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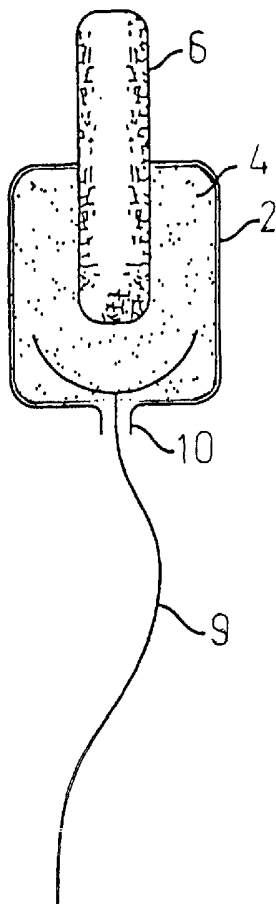
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(54) Title: INTRAVAGINAL CATAMENIAL DEVICE FOR BLOOD LEAKAGE PREVENTION



(57) Abstract: A catamenial device for blood leakage prevention (1) composed of an impermeable balloon or inflatable member (2) housing a resiliently expandable inflation member (4) generally made of open cell foam. The balloon (2) has an opening (10) for airflow communication between the interior of the balloon (2) and the outside environment. During insertion into a vaginal canal, the inflation member (4) is inserted in a contracted state. Upon placement to proper vaginal location, the inflation member (4) expands by resiliency drawing air from the outside environment in to the balloon (2) via the opening (10) in the balloon (2). Once in the vaginal canal the balloon inflated (2) is capable of providing sealable closure of the vaginal canal for the prevention of exit of menstrual blood from the vaginal orifice. The balloon (2) housing the inflation member (4) can be combined with an absorbent member (6) or can be a stand-alone device. Inflation of the inflatable member (2) can be activated manually by the user or via an intravaginal applicator which has the dual function of inserting and delivering the device into the vaginal and that of actuating the inflation of the inflatable member (2).

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INTRAVAGINAL CATAMENIAL DEVICE FOR BLOOD LEAKAGE PREVENTION

TECHNICAL FIELD

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This invention relates to catamenial devices, more specifically to intravaginal catamenial devices.

BACKGROUND ART

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Various catamenial devices have been disclosed for the purpose of delaying exit of menstrual blood from the vagina such as tampons and menstrual cups, alone or in combination.

Tampons are made of absorbing material and are inserted into the vagina by the female user at the time of the onset of the menstruation. Their purpose is to absorb menstrual blood delaying its exit from the vaginal orifice. Due to their absorbing properties, tampons, once inserted into the vagina, begin to absorb the blood they become in contact with, blood which outflows from the cervical os into the vagina. Tampons function as reservoirs aiming at delaying exit of the blood from the vaginal orifice conceivably until they become saturated with blood.

However, regardless of their absorbency capabilities, tampons, for various reasons, are known to allow leakage of menstrual blood at rather unpredictable time generally after saturation but, not unusually prior to that, and at times shortly after insertion, falling short of providing the protection to the female user, protection which is the very reason for their indication and use. Blood may leak from the vaginal orifice because the tampon is too quickly saturated with blood or because the blood flow is disproportionately heavy for the absorbency capabilities of the inserted tampon or because the tampon does

not provide an adequate sealing with the vaginal walls or with the vaginal orifice or for all the above reasons variously combined. No known tampon is capable of preventing leakage of blood from the vaginal orifice, regardless of shape, size, and absorbency capabilities of the material or materials which they
5 are made of.

Despite the use of tampons, therefore, leakage of blood from the vaginal orifice is almost the rule during the days of the menstrual vaginal bleeding and its occurrence may result in a great deal of annoyance and inconvenience to the woman: leakage indeed actually defeats the main purpose for which
10 tampons are used.

Prior art deals with the problem of leakage of menstrual blood through the tampons in various way: some inventions by providing additional blood reservoirs to the tampons, some others by increasing the tampons absorbing capabilities by means of improved absorbing material, and others by using
15 absorbing pads to apply in correspondence of the vaginal orifice to capture the blood escaped from the tampon. In all such cases, main object of the prior art is rather to minimize and possibly delay the outflow of blood, rather than reliably preventing the leakage of blood until it is the appropriate time for the woman, as determined by the woman rather than by her endometrium, to
20 permit exit of the menstrual blood from the vaginal orifice.

