath 12. Any stone fragments captured upon retraction within the expansible member 20, or between the expansible member 20 and the internal lumen 16 of the sheath 12, can be safely removed from the patient upon withdrawal of the medical device 10. In addition, stones and fragments can be immobilized and positioned for removal (in the direction of arrow 44) at the distal end of the medical device 10, between sheath 12 and expansible member 20, without necessarily being captured within internal lumen 16 of the sheath 12.

[043] FIGS. 3A and 3B illustrate an additional embodiment of the present invention directed to a medical device 10' including an alternative sheath 12' for use with immobilization device 13. Sheath 12' is larger in comparison to previously described sheath 12 and includes a tapered distal end 46 and an enlarged distal opening 14'. During a medical procedure, the sheath 12 of FIGS. 1A to 2D may be completely removable from the elongate member 18 after deployment of the expansible member 20. In an alternative embodiment, not shown, the sheath 12 could be designed to tear away from the rest of the device 10, by the placement of a longitudinal split along the length of the sheath.

[044] During use of the embodiment of FIGS. 3A-3B, after the initial sheath 12 is removed, larger sheath 12' is tracked over the proximal end of the elongate member 18 and advanced to facilitate encapsulation of the deployed and hydrated expansible member 20. The larger lumen and distal opening 14' of sheath 12' serve to more easily surround and collapse the deployed expansible member 20 upon retraction

within the sheath 12'. In addition, the larger lumen and distal opening 14' can act as a retrieval device by trapping stones 42 within the lumen and/or between the sheath 12' and the expansible member 20, when the expansible member 20 is retracted proximally in the direction of arrow 48.

[045] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

WHAT IS CLAIMED IS:

1. A medical device, comprising:  
a sheath including a lumen, a distal end, and a proximal end; and  
an elongate member including an expansible member connected to a distal portion of the elongate member, the elongate member and expansible member being movable relative to the sheath to achieve a first state of the expansible member when the expansible member is within the lumen of the sheath and an expanded state when the expansible member extends from the distal end of the sheath,  
wherein the expansible member comprises a material that expands to the expanded state due to the presence of fluid.
2. The medical device of claim 1, wherein the first state is a compressed state.
3. The medical device of claim 1, wherein the elongate member is a flexible wire.
4. The medical device of claim 1, further comprising a handle at a proximal end of the medical device and configured to control axial movement of the expansible member relative to the sheath.
5. The medical device of claim 1, wherein the expansible member has a proximal end and a distal end, and markers are positioned along the elongate member proximate the distal and proximal ends of the expansible member.
6. The medical device of claim 1, wherein the expansible member has a tapered proximal end to facilitate movement of the expansible member into the lumen of the sheath.
7. The medical device of claim 1, wherein the expansible member has a tapered distal end to facilitate movement of the expansible member out of the lumen of the sheath.

8. The medical device of claim 1, wherein the expansible member comprises a material that exhibits an expansion/compression size ratio of approximately 10:1.
9. The medical device of claim 1, wherein the expansible member comprises Poly-vinyl Alcohol (PVA).
10. The medical device of claim 1, wherein the expansible member comprises a sponge.
11. The medical device of claim 1, wherein the expansible member defines holes formed therein for passing irrigation therethrough in the expanded state.
12. The medical device of claim 1, wherein the expansible member comprises a material less susceptible to laser-energy induced damage than alloys of nickel/titanium, copper, cobalt, vanadium, chromium, and iron.
13. The medical device of claim 1, wherein the sheath includes a longitudinal split along the length such that the sheath can be separated from the expansible member and elongate member by separation along the split.
14. The medical device of claim 1, wherein the sheath comprises a first sheath and the medical device further includes a second sheath for tracking over a proximal end of the elongate member after removal of the first sheath, the second sheath having a lumen larger than the lumen of the first sheath and a distal end for receiving the expansible member.
15. The medical device of claim 14, wherein the second sheath includes a tapered distal end extending to an enlarged distal opening.
16. A medical device, comprising:  
a sheath including a lumen, a distal end, and a proximal end; and



an elongate member including an expansible member connected to a distal portion of the elongate member, the elongate member and expansible member being movable relative to the sheath to achieve a first state of the expansible member when the expansible member is within the lumen of the sheath and an expanded state when the expansible member extends from the distal end of the sheath,

wherein the expansible member comprises a sponge.

