VIBRANT SOUND BRIDGE
Information for Surgeons (VORP 503)
Acknowledgements:

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To learn more about how the SOUNDBRIDGE system works visit www.medel.com/soundbridge or simply scan the code to watch the videos.
Information for Surgeons
For the VORP 503 Implant

The Information for Surgeons brochure describes the VORP 503 of the SOUNDBRIDGE (VSB) System, the surgical tools provided by VIBRANT MED-EL and the different Vibroplasty Couplers that are available.

This brochure is a reference for surgeons implanting the VSB and describes the procedures of attaching the FMT and Vibroplasty Coupler assembly, to a mobile middle ear structure. Patient management methods are also briefly described.

Key points and helpful hints can be found at the back with illustrations and graphics included throughout the brochure.

This brochure can be used with the VORP 503 Instructions for Use which is shipped with each implant. The VORP 503 Instructions for Use explains current indications, contraindications, warnings and precautions and possible adverse events. Instructions for Use for the different Couplers are shipped with the respective Couplers.
Overview of the Vibroplasty Couplers

In this brochure the four main Couplers are described.

**Incus-SP-Coupler**
- For sensorineural hearing loss
- One version suitable for both left and right ear

For placement onto the short process of the incus via a posterior epitympanotomy (left ear)

**Incus-LP-Coupler**
- For sensorineural hearing loss
- Left and right version

For placement onto the long process of the incus via a posterior tympanotomy (left ear)

**RW-Soft-Coupler**
- For conductive or mixed hearing loss
- One version suitable for both left and right ear

For placement onto the round window membrane

**Vibroplasty-CliP-Coupler**
- For conductive or mixed hearing loss
- One version suitable for both left and right ear

For standardized placement onto the head of the stapes when the stapes is strong enough and mobile.
Additional Vibroplasty Couplers

Further Couplers are available and shown below but are not described in detail within this brochure.

**Incus-Symphonix-Coupler**

- For sensorineural hearing loss
- Left and right version
- To be placed onto the long process of the incus via a posterior tympanotomy
- Crimping is needed for a tighter fixation by using, for example, the forming forceps.

**Vibroplasty-Bell-Coupler**

- For conductive or mixed hearing loss
- One version
- To be placed onto the head of the stapes

**Vibroplasty-OW-Coupler**

- For conductive or mixed hearing loss
- One version
- To be placed onto the stapes footplate

**Vibroplasty-RW-Coupler**

- For conductive or mixed hearing loss
- One version
- To be placed onto the round window membrane
The SOUNDBRIDGE (VSB) is an active middle ear implant for persons with sensorineural, conductive or mixed hearing loss.

The SOUNDBRIDGE comprises of an external part, the audio processor (AP), and an implanted part, the Vibrating Ossicular Prosthesis (VORP). The audio processor is worn on the head and contains the microphones, the digital signal processing unit and a zinc-air battery as the power source.

The VORP 503, the implantable part of the VSB, consists of a receiver coil, a conductor link, and a transducer. Information from the AP is sent to the VORP 503 so that the transducer [the Floating Mass Transducer (FMT)] vibrates in a controlled manner, specific to each patient’s hearing needs. The FMT is 2.3 mm in length, 1.8 mm in diameter and weighs about 25 mg. The conductor link has a diameter of 0.5 mm. The VORP 503 can be seen in Figure 1 and the FMT (not to scale) in Figure 2.

The VSB is implanted using a Vibroplasty technique. Vibroplasty is the treatment for hearing loss via vibratory stimulation in the middle ear. When the FMT is in proximity to a vibratory structure of the middle ear, it vibrates the structure and stimulates the auditory system.

- In the case of sensorineural hearing loss Incus Vibroplasty will be required, where the FMT is placed onto the incus.
- In cases of conductive or mixed hearing loss either Round Window (RW) or Oval Window (OW) Vibroplasty is required.

Surgeons and audiologists work together when selecting patients for implantation. Thorough audiological and medical evaluations are performed and reviewed in conjunction with candidacy information which is provided in the VORP 503 Instructions for Use. Before surgery, patients are counselled about the risks and benefits of VSB implantation. Success is most likely when the patient is well selected and has realistic expectations of using the VSB system. It is recommended that a CT scan is done before surgery.

Surgery typically lasts between 1½ to 2½ hours and is performed either on an outpatient or inpatient basis. Approximately eight weeks after surgery, the surgeon medically evaluates the patient, and an audiologist programs the AP so the SOUNDBRIDGE can be activated. The patient typically wears the device for several hours a day, or all day, immediately after activation.

In this brochure the surgical procedure is described for a right ear, unless otherwise mentioned.

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**Figure 1:** Components and dimensions of the Vibrating Ossicular Prosthesis VORP 503
a) shown from above b) shown from the side.

**Figure 2:** Floating Mass Transducer (FMT)
Surgical Tools

What instruments and tools are needed for an implantation of the VORP 503? Most instruments needed are included in standard micro-instrument sets. In addition the VORP 503 Implant Kit contains a single-use screwdriver and three self-drilling cortical screws. The VORP 503 Implant Kit is also shipped with a VORP 503 Sizer Kit. The Skin Flap Gauge 7 is a generic surgical tool that needs to be requested separately.

