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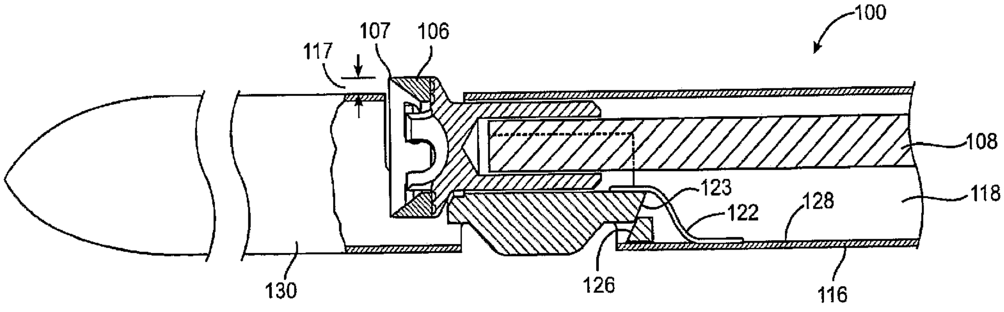

(57) Abstract: A tissue cutting device includes a sizing element which detects the diameter of the vessel in which the cutting device is positioned. The sizing element is coupled to the cutting element so that the amount of the cutting element that is exposed varies in response to movement of the sizing element.

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METHODS AND DEVICES FOR CUTTING TISSUE AT A VASCULAR LOCATION

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a continuation in part of Serial No. 10/421,980, filed April 22, 2003 which is hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention is directed to devices and methods for cutting tissue. In a specific application, the present invention is directed to devices and methods for re-entering the true lumen from a subintimal space such as a dissection plane or so-called "false lumen."

Guidewires and other interventional devices are used to treat vessels and organs using endovascular approaches. A guidewire is typically guided through blood vessels to the treatment site and the device is then advanced over the guidewire. For example, angioplasty and stenting are generally accomplished by first introducing a guidewire to the desired site and then advancing the angioplasty or stent catheter over the guidewire.

When attempting to advance a guidewire or other interventional device through a highly stenosed region or chronic total occlusion (CTO), the guidewire or device may inadvertently enter into the wall of the vessel to create a sub-intimal space. Once in a sub-intimal space, it can be difficult to re-enter the vessel true lumen. Devices for reentering a vessel true lumen from a subintimal location are described in WO 02/45598 which is hereby incorporated by reference.

BRIEF SUMMARY OF THE INVENTION

Various aspects of the invention are directed to methods and devices for re-entering a lumen during an endovascular procedure. In one embodiment, the device has a cutter, an opening, and an energy emitter coupled to the cutter. The device is advanced into the subintimal space and energy is then emitted from the energy emitter to locate the true lumen. In one aspect, the energy emitter and cutting element are moved together which exposes the cutting element to cut an access path into the true lumen. In another aspect of the present invention, the device may have a bendable tip which is bent while cutting tissue to create the access path or may be bent to direct the device or a guidewire through the access path.

In another aspect of the present invention, the device has a rotatable cutting element which may be moved from a stored position to a cutting position which exposes over 180 degrees, and even 220 or even 270 degrees of the cutting element relative to the axis of rotation. In another aspect of the invention, the cutter may be gradually exposed as necessary. In still another aspect of the present invention, the body of device may be wider along a portion of the device to urge tissue toward the cutting element. The opening is relatively large and may be open at the distal end and may expose at least part of the cutter at all positions distal to the opening. The open end of the device permits the tissue to naturally move toward the cutter due to the generally open nature of the distal end.

In still another aspect of the present invention, a system for accessing a subintimal space includes a catheter through which the tissue cutting device is advanced. The catheter may be coupled to a fluid source to inject contrast or the like and may also be coupled to a pressure monitor for monitoring pressure to determine when the access path has been created as described in greater detail below.

In a still further aspect of the invention, a method of entering a true lumen from a false lumen during an endovascular procedure is provided. A guidewire is positioned in the subintimal space. A reentry device is then advanced over the guidewire to the target location in the subintimal space. The access path is then created using the reentry device to cut the access path. The same guidewire is then directed through the access path. The reentry device may have two different openings with the first being used during advancement of the reentry device and a second opening through which the guidewire extends when being directed through the access path. The first opening may be configured to direct the guidewire substantially longitudinal while the second opening directs the guidewire at an angle relative to the longitudinal axis.

The present invention is also directed to a device for cutting tissue which automatically adjusts the position of the tissue cutting element in response to changes in vessel size. The device has a sizer coupled to the body which moves in response changes in vessel size. The sizer is coupled to the tissue cutting element so that the tissue cutting element changes position relative to the body when the vessel size changes. When the vessel size decreases, the tissue cutting element is moved to expose more of the cutting element. When the vessel size increases, the cutting element is moved to expose less of the cutting element. The term vessel size as used herein is used to generally describe a lateral dimension of the vessel.

These and other aspects of the invention will become apparent from the following description, drawings and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows a view of the system of the present invention.

Fig. 2 shows a guidewire positioned proximate to a total occlusion.

Fig. 3 shows a subintimal space created adjacent a true lumen by the guidewire.

Fig. 4 shows a reentry device of the present invention advanced over the guidewire to the subintimal space.

Fig. 5 shows a guidewire positioned in the true lumen.

Fig. 6 shows the reentry device with the cutting element in a stored position.

Fig. 7 shows the reentry device with the cutting element in a cutting position.

Fig. 8 is a side view of the reentry device of Fig. 7.

Fig. 9 shows another reentry device with the cutting element in a stored position.

Fig. 10 shows the reentry device of Fig. 9 with the cutting element in a cutting position and the distal portion bent.

Fig. 11 shows the reentry device of Figs. 9 and 10 with the cutting element advanced to another cutting position which exposes even more of the cutting element and also bends the distal tip further.

Fig. 12 shows another reentry device which has a bendable distal portion.

Fig. 13 shows the reentry device of Fig. 12 with the distal portion bent.

Fig. 14 shows still another reentry device with a cutting element which may be tilted.

Fig. 15 shows the reentry device of Fig. 14 with the cutting element tilted to expose more of the cutting element and to move the cutting element through the opening in the body of the device.

Fig. 16 shows the reentry device of Fig. 6 having a junction leading to two separate guidewire outlets with the guidewire positioned in the first outlet during advancement of the device over the guidewire.

Fig.17 shows the reentry device of Fig. 16 with the guidewire extending through the second outlet for directing the guidewire into the true lumen.

Fig. 18 shows a catheter having a lumen for receiving a guidewire and another lumen which receives the reentry device.

Fig. 19 shows another catheter having a single lumen through which the guidewire and reentry device pass.

Fig. 20 shows an external view of another device for cutting tissue having a sizer.

Fig. 21 shows another external view of the device of Fig. 20.

Fig. 22 is a cross-sectional view of the device of Figs. 20 and 21.

Fig. 23 is a cross-sectional view of the device of Figs. 20 and 21 with the sizer moved inward.

DETAILED DESCRIPTION OF THE INVENTION

Referring to Figs. 1-8, a system 2 and device 4 for reentering a true lumen from a subintimal space, dissection plane or so-called false lumen is shown. The device 4 includes a cutting element 6 coupled to a torque transmitting element 8, such as a wire 10, which rotates the cutting element 6. The device 4 has an opening 12 at a distal end 14 with the cutting element 6 movable between a stored position (Fig. 6) and a cutting position (Figs. 7 and 8) which exposes the cutting element 6. The cutting element 6 may be any suitable cutting element 6 such as the cutting element 6 described in patents incorporated by reference above. The cutting element 6 has a circular cutting edge which has a diameter of about 1 mm although any suitable size may be used depending upon the particular application. The cutting element 6 may also be any other type of cutter such as a laser, ultrasound, RF or other type of cutter without departing from various aspects of the present invention.

The device 4 has a flexible body 16 to navigate through blood vessels or other body lumens to a target location. The body 16 may be made of any suitable material as is known in the art such as Pebax. The torque transmitting element 8 extends through a lumen 18 in the body 16. The body 16 may have more lumens for various reasons such as introduction of fluids, such as contrast, or for delivery of another device 4 such as a guidewire or interventional device. The torque transmitting element 8 is coupled to a driver 20 which rotates the torque transmitting element 8 at a variable or fixed speed.

The device 4 may also have an energy emitting element 22, such as an ultrasound element 25, which emits (and may receive) energy to determine the location of the true lumen as explained below. The energy emitting element 22 is coupled to the cutting element 6 so that the energy emitting element 22 and cutting element 6 are rotated together. The cutting element 6 is in the stored position when locating the true lumen so that the cutting element 6 is not exposed and will not cut or damage tissue. The energy emitting element 22 is positioned adjacent a window 24 which may be a side opening 26 or may simply be a portion of the sidewall which transmits a sufficient amount of the energy therethrough. Any suitable energy emitting element 22 may be used such as the ultrasound emitting element available from Boston Scientific and is marketed under the name Atlantis™. The cutting element 6 may be mounted to a collar which is then mounted to an ultrasound element holder 28 or the cutting element 6 may be integrally formed with the ultrasound element holder 28.

The device 4 has an atraumatic tip 34 which is relatively flexible to prevent damaging tissue. The tip 34 may be a separate piece laminated or glued to the body 16. The tip 34 is preferably made out of a relatively soft, flexible material, such as tecothane, and may be used for blunt dissection as necessary. A reinforcing element 36 is encapsulated in the tip 34 to help the tip 34 maintain its general shape. The tip 34 may also have one or more guidewire lumens 38 or any of the guidewire features described herein.

The opening 12 in the distal portion may be designed to expose over 180 degrees of the cutting element 6 and may even expose 220 degrees or even 270 degrees of the cutting element 6 as defined by the axis of rotation. This provides advantages over WO 02/45598 which does not expose much of the cutting element 6 and requires invagination of the tissue within the opening to cut tissue. In another aspect of the invention, the cutting element 6 may be gradually exposed. For example, the cutting element 6 may be gradually exposed from 180-220 degrees or even 200-270 degrees. As explained below, this feature provides the user with the ability to change the amount of cutter 6 that is exposed depending upon the tissue thickness between the subintimal location and true lumen. The term opening 12 and amount of exposure of the cutting element 6 are defined by the outer bounds of the opening 12 and the axis of rotation. Referring to Figs. 7 and 8, the cutting element 6 is exposed relative to the outer bounds of the opening 12 due to the relatively open distal end.

Referring to Figs. 9-11, another device 4A for reentering a true lumen from a subintimal location is shown wherein the same or similar reference numbers refer to the same or similar structure. The device 4A also has an opening 12A at the distal end to expose the cutting element 6A. Fig. 9 shows the cutting element 6A in a stored position, Fig. 10 shows the cutting element 6A in a first cutting position and Fig. 11 shows the cutting element 6A in a second cutting position which further exposes the element 6A. The device 4A also has the window 24 through which the energy emitting element 22, such as the ultrasound element, may emit energy when the cutting element 6A is in the stored position.

A distal portion 40 of the body can bend or articulate to further expose the cutting element 6A and to move the cutting element 6A toward true lumen. The body has slots 42 formed therein to increase the flexibility of the distal portion 40. The cutting element 6A has a surface 44 which engages a lip 46 on the body. As the cutting element 6A is advanced, the interaction between the surface 44 and lip 46 causes the distal portion 40 to deflect. Bending the distal portion 40 can be helpful in moving the cutting element 6A toward the tissue and may also expose more of the cutting element 6A. As also explained below, the tip 40 may also be bent to direct the device 4A itself or a guidewire into the true lumen. The cutting element 6A may also be gradually exposed as the cutting element 6A moves distally and may be gradually exposed in the same manner described above.

Referring to Figs. 12 and 13, another reentry device 4B is shown which has a distal portion or tip 60 which bends or articulates. The tip 60 may be articulated and actuated in any suitable manner. For example, the tip 60 may be bent upon longitudinal movement of the cutting element 6 (as shown above) or a separate actuator, such as a pull wire 62, may be used. As can be appreciated from Fig. 13, the tip 60 is bent or articulated to move the cutting element 6 toward the true lumen and to expose more of the cutting element 6. The device 4B may also be bent to direct the device 4B itself or another device or guidewire through the guidewire lumen 38 to the access path into the true lumen as described further below.

Referring to Figs. 14 and 15, still another device 4C for cutting tissue is shown wherein the same or similar numbers refer to the same or similar structure. The device 4C includes a cutting element 6C, an energy emitting element 22C and a torque transmitter 8C for rotating the elements. The device 4C has an opening 64 along one side. The cutting element 6C is contained within the opening 64 in the stored position of Fig. 14 and extends out of the opening 64 in the cutting position of Fig. 15. The cutting element 6C is moved out of the window 24 using an actuator 68, such as a wire 70, which tilts a bearing 72 supporting the shaft of the rotatable cutting element 6C. Of course, any other suitable structure may be used to move the cutting element 6C outside the opening 64 such as those described in U.S. Patent No. 6,447,525 which is hereby incorporated by reference. Furthermore, the cutting element 6C may be moved out of the opening 64 by bending the distal portion or tip as described herein.

Use of the devices 4, 4A-C is now described with reference to the device 4 although it is understood that any of the devices 4, 4A-C may be used. As mentioned above, the device 4 may be used to perform any suitable procedure to cut from one location to another in the body such as a procedure to reenter a true lumen. The device 4 is initially advanced to a position within a subintimal space SS. As described above, the subintimal space SS may be inadvertently created during an endovascular procedure with a guidewire GW or other device creating the subintimal space SS as shown in Figs. 2 and 3. The device 4 may be introduced over the same guidewire GW or device which created the subintimal space SS as shown in Figs. 4 and 5. Of course, the device 4 may also be advanced over the guidewire GW to a position proximate to the subintimal space SS after which the device 4 is then advanced by itself into the subintimal space SS.

After the device 4 is positioned at the appropriate location in the subintimal space SS, the energy emitting element 22 is used to determine the location of the true lumen. When using the ultrasound element 28, for example, the ultrasound element 28 is rotated while emitting ultrasound energy and the energy emitted through the window 24 and reflected back through the window 24 is processed as is known in the art. The entire device 4 is rotated within the subintimal space SS to orient the window 24 until the true lumen is located. The angular orientation of the device 4 is then maintained so that the opening 12 and window 24 are directed toward the true lumen.

The cutting element 6 is then moved to the cutting position to expose the cutting element 6. The cutting element 6 may be rotated with the driver 20 during this time so that cutting is initiated as the cutting element 6 is exposed. In another aspect of the invention, the entire device 4 itself may be moved through the subintimal space to cut tissue. This provides advantages over the method of WO 02/45598 which requires invagination of tissue through a window to attempt a cut at one location. If the tissue does not invaginate sufficiently into the window, such as when the tissue is too thick, the device of WO 02/45598 will not be able to cut completely through the tissue to create the access path to the true lumen. The user must then move the device and again attempt to invaginate enough tissue to cut an access path. The present invention provides the ability to move the entire device 4 through the subintimal space to create the access path rather than attempting a cut at a single discrete location as in WO 02/45598. Of course, the device 4 may also be used by moving only the cutting element 6 rather than the entire device 4 without departing from the invention.

The cutting element 6 may also be exposed to varying degrees, as described above, until enough of the cutting element 6 is exposed to cut through to the true lumen. For example, the user may choose to expose half of the cutting element 6 and attempt to create an access path to the true lumen. If an access path is not created, the user may then choose to expose more of the cutting element 6 and again attempt to create an access path. This procedure can be repeated until the access path is formed to the true lumen. The device 4A, 4B may be also have a distal tip or portion 40, 60 which bends to move the cutting element 6 toward the tissue and/or expose more of the cutting element 6 during cutting.

After successfully creating the access path into the true lumen, the device 4 itself or part thereof may be directed toward or through the access path. Referring to Fig. 9-13, for example, the distal portion or tip 40, 60 may be bent to help direct the device 4A, 4B itself or the guidewire GW through the access path.

Referring to Figs. 16 and 17, another device 4D, similar to device 4, is shown which has a guidewire lumen 74 having a junction 76 so the guidewire can be directed through either a first lumen 77 having a first outlet 78 or a second lumen 79 having a second outlet 80. The first outlet 78 directs the guidewire substantially longitudinally for advancing the device 4D over the guidewire to the target area in a conventional manner. The second outlet 80 directs the guidewire at an angle relative to the longitudinal axis, such as 30-75 degrees, to direct the guidewire through the access path into the true lumen.

The junction 76 may include a feature which directs the guidewire into the second outlet 80. Referring to Fig. 17, for example, the junction 76 may include a flap or stop 82 which closes and prevents or inhibits the guidewire from passing through the first outlet 78 after the guidewire has been withdrawn proximal to the junction 76. When the guidewire is advanced again as shown in Fig. 17, the guidewire passes through the second outlet 80 due to the stop 82. The device 4 and/or guidewire GW are then manipulated to direct the guidewire GW through the access path. Although the stop 82 may be provided, the junction 76 may also simply be a relatively open junction 76 with the user manipulating and rotating the guidewire GW to direct the guidewire GW through the desired outlet 78, 80. The device is rotated about 180 degrees after creating the access path to direct the GW through outlet 80 and into the true lumen.

Referring to Figs. 18 and 19, the system 2 may also include a sheath or catheter 90 which is advanced proximal to the treatment site. The sheath 90 may help provide better control of the guidewire GW and devices 4 of the present invention during manipulation in the subintimal space. The sheath 90 may also used to deliver contrast solution to the treatment site from a source of contrast 97 (see Fig. 1) or may be coupled to a pressure sensor 94. The pressure sensor 94 may be part of the contrast delivery system 97 or may be a separate component. Deliver of contrast and/or pressure monitoring may be used to determine when the access path has been created.

The sheath 90 may include only one lumen 92 with fluid delivery and pressure sensing being accomplished in the annular space between the device and sheath as shown in Fig. 19. The sheath 90 may also have first and second lumens 96, 98 for separate delivery of the device 4 and guidewire GW. As mentioned above, the devices 4 of the present invention may be advanced over the same guidewire or device that created the subintimal space or may be advanced over another guidewire or even through the sheath 90 by itself.

