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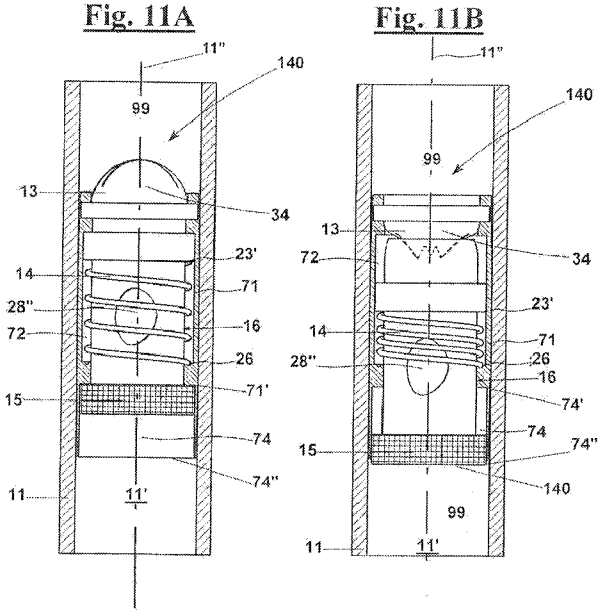


(57) Abstract: A structure (140) of artificial endo-urethral sphincter for treating the urinary incontinence comprising at least one hollow rigid body (71), configured for being fixed within the walls (3) of the urethral-bladder lumen of a patient, inside it being provided: a longitudinal channel (11'); a valve element (13) housed within the longitudinal channel (11'); a closure means for moving the valve element (13) between a closed configuration and an open configuration. In a first aspect of the invention, the structure comprises a safety element (16) arranged within the longitudinal channel (11') downstream of the valve element (13), also comprises a block means structured for turning between a block configuration and a release configuration, where the safety element (16) is configured for preventing an unwanted / allowing a massive flow of urine (99), respectively, through the valve element (13). The structure prevents unwanted urine leakage, in particular urine leakages due to a seal defect of the sphincter, or in the case of an uncontrolled increase of the intravesical pressure due to coughs and efforts of any other nature. In an exemplary embodiment, a safety abutment member (16) is provided on a valve element (13) comprising preferably shell-shaped (34) resilient walls, which in the release configuration is at a distance from the valve element (13) and enables the latter to open. A return elastic element (14) may be arranged for firmly keeping the safety element (16) in the block configuration. In a second aspect of the invention, the safety element (16) may comprise, at an own end (21,21'), a magnetically sensitive element (15), configured such that, by arranging an external (electro)magnetic element (17) with the same polarization direction, a magnetic coupling is formed of the two elements (15,17) and the safety element (16) turns to the release configuration.

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# A STRUCTURE OF ARTIFICIAL ENDO-URETHRAL SPHINCTER

## DESCRIPTION

### Field of the invention

The present invention relates to the medical field and, in particular, it relates to an artificial endo-urethral sphincter, for example to be implanted into patients who suffer from urinary incontinence.

### Background of the invention

Many types of artificial urethral sphincters are known for treating urinary incontinence. They are used when such remedies as the outpatient therapy, the pharmacological therapy and the pelvic re-education are not effective. The artificial urethral sphincters are used also as alternative to the traditional surgical techniques, which provide a reconstruction of the bladder support structures.

For the implant of urethral sphincters mini-invasive techniques exist, such as the TVT (Tension-free Vaginal Tape Procedure), or other techniques, described for instance in WO2005009293, or also in WO2011121591, which describes a device to be put into the vagina, having a distal portion to be positioned in a subvesical position and a proximal portion to be arranged in a suburethral position. The distal and proximal portions are configured for turning from a non-deformable condition to a deformable condition, and vice-versa. The device also comprises a mechanism for controlling the deformation, in order to apply a pressure to the urethra.

Other artificial endo-urethral sphincters are described in US2005187428, ES2343449, WO2006115225, US6638208, US2008015548, WO2005077301, WO2004037134, US6623421, WO0015140, WO0002499, US6193646, WO9901172, US6237623, EP0700668.

WO 2011/073969 describes a urological device comprising a urological valve and a plurality of leaflet valve members that have a region of mutual co-action. The valve has a configuration normally closed, in which the valve members are engaged at region of co-action, and an open configuration, in which the stopper members are separated in order to allow a flow of urine

through the valve. The valve is configured for turning from the closed configuration to that open by applying a urological pressure.

US 6,464,999 B1 describes a urethral valve in implants or devices for controlling the urinary incontinence, which have a variable opening pressure responsive to changes of physiological parameters such as the increase of the abdominal pressure caused by coughs.

Nevertheless, the above artificial sphincters have at least one of the following drawbacks:

- a sudden or impulsive action of the patient, such as a cough, an effort of any nature like when lifting weights, may increase the intravesical pressure up to opening the sphincter, which causes leakage of urine;
- a closure defect, or in any case a sealing defect, of the sphincter may cause a leakage of urine;
- they make it difficult or impossible the insertion of inspection and/or surgical medical equipment, or they damage the tightness after the insertion.

Summary of the invention

Therefore, it is a feature of the invention to provide a structure of artificial endo-urethral sphincter that can prevent unwanted urine leakage.

It is a particular feature of the invention to provide such a structure that solves the tightness problems of the prior art, preventing the leakage of urine through the sphincter.

It is another particular feature of the invention to provide such a structure that prevents urine leakage in the case of an uncontrolled increase of intravesical pressure, due to coughs and efforts of other nature.

It is another feature of the invention to provide a structure of artificial endo-urethral sphincter that can be implanted in an outpatient procedure, without requiring any invasive surgical operation.

It is also a feature of the invention to provide a structure of artificial endo-urethral sphincter that allows, once implanted, the insertion of inspective or surgical medical equipment, in order not to preclude the patient from any medical examination or treatment.

It is also a feature of the invention to provide a structure of artificial endo-

urethral sphincter that, in case of defect of a component, makes it possible to an easy change, for restoring the correct operation without surgery.

These and other objects are achieved by a structure of artificial endo-urethral sphincter comprising:

- at least one hollow rigid body, configured for being fixed within the walls of a urethral-bladder lumen of a patient, in particular for being fixed within the urethra walls, the hollow rigid body defining a longitudinal channel arranged to convey urine from an upstream section towards a downstream section;
- a valve element housed within the longitudinal channel;
- a closure means for causing the valve element to turn from a closed configuration, in which the urine cannot flow through the longitudinal channel, to an open configuration, in which the urine can flow through the longitudinal channel, and vice-versa.

In a first aspect of the invention, the structure comprises a safety element arranged within the longitudinal channel of the hollow rigid body downstream of the valve element, wherein the safety element comprises a block means structured for turning from a block configuration to a release configuration, wherein the safety element is configured, in the block configuration, for preventing an unwanted flow of urine through the valve element and wherein, in the release configuration, the safety element is configured for enabling a free flow of urine that has flown through the valve element.

In some exemplary embodiments, the safety element comprises a safety valve element serially arranged downstream of the valve element.

In particular in an exemplary embodiment, the closure means of the valve element comprises resilient walls that, in the closed configuration, are at a rest condition and, in the open configuration, are configured for being deformed due to an abdominal pressure increase caused by the patient, up to a predetermined opening pressure of the valve element.

In an exemplary embodiment, regardless of the upstream safety element, the block means of the safety valve element comprises resilient walls that, in the block configuration, are at a rest condition and, in the release configuration, are configured for being deformed due to an abdominal pressure increase caused by the patient, up to a predetermined release pressure of the

safety valve element.

In a structure in which both the closure means and the safety means comprise resilient walls that can be deformed by increasing the abdominal pressure, the two valve elements cooperate to define the true opening pressure of the structure, which is normally set between the highest opening pressure between the two valve elements or the common opening pressure of the two valve elements, and the sum of these pressures.

Such a valve element allows the passage of an inspection or surgical medical equipment. In fact, it can be opened by pressing the lower face of the shell portion of the equipment, in such a way that the wings defined by the slits are spaced apart, and an opening is formed wide enough to allow such passage. Moreover, once the medical equipment has been applied through the valve, the original tightness is maintained, since the resilient walls of both valve elements are less likely to be damaged.

The release pressure of the safety valve element may be lower than the opening pressure of the valve element.

In an alternative embodiment, the release pressure of the safety valve element may be higher than the opening pressure of the valve element. This way, a safer seal can be obtained, due to the cooperation of the shell-shaped portions of both valve element to block the lumen.

In an exemplary embodiment, the valve element may have an opening pressure that is higher than the opening pressure of the safety valve element, in order to clear the longitudinal channel between both valve elements from the fluid, once the urine has been evacuated.

Preferably, the resilient walls comprise a shell portion equipped with at least one through slit, wherein:

- in the closed or block configuration, the shell portion has a convex shape on the bladder side, thus forming a diaphragm, such that a urine pressure acting upon the shell portion keeps the through slit closed;
- in the open or release configuration, the shell portion has a concave shape opposite to the convex shape, wherein the through slit is deformed and open, and is configured for enabling a flow of urine,

  In the convex shape, the shell portion is configured for bearing the urine pressure up to an ultimate pressure selected between the release

pressure and the opening pressure such that, upon exceeding the ultimate pressure, the shell portion collapses into the concave shape, and enables a passage of urine through the through slit. This way, the true opening pressure is higher than the nominal opening pressure of the valve element, which prevents urine leakage.

Advantageously, the shell portion has a cap shape that has a plurality of converging star-shaped slits, in particular said slits converging to a central point of the cap shape.

In other exemplary embodiments, the safety element comprises an abutment member that, in the block configuration of the safety element, is structured for preventing the valve element from turning from the closed configuration to the open configuration, and in the release configuration is structured for moving away from the valve element and enables the latter to open. This way, the true opening pressure of the valve element is substantially infinite as long as the safety element is in the block position, and returns to the value of the nominal opening pressure, which depends upon the material and upon the geometric features when the safety element is in the release configuration. This prevents the structure from being actuated by a sudden increase of the intravesical pressure, as in the case of coughs and of a patient's physical effort.

More in detail, in these exemplary embodiments, the safety element, which is movable within the hollow rigid body, is a safety slider configured for constraining the resilient deformation of the shell portion, so that the opening pressure becomes high enough to prevent the deformable portion, which may have a shell shape, from turning from the closed configuration to the open configuration if a sudden increase of the urine pressure occurs, as in the case of a cough or of any patient's physical effort.

Preferably, the safety element comprises a return elastic element, in particular a spring, which is configured for firmly keeping the safety element in the block configuration. More in detail, the return elastic element is arranged to move back to a position where it does not interfere with the deformation of the shell portion, once the opening pressure has been exceeded. In particular, the elastic constant of the spring can be selected to prevent the deformable valve

element from turning from the closed configuration to the open configuration for any sudden urine pressure increase.

Advantageously, the safety element comprises a magnetically sensitive element at an own end opposite to the shell portion, said magnetically sensitive element configured such that, by arranging an external magnetic or electromagnetic element with a same polarity as the magnetically sensitive element, a magnetic coupling is formed between the external magnetic or electromagnetic element and the magnetically sensitive element, and the safety element turns to the release configuration.

In further exemplary embodiments, the valve element is longitudinally slidingly arranged within the longitudinal channel, and the safety element comprises a shell portion.

Advantageously, the valve element comprises a return elastic element associated with the stopper member and arranged to normally keep the valve stopper member in the closed configuration.

In a second aspect of the invention, the valve element comprises a valve stopper member that has at least one magnetically sensitive element configured such that, by arranging an external magnetic or electromagnetic element with a same polarity as the magnetically sensitive element, a magnetic coupling is formed between the external magnetic or electromagnetic element and the magnetically sensitive element, and the valve element turns to the open configuration.

For example, this valve stopper member may be selected from the group consisting of:

- a rotatable valve stopper member arranged within the hollow rigid body about a rotation axis transversal with respect to the longitudinal channel of the hollow rigid body, the rotatable stopper member selected from the group consisting of:
  - a valve stopper member having an axisymmetric shape, in particular a ball stopper member, that has a through hole and is rotatably arranged between the open configuration, in which the through hole forms a hydraulic continuity with the longitudinal channel, and the closed configuration, in which the ball stopper member blocks the hydraulic continuity;

- a clapet stopper member rotatably arranged between the closed configuration, in which the clapet stopper member fluid-tightly engages with a support seat within the longitudinal channel, and the open configuration, in which the clapet stopper member is at a distance from the sealing support seat, such that a passageway is formed within the longitudinal channel;
- a gate stopper member slidingly arranged between the closed configuration, in which a surface of the gate stopper member fluid-tightly engages with a corresponding inner surface of the hollow rigid body, and the open configuration, in which the surface of the gate stopper member is at a distance from the inner surface of the hollow rigid body, such that a passageway is cleared within said longitudinal channel;
- a spiral-shaped stopper member comprising coils, the spiral-shaped stopper member movably arranged within the longitudinal channel between the closed configuration, in which the coils have a compressed configuration, i.e. they are longitudinally aligned to form a fluid-tight seal along the longitudinal channel, and the open configuration, in which the coils have a released configuration, i.e. they are reciprocally arranged along a longitudinal unwinding axis in such a way that passageways are formed among the coils and the hydraulic continuity of the longitudinal channel is restored.

Preferably, the movable valve stopper member has a return elastic element arranged to constrain the movement of the movable valve stopper member with respect to the hollow rigid body, such that, if a magnetic interaction of the magnetically sensitive portion is not present, the movable valve stopper member is kept at the closed position.

In order to releasably fasten the structure to the urethral-bladder lumen, the hollow rigid body may be associated with a stent. In particular, the stent may comprise a plurality of resiliently radially compliant coils, or may be a tubular stent provided with shape memory flared end portions configured to fit the end portions of the urethral-bladder lumen. This way, the structure can be put into the urethral-bladder lumen by a tubular introducer body, within which the stent fits by radial compression. Once the introducer body has been extracted, the structure is released, and the coils or the flared end portions

return to their own rest positions, thus fastening the valve body to the urethra and to the mouth of the bladder.

The apparatus comprising a fastening system, a hollow rigid body and a shell portion is a further preferred exemplary embodiment of the invention. The same type of magnetic coupling with a device operated from outside can be exploited for obtaining further preferred exemplary embodiments of the valve.

