(57) Abrégé/Abstract:
Occluding structures may be created within a body lumen by advancing a length of material distally through the body lumen. By drawing a distal location on the advanced length of material in a proximal direction, the material may be compacted into a structure which at least partially occludes the lumen. The occluding structure may be used for a variety of purposes, including removing obstructions from the body lumen, such as kidney stones from the ureter; providing hemostasis in a blood vessel; providing occlusion of a fallopian tube; temporary constraint of stone fragments in the urinary tract; capture or restraint of clot in blood vessels; and the like. Apparatus for performing the method may comprise a length of material attached at its distal end to tubular guide or other advancement member. Tensioning members may also be provided for collapsing and compacting the length of material within the body lumen.
METHODS AND APPARATUS FOR DEPLOYING CONFORMED STRUCTURES IN BODY LUMENS

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METHODS AND APPARATUS FOR DEPLOYING CONFORMED STRUCTURES IN BODY LUMENS

BACKGROUND OF THE INVENTION

[0001] 1. Field of the Invention. The present invention relates generally to medical apparatus and methods. More particularly, the present invention relates to methods and apparatus for deploying conformable structures in the ureter and other body lumens.

[0002] It is common for kidney stones to pass from the kidney through the ureter to the urinary bladder. While muscular peristalsis of the ureter will often pass the stones into the bladder without complication, in some instances large and/or irregularly shaped stones may become lodged within the ureter causing discomfort and potential damage to the ureter and upper collective system.

[0003] A number of ways have been proposed for dislodging such kidney stones. For example, extracorporeal shock wave lithotripsy (ESWL) can be used to break up the kidney stones but is often ineffective when the stones are present in the ureter. Moreover, ESWL can produce irregularly-shaped fragments which, while smaller than the original stone, may have sharp edges that will prevent spontaneous passage of the particles through the ureter. In the case of a stone or fragment, impacted in the ureter, it is common practice to attempt capture, using a wire stone basket. The basket is introduced through a ureteroscope which itself is typically introduced retrograde through the urinary tract.

[0004] In many cases, further lithotripsy through the scope is performed (ISWL). It is often difficult to advance such stone baskets past the obstructing material. Attempts to pass wire baskets or other grasping apparatus past a stone lodged in the ureter also presents risk of damage to the ureter. Abrasion, stretching, or perforation of the ureter at the impaction site can cause local urine leakage or edema even if the stone or resulting debris is successfully captured; and removal of the basket with the stone may be quite difficult. In some instances, baskets containing captured stones or fragments cannot themselves be removed, and it is difficult if not impossible to release the captured stone material back into the lumen of the ureter. In those cases, the basket must often be retrieved surgically. Finally, if and/or when ISWL is performed, it would be useful to have some means of stabilizing stone fragments at the treatment site, rather than letting them escape up the ureter in a retrograde direction.
[0005] For these reasons, it would be desirable to provide improved methods and apparatus for capturing and removing kidney stones from the ureter. It would be further desirable if the methods and apparatus were useful for containing and/or retrieving other materials from other body lumens, such as for extracting clot, thrombus, and/or other obstructing materials from blood vessels in embolectomy procedures. It would still further be desirable if the methods and apparatus were useful for still other procedures, including luminal occlusion, for example vascular occlusion for hemostasis, restricting blood flow to target tissue regions, and the like. The methods and apparatus of the present invention should be generally atraumatic in use, require significantly less skill than basket manipulation, optionally allow the release of captured material, should be simple and economical in construction and use, and should provide minimum risk and trauma to the patient. At least some of these objectives will be met by the inventions described hereinbelow.

[0006] 2. Description of the Background Art. The use of an everting sleeve composed of thin, tensilized polytetrafluoroethylene for introducing catheters to body lumens is described in U.S. Patent Nos. 5,531,717; 5,676,688; 5,711,841; 5,897,535; 6,007,488; 6,240,968; and EP605427B1. A wire basket for advancing stone through a body lumen during lithotripsy procedure is available under the Stone Cone tradename from Boston Scientific Corporation. See Published U.S. Application No. 2003/0120281. Copending application no. 10/794,337, filed on March 5, 2004, the full disclosure of which is incorporated herein by reference, describes a sheath delivery system that could be used in performing some of the methods described herein.

BRIEF SUMMARY OF THE INVENTION

[0007] The present invention provides methods and apparatus for deploying an occluding structure in a body lumen. The occluding structure will usually be intended for temporary placement and will often be used for removing kidney stones and other urinary calculi, blood clots, thrombus, and other materials which obstruct body lumens. In other instances, however, the occluding structures could be deployed permanently for occluding blood vessels, fallopian tubes, and the like for a variety of purposes, particularly when the occluding structure is lodged in a lumen having a diameter which decreases in the direction of blood or other fluid flow.

[0008] The occluding structure typically comprises a length of material which is initially positioned in the body lumen in a generally elongate or unfurled configuration. The length of
material is subsequently pulled, furled, or drawn back on itself so that the material compresses or compacts into the desired occluding structure. The material typically comprises a polymer film, a woven fabric, a non-woven fabric, and composites and laminates thereof. Exemplary polymer materials include polytetrafluoroethylene (PTFE), polyethylene (PE), perfluorooalkoxy (PFA), polyurethane (PU), perfluoromethylvinylether (MFA), and perfluoropropylvinylether (PPVE). Other exemplary materials include films, fabrics woven of any supple material such as nylon, polyester, silk, etc., lamination of these materials, and the like. The materials will generally be chosen so that they compress or compact into a relatively soft, non-traumatic mass of material. The compaction may be by folding, twisting, spiraling, or otherwise collapsing so that the length of the material becomes shorter and the width becomes greater, where length is a dimension generally aligned with the axis of the body lumen and width is the dimension generally transverse to the axis when the material is in the body lumen. The length of material may be formed as a ribbon, a tube, a rope, a bundle, a coil, or other elongated structure(s) capable of being collapsed and compacted. In an exemplary embodiment, the material is formed from a tube by expansion, weaving, braiding, or slitting. In the exemplary embodiments, the length of material prior to compaction is in the range from 1 cm to 10 cm, usually from 2 cm to 6 cm, and most typically from 3 cm to 5 cm. The original length will be foreshortened so that the resulting compacted mass has a width that approximates the internal diameter of the lumen in the range from 1 mm to 10 mm, usually from 2 mm to 6 mm, and preferably from 3 mm to 5 mm.

[0009] By deploying the length of material in its elongated, narrow-diameter configuration, the material will have a very low profile which permits it to be advanced through narrow body lumens, and more particularly, past obstruction(s) which may be present within the lumen, along the way bypassing structures, valves, sphincters, etc. For example, the length of material may be deployed past stones and other urinary calculi, past blood clots, past regions of thrombosis in blood vessels, and the like. By then compacting the length of material on a distal side of the obstruction, the compacted material may then be drawn in a proximal direction to form a relatively stiff plug or occlusion which is drawn proximally in order to move or more usually remove the obstruction from the body lumen. Deployment of the occluding member, however, may be used for other purposes, including containment of materials, e.g., stone debris during lithotripsy and distal protection against the release of emboli in performing vascular procedures; hemostasis when deployed in blood vessels; contraception when deployed in the fallopian tubes; and the like.
[0010] In some instances, the devices of the present invention may be used as guidewires when the length material is in its elongated, narrow-diameter configuration. In particular, in some cases a tubular length of material may be attached to an advancement member which has many of the features of a guidewire, including a pushable, torquable shaft and a floppy distal tip to allow steering through a body lumen.

[0011] In a first specific aspect, a method for compacting a structure in a body lumen comprises advancing a length of material distally in the body lumen and drawing a distal location on the advanced length of material proximally to compact the material into a structure which at least partially occludes the body lumen. Typically, the length of material is advanced distally past an obstruction in the body lumen and thereafter drawn proximally against the obstruction. The obstruction may then be moved by pulling or drawing the compacted material against the obstruction to reposition the obstruction within or outside of the body lumen. Additionally or alternatively, the compacted structure may prevent the obstruction from moving in a distal direction without movement or removal of the material.

In a specific embodiment, the body lumen is a ureter, cystic duct, or common bile duct, and the obstruction comprises one or more stones or other calculi. In a more specific embodiment, the body lumen is a ureter and the length of material is advanced from the urinary bladder into the ureter and past the kidney stone(s) lodged within. Optionally, energy may be directed to disrupt the kidney stones while engaged by the compacted material.

