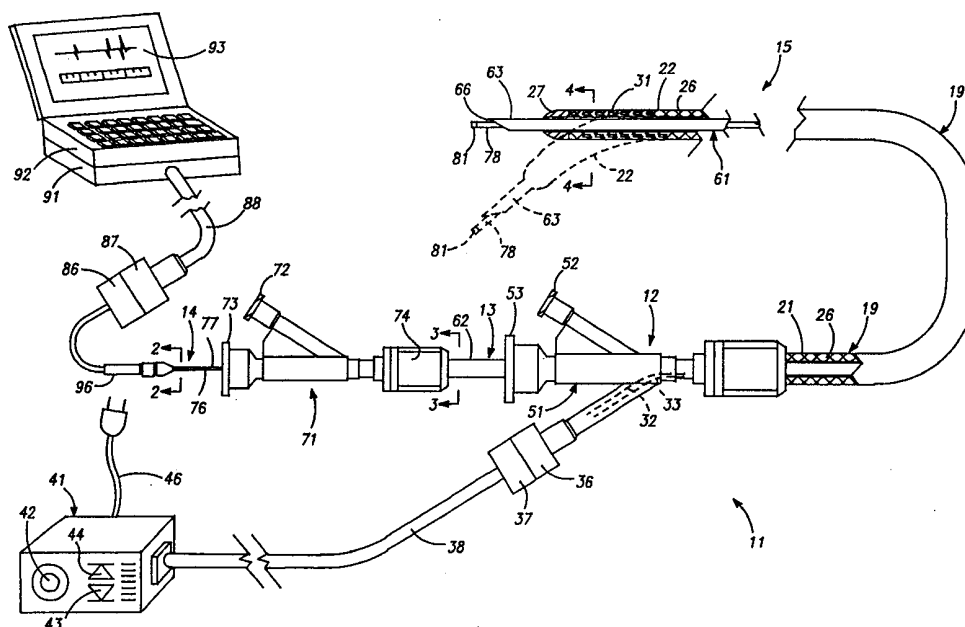


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(54) Title: RECANALIZATION APPARATUS AND DEVICES FOR USE THEREIN AND METHOD



(57) Abstract

A recanalization apparatus (11) for use in crossing a stenosis forming a total occlusion in a vessel formed by a vessel wall. The apparatus includes an outer tubular sheath (12) and an inner flexible tubular sheath (13) having a sharpened distal tip (66). The inner sheath being of a length such that when the sharpened tip is exposed past the distal end of the outer sheath, the proximal end of the inner sheath extends proximally of the proximal end of the outer sheath. An imaging guide wire (14) is slidably mounted in the lumen of the inner sheath and has a transducer (81) mounted on its distal extremity.

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**RECANALIZATION APPARATUS AND DEVICES
FOR USE THEREIN AND METHOD**

This invention relates to a recanalization apparatus and devices for use therein and method for the treatment of total occlusions.

In treating total occlusions, difficulty has been
5 experienced in penetrating the distal fibrous cap of
such total occlusions. Such difficulties have been
encountered because when it is attempted to push a guide
wire through the distal end cap, the guide wire actually
follows a false lumen alongside the vessel wall and,
10 after puncturing a vessel wall, rather than puncturing
through the fibrous cap and forming a true lumen without
puncturing the vessel wall. There is therefore a need
for a recanalization apparatus and devices for use
therein and a method which overcomes such difficulties
15 and makes it possible to form a true lumen.

In general, it is an object of the present
invention to provide a recanalization apparatus and
devices for use therein and a method which makes it
possible to penetrate a stenosis forming a total
20 occlusion even if there are false lumens in the
stenosis.

Another object of the invention is to provide an apparatus, devices and method of the above character which makes it possible to form a passage through a stenosis forming a total occlusion even though a fissure
5 leading toward a vessel wall is followed during the procedure.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in
10 conjunction with the accompanying drawings.

Figure 1 is an illustration of a recanalization apparatus incorporating the present invention and devices for use therein in a coaxial arrangement as used for performing the method of the present invention.

15 Figures 2, 3 and 4 are cross-sectional views taken along the lines 2-2 and 3-3 and 4-4, respectively, of Figure 1.

Figure 5 is a cartoon showing the manner in which the recanalization apparatus in Figures 1-4 is utilized
20 in performing the method of the present invention.

Figure 6 is an illustration of a recanalization apparatus incorporating another embodiment of the present invention.

Figure 7 is a cross-sectional view taken along the
25 line 7-7 of Figure 6.

Figure 8 is a cartoon similar to Figure 5 showing use of the recanalization apparatus of Figures 6-7.

In general, the recanalization apparatus of the present invention is for use in crossing a stenosis
30 forming a total occlusion in a vessel formed by a vessel wall, the stenosis having a distal end cap which is convex facing in a proximal direction. The apparatus is

comprised of an outer sheath formed of an elongate flexible tubular member having proximal and distal extremities and having a lumen extending from the proximal extremity to the distal extremity. An inner
5 sheath is slidably mounted in the lumen of the outer sheath and is formed of a flexible elongate tubular member having proximal and distal extremities. The distal extremity has a sharpened tip. The inner sheath has a length so that when the sharpened tip is disposed
10 distally of the distal extremity of the outer sheath, the proximal extremity extends proximally of the proximal extremity of the outer sheath. An imaging guide wire is slidably mounted in the lumen of the inner sheath and has proximal and distal extremities. A
15 transducer is mounted on the distal extremity of the imaging guide wire. The imaging guide wire has a length so that the transducer can extend beyond the distal extremity of the inner sheath with the proximal extremity extending proximally of the proximal extremity
20 of the inner sheath.

More specifically, the recanalization apparatus and the devices for use therein incorporating the present invention are shown Figure 1. As shown therein, the recanalization apparatus 11 consists of an outer sheath
25 12, an inner sheath 13 and an electrical guide wire 14 which as shown are assembled into an assembly 15. It also consists of a power supply 16 for supplying electrical energy to the outer sheath 12 and an ultrasonic power supply 17 for the electrical guide wire
30 14.

