



Complete Vacuum Delivery System

# Complete Vacuum Delivery System with PalmPump™

INSTRUCTIONS FOR USE

**VAC-6000S**

## Contents

One Kiwi ProCup 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, or 2) 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 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 ProCup for outlet and low occiput anterior positions.

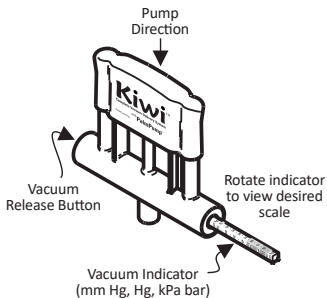
These instructions are not meant to replace established hospital protocol.

### 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:

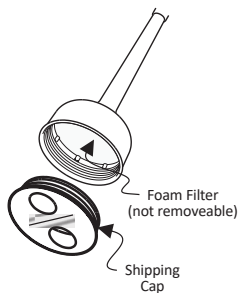
- A simple hand vacuum pump
- Thumb or finger activated vacuum release valve
- Vacuum indicator\*
- All in an ergonomic handle



### ProCup®

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



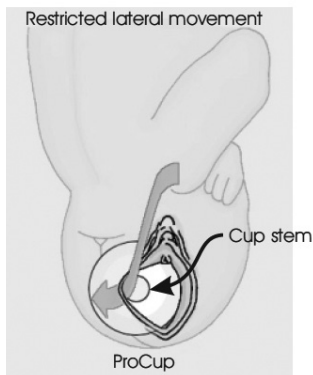
## ProCup (occipitoanterior presentations)

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 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.



## CUP INSERTION

---

- Perform vaginal exam to ensure amniotic membranes are ruptured, cervix is completely dilated and effaced and to determine fetal station, 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.
- Slightly rotate to ensure cup edges unfold.
- Press cup against fetal head and maneuver until its center lies over flexion point.
- Check that there is no maternal tissue, or a fetal electrode trapped between cup and scalp by holding cup in position with one hand and running index finger of other hand around rim of cup.
- Initiate cup seal by raising vacuum to approximately 100 mm Hg (yellow zone) on PalmPump 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 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.

## 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.
5. For maximum efficiency and best results, direct pull perpendicular to cup.
6. Pendulum or rocking movements from side to side may also increase predisposition to cup detachment.
7. Discontinue traction between contractions or if an audible hiss is heard, signaling loss of vacuum.

**Table 2: Equivalent negative gauge pressures**

Kg/cm <sup>2</sup>	kPa	mm Hg	Inches		lb/in <sup>2</sup>	bar
			Hg	H <sub>2</sub> 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 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.

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

 **DO NOT REAPPLY IF CUP HAS POPPED-OFF 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.
- Neonatal care providers should be made aware of the mode of delivery in order to

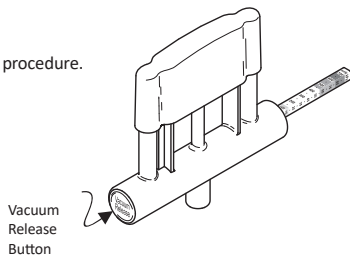


observe for potential complications associated with operative vaginal delivery.




- 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 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



Clinical Innovations  
747 West 4170 South  
Murray, Utah USA 84123  
P. 801-268-8200  
Toll Free: 888-268-6222

[clinicalinnovations.com](http://clinicalinnovations.com)

CE 0086



Clinical Innovations Europe, Ltd.  
6-9 The Square | Stockley Park,  
Heathrow UB11 1FW | United Kingdom  
Tel +44 (0) 333 370 4408



**CLINICAL  
INNOVATIONS**

**forMOM. forBABY. forLIFE.**

Copyright 2018, Clinical Innovations, LLC.  
All rights reserved. ART-0089 REV 1