




Complete Vacuum Delivery System

Complete Vacuum Delivery System with PalmPump™

INSTRUCTIONS FOR USE

VAC-6000M, VAC6000ME, VAC-6000MT, VAC-6000MTE, VAC-6000C, VAC-6000S

 **WARNING:** Do not reuse. Discard after one procedure. Function may be impaired through reuse or cleaning. The product is very difficult to clean after exposure to biological materials and may cause adverse patient reactions if reused. Clinical Innovations will not be responsible for any direct, incidental, or consequential damages resulting from reuse of the product.

Do not resterilize or use if the package is damaged or broken and sterility may be compromised.

Contents

One Kiwi OmniCup[®] with Palm Pump[™] (VAC-6000M/ME/MT/MTE/C).

One Kiwi ProCup with Palm Pump[™] (VAC-6000S)

Description

The Clinical Innovations' Kiwi is a disposable vacuum assisted fetal delivery system. It is a sterile, single-patient-use device designed to provide assistance in childbirth under the following conditions: 1) Term pregnancy, 2) Ruptured amniotic membranes, 3) Engaged head, 4) Complete cervical dilation, and 5) Adequately trained or supervised operator.

Indications

Standard Vacuum Assisted Delivery:

Use for vacuum assisted fetal delivery in conditions of 1) prolonged second stage of labor (arrest of descent) where fetopelvic relationships are adequate, 2) presumed fetal jeopardy which is not considered to be severe, or 3) elective shortening of the second stage for selected maternal or fetal conditions.

Abandonment of a vacuum delivery should be considered 1) if no descent (progress) of the head occurs after 2 tractions, 2) if delivery is not achieved or imminent after 4 tractions, or 3) if the vacuum cup detaches ("pops-off") twice.

Contraindications

Standard Vacuum Assisted Delivery:

1) Arrest of descent where fetopelvic relationships are considered to be inadequate, 2) unengaged presenting part, 3) All non-vertex presentations (breech, face, brow, transverse lie), 4) Non-ruptured membranes, 5) Incomplete cervical dilation and effacement, 6) Extreme prematurity, 7) Known fetal coagulopathies or bone demineralization disorders.

Cautions

ACOG Technical Bulletin #219 April 2020: "As with forceps procedures, there should be a willingness to abandon attempts at vacuum delivery if satisfactory progress is not made."

Additional conditions for close observations:

1) Gestational age less than 36 weeks or estimated fetal weight (EFW) less than 2500 grams, 2) Previous scalp sampling, 3) Scalp damage, 4) Failure of efforts after 20 minutes, 5) Delivery requiring unusual amounts of traction force (>25 lbs/12kgs), 6) Suspected macrosomia.

Adverse Events

Fetal Injuries: cephalohematoma, subdural, subgaleal hemorrhage, intraventricular, or parenchymal hematoma, subconjunctival, intracranial, or retinal hemorrhage, nerve injuries, subjective jaundice, elevated bilirubin, bruises, contusions, lacerations, fractures.

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

Warnings

R_x ONLY Federal (USA) law restricts this device to sale by or on the order of a Physician

Limit use to trained, experienced, or supervised operators. Insertion should be performed carefully, using aseptic technique. Forced insertion may result in malfunction, patient discomfort, or patient/fetal trauma.

Never apply cup to any portion of infant's face or exceed recommended vacuum level, time limits, or cup "pop-off" applications.

Read instructions before using this product.

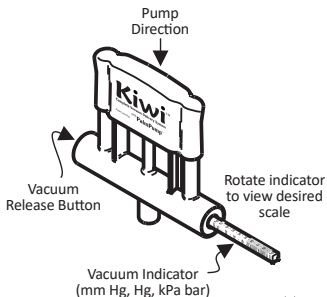
DEVICE DESCRIPTION

The Kiwi system includes PalmPump™ with the OmniCup® for VAC-6000M/ME/MT/MTE/C and ProCup™ for VAC-6000S.

PalmPump™

The PalmPump's integral design provides:

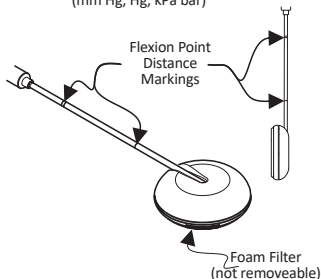
- A simple hand vacuum pump
- Vacuum release button
- Vacuum indicator*
- All in an ergonomic handle



OmniCup®

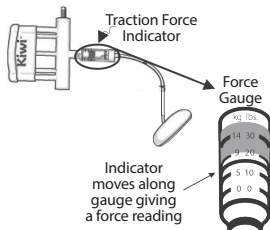
The Kiwi OmniCup (a universal cup for all positions) has a low profile for easy insertion.

