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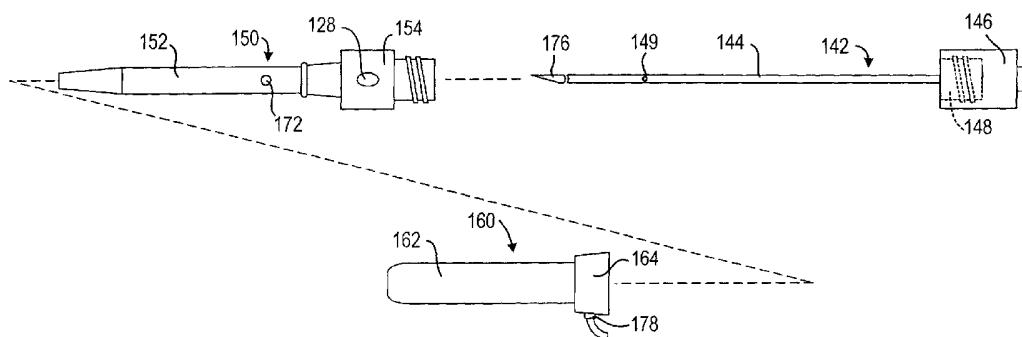
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(54) Title: VASCULAR ACCESS DEVICE



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(57) Abstract: A vascular access system comprises a needle having a distal tip and a proximal fitting section and a dilator having a solid distal section connected to a solid proximal section and an annular recess therebetween, the dilator having a passageway so that the dilator is coaxially positioned around the needle. The needle has at least one opening positioned proximal to its distal tip so that, when the distal end of the needle enters a blood vessel, blood enters the annular recess to show the operator that access has been achieved. Optionally, a sheath having a distal tip, a proximal fitting section, and a lumen sufficient to coaxially fit over the dilator.

VASCULAR ACCESS DEVICE

5

CROSS-REFERENCE TO RELATED APPLICATION

This application is based upon co-pending U.S. provisional patent application

Serial No. 60/343,814, filed December 26, 2002.

10

FIELD OF THE INVENTION

This invention is directed to vascular access. More particularly, this invention is directed to a vascular access device that is easier, safer, and faster to use than prior such devices.

BACKGROUND OF THE INVENTION

A preferred non-surgical method for inserting a catheter or vascular sheath into a blood vessel involves the use of the Seldinger technique, which includes an access needle that is inserted into a patient's blood vessel. A guidewire is inserted through the needle and into the vessel. The needle is removed, and a dilator and sheath combination are then inserted over the guidewire. The dilator and sheath combination is then inserted a short distance through the tissue into the vessel, after which the dilator is removed and discarded. The catheter is then inserted through the sheath into the vessel to a desired location.

25 A number of vascular access devices are known. See, for example, U.S. Patents Nos. 4,581,019, 4,629,450, 4,772,264, 4,978,334, 5,158,544, 5,424,410, 5,312,355, 5,512,052, 5,728,132, 5,885,217, 5,919,160, 6,120,494, 6,179,823, and 6,210,366, each of which is incorporated herein by reference, wherein various devices for vascular access are described. However, none of these devices has the ease and safety of use that physicians would prefer, 30 and there is thus a need for an easier-to-use and safer vascular access device, especially one that would clearly indicate when a blood vessel has been punctured.

OBJECTS OF THE INVENTION

It is an object of the invention to provide vascular access.

It is also an object of the invention to provide easier, safer, and faster vascular access.

5 It is additionally an object of the invention to provide a vascular access device that eliminates the possibility of inadvertent guidewire misplacement into the vascular system during the vascular access procedure.

10 It is a further object of the invention to provide a method of introducing catheters or other medical devices in an easier, safer, and faster procedure, where the appearance of a patient's blood in the vascular access device indicates to the practitioner that the needle has accessed the desired vessel.

These and other objects of the invention will become more apparent in the discussion below.

15

SUMMARY OF THE INVENTION

According to the invention, a dilator or a sheath and dilator are mounted on a needle, which needle has a lateral opening proximal to the needle distal tip. Prior to insertion, the needle is positioned so that the distal end of the needle is distal to the distal end of the dilator.

20 After insertion of the needle into a blood vessel, the needle opening permits blood to flow into an annular space in the dilator or between the needle and the dilator to indicate that the distal end of the needle has punctured the blood vessel. Additionally or alternatively, blood flows into an annular space formed by the sheath to indicate that the blood vessel has been punctured. In addition, blood may flow to an optional side port to provide further indication access has been achieved.

25 Once vascular access is achieved, that is, once the distal tip of the needle punctures a blood vessel and blood flows through a lateral opening in the needle to one of the annular spaces described above and as appropriate, into a side port, a guidewire is threaded through

the needle, and then the entire apparatus, including the needle, the dilator, and a sheath, can be advanced over the guidewire into the blood vessel. At a desired time the sheath, needle, and dilator can be advanced over the guidewire. When the sheath is in position, the inner dilator, needle and guidewire can be removed together. Thus, the guidewire protects the 5 needle tip, and the needle, with the guidewire in it, can then be bent for added safety, to prevent removal of the guidewire and consequential exposure of the needle tip.

Alternatively, the guidewire can be left in place for catheter placement.

In one embodiment of the invention, the dilator has a distal member that can be advanced distally or the distal tip of the needle can be retracted so that the distal tip of the 10 dilator distal member extends distally over the distal tip of the needle. The dilator distal member then protects the blood vessel wall as the needle, dilator or needle, dilator, sheath are advanced or withdrawn from a blood vessel, preferably over a guidewire. In addition, when the needle, dilator or needle, dilator, sheath are pulled out, the healthcare worker is protected.

15 In another embodiment of the invention, there is a coaxial dilator system, with an inner dilator and an outer dilator. The inner dilator can be advanced independently distally to the distal tip of the needle. The inner dilator then covers the needle tip, the inner dilator distal member then protects the blood vessel wall as the needle, dilator or the needle, dilator, sheath are advanced or withdrawn from a blood vessel, preferably over a guidewire. In 20 addition, when the needle or needle, dilator, and/or sheath are pulled out, the worker is protected.

In another embodiment of the invention the needle can be rotated relative to the dilator or the dilator and sheath, so that the needle tip, which is inserted into a blood vessel with the needle distal tip bevel up, can be rotated 180° so that the needle distal tip bevel is 25 down. When the needle distal tip is in this position, it is less likely that movement of the needle distal tip will cause injury to the blood vessel. The proximate portion of the needle member may have color coding, words, or other indicia to indicate the relative position of the needle tip level. Also, the needle member proximal portion may have a notch, pivot, indent,

or other mechanism to indicate relative position and/or to hold the needle member in position relative to the dilator or the dilator and sheath.