Brief description of the drawings

The invention will be now shown with the following description of an exemplary embodiment thereof, exemplifying but not limitative, with reference to the attached drawings in which:

- Fig. 1 shows a structure, according to the invention, arranged in a urethral-bladder lumen;
- Figs. 2A-2C show sectional, partially sectioned, perspective partially sectioned views of a structure, according to the invention, comprising two shell valve elements;
- Figs. 2D-2F show the structure of Figs. 2A-2C in three consecutive opening steps of the valve apparatus;
- Fig. 3A-3C shows a diaphragm valve element as in the structure of Figs. 2A-2F, in an elevation view, in a plan view and in a perspective view;
- Figs. 4A to 8D show shell valve elements of another exemplary embodiments;
- Fig. 9 is a perspective view of a structure comprising a stent made as a same workpiece with the hollow rigid body;
- Fig. 10A is a perspective view of a structure that has a stent mounted to the hollow rigid body;
- Figs. 10B-10C are sectional views of the structure of Fig. 10A in a positioning configuration and in a use configuration;
- Figs. 10D-10E are a longitudinal sectional view and a partially sectioned perspective view of the valve apparatus of the structure of Fig. 10A;
- Figs. 11A-11B are sectional views of a structure equipped with a safety slider in the block configuration and in the release configuration;
- Figs. 11C-11E show the structure of Figs. 11A and 11B in a cross sectional view, in a partially sectioned view, and in a partially sectioned

perspective view;

- Figs. 11F,14C,20E,21C,22D,23E show magnetic or electromagnetic elements outside of the body of the patient, associated respectively to the structures of Figs. 11B,14B,20D,21B,22B,23B;
- Figs. 12A-12B show the safety slider of the structure of Figs. 11A-11E in a perspective view and in an elevation side view;
- Fig. 13 is a partially sectioned perspective view of a structure according to the invention, comprising a sliding valve element and a shell safety element;
- Figs. 14A-14B are longitudinal sectional views of the structure of Fig. 13 in a closed configuration and in an open configuration;
- Fig. 15 is a partially sectioned perspective view of a structure, according to the invention, comprising fastening elements to be fastened to the inside walls of the urethral-bladder lumen;
- Figs. 16A-16B are longitudinal sectional views of the structure of Fig. 15, with the fastening elements in an introduction configuration and in a use configuration, respectively;
- Figs. 17A-17B are partial cross sectional views of a structure according to the invention, equipped with a stent comprising radially expansible coils, in an introduction configuration and in a use configuration;
- Figs. 18A-18B are partial cross sectional views of a structure according to the invention, with a different stent of a different type, in an introduction configuration and in a use configuration;
- Figs. 19A-19B are partially sectioned perspective views of a structure with a valve ball valve element, in an open configuration and in a closed configuration;
- Figs. 20A-20B show a structure comprising a clapet valve element, in two partially sectioned views;
- Figs. 20C-20D are longitudinal sectional views of the structure of Figs. 20A-20B in the open configuration and in the closed configuration;
- Figs. 21A-21B are partially sectioned perspective views of a structure comprising a gate valve element, in the open configuration and in the closed configuration;
- Figs. 22A-22B are partially sectioned perspective views of a structure

comprising a different gate valve element, in the open configuration and in the closed configuration;

- Fig. 22C is a partially sectioned perspective view of the valve apparatus shown in Fig. 22B;
- Figs. 23A-23B are partially sectioned perspective views of a structure comprising a spiral-shaped disc valve element, in the open configuration and in the closed configuration;
- Figs. 23C-23D are partially sectioned side views of the apparatus of Figs. 23A-23B.

Description of preferred exemplary embodiments

With reference to Fig. 1, a structure of artificial endo-urethral sphincter 100 is diagrammatically shown arranged within the urethral-bladder lumen 2 of a patient 1. Structure 100 comprises a hollow rigid body 11 that defines a longitudinal channel 11', and has an engagement means 12 to engage with inner walls 3 of urethral-bladder lumen 2 for fixing structure 100 within it.

In the case of Fig. 1, the engagement means may be provided by a stent 12. For instance, stent 12 may comprise coils 28 configured for radially expanding at end portions 2',2" of urethral-bladder lumen 2, as also shown in Figs. 17A-17B.

In alternative, in an exemplary embodiment, the structures 120,130 shown in Figs. 9 and 10A-C comprise a stent 29 that has flared shape memory end portions 30. In particular, in the structure 110 (Fig. 9), stent 29 is manufactured integral to hollow rigid body 11, whereas in the structure 110 (Figs. 10A-C) hollow rigid body 11 and stent 29 are two distinct bodies integrally connected to each other.

In Fig. 10B, structure 130 is shown in an introduction retracted configuration, where stent 29 fits within walls of a positioning device 8, such as a cannula, which can be put into urethral-bladder lumen 2 (Fig. 1). In Fig. 10C, structure 130 is shown in a use configuration, in which end portions 30 of stent 29 have recovered their own original shape, once it has been put into urethral-bladder lumen 2, ensuring a steady coupling with inner walls 3 thereof.

Stent 29 can be connected with respect to hollow rigid body 11 by a co-moulding technique. In order to assist the biocompatible material of stent 29,

for example silicone rubber, to anchor on the structural material of hollow rigid body 11, the latter is provided with anchoring pockets 31 (Figs. 10A-10C), preferably also with holes 31' to cause the biocompatible material of stent 29 to flow into in anchoring pockets 31.

In alternative, in an exemplary embodiment, the structure 180 of Figs. 18A-18B comprises a stent 45 that has retractable shape memory longitudinal elements 46,49, which, in an extended configuration, allow the structure 180 to be introduced into urethral-bladder lumen 2 (Fig. 18A), and after the introduction recover their own original retracted shape, thus a steady coupling with inner walls 3 of urethral-bladder lumen 2 (Fig. 18B). Retractable elements 46, which are frontally arranged according to the insertion direction of structure 180 into the urethral-bladder lumen, preferably have their own end connected to a collection cuff 47.

As shown in Figs. 15 and 16A-16B, in an exemplary embodiment, the engagement means of a structure 160 may comprise fastening means 32 including fastening teeth 33 that are configured for engaging with inner walls 3 of urethral-bladder lumen 2 (Fig. 1). For instance, these fastening means may comprise a plurality of longitudinal elements 32 externally arranged along hollow rigid body 11, with fastening teeth 33 that protrude in a substantially radial direction with respect to hollow rigid body 11.

Fastening means 32 may be shape memory means, which turns from an introduction configuration (Fig. 16A) to an implant configuration (Fig. 16B) during the implant.

Hollow rigid body 11, as well as engagement means 12,28,29,32,33,45, may be made of any biocompatible material, such as Teflon, titanium, PVC or polyurethane, since it comes directly into contact with the tissues of inner wall 3 of urethral-bladder lumen 2.

Still with reference to Fig. 1, the structure of artificial endo-urethral sphincter 100 has a valve apparatus 10 that is arranged within hollow rigid body 11 comprising a valve element 13,36 that is housed within longitudinal channel 11', shown more in detail in Figs. 2A-2F and 9-18. Valve apparatus 10 also comprises a closure means for causing valve element 13,36 to turn from a closed configuration, in which valve element 13,36 prevents urine 99, which is contained within bladder 5 of patient 1, from flowing through longitudinal

channel 11', to an open configuration, in which urine 99 can flow through it, and vice-versa;

Figs. 2A-2F and 9-18 refer to exemplary embodiments according to a first aspect of the invention, in which valve apparatus 9 of the structure of endo-urethral sphincter 110,120,130,140,150,160,170,180 comprises a safety element 23,16 arranged within longitudinal channel 11' downstream of valve element 13,36. Safety element 23,16 comprises a block means that is structured to turn from a block configuration, in which it is configured for preventing an unwanted flow of urine 99 through valve element 13,36, to a release configuration, in which the safety element is configured for enabling a free flow of urine 99 that has flown through valve element 13,36.

A structure of artificial sphincter according to the invention may comprise two valve elements 13,23 or 16,23 serially arranged to each other in same hollow rigid body 11 or, according to an exemplary embodiment, not shown, in distinct rigid hollow bodies. Upstream valve element 13,36 is then a main valve element, or of control, whereas downstream valve element 23 is a safety valve element.

In particular, Figs. 2A-2F show a structure 110 in which the two valve elements are resilient deformable valve elements 13,23, each configured for turning from a closed configuration to an open configuration when the pressure of urine 99 exceeds a respective opening value, typically by an action of patient 1, such as an increase of the abdominal pressure. This opening value is indicated as the opening or release pressure of main valve element 13 and of safety valve element 23, respectively.

For example, valve elements 13,23 may be of the type shown in Figs. 3A-3C, in which resilient valve element 13,23 comprises a shell portion 34 and an engagement portion 35 for engaging with hollow rigid body 11. In particular, shell 34 has a cap, i.e. a convex portion 20 which may be substantially hemispherical or have the shape of a spherical sector. Shell 34 has at least one through slit 18, in particular a plurality of through slits 18 are made that converge towards a same portion of shell 34, preferably a top portion of cap 20.

In a version of structure 110, the release pressure of main valve element 23 is higher than the opening pressure of safety valve element 13.

In another version of structure 110, the release pressure of main valve element 23 is lower than the opening pressure of safety valve element 13.

Figs. 2D-2F show the operation of structure 110. Fig. 2D shows a rest condition of structure 110 in which the pressure of urine 99 is lower than the opening pressure of main valve element 13, and both valve elements 13,23 are in the closed configuration. Fig. 2E shows a condition in which valve elements 13 and 23 are in the open configuration and in the block configuration, respectively, the first under the action of the pressure of urine 99, which is higher than the opening pressure of main valve element 13 but is lower than the release pressure of safety valve element 23. Fig. 2F shows a condition in which both valve elements 13 and 23 are open, i.e. they are in the open configuration and in the release configuration, respectively, under the action of the pressure of urine 99, which is higher than both the opening pressure of valve element 13 and the release pressure of valve element 23.

The condition of Fig. 2E may take place in an initial step when normally using structure 110 to expel urine 99 from bladder 5, in which the pressure of urine 99 is progressively raised until it exceeds the opening pressure of the main valve element and then exceeds the release pressure of safety valve element 13, thus attaining the condition of Fig. 2F.

However, the condition of Fig. 2E make take place in the case of a sudden action of patient 1, such as a cough, or any efforts such as when lifting weights, which causes the urine pressure to exceed the opening pressure of main valve element 13 but not the exceeding the release pressure of safety element 23, so that valve element 23 remains in the block condition and prevents any unwanted outflow of urine through urethral-bladder lumen 2.

Still with reference to Fig. 2D and 2E, in the undeformed configuration shell portion 34 of valve element 13,23 has a convex portion in use oriented towards bladder 5. This way, urine 99 normally exerts a pressure on shell portion 34 that keeps slits 18 closed. By increasing the pressure of urine 18 the opening or release value, a critical stress condition of shell 34 is exceeded, beyond which the shell collapses and takes the deformed configuration of Fig. 2E, for upper valve element 13, and of Fig. 2F for both valve elements. In the deformed configuration, shell 34 has a convexity opposite with respect to the undeformed configuration, and slits 18 have their respective wings 18' spaced

apart from one another, thus creating an opening in the shell 34. This opening allows urine 99 to massively flow through valve element 13,23.

Figs. 4A-8D show alternative embodiments of the resiliently deformable valve element 13,23. In particular, Figs. 4A,4B show a low curvature shell 43 that is provided with through slits 18 converging towards a central zone of the shell. Figs. 5A-5C show a shell 53 that has a convex cap portion 20', comprising opposite concavity portions 20",20"', as an alternative to spherical cap 20 of Figs. 3A-C, which also has through slits 18. As shown in Figs. 6A-6B and 7A-7C, in other exemplary embodiments, a shell 63,73 may have a suitably reamed hole 19, preferably made at the centre of the shell. Even in this case, the shell, in its undeformed configuration, may have a low curvature, like shell 63 of Figs. 6A-6B, or may have a cap portion 20', like shell 73 of Figs. 7A-7C. Figs. 8A-8D show a substantially ellipsoidal shell 83 that has a through slit 18 preferably at the peak of a cap portion 25 and/or oriented according to an axis of its elliptical cross section.

Shells 33,34,43,53,63,73 of Figs. 3A-8D are configured for resiliently collapse due to the absence of a stiff constraint member in their own central parts. This allows a quick deformation when the pressure of urine 99 on it passes the opening/releasing value, and allows, furthermore, a ready back stroke in the undeformed configuration when the pressure of urine 99 decreases below a corresponding closure/block value which, in particular, is lower than or the same as the opening/releasing value.

The ultimate opening pressure of resiliently deformable valve element 13,23 can be predetermined according to the shell stiffness and then flexural stiffness in the open configuration of shell 33,34,43,53,63,73,83. The stiffness, i.e. the resistance against the deformation, can be predetermined by choosing a predetermined thickness or thickness profile (for example, Fig. 7C), and/or by choosing a material that has predetermined elastic features, and/or by choosing other geometric features of the shell portion, for example the presence, the number, the size and the arrangement of slits 18, the presence and the shape of convex portion 20,20',25, of suitably reamed hole 19, in particular central of a central hole (Figs. 3A-8D).

The resiliently deformable valve element 13,23 comprises a stiff engagement portion 35 to engage with hollow rigid body 11, which may have

form of a thick ring 35. In this case, hollow rigid body 11 has a circumferential inner groove 35' (Figs. 2A,2C) that serves as a housing for the engagement portion 35, in order to form a fluid-tight coupling. This allows a steady connection of valve element 13,23 with hollow rigid body 11, while allowing an opening/closing resilient deformation. Valve element 13,23, in particular its engagement portion 35, may be made of a resilient polymeric material such as polyurethane or silicone rubber, or may be made of a metal such as steel, Nitinol, titanium, or may be made of a different type of material, such as turbostratic carbon or graphite.

The shell portion, which is steadily mounted to the hollow rigid body by its own boundary portion, contributes specifically to the fluid-tightness of the sphincter. In a rest position, the shell portion is firmly closed, but it is opened once it has been deformed by increasing the urine pressure, under an arbitrary action of the patient. For instance, the shell portion can be opened by increasing the abdominal pressure.

The hollow rigid body is used to provide a dimensional stability to the structure as well as an internal fluid tightness. This requires a precise fluid-tight coupling between the hollow rigid body and the valve element or apparatus, along with a precise outer coupling between the hollow rigid body and the urethral-bladder lumen, in order to firmly engage with the latter.

In other exemplary embodiments, the main valve and safety valve elements may be of various types. For instance, Figs. 13-14B show a structure 150 in which a valve apparatus 200 comprises a valve element 36 slidingly arranged within the longitudinal recess of the hollow rigid body or body-valve 11 and, downstream of it, a safety valve element 23 provided with shell-shaped resilient walls. For instance, safety valve element 23 may be one of the valve elements of Figs. 3A-8D.

Main valve element 36 comprises a preferably frustoconical plug stopper member 37, movable between a closed position (Figs. 13,15A), at which plug stopper member 37 is arranged to create a seal in a seat 38 integral to body-valve 11, and an open position (Fig. 14B), at which stopper member 37 is at a distance from seat 38, so that a hydraulic continuity is restored in passageway 11'. A preferably cylindrical stem 39 extends from stopper member 37 and is slidingly arranged in a hole 40 of a guide element 41 integral to body-valve 11,

which may be releasably arranged within a housing 41' formed inside body-valve 11.

A resilient return element, for example a return spring 44, is advantageously provided that can be arranged about stem 39 of main valve element 36. In this case, spring 44 has a first end that biases a protruding element of body-valve 11, for example a surface of guide element 41, and a second end that biases plug stopper member 37. Therefore, in absence of external actions, stopper member 37 is normally located in the closed position of Fig. 13 or 14A.

Valve apparatus 200 may comprise a magnetically sensitive element 15 that is integral to plug stopper member 37 and is arranged with a predetermined polarization direction, for instance according to the direction of longitudinal channel 11', and an (electro)magnetic element 17 may also be provided outside of the body of the patient. Magnetically sensitive element 15 can be made of a ferromagnetic or permanently magnetic material. It may be arranged at the second end of stem 39, preferably at the same side of the latter with respect to guide element 41.

By arranging (electro)magnetic element 17 with a same polarity as magnet 15, it is possible to move plug stopper member 37 from the closed position (Fig. 14A) back to the open position (Fig. 14B), which allows the flow of urine 99 through main valve element 36.

By physiologically increasing the pressure of the urine, shall 34 can be collapsed and therefore safety valve element 23 can be opened and the urine 99 is allowed to flow out of bladder 5 (Fig. 1).

Safety valve element 23 prevents leakage of urine if main valve element 36 is accidentally actuated, which may occur, for instance, if the patient is in a magnetic field adapted to move main valve element 36.

Safety valve element 23 also allows preventing urine leakage in case of a faulty seal of main valve element 36, which may occur, for instance, if the sphincter has been being used for a long time.