Menstrual Cups are catamenial devices made generally of cup shaped resilient material such as rubber provided with a reservoir apt to collect the menstrual blood. The circular rim of the cup is generally in contact with the vaginal wall providing sealable closure of the vaginal canal.

25 The menstrual blood is collected in the cup reservoir and once the cup reservoir is filled with menstrual blood, the user empties the cup.

Zadini et al. disclose in their US patent 5,674,239, 5,947,992, 5,609,586, 5,772,645 and 6,540,728 various catamenial devices composed of an expandable or inflatable member apt to seal the vaginal canal.

5 The disclosed catamenial devices can be used as stand-alone devices or in association with an intravaginal absorbent member such as a tampon. These catamenial devices when the expandable or inflatable member is expanded to the point of sealingly engaging the vaginal walls, appear to be capable of preventing or at least of delaying blood exit from the vaginal orifice. Indeed

10 the balloon when inflated or the resiliently expandable member when fully expanded sealingly engages the vaginal walls, obstructing the lumen of the vaginal canal. None of the above patents however disclose a catamenial device formed of an impermeable or substantially impermeable balloon or envelop or inflatable member, enveloping an inflation or air suctioning member such as a

15 foam member or spongiform member, said balloon having the characteristics of being provided with a communication with the exterior via a conduit or generally via an opening, allowing self-suctioning of air into the balloon for the purpose of inflation.

20

DISCLOSURE OF THE INVENTION

The present invention seeks to provide the female user with an intravaginal catamenial device that effectively prevents menstrual blood leakage and that at the same time is very easy to operate and comfortable to

25 the user.

In accordance with this invention, this object is accomplished in a catamenial device for intravaginal use which comprises a substantially impermeable envelop member or balloon enveloping a resiliently expandable or inflation member such as a foam member or rubber member. The balloon is
5 provided with air communication with the exterior in order to be able to suction air from the environment.

The resilient expandable inflation or inflating member made of foam or rubber or any other suitable resilient material, enveloped within the balloon is compressed prior to insertion. Once inserted into the vagina via the user
10 fingers or via an applicator, compression is released and the resilient expandable member expands sucking air from the environment resulting in its expansion. The foam member by expanding carries in its expansion the envelope member, inflating it for the purpose of sealingly engaging the vaginal walls.

15 Such device can be variously shaped. It can be for instance cylinder-like, pear-like or cup-like . The device can be used alone or in combination with an absorbent member such as a tampon. Indeed when the balloon is expanded or inflated by the underlying expanded foam member within the vaginal canal, it seals the vaginal canal not allowing exit of menstrual blood
20 from the canal. When associated with an absorbent member, absorption of menstrual blood is carried out by the absorbent member.

Removal of the device from the vagina is simple and void of any discomfort for the user. Removal is in all similar to the removal of an ordinary
25 tampon without a balloon. The female user pulls on the string connected to the

device causing the balloon and foam member to elongate to facilitate the removal from the vaginal canal and orifice.

The usefulness and advantage of this present invention in respect to the prior art lies also in the manufacturability simplicity. The balloon can be commonly manufactured as an extruded cylindrical tube and not necessarily by a blow-molding process. After the foam member is inserted in the balloon, the balloon obtained by extrusion technology can be cut to the desired length and heat-sealed.

BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 is a cross sectional view of the catamenial device alone without a tampon.

Fig. 2 is a cross sectional view of the catamenial device combined with a tampon.

Fig. 3 is a cross sectional view of another type of the device provided with a reservoir for blood collection.

Fig. 4 is a cross sectional view of the device of Fig. 3 associated with a tampon.

Fig. 5 is a cross sectional view of another embodiment of the device in which the expandable member is a hollow rubber bulb.

Fig. 6 is a cross sectional view of another version of the device illustrated in Fig. 4.

Fig. 7 is a cross sectional view of the device illustrated in Fig. 6 within

a tampon applicator for insertion and delivery of the device into the vaginal canal.

5 DETAILED DESCRIPTION OF THE INVENTION

The catamenial device for menstrual blood leakage prevention is below disclosed in different embodiments and illustrated in Fig. 1 to 7. In all these embodiments inflation of the balloon or inflatable member occurs by air or gas
10 drawn from the outside into the interior of the balloon.

More specifically expansion by inflation of the balloon occurs by suctioning of air or gas from the outside environment into the interior of the inflatable member or balloon. Suctioning occurs as a result of negative pressure gradient being created within the inflatable expandable member or balloon which
15 causes movement of air or gas from the outside into the interior of the expandable member or balloon via an airflow communication between the interior of the balloon and the outside environment.

A typical embodiment of the invention is illustrated in Fig. 1. Device 1, shown in sagittal cross section view in Fig. 1 and in transversal cross section
20 view in Fig. 1A, is composed of inflatable member or balloon or envelop 2, substantially impermeable to gas and fluids, enveloping inflation member or air suctioning member or open cell foam member or expandable member 4. In this embodiment balloon 2 when fully inflated is grossly of cylindrical or of conic shape. Inflation member 4 can be also of spongiform structure.
25 Inflatable member or balloon 2 is formed with opening 10 at its base for airflow communication with the outside environment. Suctioning of air into

balloon 2, i.e. inflation of balloon 2, occurs by spontaneous distention of open cells foam member 4 housed within balloon 2, from a forced compressed state to a resting distended state. The forced compressed state of open cell foam member 4 can be variously achieved and maintained either by actual
5 mechanical compression of the open cell foam member 4 or by sealing the air flow communication opening 10 between the interior of balloon 2 and the outside environment, once the air or gas is squeezed out or aspirated from foam member 4. Upon sealing of opening 10, after compression of foam member 4 or aspiration of air from balloon or inflatable member 2, a vacuum
10 pressure will be maintained within inflatable member 2, therefore inflatable member 2 will remain in a contracted state, being inflatable member 2 substantially impermeable to gas beside to fluids. Contraction of inflatable member 2 will facilitate insertion of catamenial device 1 in the vaginal canal. For the purpose of removal from the vaginal canal device 1 is provided with
15 string 9.

Fig.2 shows a version of device 1 in which device 1' is housing and encircling a segment of intravaginal tampon 6. Balloon 2 with foam member 4 can be also placed behind tampon 6, beside encircling it as above described, as
20 shown in Fig.2.

Figure 3 shows an alternative version of the catamenial device of Fig.1, generally indicated at 20, in which balloon 22 is cup shaped upon expansion, being formed with reservoir 5 delimited by circular walls 7 for blood
25 collection. As in device 1, balloon or inflatable member 22 houses open cell

foam member or air suctioning member or inflation member 24 and is formed also with opening or conduit 10.

Inflation member 24 can be made of sponge-like material as inflation member 4 of device 1.

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Fig.4 shows device 20' in which device 20 is combined with tampon 6 leaving a portion of the tampon open for absorption.

Fig. 5 shows an alternative form of the catamenial device, generally indicated at 30, in which suctioning of air into balloon 32 occurs by spontaneous distention of inflation member 34 which is a hollow resiliently expandable suction bulb member which spontaneously regains its shape after having been compressed if airflow communication has not been closed after compression. Balloon 32 houses suction bulb member 34 visible in Fig.5 through window 33, created in the drawing for visualization of bulb member 34. Bulb member 34 is provided with conduit 37 having opening 38 for flow communication with the outside environment. Alternatively, suction bulb member 34 may be part of the wall of balloon 32 or fused with it.

Fig.6 shows device 40 which is an alternative form of the catamenial device of Fig 4 similar to device 20' of Fig.4 except for the design and structure of string 9' attachment. In this device, string 9' is attached to the body of tampon 6. A slack 9" of string 9' is housed within the body of resiliently expandable member 24. String 9' is attached to balloon 22 via non-airtight attachment 11 in proximity of air conduit or opening 10. Slack 9" facilitates elongation and streaming of balloon or inflatable member 22, which houses foam member 24,

upon extraction of device 40 from the vagina by the user pulling on string 9' which in turn will pull attachment 11 causing the above mentioned elongation of inflatable member 22. This action facilitates extraction of device 40 from the vaginal canal.

