



BasIQ-4[®]

Surgical knife for performing a mediolateral episiotomy

Instructions For Use

The BasIQ-4[®] is a surgical knife, embedded in a plastic molded housing, intended for use in obstetrics and designed to perform a mediolateral episiotomy of approximately 4 cm.

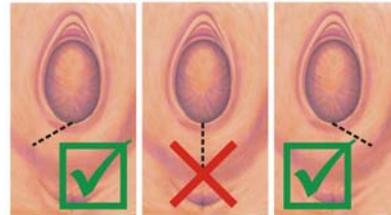
The mediolateral episiotomy can be performed to either the right-hand side or the left-hand side.

The BasIQ-4[®] is intended for use, exclusively by physicians and midwives well trained and experienced in obstetric management, obstetric anatomy and skilled in the performance of mediolateral episiotomies. Standard obstetric judgment should be utilized for the proper use of this device.

Indications

All indications for a mediolateral episiotomy.

The BasIQ-4[®] performs a standardized episiotomy of approximately 4 cm; for that reason a midline episiotomy is discouraged due to the short length of the perineal body with higher risk for injury of the anal sphincter.



Contraindications:

- All contraindications for episiotomy.
- When any part of the child could be in the jaw area.
- A patient's absolute refusal for the procedure to be performed.

Warnings:

- ⚠ • Before operating the BasIQ-4[®] make sure you are well trained and acquainted with the device.
- The obstetrician should be aware that he/she is utilizing a surgical knife, **act accordingly!**
- Before entering the BasIQ-4[®] make sure you have executed sufficient pelvic examinations.
- The BasIQ-4[®] cannot be operated with the red protection shield in place.
- Check if the BasIQ-4[®] is in its secured position (the transport lock, Fig.1). If it is not in its secured position, put it in its secured position.
- Do not push, press or use force during the placement of the BasIQ-4[®].
- Do not press the thumb ridge while inserting the BasIQ-4[®].
- To avoid perineal damage never use force while removing the BasIQ-4[®] from the perineal area.
- To minimize soft tissue damage, the incision must be made before the supporting structures have been damaged to the extent that they cannot recover.

Precautions:

- Please make sure that a water based lubricant is at hand.
- Dispose of the BasIQ-4[®] according to the hospital protocol concerning surgical, contaminated goods.
- ⊠ • Check the packaging and the BasIQ-4[®] for damages. If either one is damaged, save the packaging and product and send both back to the manufacturer or your local distributor.
- ⌘ • The BasIQ-4[®] is intended for single use only. Do not reuse, re-sterilize or autoclave. Reuse of single use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure. The manufacturer will not be responsible for any direct, incidental or consequential damages resulting from re-sterilization or re-use.
- Do not use after the expiry date indicated on the package. Do not use when sterility is compromised.

These recommendations are designed to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgments concerning patient care.

Pain treatment should be according to local protocol.

Patents, patents pending: EP 2352448; EP 2934353; US 9138256; US 2015/0342640; WO 2014/098602.

Instructions For Use

How to hold the BasIQ-4®

- Remove the protection shield (Fig. 3). The device is now ready for use.
- Form a U-shape with your thumb, middle and index finger of your dominant hand (Fig. 4). Slide the fin of the BasIQ-4® between your index and middle finger and put your thumb on the profiled ridge of the thumb ridge. The fingertips of both your middle finger as well as your index finger should be in front of the BasIQ-4® and visible when looking from above (Fig. 5).
- Put your thumb as far as possible in the direction of the vertical spring lip without touching the vertical spring lip with your thumb (Fig. 6).

How to test the BasIQ-4®

- By pressing your thumb firmly downwards you will push the vertical spring lip out of the transport lock (Fig. 1) and pierce the surgical knife through the jaw into the landing zone of the base (operational lock, Fig. 2). You will hear or feel a 'click'. Make sure the thumb ridge spring locks into the operational lock.
- To release the knife push or pull the vertical spring lip to the front AND take the upper lip between your thumb and index finger and gently pull and release the knife from the landing zone. If the knife gets stuck in the landing zone you may jerk a little bit but never use excessive force. Release the vertical spring lip and push the thumb ridge into its original starting position, the transport lock.
- Repeat for more 'touch and feel' of the device.

