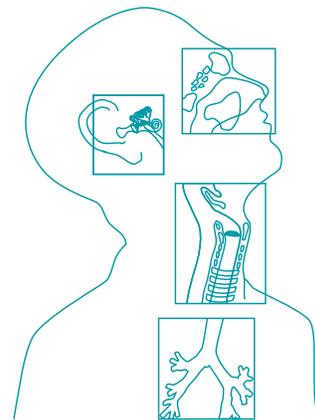
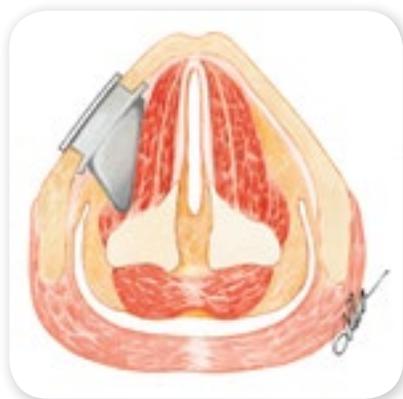




Montgomery[®] Thyroplasty Implant System



Montgomery® Thyroplasty Implant System



The **Montgomery® Thyroplasty Implant System** is the result of over a decade of research and development.

Designed to treat unilateral vocal cord paralysis, this revolutionary system is standardized, eliminating the time-consuming process of customizing implants at the time of surgery. Standardization translates to consistent results. Solid clinical experience involving thousands of patients has produced outstanding voice improvement while reducing long procedures and complications associated with hand-carved implants and injection techniques.

Features

- Complete standardized system
- Eliminates need to hand-fashion implants
- Self-retaining implant design
- No suturing is necessary
- Reduced trauma and surgery time
- Reversible
- Proven clinical success



Montgomery® Thyroplasty Implant System



The Design

The system consists of specially designed surgical instruments, devices for measuring medialization distance prior to implant insertion, and a range of six implant sizes for female patients and six sizes for males. The implants are constructed using implant-grade silicone which has undergone extensive biocompatibility testing.

The surgical procedure has been fine-tuned and involves a step-by-step process for locating the thyroplasty window, creating the window, determining implant size, and inserting the implant. The procedure reduces surgery time and is completely reversible. Procedural videos are available at www.bosmed.com/thyroplasty.

The unique design of the Montgomery® Thyroplasty Implant consists of two major components: the rectangular base and the triangular top. The base is constructed of firm silicone and features three tiers. The lateral, or outer tier, remains on the outer surface of the thyroid lamina and prevents medial displacement of the implant. The middle tier stabilizes the implant and prevents rotation. The inner tier rests against the inner surface of the thyroid lamina and prevents outward displacement. There is a common base for females and a common base for males.

The triangular portion is made using soft silicone and serves to medialize the vocal cord and the vocal process of the arytenoid. The hypotenuse of the triangle corresponds to the long axis of the vocal cord. The height of the triangle is measured in millimeters and is available in 6, 7, 8, 9, 10 and 11 mm for females and 8, 9, 10, 11, 12 and 13 mm for males.

Special measuring devices have been designed to accurately simulate vocal cord medialization eliminating the need to insert and replace multiple implants. This results in less trauma to the patient and reduced surgery time. The disposable set includes five sizes to correspond to the five smallest implant sizes, and is available in both female and male kits.

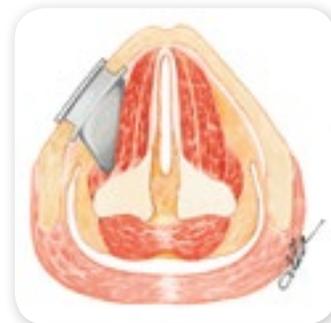
Custom surgical instruments to facilitate locating, designing, and creating the window and inserting the implant are available individually, or as a complete 13-piece set with sterilization tray.

Boston Medical Products now makes it even easier to use the Montgomery Thyroplasty Implant System!

A Single Procedure Kit is available and includes everything you need to perform one thyroplasty procedure. We will send you a complete instrument set, measuring kit, and six implants. After performing the case, simply send back the instruments and unused implants in the convenient supplied container.



scan this QR-Code to reach the thyroplasty website on bosmed.com



System Options

Option 1 – Individual System Components

Montgomery® Thyroplasty Implants, supplied sterile, one implant per carton.

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



16-Implant Sets, contains 16 implants. Significant savings over purchasing individual implants.

