APrevent® VOIS

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Instructions for use

REF	Poduct Name
APV001	VOIS-XS
APV002	VOIS-S
APV003	VOIS-M
APV004	VOIS-L
APV008	VOIS-XS_3.0
APV009	VOIS-S_3.0
APV010	VOIS-M_3.5
APV011	VOIS-L_3.5
APT100	Instrument Set
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

APV001-APV004, APV008-APV011 CE 0297 APT100-APT116 CE

STERILE EO MR B_{max} = 3T Rx Use Only

APrevent Better Voice, Better Life

1.1 Product Name-REF

Name of the complete System including all implants and instruments:

➔ Vocal Implant System (VOIS)

Instruments:

REF	Product name
APT100	Instrument Set
APT101	Blunt Elevator
APT102	Sharp Elevator
APT103	Thyroid Cartilage Ruler (metric)
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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

Implants:

REF	Product name
APV001	VOIS-XS
APV002	VOIS-S
APV003	VOIS-M
APV004	VOIS-L
APV008	VOIS-XS_3.0
APV009	VOIS-S_3.0
APV010	VOIS-M_3.5
APV011	VOIS-L_3.5

1.2 Language

English.

1.3 Terminology / Abbreviation

VOIS → **V**ocal **I**mplant **S**ystem

1.4 Product Description

APrevent® Vocal Implant System (VOIS) is intended to be used for treatment of unilateral vocal fold paralysis (UVFP)/glottic insufficiency. It includes the following surgical instrument set and implants:

The VOIS Instruments are specifically designed for the thyroplasty procedure, facilitating location and design of the thyroplasty window. These are placed in a reusable sterilization tray. The instrument set is supplied non-sterile.

The VOIS Implants consist of three components:

1) titanium housing with integrated port-chamber and port-membrane

2) fixation plate with screw, and

3) the in- and deflatable silicone cushion(or balloon).

The silicone cushion of the inserted implant presses the mid-membranous and the ligamentous part of the vocal fold towards the midline of the larynx(or the contralateral vocal fold) as well as against the vocal process of the arytenoid cartilage, whereby the turning of the arytenoid cartilage is promoted. This procedure leads to the fact that the vocal fold already slightly moves towards a medial direction during the implantation of the product through compression on the mid-membranous part of the vocal fold(spacer-effect). However, an optimal medialization and elongation of the vocal fold with tensioning mostly occur after the inflation of the balloon, whereby additional pressure is exerted onto the ligamentous part of the vocal fold and vocal process of the arytenoid cartilage.

The implants are available in four sizes without consideration of genders. Different implant sizes correspond to various heights of the triangular portion of the silicone cushion and expansion vector of the silicone cushion. Each implant size is available in two heights of anterior flange of the titanium housing to fit in various thickness of thyroid cartilage. The implant is for single use only and supplied sterile.

The injection needles are used for in- and deflation of the silicone cushion via the integrated port-system. Users shall choose the needles meeting specifications listed in combination products for operation.

REF	Product Name	Implant Size	Anterior Flange Height of Housing
APV001	VOIS-XS	XS	2.5 mm
APV002	VOIS-S	S	2.5 mm
APV003	VOIS-M	M	3.0 mm
APV004	VOIS-L	L	3.0 mm
APV008	VOIS-XS_3.0	XS	3.0 mm
APV009	VOIS-S_3.0	S	3.0 mm
APV010	VOIS-M_3.5	M	3.5 mm
APV011	VOIS-L_3.5	L	3.5 mm

1.5 Intended Use

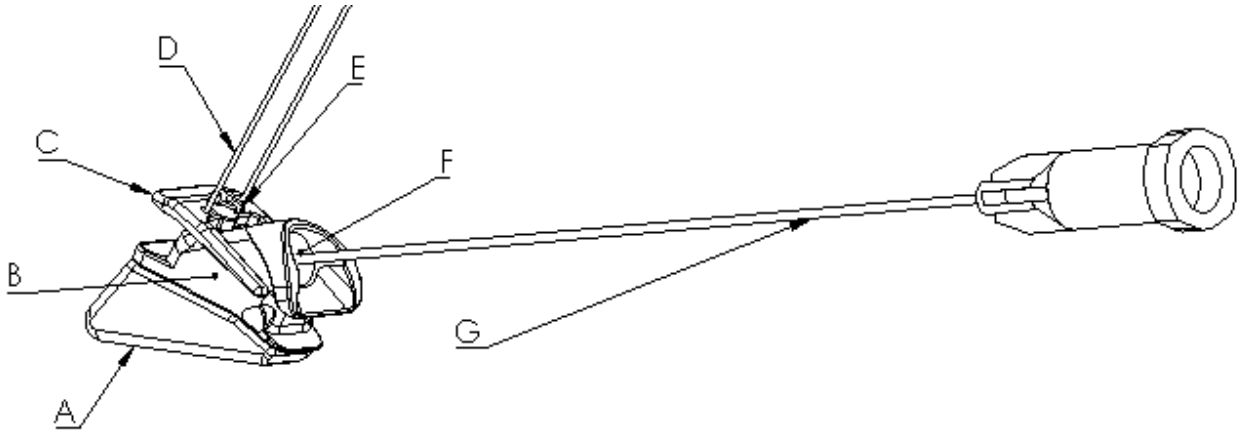
The VOIS implants are intended to be used for Type I Thyroplasty operations in patients with unilateral vocal fold paralysis (UVFP)/glottic insufficiency to improve voice quality.

The VOIS instrument set is intended only to be used in Type I Thyroplasty surgical procedures for facilitating location and design of the thyroplasty window for installing the VOIS implants.

Indication:
Type I Thyroplasty in patients with glottic insufficiency (or unilateral vocal fold paralysis) for voice quality improvement. The VOIS Instrument set is only to be used with the VOIS Implants for treatment of glottic insufficiency.

1.6 Definitions

VOIS Implant:



A: Balloon

B: Housing

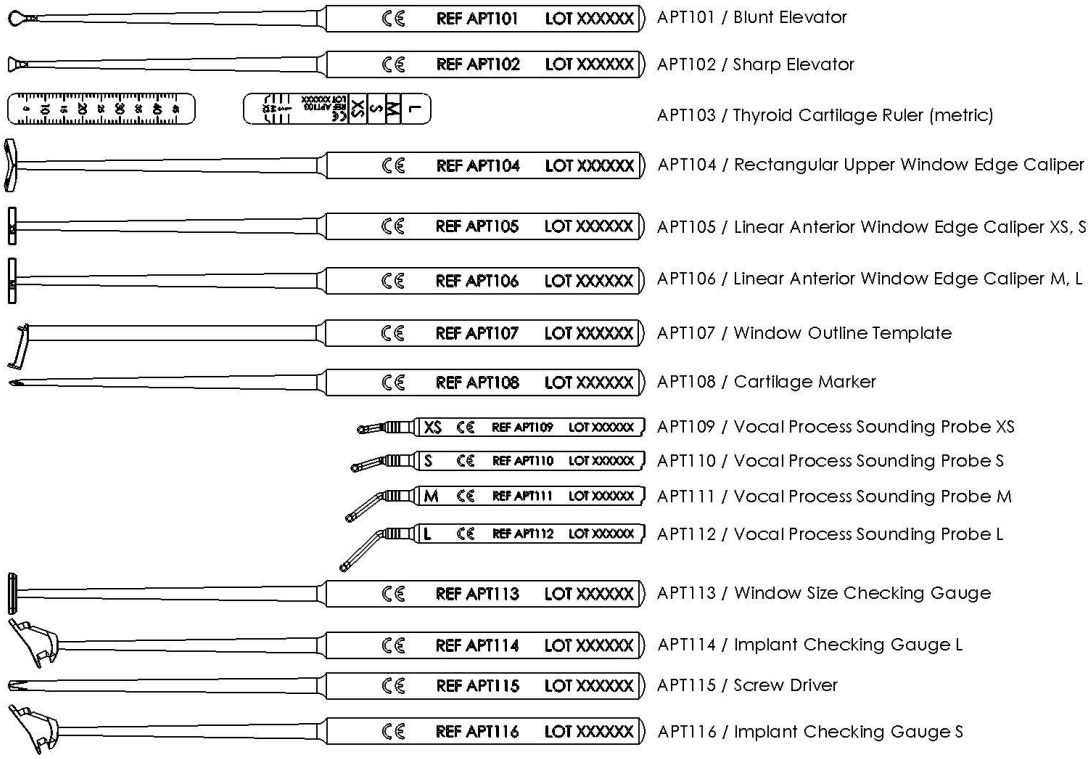
C: Fixation plate

D: Sliding sutures

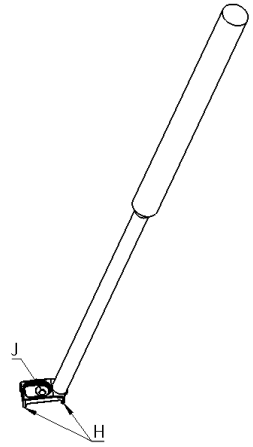
E: Fixation screw

F: Port membrane

Instruments:



