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- (71) Applicant (for all designated States except US): **OHIO UROLOGIC RESEARCH, LLC** [US/US]; 1998 Cambridge Boulevard, Columbus, OH 43221-4102 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **SINGH, Errol, O.** [US/US]; 1998 Cambridge Blvd., Columbus, OH 43221 (US). **HELLSTROM, Ake, A.** [SE/US]; 5714 Brinkley Court, Columbus, OH 43235 (US).
- (74) Agent: **GUBINSKY, Louis**; Vorys Sater Seymour & Pease LLP, 1909 K Street, N.W. Suite 900, Washington, DC 20006 (US).

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(54) Title: SURGICAL DRAPE SYSTEM FOR UROLOGY PROCEDURES ON MALE PATIENTS

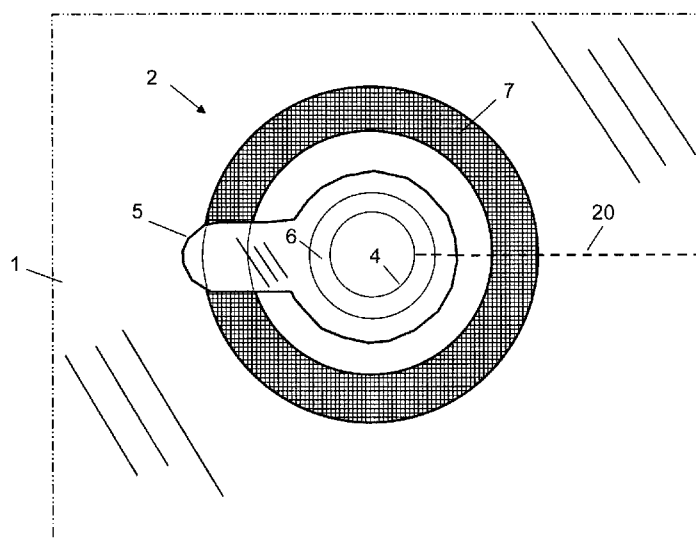


Fig. 5

(57) Abstract: A simple surgical drape system of generally flat shape for male urology procedures that provides full isolation of top versus bottom surface by a sealing fenestration surrounding the meatus area. It is achieved by manually forming the flat drape to a tent-like shape around the penis with a fenestration aperture smaller than glans diameter, supported by and sealing to the glans tip, and then attaching a penile clamp to hold the drape. This allows a simplified, safer antibacterial preparation and less chance of infection complications. The sealed design permits better management of urology liquids, and can use absorption pad on drape top side. The drape wrinkles act as a penile position stabilizer, reducing need for extended use of one operator hand for penile support. Drape is removable with catheter in place.

Surgical Drape System for Urology Procedures on Male Patients

Reference to related application:

This application claims benefit of provisional application 61/441267, filed February 9, 2011.

BACKGROUND OF THE INVENTION

[0001] This invention is in the technical field of medical equipment, in particular for surgical drape systems utilized in urology procedures on male patients. Such procedures are relatively common but still have demonstrated less than desired outcome in many cases. Problems may arise with infections and patient discomfort that require prolonged patient care and procedure re-work in best cases, but can in worse cases introduce serious long term consequences both for patients and care givers. This occurs currently despite more stringent medical guidelines being in place. There is a very active demand today by the entire society to reduce health care cost, and medical procedure infections and other procedure complications is one important factor.

[0002] As part of preparation for urology procedures like catheterization, the patient is scrubbed with antibacterial agents in the entire pubic area. This process has the drawback that this particular area is typically covered with body hair and has several skin folds, resulting in risk for incomplete bacteria elimination. Furthermore, loose hair and skin particles from this area may easily become dislodged during the urology procedure and can contaminate instruments or the urethral meatus and nearby areas. This may call for using extra potent antibacterial agents. However, increasing the amount, or potency, of antibacterial agents can lead to the long term drawback of breeding more resistant bacteria strains.

[0003] In the male urology procedure, the patient is typically cleaned and prepared, and then covered at least partially with a sterile surgical drape. The drape may use multiple sections or have one or more fenestrations included to access to the male organ. It is common that sizeable amounts of liquids emerge from the urethra or instruments during the procedure. Such liquids may however flow down through fenestration apertures and reach other parts of the patient body and the operating table, causing inconvenience and a less clean environment. Medical spent liquids disposal also needs special procedures and equipment to avoid spills or undesired contact.

[0004] At urethral catheterization or endoscopy, proper insertion and control of the instrument is critical to avoid tissue damage or patient discomfort. This is complicated by the need to use one of the hands to fully support the penis which is typically flaccid. One of the operator's hands may be in use to support the penis during most of the procedure of current art, making it inconvenient to perform other duties during the process.

[0005] Sometimes it is necessary to let catheters or other connected instruments remain in the patient for an extended time after the procedure. This requires a drape design that can be easily removed with instruments in place. Condom-like male drape features would not be practical for this.

[0006] The prior art known to the present inventors can be divided into two main categories of male urological surgical drapes. First, there are the flat drapes containing one or more fenestrations for accessing the penis, and second, there are the condom or sheath-containing male surgical drapes.

[0007] The above-referenced drawbacks have been attempted to be solved to varying degree by prior art, but there is our knowledge not any solutions disclosed that solves of all these issues with one surgical drape system and minimum drawbacks.

SUMMARY OF THE INVENTION

[0008] The present invention is a drape system for reduced risk and simplified urological procedures for male patients. The drape system isolates the pelvic area as a non-sterile environment below the drape and a sterile area above the drape, with a sealed fenestration between these areas preventing contamination from below to reach the top side and urology fluids to reach the bottom side. The exposed patient area on the top sterile side is limited to only the urethral meatus with small surroundings of the glans tip, and provides a seal from the non sterile areas below. This simplifies antibacterial preparation of the patient ahead of the urological procedure and reduces infection risk by isolating the urology procedure entry location from the general pubic area.

[0009] The drape may have a simple, generally flat shape made of flexible translucent plastics or a thin elastic sheet material. It is draped around the penis in an initially tent-like fashion and held in place by means of a surrounding penile drape clamp. A removable drape cover will upon removal expose only a small area around the meatus for antibacterial preparation and accessible for urology procedures.

[0010] This penile protruded shape draping starting from a flat shape creates longitudinal drape wrinkles that can actually improve the drape functionality. An unexpected observation is

that the longitudinally rippled shape of the drape may act as an external penile stiffening structure connected to the surrounding drape for stabilized penile positioning even in a flaccid state. This reduces the need for the operator to manually hold the penis in position and therefore occupying one hand during most of the urological procedure.

[0011] Because this drape design creates a sealed area above the patient except the meatus area, control and collection of urology liquids is simplified. For instance, a disposable and safe to handle absorbing or liquid gelling pad may be placed on portions of drape top side.

