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(54) **DISTRIBUTED PRESSURE FENESTRATED URETHRAL COMPRESSION APPARATUS FOR TREATMENT OF MALE URINARY SPHINCTER DEFICIENCY WITH PRESERVATION OF BLOOD FLOW**

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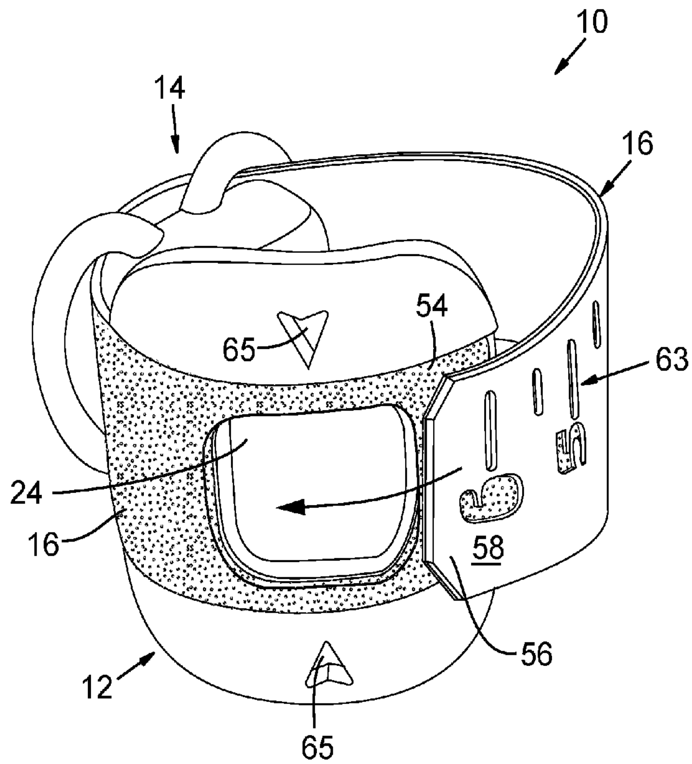
(57) **ABSTRACT**

An urethral compression apparatus is defined by a semi-cylindrical fenestrated dorsal hood that is worn dorsally on the penis and which is interconnected with a strap to a urethral compressor that is oriented ventrally to apply compressive pressure on the urethra to prevent urine leakage. The dorsal hood and the urethral compressor apply distributed pressure that prevents compromised venous and arterial circulation but eliminate incontinence. The device may be worn continually and is easily removed to allow voiding, then reattached. The fenestration in the dorsal hood (or plural fenestrations as the case may be) allows distribution of pressure to avoid venous and arterial blood flow interruption. The dorsal hood partially encircles the penile shaft and the urethral compressor is oriented ventrally and applies the desired pressure to the soft ventral tissues and the urethra. A strap applies tension between the dorsal hood and the urethral compressor, and thus the necessary compression between these two components.



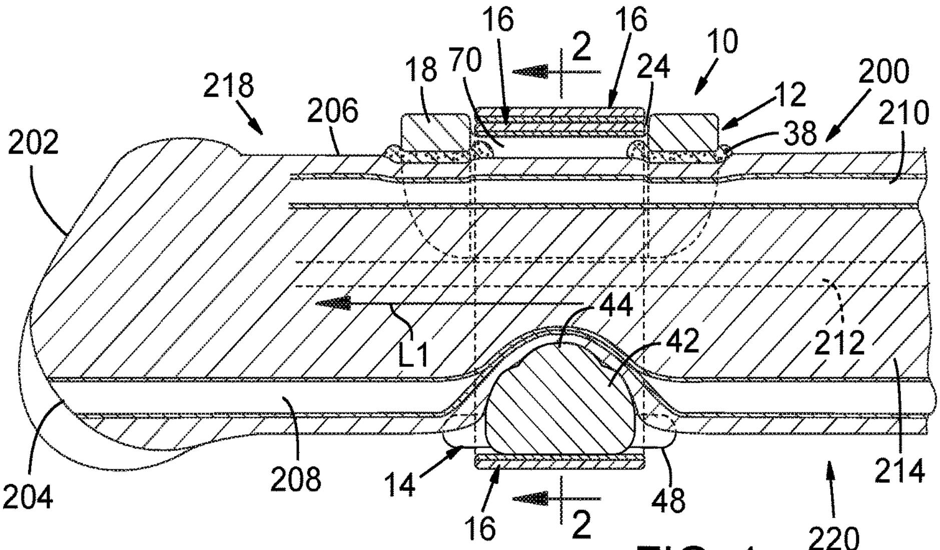

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FIG. 1

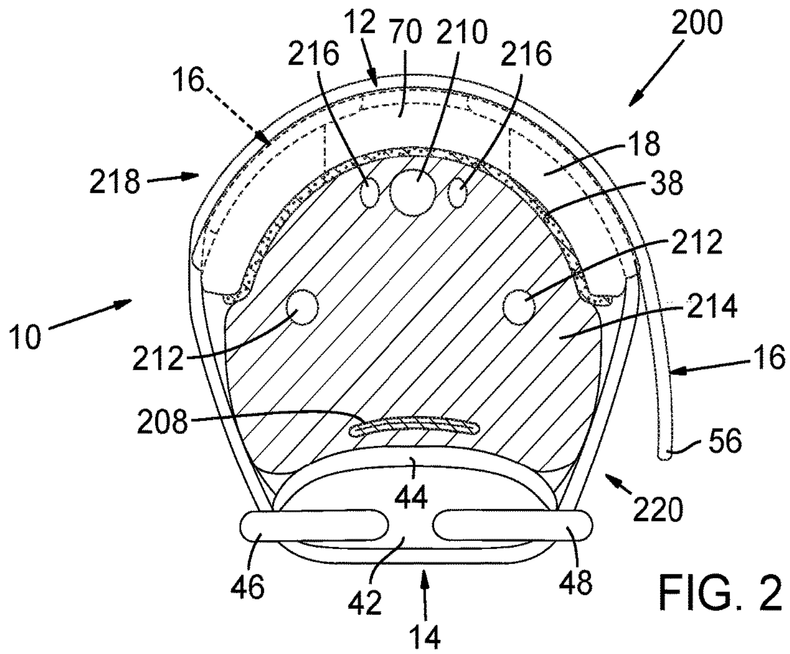
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FIG. 2

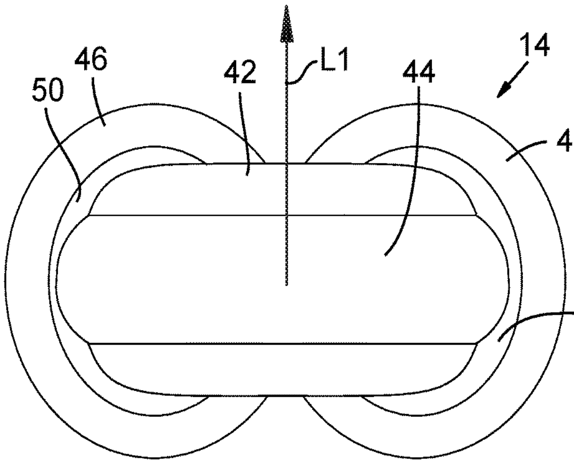


FIG. 3

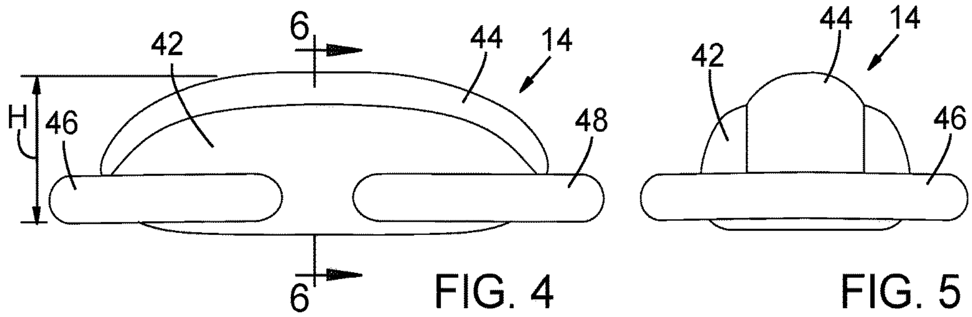
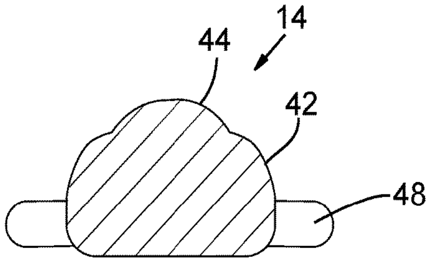