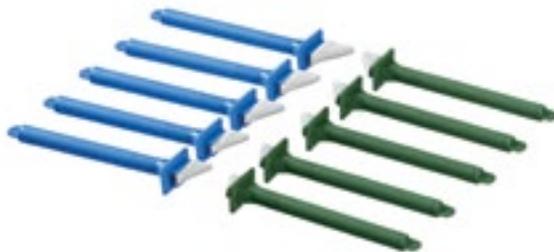
REF	
MTC-01	Male and Female Combination Implant Set, contains 16 implants: 1 ea. female sizes 6, 7, 8, 11 / 2 ea. female sizes 9, 10 1 ea. male sizes 8, 9, 10, 13 / 2 ea. male sizes 11, 12
MTF-01	Female Implant Set, contains 16 implants: 2 ea. female sizes 6, 11 / 3 ea. female sizes 7, 8, 9, 10
MTM-01	Male Implant Set, contains 16 implants: 2 ea. male sizes 8, 13 / 3 ea. male sizes 9, 10, 11, 12



Montgomery® Thyroplasty Measuring Device Kits

Supplied sterile, disposable. Kits include one of each size measuring device (5 sizes per kit).

REF	
MT-300	Female Measuring Device Kit
MT-400	Male Measuring Device Kit



REF	
MT-200	13-piece Surgical Instruments Set with Custom Sterilization Tray



Montgomery® Thyroplasty Surgical Instruments, supplied non sterile.

	REF	
(A)	MT-201	7mm Female Window Caliper
(B)	MT-202	9mm Male Window Caliper
(C)	MT-203	Female Window Outline Instrument
(D)	MT-204	Male Window Outline Instrument
(E)	MT-205	Small Curved Hook
(F)	MT-206	Large Curved Hook
(G)	MT-207	Small Sharp Hook
(H)	MT-208	Large Sharp Hook
(I)	MT-209	3mm Duckbill Elevator
(J)	MT-210	5mm Duckbill Elevator
(K)	MT-211	Chisel Elevator
(L)	MT-212	Female Implant Inserter
(M)	MT-213	Male Implant Inserter



A convenient 13-piece custom sterilization tray is available (REF MT-200). Individual instruments may also be purchased separately.

Option 2 – Single Procedure Thyroplasty Kit

A cost-effective and convenient option designed for surgeons who perform a limited number of thyroplasty procedures. Choose either a female or male kit. Boston Medical Products will send you the complete 13-piece instrument set in sterilization tray, one disposable measuring device kit, and six thyroplasty implants. Following the surgery, simply return the instrument set and five unused implants.

Montgomery® Thyroplasty Single Procedure Kit

REF		REF	
MT-SPF	Female Single Procedure Kit	MT-SPM	Male Single Procedure Kit

Option 3 – Multiple Procedure Thyroplasty Kit

Designed for surgeons or facilities performing multiple thyroplasty procedures annually.

Montgomery® Thyroplasty Multiple Procedure Kit

REF	
MT-MP	Thyroplasty Multiple Procedure Kit, includes: 1 ea. MT-200 13-piece Surgical Instrument Set with Custom Sterilization Tray 4 ea. MT-300 Female Measuring Device Kits 4 ea. MT-400 Male Measuring Device Kits 1 ea. MTC-01 Male and Female Combination Implant Set (16 implants)



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Operating Information (Surgical Procedure)

Caution: The use of this device should only be performed by a surgeon qualified by training in the Thyroplasty Type I procedure, and after reviewing the entire Operating Information section.

Recommended Preoperative Evaluation of the Patient

- The larynx of the patient can be evaluated by videolaryngoscopy and/or videolaryngostroboscopy. The parameters of this evaluation include amplitude, range, fundamental frequency, jitter, and maximum phonation time.
- These evaluations can be repeated 2 months and 6 months postoperatively to determine the position of the paralyzed cord and confirm a successful outcome.
- Photographs can be taken during maximum abduction and maximum adduction and then retained in the patient's record.

Recommended Anesthesia

Conscious sedation is used throughout the procedure. The correct balance between sedation and responsiveness has to be maintained during the entire operation. Anesthesia should be discussed and planned by the surgeon and anesthesiologist prior to the procedure. The suggested anesthesia for thyroplasty in the average 70-kg patient is as follows:

- Midazolam, 1 to 2 mg intravenously administered in the holding area.
- Fentanyl citrate, 50 mg/ml administered in the holding room or on the way to the O.R.
- Fentanyl citrate, 25 mg/ml administered at the beginning of the procedure.
- Propofol, incremental doses are used 30-20-10 mg, etc.
- Intravenous dexamethasone (8 - 12 mg) is given at the beginning of the operation and continued for two additional doses at eight hour intervals.

