

APrevent® VOIS

Vocal Implant System



Adjustable implant system for glottic insufficiency

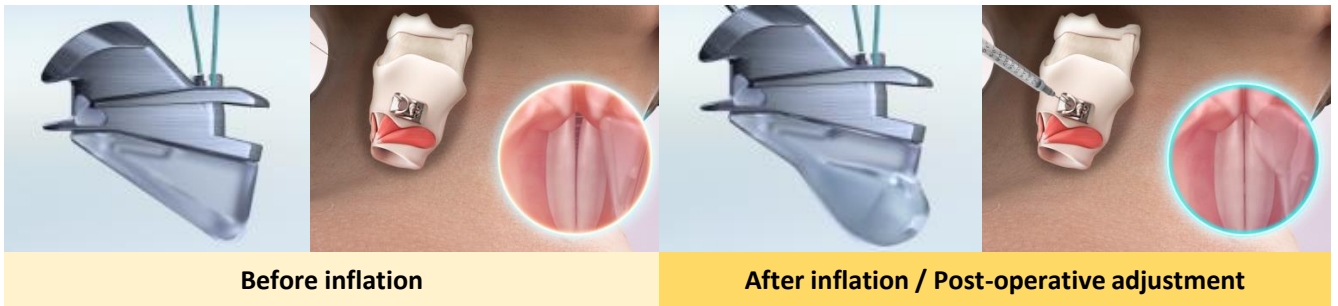
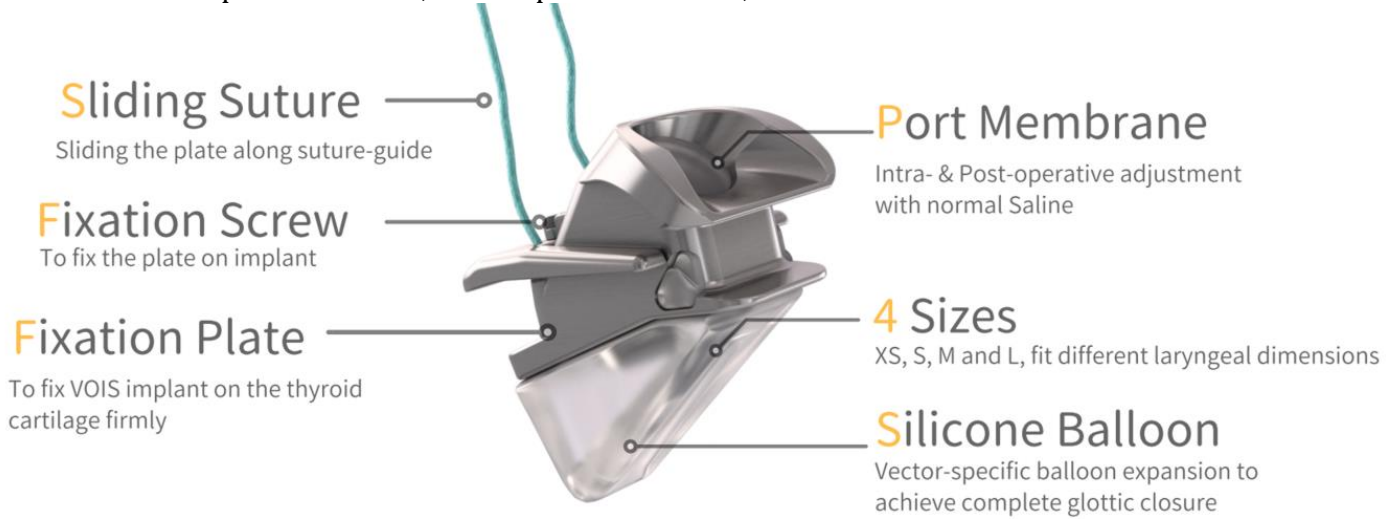
- *Long-term , intra and post-operative adjustable implant*
- *Complete closure of anterior and posterior glottic gap*
- *Minimal invasive and optimal outcome for each patient*



The APrevent® Vocal Implant System (VOIS) is designed for treatment of glottic insufficiency and unilateral vocal fold paralysis (UVFP). It is used in type I thyroplasty procedure to improve voice quality and to achieve a complete closure of the glottic gap by complete medialization of the paralyzed vocal fold in its full length.

The APrevent® VOIS is a long-term implant available in four different sizes (XS, S, M and L), with a specifically designed instrument set. Each implant size has two versions differing in the heights of the anterior flange of the titanium housing to fit to various thickness of thyroid cartilage.

