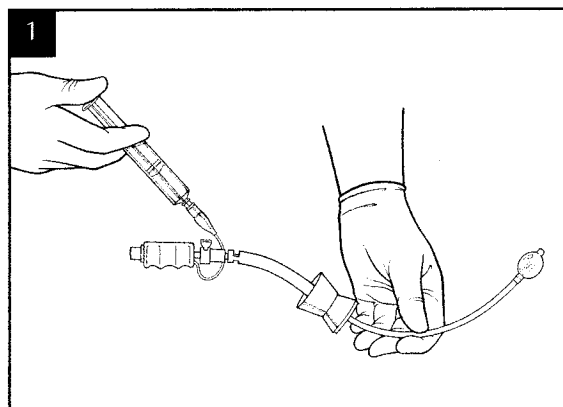
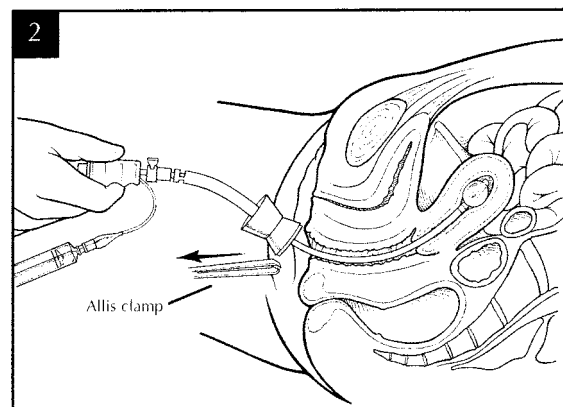


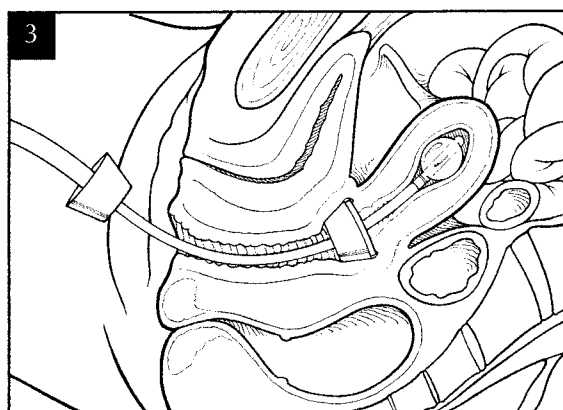
DIRECTIONS FOR USE OF VCARE®



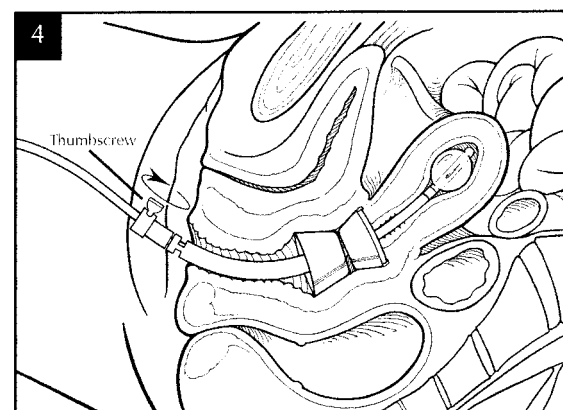
Examine sterile pouch, remove instrument on to sterile field. Attach air filled syringe to air port. Inflate intrauterine balloon and remove syringe to confirm balloon integrity. Reattach syringe and fully evacuate air prior to use.



Expose patient's cervical OS. Grasp anterior lip of cervix with single-toothed tenaculum. Sound uterus for depth and direction. If necessary dilate the cervix to accommodate the 5mm diameter of the manipulator tube.



Lubricate uterine balloon and tip with a sterile lubricant. Carefully insert the proximal tip of Vcare® through the cervical OS until the balloon is in the desired position within the uterine cavity. Remove the clamp from the cervix. Stabilize the distal (external) end of Vcare® to prevent accidental dislodging. Attach a syringe to the lower adapter on the pilot balloon on the handle and inflate the intrauterine balloon with at least 7cc of air (maximum inflation is 10cc).



Slide the cervical cup along the manipulator tube until its outer edges surround the vaginal fornix. Ensure proper positioning of this cup before proceeding. Slide the vaginal cup along the manipulator tube until it meets the cervical cup and is completely seated against the vaginal walls. Secure the lock in place by turning screw clockwise until tight. The locking mechanism must be locked at all times when using Vcare® for uterine manipulation. If lock inadvertently becomes open, secure immediately before proceeding.

Warning: Read and become familiar with all instructions, warnings, and cautions before using this product. Improper use of this or any intrauterine instrument can result in perforation of the uterine wall and subsequent bleeding. When performing colpotomy do not use laser with this product. To avoid balloon failure, use only air when inflating the uterine balloon.

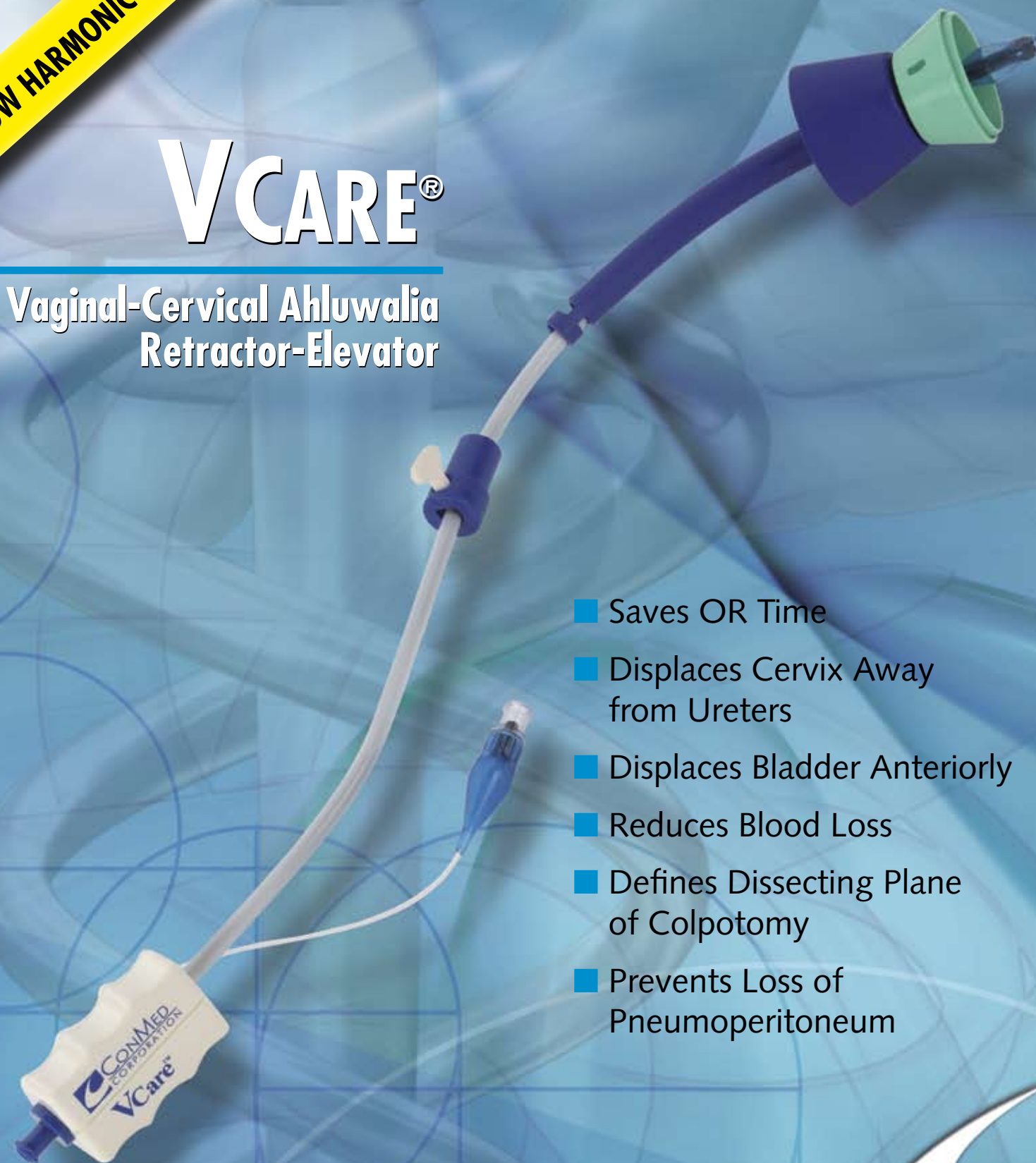
ORDERING INFORMATION

Reference No.	Product Description	Packaging
60-6085-100	Vcare®, Standard Cervical Cup	1/pkg, 8/cs
60-6085-101	Vcare®, Small Cervical Cup	1/pkg, 8/cs
60-6085-102	Vcare®, Large Cervical Cup	1/pkg, 8/cs

NOW HARMONIC COMPATIBLE

VCARE®

Vaginal-Cervical Ahluwalia Retractor-Elevator



- Saves OR Time
- Displaces Cervix Away from Ureters
- Displaces Bladder Anteriorly
- Reduces Blood Loss
- Defines Dissecting Plane of Colpotomy
- Prevents Loss of Pneumoperitoneum



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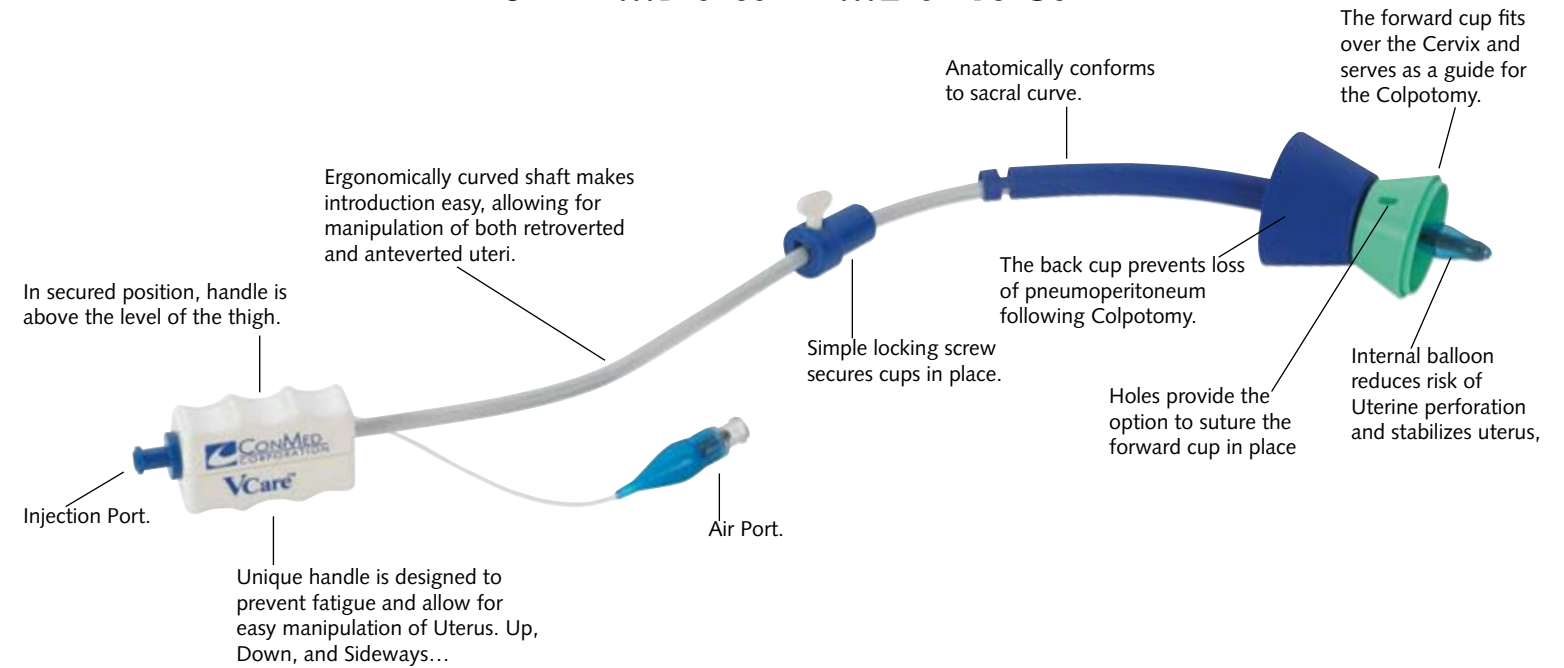
MBR 9090 Rev 2

VAGINAL-CERVICAL AHLUWALIA RETRACTOR-ELEVATOR

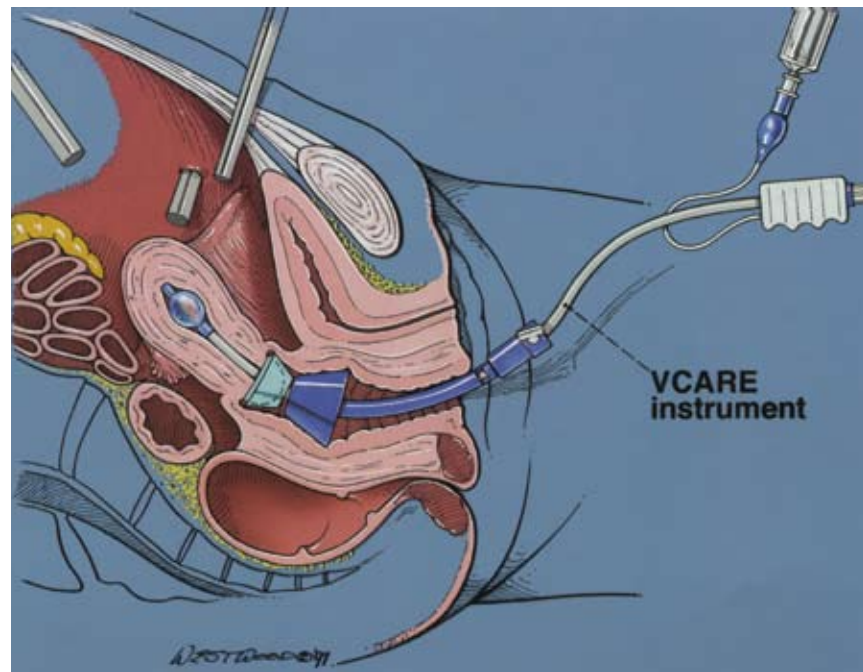
Vcare® is a specialized Uterine Manipulator/Elevator invented, developed and patented by Dr. Prabhat K. Ahluwalia. The Vcare® Uterine Manipulator/Elevator is intended for use in Laparoscopically Assisted Vaginal Hysterectomy (LAVH) Total Laparoscopic Hysterectomy (TLH) and Laparoscopic Supracervical Hysterectomy (LSH). Vcare® features a specially designed double-cup system; the forward cup displaces the cervix away from the ureters, retracts the urinary bladder and defines the colpotomy incision. The back cup prevents loss of pneumoperitoneum. The manipulator tube conforms to the angle of the sacral curve and allows for easy manipulation of the uterus. A 10cc inflatable balloon at the distal end is used to stabilize the manipulator tube within the uterine cavity.



STERILE...DISPOSABLE...EASY TO USE



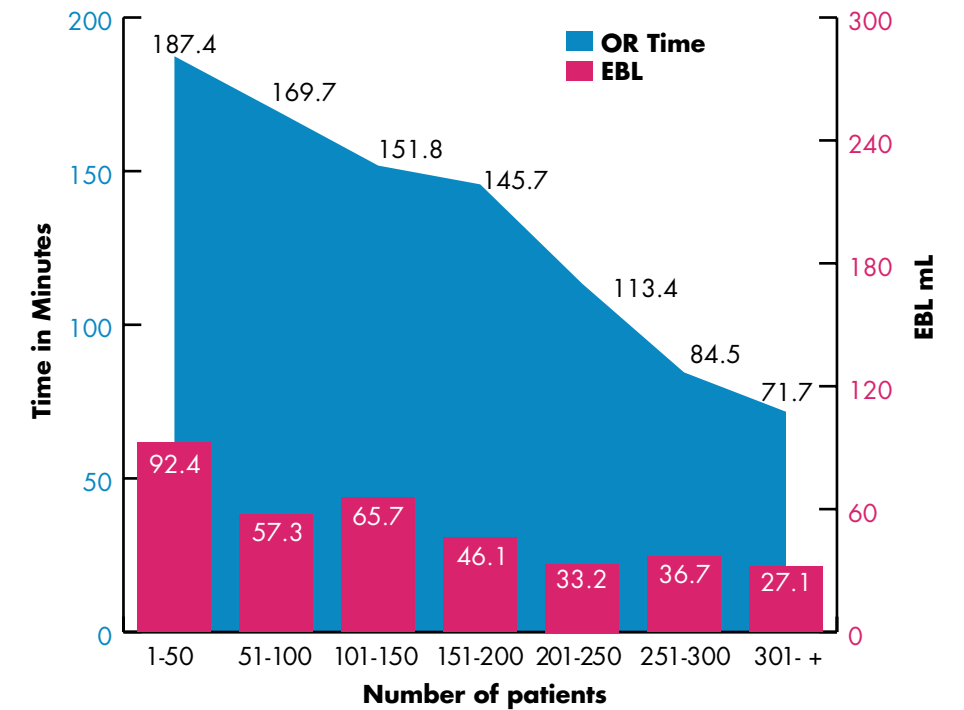
VCARE® in place



REDUCES BLOOD LOSS AND OR PROCEDURE TIME*

Table 1 shows the comparison of the estimated blood loss and OR times for 400 patients undergoing Laparoscopic Hysterectomy using the Vcare® Manipulator, including 336 Total Laparoscopic Hysterectomy (TLH) and 64 Laparoscopically Assisted Vaginal Hysterectomy (LAVH) procedures. Blood loss is minimized with the use of Vcare® by the compression of the Uterine Arteries. Blood loss was seen to be lower than that of patients reported within this series who had Total Abdominal Hysterectomy with open surgery. The decrease in OR time is related to both the increased experience of the surgeon (learning curve) and the benefits of the Vcare® in outlining the pelvic anatomy, decreasing operative blood loss, and in maintaining the pneumoperitoneum during and following colpotomy.

Table 1: Comparison of OR time and estimated blood loss (EBL).



* Dr. Ahluwalia's clinical data is available upon request.