

[54] **IMPLANTABLE BULB FOR INFLATION OF SURGICAL IMPLEMENTS**

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[*] Notice: The portion of the term of this patent subsequent to May 1, 1990, has been disclaimed.

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Related U.S. Application Data

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[52] U.S. Cl. **128/1 R, 3/1, 128/346**

[51] Int. Cl. **A61b 19/00**

[58] Field of Search **128/325, 326, 327, 344, 128/346, DIG. 25, 1 R; 3/1**

[56] **References Cited**

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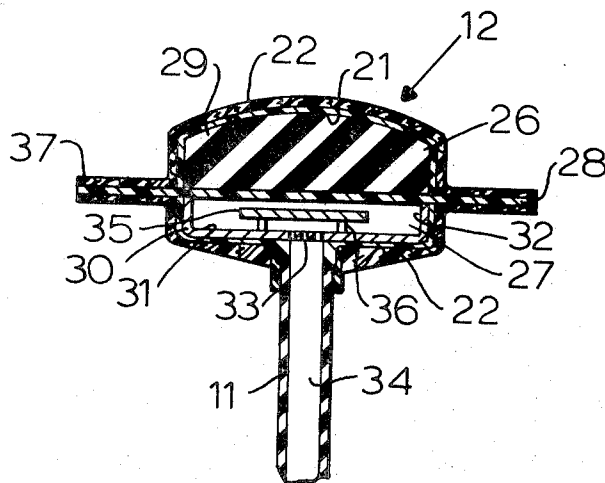
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[57] **ABSTRACT**

A device, completely implantable within the human body, for restricting the flow of blood through a major blood vessel, such as an artery, especially the pulmonary artery. An inflatable, flexible annulus, generally circular in shape but not a closed circle, has a non-distensible outer wall so that upon inflation all distension or expansion is inward. The device is placed around an artery or other blood vessel, and the ring may then be closed, as by suturing together preformed tabs attached to the annulus, or by suturing together the ends of an overlapping tape, for instance, to firmly hold the vessel. Upon inflation, inward distension of the inflatable annulus constricts the vessel, and flow of blood therethrough is accordingly restricted. Inflation and deflation are effected through a self-sealing hollow bulb and a non-distensible tube connecting the bulb to the interior of the inflatable annulus, pressure fluid being introduced into the bulb by a fine hypodermic needle. The device may be wholly contained within the patient's body, and all surfaces thereof are of a substance, such as a medical elastomer, that is compatible with and resistant to the action of body fluids.

9 Claims, 5 Drawing Figures



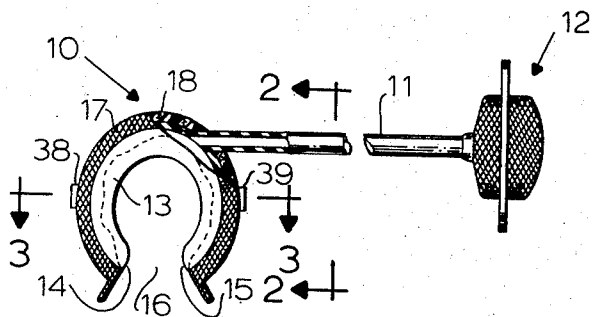


FIG. 1

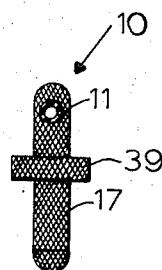


FIG. 2

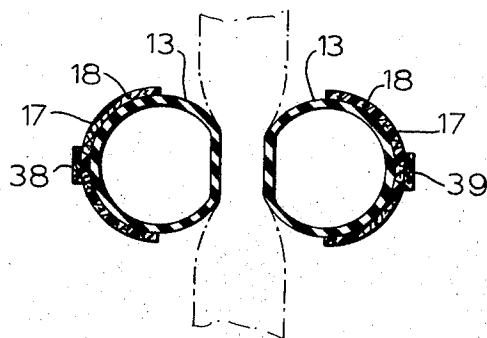


FIG. 3

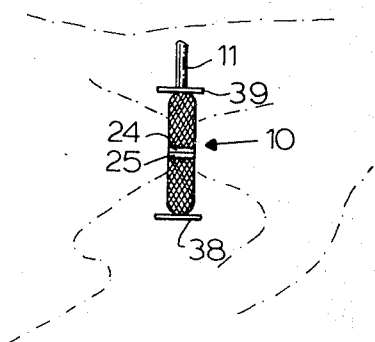


FIG. 4

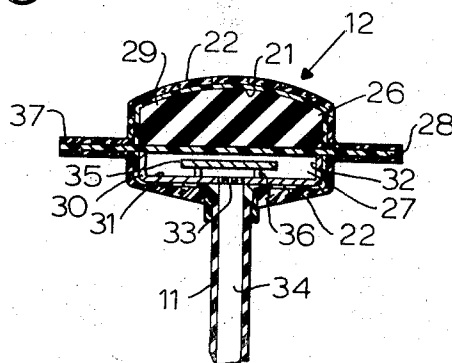


FIG. 5

IMPLANTABLE BULB FOR INFLATION OF SURGICAL IMPLEMENTS

This is a continuation, of application Ser. No. 121,406, filed Mar. 5, 1971.

