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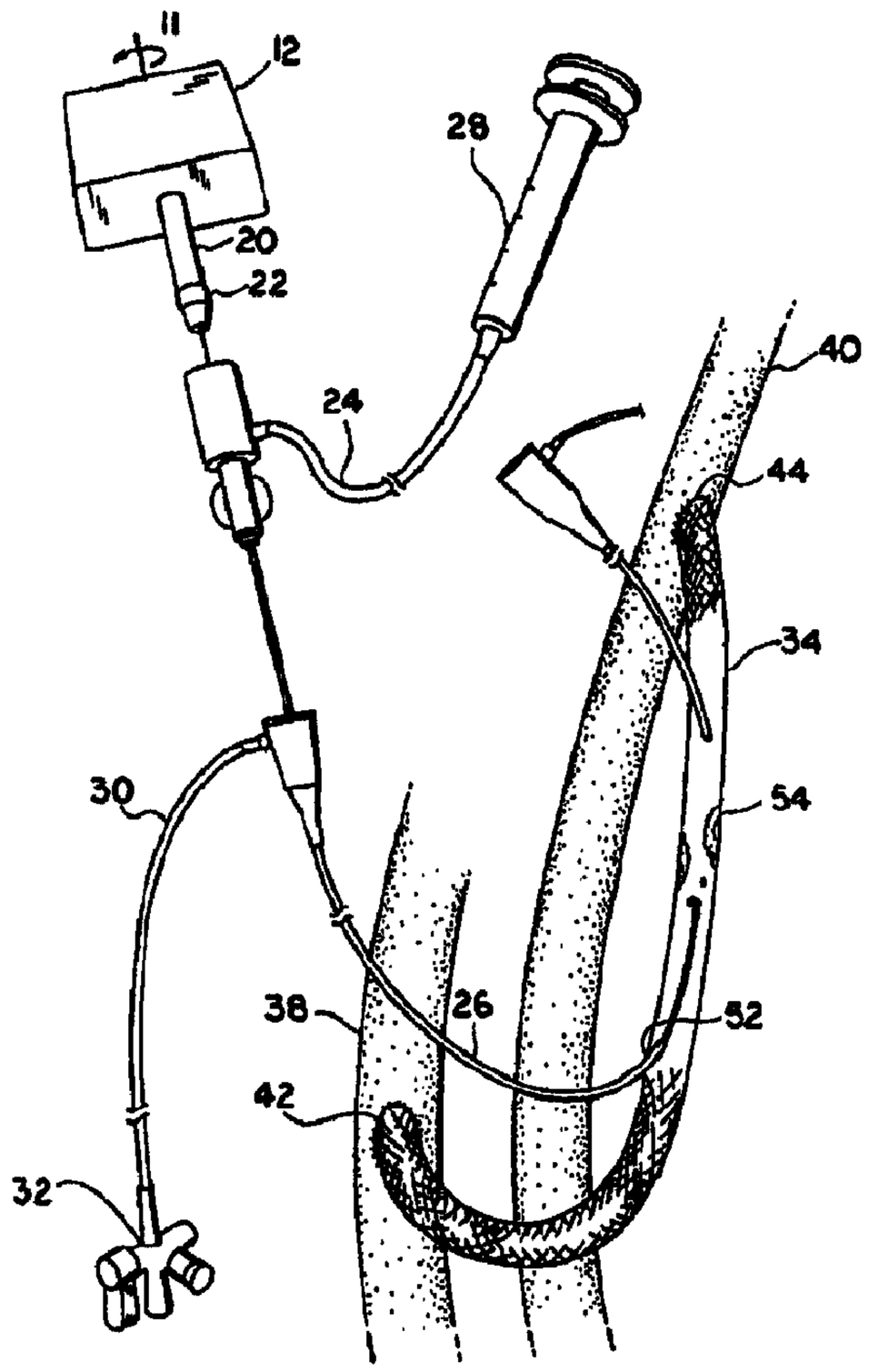


(57) Abrégé/Abstract:
The method and apparatus for clearing lumens of thrombolytic material includes a motor having control means for operable using one hand holding the motor, an elongated wire connected to the motor and rotatable thereby, a catheter for enveloping a length of

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(57) Abrégé(suite)/Abstract(continued):
the wire and gripping means facilitating manual rotation of the catheter by one hand independently of the wire as the wire is rotated by the motor at a speed sufficient to create a standing wave in a portion of the wire extending from the catheter.

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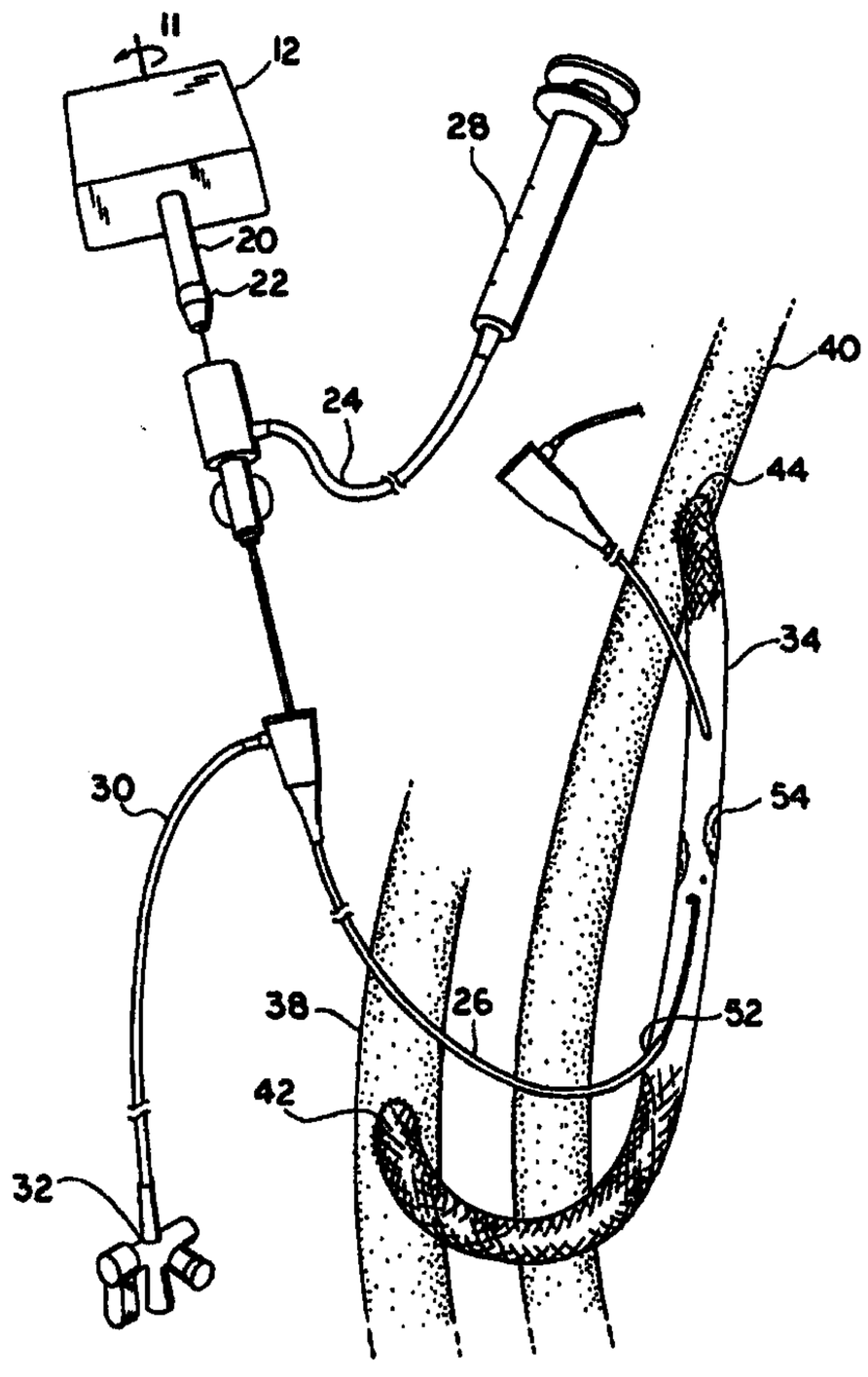
**(54) Title:** ROTATIONAL THROMBECTOMY APPARATUS AND METHOD WITH STANDING WAVE

**(57) Abstract**

The method and apparatus for clearing lumens of thrombolytic material includes a motor having control means for operable using one hand holding the motor, an elongated wire connected to the motor and rotatable thereby, a catheter for enveloping a length of the wire and gripping means facilitating manual rotation of the catheter by one hand independently of the wire as the wire is rotated by the motor at a speed sufficient to create a standing wave in a portion of the wire extending from the catheter.



# ROTATIONAL THROMBECTOMY APPARATUS WITH STANDING WAVE

## Field of the Invention

This invention relates to surgical apparatus for use in clearing recurring thrombosis of hemodialysis grafts.

## Background of the Invention and Description of the Prior Art

Modern hernodialysis technology enables patients with chronic renal failure to live independently between dialysis treatments. Patients utilize this technology as a means of filtering the toxins from their blood by passing blood out of their body through a hemodialysis machine. The hemodialysis machine removes blood toxins by exposing the blood to dialyzing fluid across a semipermeable membrane, in effect creating an artificial kidney.

In order to properly process a patient's blood a graft is made, preferably in patient's arm. At the site of the graft a shunt is placed to connect an artery having a high rate of blood flow with a vein. The shunt provides a convenient inlet on the artery side for blood requiring dialysis filtration processing; the outlet is located on the vein side for return of dialysis processed blood from the hemodialysis station.

The dialysis shunt, while providing a convenient arrangement for hemodialysis processing, may become inoperable after a period of time due to stenosis caused by the high rate

of blood flow through the shunt and repetitive injury at the venous anastomosis. Typically, patients must have these constricting portions of the shunt widened periodically in order to continue hemodialysis processing through the shunt.

Shunt blockage is generally treated through a combination of surgical devices and/or pharmaceutical treatments; these techniques are often cost prohibitive and/or require an incision. For example, pharmaceutical treatments generally employ urokinase which, depending on the amount used, can be costly for each application and possibly cause bleeding complications.

Mechanical thrombolysis apparatus and methods for performing thrombolysis are known, being disclosed in United States patents 4,646,736 to Auth, 5,078,722 to Stevens and 5,696,507 to Auth et al.

The apparatus disclosed in these patents seeks to penetrate thrombolytic structures by introducing, for example in the case of '507, a rotating core wire into the thrombus, seeking to withdraw fibrin from the thrombus into the rotating core wire thereby breaking up the network of the thrombus which is preventing blood flow.

## Summary of the Invention

In one aspect of the present invention there is provided an apparatus for clearing lumens of thrombolytic material including the combination of a motor including speed control

means therefor, an elongated wire connected to the motor for rotation thereof by the motor and a catheter extending from the motor and enveloping only a part of the wire, the improvement characterized by the rotatable elongated wire having a uniform diameter tip portion which is asymmetrical respecting the wire axis, the motor and the control means being facilely operable using one hand holding the motor for rotating the wire at a speed sufficient to form a standing wave having at least one node in the portion of the wire extending from the catheter resulting from the asymmetrical configuration of the wire tip remote from the motor, movement of the motor in the direction of elongation of the wire serving to move the wire axially within the lumen as the wire has a standing wave formed therein with wire rotation in the standing wave form circumferentially sweeping the lumen clear of thrombolytic material, the wire portion extending from the catheter being of uniform diameter to and including the wire tip portion remote from the catheter, and gripping means facilitating manual rotation and axial movement of the catheter independently of the wire by hand holding the motor as the wire is rotated by the motor to form the standing wave in at least the portion of the wire extending from the catheter.

