OBSolve Origins®

Discreet Induction System with Introducer Stylet

Product code: CRB-00

Instructions for Use

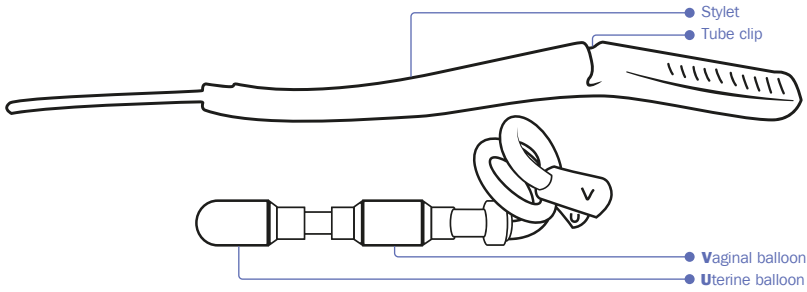


Figure 1. Device overview

Product description

The OBSolve Origins® Discreet Induction System with Introducer Stylet is a sterile, silicone dual-balloon cervical ripening catheter incorporating an integrated stylet and coiled filling tube.

The device comprises:

- A catheter shaft with two balloons.
- A coiled filling tube with separate inflation lumens and access ports marked vaginal balloon (V) and uterine balloon (U).
- A stylet (introducer handle) to assist passage through the cervix with a handle and clip feature to support preparation and control of the coiled inflation tubing during placement.

The device is supplied in a coiled state with the stylet pre-inserted. During preparation, the tubing is extended for use and may remain clipped to handle during balloon placement and inflation.

Intended Use / Indications for Use

The OBSolve Origins Discreet Induction System with Introducer Stylet is intended for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

Intended users and use environment

The device is intended for use by appropriately trained healthcare professionals experienced in obstetric procedures and cervical balloon placement, in a suitably equipped obstetric or labor ward setting with maternal and fetal monitoring available in accordance with local protocol.

How supplied

The device is supplied sterile in a peel-open pack and is intended for single use only.
Do not use if:

- The package is opened or damaged.
- Sterility is in doubt.
- The device has visible damage.

Store in a cool, dry place away from excessive heat, moisture, and prolonged light exposure.

Quick user guide

Parameter	Instruction
Initial uterine balloon fill	20 mL, then a further 20 mL
Initial vaginal balloon fill	20 mL, then a further 20 mL
Optional further inflation	10 mL increments, if clinically required
Maximum balloon volume	80 mL per balloon
Maximum indwell time	12 hours
Earlier removal triggers	Spontaneous expulsion, rupture of membranes, onset of labor, maternal/fetal concern, clinician decision

Instructions for use

Patient preparation

1. Confirm that the patient is an appropriate candidate for mechanical cervical ripening and that no contraindications are present.
2. Confirm gestational age and fetal presentation in accordance with local protocol.
3. Confirm that informed consent for the induction procedure has been obtained in accordance with institutional practice.
4. Assess the maternal condition, fetal condition, and baseline fetal heart rate according to local protocol.
5. Where used in your practice, perform ultrasound to confirm singleton, vertex presentation and to exclude placenta praevia and other relevant placental abnormalities.
6. Position the patient in lithotomy position.
7. Insert an appropriate vaginal speculum to visualise the cervix.
8. Clean the cervix and vaginal fornices using an appropriate antiseptic or cleansing solution in accordance with local protocol.

Device preparation

1. Open the package using aseptic technique.
2. Remove the device and inspect it for damage.



Figure 2. The device

3. Extend the inflation tubing from its coiled state into a straight position.
4. Clip the tubing onto the handle, if desired, to assist control during placement and inflation.
5. Confirm that both balloons are fully deflated prior to insertion.
6. Prepare two sterile Luer slip syringes containing sterile normal saline.

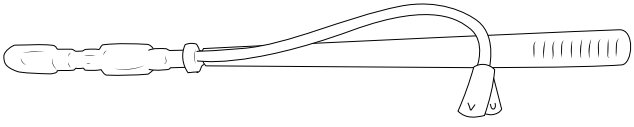


Figure 3. Device preparation

Insertion and positioning

1. Introduce the distal end of the catheter through the cervical canal using direct visualization.
2. Advance the catheter until the uterine balloon has passed beyond the internal os.

