

138852/JH

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Patent Application No.:

New

Applicant:

Nordlandssykehuset

Title:

"Balloon catheter for bulb induction "

The present invention relates to a bulb catheter for bulb induction to induce childbirth. The bulb catheter may be a Prefilled Induction Catheter, (PIC).

5 Some women find the insertion of a bulb / balloon catheter (hereinafter balloon catheter) unpleasant and painful. Furthermore, does the use of traditional balloon catheters involve allowing a portion of the balloon catheter to be on the outside of the vagina, and this portion is typically taped to the thigh. This practice is by some considered as disgraceful and unpleasant. Traditional balloon catheters also appear as typical medical equipment that is considered unappealing by some.

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The invention seeks to simplify and improve equipment used for bulb induction during childbirth and in that way contribute to improve the experience for the mother when giving birth.

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US 2019310707 discloses a method and an apparatus for child-birth monitoring and assistance through stimulation of cervical canal, induction of labor, monitoring and control of reproductive system conditions. An inflatable system with one or more balloons is configured to keep the system in an exact position within woman's reproductive system.

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WO 2018 093883 systems and methods using certain embodiments of a medical device to facilitate childbirth through cervical ripening. An elongated body has a proximal end and a distal end. The distal end terminates in a tip. The tip may be covered by a balloon disposed adjacent to the tip, and an expandable member may be positioned adjacent to the balloon such that when expanded, the expandable member may at least partially cover the balloon, and accommodate the user's finger to guide and place the device through the cervix and into the internal os. Upon expansion of the balloon, pressure is applied to the internal os to facilitate cervical ripening and child birth.

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CN 2133589481 disclose a uterine orifice expansion balloon catheter which can reduce compression of a balloon on a fetus and can restrain damage of the front end of the balloon catheter on an amniotic membrane or the fetus. The balloon

catheter is provided with a main body tube having a predetermined length. A plurality of disc-shaped balloons for enlarging the uterine orifice are provided at predetermined intervals at the front end of the main body tube. The balloons are arranged in series so that the dimensions thereof decrease from the front end of the main body tube toward the rear end side thereof.

It is an aim to reduce the time required to insert the balloon catheter, to reduce the discomfort during implementation and use, to provide a solution without any parts that extend out of the vagina when implemented, that gives an appealing visual impression, that is safe and hygienic, that is easy to operate for the doctor or midwife, that is simple to remove and that reduces the risk of spillage of the saltwater solution.

The present invention is provided to alleviate some of the problems with the prior art and discloses a balloon catheter for balloon induction in connection with childbirth.

The balloon catheter includes a liquid supply tube and a mandrin guide tube extending parallel to the liquid supply tube. A liquid supply connecting portion is attached to a first end of the liquid supply tube. The first end of the liquid supply tube with the liquid supply connecting portion is adapted to be connected to a liquid supply element. An inner balloon with a continuous outer surface apart from a tube connecting portion is in liquid connection with a second end of the liquid supply tube.

The mandrin guide tube and the liquid supply tube may be flexible and foldable.

The mandrin guide tube and the liquid supply tube may be adapted to allow the first end of the mandrin guide tube and the liquid supply tube to be folded and inserted into a vagina of a user.

The mandrin guide tube may be a separate tube with a larger inner diameter than the liquid supply tube, and the liquid supply tube may extend through the mandrin guide tube.

- 5 The tube valve in the form of a liquid supply connecting portion may be a check valve.

The liquid supply connecting portion may include a flexible element with a slit that is normally sealed to prevent fluid from escaping through the liquid supply
10 connecting portion while allowing a tube to be inserted through the slit to inject or withdraw fluid through the flexible element.

The the liquid supply connecting portion ~~tube valve~~ may include an outer sleeve inserted into the first end of the liquid supply tube.

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The the liquid supply connecting portion ~~tube valve~~ may include a penetrable flexible element ~~valve ball~~ projecting out of the outer sleeve, ~~allowing the ball to be manually actuated to open the valve.~~

- 20 The liquid supply element may be a squeezable fluid container with a tube connection.

The tube connection may include a fluid valve that is adapted to open upon connection with the liquid supply tube.

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The balloon catheter may further include a mandrin with a gripping portion and a rod-shaped portion inserted into the mandrin guide tube.

The mandrin may include marking notches to indicate the position of the balloon
30 catheter.

The balloon catheter may further include an inner ball inside the inner balloon, connected to the second end of the liquid supply tube.

The inner ball may be connected to the second end of the liquid supply tube through a guiding tube attached to the the inner ball and extending into the liquid supply tube.

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The inner balloon may include an inner balloon fold along the guiding tube when the inner balloon is in the deflated state to maintain the inner balloon in a compact configuration for insertion before inflation while ensuring enough material for the inner balloon expand.

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The balloon catheter may further include an inner fluid channel extending through the guiding tube and the inner ball.

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~~The inner balloon may include an inner balloon fold along the guiding tube when the inner balloon is in the deflated state to maintain the inner balloon in a compact configuration for insertion before inflation while ensuring enough material for the inner balloon expand.~~

Brief description of the enclosed drawings:

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Fig. 1 is a side view of a balloon catheter of the invention;

Fig. 2 is a top view of the balloon catheter as shown in fig. 1;

Fig. 3 is an end view of the balloon catheter as shown in fig. 1 and 2;

Fig. 4 is a perspective view of a squeezable fluid container;

Fig. 5 is a perspective view of the balloon catheter of the invention;

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Fig. 6 is a perspective view of a mandrin;

Fig. 7 is a cross section of an inner part of a balloon catheter of the invention in an uninflated state; and

Fig. 8 is a cross section of an inner part of a balloon catheter of the invention in an inflated state;

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Fig 9, is a cross section of the squeezable fluid container with the tube connection including the cylindrical friction portion; and

Fig 10, is a perspective view of the squeezable fluid container with the tube connection including the cylindrical friction portion.