The outer sheath 12 comprises a flexible elongate tubular member 19 having proximal and distal extremities

21 and 22 and a lumen 23 extending therethrough from the proximal extremity 21 to the distal extremity 22. The tubular member 19 can have a suitable length as for example 120-150 cm having a lumen 23 having a size
5 ranging from 0.02" to 0.023" with an outside diameter of 0.035" corresponding to approximately 2.8 French to provide a wall thickness of approximately 0.006". The outer sheath 12 is formed of a suitable material such as plastic and in order to provide kink resistance and
10 torquability, a braid or coil 26 is provided in the plastic material forming the lumen 23 typically extending from the proximal extremity to the distal extremity. A soft tip 27 of low durometer plastic is formed on the distal extremity 22. In accordance with
15 the present invention it is desired that the distal extremity 22 be deflectable under the control of the physician utilizing the recanalization apparatus 11. As disclosed in co-pending application Serial No. 08/970,911 filed November 14, 1997. This can be accomplished by
20 placing a shape memory member 31 centered in the distal extremity 22 of the outer sheath 12 and can take the form of a helical coil wound from a flat ribbon of a suitable nickel-titanium alloy which has been heat treated and annealed so that it is martensitic at body
25 temperature of 98.6°F or 37°C and has a straight shape and when heated above a body temperature becomes austenitic and assumes a predetermined shape of, for example, forming a substantially 90° bend in the coil to thereby yieldably urge the distal extremity 22 to a
30 curved or bent configuration as shown by the dotted lines in Figure 1. Heat is supplied to the shape memory member 31 in a suitable manner such as by supplying

electrical energy to the same by use of conductors 32 and 33 connected at opposite ends of the shape memory member 31. The conductors 32 and 33 extend proximally through the member 31 and are connected into a connector 5 36 which is mated with another connector 37 connected to a cord 38 and connected to a deflection power supply 41 of a conventional type. The power supply 41 is provided with an on-off switch 42 and up and down switches 43 and 44 for controlling the amount of energy supplied to the 10 shape memory member 31 and thereby controlling the degree of bending of the distal extremity 22 of the outer sheath 12. The power supply 41 is provided with a power cord 46 for connection to a conventional AC power supply.

15 A fitting 51 is mounted on the proximal extremity 21 of the tubular member 19 and carries the connector 36. The fitting 51 is provided with a flushing port 52 through which a suitable flushing liquid such as a saline solution can be introduced by suitable means such 20 as a syringe (not shown). The fitting also carries a hemostasis valve assembly 53 through which the inner sheath 13 extends.

The inner sheath 13 consists of a flexible elongate tubular member 61 having proximal and distal extremities 25 62 and 63 and having a lumen 64 extending therethrough from the proximal extremity 62 to the distal extremity 63. The tubular member 61 is formed of a suitable material such as a plastic or stainless steel or a combination thereof. When formed of plastic, at least 30 the distal extremity 63 should be formed of stainless steel or a nickel-titanium alloy so that it can be provided with a sharp tip 66 at the distal extremity so

that the inner sheath 13 can serve as a needle cannula. It should have a length which is greater than the length of the outer sheath 12 so that its distal extremity 63 can extend beyond the soft tip 27 while the proximal
5 extremity 62 is proximal of the hemostasis valve assembly 53 a sufficient distance so that it can be readily grasped by the hand of the physician.

The flexible elongate tubular member 61 is sized so that it can slidably extend through the lumen 23 of the
10 outer sheath 12. Thus by way of example, the flexible elongate tubular member 61 can have a suitable outside diameter as for example 0.02" and a lumen having a diameter of 0.010" to provide a wall thickness of 0.005". It can be seen that it has a sufficient wall
15 thickness to provide the pushability required for slidably moving the flexible elongate tubular member 61 within the outer sheath.

A conventional fitting 71 is mounted on the proximal extremity 62 of the tubular member 61 and is
20 provided with a sidewise extending flush port 72 and a conventional hemostasis valve 73 and a rotating joint 74.

The electrical guide wire 14 can be of a conventional type. It typically consists of a flexible
25 elongate tubular member 76 having proximal and distal extremities 77 and 78. As is well known to those skilled in the art, the distal extremity 78 is typically provided with a coil (not shown) to provide additional flexibility for the distal extremity 78 to facilitate
30 guiding of the guide wire 14 through vessels in the human body. An ultrasonic transducer 81 is mounted on the distal extremity 78 and also is of conventional type

which operates in the A-mode to propagate forwardly looking wave trains of ultrasonic pulses which are used for ranging purposes with the reflected ultrasonic waves being received by the transducer 81. Electrical energy is supplied to the transducer 81 and is converted to ultrasound waves by the transducer 81. This electrical energy is supplied to and the electrical energy is received from the transducer 81 by conducting wires 82 and 83 connected to the transducer 81 and which extend interiorly of the flexible elongate tubular member 76 to the proximal extremity 77 and are connected to a conventional removable connector 86 which permits rotation of the flexible elongate tubular member 76 with respect to the connector 86 while the connector 86 maintains electrical contact with the wires 82 and 83. The connector 86 is mated with another connector 87 that is connected to a cord 88 which is connected to an ultrasonic power supply 91 having a frequency output ranging from 5-20 Mhz. A notebook-type or lap-type computer 92 interfaces with the power supply 91 for controlling the same and at the same time providing a display of the output on a screen 93.

A torquer 96 of a conventional type is mounted on the proximal extremity 77 of the guide wire 14 and, as is well known to those skilled in the art, is utilized for rotating the guide wire to facilitate advancing the distal extremity of the guide wire 14 through tortuous vessels. The guide wire 14 of the present invention has an outside diameter of 0.009" to 0.010" and has a length ranging from 150-175 cm so that its distal extremity 78 extends out of the distal extremity 63 of the inner sheath 13 while having its proximal extremity 77

accessible outside the human body in which the device is placed to permit manipulation of the proximal extremity 77 and the use of the torquer 96.

