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Catheter for injecting fluid medication into an arterial wall

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CATHETER FOR INJECTING FLUID MEDICATION INTO AN ARTERIAL WALL

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A device (10) for injecting medication into a vessel wall includes an inflatable balloon (16) mounted on a catheter (14). Additionally, a tubular sleeve (18) surrounds the balloon (16) to create an infusion chamber (26) between the sleeve and the balloon, and a plurality of injectors (20) are mounted on the sleeve (18) in fluid communication with the infusion chamber(26). During use of the device (10), the balloon (16) is first positioned in a vessel and then inflated to embed the injectors (20) into the vessel wall. Next, a fluid medicament is introduced into the infusion chamber (26) for futher infusion from the chamber (26) and through the injectors (20) into the vessel wall.

1. A device for injecting fluid medication into the wall of a vessel which comprises:

a fluid source;

means for penetrating said vessel wall;

inflatable means for holding said penetrating means;

means interconnecting said fluid source with said penetrating means for establishing fluid communication therebetween; and

means for inflating said holding means to move said penetrating means toward said vessel wall for penetration of said penetrating means into said arterial wall.

Catheter for Injecting Fluid Medication into an Arterial Wall

Abstract

A device (10) for injecting medication into a vessel wall includes an inflatable balloon (16) mounted on a catheter (14). Additionally, a tubular sleeve (18) surrounds the balloon (16) to create an infusion chamber (26) between the sleeve and the balloon, and a plurality of injectors (20) are mounted on the sleeve (18) in fluid communication with the infusion chamber(26). During use of the device (10), the balloon (16) is first positioned in a vessel and then inflated to embed the injectors (20) into the vessel wall. Next, a fluid medicament is introduced into the infusion chamber (26) for futher infusion from the chamber (26) and through the injectors (20) into the vessel wall.

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COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

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Invention Title:	Catheter for Injecting Fluid Medication into an Arterial Wall

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

FIELD OF THE INVENTION

The present invention pertains generally to invasive medical devices which are useful for the purpose of infusing fluid medicaments into a patient. More specifically, the present invention pertains to medical devices which can be inserted into a vessel of a patient's cardiovascular system. The present invention is particularly, but not exclusively, useful for infusing fluid medicaments directly into a vessel wall.

BACKGROUND OF THE INVENTION

Depending on the particular ailment it is known in the medical field that fluid medications can be infused directly into the wall of a vessel of a patient's cardiovascular system with beneficial results. For example, one such application involves the administration of medicaments into an arterial wall which will inhibit or prevent the restenosis of plaque in the artery. Any procedure involving the direct infusion of fluid medicaments into a vessel wall, however, requires the consideration of several factors. First, the procedure must be safe. For instance, due to the toxic nature of some medicaments, such a procedure must insure that only minimal amounts of medication are ever washed away into the blood stream and not actually infused into the vessel wall. Second, the device which infuses the medication into the vessel wall must be easy to use, accurate in its delivery capability and reliable in its operation.

Several devices have been suggested for the purpose of infusing fluid medicaments directly into a vessel wall. One example of such a device is disclosed in U.S. Patent No. 5,354,279 which issued to Hofling for an invention entitled "Plural Needle Injection Catheter". The specific device disclosed in this patent employs prebent hollow

needles which are extendable from a catheter to penetrate into a vessel wall. The extended needles are then used for infusion of the fluid medicament. Also, U.S. Patent No. 5,364,356, was issued to Hofling for another invention entitled "Sleeve Catheter". This second patent to Hofling discloses a device which employs a balloon expandable sleeve that delivers fluid medication to a vessel wall. More specifically, this device of Hofling's includes a reconfigurable sleeve which is expanded by an inflatable balloon. It is intended that, as the sleeve expands, openings which are formed into the sleeve spread to discharge fluid medications onto the surface of the vessel walls. Still another example of a device for medicating a vessel wall is disclosed in U.S. Patent No. 5,112,305 which issued to Barath et al. for an invention entitled "Catheter Device for Intramural Delivery of Therapeutic Agents". This same device is also disclosed in a related U.S. Patent No. 5,242,397 which issued to Barath et al. for an invention entitled "Catheter Device and Method of Use for Intramural Delivery of Protein Kinase C and Tyrosine Protein Kinase Inhibitors to Prevent Restenosis after Balloon Angioplasty". Specifically, the device disclosed by Barath et al. employs a balloon which requires an initial slow filling of the balloon with a medicament to expand the balloon and position the balloon's surface against the vessel wall. This initial slow filling is then followed by a rapid filling of the balloon which reconfigures tubular extensions on the surface of the balloon for the infusion of medicaments through the tubular extensions and into the vessel wall.

