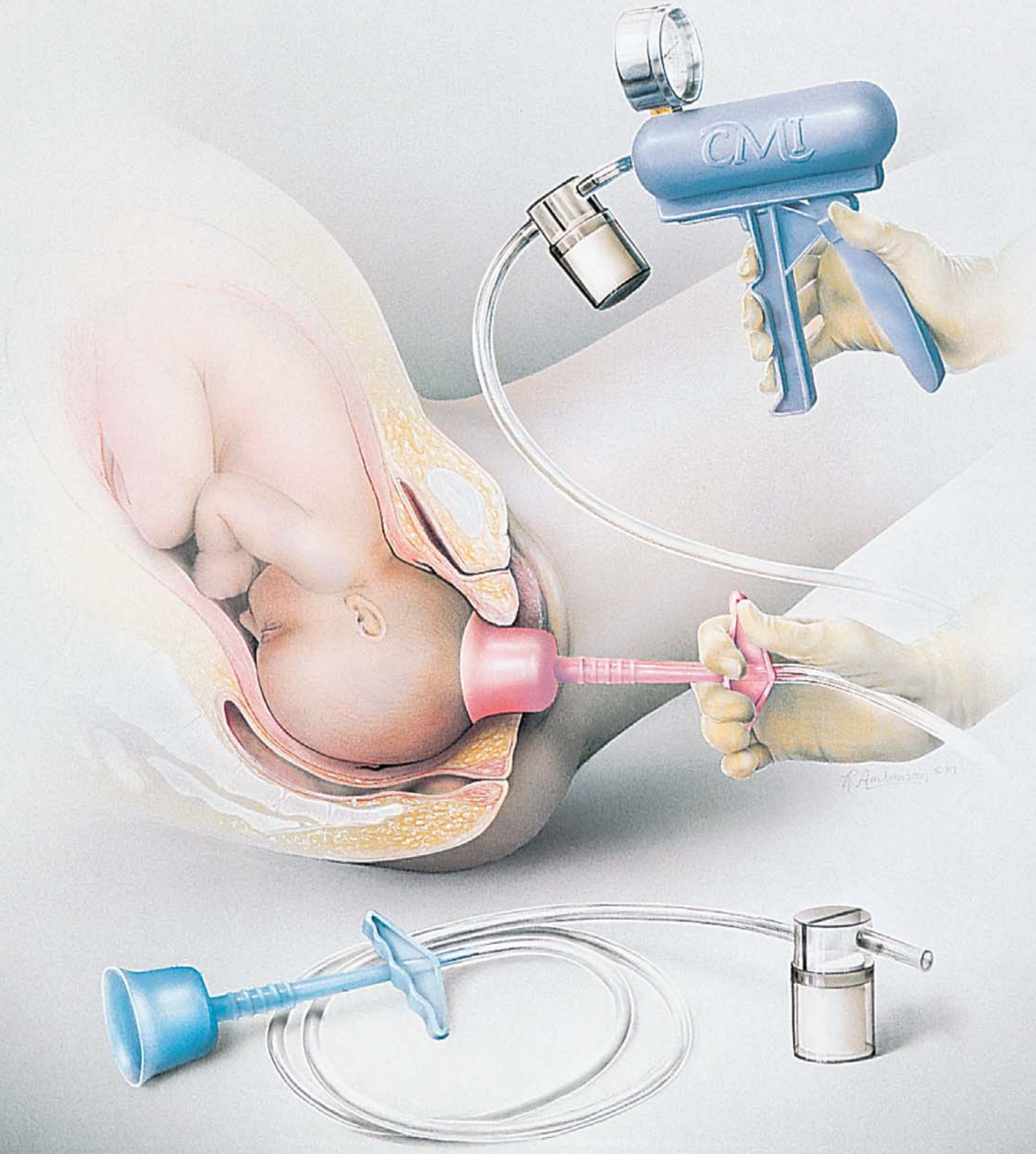
Instruction Booklet for Vacuum Delivery Systems

UTAH MEDICAL PRODUCTS INC.

Please read carefully before operating instrument.