Additional Recommendations

- Prior to fiberoptic laryngoscope insertion, one nasal cavity is sprayed with a mixture of 3% lidocaine hydrochloride and 2% phenylephrine hydrochloride or packed with a pledget saturated with 4% cocaine hydrochloride solution. The pack remains in place until introduction of the scope.
- The line of the incision and the underlying muscles are injected with 1% lidocaine hydrochloride and 1:100,000 epinephrine hydrochloride.
- Two to five minutes prior to insertion of the implant, 50 to 100 mg of lidocaine hydrochloride is administered intravenously, followed by additional propofol.

Technique of Surgery

Step 1. Prep and Drape

Patient's anterior neck is prepared and draped to expose ipsilateral and contralateral sides. The face remains exposed. Oxygen can be administered by nasal prongs. The thyroid notch, cricothyroid membrane, and the inferior margin of the cricoid cartilage are identified and marked with dots using a surgical marker. A horizontal skin incision line is marked approximately 5 mm above the inferior margin of the thyroid cartilage. Hatch marks are made to facilitate approximation during closure (figure 1).



figure 1

Step 2. Incision

The area surrounding the incision and the deep tissues are infiltrated with 1% lidocaine hydrochloride mixed with 1:100,000 epinephrine hydrochloride. The incision begins 2 cm from the midline on the contralateral side and extends on the ipsilateral side of the neck to the anterior border of the sternocleidomastoid muscle.

Step 3. Dissection and Exposure

- The skin incision is extended through the platysma layer so as to expose the sternohyoid and omohyoid muscles. Flaps are established superiorly and inferiorly in a plane superficial to fascia covering these strap muscles. Flaps are separated with self-retaining retractors. The midline (median raphe) is identified, and the two sternohyoid muscles are separated to expose the thyroid notch, anterior aspect of the thyroid cartilage, cricothyroid membrane, and cricoid cartilage (figure 2).

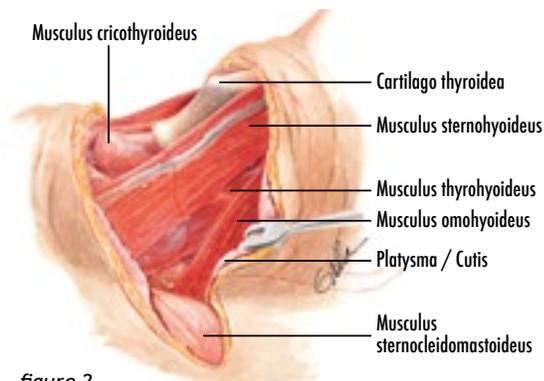


figure 2

- The undersurfaces of the ipsilateral sternohyoid and omohyoid muscles are dissected so that they can be retracted laterally. A Gelpi retractor is useful for this lateral retraction. If there has been much scarring from previous surgery, it may be necessary to transect these muscles in order to obtain adequate exposure (figure 3).
- The strap muscles are retracted laterally to expose the thyrohyoid muscle on the surface of the thyroid lamina. This muscle is transected just above the inferior border of the thyroid lamina.
- The thyrohyoid muscle is detached from its inferior attachment using the Chisel Elevator or cutting current on the cautery (figure 4).
- The thyroid lamina, its inferior border, and the inferior thyroid tubercle are exposed.

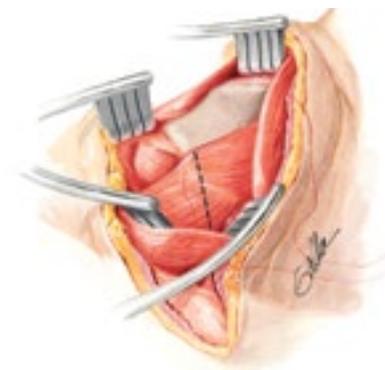


figure 3



figure 4

Step 4. Location of “Key Point”

- The Window Caliper (female or male) is used to locate the superior border and the anterosuperior angle of the thyroplasty window. There is a Window Caliper for female patients and one for males.
- After the inferior thyroid tubercle has been defined and exposed, the inferior border of the thyroid lamina is exposed anteriorly and posteriorly to this structure. One point of the caliper touches the inferior border of the thyroid lamina anterior to the inferior thyroid tubercle and the other, a point directly superior. As the inferior point of the caliper is lifted free, electrocautery is applied to the shaft of the caliper and a cautery mark will appear at the superior point. This is “Point 1” (figure 5).

