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Jong Kwan [KR/KR]; #102-1605 Seocho Samsun-graemian, Seocho-1dong Seocho-ku, Seoul 137-071 (KR).

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(74) Agent: **LEE, Won-Hee**; 8th Fl. Sung-ji Heights II 642-16, Yoksam-dong Kangnam-ku, Seoul 135-080 (KR).

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(71) Applicant (for all designated States except US): **SEOUL NATIONAL UNIVERSITY INDUSTRY FOUNDATION** [KR/KR]; San 4-2 Bongcheon-dong Gwanak-ku, Seoul 151-050 (KR).

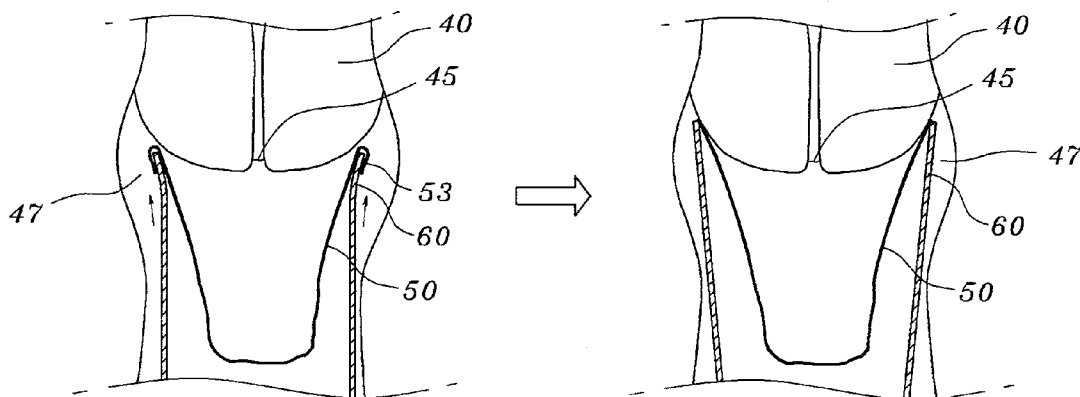
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(72) Inventors; and

(75) Inventors/Applicants (for US only): **PARK, Joong Shin** [KR/KR]; #F-2102 Tower-palace Dogok-dong Kangnam-ku, Seoul 135-536 (KR). **YOON, Bo Hyun** [KR/KR]; #102-804 Bangbae E-pyonhansesang Apt., Bangbae-1dong Seocho-ku, Seoul 137-061 (KR). **JUN,**

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(54) Title: APPARATUS FOR COLLECTING THE AMNIOTIC FLUID FROM THE UTERUS



(57) Abstract: An apparatus is provided for collecting amniotic fluid from the uterus. In order to collect the amniotic fluid from the uterus through the external orifice of the cervix of a pregnant woman, an amniotic fluid collecting unit is adapted to bring a mouth, which is foldably formed at the upper end of an amniotic fluid collecting bag, into close contact with an end of the external orifice of the cervix. Thereby, the apparatus can not only significantly decrease the risk occurring when a needle is directly inserted into the uterus in order to carry out the amniocentesis (amniotic fluid testing), but also eliminate pain and anxiety caused by the direct insertion of the needle.

[DESCRIPTION]**[Invention Title]****APPARATUS FOR COLLECTING THE AMNIOTIC FLUID FROM THE
UTERUS****5 [Technical Field]**

The present invention relates, in general, to an apparatus for collecting amniotic fluid from the uterus through the cervix of a pregnant woman and, more particularly, to an apparatus for collecting amniotic fluid
10 from the uterus through the external orifice of the cervix of a pregnant woman, in which the mouth of an amniotic fluid collecting bag is brought into close contact with the end of the external orifice of the cervix.

[Background Art]

15 Within the uterus of a pregnant woman, a growing fetus is surrounded and cushioned by amniotic fluid, which is watery liquid within the amnion. Also, amniotic fluid is one of the main samples used for the medical examination of the pregnant woman and her fetus.

20 For gathering information about the fetus's health and development, particularly about the possibility of premature birth, amniotic fluid infection, fetal inflammation and infection, fetal damage, fetal maturity,

fetal diseases and chromosomal abnormalities, and component analysis of amniotic fluid, amniocentesis (Transabdominal amniotic fluid collection) is carried out by inserting a thin, hollow needle through the abdomen into the uterus and
5 taking a small sample of amniotic fluid. Currently, abdominal puncture with a needle for collecting amniotic fluid from the uterus is used for various amniotic fluid tests including the identification of fetal abnormality and amniotic fluid infection.