Instruction Booklet for CMI® Vacuum-Assisted Delivery Systems (VADS)

This booklet includes instructions for the setup, use, cleaning and maintenance of the following products:

Manual Vacuum Pumps

1. 101A (Blue) Pump, Autoclavable or ETO Gas Sterilizable
2. 001C (White) Pump, ETO Gas Sterilizable Only

Disposable Vacuum Cups

1. 003CB Soft Touch® Cup, polyethylene bell-shaped (60mm dia.) with 4' tubing (no fluid trap).
2. 004CB Soft Touch® Cup, polyethylene bell-shaped (60mm dia.) with fluid trap and 4' tubing.
3. 303TT Tender Touch® Ultra Cup, silicone bell-shaped (60mm dia.) with fluid trap and 4' tubing.
4. 303TTL Tender Touch® Ultra Cup, silicone bell-shaped (65mm dia.) with fluid trap and 4' tubing.
5. 404TT Tender Touch® Cup, silicone deep bell-shaped (60mm dia.) with fluid trap and 4' tubing.
6. 505TT Tender Touch® Ultra Cup, silicone bell-shaped (60mm dia.) with vacuum relief valve, fluid trap and 4' tubing.
7. 505TTL Tender Touch® Ultra Cup, silicone bell-shaped (65mm dia.) with vacuum relief valve, fluid trap and 4' tubing.
8. 506TTL Tender Touch® Ultra Cup, silicone bell-shaped (65mm dia.) with vacuum relief valve, 6' tubing, adapter for electric pump (no fluid trap).
9. 444FC Flex Cup, polyurethane mushroom-shaped (60mm interior dia.) with fluid trap and 4' tubing.
10. 600TT Secure Cup® thermoplastic rubber mushroom-shaped (63mm dia.) with fluid trap and 4' tubing.
11. 606TT Secure Cup® thermoplastic rubber mushroom-shaped (63mm dia.) with vacuum relief valve, 6' tubing, adapter for electric pump (no fluid trap).

The following patents apply to one or more of the above products:
U.S. Patent Numbers 4,957,629; 5,224,947; des 320,855; and des 321,927.

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Introduction

Vacuum extraction, or vacuum-assisted delivery (VAD), has been practiced for obstetric indications for more than 150 years. The major clinical issues concerning VAD are the same as those encountered with forceps as a vaginal operative delivery technique. When the natural progression of childbirth becomes arrested near the end of the second stage of labor, assuming no cephalopelvic disproportion or other constraints that contraindicate a vaginal delivery, or if the physician believes the fetus is at risk of mortality during the late stages of a normal progression of labor, then an operative technique to hasten the delivery may convey great benefit, although containing inherent risk of injury. As in any instrumental delivery, the training, experience and skill of the practitioner is central to patient safety and operational success. Although the clinical indications are the same for the two methods of vaginal operative delivery, practitioner training required is quite different. In more recent years, VAD has become increasingly popular in medical schools as the preferred choice. UTMD estimates that vaginal operative techniques are currently attempted in 10-15% of U.S. births.

As an alternative to forceps, VAD risk of maternal injury is remarkably lower. Probably the best correlation to fetal risk associated with an instrumental delivery is the position of the fetal head in the birth canal prior to the initiation of the procedure, referred to as fetal station: the higher the station, the more difficult the delivery. At outlet station, the fetal skull has descended to the pelvic floor and is presenting at the introitus. This station is where operative deliveries are clinically indicated. At mid-station, the leading edge of the engaged fetal skull is less than 2 cm beyond the tip of the plane of the maternal ischial spines. At mid-station and higher in the birth canal, operative vaginal delivery techniques are contraindicated, requiring cesarean section if fetal descent has become arrested or in the case of fetal distress. Low station, the region between the outlet and mid-stations, is the region where physicians require careful consideration and skill to perform an operative vaginal delivery.

As part of its focus on providing specialized medical devices for L&D, UTMD entered the VAD arena in 1997 by acquiring Columbia Medical Inc. (CMI), an early developer of soft VAD cups. Minimizing risk of injury to the fetus relative to the use of forceps as well as other VAD devices is what differentiates Utah Medical Products, Inc.'s (UTMD's) VAD products.