With reference to Figs. 11A-11E, a valve apparatus of a structure of artificial endo-urethral sphincter 140 comprises a resiliently deformable valve element 13, for example like in Figs. 3A-8D, and a safety element 16 that is movable within longitudinal channel 11'. Safety element 16 may have the

shape of a safety slider 16 movably arranged between a block position (Fig. 11A) and a release position (Fig. 11B). In the block position (Fig. 11A), safety slider 16 abuts against the face normally concave of shell 34 of valve element 13, i.e. against the face of shell 13 which, in use, is oriented opposite to bladder 5. In this position, slider 16 prevents valve element 13 from leaving the closed configuration. In the release position (Fig. 11B) slider 16 is located at a prefixed distance from valve element 13, such that shell 34 is free to deform under the action of the pressure of urine 99, if this exceeds the opening pressure, then valve element 13 can leave the closed configuration and have the open configuration.

Valve apparatus 140 may also comprise a resilient return element 14 such as a return spring 14 that resists the movement of safety slider 16 from the block position (Fig. 11A) to the release position (Fig. 11B), so that safety slider 16, without any action from outside, is kept/brought in the block position of Fig. 11A. In the depicted shape, return spring 14 is wound about a preferably cylindrical portion of safety slider 16 and abuts, in the upper side, against a protruding portion 23' of safety slider 16 and, in the upper side, against an abutment portion 26 of hollow rigid body 71, that has an inner annular side 72 for housing spring 14 and slider 16.

Safety slider 16 may have the shape shown in Figs. 12A-12B, which comprises a stem 21, a head 22 and an enlarged intermediate portion 23, and the three portions 21,22,23 have advantageously a substantially cylindrical shape. Head 22 is configured for engaging with shell portion 34 in the block position, provides a portion for winding spring 14 and the protruding face ring 23' of enlarged portion 23, which is oriented towards stem 21, provides the protruding portion against which abutment return spring 14 abuts. Advantageously, safety slider 16 comprises an inner passageway 24 between an upper opening 28', made through the portion facing valve element 13, and a lower opening 28", in the picture a side opening, made along stem 21, in order to let urine 99 when valve element 13 is in the open configuration under the pressure of urine 99 (Fig. 11B).

Hollow rigid body 71 may also comprise an annular ring surface 27 (Fig. 11C) of abutment for safety slider 16, with which enlarged portion 23 of slider 16 can abut when the safety slider is in the safety position.

Valve apparatus 140 may comprise a magnetically sensitive element 15 integral to safety slider 16 and arranged with a predetermined polarization direction, for example according to the direction of longitudinal channel 11', and an (electro)magnetic element 17 may also be provided outside of the body of the patient. Magnetically sensitive element 15 may be a permanent magnet or an element made of a ferromagnetic material. It may be arranged at the second free end 21' of stem 21, preferably on the opposite side with respect to valve element 13.

By arranging (electro)magnetic element 17 with a same polarity as magnet 15, safety slider 16 can be moved from block position (Fig. 11A) back to the release position (Fig. 11B), which allows the flow of urine 99 through main valve element 36.

By physiologically increasing the pressure of the urine, shell 34 can be collapsed and therefore valve element 13 can be opened, which enables urine 99 to flow out from bladder 5 (Fig. 1).

Magnetically sensitive ring 15 may be housed within a recess 74 of hollow rigid body 71 in which at least one upper end-stroke abutment surface 74',74" is preferably provided (Figs. 11A-11B).

In another exemplary embodiment, not shown, a valve apparatus comprises a deformable safety slider that is configured for radially collapsing under the action of a magnetic coupling transversal with respect to the axis of the valve apparatus, and also configured for resiliently recovering its own undeformed configuration, by removing the magnetic coupling, at which the safety slider keeps shell portion 34 in the undeformed configuration and, accordingly, valve element 13 remains closed.

Safety valve element 23 prevents urine leakage if valve element 13 accidentally opens, which may occur, for instance, in the case of a sudden action by patient 1, such as a cough, or any effort like when lifting weights, which may cause the pressure of urine 99 to exceed the opening pressure of valve element 13.

With reference to Figs. 19A-23D, structures 50,60,70,80,90 of urethral-bladder endo-urethral sphincter are described according to a second aspect of the invention, in which the valve elements comprise a movable valve stopper member that has at least one magnetically sensitive portion. These valve

elements may be advantageously used in structures, not shown, like structure 150 of Fig. 14A-B, instead of slidable valve element 36;

Figs. 19A-20D show structures 50,60, in which a valve element is provided that comprises a rotatable valve stopper member 51,61 within hollow rigid body or body-valve 11.

For instance, valve stopper member 51 may have an axisymmetric shape, in particular it is a ball stopper member (Figs. 19A-19D). Its rotation axis 52 may be arranged transverse and incident to the longitudinal axis 11" of body-valve 11. Valve stopper member 51 has a through hole 54 that can be oriented by rotating valve stopper member 51 between a closed position (Fig. 19A), in which through hole 54 is arranged transversally with respect to longitudinal channel 11' to provide a seal along longitudinal channel 11', and an open position (Fig. 19B), in which hole 54 is aligned with longitudinal channel 11', such that a passageway is formed that restores the continuity of longitudinal channel 11'.

In alternative, (Figs. 20A-20D), valve stopper member 61, which is preferably made of a metal, such as steel, or of a polymeric material such as Teflon or PVC, may be a clapet stopper member, which is pivotally connected to an inner wall of body-valve 11, for example by a hinge, as shown. Clapet stopper member 61 may also be manufactured as a flexible portion, not shown, of a same workpiece which also comprises body-valve 11. Body-valve 11 comprises a seal seat 65 configured for receiving a peripheral portion 64 of valve stopper member 61. Valve stopper member 61 can rotate between a closed position (Fig. 20C), in blocks longitudinal channel 11', and an open position (Fig. 20D), in which peripheral portion 64 is located at a distance from support seal seat 65, thus restoring the continuity of longitudinal channel 11';

Figs. 21A-21B show a structure 70 in which a gate valve element is provided that comprises a seal seat 55 integral to body-valve 11, and a valve stopper member 56 slidably arranged with body-valve 11. Seat 55 and valve stopper member 56 have respective inner recesses 84',84" that are manufactured in such a way that, when valve stopper member 56 is in the closed position (Fig. 21A), recesses 84',84" are plugged by an opposite solid portion of valve stopper member 56 and of fixed portion 55, respectively, which forms a seal along longitudinal channel 11'. On the contrary, when valve

stopper member 56 is in the open position (Fig. 21B) away from fixed portion 55, a flow section 85 is formed between recesses 84' and 84", which restores the continuity of longitudinal channel 11'.

Figs. 22A-22C show a structure 80 in which a gate valve element is provided that comprises a seal seat 65 integral to body-valve 11 and a valve stopper member 66, which have respective seal surfaces 65',66'. Valve stopper member 66 can slide transversally with respect to the axis of longitudinal channel 11' between a closed position (Fig. 22A), in which seal surfaces 65',66' are in contact with each other, which forms a seal along longitudinal channel 11', and an open position (Fig. 22B), in which seal surfaces 65',66' are at a distance forma each other, such that a passageway 85 is formed that restores the continuity of longitudinal channel 11'.

Figs. 23A-23D show a structure 90 in which a valve element is provided that comprises a spiral-shaped stopper member 88 that is movably arranged in body-valve 11 between a compressed position (Figs. 23A,23C), in which said valve stopper member forms a seal along longitudinal channel 11', and an extended position (Figs. 23B,23D) in which coils 89 of spiral-shaped stopper member 88 are reciprocally arranged to form passageways among one another, which restores the continuity of longitudinal channel 11'. In particular, spiral-shaped stopper member 88 has an upper central part that is fastened to body-valve 11, and an external lower part that is connected to magnetic element 17.

Preferably, a return elastic element, not shown, is associated with valve stopper member 51,61,56,66,88, for recalling/keeping the stopper member in the closed position (Figs. 19A,20C,21A,22A,23A), so that the valve element is normally in its closed position. In the case of valve element 90, this recall operation only depends upon the tendency of valve stopper member 88 to maintaining/resiliently going back to its disc configuration (Fig. 23A,23C), however a further return elastic element may be provided.

Valve stopper member 51,61,56,66,88 has at least one portion 15 made of a magnetically sensitive material, for example a permanently magnetic material or a ferromagnetic material. For instance, portion 15 can be a flat element arranged on clapet stopper member 61 or on the spiral-shaped stopper member, or a half-ring element radially or longitudinally arranged on

gate stopper member 70,80, respectively. In alternative, the rotatable valve stopper member is integrally made of a magnetically sensitive material. This way, (Figs. 20D,21B,22B,23B) by suitably arranging an (electro)magnetic element 17 (Figs. 20E,21C,22D,23E) outside of the patient's body with respect to magnetically sensitive portion 15, in particular with the same polarization direction as magnetically sensitive portion 15, valve stopper member 51,61,56,66,88 is brought to its open position, by exceeding the return force or torque of a possible return resilient element, or due to the intrinsic elasticity of valve stopper member, in particular, 88.

Obviously, even if engagement means 12,28,29,32,33,45 are always shown with reference to a structure of sphincter equipped with both resiliently deformable main and safety valve elements 13,23 (Fig. 2A), any type of engagement means can be used in other exemplary embodiments of the structure, such as the embodiments shown in Fig. 11A and 13.

Moreover, a valve element of any type described with reference to the second aspect of the invention (Figs. 19A-23D) can be used instead of plug stopper member 37, in a structure that also comprises a downstream safety element, typically a resiliently deformable safety valve element 23 like in Fig. 13.

The foregoing description exemplary specific embodiments will so fully reveal the invention according to the conceptual point of view, so that others, by applying current knowledge, will be able to modify and/or adapt in various applications such exemplary embodiments without further research and without parting from the invention, and, accordingly, it is meant that such adaptations and modifications will have to be considered as equivalent to an exemplary embodiments exemplified. The means and the materials to realise the different functions described herein could have a different nature without, for this reason, departing from the field of the invention. It is to be understood that the phraseology or terminology that is employed herein is for the purpose of description and not of limitation.

CLAIMS

1. A structure (110,120,130,140,150,160,170,180) of artificial endo-urethral sphincter comprising:
   - at least one hollow rigid body (11,71), configured for being fixed within the walls (3) of a urethral-bladder lumen (2) of a patient (1), in particular for being fixed within the urethral walls, said hollow rigid body (11,71) defining a longitudinal channel (11') arranged to convey urine from an upstream section towards a downstream section;
   - a valve element (13,36) housed within said longitudinal channel (11');
   - a closure means for causing said valve element (13,36) to turn from a closed configuration, in which said urine (99) cannot flow through said longitudinal channel (11'), to an open configuration, in which said urine (99) can flow through said longitudinal channel (11'), and vice-versa,

   **characterised in that it comprises** a safety element (23,16) that is arranged within said longitudinal channel (11') of said hollow rigid body (11,71) downstream of said valve element (13,36),
   wherein said safety element (23,16) comprises a block means structured for turning from a block configuration to a release configuration,
   wherein said safety element (23,16) is configured, in said block configuration, for preventing an unwanted flow of urine (99) through said valve element (13,36),
   and wherein said safety element is configured, in said release configuration, for enabling a free flow of urine (99) that has flown through said valve element (13,36).

2. A structure (110,120,130,150,160,170,180) according to claim 1, wherein said safety element comprises a safety valve element (23) serially arranged downstream of said valve element (13,36).

3. A structure (110,120,130,140,150,160,170,180) according to claim 1, wherein said closure means of said valve element (13) comprises resilient walls that, in said closed configuration, are at a rest condition and, in said open configuration, are configured for being deformed due to an

abdominal pressure increase caused by said patient (1), up to a predetermined opening pressure of said valve element (13).

**4.** A structure (110,120,130,150,160,170,180) according to claim 2, wherein said block means of said safety valve element (23) comprises resilient walls that, in said block configuration, are at a rest condition and, in said release configuration, are configured for being deformed due to an abdominal pressure increase caused by said patient (1), up to a predetermined release pressure of said safety valve element (23).

**5.** A structure according to claims 3 and 4, wherein said release pressure of said safety valve element (23) is lower than said opening pressure of said valve element (13).

**6.** A structure according to claims 3 and 4, wherein said release pressure of said safety valve element (23) is higher than said opening pressure of said valve element (13).

**7.** A structure according to claims 3 and 4, wherein said valve element (13) has a opening pressure that is higher than the opening pressure of the safety valve element (23), such that a portion of said longitudinal channel (11') defined between two valve elements (13,23) is cleared of said urine, once said urine (99) has been evacuated.

**8.** A structure (110,120,130,140,150,160,170,180) according to claim 3 or 4, wherein said resilient walls comprise a shell portion (34,43,53,63,73,83) that has at least one through slit (18,19), wherein:

- in said closed or block configuration, said shell portion (34,43,53,63,73,83) has a convex shape on the bladder side forming a diaphragm, such that a urine pressure acting upon said shell portion (34,43,53,63,73,83) keeps said through slit (18,19) closed;
- in said open or release configuration, said shell portion (34,43,53,63,73,83) has a concave shape opposite to said convex shape, wherein said through slit (18,19) is deformed and open, and is configured for enabling a flow of urine (99),

in said convex shape, said shell portion (34,43,53,63,73,83) configured for bearing said urine pressure (99) up to an ultimate pressure selected

between said release pressure and said opening pressure such that, upon exceeding said ultimate pressure, said shell portion (34,43,53,63,73,83) collapses into said concave shape, and enables a passage of urine (99) through said through slit (18,19).

**9.** A structure (110,120,130,150,160,170,180) according to claim 8, wherein said shell portion (34,43,53,63,73,83) has a cap shape (20,20',25) that has a plurality of converging slits (18,19), in particular said slits converging to a central point of said cap shape.

**10.** A structure (140) according to claim 3, wherein said safety element comprises an abutment member (16) that, in said block configuration of said safety element (16), is structured for preventing said valve element (13) from turning from said closed configuration to said open configuration and, in said release configuration, is structured for moving away from said valve element (13) and enables the latter to open.

**11.** A structure (140) according to claim 10, wherein said safety element (16) comprises a return elastic element (14), in particular a spring (14), configured for firmly keeping said safety element (16) in said block configuration.

**12.** A structure (140) according to claim 10, wherein said safety element (16) comprises a magnetically sensitive element (15) at an own end (21,21') opposite to said shell portion (34), said magnetically sensitive element configured such that, by arranging an external magnetic or electromagnetic element (17) with a same polarity as said magnetically sensitive element (15), a magnetic coupling is formed between said external magnetic or electromagnetic element (17) and said magnetically sensitive element (15), and said safety element (16) turns to said release configuration.

**13.** A structure (150) according to claim 1, wherein

- said valve element (36) is longitudinally slidingly arranged within said longitudinal channel (11'),
- said safety element (23) comprises a shell portion (34,43,53,63,73,83).

**14.** A structure (150) according to claim 13, wherein said valve element (36) comprises:

- a plug stopper member (37) movably arranged between a block position at a seal seat (38) of said longitudinal channel (11') and a release position where said plug stopper member (37) is at a distance from said seal seat (38), such that a hydraulic continuity is formed between said urethral-bladder lumen (2) and said valve element (13),
- a return elastic element (44) associated with said stopper member and arranged to normally keep said plug stopper member (37) in said closed configuration;
- a magnetically sensitive element (15) configured such that, by positioning an external magnetic or electromagnetic element (17) at a position outside of said patient with a same polarity as said magnetically sensitive element (15), a magnetic coupling is formed between said external magnetic or electromagnetic element (17) and said magnetically sensitive element (15) and said valve element (36) can be recalled from said closed configuration to said open configuration.

