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(71) Applicant *(for all designated States except US)*: **TRICARDIA, LLC** [US/US]; 6420 Bayview Place, Excelsior, Minnesota 55331 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SCHWARTZ, Robert, S.** [US/US]; 8971 Coffman Path, Inver Grove Heights, Minnesota 55076 (US). **VAN TASSEL, Robert, A.** [US/US]; 6420 Bayview Place, Excelsior, Minnesota 55331 (US).

(74) Agent: **INSKEEP, James, W.**; Inskeep Intellectual Property Group, Inc., 2281 W. 190th Street, Ste. 200, Torrance, CA 90504 (US).

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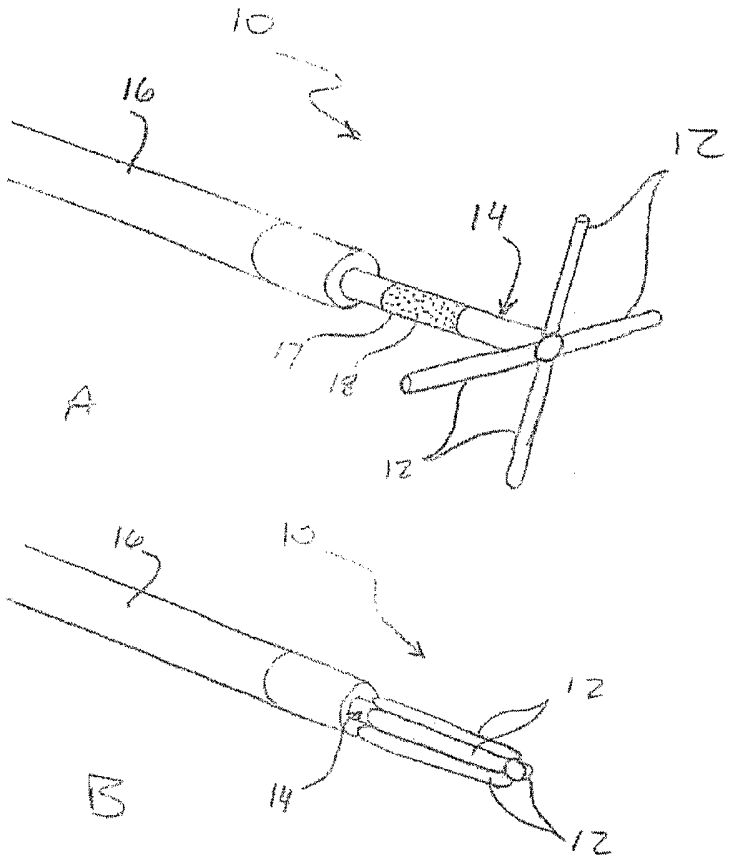
(54) Title: DIFFUSION CATHETER



(57) Abstract: A catheter that has a centering tip keeps the catheter in the center of a blood vessel during insertion, injection and retraction results in a better injectate flow pattern and less trauma to the blood vessel. A porous section is provided as a discharge port on either the catheter or tip, or both. The porous section creates a cloud like bolus of injectate, reducing the amount of injectate necessary for imaging functions.

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DIFFUSION CATHETER

RELATION TO PRIOR APPLICATIONS

[0001] This utility application claims priority from provisional patent application Serial Number 60/641,325 filed on January 3, 2005, entitled *Diffusion Catheter For Injection Into A Body Structure; a*nd provisional patent application Serial Number 60/685,684, filed on May 27, 2005, entitled *Diffusion Catheter Part II.* Both of these references are incorporated by reference herein in their entireties.

FIELD OF THE INVENTION

[0002] The present invention relates to a specialized catheter for injection into an artery, vein, or other body structure, with principal use for contrast injection during an X-Ray, MRI, CT, CTA or other imaging or therapeutic procedure. Because the device may be made for arterial application, or because of its arterial or venous concentrating capability, it decreases contrast dose, making it ideal for use in treatment or diagnosis of diabetic renal disease or other renal dysfunctions that mandate contrast dose reduction.

BACKGROUND OF THE INVENTION

[0003] Internal imaging is often enhanced through the use of injected imaging agents that allow an imaging technique (MRI, CTA, x-ray, ultrasound, etc.) to provide an image that defines one or more anatomic structures for imaging purposes. Imaging agents are formulated for a particular type of imaging technology and are used to better detect and differentiate the imaging source from the machine much better than the various tissues found in the human body alone. The result is an image that clearly delineates the shape of the contrast agent.

[0004] Many agents are directed toward imaging of the vasculature system. These agents are injected into the blood stream, either by artery or vein, and delineate the presence or absence of blood in the human vasculature. This type of imaging presents

problems not encountered during other types of internal imaging, such as orthopedic, where a simple needle is used to inject contrast agent into a joint socket or the like.

[0005] For example, vascular imaging presents the added difficulty of capturing the image of a moving target. Because the imaging agent is injected directly into the flow of the blood stream, the agent is immediately carried away and mixed with the blood, thereby weakening the contrast concentration it provides. Hence, the agent is typically delivered through a long catheter threaded through the vasculature to a location proximate the target area. Delivery catheters typically have an open end from which the agent is injected. Because the blood is flowing in the same direction the agent is expelled from the catheter, the agent is carried away quickly, necessitating the injection of a large volume of agent in order to achieve the desired results.

[0006] Some catheters attempt to mitigate this effect by providing openings in the sides of the catheter rather than just at the end. Quite often, however, these side openings are blocked because the catheter is resting along an inside wall of the vessel lumen. This can result in a diminished contrast effect and, due to the increased fluid pressure through the holes that are not blocked, trauma to the vessel. Furthermore, due to the large volume of agent being injected, the exit holes from the catheter are typically large, thereby reducing the amount of force necessary to inject the agent at a high flow rate. The large volume of agent being pushed through these holes adds to the potential vessel trauma. This may also occur as the large catheter holes create a jet effect that of itself may injure tissues, but also the rapid contrast injection jet causes catheters to move or whip during injection.

[0007] One example of a needle or catheter that incorporates holes along its sides is shown and described in U.S. Patent 6,855,132, issued February 15, 2005 to Van Tassel, et al., entitled *Apparatus With Weeping Tip And Method Of Use*, and in U.S. Patent 6,969,373, issued November 29, 2005 to Schwartz, et al., entitled *Syringe System*. Both of these references are incorporated by reference herein.

[0008] Another characteristic of prior art catheters that sometimes results in vessel trauma is catheter size. Because a large volume of agent is injected for the aforementioned reasons, catheter size tends to be large such that a large lumen is created for agent flow. Accordingly, reducing the amount of agent necessary could result in a smaller catheter size, which would increase flexibility and ease of insertion, and minimize trauma to the vessel.

[0009] Snaking a catheter through the vasculature to a target site requires skill and patience due to the numerous branches inherent in a vascular system. Though a large catheter may naturally avoid taking "wrong turns" down smaller branches, as mentioned above, a large catheter also imparts more trauma to the vessels due to its width and stiffness, or reduced flexibility. However, a smaller catheter can sometimes be more difficult to maneuver to a target location because it has an increased tendency to track into a branch vessel. Moreover, a smaller catheter presents a higher risk of perforating a vessel during implantation.

[0010] Accordingly, there is a need in the art for new and better catheter tips and/or needles for injection systems or surgical assemblages suitable for injection of controlled amounts of contrast agents and therapeutic substances without substantial loss of injectate and without substantial damage to tissue, even upon repeat injections. There is a particular need for catheter tips that are adapted for attachment to various types of catheters for such controlled delivery of therapeutic substances at remote locations within the body.

SUMMARY OF THE INVENTION

[0011] The present invention overcomes many of the problems in the art by providing a catheter tip that is self-centering within a lumen and includes a plurality of discharge holes that are constructed and arranged to create a cloud, rather than a jet bolus of injectate. The bolus cloud, in contradistinction to an injectate stream from an end port of a catheter, is a concentrated mass of injectate that maximizes imaging while minimizing the amount of injectate necessary, providing atraumatic vascular injection.

The holes may have a spatial/longitudinal gradient down the catheter to provide equal injection of contrast (or other injectate) volume per unit of catheter length. Hence, a bolus concentrator is formed as all exiting contrast in cloud form displaces blood retrograde and antegrade at the injection site. By controlling flow rate through the injection catheter, any bolus spatial length and concentration can be achieved. Such bolus concentration-time control is not obtainable using end-hole devices. The plurality of holes also permits excellent blood-agent mixing, if desired. The smaller nature of the holes create a pressure gradient that uses energy from the flowing injectate, and thus by decreasing energy causes less likelihood of injuring tissue, or whipping the catheter.

