Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Niki Svensson - NIKSVE	2022-12-14 - 10:09
Reviewed:	QA	Abdallah Almashharawi - ABDALM	2022-12-14 - 10:39
Approved:	QA	Elin Andersson - ELIAND	2022-12-14 - 16:14
Released:	QA	Niki Svensson - NIKSVE	2023-03-16 - 13:13

This document has been electronically signed by the persons above.

Product description:

Provox Dilator is a stepwise tapered, about 140 mm (5.5 inch) long solid curved rod made of medical grade silicone. The diameter is 15 Fr at the tip and increases to 24 Fr. At the end of each diameter step, i.e. 18, 20 and 22 Fr respectively, a small retaining collar is made to prevent the dilator from gliding back to the thinner section. The dilator also has a retainer strap with medallion intended to reduce the risk of accidental aspiration.

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Product Information

Document ID:	PF005-01-TechInfo	**Edition:**	09

Manufacturer:
Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby,Sweden

Classification: (MDD 93/42/EEC) IIa (2.1 Rule 5)

Intended Use: The Provox Dilator is intended for upsizing smaller tracheo-esophageal (TE) punctures (i.e. from 16 Fr diameter) to allow fitting of Provox voice prostheses, or upsizing a shrunken puncture to an adequate diameter, i.e. after loss of a voice prosthesis. The dilator may also be used for temporary blockage of a TE puncture or to temporarily prevent such from shrinkage. It is only intended to be used by physicians or speech pathologists/therapists trained in the care and rehabilitation of laryngectomized patients.

Use specifications:

Intended medical indication
Laryngectomized patients with a tracheo-esophageal (TE) fistula.

Intended patient population
Male and female.
Typical average age for a laryngectomy is 65 years.

Intended usage
The Provox Dilator is intended for upsizing smaller tracheo-esophageal (TE) punctures (i.e. from 16 Fr diameter) to allow fitting of Provox voice prostheses, or upsizing a shrunken puncture to an adequate diameter, i.e. after loss of a voice prosthesis. The dilator may also be used for temporary blockage of a TE puncture or to temporarily prevent such from shrinkage. It is only intended to be used by physicians or speech pathologists/therapists trained in the care and rehabilitation of laryngectomized patients.

Intended part of the body/type of tissue applied to or interacted with
Stoma; tissue.

Intended user profile
Physicians or speech pathologists/therapists trained in the care and rehabilitation of laryngectomized patients.

Intended conditions of use
Hospital use.

Contraindications: The device is not intended to be used by patients that have not received adequate training by their clinician.

The device is not intended to be used for puncture dilation at the time of surgical creation of the puncture.

Do not use the device in case of a small tracheostoma where the dilator could obstruct breathing.

CE Mark: Yes. Device is CE-marked.

GMDN code: 62125 (Tracheoesophageal fistula dilator)

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Product Information

Sterilization:	Non-sterile, sterilizable by steam.
Raw material:	Silicone with blue masterbatch.
Latex information:	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with materials derived from human or animal source.
Handling and storage:	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.
Waste handling and disposal:	Waste handling and disposal should be carried out in agreement with medical practice and applicable national laws and legislations. Used product may be a potential biohazard.
Hazardous components:	None.
Expiration date:	5 years after manufacturing.
Packaging:	The Provox Dilator is separately packed together with instructions for use in a plastic bag made of polyethylene and thereafter packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-00R-0007-BR

REF	Name	UDI-DI
7211	Provox® Dilator	7331791000850

Atos Medical AB compatible products:

Range	BASIC UDI-DI
N/A	N/A

Document No: 10000038301 Edition: 09 Release date: 2023-03-16