Instructions for Use

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.

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US Patents 6,059,795;
6,074,399; 6,355,047
and other patents pending
P/N 050-0142 Rev. H
Kiwi System

Device Description

The Kiwi vacuum delivery device is an integral unit designed for complete control without an assistant. The PalmPump provides safe and effective vacuum control.

The Kiwi system has been designed with two different style cups: The ProCup for outlet and low occipit anterior positions and the OmniCup for all positions including asyntclitic occiput posterior and lateral fetal malpositions.

These instructions are not meant to replace established hospital protocol.

Palm Pump™

The PalmPump puts complete control in the hands of a single operator and frees up delivery room personnel.

The PalmPump’s integral design provides:
- A simple hand vacuum pump,
- Thumb or finger activated vacuum release valve, and
- Accurate vacuum indicator.
- All in an ergonomic handle

OmniCup®

The Kiwi OmniCup (a universal cup for all presentations) has a low profile with a handle grip for easy insertion. This assists with proper placement in fetal malpresentations 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.

Omni-C Cup

The Kiwi Omni-C Cup has been designed specifically for the confined abdominal space of C-Sections. It has a low profile cup for easy insertion and maneuverability. It also has two finger grooves for an improved cup grip, facilitating proper placement on the flexion point.

ProCup®

The Kiwi ProCup is for use with low occiput anterior, and outlet presentations and is designed to reduce chignon.

The soft flexible cup expands and molds to the fetal head which safely increases cup contact area and vacuum hold.

Kiwi® for VacuLink™

The Kiwi OmniCup and ProCup (VAC-7000M and VAC-7000OS) are compatible with Medevco’s VacuLink, which is a disposable device that connects to the maternal/fetal monitor and records clinical vacuum values in real time.
Flexion Point

Labor Process Enhancement
- Correct technique should enhance the normal processes of labor and should not depend on traction alone to effect delivery of the baby.
- The key is to locate the flexion point and place the vacuum cup properly over it.
- The flexion point is situated on the sagittal suture 3 cm in front of the posterior fontanelle.

Diameters of Fetal Head
- When a vacuum cup is attached to the head and traction is applied, the cup becomes the leading part.
- The center of the cup should correspond to the flexion point so that traction in the line of the pelvic axis will promote flexion and synolism.
- This will result in the most favorable presenting diameters of the head leading through the birth canal.

Flexion Point Location
The flexion point may be located during vaginal examination by identifying the posterior fontanelle and then moving the finger anteriorly a distance of approximately 3 cm along the sagittal suture. The tip of the finger will mark the flexion point.
Two observations are required:
- Distance from flexion point to posterior fourchette.
- Degree of lateral displacement of the flexion point from the midline axis of the pelvis.

Distance Measurement
- Place tip of examining finger on flexion point.
- Calculate distance from flexion point to fourchette by measuring distance from tip to where finger makes contact with fourchette.
- The distance from the tip of the middle finger to the proximal interphalangeal joint is 5 - 6 cm, and to the metacarpophalangeal joint is 10 - 11 cm.
- OmniCup tubing has markings to assist the user in the location of these distances as shown in the figures. These markings also help to identify how much progress is made during each contraction.

Lateral Displacement
- Place tip of index finger of left hand under symphysis pubis to mark midline reference position.
- Identify flexion point as previously described.
- Observe distance between finger tips to estimate extent of lateral displacement or rotation of flexion point.
2.
Cup Type Selection

**OmniCup** (occipitoposterior/lateral presentations)

The OmniCup is not restricted by the soft tissues of the vulva and perineum in its movements because the suction tube is in the same plane as the body of the cup. This feature allows the cup to be easily inserted through the introitus, maneuvered under the caput and can be directed towards and over the flexion point.

Movement of the OmniCup in the birth canal is limited only by the amount of space between the fetal head and mother's sacrum posteriorly and the side walls of the pelvis laterally.

Provided the operator is skilled in the use of this cup, flexing median applications may be achieved consistently in nearly all malpositions of the occiput.

Thus, the OmniCup should, by permitting better applications, decrease failure rate when the occiput is lateral or obliquely posterior. The OmniCup can also be used in outlet and low occiput anterior presentations.

**ProCup** (occipitoanterior presentations)

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 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.

**Omni-C Cup** (Cesarean Section)

The Kiwi Omni-C Cup is suitable for cesarean section deliveries. Its low profile cup is ideal for easy insertion and maneuverability in the confined abdominal space. It also has two finger grooves for an improved cup grip, facilitating proper placement on the flexion point.
Device Preparation

1. Open Package
   Open sterilized package using aseptic technique and remove Kiwi from package.

2. Remove Shipping Cap
   (ProCup only)

3. Check Vacuum
   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)

Cup Insertion

- Perform vaginal exam to ensure amniotic membranes are ruptured, cervix is completely dilated and effaced and to determine fetal presentation, position, and flexion point location.
- Retract perineum with two fingers of non-pulling hand to form a space into which cup is inserted gently in one movement.
- If using ProCup, slightly rotate to ensure cup edges unfold.
- Press cup against fetal head and manoeuvre until its center lies over flexion point.
- Check that cup is correctly placed by noting that there is a distance of at least 3cm between anterior fontanelle and nearest part of cup (application distance) and that sagittal suture passes under middle of cup.
- Check that there is no maternal tissue or a fetal electrode trapped between cup and scalp in anterior positions, by holding cup in position with one hand and running index finger of other hand around rim of cup (With occipitofrontal and posterior positions, it is usually impossible to reach behind a correctly placed cup without displacing the cup).
- Initiate cup seal by raising vacuum to approximately 100 mm Hg (yellow zone) on Palm Pump vacuum indicator.
- Re-examine to ensure no maternal tissue has been drawn under cup and reapply cup if necessary.

