10. Post-operative evaluation after vaginal or abdominal pelvic relaxation surgical procedures.

The following are some of the recommendations for the use of LLETZ-Coated Vaginal Specula:

- Monopolar electrosurgical procedures (patient must be grounded) E.g., Electro surgery/LLETZ procedures
- General exam
- Colposcopy
- Cervical Polypectomy
- Bipolar Cauterization
- Endometrial biopsy
- Hysterography
- Conization

Contraindications: None.

Warnings:
Before each use carefully examine the coating on the instrument to ensure that there are no visible scratches, chips, voids, etc. Regularly check the instrument under a 10x or greater magnification microscope to ensure there are no microscopic scratches, chips, voids, etc. These could cause the instrument to lose its protective non-conductivity thereby possibly compromising safety.

The patient should be informed when the speculum is to be introduced and removed. Adjustments may be necessary to provide improved comfort.

Under standard use conditions, the LLETZ coating is expected to retain non-conductivity for two years. Gynex recommends that the instrument is either replaced or returned for re-coating after two years.

Precautions:
The size and shape of the speculum is determined by the patient’s anatomy and need for surgical procedure. For example, electrosurgery procedures require the instruments to be non-conductive and cannot be interchanged. This is the reason for the Lavender color to GYNEX LLETZ-Coated instruments. Injury to the patient or examiner can occur if a non-insulated speculum is not used.

Note: Avoid flash autoclaving at 270°. Never use an ultrasonic cleaner for LLETZ-Coated instruments.

The lavender coating on GYNEX instruments should be checked to see that it is smooth and intact prior to instrument use. Smoke evacuation tubing should be inserted prior to use in electrosurgery procedures.

Instructions for Use:

General Operation:
The size and type of speculum is determined by the patient’s anatomy and planned need for the use of the instrument.
- While the patient is in lithotomy position, a warmed speculum, usually with out any lubrication, is gently inserted into the patient.
- In a horizontal fashion, hold the instrument in the dominant hand.
- While the second and third fingers of the non-dominant hand spread the labia minora, 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 hand locks; allowing for optimum visualization and patient comfort. Note: The introduction of a speculum cannot be forced and should not be painful.
- After visualization and completion of the examination or vaginal surgical procedure(s), loosen the locks, slightly open the speculum, and release.
- Then gently remove the instrument. Lubrication may be used if no cytology or colposcopic exam will be done.

Care:
It is important to clean and sterilize each instrument before first use, and after each use. Care should be taken not to scratch or chip the material, as it could compromise the safety of the instrument.

New Instruments:
All GYNEX specula are supplied in a “cleanly” status, and must be cleaned and sterilized prior to each use.

All packaging should be inspected on arrival for evidence of shipping damage. Damaged packaging may indicate the presence of an unsafe product and it should not be used until carefully inspected. Any shipping damaged product should be returned promptly. Product for use in the operating room must be opened, processed, handled, and placed into use following accepted operating room sterile technique.

Cleaning and Sterilization:
Remove all labels and packaging materials before cleaning and sterilization. Wash the GYNEX instrument thoroughly with hot water using a typical hospital grade pH-neutral (7.0) surgical instrument detergent or soap.

CAUTION: Never use the following to clean LLETZ-Coated instruments.
- Enzyme-based cleaners, Ultrasonic cleaners, Bleach, Dishwashing soap (bottled), Powdered or gel dishwashing detergent, or Hand soap.

Cleaning, rinsing, and sterilization must be performed in accordance with usual hospital practice before use.

For removal of tough stains from GYNEX LLETZ-Coated instruments, use Stain-Ex™ SS10. It is a phosphate-free, bio-degradable, specially denatured alcohol solution that removes tough stains from GYNEX LLETZ-Coated instruments. Soaking the instruments in Stain-Ex will remove a variety of stains, including blood and Lugol’s, and Stain-Ex will not harm your instruments.

The recommended process for sterilizing GYNEX LLETZ-Coated Specula is steam autoclave.

- Use only distilled water in the autoclave.
- Ensure that all towels the instruments are laid out on are free of residual soap, and are essentially pH neutral.
- Autoclave instruments constructed of like materials at the same time. E.g., autoclave only GYNEX LLETZ-Coated instruments together.
- The recommended sterilization cycle is saturated steam at 250 for 25–30 minutes. Use of this cycle will produce a Sterility Assurance Level (SAL) of at least 10−6.
- Validation of the recommended sterilization cycle will be achieved via the overkill method, the Kilmer method, or a modified AAMI 5732 method 3, protocol B as selected by the biological testing laboratory.
- Do not allow instruments to touch each other during the autoclaving process, and assure that all instruments are completely dry when removed from the autoclave.

Instructions for Use

LLETZ-Coated Vaginal Specula

Indications for Use:

GYNEX LLETZ-Coated Vaginal Specula are available in a wide variety of sizes and configurations specifically designed for use in many situations. Although LLETZ-Coated Vaginal Specula may be used for any applications where ordinary stainless steel specula are used, they are especially designed for use in electrosurgery procedures.

Vaginal speculums are indicated whenever a visual examination of the vagina and cervix is necessary. The instruments are also necessary for visualization when treating vaginal/cervical lesions. Some of the specific indications include (not a complete list):

1. General pelvic exam—visualization of cervix and 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 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 cervical lesions.
6. In conjunction with biopsy, electrosurgery 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.

To Reorder:
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