

[54] **IMPLANTABLE CLAMP**

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[51] Int. Cl.² **A61B 19/00**

[58] Field of Search 128/1 R, 346, DIG. 25;
3/1; 251/4, 5, 9, 10

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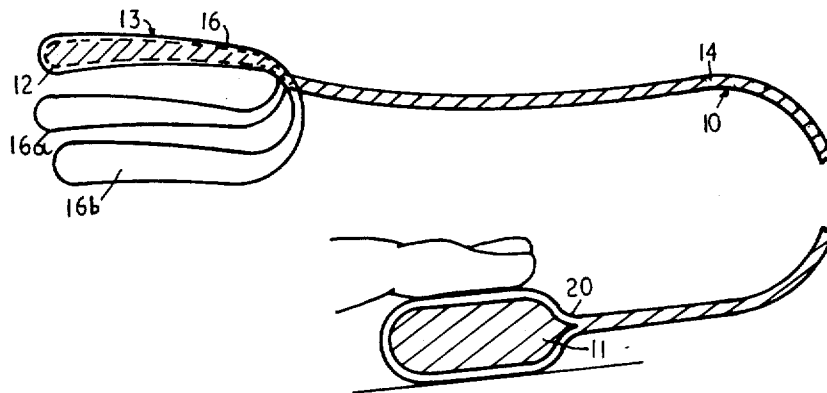
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[57] **ABSTRACT**

An implantable prosthetic clamp comprising a fluid filled actuating bulb operately connected through a fluid duct to an operating balloon affixed to the clamp, actuation of the bulb serving to expand the balloon which transposes the clamp from an "open" to a "closed" condition or vice versa.

4 Claims, 5 Drawing Figures



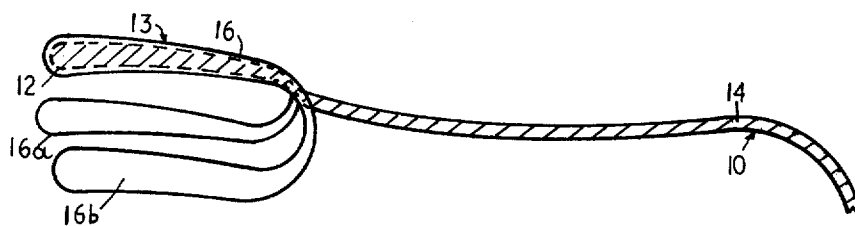


FIG. 1

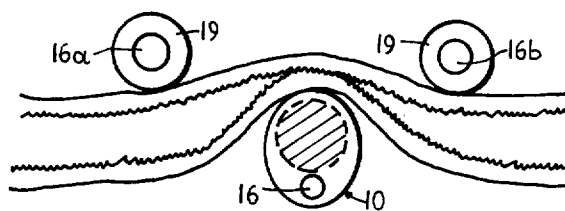
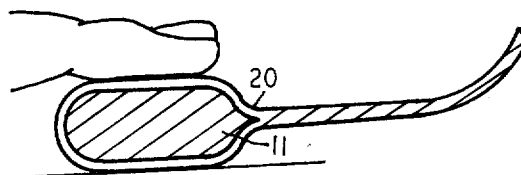


FIG. 2

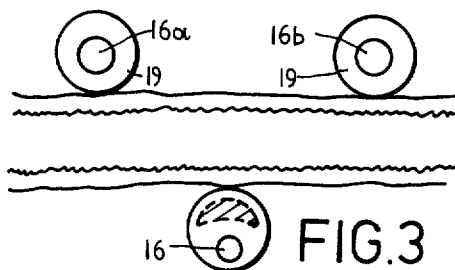


FIG. 3

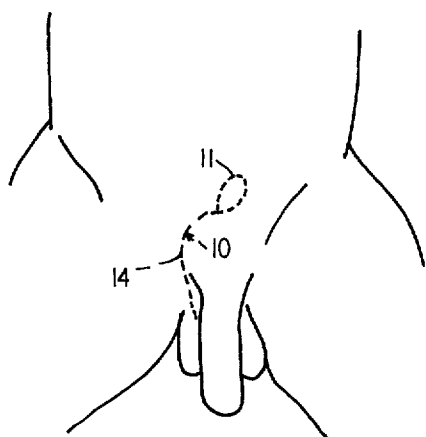


FIG. 4

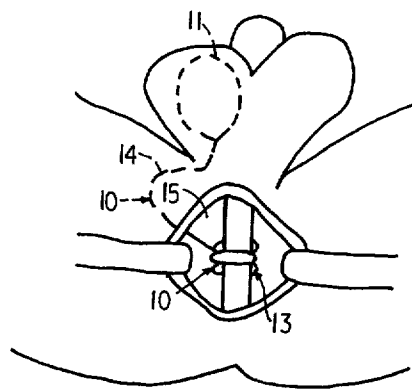


FIG. 5

IMPLANTABLE CLAMP

The present invention relates to a clamp which is implantable in the body of a human, or of another animal, to restrict the flow of a liquid along a vessel or duct of the body.

Urinary incontinence has been recognised as a condition occurring in both males and females. Various surgical procedures have been proposed to treat this condition; however, these still remains a proportion of patients who do not respond. The device according to this invention is designed, inter alia, to provide a prosthetic device for persons suffering urinary incontinence. It will be clear to persons skilled in the art, however, that the implantable clamp according to this invention may be used in numerous applications other than for the correction of urinary incontinence.

The present invention consists in an implantable prosthetic device comprising a compressible fluid reservoir, jaw means moveable between an "open" and a "closed" condition, the jaw means being biased towards one of these conditions, and a fluid expandable actuating member connected to the reservoir by a fluid duct, the actuating member being adapted to move the jaw means to the other of said conditions upon being expanded by the compression of the fluid reservoir.

The jaw means may either be biased towards an open or a closed position and inflation of the actuating member serves to force the jaw means towards the other position, e.g. if the jaw means are normally biased to a position closely adjacent one another, i.e. a closed position, the actuating member will be so disposed that its expansion will cause the jaw means to be forced apart to the open position. In the converse situation the jaw means may be biased to an open position and compression of the reservoir will move the jaw means to a closed position. In this latter case valve means will be required on the reservoir to allow the jaw means to be maintained in a closed position for a prolonged period. The valve means may conveniently comprise an operable one way flap valve fitted between the reservoir and the fluid duct.

The clamp according to this invention is designed to be totally implanted in the body with the jaw means extending transversely of the vessel or duct to be controlled.

The compressible fluid reservoir is preferably provided with a wall which is at least in part flexible such that pressure applied to that portion of the wall will be transmitted to the fluid therein; the fluid pressure in the reservoir is transmitted to the actuating means to cause the jaw means to be re-oriented. The reservoir is preferably a flexible bulb which can be compressed by pressure from any direction such that the bulb may be implanted in the body in any orientation without affecting the ability of the reservoir to be compressed to create a source of fluid pressure to actuate the jaw means. The bulb is preferably implanted in the body intermediate the skin and a firm underlayer such as an area of hard muscle, cartilage or bone or alternatively in the scrotum of a male patient.

The fluid duct interconnecting the fluid reservoir and the activating member is preferably formed integrally with the reservoir and the actuating means. The system being filled, most preferably, with a liquid such as a non-toxic silicone oil. In an alternative embodiment of

the invention, the system may be filled with air or with some other fluid such as an isotonic saline solution.

The reservoir, actuating member and duct as well as the jaw members are preferably made of a silicone elastomer such as that sold under the trade name SILASTIC. This material is advantageous in being non-irritating to the tissues of humans or other animals as well as being subject to negligible deterioration or structural degradation. The reservoir and the jaw means and/or the actuating member are preferably provided with a covering of "dacron" velour, or with some other means, into which the surrounding tissues may grow to anchor the various members in place in the body. If desired a stitch or stitches may be provided to anchor the parts of the clamp in place until the surrounding tissue has had a chance to grow into the anchoring means.

The jaw means itself is preferably so constructed and arranged that on one side of the duct there are a pair of spaced apart arms while there is on the other side of the duct a single arm spaced, in a longitudinal sense, intermediate the arms on the one side of the duct.

The jaw means are preferably formed integrally with a resiliently flexible bight portion, the actuating member being disposed adjacent the bight portion between arms of the jaw means. Expansion of the actuating members will serve to bias the arms apart with a consequent flexing of the bight portion. When the actuating member is allowed to contract, the resilience of the bight portion will return the arms of the jaw means to their initial positions.

In another embodiment of the invention, the actuating means is formed as an elongate balloon extending along one of the arms of the jaw means, the compression of the reservoir serving to expand the balloon such that the duct is constricted between the expanded balloon and the outer arm or arms of the jaw means.

The surgical procedure for the implantation of the clamp will depend upon the vessel or duct to be controlled and the manner in which fluid pressure is to be generated in the reservoir. If the device is to be used to control urinary incontinence in males it is envisaged that perineal and supra-pubic incisions would be required to allow placement of the clamp across the urethra and the reservoir in a position ventrally of the pelvis. Alternatively, the device could be inserted via one incision with the reservoir located in the scrotum. In females the device according to the invention could be used for, inter alia, the treatment of failed stress incontinence in which case the clamp could be placed across the urethra from a retropubic approach and the whole device inserted via the one incision, again with the reservoir placed in the pelvic region.

