



Scope Brushes (Reusable)

INTENDED USE:

Key Surgical® Scope Brushes (BR-3300, BR-3305, BR-3307, BR-3701, BR-3702, and BR-3703) are reusable and intended to be used as an aid in cleaning and disinfecting flexible endoscopes. The brushes are used to clean the inside of the endoscope channel and loosen soil present.

CONTRAINDICATIONS:

Do not use these brushes for any purpose other than their intended use. Do not use reusable cleaning brushes for cytological tissue sampling or any other diagnostic or therapeutic purposes. Patient injury, cross-contamination and equipment damage may occur.

PREPARATION:

Brushes are reusable and must be cleaned and high-level disinfected prior to reuse.

CLEANING & DISINFECTION:

Clean and high-level disinfect brushes after every use on every endoscope. Brushes can be cleaned manually or using an automatic washer/disinfector prior to high-level disinfection.

MANUAL CLEANING:

1. Pre-rinse soiled brushes under cold tap water for one (1) minute to remove gross debris.
2. Prepare an enzymatic cleaning solution with suitable enzymes for cleaning the types of soil the brush may have come in contact with during use- follow the cleaning solution manufacturer’s written IFU for minimum effective concentration.
3. Soak brushes in prepared enzymatic solution for two (2) minutes (*Agitating bristles during this step may improve results).
4. Rinse brushes under cold tap water for one (1) minute.
5. Visually inspect brushes to ensure complete removal of soil from surfaces. No visible soil should be observed.
6. If soil is still visible, repeat above steps until brush is free from visible soil.
7. Protein assay tests may be used to ensure complete removal of protein residual.

MECHANICAL/AUTOMATED CLEANING:

1. Pre-rinse soiled brushes under cold tap water for one (1) minute to remove gross debris.
2. Prepare an enzymatic cleaning solution with suitable enzymes for cleaning the types of soil the brush may have come in contact with during use in an ultrasonic bath and sonicate brushes for five (5) minutes- follow the cleaning solution manufacturer’s written IFU for minimum effective concentration.
3. Rinse brushes under cold tap water for one (1) minute.
4. Load brushes into wire mesh tray with lid and place in mechanical washer (*Brushes can be cleaned with the facility’s approved cleaning solution used in a FDA cleared washer/disinfector).
5. Wash cycle with detergent at temperature recommended by the detergent manufacturer for a minimum of 5 minutes.
6. Rinse cycle for a minimum of 1 minute.
7. Dry cycle at temperature 194 degrees F for minimum of seven (7) minutes.
8. Visually inspect brushes to ensure complete removal of soil from surfaces. No visible soil should be observed.
9. If soil is still visible, repeat above steps until brush is free from visible soil.
10. Protein assay tests may be used to ensure complete removal of protein residual.

DISINFECTION:

1. Brushes may be disinfected with liquid chemical disinfectants in accordance with the disinfectant manufacturer’s written IFU. Confirm material compatibility (nylon and stainless steel) information with the disinfectant manufacturer.

INSPECTION:

Brushes should be inspected between uses and replaced when worn, frayed, bent or otherwise damaged. Worn or damaged bristles and handles are ineffective in cleaning, and may damage the scope.

USE:

1. Ensure brush is the proper diameter and length for the channel it is being used to clean.
2. Advance the brush in short strokes to avoid kinking of the handle.
3. Brushes should not be coiled in loops smaller than 10” (25cm).
4. To remove gross soil from the scope after brushing, flush the scope with water until the soil is removed.

5. For specific scope cleaning instructions, refer to the scope manufacturer’s IFU.

STERILIZATION:

Brushes are provided non-sterile. They have been validated according to applicable international process standards and guidance for one-time steam sterilization at the following cycle parameters:

Cycle Type	Temperature	Minimum Time – Full Cycle
Gravity	121° C (250° F)	30 minutes
Pre-Vacuum	132° C (270° F)	4 minutes
Pre-Vacuum	134° C (273° F)	3 minutes


It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

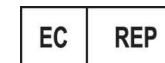
STORAGE:

Store brushes in a manner that will reduce cross-contamination.

DISPOSAL:

There are no special disposal instructions.

 MANUFACTURER: KEY SURGICAL LLC
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