United States Patent

Ersek

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[54] METHOD FOR FIXING PROSTHETIC IMPLANTS IN A LIVING BODY

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[21] Appl. No.: **35,815**

[52] **U.S. Cl.**.....**3/1,** 3/DIG. 1, 3/DIG. 3, 128/334 R

[51] **Int. Cl.** **A61f 1/22,** A61f 1/24

[58] **Field of Search**.....128/334 R, 334 C, 341, 343, 128/348; 3/1, DIG. 1, DIG. 3

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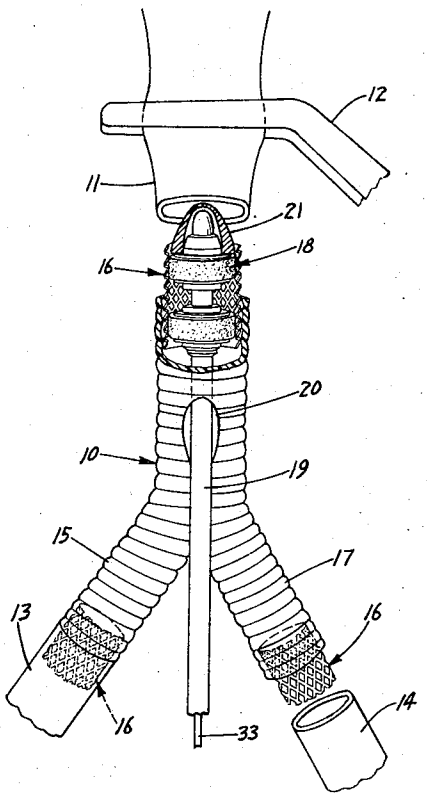
[57] **ABSTRACT**

A device and method for facilitating the rapid positive fixation of implanted prosthetic members in a living body. The device comprises a tubular sleeve of deformable material to which the prosthetic member is secured and which is capable of being expanded radially into intimate engagement with surrounding tissue. The fixation device and prosthetic member, such as heart valve, vessel graft, etc., are prepared by assembly prior to surgery. The assembly may be rapidly introduced into the transplant situs during surgery and secured in place by expansion of the deformable sleeve by use of an expansion tool.

3 Claims, 9 Drawing Figures



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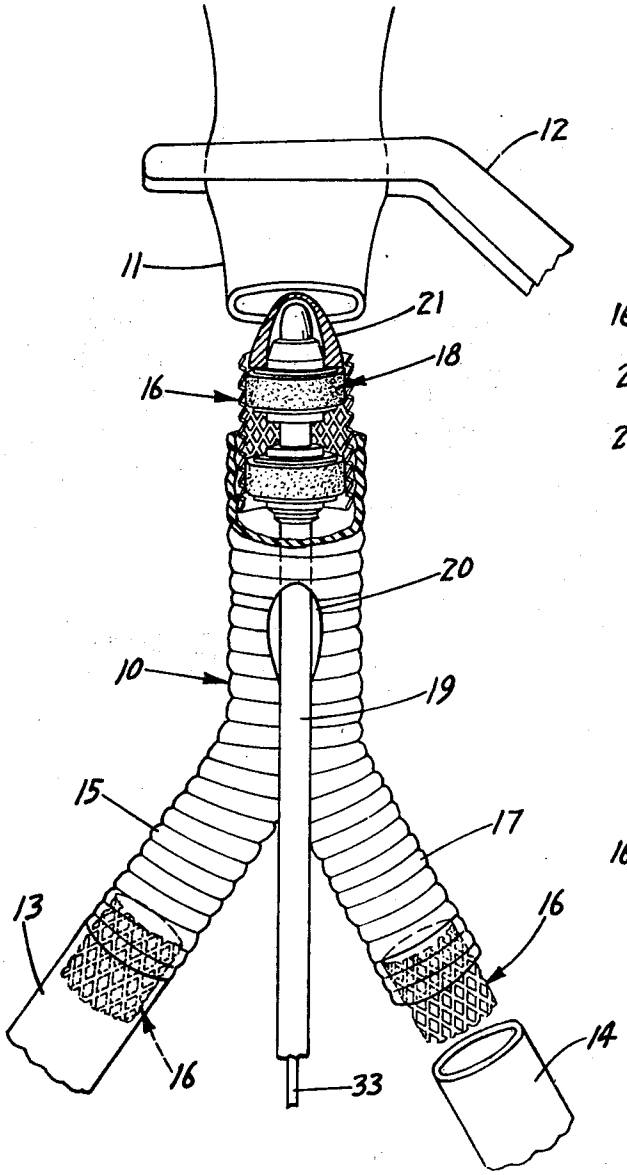