- A second cautery mark is made by placing one point of the caliper on the posterior inferior border of the tubercle, and the other point directly superior (i.e. "Point 2"), again lifting the inferior point of caliper prior to cautery (figure 6).
- The anterior and posterior cautery marks (Points 1 and 2) are connected using a surgical marking pen. This line is extended to the anterior aspect of the thyroid lamina and represents the superior margin of the thyroplasty window.
- Measuring from the anterior midline along the line connecting Points 1 and 2, a third cautery mark is made. This is the "Key Point" (figure 7). The "Key Point" represents the anterior superior angle of the thyroplasty window.

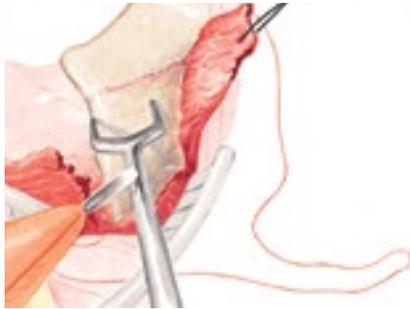


figure 5

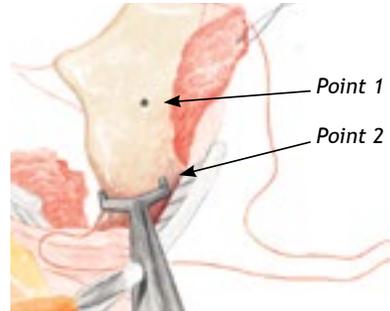


figure 6



figure 7

Step 5. Window Outline

- The Window Outline Instruments measure 5 x 10 mm for females and 7 x 12 mm for males and have four points representing the four corners of the window. The shaft of the instrument is inserted into an electrocautery handle. The anterosuperior point of the Window Outline Instrument is placed on the "Key Point" (figure 8).
- The posterosuperior point of the instrument is placed along the line indicating the superior border of the thyroplasty window. Cautery current is applied making four marks designating the four corners of the window. The four marks are connected with a surgical marker (figure 9).

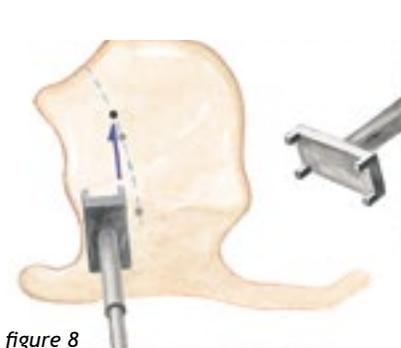


figure 8

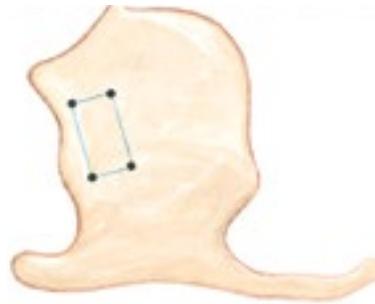


figure 9

Step 6. Cutting the Window

CAUTION: Use care when cutting the thyroplasty window so as not to injure underlying soft tissue.

- A small tangential saw works best for cutting the thyroplasty window. Please call the Customer Service for saw equipment supplier information.
- It is best to start cutting the window posteriorly in case bleeding is encountered. Cut either directly on the lines or towards the inside margin of the lines (figure 10).

CAUTION: Care should be taken not to make the window too large.

- As soon as the four sides of the window are completely cut, the piece of cartilage in the window will become loose ("floating").
- The anterior margin of the cartilage is grasped with the Small Sharp Hook and gently elevated. The underlying perichondrium is separated from the cartilage using the Chisel Elevator as the cartilage is removed (figure 11).

