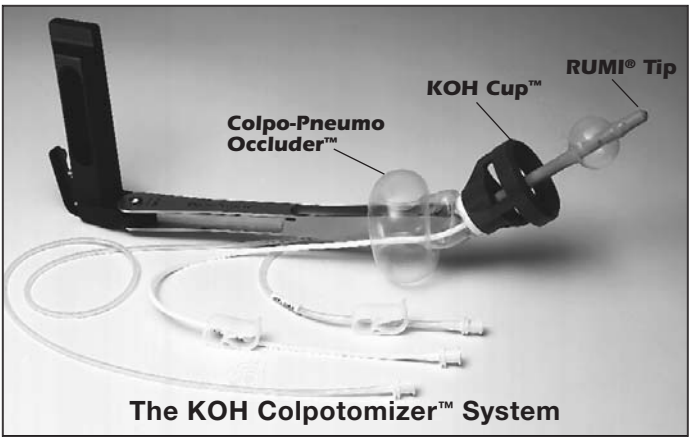
THE KOH COLPOTOMIZER™ SYSTEM

KOH Cup™ Vaginal Fornices Delineator & Colpo-Pneumo Occluder™

DIRECTIONS FOR USE



The KOH Colpotomizer™ System

NON-STERILE

PRODUCT #'s KCS-Kit TL • Stainless steel KOH Cups for use with laser or harmonic scalpel.

KCP-Kit TL • Ultem Polymeric Resin KOH Cups for use during electrosurgery.

STERILE

PRODUCT #'s CPO-6 TL • Colpo-Pneumo Occluder

Sterile unless package has been opened or damaged. Ethylene Oxide Gas Sterilized.

DISPOSABLE Discard after single-use.

CAUTION U.S. Federal law restricts this device to sale by or on the order of a physician.

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DESCRIPTION

KOH Cup™ Vaginal Fornices Delineator is designed for use with The RUMI® System and Colpo-Pneumo Occluder™. The KOH Colpotomizer™ System is intended to be used in laparoscopic procedures where it is desirable to locate the position of the vaginal fornices. The KOH Cup™ is available in either Ultem® plastic or stainless steel in sizes 3.0cm, 3.5cm and 4.0cm. These devices are non-sterile and must be sterilized according to standard procedure prior to use.

The Colpo-Pneumo Occluder™ is a sterile single use medical grade silicone device designed for use with The RUMI® System and the KOH Cup™ Vaginal Fornices Delineator. The KOH Colpotomizer™ System is intended for use in laparoscopic procedures where it is desirable to minimize the loss of pneumoperitoneum after a colpotomy incision has been made.

INDICATIONS FOR USE

The KOH Colpotomizer™ System is indicated for use in laparoscopic procedures where use of a uterine manipulator is appropriate and the surgeon intends to remove or access intraperitoneal tissue through the vagina by use of a colpotomy or culdotomy incision.

CONTRAINDICATIONS

The KOH Colpotomizer™ System should not be used in patients who are pregnant or who are suspected of being pregnant, in patients that have an IUD in place, in patients planning gamete intrafallopian transfer, and in cases where the surgeon deems it inadvisable or finds it difficult to insert the silicone tip into the cervix or uterus.

WARNINGS

The Colpo-Pneumo Occluder™ is designed to accommodate no more than 180cc of inflation. It is supplied as a sterile single use device and should never be reused.

The KOH Cup™ Vaginal Fornices Delineator is non-sterile and should be sterilized prior to use. The Ultem® plastic KOH Cup™ is not intended to be used with harmonic or other types of ultrasonic energy sources.

Insure that placement of the KOH Cup™ Vaginal Fornices Delineator and Colpo-Pneumo Occluder™ on the CooperSurgical RUMI® Uterine Manipulator does not interfere or restrict the operation of the uterine manipulator in any way. The RUMI® Uterine Manipulator with KOH Colpotomizer™ System devices attached should always be inserted into the vagina slowly and under direct vision. The cervix should be adequately dilated prior to insertion of The RUMI® Uterine Manipulator Tip. Follow The RUMI® Uterine Manipulator Directions for Use for a detailed description of cervix dilation.

ADVERSE REACTIONS

During surgery, the KOH Colpotomizer™ System with KOH Cup™ Vaginal Fornices Delineator and the Colpo-Pneumo Occluder™ become part of The RUMI System® Uterine Manipulator. Adverse reactions which have been suspected or reported to be associated with the uterine manipulators are cramping, infection, uterine perforation and uterine spasm with accompanying temporary physiologic blockage of patent fallopian tubes. (The order of listing does not indicate frequency or severity.)

