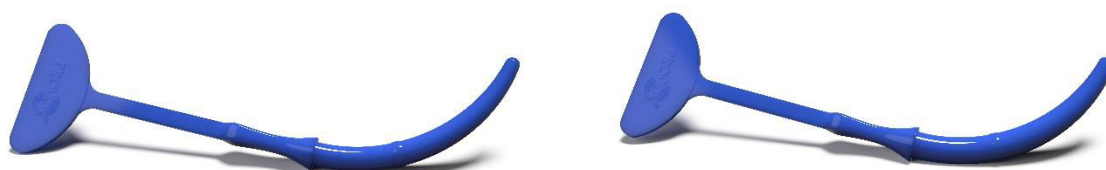


Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Niki Svensson - NIKSVE	2022-12-12 - 15:51
Reviewed:	QA	Abdallah Almashharawi - ABDALM	2022-12-12 - 16:36
Approved:	QA	Elin Andersson - ELIAND	2022-12-14 - 08:42
Released:	QA	Niki Svensson - NIKSVE	2023-03-16 - 13:13

This document has been electronically signed by the persons above.



Product description:

Provox Dilator 17 and Provox Dilator 20 are tapered curved silicone rods used for dilating (increase the diameter of) TE punctures. Provox Dilator 17 shall be used with Provox voice prostheses with an outer diameter of 17 Fr and Provox Dilator 20 with outer diameter 20 Fr. The dilator shall only be used and be prescribed for patient use, by clinicians trained in the care and rehabilitation of laryngectomized patients. The Provox Dilator 17 and 20 have a retainer strap with medallion intended to reduce the risk of accidental aspiration

Product Information

Document ID:	PF005-02-TechInfo	Edition:	08
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 17 and 20 are used for dilating tracheo-esophageal (TE) punctures that shrinks very fast or are too narrow to insert the selected Provox voice prosthesis. The Dilator may also be used to temporarily block or stent the TE puncture		
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 voice prosthesis system is intended for use of prosthetic voice restoration after total laryngectomy. The Provox Dilator 17 and 20 are used for dilating tracheo-esophageal (TE) punctures that shrinks very fast or are too narrow to insert the selected Provox voice prosthesis. The Dilator may also be used to temporarily block or stent the TE puncture. Intended part of the body/type of tissue applied to or interacted with Stoma; tissue. Intended user profile For Home Care Use the Dilator is intended for single patient re-use, and may only be used as part of the Provox NID system. It shall only be used by patients with sufficient manual dexterity, acceptable vision and satisfactory cognitive ability. The Dilator shall always be prescribed by a clinician trained in the dilation procedure. For Professional Use the Dilator may be re-used by a clinician in clinic and shall then be re-sterilized between patients. Intended conditions of use Hospital and home care 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. Devices are CE-marked.		
GMDN code:	62125 (Tracheoesophageal fistula dilator)		
Sterilization:	Non-sterile, sterilizable by steam.		
Raw material:	Silicone with blue masterbatch.		

Product Information

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
7122	Provox Dilator 17	07331791000393
7123	Provox Dilator 20	07331791000409



Provox Dilator 17 (REF 7122)



Provox Dilator 20 (REF 7123)

Atos Medical AB compatible products:

Range	BASIC UDI-DI
N/A	N/A