US 20090005758A1

(19) United States

(12) Patent Application Publication

SHAH et al.

(10) Pub. No.: US 2009/0005758 A1

(43) Pub. Date: Jan. 1, 2009

(54) **GUIDE CATHETER**

(76) Inventors: **SONAR SHAH**, Los Angeles, CA (US); **Johnson E, Goode**, Austin, TX (US); **James F. Kelley**, Coon Rapids, MN (US); **Mark D. Schneider**, Mound, MN (US); **Jeff Jannicke**, Andover, MN (US); **Stanten C. Spear**, Arden Hills, MN (US)

Correspondence Address:
MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924 (US)

(21) Appl. No.: **12/038,251**

(22) Filed: **Feb. 27, 2008**

Related U.S. Application Data

(60) Division of application No. 10/682,220, filed on Oct. 9, 2003, which is a continuation-in-part of application No. 10/016,114, filed on Dec. 12, 2001, now Pat. No. 7,065,394.

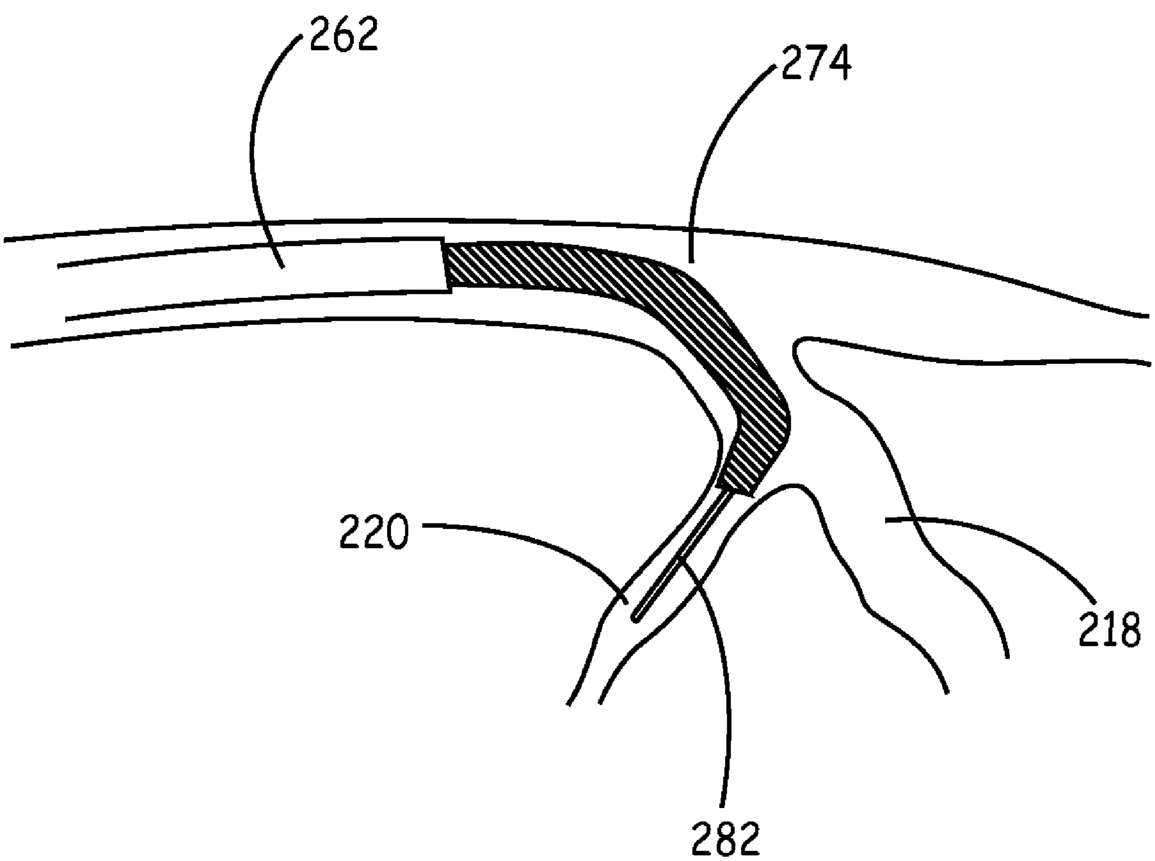
Publication Classification

(51) **Int. Cl.**
A61M 25/098 (2006.01)

(52) **U.S. Cl.** **604/529**

(57) **ABSTRACT**

An elongated sheath of a guide catheter includes a fully radiopaque and echogenic distal tip having a length greater than approximately 0.08 inch.



