



Toothbrush-Style Cleaning Brushes

INTENDED USE:

Key Surgical® Toothbrush-Style Cleaning Brushes are intended to clean dirty instruments during the cleaning and decontamination processes. The cleaning brushes containing brass and stainless steel bristles are intended to effectively remove debris and bioburden that cannot be removed by using a nylon brush.

PRECAUTION:

Stainless steel and brass bristles are not intended for use on insulated, plated, or coated instruments. For cleaning these, nylon bristles are recommended. Consult device manufacturer IFU for specific bristle recommendations.

CONTRAINDICATIONS:

There are no known contraindications and/or adverse effects.

PREPARATION:

Brushes must be cleaned and disinfected prior to reuse.

CLEANING & DISINFECTION:

Clean and disinfect brushes daily, at a minimum, prior to reuse. Brushes can be cleaned manually or using an automatic washer/disinfector.

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. 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. 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.

This validation is for stainless steel bristle brushes ONLY.

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 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)	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.

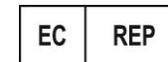
STORAGE:

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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BROC-3115 Rev G, 05/2019