If a well-trained physician correctly determines that fetal condition, station and position indicates a VAD, places a vacuum cup properly on the fetal occiput, applies vacuum within correct limits and pulls steadily in conjunction with the rise and fall of maternal contractions in a vector of force in alignment with the maternal spine, the design of the cup becomes the most important consideration for the safety of the fetal patient. The cup rigidity and shape creates a trade-off between allowed tractive force and safety for fetal tissues. By UTMD's estimate, in more than 90% of operative deliveries, the fetus is at outlet station in occiput anterior presentation. UTMD's thesis is that, since about any cup design will allow adequate tractive force to achieve a successful delivery within accepted time constraints and limits on number of pulls, the cup with the most tissue-friendly material and shape should be used. In the other 10% of cases that require careful consideration, more rigid mechanical-hold shaped cups should be available for an individual skilled physician's order. The exceptions should not put the vast majority at undue risk of injury.

The ideal case for a VAD procedure would be a physician wanting to hasten delivery for a multiparous mother having a normal progression of labor, with fetus showing non-reassuring fetal heart rate signs, presenting at the outlet station in an occiput anterior position. The patented silicone bell-shaped Tender Touch® cup is clearly the optimal cup design for this situation.

General Information

A VAD system is obviously only safe and effective when prescribed and employed by a skilled obstetrical practitioner. UTMD relies on the experience and knowledge of such physicians when designing its products, and completing instructions for their use. Input from the following references have been incorporated in the information in this booklet. UTMD strongly recommends that these materials be obtained and studied prior to the use of its VADS.

1. Vacuum Extraction in Modern Obstetric Practice, John Patrick O'Grady, Martin L. Gimovsky, Cyril J. McIlhargie, Copyright 1995 Parthenon Publishing Group. Available for sale, P/N 58183.

2. OBG Management, Volume 14, Issue 4, April 2002, p.88-94. "Vacuum Extraction - Optimizing Outcomes; Reducing Legal Risk." (Karen Koscica, DO, Albert Einstein College of Medicine, Bronx, NY; Martin Gimovsky, MD, Newark Beth Israel Medical Center, Newark, NJ). UTMD has purchased reprints of this article that are available to customers upon request, P/N 58181.

3. Contemporary OB/GYN, May 2002, p.114-123. "The obstetric vacuum extractor: recent innovations and best practices" (Martin Schwartz, MD, PhD, Northwest Permanente, Portland, OR; John Patrick O'Grady, MD, Baystate Medical Center, Springfield, MA). UTMD has purchased reprints of this article that are available to customers upon request, P/N 58182.

4. OBG Management, March 1999. "Cutting Your Legal Risks with Vacuum-Assisted Deliveries" (Reprint not available from UTMD)

5. "Introduction to Soft Cup V.E.," UTMD instructional VHS format video for care and use of VADS products. Available to customers upon request, P/N 58006.

6. "Vacuum-Assisted Vaginal Delivery: A Well-Accepted and Safe Way to Assist in Childbirth," Patient Disclosure Brochure, P/N 58169, available for use by UTMD customers in obtaining patients' informed consent.

Vacuum-Assisted Delivery (VAD)

Indications for Use:

1. Gestational age > 36 weeks.
2. No demonstrable cephalopelvic disproportion (CPD).
3. Full dilation and effacement of the cervix.
4. Ruptured membranes.
5. Engaged fetal head at Outlet or Low Station.

Contraindications for Use:

1. CPD.
2. Unengaged or Mid-Station fetal head.
3. All non-vertex presentations.
4. Incomplete cervical dilation.
5. Gestational age <36 weeks or estimated fetal weight (EFW) <2500 grams.
6. Cup attachment to fetal head at any other position than the occiput pivot point.
7. Lack of obvious progress in fetal descent during first two pulls (contractions).
8. Lack of delivery or lack of imminent delivery after four pulls.
9. Disengagement of the vacuum cup from the fetal head three times.
10. Failure to deliver after 20 minutes duration, or 10 accrued minutes at full applied vacuum, whichever comes first.
11. Prior use of forceps.

POSSIBLE ADVERSE REACTIONS: In addition to cephalhematoma, subconjunctival hemorrhage and vaginal lacerations, other adverse conditions may include neonatal intracranial hemorrhage, shoulder dystocia, Erb palsy, subjective jaundice and elevated bilirubin.

Use and Care of the CMI® Manual Vacuum Pump

General:

The UTMD pump with vacuum gauge is a reusable medical grade precision instrument. To retain accurate measurement of vacuum pressure, exercise care in handling to avoid dropping or knocking against hard surfaces.