Operation and use of the recanalization apparatus 11 of the present invention may now be briefly described as follows in performing a method or procedure for traversing a total occlusion and particularly a chronic total occlusion with the use of the cartoon shown in Figure 5. An arterial vessel 101 on the wall of the heart in the body of a human being is shown with the vessel 101 having a vessel wall 102 defining a lumen 103 through which blood normally flows. The vessel 101 is provided with side branches 106 and 107 which have walls 108 and 109, respectively, which define branch lumens 111 and 112 in communication with the main lumen 103.

As shown in the cartoon in Figure 5 let it be assumed that a total occlusion which in fact can be a chronic total occlusion is formed by a stenosis or lesion 116 in the vessel 101 between the branches 106 and 107. Typically such chronic or aged total occlusions are comprised of pre-existing old plaque 117 which typically is fissured. Such pre-existing plaque has a complex structure in which fibrous or calcified tissues are intermingled with loose tissues often having sidewise extending fissures 121 in the same. In addition such pre-existing plaque has proximal and distal fibrous end caps 122 and 123 which develop as fibrous layers of organized thrombus. Typically this progression of the pre-existing plaque 117 continues to the proximal and distal side branches 106 and 107. As shown, the proximal end cap 122 is typically concave when viewed from the proximal direction, whereas the distal end cap 123 is convex when viewed from a proximal direction. In order to treat the total occlusion as shown in Figure 5, the recanalization apparatus is utilized.

The femoral artery is accessed in a conventional manner. The outer sheath 12, the inner sheath 13 and the electrical guide wire 14 are assembly coaxially into the assembly 15 and can be advanced as an assembly 15 through the femoral artery with the distal extremity 63 of the inner sheath 13 being retracted proximally of the soft tip 27 and similarly the distal extremity 78 of the guide wire 14 being retracted into the distal extremity 63 of the tubular member 61 of the inner sheath 13. The distal extremity 22 of the outer sheath 12 is guided through the vessel of interest by use of the power

supply 41 to apply energy to the shape memory member 31 to cause the desired bending of the distal extremity 22. At the same time the physician can apply torque to the proximal extremity 21 of the outer sheath 12 by grasping
5 the proximal extremity 21 extending out of the body to thereby manipulate the distal extremity 22 to cause it to traverse the vessel 101 until it has been advanced into close proximity to the proximal end cap 122. Since the end cap 122 is concave, there will be a tendency for
10 the distal extremity 22 to center in the concave side of the hemispherical end cap 122 so that its longitudinally axis is perpendicular to the face of the end cap 122. The guide wire 14 then can be advanced out of the inner sheath 13 and pushed distally to perforate the proximal
15 end cap 122 while using its ultrasonic ranging capabilities. If this proves to be too difficult for the small diameter guide wire 14, the inner sheath 13 which serves as a needle cannula carrying the sharpened tip 66 can be advanced during the same time that
20 ultrasonic waves are being propagated from the transducer 81 to ascertain the spacing from the end cap and to help ensure that the sharpened tip 66 is advancing through the concave surface of the proximal end cap 122 and not through the wall 102 defining the
25 lumen 103.

As soon as the proximal end cap 122 has been pierced by the sharpened tip 66, the entire assembly 15 can be advanced through the stenosis 116 forming the total occlusion after the sharpened tip 66 and the guide
30 wire 14 therein have been withdrawn proximally of the soft tip 27 of the outer sheath 12. Thereafter, the soft tip 27 is advanced through the pre-existing plaque

117 and into engagement with the distal cap 123 which, because of its convex shape, causes the soft tip 27 to be deflected sideways and enter a fissure 121 in the plaque 117 and thus slip to one side of the distal end cap 123 to create an undesirable false lumen 126. To remedy this situation, let it be assumed that it is necessary to reach the true lumen 103 from the false lumen 126. As this is being accomplished, the advancement of the assembly 15 is monitored by viewing the screen 93 so that deflection of the distal extremity 63 of the outer sheath 12 can be controlled utilizing the power supply 41. During rotation of the outer sheath 12 or alternatively during rotation of the guide wire 14, it is possible to orient the outer sheath 12 as well as the guide wire 14 to ascertain the orientation of the distal extremity 22 of the outer sheath 12. By observing the echoes received from the transducer 81, it is possible to orient the coaxially mounted inner sheath 13 so that its sharpened tip 66 is properly oriented toward the true lumen 103. The proximal extremity 62 of the inner sheath 13 can then be grasped by the physician and pushed to advance the sharpened tip 66 through the outer perimeter of the distal end cap 123 into the true lumen 103 from the false lumen 126. The imaging guide wire 14 is advanced into the true lumen 103. As soon as it has been ascertained that the distal extremity 78 of the imaging guide wire 14 is disposed in the true lumen 103, the outer sheath 12 and the inner sheath 13 can be removed over the proximal extremity 77 of the imaging guide wire by removal of the torquer 96 and removal of the removable connector 86 while leaving the imaging guide wire 14 in place. This can be readily

accomplished in a manner well known to those skilled in the art by use of an extension guide wire (not shown). As soon as this has been accomplished, other treatment devices such as a balloon dilatation catheter (not shown) can be advanced over the imaging guide wire 14 by following the imaging guide wire through the stenosis 116 past the distal end cap 123. As soon as the balloon catheter is in place, the imaging guide wire 14 can be removed and in its place, a larger diameter conventional guide wire (not shown), as for example a 0.014" guide wire is inserted. This conventional 0.014" guide wire is advanced so that its distal extremity extends through the balloon catheter and beyond the distal extremity of the balloon catheter and into the lumen 103 beyond the distal end cap 123 of the stenosis 116. Thereafter, the balloon on the balloon catheter can be inflated to compress the plaque 117 forming the stenosis 116 to provide a greatly increased flow passage through the stenosis 116 for establishing a blood flow through the lumen 103. Typical angioplasty procedures can be utilized to obtain the desired size of opening through the stenosis. For example leaving the .014" guide wire in place, the balloon catheter mounted thereon can be slidably removed and a balloon catheter having a larger size balloon can be advanced over the guide wire into the stenosis 116 to provide a still larger flow passage through the stenosis. Additionally at the same time if desired, a stent can be deployed into the stenosis 116. Thereafter, the additional catheter and the .014" guide wire can be removed in a conventional manner to complete the recanalization procedure.

