United States Patent

[11] **3,568,660**

[72] Inventors **Nelson A. Crites; Samuel P. Chambers, Columbus, Ohio**

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[22] Filed **Nov. 20, 1967**
[45] Patented **Mar. 9, 1971**
[73] Assignee **The Battelle Development Corporation Columbus, Ohio**

[54] **PACEMAKER CATHETER**
5 Claims, 12 Drawing Figs.

[52] **U.S. Cl.** **128/2,** 128/2.1, 128/172.1, 128/419
[51] **Int. Cl.** **A61b 5/10**
[50] **Field of Search** 128/2, 2.05, 2.06, 2.1, 172.1, 348, 416, 418, 419, 404

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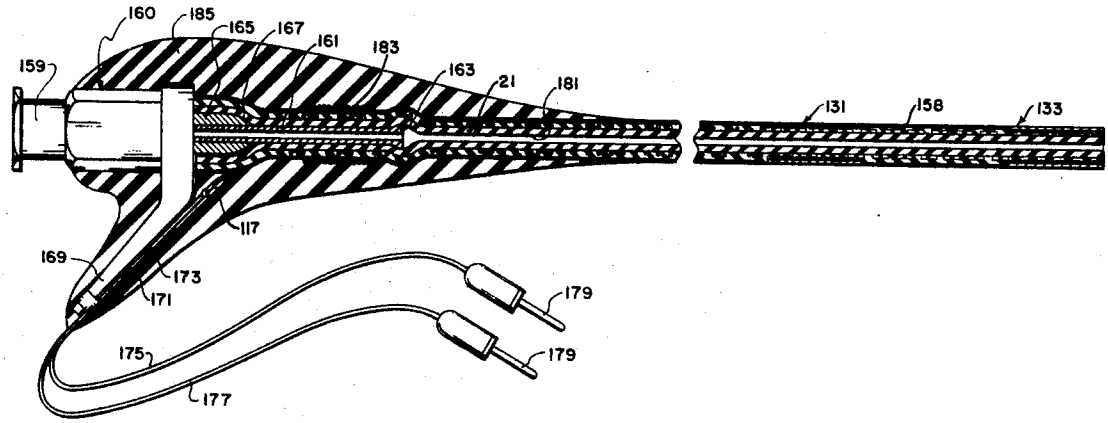
Primary Examiner—Delbert B. Lowe
Attorney—Gray, Mase and Dunson

ABSTRACT: A multipurpose catheter and method of producing the same which involves applying a thin, first layer of rubber over the external surface of a selected length of flexible tubing, with the rubber being dissolved in a solvent and applied to the tubing in an atmosphere of the solvent, partially drying the first layer of rubber, helically winding at least two electrical conducting wires over the surface of the tubing and embedding the wires in the first layer of rubber, drying the first layer of rubber, extracting an end portion of each conductor from beneath the first coating near one end of the tubing and flat winding each end portion to form spaced electrode bases, providing a metal contact sleeve over each base to form electrodes, applying a thin second layer of rubber over the first layer in an atmosphere of the rubber solvent, drying the second layer of rubber, and connecting the opposite ends of the conductors to electrical jacks. A split needle is provided for use in inserting the catheter, the needle being thereafter withdrawn. For facilitating such withdrawal, the needle is constructed in two halves with a slidable cylindrical lock ring.



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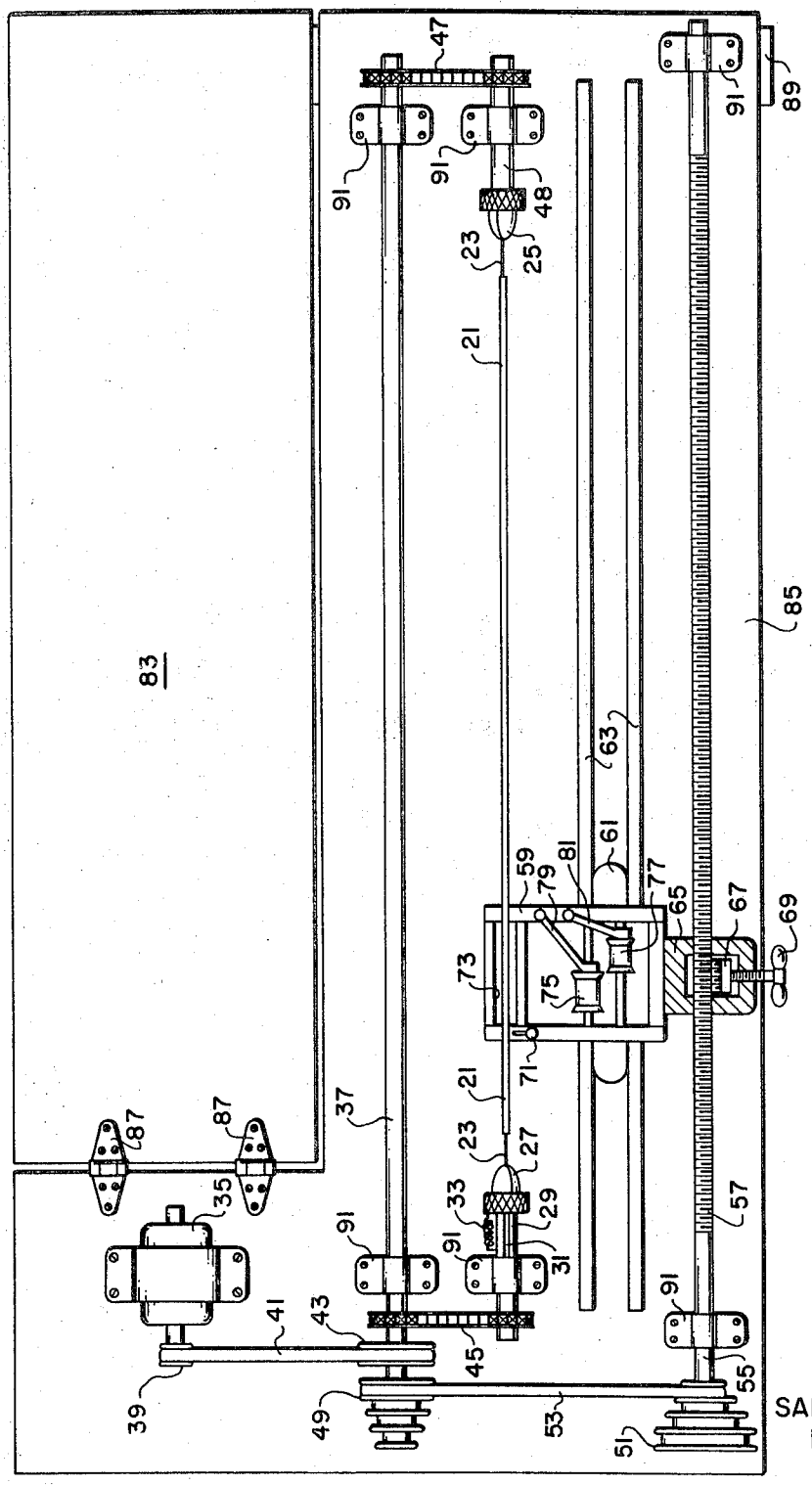

