





## INSTRUCTIONS FOR USE


 In this document, indicates conditions or practices that could lead to illness, injury, or death ("WARNING").

 In this document, indicates conditions or practices may result in minor or moderate injury to the user or patient or damage to the equipment or other property ("CAUTION").

 Consult Instructions for Use.


 Federal law restricts this device to sale by or on the order of a medical professional.

 Do not use if packaging is damaged.


 Not made with natural rubber latex.

 Fragile

 Store at room temperature.

 Store out of direct sunlight.

 Product Identifier

 Lot Identifier

 Date of Manufacture

## DESCRIPTION

The Nella NuSpec is a reusable polymer speculum with integrated sidewall retractors.

## INTENDED USE

The Nella NuSpec is intended to dilate the vagina and expose the interior of the vagina and exterior of the cervix during gynecologic examinations and procedures.

## WARNINGS AND PRECAUTIONS

**WARNING:** Speculum not provided sterile. Clean and sterilize before first use.

**WARNING:** Clean and sterilize speculum after each use.

**WARNING:** Inspect speculum prior to every use. Do not use if damaged.

**CAUTION:** No modification of this equipment is allowed.

**CAUTION:** NuSpec not tested with laser or electrosurgical equipment.

## DIRECTIONS FOR USE

- NuSpec can be used with or without water-based lubricant.
  - Warming NuSpec prior to use is not necessary.
  - Clean and sterilize the NuSpec as soon as possible after each use.
  - Always inspect NuSpec for integrity of movable parts (bills, hinges, locking mechanism, etc.) and check surfaces for smoothness and intactness prior to use.
  - Do not use if any flaws or signs of damage are found. Damage to movable parts can result in sub-standard performance of the NuSpec.
- Start with toggle in unlocked position and insert into vaginal canal (A).
  - Once inserted, open by depressing thumb tab (B).
  - When opened sufficiently, push down bottom of toggle to lock bills in position (C).
  - If necessary, increase open angle by further pushing down thumb tab (D).
  - To unlock, apply pressure to top of toggle while simultaneously squeezing down thumb tab (E).