Another embodiment of a recanalization apparatus incorporating the present invention is shown in Figure 6. As shown in Figure 6, the recanalization apparatus consists of a non-coaxial assembly 142
5 comprised of an outer sheath 143, an inner sheath 144 and an imaging guide wire 146. There is also provided another larger size guide wire 147.

The outer sheath 143 consists of a flexible elongate tubular member 151 having proximal and distal
10 extremities 152 and 153 and has lumens 156 and 157 extending from the proximal extremity 152 to the distal extremity 153. The distal extremity 153 is provided with a soft tip 161 through which the lumens 156 and 157 extend with the lumen 156 extending through an opening
15 162 which is substantially perpendicular to the longitudinal axis of the outer sheath 143 and with another opening 163 extending at an angle with respect to the longitudinal axis as for example at an angle of approximately 45° as shown in Figure 6. The tubular
20 member 151 can be of a suitable size as for example 0.039" with the lumens 156 and 157 having a suitable inside diameter as for example 0.016".

The guide wire 147 which is of a conventional type as for example a 0.14" guide wire which has proximal and
25 distal extremities 166 and 167. The distal extremity 167 is typically formed of a coil as shown and is relatively flexible. The proximal extremity 166 extends from the sheath 143 through a tubular member 171 having a conventional hemostasis valve assembly 172 mounted
30 thereon. A torquer 176 of a conventional type is mounted on the proximal extremity 166 of the guide wire

147 for torquing of the guide wire 147 as the guide wire 147 is advanced as hereinafter described.

A fitting 181 is mounted on the proximal extremity 152 of the outer sheath 151 and provides an enclosed
5 space 182 which is adapted to receive a flushing solution as for example a saline solution from a flush port 183 which is adapted to be connected to a conventional syringe 184 for supplying the flushing liquid into the enclosed space 182. The tubular member
10 171 is provided with an opening 186 therein which is in communication with the interior of the tubular member 171 and which is in communication with the lumen 156 so that a flushing solution can be discharged through the opening 162 into a vessel which is being treated.

15 If desired and as shown in Figure 6, means is provided for causing bending of the distal extremity 153 of the outer sheath 143. This means 191 consists of a cylindrical shape memory member 192 of the type hereinbefore described embedded within the distal
20 extremity which is connected to conductors 193 and 194 which extend through a lumen 195 to the proximal extremity 152 of the tubular member 151. The conductors 193 and 194 are connected into a cable 196 which extends through the fitting 181 and are connected to a connector
25 197 which is connected to another mating connector 198. The connector 198 is connected to a cord 199 which is connected to a power supply 201 of the type hereinbefore described as power supply 41. As hereinbefore described, by supplying energy to the shape memory
30 member 192 from the power supply 201, the distal extremity can be bent in the manner hereinbefore

described with the embodiment of the invention shown in Figure 1.

A subassembly 211 consisting of the inner sheath 144 and imaging guide wire 146 is slidably mounted in the other lumen 157 in the outer sheath 143. The inner sheath 144 consists of a flexible elongate tubular member 216 having proximal and distal extremities 217 and 218 with a lumen 219 extending from the proximal extremity 217 to the distal extremity 218. The flexible elongate tubular member 216 can be formed of a suitable material such as plastic or stainless steel. If formed of plastic, at least a portion of the distal extremity should be formed of stainless steel to provide a sharpened tip 221 as shown in Figure 6. The proximal extremity 217 extends through a tubular member 222 extending through the fitting 181 and coupled to establish communication with the lumen 157. The tubular member 222 is provided with an opening 223 through which a flushing liquid in the chamber 182 can pass into the lumen 219. A hemostasis valve assembly 226 is mounted on the proximal extremity of the tubular member 222 and is adapted to form a liquid-tight seal with respect to the inner sheath 144 and the coaxially mounted imaging guide wire 146 extending therethrough.

The imaging guide wire 146 is provided with proximal and distal extremities 231 and 232. An ultrasonic transducer 236 of the type hereinbefore described is mounted on the distal extremity 232 and is provided for propagating ultrasound waves distally of the transducer 236. Conductors (not shown) are connected to the transducer 236 extend interiorly of the guide wire 146 and are connected to a conventional

removable connector 241 which is connected to another mating connector 242. Connector 242 is connected by a cord 243 to an ultrasonic power supply 246 of the type hereinbefore described which is controlled by a laptop
5 computer 247 mounted thereon which is provided with a screen 248. A torquer 251 of a conventional type is mounted on the proximal extremity 231 and is used for rotating the imaging guide wire 146.

The inner sheath or cannula 144 can have a suitable
10 outside diameter as for example 0.014" to 0.015" and the imaging guide wire 146 can have a suitable outside diameter as for example 0.010" to 0.011".

