

The Provox ActiValve is a voice rehabilitation system intended for use in prosthetic voice restoration following a total laryngectomy manufactured by Atos Medical (Atos). It is specifically designed to address prosthesis users that experience frequent changes of their voice prosthesis and is available in three configurations, which vary according to the force that is required to open the valve for speech. A Provox ActiValve device is intended for patients who are experiencing early leakage with previous voice prosthesis (device life less than 4 – 8 weeks).

Provox ActiValve Warranty Start Date

The Warranty Start Date begins on the date of placement as recorded in the patient's clinical notes. It applies only to new Provox ActiValve Users (first time users) and only for the initial placement. The Warranty period cannot be extended or renewed or otherwise affected due to subsequent replacements.

Strength and Voice

If during the first 30 days following the Start Date a different valve strength (ie Light, Strong, XtraStrong) is required, the Provox ActiValve device may be exchanged at no charge for a device of higher or lower valve strength. This exchange is available only within the first 30 days and only one "valve strength" exchange is permitted. If following the exchange, voicing remains difficult, the device may be returned to Atos for a full credit by the Purchaser, up to 60 days from the Warranty Start Date.

Days Inserted	Issue	Exchange	Credit	%
0 – 30	Incorrect Strength	X		100%
31 – 60	Incorrect Strength		X	100%
61+	Incorrect Strength	NA	NA	NA

Leakage Through

If during the first 30 days following the Start Date the user experiences leakage through, Atos will replace the prosthesis OR apply a credit towards the purchase of any other Atos Provox product. This Warranty is limited to leakage through the prosthesis as identified by a clinical professional. The Warranty does not cover device removal or dislodgement due to diagnostic tests, treatment procedures, improper care or leakage around. If the user experiences leakage through beyond the 30 day exchange period, the Purchaser will be credited as outlined in the chart below.

Days Inserted	Issue	Exchange	Credit	%
0 – 30	Leakage Through	X	X	100%
31 – 60	Leakage Through		X	100%
61-90	Leakage Through		X	50%

** Credit(s) are limited to the purchase of another Provox ActiValve or other Atos Provox products

Product Return

To return or exchange a device please contact Atos at 800.217.0025 for a Returned Goods Authorization (RGA) number and a special return package before returning the Provox ActiValve device. Insurance adjustments are the responsibility of the purchaser.

Information for Users and Clinicians Regarding Product Replacement

It is ultimately the responsibility of the clinician to select the appropriate opening force configuration for each Provox ActiValve user. Because each user's needs are different and distinct, it may not be obvious from the outset which configuration is best suited for any given individual. For this reason, users who meet all of the criteria set forth in the Product Replacement Protocol may apply to exchange their originally selected Provox ActiValve for a replacement with a different opening force configuration at no additional cost. For the purpose of the Product Replacement Protocol, the term "user" means an individual user of a Provox ActiValve Prosthesis or a clinician action on behalf of such user.

Product Replacement Protocol

1. Users must notify their supplier of any problems they experience with the opening force of their originally selected Provox ActiValve prosthesis within thirty (30) days of insertion of the product. In addition, users must complete and send the Replacement Request Form within thirty (30) days of insertion of the originally selected Provox ActiValve.
2. Users who meet the notification requirements set forth above, are eligible solely to receive a Provox ActiValve that is of the same size (length between flanges) but configured differently from the originally selected Provox ActiValve. Atos does not offer, and users are not eligible to obtain, any free replacement prostheses that have the same opening force configuration as the originally selected or a different size from the originally selected Provox ActiValve.
3. Users' Provox ActiValve prosthesis will not be replaced if: (a) they have failed to comply with the instructions set forth in the Provox ActiValve Clinician's and Patient's Manuals; or (b) their originally selected Provox ActiValve has been damaged due to improper use or clinician insertion, maintenance or other handling.
4. Users who have received a free Provox ActiValve replacement must return their originally selected Provox ActiValve to the supplier within ten (10) days of receipt of the replacement prosthesis. Users are required to return their originally selected Provox ActiValve in secure packaging with the prosthesis immersed in (max 25mL or 1oz) 70% alcohol. Atos reserves the right to require payment for the replacement of any Provox ActiValve if: (a) the user fails to return the originally selected Provox ActiValve; or (b) the returned prosthesis has been damaged due to improper user or clinician insertion, maintenance, packaging or other handling.

Disclaimer of Warranty and Limitation of Liability

Atos reserves the right to refuse free replacement of the Provox ActiValve at any time. Atos warrants that the product ("Product") is sold free from defects in material and workmanship for a period of thirty days. **EXCEPT AS SET FORTH IN THE PRECEDING SENTENCE, THERE ARE NO EXPRESS OR IMPLIED WARRANTIES, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.** Your sole remedy for any breach of this warranty will be the replacement of the Product. The above Information for Users, Clinicians, and Product Replacement Protocol do not represent or constitute an acknowledgement or admission, either express or implied, of any defect, fault or liability of any kind on the part of Atos.

CAUTION: United States Federal law restricts this device to sale, distribution and use by or on order of a physician or a licensed practitioner trained in the procedure. Please review the Instructions for Use (IFU) before proceeding. Copies of the IFU are available at www.atosmedical.us or from Atos Medical Inc. The prosthesis should be inspected regularly, at least every six months. For additional information contact your Atos Medical Representative or Atos Medical Customer Service at 800.217.0025.

FACILITY INFORMATION

Facility Name		Request Date	
Department	Address		
City	State	Zip	
Phone	Email		

REPLACEMENT INFORMATION

We have filed your replacement request under the RGA Number listed below. Please be sure to provide this number in all correspondence pertaining to your replacement request.

Patient Name		Insertion Date Current ActiValve (MM/DD/YYYY)	
RGA Number	REF Number	Lot Number	
Description of problems experienced with current prosthesis			
Has the voice prosthesis been removed? ☐ No ☐ Yes (If Yes, provide removal date)		Removal Date (MM/DD/YYYY)	
Which prosthesis do you request as a replacement? Model: ☐ Provox ActiValve Light ☐ Provox ActiValve Strong ☐ Provox ActiValve XtraStrong Size: ☐ 6mm ☐ 8mm ☐ 10mm ☐ 12.5mm			
Ship To Name			
Ship To Address			
Ship To City		Ship To State	Ship To Zip

CLINICIAN INFORMATION

Clinician Name	Clinician Signature	Date
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