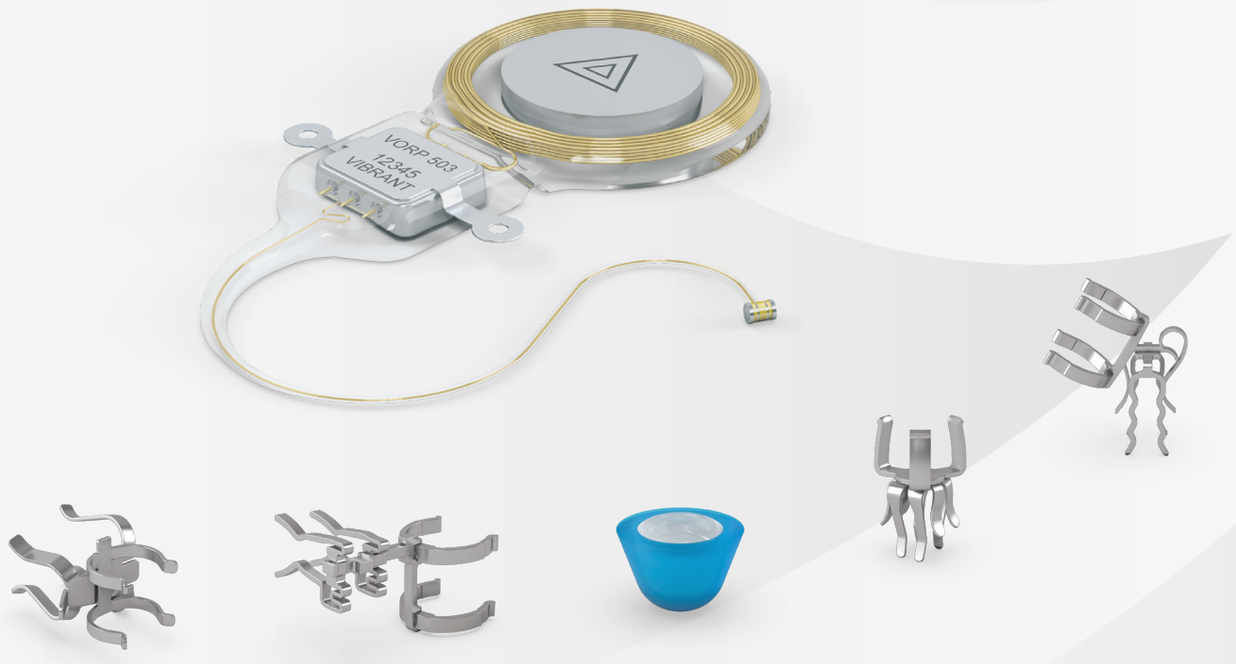
MED-EL

VIBRANT SOUNDBRIDGE (VORP 503)

Surgical Guide



hearLIFE

AW52689_1.0 (English)

Table of Contents

Surgical Guide

For the VORP 503 Implant

This guide describes the surgical procedure for the implantation of the VORP 503 implant, which is part of the VIBRANT SOUNDBRIDGE (VSB) system. In addition to that, surgical tools provided by MED-EL and different Vibroplasty Couplers are described as well as perioperative patient management. Key points and helpful references are presented at the end of this guide.

Acknowledgements:
Special thanks to the following surgeons:
- M. Beltrame (Rovereto, Italy), B. Schwab (Hannover, Germany), I. Todt (Berlin, Germany), G. Sprinzl (St.Pölten, Austria) and M. Profant (Bratislava, Slovakia): for their contributions to the RW Vibroplasty section in this guide.
- R. Mlynski (Würzburg, Rostock, Germany): for his contribution to the Vibroplasty-SP-Coupler section in this guide.
- K-B. Hüttenbrink (Cologne, Germany): for his contribution to the Vibroplasty-CliP-Coupler section in this guide.

The watercolour drawings were created by Gabriele Fritz and Robert Schweissgut, medical illustrators from Austria.

Please find detailed information and specific conditions for use for each product in the respective instructions for use.

Introduction

The VIBRANT SOUNDBRIDGE is an active middle ear implant for persons 5 years of age and above with sensorineural, conductive or mixed hearing loss.