**15.** A structure (150) according to claim 1, wherein said valve element comprises a valve stopper member (51,56,61,66,88) that has at least one magnetically sensitive element (15) configured such that, by arranging an external magnetic or electromagnetic element (17) with a same polarity as said magnetically sensitive element (15), a magnetic coupling is formed between said external magnetic or electromagnetic element (17) and said magnetically sensitive element (15), and said valve element (16) turns to said open configuration.

**16.** A structure (50,80,70,80,90) of artificial endo-urethral sphincter comprising:

- at least one hollow rigid body (11), configured for being fixed within the walls (3) of a urethral-bladder lumen (2) of a patient (1), in particular for being fixed within the urethra walls, said hollow rigid body (11) having a longitudinal channel (11') arranged to convey urine from an upstream section towards a downstream section;
- a valve element housed within said longitudinal channel (11');

– a closure means for causing pass said valve element from a closed configuration, in which a fluid (99) cannot flow through said longitudinal channel (11') to an open configuration, in which said urine (99) can flow through said longitudinal channel (11'), and vice-versa,

**characterised in that** said valve element comprises a valve stopper member (51,56,61,66,88) that has at least one magnetically sensitive element (15) configured such that, by arranging an external magnetic or electromagnetic element (17) with a same polarity as said magnetically sensitive element (15), a magnetic coupling is formed between said external magnetic or electromagnetic element (17) and said magnetically sensitive element (15), and said valve element (16) turns to said open configuration.

**17.** A structure (50,60,70,80,90) according to claim 15 or 16, wherein said valve stopper member (51,56,61,66,88) is selected from the group consisting of:

– a rotatable valve stopper member (51,61) rotatably arranged within said hollow rigid body (11) about a rotation axis (52,62) transversal with respect to said longitudinal channel (11') of said hollow rigid body (11),

said rotatable stopper member (51,61) selected from the group consisting of:

– a valve stopper member having an axisymmetric shape, in particular a ball stopper member (51), that has a through hole (54) and is rotatably arranged between said open configuration, in which said through hole (54) forms a hydraulic continuity with said longitudinal channel (11'), and said closed configuration, in which said ball stopper member (51) blocks said hydraulic continuity;

– a clapet stopper member (61) rotatably arranged between said closed configuration, in which said clapet stopper member fluid-tightly engages with a support seat (65) within said longitudinal channel (11'), and said open configuration, in which

said clapet stopper member (61) is at a distance from said sealing support seat (65), such that a passageway is formed within said longitudinal channel (11');

- a gate stopper member (56,66) slidingly arranged between said closed configuration, in which a surface (57,66') of said gate stopper member (56,66) fluid-tightly engages with a corresponding inner surface (57,65') of said hollow rigid body (11), and said open configuration, in which said surface (57,66') of said plug stopper member (37) is at a distance from said inner surface (57,65') of said hollow rigid body (11), such that a passageway (84'-84",85) is cleared within said longitudinal channel (11');
- a spiral-shaped stopper member (88) comprising coils (89), said spiral-shaped stopper member (88) movably arranged within said longitudinal channel (11') between said closed configuration, in which said coils (89) are longitudinally aligned to form a fluid-tight seal along said longitudinal channel (11'), and said open configuration, in which said coils (89) are reciprocally arranged along a longitudinal unwinding axis in such a way that passageways are formed among said coils (89) and the hydraulic continuity of said longitudinal channel (11') is restored.

**18.** A structure according to claim 16, comprising a safety element (23) arranged within said longitudinal channel (11') of said hollow rigid body (11) downstream of said valve element (13,36),

wherein said safety element (23) comprises a block means structured for turning from a block configuration to a release configuration,

wherein, in said block configuration, said safety element (23) is configured for preventing an unwanted flow of urine (99) through said valve element,

and wherein, in said release configuration, said safety element (23) is configured for enabling a free flow of urine (99) that has flown through said valve element.

**19.** A structure according to claim 16, wherein said movable valve stopper member (51,56,61,66,88) has a return elastic element arranged to constrain the movement of said movable valve stopper member

(51,56,61,66,88) with respect to said hollow rigid body (11), such that, if a magnetic interaction of said magnetically sensitive portion (15) is not present, said movable valve stopper member (51,56,61,66,88) is kept at said closed position.

**20.** A structure (120,130,160,170,180) according to claim 1 or 16, wherein said hollow rigid body (11,71) is associated with a stent (12,29,45) configured to reversibly anchor said structure to said urethral-bladder lumen (2), said stent (12,29,45) selected from the group consisting of:

- a stent (12) comprising a plurality of resiliently radially compliant coils (28);
- a tubular stent (29,45) having shape memory flared (30,46,49) end portions.

Fig. 1

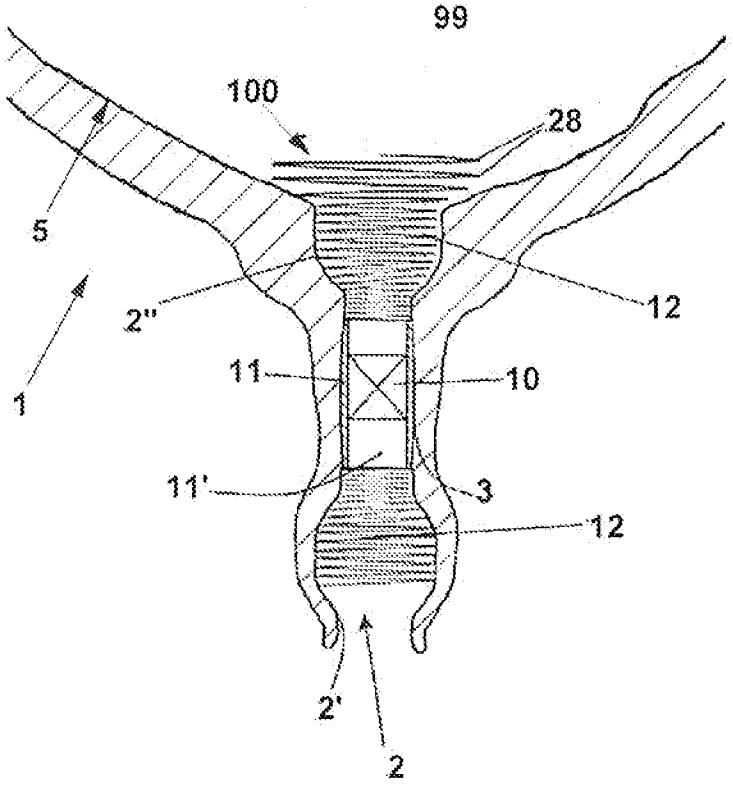



Fig. 2A

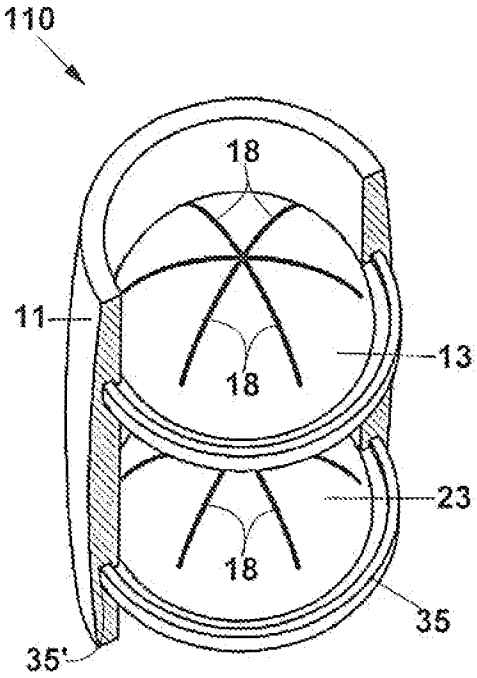



Fig. 2B

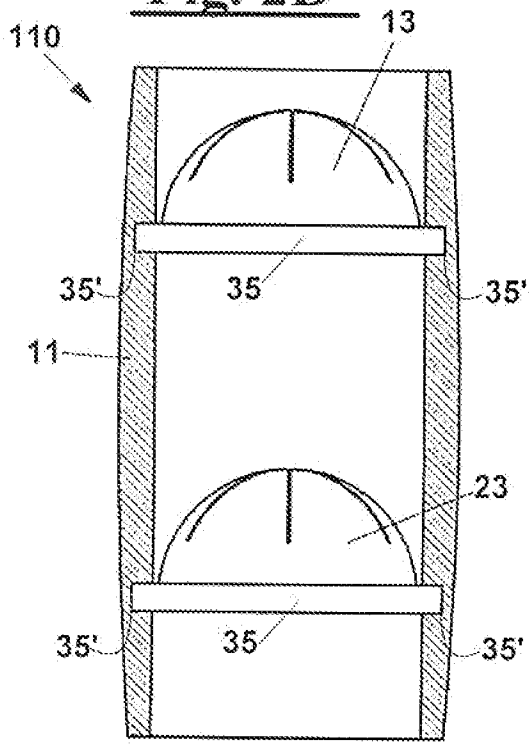



Fig. 2C

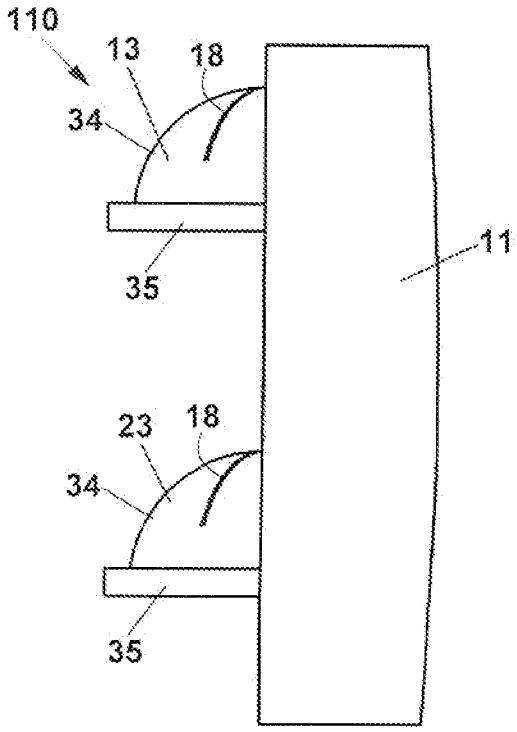


Fig. 2D

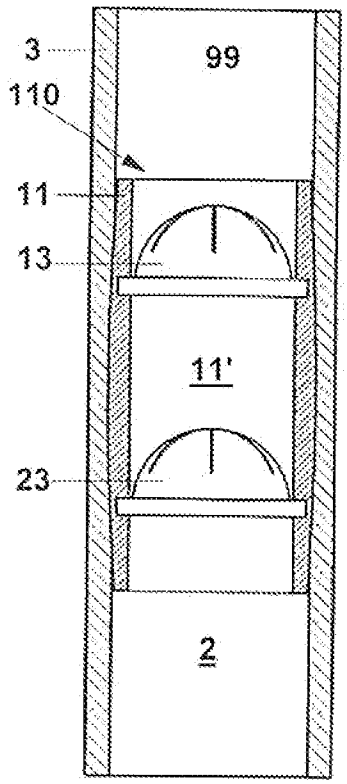



Fig. 2E

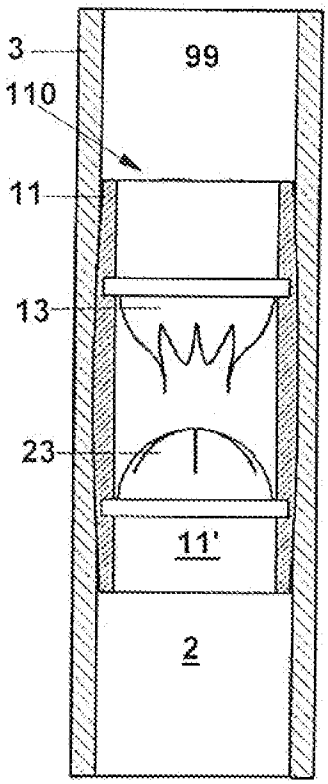



Fig. 2F

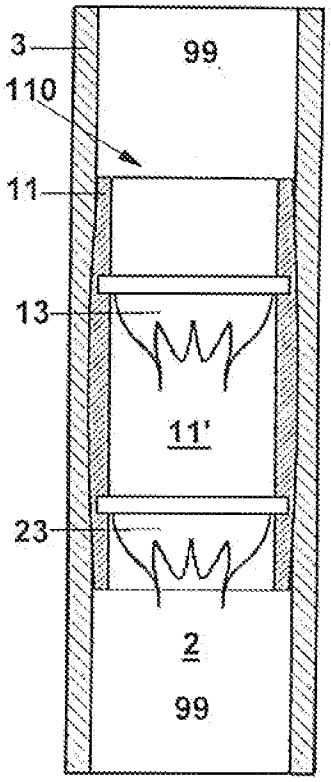
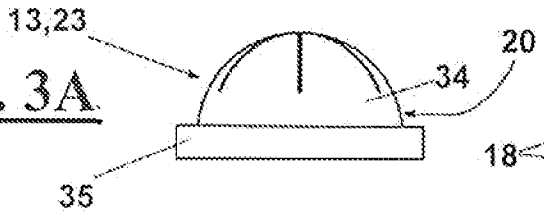



Fig. 3A



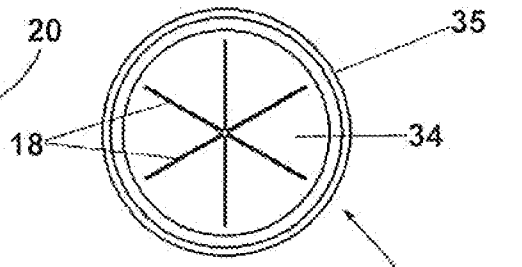
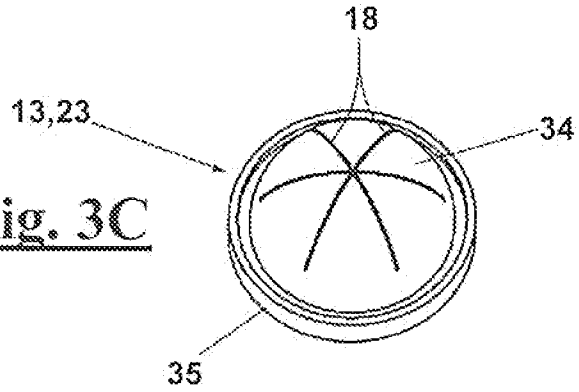