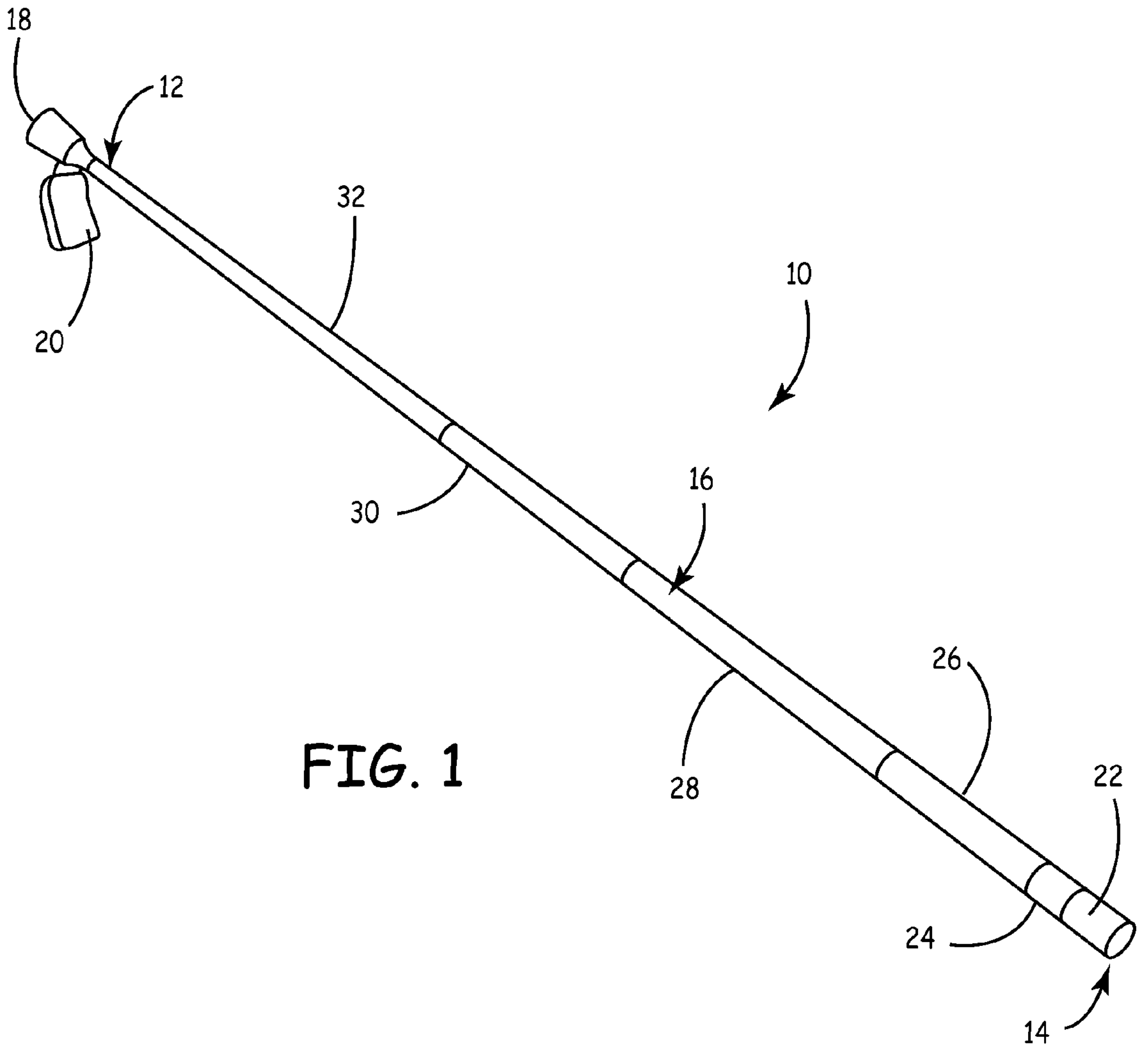


FIG. 1

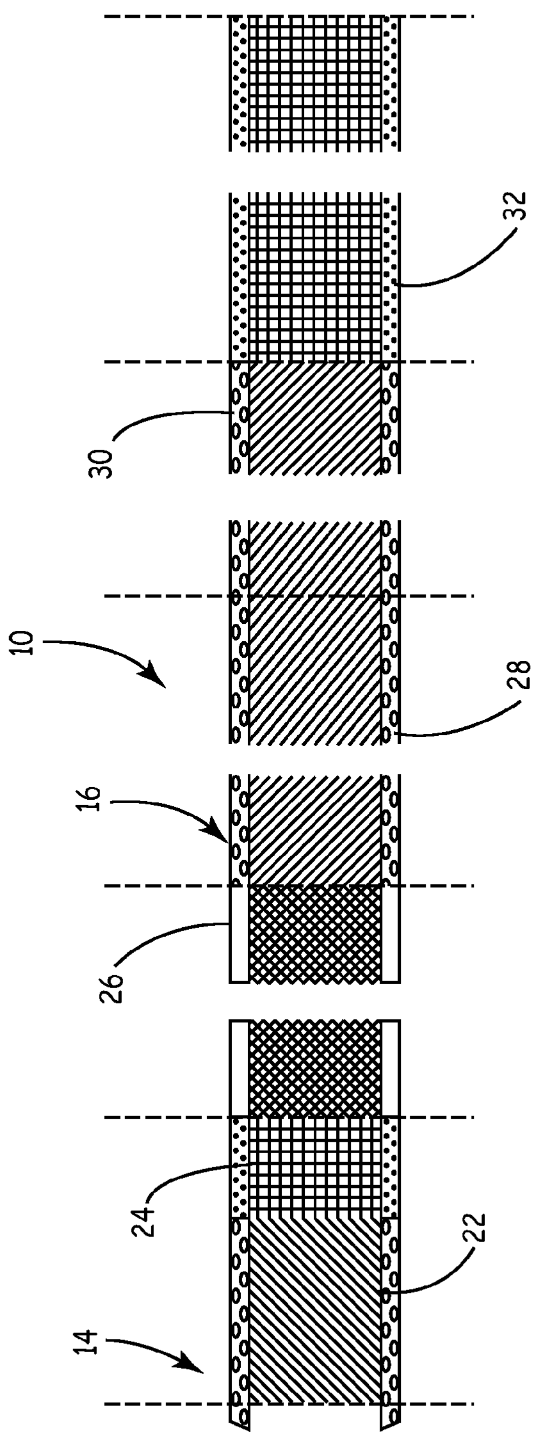


FIG. 2

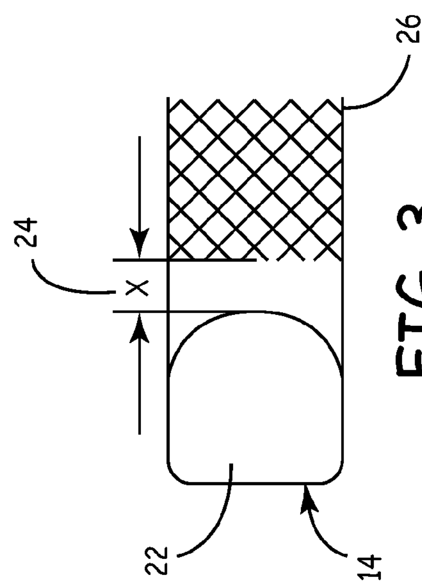


FIG. 3

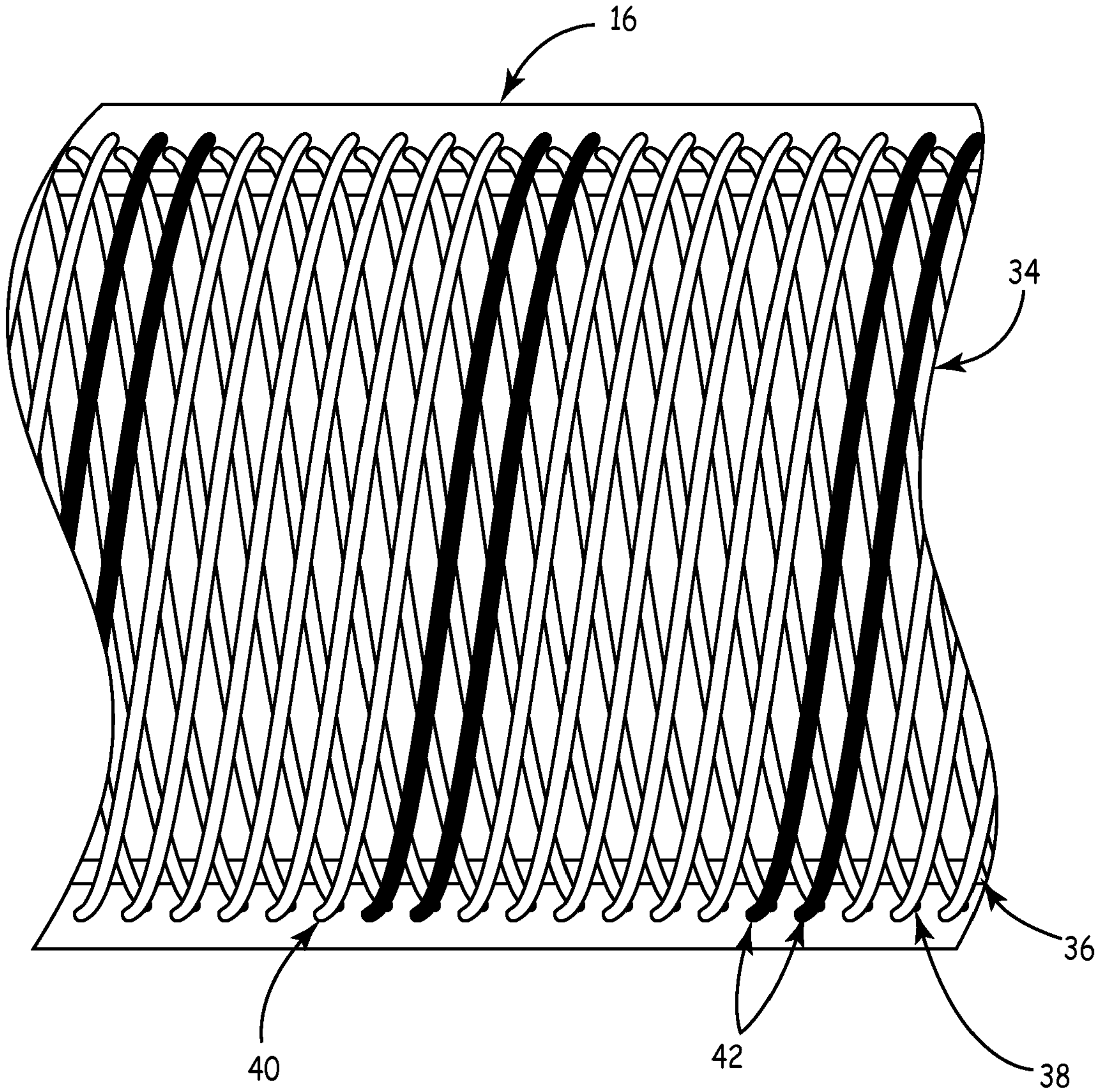


FIG. 4

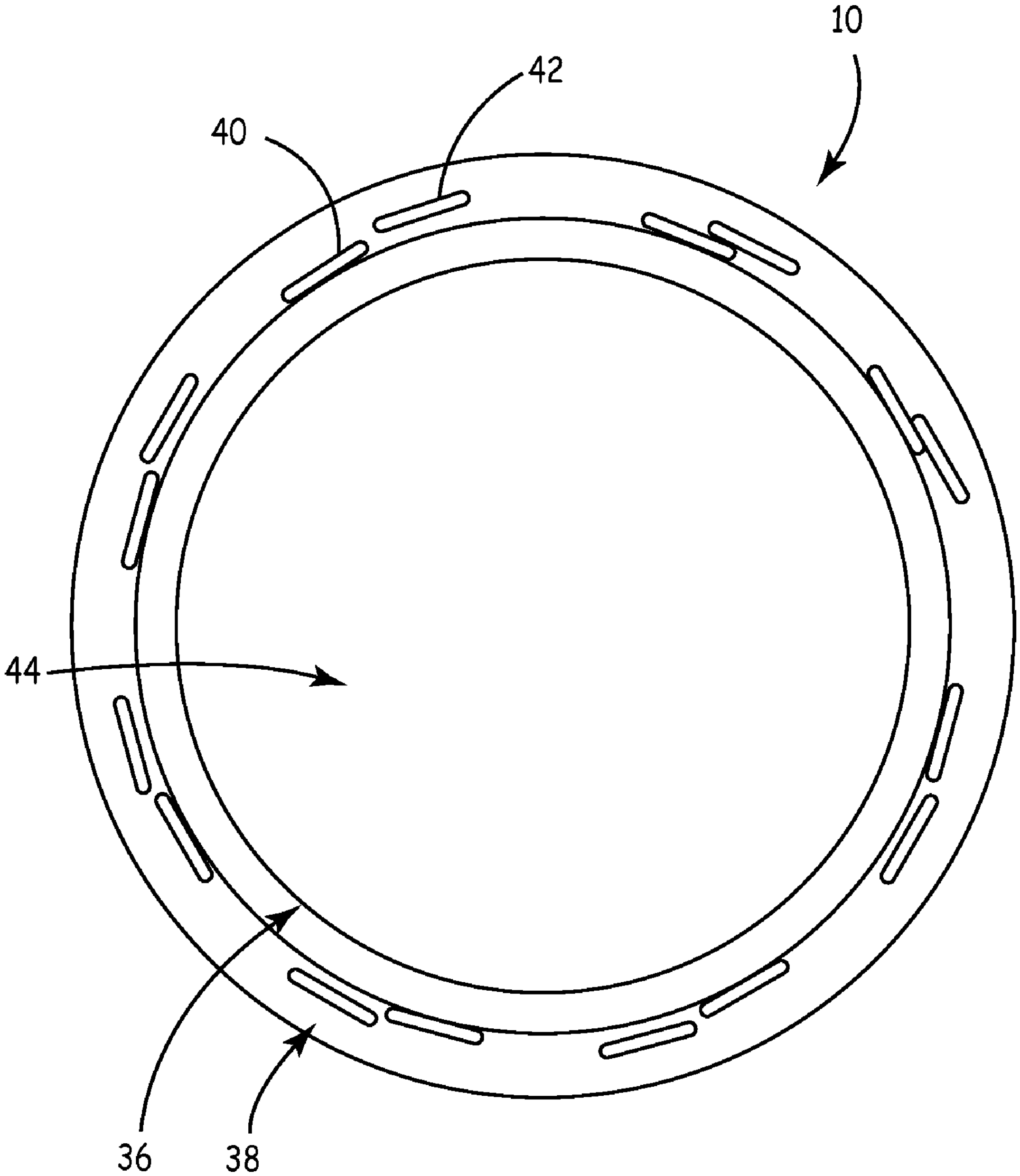


FIG. 5

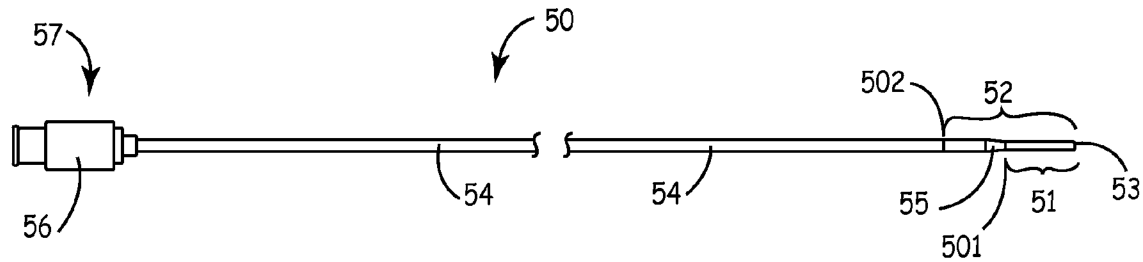


FIG. 6A

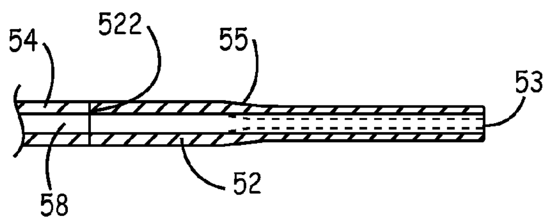


FIG. 6B