The vascular access device of the invention has several uses, including access to every vessel when a vascular sheath is needed as in stent placement, Percutaneous Transluminal 5 Coronary Angioplasty (PTCA), etc. or when a peel-away sheath is needed, for example, for inserting PICC lines, pacemaker leads, etc. In addition, the invention would be useful for access to dialysis grafts and fistulas, which are superficial structures and where access is sometimes needed quickly, especially during a de-clotting procedure. Another use would be for placement of central lines (subclavian or internal jugular). Instead of use of a large 10 (18 G) needle (current technique), followed by advancement of a dilator over a guidewire and exchanging it for a triple lumen catheter or vascular sheath, according to the invention a large needle or a small needle can be used to gain vascular access with a vascular sheath through which a triple lumen or any other catheter can be safely placed.

The present invention has several advantages, the first of which is its efficiency.

15 Instead of the current multi-step access method with an exchange of guidewires and sheaths, this invention reduces the number of steps and simplifies access. Another advantage is safety. After a vessel is accessed, the guidewire can be left in to protect the needle tip. The needle, dilator and guidewire can be removed together after the sheath is in place. If no additional access is needed in the same procedure, the needle can be bent for added safety. 20 This is contrary to the current technique where the unprotected bloody needle is removed from the guidewire after vascular access is gained. Alternatively, the guidewire can be left in place to provide further access through the sheath and the dilator distal member protects the distal tip of the needle and ultimately the user. Another advantage is the reduction of infection. By minimizing the number of guidewires and sheaths necessary to obtain vascular 25 access, the opportunities for inadvertent contamination are decreased. A further advantage is that under non-hospital or field conditions, use of the invention will decrease the possibility of infection due to a non-sterile environment. A yet further advantage is the added stiffness of the system. The added stiffness provided by the needle is enabling advancement of the

system without multiple dilatations and reduced trauma to the patient.

An even further advantage relates to the bleeding from the needle, the dilator, and around the wires that occurs during guidewire exchanges with current techniques. Such bleeding increases the spread of blood over the surgical field and the operator's gloves, 5 thereby, increasing the chance of infection in case an inadvertent needle stick happens. The device of the invention will decrease this risk of infection because the blood will flow into the sheath rather than into the surgical field as in the current technique.

Another and further advantage of one embodiment of the invention, is that there is no need for over-the-wire exchanges. The device can be configured to eliminate the possibility 10 of inadvertent guidewire misplacement into the vascular system during the access procedure. In the current technique, with exchange of the needle for a dilator and then for the sheath, it is a known complication that the operator fails to grasp the guidewire during those exchanges and the guidewire is inadvertently advanced with the dilator or catheter into the patient's 15 vascular system. The guidewire then has to be removed either surgically or snared percutaneously.

Lastly, the present invention will be cost-effective. The system of the invention will eliminate the need for an additional guidewire and coaxial dilator to be used in gaining vascular access.

20

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1 and 2 are each a schematic representation of one embodiment of the invention;

Figs. 3 and 4 are each a schematic representation of another embodiment of the invention;

Fig. 5 is a partly cross-sectional view of a further embodiment of the invention;

25

Fig. 5a is a cross-section along line 5a--5a;

Fig. 6 is a partly cross-sectional view of another aspect of the invention;

Fig. 7 is a partly cross-sectional view of a further aspect of the invention;

Fig. 8 is a partly cross-sectional view of an embodiment of the invention where the distal portion of the dilator extends distally;

Figs. 9a to 9c are schematic representations of use of the embodiment of the invention
5 shown in Fig. 8;

Figs. 10a and 10b are schematic representations of an embodiment of the invention with a coaxial dilator system;

Fig. 11 is a schematic cross-sectional view of the proximal portion of the system of
Figs. 10a and 10b.

10 DETAILED DESCRIPTION OF THE INVENTION

The invention can perhaps be better appreciated from the drawings. In Figs. 1 and 2 a needle section 102 comprises a needle 104 and a proximal portion 106 with a twist lock member 108, and a dilator section 112 comprises a dilator 114 and a hub 116. In a preferred embodiment of the invention, needle 104 has one or more openings 120. Dilator 114 is
15 preferably clear, semi-opaque, or translucent so that when blood flows into needle 104 and then through an opening 120 either (1) into an annular space 122 between needle 104 and dilator 114 or (2) into or through spaces (not shown) in dilator 114, the physician can see the blood. This will indicate to the physician that the distal end 124 of needle 104 has punctured a blood vessel (not shown).

20 As can be seen in Fig. 2, dilator hub 116 releasably engages needle proximal section 106. Here, dilator hub 116 comprises a conical recess 117 that receives a conical member 119 forming a part of needle proximal section 106. Needle proximal section 106 comprises an annular portion 121 having threading 123 that engages reciprocal threading 125 on hub 116. Other arrangements of threading, detents, or other snap- or force-fit configurations that
25 achieve the same purpose of releasably engaging the proximal portions of the needle and dilator sections are also within the scope of the invention.

Hub 116 may optionally have a porous vent 128. Needle proximal portion 106 may optionally have a porous vent plug 130 that fits a channel 132 in fluid communication with lumen 134 of needle 104, recess 117, and needle proximal portion 106 having lumen 136.

5 Needle proximal portion 106 may have color coding, words, or other indicia, such as a pivot or notch, to indicate to the operator the position of the bevel of distal tip 124 relative to dilator 114. Also, there may be a mechanical fit between dilator 114 and needle 104 so that the operator would sense by feel or sound when the needle has been rotated to change the position of the needle tip bevel.

10 In the embodiment of the invention shown in Figs. 3 and 4, a needle section 142 comprises a needle 144 and a proximal portion 146 with a twist lock member 148, a dilator section 150 comprises a dilator 152 and a hub 154, and a sheath section 160 comprises a sheath 162 and a proximal portion 164. In a preferred embodiment of the invention, needle 144 has one or more openings 149. Dilator 152 and sheath 162 are preferably clear, semi-15 opaque, or translucent so that when blood flows into needle 144 and then through opening 149 (1) into an annular space 170 between needle 144 and dilator 152, (2) into or through spaces (not shown) in dilator 152, or (3) through an opening 172 into an annular space 174 between dilator 152 and sheath 162, the physician can see the blood. As above, this will indicate to the physician that the distal end 176 of needle 144 has punctured a blood vessel 20 (not shown). Preferably sheath proximal portion 164 has a port 178 so that blood can be aspirated through a syringe (not shown). The sheath may contain a hemostatic valve (not shown) in the distal end 164 to prevent blood flow out the distal end of the sheath.

