United States Patent [19]

Small et al.

[11] **3,893,456**

[45] **July 8, 1975**

[54] **PENILE PROSTHESIS**

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[73] Assignee: **Heyer-Schulte Corporation**, Goleta, Calif. ; by said James E. Cox

[22] Filed: **Aug. 7, 1974**

[21] Appl. No.: **495,315**

[52] **U.S. Cl.** **128/79**; 128/305; 3/1

[51] **Int. Cl.** **A61f 5/00**

[58] **Field of Search** 128/79, 305; 3/1

[56] **References Cited**

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Journal of Urology, Vol. 100, 1968, pp. 709–710: Lash, Silicone Implant for Impotence.

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Journal of Urology, Vol. 109, April 1973, pp. 641–645, Morales et al., Penile Implant for Erectile Impotence.

Primary Examiner—Lawrence W. Trapp

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[57] **ABSTRACT**

A prosthesis for implantation in the penis to provide a flaccid penis with rigidified dimensions of length and of width, and with the property of flexural stiffness. The prosthesis is used in pairs, each of which is a one-piece member that includes a composite rod having a dimension of axial length and, for the major proportion of its length, is composed of two physically distinct bodies which are integrally joined to each other, one of which is more resistant to bending and to compressive deformation than the other, and a prong extending from said rod, said prong decreasing in lateral cross-section as it extends away from the rod. One of the bodies is stiffly flexible. In the preferred embodiment of the invention, the first of the bodies is a tube of solid material having an inner wall and an outer wall, the inner wall defining an axially extending cavity, the second body filling the cavity, the said first body being the one which is stiffly flexible. The second body is preferably made of a gel or of a foam.

