

# Instruction for Use for Obstetric Suction Cup

## Product description:

Vacuum Cup extractor is a single use device provided sterile. It consists of a vacuum pump coupled to a cup for contact with the fetal head. The cup is coupled through a tube and wire, to the combined pump and traction-handle.

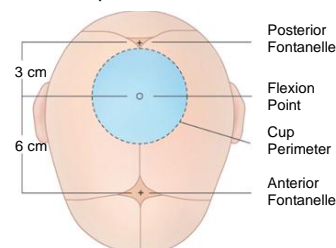
## Precaution:

1. The device is only to be used by trained personnel or under supervision by a trained physician.
2. This device is only to be sold to physicians or under direct order of a physician.

## Instruction for use:

**A . Vaginal delivery:** Always follow hospital procedure for use of vacuum delivery devices.

1. Unpack the device with aseptic technique and test the device on the palm of a gloved hand.
2. Schematic illustration of the advised, right placement of cup over flexion point.
3. With two fingers locate head position and flexion point of the fetal head.
4. Place cup over occiput (flexion point). Gently press on cup surface and compress the handle a few times to initiate vacuum.
5. Use a finger to check that no maternal tissue is trapped between the cup edge and the fetal head. If clear increase vacuum to prescribed vacuum 0,5 – 0,8 bar (375-600mmHg ) and wait a few seconds.
6. Use full pump stroke for efficient vacuum and check for steady vacuum level at the indicator on the side of the device. Note the indicator is for indication only.
7. Before every new set of pulls, compress the pump a few times and check vacuum. Apply a steady traction force in line with axis of the pelvis, synchronously with every contraction, and observe progression of fetal head with every pull.
8. Proceed until fetal head is born. Avoid rotation of the cup due to risk of fetal cuts.
9. When the fetal head is born release vacuum by pushing in the release button and complete birth in normal manner.



## B. Caesarean section:

For use during caesarean section (C-section). Please follow normal procedure for incision.

1. Unpack a new sterile device with aseptic technique and test the device in the palm of a gloved hand.
2. Place cup, through incision, over occiput (flexion point) and apply vacuum. Check cup edges and pump to 0,5 - 0,8 bar (375-600mmHg).
3. Gently pull out fetal head through incision, when delivered release vacuum and complete C-section in normal manner.

Note: After delivery with cup, always check the fetal head for scalp trauma and after vaginal use always check vagina for injuries. After use, dispose of the product as required by hospital policy.

## Warnings:

- The Vacuum Cup is supplied STERILE using an ethylene oxide process. Carefully inspect the packaging for any damage prior to use. Do NOT use if sterile barrier is damaged. Do NOT use past expiration date.
- For single use only. Do NOT reuse, reprocess or re-sterilize this device. Any reprocessing may impede the functions of this device. Reusing single use devices may also increase the risk of cross contamination. Attempts to clean the device results in risk of device malfunction.
- Do not proceed the assisted vacuum delivery if;
  1. There is no progression in descent of the fetal head when traction force is applied, throughout 2-3 pulls.
  2. 2-3 pop-offs happens.
  3. The cup has been applied for more than 20min.
 After 10 min a higher caution should be shown and after 20 min the vaginal delivery attempt should be abandoned.
- Do not place cup or part of cup on fetal face, nose, ear or eye.
- It is not recommended to apply vacuum above 0,8 bar (600mmHg) due to risk of fetal trauma.

## Intended use:

The product is intended to assist a clinician in the delivery of a fetus during childbirth in case instrumental delivery is indicated due to maternal exhaustion, lack of delivery progress and/or fetal distress.

## Contraindications:

The obstetrician is ultimately responsible for careful evaluation of the relativity of the contraindications and their weight against other risks associated with the actual delivery situation.

Other contraindications or modifications of existing contraindications may exist in local instructions or literature and should be respected on equal terms with the following:

- Fetal head above the ischial spines
- Incomplete orificial dilatation(min. 8 cm)
- Prematurity (<34 weeks of gestation)
- Known fetal intracerebral malformations
- Known fetal demineralization diseases (e.g, osteogenesis imperfecta)
- Known connective tissue disorders (e.g, Ehlers- Danlos and Marfan's syndromes)
- Fetal bleeding disorders (e.g, hemophilia)
- Absolute indications for caesarean section
- Irregular presentations where the cup cannot be placed on the scalp portion of the fetus (Ex: Facial presentation)

## Obstetric Suction Cup



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