17. The medical device of claim 16, wherein the first state is a compressed state.

18. The medical device of claim 16, wherein the elongate member is a flexible wire.

19. The medical device of claim 16, further comprising a handle at a proximal end of the medical device and configured to control axial movement of the expansible member relative to the sheath.

20. The medical device of claim 16, wherein the expansible member has a proximal end and a distal end, and markers are positioned along the elongate member proximate the distal and proximal ends of the expansible member.

21. The medical device of claim 16, wherein the expansible member has a tapered proximal end to facilitate movement of the expansible member into the lumen of the sheath.

22. The medical device of claim 16, wherein the expansible member has a tapered distal end to facilitate movement of the expansible member out of the lumen of the sheath.

23. The medical device of claim 16, wherein the expansible member comprises a material that exhibits an expansion/compression size ratio of approximately 10:1.

24. The medical device of claim 16, wherein the sponge comprises Poly-vinyl Alcohol (PVA).

25. The medical device of claim 16, wherein the sponge defines holes formed therein for passing irrigation therethrough in the expanded state.

26. The medical device of claim 16, wherein the sponge comprises a material less susceptible to laser-energy induced damage than alloys of nickel/titanium, copper, cobalt, vanadium, chromium, and iron.

27. The medical device of claim 16, wherein the sheath comprises a first sheath and the medical device further includes a second sheath for tracking over a proximal end of the elongate member after removal of the first sheath, the second sheath having a lumen larger than the lumen of the first sheath and a distal end for receiving the expansible member.

28. The medical device of claim 27, wherein the second sheath includes a tapered distal end extending to an enlarged distal opening.

29. A method for immobilizing material in a body comprising:  
providing a medical device comprising:

a sheath including a lumen, a distal end, and a proximal end; and  
an elongate member including an expansible member connected to a distal portion of the elongate member, the elongate member and expansible member being movable relative to the sheath to achieve a first state of the expansible member when the expansible member is within the lumen of the sheath and an expanded state when the expansible member extends from the distal end of the sheath, wherein the expansible member comprises a material that expands to the expanded state due to the presence of fluid.

inserting the medical device into an anatomical lumen of the body, with the expansible member of the medical device in a collapsed configuration;

positioning the distal end of the sheath beyond the material to be immobilized;  
and

moving the sheath relative to the elongate member and expansible member, such that the expansible member is expanded to the expanded state outside the distal end of the sheath and at least partially occludes the anatomical lumen.

30. The method of claim 29, further comprising performing a lithotripsy procedure on the material.

31. The method of claim 29, further comprising irrigating the lumen of the body.

32. The method of claim 29, further comprising retrieving the immobilized material by proximally pulling the elongate member through the anatomical lumen with the expansible member in the expanded state.

33. The method of claim 32, further comprising retracting the expansible member by moving the sheath relative to the elongate member and expansible member, such that the expansible member is retracted to a compressed state inside the lumen of the sheath.

34. The method of claim 29, wherein the anatomical lumen includes an interior surface and the expansible member expands to contact the interior surface of the anatomical lumen.

35. The method of claim 29, wherein the expansible member comprises a material that exhibits an expansion/compression size ratio of approximately 10:1.

36. The method of claim 29, wherein the expansible member comprises Poly-vinyl Alcohol (PVA).

37. The method of claim 29, wherein the expansible member comprises a sponge.

38. The method of claim 29, wherein the expansible member defines holes formed therein for passing irrigation therethrough in the expanded state.

39. The method of claim 29, wherein the expansible member comprises a material less susceptible to laser-energy induced damage than alloys of nickel/titanium, copper, cobalt, vanadium, chromium, and iron.

40. The method of claim 29, wherein the expansible member has a proximal end and a distal end, and markers are positioned along the elongate member proximate the distal and proximal ends of the expansible member.

41. The method of claim 40, wherein the step of positioning further includes visualizing the position of the markers through a medical imaging device.

42. The method of claim 29, further comprising removing the sheath by completely removing the sheath from the elongate member.

43. The method of claim 42, further comprising providing a second sheath for tracking over a proximal end of the elongate member after removal of the first sheath, the second sheath having a lumen larger than the lumen of the first sheath and a distal end for receiving the expansible member.

