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Released:	DD	Pontus Eklund - X-PONEKL	2020-10-28 - 16:34

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Product Information

Provox® Flush

Product description:

The Provox Flush device has two components, the Flushing Tube and the Flushing Bladder, which should be assembled by the user. The tip has been designed to fit all sizes of Provox Prosthesis. Squeezing the bladder and there after releasing it allows the flush to be filled with water or air. After sealing the flush against the prosthesis, another squeeze of the bladder will flush water (or air) through the prosthesis. The Flushing tube is bendable to facilitate the best possible seal regardless of tracheoesophageal (TE)-puncture angle.

Document No: 10000032569 Edition: 10 Release date: 2020-10-28

Atos Medical AB
Kraftgatan 8, P.O Box 183
SE-242 22 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID:	PF006-01-TechInfo	**Edition:**	10

Manufacturer: Atos Medical AB
Kraftgatan 8, P.O. Box 183,
SE-242 22 Hörby, Sweden

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

Intended Use: The Provox Flush is intended to be used to flush drinking water or air through the inner lumen of a Provox voice prosthesis for cleaning purposes. The Flush is intended for both home and clinical use by patient or clinician.

CE Mark: Yes, the devices are CE marked.

GMDN code: 62096 (Tracheoesophageal speech valve irrigation device)

Sterilization: Non-sterile.

Raw material: Flushing tube: Polypropylene (PP) with blue masterbatch
Flushing Bladder: Silicone.

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: Provox Flush is separately packed in a plastic bag and then, together with Instructions for use, packed in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-000-0001-RK

REF	Name	UDI-DI
8109	Provox Flush	07331791005930
8109-18	Provox Flush	07331791013843

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 NID	7331791-VPS-0-00I-0000-NQ
Provox ActiValve	7331791-VPS-0-00I-0001-NT

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Released:	DD	Mårten Cervin - SEHRBCNM	2021-07-07 - 14:48

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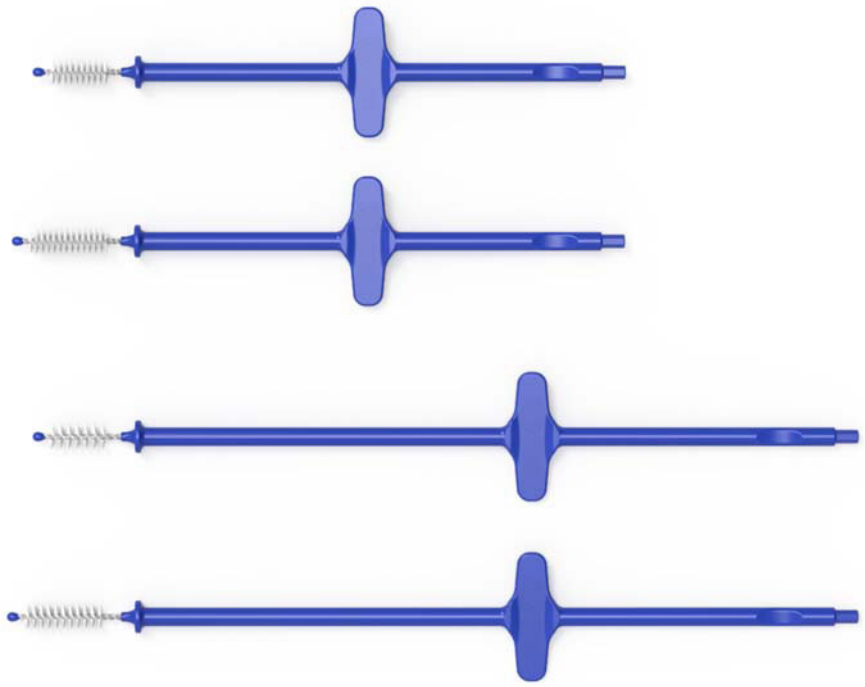
Product Information

Provox® Brush



REF	Length Brush Head	Length Handle
7204	22	105
7225	27,5	105
8404	22	155
8425	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 Flourosilicone 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: 12 Release date: 2021-07-07

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Product Information

Document ID: PF007-01-TechInfo **Edition:** 12

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:

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

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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

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

Document No: 10000038302 Edition: 12 Release date: 2021-07-07

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Released:	QA	Sara Dahl - X-SARDAH	2021-12-10 - 09:52

This document has been electronically signed by the persons above.

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Product Information

Provox® Measure

Product description:

Reusable instrument for measuring the length (corresponding to voice prosthesis size) of TE punctures. The single-use flanges of Provox Measure can be attached to the instrument in two different ways, facilitating measurement of fistulas made for different voice prosthesis diameters.

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Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID:	PF010-01-TechInfo	**Edition:**	11

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

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

Intended Use:
The Provox Measure is intended for sizing the length (corresponding to voice prosthesis length) of tracheoesophageal (TE) punctures.

Use specifications:
Intended medical indication:
For measuring the length (corresponding to voice prosthesis length) of the tracheoesophageal (TE) punctures 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:
Provox Measure is sterilizable. Provox Measure Flanges are for single use.
Intended part of the body/type of tissue applied to or interacted with:
The device will contact intact skin and mucosal membrane in the tracheoesophageal puncture.
Intended user profile:
The product is supposed to be handled by physicians, trained nurses, SLPs and clinicians.
Intended conditions of use:
Hospital use. Not continuous use.

Contraindications:
Do not use the device on punctures of diameter less than 20 Fr as this may cause damage and/or bleeding of the puncture.
The device is not intended to be used at the time of surgical creation of the puncture.

CE Mark:
Yes. Devices are CE-marked.

GMDN code:
62126 (Tracheoesophageal fistula gauge)

Sterilization:
Non-Sterile, The Provox Measure instrument is sterilizable by steam.

Raw material:
Rod: Stainless steel
Tube: Polyoxymethylene (POM)
Flange: 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.

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Product Information

Hazardous components: None

Expiration date: 5 years after manufacturing.

Packaging:

7270 Provox Measure:
The Provox Measure instrument and 6 pieces Provox Measure Flanges are packed separately in plastic bags together with instructions for use (90727) and cleaning/sterilization instructions (10025-1). The bags are packed in a cardboard box.

7271 Provox Measure Flanges:
The Provox Measure Flanges are packed 5 pieces in a plastic bag together with 1 instructions for use (90727).

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-00R-0005-BK

REF	Name	UDI-DI
7270	Provox Measure	07331791001710
7271	Provox Measure Flanges	07331791001727

Atos Medical AB compatible products:

None.

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Released:	QA	Sara Dahl - X-SARDAH	2021-09-09 - 10:23

This document has been electronically signed by the persons above.

Product Information

Provox® GuideWire

Product description:

The Provox GuideWire is a sterile, single use device for introduction and replacement of sterile Provox indwelling Voice Prostheses. The GuideWire has a connector for attachment of the safety strap of the new voice prosthesis and an 8 mm Stopper for transoral removal of the remnant of the old voice prosthesis.

Document No: 10000043700 Edition: 06 Release date: 2021-09-09

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Product Information

Document ID:	PF024-01-TechInfo	**Edition:**	06

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

Classification: (MDD 93/42/EEC) Class IIa (2.2 rule 6)

Intended Use: The Provox GuideWire is a sterile single use insertion device intended for placement of a sterile Provox indwelling voice prosthesis after total laryngectomy (primary or secondary puncture), or for retrograde replacement of a Provox indwelling voice prosthesis

Use specifications:

Intended medical indication
For voice rehabilitation in laryngectomized patients

Intended patient population
Male and female of any age.
All health states. Post-operative adverse effects, post (chemo) radiation therapy adverse effects.

Intended usage
Single use, Prescription only.

Intended part of the body/type of tissue applied to or interacted with
Primary interaction (short and long term): Tracheoesophageal wall
Secondary interaction (transient): Trachea, Esophagus, Pharynx, Mouth.

Intended user profile
Head and Neck Surgeon for placement of voice prosthesis. Trained clinician (e.g. physician, SLP) for replacement of voice prosthesis.

Intended conditions of use
Placement of voice prothesis is performed at the time of, and in the environment of, tracheoesophageal puncture.
Replacement of voice prosthesis is performed in outpatient hospital settings, on average 4 times per year.

Contraindications: Do not use if the patient has anatomical abnormalities, e.g. significant pharyngeal stenosis above the puncture site or severe trismus.

CE Mark: Yes, the devices are CE marked.

GMDN code: 65394 Tracheoesophageal speech valve guidewire

Sterilization: EO-sterilization

Raw material: Acrylonitrile butadiene styrene (ABS), Polyvinyl chloride (PVC), Polyamide (PA).

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.

Product Information

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: Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.

Expiration date: 5 years after manufacturing.

Packaging: GuideWire is packed in a sterility bag. It is then packed in a carboard box together with instructions for use.

Devices under Basic UDI-DI: 7331791-VPS-A-0E0-0006-5Z

REF	Name	UDI-DI
7215	Provox GuideWire	7331791000867

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Vega	7331791-VPS-0-0EI-0002-2V
Provox Vega XtraSeal	7331791-VPS-0-0EI-0004-33
Provox2 Voice Prosthesis 6mm	7331791-VPS-0-0EI-0005-36

Document No: 10000043700 Edition: 06 Release date: 2021-09-09

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Quality Management System | Page No. 1 of 1

Technical Info / Material Data Sheet

Document ID: PF056-01 TechInfo | Edition: 05

REF Number	7275, 7276, 7277
Product Name	Provox® XtraFlange
Models:	3 sizes: Provox XtraFlange 22.5, Provox XtraFlange 20, Provox XtraFlange 17
Classification: (MDD 93/42/EEC)	IIb (2.4, rule 8)
CE Mark:	Yes
GMDN code:	42533 (Tracheoesophageal speech valve, indwelling)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	Provox XtraFlange is a silicone washer intended to reduce periprosthetic leakage that is detected on patients using indwelling Provox voice prostheses. Placement is performed by a medical doctor or a trained medical professional in accordance with local or national guidelines.
Description:	Provox XtraFlange is a white silicone washer that is intended to be placed between the tracheal flange of the prosthesis and the tracheal mucosa. It provides an extra seal against periprosthetic leakage through the adherence of the thin silicone sheet to the tracheal mucosa. The device is supplied sterile and is intended for single use only.
Sterilization:	EO-sterilization
Raw material:	Silicone with 10 % barium sulphate ($BaSO_4$)
Latex information	Not manufactured with natural rubber latex
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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 product is packed in a sterile bag and then packed in a cardboard box together with a instruction for use. Finally tamper proof.

Reviewed by:
.....
Vice President Quality Assurance
2014-01-30
.....
Date

Approved by:
.....
Vice President Design & Development
2014-01-30
.....
Date

Released
Document No: 10000019707 Edition: 05 Release date: 2014-02-17

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Released:	QA	Elin Andersson - ELIAND	2021-07-07 - 13:42

This document has been electronically signed by the persons above.

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Product Information

Provox® Capsule

Product description:

The esophageal flange of the voice prosthesis is folded into the Capsule and the voice prosthesis is placed in the TE-puncture. The voice prosthesis is manually kept in place, while the patient is drinking water until the Capsule is dissolved and the esophageal flange have unfolded on the esophageal side of the TE-puncture.

Document No: 10000043073 Edition: 06 Release date: 2021-07-07

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Atos
atosmedical.com

Product Information

Document ID:	PF073-01-TechInfo	**Edition:**	06

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

Classification: (EU) 2017/745 Class I, Rule 1

Intended Use: The Provox Capsule is a single use accessory for anterograde insertion of a standard voice prosthesis by a clinician into the tracheoesophageal puncture of laryngectomized patients.

Use specifications: The holder is disconnected from the Capsule and discarded. The esophageal flange of the voice prosthesis is folded into the Capsule and the voice prosthesis is placed in the TE-puncture. The voice prosthesis is manually kept in place, while the patient is drinking water until the Capsule is dissolved and the esophageal flange have unfolded on the esophageal side of the TE-puncture.

Contraindications: None

CE Mark: Yes. Devices are CE-marked.

GMDN code: 62134 (Tracheoesophageal device insertion cap)

Sterilization: Non-Sterile

Raw material: Hypromellose, (HPMC).

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: 3 years after manufacturing.

Packaging: 15 pcs Provox Capsules are packed in a plastic container and then in a cardboard box.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-000-0000-RG

REF	Name	UDI-DI
7794	Provox Capsule 16Fr	07331791008993
7795	Provox Capsule 17Fr	07331791009006
7796	Provox Capsule 20Fr	07331791009013
7797	Provox Capsule 22.5Fr	07331791009020

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Vega	7331791-VPS-0-0EI-0002-2V

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Approved:	DD	Jon Berg - JONBER	2022-01-31 - 09:18
Released:	QA	Elin Andersson - ELIAND	2022-02-22 - 09:01

This document has been electronically signed by the persons above.

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Product Information

Provox® TwistLock

Product description:

The Provox TwistLock is placed on the top of the Insertion System folding tool and securely locked by twisting it clockwise. The TwistLock is keeping the folding tool in a closed position to facilitate easy insertion of a voice prosthesis into a Provox Capsule. After the voice prosthesis is placed into the Capsule, TwistLock is to be removed and discarded.

Document No: 10000035434 Edition: 05 Release date: 2022-02-22

Atos Medical AB *SE-242 35 Hörby, Sweden* *Web Site: www.atosmedical.com* *Org.nr 556268-7607*
Kraftgatan 8 *Tel: +46 (0) 415 198 00* *E-mail: info@atosmedical.com* *VAT no. SE556268760701*

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atosmedical.com

Product Information

Document ID:	*PF100-00-TechInfo*	**Edition:**	*05*

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

Classification: (EU) 2017/745 *Class I, Rule 1*

Intended Use: *Provox TwistLock is a single use Provox Insertion System accessory for easier loading of Provox Vega Voice Prosthesis into Provox Capsule by clinician.*

Use specifications:

Intended medical indication
For 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
Single use, Prescription only.
Intended part of the body/type of tissue applied to or interacted with
The device will only be in contact with the operator´s skin or glove.
Intended user profile
Head and Neck Surgeon for placement of voice prosthesis. Trained clinician (eg physician, SLP) for replacement of voice prosthesis.
Intended conditions of use
Placement of voice prothesis is performed at the time of, and in the environment of, tracheoesophageal puncture.
Replacement of voice prosthesis is performed in outpatient hospital settings, on average 4 times per year.

Contraindications: *None.*

CE Mark: *Yes. Devices are CE-marked.*

GMDN code: *63307 (Tracheoesophageal speech valve capsule mounting cap)*

Sterilization: *Non-sterile*

Raw material: *Polyamide PA2200*

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: *3 years after manufacturing.*

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Product Information

Packaging: *10 pcs Provox TwistLock are packed in a plastic zipper bag and then in a cardboard box together with IFU.*

Product Information

Devices under Basic UDI-DI: *7331791-VPS-A-000-0009-SB*

REF	Name	UDI-DI
8030	*Provox TwistLock 17Fr*	*07331791012747*
8031	*Provox TwistLock 20Fr*	*07331791012754*
8032	*Provox TwistLock 22.5Fr*	*07331791012761*

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox Vega	*7331791-VPS-0-0EI-0002-2V*
Provox Capsule	*7331791-VPS-A-000-0000-RG*

Document No: 10000035434 Edition: 05 Release date: 2022-02-22

Product Information

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Approved:	DD	Jon Berg - JONBER	2022-01-13 - 13:21
Released:	DD	Maria Persson - X-MARPER	2022-01-13 - 14:38

This document has been electronically signed by the persons above.

Provox® Protector

Product description:

Provox Protector is a reusable cover that provides protection and coverage of the tracheostoma. The Provox Protector is to be placed around the neck during the daytime to be an esthetic coverage and protect against items accidentally entering the tracheostoma. For hygienic reasons, the Provox Protector should be changed daily or sooner if required.

Document No: 10000036618 Edition: 04 Release date: 2022-01-13

Released

Atos Medical AB
Kraftgatan 8
SE-242 35 Hörby, Sweden
Tel: +46 (0) 415 198 00
Web Site: www.atosmedical.com
E-mail: info@atosmedical.com
Org.nr 556268-7607
VAT no. SE556268760701

Product Information

Document ID:	PF102-01-TechInfo	**Edition:**	04

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

Classification: (EU) 2017/745 Class I (1.1 rule 1)

Intended Use: Provox Protector is a reusable cover that provides protection and coverage of the tracheostoma.

Use specifications:

Intended medical indication: Product for rehabilitation for patients breathing through a tracheostoma.

Intended patient population: Patients after a tracheostomy or laryngectomy. Intended to be used by medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.

Intended usage: Reusable. Hand washing maximum three times and air dried.

Intended part of the body/type of tissue applied to or interacted with: Neck and upper body.

Intended user profile: Medical personnel or patients with sufficient cognitive ability and manual dexterity who are judged as able to manage the device independently by a clinician.

Intended conditions of use: The Provox Protector act as a protective and cosmetic cover of the tracheostoma for daytime use. Intended for use at home (indoor and outdoor), care facilities and hospitals and exercising under normal daily environment without any hygienic or environmental restrictions regarding temperature, moisture etc.

Frequency of use: Daily

Contraindications: No identified or known contraindications

CE Mark: Yes, the devices are CE marked.

GMDN code: 31065 (Tracheostoma protector, reusable)

Sterilization: Non-sterile

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Product Information

Raw material:

Provox Protector
- Polyester mesh
- Polyurethane foam
- Polyester brushed

Provox Protector Slim
- Polyester mesh
- PP non-woven
- Polyester brushed

Provox Protector Air
- PE spacer mesh
- Cotton textile

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. Temporary deviations within 2°C - 42°C are allowed.

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: Single packed in polyethylene bag and 10 pcs are packed in cardboard box.

Document No: 10000036618 Edition: 04 Release date: 2022-01-13

Product Information

Devices under Basic UDI-DI: 7331791-TEX-0-000-0001-WN

REF	Name	UDI-DI
7385	Provox Protector Small White 10 pcs	07331791012815
7385	Provox Protector Small White 1 pc	07331791015892
7386	Provox Protector Large White 10 pcs	07331791012822
7386	Provox Protector Large White 1 pc	07331791015908
7387	Provox Protector Slim Small White 10 pcs	07331791012839
7387	Provox Protector Slim Small White 1 pc	07331791015915
7388	Provox Protector Slim Small Blue 10 pcs	07331791012846
7388	Provox Protector Slim Small Blue 1 pc	07331791015922
7389	Provox Protector Slim Large White 10 pcs	07331791012853
7389	Provox Protector Slim Large White 1 pc	07331791015939
7390	Provox Protector Slim Large Blue 10 pcs	07331791012860
7390	Provox Protector Slim Large Blue 1 pc	07331791015946
7391	Provox Protector Air Small White 10 pcs	07331791012877
7391	Provox Protector Air Small White 1 pc	07331791015953
7392	Provox Protector Air Small Blue 10 pcs	07331791012884
7392	Provox Protector Air Small Blue 1 pc	07331791015960
7393	Provox Protector Air Large White 10 pcs	07331791012891
7393	Provox Protector Air Large White 1 pc	07331791015977
7394	Provox Protector Air Large Blue 10 pcs	07331791012907
7394	Provox Protector Air Large Blue 1 pc	07331791015984

Large White

Small White

Air Large

Slim Large

Atos Medical AB Compatible products:
Not applicable

Document No: 10000036618 Edition: 04 Release date: 2022-01-13

Quality Management System

Technical Info / Material Data Sheet

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Alexandra Holmberg - ALEHOL	2018-11-21 - 11:26
Reviewed:	QA	John Wennborg - JOHWEN	2018-11-24 - 17:02
Approved:	DD	Mikael Melefors - SEHRBSGM	2018-11-29 - 20:02
Released:	DD	Alexandra Holmberg - ALEHOL	2019-01-03 - 09:08

This document has been electronically signed by the persons above.

Document ID: PF005-02-TechInfo	Edition: 07

REF Number 7122, 7123

Product Name Provox® Dilator 17, Provox® Dilator 20

Models: 2 models: for 17Fr (dilates 19Fr), for 20Fr (dilates 22 Fr).

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

CE Mark: Yes

GMDN code: 62125 (Tracheoesophageal fistula dilator)

EAN code:

REF	Description	EAN code
7122	Provox Dilator 17	7331791000393
7123	Provox Dilator 20	7331791000409

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

Intended Use: 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 tracheoesophageal (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.

Description: The Provox Dilator 17 and the Provox Dilator 20 are tapered curved silicone rods used for dilating (increase the diameter of) TE punctures. The Provox Dilator 17 shall be used with Provox voice prostheses with an outer diameter of 17 Fr and the 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

Sterilization: Non-sterile, sterilizable by steam.

Raw material: Silicone with blue masterbatch.

Release date: 2019-01-03
Edition: 07
Document No: 1000038299

Released

Technical Info / Material Data Sheet

Latex information:	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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 and thereafter packed in a cardboard box.

Release date: 2019-01-03
Edition: 07
Document No: 1000038299

Quality Management System

Technical Info / Material Data Sheet

Justification:	Function:	Electronic signature justification:	Signed: Date (yyyy-mm-dd) - Time (hh:mm):
Issued:	DD	Alexandra Holmberg - ALEHOL	2018-12-20 - 11:48
Reviewed:	QA	John Wennborg - JOHWEN	2018-12-20 - 11:55
Approved:	DD	Mikael Melefors - SEHRBSGM	2018-12-21 - 10:50
Released:	DD	Alexandra Holmberg - ALEHOL	2019-01-03 - 09:08

This document has been electronically signed by the persons above.

