



Channel Cleaning
(including Fan Tip & Lumen Guard Brushes)

INTENDED USE:

Key Surgical® Channel Cleaning, Lumen Guard Brushes, and Fan Tip Brushes are intended to clean the channels or lumens of dirty instruments during the cleaning and decontamination processes. They can also be used as a cleaning verification tool.

CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

PREPARATION:

Brushes must be cleaned and disinfected prior to reuse.

CLEANING & DISINFECTION:

Clean brushes after each use and disinfect between cases or daily, at a minimum. Brushes can be cleaned manually or using an automatic washer/disinfectant.

NOTE: If used as a cleaning verification tool, must be treated as single-use to eliminate cross contamination.

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/disinfectant).
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. The thermal disinfection stage of an automated washer is sufficient for disinfection of the cleaning brushes.
2. 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. Damaged brushes cannot be cleaned effectively. Worn or damaged bristles and handles are ineffective in cleaning, and may damage the device.

STERILIZATION:

This sterilization is intended for one time use of brushes in a sterile setting and is not for brushes that have already been used.

New, unused brushes are provided non-sterile and have been validated for sterilization efficacy using gravity and pre-vacuum

steam sterilization methods according to applicable international process standards and guidance at the following 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)	18 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.

Due to the steam sterilization process, there may be a slight discoloration of the nylon brush bristles; however this does not impair the fit, form, or function of the brush.

STORAGE:

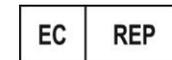
Store brushes in a manner that will reduce cross-contamination.

DISPOSAL:

There are no special disposal instructions.

 MANUFACTURER: KEY SURGICAL LLC
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 REF CATALOG NUMBER

 LOT NUMBER

 CONSULT INSTRUCTIONS FOR USE