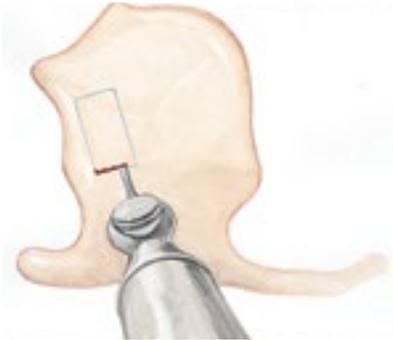


figure 10

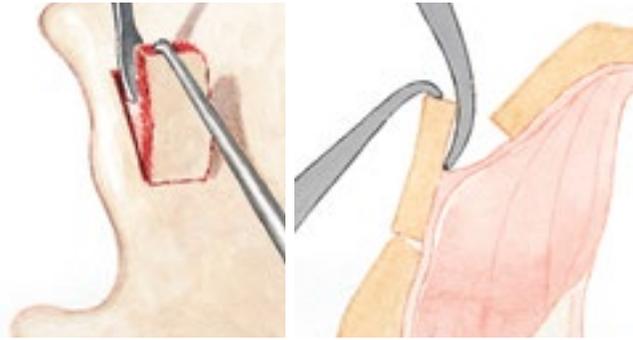


figure 11

Step 7. Confirming the Window Size

- Once the cartilage has been removed from the window, the Window Outline Instrument is used as a template to confirm that the window is the correct size.

Note: The Window Outline Instrument is not attached to cautery for this procedure.

- The Window Outline Instrument is inserted into the window to check the fit (figure 12). A tight fit is ideal. If the window is too small, slight adjustments can be made with the saw.

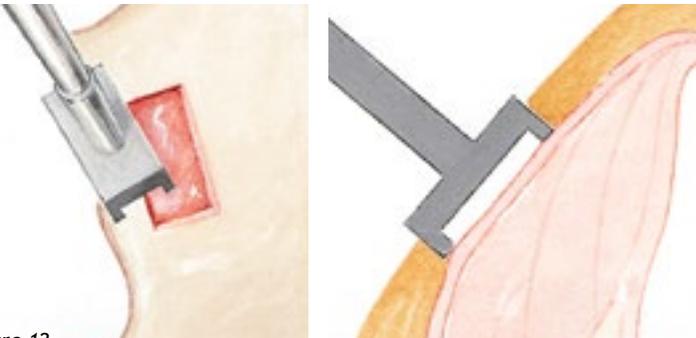


figure 12

Step 8. Elevating the Inner Perichondrium

After confirming the accurate window size, the inner perichondrium is elevated around the window from the cartilage in all directions using the Chisel Elevator (figure 13). Make sure to elevate the perichondrium posteriorly to the level of the vocal process of the arytenoid.



figure 13

Step 9. Using the Implant Measuring Devices (Sizers) to Determine the Implant Size

- The fiberoptic laryngoscope is inserted at this time. The size and gender of each sizer is embossed at the end of the handle. Determine the implant size by starting with the smallest sizer. Its triangular portion is inserted into the window with the posterior tip of the triangle pointing in the direction of the vocal process of the arytenoid. The sizer is pushed into the window until the rectangular “platform” of the device touches the thyroid lamina (figure 14).
- As the sizer is engaged, the patient is asked to phonate while the medialization is viewed through the fiberoptic laryngoscope.
- Each sizer is applied in the same manner until the optimum voice is achieved. Complete closure during adduction and good voice are end points. The selected size is noted.

Note: If the largest sizer is not adequate to create optimum voice quality, the larger additional-size implant (Female 11 or Male 13) should be used.



figure 14

Step 10. Insertion of the Montgomery® Thyroplasty Implant

- 50 to 100 mg of lidocaine hydrochloride is administered intravenously prior to insertion of the implant.
- The implant is grasped with broad forceps, and the posterior tip of the triangular portion is inserted through the window in the direction of the vocal process of the arytenoid (figure 15).
- The middle tier of the base is engaged in the posterior rim of the window with the top and bottom tiers of the base on either side of the thyroid lamina.
- An additional dose of intravenous anesthesia is given prior to final implant insertion, for it can be painful. The implant is held in position with the index finger of the non-dominant hand (figure 16). The Implant Inserter (female or male) is placed in the middle tier of the anterior base and is used to snap the implant in place (figures 16 and 17).
- The fiberoptic laryngoscope can again be used to confirm vocal cord medialization while the patient phonates.
- The implant size is recorded in the patient’s record and the fiberoptic laryngoscope removed (figure 18).

NOTE: In case of a fracture of the inferior rim of the thyroid cartilage window, a nonabsorbable suture may be placed to allow for proper implant stabilization.



figure 15

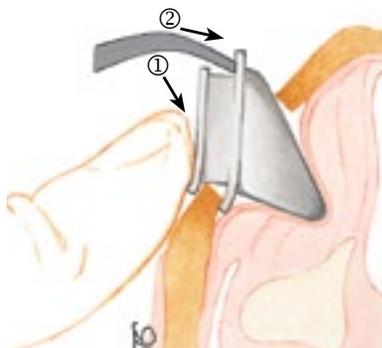


figure 16



figure 17

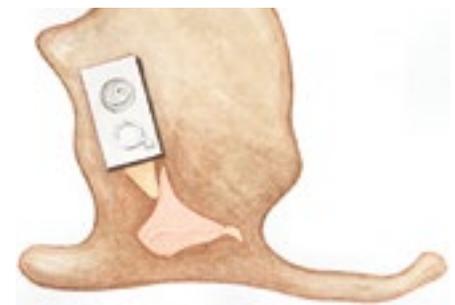


figure 18

Step 11. Repair

- The sternohyoid muscles are reapproximated in the anterior midline with 3-0 or 4-0 chromic catgut (figure 19).
- A closed suction drainage tubing is inserted and the platysma layer is closed (figure 20). The subcutaneous layer is closed with 4-0 chromic catgut and the skin is approximated with continuous 6-0 fast-absorbing chromic suture. The skin is prepared with a tincture of benzoin or equivalent, and Steri-strips are applied over the entire suture line.
- If desired, a red-top vacuum tube may be attached to the drainage tubing (figure 21).

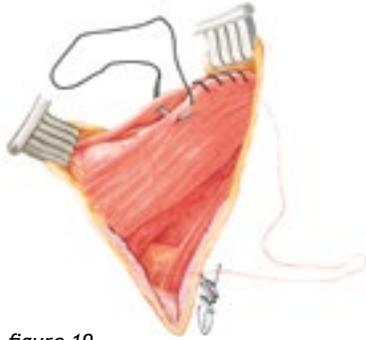


figure 19

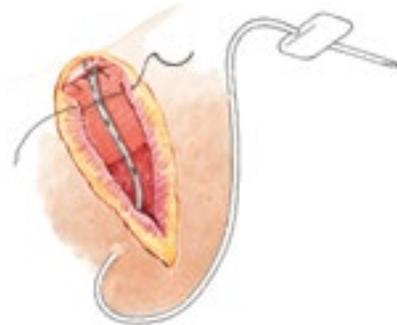


figure 20



figure 21

Step 12. Post-Operative Care

- Red-top vacuum tubes are changed at 2 - 4 hour intervals or as soon as they are ¼ filled with blood. This requires careful nurse surveillance. The total volume and the type of drainage is recorded in patient's record.
- Medication for pain may be needed the first day.
- Antibiotics which have been started preoperatively, are continued for one week. Intravenous dexamethasone (8 - 12 mg), given at the beginning of the operation, is continued for two additional doses at eight hour intervals.
- The closed suction drainage tubing is removed the morning following surgery and the patient is discharged from the hospital. Discharge on the day of surgery is not advised because of the possibility of laryngeal edema or intra-laryngeal bleeding that could interfere with the laryngeal airway.
- The implant is made using radiopaque material so that, if indicated, its exact position can be determined using axial CT scan at the level of the vocal cords by several 2 mm cuts.
- The patient is evaluated two, six, and twelve months postoperatively. Vocal therapy may be indicated to further improve the voice.



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Professional References

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To Place an Order

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- Customer Service: 800-433-2674 (toll-free in the U.S.)
- Main Telephone: 508-898-9300
- 24-hour-Fax: 508-898-2373

Prescription Policy

U.S. federal law restricts these products to sale by or on the order of a physician.

Shipment

- Standard shipping within the U.S. is FedEx two-day delivery.
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- Most orders are shipped the same day.
- Saturday delivery is available in many areas.

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Boston Medical Products, Inc. warrants that reasonable care has been used in the manufacturing of all products. All products are warranted to be free of defects at the time of shipment. For specific product warranties, please refer to individual product Instructions for Use.

Return Policy

Boston Medical Products, Inc. will accept returned items that are unopened in the original packaging.

- Please call Customer Service to obtain a Return Authorization.
- Returns accepted within 30 days from invoice date.
- A Return Authorization is required for all returns.
- All returns are subject to a restocking fee.
- Merchandise credit only.



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