United States Patent [19]

Schulte

[11] **3,853,126**

[45] **Dec. 10, 1974**

[54] **ARTERY-TO-VEIN SHUNT**

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[22] Filed: **Nov. 15, 1973**

[21] Appl. No.: **416,033**

[52] **U.S. Cl.** ..... **128/214 R,** 128/348, 3/1

[51] **Int. Cl.** **A61m 5/00,** A61m 25/00

[58] **Field of Search** ..... 128/214 R, 334 C, 348, 128/350, 1 R; 3/1

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[57] **ABSTRACT**

An artery-to-vein shunt for long-term implantation in a human body to give external access to the arterial and venous system. The shunt includes a first and a second button adapted to be engaged in an aperture through the skin. A peripheral groove in a peripheral wall of each button receives an adjacent edge of the skin and may include seal means to act as a fluid seal and as a stop for infection. A first and a second shunt tube respectively pass through the first and second buttons and include a connector portion adapted to be connected to a vein or an artery, and a coupler portion adapted to be connected to a third shunt tube which interconnects the first and second shunt tubes. A fixation cuff may be provided on the outer wall of each connector portion adjacent to the respective free end. The fixation cuff and the stabilizer means comprise a material with openings into which tissue can penetrate, for example, a velour fabric. A pair of couplings is adapted detachably to join respective free ends of the third shunt tube to respective free ends of one of the coupler portions so as to interconnect the flow conduits of the first and second shunt tubes through the flow conduit of the third shunt tube.

