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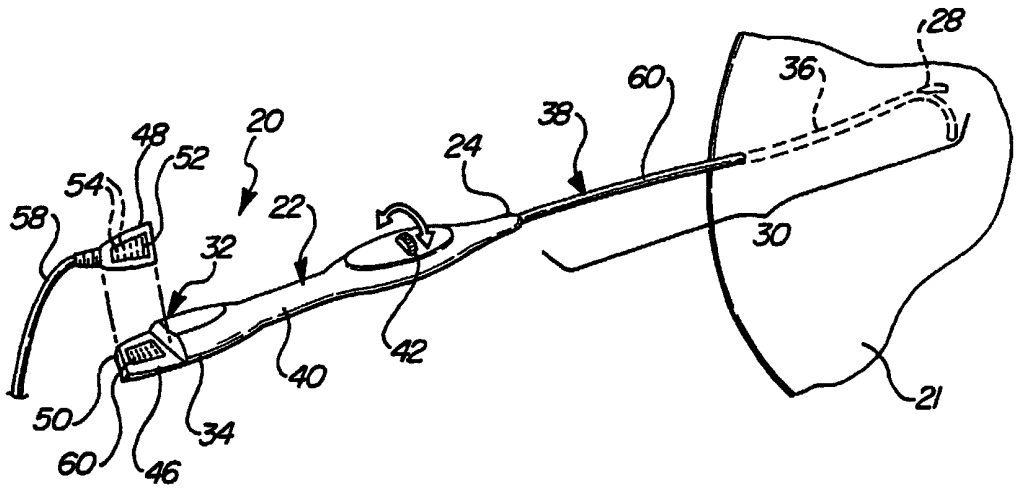
(54) Title: CATHETER ASSEMBLY HAVING INTEGRAL ELECTRICAL CONNECTOR DISPOSED THEREIN



(57) Abstract: A catheter assembly includes an elongated catheter body having a proximal end and a distal end, an actuating assembly disposed at the proximal end of the catheter body. The actuating assembly comprises a catheter base having proximal and distal ends, the distal end of the catheter base coupled to the proximal end of the deflectable segment, at least one electrical device disposed at the proximal end of the catheter body, and an electrical connector disposed on the catheter base. The electrical connector comprises a first portion affixed to the base and a second, removable portion matingly engageable with the first portion.

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CATHETER ASSEMBLY HAVING INTEGRAL ELECTRICAL CONNECTOR DISPOSED THEREIN

Technical Field

The present invention relates generally to catheters. More particularly, the present invention relates to a catheter device to enhance the ability of the device utilized to acquire diagnostic data or to perform therapeutic applications including cardiovascular access, drug delivery, electrophysiology, and other applications where steering or access to a body cavity or vasculature is desired.

Background of the Invention

Catheters have been utilized in medical treatment for many years. Catheters are commonly used for such purposes as drug delivery, fluid removal, acquisition of diagnostic data, and the performance of therapeutic applications such as TMR, drug delivery, and the acquisition of electrophysiology signals from the heart.

As the trend in the application of medicine has moved towards the use of less invasive techniques for performing certain procedures, the growing use of catheters and their specialized uses have increased the specificity and design of the catheters. As the use of catheters has increased, so too have the demands placed on catheter manufacturers and designers to provide catheters capable of meeting specific needs for given procedures. These new demands have brought about the development of catheters which are more capable and more useful than their predecessors through the incorporation of specific features designed to aid in their use, such as the electrophysiology and/or ablation catheter.

There are many catheter systems and designs which are well known in the art. However, there remains a need in the art for a catheter which allows for simple, fast, and positive connection of multiple electrical and/or electronic devices such as electrophysiology sensors/electrodes, power sources, and other devices which could also require multiple electrical connections within the catheter assembly.

Summary of the Invention

A catheter assembly includes an elongated catheter body having a proximal end and a distal end, an actuating assembly disposed at the proximal end of the catheter body, the actuating assembly comprising a catheter base having proximal and distal ends, the distal end of the catheter base coupled to the proximal end of the deflectable segment, at least one electrical device disposed at the proximal end of the catheter body, and an electrical connector disposed on the catheter base, the electrical connector comprising a first portion affixed to the base and a second removable portion matingly engageable with the first portion.

Brief Description of the Drawings

Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

Figure 1 is an exploded view of a catheter assembly constructed in accordance with the present invention;

Figure 2 illustrates a flexible circuit attached to a printed circuit board in accordance with the present invention;

Figure 3 is a plan view of a flexible circuit in accordance with the present invention;

Figure 4 is an alternative embodiment of a flexible circuit of the present invention;

Figure 5 is a further alternative embodiment of a flexible circuit board in accordance with the present invention;

Figure 6 is a schematic illustration of the present invention;

Figure 7 is a drawing of a further embodiment of the flexible circuit in accordance with the present invention;

Figure 8 is a schematic illustration of a circuit board for use in accordance with the present invention;

Figure 9 is a schematic illustration of an alternative circuit board in accordance with the present invention;

Figure 10 is an exploded perspective view of a housing of an actuator handle assembly in accordance with the present invention;

Figure 11 is a perspective view illustrating the connection between a first and a second component of the actuator handle assembly in accordance with the present invention;

Figure 12 is a perspective view of a removable portion of the actuator handle assembly in accordance with the present invention;

Figure 13 is a top view of a portion of the housing of the actuator handle assembly in accordance with the present invention;

Figure 14 is a top view of a portion of the housing including a printed circuit board in accordance with the present invention;

Figure 15 is a top view of a portion of the housing of the actuator handle assembly including a female receptacle in accordance with the present invention;

Figure 16 is a top view of a second half of the housing of the actuator handle assembly in accordance with the present invention; and

Figure 17 is a top view of a half of the housing of the actuator handle assembly in accordance with the present invention.

Detailed Description of the Invention

Referring to Figure 1, a representative view of a catheter assembly of the present invention is generally shown at 20 inserted into a subject 21. The catheter assembly 20 has an actuator handle assembly 22 at its proximal end 24 and an insertable end portion 26 at its distal end 28. A central catheter body 30 substantially extends between the actuator handle assembly 22 and the distal end 28.

The catheter assembly 20 includes an electrical connector 32 disposed at an end 34 of the actuator handle assembly 22.

Referring again to Figure 1, a partially exploded view of the electrical connector 32 of actuator handle 22 of the present invention is shown. The actuator handle 22 includes a housing 40. A thumb wheel 42 can be disposed

within the housing 40 which is operatively connected to the distal end 28 of the catheter body 30 for controlling the movement of the catheter body 30. The electrical connector assembly 32 includes a first portion 46 fixedly disposed on or integral with the actuator handle housing 40. A second, removable portion 48 is matingly engaged and secured to the first portion 46. In a preferred embodiment, the first portion 46 includes a female receptacle 50 disposed thereon for receiving a male plug 52 disposed on the second portion 48; however, this orientation can be reversed. The male plug 52 includes a multiplicity of pins or conductors 54 disposed thereon for being received within sockets or conductors 60 disposed in the first portion 46. Preferably, the electrical connector assembly 32 comprises a multi-pin plug and socket-type connector such as a SAMTECH TOLC-120-02-4-G-A and is longitudinally oriented with respect to the actuator handle assembly 22 to further allow the shape and the profile of the catheter assembly 20 to be maintained.

