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2018-10
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Blox™

WITH DENTAL RETENTION RIM

WITHOUT DENTAL RETENTION RIM

Endoscopic Bite Block with Elastic Cloth Strap

Rx ONLY

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

WARNING

Contents supplied NON-STERILE. Do not use if damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization 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. Reuse or 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.

DEVICE DESCRIPTION

The Blox Endoscopic Bite Block with Elastic Cloth Strap consists of a pliable polymer block and an elastic cloth strap. The bite block is positioned in the mouth to protect the patient's teeth and gums, as well as the endoscope equipment, from any damage. When present, the dental retention rim helps keep the device in place. The large upper flange helps prevent the bite block from resting against the patient's gums. Large lateral openings allow the user to position and guide the scope.

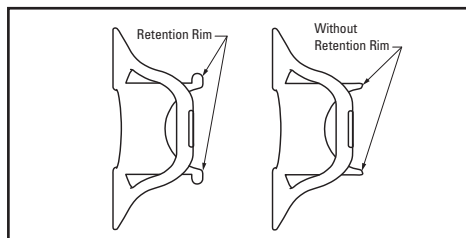
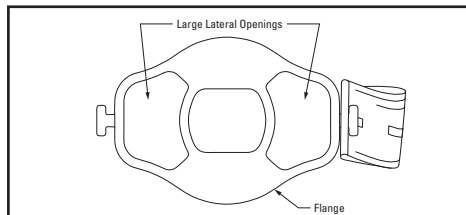


Figure 1. Blox Endoscopic Bite Block with Elastic Cloth Strap

User Information

This device must only be used by persons having adequate training and familiarity with endoscopic techniques.

Contents

(1) Blox Endoscopic Bite Block with Elastic Cloth Strap

INTENDED USE/INDICATIONS FOR USE

The Blox Endoscopic Bite Block with Elastic Cloth Strap is intended to provide safe passage through the patient's mouth during upper endoscopic procedures thus protecting the patient's teeth and gums as well as protecting endoscopic equipment.

CONTRAINDICATIONS

There are no known contraindications.

WARNING

- Do not use if there is any apparent shipping or handling damage.

PRECAUTION

- Care should be exercised to avoid placing fingers between the bite block and the patient's teeth.

ADVERSE EVENTS

None known.

HOW SUPPLIED

The device is supplied non-sterile and intended for single use only. The packaging and device should be inspected prior to use.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

- Remove the bite block from the package and inspect for any damage or irregularities. Do not use if damage or irregularities are present.
- Remove the elastic strap from the center hole of the bite block.
- Advance the bite block into the patient's mouth.
- Ensure that the slit on one end of the elastic strap is secured over the cleat on the side of the bite block. Secure the bite block into the patient's mouth by advancing the other end of the elastic strap around the back of the head and threading the appropriate slit in the elastic strap over the cleat located on the other side of the bite block.
- To make an adjustment to the position of the bite block, access the bite block through its lateral openings taking care to avoid placing fingers between the patient's teeth and the bite block.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express 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 instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or sterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

REF Catalog Number


 Consult instructions for use.

 Contents

EC REP EU Authorized Representative

 Legal Manufacturer


LOT Lot


 Recyclable Package

 Date of Manufacture

AUS Australian Sponsor Address

ARG Argentina Local Contact

 For single use only. Do not reuse.

 Do not use if package is damaged.

 Non-Sterile

EC REP **EU Authorized Representative**

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ARG **Argentina Local Contact**

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USA Customer Service 888-272-1001

 **Do not use if package is damaged.**

 **Recyclable Package**

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