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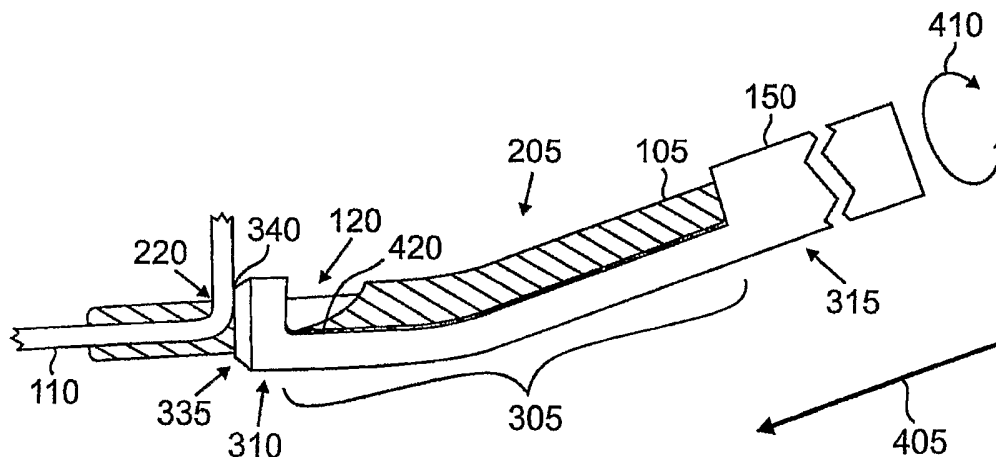
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[Continued on next page]

(54) Title: TRANSMITTING AN ACTUATING FORCE ALONG A CURVED INSTRUMENT



(57) Abstract: In one aspect there is a curved medical instrument comprising an outer member (150) and an inner member (105). The inner member has a curved portion at a distal region of the inner member. The outer member is concentrically and movably coupled to the inner member and has a flexible transmission mechanism (305) at a distal region of the outer member. The flexible transmission mechanism transmits a linear and/or rotational actuating force along the curved portion of the instrument. The inner member can include an opening configured to receive a target for cutting, such as a flexible fixating member and/or biological tissue.

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Transmitting an Actuating Force Along a Curved Instrument

TECHNICAL FIELD

This invention relates to medical devices, and more particularly to transmitting an actuating force along a curved instrument.

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BACKGROUND

To assist a surgeon when performing a meniscal repair, there is a knot pusher and suture cutter with a straight distal end. The straight suture cutter includes two components at its distal end, one inside the other. The inner component has a hollow tip at the distal end so a surgeon can pass a suture through the tip and out a port on the side of the inner
10 component. The tip of the inner component is designed to push a knot and or receive an attachment to push a knot. The outer component slides over the straight inner component and cuts any suture protruding from the port of the inner component.

SUMMARY

The present application teaches a medical instrument with a curved distal end and a
15 flexible transmission mechanism to transmit an actuating force along that curved distal end. The flexible transmission mechanism is able to negotiate or manage the connection of rigid components over a curved axis. The mechanism permits smooth translation between the rigid elements and an actuating mechanism, between which the flexible transmission mechanism is disposed.

20 For example, the mechanism allows concentric actuating tube(s) to follow along a rigid, yet curved axis. In one example, the actuating translation is achieved by the placement of strategic relief geometry along the body of a mating component to generate the flexible transmission mechanism. This strategic geometry creates the relief and clearance necessary for the concentrically mating member to transfer linear and/or rotary
25 motion along the curved portion in a smooth translation without binding. The distal working end of the device is curved so that it may provide accessibility to the desired areas that may be inaccessible by traditional non-invasive means. The curved portion negotiates the working trajectory, such as in the application of maneuvering and or accommodating anatomical structures.

In one aspect, there is a medical instrument including an inner member and an outer member. The inner member has a curved portion at its distal region. The outer member is concentrically and movably coupled to the inner member. The outer member includes a flexible transmission mechanism at its distal region.

5 The medical instrument can have one or more of the following features:

The flexible transmission mechanism of the outer member can have less material than another portion of the outer member that is less flexible than the flexible transmission mechanism. The outer member can include a wall defining a passage through which the inner member passes. In this example, the wall of the flexible transmission mechanism
10 does not fully enclose the passage of the outer member. In one example, the wall of the flexible transmission mechanism of the outer member can be disposed on a concave side of the curved portion of the inner member. In another example, the wall within the flexible transmission mechanism of the outer member can enclose approximately a range of 30% to 40% of the circumference of the passage.

15 The outer member can include a first less-flexible portion and a second less-flexible portion. The first less-flexible portion is disposed distal to the flexible transmission mechanism. The second less-flexible portion is disposed proximal to the flexible transmission mechanism. The flexible transmission mechanism is configured to conform to the curved portion while transferring motional forces from the second less-
20 flexible portion to the first less-flexible portion. The motional forces can include linear and/or rotational forces. The outer member can include a first portion and a second portion. The first portion includes a first lumen through which a portion of the inner member passes. The second portion includes a second lumen through which a portion of the inner member passes. In this example, the flexible transmission mechanism is
25 disposed between the first portion and the second portion. The first portion can include a cutting surface disposed distal to the flexible transmission mechanism.