Tools Shipped with the VORP 503 Implant (Sterilized)

The VORP 503 is shipped in a sterile tray, which contains a screwdriver and three self-drilling cortical screws for an easy fixation of the implant.

Self-Drilling Cortical Screws

The three self-drilling cortical screws are made from titanium alloy and are each 4 mm in length with a diameter of 1.6 mm.

For the fixation of the implant two screws are needed. The third screw is a back-up screw.

Screwdriver

The screwdriver is a single-use device which has a rotatable top piece. The screwdriver is used for tightening the cortical screws.

VORP 503 Sizer Kit (Sterilized)

The VORP 503 Sizer Kit is indicated to be used during implantation of the VORP 503 implant only. It contains the single-use VORP 503 Template and the FMT Sizer. The VORP 503 Template is made from a medical grade thermoplastic elastomere and the FMT Sizer from medical grade polypropylene. Both are non-functional. The VORP 503 Sizer Kit is shipped sterile and is for single-use only. The device is sterilized using irradiation and packaged for aseptic presentation. If the package is opened, damaged, or exceeded its expiration date, then neither the VORP 503 Template nor the FMT Sizer should be used.

Single-use VORP 503 Template

The VORP 503 Template is a template that has the size of the body of the VORP 503 implant. It is used to determine the optimum implant placement on the head before incising the skin. It is also used to outline the exact size of the bone bed before drilling the bed. By placing it into the drilled out bone bed, it is used to verify the size and the depth of the bone bed before placing and screwing the VORP 503 implant to the skull.

Figure 3: VORP 503 Implant Kit consists of: 1) VORP 503 Implant, 2) three self-drilling cortical screws and 3) single-use screwdriver

Figure 4: VORP 503 Template
**Single-use FMT Sizer**

The FMT Sizer has the same dimensions as the Floating Mass Transducer of the VORP 503. It is used, when needed, to assess FMT placement prior to introduction of the VORP 503 into the surgical field, in order to ensure that appropriate position and placement of the FMT can be achieved and that the FMT motion will not be impeded by any non-vibratory structures of the ear.

After use, the single-use tools should be disposed of as medical waste.

**Tool Available Separately (not Sterilized)**

**Skin Flap Gauge 7**

The Skin Flap Gauge 7 can be reused after cleaning and re-sterilization, using standard procedures for decontamination of surgical instruments. It can be ordered separately.

The Skin Flap Gauge 7, made of stainless steel, is used to estimate the thickness of the skin flap over the coil section of the VORP 503 to assure good attachment of the external audio processor to the head.

It is used to check that the skin thickness over the coil does not exceed 7 mm of thickness and therefore allows for a good coupling of the audio processor to the implant.
In order to fix the FMT to a mobile middle ear structure, one of the Vibroplasty Couplers is needed. They can be ordered together with the Implant Kit or separately. The Vibroplasty Couplers are middle ear prostheses to be used exclusively with the VORP to treat sensorineural hearing loss, conductive hearing loss and mixed hearing loss. The Couplers are intended to be used in combination with the SOUNDBRIDGE to facilitate the coupling between the FMT and a vibratory structure of the middle ear. The prosthesis type is chosen on the basis of the ossicular remnants once all primary disease has been removed from the middle ear. The Vibroplasty Couplers are shipped sterile and are for single patient use only. They shall not be used if the sterile packaging is damaged or the expiration date has been exceeded.

The Couplers are packaged separately and contain peel-off labels. These labels are intended to be placed on the VIBRANT MED-EL SOUNDBRIDGE implant registration card and in the patient’s record.

**Couplers for Sensorineural Hearing Loss**

**Incus-SP-Coupler**

Only one version of the Incus-SP-Coupler is available as it is suitable for both the left and right ear. The Incus-SP-Coupler is used to place the FMT onto the short process of the incus via an attico-antrotomy (posterior epitympanotomy). No crimping is needed.

**Incus-LP-Coupler**

A left and a right version of the Incus-LP-Coupler are available. The Incus-LP-Coupler is used to place the FMT onto the long process of the incus via a posterior tympanotomy. No additional crimping is needed.

**Couplers for Conductive or Mixed Hearing Loss**

**RW-Soft-Coupler**

The RW-Soft-Coupler is placed on the round window membrane. The Coupler is placed onto the FMT by using its adhesive pad. There are two RW-Soft-Couplers in one box. One can be used on the FMT Sizer, the other one on the real FMT.

**Vibroplasty-CliP-Coupler**

The Vibroplasty-CliP-Coupler is placed on the head of the stapes if the stapes is mobile and strong enough to endure the weight of the Coupler plus FMT.
When implanting a VORP 503, the FMT needs to be fixed onto a mobile middle ear structure with the help of an appropriate Coupler. The surgeon needs to determine which route to the middle ear to use from the medical status of the patient’s ear.

In cases of sensorineural hearing loss, there are two placement possibilities for the FMT. When the FMT is placed onto the short process of the incus only a posterior epitympanotomy (also called attico-antrotomy) is needed. If the FMT is placed on the long process of the incus, the middle ear needs to be accessed via the facial recess route (mastoidectomy and posterior tympanotomy).

In cases of conductive or mixed hearing loss, the FMT is placed either via a facial recess route or via a radical cavity.

General Precautions

Facial nerve monitoring is recommended, especially in cases of congenital temporal bone anomalies, revision surgeries, and other situations in which surgical risk to the facial nerve is possible.

After general anesthesia has begun, but before the sterile surgical field is prepared, the position of the implant and incision should be determined. Consider the patient’s use of eyeglasses and headwear when determining the implant position.

Do not remove the VORP 503 from its sterile packaging until the bone bed is prepared and it is time to place the device.

Registration Card

The VORP 503 registration card, contained in the packaging, should be completed and returned promptly to VIBRANT MED-EL.

The peel-off label from the Coupler used should also be stuck onto the registration card.
Surgical Steps

Step 1: Preparation

Shave the hair approximately 2cm beyond the intended incision, removing the least amount of hair possible (for cosmetic reasons but taking care not to increase the risk of infection). Place the VORP 503 Template onto the skin with the anterior edge at the postauricular sulcus just behind the ear, and angled approximately 45 degrees postero superiorly. The VORP 503 should not lie under the auricle.

Mark the incision line at least 2cm from the edge of the template to minimize the risk of device extrusion and postoperative infection. The incision only needs to be large enough to perform the access to the middle ear, drill the bone bed for the demodulator portion of the VORP 503, and screw it to bone.

Two common incision shapes are the extended postauricular incision (see Figure 11) and the small incision. Prepare the surgical field using standard procedures.

Figure 11: Positioning the VORP 503 template and planning the incision. An extended postauricular incision is shown.

Step 2: Incision

First infuse the incision site with a vasoconstriction agent and then create the incision.

The surgeon can decide whether to make a single or a double layer flap. Here a double layer flap is described. If using an extended postauricular incision, incise the skin to the level of the temporalis fascia. Begin superiorly and inferiorly until the posterior canal wall is identified and a space large enough for the VORP 503 demodulator is cleared on the skull. Retract the auricle anteriorly. Next, create an anteriorly-based pericranial fascia incision. The portion of the pericranial flap overlying the receiving coil and magnet may be excised, but the anterior portion of the flap must be preserved to provide a continuous tissue layer over the anterior portion of the demodulator, the transition, and the conductor link.

If using a small incision, a pericranial fascia incision approximately 1cm anterior to the skin incision can be made. Hemostasis could be achieved with monopolar or bipolar electrocautery at this stage. Note that only bipolar electrocautery is used once the VORP 503 is in the surgical field, or if the patient has an implant on the other side. Place the sterilized VORP 503 Template on the skull to verify that sufficient space has been created.

Evaluate the thickness of the portion of the flap over the magnet and receiver coil using the Skin Flap Gauge 7 (see Figure 12). Recall that the portion of the pericranial flap over the magnet and the receiver coil may be excised. If the flap does not fit in the gauge loosely, carefully thin the flap until it does. It is important to avoid over thinning of the flap as wound complications may occur. To ensure proper transmission of the signal from the audio processor and proper attraction of the magnet, the total tissue thickness must not exceed 7 mm over the receiver coil.
CHAPTER

Figure 12: The Skin Flap Gauge 7 is used to ensure that the flap covering the magnet does not exceed a thickness of 7 mm.

Step 3: Drill out Mastoid

Perform a simple mastoidectomy only to the point where the short process of the incus is visible: The posterior tympanotomy is not performed at this time, to limit bone dust from entering the middle ear. When exposing the antrum, care must be taken to avoid making contact to the incus with the drill.

CAUTION
USE ONLY A DIAMOND BURR WHEN DRILLING NEAR THE FACIAL NERVE AND DO NOT TOUCH THE OSSICLES.

The mastoidectomy may need to be extended slightly posteriorly and inferiorly when access to the long process, the stapes or the round window is needed to allow better visualization of the ossicles through the facial recess later in the procedure. Leave overhangs superiorly and inferiorly.

Place gelfoam in the opening of the antrum to decrease the likelihood of bone dust entering the middle ear whilst drilling the bone bed.

Step 4: Bone Bed

The primary objective of creating the bone bed is to allow the pre-bent transition of the conductor link to slope deeply into the mastoid cavity so that the conductor link is as medial to the skull surface as possible. The bone bed also provides a secure and stable position for the VORP 503.

Position the VORP 503 Sizer on the skull surface. The position of the template should lie approximately on the 45 degree angle as described earlier (see figure 11) and the transition should lie on the posterior edge of the mastoid cavity and should be placed in such a way that sharp edges in the conductor link are avoided (see Figure 13). Positioning the transition is critical to device placement and therefore, the final position of the magnet may move slightly anterior or posterior depending upon the size of the mastoid cavity.

Although the VORP 503 can be implanted without a drilled out bone bed, a preparation of an implant bed is recommended to recess the demodulator a bit and a protection for the transition sleeve is needed at all times.

Mark the boundary of the template corresponding to the demodulator portion of the implant in the temporal fossa. The bone should be removed to the level of the anchor holes (1.9 mm), so that the wings sit nicely on the bone. The anterior edge of the bone bed should be deeper than the posterior edge, allowing a gradual slope into the mastoid cavity.

Drill a channel between the bone bed and the mastoid cavity to allow placement of the VORP 503 transition. Figure 13 shows the drilled out mastoid (the bone bed and the channel drilled for the conductor link).
Figure 13: Drill a bone bed for the demodulator and a channel for the conductor link. The anterior edge of the bed should be the deepest, allowing a gradual slope into the mastoid cavity.

The channel should be tapered towards the mastoid cavity, slightly deeper at the anterior end of the channel, so that the VORP 503 transition slopes downward into the mastoid cavity.

Instead of drilling a channel between the bone bed for the demodulator and the mastoid cavity, an open bony bridge may be created. By opening this bridge on the superior side, the VORP 503 transition can easily slide under the bridge, thus giving more protection (see Figure 14).

Figure 14: An open bony bridge provides additional protection for the VORP transition. The placement for the VORP 503 is checked with the VORP 503 Template.

With a rasparatory, the periosteum is elevated off the bone in the region where the coil will be placed.

Irrigate the bone bed and position the VORP 503 Template to verify size and depth of the bone bed and depth of the channel.
Step 5: Routes to the Middle Ear

Depending on the status of hearing loss and the status of the ossicles, different approaches to the middle ear may be chosen.

CAUTION
USE ONLY A DIAMOND BURR WHEN DRILLING NEAR THE OSSICLES. TAKE METICULOUS CARE SO AS TO AVOID TOUCHING THE OSSICLES.

5a: Posterior Epitympanotomy for the Incus-SP-Coupler

For the Incus-SP-Coupler, the area close to the short process of the incus needs to be widened. Since the Incus-SP-Coupler and FMT assembly should not touch bone, more bone needs to be removed in the tegmen tympani and between the short process of the incus and the outer ear canal. In particular, the root of Koerner’s septum and the lateral part of the attic wall have to be reduced. This can be done by either using a small diamond burr and drilling away from the ossicles or using a house spoon. Meticulous care should be taken to avoid touching the ossicles and their ligaments especially close to the fossa incudis. After finishing the posterior epitympanotomy, the body of the incus and the head of the malleus should be clearly exposed. The FMT Sizer is used to check whether enough bone has been removed so that the FMT does not touch bone. With a small antrum hook carefully check the space around the short process of the incus. This will ensure that the clip of the Incus-SP-Coupler will fit. The mobility of the ossicular chain should also be checked.

5b: Posterior Tympanotomy

If the Incus-SP-Coupler is not used, create a posterior tympanotomy through the facial recess. Identify the facial nerve and leave a thin shelf of bone to cover it. Care must be taken to avoid the drill coming into contact with middle ear structures and to preserve the chorda tympani, if possible, while still allowing adequate space for drilling. The buttress between the posterior tympanotomy and the opening of the antrum should be preserved, so that damage to the ligament attached to the short process of the incus is avoided. Irrigation and suctioning of the middle ear to remove any residual bone dust should be carried out.
Incus Vibroplasty

In Incus Vibroplasty the posterior tympanotomy should be enlarged so the long process of the incus is clearly visible (see Figure 16). Compared to a cochlear implantation, the posterior tympanotomy needs to be extended anteriorly and superiorly so that the FMT with the Coupler can be safely introduced.

Figure 16: For the Incus-LP-Coupler, enough bone must be removed in the posterior tympanotomy to gain good access to the long process of the incus.

A 3.0 mm drill burr or the FMT Sizer should be able to pass through the posterior tympanotomy.

RW Vibroplasty

In RW Vibroplasty, the posterior tympanotomy needs to be enlarged inferiorly so that a clear view onto the RW area is possible (see Figure 17).

Figure 17: For the RW-Soft-Coupler, the posterior tympanotomy should be large enough to allow good access to the RW niche.

When performing a RW Vibroplasty, a wide and bloodless access to the round window is needed. The round window membrane needs to be identified and carefully exposed.

With the help of the preoperative CT scan, the round window area, including the jugular bulb, should be analysed. Figure 18 illustrates a horizontal section through the round window area, showing the bony overhang (tegmen), the round window membrane, a potential mucosal fold, and the jugular bulb.
Figure 18: Horizontal cross section through the round window area that shows the promontory (P), RW membrane (RWM), a potential mucosal fold (MF), and the jugular bulb (JB). The red shaded area indicates where bone should be removed.

Use a 0.8 to 1.3 mm diamond burr (or a skeeter) to enlarge the round window niche, starting anteriorly and moving to the superior section of the niche. Leave a bony rim anteriorly and posteriorly which will later help to stabilize the FMT.

Drilling should be performed with a diamond burr and at a low speed to avoid RW membrane damage. If a mucosal fold is present, it should be removed as carefully as possible.

Use a 1.4 to 1.8 mm burr to drill a bed for the FMT in the hypotympanum.

5c: Radical Cavity

In case of a radical cavity it is recommended to drill a groove for the conductor link in the inferior region. This groove should be 0.5 to 1.0 mm wide and as deep as possible. It is safer to drill away from the middle ear to avoid damaging any remnants of the ossicular chain. A small bony bed is drilled on the skull to accommodate the extra lengths of the conductor link (see Figure 19).