It is desirable the extremity of the catheter remote from the motor and proximate to the tip portion of the wire is

angularly disposed with respect to the remainder of the catheter, the tip portion of the wire remote from the catheter is J-shaped and a housing for the motor and the control means, adapted for grasping by one hand, wherein the wire passes through the housing and emerges from opposite sides thereof.

It is also desirable the wire is twisted and the motor rotates the wire in a direction opposite to the twist, the wire tip is disposed at an angle respecting the axis of rotation of the wire, the wire tip is J-shaped and extending back towards the motor.

Further, it is preferable a conduit communicating with the interior of the catheter for selectably supplying or exhausting fluid to and from the interior of the catheter; a tubular sheath enveloping the catheter; a second conduit communicating with the interior of the sheath for selectably supplying or exhausting fluid to and from the interior of the sheath outside of the catheter; the wire tip being at an angle respecting the axis of rotation of the wire and extending axially outwardly beyond the catheter and the sheath, the gripping means being fixedly connected to the conduit communicating with the catheter for rotating the catheter, the conduits, the motor, the catheter and the wire all being manually disassemblable one from another without use of tools, and the wire being twisted and the motor rotating the wire in

a direction opposite to the twist.

Desirably, a housing for the motor and the control is adapted for grasping by one hand for operator control of the apparatus, with a portion of the wire remote from the catheter passing through the housing and emerging therefrom in a direction opposite that of the catheter, a housing for the motor and the control is adapted for grasping by one hand for operator control of the apparatus, with a portion of the wire remote from the catheter passing through the housing and emerging therefrom in a direction opposite that of the catheter and the sheath.

In another aspect of the present invention there is provided an apparatus for clearing lumens of thrombolytic material, comprising:

a) a motor including control means therefor operable using one hand holding the motor;

b) an elongated wire connected to the motor for rotation thereof by the motor;

c) a catheter for enveloping a length of the wire;

d) gripping means facilitating manual rotation of the catheter by the one hand independently of the wire as the wire is rotated by the motor at a speed sufficient to create a standing wave in a portion of the wire extending from the catheter;

e) first conduit means communicating with the interior of the catheter for selectably supplying or exhausting fluid to and from the catheter interior;

f) a sheath enveloping the catheter; and

g) second conduit means communicating with the interior of the sheath for selectably supplying or exhausting fluid to and from the sheath interior externally of the catheter, the second conduit means being movable longitudinally along the wire with the sheath.

Preferably, the above aspect further comprises manually actuable means for selectably connecting the wire to the motor, the gripping means is fixedly connected to the first conduit means communicating with the catheter interior and rotatable unitarily therewith about the wire, the wire is hydrophilic, not permanently deformable at room temperature, the extremity of the wire remote from the catheter is angularly disposed with respect to the remainder of the wire, and an extremity portion of the catheter is angularly disposed with respect to the catheter.

It is also desirable the extremity of the catheter remote from the motor is angularly disposed with respect to the remainder of the catheter, the catheter is sufficiently resistive to twisting that torque manually applied to the catheter proximate the motor results in angular movement of the

extremity of the catheter remote from the motor, the extremity of the wire remote from the catheter is J-shaped, and the second conduit, the sheath, the motor, the catheter, the first conduit and the wire are all manually disassemblable from one another.

Moreover, it is preferable there is further provided a housing for the motor and the control means, adapted for grasping by the one hand, wherein the wire passes through the housing and emerges from opposite sides thereof, and the motor is electrically powered.

In another embodiment of the present invention there is provided an apparatus for clearing thrombus from a shunt or body lumen characterized by a motor, a single non-abrasive flexible wire element for guiding a catheter to the desired site, the wire element operatively connected to the motor, the catheter enveloping a length of the wire element and relatively movable with respect to the wire element to control an amount of a distal portion of the wire element exposed, the wire element activated by the motor for rotational movement with respect to the catheter, without rotation of the catheter, creating multiple vortices along its length such that an outer surface of the wire element directly contacts and macerates thrombus within the shunt or body lumen, and wherein during rotation of the wire element an axis of

rotation is different from a curvature of the wire element, and a first conduit communicating with the catheter.

In all of the above embodiments, desirably, the wire is braided, the wire element is rotated in a direction to resist untwisting of the braid, the wire is a filament, the extremity of the filament extending from the catheter is at an angle to an axis of the filament, and the catheter is manually rotatable.

Desirably, the above embodiment further comprises a sheath enveloping the catheter and a second conduit communicating with the interior of the sheath and externally of the catheter.

It is desirable the apparatus in the above embodiment provided is for use for clearing a lumen of thrombolytic material.

More particularly, in the present invention there is provided the use of an apparatus for clearing a lumen of thrombolytic material, in which the apparatus has a rotatable wire adapted for insertion into the interior of a lumen, the wire being hydrophilic and rotatable at a speed at which the wire forms at least one vibrational node in the portion of the wire within the lumen.

Desirably, the apparatus includes a motor for rotating the wire within the lumen at a speed at which the wire forms at least one vibrational node in the portion of the wire within the lumen; the motor being adapted to move the wire along the lumen; and said wire having a surrounding catheter for controlling orientation of the wire within the lumen, the motor is a hand held motor and the wire is movable axially along the lumen by manually moving the motor; and having a surrounding catheter manually controlling angular orientation of the wire within the lumen, and the apparatus is adapted to be manually operable.

There is also provided in one embodiment of the present invention the use of an apparatus for clearing a surgical lumen or similar body lumen of thrombolytic material wherein the apparatus is adapted to form an aperture in the lumen to insert the rotatable hydrophilic wire into the interior of the lumen through the aperture; the wire being rotatable within the lumen at a speed sufficient to create a standing wave in the portion of the wire within the lumen.

It is preferable the wire is movable with the at least one vibrational node therein axially along the lumen to rotationally sweep thrombolytic material from the lumen, the wire includes a portion extending beyond the surrounding catheter is adapted to be inserted into the interior of the

lumen, the catheter is a non-rotatable catheter when the rotatable wire is within the lumen at a speed at which the wire forms at least one vibrational node in the portion of the wire within the lumen, and the apparatus is manually operable.

It is also preferable the wire macerates the thrombolytic material within the lumen to produce a standing column of liquified material within the lumen, the apparatus is adapted to remove the liquified material from the lumen, and the wire is rotatable at a speed of from about 100 to about 10,000 RPM.

**Brief Description of the Drawings**

Figure 1 which is presented as Figures 1(a) through 1(f) on separate pages, is a flow chart of a surgical method utilizing the apparatus of the present invention.

Figure 2 is a partially exploded side sectional view of one embodiment of apparatus manifesting aspects of the invention.

Figure 3 is an unexploded top view of the apparatus shown in Figure 2.

Figure 4 is a top view of a second embodiment of apparatus in which the rotating wire extends through the handpiece.

Figure 5 illustrates apparatus in accordance with the invention in place within a dialysis shunt.

Figure 6 is a broken view illustrating an embodiment of

the apparatus having a catheter with a bent end to facilitate directional control of the wire.

Figure 7 is a schematic illustrating hand operation of the apparatus in accordance with the invention.

Figure 8 depicts rotation of the wire in the catheter.

Figure 9 shows the standing wave formed by the wire resident in the shunt.

Figures 10 through 13 are alternative tip configurations of the rotating wire.

**Detailed Description of the Preferred Embodiment**

This invention provides a surgical apparatus and method for clearing of dialysis shunt blockages in hemodialysis patients.

Part of the surgical apparatus rotates, separating the blockage material from the inside surface of the dialysis shunt while macerating any thrombus within the shunt. Thus, the shunt is cleared with a minimum of trauma and without use of costly pharmaceuticals.

Referring to Figures 2 through 4, the surgical apparatus in accordance with the invention is generally designated 10 and includes a rotatable hydrophilic wire 16 with a deformed tip 25.

Wire 16 rotates about an axis 11. Rotation of wire 16 of apparatus 10 is preferably performed by an electric motor 12, equipped with a mechanical hand control. However, wire 16 may be turned by a pneumatic or hydraulic motor or even manually.

Hydrophilic wire 16 is preferably selected such that it rotates and oscillates so that a maximum number of points of maximum deflection between nodes of the standing wave reach the inner shunt wall to scour and remove adherent thrombus.

Apparatus 10 may be utilized to perform a number of procedures. Wire 16 is advanced through a catheter entrance port 52 of a dialysis shunt 34. Wire 16 is advanced along the interior surface of shunt 34 in the direction of a blockage; the tip of wire 16 may be translated into a thrombus, extending out of a distal tip of a directional lubricated catheter by the operator handling apparatus 10. As wire tip 25 rotates about axis 11, an adherent clot is separated from the interior surface 54 of dialysis shunt 34 by rotating contact of deformable wire tip 25 as well as oscillatory flexing of wire 16 in both directions along the longitudinal axis of the shunt as a standing

wave is desirably formed in wire 16.

The clot material is broken up by rotation of wire 16 sufficiently such that passage of clot material does not present a physiological problem for the patient; alternatively the clot material may be aspirated out of the shunt via an access port.

Referring to Figures 2, 3 and 4, motor 12 preferably includes control means for the motor which is operable using the hand which holds the motor. One hand preferably grasps motor 12 and operates the control means therefor. Elongated wire 16, which is also sometime called the instrument wire, is connected to motor 12 for rotation thereof by motor 12. A catheter 18 envelops wire 16. The tubular gripping means 20 fits about catheter 18 to facilitate manual rotation of catheter 18. A manually chuck 22 provides means for selectively connecting wire 16 to motor 12.

A first conduit 24 is provided communicating with the interior of catheter 18 via a first fitting 28 which connects the first conduit to the interior of catheter 18. A second conduit 30 provides communication with the interior of sheath 26 via a second fitting 32 providing such connection. A surgical shunt 34 is provided between the vein and artery of the patient to under dialysis.

In the apparatus illustrated in Figures 2 and 3, motor 12 turns wire 16 while catheter 18 is rotated by manually actuating gripping means 20. Gripping means 20 together with fitting 28 is moveable axially along wire 16 to control the amount of wire 16 which is exposed beyond the extremity of catheter 18.

In the embodiment of the apparatus illustrated in Figure 4, wire 16 desirably extends out the rear of a housing for motor 12. This facilitates withdrawal of wire 16 to and from the shunt, artery and vein of interest.

In the embodiment illustrated in Figure 4, a second fitting 32 has not been provided nor has a second conduit been provided for input of fluid to interior of sheath 26.

The portion of wire 16 which is exposed beyond the tip of catheter 18 is designated 50 in the drawings.

Not only are first fitting 28 and first conduit 24 moveable together with gripping means 20 with catheter 18 respecting wire 16 but also second fitting 32 and second conduit 30 are preferably moveable with sheath 26 relative to wire 16.

