



Complete Vacuum Delivery System

Complete Vacuum Delivery System with PalmPump™

INSTRUCTIONS FOR USE

VAC-6000MT, VAC-6000MTE

Contents

One Kiwi OmniCup® with Palm Pump™.

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) failure to deliver spontaneously following an appropriately managed second stage, 2) prolonged second stage of labor (arrest of descent) where fetopelvic relationships are adequate, 3) presumed fetal jeopardy which is not considered to be severe, or 4) elective shortening of the second stage for selected maternal or fetal conditions.

Trial of Vacuum Assisted Delivery:

Vacuum delivery should be regarded as a "trial" 1) if there is arrest of descent in the second stage and fetopelvic relationships are considered to be borderline, 2) in a mid-pelvic delivery when position and station are known, or 3) in a mid-pelvic delivery when the degree of presumed fetal jeopardy is considered to be more than mild.

Vacuum assisted delivery should be abandoned and birth completed by cesarean section 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

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.

Precautions

ACOG Technical Bulletin #154 Nov. 2015: “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 37 weeks or estimated fetal weight (EFW) less than 2500 grams, 2) Previous scalp sampling, 3) Scalp damage, 4) Failure of efforts during prolonged period after properly assessed placement, 5) Delivery requiring unusual amounts of traction, 6) Suspected macrosomia.

Adverse Events

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

Maternal Injuries: Soft tissue injuries, episiotomy extensions.

Warnings

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.**

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 the OmniCup for all positions including asynclitic occiput posterior and transverse fetal malpositions.

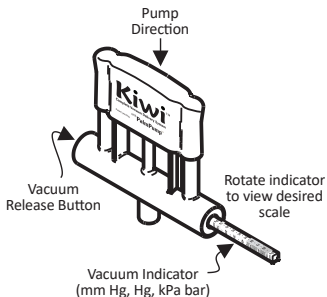
These instructions are not meant to replace established hospital protocol.

PalmPump™

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

The PalmPump's integral design provides:

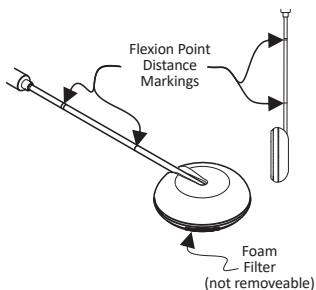
- A simple hand vacuum pump
- Vacuum release button
- Vacuum indicator*
- All in an ergonomic handle



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.



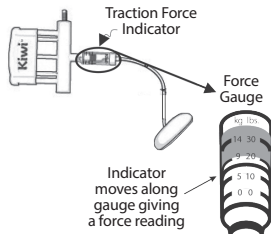
*The vacuum gauge has demonstrated an accuracy of +/- 10% of the range.

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 Traction Force Indicator has demonstrated an accuracy of +/- 15% of the range.

In general, the recommended maximum traction force is 25-30lbs (11-13 kgs). The traction applied is an adjunct to the mother's expulsive effort, not the primary force to overcome resistance to descent. The greater the maternal expulsive effort, the less traction force is required to assist birth, thus reducing the incidence of complications. Technique is also a major influencing factor in the traction force required during deliveries. (ie., proper flexion point application and angle of traction.) 1Vacca demonstrated that deliveries can be completed with a traction force of 30 lbs or less, and at higher traction levels, there is an increase in fetal scalp injury. 2Baskett showed the maximum traction force used in 86% of deliveries was ≤ 25 lbs and >25 in 14%.



OmniCup (occipitoposterior/transverse positions)

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 transverse or posterior. The OmniCup can also be used in outlet and low occiput anterior positions.



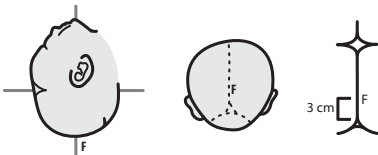
The OmniCup is not restricted by the soft tissues of the vulva and perineum in its movements because the suction tube is in the same plane as the body of the cup.

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.