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

VIBRANT SOUNDBRIDGE is for sensorineural, conductive, or mixed hearing loss.

The VORP 503, the implantable part of the VIBRANT SOUNDBRIDGE, consists of a magnet surrounded by a receiver coil, a demodulator, two fixation wings, a conductor link, and a transducer. Information from the audio processor 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.

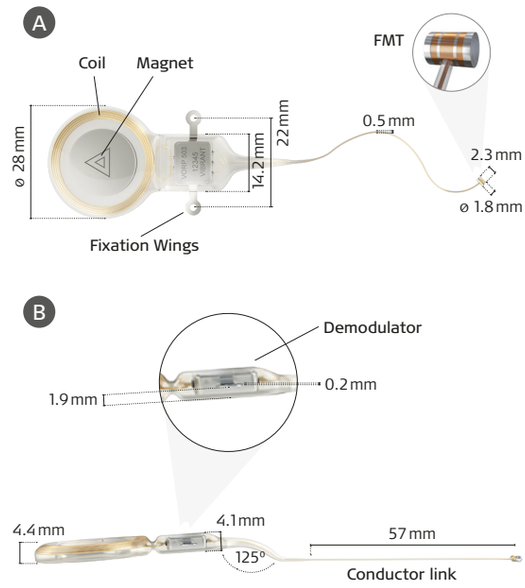


Figure 1: Components and dimensions of the Vibrating Ossicular Prosthesis VORP 503 (A) shown from above (B) shown from the side.

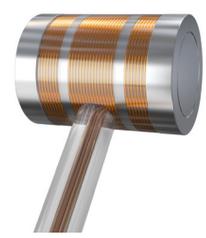


Figure 2: Floating Mass Transducer (FMT)

The VIBRANT SOUNDBRIDGE is implanted using a Vibroplasty technique. Vibroplasty is the treatment of hearing loss via vibratory stimulation in the middle ear. When the FMT is in contact with a vibratory structure of the middle ear, it vibrates the structure and stimulates the auditory system.
In order to get the FMT into contact, different Vibroplasty Couplers may be used.

For placement onto the incus three different Vibroplasty Couplers are available:
- Incus-SP-Coupler for placement onto the short process of the incus
- Incus-LP-Coupler for placement onto the long process of the incus
- Incus-Symphonix-Coupler for placement onto the long process of the incus (not described in detail within this guide)

In addition, many other Couplers are available for placement onto other middle ear structures:
- Stapes-SH-Coupler for placement onto the head of the stapes
- Vibroplasty-CliP-Coupler for placement onto the head of the stapes
- Vibroplasty-Bell-Coupler for placement onto the head of the stapes (not described in detail within this guide)
- Vibroplasty-OW-Coupler for placement onto the stapes footplate (not described in detail within this guide)
- RW-Soft-Coupler for placement onto the round window membrane
- Vibroplasty-RW-Coupler for placement onto the round window membrane (not described in detail within this guide)

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 VIBRANT SOUNDBRIDGE implantation. Success is most likely when the patient is well selected and has realistic expectations of using the VIBRANT SOUNDBRIDGE system.

It is recommended that a CT scan is performed before surgery.

Surgery 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 audio processor so the VIBRANT SOUNDBRIDGE can be activated. The patient typically wears the device for several hours a day, or all day, immediately after activation.

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

Surgical Tools

Most instruments needed for the implantation of the VORP 503 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 shipped with a VORP 503 Sizer Kit. The Skin Flap Gauge 7 is a generic surgical tool that needs to be ordered separately.

Tools Shipped with the VORP 503 Implant (Sterilized)

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

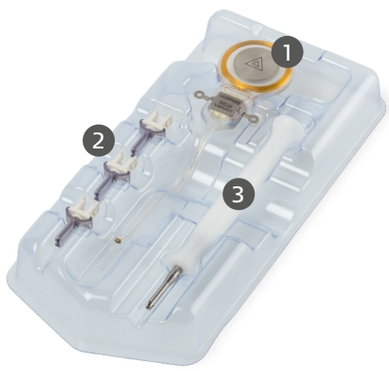


Figure 3: VORP 503 Implant Kit consisting of:
1) VORP 503 Implant, 2) three self-drilling cortical screws and
3) single-use screwdriver

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 backup screw.