After accessing the true lumen, another interventional device may be introduced into the true lumen for the intended therapy or procedure. For example, a stent catheter, angioplasty catheter, or atherectomy device may be used to treat the occlusion. The present invention has been described for reentering a true lumen from a subintimal space but, of course, may be used for other purposes to gain access from one space to another anywhere within the body.

Referring to Figs. 20-23, another device 100 for cutting tissue is shown wherein the same or similar reference numbers refer to the same or similar structure. The device 100 includes an elongate body 116 and a cutting element 106 coupled to a drive element 108 which is rotated to drive the cutting element 106. The drive element 108 extends through a lumen 118 in the body 116 and is driven by a driver (not shown) at the proximal end. The cutting element 106 may be any suitable cutting element 106 including those described in the applications incorporated herein. The cutting element 106 has an essentially circular cutting surface 107 along the leading edge of the cutting element 106.

The body 116 has an opening 112 therein and the tissue cutter 106 is movable from the stored position of Figs. 20 and 22 to the cutting position of Fig. 23. When moved to the cutting position of Fig. 23, part of the tissue cutting element 116 becomes exposed relative to opening 112. The opening 112 may be a side opening as shown in Figs. 20-23 or may be a distal opening as shown in other devices described herein such as the devices of Figs. 1-19. The tissue cutting element 106 moves relative to the body 116 so that a cutting height 117 of the tissue cutting element 106 changes as the position of the cutting element changes relative to the body 116. The cutting height 117 is defined by a maximum distance from the cutting surface 107 to an outer surface 109 of the body 116.

The device 100 has a sizer 119 coupled to the body 116 which automatically adjusts the cutting height 117 based on vessel size. The sizer 119 is naturally biased to an outer position of Fig. 22 by a spring 122 which defines a maximum width of the device along the sizer 119. The sizer 119 is moved inward from the position of Fig. 22 when contact with the vessel wall overcomes the force biasing the sizer 119 outward. In simplistic terms, the sizer 119 is essentially moved inward by the vessel wall when the vessel size is smaller than the width of the device 100. Thus, the sizer 119 moves between the positions of Figs. 22 and 23 as the diameter of the vessel varies within a given range. When the vessel diameter is larger than the diameter of the device 100, the tissue cutting element 106 will remain in the stored position of Fig. 22. Stated another way, the sizer 119 is coupled to the tissue cutting element 106 so that an outward force is applied to the tissue cutting element 106 when the sizer 119 moves inward. The outward force on the tissue cutting element 106 being directed away from the body 116.

The sizer 119 is coupled to the tissue cutting element 106 so that the amount of exposure of the cutting element, such as the cutter height 117, changes when the vessel diameter changes. In the embodiment of Fig. 16, the exposure of the tissue cutting element 106 is increased when the vessel diameter decreases so that a deeper cut is made in smaller vessels. A deeper cut may be desired when removing tissue in smaller vessels to increase the flow of blood through the vessel. The user may still move the tissue cutting element 106 to the cutting position of Fig. 23 by pulling on the drive element 108 so that a contact surface 123 on the sizer 119 engages a ramp 126 on an inner wall 128 of the body 116 to move the cutting element 106 to the position of Fig. 23.

The tissue cutting device 100 may be used to cut tissue for any purpose. Furthermore, the device 100 has been described in connection with cutting tissue in blood vessels but may be used for any other purpose in the vasculature. The tissue may be cut and left within the body or may be removed in any suitable manner. For example, the device 100 may include a tissue collection chamber 130 coupled to the body 116 distal to the cutting element 106. The tissue cutting element 106 cuts tissue and directs the tissue into the collection chamber 130. The tissue cut by the tissue cutting element 106 is parted off from the surrounding tissue by moving the cutting element 106 back to the stored position.

The present invention has been described in connection with the preferred embodiments, however, it is understood that numerous alternatives and modifications can be made within the scope of the present invention as defined by the claims.

WHAT IS CLAIMED IS:

1. A device for cutting tissue at a vascular location, comprising:

an elongate body having an outer surface;

a tissue cutting element having a cutting surface, the tissue cutting element being coupled to the elongate body and movable relative to the body to a plurality of operating positions, wherein an amount of exposure of the tissue cutting element changes in the plurality of operating positions; and

a sizer coupled to the body and movable relative to the body, the sizer being biased outward from the body to an outer position and being movable inward from the outer position, the sizer being operatively coupled to the tissue cutting element so that the tissue cutting element is in one of the plurality of different operating positions in response to a position of the sizer.

2. The device of claim 1, wherein:

the sizer automatically moves in response to a change in the size of the vascular location in which the tissue cutting device is positioned.

3. The device of claim 1, wherein:

the tissue cutting element is movable relative to the body so that a cutting height of the tissue cutting element changes in each of the plurality of operating positions, the cutting height being a maximum distance from the cutting surface to the outer surface of the body.

4. The device of claim 3, wherein:

the cutting height of the tissue cutting element increases when the sizer moves inward in response to a decrease in size of the vascular location.

5. The device of claim 3, wherein:

the cutting height of the tissue cutting element decreases when the sizer moves outward in response to an increase in size of the vascular location.

6. The device of claim 1, wherein:

the body has an opening; and

the tissue cutting element moves relative to the opening in response to the position of the sizer, the tissue cutting element being movable relative to the opening to change an amount of the tissue cutting element exposed through the opening.

7. The device of claim 1, further comprising:

a tissue collection element coupled to the body, the tissue collection element being positioned distal to the tissue cutting element.

8. The device of claim 7, wherein:

the body has an opening therein;

the tissue cutting element rotates during cutting, the tissue cutting element configured to direct tissue into the opening and distally into the tissue collection element when the tissue cutting element and the opening are moved together.

9. The device of claim 1, wherein:

the sizer is biased outward to an outermost position, the outermost position defining a maximum width of the device along the sizer, the sizer being moved inwardly by contact with the vascular location when the size of the vascular location is smaller than the maximum width.

10. A method of cutting tissue at a vascular location, comprising the steps of:

providing a tissue cutting device having an elongate body with an outer surface, a tissue cutting element, and a sizer, the tissue cutting element being coupled to the elongate body and being movable relative to the body to a plurality of different operating positions relative to the body, the sizer also being movable relative to the body in response to a size of a vascular location in which the tissue cutting device is positioned, the sizer being operatively coupled to the tissue cutting element so that the tissue cutting element is in one of the plurality of different operating positions in response to a position of the sizer;

advancing the tissue cutting device through a blood vessel;

positioning the tissue cutting device at a vascular location, the sizer moving relative to the body in response to the size of the vascular location and the tissue cutting element moving relative to the body in response to movement of the sizer; and

cutting tissue with the tissue cutting element.

11. The method of claim 10, wherein:

the positioning step is carried out with the sizer automatically moving in response to a change in the size of the vascular location in which the tissue cutting device is positioned.

12. The method of claim 10, wherein:

the providing step is carried out with the tissue cutting element being movable relative to the body so that a cutting height of the tissue cutting element changes in each of the plurality of operating positions, the cutting height being a maximum distance from the cutting surface to the outer surface of the body.

13. The method of claim 12, wherein:

the providing step is carried out with the cutting height of the tissue cutting element increasing when the sizer moves inward in response to a decrease in size of the vascular location.

14. The method of claim 12, wherein:

the providing step is carried out with the cutting height of the tissue cutting element decreasing when the sizer moves outward in response to an increase in size of the vascular location.

15. The method of claim 10, wherein:

the providing step is carried out with the body having an opening, the tissue cutting element being movable relative to the opening so that an amount of the tissue cutting element exposed through the opening is dependent upon a position of the sizer.

16. The method of claim 10, wherein:

the providing step is carried out with the elongate body having an opening;

the cutting step being carried out with the tissue cutting element directing the tissue through the opening.

17. The method of claim 10, wherein:

the cutting step is carried out by moving the tissue cutting element and the opening together, the tissue cutting element being rotated during cutting.

18. The method of claim 17, wherein:

the providing step is carried out with the tissue cutting device having a tissue collection element, the tissue collection element being positioned distal to the tissue cutting element;

the cutting step is carried out with the tissue cutting element being moved distally, the tissue cutting element directing the tissue distally into the tissue collection element as the tissue cutting element moves distally.

19. The method of claim 10, wherein:

the providing step is carried out with the sizer being biased outward to an outermost position, the outermost position defining a maximum width of the device defined along the sizer;

the cutting step being carried out with the sizer being moved inward by contact with the vascular location when the size of the vascular location is smaller than the maximum width of the device.

20. A device for cutting tissue at a vascular location, comprising:

an elongate body having an outer surface;

a tissue cutting element coupled to the elongate body, the tissue cutting element being movable relative to the body between a stored position and an operating position, the tissue cutting element having a cutting surface which cuts tissue; and

a sizer coupled to the body and movable relative to the body, the sizer being naturally biased outward from the body to an outer position and being movable inward from the outer position, the sizer being coupled to the tissue cutting element so that an outward force is applied to the tissue cutting element when the sizer moves inward from the outer position, the outward force applied to the tissue cutting element being directed away from the body.

