A method and device for reducing constriction of the lumen of a tubular organ during healing subsequent to an operation. A device such as an implant is introduced into a tubular organ at least at the region thereof where surgical procedures are performed with the implant being capable of supporting the tubular organ at this latter region in such a way that it will prevent the tubular organ from becoming constricted due to compressive forces resulting from the formation of scar tissue. Preferably the implant extends along the interior of the tubular organ not only at the region where scar tissue forms but also in opposite directions beyond this region with the implant having a construction which will permit pumping action of the tubular organ to continue while the tubular organ is supported to oppose the action by the scar tissue which tends to contract the tubular organ.

24 Claims, 27 Drawing Figures
METHODS AND DEVICES FOR REDUCING LUMEN CONSTRICTION

BACKGROUND OF THE INVENTION

The present invention relates to implanting methods and implants capable of reducing constriction of a tubular organ of a living being as a result of the formation of scar tissue. As is well known, when an implant is to be introduced into a tubular organ of a living being such as a human being, surgical procedures are necessarily performed at the region of the tubular organ so as to provide access to the interior thereof. After obtaining this access to the interior of the tubular organ, an implant is conventionally introduced into the tubular organ, and then surgical procedures are performed in order to close the incision or the like which is formed in order to have access to the interior of the tubular organ. As a result of these surgical procedures scar tissue or fibroblasts will form during the healing process. It has been found that such scar tissue will generate compressive forces on the tubular organ which may tend to contact the tubular organ so that the interior volume thereof becomes constricted.

Thus, it is essential to carry out the surgical procedures in connection with introducing the implant into the tubular organ at a given region which extends through a given distance along the tubular organ, and along this latter distance the scar tissue will form, generating forces which are directed inwardly toward the lumen for reducing the interior cross section of the tubular organ, sometimes to such an extent that it becomes completely closed. In the event that the implant is shorter than the region along which the scar tissue grows, the tubular organ may become closed or nearly closed at a region upstream or downstream or both upstream and downstream of the implant.

The above problem is encountered at various parts of the body where tubular organs are situated. For example, one type of implant is a vas value to be introduced into a vas deferens for reversibly interrupting the flow of sperm-carrying fluid therethrough. If the implant in this case does not extend along the interior of the vas throughout and beyond the range where scar tissue forms along the exterior of the vas, the vas will become constricted due to the formation of the scar tissue to such an extent that even when the vas valve is open an inadequate flow of sperm-carrying fluid will result.

A further example of regions where the above problem is encountered is in connection with tubular body conduits such as blood vessels. Thus, it is known that in connection with surgical procedures or wounds resulting from injuries or the like it is necessary to splice separated portions of such a conduit together. This procedure may conventionally be performed by connecting the severed ends of a body conduit together while situating in the interior of the conduit a tubular structure which extends across the severed ends which are surgically connected to each other. In this case also where the implant does not extend through and beyond the region where scar tissue subsequently grows, the body conduit will become undesirably constricted as a result of the formation of the scar tissue, and the flow of body fluid will be undesirably constricted, creating problems similar to those which are encountered in connection with various types of sclerosis such as arteriosclerosis and arteriolosclerosis.

SUMMARY OF THE INVENTION

It is accordingly a primary object of the present invention to provide an implanting method and implant which will avoid these problems. In particular, it is an object of the present invention to provide an implanting method and implant capable of supporting a tubular organ at the interior thereof in such a way that the tubular organ will not become undesirably constricted due to formation of scar tissue. Also it is an object of the present invention to provide an implanting method and implant which will prevent kinking of a tubular organ so that flow of a fluid therethrough will not be prevented by kinks which might otherwise form.

In addition it is an object of the present invention to provide in the case of vas value implants, a method and apparatus for reliably preventing any possibility of sperm bypassing the valve along the exterior thereof.

When surgical procedures are performed such as in connection with introduction of an implant into a tubular organ, there is a region along the exterior of the tubular organ where scar tissue will grow during healing. According to the invention the implant has a length sufficiently great to enable it to extend through and beyond the region of the tubular organ where scar tissue forms at the exterior of the latter, with the implant being capable of supporting the tubular organ in such a way that it will not become constricted due to the formation of scar tissue.

The implant of the invention preferably extends not only along the interior of the tubular organ at an operative region where scar tissue forms, but also in opposite directions beyond the operative region into non-operative regions of the tubular organ where scar tissue does not grow, the implant having a pair of elongated flexible means which extend in opposite directions into the latter non-operative regions in such a way that these regions cannot kink but instead remain flexible and are capable of contracting and expanding to perform a pumping action such as a peristaltic action, so that kinking of the tubular organ is prevented and constriction due to formation of scar tissue is also avoided.