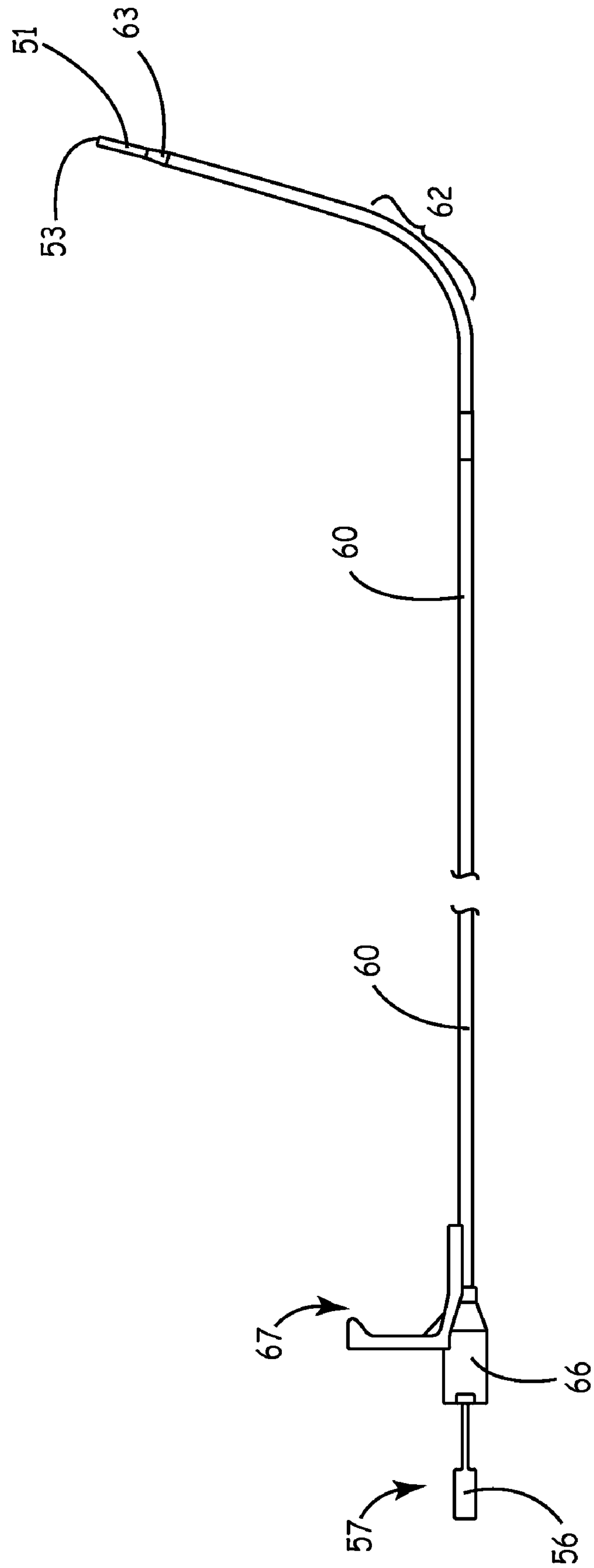


FIG. 7

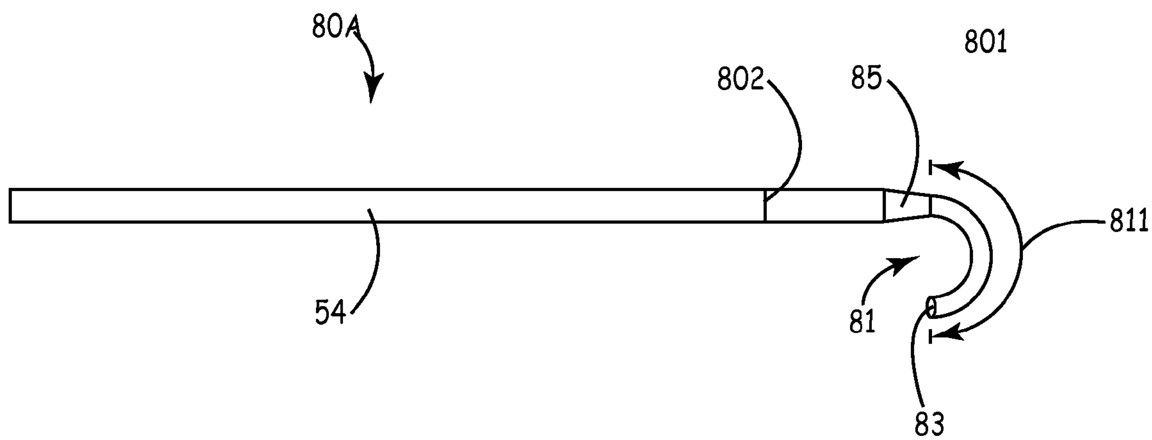


FIG. 8A

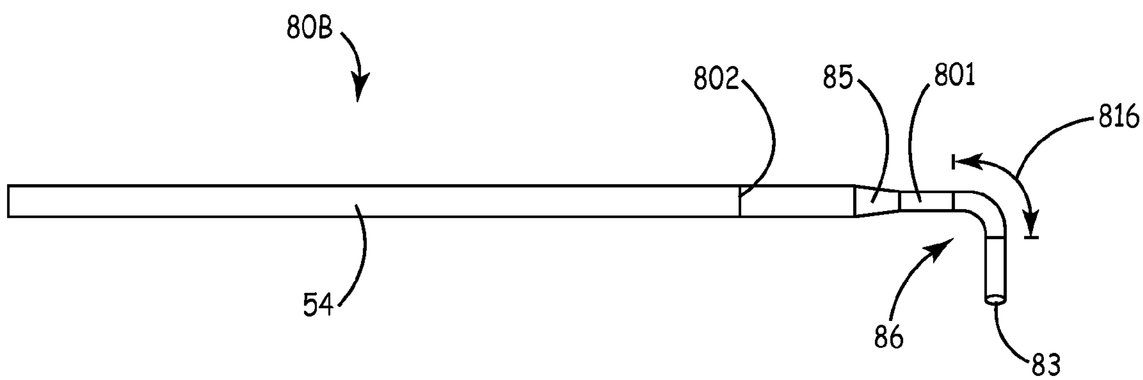


FIG. 8B

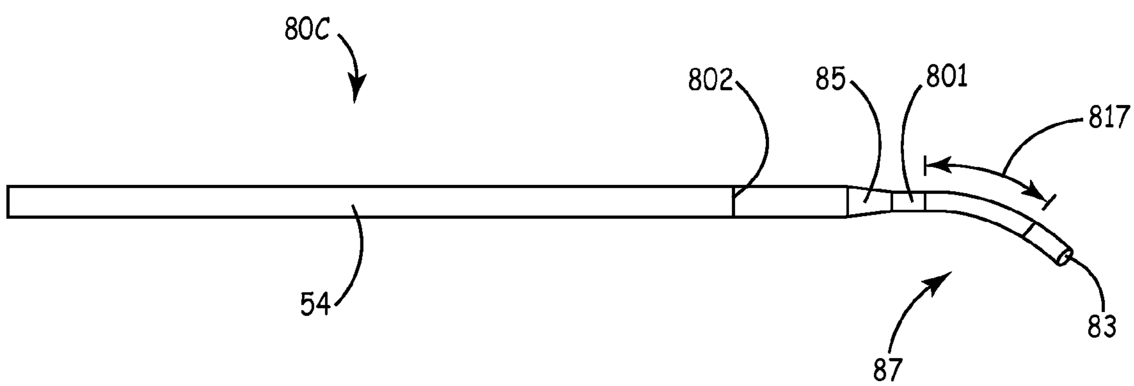


FIG. 8C

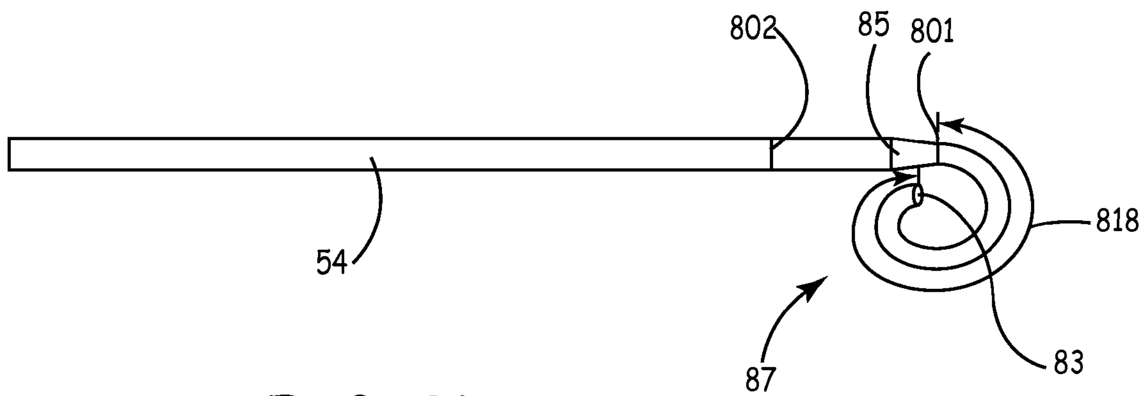


FIG. 8D

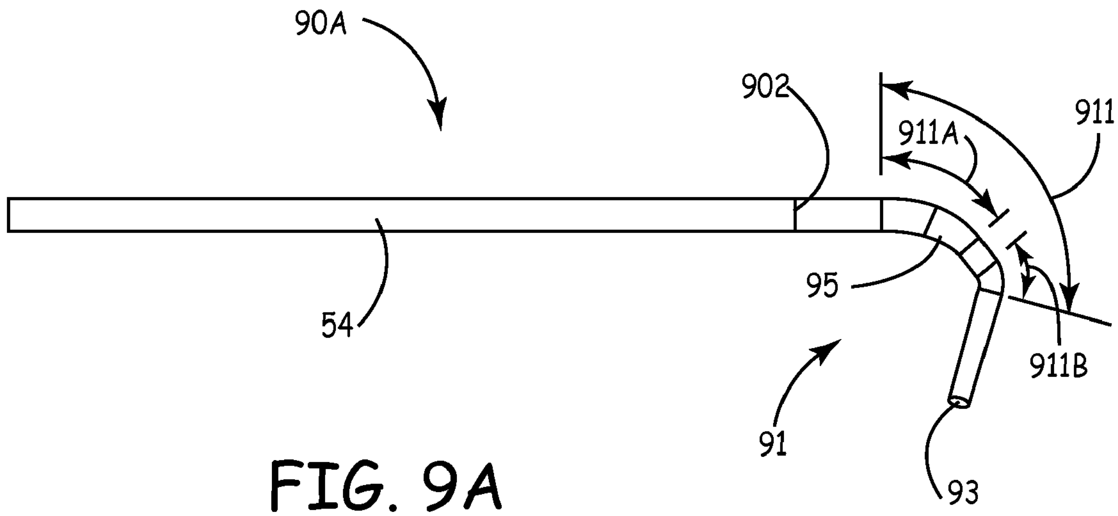


FIG. 9A

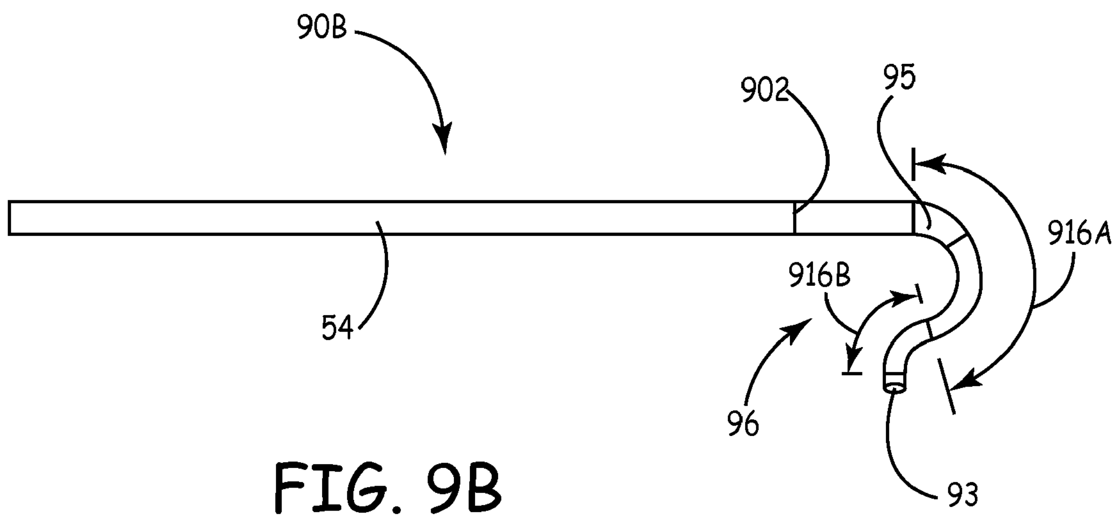


FIG. 9B

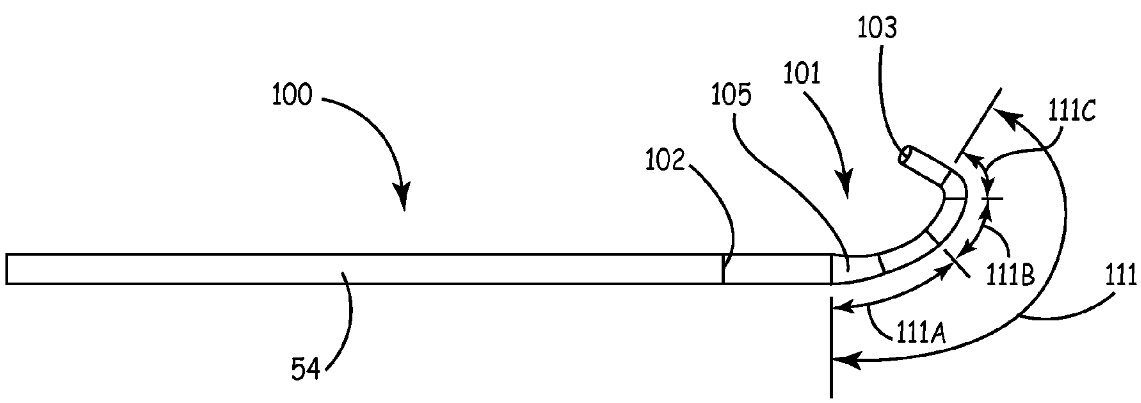