Fig. 1

SAMUEL P. CHAMBERS
NELSON A. CRITES
INVENTOR

BY Gray, Mase and Dunson ATTORNEYS

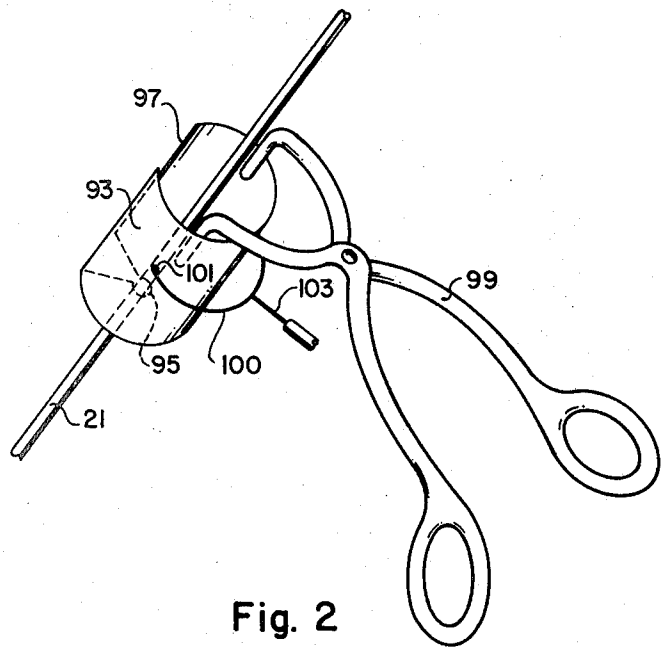

Fig. 2

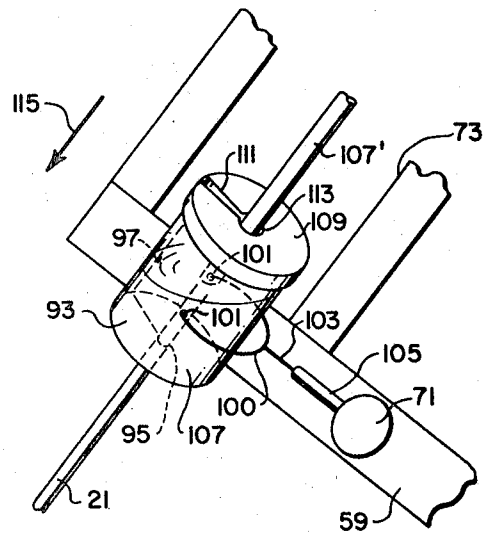

Fig. 3

SAMUEL P. CHAMBERS
NELSON A. CRITES
INVENTOR

BY Gray, Mase and Dunson ATTORNEYS

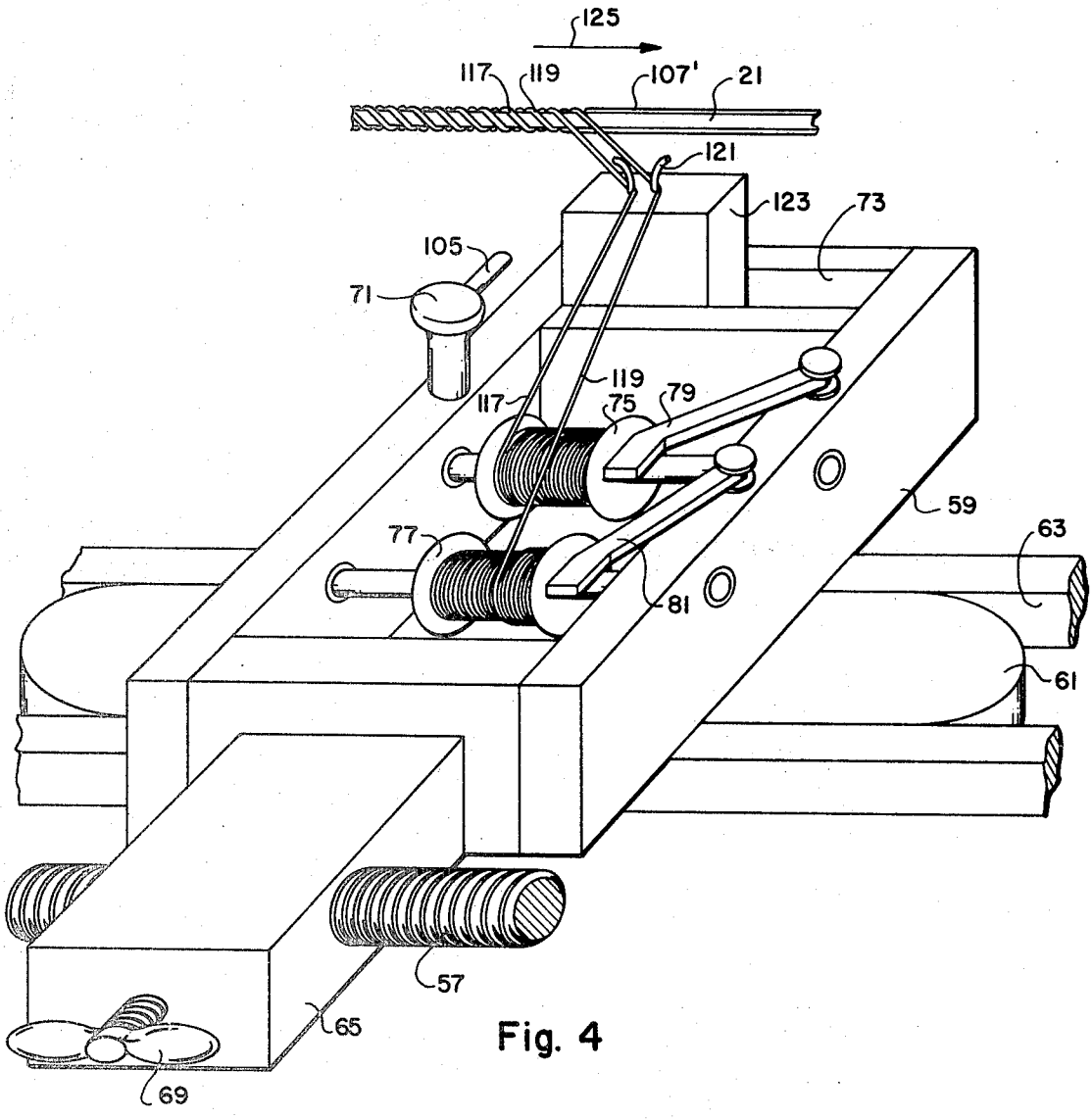

Fig. 4

SAMUEL P. CHAMBERS
NELSON A. CRITES
INVENTOR

BY Gray, Mase and Dunson ATTORNEYS

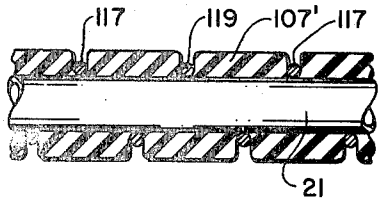

Fig. 5

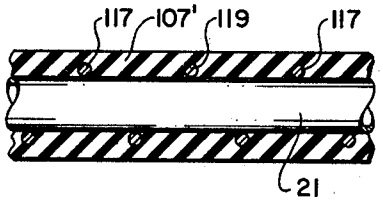

Fig. 6

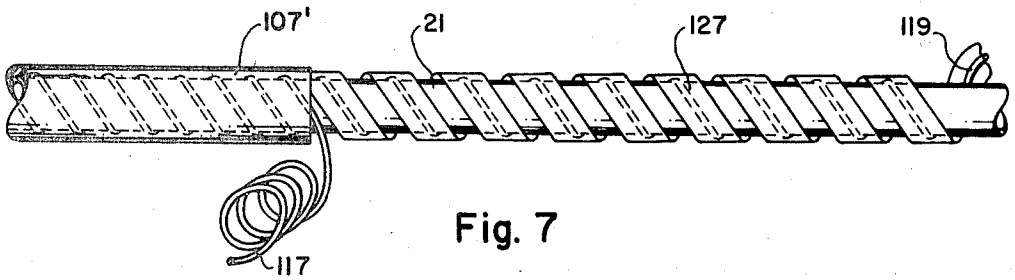

Fig. 7

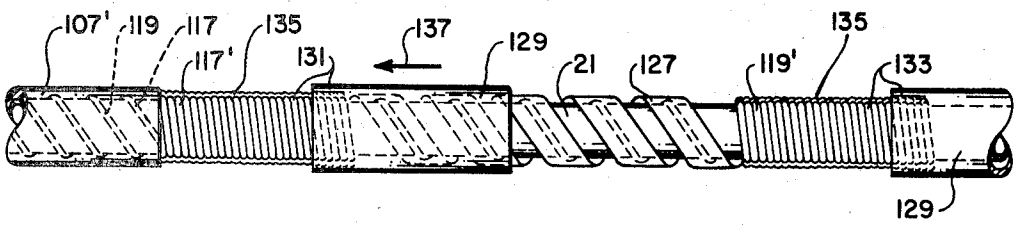

Fig. 8

SAMUEL P. CHAMBERS
NELSON A. CRITES
INVENTOR

BY Gray, Mase and Dunson ATTORNEYS

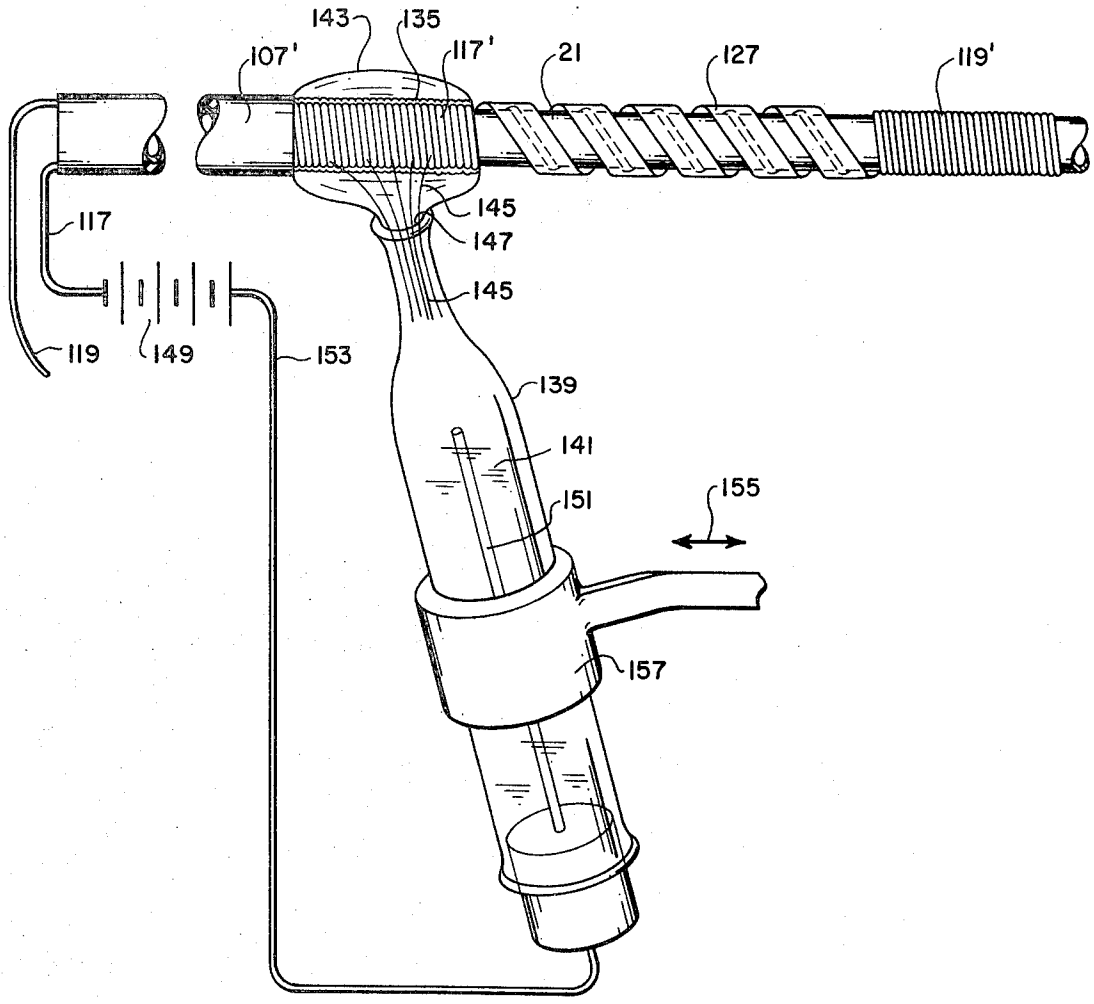

Fig. 9

SAMUEL P. CHAMBERS
NELSON A. CRITES
INVENTOR

BY Gray, Mase and Dunson ATTORNEYS

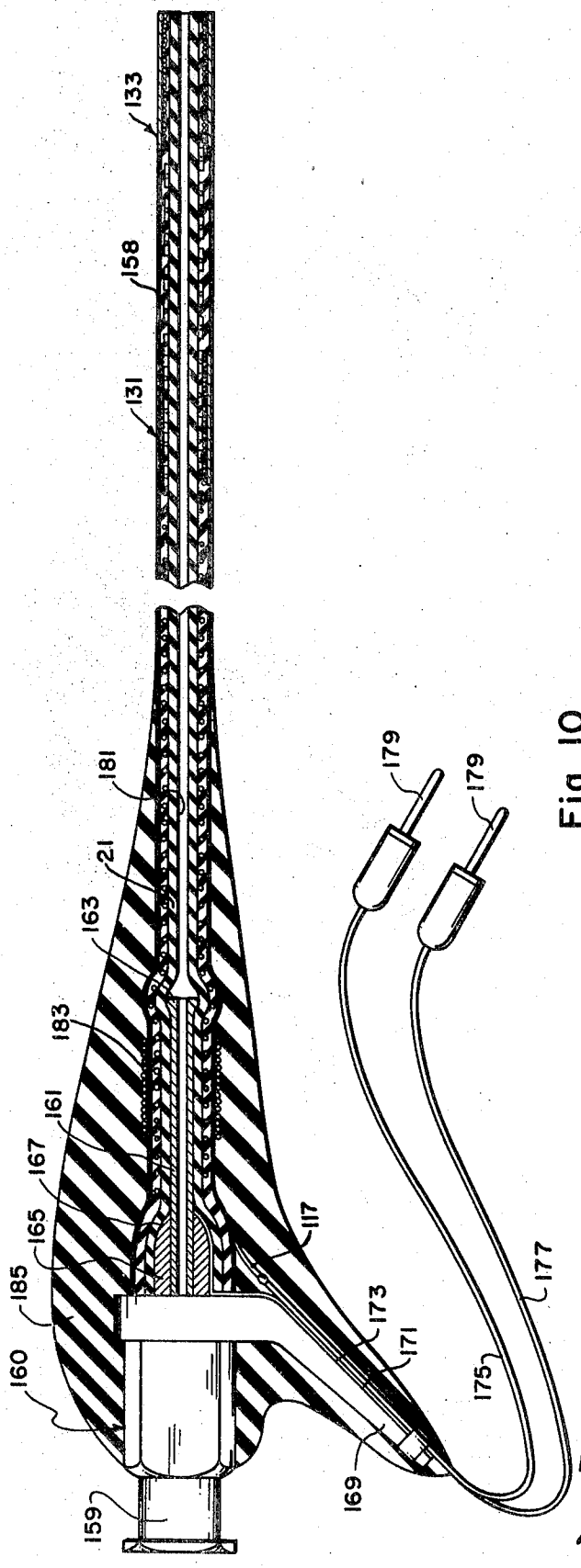

Fig. 10

SAMUEL P. CHAMBERS
NELSON A. CRITES
INVENTOR

BY Gray, Mase and Dunson ATTORNEYS

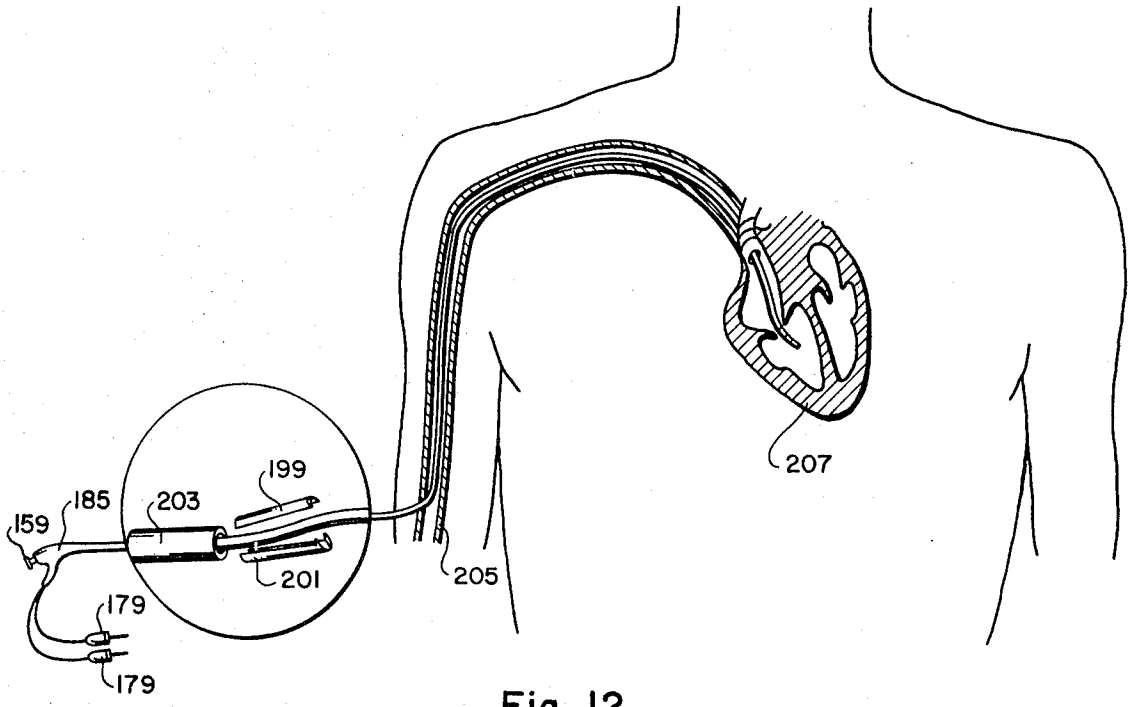

Fig. 12

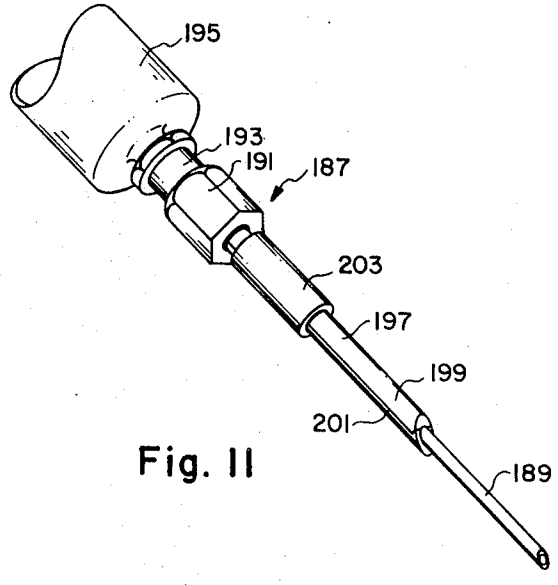

Fig. 11

SAMUEL P. CHAMBERS
NELSON A. CRITES
INVENTOR

BY Gray, Mase and Dunson ATTORNEYS

PACEMAKER CATHETER

BACKGROUND OF THE INVENTION

This invention concerns a medical device for insertion into the circulatory system to obtain blood samples, introduce fluids into the circulatory system, detect cardiac ailments, or provide electrical impulses for stimulating heart beat as a temporary pacemaker.

