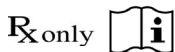


Disposable Bite Block

Instructions for Use



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.

INTENDED USE

Disposable bite blocks are used for endoscopic procedures in the upper intestinal tract. They keep the patient mouth open guaranteeing the respiration of the patient during the examination. Additionally, they prevent damages on the scope caused by patient bites. Disposable bite blocks should only be used by or under the supervision of medical practitioners with thorough training and experience in endoscopic procedures of the upper intestinal tract. Disposable bite blocks are for single-use only. Do not re-sterilize them.

WARNINGS

1. **The product is intended for single use only! DO NOT re-use, re-sterilize, and/or reprocess.** Re-use, re-sterilization 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, re-sterilization 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, re-sterilized or reprocessed.
2. Do not use this instrument for any purpose other than its intended use.
3. The product is only intended for adult populations and children.
4. This device is not made with natural rubber latex.
5. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.
6. **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.

7. If the product fails during use, replace the new one.
8. Do not use this product for any purpose other than the stated intended use. The product is supplied clean and ready for immediate use.
9. Do not use the product if the package is broken.

【 Product Name 】 Disposable Bite Block
【 Packaging 】 Packed in Pouch
【 Production Date 】 See packaging
【 Shelf Life 】 5 years

PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied NON-STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged. Open the package carefully after verifying the shelf life.
4. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
5. 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. Visually inspect the bite blocks with particular attention to sharp edges, burrs or breaks. If it appears damaged, do not use the device and contact Micro-Tech.
2. Remove dental prosthesis from the mouth of the patient.
3. Put the bite block in the mouth of the patient and let him carefully bite on it. The patient teeth / jaw have to be in front of the bite block's rear edge to keep it in position during the examination.
4. Place the strap around the patient's head and use the holes in the strap to fix it tightly at the lateral hooks.

5. Insert the endoscope through the centre front opening of the bite block.
6. The lateral front openings allow to grasp into the patient's mouth while the endoscope is in place.
7. Only remove the bite block out of the patient's mouth if the endoscope is completely withdrawn through the bite block's front opening.
8. Upon completion of the procedure, dispose of the disposable bite block according to the guidelines for

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.

The product shelf life is 5 years.

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. In the event that Micro-tech USA gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-tech USA's part. Any

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**Manufacture****Micro-Tech (Nanjing) Co., Ltd.**

No.10 Gaoke Third Road, Nanjing National Hi-Tech Industrial
Development Zone, Nanjing 210032 ,Jiangsu Province, PRC

TEL:+ 86 25 58609879, 58646393

FAX:+ 86 25 58744269

Email: info@micro-tech.com.cn

www.micro-tech.com.cn;

Distributed By**Micro-Tech USA Inc.**

2855 Boardwalk Drive, Ann Arbor, MI 48104 USA

Tel: 734-259-3768

Toll free: 877-552-4027

info@micro-tech-usa.com



Shanghai International Holding Corp. GmbH(Europe)

Eiffestrasse 80, 20537 Hamburg Germany

MTN-KD-SM-USA-01 REV:2
2018.02.24