

# 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 glottis gap
- Minimal invasive and optimal outcome for each patient

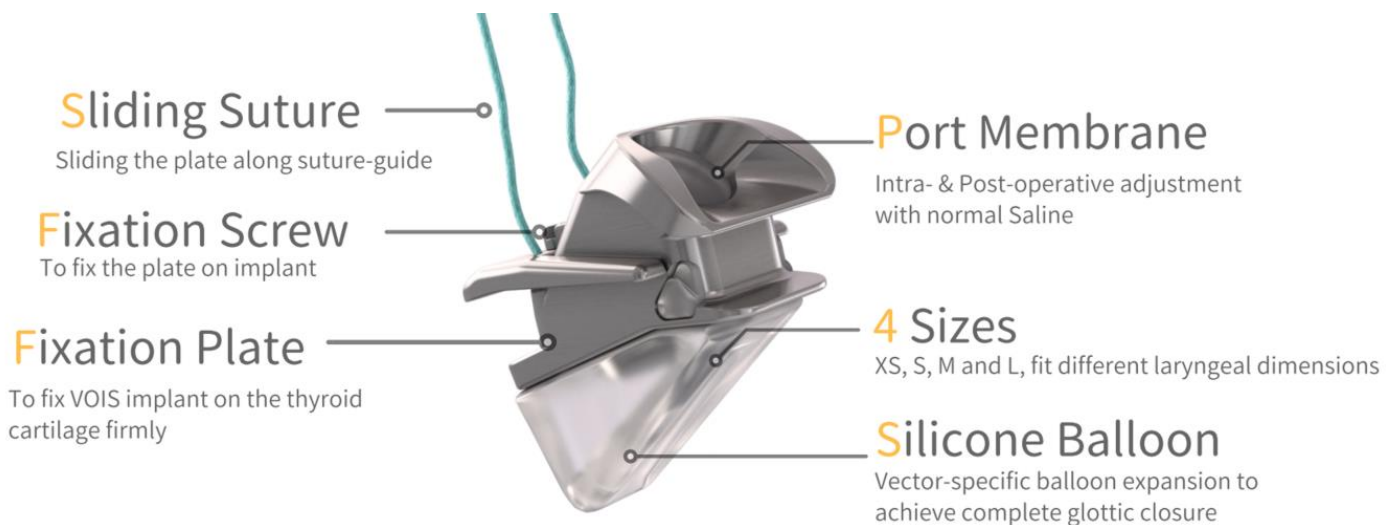


 <http://www.apreventmed.com/>

**The APrevent® Vocal Implant System (VOIS)** is designed for treatment of unilateral vocal fold paralysis (UVFP). It is used in type I thyroplasty procedures to improve the phonation in patients with UVFP, which is designed to achieve a complete closure of the glottic gap or complete medialization of the paralyzed vocal fold in its full length.

**The APrevent® VOIS is a long-term implants** are available in four different dimensions (XS, S, M and L), as well as a wide range of different and application-specific accessories and instruments.