The medical instrument can also include a first cylindrical portion within the inner member and a second cylindrical portion within the outer member. In this example, the first cylindrical portion is disposed concentrically within the second cylindrical portion.
30 The inner member can also include an opening configured to receive a target. The opening can be disposed distal to the curved portion. The cutting surface of the outer member and an edge of the opening can include a sharp edge. The target can include

suture and/or biological tissue. The distal end of the inner member can be configured to push a knot. The distal end of the inner member can include a rounded edge. The medical instrument can also include an actuating member coupled to at least one of the inner member and the outer member.

5 In another aspect, there is a medical instrument including an outer member and an inner member. The outer member has a passage extending therethrough. The inner member is slidably positioned within the passage. The inner member includes a curved portion at its distal region and an opening within the distal region for receiving a target. The inner member and outer member are configured such that when at least one of the
10 inner member and the outer member moves, the target positioned within the opening is cut between an edge of the outer member and an edge of the opening.

The medical instrument can include one or more of the following features:

The outer member can include a flexible portion at a distal region of the outer member. The edge of the outer member can be disposed distal to the flexible member.

15 The flexible portion of the outer member can have less material than another portion of the outer member that is less flexible than the flexible portion. The passage can include a wall defining the passage. In this example, the wall does not fully enclose the passage within the flexible portion of the outer member. The wall of the flexible portion of the outer member can be disposed on a concave side of the curved portion of the inner
20 member. The wall within the flexible portion of the outer member encloses approximately a range of 30% to 40% of the circumference of the passage. The outer member can include a first less-flexible portion and a second less-flexible portion. The first less-flexible portion includes the edge of the outer member, and is disposed distal to the flexible member. The second less-flexible portion is disposed proximal to the flexible
25 portion. In this example, the flexible portion is configured to conform to the curved portion while transferring motional forces from the second less-flexible portion to the first less-flexible portion. The motional forces can include linear and/or rotational forces.

The outer member can include a first portion and a second portion. The first portion includes a first lumen through which a portion of the inner member passes. The
30 second portion includes a second lumen through which a portion of the inner member passes. In this example, the flexible portion is disposed between the first portion and the second portion. The first portion can include the edge of the outer member and can be

disposed distal to the flexible portion. The medical instrument can include a first cylindrical portion within the inner member and a second cylindrical portion within the outer member. In this example, the first cylindrical portion is disposed concentrically within the second cylindrical portion.

5 The opening can be disposed on a side of the inner member in contact with the outer member. The opening can be disposed at a distal end of the curved portion. The opening can be disposed distal to the curved portion. The edge of the outer member and/or the edge of the opening can include a sharp edge. The distal end of the inner member can be configured to push a knot. The distal end of the inner member can include
10 a rounded edge. The medical instrument can also include an actuating member coupled to at least one of the inner member and the outer member. The target can include suture and/or biological tissue.

In another aspect, there is a method for generating a curved medical instrument. The method includes bending an inner member to form a curve at a distal region of the
15 inner member and providing an outer member with a passage, where the passage is sized to allow the inner member to pass therethrough. The method also includes removing a portion of a wall of the outer member at a distal region of the outer member. The method can also include providing the inner member with an opening, where the opening sized to receive a target, and where bending further comprises bending the inner member to form a
20 curve proximal to the opening.

The method can also include providing a cutting surface adjacent the opening. The method can also include providing a cutting surface on the outer member adjacent the removed portion of the wall. The method can also include providing a cutting surface at a distal end of the outer member. The method can also include locating the inner member
25 concentrically within the outer member. The method can also include coupling an actuating member to the inner member and/or the outer member. The method can also include rounding an edge of a distal tip of the inner member.

In another aspect, there is a method for using a curved medical instrument. The method includes moving an outer member and/or an inner member concentrically disposed
30 within the outer member, to cause the outer member to slide over an opening disposed distal to a curved portion of the inner member and to cut a target extending through the opening. In an example where the target include a flexible fixating member, such as

suture, the method can also include threading the flexible fixating member through the opening of the inner member. The method can also include pushing a knot with a distal end of the inner member. The details of one or more embodiments of the invention are set forth in the accompanying drawings and the description below. Other features, objects, and advantages of the invention will be apparent from the description and drawings, and from the claims.

DESCRIPTION OF DRAWINGS

FIG. 1A is a side view of a curved medical instrument.

FIG. 1B is a close-up view of the distal end of the curved medical instrument of FIG. 1A.

FIG. 2A is a side view of an inner member of the curved medical instrument.

FIG. 2B is a front view of the inner member of FIG. 2A.

FIG. 2C is a top view of the inner member of FIG. 2A.

FIG. 2D is a cross-sectional side view of the inner member of FIG. 2C.

FIGS. 2E is a perspective view of the inner member of the curved medical instrument.

FIG. 3A is a side view of an outer member of the curved medical instrument.

FIG. 3B is a cross-sectional transverse view of portions of the outer member of FIG. 3A.

FIG. 3C is a top view of the outer member of FIG. 3A.

