APrevent® VOIS (Vocal Implant System)

Innovative Treatment for Glottic Insufficiency

31st Jan. 2022

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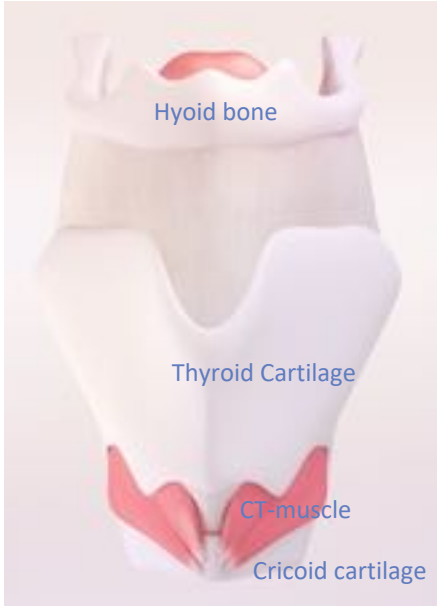
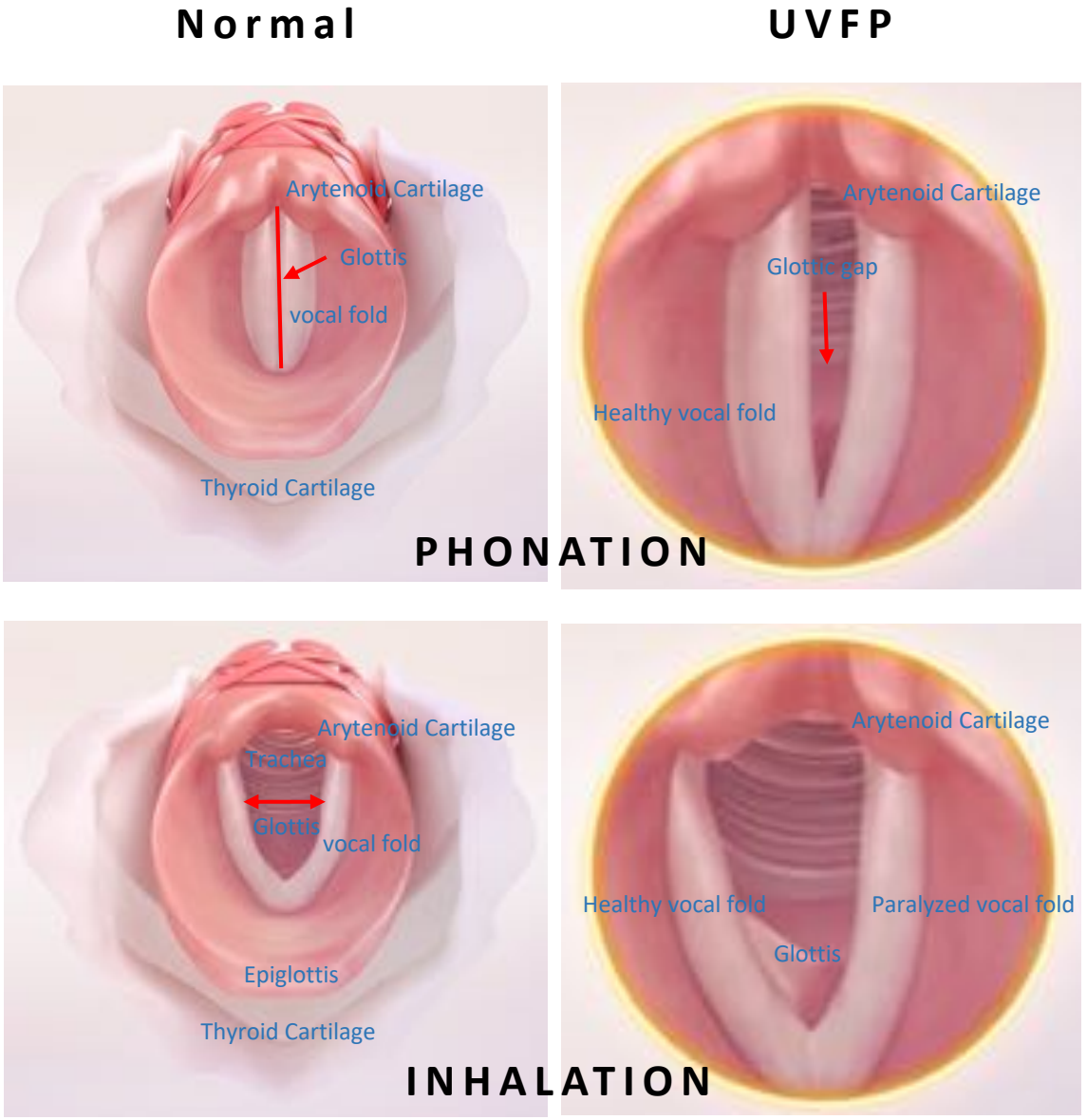
Med. Indication / Application:

Treatment of patients with glottic insufficiency / unilateral vocal fold paralysis to improve voice quality with type I thyroplasty surgery.

Glottis / Vocal Fold

- Glottis lies between the two vocal folds.
- The glottis closes during phonation and swallowing.
- The glottis opens during inhalation.
- In unilateral vocal fold paralysis (UVFP), the glottic closure is incomplete during phonation and swallowing. It is called “glottic insufficiency”.
- Symptoms of glottic insufficiency/ UVFP include hoarseness, shortness of breath, and swallowing difficulty.





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Glottic Insufficiency / UVFP

Unilateral vocal fold paralysis / glottic insufficiency is caused by a central lesion in the nucleus of the vagal nerve (CN X) or peripheral damage to the vagal nerve or its branch recurrent laryngeal nerve or changes of the vocal fold caused by the aging process (presbylaryngis).

Central / peripheral causes:

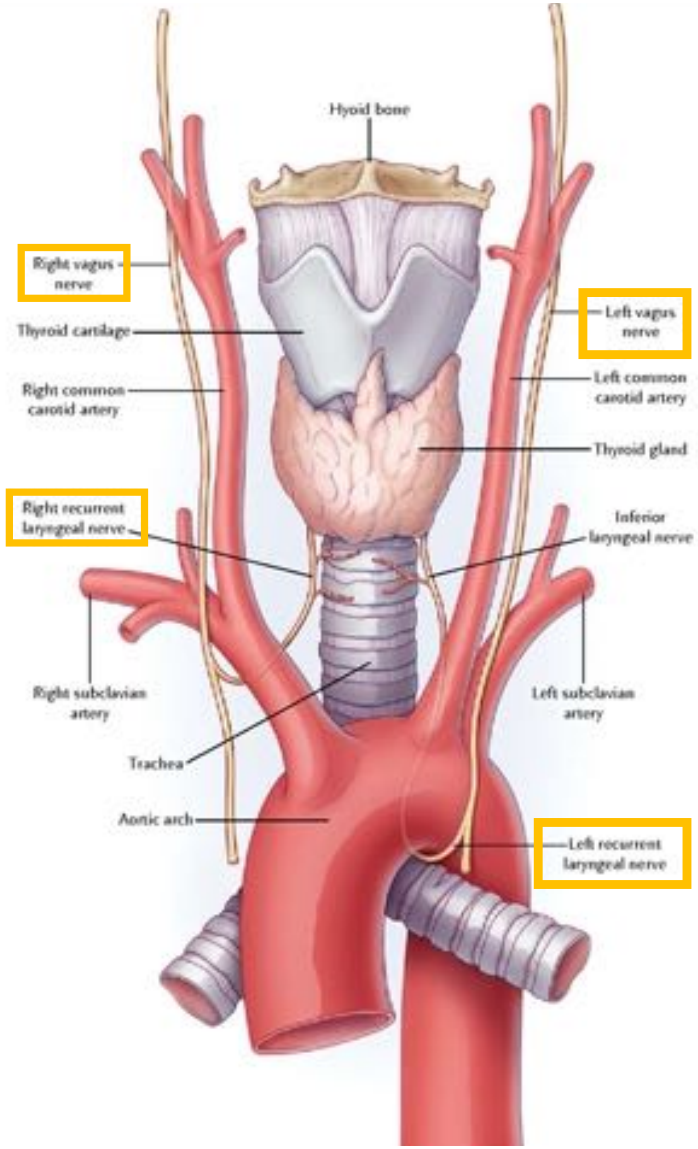
- Stroke
- Brain tumors, brain traumas
- Iatrogenic (thyroid-, cervical disc-, esophagus-, heart-, lung-surgeries, intubation trauma)
- Infections in the head and neck area (bacterial, viral)
- Idiopathic

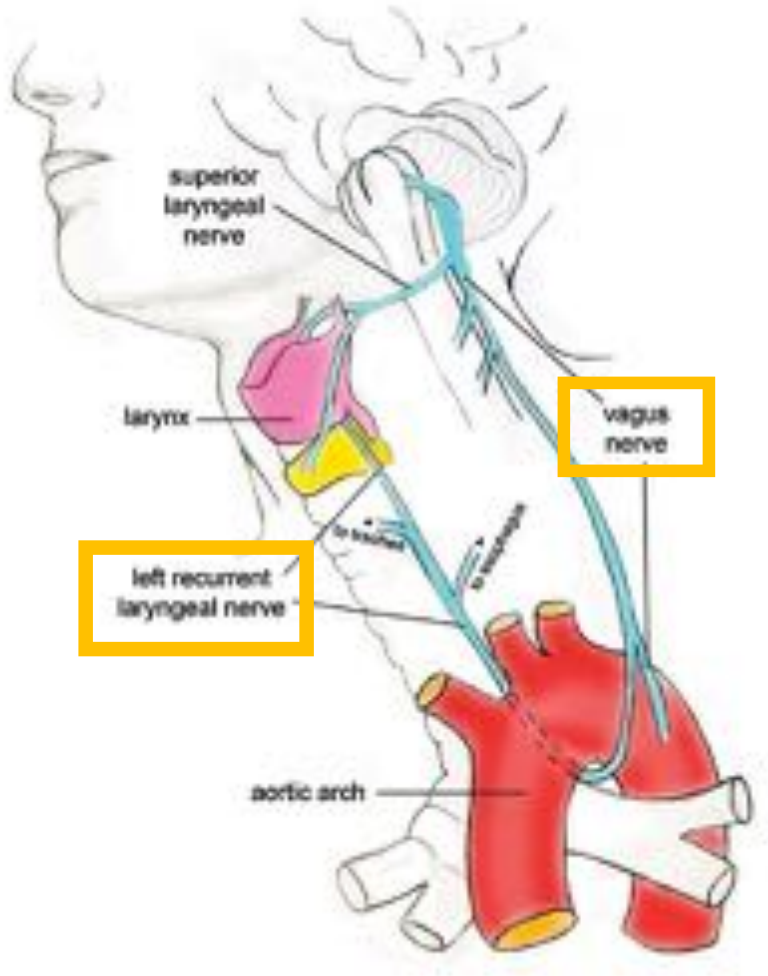
Symptoms:

- Dysphonia
- Dysphagia
- Swallowing difficulty / aspiration

Sequels:

- Aspiration pneumonia
- Mortality





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Type I thyroplasty/ Medialization Thyroplasty(MT)

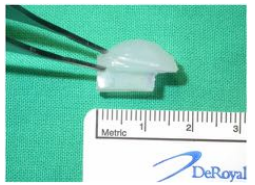
- Introduced by Dr. Payr in 1915
- Popularized in 1974 by the Japanese doctor, Dr. Isshiki
- MT is the gold standard for the treatment of glottic insufficiency and unilateral vocal fold paralysis.
- Performed under general anesthesia or conscious sedation (sedoanalgesia)
- Implants:

- Synthetic free form: silicone block, Gore-Tex strips

- Synthetic prefabricated: Montgomery, TVFMI VoCOM

- Autologous implant: cartilage, fat

Synthetic freeform



Silicone block

Gore-Tex Strip

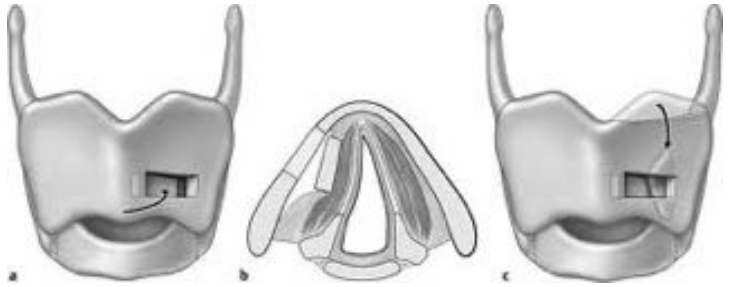
Synthetic prefabricated

Montgomery

TVFMI

VoCOM

Autologous Implant



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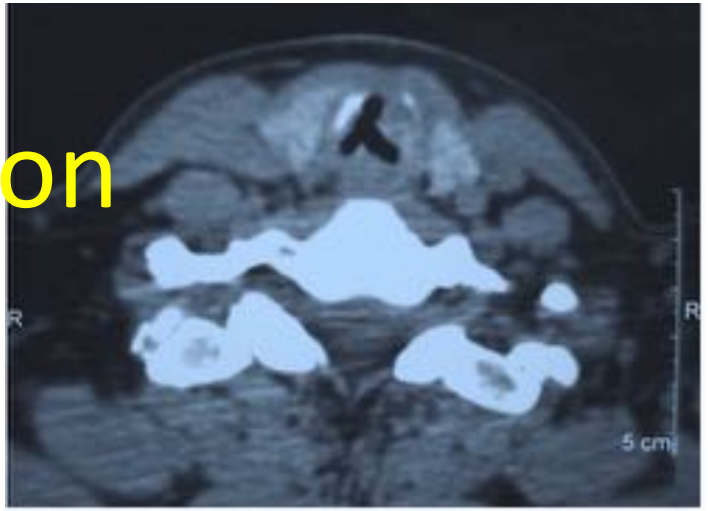
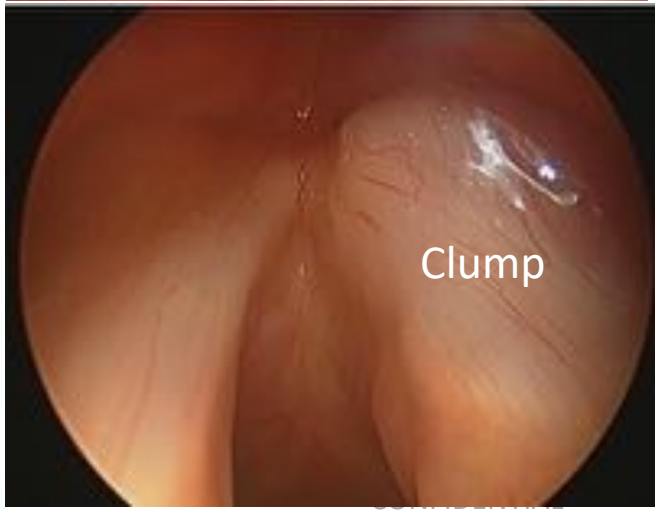
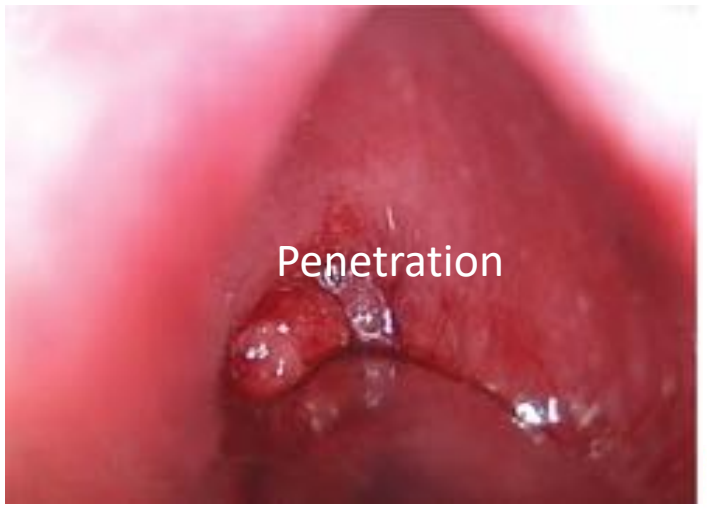
Gore-Tex Complications

Reason: insufficient fixation







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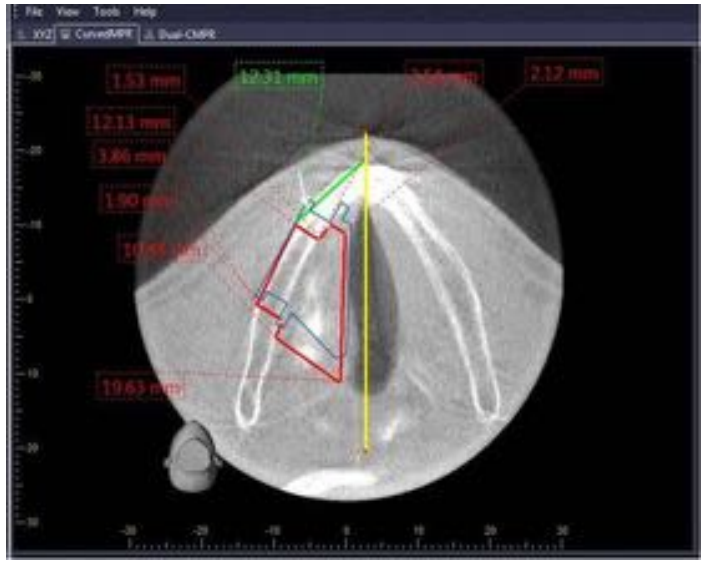
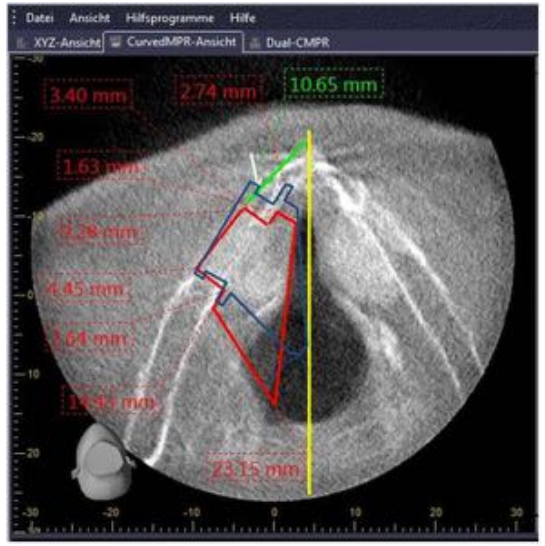
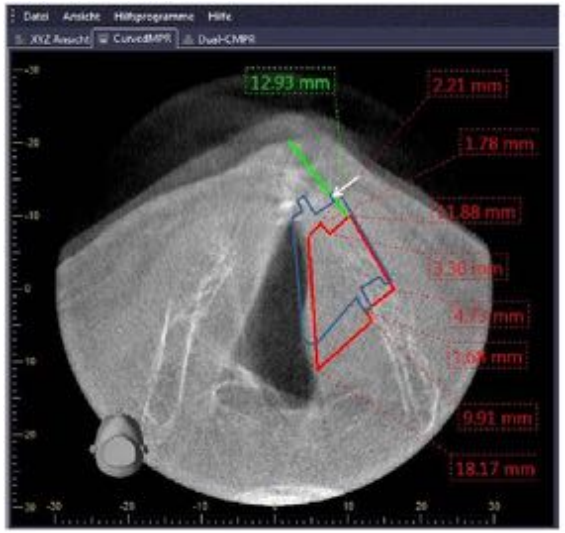
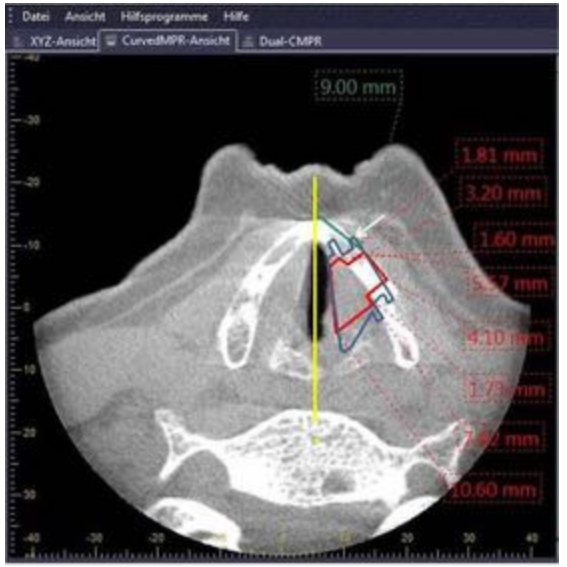
Montgomery DVT - Study









Montgomery: **Blue**
Ideal Size/Shape: **Red**

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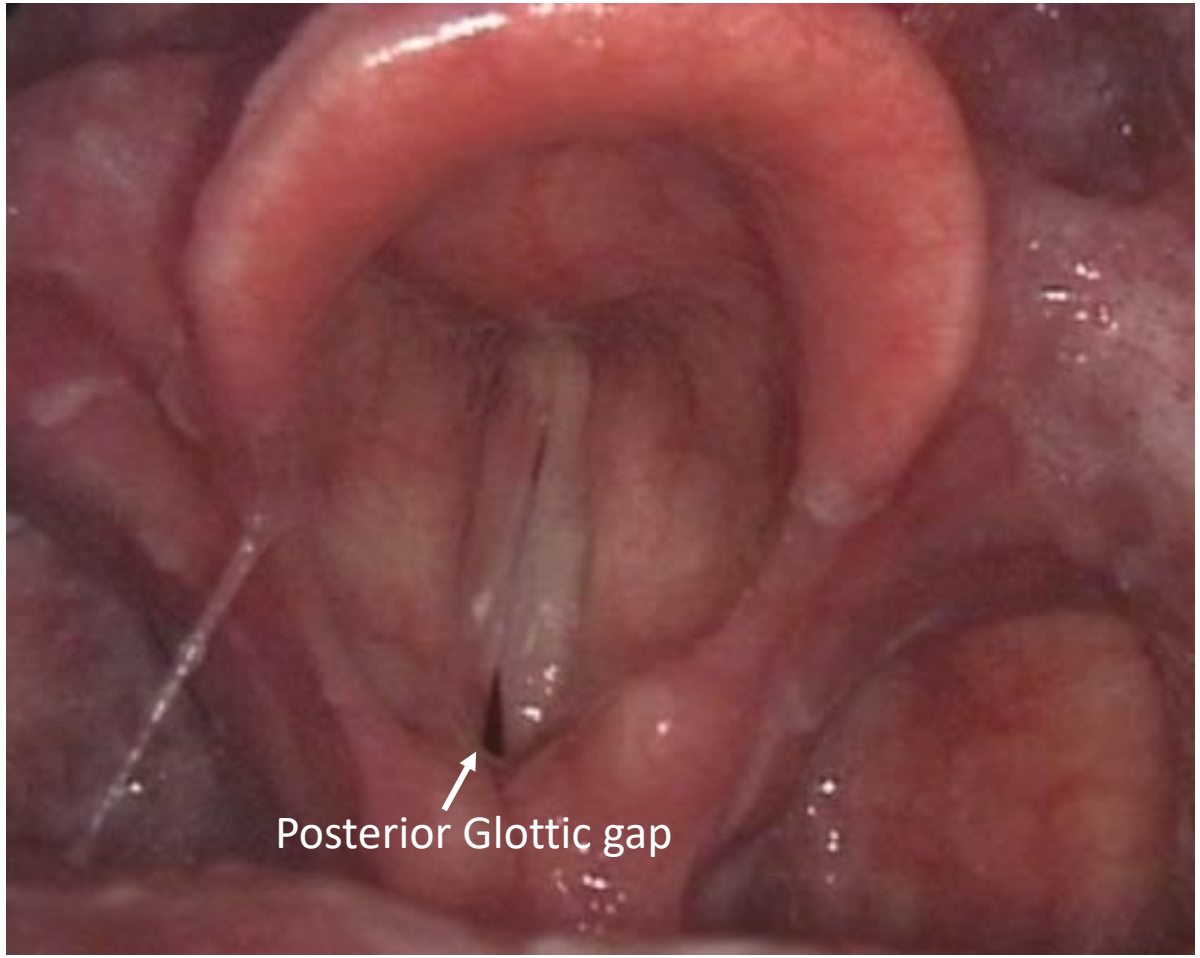
Titanium Vocal Fold Medialization Implant (TVFMI)



4 Days after OP

4 Weeks after OP

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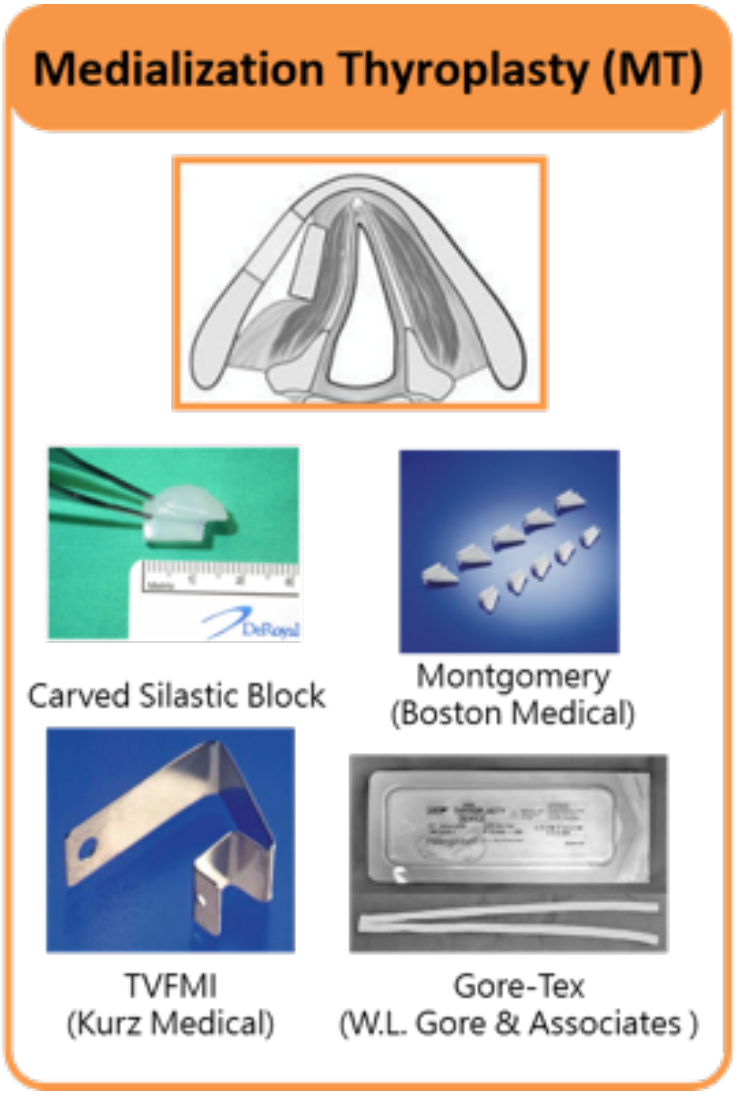
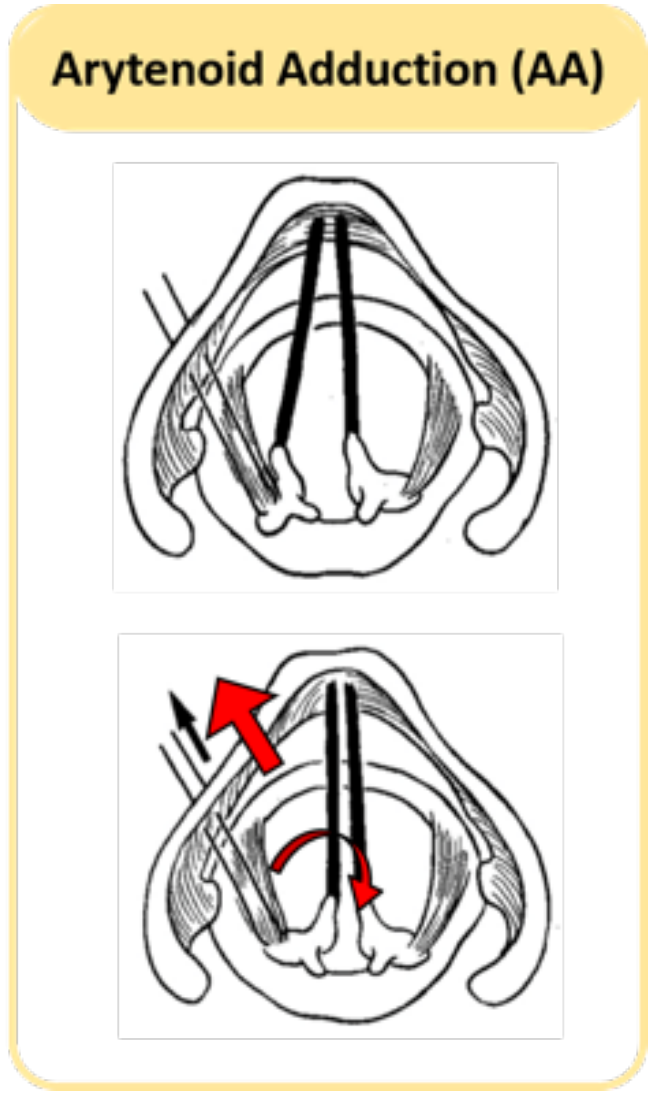
Arytenoid Adduction (AA)

- In 1978, Dr. Isshiki introduced the AA method to close the posterior glottic gap.
- Thread is sutured to the muscular process of the arytenoid cartilage and pulled in forward and outward direction and fixed.
- AA is technically demanding and not without complications.
- AA is usually performed in combination with MT to achieve complete glottic closure.
- General anesthesia required





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Injection laryngoplasty

- **Vocal fold augmentation** by injecting the body's own fat, calcium hydroxylapatite (Radiesse™), hyaluronic acid (Restylane®), polydimethylsiloxane elastomer (VOX Vocal fold Implant).

- Advantages:

Outpatient treatment, no skin incision necessary

- Disadvantages:

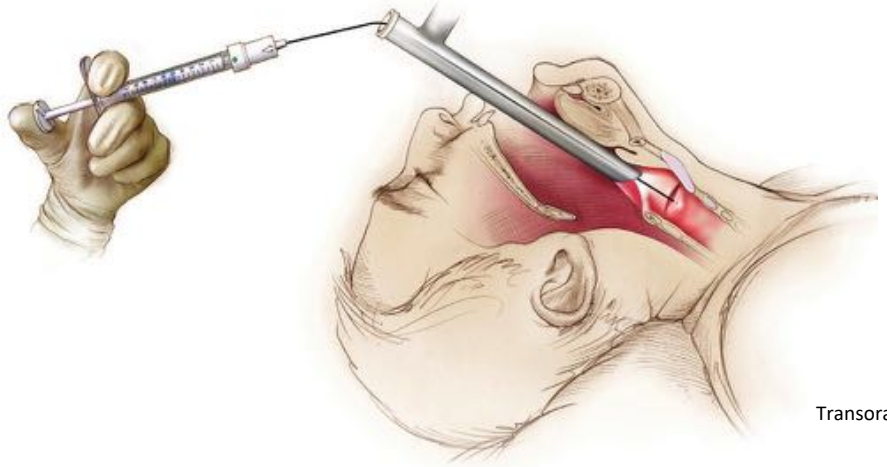
Temporary effect (except VOX)

Repeated injection necessary

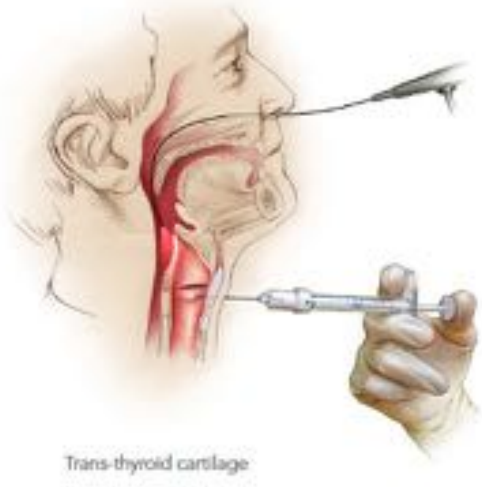
Cannot close the posterior glottic gap

May affect the vibration of the vocal folds

Different approaches to injection:



Transoral



Trans-thyroid cartilage

Trans-cricothyroid membrane

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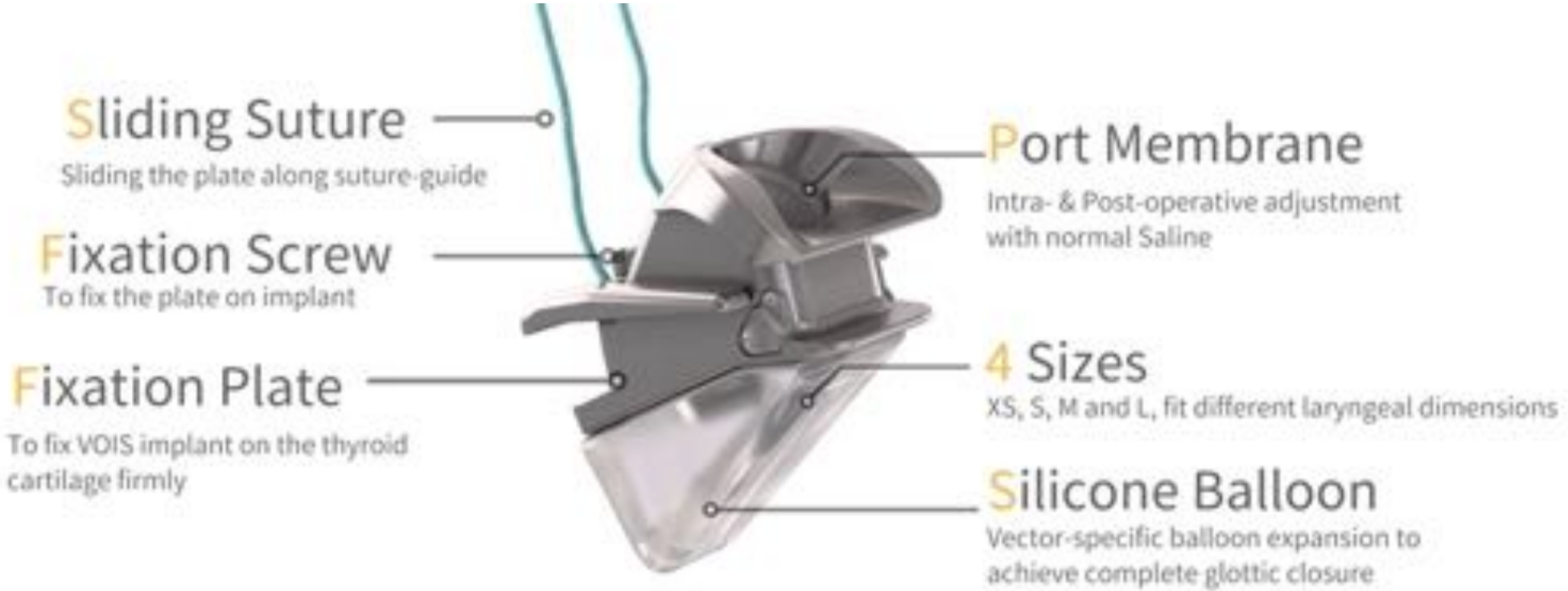
APrevent® VOIS



Features of APrevent® VOIS

- Standardized procedure
- Adjustability
- Secure attachment
- Result optimization
- Individual fine-tuning
- Minimally invasive
- Complete glottic closure

APrevent® VOIS system

The set contains 16 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.

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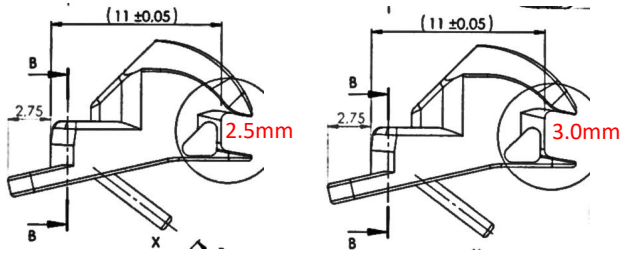
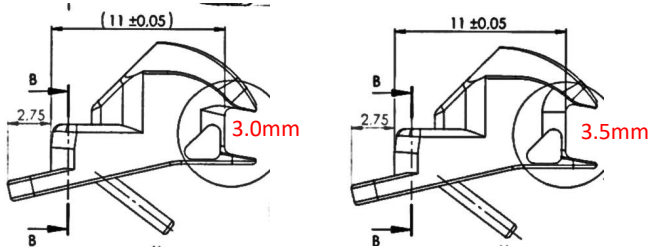
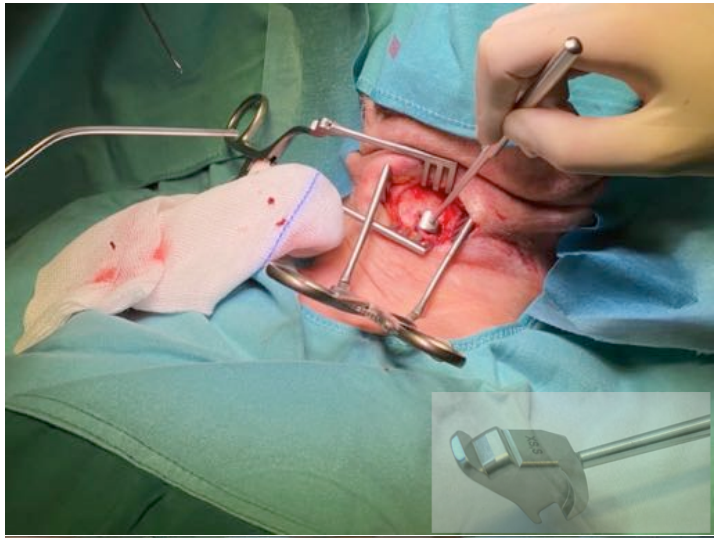
APrevent® VOIS system

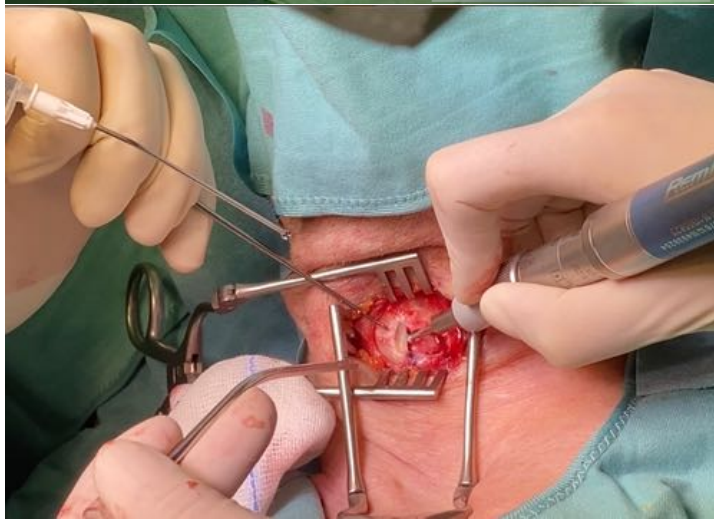
Gehäuseversionen:
VOIS-XS, VOIS-S
APT001, APT002 – 2.5mm
APT008, APT009 – 3.0mm



VOIS-M, VOIS-L
APT003, APT004 – 3.0mm
APT010, APT011 – 3.5mm







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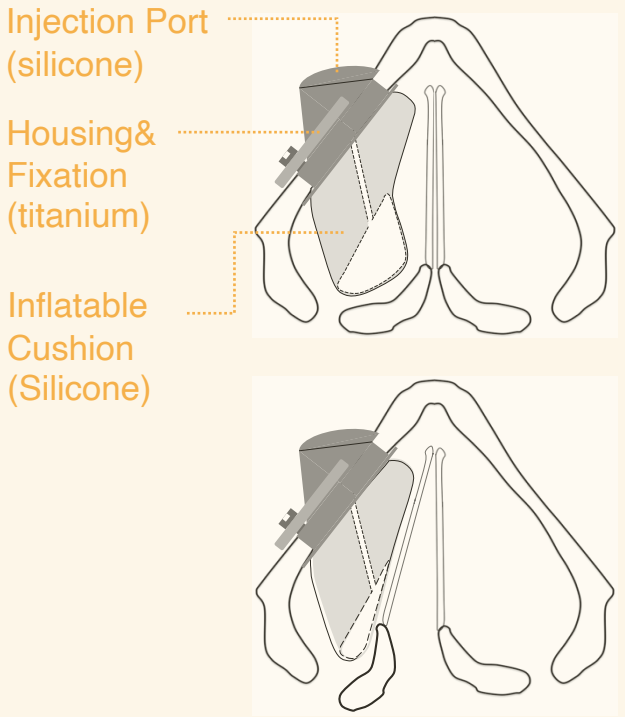
Type I Thyroplasty

How to achieve optimal glottal closure?

Important factor for better glottal gap closure is the repositioning of arytenoid cartilage. This can be achieved if the implant has the following features:

- Posteromedial expansion

- Adjustable in dimensions to conform to variations of different larynges,



Advantages of Aprevent®VOIS

- Better reproducible results (standardized procedure)
- Reduction of intra- and post-operative complications (shorter operation time, firm implant fixation)
- Post-operative fine-tuning enables individual result optimization
- No revision surgery necessary

Typ I Thyroplastic

Criteria for Successful Thyroplasty

- **Windowposition**
  How to localize the ideal window position?
- **Implantsize and -shape**
  How to choose the optimal implant size and shape?
- **Implant-fixation**
  How to avoid implant migration?

Surgical procedure of APrevent® VOIS

1. Allocation of key points
2. Outline the rectangular window
* Optional procedure
3. Marking, drilling and trimming of the window
4. Insert the VOIS implant

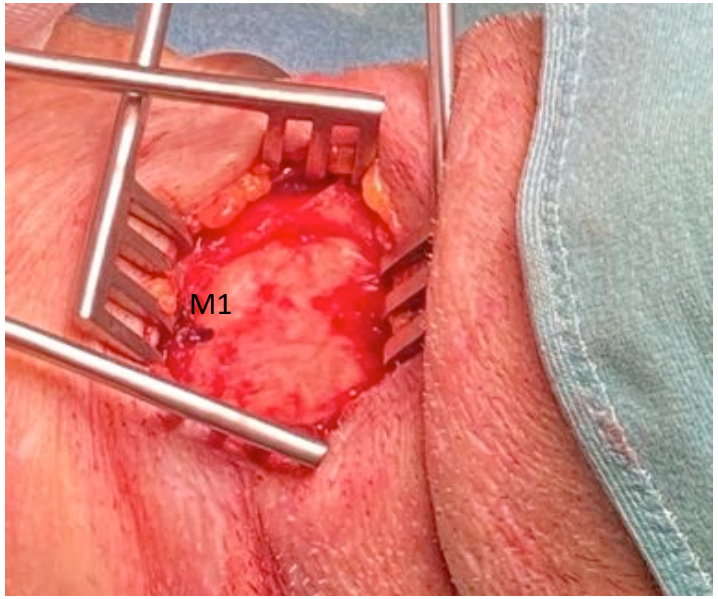
1. Allocation of key points

A. Find “M1”, midpoint of anterior thyroid cartilage border

B. Find inferior tubercle, define the points “A” ,“B” and inferior border line “I”

C. Find “M2”, posterior thyroid cartilage border, then define superior line “S” passing through “M1” and “M2”, running parallel to the inferior borderline “I”, followed by defining the implant size with the thyroid cartilage ruler APT103 by length “S”.

D. Use the APT104 instrument to define the upper margin of the window and line “H”



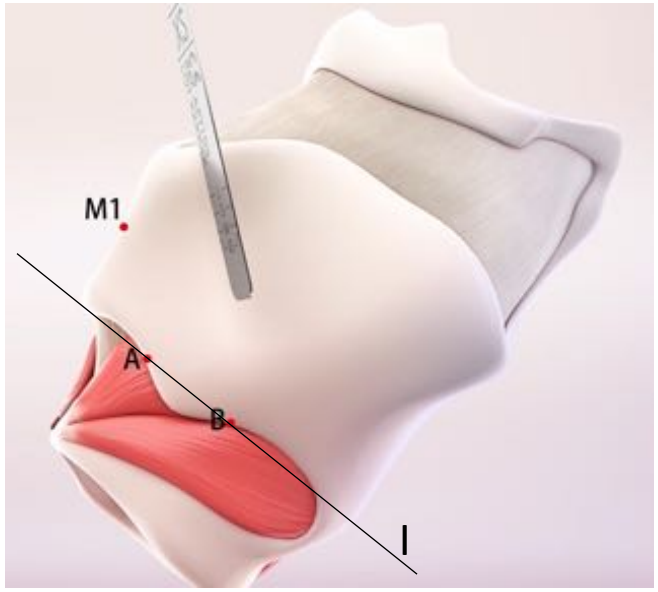
1. Allocation of key points

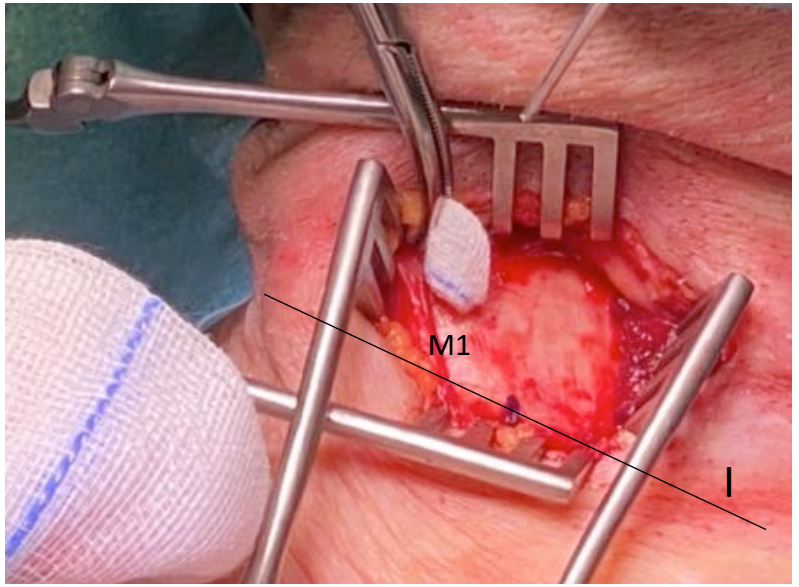
A. Find “M1”, midpoint of anterior thyroid cartilage border

B. Find inferior tubercle, define the points “A” ,“B” and inferior border line “l”

C. Find “M2”, posterior thyroid cartilage border, then define superior line “S” passing through “M1” and “M2”, running parallel to the inferior borderline “l”, followed by defining the implant size with the thyroid cartilage ruler APT103 by length “S”.

D. Use the APT104 instrument to define the upper margin of the window and line “H”





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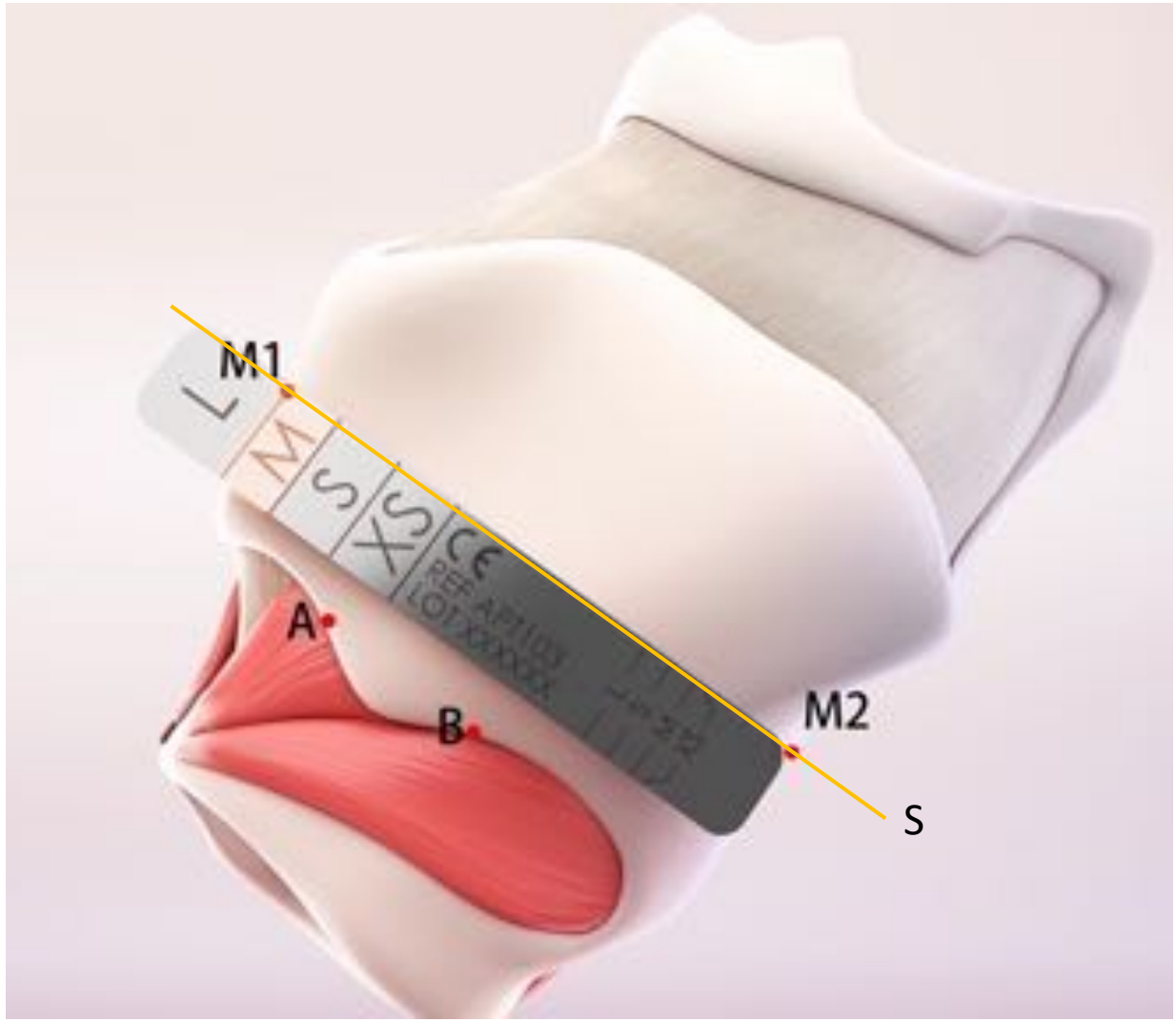
D. Use the APT104 instrument to define the upper margin of the window and line “H”



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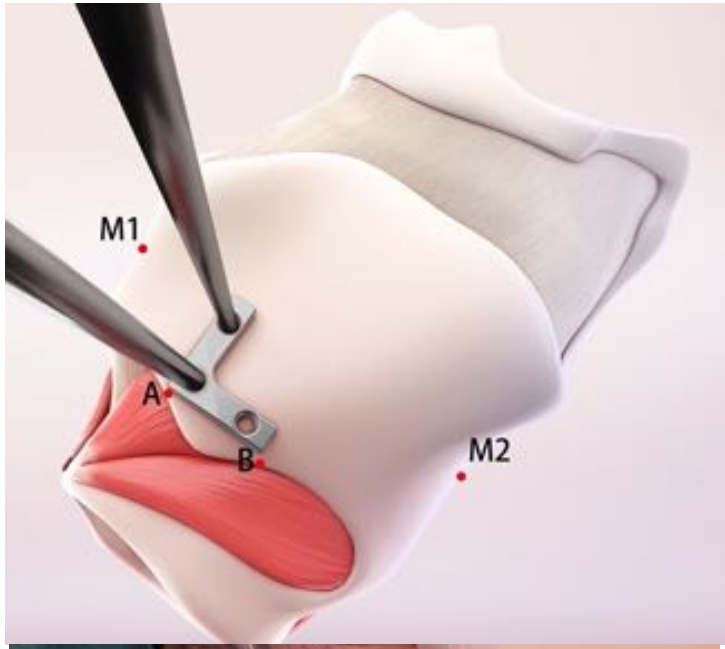
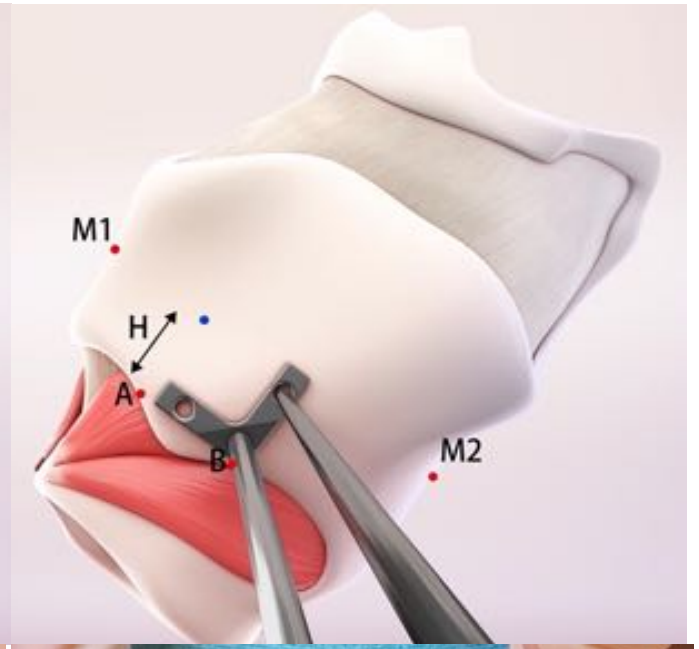
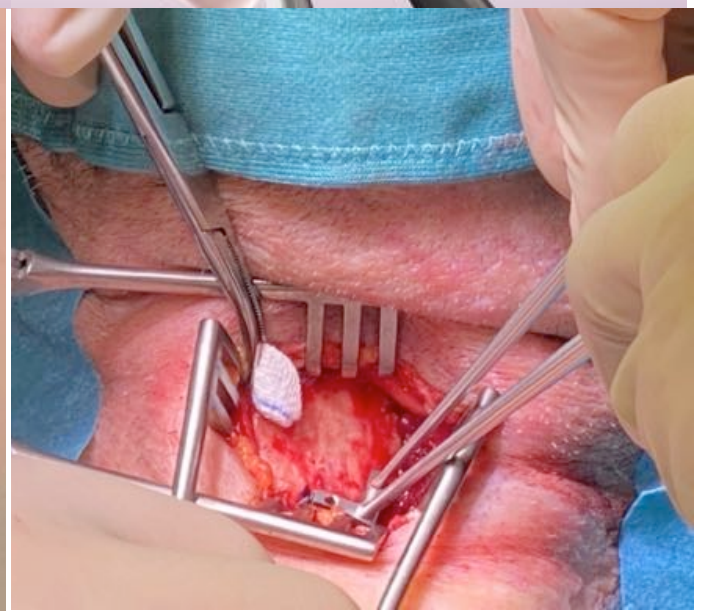




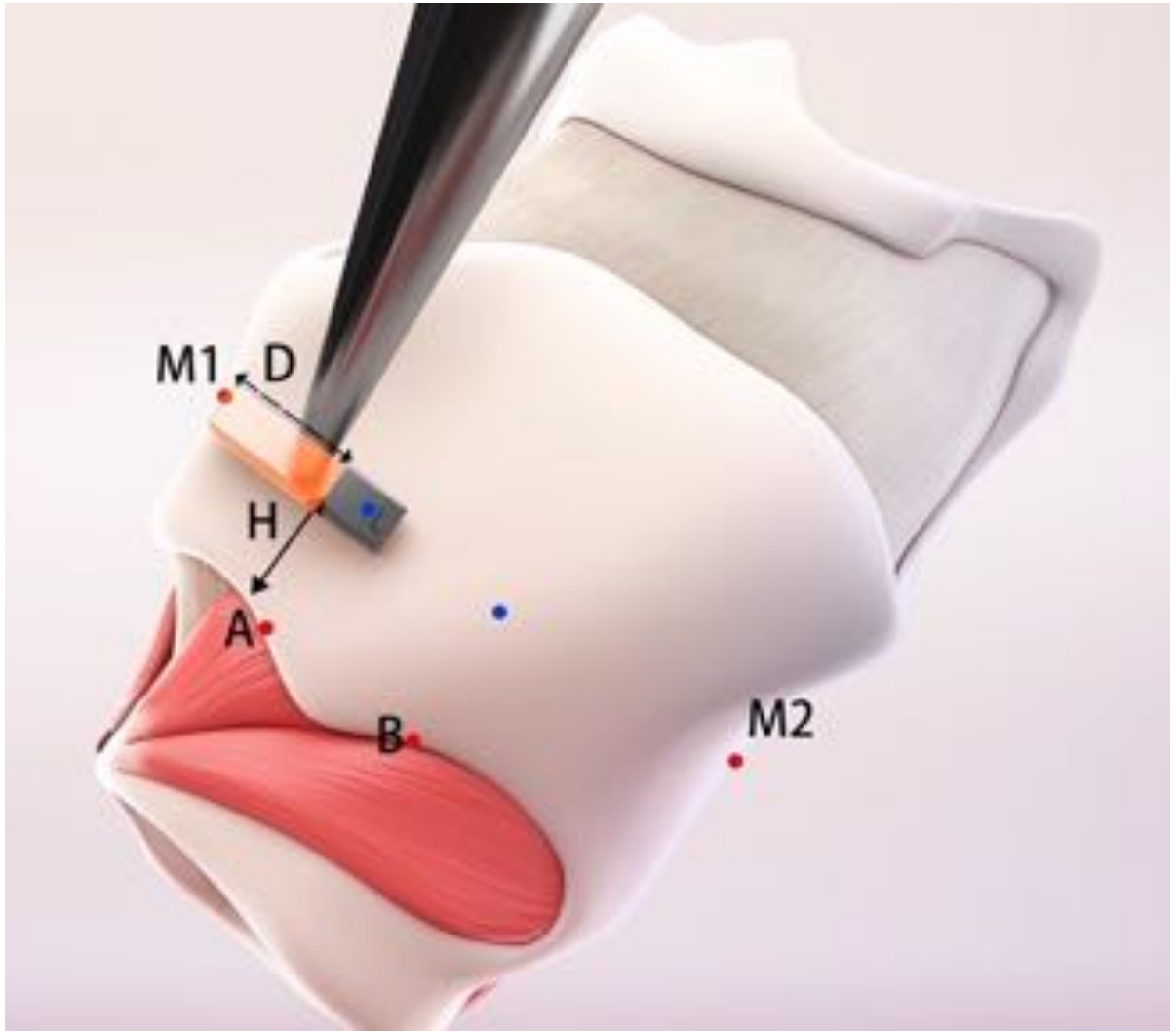


1. Allocation of key points

E. Distance “D” is specific to each implant size and is measured with APT105/106 instruments (see table below)

M1M2/Distance S	Implant size	Distance D
28-33mm	X-Small	7mm
33-38mm	Small	10mm
38-42mm	Medium	8mm
>42mm	Large	12mm

F. Cross distances “D” and “H” to define the location of window



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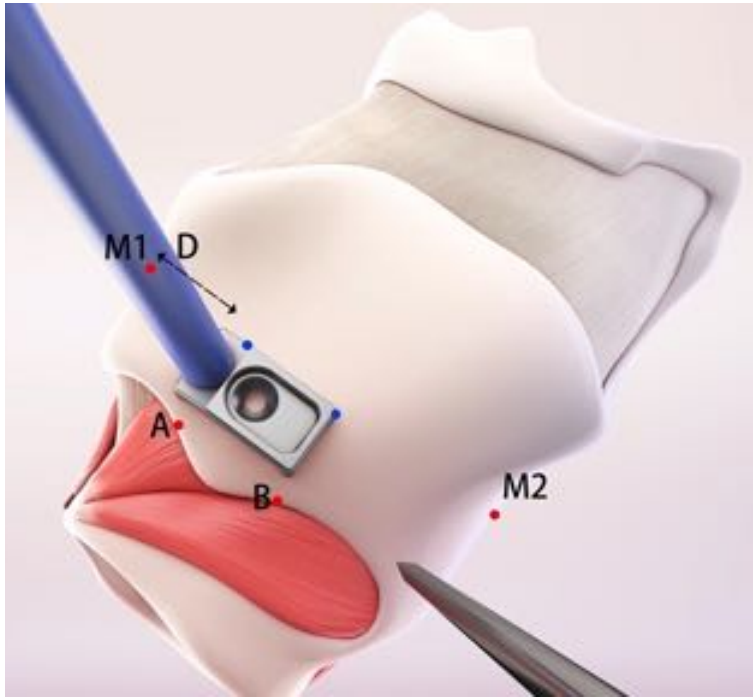
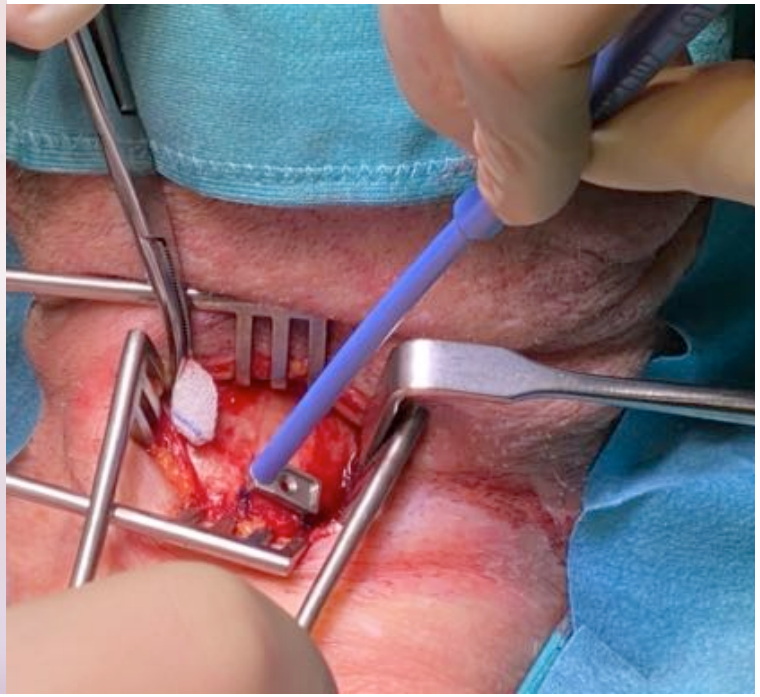
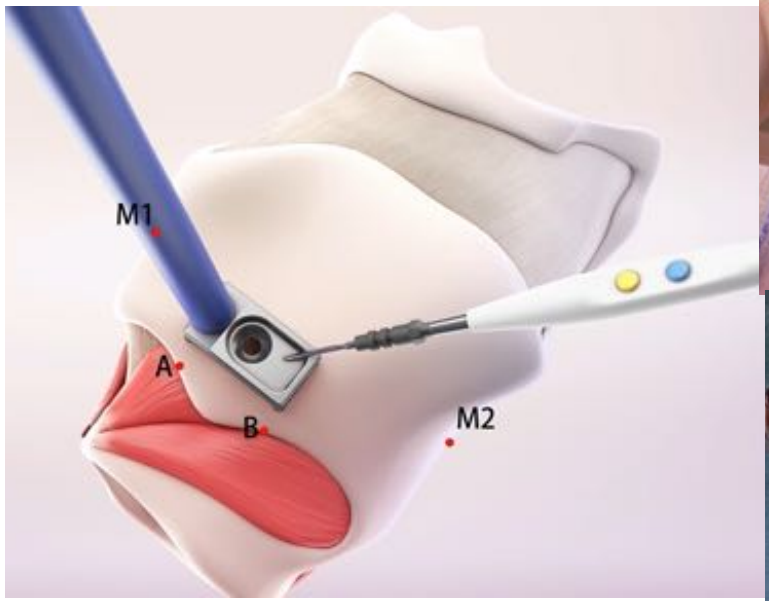
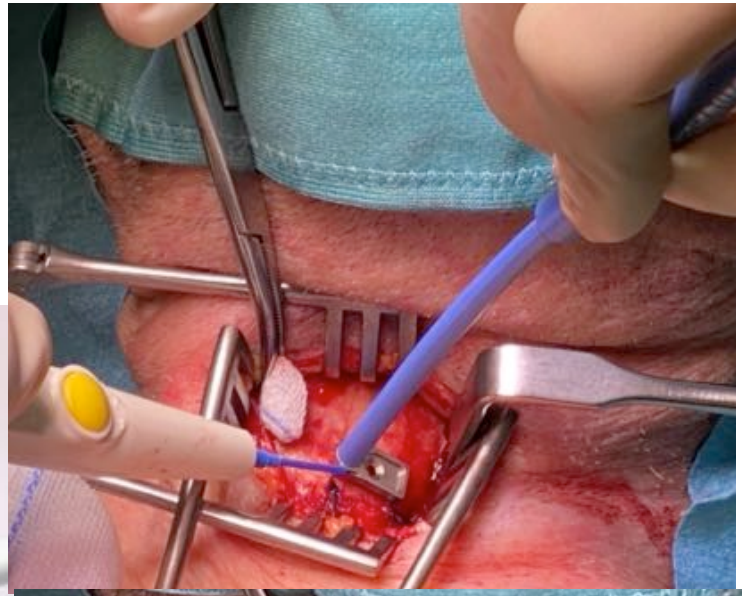


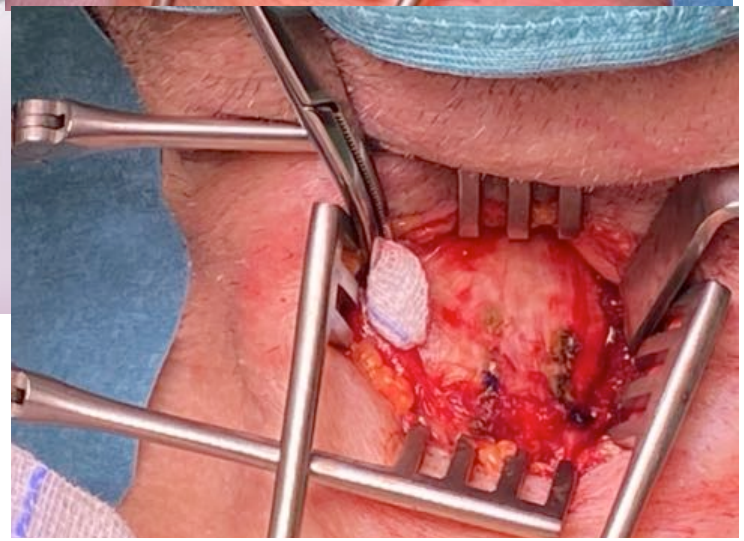


2. Outline the rectangular window

A. An 11 x 6mm rectangular thyroplasty window is outlined using the APT107 “Window Outline Template” with low-energy electrocautery.



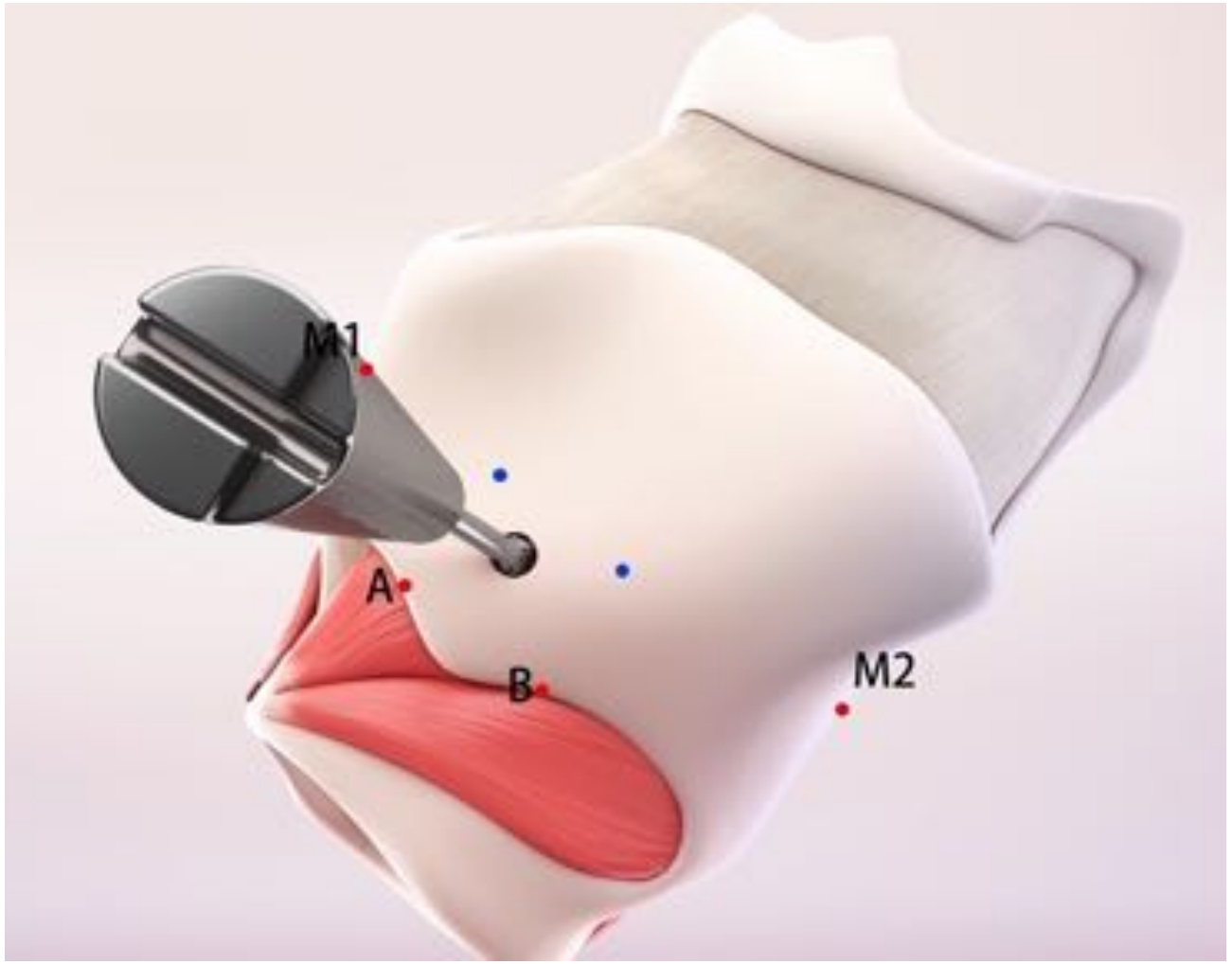




*Optional procedure

Confirm window position with “vocal process sounding probe”

*Window location is the most critical factor to achieve a good implantation result. A surgeon with less experience in type I thyroplasty can use the ***“vocal process sounding probe”*** APT109/110/111/112, available in ***four sizes***, corresponding to each of the four Implant sizes XS/S/M/L to ***confirm the window position*** by inserting the instrument through a hole under endoscopic control before drilling out the rectangular window.

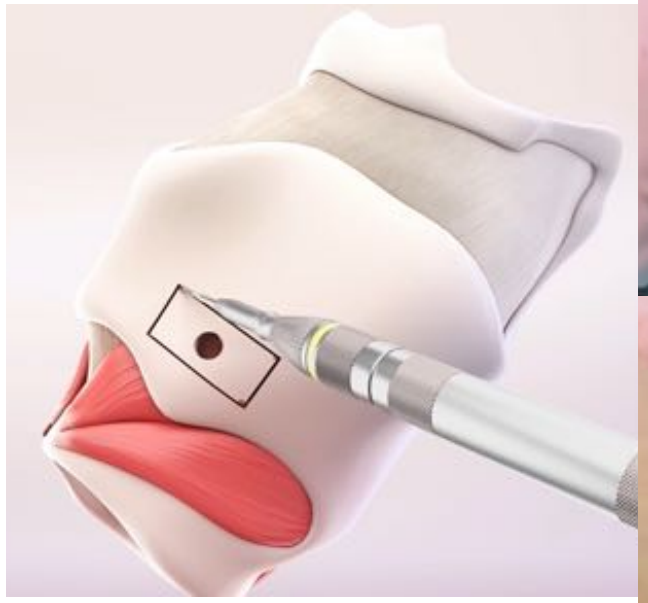


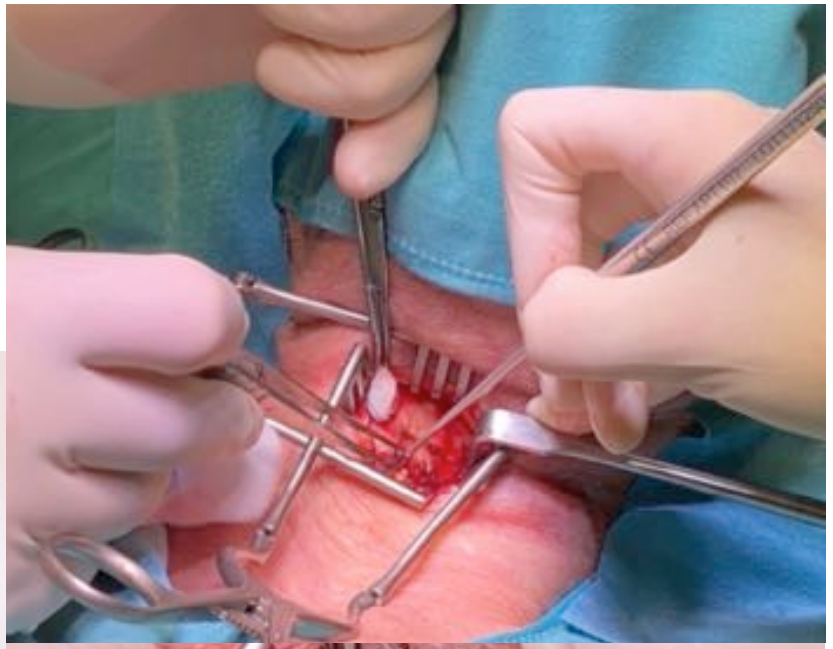
3. Marking, Drilling and Trimming of the window

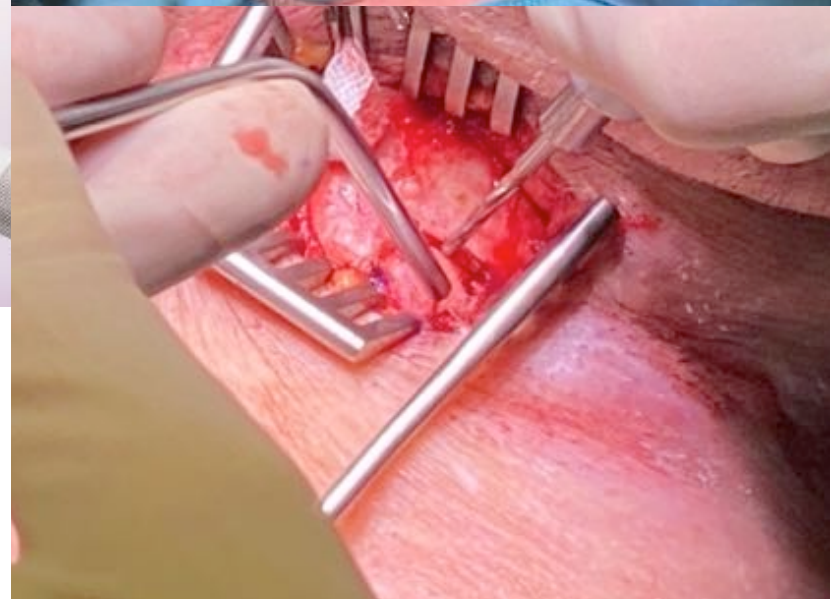
A. Mark and drill out an 11x6mm rectangular window.

B. APT113 “window size checking gauge” is applied to confirm the accurate size of the window.

C. 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.







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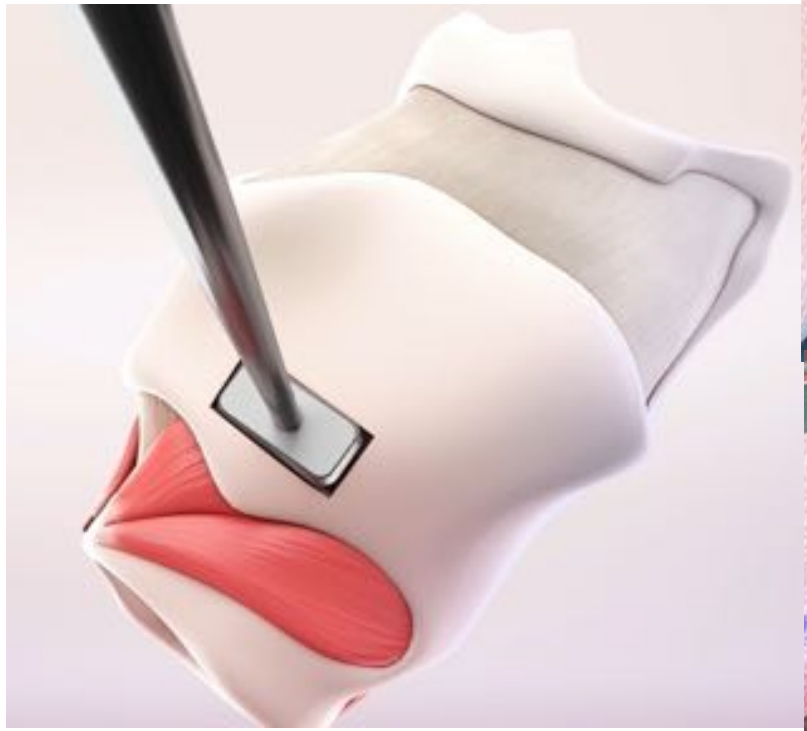

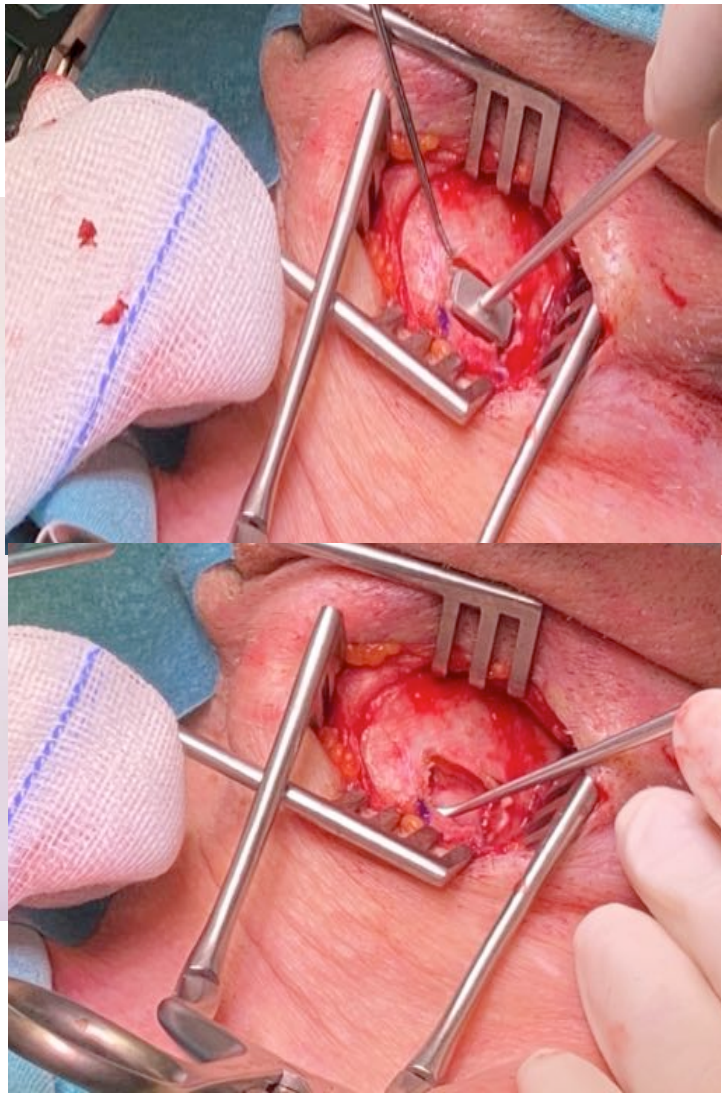

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A. Mark and drill out an 11x6mm rectangular window.

B. APT113 “window size checking gauge” is applied to confirm the accurate size of the window.

C. After careful mobilization of the endolaryngeal tissue, an “implant checking gauge” is used to test the fitting of the implant’s titanium housing into the window.

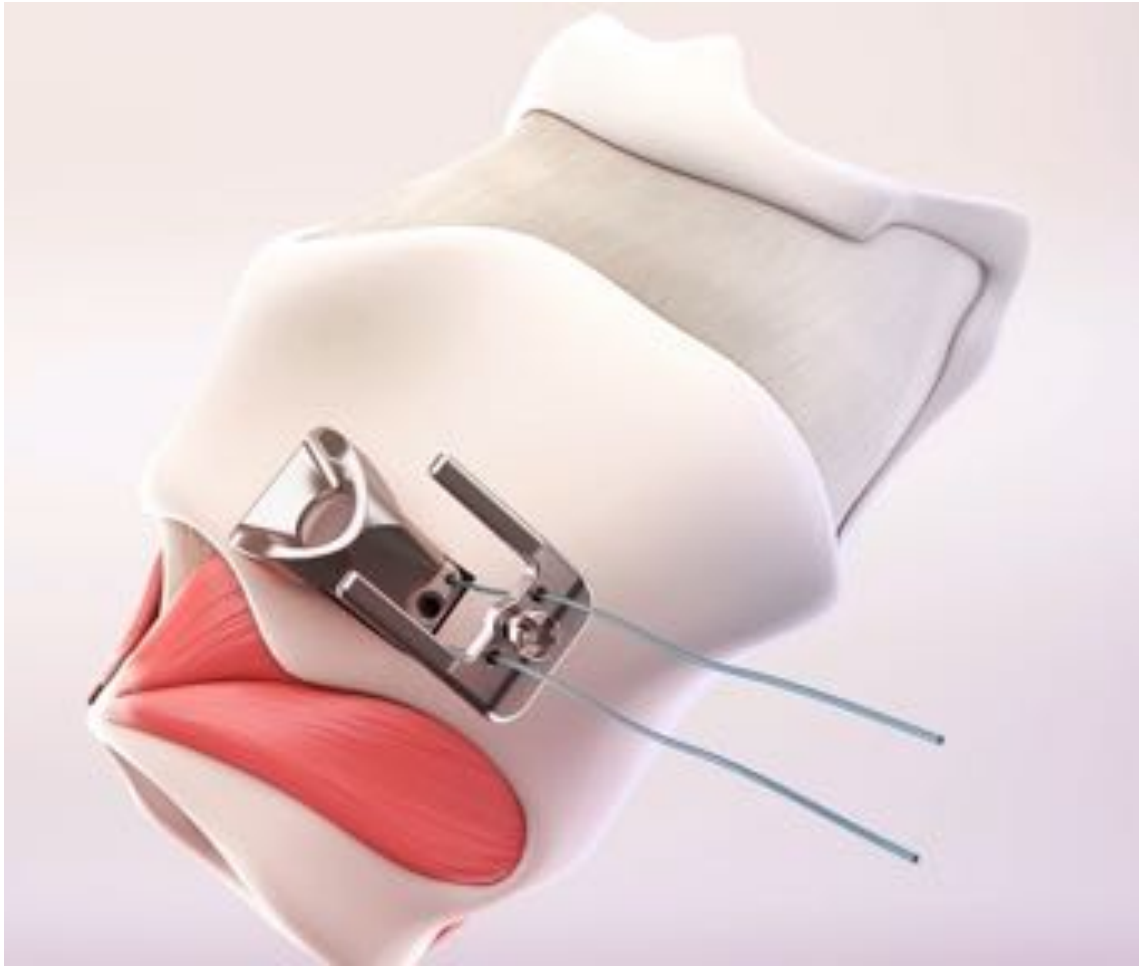
4. Insert VOIS implant

A. Before implantation, check if the balloon is functional.

B. The implant is inserted. The fixation-plate is then slid along the suture-loop down to the posterior part of the thyroplasty window.

C. Fixation plate is screwed clockwise to firmly secure the implant on the thyroid lamina. After screwing, the sliding suture is knotted and cut.