20 Claims, 4 Drawing Figures

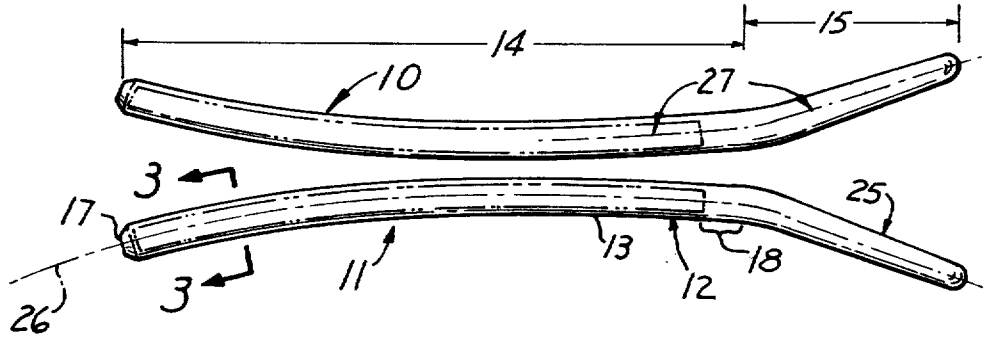


FIG. 1

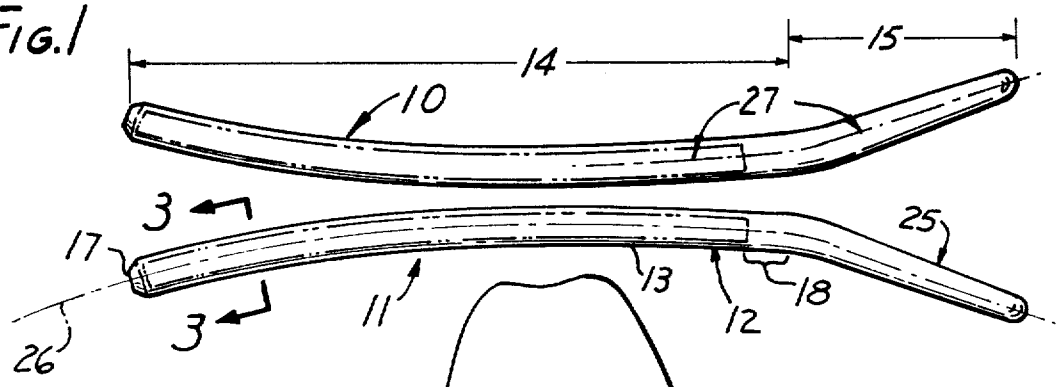


FIG. 2

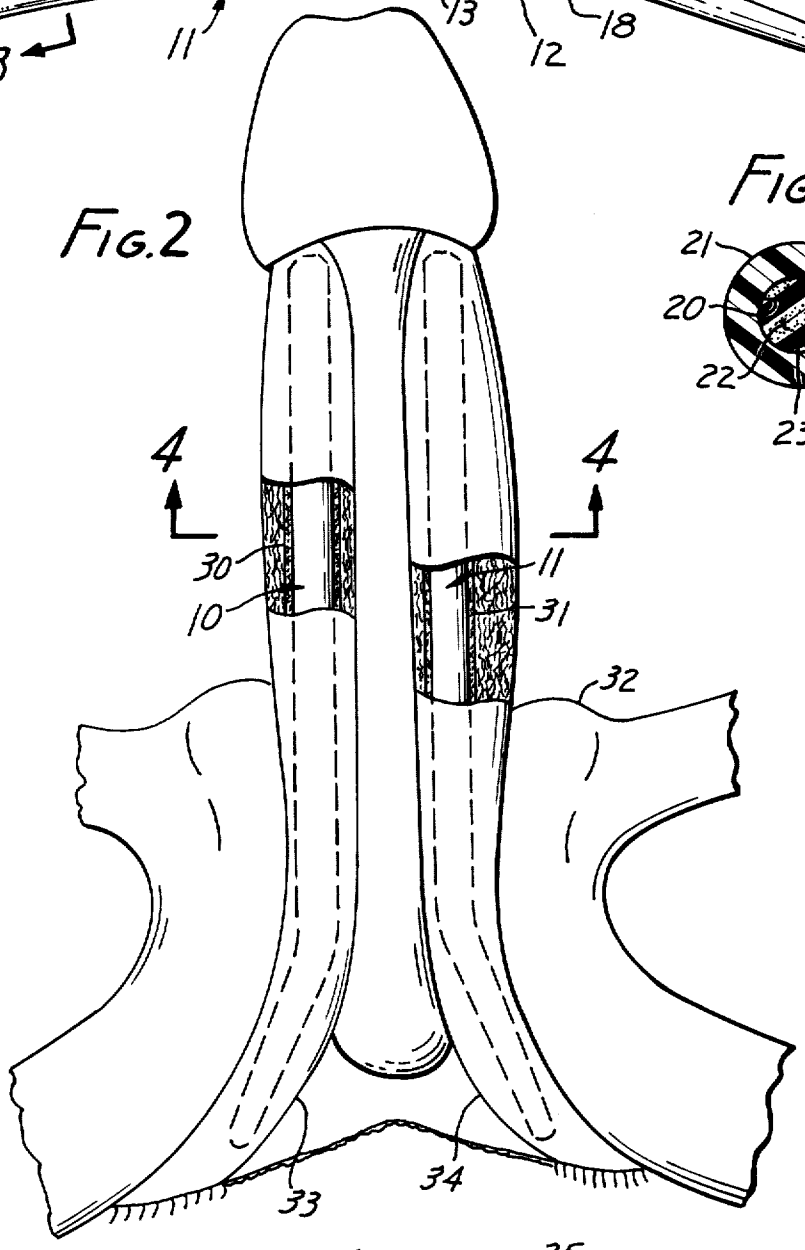


FIG. 3

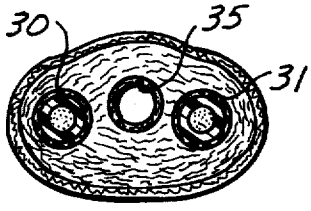


FIG. 4

PENILE PROSTHESIS

This invention relates to a penile prosthesis for implantation in the penis to provide it with rigidified dimensions of length and width, and having the property of flexural stiffness.

Male impotence stemming from neurologic disease, trauma, vascular disease, and endocrinologic metabolic disease is a matter of frequent occurrence, and has been the subject of attempts to provide an implant or other means which is useful to provide the penis with useful stiffness. Examples of previously known implants are shown in the following U.S. Pat. Nos. **844,798; 1,362,398; 2,455,859** and **3,446,206.**

A disadvantage common to prior art prostheses is their inability to provide at the same time sufficient rigidified dimensions of length and of width. It is a feature of this invention that implantation of a pair of the subject prostheses provides not only flexural stiffness, but maintains the length, girth and width of the penis at useful values. Furthermore, the flexural stiffness (which is permanent) is such as to be manageable without embarrassment by the wearing of suitable undergarments.