[0012] The catheter tip of the present invention is self-centering by means of a centering feature on the tip. The various embodiments of the present invention utilize centering features having many different forms but generally, the centering features include arms or fins that extend radially from the catheter tip and gently contact the walls of the lumen into which the catheter is deployed. The catheter may move slowly and carefully, seeking the largest lumen not injuring the vascular wall as it is advanced.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Fig. 1A is a perspective view of a catheter and tip of the present invention;

[0014] Fig. 1B is a perspective view of the catheter and tip of Fig. 1A in a collapsed state;

[0015] Fig. 1C is a perspective view of the catheter and tip of Fig. 1A being retracted through a blood vessel;

[0016] Fig. 2 is a perspective view of a catheter and tip of the present invention;

[0017] Fig. 3A is a perspective view of a catheter and tip of the present invention;

[0018] Fig. 3B is a perspective view of the catheter and tip of Fig. 5A in a collapsed state;

[0019] Fig. 4 is a perspective view of a catheter and tip of the present invention;

[0020] Fig. 5 is a perspective view of a catheter and tip of the present invention;

[0021] Fig. 6 is a perspective view of a catheter and tip of the present invention;

[0022] Fig. 7 is a perspective view of a catheter and tip of the present invention;

[0023] Fig. 8 is a perspective view of a catheter and tip of the present invention;

[0024] Fig. 9 is a perspective view of a catheter and tip of the present invention;

[0025] Fig. 10 is a perspective view of a catheter and tip of the present invention;

[0026] Fig. 11 is a perspective view of a catheter and tip of the present invention;

[0027] Fig. 12A is a side elevation of a prior art injection catheter in a blood vessel;

[0028] Fig. 12B is a side elevation of an injection catheter of the present invention in a blood vessel;

[0029] Fig. 13 is a cutaway view of a porous section of the present invention;

[0030] Fig. 14 is a perspective view of a porous section of the present invention;

[0031] Fig. 15 is a perspective view of a catheter and tip of the present invention;

[0032] Fig. 16 is a perspective view of a porous section of the present invention;

[0033] Fig. 17 is a perspective view of a catheter and tip of the present invention with a cover that is partially cut-away;

[0034] Fig. 18 is a perspective view of a catheter of the present invention contained within a casing of the present invention that is partially cut-away; and,

[0035] Fig. 19 is a side elevation of a catheter and tip of the present invention being used in the left ventricle of a heart.

DETAILED DESCRIPTION OF THE INVENTION

Porous Centering Tips

[0036] Referring now to the Figures, and first to Figures 1A through 1C, there is shown a diffusion catheter tip 10 of the present invention. Figure 1A shows the tip 10 in a deployed configuration, the tip including a plurality of radial arms 12 extending from a tip body 14. The tip body 14 is attached to a distal end of a catheter 16 and has a central lumen (not shown) that is in fluid communication with a central lumen 15 of the catheter 16 (shown in Figs. 3-5). The tip body 14 further includes a porous section 17 having a plurality of diffusion holes 18 through which contrast agent or other fluid is emitted from the central lumen of the tip body 14. With a porous section 17 having a plurality of holes 18, the catheter 16 of the present invention may be extremely small, as small as 3 Fr, while still maintaining a high flow rate. Furthermore, the catheter 16 of the present invention may be a venous catheter for central circulation seeking applications, or an arterial catheter for central arterial or aortic circulation applications.

[0037] The radial arms 12 serve to center the catheter 16 in a main artery or vein channel as the catheter 16 is advanced, so as to permit advancing the catheter 16 through the central circulation system, possibly obviating the need for imaging guidance. The radial arms 12 accomplish this by keeping the catheter in the large lumen of a major vascular channel and prevent the catheter from entering side branches.

[0038] Figure 1B shows the tip 10 in a collapsed state prior to deployment. In the collapsed state, the radial arms 12 are folded back onto the tip body 14 in a proximal direction. The radial arms may be held in the collapsed state during insertion by means of a sheath (see sheath 26 in Figs. 3 and 4). Alternatively, the tip body 10, along with the arms 12, may be retracted into the catheter 16 during insertion and ejected from the catheter 16 when a targeted site is achieved. Radial force necessary for expansion of the arms 12 may be inherent in the material forming the arms 12. For example, the arms 12 may be formed of wires, preferably coated, more preferably hydrogel coated,

that are collapsed resiliently and held prior to insertion, when released, spring pressure may be utilized to cause the arms 12 to expand. Another preferred option is to form the arms out of Nitinol. For example, if heat-activated Nitinol were to be used, the arms 12 could be made to expand at the target site when the body heat of the lumen is encountered. It is envisioned also that expansion could occur prior to the target site, thereby utilizing the arms 12 to maintain the catheter 16 in the center of the vessel lumen and to prevent the catheter 16 from being allowed to enter a side branch of the vessel. In this case, the arms 12 should be formed such that a minimal amount of force is exerted against the vessel walls to prevent trauma thereto during insertion and retraction.

[0039] Another alternative is to provide radial arms 12 that are hollow and in fluid communication with the internal lumen of the tip body 14. Hence, the radial arms 12 expand as the fluid pressure in the arms increases. This embodiment adequately protects the vessel from trauma and automatically opens the arms 12 during the injection of the contrast agent and allows the arms 12 to collapse after the agent has been injected. However, the arms would not be useful during insertion to maintain the device 10 in the center of the vessel lumen or to prevent the catheter 16 from being deployed down a side branch of the vessel. If it is desired to provide a tip having inflatable radial arms that are deployed during insertion of the catheter, a separate fluid source, such as saline, could be used to inflate the radial arms 12. Alternatively, a sheath could block the diffusion holes 18 until the tip 10 has reached the target site where the agent is to be discharged. Thus, fluid pressure from the agent would be maintained during implantation of the catheter 16 and inflation of the radial arms 12.

[0040] Preferably, as shown in Fig. 1C, the radial arms 12 are sufficiently flexible to evert when retracted from a body vessel 20. Everted arms 12 keep the catheter 16 centered within the vessel 20 during retraction, thereby preventing undo pressure from being placed on the vessel sides, especially through bends in the vessel 20. Furthermore, the ability to evert obviates the need for an intricate arm retraction device.

[0041] The flexibility of the radial arms 12, as discussed above, may be controlled through material selection or, in the case of inflatable arms, through fluid pressure. Another way to vary the flexibility of the radial arms 12 is by varying the width of the arms 12, as shown in Fig. 2. The arms 12 in Fig. 2 have wide bases 22 with relatively thin distal portions 24. This configuration provides a strong radial force while still maintaining a gentle contact with the vessel walls. Additionally, the arms 12 may be coated, preferably with a hydrogel, for lubricity. Further protection to the vessel walls may be accomplished by constructing a catheter 16 that gradually becomes more flexible toward its distal end. This catheter design has variable longitudinal flexibility.

[0042] Turning now to Figs. 3A-B, there is shown a catheter 16 with another embodiment of a tip 10 of the present invention. The tip 10 comprises a plurality of inflatable fins 28. The fins 28 are shown as being relatively flat and ribbon-like but could also comprise spirals, sinusoids, or a single spiral, for example. Each of the fins 28 may include a plurality of discharge holes 30 through which injectate delivered through the central lumen 15 of the catheter 16. Alternatively, the discharge holes 30 could be provided between the fins 28 or proximal of the tip 10 on the catheter 16. Fig. 3A shows the fins 28 in a deployed, inflated state while Fig. 3B shows the fins 28 in a deflated, compressed state. Like the arms 12 of the previously described embodiments, the fins 28 may act against the walls of a vessel to keep the catheter 16 centered within the vessel lumen and to track the large vessel lumen as it is advanced forward. Additionally, the fins 28, having longitudinal length and hydrodynamic design, are acted upon by the flow of the bloodstream, causing the fins to seek the center of the blood flow, thereby maintaining the catheter 16 in the center of the lumen, even if the vessel lumen is wider than the radial reach of the fins 28. The fins 28 of the tip 10 of Figs. 3A-B are shown as being formed in a shaped balloon-like device that controls flow rate through the holes 30 by the size and number of the holes 30.

[0043] Fig. 4 shows another finned embodiment of the tip 10 of the present invention, which has a plurality of fins 32 formed from a plurality of fibers 34. The fibers 34 are flexible and capable of being compressed and held in a compressed state by a sheath.

The tip 10 of Fig. 4 includes a plurality of discharge holes 36 for discharging a cloud of imaging agent delivered via the lumen 15 of the catheter 16. The discharge holes 36 are shown as being located on the tip body 14 between the fins 32. Alternatively, the discharge holes 36 may be located within the rows of fibers 34 forming the fins 32.

[0044] Another finned embodiment of the tip 10 of the present invention is shown in Fig. 5. The fins 32, formed from flexible fibers 34, are separated by a plurality of elongate balloons 38. The balloons 38 are constructed and arranged to compress the fibers 34 when inflated, thereby causing the fibers 34 to stand up and form the fins 32. When the balloons are deflated, the fibers 34 are more flexible and are easily folded into a compact state whereby they may be contained in a sheath prior to deployment. When the balloons 38 are inflated, the fibers 34 are given a differential stiffness as a function of radial distance from the catheter 16. Hence, the fibers 34 are more flexible at their distal ends resulting in a progressive resistance being applied against the vessel walls. The closer the catheter 16 gets to the vessel walls, the more resistance the fins 32 place against the walls. Discharge holes for the embodiment of Fig. 5 may be provided in the tip body 14 within the fibers 34, through some or all of the fibers 34, provided the fibers are hollow and in fluid communication with the lumen 15 of the catheter 16, through a porous section of the catheter 16 (see, for example, porous section 42 of the catheter 16 shown in Fig. 8), or through holes formed in the elongate balloons 38, similar to those described above in reference to Fig. 3A. The catheter may also have a device that limits retrograde flow, allowing for all or most contrast to be pushed antegrade with either contrast or saline injection. This allows clearing of contrast agent from the superior vena cava, a problem commonly found with venous injections where contrast circulates in this large vein for longer periods of time rather than leaving this vessel for the right atrium.

