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Burns et al.

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[45] **Nov. 20, 1973**

[54] **STEERABLE CATHETER**

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[21] Appl. No.: **201,912**

[52] **U.S. Cl.** .... **128/2 M,** 128/DIG. 9, 128/348

[51] **Int. Cl.** **A61m 25/00**

[58] **Field of Search** .... 128/4, 6–8, 128/348–351, 356, DIG. 9, 2 M, 2 R, 2.05 D, 2.05 R

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[57] **ABSTRACT**

A tip on a catheter is bent to steer the distal end of the catheter by displacing a control fluid within an elongated fluid conduit to stretch one longitudinally extending side of the tip relative to an opposite longitudinally extending side of the tip. The stretched side bends about the shorter side with a radius of curvature larger than the radius of curvature for the shorter side of the tip. A longitudinal restraining means may be applied to the tip to assure that the tip always bends in the same direction with the fluid displacement. On the other hand, other catheters may be bent in several and predetermined directions by providing a plurality of discrete fluid control conduits and by establishing a fluid pressure differential in at least one of the conduits to cause its associated side to lengthen and bend relative to a portion of the tip associated with another control conduit. The catheter may be small in dimension, made inexpensively and restrained against expanding in diameter by a circumferential restraining means.

12 Claims, 7 Drawing Figures

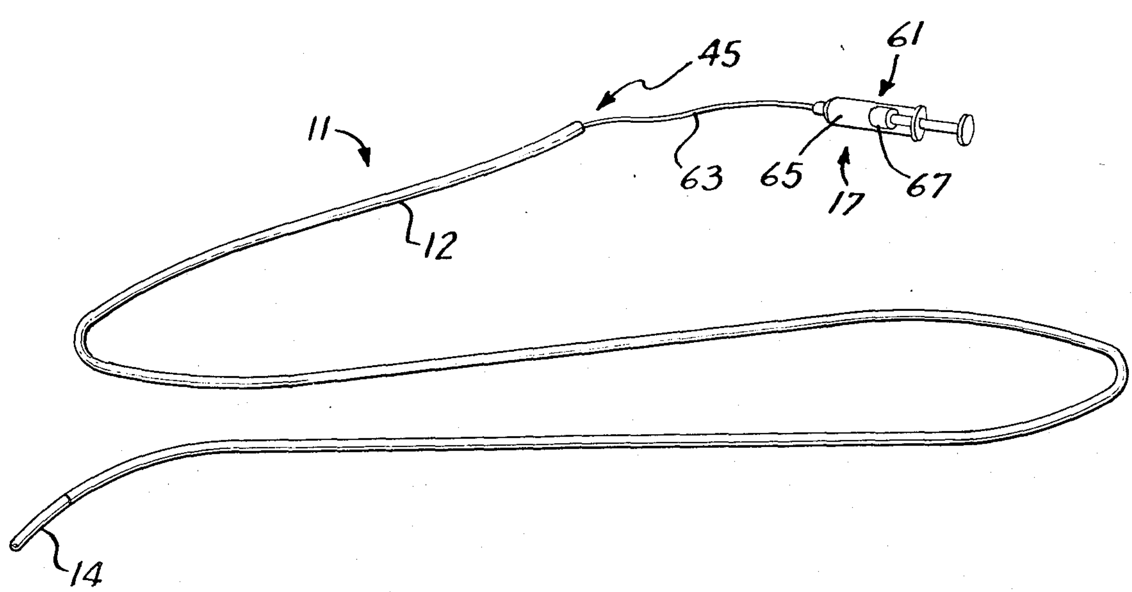

FIG. 1

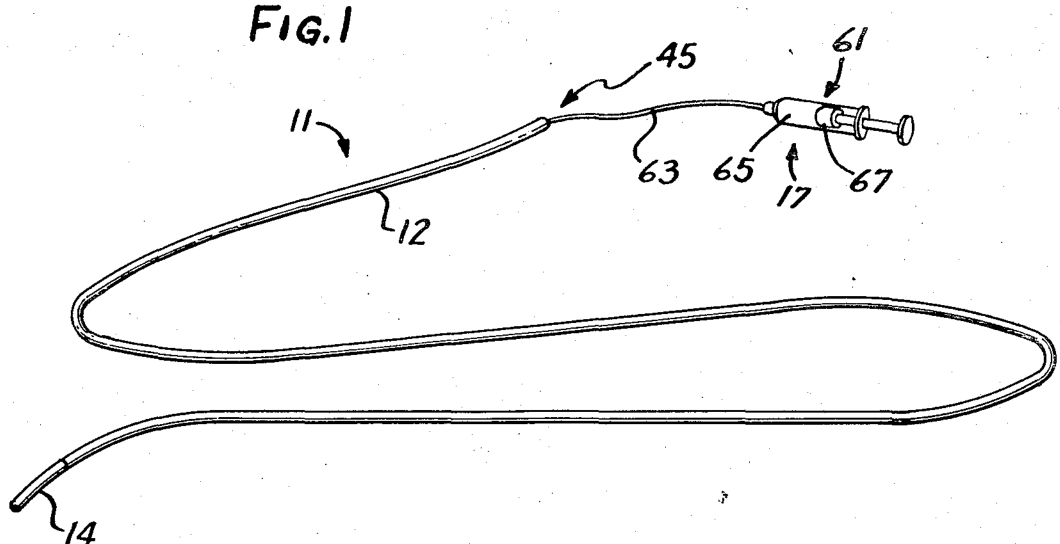

FIG. 2

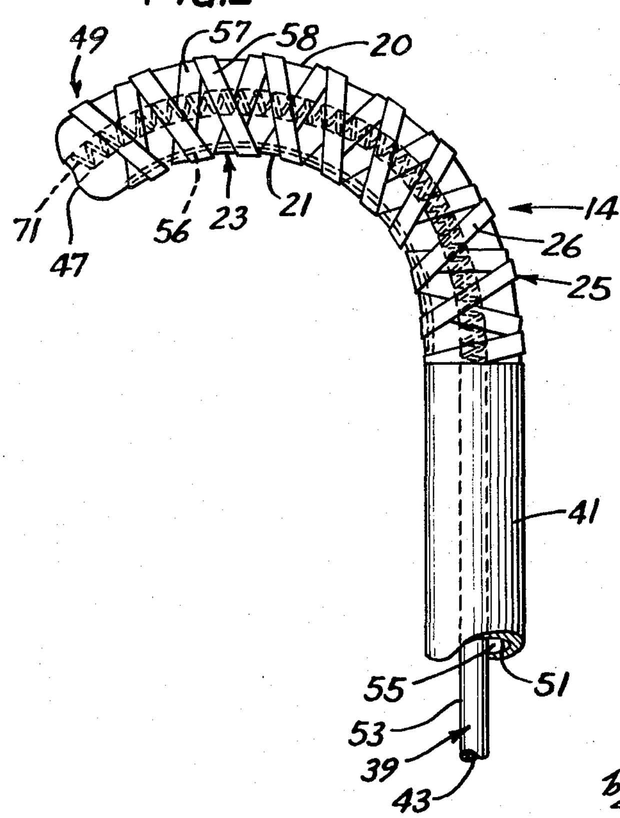

FIG. 3

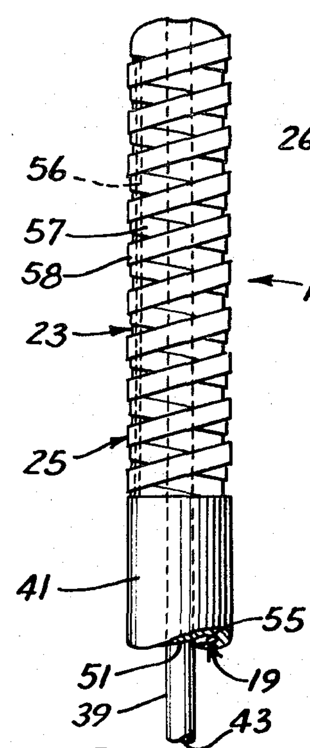

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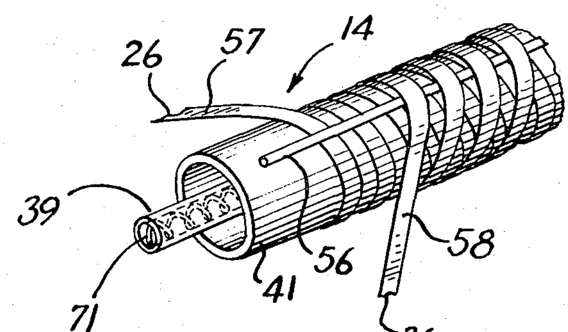
FIG. 4



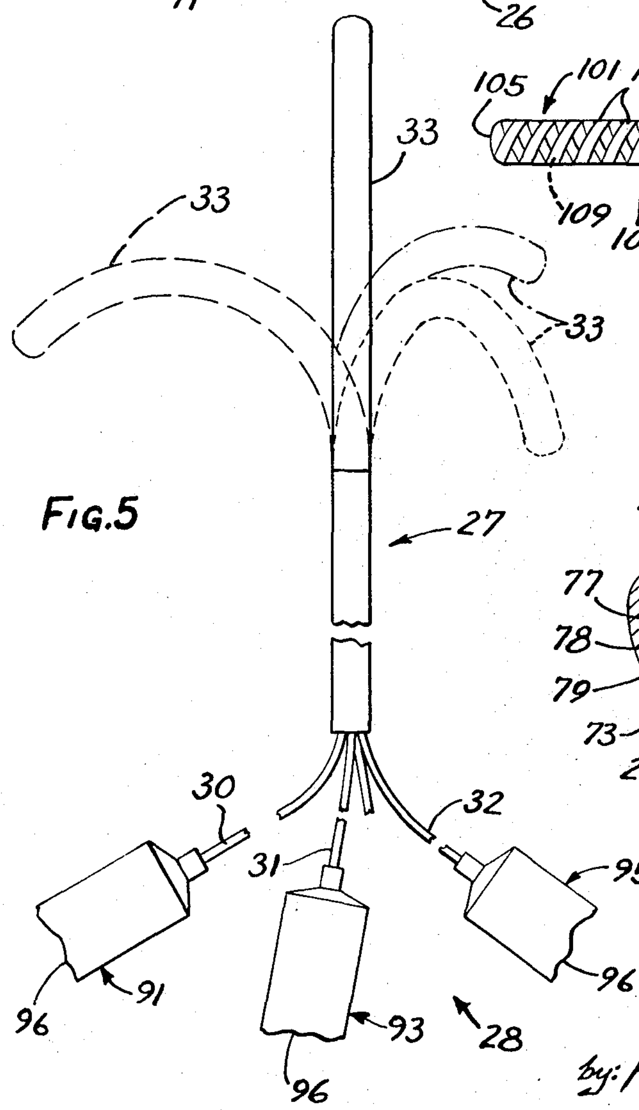


FIG. 5

FIG. 7

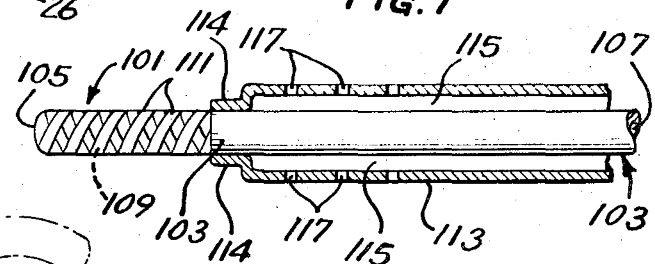
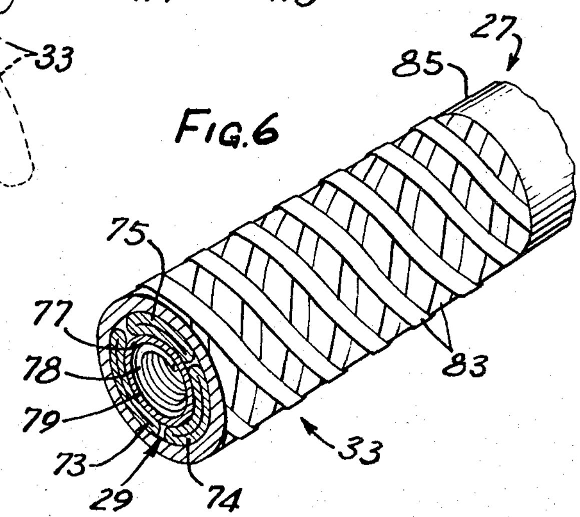


FIG. 6



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STEERABLE CATHETER

This invention relates to catheters and more particularly to catheters having distal ends which may be deflected or bent to facilitate its introduction into or travel through channels within the human body.

