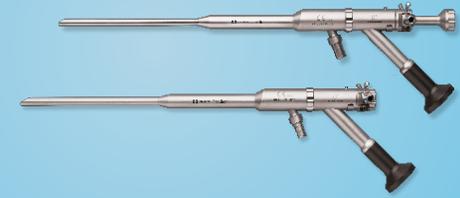


# CLEANING AND STERILIZATION GUIDE

## TruClear™ System Elite Hysteroscopes



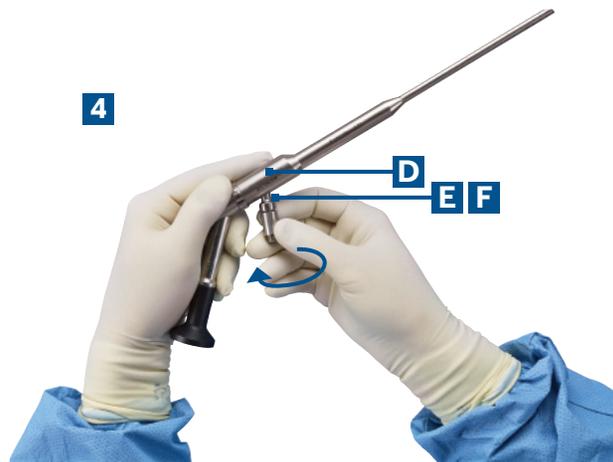
This guide is in reference to the following products only: Elite Hysteroscope Mini, product code 72204878, Elite Hysteroscope Plus, product code 72204879  
Smith & Nephew/Wolf™\* light adaptor, product code 4347, Storz™\* light adaptor, product code 7207900

### PREPARATION BEFORE CLEANING

1. The working channel insert (B) must be disconnected and removed from the hysteroscope (A).
2. Disconnect by pressing the release button (C).



3. Slowly withdraw the working channel insert.
4. Adapters, Smith & Nephew/Wolf™\* (E) and Storz™\* (F) must be removed from light post (D).

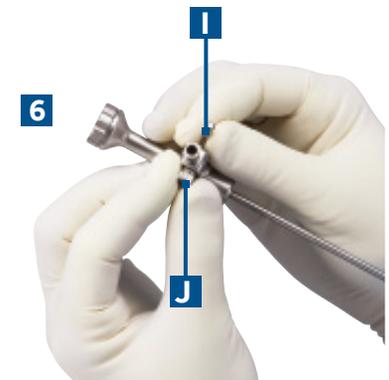
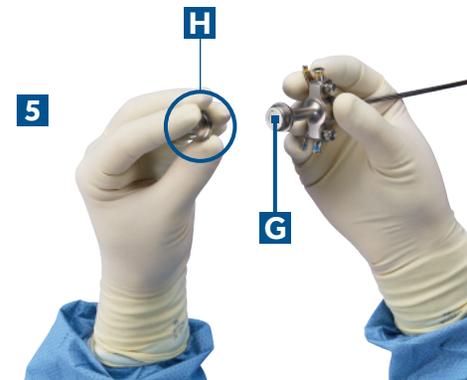


5. The retaining cap (H) must be removed. Remove excess soil on the operative hysteroscope, seal cap, sheath, and obturator with disposable wipes.

**NOTE: The hysteroscope seal (G) is single-use and must be disposed of as biohazard waste following use. Do not attempt to reprocess or reuse the hysteroscope seal.**

**NOTE: The blue hysteroscope seal should remain in the working channel of the scope at all times.**

6. Stopcocks must be disassembled. Disassemble by loosening thumb nuts (J) and removing stopcock plugs (I).



## PREPARATION BEFORE CLEANING

**NOTE: Perform the following manual or automatic cleaning instructions.**

### Manual Cleaning

Manually clean the hysteroscope and disassembled components (working channel insert, retaining cap, and stopcocks) using the following procedure:

1. Under 32-40°C (90-104°F) running tap water, rinse the hysteroscope and disassembled components to remove all blood and surgical debris.
2. Using a water pistol, flush the lumen of the hysteroscope and the lumen of the working channel insert for 30 seconds each.
  - If a water pistol is not available, using a manual syringe flush the lumen of the hysteroscope and the lumen of the working channel insert with 30ml of 32-40°C (90-104°F) tap water four times each.
3. Immerse the hysteroscope and disassembled components in a 32-40°C (90-104°F) pH neutral enzymatic bath diluted per the label instructions and soak for a minimum of five minutes and up to ten minutes.
  - Steris Prolystica™ 2x Concentrate Enzymatic or an equivalent detergent may be used in accordance with its label instructions.
4. While the hysteroscope is immersed, prime the hysteroscope lumen with 30ml of detergent solution. While the working channel insert is immersed, prime the working channel insert lumen with 30ml of detergent solution.
5. While the hysteroscope and disassembled components are immersed, scrub the device and disassembled components for 1-2 minutes.
  - Use a small soft nylon bristle general instrument brush for the exterior.
  - Use a 5 mm soft nylon bristle brush for the interior.
  - Use a gauze pad soaked with detergent solution to wipe the optical surfaces (K, L, M). Do not scratch any of the optical surfaces.
6. Using a water pistol, flush the lumen of the hysteroscope and the lumen of the working channel insert for 30 seconds each.
  - If a water pistol is not available, using a manual syringe flush the lumen of the hysteroscope and the lumen of the working channel insert with 30ml of 32-40°C (90-104°F) tap water four times each.
7. Under 32-40°C (90-104°F) running tap water, scrub the device and disassembled components for 30-60 seconds:
  - Use a small soft nylon bristle general instrument brush for the exterior.
  - Use a 5 mm soft nylon bristle brush for the interior.
  - Use a gauze pad soaked with tap water to wipe the optical lens. Do not scratch any of the optical surfaces.

8. Under 32-40°C (90-104°F) running tap water, rinse the device and disassembled components for 60-90 seconds.
9. Rinse the hysteroscope and disassembled components under purified water for 60-90 seconds.
10. Dry the hysteroscope and disassembled components with medical grade compressed air (20-30 psi).
11. Inspect the hysteroscope and disassembled components. If not visually clean, repeat the cleaning process from Step 2.

### Automatic Cleaning

Automatically clean the hysteroscope and disassembled components (working channel insert, retaining cap, and stopcocks) using the following procedure:

1. Under 32-40°C (90-104°F) running tap water, rinse the hysteroscope and disassembled components to remove all blood and surgical debris.
2. Using a water pistol, flush the lumen of the hysteroscope and the lumen of the working channel inset for 30 seconds each.
  - If a water pistol is not available, using a manual syringe flush the lumen of the hysteroscope and the lumen of the working channel insert with 30ml of 32-40°C (90-104°F) tap water four times each.
3. Under 32-40°C (90-104°F) running tap water, scrub the device and disassembled components for 1-2 minutes.
  - Use a small soft nylon bristle general instrument brush for the exterior
  - Use a 5 mm soft nylon bristle brush for the interior.
  - Use a gauze pad soaked with tap water to wipe the optical surfaces (K, L, M). Do not scratch any of the optical surfaces.
4. Perform the automatic cleaning cycle, following the recommendations in the table (below):

**NOTE: Place hysteroscope and disassembled components into the washer-disinfector in a manner that will protect them from unwanted motion or potential mechanical damage during the automated wash cycle.**

5. Dry the hysteroscope and disassembled components with medical grade compressed air (20-30 psi).
6. Inspect the hysteroscope and disassembled components. If not visually clean, repeat the cleaning process from step 2.

### Pre-sterilization disinfection

(optional)

1. In facilities that require disinfection before sterilization, the thermal rinse cycle during the automatic cleaning process should be programmed for 1 minute at 91°C (196°F).

## To remove deposits from autoclavable scope optical surfaces

(K, L, M)

1. Aluminum oxide powder is provided as an accessory to the TruClear™ Elite hysteroscopes and is intended to be used, when required, to remove deposits on optical surfaces, thus maintaining optical integrity.

**NOTE: Cleaning with aluminum oxide powder should only be performed when the image viewed through the hysteroscope is cloudy and not as part of routine cleaning procedures.**

2. To remove deposits, moisten a cotton-tipped swab with water. Dip the moistened swab into the aluminum oxide powder. Position the swab tip against the optical surface of the operative hysteroscope to be cleaned. While applying gentle pressure to the swab, scrub the window to remove any deposits. For smaller windows, rotate the swab instead of scrubbing. Rinse the optical surface thoroughly with warm tap water and brush with a soft bristled brush while under running water to remove the aluminum oxide powder.

**NOTE: Do not use ultrasonic cleaning methods. The energy transmitted through fluid cavitation damages seals and optical surfaces and voids the warranty.**

**NOTE: Foreign matter remaining on the fiber surface of the light post after cleaning may tend to burn and discolor the surface when exposed to a high intensity light source.**

## Sterilization parameters

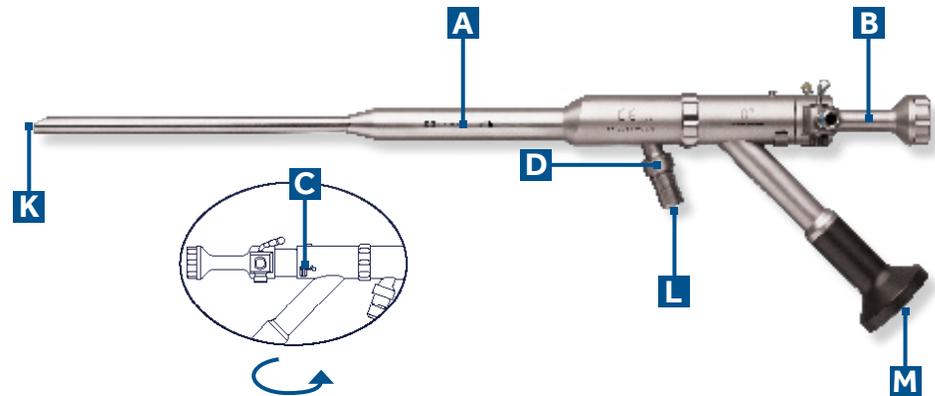
TruClear™ Elite hysteroscopes must be sterilized by high temperature prevacuum steam.

Wrap		
Two single-ply layers of central supply wrap or one layer of double-ply central supply wrap (Kimberly Clark™, catalog #K300 or equivalent) prior to sterilization.		
Sterilization Method		
Steam, prevacuum		
Temperature	Sterilization Time	Drying Time
270°F (132°C)	4 minutes	30 minutes
270°F (132°C)	3 minutes	30 minutes

Outside USA (OUS)		
Wrap		
Two single-ply layers of central supply wrap or one layer of double-ply central supply wrap (Kimberly Clark™, catalog #K300 or equivalent) prior to sterilization.		
Sterilization Method		
Steam, prevacuum		
Temperature	Sterilization Time	Drying Time
132°C (270°F)	4 minutes	30 minutes
134°C-137°C (273°F-279°F)	3 minutes	30 minutes
134°C (273°F)	18 minutes	30 minutes
135°C (275°F)	3 minutes	30 minutes

## FOR FURTHER INFORMATION

For further information refer to the product Instructions For Use provided with the product, or contact your Medtronic representative.



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Manufactured by: Covidien LLC, 15 Hampshire Street, Mansfield, MA, 02048 USA.

CA-SI-0318-E Rev.2 05/2020 (US200319)

16720 Trans-Canada, Suite 200  
Kirkland, QC, H9H 4M7

877.664.8926 [t]  
800.567.1939 [f]