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Fig. 7 shows, in cross section, catamenial device 40 of figure 6 housed within tampon applicator 42. Applicator 42 may have an enlarged segment 44, in correspondence of which expandable member or inflation member 24 may be stored for a long period of time without compromising its full distensibility required after ejection from applicator 42, although some material appears to maintain satisfactory distensibility after being subjected to high degree of compression for long period of time. Applicator 42 has a distal tubular segment 43 for housing tampon 6 prior to use, and a proximal tubular segment 45 within which, applicator plunger 48 is slideably engaged. Applicator plunger 48 is formed with contact head 47.

In use, after insertion of distal tubular segment of applicator 42 into a woman's vagina, plunger 48 is pushed in by the female user to advance catamenial device 40 into the vagina. If expandable member 24 is stored in an enlarged segment of applicator 44, as shown in Fig. 7, expandable member 24, upon forward displacement, will be compressed within segment 43 of applicator 42, with consequent expulsion of air through opening or conduit 10 of inflatable member 22. Upon exiting of expandable member 24 from applicator 42 through applicator opening 47, expandable member 24 will distend by resiliency creating a negative pressure gradient between the inside of inflatable member 22 and the outside environment causing air to be drawn into inflatable member 22. In applicators without enlarged segment 44, expandable member

24 will remain housed in a compressed state within a tubular segment such as tubular segment of applicator 42, and will expand upon ejection from the applicator from such compressed state maintained during storage of the device.

5 What we claims is:

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CLAIMS

Claim 1:

A catamenial device for insertion into a vaginal canal having a wall,
5 comprising:
an inflatable member to seal the vaginal canal upon inflation; and
an inflation member housed within said inflatable member to inflate said
inflatable member, said inflatable member comprising an airflow
communication between interior and outside of said inflatable member.

10

Claim 2.

The catamenial device of claim 1, wherein said inflation member housed within
said inflatable member to inflate said inflatable member is a resiliently
expandable member to expand said inflatable member to create a negative
15 pressure gradient between air pressure inside said inflatable member and air
pressure outside said inflatable member and, consequently, via said airflow
communication, creating an airflow into said inflatable member to inflate said
inflatable member.

20 Claim 3.

The catamenial device of claim 1 further comprising an absorbent member.

Claim 4.

The catamenial device of claim 1, wherein said inflation member is an open
25 cells foam.

Claim 5.

The catamenial device of claim 1, wherein said inflation member is a sponge.

Claim 6.

- 5 The catamenial device of claim 1, wherein said inflation member is a hollow resiliently expandable member.

Claim 7.

- 10 The device of claim 1 wherein said inflation member self-suctions air from the outside upon decompression.

Claim 8.

- 15 The catamenial device of claim 3, wherein said inflation member is open cells foam.

Claim 9.

The catamenial device of claim 3, wherein said inflation member is a sponge.

Claim 10.

- 20 The catamenial device of claim 3, wherein said inflation member is a hollow resiliently expandable member.

Claim 11.

- 25 The device of claim 3 wherein said inflation member self-suctions air from the outside upon decompression.

Claim 12.

The catamenial device of claim 1 further comprising a tubular member to carry said inflatable member housing said inflation member into the vaginal canal said tubular member having an enlarged segment apt to house said inflation member housing said inflating member in a decompressed state prior to insertion.

Claim 13.

The catamenial device of claim 3 further comprising a tubular member to carry said absorbent member and said inflatable member housing said inflation member into the vaginal canal said tubular member having an enlarged segment apt to house said inflation member in a decompressed state prior to insertion.

Claim 14.

The catamenial device of claim 3 wherein said inflatable member housing said inflation member encircles the absorbent member.

Claim 15.

The catamenial device of claim 3 wherein said inflatable member housing said inflation member is positioned behind the absorbent member.

Claim 16.