Fig. 1 is a side view of a balloon catheter of the invention. A first balloon or squeezable fluid container 1 with a saltwater solution 5 includes a tube connection 3 and a fluid valve 9. A liquid supply tube 7 with a liquid supply connecting portion 8 is releasably connected to the squeezable fluid container 1 in the tube connection 3 at a first end and to an expandable bulb or inner balloon 2 at the other end. The tube connection 3 may include a small tube that may be used to penetrate the liquid supply connecting portion 8 and may include a flexible element 13 with a slit that is normally sealed to prevent fluid from escaping through the liquid supply connecting portion 8 while allowing a tubular portion / small tube to be inserted through the slit to inject or withdraw fluid through the flexible element. A large syringe or rectal syringe with a tubular portion added may be used in place of the squeezable fluid container 1. The mandrin guide tube 4 surrounding the liquid supply tube 7 extends along a portion of the length of the liquid supply tube 7 and serves as a guide for a mandrin 6 with a gripping portion 10 at an end facing the squeezable fluid container 1. The mandrin 6 is slidably installed in the mandrin guide tube 4 and can be pulled out of the mandrin guide tube by pulling the gripping portion 10. The mandrin 6 makes the assembly of the mandrin 6, the liquid supply tube 7 and the mandrin guide tube 4 stiff to facilitate insertion of the inner balloon 2 through the vagina, through the cervix and to a location adjacent the fetus. The mandrin 6 may then be removed and the liquid supply tube 7 and the mandrin guide tube 4 may be folded and inserted into the vagina of the uses to allow the balloon catheter to be completely concealed inside the body. The mandrin 6 and the liquid supply tube 7 are thus flexible and foldable hoses. The squeezable fluid container 1 typically holds 80 ml of the saltwater solution 5. The overall length a of the balloon catheter is typically 206mm and the outer diameter b of the mandrin guide tube 4 is typically 6mm. The liquid supply connecting portion 8 may include a one-way valve allowing the saltwater solution 5 to flow from the squeezable fluid container 1 and into the inner balloon 2 to inflate the inner balloon 2 when the squeezable fluid container 1. The fluid valve 9 seals the squeezable fluid container 1 when the liquid supply tube 7 is pulled out of and released from the tube connection 3 to prevent spillage of any remaining saltwater solution 5 when the squeezable fluid container 1 is removed. The inner balloon 2 is flexible to

allow inflation with the saltwater solution. The inner balloon 2 is designed to accept 80 ml of saltwater solution 5.

Fig. 2 is a top view of the balloon catheter as shown in fig 1. The mandrin 6 extends inside the mandrin guide tube 4, parallel to the liquid supply tube 7. The inner balloon 2 is uninflated and the liquid supply tube 7 is connected to the squeezable fluid container 1. The gripping portion 10 at the end of the mandrin 6 is shaped as a ring, typically dimensioned to allow a finger to extend through the ring to facilitate the pulling of the mandrin 6 out of the mandrin guide tube 4.

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Fig. 3 is an end view of the balloon catheter as shown in fig. 1 and 2, with the squeezable fluid container 1 partly transparent. The diameter d of the squeezable fluid container 1 is typically 60mm. The ring-shaped gripping portion 10 is partly extending above the squeezable fluid container 1.

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Fig. 4 is a perspective view of the squeezable fluid container 1 with the tube connection 3, the fluid valve 9 and a cylindrical friction portion 11 forming a pressure fit with the liquid supply tube. This tube connection is in place of or in addition to the thin tube and the tube connection 3 could involve other types of connections such as a screw connection or a bayonet connection. It is however a major advantage if the liquid supply tube does not include any dedicated connecting element as the liquid supply tube ideally can be folded and inserted into a vagina to avoid any elements extending out of the vagina. Any elements that could cause discomfort or that runs a risk of penetrating the skin should thus be avoided. The squeezable fluid container 1 is typically a disposable container that is supplied prefilled with saltwater solution.

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The squeezable fluid container 1 is typically made of a soft and elastomeric material to allow the squeezable/compressible fluid container to be pressed manually to eject the fluid from the container.

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The fluid valve 9 may be of a type that opens when the tube connecting portion is inserted into the tube connection 3.

Fig. 5 shows the balloon catheter of the invention without the squeezable fluid container and with the inner balloon 2 inflated. The inner balloon is connected to the liquid supply tube 7 at a tube connecting portion 14. The balloon 2 thus represents the outer end portion of the balloon catheter and has a smooth outer surface. The balloon catheter thus has no protruding elements beyond the balloon 2, and the liquid supply tube 7 or the mandrin does not extend through the inner balloon 2. The mandrin is withdrawn from the mandrin guide tube 4. The liquid supply connecting portion 8 may include an outer sleeve 15 that also serves to produce a stiffened tube connecting portion 12 forming a press fit with the tube connection of the squeezable fluid container. The liquid supply connecting portion 8 may include a check valve/one-way valve in place of a penetrable flexible element 13 and may include an outer sleeve 15. The penetrable flexible element 13 projects from the outer sleeve 15 to enable the penetrable flexible element 13 to be penetrated with a tubular object to deflate the inner balloon 2 (for instance for cessation of the treatment). The outer sleeve 15 is pressed into the liquid supply tube 7 and the soft material of the liquid supply tube 7 will seal against the cylindrical friction portion of the tube connection of the squeezable fluid container.

