

DEVICE FOR THE PREPRATION AND FACILITATION OF GIVING BIRTH AND EXERCISE METHOD FOR PREPARING TO GIVE BIRTH

5 The present invention relates to a device and method for helping
a pregnant women to prepare for giving birth and to make giving birth
easier.

10 In Germany, there are approximately 850,000 births per year.
According to the most recent available perinatal statistics of 1995, the
rate of episiotomy, among both first time and subsequent births, was a
total of 58.9% (less the rate of cesarean section of 17.4%). This means
that approximately 500,650 episiotomies are carried out yearly in
Germany (Commission for Perinatology and Neonatology, BPE Annual
Report 1995). In about 20% of all births a tear in the perineum occurs
15 as a result of which the risk of death due to complications is further
increased. In spite of numerous traditional and modern methods for
preparing and for facilitating giving birth (e.g. Leboyer, Read, Odent),
the mentioned statistics remain unchanged in relation to one another
after decades. Even the new age pregnancy exercises to prepare for
20 giving birth and the pregnancy consultation of midwives have only
improved these figures unsubstantially.

25 The episiotomy, first described by Ould in 1742, still conjures up
a horrible image even after 250 years. Although, it was proposed and
carried out as a relief for women and to accelerate delivery, it is still
feared by many women to this day due to its painfulness, and it is hated
for its negative consequences. Avoidance of the episiotomy has
therefore been a long felt need in the field along with the goal to make
the delivery easier for mothers with less fear involved.

30 An additional problem of modern birthing assistance is the
increasing disproportion between the fetal/infant head and the female
pelvis. The cranial circumference of newborns is steadily increasing
such that the measurement program established by Hausmann for the
standard size of the biparietal diameter using ultrasound must be
continuously upwardly corrected. The cause for this might be seen, on
35 the one hand, to be the result of increasing exposure of pregnant women
to light, noise, and other stimulation (for example neon lights, electro
smog, car noise, etc...), and on the other hand, due to the natural,



modern androgenous type of woman (tall, narrow female pelvis and narrow hips) which naturally makes giving birth more difficult.

It is known for treating sedimentation of the blood and incontinence problems in women to insert an inflatable balloon deep
5 into the vagina in order to provide, in the inflated state, a mechanical blockage of the bladder while raising the uterus. For example, European Patent publication EP 0,663,197 A1 describes a support body which keeps its shape and is made of elastic rubber material with areas of different wall thickness which expands conically from a base region
10 in the direction of a top surface at the opposite end of the support body in a conical manner, a piece of hose being sealingly connected to the base region. The top surface is reinforced in a ring-shape and has a soft concavely formed inner region. The support body is inserted into the vagina with the base downward and is left in place for hours to support
15 the vaginal wall.

U.S. Patent 3,626,949 describes a cervical dilator which has not however achieved any significant success in practice. It discloses a PVC container having a hose connection for filling up the case with a fluid under pressure. The container can be inserted into the cervical
20 canal while folded up and is then periodically expanded under pressure such that the case expands radially against the cervical wall to thereby simulate contractions. Between opposed ends of the container there is a waist portion which is not expandable in a radial direction, which waist portion is positioned inside the edge of the cervix in order to prevent
25 that the expanded waist portion moves in an axial direction under pressure.

It is the object of the present invention to avoid as much as possible episiotomies and tearing in the perineum, to reduce surgical intervention during delivery, to minimize fear of giving birth and to
30 lower the incidence of death during delivery. Associated therewith, an undesired drop in the pelvic floor, and later occurrences of bladder incontinence and sexual disturbance as a result of physiological and psychosomatic complications occurring post-partum can be prevented.

This object is provided by a device having the characteristics of
35 claim 1 as well as a method having the characteristics of claim 14.

The device according to the invention comprises an expandable elongated shaped body which is positionable in the region of the vaginal



orifice such that it is located partway inside the vagina and partway outside the vagina. By the expansion of the elongated body, the vagina can be substantially expanded and the birth canal as well as the vaginal orifice can be expanded in advance to facilitate giving birth. With this
5 training and stretching effect, episiotomies as well as an undesirable drop in the pelvic floor can be avoided to a large extent along with complications associated therewith. The expandable body maintains its distance from the cervix which it should never contact in order avoid irritations.

10 By shaping the expandable elongated body such that the shape facilitates its positioning in the area of the vaginal orifice, the device is self-centering in the region of the vaginal orifice and self-anchoring. This can be achieved for example by shaping the body as a figure 8 in its lengthwise axis. It is essential that the expandable body is
15 expandable in its entirety (i.e. the whole shape expands), since specifically the expansion in the area of the vaginal orifice is to be exercised.