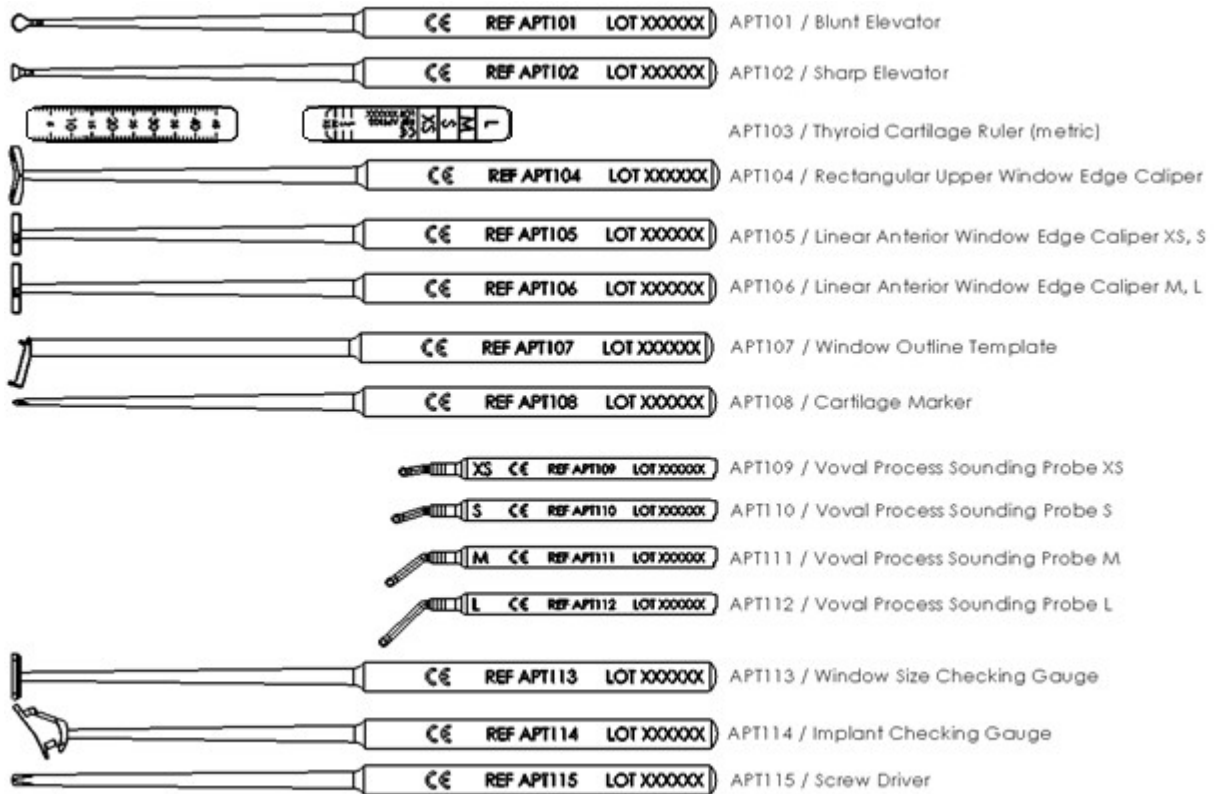
The APrevent® VOIS consists of three components, the titanium housing with integrated port-chamber and port-membrane, fixation plate with screw, and the in- and deflatable silicone cushion.



#### Features of APrevent® VOIS

- Non-allergic material    **Implant is made by medical grade titanium, silicone and PET suture**
- Delicate design         **All functional components are integrated in one implant**
- Individualized         **Surgeon determines the fill volume of cushion to fit each patient**
- Adjustability           **Cushion can be adjusted intra and post-operatively**
- Best result              **Fully closure of anterior and posterior glottis gap**
- Minimal invasive       **The operation is the same as existed; adjustment requires no surgery**

In order to facilitate the implantation a comprehensive instrument set is available which mainly helps in defining the correct orientation, position and size of the thyroplasty window.



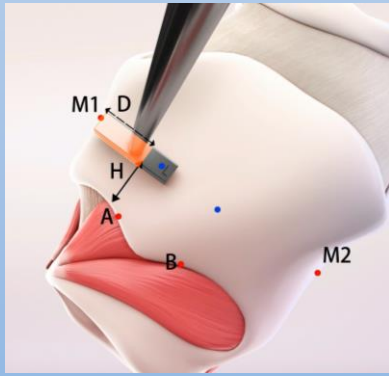
**The APrevent® VOIS Instrument Set** contains 15 instruments, all accessories and instruments can only be used during a type I thyroplasty procedure in adjunction with the insertion of the VOIS-Implants. These are specifically designed for the precise creation of the thyroplasty window on the thyroid lamina, fitting and securing of the implant in the thyroplasty window.