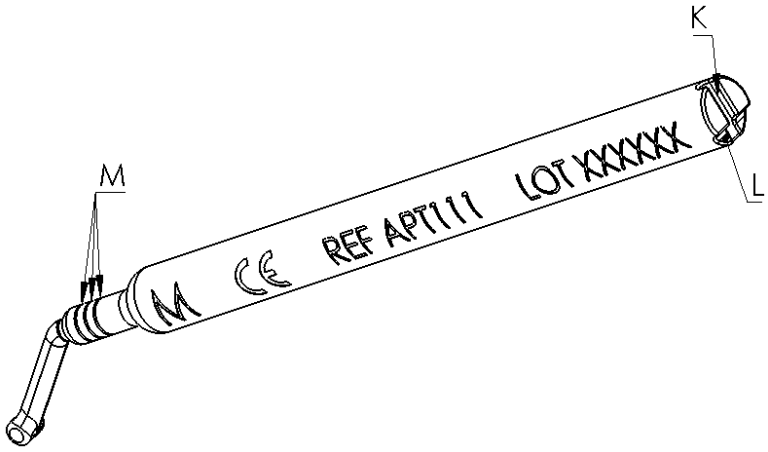
Window Outline Template:



H: Legs

J: Pit and hole

Vocal Process Sounding Probe:

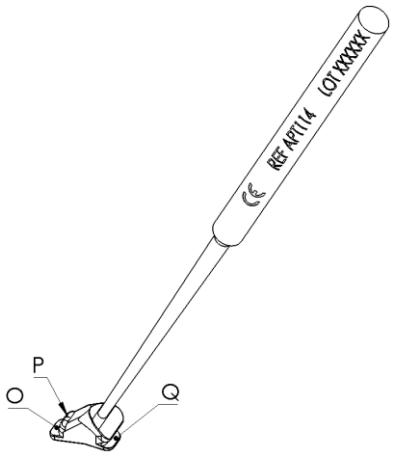


K: Marking orientation (Anterior - Posterior)

L: Marking posterior

M: Marking depth

Implant checking gauge:

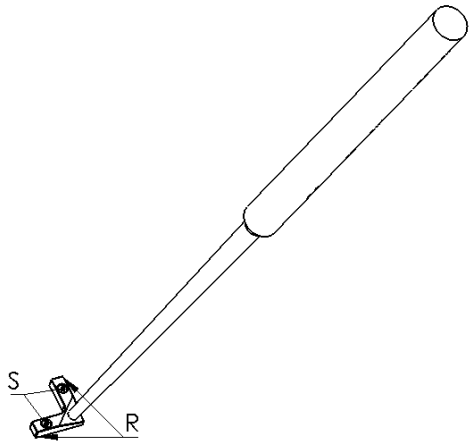


O: Posterior flange

P: Marking screw-hole position

Q: Anterior flange (size medium and large)

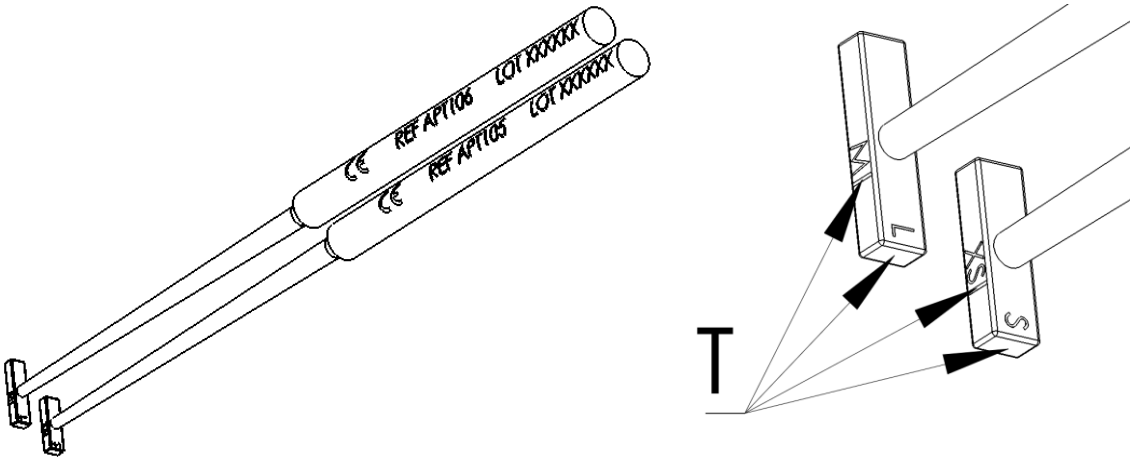
Rectangular Upper Window Edge Caliper:



R: Angle legs

S: Positioning holes

Linear Anterior Window Edge Caliper:



T: Marking anterior distance

1.7 Product-Features

- ➔ *Adjustable implant intra- and post-operatively (filler: physiologic saline solution)*
- ➔ *Biocompatible materials for long-term implantation*
- ➔ *Available in four sizes (XS, S, M, and L)*
- ➔ *Secure Implant-mounting with screw-fixation*
- ➔ *Easy to clean Instrument set for determination of optimal window–orientation and -positioning*

1.8 Contraindications

The user has to gather all information from the patients regarding all known allergies. Do not use this product
- In case of infection
- In patients under age of 18
- In case of known sensitivity / allergies against the utilized materials (silicone, polyester, titanium)

1.9 Complications

Complications may include:
- Laryngeal edema or intralaryngeal bleeding with airway compromise
- Dyspnea after implantation
- Edema of the true vocal fold
- Granuloma formation of the contralateral arytenoid mucosa
- Laryngeal mucosal perforation
- Subcutaneous wound hemorrhage

1.10 Safety-Related Information

Warnings: 
Safety information marked with the key word “Warning” refers to dangerous situations, which could lead to injury of the patient, user or third parties if they are not followed.

Caution: 
Safety information marked with the key word “Caution” refers to measures that must be adhered to and which could lead to damage of the product if they are not followed.

Note: 
Safety information marked with the key word “Note“ refers to measures that must be adhered to and information to be understood, as well as tips and recommendations to use the product effectively.

User group/user qualifications

The products are to be used by qualified medical professionals. The user should not use the product when under a heavy workload, under stress and/or overtired. Knowledge of the principles of type I thyroplasty, as well as knowledge related to fiberoptic examination of the larynx is presumed.

Checking before use

Before using the product, a visual check must be carried out paying close attention to the following:

- *Integrity of the sterile barrier packaging*
- *Expiry date of the sterile barrier packaging*
- *Damages caused by improper transportation or storage*
- *Proper functioning of the port, whether filler can be delivered/removed to/from the implant system*
- *Proper functioning of the silicone cushion*
- *Visible alterations. The surgeon should be able to read the labeling clearly before using the instrument*
- *Presence of all components of the implant system*

Do not use the product if you notice any damage of the product or any reduction of performance.