Physicians currently use catheters to therapeutically explore the cardiovascular and veinous systems of the human body. The movement of a catheter through the blood vessels within the human body to probe deeply for a considerable depth or through branching vessels requires that the tip of the catheter be steerable, that is, bendable or deflectable to travel at an angle when a branch of the blood vessel is reached. Usually, the catheter has a lumen, i.e., a passageway therein, through which fluids or contrast media may be transmitted or a medical instrumentality may be inserted. It will be appreciated that the catheters must be extremely small in diameter to move through the blood vessels and that the controls therefore must also be relatively small if there is to be sufficient space remaining for the lumen.

One presently known form of cathether having a steerable tip at the distal end has several control wires running from the steerable tip to a proximal end at which steering means are provided for operating the control wires to bend the steerable tip. One shortcoming of control wires is that they add considerable stiffness to the catheter. Also, because the wire must be very small in diameter and often are curved and are frictionally retarded against movement while within the blood vessel, the wires sometimes fail when forces are exerted thereon to steer the same.

Steerable catheters heretofore have been relatively expensive and definitely are not so inexpensive that they may be discarded after use, as in the case with many disposable medical instruments.

In accordance with the present invention, the use of wires may be dispensed with and the catheter may be steered by a fluid displacement technique. That is, a displacement of fluid and a change of fluid pressure within control passages within the catheter is used to bend the tip to control its curvature for movement through the blood vessels. Also, in accordance with another aspect of the invention, the catheter may be made from plastic materials and at sufficiently low cost as to be a disposable instrument.

Accordingly, a general object of the invention is to provide a new and improved steerable catheter.

Other objects and advantages of the invention will become apparent from the following detailed description taken in connection with the accompanying drawings in which:

FIG. 1 is a diagrammatic perspective view of a steerable catheter embodying the novel features of the invention;

FIG. 2 is an enlarged elevational view of the steerable tip of the catheter of FIG. 1 bent by fluid displacement;

FIG. 3 is a view of the tip shown in FIG. 2 with the tip straightened;

FIG. 4 is an enlarged fragmentary view showing the fabrication of the tip of FIG. 2;

FIG. 5 is a diagrammatic perspective view of a multi-directional bendable tip constructed in accordance with a further embodiment of the invention;

FIG. 6 is an enlarged cross-sectioned perspective view of the tip of FIG. 5; and

FIG. 7 illustrates another embodiment of the invention.

As shown in the drawings for purposes of illustration, the invention is embodied in a steerable catheter **11** comprising an elongated flexible tubular member **12** having a steerable tip **14** at its distal end. At the opposite end of the tubular member **12**, a steering control means **17** is provided for displacing fluid within a control conduit means **19** (FIG. **2**) associated with the tubular member **12** and extending to the steerable tip **14** at which the displacement of fluid results in one side of the steerable tip being lengthened relative to the other side of the tip with the result that the steerable tip bends.

More specifically, as best seen in FIG. **2**, the steerable tip **14** is formed of a stretchable material which is free to lengthen when sufficient fluid force is applied to stretch one longitudinally extending portion or side **20** of the tip relative to another or opposite longitudinally extending area or side **21** causing the tip to bend with its lengthened side **20** having a larger curvature and with its shorter side **21** having a smaller curvature. The catheter illustrated in FIGS. **1–4** is a unidirectional catheter with the side **21** constrained against lengthening by an axial restraint means **23** while the other side is free to lengthen. Additionally, a circumferential restraining means **25** in the form of helically wrapped bands or tapes **26** wound in opposite directions constrain the tip against a substantial increase in diameter while the side **20** is lengthening. The catheter **11** illustrated in FIGS. **1–4** is termed a unidirectional catheter in that it bends in the same and only one direction; and hence it will be necessary to rotate the entire tubular member **12** to turn the tip **14** if it is not already positioned to bend toward the branch blood vessel into which it is to be inserted.