Porous Catheters

[0045] The catheter 16 of the present invention is shown in Figures 1A-C and 2 as being relatively straight. However, referring now to Figures 6 and 7, there are shown

embodiments of the present invention utilizing curved catheters 16. Figure 6 shows a catheter 16 formed with a retroflexed curved portion 25 formed to be advanced from the brachial-radial artery system to the innominate, retroflexing into the ascending aorta. The retroflexed curved portion 25 allows the catheter tip 10 to be advanced into the aortic root without the need for fluoroscopic or other imaging guidance. The retroflexed curved portion 25 is also useful in advancing the catheter 16 from the brachial venous systems to the subclavian vein, possibly to the superior vena cava, right atrium or inferior vena cava. The curved portion may be formed by an internal wire or spring 19, that is preferably formed from a metal with shape memory, such as nitinol, or a spring or polymer with a curved configuration. The curve 25 is gentle and grows to conform to the internal aspect of the chamber into which the catheter 16 is advanced.

[0046] Optionally, the curved portion 25 includes a porous section 23 containing discharge holes, thereby permitting the device to inject material from the most distal portion of the device, as opposed to the true end of the catheter 16. The tip 10 is as described above but is shown with a sheath 26 for maintaining the radial arms 12 in a collapsed state until deployment is desired. The sheath 26 is shown as being transparent for illustrative purposes. One skilled in the art will realize that, though not necessarily shown, the sheath 26 could be used on any of the embodiments described herein.

[0047] Fig. 7 shows a catheter 16 of the present invention formed with an ante-flexed portion 27. This catheter 16 is shaped for optimal use in finding the aortic arch/descending aorta. As this catheter is advanced from the peripheral arteries to the aorta, the diameter of the tips expands to maintain contact with arterial wall. A retroflexing curve on the catheter permits it to retroflex into ascending aorta from brachial (right or left) artery, thus self-seeking a very central vascular position, without the need for catheter guidance under fluoroscopy or other imaging modality. As in Fig. 6, the distal end of the catheter 16 includes a tip 10 of the present invention, shown with a sheath 26.

Centering Tips for use with Porous Catheters

[0048] Referring now to Fig. 8, it is shown that utilizing a porous section 42 on the catheter 16, allows a simpler tip 10 to be employed. The tip 10 of Fig. 8 includes an inflatable balloon 40 that permits blood flow around the device while preventing the tip 10 from tracking into a branch vein. Moreover, the tip 10 of Fig. 8 may simply be a balloon 40 operably attached to the distal end of the catheter, rather than a separate device extending from the distal end of the catheter 16. For purposes of illustration, the device of Fig. 8 is equipped with an internal flow monitoring device 44 located within the lumen 15 of the catheter 16 and an external flow monitoring device 46 located on the outside of the catheter 16. It is understood that either or both of these device could be placed on any of the devices shown or described herein.

[0049] The internal flow monitoring device 44 is a measuring device that provides instant feedback utilizing hot wire anemometry, Doppler, an electromagnetic flow transducer, or any other flow monitoring device. The device 44 is used for instantaneous feedback regarding injectate flow rate. Hence, the device 44 facilitates control over injection rate, allowing the contrast mixed in the blood to remain at a constant or controlled ratio.

[0050] The external flow monitoring device 46 is also a flow measuring device and may be a wholly different device from the internal monitoring device 44 or may differ from the internal flow monitoring device 44 in location only. The device 46 is positioned on an external surface of the catheter 16 such that it may measure the blood flow rate around the catheter 16.

[0051] Additional embodiments of a catheter 16 and tip 10 of the present invention are shown in Figs. 9-11. Fig. 9 shows a catheter 16 having a porous section 42 near its distal end through which injectate is ejected to form a cloud. A tip 10 extends from the distal end of the catheter 16 that has a spiral-shaped centering mechanism 48. The catheter 16 also accommodates a guide wire 50. Like all of the features shown and described herein, the guidewire feature of Fig. 9 is included in the embodiment of Fig. 9

for illustrative purposes and it is to be understood that this feature could be incorporated into any of the other embodiments.

[0052] The spiral-shaped centering mechanism 48 of the tip 10 is extendable and retractable from and into the catheter 16. The spiral-shape allows the tip 10 to yield longitudinally when being advanced or retracted through a body vessel thereby protecting the vessel from injury. Prior to deployment from a delivery sheath, such as sheath 26 of Figs. 3 and 4, the spiral-shaped centering mechanism is contained within the sheath in a relatively straight configuration. Preferably, the centering mechanism 48 is formed of Nitinol or similar shaped memory metal. Alternatively, a polymer, spring steel or any material having spring-like properties is used. When extended, the centering mechanism 48 assumes an expanded three dimensional configuration such as that shown in Fig. 9. The expanded configuration allows the tip 10 to maintain a center position within the vessel and to seek the main channel of the vessel and to avoid side branches. When the injection is complete, the tip 10 may be retracted into the catheter 16 or the entire device may be removed with the tip 10 in the deployed state without injuring the vessel. Though the tip 10 is shown as a spiral, other wisk-like configurations or random structures are contemplated.

[0053] For example, the device shown in Fig. 10 includes a catheter 16 with a tip 10 that has a centering mechanism 52 with a plurality of petals 54. The petals 54 are self-expanding and the centering mechanism 52 behaves and performs similarly to the spiral-shaped centering mechanism 48 shown in Fig. 9. The catheter 16 is shown having a porous section 42 and a skive 56 that allows the catheter 16 to be placed over a guidewire 50 that otherwise remains external to the catheter 16. The skive 56 is associated with the catheter 16 shown in Fig. 10 for illustrative purposes only. The skive 56 allows the device to be advanced over a distal end of the guidewire 50 and removed while a second catheter, such as an angiography catheter is simultaneously being advanced over the guidewire 50. The guidewire 50 may include any of the centering devices mentioned herein.

[0054] Yet another embodiment of a tip 10 is shown extending from a catheter 16 in Fig. 11. The tip 10 comprises a basket centering device 58. Like the other aforementioned tip embodiments, the basket centering device 58 permits atraumatic advancing and retracting through a vessel and also does not interfere with blood flow. The basket centering device 58 is shown illustrating a feature that could be incorporated into the other tip embodiments. The three dimensional members of the basket centering device 58 include diffusion holes 60 through which injectate may flow. Necessarily, the basket centering device 58 is constructed of hollow members having interior lumens in fluid communication with the central lumen 15 (Fig. 6 and 7, for example) of the catheter 16. The diffusion holes 60 may be provided in combination with, or instead of, a porous section 42 on the distal end of the catheter 16. Like all of the embodiments of the tip 10 described herein, the tip 10 is preferably coated with a lubricious coating, such as a hydrogel, further protecting a body vessel from trauma.

[0055] Another feature shown for illustrative purposes on Fig. 11 is a marker band 62 at the distal end of the catheter 16. The marker band 62 is preferably radiopaque and MRI visible, and not ferromagnetic. The band 62 may be embodied as a feature that extends the length of the catheter 16 or just at the distal tip as shown. Similarly, the tip 10 could also be radiopaque. If desired, the marker band 62, rather than being an area of radiopaque material, could be a small electronic transmitting chip. The chip could also include an antenna.

Flow Pattern, Hole Design and Distribution

[0056] Turning the discussion now to the flow pattern of the injectate from the various aforementioned embodiments, attention is first drawn to Figs. 12A and 12B. Fig. 12A shows a typical flow pattern 64 injected into a vessel that one could expect to emit from a prior art end-hole catheter. The flow pattern 64 is generally conical in form and is characterized by a high flow rate as the pressure of the injection adds constructively to the flow 65 of the blood stream into which the agent is being injected. Fig. 12B represents a flow pattern 66 of the present invention having roughly the same amount of

contrast agent as that in Fig. 12A but occupying a much smaller volume. Hence, the flow pattern 66 of the present invention is a much more concentrated bolus of injectate than the flow pattern 64 of the prior art.

[0057] In order to create the desired flow pattern 66 from the various embodiments of the catheter 16 of the present invention, attention is given to the size, placement, and formation of the various discharge holes of the porous sections and tips 10 described above. Referring first to Fig. 13, there is shown a magnified cross section of a porous section, such as porous section 17 of Fig. 1, porous section 23 of Fig. 3, or porous section 42 of Figs. 8-11. For purposes of brevity, the porous section of Fig. 13 is given reference numeral 68, which will represent any or all of the aforementioned porous sections. Furthermore, the holes of porous section will be numbered 70 and will represent any or all of the aforementioned discharge or diffusion holes of the present invention.

[0058] A variety of different hole styles 70A-E are presented in Fig. 13. As these holes 70 are herein described, it is to be understood that the various characteristics may be employed singly or in any combination when practicing the present invention. Beginning with hole 70A, there are a plurality of burrs 74 that encompass the internal opening. Burrs 74 serve to increase the effective length of the hole and also mix the fluid, creating turbulent flow through the hole 70A. Hole 70A is oriented relatively radially to a longitudinal axis 76 of the catheter 16. Burrs 74 may comprise a buildup of catheter material, such as is caused by drilling, laser cutting, ultrasound, heat, etc. The burrs 74 also favorably impact the exit velocity of the injectate.

