

CLEANING

PREPARATION for DECONTAMINATION

- Blade assembly should be properly disposed of in appropriate container.
 - Decontamination of reusable components should occur immediately after completion of the surgical procedure.
 - Disassemble endoscope from handpiece and disassemble light-post adapters from endoscope.
- DO NOT** re-sterilize blade assembly – it is designed for single use only.

Instrument Cleaning - Manual

- At point of use – remove gross soil from the handpiece, dilator, elevator and dilators using a low-linting cloth saturated with sterile water.
- Cover the reusable instruments in a clean cloth saturated with sterile water for transportation to the decontamination area. Clean the handpiece and instruments within 30 minutes of end of use.
- Prepare a neutral enzymatic detergent (such as Steris Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner) using warm tap water (30 – 40°C) according to the manufacturer's instructions.
- Immerse all reusable instruments in the prepared detergent solution and soak for 3 – 5 minutes until visibly clean.
- While immersed in the detergent scrub the handpiece's internal shuttle and scope port, locking screw, trigger surface, and trigger through-hole using a brush (such as the Sklar® 10-1650 and 10-1398) and warm tap water (30 – 40°C) for 1 – 2 minutes to agitate any soil. Depress and release the locking screw and trigger multiple times to clean the crevices around the moving parts.
- While immersed in the detergent scrub all external surfaces using a brush (i.e. Sklar 10-1650) for 1 - 2 minutes until visibly clean, paying close attention to crevices, openings and joints.
- Immerse the handpiece and instruments in a warm critical water (30 – 40°C) bath for 2 – 5 minutes. Use a wetted low-linting wipe (i.e. Spec-Wipe® 5 wiper) to wipe the handpiece and instruments for 1 – 2 minutes. Use a syringe to flush the shuttle, scope port, locking screw and trigger with a minimum of 30 ml of water in each location.
- Scrub the endoscope and adapters with a soft brush in a solution of mild soap and water. Rinse the endoscope thoroughly under running water (< 50°C /122°F) for a minimum of 2 minutes. If possible, use distilled water for the final rinse. Dry thoroughly.

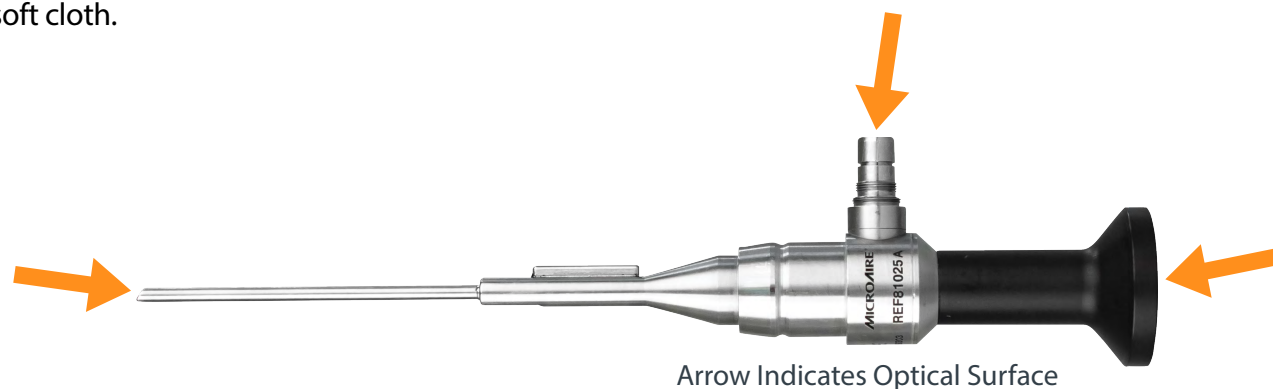
NOTE: Use a cotton swab moistened in isopropyl alcohol to clean the lenses of the endoscope at the tip, camera-mount and fiber-optic light ends to ensure a clear endoscopic view.

NOTE: Do not use hard brushes, abrasives or strong chemical solutions to clean the instruments.

- Using the unaided eye from approximately 12 inches and in a well-lit area, visually inspect each instrument for remaining soil. If soil is observed, repeat the manual pre-cleaning steps.
- Dry all reusable instruments with a clean, lint-free dry cloth. Use compressed air to dry the gaps and blind holes around the locking screw, trigger, shuttle port, scope port and trigger through-hole on the handpiece.

Endoscope Cleaning - Manual

- Remove the light post adapters.
- Remove coarse contamination from the endoscope. Clean the endoscope with a soft brush under cold tap water until all visible contaminants have been removed.
- Disinfect the endoscope observing the disinfectant solution manufacturer specifications for temperature, concentration and application time.
- Rinse the endoscope with running water.
- Dry the endoscope with a soft cloth.