FIG. 3D is a cross-sectional front view of a flexible portion of the outer member.

FIG. 4A is a side view of the inner member and the outer member during a cutting process.

FIG. 4B is a side view of another example of the inner member and the outer member during a cutting process.

Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

FIG. 1A illustrates a curved medical instrument 100 that serves both as a suture cutter and a knot pusher. The distal end of instrument 100 has a curved inner member 105, which is positioned within an outer member 150. Curved inner member 105 is cylindrical

in shape and has a channel through which a surgeon threads suture 110. The surgeon introduces suture 110 into the channel through an opening at the distal tip 115 and exits at an opening 120, located on the side of inner member 105. In operation, the surgeon pulls suture 110 in the direction of arrow 125 while moving instrument 100 in the direction of arrow 130 until distal tip 115 touches knot 135. The surgeon continues moving instrument 100 in the direction of arrow 130, while pulling suture 110 in the direction of arrow 125. This pushes knot 135 in the direction of arrow 130 towards surgical site 140. This allows the surgeon to tension a pre-tied knot 135 or tie a knot outside of the body and push knot 135 to surgical site 140 within the body to secure the repair.

Once knot 135 is in place to secure the repair, the surgeon uses instrument 100 to cut any excess suture 110. The surgeon slides trigger 145 towards the distal end of instrument 100. Trigger 145 connects to the cylindrical outer member 150 and moves outer member 150 towards the distal end of instrument 100. Outer member 150 is configured, as described below, such that it can conform to the curve of inner member 120 while sliding along and over inner member 120. Outer member 150 slides over curved inner member 105 and eventually reaches opening 120. As outer member 150 slides over opening 120, the distal tip of outer member 150 pinches suture 110 against a distal side of opening 120, cutting suture 110 at opening 120, as will be described in more detail below. FIG. 1B illustrates a close-up view of the distal end of instrument 100.

As described above, outer member 150 slides along and over curved inner member 105, which includes distal tip 115 for pushing knot 135 and opening 120 through which suture 110 passes. FIGS. 2A-F illustrate the inner member 105 in more detail. FIG. 2A shows inner member 105 removed from medical instrument 100. As shown, inner member 105 includes a curved portion 205 at a distal region. As show in FIG. 2B, distal tip 115 of inner member 105 includes an opening 210 through which the surgeon threads the suture 110. The diameter of opening 210 is sized so that it is not much larger than the diameter of suture 110. This allows suture 110 to pass freely through opening 210, but prevents a knot (e.g., knot 135, FIG. 1) from passing through opening 210. Instead, wall material 215 pushes the knot while the surgeon pulls a single thread of suture 110 through opening 210. There are other possible configurations for distal tip 115, as described in the alternatives below.

As shown in FIG. 2C, the distal end of opening 120 includes a cutting surface 220 against which suture 110 is pushed during the cutting process. Cutting surface 220 can also include a sharp edge to assist in the cutting process. FIGS. 2D and 2E illustrate a channel 225 through which suture 110 passes when the surgeon is pushing a knot as
5 described above. Wall material 215 at distal tip 115 is rounded.

As described above, outer member 150 slides along and over inner member 105 during the cutting process. FIGS. 3A-D illustrate outer member 150 in more detail. FIG. 3A shows the outer member 150 removed from medical instrument 100. As shown, the distal region of outer member 150 includes a flexible portion 305 that accommodates and
10 conforms to curved region 205 (FIG. 2A) as outer member 150 slides over and along inner member 105. Outer member 150 also includes a less-flexible portion 310 distal to flexible portion 305 and a less-flexible portion 315 proximal to flexible portion 305. For ease of understanding, portions 310 and 315 are referred to as distal portion 310 and proximal portion 315, indicating their positions relative to flexible portion 305. FIG. 3B shows a
15 transverse cross-sectional view 320 of portions 310 and 315. Wall material 325 encloses a circular passage 330, through which inner member 105 passes. The diameter of passage 330 is sized so that it is not much larger than the diameter of inner member 105. This allows portions 310 and 315 to slide freely over and along the cylindrical inner member 105.

Flexible region 305 accommodates both being flexible enough to conform to curved portion 205 and being strong enough to push distal portion 310 as a surgeon moves trigger 145 (FIG. 1), connected to proximal portion 315 of outer member 150. As shown in FIGS. 3A and 3C, this is accomplished by removing some of the wall material 325 enclosing passage 330 along flexible portion 305. In the illustrated example of FIG. 3D,
25 wall material 325 is removed from about a range of 60% to 70% of the circumference (indicated by dashed line 333) of passage 330 along flexible portion 305.

Referring back to FIGS. 3A and 3C, proximal portion 315 does not extend over the curve of curved portion 205 (FIG. 2) of inner member 105. Thus, proximal portion 315 does not have to be flexible enough to accommodate and conform to curved portion 205.
30 Distal portion 310, however, does extend along and over curved portion 205 of inner member 105. As described below, distal tip 335 of outer member 150 cuts suture 110. To accommodate both being able to travel along curved portion 205 and being sufficiently

rigid to be able to cut suture 110, the length of distal portion 310 is relatively small compared to the radius of curved portion 205. The length of flexible portion 305 is large enough to allow distal portion 310 to accomplish cutting while preventing proximal portion 315 from reaching the curve of curved portion 206. The distal tip 335 of distal
5 portion 310 includes a cutting surface 340 that pushes against suture 110 during the cutting process. Cutting surface 340 can also include a sharp edge to assist in the cutting process.