[0012] Removal of the drape after the urology procedure with instruments like catheters still in place can be achieved by a splittable line in the drape all the way in from an external drape edge and in to the fenestration. This is simple to achieve due to the generally flat sheet design of the drape, compared to the difficult to split molded drape protrusions in some prior art.

[0013] As a summary, this male patient urology drape system can offer major advantages in safety, functionality, simplicity, ease of doing procedures and cost versus prior art

BRIEF DESCRIPTION OF THE DRAWING

- [0014] Fig. 1 shows a representation of antibacterial cleaning in prior art.
- [0015] Fig. 2 shows a urological procedure in prior art
- [0016] Fig. 3 shows a planar view of the drape of the invention
- [0017] Fig. 4 shows a planar view of the drape of including a different material insert
- [0018] Fig. 5 shows an enlarged planar view of the fenestration in the drape
- [0019] Fig. 6 shows a cross section of the fenestration in which the seal ring has substantially the same inside diameter as the diameter of the fenestration
- [0020] Fig. 7 shows the first step, a drape laid down on a male patient
- [0021] Fig. 8 shows the drape formed to shape by hand
- [0022] Fig. 9 shows the drape protective cover removed
- [0023] Fig. 10 shows antibacterial preparation of the patient
- [0024] Fig. 11 shows application of the clamp to hold the drape
- [0025] Fig. 12 shows the liquid absorbent pad
- [0026] Fig. 13 shows an example of urological procedure including the invention drape.

[0027] Fig. 14 shows a cross section of the fenestration in which, as compared to the embodiment depicted in Fig. 6, the seal ring has a smaller inside diameter than the diameter of the fenestration.

DETAILED DESCRIPTION OF THE INVENTION

[0028] The purpose of the invention is easiest clarified by first a brief comparison to prior art.

[0029] Figure 1 (prior art) shows a male patient being prepared by antibacterial swab before a urological procedure according to prior art. The whole exposed genital area must be treated. It is noted that exposed body hair and skin folds will create crevices that may harbor particles and bacteria that is difficult to fully reach with the swab.

[0030] Figure 2 (prior art) shows a catheterization or similar urology procedure performed according to prior art. It is noted that hair or particles in the genital area may become dislodged during the process and reach the meatus, or the operator's sterile gloves, or insertable urology instruments. It is also noted that the usually flaccid penis must be supported by hand during the process, or it may fall down and reach contamination. Furthermore, the need for one hand providing support during most of the process makes it inconvenient for the operator to do other duties during the procedure. It is also noted that due to the open path to the pubic area, liquids emerging from the patient or from treatment may flow down under the drapes and onto the patient and operating table.

[0031] The invention drape system is shown in Fig. 3 and includes a drape 1 with a fenestration 2 and a split line 20. The drape 1 may be made of a transparent material, for instance clear plastics, or by a thin elastic film, for instance latex. The purpose of the fenestration and the split line will be explained in subsequent paragraphs. The shape of the drape can be planar and rectangular as shown, but may be cut to any shape or formed to fit the patient and also include additional features known from prior art. Thus, the shape of the drape can be non-rectangular, such as circular. In Fig. 4 is shown a variation of the design where the drape 1 is attached in a

sealed fashion to a surrounding larger drape sheet 3 that is made of a different material, for instance textile, non- wovens, or opaque plastics.

[0032] The drape 1, preferably translucent, can be transparent. In the embodiment of Figure 4, surrounding sheet 3, for example formed of standard medical non-woven disposable material, can be more opaque than central translucent sheet 1, providing a feeling of privacy for the patient.

[0033] The translucent sheet 1 is constructed from readily available plastic film used in the medical field, for example, vinyl (such as polyvinyl chloride), polyethylene, polypropylene, polycarbonate, polyester, silicone elastomer, acetate and so forth film materials. In selecting a film material for use as sheet 1, factors such as the softness of the film, the ease of application of the film when used as a male drape, adaptability of the film to body contour, patient comfort and wrinkle stiffening properties of the film can be evaluated. For example, a 3 mil (0.070mm) soft grade vinyl film can be used for construction of sheet 1. Sheet 1 may be constructed of plastic film used in forming prior art drape materials, for example, plastic film of about 1 to 5 mil (0.025 to 0.125 mm) in thickness. A sheet made of soft material may need to be made thicker than a drape made of a harder grade material in order to provide similar stiffening effects.

[0034] The male drape of the present invention must be sterile as packaged and remains sterile until use. The inventive drape can be uncoated or completely or partially coated or impregnated with agents known in the art, such as antibacterial, adhesive and sealing compounds.

[0035] Fig. 5 is an enlarged and more detailed description of the fenestration 2 with a planar view on the top side away from the patient, while Fig. 6 shows a cross section. The drape 1 includes a generally circular aperture 4 that is initially covered by a pull-away capable cover 5. This is preferably made of a transparent thin material for operator see-

through, or it may be made of stretchable thin film like latex. The cover 5 may be attached and sealed to the drape 1 by means of a temporary adhesive, and shaped with a finger tab for manual removal. Additionally, the aperture 4 in the drape 1 may also have a seal ring 6 or 16 attached around the aperture 1 to provide seal to the male body parts as will be explained later, and also for reinforcement of the aperture. The inside diameter of the aperture 4 and the seal ring 6 or 16 are chosen to be smaller than the diameter of the male glans such that it will rest on the glans without full penetration.

[0036] The sealing ring 6 or sealing ring 16 that is attached to the drape 1 can be formed of a material which possess the same degree of flexibility and rigidity as, or be softer or more rigid than the film material used for sheet 1. For example, sealing ring 6 or sealing ring 16 may be die cut from a soft sheet material or molded as a more rigid plastic material. Soft sealing ring materials may provide better patient comfort while still functioning as an adaptable gasket. On the other hand, harder sealing ring materials provide a greater dimensional stability. Routine experimentation will provide a sealing ring possessing a balance of desired properties. For example, the sealing ring 6 or sealing ring 16 may be constructed of a silicone elastomer, or could be made of a soft sponge-like material. It may furthermore be made of a homogeneous material or coated or infused with antibacterial or liquid sealing agents.

[0037] The degree of partial penetration of the male glans by drape aperture 4 and by sealing ring 6 as depicted in Figure 6 in which the diameter of aperture 4 and inside diameter of sealing ring 6 are substantially identical, can vary with the diameter of the patient's glans. Figure 14 depicts an embodiment of the invention distinct from the embodiment of Figure 6. In Figure 14, the sealing ring 16 has a smaller inside diameter than the diameter of drape

aperture 4. By selecting a soft and elastic material for construction of sealing ring 16 in the Figure 14 arrangement, a flexible seal is provided that will accommodate a wide range of glans diameters, because the sealing ring 16 will elastically deform to the glans contour.

[0038] In Fig 5 is also shown a marking 7 that can be printed or attached on the drape 1 to enable the operator to quickly locate the fenestration 2 on the drape, which will be of particular value if both the drape 1 and the cover 5 are made of translucent materials.