FIG. 4

FIG. 5



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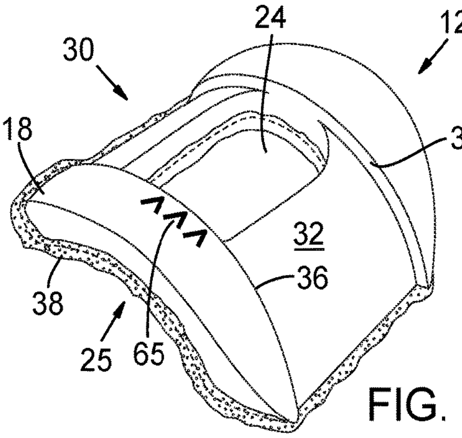

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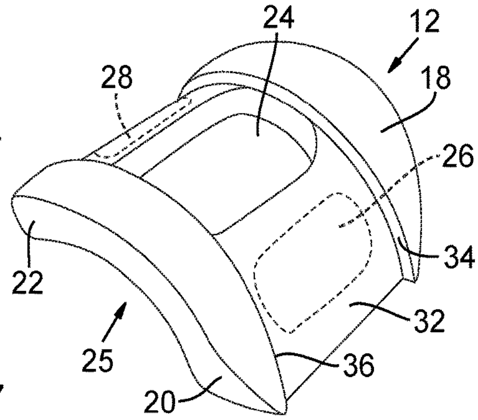

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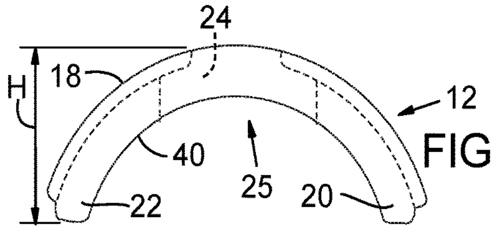

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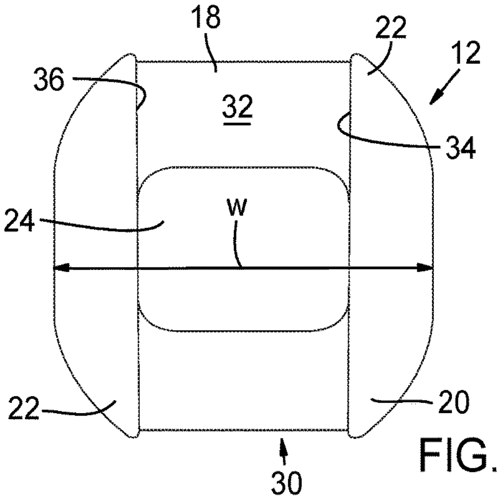

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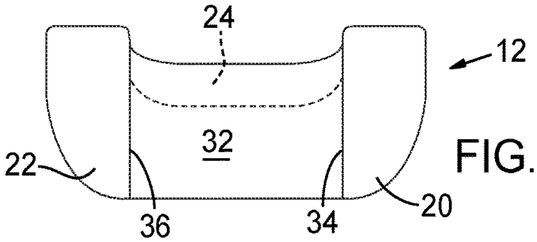

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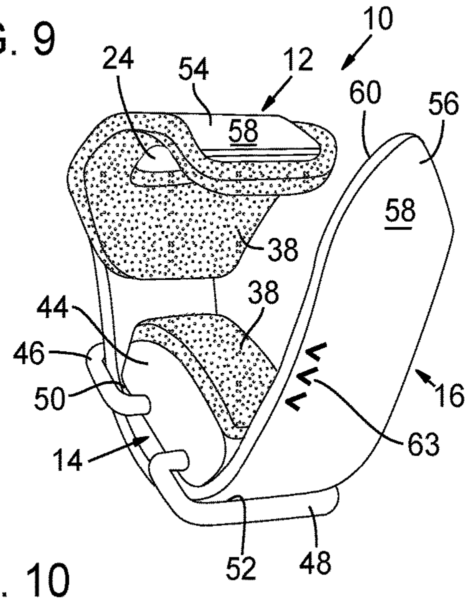

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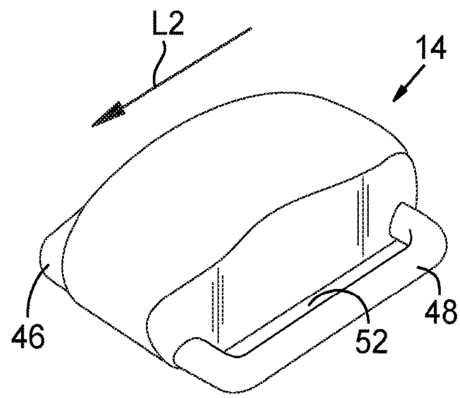

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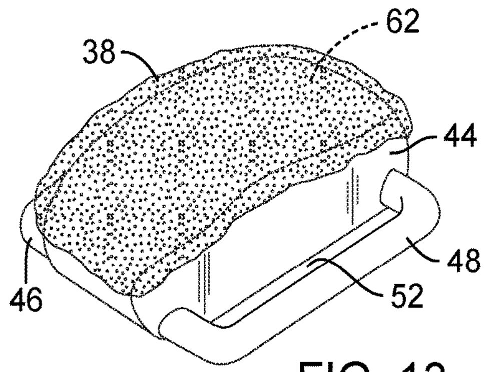

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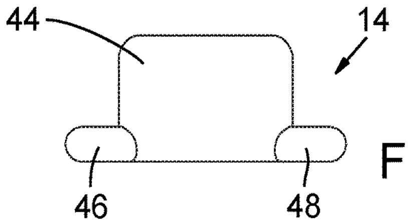

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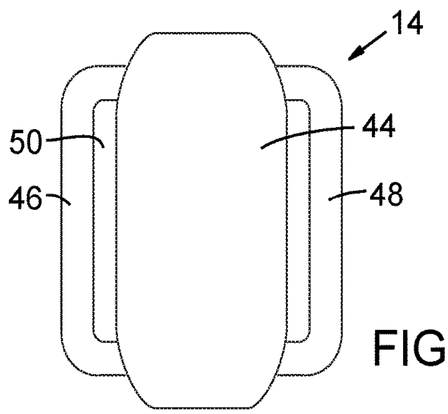

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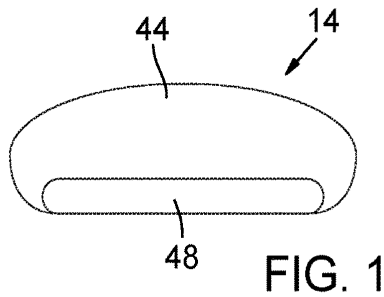

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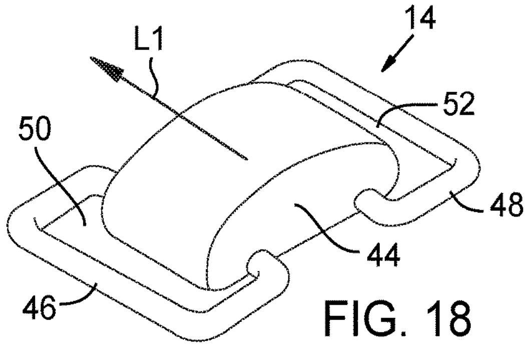

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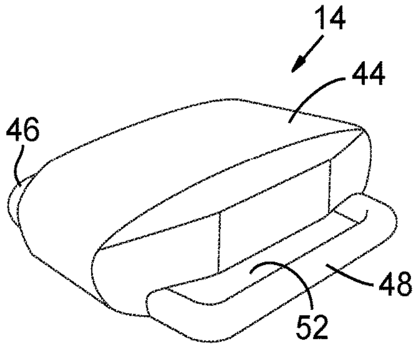