None of the above discussed devices, however, address the problem from the same perspective as the present invention. Specifically, the present invention recognizes that it is preferable to have a mechanism for infusing medication into a vessel wall which is independent and separately operable from the mechanisms which position the

device in the artery and which cause at least one medication injector to penetrate into the vessel wall. Consequently, as recognized by the present invention, it is preferable to isolate the mechanism for actual infusion of medications into the vessel wall from other operable mechanisms of the device. Further, the present invention recognizes that, depending on the nature and condition of the vessel wall, it is preferable to have the capability of selectively applying a variable force to the injectors of the device as they penetrate into the vessel wall.

It is an object of the present invention to overcome or ameliorate some of the disadvantages of the prior art, or at least to provide a useful alternative.

SUMMARY OF THE INVENTION

Accordingly, in a first aspect, the invention provides a device for injecting a fluid into a wall of a vessel which comprises:

an inflatable balloon;

a tubular sleeve defining an infusion chamber;

at least one injector for penetrating the wall of the vessel, the injector being mounted on and extending away from the tubular sleeve with the sleeve positioned between the injector and the balloon, the injector being in fluid communication with the infusion chamber;

means for inflating the balloon so that injector penetrates into the vessel wall; and

means for selectively injecting the fluid into the infusion chamber and through the injector into the vessel wall.

In a second aspect, the invention provides a device for injecting a fluid from a fluid source into a treatment area in a wall of a vessel, the device comprising:

an inflatable balloon that at least can be expanded from a first configuration to a larger, second configuration;

a tubular sleeve which substantially encircles at least a portion of the inflatable balloon and defines an infusion chamber, at least a portion of the tubular sleeve moving with the inflatable balloon between the first configuration and the second configuration;

a plurality of injectors, each injector is suitable for penetrating the treatment area and releasing the fluid into the treatment area when the balloon is substantially in the second configuration, each injector comprises a substantially tubular protrusion defining a fluid channel which is in fluid communication with the infusion chamber, each tubular protrusion having an open, cutting edge which extends away from the tubular sleeve for penetrating the treatment area and releasing the fluid into the treatment area; and

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means for injecting the fluid into the infusion chamber and through each injector into the vessel wall.

In a third aspect, the invention provides a method for delivering a fluid from a fluid source to a treatment area in a vessel wall, the method comprising the steps of:

providing a device which includes a balloon, a tubular sleeve which substantially encircles a portion of the balloon to form an infusion chamber and an injector which is secured to the tubular sleeve and extends away from the tubular sleeve;

advancing the device in the vessel with the balloon in a first configuration; expanding the balloon to a larger, second configuration so that the injector penetrates the treatment area; and

selectively releasing the fluid from the injector into the treatment area.

The present invention preferably provides a device for injecting medication into the wall of a vessel which includes a mechanism for penetrating a vessel wall with medication delivery injectors that is separate from the mechanism which infuses the medication into the vessel wall.

The present invention further preferably provides a device for injecting medication into the wall of a vessel which can selectively vary the force that is used to penetrate the vessel wall with a fluid medication injector.

The present invention also preferably provides a device for injecting medication into the wall of a vessel which is easy to use, relatively simple to manufacture and comparatively cost effective.

In accordance with a preferred embodiment of the present invention, a device for injecting medication into the wall of a vessel includes an inflatable PET balloon which is mounted on a multi-lumen catheter. A flexible tubular sleeve, preferably made of polyurethane, is provided. This sleeve effectively surrounds most of the inflatable balloon, and thereby creates an infusion chamber between the balloon and the sleeve. To create this chamber, the distal end of the tubular sleeve is attached directly onto the surface of the

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balloon, and the proximal end of the sleeve is extended proximally from the balloon. The open proximal end of the tubular sleeve thus establishes a port for fluid access into the infusion chamber.

For the device of the present invention, a plurality of injectors are mounted directly onto the sleeve and are placed in fluid communication with the infusion chamber. More specifically, each injector includes a base plate and a hollow protrusion which projects from the base of the injector to create a fluid channel through the injector. To establish a fluid path from the infusion chamber through the channel of the injector, the base of the injector is mounted onto the tubular sleeve over holes that may either be preformed into the sleeve or formed into the sleeve after the injectors have been attached to the sleeve.