The proximal region of the catheter body 30 can also contain a flexible circuit board 60 disposed therein. Referring to Figures 2-6, the flexible circuit board or flex circuit 60 is shown in greater detail. Referring specifically to Figure 2, the flexible circuit board 60 is shown disposed in a portion of the rigid section 38 of the catheter body 30. Wires 62 connected to electrodes or other devices (not shown) disposed at or near the distal end 28 of the catheter body 30 for sensing or performing other functions terminate at, and are affixed to, terminals 68 disposed on the flexible circuit board 60 as shown in Figure 6. The wires 62 can be in the form of a flexible cable (microflex cable) or bundle

64. By this design, wires 62 from any devices or any complex wiring assembly disposed at the distal end of the catheter body 30 can be connected directly to the flexible circuit board 60 to allow for ease of assembly of the catheter assembly 20 and to allow for preassembly of the catheter assembly 20 without first having to determine what electric or electronic devices or electrodes will be utilized with the catheter assembly 20. That is, the catheter assembly 20 can be preassembled to the point where the flexible circuit board 60 is in place but wherein electrodes or other devices to be utilized with the catheter assembly 20 are not attached until they are determined. This allows for independent attachment of from one to a multitude of electrodes or devices to the flexible circuit board 60 depending only on the number of pins or terminals, e.g., 1-80. Other advantages in assembly of the catheter assembly 20 imparted by the flexible circuit board 60 include the ability to insulate wires, to reduce or inhibit electrical noise, to prevent thermal damage, and to prevent current and/or fluid leakage.

Referring to Figures 6 and 7, the flexible circuit board 60 includes a cable 66 comprised of a number of individual wires (not shown) which are connected at one end to terminals of connectors 68 disposed on the flexible circuit board 60. The cable 66 is preferably flexible and the individual wires or connectors disposed therein can be arranged as a stacked ribbon or as a round cable. The cable 66 can also be further insulated to add further protection to the individual wires or conductors. At the opposite end of the cable 66, a flexible circuit termination 70 is disposed. The flexible circuit termination 70

is designed to be attached to a printed circuit board 72, disposed in the housing 40, such as by laser welding, soldering or other suitable technique. Additionally, as shown in Figure 7, the flexible circuit termination 70 can include alignment holes 74 to align the flexible circuit termination 70 with the printed circuit board 72.

The use of the flexible circuit termination 70 can be eliminated, if desired, and the electrodes or devices disposed at the distal end 28 of the catheter body 30 can be connected directly to the printed circuit board 72.

The wires 62 terminate at terminals or connections 76 disposed on the flexible circuit termination 70. These terminals or connectors 76 are superimposed over terminals or connectors 78 disposed on the printed circuit board 72 in order to make an electrical connection between the flexible circuit termination 70 and the printed circuit board 72.

Referring back to Figures 3, 4, and 5, several alternative embodiments for the flexible circuit board 60 are shown. Referring to Figure 3, the terminals 68 are shown in groups which have their terminals aligned at an approximately 90 degree angle to one another. Several groups of terminals are disposed adjacent to one another along the flexible circuit board 60. Referring now to Figure 4, an embodiment of the flexible circuit board 60 is shown wherein the groups of terminals 60 are disposed in an alternating fashion wherein adjacent groups of terminals are disposed such that one set of terminals is disposed facing a first edge of the flexible circuit board 60 while the directly adjacent group of terminals are disposed facing the opposite side of the flexible circuit

board 60. The variation in the orientation of the terminals and/or their groupings allows for greater ease and flexibility in the design of the flexible circuit board 60 and the attachment of wires 62 thereto. Referring to Figure 5, an embodiment similar to that shown in Figure 4 is shown wherein the distance between adjacent terminals or connectors 68 can be varied in order to add flexibility to the design of the flexible circuit board 60.

Referring now to Figure 8, a printed circuit board 72 attached to the electrical connector 32 of the present invention is shown. The embodiment detailed in Figure 8 includes a connector attachment 78 for use with a conformal catheter assembly similar to the type set forth in United States Serial No. 08/621,232. The attachment 78 allows for connection of a keypad or other activation device (buttons) for the connection of a ZIF-type or a LIF-type connector or other such connector 80 as shown in Figure 9.

Referring to Figure 10, the housing 40 of the catheter assembly 20 is shown with the first portion 46 and second portion 48 separated from one another. Figure 11 illustrates the overlapping connection between the first portion 46 and second portion 48 when the first portion 46 and second portion 48 are disposed in mating engagement with one another. As shown in this Figure, the removable portion 48 matingly connects to the first portion 46 forms a connection between the portions 46,48 which is fluid tight and forms an actuator handle assembly 22 which has a profile that is easy to grip or handle by a user and which does not depart from the overall look and feel of the actuator handle 22. Also, as described above, the orientation of the

electrical connector 32 within the actuator handle assembly 22 further aids in maintaining the profile and shape of the actuator handle assembly 22.

Referring now to Figure 12, the removable portion 48 is shown in greater detail. The removable portion 48 includes an abutment 82 and a deck 84 which are disposed at approximately right angles to one another. The deck 84 includes a recess or channel 86 disposed therein for receiving a ridge (discussed below) disposed on the first portion 46 to form a seat therebetween. The channel or recess 86 is disposed substantially about the periphery of the deck 84 to provide a positive seal between the first portion 46 and the second portion 48 to isolate the interior of the housing 40 from the external environment.

Referring to Figure 13, a first half 86 of the housing 40 is shown. The first half 86 includes a ridge 88 disposed thereon for engagement with the channel or recess 86 of the portion 48. The ridge 88 is matingly received within the channel or recess 86 to form a seal therebetween.

A disconnection mechanism shown in the form of a button 90 is integrally formed in the first half 86 by removing a portion of the structure of the half 86 to allow the button 90 to be deflected to cause disengagement elements/feet 92 to come into contact with a portion or surface of the second portion 48 to push the second portion 48 out of engagement with the first portion 46.

Referring now to Figure 14, the half 86 is shown with the circuit board 72 disposed therein. Referring to Figure 15, the female receptacle 50 is shown disposed in electrical communication with the circuit board 72.

Referring to Figure 16, a second half 94 of the housing 40 is shown affixed to the first half 86. The second half 94 is aligned or indexed with the first half 86 by tabs 96 which are received and retained in recesses (not shown) in the first half 86. The second half 94 of the housing 40 includes a central aperture 98 which is disposed in such a manner as to allow the female receptacle 50 to be accessed therethrough. Apertures 100 disposed in the second half 94 allow for the disengagement elements/feet 92 to pass therethrough.

The second half 94 also includes an abutment surface 102 which abuts with abutment surface 83 disposed on the removable portion 48 to provide positive engagement of the first portion 46 and the second removable portion 48. Abutment 103 on the second half 94 abuts with abutment 82 on portion 48 to index and/or align the portions 46,48.

Referring to Figure 1, the insertion force of the pins 54 into the sockets 60 of the electrical connector assembly 32 retains the first portion 46 and second, removable portion 48 in mating engagement.

Figure 17 illustrates the outer surface of the first half 86 including the disengagement button 90.

The electrodes (not shown) disposed on the distal end 28 of the catheter assembly 20 can be disposed in electrical communication with an external

power source or monitoring device (not shown) through the electrical connector assembly 32 to facilitate the transmission of electrical signals and/or energy through the catheter assembly 20.

A cord or cable 58 can be connected to the second portion 48 to conduct electrical energy or other types of energy to or from the catheter assembly 20. The cord or cable 58 can include one or more individual wires or conductors therein to allow for multiple signals or currents to be simultaneously transmitted to or received from the catheter assembly 20.

The catheter assembly 20 of the present invention can be used for the access of coronary vessels, heart chambers, or vascular access where fine, minute deflection and control is required. Additionally, the catheter assembly 20 may be a conformal catheter as set forth in United States Serial No. 08/621,232, a steerable angiographic catheter, a steerable guide catheter, a drug delivery catheter, an ablation catheter, a percutaneous transmyocardial revascularization (TMR) catheter or for any application where multi-plane and multi-segmented deflection control would allow the user more precise access to a region, location, vessel, or chamber for diagnostic and/or therapeutic use.