To build vacuum pressure, squeeze the pump handle several times until the gauge needle reaches the desired pressure for the vacuum cup being used. To reduce vacuum pressure, pull and hold the vacuum release trigger, monitoring pressure on the gauge.

The internal mechanism of the pump must be kept free of debris from bodily fluids. Should blood or serous fluid be allowed to dry and harden within the pump mechanism, the efficiency of the pump may be compromised or rendered useless. The purpose of the fluid trap included with a disposable vacuum cup is to capture bodily fluids which may be drawn toward the pump. The capacity of the fluid trap is 65 ml. UTMD suggests that clinicians monitor the status of fill of the trap to be aware if the pump may be subject to ingress of bodily fluids.

If blood or serous fluids are drawn into the internal pump mechanism, it will be necessary to flush the device IMMEDIATELY using ONLY DISTILLED OR DEMINERALIZED WATER. Failure to do so will render the pump inoperable and will void the manufacturer's warranty. Note: Use of tap water and disinfectants is NOT recommended as they may corrode the pump's internal mechanisms.

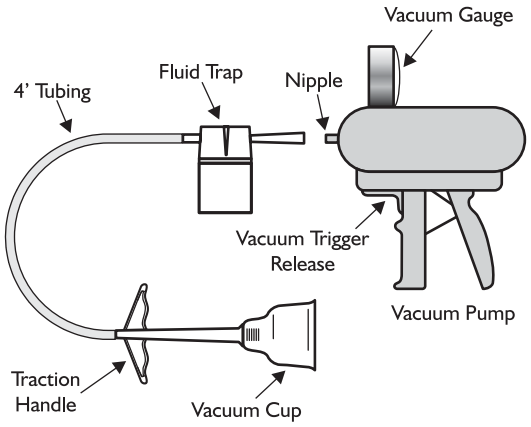
UTMD recommends use of the CMI vacuum pump ONLY with UTMD vacuum cups and tubing WITH fluid traps.

Pump Testing Instructions:

Before using the CMI vacuum pump, check vacuum pressure.
The best way to check vacuum pressure function is to:

1. Attach a two-foot piece of tubing to the tapered pump nipple.
2. Tightly clamp off the distal end of the tubing.
3. Squeeze the pump handle repeatedly, and stop when the gauge needle reaches the top of the green area on the gauge face (59 cmHg or 23 inHg). If the pump is working properly, THE GAUGE NEEDLE SHOULD REMAIN STEADY AT THE APPLIED VACUUM.

4. Release pressure by depressing the vacuum release trigger.



CAUTION: Pressing a finger over the tapered pump nipple and increasing vacuum pressure in order to test pump function is contraindicated. This method may alter pump operation and may render the pump inaccurate and/or inoperative.

Pump Cleaning Instructions:

In most cases, wiping the surface of the vacuum pump with disinfectant after completion of the birthing procedure is sufficient.

Following each delivery, the tubing between the fluid trap and the pump nipple should be closely examined for evidence of residual blood or serous fluid. If this material is found, the pump should be considered contaminated and flushed immediately with distilled water, as follows: Submerge the tapered pump nipple in clean distilled or demineralized water. With the pump nipple submerged, squeeze the pump handle several times to flush out any undesirable fluids. Repeat as necessary until the water expelled is clear. Do not allow body fluids to dry inside the pump. If necessary, the entire pump may be submerged. Remove the pump from the water and squeeze the handle several times until all water is expelled from the pump chamber.

Pump Sterilization:

101A (blue) CMI Vacuum Pump may be autoclaved or ETO gas sterilized. The following cycle has been qualified for sterilization using a Prevacuum steam sterilizer:

Precondition Pulses: 3
Temperature Setting: 134°C (273°F)
Full Cycle Time: 3 minutes
Minimum Dry Time: 0 minutes

For other autoclave types, follow the directions of the manufacturer of your steam sterilizer for length of time and temperature, but do not exceed 300°F.

001C (white) CMI Vacuum Pump may be ETO gas sterilized only. Do not autoclave. Follow the directions of the gas sterilizer for duration of cycle, temperature and aeration. Do not exceed 120°F.