The balloon is typically made of an elastomeric material with a considerable elasticity to enable the balloon to expand to the required size.

Fig. 6 is a perspective view of the mandrin 6 with the ring-shaped gripping portion 10 and the rod-shaped portion 17. Indentations or marking notches 16 indicates how far the mandrin 6 is pulled out of the Mandrin guide tube 4. The marking notches 16 can also be seen or felt through the Mandrin guide tube and can be used to and how far in the balloon catheter is inserted. The mandrin 6 is typically made of a relatively stiff plastic material.

Fig 7 is a perspective view of a cross section of an inner end of a balloon catheter of the invention. The inner balloon 2 is uninflated and is located on the outside of an inner ball 19 secured to a guiding tube 20. An inner fluid channel 22 extends through the inner ball 19 and the guiding tube 20. The guiding tube 20 extends into the liquid supply tube 7. The inner balloon 2 includes an inner balloon fold 18 to

maintain the inner balloon 2 in a compact configuration for insertion before inflation while ensuring enough material for the balloon. The inner ball 19 provides a smooth outer surface of the inner balloon 2 before it is inflated to reduce discomfort during insertion while the risk of puncturing the balloon is reduced. The inner ball also forms a guide and a reinforcement, making it easier to enter cervix. The inner ball does not have to be completely round but could also for instance have a slightly elongated shape or tapered shape.

A mandrin end stop 21 at the end of the mandrin guide tube 4 ensures that the mandrin not extends out of the mandrin guide tube 4 and that the mandrin is effective for inserting the balloon catheter.

Fig. 8 corresponds to fig. 7 but shows the inner balloon 2 in an inflated state and a major part of the inner balloon 2 is no longer in contact with the inner ball 19. The inner balloon 2 is inflated with liquid through the inner fluid channel 22 in the inner ball 19 and the guiding tube 20. The guiding tube 20 ensures that the assembly of the balloon catheter and the mandrin forms a stiff assembly at the inner end to facilitate insertion.

Fig 9, is a cross section of the squeezable fluid container 1 with the tube connection 3 including the cylindrical friction portion 11. The penetrable flexible element 13 is inserted into the liquid supply tube 7 and forms the tube connecting portion 12 extending into the cylindrical friction portion 11 to hold the squeezable fluid container 1 to the liquid supply tube 7 and to reinforce the transition between the two. A connecting tube 23 with a pointed end 24 extends through the penetrable flexible element 13 to allow the squeezable fluid container 1 to fill or drain the balloon catheter. The penetrable flexible element 13 seals the liquid supply tube 7 when the connecting tube 23 is pulled out of the penetrable flexible element 13. The tube connecting portion 12 extending into the cylindrical friction portion 11 reduces the stresses on the connecting tube 23 when the squeezable fluid container 1 is in use. The penetrable flexible element 13 inserted into the liquid supply tube 7 in combination with the cylindrical friction portion 11 reduces the risk of kinking the liquid supply tube 7.

- Fig 10, is a perspective view of the squeezable fluid container 1 with the tube connection 3 including the cylindrical friction portion 11, and the connecting tube 23 with the pointed end 24. The connecting tube 23 is typically a blunt plastic tube.
- 5 The pointed end 24 facilitates connection of the squeezable fluid container 1 to the balloon catheter. The plastic connecting tube 24 is considered to be safe and prevents inadvertently stabbing the patient, the personnel or puncturing the inner balloon. It is thus an advantage not using a hypodermic needle.
- 10 The balloon catheter for bulb induction of the invention may be an inexpensive and disposable / recyclable balloon catheter to ensure ease of use and good hygiene. The present invention does not exclude a further liquid tube extending in parallel to the liquid supply tube to facilitate draining and deflation of the inner balloon.

1	Squeezable fluid container	13	Penetrable flexible element
2	Inner balloon	14	Tube connecting portion
3	Tube connection	15	Outer sleeve
4	Mandrin guide tube	16	Marking notches
5	Saltwater	17	Rod shaped portion
6	Mandrin	18	Fold of inner balloon
7	Liquid supply tube	19	Inner ball
8	Tube valve/ <u>liquid supply connecting portion</u>	20	Guiding tube
9	Fluid valve	21	Mandrin end stop
10	Gripping portion	22	Inner fluid channel
11	Cylindrical friction portion	23	Connecting tube
12	Tube connecting portion	24	Pointed end

CLAIMS

1. A balloon catheter for balloon induction in connection with childbirth comprising:
a liquid supply tube (7);
5 a mandrin guide tube (4) extending parallel to the liquid supply tube (7);
a liquid supply connecting portion (8) attached to a first end of the liquid supply tube (7), and wherein the first end of the liquid supply tube (7) with the liquid supply connecting portion (8) is adapted to be connected to a liquid supply element; and
10 an inner balloon (2) adapted to accommodate a deflated mode and an expanded liquid filled mode, and with a continuous outer surface apart from a tube connecting portion (14) in liquid connection with a second end of the liquid supply tube (7).
- 15 2. The balloon catheter of claim 1, wherein the mandrin guide tube (4) and the liquid supply tube (7) are flexible and foldable, whereby the mandrin guide tube (4) and the liquid supply tube (7) are adapted to allow the first end of the mandrin guide tube (4) and the liquid supply tube (7) to be folded and inserted into a vagina of a user.
- 20 3. The balloon catheter of claim 1, wherein the mandrin guide tube (4) is a separate tube with a larger inner diameter than the liquid supply tube (7); and wherein the liquid supply tube (7) extends through the mandrin guide tube (4).
- 25 4. The balloon catheter of claim 1 or 2, wherein the liquid supply connecting portion (8) is a check valve.
- 30 5. The balloon catheter of claim 1 or 2, wherein the liquid supply connecting portion (8) includes a flexible element (13) with a slit that is normally sealed to prevent fluid from escaping through the liquid supply connecting portion (8) while allowing a tube to be inserted through the slit to inject or withdraw fluid through the flexible element (13).