FIG. 1

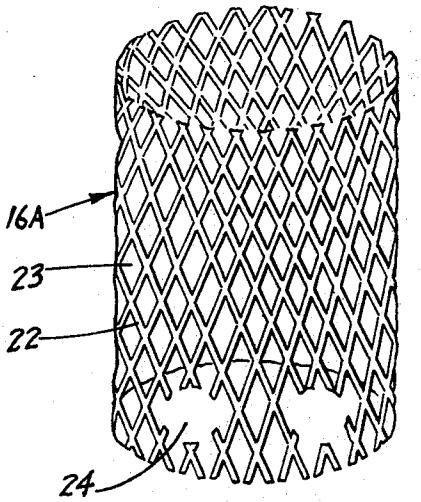

FIG. 2

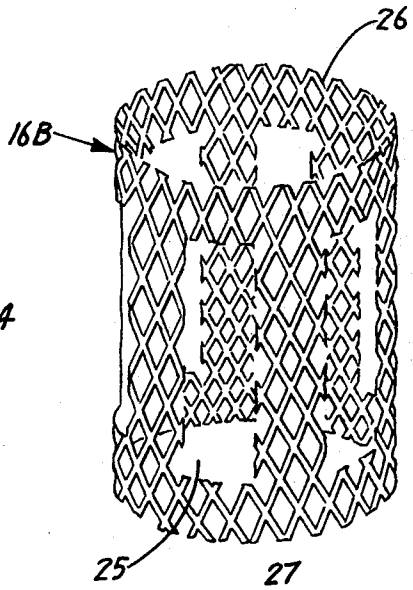

FIG. 3

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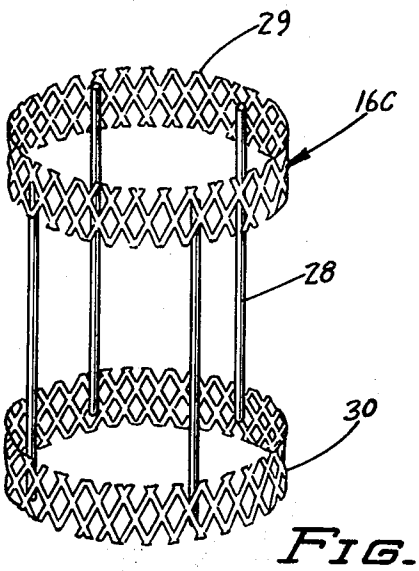

FIG. 4

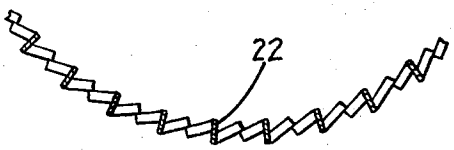

FIG. 5

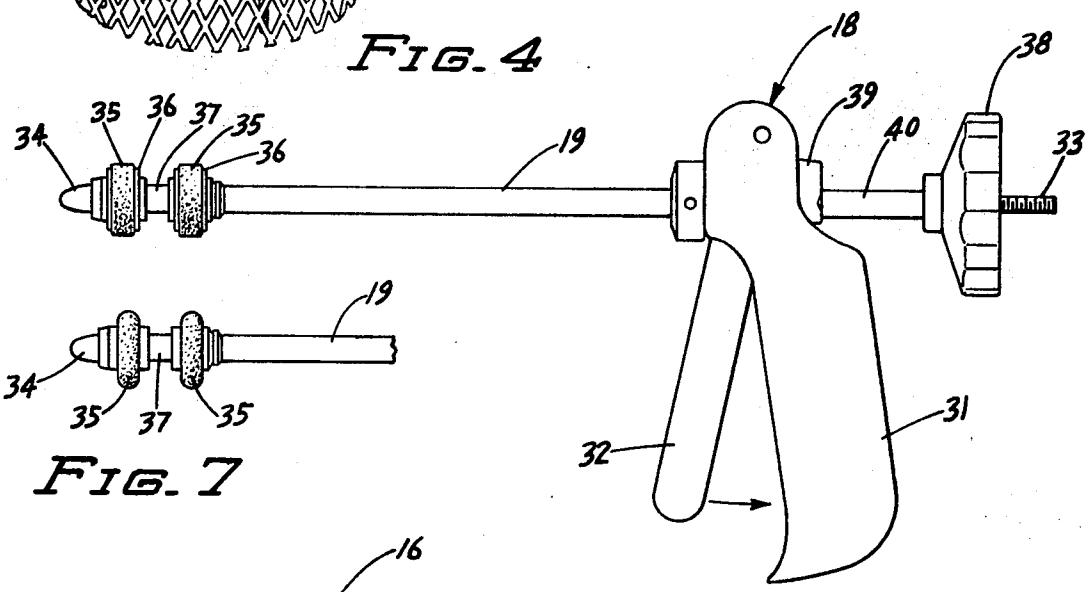

FIG. 6

FIG. 7

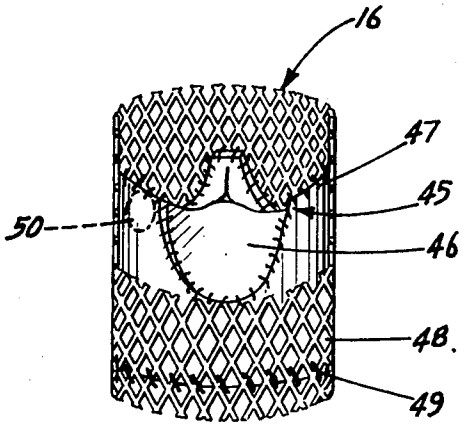

FIG. 8

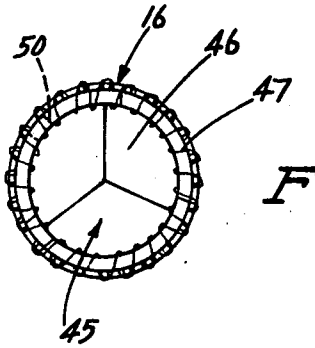

FIG. 9

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METHOD FOR FIXING PROSTHETIC IMPLANTS IN A LIVING BODY

This invention relates to a device and method for the rapid positive fixation of implanted prosthetic members in a living being. Many thousands of implants of prosthetic members, either artificial members or homografts or grafts from other animal species are made annually. Vessel grafts and heart valve implants are becoming commonplace. Transplantation of large organs such as the heart, lungs, liver, etc. is taking place in ever increasing numbers.

The fixation device according to the present invention comprises a tubular sleeve of deformable material to which the prosthetic member is secured and which is capable of being expanded radially into intimate engagement with the tissue surrounding the implant situs. It has been found through animal experimentation that the implant may be made rapidly and positively, without fear of dislodgment or leakage. When formed of a compatible material, the fixation device is well tolerated by the body and becomes completely covered by tissue leaving no exposed surface for the formation of clots and thrombi.

According to the prior art, artificial heart valves are installed by the careful placing of a plurality of stitches around the rim of tissue that will house the valve. These stitches are passed through a suture ring around the outside of the heart valve. The valve to be implanted is held outside of the heart 6 or 8 inches and each stitch is brought up through the suture ring while the valve is still so held. When the sewing is finished, the valve stands some distance above the heart and has 20 or 30 sutures going down to the tissue where it will finally rest. The sutures are held tight and the heart valve is slid down them into place and each suture is then individually tied. This process takes 30 to 45 minutes in the best hands and from an hour to an hour and one-half in the less then best.

