INTENDED USE/INDICATIONS FOR USE

(1) Blox Endoscopic Bite Block with Elastic Cloth Strap

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 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.

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 located on the other 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.

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.

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 the use of 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.