FIG. 10

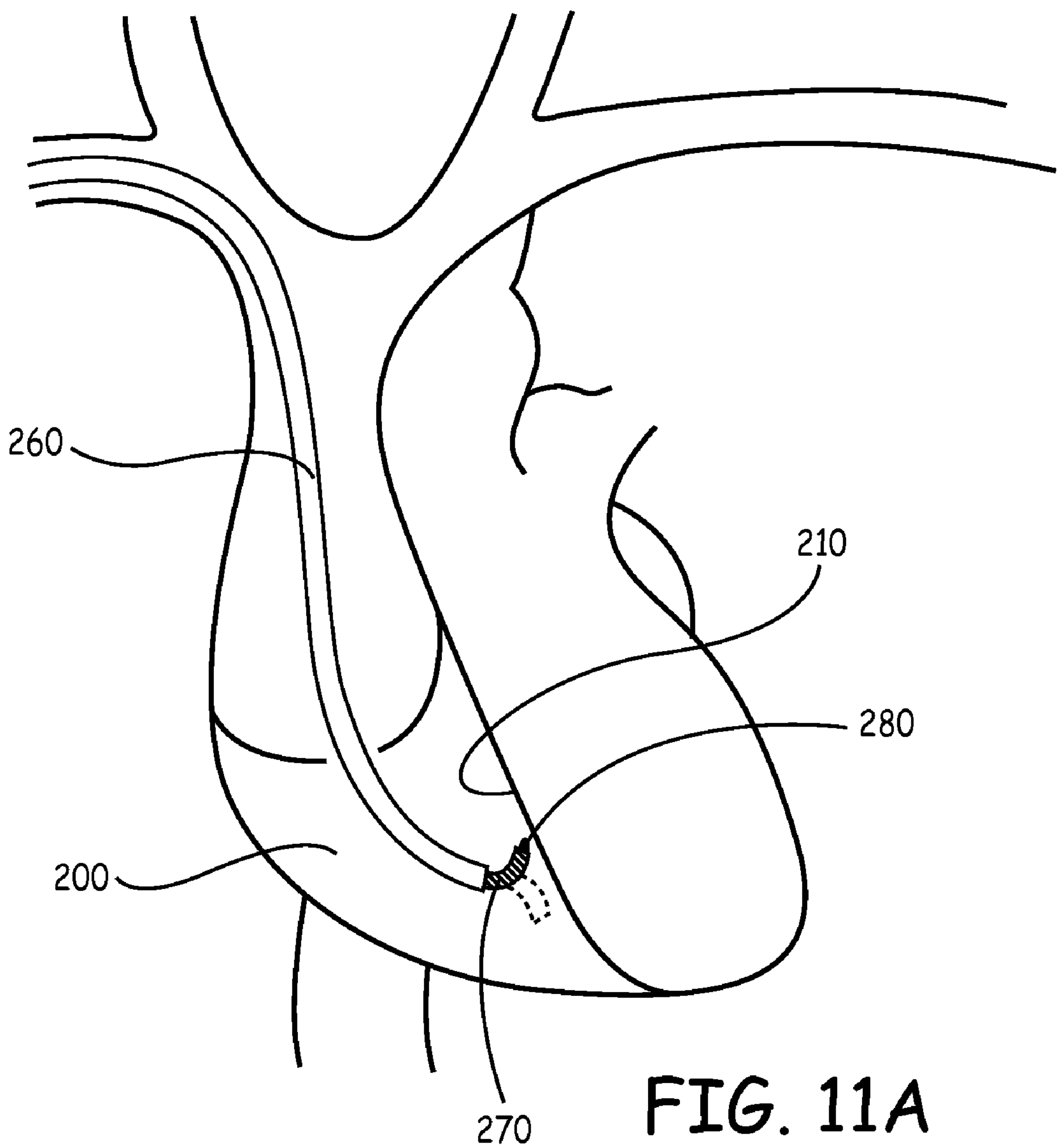


FIG. 11A

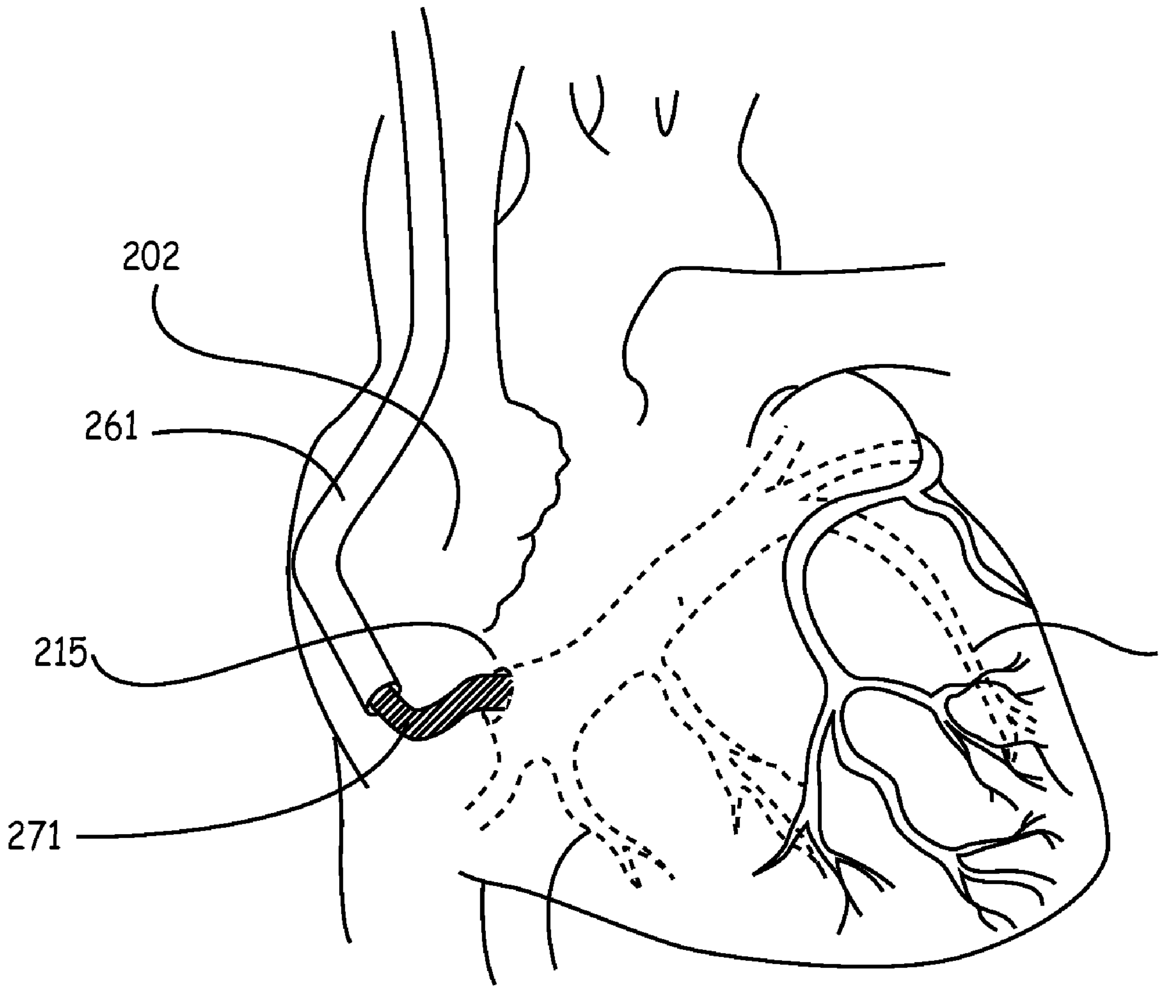


FIG. 11B

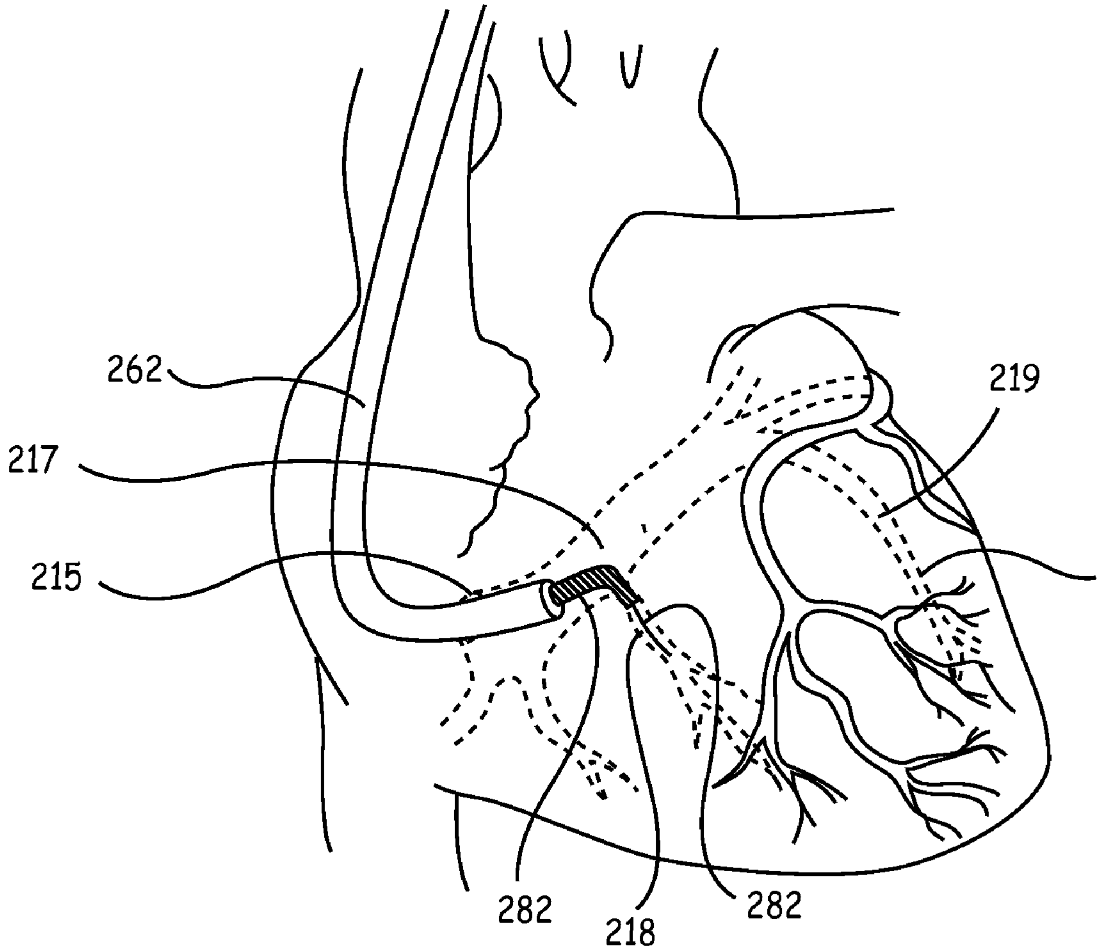


FIG. 11C

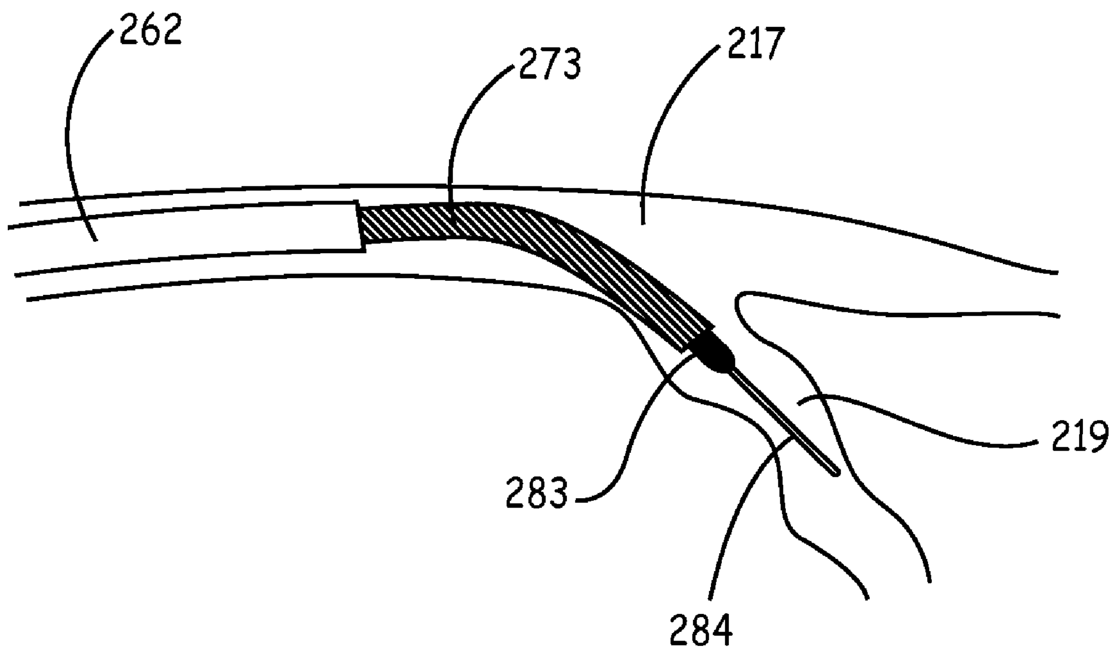


FIG. 11D

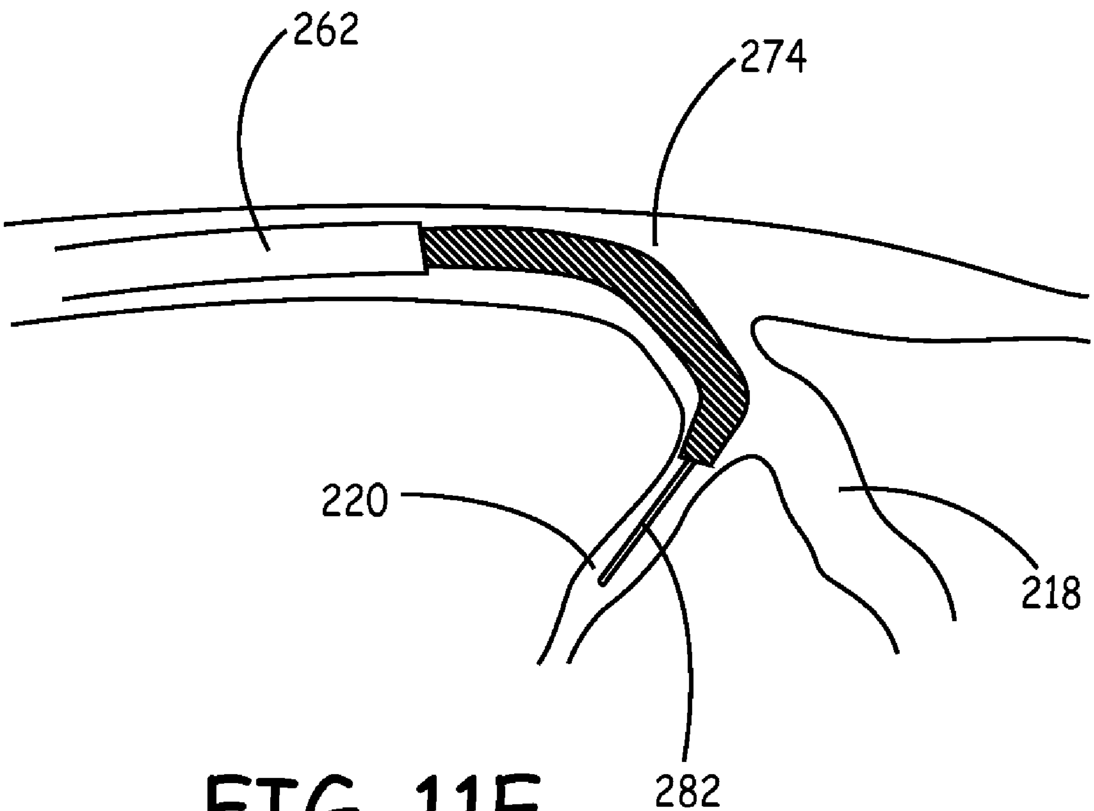


FIG. 11E

GUIDE CATHETER

RELATED APPLICATIONS

[0001] This application is a divisional of application Ser. No. 10/682,220 (Attorney Docket P0010137.02) filed on Oct. 9, 2003, which is a continuation in part of application Ser. No. 10/016,114 (Attorney Docket P0010137.00) filed on Dec. 12, 2001.

TECHNICAL FIELD

[0002] The invention relates generally to catheters and, more particularly, to guide catheters for introducing medical devices and or agents into a body of a patient.