Operation and use of the canalization apparatus 141 shown in Figures 6 and 7 may be briefly described as
15 follows. Let it be assumed that a method or procedure for traversing a total occlusion and particularly a chronic total occlusion is to be performed. In many respects, the method or procedure utilized is similar to that utilized with the recanalization apparatus 11
20 hereinbefore described. This operation and use also can be described in conjunction with the cartoon shown in Figure 8. The femoral artery of the patient is accessed in a conventional manner and then the entire assembly 142 can be advanced into the arterial vessel with the
25 inner sheath 144 and the imaging guide wire 146 retracted within the opening 163. The larger guide wire 147 which is part of the assembly can either have been placed first in the arterial vessel by advancing it into the desired position and thereafter introducing the
30 outer sheath over the guide wire 147 by inserting the proximal extremity of the guide wire 146 into the opening 162 and then progressively advancing the outer

sheath 143 over the guide wire until the sheath 143 has reached the proximal end cap 122 of the stenosis 116 in the lumen 103 of the arterial vessel 101. During the procedure, when advancing the distal extremity 153 to
5 the desired position it may be necessary to bend the distal extremity 153 while the proximal extremity 152 is being rotated by hand to cause the distal extremity to be advanced so that it is adjacent the proximal end cap 122. If the large guide wire 147 has been able to
10 penetrate the proximal fibrous cap 122 and advance therethrough and through the plaque 117 and then is deflected by the distal fibrous cap 123 into a false lumen 126 as hereinbefore described, the distal extremity 161 of the outer sheath 143 can be advanced
15 over the guide wire through the proximal fibrous cap 122, then through the plaque 117 and then through the false lumen 126. During the time this is occurring, the imaging guide wire 146 can be advanced a slight distance beyond the soft tip 161 and imaging carried out in the
20 manner hereinbefore described to ascertain the position of the distal extremity of the imaging guide wire 146 and at the same time to ascertain the position of the soft tip 161 of the outer sheath 143. If it is ascertained that the soft tip 161 is in the desired
25 position so as to be able to make possible a penetration of the distal end cap 123, the inner sheath 144 carrying the sharpened distal extremity 221 serving as a needle cannula can be advanced by grasping the proximal extremity 217 and pushing it to cause it to slidably
30 advance through the lumen 157 to push the sharpened tip 221 through the opening 163 at an angle to the longitudinal axis of the inner sheath 144 and through

the perimeter of the distal fibrous end cap 123 while at the same time the imaging guide wire 146 is advanced to continuously ascertain the position of the distal extremity of the guide wire 146 which is coaxially mounted within the inner sheath 144 to thereby progressively monitor the positioning of the distal extremity 218 of the sheath 144 and thereby ascertain when the true lumen 103 has been reached as for example as shown in Figure 8.

10 As soon as it has been ascertained that the tip of the imaging guide wire 146 is in the true lumen 103, the guide wire 147 can be removed along with the outer sheath 143 and the inner sheath 144, leaving the imaging guide wire 146 in place. As soon as this has been
15 accomplished, the devices to be utilized for creating a flow passage through the stenosis 116 can be advanced over the imaging guide 146 as for example a balloon dilatation catheter until the balloon of the balloon dilatation catheter has been advanced through the
20 stenosis 116 with the balloon being in the stenosis and past the distal end cap 123. As soon as this has been accomplished, the imaging guide wire 146 can be removed and the larger sized conventional guide wire 147 can be advanced through the balloon dilatation catheter so that
25 it extends beyond the distal extremity of the balloon dilatation catheter and so that it is disposed within the lumen 103 of the vessel. In connection with the previous embodiment shown in Figure 1, the balloon on the balloon dilatation catheter can now be inflated to
30 compress the plaque 117 forming the stenosis 116 and to also increase the size of the openings through the proximal and distal caps 122 and 123 to provide a

greatly increased flow passage through the stenosis 116
corresponding generally to the size of the lumen 103 to
reestablish blood flow through the stenosis or lesion
116.

5 During the foregoing procedure, it should be
appreciated that a contrast liquid can be introduced
into the vessel during any of the procedures to
facilitate observation fluoroscopically what is
occurring during the procedure. As hereinbefore
10 explained if larger size balloon dilatation catheters
are desired to be utilized, the previous balloon
dilatation catheter can be removed leaving the
conventional larger size guide wire in place and
thereafter advancing other devices as for example a
15 larger size balloon dilatation catheter and thereafter
inflating the balloon to create a still larger flow
passage in the vessel. As hereinafter described it
should be appreciated that if desired a stent can be
deployed into the stenosis by the same or another
20 catheter. Thereafter, the additional catheters can be
removed followed by removal of the larger sized guide
wire and the femoral artery closed in a conventional
manner.

From the foregoing it can be seen that there has
25 been provided a recanalization apparatus and method
which is particularly efficacious for the treatment of
total occlusions and more particularly chronic total
occlusions to reestablish true lumens extending through
the same. In this procedure and by the use of this
30 apparatus it is possible to create true lumens without
the danger of puncturing the vessel wall and which makes

it possible to penetrate fibrous end caps which have convex surfaces facing in a proximal direction.

WHAT IS CLAIMED:

1. A recanalization apparatus for use in crossing
a stenosis forming a total occlusion in a vessel formed
5 by a vessel wall, the stenosis having a distal end cap
which is convex, facing in a proximal direction,
comprising an outer sheath formed of an elongate
flexible tubular member having proximal and distal
extremities and having a lumen extending from the
10 proximal extremity to the distal extremity, an inner
sheath slidably mounted in the lumen of the outer sheath
and being formed of a flexible elongate tubular member
having proximal and distal extremities, the distal
extremity having a sharpened tip, the inner sheath
15 having a length so that when the sharpened tip is
disposed distally of the distal extremity of the outer
sheath, the proximal extremity extends proximally of the
proximal extremity of the outer sheath, an imaging guide
wire slidably mounted in the lumen of the inner sheath
20 and having proximal and distal extremities and a
transducer mounted on the distal extremity of the
imaging guide wire, the imaging guide wire having a
length so that the transducer can extend beyond the
distal extremity of the inner sheath with the proximal
25 extremity extending proximally of the proximal extremity
of the inner sheath.