The prosthesis according to this invention can readily be implanted with straightforward surgical techniques and remains in place as a permanent and useful implantation.

A prosthesis according to this invention comprises a one-piece member which includes a composite rod that has a dimension of axial length and, for the major proportion of its length, is composed of two physically distinct bodies that are integrally joined to each other. One of the bodies is more resistant to bending and to compressive deformation than the other. A prong extends away from said rod, the prong decreasing in lateral cross-section as it extends away from the rod. One of the bodies is stiffly flexible.

According to a preferred but optional feature of the invention, the first of the said bodies is a tube of solid material which has an inner wall and an outer wall. The inner wall defines an axially extending cavity, and the second body fills the cavity. The first body is the one which is stiffly flexible.

According to another preferred but optional feature of the invention, the material of the second body is a gel or a foam.

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 shows a pair of prostheses according to the presently preferred embodiment of the invention;

FIG. 2 shows the pair of prostheses of FIG. 1 implanted in the penis;

FIG. 3 is a cross-section taken at line 3—3 of FIG. 1; and

FIG. 4 is a cross-section taken at line 4—4 of FIG. 2.

In FIG. 1 there is shown a pair of identical prostheses **10, 11** and indicating their curvatures in the undistorted position. Only prosthesis **11** will be described in detail, because they are identical. This prosthesis comprises a one-piece member **12** which includes a composite rod **13**, whose dimension of axial length is indicated by dimension **14.** For a major proportion of this dimension of length, the rod is composed of two physically distinct bodies that are integrally joined with one another. The first body **15** is the outer body, and the second body **16** is inside it.

The second body extends for substantially the full length of the composite rod, except for the length of an end closure **17** and of a small solid transition portion **18** at the other end.

The first body **15** is a tube of solid material having an inner wall **20** and an outer wall **21.** The inner wall defines an axially extending cavity **22,** and the second body fills this cavity.

One of the bodies is more resistant to bending and to compressive deformation than the other. In the preferred embodiment, the first, outer, body is the more stiffly flexible, and this stiff flexibility is derived from the fact that it is made of solid material and of a tube-like construction which tends to resist bending and tends to restore itself inherently as a function of its stiff flexibility to the undistorted shape shown in FIG. **1.**

The second, inner, body is less resistant to bending and to compressive deformation. The presently preferred material of which the second body is made is a cellular foam which has some structural integrity, but less than that of the solid material, because of the formation of voids **23** in the foam.

As an alternate material of construction for the second body, a gel may be used instead of a foam. Both the gel and the foam tend to fill the volume of the cavity and, by doing so, tend to be resistant to compression of the cavity and thereby lend some side support to the outer wall, tending to resist buckling and crumpling. The foam is more reliable for this purpose than the gel, but both are suitable.

A prong **25** forms another part of the one-piece member and extends continuously from the transition portion **18** of the prong. It may be separately manufactured and cemented to the rod. The outer boundary of any lateral cross-section of the rod and of the prong is circular, as can best be seen in FIG. **3.** The term "lateral cross-section" means a cross-section which is taken normally to the axis **26** of the prosthesis, meaning its general direction of length.

The prong makes an obtuse angle **27** with the rod. The prong is solid and of a uniform material throughout.

A suitable material of construction for the entire prosthesis (including the foam or gel) is silicone rubber which can readily be formulated by known techniques. This material when solid is inherently flexible and tends to be shape-retaining. The foam also has this property, but less so than the solid, continuous material without any voids.

The basic material used for both bodies may be the same, namely a medical grade silicone elastomer, for example, the silicone elastomer sold by Dow-Corning Corporation of Midland, Mich., under its trade style MDX-4-4515. In its purchased state it is gummy, but upon being heated in a mold or extruder to form the first body, a heat-sensitive catalyst in the composition sets the material into a solid, non-gummy structure. The durometer hardness can be controlled by appropriate selection of heat and curing time, and this will be selected properties for the prosthesis.

The material for the second body is preferably the same elastomer, but cured while mixed with a blowing agent which while curing decomposes so as to put gas, usually nitrogen, into the material to form the voids. In general, void proportion between about **20** percent and about **50** percent appears to be appropriate. A suitable

blowing agent is sold by E. I. duPont Chemical Company under its trade style "Nitrosan."