The extremity of wire 16 remote from the catheter, denoted 50 in the drawings, may be angularly disposed with respect to the remainder of the wire. Alternatively, extremity 50 and wire 16 remote from the tip end of the catheter may be J-shaped.

The extremity portion of catheter 18 remote from motor 12 may be angularly disposed with respect to the remainder of the catheter; this configuration helps positioning of exposed portion of wire 16 by manual movement of catheter 18.

Preferably, second conduit 30, second fitting 32, sheath 26, motor 12, catheter 18, first conduit 24, fitting 28 and wire 16 are all manually disassemblable from one another.

Figure 5 depicts the apparatus according to one of the aspects of the invention in place within a surgical dialysis shunt where the shunt is denoted generally 34 and connects a vein 38 with an artery 40. Vein shunt-juncture is denoted 42 while

artery shunt-juncture is denoted 44.

In the practice of the method of the invention for clearing a lumen or shunt of thrombolytic material, rotatable hydrophilic wire 16 is inserted into the interior of the shunt or lumen through a suitable aperture which may be created by puncturing the shunt or lumen with a needle. The wire is then rotated within the lumen at a speed of which the wire forms at least one vibrational node in the portion of the wire within the lumen; this configuration of the wire is depicted in Figure 8. The wire is preferably moved with the vibrational nodes therein axially along the lumen to rotational sweep the thrombolytic material from the lumen; this motion is depicted by arrow A in Figure 8. Preferably not only the wire but also the catheter extremity is inserted into the lumen through the selected aperture. When the wire is rotated, the catheter is maintained stationary relative to the wire and is manually manipulated in order to guide the wire through the shunt and, as necessary, into the shunt-vein or shunt-artery juncture and in the course of performing the most comprehensive aspect of the method of the invention, into the vein or artery to cleanse thrombolytic material therefrom.

The wire is preferably rotated at a speed at which the wire forms at least one vibrational node in the portion 55 of wire 16 extending from catheter 18 into the lumen or shunt. All of this is performed while grasping motor 12 with one hand. Motor 12 preferably has a control by the thumb or forefinger of the hand holding motor 12 so that by using a single hand, the physician or other attending health professional can control not only rotation of wire 16 but also position of catheter 18 thereby

controlling the position of wire 16 within the shunt or other lumen to be cleansed. This frees the second hand of the operator to supply medication or lubricant through conduits 24 or 30 or to perform other activity.

As illustrated in Figure 8, the wire 16 is preferably braided and is rotated in a direction to resist untwisting of the braid.

Manual manipulation of the catheter is illustrated in Figure 7. The angular tip of the catheter 18 when rotated by hand as illustrated permits accurate and close positioning of exposed portion 50 of rotating wire 16. The preferred angular orientation of catheter 18 is illustrated in Figure 6.

Catheter 18 is preferably sufficiently resistive to twisting that torque manually applied to the catheter proximate to motor 12, for example via gripping means 20, causes corresponding angular movement of the extremity of the catheter remote from the motor.

While a braided wire is preferable, a filament wire may be used.

The motor is preferably operated to rotate the wire at a speed to create at least one vibrational node therein. The rotation speed of the wire may be from about 100 revolutions per minute to about 10,000 revolutions per minute. The motor used to turn the wire is desirably electrically powered but may also be pneumatically or hydraulically powered. Also, the wire 16 may be rotated manually if necessary.

Not only does the invention have utility with respect to cleansing of dialysis shunts and the juncture of such shunts with

veins and arteries, the invention also has utility in cleansing such arteries and veins blockages all the way to the heart.

This comprehensive shunt/vein/artery cleansing procedure begins with inserting a needle through skin and into the shunt. The next step is that of inserting a small wire through the needle. The next step is that of using the tactile sensation transmitted by the wire to determine whether the wire is in the shunt. The next step is that of inspecting the skin site with x-ray to determine position of the wire and whether it is within the shunt.

The next step is that of removing the needle when the wire is determined to be in the shunt interior. The next step is that of placing a small catheter over wire with the discharge orifice within the shunt. The next step is that of removing the wire leaving the catheter with its discharge end within the shunt.

The next step is that of inserting a larger wire through the catheter into the shunt interior. The next step is that of removing the catheter. The next step is that of inserting a sheath over the larger wire and into the shunt.

The next step is that of removing the larger second wire. The next step is that of inserting an instrument wire and the catheter through the sheath. The next step is that of supplying lubricating fluid to the catheter interior.

The next step is that of rotating the wire, but not the catheter, and sweeping through the graft to liquify thrombus material therein. The next step is that of removing the instrument wire and the catheter from the sheath. The next step is that of applying suction to the sheath to remove liquid

thrombus material from the shunt.

The next step is that of inserting a anti-coagulant into the shunt through the sheath. The next step is that of removing the instrument wire from the catheter. The next step is that of disconnecting the instrument wire from the motor.

The next step is that of re-inserting the instrument wire without the catheter through the sheath into the shunt, through any blockage at the shunt end into the vein. The next step is that of placing an angioplasty balloon over the wire. The next step is that of pushing a balloon into position within venous anastomosis at vein-shunt juncture. The next step is that of removing the wire leaving the angioplasty balloon in position.

The next step is that of injecting contrast radiology dye through the balloon lumen vacated by the wire. The next step is that of observing dye travel through the vein to the heart using a fluoroscope revealing any additional venous blockages. The next step is that of inserting a wire back into the balloon lumen. The next step is that of inflating the balloon to crush venous anastomosis and open the shunt-vein juncture.

The next step is that of removing the balloon and wire. The next step is that of inserting a second sheath between the position of the first sheath insertion and shunt-vein juncture, into a clean shunt region. The next step is that of re-inserting the instrument wire without the catheter through the sheath into the shunt, through any blockage at the shunt-artery juncture. The next step is that of placing an angioplasty balloon over the wire.

The next step is that of pushing the balloon into position within arterial anastomosis at artery-shunt juncture. The next step is that of removing the wire leaving the angioplasty balloon in position. The next step is that of injecting contrast radiology dye through the balloon lumen vacated by the wire.

The next step is that of observing dye travel through the artery to the heart using a fluoroscope and revealing any additional arterial blockages. The next step is that of inserting a wire back into the balloon lumen.

The next step is that of inflating the balloon to crush any arterial anastomosis and open the shunt-artery juncture. The next step is that of removing a platelet plug and residual arterial anastomosis from the shunt-artery juncture by pulling on the balloon. The final step is that of removing the balloon, wire and the sheath.

**CLAIMS:**

1. In apparatus for clearing lumens of thrombolytic material including the combination of a motor including speed control means therefor, an elongated wire connected to the motor for rotation thereof by the motor and a catheter extending from the motor and enveloping only a part of the wire, the improvement characterized by the rotatable elongated wire having a uniform diameter tip portion which is asymmetrical respecting the wire axis, the motor and the control means being facilely operable using one hand holding the motor for rotating the wire at a speed sufficient to form a standing wave having at least one node in the portion of the wire extending from the catheter resulting from the asymmetrical configuration of the wire tip remote from the motor, movement of the motor in the direction of elongation of the wire serving to move the wire axially within the lumen as the wire has a standing wave formed therein with wire rotation in the standing wave form circumferentially sweeping the lumen clear of thrombolytic material, the wire portion extending from said catheter being of uniform diameter to and including the wire tip portion remote from the catheter, and gripping means facilitating manual rotation and axial movement of the catheter independently of the wire by hand holding the motor as the wire is rotated by the motor to form the standing wave in at least the portion of the wire extending from the catheter.

2. Lumen clearing apparatus of claim 1 further characterized by the extremity of the catheter remote from the motor and proximate to the tip portion of the wire being angularly disposed with respect to the remainder of the catheter.

3. Lumen clearing apparatus of claim 1 or claim 2 further characterized by the tip portion of the wire remote from the catheter being J-shaped.

4. Lumen clearing apparatus of any one of claims 1 to 3 further characterized by a housing for the motor and the control means, adapted for grasping by one hand, wherein the wire passes through said housing and emerges from opposite sides thereof.

5. Lumen clearing apparatus of any one of claims 1 to 4 further characterized by the wire being twisted and the motor rotates the wire in a direction opposite to the twist.

6. Lumen clearing apparatus of any one of claims 1 to 5 further characterized by the wire tip being disposed at an angle respecting the axis of rotation of the wire.

7. Lumen clearing apparatus of any one of claims 1 to 6 further characterized by the wire tip being J-shaped and extending back towards the motor.

8. Lumen clearing apparatus of any one of claims 1 to 7 further characterized by a conduit communicating with the interior of the catheter for selectably supplying or exhausting fluid to and from the interior of the catheter; a tubular sheath enveloping the catheter; a second conduit communicating with the interior of the sheath for selectably supplying or exhausting fluid to and from the interior of the sheath outside of the catheter; the wire tip being at an angle respecting the axis of rotation of the wire and extending axially

outwardly beyond the catheter and the sheath.

9. Lumen clearing apparatus of claim 8 further characterized by gripping means being fixedly connected to the conduit communicating with the catheter for rotating the catheter.

10. Lumen clearing apparatus of claim 8 or claim 9 further characterized by the conduits, the motor, the catheter and the wire all being manually disassemblable one from another without use of tools.

11. Lumen clearing apparatus of any one of claims 1 to 10 further characterized by the wire being twisted and the motor rotating the wire in a direction opposite to the twist.

12. Lumen clearing apparatus of any one of claims 1 to 11 further characterized by a housing for the motor and the control being adapted for grasping by one hand for operator control of the apparatus, with a portion of the wire remote from the catheter passing through the housing and emerging therefrom in a direction opposite that of the catheter.

13. Lumen clearing apparatus of any one of claims 8 to 10 further characterized by a housing for the motor and the control being adapted for grasping by one hand for operator control of the apparatus, with a portion of the wire remote from the catheter passing through the housing and emerging therefrom in a direction opposite that of the catheter and the sheath.

14. Apparatus for clearing lumens of thrombolytic material, comprising:

a) a motor including control means therefor operable using one hand holding said motor;

b) an elongated wire connected to said motor for rotation thereof by said motor;

c) a catheter for enveloping a length of said wire;

d) gripping means facilitating manual rotation of said catheter by said one hand independently of said wire as said wire is rotated by said motor at a speed sufficient to create a standing wave in a portion of said wire extending from said catheter;

e) first conduit means communicating with the interior of said catheter for selectably supplying or exhausting fluid to and from said catheter interior;

f) a sheath enveloping said catheter; and

g) second conduit means communicating with the interior of said sheath for selectably supplying or exhausting fluid to and from said sheath interior externally of said catheter, said second conduit means being movable longitudinally along said wire with said sheath.

15. Apparatus of claim 14 further comprising manually actuable means for selectably connecting said wire to said motor.

16. Apparatus of claim 14 or claim 15 wherein said gripping means is fixedly connected to said first conduit means communicating with said catheter interior and rotatable unitarily therewith about said wire.

17. Apparatus of any one of claims 14 to 16 wherein said wire is hydrophilic.

18. Apparatus of any one of claims 14 to 17 wherein said wire is not permanently deformable at room temperature.

19. Apparatus of any one of claims 14 to 18 wherein the extremity of said wire remote from said catheter is angularly disposed with respect to the remainder of said wire.