FIG. 4A illustrates inner member 105 and outer member 150 during the cutting process. To better show suture 110 in channel 225 (FIG. 2D), FIG. 4A represents inner member 105 using a side cross-sectional view (i.e., an extended view of FIG. 2D). During
10 the cutting process, a surgeon moves trigger 145 (FIG. 1) towards the distal end of outer member 150. Trigger 145 is connected to the proximal portion 315 and causes outer member 150 to move towards the distal end, as indicated by arrow 405. Distal portion 310 of outer member 150, being relatively short, moves along and over curved region 205 without having to adapt its form. Flexible portion 305, however, does bend to adapt and
15 conform to curved portion 205. As outer member 150 moves along in the direction indicated by arrow 405, the distal tip 335 of outer member 150 eventually encounters suture 110 that is extending beyond opening 120 of inner member 105. As distal tip 335 encounters suture 110, suture 110 becomes pinched between cutting surface 220 of inner member 105 and cutting surface 340 of outer member 150. As outer member 150
20 continues to move distally, the cutting surfaces 220 and 340 compress and eventually cut through suture 110. As described above, sharp edges can be included on either or both cutting surfaces 220 and 340 to assist in this cutting process.

As shown in FIG. 4A, the wall 325 of flexible portion 305 is disposed on the concave side of curved portion 205. FIG. 4B shows an example in which flexible portion
25 305 is disposed on the convex side of curved portion 205. In some of the examples described above, for clarity, the motion of outer member 150 is described as linear along the concentric axis. In other words, the position of outer member 150 is fixed with respect to rotation about the concentric axis. The motion of outer member 150, however, is not limited to only linear motion. As shown in FIGS. 4A and 4B, outer member 150 can also
30 rotate about the concentric axis in either direction, as indicated by arrows 410. As described above, the flexible portion 305 is a flexible transmission mechanism that can translate both linear and rotational forces from an actuating mechanism.

With rotational transmission as an alternative or in addition to the linear transmission, flexible portion 305 enables a surgeon to use medical instrument 100 for additional procedures beyond the linear cutting described above. For example, a surface 415, 420, and/or a portion thereof of the wall of flexible portion 305 can be a cutting surface during rotational motion in the directions of arrows 410. Surfaces 415, 420, and/or a portion thereof can also include sharp edges. Suture 110 can be located on the proximal side of distal portion 310. As outer member 150 is rotated, surface 410 or 415 pinches and cuts any portion of suture 110 extending beyond opening 120. In addition to cutting suture, a surgeon can use medical device 100 to cut tissue. For example, a surgeon can place opening 120 over a polyp and using rotational and/or linear motion, cut to polyp similar to any of the cutting procedures described above, and remove the polyp from the surgical site. To perform complex procedures, medical instrument 100 can include two or more outer members. Similar to outer member 150, the additional outer member (not shown) includes a passage, through which inner member 105 and outer member 150 passes, and a flexible member that accommodates and conforms to curved region 205 (FIG. 2A) as the alternative outer member (not shown) slides over and along inner member 105 and outer member 150. Outer member 150 and the alternative outer member (not shown) can be actuated independently from one another.

To provide another example, the dimensions and materials for an example medical instrument 100' (not shown) follow. Curved portion 205 is located within 1.00 inch (2.54 cm) from distal tip 115. The inside radius of the curve of curved portion 205 is 2.25 inches (5.72 cm), with a tolerance of 0.25 inches (0.64 cm). Opening 120 is located within 0.41 inches (1.04 cm) from distal tip 115. The diameter of channel 225 is 0.024 inches (0.61 mm). The diameter of passage 330 of outer member 150 is 0.065 inches (1.65 mm). The diameter of outer member 150 is 0.083 inches (2.11 mm). The length of distal region 310 is 0.05 inches (1.27 mm). The length of flexible portion 305 is 0.95 inches (2.51 cm). The inner member 105 is made out of 17-4 PH stainless steel. The outer member 150 is made out of 304 stainless steel.

A number of embodiments of the invention have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the invention. For example only and not to limit other alternatives, the distal tip and channel of the inner member can have different configurations. The

diameter of the distal tip and channel can be sized to accommodate two strands of suture, so that the surgeon can pull the suture for both ends of a knot, for example a square knot. Also, although the term suture is used for clarity, the invention is not limited to use with only suture. Any flexible fixating material to effect a repair can be used. Also, the

5 elements of the medical instrument that move can vary. For example, the trigger can move the inner member while the outer member remains stationary. The trigger can also move both the inner member and the outer member simultaneously in opposite directions. Similarly, if more than one outer member is used, the inner member and/or any combination of outer members can be configured to move with one or more actuating

10 mechanisms. Also, although the inner and outer members are described using circular and cylindrical geometries, the invention can also be used with other geometries, such as squares, polygons, and the like. Accordingly, other embodiments are within the scope of the following claims.