Screwdriver

The screwdriver is a single-use device. 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 single-use FMT Sizer. The VORP 503 Sizer Kit is shipped in sterile condition.

VORP 503 Template

The VORP 503 Template is a single-use 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.

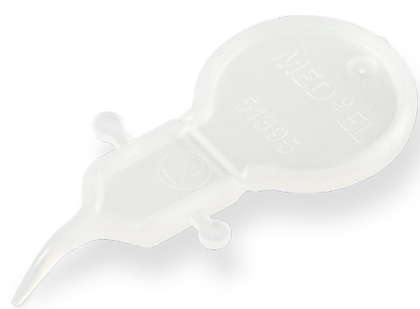


Figure 4: VORP 503 Template

FMT Sizer

The single-use 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 the 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.

Figure 5: FMT Sizer

Skin Flap Gauge 7 (Not Sterilized)

The Skin Flap Gauge 7, made of stainless steel, is an optional tool used to estimate the thickness of the skin flap over the coil section of the VORP 503 to ensure 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 and therefore allows for a good coupling of the audio processor to the implant.

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

Figure 6: Skin Flap Gauge 7

Surgical Accessories

Vibroplasty Couplers (Sterilized)

A Vibroplasty Coupler can be used to affix the FMT to a mobile middle ear structure. They can be ordered together with the VORP 503 Implant Kit or separately.

The Vibroplasty Couplers are 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 VIBRANT 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.

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

Couplers for Placement onto the Incus

Incus-SP-Coupler

The Incus-SP-Coupler (see Figure 7) is used to place the FMT onto the short process of the incus via a posterior epitympanotomy (attico-antrotomy). No additional crimping is needed.

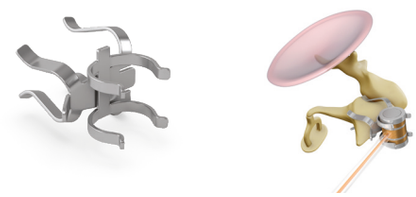


Figure 7: The Incus-SP-Coupler is placed onto the short process of the incus.

Incus-LP-Coupler

The Incus-LP-Coupler (see Figure 8) is used to place the FMT onto the long process of the incus via a posterior tympanotomy. No additional crimping is needed. A left and a right version of the Incus-LP-Coupler are available.

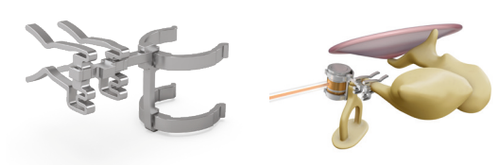


Figure 8: The Incus-LP-Coupler is placed onto the long process of the incus.

Coupler for Placement on the Round Window Membrane

RW-Soft-Coupler

The RW-Soft-Coupler (see Figure 9) is used to place the FMT on the round window membrane. The Coupler is attached to 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 FMT of the implant.

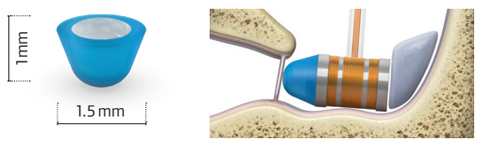


Figure 9: The RW-Soft-Coupler is used to place the FMT on the round window membrane.

Couplers for Head of the Stapes Placement

Stapes-SH-Coupler and Vibroplasty-CliP-Coupler

Both Couplers are placed on the head of the stapes if the stapes and stapes footplate are mobile and strong enough to endure the weight of the Coupler plus FMT. No additional crimping is needed for both Couplers. The decision which Coupler to use depends on the patient's anatomy.

Figure 10: The Stapes-SH-Coupler and Vibroplasty-CliP-Coupler are placed onto the stapes head.

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.

General Surgical Considerations

When implanting a VORP 503, the FMT needs to be fixed onto a mobile middle ear structure with the help of an appropriate Vibroplasty Coupler. The surgeon needs to determine which route to the middle ear to use from the medical status of the patient's ear.

In case of an intact ossicular chain, 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 case the ossicular chain is not intact, the FMT is placed either via a facial recess route or via a radical cavity.