In the case of the transplantation of a graft valve from another patient or from an animal, sewing takes more than an hour. Although excellent results have been reported with these transplanted valves, few surgeons are using them today because of the great time that must be taken to sew them in. Valve installation takes place while the patient is on an artificial heart-lung machine and every minute is very important.

One form of prior art heart valve is available wherein a caged ball valve is provided in its outer rim with a plurality of radially extending teeth which by screw means are caused to engage the aortic wall. Such valves, though expensive, are satisfactory where there is a very tight initial fit and where the aortic wall is of uniform consistency and size, conditions which cannot always be depended upon to exist. Accordingly, problems have arisen relating to aortic incompetence due to blood flow working its way between the prosthesis and the aortic wall in the many instances where no positive fixation is achieved by the tooth members.

The device of the present invention permits instant and positive fixation of heart valves, vessel grafts and other prosthetic members. The valve or other prosthetic member is prepared for implantation by attachment to the openwork sleeve. The valve and its skirt composed of the sleeve is assembled on an expanding tool device. This assembly can be quickly and easily forced into place and the tubular sleeve expanded to hold the valve or other member in place. This is done in a small fraction of the time required for other transplants so that in many instances use of the heart-lung machine is not required. The fixation sleeve expands so that a snug fit is assured regardless of the size, shape or consistency of the tissue wall at the implantation situs. Since the sleeve becomes incorporated into the tissue wall, no foreign material is left in contact with the blood, as opposed to prior art devices.

The invention is illustrated by the accompanying drawings in which:

FIG. 1 is a schematic view showing three stages of the grafting of an artificial bifurcation vessel graft utilizing the fixation device according to the present invention;

FIG. 2 is a perspective schematic view of one modified form of prosthetic fixation device;

FIG. 3 is a perspective view of another modification;

FIG. 4 is a perspective view of a further modification;

FIG. 5 is a schematic representation of a portion of the perimeter of any one of the devices of the preceding FIGS., as seen in transverse section;

FIG. 6 is an elevation of one form of expanding tool which may be utilized with the fixation device;

FIG. 7 is a fragmentary elevation of the operating end of the expanding tool showing the tool in expanded condition;

FIG. 8 is a perspective elevational view with the upper half of the fixation device in section, and showing the fixation device with a heart valve attached for implantation; and

FIG. 9 is a top plan view of the assembly of FIG. 8.

Referring to the drawings, and particularly to FIG. 1, there is shown schematically one manner in which the prosthesis fixation device according to the present invention is used. This use is illustrated with respect to the implantation of an artificial bifurcated aortic Dacron graft, indicated generally at **10**, between the severed aorta **11**, shown with a Satinsky clamp preventing flow, and the common iliac arteries **13** and **14**. A completed joint is shown between the artery **13** and one branch **15** of the artificial vessel transplant. The ends of the artery and prosthesis are in butting relation held by an expanded fixation sleeve, indicated generally at **16**, within the host-prosthesis junction. A similar sleeve **16** is shown partially within the branch **17** of the prosthesis **10** about to be connected to the artery **14**.

The manner in which the junction is made is shown with respect to the severed end of the aorta **11**. An expandable sleeve fixation device **16** is shown extending from the end of the artificial vessel graft **10** with about half of its length engaging the inside wall of the graft. The head of an expander tool, indicated generally at **18**, whose tubular barrel **19** extends through a slit **20** in the graft, is positioned within the sleeve. A tapered tip **21** placed on the end of the expanding tool facilitates entry of the assembled graft, tool and fixation device **16** into the aorta. When in place, with the ends of aorta **11** and graft **10** butting, the sleeve is expanded by operation of the expanding tool to force the fenestrations of the sleeve into the wall of the aorta to achieve a leak-proof union and forcing the walls of the sleeve into tighter engagement with the inside wall of the graft **10**.

After the sleeve is expanded, the tool is withdrawn. A smaller headed tool is inserted through slit **20** from the opposite direction to within the fixation device **16** of lesser diameter for connection with artery **14**. The exposed end of sleeve **16** is inserted into the lumen of the artery **14** and the sleeve is expanded to make the joint. The tool is withdrawn, slit **20** is clamped shut and clamp **12** is removed to permit resumption of blood flow. The entire transplant can be made in a matter of a very few minutes to the point of restoration of the blood supply. The longitudinal slit in the graft may then be sewn closed at leisure in confidence that the blood is being supplied distal to the graft site.