VADS Instructions for Use:

1. Connect the tubing to the pump nipple, with the cup, tubing and fluid trap assembled as shown in the diagram on page 5. Be sure all connections are secure. Prior to cup placement, check for vacuum pump function per the pump test procedure on page 5. An alternative approach is to test by pumping with assembled cup pressed to the palm of a gloved hand. The pump gauge needle should remain steady.

2. Conduct a vaginal examination to determine the degree of dilation and effacement of the cervix, the condition of the membranes, the presentation and fetal position with reference to the size and shape of the birth canal.

3. Wipe the fetal scalp as clean as possible.

4. For a bell-shaped cup, squeeze the cup rim edges together and press the leading edge of the cup into the posterior vagina. Hold the cup with the fingers of one hand, and separate the labia with fingers of the opposite hand. With the cup inserted into the vagina, allow the cup to unfold and place on the fetal occiput. For other shaped cups, follow the specific instructions on the packaging.

WARNING: APPLY CUP ONLY to the PIVOT POINT on the OCCIPUT of the FETAL HEAD, CENTERED OVER THE SAGITTAL SUTURE.

5. Press the cup to the occipital area with a slight rotating motion. Apply slight (not to exceed 5 cmHg) vacuum while this rotation is taking place.

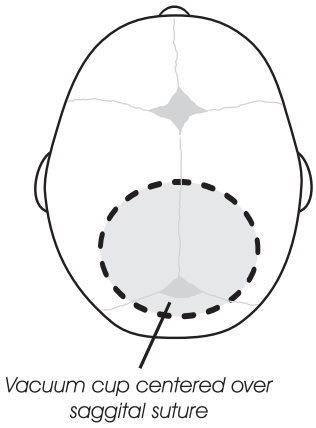
WARNING: PASS A FINGER AROUND the EDGE of the CUP to ENSURE THAT NO EXTRANEOUS MATERNAL TISSUE HAS BEEN INADVERTENTLY DRAWN UNDER THE EDGE of the CUP PRIOR to INITIATING FULL VACUUM.

6. When a contraction begins, rapidly raise vacuum to the upper portion of the green zone on the gauge (59 cmHg or 23 inHg).

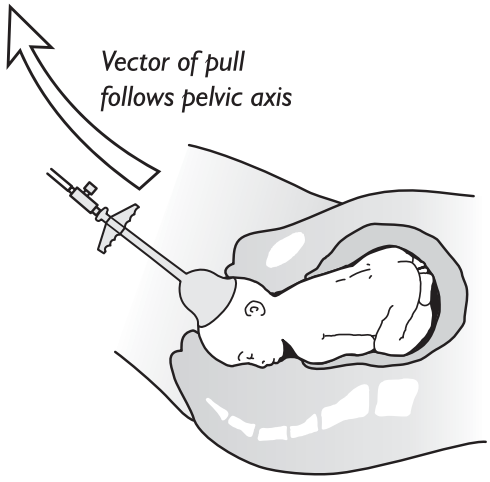
WARNING: 59 cmHg IS THE MAXIMUM RECOMMENDED VACUUM PRESSURE.

7. Begin traction. Each pull or traction should last the duration of a contraction. Always pull in synchronization with the contraction, with the vector of force following the pelvic axis.

WARNING: DO NOT ATTEMPT to MANUALLY ROTATE the FETAL HEAD. DO NOT PULL OFF-AXIS or WITH JERKY EFFORT.



Vacuum cup centered over saggital suture



If traction is misdirected or excessive, the cup may disengage. This acts as a built-in fetal safety factor. Should this occur, reapply the cup if it is within the accrued time limit.

WARNING: DO NOT REAPPLY CUP IF IT HAS DISENGAGED 3 TIMES.

8. When each contraction subsides, stop traction and reduce vacuum to the yellow zone on the gauge (10 cmHg or 4 inHg). Await the next contraction.

WARNING: DISCONTINUE TRACTION BETWEEN CONTRACTIONS.

WARNING: OBVIOUS PROGRESS in FETAL DESCENT SHOULD OCCUR with THE FIRST or SECOND PULL. IF NOT, ABANDON THE PROCEDURE.