Fig. 3B

Fig. 3C




*Ing. Marco Celestino*
*ABM Agenzia Brevetti & Marchi*
*Iscritto all'albo N.544*

Fig. 4A

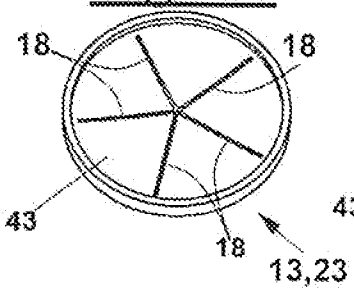



Fig. 4B

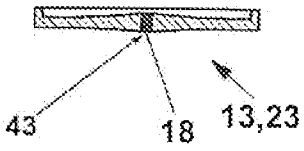



Fig. 6A

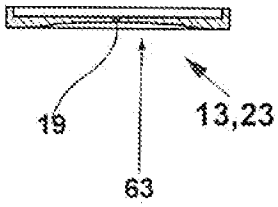



Fig. 6B

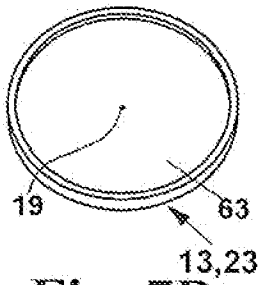



Fig. 5A

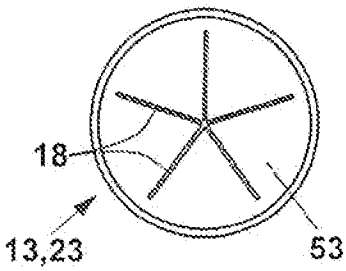



Fig. 5B

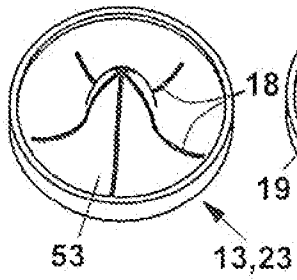



Fig. 7A

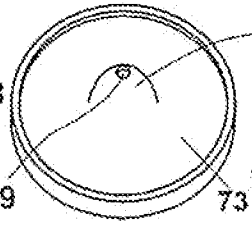



Fig. 7B

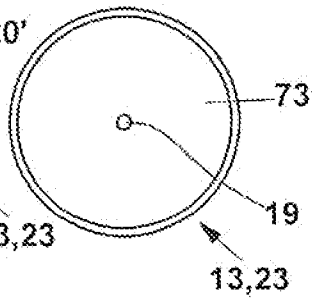



Fig. 5C

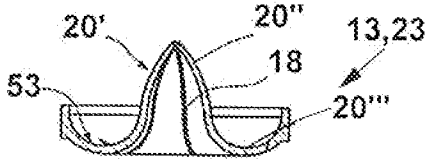



Fig. 7C

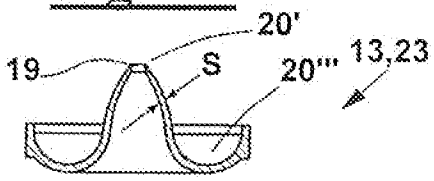



Fig. 9

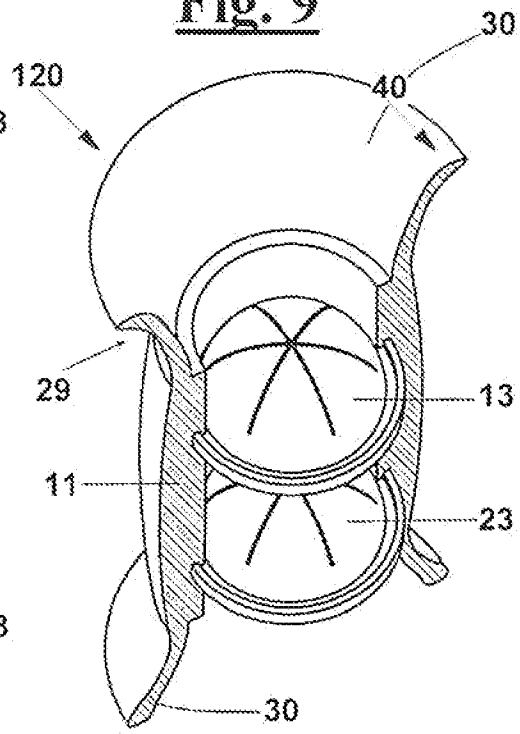



Fig. 8A

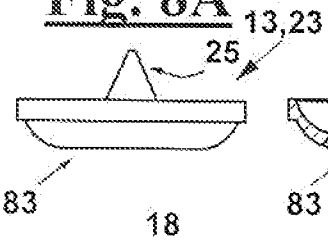
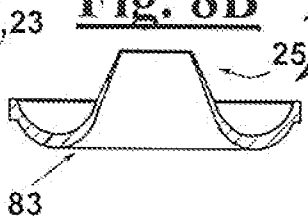