2. Apparatus as in Claim 1 wherein said outer
sheath, said inner sheath and said imaging guide wire
30 are coaxially mounted with respect to each other.

3. Apparatus as in Claim 1 wherein said outer sheath has first and second spaced-apart lumens and wherein said sheath and said imaging guide wire are disposed in the first lumen together with a conventional
5 guide wire slidably mounted in the second lumen.

4. Apparatus as in Claim 1 together with means connected to the proximal extremity of the imaging guide wire for supplying electrical energy to the transducer.
10

5. Apparatus as in Claim 1 wherein said outer sheath has a shape memory element disposed in the distal extremity, said shape memory element having a predetermined bent shape when heated and means connected
15 to the proximal extremity of the outer sheath for supplying heat to the shape memory element to cause bending of the distal extremity of the outer sheath.

6. Apparatus as in Claim 1 together with means
20 for introducing a flushing solution through the lumen of the outer sheath and through the lumen of the inner sheath.

7. A method for crossing a stenosis forming a
25 total occlusion in a lumen in a vessel formed by a vessel wall, the distal extremity of the stenosis having an end cap which is convex facing in a proximal direction, by the use of an outer sheath having proximal and distal extremities and a lumen extending from the
30 proximal extremity to the distal extremity, an inner sheath slidably mounted in the lumen in the outer sheath and having proximal and distal extremities and having a

lumen extending from the proximal extremity to the distal extremity, the distal extremity having a sharpened tip, the inner sheath having a length so that when its sharpened tip extends beyond the distal

5 extremity of the outer sheath, the proximal extremity extends proximal of the proximal extremity of the outer sheath, an imaging guide wire slidably mounted in the lumen in the inner sheath and having proximal and distal extremities and having a transducer mounted on the

10 proximal extremity, the method comprising advancing the outer sheath so that its distal extremity is in the vicinity of the distal end cap so it engages the convex surface of the end cap and is deflected sideways in the vessel in a direction towards the wall of the vessel to

15 form a false lumen, utilizing the imaging guide wire to image the wall of the vessel during the time that the outer sheath is being advanced to ascertain the position of the distal extremity of the outer sheath, to ascertain when the distal extremity of the inner sheath

20 is facing in a direction which is toward the true lumen in the vessel, advancing the inner sheath to cause the sharpened tip to penetrate through the outer perimeter of the distal end cap and into the true lumen, withdrawing the inner sheath and the outer sheath while

25 leaving the imaging guide wire in place and thereafter advancing at least one device over the imaging guide wire through the distal end cap and into the true lumen to perform additional procedures in the stenosis in the vessel.

8. A method as in Claim 7 wherein the sharpened tip of the distal extremity of the inner sheath is advanced through the distal end cap at an angle with respect to the distal end cap.

5

9. A method as in Claim 7 together with the step of withdrawing the imaging guide wire from the additional device after the at least one additional device has been advanced into the true lumen and
10 thereafter inserting a conventional guide wire into the additional device and advancing it through the stenosis.