BRIEF DESCRIPTION OF DRAWINGS

The invention is illustrated by way of example in the accompanying drawings which form part of this application and in which:

FIG. 1 is a schematic illustration of the problem which is solved by the present invention;
FIG. 2 schematically illustrates a solution to the problem with the method and implant of the invention;
FIG. 3 illustrates a specific type of solution to the problem, in accordance with the invention;
FIG. 4 is a schematic longitudinal sectional elevation of a specific vas value implant and implanting method of the invention, including a sperm barrier;
FIGS. 5-7 are respectively transverse sections taken along lines 5—5, 6—6, and 7—7 of FIG. 4 in the direction of the arrows;

FIG. 8 illustrates how an arrangement as shown in FIG. 6, for example, enables the pumping action to continue;

FIGS. 9-12 respectively illustrate different possible embodiments of elongated means which may be used with and form part of implants of the invention, to carry out the method of the invention;

FIG. 13 is a fragmentary schematic longitudinal sectional illustration of yet another embodiment of a method and implant of the invention;

FIG. 14 is a transverse section taken along line 14—14 of FIG. 13 in the direction of the arrows;

FIGS. 15-21 respectively illustrate various embodiments of the invention, in connection with tubular organ implants, in schematic longitudinal sectional elevations;

FIG. 22 is a longitudinal schematic sectional elevation of yet another embodiment where structure is placed around the exterior of the tubular organ;

FIG. 23 shows yet another embodiment of the invention where a temporary support is provided to oppose constriction of the tubular organ;

FIG. 24 illustrates a further embodiment of the invention where a cluster of dissolvable particles oppose constriction of a lumen;

FIG. 25 is a schematic illustration of a method according to which it is possible to manufacture a further embodiment of an implant according to the invention; FIG. 26 illustrates the implant resulting from the method of manufacture shown in FIG. 25 situated in a tubular body organ; and

FIG. 27 is a schematic fragmentary illustration of a sperm barrier utilized with vas valve implants and implanting methods according to the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIG. 1, the problem solved by the present invention is illustrated therein. Thus, FIG. 1 schematically illustrates part of an elongated tubular body organ 20. This tubular body organ may be a vas deferens, a blood vessel or any tubular body conduit for conveying a body fluid. It is assumed that an implant 22 is to be situated in the tubular organ 20 in the manner illustrated schematically in FIG. 1 which shows the previously formed incision closed at 23. This implant 22 will have a tubular construction enabling a body fluid to flow through the organ 20 after the implant 22 has been introduced. Thus in the case of a vas deferens, the implant 22 may have a valve structure for reversibly interrupting the flow of sperm-carrying fluid, or in the case of a blood vessel which has been ruptured or severed for any reason, the implant 22 will be in the form of a simple splicing tube situated in the interior of the organ 20 extending across the parts of the tubular organ 20 which are connected together. The implant has at its exterior a means 25 for promoting the ingrowth of tissue.

In any case, in order to introduce the implant 22, surgical procedures will be performed at the region 24 of the body tissue which surrounds the tubular organ 20 and which is indicated by the dot-dash line. This region 24 may be considered an operating or operative region where an incision is formed so as to give access to the interior of the tubular organ 20. It is in this region 24 that scar tissue forms during healing of the tissue surrounding the tubular organ 20 after the implant 22 has been introduced. As may be seen from FIG. 1, the incision area 24 where scar tissue forms extends beyond the ends of the implant 22. Thus, after the incision is made and closed subsequent to the introduction of the implant 22 into the tubular organ 20, the tissue heals at the region 24. During healing the tissue swells and fibroblast growth takes place during healing. This fibroblast or scar tissue is very tough and grows rapidly. Upon healing, the scar tissue presses radially inwardly against the wall of the tubular organ 20, as indicated by the arrows 26, causing constriction and collapse of the wall of the tubular organ 20, particularly at locations just beyond the ends of the implant 22. Thus, this radial inwardly directed pressure resulting from the formation of the scar tissue may close and seal the tubular organ 20 for a period which may last for many months and even years. In the case of a vas deferens, such unforeseen closure thereof may go unnoticed for such a long period of time, whereas in the case of a blood vessel, any appreciable constriction of this type will create serious problems such as those encountered with sclerosis conditions.

Referring now to FIG. 2, the principles of the present invention are illustrated therein. Thus, FIG. 2 shows an elongated body organ 20 which may be the same as that illustrated in FIG. 1. FIG. 2 also shows the region 24 which may be considered the surgical or operative area, whereas non-surgical regions are indicated beyond the region 24 where the scar tissue grows. FIG. 2 also illustrates an implant 27 replacing implant 22 shown in FIG. 1.

According to the invention the implant 27 has connected thereto a pair of elongated means 28 which extend in opposite directions from the intermediate part of the implant which is designed to perform a specific function such as reversibly interrupting the flow of sperm-carrying fluid or forming a splice between severed portions of a blood vessel. The pair of elongated means 28 which thus form implant extensions are sufficiently long to extend beyond the area 24 into the non-surgical areas 30 where scar tissue does not grow. These elongated means 28 may have any one of several constructions referred to in detail below, according to which they are capable of supporting the tubular organ 20 in the interior such a way that inward constriction of the tubular organ cannot occur in the manner described above in connection with FIG. 1.

A specific example of the present invention which has been used in practice is illustrated in FIG. 3. In FIG. 3 the tubular organ 20 is a vas deferens which in the illustrated example receives a two-piece vas valve 32 through incision 35. This two-piece vas valve has a left section 34 joined to a right section 36, as viewed in FIG. 3. One of the advantages of the two-piece vas valve 32 is that the incision required for such a vas valve can be made extremely small so that the surgical area 38 in the case of FIG. 3 is limited as compared to conventional surgical areas in connection with gaining access to the interior of a tubular organ. Thus, because the valve 32 is made in the separate sections 34,36, an extremely short incision will enable the separate sections 34 and 36, to be independently introduced while they are separate from each other, and thereafter they can be joined together. In this way the extent to which the surgical operations must extend longitudinally
along the tubular organ 20 is reduced, and the length of the sections 34 and 36 after they are joined to each other is such that the assembled vas valve 32 extends throughout the region 38 and beyond the latter into the non-surgical areas 40 where the opposed free end regions of the sections 34 and 36 are situated in areas of the tubular organ 20 which are free of the trauma resulting from the surgical procedures at the region 38. Actual experience with this type of implant has demonstrated that immediately after introduction of the implant, when it is maintained open until healing is completed, and throughout the healing period, a full uninterrupted flow of sperm-carrying fluid is maintained, as demonstrated by actual sperm counts taken under the above conditions. In contrast, with an arrangement as shown in FIG. 1 where the implant 22 is in the form of a vas valve, the sperm count is greatly reduced as compared to that which is achieved with the arrangement of FIG. 3, demonstrating that the scar tissue substantially restricts the tubular organ 20 at the regions thereof located just beyond the implant 22. Thus, by resorting to the implanting method and implant of the invention, as demonstrated in FIG. 2 for a general case, it is possible to avoid the above problems.

Referring to FIG. 4, a specific application of the present invention is illustrated therein. Thus, FIG. 4 shows a pair of sections 42 of a vas which has been cut through between these sections so as to receive the implant 44 which in the illustrated example is a vas valve having intermediate its ends the valve assembly 46 capable of opening and closing the elongated tubular means 48 which is rigid and which extends into the lumen of the sections 42 in the manner illustrated schematically in FIG. 4. This structure carries at its exterior a tissue-ingrowth means 50 for promoting the ingrowth of tissue at the exterior of the elongated tubular means 48. In accordance with the features of the present invention the space between the vas sections 42 is filled with a barrier means 200 surrounding and covering the part of the valve assembly 46 which is situated in this space. The barrier means 200 is in the form of any jelly or other relatively thick highly viscous substance such as a medical silicone paste. Thus if it should happen that any sperm should travel along the exterior of the implant and reach the space between the vas sections 42, such sperm will be incapable of travelling through the space between the vas sections 42 from one of these sections to the other because the thick paste or jelly which forms the barrier means 200 will prevent the sperm an obstacle through which the sperm cannot travel. In this way bypassing of the valve by sperm is reliably avoided.

In accordance with the invention, a pair of elongated means 52 are connected with the tubular means 48 at the opposed end regions thereof. These elongated means 52 may have a press fit into the interior of the tubular means 48. As is apparent from FIGS. 5–7, the elongated means extending from each end of the tubular means 48 has a central region 54 extending along the axis of the lumen and a plurality of ribs 56 projecting radially from the central region 54. Each elongated means 52 is made of a flexible plastic material compatible with human tissue. Thus, in the illustrated example each elongated means 52 has the cross section of a cross. The ribs 56 terminate in outer edge regions which extend along the inner surface of the tubular organ 42. Moreover, as is apparent from a comparison of FIGS. 5–7 and as is illustrated in FIG. 4, each elongated means 52 tapers so as to terminate in a small tip situated distant from the tubular means 48. As a result of the use of such elongated means 52, the tubular organ 42 will be supported at its interior against constriction resulting from growth of scar tissue, inasmuch as the total length of the implant, between the outer tips of the elongated means 52, is considerably longer than the region where scar tissue will grow, this region being occupied at least partly by the rigid tubular means 48. Because of the flexibility of the elongated means 52, the tubular organ can bend without kinking, so that it cannot become closed by kinking. At the same time, the elongated means 52 has a strength sufficient to prevent inward constriction of the tubular organ at those parts thereof where scar tissue grows and where the thicker parts of the elongated means 52 are located at the region of the ends of the tubular means 48.

Moreover, it will be noted that free hollow spaces are left in the interior of the tubular organ on opposite sides of each of the ribs. This is a further important feature of the invention as may be seen from a comparison of FIGS. 6 and 8. A tubular organ such as a vas deferens or other tubular organs function to pump a body liquid along the interior of the tubular organ by an action such as a peristaltic action during which the tubular organ forms convolutions which move longitudinally along the tubular organ. Because of the construction of the elongated means 52 it is possible for tubular organ to contract into the spaces between the ribs 56, assuming a configuration as illustrated schematically in FIG. 8, and thus the pumping action can proceed so that the body fluid can be pumped even though the tubular organ is supported at its interior against undesirable constriction from the growth of scar tissue. Thus, FIG. 6 may be considered as showing the tubular organ in a substantially open condition while FIG. 8 may be considered as showing a peristaltic constriction which the organ assumes for carrying out a pumping action.

The above-described configuration of the elongated means 52 is highly desirable but is not essential. Thus FIG. 9 shows an elongated means 60 of V-shaped configuration situated in a tubular organ 62. FIG. 10 shows an elongated means 64 in the form of a simple strip having only a pair of opposed edge regions next to the inner surface of the tubular organ 66. FIG. 11 shows an elongated means 68 also made of a flexible plastic sheet material and having a substantially U-shaped cross section so that while it supports the tubular organ 70 against contraction from scar tissue nevertheless the flexibility of the elongated means 68 permits a pumping action to take place as described above. FIG. 12 shows an elongated means 72 also made of a flexible plastic material, as is the case with the above embodiments of the elongated means of the invention, but in this case the elongated means 72 is of a spiral-shaped cross section. Thus, the tubular organ 74 will also be prevented by such a construction from collapsing due to the inward radial pressure of scar tissue while at the same time it is possible for the elongated means 72 to yield and expand as a result of peristaltic action or the like.

Any of the embodiments of FIGS. 9–12 may be substituted for that of FIGS. 5–8 and connected in the same way to tubular valve portions 48.

A further possible embodiment of the invention is illustrated in FIGS. 13 and 14 where a tubular means 76
corresponding to any of the tubular means described above is shown in a tubular organ 78. This tubular means 76 fixedly carries at its interior in the region of its opposed ends a ring 80 fixed to free ends of elongated extremely fine filaments or wires 82 which project freely beyond the tubular means 76 at each of the ends thereof, only one of these ends being shown in FIG. 13. The extent to which the bundle of filaments or wires 82, which are flexible, extend beyond the tubular means 76 at each of the ends thereof is sufficient to locate these filaments or wires well beyond the region where scar tissue will grow. Only a small number of filaments 82 are shown for the sake of clarity. Such bundles of filaments or wires are capable of moving inwardly toward each other and spreading apart from each other so that they also will prevent constriction due to scar tissue while at the same time enabling traveling contractions to occur in connection with the pumping action.

In conjunction with FIGS. 13 and 14, the filaments 82 may be held together in any suitable way if necessary to facilitate insertion thereof. Thus, the surgeon may hold the filaments together with a finger. However, if desired, the filaments may be embedded in a body of gelatin which dissolves subsequent to insertion. Also, the filaments 82 may be made of the same material as known dissolving sutures so that after healing is completed the filaments will be absorbed and entirely disappear.

Referring to FIG. 15, the implant illustrated therein in the tubular body 20 which may be the vas deferens is in the form of an elongated valve means 84 having a central valve section 86 and a pair of elongated tubular portions 88 respectively extending in opposite directions from the central valve section 86 through the area 90 where scar tissue subsequently grows into the areas 92 where scar tissue does not grow. These elongated tubular portions 88 each have next to the central valve section 86 a section 94 which is flexible so that in this way kinking of the tubular organ will be avoided, while beyond these flexible sections 94 each tubular portion 88 has a section 96 carrying a tissue-ingrowth means 98 such as a suitable wire wound around the cylindrical free end portion 96 which extends into the area where scar tissue does not grow. The flexible portions 94 are fully capable of opposing constriction due to formation of scar tissue. They are formed by circular convolutions so that each section 94 has a construction similar to a bellows and while made of metal is nevertheless thin enough to flex to prevent kinking. The material used for the tubular portion as well as the remainder of the valve is any material compatible with the human body, such as gold, for example.

After obtaining access to the interior of a tubular body organ for any reason, an implant of the invention, illustrated in FIG. 16, for example, may be introduced only to prevent constriction of the lumen. In the embodiment of FIG. 16 the elongated implant 100 has a single elongated continuous tubular portion 102 which is flexible along its entire length and formed of convolutions so as to have the bellows-type of construction referred to above in connection with sections 94. In this case the entire exterior surface of the elongated flexible tube 102 carries the tissue-ingrowth means 104 which may be in the form of a suitable filament wound around the tube 102 as illustrated in FIG. 16.

FIG. 17 shows an embodiment of the invention where the control means formed by the implant is not a valve (FIGS. 3, 4, and 15) or a tube (FIG. 16) but instead has a central control region 106 to act on the fluid differently in different positions, as shown, for example, in U.S. Pat. No. 3,742,933. However, in this case the elongated tubular portions 108 which are of constant diameter and which are substantially rigid are located next to the central control organ 106 and carry the tissue-ingrowth means 112 while beyond these portions 108 the elongated tubular portions are each provided with the flexible bellows-type of construction 114 according to which the circular convolutions are arranged as illustrated.

With the embodiment of FIG. 18 the central control means 106 is shown in a position different from FIG. 17 and the elongated tubular portions 120 carry the tissue-ingrowth means 122 so that except for the convoluted outer free end portions 114 the embodiment of FIG. 18 is identical with that of FIG. 17. According to FIG. 18 a pair of elongated coil springs 124 are pressed at their inner ends onto free ends of the portions 120 so that these coil springs, also made of any suitable wire which is compatible with the human body, such as gold wire, for example, will permit the tubular organ to flex, thus avoiding kinking thereof, while at the same time these coil springs are capable of opposing any tendency for the organ to become constricted due to formation of scar tissue.

In the embodiment of FIGS. 17 and 18, the central control region 106 has its rotary body 110 formed with a through-bore 117 which extends along the axis of the body 110 and with a U-bore 118 which bypasses the bore 117. In the position of FIG. 17 the V-bore 118 provides communication between the tubular portions 108 while the bore 117 is closed. In the position of FIG. 18 the bore 117 provides communication between the tubular portions 120 while the V-bore 118 is closed. These bores 117 and 118 may carry at their surfaces suitable chemicals or other deposits for acting on the body fluid in any desirable manner, or only one of the bores may have such a coating at its inner surface while the other bore is uncoated. In this way without acting to regulate the fluid flow in any way it is possible to influence the body fluid in different ways.

According to the embodiments of the invention which is illustrated in FIG. 19, the control means formed by implant 124 is also in the form of a valve means or other means for acting on the body fluid and adapted to be introduced into a tubular organ, as illustrated. In this case also the control means 124 has the central control region 126 and the pair of substantially rigid elongated tubular portions 128 respectively carrying the tissue ingrowth means 130 and extending along the region where scar tissue will normally grow. However, in this case the walls which form tubular portions 128 extend along the entire length of the implant between the opposed ends thereof but beyond the region which carries the tissue ingrowth means 130. Where these walls extend beyond the scar tissue region they have been cut through with a suitable tool along a spiral path so as to form in this way elongated spring extensions 132 which are integral with and extend from the solid wall sections 128. These sections 132 will perform in the same way as the springs 122 described above in connection with FIG. 18.
FIG. 20 illustrates an embodiment of the invention where in the illustrated tubular body organ 20 there is introduced an implant in the form of a control means 134 having the central control region 136 and the pair of elongated tubular portions 138 respectively extending in opposite directions from the central valve sections 136 and carrying the tissue ingrowth means 140. According to this embodiment a pair of elongated cylindrical highly porous cylinders 142 of a material such as that used for dissolving sutures are initially situated in the interior of the tubular portions 138 and extend freely beyond the latter through a distance as illustrated in FIG. 20. These cylinders 142 do not appreciably oppose the flow of a body fluid and are capable also of supporting the tubular organ 20 against constriction during healing but at the same time they are capable of being absorbed into the system while they dissolve so that eventually they will disappear leaving subsequent to complete healing only the valve means 134 without the plugs 142. In this way also it is possible to oppose constriction due to formation of scar tissue while leaving the tubular organ in its initial condition except for the implant 134.

In the embodiment of the invention which is illustrated in FIG. 21 there is a control means 134 identical with the control means 134 of FIG. 20 and carrying the tissue ingrowth means 140 in exactly the same way at the tubular portions 138. However, in this case instead of cylinders 142, elongated tapered convoluted tubular extensions 144 are provided. These extensions have inner cylindrical hollow portions 146 which are received in the interior of the portions 138 as illustrated. These tapered portions 144 which thus also have the circular convolutions forming a bellows type of construction will provide the required flexing to prevent kinking but at the same time opposing any tendency of construction due to formation of scar tissue.

According to the embodiment of the invention which is illustrated in FIG. 22, the control means 148 is also shown as situated in a tubular body organ 150 extending between the parts thereof into which the tubular portions 152 of the control means extend as illustrated. These tubular portions carry the tissue-ingrowth means 154 in the form of a porous matrix or of a wire, for example, wound around the exterior of the tubular portions 152. These portions 152 extend through and beyond the area where scar tissue will form so as to oppose any tendency for constriction to take place. However, with this embodiment after the implant is introduced the surgeon will wind a springy wire 156 of gold, platinum, or other material which is compatible with the human body around the exterior of the organ 150 so as to achieve a construction as illustrated in FIG. 22. With this located the springs 156 form a means located around the exterior of the tubular organ to permit the latter to flex without kinking. According to the embodiment of the invention which is illustrated in FIG. 23, any tubular organ 160, such as any blood vessel, for example, may be repaired as by having a severed portion interconnected through the sutures 162. However, prior to interconnecting the severed portions of the tubular organ 160 the elongated implant 164 is introduced. This implant 164 in this case is formed in its entirety of an elongated cylindrical tube of a material capable of being dissolved and absorbed into the system such as the material used for dissolving sutures. Thus the elongated tube 164 is introduced into the tubular organ 160 so that it will assume a position as indicated in FIG. 23. With this construction the tubular organ will resume its initial condition after healing with the entire implant 164 disappearing completely. It is to be noted that the elongated tube 164 will support the tubular organ against constriction while permitting the required body fluid to flow through.

Of course, as was pointed out above in connection with FIGS. 13 and 14, the filaments 82 may be situated in a body of gelatin or other material which will dissolve so as to facilitate introduction of the filaments 82, and in this case these filaments 82 will be located in a material such as that used to form the implant 164 of FIG. 23, and in fact the arrangement of FIG. 23 may be used in combination with the arrangement of FIGS. 13 and 14 for the purpose of holding the filaments 82 properly during insertion of the implant.

According to the embodiment of the invention which is shown in FIG. 24, the tubular body organ 160 may be identical with that of FIG. 23. After it has been cut through for any reason, the ends may be held together upon closing of the tubular organ by sutures 162, as pointed out above in connection with FIG. 23. However, in this case the implant 166 is composed of a cluster of particles which have an irregular configuration. These particles may have a shape and size similar to that of large particles of sand, except that the particles which form the cluster 166 are made of a material which will be absorbed into the body upon dissolving, as is known in connection with dissolvable sutures, for example. The body fluid flows in the direction of the arrow 168. At the right end of the cluster 166 is located a filter 170 which is made of a number of elongated fibers of dissolvable material such as dissolvable suture material, these fibers being pressed together so as to form the filter 170 through which the fluid also can flow. The filter 170 is placed by the surgeon at the location shown in FIG. 24 where it remains simply by friction, and as a result the particles 166 are prevented from flowing away from the region shown in FIG. 24, where they serve to support the interior of the tubular organ 160 against constriction due to the formation of scar tissue. It will be noted that the cluster of particles 166 is distributed along the interior of the tubular organ 160 through a distance which extends not only through the region where scar tissue grows but also substantially beyond this region. Thus, after the tubular organ has been opened for any reason and is to be closed the surgeon will introduce one portion of the cluster of particles 166 in the right part 160a and the other portion in the left part 160b of the tubular organ 160, as viewed in FIG. 24, so that upon closing of the tubular organ by the sutures 162, for example, the continuous cluster of particles 166 will be formed. Because of their size and irregular configuration these particles while capable of reliably supporting the tubular organ against constriction due to the growth of scar tissue nevertheless will permit the fluid to flow freely through the tubular body organ in the direction shown by the arrow 168.

FIG. 26 illustrates yet another embodiment of an implant according to the invention, schematically shown in FIG. 26 in the interior of a tubular body organ, while FIG. 25 schematically illustrates a stage in the method of manufacture of the implant of FIG. 26.

Thus, referring to FIG. 25, an inner filament 172 of very fine wire or other suitable material is wound in one
direction around a suitable mandrel 174 which may be made of a material such as aluminum, for example. The fine filament 172 may be made of a springy material so that it forms an elongated coil spring wound around the mandrel 174. The opposed ends of the wire 172 are wrapped around inner free ends of a plurality of bars 176 also made of any suitable metal, for example, and distributed about the axis of the mandrel 174 as illustrated. Any desired number of bars 176 may be situated at each end region of the wire 172 as illustrated. In this way the bars 176 are held on the mandrel 174 assembled with the wire 172.

Then, an outer fine filament 178, which may be identical with the material of the filament 172 is wound around and against the coil 172 but the convolutions of the filament 178 are wound in a direction opposite to the direction of winding of the convolutions of the filament 172. In this way the convolutions of the two wound filaments 172 and 178 will engage each other while being inclined in opposite directions to define a plurality of apertures. It is to be understood that this construction is illustrated schematically only for the sake of clarity. Actually the windings will be located closer to each other and the pitch of the convolutions will be much sharper so that the inclination of the convolutions will be more pronounced than illustrated. The ends of the outer wound filament 178 will also be wrapped around the inner axially extending ends of the bars 176 so as to contribute to the security of the assembly of the components shown in FIG. 25.

This latter assembly is then placed in a suitable evacuated chamber wherein a known way a metal, preferably gold, is vapor-deposited over the entire assembly so as to form a coating on the exterior surfaces of the springy filaments 172 and 178 and the bars 176. When using a vapor-deposited material such as gold, the structure is rendered compatible with the human body. At the same time, the part of the deposited metal situated at the intersecting portions of the coils and bars serve as welds to fasten these components together at the locations where they engage each other.

After vapor deposition has been carried out in the above manner the mandrel 174, which may be made of a material such as aluminum, as pointed out above, is melted and the coated assembly of wound springy filaments 172 and 178 together with the bars 176. The resulting implant 180 which is illustrated in FIG. 26 thus includes an elongated tubular foraminous wall constituted by the intersecting coil spring filaments 172 and 178 which are coated with a metal as described above, with this foraminous tubular wall carrying at the region of its ends the bars 176 which have their pointed ends directed outwardly away from the axis of the tube and toward a central plane which is normal to the tube.

Thus, with this construction when the tubular organ 182 is cut through for any reason so as to have access to the interior thereof, before the ends 184 of the tubular organ are again placed in engagement with each other, the implant 180 is introduced. The bars 176 will act in a highly effective manner to dig into the tissue of the tubular organ 172 so as to hold the ends 184 butting against each other to achieve healing in a highly effective manner without the use of sutures. At the same time the foraminous wall which is constituted by the springs 172 and 178 has a sufficient rigidity to oppose constriction of the lumen of the tubular organ.

It will be noted that the length of the implant 180 is such that it extends through and substantially beyond the trauma area 186 where scar tissue will grow. Moreover, because of the springy nature of the foraminous tubular wall it will prevent kinking of the tubular organ.

In addition, one of the great advantages achieved with this particular embodiment of the invention resides in the fact that the foraminous tubular wall constituted by the coated springs 172 and 178 itself forms a tissue-ingrowth means since the tissue will readily grow through and fill the tiny spaces formed between the oppositely directed coil springs. Thus, an extremely secure joiner of the implant into the wall of the tubular organ which grows through and around the foraminous wall of the implant is achieved, so that particularly outstanding results will follow from this particular embodiment of the invention.

Referring to FIG. 27, there is illustrated therein an embodiment of the invention according to which the barrier means 200 of FIG. 4 is used by itself with a vas implant since this feature need not necessarily be combined with the other features of the invention. Thus FIG. 27 shows a pair of spaced vas sections 204a and 204b between which is located the central valve assembly 202 of a vas valve which is implanted in the manner illustrated in FIG. 27 with the elongated tubular parts 206a and 206b of the valve being covered with a suitable tissue ingrowth means and extending along the interiors of the lumens of the vas section 204a and 204b. Thus, this arrangement is identical with that of FIG. 4 except that the valve need not have the components 52.

The space between the vas sections 204a and 204b is filled with the barrier means 200 which is precisely the same as the barrier means 200 described above in connection with FIG. 4. Thus with the embodiment of FIG. 27, even if it is decided not to use the elements 52 of FIG. 4, nevertheless this embodiment will achieve the advantage of preventing the sperm from bypassing the valve along the exterior thereof since the sperm will be incapable of travelling through the thick substance 200, as described above in connection with FIG. 4.

It is apparent, therefore, that with the above described methods and devices of the invention it becomes possible to carry out surgical procedures in such a way that the formation of scar tissue will not undesirably cause constriction of a tubular body organ, with the added advantages of preventing kinking of the body organ and permitting a pumping action such as a periostaltic action to take place.

What is claimed is:

1. In a surgical method to be performed at the region of a tubular body organ, the steps of performing surgical procedures at the region of the tubular body organ for obtaining access to the interior thereof, so that subsequent to the surgical procedure scar tissue will form at the latter region during healing of tissue at said region, and introducing into the tubular body organ after access is obtained thereto by the surgical procedures a tubular implant which is longer than said region, the implant having an intermediate portion for opposing constriction by scar tissue which forms at said region and for performing a specific function for which the implant is designed and a pair of opposed elongated flexible portions extending in opposite directions beyond the intermediate portion and while being substantially less rigid than said intermediate portion and bendable with respect thereto also having sufficient rigidity to
support the wall of the tubular organ in the interior thereof for opposing constriction and preventing kinking of the tubular organ in opposite directions beyond the intermediate portion of the implant while providing beyond the intermediate portion of the implant in the lumen of the tubular organ clearance sufficient to permit fluid to flow through the tubular organ, and introducing the implant into the tubular organ with the intermediate portion thereof situated at the region where scar tissue forms while locating said elongated flexible portions at regions extending along the interior of the tubular organ in opposite directions beyond opposed ends of the intermediate portion situated at said region where scar tissue forms.

2. In a method as recited in claim 1, and wherein the tubular organ is of the type which pumps a body fluid by a contracting and expanding action such as a peristaltic action, and situating said elongated portions of the implant along the interior of the tubular organ in such a way that while the tubular organ is supported by said elongated portions of the implant the latter will not inhibit the pumping action of the tubular organ.

3. In a method as recited in claim 1 and including the step of introducing as at least part of the implant a material which is capable of being absorbed at a rate enabling the latter material to contribute to internal support of the tubular body organ opposing constriction thereof during healing while subsequent to healing the latter material will disappear.

4. In a method as recited in claim 3 and wherein the material which is capable of being absorbed holds together parts of the implant for facilitating introduction thereof.

5. In a method as recited in claim 3 and wherein the implant includes a valve while the tubular organ is a vas deferens, and the material which is capable of being absorbed extends beyond the valve in opposite directions from the area where scar tissue grows into an area where scar tissue does not grow.

6. In a method as recited in claim 1 and including the step of situating around the exterior of the implant a means for promoting the ingrowth of tissue.

7. An implant to be introduced into a tubular organ after surgical procedures are performed to give access to the interior of the tubular organ at a region along the tubular organ where scar tissue will form during healing subsequent to the introduction of the implant into the tubular organ, said implant having a length which is greater than the length required to occupy the interior of the tubular organ at the region thereof where the scar tissue subsequently grows and said implant including elongated tubular means for permitting a body fluid to flow along the interior of the tubular organ through the implant, said tubular means having a rigidity sufficiently great to support the tubular organ and oppose substantial constriction thereof by the scar tissues the implant further including a pair of elongated flexible means of substantially greater flexibility than said tubular means connected with and extending in opposite directions beyond opposed ends of said tubular means for extending therefrom respectively beyond said opposed ends into regions of the tubular organ beyond the region where scar tissue subsequently grows, said pair of elongated flexible means while being bendable nevertheless having sufficient rigidity to support the wall of the tubular organ and permit curving thereof without kinking at regions beyond the region where scar tissue subsequently grows, and said pair of flexible means each having a cross section adapted to occupy only part of the cross section of the lumen of the tubular organ for leaving therein a clearance extending longitudinally along the lumen sufficiently great for fluid to flow therethrough.

8. An implant as recited in claim 7 and wherein said implant carries at its exterior a means for promoting the ingrowth of tissue.

9. An implant as recited in claim 7 and wherein the pair of elongated means support the tubular organ while permitting contraction and expansion thereof so that the tubular organ can carry out a pumping action.

10. An implant as recited in claim 9 and wherein each of the elongated means has at least a pair of opposed edge regions for engaging the interior surface of the tubular organ while leaving on opposite sides of each edge region free spaces in the tubular organ.

11. An implant as recited in claim 10 and wherein each of said elongated means has the configuration of an elongated strip.

12. An implant as recited in claim 10 and wherein each of the elongated means has a central region extending centrally along the interior of the tubular organ and a plurality of ribs projecting from the central region and having the edge regions which engage the inner surface of the tubular organ.

13. An implant as recited in claim 10 and wherein each elongated means is of a V-shaped cross section.

14. An implant as recited in claim 9 and wherein each of said elongated means is made of a flexible material of a substantially U-shaped cross section.

15. An implant as recited in claim 9 and wherein each of said elongated means is made of a flexible material having a substantially spiral-shaped cross section.

16. An implant as recited in claim 9 and wherein each of said elongated means is in the form of a plurality of elongated filaments extending from said tubular portions and free to move inwardly toward and outwardly away from each other.

17. The combination of claim 7 and wherein the implant is in the form of a control means adapted to be introduced into a tubular organ for acting on fluid therein, said control means having a central control region and a pair of elongated tubular portions extending in opposite directions from said central control region and having a length great enough to extend through and beyond a region where scar tissue will form into a region where scar tissue will not form, each of said tubular portions having along at least part of its length a section which is flexible to enable the tubular organ to bend, so as to prevent kinking thereof, while at the same time capable of opposing constriction of the tubular organ during healing thereof.

18. The combination of claim 17 and wherein the flexible sections of said tubular portions are respectively situated next to the central region.

19. The combination of claim 7 and wherein said implant includes a flexible tubular wall extending along the entire length of the implant.

20. The combination of claim 17 and wherein said implant includes a flexible tubular wall extending along the entire length of the implant.

21. The combination of claim 17 and wherein the flexible section of each tubular portion is situated at an outer end region thereof distant from the central control region.
22. The combination of claim 17 and wherein the flexible sections of said tubular portion are each in the form of coil springs fixed to and extending from the remainder of the tubular portions.

23. The combination of claim 17 and wherein each tubular portion has a solid wall portion next to the central control region and beyond said solid wall portion an elongated free end portion which is cut through along a spiral to form a spring from the part of each tubular portion which extends beyond its solid wall portion.

24. The combination of claim 17 and wherein the flexible sections of said tubular portions are respectively in the form of elongated tapered free end portions of each tubular portion situated distant from the central control region and having a tapered as well as a convoluted configuration.

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