[0039] Now referring to Figures 7, 8, 9, 10 and 11, these show a suitable sequence in applying the drape 1 onto a patient and prepare the patient for the urological procedure.

[0040] Fig. 7 shows the drape 1 that is laid over the patient with the cover 2 away from the patient. The drape 1 will from now on isolate the non-sterile patient area on the bottom side from the sterile and sealed top side of the drape 1.

[0041] Fig. 8 shows the drape 1 being positioned around the penis in an initially tent like shape such that the cover 5 and the sealed aperture 4 are approximately centered over the urethral meatus. This can be done by vision through a translucent drape or cover, or via tactile feel through a thin elastic and less translucent drape. By this procedure, the drape 1 will form wrinkles 10 that are essentially longitudinal to the penis. These wrinkles will be most evident and hard if the material in the drape 1 is of moderate thickness, and smaller in effect if the material in drape 1 is very thin and elastic. The presence of these wrinkles provides an unexpected and simple means of penile positioning that will be further explained in later paragraphs.

[0042] Fig.9 shows the removal of the cover 5 from the drape 1, exposing the urethral meatus approximately in center of the aperture 4. The diameter of the aperture 4 is less than the diameter of the patient's glans, making the seal ring 6 resting and sealing against the glans tip

surrounding the meatus. The use of seal ring 6 is optional depending on the softness and edge characteristics of drape 1 to perform the sealing task.

[0043] In Fig. 10, a sponge with antibacterial agents is applied to wipe and sterilize the meatus and small exposed portion of the glans tip. It is remarked that the area requiring treatment is very small compared to prior art, and all accessible areas from the top side of drape including the active urology area are now sterile and safely sealed from the bottom side.

[0044] Fig. 11 shows a clamp 10 applied around the exterior of the penile portion of the drape 1. The clamp 10 is a sterile device that may utilize a Velcro® loop, elastic bandes, or a molded medical clamp preferably made in two halves, and is applied with light pressure to not constrict the urethra. This clamp locks the drape in place to the penis, aids in sealing between above and below the drape, and generates further stiffness and position control of the shaped drape portion including longitudinal wrinkles. This allows the operator to not have to support the penis with one hand most of the time for a typical urological procedure. In order to best secure the drape 1, the clamp 10 is preferably applied right below the glans. The clamp 10 may also allow a second clamp where one clamp is positioning the penis and a second clamp may be temporary applied to close the urethra to retain medications or other purposes. The clamp 10, in a preferred embodiment of the invention, is packaged together with the inventive drape in a convenient, single-use surgical drape system.

[0045] The sealed separation of a top side from a bottom side provided by this drape can now preferably also be utilized to create an improved liquid waste collection system that reduces liquids reaching the patient, the operating table or the floor. Figure 12 shows one possible shape of a liquid absorbing pad 21 with a penile notch 22 that may be positioned on top of the drape of the invention. The illustrated shape is just one example, other shapes may include as example a

ring like shape with a slit for easy removal, or one or more of rectangular shape individual pads. The pad can be made of conventional fibrous materials but may preferably utilize superabsorbent materials that allow large liquid absorption without seeping out. Antibacterial agents may be incorporated in this pad. It may also include a special exterior layer for dryness and internal gelling chemicals that convert liquid waste to semi-solid waste. Handling semi-solid medical waste is usually easier and safer than handling liquid waste that may involve open tanks, plastic bags, containers with lid, tubing and pumps, and risk for spills, leaks and personnel exposure.

[0046] In Fig. 13 is shown a complete drape system in conjunction with a urological procedure. The drape 1 is placed on the patient, a clamp 10 is applied around the penile area of the drape 1, and the cleaned meatus is exposed in the drape aperture 4. The operator may initially use one hand holding the penile section of the drape 1 or clamp 10 but once the critical meatus entry of urology instruments is completed, this hand can be free.

[0047] On top of the drape 1 is placed one or more absorbing pads 21 with a penile notch 22 in suitable positions to collect liquids emerging during the procedure. The sealed aperture 4 reduces chance for liquids reaching the rest of the patient body and operating table.

[0048] Upon completion of the urology procedure shown in Fig. 13 a catheter or other instruments may need to be left in place in the patient for extended time. This is simplified by the split line 20 in the drape 1 allowing it to be torn apart, and made practical due to the simple flat shape of drape 1 with no protruding molded shapes.

[0049] While the foregoing written description of the invention enables one of ordinary skill to make and use what is considered presently to be the best mode thereof, those of ordinary skill will understand and appreciate the existence of variations, combinations, and equivalents of the

specific embodiment, method, and examples herein. The invention should therefore not be limited by the above described embodiment, method, and examples, but by all embodiments and methods within the scope and spirit of the invention as claimed.

CLAIMS

What is claimed is:

1. A urological surgical drape for a male patient comprising a flat, planar, flexible sheet containing an internal aperture, the aperture being larger in size than a meatus area of the patient and smaller in size than a glans diameter of the patient, and a removable cover completely overlaying the aperture.
2. The surgical drape of claim 1 wherein the sheet is translucent and the cover is translucent or transparent.
3. The surgical drape of claim 1 wherein the flexible sheet is substantially rectangular in peripheral shape and the aperture is substantially circular.
4. The surgical drape of claim 1 wherein the flexible sheet is non-rectangular in peripheral shape.
5. The surgical drape of claim 4 wherein the flexible sheet is substantially circular in peripheral shape.
6. The surgical drape of claim 1 wherein the aperture is approximately centrally located in the sheet.
7. The surgical drape of claim 1 wherein the removable cover is adhesively attached to the sheet and includes a graspable separation tab.
8. The surgical drape of claim 1 wherein the flexible sheet includes a splittable tear line extending from a sheet edge to the aperture.
9. The surgical drape of claim 1 including a penile sealing ring positioned on the underside of the flexible sheet and surrounding the aperture.
10. The surgical drape of claim 1 including indicia indicating the location of the aperture.

11. The surgical drape of claim 10 wherein the indicia surrounds the aperture and is spaced apart from the aperture.
12. A urological surgical drape for a male patient comprising a planar, flat, flexible sheet, the sheet having a translucent central section containing an internal aperture, the aperture being larger in size than a meatus area of the patient and smaller in size than a glans diameter of the patient, and with a removable cover completely overlaying the aperture, and a section more opaque than the central section surrounding the translucent central section.
13. The surgical drape of claim 12 wherein the drape and the central section are rectangular in peripheral shape.
14. The surgical drape of claim 12 wherein the central section is circular in peripheral shape.
15. The surgical drape of claim 12 wherein the drape is non-rectangular in peripheral shape.
16. The surgical drape of claim 12 wherein the central section sheet is formed of a translucent plastic film and the surrounding section is formed of an opaque non-woven material.
17. The surgical drape of claim 12 wherein the aperture is approximately centrally located within the drape.
18. The surgical drape of claim 12 wherein the removable cover is adhesively attached to the sheet and includes a graspable separation tab.
19. The surgical drape of claim 12 wherein the drape includes a splittable tear line extending from a drape edge to the aperture.
20. The surgical drape of claim 12 including a penile sealing ring positioned on the underside of the sheet and surrounding the aperture.
21. The surgical drape of claim 12 including indicia indicating the location of the aperture.

