



MEDORAH® BITE BLOCK

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

MEDORAH® Bite Block

Intended Use/Indications for Use

Intended use- MEDORAH® Bite block is intended to keep the mouth open comfortably during the endoscopic procedure. This bite block ensures that the patients will not bite down on the endoscope or their tongue during the diagnostic or interventional procedures.

MEDORAH® Bite Block is supplied non-sterile and is intended for single use only.

Device Description

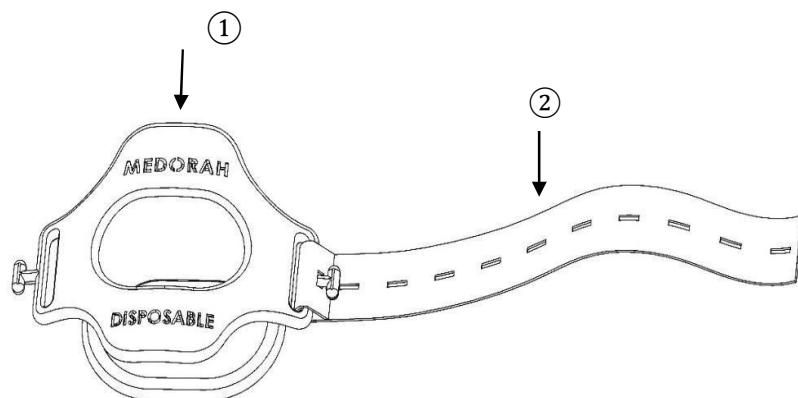
MEDORAH® Bite Block consists of a bite block with attached strap which helps in securing the head of the patient in the endoscopic procedure. Bite block comes in two variants. One for adult population and another for pediatric population.

Specifications:

Cavity Size- 12mm and 18mm

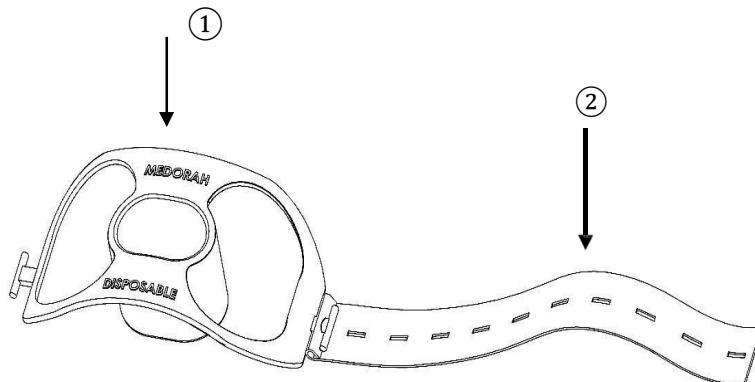
Variants:

Adult Bite block



①	Bite Block
②	Adjustable strap

Pediatric Bite Block



(1)	Bite Block
(2)	Adjustable strap

Contraindications

Not Known

Warnings

- DO NOT use if pouch is opened or damaged.
- Do not use the instrument for any purpose other than its intended use
- The product is designed for adult population and children exclusively.
- For single use only. Do not reuse or reprocess
- Reuse and reprocessing may compromise the structural integrity of the device
- Reuse and reprocessing may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- Patients should be informed of the potential risks or complications, which may lead to injury, illness or death of the patient.
- The instrument should be used solely under the direct supervision of a suitably trained physician.
- In case of product failure during use, replace it with a new one

Precautions

- Before using, ensure that the device is in good condition. Do not utilize anything that is damaged or broken.
- Exercise caution when inserting the bite block into the patient's mouth to prevent accidental finger placement between the block and the patient's teeth.

Procedure

- Carefully examine the bite blocks for any signs of damage, paying close attention to sharp edges, cracks, or breaks. If any damage is detected, refrain from using the device.
- Take out the dental prosthesis (if any) from the patient's mouth.
- Place the bite block gently in the patient's mouth and position the bite block between the upper and lower jaw of the patient. Make sure that teeth and tongue are not damaged.
- Secure the strap around the patient's head, utilizing the strap's holes to firmly fasten it at the lateral hooks.
- Insert the endoscope through the central front opening of the bite block.
- The side front openings enable access to the patient's mouth while the endoscope remains in position.
- Only remove the bite block from the patient's mouth once the endoscope has been fully withdrawn through the front opening of the bite block.
- After the procedure, discard the disposable bite block according to the hospital, local and country regulations.

Change of performance

If the device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

Disposal of a used device

After use, this product may be a potential biohazard. It must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

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.

Explanation of Symbols

	Date of Manufacture		Caution
	Catalogue Number		Batch Code
	Manufacturer		Do not use if package is damaged
	Non-Sterile		

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.



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