20. Apparatus of any one of claims 14 to 19 wherein the extremity of said catheter remote from said motor is angularly disposed with respect to the remainder of said catheter.

21. Apparatus of any one of claims 14 to 20 wherein said catheter is sufficiently resistive to twisting that torque manually applied to said catheter proximate said motor results in angular movement of the extremity of said catheter remote from said motor.

22. Apparatus of any one of claims 14 to 21 wherein the extremity of said wire remote from said catheter is J-shaped.

23. Apparatus of any one of claims 14 to 22 wherein said second conduit, said sheath, said motor, said catheter, said first conduit and said wire are all manually disassemblable from one another.

24. Apparatus of any one of claims 14 to 23 further characterized by a housing for said motor and said control means, adapted for grasping by said one hand, wherein said wire passes through said housing and emerges from opposite sides thereof.

25. Apparatus of any one of claims 14 to 24 wherein said motor is electrically powered.

26. An apparatus for clearing thrombus from a shunt or body lumen characterized by a motor, a single non-abrasive flexible wire element for guiding a catheter to the desired site, the wire element operatively connected to the motor, the catheter enveloping a length of the wire element and relatively movable with respect to the wire element to control an amount of a distal portion of the wire element exposed, the wire element activated by the motor for rotational movement with respect to the catheter, without rotation of the catheter, creating multiple vortices along its length such that an outer surface of the wire element directly contacts and macerates thrombus within the shunt or body lumen, and wherein during rotation of the wire element an axis of rotation is different from a curvature of the wire element, and a first conduit communicating with the catheter.

27. Apparatus of any one of claims 1 to 26 wherein said wire is braided.

28. The apparatus of claim 27 wherein the wire element is rotated in a direction to resist untwisting of the braid.

29. Apparatus of any one of claims 1 to 28 wherein said wire is a filament.

30. Apparatus of claim 29 wherein the extremity of said filament extending from said catheter is at an angle to an axis of said filament.

31. The apparatus of any one of claims 1 to 30 wherein the catheter is manually rotatable.

32. The apparatus of claim 18 wherein an extremity portion of the catheter is angularly disposed with respect to the catheter.

33. The apparatus of any one of claims 1 to 7 and claims 26 to 32 further comprising a sheath enveloping the catheter and a second conduit communicating with the interior of the sheath and externally of the catheter.

34. Use of the apparatus of any one of claims 1 to 33, for clearing a lumen of thrombolytic material.

35. Use of an apparatus for clearing a lumen of thrombolytic material, in which the apparatus has a rotatable wire adapted for insertion into the interior of a lumen, the wire being hydrophilic and rotatable at a speed at which the wire forms at least one vibrational node in the portion of the wire within the lumen.

36. The use according to claim 35 wherein the apparatus includes a motor for rotating the wire within the lumen at a speed at which the wire forms at least one vibrational node in the portion of the wire within the lumen; the motor being adapted to move the wire along the lumen; and said wire having a surrounding catheter for controlling orientation of the wire within the lumen.

37. The use according to claim 34 to claim 36, wherein the motor is a hand held motor and the wire is movable axially along the lumen by manually moving the motor; and having a surrounding catheter manually controlling angular orientation of the wire within the lumen.

38. The use according to any one of claims 34 to 37 wherein the apparatus is adapted to be manually operable.

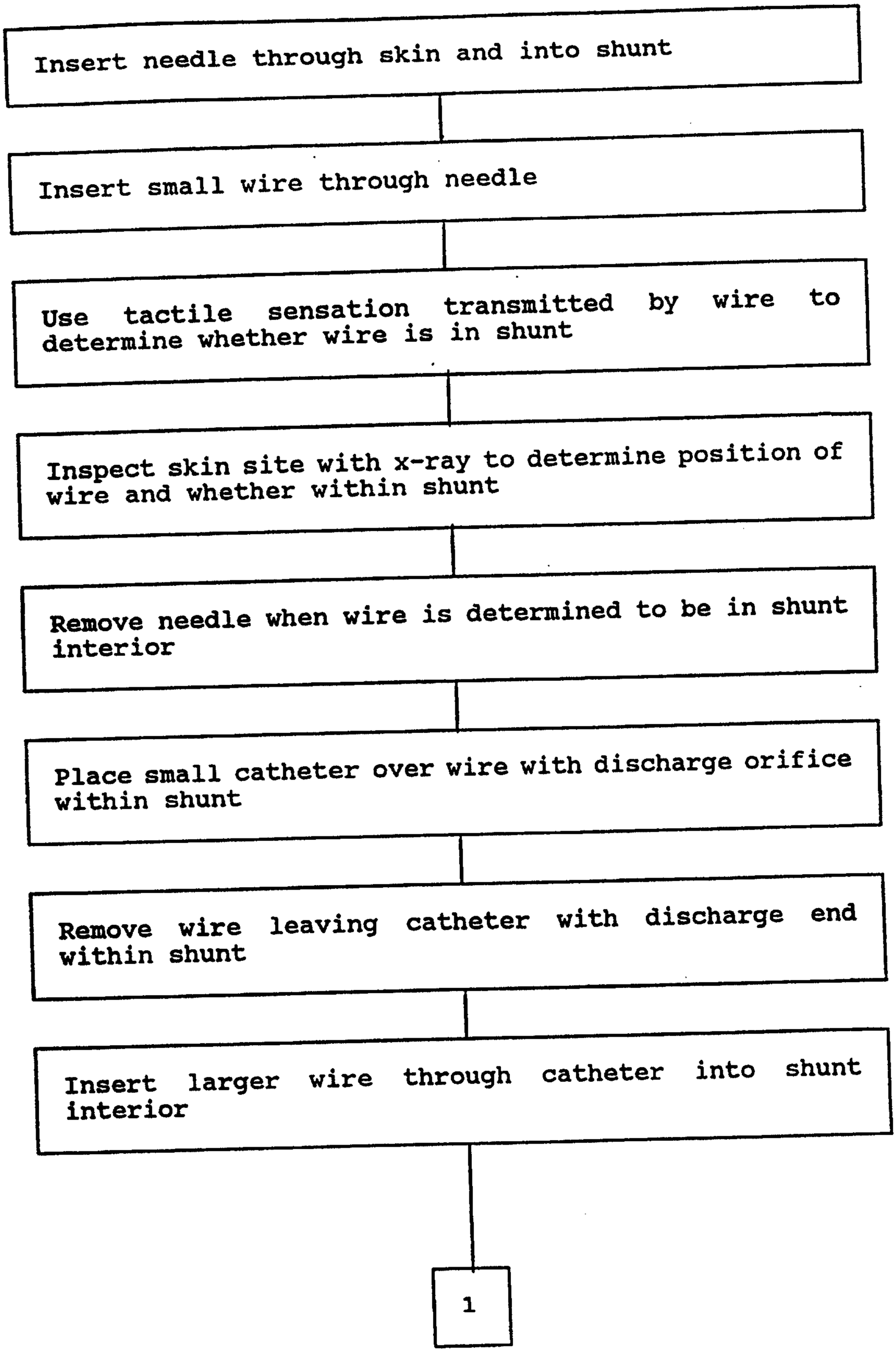

Insert needle through skin and into shunt
Insert small wire through needle
Use tactile sensation transmitted by wire to determine whether wire is in shunt
Inspect skin site with x-ray to determine position of wire and whether within shunt
Remove needle when wire is determined to be in shunt interior
Place small catheter over wire with discharge orifice within shunt
Remove wire leaving catheter with discharge end within shunt
Insert larger wire through catheter into shunt interior
1

Figure 1(a)

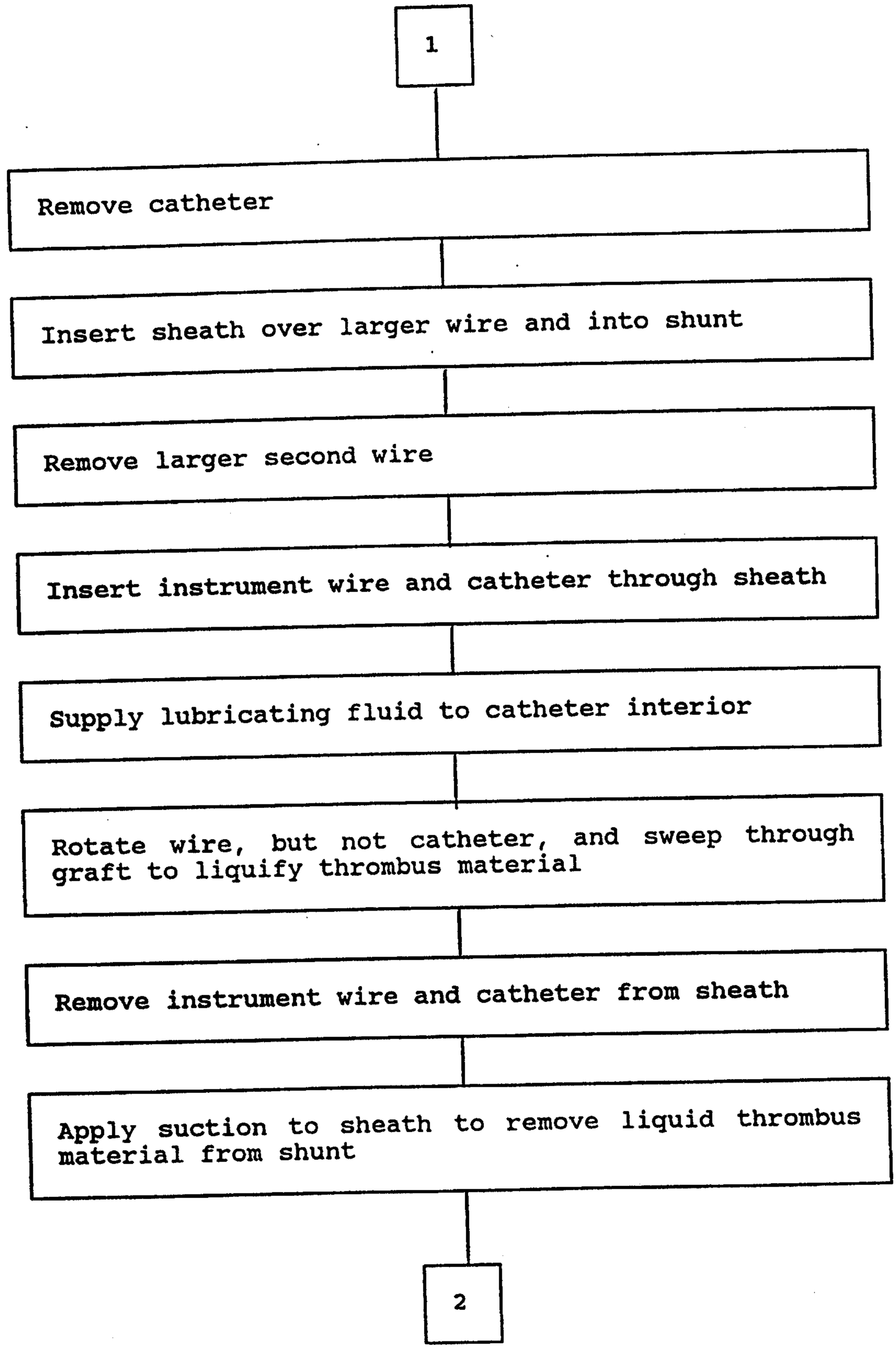

1
Remove catheter
Insert sheath over larger wire and into shunt
Remove larger second wire
Insert instrument wire and catheter through sheath
Supply lubricating fluid to catheter interior
Rotate wire, but not catheter, and sweep through graft to liquify thrombus material
Remove instrument wire and catheter from sheath
Apply suction to sheath to remove liquid thrombus material from shunt
2

Figure 1(b)

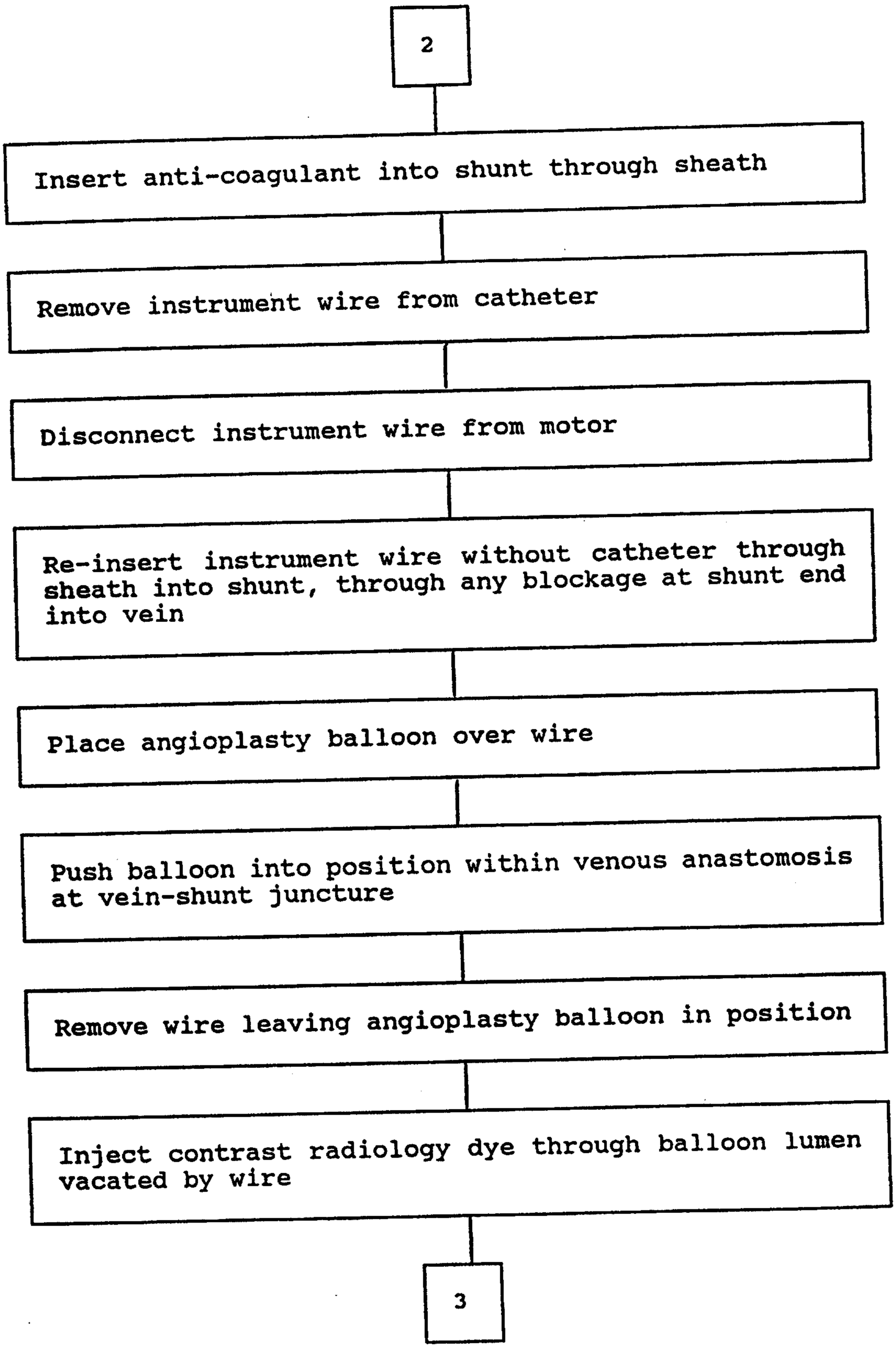

2
Insert anti-coagulant into shunt through sheath
Remove instrument wire from catheter
Disconnect instrument wire from motor
Re-insert instrument wire without catheter through sheath into shunt, through any blockage at shunt end into vein
Place angioplasty balloon over wire
Push balloon into position within venous anastomosis at vein-shunt juncture
Remove wire leaving angioplasty balloon in position
Inject contrast radiology dye through balloon lumen vacated by wire
3

Figure 1(c)

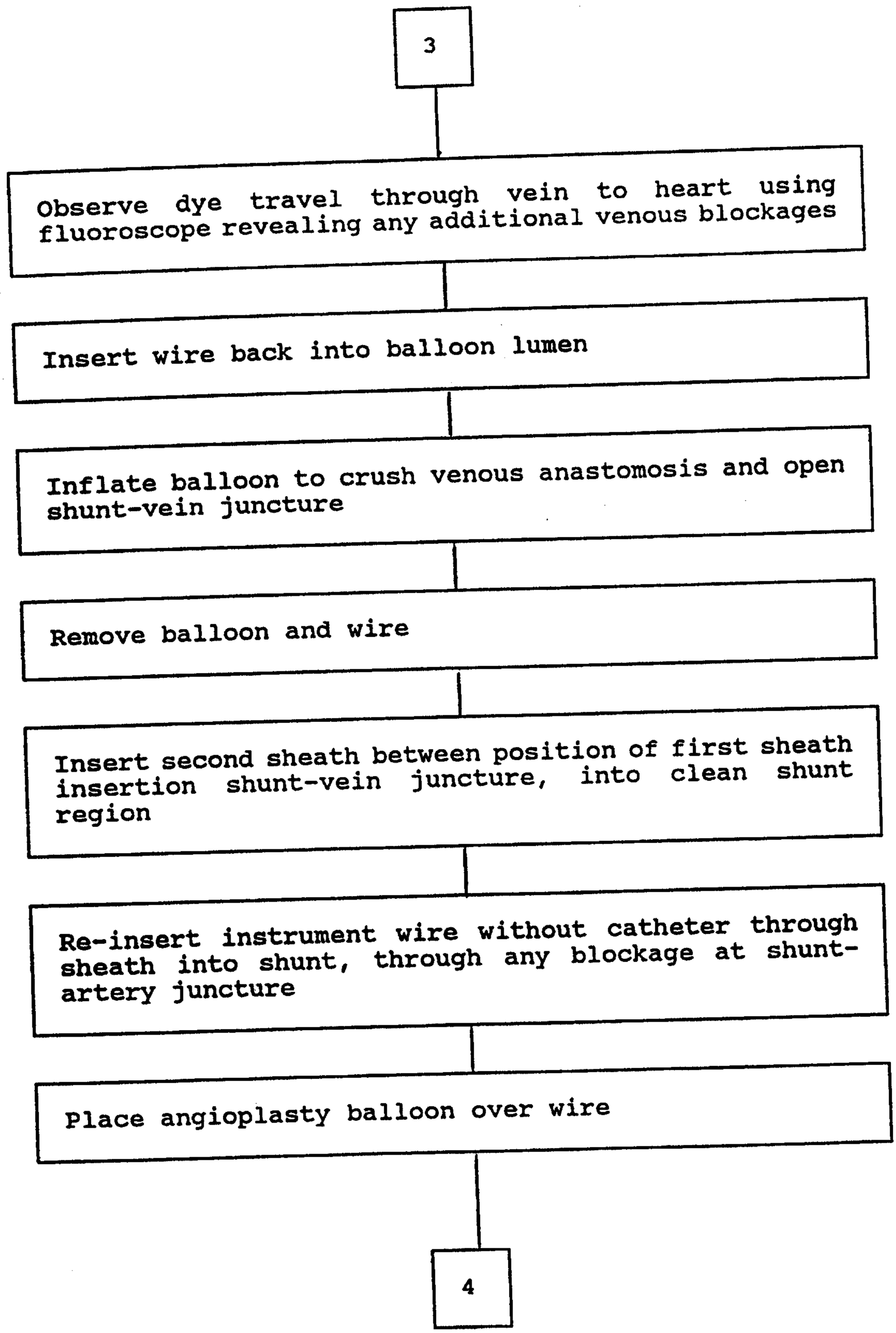

3
Observe dye travel through vein to heart using fluoroscope revealing any additional venous blockages
Insert wire back into balloon lumen
Inflate balloon to crush venous anastomosis and open shunt-vein juncture
Remove balloon and wire
Insert second sheath between position of first sheath insertion shunt-vein juncture, into clean shunt region
Re-insert instrument wire without catheter through sheath into shunt, through any blockage at shunt-artery juncture
Place angioplasty balloon over wire
4

Figure 1(d)