FIG. 19

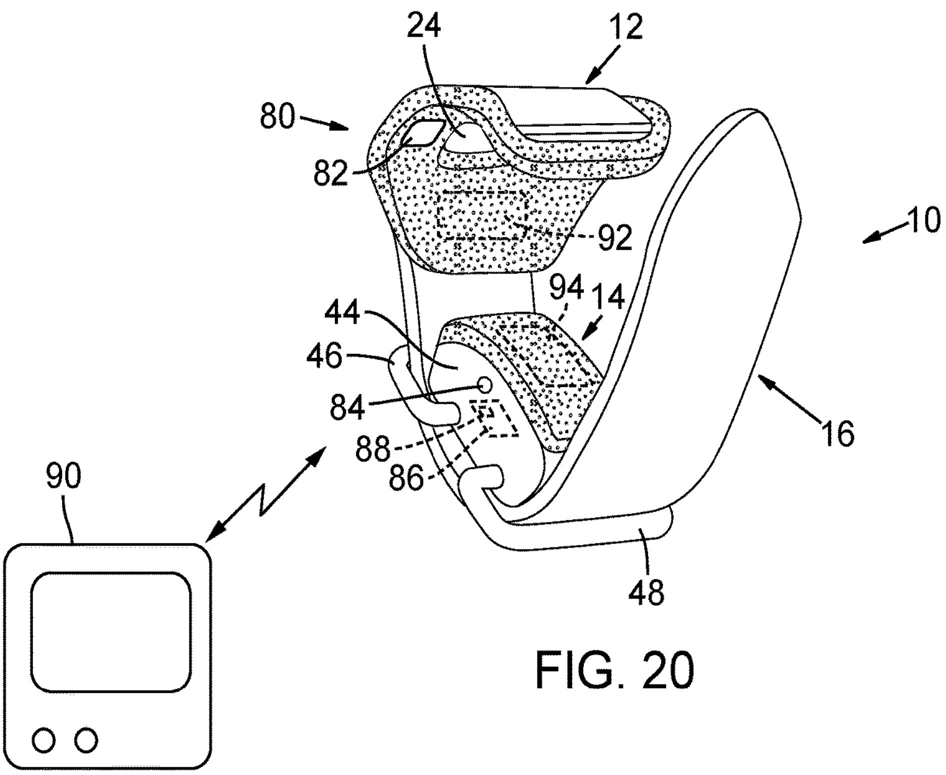

FIG. 20

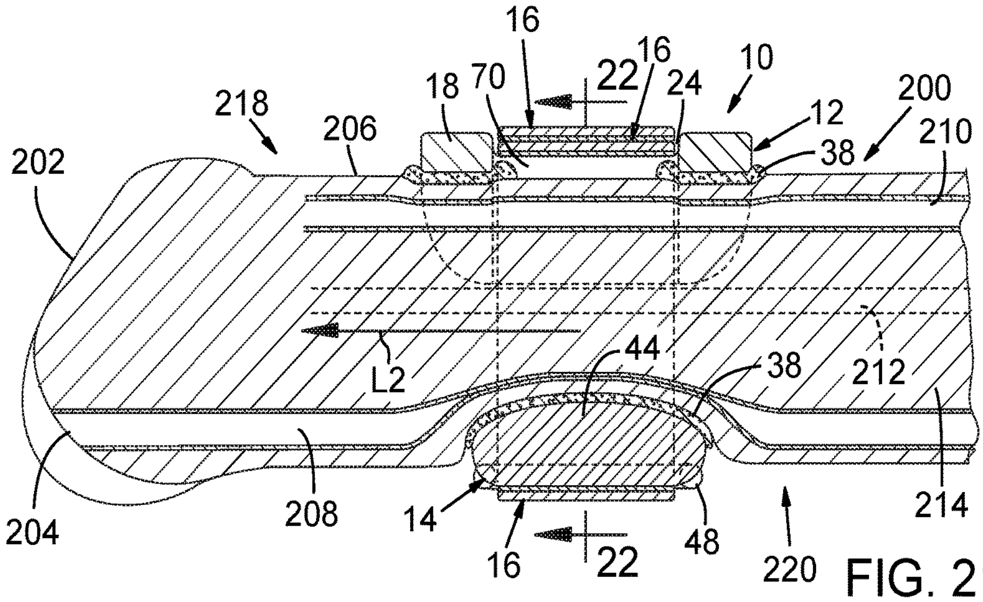
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FIG. 21

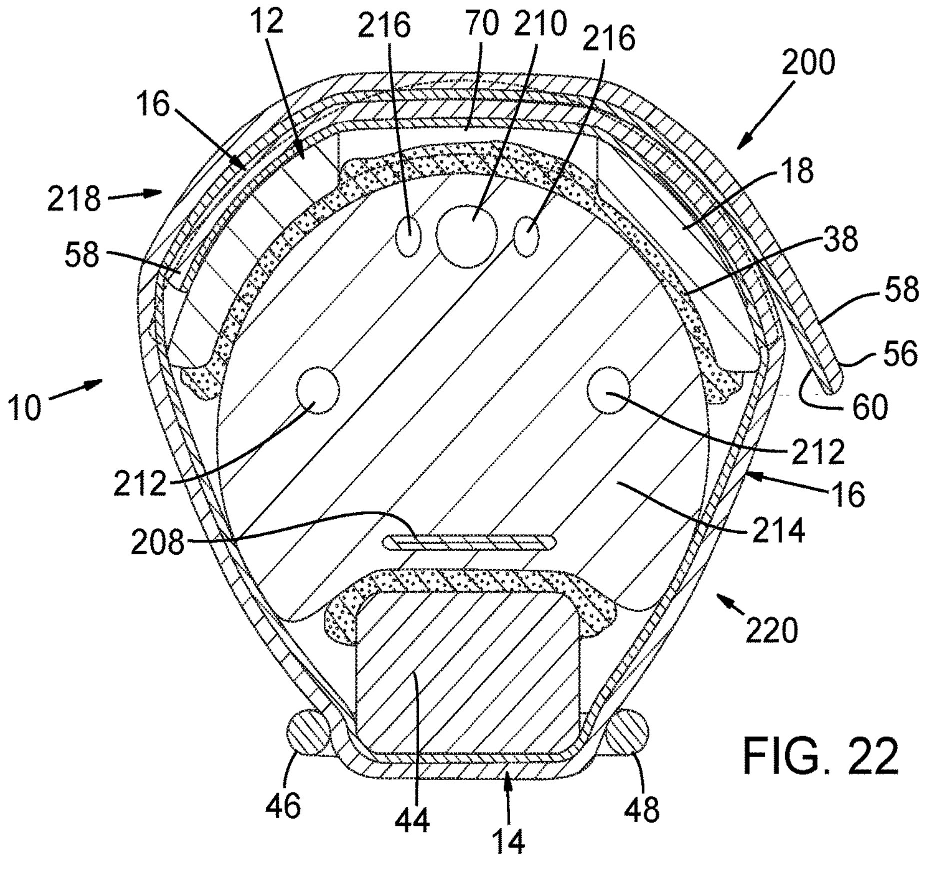
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FIG. 22

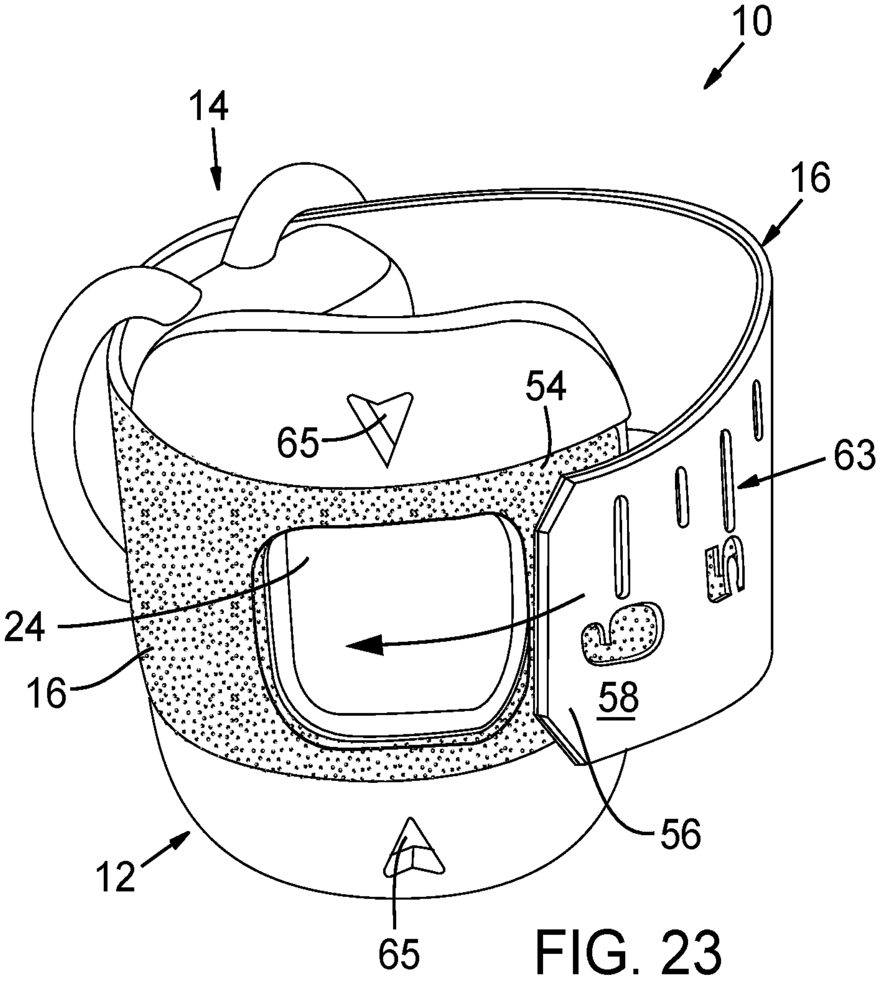

FIG. 23

DISTRIBUTED PRESSURE FENESTRATED URETHRAL COMPRESSION APPARATUS FOR TREATMENT OF MALE URINARY SPHINCTER DEFICIENCY WITH PRESERVATION OF BLOOD FLOW

TECHNICAL FIELD

[0001] The present invention relates to medical devices and more particularly devices used to treat urinary incontinence in males. More specifically the present invention relates to a urethral compression apparatus that uses a fenestrated dorsal hood that applies distributed pressure to the dorsum of the penis and a ventral urethral compressor so that incontinence is resolved and blood flow is maintained.

BACKGROUND

[0002] Urinary incontinence in male patients has been an increasingly common problem over the past years in part because of a general trend toward increased longevity, and also due to an increase in urinary tract surgery. Thus, with an increasingly aging population and an increasing number of surgical interventions to treat prostate cancer, the number of males experiencing urinary incontinence has markedly increased. There are a variety of approaches to control of the urine stream from incontinence in males, including management surgically at the bladder neck level, through the use of intra-urethral devices or valves, and by apparatus worn externally and which apply pressure to the penis to compress the urethra.

[0003] As examples of surgical management, an implantable controlled valve device known as the AMS 800 is commonly regarded as the surgical standard solution. The AMS 800 is a relatively complex surgical solution; it provides a device that encircles the bulbar urethra with a water-filled ring that is fluidly connected to a valve and a reservoir. The device has been moderately successful in controlling incontinence but while it is very expensive it fails to control urine flow around 30% of the time. Moreover, surgical management always carries risk of complications such as infection and is not indicated for all patients.

[0004] Male sling procedures are available examples of other surgical control techniques but like all surgical procedures have some negative outcomes that limit use to very experienced surgical centers.

[0005] Another surgical management approach is with magnetic and non-magnetic valves surgically placed at the bladder neck, but these devices have not achieved popularity in clinical practice. Among other reasons for the relatively low levels of acceptance for these devices is the risk of infection that may accompany any device that is positioned in the urethra at the bladder outlet as the foreign body eventually attracts bacterial growth, which cannot be completely eliminated without removal of the nidus of infection.

[0006] Intra urethral blocking devices are currently under development and may soon be marketed to compete with the many penile clamps that are known in the marketplace. Examples of current standard penile clamps include the "Dribble Stop" device, the "Cunningham Clamp," a device called the "Squeezer Klip" and others. Yet these centuries old technologies are little better than a clothes peg because of the use of directly opposed compressive parts.

[0007] Most early external clamps compromise blood circulation. As an example, the Baumrucker innovation, which is described in U.S. Pat. No. 3,866,611, uses two bars on one side of the clamp and 1 bar on the opposing side. When applied, the opposed clamps guide the penis in a pronounced curve to address incontinence but the device applies pressure to the blood supply in proportion to the pressure on the urethra. The patent describes applying maximal pressure to the dorsal vascular bundle because the single bar of the clamp crosses the top of the penis.

[0008] Convenience of use and concern about pressure symptoms are notable factors in acceptance of any externally worn device. Application of sufficient external pressure to the penile shaft to control the increased pressure of a filling bladder has usually resulted in impaired blood flow to or from the penis. The Cunningham Clamp mentioned above is preferred by users in some studies but it has been shown to markedly reduce penile blood flow. It is thus recommended that it be removed every few hours during the day and not used at night because off the risk to the viability of the penile shaft. Generally speaking, there is a dearth of successful devices that have a balance of pressure and leakage that produces a comfortable solution, but in which some amount of urine leakage must be expected. But clamps typically are not used at night because of the pressure symptoms and the concern that continuous 24 hour pressure will cause irritation to the penis, skin, and in the worst possible case ischemic necrosis of the organ. Excessive pressure could result in serious tissue damage when applied at night to users who are non-compos mentis or who have drug-induced sleep.

[0009] There are many examples of patented apparatus for treatment of male urinary incontinence. The device described in U.S. Pat. No. 5,842,968 attempted to solve the problem of leakage by using a soft circumferential clamp device that compresses all of the structures of the penis with the same pressure. The device utilizes an inflatable mechanism to produce even distribution of pressure. But the device is inconvenient because it is necessary to carry and use a syringe to relieve or add pressure and there is no attempt to relieve or offset the forces applied on the part of the device that covers the dorsal portion of the penis.

[0010] In U.S. Pat. No. 6,349,727, inventor Edward Stewart describes a two-armed device with elastic memory that had a special arm extension that brought pressure to bear on the urethral area. The devise is essentially a transverse clamp with opposing pressure elements that would be expected to impair blood flow through vessels whenever it applies pressure to constrain urethral flow.

[0011] U.S. Pat. No. 6,289,895 describes an attempt to provide specific urethral pressure by using a piston that was advanced into a constricted circular penile clamp that provided counter-pressure from the top, in a manner this is not dissimilar to most clamping devices. There is no attempt to diminish the compression of the dorsal arteries with this devise and this results in vascular compression, as with the other known prior art devices. Inventor Shah in U.S. Pat. No. 6,805,662 describes a cylindrical compression device with multiple linear chambers to accommodate greater or lesser amounts of fluid. This device fails to provide pressure selectively to the urethra and there is no circulatory protection.

[0012] Finally, the device known as the Jackson Medical J Clamp has been developed in the field and is featured by a large hood and a narrow rubber urethral occluder that has a prominent lever that extends outwardly from the device.

Users report that the occluder is position-sensitive, with some positions resulting in leakage. Plus, according to some users the device is difficult to position and requires the user to take care that it does not slip from its position just above the glans penis. The device, which has increased surface area, is not recommended for continuous use.

[0013] In view of the foregoing it is clear that there is an ongoing need for a device that is better suited to control incontinence while eliminating the constrained blood flow that is characteristic of the prior art external devices and which makes such prior art devices potentially hazardous to wear at night, and painful due to pressure symptoms.

SUMMARY OF THE INVENTION

[0014] The present invention is a urinary incontinence control apparatus that addresses the shortcomings of known devices. The invention as described herein and shown in the drawings defines an effective apparatus for controlling incontinence while allowing a patient to wear the apparatus continually without discomfort and without impairment of circulation. The apparatus may be worn by the patient throughout the range of normal activity for the patient, including patients who are active in sports and the like.