Any patents, applications, or publications mentioned in the specification are indicative of the levels of those skilled in the art to which the invention pertains. These patents and publications are herein incorporated by reference to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

In view of the teaching presented herein, other modifications and variations of the present invention will readily be apparent to those of skill in the art. The discussion and description are illustrative of some embodiments of the present invention, but are not meant to be limitations on the practice thereof. It is the following claims, including all equivalents, which define the scope of the invention.

Claims

1. A catheter assembly comprising:

an elongated catheter body having a proximal end and a distal end,

an actuating assembly disposed at the proximal end of said catheter body, said actuating assembly comprising a catheter base having proximal and distal ends, the distal end of the catheter base coupled to the proximal end of a deflectable segment;

at least one electrical device disposed at said proximal end of said catheter body; and

an electrical connector disposed on said catheter base, said electrical connector having a first portion affixed to said base and a second, removable portion matingly engageable with said first portion, said electrical connector being connected in electrical communication with said at least one electrical device.

2. The catheter assembly according to claim 1, wherein a circuit board is disposed in said catheter body, said circuit board being connected to said at least one electrical device.

3. The catheter assembly according to claim 1, wherein said circuit board is flexible.

4. The catheter assembly according to claim 1, wherein said actuator assembly forms a handle.

5. The catheter assembly of claim 1, wherein said actuator assembly further comprises a thumb wheel.

6. The catheter assembly of claim 1, wherein the first portion of said electrical connector is formed as a female fitting adapted to engage the second removable portion formed as a male plug.

7. The catheter assembly according to claim 1, wherein the first portion said electrical connector further comprises a ridge disposed for engagement with a complementary recess of the second removable portion.

8. The catheter assembly according to claim 1, wherein said electrical connector further comprises a disengagement mechanism.

9. The catheter assembly according to claim 8, wherein said disconnect mechanism is a button.

10. The catheter assembly according to claim 1, wherein said electrical connector is selected from the group consisting of: multi-pin and socket connector.

11. The catheter assembly according to claim 1, wherein the second removable portion of said electrical connector has an abutment and a deck disposed at approximately right angles to one another.

12. The catheter assembly according to claim 1, further comprising a flexible circuit board within said catheter body.

13. The use of a flexible circuit board within a catheter assembly.

14. The use of claim 13 wherein the flexible circuit board has a group of terminals disposed in an alternating fashion having adjacent groups of terminals disposed such that one set of terminals is disposed facing a first edge of the flexible circuit board while a directly adjacent group of terminals are disposed facing a second edge opposite the first edge.

15. The use of an integral electrical connector disposed within a catheter assembly.

FIG-1

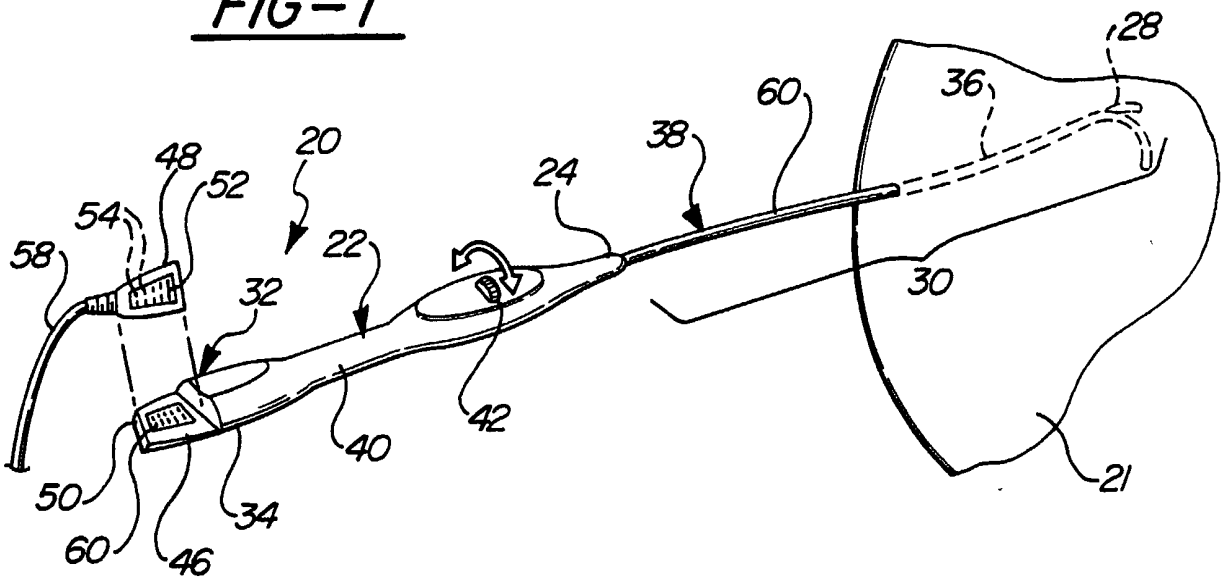


FIG-2

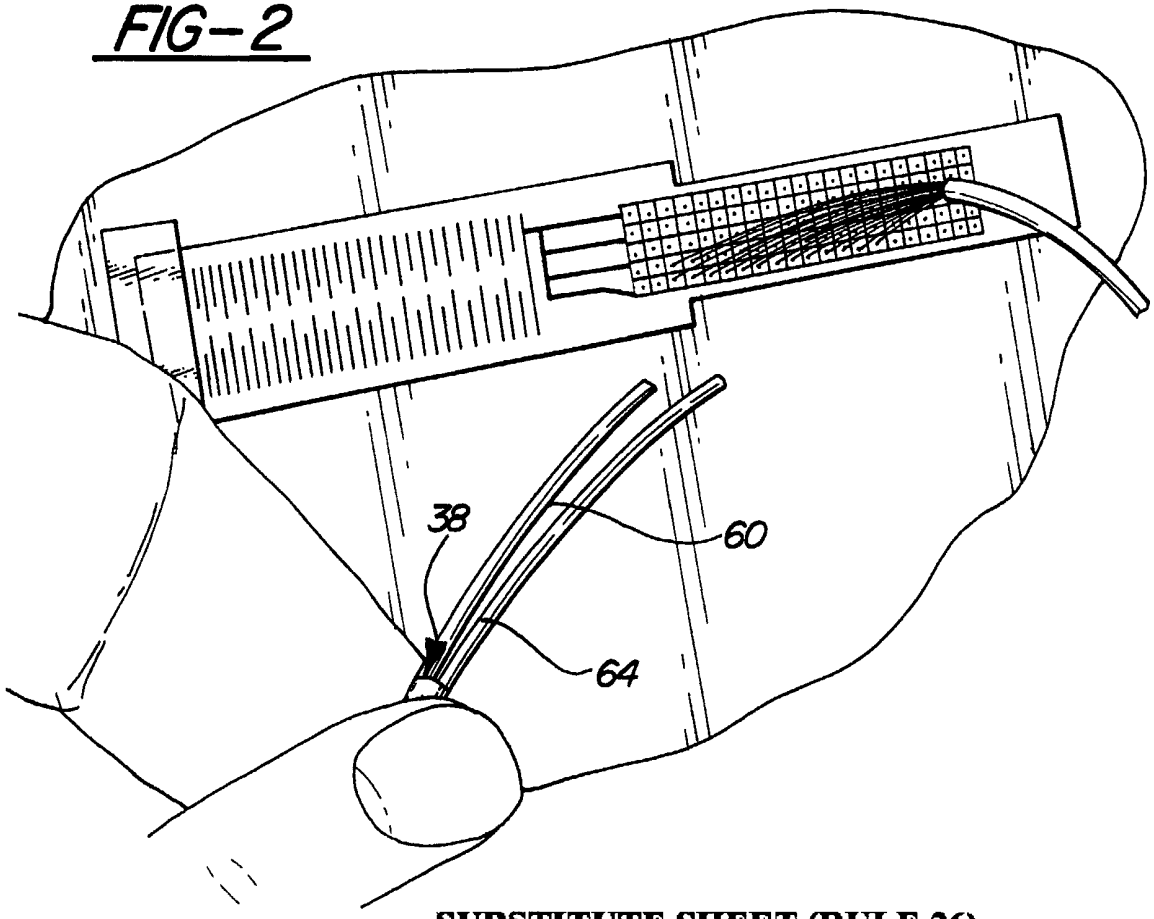


FIG-3

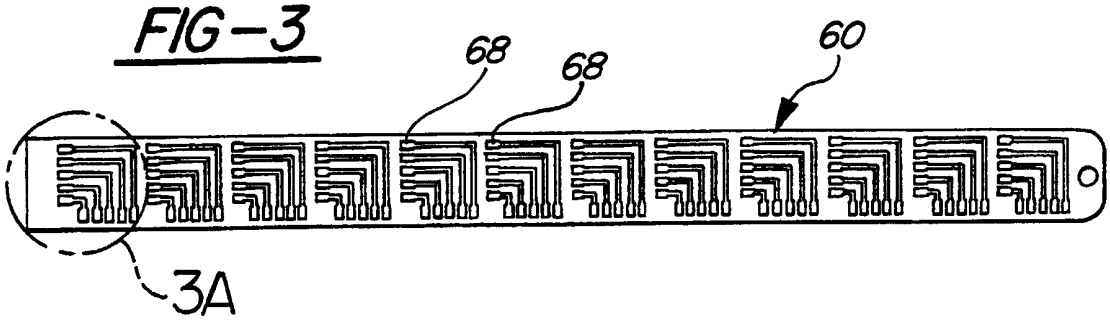


FIG-3A

