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(54) Title: VAGINAL SUPPORT DEVICE FOR PRE- AND POST-OPERATIVE USE

(57) Abstract: A vaginal support device (1), particularly for pre- and post-operative use, comprising a central body (2) and provided with at least one additional body (4), the additional body (4) being adapted to be filled with filler material.

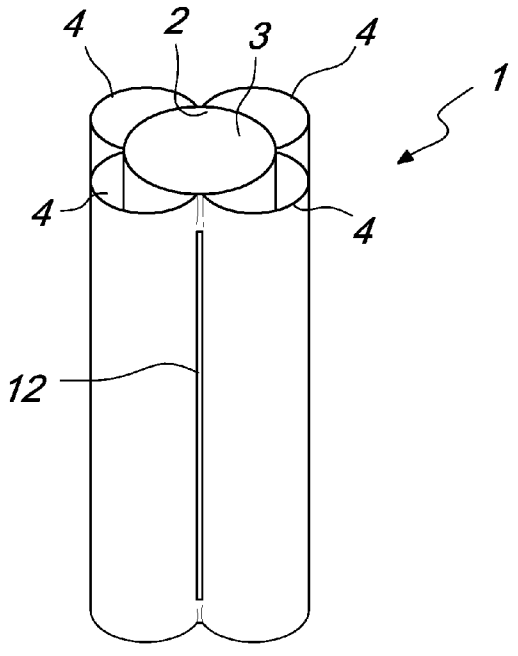

Fig. 1

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VAGINAL SUPPORT DEVICE FOR PRE- AND POST-OPERATIVE USE

The present invention relates to a vaginal support device for pre- and post-operative use. More particularly, the invention relates to a vaginal support device adapted to be used during the first three weeks following surgery on the urogenital system in order to reduce the stresses caused by the craniocaudal forces that are applied every day to the abdominal muscles and therefore to the urogenital system, in order to improve the clinical outcome.

As is known, after fascial and prosthetic surgery affecting the urogenital system, approximately three weeks are required for scar consolidation; during these three weeks the tissues undergo considerable stresses.

As is known, intravaginal medications (plugs) are used in the postoperative period and are placed by the surgeon so as to reduce any vaginal bleeding. Such medications are kept in place for 24-48 hours and are then removed in order to avoid any infective complications, and therefore they are not suitable for longer retention.

The aim of the present invention is to provide a vaginal support device for use after vaginal surgery, which can be kept in place for a period that substantially covers the healing step.

Within the scope of this aim, an object of the present invention is to provide a vaginal support device that can be inserted by the surgeon directly in the operating room at the end of the operation or, at his or her discretion, when the patient is discharged.

Another object of the present invention is to provide a vaginal support device that has no abrasive surface that could damage the tissues with which it comes into contact, and which can be medicated.

Another object of the present invention is to provide a vaginal support device that can perform a medicinal action.

Another object of the present invention is to provide a vaginal

support device that can have a prediagnostic use, particularly in stress urinary incontinence (SUI).

Another object of the present invention is to provide a vaginal support device that can be inserted and extracted easily and rapidly.

Another object of the present invention is to provide a vaginal support device that is highly reliable, simple to provide, and low cost.

This aim and these and other objects which will become better apparent hereinafter are achieved by a urogenital support device, particularly for pre- and post-operative use, for diagnostic use and for other medicinal mechanisms, characterized in that it comprises a central body and is provided with at least one additional body connected thereto, said additional body being adapted to be filled with filler material.

The need for the cylindrical hole is linked to the fact of ensuring normal menstrual discharge or, alternatively, for performing intravaginal douches.

Further characteristics and advantages of the invention will become better apparent from the description of preferred but not exclusive embodiments of the device according to the present invention, which are illustrated by way of non-limiting example in the accompanying drawings, wherein:

Figure 1 is a cross-sectional perspective view of the support device according to the present invention;

Figure 2 is a perspective view of the support device according to the invention in the active condition, before being used by the surgeon;

Figure 3 is a perspective view of the device according to the invention in the condition of use;

Figure 4 is an exploded perspective view of an embodiment of the device according to the invention;

Figure 5 is a perspective view of the device according to the invention in a step of assembly.

With reference to the figures, the vaginal support device according to the invention, generally designated by the reference numeral 1, comprises a body 2 and is provided with at least one additional body 4 that is external to the body 2 and is connected thereto, and is adapted to be filled with material in gel form or other, similar material.

In an alternative embodiment, the body 2 can be provided monolithically with the additional body 4.

The body 2 is preferably but not exclusively provided substantially in the form of a tubular element.

The body 2 is preferably provided with a central through hole 3 and the at least one additional body 4 is likewise cylindrical or semicylindrical or has other appropriate shapes.

Conveniently, as shown in the figures, the device 1 preferably has a plurality of cylindrical or semicylindrical bodies 4, which are closely adjacent to the central cylindrical body 2 and are connected thereto (or provided monolithically with the body 2) so as to constitute a lobate or sectored structure.

The cylindrical or semicylindrical body 4 is advantageously closed in an upward region and in a downward region so as to contain the filler material.

A toroidal element 15 can be coupled, in an upward region and in a downward region, to the device 1 in order to avoid discomfort from compression or decubitus.

Conveniently, the device according to the invention can for example be provided, as mentioned, monolithically, or, as shown in Figures 4 and 5, by arranging a first sheet of polymeric material 10 (polymeric film) which is intended to define the cylindrical body 2 by way of rolling the sheet 10 onto itself, and a second sheet 11 of polymeric material (polymeric film) which is adapted to be heat-sealed to the first sheet 10 along heat-sealing lines 12 that affect only partially the transverse extension of the first sheet 10.

The second sheet 11 makes it possible to provide the additional cylindrical bodies or portions 4 that are external to the cylindrical body 2.

The portions 4 are internally connected to each other by virtue of the fact that the heat-sealing lines 12 that allow the connection of the portions 4 to the cylindrical body 2 are not extended along the entire length of the portions 4 but there is a part that is not heat-sealed and therefore creates a passage channel for the simultaneous filling of all the portions 4, which are therefore all mutually connected.

The device thus provided is adapted, as mentioned, to be filled with gel or any other type of gas, liquid or foam, so as to obtain an inflated shape.

The device is furthermore provided with a tube 6 with a variable diameter, which makes it possible to introduce and remove gel or other liquid, for example by way of a syringe, and is provided furthermore with a valve 7 that is suitable both to prevent the escape of the gas, liquid or gel introduced into the device and to allow its removal.

The device is conveniently provided, for example, with an instrument that makes it possible to establish the degree of filling of the device.

The filler material that is preferred for use is ultrasound gel, or water, or foam, or a gas. In any case, the filler material has the purpose of increasing the useful volume of the device, thus making it adhere to the walls of the vagina.

As an alternative, the device can be provided with a rigid or semirigid or flexible central core.

The central hole 3 can be of any size suitable for use.

The material of which the device is made is preferably a material such as for example silicone of the medical type, polyisoprene or polyurethane.

More generally, the material that can be used is any polymer that has good resistance to abrasion, strength, transparency, very good low-temperature stability, hydrolytic stability and resistance to fungi, in addition to having excellent damping characteristics and exceptional resistance to

tear propagation.

Furthermore, it is possible to provide the device by coupling different polymeric films, containing one or more appropriately dosed drugs that are released all together, or one at a time, with a controlled time spacing over a period of, for example, 21 days.

In practice it has been found that the support device according to the present invention fully achieves the intended aim and objects, since it can be introduced into the vagina, directly after surgery, in the operating room or, at discharge time, by the surgeon.

The device can be kept in place for the time needed to have complete healing of the part affected by surgery.

The device thus conceived is susceptible of numerous modifications and variations, all of which are within the scope of the accompanying claims. All the details may furthermore be replaced with other, technically equivalent elements.

In practice, the materials used, as well as the contingent shapes and dimensions, may be any according to the requirements and the state of the art.

The disclosures in Italian Patent Application no. MI2013A002153, from which this application claims priority, are incorporated herein by reference.

Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly such reference signs do not have any limiting effect on the interpretation of each element identified by way of example by such reference signs.

CLAIMS

1. A urogenital support device (1), particularly for pre- and post-operative use, for diagnostic use and for other medicinal mechanisms, characterized in that it comprises a central body (2) and is provided with at least one additional body (4) connected thereto, said additional body (4) being adapted to be filled with filler material.

2. The support device according to claim 1, characterized in that said body (2) is substantially cylindrical, semicylindrical or has other shapes and is provided with a central through hole (3), and in that said at least one additional body (4) is cylindrical or semicylindrical or has other shapes.

3. The support device according to claim 1, characterized in that said filler material is a gel, a filler liquid or a gas.

4. The support device according to claim 1, characterized in that it comprises a tube (6) with a variable diameter, which is connected between said body (2) and said at least one additional body (4) and is adapted to allow the filling of said at least one additional body (4), and in that it comprises an instrument that makes it possible to establish the degree of filling of the device.

5. The support device according to one or more of the preceding claims, characterized in that said body (2) and said at least one additional body (4) are made of soft material that is adapted to swell following the insertion of said filler material.

6. The support device according to one or more of the preceding claims, characterized in that said variable-diameter tube (6) is provided with a valve (7) that is adapted both to prevent the escape of material introduced into the device, and to allow its removal.

7. The support device according to one or more of the preceding claims, characterized in that it is made of at least one type of polymer.

8. The support device according to one or more of the preceding claims, characterized in that said body (2) is provided by a first sheet (10)

made of polymeric material, which is adapted to be folded onto itself so as to define a cylindrical body.

9. The support device according to claim 6, characterized in that said at least one additional body (4) is provided by way of a second sheet (11) that is adapted to be heat-sealed to said first sheet (10) along heat-sealing lines (12), in order to define said at least one additional body (4).

10. The support device according to one or more of the preceding claims, characterized in that it comprises a toroidal element (15) adapted to be coupled to the respective ends of said device.