44. The method of claim 43, wherein the second sheath includes a tapered distal end extending to an enlarged distal opening.

45. The method of claim 43, further comprising tracking the second sheath over the proximal end of the elongate member.

46. The method of claim 45, further comprising retrieving the immobilized material within the lumen of the second sheath by positioning the material between the distal end of the second sheath and the expansible member and then moving the second sheath relative to the elongate member, such that the expansible member is

retracted to a compressed state inside the lumen of the second sheath along with the material.

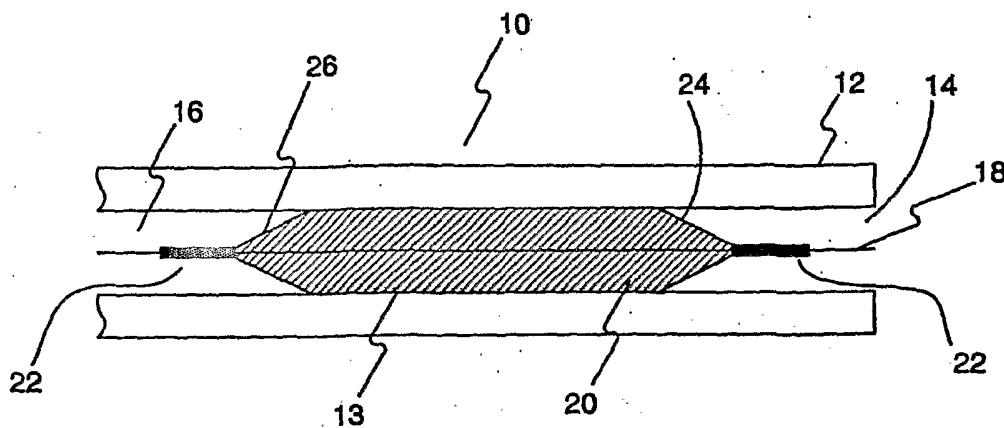


FIG. 1A

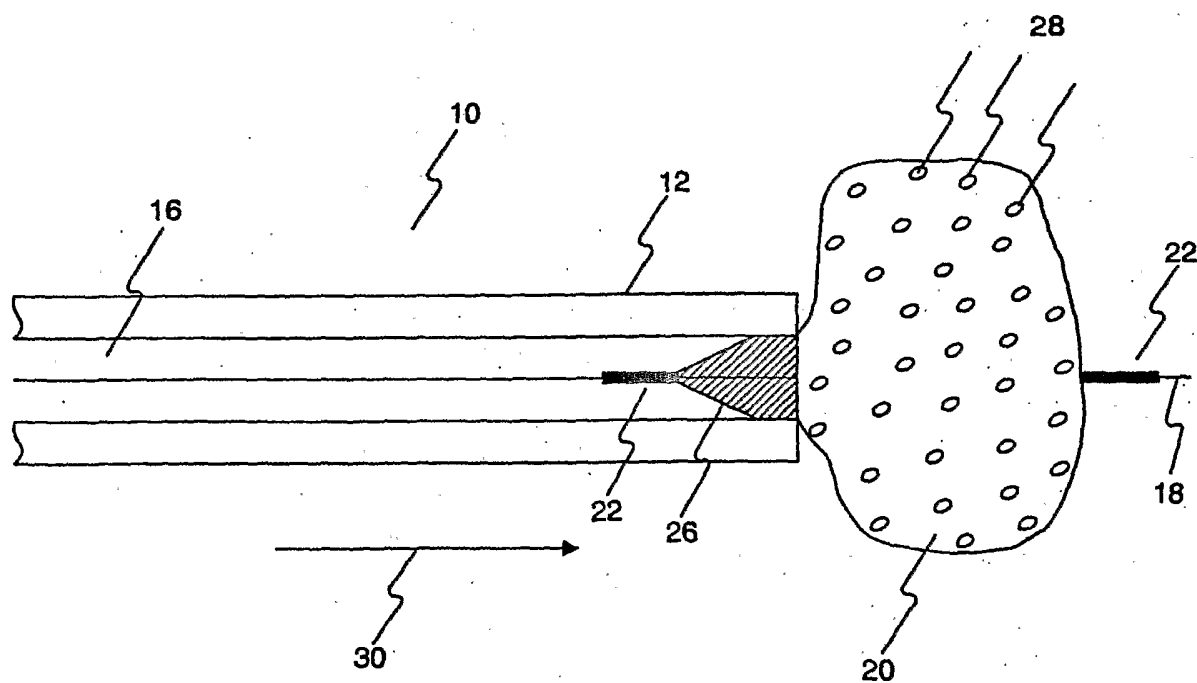


FIG. 1B

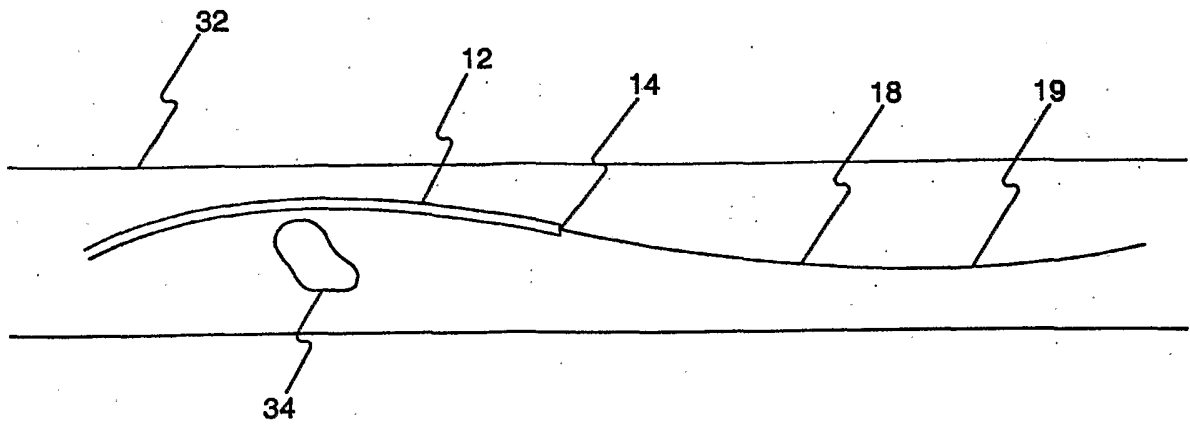


FIG. 2A

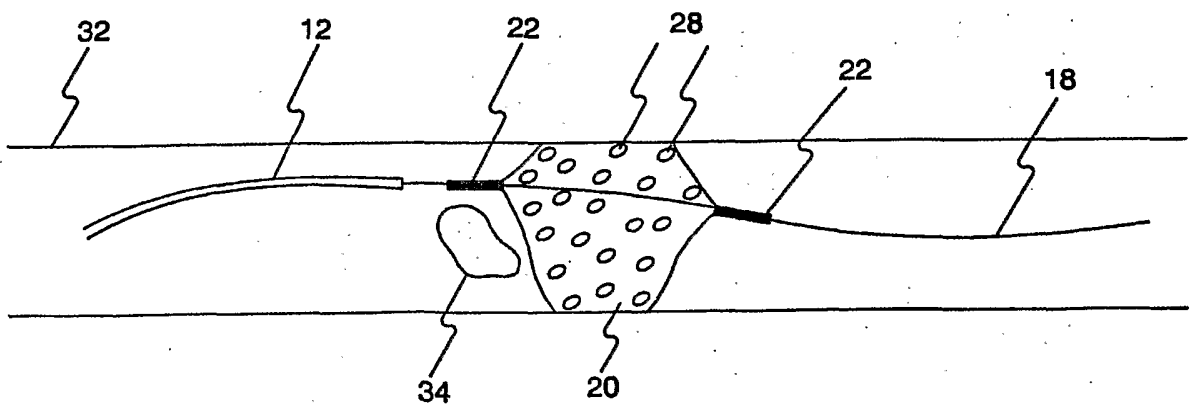


FIG. 2B

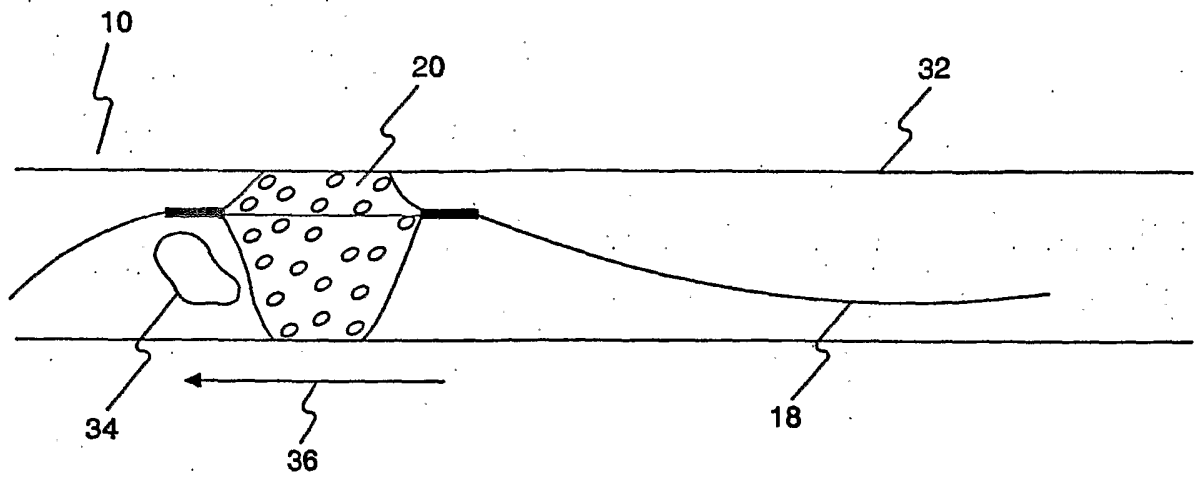


FIG. 2C

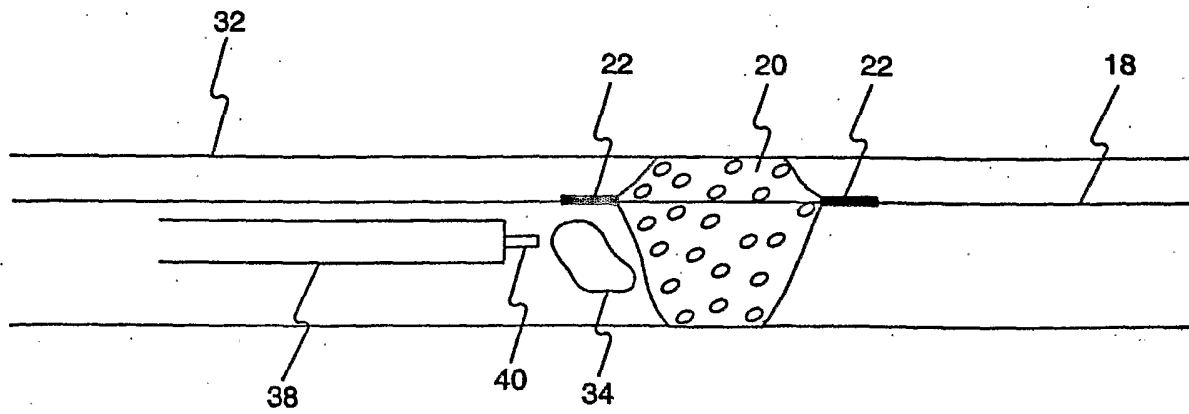


FIG. 2D



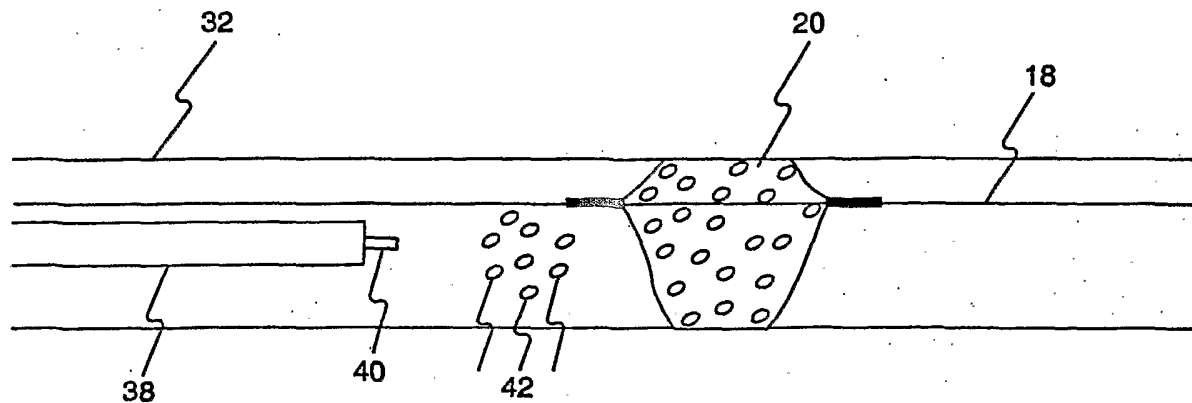


FIG. 2E

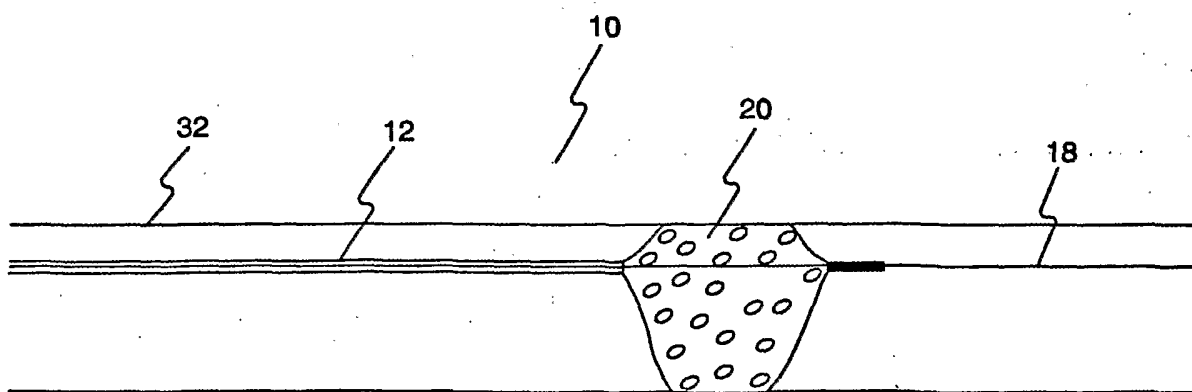


FIG. 2F

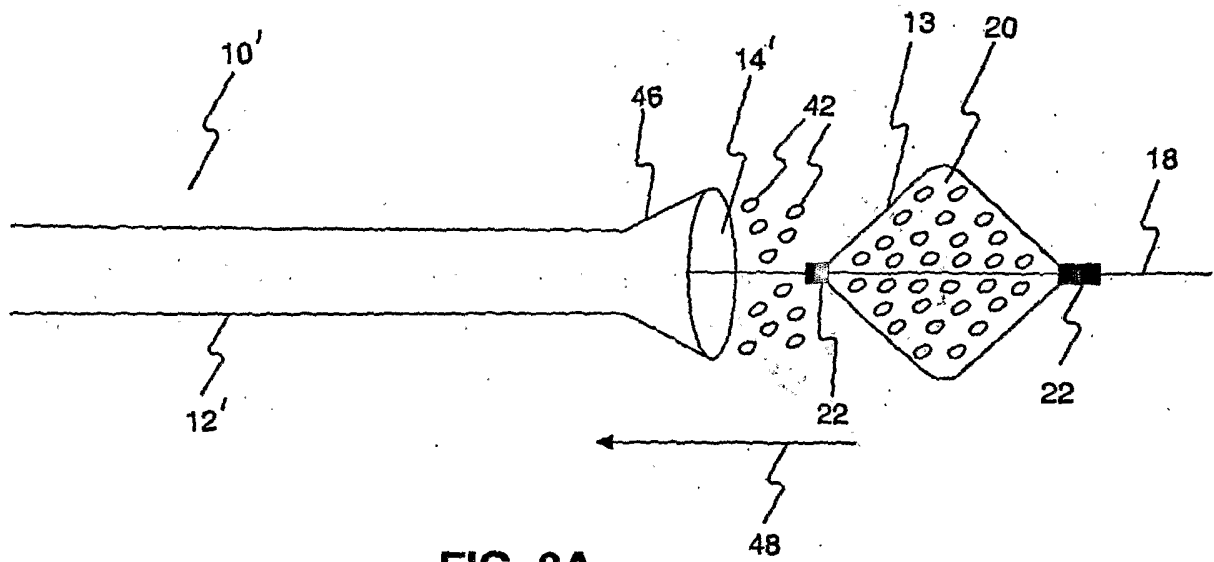


FIG. 3A

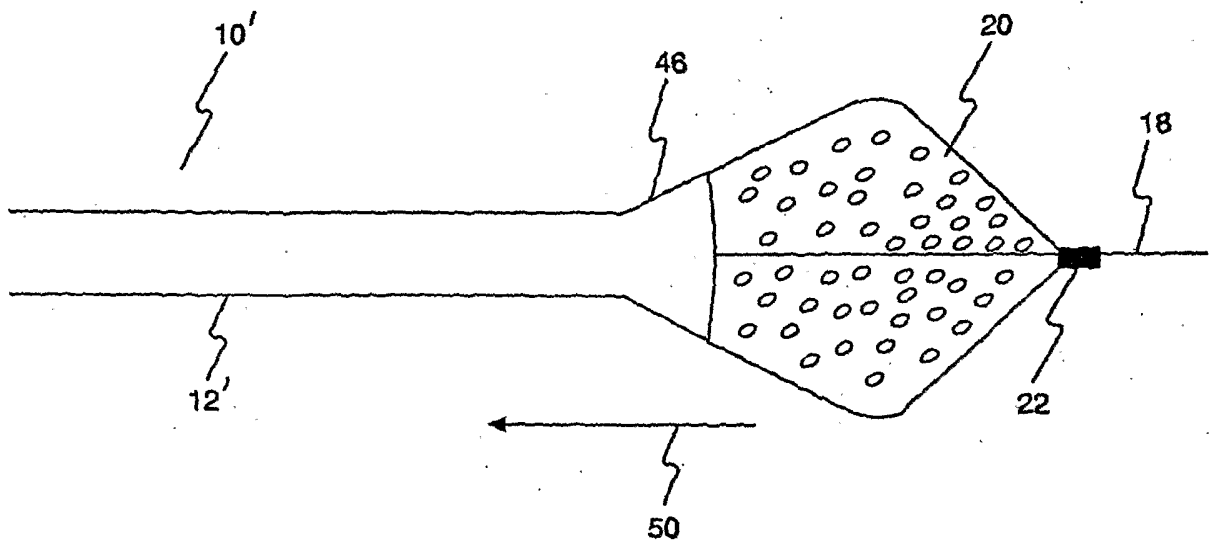


FIG. 3B

# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/007557

**A. CLASSIFICATION OF SUBJECT MATTER**  
 INV. A61B17/22 A61F2/01 A61M25/10 A61M25/00  
 ADD. A61B18/26

