

# VALTCHEV®

## VAGINAL DELINEATOR

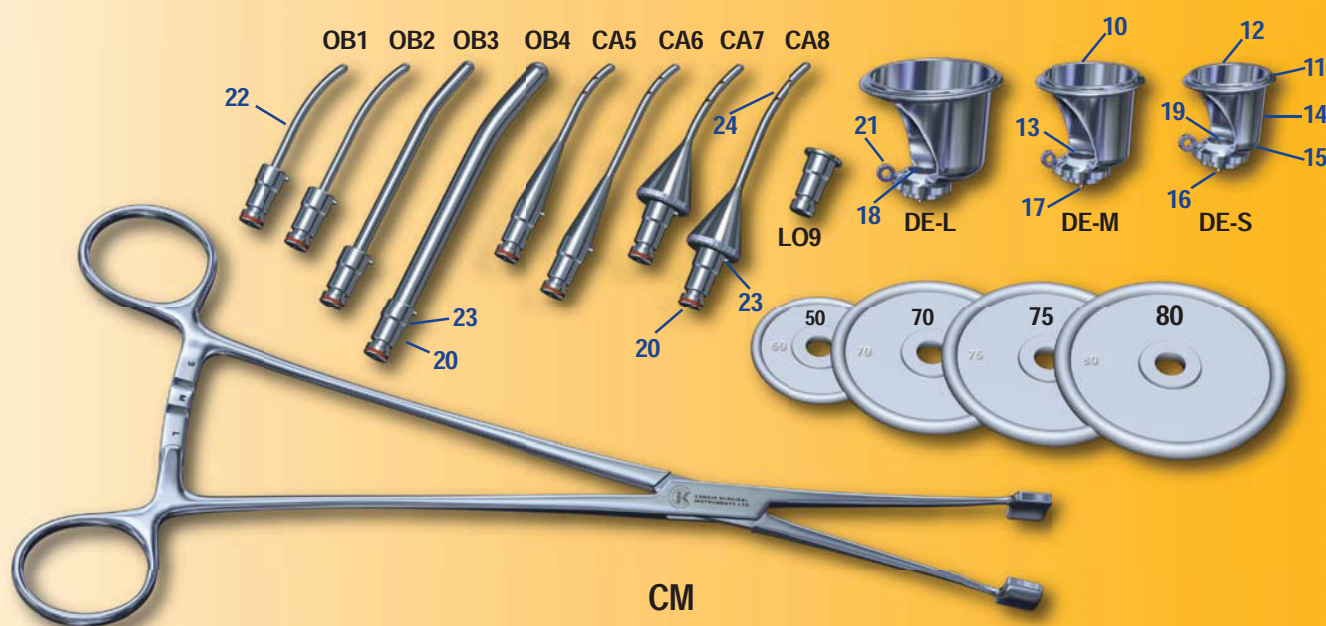


FIG.1

### INSTRUCTIONS FOR USE OF THE VALTCHEV® VAGINAL DELINEATOR SET

#### VALTCHEV® VAGINAL DELINEATOR SET

##### INDICATIONS FOR USE

The Valtchev® Vaginal Delineator Set (VVD) is designed for use during Total Laparoscopic Hysterectomy (TLH), Laparoscopically Assisted Vaginal Hysterectomy (LAVH), Laparoscopic Supra-cervical Hysterectomy (LSH), Vaginal Vault Suspension, Laparoscopic Surgery for Endometriosis, Injection of dye and any other laparoscopic operations where delineation of the fornices of the vagina is necessary.

##### DESCRIPTION

The Valtchev® Vaginal Delineator is an attachment which fits only onto the Valtchev® Uterine Mobilizer model VUM-6.

The Valtchev® Vaginal Delineator Set VVD FIG. 1 consists of three vaginal delineators: a small (DE-S)- with a 24 mm I.D. (Inside Diameter), of the rim (10), a medium (DE-M) with a 30 mm I.D.

and a large (DE-L) with a 40 mm I.D. The rim (10) of the delineator has a protrusion (11). Between the rim and the protrusion a groove is formed (12). At the front side of the delineator there is a window (13). The back of the delineator is a solid wall (14). There is also a cervicometer (CM) for measuring of the outside diameter of the cervix and indicates which delineator, small, medium or large should be used. The construction and dimensions of the base (15) and the locking end (16) of the three delineators are the same. At the distal end of the base (15) there is a pin (17), and on the proximal end of the base a slot (18).

There is an opening (19) in the base into which is inserted either the locking end (20) of an obturator (OB 1, OB2, OB3 and OB4), the locking end (20) of a cannula (CA 5, CA6, CA7 and CA8) or the locking end (20) of a delineator lock (LO9). On the front side of the base there is a loop (21).

There are four obturators. Two of them (OB1 and

OB2) have a stem (22) with 3 mm O.D. (Outside Diameter) and different lengths: 45 mm (OB1) and 55 mm (OB2). The obturator (OB3) has a 6 mm O.D. of the stem (22) and length of 80 mm and the last obturator (OB4) has a stem of 8 mm O.D. and lengths of 100 mm (OB4). At the proximal end of the locking end (20) of obturators and cannulas there is a pin (23) The set includes a delineator lock (LO9).

There are four cannulas. Two of them are for nuliparas (CA5, CA6) with a small diameter cone, and two for multiparas (CA7, CA8) with a large diameter cone. The O.D. of the tube (24) of all cannulas is 3 mm. The cannulas come in two different lengths – 55 mm (CA5, CA7) and 65 mm (CA6, CA8)

There are four silicone rings: 50 mm in diameter (SR50), 70 mm in diameter (SR70), 75 mm in diameter (SR75), and 80 mm in diameter (SR80).

FIG.2



FIG.3



FIG.4



#### INSTRUCTIONS FOR USE

When TLH is going to be performed, after the patient is prepped, draped and catheterized, she is examined vaginally to determine the size and position of the uterus. If the appropriate size silicone ring has not yet been determined, it is advised to try and select a proper size silicone ring by insertion into the vagina. The silicone ring should fit snugly. The vaginal walls are then retracted by vaginal retractors and the cervix is visualized. The outside diameter of the cervix is measured using the cervicometer CM (FIG1) in order to determine which size delineator should be used. There are two options for holding the cervix. One is to use a single tooth tenaculum, the second is to place two strong sutures on the cervix. Regardless of the method chosen to hold the cervix, the length of the uterine cavity is measured in order to select the proper size obturator. If the suture method is chosen, two strong sutures are placed, the first on the anterior, and the second on the posterior lip of the cervix. After the sutures are tied, they are pulled through the opening of the rim (10) of the delineator and out from the window (13). By pulling the sutures, the cervix will come down, for easier insertion of an obturator into the cervical canal. At the end of the operation the sutures can be used to help pull out the uterus. After selection of the appropriate size, delineator, silicone ring and obturator, the pieces are assembled. The selected size silicone ring is pulled down over the head of the mobilizer until it goes below the lock. (FIG2) The obturator is inserted through the opening of the rim (10) of the delineator and is inserted into the opening (19) of the base (15) of the delineator. The pin on the obturator (23) should enter the slot (18) on the delineator. (FIG3) The locking end (20) of the obturator is now inserted into the head of the mobilizer and the pin (17) of the delineator must enter the slot on the head of the mobilizer. The locking end (20) of the obturator is locked into the head of the mobilizer and is now firmly holding the delineator. At this point the silicone ring is pushed up into the groove created between the head of the mobilizer and the delineator.

**CARE SHOULD BE TAKEN NOT TO UNLOCK THE LOCK, BECAUSE IF THIS HAPPENS, THE DELINEATOR MAY FLY ACROSS THE OPERATING-**

#### ROOM DUE TO THE PRESSURE EXERTED ON THE DELINEATOR BY THE SILICONE RING.

The mobilizer is locked in a straight position. The Valtchev® tenaculum is opened and the teeth are passed through the loop (21) and the tenaculum is inserted and locked into the tenaculum holder. In this position, the Valtchev® tenaculum pushes the rim of the silicone ring toward the mobilizer, which otherwise will obstruct the view of the cervix. Now is the time to insert the lubricated delineator into the vagina. (FIG4) The cervix is pulled as far down as possible by a tenaculum or sutures and the obturator is inserted into the cervical canal. The vaginal retractors are removed and the delineator, followed by the silicone ring are inserted into the vagina until the silicone ring enters the vagina completely and the rim of the delineator reaches the fornix of the vagina. Now the tenaculum/a is removed, because if it remains in place, the silicone ring will not obstruct the vagina and CO2 will leak. Usually, the mobilizer will not drop out of the vagina when the tenaculum is removed, because of the friction between the silicone ring and the vaginal wall. But if the vagina is lax, the mobilizer should be supported by bringing the sheets together, below the mobilizer with a towel clip.

For better visualization of the fornix, the delineator should be pushed firmly against the fornix of the vagina and the mobilizer should be moderately anteverted. The rim of the delineator is easily identified laparoscopically. Colpotomy is facilitated by placing the tip of the cutting instrument into the groove (12) of the delineator. After the colpotomy the mobilizer is removed from the vagina. The uterus is pulled down and left into the vagina to obstruct the vagina if the vaginal cuff will be closed laparoscopically.

If the uterus is not left in the vagina as a plug, the silicone ring is pulled down over the head of the mobilizer until it goes below the lock. The delineator lock (LO9) is inserted into the opening (19) of the base (15) of the delineator and is locked to the head of the mobilizer. The silicone ring is pushed up into the groove created by the head of the mobilizer and the delineator should be reinserted into the vagina and removed after the suturing of the cuff is completed.

The delineator can be used for other laparoscopic operations as mentioned above. If the patency of the Fallopian tubes has to be checked for multiparas, it is preferable to use a cannula with a large

diameter cone and for nuliparas with a small diameter cone. If only a delineator is going to be used, it is locked into the head of the mobilizer by the delineator lock.

#### PRECAUTIONS

The vagina can be damaged and the uterus can be perforated if an appropriate size obturator or cannula are not used. Damage of the soft tissue can occur, if excessive force is applied or an inappropriate size delineator is used.

#### DIRECTIONS FOR CLEANING AND STERILIZATION

Immediately after use, remove the obturator or if a cannula was used keep it attached to the Mobilizer. Flush the instrument with 100 ml soapy water by a syringe attached to the luer lock. The soapy water is prepared by adding 1 ml dishwashing soap having a pH 9 and 1 litre clean tap water at 22°C. The entire instrument is cleaned by a plastic brush and soapy water for 1 minute. The instrument is disassembled (for detailed disassembly instructions see: INSTRUCTIONS FOR USE OF THE VALTCHEV® UTERINE MOBILIZER, MODEL VUM-6 - Directions for Cleaning and Sterilization). Each part is cleaned with a brush and soapy water at 22°C for 1 minute. Then the parts are rinsed very well under clean running tap water for 1 minute. The Mobilizer is reassembled. The Mobilizer is flushed with 100 ml clean tap water at 22°C by a syringe attached to the luer lock. This is repeated with 100 ml distilled water. The whole instrument is rinsed with distilled water. The Mobilizer and attachments can be sterilized by pre-vacuum at 132°C + 3°C for 2 minutes, 20 minutes dry time, single wrapped. Sterilization of the silicone rings prior to use is mandatory. The silicone rings, SR50, SR70, SR75 and SR80 that come with the Valtchev® Vaginal Delineator attachment are sterilized, single wrapped using the same cycle parameters that are used for the instrument. They are intended for single use and should be discarded.

For more detailed information about cleaning and sterilization see our "Manual for Cleaning and Sterilization of The Valtchev® Uterine Mobilizer and Attachments".

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