The material of which the second body is made need not be made of silicone rubber, for the reason that it will not make contact with the human tissue, but it is convenient to make it of the same material. Silicone rubber, of course, is inert to the tissue which surrounds it.

The dimension of axial length **14** is conveniently approximately **13** cm., and the length of the prong is conveniently approximately **4.5** cm. The outer diameter of the outer wall will tend to be on the order of about **0.9** to **1.1** cm. These dimensions are arbitrary and are dependent upon the physical characteristics of the person in whom the prosthesis is to be implanted. In a device having a rod of outer diameter of approximately **1.1** cm., the diameter of the inner wall is on the order of **0.55** cm., and the wall thickness is uniform. The prong decreases to approximately two-thirds its initial diameter as it extends away from end to end.

A pair of the prostheses is shown being implanted in the penis in FIG. **2**. For general information, the corpus cavernosa **30, 31** are shown, which are generally tubular structures within the penis into which the respective rods will be fitted. The pubic symphysis **32** is shown as are the crus **33, 34** of the corpus cavernosa. The ischeal tuberosity is disposed toward the base and rearward of the section shown in FIG. **2** in accordance with known physiology.

It will be noted in FIG. **1** that the rod has a gentle curvature, and the curvature is substantially as shown to scale.

FIG. **4** shows the prostheses implanted, the urethra **35** being schematically shown as are the corpus cavernosa.

The following information concerning implantation, selection, and postoperative care have been found to be useful, although the individual surgeon is expected to evaluate the procedures to be used on the basis of his own medical training and experience.

The patient is placed in the lithotomy position, and the perineum and genitalia are completely prepped and draped. A No. **16** Fr. Foley catheter is inserted into the urethra to be used for identification purposes only, and is removed at the completion of the operative procedure. A vertical midline incision is made in the perineum from the base of the scrotum. The incision is carried down to the bulbocavernosus muscle which is identified from its appearance, as well as with the indwelling catheter. All fat is removed from this muscle, as well as from each of the ischiocavernosus muscles. The bulbocavernosus muscle and urethra are then retracted laterally, and all overlying fat is removed from the right ischiocavernosus muscle. A vertical incision is then made in the right ischiocavernosus muscle and crus of the penis for a distance of approximately 2½ cm. The edges of the ischiocavernosus muscle and crus of the penis are then grasped with Allis clamps, and the corpus cavernosa is gradually dilated with Hegar dilators. The dilation is first carried distally to the most distal extent of the corpus cavernosa so that the dilator can be felt under the glans penis. The dilation is then carried proximally to the ischial tuberosity. Care must be taken in dilating proximally as it is quite easy to perforate the ischiocavernosus muscle in this area. Dilation will usually start with a No. **4** or No. **5** Hegar dilator, and the corpus cavernosa will usually dilate to a No. **9** or No. **10** Hegar dilator. The rod of the prosthesis is then placed within the corpus cavernosa so that the prosthesis is sitting under the glans penis. The prong of the prosthesis is then placed within the ischiocavernosus muscle so that it sits firmly at the ischial tuberosity.

The incision in the corpus cavernosa and ischial cavernosus muscle is then closed with a continuous suture of **3-0** chromic catgut. The bulbocavernosus and muscle and urethra are then retracted to the chondral laterial side and, using the same technique, another of these prostheses is inserted in the chondral lateral corpus cavernosa. After this prosthesis has been inserted in the incision in the ischiocavernosus, and the corpus cavernosa have been closed, the subcutaneous tissues are closed with multiple interrupted sutures of **3-0** plain catgut, and the skin is closed with multiple interrupted sutures of **4-0** chromic catgut. The Foley catheter is then removed.

The proper prosthesis size depends upon the length of the corpus cavernosa and must be determined at the time of surgery. The longest prosthesis is used which will comfortably fit within the corpus cavernosa, so that the prosthesis will fit underneath the glans without slippage of the glans over the top of the prosthesis.

Postoperatively, the penis follows the normal curve of the prosthesis and tends to lie toward the abdomen. However, after the wounds have healed, the penis can then be placed in its normal position and can be held there with jockey shorts. Complete healing usually takes about **2** weeks, and the patients are ready for intercourse in **2** to **3** weeks after surgery.

At the time of surgery, as well as for the next several days, the patients are prophylatically given Garamycin to prevent any infection in the corpora.