This assists with proper placement in fetal malpositions such as occiput posterior.



OmniCup® with Traction Force Indicator

The Kiwi OmniCup with Traction Force Indicator is designed to measure the force exerted during traction. It allows the operator to correlate tactile sensation of traction force with a visual scale, which is especially valuable for training and documentation purposes.

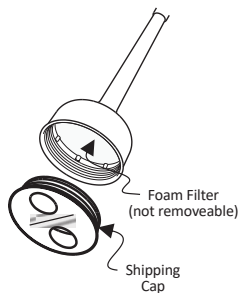


*The vacuum gauge has demonstrated an accuracy of +/- 10% of the range.

ProCup®

The Kiwi ProCup is for use with low occiput anterior and outlet positions. The soft flexible cup expands and molds to the fetal head which increases cup contact area on the fetal scalp.

*The vacuum gauge has demonstrated an accuracy of +/- 10% of the range.



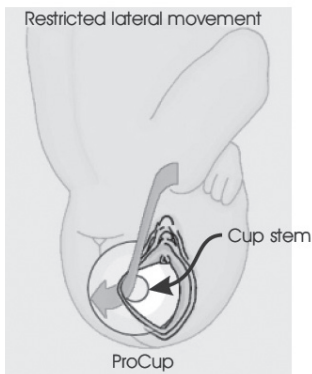
ProCup (occipitoanterior/OA positions)

The Kiwi ProCup is suitable for occipitoanterior positions where the flexion point is near the introitus. Maneuverability of the ProCup cup is limited by the rigid cup stem pressing against the labial tissues and perineum.

The ProCup cup is maneuvered by pushing the cup in the direction of the flexion point until further movement is inhibited as seen below.

The ProCup is not suitable for use in the majority of midcavity occipitoposterior or deflexed occipitolateral positions because the flexion point in these cases is usually located outside the range of movement of the cup, thus making it difficult or impossible to achieve a correct (flexing median) application.

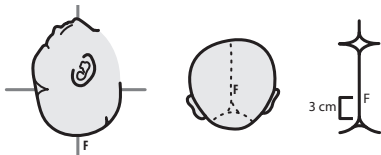
The Kiwi ProCup is for outlet and low occiput anterior presentations.



FLEXION POINT

Labor Process Enhancement

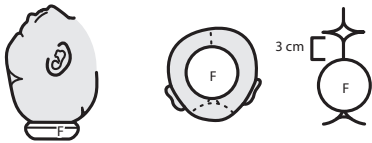
- The flexion point is situated on the sagittal suture 3 cm in front of the posterior fontanelle.
- Place vacuum cup over flexion point only.
- Do not depend on traction alone to deliver the baby.



The flexion point is situated on the sagittal suture 3 cm forward of the posterior fontanelle.

Diameters of Fetal Head

- The cup becomes the leading part when a vacuum cup is attached to the head and traction is applied.
- The center of the cup should be placed over the flexion point, as traction is applied in line with the pelvic axis it promotes flexion and synclitism.



Flexing Median Application

The center of the vacuum cup should be placed over the flexion point with the sagittal suture in the midline.

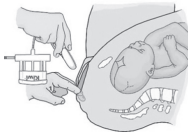
INSTRUCTIONS FOR VAGINAL DELIVERY

Device Preparation (VAC-6000M/ME/MT/MTE/S)

1. Open sterilized package using aseptic technique and remove Kiwi vacuum device from package.
2. Check vacuum by pumping with cup pressed to gloved hand and watching for stable vacuum indicator reading. (One only needs test to 100-200 mm Hg)

Vaginal Delivery Cup Insertion

3. Perform vaginal exam to ensure amniotic membranes are ruptured, cervix is completely dilated and to determine fetal station, position, and flexion point location.
4. Note the distance from the flexion point to the posterior fourchette (insertion distance).
5. Retract perineum with two fingers of non-pulling hand to form a space into which cup is gently inserted.



