



Complete Vacuum Delivery System

Complete Vacuum Delivery System with PalmPump™

INSTRUCTIONS FOR USE

VAC-6000C

Contents

One Kiwi Omni-C Cup 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 delivering the fetal head at cesarean section under the following conditions: 1) Term pregnancy, 2) Ruptured amniotic membranes, and 3) Adequately trained or supervised operator.

Indications

Use for vacuum assisted fetal delivery at cesarean section to assist in the delivery of the fetal head.

Contraindications

1) All non-vertex presentations 2) Extreme prematurity, 3) Known fetal coagulopathies.

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.

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, bowel, bladder and reproductive organ injuries.

Warnings

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

Vacuum assisted delivery should be abandoned if the vacuum cup detaches (“pop-off”) twice.

- ⊘ **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 Omni C Cup to assist in delivery of the fetal head at cesarean section.

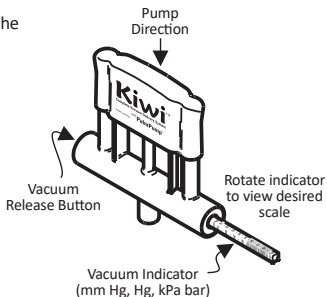
These instructions are not meant to replace established hospital protocol.

PalmPump™

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

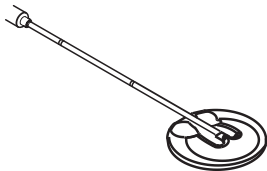
The PalmPump's integral design provides:

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



Omni-C Cup

The Kiwi Omni-C Cup has been designed specifically for the confined abdominal space of cesarean 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.

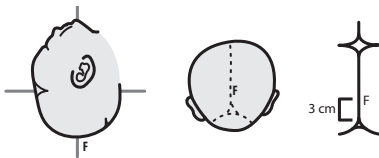


*The vacuum gauge has demonstrated an accuracy of +/- 10% of the range.

FLEXION POINT

Labor Process Enhancement

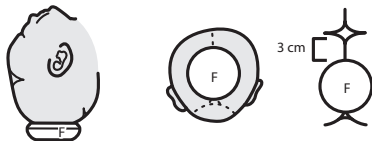
- Correct technique should enhance the delivery of the fetal head through the surgical incision and should not depend on traction alone to effect delivery of the baby.
- The key is to locate the flexion point and place the vacuum cup properly over it.
- The flexion point is situated on the sagittal suture 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.
- This will result in the most favorable presenting diameters of the head leading through the surgical incision.



Flexing Median Application

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

Table 2: Equivalent negative gauge pressures

	Inches cm					
Kg/cm ²	kPa	mm Hg	Hg	H ₂ O	lb/in ²	bar
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

CESAREAN DELIVERY

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

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 flexion point.

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

 **ONLY PLACE CUP OVER FLEXION POINT.**

- 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 450-600 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.

After Delivery

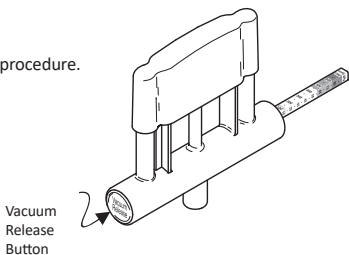
- Examine baby's head immediately after birth for scalp injury and note cup application site.
- Inspect scalp regularly if difficulty was experienced to exclude bleeding into the subgaleal space.
- Reassure parents that chignon should disappear in a matter of hours and that marks from cup should leave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

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




⊘ **DO NOT REAPPLY IF CUP HAS POPED-OFF TWO TIMES**











Disposal

- Discard device using appropriate procedure.



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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