Boston
Medical Products
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Instructions for Use
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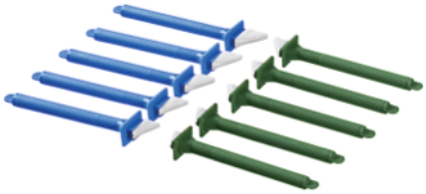
EN

Montgomery® Thyroplasty Implant

Thyroplasty Implant

Montgomery® Thyroplasty Measuring Kit

Thyroplasty Sizer Kit



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1 About these Instructions for Use

1.1 Symbols Glossary

Symbol	Title/Description of Symbol	Standard Designation Number + Symbol Designation Number
	Caution: Consult Instructions for Use	ISO 15223-1:2016 – 5.4.4
	Do not use if package is damaged	ISO 15223-1:2016 – 5.2.8
	Keep away from direct sunlight	ISO 15223-1:2016 – 5.3.2
	Keep dry	ISO 15223-1:2016 – 5.3.4
	Use-by date	ISO 15223-1:2016 – 5.1.4
	Sterilized using ethylene oxide	ISO 15223-1:2016 – 5.2.3
	Do not re-use	ISO 15223-1:2016 – 5.4.2
	Do not resterilize	ISO 15223-1:2016 – 5.2.6
	MR safe	ASTM F2503-13 – 7.3.1
	Catalog number	ISO 15223-1:2016 – 5.1.6
	Batch code	ISO 15223-1:2016 – 5.1.5
	Quantity per packaging unit	N/A
	Manufacturer	ISO 15223-1:2016 – 5.1.1
	(EU) Authorized representative in the European Community	ISO 15223-1:2016 – 5.1.2
	(USA) Caution: Federal Law restricts this device to sale by or on the order of a physician.	N/A
	Consult Instructions for Use. The Instructions for Use are provided in electronic form (e-labelling).	N.a.

Table 1: Symbols Glossary

Standard Designation Number	Standard Title
ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
ASTM F2503-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Table 2: Titles of Standards used in the Symbols Glossary

1.2 Safety Information Marking

⚠ WARNING

Non-compliance may result in serious injuries, serious deterioration of the general condition or the death of the patient, user, or a third party.

NOTICE

Product damage or other damage may occur in case of non-compliance.

2 Important Safety Information

⚠ WARNING

- Before using the product, read the Instructions for Use. Adhere to and save the Instructions for Use. Otherwise there are risks to the health of your patient.
- Application only by a physician trained in the procedure. Otherwise there are risks to the health of your patient.
- Use the product exclusively in the configuration specified in these Instructions for Use. Otherwise there are risks to the health of your patient.

3 Product Codes / REF

3.1 Thyroplasty Implant

REF	Name
MTF-06	Thyroplasty Implant: Size Female 6
MTF-07	Thyroplasty Implant: Size Female 7
MTF-08	Thyroplasty Implant: Size Female 8
MTF-09	Thyroplasty Implant: Size Female 9
MTF-10	Thyroplasty Implant: Size Female 10
MTF-11	Thyroplasty Implant: Size Female 11
MTM-08	Thyroplasty Implant: Size Male 8
MTM-09	Thyroplasty Implant: Size Male 9
MTM-10	Thyroplasty Implant: Size Male 10
MTM-11	Thyroplasty Implant: Size Male 11
MTM-12	Thyroplasty Implant: Size Male 12
MTM-13	Thyroplasty Implant: Size Male 13

3.2 Thyroplasty Sizer Kit

REF	Name
MT-300	Thyroplasty Sizer Kit: Female
MT-400	Thyroplasty Sizer Kit: Male

4 Scope of Delivery

4.1 Thyroplasty Implant

- 1 x Thyroplasty Implant
- 1 x Product Registration Card (for US use only)
- 3 x product label

Product sterile, in blister pack.

4.2 Thyroplasty Sizer Kit

- 5 x Thyroplasty Sizer
- 1 x Product Registration Card (for US use only)

Product sterile, in blister pack.

5 Intended Use

The *Montgomery Thyroplasty Implant System* is designed as part of a surgical operation, which accomplishes medialization of a paralyzed vocal cord in order to improve voice quality.

6 Indication

- Unilateral vocal cord paralysis

7 Contraindication

There are no known contraindications.

8 Special Patient Groups

Does not apply.

