STORAGE
Thoroughly dried instrument(s) should be stored individually in a moisture-free area in a protective tray with partitions. Protect with cloth or gauze if stored in drawers.

WARRANTY
CooperSurgical, Inc., warrants that the LEEP coated instruments (the "Product") will be free from defects in materials and workmanship for a period of two (2) years from the original date of purchase. If the Product should become inoperable due to a defect in material or workmanship during this two-year warranty period, CooperSurgical will, at its option, repair or replace the Product. This limited warranty does not include replacement or service to repair damage resulting from improper installation, external electrical fault, accident, disaster, use for a purpose other than that for which originally designed or indicated in this manual, negligence, modification, service or repair by personnel not authorized by CooperSurgical or normal wear and tear, and also does not apply to disposable or single- or limited-use items or components. The sole and exclusive remedy under this limited warranty shall be repair or replacement as provided herein. The foregoing limited warranty states the sole warranty made by CooperSurgical with respect to the Product and all parts thereof, and is in lieu of any other warranty by CooperSurgical with respect to Product. COOPERSURGICAL NEITHER MAKES NOR GRANTS ANY OTHER WARRANTY, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL COOPERSURGICAL BE LIABLE FOR ANY DAMAGES ARISING OUT OF THE LOSS OF USE OF THE PRODUCT, OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER OR NOT COOPERSURGICAL HAS ADVANCE KNOWLEDGE OF THE POSSIBILITY OF SAME. No person, agent, distributor, dealer or company is authorized to change or modify the terms of this limited warranty.

Explanation of Symbols

REF Reorder Number	Do not use if package is damaged
LOT Batch Code	Not made with natural rubber latex
Non-sterile	Manufacturer
Consult instructions for use	R_x Only U.S. Federal law restricts this device to sale by or on the order of a physician

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LEEPCOATED-IFU • Rev. A • 10/19

Made in the USA

Euro-Med® • LEEP Non-Conductive Rose-Coated Instruments

Specula • Retractors • Forceps • Hooks • Tenaculums • Rulers

Instructions for Use — Non-Sterile: sterilize before use

DESCRIPTION
The Euro-Med® LEEP Non-Conductive Rose-Coated Instruments are reusable, manual instruments designed for use in LEEP procedures in a office or operating room setting. The Euro-Med LEEP Instruments are made from coated stainless-steel and can be sterilized in an autoclave. The Euro-Med LEEP Instruments are available in a variety of styles that include Specula, Retractors, Forceps, Hooks, Tenaculums and Rulers. Many of the Specula styles include either permanent or disposable smoke evacuator tubing.

INDICATIONS FOR USE
The Euro-Med LEEP Non-Conductive Rose-Coated Instruments are intended for use during LEEP procedures for the following:

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

Note: The Euro-Med LEEP Non-Conductive Rose-Coated Instruments can also be used in applications where stainless-steel instruments are indicated.

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

CONTRAINDICATIONS
Refer to the LEEP Precision Generator Operating Manual for a list of Contraindications.

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.
- Only use these instruments with CooperSurgical LEEP Electrosurgical units in order to achieve the maximum usage of the device. All CooperSurgical LEEP Electrosurgical units have floating returns and carry the marking: F

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 and instrumentation is not chosen.

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

Stainless steel or reusable plastic

General exam, cervical polypectomy, endometrial biopsy, cryosurgery, colposcopy, bipolar cauterization, hysterography, and conization.

Euro-Med LEEP Non-Conductive Rose-Coated Instruments

LEEP rose-coated instruments must be used during LEEP procedures (monopolar electrosurgical procedures) when the patient must be grounded. The surfaces and coating of these instruments 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 into the specula prior to use in LEEP procedures. These speculums can also be used wherever stainless steel speculums 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.

INSTRUCTIONS FOR USE

Note: Sterilize instruments before use.

Specula

- The size and type of the speculum is determined by the patient's anatomy and the intended use.
- With the patient in the lithotomy position, insert a warmed speculum in a horizontal fashion, holding the speculum in the dominant hand while the 2nd and 3rd fingers of the non-dominant hand spread the labia minora and slightly depress the posterior fourchette. This is typically performed without lubrication.
- Gently advance the partially-opened speculum until the cervix is clearly visualized. Open the speculum more fully and fix it with the blade and handle locks to allow 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), loosen the locks to release the speculum and gently remove it.
- Clean and sterilize the speculum per the cleaning and sterilization instructions below.

CLEANING AND STERILIZATION

CARE

Thorough maintenance will ensure proper function of the Euro-Med LEEP 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).

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.

- Wear protective gloves during the cleaning procedure
- Never use a glass sterilizer with LEEP coated instruments

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 (Enzol®) at 75% concentration (11.7mL/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 (Enzol®) 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°	30 minutes	30 minutes
Pre-vacuum	270° F / 132°	4 minutes	30 minutes
Pre-vacuum	273° F / 134°	3 minutes	30 minutes