The tubular sleeve **16** is made of deformable material such that it retains its expanded dimensions after expansion in place. It is formed from a non-toxic material compatible with blood and other body fluids, such as stainless steel. Its walls desirably have a large percentage of open area so as to permit proliferation of the intima of the vessels through the openings and over the intervening strand-like or ribbon-like members. Preferably the openwork sleeve is formed from so-called "expanded metal" sheeting which is produced by forming a series of staggered parallel slits in an impervious metal sheet and then stretching the sheet in a direction perpendicular to the slits to open the slits into apertures and expand the metal sheet in that direction while contracting it slightly in the opposite direction. The stretching operation by which the metal sheet is expanded imparts a twist or bend to the undulating flat ribbon-like portions **22** of the metal sheet separating the diamond-shaped apertures **23** which are generally uniformly sized and distributed. This twisting or bending of the metal members **22** between adjacent apertures imparts an angle or direction to the apertures themselves and to the ribbon-like members.

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The expanded metal sheeting is desirably not flattened prior to forming into a sleeve. The result, as seen schematically in FIG. 5, is that the ribbon-like portions 22 of the sleeve extend angularly relative to the perimeter of the sleeve providing a multitude of narrow projecting edges which embed themselves into the tissue wall upon expansion of the sleeve. After being formed with the members 22 extending generally longitudinally, the sleeve is desirably spot welded to form a longitudinal seam. The tubular sleeve may be circular, oval, or polygonal (hexagonal, octagonal or the like) in cross-section. The cross-sectional area may be uniform along the length of the sleeve or it may vary, giving the sleeve generally a barrel shape or that of a truncated cone. The edges may be cuffed if desired or simply smoothed to facilitate entry. The sleeve may easily be expanded by about 50 percent beyond its original diameter. The sleeves are formed to be a size appropriate for the implant being made. The strands 22 and apertures 23 are sized proportionately.

Because of the twisted relation of the ribbon-like portions of the sleeve, protrusion of the vessel lining is facilitated with the result that very little metal is actually in contact with the blood stream. Experimentally it has been determined that within a few seconds a fine clot layer is laid down over the stainless steel struts forming a physiological bridge from the islands of intima where the vessel lining protrudes through the apertures in the sleeve.

Instead of metal, the tubular fixation sleeve may be formed from other natural or synthetic materials having the requisite properties and characteristics permitting the sleeve to be expanded into secure attachment with surrounding tissue. Desirably the material is one which is capable of being absorbed over an extended period of time by the tissue to which the sleeve is attached. A number of such absorbable materials are known.

In the form of fixation device shown in FIG. 2, sleeve 16A is provided with a plurality of circular holes 24 (which are of larger area than apertures 23) punched through the openwork wall around the sleeve adjacent one end to allow for the ostia of the coronary arteries.

In FIG. 3, a modified form of sleeve 16B is provided with a plurality of relatively large rectangular openings 25 extending longitudinally to permit exposure of wide areas around the coronary artery ostia. This form of fixation device is intended for the implantation of heart valves. The valve is hung with its commissures secured along the upper and lower ring portions 26 and 27, respectively, whose widths are about one-eighth to one-fourth the length of the sleeve.

In FIG. 4, the fixation device includes a plurality of longitudinal wire struts 28 separating two expandable and relatively narrow metal mesh ring sections 29 and 30. A three-pronged commissure valve is inserted in the upper expandable ring section 29 and secured to the bottom mesh ring 30 circumferentially.