22. The surgical drape of claim 21 wherein the indicia surrounds the aperture and is spaced apart from the aperture.
23. A method for preparing a male patient for a urological procedure comprising
- (1) Laying the surgical drape of claim 1 over a genital area of the patient with the aperture cover facing away from the patient;
 - (2) Positioning the surgical drape in a tent-like shape around the penis of the patient with the covered aperture substantially centered over an urethral meatus area of the patient; and
 - (3) Removing the aperture cover to expose the urethral meatus in approximately the center of the aperture.
24. A method for preparing a male patient for a urological procedure comprising.
- (1) Laying the surgical drape of claim 9 over a genital area of the patient with the aperture cover facing away from the patient;
 - (2) Positioning the surgical drape in a tent-like shape around the penis of the patient with the covered aperture substantially centered over an urethral meatus area of the patient; and
 - (3) Removing the aperture cover to expose the urethral meatus in approximately the center of the aperture and allowing the sealing ring to sealingly engage the glans area.
25. The process of claim 23 or claim 24 wherein (4) an antibacterial agent is applied to the exposed areas of the penis of the patient.
26. The process of claim 23 or 24 wherein (4) a penile clamp is applied beneath the glans of the patient.
27. The process of claim 23 or claim 24 wherein an absorbent sheet having a penile opening is applied over the surgical drape.
28. A urological surgical drape system for a male patient comprising

(1) The urological surgical drape of claim 1 or of claim 12 and

(2) A penile clamp.

29. The surgical drape of claim 9 wherein the penile sealing ring has an inside diameter that is substantially identical to the diameter of the internal aperture, or has an inside diameter that is smaller than the diameter of the internal aperture.

30. The surgical drape of claim 20 wherein the penile sealing ring has an inside diameter that is substantially identical to the diameter of the internal aperture, or has an inside diameter that is smaller than the diameter of the internal aperture.

31. A method for preparing a male patient for a urological procedure comprising

(4) Laying the surgical drape of claim 12 over a genital area of the patient with the aperture cover facing away from the patient;

(5) Positioning the surgical drape in a tent-like shape around the penis of the patient with the covered aperture substantially centered over an urethral meatus area of the patient; and

(6) Removing the aperture cover to expose the urethral meatus in approximately the center of the aperture.

32. A method for preparing a male patient for a urological procedure comprising

(1) Laying the surgical drape of claim 20 over a genital area of the patient with the aperture cover facing away from the patient;

(2) Positioning the surgical drape in a tent-like shape around the penis of the patient with the covered aperture substantially centered over an urethral meatus area of the patient; and

(3) Removing the aperture cover to expose the urethral meatus in approximately the center of the aperture and allowing the sealing ring to sealingly engage the glans area.

33. The process of claim 31 or claim 32 wherein (4) an antibacterial agent is applied to the exposed areas of the penis of the patient.
34. The process of claim 31 or claim 32 wherein (4) a penile clamp is applied beneath the glans of the patient.
35. The process of claim 31 or claim 32 wherein an absorbent sheet having a penile opening is applied over the surgical drape.

