

Instructions for Use

IOPI® Tongue Bulb

REF 5-6010

The IOPI® Tongue Bulb is an approved component for use only with the IOPI® System. Please carefully read the IOPI® User Manual prior to using the Tongue Bulbs with a patient.

INDICATIONS FOR USE

IOPI® Tongue Bulbs are intended for use with the IOPI® Pro (Model 3.1).

The IOPI® Pro (Model 3.1) is used by healthcare professionals to measure, evaluate, and increase the strength and endurance of the tongue and lip in patients with oral motor disorders, including dysphagia, dysarthria, and obstructive sleep apnea.

The IOPI® Pro is intended for clinical use by healthcare professionals.

CONTRAINDICATIONS

- **Do not** use with children under the age of 3.
- **Do not** use the Tongue Bulb with a patient who has any current or past problem with pain disorders involving the jaw muscles or temporomandibular joint (“TMJ Disorder,” “Myofascial Pain Disorder”).

PRECAUTIONS

- **WARNING: Do not** place a plastic or latex film over the Tongue Bulb. This presents an unlikely but serious risk of airway blockage due to the patient swallowing or choking on the film, or a risk of toxic or allergic reaction to the film material.
- **CAUTION: Do not** use if there are any signs of damage to the packaging; damaged packaging could lead to bulb contamination during transportation or storage.
- **CAUTION: Do not** use a Tongue Bulb with more than one patient. Single patient use is necessary to prevent cross-contamination.
- **CAUTION: Do not** put the Tongue Bulb in a patient’s mouth if there is an imminent risk of the patient having a seizure. This could pose a choking or ingestion hazard if the bulb detaches during the episode.
- **CAUTION: Always** hold on to the Tongue Bulb tubing when it is in the patient’s mouth to prevent choking or ingestion.
- **CAUTION: Only** use Tongue Bulbs to measure oral motor structures. Using the bulb in another body orifice and then placing it in the patient’s mouth could lead to sickness.
- **CAUTION: Tongue Bulbs** are intended for supervised use with adults and children ages 3 and older. Supervision is necessary to prevent choking or ingestion and to ensure accurate measurements.
- **CAUTION: Tongue Bulbs** can be reused with a single patient for up to one month after initial use if cleaning and storage instructions are followed. Reuse for a longer period could lead to leaks, impacting device effectiveness.

REORDER INFORMATION

Reorder PN 5-6010

CARE INSTRUCTIONS

CLEANING

Only for cleaning Tongue Bulbs between uses by the same patient!

1. Avoid getting liquid in the Tongue Bulb tubing. To do so, plug the end of the tubing using one of the black rods provided in the box of Tongue Bulbs.
2. Clean the Tongue Bulb by rubbing all surfaces with a mild dishwashing detergent solution. This cleaning should be done manually; bulbs cannot withstand automated cleaning.
3. Rinse thoroughly, shake off excess water, and air dry.

CAUTION: Do not sterilize the IOPI Tongue Bulbs. Sterilization could melt or otherwise damage the bulbs.

STORAGE

Between uses by the same patient, store in a clean, sealed container with the black rod plugging the tubing and in a manner which does not compress the blue bulb.

CAUTION: Keep bulbs out of reach of children. The small parts present a swallowing or gagging hazard for young children.

DISPOSAL

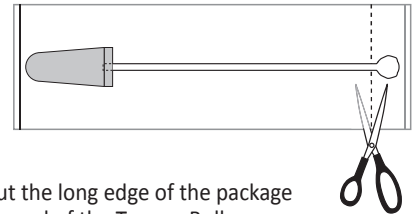
Dispose of as medical waste and out of the reach of children.

DIRECTIONS FOR USE

To prepare the Tongue Bulb for use with the IOPI® System:

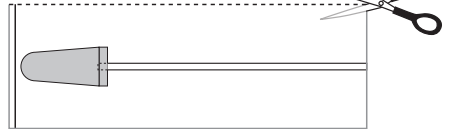
1. Use scissors to cut the seal off the end of the Tongue Bulb tube by cutting across the package while the Tongue Bulb is still in its package (see Figure 1).

Figure 1.



2. Use scissors to cut the long edge of the package to allow easy removal of the Tongue Bulb (see Figure 2).

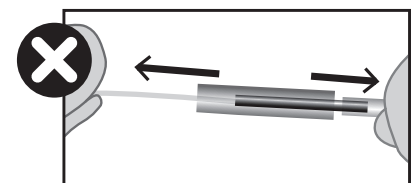
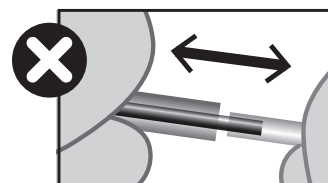
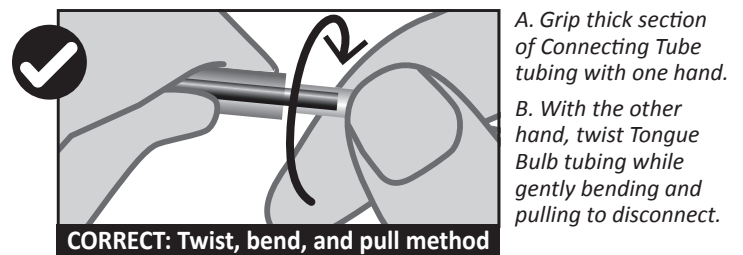
Figure 2.












3. Insert the metal (male) end of the IOPI® Connecting Tube into the opened end of the Tongue Bulb tubing.
4. Remove the Tongue Bulb from its package to use it with a patient, taking care to not touch the parts of the Tongue Bulb that go into the patient’s mouth.

DISASSEMBLY

- The Tongue Bulb should be disconnected from the Connecting Tube prior to cleaning or storage. To disconnect, **hold on to the thicker Connecting Tube tubing and gently pull apart while twisting and bending the Tongue Bulb tubing** to break the air seal.




IOPI® Icons

| SYMBOL | TITLE | DESCRIPTION | REFERENCE ¹ |
|---|---|---|-------------------------------------|
|  | Catalogue Number | Indicates the manufacturer's reference number so that the medical device can be identified | ISO 15223-1, Clause 5.1.6 |
|  | Lot Number | Indicates the manufacturer's lot number so that the lot can be identified | ISO 15223-1, Clause 5.1.5 |
|  | Expiration Date | Indicates the date after which the medical device is not to be used | ISO 15223-1, Clause 5.1.4 |
|  | Manufacturer | Indicates the medical device manufacturer | ISO 15223-1, Clause 5.1.1 |
|  | UK Conformity Assessed | Signifies United Kingdom technical conformity | Regulation (EC) No 765/2008 Annex 2 |
|  | Refer to Instruction Manual | Indicates that the instruction manual must be read | ISO 7010-M002 |
|  | Caution | Indicates that caution is necessary when operating the device close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences | ISO 7000-0434B |
|  | Single Patient Multiple Use | Indicates a medical device that may be used multiple times on a single patient | ISO 15223-1, Clause 5.4.12 |
|  | Do Not Use with Children Under 3 | Indicates that the medical device is not suitable for children under 3 years old | N/A |

1. Standards used: BS EN ISO 15223-1:2021, *Medical devices – Symbols to be used with information to be supplied by the manufacturer*. ISO 7000:2019, *Graphical symbols for use on equipment – Registered symbols*. ISO 7010:2019, *Graphical symbols – Safety colors and safety signs – Registered safety signs*.

Technical Specifications

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|---|--|
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| DIMENSIONS: | |
| Height x Width x Length | 1 cm x 2 cm x 14.3 cm |
| Weight | 1.8 g |
| OPERATING: | |
| Temperature | 5°C to 40°C (41°F to 104°F) |
| Humidity | 15% to 93% relative humidity |
| Atmospheric Pressure | 70 kPa to 106 kPa |
| STORAGE/TRANSPORT: | |
| Temperature | -25°C to 65°C (-13°F to 149°F) |
| Humidity | 10% to 93% relative humidity |
| Atmospheric Pressure | 70 kPa to 106 kPa |
| MANUFACTURER: | |
|  | IOPI® Medical LLC 18500 156th Ave NE, STE 104 Woodinville, WA 98072 U.S.A. Tel: +1 (425) 549-0139 |
| AUSTRALIAN SPONSOR: | |
| | EMERGO AUSTRALIA Level 20 Tower II Darling Park, 201 Sussex Street Sydney, NSW 2000 Australia |
| UK RESPONSIBLE PERSON: | |
| | SEVERN HEALTHCARE TECHNOLOGIES LTD. 42 Kingfisher Court, Hambridge Rd. Newbury, Berkshire RG14 5SJ United Kingdom |