9 Product Description

Part of the *Montgomery Thyroplasty Implant System.*

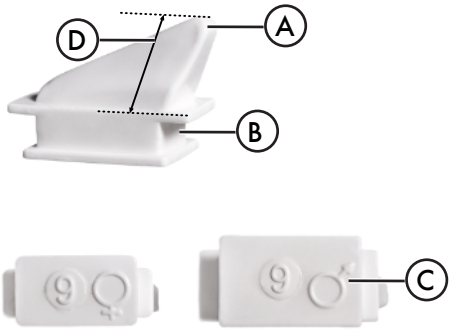


Illustration 1: Thyroplasty Implant

A Tip
B Notch
C Base with indication of gender and size (= distance D in mm)
D Reference for size indication

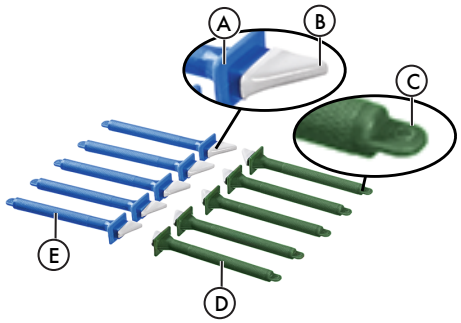


Illustration 2: Thyroplasty Sizer Kit

A Base
B Tip
C Handle with indication of gender and size
D Thyroplasty Sizer Kit: Female
E Thyroplasty Sizer Kit: Male

10 Material

- Thyroplasty Implant : Silicone (unrestricted)
- Thyroplasty Sizer: Silicone (restricted)

11 Lifetime

11.1 Thyroplasty Implant

Maximum application duration: Unlimited
Duration of treatment at the discretion of the treating physician.
Regular check-ups are needed.

11.2 Thyroplasty Sizer Kit

For single patient use only.
[Reprocessing, page 6]

12 Shelf Life and Storage

For date of expiry, see the product label.
Store the product in unopened original packaging.

13 Possible Complications and Side Effects

- Failure to obtain satisfactory phonation, sometimes resulting in a second procedure to replace the implant with an implant of a different size
- Difficulty to stabilize the implant as intended in the thyroplasty window
- Laryngeal edema / intra-laryngeal bleeding that could interfere with the laryngeal airway
- Laryngeal dyspnea
- Late postoperative problems such as keloid scar, edema of the paralyzed true vocal cord, and granuloma of the contralateral mobile arytenoid cartilage

14 Combining with Other Procedures

⚠ WARNING

- Laser therapy, argon plasma therapy, high-frequency surgery, and other procedures, the effect of which is due to heat: Do not use those methods directly on the product.
  Otherwise, injury to the tissue and product damage are possible.

The product is MRI safe.

15 Reprocessing

⚠ WARNING

- Single use product: Do not reprocess (e.g., clean, disinfect, sterilize), resterilize or reuse the product. This is the only way to ensure the product is germ-free and functional. Due to the mechanical properties of the product, reprocessing or resterilization could lead to material degradation.

16 Application Instructions

⚠ WARNING

- Do not use the product if the packaging or the product is damaged or expired. This is the only way to ensure the product is germ-free and functional.
- Only remove the product from storage packaging immediately before use. When the product is removed from the packaging, observe the relevant asepsis regulations. Otherwise there are risks for the health of your patient.

Procedure and equipment: As usual for the thyroplasty type I procedure.

Ensure the presence of hygienic / sterile conditions needed for the intervention.

Perform intervention under conscious sedation.

Preoperative, intraoperative, and postoperative coverage with appropriate antibiotics is indicated.

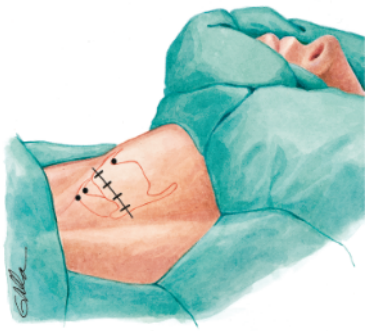
16.1 Required Equipment and Materials

- Montgomery Thyroplasty Instrument Set:
  - Window Caliper, 7 mm, Female / 9 mm, Male
  - Outline Instrument, Female / Male
  - Implant Inserter, Female / Male
  - Curved Hook, Small / Large
  - Sharp Hook, Small / Large
  - Duckbill Elevator, 3 mm / 5 mm
  - Chisel Elevator

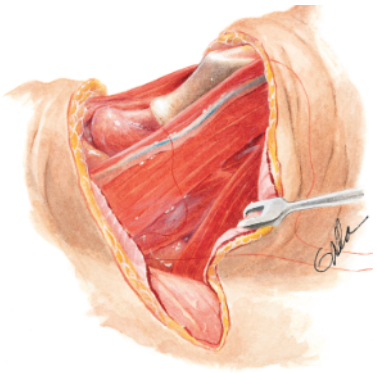
Other equipment / material as required for thyroplasty type I procedure.

16.2 Implantation Technique

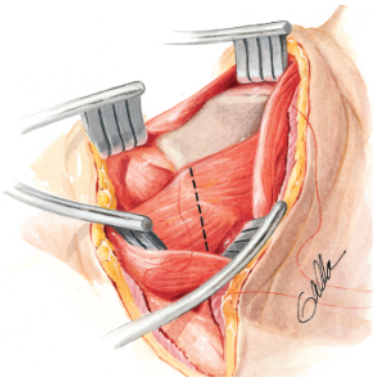
16.2.1 Access



1. Mark the thyroid notch, cricothyroid membrane, and the inferior margin of the cricoid cartilage using a surgical skin marker.
2. Mark a horizontal skin incision line approximately 5 mm above the inferior margin of the thyroid cartilage.
3. Draw hatch marks.
4. Make incision: Begin incision 2 cm from the midline on the contralateral side and extend it on the ipsilateral side of the neck to the anterior border of the sternocleidomastoid muscle.
5. Extend the skin incision through the platysma layer so as to expose the sternohyoid and omohyoid muscles.
6. Establish flaps superiorly and inferiorly in a plane superficial to fascia covering these strap muscles.
7. Separate the flaps with self-retaining retractors.

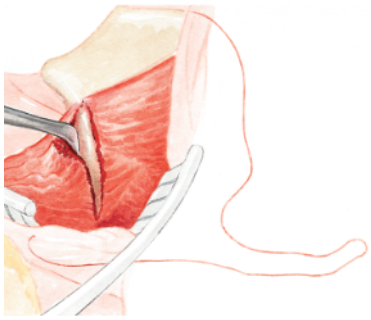


8. Identify midline. Separate both sternohyoid muscles to expose the thyroid notch, anterior aspect of the thyroid cartilage, cricothyroid membrane, and cricoid cartilage.



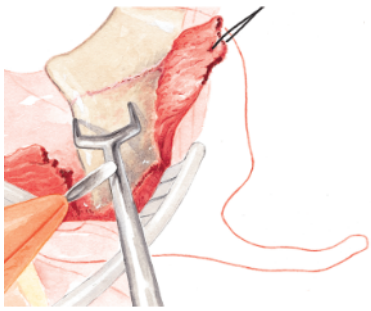
9. Dissect the undersurfaces of the ipsilateral sternohyoid and omohyoid muscles using a Gelpi retractor so that they can be retracted laterally.

10. Retract the strap muscles laterally to expose the thyrohyoid muscle on the surface of the thyroid lamina.
11. Transect the thyrohyoid muscle just above the inferior border of the thyroid lamina.

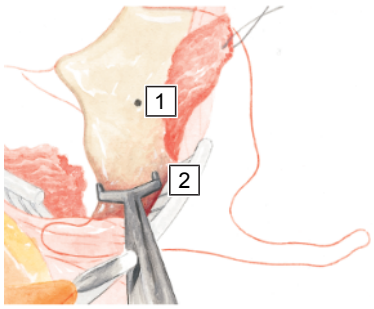


12. Detach the thyrohyoid muscle from its inferior attachment using the chisel elevator or cutting current on the cautery.
13. Expose the thyroid lamina, its inferior border, and the inferior thyroid tubercle.

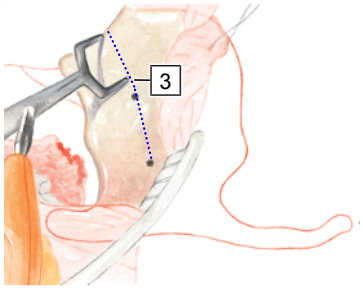
16.2.2 Locate the Key Point



1. Place one pin of the window caliper onto the inferior border of the thyroid lamina anterior to the inferior thyroid tubercle, the second pin is placed onto a point directly superior.
2. Mark the superior point (1) using electrocautery. To do so, slightly lift the inferior pin of the window caliper and apply electrocautery to the shaft of the window caliper.

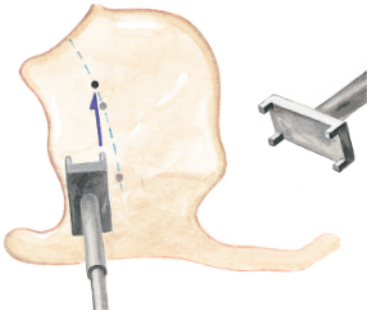


3. Repeat on the posterior side of the the inferior thyroid tubercle (2).
4. Connect point 1 and point 2 using a surgical skin marker. Extend this line to the anterior aspect of the thyroid lamina. The line represents the superior margin of the thyroplasty window.

