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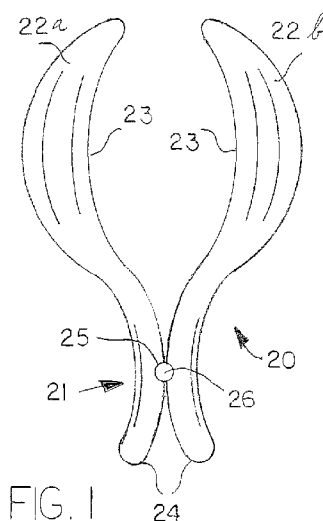
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(54) Title: PROCESS FOR IMPLANTATION OF AN INFLATABLE PENILE PROSTHESIS AND DEVICE USED IN THE
PROCESS



(57) Abstract: A surgical process, and a device used in the process, to prevent post-operative migration of the pump of an inflatable penis prosthesis system within the scrotum. The process is comprised of implantation of the inflatable penis prosthesis system in typical surgical manner, including the step of positioning the IPP pump within the scrotum to provide access for subsequent utilization of the pump, with the added steps of providing an external clamp, post-operatively positioning the clamp exteriorly on the scrotum in a manner that restricts movement of the pump within the scrotum.



PROCESS FOR IMPLANTATION OF AN INFLATABLE PENILE PROSTHESIS AND
DEVICE USED IN THE PROCESS

Cross-Reference to Related Application

5 The present application claims the benefit of U.S. patent application serial No. 61/835,022, filed June 14, 2013, which is hereby incorporated by reference in its entirety.

Technical Field

10 This invention relates generally to the field of inflatable penile prostheses and surgical methodologies for the implantation of inflatable penile prostheses. More particularly, the invention relates to an improved implantation process and devices used in the improved process.

Background

15 Inflatable penile prostheses address the problem of erectile dysfunction in men. Inflatable penile prosthesis systems are known, and may comprise a pair of inflatable elongated cylinders positioned within the penis, a pump positioned within the scrotum, and a fluid reservoir implanted within the abdomen. Flexible tubular conduits connect the elements of the system. An example of such a system is shown in U.S. Patent No. 8,192,352, the
20 disclosure of which is incorporated herein by reference, which issued on June 5, 2012, to Morningstar et al. To create an erection, the pump is repeatedly compressed to transfer fluid from the reservoir to the cylinders. A release mechanism is provided in conjunction with the pump which when activated allows the fluid to return to the reservoir.

25 Typically, the scrotum or lower abdomen of a patient is incised to gain access to the penile corpora cavernosa. The paired corpora are then incised in order to provide access to the internal portion of the erectile bodies. The corpora cavernosa are then dilated with one or more dilation tools and prosthetic cylinders are inserted into the penis. The pump is positioned within the scrotum and connected by tubing to the other elements of the device. The reservoir is placed in the abdomen and also connected by tubing to the other device
30 elements.

 A common problem in inflatable penile prosthesis (IPP) surgery, particularly with the infrapubic approach, is post-operative migration of the pump away from the dependent portion of the scrotum (which is the preferred location for easier access by the patient). The pump frequently migrates cephalad during the first 24 hours following surgery, likely due to

accumulation of pooled blood and edematous fluid in the scrotum. Once the pump has migrated, it can become fixed or tethered in the undesirable position. It therefore becomes extremely difficult for the patient to use the IPP device and may result in the need for revision surgery to re-position the pump. One idea that has been proposed to address the pump migration issue has been to place a suture in the dependent portion of the scrotum and tie the suture around the pump to secure it. There are several problems with this method, in that it is 1) difficult to safely reach the dependent scrotal dartos from an infrapubic incision, 2) placing a suture in the thin scrotal wall risks violating the skin and potentially increasing infection risk, and 3) permanently fixing a pump into position may cause significant discomfort or pain, including the possibility of testicular discomfort since the pump cannot migrate to the portion of the scrotum with the least amount of pressure as it otherwise would. This last point becomes particularly relevant as patients sit on a chair or bicycle seat. Pumps that are not fixed tend to move to the location of least pressure within the scrotum, thereby minimizing the risk of pump bother or testicular discomfort. Finally, it is preferable to have a pump that is not fixed rigidly in place because the deflation bar release mechanisms may not be positioned in an optimal orientation for the patient. With a non-fixed pump, the patient can easily maneuver or twist the pump to better position the release mechanisms for activation.

