



<http://www.bkendo.com>

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Disposable Soft Channel Cleaning Brush Kit IFU

Intended Purpose:

The BKS1005 Disposable Soft Channel Cleaning Brush Kit contains BKPB-Y101016 Disposable soft channel cleaning brush (double ended) and BKCS-B5 Double head water channel brush.

The BKS1005 Disposable combination brush kit is attached to a flexible plastic sheath designed to safely and effectively remove biomaterial from flexible endoscopes.

Clinical Benefit:

Proper manual cleaning of endoscopes is essential in removing bioburden and preparing the endoscope for high-level disinfection, ultimately helping to reduce the risk of infections.

The Cleaning Brushes help remove bioburden and debris from endoscope channels during the manual cleaning process in the endoscope decontamination area.

Warnings and Precautions:

Guidelines for Preventing Cross Contamination:

- NEVER use Endoscope Cleaning Brushes as a cytology brush.
- ALWAYS wear gloves and other protective equipment while cleaning endoscopes as dictated by your organization's policies and procedures.
- DISCARD brush if sharp bends in the plastic sheath are observed during insertion of the brush to avoid the risk of damaging the endoscopes access channels.
- NEVER transfer a used cleaning brush from one endoscope to another endoscope, since cross-contamination could occur and result in patient complications. Disposable cleaning brushes are designed to remove biomaterial, some of which can be retained in the bristles.
- DISPOSE of the cleaning brush after each use. The mechanical attachment of the brush(es) to the plastic sheath can not be guaranteed to be reliable or secure following initial use.
- These products are intended for SINGLE USE ONLY. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, and /or reuses these disposable devices must bear full responsibility for their safety and effectiveness.
- NEVER insert the valve brush into the biopsy channel. Damage to the endoscope may occur as a result.

Adverse Event Reporting:

User facilities shall report adverse events to Boke Endo Medical.

Instructions for Use (by product number):

BKCS-B5

Double head water channel brush:

Nylon Flat brush: Ø5*20 mm
Ø11*30 mm

BKPB-Y101016

Disposable soft channel cleaning brush (double ended)

Nylon brush: Ø6*30–Ø6*30 mm

Long velvet brush: Ø5*125 mm

Catheter: Ø1.7*2300 mm

1. Remove BKS1005 Disposable combination brush kit from package.
2. Advance the channel brush through the valve stem openings using the cleaning media of choice.
3. Dispose of brush after use.
4. If the Channel(s) are known to be occluded or resistance is met while attempting to pass the brush through the endoscope, DO NOT FORCE the cleaning brush through the endoscope as this may result in damage to the channel.
5. After use, these products may be potential biohazards. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.