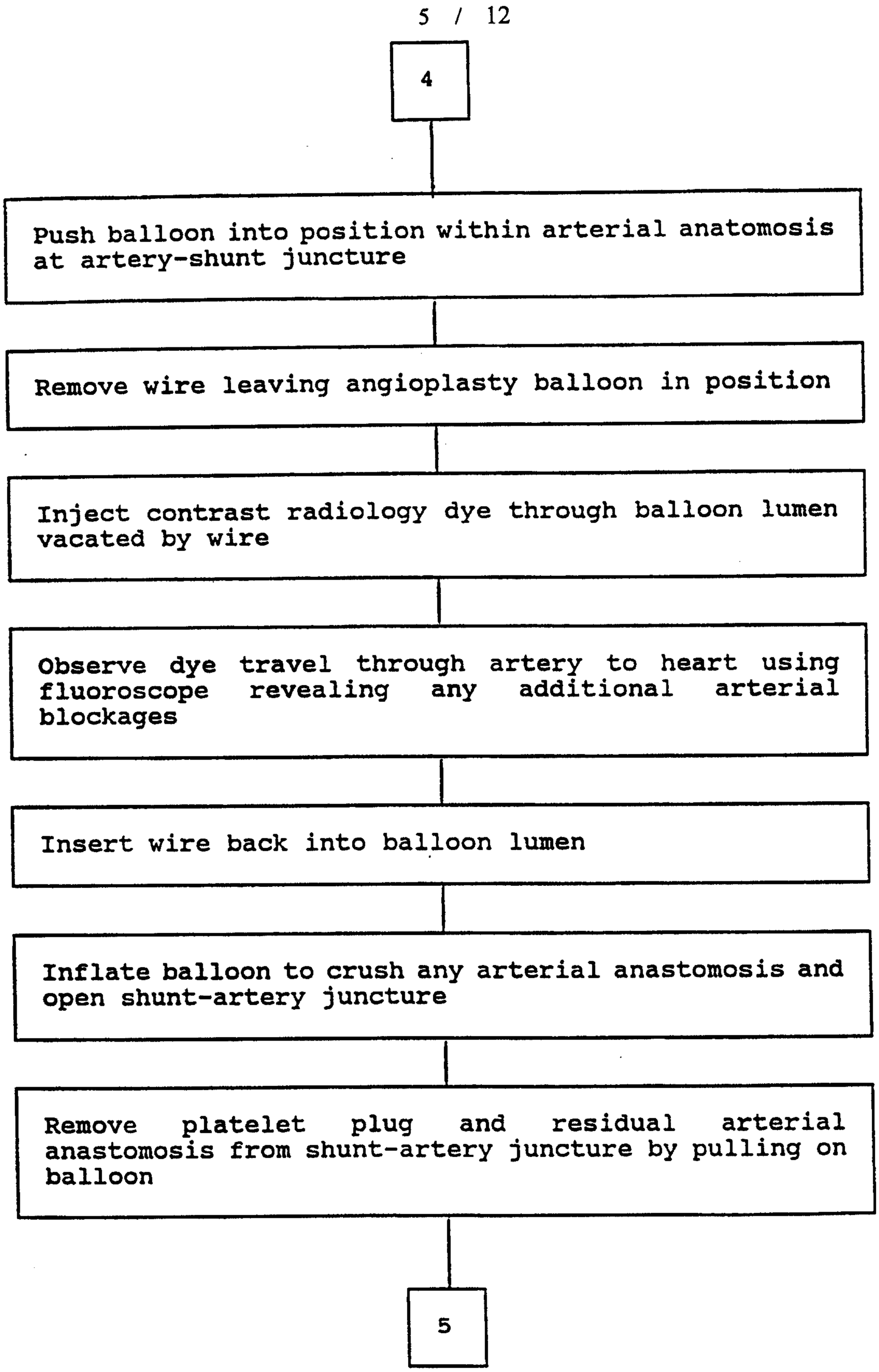

4
Push balloon into position within arterial anatomosis at artery-shunt juncture
Remove wire leaving angioplasty balloon in position
Inject contrast radiology dye through balloon lumen vacated by wire
Observe dye travel through artery to heart using fluoroscope revealing any additional arterial blockages
Insert wire back into balloon lumen
Inflate balloon to crush any arterial anastomosis and open shunt-artery juncture
Remove platelet plug and residual arterial anastomosis from shunt-artery juncture by pulling on balloon
5

Figure 1(e)

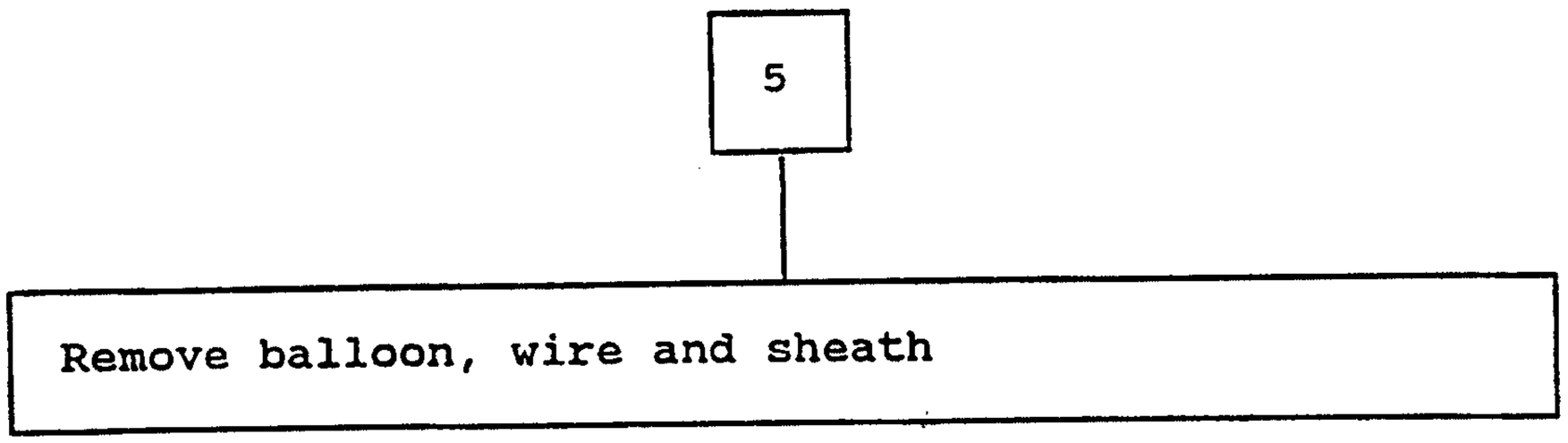



Figure 1(f)