[0012] The length of material may be advanced in a variety of ways. For example, the length of material may be advanced or otherwise introduced through a tubular guide. In one instance, the tubular guide is first positioned through the body lumen and the length of material is advanced therethrough, typically using a separate advancement member. In a second instance, the tubular guide and the length of material are introduced simultaneously. Note that the tubular guide may subsequently be drawn proximally in order to expose an unsupported portion of the material. In a third instance, the length of material is advanced using an advancement member. The length of material is attached at or near a distal end of the advancement member, such as a guidewire, and the advancement member and length of material are simultaneously introduced through the body lumen and optionally past an obstruction. In a fourth and presently preferred instance, the tubular guide is introduced through the body lumen where a length of material is originally carried within the interior of the tubular guide. The length of material is everted over a distal end of the tube as the tube is introduced and acts as a barrier to protect the wall of the body lumen since the everted
material will remain generally stationary relative to the wall. In the latter instance, the length of material is typically in the form of a sleeve which emerges from an interior lumen, passage, or receptacle of the tubular guide to cover an exterior of the tubular guide as the tubular guide is advanced and the sleeve everts.

[0013] In some instances, the tubular guide or other advancement member will also be used to draw back the advanced length of material proximally to compact the material into the occluding structure. In such instances, the systems used to perform the methods of the present invention may consist only of the length of material and the tubular guide or other advancement member, e.g., a guidewire-like advancement member as described previously. More usually, however, the systems of the present invention will include at least a third component which comprises a tension member for drawing proximally on the length of material after it has been advanced by the tubular guide or other advancement member. The tension member may have a wide variety of forms and may comprise suture, filament, a thread, a wire, a tube, or other elongate element that can be permanently or releasably attached to a distal location on the length of material. Frequently, the tension member will be woven, threaded, or otherwise incorporated into the length of material to facilitate the compaction of the material as the tension member is pulled backward. In an illustrated embodiment, the tension member is a filament which is woven in and out of axially spaced-apart locations on the length of material to permit folding of the length of material as the tension member is drawn proximally. The tension member could alternatively pass through loops or other attachment points on the length of material or could be woven in as part of the fabric of the length of material. Alternately, the tension member could pass through the lumen of a tubular sleeve of the material. In still other alternate configurations, the tension member may pass through the center of a tubular sleeve of collapsible material and loop around the open distal end of the sleeve. The tension member can then pass back along the outside of the sleeve to form a loop over the sleeve where pulling on either or both ends of the loop will collapse the material to form the expanded material mass.

[0014] When using a separate tension member, the methods of the present invention will frequently comprise detaching the tension guide or other advancement member from the length of material prior to compacting the material. Alternatively, when using a tubular guide disposed within a sleeve-like length of material, the tubular guide may be partially withdrawn in a proximal direction leaving a distal portion of the length of material unsupported and ready for compaction. In many cases, it will be possible to reverse compaction of the length
of material by distally advancing the tension member prior to detachment. For example, it may be desirable under certain circumstances to reverse compaction to release entrapped materials that cannot be removed. By releasing and recapturing, removal could be completed.

[0015] In a particular embodiment, the distal end of the length of material may be attached at or near the distal end of an advancing member, e.g. immediately proximally of the floppy tip of a guidewire-like advancement member. The proximal end of the length of material may be attached to a tubular guide through which the advancement member can be advanced and retracted. By advancing the advancement member in the distal direction relative to the tubular guide, the length of material (which will itself typically be in a tubular form) will be lengthened and elongated to its narrow diameter configuration. Conversely, by drawing the advancement member proximally relative to the tension member, the length of material will be expanded into an occlusive mass. An advantage of this configuration is that the tubular guide may replace a portion of the length of the "length of material" while still allowing the material to be readily manipulated when advanced well into a body lumen.

[0016] In certain embodiments, the length of material will comprise fold structures such as lines or other scored notched, or weakened regions or variations in thickness or geometry which impart a preferential folding pattern upon drawing the length of material in the proximal direction. Exemplary lengths of material may comprise strips, sleeves, ribbons, tubes, and the like, and preferred materials have been set forth above.

[0017] In a preferred method for introduction, a sleeve-like length of material is introduced using a tubular guide. The sleeve material is initially stowed within a central lumen or other passage or receptacle in the tubular guide. A first end of the sleeve is immobilized relative to an entry point into the body lumen being treated. The tubular guide is then advanced in a distal direction, and the length of material emerges from a distal end of the tube and everts so that the sleeve material covers the inner wall of the body lumen. Thus, as the apparatus is introduced, the length of material acts as a protective barrier to reduce trauma to the wall of the body lumen. It may further act to facilitate passage of the device past any stones or other obstructions which are present in the body lumen. Pulling back on the tubular guide and/or the tension member with tubular guide in distal position will reverse advancement of the tubular guide. Finally, after the apparatus has been introduced a sufficient distance beyond any obstruction or other target location, the tubular guide may be withdrawn proximally from
the sleeve until it is proximal to the obstruction. The sleeve can then be pulled back to provide the compacted material which is useful for removal of the obstruction, temporary or permanent occlusion of the body lumen, hemostasis, or other purposes. Pulling back the sleeve could be accomplished using the tubular guide, itself, but will more usually be accomplished using a separate tension member as described above.

