

[54] **IMPLANTING METHOD**

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[22] Filed: **Oct. 16, 1972**

[21] Appl. No.: **298,024**

[52] U.S. Cl. **128/1 R, 3/1, 128/92 C, 128/334 R, 128/419 P, 32/10 A**

[51] Int. Cl. **A61f 1/24, A61b 19/00**

[58] Field of Search **3/1, DIG. 3; 128/1 R, 334 R, 128/92 C, 92 CA, 419 P; 32/10 A**

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[57] **ABSTRACT**

A method for implanting artificial devices in the bodies of living creatures such as human beings. The device is initially embedded in tissue of the living creature where the device is permitted to remain until ingrowth of tissue into intimate contact with the exterior surface of the device is completed. Then the device is removed while retaining thereon a layer of the tissue which has grown into contact with the device, and the device with this layer of tissue thereon is then implanted in the body at the location where the device is to be used in the body with tissue at this latter part of the body engaging the tissue which has previously grown onto the device, so that the possibility of rejection of the device is reduced.

9 Claims, 4 Drawing Figures

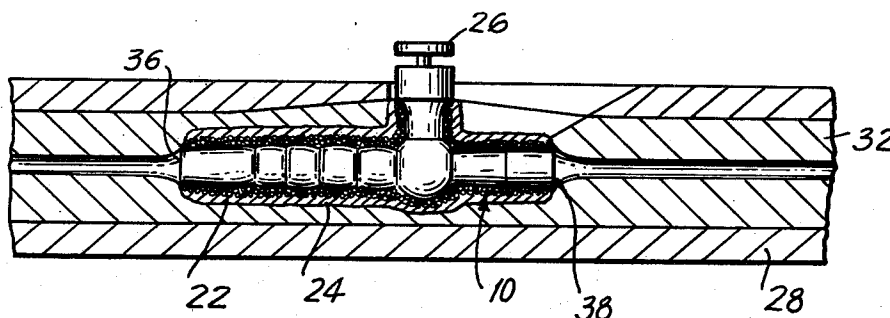


FIG. 1

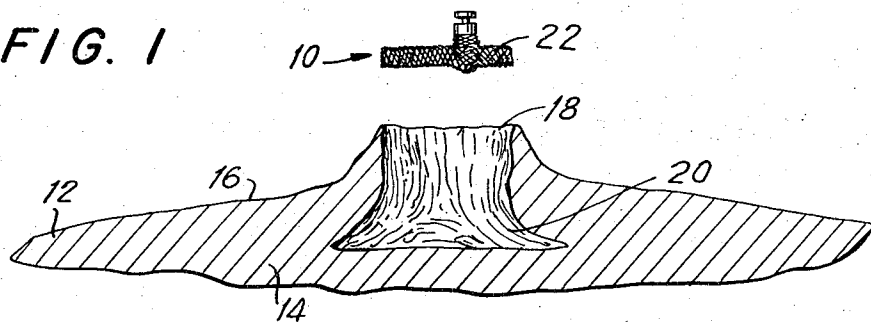


FIG. 2

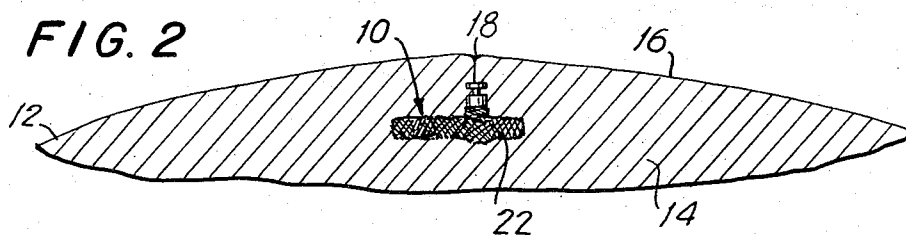


FIG. 3

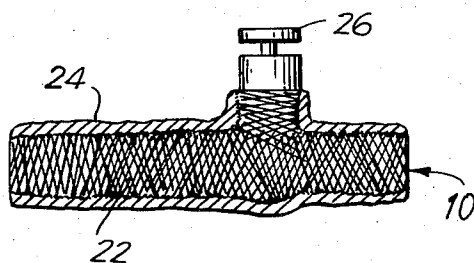
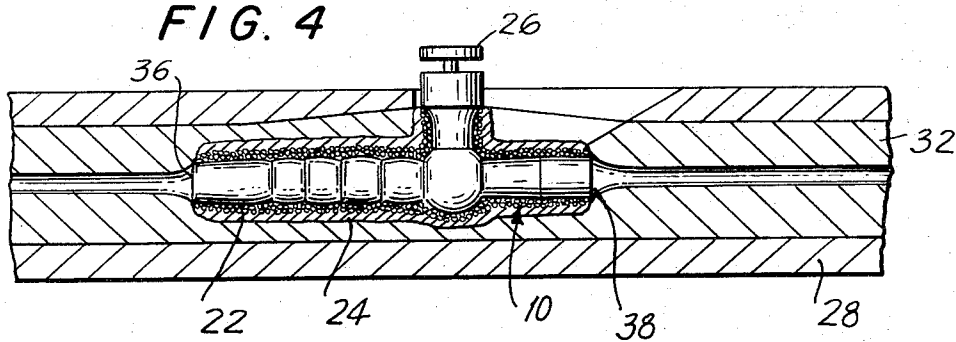


FIG. 4



IMPLANTING METHOD

BACKGROUND OF THE INVENTION

The present invention relates to the implanting of devices in the bodies of living creatures such as human beings.

As is well known, it is advisable and necessary under certain conditions to introduce an artificial implant device into the body of a living creature such as a human being. Such devices may take many different forms. For example pacemakers may be implanted to control the operations of the heart. An artificial heart itself may be implanted. Artificial bones or parts of bones, including artificial teeth, may be implanted. Valves may be implanted to control the flow of body fluids.

One of the major problems encountered when dealing with implants is that in many cases the body rejects the implant. Although great care may be exercised in the choice of the materials used for the device which is to be implanted, the number of different materials which are known to be compatible with human tissue is extremely small, and when a compatible material, such as gold, is used, the costs are extremely high.