In accordance with a preferred embodiment, it is provided that the body is expandable by means of a variable fluid filling system. The
20 fluid can be for example a gel or an aqueous liquid which may be temperature controlled if need be, or the fluid may be a gas such as air. In particular cases, air pressure provided by blowing with the mouth may be used. Also preferably, the body may be formed as a balloon having a filling tube connected to an end which during use is oriented
25 externally. Latex or a silicone product are examples of skin compatible materials which may be used.

According to a preferred embodiment, the balloon is assembled from two parts or half-shells which are connected together along a circumferential seam. The circumferential seam is preferably
30 positioned in the area of the waist portion. The half of the device positioned outside of the vagina has a greater wall strength than the half positioned inside. In this way, it is provided that the balloon is self-stabilized under high pressure and leads to a minimal rise in pressure for vaginal dilation.

35 In a further preferred embodiment, the device comprises an air pump with a manometer or pressure gauge connected to the filling hose of the balloon. The pump which may comprise a hand-pump can be



used to pump up the expandable body in steps or stages up to a maximum pressure which may be about 160 mm Hg, measured using the pressure gauge.

5 The pressure gauge preferably comprises an air-release screw which is used to release the pressure at the end of the therapy or for relief during use.

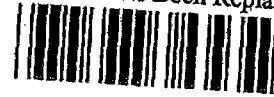
10 Finally, it is important to make sure that the maximum expansion of the balloon transversely to the lengthwise axis measures 9 to 10 cm, preferably 9.4 to 9.6 cm. This corresponds approximately to the average diameter of a newborn head with a cranial circumference of approximately 35 cm at birth.

15 A further embodiment provides that a safety valve be arranged on the pressure gauge in order to limit the maximum pressure. The pressure may be limited, for example, to 200 mm Hg. The safety valve opens when the pressure limit is exceeded.

20 According to another preferred embodiment, the balloon assembled from two-half shells is constructed such that the half shelves form two gas-tight chambers separated from one another. In this way, they can be each independently filled or deflated such that the balloon can be adjusted to the individual needs of the patient. The hose for inflating and deflating the half-shell positioned inside the vagina is provided to pass through the other half-shell. Both hoses exit at the end of the balloon directed outwardly. The device is particularly advantageous for patients who have already given birth and who have
25 during the previous birth endured tearing of the perineum leading to painful scarring. For this purpose, the device can be pumped up alternately in pressure steps of 10 mm Hg in order to exert pressure on alternating sides of the vaginal orifice.

30 In a further preferred embodiment, the half shell positioned in the vagina is fillable by means of a separate inflation hose. The separate filling hose can either pass outside of the device or through the inside of the half-shell positioned outside of the vagina such that both tubes extend outwardly from the birth canal. Furthermore, according to a variant embodiment, the two hoses extend concentrically one inside the
35 other.

Finally, it preferred that the device comprises a three-way valve for selecting the filling mode of the two half-shells. The two separated



fillable half-shells can be filled together or individually inflated. The filling pressure is monitored for each corresponding filling mode using the pressure gauge. Also, the order for deflation can be selected using the three-way valve. When using concentrically extending hoses, a
5 corresponding constructively built three-way valve can be provided.

In addition to the above-mentioned device, the invention further relates to a method for preparing to give birth using exercises in which the device according to the invention is used such that the expandable body is positioned partly outside and partly inside the vaginal orifice,
10 and thereafter is expanded to a desired size and finally maintained in an expanded state for a predetermined time in its position. Preferably, the expansion of the device is increased with each repeated use in order to achieve an increasing preparatory expansion of the birth canal. The method carried out as a stretching or expansion exercise should be
15 carried out several times per day as of the thirty-sixth week of pregnancy. Additionally, it is preferable that the expanded body be removed carefully in a direction of the vaginal orifice after a predetermined time period. The time period that the device should remain in the birth canal is between 10 to 20 minutes, preferably 15
20 minutes, in accordance with the subjective feeling of the patient: too much stretching tension indicates too high a pressure in the balloon. Relief is achieved by the step-wise actuation of the air pressure release screw.

The numerous advantages of the mentioned method are: an easier
25 delivery resulting from prior stretching or expansion of the birth canal and the outer vaginal orifice; a faster delivery, in particular in the case of first time mothers; better oxygen supply to the child as a result of minimal pressure on the fetal cranium as it emerges; a reduction of labor-inducing medication, in particular in the case of first time
30 mothers; a reduction in the pain of childbirth and minimal cramping caused by stretchable musculature; a clear reduction in the use of pain killers and local anesthesia; less risk of allergic shock due to local anesthesia; a reduction in the use of peridural and epidural anesthesia (spinal cord anesthetic); a significant reduction in the need to resort an
35 episiotomy which is always painful for the mother (and therefore feared by her) and the inevitable stitches following the episiotomy; as well as a quicker recovery of the vaginal musculature by sparing the *musculus*



bulbo cavernosus, *musculus bulbo spongiosus* and the *musculus sphincter ani* since the incidence of macro and micro muscle tearing is reduced.

