

Diversatek Healthcare CareGuard® Bite Blocks

*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.



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**DIVERSATEK HEALTHCARE
CAREGUARD® BITE BLOCKS**
*Instructions for Use and Cleaning.
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INTENDED USE

The bite block is used to protect the endoscope insertion tube and esophageal dilators from being bitten by the patient. Bite blocks are available with and without straps.

WARNINGS AND PRECAUTIONS

1. Avoid placing fingers between the bite block and the patient's teeth when placing the bite block in the patient's mouth.
2. Flexible endoscopy procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, complications and hazards prior to the performance of an endoscopic procedure.
3. This device was not designed to be reprocessed nor reused. Diversatek Healthcare cannot guarantee that reprocessing will clean or sterilize the bite block. Diversatek Healthcare cannot guarantee the bite block will maintain structural integrity to ensure patient and/or user safety after cleaning and/or sterilizing.
4. The bite block is intended for single patient use only. 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 may 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.
5. Remove the strap from the patient before removing the bite block from the patient's mouth.

DIRECTIONS FOR USE

1. The bite block is provided non-sterile. If an end user wishes to sterilize the device, ethylene oxide (EO) gas is compatible with the bite block materials. Some cold soak

disinfectant solutions may also be compatible with the bite block materials. However, all disinfection solutions and sterilization methods must be validated by the end user for safety and effectiveness. Bite blocks cannot be flash or steam autoclaved.

2. Place the bite block in the patient's mouth. If the strap is used, secure the strap on the bite block (see note 3).
3. To secure and remove strap (if applicable): Insert the strap through posterior aspect of side port and thread over cleat. Reverse these directions to remove the strap at the end of the procedure. The strap must be removed from the patient's mouth before the bite block is removed.

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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