Product Information

Provox Dilator 17, Provox Dilator 20

Product description:

Provox Dilator 17 and Provox Dilator 20 are for single patient multiple use only. The dilators are tapered curved rods made of medical grade silicone used for dilating (increase the diameter of) or stenting (blocking) TE punctures. Provox Dilator 17 shall be used with Provox voice prostheses with an outer diameter of 17 Fr and Provox Dilator 20 with Provox voice prostheses with an outer diameter of 20 Fr. The dilator shall only be used and prescribed for patient use, by HCPs trained in the care and rehabilitation of laryngectomized patients. Provox Dilator 17 and Provox Dilator 20 have a small retention collar to prevent the dilator from sliding back to the thinner section. They also have a safety strap with medallion that can be taped to the neck to keep the dilator in place and that is designed to reduce the risk of accidental aspiration of the device.

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Product Information

Document ID:	PF130-02-TechInfo	**Edition:**	2.0
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby,Sweden		
Classification: (EU) 2017/745	Class IIa (Rule 5)		

Intended Use: The Provox Dilator 17 and 20 is intended to dilate or stent the tracheoesophageal puncture in laryngectomized patients.

Use specifications:

Intended medical indication
Provox Dilator 17 and Provox Dilator 20 are intended for laryngectomized patients with a tracheoesophageal (TE) puncture.

Intended patient population
Adult patients, 18+ years.
Cognitive ability, by a clinician judged as sufficient.
Manual dexterity, by a clinician judged as sufficient.

Intended usage
Single patient multiple use, Prescription.

Intended part of the body/type of tissue applied to or interacted with
Tracheostoma: Mucosal membrane.
In contact with wall between the trachea and esophagus.

Intended user profile
Health care professionals (HCP), patients, and lay caregivers.

Intended conditions of use
Environment: Hospital use. Home use.
Replacement rate: The dilator shall be replaced every 2 years or after 208 cleaning and disinfection cycles. If the device shows any signs of damage, it shall be replaced earlier.

Operating principles

Provox Dilator 17 and Provox Dilator 20 are single patient multiple use dilatation and stenting tools for the TE puncture. The dilators enable the dilation of the TE puncture to fit Provox voice prostheses with an outer diameter of 17 Fr and 20 Fr respectively. The presence of the dilator also keeps the TE puncture open and prevents esophageal contents from entering the trachea. The tip of the device is inserted into the TE puncture until a slight resistance is felt and is held there for a desired amount of time to allow sufficient dilatation or stenting. A small retention collar is present to prevent the dilator from sliding back to a thinner section. The dilators also have a safety strap and medallion that is designed to reduce the risk of accidental aspiration of the device.

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Contraindications:	The device is not intended to be used by patients and/or lay caregivers who have not received adequate training from their clinician and, as assessed by a clinician who prescribes the device, have demonstrated the ability to understand and consistently follow the Instructions for Use (IFU) without clinician supervision. The device is not intended to be used for TE puncture dilation at the time of surgical creation of the TE puncture.
CE Mark:	Yes. Devices are CE-marked.
GMDN code:	62125 (Tracheoesophageal fistula dilator, reusable)
Sterilization:	Non-sterile.
Raw material:	Silicone with blue masterbatch (Direct contact with patient).
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.
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 product is separately packed in a plastic bag made of polyethylene and thereafter packed in a cardboard box together with instructions for use.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-000-0012-RT

REF	Name	UDI-DI
8342	Provox Dilator 17	07331791181177
8343	Provox Dilator 20	07331791181184

Atos Medical AB compatible products:

Range	BASIC UDI-DI
N/A	N/A

Document Approvals

Approved Date: 2025-06-18

Task: Approval Task Verdict: Approve	ABDALM Abdallah Almashharawi, Senior Sustaining Engineer (abdallah.almashharawi-atosmedical@coloplast.com) Issuer 16-Jun-2025 11:30:54 GMT+0000

Task: Final Approval Verdict: Approve	SEHRBHNU Ulrika Svensson, Regulatory Affairs Professional (ulrika.svensson-atosmedical@coloplast.com) Regulatory 18-Jun-2025 14:30:30 GMT+0000