DO NOT PLACE CUP ON ANY PORTION OF FETAL FACE OR EAR. ONLY PLACE CUP OVER FLEXION POINT.
Vaginal Delivery

Positioning of the Operator

The operator should sit on a stool until the head has descended to the level of the pelvic outlet so that traction will be exerted in a downward direction and assist descent of presenting part by maintaining the flexion point on or just behind side of pelvis.

The operator should change the direction of traction progressively upwards for low extractions or as the fetal head descends to the outlet. As this is done, the standing position becomes more appropriate.

For rotational extractions from the midpelvis, the operator may find it easier to direct traction towards the floor by getting down on one knee for the initial pull.

Eye contact should be maintained between the mother and operator at all times so that communication and interaction can occur freely.

Traction

- Once contraction begins, rapidly raise vacuum to 450-600 mm Hg (green zone) according to hospital protocol.
  **DO NOT EXCEED 620 mm Hg (RED ZONE)**
- Press against dome of cup with thumb of non-pulling hand and feel cup edge to help prevent cup detachment from scalp and detect early signs of detachment. Reduce traction force accordingly.
- Rest index finger of same hand on scalp in front of cup and monitor descent of head.
- Apply traction in line with pelvic axis and draw fetal head down over perineum with each contraction.
- For maximum efficiency and best results, direct pull perpendicular to cup. However, with midpelvic rotational procedures, oblique traction is often necessary and caution must be exercised because oblique tractional forces may increase predisposition to cup detachments.
- Exercise caution. Pendulum or rocking movements from side to side may also increase predisposition to cup detachment.
- Maintain constant traction for duration of contraction.
- Discontinue traction between contractions or if an audible hiss is heard, signaling loss of vacuum.
- Reduce vacuum (yellow zone) between contractions (optional) per hospital protocol.
- Repeat steps until delivery of head is complete or until maximum recommended time or re-application limits are met.

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Table 2  Equivalent negative gauge pressures

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<th>kPa</th>
<th>mm Hg</th>
<th>Hg</th>
<th>cm H₂O</th>
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From: Vacca A. Handbook of Vacuum Extraction.
Progress
The first pull should cause flexion of the head and some descent. By the end of the second pull the head should be on the pelvic floor and with the third pull, delivery of the head should be complete or imminent.

With strong contractions and effective maternal expulsive effort, delivery should be achieved as follows:
- 1 or 2 pulls for outlet vacuum extractions,
- 2 or 3 pulls for low vacuum extractions,
- 3 or 4 pulls for mid pelvic procedures.

Note: If traction is misdirected or too forceful, vacuum may be broken. Before replacing cup, examine fetal scalp for trauma and re-assess presentation and position.

DO NOT TWIST, TORQUE, OR USE EXCESSIVE FORCE.
DO NOT REAPPLY IF CUP HAS BEEN DISENGAGED TWO TIMES

Delivery
- Release vacuum with release button after delivery of head.
- Ease cup off the scalp.
- Complete birth in normal manner.

After Delivery
- Examine baby's head immediately after birth for scalp injury and note cup application site.
- Inspect scalp regularly if difficulty was experienced to exclude bleeding into the subgaleal space.
- Reassure parents that chignon should disappear in a matter of hours and that marks from cup should leave no traces after a few days.
- Reexamine baby within 24 hours to check the application site of vacuum cup.

Disposal
- Discard disposable cup and PalmPump using appropriate procedure.
Cesarean Delivery

Preparation
- Follow device preparation steps.
- Prepare the mother for C-Section according to hospital protocol.
- Use hospital protocol for abdominal and uterine incisions.
- Assess fetal head position, locating the flexion point 3 cm in front of the posterior fontanelle along the sagittal suture.

Cup Insertion
- Grip the Omni-C Cup by the finger grooves and insert cup into the incision.
- If the fetal head is high, place cup over occiput on flexion point.
- If the fetal head is low, gently flex the head upward into the uterine incision with fingers and place the cup over the occiput on flexion point.
- **DO NOT PLACE CUP ON ANY PORTION OF FETAL FACE OR EAR**
- Check the edges of the cup to ensure that no maternal, placental or other tissues have been drawn underneath the cup.
- Raise vacuum level to 100 mmHg (yellow zone) and recheck the cup edges.

Delivery
- Raise vacuum to 450-500 mm Hg (green zone)
- Gently draw fetal head upward through incision
- When fetal head is delivered, release vacuum with release valve and remove cup before continuing delivery of shoulders and body.

Note: If traction is misdirected or too forceful, vacuum may be broken. Before replacing cup, examine fetal scalp for trauma and re-assess position.

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7.

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