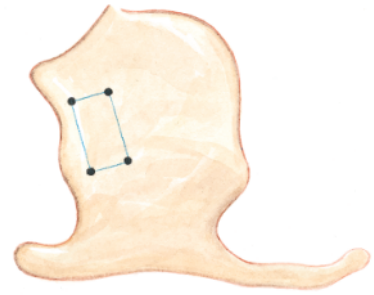


5. Place one pin of the window caliper onto the intersection between the anterior midline and the connecting line between point 1 and point 2. Place the second pin onto the ipsilateral portion of the connecting line. The position of the second pin is the key point (3). The key point marks the position of the anterior superior angle of the thyroplasty window.

16.2.3 Marking the Thyroplasty Window

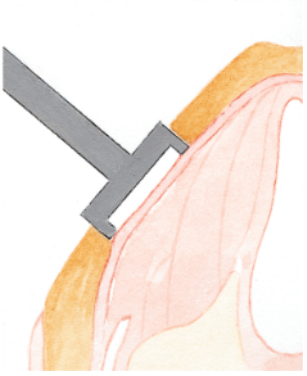


1. Take the outline instrument. Place the antero-superior pin onto the key point.
2. Place the postero-superior pin onto the connecting line between point 1 and point 2. Make sure the remaining 2 pins also touch the surface of the cartilage.

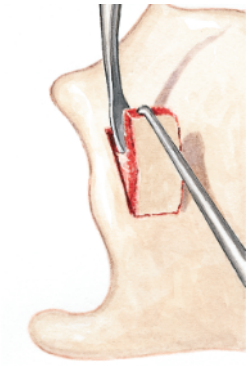


3. Mark the position of all 4 pins using electrocautery. To do so, insert the shaft of the outline instrument into an electrocautery handle.
4. Use a surgical marker to connect the 4 markings to a rectangle.

16.2.4 Cutting the Thyroplasty Window



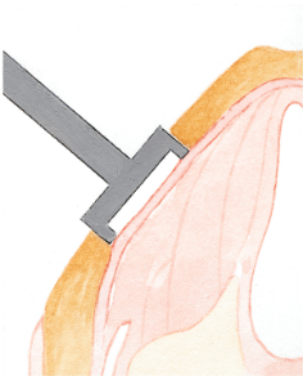
1. Cut the window using a small oscillating saw. Make sure not to cut the window too big. To do so, cut either directly on the lines or towards the inside margin of the lines. Start cutting posteriorly in case bleeding is encountered.



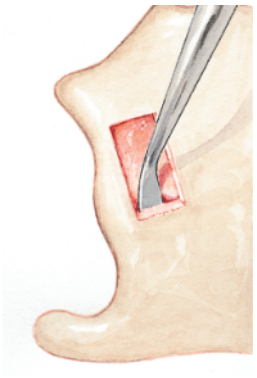
2. As soon as the four sides of the window are completely cut: Grasp the loose piece of cartilage with the sharp hook and elevate it.

3. Use the chisel elevator to separate the underlying perichondrium from the piece of cartilage.

16.2.5 Confirming the Window Size

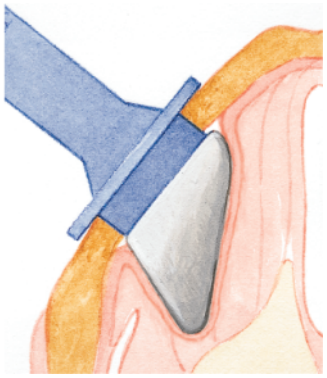


1. Confirm that the window is the correct size. To do so, insert the outline instrument into the window. The outline instrument must fit tighly into the window. If needed, enlarge the window using the saw.
   ATTENTION: At this phase, do not apply electrocautery to the outline instrument.



2. Use a duckbill elevator to elevate the perichondrium around the window from the cartilage in all directions. ATTENTION: Elevate the perichondrium posteriorly to the level of the vocal process of the arytenoid.