WHAT IS CLAIMED IS:

1. A medical instrument comprising:
 - an inner member having a curved portion at a distal region of the inner member;
 - and
 - 5 an outer member concentrically and movably coupled to the inner member, the outer member including a flexible transmission mechanism at a distal region of the outer member.
2. The medical instrument of claim 1 wherein the flexible transmission mechanism of the outer member comprises less material than another portion of the outer member that is
- 10 less flexible than the flexible transmission mechanism.
3. The medical instrument of claims 1 or 2 wherein the outer member further comprises:
 - a wall defining a passage through which the inner member passes, and
 - wherein the wall does not fully enclose the passage within the flexible transmission mechanism of the outer member.
- 15 4. The medical instrument of claim 3 wherein the wall of the flexible transmission mechanism of the outer member is disposed on a concave side of the curved portion of the inner member.
5. The medical instrument of claim 3 wherein the wall within the flexible transmission mechanism of the outer member encloses approximately a range of 30% to 40% of the
- 20 circumference of the passage.
6. The medical instrument of any of claims 1 to 5 wherein the outer member further comprises:
 - a first less-flexible portion disposed distal to the flexible transmission mechanism;
 - and
 - 25 a second less-flexible portion disposed proximal to the flexible transmission mechanism,
 - wherein the flexible transmission mechanism is configured to conform to the curved portion while transferring motional forces from the second less-flexible portion to the first less-flexible portion.

7. The medical instrument of claim 6 wherein the motional forces comprise at least one of linear and rotational forces.
8. The medical instrument of any of claims 1 to 7 wherein the outer member further comprises:
 - 5 a first portion including a first lumen through which a portion of the inner member passes; and
 - a second portion including a second lumen through which a portion of the inner member passes,
 - wherein the flexible transmission mechanism is disposed between the first portion
 - 10 and the second portion.
9. The medical instrument of claim 8 wherein the first portion includes a cutting surface disposed distal to the flexible transmission mechanism.
10. The medical instrument of any of claims 1 to 9 further comprising:
 - a first cylindrical portion within the inner member; and
 - 15 a second cylindrical portion within the outer member,
 - wherein the first cylindrical portion is disposed concentrically within the second cylindrical portion.
11. The medical instrument of any of claims 1 to 10 wherein the inner member further comprises an opening configured to receive a target.
- 20 12. The medical instrument of claim 11 wherein cutting surface of the outer member and an edge of the opening comprise a sharp edge.
13. The medical instrument of any of claims 1 to 10, wherein
 - the outer member includes a passage extending therethrough, and
 - the inner member is slidably positioned within the passage, and the inner member
 - 25 includes an opening within the distal region for receiving a target,
 - wherein the inner member and outer member are configured such that when at least one of the inner member and the outer member moves, the target positioned within the opening is cut between an edge of the outer member and an edge of the opening.

14. The medical instrument of claim 13 wherein the edge of the outer member is disposed distal to the flexible transmission mechanism.
15. The medical instrument of any of claims 13 or 14 wherein at least one of the edge of the outer member and the edge of the opening comprises a sharp edge.
- 5 16. The medical instrument of any of claims 11 to 15 wherein the opening is disposed on a side of the inner member in contact with the outer member.
17. The medical instrument of any of claims 11 to 16 wherein the opening is disposed at a distal end of the curved portion.
18. The medical instrument of any of claims 11 to 17 wherein the opening is disposed
10 distal to the curved portion.
19. The medical instrument of any of claims 11 to 18 wherein the target comprises suture.
20. The medical instrument of any of claims 11 to 19 wherein the target comprises biological tissue.
21. The medical instrument of any of claims 1 to 20 wherein a distal end of the inner
15 member is configured to push a knot.
22. The medical instrument of any of claims 1 to 21 wherein a distal end of the inner member comprises a rounded edge.
23. The medical instrument of any of claims 1 to 22 further comprising an actuating member coupled to at least one of the inner member and the outer member.
- 20 24. A method for generating a curved medical instrument, the method comprising:
bending an inner member to form a curve at a distal region of the inner member;
providing an outer member with a passage, the passage sized to allow the inner
member to pass therethrough; and
removing a portion of a wall of the outer member at a distal region of the outer
25 member.

25. The method of claim 24 further comprising:
providing the inner member with an opening, the opening sized to receive a target,
wherein bending further comprises bending the inner member to form a curve
proximal to the opening.
- 5 26. The method of claim 25 further comprising providing a cutting surface adjacent the
opening.
27. The method of any of claims 24 to 26 further comprising providing a cutting surface
on the outer member adjacent the removed portion of the wall.
28. The method of any of claims 24 to 26 further comprising providing a cutting surface at
10 a distal end of the outer member.
29. The method of any of claims 24 to 26 further comprising locating the inner member
concentrically within the outer member.
30. The method of any of claims 24 to 26 further comprising coupling an actuating
member to at least one of the inner member and the outer member.
- 15 31. The method of any of claims 24 to 26 further comprising rounding an edge of a distal
tip of the inner member.
32. A method for using a curved medical instrument, the method comprising:
moving at least one of an outer member and an inner member concentrically
disposed within the outer member, to cause the outer member to slide over an opening
20 disposed distal to a curved portion of the inner member and to cut a target extending
through the opening.
33. The method of claim 32 wherein the target comprises a flexible fixating member, the
method further comprising threading the flexible fixating member through the opening
of the inner member.
- 25 34. The method of claim 32 further comprising pushing a knot with a distal end of the
inner member.