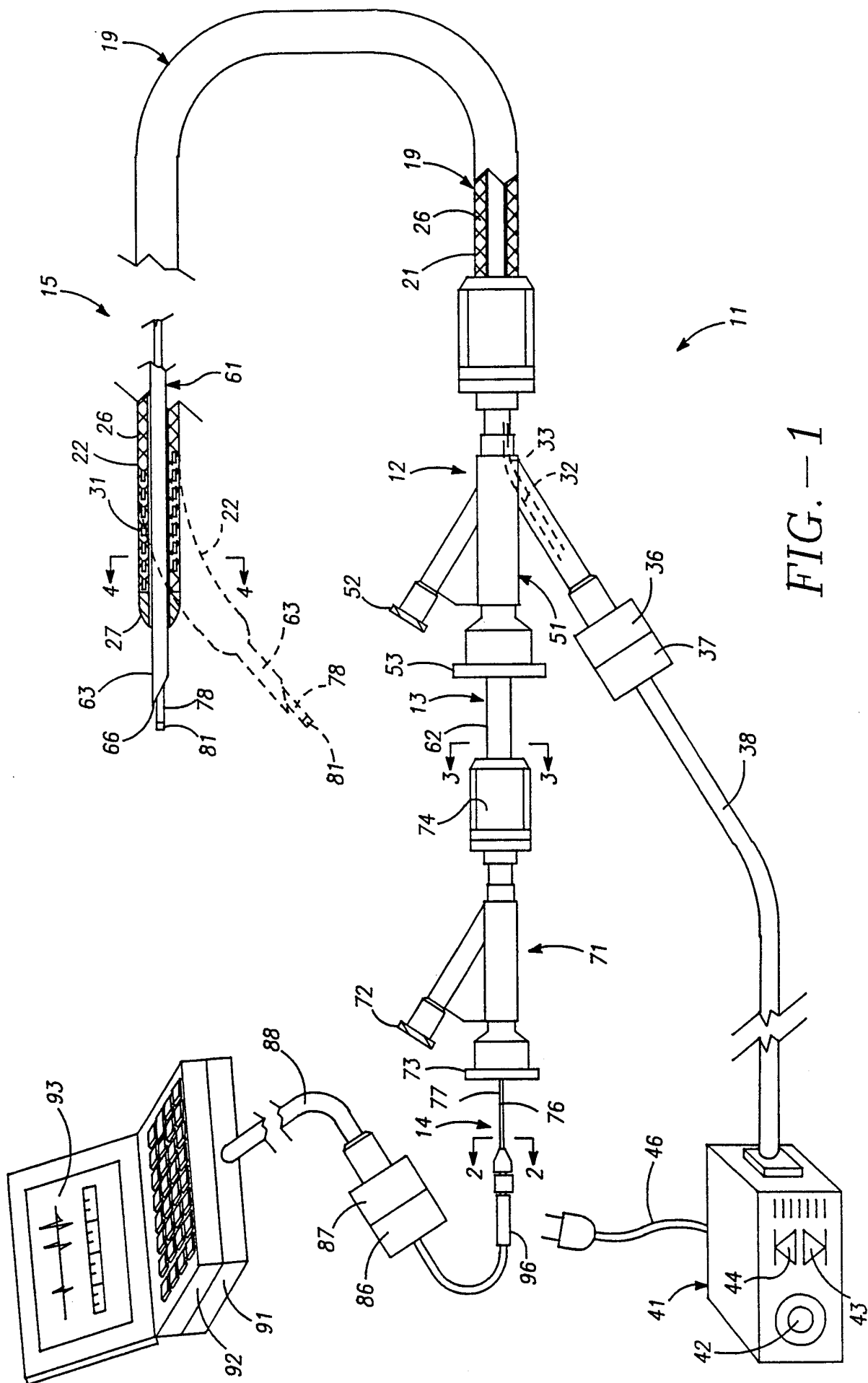
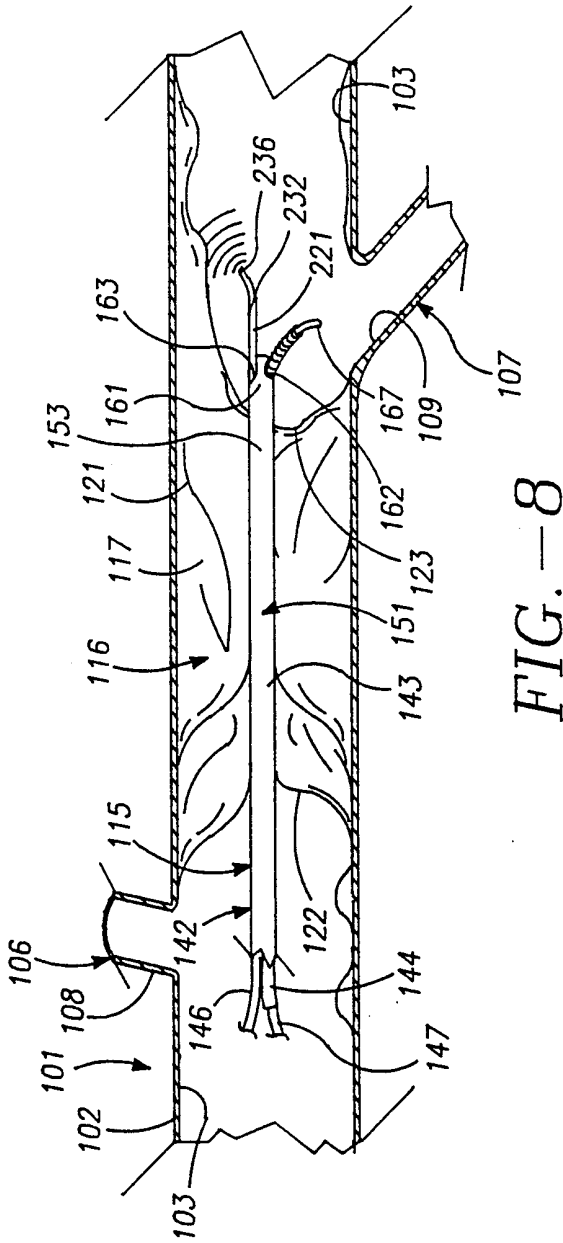
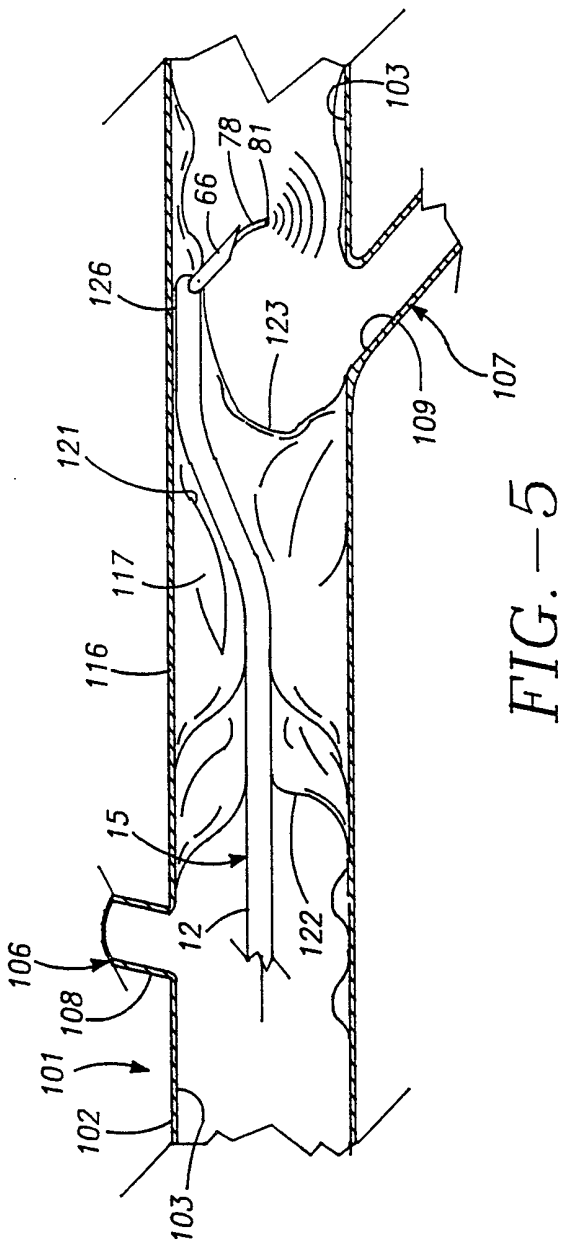
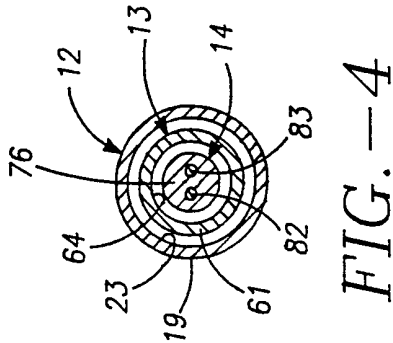
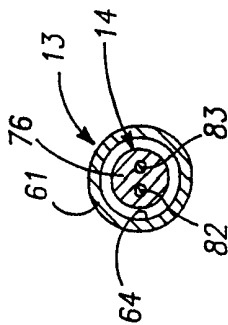
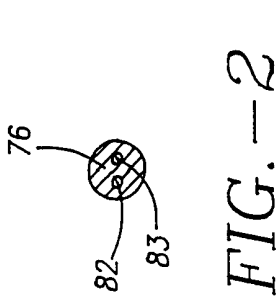