25 Proximal sections 108 and 116 and 146 and 154, respectively, may optionally have luer connecting members. For example, section 108 may have a male luer lock 129, and section 116 may have a female luer connector 131. Sections 146 and 154 may have comparable members, respectively.

As shown in Fig. 4 sections 142, 150, and 160 can be inserted into one another.

Proximal sections 146, 154, 164 can twist or snuggly fit together, such as with a luer connector, threading, a pressure or snap fit, a detent/groove arrangement, or a combination thereof. The structure shown in Fig. 2 is especially applicable here.

In another embodiment of the invention as shown in a partial cross-section in Fig. 5, 5 needle 180 has an opening or side hole 182. Dilator 184, which is arranged coaxially to needle 180, has a substantially hollow distal section 186 and a substantially solid proximal section 188, which sections 186 and 188 are connected by rigid or substantially rigid longitudinal members 190, to form an interrupted or discontinuous structure. The space between sections 186 and 188 not occupied by members 190 constitutes an annular or 10 substantially annular space 194, into which blood can flow from opening 182. Sheath 196 is transparent or translucent, so that the blood in space 194 can be observed by the physician.

Preferably dilator 184 has one or more small openings, pores, or porous material 200, for example, in sheath 196, to allow air or gas to leave annular space 194 as blood enters. The openings themselves, or the openings in the porous material, are small enough that air 15 will escape but blood will be retained. Suitable porous materials include a porous polymer such as self-sealing, white porous HDPE of pore size 2.5 microns.

The distal end 202 of a guidewire 204 is preferably preloaded, that is, positioned within a lumen 206 of needle 180. In this way blood will flow into needle 180 and out through opening 182, and not proximally out lumen 206. Once the physician sees the blood 20 in annular space 194, guidewire 204 can be advanced distally through lumen 206 into a blood vessel (not shown). Another view of the relationship between needle 180, dilator longitudinal members 190, and sheath 196 can be seen in the cross-sectional view shown in Fig. 5a.

Separate designs for a dilator member according to the invention are shown in more 25 detail in Figs. 6 and 7. In Fig. 6, a dilator 210 shown has conical elements. A distal dilation section 212 comprises a double cone design with a passageway 214 extending from the tip of one conical element 216 to the tip of another conical element 218. At least two stabilizing

longitudinal members 220 extend from distal section 212 to a proximal section 222, which preferably comprises a single conical element 224 with a passageway 226 and a proximal twist or locking section 228.

The embodiment of the invention shown in Fig. 7 comprises a dilator-needle

5 combination where the dilator device described in Fig. 6 also comprises a needle 232 that extends through passageway 214 to and through passageway 226. Needle 232 has a proximal section 234 that comprises a twist or locking arrangement.

In the partial representation of an embodiment of the invention shown in Fig. 8, a

10 dilator 240 is arranged circumferentially around a needle 242. Dilator 240 has a distal portion 244 that extends distally toward the distal tip 246 of needle 242. Alternatively, the inner, elongated dilator is coaxially located within the larger outer dilator. The inner 15 elongated member can be advanced over the needle to protect the tip. As depicted in Figures 9a to 9c, a needle 252 is positioned in a puncture opening 254 in a blood vessel 256. A guidewire 258 extends distally from needle 252 into a lumen 260 of blood vessel 256. A dilator 262 positioned circumferentially around needle 252 has a distal portion 264. As 20 shown in Fig. 9b, dilator distal portion 264 can be advanced over needle 252 so that the distal tip 268 of dilator distal portion 264 extends distally of the distal tip 270 of needle 252. Then, when, as shown in Fig. 9c, needle 252 and dilator 262 are advanced distally over guidewire 258, needle distal tip 270 is protected by dilator distal portion 264.

20 The embodiment of the invention shown in Figs. 10a and 10b comprises a coaxial

dilator system comprising inner dilator 276 and outer dilator 278. Dilators 276 and 278 are arranged around needle 280, and the distal end 282 of inner dilator 276 is initially slightly distal of the distal end 284 of outer dilator 278. The proximal end (not shown) of inner 25 dilator 276 is advanced distally to cause inner dilation distal end 282 to cover the distal end 288 of needle 280. Preferably dilators 276 and 278 interact or are held so that they retain their relative positions with regard to each other and needle 280 as the needle, dilator or 30 needle, dilator, sheath combination is advanced into or withdrawn from a blood vessel (not

shown), optimally over a guidewire (not shown).

The coaxial dilator system shown in Figs. 10a and 10b requires an activation system that causes one dilator to move in relation to the other dilator. It is preferred that the inner dilator would be advanced distally to cover the distal end of the needle while the outer dilator remains constant, or in place. Preferably the dilator system would be configured so that the outer dilator would remain relatively, substantially in place while the inner dilator is pushed, pulled, or slid in the distal direction. In the embodiment shown in Fig. 11, a proximal needle section 290 is circumferentially surrounded by a proximal inner dilator section 292 and an outer dilator section 294. Tapered needle hub 296 has at least one annular projection or ring 298 that is received in an annular groove 302 in the tapered outer dilator proximal hub 304. Inner dilator hub 306 has threading 308 that engages reciprocal threading 310 on needle 290 or on a separate needle member attached to needle 290 or needle hub 296. Inner dilator hub 304 has a projection or wing 312 that moves within, and is guided by, a slot 316 that prevents rotation of inner dilator 292 with respect to outer dilator 294. It is within the scope of the invention that other mechanical arrangements known or discernible to those skilled in the art would be acceptable, so long as they permitted advancement of the distal portion of the inner dilator over the distal portion of the needle without rotation of the inner dilator relative to the outer dilator.

The invention herein is comprised of conventional, physiologically acceptable materials. For example, the needle consists of a rigid polymer or a metal such as stainless steel, nitinol, or the like. The other elements will typically consist of suitable polymeric materials, such as polyethylene, polypropylene, fluoropolymers and copolymers such as perfluoro (ethylene-propylene) copolymer, polyurethane polymers or co-polymers.

The preceding specific embodiments are illustrative of the practice of the invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein, may be employed without departing from the spirit of the invention or the scope of the appended claims.