CAUTION: Do not use fixating cleaning agents or hot water (>40° C, 104° F) as it can cause fixation of the contaminants and jeopardize successful cleaning.

CAUTION: Do not use hard objects to scratch off contaminants as this can result in damage to the optical end surfaces.

CAUTION: Non-compliance with the disinfection solution manufacturer's specifications can result in damage to the endoscope.

STERILIZATION

PREPARATION for DECONTAMINATION

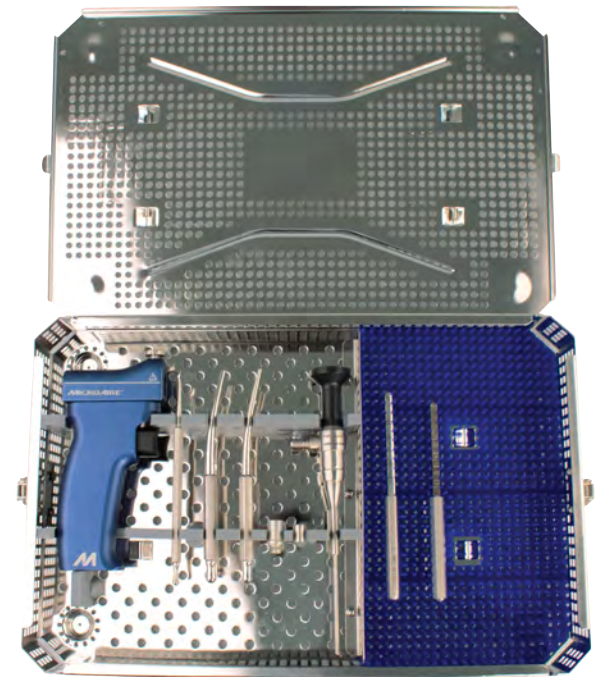
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Steam Sterilization

- INSTRUMENTS (REF IFU IM-EPFR-EGR): REF 85014, REF 81025, REF 81025A, REF 81151, REF 81152, REF 84061, REF 85061, REF 85026, REF 85027, REF 85029, REF 85040
- Steam sterilize using one of the following cycles for a sterilization assurance of at least 10⁻⁶.

GRAVITY-DISPLACEMENT STEAM		Instruments alone or in a sterilization case
Exposure Time		15-minute full cycle
Exposure Temperature		270-275°F (132-135°C)
Minimum Dry Time		20 minutes
Materials	Double wrapped in a standard medical grade steam sterilization wrap	

DYNAMIC AIR REMOVAL (PRE-VAC)		Instruments alone or in a sterilization case
Exposure Time		4-minute Full Cycle
Exposure Temperature		270-275°F (132-135°C)
Minimum Dry Time		20 minutes
Materials	Double wrapped in a standard medical grade steam sterilization wrap	



Endoscope Only

Hydrogen Peroxide Sterilization (Sterrad[®] Method)

1. REF 81025 & REF 81025A endoscope has been validated for sterilization in the following STERRAD[®] systems: STERRAD 100S, STERRAD NX, STERRAD 100NX.
2. Observe manufacturer (Ethicon) specifications for the corresponding method.

Ethylene Oxide Sterilization

1. REF 81025 & REF 81025A endoscope is compatible with ethylene oxide sterilization.

NOTE: The endoscope may be sterilized together with the handpiece and accessories as a system in the SmartRelease[®] Sterilization Tray REF 83040.

“Flash” Sterilization

Surgical centers that wish to steam-sterilize patient care items for immediate use shall at a minimum follow the requirements of ANSI/AAMI ST79:2010. The reduction of bioburden and removal of gross soil is an essential step in preparing an item for sterilization by any method. Prior to any sterilization process including “Flash” sterilization, follow the steps for decontamination of the instrument. Processed items must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use. There is NO storage or shelf life of flash-sterilized items because of the probability of contamination after the sterilizer door is opened and the items are removed. When performed correctly, flash sterilization is safe and effective for sterilization of medical devices (AAMI ST79:2010). Reusable surgical instruments with moving parts require a dry cycle to keep the product functioning appropriately. “Flash” Gravity-Steam sterilization with NO dry time is NOT recommended as a normal process of sterilization. After steam sterilization, cool down to room temperature without additional cooling. Sudden changes in temperature may damage the endoscope.

CAUTION: DO not exceed a temperature of 280° F (138° C).

CAUTION: Do not ultrasonically clean the endoscope or use solvents other than isopropyl alcohol.

CAUTION: Other sterilization systems have not been tested and are not recommended.

NOTE: REF 81025 & REF 81025A Endoscope Sterilization:

1. Packaged yellow eye piece cap, yellow tip cap, light post cap - Remove, NON-AUTOCLAVABLE
2. Blue protective sleeve – Keep, AUTOCLAVABLE
3. Polishing paste – Keep, see instructions for removing deposits on optical surfaces.