The APrevent® VOIS consists of three components: titanium housing with integrated port-chamber and port-membrane, fixation plate with screw, and an in- and deflatable silicone cushion.



Features of APrevent® VOIS

- **Adjustability**

Cushion can be adjusted intra and post-operatively

- **Standardized procedure**

Instrument set designed for standardization of surgical procedure

- **Optimization**

Individual fine tuning with result optimization, even after the operation

- **Delicate design**

Vector specific expansion of silicon cushion with complete glottic gap

- **Non-allergic material**

Implant is made by medical grade titanium, silicone and PET suture

- **Minimally Invasive**

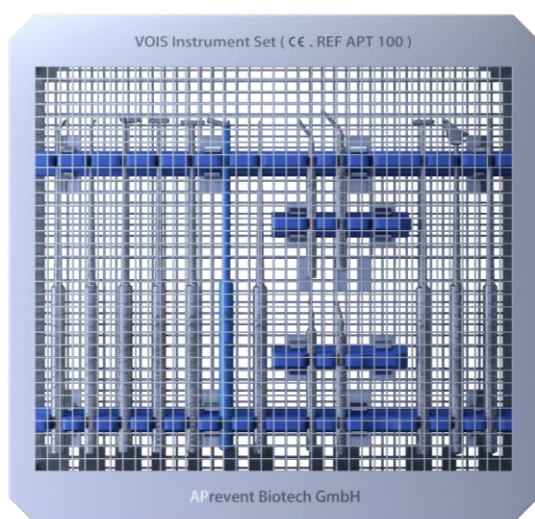
Shorter operation time with reduced complication risks



APrevent® VOIS-Instruments are specifically designed for type I Thyroplasty to help defining the correct orientation, precise positioning and proper size of the thyroplasty window, in order to facilitate the implantation. They are available in a 15 instrument-set (APT101-APT115) placed in a reusable stainless box and are delivered unsterile. The instrument APT116 is used for titanium housing selection and is offered as a supplement.



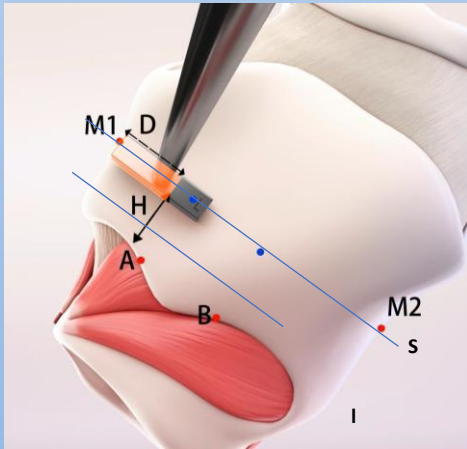
The APrevent® VOIS Instruments contain 16 instruments to facilitate the smooth implantation of the VOIS-Implant. They are specifically designed for the precise creation of the thyroplasty window on the thyroid lamina, fitting and securing of the implant into the thyroplasty window and to support the surgeons in selecting the optimal size, position and function of the VOIS-implant. All accessories and instruments can only be used during a type I thyroplasty procedure in adjunction with the insertion of the VOIS-Implant.



Features of APrevent® VOIS instrument set

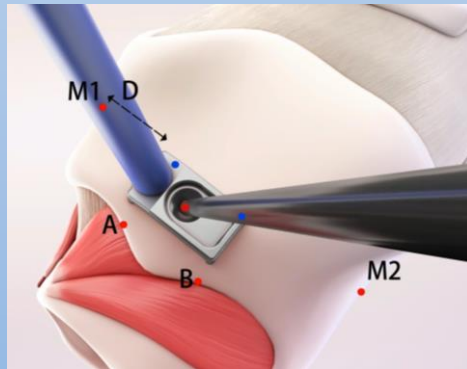
- **Non-allergic material**
Instruments are made of medical grade stainless steel and peek
- **Measurement**
Precise definition of implant size and window location
- **Window size checking**
Confirm accurate size of thyroid window before implantation
- **Standardization**
Standardized procedure to lower the learning curve

* Please read the IFU to understand all processes before using this product.



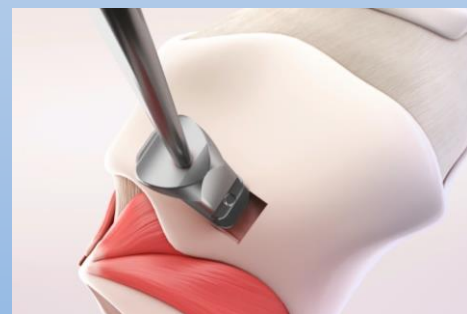
Allocation of key points, use specific VOIS instrument set

- Find "M1", midpoint of anterior thyroid cartilage border
- Find inferior tubercle, define "A", "B" and inferior border line "I"
- Find "M2", posterior thyroid cartilage border, then define superior line "S" passing through "M1M2", parallel to "I"
- Use APT104 instrument to find the height of window "H"
- Evaluate overall length "S", use APT105/106 to decide distance "D"
- Cross "D" and "H", find the location of window



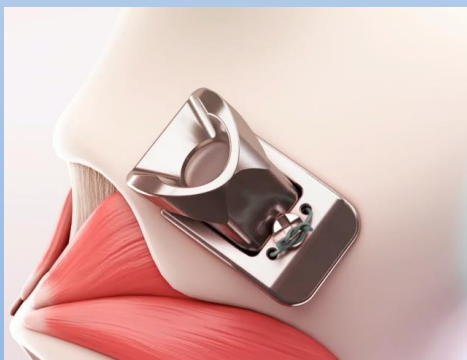
Window outline and drilling

- An 11x6mm rectangular thyroplasty window is outlined using the APT107 "Window Outline Template" under low-energy electrocautery current for marking.
- A 4mm hole is then drilled at the center of the rectangle until the inner perichondrium is visible.



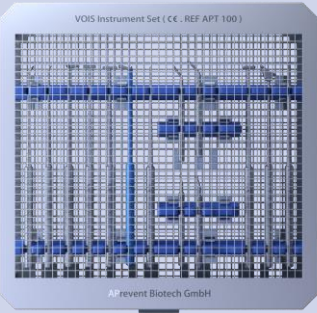
Window trimming

- APT113 "window size checking gauge" is applied to confirm the accurate size of the window.
- After careful mobilization of the endolaryngeal tissue, an "implant checking gauge" is used to test the fitting of the implant titanium housing into the window.



VOIS implantation

- Before implantation, check if the balloon is functional.
- The implant is inserted. The fixation-plate is then slid along the suture-loop down to the posterior part of the thyroplasty window.
- Fixation plate is screwed clockwise to firmly secure the implant on the thyroid lamina. After screwing, the sliding suture is knotted and cut.

Product Code	Product Description	Technical Detail
APV001 APV008 	APV001 VOIS-XS Height of housing anterior flange: 2.5mm APV008 VOIS-XS_3.0 Height of housing anterior flange: 3.0mm	1 box, delivered sterile Size: XSmall Maximal filling volume: 0.17ml Dimensions of balloon: 7 x 9mm
APV002 APV009 	APV002 VOIS-S Height of housing anterior flange: 2.5mm APV009 VOIS-S_3.0 Height of housing anterior flange: 3.0mm	1 box, delivered sterile Size: Small Maximal filling volume: 0.25ml Dimensions of balloon: 8 x 11mm
APV003 APV010 	APV003 VOIS-M Height of housing anterior flange: 3.0mm APV010 VOIS-M_3.5 Height of housing anterior flange: 3.5mm	1 box, delivered sterile Size: Medium Maximal filling volume: 0.30ml Dimensions of balloon: 8 x 15mm
APV004 APV011 	APV004 VOIS-L Height of housing anterior flange: 3.0mm APV011 VOIS-L_3.5 Height of housing anterior flange: 3.5mm	1 box, delivered sterile Size: Large Maximal filling volume: 0.30ml Dimensions of balloon: 8 x 18mm
APT100 	VOIS Instrument Set VOIS instrument set only to be used in Type I thyroplasty surgical procedure for facilitating location and design of the thyroplasty window for installing the VOIS-implant. APT100- Instrument Set 1 x Instrument tray 15 x Instruments (APT101-APT115) APT101- Blunt Elevator APT102- Sharp Elevator APT103- Thyroid Cartilage Ruler (metric) APT104- Rectangular Upper Window Edge Caliper APT105- Linear Anterior Window Edge Caliper XS, S APT106- Linear Anterior Window Edge Caliper M, L APT107- Window Outline Template APT108- Cartilage Marker APT109- Vocal Process Sounding Probe XS APT110- Vocal Process Sounding Probe S APT111- Vocal Process Sounding Probe M APT112- Vocal Process Sounding Probe L APT113- Window Size Checking Gauge APT114- Implant Checking Gauge APT115- Screw Driver APT116- Implant Checking Gauge S	1 set/tray Reusable Delivered non-sterile, autoclavable The instruments also can be ordered individually.

