VoCoM.®
SPEAKING VOLUMES.

THE VOCAL CORD MEDIALIZATION SYSTEM
OPERATIVE TECHNIQUE
VoCoM®

The Complete Surgical System Of Implants And Instruments That Increases Accuracy And Decreases Surgical Time In Vocal Cord Medialization.

Surgical Technique described by
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Note: The opinions expressed and procedures used by the physicians herein are those of the physicians themselves, and not of Gyrus ENT, L.L.C. ("Gyrus ACMI"). This training is not a substitute for reading and learning the instructions for use provided with the VoCom System and understanding which treatment options are appropriate for your patients. As with any medical device, you should read the entire instructions for use manual prior to use. Gyrus ACMI cannot encourage or recommend any actions that deviate from or are not covered by the instructions for use and Gyrus ACMI is not responsible for any actions that you may or may not take in connection with the treatment of your patients.
Now, there’s a better way to correct the symptoms of incomplete glottic closure. The VoCoM System of implants and instruments offers a method of performing vocal cord medialization that is flexible, easy and accurate.

**SELF-CONTAINED SYSTEM**

A complete system of implants and instruments puts everything at the surgeon’s fingertips.

**ENHANCES ACCURACY**

- Prefabricated shims allow for specific implant placement and precise tuning.
- Sizing instruments provide a quick, accurate way to determine appropriate implant size.
- Fenestra template allows for accurate sizing of thyroid cartilage window.

**PROVIDES FLEXIBILITY, VERSATILITY**

The implant head is designed for easy holding, manipulation, inserting and tuning.

**HIGHLY COMPATIBLE**

The implant and shims are made of dense hydroxylapatite, which closely resembles the minerals that comprise 60% of human bone, for maximum compatibility and long-term result.
ABBREVIATED SURGICAL TECHNIQUE

The patient is placed in the supine position and given local anesthesia and sedation. The anterior portion of the neck is draped and prepared in the usual sterile manner. A 1% lidocaine with 1:100,000 epinephrine solution is injected over the main aspect of the thyroid cartilage.

A horizontal incision is made approximately 4 to 5 cm in length over the lateral aspect of the thyroid lamina and carried 1 cm across the midline of the neck (Figure 1).

Superior and inferior subplatysmal flaps are then elevated and the strap muscles are separated in the midline and retracted laterally to expose the thyroid cartilage (Figure 2).
With the entire thyroid lamina exposed, the fenestra template (Cat. No. 13-4004) is placed with the long axis in the horizontal dimension. The superior aspect of the fenestra is at the vocal fold level approximately 0.8 to 1.0 cm posterior to the anterior margin of the thyroid cartilage (Figure 3). Positioning of fenestra relative to landmarks is depicted in Figure 8 on page 7.

A knife is used to score the perichondrium around the edges of the template (Figure 4).
A drill is then used with a 3-4 mm cutting bur to create the window in the thyroid lamina being careful not to penetrate the inner perichondrium (Figure 5).

The inner perichondrium is elevated off the thyroid lamina using the perichondrium elevator (Cat. No. 13-4005) (Figure 6).
A series of trial instruments, ranging from 3 mm to 7 mm in displacement, is provided to help determine the optimum size and position of the implant (Figure 7).
A trial instrument is then selected and introduced into the fenestra by inserting the large end first in an anterior to posterior fashion. The trial is then positioned perpendicular to the fenestra.

After insertion, the patient is asked to phonate. The trial is then moved within the fenestra in both superior and anterior directions to determine the best position for optimal phonation (Figure 8).

As necessary, repeat the above procedure with different size trials until optimal phonation is obtained.

Once optimal phonation is achieved, note the size of the trial (as indicated on the instrument flat) and its position in the fenestra. This will determine the implant and shim that will be used.
Completely retract the knob on the handle of the implant inserter (Cat. No. 7013-4009). Secure the implant into the inserter (*Figure 9*). Insert the implant into the fenestra. Insert the large end first in an anterior to posterior fashion. Position the implant in the previously determined optimal position. Push the knob on the handle of the inserter forward and release the implant.
The range of implant sizes and shim configurations is indicated in Figure 10. The positioning of the implant in the fenestra is determined by the shim (Figure 11).

The correct shim is selected. Using a smooth dressing forceps, place the shim around the shaft of the implant. Fully press the shim into the window of the thyroid cartilage.

The wound is then irrigated thoroughly with saline solution and closed using interrupted Vicryl® sutures in the deep layer and the platysma layer. Often a Penrose drain is placed in the wound and brought out through the skin incision. The skin is usually closed using a running nylon suture or subcuticular Vicryl suture.
INDICATIONS
Indications for revision surgery would possibly include: inappropriate initial placement of the prosthesis, under- and over-correction of the deficit, soft tissue changes imparted by previously placed Teflon® paste, and further thyroarytenoid atrophy secondary to nerve degeneration or other demyelinating entities. Additionally, patients who display persistent glottic incompetence over time despite medialization thyroplasty become candidates for revision.