[0059] Hole 70B is tilted at an angle other than normal to the longitudinal axis 76 of the catheter. It is thought that providing a porous section 68 comprised of holes having varying angles will result in injectate streams that interfere with each other, softening the collective impact on the vessel wall and creating a tighter bolus of injectate around the catheter 16. Hole 70B also include a radially increasing cross section such that the hole 70B has a greater area at the outer wall 78 of the catheter 16 than it does at the inner

wall 80. Providing holes having different cross-sectional profiles also results in a softer, more compact bolus. Hole 70B, like the rest of the holes 70, has burrs 74 extending around the circumference of the opening in the inner wall 80.

[0060] Hole 70C is angled in a proximal direction at an angle other than normal to the longitudinal axis 76. Hole 70C also has a relatively uniform cross-sectional area.

[0061] Hole 70D extends in a direction somewhat normal to the longitudinal axis 76. The hole 70D is also characterized by a cross-sectional profile that decreases in a radial direction.

[0062] Hole 70E is similar to hole 70C but is positioned in an area of the catheter 16 of increased thickness. Hence, the hole 70D is longer than hole 70C. Providing holes of different lengths results in fluid jets having different lengths, further adding to the turbulence of the bolus.

[0063] All of the holes 70 in Fig. 13 are placed so that a lateral injection occurs, as opposed to an injection that travels in the same direction as the blood stream. The catheter has an end plug 72 that forces the injectate out of the holes 70. Alternatively, additional holes could be provided through the end plug 72 of any configuration if desired.

[0064] The resulting bolus shape can also be controlled by the distribution of the holes 70 in a porous section 68. For example, Fig. 14 shows a porous section 68 having a plurality of holes 70. The density of the holes increases in a distal direction. Fig. 15, alternatively, shows a porous section 68 with a relatively uniform hole density. However, the size of the holes 70 increases distally. Fig. 16 shows a porous section 68 having holes 70 that both increase in size and have different shapes such as ovals, rectangles, slots and slits. If the porous section 68 were to be used to draw blood, as during a phlebotomy procedure, the holes 70 could be sized slightly smaller than white blood cells such that red blood cells could be drawn through them, leaving the larger white blood cells in the blood stream. The holes 70 may also be placed and shaped to

make the catheter 16 more flexible. To this end, some of the holes 70 could be formed such that they do not pass all the way through the catheter 16. Hence, a desired flow pattern as well as a desired flexibility could be attained. Furthermore, such "blind holes" or slots would allow the catheter 16 to bend at the groove sites, without fracturing or rupturing despite multiple movements. As such, the holes or slots would function much like a bellows.

[0065] Fig. 15 also shows another feature of the present invention that may be used to create a more concentrated bolus. A tip 10 is shown having radial arms 12 connected together with a web 82. The web 82, when the tip is deployed, will slow or block blood flow during injection. Doing so prevents the blood flow from sweeping the injectate cloud away until the injection is completed and the tip is retracted.

Additional Features

[0066] Turning now to Fig. 17, there is shown a catheter 16 and tip 10 of the present invention surrounded by a sterile covering 82. The covering 82 is pleated such that the catheter may be inserted into a patient without first removing the sterile covering 82 and exposing the catheter 16 to potential contaminants prior to insertion. The covering is relatively loose fitting and thin such that as the covering 82 compresses during insertion, the covering 82 does not overly bunch and impede the insertion of catheter 16. Alternatively, as shown in Fig. 18, a casing 18 provides a sterile housing for the catheter 16, which can be extended from the casing directly into the patient using a crank 88 or similar mechanism.

[0067] Fig. 19 shows an additional use for a tip 10 of the present invention. In addition to the centering and vascular finding purposes described above, an embodiment of a tip 10 is shown whereby the body 14 attaching the tip to the catheter 16 is quite long and the distal end of the tip 10 is sharp enough to penetrate the heart muscle. Hence, the tip 10 could be fed into the right ventricle of the heart, used to puncture the septum, fed across the left ventricle, and used to puncture the left

ventricular myocardium as shown. The arms 12 of the tip 10 are then usable as an anchor to prevent the tip from retromigration back through the heart wall.

[0068] The tip body 14 of this embodiment comprises a spring lead operably attached to a transducer such that the body 14 may be used to measure parameters such as systole and diastole left ventricular chamber dimensions, cavity pressure, blood flow and the like. The tip 10 may further include an electrode or series of electrodes that permit pacing or RF transmission and may allow detection of position via an external detector mechanism.

[0069] The small hole configuration of the present invention can be used to create high-velocity injections. This capability gives rise to a method of injecting a substance internally, whereby a gas, preferably an easily absorbable gas like carbon dioxide, is first injected to create a tissue penetration that can be subsequently filled by an injection of a therapeutic fluid. The gas is rapidly absorbed into the blood so that it does not pose a risk of entering the systemic (cerebral) or coronary circulation. The gas injection may be of micro-bubbles that separate tissue briefly to allow the tissue voids to fill with cells, drugs, or other therapeutic or contrast agents in a subsequent or simultaneous injection. The first, gaseous injection may contain bubbles dissolved within a fluid, such as carbonated water, or it may be a gas-containing liquid such as is often used for ultrasonic contrast agents, fluosol or another hydrocarbon. By creating a mild injury with the first injection, the healing process may include or promote the formation of locally useful cells. For example, the locally useful cells might include muscle cells for the myocardium, bone or cartilage cells for bone sites, or arterial cells at sites requiring arterial, capillary, or arteriolar ingrowth.

[0070] Control over injection speed and pressure greatly enhances the catheter of the present invention to accomplish the aforementioned injection technique. This makes the present invention ideally suited for use with automated injection systems. An example of an automated injection system is shown and described in U.S. Patent 6,099,502 to Duchon et al. issued August 8, 2000 and entitled Dual Port Syringe, which

is incorporated by reference herein. Such a device would give rise to another, digitally controlled, injection sequence.

[0071] This sequence begins with a first injection that creates a local edema, and may be at a higher or lower pressure or injection time than a subsequent second injection. The first injection spreads a channel, opens tissue planes, and creates a continuous fluid reservoir for a second injection to fill.

[0072] The second injection fills the edema with fluid and allows for a slower, more careful, less traumatic injection of cells, viruses, or fragile substances into the site.

[0073] The sequence is automated, and may involve digital control. The injectate is switched manually or automatically to inject similar or different material into the target tissue.

[0074] There may also be a post injection to drive injectate into the tissue in a favorable yet less traumatic fashion, creating more edema or swelling, or more tissue channels.

[0075] While the invention has been described in detail with reference to certain preferred embodiments thereof, it will be understood that modifications and variations are within the spirit and scope of that which is described and claimed. For example, the burrs, hole distribution, injection methods, and other embodiments of the present invention are applicable to needle technology as well as catheter technology.

We claim:

1. A tip for use with an intravascular device comprising:

a body;

a guide mechanism extending radially from said body, said guide mechanism constructed and arranged to keep said body proximate a center of a vessel lumen.

2. The tip of claim 1 wherein said guide mechanism comprises a plurality of radial arms.

3. The tip of claim 2 wherein at least one of said radial arms comprise base portions and distal portions, the base portions being wider than the distal portions.

4. The tip of claim 1 wherein said guide mechanism comprises Nitinol.

5. The tip of claim 1 wherein said guide mechanism comprises a collapsed state and a deployed state.

6. The tip of claim 1 wherein said body comprises an internal lumen and a porous section in fluid communication with said internal lumen such that fluid in said internal lumen can exit the body through the porous section.

7. The tip of claim 1 wherein said guide mechanism comprises a coating.

8. The tip of claim 7 wherein said coating comprises hydrogel.

9. The tip of claim 6 wherein said guide mechanism comprises radial arms with internal lumens in fluid communication with said internal lumen of said body.

10. The tip of claim 1 wherein said guide mechanism comprises a plurality of fins.

11. The tip of claim 10 wherein said plurality of fins comprise inflatable fins.

12. The tip of claim 10 wherein said plurality of fins comprise internal lumens in fluid communication of an internal lumen of said body.

13. The tip of claim 12 wherein at least one of said plurality of fins further comprises a plurality of discharge holes in fluid communication with said internal lumen of said at least one of said plurality of fins.

14. The tip of claim 10 wherein said plurality of fins comprise a plurality of fibers arranged to form said plurality of fins.

15. The tip of claim 14 further comprising a plurality of balloons in fluid communication with an internal lumen of said body and positioned between said fins such that, when inflated, said balloons cause said fibers to become oriented radially from said body.

16. The tip of claim 1 wherein said guide mechanism comprises a spiral radiating from said body.

17. The tip of claim 1 wherein said guide mechanism comprises a plurality of petals radiating from said body.

18. The tip of claim 1 wherein said guide mechanism comprises a basket.

19. The tip of claim 1 wherein said guide mechanism comprises a plurality of arms radiating from said body and a membrane attached between each of said plurality of arms.

20. A catheter comprising:

an elongate body defining a central lumen;

a guide mechanism at a distal end of said body and extending radially therefrom;

a porous section having a plurality of discharge holes extending from said central lumen to an exterior of said body.

21. The catheter of claim 20 further comprising a curved portion proximate the distal end of said body.

22. The catheter of claim 21 wherein said curved portion comprises a retroflexed curved portion.

23. The catheter of claim 21 wherein said curved portion comprises an ante-flexed curved portion.

24. The catheter of claim 21 wherein said porous section is located on said curved portion.

25. The catheter of claim 20 wherein said guide mechanism comprises an inflatable balloon sized to fit within a lumen of a body vessel allowing enough space between said balloon and said vessel for blood to flow around said balloon, said balloon being further sized to prevent said catheter from entering side branches of said body vessel.

