






Breathe EZ Disposable Bite Block
Instructions for Use

-  Consult Instructions for Use
-  Do Not Reuse
-  Do Not Use if Package is Damaged
-  Non-Sterile
-  Rx only

IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech USA.

INTENDED USE

To aid in the passage of and to protect an endoscope as it passes through a patient's mouth during an upper endoscopic procedure.

CONTRAINDICATIONS

- There are no known contraindications.

WARNINGS AND PRECAUTIONS

- The product is intended for single use only! DO NOT re-use, and/or reprocess. Re-use, or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Re-use, or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, or reprocessed.
- Do not use this instrument for any purpose other than its intended use.
- The product is intended for adult populations only.
- Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
- The instrument is intended for use under the direct supervision of a suitably trained physician only. A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

• Do not use this product for any purpose other than the stated intended use. The product is supplied clean and ready for immediate use.

• Do not use the product if the package is broken.

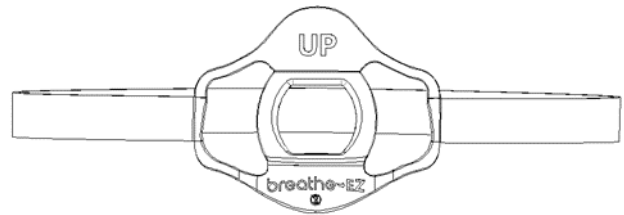
【 Product Name 】 Breathe EZ Disposable Bite Block

【 Production Date 】 See packaging

【 Shelf Life 】 3 years

Contents supplied non-sterile.

This device is not made with natural rubber latex.



PREPARATION

1. Inspect the package before use for any damage. Do not use if package is damaged. Open the package carefully after verifying the shelf life.
2. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.

INSTRUCTIONS FOR USE

1. Remove any dental prosthesis from the mouth of the patient.
2. Place the bite block in the mouth of the patient with the UP designation in the upper position; instruct patient to carefully bite down on it. The patient's teeth and jaw have to be in front of the bite block's rear edge to keep it in position during the examination.
3. Place the strap around the patient's head and affix snugly.
4. Insert the endoscope in the opening through the bite plate of the bite block.
5. The side port/lateral openings in the face plate allow access to the patient's oral cavity while the endoscope is in place.
6. The bite block should only be removed from the patient's mouth after the endoscope is completely withdrawn from the bite block.
Note: Detach the strap from the patient before removing the bite block from the patient's mouth.
7. Upon completion of the procedure, handle and dispose of in accordance with hospital, local and administrative laws and regulations.

STORAGE

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment. Do not expose the package to organic solvent, ionizing radiation, or ultraviolet radiation.

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

Limited Warranty and Disclaimers

1. Limited Warranty to Buyer. Micro-Tech USA warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer. The products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech USA and in accordance with applicable regulatory requirements.

Descriptions or specifications appearing in Micro-Tech USA's literature are meant to generally describe the products and do not constitute any express warranties.

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