6. The balloon catheter of one of claims 1-3, wherein the liquid supply connecting portion (8) includes an outer sleeve (15) inserted into the first end of the liquid supply tube (7).

5 7. The balloon catheter of claim 4, wherein the liquid supply connecting portion (8) includes a penetrable flexible element (13) projecting out of the outer sleeve (15).
~~allowing the ball to be actuated to open the valve.~~

10 ~~6~~8. The balloon catheter of any of the preceding claims, wherein the liquid supply element is a squeezable fluid container (1) with a tube connection (3).

~~7~~9. The balloon catheter of claim 8, wherein the tube connection (3) includes a fluid valve (9) that is adapted to open upon connection with the liquid supply tube (7).

15 ~~8~~10. The balloon catheter of any of the preceding claims, further including a mandrin (6) with gripping portion (10) and a rod-shaped portion (17) inserted into the mandrin guide tube (4).

20 ~~9~~11. The balloon catheter of claim ~~8~~10, wherein the mandrin (6) includes marking notches (17) to indicate the position of the balloon catheter.

25 ~~40~~12. The balloon catheter of any of the preceding claims, further including an inner ball (19) inside the inner balloon (2), connected to the second end of the liquid supply tube (7).

~~41~~13. The balloon catheter of claim ~~9~~12, wherein the inner ball (19) is connected to the second end of the liquid supply tube (7) through a guiding tube (20) attached to the the inner ball (19) and extending into the liquid supply tube (7).

30 ~~42~~14. The balloon catheter of claim ~~41~~13, wherein the inner balloon (2) includes an inner balloon fold (18) along the guiding tube (20) when the inner balloon (~~48~~2) is in the deflated state to maintain the inner balloon (2) in a compact configuration

for insertion before inflation while ensuring enough material for the inner balloon (2) to expand.

5 | ~~13~~15. The balloon catheter of claim ~~14~~12, further including an inner fluid channel (22) extending through the guiding tube (20) and the inner ball (19).

1. Ballongkateter for ballonginduksjon brukt i forbindelse med fødsel omfattende:
et væsketilførselsrør (7);
et mandrengføringsrør (4) som strekker seg parallelt med væsketilførselsrøret (7);
en væsketilførsels-forbindelsesdel (8) festet til en første ende av
5 væsketilførselsrøret (7), og hvori den første enden av væsketilførselsrøret (7) med
væsketilførsels-forbindelsesdelen (8) er tilpasset til å kobles til et væsketilførsels-
element; og
en indre ballong (2) tilpasset for å kunne innta en deflatert modus og en utvidet
væskefylt modus, og som innehar en kontinuerlig ytre overflate bortsett fra en
10 rørforbindelsesdel (14) i væskeforbindelse med en andre ende av væsketilførsels-
røret (7).

2. Ballongkateter ifølge krav 1, hvori mandrengføringsrøret (4) og
væsketilførselsrøret (7) er fleksible og sammenbrettbare, hvorved
15 mandrengføringsrøret (4) og væsketilførselsrøret (7) er tilpasset for å tillate at den
første enden av mandrengføringsrøret (4) og væsketilførselsrøret (7) kan brettes
og settes inn i en brukers vagina.

3. Ballongkateter ifølge krav 1, hvori mandrengføringsrøret (4) er et separat rør
20 med en større indre diameter enn væsketilførselsrøret (7); og
hvori væsketilførselsrøret (7) strekker seg gjennom mandrengføringsrøret (4).

4. Ballongkateter ifølge krav 1 eller 2, hvori væsketilførsels-forbindelsesdelen (8)
er en tilbakeslagsventil.

25 5. Ballongkateter ifølge krav 1 eller 2, hvori væsketilførsels-forbindelsesdelen (8)
inkluderer et fleksibelt element (13) med en spalte som normalt er tett for å hindre
fluid fra å unnslippe gjennom væsketilførsels-forbindelsesdelen (8) mens den
tillater at et rør kan føres inn gjennom spalten for å injisere eller trekke ut væske
30 gjennom det fleksible elementet (13).

6. Ballongkateter ifølge ett av kravene 1-3, hvori væsketilførsels-forbindelsesdelen (8) inkluderer en ytre hylse (15) innført i den første enden av væsketilførselsrøret (7).

5 7. Ballongkateter ifølge krav 4, hvori væsketilførsels-forbindelsesdelen (8) inkluderer et gjennomtrengelig, fleksibelt element (13) som stikker ut av den ytre hylsen (15).

8. Ballongkateter ifølge hvilket som helst av de foregående kravene, hvori
10 væsketilførselselementet er en sammenklembar væskebeholder (1) med en rørforbindelse (3).

9. Ballongkateter ifølge krav 6, hvori rørforbindelsen (3) inkluderer en fluidventil (9) som er tilpasset til å åpne ved forbindelse med væsketilførselsrøret (7).

15 10. Ballongkateter ifølge et hvilket som helst av de foregående kravene, videre innbefattende en mandreng (6) med gripedel (10) og en stavformet del (17) innført i mandrengføringsrøret (4).

20 11. Ballongkateter ifølge krav 8, hvori mandrengen (6) inkluderer markør-hakk (17) for å indikere posisjonen til ballongkateteret.