26. The catheter of claim 20 further comprising an internal flow monitoring device within said central lumen.

27. The catheter of claim 20 further comprising an external flow monitoring device located on an external surface of said elongate body.

28. The catheter of claim 20 further comprising a skive proximate said distal end of said body useable to guide said distal end of said catheter along a guidewire.

29. The catheter of claim 20 further comprising a marker band proximate said distal end of said body.

30. The catheter of claim 29 wherein said marker band comprises an electronic transmitting chip.

31. The catheter of claim 20 wherein at least some of said discharge holes comprise at least one burr extending inwardly into said central lumen.

32. A method of injecting a substance into a body comprising:

injecting a first substance in such a manner so as to cause tissue to temporarily separate, thereby creating a void in the tissue;

injecting a second substance into said void.

33. The method of claim 32 wherein injecting a first substance comprises injecting a gas.

34. The method of claim 32 wherein injecting a first substance comprises injecting a gas dissolved in a liquid.

35. The method of claim 32 wherein injecting a first substance comprises creating a mild injury which, when healing, promotes the formation of locally useful cells.

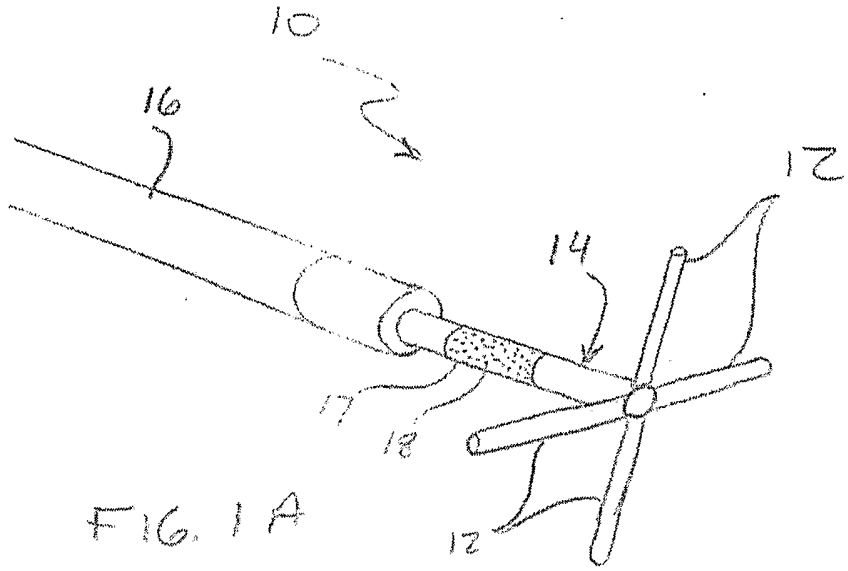

FIG. 1A

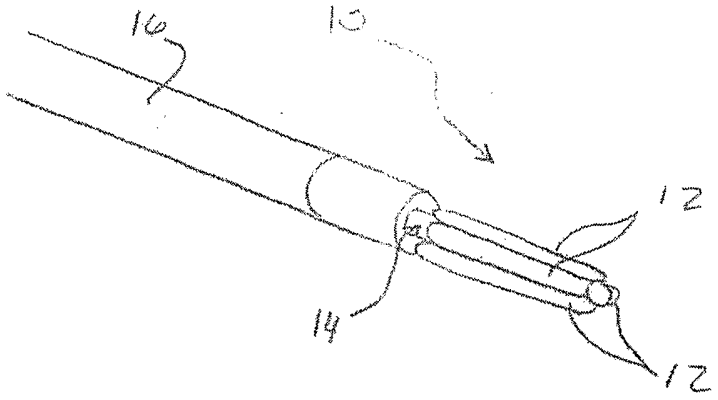

FIG. 1B

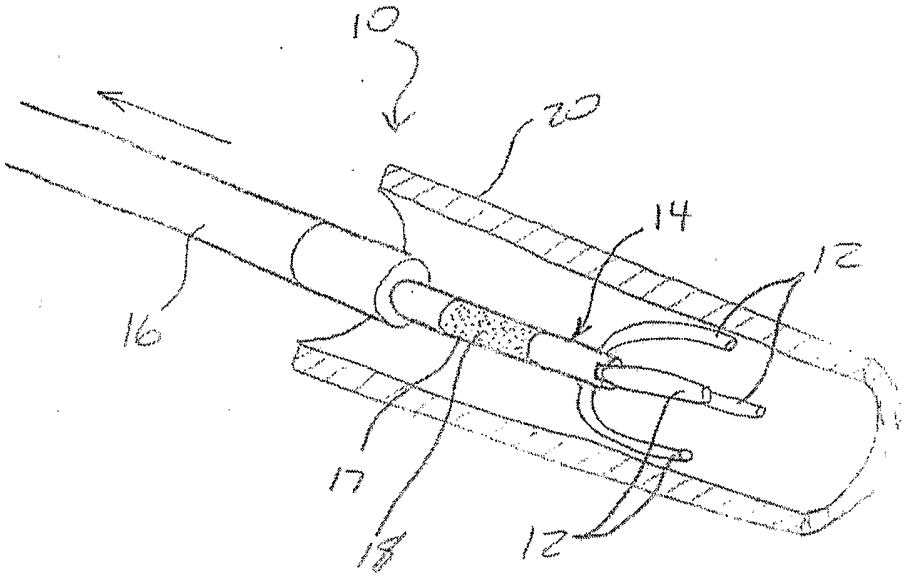

FIG. 1C

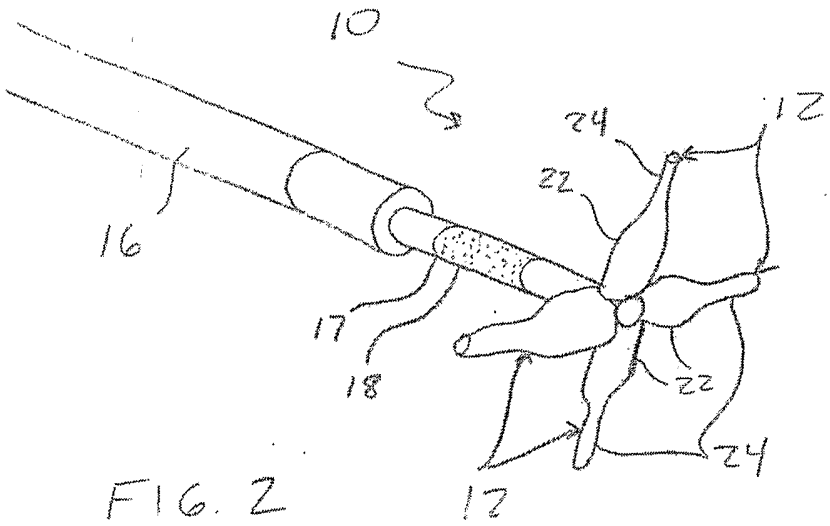

FIG. 2

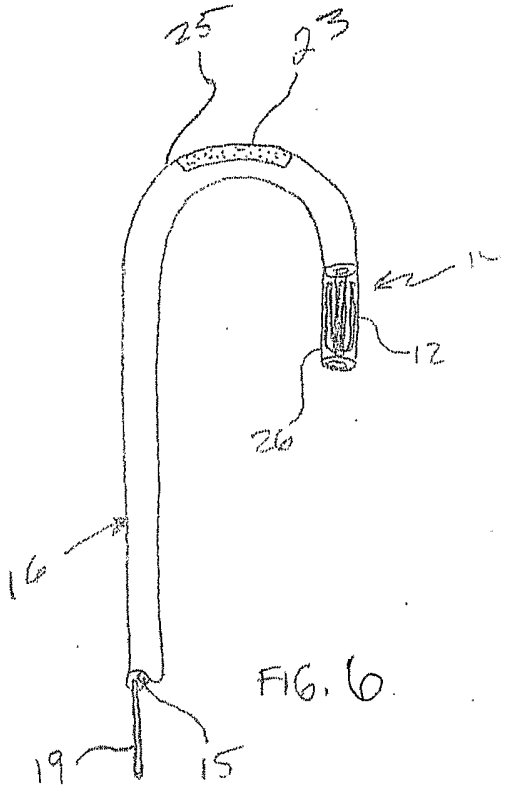

FIG. 6

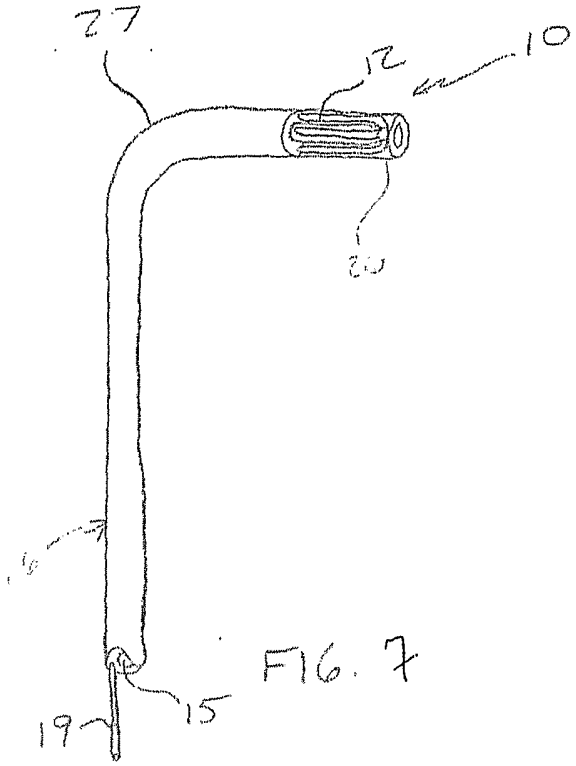

FIG. 7

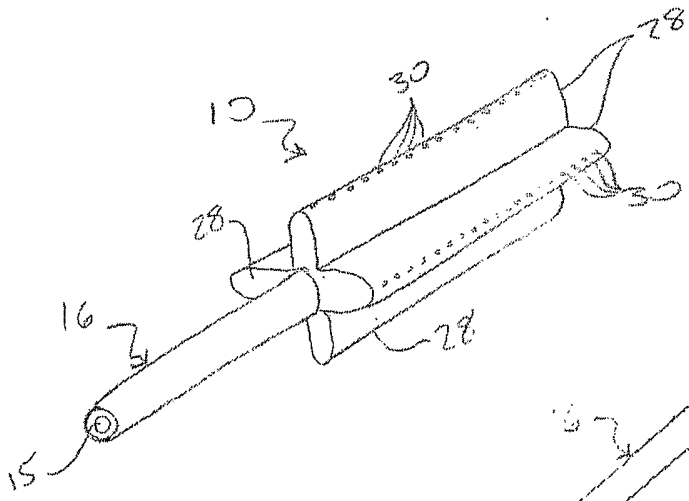

FIG. 3A

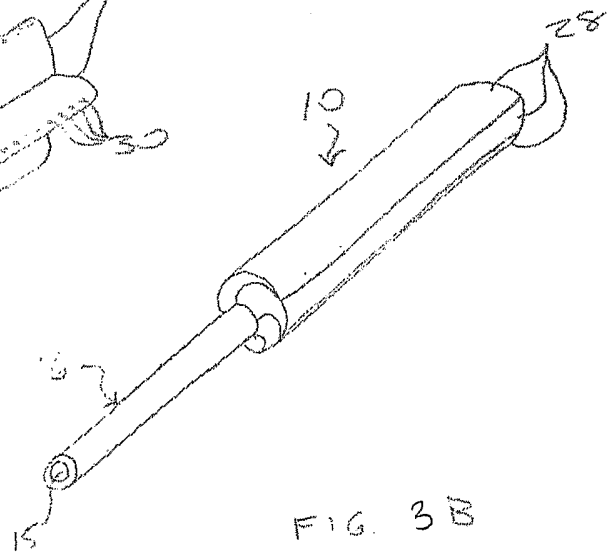

FIG. 3B

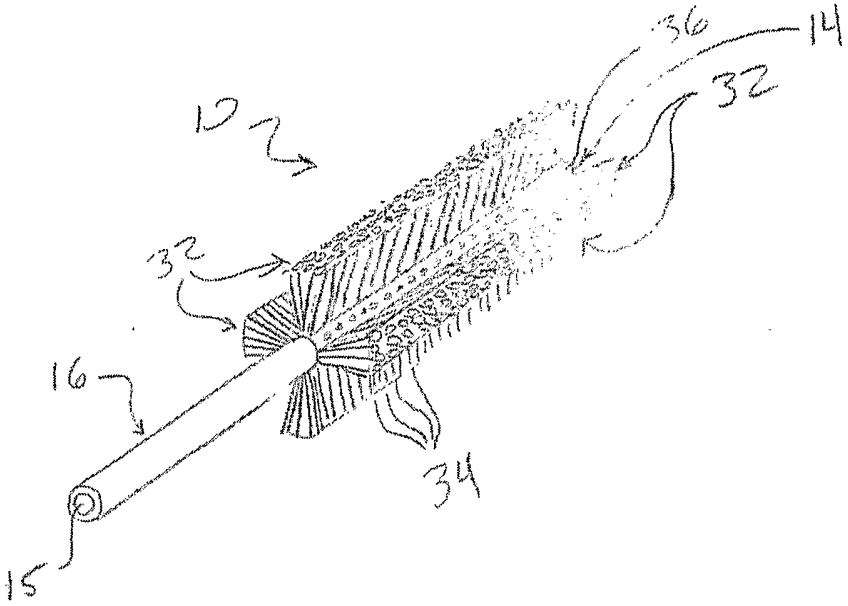

FIG. 4

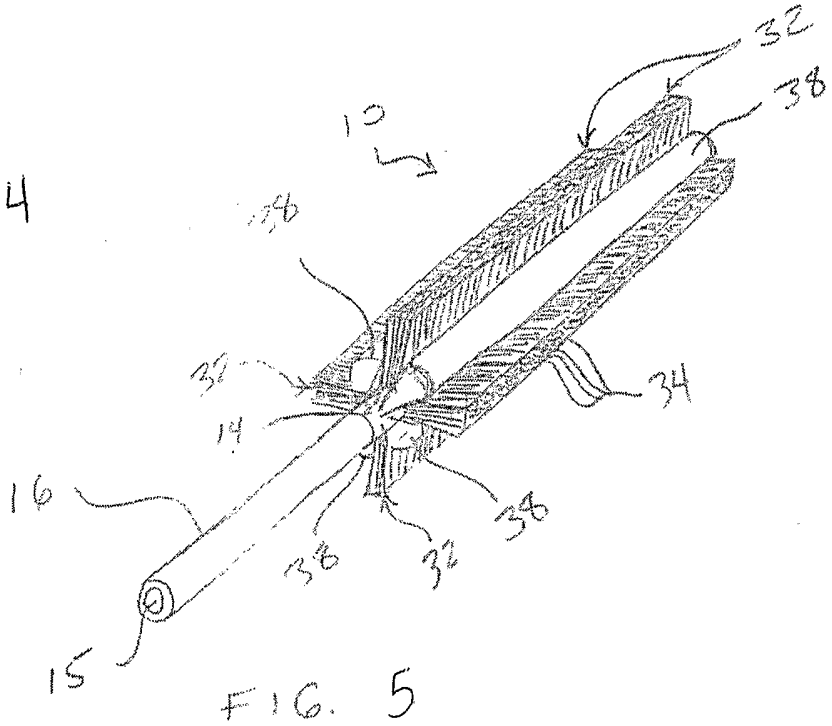

FIG. 5

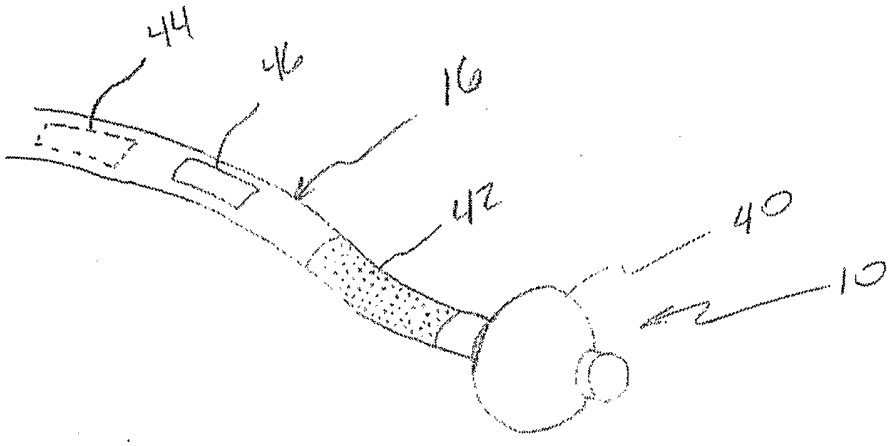

FIG 8

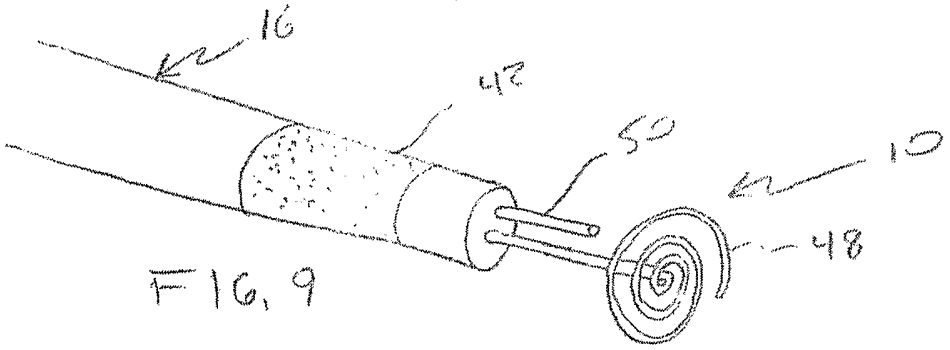

FIG. 9

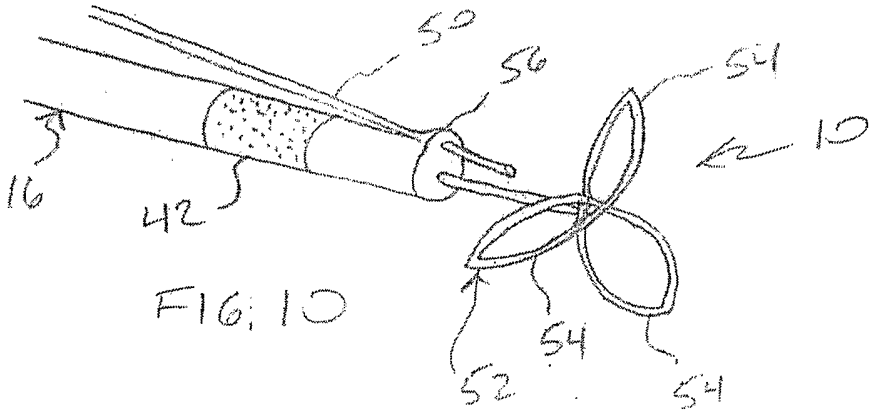

FIG. 10

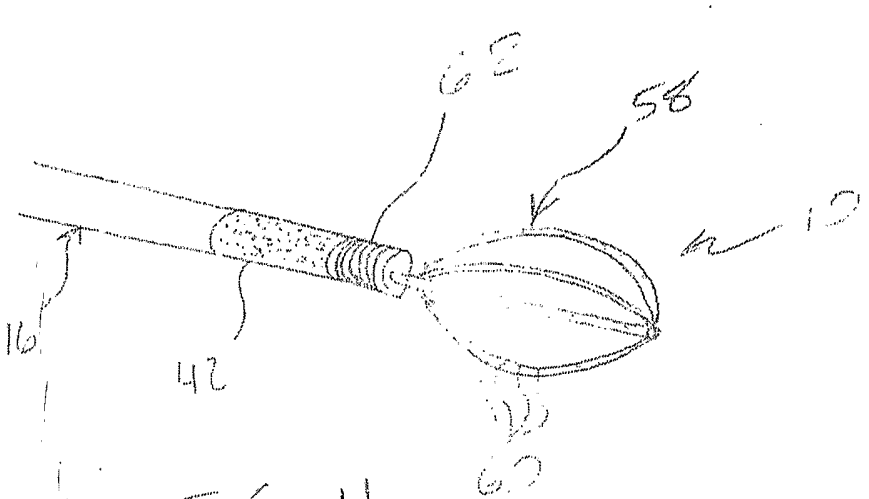

FIG. 11

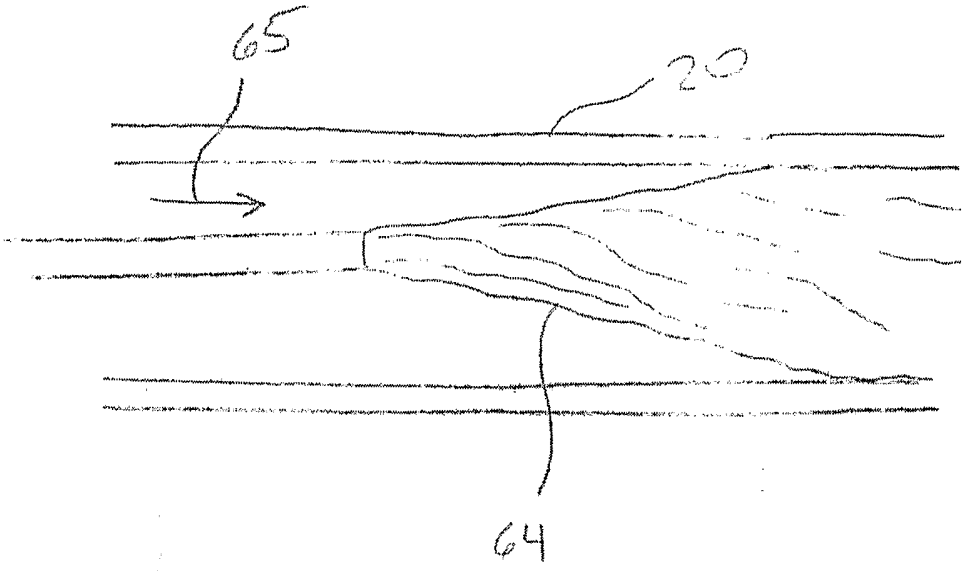

FIG. 12A
(PRIOR ART)