The device of the present invention also includes a system for selectively inflating the balloon. As intended for the present invention, the balloon inflating system can be directly connected to a lumen of the catheter. The catheter lumen, in turn, is in fluid communication with the interior of the inflatable balloon. Additionally, the device includes a fluid pump which is engageable in fluid communication with the infusion chamber between the balloon and the sleeve for injecting fluid medicaments from a fluid source into the infusion chamber. Further, in an alternate embodiment of the present invention, instead of having single port injectors, a plurality of hollow protrusions can be formed onto the same base plate to create an injector having a plurality of outlet ports.

In the operation of the device of the present invention, a guidewire is first positioned into an artery of the patient. This is done to establish a mechanical pathway through the artery to the site where the fluid medication is to be infused. The extracorporeal end of the guidewire is then inserted into a lumen of the catheter and

the balloon on the catheter is advanced over the guidewire and to the site where the medication is to be infused.

Once the balloon has been properly positioned for the infusion of fluid medicaments into the arterial wall, the balloon is inflated. This inflation of the balloon, in turn, urges the tubular sleeve to move outwardly with the expansion of the balloon. This action also causes the injectors to penetrate into the arterial wall. After the balloon has been inflated, and while the injectors remain penetrated into the arterial wall, the fluid pump is activated to inject fluid from the fluid source into the infusion chamber. Importantly, this pumping action also forces fluid from the infusion chamber through the injectors and into the arterial wall.

BRIEF DESCRIPTION OF THE DRAWINGS

A preferred form of the present invention will now be described by way of example with reference to the accompanying drawings, wherein:

Figure 1 is a perspective view of a patient with the catheter of the present invention positioned in an artery of the patient for operation of the device;

Figure 2 is a perspective view of the device of the present invention;

Figure 3 is a cross-sectional view of the device of the present invention as seen along the line 3-3 in Figure 2 and positioned in an artery of a patient for infusion of fluid medications into the arterial wall;

Figure 4A is a perspective view of an embodiment for a single port injector of the present invention;

Figure 4B is a perspective view of another embodiment for a single port injector of the present invention;

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Figure 5A is a perspective view of an embodiment of a multi-port injector of the present invention; and

Figure 5B is a perspective view of another embodiment of a multi-port injector of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring initially to Figure 1, a device for injecting fluid medication into the wall of a vessel in accordance with the present invention is shown and generally designated 10. More specifically, the device 10 is shown positioned in the artery of a patient 12. As will be appreciated by the skilled artisan, the device 10 is shown schematically positioned in the patient 12, and it is to be understood that use of the device 10 is not confined to only upper body arteries and vessels but, instead, can be used in arteries and vessels throughout the patient 12.

Figure 2 clearly shows that the components of device 10 include a multi-lumen catheter 14 which has an inflatable balloon 16 mounted thereon. Further, Figure 2 indicates that a tubular sleeve 18 surrounds a substantial portion of the inflatable balloon 16, and that a plurality of injectors 20 are mounted onto the sleeve 18. Of these, the injectors 20a-20b are only exemplary. For purposes of the present invention, balloon 16 is preferably made of polyethylene terephthalate (PET). Additionally, the sleeve 18 can also be made of polyethylene terephthalate (PET).

A more complete appreciation of the structural cooperation between balloon 16, sleeve 18 and the injectors 20 is provided by Figure 3 wherein it will be seen that the distal end 22 of sleeve 18 is attached directly to the surface of balloon 16. Figure 3 also shows that the tubular sleeve 18 substantially surrounds the balloon 16 and that the proximal end 24 of sleeve 18 extends proximally from and beyond the balloon 16 over catheter 14. With this structural relationship, an infusion chamber 26

is formed between the balloon 16 and the sleeve 18. Additionally, as best seen in Figure 3, a fluid port 27 is formed between the sleeve 18 and catheter 14 through which fluid medication can be injected into the infusion chamber 26.

Figure 3 further shows that the distal end 28 of balloon 16 is affixed to the catheter 14, and that the proximal end of the balloon 16 closes onto the catheter 14 to create an inflation chamber 32 in the interior of the balloon 16. A port 34 is shown which provides fluid access into the inflation chamber 32. For purposes of the present invention, the port 34 can be connected in fluid communication with a lumen (not shown) of the catheter 14. Figure 3 also shows that catheter 14 is formed with a lumen 36 which is dimensioned to receive a guidewire 38 therethrough.

Turning now to Figure 4A, an injector 20 is shown to include a base plate 40 and a hollow protrusion 42 which projects therefrom. Further, it is seen that the end 44 of body 42 is affixed to or integral with the base plate 40. Preferably, the injector 20 is made of nickel and the protrusion 42 is formed by punching out the base plate 40. In any event, a cutting edge 46 is formed around the end of body 42 that is opposite from the end 44 on plate 40 and the resultant structure establishes a fluid channel 48 which extends through the injector 20. As shown, the injector 20 has a substantially cylindrical shaped protrusion 42.

In Figure 4B, another embodiment for an injector of the present invention is shown and designated 70. Rather than having a cylindrical shaped protrusion 42 like the injector 20, however, the injector 70 has a substantially conical shaped protrusion 72. Like injector 20, the injector 70 is preferably made of nickel and is formed to have a fluid channel 48 which extends through the injector 70.

For a multi-port injector version of the present invention, a plurality of protrusions 42 can be formed from the same base plate. Figure 5A shows such an embodiment. Specifically, Figure 5A shows an elongated base plate 50 from which the protrusions 42a', 42b' and 42c' have been formed. In all important respects, the protrusions 42' shown in Figure 5A are structurally the same as the protrusion 42 discussed above with reference to Figure 4A. The only difference being that they are collectively mounted on the same base plate 50. Similarly, Figure 5B shows a multi-port injector wherein the protrusion 72a', 72b' and 72c' have been formed from a base 50. In all important respects, the protrusions 72' shown in Figure 5B are structurally the same as the protrusion 72 discussed above with reference to Figure 4B. Again, the only difference being that they are collectively mounted on the same base plate 50.

For purposes of the present invention, the injectors 20 are mounted onto the sleeve 18 so that the channel 48 of each respective injector 20 is aligned with a hole 52 in the sleeve 18. This is done to establish fluid communication between the particular injector 20 and the infusion chamber 26. As a practical matter, it may be preferable in the construction of the device 10 to first mount the injector 20, 70 onto sleeve 18, which can be done in any manner well known in the pertinent art, such as by bonding, and then pierce the sleeve 18 through the channel 48.

In the operation of the present invention the guidewire 38 is first positioned in the vessel to establish a mechanical path for the device 10 to the site, as shown in Figure 3, where fluid medications are to be infused into a vessel wall 54. Once the balloon 16 of device 10 is properly positioned, an inflator 56 is activated to inflate the balloon 16. As shown in Figure 2, inflator 56 is connected to the proximal (extracorporeal) end of the

device 10. Referring back to Figure 3, it will be appreciated that, as balloon 16 is inflated, the expanding balloon 16 urges against the tubular sleeve 18 and causes the sleeve 18 to likewise expand. Consequently, the injectors 20,70 which are mounted on the surface of sleeve 18 move radially from the catheter 14 and are embedded into the vessel wall 54.

With the injectors 20,70 embedded into the vessel wall 54, the fluid pump 58 shown in Figure 2 is activated to pump fluid from the fluid source 60 into the infusion chamber 26 through the port 34. Importantly, this pumping action also causes any fluid medication which has already been pumped into the infusion chamber 26 to be expelled through the channels 48 of injectors 20,70 and into the tissue of vessel wall 54.

After the fluid medication from fluid source 60 has been infused into the vessel wall 54, the balloon 16 can be deflated by reversing the inflator 56. This action will cause the balloon 16 to collapse and to thereby withdraw the injectors 20,70 from the vessel wall 54. The entire device 10 can then be withdrawn from the patient 12 over the guidewire 38.

While the particular device for injecting medication into the wall of a vessel as herein shown and disclosed in detail is fully capable of obtaining the objects and providing the advantages herein before stated, it is to be understood that it is merely illustrative of the presently preferred embodiments of the invention and that no limitations are intended to the details of the construction or design herein shown other than as defined in the appended claims.

The claims defining the invention are as follows:

1. A device for injecting a fluid into a wall of a vessel which comprises:

an inflatable balloon;

a tubular sleeve defining an infusion chamber;

at least one injector for penetrating the wall of the vessel, the injector being mounted on and extending away from the tubular sleeve with the sleeve positioned between the injector and the balloon, the injector being in fluid communication with the infusion chamber;

means for inflating the balloon so that injector penetrates into the vessel wall; and

means for selectively injecting the fluid into the infusion chamber and through the injector into the vessel wall.