[0018] The present invention further provides apparatus useful for performing the methods just described. The apparatus may comprise a length of material and a tension member attached to a distal location on the length of material. The tension member will be adapted to compact the material into an occluding structure when the member is pulled proximally relative to the length of material when present in the body lumen. Frequently, the apparatus will further comprise a tubular guide or other advancement member for facilitating introduction of the apparatus into the target body lumen. Other aspects of the apparatus have been described above in connection with the methods of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Fig. 1 illustrates a ureter having a kidney stone lodged between the kidney and bladder.

[0020] Figs. 2A and 2B illustrate a first apparatus in accordance with the present invention which comprises a sleeve-like length of material, a tubular guide, and a tension member.

[0021] Figs. 3A-3H illustrate use of the apparatus of Figs. 2A and 2B for removing a kidney stone from a ureter.

[0022] Figs. 4A and 4B illustrate a variation in the protocol of the method of Figs. 3A-3H.

[0023] Fig. 5A illustrates a second apparatus constructed in accordance with the principles of the present invention consisting of a length of material and a separate advancement member.

[0024] Fig. 5B illustrates a third apparatus similar to the second apparatus of Fig. 5A, except that the advancement member is threaded through a portion of the ribbon-like length of material.

[0025] Figs. 6A-6C illustrate use of the apparatus of Fig. 5A in accordance with the principles of the present invention.
[0026] Figs. 7A and 7B illustrate a modified protocol according to the principles of the present invention.

[0027] Fig. 8 illustrates apparatus according to the present invention having a guidewire-like advancement member.

[0028] Fig. 9 illustrates an embodiment of the present invention similar to that shown in Fig. 8, but further including a stiffening tube which may be slidingly advanced over a proximal portion of the guidewire.

[0029] Fig. 10 illustrates an embodiment of the present invention comprising a guidewire-like advancement member, a tubular sheath, and a tubular length of material connected between the advancement member and tubular sheath.

[0030] Figs. 11A and 11B illustrate alternative detailed constructions taken along line 11-11 of Fig. 10.

[0031] Fig. 12 illustrates one possible manner in which the length of material of the apparatus of Fig. 10 may be stowed.

[0032] Fig. 13 illustrates a further embodiment of the apparatus of the present invention where the length of material may be tensioned directly from its proximal end.

DETAILED DESCRIPTION OF THE INVENTION

[0033] The methods and apparatus of the present invention are useful for intervening in any body lumen of a patient where it is desired to temporarily or permanently occlude at least a portion of the lumen. Most commonly, the methods will be used to move or remove an obstruction from the body lumen, but the methods will also find use in stabilizing such obstructions, particularly while the obstructions are undergoing other treatments such as lithotripsy; preventing distal embolization in vascular procedures; providing temporary or permanent hemostasis in the vasculature; treating aneurysms, particularly in the cerebral vasculature; providing contraception by occlusion of the fallopian tubes; and the like. Thus, potential target body lumens include the urinary tract, particularly the ureter; the vasculature, including the cerebral, peripheral, and coronary vasculature; the fallopian tubes, and the like. The following description is directed particularly at the removal of kidney stones from the ureter, but it will be appreciated that the principles of the present invention described will apply more broadly as discussed above.
Referring now to Fig. 1, the present invention may be used for engaging and retrieving a kidney stone KS or fragments from a ureter U between a kidney K and a bladder B. Access to the bladder will be through the urethra UA using conventional access devices which will not be described herein. Access to the ureter U will be through the os O in a wall of the bladder leading into the lumen of the ureter.

A first exemplary system 10 for performing the methods of the present invention comprises a sleeve-like length of material 12 and a tubular guide 14, as shown in Figs. 2A and 2B. The sleeve-like length of material 12 has a trailing end 16 and an anchor end 18. The length of the sleeve-like length of material will typically be in the range from 1 cm to 10 cm, usually from 2 cm to 6 cm, although much longer lengths may find use in different circumstances. The sleeve will usually have a continuous sidewall with no openings (other than at the trailing end 16 and anchor end 18), but could also have open regions, have a loose weave in the case of woven materials, or otherwise have openings or discontinuities in the sidewall without departing from the principles of the present invention.