Performing a mediolateral episiotomy

- Examine the interior of the perineum, examine the area where you are about to place the BasIQ-4®, also check local anatomy and make absolutely sure that in the area where you are going to position the BasIQ-4® there is nothing that could end up in the jaw of the BasIQ-4® except the tissue of the perineum.
- Insert the index and middle finger of the non-dominant hand into the vagina between the perineum and the fetal head (or breech) (Fig. 7; in this figure, the left hand is non-dominant).
- To create space gently pull the non-dominant hand towards yourself thus creating space for the insertion of the BasIQ-4® in the dominant hand (Fig. 8).
- Insert the BasIQ-4® towards the anus six o'clock (Fig. 9).
- Be sure there is contact of the BasIQ-4® with the midline of the posterior fourchette.
- Starting from the "six o'clock" position, rotate the BasIQ-4® towards "eight o'clock" (Fig. 10) or "four o'clock" (Fig. 13) depending on your dominant hand.
- Close the BasIQ-4® at the beginning of the next contraction. By pressing your thumb firmly you will push the thumb ridge out of its transport lock and the surgical knife will pierce through the perineal skin.
- Make sure the thumb ridge locks into the operational lock (Fig. 11 or Fig. 14).
- After you heard and felt the 'click' you can gently pull the BasIQ-4® moving the knife in the direction of the midline of the posterior fourchette, leaving an incision of approximately 4 cm (Fig. 12 or Fig. 15).

Insertion of the BasIQ-4® with limited space

- Examine the interior of the perineum, examine the area where you are about to place the BasIQ-4®, also check local anatomy and make absolutely sure that in the area where you are going to position the BasIQ-4® there is nothing that could end up in the jaw of the BasIQ-4® except the tissue of the perineum.
- Insert the index and middle finger of your dominant hand into the vagina between the perineum and the fetal head (or breech) and curve your fingers to create space to receive the tip of the BasIQ-4® (Fig. 16).
- Direct the tip of the BasIQ-4® towards the space just created by the flexion movement of the fingers of the dominant hand and insert the tip of the BasIQ-4® under the perineal skin.
- Slide the BasIQ-4® with the fin between the index and middle finger over your fingers under the perineum towards the ischial tuberosity. While sliding the BasIQ-4® over your fingers direct the tip of the BasIQ-4® to "six o'clock" (Fig. 17) and continue according to Fig. 10-12.

Packaging

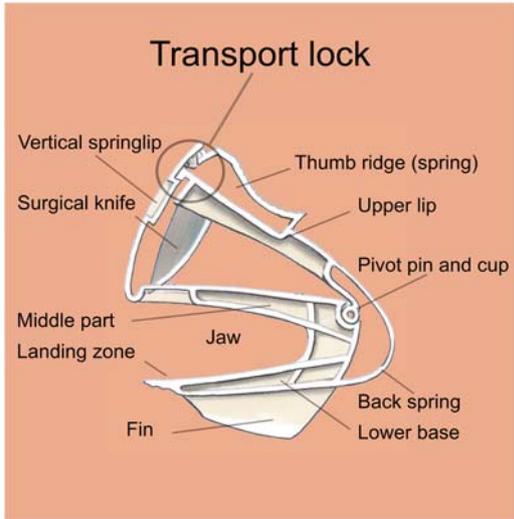
The BasIQ-4® is sterilized with gamma radiation and supplied in peel open package. Do not use when sterility is compromised.



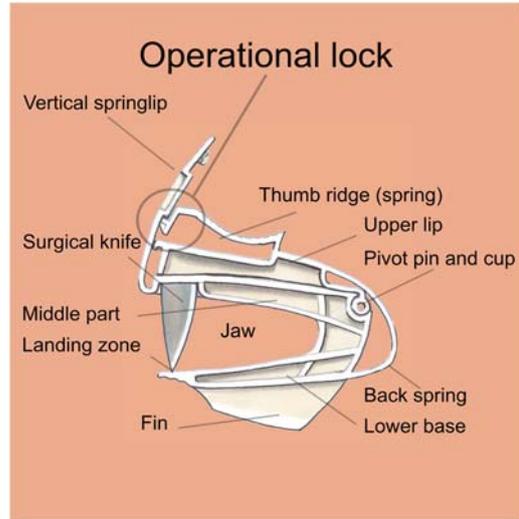
Storage and transport conditions The BasIQ-4® kit should be stored in a dry room suited for storage and at a temperature between +10 °C and +25 °C. During transport of the BasIQ-4® the products may temporarily, not longer than 8 hours, be exposed to temperatures between -29 °C and +60 °C.