It is an object of this invention to provide an improved process for implantation of an inflatable prosthesis system by providing a methodology and devices of various embodiments for use in the process, whereby the undesirable post-operative migration of the pump within the scrotum is minimized or obviated. It is a further object to provide such a process wherein a clamping device is positioned externally on the scrotum post-operatively, the clamping device restricting migration of the pump from the lower portion of the scrotum during the period of time when accumulation of pooled blood and edematous fluid in the scrotum is likely to occur.

Summary

The invention is in general a process, and a device used in the process, to prevent post-operative migration of the pump of an inflatable penis prosthesis system within the scrotum. The process comprises implantation of the inflatable penis prosthesis system in typical surgical manner, including the step of positioning the IPP pump in the scrotum to provide access for insertion of the pump, with the added steps of providing an external clamp, immediately post-operatively positioning the clamp externally on the scrotum in a manner that restricts movement of the pump within the scrotum, and leaving the clamp in

position until the problem of accumulation of pooled blood and edematous fluid in the scrotum has minimized or is no longer present, preferably for a time period of about 4 to 48 hours and preferably for a time period of about 6 to 24 hours. Once the initial post-surgical period has passed, the pump would be overwhelmingly more likely to remain in position even
5 if the scrotum continues to experience some degree of swelling for the next several days.

The clamping device may have various embodiments differing in size, shape and closure mechanism suitable for retention and restriction of the pump, the release mechanism or the tubular conduits. For example, the clamping device may be clamshell-shaped or ring-shaped with a pair of opposing encircling arms, the configuration being preferably optimized
10 to minimize focused pressure points and overall compressive force. The clamping device may be formed of a transparent material or be fenestrated for observation of the underlying skin tissue. The clamping device may for example be self-biasing because of the material of composition or be provided with a mechanical biasing mechanism, such as a spring or a turn-screw, to maintain the opposing halves of the clamps in the closed status. The biasing
15 mechanism may be adjustable to allow for adjustment of the compressive force or may be structured to automatically expand in order to accommodate excessive swelling. Padding, foam or the like may be positioned on the interior sides of the clamp.

Brief Description of the Drawing Figures

20 A more complete understanding of the invention and its many features and advantages will be attained by reference to the following detailed description and the accompanying drawings. It is important to note that the drawings illustrates only a few embodiments of the present invention and therefore should not be considered to limit its scope.

Fig. 1 is a side view of a clamp according to one embodiment of the invention;

25 Fig. 2 is a front view of the clamp of Fig. 1;

Fig. 3 is a front view of a clamp according to an alternative embodiment of the invention;

Fig. 4 is a side view of the clamp of Fig. 3;

Fig. 5 is a top view of the clamp of Fig. 3;

30 Fig. 6 is a front view of a clamp according to another alternative embodiment of the invention;

Fig. 7 is a top view of the clamp of Fig. 6;

Fig. 8 is a schematic showing the clamp of Fig. 2 positioned on a patient to prevent migration of the pump; and

Fig. 9 is a side view of the clamp of Fig. 1 with padding provided thereon.

Detailed Description of Certain Embodiments

With reference to the drawings, the invention will be described in greater detail with the intent that the illustrations and embodiments be non-limiting. The invention is in general a process, and a device used in the process, to prevent post-operative migration of the pump of an inflatable penis prosthesis system within the scrotum. The process comprises implantation of the inflatable penis prosthesis system in typical surgical manner, including the step of providing an incision in the scrotum and/or lower abdomen to provide access for insertion of the IPP device including the scrotal pump, with the added steps of providing an external clamp, immediately post-operatively positioning the clamp externally on the scrotum in a manner that restricts movement of the pump within the scrotum, and leaving the clamp in position until the problem of accumulation of pooled blood and edematous fluid in the scrotum is no longer likely to displace the pump from a dependent position within the scrotum, for a time period of about 4 to 48 hours and preferably for a time period of about 6 to 24 hours. Once the initial post-surgical period has passed, the pump would be overwhelmingly more likely to remain in position even if the scrotum continues to experience some degree of swelling for the next several days. The implanted pump is thus captured and nested within the structure of the clamp so as to retain the implanted pump in place within the scrotum and prevent or restrict migration of the pump within the scrotum. The retaining force applied by the clamp is transferred through the scrotum to the implanted pump. In other words, since both the scrotum and implanted pump lie between the clamp body, clamping forces generated by the clamp body are exerted on both the scrotum and implanted pump. While the forces applied are sufficient to achieve the stated objective, the forces do not adversely impact the patient's health and do not adversely impact the integrity and operation of the parts of the prosthesis system.