Referring now in particular to Fig. 2B, the sleeve-like length of material 12 may be arranged so that it is initially within a central passage 20 of the tubular guide 14. The material 12 can be arranged so that the anchor and 18 of the sleeve-like length of material 12 will initially be on the exterior of the tubular guide 14 and generally held stationary as the tubular guide is advanced. As the tubular guide 14 is advanced through the body lumen, the trailing end 16 is everted over the distal end 22 of the guide member, generally as shown in Fig. 2B. The trailing end 16 will usually include a tension member 24 which may be a suture, filament, thin wire, or other element which is attached at or near the terminus of the trailing end 16 and which preferably is woven and out of the material 12 over at least a portion of the length of material 12. Such woven or pleated structures will be described in more detail hereinbelow. Pulling on the tension member 24 will collapse and compact the length of material 12 in order to provide the desired luminal occlusion.

Referring now to Figs. 3A-3H, use of the system 10 for removing a kidney stone KS from a lumen L of a ureter U will be described. Initially, access is gained to the os O of the bladder B (Fig. 1) in a conventional manner. The tubular guide 14 will then be passed through the os O and into the lumen L of the ureter with the anchor end 18 of the sleeve-like member 12 being held stationary relative to the os. Specific systems for doing this are
described in copending application no. 10/794,337, the full disclosure of which is
incorporated herein by reference.

[0038] Referring now to Fig. 3B, the tubular guide 14 is advanced so that the sleeve-like
length of material 12 everts from the distal end 22 of the guide. As the everting end 23 of the
tubular guide 14 approaches the kidney stone KS, the sleeve-like length of material 12 will
continue to be everted, but will have an exposed surface 13 which remains generally
stationary relative to the inner wall of the ureter U and the exterior of the kidney stone KS.
Such eversion of the sleeve-like length of material 12 acts like a "tractor tread" in allowing
the tubular guide 12 to bypass the kidney stone, as illustrated in Fig. 3C. In addition to
facilitating bypass of the kidney stone KS, the eversion of the length of material 12 also
reduces the risk of perforation or other trauma to the ureter.

[0039] Referring now to Fig. 3D, once past the kidney stone KS, the tubular guide 14 will
continue to be advanced through the lumen L in the distal direction (toward the kidney K)
until the trailing end 16 has been partly or fully exposed so that the region including the
tension member 24 lies distal to the kidney stone KS.

[0040] At this point, the tubular guide 14 will be at least partly withdrawn in a proximal
direction so that its distal end 22 is located proximal of the kidney stone KS, as shown in Fig.
3E. The portion of the sleeve-like member 12 which lies distal to the kidney stone will
radially collapse (since its internal support has been withdrawn) leaving a slack "shell"
having the tension member 24 laced therethrough in place. By drawing in a proximal
direction (arrow 30) on tension member 24, the trailing end 16 of the sleeve-like member 12
will be caused to axially collapse, generally in the manner of an accordion, as shown in Fig.
3F. By continuing to draw on the tension member 24 the trailing end 16 of the sleeve-like
member 12 will be fully compacted against a distal surface of the kidney stone KS, as shown
in Fig. 3G. By then pulling on any or all of the sleeve-like member 12, tubular guide 14, and
tension member 24 in a proximal direction, the compacted trailing end 12 of the sleeve-like
length of material will draw the kidney stone in a proximal direction toward the bladder, as
shown in Fig. 3H. Note that at any time after the trailing end 16 had been compacted, it
would have been possible to apply laser or other energy in order to fragment the kidney stone
and further facilitate its withdrawal. The presence of the compacted trailing end 16 would
help prevent loss of the resulting stone fragments into the kidney.
[0041] Referring now to Fig. 4A and 4B, it will also be possible to additionally compact a portion of the sleeve-like length of material 12 against the proximal or bladder-side of the stone S prior to fragmentation and/or removal. Initially, the trailing end 16 of the sleeve-like member 12 is compacted, as generally described above and shown in Fig. 4A. By then further withdrawing the guide member in a proximal direction toward the bladder, an additional length 36 of the sleeve-like length of material 12 will be allowed to collapse. That additional collapsed section may then be compacted against the proximal side of the kidney stone by either further drawing on the tension member 24 (moving the stone proximally) or by simply advancing the tubular guide 14 and collapsed sleeve in a distal direction. Either way, a proximal portion 36 of the sleeve-like length of material 12 will be compacted, as shown in Fig. 4B. Lithotripsy or other energy-based disruption of the kidney stone KS may then be performed with loss of the fragments in either direction being inhibited. The kidney stone and/or resulting fragments may then be withdrawn from the ureter U as generally described above, except that the stone/fragments will be substantially encapsulated by the sleeve-like material.

