

# Bite Block OF-Z5

## 1 Intended use

The bite block should be used to prevent patients from biting on the insertion tube of a flexible endoscope during an endoscopic examination. Never use it for any purpose other than that for which it has been designed.

### Note

Do not attempt to use this bite block with endoscopic instruments whose outside diameter exceeds 14 mm.

## 2 Inspection For Use

### Caution

Wear personal protective equipment (PPE) to minimize risk of cross contamination and protect users from chemical injury.

Inspect for cracks, chips, sharp edges on the all surface of the bite block. To protect the patient from injury and avoid damage to the endoscope, check the condition of the bite block before each use. Before using a bite block, it must be properly high - level disinfected or sterilized to minimize the risk of cross contamination.

## 3 Signal words

The following signal words are used throughout this IFU.

### Warning

Indicates a situation that could result in death or serious injury if not avoided.

### Caution

Indicates a potentially hazardous situation that could result in minor or moderate injury or damage to equipment if not avoided.

### Note

Indicates supplementary or useful information regarding use.

## 4 Symbols

The meaning(s) of the symbol(s) on this product, and / or on its packaging are as follows:

Symbol	Description
	Manufacturer
	Date of manufacture
	Authorised representative in the European Community
	Batch Code
	The CE mark confirms the compliance to applicable European(EU) requirements.
	Medical device in the EU

## 5 Care after Use

The following steps summarize the basic reprocessing procedures for the PENTAX accessory supplied with these instructions:

1. Immediately after procedure, clean accessory in enzymatic detergent.
2. While completely immersed in detergent, manually clean (brush, scrub, wipe, etc.) all exposed surface areas.
3. Subject accessory to ultrasonic cleaning.  
(Note: Frequency Range: 44 kHz  $\pm$  6% Time: 5 minutes)
4. After cleaning, thoroughly rinse all surfaces with clean water.
5. Expose all areas of accessory to a high - level disinfectant for appropriate time period.
6. Rinse and dry thoroughly.

7. If sterilization is required. ETO Gas or steam sterilization can be performed.

### ► Steam Sterilization (Autoclaving)

Sterilizer Type :	Prevacuum
Temperature:	132 to 135 °C (270 to 275 °F)
Time:	5 minutes

### ► Ethylene - Oxide Gas Sterilization

Temperature:	55 °C (131 °F)
Relative Humidity:	50% RH
EO Concentration:	600 to 650 mg / L
Gas Exposure Time:	5 Hours
Aeration:	12 Hours at 55 °C (131 °F)

### Warning

Do the following:

- Take off the accessory from the endoscope.
- Do NOT store the accessory in areas of high humidity or high temperature.
- Do NOT store the accessory in the carrying case.
- Ensure that the accessory are completely moisture - free before storage.
- The accessory NOT stored properly or stored longer than allowed by the health care facility must be completely reprocessed (e.g., cleaning, high - level disinfection or sterilization), as described in the endoscope's IFU (reprocessing), before using.

Failure to do so results in contamination of the accessory with bacteria and pose an infection control risk to patients and / or users.

### Caution

Do the following:

- Keep the accessory away from chemicals, direct sunlight, or ultraviolet rays.
- Maintain enough distance between the endoscope and the accessory so they do NOT touch during storage.

Failure to do so results in damage to the accessory.

For further information about this product, contact your local PENTAX service facility or sales representative.

## 6 Disposal

### Warning

Follow the national or local laws / guidelines to appropriately dispose of the consumables. Failure to do so may create a risk of cross contamination or infection.

### Note

As per the Regulation (EU) 2017 / 745 (EU - MDR) users should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user is established.

### Contacts

#### Manufacturer

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