I Claim:

1. A vascular access system comprising:
 - a needle having a distal tip and a proximal fitting section; and
 - a dilator having a solid distal section connected to a solid proximal section and
- 5 a recess therebetween, the dilator having a passageway so that the dilator is coaxially positioned around the needle,

wherein the needle has at least one opening positioned proximal to its distal tip and wherein the dilator has a substantially annular recess to receive blood when the distal tip of the needle punctures a vessel.
- 10 2. The system of Claim 1, wherein the dilator is discontinuous.
3. The system of Claim 1, wherein the dilator is clear, semi-opaque, or translucent.
4. The system of Claim 1, wherein the dilator has a lateral access to aspirate blood through a syringe.
- 15 5. The system of Claim 1, wherein the needle and dilator can be advanced together over a guidewire into a blood vessel.
6. The system of Claim 5, wherein the guidewire protects the needle from injuring intravascular structures.
7. The system of Claim 1, wherein the needle has a lumen and the distal end of a
- 20 guidewire extends into the needle lumen.
8. The system of Claim 1, wherein the possibility of guidewire displacement into a patient's vascular system is eliminated.

9. The system of Claim 1, wherein the dilator has one or more openings or pores to expel air.

10. The system of Claim 1, wherein the dilator has one or more spots of porous material.

5 11. The system of Claim 1, wherein the needle is left on the guidewire to protect the user.

12. The system of Claim 1, wherein the needle can be retracted into the dilator and locked in place to protect the blood vessel and, when the dilator needle is removed, the user.

10 13. The system of Claim 1, wherein the dilator has a distally extending distal section.

14. The system of Claim 1, wherein the needle proximal section has color coding, wording, or other indicia to indicate the direction of the distal tip bevel.

15 15. The system of Claim 1, wherein the dilator has a distally extending distal section with a distal end to cover the distal tip of the needle.

16. The system of Claim 1, wherein after the needle is inserted into the blood vessel, the needle has a function to indicate or lock in place the orientation of the bevel of the needle distal tip.

17. The system of Claim 1, wherein a coaxial dilator system with the inner dilator 20 can be extended distally over the needle.

18. A vascular access system comprising:

a needle having a distal tip and a proximal fitting section;

a dilator having a solid distal section connected to a solid proximal section and a recess therebetween, the dilator having a passageway so that the dilator is coaxially positioned around the needle, and;

5 a sheath having a distal tip, a proximal fitting section and a lumen sufficient to coaxially fit over the dilator,

wherein the needle has at least one opening positioned proximal to its distal tip and wherein the sheath and the dilator form a substantially annular recess to receive blood when the distal tip of the needle punctures a vessel.

10 19. The system of Claim 18, wherein the sheath is clear, semi-opaque, or translucent.

20. The system of Claim 18, wherein the dilator is discontinuous.

21. The system of Claim 18, wherein the dilator is transparent or semi-opaque.

22. The system of Claim 18, wherein the sheath or the dilator has a lateral access 15 to aspirate blood through a syringe.

23. The system of Claim 18, wherein the needle, dilator, and sheath are advanced together over a guidewire into a blood vessel.

24. The system of Claim 18, wherein the guidewire protects the needle from injuring intravascular structures.

20 25. The system of Claim 18, wherein the dilator or the sheath has one or more openings or pores to expel air.

26. The system of Claim 18, wherein the sheath has one or more spots of porous material.

27. The system of Claim 18, wherein the needle is left on the guidewire to protect the user.

28. The system of Claim 18, wherein the needle can be drawn into the dilator and locked in place to protect the blood vessel when dilator/needle or dilator/needle and sheath is advanced.

29. The system of Claim 18, wherein when the guidewire is left in place, the needle can be drawn into the dilator and locked in place to protect the user.

30. The system of Claim 18, wherein the dilator has a distally extending distal section with a distal end to cover the distal tip of the needle.

10 31. The system of Claim 18, wherein after the needle is inserted into the blood vessel, the system has a function to indicate or lock in place the orientation of the bevel of the needle distal tip.

15 32. In a method of introducing a catheter or other medical device into a patient's cardiovascular system wherein a needle is introduced into a blood vessel, a guidewire is inserted through the needle into the blood vessel, a dilator is inserted over the guidewire, and a catheter or other medical device is introduced, the improvement wherein the needle and dilator are advanced together over the guidewire.

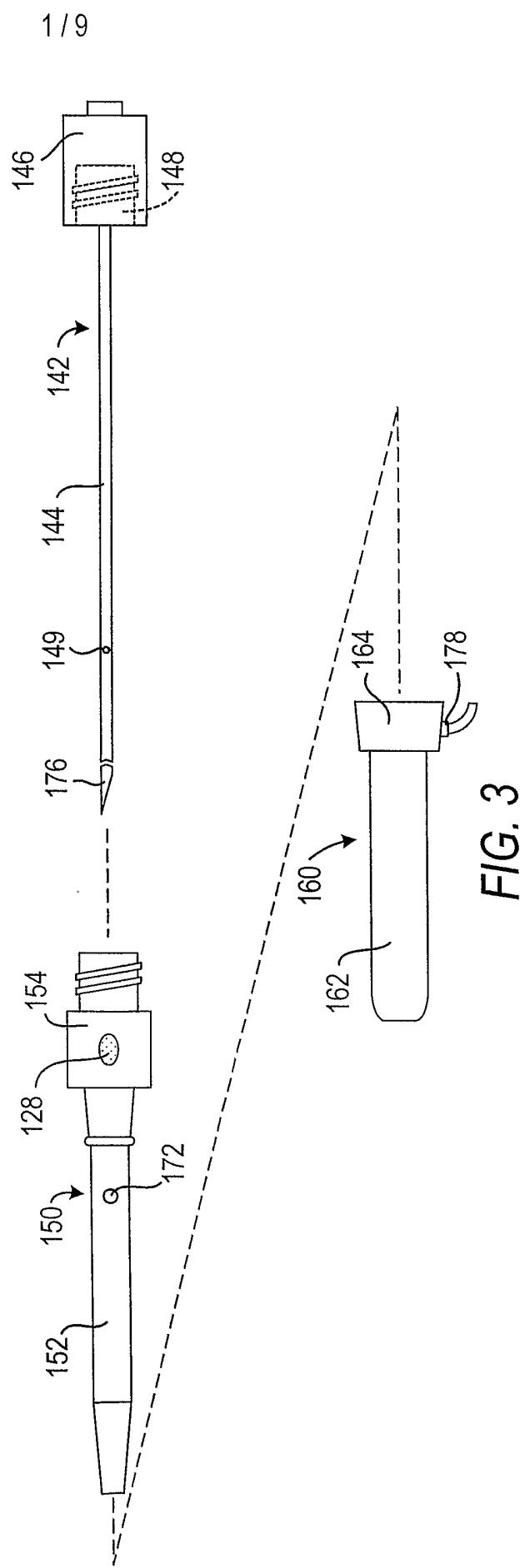
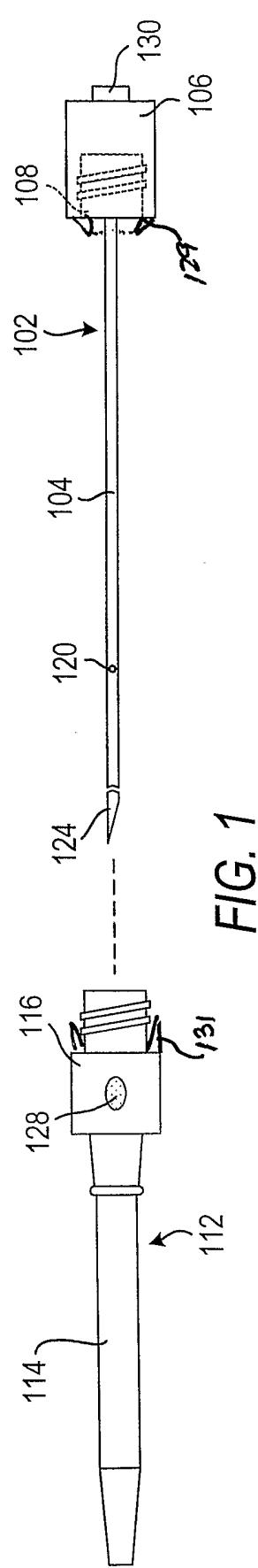
20 33. In a method of introducing a catheter or other medical device into a patient's cardiovascular system wherein a needle is introduced into a blood vessel, a guidewire is inserted through the needle into the blood vessel, a dilator and a sheath are inserted over the guidewire, and a catheter or other medical device is introduced through the sheath, the improvement wherein the needle, dilator, and sheath are advanced together over the guidewire.