BACKGROUND

[0003] Guide catheters are used to position medical devices, such as catheters and electrode leads, and or to place auxiliary implant tools, such as guide wires, and or to infuse agents such as therapeutic fluids or contrast media in desired locations within the body of a patient. A guide catheter typically includes an elongated sheath defining an inner channel through which the medical devices or agents are delivered, once the sheath has been inserted into the body.

[0004] To enable precise positioning of a guide catheter, the guide catheter often includes radio-opaque and or echogenic portions so that, using fluoroscopic or ultrasonic imaging techniques, the physician can visualize the guide catheter. Fully radiopaque or fully radiopaque and echogenic guide catheter distal tips, which may also further facilitate navigation through tortuous anatomy, are particularly desirable.

BRIEF DESCRIPTION OF DRAWINGS

[0005] The following drawings are of particular embodiments of the invention and therefore do not limit its scope, but are presented to assist in providing a proper understanding of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description.

[0006] FIG. **1** is a perspective view of a guide catheter.

[0007] FIG. **2** is a cross-sectional side view of the guide catheter of FIG. **1** illustrating incorporation of a radio-opaque and echogenic material in the distal tip.

[0008] FIG. **3** is an enlarged cross-sectional side view of the distal tip of the guide catheter shown in FIGS. **1** and **2**.

[0009] FIG. **4** is a side view of the guide catheter of FIG. **1** with an exposed illustration of a reinforcing braid with radio-opaque strands.

[0010] FIG. **5** is a cross-sectional view of the inner lumen and sheath of the guide catheter of FIG. **1**.

[0011] FIG. **6**A is a plan view of an elongated sheath of a guide catheter according to embodiments of the present invention.

[0012] FIG. **6**B is an axial section view of a distal portion of the sheath shown in FIG. **6**A.

[0013] FIG. **7** is a plan view of a guide catheter wherein the sheath shown in FIGS. **6**A-B is slideably received within an outer sheath according to some embodiments of the present invention.

[0014] FIGS. **8**A-D are plan views of a distal portion of a guide catheter elongated sheath according to alternate embodiments of the present invention.

[0015] FIGS. **9**A-B are plan views of a distal portion of a guide catheter elongated sheath according to further alternate embodiments of the present invention.

[0016] FIG. **10** is a plan view of a distal portion of a guide catheter elongated sheath according to yet another embodiment.

[0017] FIG. **11**A is a schematic view of a guide catheter positioned within a chamber of a heart according an embodiment of the present invention.

[0018] FIG. **11**B is a schematic view of guide catheter elongated sheath cannulating a coronary sinus according to another embodiment of the present invention.

[0019] FIGS. **11**C-E are schematic views of a guide catheter positioned in the coronary vasculature according to additional embodiments of the present invention.

DETAILED DESCRIPTION

[0020] The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides a practical illustration for implementing exemplary embodiments of the invention.

[0021] FIG. **1** is a perspective view of a guide catheter **10**. As shown in FIG. **1**, guide catheter **10** includes a proximal end **12**, distal tip **14**, and an elongated sheath **16** extending between the proximal and distal ends. Guide catheter **10** is sized for insertion into a lumen, such as a blood vessel, within the human body. Guide catheter **10** defines an inner channel (not shown in FIG. **1**) through which other elements such as catheters and electrode leads may be inserted. A luer fitting **18** and handle **20** may be coupled to proximal end **12** of catheter **10**. A slitter (not shown) may be positioned near proximal end **12**, e.g., adjacent handle **20**.

[0022] FIG. **2** is a cross-sectional side view of the guide catheter of FIG. **1** illustrating incorporation of a radio-opaque and echogenic material in the distal tip of guide catheter **10**. As shown in FIGS. **1** and **2**, sheath **16** may include a number of sheath segments **22**, **24**, **26**, **28**, **30**, **32** disposed along the length of catheter **10**. Sheath **16** may be formed to provide either a straight or pre-bent shape to guide catheter **10**, depending on the desired end application.

[0023] Sheath **16** is made from a material that permits slitting along the length of catheter **10** and promotes maneuverability. In particular, each sheath segment **22**, **24**, **26**, **28**, **30**, **32** may be constructed of a polymeric material, such as polyether block amide, nylon block polymer, silicone, or polyurethane, as well as composites or mono-polymers. An example of one suitable polymeric material is the polyether block amide marketed under the trademark PEBAX® and commercially available from Atofina Chemicals Inc., of King of Prussia, Pa.

[0024] Guide catheter **10** is constructed to exhibit properties that promote enhanced visibility of the catheter **10** using fluoroscopic or ultrasonic imaging techniques. With reference to FIG. **1**, sheath segment **22** forms a distal tip of guide catheter **10**, and incorporates a material that is both fluoro and echo visible. The material also may be provided along the length of the guide catheter. For example, the material may be distributed continuously along the length of catheter **10** or at intermittent positions.

[0025] The material incorporated in distal tip **22** is tungsten carbide, which exhibits both radio-opacity and echogenicity. For enhanced echogenicity, the tungsten carbide may be jet milled and has an average particle size of less than approximately 500 nanometers and, more preferably, less than approximately 200 nanometers. The particle size may refer generally to a diameter of the tungsten carbide particles, although spherical particles are not necessary and the particle size may refer to a maximum width dimension. Particle sizes in the above ranges provide increased surface area for reflection of ultrasonic energy, thereby enhancing visibility of portions of guide catheter **10** in which the particles are dispersed. At the same time, tungsten carbide is highly radio-opaque, and facilitates fluoroscopic imaging of guide catheter **10**.

[0026] The same tungsten carbide particles can be incorporated along the length of guide catheter **10** in sheath segments **24**, **26**, **28**, **30**, **32**. In particular, the tungsten carbide particles can be dispersed in polymeric material that is molded or extruded to form sheath **16**. Alternatively, in one embodiment, the tungsten carbide may be provided in sheath segment **22** in distal tip **14** and sheath segment **24**, with the remaining sheath segments **26**, **28**, **30**, **32** carrying barium sulfate particles.

[0027] Each sheath segment **22**, **24**, **26**, **28**, **30**, **32** may be constructed from a similar material with a similar concentration of tungsten carbide particles. However, sheath segments **22**, **24**, **26**, **28**, **30**, **32** may have different hardness characteristics. As a particular illustration, sheath segments **22**, **24**, **26**, **28**, **30**, **32** may be constructed from PEBAX material with 25, 35, 55, 63 and 72 Shore D hardnesses, respectively. The tungsten carbide particles can be added to sheath segments **22**, **24**, **26**, **28**, **30**, **32** in a concentration on the order of approximately 40 to 75 percent by weight without significantly degrading the overall mechanical properties of guide catheter **10**.

[0028] As one particular example, the tungsten carbide may be added to the polymeric material in the amount of approximately 70 to 75 percent by weight and, more preferably, approximately 73 to 74 percent by weight. In an exemplary embodiment, the jet milled tungsten carbide material is added to the polymeric material in a weight of approximately 73.2 percent by weight. A concentration of 73.2 percent by weight tungsten carbide particles to PEBAX™ Shore D material corresponds to a concentration of approximately 15 percent by volume. The barium sulfate particles may be added to sheath segments **26**, **28**, **30**, **32** in the amount of approximately 25 to 35 percent by weight and, more preferably, approximately 30 percent by weight.

[0029] The jet milled tungsten carbide particles offer exceptional echogenicity and, when added to the polymeric material, permit ready slitting along the length of guide catheter **10**. For these reason, in determining the concentration of tungsten carbide particles, it is desirable to balance the degree of echogenicity against the slittability of sheath **16**. As more tungsten carbide particles are added to segments **22**, **24**, **26**, **28**, **30**, **32**, the material forming guide catheter **10** becomes difficult to process and, in some cases, difficult to maneuver for insertion into and removal from the body of a patient. A guide catheter **10** constructed as described herein retains desirable mechanical properties, enabling ease of maneuverability and atraumatic use.

[0030] FIG. **3** is an enlarged cross-sectional side view of distal tip **14** of guide catheter **10**. As shown in FIG. **3**, distal tip **14** may comprise a sheath segment **22** that is separated from sheath segment **26** by in intermediate sheath segment **24**. Sheath segment **24** may provide a spacing "x" between sheath segments **22**, **26**. In particular, a reinforcing braid (not shown in FIG. **3**) may extend along substantially the entire length of guide catheter **10** and be embedded between inner and outer walls of sheath **16**. However, the distal end of the reinforcing braid terminates in sheath segment **26**, and does not extend into distal tip **14**. The distance "x" may be on the order of 0.25 to 0.35 inches (0.64 to 0.89 centimeters).

[0031] FIG. **4** is a side view of guide catheter **10** with an exposed illustration of a reinforcing braid **34**. Reinforcing braid **34** is substantially tubular in shape, and includes an inter-woven array of strands **40**. Braid **34** may be formed between inner wall **36** and outer wall **38** of sheath **16**. To promote visibility, some of the strands may be radio-opaque. In particular, in the example of FIG. **4**, two strands **42** are formed from a radio-opaque material. The radio-opaque material use in strands **42** may be formed from a variety of materials such as platinum iridium, gold, tantalum, platinum tungsten carbide, and the like. Strands **40** may be formed from a variety of conventional metallic materials such as steel, or plastic materials such as polyester. Thus, the radio-opaque material is formed into strands that are braided among the steel strands. Incorporation of a relatively small number of strands, e.g., one to three strands, can significantly improve fluoro visibility of the guide catheter.

[0032] FIG. **5** is a cross-sectional view of the inner channel **44** and sheath **16** of guide catheter **10**. Incorporation of strands **42** promotes visibility but does not significantly affect the mechanical properties of guide catheter **10**. With strands **42**, guide catheter **10** remains readily slittable, unlike other types of guide catheters that may use radio-opaque marker bands. In addition, use of radio-opaque strands **42** offsets the need to provide additional radio-opaque material within walls **36**, **38**.

[0033] FIG. **6**A is a plan view of an elongated sheath **50** of a guide catheter according to embodiments of the present invention. FIG. **6**A illustrates elongated sheath **50** including a proximal portion **54** to which a hub **56** is joined at a proximal end **57** and a distal tip **51** or **52** extending to a sheath distal end **53** and joined to a distal end **501** or **502** of proximal portion **54**, respectively. Materials forming proximal portion **54** of sheath **50** include but are not limited to polyether block amide, nylon block polymer, silicone, or polyurethane. An example of one suitable polymeric material is the polyether block amide marketed under the trademark PEBAX® and commercially available from Atofina Chemicals Inc., of King of Prussia, Pa. Proximal portion **54** may further incorporate a reinforcing braid, for example braid **34** as described in conjunction with FIGS. **4** and **5**.