20 Claims, 11 Drawing Figures

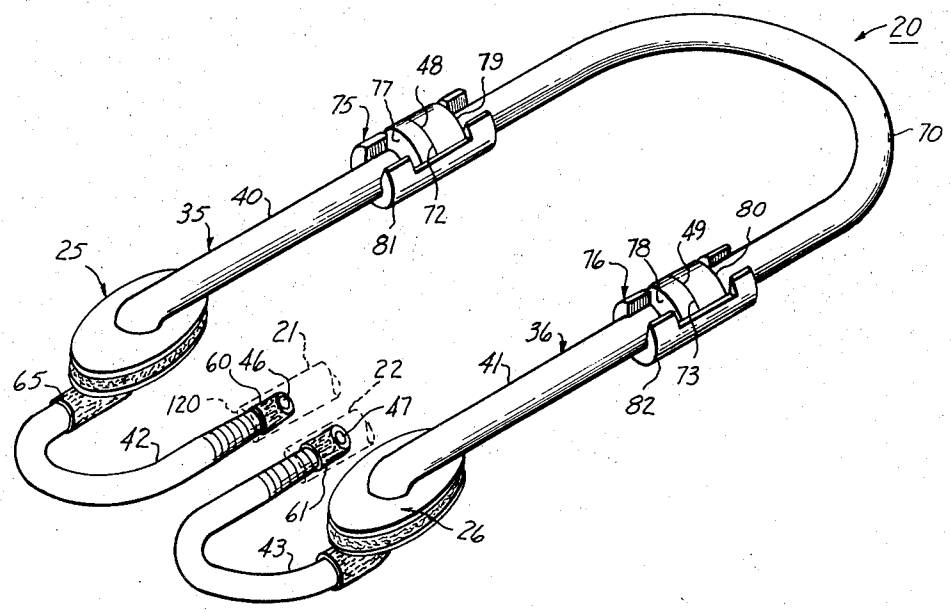


FIG. 1

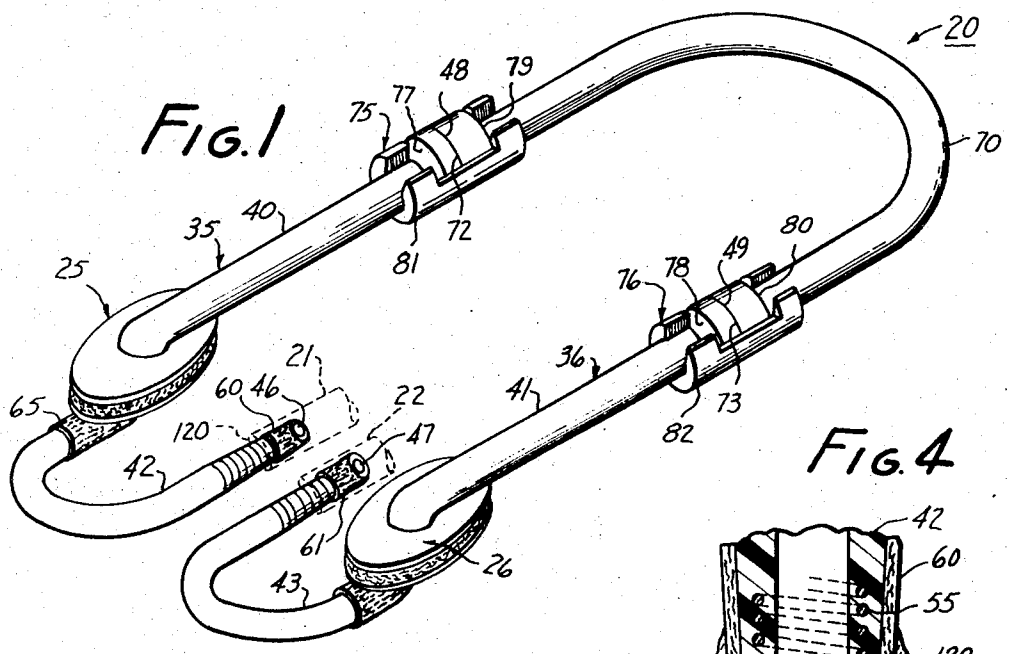


FIG. 2

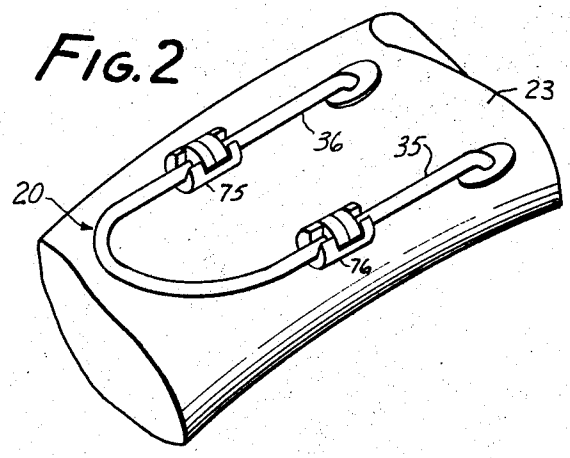


FIG. 3

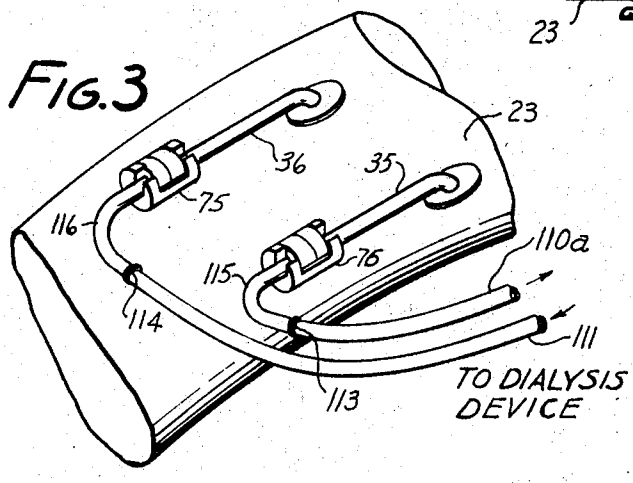
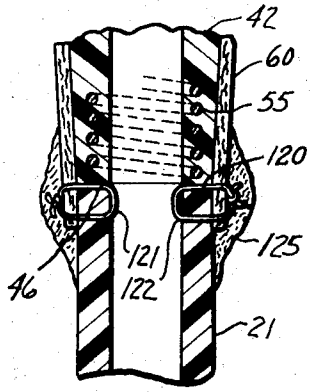