As shown in Fig. 8, a representative inflatable penile prosthesis system 10 is shown to comprise a pair of cylinders (inflatable members) 11 inserted into the penis, a reservoir 12 implanted within the body and suitable for retention of a fluid, a pump 13 suitable for transferring the fluid from the reservoir 12 to the cylinders 11, flexible tubular conduits 14 connecting the reservoir 12, pump 13 and cylinders 11, and a fluid release mechanism 15 to allow the fluid to return from the cylinders 11 to the reservoir 12. In one embodiment, there is a first conduit that fluidly connects the reservoir and pump, a second conduit that fluidly connects the pump to one cylinder and a third conduit that fluidly connects the pump to

another cylinder. The pump 13 is typically a hand-operated device, whereby the patient transfers fluid by successively compressing the pump 13 in a bellows-type manner using his fingers to apply pressure through the scrotum. The pumps 13 may be round, elliptical, cylindrical, barrel-shaped, etc. The fluid release mechanism 15 is likewise operated by finger manipulation through the scrotum. Such systems are known in the art.

Implantation of the inflatable penile prosthesis system 10 is typically accomplished by a method comprising making incisions in the erectile bodies (corpora cavernosa) for insertion of the cylinders 11 and positioning the pump 13 within the scrotum. After proper positioning of the operational components of the inflatable penile prosthesis system 10, the incisions are sutured or otherwise closed.

Immediately or as soon as possible after the surgical implantation, the additional step of restricting migration of the pump 13 is undertaken. A clamping device 20 is externally positioned and affixed onto the scrotum, the clamping device 20 being sized and shaped to restrict movement of the pump 13 within the scrotum, and in particular being adapted to restrict movement of the pump 13 away from the more dependent or lowermost portion of the scrotum which may occur as the result of post-operative accumulation of pooled blood and edematous fluid in the scrotum or other forces that displace the pump 13, and to keep it positioned in the most optimal location for the patient to access the pump once the immediate post-operative period has passed.

The clamping device 20 may have various embodiments differing in size, shape and closure mechanism 21 suitable for retention and restriction of the pump 13 by encasing and securing the pump 13, the release mechanism 15 and/or the tubular conduits 14, several embodiments of which are illustrated in Figs. 1-4.

For example, as shown in Figs. 1 and 2, the clamping device 20 is formed of a clamp body and may be a generally clamshell-shaped device with a pair of opposing halves 22a and 22b (first and second sections) (e.g., cup-shaped members which can be thought of as being tissue contacting portions) each possessing a concave or cupped interior side 23, a pair of handle members 24, and a closure mechanism 21 comprising a spring member 25 mounted at a pivot or hinge axis 26, the closure mechanism 21 being structured such that the opposing halves 22a and 22b are biased toward each other in a clamping status when no force is applied to the handle members 24 and may be separated for affixation or removal of the clamping device 20 by forcing the handle members 24 together to widen the gap between the opposing halves 22a and 22b. Most preferably, the opposing halves 22a and 22b do not contact each other when in the clamping position to ensure that the intervening scrotal tissue

and IPP components are not under undue pressure when it is applied to the scrotum. The configuration of the opposing halves 22a and 22b are preferably optimized to maximize contact surface area for a given closing force, thereby reducing focused pressure points.

The clamp body can thus be thought of as having first and second sections (first and second parts) with the cup-shaped halves 22a, 22b being formed at upper portions thereof and the handle members 24 are formed at lower portions thereof. The halves 22a, 22b thus move between an open position (to allow insertion of the scrotum) and a closed position (normal rest position and a position when the clamp body is seated against the exterior of the scrotum); however, the halves 22a, 22b are preferably spaced from one another and not in contact in both the open and closed positions.

In an alternative embodiment as shown in Figs. 3, 4 and 5, the clamping device 20 may comprise a generally ring-shaped main body (arcuate-shaped body) 27 with a pair of opposing encircling arms 28 extending laterally from the main body 27. The ring-shaped body 27 is not a continuous structure in that the body has two ends that are spaced apart so as to define a gap (space) therebetween. The opposing arms 28 (which can be arcuate-shaped) are formed at or proximate the ends of the main body 27. The main body 27 is composed of a resilient material, such as a polymer for example, whereby the generally curved, U-shaped or C-shaped arms 28 may be spread apart manually or with a tool such that the clamping device 20 may be properly positioned on the scrotum to limit migration of the pump 13.

In another alternative embodiment as shown in Figs. 6 and 7, the clamp 30 is provided with wider halves 32 similar to those of the embodiment shown in Figs. 1 and 2, the halves 32 being opened by pressing together handles 34, wherein the halves 32 are provided with opposing arms 38 similar to the embodiment of Figs. 3, 4 and 5, such that with the clamp 30 closed about the pump 13, an opening is provided of sufficient diameter such that passage of the conduits 14 is not interfered with.

The clamping device 20 may be formed of a transparent material or be fenestrated for observation of the underlying skin tissue. The clamping device 20 may for example be self-biasing because of the material of composition, as shown in the embodiment of Figs. 3 and 4, or may be provided with a mechanical biasing mechanism 21, as shown in Figs. 1 and 2, such as with the spring member 25, a turn-screw or mechanical device (not shown). The biasing mechanism 21 may be adjustable to allow for adjustment of the compressive force or may be structured to automatically expand in order to accommodate excessive swelling. In other words, the biasing mechanism can be manipulated (using an actuator or the like) to reduce (lessen) the degree of the applied compressive force or the biasing mechanism itself can be

designed such that if a counter force (swelling) is generated, the opposing sections (e.g., halves) can separate further apart to accommodate such counter force. As shown in Fig. 9, padding, foam or the like (generally indicated at 35) may be positioned on the interior sides 23 or along the edges of the clamp 20. It will be appreciated that the padding 35 can be provided on at least any of the tissue contacting surfaces of any of the clamps shown herein. For example, padding can be provided along the inner concave-shaped surfaces of the arms 28 of the clamp shown in Figs. 3-5.

It will be appreciated various components described herein can be part of a kit that is available for use by surgeons, etc. The kit includes the clamping device described herein and one or more component of the penis prosthesis system. For example, the kit can include the clamping device and at least the pump. The clamping device is preferably selected in view of the pump and in particular, the pump is selected in view of the shape and/or dimensions of the pump to allow the clamping device to capture and retain the pump as described herein. The kit can also include the other components of the system including one or more of the conduits, inflatable members, and reservoir.

Although the present invention has been described above using specific embodiments and examples, there are many variations and modifications that will be apparent to those having ordinary skill in the art. As such, the described embodiments are to be considered in all respects as illustrative, and not restrictive. Therefore, the scope of the invention is indicated by the appended claims, rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A clamping device for use in a penile prosthesis system for preventing or limiting post-operative migration of an implanted pump that forms a part of the system comprising:
5 a clamp body having first and second sections that are spaced apart from one another and move between an open position and a closed position, wherein an open space is defined between the first and second sections, the clamp body being configured to be placed externally on the scrotum so as to retain and restrict movement of the implanted pump which is within the scrotum by retaining the implanted pump between the first and second sections.
- 10 2. The clamping device of claim 1, wherein in both the open and closed positions, tissue contacting portions of the first and second sections are spaced apart and not in contact with one another.
3. The clamping device of claim 1, wherein the clamp body comprises a clamshell-shaped structure with the spaced first and second sections comprising opposing halves, each
15 half including a concave shaped interior surface.
4. The clamping device of claim 3, wherein bottom portions of the first and second sections comprise first and second handle members and the first and second sections are pivotally coupled to one another to permit the first and second sections to move between the open and closed positions.
- 20 5. The clamping device of claim 4, further including a closure mechanism which applies a biasing force to the first and second sections such that the first and second sections are biased toward one another and assume the closed position in a rest condition.
6. The clamping device of claim 4, wherein the first and second sections are pivotally coupled such that separation of the first and second handles causes a distance between the
25 first and second sections to increase for allowing insertion or withdrawal of the scrotum from the space between the first and second sections.
7. The clamping device of claim 4, wherein upper portions of the first and second sections have greater widths than the first and second handle members to provide the clamshell-shaped structure.
- 30 8. The clamping device of claim 1, wherein the clamp body comprises an arcuate-shaped structure with the first and second sections defining ends of the structure that are spaced apart so as to define a gap in the arcuate-shaped structure, the clamp body further including first and second arms extending laterally from the first and second sections of the clamp body.

9. The clamping device of claim 8, wherein the first and second arms are disposed at or proximate to the ends of the arcuate-shaped structure.

10. The clamping device of claim 9, wherein the first and second arms comprise arcuate shaped segments positioned such that concave shaped interior surfaces thereof face one

5 another across the gap.

11. The clamping device of claim 9, wherein the arcuate-shaped structure is formed of a resilient material, whereby the arcuate-shaped structure can be flexed between the open and closed positions.

12. The clamping device of claim 1, wherein the first and second sections are joined
10 together along bottom portions thereof and further include first and second arms formed at upper portions thereof.

13. The clamping device of claim 12, wherein upper portions of the first and second sections include first and second arcuate-shaped arms positioned such that concave shaped interior surfaces thereof face one another across the open space.

14. The clamping device of claim 3, wherein upper portions of each half comprises a
15 circular cup-shaped structure that includes the concave shaped interior surface, the circular cup-shaped structure being configured to be clamped about the scrotum.

15. A penile prosthesis system comprising:

a pump that is configured for implantation in the scrotum; and

20 a clamping device configured for preventing or limiting post-operative migration of the pump, the clamping device comprising a clamp body having first and second sections that are spaced apart from one another and move between an open position and a closed position, wherein an open space is defined between the first and second sections, the clamp body being configured to be placed externally on the scrotum so as to retain and restrict movement of the
25 implanted pump which is within the scrotum by retaining the implanted pump between the first and second sections.

16. The system of claim 15, wherein the clamp body is configured to apply a sufficient clamping force to restrict movement of the pump within the scrotum when the clamp is clamped externally on the scrotum.

30 17. The system of claim 15, wherein the clamp body is configured to cradle the scrotum.

18. The system of claim 15, wherein in both the open and closed positions, tissue contacting portions of the first and second sections are spaced apart and not in contact with one another.

19. The system of claim 15, wherein the system further includes an inflatable member for placement in the penis, a reservoir for holding an inflation fluid, a conduit for delivering and evacuating the inflation fluid from the inflatable member, and wherein the pump is configured to control flow of the inflation fluid throughout the system.

5 20. The system of claim 19, wherein there are at least two inflatable members, a first conduit between the reservoir and the pump, a second conduit between the pump and the one inflatable member and a third conduit between the pump and the other inflatable member, wherein the open space between the first and second sections is of sufficient size in both the open and closed positions to allow passage of the first, second and third conduits.

10 21. The system of claim 15, wherein the clamp body comprises a clamshell-shaped structure with the spaced first and second sections comprising opposing halves, each half including a concave shaped interior surface.

22. The system of claim 21, wherein bottom portions of the first and second sections comprise first and second handle members and the first and second sections are pivotally
15 coupled to one another to permit the first and second sections to move between the open and closed positions.

23. The system of claim 22, further including a closure mechanism which applies a biasing force to the first and second sections such that the first and second sections are biased toward one another and assume the closed position in a rest condition.

20 24. The system of claim 22, wherein the first and second sections are pivotally coupled such that separation of the first and second handles causes a distance between the first and second sections to increase for allowing insertion or withdrawal of the scrotum from the space between the first and second sections.

25 25. The system of claim 22, wherein upper portions of the first and second sections have greater widths than the first and second handle members to provide the clamshell-shaped structure.

26. The system of claim 15, wherein the clamp body comprises an arcuate-shaped structure with the first and second sections defining ends of the structure that are spaced apart so as to define a gap in the arcuate-shaped structure, the clamp body further including first
30 and second arms extending laterally from the first and second sections of the clamp body.

27. The system of claim 26, wherein the first and second arms are disposed at or proximate to the ends of the arcuate-shaped structure.

28. The system of claim 27, wherein the first and second arms comprise arcuate shaped segments positioned such that concave shaped interior surfaces thereof face one another across the gap.

29. The system of claim 27, wherein the arcuate-shaped structure is formed of a resilient material, whereby the arcuate-shaped structure can be flexed between the open and closed positions.

30. The system of claim 15, wherein the first and second sections are joined together along bottom portions thereof and further include first and second arms formed at upper portions thereof.

31. The system of claim 30, wherein upper portions of the first and second sections include first and second arcuate-shaped arms positioned such that concave shaped interior surfaces thereof face one another across the open space.

32. The system of claim 21, wherein upper portions of each half comprises a circular cup-shaped structure that includes the concave shaped interior surface, the circular cup-shaped structure being configured to be clamped about the scrotum.

33. The system of claim 15, wherein the clamping device is formed of a transparent material.

34. A penile prosthesis kit:

a pump that is configured for implantation in the scrotum; and

a clamping device configured for preventing or limiting post-operative migration of the pump, the clamping device comprising a clamp body having first and second sections that are spaced apart from one another and move between an open position and a closed position, wherein an open space is defined between the first and second sections, the clamp body being configured to be placed externally on the scrotum so as to retain and restrict movement of the implanted pump which is within the scrotum by retaining the implanted pump between the first and second sections.

35. The kit of claim 34, wherein the clamp body is configured to apply a sufficient clamping force to restrict movement of the pump within the scrotum when the clamp is clamped externally on the scrotum.

36. The kit of claim 34, wherein the clamp body is configured to cradle the scrotum.

37. The kit of claim 34, wherein in both the open and closed positions, tissue contacting portions of the first and second sections are spaced apart and not in contact with one another.

38. The kit of claim 34, further including an inflatable member for placement in the penis, a reservoir for holding an inflation fluid, a conduit for delivering and evacuating the inflation

fluid from the inflatable member, and wherein the pump is configured to control flow of the inflation fluid.

39. The kit of claim 38, wherein there are at least two inflatable members, a first conduit between the reservoir and the pump, a second conduit between the pump and the one
5 inflatable member and a third conduit between the pump and the other inflatable member, wherein the open space between the first and second sections is of sufficient size in both the open and closed positions to allow passage of the first, second and third conduits.

40. The kit of claim 34, wherein the clamp body comprises a clamshell-shaped structure with the spaced first and second sections comprising opposing halves, each half including a
10 concave shaped interior surface.

41. The kit of claim 40, wherein bottom portions of the first and second sections comprise first and second handle members and the first and second sections are pivotally coupled to one another to permit the first and second sections to move between the open and closed positions.

42. The kit of claim 34, wherein the clamp body comprises an arcuate-shaped structure with the first and second sections defining ends of the structure that are spaced apart so as to define a gap in the arcuate-shaped structure, the clamp body further including first and
15 second arms extending laterally from the first and second sections of the clamp body.

43. The kit of claim 42, wherein the first and second arms are disposed at or proximate to
20 the ends of the arcuate-shaped structure.

44. The kit of claim 42, wherein the first and second arms comprise arcuate shaped segments positioned such that concave shaped interior surfaces thereof face one another across the gap.

45. The kit of claim 42, wherein the arcuate-shaped structure is formed of a resilient
25 material, whereby the arcuate-shaped structure can be flexed between the open and closed positions.

46. The kit of claim 33, wherein the first and second sections are joined together along bottom portions thereof and further include first and second arms formed at upper portions thereof.

47. The kit of claim 40, wherein upper portions of each half comprises a circular cup-shaped structure that includes the concave shaped interior surface, the circular cup-shaped structure being configured to be clamped about the scrotum.

48. A method for preventing or limiting post-operative migration of a pump that is implanted within a scrotum as part of an inflatable penile prosthesis comprising the steps of:

applying a clamping device externally on the scrotum such that the implanted pump is captured by the clamping device resulting in movement of the implanted pump being restricted.

49. The method of claim 48, wherein the clamping device is biased so as to apply a force to the scrotum resulting in retention of the pump within the scrotum.

50. The method of claim 48, wherein the clamping device is applied onto the scrotum so as to prevent or restrict migration of the pump from a lower portion of the scrotum.

51. The method of claim 48, wherein the clamping device comprises a clamp body having first and second sections that are spaced apart from one another and move between an open position and a closed position, wherein an open space is defined between the first and second sections, and the step of applying the clamping device comprises the steps of positioning the first and second sections in the open position; inserting the scrotum between the open first and second sections; positioning the clamping device about the scrotum such that the pump is disposed between the first and second sections; and releasing the first and second sections resulting in the first and second sections applying a retention force to the scrotum which is sufficient to retain and restrict movement of the implanted pump within the scrotum.

52. The method of claim 51, wherein the clamp body comprises a clamshell-shaped structure with the spaced first and second sections comprising opposing halves, each half including a concave shaped interior surface which seats against the scrotum.

53. The method of claim 52, wherein bottom portions of the first and second sections comprise first and second handle members and the first and second sections are pivotally coupled to one another to permit the first and second sections to move between the open and closed positions.

54. The method of claim 51, wherein the clamp body comprises an arcuate-shaped structure with the first and second sections defining ends of the structure that are spaced apart so as to define a gap in the arcuate-shaped structure, the clamp body further including first and second arms extending laterally from the first and second sections of the clamp body, the first and second arms having concave shaped interior surfaces thereof face one another and the concave shaped interior surfaces seat against the scrotum.

55. The method of claim 49, wherein the clamping device is biased due to either the clamping device being formed of a resilient material (self-biasing) or a mechanical biasing mechanism being incorporated within the clamping device.