2. A device as recited in Claim 1 wherein the injector includes a base secured to an external, outer surface of the tubular sleeve.

3. A device as recited in Claim 1 wherein the injector includes a base and a hollow protrusion projecting away from the base, the protrusion having a first end and a second end, the first end of the protrusion being affixed to the base and the second end formed with a cutting edge.

4. A device as recited in Claim 3 which comprises a plurality of injectors.

5. A device as recited in Claim 3 further comprising a plurality of the protrusions projecting from the base.

6. A device as recited in Claim 3 wherein the protrusion is substantially cylindrical shaped.

7. A device as recited in Claim 3 wherein the protrusion is substantially conical shaped.

8. A device as recited in Claim 1 which further comprises a catheter formed with a plurality of lumens, one of the lumens being dimensioned to receive a guidewire therethrough for guiding and positioning the balloon in the vessel.

9. A device as recited in Claim 8 wherein one of the lumens of the catheter establishes fluid communication between the balloon and the inflating means.

10. A device as recited in Claim 1 wherein the tubular sleeve substantially encircles at least a portion of the balloon.

11. A device for injecting a fluid from a fluid source into a treatment area in a wall of a vessel, the device comprising:

an inflatable balloon that at least can be expanded from a first configuration to a larger, second configuration;

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a tubular sleeve which substantially encircles at least a portion of the inflatable balloon and defines an infusion chamber, at least a portion of the tubular sleeve moving with the inflatable balloon between the first configuration and the second configuration;

a plurality of injectors, each injector is suitable for penetrating the treatment area and releasing the fluid into the treatment area when the balloon is substantially in the second configuration, each injector comprises a substantially tubular protrusion defining a fluid channel which is in fluid communication with the infusion chamber, each tubular protrusion having an open, cutting edge which extends away from the tubular sleeve for penetrating the treatment area and releasing the fluid into the treatment area; and

means for injecting the fluid into the infusion chamber and through each injector into the vessel wall.

12. A device as recited in claim 11 wherein the each tubular protrusion has a base which is secured to an external outer surface of the tubular sleeve.

13. A device as recited in Claim 11 wherein each protrusion is substantially conical shaped.

14. A method for delivering a fluid from a fluid source to a treatment area in a vessel wall, the method comprising the steps of:

providing a device which includes a balloon, a tubular sleeve which substantially encircles a portion of the balloon to form an infusion chamber and an injector which is secured to the tubular sleeve and extends away from the tubular sleeve;

advancing the device in the vessel with the balloon in a first configuration; expanding the balloon to a larger, second configuration so that the injector penetrates the treatment area; and

selectively releasing the fluid from the injector into the treatment area.

15. The method of Claim 14 wherein the step of providing a device includes the step of providing a device which includes a plurality of injectors which extend away from the tubular sleeve.

16. The method of Claim 14 wherein the step of providing a device includes the step of providing a device in which the at least one injector is secured to an external outer surface of the tubular sleeve.

17. The method of Claim 14 wherein the step of providing a device includes the step of providing a device in which the injector includes a protrusion which is conical shaped.

18. A device for injecting a fluid into a wall of a vessel substantially as hereinbefore described with reference to the accompanying drawings.

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19. A device for injecting a fluid from a fluid source into a treatment area in a wall of a vessel, the device substantially as hereinbefore described with reference to the accompanying drawings.

20. A method for delivering a fluid from a fluid source to a treatment area in a vessel wall, the method substantially as hereinbefore described with reference to the accompanying drawings.

Dated 15 February, 1999
InterVentional Technologies, Inc.
Patent Attorneys for the Applicant/Nominated Person
SPRUSON & FERGUSON

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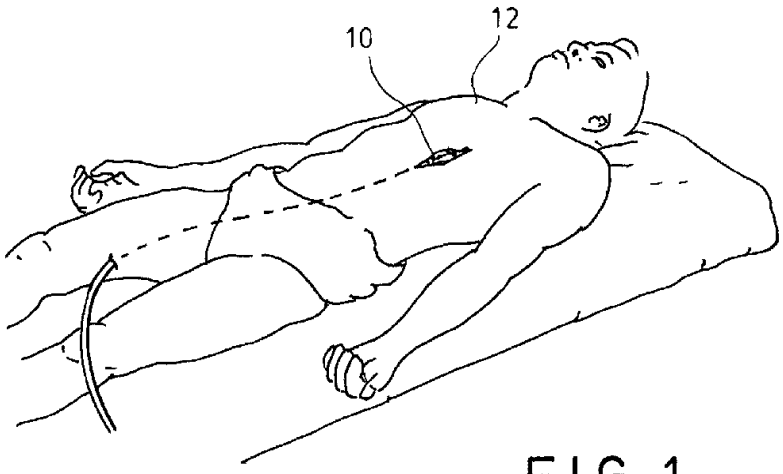