FIG. 4



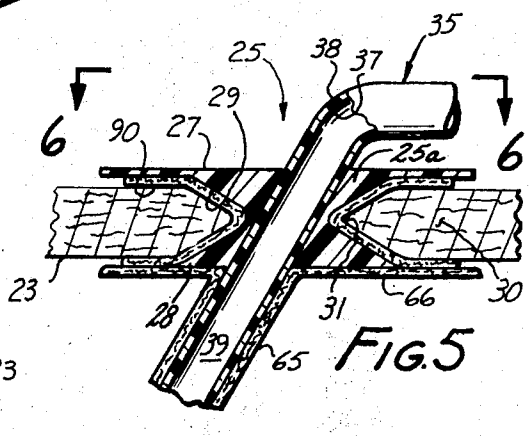


FIG. 5

FIG. 6

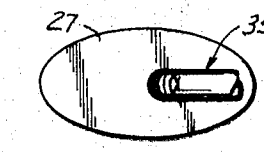


FIG. 8

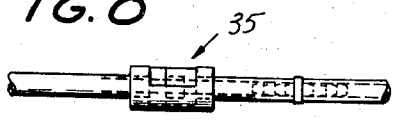
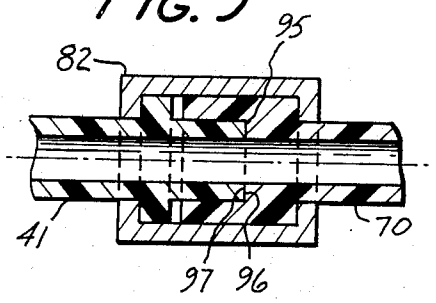


FIG. 7

FIG. 9



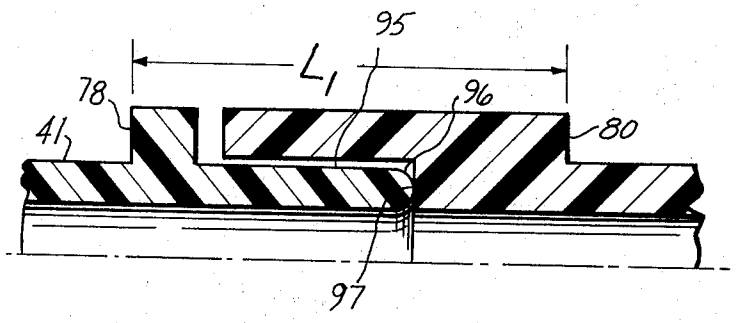


FIG. 10

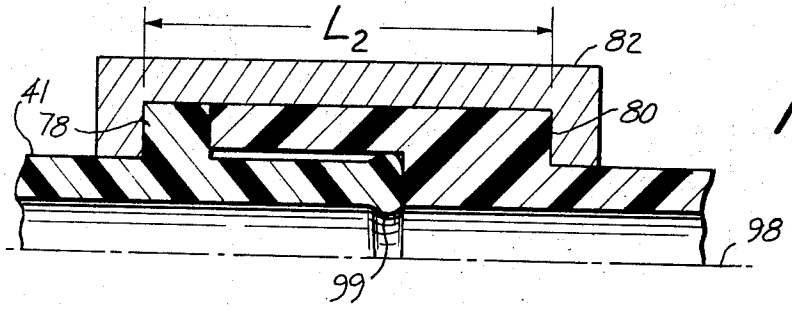


FIG. 11

ARTERY-TO-VEIN SHUNT

This invention relates to an artery-to-vein shunt for long-term implantation in a human body to give external access to the arterial and venous system.

A serious problem faced by persons who require periodic treatment of their blood, such as by dialysis as a consequence of kidney malfunction, is that each time they are connected to the dialysis machine, a new incision must be made in a vein and an artery. This is a source of considerable pain and discomfort, and further, after many incisions are made, the person begins to run out of locations where a connection can be made. In fact, the problem of connecting the dialysis machine to the patient periodically over an extended period of time is one of the most severe problems faced by the patient.

Furthermore, the presently-known means for connecting dialysis devices to patients simply utilizes a trochar needle which penetrates the wall of the respective vein or artery. The needle is strapped to the body during treatment. Motion of the arm or other body member soon constitutes a source of exquisite pain for the patient, and should be avoided if possible.

It is an object of this invention to provide an artery-to-vein shunt which can surgically be implanted for long-term access to the arterial and venous systems so that connections and re-connections are done on articles which are physically separate from the human body. If re-implantation is necessary, it is an infrequent, rather than a frequent matter, and a single invasion of a vein and artery lasts for many treatments.

It is an object of this invention to provide such a shunt which enables ready connection to be made to the dialysis device, using inexpensively replaced throw-away parts.

It is still another object of this invention to provide fixation means and stabilizer means which will hold the shunt relative to surrounding tissue so as to minimize movement of the shunt relative to the vein and thereby decrease the incidence of pain in its use.