A multi-directional steerable catheter **27**, such as illustrated in FIGS. **5** and **6**, may be bent at various directions and with varying amounts of curvature upon operation of the steerable control means **28** (FIG. **5**) connected to several discrete lines **30, 31** and **32** of a fluid control means **29** which also comprises several fluid control tubes. By establishing a fluid pressure differential between the control tubes and by displacing fluid in at least one of the control tubes, a steerable tip **33** may be bent from a straight position, as shown in solid lines in FIG. **5**, to the bent position, as shown in dotted lines in FIG. **5**. The bending is accomplished in general the same way as in the unidirectional catheter. That is, by displacing fluid to lengthen one side of the tip relative to an opposite side of the tip.

Referring first in greater detail to the unidirectional catheter **11** shown in FIGS. **1–4**, it is formed with a pair of coaxial tubes comprising an inner, elongated flexible tube **39** and an outer concentric elongated flexible tube **41** formed of a flexible elastomeric material such as a plastic. The innermost tube **39** has a central lumen **43** through which test fluids or instrumentation may be inserted at a proximal end **45** of the catheter. To form the control conduit means **19** for the control fluid, the inner and outer tubes **39** and **41** are joined together at a fluid tight juncture **47** at a distal end **49** for the catheter to prevent the loss of control fluid which is introduced between interior surface **51** of the outer tube and exterior surface **53** of the innermost tube **39** and within an annular control conduit passageway **55** therebetween.

A longitudinal restraint means 23 will assure that the steerable tip 14 will bend in a predetermined and predictable direction; and in this instance, the restraint means is in the form of a longitudinally extending solid filament or cord 56 such as illustrated in FIG. 4. The cord 56 is fastened to the outer side of the outer tube 41, for example, by being disposed between an inner wrap 57 of tape or cord 26 and an outer wrap 58 of a flat helically wound dacron tape or cords 26. The helically wound wraps 57 and 58 of tape serve as a constraint against substantial enlargement of the tip diameter with increased pressure of the fluid in the passageway 55. The longitudinal restraint cord 56 is disposed parallel to the longitudinal axes of the respective tubes 39 and 41 and extends substantially the length of the tip 14. To reduce the thickness of the overlapping cords, a substantially circular cross-sectioned cord 56 may be flattened into a more oval or flat cross section by passing it through a nip of a pair of rollers.

With an increase in fluid pressure in the control passageway 55, the pressure acts on the joined tube ends 47 and is longitudinally directed to cause the unrestrained side 20 of the outer tube 41 to lengthen appreciably relative to its other side 21 to which is bound the restraint cord 56. This cord is bendable but does not readily lengthen when placed in tension. The cord resists elongation and the cord 56 is bound to the underlying tape wraps 57 and thereby to the side 21 of the outer tube 41 by the outer tape wraps 58. Thus, when the tip bends, the restraining cord 56 will be at the inner smaller diameter curve, as best seen in FIG. 2, opposite the outer, larger diameter curve.

The steerable fluid control means 17 for displacing and increasing the fluid pressure within the fluid control passageway 55 may be in the form of a conventional syringe 61, as best seen in FIG. 1, which has its discharge end attached to a tube 63 which has its other end secured to the tubes 41 and 39 and disposed in fluid communication with the annular fluid control passageway 55 therebetween. The syringe has a central barrel 65 containing a supply of control liquid which is acted upon by a piston at the inner end of the plunger 67. Thus, a pressing inwardly on the plunger 67 increases the liquid pressure and displaces liquid from the syringe as the liquid acting on the tip end wall 47 forces the same forwardly with a stretching of the side 20 of the tube 41 and a bending about the constrained side 21, such as to the position shown in FIG. 2. With release of the syringe plunger 67, the liquid pressure will be reduced inside the control passageway and the stretched side 20 of the outer tube 41 will contract and straighten to return and straighten the tip.