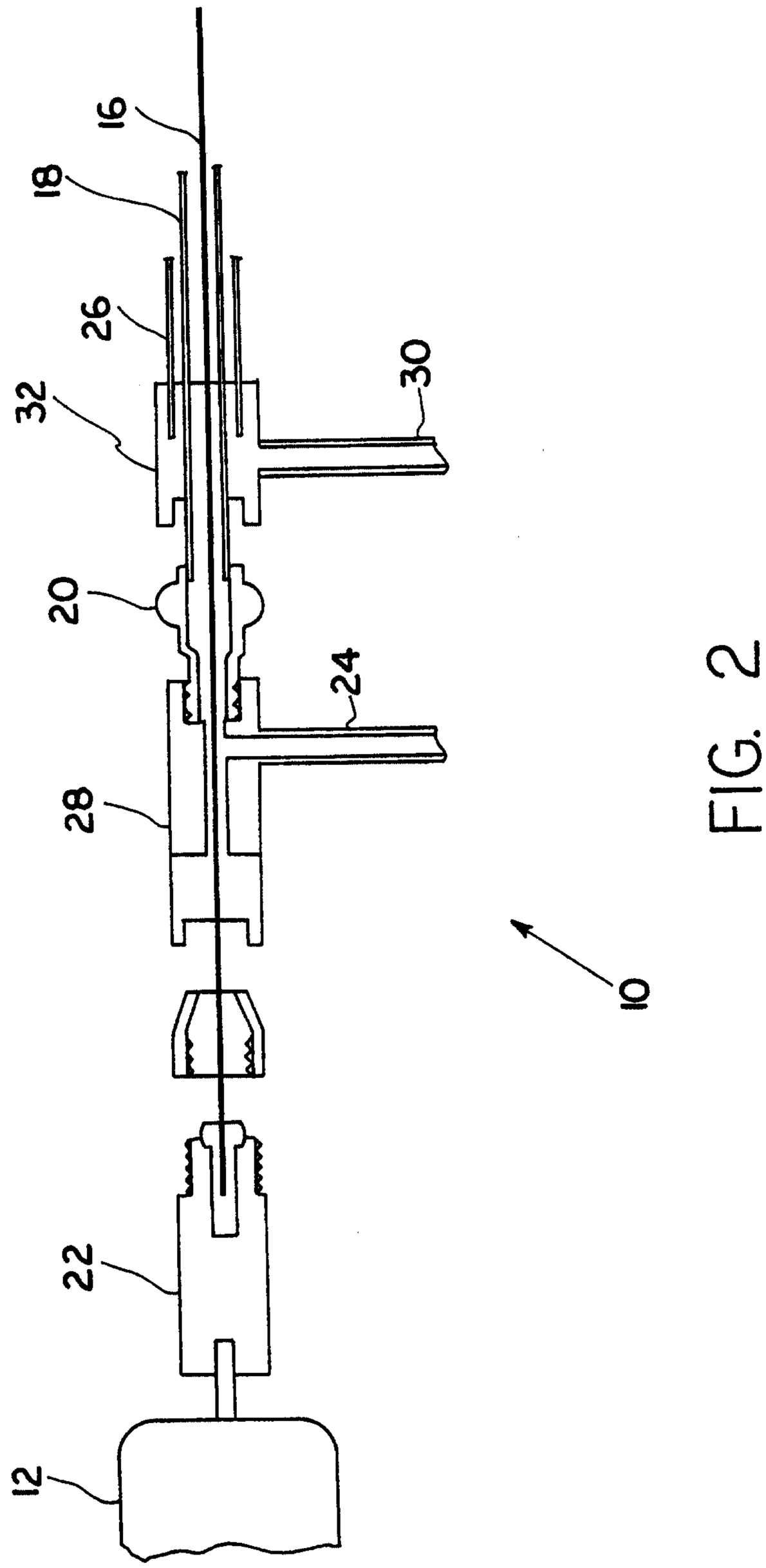



FIG. 2

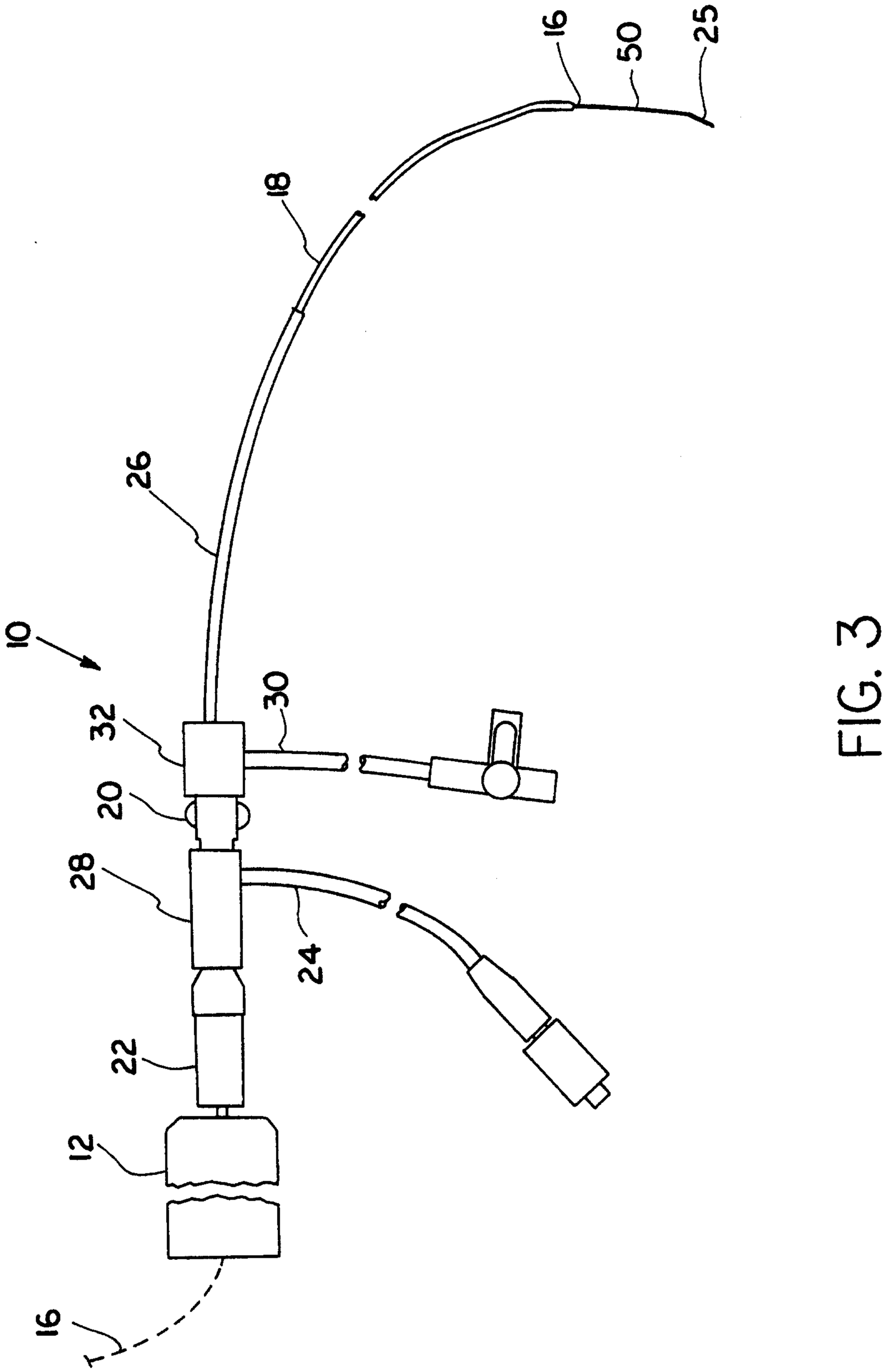



FIG. 3



*rB

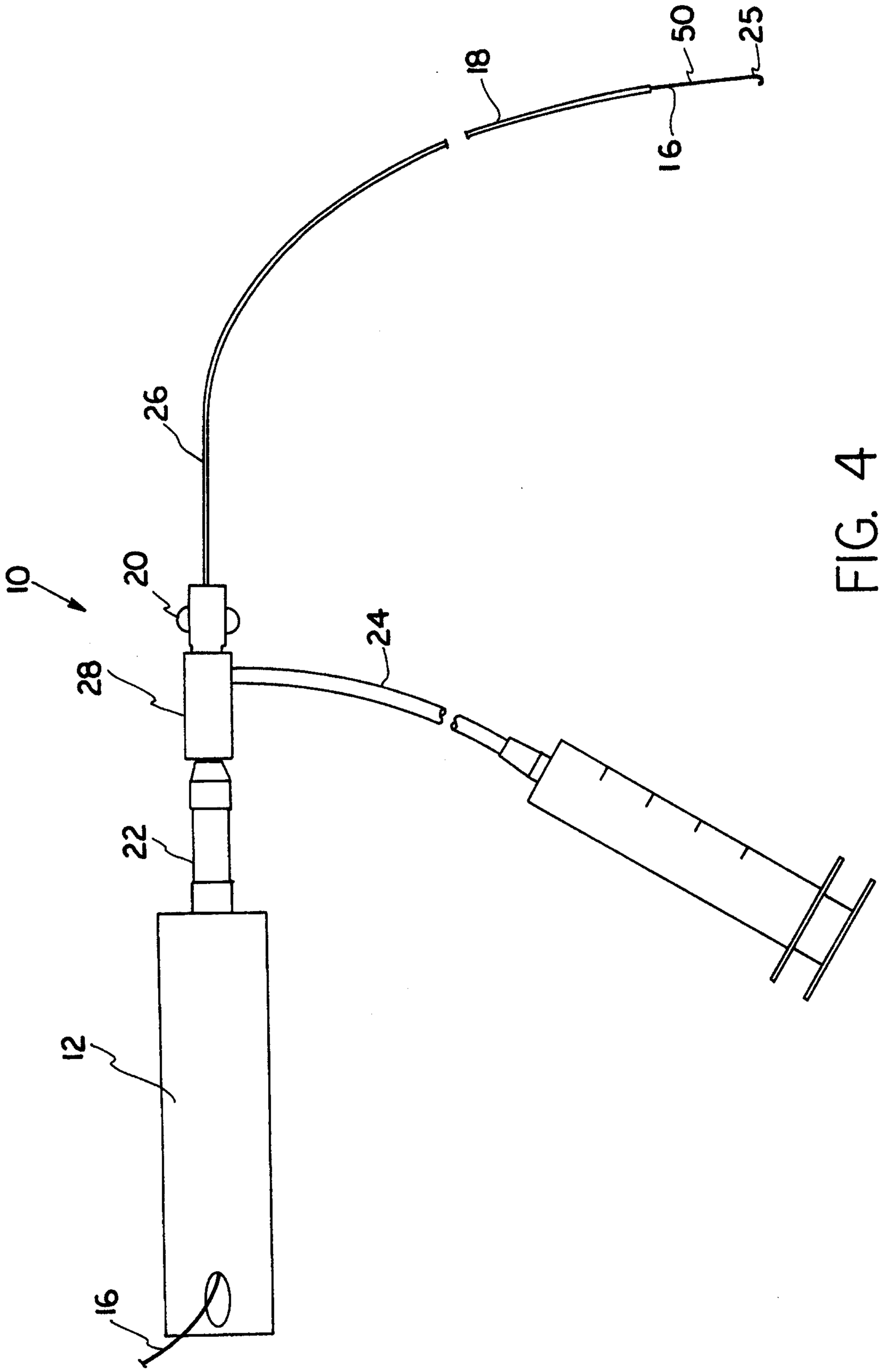



FIG. 4

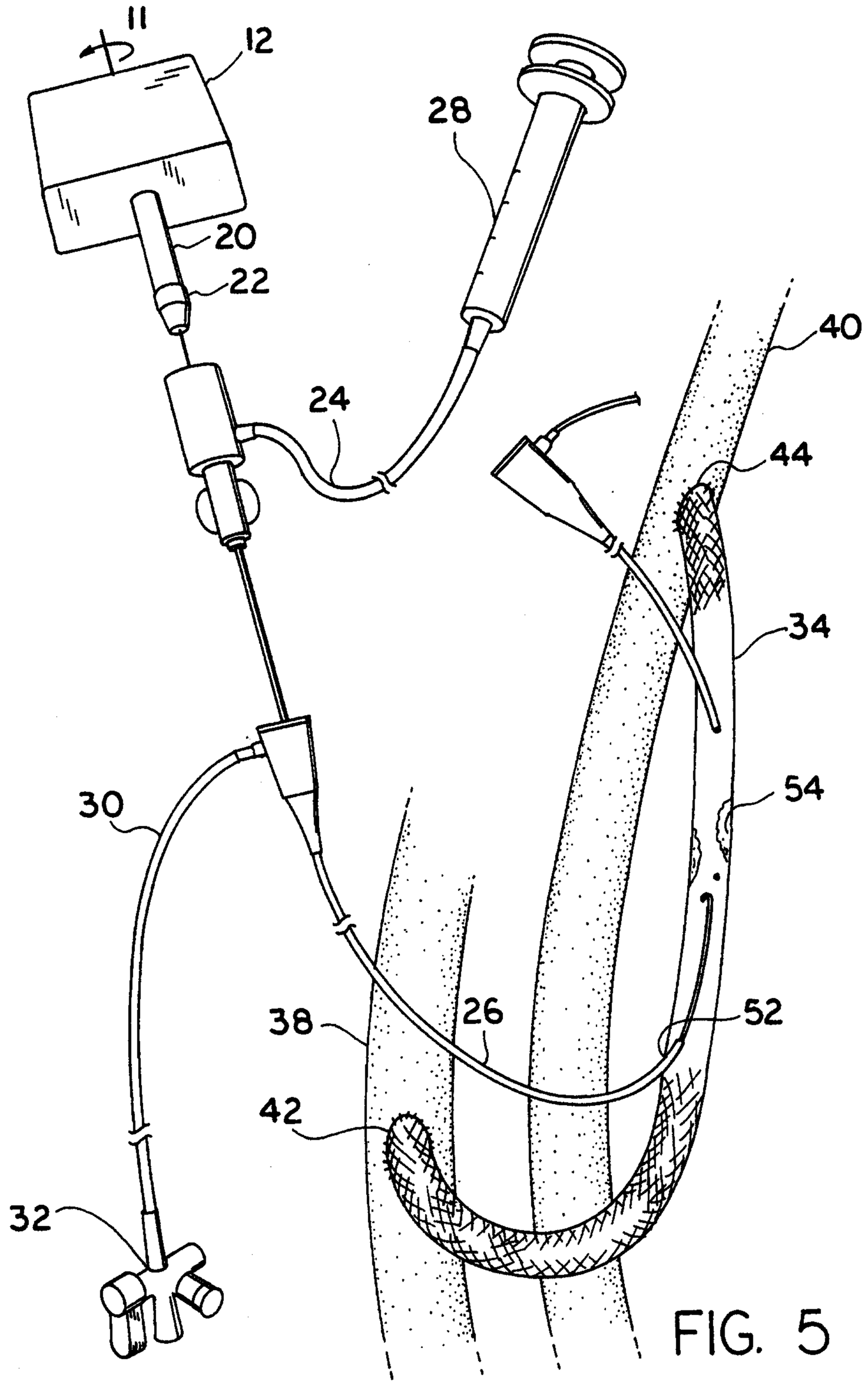



FIG. 5

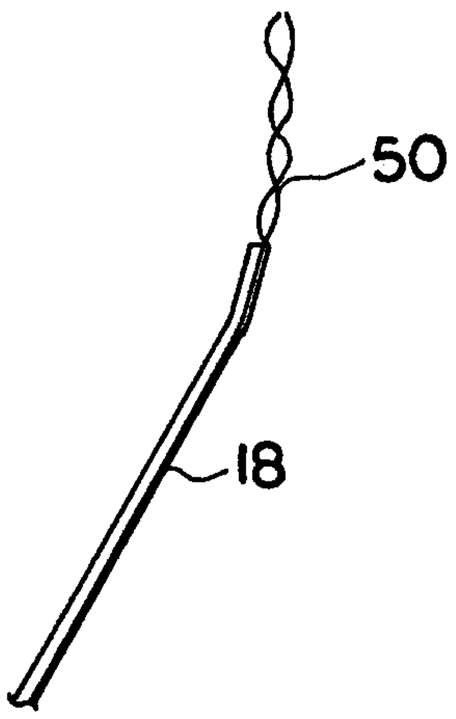



FIG. 6

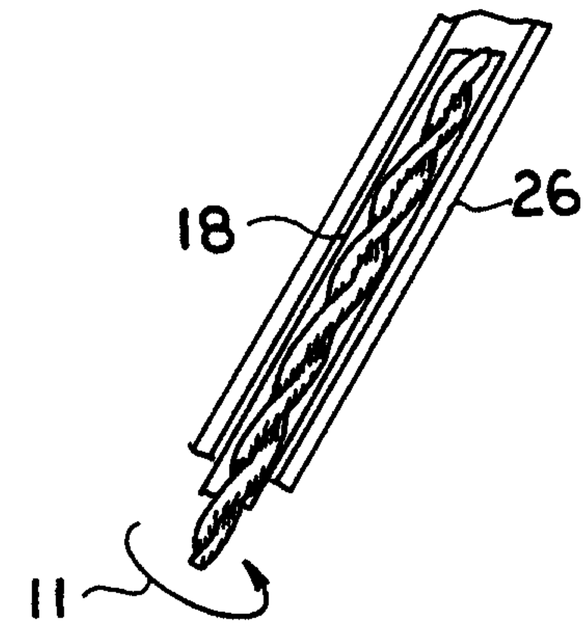



FIG. 8

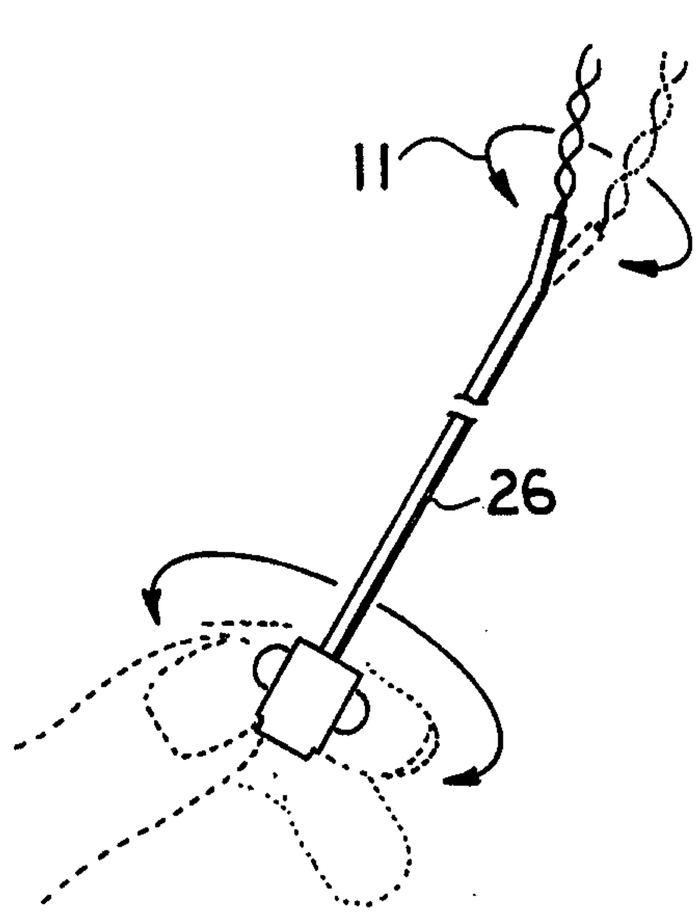