FIG.1

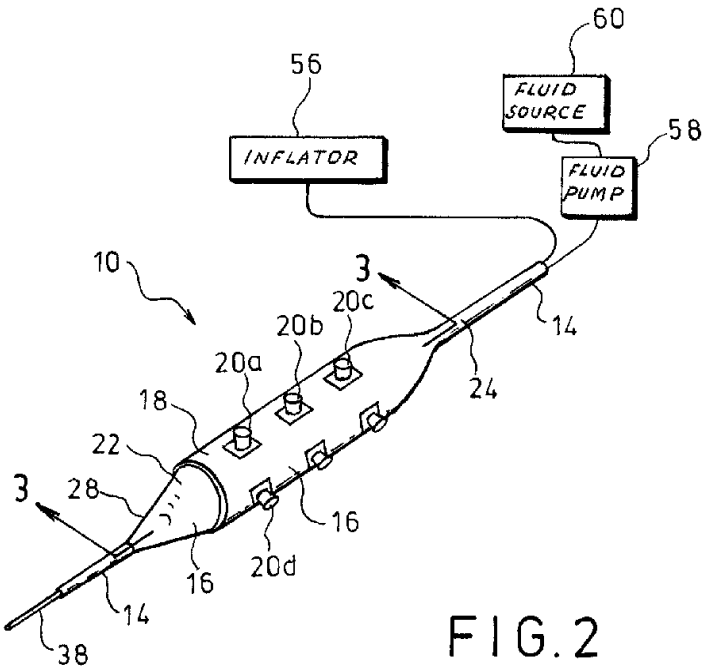


FIG.2

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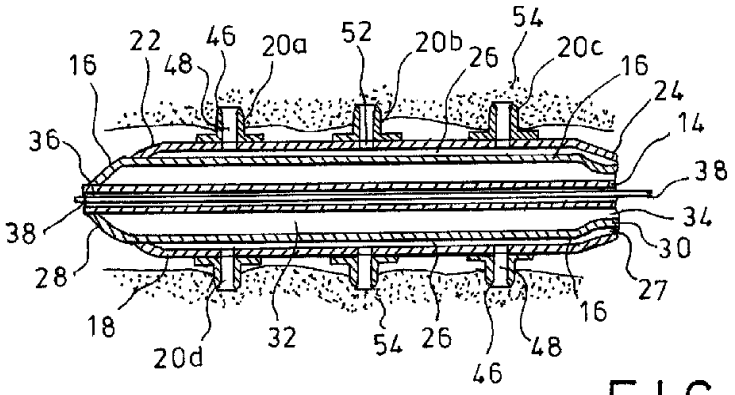


FIG.3

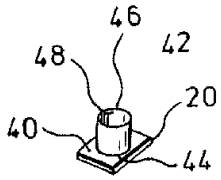


FIG.4A

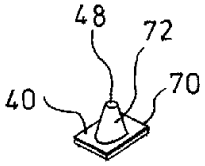


FIG.4B

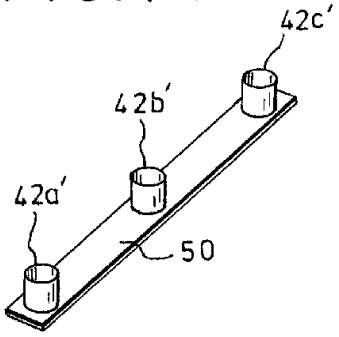


FIG.5A

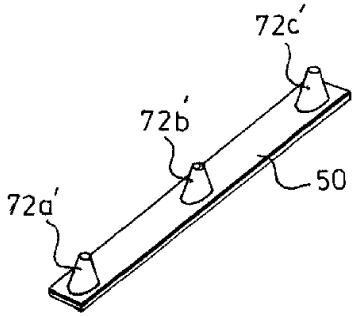


FIG.5B