If the reservoir is placed in the pubic region or the scrotum as discussed above, it may be operated digitally. In another embodiment of the invention, the reservoir may be mounted for operation by some other part of the body, e.g. it could be mounted behind the knee for operation by a bending of the knee or it could be mounted on the hip for actuation by the elbow of a patient. These latter arrangements would be of obvious advantage to incapacitated persons without the use of hands.

Hereinafter given by way of example only is a preferred embodiment of the invention which is described with reference to the accompanying drawings in which:

FIG. 1 shows a clamp device according to this invention in an open position.

FIG. 2 shows a cross sectional view along A A of FIG. 1 when the clamping device is closed.

FIG. 3 shows a cross sectional view along A A of FIG. 1 when the clamping device is open, and

FIGS. 4 and 5 depict two surgical procedures for implantation of a clamp according to this invention.

The implantable clamp 10 comprises a bulbous reservoir 11, and actuating balloon 12 and jaw means 13.

The reservoir 11 is a flexible bulb made of a SILASTIC material and is formed integrally with a duct 14 which interconnects the reservoir 11 and the actuating balloon 12. The duct 14 is itself made of a flexible SILASTIC material. The actuating balloon 12 is connected to the duct 14 in a fluid tight manner and is also made of a flexible grade of SILASTIC. The reservoir 11, duct 14 and actuating balloon 12 are completely filled with a silicone oil of low viscosity such that the application of pressure to the reservoir 11 will result in the expansion of the actuating balloon 12. An operable one way flap valve 20 is provided between the reservoir 11 and the fluid duct 14. The valve is so arranged as to enable the balloon 12 to be maintained in an inflated condition. When it is desired to deflate the balloon the valve is squeezed to render it inoperative and the natural resilience of the material of the balloon 12 will force the fluid back into the reservoir 11.

The actuating balloon 12 is disposed along the arm 16 of the clamping device 15 and faces towards the spaced apart arms 16a and 16b. The arms 16 are connected together by a bight portion 16. The arms of the clamping device are formed from stainless steel with a coating of a resilient grade of SILASTIC material which is thickened to form cushions 19 on those portions of the arms in contact with the duct.

The provision of the silastic cushions on the arms and the 3 arm construction of the jaw means eliminates possible crushing of the duct and instead closes the duct by kinking it. This arrangement prevents pressure necrosis of the duct as well as kinking and lengthening the mucosa which is desirable in attaining continence.

The clamping device and the reservoir are each covered with a layer of dacron velour (not shown) to assist in maintaining the device in position in the body.

FIGS. 4 and 5 show alternative method for the insertion of the device according to this invention for the purpose of controlling urinary incontinence in males. In the arrangement of FIG. 4 the clamping device 15 is inserted through a perineal incision such that it extends transversely of the urethra. By tunnelling through the groin and into the suprapubic region a passage is formed for placement of the duct. A suprapubic incision is made to assist placement of the reservoir and to allow it to be fastened to the fascia over the rectus muscle. In the arrangement shown in FIG. 5 the reservoir is placed in the scrotum which allows placement of the device through a single incision.

Actuation of the device is achieved by manually pressing the area over the reservoir, or by squeezing the scrotum, to cause the actuating balloon to expand with consequent actuation of the jaws. Thus a person fitted with the implant can readily control urination.

The claims defining the invention are as follows:

1. An implantable prosthetic device comprising a compressible fluid reservoir, jaw means transportable between an "open" and a "closed" condition, the jaw means being biased towards one of these conditions, and a fluid expandable actuating member connected to the reservoir by a fluid duct, the actuating member being adapted to transpose the jaw means to the other of said conditions upon being expanded by the compression of the fluid reservoir, said jaw means comprising three spaced apart parallel arms, the arms being connected together by a bight portion and being so disposed as to be, when viewed in cross-section, at the apices of a notational equilateral triangle.

2. An implantable clamp as claimed in claim 1, in which the actuating member comprises a balloon disposed along one arm of the jaw means, the jaw means being biased to the open position by the elasticity of the balloon.

3. An implantable clamp as claimed in claim 1, in which an operable one way valve is provided between the reservoir and the fluid duct.

4. An implantable clamp as claimed in claim 1 in which the reservoir, the fluid duct and the actuating means are filled with a silicone oil.

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