FIG. -1



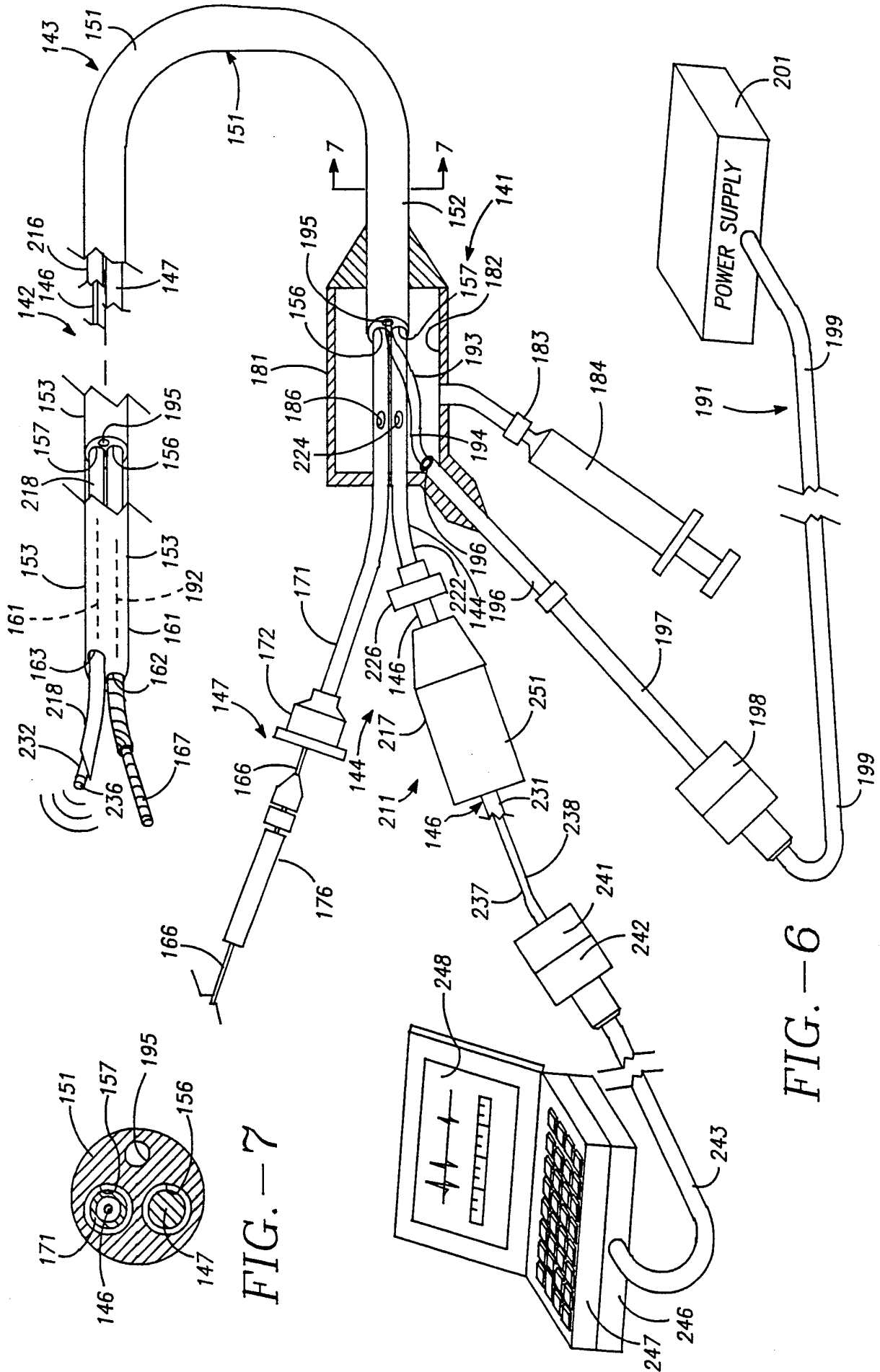


FIG. -6

FIG. -7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/24154

A. CLASSIFICATION OF SUBJECT MATTER IPC(6) : A61B 17/22 US CL : 606/159 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 604/272, 280, 282; 606/001, 108, 159, 167, 170 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,531,685 A (HEMMER et al) 02 July 1996, entire document.	5
Y	US 5,520,189 A (MALINOWSKI et al) 28 May 1996, entire document.	1, 2, 4-6
Y	EP 0 229 620 A (AUTH) 22 July 1987, entire document.	1, 2, 4-6
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
A	document defining the general state of the art which is not considered to be of particular relevance	*T*
E	earlier document published on or after the international filing date	*X*
L	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y*
O	document referring to an oral disclosure, use, exhibition or other means	*Z*
P	document published prior to the international filing date but later than the priority date claimed	*G*
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		document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
		document member of the same patent family
Date of the actual completion of the international search 21 DECEMBER 1998		Date of mailing of the international search report 15 JAN 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer: <i>Glenn K. Dawson</i> GLENN K. DAWSON Telephone No. (703) 308-4304