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)  
 A61B A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X  A	WO 03/024299 A (JOMED GMBH; JOERGENSEN, ERLING, IB; SEIBOLD, GERD; QUINT, BODO, STEFAN) 27 March 2003 (2003-03-27)  page 11, line 1 - page 13, line 7; figure 1A  page 17, line 10 - page 18, line 32; figure 4 figures 5A-5E  ----- -/--	1-3, 5-7, 9-12, 16-18, 20-22, 24-26 4, 8, 13-15, 19, 23, 27, 28

Further documents are listed in the continuation of Box C.       See patent family annex.

\* Special categories of cited documents :

*A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *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
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Date of the actual completion of the international search	Date of mailing of the international search report
5 July 2006	17/07/2006

Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer  Filali, S
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INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2006/007557

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2001/025155 A1 (YOON INBAE) 27 September 2001 (2001-09-27)  paragraph [0048] - paragraph [0050]; figure 1  -----	1-4,6, 8-10,12, 13, 16-19, 22-26
A	US 5 935 139 A (BATES ET AL) 10 August 1999 (1999-08-10)  column 2, line 56 - column 4, line 32; figures 1,2 column 5, line 33 - column 6, line 16; figures 7,8A-8D  -----	1-4,6, 8-10,12, 13, 16-19, 22-26

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2006/007557

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 29-46  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2.  Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2006/007557
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Patent document cited in search report		Publication date		Patent family member(s)	Publication date
WO 03024299	A	27-03-2003	US	2004098026 A1	20-05-2004
			US	2003055452 A1	20-03-2003
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US 5935139	A	10-08-1999	US	6096053 A	01-08-2000
			WO	9741782 A1	13-11-1997