To assure that the lumen 43 remains open and doesn't collapse during the bending of the tip 14, an internal circumferential restraint in the form of a close wound coiled spring 71 may be placed within the lumen 43 to support the interior wall of the inner tube 43. Preferably, the spring is helically wound and made of stainless steel and allows bending of the tip without collapsing the inner tube and closing the central lumen. That is, the coils of the spring resist the inward movement of the wall of tube 39 when the pressure of the fluid is increased during bending. Stainless steel is preferred for the spring to prevent contamination of the fluid being injected into the blood vessel.

Turning now for a more detailed discussion of the multi-directional catheter 27 described hereinafter in connection with FIGS. 5 and 6, it is provided with a fluid control means having a plurality of control passageways in the form of tubes 73, 74 and 75 (FIG. 6) bonded along the exterior of an inner tube 77 having an inner lumen 79 through which a contrasting fluid or instrument may be inserted. The control tubes 73, 74 and 75 are spaced circumferentially about the outer surface of the innermost tube and bonded thereto at equi-angularly spaced locations. The control tubes have closed ends located at distal end 81 of the bendable tip 33 against which pressurized liquid in the tube will exert longitudinally directed forces to stretch the control tube and the underlying portion of the inner tube 77.

To constrain the control tubes 73, 74 and 75 against enlarging appreciably in diameter when fluid is displaced therein, the control tubes are preferably overwrapped with oppositely disposed lays of helically wound tape 83, of a thin flat dacron material. The helical windings will allow bending and stretching of the inner tube 77 and control tubes 73, 74 and 75 but constrain the latter against substantial enlargement of the diameter thereof with increase in pressure of the liquid during bending of the tip. Preferably, the windings of tape are disposed side by side in each lay to prevent the bulging of an expanded tube between adjacent windings while still keeping the bulk of winding reduced. Preferably, an elastomeric coating 85 of plastic is applied to outer wraps of the tape 83 to impregnate the same and form a smooth outer wall of plastic for the catheter tip 33. For example, successive applications of urethane may be applied to impregnate the tape windings and to build a plastic coating for the tip.

An internal circumferential restraint in the form of a close wound coiled spring 78 may be placed within the lumen 79 to resist the inward movement of the wall of the inner tube 77 when the pressure of the fluid in the control tubes 73, 74 and 75 is increased during the bending of the tip 33. Preferably, the spring is helically wound and allows bending of the tip without collapsing the inner tube and closing the lumen. Stainless steel is the preferred material for the spring to prevent contamination of fluids being injected into the blood vessel.

The steering control means 28 for the multi-directional catheter 27 may be of several types. For example, the illustrated steering control means 28 comprises three syringes 91, 93 and 95 each attached to one of the tubular line 30, 31 and 32 leading to and connected in fluid communication with one of the control tubes 73, 74 and 75. By depressing inwardly on a plunger of one of the syringes, fluid within its syringe barrel 96 may be placed under increased pressure and displaced therefrom into its associated line and control tube to cause stretching of its control tube and its attached portion of the inner tube 77. A simultaneous operation of two of the syringes to increase liquid pressure within two control tubes causes the bending to occur along a path between the bending positions caused with operation of only a single one of the syringes.

A more compact steering control means 28 more readily operable with one hand may be achieved by replacing the three individual syringes with one pistol grip handle having three plunger operating triggers or buttons incorporated therein for operation by each one of three fingers gripping the handle. Then, either one or a combination of two buttons may be depressed to increase pressure in attached fluid control lines **30, 31** and **32** to cause the tip **33** of the multi-directional catheter **27** to bend and steer in the desired direction such as shown in dotted lines in FIG. **5.**

The multi-directional catheter **27** having three control tubes **73, 74** and **75** has been found to be relatively stable and predictable as to its direction of turning and may be operable with reasonable fluid operating pressures. Multi-directional catheter have been made with two control tubes (now shown) but they have not been found to possess the stability and the predictability in turning that the three tube multi-directional catheters possess. On the other hand, increasing the number of control tubes from three to four has been found to result in the necessity for a greater-operating fluid pressure to cause bending because of increased frictional losses due to the small size of the four individual control tubes. Thus, the catheter with three control tubes is preferred.