An artery-to-vein shunt according to this invention comprises a first and a second button, each button having a peripheral groove and peripheral button-sealing means in the peripheral groove. The button-sealing means make a fluid seal and a stop for infection at the skin level. A first and a second shunt tube are respectively attached to and passed through the first and second buttons, each of which has a flow conduit, a coupler portion adjacent to and extending from the surface of the button outside the body, and a connector portion adjacent to and extending from the other surface of the body and adapted to be connected to a respective artery or vein.

A fixation cuff is provided on the outer wall of each connector portion adjacent to its respective free end, and shunt tube stabilizer means extends peripherally around the outer wall of the first and second shunt tubes adjacent to the button so as to minimize its motion relative to the body. The fixation cuff and the shunt tube stabilizer means comprise a material with openings into which tissue can penetrate.

A third shunt tube has a flow conduit and a pair of free ends. A pair of couplings detachably joins the free ends of the third shunt tube to respective free ends of the coupler portions so as to interconnect the flow conduits of the first and second shunt tubes through the flow conduit of the third shunt tube when they are joined by the couplings.

According to a preferred but optional feature of the invention, the material of the fixation cuff and the shunt tube stabilizer means is woven, and preferably is a velour.

According to another preferred but optional feature of the invention, a flexible and resilient coil spring is formed between the inner and outer walls of the connector portions adjacent to their free ends.

According to yet another preferred but optional feature of the invention, seal means seals the assembled three shunt tubes against leakage at the free ends of the coupler portions.

The above and other features of this invention will be fully understood from the following detailed description and the accompanying drawings in which:

FIG. **1** is a perspective view of the presently preferred embodiment of the invention;

FIGS. **2** and **3** are fragmentary perspective views showing the device of FIG. **1** implanted and in two conditions of use;

FIG. **4** is a longitudinal, fragmentary cross-section showing a portion of FIG. **1** implanted;

FIG. **5** is a fragmentary axial cross-section showing another portion of the device of FIG. **1** implanted;

FIG. **6** is a plan view taken at line **6—6** of FIG. **5**;

FIG. **7** is an exploded view of parts comprising a portion of FIG. **1**;

FIG. **8** shows a portion of FIG. **7** in the operating condition of FIG. **3**;

FIG. **9** shows a form of seal means useful with the invention; and

FIGS. **10** and **11** show a modification of the construction of FIG. **9** with its operational features emphasized.

The presently preferred embodiment of an artery-to-vein shunt **20** is shown assembled in FIG. **1.** It is intended surgically to be implanted relative to the skin with part of it beneath the skin and part of it above the skin, such as on an arm or on a leg. The shunt **20** is shown attached to an artery **21** and a vein **22** which lie beneath skin **23.**

The shunt comprises a first and a second button **25, 26.** While these buttons may take a number of shapes, the presently preferred form is ovular, i.e., relatively elliptical in plan view (FIG. **6**). It has been found that generally elongated form such as this enables the button to be planted in the skin in a relative long slit and be accommodated thereby better than when a circular or other shape is used instead, especially in the arm or leg.

The buttons are identical, and only button **25** will be described in detail. The body member **25***a* is preferably flat with a top surface **27** and a bottom surface **28,** the terms "top" and "bottom" referring to outside and inside the skin level in which the button is placed. A peripheral wall **29** extends around the body and interconnects the top and bottom surfaces. A peripheral groove **30,** which may have a relatively sharp apex **31,** extends peripherally around the wall. The skin **23** of the patient will have been cut, and the edges of the cut will be received in the peripheral groove in a manner yet to be described.

A first and second shunt tube **35** and **36** are respectively attached to and pass through the first and second buttons. The constructions of the first and second shunt

tubes are identical, except that they are mirror images, so that only shunt tube **35** will be described in detail. Shunt tube **35** has an inner wall **37**, an outer wall **38**, and a flow conduit **39** passing therethrough.

The first and second shunt tubes respectively include coupler portions **40, 41** which are positioned on the outside of the device when installed, i.e., above the top surface. They also include respective connector portions **42, 43** which extend from the bottom wall and are intended for long-term attachment to a respective vein **22** or artery **21.** First and second shunt tubes **35** and **36** have free ends **46, 47** on the connector portions and free ends **48, 49** on the coupler portions at the end thereof.

According to a preferred but optional feature of the invention, a flexible and resilient coil spring **55** is formed between the inner and outer walls of each of the connector portions adjacent to the free ends thereof. This spring may readily be molded into the material of the connector portion at the time it is made. It provides springy support to maintain the circular shape of the tubes at the point of attachment to the artery or vein.

A fixation cuff **60, 61** is attached to the shunt tube adjacent to the respective free ends of **46** and **47** of the connector portions. They are made of a material yet to be described, and can be cemented or sewed into place on the outer wall of the respective conductor portion.

Shunt tube stabilizer means **65** (FIG. **5**) is attached to and extends peripherally around the outer wall of the connector portions of the first and second shunt tubes adjacent to the bottom surface of the respective button. It extends axially along the connector portion as shown. Optionally, the shunt tube stabilizer means may further include said material applied as a layer **66** to the said bottom surface of the respective button for purposes yet to be described.

A third shunt tube **70** is generally U-shaped and has a flow conduit **71** and a pair of free ends **72, 73** respectively adapted to make a fluid-tight connection with the free ends **48** and **49** of the coupler portions.

Couplings **75, 76** are provided, one for joining each of the free ends of the third shunt tube to a respective free end of the coupler portions of the first and second shunt tubes. These couplings include shoulders **77, 78** on the coupler portions, and shoulders **79, 80** on the respective free ends of the third shunt tube. The free ends are brought together and the shoulders are engaged by respective clamps **81, 82** which also form a part of the couplings. Only clamp **82** will be described in detail (see FIG. 7). Clamp **81** is identical to it. Clamp **82** has a central channel **83** to pass the connector portion and the third shunt and to receive their free ends. It also includes a pair of shoulders **84, 85** on the clamp which can be brought to bear against shoulders **78** and **80** so as to hold the free ends together in a compressive fit. The material of the clamp may be inherently springy such that it can be snapped into place and will retain itself under those circumstances. It can also readily be removed by reverse motion.

Peripheral button-sealing means **90** are attached to the inside wall **91** of peripheral groove **30.** The purpose of this material is to form a fluid seal and a stop for infection at the point of entry of the shunt system. Materials suitable for this button-sealing means will be described below.

Seal means **95** (FIGS. **9–11**) may be provided to seal the assembled three shunt tubes against leakage at the free ends of the coupler portions. Although relatively complicated conventional fluid-seals such as O-rings and the like could be used, when relatively resilient materials such as polyethylene or medical grade silicone rubber (silicon elastomer) is used as a material of construction, a satisfactory fluid seal can be obtained by direct surface-to-surface abutting fit.

For example, in FIG. **9,** the seal means **95** comprises peripheral end surfaces **96, 97** on the coupler portion **41** and on the third shunt tube **70,** respectively. These surfaces are flat annuli and are brought together against one another at the time the clamp is applied. The sealing action can be improved by the means shown in FIGS. **10** and **11** wherein, instead of forming end surfaces **96** and **97** both as inherently deformable flat surfaces, end surface **96** is formed rounded. When first contact is made between surfaces **96** and **97,** the spacing apart L_1 of shoulders **78** and **80** will be as shown in FIG. **10.** When the clamp is applied as in FIG. **11,** there will have been an axial compression along axis **98,** causing a resilient distortion shown as a bulb **99** on the free end of connector portion **41.** The spacing apart of shoulders **78** and **80** is then L_2 as shown, and a more reliable fluid seal is formed at this point by the spring-back force of the material forming bulb **99.**

The material of which the fixation cuffs **60** and **61,** the shunt tube stabilization means **65,** and the peripheral button-sealing means **90** can be made is a material with openings into which tissue can penetrate, and which is not harmful to or absorbed by body tissue. Such a material is necessary for the fixation cuffs and shunt tube stabilizer means, but the button-sealing means may, instead, merely use compatible resilient material, such as a compressible open or closed cell silicon elastomer foam or sponge if desired. However, it is an advantage to utilize the same material in all three applications. The preferred material is a woven dacron mesh, preferably in the form of a velour. This cloth construction forms a group of openings into which tissue can penetrate. This material is not deleterious to the surrounding tissue, and, after a period of implantation, it will be noted that tissue has grown into this material to hold it in place, and as to the botton-sealing means, prevents leakage of fluid past it and also provides a bar to the penetration of organisms which might prove to be a source of infection.