10 However, the insertion of the needle entails the risk of complications and medical accidents, causing anxiety and pain to the pregnant woman.

[Disclosure]

[Technical Problem]

15 Accordingly, the present invention has been made keeping in mind the above problems occurring in the prior art, and an object of the present invention is to provide an apparatus for collecting amniotic fluid from the uterus, which can not only significantly decrease the risk
20 occurring when a needle is directly inserted into the uterus in order to diagnose the possibility of premature birth, amniotic fluid infection, fetal inflammation and infection, fetal damage, fetal maturity, and fetus diseases and chromosomal abnormalities, and conduct component
25 analysis on amniotic fluid, but also eliminate pain and

anxiety caused by the direct insertion of the needle.

[Technical Solution]

In order to accomplish the above object, according to a first embodiment of the present invention, there is
5 provided an apparatus for collecting amniotic fluid from the uterus, which comprises: an amniotic fluid collecting bag, which is provided at a lower end of the external orifice of the cervix so as to collect the amniotic fluid from the uterus through the external orifice of the cervix;
10 and an amniotic fluid collecting unit, which brings the amniotic fluid collecting bag into close contact with the lower end of the external orifice of the cervix.

Here, the amniotic fluid collecting bag includes a mouth, which is folded to a predetermined length at an
15 upper end thereof so as to be in close contact with the lower end of the external orifice of the cervix.

Further, the mouth of the amniotic fluid collecting bag can be expanded by the amniotic fluid collecting unit so that the amniotic fluid collecting bag can be brought
20 into close contact with the lower end of the external orifice of the cervix.

Also, the amniotic fluid collecting bag is made of a material harmless to the human body, which is selected from natural rubber and urethane.

25 Further, the mouth of the amniotic fluid collecting

bag is made of a hydrophilic material.

Meanwhile, the amniotic fluid collecting unit includes a cylindrical contact guide, which extends from a handle having an O-ring shape in one direction.

5 In addition, the number of contact guides is at least two.

According to a second embodiment of the present invention, there is provided an apparatus for collecting amniotic fluid from the uterus, which comprises: an
10 amniotic fluid collecting bag, which includes a mouth, which is folded at a predetermined length at an upper end thereof so as to be in close contact with a lower end of the external orifice of the cervix in order to collect the amniotic fluid from the uterus through the external orifice
15 of the cervix; and an amniotic fluid collecting unit, which expands the mouth so as to bring the amniotic fluid collecting bag into close contact with the lower end of the external orifice of the cervix.

Here, the amniotic fluid collecting bag is made of a
20 material harmless to the human body, which is selected from natural rubber and urethane.

Further, the mouth of the amniotic fluid collecting bag is made of a hydrophilic material.

In addition, the amniotic fluid collecting unit has a
25 hollow cylindrical shape.

[Advantageous Effects]

With the apparatus for collecting amniotic fluid from the uterus according to the present invention, in order to collect the amniotic fluid from the uterus through the external orifice of the cervix of a pregnant woman, an amniotic fluid collecting unit is adapted to bring a mouth, which is foldably formed at the upper end of an amniotic fluid collecting bag, into close contact with an end of the external orifice of the cervix. Thereby, the apparatus can not only significantly decrease the risk occurring when a needle is directly inserted into the uterus for the acquisition of amniotic fluid in order to diagnose the possibility of premature birth, amniotic fluid infection, fetal inflammation and infection, fetal damage, fetal maturity, and fetal diseases and chromosomal abnormalities, and perform component analysis on amniotic fluid, but also eliminate pain and anxiety caused by the direct insertion of the needle.

[Description of Drawings]

FIG. 1 is a sectional view illustrating a female reproductive organ;

FIG. 2 is an enlarged sectional view illustrating the state in which an amniotic fluid collecting bag is in close contact with the cervix in accordance with a first embodiment of the present invention;

FIG. 3 is an enlarged sectional view illustrating the process of bringing an amniotic fluid collecting bag into close contact with the cervix in accordance with a first embodiment of the present invention;

5 FIG. 4 is a sectional view and a perspective view of an amniotic fluid collecting bag in accordance with a first embodiment of the present invention;

FIGS. 5, 6 and 7 are schematic perspective views illustrating an amniotic fluid collecting unit in accordance with a first embodiment of the present invention and its variations;

FIG. 8 is an enlarged sectional view illustrating the process of bringing an amniotic fluid collecting bag into close contact with the cervix in accordance with a second embodiment of the present invention; and

FIG. 9 is a schematic perspective view illustrating an amniotic fluid collecting unit in accordance with a second embodiment of the present invention.