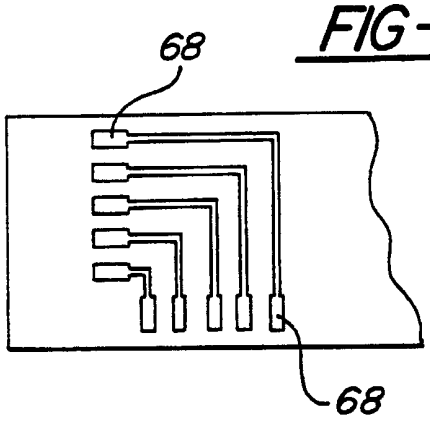


FIG-4A

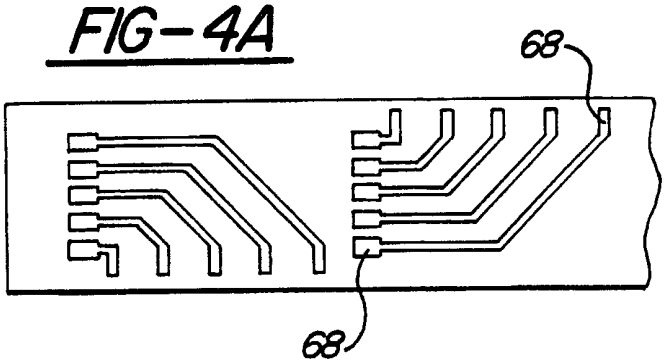


FIG-4

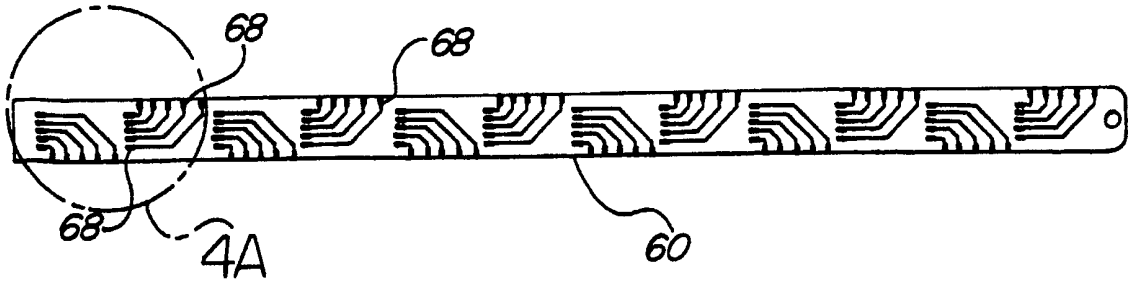


FIG-5

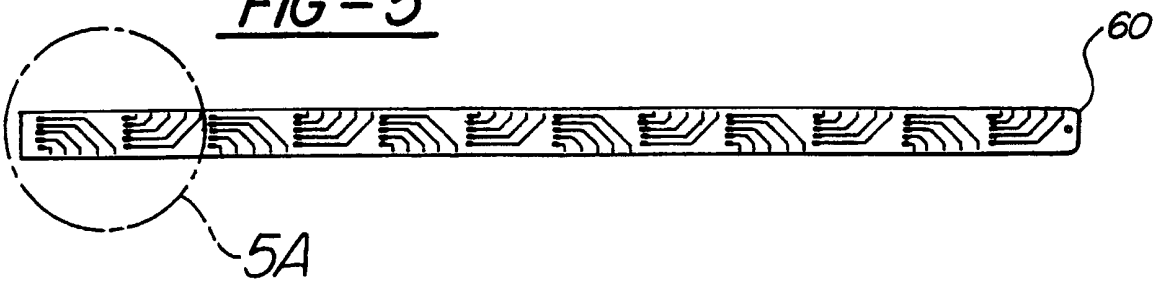


FIG-5A

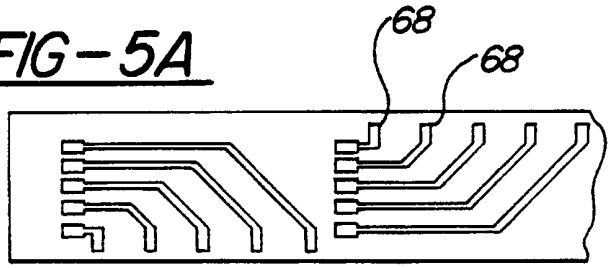
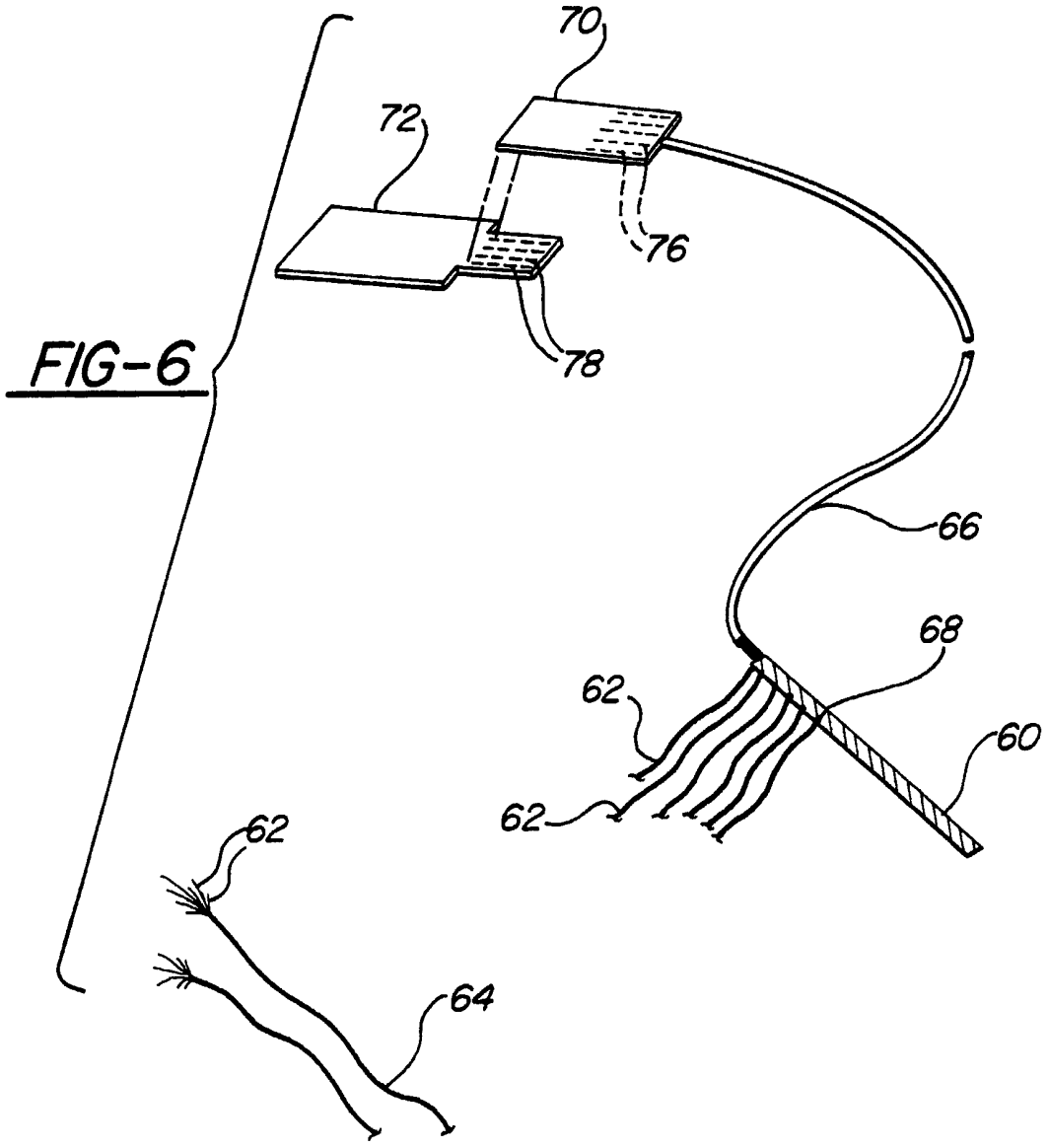


FIG-6



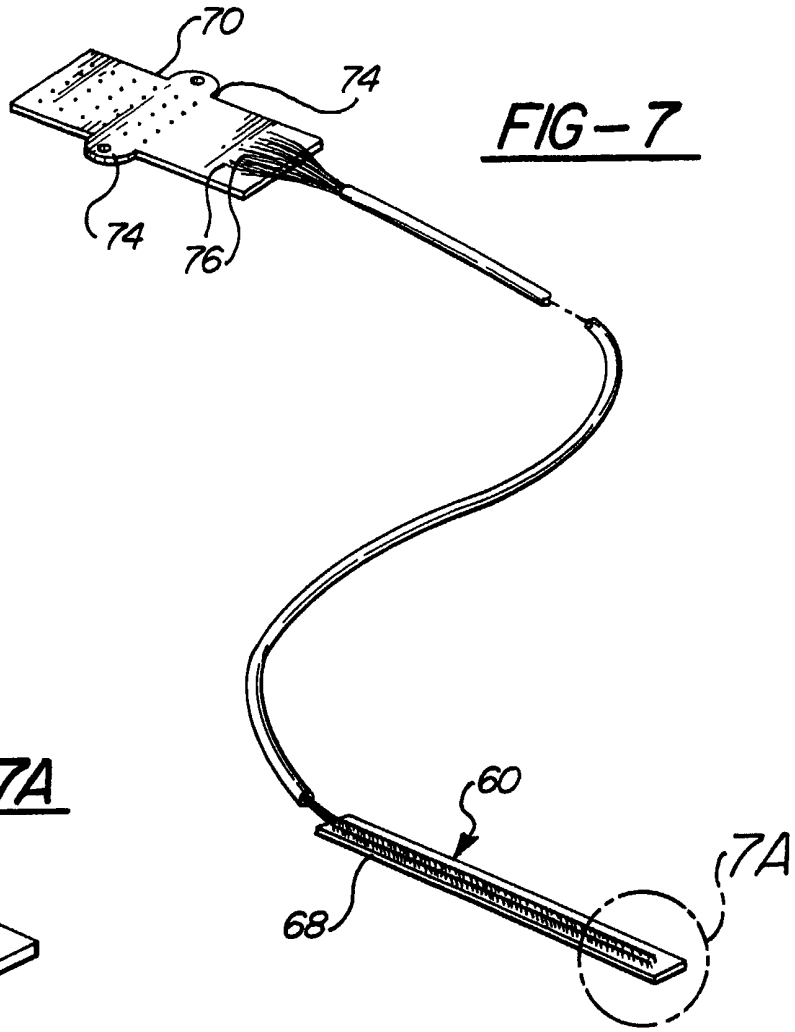


FIG-7

FIG-7A

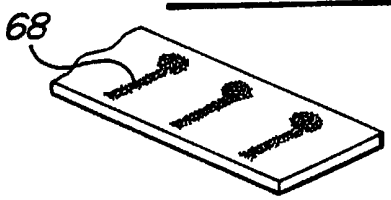


FIG-8

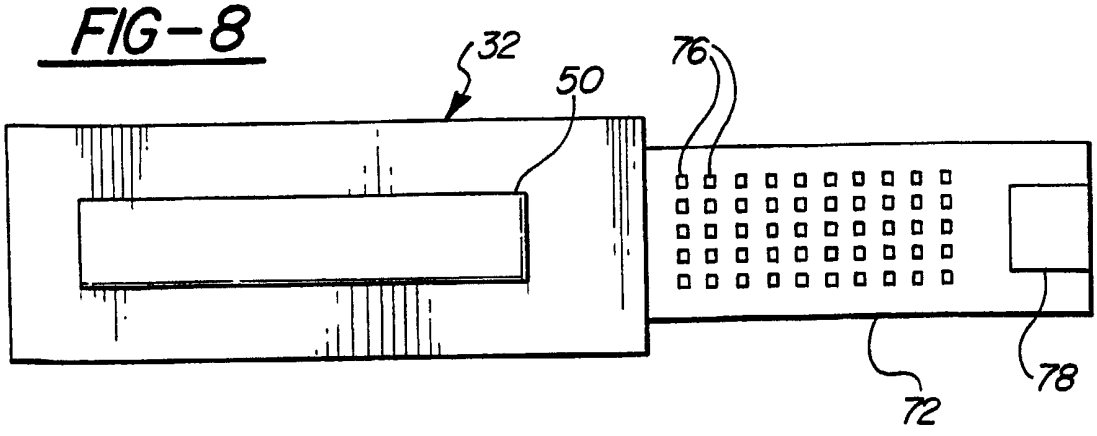


FIG-9A

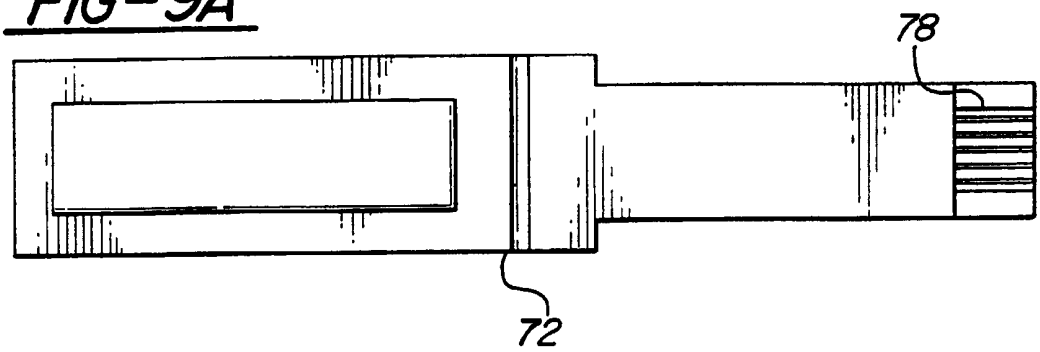


FIG-9B

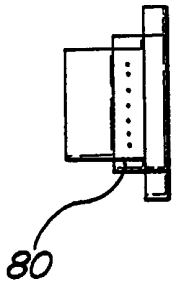


FIG-10

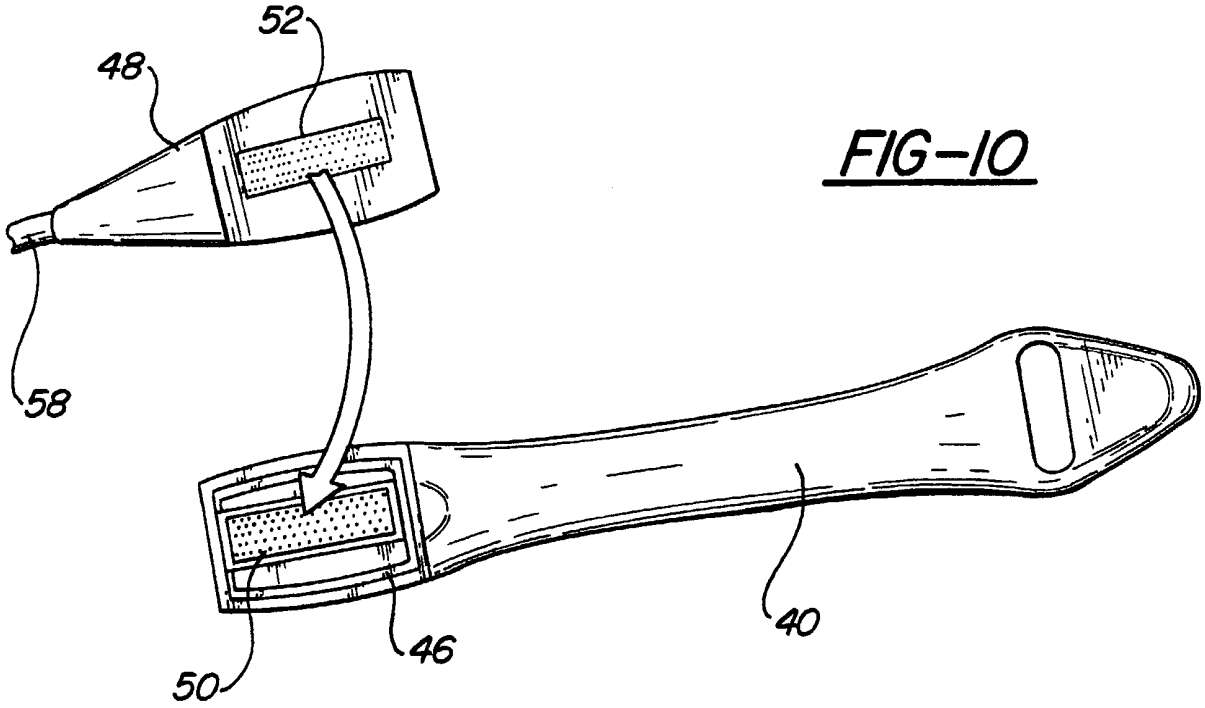
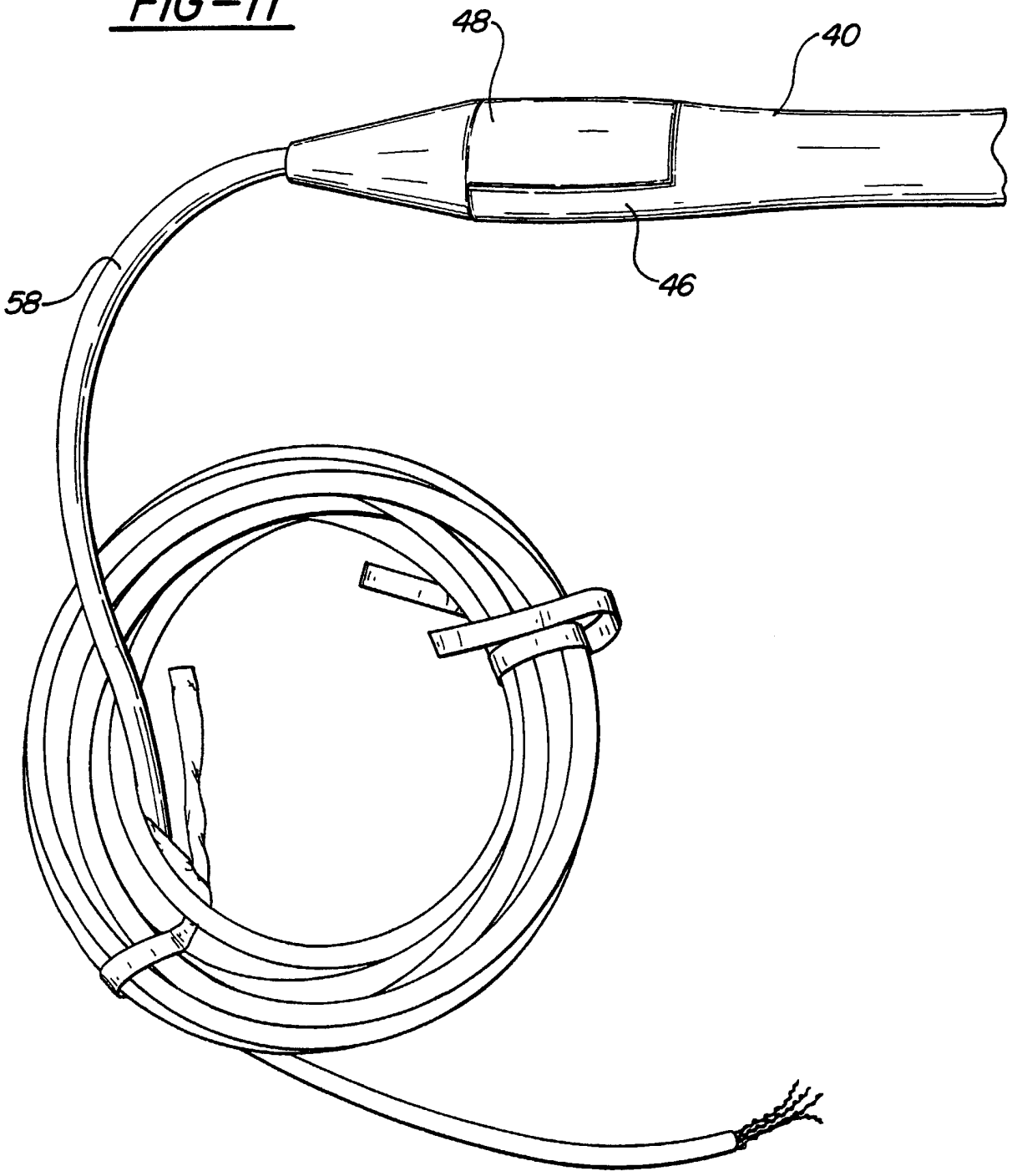


