

[54] **IMPLANT**

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128/348

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[58] **Field of Search**..... 128/1, 214 R, 334 R,
128/348; 3/1

[56] **References Cited**

UNITED STATES PATENTS

3,482,574	12/1969	Stoever	128/214 R
3,540,451	11/1970	Zeman	128/334 R

3,638,649	2/1972	Ersek	128/348
3,663,965	5/1972	Lee et al.	128/1 R

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[57]

ABSTRACT

An implant device including a tube for connection at one end thereof to a blood vessel under the skin of a patient, with an opposite end of the tube projecting through the skin, and a valve at the opposite end of the tube for selectively blocking and passing blood. The tube is preferably affixed to the skin with fastening means. One embodiment of the tube is an elbow, and another embodiment has a T configuration.

18 Claims, 6 Drawing Figures

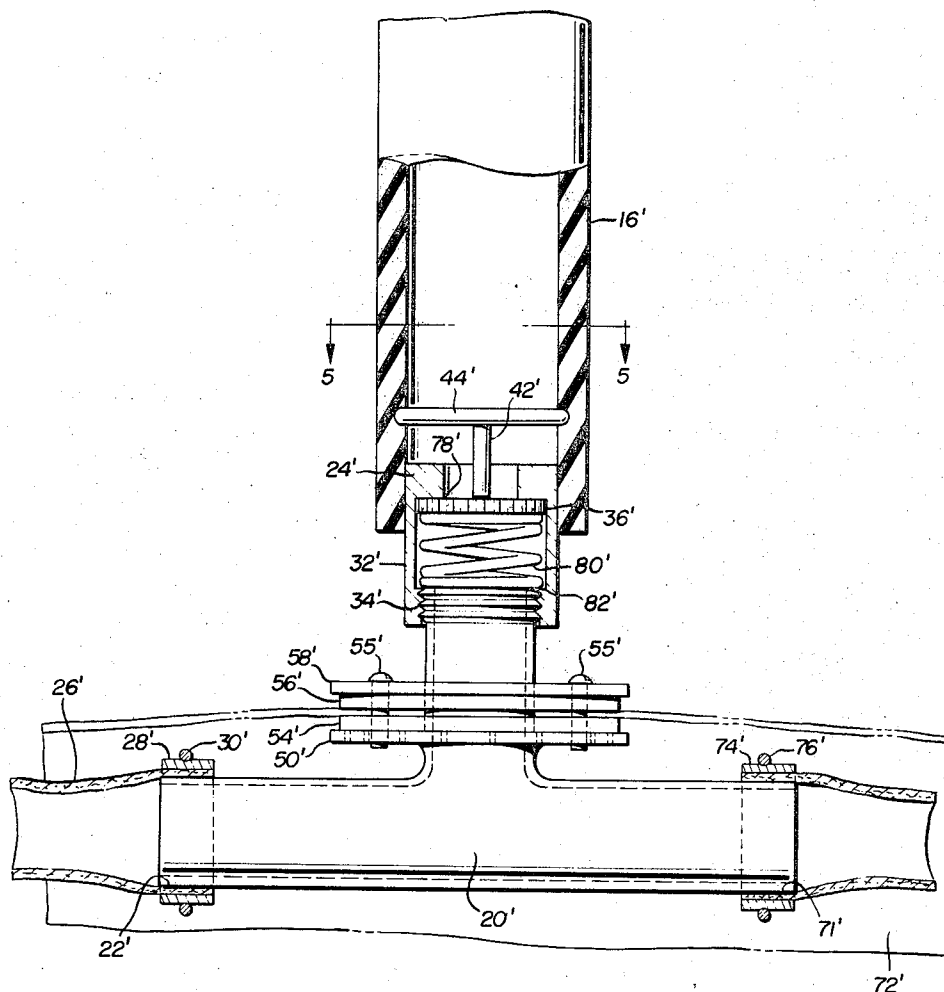


FIG. 4

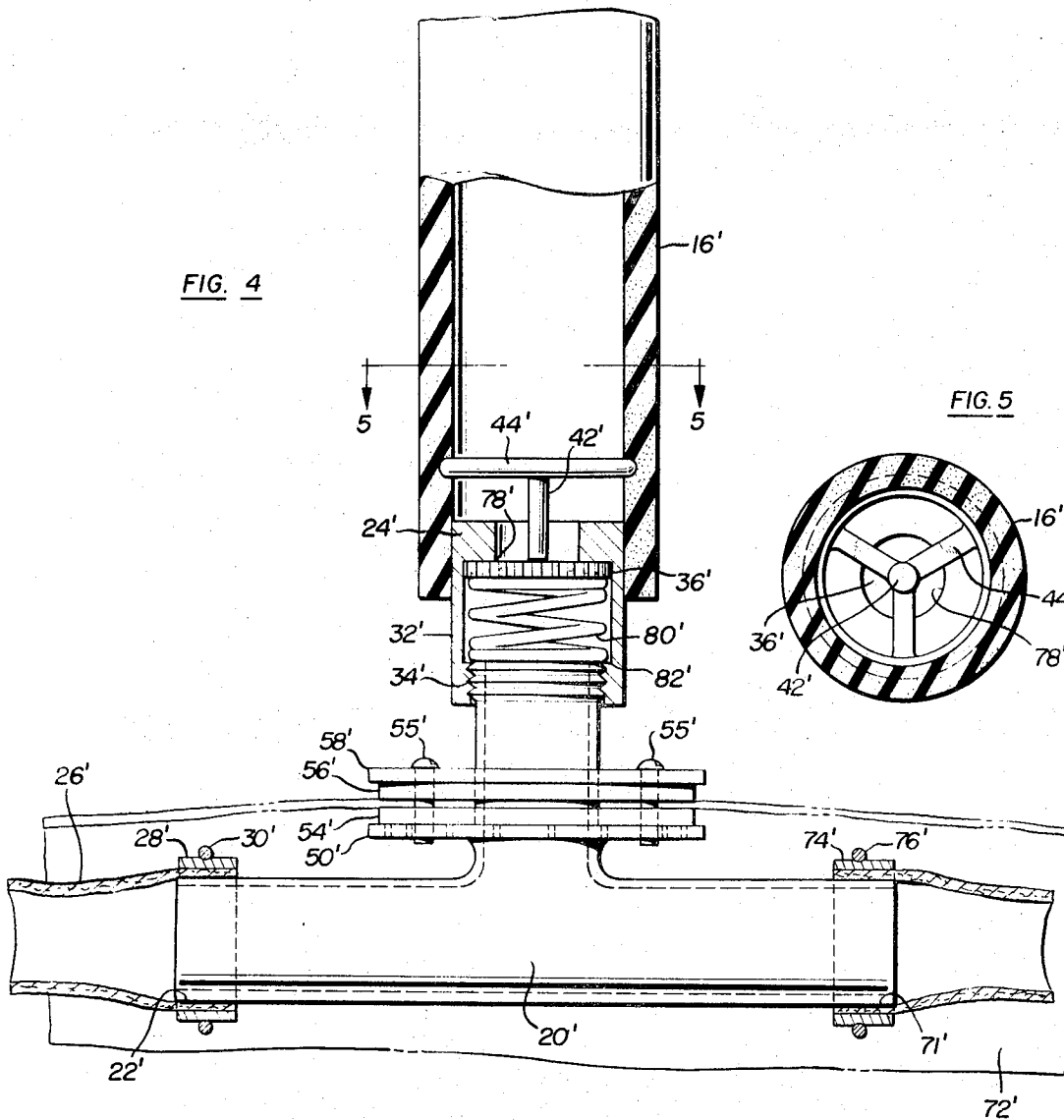


FIG. 5

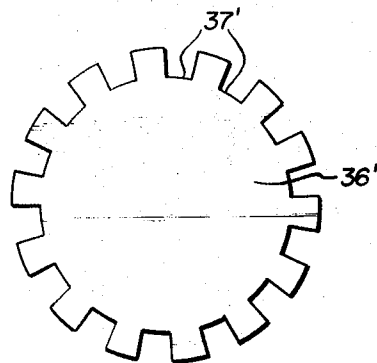
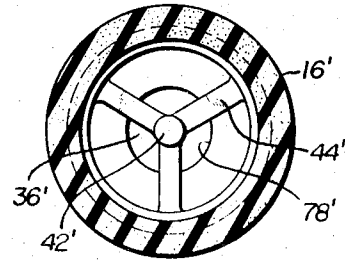