The foregoing penile implant (prosthesis) provides a unitary construction which, when implanted in pairs as shown, provides a substantial dimension of width and of length to the flaccid penis, as well as a suitable flexural rigidity. A solid rod of silicone rubber would not be suitable, because it would be too rigid when made in the required dimensions. On the other hand, the use of an unsupported thin-walled tube would be unsatisfactory, because an unsupported tube of the dimensions involved would tend to buckle too readily to give the desired support. Providing the second body of a material which tends to either build up an internal pressure that resists deformation (when a gel), or itself inherently provides structural wall support (when a foam), results in a total rod construction which gives an optimal property to the penis when installed. The term "foam" relates to a material which forms a continuous matrix interspersed with voids.

The prong is shaped to fit nicely in the intended region and serves as an anchor to prevent the rod from turning to a position where it might not given an appropriate angular support.

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

We claim:

1. A prosthesis for implantation in the penis to provide a flaccid penis with rigidified dimensions of length and width and with the property of flexural stiffness, said prosthesis comprising a one-piece member which

includes a composite rod having a dimension of axial length and, for the major proportion of its length, comprising two physically distinct bodies that are integrally joined to each other, one of which is more resistant to bending and to compressive deformation than the other, and a prong extending from said rod, said prong decreasing in lateral cross-section as it extends away from the rod, one of the bodies being stiffly flexible.

2. A prosthesis according to claim **1** in which the prong is solid and stiffly flexible.

3. A prosthesis according to claim **1** in which the material of the prong is solid and uniform throughout the prong.

4. A prosthesis according to claim **1** in which a first of said bodies is a tube of solid material having an inner wall and an outer wall, the inner wall defining an axially extending cavity, the second body filling the said cavity, the said first body being the one which is stiffly flexible.

5. A prosthesis according to claim **4** in which the material of the second body is a gel.

6. A prosthesis according to claim **4** in which the material of the second body is a foam.

7. A prosthesis according to claim **6** in which the foam is cellular.

8. A prosthesis according to claim **4** in which the material of the first body is silicone rubber.

9. A prosthesis according to claim **4** in which the material of both bodies is silicone rubber, the material of the second body being a gel.

10. A prosthesis according to claim **4** in which the material of both bodies is silicone rubber, the material of the second body being a foam.

11. A prosthesis according to claim **4** in which the material of the prong is identical to the material of the first body.

12. A prosthesis according to claim **1** in which the outer boundary of a lateral cross-section taken at any location along the length of the rod is substantially circular.

13. A prosthesis according to claim **12** in which the diameter of the said outer boundary is substantially that of the inner diameter of a dilated corpus cavernosa, and the dimensions of the prong are such as to fit firmly in the ischial tuberosity of the crus of the penis.

14. A prosthesis according to claim **1** in which the prong forms an obtuse angle with the rod.

15. A prosthesis according to claim **14** in which the outer boundary of a lateral cross-section taken at any location along the length of the rod is substantially circular.

16. A prosthesis according to claim **15** in which the diameter of the said outer boundary is substantially that of the inner diameter of a dilated corpus cavernosa, and the dimensions of the prong are such as to fit firmly in the ischial tuberosity of the crus of the penis.

17. A prosthesis according to claim **16** in which a first of said bodies is a tube of solid material having an inner wall and an outer wall, the inner wall defining an axially extending cavity, the second body filling the said cavity, the said first body being the one which is stiffly flexible.

18. A prosthesis according to claim **17** in which the material of the second body is a gel.

19. A prosthesis according to claim **17** in which the material of the second body is a foam.

20. A prosthesis according to claim **19** in which the foam is cellular.

* * * * *

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 3,893,456

DATED : July 8, 1975

INVENTOR(S) : MICHAEL P. SMALL AND JAMES E. COX

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Abstract, line 16	"axially extending" should read --axially-extending--
Col. 1, line 41	"axially extending" should read --axially-extending--
Col. 2, line 7	"axially extending" should read --axially-extending--
Col. 4, line 57	"given" should read --give--
Col. 5, line 16 (Claim 4, line 3)	"axially extending" should read --axially-extending--
Col. 6, line 24 (Claim 17, line 3)	"axially extending" should read --axially-extending--

Signed and Sealed this

twentieth Day of April 1976

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks