




Product Information

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	QA	Carolina Johansson - SEHRBJNC	2023-06-27 - 16:13
Reviewed:	QA	Niki Svensson - NIKSVE	2023-06-27 - 16:21
Approved:	DD	Christian Engelhardt - CHRENG	2023-06-30 - 14:59
Released:			

gth
dle

This document has been electronically signed by the persons above.

105

	7225	27,5	105
	8404 8404-18	22	155
	8425 8425-18	27,5	155

Product description:

The Provox Brush is a device helping to clean Provox voice prostheses or fenestration holes in LaryTube or can be used for application of Fluorosilicone oil or Anti-Candida medication into Provox voice prostheses. The distal end of the brush can help to place Provox Plug and Provox Vega Plug into the voice prosthesis.

The brush is intended for single patient re-use and is intended for both home and clinical use by patient or clinician. Maximal use 30 days.

Document No: 10000038302 Edition: 13 Release date: 2023-07-14

Released

Product Information

Document ID: PF007-01-TechInfo **Edition:** 13

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

Classification: (EU) 2017/745 Class I, Rule 5

Intended Use: Provox Brush is a single patient use device intended for cleaning Provox voice prostheses, for insertion of Provox Plug and Provox Vega Plug, for applying lubricant and anti-candida agents and for cleaning of fenestration holes on Provox LaryTubes. The product is intended for use by the patient.

Use specifications: Intended medical indication:
For cleaning Provox Voice Prosthesis/LaryTube/Life LaryTube, insertion tool for Provox Plug, applying tool lubricant/agent in laryngectomized patients.

Intended patient population:

Patients of any age.

Cognitive ability, by a clinician judged as sufficient.

Manual dexterity, by a clinician judged as sufficient.

Intended usage:

Single patient- multiple use, Over-the-counter

Intended part of the body/type of tissue applied to or interacted with:

Mucosal membrane

Intended user profile:

The product is supposed to be handled by the patient but is also handled by physicians, trained nurses, SLPs, clinicians and caregivers.

Intended conditions of use:

Environment: Home use (keep away from sunlight and keep dry).

Frequency of use: Continuous use.

Replacement rate: Max 30 days, then discarded.

Contraindications: No contraindications.

CE Mark: Yes. Devices are CE-marked

GMDN code: 62095 (Airway device cleaning utensil, invasive)

Sterilization: Non-sterile

Product Information

Raw material:	Brush head: Stainless steel, Polyamide (PA) Handle/Tip: Polypropylene (PP) with blue masterbatch. Soft Part: Thermoplastic elastomer (TPE)
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:	6 pcs packed in a tamperproof plastic bag together with Instructions for Use.

Product Information

Devices under Basic UDI-DI:

REF	Name	UDI-DI
7204	Provox Brush	07331791000775
7225	Provox Brush XL	07331791001451
8404	Provox Brush Long	07331791015588
8425	Provox Brush Long XL	07331791015595
8404-18	Provox Brush Long	07331791016431
8425-18	Provox Brush Long XL	07331791016448

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox2 Voice Prosthesis	7331791-VPS-0-0EI-0005-36
Provox Vega	7331791-VPS-0-0EI-0002-2V
Provox Vega XtraSeal	7331791-VPS-0-0EI-0004-33
Provox Vega Puncture Set	7331791-VPS-0-0EI-0003-2Y
Provox NID	7331791-VPS-0-00I-0000-NQ
Provox ActiValve	7331791-VPS-0-00I-0001-NT
Provox ActiValve Lubricant	7331791-GEN-A-000-0004-EJ
Provox LaryTube Fenestrated	7331791-LTU-0-000-0002-3E
Provox Life LaryTube Fenestrated	7331791-LTU-0-000-0004-3L
Provox Plug/Provox Vega Plug	7331791-VPS-A-000-0004-RU