



EPI·NO[®] *Delphine*
Delphine Plus
+ Biofeedback

Instructions For Use

Gebrauchsanweisung

Mode d`Emploi

Istruzioni per l`Uso

Instrucciones de Uso

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EPI·NO® *Delphine*



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+ Biofeedback

TECSANA
Munich · Germany

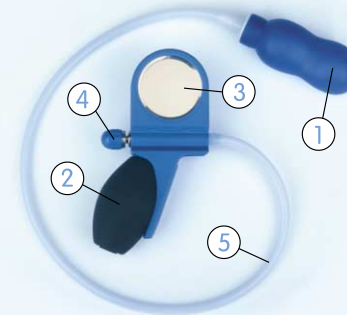
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Product Description

The **EPI·NO Delphine** and the **Delphine Plus** Birth and Postnatal Trainer were designed, developed and manufactured in Germany in close co-operation with gynaecologists, midwives and pregnant women.

It consists of (1) a narrow contoured silicone balloon, (2) a hand pump, (3) a mirror (**EPI·NO Delphine**) or a pressure display (**EPI·NO Delphine Plus**), (4) an air release valve, (5) connected by a flexible plastic tube.



EPI·NO Delphine



EPI·NO Delphine Plus

Indication

EPI·NO Delphine and **Delphine Plus** are patented and intended to be used as a Birth Trainer and a Pelvic Floor Muscle Trainer.

Applications

First, **EPI·NO Delphine** and **Delphine Plus** can gently prepare your perineum for childbirth:

Birth Preparation

Second, **EPI·NO Delphine Plus** exercises promote optimal postnatal recovery:

Pelvic Floor Muscle Training

Training methods

Three Stage Birth Program

(**EPI·NO Delphine** and **Delphine Plus**)

- Exercise the Pelvic Floor Muscles
To strengthen the pelvic floor muscles before birth.
- Stretch the Perineum
For the gradual stretching of the vaginal passage, the perineum and the vaginal muscles prior to birth.
- Prepare for the Birth
To train for the delivery phase of childbirth.

Postnatal Pelvic Floor Muscle Training Program

(Note: Only **EPI·NO Delphine Plus** offers biofeedback)

Pelvic Floor Muscle Training

To strengthen the pelvic floor muscles following birth.



All exercises are simple and can be done on your own in the privacy of your home. You can adjust **EPI-NO Delphine** and **Delphine Plus** training to your specific requirements.

Clinical studies and practical experience have shown the effectiveness of choosing an **EPI-NO Delphine** or **Delphine Plus** training regimen.

During the stretching exercises for birth preparation, the **pressure display** (only **EPI-NO Delphine Plus**) **does not indicate the balloon size**.

You can determine your training progress with the measurement template included, or use a tape measure (A measurement of the balloon size is possible only outside the body).

However, during pelvic floor muscle training, your exercise progress is indicated by the movement of the pressure display needle (only **EPI-NO Delphine Plus**).

If a caesarean section is planned you will not benefit from perineal stretching, however **EPI-NO** may still be used to ensure effective pelvic floor muscle training.

Contraindications

You must not use **EPI-NO** if any of the following are present:

- The baby is in an unusual position, with identified risks making a vaginal birth impossible (e.g. Placenta previa), meaning a caesarean delivery is necessary.
- There is a risk of an ascending infection (e.g. premature rupture of membranes, open cervix).
- You have injuries in your genital area which have not yet healed.
- You are under the influence of alcohol or drugs.
- You have vaginal bleeding.

EPI-NO should only be used under the supervision or guidance of a physician or midwife:

- If you have any nerve damage as a result of permanently raised blood sugar diabetic neuropathy.
- If you are a paraplegic (paralysed lower body).
- If you have been diagnosed with Multiple Sclerosis.
- If pain killers reducing the feeling of pain in the vaginal area have been administered or prescribed.
- Vaginal Varicosities (varicose veins of the vagina and vulva).

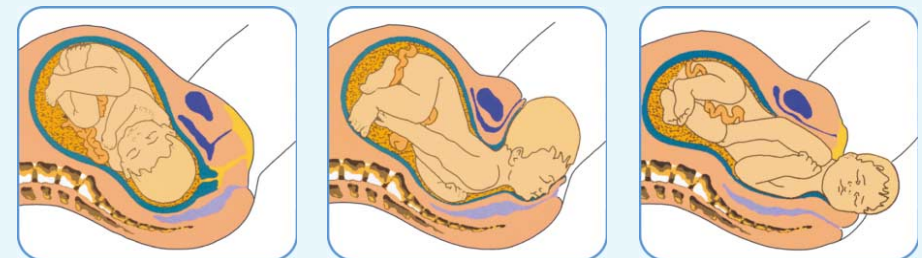
Discuss contraindications and use of **EPI-NO** with your physician or midwife.

