

March 31, 1970

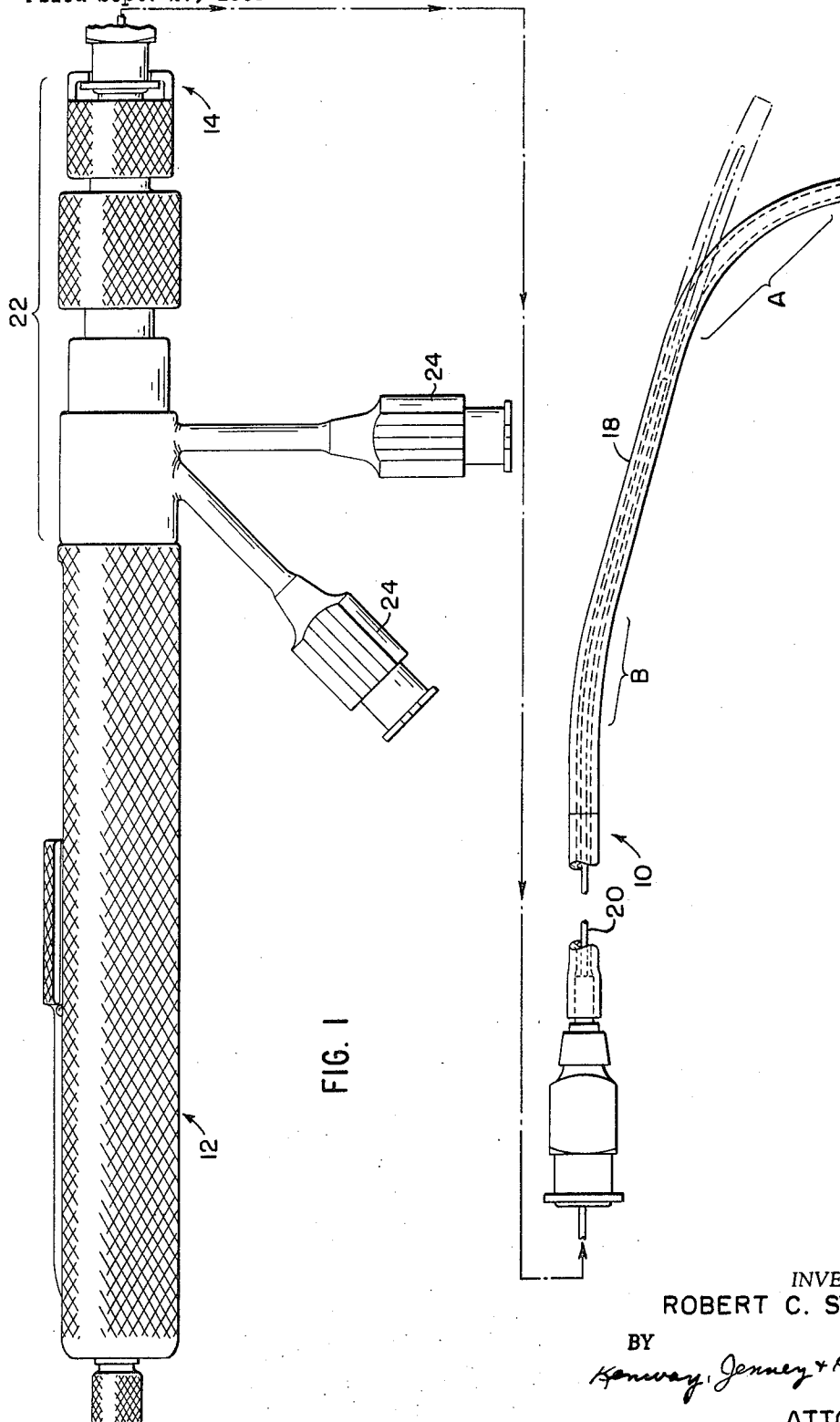
R. C. STEVENS

3,503,385

GUIDABLE CATHETER ASSEMBLY AND MANIPULATOR THEREFOR

Filed Sept. 27, 1965

2 Sheets-Sheet 1



INVENTOR
ROBERT C. STEVENS

BY

Konway, Jenney & Hildreth

ATTORNEYS

March 31, 1970

R. C. STEVENS

3,503,385

GUIDABLE CATHETER ASSEMBLY AND MANIPULATOR THEREFOR

Filed Sept. 27, 1965

2 Sheets-Sheet 2

FIG. 2

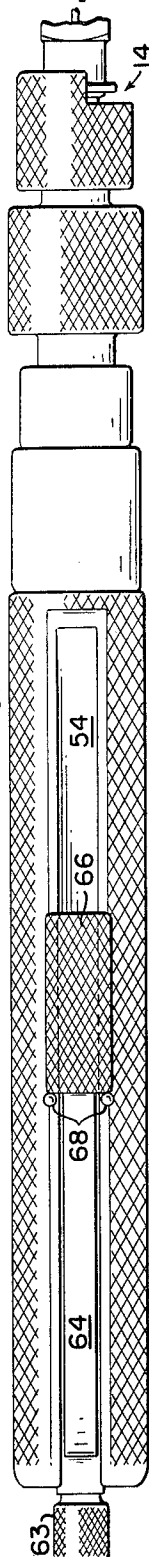
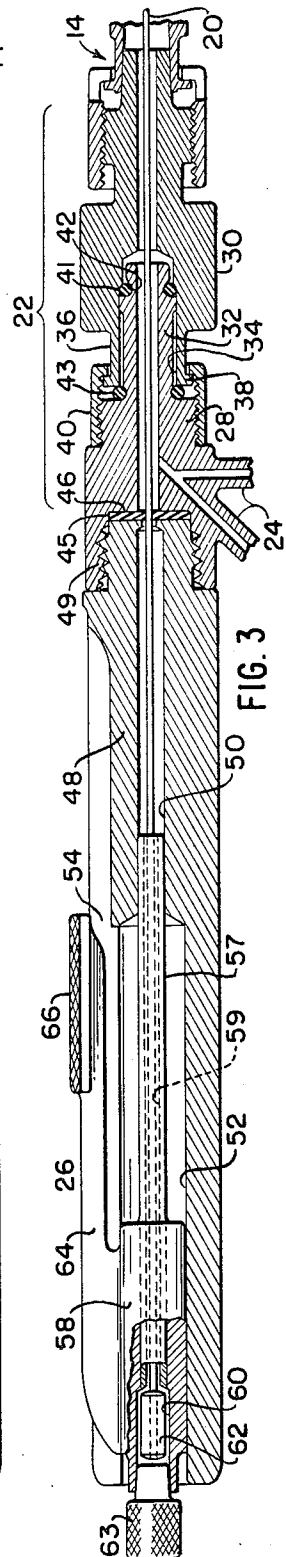


FIG. 3



INVENTOR
ROBERT C. STEVENS

BY
Kenway, Jenney & Hildreth
ATTORNEYS

1

3,503,385

GUIDABLE CATHETER ASSEMBLY AND
MANIPULATOR THEREFORRobert C. Stevens, Miami, Fla., assignor to Cordis Cor-
poration, Miami, Fla., a corporation of Florida

Filed Sept. 27, 1965, Ser. No. 490,253

Int. Cl. A61b 5/10; A61m 25/00

U.S. Cl. 128—2

4 Claims

ABSTRACT OF THE DISCLOSURE

A guidable catheter which includes a control wire extending the length of the lumen movable axially to control the curvature of the catheter tip is operated by a manipulator by which the control wire may be moved while fluid is supplied to the catheter. The manipulation includes a forward fluid supply channel, which preferably includes relatively rotatable forward and rearward members through which the catheter may also be rotated. The fluid supply portion is closed at its rearward end by a fixed resilient dam through which the control wire penetrates, and is supplied with fluid by a conduit forward of the dam. The control wire is manipulated by a slidable member mounted to the rearward of the dam and connecting with the control wire.

