Reprocessing instructions were developed in accordance with ISO 17664. Cleaning and sterilization processes are compatible with ISO 15883 and ISO 17665.

1. Device Description

Reusable surgical instrument intended to manipulate and position the uterus during gynecological procedures.

2. Intended Use

The device is intended for use by qualified healthcare professionals to position and stabilize the uterus during surgical procedures.

3. Contraindications

Not intended for use on the central nervous or circulatory systems.

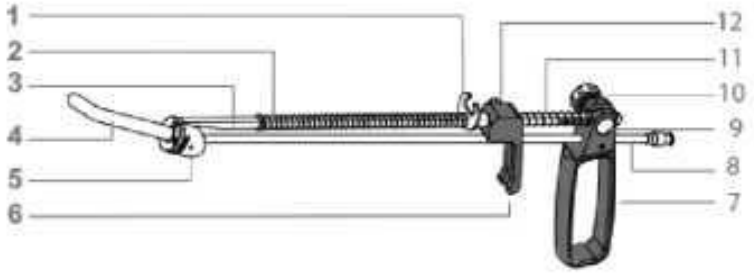
4. Warnings

- Do not use if damaged.
- Device is supplied non-sterile and must be cleaned and sterilized before use.
- Use only by qualified healthcare professionals.
- If used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD), the device must be disposed of and not reprocessed.

5. Assembly

Components

1. Slider
2. Long spring
3. Rod
4. Adapter
5. Adapter mount
6. Handle
7. Handle piece
8. Rinsing tube with Luer lock connection
9. Locking screw
10. Tensioning screw
11. Short spring
12. Fixing screw



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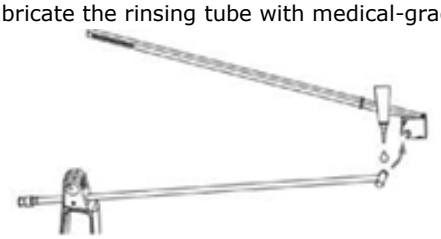
Prerequisite: Ensure O-ring is installed on the rinsing tube.

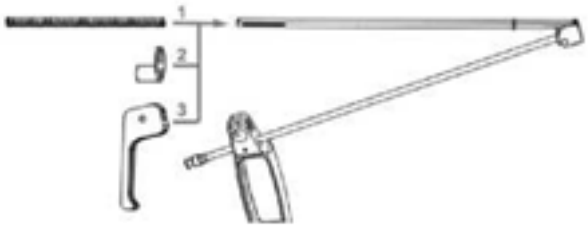
Assembly:

- Lubricate the rinsing tube with medical-grade lubricant and insert into adapter mount.



- Insert bolt into handle.

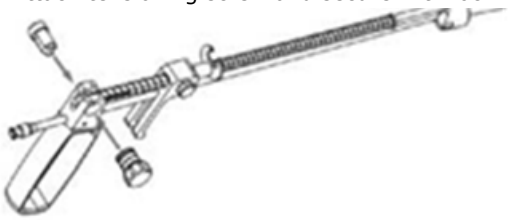
- Install long spring, slider, and handle onto rod.



- Align handle and rod holes and secure with fixing screw.

- Push the short spring over the rod and push against the handle until the rod fits into the guide on the handle piece. Insert the rod into the handle piece.

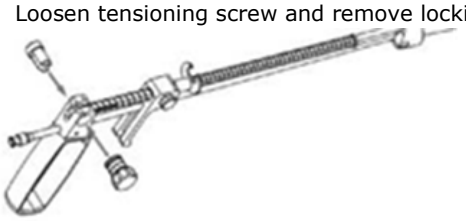
- Attach tensioning screw and secure with locking screw.



6. Disassembly

- Open adapter locking mechanism and remove adapter.

- Loosen tensioning screw and remove locking screw.



- Loosen the fixing screw on the handle.

- Push short spring and release the rod.

- Remove springs, handle, and slider.

- Pull the rinsing tube out of the adapter mount.

- Remove the bolt from the handle.

7. Functional Check

Perform a functional check after assembly to ensure proper operation.

Prerequisite: The tensioning screw on the handle piece is loosened.

Procedure:

- Move handle toward handle piece.
- Verify adapter moves upward.
- Release handle slowly.
- Verify adapter returns to neutral position.

8. 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.

8.1 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)

8.2 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

8.3 Transportation

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

- contamination of the environment
- mechanical damage

8.4 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

8.5 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

8.6 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

8.7 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

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8.8 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.

9. Packaging

Package in accordance with ISO 11607 using an appropriate sterile barrier system.

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10. Steam Sterilization Parameters

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

Healthcare facilities are responsible for validating their sterilization equipment and procedures in accordance with applicable 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.

Sterilization parameters may vary based on load configuration and equipment performance.

11. Storage

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

12. Limitations on Reprocessing

Repeated reprocessing has minimal effect on surgical instruments. End of life is determined by wear, damage, or loss of function.

13. Disposal

Dispose in accordance with local regulations.