BACKGROUND OF THE INVENTION

This invention concerns a means for restricting the rate of flow of blood through an animal blood vessel and particularly through an artery. More especially, it relates to an internal pulmonary arterial band, i.e., a device implantable within a human body for restricting blood flow through the pulmonary artery. The device is suitable for prolonged use within the human body, i.e., for months or even years of such use.

The invention described herein was made in the performance of work under a research grant from the United States Public Health Service.

It has been recognized that approximately eight babies per thousand have congenital heart disease, and, of these, four have greater than normal pulmonary arterial blood flow. Such mechanical defects have led to attempts to develop a safe, reliable, adjustable device to effect arterial banding. Attempts previously have required that mechanical control be applied from outside the body, as by a screw device to manipulate a tape encircling a blood vessel, and heretofore no such device has been capable of being implanted in the body for permanent or at least long-term use.

The present invention provides a device for arterial banding and mechanical restriction of blood flow through an artery, or other major blood vessel. It is safe, is compatible with body fluids, and is controllable externally while being totally contained within the patient's body. An advantage of the present invention is that the device is adjustable to conform to the size of the artery being banded and can be permanently emplaced, while yet periodic adjustments continue to be possible, as desired. Furthermore, the device is wholly implanted in the body and yet is later controllable without surgery. Further advantages are that adjustments can easily be made in the amount of inflation to accommodate for somatic growth, pulmonary pressure can be determined with the aid of this device, the band or annulus can be easily reached in order to close it upon emplacement and the connecting tube is short and non-twisting thus preventing interference in any desired flow of liquid.

SUMMARY OF THE INVENTION

The present invention provides, in combination, (1) an unclosed annulus or "doughnut" ring, capable of inward distention only, (2) a non-distensible bulb, (3) a non-distensible tube connecting the bulb to the annulus, and (4) means to control penetration by a later-inserted needle or the like and to protect the bulb from undesired punctures.

The annulus is shaped to form an unclosed circle, the circle being left open to enable insertion around an artery. The annulus is closed at both ends and has a distensible inner wall and a non-distensible or substantially non-distensible outer wall. The small non-distensible tube is affixed to the outer wall of the annulus at any convenient point and provides a conduit in open communication with the interior of the annulus through a suitable aperture in the outer wall of the latter. At the end of the tube distant from the annulus is

the bulb, which is used to pump fluid through the conduit and into the banding annulus, thereby inflating the annulus and distending the inner wall. The distending of the inner wall exerts pressure on the enclosed portion of the artery or other blood vessel and completely or partially restricts the flow of blood therethrough.

The purposes of having a non-distensible outer wall of the annulus are (1) that the effect of inflation of the annulus be directed substantially entirely inwardly toward the enclosed artery, and (2) that any pressure on the surrounding body structure be avoided or minimized. The desired restraint on the outer wall can be effected in any desired manner, one advantageous means being to affix thereto a reinforcing layer of Teflon (tetrafluoroethylene) tape.

The banding annulus can be made in several sizes to accommodate different situations or needs. For instance, annuli can be supplied in various internal diameters of from about 1.0 cm. to 3.0 cm., e.g., in steps of 0.5 cm. of intervals, the diameters being measured when the annuli are uninflated.

The tube that connects the interior of the annulus to the interior of the bulb is not distensible and is suitably made of Dacron or possibly of hard, non-distensible medical elastomer, such as silicone rubber. The hollow bulb is also not distensible and can be made from the same or similar material. The volume of this bulb is suitably about from 3 to 6 ml. A sink or pan of suitable body-compatible metal, e.g., titanium, and having a base and a side wall conforming to the interior shape of the bulb is disposed within the base of the bulb and facilitates location of the injection chamber with a needle and prevents perforation of the floor or lower wall of the bulb itself. This will be further explained in the more detailed description below. In the insertion or emplacement of the device, the bulb is preferably disposed on the sternum just underneath the patient's skin, where it can be readily located by palpation and inflated by means of a needle inserted through the skin.

The interior of the ring, tube and bulb are in open communication with each other and are self-sealing, and they must not leak. All surfaces of such a device to be wholly implanted in the body are made of a substance compatible with and resistant to the action of body fluids. Such a substance is suitably a medical elastomer such as silicone rubber, of varying degrees of hardness or cure to accommodate the need for distensible or non-distensible portions.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention and an advantageous mode of carrying it out are illustrated by the following description and by the annexed drawings, wherein:

FIG. 1 is a view in front elevation of an embodiment of an implantable pulmonary arterial band with the annulus partially inflated; the inner periphery is shown deflated in a broken line.

FIG. 2 is a view in side elevation of the band of FIG. 1.

FIG. 3 is a view in section taken on the line 3—3 of FIG. 1 of an inserted inflated annulus and its relationship to an enclosed artery.

FIG. 4 is a somewhat schematic view in side elevation of the device in place around the pulmonary artery of a patient.

FIG. 5 is a cross-sectional view of an embodiment of a non-distensible bulb of a device according to this invention showing the interior elements.

DETAILED DESCRIPTION OF THE INVENTION

For purposes of illustration only, the invention is illustrated by the device shown in the accompanying drawings.

This device is a pulmonary arterial band or extravascular occluder and comprises an inflatable non-closed ring or annulus 10 of flexible material to enable its introduction around an artery to enclose it, a connecting tube 11 and a bulb 12. Each of these components is made of or covered by material which is non-toxic and resistant to attack by body fluids, i.e., does not deteriorate within the body, because the entire device is to be implanted.

The annulus 10 includes an inflatable or balloon inner portion 13 which is formed from a medical elastomer and is flexible and distensible. An advantageous type of such elastomer is the silicone rubber widely available in commerce in medical grades. Preferably, it is made from or includes a self-sealing latex or elastomer. The annulus 10 is in the form of an incomplete or non-closed ring or circle, having two closed, sealed ends 14 and 15 forming an opening 16 therebetween. The outer wall 17 of the annulus 10 is reinforced so that it is not distensible when internal fluid pressure is applied although it, too, remains flexible. This reinforcement can be accomplished in one embodiment as shown by incorporating or embedding a fabric 18, such as nylon or Dacron mesh or cloth, within the outer portion 17 of the silicone rubber annulus 10. The curvature of the casing or annulus 10 helps to direct the non-reinforced inflatable or balloon portion 13 inwardly as it is inflated and to prevent rolling or distortion of such portion 13. An advantageous method of incorporating the fabric 18 in the annulus 10 is to form a coating piece or wire, of the required size and curvature, of such fabric molded into silicone rubber and to weld such tire to the outer surface of an inflatable tube of medical rubber.

The connecting tube 11 can be made from a harder, nondistensible silicone rubber, or of Dacron-reinforced silicone rubber, so that it remains of constant dimensions under the pressures to be applied. It is relatively short and relatively thickwalled so as to be twist-resistant and non-kinking. That is, the wall thereof may be from 0.062 to 0.065 inch thick and the tube is of such length as to extend in a substantially straight path, i.e., without curling upon itself, from adjacent the inner surface of the skin to the blood vessel to be treated. For example, the tube so extends from the sternum to the pulmonary artery area, in one embodiment, and is about 4 inches long. The tube 11 connects with a suitable aperture in the reinforced casing portion 17 and debouches into the interior of the annulus 10, being sealed thereto to prevent leakage. At the end remote from the annulus 10, the tube connects with a suitable aperture in the bulb 12 similarly and is also sealed thereto. Advantageously, the tube 11 connects tangentially to the outer surface of annulus 10, which provides for smoother flow of liquid therethrough and makes easier the placement of the annulus 10 relative to the artery.

The bulb 12 can be formed of a flexible, non-distensible and self-sealing elastomer, such as a suitable

reinforced or nonreinforced silicone rubber. It is adapted to being punctured and filled or emptied of a pressure-providing fluid, such as 0.9 percent aqueous saline solution, by using a very fine hypodermic needle, e.g., a No. 22 or 25 needle. Upon withdrawal of the needle the bulb 12 seals itself. This result may be advantageously obtained by providing a bulb 21 of a self-sealing elastomer. In one advantageous embodiment, the bulb 21 contains an upper chamber 26 and a lower chamber 27 separated by an impervious diaphragm 28. Upper chamber 26 contains silicone gel 29, which acts to seal any puncture in bulb 21 caused by insertion of the liquid-injecting needle.