 **Manufactured by** BasIQ B.V., World Trade Center Rotterdam, Beursplein 37, Suite 1960, 3011 AA Rotterdam; The Netherlands

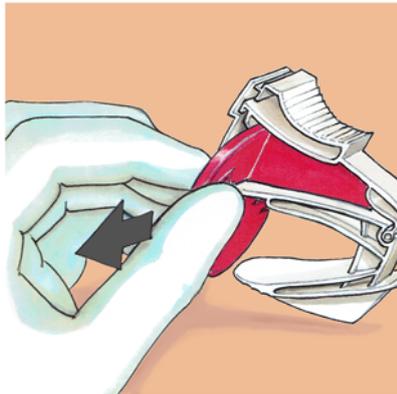
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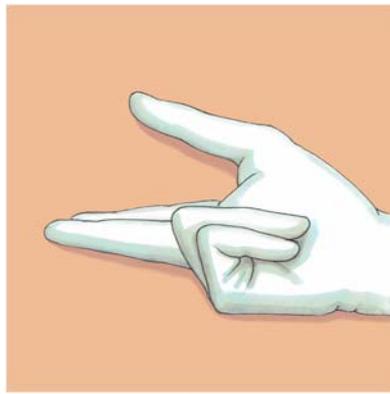
Afb. 1



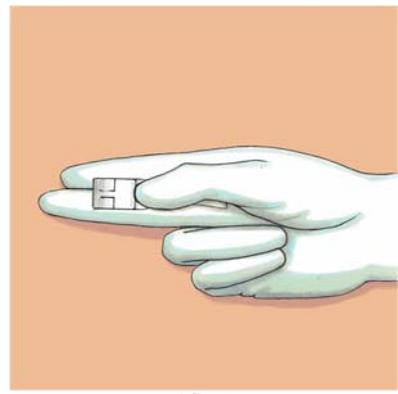
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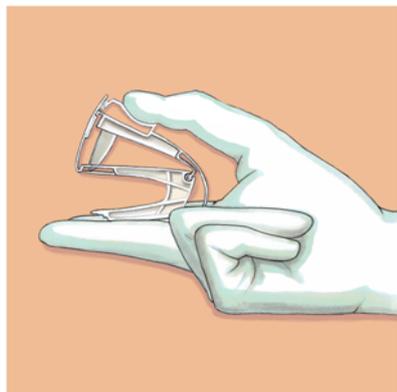
Afb. 3



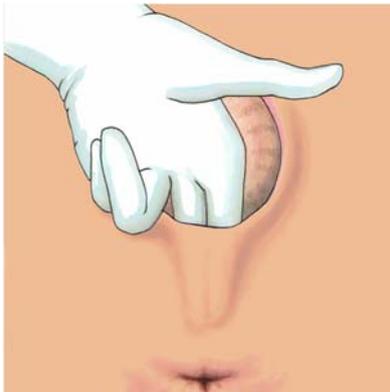
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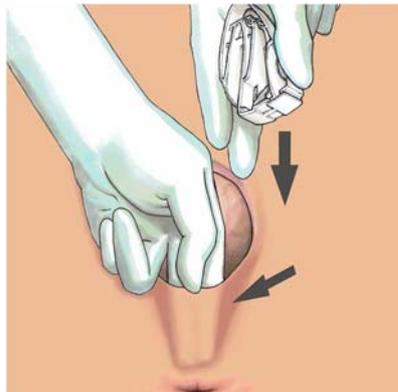
Afb. 5