9. Repeat steps #6 - #8 until delivery of the head is complete. (Usually, 2 or 3 pulls are sufficient.)

WARNING: AFTER 4 PULLS, DELIVERY SHOULD BE IMMINENT. OTHERWISE, THE PROCEDURE SHOULD BE CAREFULLY RECONSIDERED or ABANDONED.

WARNING: DO NOT EXCEED TIME LIMITS:

1) 20 MINUTES TOTAL PROCEDURE DURATION, or

2) 10 ACCRUED MINUTES at MAXIMUM VACUUM PRESSURE, WHICHEVER OCCURS FIRST.

10. Draw the fetal head gently over the perineum. When the head is delivered, release the vacuum to zero, remove the cup and proceed with the delivery of the infant's shoulders and body as in a normal vaginal delivery procedure.

11. Following the procedure, notify the pediatrician that a vacuum assisted delivery was performed in order to monitor for complications that may not be apparent at birth.

12. Dispose of the cup, tubing and fluid trap. Inspect and clean the vacuum pump according to its Instructions for Use.

Cesarean Section Procedures:

The UTMD VADS has been proven extremely effective during cesarean sections for controlling and delivery of a "floating head". In addition, the length of the incision may be decreased, as in most cases the vacuum cup eliminates the need to place both hands within the uterus.

In Cesarean Section procedures, prepare the VADS, heed all Warnings listed previously, and dispose/clean per the above instructions.

ADDITIONAL SUGGESTIONS FOR CESAREAN SECTION

1. Position the fetal head beneath the proposed incision site. Once the incision is made, the uterus may be entered routinely.

2. After making the uterine incision and entering the uterus, carefully determine the position of the fetal head.

WARNING: APPLY CUP ONLY to the PIVOT POINT on the OCCIPUT of the FETAL HEAD, CENTERED OVER THE SAGITTAL SUTURE.

   A. If the fetal head is high and readily accessible beneath the uterine incision, place the cup over the fetal occiput.

   B. If the fetal head is low and inaccessible, place the gloved fingers under the head and flex upward, bringing the head closer to the uterine incision. Place the cup over the fetal occiput.

3. Rapidly raise vacuum to the upper portion of the green zone on the gauge (59 cmHg or 23 inHg) and deliver the fetal head through the incision.

WARNING: 59 cmHg IS THE MAXIMUM RECOMMENDED VACUUM PRESSURE.

4. After delivery of the fetal head, reduce vacuum to zero and remove cup.

5. Delivery of the shoulders and body is continued as in a normal cesarean delivery procedure.

Additional Suggestions for Achieving Optimum Results:

Care should be taken when examining the patient to be sure cephalopelvic disproportion (CPD) does not exist and engaged fetal station is low or outlet. If these conditions are marginal, immediate preparation for cesarean section should be seriously considered.

Always follow the specific instructions that accompany the vacuum cup you are using. Do not exceed recommended pressures or time limits or reapply the cup more than 3 times if disengagement occurs.

When using traction always pull so that the angle of the vacuum cup stem remains straight or "on-axis" with the maternal pelvis. If the angle of the stem is not straight, uneven scalp pressure may be produced and the vacuum cup may disengage. The technique of applying tractive force on-axis with the arm straight and pulling "from the shoulder" usually eliminates this possibility. Do not manually rotate the cup. When used correctly, the UTMD vacuum cup encourages the fetal head to follow the path of least resistance. This is often sufficient to easily correct malposition of the fetal head.

You should reduce vacuum pressure into the yellow zone (5 inHg) on the hand pump gauge between contractions. Failure to do so may cause unnecessary trauma to the fetal scalp.

VAD with Electric Pumps or Wall Suction:

UTMD provides vacuum cups and tubing sets without a fluid trap when used in conjunction with an electric vacuum pump or controllable wall suction which has its own fluid collection jar. It may be necessary to use an adapter to connect the tubing to an electric pump or wall suction apparatus. Control of the electric pump or wall suction vacuum within the guidelines provided in this booklet is essential.

Many hospitals still use a UTMD vacuum cup with fluid trap in conjunction with their electric vacuum pump, thus eliminating the need to clean the reusable glass fluid collection jar. If blood or other contaminated matter enters the electric pump fluid collection vessel, sterilization of the contaminated part of the system must be undertaken in conjunction with the policies and procedures of the hospital, and the recommendations of the electric vacuum pump manufacturer.

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