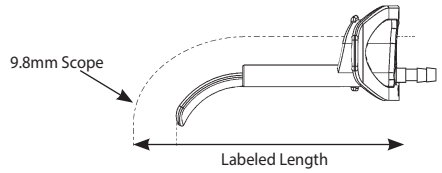
TIO™ THREE IN ONE

ENGLISH

ORAL AIRWAY * BITE BLOCK * O2 PORT

DESCRIPTION:
The TIO™ device, incorporates oral airway, oxygen administration port and bite block into a single device. The device has a large opening to accommodate a wide array of scopes for endoscopic and bronchoscopic procedures. The opening helps prevent the patient from biting down on the scope during the procedure. The device also incorporates a stepped barb fitting to allow oxygen administration as well as an oral airway feature that is designed to prevent the tongue from obstructing the airway.



Actual device length is the device size (90mm, 100mm, 110mm) minus 9.8mm (standard scope)

INDICATIONS FOR USE:
The TIO device is intended to maintain a patent airway during endoscopic and bronchoscopic procedures. The device also incorporates a bite block to protect endoscopic or bronchoscopic equipment from the patient's teeth and an oxygen administration port is designed to administer supplemental oxygen.

PRECAUTIONS:
Inspect the TIO device. Do not use product if opened or damaged and contact Customer Service

Keep fingers away from patient's teeth. Fingers caught between TIO device and patient's teeth can cause damage to fingers.

Securely connect all components. Loose connections or failure to correctly connect may cause dislodgement of the TIO device or oxygen supply.

WARNINGS:
Partial blockage of the oral airway due to scope positioning or inaccurate sizing of the TIO device or gag induced aspiration may cause periods of low oxygen. Oxygen levels should be monitored at all times, taking necessary steps to ensure patient safety.

Oxygen administration port is designed for oxygen administration only. Do not attempt to aspirate or inject through this port.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

INSTRUCTIONS FOR USE:
DEVICE INSERTION
1. Choose an appropriate TIO™ Device to accommodate the patient's anatomy.
2. Insert the TIO device into the patient's mouth and secure by attaching the strap around the patient's head.
3. Secure the oxygen tubing by pressing the tubing firmly onto the oxygen administration port.

CLINICAL BENEFITS
- Oral airway provided in 90mm, 100mm, and 110mm blade lengths for various anatomical requirements.
- Sizes are color coded for easy identification.
- Accepts a wide range of endoscopes and bronchoscopes.
- Designed to deliver supplemental oxygen, up to 6.0L/min.
- Intended to protect patient teeth, endoscopes, bronchoscopes, and other endoscopic procedural devices.

DEVICE DISPOSAL
Remove the TIO device from the patient's mouth. Dispose of used device consistent with standard protocols for biohazard waste disposal.

STORAGE:
Store in a cool, dry place.

WARRANTY:
The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is exclusive and manufacturer makes no other representations or warranties of any kind to customers, its end users, or to any third parties with respect to the device and hereby expressly disclaims any and all other warranties, express or implied, statutory or otherwise, including, but not limited to, infringement and the implied warranties of merchantability and fitness for a particular purpose, even if manufacturer is aware of such purpose. Handling and storage of this device, as well as other factors relating to the patient, diagnosis, treatment, implant procedures, and other matters beyond the control of the manufacturer, directly affect the device and the results obtained from its use. The manufacturer's obligation under this warranty is limited to the replacement of the device. Under no circumstances shall manufacturer be liable to customer or any other person or entity for any punitive, special, incidental or consequential damages directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. This warranty shall not apply, and manufacturer assumes no liability with respect to, devices that have been (i) modified, changed, altered, misused, mishandled, repaired, reused, reprocessed, refurbished or resterilized; (ii) subjected to improper maintenance, testing or storage, accident, tampering, or inadequate protection against shock, vibration, excessively high or low temperatures, overpressure, or physical, environmental or electrical stress; (iii) been used outside the approved "Indications for Use" as cleared by the relevant competent authority, used contrary to the use outlined in the device specifications, or in an application or environment for which such device was not designed or contemplated; or (iv) distributed or used contrary to applicable federal, state, local or regulatory standards.

	Single Use
	Caution: Consult accompanying document
R_X ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.

US and foreign patents issued and pending

Latex free

MERIT MEDICAL ENDOTEK™

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endotek.merit.com

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