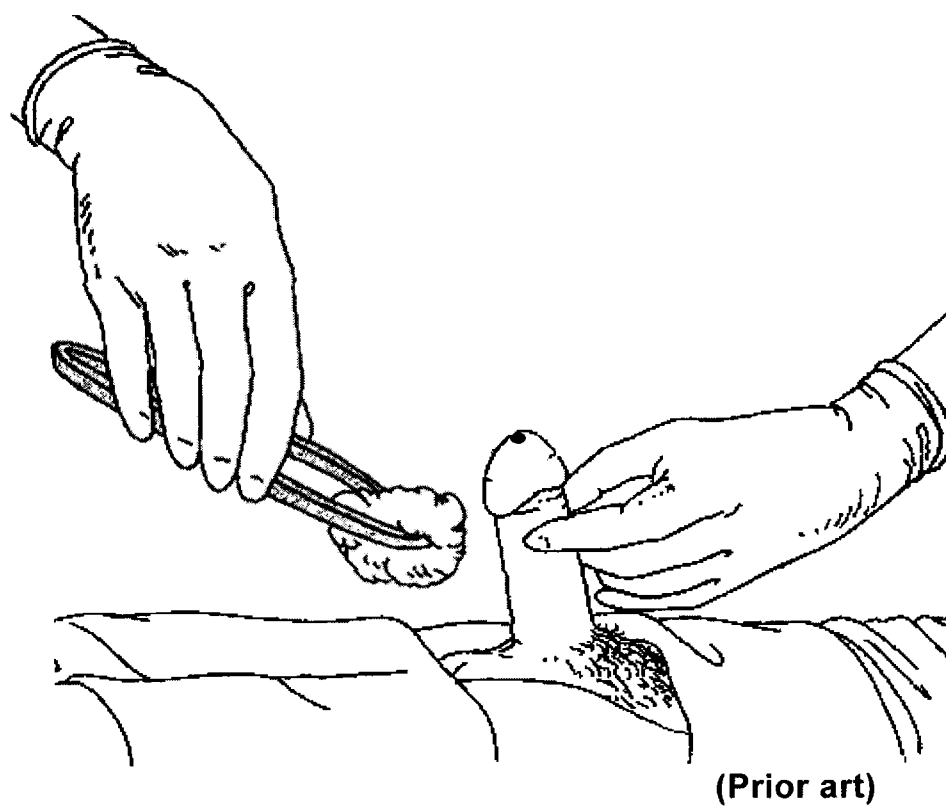


Fig. 1

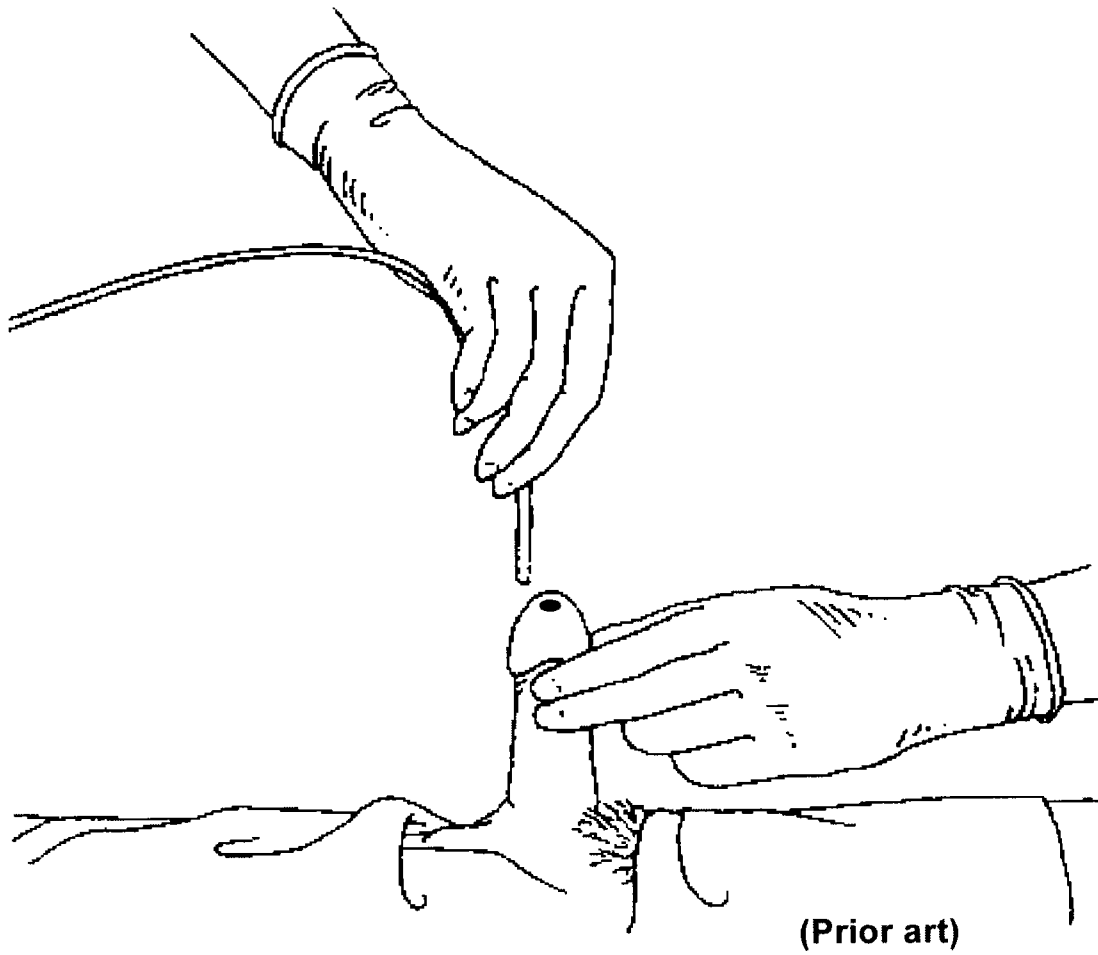


Fig. 2

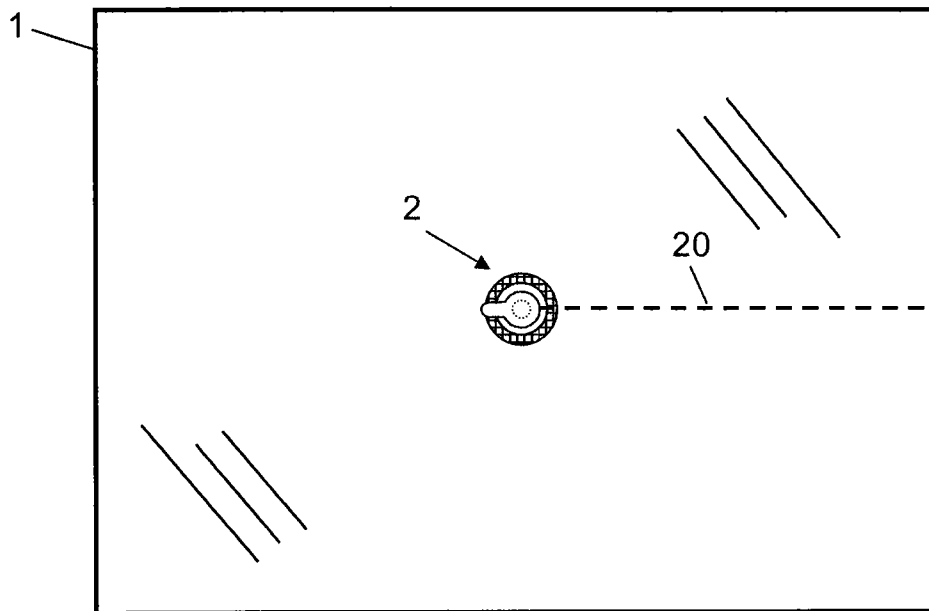


Fig. 3

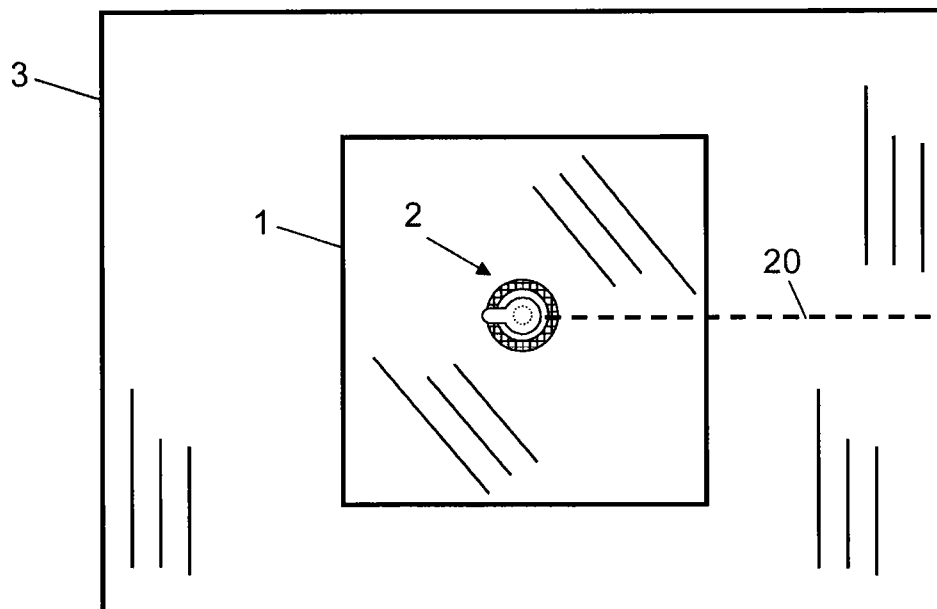