1.11 Warnings and precautions


The information in the current instructions for use, as well as the information accompanying the products used in combination must be adhered to. 


The product must not be used for any purposes other than the purpose mentioned above.


Any modification of the product can put the patient, user and/or third parties at risk


Do not use damaged products or products, which do not function properly.


The reusable instrument set (APT100 – APT116) must be sterilized before clinical application. 


Do not resterilize or reuse disposable products (APV001 – APV004, APV008 – APV011) Resterilization or reuse of disposable product without manufacture’s 

judgement may cause contamination of the product and increase infection risks to patient.

⚠ Do not use the product after the expire date.

⚠ Do not use the products that have open or defective sterile barrier packaging.

⚠ A new product has to be used, if the product is contaminated after opening of the packaging.

⚠ Open the sterile packaging only shortly before implantation of the product.

⚠ This implant system may be only used by a qualified surgeon with training in type I thyroplasty procedure and after reviewing of all instructions.

⚠ Implant should only be removed from the storage packaging immediately before placements under strict adherence to the standards of asepsis.

⚠ This product represents a potential biohazard after use. Handle and dispose the product as required by hospital policy and applicable laws.

⚠ Do not insert the implant if the Implant checking gauge cannot fit properly into the thyroplasty window. Otherwise the silicone cushion can be damaged.

⚠ Precisely inject the required amount of filling volume and do not exceed the suggested maximum injectable volume (see table II) during filler delivery to prevent damage of the VOIS implant (APV001-APV004, APV008 – APV011).

⚠ Make sure that the complete filling volume is removed when re-adjusting the implant, in order not to overfill the implant. Injection volumes have to be recorded after each adjustment.

⚠ Lift the fixation plate during removal of the fixation screw. Otherwise the screw will detach from the fixation plate and can get lost.

⚠ Avoid touching the sharp edges of the window to prevent damage to the silicone cushion.

⚠ Do not inject more filling media as suggested in Table II. Push slowly!

⚠ Make sure that the setting of the electric cautery device is compliant to the intended use. Surgeons should use the lowest possible power for coagulation of bleeder for marking and increase it on demand.

⚠ Ensure that you can clearly see the inferior border of the thyroid cartilage so that you can precisely measure the distance with the Rectangular Upper Window Edge Caliper. Otherwise the window will not have the correct orientation and position.

⚠ Do not enlarge the window more than 11x6mm. Otherwise the fixation of the implant could be insufficient.

⚠ Ensure that no air is entrapped in the balloon when filling the VOIS implant. This could lead to overload of the balloon and will lead to reduced function once the air migrates through the silicone balloon.

⚠ In order to avoid any risk of electric shock or burning only hold the instrument on the back part of the isolated handle and not on the shaft or close to the head of the instrument.

⚠ The silicone cushion of the VOIS Implant may not come into contact with any surgical instruments.

⚠ The fixation screw has to be tightened and to be turned three times at minimum. Further winding till resistance is noted. The screw and the screw-hole should be freed of all tissues

before winding. Additionally there must be no tissue between fixation plate and housing. The screw should not be winded with excessive force. If the user senses increased resistance, the screw or the screw-hole has to be checked for possible blockage (e.g. muscles, cartilage, perichondrium etc.).

After the fixation screw is fixed, always examine it for stability and additionally check the fixation of the implant (e.g. by pushing and pulling on the implant). Then knot above the screw with the PET suture and cut the ends of the suture leaving sufficient distance/length to the knot.

⚠ Special care is to be taken, when inserting the implant into the paraglottic space through the thyroplasty window. Avoid touching the sharp edges of the window and instruments with the silicone part of the implant.

⚠ Use only physiologic saline solution to fill the implant. Do not mix the physiologic saline solution with other substances (e.g. contrast media).

⚠ Only use the needles meet the specifications listed in the IFU for implant adjustment. The use of any needles not meeting the specifications might damage the product.

⚠ Before implantation the VOIS Implant is repeatedly flushed with physiologic saline to remove the air in the filling compartment of the implant and to check its function.

⚠ Always use a 3mm milling tool for drilling the hole for introduction of the vocal process sounding probe.

⚠ Do not use the Blunt Elevator for manipulations in the paraglottic space.

⚠ When puncturing the port, it is important that the needle has approximately the same direction as the axis of the port chamber (i.e. perpendicular to the port membrane). Try to hit the center of the port membrane as far as possible. If you encounter extraordinary forces, then pull back the needle and try again.

⚠ Make sure that the needle has completely penetrated through the port membrane into the port chamber. Depending on the entrance position and angle of the needle, the force needed to completely push the needle into the port chamber may vary. If the needle is not completely pushed into the port chamber, it may happen that the filler can be delivered but not removed.

⚠ Patency of the airway has to be ensured when performing Implantation of VOIS Implant on both sides of the larynx to prevent possible complication. (e.g. shortage of breath).

⚠ Before filling the balloon make sure that the balloon is empty so that it does not get overfilled by the subsequent filling process.

⚠ When sliding down the fixation plate along the sliding sutures, make sure that the suture does not get tangled between housing and fixation plate.

⚠ Pay attention that you always use the vocal process sounding probe with the correct orientation. On the end of the handle there is a marking groove, which has to show in posterior direction (towards the arytenoid cartilage), to prevent damage of the paraglottic structures.

⚠ If the window is created in the correct dimension, the insertion or removal of the window size checking gauge can be done smoothly. Therefore, confirm the accurate size of the window with the window size checking gauge without using much force. Otherwise the instrument can get stuck in the window and will be difficult to remove.

⚠ During insertion of the implant checking gauge, it is very important to push the instrument slightly medially and all the way back to the posterior window margin so that the anterior flange of the instrument can be advanced to the anterior thyroplasty window margin. Even if the implant checking gauge can fit into the window, it may happen that the XSmall and Small implants can get clamped anteriorly. In case of obvious tissue swelling skip the filling procedure after proper fixation and confirmation of the correct implant position. Perform the filling procedure postoperatively after the tissue swelling has subsided.

⚠ The patient has to visit the physician for examination in case of any voice changes or throat discomfort.

⚠ Read and follow any safety precautions of the electrocautery device, which you use together with the Window Outline Template.

⚠ If the device gets in touch with non-sterile parts/fluids etc. replace it with a new sterile device.

⚠ Replace instrument with a new one, if marking is difficult to be interpreted.

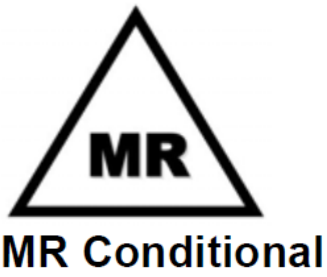
⚠ The non-absorbable suture may lead to minimal acute inflammatory tissue reaction and transitory local irritation at the implantation site.

1.12 Notes on electromagnetic compatibility (EMC)

➔ Not applicable

1.13 Notes on magnetic resonance imaging (MRI)

MRI Safety Information:



Non-clinical testing and MRI simulations were performed to evaluate all sizes of the VOIS Implant. Non-clinical testing demonstrated that all sizes of the VOIS Implant are MR Conditional. A patient with this implant can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, only
- Maximum spatial gradient magnetic field of 2,000 gauss/cm (20 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the normal operating mode.

Under the scan conditions defined, the implant is expected to produce a maximum temperature rise of 2.1°C after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by this implant extends approximately 10mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

1.14 Product combinations and accessories

The APrevent® Vocal Implant System (VOIS) must be used with the products mentioned below:

- Commercial 1ml syringes
- Commercial normal saline solution 0.9%
- Surgical Instruments: curved dissecting forceps, surgical- & dissecting forceps, and scissors
- 24G (0.5mm) needle, length: 25-30mm

1.15 Assembling Instructions

➔ Not applicable

1.16 Instructions

Surgical Procedure

Caution: The device-implantation should only be performed by surgeons familiar with and qualified by training in type I Thyroplasty procedure, and after reviewing of the entire Surgical Procedure Section.