As can be seen in the Figs., the coupler portions and the connector portions lie primarily in planes which are spaced apart from one another on opposite sides of the buttons, and the planes lie substantially parallel to the plane of the peripheral groove in the button which is, of course, the plane of the skin in which the button is implanted. The first and second shunt tubes are mirror images of each other, and the free ends of their connector portions are generally parallel to one another. The connector portions may be made U-shaped more conveniently to be connected to the artery or vein.

The material of which the shunt tubes are made is preferably slightly resilient, but stiff enough to be shape-retentive. Polyethylene is a suitable material of construction, as is medical grade silicone rubber (silicon elastomer). The third shunt tube should be made of readily cuttable material, such as a realtively softer

polyethylene, in order that it may receive an adapter **110.**

When the device is implanted in the patient, and the patient is not connected to a dialysis machine, the third shunt tube will be in place as shown in FIG. **1,** and flow will be directly from the artery to the vein. The bypassed regions of the body downstream of the artery will be supplied by peripheral circulation. When it is desired to connect tubes **110**a and **111** to first and second shunt tubes, a single cut **112** may be made, and identical adapters **113, 114** are plugged into the stub ends **115, 116** of the U-shaped third shunt tube. This arrangement is shown in FIG. **3.** In FIG. **7** is shown a situation where two cuts are made in the third shunt tube, and the bight **117** of the third shunt tube is discarded. It will be noted now that the dialysis machine has been connected to the patient without necessity for elaborate sterility precautions and that the conduitry to the point of attachment is full of blood. Accordingly, this is a very simple form of attachment, and the dialysis can proceed. When the dialysis is to be terminated, all that is necessary is to pinch the tubes going to the dialysis machine, remove the clamps, and substitute a new U-shaped third shunt tube (which has been filled with fluid), and connect it as shown. The individual then resumes his daily work

FIG. **4** illustrates the means of implanting the connector portion in the human body. It is, of course, a surgical technique. For this purpose, artery **22** (or vein **21**) is cut off to a square face **120** which is brought against the free end of the connector portion of the first shunt tube. Then it is sutured by sutures **121, 122** in accordance with known surgical techniques. The sutures preferably pass through the fixation cuff, and the fixation cuff extends tubularly over the end of the vein or artery. If desired, the suture may also be looped through one of the convolutions of the coil spring, but this is not necessary. After awhile, a layer of tissue **125** will have grown into the fixation means and also over the joinder and over the artery, so as to form a more reliable fluid fit and one which will stabilize the relative positions of the connector portion and the vein or artery.

Similarly, the shunt tube stabilizer means, i.e., that portion which extends along the connector portion next to the button and, when used on the bottom surface of the button, also there, will enable tissue ingrowth to occur which will stabilize the button relative to the skin and surrounding structure. The button-sealing means will prevent the leakage of the fluid and will also further tend to stabilize the button, particularly against turning, although the non-circular construction of the button will in itself aid in resisting that motion.

As a consequence, there is provided an artery-to-vein shunt which can be implanted for long-term use in the human body and which can be worn without discomfort. When it is time for it to be used, a cut or cuts is or are made in the U-shaped third shunt tube, and the stub ends are connected at the dialysis machine. When the dialysis procedure is completed, the U-shaped third shunt tube is replaced. Each time there is used and thrown away only an inexpensive U-shaped piece of plastic.

The dimensions of the device are arbitrary, and will be suited to the flow rates and intended locations of implantation. In one suitable device, the inside diameter of the conduits is 1/8 inch, and the button is about 1/2 inch by 3/16 inch in its major and minor dimension. The button is about 3/16 inch thick.

The constructions comprising a button and the first or second shunt tube is sometimes herein called an "implant."

This invention is not to be limited by the embodiments shown in the drawings and described in the description, which are given by way of example and not of limitation, but only in accordance with the scope of the appended claims.

I claim:

1. An artery-to-vein shunt for long-term implantation in a human body to give external access to the arterial and venous system, comprising: a first and a second button, each button comprising a body member having a top and a bottom surface, a peripheral wall extending around the body and interconnecting said top and bottom surfaces, a peripheral groove in said peripheral wall, and peripheral button-sealing means in said peripheral groove; a first and a second shunt tube, respectively attached to and passing through the first and second buttons, each of said first and second shunt tubes having an inner and outer wall, and a flow conduit defined by the respective inner wall, each of said shunt tubes forming a coupler portion adjacent to and extending from the top surface of the button, and a connector portion adjacent to and extending from the bottom surface of the body, each said portion having a free end spaced from the button, the free end of the connector portion being intended for long-term attachment to a respective artery or vein; a fixation cuff on the outer wall of each connector portion adjacent to the respective free end; shunt tube stabilizer means extending peripherally around the outer wall of the connector portions of the first and second shunt tubes, adjacent to the bottom surface of the respective button, the fixation cuff and the shunt tube stabilizer means comprising a material with openings into which tissue can penetrate; a third shunt tube having a flow conduit and a pair of free ends; and a pair of couplings, each detachably joined to a respective free end of the third shunt tube to a respective free end of one of the coupler portions so as to interconnect the flow conduits of the first and second shunt tubes through the flow conduit of the third shunt tube when they are joined by the couplings.

