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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.

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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