While the illustrated multi-directional catheter **27** is fabricated with separate fluid control tubes **73, 74** and **75** which are individually preformed and then secured by adhesive to the inner tube **77,** reduced cost for the catheter may be achieved by integrally molding the innermost tube and control fluid passageways from a suitable plastic material. A one-piece molded catheter having fluid control passages may be sufficiently low in cost to be disposable.

In another smaller diameter embodiment of the invention, a steerable tip **101,** as best seen in FIG. **7,** comprises a flexible resilient tube **103** with a closed end **105** having a central control conduit means in the form of a hollow interior passageway **107** in the tube **103.** A longitudinal restraint **109** is secured along the one side of the tube **103** by a circumferential restraint which is formed with opposed helical wraps of tape **111.** The tube **103** extends to the proximal end of the catheter for connection to a syringe (not shown) of its associated steering control means. An outer concentric tube **113** having a larger diameter is joined to the inner tube **103** at a juncture wall **114** adjacent the steerable tip but rearwardly thereof to form an annular passageway **115** extending rearwardly to the proximal end of the tube. A series of apertures **117** are formed in the outer tube **113** adjacent the steerable tip for allowing contrast media or catheter test fluid to be ejected from the annular passageway **115.** For example, such test fluids may be supplied from a syringe (not shown) and forced through a line extending therefrom to the annular passageway **115** whereby such test fluid may flow from the apertures **117** adjacent the steerable tip. The latter is bent when liquid under pressure from the steering control syringe is forced through the central passageway **107** in the inner conduit to stretch the side of the tip **101** opposite the longitudinal restraint **109.** As the steerable tip does not include the outer tube **113,** the outside diameter of the tip including the circumferential wraps **111** may be kept smaller.

From the foregoing, it will be seen that the present invention is directed to a fluid displacement steerable catheter which eliminates the stiffness and frictional resistance of control wires or the like used in prior art catheters. The fluid displacement catheter may be made with relatively inexpensive flexible, resilient plastic tubes or flexible, resilient elastomeric material molded in one piece. The desired degree and direction of bending of the tip may be attained by controlling the amount of fluid displaced and the pressure exerted on one longitudinal side of the tip relative to another longitudinal side thereof. Additionally, the catheter may be made with dimensions sufficiently small to pass through blood vessels and still provide a lumen for the injection of contrasting media or instrumentation into the human body.

While a preferred embodiment has been shown and described, it will be understood that there is no intent to limit the invention by such disclosure but, rather, it is intended to cover all modifications and alternate constructions falling within the spirit and scope of the invention as defined in the appended claims.

What is claimed is:

1. An elongated steerable catheter extending from a proximal to a distal end for passing through channels defined by walls in a body, said catheter comprising an elongated tube having a longitudinally extending passageway therein extending from the proximal end to a discharge opening adjacent the distal end, at least one control conduit means receiving a control fluid associated with the elongated tube and extending longitudinally from said proximal end to said distal end, said distal end of said tube being formed of a flexible, thin stretchable and contractible material for axial elongation with increase in pressure in said control conduit means and for contraction with reduction of said increase in pressure, said catheter having a predetermined overall length and a predetermined external cross-sectional dimension remaining substantially unchanged with increase of pressure in said control tube, and steering control means for displacing said control fluid in said control conduit means to cause one portion of said elongated tube at the distal end of the catheter which is the least restrained by the walls of the channel to stretch and to lengthen further into said channel and relative to another portion of said elongated tube which is more restrained by engagement with the walls of said channels, said lengthened portion being free to bend about said another portion in proportion to the pressure of control fluid and at various locations dependent upon the location of the restraint of said another portion so that tip may bend with varying radii dependent upon the radii of the channel.

2. A catheter in accordance with claim **1** in which said control conduit means is an inner tube having a hollow central passageway and in which said elongated tube is an outer tube coaxial with said inner tube and in which said passageway of said elongated tube is annular in cross section, said discharge opening of said elongated tube being radially directed and in said outer tube.