FIG. 6

IMPLANT

BACKGROUND OF THE INVENTION

It is sometimes necessary or desirable to supply blood from a patient to an external equipment, such as a kidney machine, where the blood is treated. After treatment the blood is returned to the patient. Some treatments of this type involve introducing a substance into the blood. Blood is sometimes derived from the patient by inserting a needle into a blood vessel, connecting the needle to the kidney machine with tubing, and returning the treated blood to another vessel through further tubing and another needle inserted into that blood vessel. When a needle is injected into a vein in this manner, there is sometimes a problem with blood clotting, and the blood vessel may collapse. These problems may be aggravated if the needle must be injected and removed many times in the same area of the body. Also, the blood or the blood vessel may react to foreign substances.

SUMMARY OF THE INVENTION

The present invention provides an implant device which is connected to a blood vessel in the body of a patient and projects through the skin of the patient so that a portion of the device is available outside the skin for connection to equipment such as a kidney machine. The implant device is generally tubular, and has a valve in the tubular portion located outside the body. The valve may be opened to supply blood to the external equipment and closed to block flow of blood. The tube is preferably affixed to the skin with fastening means which may include discs with porous material between them to allow body fluid to reach the area where the tube projects through the skin for healing purposes. The inner end of the tube is connected to the blood vessel with a clamp to prevent the blood vessel from pulling away from the tube due to foreign body reaction and pulsing pressure. The external portion of the tube preferably includes a detachable section in which the valve is mounted so that the section including the valve may be replaced easily. A cap may also be provided for this detachable section to close the external end of the tube when it is not in use.

Accordingly, it is an object of the present invention to provide an implant in the form of a tube which can be connected to a blood vessel in the body and has a portion outside the body available for supplying blood from the body to an external equipment. Another implant is provided in another portion of the body for a return of the blood to the body.

Another object of the invention is to provide a valve in the implant for selectively blocking and passing blood.

A further object of the invention is to enable fastening of the implant device to the skin of the patient where the tube of the device projects through the skin.

A further object of the invention is to enable substances to be introduced into the blood stream of a patient without inserting a needle into a blood vessel.

A further object of the invention is to make it possible to supply blood from a patient to an external equipment without inserting a needle into a blood vessel of the patient.

Still another, and no less important object of the invention is to facilitate supply of body fluid to a region

where an implant device projects through the skin of a patient.

Among the other objects of the invention are to provide an implant device which clamps to a blood vessel for accommodating pulsing pressure and foreign body reaction; which allows free flow of blood without passing through crevices or cracks to minimize clotting; which is made of material compatible with the blood vessels of a patient; and which is simple and economical to manufacture.

Other objects of this invention will appear from the following description and appended claims, reference being had to the accompanying drawings forming a part of this specification wherein like reference characters designate corresponding parts in the several views.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is perspective view showing two implant devices projecting from a patient and connected to an external piece of equipment such as a kidney machine;

FIG. 2 is an exploded perspective view of an implant device in accordance with one embodiment of the invention;

FIG. 3 is a vertical sectional view of the implant device of FIG. 2;

FIG. 4 is a view partly in elevation and partly in section showing an implant device in accordance with another embodiment of the invention;

FIG. 5 is a cross sectional view taken along line 5—5 of FIG. 4 and looking in the direction of the arrows; and

FIG. 6 is a plan view of a valve member included in the device of FIG. 4.

Before explaining the present invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and arrangement of parts illustrated in the accompanying drawings, since the invention is capable of other embodiments and of being practiced or carried out in various ways. Also, it is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation.

DETAILED DESCRIPTION

A pair of implant devices 10 and 12 are shown projecting through the skin at the wrists of a patient in FIG. 1, and the implant devices 10 and 12 are connected to a kidney machine 14 which is indicated schematically. In use, blood flows from the implant device 10 via tubing 16 to the machine 14 where it is treated, and then returns via tubing 18 to the patient through the implant device 12. The implant devices 10 and 12 may be located between the radius and ulna bones in the wrists of the patient.

