

## Provox Dilator



### Product description:

Provox Dilator is a single use, disposable device used for dilating or stenting a tracheoesophageal (TE) puncture. The device is intended for use by Health care professionals (HCPs) trained in the management of laryngectomy patients, only. Provox Dilator is a stepwise tapered, about 140 mm (5.5 inch) long, solid curved rod made of medical grade silicone. The diameter 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 retention collar is present that is designed to prevent the dilator from sliding back to a thinner section. The dilator has a safety strap with medallion that can be taped to the neck to keep the dilator in place and that is designed to reduce the risk of accidental aspiration of the device.

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|--------------------------------------|---|-----------------|-----|
| <b>Document ID:</b>                  | PF130-01-TechInfo   | <b>Edition:</b> | 2.0 |
| <b>Manufacturer:</b>                 | Atos Medical AB<br>Kraftgatan 8<br>SE-242 35 Hörby, Sweden  |                 |     |
| <b>Classification: (EU) 2017/745</b> | Class IIa (Rule 5)  |                 |     |
| <b>Intended Use:</b>                 | The Provox Dilator is intended to dilate or stent the tracheoesophageal puncture in laryngectomized patients.   |                 |     |
| <b>Use specifications:</b>           | <b>Intended medical indication</b><br>Provox Dilator is intended for laryngectomized patients with a tracheoesophageal (TE) puncture.<br><br><b>Intended patient population</b><br>Adult patients, 18+ years.<br><br><b>Intended usage</b><br>Single use, Prescription.<br><br><b>Intended part of the body/type of tissue applied to or interacted with</b><br>Tracheostoma: Mucosal membrane.<br>In contact with wall between the trachea and esophagus.<br><br><b>Intended user profile</b><br>Health care professionals.<br><br><b>Intended conditions of use</b><br>Environment: Hospital use.<br>Replacement rate: The dilator shall be replaced after each use.  |                 |     |
| <b>Operating principles</b>          | Provox Dilator is a single use dilatation and stenting tool for the TE puncture. The dilator enables the dilation of the TE puncture to fit different voice prostheses. This is possible due to its varying diameter size. The presence of the dilator also keeps the TE puncture open and prevents esophageal contents from entering the trachea. The tip of the device is inserted into the TE puncture until a slight resistance is felt and is held there for a desired amount of time to allow sufficient dilatation or stenting. For further dilatation the dilator is moved further down into the esophagus. Small retention collars are present to prevent the dilator from sliding back to a thinner section. Provox Dilator also has a safety strap and medallion that is designed to reduce the risk of accidental aspiration of the device. |                 |     |
| <b>Contraindications:</b>            | The device is not intended to be used for puncture dilation at the time of surgical creation of the puncture.   |                 |     |
| <b>CE Mark:</b>                      | Yes. Devices are CE-marked.   |                 |     |
| <b>GMDN code:</b>                    | 67401 (Tracheoesophageal fistula dilator, single-use)   |                 |     |
| <b>Sterilization:</b>                | Non-sterile.  |                 |     |
| <b>Raw material:</b>                 | Silicone with blue masterbatch (Direct contact with patient).   |                 |     |

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| <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.  |
| <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>             | 5 years after manufacturing.   |
| <b>Packaging:</b>                   | Provox Dilator is packed 10 pcs together in separate plastic bags made of polyethylene. They are packaged together with instructions for use in a cardboard box.               |

**Devices under Basic UDI-DI: 7331791-VPS-A-000-0011-RQ**

| REF  | Name           | UDI-DI         |
|------|----------------|----------------|
| 8341 | Provox Dilator | 07331791181207 |

**Atos Medical AB compatible products:**

| Range | BASIC UDI-DI |
|-------|--------------|
| N/A   | N/A          |

Document Approvals  
Approved Date: 2025-04-10

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