

Inventeur, LLC

REF 107-000700

AIM TM

QTY: 1

AIM is a bite block intended for use in patients 18 years and older who require supplemental oxygen delivery and CO₂ monitoring during procedures where the patient is expected to be minimally or moderately sedated. It is not indicated for use during procedures that are expected to require deep sedation.

GTIN 00860010535882



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LOT



Rx Only

Manufactured for: Inventeur, LLC
16192 Coastal Hwy Lewes, DE 19958
MacModule.com
US 10,252,018 B2 and US 10,987,476 B2
Assembled in USA

<https://macmodule.com/instructions>

Label P/N 107-000500 Rev. E

INSTRUCTIONS FOR USE

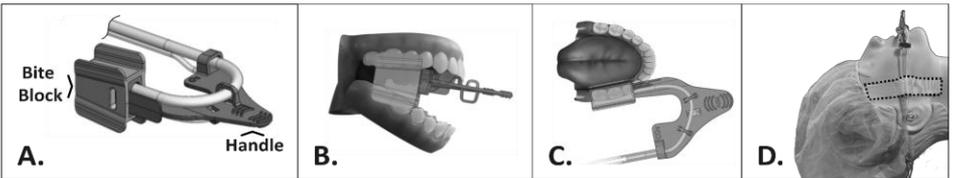
Device Preparation

1. Evaluate AIM for damage or defects. Defective devices should not be used.
2. Attach oxygen supply tube to oxygen source and luer connector to CO₂ monitor.
3. Ensure oxygen is flowing through the device before use on patient.



To Insert

4. Insert the bite block into either the right or left side of the patient's mouth. If used in lateral position, AIM should be placed on the top side of patient.
5. Seat the biting surface against the lower molars or pre-molars (See B and C).
6. Check the position of the bite block and adjust as required.
7. Check Capnography. If no waveform is present, ask patient to breathe through the mouth. Ensure baseline capnography before administering sedatives or narcotics to the patient.
8. Secure AIM with tape (See D).



During Use

- If capnography waveform is lost during the procedure:
 - a) Evaluate for apnea or airway obstruction.
 - b) If patient is breathing and oxygen saturation is adequate, begin using a secondary capnography device (e.g. sampling nasal cannula).
 - c) Continue oxygen delivery via AIM while sampling via the second capnography method.
- If AIM is dislodged during use, reposition as needed.

To Remove

9. Remove the tape securing AIM.
10. Slide the bite block out using atraumatic technique.

WARNING

AIM is not intended for use in procedures requiring deep sedation. Only use AIM as directed for procedures involving minimal or moderate sedation in patients 18 years and older.



CAUTION

- Do not use AIM as a lever to pry open a patient's mouth.
- Do not use in edentulous patients or those with signs of altered oral anatomy.
- Use of sterilization or cleaning solutions may leave this device nonfunctional.
- O₂ flow greater than 8L/min may cause CO₂ washout that underestimates EtCO₂ values.
- AIM should be used for less than 24 hours.
- AIM is not recommended for use in the prone position.