There have been a number of catheters developed in the past usually designed for a specific requirement or test on the heart. Here have been phonocardiac catheters, pacemaker catheters, catheters with thermistors, platinum electrodes, strain gauges sampling lumen, etc. There are very few catheters that combine a number of the various recording or activating elements and, as a consequence, right heart catheterization usually requires more than one catheter if there are a number of tasks to be done. Once a catheter position has been reached it is time consuming and often impossible to duplicate the position with a second catheter for additional different measurements or treatments. Also, present catheters (especially catheters for taking more than one reading or having a central lumen) are no smaller than a No. 6 French (.078 inch outside diameter) and usually require the aid of a fluoroscope for insertion through the blood vessels into the heart.

There is little time to spare with a heart failure patient. When a patient would benefit from a pacemaker the quickest solution has been to apply an external pacemaker to the chest over the heart area. This type of pacemaker sends a heavy electric charge through the chest wall and frequently causes damage to tissue. Therefore, there is a need for a catheter that can be quickly inserted directly into the heart so that the pacemaker voltage can be small. Such a pacemaker can be maintained for prolonged periods until the patient recovers or a more permanent battery operated pacemaker can be installed by surgery.

In order to establish a diagnosis or evaluate the severity of heart problems, other catheter functions are extremely useful, such as: blood samples for oxygen determination, intercavity electrocardiograms, hydrogen-sensing electrodes to detect cardiac shunts, pressure recording in cardiac chambers, great vessels and from pulmonary wedge positions, injection of radiopaque substances for X-ray studies, and injection of an indicator dye to determine circulatory dynamics.

Ordinarily, the catheter is inserted in an appropriate vein (usually the median basilic vein of an adult or the saphenous vein in the groin of an infant) and the tip of the catheter is maneuvered while the patient is under a fluoroscope until the catheter reaches the accessible intracardiac chamber or great vessels. A hypodermic needle of appropriate size is first inserted into the vein and the catheter is then inserted through the hydpodermic needle. The needle withdrawn remains in the body until the catheter is withdrawn. Flexibility is an important factor, since, if the catheter is too stiff, it will tend to pierce the walls of the vessels. The catheter of this invention is both small in diameter and flexible so that it tends to follow the blood vessel readily, thereby eliminating the need for a fluoroscope. Furthermore, use of the split needle disclosed herein allows the entering and guiding hypodermic needle to be removed from the body after the catheter is in position to reduce tissue damage and discomfort in the area of catheter insertion. The small outside diameter of the catheter is especially advantageous in the catheterization of infants who naturally have small blood vessels. Thus, the .048 inch outside diameter of the catheter disclosed is an important factor.

SUMMARY OF THE INVENTION

The apparatus of this invention includes a flexible tubing base having a central lumen, a first coating of rubber over the tubing, at least two conductors helically wrapped around the tubing base and embedded in the first coating of rubber, a second coating of rubber over the conductors, at least two electrodes spaced from one another near one end of the tubing, each electrode connected to one of the conductors, and means at the opposite end of the tubing for providing electrical jacks for the conductors and a connector to provide access to the central lumen. Some special provisions include platinum electrodes plated over the conductors which are flat wound over the tubing base at the desired positions for the electrodes. Also, another embodiment includes fiber glass or dacron woven sleeving over the outside of the catheter which may be impregnated with rubber.

