ENGLISH

Instructions for Use

IOPI® CONNECTING TUBE

REF 5-0001

The IOPI® Connecting Tube is an approved component for use only with the IOPI® System. Please carefully read the IOPI® User Manual, as supplied with the IOPI® System, prior to using this component.

INDICATIONS FOR USE

The IOPI® Connecting Tube is 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.

PRECAUTIONS

- CAUTION: Keep out of reach of children. The Connecting Tube's small parts present a swallowing or gagging hazard for young children.
- CAUTION: Clean the Connecting Tube before and after each use. This is necessary to prevent cross-contamination.
- CAUTION: **Do not** reuse the Connecting Tube if it comes into contact with bodily fluids. This could result in patient exposure to bacteria or viruses, leading to sickness.

CARE INSTRUCTIONS

CLEANING

1. The outside of the Connecting Tube may be cleaned with a germicidal cloth.
2. **Do not** introduce water or any fluid into the Connecting Tube, as this may lead to inaccurate pressure readings.

STORAGE

Between uses, store in a clean, dry, sealed container out of direct sunlight.

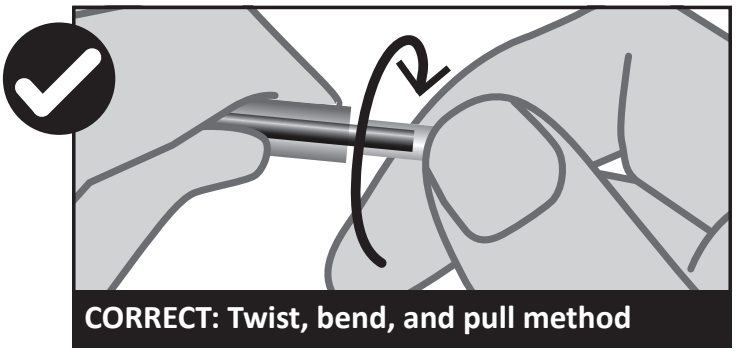
DISPOSAL

Dispose of the Connecting Tube if the plastic tubing tears, the metal pin detaches from the tubing, or it shows other signs of aging or degradation.

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

DIRECTIONS FOR USE

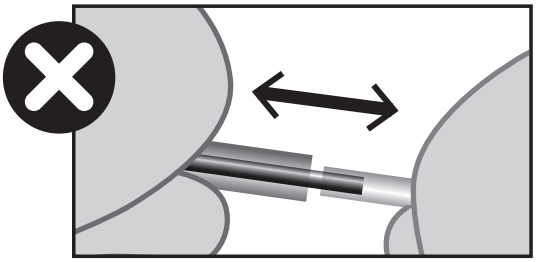
1. Connect the non-metal tubing end of the Connecting Tube to the Pressure In port [⇦] on the IOPI® device.
2. Connect the metal end of the Connecting Tube to the Tongue Bulb tubing.
3. To disconnect the Connecting Tube from the Tongue Bulb tubing, **hold on to the thicker tubing and gently pull apart while twisting and bending the Tongue Bulb tubing** to break the air seal.



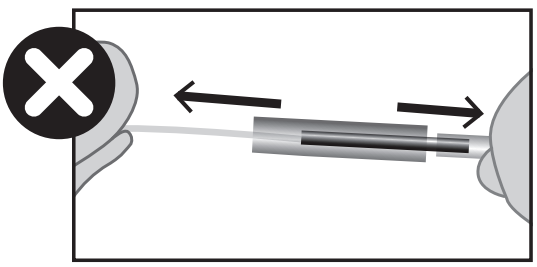
CORRECT: Twist, bend, and pull method

A. Grip thick section of Connecting Tube tubing with one hand.

B. With the other hand, twist Tongue Bulb tubing while gently bending and pulling to disconnect.



DO NOT pull directly apart



DO NOT pull on thin tube

4. To disconnect the Connecting Tube from the Pressure In port [⇦], grip the thicker part of the tubing and gently pull the Connecting Tube away from the device.

REORDER INFORMATION

Reorder PN 5-0001

IOPI® Icons

SYMBOL	TITLE	DESCRIPTION	REFERENCE[1]
REF	**Catalogue Number**	Indicates the manufacturer's reference number so that the medical device can be identified	ISO 15223-1, Clause 5.1.6
LOT	**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
	**Keep Away From Sunlight**	Indicates a medical device that needs protection from light sources	ISO 15223-1, Clause 5.3.2
	**Refer to Instruction Manual**	Indicates that the instruction manual must be read	ISO 7010-M002
UK CA	**UK Conformity Assessed**	Signifies United Kingdom technical conformity	Regulation (EC) No 765/2008 Annex 2

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

Technical Specifications

INDICATIONS FOR USE:	The IOPI® Connecting Tube is 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.
DIMENSIONS:	
Length	68 cm
End Diameter	5 mm
Middle Diameter	1.5 mm
Weight	2.3 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