

Amniotic Membrane Perforator

Single Patient Use Only Disposable • Sterile **Rx Only**

IMPORTANT

Read carefully and completely before use.

INTENDED USE

The amniotic membrane perforator is intended for performing amniotomy, or artificial rupture of the amniotic membrane, commonly used to induce or augment labor.

INDICATIONS

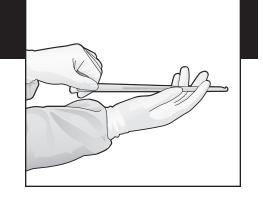
Use of this device is indicated when a physician deems amniotomy necessary in the course of normal vaginal delivery.

PRECAUTIONS

- The package should be opened using sterile technique.
- Care should be taken in handling the device as the distal end is very sharp and could cause scratches, lacerations, and glove perforations to the user, assistants, or patients.

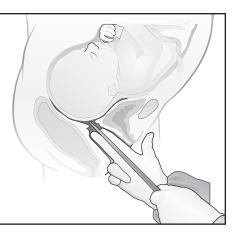
CAUTIONS

- Care should be taken while performing amniotomy to prevent lacerating or scratching the fetus' head.
- In order to minimize the risk of umbilical cord prolapse, care should be taken to avoid dislodging the fetal head. An assistant ap-



plying fundal and suprapubic pressure may reduce the risk of cord prolapse. Alternatively, membrane rupture may be performed during a uterine contraction.

 The fetal heart rate should be assessed prior to and immediately after the procedure.



DIRECTIONS FOR USE

- 1. Visually examine the package for damage before opening the package. Replace perforator if the package or the device itself show signs of damage.
- 2. Open package using sterile technique.
- **3.** Position the membrane perforator, point up, recessed on the index and middle fingers of



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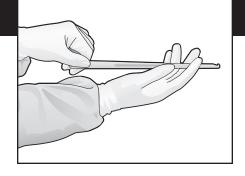
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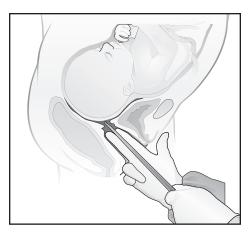
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- 2. Open package using sterile technique.
- **3.** Position the membrane perforator, point up, recessed on the index and middle fingers of



the examining hand. The grips at the distal end of the hook may be used for a firmer grip.

- **4.** Guide fingers and hook into the cervix until able to palpate the amniotic membrane.
- **5.** Slide forward the operative end of the hook, point upward, further into the cervix along finger groove. The index marks at the distal end of the hook may be used to determine the direction the hook is pointing.
- 6. During uterine contraction, press hook against membrane and gently draw hook up and toward you, catching the tissue until rupturing sac.
- Recess the hook again on protective finger groove, then remove fingers and instrument.
- **8.** Discard the perforator after use. Do not resterilize.

Contents sterile unless package has been opened or damaged.

7DeRoyal®

Manufacturer DeRoyal 200 DeBusk Lane, Powell, TN 37849 U.S.A. 888.938.7828

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