Warning / Caution

- For hygienic reasons, **EPI-NO Delphine** and **Delphine Plus** are intended as single user devices; meaning only one woman should use the device.
- Childbirth training should not begin more than three weeks before the expected delivery date or as established by your physician or midwife.
- Do not use **EPI-NO Delphine** or **Delphine Plus** for more than two pregnancies, or after the end of its recommended life span (as shown on the label on the hand pump).
- Stop exercising with **EPI-NO Delphine** or **Delphine Plus** if you experience any pain.
- Before you use **EPI-NO Delphine** or **Delphine Plus** for the first time or if it has not been used for more than four weeks, you should inflate the balloon by first closing the air release valve, then squeezing the hand pump about ten times in sequence.
Open the air release valve to let the air out and return the balloon to its original shape. This allows you to test the device. If your **EPI-NO Delphine** or **Delphine Plus** is not in perfect working order contact your supplier before use.
- We recommend you thoroughly wash your hands with soap and water before each use of **EPI-NO Delphine** or **Delphine Plus**. Please strictly observe the guidelines for cleaning and disinfecting **EPI-NO Delphine** and **Delphine Plus** (see section "Cleaning and Disinfecting").
- Do not use any lubricants that contain additives or essential oils. These may damage the balloon.
- When the balloon is inserted and inflated, you should not move excessively to avoid uncontrolled movements of the balloon.
- **EPI-NO Delphine** or **Delphine Plus** must not be used under water (e.g. in the bath) as penetrating water can impair function.
- Store **EPI-NO Delphine** and **Delphine Plus** carefully to avoid extended exposure to direct sunlight.
- **EPI-NO Delphine** and **Delphine Plus** should be kept out of reach of children!

EPI-NO - Birth Preparation

EPI-NO Delphine and **Delphine Plus** Birth Trainer are designed to be used by



both primiparae, (mothers expecting their first child), as well as by multiparae, where no medical reasons make it's use inappropriate (see section on "Contraindications").

If your physician or your midwife, has not recommended a specific training regimen, you should begin **EPI-NO Delphine** or **Delphine Plus** training 3 weeks before your expected delivery date.

Through the gradual strengthening and stretching of the muscles and tissue, the entire pelvic floor will become stronger and more elastic.

This reduces the chance of a tear of the perineum or the need for an episiotomy during delivery.

If the perineum remains undamaged, the muscles and tissue can more easily recover following childbirth. Furthermore, any unpleasant after-effects, such as scars, prolapse or incontinence may be avoided.

Instructions

Select a pleasant place for your exercise with **EPI-NO Delphine** or **Delphine Plus**. Ensure you are not disturbed. Choose a comfortable position (e.g. semi reclined). With time and practice you will find the most appropriate position for you.

Under some circumstances you may also discover a suitable position for giving birth to your child.

Close the air release valve before introducing the balloon into the vagina. In some cases it may be necessary to lubricate the tip of the balloon (see section "Warning / Caution").

Three Stage Birth Program

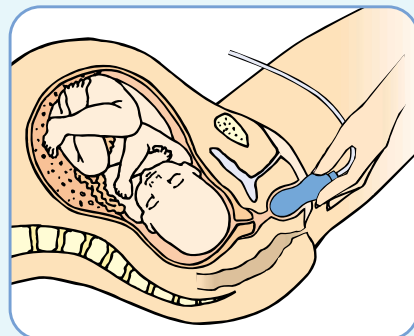
1. Exercise the Pelvic Floor Muscles

Insert about two thirds of the balloon into the vagina (see illustration). By gently gliding the balloon up and down you will obtain a feeling of the elasticity within the perineal area. Remain relaxed during your exercises even if the training is unfamiliar at the beginning.

Experience has shown that a certain routine is achieved after about three training sessions. You will develop a feeling for the best routine for you.

While tensing the pelvic floor muscles try to draw the balloon upward for about 10 seconds. Then relax for 10 seconds and repeat this exercise for a minimum of 10 minutes. Gently touch the balloon and feel it moving upwards with the muscle tension. This way you can check that you are exercising correctly.