Briefly described, the method of producing a multipurpose catheter includes applying a thin, first layer of rubber over the external surface of a selected length of flexible tubing, with the rubber being dissolved in a solvent and applied to the tubing in an atmosphere of the solvent; partially drying the first layer of rubber; helically winding at least two electrical conducting wires over the surface of the tubing and embedding the wires in the first layer of rubber; drying the first layer of rubber; applying a thin second layer of rubber in an atmosphere of the rubber solvent; drying the second layer of rubber; and connecting an electrode to each of the wires with the electrodes fitting closely around the tubing, spaced from one another, and near one end of the tubing.

One object of this invention is to provide a medical device for use in the catheterization of the circulatory system that acts as a pacemaker, means for introducing fluids into the blood stream at selected locations, and a blood pressure measuring device, detecting various pathological conditions and measuring electrical impulses from the heart.

Another object of this invention is to provide a medical device including a very small catheter having a useful central lumen to reduce trauma and other difficulties associated with catheterization.

Still another object of this invention is to provide a method of fabricating a miniaturized catheter having all the features and advantages of larger catheters and combining the uses of a number of catheters.

One advantage of this invention is that the catheter has a small outside diameter but still has a central lumen that has a sufficiently large inside diameter to be useful in taking blood samples, administering fluids, etc.

Still other objects and advantages of the invention will be apparent from the detailed description of the process and apparatus, the drawings, and claims that follow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of an apparatus suitable for constructing the catheter of this invention;

FIG. 2 shows a method of positioning a cup around the tubing base in preparing to apply a rubber coating to the tubing;

FIG. 3 shows a method of applying a rubber coating to the tubing;

FIG. 4 is an enlarged view of the carriage of the apparatus of FIG. 1 showing the application of the wire conductors to the catheter;

FIG. 5 is a cross section of the catheter showing the conductor wires after they have been wound onto the catheter through the first soft rubber coating;

FIG. 6 is a cross section of the catheter showing the condition after the first coating of rubber heals over the conductor wires and hardens;

FIG. 7 is a view of the eventual electrode end of the catheter showing some of the steps in applying the electrodes;

FIG. 8 is a view of the eventual electrode end of the catheter showing one method of applying the electrodes;

FIG. 9 is a view of the electrode end of the catheter showing a plating method of applying the electrodes;

FIG. 10 is a cross-sectional view of the catheter showing the attachment of the catheter tube to a Luer-Lok and the attachment of the wire conductors to electrical jacks;

FIG. 11 is a perspective view of the split needle; and

FIG. 12 is a diagram of the catheter inserted into a patient and having an enlarged insert showing the removal of the split needle after the catheter is in position in the body.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the drawings, the same reference numerals are applied to identical parts in all embodiments and such identically numbered parts are substantially identical in structure, function and operation. Therefore, to eliminate confusing duplication, these parts, their interrelationship and their function will be described only in conjunction with a single embodiment, such description applying to all embodiments where there parts appear.

Referring to FIG. 1, the tubing base 21 is threaded onto a mounting wire 23 and one end of 29 wire 23 is positioned in the tailstock chuck 25 which is tightened to hold the wire 23 firmly at one end. One way of making it easier to thread the tubing 21 onto the mounting wire 23 is to coat the wire with sodium bicarbonate which then acts as a lubricant when the tubing 21 is threaded onto the wire 23. The opposite end of wire 23 is affixed in the headstock chuck 27. Headstock chuck 27 is slideably mounted on shaft 29 by means of a key (not shown) fitted into a groove 31 on shaft 29. A spring 33 is attached between shaft 29 and chuck 27 and is adjusted to exert a pulling force (preferably about 10 pounds) on chuck 27 which is applied along wire 23.

A power source 35 (such as an electric motor) rotates shaft 37 by means of pulley 39, belt 41, and pulley 43. A chain and sprocket device 45, connected between shafts 37 and 29, drives headstock chuck 27 and similarly a chain and sprocket device 47 drives shaft 48 of the tailstock chuck 25. The positive drive, such as a chain and sprocket, is preferred to ensure that both of the chucks 25 and 27 rotate at the same speed, thus eliminating any twisting of the mounting wire 23. A step pulley 49 is attached to shaft 37 and drives another step pulley 51 by means of a belt 53. Step pullet 51 is affixed to a shaft 55 which has threads 57 over most of its length. The belt 53 may be positioned on different steps of pulleys 49 and 51 to adjust the rotational speed of shaft 55.

A carriage 59 is provided with a guide 61 that is fitted into a track 63 running parallel to the length of the tubing 21. A projection 65 on the carriage 59 includes thread-engaging means 67 that is moved into and out of engagement with threads 57 by rotating a handle 69 so that the carriage 59 is driven along the track 63 when thread engaging means 67 is pressed against threads 57. The carriage 59 is movable in either direction. Direction change is accomplished by twisting belt 53 into a figure eight. Carriage 59 includes a number of devices that are used to construct the catheter. These include a cup holder 71, comb slot 73, wire spools 75 and 77 and spool brakes 79 and 81.

The entire device is mounted on a table having a fixed portion 83 and a tiltable portion 85. The two table portion 83 and 85 are connected by hinges 87–87. A stop or rest 89 is positioned under tiltable portion 85 to maintain it in the horizontal position. During the application of rubber coatings to the tube 21 the tiltable portion 85 is raised until the tube 21 is inclined at an angle of at least 45° degrees above the horizontal. Suitable bearing mounts 91–91 are provided for shafts 29, 37, 48, and 55.

After the mounting wire 23 is affixed in the chucks 25 and 27, a stretching force (of about 1 pound, preferably) is applied to the tube 21 manually and the ends of the tube are taped to the wire 23. The wire 23 and tube 21 are then rotated and hot air (at about 350 to 450° F.) is blown over the tubing 21. The hot air softens the tubing 21 (preferably constructed of Teflon) removing any kinks or undulations that may have been originally constructed into the tubing 21.