Fig. 4

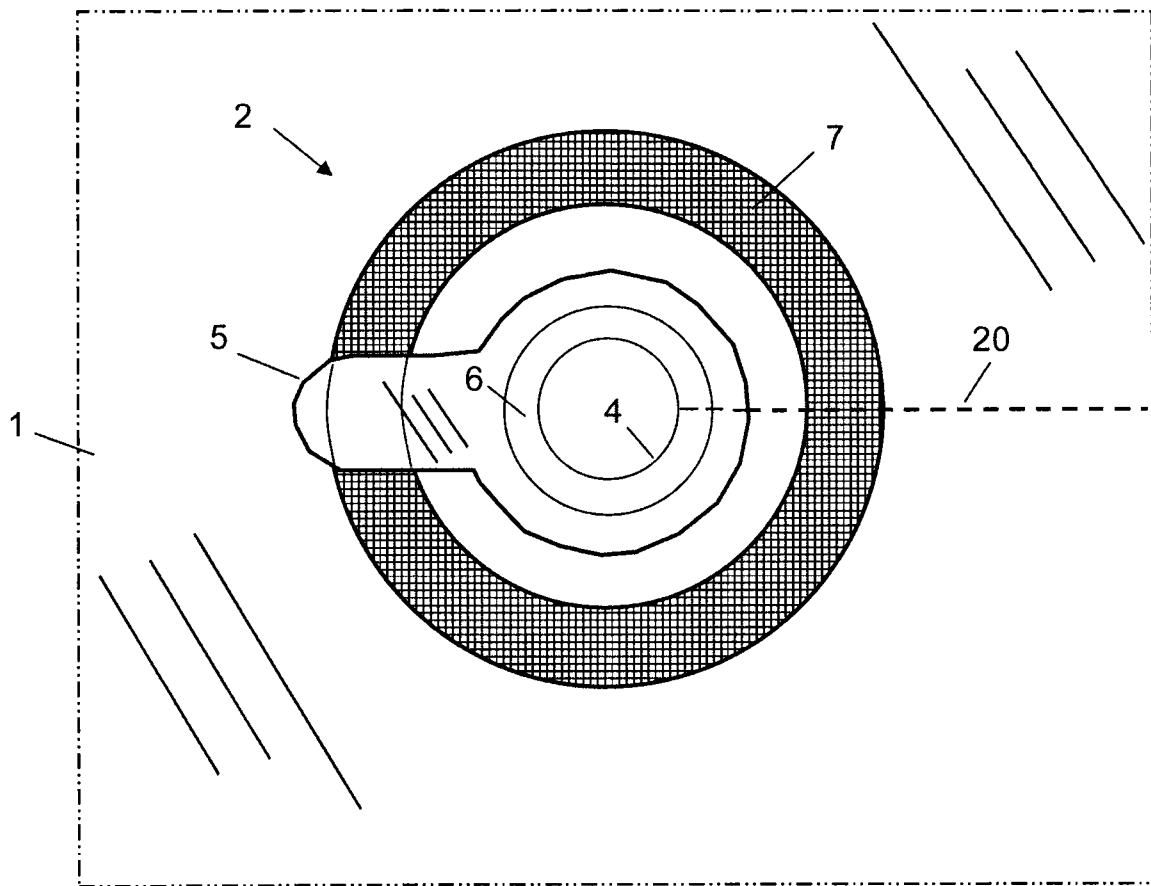


Fig. 5

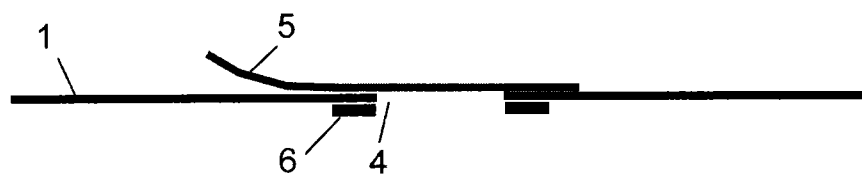


Fig. 6

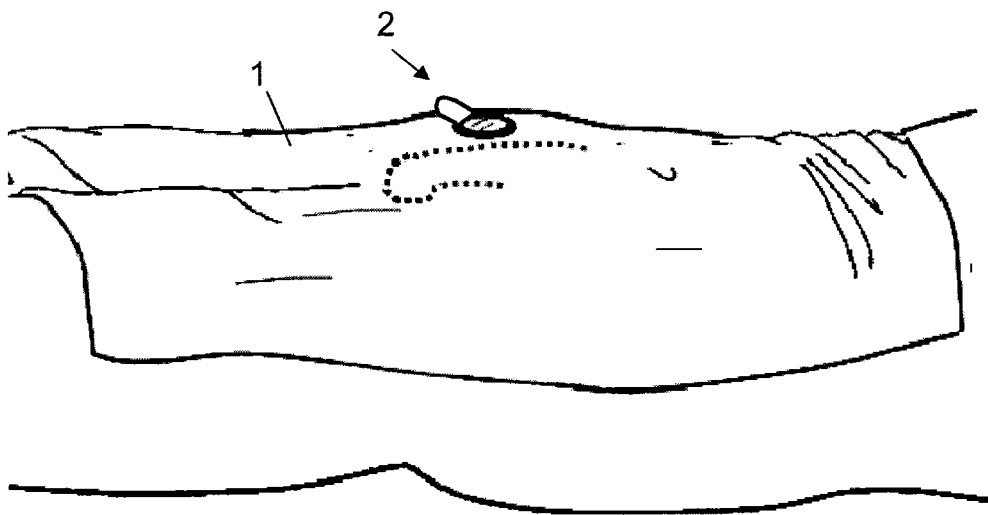


Fig. 7