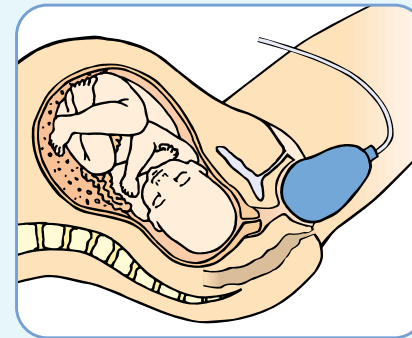
EPI-NO Delphine Plus Only: Observe the needle on the pressure display before and after tensing the pelvic floor muscles. You may not notice any appreciable pressure difference when you first commence your exercises. However, after a few days you will begin to achieve your first results.



2. Stretch the Perineum

Slowly inflate the balloon, as far as your personal comfort level permits (a slight stinging sensation indicates stretch). Leave the inflated balloon in the vagina for a period of about ten minutes.

With this exercise the skin and muscles, the perineal area, as well as the birth canal are gradually and gently expanded.



The balloon size should be increased gradually from one training session to the next. **However, you should always stay within your personal comfort level.**

By operating the air release valve you can reduce the balloon size at any time. The reading on the pressure display (only **EPI-NO Delphine Plus**) does not indicate the balloon size.

Do not rely on the pressure readings on the pressure display in this training phase - simply trust your body feeling.

3. Prepare for Birth

At the end of the stretch, relax your pelvic floor muscles and allow the balloon to gently expel itself from the vagina. This simulation of birth allows you to experience the sensation of birth ahead of time.

You can determine your training progress with the measurement template included, or use a tape measure (A measurement of the balloon size is possible only outside the body).

Further Information

Sometimes the pelvic floor tension may be intensified when letting the balloon glide out. In the first training session we recommend you reduce the size of the balloon by letting a little air out to become familiar with this exercise.

As your training progresses you will find it easier to let the balloon glide out. Gradually increase the balloon diameter, building your confidence and strength.

Each session should not last longer than 30 minutes and not be performed more than twice a day.

Clean your **EPI-NO Delphine** and **Delphine Plus** according to the method described (see section on "Cleaning and Disinfecting") at the end of each training session.

Each training session reduces the risk of damage to your perineum during childbirth. Optimum training is achieved when the balloon has reached a diameter of 8-10 cm (3-4 inches) and can be glided out while inflated after about two weeks of training.

Once you have reached a balloon diameter of 8-10 cm (3-4 inches) you should then focus on training the pelvic floor and practising for the delivery phase.

It is not recommended, to further increase the balloon size. A diameter of 10 cm (4 inches) represents the approximate space needed for delivering your baby.

Occasionally the balloon may be expelled prematurely (e.g. because of excess lubricant). Avoid this by holding it in place or closing your legs.

You can also feed the balloon in slightly further. Even if the balloon slips totally into the vagina and touches the cervix, it can be returned to the correct position by pulling slightly at the base of the balloon.

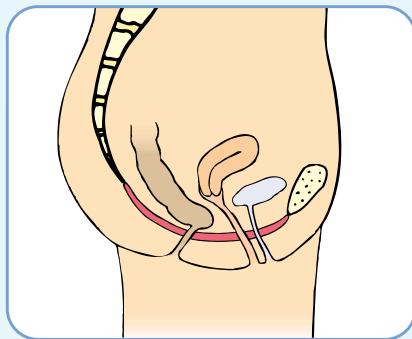
If any complications should arise when using the **EPI-NO Delphine** or **Delphine Plus** please consult your physician or midwife immediately.

Postnatal Pelvic Floor Muscle Training Program

(Note: Only **EPI-NO Delphine Plus** offers biofeedback)

Before commencing **EPI-NO Delphine Plus** postnatal pelvic floor muscle training any vaginal discharge should have subsided and any perineal injuries allowed to heal.

We recommend using **EPI-NO Delphine Plus** not before 3 weeks after your delivery.



Pelvic floor muscles (red)

We also recommend the exercises should continue for a minimum of 3 weeks (usually postnatal training extends for 4 to 6 months).

Typical symptoms of weakened pelvic floor muscles are:

- Leaking of urine when coughing, sneezing, climbing stairs, and carrying heavy objects.
- Constant urge to urinate, even with an empty bladder.
- A strong feeling of downward pressure.
- Prolapse of the vaginal tissues or the uterus.
- Involuntary loss of wind (flatus) and stool (anal incontinence).

Select a pleasant place for your exercise with **EPI-NO Delphine Plus**. Ensure you are not disturbed.

Choose a comfortable position (e.g. semi reclined). With time and practice you will find the most appropriate position for you.