Figure 19: In a radical cavity certain precautions need to be taken to accommodate the conductor link. A groove should be drilled inferiorly, far away from the facial nerve, and a small bony bed in the cortical bone should be drilled for the excess conductor link.
Step 6: Attaching the Coupler to the FMT

Not all Couplers may be available in all countries. Please check with your local MED-EL representative as to which Couplers are registered in your country. For further information on the different Couplers, please refer to the Instructions for Use for the respective Coupler. More detailed instruction on how to attach the FMT to the Coupler can be found in the Instructions for Use.

With the exception of the Vibroplasty-CliP-Coupler, the Couplers are delivered with a holding frame and a retainer which hold the Coupler in place. The FMT should be attached to the Coupler while the Coupler is still secured by the holding frame and the retainer. This ensures a safe and correct connection.

Remove the VORP 503 from its sterile package and bring it into the surgical field. VIBRANT MED-EL recommends that only the surgeon handles the device. Care should be taken when handling the VORP 503 to avoid stress or elongation to the conductor link. Do not allow the FMT or the attached Coupler to contact surgical drapes, sponges, or towels. Keep in mind that the FMT contains a magnet and may be attracted to the magnet in the VORP 503 and to surgical instruments.

CAUTION

ACCIDENTAL BENDING OF THE COUPLER DURING REMOVAL FROM ITS PACKAGE MUST BE AVOIDED IN ORDER TO PREVENT FUNCTIONAL DAMAGE.

ALWAYS ATTACH THE FMT TO THE COUPLER IN THE HOLDING FRAME. THIS GUARANTEES THE CORRECT POSITIONING OF THE COUPLER ONTO THE FMT AND OF THE CONDUCTOR LINK.

6a: Incus-SP-Coupler, Incus-LP-Coupler

Place the FMT onto the cage of the Coupler and push it down using surgical tweezers, a needle or a similar tool. Ensure that the conductor link is properly placed into the groove on the holding frame. This can be achieved by pushing the conductor link down using a finger or a surgical instrument. Placing the conductor link into the groove ensures proper positioning of the FMT onto the Coupler and the correct orientation of the conductor link. This minimizes unnecessary bending of the conductor link during implantation.

Figure 20: For a correct connection of the FMT and the Coupler, the FMT is connected while the Coupler is still in the holding frame. The FMT is placed in such a way that the conductor link lies in the groove.

After attaching the FMT to the Coupler, the retainer must be removed from the holding frame and the Coupler by squeezing the two handles of the retainer together and by tilting the retainer into the direction of the holding frame.

Use surgical tweezers or a similar instrument to remove the Coupler with the FMT from the holding frame. Do not pull on the conductor link.
6b: RW-Soft-Coupler

First remove the retainer above the RW-Soft-Coupler and place the FMT onto the Coupler’s adhesive pad and then press down slightly.

**CAUTION**
ENSURE THAT THE FMT DOES NOT COME INTO CONTACT WITH BODILY FLUIDS BEFORE IT IS ATTACHED TO THE RW-SOFT COUPLER. SHOULD THIS HAPPEN, CLEAN THE FMT WITH A LINT-FREE TISSUE BEFORE ATTACHING THE RW-SOFT-COUPLER.

Figure 21: After the retainer is removed, the RW-Soft-Coupler is visible. The FMT is then pushed onto the Coupler while it is still in the holding frame.

Use a microscope to verify the correct position of the FMT on the Coupler. After attaching the Coupler, press the Coupler and the FMT together firmly to ensure a secure connection. If the Coupler is not attached centrally, it is possible to move it again as the adhesive pad does not harden.

There are two RW-Soft-Couplers in one holding frame. One is to be attached to the FMT. The other one can be used on the FMT Sizer in order to check whether enough bone has been removed.

Figure 22: The Coupler and the FMT are pressed together firmly with tweezers in order to ensure a safe connection.

6c: Vibroplasty-CliP-Coupler

It is easier to stabilize the FMT before attaching the Coupler. Either stabilize it by pushing it into a small piece of bone wax, placing it onto a metal plate or drill a 1.5 mm hole in which the FMT is placed. By stabilizing the FMT in this way the surgeon then has both hands free to attach the Coupler.

Carefully attach the Coupler to the FMT in such a way that the conductor link exits above the shorter legs of the Coupler clip and that the conductor link does not touch any of the three legs that hold the FMT.

Once the Coupler is attached to the FMT, it should be pressed onto the FMT in order to ensure a secure connection. This can be done, for example, with a needle (see Figure 23).

Figure 23: The FMT is stabilized with a piece of bone wax and the 3 legs of the Coupler are placed over the FMT in such a way that the conductor link exits above the shorter legs. Afterwards a needle is used to push the Coupler onto the FMT for a secure connection.
CAUTION

Step 7: Fixation of Demodulator

CAUTION
ONCE THE VORP 503 IS IN THE SURGICAL FIELD, MONO-POLAR ELECTROCAUTERY SHOULD NEVER BE USED.

Arrange the VORP 503 over the surgical site so that the triangle shape on the magnet (see Figure 24) is facing up.

Place the VORP 503 in such a way that the transition sleeve angles down into the mastoid cavity. Using two of the supplied screws, screw the demodulator in place with the screwdriver supplied in the VORP 503 Implant Kit. The screws will enter the cortical bone for approx. 3 mm.

Figure 24: The VORP 503 is placed so that the triangle shape is facing upwards.

Figure 25: The VORP 503 is placed so that the transition sleeve angles down into the mastoid cavity. Then the implant is screwed into the cortical bone with the screwdriver and the cortical screws supplied in the VORP 503 Implant Kit.
Step 8: FMT Placement

With smooth alligator forceps, two needles or a suction tip, insert the FMT with the attached Coupler into the middle ear. Some surgeons like to use amagnetic tools (which can be obtained from Spiggle & Theiss) since the FMT has a magnet included. Avoid grasping the FMT at its junction to the conductor link wire.

**CAUTION**
PRE-BEND A SMALL CURVE IN THE CONDUCTOR LINK A FEW MILLIMETRES FROM THE FMT, SO THAT IT DOES NOT IMPEDE MOVEMENT OF THE FMT WHEN IN ITS FINAL POSITION.

8a: Incus Vibroplasty

**Incus-SP-Coupler**
The Incus-SP-Coupler is used to place the FMT onto the short process of the incus via a posterior epitympanotomy (also known as attico-antrotomy). To place the Incus-SP-Coupler, clamp the flexible structure of the Coupler onto the short process of the incus. The two shorter legs of the Coupler shall be placed inferiorly on the short process of the incus, the two longer legs shall hold the incus body superiorly (see Figure 26). The FMT should not touch bone. The Coupler should not move on the incus. No further crimping is needed.

**Incus-LP-Coupler**
The Incus-LP-Coupler is used to place the FMT onto the long process of the incus via a posterior tympanotomy. Ensure that the FMT is as close as possible or actually touches the stapes. In some anatomies it might be needed to bend the connection rod to bring the FMT closer to the stapes. It is possible to bend the connection rod before positioning the FMT with the Coupler in the middle ear. Hold the Coupler with tweezers as close to the FMT cage as possible and then gently push the LP clip with a 90° hook forward (see Figure 27).

Figure 26: Incus-SP-Coupler: the longer legs are over the incus body and the shorter legs over the short process of the incus.

Figure 27: If necessary the connection rod of the Coupler can be bent by holding it with tweezers and pushing the clip gently forward with a 90° hook.

To place the Incus-LP-Coupler, wiggle the flexible incus clipping structure of the Coupler onto the long process of the incus. Ensure that the FMT is as close as possible or actually touches the stapes. No further crimping is needed.

Figure 28: Incus-LP-Coupler with the clip positioned on the long process of the incus. The FMT is in contact with the stapes.
8b: In Round Window Vibroplasty

**RW-Soft-Coupler**

Attach one of the RW-Soft-Couplers onto the FMT Sizer and use it to ensure that the FMT will fit in the round window niche without touching the bony overhang or any other obstruction. Bone and other protuberances should not interfere.

The stiffness of the conductor link helps to hold the FMT with the Coupler in place. Pre-bend a small curve in the conductor link a few millimetres from the FMT, so that it does not impede movement of the FMT when in its final position. This helps to hold the FMT in place and facilitates the attachment of the FMT with Coupler in the RW niche.

The FMT with the attached Coupler is passed into the middle ear space. This can be done by using smooth alligator forceps. Avoid grasping the FMT at its junction to the conductor link.

Ensure that the Coupler does not come off during surgery. When positioning the Coupler and the FMT in the middle ear, be careful not to stick a needle (or similar tool) between the Coupler and the FMT.

FMT movement should not be impeded by the walls of the middle ear space and/or bony protuberances. The long axis of the FMT should be perpendicular to the RW membrane. The FMT may be gently palpated to confirm that its movement is not impeded.

Then place cartilage on the contralateral side of the FMT to give the FMT a prestress that helps maintain its position. Lastly, a piece of tissue (or artificial fascia) is placed over the FMT in order to promote additional fixation from fibrous tissue growth. The final FMT position is shown in Figure 29.

With the FMT placement described above, a four point fixation is guaranteed. The first two points are the bony rims in the round window niche that are left anteriorly and posteriorly (see chapter Round Window Vibroplasty). The third point is the stiffness of the conductor link that helps to keep the FMT in place. The last point that adds to a stable fixation is the cartilage placed behind the FMT.

**Radical cavity**

The FMT with the Coupler is placed into the middle ear by directing the conductor link down the surgically created groove. The conductor link is placed into the groove, leaving a bit of a slack cable, and fixed with bone paté. Arrange the excess conductor link in the small drilled out bony bed on the skull. Ensure that there are no sharp bends or kinks in the conductor link, especially as it exits the transition. Confirm that there is slack in the conductor link close to the FMT.
In this brochure the technique for the Vibroplasty-CliP-Coupler will be described. For information on the procedure for the other Couplers please refer to the Instructions for Use of the respective Coupler.

Vibroplasty-CliP-Coupler
This Coupler looks similar to a passive middle ear prosthesis but varies considerably because it is only needed to hold the FMT in place and not to reconstruct the middle ear. Therefore this Coupler can be used independently from middle ear ventilation.

The head of the stapes should be cleaned from scars and granulation tissue, before the Coupler-FMT assembly is placed into the middle ear. Pre-bend a small curve in the conductor link a few millimetres from the FMT, so that it does not impede movement of the FMT when in its final position. Place the Coupler-FMT assembly onto the head of the stapes in such a way that the longer legs are parallel to the stapes and the shorter legs are over the stapedial tendon (see Figure 31). Palpate the entire assembly in order to ensure its stability.

Since middle ear ventilation is not required, fascia and cartilage can be used in order to give additional stability to the Coupler-FMT assembly. Place cartilage onto the bony canal/cavity walls to seal the entire construction towards the tympanum/auditory canal. Contrary to passive middle ear prostheses, the cartilage does not have to transfer sound but is needed to stabilize the FMT and should therefore be thicker (approx. 1 mm).

CAUTION
VIBROPLASTY COUPLERS DO NOT FUNCTION AS PASSIVE MIDDLE EAR PROSTHESSES. THE CARTILAGE BEHIND THE FMT IS NOT USED FOR SOUND TRANSFER BUT TO MAKE THE COUPLER-FMT ASSEMBLY MORE STABLE.

If the connection seems loose the Coupler-FMT assembly should be carefully removed from the stapes. The clips can then be carefully bent as necessary, to make the connection stable. Be careful not to damage the stapes by making the clips too tight.

Once the Coupler has been placed onto the stapes, no further crimping is necessary.

Figure 30: Before placing the RWS-Coupler, the conductor link is placed into the groove, leaving a bit of a slack cable. Then it is fixed with bone paté.

Figure 31: The Vibroplasty-CliP-Coupler is attached to a mobile head of the stapes. The shorter legs are over the crura and the conductor link exits above the shorter legs.
Step 9: Conductor Link

One part of the surgery that is important for avoiding (post-operation) complications is the positioning of the conductor link. When placing it, care should be taken in ensuring that no sharp angle in the conductor link is made. Ensure that there are no sharp edges from the channel or the open bony bridge and that the midpoint of the transition lies on the posterior edge of the mastoid cavity.

Posterior Tympanotomy

Figure 32 illustrates the final position of the conductor link in a facial recess route with an open bony bridge in an Incus Vibroplasty. Arrange the conductor link so that it does not make contact with the edges of the bony wall of the facial recess. In an Incus Vibroplasty via a facial recess route do not pack the facial recess.

Radical Cavity

Figure 33 illustrates the final position of the conductor link in a radical cavity with a RW Vibroplasty. There is a bit of slack cable close to the FMT, the conductor link is in the drilled out groove and the excess conductor link is placed in the small bony bed on the skull. Bone paté is used to fix the conductor link and cover it to avoid extrusions. Special care should be taken in the middle ear and close to the implant where the conductor link exits the implant body.

Figure 32: The conductor link is arranged so that it does not contact the edges of the bony wall of the facial recess. The excess conductor link is placed in the mastoidectomy, under the overhangs of the inferior and anterior wall. There should be no sharp bends or kinks in the conductor link, especially as it exits the transition.

Figure 33: In radical cavities, the conductor link is placed into the drilled out groove and the excess conductor link is arranged in a small drilled out bony bed on the skull. Bone paté is used to fix the conductor link and to cover it to avoid extrusions. The FMT is covered with soft tissue in order to promote additional fixation from fibrous tissue growth (see detailed drawing).

In addition cartilage and fascia should be placed on top of the bone paté before the skin is replaced.
Step 10: Closure

**CAUTION**
MONOPOLAR ELECTROCAUTERY MUST NOT BE USED.
TO ACHIEVE HEMOSTASIS, ONLY USE BIPOLAR ELECTROSURGICAL INSTRUMENTS AND ENSURE THAT THEY ARE NEVER IN CONTACT WITH THE VORP 503.

Once the conductor link is in place and before closing the wound, verify the FMT position once again.

In an Incus Vibroplasty with the Incus-SP-Coupler, the FMT should not touch the surrounding bone and the Coupler should not move on the incus.

With the Incus-LP-Coupler, the axis of the FMT should be parallel to the axis of motion of the stapes. The FMT must be in contact with the stapes, preferably against the incudostapedial joint. The FMT must not contact the promontory, tympanic membrane, or pyramidal eminence.

In a Round Window Vibroplasty the RW-Soft-Coupler is placed in contact with the RW membrane, and the long axis of the FMT should be perpendicular to the RW membrane. The FMT should not be impeded by the walls of the middle ear space and/or bony protuberances. Cartilage and tissue are placed behind the FMT. The cartilage should give the FMT a prestress so that there is a good contact to the RW membrane. It is also important that there is a bit of a slack in the conductor link so that fibrous tissue won’t pull the FMT out of the RW niche over time.

In an Oval Window Vibroplasty the Coupler sits on the head of the stapes.

Close the scalp wound in layers. Take care not to make contact with the conductor link while closing. If a pericranial flap was created in addition to a skin flap, it should be sutured in place over the anterior portion of the demodulator, the transition, and the conductor link. Then suture the skin flap with a double layer closure. Clean the incision site and apply a pressure dressing to the wound.
CHAPTER

PRESERVE RESIDUAL HEARING AND MIDDLE EAR STRUCTURES
Do not make contact with middle ear structures with the drill when exposing the antrum or opening the facial recess. Use only a diamond burr when drilling near the ossicles and do not touch them with the burr.
Temporarily, place gelfoam in the opening of the antrum to decrease the likelihood of bone dust entering the middle ear during burring the skull surface.
Do not remove the buttress at the short process of the incus when creating the posterior tympanotomy.
Use irrigation liberally to remove any bone dust that may have entered middle ear space during surgery.
The conductor link at the FMT should have some slack.