FIG-11



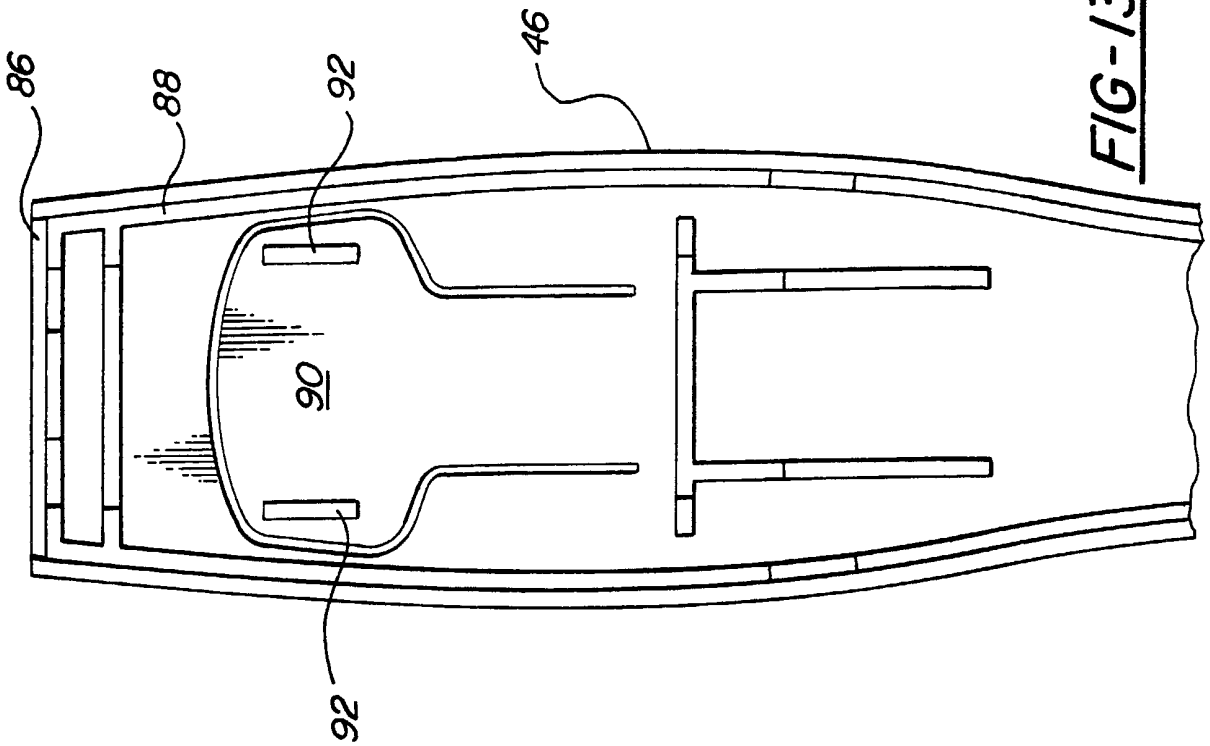


FIG-13

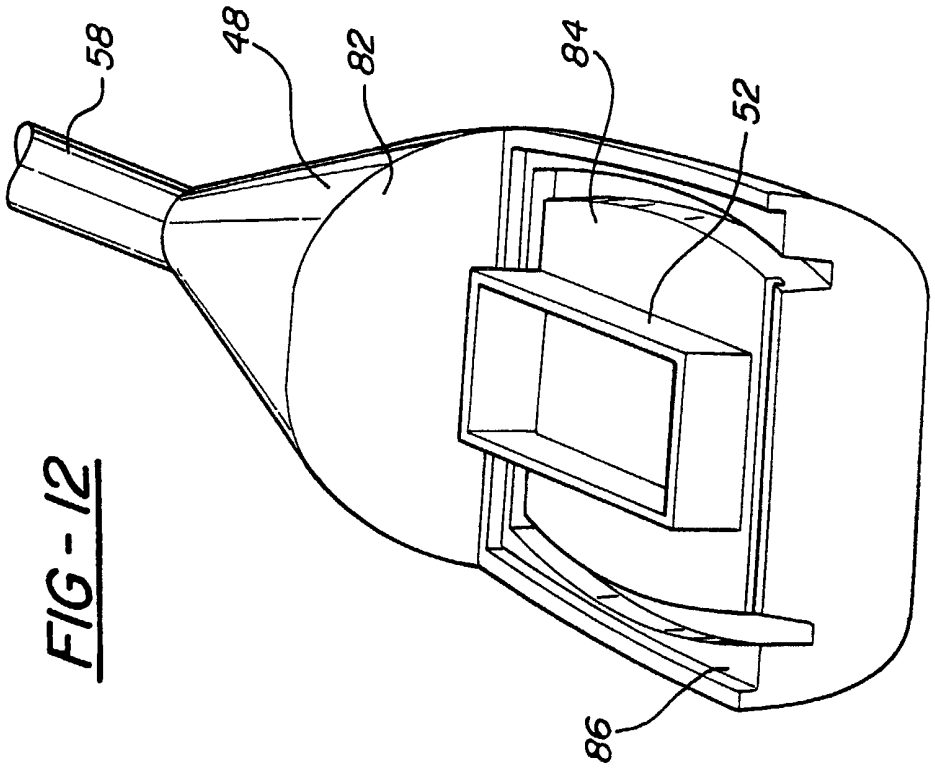


FIG-12

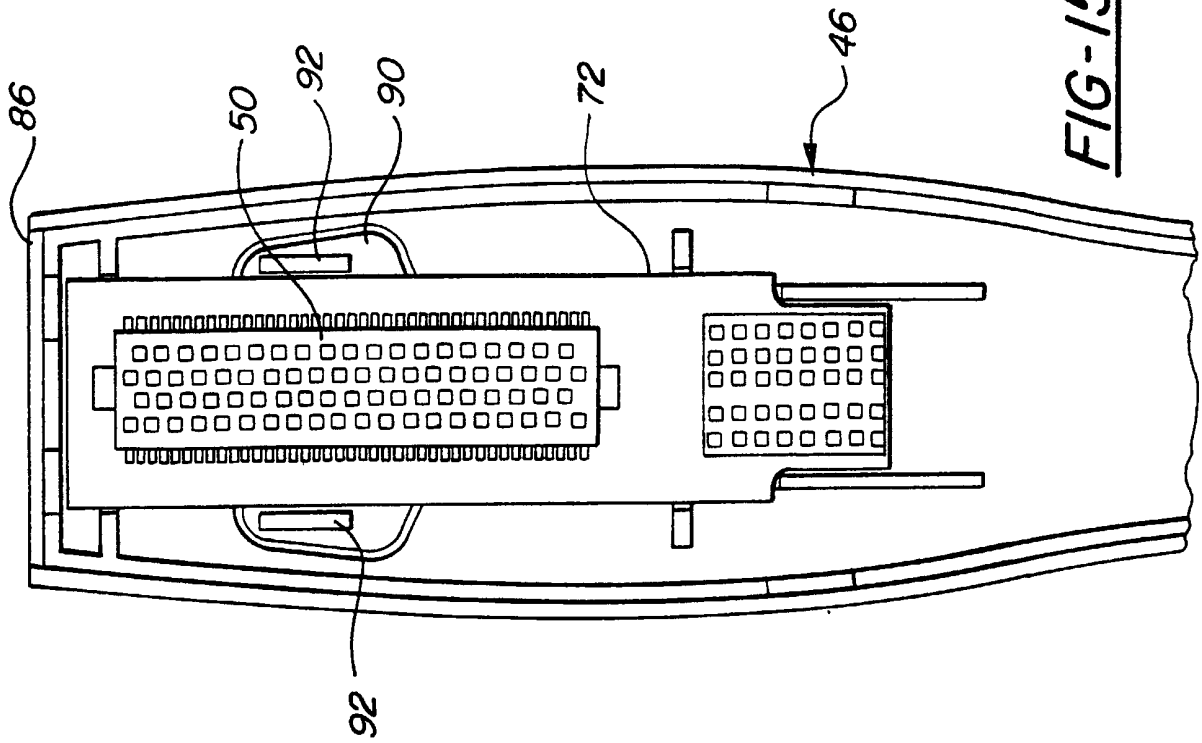