This invention relates to vascular catheters and in particular to the guidance of catheters during their introduction in such techniques as angiography and arteriography.

In certain diagnostic techniques it is necessary to insert a catheter through the blood vessels to a particular destination, and this frequently makes it necessary to guide the catheter into one of several alternate channels, as into a branching vessel. Vascular catheters are commonly formed with a curved but flexible distal tip portion which may be used to guide the cannula by twisting it from side to side during insertion to select the desired one of several vessels. In addition, attempts have been made to control the curvature of the distal tip so that it may be directed forward or to the side as desired during its insertion. None of these has until now however been satisfactory.

I have now developed a catheter construction and guide system by which the catheter may be directed forward or to the side by varying degrees while the catheter is being inserted. In addition, the catheter may be directed from side to side in more or less the conventional manner of twisting it during insertion. With my new construction, the catheter is more precisely controlled and more easily inserted than has heretofore been the case. In particular, the catheter may be simply directed past a branching vessel by causing the tip to straighten, whereas in the past it would have been necessary to rotate the catheter so that the tip is not aligned to enter the branching vessel. Moreover, where a vessel branches from the vessel through which the catheter is being inserted, the curvature of the tip may be adjusted to correspond with the angle of intersection to facilitate the directing of the tip into the other vessel.

The catheter construction of my invention features a flexible catheter body tube which is preferably formed to be as rigid in torsion as possible, while being longitudinally flexible, so that the entire body of the catheter may be twisted from side to side even though it be in a circuitous or tortuous path, and without a tendency to whiplash, that is to resist turning until a certain torque is applied at which time the entire rotation applied to the proximally end is unleashed. These problems are encountered with conventional catheters which is to say that the known constructions providing the best rotational control are preferred for the practice of this invention. Forward guidance is

2

provided by forming the distal end of the catheter with a flexible resilient curve and by providing a control wire within the lumen during insertion. The control wire is held by a control mechanism or manipulator which permits it to be moved axially of the catheter, forwardly into the curve, to within a fraction of an inch of the distal end and rearwardly from the curve. When the control wire is in its forward most position, extending past the curve, it causes the curve to substantially straighten so that the catheter may be directed forwardly during insertion. When the wire is withdrawn from the tip, its curved shape is resumed and the catheter may be caused to enter a branching vessel.

Preferably, the tip of the catheter is formed with a double curvature, a distal curve which functions as described above, and a few inches proximally thereof a secondary curve, which facilitates the leading of the catheter by riding against the wall opposite the cannulated orifice.

The catheter manipulator consists of a manually operated assembly to which the proximal end of the catheter is connected to communicate with a fluid supply channel formed in the forward portion of the device. This portion preferably includes a swivel joint by which the forward end may be rotated independently of the rearward portion to rotate the catheter during insertion.

The rearward portion of the fluid supply channel communicates with one or more fluid inlet fittings, and terminates in a fluid-tight gland through which the control wire passes.

To the rearward of the fluid supply channel is a slide mechanism controlling the fore and aft motion of the wire. This consists of a slidable member to which the end of the control wire is attached and which is free to slide back and forth axially of the fluid supply channel.

The manipulator thus provides not only for control of the catheter, both by rotation and fore and aft motion of the control wire, but also for the introduction of appropriate fluids both during the time that the catheter is being inserted and afterwards when an injection is to be made. In addition, the manipulator is designed to be easily disassembled for cleaning.

A preferred embodiment of the invention is described in detail below with reference to the accompanying drawings in which:

FIG. 1 is a side view showing the catheter manipulator with the catheter attached;

FIG. 2 is a top view of the manipulator; and

FIG. 3 is a side view of the manipulator in cross section.

As shown in FIG. 1, the catheter 10 is fastened to the forward end of the manipulator 12 by a conventional Luer Lok arrangement 14.