General Precautions

The surgery is standard otologic practice and includes the normal risk of a surgical procedure as well as the risk of general or local anaesthesia.

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 Form

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

The peel-off label from the Coupler used should also be placed onto the registration form.

Surgical Steps

STEP 1: Preparation

Shave the hair approximately 2 cm 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 2 cm 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 fixate it with screws in the bone.

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

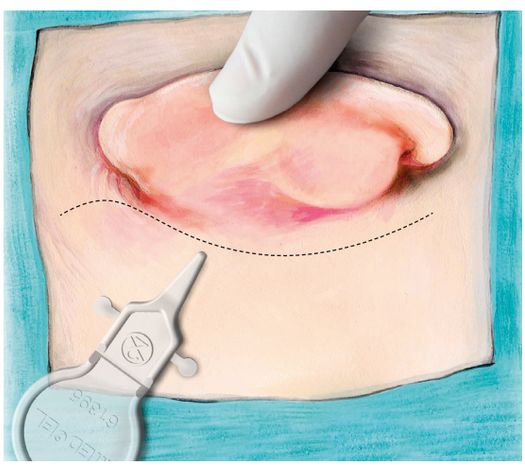


Figure 11: Positioning the VORP 503 Template and planning the incision. An extended postauricular incision is shown.

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 1 cm 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 must be used once the VORP 503 is in the surgical field, or if the patient has an implant on the other side. Place the sterile 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 (e.g., by using the Skin Flap Gauge 7). 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.

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 in order to keep the conductor link inside mastoidectomy (see Figure 12). Place gelfoam in the opening of the antrum to decrease the likelihood of bone dust entering the middle ear whilst drilling the bone bed.

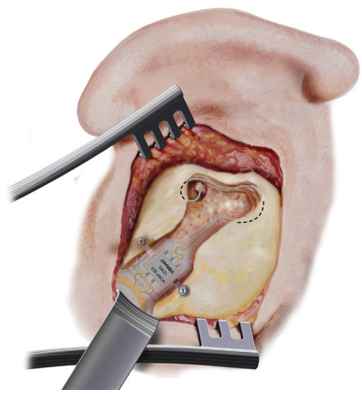


Figure 12: Leave overhangs superiorly and inferiorly in order to keep the conductor link inside the mastoidectomy. For better visualization, this figure shows the implant already in place.

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. In addition to that the bone bed also provides a secure and stable position for the VORP 503.

With a rasparatory, the periosteum is elevated off the bone in the region where the coil will be placed. Position the VORP 503 Template 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. 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.

Mark the outline of the demodulator portion of the template. 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.

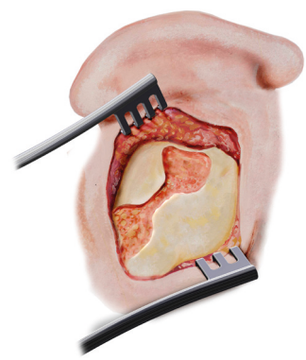


Figure 13: Drill a bone bed for the demodulator and a channel for the conductor link. The anterior edge of the bed should be the deepest, allowing a gradual slope into the mastoid cavity.

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 (see Figure 14).

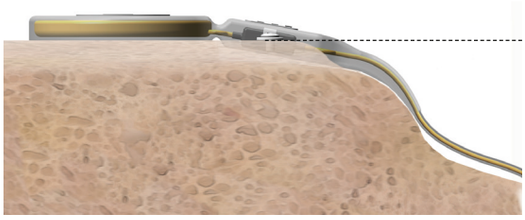


Figure 14: The anterior edge of the bone bed is deeper than the posterior edge and a channel is drilled between the bone bed and the mastoid cavity. Like this, the implant can gradually slope down into the mastoidectomy. For better visualization, this figure shows the implant already in place.

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 15).

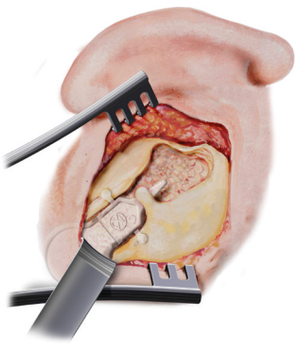


Figure 15: An open bony bridge provides additional protection for the VORP transition. The placement of the VORP 503 is checked with the VORP 503 Template.

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 to avoid touching the ossicles.

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

For attachment of the FMT to short process of the incus an intact ossicular chain is necessary. Therefore the mobility of the ossicular chain should be checked before further steps are taken. For the Incus-SP-Coupler, the area close to the short process of the incus needs to be widened. Since the FMT Incus-SP-Coupler 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. To remove the bone close to the incus, a house spoon or a diamond burr can be used. The last step should be to flatten the bone by using a small diamond burr and drilling away from the ossicles.

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.

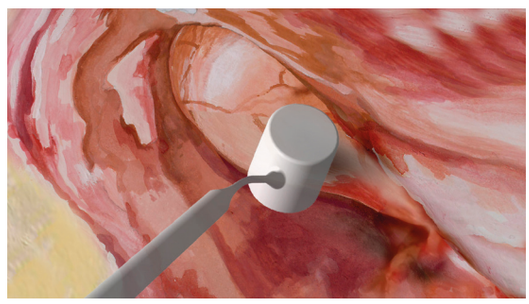


Figure 16: Widen the posterior epitympanotomy to such an extent that the FMT Sizer fits well, without touching bone. The last step should be to flatten the bone close to the short process.

STEP 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 that the long process of the incus is clearly visible (see Figure 17). 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.

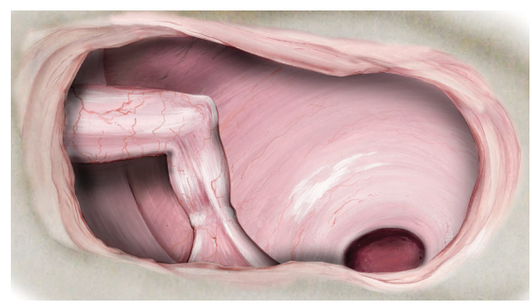


Figure 17: For the Incus-LP-Coupler, enough bone must be removed in the posterior tympanotomy to gain good access to the long process of the incus.

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

Round Window (RW) Vibroplasty
In RW Vibroplasty, the posterior tympanotomy needs to be enlarged inferiorly so that a clear view onto the round window area is possible (see Figure 18).

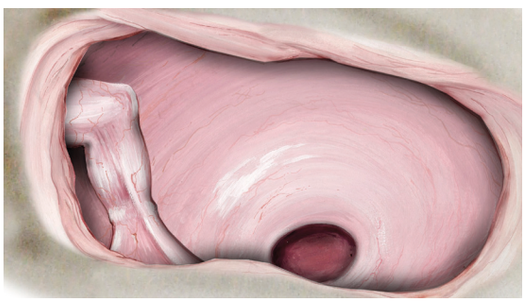


Figure 18: For the RW-Soft-Coupler, the posterior tympanotomy should be large enough to allow good access to the RW niche.

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 analyzed. Figure 19 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.

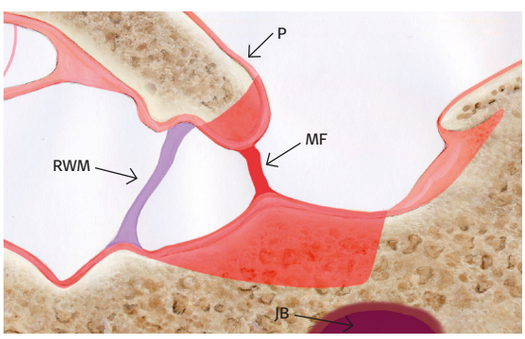


Figure 19: Horizontal cross section through the round window area that shows the promontory (P), RW membrane (RWM), a potential mucosal fold (MF), and the jugular bulb (JB). The red shaded area indicates where bone should be removed.

Use a 0.8 mm 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 mm to 1.8 mm burr to drill a bed for the FMT in the hypotympanum. During this whole process the FMT Sizer might be used to check if sufficient space has been generated.

STEP 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 mm 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 20).

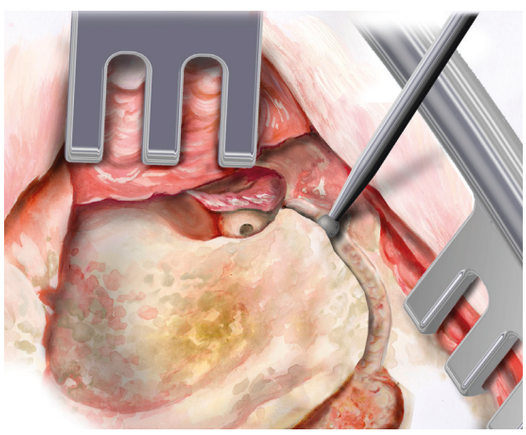


Figure 20: In a radical cavity certain precautions need to be taken to accommodate the conductor link. A groove should be drilled inferiorly, far away from the facial nerve, and a small bony bed in the cortical bone should be drilled for the excess conductor link.

STEP 6: Attaching the Coupler to the FMT

All Couplers discussed in this guide (except for the Vibroplasty-CliP-Coupler) are delivered with a holding frame and a retainer which holds 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. It is recommended 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 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.

More detailed instructions on how to attach the FMT to the Coupler can be found in the instructions for use.

STEP 6a: Incus-SP-Coupler, Incus-LP-Coupler, Stapes-SH-Coupler

Place the FMT onto the cage of the Coupler and push it down using surgical tweezers, a needle or a similar tool. The position of the conductor link depends on the Coupler and on the side of implantation.

For proper alignment of the conductor link please follow the instructions on the sticker on the holding tray.

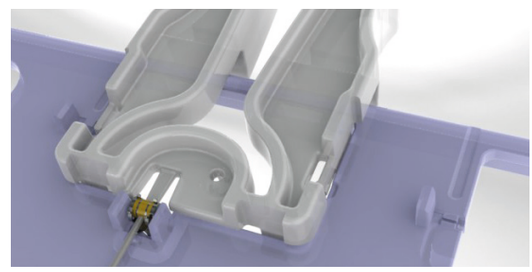


Figure 21: For a correct connection of the FMT and the Coupler, the FMT is connected while the Coupler is still in the holding frame. The FMT is placed in such a way that the conductor link lies in the groove.

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

STEP 6b: Vibroplasty-CliP-Coupler

The Vibroplasty-CliP-Coupler is delivered in a small box. Open that box and take the Coupler out using surgical tweezers. It is recommended to stabilize the FMT by pushing it into a piece of bone wax before attaching the Coupler. 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 to ensure a secure connection. This can be done, for example, with a needle (see Figure 22).

Figure 22: 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.

STEP 6c: 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.

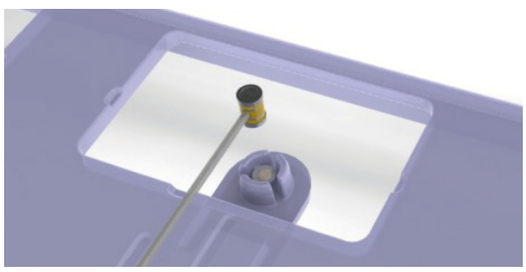


Figure 23: After the retainer is removed, the RW-Soft-Coupler is visible. The FMT is then pushed onto the Coupler while it is still in the holding frame.

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 to check whether enough bone has been removed.

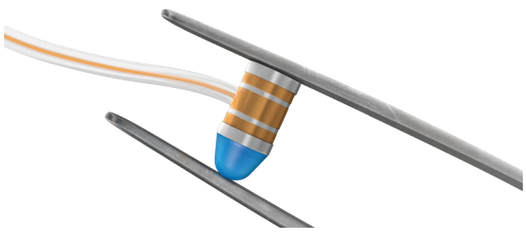


Figure 24: The Coupler and the FMT are pressed together firmly with tweezers to ensure a safe connection.

STEP 7: Fixation of the Demodulator

CAUTION
Once the VORP 503 is in the surgical field, monopolar electrocautery must never be used.

Arrange the VORP 503 over the surgical site so that the triangle shape on the magnet 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. When secured, the depth of the screws in the cortical bone is approx. 3 mm.

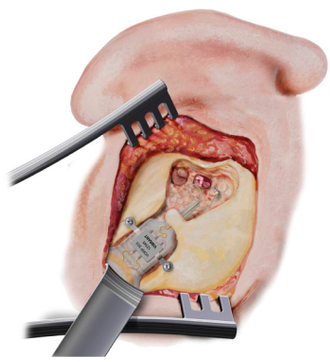


Figure 25: Fixation of the implant

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 non-magnetic tools 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 millimeters from the FMT, so that it does not impede the movement of the FMT when in its final position.

STEP 8a: Incus Vibroplasty

Incus-SP-Coupler

To place the Incus-SP-Coupler, the flexible structure of the Coupler is clamped onto the short process of the incus. First the two shorter legs of the Coupler shall be placed inferiorly on the short process of the incus, then the two longer legs shall hold the incus body superiorly. The spur of the Coupler must not touch the buttress. For manipulation of the FMT Coupler assembly it is recommended to use a small suction tube (1.2 mm to 1.4 mm) or a forceps and to push it onto the incus using a needle or a similar surgical instrument. No further crimping is needed. Neither the FMT nor the Coupler should touch bone. To check the stability of the connection, touch the FMT and check if that leads to a simultaneous movement of the ossicles. Remove all bone dust from the posterior epitympanum.

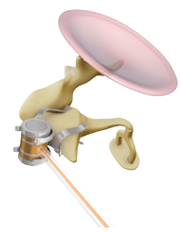


Figure 26: Incus-SP-Coupler: the longer legs are over the incus body and the shorter legs over the short process of the incus

Incus-LP-Coupler
To place the Incus-LP-Coupler the flexible structure of the Coupler is clamped onto the long process of the incus. For manipulation of the FMT Coupler assembly it is recommended to use a smooth alligator forceps, a suction tip or two needles. To get the FMT Coupler assembly through the posterior tympanotomy, enter it with the FMT first. Then rotate it into its final position. Use a wobbling motion when placing the assembly onto the long process of the incus. No further crimping is needed. Best results are achieved when the FMT is placed parallel and as close as possible to the stapes (even touching it).

Neither the FMT nor the Coupler should touch the promontory, tympanic membrane or pyramidal eminence. To check the stability of the connection, touch the FMT and check if that leads to a simultaneous movement of the ossicles and stapes footplate.

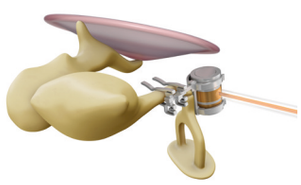


Figure 27: Incus-LP-Coupler with the clip positioned on the long process of the incus. The FMT is in contact with the stapes.

STEP 8b: 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 millimeters 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 a 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.

Put the FMT Coupler assembly into round window niche, with the Coupler facing towards the round window. 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. The FMT in this position is shown in Figure 28. Lastly, a piece of tissue (or artificial fascia) is placed over the FMT to promote additional fixation from fibrous tissue growth.

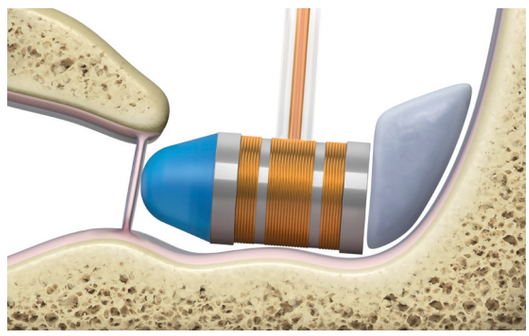


Figure 28: FMT placement on the RW membrane encapsulated in perichondrium or similar tissue. Cartilage behind the FMT gently pushes the FMT against the RWM and thus gives a prestress.

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 section Round Window Vibroplasty). The third point is the stiffness of the conductor link that helps keeping the FMT in place. The last point that adds to a stable fixation is the cartilage placed behind the FMT.

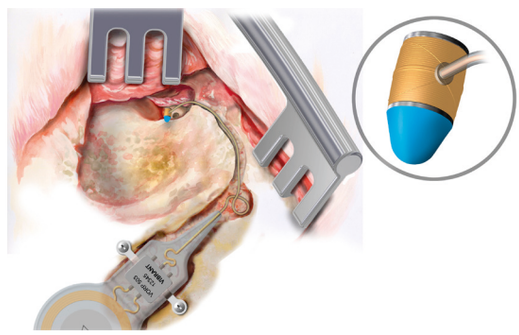


Figure 29: Before placing the RWS-Coupler, the conductor link is placed into the groove, leaving a bit of a slack cable. Then it is fixated with bone paté.

