Mystic® II

Obstetrical Vacuum Assist Delivery System

QUICK REFERENCE GUIDE

This document is not intended to be the directions for use. Please refer to the instructions for use included with each Mystic II device.

Mitysoft® Bell Cup: Part # 10058

Soft Bell Style Cups should be used for OA presentations (70% - 85% of deliveries)

The Cochrane Database[1] and UpToDate[2] both suggest using soft, bell-shaped vacuum extractors for uncomplicated, occiput anterior deliveries. Mystic II MitySoft Bell Cup happens to be one of the softest most patient friendly bell cups on the market today.

[1] Bofill, James A., MD, et al., "The Mississippi Operative Vaginal Delivery Trial: Lessons Learned", Contemporary OB/GYN, October 1998.

[2] Schifrin, Barry S., MD, et al., "Cutting Your Legal Risks with Vacuum Assisted Delivery", OBG Management, June 1994.

M-Style® Low Profile Mushroom® Cup: Part # 10057

For Non OA Presentations use the NEW Mystic II M-Style® Low Profile Mushroom® Cup (roughly 20% of all deliveries are Non OA).

Vacuum Assisted Vaginal Delivery Guideliines

1. For **MitySoft Bell Cup**, remove the protective lid from the cup before use.
2. Check the integrity of the Mityvac Mystic II 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.
3. **Optional**: Connect a vacuum tracking device such as the Medevco VacuLink™ to the Luer Lock fiitting after unscrewing the cap. Then follow their directions for use provided.
4. Carefully examine fetal presentation and position prior to placing the cup over the flexion point.

   WARNING: DO NOT USE PRODUCT IF FLEXION POINT IS NOT ACCESSIBLE.
5. Wipe the scalp as clean as possible.
6. To insert the MitySoft Bell Cup, grasp the cup with the fingers and fold edges inward to facilitate insertion (see Figure 1). To insert the M-Style Mushroom Cup, fold the cup against the stem at a 90 degree angle (see Figure 2).

Figure 1 MitySoft Bell Cup

Figure 2 M-Style Mushroom Cup

7. **M-Style Mushroom Cup** - 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 3). The flexion point can be located by identifying the posterior fontanelle and then moving the finger anteriorly along the sagittal suture approximately 3 cm. The sagittal suture should pass under the middle of the cup.

   MitySoft Bell Cup - Separate the labia with the other hand. 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 3). The flexion point can be located by identifying the posterior fontanelle and then moving the finger anteriorly along the sagittal suture approximately 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

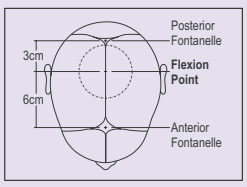


Figure 3 - Infant head

8. Gently move a finger around the rim of the cup to remove intrusion of extraneous tissues and to ensure proper cup placement.
9. With the cup placed over the flexion point, raise the vacuum level to approximately **10 cm Hg** (yellow shaded area on gauge face) to initiate vacuum. Recheck the rim of the cup for interposed extraneous tissue.
10. With the onset of contraction, rapidly raise the vacuum to **38-58 cm Hg** (green shaded area on gauge face) and begin applying traction.[1,2] Always apply traction in harmony with contractions and along the pelvic axis.

    CAUTION: DO NOT EXCEED RECOMMENDED VACUUM LEVELS.
    Note: Mystic II is self limiting. Mystic II will not allow you to pump into the red area on the gauge.
11. When the contraction is no longer effective, discontinue traction. You may reduce the vacuum to approximately **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 4).

Figure 4 - Vacuum release lever

12. Recheck for interposed extraneous tissue prior to each tractive effort.
13. 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.

    CAUTION: ABANDON VACUUM ASSISTED DELIVERY IF THE VACUUM CUP DISENGAGES (POPS-OFF) THREE TIMES.
14. With each successive contraction, draw the head gently over the perineum. Once the head is delivered, release vacuum and remove the cup. Continue delivery in the usual manner. In the unlikely event the vacuum does not release, unscrew Luer Lock cap at the bottom of the handle.

    CAUTION: DO NOT OPERATE VACUUM PUMP AT TRACTIVE LEVELS FOR MORE THAN TEN CUMULATIVE MINUTES OF TRACTION OR TOTAL PROCEDURE TIME OF 15 TO 30 MINUTES.
15. Carefully examine infant's head and observe vital signs at regular intervals to ensure infant's well being.
16. Dispose of the Mityvac Mystic II delivery system in accordance with all applicable Federal, State and local Medical/ Hazardous waste practices.
17. Document the use of the Mityvac Mystic II delivery system and notify nursery staff per hospital protocol.

Vacuum Assisted Cesarean Delivery Guidelines

1. MitySoft Bell Cup, remove the protective lid from the cup before use.
2. Check the integrity of the Mityvac Mystic II 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.
3. **Optional:** Connect a vacuum tracking lock device such as the Medevco VacuLink™ to the Luer fitting after unscrewing the cap. Then follow directions for use provided.
4. Enter the uterus routinely and assess fetal head position.
5. If the fetal head is high and accessible beneath the uterine incision, wipe the scalp as clean as possible and place vacuum cup over the flexion point. If the head is low and in accessible, place gloved fingers under the head and flex upward to bring the scalp under the uterine incision. Wipe scalp as clean as possible and apply the vacuum cup to the flexion point.

   CAUTION: NEVER APPLY THE CUP TO ANY PORTION OF THE INFANT'S FACE.
6. Raise the vacuum to 38-58 cm Hg (green shaded area on gauge face) and begin applying traction to gently bring the head upward through the incision.[1,2]
7. Once the head is delivered, release vacuum by slowly pushing or pulling on the vacuum release lever (Figure 4) and remove the cup. Continue delivery in the usual manner. In the unlikely event that vacuum does not release, unscrew Luer Lock cap at the bottom of the handle.
8. Carefully examine infant's head and observe vital signs at regular intervals to ensure infant's well being.
9. Dispose of the Mityvac Mystic II delivery system in accordance with all applicable Federal, State and local Medical/Hazardous waste practices.
10. Document the use of the Mityvac Mystic II delivery system and notify nursery staff per hospital protocol.

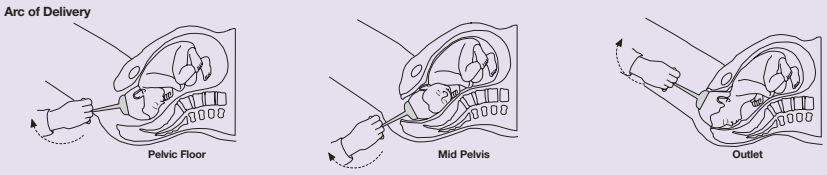
Prerequisites For Vacuum Assisted Cesarean Delivery

- Proper indication for operative delivery
- Proper indication for use of the vacuum assisted delivery device

[1] Bofill, James A., MD, et al., "The Mississippi Operative Vaginal Delivery Trial: Lessons Learned", Contemporary OB/GYN, October 1998.

[2] Schifrin, Barry S., MD, et al., "Cutting Your Legal Risks with Vacuum Assisted Delivery", OBG Management, June 1994.

Arc of Delivery



Warnings

- DO NOT exceed recommended vacuum levels.
- Never apply the vacuum cup to any portion of the infant's face.
- Vacuum assisted delivery should only be performed or supervised by a trained and experienced healthcare provider.
- There should be a willingness to abandon attempts at vacuum extraction if satisfactory progress is not made." (ACOG Technical Bulletin #196, Aug. 1994).
- Abandon vacuum assisted delivery if:
  - **a.** Vacuum cup becomes disengaged (pops-off) three times.
  - **b.** Vertex has not advanced substantially with each traction attempt.
  - **c.** There is evidence of fetal scalp trauma.
  - **d.** Cumulative traction time exceeds 10 minutes or total vacuum procedure time exceeds 15 to 30 minutes.
- If the extractor cup becomes disengaged, check for trauma to the fetal scalp before reapplying.

Indications for Vacuum Assisted Vaginal Delivery

No Indication is absolute.

Fetal: Non-reassuring fetal status
Failure to deliver spontaneously following an appropriately managed second stage of labor

Maternal: Need to avoid voluntary expulsive efforts
Inadequate expulsive efforts

Contraindications

Do not initiate vacuum if any of the following conditions exist:

- Non-vertex positions (breech or transverse lie/position) or face or brow presentation
- Suspected cephalopelvic disproportion
- Previous scalp sampling
- Suspected macrosomia, or risk of shoulder dystocia
- Failed vacuum or forceps attempt
- Less than 34 weeks gestation
- Unengaged vertex
- Incompletely dilated cervix
- Need for device rotation
- Suspected fetal bleeding abnormalities

Adverse Events

Fetal Injuries: Head trauma, bruises, contusions, lacerations, scalp edema, skull fracture, cephalhematoma, subgaleal hematoma, subdural hemorrhage, parenchymal hemorrhage, intracranial hemorrhage, retinal hemorrhage.

Maternal Injuries: Vaginal, cervical, uterine, bladder, rectal tissue tears.

Prerequisites For Vacuum Assisted Vaginal Delivery

- Term infant
- Ruptured membranes
- Empty bladder
- 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.

Important Landmarks