[0034] According to the present invention, distal tip **51** or **52** is fully radiopaque or fully radiopaque and echogenic, having radiopaque or radiopaque and echogenic particles dispersed within a polymer, for example PEBAX®, forming tip. It should be understood that the term "fully" preceding "radiopaque" and "radiopaque and echogenic" is used to describe distal tips according the present invention wherein an entirety of a material forming the distal tips includes either radiopaque particles/filler or radiopaque and echogenic particles/filler. Barium sulfate is an example of an appropriate radiopaque filler, which is well known to those skilled in the art, and tungsten carbide an example of an appropriate radiopaque and echogenic filler, which is described herein. Although tungsten carbide is preferred as a radiopaque and echogenic filler, alternate embodiments of the present invention include a filler comprising tungsten particles and some of the fillers described in commonly assigned U.S. Pat. No. 5,921,933 of Sarkis et al. Sarkis et al. describe echogenic fillers, some of which also happen to be sufficiently radiopaque to be included within the scope of the present invention, for example titanium dioxide and platinum oxide; therefore the teaching of Sarkis et al. related to forming materials including these fillers, in U.S. Pat. No. 5,921,933, is hereby incorporated herein.

[0035] According to another aspect of the present invention, some embodiments include a distal tip, i.e. distal tip **51** or **52**, or others described herein below, having a relatively short length, for example between approximately 0.08 inch and approximately 0.2 inch, while, in alternate embodiments, a distal tip is longer than approximately 0.2 inch, and, in preferred embodiments, having a length between approximately 0.2 inch and approximately 2 inches. Furthermore, according to alternate embodiments, distal tip **51** or **52** includes at least one resilient preformed curve, examples of which are described herein in conjunction with FIGS. **8**A-**11**E.

[0036] According to some embodiments of the present invention, distal tip **51** or **52** is atraumatic to adjacent walls when advanced within structures of a body, that is the tip will tend to give, either compressing or bending, if pushed up against a wall of an internal organ or vessel. Distal tip **51** or **52** may be described as being relatively soft, and, according to one embodiment, has a hardness between approximately 25D and approximately 35D durometer. Furthermore, distal tip **51** or **52** may have a stiffness less than that of proximal portion **54** accomplished by a thinner wall thickness of distal tip **51** or **52**, incorporation of a braid reinforcement in proximal portion **54**, as previously described, a reduced flexural modulus of material forming distal tip **51** or **52**, or any combination thereof. Furthermore, according to some, embodiments of the present invention, proximal portion **54** includes at least two stiffnesses wherein a stiffness in proximity to distal end **501** or **502** is less than a stiffness in proximity to proximal end **57**.

[0037] As is further illustrated in FIG. **6**A, sheath **50** includes a tapered transition **55**. According to one embodiment, proximal portion **54** includes a tapered transition **55** in proximity to distal end **501** where distal tip, designated as **51**, is joined. While, according to an alternate embodiment, distal tip, designated as **52**, which is joined to proximal portion **54** at distal end **502**, includes tapered transition **55**; according to yet another embodiment, tapered transition **55** is not included in either proximal portion **54** or distal tip **52**. Tapered transition **55**, as well as other tapered transitions described herein, includes only a reduction in outer diameter, according to one embodiment, and both a reduction in inner and outer diameters, according to another embodiment; FIG. **6**B illustrates the former and the latter, the latter with dashed lines.

[0038] FIG. **6**B is an axial section view of a distal portion of the sheath shown in FIG. **6**A. FIG. **6**B illustrates a lumen **58** formed by sheath **50** extending through proximal portion **54** and distal tip **52**. Lumen **58** is adapted to slideably engage an implant tool or an electrode lead, a diameter of lumen **58** sized to accommodate one or the other or both, according to alternate embodiments of the present invention; furthermore, lumen **58** may be used to deliver a fluid, either a contrast medium for fluoroscopic visualization or a therapeutic agent.

[0039] FIG. **6**B further illustrates distal tip **52** coupled to proximal portion **54** in a butt joint **522**. According to some embodiments of the present invention, tip **52** is heat fused to proximal portion **54** using methods known to those skilled in the art. According to one embodiment, proximal portion **54** and distal tip **52** are placed together on a mandrel, a piece of FEP shrink tubing is placed over butt joint **522**, and the assembly is heated to the melting point by a hot air device. Once removed from the heat and cooled, the FEP is stripped off the finished joint. In another embodiment, proximal portion **54** and distal tip **52** are placed on a mandrel in a die, with ends joined as illustrated in FIG. **6**B, and radio frequency (RF) energy is applied to heat the die in order to fuse the ends together; the die and or mandrel may also be designed to form taper **55** and or one or more curves in distal tip **52**. Although not illustrated, distal tip **52** and proximal portion **54** may be coupled via a lap joint.

[0040] FIG. **7** is a plan view of a guide catheter wherein sheath **50** (FIGS. **6**A-B) is slideably received within an outer sheath **60** according to some embodiments of the present invention. FIG. **7** illustrates outer sheath **60** including a proximal end **67**, to which a hub **66** is coupled, and a distal end **63**; distal tip **51** of sheath **50** protrudes from distal end **63** of sheath **60** having been pushed through outer sheath **60** from proximal end **57**, which is shown protruding from proximal end **67** of outer sheath **60**. FIG. **7** further illustrates outer sheath **60** including a curve **62** which may either be preformed, that is formed by the manufacturer of the sheath, or formed by a guide catheter operator via a deflection mechanism built into outer sheath **60**. Embodiments of outer sheath **60** will typically include braid reinforced polymer walls, similar to that previously described for guide catheter **10** and well known to those skilled in the art. An example of a sheath including a preformed curve is the Medtronic catheter model number 6216A and an example of sheath including a deflection mechanism is the Medtronic catheter model number 6226DEF. According to some embodiments of the present invention, distal end **53** of distal tip **51** of sheath **50** is directed toward a target site via curve **62** of outer sheath **60**; a reduced diameter of distal tip **51** may facilitate cannulation of a vessel. Furthermore, if distal tip **51** were to include one or more resilient preformed curves, manipulation, via push and torque, of sheath **50** within outer sheath **60** would further facilitate selective orientation of distal end **53**.

[0041] According to alternate embodiments of the present invention, fully radiopaque or fully radiopaque and echogenic distal tips include at least one resilient curve sweeping about an angle from approximately 100 to approximately 360°. It should be noted that angles cited herein are understood to have a tolerance of +/−10 degrees. FIGS. **8**A-D are plan views of exemplary distal portions of a guide catheter elongated sheath illustrating some of these embodiments. FIGS. **8**A-D illustrate sheaths **80**A-D each including proximal portion **54** to which distal tips **81**, **86**, **87** and **88**, respectively, are coupled via a junction at either a distal end point **801** or a distal end point **802**; a tapered transition **85** is present within either proximal portion **54** or within distal tips **81**, **86**, **87** and **88**. According to alternate embodiments, a tapered transition is not included. Each of distal tips **81**, **86**, **87** and **88** are fully radiopaque or fully radiopaque and echogenic, as previously described in terms of tip **51** or **52**, according to alternate embodiments. Furthermore, according to some embodiments tips **81**, **86**, **87** and **88** are atraumatic as previously described in conjunction with FIG. **6**A. FIG. **8**A illustrates tip **81** including a resilient preformed curve **811** sweeping about an angle of approximately 180° extending from a point in proximity to point **801** to a distal tip distal end **83**. FIG. **8**B illustrates tip **86** including a resilient preformed curve **816** sweeping about an angle of approximately 90° from a point in proximity to point **801** to a point in proximity to distal tip distal end **83**. FIG. **8**C illustrates tip **87** including a resilient preformed curve **817** sweeping about an angle between approximately 10° and approximately 45° from a point in proximity to point **801** to a point in proximity to distal tip distal end **83**. FIG. **8**D illustrates tip **88** including a resilient preformed curve **818** sweeping about an angle approaching approximately 360° from a point in proximity to point **801** to a point in proximity to distal tip distal end **83**.

[0042] FIGS. **9**A-B are plan views of a distal portion of a guide catheter elongated sheath according to further alternate embodiments of the present invention, wherein a distal tip includes two resilient preformed curves. FIG. **9**A illustrates sheath **90**A including proximal portion **54** to which distal tip **91** is coupled via a junction in proximity to a point **902**; distal tip **91** includes a first resilient preformed curve **911**A and a second resilient preformed curve **911**B forming a compound curve **911**, which sweeps about an angle greater than approximately 90° from a point in proximity to point **902** to a point in proximity to a distal tip distal end **93**. FIG. **9**B illustrates sheath **90**B including proximal portion **54** to which distal tip **96** is coupled via a junction in proximity to point **902**; distal tip **96** includes a first resilient preformed curve **916**A, which sweeps about an angle between approximately 160° and approximately 180°, and second resilient preformed curve **916**B, extending in an opposite direction from first curve **916**A and sweeping about, an angle between approximately 40° and approximately 80°. A combination of curves **916**A and **916**B in distal tip **96** is alternately described as an Amplatz style curve, which is well known to those skilled in the art. Each of distal tips **91** and **96** are fully radiopaque or fully radiopaque and echogenic, as previously described in conjunction with FIG. **6**A, according to alternate embodiments. Furthermore, according to some embodiments tips **91** and **96** are atraumatic as previously described herein.

[0043] Although FIGS. **9**A-B illustrate distal tips **91** and **96** including a tapered transition **95** located within first curves **911**A and **916**A, tapered transition **95** may alternately be positioned proximal to first curves **911**A and **916**A either as part of distal tips **91** and **96** or as a part of proximal portion **54**, as previously described herein. Additional embodiments include no tapered transition.

[0044] FIG. **10** is a plan view of a distal portion of a guide catheter elongated sheath according to yet another embodiment, wherein a distal tip **101** includes three resilient preformed curves. FIG. **10** illustrates sheath **100** including proximal portion **54** to which distal tip **101** is coupled via a junction in proximity to a point **102**; distal tip **101** includes a first resilient preformed curve **111**A, a second resilient preformed curve **111**B and a third resilient preformed curve **111**C forming a compound curve **111**, which sweeps about an angle greater than approximately 100° from a point in proximity to point **102** to a point in proximity to a distal tip distal end **103**. Distal tip **101** is fully radiopaque or fully radiopaque and echogenic, as previously described in conjunction with FIG. **6**A, according to alternate embodiments. Furthermore, according to some embodiments tip **101** is atraumatic as previously described herein.