CLEANING OF KOH™ CUP VAGINAL FORNICES DELINEATOR

1 Submerge the KOH Cup™ in warm water and mild soap.

2 Scrub the submerged cup with a soft bristled brush and the mild detergent.

3 Rinse with filtered warm water.

4 Place in an enzymatic detergent and soak according to manufacturer's instructions.

5 Rinse with filtered warm water.

6 Inspect for cleanliness and marks. Verify that the instrument is clean. The KOH Cup™ should be inspected prior to each use to ensure that no surface defects are present. If not acceptable, dispose of the cup as a biohazard material after cleaning or sterilization.

STERILIZATION OF KOH CUP™ VAGINAL FORNICES DELINEATOR

WARNING *The KOH Cup™ must be meticulously cleaned prior to disinfection or sterilization. The methods employed are left to the discretion of the surgeon, hospital infection control committee, etc. Sterilization and Disinfection methods should be selected and evaluated in accordance with generally accepted medical practice, taking into account the medical procedure in which the KOH Cup™ will be used.*

The KOH Cup™ can be sterilized by the following methods—

GLUTARALDEYDE Sterilization

The KOH Cup™ may be sterilized via glutaraldeyde solutions. Consult the manufacturer of the glutaraldehyde solutions for detailed instructions for use. The KOH Cup™ may be completely immersed in a disinfecting solution. The device should then be thoroughly rinsed with saline or distilled water and dried by wiping with a soft, lint free cloth.

The recommended dilution percentage and contact time should be strictly followed. When the liquid chemical sterilant solution has been in contact with the instrument for the recommended time, remove the instrument from the disinfectant and rinse thoroughly to remove all toxic residues and to prevent instrument deterioration.

STEAM AUTOCLAVE Sterilization

- The instrument should be thoroughly cleaned of all foreign matter prior to sterilization.
- Follow the manufacturer's instructions for operation and loading of steam autoclave.
- There must be direct steam exposure to all surfaces of the instrument being sterilized.
- Autoclave temperatures should not exceed 280°F (137°C); pressure should not exceed 32 psi (2.2 atmospheres).
- Standard cycle of 270°F (132°C) for 10 minutes will vary depending on autoclave model, autoclave size, load size, and load configuration.

Allow longer times for lower temperatures. Allow instruments to cool down from autoclave to room temperature. Do not immerse in any fluid until the instrument has been allowed to cool.

Gravity Displacement Cycles
270°—275°F / 10-15 minutes or
250°F / 15-30 minutes

Prevacuum Cycles
270°—275°F / 3-4 minutes

ETHYLENE OXIDE Sterilization

- Items should be thoroughly cleaned of all foreign matter prior to sterilization, following steps A and B.
- Follow the manufacturer's instructions for operation and loading of sterilizer. There must be direct exposure to all surfaces of the instruments being sterilized.
- Instruments should be sterilized in their "open" position.
- Contact of plastic to bare metal should be avoided.

RECOMMENDED HOSPITAL ETHYLENE OXIDE CYCLE

Temperature	125-130°F
50% RH (pre-humidity)	60 minutes
	-0/+10 minutes
Pre Vacuum	24" Hg ± 2" Hg
Gas Pressure	6-8 psig (550-660 mg/L EO)
Exposure Time	4 hours minimum
Post Vacuum	24" Hg 2X ± 2" Hg
Aeration	12-0/+1 hours at 120°F

NOTE The particular EO cycle should be validated per the equipment manufacturers requirements. It is recommended that each institution employ procedures which include the use of biological indicators in order to determine the effectiveness of the ethylene oxide process.

INSPECTION PRIOR TO USE

CAUTION *DO NOT USE IF DAMAGED OR OPENED*

Inspect the KOH Cup™ for physical damage or irregularities (e.g., visible cuts or deep scratches on the surface). The KOH Cup™ must be inspected to ensure no surface defects are present which could harbor biological residue or debris, or cause perforation of the Colpo-Pneumo Occluder Balloon. Do not use the KOH Cup™ if any surface discontinuities are found.

Figure 1

Figure 2

Figure 3

Figure 4

DIRECTIONS

FOR USE

1 *Prepare the patient for surgery according to standard surgical practices. Prepare the RUMI® Uterine Manipulator for use in accordance with the RUMI® Tip Directions For Use.*

2 *Prior to patient insertion, slide the Colpo-Pneumo Occluder™ over the RUMI® disposable tip to extend over the distal shaft of the uterine manipulator.* (See Figures 1 and 2).

3 *Select the appropriate size KOH Cup™ by visually inspecting the diameter of the patient's cervix. Choose a KOH Cup™ with sufficient diameter to readily accept the cervix. If in question, it is recommended that the selected KOH Cup™ be tried on the cervix prior to attachment to the uterine manipulator. To do so, simply grasp the cup with an appropriate grasper and place it over the cervix to ensure that it fits correctly. (It is further recommended that a KOH Cup™ that is slightly too large be selected over one that is slightly too small.)*

DIRECTIONS FOR USE (continued)

DIRECTIONS FOR USE (continued)

4 Slide the selected KOH Cup™, small end first, over the RUMI® disposable tip and onto the tip base until it is snugly attached to the tip base. The distal end of the Colpo-Pneumo Occluder™ will be sandwiched between the KOH Cup™ and the tip base when properly installed. (See Figures 3 and 4 on previous panel).

5 Test inflate the Colpo-Pneumo Occluder™ with 20-60 cc of sterile saline prior to patient insertion in order to verify proper operation of the occluding balloon and then deflate prior to patient insertion. Test inflate the RUMI® tip balloon according to the RUMI® Directions For Use.

6 With assembly complete, dilate the cervix to a sufficient diameter to easily accommodate the insertion of the uterine manipulator tip. Use a speculum or a combination of vaginal retractors to gain sufficient exposure of the cervix for device insertion. Slowly insert the manipulator device into the vagina and manipulator tip into the uterus under direct vision and in accordance with the RUMI® Directions For Use. Once insertion is complete and the KOH Cup™ is fully engaged on the cervix, The RUMI™ Uterine Manipulator may be operated as normal.

7 Prior to making colpotomy incisions, inflate the Colpo-Pneumo Occluder™ balloon with sufficient sterile saline or water (do not use air) to cause the inflated balloon to make continuous radial contact with the vaginal wall. 90cc to 120cc of inflation will generally be sufficient. With the KOH Colpotomizer™ System attached to The RUMI® Uterine Manipulator and properly inserted in the patient, inflation of the Colop-Pneumo Occluder™ will not impede movement of the RUMI's articulating tip and will prevent leakage of the pneumoperitoneum from the vagina during and after any colpotomy incisions for as long as the Colpo-Pneumo Occluder™ is inflated.

8 Laparoscopic identification and delineation of the vaginal fornices is aided by using the uterine manipulator to articulate the uterus into a position opposite the point of desired delineation while applying distal pressure to the uterine manipulator handle. This will increase tissue traction in the desired area of delineation so that the location of the rim of the KOH Cup™ (which marks the position of the vaginal fornices) may easily be determined.

9 After dissection is complete, deflate the Colpo-Pneumo Occluder™ only. Do not deflate the uterine manipulator tip balloon.

10 Extend a tenaculum into the vagina through one of the windows on the KOH Cup™ and grasp the cervix.

11 Using the manipulator handle and tenaculum, pull the uterus into the vagina.

12 Removal of the uterus and the KOH Colpotomizer™ System—

- **A** For vaginal closure, continue to use the tenaculum and manipulator to pull the uterus through the vaginal canal until it is removed from the patient. The KOH Colpotomizer™ System will be removed during this process along with the uterus and uterine manipulator.
- **B** For laparoscopic closure, with the Colpo-Pneumo Occluder™ deflated, leave the uterus lodged in the vaginal canal so that it may serve to occlude the vagina. Once the pneumoperitoneum is reestablished, closure may proceed in the usual manner. The KOH Colpotomizer™ System will be removed along with the uterus and uterine manipulator during this process.
- **C** Check carefully to be sure the system is intact and no parts remain in the patient.

13 After surgery, discard the disposable components of the KOH Colpotomizer™ System according to standard hospital practices.

Legal Community Representative—

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Leibnizstraße 32
D-10625, Berlin GERMANY

⚠	See Instructions for Use
②	Single Use Only/Do Not Reuse
LOT	Batch Code/Lot
	Expiration Date (e.g. YYYY-MM)
STERILE EO	Ethylene Oxide Sterilized
LATEX	Latex-Free
Rx Only	**Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician.
REF	Catalog/Reorder Number

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