

Vaginal Reusable Specula

DIRECTIONS FOR USE

REF

Snowman™ L x W

| <i>Stainless</i> | | |
|--------------------|--|----------------|
| 64-107 | Graves Blade | 152 mm x 36 mm |
| 64-117 | Pederson Blade | 152 mm x 25 mm |
| 64-127 | Set: One of each: Graves & Pederson | |
| <i>LEEP Coated</i> | | |
| F107 | Graves Blade | 152 mm x 36 mm |
| F117 | Pederson Blade | 152 mm x 25 mm |
| F127 | Set: One of each: Graves & Pederson | |

Vu-Max™ L x W

| <i>Graves Blade Stainless</i> | | |
|-----------------------------------|--------|----------------|
| 64-218 | Medium | 114 mm x 35 mm |
| 64-219 | Large | 128 mm x 35 mm |
| <i>Graves Blade LEEP Coated</i> | | |
| F218 | Medium | 114 mm x 35 mm |
| F219 | Large | 128 mm x 35 mm |
| <i>Pederson Blade Stainless</i> | | |
| 64-113 | Medium | 114 mm x 22 mm |
| 64-115 | Large | 120 mm x 25 mm |
| <i>Pederson Blade LEEP Coated</i> | | |
| F222 | Medium | 114 mm x 22 mm |
| F224 | Large | 120 mm x 25 mm |

LEEP Coated L x W

| <i>Pederson</i> | | |
|----------------------|--------|----------------|
| F223 | Small | 86 mm x 13 mm |
| F221 | Medium | 114 mm x 22 mm |
| F220 | Large | 120 mm x 25 mm |
| <i>Graves</i> | | |
| F205 | Medium | 108 mm x 34 mm |
| F200 | Large | 127 mm x 36 mm |
| <i>Vu-More™</i> | | |
| F217 | Medium | 117 mm x 33 mm |
| F215 | Large | 127 mm x 33 mm |
| <i>Mini Vu-More™</i> | | |
| F250 | | 89 mm x 30 mm |

REF

Stainless Steel L x W

| <i>Graves</i> | | |
|-----------------|------------|----------------|
| 64-100 | Small | 85 mm x 20 mm |
| 64-102 | Medium | 108 mm x 34 mm |
| 64-104 | Large | 127 mm x 36 mm |
| 64-108 | Open-sided | 110 mm x 36 mm |
| <i>Pederson</i> | | |
| 64-110 | Small | 81 mm x 13 mm |
| 64-112 | Medium | 114 mm x 22 mm |
| 64-114 | Large | 120 mm x 25 mm |
| <i>Collin</i> | | |
| 64-124 | Small | 101 mm x 31 mm |
| 64-126 | Medium | 104 mm x 36 mm |
| 64-128 | Large | 114 mm x 41 mm |
| <i>Auvard</i> | | |
| 64-422 | Wide blade | 59 mm x 43 mm |
| 64-421 | Thin blade | 79 mm x 36 mm |

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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.

CAUTION **Rx ONLY**

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.

ETHYLENE OXIDE

- Specula should be thoroughly cleaned of all foreign matter prior to sterilization, following steps A through C (see page 3-4).
- Follow the manufacturer's instructions for operation and loading of sterilizer and utilize a valid EO cycle.
- Specula 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 \pm 2" Hg |
| Gas Pressure | 6-8 psig (550-660 mg/L) |
| Exposure Time | 4 hours -0/+0.25 hours |
| Post Vacuum | 24" Hg 2X \pm 2" Hg |
| Aeration | 12-0/+1 hours at 120°F |

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.

STERILIZATION

Steam Autoclave Sterilization

- The specula should be thoroughly cleaned of all foreign matter prior to sterilization following A through C (see page 3-4).
- Follow the manufacturer's instructions for operation and loading of steam autoclave.
- There must be direct steam exposure to all surfaces of the specula being sterilized.
- Autoclave temperatures should not exceed 280°F (137°C); pressure should not exceed 32 p.s.i. (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

STERRAD STERILIZATION

The Sterrad Sterilization process has been approved for the LEEP coated and plastic PSU instruments. Please follow the manufacturer's guidelines for the recommended procedure.

