m|devices®

OB010020
Cervical Dilating Balloon

INSTRUCTION FOR USE

PATIENT PREPARATION

Sterile gloves and equipment should be used.

1. Ensure there are no contraindications to the procedure and obtain informed consent for the procedure.
2. Perform an abdominal ultrasound to confirm placental location and fetal presentation.
3. Place the patient in the lithotomy position.
4. Insert an appropriately sized vaginal speculum and visualise the cervix.

FOR USE BY A QUALIFIED CLINICIAN. THE BELOW IS ONLY A SUGGESTION AND FACILITY PROTOCOL MUST BE FOLLOWED FOR ALL CLINICAL PROCEDURES WHERE THIS PRODUCT IS USED.

⚠ CAUTION

- Cervical Dilating Balloon is only to remain in situ for up to a maximum of 12 hours or until clinically indicated.
- NOT for use where clinically contraindicated
- DO NOT use saline to inflate the balloon.
- Single use.
- DO NOT re-sterilise.
- DO NOT store at extreme temperatures and humidity, avoid direct sunlight. Handle with care.
- STERILE (EO), DO NOT use if the package or product has been damaged or contaminated.
- EU Notice: any serious incident that has occurred in relation to the device should be reported to the manufacture and the competent authority of the Member State in which the user and /or patient is established.

DEVICE PLACEMENT

1. Insert the shaft tip of the Cervical Dilating Balloon into the vagina and advance through the cervix until the balloon has entered the cervical canal.
2. Using a sterile syringe inflate the balloon with sterile water via the **YELLOW** non-return valve to a volume of 80mL.
3. Remove vaginal speculum.
4. Perform a digital vaginal examination or ultra sound to ensure the balloon is above the internal orifice of the cervical canal. Ensure the catheter is pulled back snug against the cervix.
5. If desired, move patient out of lithotomy position to a comfortable recline. Secure the balloon catheter to the thigh under light traction using the m|devices Securement Device.
6. Use of the m|devices Securement Device is recommended to secure the Cervical Dilating Balloon to the thigh. Start by removing the adhesive backing and placing the balloon shaft on sticky tab. Secure the balloon catheter in place with tabs, by feeding the smaller tab through the opening of the larger tab and secure to the fabric.

PRECAUTION

- Do not over inflate balloon.
- Balloon lumen is clearly labelled "Balloon 80mL" with **YELLOW** non-return valve.
- Ensure dressing component of the Securement Device is applied evenly to skin without creases.

DEVICE REMOVAL

1. m|devices Securement Device removal; Gently lift one edge of the dressing component and slowly peel away from the skin. To release the Cervical Dilating Balloon, peel and lift the two tabs one at a time for removal.
2. Deflate balloon completely with a syringe via the **YELLOW** non-return valve on the balloon lumen.
3. Carefully pull device out of vagina and inspect to ensure it is intact and complete.
4. Dispose of Cervical Dilating balloon and securement device as per facility protocol.

NOTE: Do not re-sterilise or re-use.

CONTRAINDICATIONS

- Patient receiving or planning to undergo exogenous prostaglandin administration
- Placenta praevia, vasa praevia, or invasive placenta (accreta, increta or percreta)
- Transverse fetal orientation
- Breech presentation
- Prolapsed umbilical cord
- Prior hysterectomy, classical uterine incision, myomectomy or any other full-thickness uterine incision
- Two or more previous caesarean sections
- Pelvic structural abnormality
- Active genital herpes infection
- Invasive cervical cancer
- Abnormal fetal heart-rate patterns
- Growth restricted foetus with abnormal umbilical artery doppler +/- abnormal amniotic fluid index
- Maternal heart disease
- Multiple gestation pregnancy
- Polyhydramnios
- Presenting part above the pelvic inlet
- Unstable fetal position
- Severe maternal hypertension
- Ruptured membranes
- Regular uterine contractions
- Significant antepartum haemorrhage
- Presence or clinical suspicion of chorioamnionitis
- Significant allergy to silicone
- Any contraindication to labour induction

WARNING

- This product should not be left indwelling for a period greater than 12 hours or until clinically indicated.
- The safety and effectiveness of the m|devices Cervical Dilating Balloon has not been established among women with an obstetric history of low transverse caesarean section.
- If spontaneous rupture of membranes or inadvertent rupture of membranes occurs while the m|devices balloon is in situ there is a risk of cord prolapse or umbilical cord entanglement with the device, both of which would necessitate urgent caesarean delivery.
- The m|devices Cervical Dilating Balloon is not for combined use with any other devices or pharmacological agents.
- Do not inflate balloon with air, carbon dioxide or any other gas.

POTENTIAL ADVERSE EVENTS

Risks associated with the use of the m|devices Cervical Dilating Balloon and labour induction may include, but are not limited to:

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

m|devices
27 Llewellyn Avenue
Villawood NSW 2163
Australia
T +61(0)2 8718 2800
F +61(0)2 8718 2801

SURGICAL & SPECIALTIES Cervical Ripening Balloon

Integral Medical Products Co Ltd
No.2 Dongze Road, High-Tech
Industrial Development Zone
312000 Shaoxing
Zhejiang, China

EC REP **Shanghai International Holding Corp. Gmbh (Europe)**
Eiffestrasse 80
20537 Hamburg
Germany

STERILE EO MD CE 0123