The catheter 10 consists of a tubular body portion 16 which is typically about 40 inches long and is preferably made up of flexible plastic material with an intermediate braided wire sheath which provides a soft flexible construction having torsional rigidity. The tip 18 of the catheter is formed of unreinforced soft plastic material of the type conventionally used and includes a distal curved portion A and about 2 inches proximal thereof a secondary curved portion B. The distal curve A serves the purpose of directing the catheter during its insertion into a desired branching vessel, depending on the rotation of the catheter and on the extent to which the distal curve is caused to be straightened as will be explained below. The secondary curved portion B is provided to assure of there always being some curvature to the catheter so that it will ride along and be guided by the wall of the vessel opposite the incision through which it is introduced and opposite the entry of any branching vessel into which it is guided.

A control wire 20 within the catheter is arranged for reciprocal motion within the distal curved portion, which, when advanced, will cause the distal curve to straighten substantially.

The wire runs the entire length of the catheter and extends outwardly from its fitting into the manipulator 12. The manipulator includes a forward fluid supply channel portion 22 which connects to one or more inlet fittings 24, and a rearward wire control slide mechanism 26 which is axially aligned with the fluid supply channel and with the end of the catheter 10.

The fluid supply channel portion of the manipulator includes two rotatably interconnected centrally bored members 28 and 30. The rearward one, 28, terminates at its forward end in an elongated snout 32, which is rotatably received in a bore 34 formed in the rearward end of the forward rotatable member 30. The bore 34 is partly surrounded by a neck 36 which terminates in an outwardly extending radial flange 38 by which the forward member 30 is held in place by an inwardly flanged sleeve 40 threaded to the forward end of the rearward rotatable member 28.

A fluid tight rotatable joint between the snout 32 and bore 34 of the fluid supply channel is provided by a pair of O rings, one, 41, at the forward end of the neck 32, retained in a groove 42, and the other O ring 43 surrounding the base of the neck 32. The forward O ring 41 is compressed radially between the neck 32 and the bore 34 while the rearward O ring 43 is compressed axially between the base of the neck 34 and the flange 38.

The forward end of the forward member 30 terminates in a standard Luer Lok arrangement 14, and the body of the forward member 30 is enlarged and knurled so that it may be easily grasped by the fingers for rotating it.

The rearward end of the fluid supply channel is closed by a dam 45 of rubber or similar flexible resilient material. The dam 45 is retained between a shoulder 46 surrounding the end of the channel 22 and the end of a guide block 48 which is threaded into the rearward end of the rearward channel member 28 in a threaded recess 49 surrounding the shoulder 46. The guide block 48 is formed with a forward central bore 50 axially aligned with the channel 22. To the rear of the bore 50 is a guide groove 52 which opens into a longitudinal slot 54. The wire 20 is held by the slide mechanism 26 which is constructed with a tubular forward portion 57 which rides in the bore 50 and an enlarged rearward portion 58 which rides in the guide groove 52. An opening 59 extends through the length of the slide mechanism 26 and terminates in an enlarged cup which is closed by a cap 63, and the wire 20 extends through the bore 59 and ends in a bead 62 which is retained in the cup 60 and provides a connection by which the wire may be moved in either direction.

A thumb control extension 64 connects from the enlarged rearward part 58 of the slide mechanism 26 through the slot 54 to a control knob 66 which is positioned toward the forward end of the guide block for easy access to the thumb.

Accidental removal of the slide mechanism 26 is prevented by a pair of beads 68 positioned at opposite edges of the slot 54 to limit the rearward motion of the control knob 66. Removal of the slide 26 requires that the knob 66 be lifted against the resilience of the control extension 64, over the beads 68.

From the foregoing it will be seen that the fluid supply channel portion of the manipulator includes a rotatable joint which includes the enlarged and knurled body portion of the forward member 30 which may be readily grasped for turning. At the same time the thumb control knob 66 for the guide wire may be moved forward and back to cause the wire to extend into or retract from the distal tip of the catheter and thereby control its curvature.

In use, the catheter is introduced into the blood vessel in the usual way. After the spring guide, or other guide

wire, has been withdrawn, the control wire 20 which has been mounted in the manipulator 12 is inserted into the catheter lumen, and the manipulator Luer Lok 14 fitting it attached to the catheter fitting. Appropriate fluid supplies are connected to the manipulator, e.g., to introduce heparinized saline during insertion, and the catheter under the control of the manipulator is pushed into the vessel. Guiding the catheter is accomplished by twisting the forward portion 30 of the fluid supply channel 22, to turn the tip 18 from side to side and by moving the central knob 66 forward and aft to control the curvature of the distal tip portion A.

After use the manipulator may be completely disassembled by lifting the knob 66, removing the slide mechanism 26, and withdrawing the wire, unscrewing the Luer Lok 14 to disconnect the catheter, unscrewing the collar 40 to separate the forward and rear portions 28 and 30 of the fluid supply channel 22, and unscrewing the guide block 48 to remove the dam 45. When thus disassembled, the several parts are easily cleaned by conventional techniques.

Although this invention may be used with conventional catheters having curved tips, I prefer a tip formed of smooth soft thermoplastic material, e.g., elastomeric polyurethane such as Estane which is described in Modern Plastics Encyclopedia for 1965, at page 170. The preferred tip is about three inches long, and heat set to give a distal curve through 120° of arc over 1½ inches of length at the distal end and a proximal curve at the proximal end through 65° of arc over about one inch of length.

Having thus disclosed my invention and described in detail the preferred embodiments thereof, I claim and desire to secure by Letters Patent:

1. A guidable catheter assembly comprising:
 - a catheter having a flexible curved distal tip portion, a control wire in the lumen of the catheter running substantially the full length of the catheter into said distal tip portion, said control wire being freely slidable within said lumen and removable therefrom,
 - a manipulator attached to the proximal end of said catheter,
 - said manipulator comprising
 - a fluid supply channel portion connected to a source of fluid to be injected including rearward and forward members connected for relative rotation,
 - slidable means on said manipulator to the rearward of said fluid supply channel portion connected to said wire and operable to cause said wire to move axially of said lumen, said slidable means being separable from said manipulator to permit complete withdrawal of said control wire from said lumen,
 - and fluid tight means immovably fixed between said slidable means and said fluid supply channel, closing the rearward end of said channel said fluid tight means being penetrated by said wire and extending completely therethrough,
 - whereby said slidable member on said manipulator may be moved back and forth to cause said wire to retract from and return to said curved distal tip portion and thereby alter the curvature thereof.
2. A guidable catheter assembly as defined by claim 1 wherein the catheter control wire manipulator comprises:
 - fluid inlet means being connected with said rearward member,
 - catheter fastening means at the forward end of the forward member for connecting with a catheter, said fluid tight means comprising
 - a resilient dam,
 - and a control member slidably mounted having means to the rearward of said dam for connecting with and controlling said control wire,

5

3. A guidable catheter assembly as defined by claim 1 wherein the catheter control wire manipulator comprises: catheter fastening means at the forward end of said fluid supply channel said fluid tight means comprising a resilient dam,

and a control member slidably mounted having means to the rearward of said dam for connecting with and controlling said control wire.

4. A guidable catheter assembly as defined by claim 2 wherein the control member is mounted in guide block fastened to the rear of the fluid supply channel portion; a guide block having

a longitudinal bore axially aligned with the fluid supply channel and a slotted opening extending

from said bore to the outside of the guide block, and said control member comprises a tubular portion slidable within said bore having an opening for the guide wire terminating in a cup,

a cap for said cup, and

an extension extending through said slotted opening

5

10

15

20

6

terminating in a knob positioned for back and forth motion at the outside of guide block.

References Cited

UNITED STATES PATENTS

3,416,531	12/1968	Edwards	128—348
2,688,329	9/1954	Wallace	128—349
2,893,395	7/1959	Buck	128—349

FOREIGN PATENTS

707,333	4/1931	France.
156,901	11/1956	Sweden.

OTHER REFERENCES

A.C.M.I. Catalogue—1960, p. 53.

DALTON L. TRULUCK, Primary Examiner

U.S. Cl. X.R.