<Description of Symbols of the Main Parts in the Drawings>

1: reproductive organ
10: uterus
20: oviduct
30: ovary
25 40: cervix
43: internal orifice of cervix

45: external orifice of cervix

47: vagina

49: orifice of vagina

50: amniotic fluid collecting bag

5 53: mouth of amniotic fluid collecting bag

60, 70: amniotic fluid collecting unit

63, 73: contact guide

65: handle

[Best Mode]

10 Hereinbelow, the embodiments of the present invention will be described in detail with reference to the accompanying drawings.

FIG. 1 is a sectional view illustrating a female reproductive organ. FIG. 2 is an enlarged sectional view illustrating the state in which an amniotic fluid
15 collecting bag is in close contact with the cervix in accordance with a first embodiment of the present invention. FIG. 3 is an enlarged sectional view illustrating the process of bringing an amniotic fluid
20 collecting bag into close contact with the cervix in accordance with a first embodiment of the present invention. FIG. 4 is a sectional view and a perspective view illustrating an amniotic fluid collecting bag in accordance with a first embodiment of the present
25 invention. FIGS. 5, 6 and 7 are schematic perspective views

illustrating an amniotic fluid collecting unit in accordance with a first embodiment of the present invention and its variations. FIG. 8 is an enlarged sectional view illustrating the process of bringing an amniotic fluid
5 collecting bag into close contact with the cervix in accordance with a second embodiment of the present invention. FIG. 9 is a schematic perspective view illustrating an amniotic fluid collecting unit in accordance with a second embodiment of the present
10 invention.

As illustrated in FIG. 1, a female reproductive organ 1 comprises an orifice of a vagina 49 and a vagina 47 which are external reproductive organs, and a uterus 10, oviducts (Fallopian tubes) 20, and ovaries 30 which are internal
15 reproductive organs.

The ovaries 30 produce ova and secrete female hormones.

When attaining the age of puberty, a woman starts to undergo ovulation, which is the process in the menstrual
20 cycle by which a mature ovarian follicle ruptures and releases an ovum from one of the ovaries 30.

Normally, each of the ovaries 30 releases an ovum every other month, so that an ovum is released at every menstrual cycle.

25 With the onset of ovulation, the uterine lining (endometrium) is thickened. Unless a fertilized egg is

implanted on the uterine wall, the thickened uterine lining is shed, resulting in menstrual bleeding.

Menstruation occurs roughly once per month, but many women suffer from irregular menstrual cycles, particularly
5 for one or two years after their first menstruation, and even into marriage.

The ovaries 30 are located at bilateral rear upper sides of the uterus 10. The ovaries in females are homologous to the testes in males. That is, the ovaries
10 produce, develop and release ova, and secrete female hormones.

In size, the ovary 30 varies depending on age. In the case of adults, before menopause, the ovary is as large as an apricot, while after menopause, the ovary
15 significantly decreases in size, and is slightly larger than a small bean.

The uterus 10 mostly consists of thick, smooth muscle, which is expandable enough to accommodate a fetus just before childbirth.

20 The uterus 10 looks like a western pear, and varies in size. The main function of the uterus 10 is to accept a fertilized ovum which becomes implanted in the endometrium, and to develop an embryo and a fetus. Additionally, the uterus is responsible for menstruation.

25 The uterus 10 is vacant in non-pregnant women. It is located inside the pelvis immediately dorsal to the urinary

bladder and ventral to the rectum.

The vagina 47 is a fibromuscular tubular tract leading from the uterus 10 to the exterior of the body in females.

5 Although there is wide anatomical variation, the length of the vagina of a virgin is approximately 7 to 10 cm. The vagina connects the superficial vulva to the cervix 40 of the uterus. The vagina has several biological functions: a passageway for menstrual blood and tissue to
10 leave the body and a sexual organ.

 During childbirth, the vagina provides the channel to deliver the baby from the uterus outside the body of the mother. Vaginal lubrication is provided by the glands near the internal orifice 43 and the external orifice 45 of the
15 cervix. The membrane of the vaginal wall also produces moisture, although it does not contain any glands, because the cervical mucus glands secrete different kinds of mucus.

 Keeping a low pH environment, the vaginal mucus prevents an infection and restrains bacterial flora from
20 the vagina.

 The labia minora (not shown) are situated between the labia majora (not shown), which are lip-like structures comprised mostly of skin and adipose tissue, with the clitoris prepuce surrounding the upper region thereof.
25 There are no hair follicles in the labia minora. During sexual arousal, the labia become engorged with blood,

typically swelling slightly and darkening or reddening in color.

[Mode for Invention]

In the first embodiment of the present invention, as
5 illustrated in FIGS. 2 through 5, in order to collect the
amniotic fluid passed through the external orifice 45 of
the cervix 40 of the pregnant woman, an amniotic fluid
collecting unit 60 (see FIG. 5) is adapted to bring a mouth
53, which is foldably formed at the upper end of an
10 amniotic fluid collecting bag 50 (see FIG. 4), into close
contact with an end of the external orifice of the cervix
40. Thereby, the amniotic fluid can be collected into the
amniotic fluid collecting bag 50.

At this time, the amniotic fluid collecting unit 60
15 comprises a handle 65 having the shape of an O-ring, and a
plurality of cylindrical contact guides 63 extending from
the handle 65 in one direction.

Now, the process of collecting the amniotic fluid
will be described in detail.

20 First, the contact guides 63 of the amniotic fluid
collecting unit 60 are fixed to the folded mouth 53 of the
amniotic fluid collecting bag 50.

The contact guides 63 are brought into contact with
the end of the external orifice of the cervix 40 through
25 the vagina 47.

The mouth 53 of the amniotic fluid collecting bag 50, which is in contact with the end of the external orifice of the cervix 40 in a circumferential direction, is further pushed in an upward direction using the handle 65 of the amniotic fluid collecting unit 60, so that the mouth 53 is uniformly expanded by the contact guide 63, and thus is brought into close contact with the end of the external orifice of the cervix 40 in a desired shape.

Thus, the amniotic fluid passed through the external orifice 45 of the cervix 40 is collected into the amniotic fluid collecting bag 50. Thereby, the amniotic fluid that obtained by this present invention can process the same characteristics as that taken using the needle, which is directly inserted into the uterus through the abdomen of the pregnant woman.

In the first embodiment of the present invention, the amniotic fluid collecting unit 60 shows that the number of cylindrical contact guides 63, which extend from the O-ring shaped handle 65 in one direction, is two. However, as illustrated in FIGS. 6 and 7, the number of cylindrical contact guides 63 can be changed to another number, for instance, three or four. In addition, the shape of the contact guide 63 can be changed to one of various other shapes.

Since a variety of tests can be performed on the pregnant woman and her fetus using the amniotic fluid

obtained and collected in this way, the amniotic fluid collecting unit can not only significantly decrease the pain and anxiety in the pregnant woman, compared to the case where the amniotic fluid is taken using the needle that is directly inserted into the uterus through the abdomen of the pregnant woman, but also be free from the risk of the outbreak of complications and medical accidents, which may take place upon the direct insertion of the needle into the uterus.

At this time, the amniotic fluid collecting bag 50 is preferably formed of a material harmless to the body, such as natural rubber or urethane, because it is inevitably in contact with the linings of the cervix 40 and the vagina 47 of the pregnant woman.

Further, the amniotic fluid collecting bag 50 is preferably made of a hydrophilic material such that the mouth 53 thereof can be in close contact with the end of the external orifice of the cervix 40 in a desired shape.

Meanwhile, in the second embodiment of the present invention, as illustrated in FIGS. 8 and 9, in order to collect the amniotic fluid passed through the external orifice 45 of the cervix 40 of the pregnant woman, an amniotic fluid collecting unit 70 (see FIG. 9) is adapted to bring a mouth 53, which is foldably formed at the upper end of an amniotic fluid collecting bag 50, into close contact with an end of the external orifice of the cervix

40 using a contact guide 73. Thereby, the amniotic fluid can be collected into the amniotic fluid collecting bag 50.

At this time, the amniotic fluid collecting unit 70 preferably has a hollow cylindrical shape.

5 Now, the process of collecting the amniotic fluid will be described in detail.

First, the contact guide 73, which is located at an upper end of the amniotic fluid collecting unit 70, is contacted with and fixed to the folded mouth 53 of the amniotic fluid collecting bag 50 in an inner circumferential direction.

The amniotic fluid collecting unit 70 is inserted into the orifice 49 of the vagina, and thereby the contact guide 73 comes into contact with the end of the external orifice of the cervix 40 via the vagina 47.

The mouth 53 of the amniotic fluid collecting bag 50, which is in contact with the end of the external orifice of the cervix 40 in a circumferential direction, is further pushed in an upward direction using a lower end of the amniotic fluid collecting unit 70, so that the mouth 53 is uniformly expanded by the contact guide 73 of the amniotic fluid collecting unit 70, and thus is brought into close contact with the end of the external orifice of the cervix 40 in a desired shape.

25 Thus, the amniotic fluid passed through the external orifice 45 of the cervix 40 is collected into the amniotic

fluid collecting bag 50. Thereby, amniotic fluid that obtained by this present invention can produce the same characteristics as that taken using the needle, which is directly inserted into the uterus through the abdomen of
5 the pregnant woman.

Since a variety of tests can be performed on the pregnant woman and her fetus using the amniotic fluid obtained and collected in this way, the amniotic fluid collecting unit can not only significantly decrease the
10 pain and anxiety in the pregnant woman, compared to the case where the amniotic fluid is taken using the needle that is directly inserted into the uterus through the abdomen of the pregnant woman, but also be very free from the risk of complications and medical accidents, which may
15 take place upon the direct insertion of the needle into the uterus.

The amniotic fluid collecting bag 50 is preferably formed of a material harmless to the body, such as natural rubber or urethane, because it is inevitably in contact
20 with the linings of the cervix 40 and the vagina 47 of the pregnant woman.

Further, the amniotic fluid collecting bag 50 is preferably made of a hydrophilic material such that the mouth 53 thereof can be in close contact with the end of
25 the external orifice of the cervix 40 in a desired shape.

Although the exemplary embodiments of the present

invention have been disclosed for illustrative purposes, those skilled in the art will appreciate that various modifications, additions and substitutions are possible, without departing from the scope and spirit of the
5 invention as disclosed in the accompanying claims.

[CLAIMS]**[Claim 1]**

An apparatus for collecting amniotic fluid from the uterus, comprising:

- 5 an amniotic fluid collecting bag (50), which is provided at a lower end of the external orifice (45) of the cervix (40) so as to collect the amniotic fluid from the uterus through the external orifice of the cervix (40); and
- 10 an amniotic fluid collecting unit (60), which brings the amniotic fluid collecting bag (50) into close contact with the lower end of the external orifice of the cervix (40).

[Claim 2]

- 15 The apparatus according to claim 1, wherein the amniotic fluid collecting bag (50) includes a mouth (53), which is folded at a predetermined length at an upper end thereof so as to be in close contact with the lower end of the external orifice of the cervix (40).

[Claim 3]

- 20 The apparatus according to claim 1 or 2, wherein the amniotic fluid collecting unit (60) expands the mouth (53) so as to cause the amniotic fluid collecting bag (50) to be in close contact with the lower end of the external orifice of the cervix (40).

【Claim 4】

The apparatus according to claim 3, wherein the amniotic fluid collecting bag (50) is made of a material harmless to the human body, which is selected from natural
5 rubber and urethane.

【Claim 5】

The apparatus according to claim 3, wherein the mouth (53) of the amniotic fluid collecting bag (50) is made of a hydrophilic material.

10 【Claim 6】

The apparatus according to claim 3, wherein the amniotic fluid collecting unit (60) includes a cylindrical contact guide (63), which extends from a handle (65) having an O-ring shape in one direction.

15 【Claim 7】

The apparatus according to claim 6, wherein the contact guide (63) is plural in number.

【Claim 8】

An apparatus for collecting amniotic fluid from the
20 uterus, comprising:

an amniotic fluid collecting bag (50), which includes

a mouth, which is folded at a predetermined length at an upper end thereof so as to be in close contact with a lower end of the external orifice (45) of the cervix (40) in order to collect the amniotic fluid from the uterus through
5 the external orifice of the cervix (40); and

an amniotic fluid collecting unit (70), which expands the mouth (53) so as to bring the amniotic fluid collecting bag (50) into close contact with the lower end of the external orifice of the cervix (40).