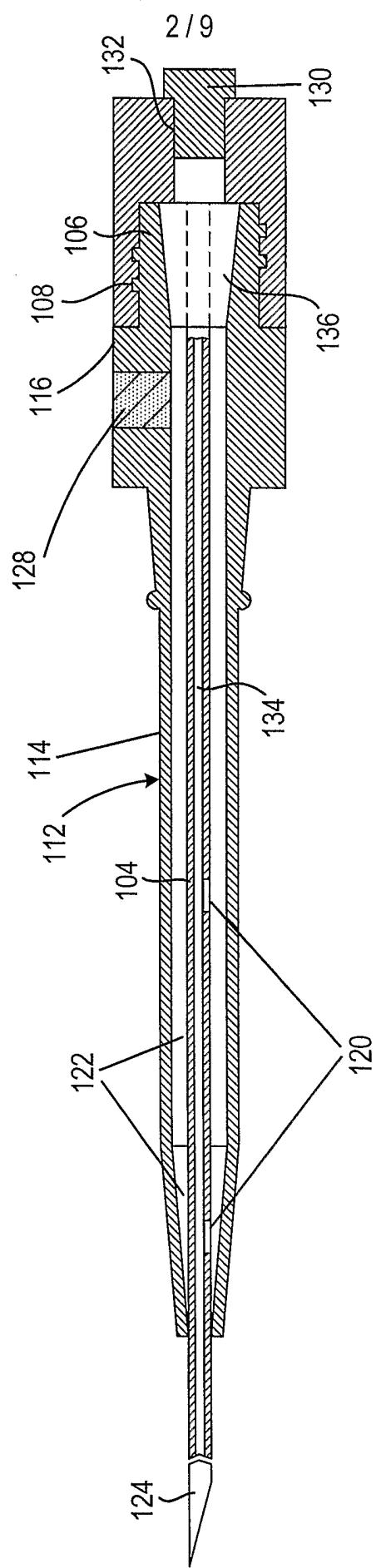
25 34. The method of Claim 32 or 33, wherein the dilator has a distally extending distal section with a distal end and the dilator is advanced relative to the needle so that the distal end of the dilator distal section is distal to the distal tip of the needle.

35. The method of Claim 32 or 33, wherein the dilator is coaxial in shape and has a distally extending inner dilator with a distal end and the inner dilator is advanced relative to the needle so that the distal end of the dilator distal section is distal to the distal tip of the needle.

5 36. The method of Claim 32 or 33, wherein after the needle is inserted into the blood vessel, the needle is rotated to reposition the bevel of the needle distal tip.