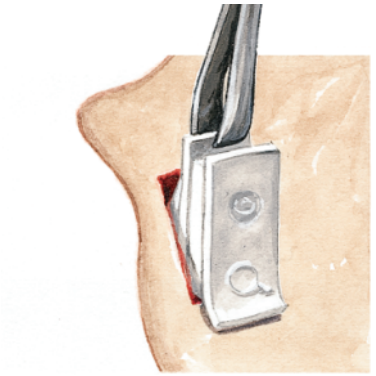
16.2.6 Determine the required Size of the Implant



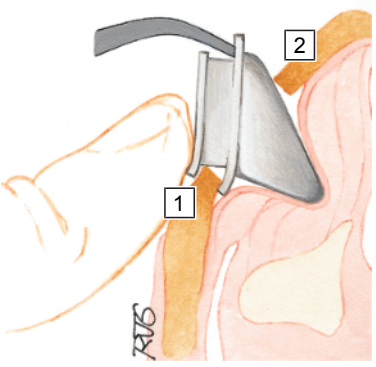
1. Insert a flexible laryngoscope.
2. Insert a thyroplasty sizer into the window with the tip of the sizer pointing into the direction of the vocal process of the arytenoid. Introduce the sizer into the window until the base of the sizer touches the the thyroid lamina.
3. Ask the patient to phonate. View the medialization through the flexible laryngoscope.
4. Iterate with sizer next in size until the optimum voice is achieved. The end points are complete closure during adduction and a good voice.

16.2.7 Inserting the Implant

1. Increase sedation if needed.

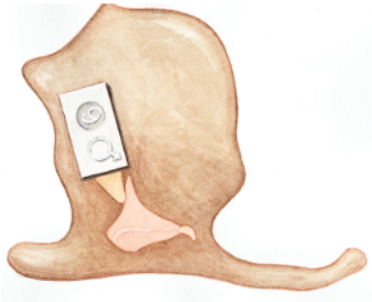


2. Insert the implant into the window with the tip of the implant pointing into the direction of the vocal process of the arytenoid.



3. Place the implant so as to engage the cartilage at the posterior rim of the window in the notch of the implant (1).
4. Hold the implant in position. Use the implant inserter to push the implant into position so as to make the cartilage at the anterior rim of the window snap into the notch of the implant (2).

5. Once the implant is positioned: Remove the laryngoscope.



In case of a fracture of the inferior rim of the thyroid cartilage window, a nonabsorb-able suture may be placed to allow for proper implant stabilization.
Afterwards: Close the wound. Insert a closed suction drainage tubing.

17 Instructing the Patient

Does not apply.

18 Aftercare

- Follow-ups as indicated by the treating physician.
- If required: Medication of pain within the first 24 h post-OP
- Remove the closed suction drainage tubing after 24 h post-OP

The patient is discharged from the hospital at the discretion of the treating physician, but not before the day after the intervention, because of the possibility of laryngeal edema / intra-laryngeal bleeding that could interfere with the laryngeal airway.

19 Maintenance

Does not apply.

20 Disposal

Disposal must be in accordance with national disposal regulations and pursuant to the corresponding risk class.

21 Warranty

The reliability of the product's material and design at the time of shipment is guaranteed. The manufacturer does not know either the diagnosis of the patient or the nature of the application and has no influence on the conditions under which the product is used. The storage conditions after delivery of the product are also beyond the manufacturer's area of responsibility.

Due to biological and individual differences, no product is 100% effective under all circumstances.

Therefore, the manufacturer cannot guarantee a positive effect or the absence of negative effects for product application. The medical staff must use the product on the basis of their medical training and experience, and they are responsible for correct application.

The warranty (repair or replacement) applies only if the product is used in accordance with these Instructions for Use (for instruments, particularly with regard to handling, cleaning, sterilization and maintenance); the warranty period starts on the delivery date.

If you have reason to believe that a new product is faulty, please contact the Customer Service in writing immediately and provide as detailed a description as possible of the fault, the REF (product code), and the LOT (batch code) and/or series number. All allegedly defective products must be returned to us for inspection. Instruments have to be completely cleaned and sterilized, appropriate documentation must be enclosed with the return.

If the manufacturer finds that despite all due care the product was defective at the time of delivery, he will repair the product or replace it promptly. If repair or replacement of the product is not possible, the buyer has the right to cancel the purchase or to reduce the payment, but by a maximum of the purchase price amount.

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, his agents, dealers and suppliers, are excluded unless existing law is contrary to the liability exclusion, e.g. in cases of intent or gross negligence or in the event of physical injury.

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

Furthermore, all claims that result from the use of products that have expired, or were used despite the obvious damage to the packaging, or resterilized and/or recycled contrary to the Instructions for Use, are excluded.

No one is allowed to change the above conditions, make further warranty or liability declarations, or guarantee any properties that surpass those specified in the Instructions.

The General Terms and Conditions of the manufacturer, which can be accessed at http://www.bosmed.com apply in all remaining instances.