Utah CVX-RIPE®
Cervical Ripening Dual Balloon Catheter

Instructions for Use

Catalog Number: CVX-100

Device Description

Utah CVX-RIPE is a silicone, dual-balloon, transcervical ripening catheter and stylet.

Indications For Use

Utah CVX-RIPE is intended to mechanically improve the favorability of the cervix of pregnant patients at term gestation, in which induction of labor is medically indicated.

Pouch Contents (10 pouches per box)

1 ea. Utah CVX-RIPE Dual-Balloon, Silicone Ripening Catheter with Stylet
1 ea. 20 mL syringe

Contraindications

- Patients with any contraindication to spontaneous or induced labor
- Patients who may simultaneously receive prostaglandin administration
- Any fetal presentation, position or orientation that contraindicates vaginal delivery
- Any abnormal placental or umbilical cord features that contraindicate vaginal delivery, including, but not limited to, placenta previa, placenta percreta and/or vasa previa.
- Any prior uterine incision(s) that contraindicates spontaneous or induced labor and/or vaginal delivery
- Ruptured amniotic membranes
- Patients with an active genital tract infection such as genital herpes
- Cervical cancer
- Abnormal fetal heart rate tracing
- Multiple gestational pregnancy

Warnings and Precautions

- Avoid contact with the device by sharp instruments or clamps which might damage the soft balloons or catheter material and result in device failure.
- **AVOID EXCESSIVE FORCE** when inserting the catheter through the vagina and into the cervix.
- The tip of the catheter should not be advanced past the internal cervical os until the stylet is removed. Insertion beyond the internal os may result in patient injury and/or rupture of membranes.
- Aggressive insertion may cause injury to mother or fetus.
- The device should not be used if the amniotic membranes have ruptured

and special care should be taken to avoid rupturing the amniotic membranes during insertion. If amniotic membranes rupture after placement, the patient should be examined to ensure the device has not contributed to any emergent condition and the device should be carefully removed.

- Close maternal and fetal monitoring is required at all times during and after catheter placement.
- Only sterile saline should be used to inflate the balloon. Do not inflate with air or any other gas.
- Do not inflate the uterine balloon with more than 80 mL, or the vaginal balloon with more than 40 mL, of sterile saline.
- The maximum indwell time for the catheter is 12 hours.
- Use of the catheter in conjunction with pharmaceutical ripening agents such as prostaglandins may result in uterine hyperstimulation and/or other serious side-effects which could result in serious patient injury or death. Concomitant use of the catheter with prostaglandins is contraindicated.
- Infusion of extra-amniotic saline while using Utah CVX-RIPE has not been studied for safety or effectiveness.

Catheter Placement

1. With the patient in lithotomy position, clean the cervix per hospital protocol. A vaginal speculum is typically used to aid in cervical cleansing and catheter placement.
2. Confirm deflation of both catheter balloons using the 20 mL syringe and the ports labeled “Uterine” and “Vaginal.”
   Note: Utah CVX-RIPE may be safely inserted with or without use of the stylet preloaded in the catheter. If the stylet is not needed, remove prior to catheter insertion
3. Using a finger as a guide, gently slide the catheter through the cervix and cervical canal until the tip of the catheter is at the internal cervical os.
4. Remove the stylet.

Warning: The tip of the catheter should not be advanced past the internal cervical os until the stylet is removed. Insertion beyond the internal os may result in patient injury and/or rupture of membranes.

5. After removing the stylet, advance the catheter until the vaginal balloon has entered the cervical canal.
6. Using the 20 mL syringe and the blue port labeled “Uterine” inflate the uterine balloon with 40 mL of sterile saline.
7. Taking care not to pull the uterine balloon into the cervical canal, gently pull the catheter so that the uterine balloon abuts the internal cervical os. The vaginal balloon may be visualized at the external cervical os.
8. Using the white port labeled “Vaginal” inflate the vaginal balloon with 40 mL of sterile saline.
9. If a speculum has been used, it may be removed.

10. Continue inflating the uterine balloon in 20 mL increments. Optimal balloon inflation volume depends on individual patient anatomy and desired cervical dilation.

Warning: Do not inflate the uterine balloon with more than 80 mL or the vaginal balloon with more than 40 mL, of sterile saline.

11. Once the balloons have been inflated, the placement procedure is complete. Continue to closely monitor the mother and fetus while the catheter is in the patient.

Catheter Removal

- If after 12 hours the catheter has not been expelled spontaneously due to adequate cervical dilation, deflate both balloons and gently slide the catheter from the cervix and vagina.

Warning: The device should be removed after 12 hours.
Warning: The device should be removed if the amniotic membranes rupture.

REUSE WARNING: Reuse of this sterile device poses a significant risk of cross contamination and sepsis and/or dependence on an unvalidated process. **This device is not structurally designed or validated for reuse.**

DISPOSAL: Dispose of the used product with other medical waste per facility protocol for products contaminated with bodily fluids and tissue.

EU NOTICE: Any serious incident (as defined in EU MDR Ch. I, Article 2 (65)) that occurs in relation to this device should be reported to the manufacturer and the competent authority of the Member State where the incident occurs.

MD	Medical Device
℞ ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician or other licensed practitioner
2	Do not re-use
2 STERILIZE	Do not resterilize
	Do not use if package is damaged
LATEX	Product is not manufactured with natural rubber latex
STERILE EO	Sterilized using ethylene oxide
	Manufacturer
EC REP	Authorized representative in the European Community
DEHP	DEHP Free

United States
Utah Medical Products, Inc.
7043 South 300 West
Midvale, UT 84047
800.533.4984 • 801.566.1200
www.utahmed.com

CE 1639

EC REP
Utah Medical Products Ltd.
Athlone Business & Technology Park
Athlone, Co. Westmeath, N37 XK74
Ireland
353.90.647.3932

United Kingdom
Femcare Ltd.
32 Premier Way
Romsey, Hampshire SO51 9DQ
44.1794.525.100
www.femcare.co.uk

Australia
Femcare Australia Pty Ltd.
Unit 12
5 Gladstone Road
Castle Hill NSW 2154
61.2.9045.4100

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