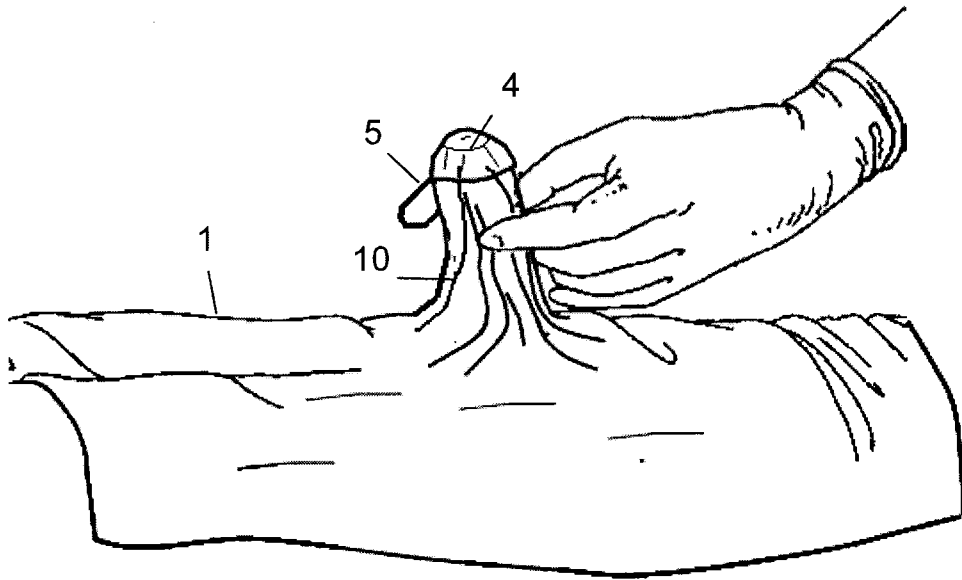


Fig. 8

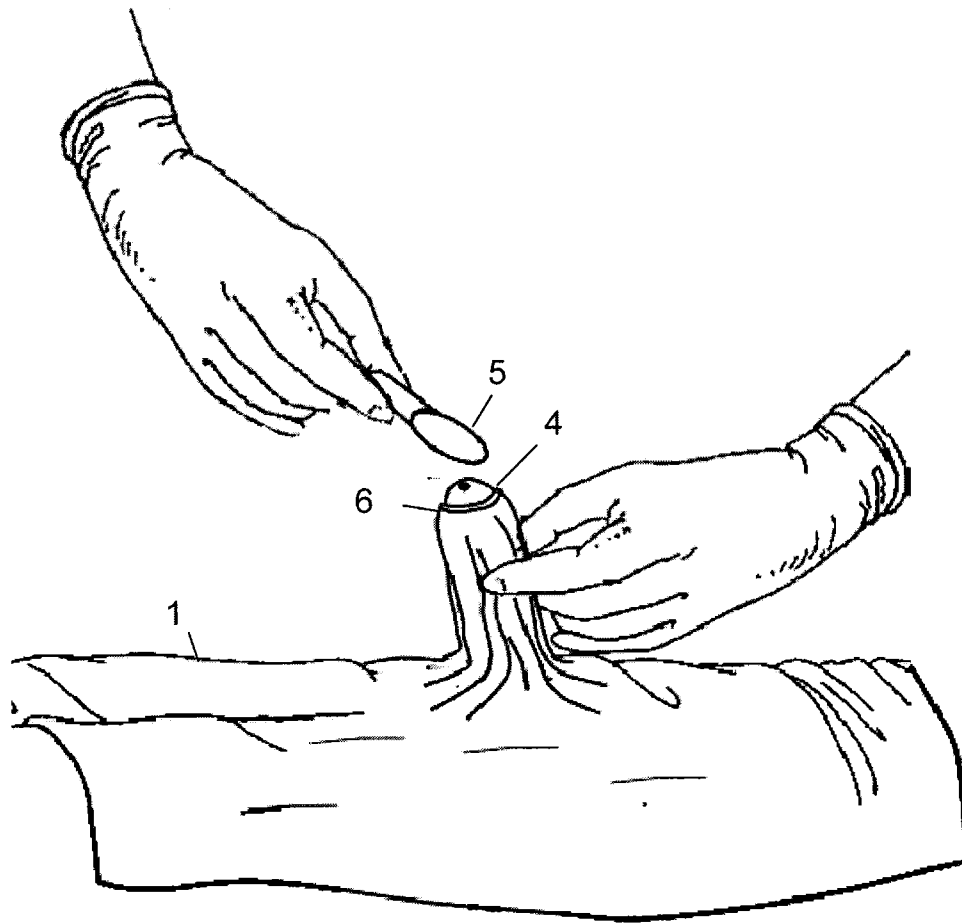


Fig. 9

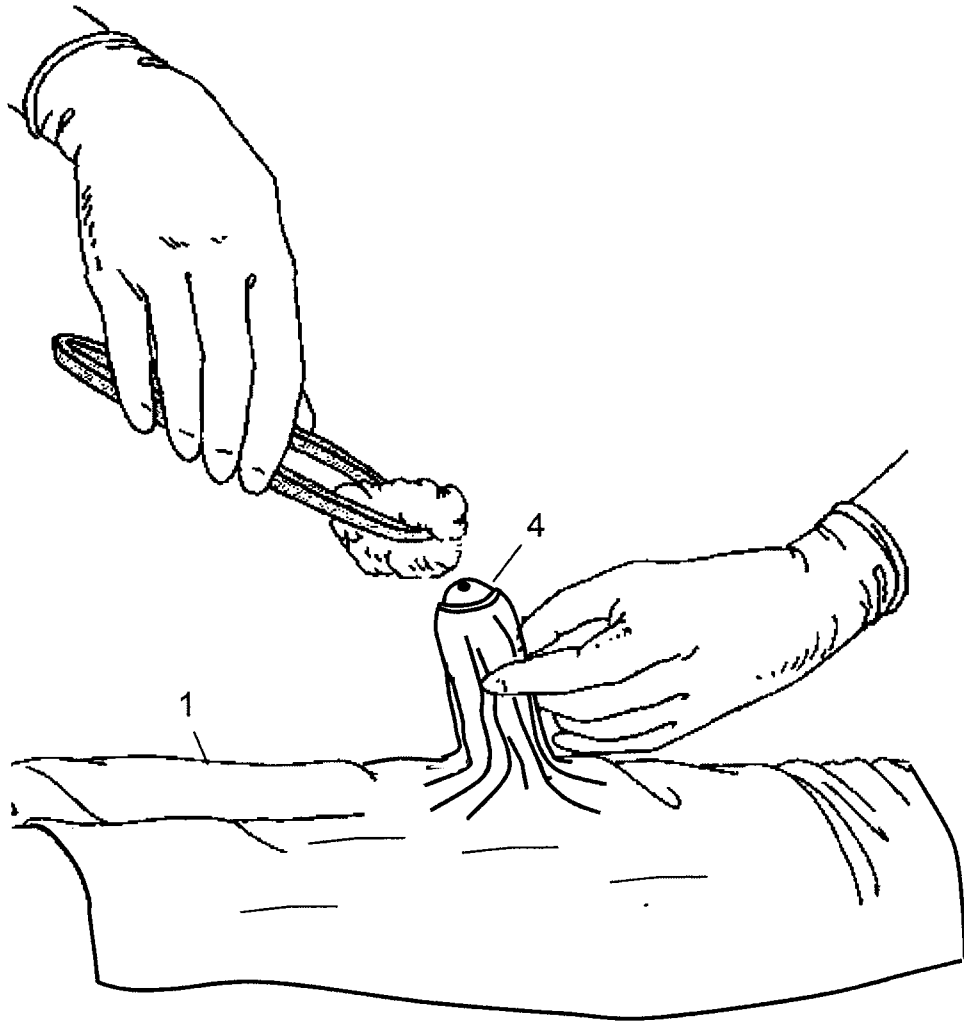


Fig. 10

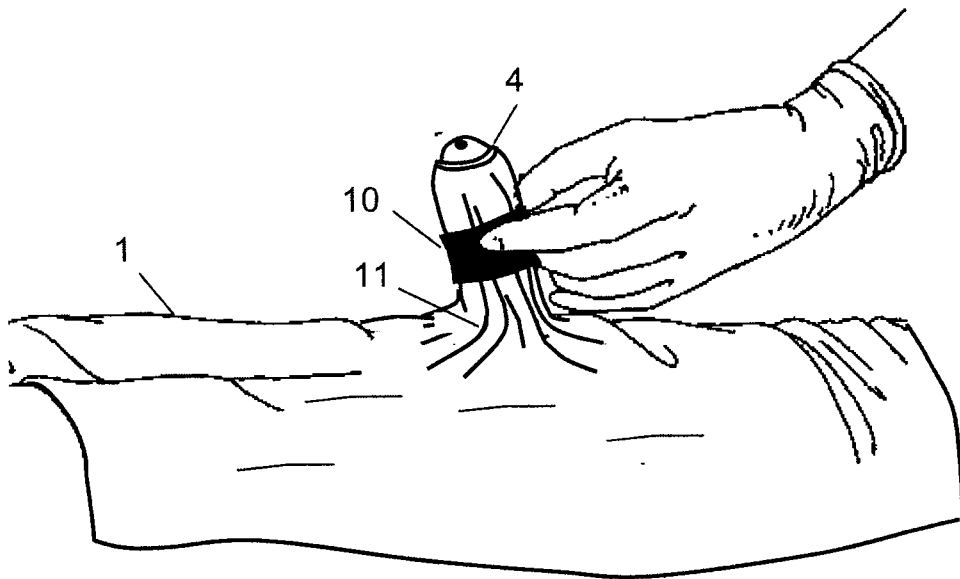