The catamenial device of claim 1 wherein said inflatable member housing said inflation member is formed with a reservoir for blood collection

Claim 17.

The catamenial device of claim 3 wherein said inflatable member housing said inflation member is formed with a reservoir for blood collection.

5 Claim 18.

The catamenial device of claim 1 wherein said inflatable member is obtained via an extrusion process.

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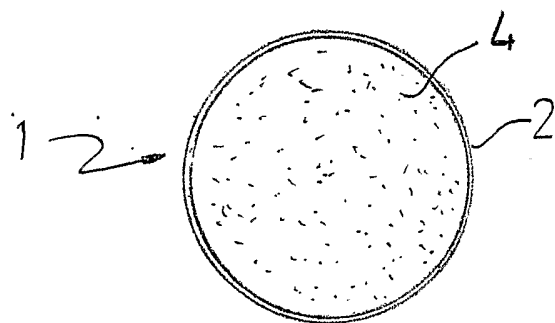


FIG. 1A

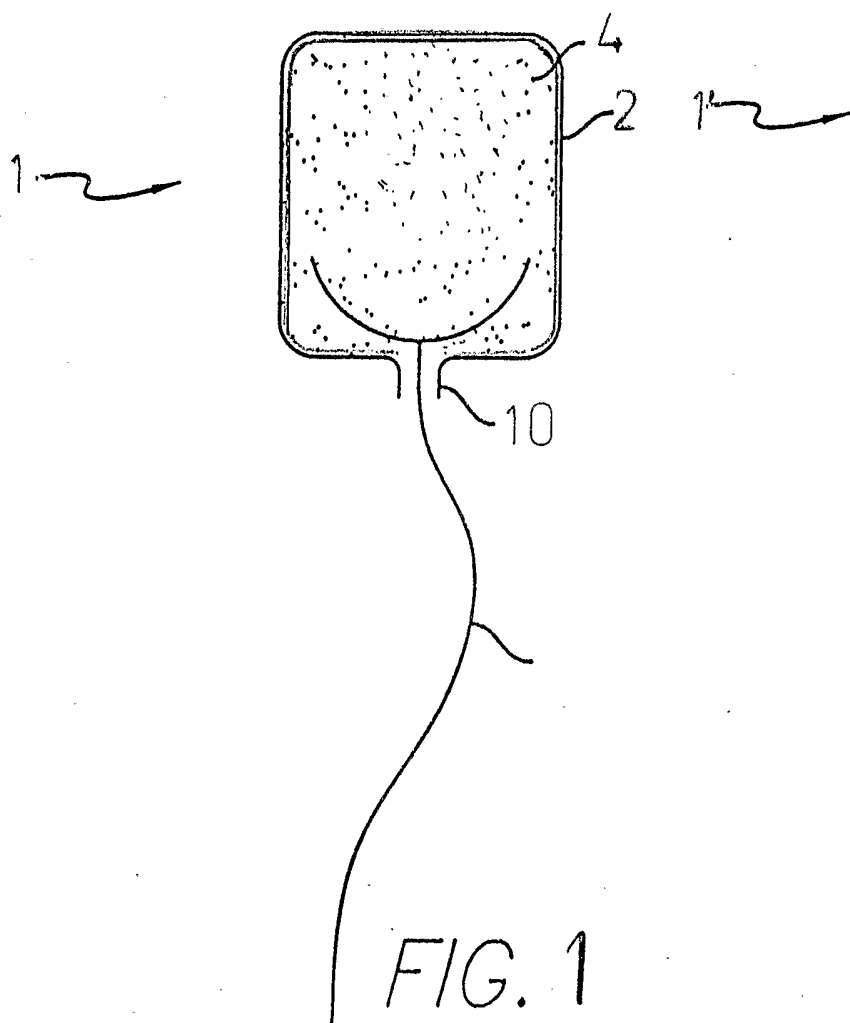


FIG. 1

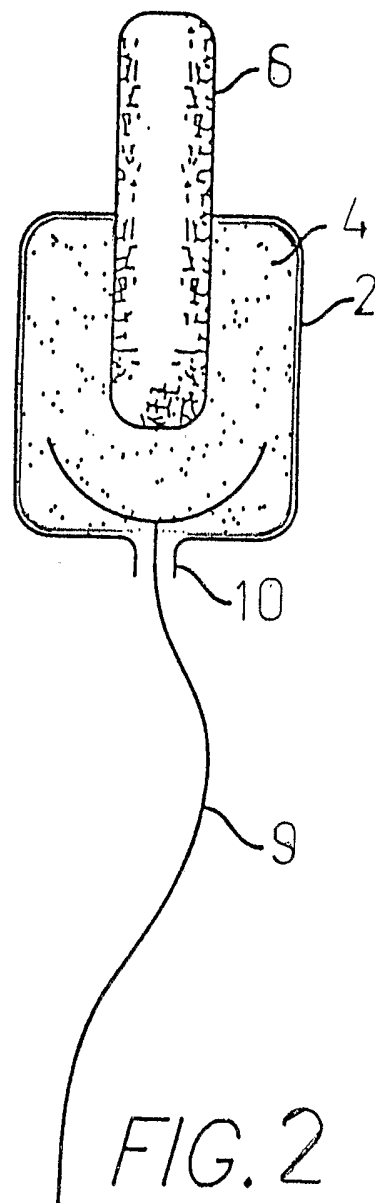
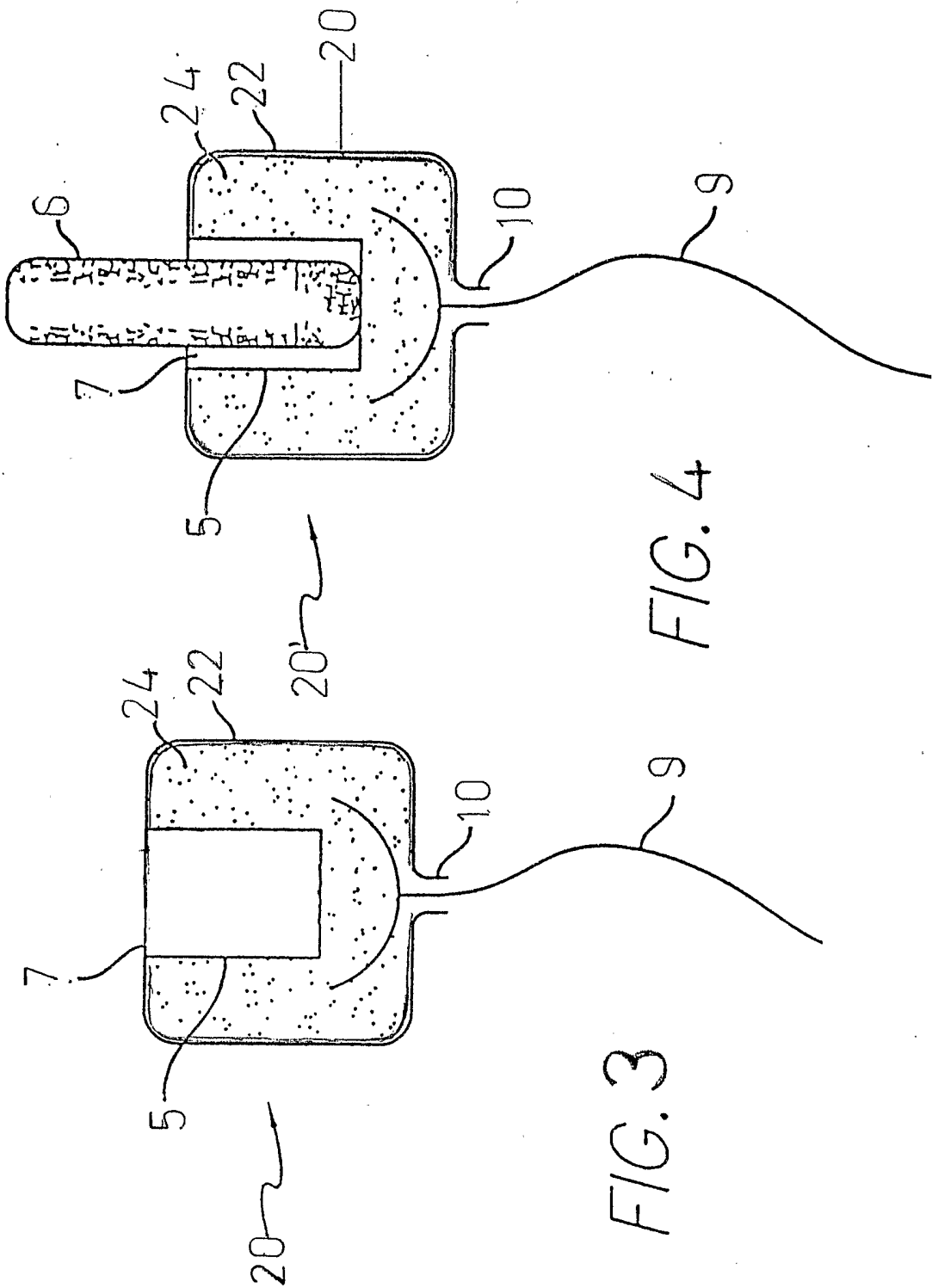
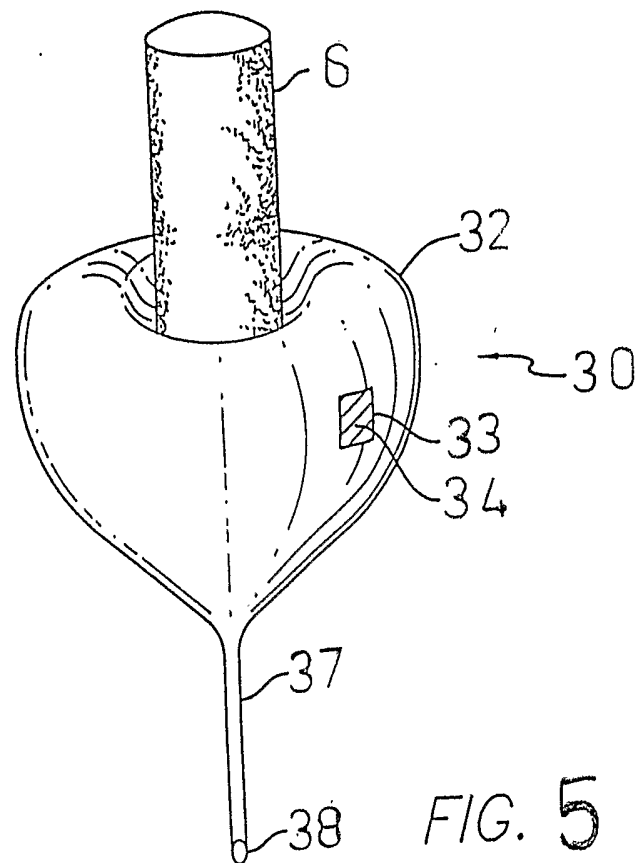
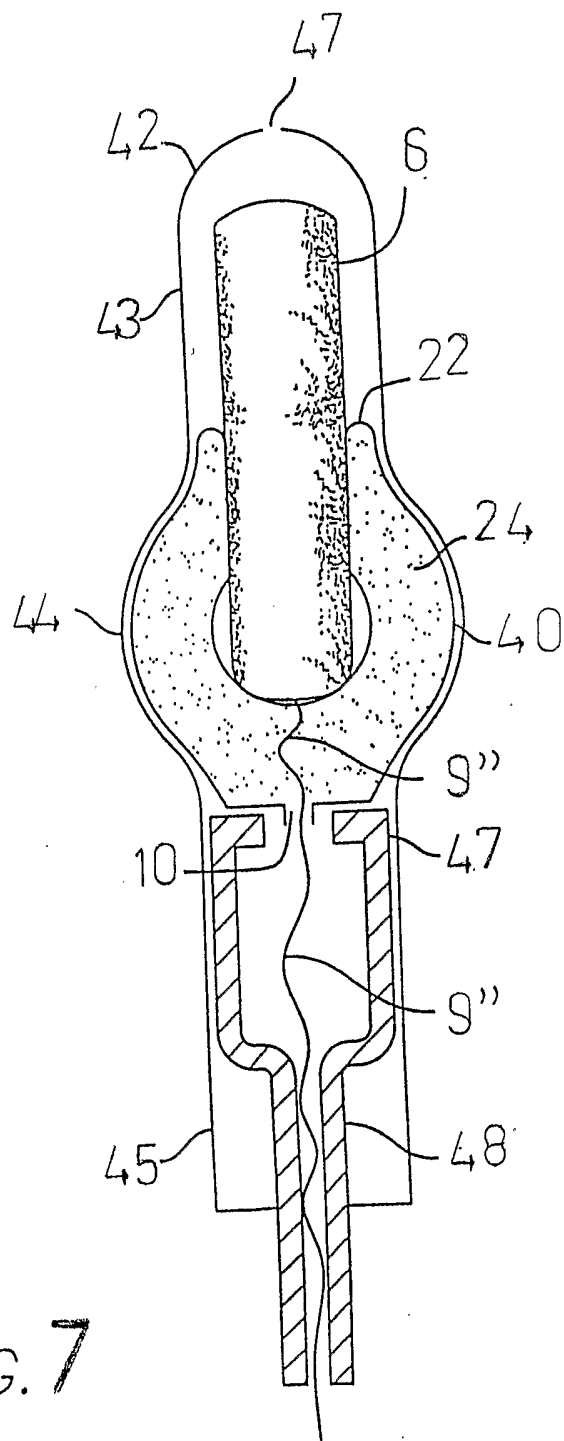
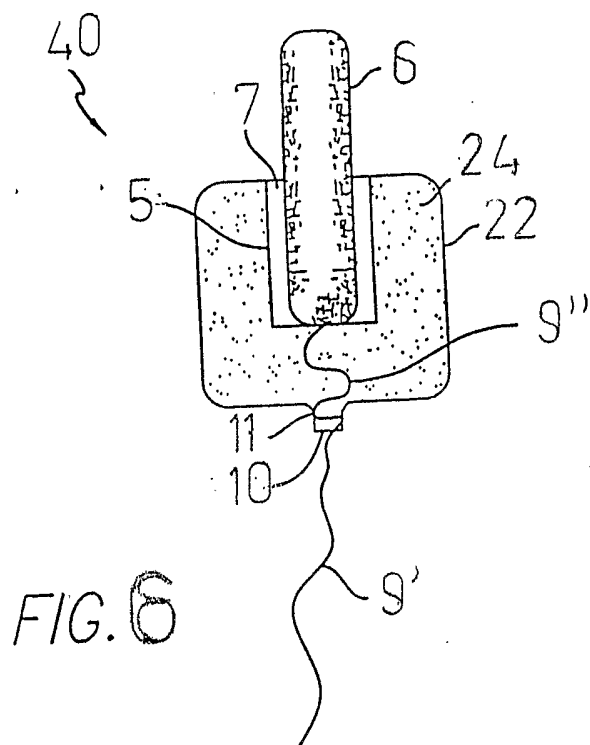


FIG. 2







INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/14525

A. CLASSIFICATION OF SUBJECT MATTER																						
IPC(7) : A61F 5/44 US CL : 604/330																						
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) U.S. : 604/330,358,367,369,374,378, 38.01,385.13,385.17																						
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) EAST/BRS - catmenial, tampon, balloon, inflatable																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
X	US 5,947,992 A (ZADINI et al.) 07 September 1999, see abstract and see all figures. , especially 24.	1,3,4,5,6,8,9,10,14-18																				
Y	US 4,341,214 A (FRIES et al.) 27 July 1982, (27.07.1982) , see abstract and fgis. 1-6.	1,3-6,8-10, 12-15																				
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.																						
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"P"	document published prior to the international filing date but later than the priority date claimed																					
Date of the actual completion of the international search 26 July 2003 (26.07.2003)		Date of mailing of the international search report 15 AUG 2003																				
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230		Authorized officer LoAn H. Thanh Telephone No. (703) 308-0858																				