CE 0197
CE Mark

Instruction for use

Medicath Ltd.

Cervical Ripening Balloon

DESCRIPTION

The Cervical Ripening Balloon is a silicone double balloon catheter. Maximum balloon inflation is 80mL/balloon.

INTENDED USE

The Cervical Ripening Balloon is indicated for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

CONTRAINDICATIONS

- Patient receiving or planning to undergo exogenous prostaglandin administration
- Placenta previa, vasa previa, or placenta percreta
- Transverse fetal orientation
- Prolapsed umbilical cord
- Prior hysterotomy, classic uterine incision, myomectomy or any other full-thickness uterine incision
- Pelvic structural abnormality
- Active genital herpes infection
- Invasive cervical cancer
- Abnormal fetal heart-rate patterns
- Breech presentation
- Maternal heart disease
- Multiple gestational pregnancy
- Polyhydramnios
- Presenting part above the pelvic inlet
- Severe maternal hypertension
- Any contraindication to labor induction
- Ruptured membranes

WARNINGS

- Concomitant use of the Cervical Ripening Balloon with exogenous prostaglandins may increase the risk of adverse events associated with prostaglandin administration, including, but not limited to: uterine hyperstimulation, impaired utero-placental circulation, tachysystole, uterine rupture, placental abruption, amniotic fluid embolism, pelvic pain, retained placenta, severe genital bleeding, shock, fetal bradycardia, fetal death, and maternal death.
- The Stylet should only be used to traverse the tip of the catheter through the cervix and should be removed as soon as the uterine balloon is above the level of the internal uterine opening (internal os) prior to full insertion of the catheter. Aggressive insertion may result in injury to the baby.
- The product should not be left indwelling for a period greater than 12 hours.
- The safety and effectiveness of the Cervical Ripening Balloon has not been established among women with an obstetrical history of low transverse caesarean section.
- The safety and effectiveness of extra-amniotic saline infusion with the Cervical Ripening Balloon has not been established.
- If spontaneous rupture of membranes occurs while the Cervical Ripening Balloon is in place, there is a risk that the uterine balloon could become entangled in the umbilical cord, necessitating emergent cesarean delivery.
- Always inflate the balloon with a sterile saline. Never inflate with air, carbon dioxide or any other gas.
- Do not overinflate. Using excessive pressure to inflate the balloon on this device can cause the balloon to rupture.

PRECAUTIONS

READ INSTRUCTIONS PRIOR TO USE.
DO NOT USE IF THE UNIT PACKAGING OR THE PRODUCT HAVE BEEN DAMAGED OR SOILED.
FOR SINGLE USE ONLY, DO NOT REUSE.

If fetal membranes rupture spontaneously while this device is in place, it is recommended that both balloons be deflated and the device removed in preparation for spontaneous active labor contractions.

POTENTIAL ADVERSE EVENTS

Risks associated with use of the Cervical Ripening Balloon and labor induction may include, but are not limited to:

- Placental abruption
- Uterine rupture
- Spontaneous rupture of membranes
- Spontaneous onset of labor
- Device expulsion
- Device entrapment and/or fragmentation
- Maternal discomfort during and after insertion
- Failed dilation or need for caesarean delivery
- Cervical laceration
- Bleeding
- Risk of pre-term labor and birth in subsequent pregnancy

INSTRUCTION FOR USE

Patient Preparation

1. Perform an abdominal ultrasound to confirm singleton, vertex presentation and to rule out partial or complete placenta previa, and/or placenta percreta.
2. Place the patient in the lithotomy position.
3. Insert a large vaginal speculum to gain cervical access.
4. Clean the cervix with an appropriate cleaning solution to prepare for device insertion.

Catheter Placement

1. Use the Cervical Ripening Balloon with stylet to traverse the cervix if necessary.

NOTE: Once the cervix has been traversed and the uterine balloon is above the level of the internal uterine opening (internal os), remove the stylet before further advancing the catheter.

2. Advance the Cervical Ripening Balloon until both balloons have entered the cervical canal.
3. Inflate the uterine balloon with 40mL of normal saline using a standard 20mL Luer-lock syringe through the red Check-Flo valve.
4. Once the uterine balloon is inflated, the device is pulled back until the uterine balloon is against the internal cervical os.
5. The vaginal balloon should now be visible outside the external cervical os. Inflate the vaginal balloon with 20mL of normal saline using a standard 20mL Luer-lock syringe through the green Check-Flo valve.
6. Once the balloons are situated on each side of the cervix and the device has been fixed in place, remove the speculum.
7. Add more fluid to each balloon in turn, in 20mL increments until each balloon contains 80mL (maximum) of fluid. **NOTE:** Do NOT over inflate the balloons.
8. If desired, the proximal end of the catheter may be taped to the patient's thigh.

NOTE: The device is not intended to be in place for longer than 12 hours. Time the placement of the device 12 hours prior to the planned induction.

Device Removal

Deflate both balloons through the corresponding Green and Red Check-Flo valves and remove vaginally.

NOTE: If the membranes rupture spontaneously before removal of the device, it is recommended to deflate the balloons and remove the device to facilitate active labor management.

DISPOSAL

The product should not be reprocessed and used again. It should be considered as healthcare waste and be treated or disposed of in facilities with the appropriate authorizations.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING


Keep dry


Do not use if package is damaged


Consult operating instructions


Keep away from sunlight


Date of Manufacture

Sterilized using ethylene oxide

Lot number


Do not reuse

Do not resterilize


Attention, see instructions for use

Catalog number


Use by

CE Mark

SCW Medicath Ltd.
NO.4 Baolong 6th Road, Baolong Industrial Town, Longgang District, Shenzhen, 518116 Guangdong, P.R.China
TEL: (86)755-89312160
FAX: (86)755-89312239

EC REP **Obelis s.a.**
Bd. Général Wahis 53, 1030 Brussels, Belgium