#### Features of APrevent® VOIS instruments

- Non-allergic material      Instruments are made by medical grade stainless and peek
- Measurement                Precisely measure the larynx size, define implant and window size
- Window localization        Clearly identify cartilage edge and window place
- Sounding probe                Check window position and implant size before window cutting
- Window size checking        Specific instruments to confirm the accurate size of the window

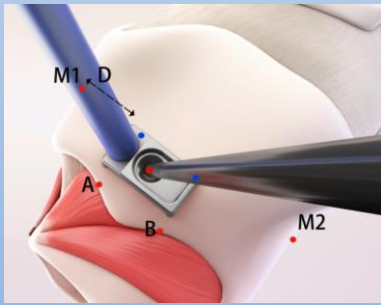
\* Please read the IFU to understand all processes before using this product.

### Allocation of key points, use specific VOIS instrument set



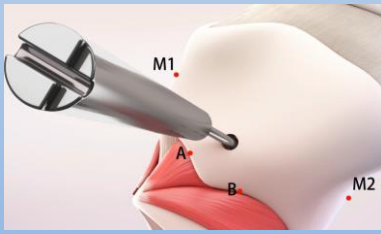
- Find “M1”, midpoint of anterior thyroid cartilage border
- Find inferior tubercle, define “A”, “B” and inferior border line “I”
- Find “M2”, posterior thyroid cartilage border, then define superior line “S” passing through “M”, parallel to “I”
- Use APT104 instrument to find the height of window “H”
- 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 checking with vocal process sounding probe



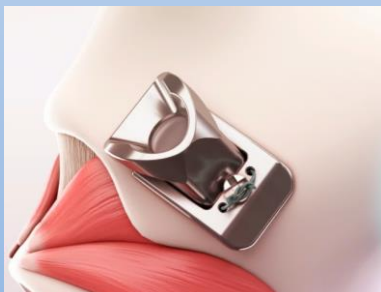
- APT109/110/111/112 “vocal process sounding probe” has XS/S/M/L 4 sizes
- It’s applied to confirm window position and implant size under scope examination.
- After checking, drill a marked 11x6mm rectangular window.

### Window trimming



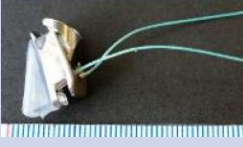


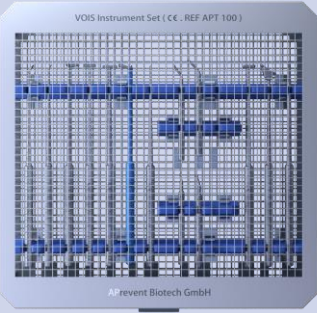


- APT113 “window size checking gauge” is applied to confirm the accurate size of the window.
- After careful mobilization of the endolaryngeal tissue, an “implant checking gauge” is used to test the fitting of the implant titanium housing into the window.

### 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
<b>APT001</b> 	<b>VOIS-XS</b> For type I thyroplasty,  1 x Implant	1 box, delivered sterile Size: XSmall <b>Maximal filling volume: 0.17ml</b> Heights of housing anterior flange: 2.5mm Dimensions of balloon: 7 x 9mm
<b>APT002</b> 	<b>VOIS-S</b> For type I thyroplasty  1 x Implant	1 box, delivered sterile Size: Small <b>Maximal filling volume: 0.25ml</b> Height of housing anterior flange: 2.5mm Dimensions of balloon: 8 x 11mm
<b>APT003</b> 	<b>VOIS-M</b> For type I thyroplasty  1 x Implant	1 box, delivered sterile Size: Medium <b>Maximal filling volume: 0.30ml</b> Height of housing anterior flange: 3mm Dimensions of balloon: 8 x 15mm
<b>APT004</b> 	<b>VOIS-L</b> For type I thyroplasty  1 x Implant	1 box, delivered sterile Size: Large <b>Maximal filling volume: 0.30ml</b> Height of housing anterior flange: 3mm Dimensions of balloon: 8 x 18mm
<b>APT100</b>  	<b>VOIS Instrument Set</b> VOIS instrument set only to be used in Type I thyroplasty surgical procedures for facilitating location and design of the thyroplasty window for installing the VOIS-implants.  1 x Instrument tray 15 x Instruments  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	1 set/tray  Reusable Delivered non-sterile, autoclavable  The instruments also can be ordered individually.