Take relaxed, regular breaths during exercise. Try to relax your buttocks, thighs and stomach. We recommend exercising 10 to 20 minutes per day.

Getting Started

Open the air release valve, squeeze the air out of the balloon with your hand, then close the air release valve. The balloon will now remain in this deflated shape. Lubricating the top half of the balloon will facilitate insertion (see section "Warning / Caution").

Hold the balloon near the end and introduce it about two thirds of the way into the

vagina. Take your time, as the vagina may be dry and tender.

Relax your pelvic floor. Now inflate the balloon to the point that you are aware of its presence (for most women the pressure gauge will show 2). Should the pressure be too strong, you can reduce it at any time by opening the air release valve.

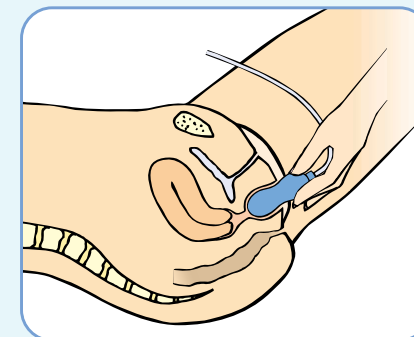
Perineal Draw Up Exercise

While tensing the pelvic floor muscles try to draw the balloon upward for about 10 seconds. Then relax for 10 seconds and repeat this exercise again.

Gently touch the balloon and feel it moving upwards with the muscle tension. This way you can check that you are exercising correctly.

EPI-NO Delphine Plus only: Observe the needle on the pressure display before and after tensing the pelvic floor muscles: See "Training Progress Table".

You may not notice any appreciable pressure difference when you first commence your exercises. However, after a few days you will begin to achieve your first results.



Further exercises with EPI-NO Delphine Plus

The following exercises give you a variety of training possibilities. Follow the instructions for use or train with the **EPI-NO Delphine Plus** exercises recommended by your physician or midwife.

Follow the instructions for inserting your **EPI-NO Delphine Plus** (see section "Postnatal Pelvic Floor Muscle Training Program").

During all exercises you can follow the needle on the pressure display and check your pelvic floor strength.

Training Progress Table:

| Pressure difference (tensed - relaxed) | Comment |
|--|-----------------------|
| < 1 | Should be improved |
| 1 - 2 | You are getting there |
| 3 - 4 | Already very good |
| > 4 | Excellent |

"Pelvis Rock"

Lie on your back and bend your knees with your feet firmly on the ground, and pressure on your heels. Alternately raise your right and left hip and repeat this 2-3 times.

"Around the Clock"

Assume the same starting position as for "Pelvis Rock". Imagine there is a clock under your pelvis. Follow the movement of the hands, first clockwise and then counter clockwise. The movements should be so smooth that the pelvis seems to continuously rotate.

“Long Legs”

Lie on your back and stretch your legs. The entire spinal column should touch the floor. Move your chin towards your chest so that the neck is stretched. Alternately push your right and left heel away as if you want to elongate your legs. Simultaneously draw your toes towards your body.

Cleaning and Disinfecting

Caution

- Make sure the pump does not get wet during cleaning and disinfecting because water may damage the interior.
- Follow cleaning and disinfecting instructions prior to first use and immediately after every subsequent use.
- If **EPI-NO Delphine** or **Delphine Plus** is not used for more than 7 days, repeat cleaning and disinfecting prior to use.

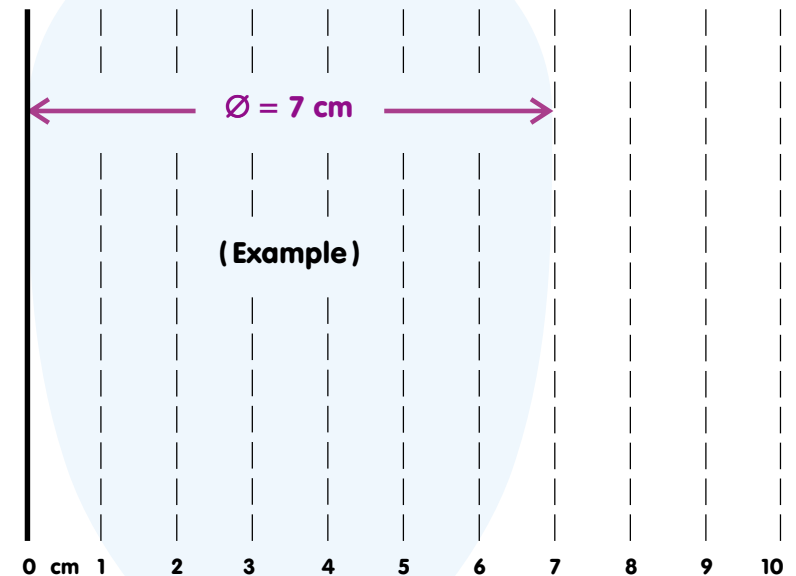
Before first usage and immediately after every use, clean **EPI-NO Delphine** or **Delphine Plus** thoroughly following these guidelines:

- Inflate the balloon by pressing the pump about 10 times.
- Carefully clean the balloon with soap and warm water (minimum 40°C / 104°F; 1-2 minutes). Take care not to wet the pump as water may damage the interior. Rinse the balloon under warm running water. Let **EPI-NO Delphine** or **Delphine Plus** dry on a clean, smooth surface.
- Disinfect **EPI-NO Delphine** or **Delphine Plus** by wiping it with 70% Isopropyl from your pharmacy. Use a cotton pad or medical alcohol pads like those supplied in your starter set.
- Only when completely dry place **EPI-NO Delphine** or **Delphine Plus** into the pouch, close zip and store in a clean, dry place.

We wish you success with your **EPI-NO Delphine** or **Delphine Plus** training.



Measurement Template



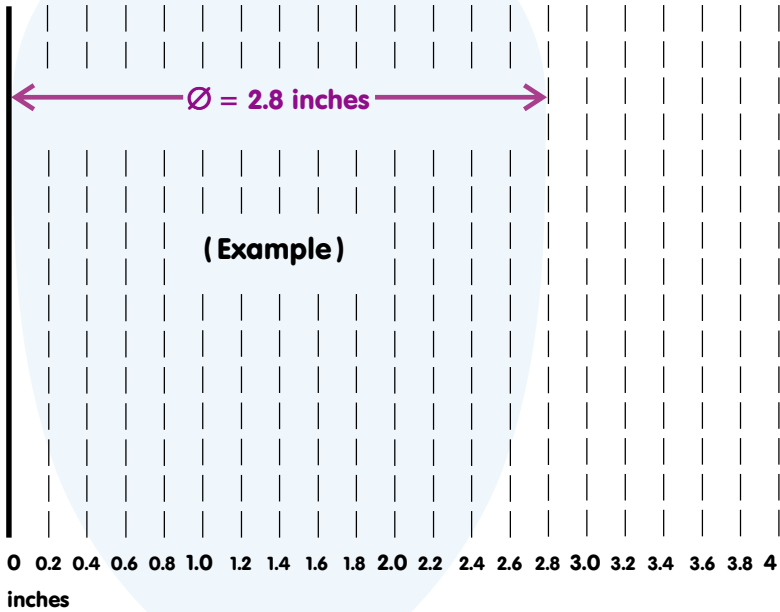
To measure the diameter of the inflated balloon, align the balloon with the solid line (0 cm) on the left of the template card as shown in the diagram.

The horizontal red arrows (example 7 cm) indicate the widest point of the balloon.

The Conversion Table opposite indicates the Circumference value for each Diameter measurement.

| Ø Diameter in cm | → | C Circumference in cm |
|------------------------|---|-----------------------------|
| 5,0 | → | 16 |
| 5,5 | → | 17 |
| 6,0 | → | 19 |
| 6,5 | → | 20 |
| 7,0 | → | 22 |
| 7,5 | → | 24 |
| 8,0 | → | 25 |
| 8,5 | → | 27 |
| 9,0 | → | 28 |
| 9,5 | → | 30 |
| 10,0 | → | 31 |

Measurement Template



To measure the diameter of the inflated balloon, align the balloon with the solid line (0 inches) on the left of the template card as shown in the diagram.

The horizontal red arrows (example 2.8 inches) indicate the widest point of the balloon.

The Conversion Table opposite indicates the Circumference value for each Diameter measurement.

| Ø Diameter in inches | → | C Circumference in inches |
|----------------------------|---|---------------------------------|
| 2.0 | → | 6.3 |
| 2.2 | → | 6.9 |
| 2.4 | → | 7.5 |
| 2.6 | → | 8.2 |
| 2.8 | → | 8.8 |
| 3.0 | → | 9.4 |
| 3.2 | → | 10.0 |
| 3.4 | → | 10.7 |
| 3.6 | → | 11.3 |
| 3.8 | → | 11.9 |
| 4.0 | → | 12.6 |



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