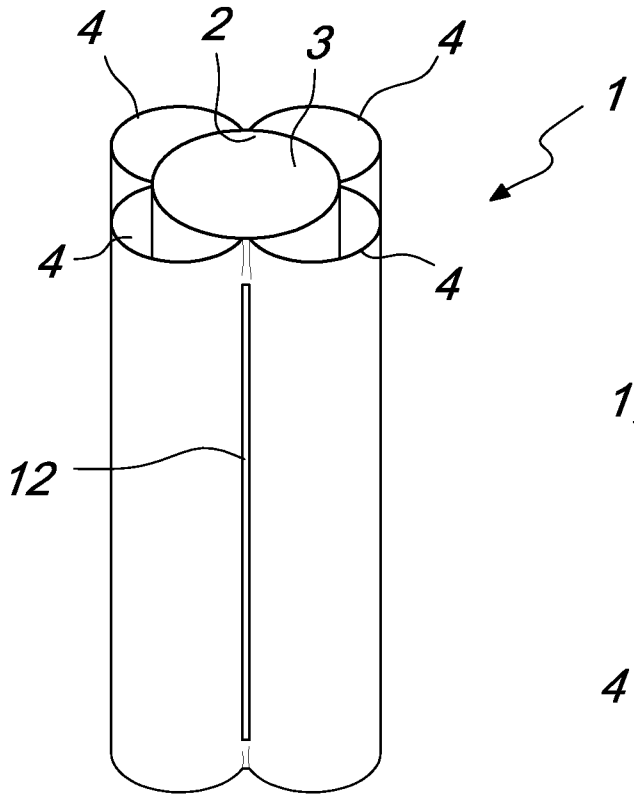

Fig. 1

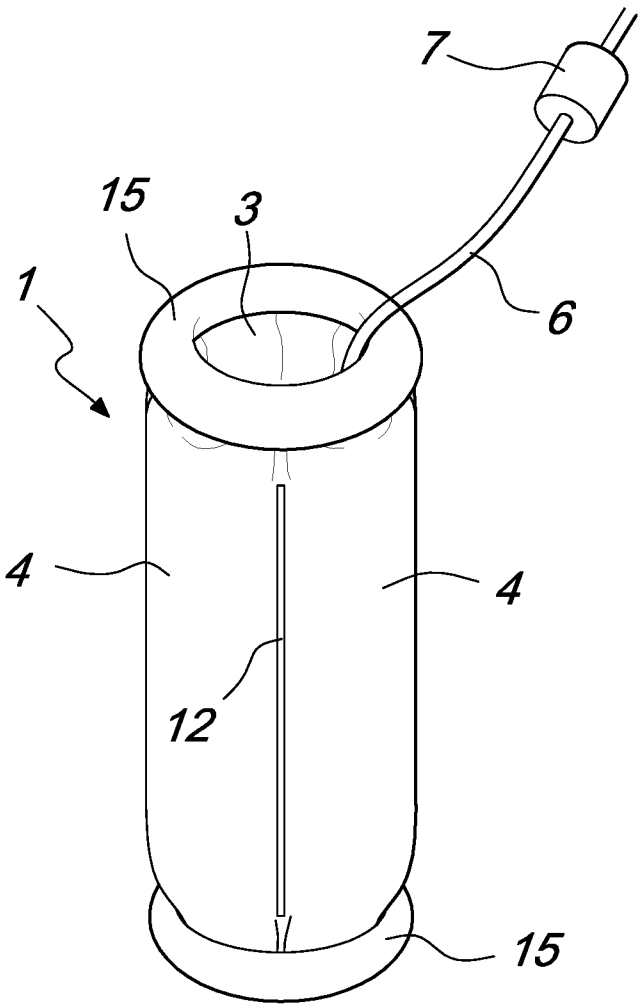

Fig. 2

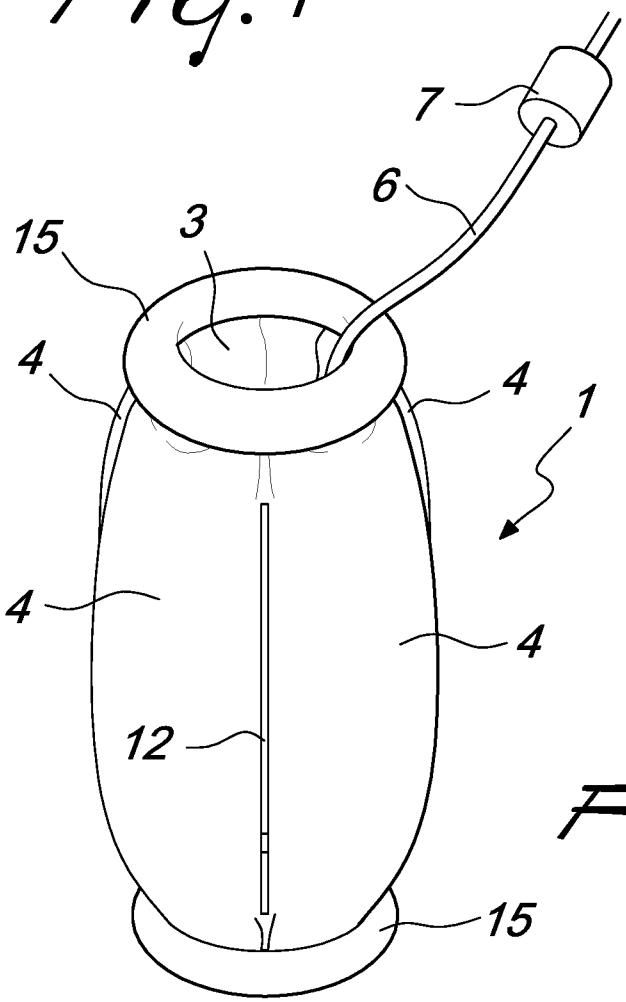

Fig. 3

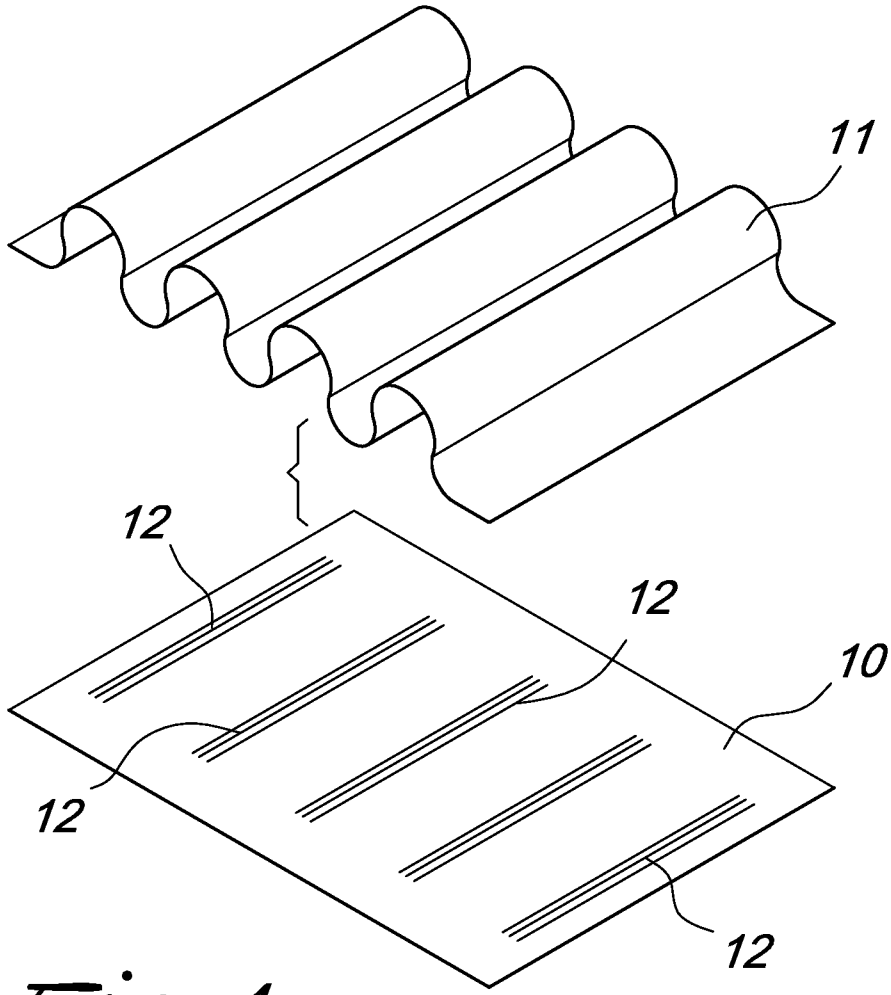

Fig. 4

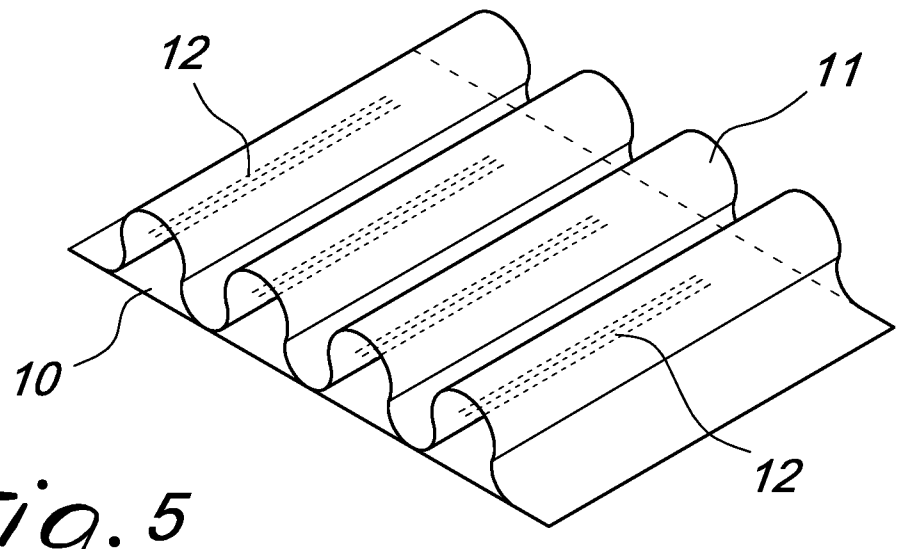

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2014/067131

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61K9/00 A61F13/00 A61F13/20 A61F13/84 A61F13/15
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 103 007 426 A (UNIV SHAOXING) 3 April 2013 (2013-04-03) abstract paragraphs [0013] - [0016]; figure 1	1-10
X	CN 203 234 871 U (ZHANG FAN) 16 October 2013 (2013-10-16) abstract figures 1-2	1-10
X	CN 202 342 111 U (WENJIE REN) 25 July 2012 (2012-07-25) abstract paragraph [0010]; figure 1	1-10

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"E" earlier application or patent but published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 March 2015	23/03/2015

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2014/067131

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2009/004246 A1 (WOOLFSON DAVID AARON [IE] ET AL) 1 January 2009 (2009-01-01) paragraphs [0036], [0037], [0057], [0087]; claims 1-33; figure 1	1-3,7-10 4-6

X Y	US 2007/043332 A1 (MALCOLM KARL [GB] ET AL) 22 February 2007 (2007-02-22) claims 1-18; figures 1-20 examples 15-17	1-3,7-10 4-6

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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