[0042] Referring now to Fig. 5A, an alternative construction of the apparatus of the present invention will be described. System 40 comprises an advancement member 42 and a ribbon-like length of material 44. The advancement member may be a solid-core wire, a tube, or other small diameter or flat/thin member having sufficient column strength to permit its advancement through body lumen and preferably past an obstruction, such as a kidney stone in a ureter. For example, the advancement member may be in the form of a guidewire of the type commonly used in urological procedures. The ribbon-like length of material 44 may be composed of any of the materials listed previously and may have a length in the ranges set forth above. The length of material 44 will typically consist of only a single layer with a width in the range from 1 mm to 10 mm, usually from 2 mm to 6 mm, and a thickness of 1 mm or less. Optionally, the ribbon-like length of material 44 will comprise a flattened tube or other multiple-layer or laminated structure instead of a single layer as illustrated. The ribbon-like length of material 44 may also have a plurality of axially spaced-apart fold structures 46 disposed over at least a distal length thereof. A distal end 48 of the length of material 44 will be attached at or near a distal end of the advancement member 42 so that the advancement member can pull or otherwise carry the ribbon-like length of material through the target body lumen as it is advanced. Optionally, as shown in Fig. 5B, the advancement member 42 can be penetrated or "laced" through axially spaced-apart locations on the ribbon-
like length of material 44. As illustrated, the lacing occurs through consecutive sections defined by the fold structures 46. In both cases, the advancement member 42 will be used to advance at least a portion of the ribbon 44 past a stone KS or other object to be retrieved or stabilized.

[0043] In use, the deployment system 40 of Fig. 5A is introduced by advancing advancement member 42 through the os O (Fig. 1) and into the lumen of the ureter U, as shown in Fig. 6A. The advancement member 42 carries the ribbon-like length of material 44 distally within the lumen and past the kidney stone KS as shown in Fig. 6B. After the desired distal positioning has been achieved, the advancement member 42 may be drawn in the proximal direction, as shown in Fig. 6C, while the proximal portion of the ribbon-like length of material 44 is left in place. In this way, a region 50 of the ribbon-like length of material 44 which is distal to the kidney stone KS, as shown in Fig. 6B, may be simultaneously or sequentially compacted into the foreshortened occluding structure 52, as shown in Fig. 6C. The compacted structure 52 may then be used in any of the ways described previously, including for moving and/or removing the kidney stone into the bladder, stabilizing the kidney stone during lithotripsy, optionally combined with the removing the fragments of the kidney stone into the bladder, or the like.

[0044] As described thus far, the material compaction systems 10 and 40 have been shown to be directly introduced, i.e. introduced without an external sheath or other introducing member. As shown in Figs. 7A and 7B, however, any of the material compaction systems may be introduced through a sheath 70 which is first introduced into the lumen of the ureter U in a conventional manner. The sheath 70 may be a simple tubular sheath or could be an everting-sleeve sheath of the type described in copending application no. 10/794,337, the full disclosure of which has previously been incorporated herein by reference. In any event, once the sheath 70 is in place past the kidney stone KS, the sheath may be withdrawn leaving the material compaction system in place. System 10 is illustrated, but system 40 or any other systems according to the present invention could be introduced through the sheath. Once the system 10 is in place, it may be foreshortened by drawing on tension member 24 using the resulting compacted component in any of the ways described previously.

[0045] In certain embodiments of the present invention, a guidewire-element can be used as the advancement member. As shown in Fig. 8, an apparatus 100 comprises a guidewire 102 having a tubular length of material 104 attached at its distal end 106. Optionally, a distal
region 108 (shown in broken line) of the tubular length of material 104 may be expanded, slit, braided, or otherwise modified so that it assumes a larger structure or mass when axially compacted in accordance with the principles of the present invention.

[0046] Referring now to Fig. 9, the apparatus of Fig. 8 may be modified to include a stiffening tube 110 which may be slid over the proximal end of the guidewire 102. This stiffening tube is advantageous in that it can improve pushability of the guidewire to advance past difficult obstructions in a body lumen. Once the guidewire is past the obstruction, the stiffening tube can be partially or wholly withdrawn, leaving the smaller guidewire 102 in place. It will be appreciated that in the embodiments of apparatus 100 shown in both Figs. 8 and 9, the guidewire can be utilized for advancing catheters or other tools thereover when the length of material 104 is in its elongated, low profile configuration.

