

Mityone Vacuum Assist Delivery Cup

The MityOne® M-Style® Mushroom® Cup is designed to assist a practitioner in the delivery of an infant during childbirth. The MityOne is an integrated pump and cup system, packaged, and sterilized for immediate use.

INDICATIONS FOR VACUUM-ASSISTED VAGINAL DELIVERY

No indication is absolute.

Fetal:

- Nonreassuring fetal status
- Failure to deliver spontaneously following an appropriately managed second stage of labor

Maternal:

- Need to avoid voluntary expulsive efforts
- Inadequate expulsive efforts

PREREQUISITES FOR VACUUM-ASSISTED VAGINAL DELIVERY

- Term infant
- Ruptured membranes
- Empty bladder and nondistended rectum
- Engaged vertex position
- Complete cervical dilation and effacement
- Willingness to abandon procedure and plan for alternate delivery route

These instructions are intended as general guidelines. Practitioners should refer to current institutional and recognized guidelines that address vacuum-assisted delivery.

VACUUM-ASSISTED VAGINAL DELIVERY GUIDELINES

1. Check the integrity of the MityOne Obstetrical Vacuum-Assist Delivery System by pressing the cup to the palm of your gloved hand and applying vacuum. The gauge needle should remain steady. (NOTE: The gauge needle should rest in the “ZERO” box when vacuum is not applied.)

CAUTION: DO NOT USE DEVICE IF GAUGE NEEDLE DOES NOT INDICATE ZERO IN THE ABSENCE OF A VACUUM.

2. Carefully examine fetal presentation and position prior to positioning the cup over the flexion point.

CAUTION: DO NOT USE PRODUCT IF FLEXION POINT IS NOT ACCESSIBLE.

3. Wipe the scalp as clean as possible.
4. To insert the M-Style Mushroom Cup, fold the cup against the stem at a 90° angle (see Figure 1).
5. With the stem in the bent position, grasp the mushroom shaped portion of the cup with the fingers. The stem should be parallel to palm and wrist. Separate the labia with the other hand. Continuing with the stem in the bent position, press the cup portion downward and inward over the fourchette to make contact with the fetal scalp. Apply the center of the cup over the flexion point (see Figure 2). The flexion

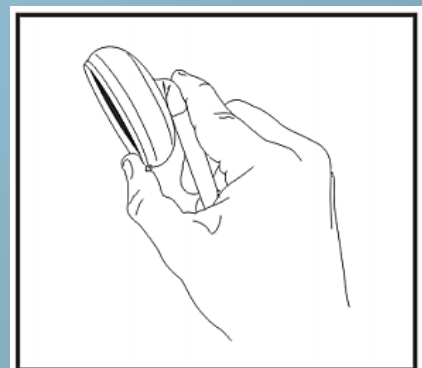


Figure 1 - M-Style Mushroom Cup

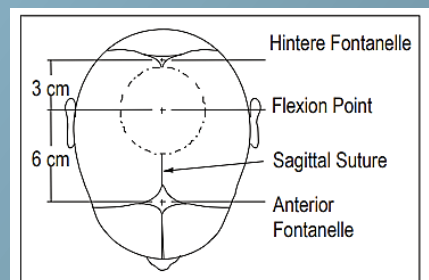


Figure 2 - Infant head

point can be located by identifying the posterior fontanelle and then moving the finger anteriorly along the sagittal suture approximately 1.2 in. (3 cm). The sagittal suture should pass under the middle of the cup.

CAUTION: NEVER APPLY THE CUP TO ANY PORTION OF THE INFANT'S FACE.

6. Gently move a finger around the rim of the cup to remove intrusion of extraneous tissues and to ensure proper cup placement.
7. With the cup placed over the flexion point, raise the vacuum level to approximately 3.9 in. (10 cm Hg) (yellow shaded area on gauge face) to initiate vacuum. Recheck the rim of the cup for interposed extraneous tissue.
8. With the onset of contraction, rapidly raise the vacuum to 15-22.8 in. Hg (38-58 cm Hg) (green shaded area on gauge face) and begin applying traction along pelvic axis.

CAUTION: DO NOT EXCEED RECOMMENDED VACUUM LEVELS.

9. When the contraction is no longer effective, discontinue traction. You may reduce the vacuum to approximately 3.9 in. Hg (10 cm HG) (yellow shaded area on gauge face) while awaiting the next contraction or maintain vacuum at current level. Reduce vacuum by slowly pushing or pulling on the vacuum release lever located directly beneath the gauge (see Figure 3).
10. Recheck for interposed extraneous tissue prior to each tractive effort.
11. If traction is misaligned or too forceful, the vacuum cup may disengage (pop off). In case of pop off, check fetal scalp for trauma before reapplying vacuum cup.

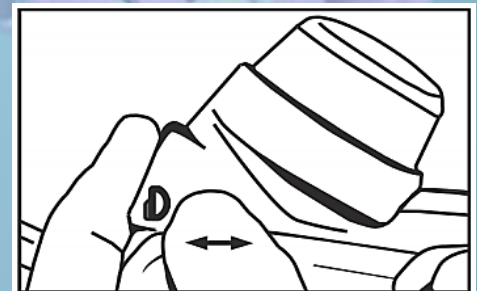


Figure 3 – Vacuum release lever

CAUTION: ABANDON VACUUM-ASSISTED DELIVERY IF THE VACUUM CUP DISENGAGES (POPS OFF) THREE TIMES.

12. With each successive contraction, draw the head gently over the perineum. Once the head is delivered, release vacuum (see Figure 3) and remove the cup. Continue delivery in the usual manner. In the unlikely event that vacuum does not release, with caution, use scissors and cut the stem, being careful to avoid the fetal scalp.

CAUTION: DO NOT OPERATE VACUUM PUMP AT TRACTIVE LEVELS FOR MORE THAN 10 CUMULATIVE MINUTES OF TRACTION OR TOTAL PROCEDURE TIME OF 15 TO 30 MINUTES.

13. Carefully examine infant's head and observe vital signs at regular intervals to ensure infant's well-being.
14. Dispose of the MityOne Delivery System in accordance with all applicable Federal, State and local Medical/Hazardous waste practices.
15. Document the use of the MityOne Delivery System and notify nursery staff per hospital protocol.