One embodiment of an implant device 10 is shown in FIGS. 2 and 3. The implant device 10 includes a tube 20 which has opposite ends 22 and 24. In FIG. 3, the end 22 of the tube is connected to a blood vessel 26 by clamping means which include a resilient split ring 28 and a wire retainer 30 encircling the ring 28 to draw the ring 28 tightly around the blood vessel 26 where it receives the end 22 of the tube on the inside of the blood vessel. This clamping means will withstand the pulsing pressure of the blood as it pulses through the blood vessel and the tube, and counteracts foreign body reaction of the blood vessel 26. Tube 20, ring 28 and wire retainer 30 are preferably made of stainless steel or other

suitable material which is compatible with the tissues of the body, particularly the blood vessel 26. An alternate material is nylon plastic.

At the outer end 24 of the tube 20, there is a section 32 which has threads 34 that screw on to matching threads on the main body of the tube 20 so that the section 32 is detachable. The section 32 of the tube 20 carries a valve 36 which, in this embodiment, is a puncturable membrane affixed to the inner wall of the tube section 32 as with cement. The membrane 36 is preferably of the self-sealing type so that when a small puncture is made in the membrane, it will seal again when the puncturing implement is removed. By making the tube section 32 detachable, it is relatively easy to replace the section 32 with another section which contains a fresh valve 36. The section 32 has external threads 38 on which a cap 40 may be screwed to close the outer end 24 of the tube when the tube is not in use.

In order to start the flow of blood from the blood vessel 26 through the tube 20, the tubing 16 preferably contains a hollow needle 42 which will puncture the valve diaphragm 36 when the tubing 16 is slipped over the end 24 of the detachable tube section 32 as shown in FIG. 3. The needle 42 may be attached to a spider 44 which is affixed inside the tubing 16.

Just above the bend portion 46 of the tube 20, the tube is fastened to the skin 48 of the patient where the tube projects through the skin. This is facilitated by making the tube in the form of an elbow as in FIGS. 2 and 3. The fastening means includes a first plate 50 that is affixed to the tube 20 either by making the plate 50 integral with the tube or by screwing the plate onto threads provided on the tube. The plate 50 has apertures 52 extending through it for allowing body fluids to pass through the plate. Just above the plate 50, a porous pad 54 is provided, this pad may be made of any suitable material which will not adversely react with the body tissues. An example of such material is "Teflon." The pad 54 contacts the skin 48 of the patient, and since it is porous, the body fluids which pass through the openings 52 can also pass through the pad 54 to reach the area of the skin 48 where the tube 20 passes through the skin. This supply of body fluids to the area where the tube passes through the skin helps to heal and keep healed the body tissues where the tube emerges from them. Another porous pad 56 identical to pad 54 is located just above the skin 48, and a second plate 58 is located above the pad 56. Pad 56 and plate 58 are both removable from the tube 20, and they can be placed down over the top of the skin 48 to receive the tube 20 where it projects through the skin. Pad 56 has a large aperture 60 and plate 58 has a large aperture 62 through which the upper end of the tube 20 extends when the device is in place. Pad 56 has smaller apertures 64, and plate 58 has smaller apertures 66. Similarly, pad 54 has apertures 68 and plate 50 has threaded apertures 70 matching apertures 68. All of the apertures 64, 66, 68 and 70 are lined up, and bolts 55 are inserted through them and screwed into the apertures 70 to clamp the plates and pads together with the skin 48 in between pads 54 and 56 as shown in FIG. 3. This affixes the tube 20 to the skin as shown. Plates 50 and 58 and bolts 55 may be made of stainless steel or nylon plastic.

FIGS. 4, 5 and 6 show another embodiment of the invention. Since this embodiment is very similar to the embodiment of FIGS. 2 and 3, the same reference num-

erals have been used for like parts with a prime designation added to distinguish the embodiments. In this embodiment, the tube 20' has a T configuration. The left end 22' is clamped to a blood vessel 26' with the clamping means including the split ring 28' and the wire retainer 30' as described previously. The upper end 24' receives the tubing 16'. The upper end 24' is actually the end of a detachable section 32' which screws onto the main body of the tube. For this purpose, threads 34' are provided.

The tube 20' has a third end 71' which is affixed to a blood vessel 72' with clamping means including a split ring 74' and a wire retainer 76' which are exactly the same as the clamping means 28', 30'.

Plates 50' and 58' and pads 54' and 56' together with bolts 55' form a fastening means which is identical to that described previously.