Document ID: PF005-01-TechInfo	Edition: 08

REF Number 7211

Product Name Provox® Dilator

Models: 1 model

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

CE Mark: Yes

GMDN code: 62125 (Tracheoesophageal fistula dilator)

EAN code:

REF	Description	EAN code
7211	Provox Dilator	7331791000850

Produced by:
Atos Medical AB
Kraftgatan 8
P.O. Box 183
242 22 Hörby
Sweden

Intended Use: The Provox Dilator is intended for upsizing smaller trachea-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.

Description:

Provox Dilator is a stepwise tapered, about 140 mm (5.5 inch) long solid curved rod made of medical grade silicone. The diamater 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 asipration.

Sterilization: Non-sterile, sterilizable by steam.

Raw material: Silicone with blue masterbatch

Technical Info / Material Data Sheet

Latex information:	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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 and thereafter packed in a cardboard box.

Release date: 2019-01-03
Edition: 08
Document No: 1000038301

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Technical Info / Material Data Sheet

Document ID: PF012-01-TechInfo	Edition: 06

REF Number	7205
Product Name	Provox® Plug
Models:	1 model
Classification: (MDD 93/42/EEC)	IIa (2.1 Rule 5)
CE Mark:	Yes
GMDN code:	62119 (Tracheoesophageal speech valve occluder, non-valved)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	• Provox Plug are intended to seal the inner lumen of the voice prosthesis and therefore stop leakage of both air and fluids through the voice prosthesis. • Provox Plug are intended to facilitate determination of the type of leakage: Leakage around or leakage through the prosthesis • Provox Plug are intended to be inserted with the shaft of a Provox Brush by the patient or a clinician. • Provox Plug should be easy to insert, remove and clean. • Provox Plug are intended for single patient use in both a home environment or in a clinic.
Description:	The Provox Plug is a first-aid tool for temporarily stopping leakage through the voice prosthesis. The device is inserted into the opening of the Provox voice prosthesis. The medallion end can be taped to the skin if desired.
Sterilization:	Non-sterile.
Raw material:	Silicone.
Latex information	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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.

Released
Document No: 1000018298 Edition: 06 Release date: 2016-09-23

Technical Info / Material Data Sheet

Packaging: Provox Plug is separately packed in a plastic bag together with one brush and two instructions for use (Provox Plug and Provox Brush).

Reviewed by:

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Vice President QA&RA

2016-06-30

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Date

Approved by:

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Vice President Design & Development

2016-07-04

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Date

Atos Medical Your voice

Technical Info / Material Data Sheet

REF Number	8119, 8129, 8139
Product Name	Provox® Vega Plug
Models:	3 models, for 17, 20 and 22,5Fr.
Classification: (MDD 93/42/EEC)	IIa (2.1 Rule 5)
CE Mark:	Yes
GMDN code:	62119 (Tracheoesophageal speech valve occluder, non-valved)
Produced by:	Atos Medical AB Kraftgatan 8 P.O. Box 183 242 22 Hörby Sweden
Intended Use:	Provox Vega Plug are intended to seal the inner lumen of the voice prosthesis and therefore stop leakage of both air and fluids through the voice prosthesis. •Provox Vega Plug are intended to facilitate determination of the type of leakage: Leakage around or leakage through the prosthesis • Provox Vega Plug are intended to be inserted with the shaft of a Provox Brush by the patient or a clinician. Provox Vega Plug should be easy to insert, remove and clean. • Provox Vega Plug should be able to be attached to Provox LaryClip and Provox Tubeholder. • Provox Vega Plug are intended for single patient use in both a home environment or in a clinic.
Description:	The Provox Vega Plug is a first-aid tool for temporarily stopping leakage through a Provox Vega voice prosthesis. The device is inserted into the opening of the Provox Vega voice prosthesis and hence blocking any leakage through the valve.
Sterilization:	Non-sterile.
Raw material:	Silicone.
Latex information	Not manufactured with natural rubber latex.
Biological origin:	The device is not manufactured with any materials derived from human or animal source.
Handling and storage:	Keep dry and away from sunlight. Temperature limit 2 - 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.

Release date: 2016-09-23 Edition: 05 Document No: 10000018301

Released

Technical Info / Material Data Sheet

Packaging: Provox Vega Plug is separately packed in a plastic bag together with one brush and two instructions for use (Provox Vega Plug and Provox Brush).

Reviewed by:

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Vice President QA&RA

2016-06-30

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Date

Approved by:

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Vice President Design & Development

2016-07-04

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Date