2. An artery-to-vein shunt according to claim **1** in which said material is woven.

3. An artery-to-vein shunt according to claim **2** in which said material is a velour.

4. An artery-to-vein shunt according to claim **1** in which the shunt tube stabilizer means further includes said material applied to said bottom surface of the button.

5. An artery-to-vein shunt according to claim **1** in which the peripheral groove is ovular in plan.

6. An artery-to-vein shunt according to claim **1** in which a flexible and resilient coil spring is formed between the inner and outer walls of the connector portions adjacent to the free end thereof.

7. An artery-to-vein shunt according to claim **1** in which each of said couplings comprises a shoulder on the respective coupler portions, adjacent its free end, a shoulder adjacent to each free end of the third shunt tube, and a clamp for engaging the said shoulders and restraining them against separation.

8. An artery-to-vein shunt according to claim 7 in which seal means seals the assembled three shunt tubes against leakage at the said free ends of the coupler portions.

9. An artery-to-vein shunt according to claim 8 in which said seal means comprises a peripheral sealing surface on each of said shunt tubes.

10. An artery-to-vein shunt according to claim 9 in which one of said sealing surfaces at each joinder of the third shunt tube with another shunt tube is resiliently deformable.

11. An artery-to-vein shunt according to claim 10 in which said resiliently deformable surface is part of one of said shunt tubes, and in which the clamp draws the shunt tubes together to cause said deformation.

12. An artery-to-vein shunt according to claim 1 in which said third shunt tube is cuttable, and in which adapter means is provided to make a fluid connection with two cut ends of the third shunt tube.

13. An artery-to-vein shunt according to claim 1 in which the first and second shunt tubes are mirror images of one another, and the third shunt tube is U-shaped.

14. An artery-to-vein shunt according to claim 13 in which the said portions lie primarily in planes which are spaced apart from one another on opposite sides of the buttons, and which planes lie substantially parallel to the plane of the peripheral groove in the button.

15. An implant for long-term implantation in a human body to give external access to an artery or a vein, comprising: a button comprising a body member having a top and a bottom surface, a peripheral wall extending around the body and interconnecting said top and bottom surfaces, a peripheral groove in said peripheral wall, and peripheral button-sealing means in said peripheral groove; a shunt tube attached to and passing through the button, said shunt tube having an inner and outer wall, and a flow conduit defined by the inner wall, the said shunt tube forming a coupler portion adjacent to and extending from the top surface of the button, and a connector portion adjacent to and extending from the bottom surface of the body, each said portion having a free end spaced from the button, the free end of the connector portion being intended for long-term attachment to a respective artery or vein; a fixation cuff on the outer wall of the connector portion adjacent to the free end; shunt tube stabilizer means extending peripherally around the outer wall of the connector portion of the shunt tube, adjacent to the bottom surface of the button, the fixation cuff and the shunt tube stabilizer means comprising a material with openings into which tissue can penetrate, whereby a third shunt tube having a flow conduit and a pair of free ends, and a pair of couplings each adapted detachably to join a respective free end of the third shunt tube to a respective free end of the coupler portion, and also the coupler portion of the shunt tube of another implant is adapted to interconnect the flow conduits of the two shunt tubes through the flow conduit of the third shunt tube when they are joined by the couplings.

16. An implant according to claim 15 in which said material is woven.

17. An implant according to claim 16 in which said material is a velour.

18. An implant according to claim 15 in which the shunt tube stabilizer means further includes said material applied to said bottom surface of the button.

19. An implant according to claim 15 in which the peripheral groove is ovular in plan.

20. An implant according to claim 15 in which a flexible and resilient coil spring is formed between the inner and outer walls of the connector portion adjacent to the free end thereof.

* * * * *