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CooperSurgical®

DuoRipe™ Cervical Ripening Balloon Products

Instructions for Use

CE 2797 UK CA 0086

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

DEVICE DESCRIPTION

The DuoRipe™ Cervical Ripening Balloon is a silicone double balloon catheter. The maximum balloon inflation is 80 mL/balloon. The balloon catheter shaft is 18.0 French size and a length of 40 centimeters. It is identified by part number J-CRB-184000, is manufactured with dual lumens and each lumen contains a check valve which indicates access to the uterine balloon by the letter “U” or the vaginal balloon with the letter “V”. The check valves are also color-coded green for the vaginal balloon and red for the uterine balloon. The DuoRipe™ Cervical Ripening Balloon, identified by part number J-CRBS-184000, includes a malleable stylet and a third lumen used to insert the stylet. The valve of the third lumen indicates access to the inner stylet lumen by the letter “S” and is color-coded blue.

INTENDED USE

The DuoRipe Cervical Ripening Balloon is intended for mechanical dilation of the cervical canal prior to labor induction at term when the cervix is unfavorable for induction.

INDICATIONS FOR USE

The DuoRipe 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.

PERFORMANCE CHARACTERISTICS

- Uterine and vaginal balloons for dilation of the cervical canal.
- Color coded valves and letter abbreviations to distinguish balloon inflation and stylet lumens.
- A lumen activated valve allows for inflation of the balloons.

INTENDED USERS

DuoRipe Cervical Ripening Balloon is intended for physicians or properly licensed practitioners trained and experienced in OBGYN techniques.

CONTRAINDICATIONS

- Patient receiving or planning to undergo exogenous prostaglandin administration
- Multiple gestational pregnancy
- Polyhydramnios
- Prior hysterotomy, classic uterine incision, myomectomy or any other full-thickness uterine incision
- Active genital herpes infection
- Invasive cervical cancer
- Any contraindication to labor induction
- Ruptured membranes
- Situations that, at the discretion of the obstetrician, would not be appropriate for labor induction / vaginal delivery, such as: placenta previa, vasa previa, or placenta percreta
- Transverse fetal orientation
- Prolapsed umbilical cord
- Pelvic structural abnormality
- Abnormal fetal heart-rate patterns
- Breech presentation
- Maternal heart disease without clearance for vaginal delivery from a cardiologist
- Severe maternal hypertension
- Presenting part above the pelvic inlet

WARNINGS

- Concomitant use of the DuoRipe 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
  - Maternal death
- The stylet should only be used to traverse the tip of the catheter through the cervix and should be removed as soon as the uterine balloon is above the level of the internal uterine opening (internal os) prior to full insertion of the catheter. Aggressive insertion may result in injury to the baby.
- The product should not be left indwelling for longer than 12 hours.
- The safety and effectiveness of the DuoRipe 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 DuoRipe Cervical Ripening Balloon has not been established.
- 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.
- If spontaneous rupture of membranes occurs while the DuoRipe 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
- Contents supplied sterile. Do not use if sterile barrier is damaged.
- Dispose of in accordance with all applicable Federal, State, and local Medical/Hazardous waste practices.

PRECAUTIONS

If fetal membranes rupture spontaneously while this device is in place, it is recommended that both balloons be deflated and the device removed in preparation for spontaneous active labor contractions.

POTENTIAL ADVERSE EVENTS

Risks associated with use of the DuoRipe Cervical Ripening Balloon and labor induction may include, but are not limited to:

- Placental abruption
- Uterine rupture
- Cord prolapse
- Device expulsion
- Device entrapment and/or fragmentation
- Failed dilation or need for caesarean delivery
- Cervical laceration
- Bleeding
- Risk of pre-term labor and birth in subsequent pregnancy

REPORTING OF SERIOUS INCIDENTS

PLEASE NOTE: If a serious incident is suspected from using the DuoRipe Cervical Ripening Balloon, report the details of the incident to CooperSurgical via the online complaint form https://www.coopersurgical.com/support/customer-complaint-form/, by email at ProductSurveillance@coopersurgical.com, or by phone number +1 203-601-5200 Ext. 3100 and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

CLINICAL BENEFITS

Cervical ripening with the goal of vaginal delivery.

PATIENT POPULATION

Pregnant patients.

INSTRUCTIONS 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.

Using The Moldable Stylet

1. Seat the stylet handle firmly into the blue port labeled “S.”
2. Use the Cervical Ripening Balloon with stylet to traverse the cervix if necessary.
   NOTE: Once the cervix has been traversed and the uterine balloon is above the level of the internal uterine opening (internal os), remove the stylet before further advancing the catheter.
3. Advance the Cervical Ripening Balloon until both balloons have entered the cervical canal.
4. Inflate the uterine balloon with 40 mL of sterile saline using a standard 20 mL Luer-lock syringe through the red Check-Flo valve marked “U“.
5. Once the uterine balloon is inflated, pull the device back until the uterine balloon is against the internal cervical os.
6. The vaginal balloon should now be visible outside the external cervical os. Inflate the vaginal balloon with 20 mL of sterile saline using a standard 20 mL Luer-lock syringe through the green Check-Flo valve marked “V“.
7. Once the balloons are situated on each side of the cervix and the device has been fixed in place, remove the speculum.
8. Add more fluid to each balloon in turn, in 20 mL increments, until each balloon contains 80 mL (maximum) of fluid. **NOTE**: Do not over inflate the balloon.
9. 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.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from the package, inspect the product to ensure no damage has occurred.

REFERENCES

Atad J, Hallak M, Ben-David Y, Auslender R, Abramovici H. Ripening and dilation of the unfavorable cervix for induction of labor by a double balloon device: experience with 250 cases. Br J Obstet Gynaecol. 1997;104 (pt 1): 29.

Atad J, Hallak M, Auslender R, Porat-Packer T, Zarfati D, Abramovici H. A randomized comparison of prostaglandin E2, oxytocin and the double-balloon device in inducing labor. Obstet Gynecol. 1996; 87:223-227.

Sherman D. Frenke E, Tovbin J, Arieli S, Caspi E, Bukovsky I. Ripening of the unfavorable cervix with extra amniotic catheter balloon: clinical experience and review. Obstet Gynecol Survey. 1996; 51 (10): 621-627.

GLOSSARY OF SYMBOLS

Source: ISO 15223-1 and ISO 7000

Symbol	Title
	Packaging unit
	Catalogue number
	Batch code
	Country of manufacture ("CC" shall be replaced by either the two letter or the three letter country code)
	Date of manufacture
	Manufacturer
	Use-by date
	Medical Device
	Do not re-use
	Do not resterilize
	Sterilized using ethylene oxide

Symbol	Title
	Single sterile barrier system
	Caution
	Consult instructions for use or consult electronic instructions for use
	Do not use if package is damaged and consult instructions for use
	Keep dry
	Keep away from sunlight
	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations
	The product conforms to the UK Device Medical Regulation 2002, as amended. The product can be freely marketed in Great Britain (England, Wales and Scotland)
	Importer
	Authorized representative in the European Community

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