12. Ballongkateter ifølge hvilket som helst av de foregående kravene, videre innbefattende en indre kule (19) inne i den indre ballongen (2), forbundet med den
25 andre enden av væsketilførselsrøret (7).

13. Ballongkateter ifølge krav 10, hvori den indre kulen (19) er koblet til den andre enden av væsketilførselsrøret (7) gjennom et føringsrør (20) festet til den indre kulen (19) og som strekker seg inn i væsketilførselsrøret (7).

30 14. Ballongkateter ifølge krav 13, hvori den indre ballongen (2) inkluderer en indre ballongfold (18) langs føringsrøret (20) når den indre ballongen (2) er i deflatert tilstand for å opprettholde den indre ballongen (2) i en kompakt konfigurasjon for

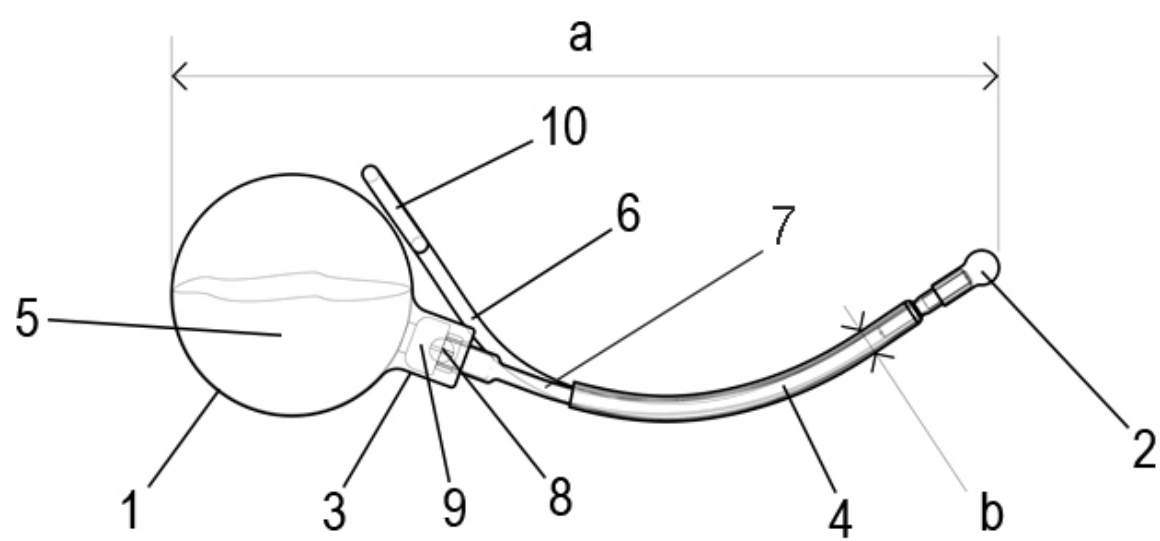
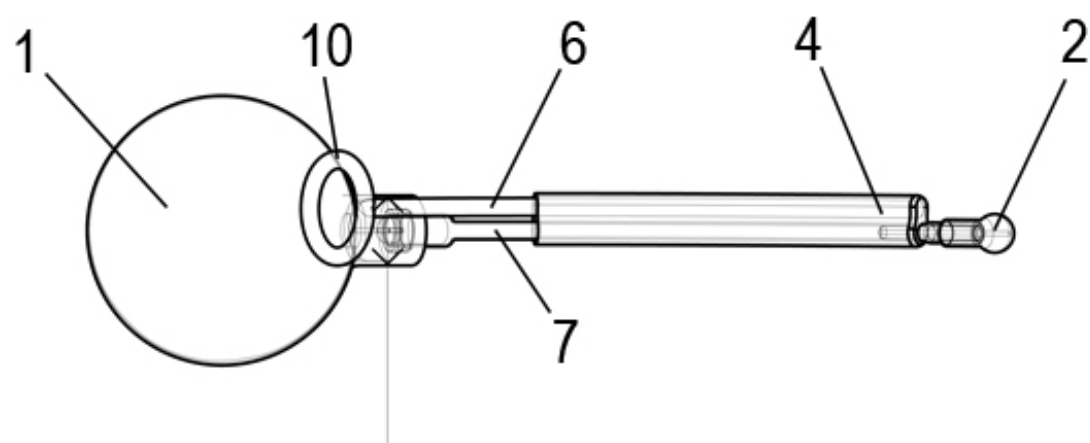
innsetting før oppblåsing samtidig som det sikres nok materiale til at den indre ballongen (2) kan utvide seg.

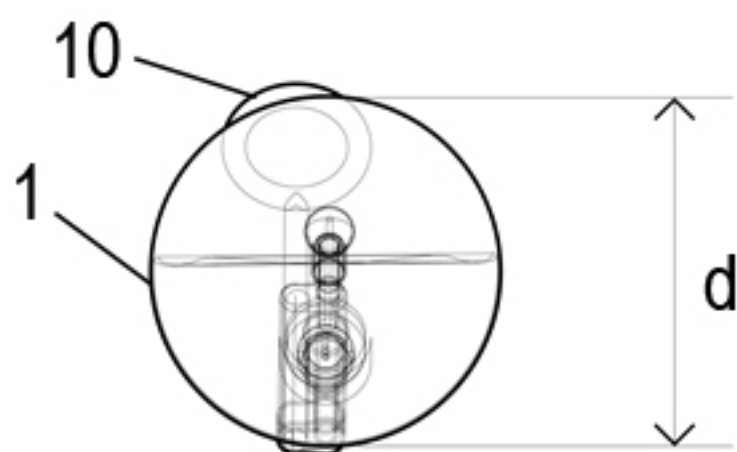
- 5 15. Ballongkateter ifølge krav 12, videre omfattende en indre fluidkanal (22) som strekker seg gjennom føringsrøret (20) og den indre kulen (19).