FIG-15

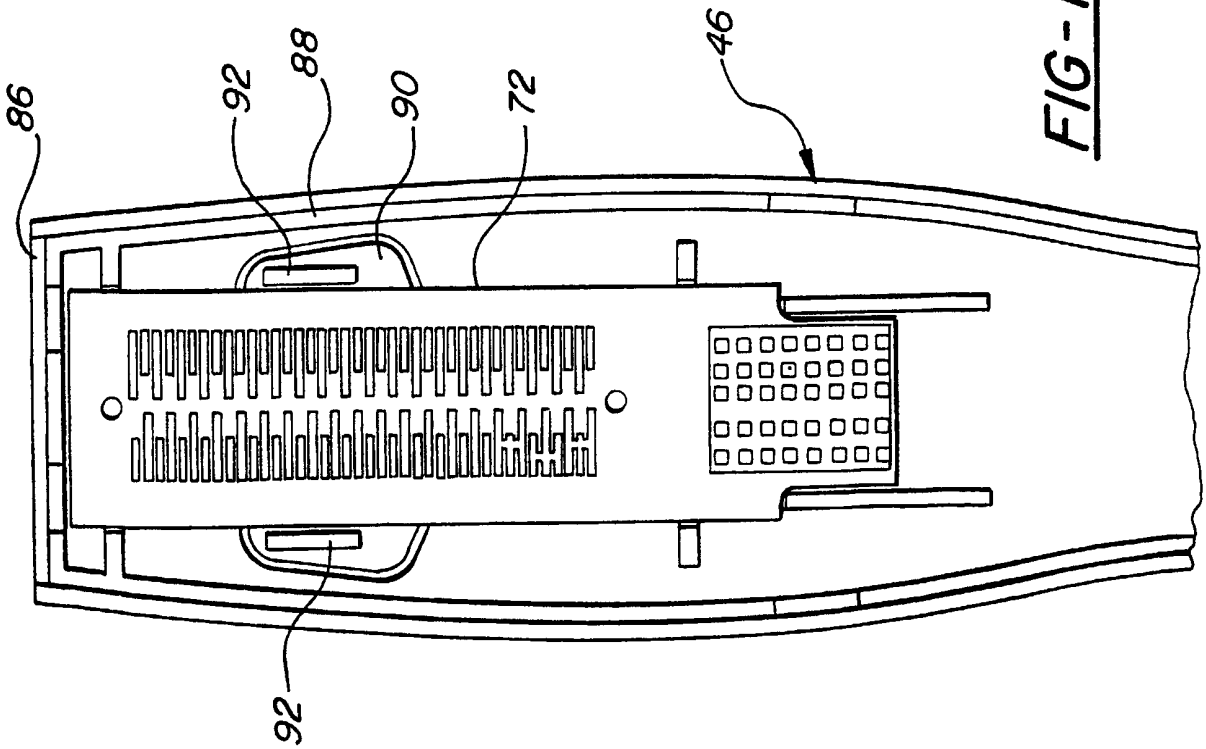


FIG-14

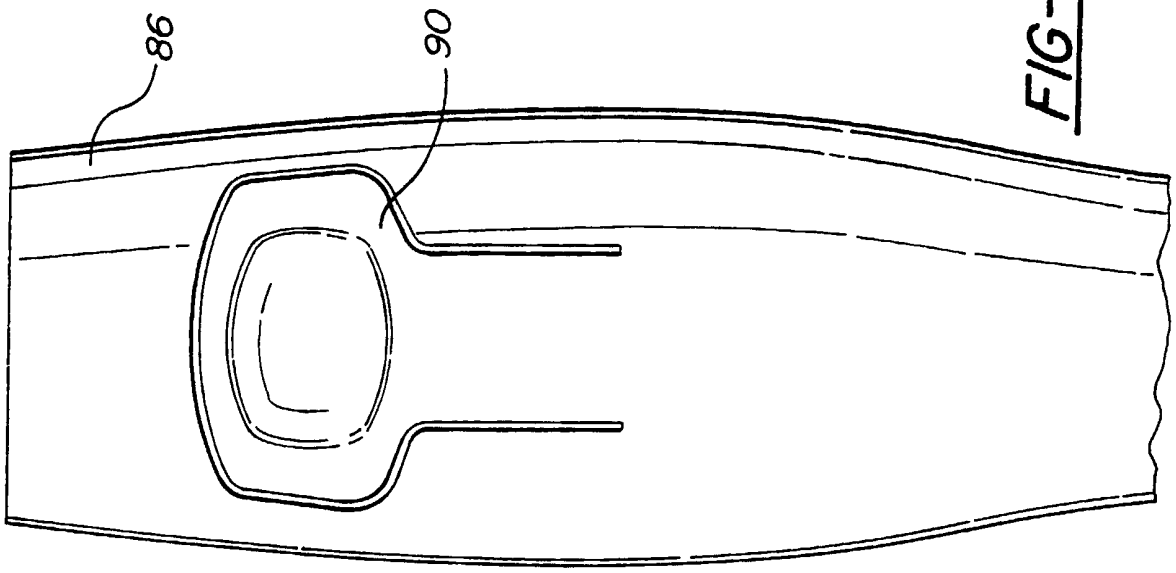


FIG-17

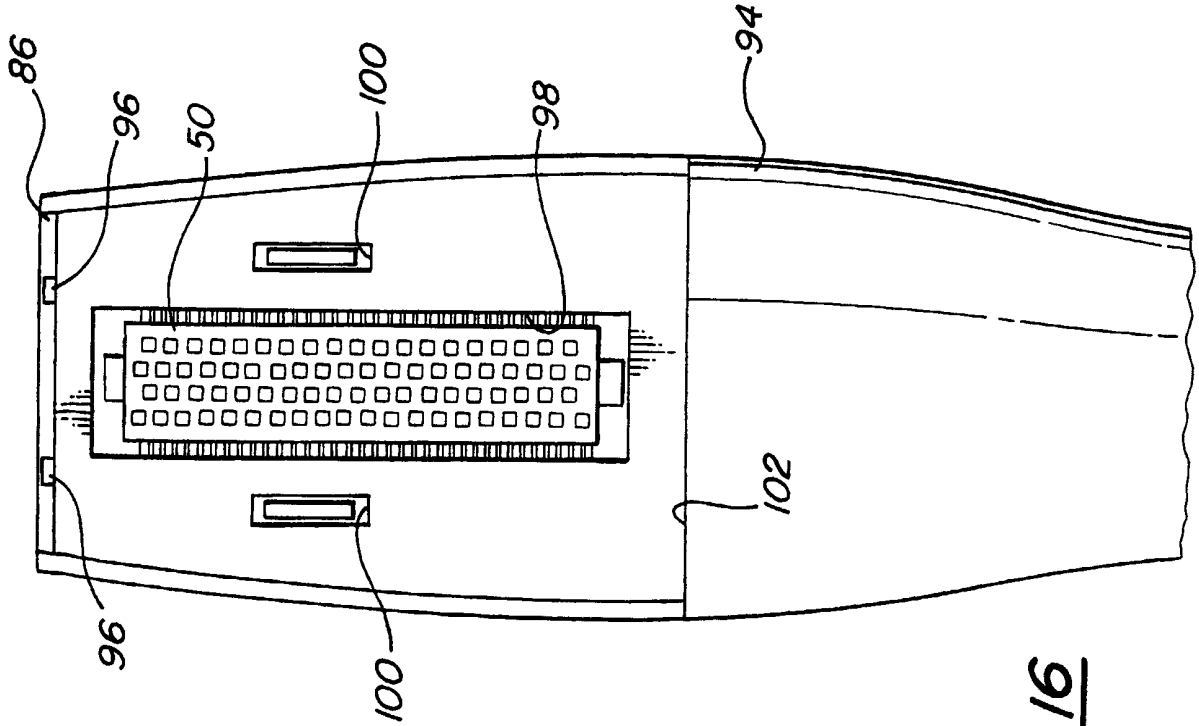


FIG-16