Disposed in lower chamber 27, fitting snugly therein and substantially covering the base and side walls thereof, is a metal sink or pan 30 having a base 31, a side wall 32, and an aperture 33 in the base 31 registering with the central passage 34 in the tube 11. A baffle 35 is spaced from the base 31 by a plurality of legs 36 to provide free flow of liquid into and from the passage 34. In this manner, location of the receptacle for injected liquid is facilitated during such operation and the bottom and side walls of the bulb are protected by the metal from punctures due to insertion of the needle. The diaphragm 28 is suitably extended beyond the exterior wall of the bulb 12 to provide a sewing flange 37. Advantageously aperture 33 can be in the form of a plurality of small holes arranged to form a pattern to register with the interior of tube 11 and to be protected by baffle 35. The elastomer bulb 21 is then provided with a protective coating 22 of silicone rubber which is reinforced with Dacron mesh or the like. Suitably, diaphragm 28 with its flange portion 37 is also of such reinforced rubber. There are also sometimes provided a pair of diametrically disposed anchor or sewing tabs 38, 39, preferably disposed transversely or at right angles to the direction of curvature of the annulus 10 and affixed to its outer surface to enable suturing to adventitia of the artery so that the device remains in stable position on the artery being treated.

In using the device of this invention, the pulmonary artery 40 is made accessible by suitable, known surgical procedures, and the artery 40 is inserted within the annulus 10 by way of the opening 16, which may be pulled apart or enlarged as necessary, the ring 10 being quite flexible. After placement of the artery 40 in the annulus 10, ends 24 and 25 of annulus 10 which extend beyond closed ends 14 and 15 thereof may be trimmed if necessary by the surgeon and are then sewn together, suitably using heavy ligatures. The bulb 12 is placed on top of the sternum (not shown) just below the skin where it can be located later by palpation and easily reached by a hypodermic needle to fill or empty the bulb 12 and, through it and connecting tube 11, the annulus 10 and the inflatable annulus 10, to inflate and force inwardly distensible portion 13 to constrict the artery 40 as desired, as shown in FIG. 3. The incision in the patient is then closed by the surgeon in the usual manner, the implanted device remaining entirely subcutaneously disposed.

In use of the device after it is emplaced and any incision closed, the hollow bulb 12 is located by palpation and is filled by means of a hypodermic needle, as noted above, introducing a fluid such as 0.9 percent aqueous saline, which flows through the connecting tube 11 into the hollow interior of the annulus 10 causing the inner wall 27 to distend and constrict the artery 26, reducing

flow of blood therethrough. The flow of pressure fluid can be aided by manual pressure on the bulb 12. Fluid can be withdrawn, when desired, also by means of a needle. In each case the interior layer of the bulb 12 seals itself, as described.

It will be understood that the above specific description and the drawings have been given for purposes of illustration only and that variations and modifications can be made therein without departing from the spirit and scope of the appended claims. For instance, instead of a permanently fluid pressure substance, the bulb 12 can be filled with a fluid plastic mixed with a catalyst which will cause it to harden in a predetermined time after it fills the inflatable element.

Having described the invention, what is claimed is:

1. A bulb, adapted to be implanted in a human body,

said bulb being non-distensible and self-sealing, and comprising
an upper chamber,
a lower chamber,
an impervious diaphragm separating said chambers,

a shield means in said lower chamber to protect said lower chamber from puncture by a needle, said shield means being a metal sink having a bottom and a side wall, said sink fitting snugly within said lower chamber substantially covering said side wall and bottom of said chamber, and having an aperture in said bottom, a flexible tube having a central passage registering with said aperture, and means to anchor said bulb within said body.

2. A totally implantable, flexible, non-distensible self-sealable bulb having a hollow interior and being adapted to penetration by a hypodermic needle, and comprising
an upper chamber,

a lower chamber,
an impervious diaphragm separating said chambers,
silicone rubber gel disposed in said upper chamber,

shield means in said lower chamber to protect said lower chamber from penetration by a needle, said shield means being a metal sink having a bottom and a side wall,

said sink fitting snugly within said lower chamber substantially covering the side wall and base of said chamber, and having an aperture in said bottom registering with the central passage of a flexible connecting tube, and

a non-distensible flexible, twist-resistant tube having a central passage providing a conduit leading from the interior of said bulb.

3. The bulb of claim 2 wherein said non-distensible tube is formed of silicone rubber.

4. The bulb of claim 2 wherein said tube is relatively thin-walled whereby to resist twisting and kinking so as to enable free and rapid flow of liquid therethrough.

5. The bulb of claim 2 wherein said shield means is a metal sink having a bottom and a side wall, said sink fitting snugly within said lower chamber substantially covering the side wall and base of said chamber, and having an aperture in said bottom.

6. The bulb of claim 2 wherein said diaphragm extends to form an annular flange around said bulb.

7. The bulb of claim 5 wherein said metal is titanium.

8. The bulb of claim 5 having a baffle in said sink spaced from and protecting said aperture.

9. The bulb of claim 5 wherein said sink has an aperture of a plurality of small holes arranged in a pattern to register with said central passage.

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