



US

INSTRUCTIONS FOR USE

Premier® Coated Instruments



Manufactured by:
Advanced Medical Innovations

Manufactured for:
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Intended Use/Indications For Use:

Coated Graves Specula can be operated whenever a visual examination of the vagina, vaginal walls or cervix is necessary. Procedures include but are not limited to the following:

General Pelvic Exam & Diagnostic Procedures:

- Expands visualization of bleeding.
- Assist during pap smears.
- Increase the visualization of the cervix and vaginal secretions for attaining cultures or wet smears.
- Aids in evaluation of Cervical Intraepithelial Neoplasia (CIN).
- Assists in evaluation of viral lesions.
- Cervical exams of pregnant women.

Surgical Procedures:

- Biopsy
- Cerclage
- Cryosurgery
- Colposcopy
- Loop Electrode Excision Procedure (LEEP)
- Cervical Conization (cone biopsy)
- Laser assisted vaginal procedures

Device Description:

Coated Graves Specula are offered in Stainless Steel (SS), the material is of the highest quality and the coating is composed of a non-conducting high temperature polymer, compatible with all types of sterilization. In addition, LEEP/LLETZ specula is offered with a permanent built in smoke evacuation tube, as well as a tube clip for disposable smoke evacuation tubing.

PRECAUTIONS:

- Electrosurgical and laser procedures demand unique instrumentation. The instruments cannot be interchanged.
- Injury to the patient or examiner can occur if the appropriate speculum is not utilized.
- Patient must be grounded during monopolar electrosurgical procedures.
- The surfaces and coatings of these instruments shall be investigated for smoothness and voids in the coating before use.
- If any defects are discovered, do not use the instrument.
- Smoke evacuation tubing should be inserted before use in electrosurgical procedures.

WARNINGS:

- Prescription device, Rx only.

Contents:

Coated Graves Specula	
9086165	Wide Medium (1 1/4" x 4 1/2" blades)

9086166	Wide Large (1 3/8" x 5" blades) – shown
9086500	Small (3/4" x 3" blades)
9086501	Medium (1 1/4" x 4 1/2" blades)
9086502	Large (1 3/8" x 5" blades)

Lateral Retractor with offset blades

9086186	Lateral Retractor with offset blades
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Materials:**High Quality Stainless Steel**

Non-Conductive Polymer compatible with high temperatures

Directions For Use:

- Avoid the use of lubrication in connection with cytological or colposcopic examination.
- The size and type of speculum required must be determined.
- Insert a warmed speculum with the handle held horizontally in the dominant hand while the second and third fingers of the other hand spread the labia minora and depress slightly the posterior fourchette, keeping the patient in the lithotomy position.
- Open the speculum fractionally and lead it gently until the cervix is visualized.
- Open the speculum completely and fix it into place with the thumbnuts.
- Lateral Retractor: The two lateral blades can be moved into the vertical position and locked into place with the attached stainless steel springs as necessary.

Cleaning:

Rinsing and cleaning needs to happen immediately after use for decontamination. Adherent particles may resist cleaning or cause staining. Instruments must be completely cleaned of all foreign matter with specific care focused on channels and moving parts in contact with body tissue and fluids. Precise cleaning is key prior to sterilization.

1. Cleaning Guidelines:

- Follow the "General maintenance guidelines" for suitable handling of the instruments.
- Completely soak instruments in cleaning agent. Do not soak in Ultrasonic Cleaning Unit.
- Avoid use of eroding cleaning agents (i.e. bleach).
- Never clean electrosurgical and laser coated instruments in a glass bead sterilizer.
- Remove tubing and expel according to hospital protocol if disposable smoking tube is used.
- Use warm water and a mild soap.
- Do not use a harsh cleaning solution.

- Do not soak coated instruments in CIDEX or other caustic cold sterilization solutions.
- Cleaning agents and rinses at or near neutral pH (7.0) are recommended.
- A soft bristle brush (similar to a toothbrush) should be used.
- Round bristle brushes are recommended to clean inside channels of smoke tubes if present.
- Immerse and extensively rinse the instruments in warm tap water to remove cleaning agents.
- An enzymatic cleaner should be used to remove protein deposits on the instruments. Follow enzymatic manufacturer's instructions and rinse thoroughly.
- A final rinse of distilled water is recommended.

2. Cleaning Method:

- Rinse and/or presoak.
- Clean manually using a mild soap and warm water with soft bristle brushes.
- Clean the inside channel of the smoke evacuation tube using a round bristle brush with warm water once again.
- Rinse
- An enzymatic cleaner should be used to remove protein deposits on the instrument. Follow enzymatic manufacturer's instructions.
- Rinse
- Dry with cloth or gauze and compressed air.
- Inspect.
- Prepare for storage and/or sterilization.

Note: Make sure to dry instruments completely with compressed air (including the inside of channels) and/or a dry oven (maximum temperature 280° F (137° C).

Sterilization:

1. Cold Soak Sterilization:

- Sterilization with an approved liquid chemical sterilant:
- Instruments have to be cleaned extensively following the above steps before cold sterilization.
- Cold soak solutions with 2% glutaraldehyde solution may be used for sterilizing the instruments. Instruments are to be fully submerged.
- For sterilization times, follow the manufacturer's instructions. Soak and rinse thoroughly in two separate sterile, de-ionized water baths.
- Dry instruments.

2. Autoclave Sterilization:

- Contact of plastic to bare metal should be avoided.
- Items should be precisely cleaned of all foreign matter before sterilization following the above steps.
- Follow the manufacturer's instructions for operation and

loading of steam autoclave. There must be direct steam exposure to all surfaces of the instruments being sterilized.

- Autoclave temperatures should not exceed 280° F (137° C); pressures should not exceed 32 psi (2.2 atmospheres).
- Instruments should be sterilized in their "OPEN" position.
- Dry instruments.

Gravity Displacement Cycles

Time	20-30 minutes	30 minutes
Temperature	270-275° F (132-135° C)	250° F (121° C)

Pre-Vacuum Cycles

Time	3-4 minutes
Temperature	270-275° F (132-135° C)

3. Ethylene Oxide Sterilization:

- Items shall be completely cleared of all foreign matter prior to sterilization, following the above steps.
- Instruments should be sterilized in THEIR "open" position.
- Follow the manufacturer's instructions for operation and loading of sterilized items.
- Direct exposure to all surfaces of the instruments being sterilized is necessary.
- Dry instruments.

Temperature	125-130° F (51-54° C)
500 RH (pre-humidity)	60 minutes - 0 - 10 minutes
Pre-Vacuum	24"Hg ± 2" Hg
Gas Pressure	6-8 psig (550-660mgL)
Exposure Time	4 hours – 0 - 0.25 hours
Post Vacuum	24" Hg 2x ± 2" Hg
Aeration	12 -0/+ 1 hours at 120° F (48° C)

4. STERRAD** Sterilization:

STERRAD® 100NX SYSTEM has been established by Advanced Sterilization Products™ as the testing model for material functionality, representing all STERRAD® System models. This is based upon the STERRAD® 100 NX Sterilizer having the maximum sterilant and pressure exposure. This can be applied to STERRAD NX 100S, 50 and 200 Systems and will be at least equivalent.

- Follow the manufacturer's instructions for operation and loading of sterilized items.
- Coating is compatible with at least 30 sterilization cycles with the 100NX System being the most challenging

system on material functionality, although 60 cycles is the average compatibility.

- After 30 cycles, surface bubbling may be visible, but this will not impact the functionality of the product.
- If cracking of the coating is observed do not use the instrument.

Reassembly:

Reassemble the yoke to the remainder of the speculum assembly using the thumbnut removed previously.

Storage:



- It is recommended that the coated instruments be stored dry in a moisture free area.
- The instruments should be stored individually in their shipping cartons or in a protective tray with partitions. If stored in drawers, protect with cloth or gauze.

Disposal:

Dispose the device as biohazardous medical waste in accordance to facility or institutional guidelines/procedures.

For Further Information:

To obtain IFU, visit premiermedicalco.com or call Premier at 610-239-6000.

Symbols	Symbol Meaning
	Manufacturer
	Caution: See instructions for use
Rx ONLY	"CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician