HAYDEN MEDICAL **Instructions for Use (IFU) Reusable Cohen Cannula**

Reprocessing instructions were developed in accordance with ISO 17664. Cleaning and disinfection processes are compatible with ISO 15883. Steam sterilization parameters are provided in accordance with ISO 17665. Healthcare facilities are responsible for validating their reprocessing equipment and procedures in accordance with applicable standards.

**1. Device Description**

The Cohen Cannula is a reusable surgical instrument designed for uterine manipulation and the instillation of contrast media during gynecological procedures.

**2. Intended Use**

The device is intended to fixate and manipulate the uterus and to facilitate the introduction of fluids for diagnostic or operative procedures.

**3. Contraindications**

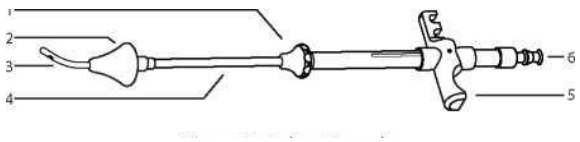
This instrument is not intended for use on the central nervous or circulatory systems.

**4. Warnings and Precautions**

- Device is supplied non-sterile and must be cleaned and sterilized prior to use.
- Use only by qualified healthcare professionals.
- Do not use damaged or defective instruments.
- If used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD), the device must be disposed of and not reprocessed.
- Inspect all components prior to each use.
- Use only compatible accessories.

**5. Device Components**

Refer to Figure 1 for component identification.
1. Knurled nut
2. Adapter
3. Adapter tube with perforation
4. Inner sheath
5. Handle
6. Luer lock (LL) connection




Note: If the set is ordered, two adapters are supplied. The adapters are two different sizes.

**6. Assembly Instructions**

- Fit spring to inner sheath.

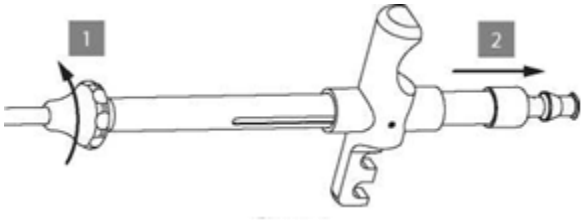
- Fit outer sheath and secure using the knurled nut.


19425 Soledad Canyon Rd Suite 411, Santa Clarita, CA 91351
661-296-7200 info@haydenmedical.com www.haydenmedical.com

**7. Disassembly Instructions**

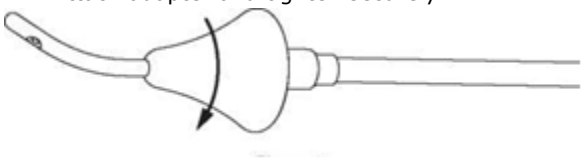
- Turn adapter slightly and remove.

- Unscrew knurled nut and remove outer shaft with spring.

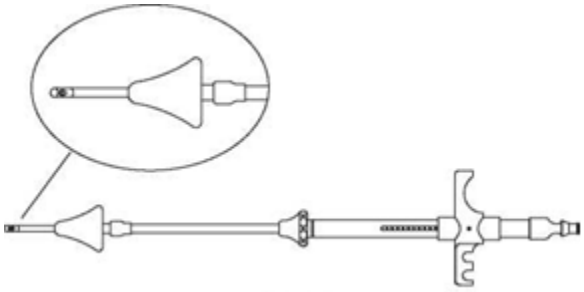



**8. Instructions for Use**

- Select appropriate adapter size.
- Attach adapter and tighten securely.



- Align inner sheath with adapter tip.



- Connect syringe with contrast media.
- Insert instrument into cervical os.
- Position uterus as required.
- Perform procedure and remove instrument.

**9. Cleaning and Disinfection**

All devices must be cleaned in a fully disassembled configuration.
All lumens, cavities, ports, and internal channels must remain open and accessible during cleaning.

Automated cleaning processes must be compatible with washer-disinfectors validated in accordance with ISO 15883.

**9.1 General Instructions**

- Disassembly must not require tools (e.g., screwdriver, pliers)
- All ports must remain in the fully open position
- Devices may be cleaned manually or automatically
- All surfaces, including internal cavities and lumens, must come into contact with cleaning solutions

**Water Quality Definitions (AAMI TIR34):**

- *Drinking Water*: Utility water
- *Treated Water*: Critical water (e.g., deionized, distilled, or reverse osmosis)

---

**9.2 Warnings and Precautions**

⚠ **Risk of infection due to insufficient reprocessing**

- Special procedures must be followed for suspected prion contamination (CJD)

⚠ **Risk of contamination from improper cleaning**

- Do not use fixing agents
- Do not rinse with hot water during initial cleaning

⚠ **Risk of product damage**

- Do not use abrasive brushes or scouring agents
- Use only approved cleaning agents
- Avoid hydrogen peroxide ($H_2O_2$) exposure for plastic components
- Use disinfectants with corrosion protection

---

**9.3 Transportation**

Transport the device safely to the reprocessing area in a manner that prevents:

- contamination of the environment
- mechanical damage

---

**9.4 Pre-Processing (Immediately After Use)**

- Begin cleaning immediately after use to prevent drying of residues
- Rinse under cold water to remove gross contamination
- Flush all cavities and internal channels

**If immediate cleaning is not possible:**

- Wrap the device in a moist cloth

Additional steps:

- Immerse in cold water with 0.8% cleaning solution for ≥5 minutes
- Brush under cold water until visibly clean
- Disassemble instrument
- Brush internal and external surfaces under water
- Flush cavities using cleaning gun:
  - ≥10 seconds at 3–5 bar
- Rinse thoroughly with cold water

**Note:** Perform rinsing below water level to prevent aerosol contamination

---

**9.5 Manual Cleaning (Enzymatic / Neutral pH Detergent)**

1. Ensure pre-processing and disassembly are complete
2. Soak in cold potable water for ≥10 minutes
3. Brush all surfaces under water until visibly clean
4. Flush cavities, drill holes, and threads:
   - ≥20 seconds at 3–5 bar
5. Ultrasonic cleaning:
   - Detergent: 0.8% enzymatic / neutral pH
   - Temperature: 40–45°C (104–113°F)
   - Frequency: ~35 kHz
   - Time: 10–15 minutes
6. Reposition components during ultrasonic cleaning
7. Rinse thoroughly using cold potable water
8. Rinse with treated (DI) water, flushing all internal channels

**Note:** Clean internal chambers below water surface using a brush

9. Dry:
   - 10 minutes at 50–100°C (122–212°F)
   - and/or sterile compressed air
10. Disinfect:

- Use disinfectant (e.g., pH ~10.5)
- Minimum 10 minutes

---

**9.6 Automated Cleaning (Enzymatic / Neutral pH Detergent)**

1. Ensure pre-processing and disassembly are complete
2. Ultrasonic pre-clean:
   - 40–45°C (104–113°F)
   - 35–45 kHz
   - 10–15 minutes
   - Reposition components during cleaning
3. Process using washer-disinfector (validated cycle)
4. Use enzymatic or neutral pH detergent per manufacturer instructions

After processing:

- Dry with lint-free cloth if needed
- Visually inspect for cleanliness
- Repeat cleaning if soil remains

**9.7 Automated Cleaning (Alkaline Detergent)**

1. Ensure pre-processing and disassembly are complete
2. Perform ultrasonic pre-clean under same conditions as above
3. Process using washer-disinfector with alkaline detergent in accordance with manufacturer recommendations

**9.8 Drying**

**Automated Drying:**

- Washer-disinfector cycle:
  - 15–25 minutes at 90–110°C (194–230°F)
- Remove immediately after cycle completion

**If required:**

- Use sterile compressed air for internal channels
- Perform additional manual drying using lint-free cloth

The cleaning procedures described are based on recognized reprocessing practices and are intended to support effective cleaning when performed using appropriately validated equipment and processes.

**10. Inspection and Maintenance**

- Inspect for damage, wear, or corrosion.
- Verify proper function of moving components.
- Do not use damaged instruments.

**11. Packaging**

Package in accordance with ISO 11607 using validated sterile barrier systems.

**12. Steam Sterilization Parameters**

Sterilization must be performed using validated steam sterilization cycles in accordance with ISO 17665 and applicable national standards.

| Method | Temperature | Exposure Time | Dry Time |
|---|---|---|---|
| Pre-vacuum | 132°C (270°F) | 4 minutes | 30 minutes |
| Gravity | 132°C (270°F) | 15 minutes | 30 minutes |

The above parameters are based on recognized steam sterilization practices in accordance with ISO 17665.

**13. Storage**

- Store in a clean, dry, and controlled environment.
- Protect from contamination and damage.

**14. Limitations on Reprocessing**

Repeated reprocessing has minimal effect on the device when performed in accordance with these instructions.
The service life of the device is dependent on use, care, and handling. End of life is typically determined by wear, damage, or loss of function.
Devices must be inspected prior to each use and removed from service if any defects are identified.

**15. Disposal**

Dispose of the device in accordance with local regulations and hospital policies.

**16. Warranty**

This product is covered by a limited warranty against manufacturing defects.


19425 Soledad Canyon Rd Suite 411, Santa Clarita, CA 91351
661-296-7200 info@haydenmedical.com www.haydenmedical.com