Preoperative Evaluation of the Patient

- Videolaryngoscopic and/or videolaryngostroboscopic evaluation of larynx and voice (vocal fold position, parameters for voice quality including amplitude, range, fundamental frequency, percent jitter, percent shimmer and maximum phonation time)
- Laryngeal dimensions can be measured on computer tomographic images for pre-OP planning, if available.

Postoperative Evaluation of the Patient

- Videolaryngoscopic and/or videolaryngostroboscopic evaluation of larynx and voice (vocal fold position, parameters for voice quality including amplitude, range, fundamental frequency, percent jitter, percent shimmer and maximum phonation time) 2 months and 6 months after the operation
- Adjustment of implant is recommended 2 months after the operation, after determination of the paralyzed vocal fold position, if necessary.

Recommended Anesthesia

It is recommended to perform the operation under sedoanalgesia (conscious sedation). Anesthesia should be discussed and planned by the surgeon and anesthetist prior to the operation.

Fiberoptic laryngoscopy examination should be performed before the surgical procedure to confirm proper local anesthesia.

The following anesthetic procedure is suggested as follows:

- Midazolam 5mg
- Prednisolone 250mg intravenous
- Remifentanil is given continuously
- Propofol, incremental doses are used 30-20-10 mg, etc.
- Single-dose broad-spectrum antibiotic intravenous
- It is recommended to administer additional propofol intravenously prior to device-implantation

Other Preoperative Preparations

- One nasal cavity is sprayed or packed with a 3% lidocaine hydrochloride and 2% phenylephedrine hydrochloride solution
- Remove nasal packing shortly before introduction of fiberoptic laryngoscope

Technique of Surgery

Preparation Steps:

- Under supine position, patient's anterior neck is prepared and draped to expose both ipsilateral and contralateral sides.
- Oxygen can be administered by nasal prongs or oxygen masks.
- Landmarks (the superior thyroid notch, inferior thyroid cartilage border, cricothyroid membrane, and the inferior cricoid cartilage border) are identified and marked with a skin marking pen.
- A 3-5 cm horizontal skin incision line is marked approximately 5mm above the inferior margin of the inferior thyroid cartilage border.
- Hatch marks are made to facilitate approximation during wound closure.

Skin Incision:

- 1% lidocaine hydrochloride mixed with 1:200,000 epinephrine hydrogen tartrate is used to infiltrate the area surrounding the incision, extending 0.5 - 1cm from the horizontal line on the contralateral side to the ipsilateral anterior border of the sternocleidomastoid muscle.

Dissection and Exposure of the Thyroid Cartilage

- The platysma is cut through to expose the sternohyoid- and omohyoid-muscles.
- Flaps superficial to the muscles are undermined superiorly and inferiorly and retracted with self-retaining retractors.
- The median raphe is identified and the two sternohyoid muscles are separated to expose the superior and inferior thyroid notches, anterior margin of the thyroid cartilage and cricothyroid membrane.
- The ipsilateral sternohyoid-, omohyhoid- and strap muscles are dissected and retracted laterally to expose the thyrohyoid muscle. The latter is transected above the inferior border of the thyroid lamina and freed from its attachment on the thyroid cartilage with an elevator, to expose the inferior thyroid tubercle.
- After sufficient exposure of the ipsilateral thyroid cartilage lamina, under preservation of the perichondrium, key points (as shown in Fig. 1) are allocated.

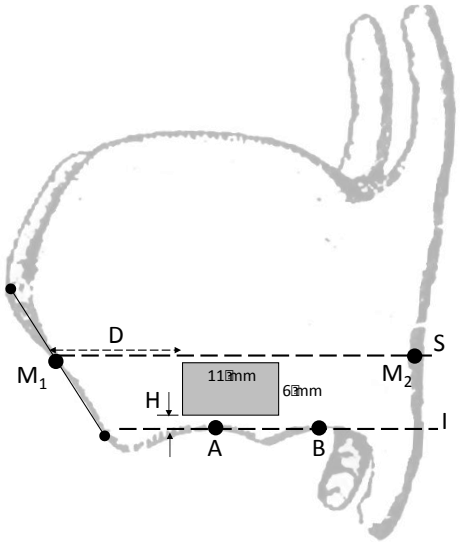


Fig. 1 Location of Key Points

- Following instruments are used to locate the key points: Thyroid Cartilage Ruler (APT103), Rectangular Upper Window Edge Caliper (APT104), Linear Anterior Window Edge Caliper (APT105, 106), Cartilage Marker (APT108).
- Point (M_1) is located on the midpoint of anterior thyroid cartilage border line, extending from incisura of the superior thyroid notch to the most anterior inferior edge of the thyroid cartilage.
- Point (M_2) is located on the posterior thyroid cartilage border, crossed by “Superior Line (S)” running parallel to the “Inferior Border Line (I)” and passing through M_1.
- Point (A) and point (B) are anterior and posterior to the inferior thyroid tubercle, respectively
- The “Inferior Border Line (I)” passes through the points (A) and (B).
- Superior Line (S) passing through points M_1 & M_2 is parallel to the Inferior Border Line (I) and corresponds to the horizontal level of the vocal folds and is used to evaluate the overall length of the thyroid cartilage from anterior to posterior and describes the preliminary implant size.
- Distance (D) along Superior Line (S) describes the preliminary anterior margin of the thyroplasty window, chosen based on the overall length of the thyroid cartilage as shown in table I or markers on the “Thyroid Cartilage Ruler”.

Table I: Relation between implant size and overall length of the thyroid cartilage

		Overall length of the thyroid cartilage (M_1 - M_2)			
		28-33mm	33-38mm	38-42mm	> 42mm
Implant Size	X-Small	7mm			
	Small		10mm		
	Medium			8mm	
	Large				≥ 12mm

- The upper window margin is evaluated by using the “Rectangular Upper Window Edge Caliper”, by placing one angle leg (R) along the Inferior Border Line (I). Then the hole (S) of the other arm of the instrument (the center of this hole has a distance of 7.5mm to the caudal edge) may be used to mark the upper window margin using the Cartilage Marker.
- It is recommended to leave an inferior strut (H) between 1.5-2mm and 2-3mm superior from line (I) for female and male, respectively.

Window Outline and Drilling Procedure

- Following instruments are used: Window Outline Template (APT107), Cartilage Marker (APT108), Vocal Process Sounding Probe XS, S, M, L (Optional, APT109 - 112), Window Size Checking Gauge (APT113), Implant Checking Gauge (APT114).
- An 11x6mm rectangular thyroplasty window is outlined using the “Window Outline Template” under low-energy electrocautery current. The contact between electrocautery device and the Window Outline Template is established by bringing any suitable tip of an electrocautery instrument for short time into contact with the pit (J) on the backside of the instrument plate just for marking. Four corners of the rectangle are marked and connected. (To avoid any risk of burning, only hold the instrument on the back part of the isolated handle and not on the shaft or close to the head of the instrument).
- The center of the rectangle is marked with the cartilage marker through the hole (J) of the Window Outline Template.
- A 4mm hole is then drilled at the center of the rectangle (always use a 3mm burr for drilling this hole) until the inner perichondrium is visible.
- (Optional procedure) The inner perichondrium is then incised using a Colorado Needle to create an access for the “Vocal Process Sounding Probe”.
- (Optional procedure) The “Vocal Process Sounding Probe” is designed to help determine the level of the vocal fold and position of the vocal process of the arytenoid cartilage to confirm optimal position of the thyroplasty window and possible deviations. Each probe size corresponds with an implant size and should be chosen according to this suggested implant size. The fiberoptic laryngoscope is used to confirm the position of the probe.
  Pay attention to the correct orientation of the Vocal Process Sounding Probe. On the end of the handle there is the marking (L), which has to show in posterior direction (towards the arytenoid cartilage).
  The “Vocal Process Sounding Probe” has three markings (M) on the shaft. The middle marking represents a medial expansion of the balloon of 1mm.
- After confirmation of the window position, an 11x6 mm rectangular thyroplasty window is drilled out until the inner perichondrium is visible. Edges and corners of the thyroplasty window are smoothed using a burr (warning: a too large window may affect the stability of implant fixation!).
- The Window Size Checking Gauge is then carefully applied using only little force to confirm the accurate size of the window.
- The inner perichondrium is then incised along the window rim using an injection needle or low-energy electrocautery. It is important not to enter the paraglottic space.

Final Window Trimming for Implantation

- After careful mobilization of the endolaryngeal tissue, the Implant Checking Gauge is used to test the fitting of the implant titanium housing into the window.
- If the window dimensions are correct (11x6mm), apply the implant checking gauges (APT114 and APT116) in the following steps to evaluate the right titanium housing:
  - In female patients apply the Implant Checking Gauge S (APT116) first. If the anterior flange can fit in smoothly, then choose the implant (APV001 or APV002) with 2.5mm anterior flange housing. If the anterior flange cannot fit in smoothly, then choose the implant (APV008 or APV009) with 3.0mm anterior flange housing.
  - In male patients apply the Implant Checking Gauge (APT114). If the anterior flange can fit in smoothly, then choose the implant (APV003 or APV004) with 3.0mm anterior flange housing. If the anterior flange cannot fit in smoothly, then choose the implant (APV010 or APV011) with 3.5mm anterior flange housing.
- If the window dimensions are correct (11x6mm) and if the anterior/posterior cartilage thickness is maximum 3/5mm then it should be possible to insert the Implant Checking Gauge.
- If you are not able to insert the Implant Checking Gauge then ensure that
  - there are no spurs on the edge (inside or outside) of the window;
  - you prepared enough space for the posterior flange of the implant;
  - you sufficiently press the instrument to the posterior side during the insertion process.

  Do not enlarge the window more than 11x6mm.
  The Implant Checking Gauge has a marking (P), which represents the screw hole of the VOIS Implant and has to be visible if the instrument is placed properly.
- The Implant Checking Gauge has a slightly different size than the VOIS implant in order to avoid injury due to frequent inserting and removing. Even if the implant checking gauge fits into the window it might happen that it is necessary to do slight trimming to the window in order to insert the VOIS Implant. Sometimes, it might still be necessary to reduce the cartilage thickness of the anterior window area before inserting the implant.

Implantation Procedure

- Before implantation of the VOIS implant (VOIS-XS, VOIS-S, VOIS-M, VOIS-L) check if the balloon is functioning.
- To do this, remove the air from the balloon and inject the maximum filling volume (Table II).
  To remove the air you can extract the air from the balloon using the syringe. Alternatively, you can repeatedly flush with the syringe filled with 0.9% normal saline solution. In this case hold the implant in a proper orientation so that the air can escape from the implant.
- Now again empty the balloon.
- The posterior flange is introduced into the thyroplasty window, pushed posteriorly until the posterior window margin is reached.
- The VOIS Implant is then gently pushed into the paraglottic space and slid anteriorly until the ventral flange has reached the anterior thyroplasty window margin. Avoid touching the sharp edges of the window and instruments with the silicone part of the implant.
- The VOIS Implant is then pulled against the thyroid lamina with the pre-attached suture-loop.
- The fixation-plate is then slid along the suture-loop down to the posterior part of the thyroplasty window.
- Place the two legs of the fixation plate below the top section of the implant (below membrane and funnel) and orient the screw above the screw hole of the housing. Doing this requires proper tilting of the fixation plate and the fixation screw.
- The screw on the fixation plate is turned clockwise to secure the VOIS Implant on the thyroid lamina.
- The fixation screw (E) has to be tightened and to be turned three times at minimum. In order to prevent damage of the screw only use the Screw Driver (APT115) delivered with the instrument set.
- After the fixation screw (E) is fixed the sliding sutures (D) is additionally knotted.
- The fiberoptic laryngoscope is again used to confirm vocal fold position. The expandable silicone cushion can be inflated/deflated by evaluating the degree of vocal fold medialization and quality of phonation (due to tissue swelling postoperative readjustment of the vocal implant might be necessary).
- It is recommended to deliver the filling volume in gradual steps under close observation of glottic closure with flexible endoscopy.

- Do not exceed the maximal filling volumes (see Table II). Otherwise the implant may get damaged (e.g. burst of the balloon).
- Record the exact amount of filling volume injected.

Table II: Maximum filling volumes

		Maximal Filling Volume [ml]
Implant Size	X-Small	0.17ml
	Small	0.25ml
	Medium	0.30ml
	Large	0.30ml

Wound Closure

- The strap muscles are reapproximated with 3-0 or 4-0 chromic catgut.
- A closed suction drainage tubing is inserted and the platysma layer is closed.
- The subcutaneous layer is closed with 4-0 chromic catgut and the skin is approximated with 4-0 nylon suture.
- A vacuum ball can be attached to the drainage tubing.

Postoperative Care

- Vacuum balls are changed as soon as they are ¼ filled. The total volume and type of drainage is recorded in patient's record.
- Medication may be needed for pain control.
- Prophylactic treatment is recommended for one week.
- Intravenous prednisolone (250mg) is given once preoperatively and at an eight-hour interval on the first postoperative day.
- The closed drainage tubing is usually removed on the day following surgery, depending on the volume drained.
- It is recommended to stay at least one night in the hospital because of the possible laryngeal edema or intralaryngeal bleeding that might cause airway complications.
- The patient has to visit the physician for examination in case of any voice changes or throat discomfort.

Postoperative Adjustment of the VOIS Implant

- Localize the VOIS Implant (see description below).
- Puncture the port with an empty 1ml-syringe and remove the filled volume completely.
- Disconnect the 1ml-syringe from the needle.
- Compare amount removed with amount injected during last adjustment procedure.
- Fill the 1ml-syringe with the implant-size-specific maximal filling volume (Table II) and connect to the needle. Only use normal 0.9% saline as filling volume.
- Inject the desired volume under close observation of glottic closure with flexible endoscopy Attention:

  Ensure that no air is entrapped in the balloon. When disconnecting the syringe from the needle small amounts of air will enter the balloon, needle and the luer. Before injection of the desired volume, pull back the injection-piston of the syringe to move this air into the filled syringe. When injecting the desired volume ensure that this air is not injected into the VOIS Implant again.
- After removing the needle from the port, check the remaining amount of filling volume in the syringe to make sure the correct amount is injected.
- Medialization of the vocal fold is examined with fiberoptic laryngoscope under phonation. It is recommended to retain the least necessary volume for best glottic closure. Do not exceed the maximum filling volumes (see table II).

- It is very important to record the final filling volume after every adjustment procedure.

Localization of the implant:

If the implant cannot sufficiently be palpated, then use ultrasound to localize the VOIS Implant. The VOIS Implant has a tilted port chamber which is optimized for the in-plane technique. It is very important that the axis of the needle shows approximately into the same direction as the port chamber (see Figure 7).

Ultrasound Imaging Steps:

1. Localize the approximate position of the implant by review of operation records and palpation.
2. Disinfection of skin.
3. Apply ultrasound gel on the neck (implanted side).
4. Choose an appropriate transducer and place it on the neck above the applied gel.
5. Search for landmarks of the implant on ultrasound images with the in-plane technique.

- First Step (Figures 2&3)
  - Identify the fixation plate as an iso-dense bright and lengthy horizontal line (long arms of the U-shaped fixation plate).
  - Identify the posterior flange caudal and posterior to the fixation plate.
  - Identify the anterior flange caudal and anterior to the fixation plate.
  - Identify the port chamber anterior to the fixation plate and cranial to the anterior flange.
  - The above mentioned landmarks indicate that the transducer is either on the cranial or the caudal side of the implant. This can be confirmed by repeatedly moving the transducer cranially or caudally.

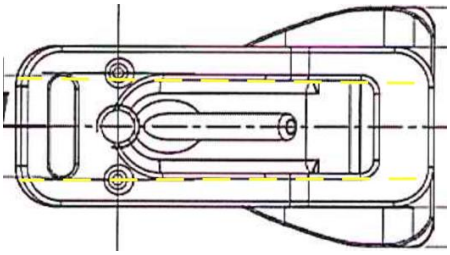
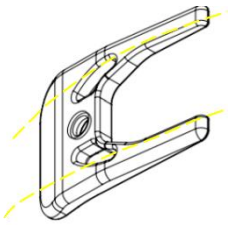
Posterior  Anterior 

Figure 2: Caudal view of the VOIS – Implant and the fixation plate (Yellow dotted lines correspond to the positions of the transducer in Figure 3).

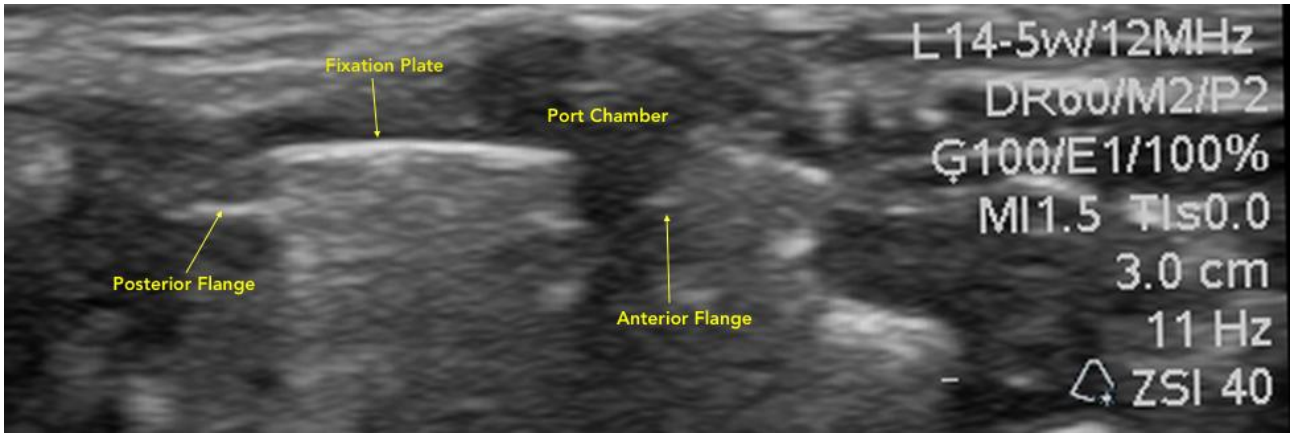
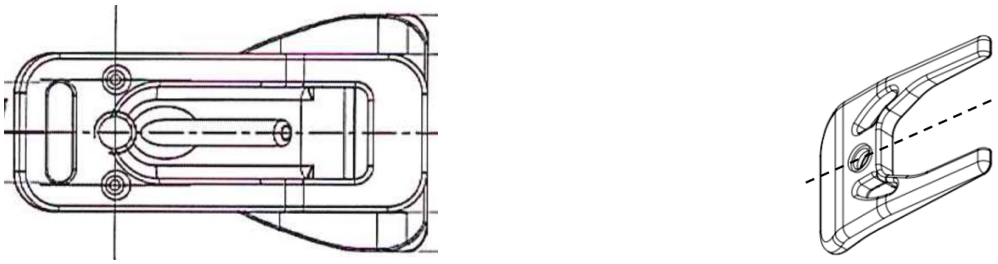


Figure 3: The transducer is at the same level as indicated by the yellow dotted line in Figure 2.

- Second Step (Figures 4-6)
  - Move the transducer either in cranial or caudal direction to locate the shortened fixation plate.
  - The shortened fixation plate implies approximately the median position of the implant (connection piece between the two long arms of the U-shaped fixation plate).
  - Locate the needle.
  - Advance the needle under ultrasound tracking into the port chamber. The examiner can feel a slight resistance when puncturing the port membrane.
    It is important that the needle has approximately the same direction than the axis of the port chamber. The angle of the needle might be slightly smaller (as shown in Figure 7) but may not be bigger.



Posterior Anterior

Figure 4: Caudal view of the VOIS – Implant and the fixation plate (black dotted line corresponds to the position of the transducer in Figures 5 and 6)

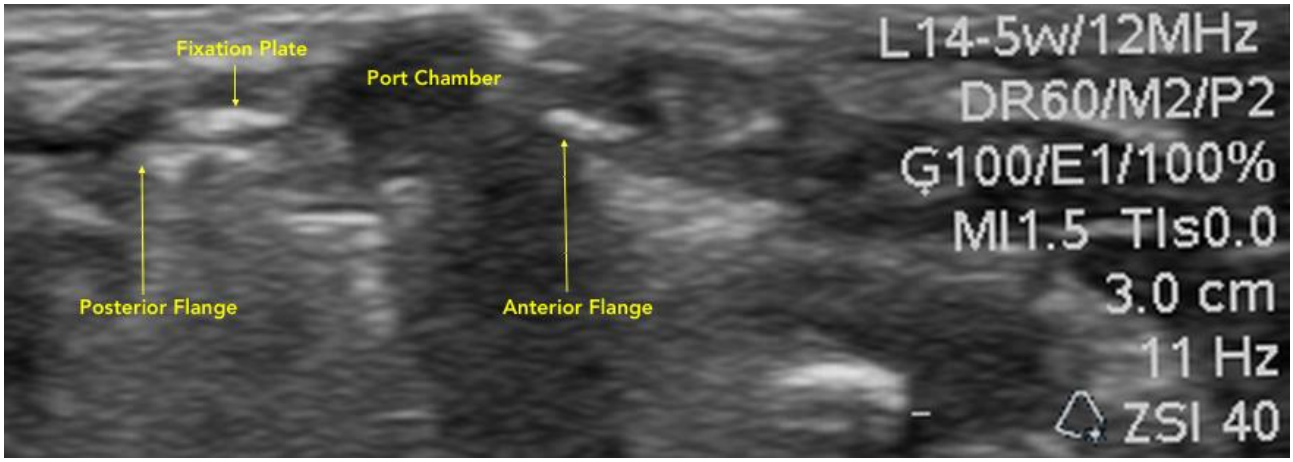


Figure 5: The transducer is at the same level as indicated by the black dotted line in Figure 4.

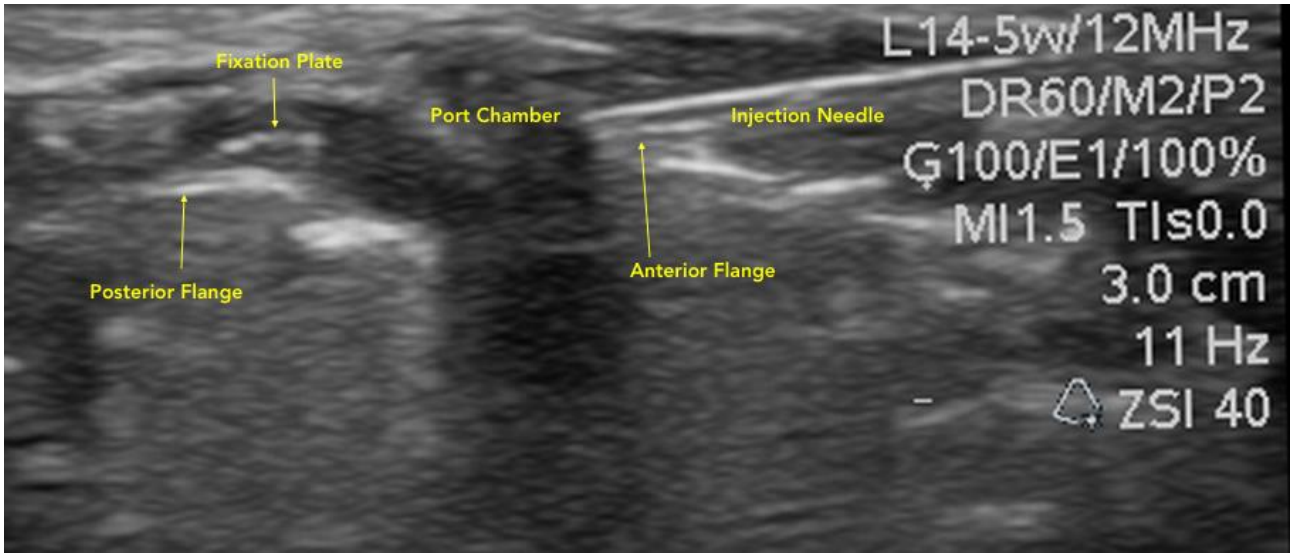


Figure 6: The transducer is at the same level as indicated by the black dotted line in Figure 4. Injection needle was advanced through the skin, subcutaneous tissues, muscles and port membrane to reach the port chamber.

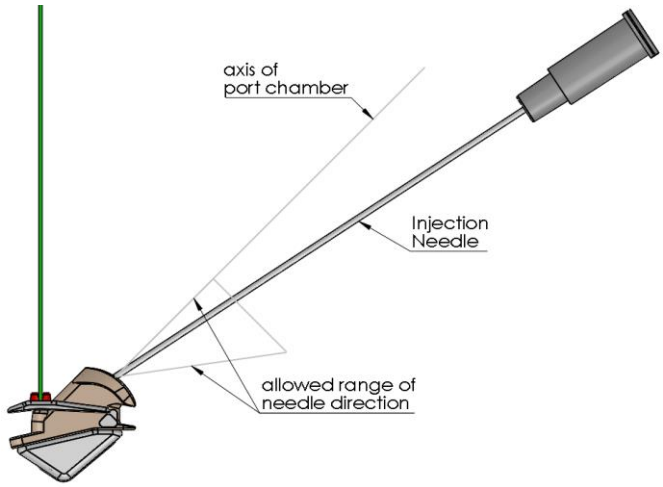


Figure 7: Puncturing Angle

1.17 Dismounting after Usage

➔ Not applicable

1.18 Disposal

⚠ After the products have surpassed their product service life, they will represent a biological risk. These products are not allowed to be disposed of with household garbage. They must be disposed of according to the RKI institute and relevant national regulations.

1.19 Cleaning and Sterilization

This is only applicable for the multiple use instruments (APT100-APT116).

Preparation at location of use:	In order to keep the instrument storage tray clean do not snap in the dirty instruments. Avoid drying-out of dirt. If possible rinse with cold, fully desalinated running water. Humidify a clean soft fuzz-free fabric using distilled or fully desalinated water and enwrap the instruments in this fabric. Do not use saline solution to humidify the fabric. In order to protect the tips of the Sharp Cutter (APT102) and the Cartilage Marker (APT108) and the user, these instruments have to be enwrapped in a way that the tip cannot touch other surfaces. Protect the instruments and the instrument storage tray against damage during transport.
Storage & Transport:	The reprocessing should be conducted as soon as possible to avoid drying-out of the stains and dirt. Maximal duration between application and reprocessing is 12 hours.
Preparation for Cleaning:	APrevent recommends pre-cleaning of the instruments. In case of pre-cleaning only cold and fully desalinated water and a soft brush may be used. Using ultrasound is not necessary and was not tested. The user takes responsibility for the decision if pre-cleaning is necessary or not.
Machinery Cleaning and Disinfection:	Position the products into the Cleaning and Disinfection Unit (CDU). All components will be placed into the CDU separately. Do not put the instruments into the instrument storage tray. The instrument storage tray is not used for cleaning but for storage of the instruments. Take care that the instruments do not come in contact with each other or with other instruments to prevent them from getting damaged. All surfaces have to be fully accessible for the alkaline cleansing solution The maximal loading capacity of the CDU must be taken notice of. Use only validated appliances. Cleaning-Program: Vario TD Program with thermal disinfection for 5 minutes at 90°C or above. (A_0-Value 3000, EN DIN ISO 15883-1) Validated Cleansing Solution: Neodisher MediClean forte 0.5% or alternative alkaline cleansing solutions (ph > 10.5) for machinery cleaning in the concentration as recommended by the supplier.
Control, Maintenance & Examination:	Examine all visible surfaces for cleanliness. Especially the holes in instruments APT104 and APT107 and the silicone profiles of the instrument storage tray should be examined for cleanliness.
Packaging:	Put the instruments into the instrument storage tray and then package the filled instrument storage tray into pouches or containers suitable for steam-sterilization. Double or simple sterile. When using pouches, take care to choose pouches which

	are strong and big enough so that they do not get damaged by sharp edges of the instrument storage tray.
Sterilization:	Put the filled and packaged instrument storage tray into the autoclave. Sterilization in autoclaves with fractionated vacuum: • 3 vacuum cycles with 60 mbar vacuum or above • Maximal residence time: 20 minutes • Minimal residence time: 3 minutes • Temperature 134°C (do not exceed 137°C) • Minimal drying time: 10 minutes at 90°C) Use only validated appliances.
Storage:	• Dry, low-dust environment • Permissible storage duration is dependent from packaging materials used Follow instructions of the packaging material suppliers.

These instructions have been validated by APrevent for the cleaning and sterilization of APrevent devices by following the mentioned cleaning-, disinfecting and auxiliary means. It is the responsibility of the person(s) carrying out the cleaning and sterilization to ensure that such cleaning and sterilization is undertaken by trained staff using the appropriate equipment and materials, and achieves the desired result. This, in turn, requires validation and routine inspections of the process used to clean and sterilize. Similarly, each and every deviation from the steps described above should be evaluated carefully by the person(s) responsible in terms of effectiveness and any adverse ramifications.

1.20 Reprocessing documentation

➔ Not applicable

1.21 Maintenance and Inspection

APrevent recommends annual inspection by the user. This inspection should include the followings:

➔ Control the dimensions of the Vocal Process Sounding Probe

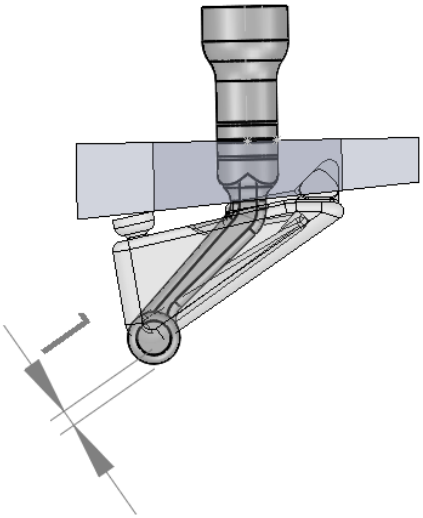
➔ Visibleness of the markings of all instruments

➔ No obvious damages

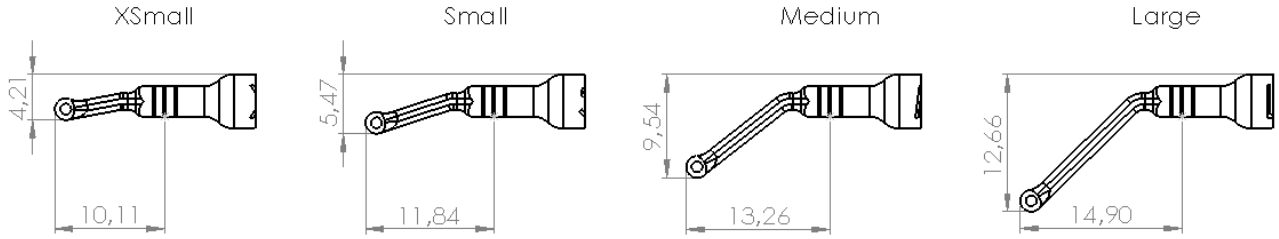
In case of a deviation, do not repair the instrument. It has to be replaced by a new one.

Control of Vocal Process Sounding Probe Dimensions:

The dimension of the Vocal Process Sounding Probe is designed to simulate a medial implant-expansion of approximately (dependant on cartilage thickness) 1mm, if placed perpendicular into the hole in the middle of the thyroplasty window and pushed medially to reach the middle marking.



In order to achieve this, the Vocal Process Sounding Probe has the following dimensions and tolerances:



The dimensions in condition as supplied to customers have an accuracy of ± 0.3mm. Through inappropriate handling the Vocal Process Sounding Probe (especially the sizes Medium and Large) can be bent.

If the deviation of the dimensions exceeds 0.5mm (control with sliding caliper), then the instrument has to be replaced by a new one.

1.22 Conditions of Operations

➔ Not applicable

1.23 Storage and Transport Conditions

Avoid heavy shocks during transportation. Transport and storage should be in a cool, dry, dark and clean environment. Product has to be protected from water and other fluids, sunlight, dust, salts etc. There is no risk regarding the ambient pressure and relative humidity.

1.24 Returns

Returns will only be accepted if all components are cleaned and sterilized before return. Contaminated components must be marked appropriately if returned.

RETURNING:

If there is a fault, the entire product along with a description of the fault must be sent back to the MANUFACTURER.

REPAIRS:

Do not undertake any repairing by yourself. This can endanger the users and the patients and would lead to loss of warranty.

1.25 Additional Information

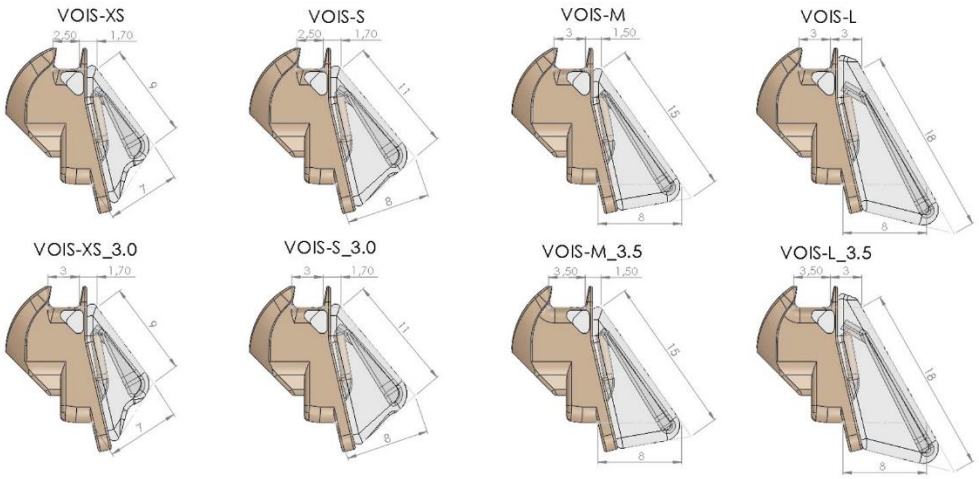
This Instruction for Use is for the correct and safe use of this medical product by medical specialists. By using this product, the surgeon or hospital declares and guarantees that all physicians using this product are familiarized in this surgical method and that all regulations governing this method in the respective country have been complied with. This product must be prepared properly for use and employed only by appropriate specialist staff. Defects and damage due to natural wear and tear, improper use or modifications to the product that do not conform with the instructions for use are excluded from the warranty. APrevent Biotech GmbH and the company's authorized distributors are neither responsible nor liable for compensating surgeons or the hospital in connection with any incidental or causal loss, damage or expense resulting directly or indirectly from the use of this product. APrevent Biotech GmbH assumes liability solely for product defects that existed before shipment of the product, provided that these defects were discovered and reported prior to using the product. In such a case, claim may only be made for replacement of the faulty product.

1.26 Symbole

Symbol	Meaning	applicable to	
		Instruments (APT100-APT116)	**Single use devices (APV001-APV004, APV008 – APV011)**
	*Read the IFU*	*x*	*x*
	*Attention. Observe accompanying documents.*	*x*	*x*
	*Do not use if the packaging is damaged*		*x*
	Manufacturer: APrevent biotech GmbH Im Letten 3A 6800 Feldkirch Austria	*x*	*x*
	*Date of manufacturing*	*x*	*x*
	*Date of expiry*		*x*
	*Non sterile*	*x*	
	*This product does not contain latex*	*x*	*x*
	*Do not reuse*		*x*
	*Do not resterilize*		*x*
	*Sterilized with EO*		*x*
	*MR conditional for MRI up to 3T according to IFU.*		*only APV001- APV004, APV008 – APV011*
			
	*The US Federal Law restrains the distribution of that product to a licensed physician or to its directive*	*x*	*x*
	*Lot number (The first two digits identify the year of manufacturing)*	*x*	*x*
	*Reference number (order code)*	*x*	*x*
	*This product is conform to the valid European guidelines*	*x*	

CE0297	*This product is conform to the valid European guidelines. The following four digits identify the number of the notified body*		*x*
	*Fragile*	*x*	*x*
	*Keep dry*	*x*	*x*
	*Keep Away from Sunlight*		*x*
	*Cleaning and Disinfection machine for thermal disinfection*	*x*	
	*Sterilizable with steam-sterilizer (autoclave) at the given temperature*	*x*	

1.27 Specifications

Lifetime VOIS Implant	Safe and effective for long-term use, of at least 5 years after implantation, at the discretion of the physician. The implant cannot be resterilized and/or reused.
Lifetime Instruments	Instruments except the cartilage ruler: 100 reprocessing cycles. cartilage ruler: 20 reprocessing cycles
Materials	Medical grade silicone, titanium and polyester. None of the materials in use contain BPA, DEHP or latex as an ingredient. In addition, silicon, titanium and polyester are virtually nonmagnetic, and therefore (correct application provided) do not seriously interfere with CT or MRI up to 3 Tesla. See chapter “MRI Safety Information”.
Dimensions	
Maintenance	No maintenance needed
Cleaning (Instruments)	suitable for cleaning in the CDU (reference chapter 1.19 Cleaning and Sterilization)
Sterilization (Instruments)	suitable for steam-sterilization (reference chapter 1.19 Cleaning and Sterilization)

1.28 Problem Solving

➔ Not applicable

Warranty

The warranty period starts on the date of delivery and is only guaranteed under proper use in accordance with the instructions provided in the manual.

The manufacturer is not liable for the effect of product application because the manufacturer does not know the diagnosis of the patient, nature of the application and has no influence on the condition under which the product is used. The medical staff must use the product based on their medical training and experience and are therefore responsible for correct application.

If you have reason to believe that the new product is damaged, please contact our Customer Service either by email (contact@apreventmed.com) or electronical submission of customer reclamation form available on our website (www.apreventmed.com), providing the article number, and the LOT number. All faulty products must be returned for inspection. Instruments must be cleaned and sterilized. The products will be repaired or replaced, if all due care of the product is undertaken.

If repair or replacement of the product is not possible, the buyer has the right to cancel the order or to reduce the payment, not exceeding the maximum of the purchase price amount.

All claims based on the consequences of non-compliance with the instruction for use, including specific indications, contraindications, warnings, instructions, application, storage and off-label-use, as well as a combination with third-party products are excluded.

Additional claims or those not mentioned here due to defect, and other claims regardless of the legal reason, including those based on illegal acts and for compensation of immaterial damages against the manufacturer, its agents, dealers and suppliers, are excluded unless they are prescribed by law, e.g. intent or gross negligence in the event of physical injury, contrary to the liability exclusion.

The General Terms and Conditions can be accessed at www.apreventmed.com.

1.30 Conformity

The APrevent® Vocal Implant System (VOIS) fulfils the requirements of the guideline 93/42/EEC concerning medical products and is labelled accordingly with the CE-Mark.

CE 0297

Notes:

Notes:

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APrevent

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