SAFETY AND PERFORMANCE INFORMATION

Adult cap-ONE Biteblock **YG-227T**

General

The YG-227T cap-ONE biteblock is inserted between the patient's teeth to prevent closure of the patient's jaws, connect to a CO₂ module, and provide oxygen (including an oxygenair mixture) to the patient during endoscopy.

Safety Information

A warning alerts the user to the possible injury or death associated with the use or misuse of the instrument.
A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property.

Pay attention to all safety information in the Operator's Manual or Installation Guide.

🗥 WARNING

Before inserting the cap-ONE biteblock between the teeth, check that the oxygen tube is firmly connected to the oxygen supply and that the flow of oxygen is not blocked.

While using the cap-ONE biteblock, keep the patient under close observation and frequently check that the oxygen tube is firmly connected to the oxygen supply and that the flow of oxygen is not blocked.

If arterial oxygen partial pressure does not increase, immediately stop using the cap-ONE biteblock and select another way to supply oxygen.

If the patient's respiratory volume is low and the oxygen flow rate is high, the CO₂ data becomes inaccurate due to the dead space of the cap-ONE biteblock.

▲ CAUTION

Never autoclave or perform EOG gas sterilization for the cap-ONE biteblock because this damages the cap-ONE biteblock and safety cannot be guaranteed.

Do not use the cap-ONE biteblock outside the healthcare facility. Strong electromagnetic interference may cause incorrect measurement data.

▲ CAUTION

Only use with a specified device. Otherwise, the maximum performance cannot be guaranteed due to larger dead space or leak, etc.

The cap-ONE biteblock is non-sterilized and disposable. Use only for a single patient and single use. Failure to follow this instruction may cause cross infection and incorrect measurement value.

▲ CAUTION

- The cap-ONE biteblock must be used under the supervision of the physician in charge and with oxygen supply prescribed by the physician.
- · The oxygen concentration depends on the patient ventilation volume. Periodically check the oxygen concentration in the patient with a monitoring device such as a pulse oximeter or blood gas analyzer to maintain the oxygen supply at an adequate level.

Failure to follow the instructions below degrades the anti-fogging ability of the transparent film and results in incorrect measurement.

- Replace the cap-ONE biteblock with a new one every 24 hours.
- Replace the cap-ONE biteblock with a new one if blood, sputum or mucus adheres to the transparent film.
- Do not damage the transparent film. Do not let dust or detergent contact the transparent film. Do not touch, wipe or clean the transparent film with fingers or cleaners.
- Do not use a cap-ONE biteblock which is past the expiration date.

Do not use a deformed or damaged cap-ONE biteblock.

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

> This Safety and Performance Information is an extract from the general and safety information sections of the most recent edition of Operator's Manual or Installation Guide. Therefore, the contents of your Operator's Manual or Installation Guide may differ from those of this Safety and Performance Information. For detailed operating procedures, follow the instructions of your Operator's Manual or Installation Guide.

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