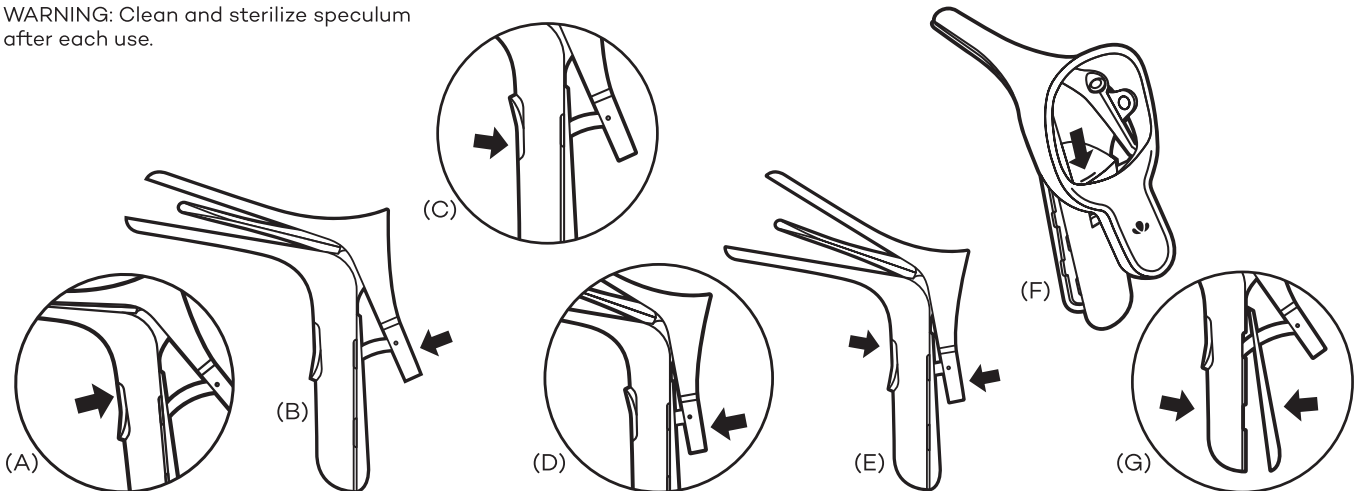
## MANUAL CLEANING GUIDELINES

- Rinsing and cleaning for decontamination must take place as soon as possible following the instrument's use.
- Wear protective gloves during the cleaning procedure.
- Use proper cleaning agents and equipment:
  - Never use an abrasive or corrosive cleaning agent (i.e. bleach).

- Cleaning agents and rinses at or near a neutral pH (7.0) are recommended.
- Use warm water and a mild soap.
- An enzymatic cleaner is recommended to remove protein deposits on the speculum. (Follow the cleaner manufacturer's instructions for recommended concentration and use.)

## MANUAL CLEANING METHOD (AFTER EACH USE)

- Push down on top of back cover to pop it open (F). Perform all cleaning with cover open.
- Rinse or pre-soak all surfaces to remove visible debris.
- Manually clean with a soft-bristle brush using a mild soap and warm water.
- Rinse with warm water.
- Fully immerse device in cleaning solution.
- While submerged in cleaning solution, manually clean device with a soft-bristle brush, paying specific attention to the areas in contact with body tissue and fluid (bills) and smaller spaces, including around hinges and joints and inside the handle. Actuate all moving parts to ensure all surfaces have contact with cleaning solution.
- Rinse under warm water, making sure to actuate moving parts to remove any residual cleaning solution (it is recommended to perform final rinse in distilled water before sterilization).
- Dry with lint-free cloth/gauze, compressed air, or a dry oven (maximum temperature 280°F).
- Inspect.
- Prepare for storage and/or sterilization (keep back cover open for sterilization).
- Once device is ready to use, snap back handle cover into place (G).



## INSTRUCTIONS FOR USE

### STERILIZATION GUIDELINES

- Device must be thoroughly cleaned of all foreign matter prior to sterilization as instructed.
- Follow the sterilization equipment manufacturer's instructions for operation and loading of any sterilization equipment and only utilize valid cycles.
- Allow direct exposure to all surfaces of the instruments being sterilized.
- Device bills and handle should be in the "open" position.

### RECOMMENDED ETHYLENE OXIDE STERILIZATION PARAMETERS

| 100% ETO STERILIZATION CYCLE: |              |
|-------------------------------|--------------|
| Concentration                 | 735mg/L      |
| Temperature:                  | 131°F (55°C) |
| Exposure time:                | 60 minutes   |
| Relative Humidity:            | 50-70%       |

### RECOMMENDED AUTOCLAVE STEAM STERILIZATION PARAMETERS

- Allow instruments to cool down from autoclave to room temperature.

| PRE-VACUUM CYCLE      |               |
|-----------------------|---------------|
| Exposure temperature: | 270°F (132°C) |
| Exposure time:        | 4 minutes     |
| Vacuum Pulses:        | 4             |

| GRAVITY DISPLACEMENT CYCLES |               |
|-----------------------------|---------------|
| Exposure temperature:       | 270°F (132°C) |
| Exposure time:              | 15 minutes    |

### STERRAD STERILIZATION

The STERRAD® 100NX® Standard Sterilization cycle has been validated for sterilizing the NuSpec. Please follow the Sterrad manufacturer's guidelines for the recommended procedure.

### WARRANTY

Please visit [ceekwomenshealth.com/warranty](http://ceekwomenshealth.com/warranty) for warranty information. Ceek Women's Health should be notified immediately of any defective units.

### MANUFACTURER

Ceek Women's Health  
 1455 NW Irving Street, Suite 200  
 Portland, OR 97209  
[ceekwomenshealth.com](http://ceekwomenshealth.com)  
 1-855-559-CEEK

Made in the USA

patents: [ceekwomenshealth.com/patents](http://ceekwomenshealth.com/patents)  
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