SURGICAL PROCEDURE
The surgical approach remains the same in revision thyroplasty. The implant and shim are visualized. If an osseous bridge has developed between the side walls of the fenestra and collar of the prosthesis, a Freer elevator is used to disrupt the osseous bridge. Alternatively, a drill with a diamond bur is used to disrupt the bridge. Removal of the implant may be facilitated by using a 4 mm diamond bur to drill off the post and central portion of the implant. Using the sharply angled keyhole dissector, the inner perichondrium is again mobilized. A no. 72 blade may facilitate development of the plane between the thyroid cartilage and the inner perichondrium. It is then feasible to remove the prosthesis in its entirety, replacing it with one of slightly larger dimensions if indicated, or alternating the position of the medializing component of the prosthesis within the fenestra to achieve improved phonatory quality.

The wound is then irrigated thoroughly with a saline solution and closed using interrupted Vicryl sutures as in the original surgical procedure. Postoperative care is handled no differently than with the original surgery.
DEVICE DESCRIPTION
The VoCoM (Vocal Cord Medialization) System consists of preformed implants and a series of shims to secure them in place. The implants and stabilizing shims are produced from dense hydroxylapatite.

INTENDED USE
The purpose of the VoCoM System is to provide an implant and securing shim to medialize the paralyzed vocal cord.

INDICATIONS
Unilateral paralyzed vocal cord with poor vocal quality with or without aspiration. Cause of paralysis can be:
1. Idiopathic.
2. Recurrent laryngeal nerve (RLN) involvement of greater than six months.
3. Known recurrent nerve disruption after pneumonectomy, cardiac surgery, laryngeal surgery, or thyroid/parathyroid surgery.
4. Trauma.

CONTRAINDICATIONS
1. Potential for return of vocal function.
2. Fragmentation of thyroid cartilage or structural abnormality resulting in the instability of shim within fenestra.

PRECAUTIONS
Preoperative
Prior to implantation, prospective patients should be counseled as to risk and benefits of implant system.

Intraoperative
Care should be taken during surgery to protect the inner perichondrium.

POSSIBLE ADVERSE SIDE EFFECTS
There is the possibility of infection at operative site, although no more than with any other surgery. If laryngeal mucosa is violated in surgical procedure, a fistula could develop in the endolarynx. The formation of a hematoma can lead to airway compromise.

Caution: Internal extrusion of implant can occur if inner perichondrium is disrupted during surgery. If the airway is entered, the procedure should be terminated.

Underaugmentation can result in unsatisfactory voice or persistence of aspiration/dysphasia while overaugmentation can result in unsatisfactory voice and possibly cause airway obstruction. Either condition may indicate the need for revision surgery.

REVISION INFORMATION
If revision surgery is indicated, the following abbreviated technique is recommended:

If an osseous bridge has developed between the side walls of the fenestra and collar of prosthesis, use a Freer elevator or a drill with a diamond bur to disrupt the bridge. Removal of the implant may be facilitated by using a 4 mm diamond bur to drill off the post and central portion of implant. The implant may then be removed and replaced with a more appropriate size.

HOW SUPPLIED
Gyrus ACMI’s implants and shims for vocal cord medialization procedures are provided sterile.

Caution: Inspect sterile packages for punctures or evidence of contamination prior to opening. Implants and shims will remain sterile in an undamaged, unopened package.

Implants and shims intended for single-use only. Do not resterilize.

IMPORTANT MEDICAL INFORMATION

ATTENTION: The instructions for use should be read prior to using the VoCoM System. Please see REF 44725, with full instructions for use, located in the VoCoM System product box.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
## IMPLANTS

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>14-3000</td>
<td>VoCoM Implant, 3 mm</td>
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<tr>
<td>14-3001</td>
<td>VoCoM Implant, 4 mm</td>
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<tr>
<td>14-3002</td>
<td>VoCoM Implant, 5 mm</td>
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<td>14-3003</td>
<td>VoCoM Implant, 6 mm</td>
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<td>14-3008</td>
<td>VoCoM Implant, 7 mm</td>
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<td>7014-3019</td>
<td>VoCoM Implant, 8 mm</td>
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## SHIMS

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<tr>
<td>14-3007</td>
<td>VoCoM Shim, 0 mm Offset</td>
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<tr>
<td>14-3004</td>
<td>VoCoM Shim, 1 mm Offset</td>
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<td>14-3005</td>
<td>VoCoM Shim, 2 mm Offset</td>
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<td>14-3006</td>
<td>VoCoM Shim, 3 mm Offset</td>
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## INSTRUMENTS

<table>
<thead>
<tr>
<th>Cat. No.</th>
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<tr>
<td>13-4004</td>
<td>VoCoM Fenestra Template</td>
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<tr>
<td>13-4005</td>
<td>VoCoM Perichondrium Elevator</td>
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<td>7013-4009</td>
<td>VoCoM Implant Inserter with Grip Tip</td>
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<td>13-4000</td>
<td>VoCoM Trial, 3 mm</td>
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<tr>
<td>13-4001</td>
<td>VoCoM Trial, 4 mm</td>
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<tr>
<td>13-4002</td>
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<td>13-4008</td>
<td>VoCoM Trial, 7 mm</td>
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<tr>
<td>7013-4011</td>
<td>VoCoM Trial, 8 mm</td>
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<tr>
<td>13-4007</td>
<td>VoCoM Instrument Sterilization Case</td>
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<tr>
<td>13-4010</td>
<td>VoCoM Instrument Set</td>
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(Includes one of each of the instruments and sterilization case.)