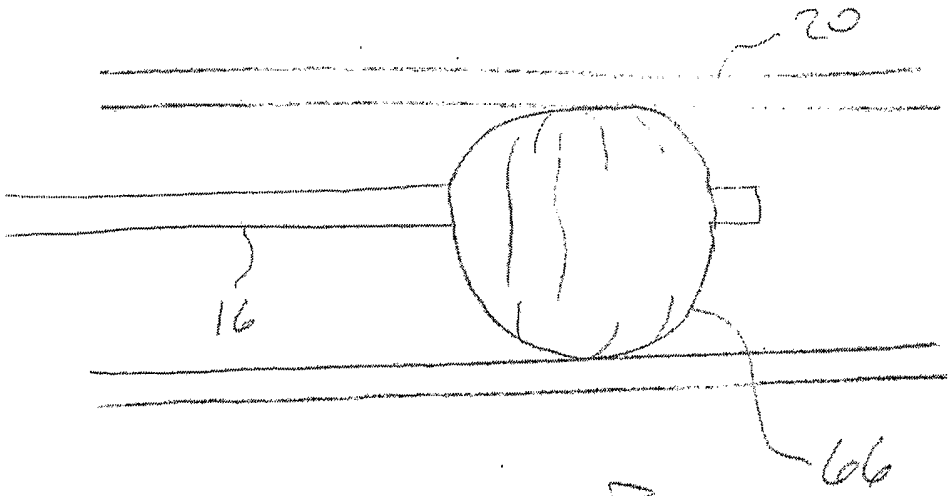

FIG. 12B

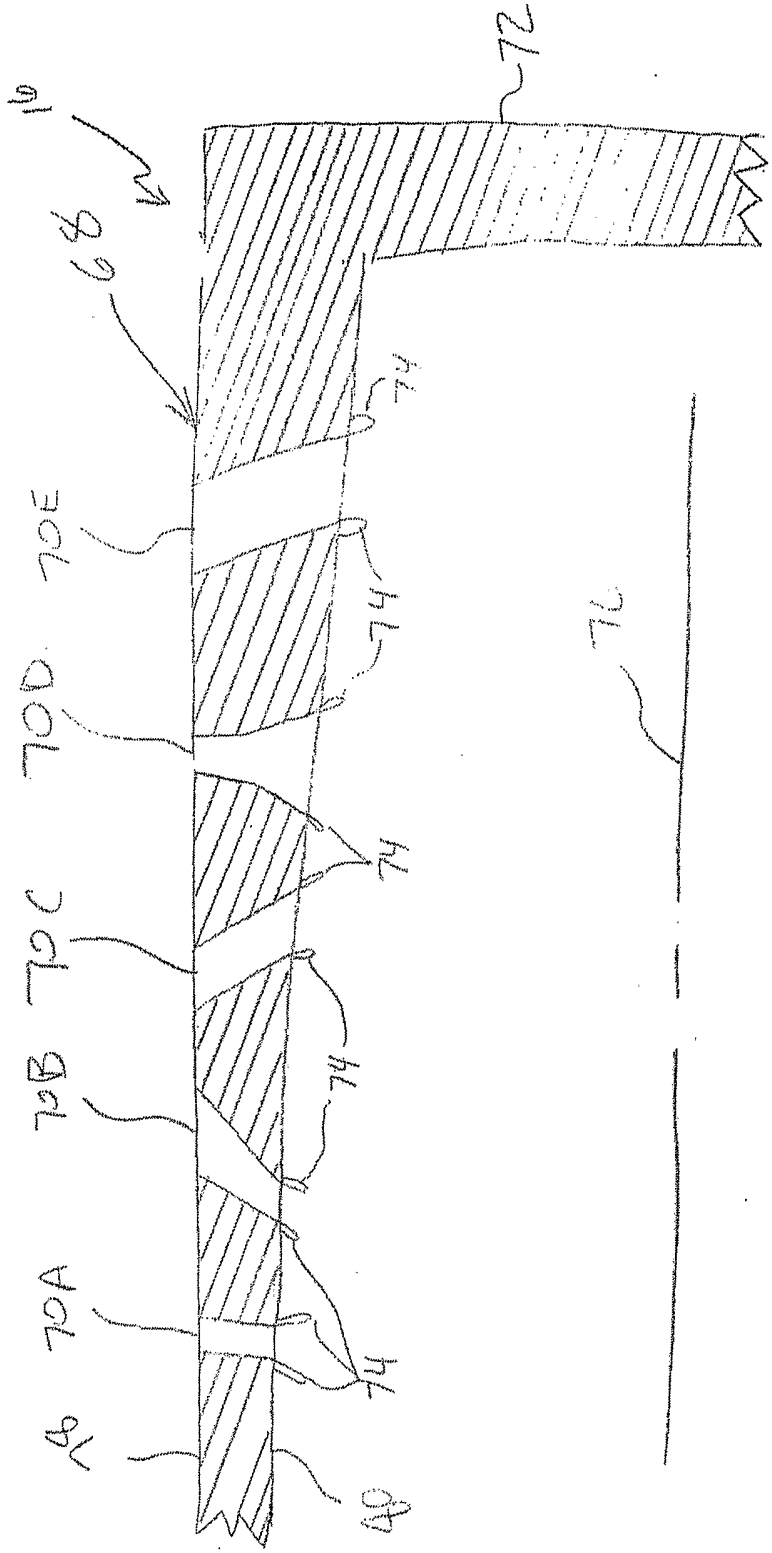

FIG. 13

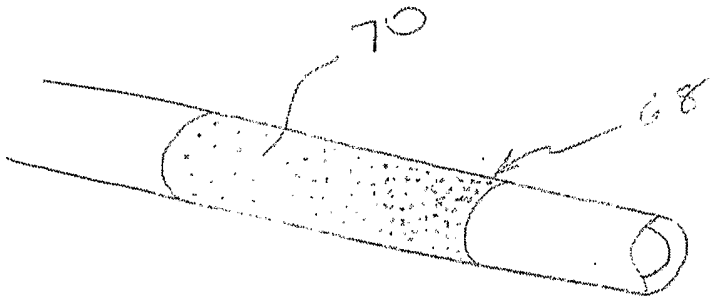

FIG 14

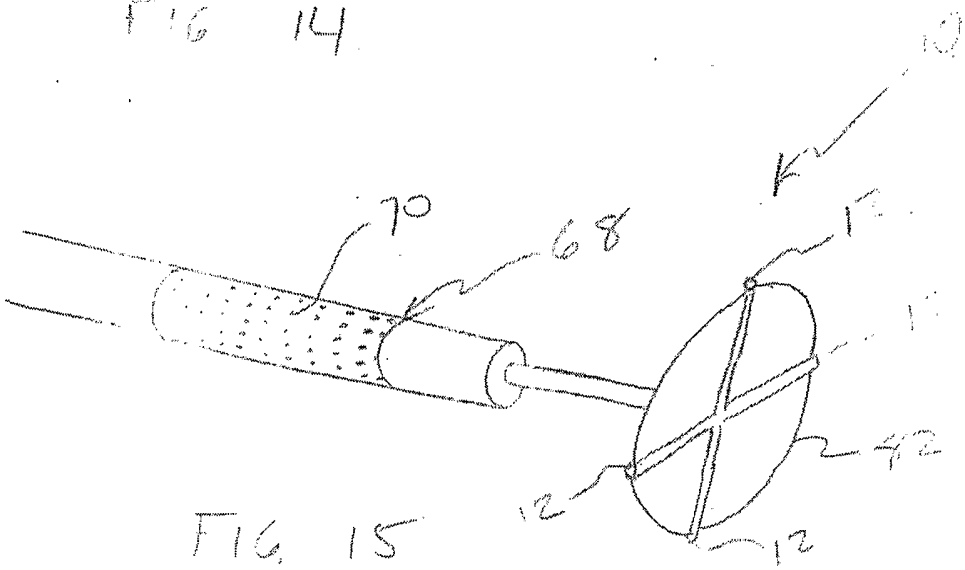

FIG. 15