FIG. 1

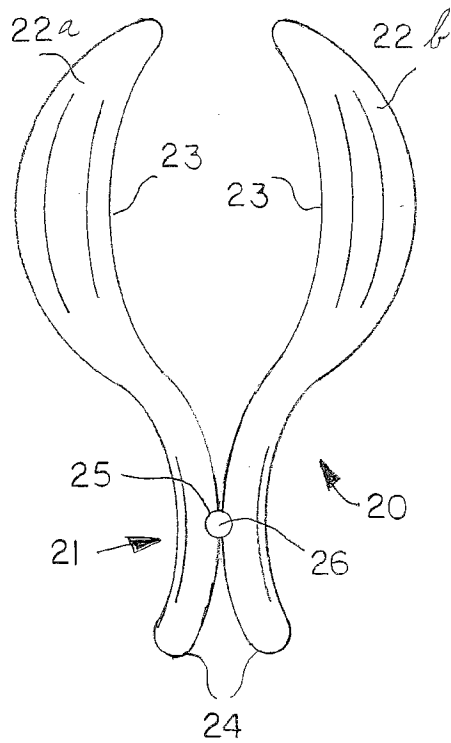


FIG. 2

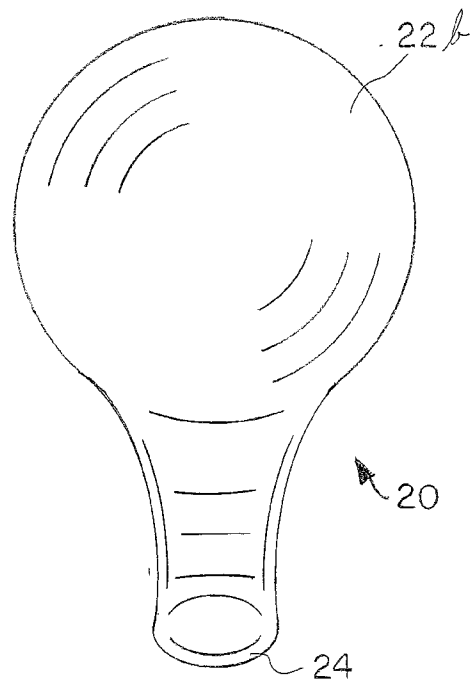


FIG. 5

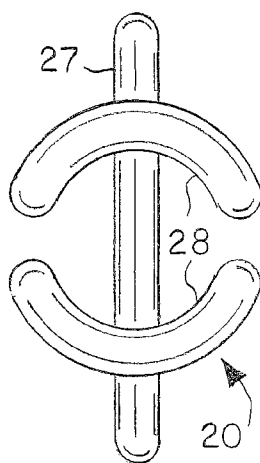


FIG. 3

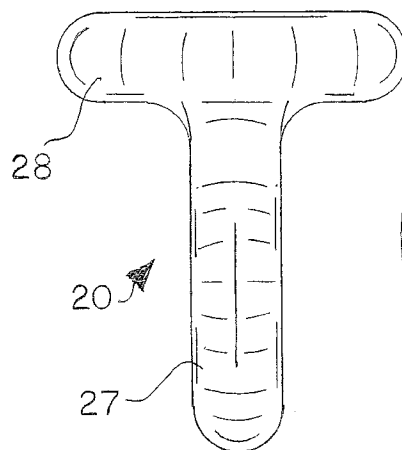
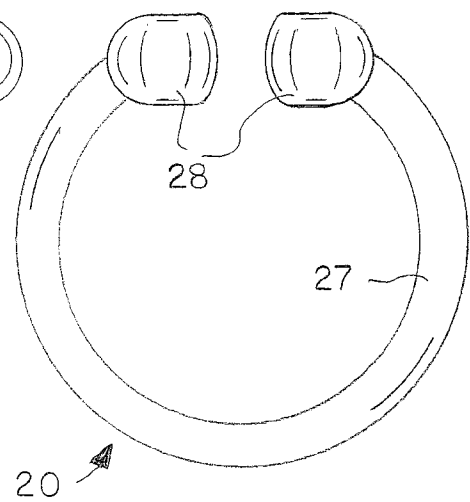


FIG. 4



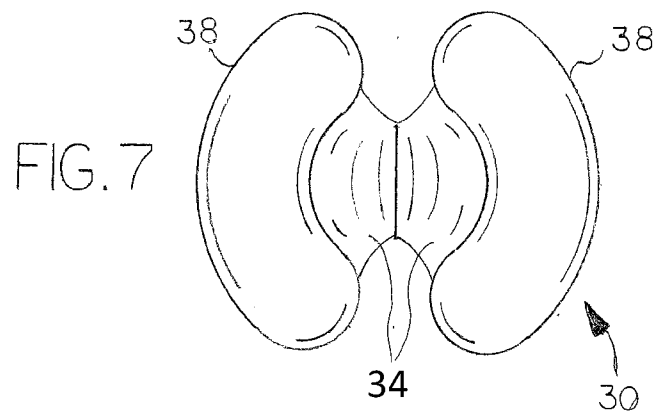
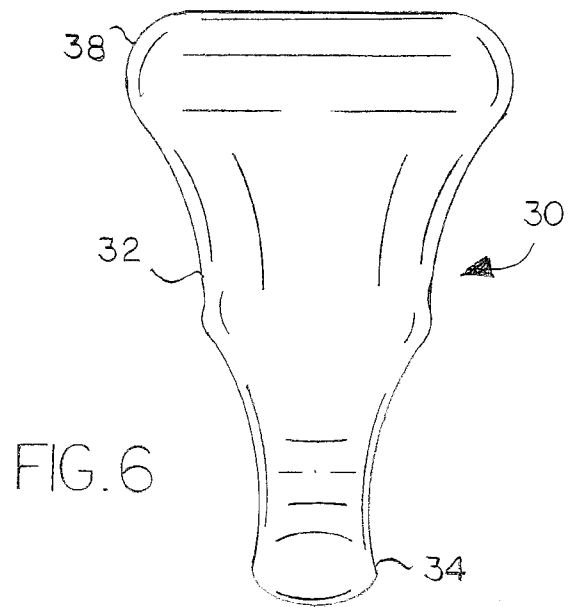