A further problem encountered in connection with implants is the reliability of the anchoring of the implant of the desired location. After a given device has been implanted it may undesirably move from its initial location. Furthermore, where a seal is required between the exterior surface of the implanted device and the tissue of the body, as is the case with valves, for example, such a seal can not always be reliably achieved.

SUMMARY OF THE INVENTION

It is accordingly a primary object of the present invention to provide a method for avoiding the above drawbacks.

In particular, it is an object of the present invention to provide an implanting method which will greatly reduce the possibility of rejection of the implanted device.

In particular, it is an object of the present invention to provide a method according to which a wide variety of devices can be treated in such a way that they are rendered highly acceptable to the tissue of the body so as to be retained reliably in the body.

In addition, it is an object of the present invention to provide a method of this type which is easy to perform at a relatively low cost and without any particular danger to the individual who is to receive the implant.

Yet another object of the present invention is to provide a method which enables implanting of a device in such a way that not only is the possibility of rejection greatly reduced but in addition the device will be reliably anchored at the desired location in a manner which will reliably avoid undesirable movement of the device and leakage of body fluids along the exterior of the device.

According to the method of the invention the device which is to be implanted is initially embedded in tissue of the body which is ultimately to receive the device, with this latter tissue being located at a part of the body different from the predetermined location which ultimately receives the device. The embedded device is permitted to remain in the tissue in which it is initially placed for a length of time sufficient to permit ingrowth

of tissue into intimate contact with the exterior surface of the device. Then the device is removed from the body while retaining on the device a layer of the tissue which has grown into contact with the exterior surface of the device. This device with the layer of tissue which has grown thereon is then implanted in the body at the predetermined location where tissue of the body is placed directly in contact with the tissue previously grown onto the device so that it is only required for the tissue at the ultimate location of the device to become united with tissue already grown onto the device in the same body in which the device is ultimately implanted, thus reducing the possibility of rejection.

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 representation of a first step in the method of the invention;

FIG. 2 is a schematic illustration of a stage in the method subsequent to that illustrated in FIG. 1;

FIG. 3 illustrates a device after it has been removed from a body with tissue remaining on the device; and

FIG. 4 is a schematic representation of the manner in which a device in the condition shown in FIG. 3 is implanted at its ultimate location in the body.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIG. 1, there is illustrated therein the device 10 which is to be implanted in the body of a living creature such as a human being. In the illustrated example this device 10 is a valve, but it is to be understood that any artificial device may be treated according to the present invention, such as pacemakers, artificial organs, artificial bones or parts thereof, teeth, etc.

FIG. 1 schematically represents a part 12 of the body of a human being, this part 12 being composed of a body of tissue 14 covered with exterior skin 16. The tissue 14 is preferably located at a part of the body where a relatively large amount of such tissue is readily accessible at the exterior skin 16. For example a buttock is particularly suitable for this purpose.

According to the first step of the method of the invention an incision 18 is made through the skin 16 into the tissue 14 so as to form in the tissue 14 a pocket 20 by stretching the tissue and skin 16 at the region of the incision 18 in the manner shown schematically in FIG. 1. The pocket 20 is of course made somewhat larger than the device 10 so that through the incision 18 the device 10 can be readily introduced into the pocket 20. Then the incision 18 is closed and sutures may be applied for this purpose, so that the device 10 remains embedded in the tissue 14 as indicated schematically in FIG. 2. The device 10 can remain in this condition shown in FIG. 2 in the body of an individual without creating any particular problems or any particular discomfort, and during a period of time which may be on the order of two or three months, the ingrowth of the tissue 14 will take place into intimate contact with the exterior surface of the device 10. For this purpose, an individual may go to a hospital for no more than overnight stay, so that the surgeon can embed the device 10 in the tissue 14. Then the individual may leave the hospital and go about his business in a usual manner for a

period of two or three months, until ingrowth of tissue has been completed.

In order to promote ingrowth of tissue it is possible to situate at the exterior of the device 10, prior to embedding thereof in the tissue 14, a means 22 which will promote the ingrowth of tissue. In the example illustrated in FIG. 1 this means takes the form of one or more strands of gold wire wound around the valve 10 at the exterior thereof to form a large number of interstices through which the tissue will grow into intimate contact with the exterior surface of the device 10. Other structures may be used to form the means 22 for promoting the ingrowth of tissue. For example any layer of porous material such as gold sprayed onto the exterior surface of the device 10 in a suitable evacuated atmosphere may be used.

After the period required for completion of ingrowth of tissue has elapsed, the individual returns to the hospital and the surgeon will remove the device 10 from the tissue 14 in which it was initially embedded. At this stage of the method of the invention the surgeon is careful to leave on the device 10 a layer 24 of the tissue which has grown into intimate contact with the exterior surface of the device 10. In the particular example shown in the drawings where a valve is used for the device 10, an operating component 26 of the valve may be left exposed so that the valve can be opened and closed. However, when dealing with other types of devices such exposure of part of the device may not be required. It is to be noted that in accordance with the invention any of the artificial devices which are to be implanted have exterior surfaces which are impervious to tissue so that tissue cannot grow into the device beyond the exterior surface thereof.

Immediately subsequent to the removal of the device 10 from the tissue 14 with the layer 24 of ingrown tissue remaining on the device 10, only at the exterior surface thereof, the surgeon will introduce the device 10 into the part of the body where the device is to remain. Thus, FIG. 4 shows by way of example, in a schematic manner, a vas deferens 28 initially formed in a wall portion thereof with a slit 30 through which the device 10 with the ingrown tissue 24 thereon is introduced in the manner shown in FIG. 4.

With this method the inner tissue 32 which lines the cavity formed by the interior of the vas 28 directly engages only the ingrown tissue 24 from the very same individual in which the device 10 is implanted. It is thus required that the tissue 32 become united only with tissue 24, and since the tissue 32 and the tissue 24 are from the same individual the possibility of rejection is very greatly reduced. In addition, the uniting of the tissue 32 with the tissue 24 by ingrowth of the tissue 32 into intimate union with the tissue 24 reliably anchors the device 10 at the desired location and in the case of a valve reliably prevents any leakage past the valve at the exterior thereof. Of course, in the case of a valve care is taken to maintain the ends 36 and 38 of the valve open so that the flow of fluids can readily be controlled by opening and closing of the valve.

Of course, after the device 10 is removed with the tissue 24 remaining thereon, the second incision which is made is again closed so that the part 12 of the body where the tissue 14 is located will heal up readily.

It is emphasized that the method of the invention is illustrated above in connection with a valve only by way of example. The method of the invention is appli-

cable to all types of devices which are to be implanted in the body of a living creature such as a human being. For example in FIG. 4 the tubes connected to the device may be arteries connected to an artificial heart. As was pointed out above pacemakers may be treated in the manner indicated above so as to be reliably retained in the body without any possibility of rejection. Furthermore the method of the invention may be practiced with any artificial materials or devices such as a section of artificial bone which is to be introduced, a tooth which is to be implanted in gums, or even tubes, plates, or the like which are to be used to repair injuries to any body cavities.

What is claimed is:

1. In a method for implanting in the body of a living creature such as a human being an artificial implant device which has an exterior surface which is impervious to the growth of tissue so that tissue cannot grow into the device beyond the exterior surface thereof, the steps of initially embedding the device in tissue of the living creature at a location different from a predetermined location at which the device is ultimately to be located and remain, while exposing only the exterior surface of the device to the tissue and permitting the device to remain in the tissue in which it is initially embedded until ingrowth of tissue into intimate contact only with the exterior surface of the device is completed, then removing the device from the location at which it was initially embedded while retaining only at the exterior of the device tissue which has grown into contact only with the exterior surface of the device, and then surgically obtaining access to said predetermined location and implanting the device with the tissue thereon only at the exterior surface thereof at said predetermined location with the tissue at the exterior of the device engaging tissue located at said predetermined location, and then surgically closing off access to said predetermined location so that at said predetermined location tissue of the body need only become united with tissue of the same body, whereby the possibility of rejection of the device is reduced.

2. A method as recited in claim 1 and including the step of preliminarily locating at the exterior surface of the device, prior to initial embedding thereof, a means which will permit the ingrowth of tissue.

3. A method as recited in claim 1 and wherein the tissue is initially embedded at a part of the body where a relatively large volume of tissue is readily accessible from the exterior of the body.

4. A method as recited in claim 3 and wherein the part of the body where the device is initially embedded is a buttock.

5. A method as recited in claim 1 and wherein said predetermined location is the interior of a body cavity which is lined with tissue placed in engagement with the tissue preliminarily grown onto the device and retained thereon when the device is removed from the location at which it is initially embedded.

6. A method as recited in claim 5 and wherein the cavity is the interior of a vas deferens of human male and the device is a valve.

7. A method as recited in claim 6 and wherein wire is preliminarily wound onto the exterior of the valve prior to initial embedding thereof for promoting ingrowth of tissue.

8. A method as recited in claim 1 and wherein the device is a valve.

9. A method as recited in claim 1 and wherein the device is implanted at said predetermined location immediately subsequent to removal of the device from the location at which it was initially embedded.

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