ATTACHMENT OF COUPLERS
Take care that the Coupler is not bent during removal from its package.
With the Incus-SP-Coupler, the Incus-LP-Coupler and the RW-Soft-Coupler, the FMT should be attached to the Coupler, while it is still in the holding frame. This guarantees the correct positioning of the Coupler onto the FMT and of the conductor link.
With the Vibroplasty-Clip-Coupler, the FMT should be stabilized before attaching the Coupler. When attaching the Coupler, care must be taken that the conductor link exits above the shorter legs of the Coupler and that the cable does not touch one of the three legs that hold the FMT.
With the RW-Soft-Coupler, the FMT needs to be dry before attaching the Coupler. If the FMT is wet it shall be cleaned with a lint-free tissue before attaching the Coupler.

CARE SHOULD BE TAKEN WHEN HANDLING THE VORP 503
Only the surgeon should handle and remove the implant from the inner sterile package. This is because the conductor link and transducer are fragile.
Never place the VORP 503 and FMT on sponges or draping. Monopolar electrocautery must not be used once the VORP 503 is in the surgical field.
Avoid grasping the FMT at its junction to the conductor link. Do not bend the conductor link excessively.

SECURE THE DEVICE
Place the device into a shallow bony bed (less than 1.9 mm) so that the anchor holes lie on the bone. Fixate the demodulator in place using the screws and the screwdriver provided in VORP 503 Implant Kit, with the transition angled down towards the mastoid cavity. The conductor link should be as medial to the skull surface as possible. The conductor link should not impede the movement of the FMT. Pre-bending a small curve in the conductor link facilitates proper position of the FMT.

POSITIONING THE FMT: INCUS VIBROPLASTY
Repeated manipulation of the Coupler is strongly discouraged.
The Incus-SP-Coupler is placed on the short process of the incus via a posterior epitympanotomy. In its final position, the FMT must not come into contact with bone. The Coupler should not move on the incus. No further crimping is needed.
With the Incus-LP-Coupler, the FMT must be in contact and parallel with the stapes, preferably against the incudostapedial joint. The FMT must not contact the promontory, tympanic membrane, or pyramidal eminence.

POSITIONING THE FMT: ROUND WINDOW VIBROPLASTY
Practice RW placement in the temporal bone lab before surgery.
When preparing the round window niche, leave a bony rim anteriorly and posteriorly which will later help to stabilize the FMT.
Attach one of the RW-Soft-Couplers onto the FMT Sizer and use the assembly to ensure that the Coupler-FMT assembly will fit in the round window niche without touching the bony overhang or without any other obstruction. Bone and other protuberances should not interfere. The stiffness of the conductor link helps
to hold the FMT with the Coupler in place. Pre-bend a small curve in the conductor link a few millimetres from the FMT, so that it does not impede movement of the FMT when in its final position.

FMT movement should not be impeded by the walls of the middle ear space and/or bony protuberances. The long axis of the FMT should be perpendicular to the RW membrane. The FMT may be gently palpated to confirm that its movement is not impeded.

Place cartilage on the contralateral side of the FMT to give the FMT a prestress that helps maintain its position. In a radical cavity, a groove should be drilled inferiorly for the conductor link and a small bony bed on the skull in which the excess conductor link can later be placed.

**POSITIONING THE FMT: OVAL WINDOW VIBROPLASTY**

The Vibroplasty-CliP-Coupler can be used independently from middle ear ventilation. The head of the stapes should be cleaned from scars and granulation tissue, before the Coupler-FMT assembly is placed into the middle ear.

Place the Coupler–FMT assembly onto the head of the stapes in such a way that the longer legs are parallel to the stapes and the shorter legs are over the stapedial tendon. Palpate the entire assembly in order to ensure its stability.

Place cartilage onto the bony ear canal/cavity walls to seal the entire construction towards the tympanum/auditory canal. Contrary to passive middle ear prostheses, the cartilage does not have to transfer sound but is needed to stabilize the FMT and should therefore be thicker (approx. 1 mm).

**ENSURE PROPER SKIN FLAP THICKNESS**

The skin flap including the temporalis fascia must be measured with the Skin Flap Gauge 7.

The total tissue thickness over the receiver coil must not exceed 7 mm. If the total thickness is greater than 7 mm, then the flap must be carefully thinned.

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**REGISTRATION CARD**

The VORP 503 registration card, contained in the packaging, should be completed and returned promptly to VIBRANT MED-EL. The peel-off label of the Coupler used should also be stuck onto the registration card.

**INITIAL ACTIVATION**

Eight weeks following surgery, the patient returns for medical clearance and initial activation of the audio processor.
MED-EL – A TRUSTED PARTNER

Meet MED-EL

At MED-EL, our goal is to overcome hearing loss as a barrier to communication and quality of life worldwide. Based in Innsbruck, Austria, MED-EL has over 1,500 employees and is present in more than 100 countries.

For nearly 40 years, MED-EL founders Ingeborg and Erwin Hochmair have been pioneering cochlear implant research. As a company, MED-EL has been driving innovation in the field of hearing implants for more than 20 years.