FIG. 8

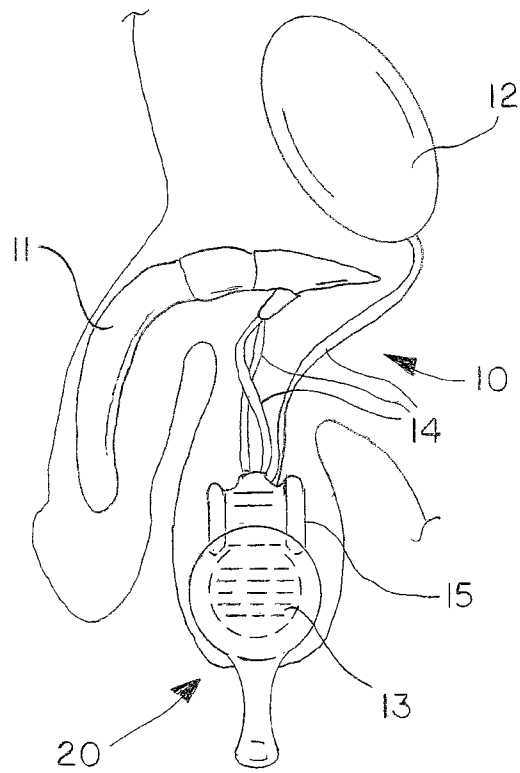
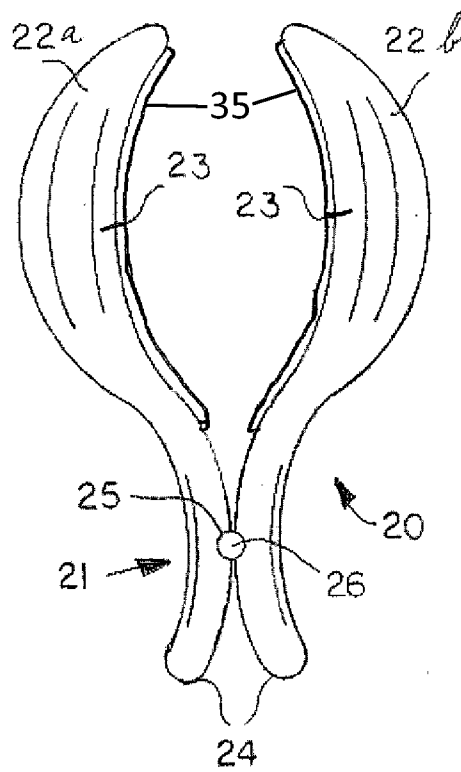


Fig. 9



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2014/042345

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/02 (2014.01)

CPC - A61F 2/02 (2014.09)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61F 2/00, 2/02, 2/04, 5/00 (2014.01)

CPC - A61F 2/00, 2/02, 2/04, 2002/047, 2002/048, 5/00 (2014.09)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 128/79; 600/30, 31, 38, 39, 40; 623/12

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

ORBIT, GOOGLE PATENT, GOOGLE SCHOLAR

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,163,897 A (PERSKY) 17 November 1992 (17.11.1992) entire document	1-55
A	US 4,318,396 A (FINNEY) 09 March 1982 (09.03.1982) entire document	1-55
A	US 4,537,183 A (FOGARTY) 27 August 1985 (27.08.1985) entire document	1-55
A	US 2004/0215056 A1 (LING et al) 28 October 2004 (28.10.2004) entire document	1-55
A	US 2005/0075534 A1 (KUYAVA) 07 April 2005 (07.04.2005) entire document	1-55

☐ Further documents are listed in the continuation of Box C.

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search

09 October 2014

Date of mailing of the international search report

03 NOV 2014

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