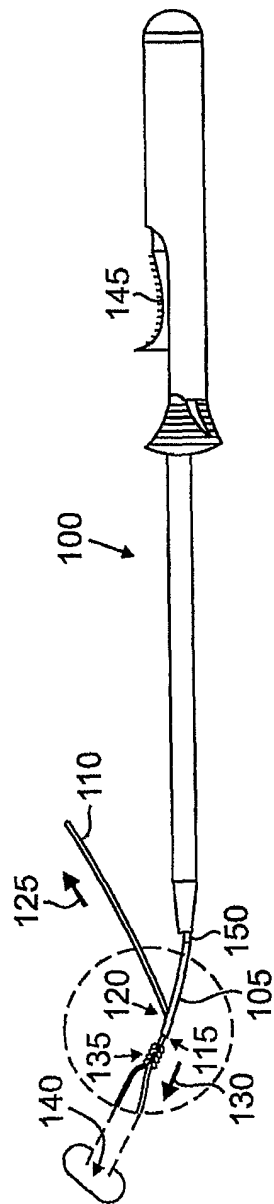


FIG. 1A

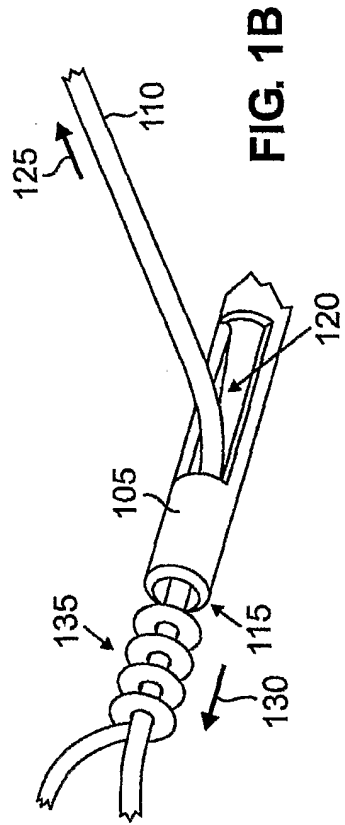
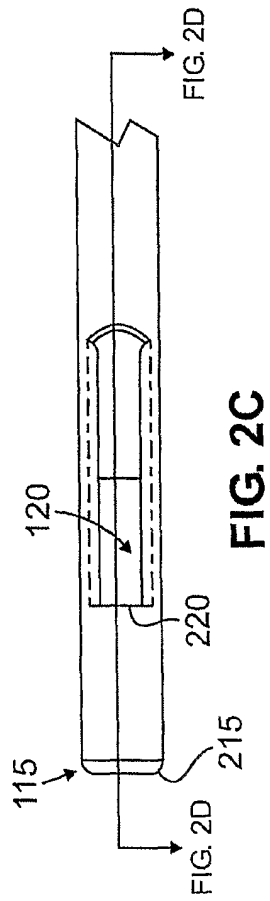
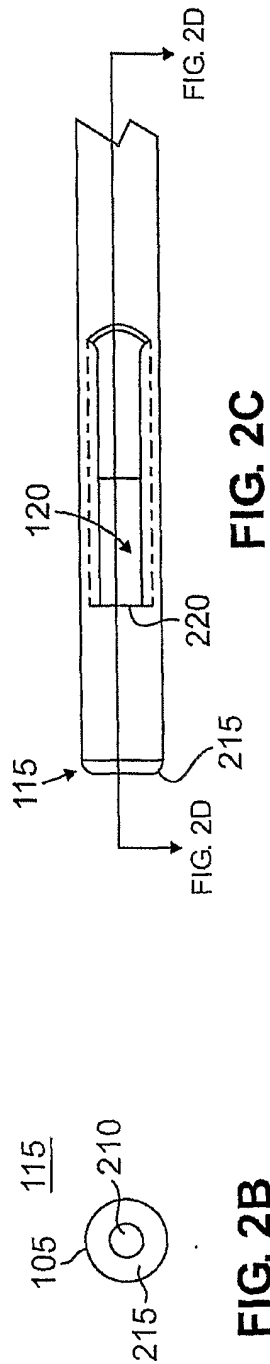
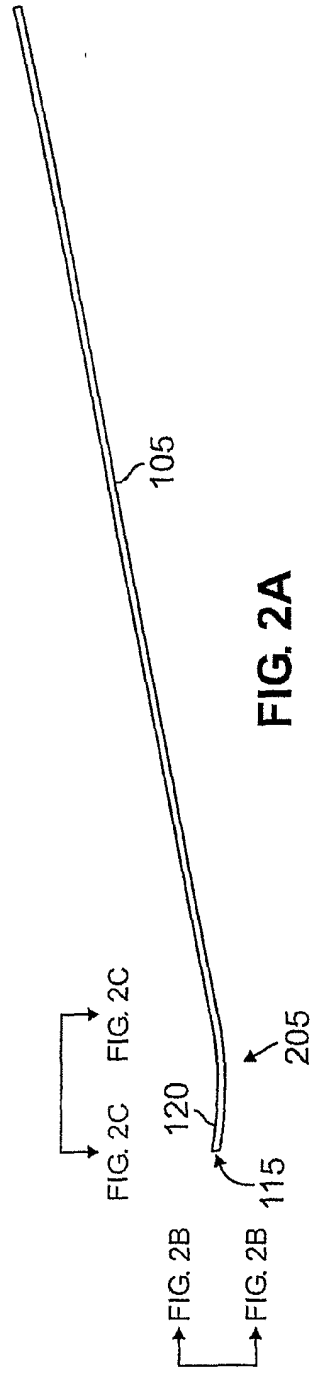