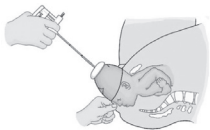
6. VAC-6000S/ ProCup ONLY--Slightly rotate to ensure cup edges unfold.
7. Press cup against fetal head and maneuver the cup posteriorly to the insertion distance noted above until its center lies over flexion point.
8. Initiate cup seal by raising vacuum to approximately 100 mm Hg (yellow zone) on PalmPump vacuum indicator.
9. Run finger around cup rim to ensure no maternal tissue or fetal electrode has been trapped under cup.
10. Raise vacuum to 450-600 mm Hg* (green zone) according to hospital protocol.
NOTE: DO NOT EXCEED 600 mm Hg (RED ZONE)

⚠️ WARNING: DO NOT PLACE CUP ON ANY PORTION OF FETAL FACE OR EAR.

⚠️ CAUTION: ONLY PLACE CUP OVER THE FLEXION POINT.

Traction

1. Press against dome of cup with thumb of non-pulling hand to help prevent cup detachment from scalp and detect early signs of detachment.
2. Rest index finger of same hand on scalp in front of cup and monitor descent of head.
3. Apply traction in line with pelvic axis in unison with contractions and draw fetal head down over perineum with each contraction.



4. For maximum efficiency and best results, direct pull perpendicular to cup.
5. Avoid pendulum or rocking movements from side to side, which may increase predisposition to cup detachment.
6. Discontinue traction between contractions or if an audible hiss is heard, signaling loss of vacuum.
7. Repeat steps until delivery of head is complete or until maximum recommended time or re-application limits are met.

*The vacuum gauge has demonstrated an accuracy of +/- 10% of the vacuum range.

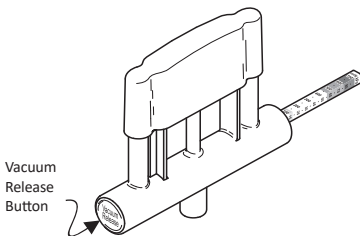
WARNING:

DO NOT TWIST, TORQUE, OR USE EXCESSIVE FORCE.

DO NOT REAPPLY CUP IF IT HAS DISENGAGED TWO TIMES.

Delivery

1. After delivery of fetal head, press the vacuum release button to remove the cup.



Disposal

- Used device should be disposed according to standard facility biohazard procedure.

INSTRUCTION FOR CESAREAN DELIVERY

Cup Insertion

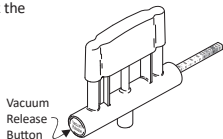
1. Insert cup into the incision over the flexion point.
2. If the fetal head is low, gently flex the head upward into the uterine incision for better access to the flexion point.
3. If the fetal head is high, place cup over occiput on flexion point.


WARNING:

DO NOT PLACE CUP ON ANY PORTION OF FETAL FACE OR EAR

ONLY PLACE CUP OVER THE FLEXION POINT.

4. Check the edges of the cup to ensure that no maternal, placental, or other tissues have been drawn underneath the cup.
5. Raise vacuum level to 100 mmHg (yellow zone) and recheck the cup edges.
6. Raise vacuum to 450-600 mm Hg (green zone)
7. Gently draw fetal head upward through incision.
8. When fetal head is delivered, release vacuum with the vacuum release button and remove cup before continuing delivery of shoulders and body.



 **Caution:** If traction is misdirected or too forceful, vacuum may be lost. Before replacing cup, examine fetal scalp for trauma and re-assess location of flexion point.

WARNING:












DO NOT TWIST, TORQUE, OR USE EXCESSIVE FORCE.




DO NOT REAPPLY IF CUP HAS POPPED-OFF TWO TIMES

Disposal

- Used device should be disposed according to standard facility biohazard procedure.

Symbols Glossary

Symbol	Symbol Description
	Indicates Device Manufacturer Includes name and address of the manufacturer
	Manufacturer Build Date
	Use By Date YYYY-MM-DD is generic placeholder for specified Use By Date
	Lot Code
	Authorized EC Representative
	Catalog Number
	Do Not Reuse
	Sterilized by irradiation. Sterility guaranteed unless package opened or damaged. Do not resterilize.
	Consult Instructions For Use
	Do not use if the product is damaged
	Medical Device

Symbol	Symbol Description
	Latex free
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Caution or warning
	Do not resterilize

To Report Product Complaints:

Email: Complaints@Clinicalinnovations.com

Phone: 1.888.268.6222; Ext 3



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