

**OB010020**

**Cervical Dilating Balloon  
and Securement Device**



## 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. THIS IS  
ONLY A SUGGESTION AND FACILITY PROTOCOL  
MUST BE FOLLOWED FOR ALL CLINICAL  
PROCEDURES WHERE THIS PRODUCT IS USED.**

### 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 ultrasound 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. Apply Securement Device to the thigh. Remove adhesive backing and place balloon shaft on sticky tab. Secure 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 resterilise or reuse.

## 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

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