FLEXION POINT

Labor Process Enhancement

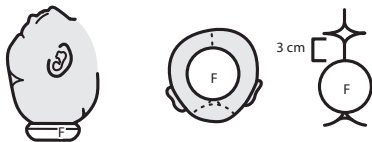
- Correct technique should enhance the normal processes of labor and should not depend on traction alone to effect delivery of the baby.
- The key is to locate the flexion point and place the vacuum cup properly over it.
- The flexion point is situated on the sagittal suture 3 cm in front of the posterior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



The flexion point is situated on the sagittal suture 3 cm forward 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 synclitism.
- This will result in the most favorable presenting diameters of the head leading through the birth canal.



Flexing Median Application

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

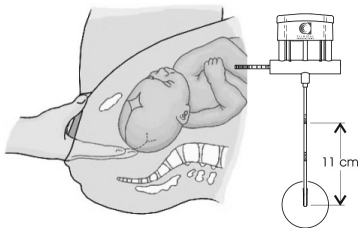
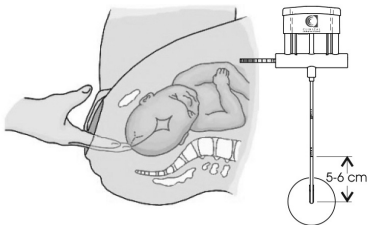
Flexion Point Location

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.

- Observation of the distance from flexion point to posterior fourchette is required.

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.

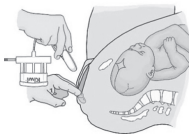


INSTRUCTIONS FOR VAGINAL DELIVERY

1. Open 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)

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 inserted gently in one movement.
6. Press cup against fetal head and maneuver the cup posteriorly the insertion distance noted above until its center lies over flexion point.
7. Check that cup is correctly placed by noting that there is a distance of at least 3 cm between anterior fontanelle and nearest part of cup (application distance) and that sagittal suture passes under middle of cup.
8. 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 occipitotransverse and posterior positions, it is usually impossible to reach behind a correctly placed cup without displacing the cup.)
9. Initiate cup seal by raising vacuum to approximately 100 mm Hg (yellow zone) on PalmPump vacuum indicator.
10. 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.

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 axis of pelvis.

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

For rotational deliveries 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.

Traction

1. 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)**
2. Press against dome of cup with thumb of non-pulling hand to help prevent cup detachment from scalp and detect early signs of detachment. Reduce traction force accordingly.
3. Rest index finger of same hand on scalp in front of cup and monitor descent of head.
4. Apply traction in line with pelvic axis and draw fetal head down over perineum with each contraction. **⊘ DO NOT EXCEED traction force 30lbs/14kgs**
5. For maximum efficiency and best results, direct pull perpendicular to cup.
6. 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.
7. Pendulum or rocking movements from side to side may also increase predisposition to cup detachment.
8. Maintain constant traction for duration of contraction.

9. Discontinue traction between contractions or if an audible hiss is heard, signaling loss of vacuum.
10. Reduce vacuum (yellow zone) between contractions (optional) per hospital protocol.
11. Repeat steps until delivery of head is complete or until maximum recommended time or re-application limits are met.

Table 2: Equivalent negative gauge pressures

Kg/cm ²	kPa	Inches		cm		
		Hg	H ₂ O	Hg	H ₂ O	
0.13	13	100	3.9	134	1.9	0.13
0.27	27	200	7.9	268	3.9	0.26
0.41	40	300	11.8	402	5.8	0.39
0.54	53	400	15.7	536	7.7	0.53
0.68	67	500	19.7	670	9.7	0.66
0.82	80	600	23.6	804	11.6	0.79
0.95	93	700	27.0	938	13.5	0.92
1.03	101	760	29.9	1018	14.7	1.00

From: Vacca A. Handbook of Vacuum Delivery: In Obstetric Practice, 3rd Edition

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.