10 **【Claim 9】**

The apparatus according to claim 8, wherein the amniotic fluid collecting bag (50) is made of a material harmless to the human body, which is selected from natural rubber and urethane.

15 **【Claim 10】**

The apparatus according to claim 8 or 9, wherein the mouth (53) of the amniotic fluid collecting bag (50) is made of a hydrophilic material.

【Claim 11】

20 The apparatus according to claim 8, wherein the amniotic fluid collecting unit (70) has a hollow cylindrical shape.

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Figures
Fig. 1

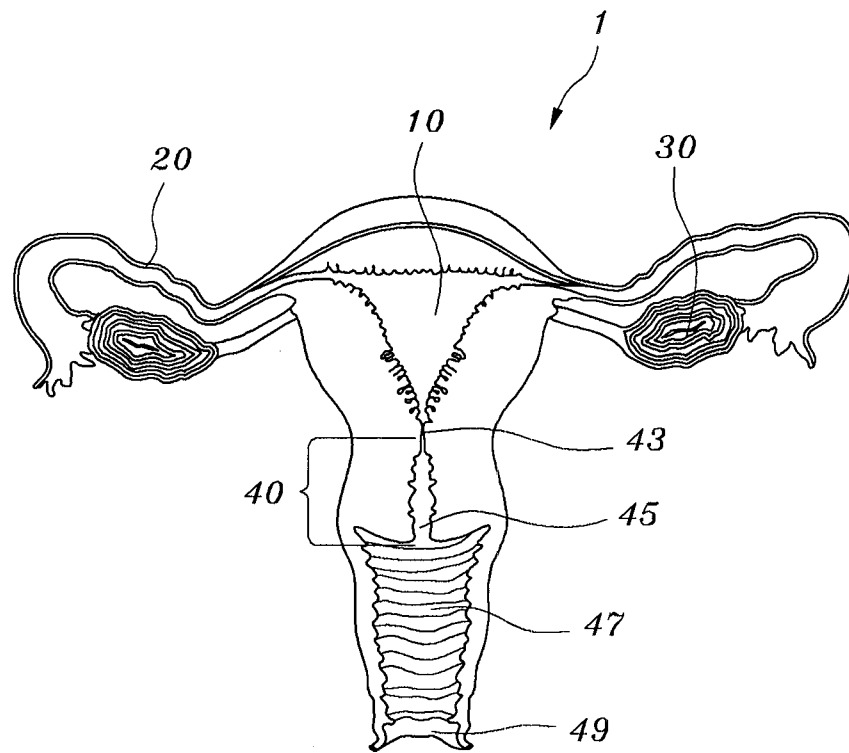
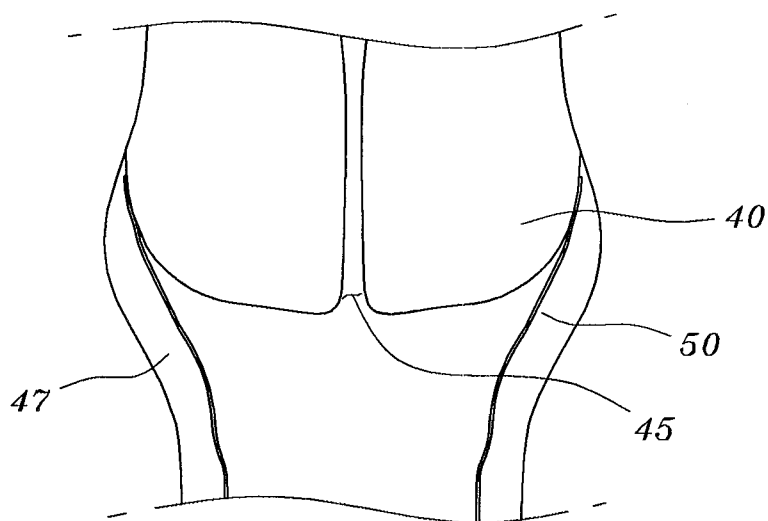