[0015] The device according to the present invention addresses these shortcomings of the prior art and includes at least the following characteristics:

[0016] Provides improved control of urine flow so that fewer pads are required for backup;

[0017] Provides for preferential pressure to the penile urethra while avoiding excessive pressure to the arterial input or venous outflow of blood, thereby alleviating pain and risk resulting from impaired blood flow;

[0018] Provides for stable and consistent positioning to avoid slippage during development of increased pressure as the column of urine from the bladder increases;

[0019] Provides a solution that is devoid of symptoms caused by mechanical factors related to the weight of the device and interference of the device during movement; the device may be used during sporting activity such as skiing, cycling, running and swimming and the device may be worn during sexual activity;

[0020] Allows for effective control of urine leakage with upright posture and during exercise;

[0021] Superior comfort such that the user does not feel the presence of the device in a manner that would discourage use;

[0022] Provides a single-use foam or other body-contact insert that allows for size adjustment and increased cleanliness by allowing weekly changes of the compression foam, optionally with adhesive backing;

[0023] May be worn during erections and sexual activity because, unlike many devices that are designed to sustain erection by constraining the venous return of blood via the dorsal vein and other venous channels, the inventive device does not constrain arterial blood flow;

[0024] Does not cause urethritis or skin irritation during use, caused by mechanical properties;

[0025] Provides the user with a means for simple adjustment of the quantity of pressure applied during use and determination of whether the pressure should be increased or decreased during use to achieve desired control of leakage;

[0026] Allows for continuous use even 24 hours per day, 7 days per week and 365 days per year if the loss of sphincter control causes significant night time leakage;

[0027] In one embodiment allows for monitoring and tracking of the pressure applied to the dorsal and urethral side of the penis and creation of an historical record for patients and managers—the amount of pressure applied to the urethra can be compared to leaking events to optimize pressure levels;

[0028] Data obtained from monitoring and tracking of pressure from the inventive device, especially during the treatment recovery period following prostatic resection will produce an individual history and create a body of knowledge that will inform clinicians;

[0029] Sensors that may be placed in the urethral compression pad and in the dorsal hood provide periodic measurements that are recorded remotely via transmission to remote computers;

[0030] In one embodiment, data from the sensors may be used to inform an increase or decrease in urethral pressure by means of a remotely controlled pressure actuator;

[0031] In another embodiment the sensors may be defined by a pulse oximeter for monitoring oxygen saturation and/or temperature sensors.

[0032] The so-called Rapoport Protocol, which was developed by Dr. Daniel Rapoport, a specialist urological surgeon, describes a supportive guide that specifies care for patients in the post "radical prostatectomy care" situation. The protocol teaches that after catheter removal and a healing period of approximately three weeks the urethral compression device described herein will provide the patient with control of urine flow until restoration of sphincter function occurs. A fundamental problem for such patients is that 60% of postoperative males have incontinence that lasts for 6-12 months and a residual 5-30% of such patients have ongoing urine leakage that can typically be managed only by pads and diapers. A vascular preservation urethral compression device enables postoperative patients to have control of their bodies but a key factor is eliminating the risk of vascular impairment, which could lead to serious adverse conditions including gangrene and venous thrombosis. The present invention provides a solution that solves these problems and addresses the needs of such patients.

[0033] The device according to the present invention solves additional problems. There is significant need for a urinary leakage control device for use in nursing facilities to provide round-the-clock urinary control to avoid bed wetting and excessive use of urinary absorption pads. Pads are known to lead to major skin problems, add costs and are associated with offensive odors. The device according to the present invention defines an alternative solution that is safe for use 24 hours per day, 7 days per week, year around. The device is safe because when used with consistent and appropriate distributed pressure the vascular supply to the penis is not compromised and the patient is thus not at risk of necrosis of the external genitalia. Further, the inventive device may be used with the non-compos mentis patient.

[0034] There is a compelling need for a device that meets the foregoing challenges. More specifically, there is a documented need for a device that provides excellent control of urine leakage during the day and night without compromising circulation of blood. Known devices exemplified by those described above rely on hourly or other periodic release of pressure to prevent damaging vascular effects and to relieve pain and discomfort.

[0035] In a first preferred and illustrated embodiment the urethral compression apparatus according to the invention is defined by a semi-cylindrical fenestrated dorsal hood that is worn dorsally on the penis and which is interconnected with a strap to a urethral compressor that is oriented ventrally to apply compressive pressure on the urethra to prevent urine leakage. The dorsal hood and the urethral compressor apply distributed pressure that prevents compromised circulation but complete prevention of incontinence. The device may be worn continually and is easily removed to allow voiding, then reattached. The fenestration in the dorsal hood (or plural fenestrations as the case may be) allows distribution of pressure to avoid venous and arterial blood flow interruption. And because the urethral compression apparatus **10** is worn either midway along the penile shaft or toward the base of the shaft, urine does not pool in the urethra.

[0036] The dorsal hood is generally C-shaped and, when worn on the dorsal aspect of the penile shaft partially encircles the shaft. The urethral compressor is oriented ventrally and applies the desired pressure to the soft ventral tissues and the urethra. A strap applies tension between the dorsal hood and the urethral compressor, and thus the necessary compression between these two components.

[0037] The invention defined herein contemplates use of the urethral compression apparatus in clinical and non-clinical settings and, particularly in the nursing home setting, use of a variety of sensors such as pulse oximetry, temperature and pressure sensors so that clinical staff may monitor the patient's condition. Data from the sensors is transmitted to a remote monitoring station and a cloud based system may be utilized to monitor and inform some nurse-patient interactions such as periodic voiding.

BRIEF DESCRIPTION OF THE DRAWINGS

[0038] The invention will be better understood and its numerous objects and advantages will be apparent by reference to the following detailed description of the invention when taken in conjunction with the following drawings.

[0039] FIG. **1** is a longitudinal sectional and elevational view of a first illustrated embodiment of the present invention applied to a human penis, which also is shown in longitudinal section and which is illustrated with certain anatomical structures to illustrate functional effects of the invention on physiology.

[0040] FIG. **2** is a cross sectional view taken along the line **2-2** of FIG. **1**. The urethral compression apparatus shown in FIGS. **1** and **2** is shown with a dorsal hood of the type shown in FIGS. **7** through **11**, and a urethral compressor of the type shown in FIGS. **3** through **6**.

[0041] FIG. **3** is a top plan view of an illustrated embodiment the lower or ventral portion of the invention, referred to herein as the urethral compressor.

[0042] FIG. **4** is a side elevation view of the ventral portion shown in FIG. **3**, in which the urethral compressor is shown in isolation.

[0043] FIG. **5** is an end elevation view of the urethral compressor shown in FIG. **3**.

[0044] FIG. **6** is a cross sectional view of the v shown in FIG. **3** and taken along the line **6-6** of FIG. **3**.

[0045] FIG. **7** is a perspective view of the upper or dorsal portion of the embodiment of the invention shown in FIG. **1**, in which the dorsal portion, referred to herein as the dorsal hood, is shown in isolation.

[0046] FIG. **8** is a perspective view of the dorsal hood shown in FIG. **7** with optional padding removed.

[0047] FIG. **9** is an end elevation view of the dorsal hood shown in FIG. **8**.

[0048] FIG. **10** a top plan view of the dorsal hood shown in FIG. **8**.

[0049] FIG. **11** is a side elevation view of the dorsal hood shown in FIG. **8**.

[0050] FIG. **12** is a perspective view of the embodiment of an illustrated embodiment of the present invention, as shown in FIGS. **21** and **22**, illustrating the invention with its components assembled with a securing strap shown in a disengaged position. The embodiment illustrated in FIG. **12** is shown with a urethral compressor of the type shown in FIGS. **13** through **17**.

[0051] FIG. **13** is a perspective view of a second illustrated embodiment of a urethral compressor as shown in FIG. **12**, in which the urethral compressor is shown in isolation and in which padding is shown.

[0052] FIG. **14** is a perspective view of the urethral compressor of FIG. **13** in which the padding is removed.

[0053] FIG. **15** is an end elevation view of the urethral compressor shown in FIG. **14**.

[0054] FIG. **16** is a top plan view of the urethral compressor shown in FIG. **14**.

[0055] FIG. **17** is a side elevation view of the urethral compressor shown in FIG. **14**.

[0056] FIG. **18** is a perspective view of an alternative design for a urethral compressor according to the invention.

[0057] FIG. **19** is a perspective view of yet another alternative design urethral compressor according to the invention.

[0058] FIG. **20** is a schematic illustration of a urethral compression apparatus according to the present invention in which sensors defining a pulse oximeter are incorporated, and including remote monitoring capabilities.

[0059] FIG. **21** is a longitudinal sectional and elevational view of a second illustrated embodiment of the present invention applied to a human penis, which also is shown in longitudinal section and which is illustrated with certain anatomical structures to illustrate functional effects of the invention on physiology.

[0060] FIG. **22** is a cross sectional view taken along the line **22-22** of FIG. **21**. The urethral compression apparatus shown in FIGS. **21** and **22** is shown with a dorsal hood of the type shown in FIGS. **7** through **11**, and a urethral compressor of the type shown in FIGS. **13** through **17**.

[0061] FIG. **23** is a perspective view of yet another alternative embodiment of a urethral compression apparatus according to the invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0062] Reference is now made to the drawings filed herewith. Because the apparatus according to the present invention is especially designed for use with the human penis, it is appropriate to include a brief discussion of some aspects of the anatomy and physiology of the penis; conventional anatomical terminology is used throughout this description. With specific reference to FIGS. **1** and **21**, a representative section of a penis **200** is shown in longitudinal section extending from the glans penis **202** and the external urethral orifice **204** (at the left side of the drawing). The first embodiment of the urethral compression apparatus **10** according to the present invention is illustrated applied to the penis **200** about midway along the shaft **206** of the penis or toward the base of the penile shaft. The urethra **208** extends from the urinary bladder (not shown) along the shaft **206** and terminates at external urethral orifice **204**. Similarly, the dorsal vein **210** and a corporal artery **212** extend through the corpus cavernosum **214** along the shaft **206**. In the cross sectional views of FIGS. **2** and **22**, which are taken midway through the urethral compression apparatus **10** of the invention, the structures shown in FIGS. **1** and **21** may be seen in cross section and of course there are two corporal arteries **212**, and the dorsal arteries **216** are also illustrated. The dorsal arteries **216** and the dorsal vein **210** are proximate the dorsal aspect of penis **200**, which is identified generally with reference number **218**. The ventral aspect of penis **200** is identified generally with reference number **220**. The urethra **208** is proximate the ventral aspect of penis **200** and in FIGS. **1**, **2**, **21** and **22** is shown as being compressed and occluded owing to the application of the urethral compression apparatus **10** according to the invention, as detailed below.

[0063] Those of skill in the art will readily understand that the penis **200** is a complex organ and the anatomy is far more complex than illustrated herein; the anatomical detail shown in the drawings is appropriate to the description of the structure and operation of the invention but is not meant to illustrate the full anatomy.

[0064] A first illustrated embodiment of the invention will now be described with particular reference to FIG. **1**, and FIGS. **3** through **12**. Urethral compression apparatus **10** comprises three primary components: a dorsal hood **12**; a urethral compressor **14**; and a strap **16** that interconnects the dorsal hood **12** and the urethral compressor **14**. Each component is described in detail beginning with dorsal hood **12** as shown in FIGS. **7** through **12**. Dorsal hood **12** is an arcuate and semi-cylindrical member that in use is designed to extend over and partially encircle the dorsal aspect **218** of penis **200** (FIGS. **1** and **21**). In the embodiment of dorsal hood **12** shown in FIGS. **7** through **12**, dorsal hood **12** is generally a U or C-shaped body **18** that has a width W (FIG. **10**) with first and second arms **20** and **22**, and a fenestration **24** between the two arms **20** and **22**. The overall shape of dorsal hood **12** may be described as a semi-cylinder in which the two arms **20** and **22** face one another interiorly to define a semi-cylindrical channel or passageway **25** in the dorsal hood. The relative length of the two arms **20** and **22** shown in the figures, and thus the degree to which the dorsal hood **12** encircles the penile shaft, may be varied; it will be appreciated that the dimensions illustrated herein are exemplary but not limiting. For the purposes of illustration only, nominal dimensions of one preferred embodiment of dorsal hood **12** are as follows: height=2.0 cm (dimension H, FIG. **9**), and width=3.7 cm (dimension W, FIG. **10**). Similarly, a nominal height dimension of urethral compressor **14** may be about 1.5 cm (dimension H, FIG. **4**).

[0065] Preferably, the dorsal hood **12** is fabricated from a semi-rigid or rigid material because, as detailed below, the dorsal hood **12** is designed specifically to apply distributed pressure to, and avoid excessive pressure on the dorsal aspect **218** of penis **200** and to thereby avoid interference with blood flow, especially through dorsal arteries **216** and dorsal vein **210**. In practice the dorsal hood **12** (and other components such as urethral compressor **14**) may beneficially be fabricated from a medical grade plastic such as K-RESIN medical grade plastic, although this is but one example. A strap-receiving channel **30** extends over the top of the outer surface **32** of body **18** between edges **34** and **36** and as detailed below, the strap **16** resides generally in the strap-receiving channel **30**.

[0066] The C-shaped body **18** shown in most of the figures includes a single fenestration **24**. It will be appreciated, however, that plural fenestrations may be incorporated into a dorsal hood **12** according to the invention. For example, and by way of illustration with reference to FIG. **8**, a second fenestration **26** and a third fenestration **28** may be formed in the opposed first and second arms **20** and **22**. Preferably, a soft foam **38** such as an adhesive-backed form is applied over the inner surface **40** of body **18**—that is, the surface of body **18** that is oriented toward penis **200** when urethral compression apparatus **10** is in use (FIG. **1**) for comfort; the foam **38** does not cover or occlude the fenestration **34** (and if plural fenestrations are used, the foam does not cover or occlude the plural fenestrations). The foam **38** is removed from FIGS. **8** through **11** to better-illustrate the body **18**. The specifics and thickness of foam **38** may be varied for customization to accommodate penis size and to, for example, allow the patient to customize the functional characteristics of apparatus **10** as healing progresses and the requirements for incontinence control change. In many post radical prostatectomy patients the degree of pressure applied to the urethra **208** tends to decrease as healing progresses. The urethral compression apparatus **10** described herein allows for simple customization and adjustment to accommodate for a patient's requirements during the healing process.

[0067] Turning now to FIGS. **3** through **6** and FIG. **12**, a first illustrated embodiment urethral compressor **14** for use with the urethral compression apparatus **10** according to the invention will be described in detail. Urethral compressor **14** comprises a base **42** and transverse ridge **44** that extends upwardly (relative to the respective position of the urethral compressor **14** relative to the dorsal hood **12** when apparatus **10** is in normal use, for instance in FIGS. **1** and **12**) and across the base **42**. Although there are numerous structures that may be used to interconnect urethral compressor **14** to dorsal hood **12** so that these two components may function together as detailed below, in the embodiment illustrated in FIGS. **3** through **6**, urethral compressor **14** includes a pair of strap loops **46** and **48** that are attached to (or formed integrally as part of) base **42** at opposite ends thereof and which define strap through-openings **50** and **52** between the strap loops and the base **42**, at opposite ends of the base, and through which strap **16** extends. Urethral compressor **14**, like dorsal hood **12**, is preferably fabricated in a single, molded part from a medical grade plastic such as K-RESIN medical grade plastic, although again this is but one example.

[0068] The ridge **44** is referred to as being a "transverse ridge" because when the urethral compression apparatus **10** is in use (see, e.g., FIGS. **1** and **2**) the ridge **44** is oriented transverse to the longitudinal axis defined by urethra **208**. Thus, in the longitudinal section view of FIG. **1** the section defines a longitudinal axis of the penis **200**—that is, line L1. The ridge **44** of the urethral compressor **14** is transverse to this longitudinal axis as shown by line L1 of FIG. **3**. Urethral compressor **14** may optionally be fitted with soft foam covering as shown in FIG. **12**, and while foam may increase comfort the foam is optional. It will further be appreciated that the shape of the strap loops **46** and **48** may be varied. As one example, in FIG. **12** the strap loops **46** and **48** are more rectangular in shape relative to the shape of the strap loops **46** and **46** of FIG. **3**—the particular shape is unimportant so long as the loops allow the strap to interconnect the urethral compressor **14** to the dorsal hood **12**.

[0069] With reference now to FIG. **12** an assembled urethral compression apparatus **10** is shown. A first end **54** of strap **16** is attached to dorsal hood **12** at outer surface **32** of body **18** between edges **34** and **36** so that the strap **16** resides generally in the strap-receiving channel **30** of the dorsal hood. The strap extends over fenestration **44**. The strap runs through opening **50** between strap arm **46** and base **44**, beneath base **44**, and through opening **52** between strap arm **48** and body **44** so that the second end **56** of strap **16** defines a free end of the strap. Strap **16** is preferably a hook and loop type of fastener material so the second, free end **56** may be looped over the first end **54** and attached thereto. For instance, the outer-facing surface **58** of strap **16** at first end **54** may be hook material and the inner-facing surface **60** of free end **56** may be loop material so that the free end **56** may be looped over the first end and secured thereto. The urethral compressor **14** is slidable relative to strap **16**. Said another way, the strap is not fixedly attached to the urethral compressor but instead simply extends through the strap openings **50** and **52**. As such, the position of the urethral compressor **14** along the strap may be varied according to a particular user's needs as detailed below.