ABSTRACT

The present invention relates to a balloon catheter used in connection with childbirth. The balloon catheter includes a liquid supply tube 7 and a mandrin guide tube 4 extending parallel to the liquid supply tube 7. A liquid supply connecting portion 8 is connected to a first end of the liquid supply tube 7, and the first end of the liquid supply tube 7 with the liquid supply connecting portion 8 is adapted to be connected to a liquid supply element. An inner balloon 2 with a continuous outer surface apart from a tube connecting portion 14 is connected to a second end of the liquid supply tube 7. The mandrin guide tube 4 and the liquid supply tube 7 are flexible and foldable allowing the first end of the mandrin guide tube 4 and the liquid supply tube 7 to be folded and inserted into a vagina of a user.

Fig. 1

**Fig. 1****Fig. 2**

**Fig. 3****Fig. 4**

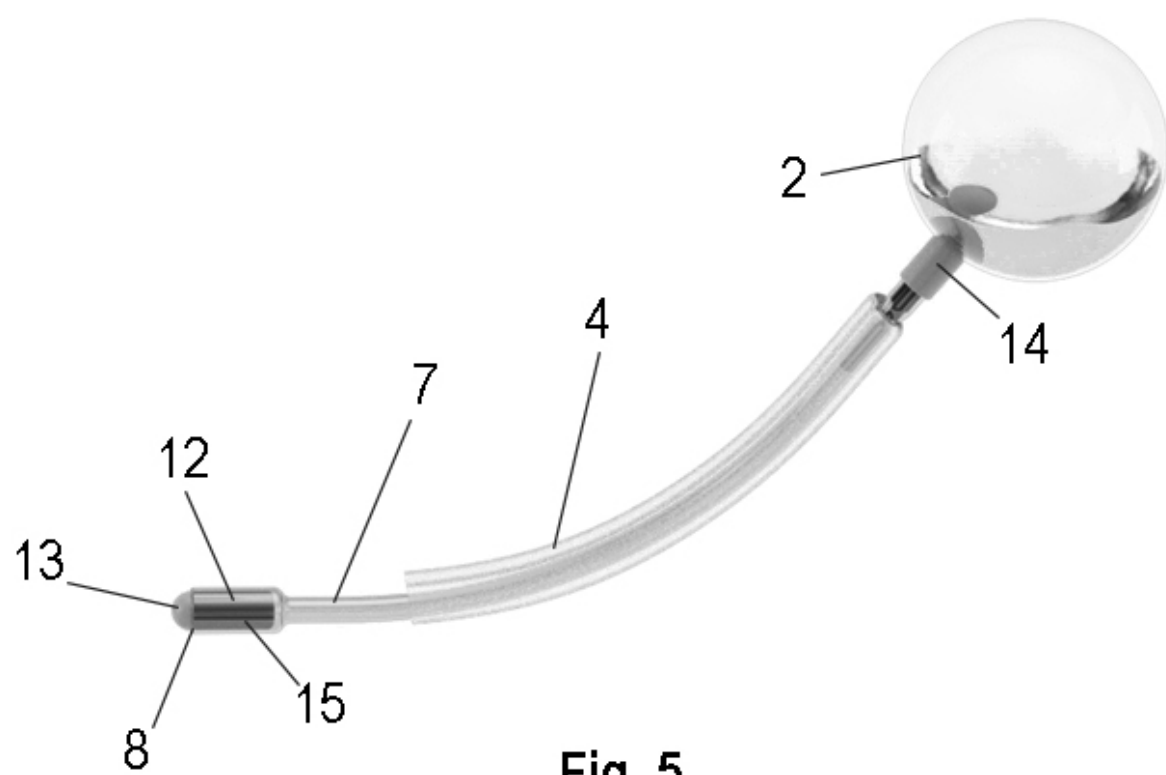
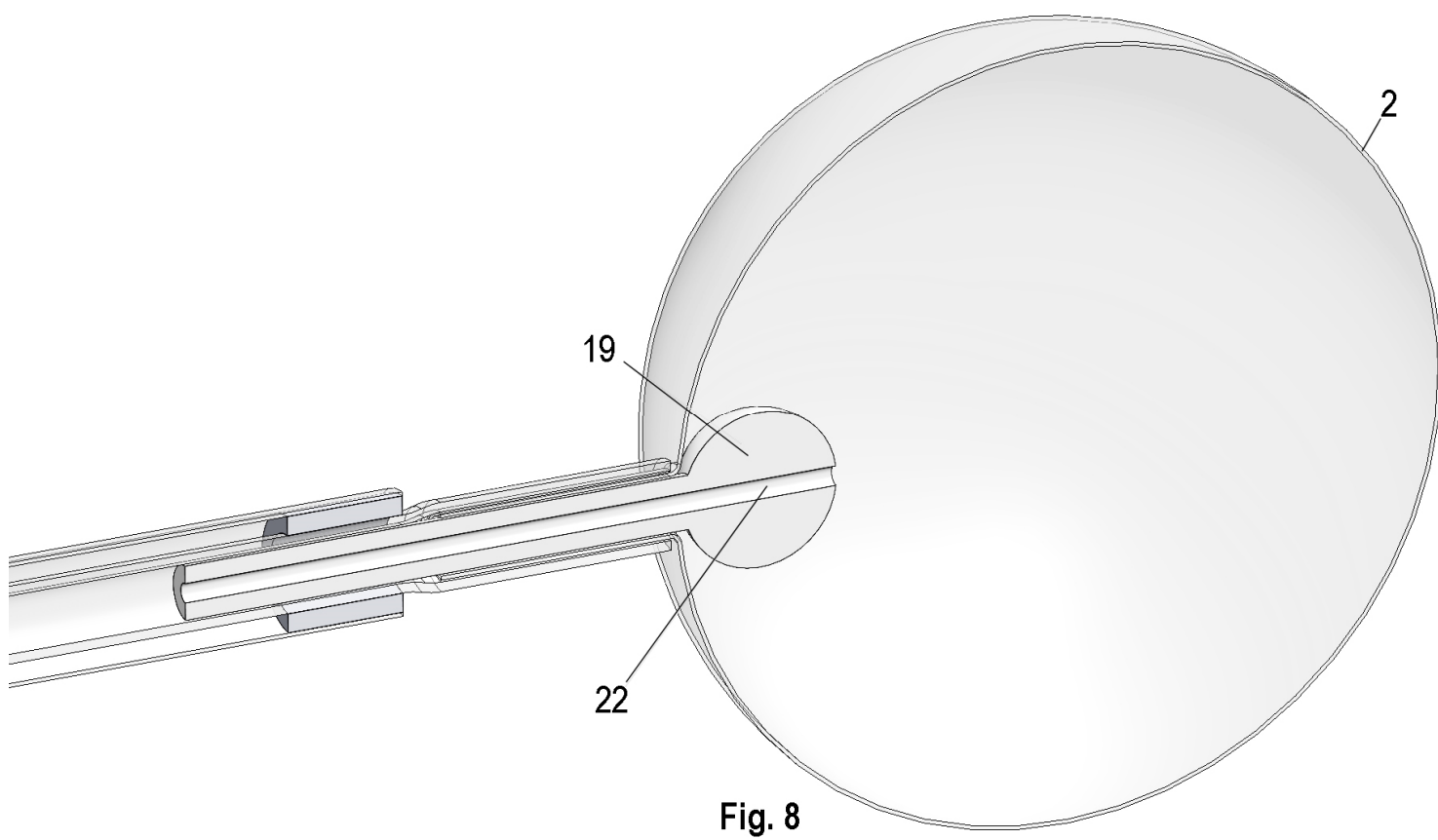
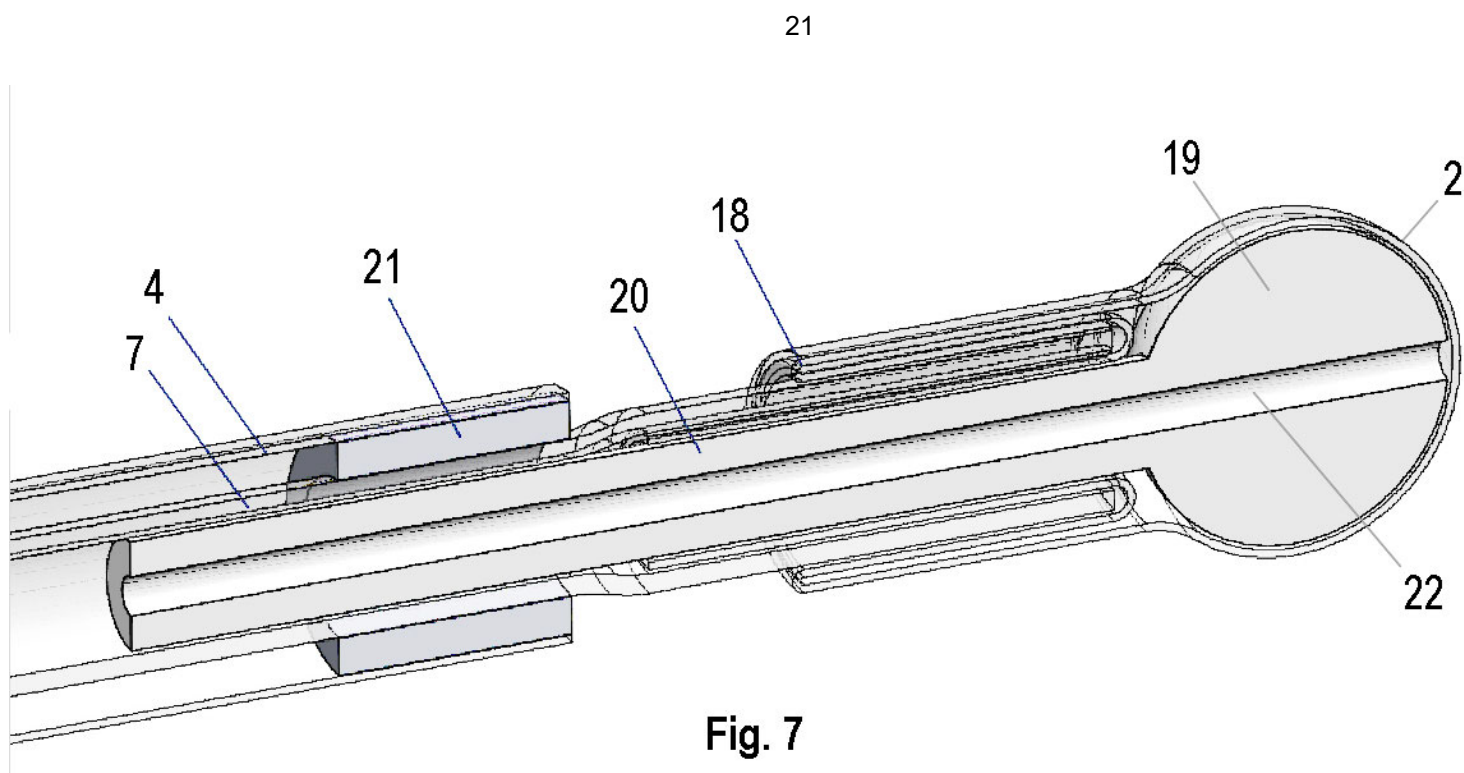