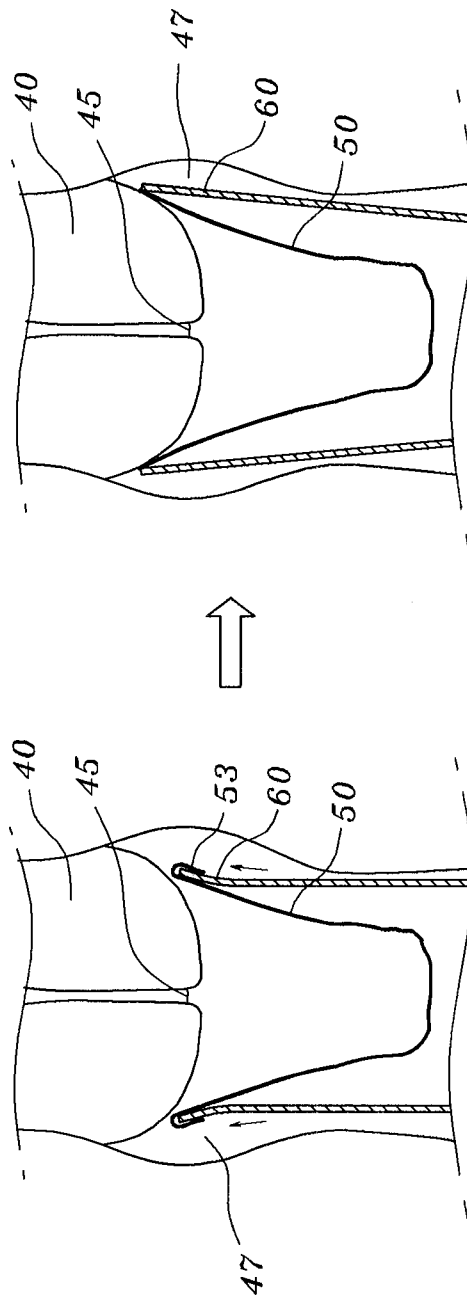
Fig. 2



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Figures

Fig. 3



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Figures
Fig. 4

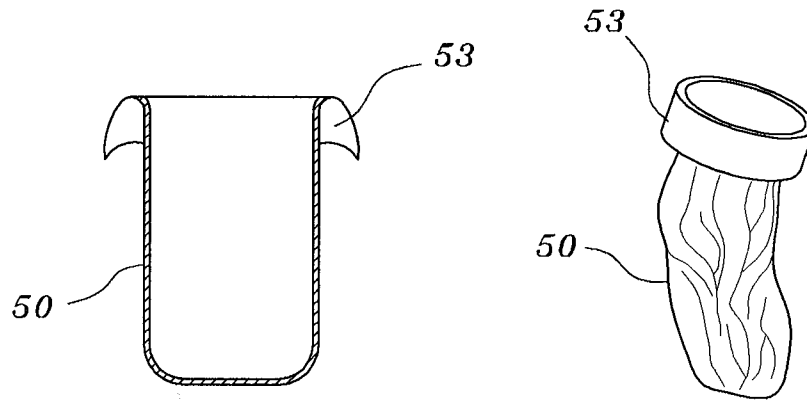
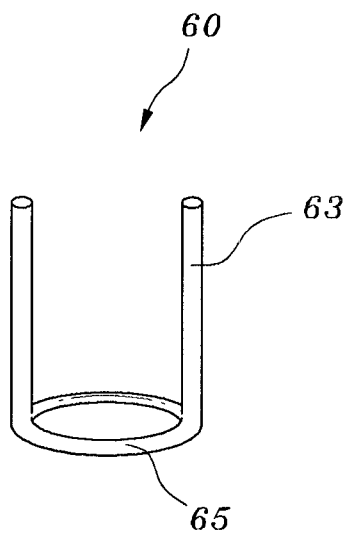


Fig. 5



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Figures

Fig. 6

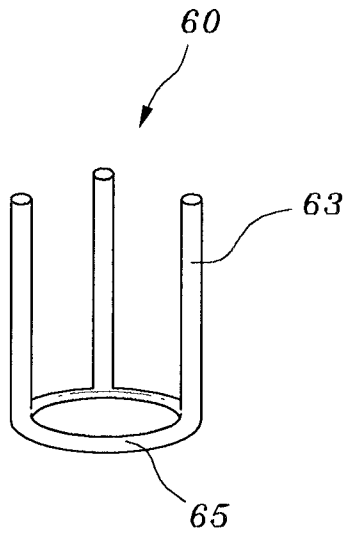
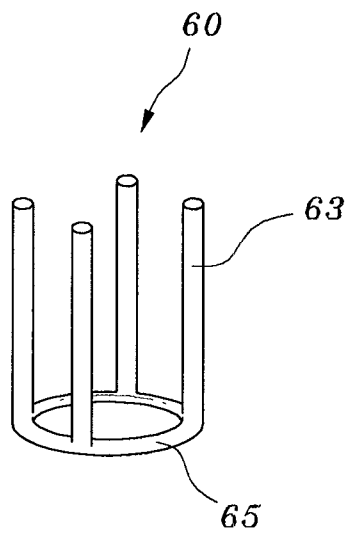