21. The device of claim 20, wherein:

the tissue cutting element is movable to a plurality of operating positions, wherein an amount of exposure of the tissue cutting element changes in the plurality of operating positions.

22. The device of claim 20, wherein:

the sizer automatically moves in response to a change in the size of the vascular location in which the tissue cutting device is positioned.

23. The device of claim 20, wherein:

the tissue cutting element is movable relative to the body so that a cutting height of the tissue cutting element changes in each of the plurality of operating positions, the cutting height being a maximum distance from the cutting surface to the outer surface of the body.

24. The device of claim 23, wherein:

the cutting height of the tissue cutting element increases when the sizer moves inward in response to a decrease in size of the vascular location.

25. The device of claim 23, wherein:

the cutting height of the tissue cutting element decreases when the sizer moves outward in response to an increase in size of the vascular location.

26. The device of claim 20, wherein:

the body has an opening; and

the tissue cutting element being movable relative to the opening in response to the position of the sizer, the tissue cutting element being movable relative to the opening to change an amount of the tissue cutting element exposed through the opening.

27. The device of claim 20, further comprising:

a tissue collection element coupled to the body, the tissue collection element being positioned distal to the tissue cutting element;

the tissue cutting element being rotatable relative to the body and being rotated during cutting, the tissue cutting element configured to direct tissue distally into the tissue collection element when the tissue cutting element is moved distally.

28. The device of claim 20, wherein:

the sizer is naturally biased outward to an outermost position, the outer most position defining a maximum lateral dimension of the device along the sizer, the sizer being deflected inwardly by contact with the vascular location when the lateral size of the vascular location is smaller than the maximum lateral dimension.

29. A method of cutting tissue at a vascular location, comprising the steps of:

providing a tissue cutting device including an elongate body having an outer surface, a tissue cutting element having a cutting surface, and a sizer, the tissue cutting element being coupled to the elongate body and being movable relative to the body between a stored position and an operating position;

the sizer also being coupled to the body and being movable relative to the body, the sizer moving relative to the body in response to a size of vascular location in which the tissue cutting device is positioned, the sizer being coupled to the tissue cutting element so that an outward force is applied to the tissue cutting element when the sizer is moved inward, the outward force on the tissue cutting element being directed away from the body;

advancing the tissue cutting device through a blood vessel;

positioning the tissue cutting device at a vascular location, the sizer moving relative to the body in response to the lateral size of the vascular location, the outward force on the tissue cutting element being applied to the tissue cutting element when the sizer moves inward relative to the body; and

cutting tissue with the tissue cutting element.

30. The method of claim 29, wherein:

the positioning step is carried out with the sizer automatically moving in response to a change in the lateral size of the vascular location in which the tissue cutting device is positioned.

31. The method of claim 29, wherein:

the providing step is carried out with the tissue cutting element being movable to a plurality of operating positions, the tissue cutting element being exposed to varying degrees in the plurality of operating positions.

32. The method of claim 31, wherein:

the providing step is carried out with the tissue cutting element being movable relative to the body so that a cutting height of the tissue cutting element changes in each of the plurality of operating positions, the cutting height being a maximum distance from the cutting surface to the outer surface of the body.

33. The method of claim 31, wherein:

the providing step is carried out with the cutting height of the tissue cutting element increasing when the sizer moves inward in response to a decrease in size of the vascular location.

34. The method of claim 29, wherein:

the providing step is carried out with the cutting height of the tissue cutting element decreasing when the sizer moves outward in response to an increase in size of the vascular location.

35. The method of claim 29, wherein:

the providing step is carried out with the body having an opening, the tissue cutting element being movable relative to the opening so that an amount of the tissue cutting element exposed through the opening is dependent upon a position of the sizer.

36. The method of claim 29, wherein:

the providing step is carried out with the tissue cutting element moves laterally relative to the body when moving to the operating position.

37. The method of claim 29, wherein:

the cutting step is carried out by moving the tissue cutting element and the opening together.

38. The method of claim 37, wherein:

the providing step is carried out with the tissue cutting device having a tissue collection element, the tissue collection element being positioned distal to the tissue cutting element; and

the cutting step is carried out with the tissue cutting element being moved distally, the tissue cutting element directing the tissue distally into the tissue collection element as the tissue cutting element moves distally.

39. The method of claim 29, wherein:

the providing step is carried out with the sizer being biased outward to an outermost position, the outermost position defining a maximum width of the device along the sizer;

the cutting step being carried out with the sizer being moved inward by contact with the vascular location when the size of the vascular location is smaller than the maximum width.

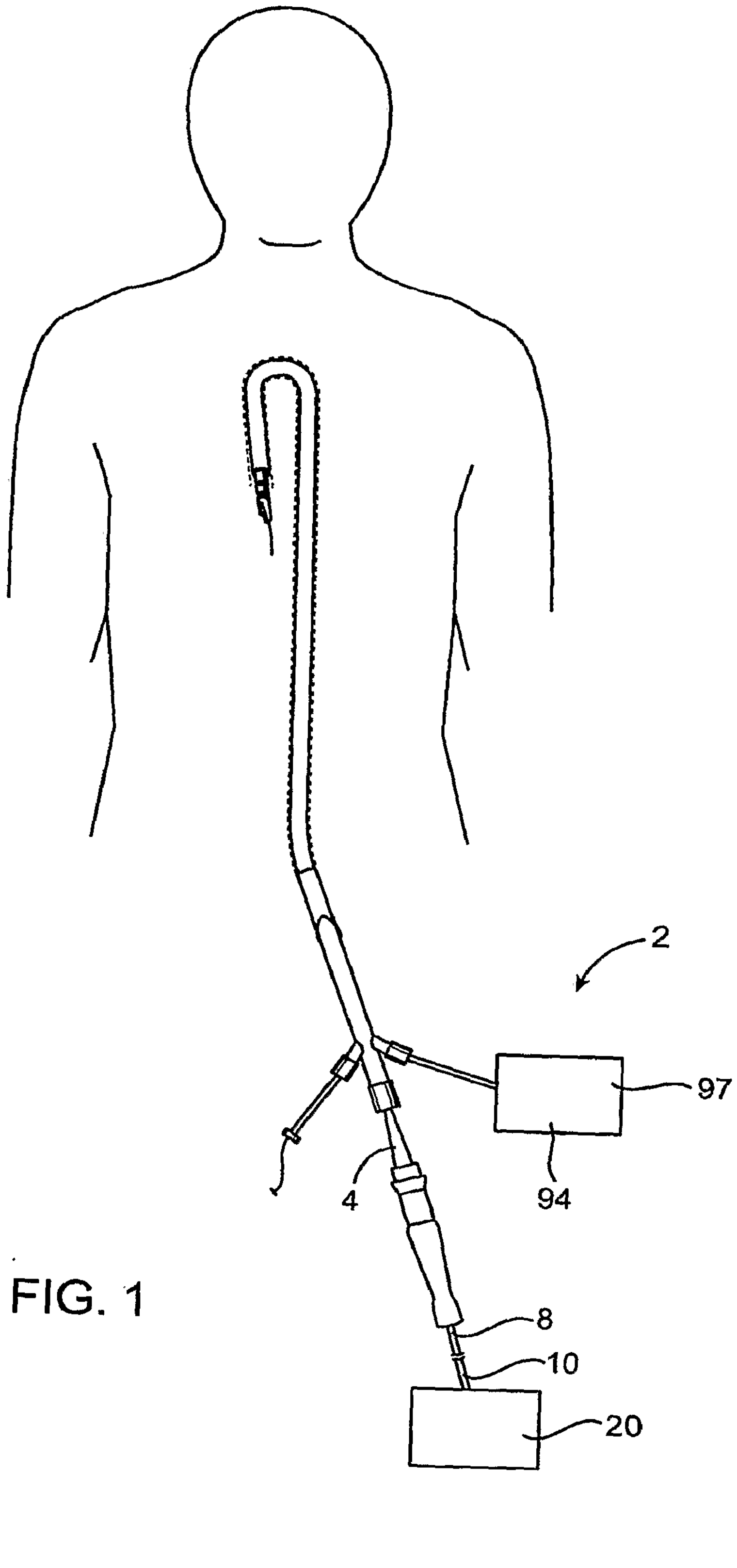
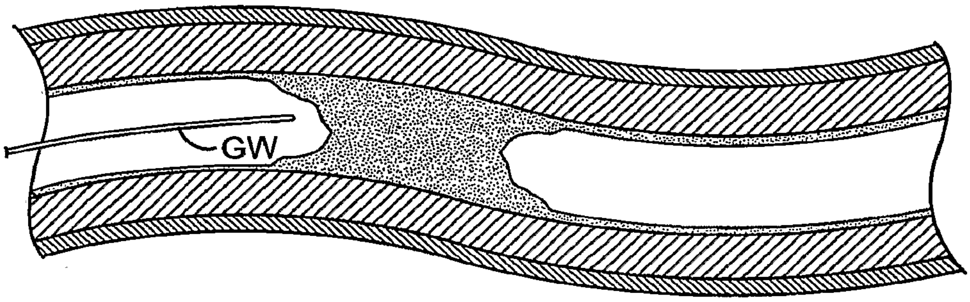


FIG. 1



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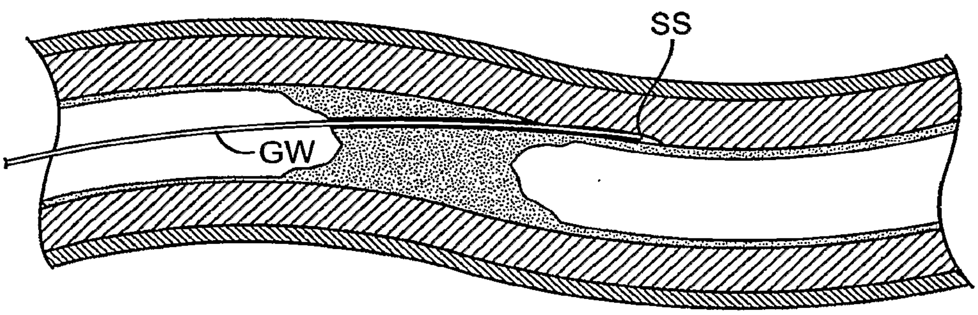

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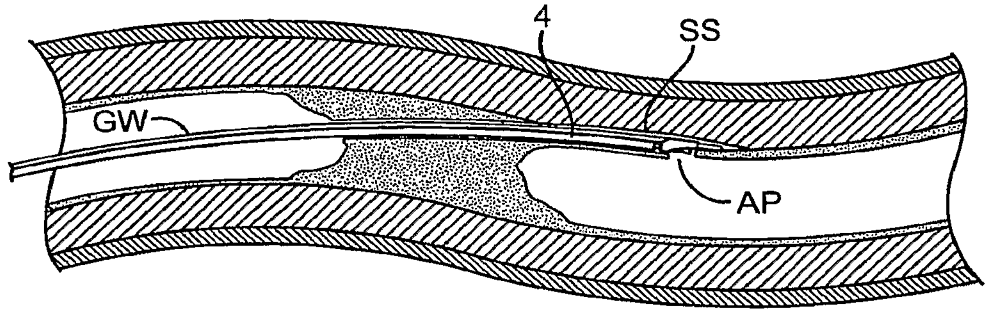

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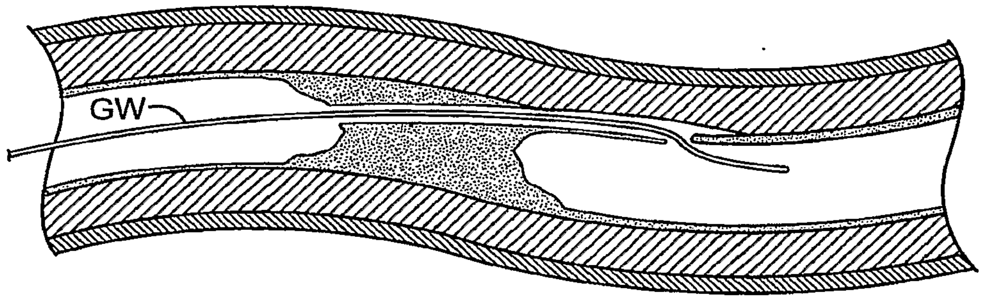

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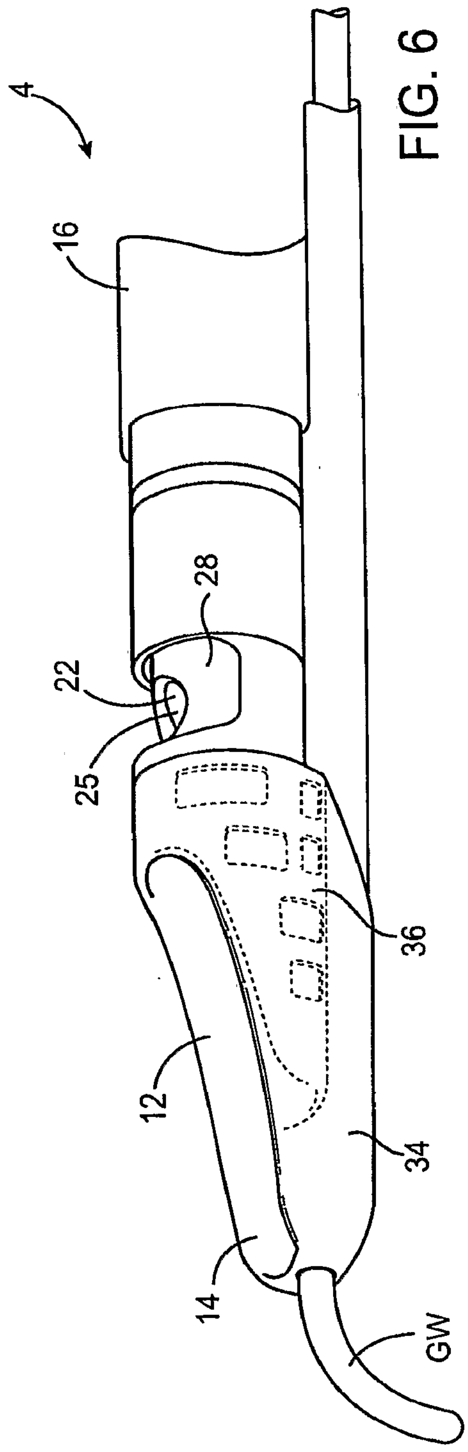

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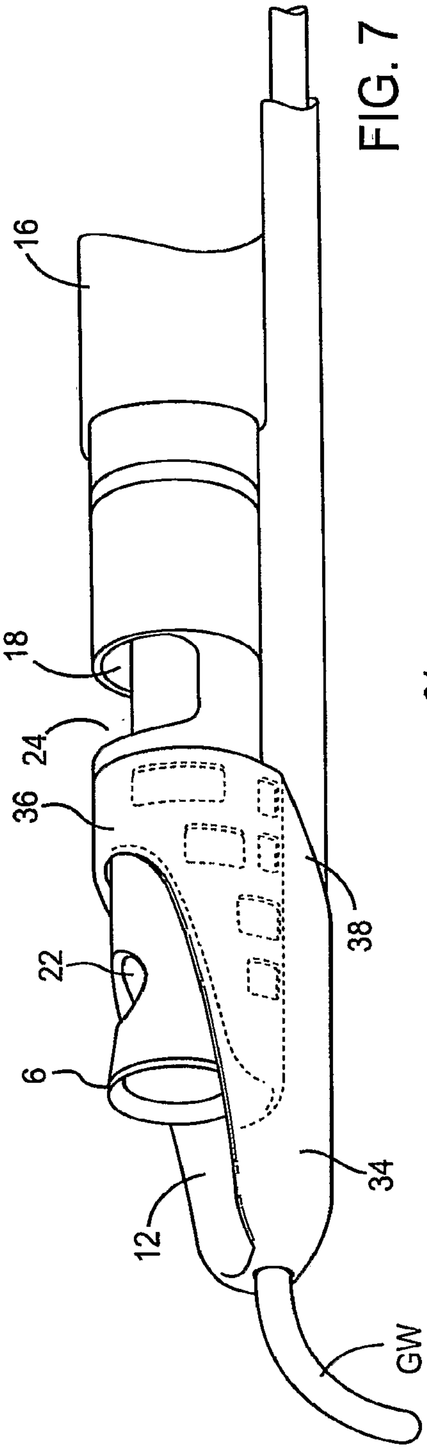

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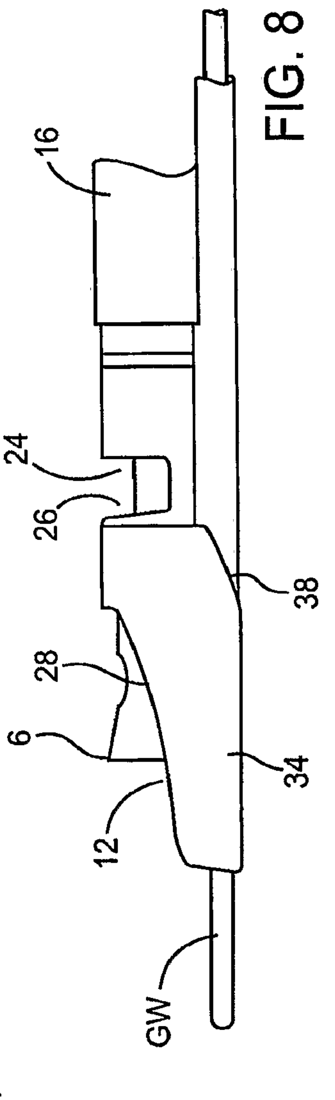

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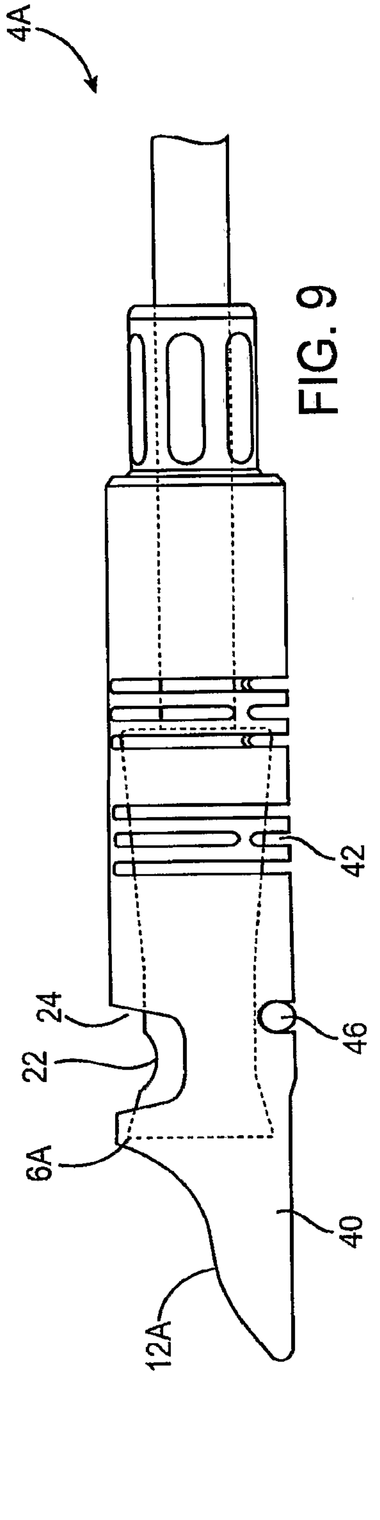

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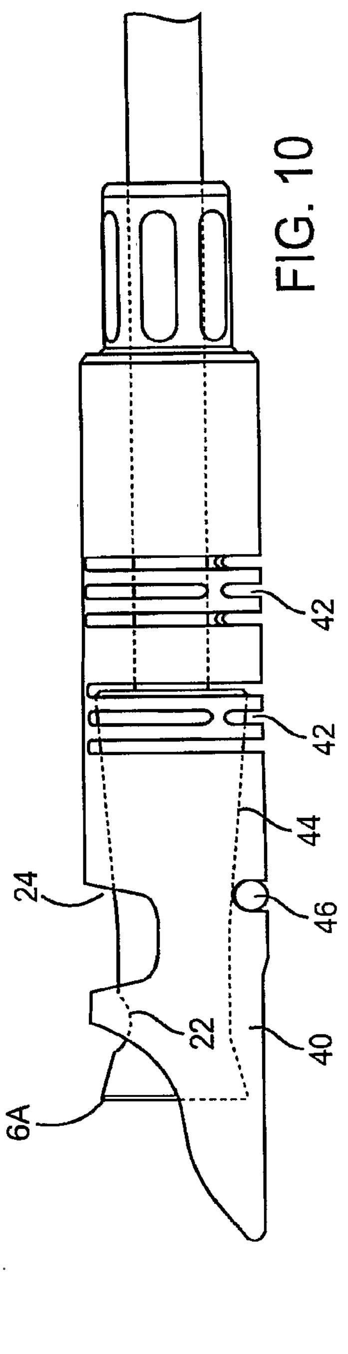


FIG. 10

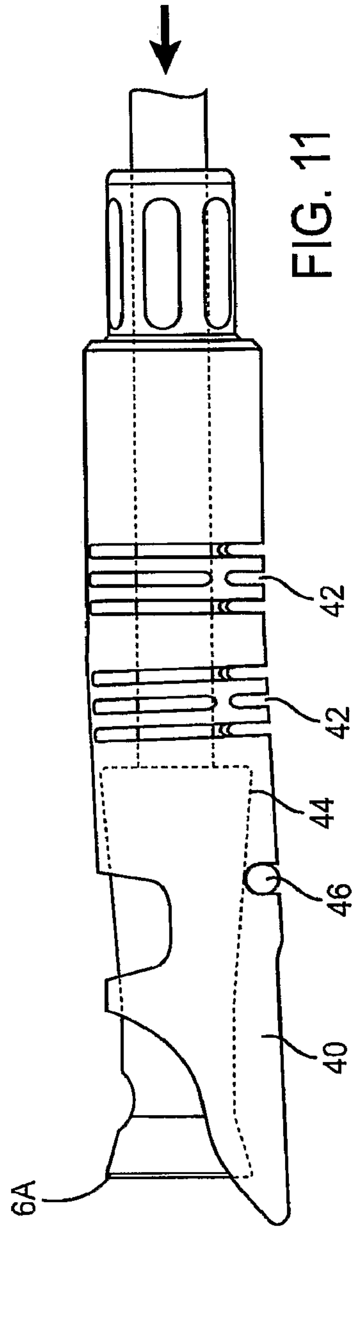


FIG. 11

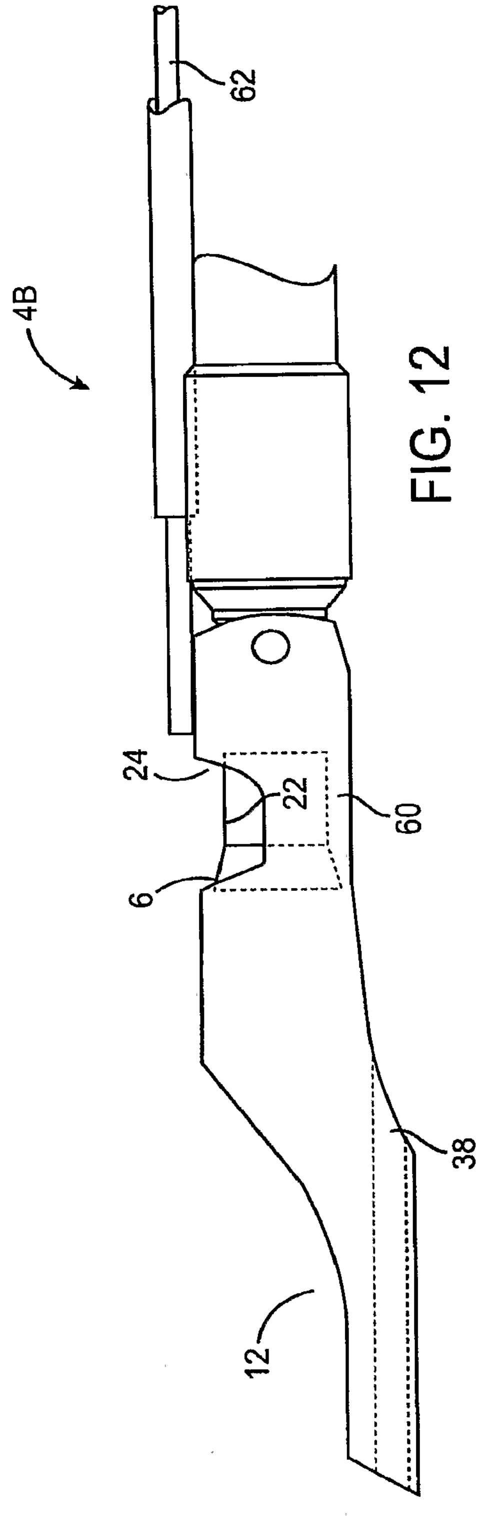
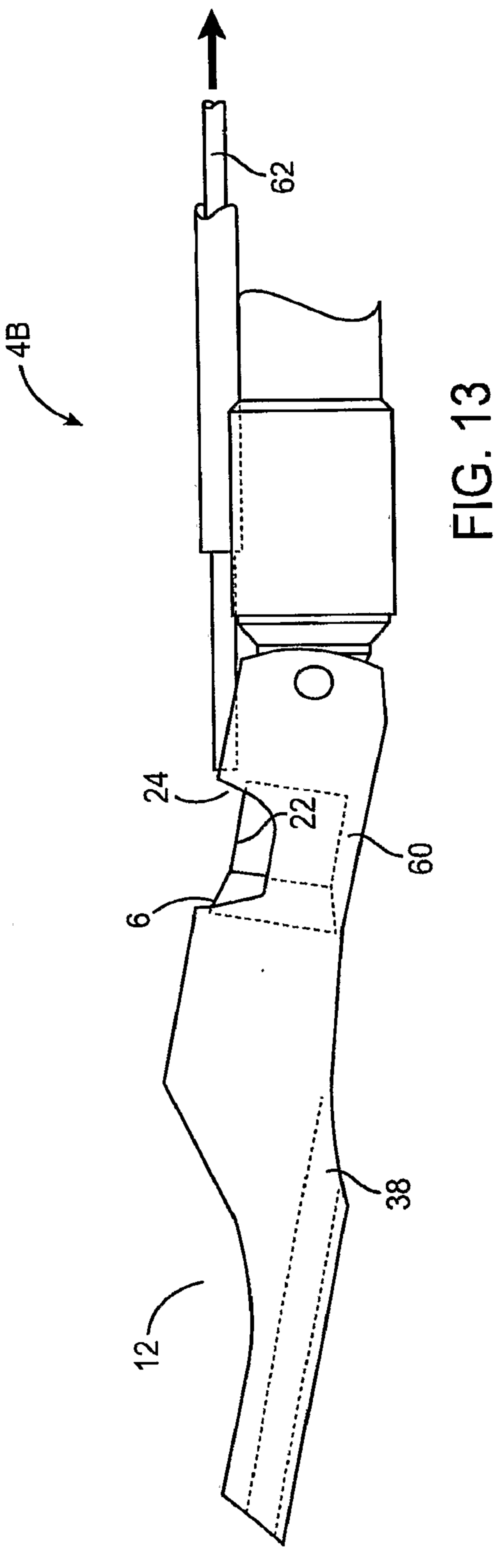


FIG. 12



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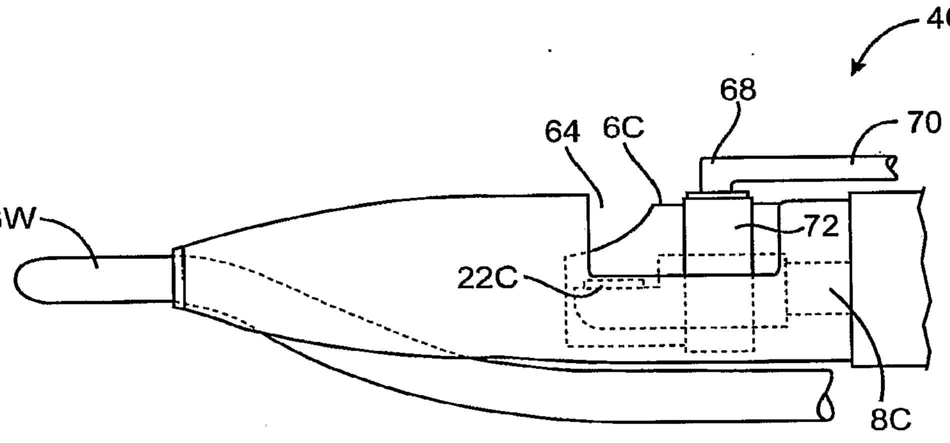
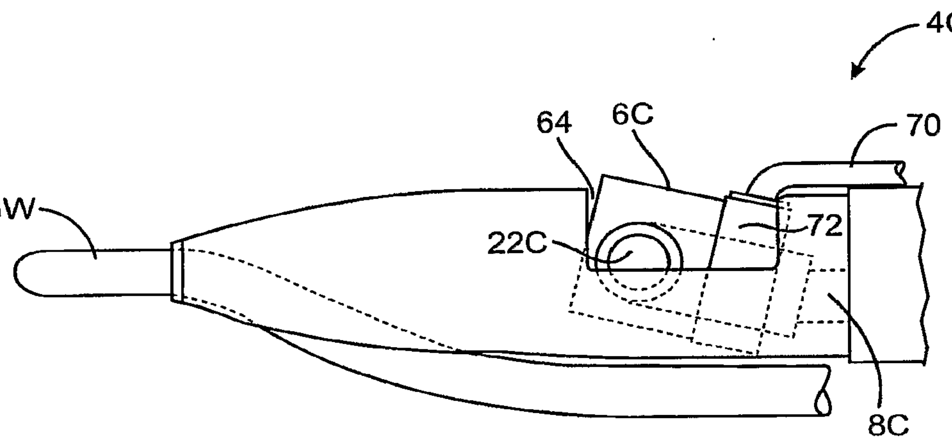


FIG. 14



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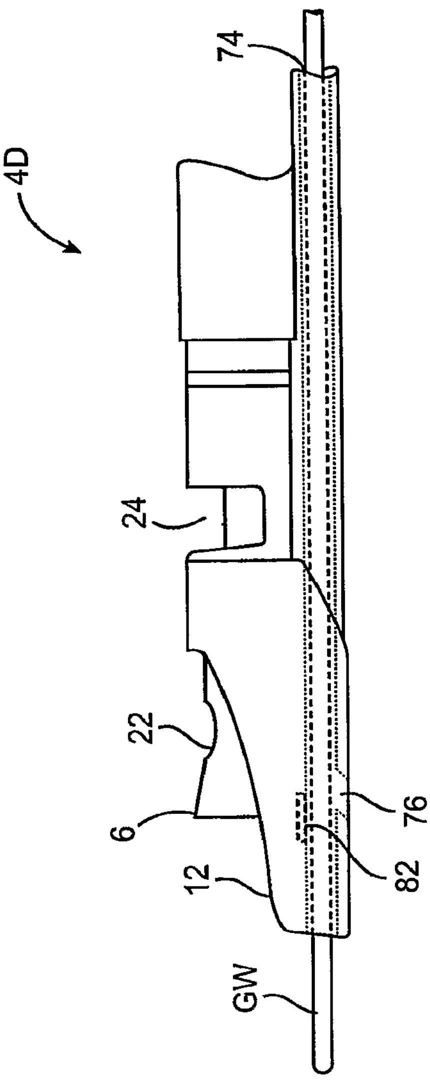

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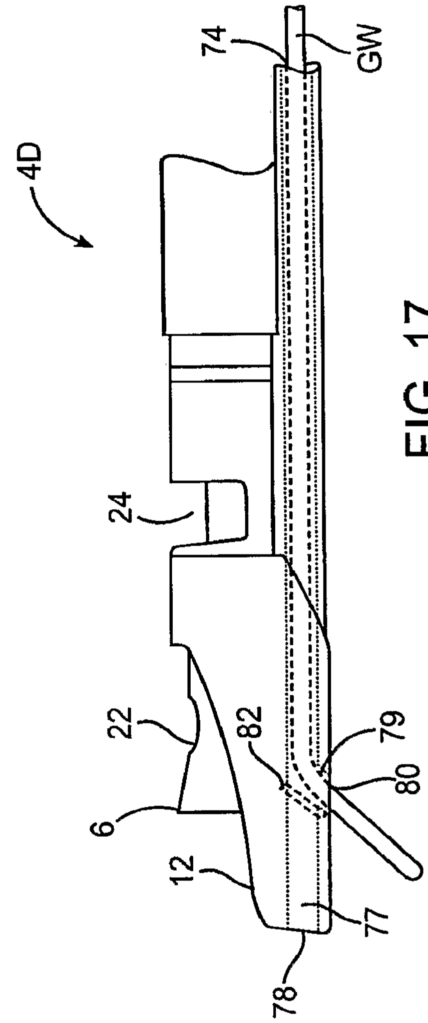

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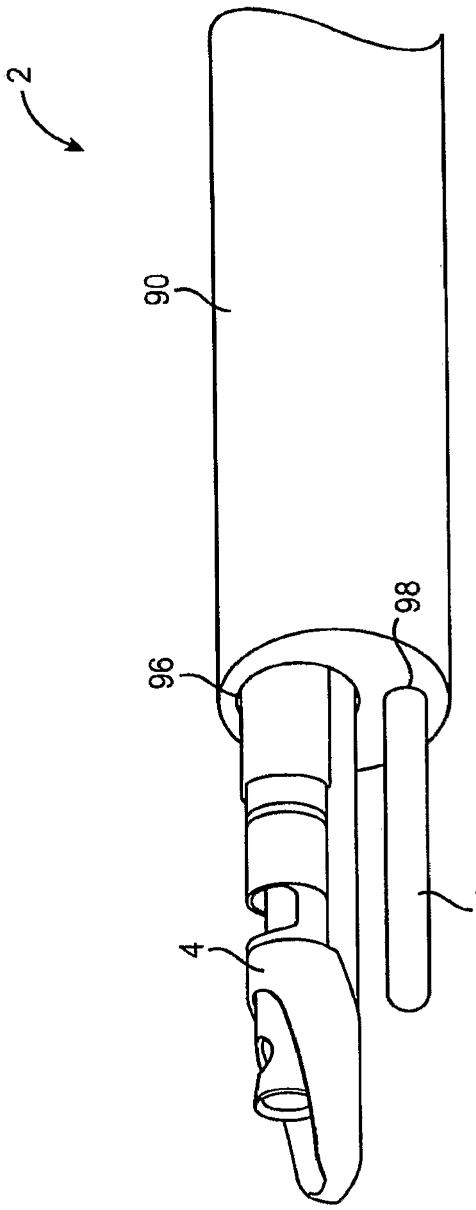

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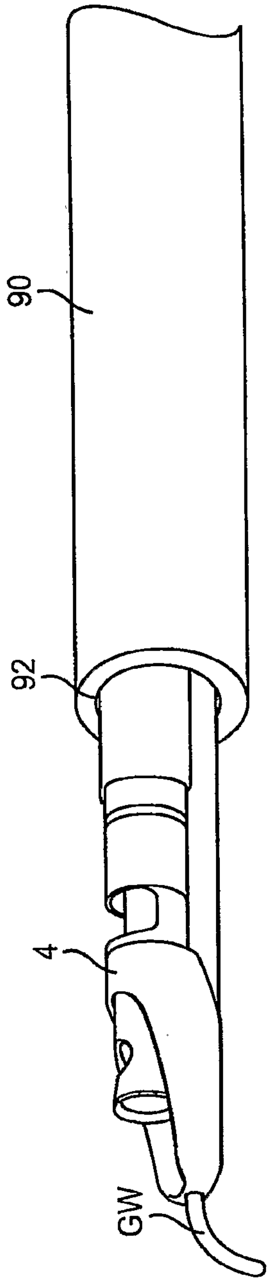