[0070] A second illustrated embodiment of a urethral compressor **14** is illustrated in FIGS. **13** through **17**—the same reference numbers are used to identify like structures in the urethral compressor **14** shown in FIGS. **3** through **6**. Thus, in the embodiment of FIGS. **13** through **19** a base **44** has strap arms **46** and **48** that define openings **50** and **52** between the strap arms and the base **44** through which the strap **16** may extend as detailed above. The optional foam **62** that may be used to cover the base **44** is shown in FIG. **13**. The base **44** of the urethral compressor **44** shown in FIGS. **13** through **17** defines a longitudinal axis (line L2 in FIG. **14**) that is generally aligned with and parallel to the longitudinal axis of the urethra **208** as described above (i.e., line L1, FIG. **1**). The base **44** shown in FIGS. **13** through **17** is interconnected with a dorsal hood **12** with a strap **16** in the same manner as described above.

[0071] Two additional embodiments of a urethral compressor **14** according to the invention are illustrated in FIGS. **18** and **19** in which the same reference numbers are assigned to the same structures as those described above. The bases **44** shown in FIGS. **18** and **19** are interconnected with a dorsal hood **12** with a strap **16** as described above.

[0072] From the several embodiments of the urethral compressors **14** shown in the figures it will be appreciated that there are several differently shaped structures that provide the equivalent functionally desired attributes described below when paired with the dorsal hood **12** illustrated and described herein.

[0073] A third illustrated embodiment of a urethral compression apparatus **10** is illustrated in FIG. **23** and again, the same reference numbers are used to identify like structures shown in other figures. In the embodiment of FIG. **23** the strap **16** is itself cut away, i.e., fenestrated, where the strap extends over fenestration **24** in dorsal hood **12** (rather than the strap extending over the fenestration **24** as shown in the embodiment of, for instance, FIG. **12**). This leaves the fenestration **24** open until the free end **56** of strap **16** is secured to the first end **54**. The adjustment indicia **65** and **65** shown in FIG. **23** are numeric and typically would be even incremental spacing such as 1 cm increments.

[0074] When urethral compression apparatus **10** is applied to penis **200** as shown in FIGS. **1**, **2**, **21** and **22**, the body **18** of dorsal hood **12** is oriented over the dorsal aspect **218** of penis **200** midway along the penile shaft such that the fenestration **24** is oriented over the dorsal aspect such that the shaft of the penis is in channel **25** of the hood. A gap or space **70** is defined between strap **16** and the dorsum of the penis at fenestration **24** so the strap does not contact the penis and does not apply pressure directly to the penis. The inner surface **40** of dorsal hood **12** is in direct contact with the penis **200** (i.e., the foam **38** is in direct contact) but the structure of body **18** with its width W, its first and second arms **20** and **22**, and a fenestration **24** between the two arms **20** and **22** applies a relatively evenly distributed pressure over the dorsal aspect of the penis to avoid excessive point pressure where the dorsal arteries and veins reside. The fenestration **24** and the gap **70** allows for some penile tissue to enter the fenestration and the space **70** so that pressure on the dorsal aspect of the penis is distributed and minimized so that circulation is not compromised. The user places the dorsal hood **12** as illustrated and the urethral compressor **14** is oriented ventrally, or inferiorly and caudad relative to the dorsal hood, as shown. As noted, the first end **54** of strap **16** is adhered to dorsal hood **12** (for instance, with suitable adhesives or by stitching and the like) and the position of the urethral compressor **14** on strap **16** may be varied according to a particular patient's needs. More specifically, a patient orients the urethral compressor **14** on strap **16** so that when the apparatus **10** is applied to the patient's penis **200** the urethral compressor **14** is oriented ventrally on the penis and preferably bilaterally centered, as shown in FIG. **2**. With urethral compression apparatus **10** oriented in this position the free end **60** of strap **16** is looped over the first end **54** and attached thereto with the facing hook and loop materials. The patient is able to fasten the strap **16** so that the transverse ridge **46** of base **44** applies the proper amount of pressure to compress the urethra **208**, as shown, but does not compromise circulation through the dorsal vein **210** and the corporal artery **212**. When the strap **16** is attached in this manner the circular enclosure defined by apparatus **10** is closed caudad to the dorsal hood **12** by the detachable, urethral compressor **14** and apparatus **10** is adjustable to apply variable pressure to the longitudinal urethral surface to transmit pressure through the soft tissue on the ventral aspect of the penis to effectively prevent leakage of urine. Indexing markings or indicia **63** on the second end of strap **16** (FIGS. **12** and **23**) and corresponding indexing indicia **65** on either the dorsal hood **12** (as shown in FIG. **7**), may be included so that the patient is able to secure the strap repeatedly in the same position so that the same pressure is applied. The indicia may be either alpha or numeric characters, as also shown in FIG. **23**.

[0075] The pressure applied by dorsal hood **12** with its fenestration **24** is distributed over a substantial area of the penile shaft, defined by the interior surface area of interior surface **40** of dorsal hood **12**. By distributing pressure over an increased surface area, combined with the fenestration(s) significantly decreases the amount of point pressure that is applied to the dorsal aspect of penis **200** so that circulation in the nearby arteries and veins is not compromised, yet allowing sufficient pressure to be applied to the ventral aspect of the penis **200** to occlude the urethra **208**. This orientation is shown in FIG. **2**. As a result, the apparatus **10** applies lower average pressure to the penis over a greater surface contact area so that there is no adverse pain or tissue effects, and no impairment of circulation even over extended periods of use. In addition the C-shape of the dorsal hood **12**, combined with the urethral compressor **14** and strap **16** results in a device that is not prone to slipping once it is properly fitted.

[0076] Testing has confirmed that the transverse ridge **46** of the urethral compressor **14** shown in FIGS. **1** and **2** is highly effective in preventing urine leakage with the apparatus **10** fitted very comfortably so that arterial and venous circulation is not compromised. As illustrated, the transverse ridge **46** (L**2**, FIG. **3**) extends generally at right angles to the longitudinal axis L**1** of the urethra **208**. As a result, the patient is able to wear apparatus **10** continually and to participate in all aspects of normal daily activity including sports, etc. without incidence of incontinence. And as noted, the C-shaped body **18** of dorsal hood **12** has proven to insure proper placement and orientation of the urethral compression apparatus **10** without slipping for long periods of time. This is due to the C-shaped dorsal hood **12**, which fixes the position of apparatus **10** on penis **200** in the sagittal plane with the semi-cylindrical enclosure defined by the opposed arms **20** and **22** essentially at least partially surrounding and cradling the penile shaft. Doppler testing has confirmed that pulsatile blood flow is not compromised when the apparatus **10** is worn as detailed above.

[0077] Testing has also confirmed that the rigidity or semi rigidity of the dorsal hood **12** prevents circumferential compression of the penis during use of apparatus **10** so that normal physiological enlargement and shrinking of the penis does not interfere with the primary function of the apparatus **10**, namely, prevention of urine leakage. Periodic removal of apparatus **10** to allow urine voiding is a very simple procedure, as is reinstallation of apparatus **10** subsequent to voiding.

[0078] FIGS. **21** and **22** illustrate an urethral compression apparatus **10** according to the invention in which a urethral compressor **14** of the type shown in FIGS. **13** through **17** is utilized. Functionally, the apparatus **10** in FIGS. **21** and **22** performs identically to the embodiment of apparatus **10** described above in respect of FIGS. **1** and **2**. However, the urethral compressor **14** applies pressure to the ventral aspect of the penis in a substantially parallel orientation to the axis of the urethra **208**. In other words, the longitudinal axis of the base **44** (i.e., line L**2**, FIG. **14**) is oriented parallel to the longitudinal axis L**1** of penis **200** and thus urethra **208**. In this instance the urethral compressor **14** applies a linearly distributed pressure on the ventral aspect of the penile shaft to compress the urethral lumen over relatively more extended length compared to the embodiment of FIG. **1**.

[0079] All of the embodiments of the urethral compressor illustrated in FIGS. **3**, **14**, **18** and **19**, when used with the dorsal hood **12** as described, provide sufficient pressure to the ventral aspect of the penis to compress the urethra **208** to eliminate incontinence and all the while providing a highly comfortable fit. In practice, a patient may choose the urethral compressor **14** that is the most comfortable and effective for that particular patient—regardless of which design is used, the apparatus **10** may be worn continuously without pain and without risk of compromised circulation.

[0080] It will be appreciated that the strap **16** defines a readily and easily adjustable means of attaching and securing the dorsal hood **12** to the urethral compressor **14** and that there are numerous equivalent ways of attaching the two parts together other than the described hook and loop fabric. Thus, other types of tensioning bands such as a band with holes in one end with anchoring pins on the overlapping portion may be used. In addition, the dimensions of the dorsal hood **12** may be varied so that a size appropriate to individual patient may be selected.