The detachable section 32' differs somewhat from detachable section 32. Section 32' is provided with a valve 36' in the form of a disc having apertures 37' spaced angularly all about its periphery as shown in FIG. 6. The tube section 32' has an annular shoulder 78' against which the valve disc 36' is biased by a coil spring 80'. The coil spring 80' is inside the tube section 32', and its lower end rests on a shoulder 82' whereas its upper end contacts the valve disc 36'.

Instead of a needle, the spider 44' carries a projection 42' which can contact the valve disc 36'. When the tubing 16' is pushed further down on the tube section 32' than the position shown in FIG. 4, the projection 42' pushes the valve disc 36' away from the shoulder 78'. Thus, the shoulder 78' no longer blocks the apertures 37', so the valve is open. Blood can then flow from the blood vessel 26' through the tube 20' and the tube section 32' to the tubing 16' for flow to the external equipment. Blood can also continue to flow through the other tube end 71' to the other blood vessel portion 72'. Another identical implant device is provided in another portion of the body, such as the other wrist in the manner shown in FIG. 1. One implant device is connected to both ends of a severed artery as shown in FIG. 4, and the second implant device is connected to both ends of a severed vein in like manner. Thus, blood is supplied from the artery to the external equipment and is returned to the vein.

It should be noted that valve 36 could replace valve 36' and vice versa. A hypodermic needle could then be used to inject a substance through valve 36 into tube 20'.

It may be seen from the foregoing description that the invention provides an implant device which can remain on a permanent or semi-permanent basis in the body of the patient. The implant device can easily be connected to external equipment. Normally, two of the implant devices are used for the patient in the manner shown in FIG. 1. Thus, any time blood must be supplied from the patient to the external equipment, tubing is connected to the implant devices, the valves of the devices are opened, and blood flows through the machine and is returned to the patient.

Having thus described my invention, I claim:

1. An implant device comprising
 - a tube means for connection to a blood vessel of a patient,
 - fastening means for affixing an intermediate portion of said tube means to the skin of the patient to retain one end of said tube means connected to the

blood vessel in the flesh under the skin of the patient with the opposite end of said tube means projecting through the skin to the outside thereof, and valve means affixed at said opposite end of said tube means for selectively blocking and passing flow of blood from said vessel through said tube means.

2. The implant device as claimed in claim 1 in which said tube means is in the form of an elbow.

3. The implant device as claimed in claim 1 in which said tube means has a third end for connection to a blood vessel under the skin.

4. The implant device as claimed in claim 3 in which said tube means has a T configuration.

5. The implant device as claimed in claim 1 in which said valve means comprises a puncturable membrane.

6. The implant device as claimed in claim 1 in which said valve means comprises a disc having apertures at the periphery thereof, and said tube means has a shoulder receiving the apertured periphery of said disc for closing said apertures, and means biasing said disc toward said shoulder.

7. The implant device as claimed in claim 1 in which said fastening means includes a first plate affixed to said tube means, a second plate having an aperture to receive said tube means, porous pad means for interposition between said plates, and means for fastening said plates together on opposite sides of the skin with said pad means contacting the skin.

8. The implant device as claimed in claim 1 in which said tube means has a detachable section at said opposite end in which said valve means is affixed.

9. The implant device as claimed in claim 8 in which said detachable section includes a removable cap for

closing said opposite end.

10. An implant device comprising tube means for connection at one end thereof to a blood vessel under the skin of a patient with the opposite end thereof projecting through the skin, and valve means at said opposite end for selectively blocking and passing flow of blood from said vessel through said tube means.

11. The implant device as claimed in claim 10 in which said tube means is in the form of an elbow.

12. The implant device as claimed in claim 10 in which said tube means has a third end for connection to a blood vessel under the skin.

13. The implant device as claimed in claim 12 in which said tube means has a T configuration.

14. The implant device as claimed in claim 10 in which said valve means comprises a puncturable membrane.

15. The implant device as claimed in claim 10 in which said valve means comprises a disc having apertures at the periphery thereof, and said tube means has a shoulder receiving the apertured periphery of said disc for closing said apertures, and means biasing said disc toward said shoulder.

16. The implant device as claimed in claim 10 in which said tube means has a detachable section at said opposite end in which said valve means is affixed.

17. The implant device as claimed in claim 16 in which said detachable section includes a removable cap for closing said opposite end.

18. The implant device as claimed in claim 10 including clamping means for clamping said one end of said tube means to the blood vessel.

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