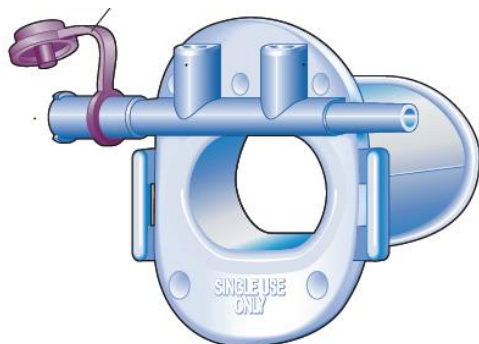


Capno Guard bite block – Non Sterile

GMDN #: 42424



Medical device class; 2A

Intended use

- Device ensures that the mouth of the patient remains open during endoscopic procedures. They are designed to provide protection for the patient's teeth as well as the endoscopic equipment that is inserted into the mouth.
- The Capno Guard bite block also allows simultaneous connection to oxygen tubing for the administration of medical oxygen to the patient and connection to CO2 monitoring if required during procedures.

Material

TPE Cap on Luer,
ABS main body

Instructions for use

- 1) If the strap is to be used, attach one side of the strap to the bite block-thread the cleat through the hole in the strap before placing the bite block into the patient's mouth
- 2) Place the bite block into the patient's mouth taking care to avoid placing fingers between the bite block and the patient's teeth.
- 3) Pass the strap around the patient's neck and attach it again to the other side of the block.
- 4) Connect the oxygen supply and CO2 monitoring line to the 7mm male connections on the bite block ensuring that the connections are secure.
- 5) Connect the oxygen tubing to an oxygen supply and set the required flow rate.
- 6) Connect the CO2 monitoring line to the CO2 monitoring equipment ensuring the connections are secure
- 7) Note; Strap must be removed before the bite block is removed

Warnings & Precautions

1. Endoscopy procedures should only be performed by persons having adequate training and familiarity with the endoscopic techniques.
2. Capno Guard bite block is supplied non-sterile and is for single patient use only, not suitable for reprocessing or reuse.
3. Be sure all connections are secure.
4. Cleaning or reprocessing for reuse will raise the risk of cross contamination.
5. Meditech Systems Ltd will not take responsibility for use outside of the intended use or by other than the intended users.
6. FIRE RISK IF OXYGEN IS USED IN THE PRESENCE OF NAKED FLAME OR HEAT SOURCE LIKELY TO CAUSE IGNITION.

WARNING – FIRE RISK IF OXYGEN IS USED IN THE PRESENCE OF NAKED FLAME OR HEAT SOURCE LIKELY TO CAUSE IGNITION.

Disposal

The devices may be disposed of using local procedures for contaminated medical waste.

The materials are capable of being recycled if a safe process for recycling medical waste is available.

Storage

- ⇒ Do not store at extreme temperature or humidity.

- ⇒ Store in clean and dry place.
- ⇒ Do not use if the package open or damaged
- ⇒ Do not store in direct sunlight

Cleaning

DISPOSABLE FOR SINGLE PATIENT USE NOT INTENDED FOR REPROCESSING

There is a risk of cross contamination if these devices are reused. They have not been validated for reprocessing or reuse.

Ordering information:

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







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Explanation of symbols:

- | | | | |
|---|---|---|--|
|  | = Single Use. The definition of single use is for use on a single patient for a single procedure. |  | = Manufacturer |
|  | = Do not reprocess / re-sterilise |  | = Temperature range |
|  | = Use by date |  | = Consult instructions for use |
|  | = Lot or batch number. |  | = Keep away from sunlight |
|  | = Date of manufacture. |  | = Keep dry |
|  | = Device catalogue number / product code / stock |  | = Contains latex |
|  | = Caution |  | = Do not use if packaging is wet or damaged. |
|  | = Device catalogue number / product code / stock |  | = Contains or Presence of Phthalates. |
|  | = CE mark with notified body number | | |

This is an explanation of the symbols that may be found on Meditech Systems Ltd's products.

ADVERSE INCIDENT REPORTING

Adverse incidents may be reported to the Competent Authority in the country / region where the incident occurred.