D. If applicable, inject normal saline as needed.



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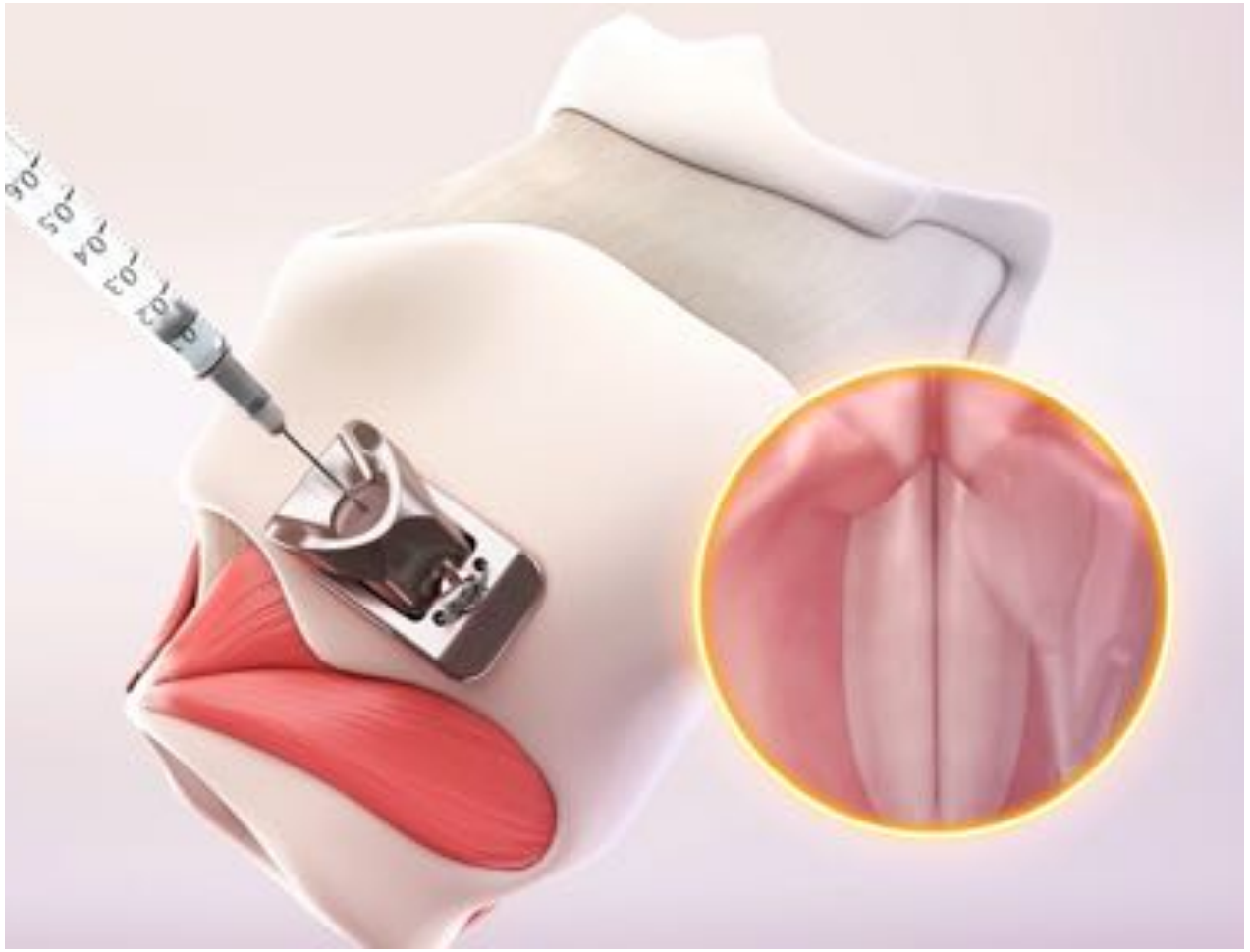
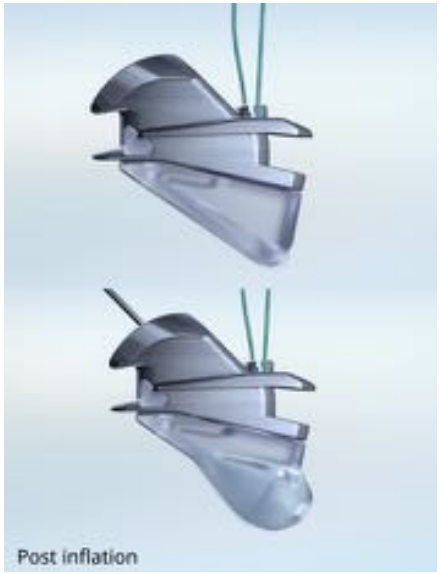
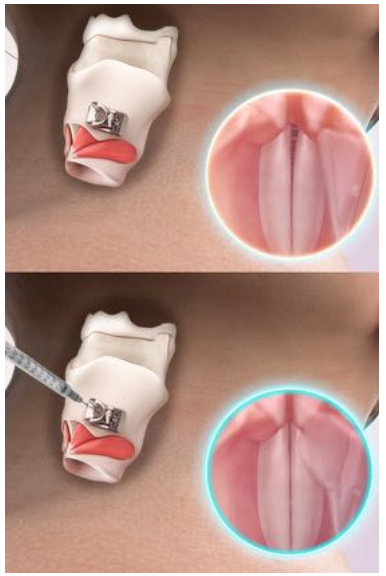
ATTENTION! Never exceed the recommended "maximum filling quantity"!



Adjustability

- Implant can be adjusted intra- and post- operatively.
- Adjustment can be performed at an outpatient setting with percutaneous injection of normal saline.
- The implant located under the skin can be either palpated or located using ultrasound
- Before further saline solution is injected into the implant, the filling volume in the implant “MUST” be completely removed.
- Puncture the port membrane with a 24G needle connected to a 1ml syringe filled with the implant-specific “maximum filling volume” of saline.
- Inject the desired amount under phonatory and / or endoscopic control.
- The balloon expands and closes the glottic gap.



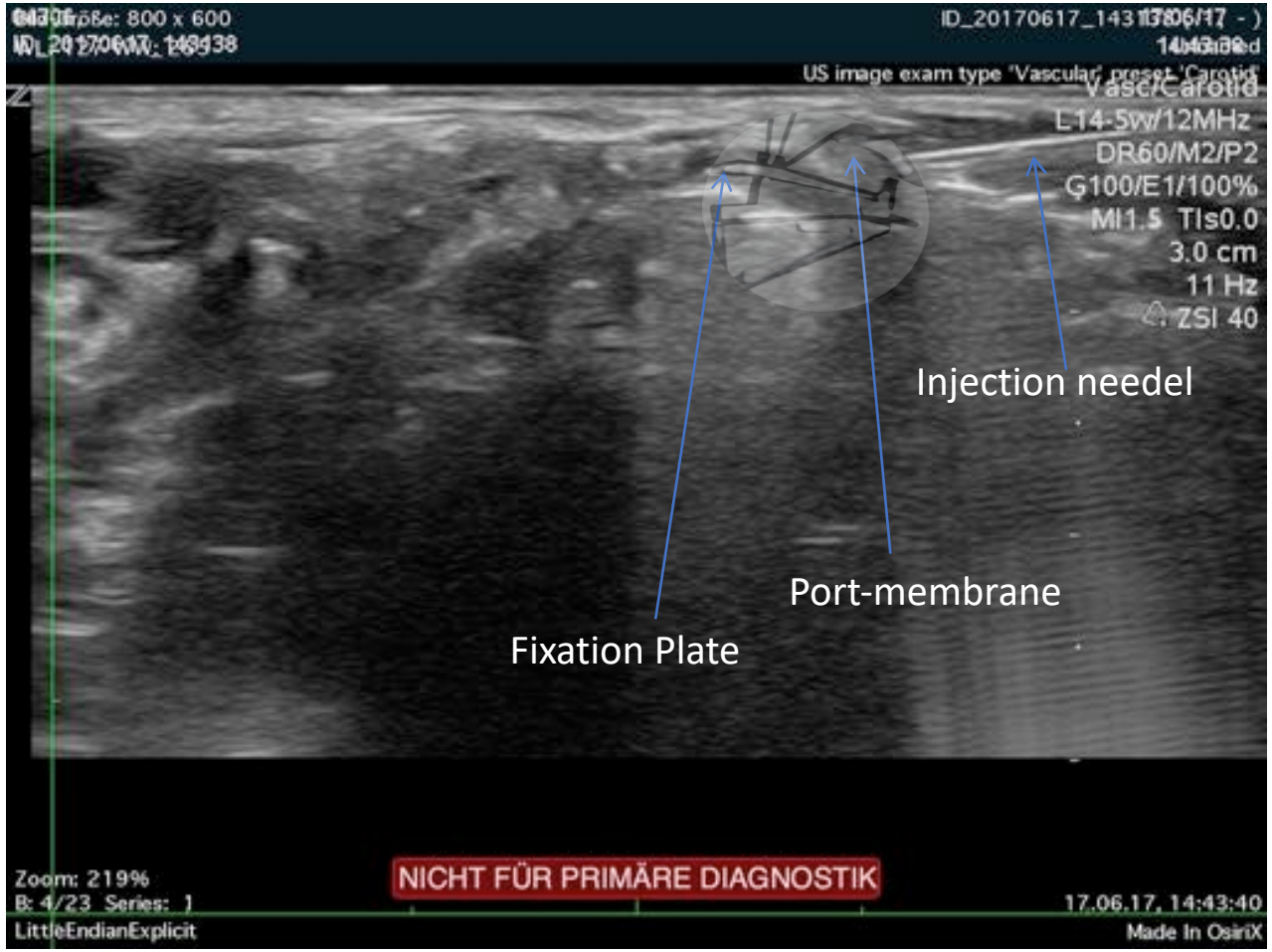


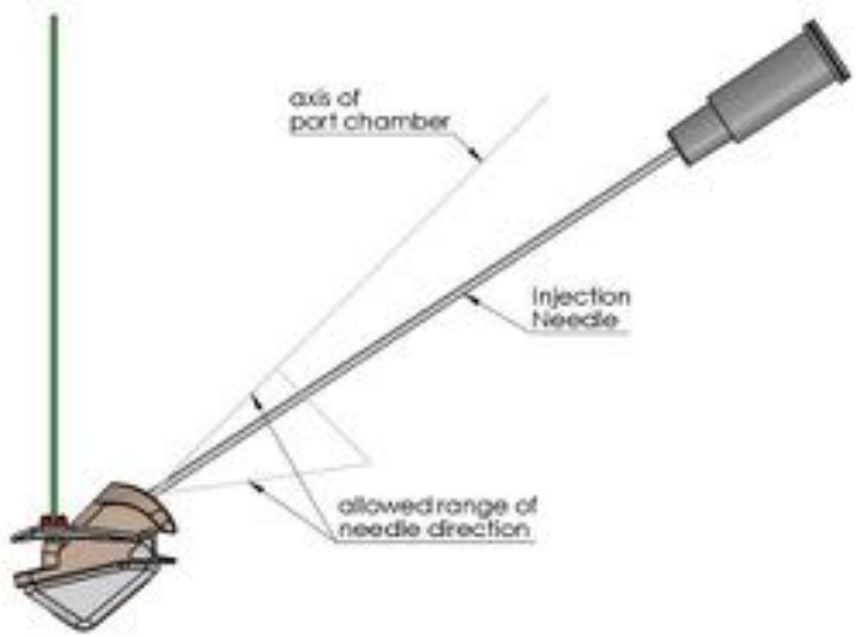
Implant Size	Maximal Filling Volume
X-Small	0.17ml
Small	0.25ml
Medium	0.30ml
Large	0.30ml

ATTENTION! Never exceed the recommended "maximum filling quantity"!

Adjustability – Ultrasound Guidance

- If the implant cannot be palpated, then use ultrasound to localize the VOIS implant.
- Implant has a tilted port chamber, which is optimized for the in-plane technique.





Advantages of APrevent® VOIS

Company / Features	APrevent®	Boston Medical Product	W. L. Gore & Associates	Heinz Kurz
Product Name	**VOIS**	**Montgomery**	**Gore ReVox**	**TVFMI**
Picture				
Intraoperative Adjustment	Yes	No	Yes	Yes
Postoperative Adjustment	Yes	No	No	No
Vocal Fold Closure	100%	60~70%	60~70%	60~70%
User Friendliness	Optimal	Suboptimal	Suboptimal	Suboptimal
Material	Silicon cushion	Silicon block	ePTFE strip	Titanium plate

Type I Thyroplasty with VOIS

Summary

- Sufficient exposure of the inferior thyroid cartilage border
- Identify the *inferior tubercle*
- Locate the landmarks to define the optimal window position
- Choose the correct implant size and fixate firmly on the window
- Adjust the silicon cushion with physiologic saline solution for result optimization

Advantages of APrevent® VOIS

- Offers the benefits of MT and AA with a single procedure.
- Postoperative adjustability replaces the need for revision.
- Can be performed under general anesthesia or conscious anesthesia.
- Shorter operation time with reduced risk of complications.
- Precise fine-tuning with patient-oriented result optimization.
- Standardized procedure using specifically designed instruments allows better reproducible results.
- The size of the implant can be adapted to the physiological postoperative changes in condition.