Diversatek Healthcare CleanFreak® Endoscope Cleaning Brushes

Instructions for use and cleaning.
Read carefully prior to use.

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.



Corporate Headquarters

102 E. Keefe Ave. Milwaukee, WI 53212 USA P 800.558.6408 | 414.265.7620

sales@diversatekhc.com

DiversatekHealthcare.com



Diversatek Healthcare, Inc. 102 E. Keefe Ave. Milwaukee, WI 53212 USA 800.558.6408 | 414.265.7620 sales@diversatekhc.com www.diversatekhealthcare.com

DIVERSATEK HEALTHCARE CLEANFREAK® ENDOSCOPE CLEANING BRUSHES

Directions for Use and Cleaning.
Read carefully prior to use.

INTENDED USE

The Endoscope Cleaning Brush(es) are used to safely remove debris from the channels, valves, and dials of flexible endoscopes.

The channel cleaning brush has a brush attached to a flexible plastic sheath that is designed to safely remove debris from the endoscope accessory/suction channel, the auxiliary water channel, and/or the balloon inflation channel (EUS endoscope) of flexible endoscopes. The control head cleaning brush is used to safely remove debris from the valve openings and dials of the control head of flexible endoscopes.

Part #1200-03, #1200-04, Part #1200-07, #1200-08

Use only in channels 2.0mm and larger

Part #1200-05, #1200-09

Use only in channels 2.0mm and larger and in control head valve openings Part #1200-06

Use only in control head valve openings

WARNINGS AND PRECAUTIONS

- 1. The cleaning brush must never be used as a cytology brush.
- Original Equipment Endoscope Manufacturer's guidelines for the care and cleaning of the individual endoscope channels, valves, and dials must be reviewed prior to the use of any cleaning brush.
- 3. The Cleaning Brushes are single use only and must be disposed of after use. This device was <u>not</u> designed to be reused or reprocessed. The mechanical attachments of the brushes to the plastic sheath and/or plastic handles are not designed to be secure for more than a one (1) use. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, resterilizes, and/or reuses this disposable device must bear full responsibility for its safety and effectiveness. The materials used in the manufacture of this device will not withstand repeated reprocessing. This device may

not perform as intended by the manufacturer if it is reused. This may lead to failure of the device to perform as intended and/or material degradation.

- 4. Never transfer a used cleaning brush from one endoscope to another endoscope. Debris can be retained in the bristles of the cleaning brushes and cause cross-contamination. Cross-contamination could occur if a cleaning brush is transferred from one endoscope to another, which could result in patient complications. The cleaning brushes are single use only.
- Avoid sharp bends of the plastic sheath and/or twisted wire of the brushes during
 insertion. If sharp bends are noticed during insertion, the brush should be removed
 immediately and disposed of to avoid causing damage to the endoscope's operating
 channels.
- Inspect the cleaning brush for breakage, damage, or missing brush head after use. If a brush head has broken and cannot be located, it is recommended that the endoscope be sent to repair for evaluation.

CONTRAINDICATIONS

- If resistance is met in 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.
 Do not use the cleaning brushes if the channel(s) are known to be occluded as this may
 result in damage to the channel.
- Follow all cleaning instructions of the endoscope's Original Equipment Manufacturer.
 Do not use a specific cleaning brush in a specific cleaning channel if use is not recommended by the endoscope's manufacturer.

DIRECTIONS FOR USE

- The cleaning brushes are provided single use only, non-sterile. Endoscope Cleaning Brushes <u>cannot</u> be reused nor reprocessed.
- 2. Channel Cleaning Brush:
 - a. Using the cleaning media of choice, advance the cleaning brush through the entire length of the endoscope before reversing direction. Reversing direction inside the endoscope could cause the brush to expand, which could potentially damage the endoscope channel.



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 Using the cleaning media of choice, pass the channel cleaning brush through the valve stem openings.

3. Control Head Cleaning Brush:

- a. Remove the valve(s) from the control head of the endoscope. Use the brush and the cleaning media of choice to gently cleanse the valve openings. Avoid twisting or torquing the brush handle. The brush handle will prevent the brush from being pushed too deeply into the valve openings.
- Use the brush and the cleaning media of choice to clean the control head and the control head dials.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of the product in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

DESCRIPTION OF SYMBOLS USED ON LABELS



Non-Sterile Device



Caution, Consult Accompanying Documents



Do Not Re-Use



Do Not Use if Package is Damaged



Not Made with Natural Rubber Latex



Use By Date (YYYY-MM-DD)

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