ELMED
SERVING THE MEDICAL PROFESSION SINCE 1955

VALTCHEV® UTERINE MOBILIZER

INSTRUCTIONS FOR USE

THE VALTCHEV® UTERINE MOBILIZER IS A REUSABLE DEVICE. IT IS:

- USED FOR POSITIONING THE UTERUS DURING LAPAROSCOPIC SURGERY AND DYE DELIVERY.
- DESIGNED FOR USE IN OPERATIVE ENDOSCOPY (LAPAROSCOPY), WHERE THE UTERUS IS PRESENT AND NEED FOR POSITIONING OF THE UTERUS, FALLOPIAN TUBES AND OVARIES OR VAGINA IS DESIRABLE.

THE CANNULAS ALSO PROVIDE DYE FOR DELIVERY IN THOSE PROCEDURES REQUIRING CHROMOPERTUBATION.

CONTRAINDICATIONS

THE VUM-6 SHOULD NOT BE USED IN PATIENTS WHO ARE PREGNANT OR WHO ARE SUSPECTED OF BEING PREGNANT, IN PATIENTS WHO SUSPECTED PELVIC INFECTIONS AND CASES WHERE THE SURGEON DECRIES IT INADVISABLE OR BELIEVES IT TO BE DIFFICULT TO INSERT THE TIPS INTO THE CERVIX OR UTERUS.

WARNINGS

- DO NOT USE THE VUM-6 AS A UTERINE SOUND.
- NEVER ATTEMPT UTERINE MANIPULATION WITHOUT A CLEAR VIEW OF THE UTERUS.
- SIMILAR TO OTHER UTERINE DEVICES, A CAREFUL CLINICAL EVALUATION SHOULD BE PERFORMED BEFORE USE.
- CERTAIN CONDITIONS MAY PRESENT A UTERUS WHICH IS PRONE TO PERFORATION AND BLEEDING.

PRECAUTIONS

- CLEAN AND FLUSH THE INSTRUMENT IMMEDIATELY AFTER USE (SEE "CLEANING" BELOW)
- STERILIZE BEFORE USE.
- DILATE THE CERVIX
- INSPECT VUM BEFORE OPERATION
- DAMAGE OF THE SOFT TISSUE CAN OCCUR IF EXCESSIVE FORCE IS APPLIED OR AN INAPPROPRIATE SIZE DELINEATOR IS USED.
- UTERINE CAVITY MUST ALWAYS BE MEASURED AND AN APPROPRIATELY SIZED UTERINE OBTURATOR OR CANNULA SELECTED. IF THE OBTURATOR OR CANNULA IS LONGER THAN THE UTERINE CAVITY, OR INSERTED IN THE WRONG DIRECTION THERE IS DANGER OF UTERINE PERFORATION.

CLEANING AND INSPECTION

- CLEANING SHOULD TAKE PLACE IMMEDIATELY AFTER USE. THE INSTRUMENT MUST BE FLUSHED, AS THE TUBE FOR DYE INJECTION MAY BECOME BLOCKED.
- ULTRASONIC CLEANING IS ACCEPTABLE AND RECOMMENDED. IF ULTRASONIC IS NOT AVAILABLE, MANUAL CLEANING WITH A BRUSH AND SUITABLE DETERGENT/ENZYMATIC WHICH HAS BEEN DESIGNED FOR USE WITH STAINLESS STEEL SURGICAL INSTRUMENTATION IS ACCEPTABLE. DO NOT USE METAL-BRISTLED BRUSHES ON THE INSTRUMENTS. ALL MOVING/ ARTICULATING COMPONENTS SHOULD BE LUBRICATED PRIOR TO STEAM STERILIZATION WITH STEAM-PENETRABLE LUBRICATION WHICH HAS BEEN DESIGNED FOR USE WITH SURGICAL INSTRUMENTS.
- ALL INSTRUMENTS MUST BE INSPECTED FOR SIGNS OF DAMAGE, WEAR OR RESIDUAL SOIL EACH TIME THEY ARE REPROCESSED. IF RESIDUAL SOIL IS NOTED DURING INSPECTION, THE CLEANING PROCESS MUST BE REPEATED FOR THE INSTRUMENT. INSPECT ALL SURFACES FOR POTENTIAL TRAPPED SOIL.
- FULLY ARTICULATE THE MOVING COMPONENTS BY WAY OF FINGER RINGS AND LOCKING PING. ENSURE THE LOCK, TENACULUM HOLDER, CANNULA/OBTURATOR LOCK MOVE EASILY. SIGNS OF DAMAGE OR POOR MOTION QUALITY MAY INDICATE A NEED TO REPLACE THE INSTRUMENT OR HAVE IT REPAIRED.

MANUAL CLEANING PROCESS

- DETACH ACCESSORIES.
- PREPARE A NEUTRAL OR ALKALINE ENZYMATIC DETERGENT SPECIFICALLY DESIGNED FOR CLEANING MEDICAL INSTRUMENTS. PREPARE A FRESH SOLUTION OF DETERGENT AT THE DETERGENT MANUFACTURER'S RECOMMENDED CONCENTRATION USING WATER AT THE DETERGENT MANUFACTURERS RECOMMENDED TEMPERATURE.
- ENSURE THAT THE INSTRUMENTS ARE FULLY IMMERSED IN THE PREPARED SOLUTION. SOAK THE INSTRUMENT FOR A MINIMUM OF TEN (10) MINUTES AT ROOM TEMPERATURE (68° F / 20° C) OR LONGER (REFER TO DETERGENT MANUFACTURER'S INSTRUCTIONS FOR USE).

- Using a soft bristled brush, scrub the regions with mated surfaces such as the space bar. Scrub regions with crevices, lumens and sides of the head and space bar. Actuate the moving parts while submerged to ensure contact between the instrument surfaces and the brush/detergent.
- Rinse the instrument in warm tap water (100° F / 38° C) for one (1) minute. Ensure that all crevices and lumens are flushed. Actuate the moving parts during rinsing.
- Place the instrument into a prepared ultra-sonicator containing a neutral or alkaline detergent. Ultra -sonicate the instrument in the detergent solution for ten (10) minutes.
- Rinse the instrument with water for at least (1) minute or until all visible signs of detergent residue are removed. Ensure that all crevices and lumens are flushed. Actuate the moving parts of the VUM-6 during rinsing.
- Examine the instrument for signs of residual soil. Repeat the cleaning process, if necessary.
- Dry the instrument with a lint-free towel or wipe.

Automated Cleaning Process

- Ensure that all gross soil has been wiped or rinsed from the surfaces of the instrument.
- Place the instruments loosely within a rack. Load the rack with the instruments into the washer/ washer-disinfector and close the door.
- Select a cycle intended for instruments that has the following parameters at a minimum:

Parameter	Tolerance
Detergent	Neutral or Alkaline medical device detergent
Pre-wash rinse	One pre-wash rinse Cold tap water or better quality 30 seconds
Wash	One Repetition Warm purified water (140° F / 60° C) Minimum concentration per detergent manufacturers IFU 2:00 minutes
Post Wash Rinse	One post-wash rinse Warm purified water (158° F / 70° C) 2:00 minutes
Drying	15 minutes (176° F / 80° C)

NOTE: Automated washing processes having additional phases or longer phase durations are anticipated to deliver equivalent or better cleaning efficacy. Additional phases and longer phase durations may be added if they are within the healthcare facility's normal procedures.

- Start the cycle and allow it run through conclusion
- Examine the instruments for signs of residual soil. If there are ANY signs of residual soil on the instrument, repeat the cleaning process.
- If the instruments are not thoroughly dry following the automated process, dry the instruments with a lint -free towel or wipe.

Sterilization—Steam (Moist Heat)

The following parameters have been validated:

Sterilization process	Exposure Temperature	Expose Time	Dry Time
Pre-Vacuum	270° F / 132° C	4 Minutes	30 Minutes
Pre-Vacuum	273° F / 134° C	3 Minutes	30 Minutes

Storage

Instruments packaged individually should be cooled to a safe handling temperature following moist heat sterilization prior to final storage. Individually packaged instruments should be transported to a clean, temperature and humidity controlled sterile supply storage area. If instrument packaging is compromised during storage, the instrument must be reprocessed through cleaning, inspection, and sterilization prior to use.

We Design, Manufacture, & Sell The Tools The Surgeons Use

ELMED INC.
35 N. Brandon Dr.
Glendale Heights, IL
60139
USA

We Subscribe To Cost Containment And Protection Of The Environment

Made In The USA

Therefore, We Manufacture Reusable Products For A Cleaner World

PH (224) 353-6446
FAX (224) 653-8178
EMAIL
MEDICAL@ELMED.COM
WWW.ELMED.COM