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This document has been electronically signed by the persons above.

## 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.

## Product Information

<b>Document ID:</b>	PF100-00-TechInfo	<b>Edition:</b>	05
<b>Manufacturer:</b>	Atos Medical AB Kraftgatan 8 SE-242 35 Hörby, Sweden		
<b>Classification: (EU) 2017/745</b>	Class I, Rule 1		
<b>Intended Use:</b>	Provox TwistLock is a single use Provox Insertion System accessory for easier loading of Provox Vega Voice Prosthesis into Provox Capsule by clinician.		
<b>Use specifications:</b>	<p><b>Intended medical indication</b> For voice rehabilitation in laryngectomized patients.</p> <p><b>Intended patient population</b> Patients of any age. Cognitive ability, by a clinician judged as sufficient. Manual dexterity, by a clinician judged as sufficient.</p> <p><b>Intended usage</b> Single use, Prescription only.</p> <p><b>Intended part of the body/type of tissue applied to or interacted with</b> The device will only be in contact with the operator's skin or glove.</p> <p><b>Intended user profile</b> Head and Neck Surgeon for placement of voice prosthesis. Trained clinician (eg physician, SLP) for replacement of voice prosthesis.</p> <p><b>Intended conditions of use</b> Placement of voice prosthesis 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.</p>		
<b>Contraindications:</b>	None.		
<b>CE Mark:</b>	Yes. Devices are CE-marked.		
<b>GMDN code:</b>	63307 (Tracheoesophageal speech valve capsule mounting cap)		
<b>Sterilization:</b>	Non-sterile		
<b>Raw material:</b>	Polyamide PA2200		
<b>Latex information:</b>	Not manufactured with natural rubber latex		
<b>Biological origin:</b>	The device is not manufactured with materials derived from human or animal source.		
<b>Handling and storage:</b>	Store the product dry and away from sunlight at room temperature. Excursions permitted between 2°C - 42°C.		
<b>Waste handling and disposal:</b>	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.		
<b>Hazardous components:</b>	None		
<b>Expiration date:</b>	3 years after manufacturing.		



## Product Information

**Packaging:**

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

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## 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