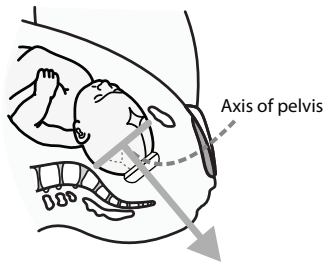
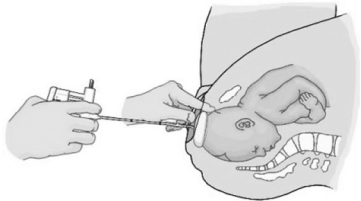
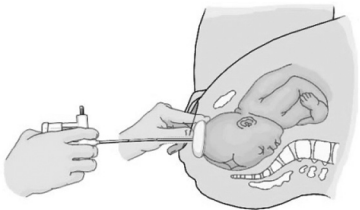
With strong contractions and effective maternal expulsive effort, delivery should be achieved as follows:

- 1 or 2 pulls for outlet vacuum deliveries,
- 2 or 3 pulls for low vacuum deliveries,
- 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 position.

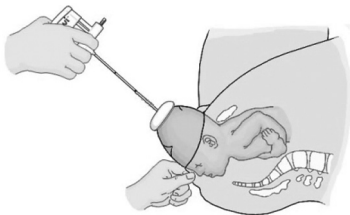
⊘ **DO NOT TWIST, TORQUE, OR USE EXCESSIVE FORCE.**

⊘ **DO NOT REAPPLY IF CUP HAS BEEN DISENGAGED TWO TIMES**



Delivery

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

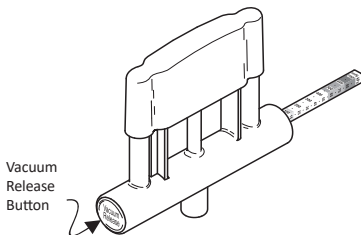


After Delivery

1. Examine baby's head immediately after birth for scalp injury and note cup application site.
2. Neonatal care providers should be made aware of the mode of delivery in order to observe for potential complications associated with operative vaginal delivery.
3. Inspect scalp regularly if difficulty was experienced to exclude bleeding into the subgaleal space.
4. Reassure parents that chignon should disappear in a matter of hours and that marks from cup should leave no traces after a few days.
5. Reexamine baby within 24 hours to check the application site of vacuum cup.

Disposal

- Discard device using established procedure.



INSTRUCTION FOR CESAREAN DELIVERY

OmniCup (Cesarean Section)

The Kiwi OmniCup is suitable for cesarean section deliveries. It's low profile cup is ideal for easy insertion and maneuverability in the confined abdominal space.

Preparation

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

Cup Insertion

1. Insert cup into the incision.
2. If the fetal head is high, place cup over occiput on flexion point.
3. If the fetal head is low, gently flex the head upward into the uterine incision with fingers and place the cup over the flexion point.

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

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.

Delivery

1. Raise vacuum to 450-600 mm Hg (green zone).
2. Gently draw fetal head upward through incision.
3. When fetal head is delivered, release vacuum with release button and remove cup before continuing delivery of shoulders and body.

Note: If traction is misdirected or too forceful, vacuum may be broken.

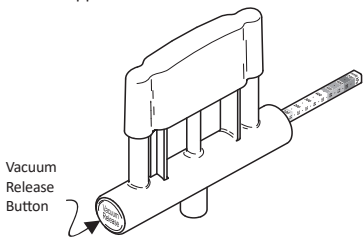
Before replacing cup, examine fetal scalp for trauma and re-assess position.

⊘ DO NOT TWIST, TORQUE, OR USE EXCESSIVE FORCE.

⊘ DO NOT REAPPLY IF CUP HAS BEEN DISENGAGED TWO TIMES

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 device using established procedure.

Bibliography

1. Vacca A. Vacuum assisted delivery: An analysis of traction force and maternal and neonatal outcomes. Australian and New Zealand Journal of Obstetrics and Gynaecology 2006;46:124-27.
2. Baskett T, et al., A Prospective Observational Study of 1000 Vacuum Assisted Deliveries With the OmniCup Device. J Obstet Gynaecol Can 2008;30(7):573-580

Symbols Glossary

Symbol	Symbol Description
	Indicates Device Manufacturer Includes name and address of the manufacturer
	Manufacturer Build Date
 YYYY-MM-DD	Use By Date YYYY-MM-DD is generic placeholder for specified Use By Date

Symbol	Symbol Description
	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 sterile barrier system or its packaging is compromised
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Warning or caution
	Do not



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