

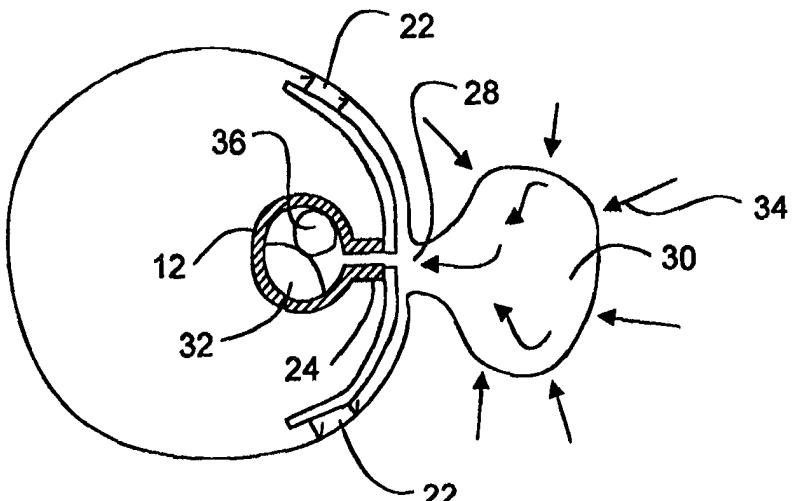
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

|                                                                                                                             |  |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------------|--|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (51) International Patent Classification <sup>6</sup> :<br><b>A61F 2/06, A61B 17/00</b>                                     |  | A1 | (11) International Publication Number: <b>WO 98/23227</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                                                                                             |  |    | (43) International Publication Date: 4 June 1998 (04.06.98)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| (21) International Application Number: PCT/US97/19392                                                                       |  |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| (22) International Filing Date: 29 October 1997 (29.10.97)                                                                  |  |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| (30) Priority Data:<br>08/756,099 25 November 1996 (25.11.96) US                                                            |  |    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
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(54) Title: ANEURYSM PATCH APPARATUS AND METHOD FOR TREATING AN ANEURYSM

## (57) Abstract

An aneurysm patch apparatus (10) for treating an aneurysm (30) formed in a vessel includes a vessel interface side (16) and an opposing non-interface side (18). A patch (14) is formed of a sufficiently flexible material to provide a patch stowed state when the patch is delivered through the vessel and a patch deployed state when the patch is at least partially positioned over the mouth of the aneurysm. The interface side of the patch is configured to form an adherence between the patch and an area of a vessel wall adjacent to the aneurysm mouth (28). The adherence (22) maintains a fixed position of the patch relative to the aneurysm mouth and can be achieved by use of vacuum, barbs, hooks, graspers, pinchers or the like. The patch delivery catheter (12) includes a first lumen (32) coupled to a low pressure source for collapsing the aneurysm, and a second lumen (36) for consequently applying adhesive to provide contact between patch and vessel wall.



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## ANEURYSM PATCH APPARATUS AND METHOD FOR TREATING AN ANEURYSM

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of Serial Number 08/708,586, entitled "DISTRIBUTED ACTIVATOR FOR A TWO-DIMENSIONAL SHAPE MEMORY ALLOY", filed by Ronald S. Maynard on September 5, 1996, incorporated herein by reference.

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**Field of the Invention**

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This application relates to a method and apparatus to treat an aneurism, and more particularly to a patch for treating an aneurism which is configured to form an adherence between the patch and an area of a vessel wall adjacent to an aneurism mouth and the adherence maintains a fixed position of the patch relative to the aneurism mouth.

**BACKGROUND**

There are several devices which exist that are used for the repair of aneurysms. U.S. Patent No. 4,512,238 discloses a device for transluminal repair of, and restoring patency of, a weakened or damaged vessel uses a nitinol wire, previously memory-shaped into a straight wire and inserted into the vessel requiring repair. When placed in the body and stripped of heat insulation the wire warms and returns to a preselected coiled dimensions to support the vessel wall. One problem with this device is the difficult task of attaching a sleeve to the wire support because the wire is many times longer than the sleeve at the time it is inserted.

U.S. Patent No. 4,140,126 discloses another device for repairing an aneurism. The device is mounted on the outside of a carrier catheter and is positioned in the vessel in a collapsed form, smaller in diameter than that of the vessel. The device is then expanded onto the vessel wall by the use of a separate mechanical expanding apparatus which is controlled by the user from outside the body.

U.S. Patent No. 4,787,899 describes a system of positioning a graft within a body lumen. The graft is loaded into a guide which is inserted into the lumen. An inflatable balloon is used to anchor the distal end of the graft onto the wall of the lumen. The guide is then pushed upstream, pulling the folded graft out of the guide and onto the wall of the lumen where staples end anchor it into the wall of the lumen. One problem with this device is that the balloon providing the anchor for the distal end of the graft while the guide is moved upstream may not provide enough pressure on the wall of the vessel to prevent slippage which could result in misplacement of the graft.

It would be desirable to provide an aneurism patch which does not have a coil configuration and which adheres to the vessel wall adjacent to the mouth of the aneurism. It would be further desirable to provide an aneurism patch which has non-electrically activated deployed state configured to be positioned adjacent to the mouth of the aneurism. Yet it would still further desirable to provide an aneurism patch which has an electrically activated deployed state that is configured to be positioned adjacent to the mouth of the aneurism.

SUMMARY

An object of the invention is to provide a method and apparatus for treating aneurysms.

5 Another object of the invention is to provide an aneurism patch which is positioned over a mouth of an aneurism.

Still another object of the invention is to provide an aneurism patch which has a non-electrically deployed state that is positioned over a mouth of an aneurism.

10 Yet another object of the invention is to provide an aneurism patch which is introduced into a vessel in a stowed state and is positioned over the mouth of the aneurism in a deployed state.

A further object of the invention is to provide an aneurism patch with a vessel interface side that includes a plurality of anchor elements.

15 Still another object of the invention is to provide an aneurism patch forms a mechanical adherence between the patch and the vessel wall adjacent to the aneurism mouth.

Yet another object of the invention is to provide an aneurism patch with an aperture configured to be coupled to a low pressure source.

20 Another object of the invention is to provide an aneurism patch at least partially made of a material with an internal stress and a pre-defined shape, where the internal stress moves the patch from a stowed state to the pre-defined state.

Still another object of the invention is provide an aneurism patch that is formed of a thermally active material that moves to a pre-defined shape when electrically heated.

25 A further object of the invention is to provide an aneurism patch which is made of an SMA element with an activation threshold greater than body temperature.

These and other objects of the invention are achieved in an aneurism patch apparatus for treating an aneurism formed in a vessel includes a patch with a vessel interface side and an opposing non-interface side. The patch is formed of a sufficiently flexible material to provide a patch stowed state when the patch is

delivered through the vessel and a patch deployed state when the patch is at least partially positioned over the mouth of the aneurism. The interface side of the patch is configured to form an adherence between the patch and an area of a vessel wall adjacent to the aneurism mouth. The adherence maintains a fixed position of the patch relative to the aneurism mouth.

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In one embodiment of the invention the patch includes a vessel interface side and an opposing non-interface side, the patch is configured to have a stowed state when delivered to a mouth of the aneurism. The patch is formed of a thermally active material that moves to a pre-defined shape when electrically heated. The pre-defined shape forms an adherence between the vessel interface side and an area of the vessel

all adjacent to the aneurism mouth. The adherence maintains a fixed position of the patch relative to the aneurism mouth.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

5 Figure 1 is a perspective of an aneurism patch apparatus of the present invention.

Figure 2 is a cross-sectional view of the patch of Figure 1 positioned adjacent to an aneurism.

10 Figure 3 is a cross-sectional view of a patch positioned on an exterior surface of a catheter when the patch is in a stowed position.

Figure 4 is a cross-sectional view of the patch in a deployed position and the evacuation of the aneurism through a lumen formed in the catheter.

Figure 5 is a cross-sectional view of the patch in a deployed/pre-shaped position, the introduction of an adhesion medium and the collapse of the aneurism.

15 Figure 6 is a cross-sectional view of the stowed patch positioned at a distal end of the catheter.

Figure 7 is an isometric view of a deactivated two-dimensional sheet according to the invention.

20 Figure 8 is an isometric view of the two-dimensional sheet of Figure 7 in the activated state.

Figure 9 is an isometric view of a portion of the two-dimensional sheet of Figure 7.

Figure 10A is a cross section of the portion of the two-dimensional of Figure 10A.

25 Figure 10B is a graph of the temperature distribution in the portion of Figure 10A.

Figure 11 is a graph of the transition between the martensitic and austenitic states as a function of temperature.

Figure 12 is a cross section of a two-dimensional sheet with an insulating layer and a coating layer.

Figure 13 is a cross section of a two-dimensional sheet with point-wise applied insulating layer and a coating layer.

Figure 14 is a cross section of a two-dimensional sheet with a coating layer.

5 Figure 15 is an exploded view illustrating the assembly of a two-dimensional sheet and the activation elements according to the invention.

Figure 16 is a diagram showing the equivalent circuit of the activation mechanism.

10 Figure 17 is a side view illustrating the deflection of a two-dimensional sheet according to the invention.

Figure 18 is a perspective view illustrating a complex pre-trained shape of a sheet according to an aspect of the invention.

Figure 19 is a diagram showing the equivalent circuit of an embodiment using deflection sensors.

15 Figure 20 is a cross sectional view of a two-dimensional sheet with deflection sensors.

Figure 21 is a cross sectional view of a two-dimensional sheet with deflection sensors mounted next to heating elements.

Figure 22 is a cross sectional view showing a two-dimensional sheet with a temperature sensor.

20 Figure 23 is a cross sectional view of a two-dimensional sheet with protective coating applied over the heating elements.

Figure 24 is a cross section of a two-dimensional sheet using vanes for heat dissipation.

25 Figure 25 is a cross section of a two-dimensional sheet using water ducts for heat dissipation.

#### **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

The present invention provides an aneurism patch apparatus for treating an aneurism formed in a vessel which includes a patch with a vessel interface side and an

opposing non-interface side. The patch is formed of a sufficiently flexible material to provide a patch stowed state when the patch is delivered through the vessel and a patch deployed state when the patch is at least partially positioned over the mouth of the aneurism. The interface side of the patch is configured to form an adherence between the patch and an area of a vessel wall adjacent to the aneurism mouth. The adherence maintains a fixed position of the patch relative to the aneurism mouth.

5 In one embodiment of the invention, the patch assumes the deployed state passively and is not electrically activated. In another embodiment, of the invention the patch is formed of a thermally active material that moves to a pre-defined shape when electrically heated. The pre-defined shape/deployed state forms the adherence between the vessel interface side and an area of the vessel wall adjacent to the aneurism mouth. In the pre-defined shape/deployed state, the patch has a circumference that is less than 360 degrees, more preferably less than 240 degrees and still more preferably less than 180 degrees. In the pre-defined shape/deployed state patch can have an interface side that is in substantial conformance (curvature) 10 with the geometry of the adjacent vessel wall.

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Passive activation of the patch is achieved with a spring force that is inherent 20 to the patch. This spring force can then drive one or more adhesive devices into the wall of the vessel surrounding the aneurism. Adhesion is achieved either by selecting materials for the patch which have internal spring forces, including SMA's and bimorphs, or with adhesion devices positioned on an interface surface of the patch to the vessel wall. Adhesion is non-frictional.

25 Referring now to Figure 1, aneurism patch apparatus is denoted as 10 and optionally includes a delivery device, including but not limited to a catheter 12. A patch 14 is illustrated in a deployed state or in a pre-defined shape. Patch 14 has an interface surface 16 and an opposing non-interface surface 18. In one embodiment, an adhesive 20 is at least partially positioned on interface surface 16. Patch 14 can be formed of a flexible material that is porous or non-porous and can include a stent type of geometry as well as a mesh. In one embodiment, one or more mechanical

adhesion devices 22 are positioned on interface 16 are become at least partially positioned in the vessel wall in which the aneurism is formed. Suitable mechanical devices 22 include but are not limited to the application of a vacuum or a low pressure source, barbs, hooks graspers, pinchers and the like.

5 When a vacuum is applied adhesion devices 22 are forced into the surface of the vessel wall surrounding the aneurism mouth and anchor aneurism mouth down. When patch 14 is porous a compliant shape is desirable between interface surface 16 and the vessel wall surrounding the aneurism mouth. Additionally, with a porous patch 14 a spring force inherent in patch 14 is used to drive adhesion devices 22 into the vessel wall. Other mechanical devices including but not limited to a balloon coupled to cannula 12 can be used to apply pressure on interface surface 16 and adhesion devices 22. Patch 14 provides an internal force the area of the vessel adjacent to the aneurism. This force can be activated by thermal energy or mechanical energy inherent and/or applied to patch 14. A releasable connector 24 couples patch 14 to catheter 12.

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Referring now to Figure 2, patch 14 includes an aperture 26 that is configured to positioned over the mouth of the aneurism. In one embodiment, connector 24 includes a catheter connector 24(a) and a patch connector 24(b). Connectors 24(a) and 24(b) provide a mechanical release of patch 14 from catheter which can be an SMA element, devices that when activated pinch off a catheter lumen from patch 14 can sever the two with a loop of wire or a heated wire that when pulled can cut, or an actual fabricated joint which is a release mechanism such as a catch. The SMA element can have an activation threshold greater than body temperature.

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Figures 3 through 5 illustrate the positioning and release of patch 14 at 25 aneurism mouth 28. In Figure 3, patch 14 is in the stowed state and positioned on an exterior of catheter 12. In other embodiments, patch 14 can be positioned in an interior of catheter 12, and at a distal end of catheter 12. In the stowed state, the surface area of patch 14 is minimized to achieve access to aneurism mouth 28 for the treatment of aneurism 30.

As illustrated in Figure 4, patch 14 is in its deployed or pre-shaped state.

Aperture 26 is positioned substantially over aneurism mouth 28. In Figure 4, catheter 12 is shown as having a catheter lumen 32 which provides for evacuation of aneurism 30 when catheter lumen 32 is coupled to a low pressure source, including but not limited to a vacuum source. Aneurism 30 is at a lower pressure than the rest of the of the vessel wall. Pressure 34, as shown with the arrows, is applied to aneurism 30, creating the possibility of creating a bursting of aneurism 30. Coupling aneurism 30 to a low pressure source with catheter lumen 32 begins an evacuation of aneurysm 30.

Patch 14 can include an SMA including but not limited to NiTi, a micro-fabricated circuit, a micro-fabricated sensor and a micro-fabricated transducer. Suitable micro-fabricated sensors include pressure, temperature, electrosomic, voltage potential, chemical, chemical potential and electronic magnetic sensors. Suitable micro-fabricated transducer include temperature, electrosonic, voltage potential and electro magnetic transducers. Patch 14 can have a one-way or two-way shaped memory effect.

Figure 5 shows aneurism 30 fully collapsed. After aneurism 30 is collapsed, adhesive 20 can be introduced through an introduction lumen 36. Introduction lumen is coupled 36 is coupled to a source of adhesive 20 or other material of interest that can retain aneurism 30 in a contacting position with interface surface 16. Such adhesives such as cyanacrylates, as known to those skilled in the art.

Adhesive 20 can partially or fully fill an interstitial area 40, which is the volume occupied between the interface surface 16 the surface of the vessel wall. Adhesive 20 can take up any irregularities between the vessel wall and interface surface 16.

The use of the adhesive 20 is optional to provide a complete or a partial contacting relationship between interface surface 16 and the vessel wall. Right. This is going, this is applying, so the blood within the vessel is applying pressure.

Figure 6 illustrates an adhesive source 42 coupled to introduction lumen 36 and a low pressure source 44 coupled to catheter lumen 32.

The following discussion pertains to a suitable material for patch 14 which is an SMA material or a bimorph.

5 A simplified embodiment of a two-dimensional sheet 46 according to an aspect of the invention is shown in Figure 1. The basic concepts discussed here can be applied directly to practical embodiments which will be described later. In this case sheet 46 is made entirely of a SMA chosen from the group of electrically conductive materials. Most common examples include NiTi alloys and CuZnAl 10 alloys. Other alloys can also be used. The ratio of the thickness of sheet 46 to the lateral extent of heating element 48 should be preferably as small as possible, while still capable of maintaining the integrity of sheet 46.

15 SMA sheet 46 is produced by a variety of common machining methods; such as rolling of thin foils from wire or thin plate stock, sectioning thin wafers from bar stock, or like methods. At present, sectioning of thin wafers from bar stock is preferred. Wafers of SMA material may be sliced from bar stock using a conventional band saw, a cold saw, an annular diamond wet saw, or electro-discharge machining (EDM) or like methods. The resulting wafer can be heat treated to a flat condition and precision-ground to any desired thickness. SMA bulk properties are 20 assured as the material is obtained directly from bulk. The SMA material contained in sheet 46 can be pre-trained prior to assembly or left untrained. The choice depends on the eventual application.

25 A plurality of heating elements 48 are positioned on top of SMA sheet 46 and insulated from sheet 46 by an electrically insulating layer 50. It is most convenient to laminate or otherwise deposit electrically insulating layer 50 on sheet 46. Electrically insulating layer 50 prevents current leakage between heating elements 48 and electrically conducting sheet 46. Electrically insulating layer 50 also preferably is a good thermal conductor. Preferred insulating materials include polyimide or silicon nitride  $\text{Si}_x\text{N}_y$ . The thickness of electrically insulating layer 50 should be small in

relation to its lateral extent. For example, electrically insulating layer 50 may be a 2000Å silicon nitride layer to ensure adequate thermal coupling, and to ensure thermal conductivity between heating elements 48 and sheet 46.

In the simplified embodiment of Figure 1, heating elements 48 are in the form of thin film resistors. Most preferably, heating elements 48 are ohmic heaters or other similar devices capable of converting electrical current to thermal energy. They can comprise any conventional resistive material such as TiW or TaO. Conveniently, the resistive material is first deposited and patterned on layer 50 by well known VLSI or micro-machining techniques. Then, heating elements 48 are patterned or otherwise formed according to well-known techniques.

In Figure 3 the thickness of sheet SMA 46 is labeled by S. For clarity, a particular heating element 48X has been selected to explain the details of the invention. Heating element 48X has associated with it an adjacent portion 52X of SMA sheet 46. As shown, heating element 48X has associated with it a section 54X of electrically insulating layer 50 as well. Portion 52X is located directly underneath heating element 48X. The width of portion 52X is denoted by D. As shown, heating element 48X provides heat to portion 52X exclusively. Heat propagates through section 54X and into section 52X which represents a localized portion of SMA sheet 46.

The operation of the simplified embodiment is best understood by comparing Figure 1 and Figure 2. In this case, the SMA material has been pre-trained to assume a predetermined shape when thermally activated to an activation threshold temperature. In FIG 1, SMA sheet 46 is shown in an inactive state.

Figure 2 shows a particular case wherein six heating elements 48, labeled as 48A-12F, are providing heat. Consequently, the heat traverses section 54A-18F of insulating layer 50 and causes adjacent portions 52A-16F of SMA sheet 46 to reach activation threshold. As a result, portions of 52A-16F assume a well-defined shape and in the process, provide useful activation forces. As shown, the local deformation is upward convex. Once portions 52A-16F assume their shape, the areas of sheet 46

surrounding those portions deform in accordance with a predetermined memory characteristic. In fact, entire sheet 46 assumes a resultant shape due to local changes as dictated by its geometry. In the simple case of Figure 2, the remainder of sheet 46 remains flat or otherwise returns to its neutral shape; neutral meaning its inactive state. More complex resultant shapes will be described in later embodiments.

The principles behind the heating process and the shape assumed by adjacent portions 52 are best illustrated in Figure 4A. We consider one heating element 48X. For clarity, the predetermined shape assumed by adjacent portion 52X upon heating has not been shown. The heat generated by element 48X, whose width is indicated by W, passes along arrows through insulating layer 50. In particular, the thermal energy traverses section 54X of layer 50. Layer 50 is proportionally very thin compared to the lateral dimensions, and thus section 54X readily transfers the heat to sheet 46. Once in sheet 46 the heat propagates throughout adjacent portion 52X.

Graph 4B represents temperature distributions at an arbitrary fixed depth below heater 48X. The graph in Figure 4B shows the temperature distribution laterally, in the X direction, inside portion 52X. Directly under element 48X the temperature remains at a maximum, as indicated by the flat portion of the curve from  $-W/2$  to  $+W/2$ . In other words, the heat delivered to portion 52X does not propagate to other portions 52, e.g., portion 52Y. Instead, the heat radiates along arrows R out of sheet 46 before reaching other portions 52.

As already mentioned, the shape of adjacent portions 52 depends on the pre-trained shape of the SMA or sheet 46 in those regions. Also, the shape depends on the temperature maintained in portions 52. Full conformity to the pre-trained shape is achieved when the temperature in portions 52 is equal or higher than the critical temperature at which the SMA material attains the austenitic state. This is best shown in the graph of Figure 5. At temperatures below  $T_1$ , the SMA material remains pliable, as dictated by the martensitic properties. Therefore, portions 52 maintained at or below  $T_1$  will conform to the shape imparted to them by the surroundings. The transition to the austenitic state occurs between temperatures  $T_1$  and  $T_2$ . When

portions 52 are kept in this temperature range they will assume an intermediate shape between the relaxed and pre-trained forms. Careful thermal regulation thus allows one to vary the shape of any portions 52 of sheet 46 in a continuous manner.

5 The overall structure of sheet 46 where heating elements 48 are mounted directly on sheet 46 with only layer 50 interposed between them is very simple. The assembly process is straightforward and low-cost.

10 Another embodiment of the invention is shown in Figure 6. Here a two-dimensional sheet 56 of SMA material is placed on a coating layer 58. In this case, layer 58 is sufficiently thick to provide mechanical stability.

15 A thin insulating layer 60 is disposed on top of sheet 56 to provide electrical insulation between heating elements 62 and sheet 56. Layer 60 is thin enough and has appropriate thermal properties to permit the free flow of heat from elements 62 to sheet 56. In this embodiment the SMA material of sheet 56 is also electrically conducting (e.g., TiNi alloy or CuZnAl alloy).

20 The operation of this embodiment is analogous to the operation of the first one. The added stability of coating layer 58 ensures conformity to a well-defined shape when all portions of sheet 56 are in the martensitic state.

25 The embodiment of Figure 7 exhibits sheet 56 of electrically conducting SMA with a coating layer 68 acting as substrate. In this case layer 68 is chosen from materials which are chemically inert and stable to protect sheet 56 from adverse effects.

Electrical insulation between heating elements 62 and sheet 56 is provided by sections of electrical insulation sections 64 deposited point-wise under elements 62. Such structure can be produced by initially applying a layer of insulating material and a layer of heating material. Then, elements 62 and a corresponding electrical insulation sections 64 are fashioned by etching or another well-known process. Preferably, a well known VLSI technique or a micro-machining technique is employed for this purpose.

Figure 8 shows yet another embodiment in which a two-dimensional sheet 70 is made up of an electrically insulating SMA material. In this configuration no insulation is necessary. Consequently, heating elements 62 are mounted directly on sheet 70. A coating layer 68 functioning as substrate is once again provided to afford mechanical stability and resistance. It is preferable that layer 68 also be a good thermal conductor to aid in the dissipation of heat from sheet 70.

The embodiments of FIGS. 6-8 all operate in the manner set forth above. The modifications introduced are intended to aid one skilled in the art in selecting the appropriate structure given a set of technical requirements.

A preferred embodiment is shown in Figure 9. A two-dimensional sheet 72 of an electrically conducting SMA material, preferably a NiTi alloy is coated with insulating layer 74. Preferably, layer 74 is made of  $\text{Si}_x\text{N}_y$  or polyimide and is sufficiently thin to readily conduct heat.

Patterned heating elements 76 are located on layer 74. Elements 76 are obtained by first sputtering TiW or TaO on top of layer 74 and then performing a patterning step. Heating elements 76 offer a very high resistance. In the preferred embodiment elements 76 have a zig-zag shape. This enables them to ensure better heat distribution in sheet 72 when active.

A second insulating layer 80 is provided on top of elements 76 and layer 74. Preferably, layer 80 is made of a flexible electrical insulation such as polyimide, which can be spun coated onto elements 76 and layer 74. A number of through-holes 86 are opened in layer 80 to permit electrical contact with elements 76. Holes 86 are sensibly aligned with the terminal portions of elements 76.

A set of conduction lines 82 are patterned on top of layer 80. Preferably, conduction lines 82 are made of a flexible and highly conductive material such as gold. Lines 82 can be defined by patterning or other suitable techniques. A common return line 82A is laid out to provide electrical contact with the left terminals of all

elements 76. Return line 82A saves surface area of top of layer 80 and is desirable as long as all elements 76 are not addressed simultaneously on a continuous basis. If continuous activation is required, then an additional full width layer would be dedicated for the return path. The other lines, 82B-42E are in electrical contact with the right terminals of elements 76 respectively.

External electrical connections are made to contact pads 84A-84E, corresponding to lines 82A-42E. For this purpose, pads 84A-84E are designed much thicker than lines 82A-42E. The actual electric connections are made with wire bonding or similar means.

Once the entire structure on sheet 72 is assembled, the SMA is "trained" by forcing sheet 72 to assume a resultant shape using well-known methods. For example, sheet 72 is formed on a mandrel and fixed in place with a clamp. The entire fixture is then placed in an annealing furnace, preferably purged with an inert gas, at approximately 450 C for about 30 minutes. Upon cooling the film is released from the mandrel. At this time sheet 72 is operationally ready.

The electrical diagram showing the electrical connections of the preferred embodiment is found in Figure 10. A control unit 88 is connected to a current supply 90. Preferably, both unit 88 and supply 90 are located away from sheet 72. Unit 88 is preferably a micro-processor capable of selecting a desired combination of elements 76. Current supply 90 is preferably an adjustable source capable of delivering current to the selected combination of elements 76. Lines 82A-42E are connected directly to supply 90. Elements 76A-76D are shown as resistors. Return line 82A is grounded.

During operation control unit 88 selects a combination of elements 76 to be activated. It then sends a corresponding command to supply 90. Supply 90 responds by delivering current to elements 76 of the chosen combination. For example, elements 76A and 76D are chosen. Current is delivered to elements 76A and 76D and the corresponding adjacent portions 78A and 78D assume a well-defined shape. If the current is sufficiently large and the temperature maintained in adjacent portions

78A and 78D is above  $T_2$  (see Figure 5) then portions 78A and 78D will assume their pre-trained shape. If the temperature is between  $T_1$  and  $T_2$  portions 78A and 78D will assume an intermediate shape. Because supply 90 is adjustable the proper current can be selected during operation and adjusted on an empirical basis.

5 Consequently, the shape of portions 78A and 78D can be varied as necessary.

Figure 11 illustrates the resultant shape of sheet 72 when adjacent portions 78C and 78D are selected. It is assumed that the SMA was pre-trained to curve upward along its entire length. Thus, together, deflections in portions 78C and 78D contribute to a much larger total deflection. Figure 12 illustrates another possible 10 resultant shape of layer 72 when sections 78B-39D are heated and the SMA was pre-trained to assume an S-shape. Throughout the description it is understood that the SMA of sheet 72 can be trained before or after assembly. Training before assembly can be preferable when working with materials which would be damaged if trained together with the SMA, e.g., due to the high annealing temperatures.

15 In another embodiment similar to the preferred embodiment sheet 72 has a coating layer 92 as shown in Figure 14. For better understanding, the deflections in sheet 72 have been indicated. Deflection sensors 94 are positioned on layer 92. Sensors 92 can be either angular deflections sensors, extension deflection sensors such as a strain gage, or bend sensors. A bend sensor is a strain gage disposed for 20 measuring bending strain and thus angular deflection. All of these devices are well known in the art. In this case sensors 94 have been placed in locations corresponding to those of elements 76. Depending on the geometry and application different placement may be preferable.

25 The electrical diagram with sensors 94 is shown in Figure 13. The dotted line represents elements mounted on sheet 72. While the connections to elements 76A-38D remain the same, all sensors 94A-94D are wired to control unit 88 via lines 96A-96D respectively. In this manner unit 88 can receive signals representative of the local deflection from each one of sensors 94A-94D individually. A shape memory 98

is connected to unit 88. Memory is capable of mapping the resultant shape of sheet 72 based on information delivered from sensors 94.

Preferably, memory 98 has an inventory of resultant shapes produced by known combinations of elements 76. In other words, memory 98 is capable of recalling mapped resultant shapes positions and storing new ones. In the most preferred embodiment memory 98 can also store the actual current values corresponding to intermediate shapes of adjacent portions. This means that in operation shapes can be recalled and stored at will. The embodiment is thus highly versatile and practical for any diverse applications, e.g., guiding catheters.

Figure 15 shows yet another embodiment which differs from the above only in that sensors 94 are positioned between elements 76. Figure 16 shows another modification in which a temperature sensor 100 is mounted between elements 76. This is advantageous for monitoring the temperature of sheet 72. In a particularly preferred embodiment this data is stored in memory 98. Checking the temperature from sensor 100 during operation can prevent overheating and other related malfunctions. Of course, more than one thermal sensor 100 can be provided. Ideally, a number of such sensors 100 can be provided. Ideally, a number of such sensors 100 are optimally positioned on sheet 72.

Figure 17 shows the embodiment of Figure 14 in the martensitic state encapsulated in a top coating layer 102. Layer 102 is applied to protect the electrical connections and elements 76 in particular from damaging environmental factors, e.g., corrosive environments.

Figure 18 and Figure 19 show two ways in which a two-dimensional sheet 104 of SMA can be cooled. For simplicity, all other elements, except for heating elements 108, have been omitted. In Figure 18 the cooling element is a set of fins 106 in direct contact with sheet 104. This arrangement ensures efficient heat transfer and dissipation. Similarly, the structure in Figure 19 efficiently dissipates heat using a substrate layer 110 with ducts 112 (only one shown). Ducts 112 carry a coolant, e.g., water, which absorbs and carries away the waste thermal energy.

5

While the invention has been described in connection with what is presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims. For example, a Peltier device could also provide an equivalent solution to heat dissipation. Therefore, persons of ordinary skill in this field are to understand that all such equivalent structures are to be included within the scope of the following claims.

What is claimed is:

## CLAIMS

1. An aneurism patch apparatus for treating an aneurism formed in a vessel, comprising:
  - 3 a patch including a vessel interface side and an opposing non-interface side, the patch being formed of a sufficiently flexible material to provide a patch stowed state when the patch is delivered through the vessel and a patch deployed state when the patch is at least partially positioned over the mouth of the aneurism, the interface side of the patch being configured to form an adherence between the patch and an area of a vessel wall adjacent to the aneurism mouth, wherein the adherence maintains a fixed position of the patch relative to the aneurism mouth.
  - 1 2. The apparatus of claim 1, wherein the patch is porous.
  - 1 3. The apparatus of claim 1, wherein the patch is non-porous.
  - 1 4. The apparatus of claim 1, wherein a surface area of the vessel interface side of the patch deployed state is less than 360 degrees.
  - 1 5. The apparatus of claim 1, wherein the adherence is non-frictional.
  - 1 6. The apparatus of claim 1, wherein the interface side of the patch includes a plurality of anchor elements.
  - 1 7. The apparatus of claim 1, wherein the plurality of anchor elements is selected from barbs, hooks, graspers or pinchers.
  - 1 8. The apparatus of claim 1, wherein the interface side includes a biocompatible adhesive.

1           9.       The apparatus of claim 1, wherein the adherence between the patch  
2       and the area of the vessel wall is a mechanical adherence formed between the patch  
3       interface side and the area of the vessel wall adjacent to the aneurism mouth.

1           10.      The apparatus of claim 1, wherein the patch includes an aperture  
2       configured to be coupled to a low pressure source.

1           11.      The apparatus of claim 1, further comprising:  
2       a catheter configured to be coupled to the patch.

1           12.      The apparatus of claim 11, wherein the patch is positionable at an  
2       exterior surface of the catheter.

1           13.      The apparatus of claim 12, wherein at least a portion of an interface  
2       between the patch and the catheter is configured to provide a separation of the patch  
3       and the catheter.

1           14.      The apparatus of claim 12, wherein the patch is positioned at a distal  
2       end of the catheter.

1           15.      The apparatus of claim 11, wherein the catheter is coupled to a low  
2       pressure reservoir device.

1           16.      The apparatus of claim 11, wherein the patch is coupled to an  
2       adhesive source and a low pressure source.

1           17.      The apparatus of claim 16, further comprising:  
2       a device configured to provide a selective coupling of the patch to the  
3       adhesive source and selective exposure of the patch to the low pressure source.

1           18. The apparatus of claim 1, wherein the patch has substantially the same  
2           curvature as the curvature of the vessel when the patch is in the deployed state.

1           19. The apparatus of claim 1, wherein at least a portion of the patch is  
2           made of a material fabricated with an internal stress and a pre-defined shape, wherein  
3           the internal stress moves the patch stowed state to the pre-defined shape.

1           20. The apparatus of claim 19, wherein the pre-defined shape is the  
2           deployed state.

1           21. The apparatus of claim 1, wherein at least a portion of the patch is a  
2           thermal bimorph structure with a pre-defined shape at body temperature.

1           22. The apparatus of claim 21, wherein the pre-defined shape is the  
2           deployed state.

1           23. The apparatus of claim 1, wherein at least a portion of the patch  
2           includes a shaped memory alloy element with a pre-defined shaped.

1           24. The apparatus of claim 23, wherein the pre-defined shape is the  
2           deployed state.

1           25. The apparatus of claim 23, wherein the shaped memory element  
2           moves to its pre-defined shape when exposed at or below body temperature.

1           26. An aneurism patch apparatus for treatment of an aneurism formed in a  
2           vessel wall, comprising:

3           a patch including a vessel interface side and an opposing non-interface side,  
4           the patch being configured to have a stowed state when delivered to a mouth of the  
5           aneurism, the patch being formed of a thermally active material that moves to a pre-  
6           defined shape when electrically heated, the pre-defined shape forming an adherence  
7           between the vessel interface side and an area of the vessel wall adjacent to the  
8           aneurism mouth, wherein the adherence maintains a fixed position of the patch  
9           relative to the aneurism mouth.

1           27.       The apparatus of claim 26, wherein the thermally active material is an  
2           SMA element with an activation threshold greater than body temperature.

1           28.       The apparatus of claim 26, wherein the patch comprises:  
2           a sheet of a shape memory alloy configured to be selectively addressable to  
3           selected site of sheet;  
4           a heating device positioned adjacent to or on a surface of the sheet and  
5           configured to provide heat to a selected section of the sheet and create a movement  
6           of at least a portion of the selected section, the heating device including at least two  
7           micro-fabricated address lines.

1           29.       The device of claim 28, wherein the sheet is a continuous sheet.

1           30.       The device of claim 28, wherein the shape memory alloy is made of  
2           NiTi.

1           31.       The device of claim 28, wherein the heating device further includes, a  
2           micro-fabricated circuit.

1           32.       The device of claim 28, wherein the heating device further includes, a  
2           micro-fabricated sensor.

1           33. The device of claim 28, wherein the heating device further includes, a  
2 micro-fabricated sensor selected from the group, a pressure sensor, a temperature  
3 sensor, an electrosonic sensor, a voltage potential sensor, a chemical sensor, a  
4 chemical potential sensor and an electronic magnetic sensor.

1           34. The device of claim 28, wherein the heating device further includes, a  
2 micro-fabricated transducer.

1           35. The device of claim 34, wherein the micro-fabricated transducer is  
2 selected from the group, a temperature transducer, an electrosonic transducer, a  
3 voltage potential transducer, and an electro magnetic transducer.

1           36. The device of claim 26, wherein a width of the sheet is 6mm or less.

1           37. The device of claim 26, wherein the sheet is configured to have a one-  
2 way shaped memory affect.

1           38. The device of claim 26, wherein the sheet is configures to have a two-  
2 way shaped memory affect.

1           39. The device of claim 26, wherein the sheet is heated by an active  
2 heater.

1           40. A method for treating an aneurism, comprising:  
2           providing a patch including a vessel interface side and an opposing non-  
3 interface side, the patch being formed of a sufficiently flexible material to provide a  
4 patch stowed state when the patch is delivered through the vessel and a patch  
5 deployed state when the patch is at least partially positioned over the mouth of the

6 aneurism, the interface side of the patch being configured to form an adherence  
7 between the patch and an area of a vessel wall adjacent to the aneurism mouth;  
8 introducing the patch through the vessel in the stowed state;  
9 positioning the patch at least partially adjacent to the aneurism;  
10 deploying the patch from the stowed state to the deployed state; and  
11 forming an adherence between the patch and an area of a vessel wall adjacent  
12 to the aneurism mouth.

1 41. The method of claim 40, wherein the adherence maintains a position  
2 of the patch relative to the aneurism.

1 42. The method of claim 41, further comprising:  
2 applying a low pressure source to the aneurism.

1 43. The method of claim 42, further comprising:  
2 at least partially collapsing the aneurism.

1 44. The method of claim 41, further comprising:  
2 delivery an adhesion material to an area between the vessel wall and the  
3 interface surface of the patch at least partially after the patch is in the deployed  
4 position.

1 45. The method of claim 41, wherein the patch is passively activated from  
2 the stowed state to the deployed shape.

1 46. The method of claim 41, wherein the patch is actively deployed from  
2 the stowed state to the deployed shape.

1           47. The method of claim 41, wherein at least a portion of the patch is  
2 made of a material that provides passive deployment to the deployed state.

1           48. The method of claim 41, wherein at least a portion of the patch is  
2 made of a material that provides active deployment to the deployed state.

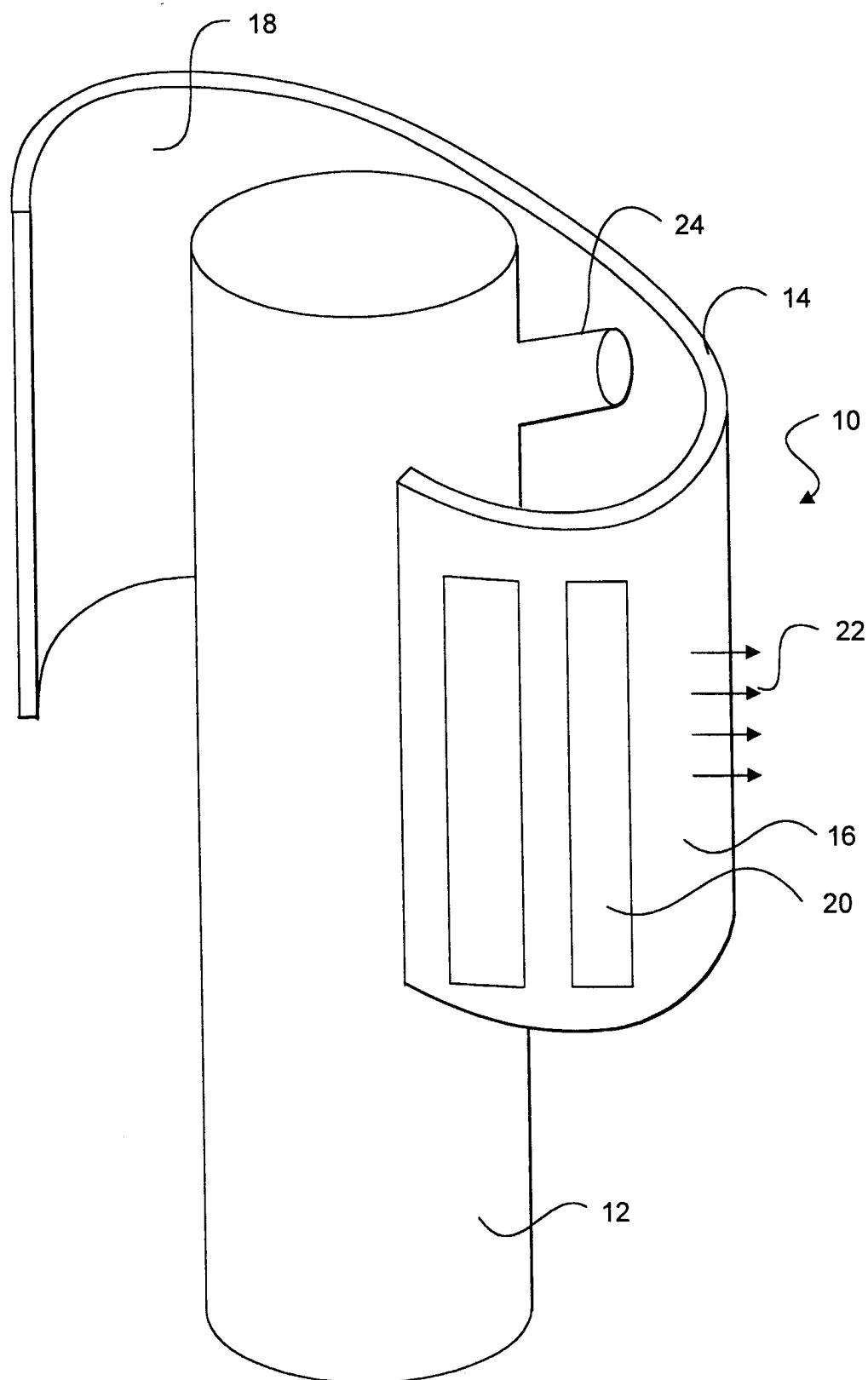


FIG. 1

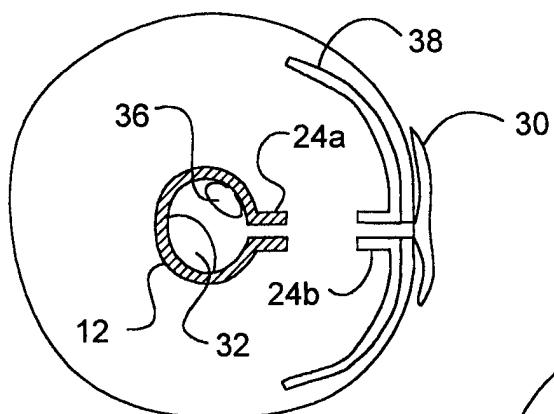


FIG. 2

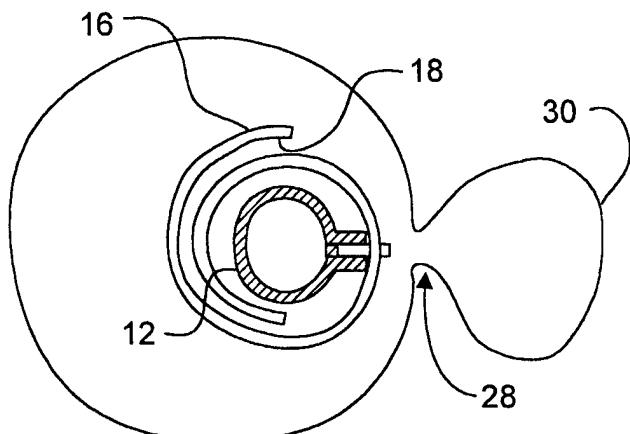


FIG. 3

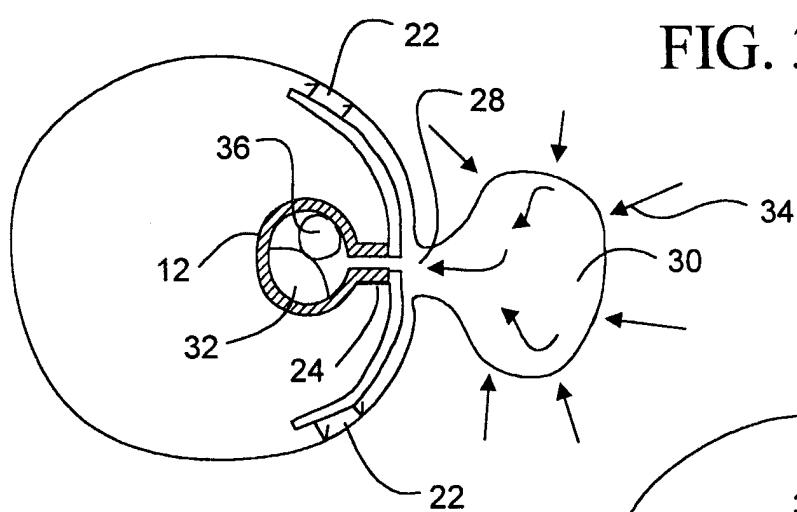


FIG. 4

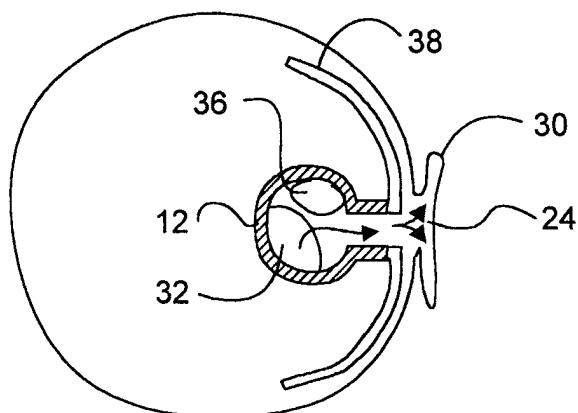


FIG. 5

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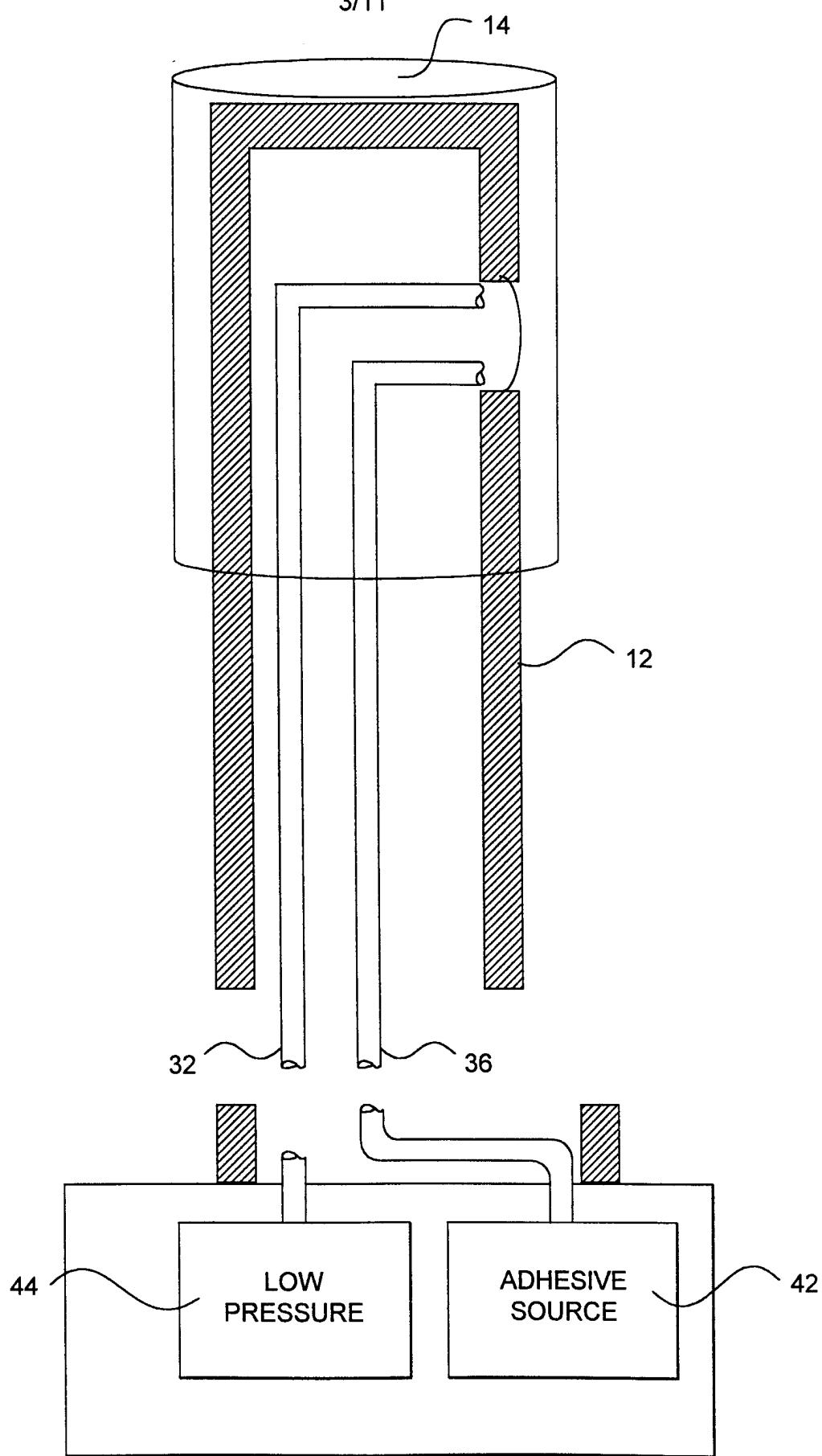


FIG. 6

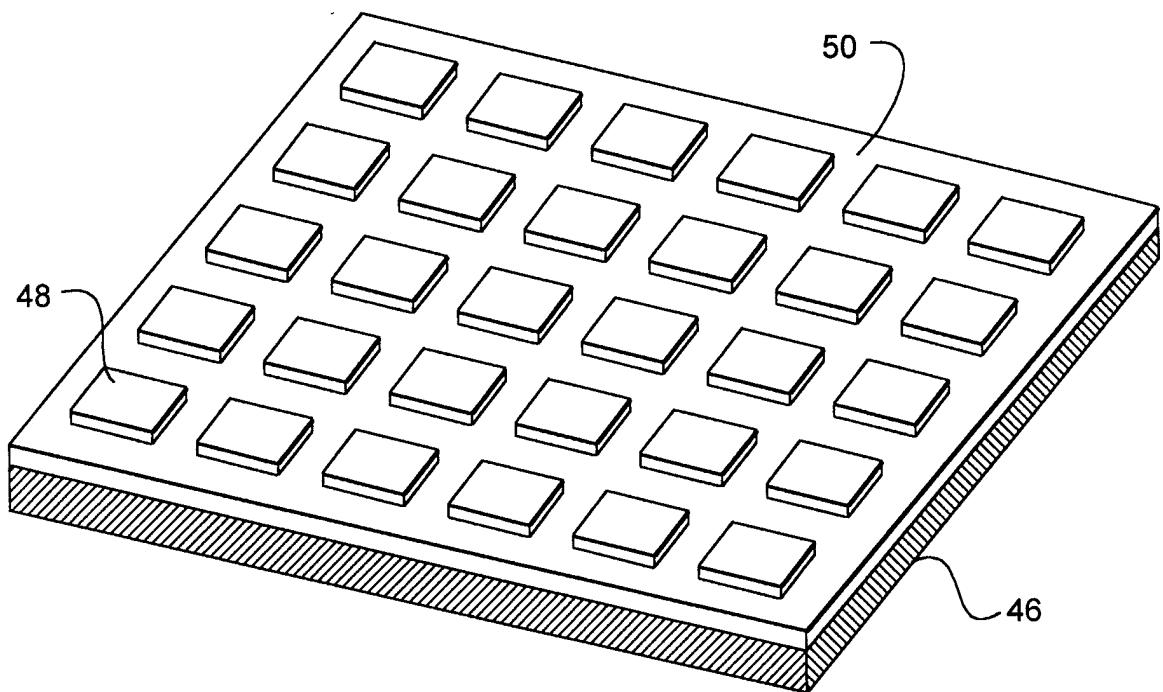


FIG. 7

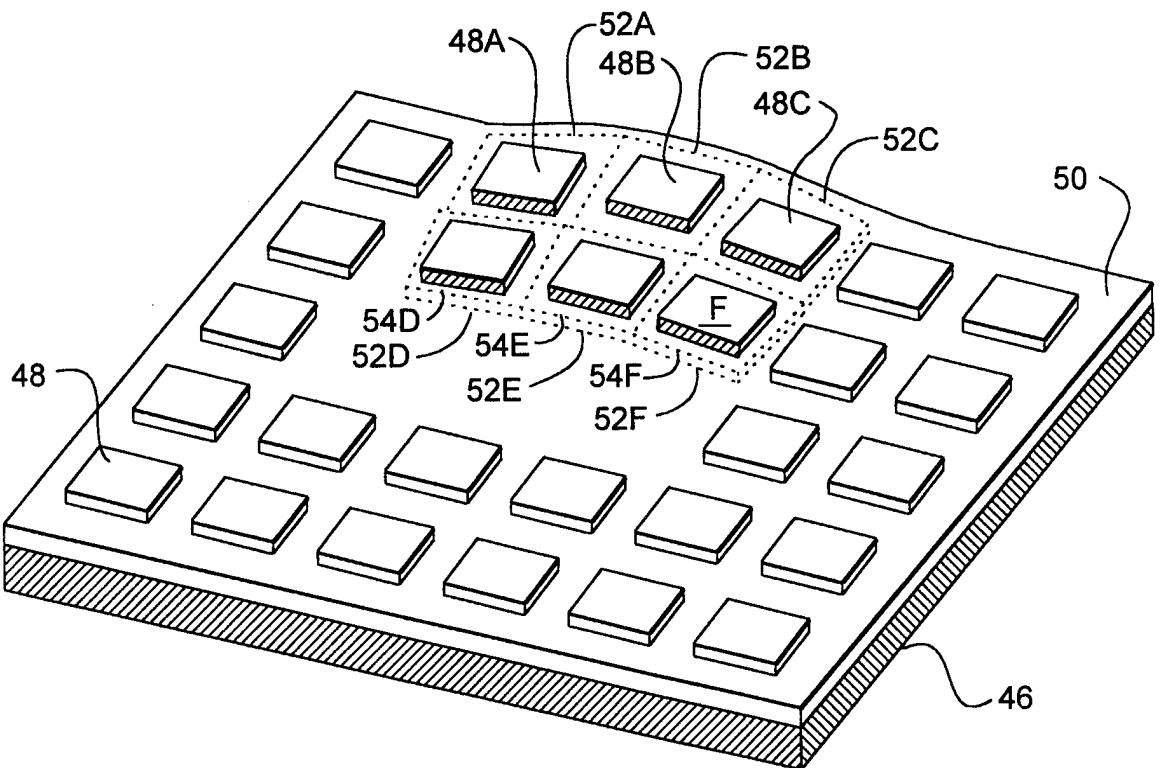


FIG. 8

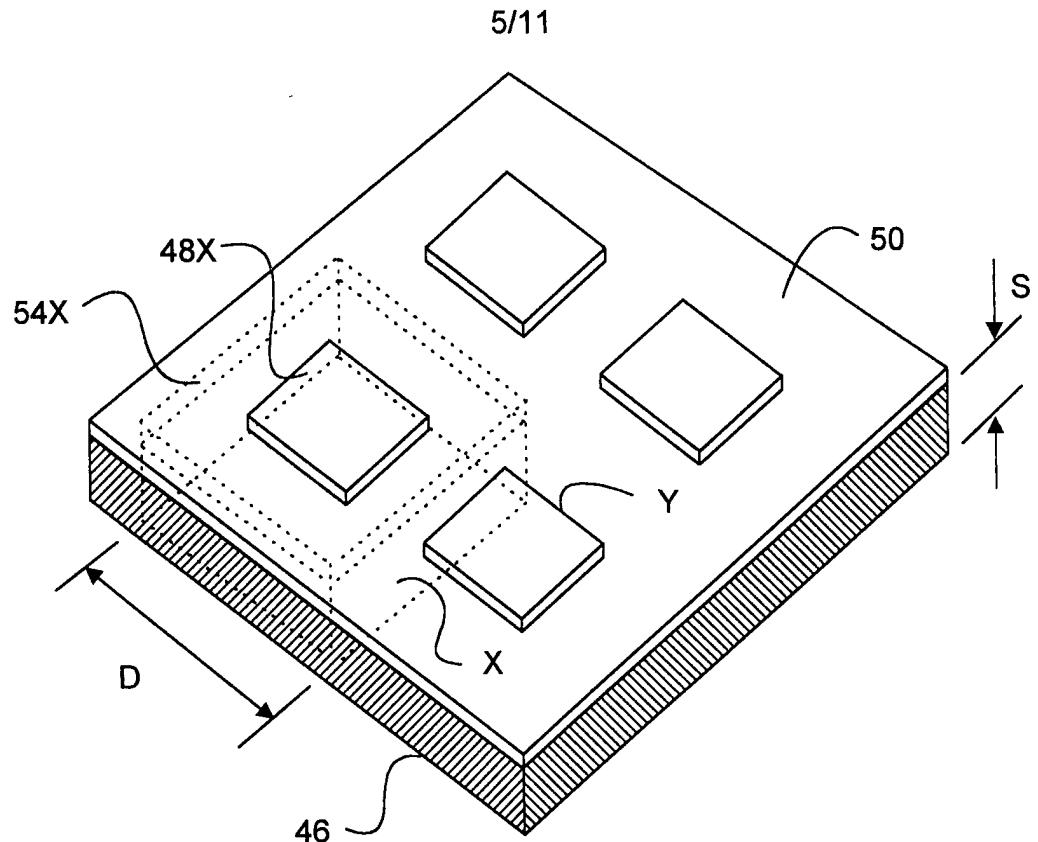


FIG. 9

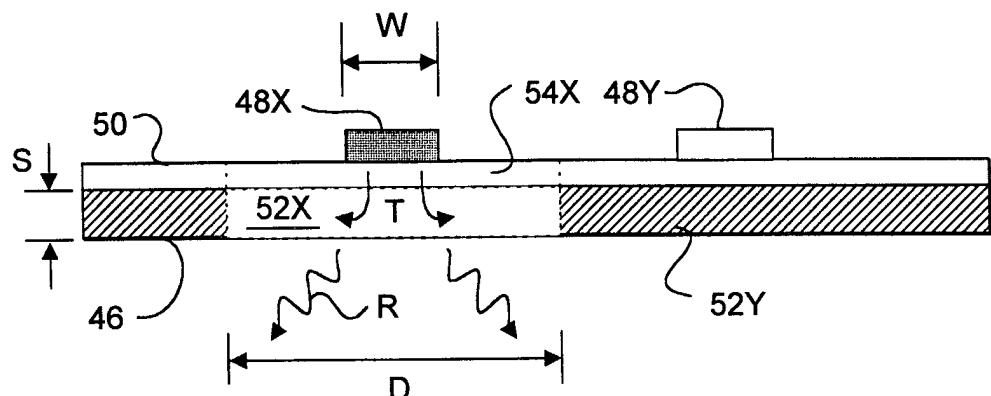


FIG. 10A

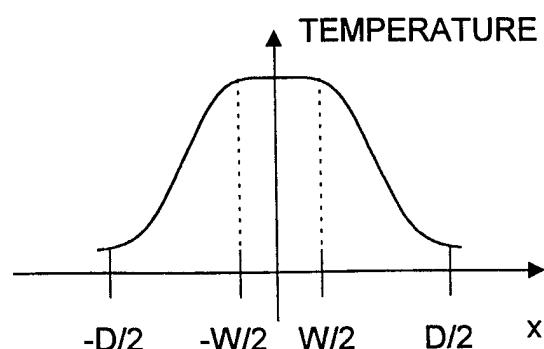


FIG. 10B

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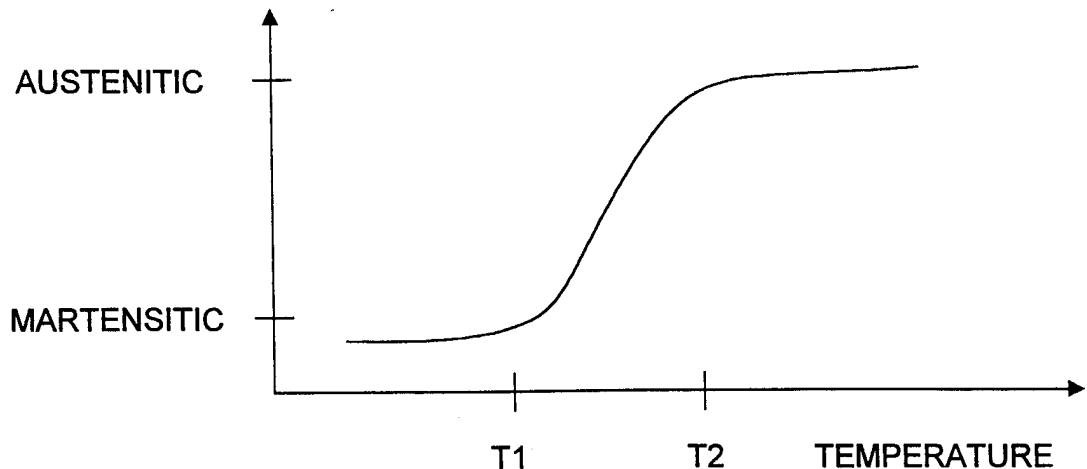


FIG. 11

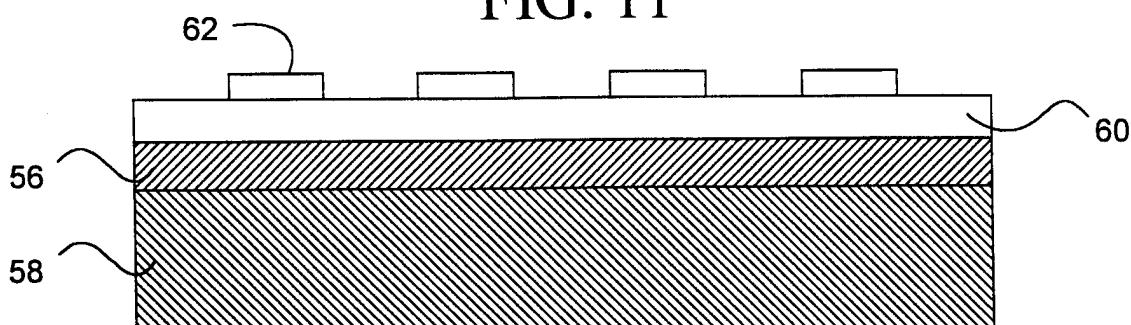


FIG. 12

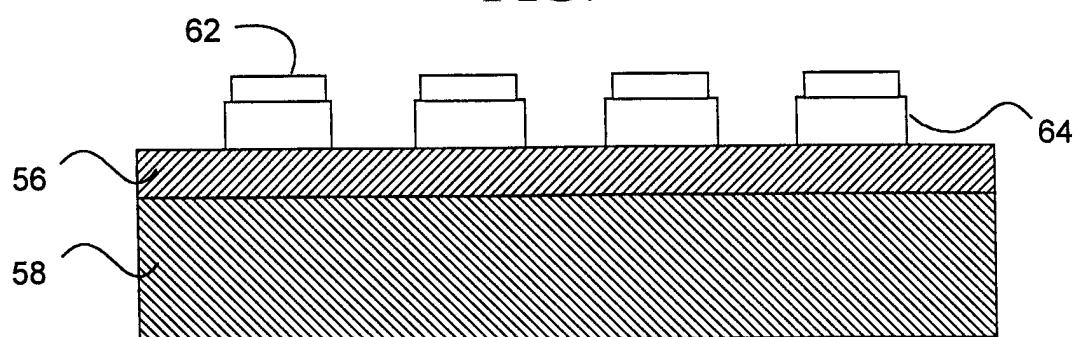


FIG. 13

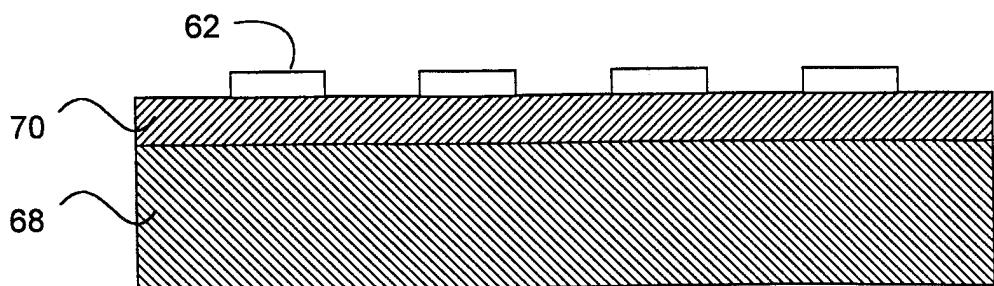


FIG. 14

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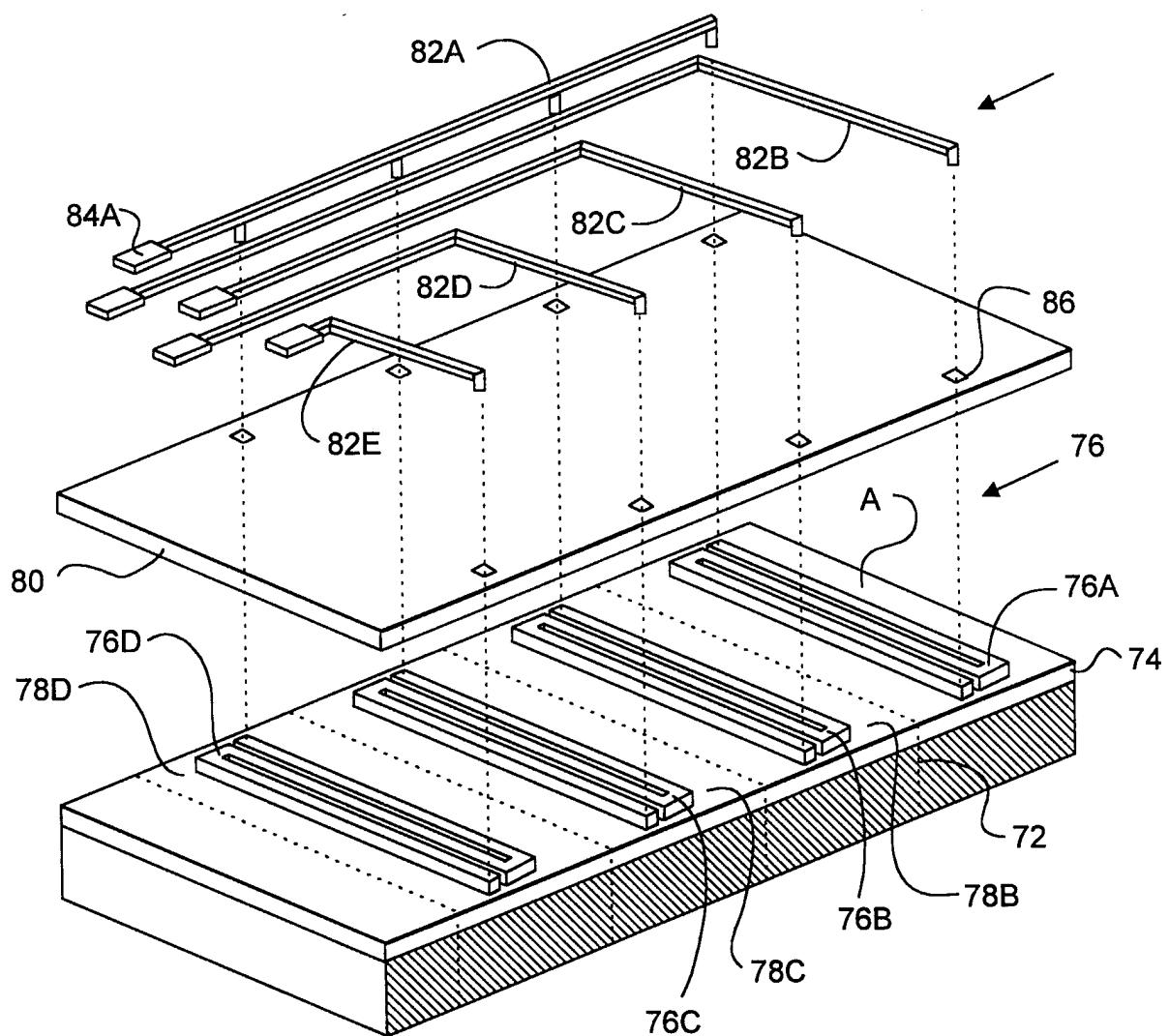


FIG. 15

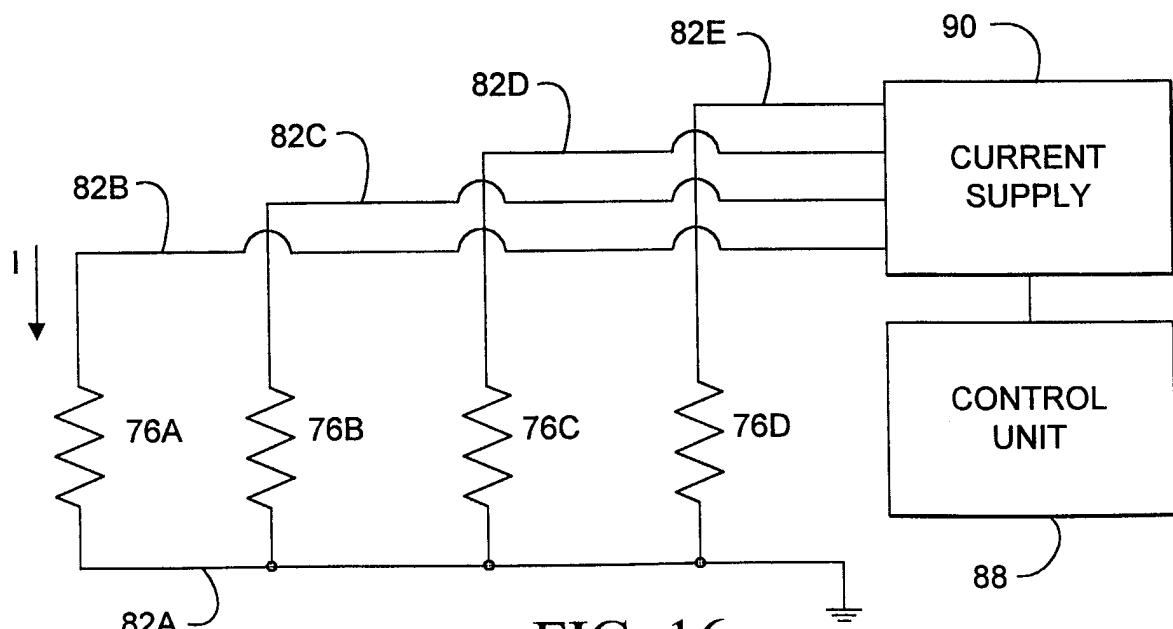


FIG. 16

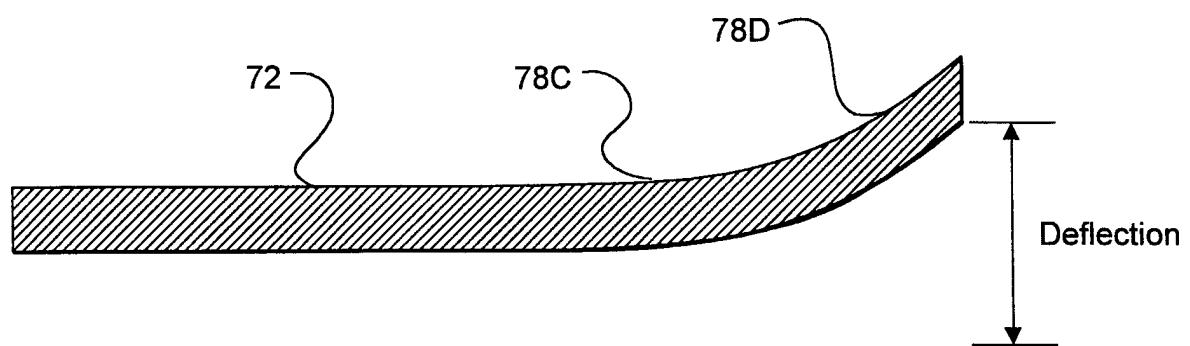


FIG. 17

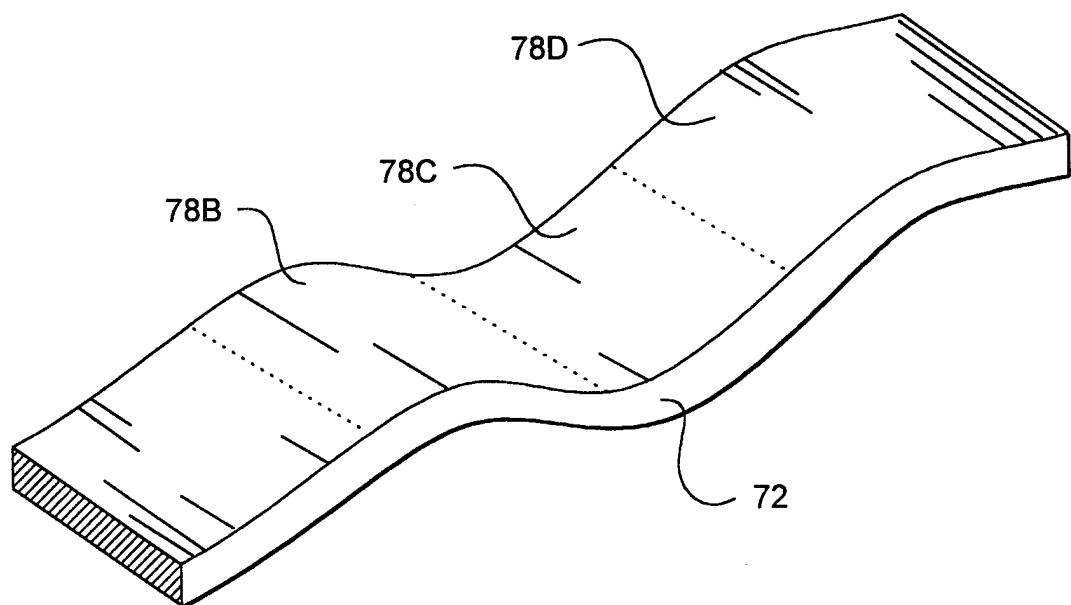


FIG. 18

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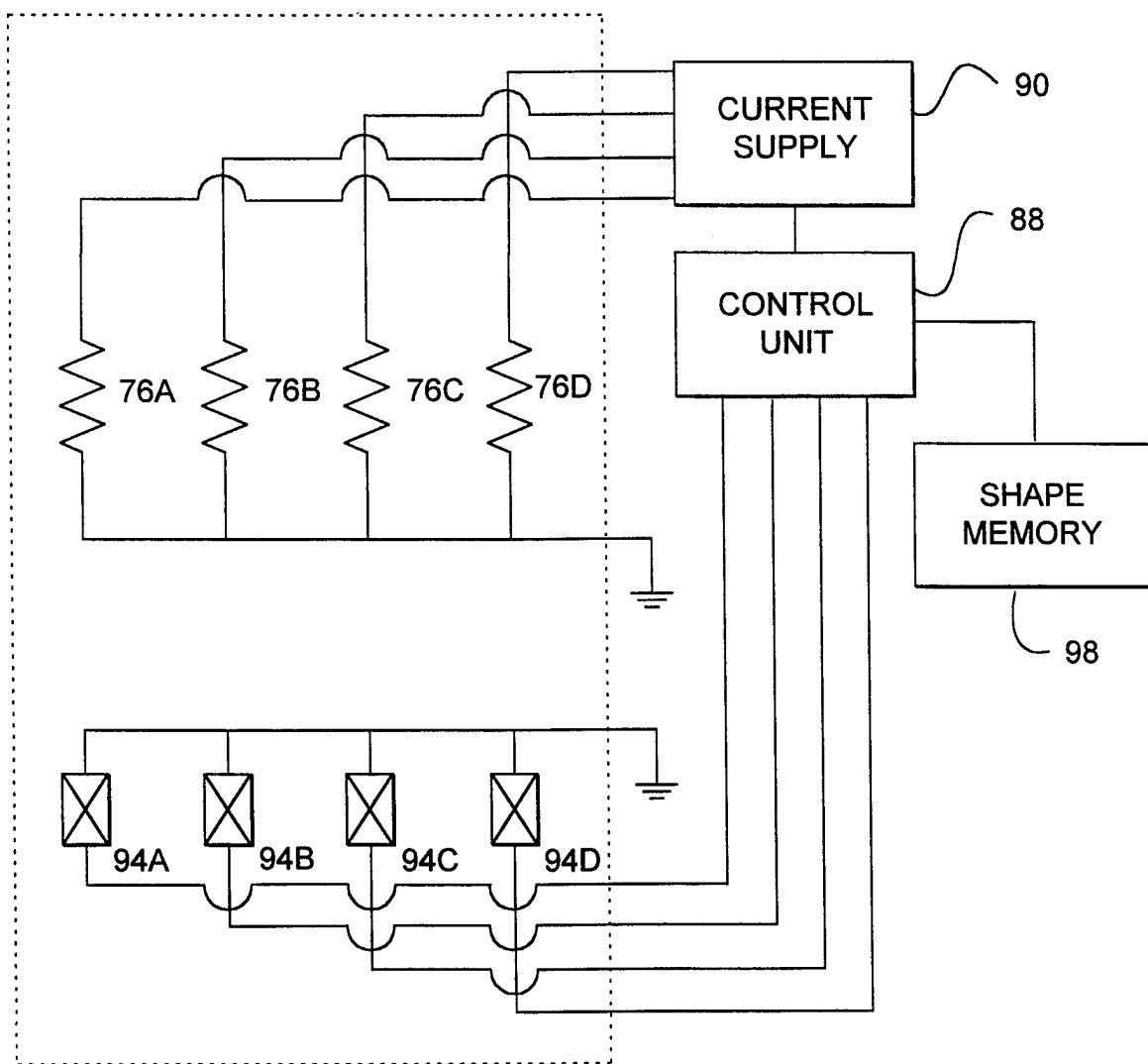


FIG. 19

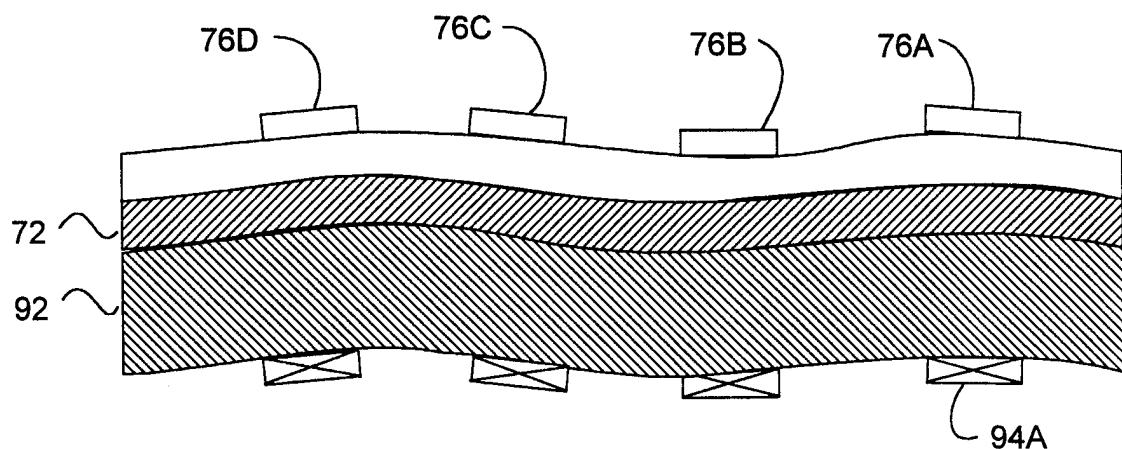


FIG. 20

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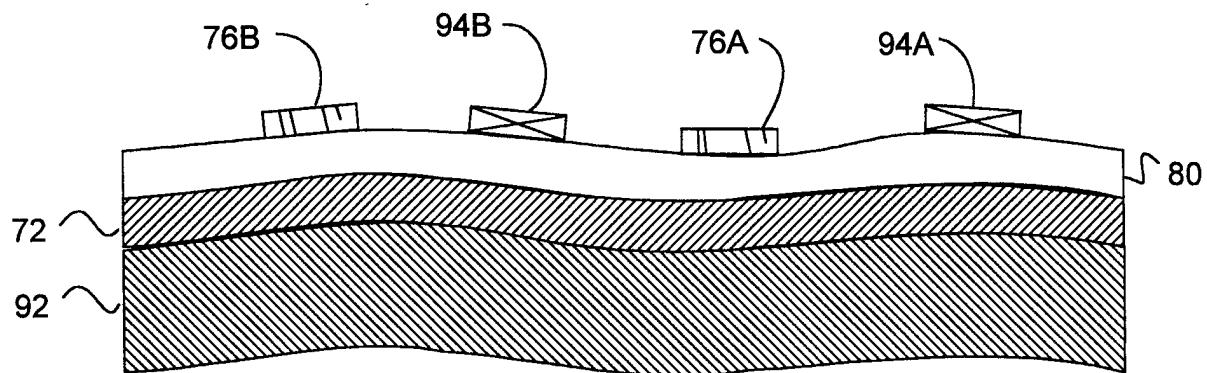


FIG. 21

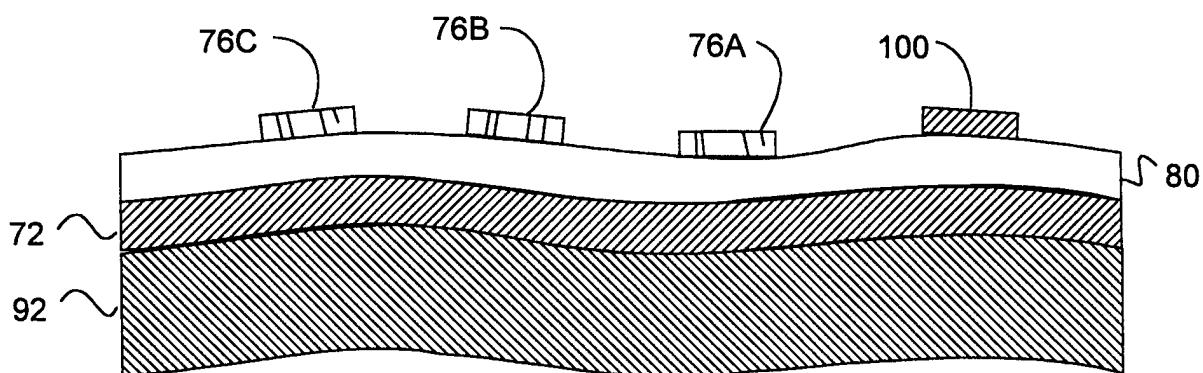


FIG. 22

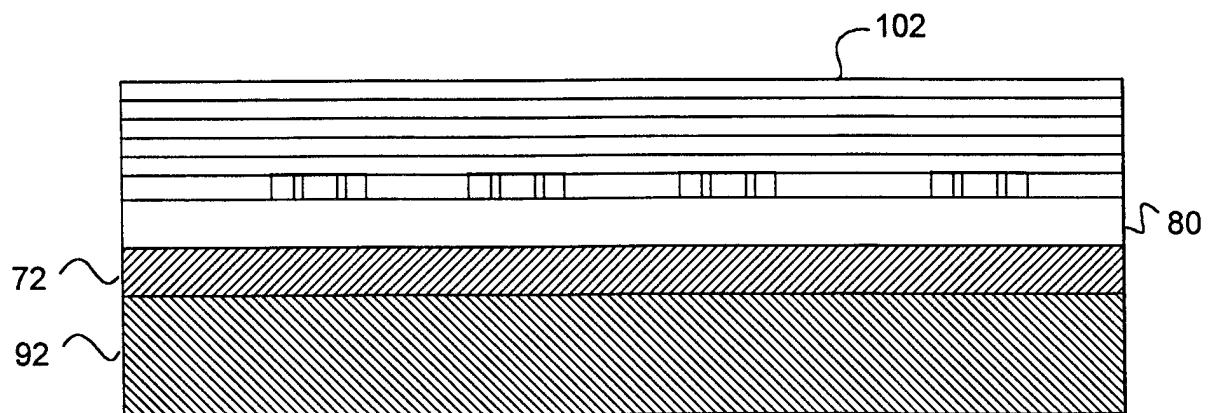


FIG. 23

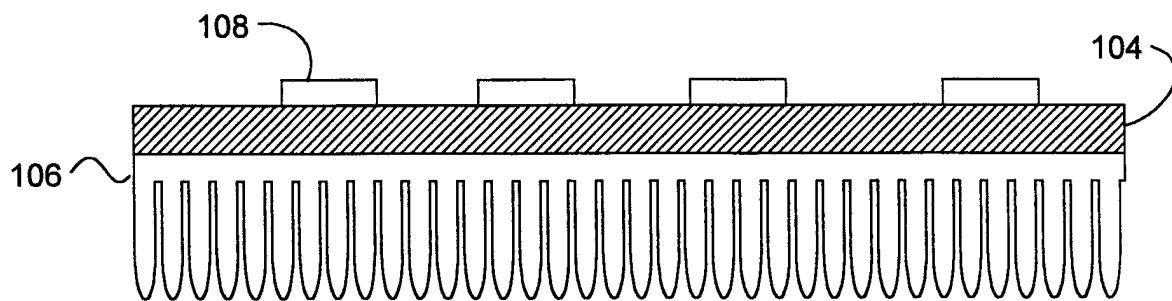


FIG. 24

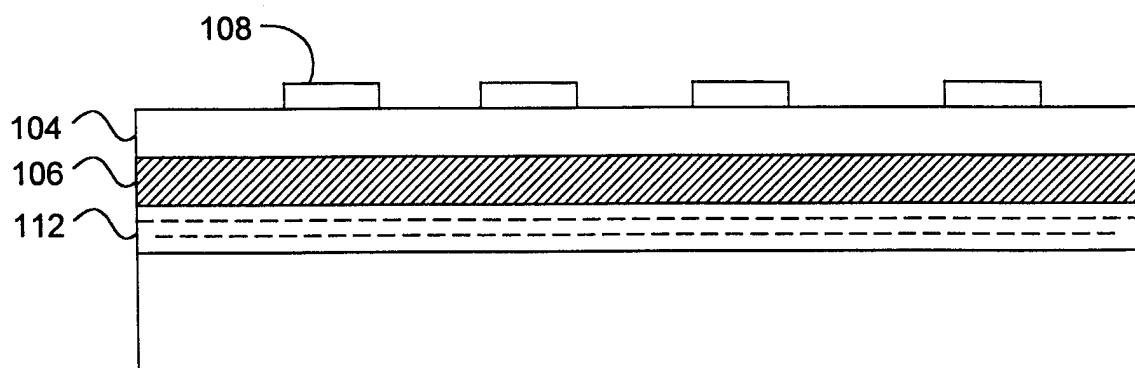


FIG. 25

# INTERNATIONAL SEARCH REPORT

International application No

PCT/US 97/19392

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 6 A61F2/06 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
 IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category <sup>o</sup> | Citation of document, with indication, where appropriate, of the relevant passages             | Relevant to claim No.     |
|-----------------------|------------------------------------------------------------------------------------------------|---------------------------|
| X                     | WO 92 01425 A (LANE) 6 February 1992<br><br>see the whole document<br>---                      | 1,3,4,<br>11,13,<br>18-20 |
| X                     | EP 0 558 352 A (SHADYSIDE HOSPITAL) 1<br>September 1993<br>see the whole document<br>---       | 1,5-7,9                   |
| A                     | EP 0 326 426 A (JAPAN MEDICAL SUPPLY) 2<br>August 1989<br>see page 3, line 17 - line 65<br>--- | 19-26,<br>37,39           |
| A                     | WO 90 15582 A (TROUT) 27 December 1990<br>see abstract; figures<br>-----                       | 6,7,9                     |

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

Date of mailing of the international search report

31 March 1998

15.04.98

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# INTERNATIONAL SEARCH REPORT

## Information on patent family members

| International   | Application No |
|-----------------|----------------|
| PCT/US 97/19392 |                |

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) |  | Publication<br>date |
|-------------------------------------------|---------------------|----------------------------|--|---------------------|
| WO 9201425 A                              | 06-02-92            | AU 651838 B                |  | 04-08-94            |
|                                           |                     | AU 8232791 A               |  | 18-02-92            |
|                                           |                     | EP 0549590 A               |  | 07-07-93            |
|                                           |                     | US 5405379 A               |  | 11-04-95            |
| -----                                     |                     |                            |  |                     |
| EP 558352 A                               | 01-09-93            | US 5234448 A               |  | 10-08-93            |
|                                           |                     | AT 156986 T                |  | 15-09-97            |
|                                           |                     | CA 2090763 A,C             |  | 29-08-93            |
|                                           |                     | CA 2173636 A               |  | 29-08-93            |
|                                           |                     | DE 69313162 D              |  | 25-09-97            |
|                                           |                     | EP 0781528 A               |  | 02-07-97            |
|                                           |                     | US 5254127 A               |  | 19-10-93            |
| -----                                     |                     |                            |  |                     |
| EP 326426 A                               | 02-08-89            | JP 1192367 A               |  | 02-08-89            |
|                                           |                     | JP 2561853 B               |  | 11-12-96            |
|                                           |                     | CA 1307885 A               |  | 29-09-92            |
|                                           |                     | DE 68920055 D              |  | 02-02-95            |
|                                           |                     | DE 68920055 T              |  | 11-05-95            |
|                                           |                     | US 4950258 A               |  | 21-08-90            |
| -----                                     |                     |                            |  |                     |
| WO 9015582 A                              | 27-12-90            | AU 632592 B                |  | 07-01-93            |
|                                           |                     | AU 5858990 A               |  | 08-01-91            |
|                                           |                     | CA 2033195 A,C             |  | 20-12-90            |
|                                           |                     | EP 0429629 A               |  | 05-06-91            |
|                                           |                     | JP 7106213 B               |  | 15-11-95            |
|                                           |                     | JP 4500328 T               |  | 23-01-92            |
|                                           |                     | KR 9512177 B               |  | 14-10-95            |
|                                           |                     | US 5207695 A               |  | 04-05-93            |
| -----                                     |                     |                            |  |                     |