Fig. 5



Fig. 6



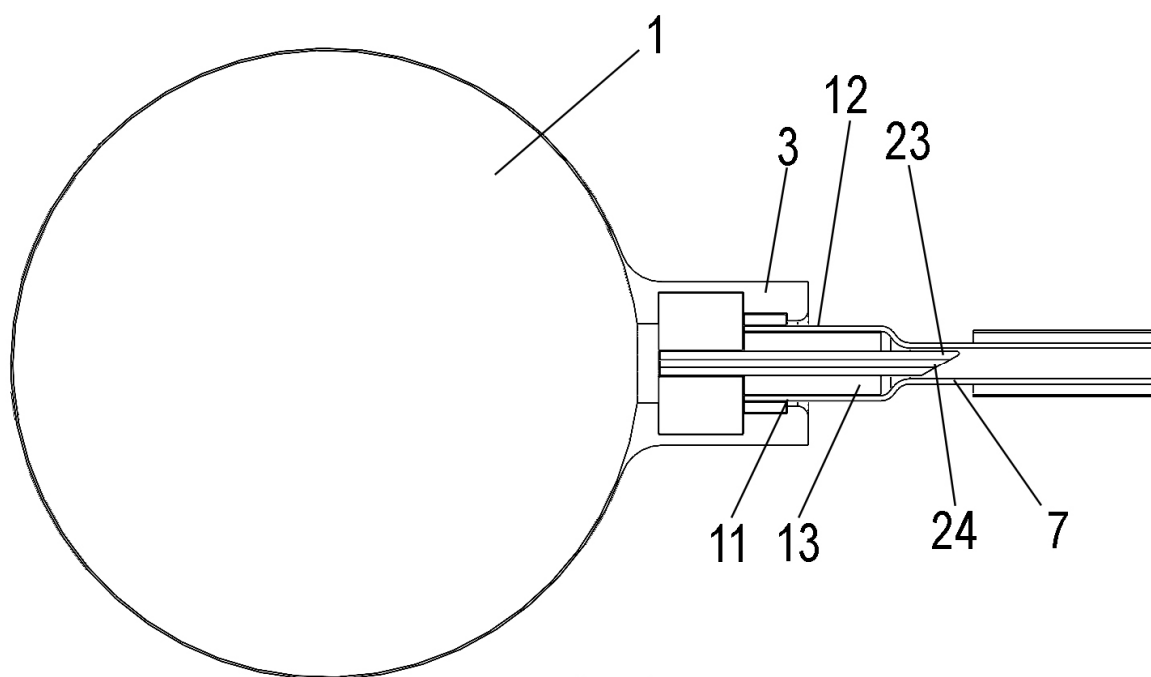


Fig. 9

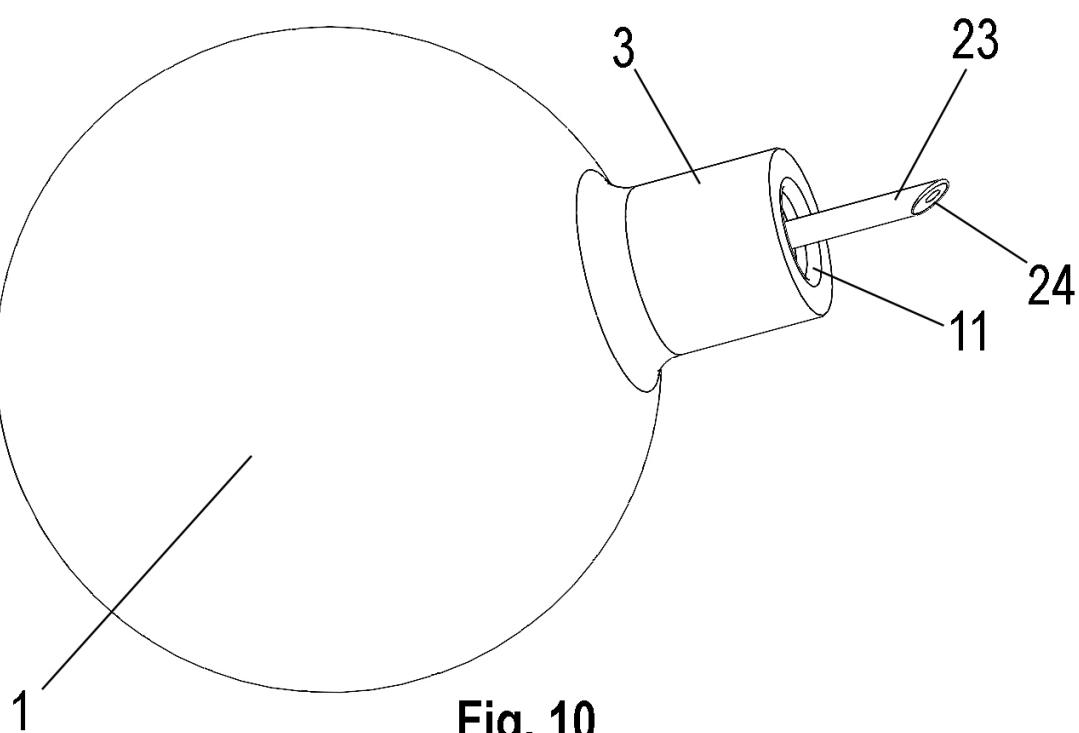


Fig. 10