[0047] Referring now to Fig. 10, a further exemplary embodiment of an apparatus 120 of the present invention comprises a guidewire-like advancement member 122, a tubular guide member 124, and a tubular length of material 126. The tubular length of material 126 is attached at its distal end 128 to the guidewire and at its proximal end 130 to the tubular guide member 124. The attachment may be as shown in Fig. 11A where a ring 132 clamps the tubular length of material 126 over necked down region 134 of the tubular guide member 124. Alternatively, a clamping ring 140 may be provided within the distal end of the lumen of the tubular guide member 124, as shown in Fig. 11B.

[0048] In the apparatus 120, the tubular length of material 126 may be elongated by advancing the advancement member 122 distally relatively to the tubular guide member 124. Alternatively, the length of material 126 may be compacted into its expanded mass, as shown in broken line in Fig. 10, by drawing the advancement member proximally relative to the tubular guide member 124. For introduction, the tubular guide 126 may be either elongated, as shown in Fig. 10, withdrawn into the lumen of the tubular guide member 124, or folded back over the exterior lumen of the guide member 124, as shown in Fig. 12.

[0049] Referring now to Fig. 13, still another embodiment 150 of the apparatus of the present invention is illustrated. The apparatus 150 comprises a guidewire-like advancement member 152, a tubular guide 154, and a distal end 160 of the length of materials attached to the distal end of the guide tube. In this way, the guide tube can be advanced over the separate guidewire 152 (having a removable hub 162). The length of material 156 can then be
enlarged into an occlusive mass by pulling proximally on the guide tube 154. Alternatively, the occlusive mass may be straightened and elongated by pulling proximally on the ring 158.

[0050] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.
WHAT IS CLAIMED IS:

1. A method for compacting a structure in a body lumen, said method comprising:
   advancing a length of material distally in the body lumen; and
   drawing a distal location on the advanced length of material proximally to compact the material into a structure which at least partially occludes the body lumen.

2. A method as in claim 1, wherein the length of material is advanced distally past an obstruction in the body lumen and drawn proximally against the obstruction.

3. A method as in claim 2, further comprising pulling the compacted material against the obstruction to reposition the obstruction within the body lumen.

4. A method as in claim 3, wherein the obstruction is withdrawn from the body lumen.

5. A method as in claim 2, wherein the compacted structure prevents the obstruction from moving distally.

6. A method as in any one of claims 2 to 5, wherein the body lumen is a ureter, cystic duct, or common bile duct, and the obstruction comprises one or more stones.

7. A method as in claim 6, wherein the body lumen is a ureter and the length of material is advanced from urinary bladder into the ureter and past the kidney stone(s).

8. A method as in claim 7, further comprising directing energy to disrupt the kidney stone(s) while engaged by the compacted material.

9. A method as in claim 1, wherein the body lumen is a blood vessel.

10. A method as in claim 9, wherein the length of material is advanced distally past an obstruction and drawn proximally to remove the obstruction.

11. A method as in claim 9, wherein the compacted material provides substantially complete hemostasis.
12. A method as in claim 1, wherein advancing comprises introducing the length of material within a tubular guide.

13. A method as in claim 12, wherein the tubular guide and the length of material are introduced simultaneously.

14. A method as in claim 12, wherein the tubular guide is positioned first and the length of material introduced after the tubular guide has been positioned.

15. A method as in any one of claims 12 to 14, wherein the tubular guide is at least partially retracted to expose the length of material within the body lumen before drawing the distal location of the length of material proximally.

16. A method as in any one of claims 15, wherein drawing comprises pulling on a tension member attached to a distal end of the length of material.

17. A method as in claim 16, wherein the tension member is embedded in the length of material.

18. A method as in claim 1, wherein advancing comprises introducing a tubular guide through the body lumen, wherein the length of material everts over a distal end of the tube as the tube is introduced.

19. A method as in claim 13, wherein the length of material is a sleeve which emerges from an interior of the tubular guide and covers an exterior of tubular guide as the sleeve everts.

20. A method as in any one of claims 18 and 19, wherein the length of material has a tension member attached to a distal location on the length of material and wherein drawing the length of material comprises pulling on the tension member after the length of material has been released from the tubular guide into the body lumen.

21. A method as in claim 20, wherein the tension member extends from the length of material and is disposed within the interior of the tubular guide.