FIG. 1B



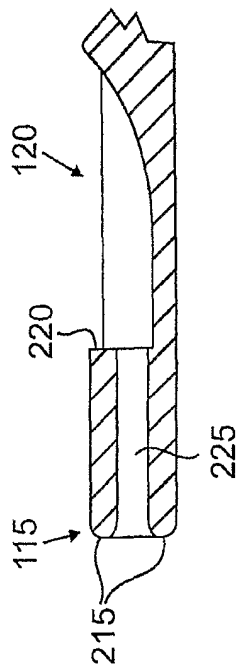


FIG. 2D

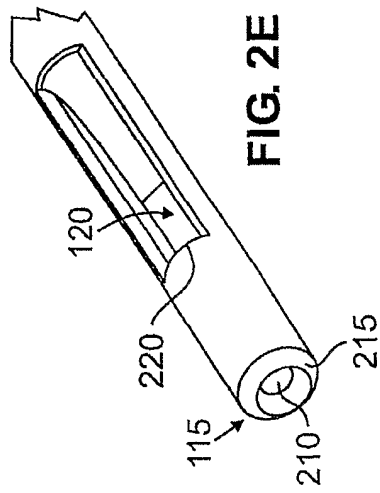


FIG. 2E

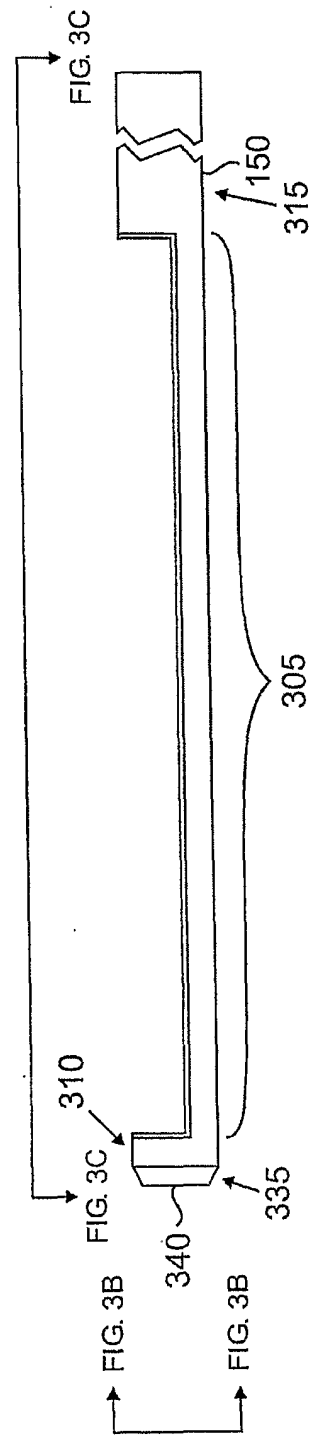


FIG. 3A

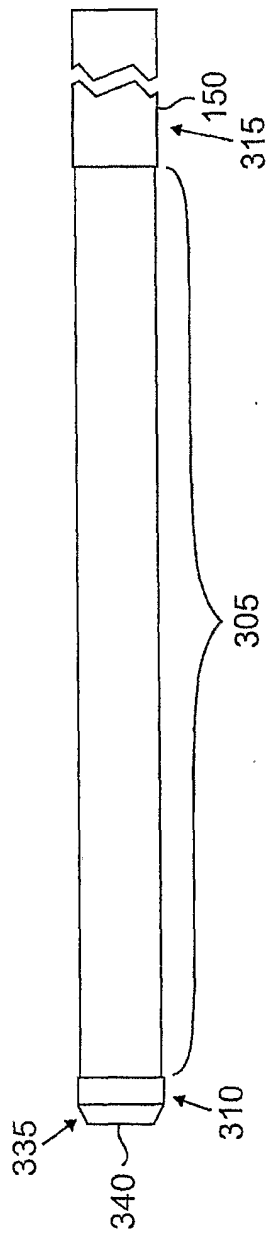
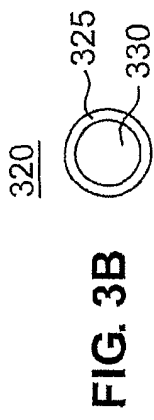
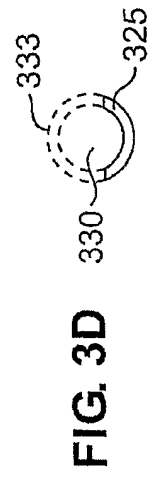