37. The method of Claim 36, wherein the needle is rotated 180 degrees.





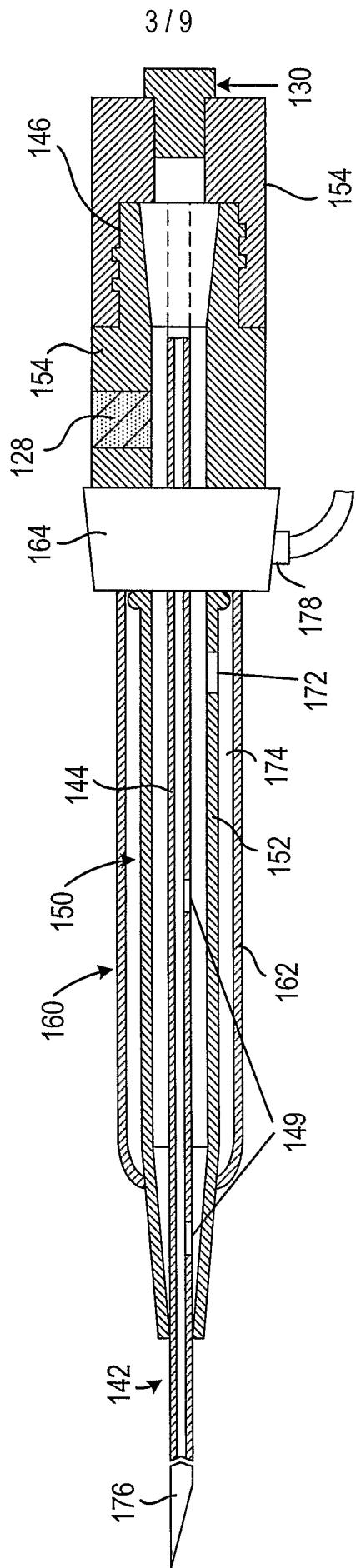


FIG. 4

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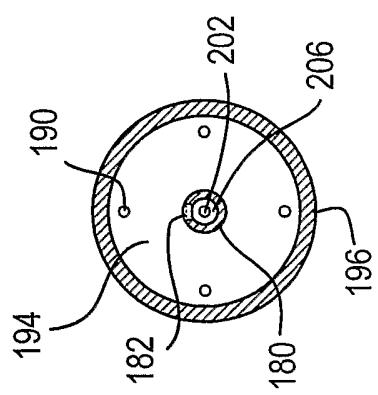
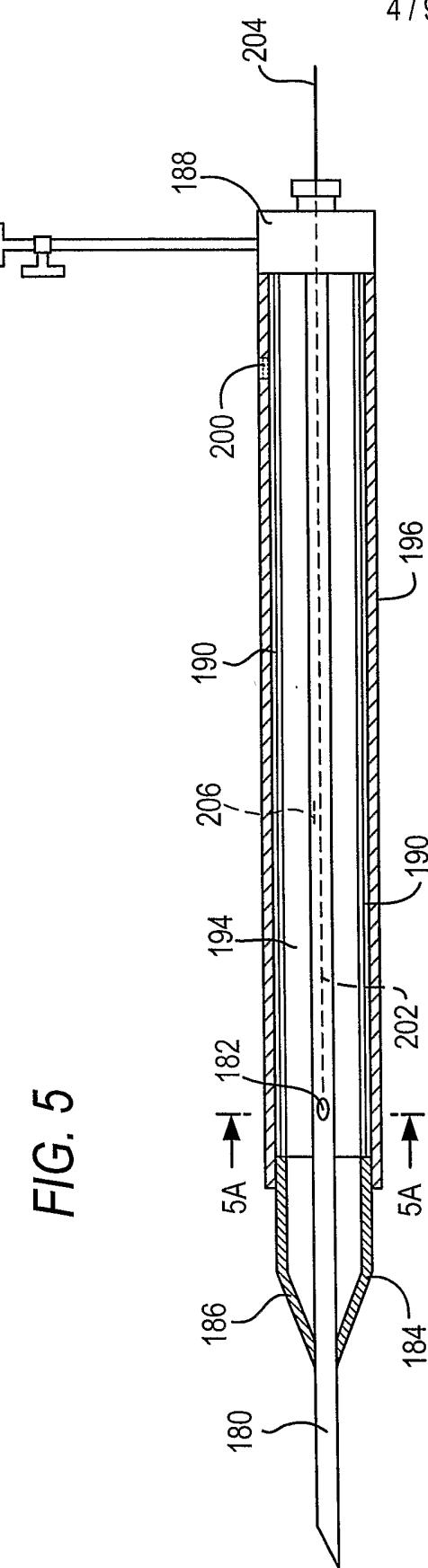


FIG. 6

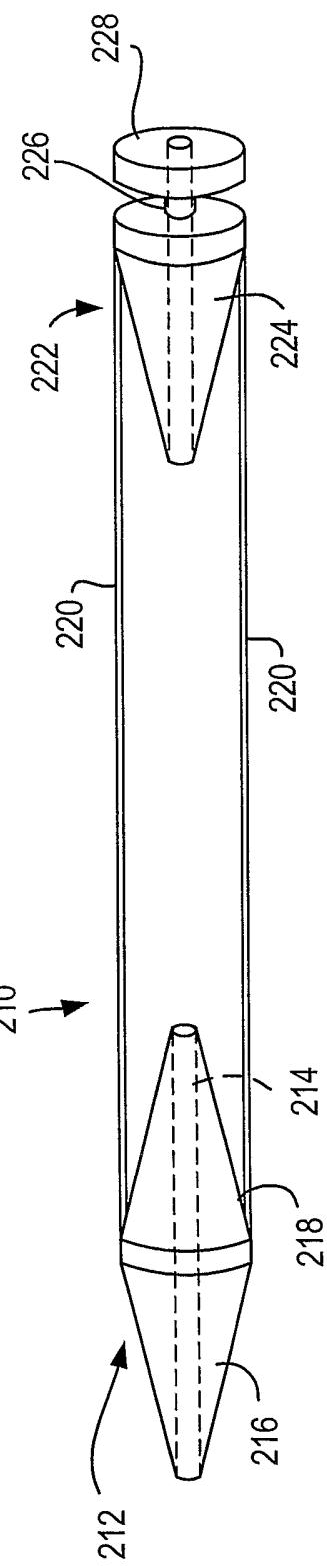
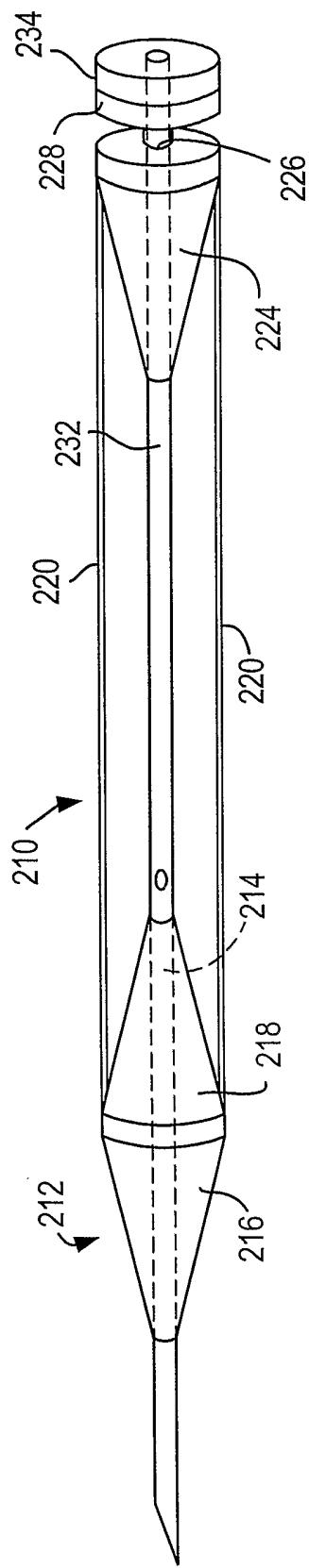


FIG. 7



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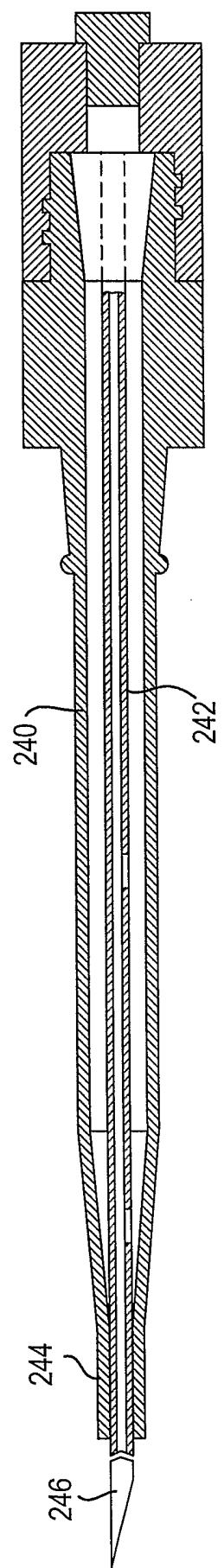


FIG. 8

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FIG. 9A

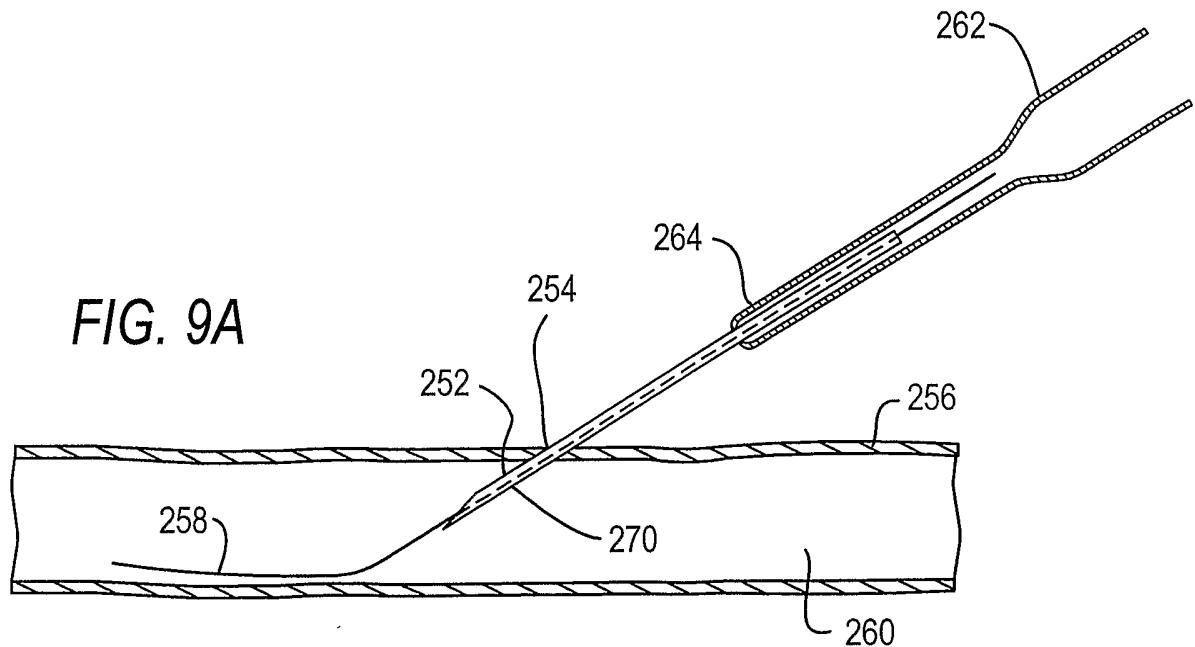


FIG. 9B

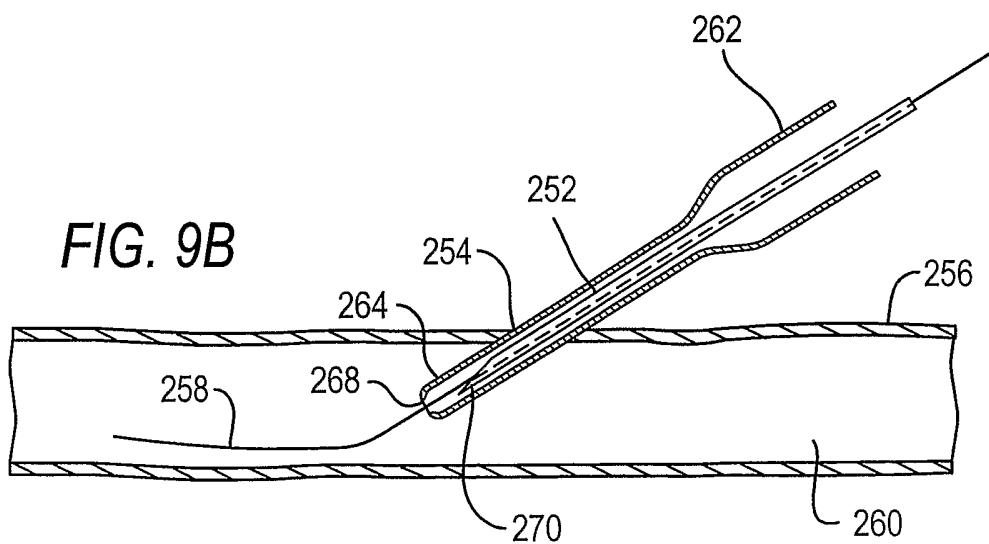
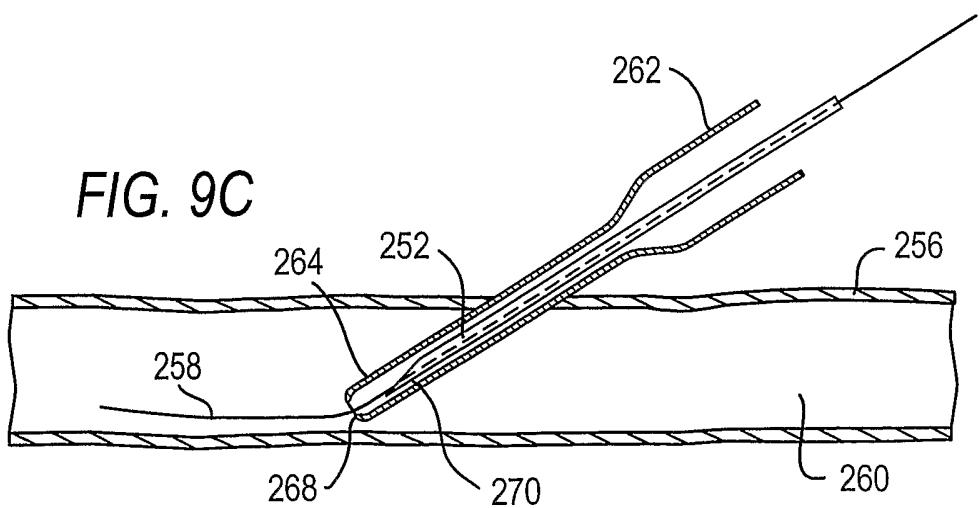