Fig. 11

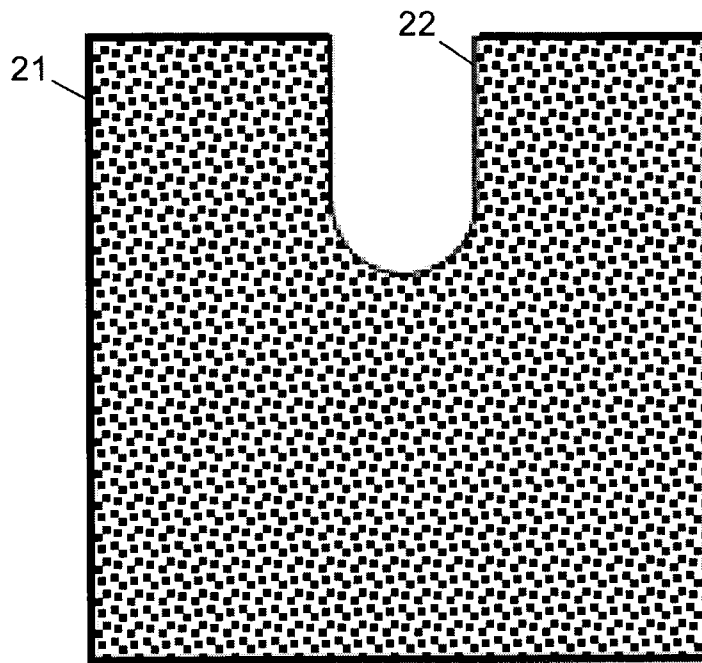


Fig. 12

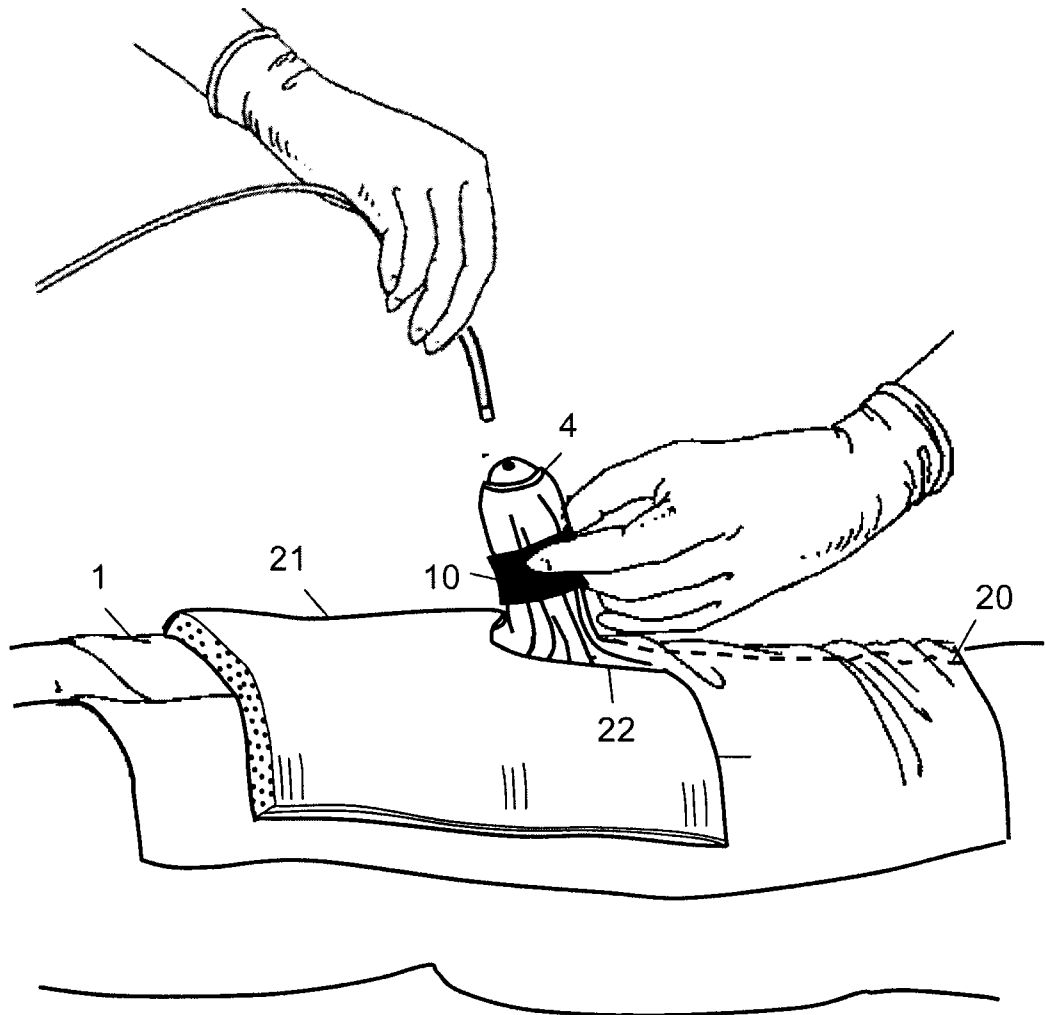


Fig. 13

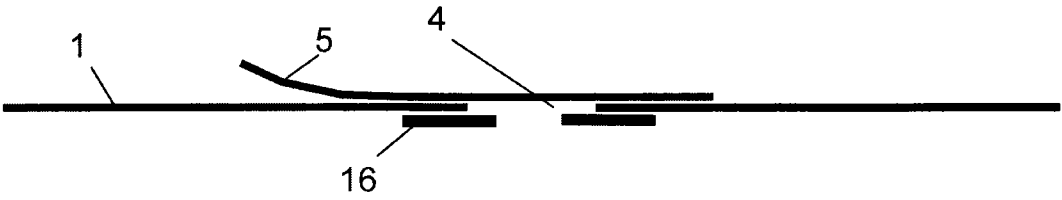


Fig. 14