Further advantages resulting from a problem-free delivery are better care of the child by the mother, who can be more active and agile in the absence of an episiotomy, such that she can care for the child herself without feeling sick and injured. As a result of the reduction of pain achieved according to the invention, the production of prolactine is increased whereby lactation (breast feeding) is improved. It is furthermore important that the physiology, function and appearance of the vagina and vulva are maintained to a large extent, and thereby the mother's sex life after giving birth is not affected. A shorter recovery time in hospital and the possibility of home birth may also contribute to relief of medical insurance plans.

The invention will be better understood by way of the following detail description of a preferred embodiment with reference to the appended drawings in which:

FIGURE 1 illustrates a preferred embodiment of the device according to the invention in use in the deflated state;

FIGURE 2 illustrates the embodiment as shown in Fig. 1 in which the device is in the expanded state;

FIGURE 3 illustrates a cross-section of the embodiment of the device according to Figs. 1 and 2; and

FIGURE 4 shows a cross-section of a further embodiment of a device according to the present invention.

Figures 1 through 3 illustrate a balloon 1 for pneumatic dilation of the birth canal which is inserted into the vagina 2 towards the cervix 7 of uterus 10. The oval and figure 8 shaped expandable balloon 1 having a middle neck or waist portion 15 comprises, in its half 14 positioned exterior of the vagina 2, a greater wall strength than the half 13 positioned inside. The waist portion 15 of the balloon 1 itself is reinforced. The balloon 1 when deflated and folded up is inserted into the vagina 2 with lubricating gel such that approximately three to four centimeters of the balloon 1 can be seen in front of vulva 3. This is important since the outermost portion of the vagina 2 in particular, and above all, the vaginal orifice 4 should be expanded. This is the most sensitive part of the female birth canal and due to the danger of a tear of



the perineum, it is at the same the most endangered anatomical part. The balloon 1 is now carefully pumped up using hand-pump 5 in steps of 20 mm Hg up to a maximum pressure of 160 mm Hg, which is monitored using manometer or pressure gauge 6. The stretching feeling
5 subjectively experienced by the pregnant woman sets the limit for inflation. After approximately 15 to 20 minutes, the device 1 is carefully and gently pulled out in the direction of the vagina so that the patient experiences a "feeling of giving birth" and this sensation can be deepened in subsequent exercises which leads to a considerable
10 tranquilizing effect. This exercise is repeated several times per day such that the patient expands the vaginal orifice continuously and completely painlessly. It is important that the desired diameter of the balloon is measured by corresponding pumping (i.e. by counting the pump strokes) outside of the vagina. The pressure on the pressure gauge
15 should never exceed 200 mm Hg. The scale of the pressure gauge is correspondingly marked.

The maximum diameter of the waist portion should be 9.5 cm since the biparietal diameter of fetal cranium at birth is on average of this size, which corresponds to a cranial circumference of 35 cm. If an
20 ultrasound examination carried out by the medical doctor determines that the child is particularly larger, the diameter of the expansion can be simply increased accordingly. However, the patient should still control the size of the balloon to suit her subjective feeling.

As a basis of measurement for the required birth dilation
25 pressures, the following test results can be used:

According to scientific studies by R CALDEIRO-BARCIA the intraamniotic pressure can rise under normal contraction activity up to 100 mm Hg. The systolic blood pressure of the mother (normally 120 mm Hg) can rise briefly during contractions during the period of expulsion
30 up to between 180 to over 200 mm Hg. The pressure of the uterus musculature reaches, towards the end of the expansion during delivery, a pressure of up to 200 mm Hg against the surrounding vaginal tissue. According to C. LINDGREN, the maximum pressure on the fetal cranium in the area of the perineum 8 can reach a peak value up to 300
35 mm Hg during contractions shortly before birth. In order to keep the artificial dilation described herein within the physiological range, a limit



of 200 mm Hg is recommended. Basically, the dilation should not be carried out before the 36th week of pregnancy.

The demonstration and explanation of the method for dilating the birth canal should basically be carried out with the patient by the physician in charge or by the midwife. It is recommended to carry out
5 the first dilation under continuous CTG control (cardio topography = continuous recordal of fetal heart sounds and contractions) by the physician in charge or the midwife.

Cleaning of the device after use can be done with soap and water
10 and air dried. Disinfecting using commercially available disinfectants is recommended.

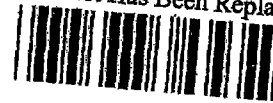
Figure 3 shows further the hose connection 16 as well as the expandable balloon 1 in its expanded state 17. The two parts or half-shells 13, 14 are glued or joined together overlapping about a
15 circumferential seam which coincides with the waist portion 15. The overlapping region is shown in dashed lines.