22. A method as in claim 20, wherein the tension member is embedded in the length of material.
23. A method as in claim 20, further comprising at least partially withdrawing the tubular guide in the proximal direction after the length of material has been released.

24. A method as in claim 1, wherein advancing comprises distally advancing an advancement member attached to a distal location on the length of material, wherein the length of material is pulled through the body lumen by distal advancement of the advancement member.

25. A method as in claim 24, further comprising detaching the advancement member from the length of material and then pulling proximally on a tension member attached to a distal location on the length of material.

26. A method as in claim 25, wherein the tension member is embedded within the length of material so that the material compacts about on the tension member as the member is pulled proximally.

27. A method as in claim 26, further comprising distally advancing the tension member to reverse compaction of the length of material.

28. A method as in claim 24, wherein drawing to compact the length of material comprises pulling proximally on the advancement member.

29. A method as in claim 24, further comprising distally advancing the advancement member to reverse compaction of the length of material.

30. A method as in claim 27 or 29, wherein entrapped stone fragments or other substances are released from the compacted material as compaction is reversed.

31. A method as in claim 1, wherein the length of material comprises a strip, sleeve, ribbon, or tube.

32. A method as in claim 31, wherein the material is selected from the group consisting of polymer films, woven fabrics, non-woven fabrics, and composites and laminates thereof.
33. A method as in claim 31 or 32, wherein the length of material has fold structures which impart a preferred folding pattern upon drawing in the proximal direction.

34. A method as in claim 24, wherein the advancement member comprises a guidewire.

35. A method as in claim 34, further comprising advancing a catheter over the guidewire while the length of material is elongated.

36. A method as in claim 34, further comprising advancing the guidewire through a catheter while the length of material is elongated.

37. A method as in any one of claims 34 to 36, further comprising positioning a sheath over the guidewire.

38. A method as in claim 37, wherein the sheath is attached to a proximal end of the length of material.

39. Apparatus for deploying a conformal structure in a body lumen, said apparatus comprising,

a length of material; and

a tension member attached to a distal location on the length of material, said tension member adapted to compact the material into an occluding structure when the member is pulled proximally relative to the length of material when present in a body lumen.

40. Apparatus as in claim 39, wherein the length of material comprises a strip, sleeve, ribbon, or tube.

41. Apparatus as in claim 40, wherein the material is selected from the group consisting of polymer films, woven fabrics, non-woven fabrics, and composites and laminates thereof.

42. Apparatus as in any of claims 39 to 41, wherein the tension member is embedded within the length of material.

43. Apparatus as in claim 40, wherein the tension member penetrates the length of material at multiple spaced-apart locations along the length.
44. Apparatus as in claim 41, wherein the length of material has fold structures between at least some of the spaced-apart locations.

45. Apparatus as in any one of claims 39 to 41, wherein the tension member is positioned in a plurality of connecting loops disposed at multiple spaced-apart locations along the length of material.

46. Apparatus as in any one of claims 39 to 41, wherein the tension member is positioned in substantially continuous passage formed in or on the length of material.

47. Apparatus as in any one of claims 39 to 41, wherein the tension member comprises a filament woven into the length of material.

48. Apparatus as in any one of claims 34 to 36, wherein the tension member is attached only at a distal end of the length of material.

49. Apparatus as in any one of claims 34 to 36, wherein the tension member has sufficient column strength to advance the length of material distally in the body lumen.

50. Apparatus as in claim 44, wherein the tension member comprises a guide wire structure.

51. Apparatus as in any of claims 34 to 36, further comprising an advancement member coupled to the length of material.

52. Apparatus as in claim 46, wherein a distal location on the length of material is frangibly attached to a distal location on the advancement member.

53. Apparatus as in claim 46, wherein the advancement member comprises a wire.

54. Apparatus as in claim 46, wherein the advancement member comprises a tubular guide.
55. Apparatus as in claim 49, wherein the length of material is disposed in a lumen of the tubular guide so that the material is deployed by everting from a distal end of the guide as the guide is advanced through the body lumen.

56. Apparatus as in claim 49, wherein the length of material is disposed to be separately passed through a lumen of the tubular guide.

57. Apparatus as in claim 39, wherein the length of material is attached at a distal end to the tension member and at a proximal end to an extension sheath.

58. Apparatus as in claim 57, wherein the tension member comprises a guidewire.

59. Apparatus as in claim 58, wherein the guidewire has a floppy distal tip, and wherein the length of material is attached proximal of the floppy distal tip.