FIG. 3C



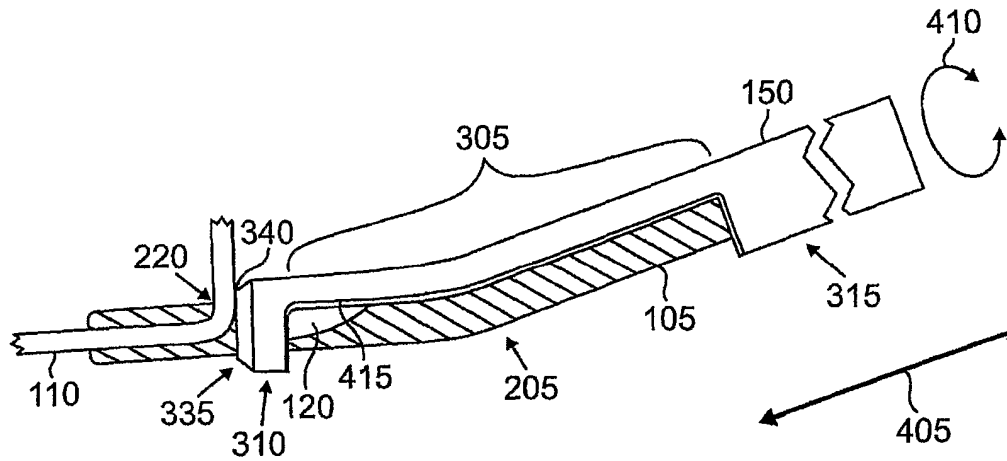


FIG. 4A

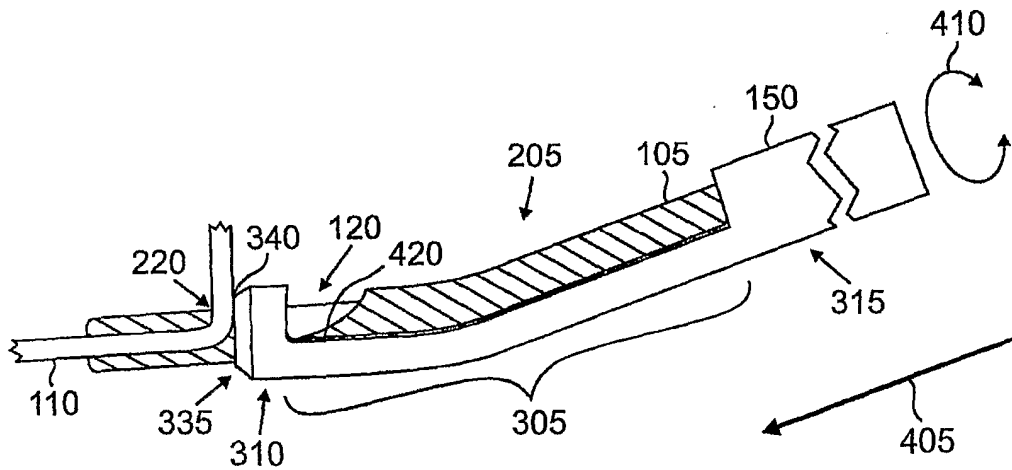


FIG. 4B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/004465

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B17/04		
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) IPC 7 A61B		
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		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 769 272 A (NISSHO KK) 23 April 1997 (1997-04-23) figures 1-13	1-3, 5, 8-16, 19-21, 23
X	column 3, line 41 -column 4, line 8 column 4, line 55 -column 5, line 10 column 5, line 24 -column 6, line 8 column 6, line 38 - line 54 -----	24-31
X	US 5 797 928 A (KOGASAKA TAKAHIRO) 25 August 1998 (1998-08-25)	1-5, 11, 17-23
X	column 10, line 54 -column 11, line 62; figures 6-21 ----- -/--	24, 25
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in 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
Date of the actual completion of the international search 22 July 2004		Date of mailing of the international search report 30/07/2004
Name and mailing address of the ISA European Patent Office, P.B. 5618 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Reinbold, S

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/004465

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	US 6 161 543 A (COX JAMES L ET AL) 19 December 2000 (2000-12-19) column 4, line 40 - line 46; figures 1-11 column 12, line 4 - line 26 ---	1-10,22
X	DE 38 31 398 A (BASHTI MOHAMMED NASSER) 29 March 1990 (1990-03-29) column 2, line 43 -column 3, line 19; claim 1; figures 1-9 ---	1,2,11, 17-22
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/004465

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.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: 32-34
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:
see FURTHER INFORMATION sheet PCT/ISA/210

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 32-34

The methods of claims 32-34 are carried out within a human body. The application does not meet the requirement of Rule 39.1 (iv), because it is implicit that the claims 32-34 are a method of treatment of the human.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/004465

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