Figure 4 shows a cross-section according to a further embodiment according to the present invention. The parts or half-shells 21, 22 and the balloon 20 are shown. In the area of the waist portion 23,
20 a membrane 24 is arranged inside the balloon which membrane comprises an opening 25 which is connected to a first hose 26. The outer half-shell 22 is connected by means of a wall orifice 27 to a further connecting hose 28. The two connecting hoses 26, 28 are connected to a three-way valve 29 which in turn is connected by a hose
25 30 to a pressure gauge 21 and hand-pump 22. An air-release screw 33 is also provided between pressure gauge 31 and hand-pump 32 as well as an elastic seam 34 where the first connecting hose 26 passes through the wall of the outer half shell 22.

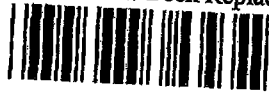
In the embodiment according to Figure 4, three configurations
30 can be selected using three-way valve 29. In the first configuration, a connection is established between hose 30 and both connecting hoses 26, 28. In this way, both chambers, i.e. both parts or half shells 21, 22 are simultaneously inflated or deflated. In the next configuration, a connection between hose 30 and connector hose 26 is established for the
35 inner half-shell 21, whereby the connection to the second connector hose 28 is interrupted. In a third configuration, a connection is established between hose 30 and connector hose 28 to the outer half-

shell 22 whereby the connection to the other connector hose 26 is interrupted. In this way, the outer half shell 22 can be inflated using the hand-pump 32 or deflated by means of the air-release screw 33. The connector hose 26 to the inner half shell 21 extends through the outer
5 half-shell 22 directly to the membrane 24 where hose 26 connects to the opening 25 in membrane 24. As a result of such a twin-chamber construction, the volume of balloon 20 can be individually adjusted to the needs of the user. The pressure of each individually controlled balloon chambers can be separately monitored using pressure gauge 31.

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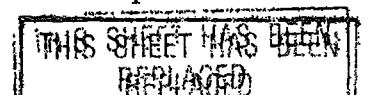
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(as published)

PATENT CLAIMS



- 5 1. Device for preparing to give birth and making delivery easier for a pregnant woman, the device having a wholly expandable elongated body which is positionable in the area of the vaginal orifice such that it is located partly inside the vagina and partly outside the vagina.
- 10 2. Device according to claim 1, characterized in that the body comprises a waist portion (15;23) expandable along with the body, the waist portion being positioned in the area of the vaginal orifice (4).
3. Device according to claim 1, characterized in that the body is
15 expandable by means of a variable air or fluid inflation.
4. Device according to claim 3, characterized in that the body is
formed as a balloon (1;20) having at least one inflation hose (12;28) on
its end directed during use outwardly.
20
5. Device according to claim 4, characterized in that the balloon
(1;20) is an assembly of two half-shells (13, 14; 21, 22) connected
together along a circumferential seam (15;23).
- 25 6. Device according to claim 5, characterized in that the
circumferential seam is arranged in the area of the waist region (15;23).
7. Device according to claim 5, characterized in that the wall
strength of the outer half-shell is larger during use than the inner half-
30 shell.
8. Device according to claim 4, characterized in that the device
includes an air-pump (5;32) with an air-pressure gauge (6;31) connected
to the inflation hose (12;30) of the balloon.
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9. Device according to claim 8, characterized in that an air-release
screw (33) is provided between the air-pump (5;32) and the air pressure



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gauge (6;31), the pressure in the balloon (1;20) being adjustable by means of the air release screw.

10. Device according to claim 8, characterized in that a safety valve
5 is provided to limit the maximum pressure.
11. Device according to claim 5, characterized in that the half-shells
(21, 22) form two air tight chambers separated from one another.
- 10 12. Device according to claim 11, characterized in that the half-shell
(21) positioned in the vagina is inflatable by means of a separate
inflation hose 26.
- 15 13. Device according to claim 11, characterized in that the device
comprises a three-way valve (29) for selecting the inflation mode of the
two half-shells (21, 22).
14. An exercise method for preparing to give birth using a device
according to claim 1,
20 characterized in that,
the expandable body is positioned partly outside and partly inside
the vaginal orifice (4), thereafter the expandable body is expanded to a
desired dimension and finally in the expanded state maintained a
predetermined time in its position.
- 25 15. Method according to claim 14, characterized in that the
expansion of the expandable body is increased with repeated use in
order to achieve an increasing preparatory stretching of the birth canal.
- 30 16. Method according to claim 15, characterized in that the
expandable body is pulled from the vagina (2) after a period of time.
17. Method according to claim 16, characterized in that the time
period is between 10 to 20 minutes, preferably 15 minutes.

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18. Method according to claim 15, characterized in that the expansion of the waist region is selected to be up to a diameter of 10 cm.



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