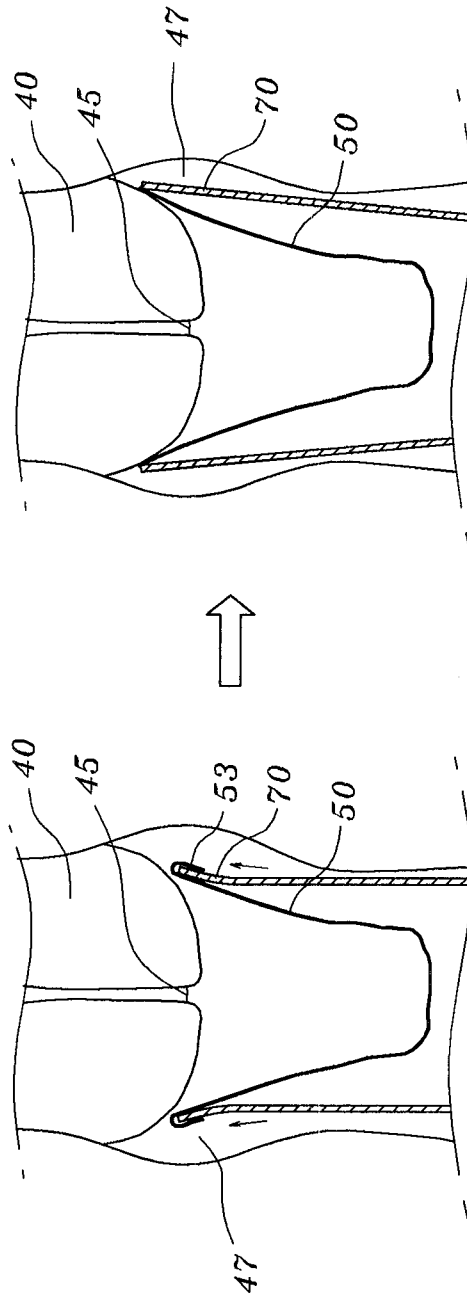
Fig. 7



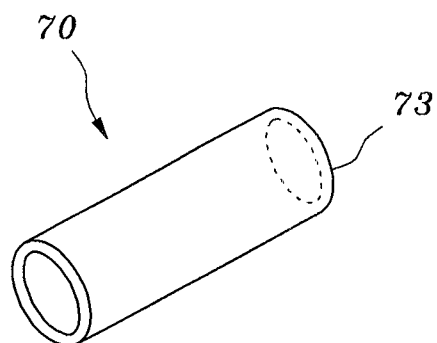
5/6

Figures

Fig. 8



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Figures
Fig. 9



INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR2008/000031**A. CLASSIFICATION OF SUBJECT MATTER****A61B 17/50(2006.01)i**

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)

IPC 8 :A61B 17/50, A61B 17/42, A61F 2/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
N.A.Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKIPASS, WPI, USPTO, PAJ "obstetrical, foetal membrane, amniotic fluid, collecting bag"**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	US4662376 A (BELANGER ROSE-ANGE) 5 May 1987 (05.05.1987) See abstract, pp 3-4, Columns 2-3.	1-11
A	US6206840 B1 (KLAUS ABRAHAM-FUCHS, et. al.) 27 March 2001 (27.03.2001) See Fig.1, Column 2:[30]-[60].	1-11
A	KR1020010110556 A (KIM SANG IL) 13 December 2001 (13.12.2001) See abstract, Figs. 1-7, pp. 3-5.	1-11
A	WO9532672 A1 (PAUL M. REES) 7 December 1995 (07.12.1995) See abstract, Figs.1,5, pp. 7-9.	1-11

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

14 APRIL 2008 (14.04.2008)

Date of mailing of the international search report

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Information on patent family members

International application No.

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