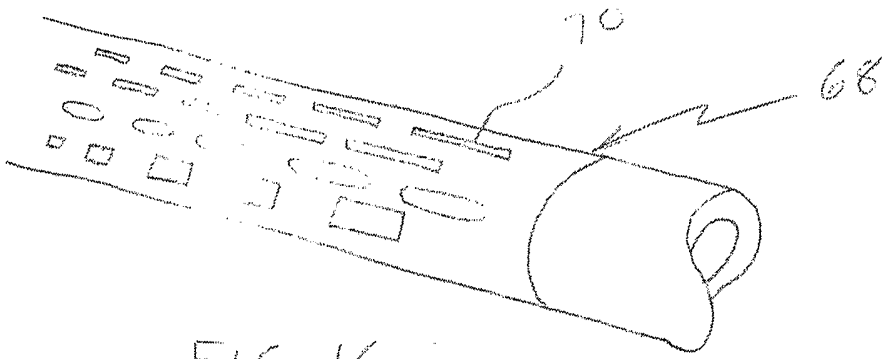

FIG. 16

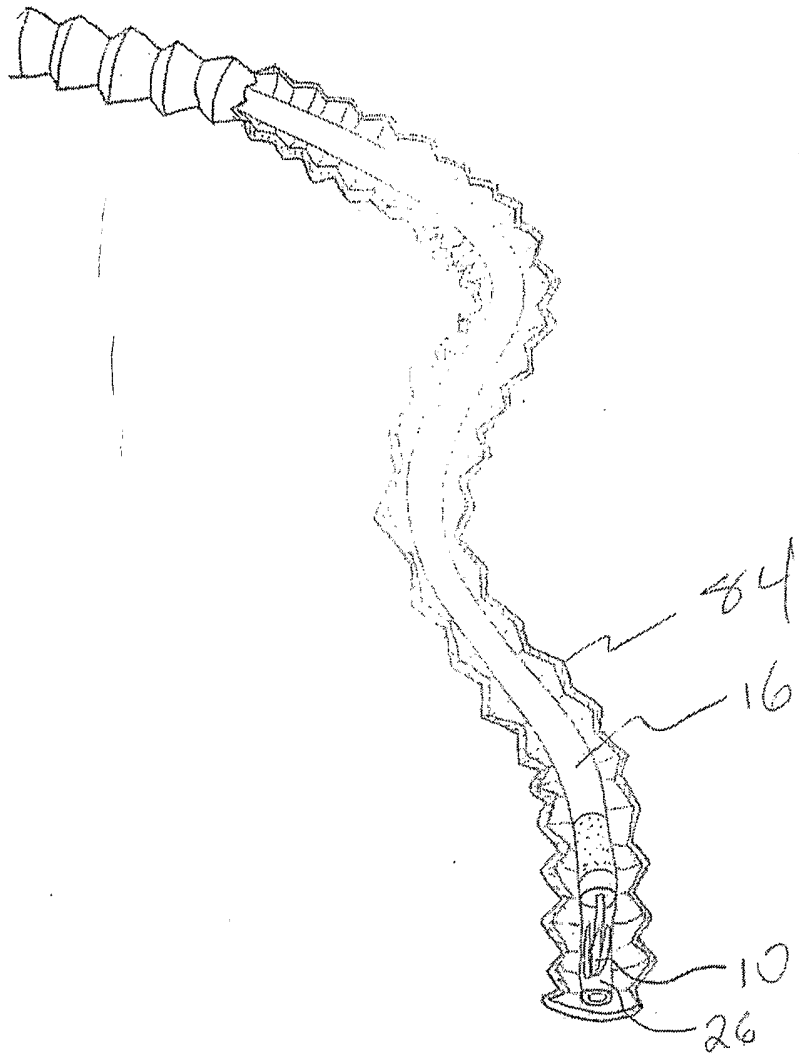

FIG. 17

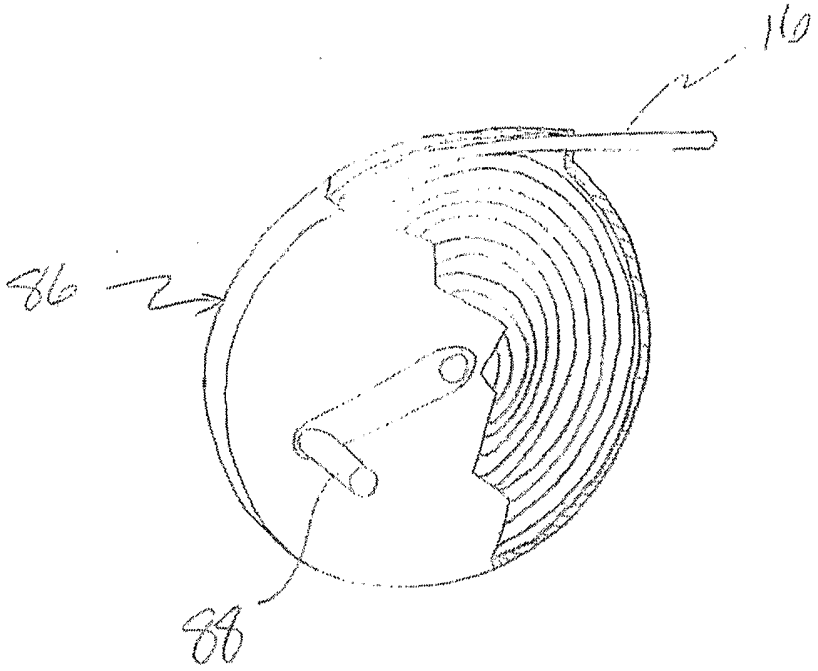

FIG. 18

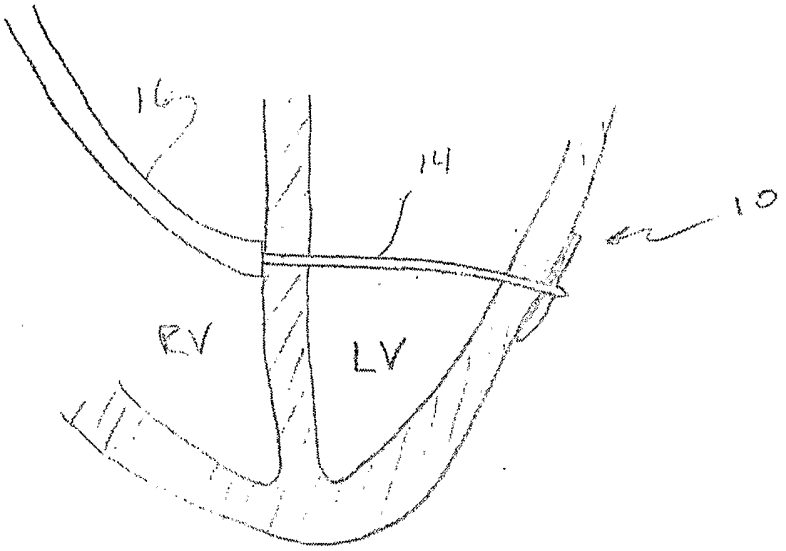

FIG. 19