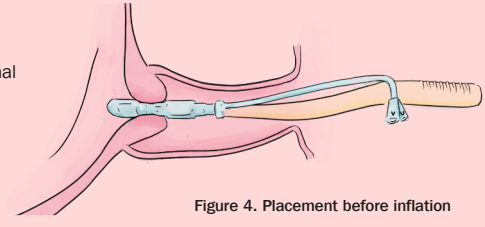


Figure 4. Placement before inflation

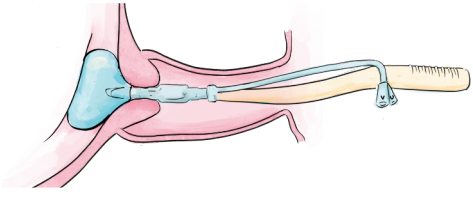


Figure 5. Final in-situ position with U balloon inflated

3. Once the uterine balloon is above the internal os, inflate the uterine balloon marked U with 20 mL sterile normal saline.
4. Retract gently so that the uterine balloon sits against the internal cervical os.
5. Add a further 20 mL sterile normal saline to the uterine balloon.

6. Apply gentle traction to the catheter ensuring the uterine balloon is seated against the internal os, and confirm that the vaginal balloon is visible outside the external os.
7. Inflate the vaginal balloon marked V with 20 mL sterile normal saline.
8. Add a further 20 mL sterile normal saline to the vaginal balloon.

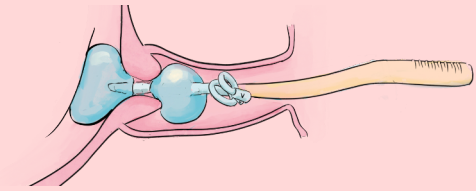


Figure 6. Final position with both balloons opposing the cervix

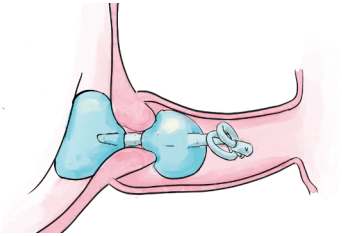


Figure 7. Stylet removed, coiled tube tucked comfortably into the vagina.

9. 40 mL in each balloon is usually sufficient. If clinically required, increase either or both balloons in 10 mL increments up to a maximum of 80 mL per balloon.
10. Do not overinflate either balloon.
11. Confirm that the uterine balloon is seated above the internal os and that the vaginal balloon lies below the cervix.
12. When final positioning is complete, the tubing may be released from the clip and allowed to return to its coiled state.
13. Remove the stylet whilst supporting the shaft of the catheter.
14. Tuck the coiled tubing comfortably and safely into the vagina.

Indwell period and monitoring

1. Record the time of placement and the final volume in each balloon.
2. The device may remain in place for up to 12 hours maximum.
3. Monitor the mother and fetus during the indwell period in accordance with local obstetric protocol.
4. If regular uterine contractions with clinical labor progress occur, assess the patient and proceed according to local protocol.
5. Remove the device promptly if any of the following occurs:
    - Spontaneous rupture of membranes.
    - Spontaneous expulsion of the device.
    - Onset of labor with a clinical decision to proceed to the next stage of induction or labor management.
    - Non-reassuring fetal heart-rate pattern.
    - Clinically significant vaginal bleeding.
    - Suspected intra-amniotic infection or maternal pyrexia requiring removal.
    - Severe maternal discomfort, intolerance, or any other clinician-determined reason.
6. Do not leave the device in place beyond 12 hours in an attempt to achieve a particular cervical dilatation.
7. If the device is expelled spontaneously, reassess the patient and proceed according to clinical judgement and local protocol.

Device removal

1. Using a gloved hand, retrieve the coiled tube from the vagina.
2. Attach an empty Luer slip syringe to the inflation port marked U and completely aspirate or allow passive drainage of the uterine balloon contents until the balloon is fully deflated.
3. Attach an empty luer slip syringe to the inflation port marked V and completely aspirate or allow passive drainage of the vaginal balloon contents until the balloon is fully deflated.
4. Once both balloons are fully deflated, gently remove the device vaginally.
5. If resistance is encountered, stop, reconfirm complete deflation of both balloons, and then remove gently.
6. Inspect the removed device to ensure that it is intact.
7. Record the time of removal and the reason for removal.
8. Continue labor induction or labor management in accordance with local protocol.

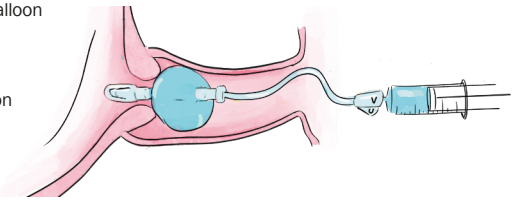


Figure 8. Removal sequence - uterine balloon deflated

Contraindications
Do not use the device in patients with any of the following:
- Any contraindication to labor induction or vaginal delivery.
- Ruptured membranes.
- Planned or ongoing administration of exogenous prostaglandins.
- Placenta previa, vasa previa, or placenta percreta.
- Prolapsed umbilical cord.
- Transverse lie or other malpresentation incompatible with vaginal delivery.
- Breech presentation.
- Abnormal fetal heart-rate pattern requiring alternative obstetric management.
- Prior classical cesarean section, prior hysterotomy, myomectomy entering the uterine cavity, or any other full-thickness uterine incision.
- Invasive cervical malignancy.
- Active genital herpes infection.
- Multiple gestation.
- Pelvic structural abnormality that may prevent safe placement or vaginal delivery.
- Polyhydramnios.
- Presenting part above the pelvic inlet.
- Severe maternal hypertension where induction is not appropriate.
- Maternal cardiac disease without clearance for vaginal delivery.

Warnings
- Do not leave the device indwelling for longer than 12 hours.
- Do not use the device concurrently with exogenous prostaglandins unless such use has been specifically established as safe and is part of an approved clinical protocol for this device.
- Use only sterile normal saline, unless an alternative sterile fill medium has been specifically validated and approved for this device.
- Do not inflate with air, carbon dioxide, or any other gas.
- Do not exceed the validated maximum inflation volume. Overinflation may result in balloon rupture or tissue injury.
- The stylet is intended only to assist passage through the cervix and to support the tube when extended from its natural coiled state.
- Aggressive insertion or advancement may cause cervical trauma, bleeding, rupture of membranes, or fetal injury.
- If spontaneous rupture of membranes occurs while the device remains in place, the uterine balloon may descend and become associated with cord prolapse or cord entanglement. Deflate both balloons completely and remove the device promptly.
- Close maternal and fetal monitoring is required during and after placement in accordance with local protocol.
- The device is for single use only. Do not reuse, reprocess, or resterilize.

Precautions
- Inspect the packaging before use. Do not use the device if the sterile barrier is damaged or if the device appears damaged.
- Use aseptic technique throughout preparation, insertion, inflation, monitoring, and removal.
- Use caution during placement to avoid rupture of the amniotic membranes.
- Record the time of insertion, the fill volume of each balloon, the time of removal, and the reason for removal.
- If resistance is encountered during removal, stop and confirm that both balloons are fully deflated before further traction is applied.
- After removal, inspect the device to confirm that it is intact.

Possible adverse events
Potential adverse events associated with the device and/or labor induction include, but are not limited to:
- Placental abruption.
- Uterine rupture.
- Spontaneous rupture of membranes.
- Device expulsion.
- Device entrapment and/or fragmentation.
- Maternal discomfort or pain during and after insertion.
- Failed cervical ripening or failed induction.
- Need for operative vaginal delivery or cesarean delivery.
- Cervical laceration or vaginal trauma.
- Vaginal bleeding.
- Intra-amniotic infection or maternal pyrexia.
- Fetal heart-rate abnormality.
- Umbilical cord prolapse or cord entanglement if membranes rupture with the device in place.
- Neonatal compromise associated with the underlying induction process.

Explanation of Symbols

REF	Catalogue Number		Do not use if package is damaged
LOT	Batch Code		Caution
	Expiry Date		Do not resterilize
STERILE EO	Sterilized using Ethylene Oxide		Not made with natural rubber latex
	Do not re-use	R_x Only	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Consult instructions for use		

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