FIGS. 2 and 3 show a method of applying a rubber coating to the tubing 21. A flexible cup 93 having a small hole 95 in the bottom and a split 97 down the side and across the bottom to the hole 95 is spread apart by suitable means such as the instrument 99, fitted over the tubing 21 and allowed to spring back so that the tube 21 passes through the hole 95 in the bottom. The cup 93 is supported by a yoke 100 having two ends 101–101 that are pivotally mounted in the sides of the cup 93 and an arm 103 fits slideably into a tube 105 of cup holder 71. The cup 93 is thus allowed to both pivot (at ends 101) and slide (arm 103 and tube 105) in gimballike arrangement so that any irregularities in the mounting wire 23 or tubing 21 are tracked or followed by the cup 93 as the tubing 21 is rotated.

The table portion 85 is tilted upward to about 45 degrees or more and the carriage 59 with the cup 93 is moved up next to the tailstock chuck 25. The cup 93 is partially filled with liquid rubber 107 in a solvent such as xylene. A cap 109 having a slot 111 and central opening 113 is placed on the cup 93 and, preferably, an atmosphere of xylene is introduced into the space above the liquid rubber 107 (for example with an atomizer). Pulleys 49 aNd 51 are connected by belt 53 so that the carriage 59 moves in the direction of the arrow 115 (from tailstock toward headstock) while the tube 21 is rotated and a thin coating of rubber 107′ is applied to the surface of the tubing 21. Preferably the tubing 21 is made of Teflon with an etched exterior surface. The etched surface aids in making a good bond between the tubing 21 and the rubber coating 107′.

FIG. 4 shows a means of adding the wire conductors 117 and 119 to the tubing 21 with rubber coating 107′. The carriage 59 has moved back to the headstock chuck 27 while applying the rubber coating 107′. The coating 107′ is allowed about 10 minutes drying time. The wires 118 and 119 are passed from spools 75 and 77 through a comb 121 affixed to a block 123 that is mounted in comb slot 73. The belt 53 is arranged so that the carriage moves from the headstock chuck 27 toward the tailstock chuck 25 as indicated by the arrow 125 in FIG. 4. The tubing 21 rotates and the wires 117 an 119 are pulled from the spools 75 and 77 and applied in a helical fashion to the tubing 21. The brakes 79 and 81 create a drag on the spools 75 and 77 ensuring that the wires 117 and 119 are wound tightly onto the tubing 21.

FIG. 5 shows how the wires 117 and 119 "bite" through the incompletely hardened rubber coating 17′ so that the wires 117 and 119 are actually wound onto the exterior surface of tubing 21. As the coating 107′ congeals more and hardens, it heals over the wires 117 and 119 as shown in FIG. 6. The step of winding the wires 117 and 119 "through" the rubber coating 107′ is important, since, by using this procedure, a smooth coating over the wires 117 and 119 results. If the wires 117 and 119 were applied before the rubber coating 107′, the result would be an undesirable series of bumps over each wire or a wavy appearance.

FIG. 7 shows the early steps in adding the electrodes to the catheter. Both of the wires 117 and 119 are "teased" out through the rubber coating 107′ at the electrode end of the catheter. A length of the rubber coating 107′ is scraped off. After the rubber coating 107′ has been removed the tubing 21 is preferably reetched and then one of the wires (for example 119) is rewrapped onto the tubing 21. The rewound wire 119 is then covered by a length of thin Teflon tape 127 which is held in place by an epoxy cement. In one embodiment, a woven (preferably Dacron) sleeve is slid over the tubing before the second coating of rubber is applied.

In FIG. 8 one type of electrode exterior is being added to the catheter shown in FIG. 7. One of the wires 117 is flat wound around the tubing 21 over the tape 127 to form an electrode base 117′ for the proximal electrode 131. The other wire 119 is flat wound around the tubing 21 closer to the end or at the end to form an electrode base 119′ for the distal electrode 133. After the wire is flat wound a silver epoxy 135 is applied over the wire and to the inside of the electrode exterior sleeves 129 (in this instance the electrode exterior sleeves 129 are machined from a suitable material such as stainless steel) and the sleeves 129 are passed over the end of the tubing 21 and pushed over the electrode bases 117′ and 119′ as shown by the arrow 137. The silver epoxy 135 acts as a solder connection to give good electrical contact between the electrode bases 117′, and 119′, and the sleeves 129–129.

Another method of forming the electrodes is shown in FIG. 9. The wire conductors 117 and 119 are again flat wound to form electrode bases 117′ and 119′. The electrode bases 117′ and 119′ are coated with a silver epoxy 135 and the electrode

exteriors are formed by plating the electrode bases 117' and 119'. A container 139 (such as an eye dropper) is filled with a plating solution 141. A droplet 143 is fed around the electrode base 117' with capillary exchange between the container 139 and droplet 143 aided by a plurality of small fibers 145 at the mouth 147 of the container 139. The conductor 117 is connected to a battery 149 so that the electrode base 117' acts as a cathode and the anode 151 is also connected to battery 149 by a conductor 153. The container 139 is oscillated gently, as shown by the double arrow 155, by a small force applied through the container holder 157. If desired, additional wire may be wound over electrode bases 117'—119' and soldered in place in order to build the final diameter of the electrodes up to a selected size.

Preferably, three layers of material are plated onto the electrode base. The first layer is a thin copper plate, followed by a thin plate of 24 carat gold and finally a plate of platinum. After the electrodes are completed, a final coat 158 of medical grade silicone rubber is applied to the entire catheter in the same manner shown in FIG. 3. In order to prevent the coating from adhering to the electrodes, they are masked off by a thin coating of adhesive which is removed after the final coating of rubber has hardened.

