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Disposable Bite Block IFU

This product is not made with natural rubber latex.

Intended Use:

The bite block is used to protect the endoscope insertion tube from being bitten by the patient. Bite blocks are available with and without retaining straps.

Warnings and Precautions:

When placing the bite block in thepatient's mouth, care should be exercised to avoid placing fingers between the bite block and thepatient's teeth.

Flexible endoscopy procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, complications and hazards prior to the performance of an endoscopic procedure.

Do not attempt to reuse, reprocess, refurbish, remanufacture, or resterilize this device. Boke Endo Medical did not design this device nor is it intended to be reused, reprocessed, refurbished, remanufactured, or resterilized. Performing such activities on this disposable medical device presents a safety risk to patients (i.e. compromised device integrity, cross-contamination, infection).

Directions for use:

Place the bite block in thepatient's mouth. If the retaining strap is used, secure the strap on the bite block.

To secure retaining strap (if applicable): Insert the retaining strap through posterior aspect of side port and thread over cleat. If strap is Velcro, press strips together to fasten and pull apart to unfasten.

Product Disposal:

After use, this product may be a potential biohazard which may present a risk of cross-contamination. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Warning:

An issued or revision date for these instructions is included for the user's information. In the event two years has elapsed between this date and product use, the user should contact Boke Endo Medical to determine if additional information is available.

Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.