FIG. 19

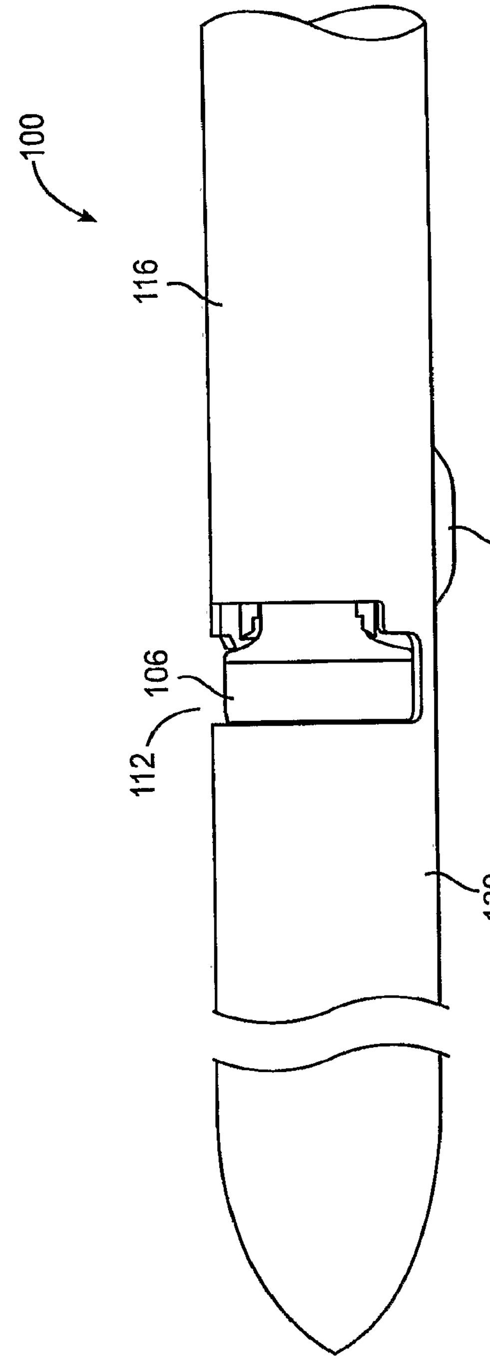

FIG. 20

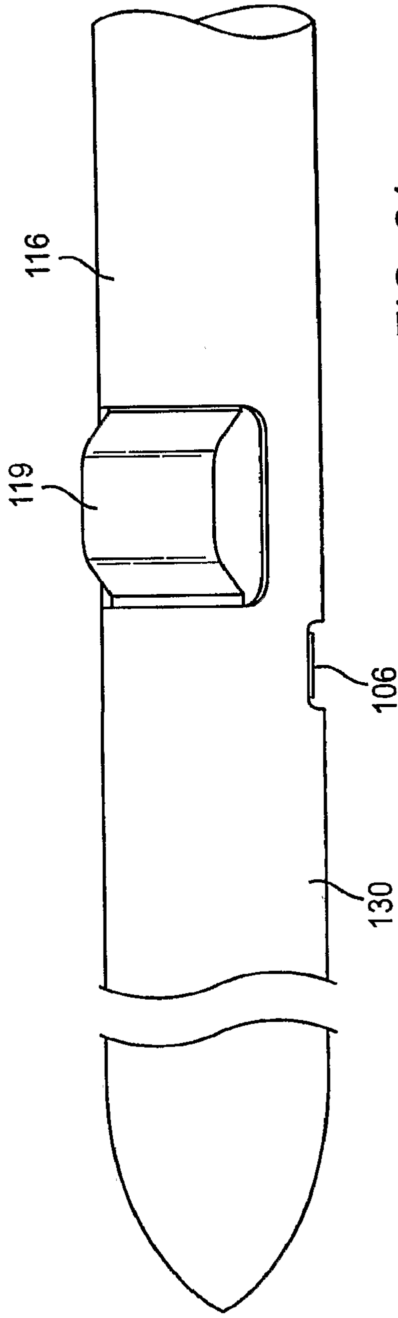

FIG. 21

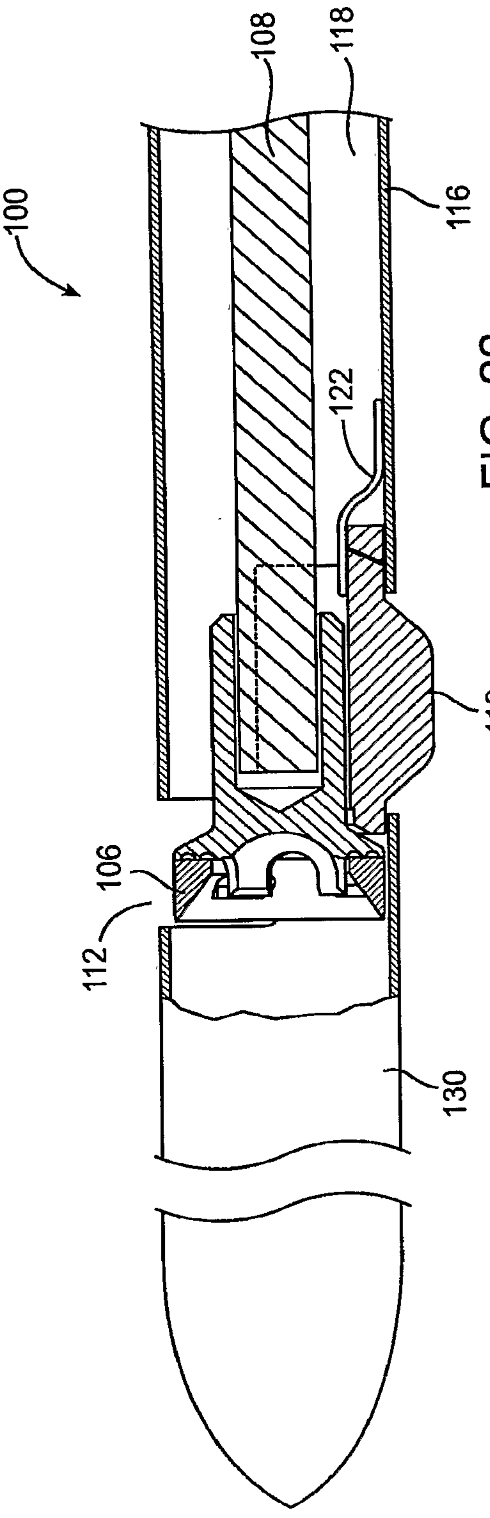
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FIG. 22

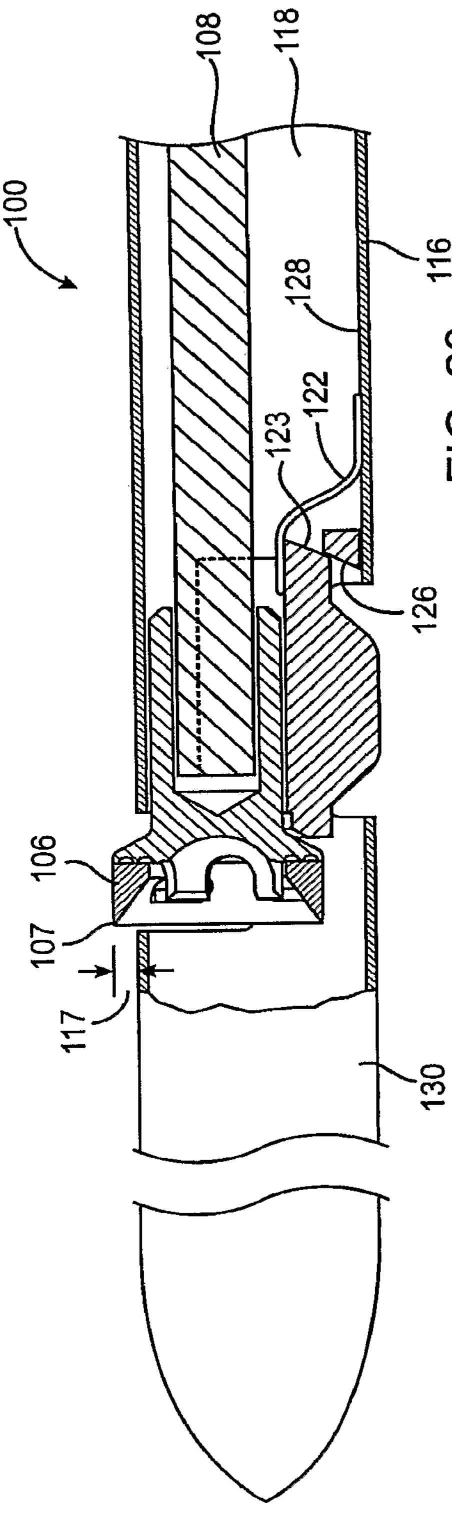
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FIG. 23