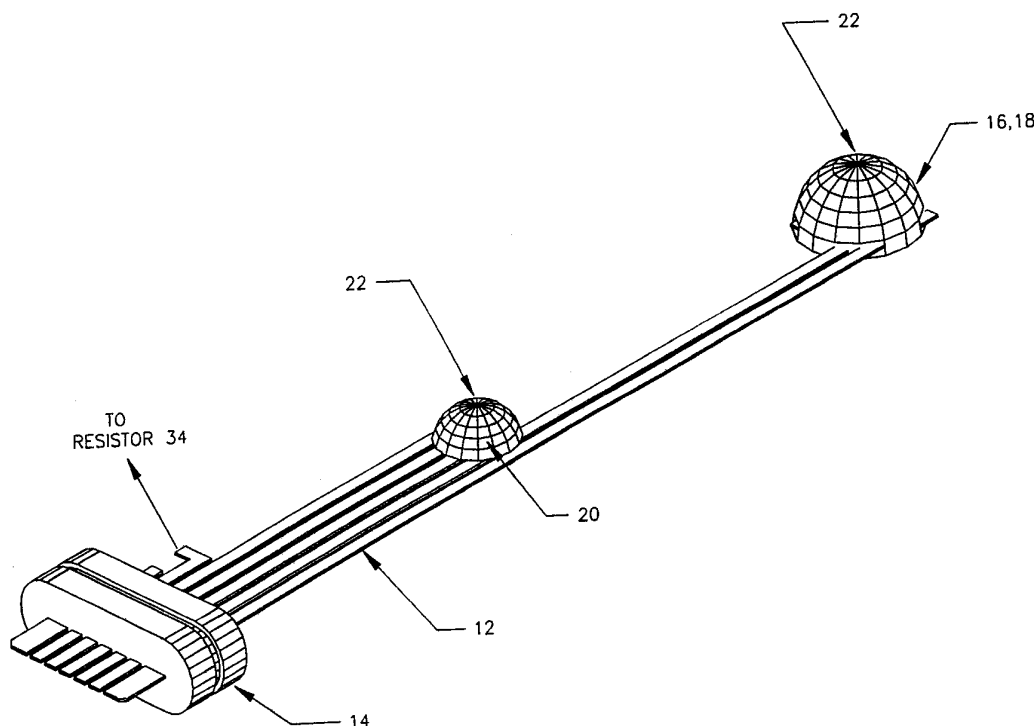




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US92/01964 (22) International Filing Date: 11 March 1992 (11.03.92) (30) Priority data: 667,817 12 March 1991 (12.03.91) US (71) Applicant: SQUARE ONE TECHNOLOGY [US/US]; 1815 Clement Avenue, Alameda, CA 94501 (US). (72) Inventor: GOLDBERGER, Daniel, S. ; 1035 Douglass Street, San Francisco, CA 94114 (US). (74) Agents: BEVILACQUA, Michael, J. et al.; Hale and Dorr, 60 State Street, Boston, MA 02109 (US).		(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent). Published <i>With international search report.</i>

(54) Title: INTEGRATED LEAD FRAME PULSE OXIMETRY SENSOR**(57) Abstract**

Disclosed is an integrated lead frame pulse oximetry sensor which includes a thin metal lead frame (12) to which is connected light emitting diodes (16, 18) and a photodiode chip (20) for the purpose of emitting light and detecting light respectively. The thin metal frame (12) is deformable to attach to perfused tissue. The lead frame (12) has a very low mass which diminishes its susceptibility to motion induced artifact.

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INTEGRATED LEAD FRAME PULSE OXIMETRY SENSOR

BACKGROUND OF THE INVENTION

This invention relates to a pulse oximetry sensor and more particularly to a lead frame for an integrated pulse oximetry sensor.

It is common in medical practice to measure pulse rate and oxygen saturation in blood. Pulse oximetry uses discrete wavelengths of light to measure the optical density of hemoglobin. Pulse oximetry can also distinguish arterial blood from venous blood and tissue.

Pulse oximeters are used extensively in critical care areas of hospitals to monitor a patient's arterial oxygen saturation (SpO_2) and pulse rate (PR). The pulse oximetry instrument records the absorption of light in perfused tissue at two or more wavelengths. The instrument computes SpO_2 and PR by comparing the time variant and time invariant portions of the light absorption signal. The history and technology of oximetry is well known in the art and it is thoroughly discussed in chapter 16 of Monitoring in Anesthesia and Critical Care Medicine which is edited by C.D. Blitt M.D., the teachings of which are incorporated herein by reference.

The preferred site for a pulse oximetry sensor is a finger tip, although other sites are commonly used. The sensor must incorporate light sources, a photodetector, means for mechanically orienting the components relative to the tissue and means for energizing the light sources and returning the optical signals to the pulse oximetry instrument. The sensor must also incorporate means for mechanical attachment to the perfused tissue.

While there are several sensors currently in use, these sensors have several shortcomings. In some cases the sensors have too great a mass and therefore a significant motion artifact is developed when the sensor

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is in use. Other known sensors conform to the perfused tissue by applying a compressive force and in some cases the compressive force, while sufficient to secure the sensor to the profuse tissue, induces vascular shut down.

It is therefore a principal object of the present invention to provide an integrated lead frame pulse oximetry sensor that can be mechanically attached to perfused tissue yet is of a very low mass.

Another object of the present invention is to provide an integrated lead frame pulse oximetry sensor which can be mechanically attached to perfused tissue without applying compressive forces thereby avoiding vascular shut down.

Still another object of the present invention is to provide an integrated lead frame pulse oximetry sensor which can be manufactured at a cost that is low compared to other known sensors.

SUMMARY OF THE INVENTION

The integrated lead frame pulse oximetry sensor of the present invention includes a thin metal lead frame to which is connected light emitting diodes and a photodiode chip for the purpose of emitting light and detecting light respectively. The thin metal frame is deformable to attach to perfused tissue. The lead frame has a very low mass which diminishes its susceptibility to motion induced artifact.

These and other features and objects of the present invention will be more fully understood from the following detailed description which should be read in light of the accompanying drawings in which corresponding reference numerals refer to corresponding parts throughout the several views.

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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a portion of the integrated lead frame sensor of the present invention and an associated female connector;

Fig. 2 is a perspective view of the entire integrated lead frame sensor of the present invention;

Fig. 3 is a perspective view of entire integrated lead frame sensor of the present invention together with a reusable cable connector;

Fig. 4 is a perspective view of the photodiode as connected to the integrated lead frame sensor shown in Figs. 1-3;

Fig. 5 is a perspective view, partly in section, of the light emitting diodes as connected to the integrated lead frame sensor shown in Figs. 1-3;

Fig. 6 is a top plan view of a panel of lead frames prior to any processing steps being performed on the lead frames;

Figs. 7(a) - 7(e) are perspective views of the lead frame of the present invention in various stages of assembly;

Figs. 8(a) - 8(b) are plan views of the lead frame of the present invention used in a butterfly shaped sensor;

Figs. 9(a) - 9(b) are schematic views of a seven lead sensor and a six lead sensor, respectively, of the present invention;

Figs. 10(a) - 10(c) are perspective views of an alternate embodiment of the lead frame shown in Fig. 1 which utilizes a grounded shield;

Figs. 11(a) - 11(b) are front sectional views of electrical connection of the connector system incorporated in the lead frame shown in Fig. 1;

Fig. 12 is a perspective view of an alternate embodiment of the integrated lead frame sensor of Fig. 3 in which the cable is permanently attached to the sensor lead frame traces;

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Figs. 13(a) - 13(b) are perspective views of another alternate embodiment of the integrated lead frame shown in Fig. 1 which utilizes a pin and socket connector system.

Figs. 14(a) - 14(b) are perspective views of another alternate embodiment of the integrated lead frame shown in Fig. 1 which utilizes a cantilevered "U" socket connector system.

Figs. 15(a) - 15(c) are perspective views of another alternate embodiment of the integrated lead frame shown in Figs. 1 - 3 which provides for two different cable attachment points and a variable number of leads.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Fig. 1 the integrated lead frame 12 for a pulse oximetry sensor of the present invention provides electrical interconnection, mechanical orientation of components, and a means for attachment to perfused tissue.

In a preferred embodiment the lead frame 12 is made from 0.1mm to 0.3mm thick steel or copper sheet and seven leads 13 are formed in the frame by stamping or chemical machining. A plastic connector shell 14 is placed near one end of the lead frame 12 and is formed by insert molding. As shown in Fig. 2, red and infrared light emitting diodes 16, 18 ("LEDs") and a photodiode chip 20 are attached directly to the lead frame 12. In a preferred embodiment the attachment is made with silver filled epoxy and electrical connections are made with gold ball or wedge bonding. The LED's and photodiode are subsequently encapsulated in plastic lenses 22 by transfer molding or casting. The assembly is subsequently sealed in an envelope of thin, transparent plastic film (not shown) to provide electrical insulation. The insulating film may or may not be coated

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with pressure sensitive adhesive and it may or may not have opaque sections between transparent windows.

As shown in Figs. 1 and 3, the male electrical connector 24 formed by the lead frame 12 and the insert molded connector shell 14 mates with a female connector 26 on the end of a cable pigtail 28. In a preferred embodiment the insert molded connector shell 14 includes a groove 15 which mates with a projection 17 in the female connector 26 in order to retain a snug connection and to provide a moisture seal. The female connector 26 also includes a silicon rubber connector boot 25 and a conductor cable 27.

In a preferred embodiment, the device to which the pulse oximetry sensor of the present invention is connected is a pulse oximeter monitor. Examples of suitable monitors are those manufactured by Nelcor Incorporated of Hayward, California under the designation N-100 or N-200 or those monitored by Ohmeda (a division of the BOC Group, Inc.) of Louisville, Colorado under the designation 3740.

In one preferred embodiment the lead frame is fabricated from .005 inch thick copper alloy C194 with .00005 inch thick nickel plating overall and with .000075 inch thick selective gold plating on wire bonding pads only. The lead frame may also be plated with gold, silver or palladium.

A suitable red light emitting diode 16 is that sold by Showa Denko of San Mateo, California as part number ARH-35. This LED has a typical light output of 9 candellas at a wavelength of 655 nanometers. A suitable infrared light emitting diode 10 is that manufactured by Showa Denko of San Mateo, California under part number IR-35 which has a typical light output of 0.9 milliwatts at a wavelength of 940 nanometers.

A suitable silicon photodiode 20 can be obtained from Silicon Detector Corporation of Camarillo, California, which sells the photodiode as part number

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150-3842. This photodiode has a typical response of 0.5 amp/watt and a wavelength of 900 nanometers. The photodiode has an active area of 0.56 inches X 0.56 inches.

The lead frame 12 provides means for electrical connection and mechanical orientation of the light sources 16, 18 and the photodetector 20 and eliminates the need for additional substrate components. The metal lead frame can be formed, plated or polished as appropriate to optimize light emission or detection. The lead frame also provides means for holding the photoactive components while a precision lens is molded to encapsulate them. The design of such precision lenses is well known in the art as described in Optoelectronics/Fiber-Optics Applications Manual which is prepared by the application engineering staff of Hewlett-Packard Optoelectronics Division and is published by McGraw-Hill Book Company and the teachings of which are incorporated herein by reference. In a preferred embodiment, the precision lens is molded out of a transparent, electrically insulating epoxy manufactured by Ablestick Laboratories of Gardena, California under the designation Ablebond® 342-3, which enables the lens to increase the amount of light coupled into and out of the perfused tissue. The lens may also be tinted to provide additional shielding from ambient light.

The lead frame 12 deforms plastically as it is bent to conform to a finger tip so that it will accurately retain its shape after it is applied to the finger tip. The material and thickness of the lead frame can be chosen to optimize this behavior. The sensor can be further retained by pressure sensitive adhesives or bandages so that it will not tend to spring open. The low mass and thin construction of the integrated lead frame of the present invention act to diminish the

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sensor's susceptibility to motion induced artifact thereby enabling the lead frame to be used with a wide variety of sensor designs.

In a preferred embodiment a calibration resistor 34 is mounted on the lead frame 12 so that the sensor incorporating the lead frame can be used with a wide variety of pulse oximetry instruments. The resistor 34 has a coded known resistance, and it enables the pulse oximetry instruments to calculate the coefficient of extinction of the wavelengths of the LEDs 16, 18. The pulse oximetry instrument is programmed at the factory to calculate the coefficient of extinction of any LEDs which may be encountered in a series of sensors. From the coefficients of extinction, the pulse rate and degree of arterial oxygen saturation is computed and displayed by the pulse oximetry instrument. A suitable calibration resistor system is described in U.S. Patent No. 4,700,708, the teachings of which are incorporated herein by reference.

The integrated lead frame sensor described above for use in conjunction with pulse oximeters lends itself to manufacture by conventional semiconductor packaging techniques. As such the integrated lead frame sensor can be fabricated by highly automated equipment at low cost. The manufacturing cost is further reduced by eliminating intermediate substrates and interconnections.

Referring to Fig. 6, the lead frames 12 are generally manufactured as a panel of lead frames which must then be separated. The lead frames can then be supplied as a single unit or in a panel of many elements. When a panel is supplied subsequent process steps can be performed on several parts simultaneously, thereby reducing the costs of the finished sensor. In addition, the external frame 36 can include features which permit automatic parts handling for additional efficiency. Retention elements

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40 may also be included to create an interlocking geometry when the connector housing 26 is molded in place.

Referring to Figs. 7(a)-7(e), the manufacturing steps for the lead frame will now be described. When the lead frame 12 is produced as part of a panel of lead frames, individual lead frames must be cut from the panel so that only the lead frame element 12 remains. As a result, the external frame element 36 must be cut from the lead frame 12. Next, as shown in Fig. 7(b) the plastic connector shell 14 is molded onto the connector housing 12, and then the LEDs 16, 18 and the photodiode 20 are wire bonded to the lead frame 12 as shown in Fig. 7(c). In Fig. 7(d) the plastic lenses which provide the transparent encapsulation are placed over the LEDs 16, 18 and the photodiode 20. Finally, the tie bars 38 are removed from the lead frame element.

After the lead frame 12 is assembled, it is then mounted in a particular type of sensor which can take on a variety of shapes for use with bodily parts such as hands, feet, fingers, toes, ears, etc. Referring to Figs. 8(a)-8(b), a butterfly sensor is shown which is designed for use around the tip of a finger or toe. In this embodiment, an opaque piece of tape 46 is cut into a butterfly shape. A second opaque piece of tape 48, with two openings 50 cut out to allow for the lenses 22 to pass through the openings 50, is then placed over the top surface of the lead frame 12. A transparent tape layer 52 is then placed over the top of each of the lenses 22 that protrude through the opaque tape 48.

While the sensor shown in Figs. 1-8 include seven leads, other embodiments will include only six leads. Referring to Fig. 9(a), a schematic for a seven lead version is shown in which two leads are connected to the calibration resistor 34, two leads are connected to the photodiode 20 and the other three leads are connected to the two LEDs 16,18. In the six lead embodiment shown in

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Fig. 9(b), two leads are also connected to the calibration code element 34 and another two are connected to the photodiode 20. The difference in the Fig. 9(b) embodiment is that only two leads are connected to the two LEDs. The selection of the particular type of lead depends on the oximetry instrument that is being used with the sensor.

Referring now to Figs. 10(a)-10(c), the lead frame 12 can be shielded with a grounded planar shield 54 as shown in Fig. 10(a). The shield is created by covering a layer of planar shield material 56 with a plastic film insulator 58. The shield is then folded length wise in half so that the plastic film insulator 58 is completely surrounded by the layer of planar shield material 56 as shown in Fig. 10(b). The shield is shown in Fig. 10(c) with one lens mounted over the shield.

In the preferred embodiment shown in Figs. 1-10, the sensor is shown with a flat flexible cable connector system which includes a detent or groove 15 that mates with a projection 17 in the female connector 26. As shown in Figs 11(a)-11(b), inside the molded female connector housing 26, a metal spring contact 60 is positioned which is designed to mate with the lead frame conductor 62 which passes through the molded connector shell 14. As shown in Fig. 11(a) the spring contact 60 will contact the lead frame conductor 62 when the two elements 14, 26 are connected.

Instead of using the connector system that utilizes the detent or groove 15 and projection 17, an alternate embodiment shown in Fig. 12 utilizes a cable 64 that is permanently attached to the sensor element. In other words, each wire will be connected to an individual lead frame trace 66 at one end of the sensor lead frame 12.

Referring to Figs. 13(a)-13(b), another alternate embodiment is shown which utilizes a pin and socket connector system. In this embodiment, the female sockets

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68 are attached to each lead frame trace 66. The female sockets 68 receive mating pins 70 that extend from the cable connector 72.

In still another embodiment of the invention shown in Figs 14(a)-14(b) a cantilevered "U" socket connector is utilized. In this embodiment, the ends of each lead frame trace 74 are shaped in the form of a U socket 76 which receives mating pins 78 that extend from the cable connector 80.

In the embodiment shown in Figs. 15(a)-15(c), the lead frame 86 can be designed to be connected to the oximetry instrument at either end as it includes a connector shell 84 at each end of the lead frame 86. An interconnection cable can be permanently attached to one end of the Fig. 15(c) configuration, and either the connector on one end or the cable on the other end can be removed if not used. This lead frame can also be adapted for use with different oximetry instruments. Once the oximetry instrument is selected, the final configuration is chosen simply by cutting the extra leads.

While the foregoing invention has been described with reference to its preferred embodiments, various alterations and modifications will occur to those skilled in the art. All such variations and modifications are intended to fall within the scope of the appended claims:

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What is claimed:

1. A pulse oximetry probe for use with a pulse oximetry instrument, said probe comprising:
 - a lead frame having a plurality of electrically conductive leads, said lead frame having a thickness between .1 and .3 millimeters;
 - at least two light sources of different wavelengths, each of said light sources being connected to at least one of said a plurality of electrically conductive leads;
 - a photodetector for detecting light emitted by said light sources, said photodetector being connected to at least one of said plurality of electrically conductive leads.
2. The pulse oximetry probe of claim 1 wherein said light sources are light emitting diodes.
3. The pulse oximetry probe of claim 1 wherein said photodetector is a silicon photodiode;
4. The pulse oximetry probe of claim 1 wherein said lead frame is made of copper or a copper alloy.
5. The pulse oximetry probe of claim 1 wherein the lead frame is plated with gold.
6. The pulse oximetry probe of claim 1 wherein the lead frame is plated with silver.
7. The pulse oximetry probe of claim 1 wherein the lead frame is plated with palladium.
8. The pulse oximetry probe of claim 1 wherein said lead frame further comprises a dish shaped reflector for supporting said light sources or photodetector.

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9. The pulse oximetry probe of claim 1 wherein said light sources and/or said photodetector are encapsulated in clear epoxy to provide mechanical integrity.

10. The pulse oximetry probe of claim 9 wherein the epoxy is formed in the shape of an optical lens to optimize the performance of the light sources, and/or photodetector.

11. The pulse oximetry probe of claim 1 wherein the lead frame further comprises a shield layer that provides additional shielding from ambient light.

12. The pulse oximetry probe of claim 1 wherein the lead frame further comprises a shield layer that provides additional shielding from electromagnetic interference.

13. The pulse oximetry probe of claim 1 wherein said lead frame is deformable plastically when applied to perfused tissue and wherein said lead frame retains the shape desired by the user.

14. The pulse oximetry probe of claim 1 further comprising a calibration element connected to at least one lead of said lead frame.

15. The pulse oximetry probe of claim 14, wherein the calibration element is a thick film chip resistor.

16. The pulse oximetry probe of claim 1 wherein said lead frame is permanently connected to an interconnection cable.

17. The pulse oximetry probe of claim 1 wherein the lead frame is terminated to a reusable connector element.

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18. The pulse oximetry probe of claim 17, wherein the connector element is configured as the male end of a flat flexible cable (FFC) connector system.

19. The pulse oximetry probe of claim 17 wherein the connector element is configured as the female end of a pin and socket connector system.

20. The pulse oximetry probe of claim 19, wherein lead traces of the lead frame are formed to create U-shaped cantilevered socket elements.

21. The pulse oximetry probe of claim 17 wherein rigid plastic is insert molded around the connector to provide mechanical spacing and electrical insulation between conductors.

22. The pulse oximetry probe of claim 21 wherein molded rigid plastic insert also incorporates a snap detent feature when connected to its mate.

23. The pulse oximetry probe of claim 21 wherein the molded rigid plastic insert further comprises a moisture seal.

24. The pulse oximetry probe of claim 9 wherein said epoxy encapsulating said photodetector is tinted to provide shielding from ambient light.

25. The pulse oximetry probe of claim 1 wherein said lead frame comprises both a reusable connector and a permanently attached interconnection cable, one of said connector or cable being removable if not required.

26. The pulse oximetry probe of claim 1 wherein the lead frame comprises at least two sets of light sources and at least two photodetectors.

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27. The pulse oximetry probe of claim 1 wherein said lead frame comprises connector elements at each end of the lead frame so that the oximetry instrument can be connected to the pulse oximetry sensor at either end of the pulse oximetry sensor.

28. The pulse oximetry probe of claim 1 further comprising:

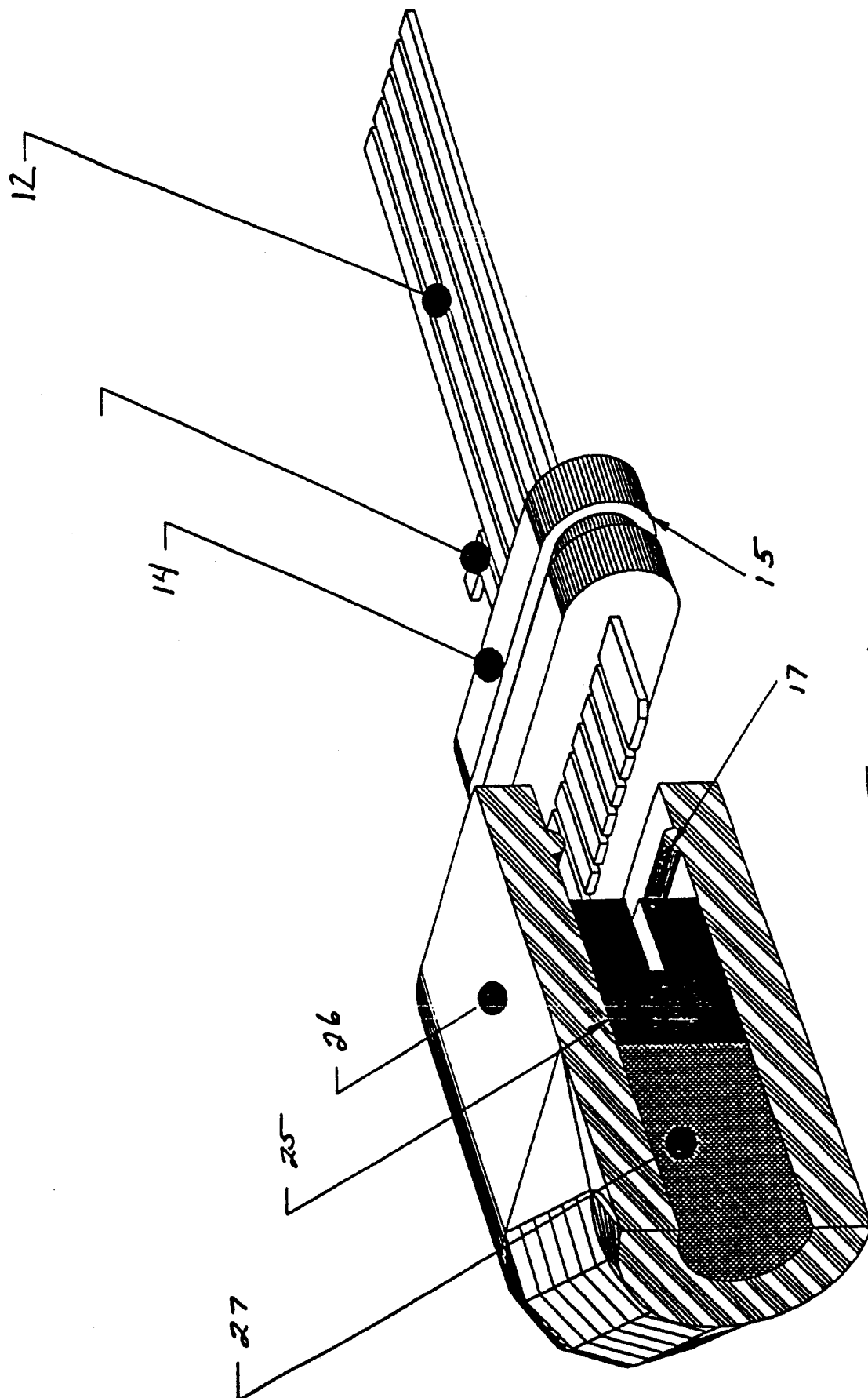
a first layer of opaque material on which said lead frame is positioned;

a second layer of opaque material positioned on a surface of said lead frame opposite the surface of said lead frame in contact with said first layer of opaque material;

at least one layer of transparent material for covering said light sources and said photodetector.

29. The pulse oximetry probe of claim 1 further comprising means to make electrical contact with a spring element housed within a connector mounted on a cable to which said pulse oximetry probe is connected.

30. The pulse oximetry probe of claim 1 wherein at least one of said conductive leads is removable if said pulse oximetry probe is to be used with a oximetry instrument which does not require use of all of the leads of the probe.



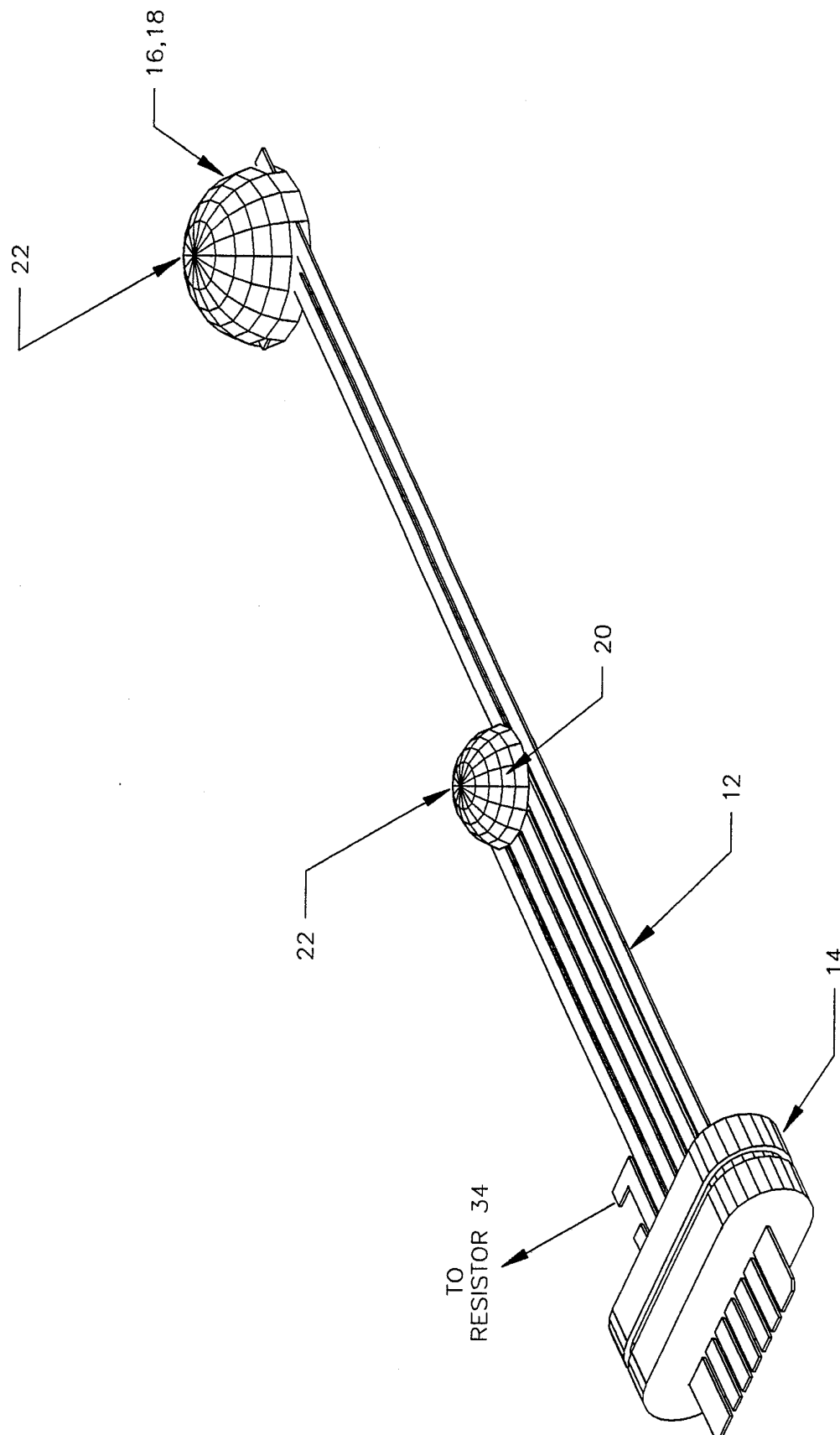


FIG. 2

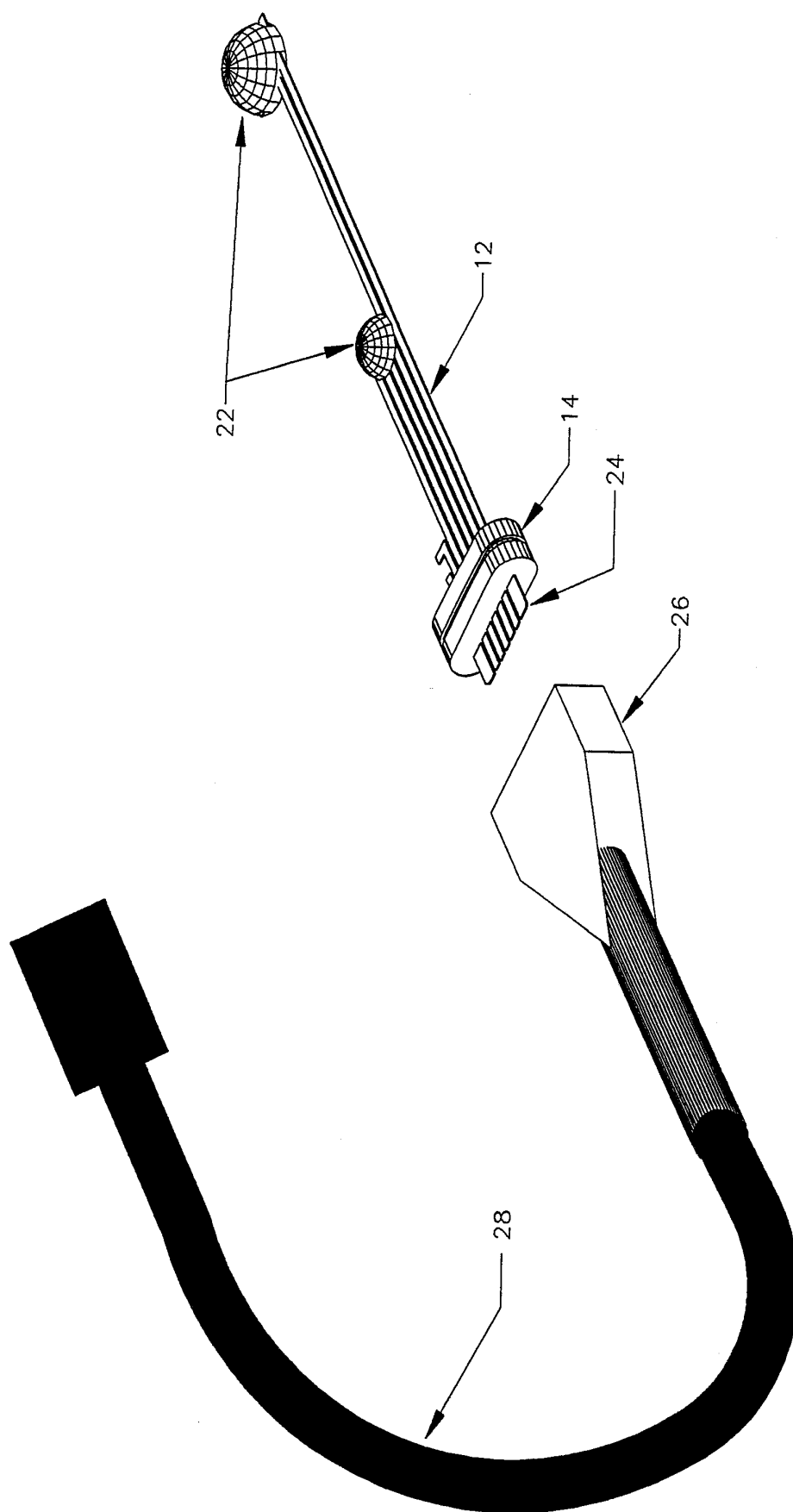


FIG. 3

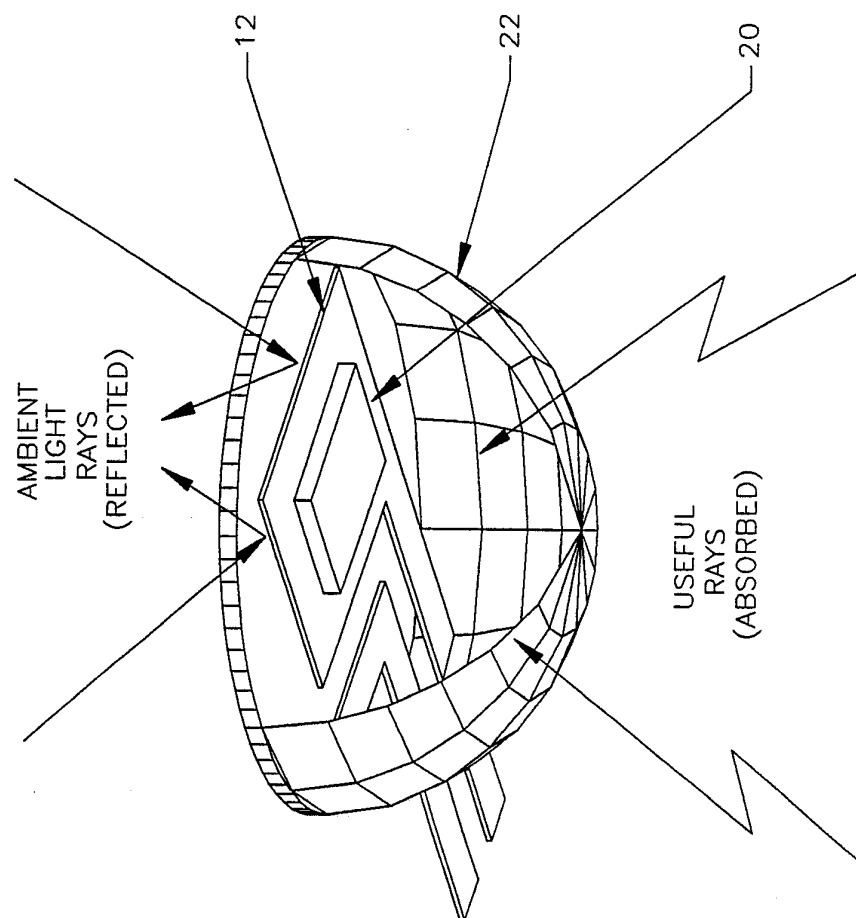


FIG. 4

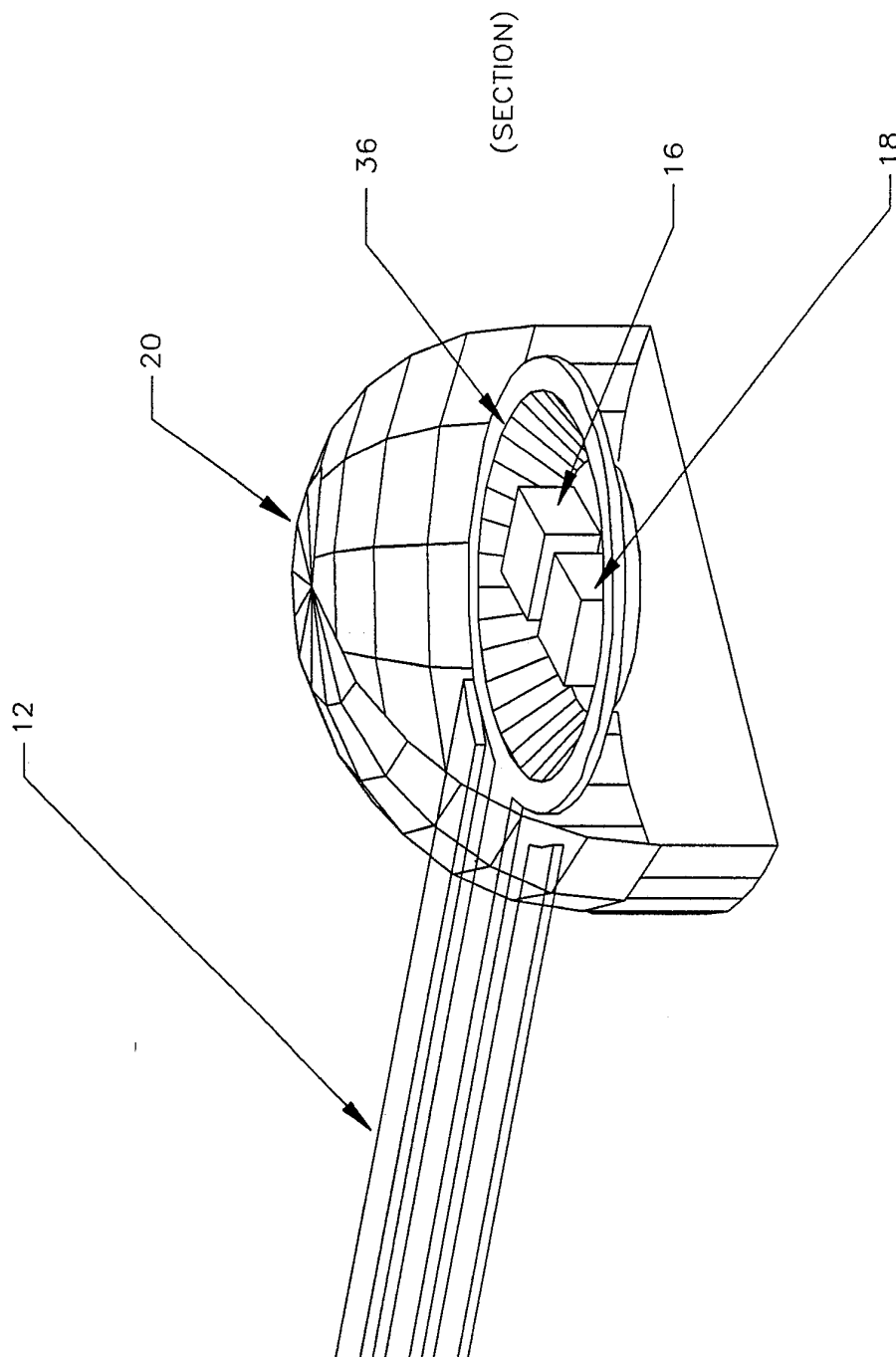


FIG. 5

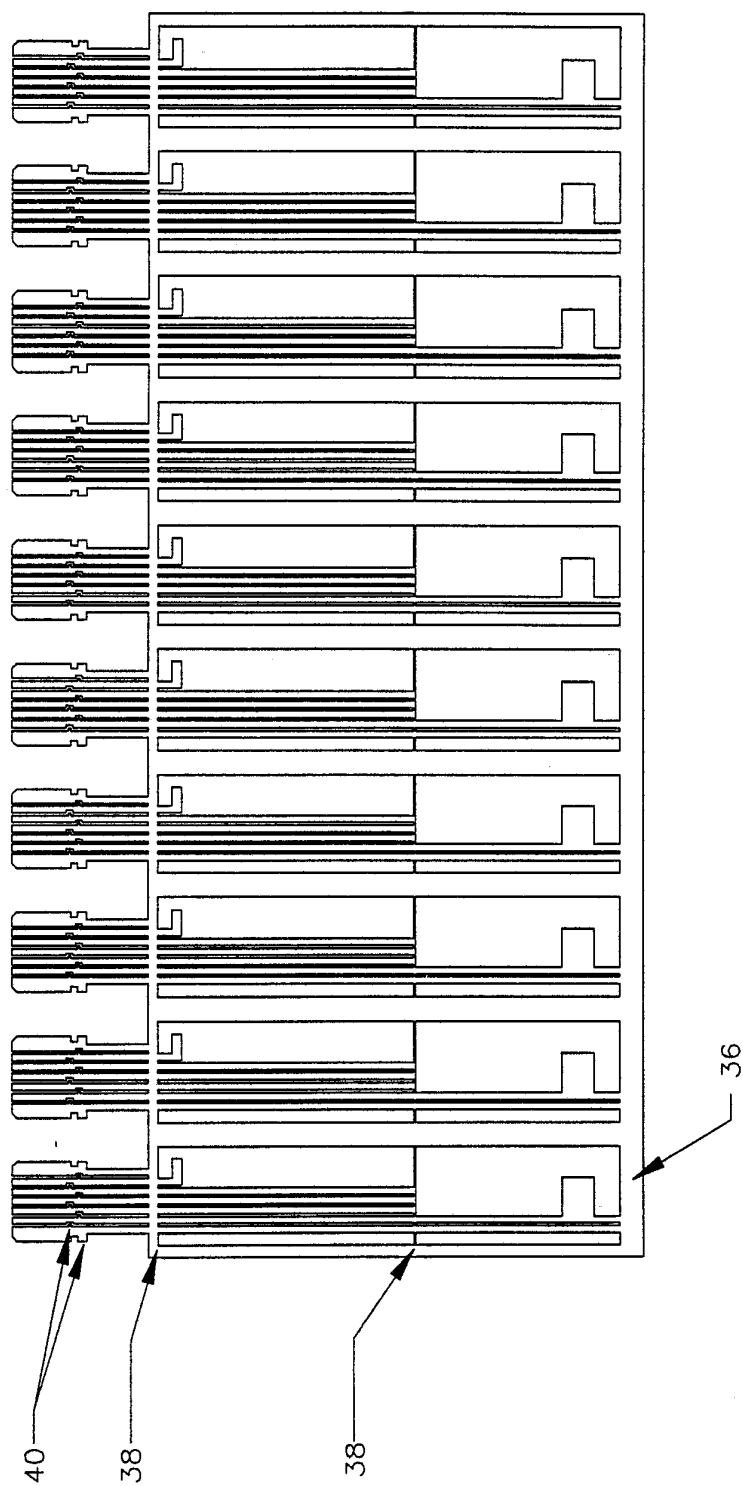


FIG. 6

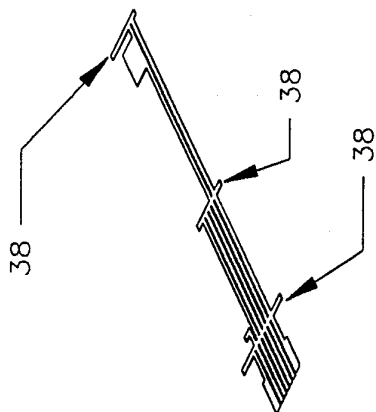


FIG. 7(a)

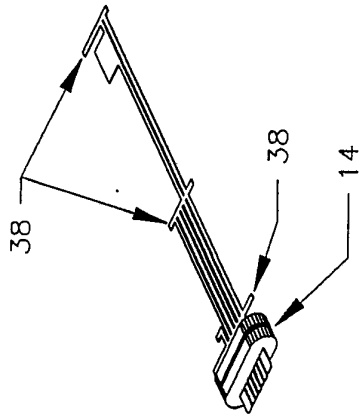


FIG. 7(b)

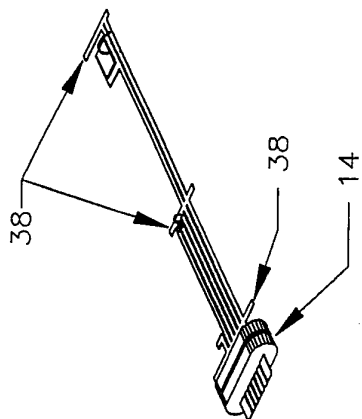


FIG. 7(c)

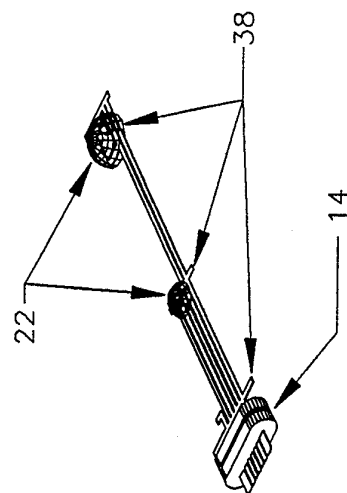


FIG. 7(d)

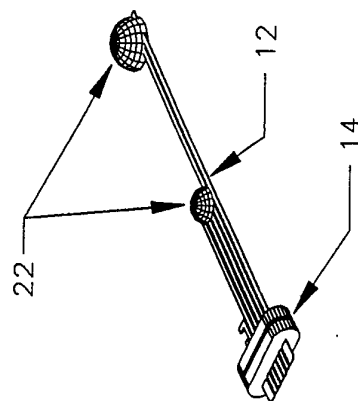


FIG. 7(e)

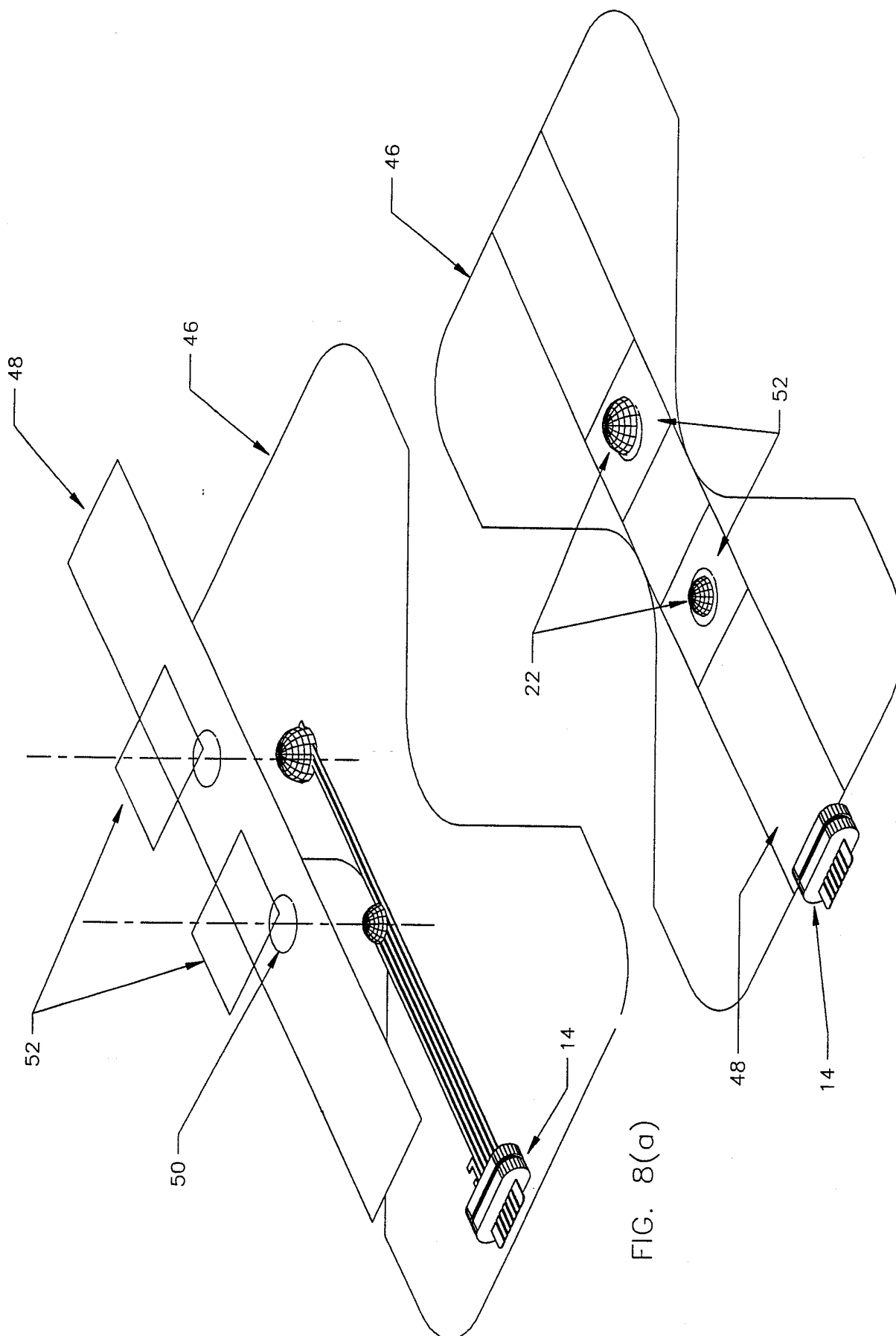
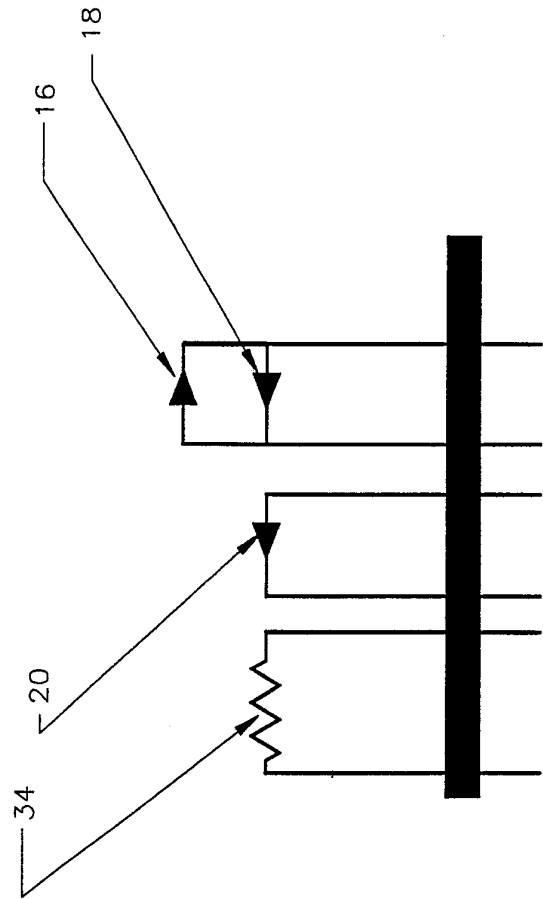
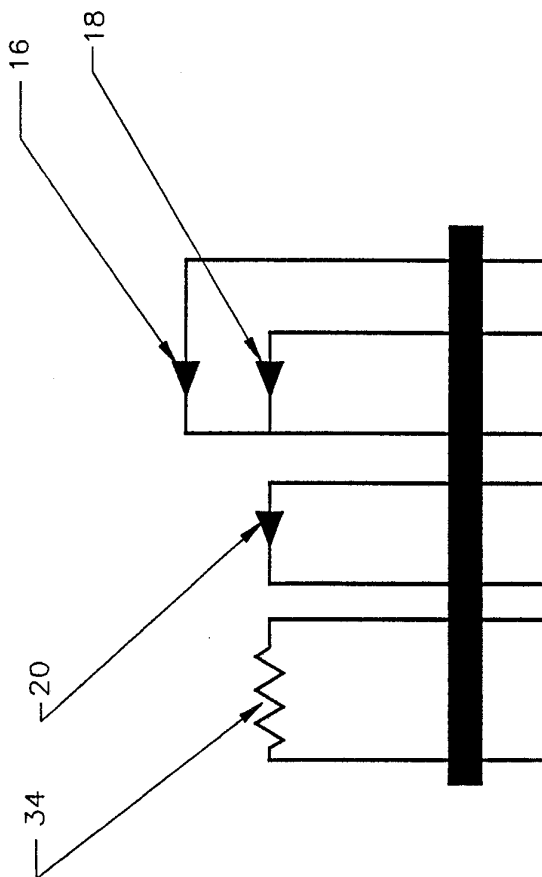
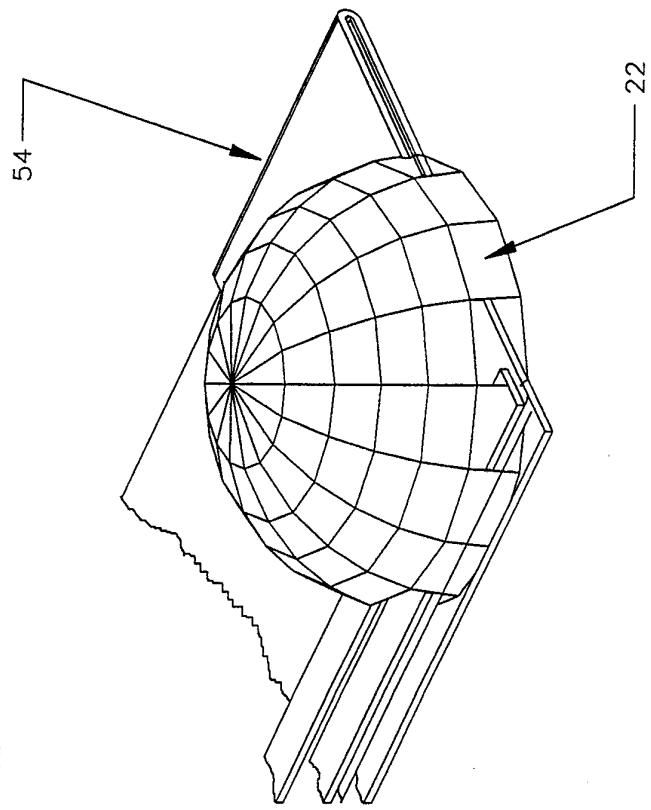
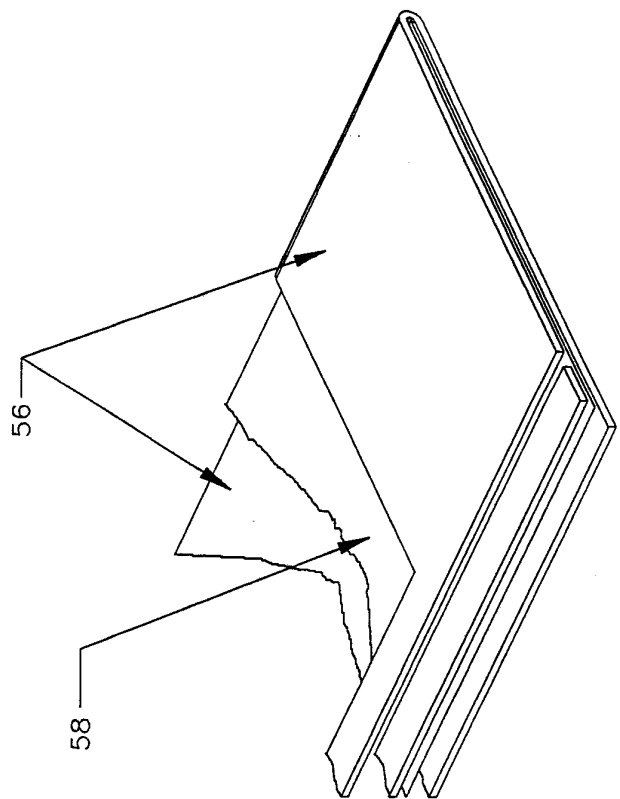
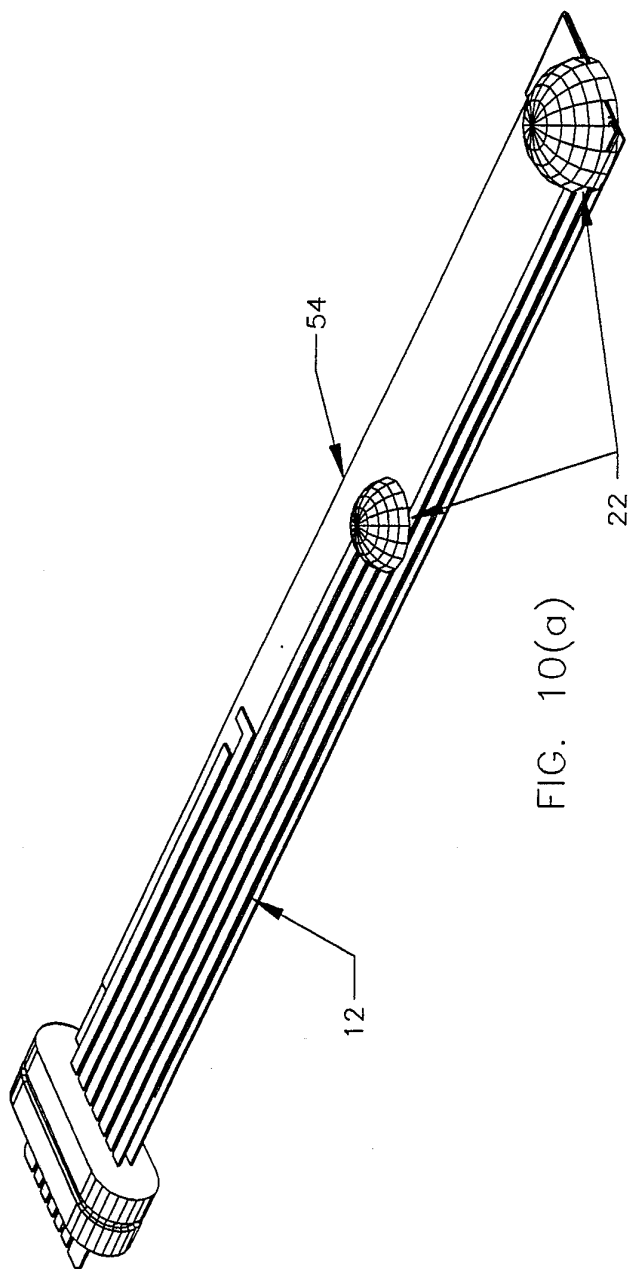
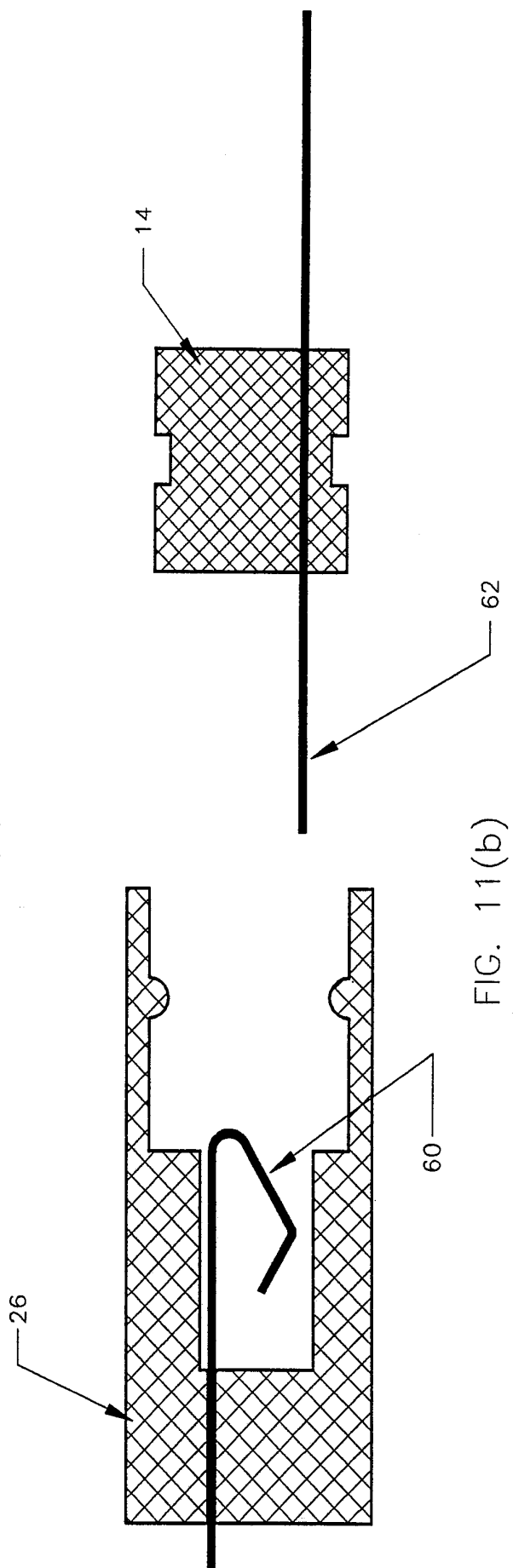
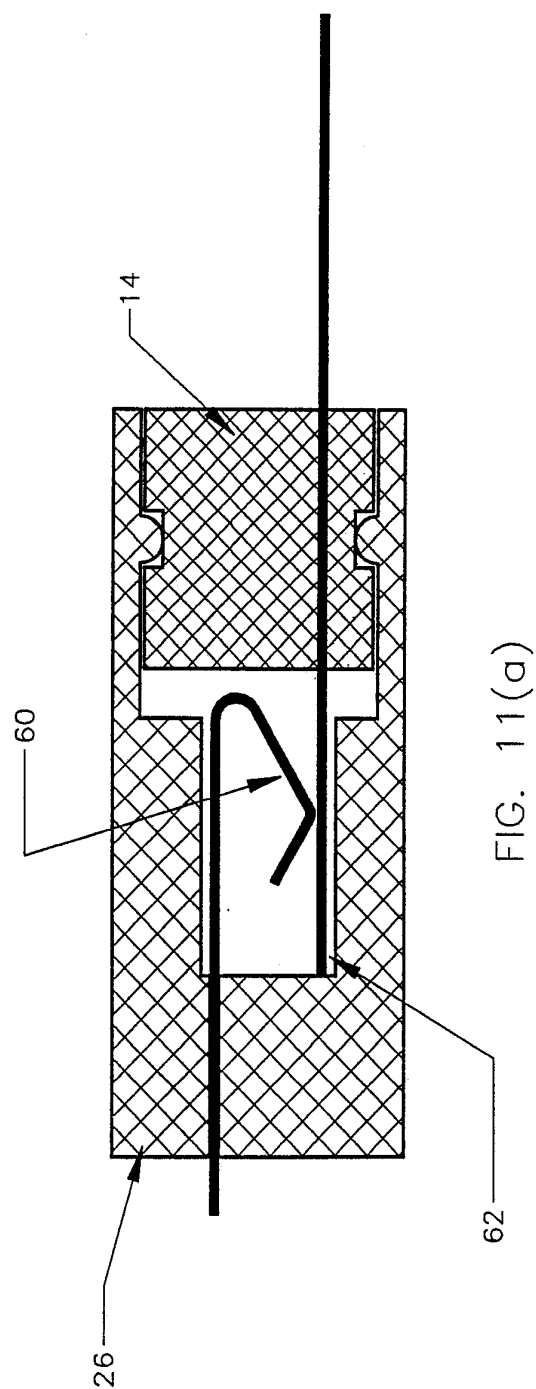


FIG. 8(b)







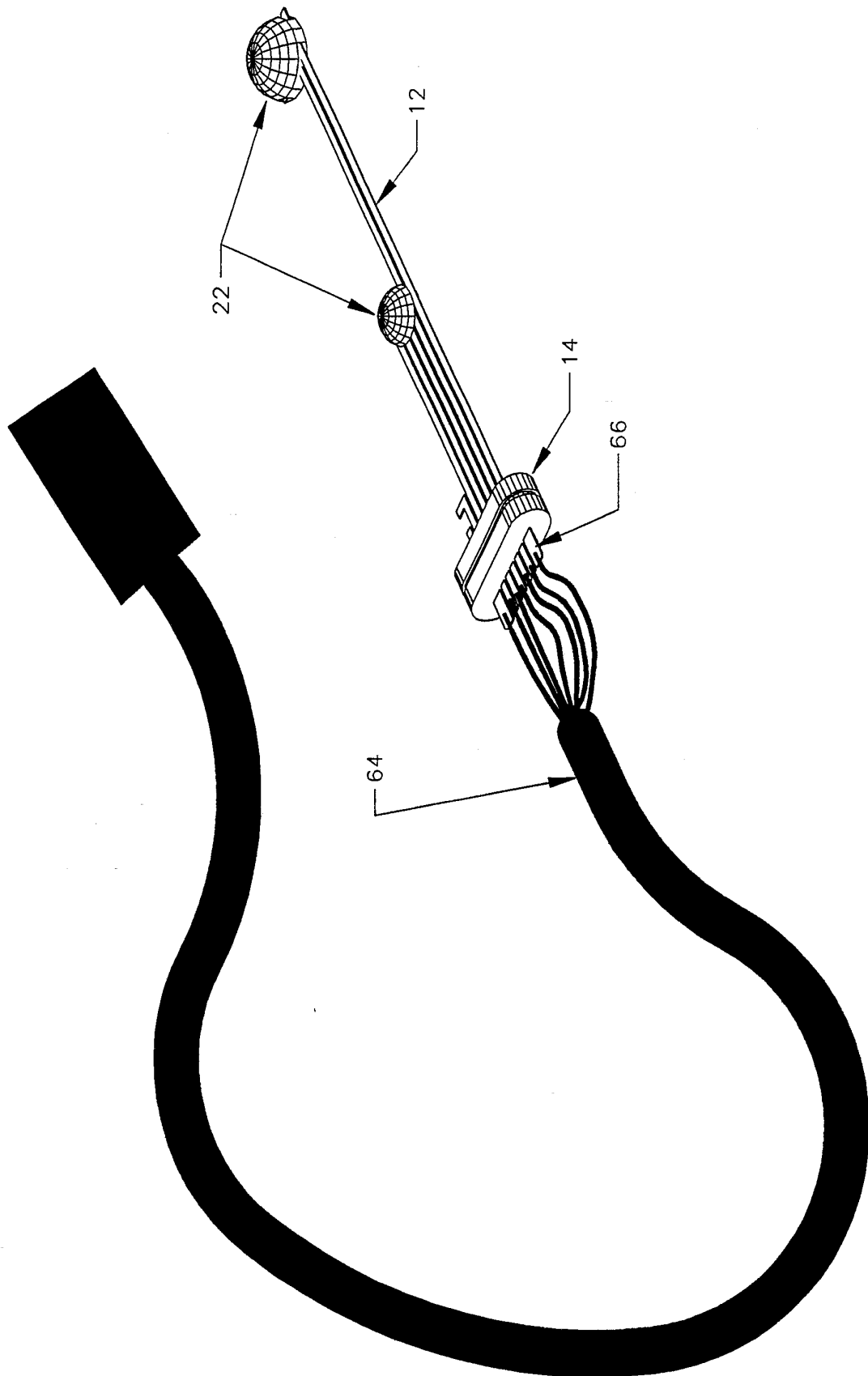


FIG. 12

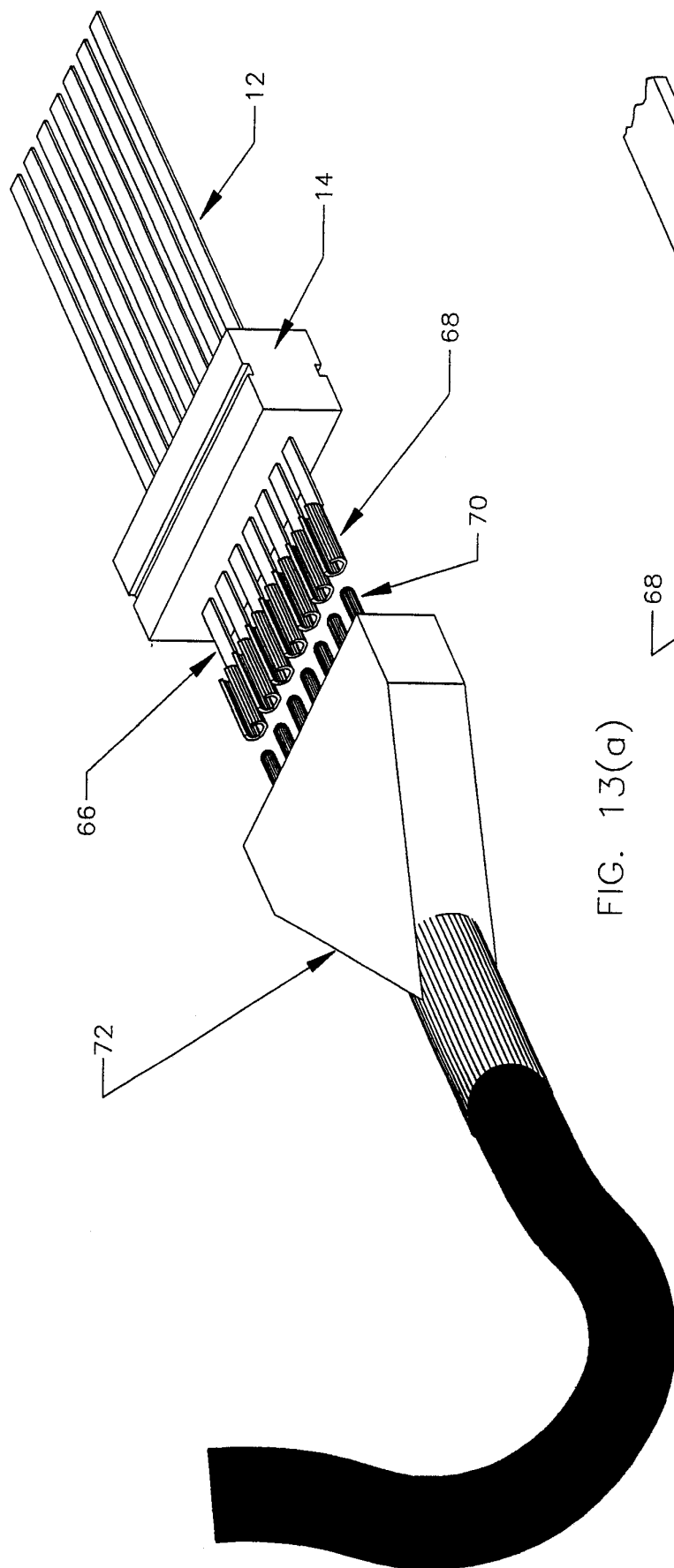


FIG. 13(a)

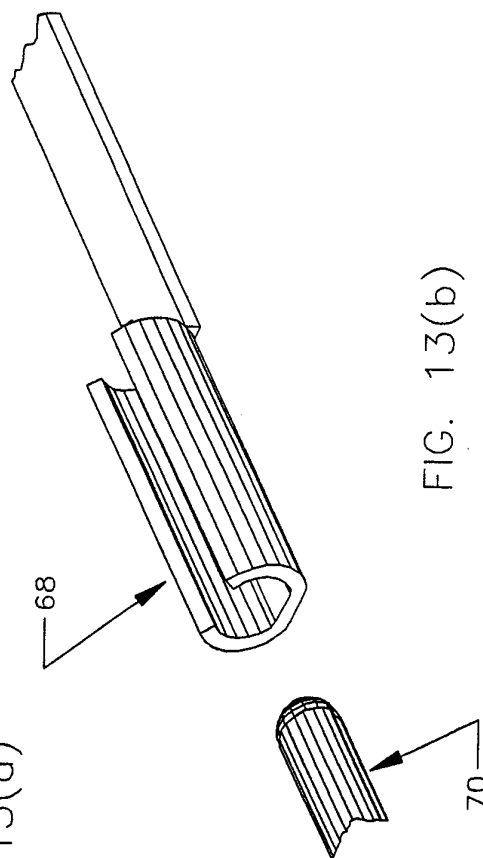


FIG. 13(b)

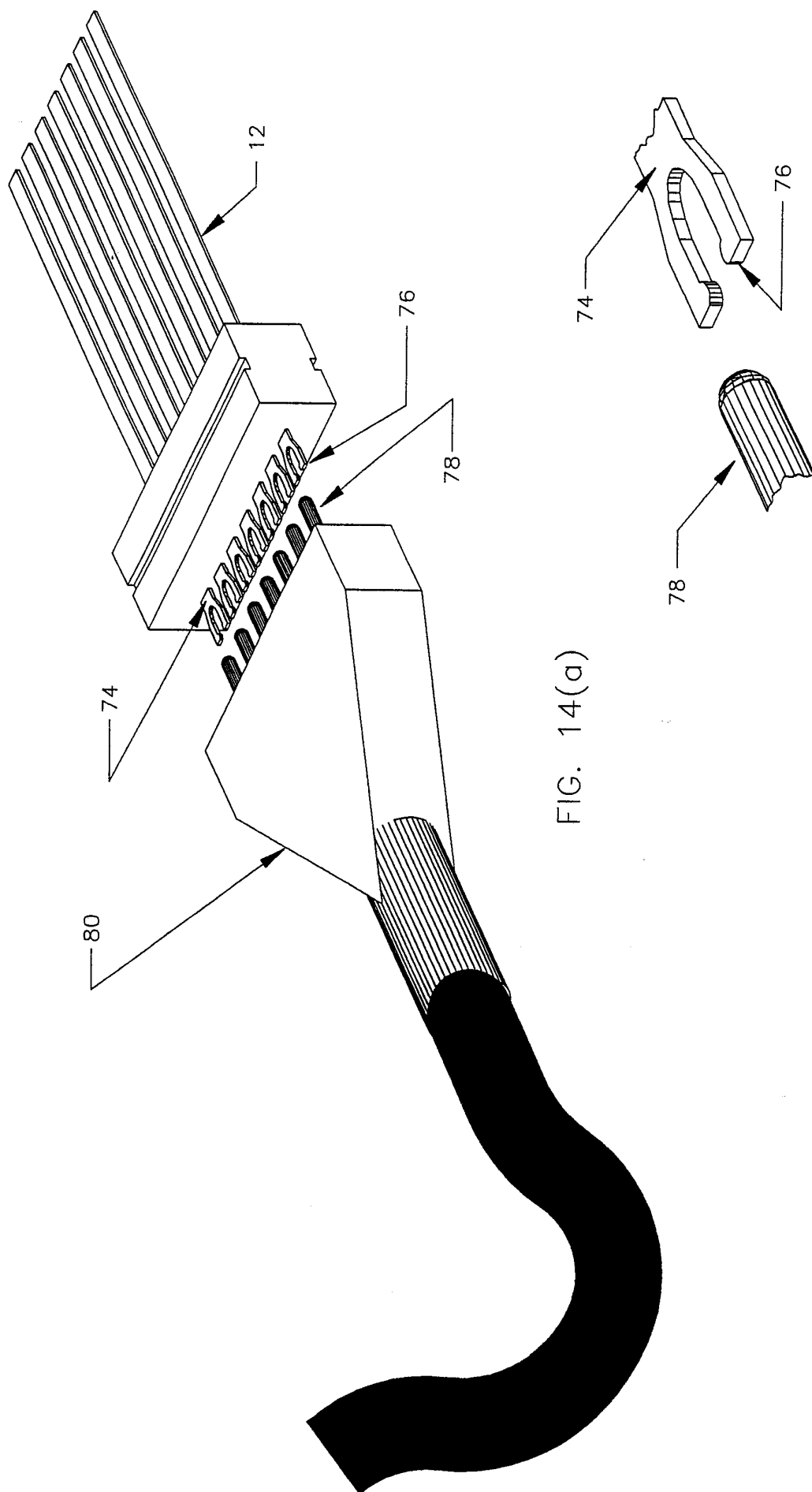
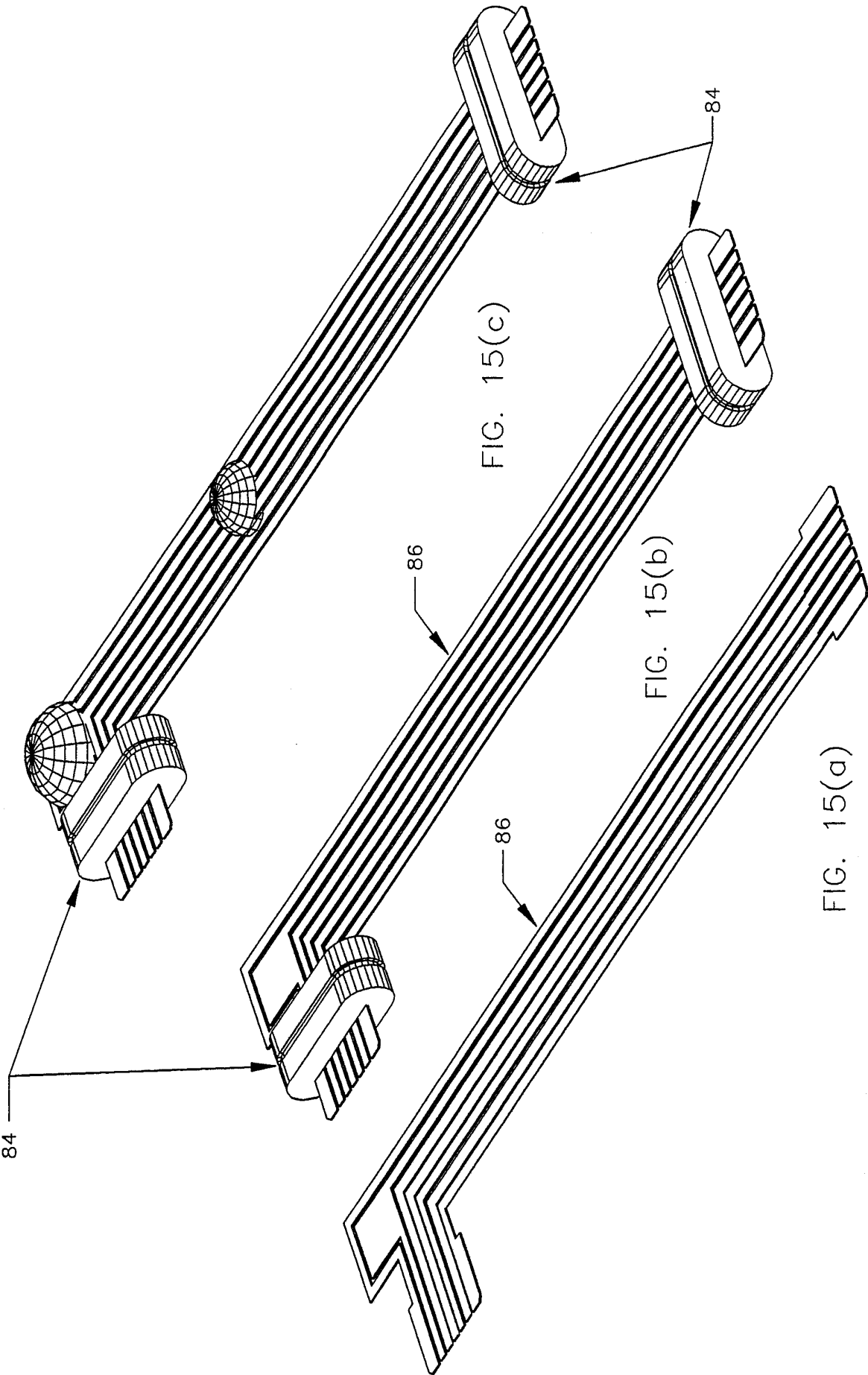


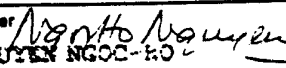
FIG. 14(a)

FIG. 14(b)



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/01964

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC(5) A61B 5/14		
US Cl.: 128/633		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
US	128/633, 664, 665	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category [*]	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X Y	US,A, 4,964,408 (Hink) 23 October 1990 (see figures 3 and 7).	1-3, 11-13, 16, 17, 21, 22, 25, 28, 29 4-7, 9, 10, 14, 15, 18-20
Y	US,A, 4,974,591 (Awazu) 04 December (see figure 14).	9, 10
Y	US,A, 4,700,708 (New) 20 October 1987 (see lines 62-68 of column 5).	14, 15
A	US,A, 4,865,038 (Rich) 12 September 1989	1-30
A,P	US,A, 5,094,240 (Muz) 10 March 1992	1-30
<p>[*] Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
18 June 1992		16 JUL 1992
International Searching Authority		Signature of Authorized Officer
ISA/US		 NGUYEN NGOC HO Kevin Pontius
		INTERNATIONAL DIVISION