[0081] Reference is now made to FIG. **20**, which illustrates somewhat schematically some of the various sensors that may be used with urethral compression apparatus **10** to enable effective remote monitoring of the apparatus by clinical staff. In the first instance, urethral compression apparatus **10** may include a transmissive pulse oximeter, shown generally with reference number **80** and including a light transmitter **82** in the interior-facing portion of dorsal hood **12** and a correspondingly placed photodetector **84** in urethral compressor **14**. A power supply and (as detailed below) electronic package **86** may be installed interiorly in base **44** of urethral compressor **14**, or for example on the bottom side of the base. Pulse oximeter **80** conventionally passes two wavelengths of light from light transmitter **82** through the patient's penis **200** to the photodetector **84**. The changing absorbance of light due to pulsing arterial blood is analyzed in known manners with the control module **86** to generate oxygen saturation data and to measure and monitor the patient's oxygen saturation to insure that circulation is not compromised. A reflective pulse oximeter may be used as well.

[0082] Control module **86** includes a power supply **88** and circuitry and associated software and/or firmware to facilitate operation of the pulse oximeter **80** and preferably is wirelessly enabled (with standard wireless communication protocols such as Bluetooth) so that data from the pulse oximeter may be transmitted to a remote monitoring station **90**. This allows clinical staff to remotely monitor patients wearing the urethral compression apparatus **10** to insure adequate circulation.

[0083] Other types of sensors may be incorporated into urethral compression apparatus **10**, including for example temperature and pressure sensors. As an example, a temperature sensor **92** may be incorporated in dorsal hood **12** (or in urethral compressor **14**) and/or a pressure sensor such as a foil-type strain gage **94** or other equivalent pressure sensor may be incorporated in urethral compressor **14** (and/or in dorsal hood **12**). Each of these types of sensors is attached with appropriate circuitry to control module **86** so that temperature and/or pressure data may be transmitted to remote monitoring station **90** for evaluation by clinical staff. Software in remote monitoring station **90** includes threshold alarms to alert staff to out-of-bounds conditions such as low oxygen saturation values, increased temperature or pressure values. A urethral compression apparatus **10** may further include conventional electronics connections to allow the apparatus to be connected by hard wiring to the monitoring station **90** in clinical settings where wireless connections cannot be utilized.

[0084] In addition to data from the various sensors may being transmitted to the remote monitoring station **90**, data may be transmitted to and stored in a cloud computing environment for access by care providers. The system may be set up to provide routine and periodic notifications to the healthcare professionals, for example, making sure that the patient voids urine regularly.

[0085] The strap **16** defines a means for adjusting the pressure applied to the penis by urethral compression apparatus **10** but the strap described above and shown in the drawings may be replaced with other equivalent devices for accomplishing the same function. As just one example, an automated (and if desired, remotely controlled) pressure actuator such as a pneumatic or electrically drive actuator may be used as a pressure application means.

[0086] While the present invention has been described in terms of preferred and illustrated embodiments, it will be appreciated by those of ordinary skill that the spirit and scope of the invention is not limited to those embodiments, but extend to the various modifications and equivalents as defined in the appended claims.

1. Urinary incontinence control apparatus, comprising:

a semi-cylindrical dorsal hood defining a semi-cylindrical channel and having an exterior surface, an interior surface facing the semi-cylindrical channel, and at least one fenestration;

a urethral compressor;

a strap interconnecting the dorsal hood and the urethral compressor and such that the urethral compressor is retained caudad to the dorsal hood.

2. The urinary incontinence control apparatus according to claim **1** in which the urethral compressor includes a ridge facing the semi-cylindrical channel and extending transverse to a longitudinal axis of the dorsal hood.

3. The urinary incontinence control apparatus according to claim **2** in which the urethral compressor includes a main body and a first loop at a first end of the main body and a second loop at a second end of the main body, wherein each loop defines a space between the respective loop and the main body.

4. The urinary incontinence control apparatus according to claim **3** in which the strap extends from the dorsal hood through the space between the first loop and the main body, beneath the urethral compressor, through the space between the second loop and the main body, and over the dorsal hood.

5. The urinary incontinence control apparatus according to claim **4** in which the dorsal hood further defines a strap channel on the exterior surface and the strap extends over the strap channel.

6. The urinary incontinence control apparatus according to claim **5** wherein a first end of the strap is connected to the dorsal hood and a second end of the strap is a free end, and wherein the second end of the strap is connectable to the dorsal hood.

7. The urinary incontinence control apparatus according to claim **6** wherein the strap extends through the strap channel and over the fenestration such that there is a space in the fenestration between the interior surface and the strap.

8. The urinary incontinence control apparatus according to claim **2** in which the dorsal hood includes more than one fenestration.

9. The urinary incontinence control apparatus according to claim **1** including a pulse oximeter adapted for measuring oxygen saturation.

10. The urinary incontinence control apparatus according to claim **9** in which the pulse oximeter generates oxygen saturation data and means for transmitting the oxygen saturation data to a remote monitoring station.

11. The urinary incontinence control apparatus according to claim **1** including a pressure sensor adapted for transmission of pressure data to a remote monitoring station.

12. The urinary incontinence control apparatus according to claim **1** including a temperature sensor adapted for transmission of temperature data to a remote monitoring station.

13. Urinary incontinence control apparatus, comprising:

a substantially C-shaped dorsal hood having an interior surface adapted for positioning on the dorsal aspect of a penis and at least partially surrounding the penile shaft, the dorsal hood having at least one fenestration;

a urethral compressor caudad to the dorsal hood and having a urethral compressing component facing the interior surface of the dorsal hood such that the urethral compressing component applies pressure to the ventral aspect of the penile shaft to thereby occlude the urethra.

14. The urinary incontinence control apparatus according to claim **13** including a connector for interconnecting the dorsal hood with the urethral compressor so that the urethral compressor is retained on the ventral aspect of the penile shaft and for varying the pressure applied to thereto.

15. The urinary incontinence control apparatus according to claim **14** in which the connector is defined by a strap having a first end attached to the dorsal hood and a second free end and wherein the urethral compressor is movable relative to the strap.

16. The urinary incontinence control apparatus according to claim **13** further comprising an oximeter for generating penis blood oxygen saturation data.

17. The urinary incontinence control apparatus according to claim **16** further including means for transmitting the penis blood oxygen saturation data to a monitoring station.

18. Urinary incontinence control apparatus, comprising:

a semi-cylindrical component adapted for at least partially encircling a penile shaft in a semi-cylindrical channel extending therethrough and having at least one opening corresponding to the dorsal aspect of the penis;

a urethra compressor having a urethral compression component facing the semi-cylindrical channel; and

strap means for connecting the semi-cylindrical component to the urethra compressor.

19. The urinary incontinence control apparatus according to claim **18** in which the urethral compression component is defined by a ridge extending transverse to a longitudinal axis of the semi-cylindrical channel.

20. The urinary incontinence control apparatus according to claim **19** including an oximeter.

* * * * *

专利名称(译)	分布压力促性尿道压缩装置治疗男性尿道括约肌缺乏症并保留血流量		
公开(公告)号	US20190314129A1	公开(公告)日	2019-10-17
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[标]发明人	PACEY JOHN ALLEN		
发明人	PACEY, JOHN ALLEN		
IPC分类号	A61F2/00 A61B5/00 A61B5/1455		
CPC分类号	A61F2/0054 A61B5/4836 A61F2230/0013 A61B5/14551 A61F2250/0097 A61F2250/001 A61B5/6831 A61B5/0008 A61B5/6813 A61B5/1455 A61B5/20 A61B5/6802 A61F2250/0002		
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摘要(译)

尿道压迫装置由半圆柱形有孔背侧罩限定，该背罩背侧戴在阴茎上，并通过一条带子与尿道压迫器相连，尿道压迫器以腹侧为方向，向尿道施加压缩压力以防止尿液漏出。背罩和尿道压缩机施加分布式压力，可防止静脉和动脉循环受损，但可消除尿失禁。该设备可能会持续磨损，很容易被移除以允许排空，然后重新安装。背罩上的开窗（或视情况而定为多个开窗）可分配压力，避免静脉和动脉血流中断。背罩部分环绕阴茎干，尿道压迫器位于腹侧，并向软腹侧组织和尿道施加所需压力。带子在背罩和尿道压迫器之间施加张力，因此在这两个组件之间施加必要的压缩力。