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Provax® XtraFlange

Product description:

Provax 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.

Product Information

Document ID:	PF056-01-TechInfo	Edition:	06
Manufacturer:	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
Classification: (MDD 93/42/EEC)	IIb (2.1, rule 5)		
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.		
Use specifications:	Intended medical indication Reduce periprosthetic leakage on patients using indwelling Provox voice prostheses. Intended patient population Age: Typically, but not limited to patients above 60 years. Gender: Male and Female with a bias towards males Weight: Representative of overall human population Health and condition: All health and condition states 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, tracheal side. Secondary interaction (transient): Trachea, Esophagus, Pharynx. Intended user profile Insertion of the Provox XtraFlange, typical an SLP or other clinical professional experienced in voice prosthesis maintenance. Intended conditions of use At the time of, and in the environment of, voice prosthesis maintenance and/or change in a clinical setting.		

Product Information

Contraindications:	Provox XtraFlange shall NOT be used: - in patients in whom the tracheoesophageal (TE) puncture is too wide to ensure adequate retention of the Provox voice prosthesis. A too wide puncture may increase the risk of dislodgement and aspiration of the device and/ or the voice prosthesis. Provox XtraFlange will NOT increase retention of the prosthesis. - on Provox NiD or other voice prosthesis of any other brands. It may increase the risk of dislodgement and aspiration of Provox XtraFlange and/or voice prosthesis
CE Mark:	Yes. Devices are CE-marked.
GMDN code:	42533 (Tracheoesophageal speech valve, indwelling)
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 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 product is packed in a blister package made of PETG film and with a Tyvek (spun-bounded polyethylene) top film. It is then packed in a cardboard box together with a instruction for use. Finally tamper proof.

Product Information

Devices under Basic UDI-DI: 7331791-VPS-A-0E0-0008-67

REF	Name	UDI-DI
7275	Provox XtraFlange 22.5	07331791006920
7276	Provox XtraFlange 20	07331791006937
7277	Provox XtraFlange 17	07331791006944

Atos Medical AB compatible products:

Range	BASIC UDI-DI
Provox2 Voice Prosthesis	7331791-VPS-0-0EI-0005-36
Provox ActivValve	7331791-VPS-0-00I-0001-NT
Provox Vega	7331791-VPS-0-0EI-0002-2V
Provox Vega XtraSeal	7331791-VPS-0-0EI-0004-33

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