A variety of expanding devices may be used to set the fixation devices in place. One form of such tool is shown in FIG. 6. The device includes a pistol-grip handle 31 and a trigger-like operating lever 32 pivoted therein. An elongated tubular barrel 19 extends out from the handle means. A concentric rod 33 extends through the handle 31 and barrel 19 terminating in a fitting 34 beyond the muzzle end of barrel 19 at its forward tip. Expansion means, comprised of a pair of resilient rings 35, each held between a pair of washers 36 and held spaced apart by a rigid spacer ring 37, are disposed between the muzzle end of barrel 19 and tip fitting 33. Operation of the lever 32 by gripping and squeezing to move it toward the handle causes rod 33 to shorten its exposed length in relation to barrel 19 such that squeezing force causes the resilient rings to decrease their longitudinal dimensions. Being non-compressible, they expand radially outwardly increasing their lateral dimensions, as shown in FIG. 7. In this way, a predictable dependable amount of expansion can be achieved. The breech end of rod 33 is threaded and fitted with a knurled knob 38. The heel 39 of operating lever 32 bearing against a spacer tube 40, which in turn bears against knob 38, causes the relative movement between barrel 19 and rod 33. Alternatively, force may be exerted simply by rotation of knob 38 and adjustment of the at-rest force exerted upon the expansion rings may be made. One, two or more expandable rings 35 may be used. The pattern of expansion can be predetermined as desired by selection of appropriate spacing between those rings.

When used for the installation of artificial vessel grafts made of Dacron, Teflon or similar artificial materials, the fixation sleeve is attached to the vessel graft some time prior to surgery and a longitudinal slit is made in the middle of the graft for the introduction of the expansion tool. At the time of surgery, the ends of the vessel to be grafted are secured through simple stay stitches or small clamps so that the fixation sleeve can be introduced thereto. The expander tool is in place in one of the sleeves at the time of introduction. This sleeve is then expanded in situ and the expander tool is removed through the longitudinal slit, turned around and used to expand the fixation sleeve at the other end and again removed. The longitudinal slit is clamped and the clamps or stitches securing the vessels to be grafted are removed to restore the blood flow. Very rapid fixation of vessel grafts is thus possible.

In FIG. 8 there is shown an aortic heart valve 45 in place in a fixation sleeve 16. The rim of valve 45 adjacent the cusps 46 is attached by sutures 47 to the sleeve near one end. A segment of the donor aorta 48 is attached by sutures 49 near the other end of sleeve 16. The opening 50 in the aorta wall for a coronary artery can be matched with the corresponding opening in the wall of the donee aorta.

When used for the fixation of heart valves, whether a transplant or artificial, the valve is secured within the fixation sleeve prior to surgery and the sleeve is assembled in the expansion tool. Then, at the time of surgery, the sleeve is rapidly expanded into place and the tool withdrawn. When used for implantation of heart valves in the aortic position, a total introduction time of only a few minutes is necessary. This means that an aortic valve may be placed without use of a heart-lung machine. Inflow of blood into the heart is occluded by placing clamps across the appropriate vessels. A longitudinal slit (aortotomy) is placed in the aorta just a few centimeters above where it begins. This slit is opened and the existing defective valve is removed. The new valve housed in the expandable sleeve is then placed in position and the sleeve is expanded in one stroke of the expanding tool. The expansion tool is then removed through the aortic slit and a clamp placed over it, thus allowing the restoration of blood flow so that only a few minutes total introduction time is required. The aortotomy can then be repaired at leisure after the heart has taken over its pumping function.

It is apparent that many modifications and variations of this invention as hereinbefore set forth may be made without departing from the spirit and scope thereof. The specific embodiments described are given by way of example only and the invention is limited only by the terms of the appended claims.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A method for rapidly and positively fixing an inplanted prosthetic device in a living body which comprises:

A. securing the prosthetic device to be implanted to at least one openwork tubular sleeve of non-toxic deformable material compatible with body fluids and capable of being expanded radially, said sleeve being of a diameter corresponding to the prosthetic member to be implanted and adapted for attachment to the prosthetic member, and including a plurality of longitudinally extending ribbon-like undulating portions disposed angularly with respect to the perimeter of said sleeve and interconnected to define a plurality of staggered closely spaced apertures,

B. introducing the sleeve and prosthetic device into a prepared transplant situs, and

C. expanding the sleeve radially outwardly against the tissue walls of said situs and forcing the undulating ribbon-like

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