Fig. 8B



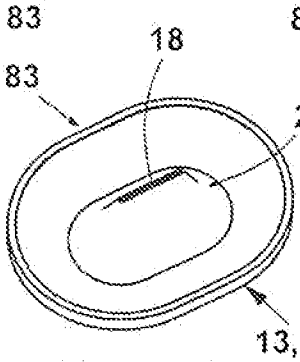




Fig. 8C

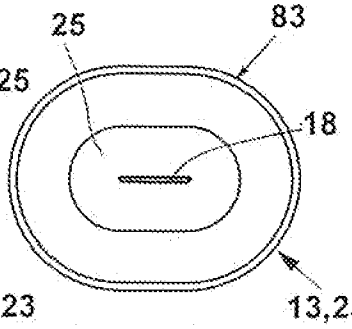



Fig. 8D

Fig. 10A

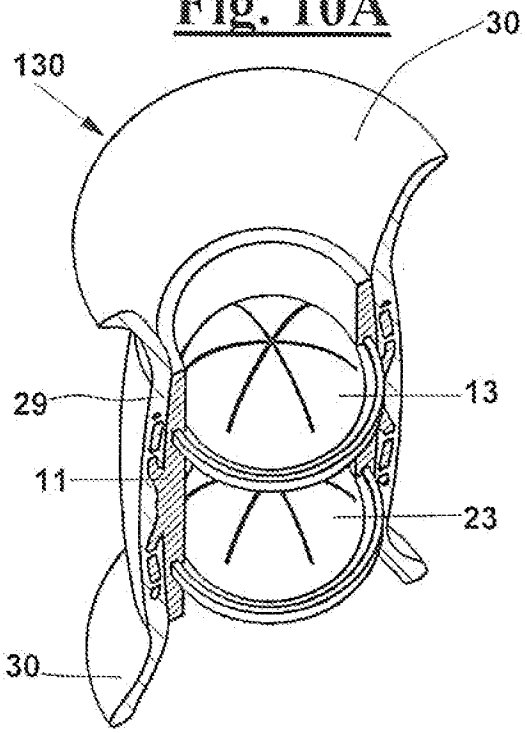



Fig. 10E

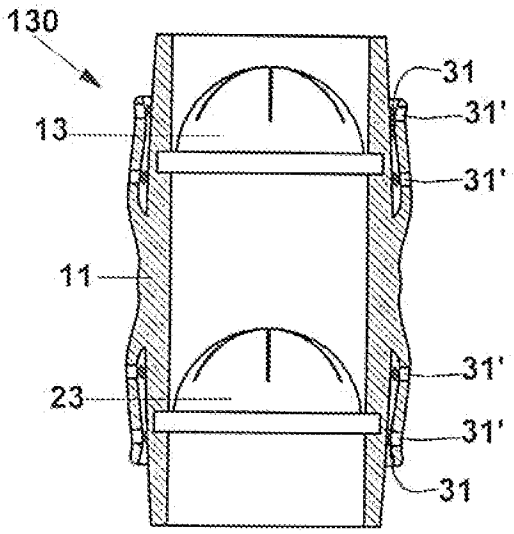



Fig. 10B

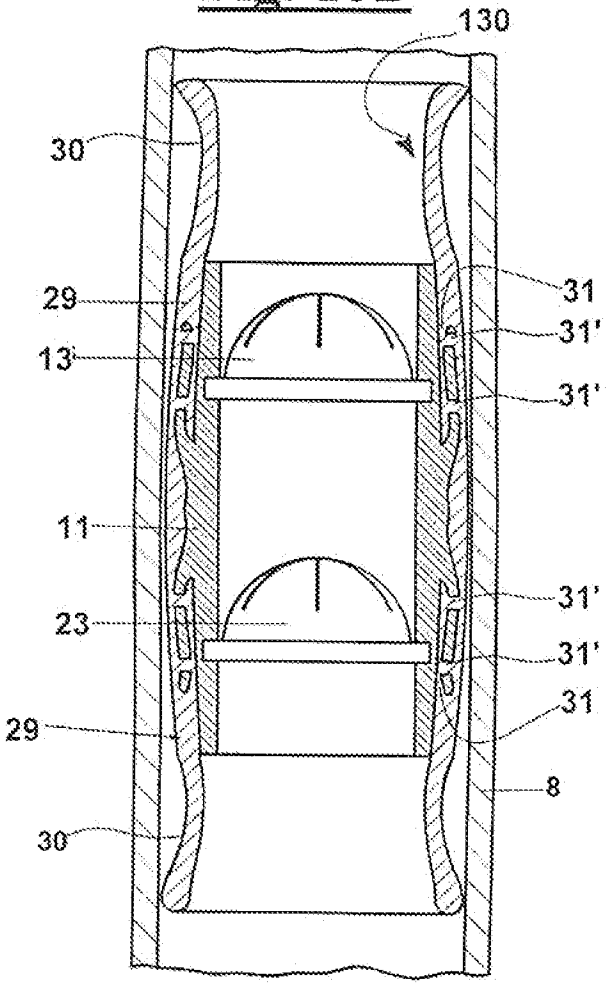



Fig. 10C

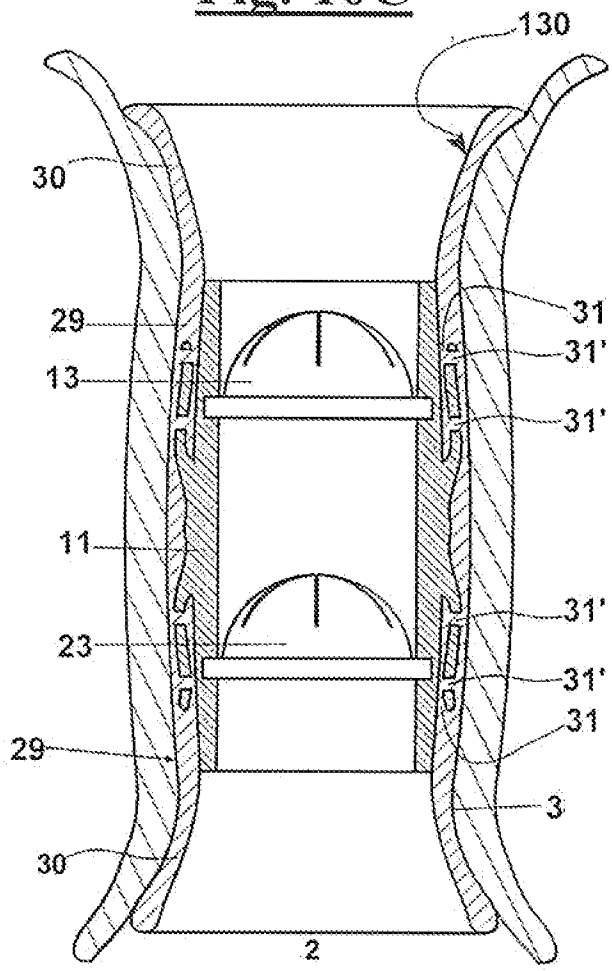


Fig. 11A

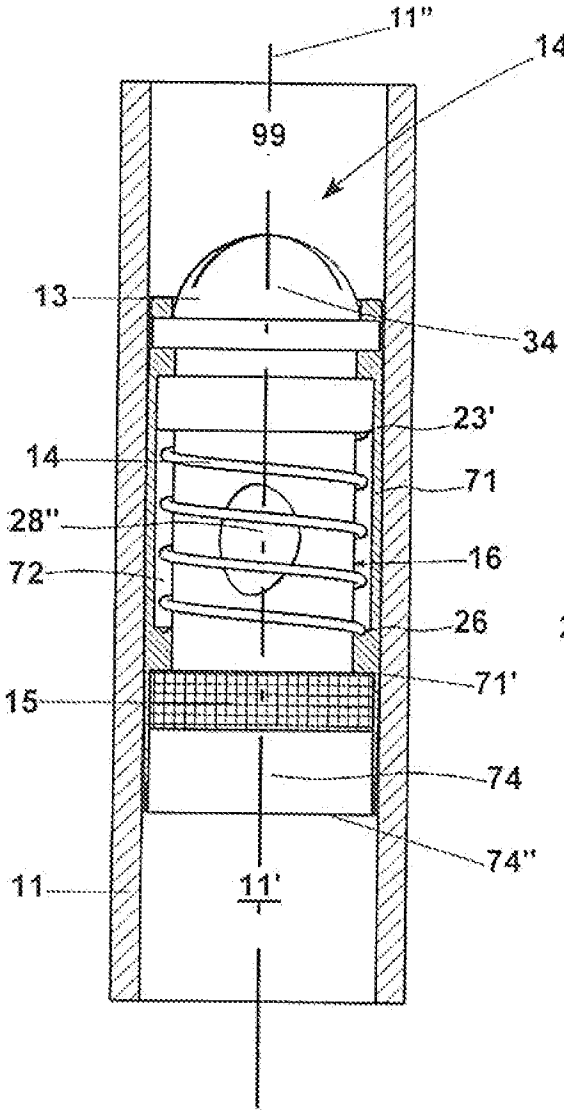



Fig. 11B

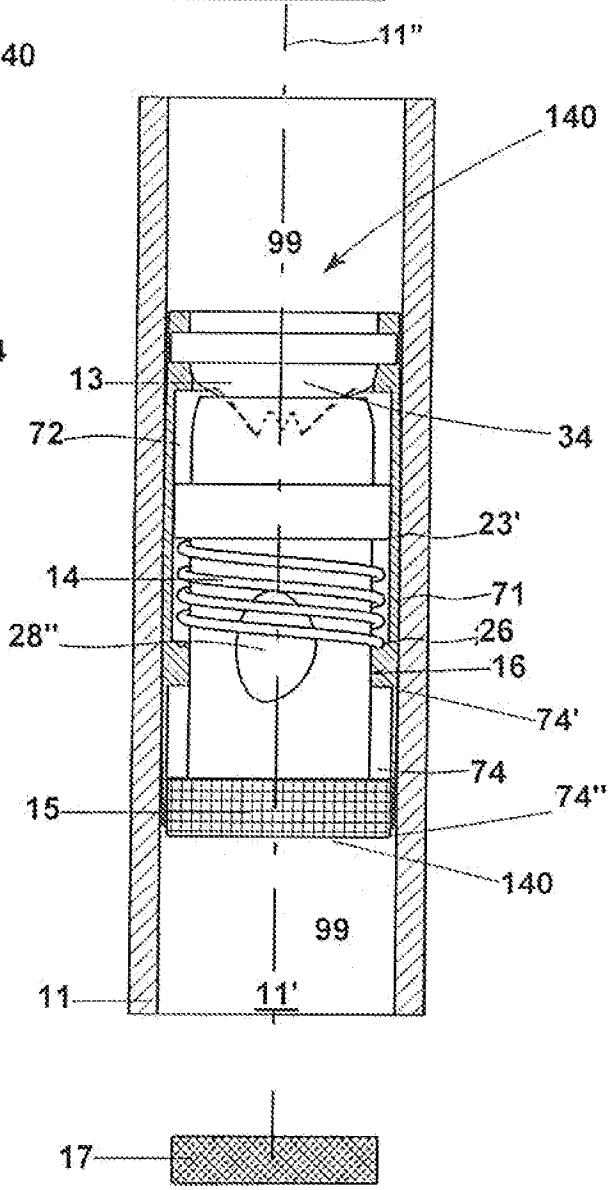



Fig. 10E

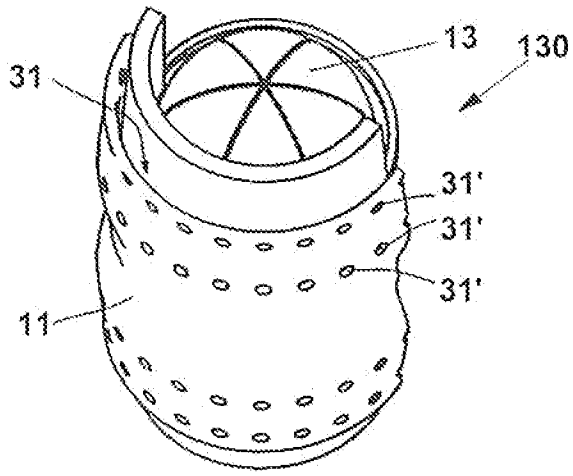






Fig. 11F

Fig. 11C

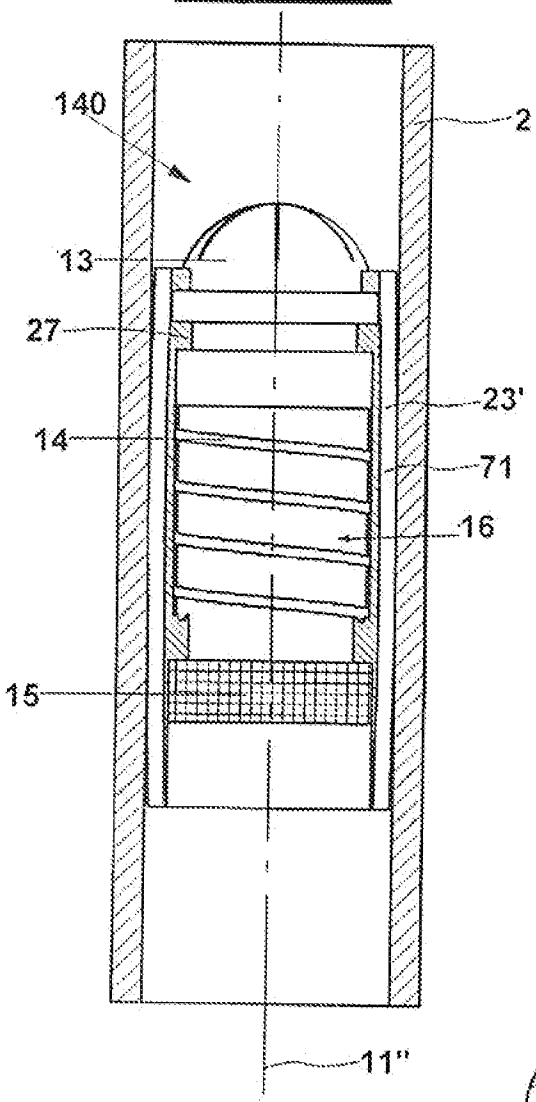
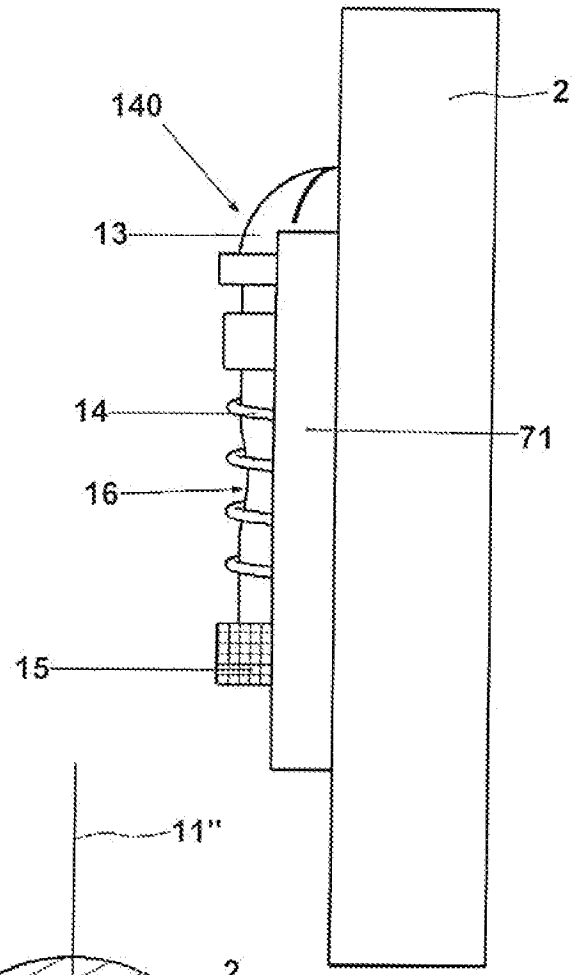



Fig. 11D



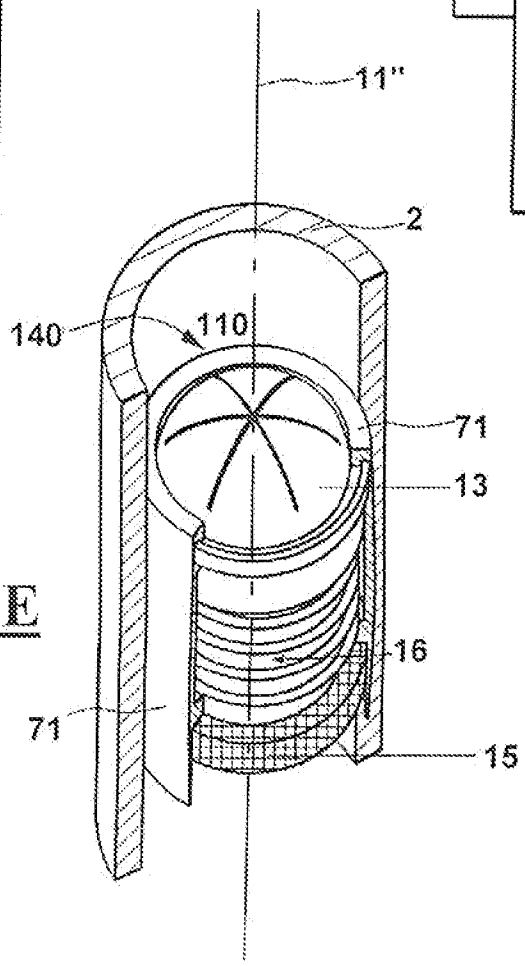




Fig. 11E

Fig. 12A

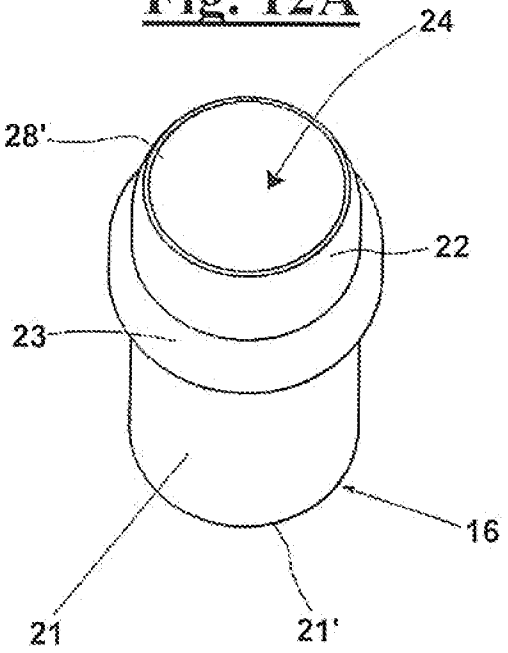



Fig. 12B

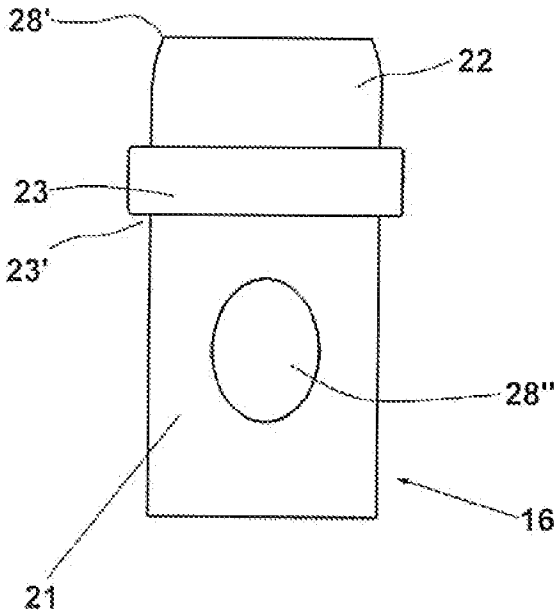



Fig. 13

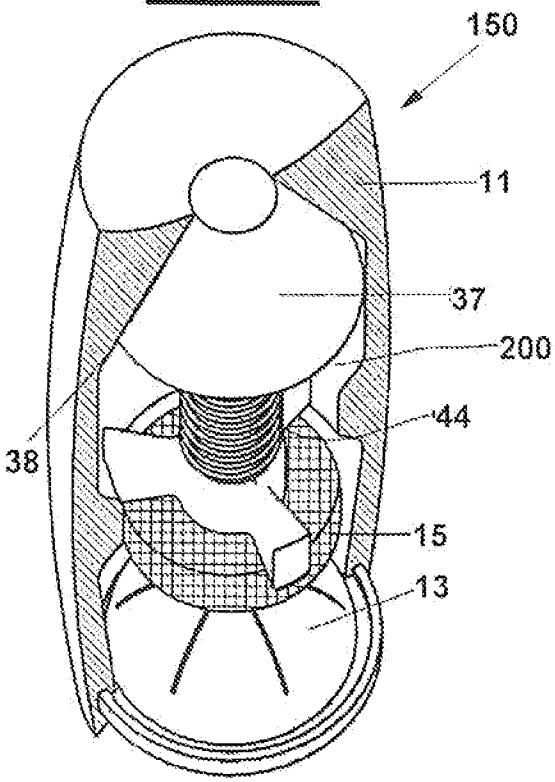



Fig. 15

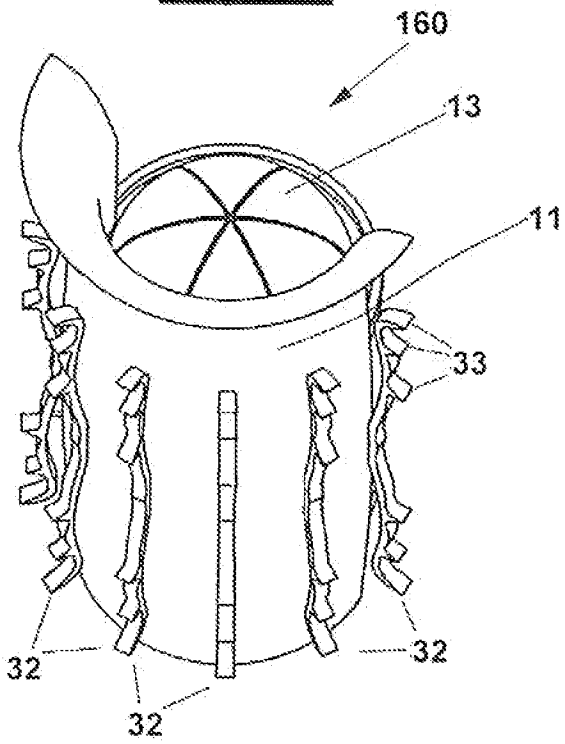


Fig. 14A

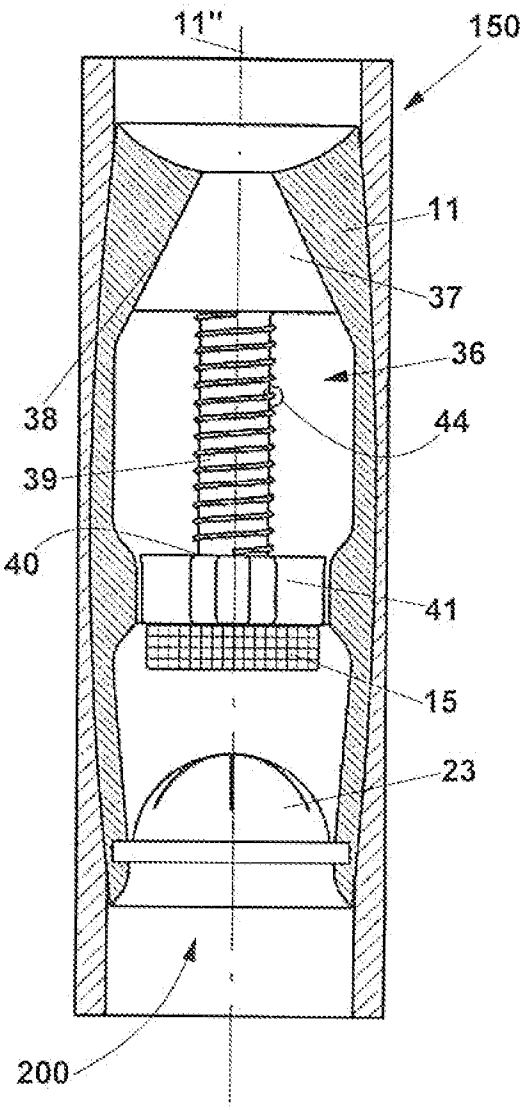



Fig. 14B

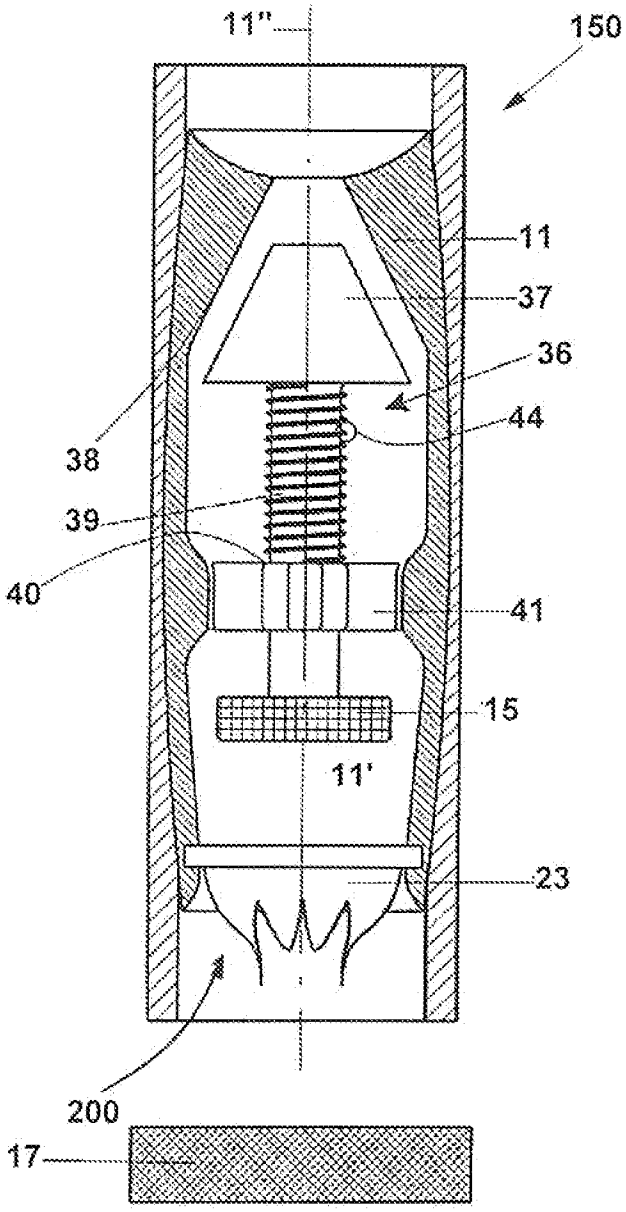



Fig. 14C

Fig. 16A

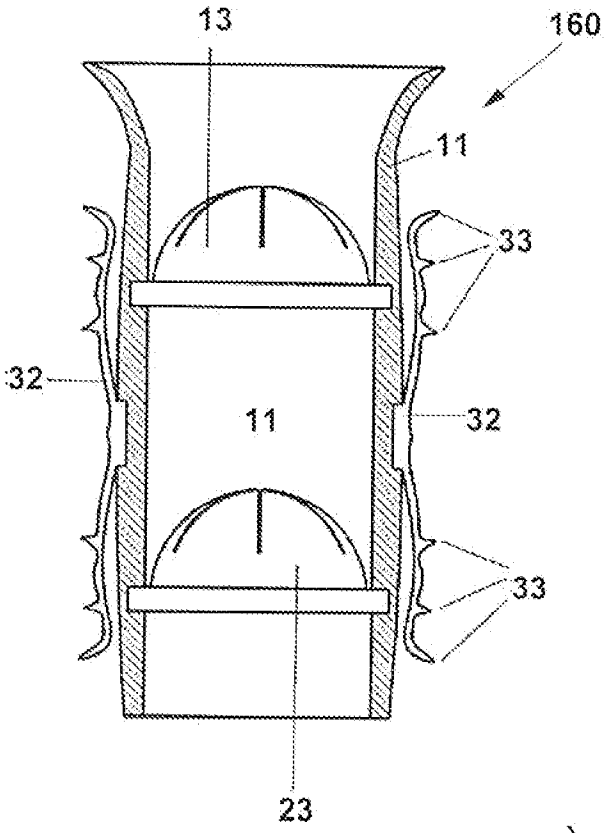



Fig. 16B

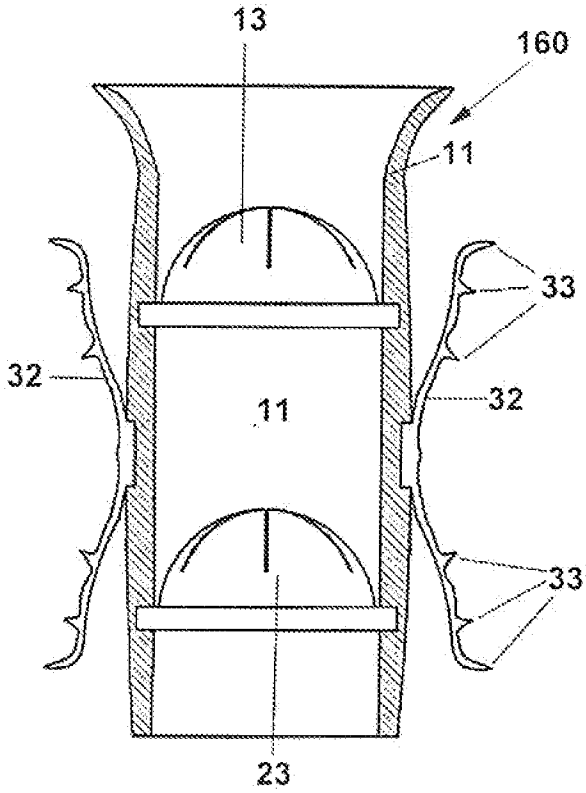
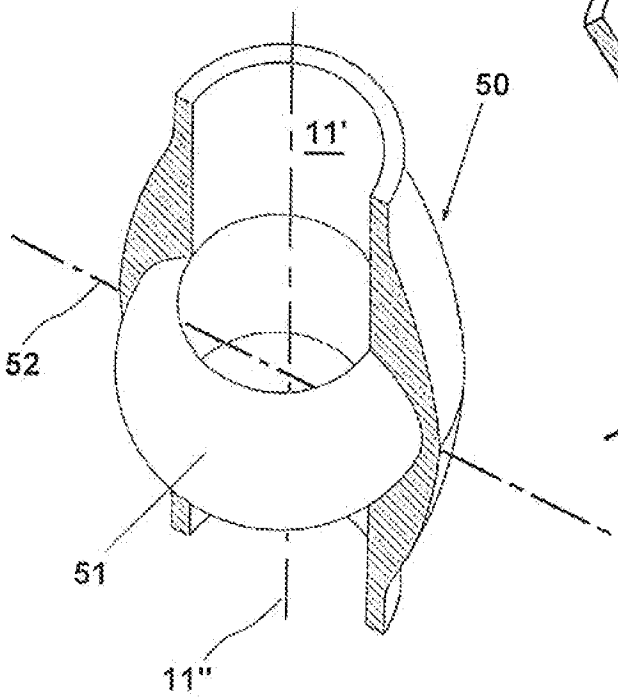



Fig. 19B



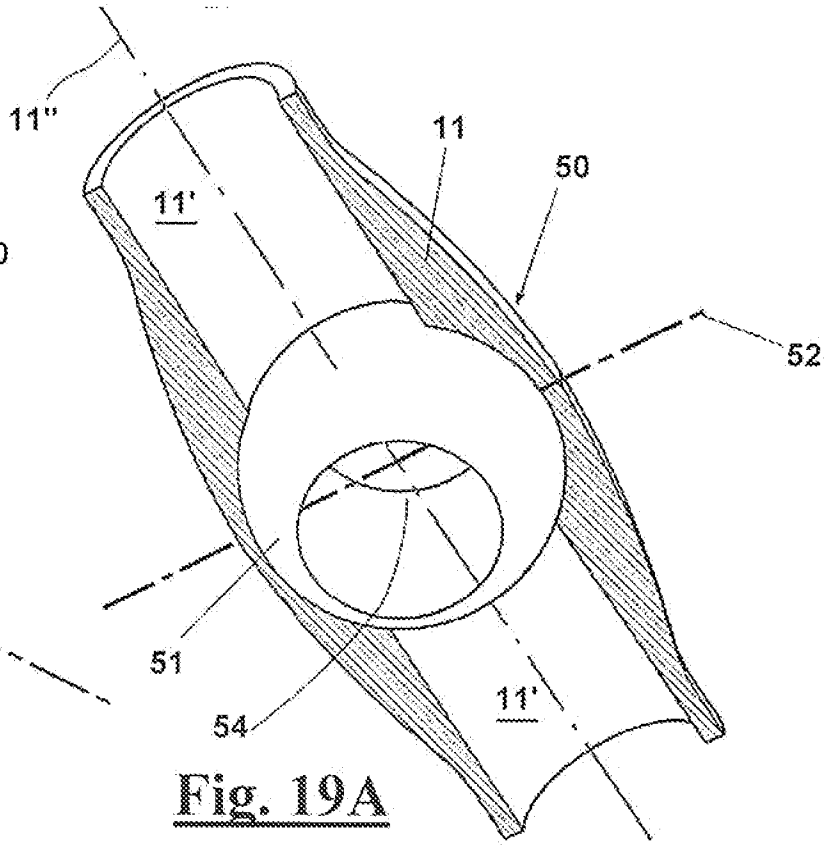




Fig. 19A

Fig. 17A

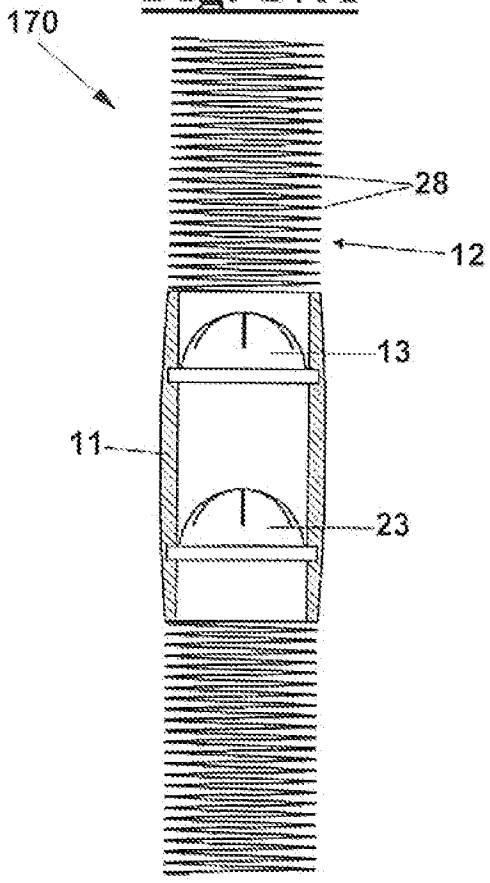



Fig. 17B

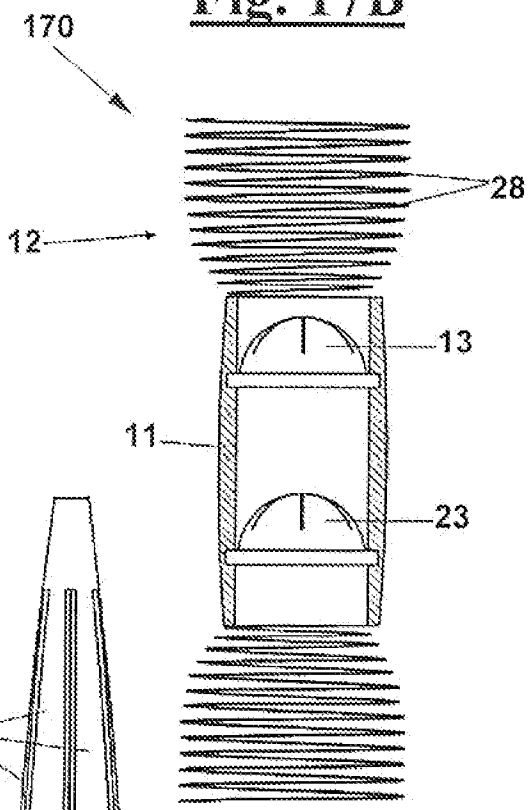



Fig. 18B

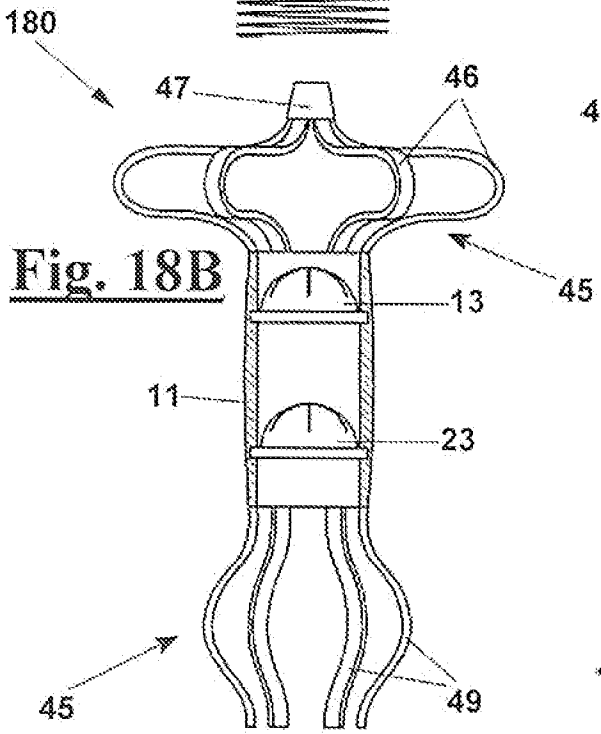



Fig. 18A

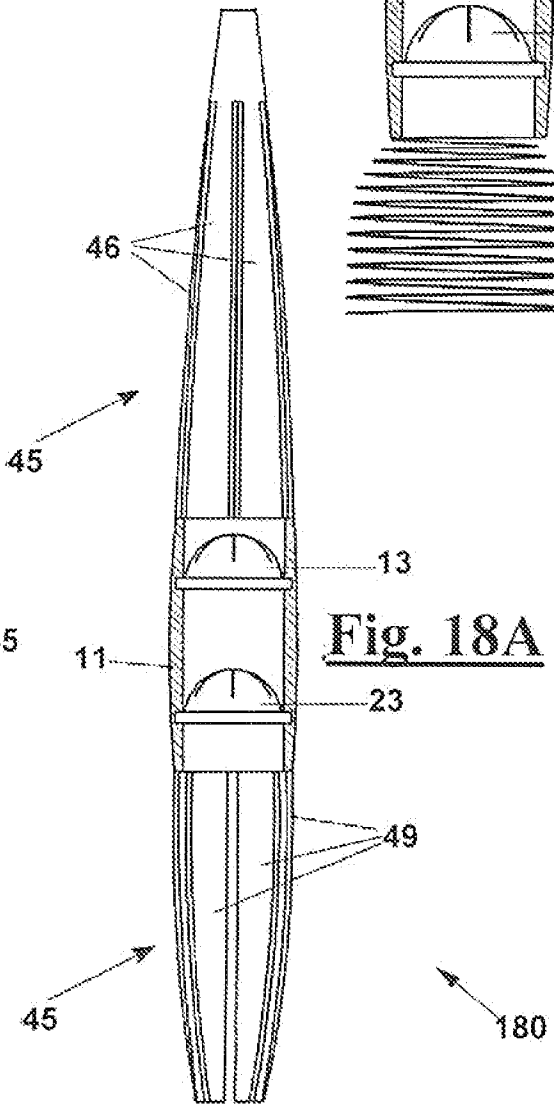


Fig. 20A

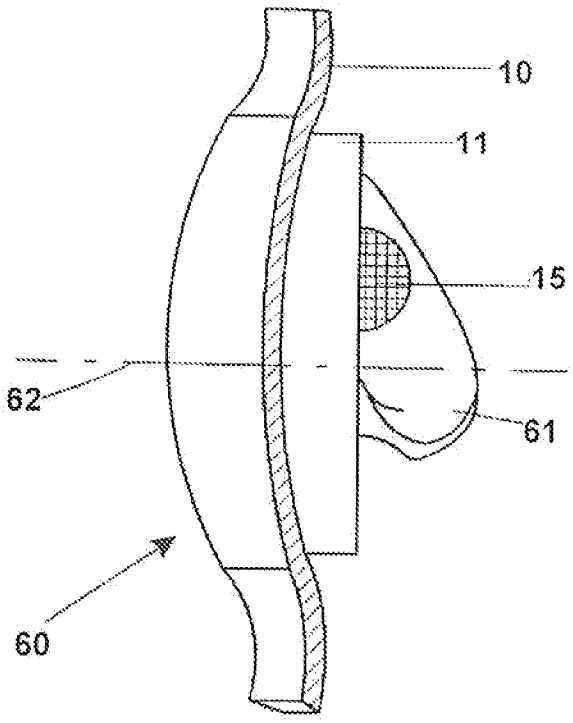



Fig. 20B

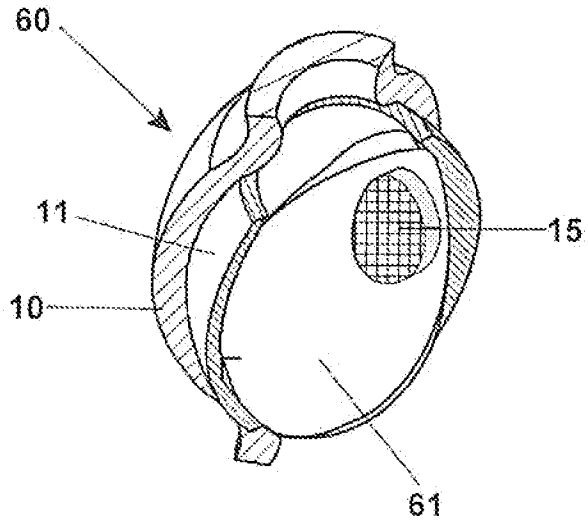



Fig. 20C

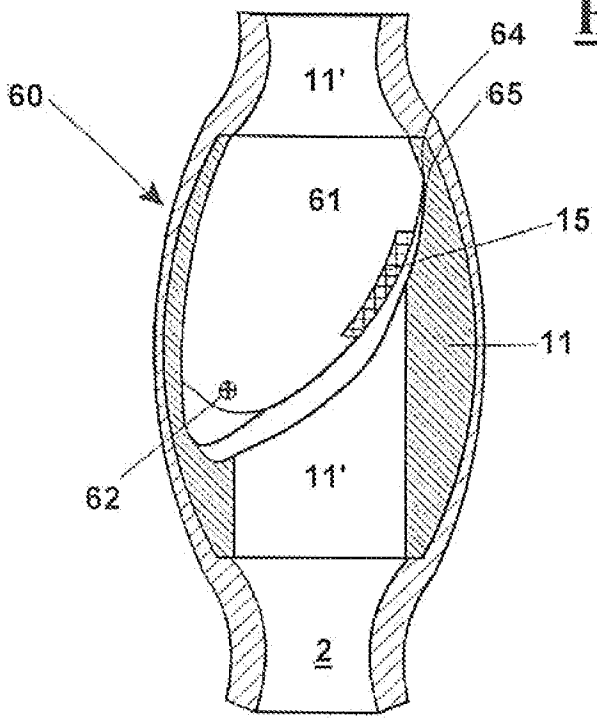



Fig. 20D

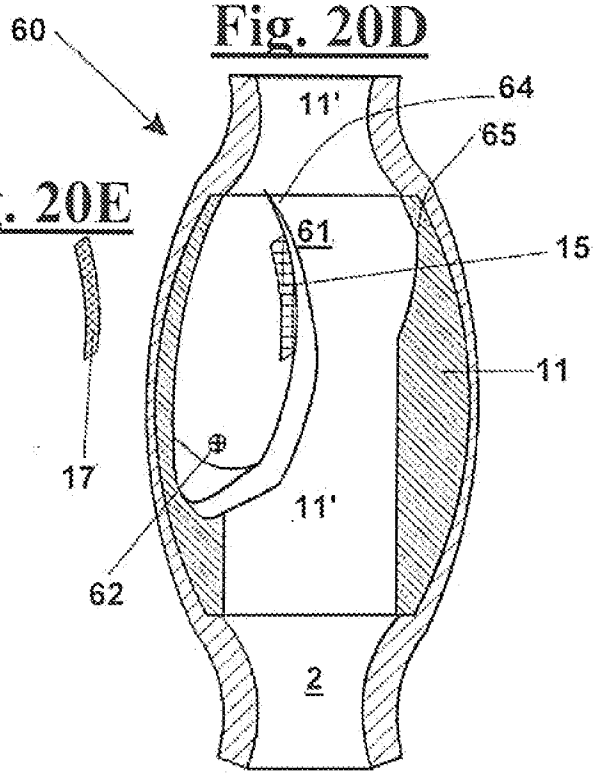



Fig. 20E

Fig. 21A

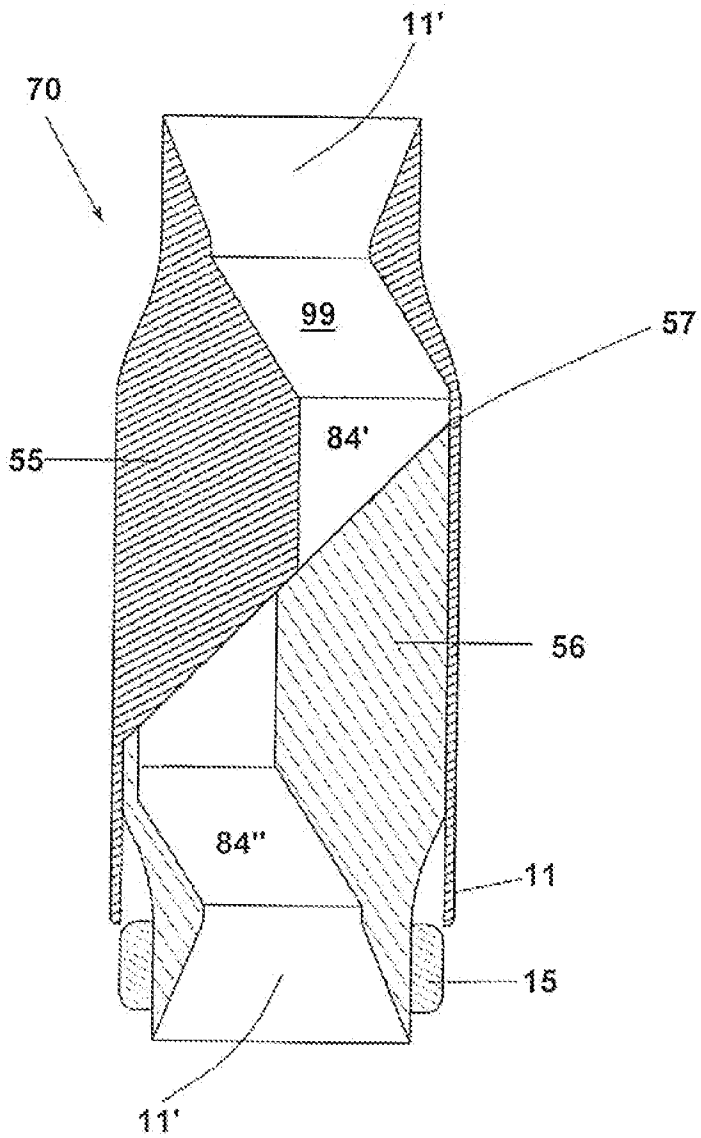



Fig. 21B

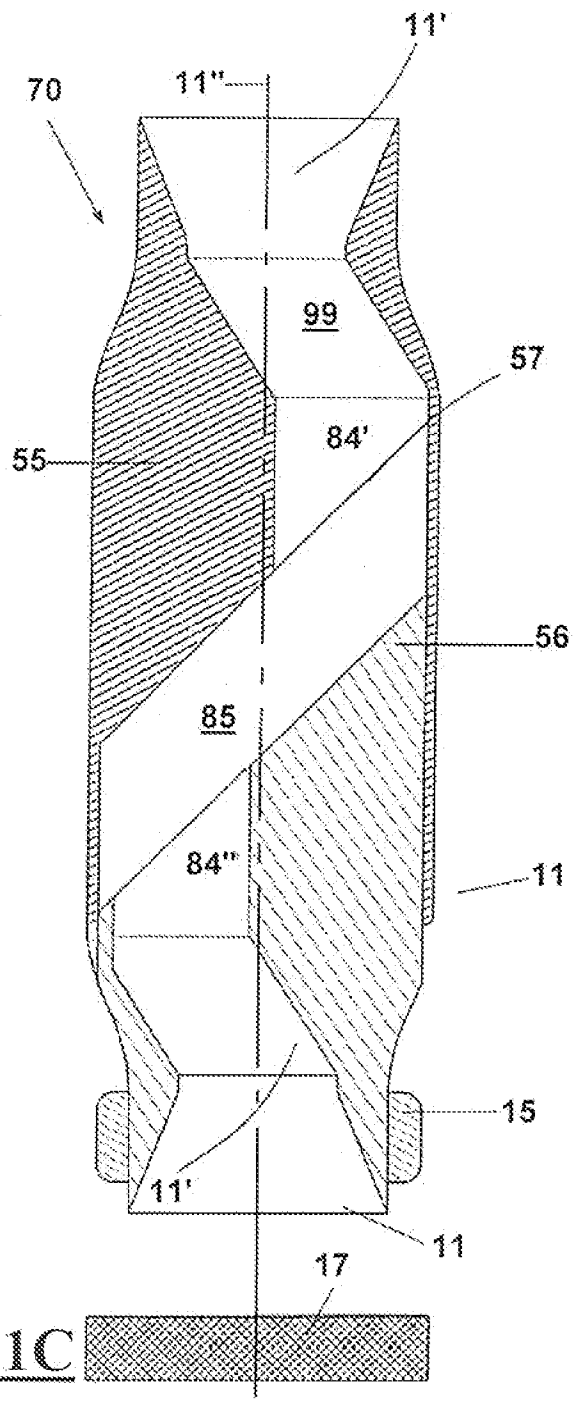



Fig. 21C

Fig. 22A

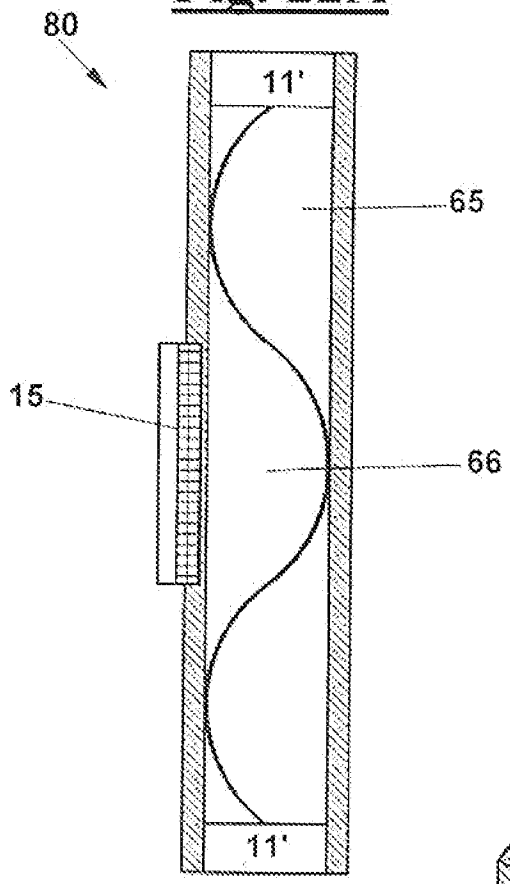



Fig. 22B

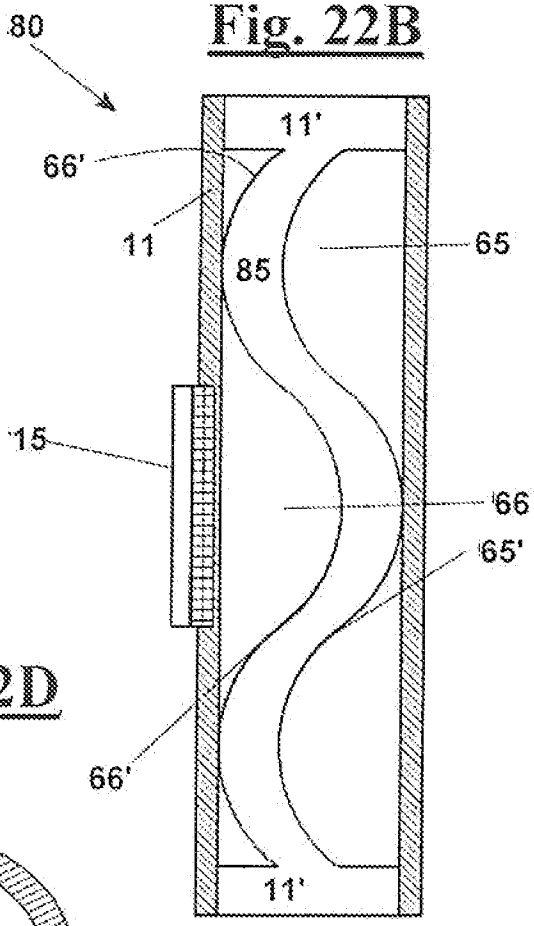




Fig. 22D

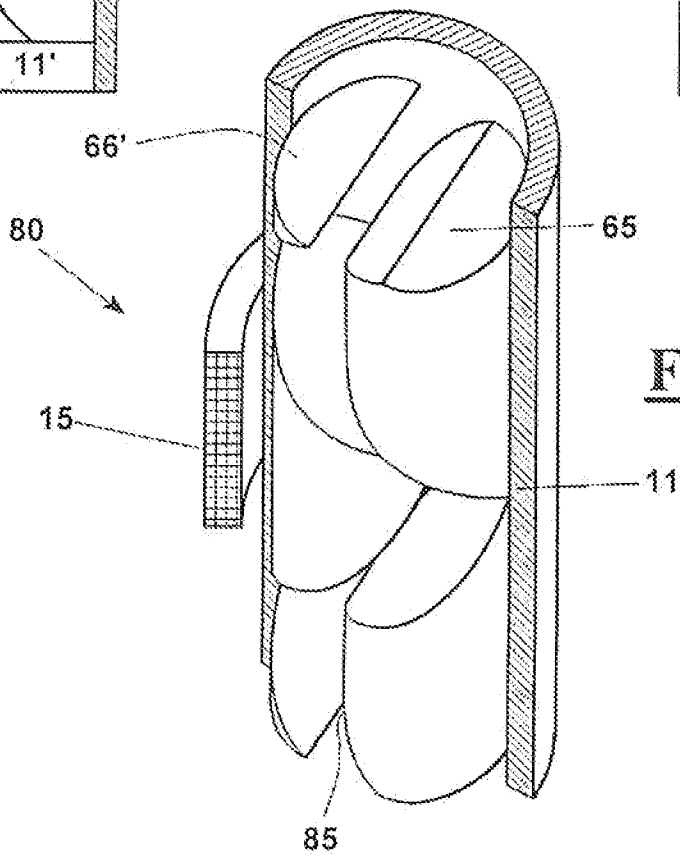



Fig. 22C

Fig. 23A

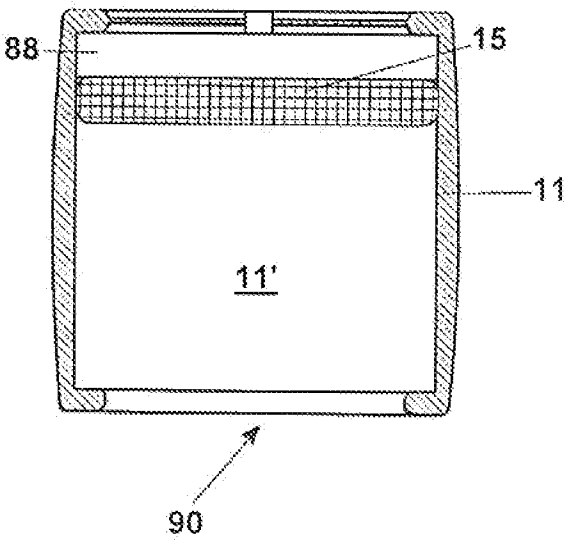



Fig. 23B

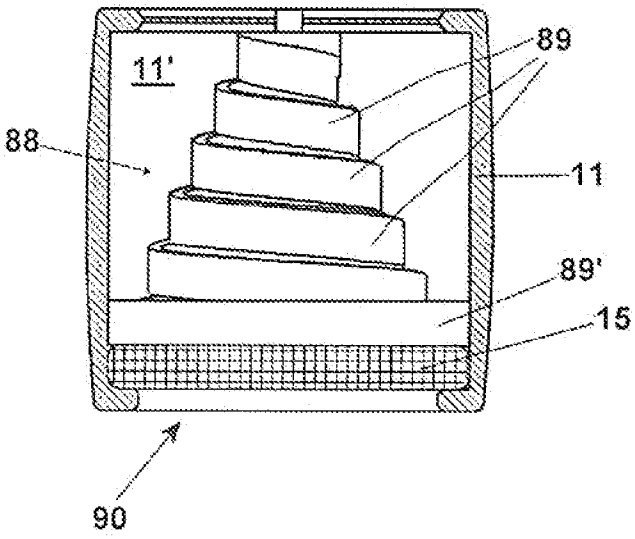



Fig. 23E

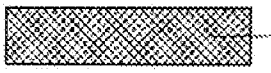



Fig. 23C

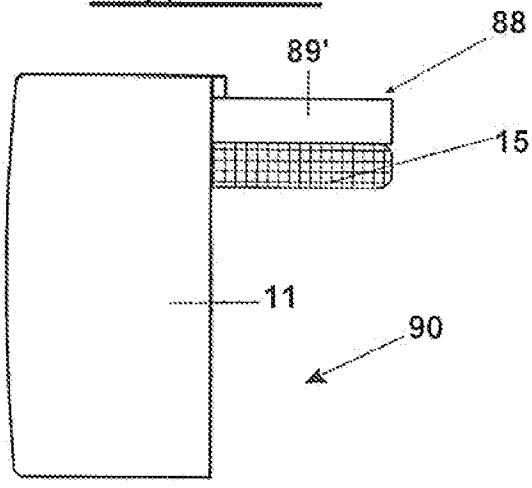



Fig. 23D