Product Information

Provox ActiValve Lubricant

Product description:

Provox ActiValve Lubricant is a medical grade silicone oil to be used with Provox ActiValve voice prosthesis. It shall be applied as a thin film on the inner lumen of Provox ActiValve voice prosthesis to help prevent occasional temporary blockage of the valve.

Product Information

Document ID:	PF003-02-TechInfo	**Edition:**	2.0

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

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

Intended Use:
For use with Provox ActiValve only.
Lubricating the inner lumen of the Provox ActiValve prosthesis helps to prevent sticking of the valve that might otherwise occur e.g., after sleep.

Use specifications:

Intended medical indication
To facilitate voice rehabilitation 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
Multiple use. Over-the-counter.

Intended part of the body/type of tissue applied to or interacted with
Primarily applied to voice prosthesis interacting with mucosal membrane.

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

Intended conditions of use
Environment: Home use (normal daily environment without any or environmental restrictions regarding temperature, moisture etc.).
Outpatient clinic use. Hospital use.
Frequency of use: Continuous use. Applied to voice prosthesis once daily.
Replacement rate: Discard open bottle after 8 months.

Operating principles
Provox ActiValve Lubricant shall be applied as a thin film on the inner lumen of Provox ActiValve voice prosthesis to help prevent occasional temporary blockage of the valve.

Contraindications:
No known contraindications.

CE Mark:
Yes. Devices are CE-marked.

GMDN code:
42533 (Tracheoesophageal speech valve, indwelling)

Sterilization:
Non-sterile.

Raw material:
Silicone fluid (direct contact with the 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.
Excursions permitted between 2°C - 42°C.

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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:	3 years after manufacturing.
Packaging:	Provox ActiValve Lubricant is contained in a dropper bottle made of low-density polyethylene and a closure made of polypropylene. The bottle is packed in a plastic bag and then in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-000-0013-RW

REF	Name	UDI-DI
7149	Provox ActiValve Lubricant	07331791000515

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox ActiValve	7331791-VPS-0-000-0001-A3

Document Approvals
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Task: Approval Task Verdict: Approve	SEHRBHNU Ulrika Svensson, Regulatory Affairs Professional (ulrika.svensson-atosmedical@coloplast.com) Issuer 30-Jan-2025 15:08:14 GMT+0000

Task: Approval Task Verdict: Approve	SEHRBJNC Carolina Johansson, Sustaining Engineer (carolina.johansson-atosmedical@coloplast.com) Quality 31-Jan-2025 06:32:28 GMT+0000

Task: Final Approval Verdict: Approve	KARNIL Karolina Nilsson, Head of Regulatory Affairs (karolina.nilsson-atosmedical@coloplast.com) Regulatory 31-Jan-2025 06:58:11 GMT+0000