3. A catheter in accordance with claim **1** in which means are provided in said distal end of said tube passageway to hold the same against collapsing inwardly and closing said tube passageway when bending the catheter distal end.

4. A catheter in accordance with claim **3** in which said means to hold said tube passageway against collapsing is a coiled spring inserted into said lumen at said distal end thereof.

5. A catheter in accordance with claim **3** in which a said control conduit means comprises plurality of longitudinal extending control conduits are spaced circumferentially about said tube and in which said steering control means is connected to each of said control conduits to provide a pressure differential within and between said control conduits to stretch said one portion of said tube thereby causing said distal end to bend.

6. A catheter in accordance with claim **1** in which a circumferential restraining means holds said control conduit means from a substantial radially outward expansion with an increase of pressure in said control conduit.

7. A catheter in accordance with claim **6** in which said circumferential restraining means comprises helically wound wraps of opposite lays which permit lengthening of one portion of the distal end of the tube relative to the other portion.

8. An elongated steerable catheter extending from a proximal to a distal end, said catheter comprising an elongated tube having a longitudinally extending passageway therein extending from the proximal end to a discharge opening adjacent the distal end, an elongated control conduit for receiving a control fluid associated with the elongated tube and extending longitudinally from said proximal end to said distal end, a constraining means for constraining one portion of said tube at said distal end against lengthening longitudinally to the extent that another portion lengthens under fluid pressure in said control conduit, and steering control means for increasing the pressure of said control fluid in said control conduit to elongate said other portion of said tube relative to said one portion causing said distal end to bend with said other portion having a larger radius of curvature than the one portion of the tube.

9. An elongated catheter extending from a proximal end to a distal end which is steerable in multiple directions, said catheter comprising an elongated tube having a longitudinally extending passageway therein extending from the proximal end to a discharge opening adjacent the distal end, said distal end of said tube being stretchable and contractible, a plurality of discrete longitudinally extending control conduits spaced circumferentially about said tube and extending from said proximal end to said distal end, said control conduits being connected to said distal end of said steerable catheter at circumferentially spaced positions for stretching an associated portion of said distal end of said tube with establishment of a differential fluid pressure and displacement of fluid among said control conduits, and a steering control means having a plurality of selectively operable pressure increasing means each associated with one of said control conduits for increasing the pressure of fluid in its associated discrete control conduit for stretching its associated portion of the distal end of said tube, selective operations of said pressure increasing means establishing pressure differentials causing the tube distal end to bend in different directions.

10. A catheter in accordance with claim **9** in which said control conduits comprise three separate tubes each extending along and secured about an outer wall for said elongated tube and in which a restraining means is helically wound about said control tubes to limit the radially outward expansion thereof with an increase in fluid pressure within the respective ones of the control tubes.

11. A catheter in accordance with claim **10** in which means are provided in said distal end of said tube passageway to hold the same against collpsing inwardly and closing said tube passageway when bending the catheter distal end.

12. An elongated steerable catheter extending from a proximal to a distal end, said catheter comprising an elongated tube having a longitudinally extending passageway therein extending from the proximal end to a discharge opening adjacent the distal end, at least one control conduit means receiving a control fluid associated with the elongated tube and extending longitudinally from said proximal end to said distal end, steering control means for displacing said control fluid in said control conduit to cause one portion of said elongated tube at the distal end of the catheter to lengthen relative to another portion of said elongated tube causing the distal end to bend with the lengthened portion having a larger radius of curvature than the other portion of the elongated tube, means in said distal end of said tube passageway for holding the same against collapsing inwardly and closing said tube passageway when bending the catheter distal end, and a constraining means constraining said other portion of the tube against lengthening longitudinally to the extent that said one portion lengthens whereby the constrained other portion of the tube is at the smaller inside radius of curvature for the bent end of the catheter.

* * * * *

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,773,034 Dated November 20, 1973

Inventor(s) MARVIN BURNS, CHARLES THOMAS OGDEN and RICHARD A. RODZEN

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

On the first sheet of the patent, the Assignee should read

--IIT Research Institute, Chicago, Illinois--.

Signed and sealed this 16th day of April 1974.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents

File No.30700