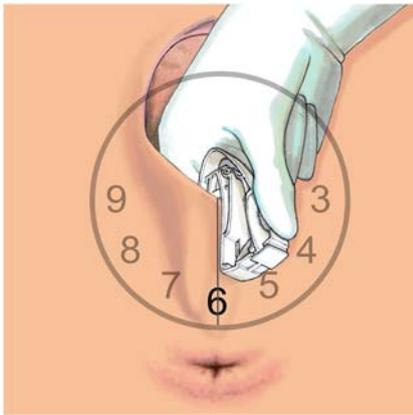
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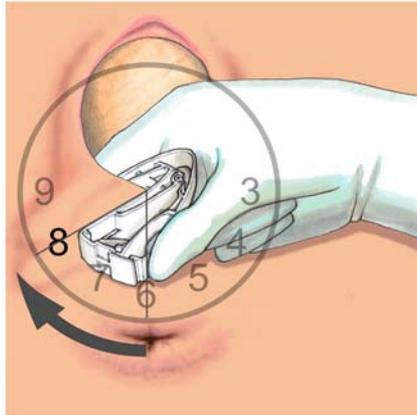
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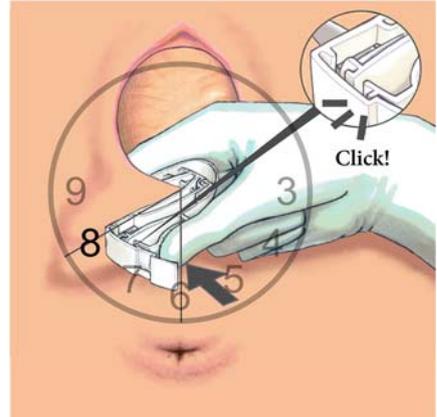
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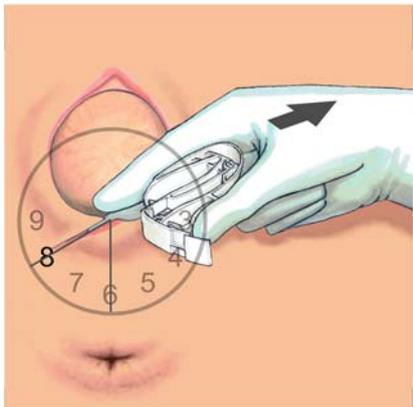
Afb. 9



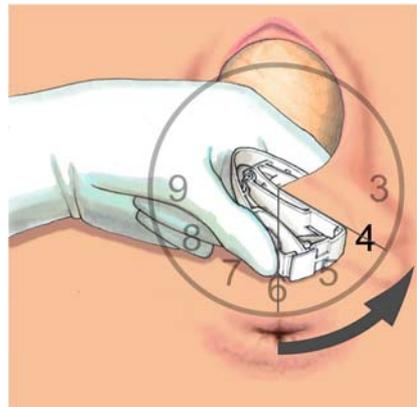
Afb. 10



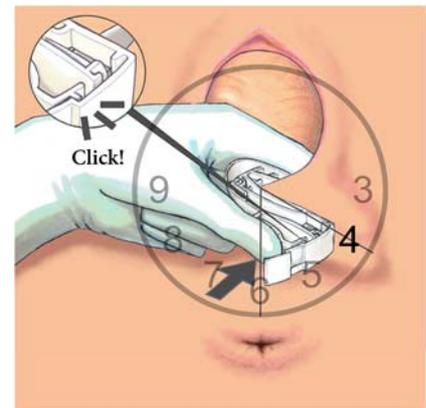
Afb. 11



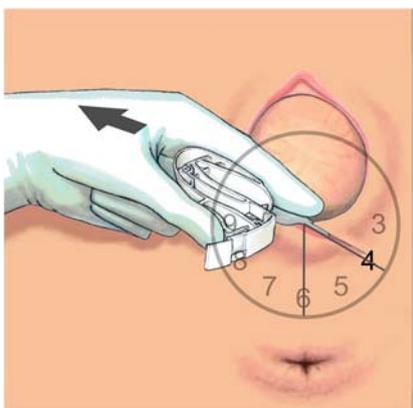
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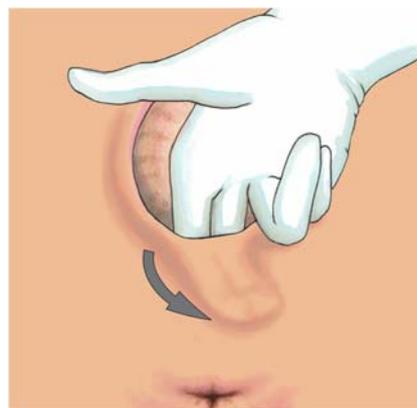
Afb. 13



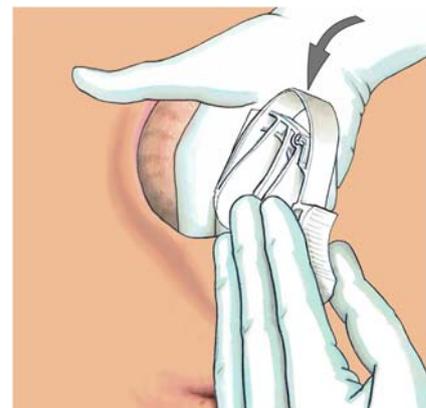
Afb. 14



Afb. 15



Afb. 16



Afb. 17