FIG. 10 shows the completed catheter with a Luer-lok 159 attached to the end opposite the electrodes 131—133. The catheter end piece 160 is constructed by cutting off part of the needle portion 161 from a standard hypodermic needle. The cut end preferably is flared very slightly to form a small end enlargement 163. A cylinder 165 having a rounded nose 167 is fitted over the needle 161 and affixed to the Luer-Lok 159. A handle 169 is fitted over the cylinder 165 and also attached to the Luer-Lok 159. An electrically insulating epoxy 171 is applied over the exposed surface of the cylinder 165 and a surface 173 of the handle 169. The conductors 175 and 177 from two electrical jacks 179–179 (or as many jacks as there are conductors woven into the catheter) are glued in place along the insulating epoxy 171 on the exposed surface 173 of the handle 169. The lumen 181 of the tubing 21 is enlarged by thrusting a heated needle or wire into the lumen 181, thereby expanding the lumen to fit over the needle portion 161 and cylinder 165. After the needle portion 161 and cylinder 165 has been inserted into the lumen 181, a length of wire 183 is wrapped over the exterior of the catheter to hold the catheter to the catheter end piece 160. The proximal ends of the conductors 117 and 119 are then soldered to the conductors 175 and 177. The Luer-Lok 159 is masked off and the end piece and proximal end of the catheter are dipper repeatedly in liquid rubber until a thick protective base 185 is built up around the junction of the end piece 160 and the catheter, the base 185 tapering off along the catheter. Preferably, the thickness of the rubber 185 at the junction of the end piece and tubing inches is about 50 mils tapering to zero at about 1¼ inches from the junction.

FIG. 11 shows the portion of the medical device that is used preliminary to inserting the catheter into the body and it is called a split needle 187. This portion of the medical device includes a needle 189 customarily provided with an end piece 191 and Luer-Lok 193. A syringe portion 195 usually containing saline is attached to the Luer-Lok 193. A split needle 197 having two portions 199 and 201 is slipped over the needle 189 and the two portions 199 and 201 are held together by a cylinder 203 that slides over the assembled split needle 197.

FIG. 12 shows the medical device in use. The standard hypodermic needle 189 (FIG. 11) is inserted into a blood vessel 205 and the split needle 197 is slid along the needle 189 until it is also positioned in the blood vessel 205. The standard needle 189 is the withdrawn and the catheter is inserted through the split needle 197. The catheter is further fed through the split needle 197 and blood vessel 205 until it reaches the desired position in the heart 207 (as determined, for example, by indication from an electrocardiograph). Once the catheter has reached the desired position in the circulatory system, the split needle 197 is withdrawn from the blood vessel 205; the sleeve 203 is slid off the split needle 197; and the two halves 199 and 201 are separated and removed from the catheter. The jacks 179–179 and Luer-Lok 159 may be connected to appropriate mechanisms any time during the procedure as desired by the operator.

It will be understood, of course, that, while the forms of the invention herein shown and described constitute the preferred embodiments of the invention, it is not intended herein to illustrate all of the possible equivalent forms or ramifications of the invention. It will also be understood that the words used are words of description rather than of limitation, and that various changes, such as changes in shape, relative size, and arrangement of parts may be substituted without departing from the spirit or scope of the invention herein disclosed.

We claim:

1. A catheter for insertion into the circulatory system comprising:
   a. a flexible tubing having a central lumen;
   b. a first coating of rubber on the outer surface of said tubing;
   c. at least two conductors helically wound over said flexible tubing and embedded in said first coating of rubber;
   d. a second coating of rubber overlying said first coating; and
   e. an electrode connected to each said at least two conductors, each said electrode including a flat wound section of the corresponding conductor overlaid by and attached to a metallic sleeve with each said electrode spaced from one another and near one end of said tubing, the conductor ends opposite the electrodes being accessible for connection to electrical jacks.

2. A catheter according to claim 1 wherein said metallic sleeve comprises at least one layer of metal having characteristics resulting from having been electroplated over the flat wound section of the conductor.

3. A catheter for insertion into said circulatory system according to claim 1 wherein a woven Dacron sleeve is positioned between said first and second coatings of rubber.

4. A method of producing a catheter comprising:
   a. applying a first coating of rubber to the outer surface of a base tubing in an atmosphere of rubber solvent;
   b. helically winding at least two conductors into said first coating of rubber before the rubber has dried;
   c. extracting an end portion of each of said conductors from beneath said first coating of rubber near one end of said base tubing and flat winding each of said end portions to form electrode bases;
   d. attaching a metal sleeve over each said electrode base to form the outer surface of the electrode;
   e. masking off the outer surface of the electrodes;
   f. applying a second coating of rubber over said first coating of rubber in an atmosphere of rubber solvent;
   g. attaching the end of said base tubing that is opposite from the end having said electrodes to a Luer-Lok and
   h. connecting said two conductors to electrical plug-in means.

5. A method of producing a catheter comprising;
   a. straightening a base tubing by threading said base tubing onto a wire, applying tension to the ends of said base tubing and applying heated air to said base tubing;
   b. applying a first coating of rubber to the outer surface of said base tubing in an atmosphere of rubber solvent;
   c. helically winding at least two conductors into said first coating of rubber before the rubber has dried;
   d. extracting an end portion of each of said conductors from beneath said first coating of rubber near one end of said base tubing and flat winding of each of said end portions to form electrode bases;
   e. electroplating a metal sleeve over each said electrode base to form the outer surface of said electrode;
   f. masking off the outer surface of the electrodes;
   g. applying a second coating of rubber over said first coating of rubber in an atmosphere of rubber solvent;
   h. attaching the end of said base tubing that is opposite from the end having said electrodes to a Luer-Lok and
   i. connecting said two conductors to electrical plug-in means.

PO-1050
(5/69)

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,568,660 Dated March 9, 1971

Inventor(s) Nelson A. Crites and Samuel P. Chambers

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

Column 1, line 12, "Here" should read -- There --;
line 23, "hwing" should read -- having --;
line 54, "withdrawn" should read -- customarily

Column 3, line 12, "29" should read -- the --.

Column 4, line 13, "aNd" should read -- and --;
line 24, "118" should read -- 117 --;
line 35, "17'" should read -- 107' --.

Column 5, line 43, "has" should read -- have --;
line 54, "tubing inches" should read -- the catheter --.

Signed and sealed this 10th day of August 1971.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents