

Vaginal Reusable Specula

Graves, Pederson, Vu-More™, Vu-Max, Snowman™, ExpandaView™,
Weisman and Auvard

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

Vaginal reusable specula are available from CooperSurgical's line that allow use in almost any situation. There are plastic and stainless steel specula for general office or operating room use, as well as rose-coated LEEP electrosurgical specula. All of the rose-coated LEEP specula are non-conductive and can be sterilized in an autoclave. Many of the styles include either permanent or disposable smoke evacuator tubing.

INDICATIONS FOR USE

Vaginal specula are indicated whenever a visual examination of the vagina or cervix is necessary. The instruments are also necessary for visualization when treating vaginal/cervical lesions.

Some of the indications include (not a complete list):

1. General pelvic exam—visualization of the cervix or vagina, and for obtaining pap smears.
2. Visualization of cervical or vaginal secretions for obtaining cultures or wet smears.
3. Visualization for evaluation of the source of bleeding: vaginal, cervical, or uterine.
4. Evaluation of the vagina and/or cervix in presence of vulvar or perineal viral (Herpes or HPV) lesions.
5. Visualization of cervix and/or vagina as part of evaluation and treatment of CIN; abnormal pap, VAIN, HPV or other cervical lesions.
6. In conjunction with biopsy, LEEP (non-conductive), cryo or cold knife treatment methods.
7. Follow-up evaluation of treatment of cervical or vaginal lesions.
8. Pre-operative evaluation of vaginal and uterine supports relating to descent and prolapse.
9. Post-operative evaluation of vaginal apex after abdominal or vaginal hysterectomy.
10. Post-operative evaluation after vaginal or abdominal pelvic relaxation surgical procedures.

CONTRAINDICATIONS

Please refer to hysteroscope or electrosurgical generator manuals.

R_x Only **CAUTION:** U.S. Federal Law restricts this device to sale by or on the order of a physician.

WARNINGS

- To avoid electric shock to patient and/or user, use only plastic or coated specula instruments during a LEEP (electrosurgical) procedure.
 - The patient should be informed when the speculum is to be introduced and removed. Adjustments may be necessary to provide improved comfort.
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PRECAUTIONS

The size and shape of the speculum is determined by the patient's anatomy and need for surgical procedure. For example, LEEP and laser procedures require special instrumentation and cannot be interchanged. Injury to the patient or examiner can occur if the proper speculum is not used.

The following are some recommendations for the use of the various types of specula:

Stainless steel or reusable plastic

General Exam

Colposcopy

Cervical Polypectomy

Bipolar Cauterization

Endometrial Biopsy

Hysterography

Cryosurgery

Conization

INSTRUCTIONS FOR USE

Sterilize specula before use.

The size and type of speculum is determined by the patients' anatomy and intended use of the instrument. With the patient in the lithotomy position, a warmed speculum is inserted, usually without lubrication, in a horizontal fashion holding the instrument in the dominant hand while the 2nd and 3rd fingers of the non-dominant hand spread the labia minora and slightly depress the posterior forchette. The speculum is gently advanced partially opened until the cervix is clearly visualized. The speculum is then opened more fully and fixed with the blade and handle locks allowing for optimum visualization and patient comfort. The introduction of a speculum cannot be forced and should not be painful. Lubrication may be used if no cytology or colposcopic exam will be done.

After visualization and completion of the examination or vaginal surgical procedure(s), the locks are loosened, the speculum slightly opened further, and then released as the instrument is gently removed.

CLEANING AND STERILIZATION

CARE

Thorough maintenance will ensure proper function of the Euro-Med instruments. It is important to clean and sterilize each instrument immediately after each procedure. Proper maintenance will also extend the life of the instrument.

- Handle each instrument individually. Do not handle in groups or stacks
- Keep track of all components when disassembling. Place in tray or tub corresponding to the specula. Do not interchange components.
- Inspect the instrument for integrity of movable parts (jaws, hinges, etc.), signs of damage (broken or cracked) or missing hardware (screws). Replacement parts should be kept on hand. Damage to movable parts can result in sub-standard performance of the specula.
- Check insulation for cuts, voids, cracks, tears, abrasions, etc. on the instrument to be used with an ESU (electrosurgical unit).

Speculum Disassembly

Remove knurled nut holding the yoke/upper assembly to lower bill. Separate the two. If disposable smoke tubing was used, remove tubing and discard per local hazardous waste procedures.

Cleaning

1. Prepare the neutral pH enzyme cleaning solution (Enzo[®]) at 75% concentration (11.7 mL/L) of that recommended by the cleaning agent manufacturer.
2. Soak the devices in the cleaning solution for 1 minute. Record the time.
3. Clean the devices by washing with a soft bristle brush in the cleaning solution until all soil has been visually removed. Record the total time spent brushing the device.
4. Remove from the cleaning solution and rinse the devices in tap water for 0.5 minute. Record the time.
5. Prepare another batch of the neutral pH enzyme cleaning solution (Enzo[®]) at 75% concentration (11.7 mL/L) of that recommended by the cleaning agent manufacturer.
6. Soak the devices for 1 minute. Record the time.
7. Remove the devices from the cleaning solution and rinse in tap water for 0.5 minute. Record the time.
8. Visually inspect the instruments for visible contamination or debris and then dry with a lint free wipe.

Speculum Reassembly

Reassemble the yoke to the remainder of the speculum assembly using the knurled nut removed earlier.

STERILIZATION

WARNING: Do not sterilize these instruments with Ethylene Oxide (EO), Liquid Chemical (Cold Soak) or Sterrad.

Recommended Steam Autoclave Sterilization Parameters

- The instrument(s) should be thoroughly cleaned of all foreign matter prior to sterilization following the steps above.

STERILIZATION PROCESS	EXPOSURE TEMPERATURE	EXPOSURE TIME	DRY TIME
Gravity Displacement	250° F / 121° C	30 minutes	30 minutes
Pre-vacuum	270° F / 132° C	4 minutes	30 minutes
Pre-vacuum	273° F / 134° C	3 minutes	30 minutes


STORAGE

Thoroughly dried specula should be stored individually in a moisture-free area in a protective tray with partitions. Protect with cloth or gauze if stored in drawers.


EXPLANATION OF SYMBOLS


 Reorder number


 Lot number

 Consult instructions for use

 Caution

 Non-sterile
Sterilize before use

 Do not use if package is damaged

 Manufacturer

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