FIG. 9C



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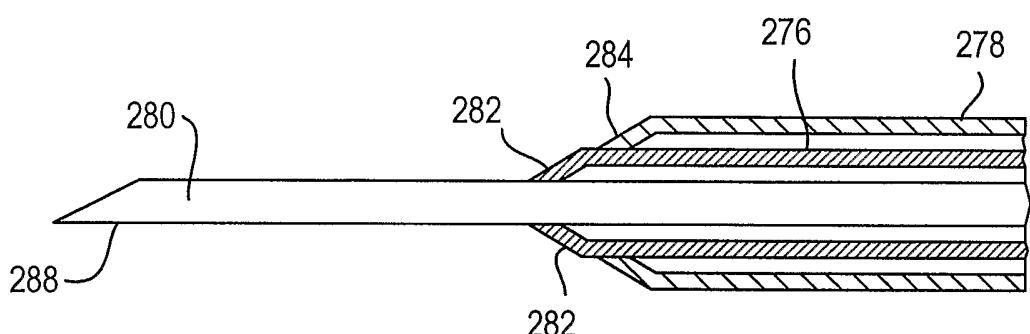


FIG. 10A

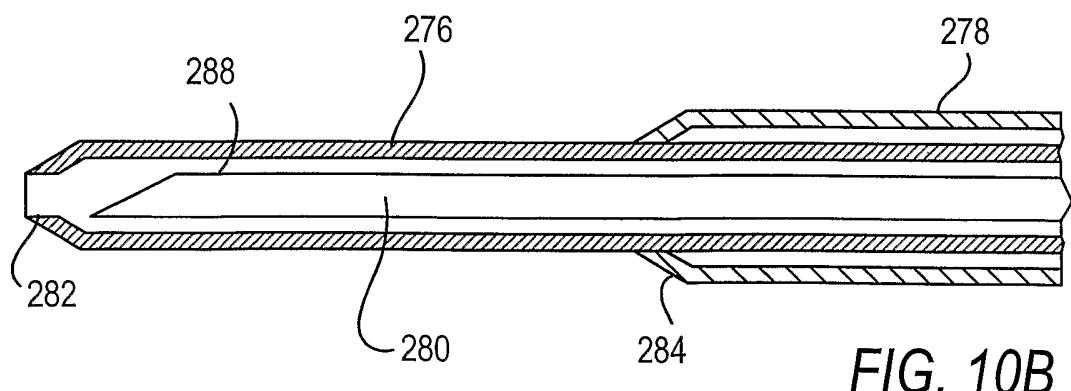


FIG. 10B

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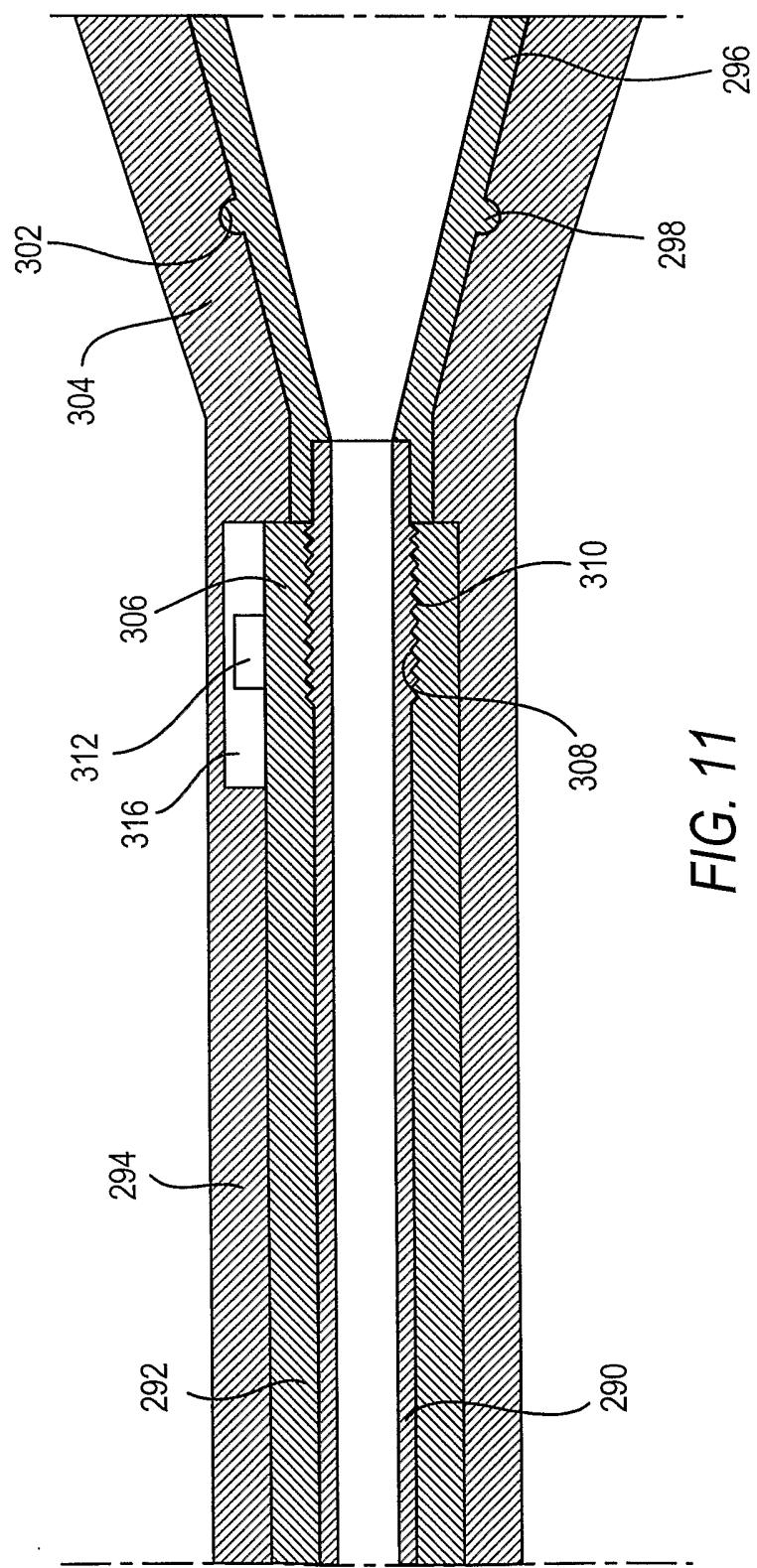


FIG. 11