

Instructions for Use

IOPI® Trainer Bulb

REF 5-6105

The IOPI® Trainer Bulb is an approved component for use with the IOPI® System only. Please carefully read the following instructions and the applicable IOPI® Pro or Trainer User Manual before using the Trainer Bulbs.

INDICATIONS FOR USE

IOPI® Trainer Bulbs are intended for use with the IOPI® Pro (Model 3.1) and IOPI® Trainer (Model 3.2).

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.

The IOPI® Trainer (Model 3.2) is used to 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® Trainer is intended for clinical use and use by patients outside their therapy sessions under the direction of a healthcare professional.

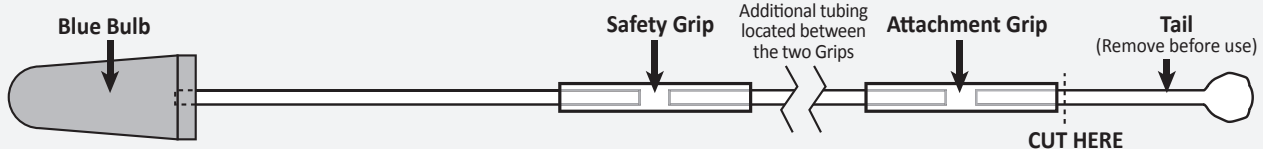
CONTRAINDICATIONS

- **Do not** use the Trainer Bulb if you have any current or past problem with pain disorders involving the jaw or jaw muscles (examples: "TMJ Disorder," "Myofascial Pain Disorder").

PRECAUTIONS

- **WARNING: Never** cover the Trainer Bulb with plastic wrap, latex, or other material, as it presents a choking hazard and may cause an allergic reaction.
- **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** share your Trainer Bulb. It is only intended for use by one person. Sharing it could spread germs or make you sick.
- **CAUTION: Do not** put the Trainer Bulb in your mouth if there is an imminent risk of you having a seizure. You could swallow or gag on the bulb during the seizure.
- **CAUTION: Always** hold on to the safety grip of the Trainer Bulb when it is in your mouth; otherwise you could swallow or gag on the bulb.
- **CAUTION:** This device is sold directly to you or your healthcare professional. Your healthcare professional is in charge of directing your use of the Trainer Bulb to make sure that you use it correctly.
- **CAUTION:** Only use the bulb for exercising your tongue and lips. Use in other areas of your body could transfer germs.

TRAINER BULB DIAGRAM



PRECAUTIONS (continued)

- **CAUTION:** Trainer Bulbs are intended for use with adults and children ages 3 and older under the direction of a healthcare professional. Direction is necessary to prevent swallowing or gagging.
- **CAUTION:** You can use the same Trainer Bulb for up to one month after initial use if cleaning and storage instructions are followed. Using the same bulb for more than a month could make it leak, which would affect your treatment.

CARE INSTRUCTIONS

CLEANING

Only for cleaning your Trainer Bulb between your uses – do not share with other people!

1. Avoid getting liquid in the Trainer Bulb tubing. To do so, plug the end of the tubing using one of the black rods provided in the box of Trainer Bulbs.
2. Clean the Trainer Bulb by rubbing all surfaces with a mild dishwashing soap and water.
3. Rinse thoroughly, shake off any extra water, and let air dry.

CAUTION: Do not place the IOPI Trainer Bulbs in a dishwasher or boiling water. This could melt or otherwise damage them.

STORAGE

Between your uses, store in a clean, sealed container with the black rod plugging the tube. Make sure that the Trainer Bulb is not being flattened.

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

DISPOSAL

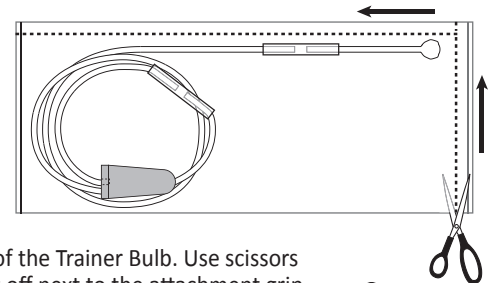
Throw away as medical waste and out of the reach of children.

DIRECTIONS FOR USE FOR PATIENT

To prepare the Trainer Bulb for use with the IOPI® Pro or Trainer:

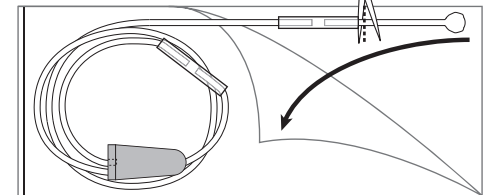
1. Use scissors to cut along the short and long edge of the package as shown in Figure 1.

Figure 1. Open the pouch as indicated by the dotted line.



2. Expose the tail end of the Trainer Bulb. Use scissors to cut the tail tubing off next to the attachment grip as shown in Figure 2.

Figure 2. Cut the end of the Trainer Bulb off without removing the entire Trainer Bulb from the pouch.












3. Connect the Trainer Bulb to the Pressure In port [↖] on the bottom of the IOPI® Pro or Trainer by sliding the attachment grip over the metal port as far as it will go.
4. Remove the Trainer Bulb from its package, taking care to not touch the parts of the Trainer Bulb that go into your mouth.

REORDER INFORMATION


Reorder PN 5-6105

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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DIMENSIONS:	
Height x Width x Length	1 cm x 2 cm x 66.5 cm
Weight	8.2 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:	
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AUSTRALIAN SPONSOR:	
	EMERGO AUSTRALIA Level 20 Tower II Darling Park, 201 Sussex Street Sydney, NSW 2000 Australia
UK RESPONSIBLE PERSON:	
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