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:

- 1 Stainless steel or reusable plastic

General Exam

Colposcopy

Cervical Polypectomy

Bipolar Cauterization

Endometrial Biopsy

Hysterography

Cryosurgery

Conization

- 2 LEEP rose-coated specula must be used during LEEP/LLETZ procedures (monopolar electrosurgical procedures) when the patient must be grounded.

The surfaces and coating of these specula should be checked for smoothness and intactness prior to their use. If any flaws are seen, do not use the instrument. Smoke evacuation tubing should be inserted prior to use in LEEP procedures. These specula can also be used wherever stainless steel specula are indicated.

Note: Coating wear at pivot points is considered normal in everyday use. Care must be taken during the procedure to avoid contact with these areas.

DIRECTION 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.

Refer to Cleaning & Sterilization on pages 3-5.

CARE

Thorough maintenance will ensure proper function of these specula. 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 specula 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 specula 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 LEEP or coated specula to be used with an ESU (electrosurgical unit).

CLEANING

Rinsing and cleaning must take place immediately following the instrument's use for decontamination. Adherent particles may resist cleaning or cause staining. Instruments are to be completely cleaned of all foreign matter with special attention focused on channels and movable parts (e.g. smoke tube) in contact with body tissue and fluid. Thorough cleaning is essential prior to sterilization.

- Follow the instructions under "care" for proper handling of the instruments.
- Wear protective gloves during the cleaning procedure.
- Never use a corrosive cleaning agent (i.e. bleach).
- Fully immerse instruments in cleaning agent.
- Never use a glass sterilizer with LEEP specula.

A 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.

B Cleaning Agents and Equipment

- Cleaning agents and rinses at or near a neutral pH (7.0) are recommended.
- Use warm water and a mild soap.
- Do not use an abrasive cleaning solution.
- A soft bristle brush (toothbrush type) should be used.
- Round bristle brushes should be used to clean inside channels of smoke tube connector.
- An enzymatic cleaner is recommended to remove protein deposits on the specula. Follow the manufacturer's instructions and rinse thoroughly.

Note: Soak and thoroughly rinse the specula in warm tap water to remove cleaning agents. A final rinse in distilled water is recommended.

C Cleaning Method (after each use)

- 1 Rinse and/or pre-soak.
- 2 Manually clean with brushes using a mild soap and warm water.
- 3 Using a round bristle brush, clean inside the tip channel as follows:
A Warm water **B** Cleaning agent **C** Warm water
- 4 Rinse.
- 5 Enzymatic cleaner.
- 6 Rinse.
- 7 Dry with cloth or gauze and compressed air.
- 8 Inspect.
- 9 Prepare for storage and/or sterilization.

Note: Dry instruments completely with compressed air (including inside channels) and/or a dry oven (maximum temperature 280°F).

Special LEEP Specula Cleaning

- 1 LEEP coated specula will be permanently stained by Lugol's unless they are immediately cleaned with StainEnder™ or a similar solution after use.
- 2 Wash the specula immediately after use with hot soapy water. Rinse with hot water. To minimize the potential of contaminating the StainEnder™ solution, disinfectant should be used prior to inserting them into the cleaning solution.
- 3 Completely immerse the specula in undiluted StainEnder™. Allow the instrument to soak until all stains are removed. Lugol's, not immediately removed from the specula, may either require additional soaking time or result in permanent staining. Any permanent Lugol stains will appear as a whitish discoloration after autoclaving.

D Sterilization with an Approved Liquid Chemical Sterilant

Specula must be cleaned thoroughly following steps A,B and C, prior to cold sterilization. Cold soak solutions with 2% glutaraldehyde solution can be used for sterilizing the instruments. Specula are to be **fully** immersed. Follow the manufacturer's instructions for sterilization times. Soak and rinse thoroughly in two separate sterile, deionized water baths. Dry specula.

E Reassembly

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