CE 0197

Brun Medical Co., Ltd.

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Cervical Ripening Balloon [INSTRUCTION FOR USE]

1. INTENDED PURPOSE

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 by professional physician.

2. INTENDED USER

Intended users are the competent physician who have the training in postpartum hemorrhage treatment.

3. INTENDED PATIENT POPULATION

Patients needing postpartum hemorrhage treatment.

4. CONTRAINDICATION

- ●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

5. HANDING AND STORAGE

Stored in the relative humidity of not more than 80%, non-corrosive gases, a common, dry, well-ventilated and clean environment.

6. STRUCTURE AND SPECIFICATIONS

The device is consist of the catheter, balloon, tip, filling valve ,locking ring and steel wire(BR-CVB-18FII).

Specifications:

Model	Volume(ml)	Length(cm)	Size(cm)	Steel wire
BR-CVB-18F	80	40	18Fr	/
BR-CVB-18FⅡ	80	40	18Fr	√

7. PRODUCT PERFORMANCE

The device has an obvious effect on promoting the cervix ripening and can ripen and dilate the cervix without phamaceuticals.Medical grade material ensure the highest level of safety and silicone material eliminate the issue of patient sensitively to latex.

8. 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.

Device Placement

1. Insert the device into the cervix and advance until both balloons have entered the cervical canal.
2. Inflate the uterine balloon with 40mL of normal saline using a standard 20mL Luer-lock syringe through the red Check-Flo valve marked “U“.
3. Once the uterine balloon is inflated, the device is pulled back until the uterine balloon is against the internal cervical os.
4. The vaginal balloon is now 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 marked “V“.
5. Once the balloons are situated on each side of the cervix and the device has been fixed in place, remove the speculum.
6. 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.

7. 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 valves marked “U” and “V” 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.

9. PRODUCT LABEL AND PACKAGING (See the label or packaging)

1.Product name, model and specification.
2.Production date, batch lot.
3.Sterilization expiry date.

10. CAUTION

●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 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 Cook Cervical Ripening Balloon has not been established.

●If spontaneous rupture of membranes occurs while the Cook 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.

Procedure must be performed by trained medical personnel.

●Sterilization is valid for three years, please confirm date of sterilization prior to use, do not use if expiry.

Caution

Use-by date

Keep dry

Keep away from sunlight

Catalogue number

Date of manufacture

Manufacturer

Do not re-use

Sterilized Using ethylene oxide

Do not use if package is damaged and consult instrction for use

Batch code

Unique device identifier

Authorized representative in the European Commutity/ European Union

Consult instructions for use or consult electronic instructions for use

Do not resterilize

Medical device

Single sterile barrier system

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