FIG. 7

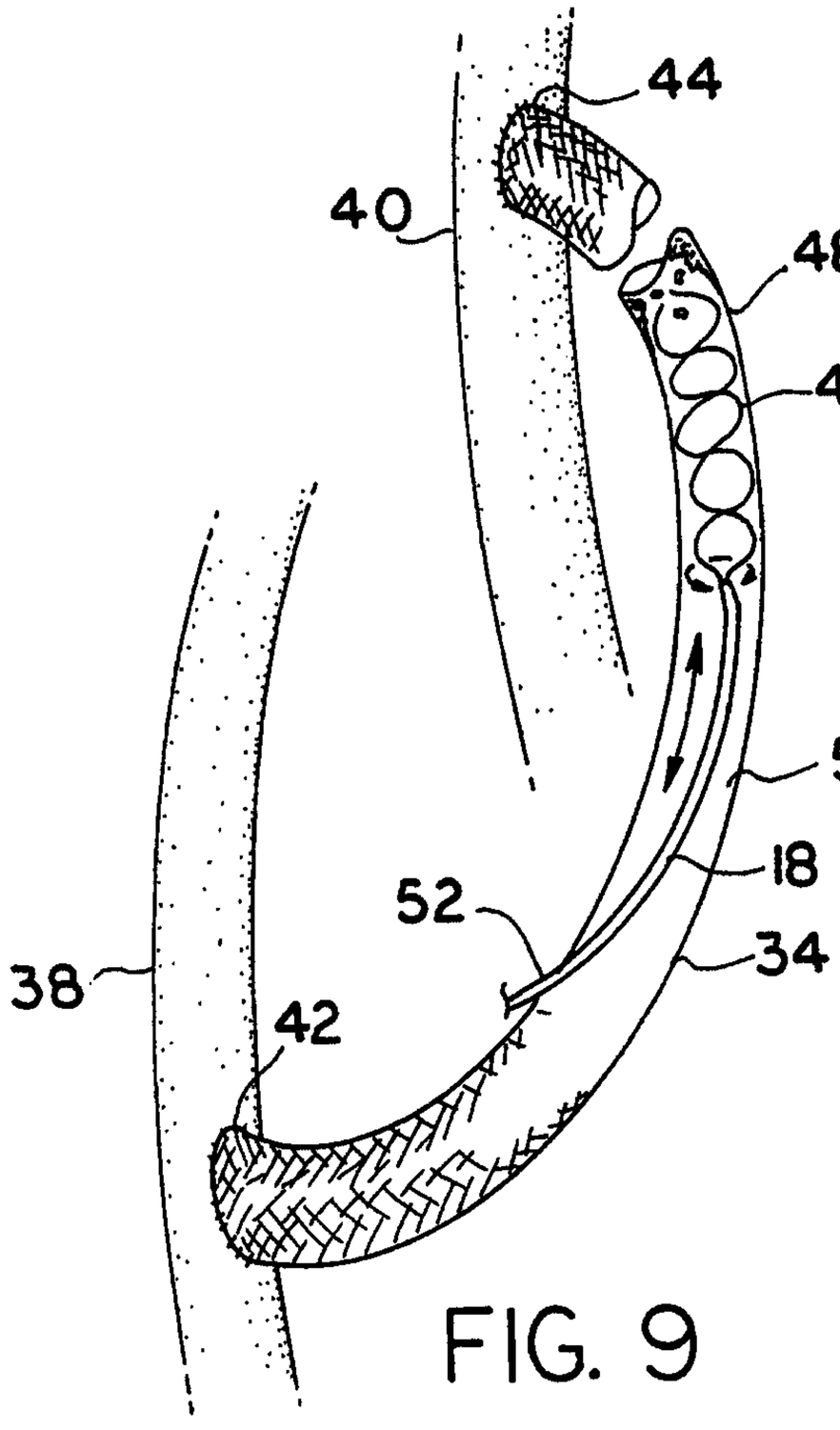



FIG. 9

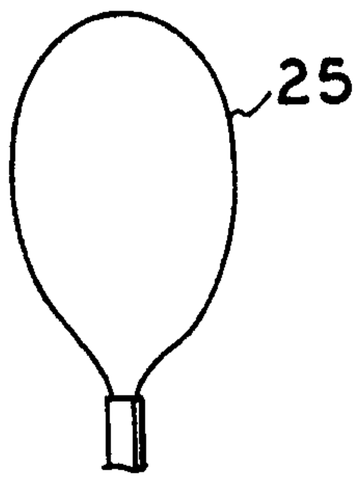



FIG. 10

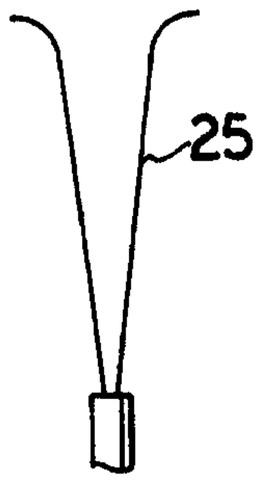



FIG. 12

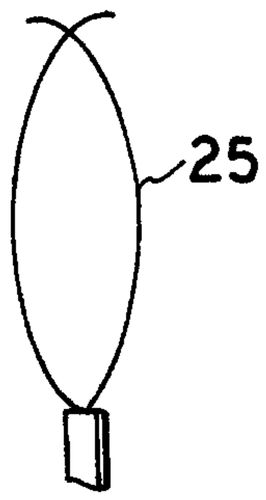



FIG. 11

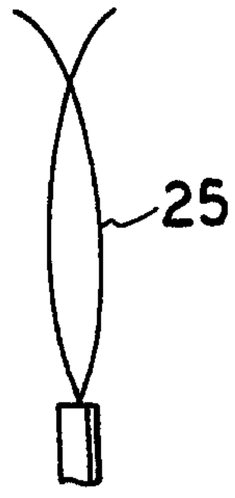
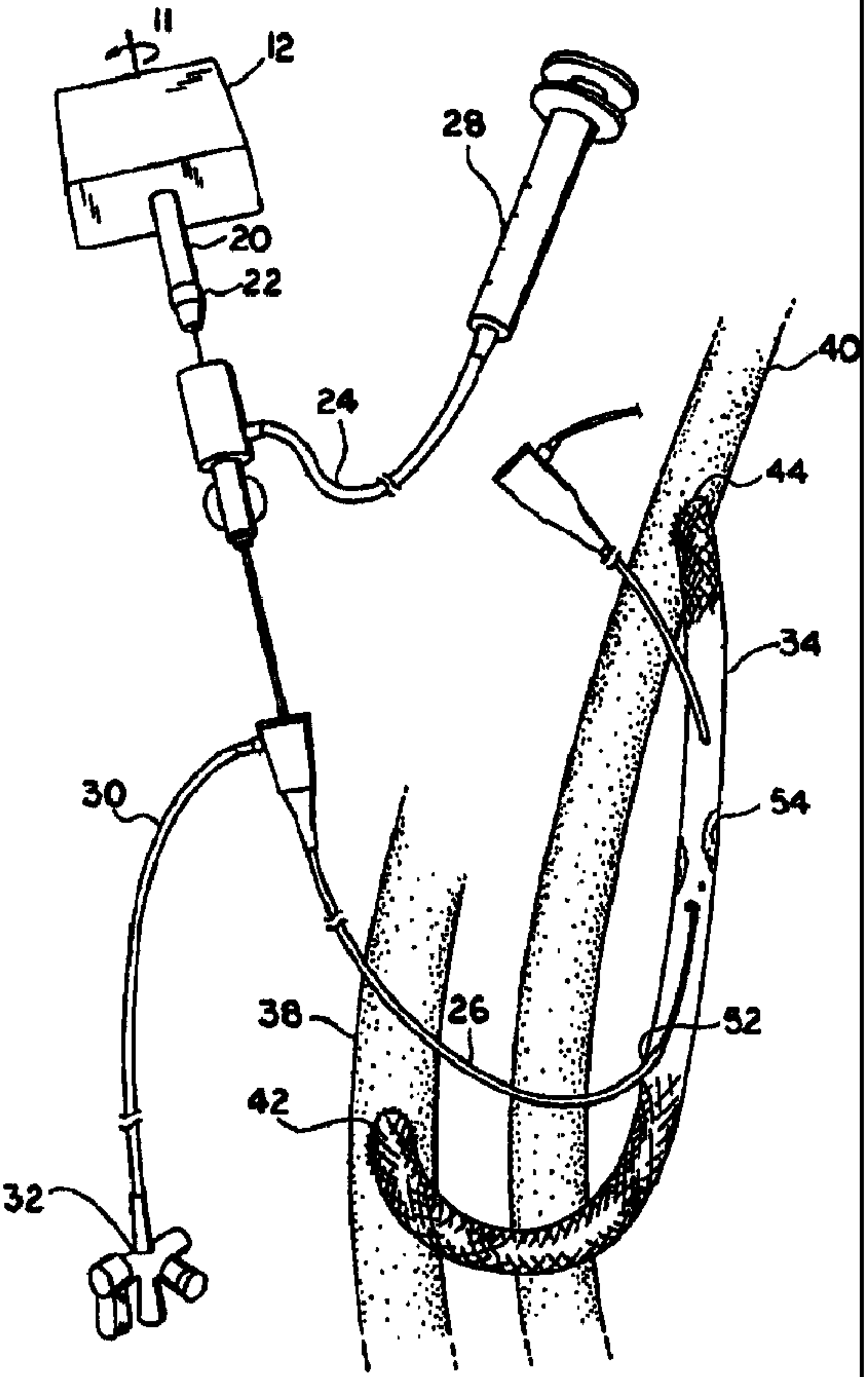



FIG. 13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