[0045] Although FIG. **10** illustrates distal tip **101** including a tapered transition **105** located within first curve **111**A, tapered transition **105** may alternately be positioned proximal to first curve **111**A either as part of distal tip **101** or as a part of proximal portion **54**, as previously described herein. Additional embodiments include no tapered transition.

[0046] Although elongated sheaths, such as those described in conjunction with FIGS. **6**A-**10**, may be used alone to deliver medical devices or agents, preferred embodiments of guide catheters include such sheaths engaged within an outer sheath, i.e. sheath **60** (FIG. **7**), in order to facilitate increased maneuverability of distal tips. Furthermore, outer sheaths preferably include a preformed curve or a deflection mechanism, as previously described herein, but the scope of the present invention also includes outer sheaths including no curves, which may engage elongated sheaths having fully radiopaque or radiopaque and echogenic distal tips including resilient preformed curves extending distally from outer sheaths. FIGS. **11**A-E illustrate exemplary scenarios in which guide catheters according to the present invention may be employed.

[0047] FIG. **11**A is a schematic view of a guide catheter positioned within a chamber of a heart according an embodiment of the present invention. FIG. **11**A illustrates an outer sheath **260**, positioned within a right ventricle **200**, from which a distal tip **270** of an elongated sheath, slideably engaged within outer sheath **260**, protrudes distally to position a lead **280**, slideably engaged therein, for implantation along a septal wall **210**. According to embodiments of the present invention, distal tip **270** is fully radiopaque or fully radiopaque and echogenic, and, as illustrated in FIG. **11**A, includes at least one resilient preformed curve, which is free to reform as distal tip **270** exits outer sheath **260**; the preformed curve is conformed to outer sheath **260** as it is advanced therethrough prior to exiting sheath **260**. FIG. **11**A further illustrates, via dashed lines, that the elongated sheath may be rotated within outer sheath **260** to direct distal tip **270** in an alternate location.

[0048] FIG. **11**B is a schematic view of guide catheter elongated sheath cannulating a coronary sinus according to another embodiment of the present invention. FIG. **11**B illustrates an outer sheath **261**, positioned in a right atrium **202**, from which a distal tip **271** of an elongated sheath, slideably engaged within outer sheath **261**, protrudes distally to cannulate a coronary sinus ostium **215**. According to embodiments of the present invention, distal tip **271** is fully radiopaque or fully radiopaque and echogenic, and, as illustrated in FIG. **11**B, includes at least two resilient preformed curves, which are free to reform as distal tip **271** exits outer sheath **261**; the preformed curves are conformed to outer sheath **261** as they are advanced therethrough prior to exiting sheath **261**.

[0049] FIGS. **11**C-E are schematic views of a guide catheter positioned in the coronary vasculature according to additional embodiments of the present invention. FIGS. **11**C-D illustrate an outer sheath **261** having cannulated coronary sinus ostium **215** and advanced within a coronary sinus **217**. FIG. **11**C a distal tip **272** of an elongated sheath is shown protruding from outer sheath **262** to cannulate a first branch vein **218**, while in FIG. **11**D a distal tip **273** of a different elongated sheath is shown protruding from outer sheath **262** to cannulate a second branch vein **219** and, in FIG. **11**E, a distal tip **274** of yet another elongated sheath is shown protruding from outer sheath **262** to cannulate a secondary branch vein **220**. According to embodiments of the present invention, each distal tip **272**, **273** and **274** is fully radiopaque or fully radiopaque and echogenic, and, as illustrated in FIGS. **11**C-E, include at least one resilient preformed curve, which are free to reform as distal tips **272**, **273**, and **274** exit outer sheath **262**; the preformed curves are conformed to outer sheath **261** as they are advanced therethrough prior to exiting sheath **262**. FIG. **11**C further illustrates an elongated element **282** slideably engaged within the sheath including distal tip **272** and extending therefrom into branch vein **218**; element **282** is a guide wire or a lead according to alternate embodiments of the present invention. If element **282** is a guidewire, elongated sheath including distal tip **272** may be removed from within outer sheath **262** once the guide wire is in position and a lead passed over the guide wire into branch vein **218**. FIG. **11**D further illustrates a lead **283** slideably engaged over a guide wire **284** which has been advanced through elongated sheath including distal tip **273** into branch vein **219**. Therefore, as previously described in conjunction with FIG. **6**B, a lumen of an elongated sheath according to the present invention may be sized to accommodate a guidewire and or a lead. FIG. **11**E further illustrates elongated element **282**, as previously described in conjunction with FIG. **11**C, slideably engaged within the sheath including distal tip **274** and extending therefrom into secondary branch vein **220**, which extends from branch vein **218**.

[0050] According to embodiments illustrated in FIGS. **11**B-E distal tips **271**, **273**, **274** and **274**, in addition to directing, by nature of their geometry, may also serve to dilate structures of surrounding coronary vasculature to facilitate cannulation in order that elements, i.e. **282**, may be advanced distally therethrough.

EXAMPLE

[0051] A distal tip, for an elongated sheath, having a geometry corresponding to any of the illustrated embodiments is formed by an injection molding process from 3533 SA01 Atofina PEBAX® pellets compounded with 73.2%+/−2%, by weight, tungsten carbide and 0.25%+/−0.03%, by weight, Tinuvin 326 UV inhibitor and 0.25%+/−0.03%, by weight, Irgonox 1010 antioxidant. The tungsten carbide additive is Jet-milled Superfine Tungsten Carbide having an average particle size less than or equal to 200 nanometers (0.2 micron) obtained from Foster Corporation of Dayville, Conn. The resulting distal tip has a hardness of approximately 35D.

[0052] Although specified at less than or equal to 200 nanometers, tungsten carbide particle sizes in the range of less than or equal to 500 nanometers are within the scope of the present invention providing increased surface area for reflection of ultrasonic energy, thereby enhancing visibility of distal tips. Furthermore, material comprising anywhere from 40% to 80%, by weight, tungsten carbide particles is also within the scope of the present invention. Furthermore, either an extrusion process followed by a secondary forming process or an insert molding process, both methods known to those skilled in the art, may used to form distal tips according to embodiments of the present invention.

[0053] In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims. For example, although distal tip curves are illustrated herein in plane with the rest of the sheath, additional embodiments of the present invention include distal tips including curves formed out of plane from the rest of the sheath. Furthermore, the inventors contemplate alternate embodiments of distal tips according to the present invention including an embedded structure, such as a coil.

What is claimed is:

1. A guide catheter, comprising:

an outer sheath; and

an inner sheath slideably engaged within the outer sheath and including a fully radiopaque distal tip having a length greater than or equal to approximately 0.2 inch;

wherein the inner sheath engaged within the outer sheath may be positioned such that the radiopaque distal tip protrudes from a distal end of the outer sheath.

2. The guide catheter of claim **1**, wherein the fully radiopaque distal tip is also fully echogenic.

3. The guide catheter of claim **2**, wherein the distal tip is formed of a material comprising tungsten carbide particles.

4. The guide catheter of claim **3**, wherein the fully radiopaque distal tip includes a first resilient preformed curve.

5. The guide catheter of claim **4**, wherein the first curve sweeps about an angle greater than or equal to approximately 180°.

6. The guide catheter of claim **4**, wherein the first curve sweeps about an angle of approximately 90°.

7. The guide catheter of claim **4**, wherein the first curve sweeps about an angle between approximately 10° and approximately 70°.

8. The guide catheter of claim **4**, wherein the fully radiopaque distal tip further includes a second resilient preformed curve extending from the first resilient preformed curve.

9. The guide catheter of claim **6**, wherein the first and second curves, together, sweep about an angle greater than approximately 90°.

10. The guide catheter of claim **6**, wherein the first curve sweeps about an angle between approximately 160° and approximately 180° and the second curve sweeps, in an opposite direction to the first curve, about an angle between approximately 40° and approximately 80°.

11. The guide catheter of claim **6**, wherein the first curve and the second curve form an Amplatz shape.

12. The guide catheter of claim **6**, wherein the fully radiopaque distal tip further includes a third resilient preformed curve extending from the second resilient preformed curve.

13. The guide catheter of claim **12**, wherein the first, second and third curves, together, sweep about an angle greater than approximately 100°.

14. The guide catheter of claim **1**, wherein the fully radiopaque distal tip includes a tapered transition.

15. The guide catheter of claim **4**, wherein the fully radiopaque distal tip includes a tapered transition.

16. The guide catheter of claim **15**, wherein the tapered transition is located proximal to the first resilient preformed curve.

17. The guide catheter of claim **6**, wherein the fully radiopaque distal tip includes a tapered transition.

18. The guide catheter of claim **17**, wherein the tapered transition is located proximal to the second resilient preformed curve.

19. The guide catheter of claim **12**, wherein the fully radiopaque distal tip includes a tapered transition.

20. The guide catheter of claim **19**, wherein the tapered transition is located proximal to the third resilient preformed curve.

21. A method for positioning a guide catheter within a body in order to deliver a medical device or agent, comprising:

advancing an inner sheath of the guide catheter through an outer sheath of the guide catheter such that distal tip of the inner sheath extends distally from a distal end of the outer sheath;

wherein the distal tip of the inner sheath is fully radiopaque.

22. The method of claim **21**, wherein the distal tip is also fully echogenic.

23. The method of claim **22**, further comprising visualizing the distal tip of the inner sheath by means of ultrasound.

24. The method of claim **21**, further comprising cannulating a coronary sinus with the distal end of the outer sheath such that advancing the inner sheath positions the distal tip of the inner sheath within the coronary vasculature.

25. The method of claim **21**, further comprising dilating of a structure of coronary vasculature when the inner sheath is advanced.

26. The method of claim **21**, further comprising cannulating a coronary sinus with the distal tip of the inner sheath.

27. The method of claim **21**, further comprising cannulating a branch vein of the coronary vasculature with the distal tip of the inner sheath.

28. The method of claim **27**, further comprising advancing a guide wire through the inner sheath, out through the distal tip of the inner sheath and into the branch vein.

29. The method of claim **27**, further comprising advancing a lead through the inner sheath, out through the distal tip of the inner sheath and into the branch vein.

30. The method of claim **28**, further comprising advancing a lead over the guide wire and into the branch vein.

* * * * *