STEP 8c: Stapes Vibroplasty

In this guide the technique for the Stapes-SH-Coupler and the Vibroplasty-CliP-Coupler will be described. For information on the procedure for the other Couplers, refer to the instructions for use of the respective Coupler.

Stapes-SH-Coupler and Vibroplasty-CliP-Coupler

Unlike a passive middle ear prosthesis those Couplers are only needed to enable placement of the FMT and not to reconstruct the middle ear. Therefore, they can be used independently from middle ear ventilation.

The head of the stapes should be cleaned from scars and granulation tissue before the FMT Coupler assembly is placed into the middle ear.

The decision which Coupler to use is based on the anatomical conditions. The FMT Sizer is used to verify the space conditions.

To place the FMT Stapes-SH-Coupler assembly onto the head of the stapes, first place it laterally to the stapes in a tilted manner. Then arrange it in an upright position and gently push it down on the head of the stapes. If possible, try to close the gap between the Coupler and the head of the stapes.

Figure 30: The Stapes-SH-Coupler is attached to the mobile head of the stapes.

The Vibroplasty-CliP-Coupler is placed on the head of the stapes with the longer legs parallel to the stapes and the shorter legs over the stapedial tendon (see Figure 31).

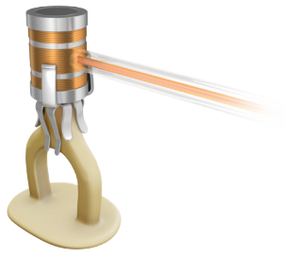


Figure 31: The Vibroplasty-CliP-Coupler is attached to the mobile head of the stapes.

If the connection seems loose, the FMT Coupler 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.

Neither the FMT nor the Coupler should touch the promontory, tympanic membrane or pyramidal eminence. To check the stability of the connection, touch the FMT and check if that leads to a simultaneous movement of the stapes and stapes footplate. Since middle ear ventilation is not required, fascia and cartilage can be used to give additional stability to the FMT Coupler assembly.

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 in a way 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.

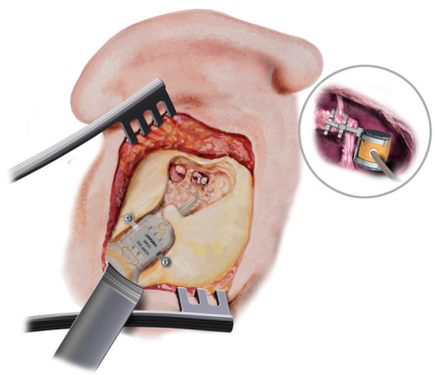


Figure 32: The conductor link is arranged in a way that it does not touch the edges of the bony wall of the facial recess. The excess conductor link is placed in the mastoidectomy, under the overhangs of the inferior and anterior wall. There should be no sharp bends or kinks in the conductor link, especially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

Radical Cavity

In radical cavities there is a bit of slack cable close to the FMT, the conductor link is placed 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 in addition cartilage and fascia should be placed on top of the bone paté to cover the conductor link and to avoid extrusions (see Figure 33). Special care should be taken in the middle ear and close to the implant where the conductor link exits the implant body.

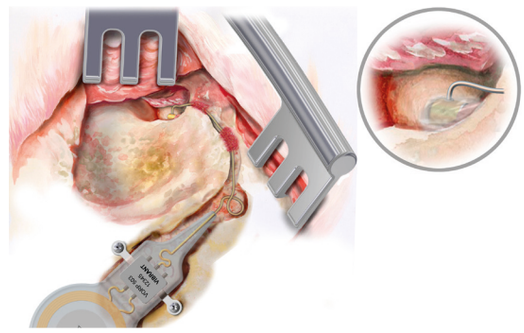


Figure 33: In radical cavities, the conductor link is placed into the drilled-out groove and the excess conductor link is arranged in a small drilled-out bony bed on the skull. Bone paté is used to fix the conductor link and to cover it to avoid extrusions. The FMT is covered with soft tissue to promote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

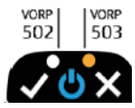
STEP 10: Integrity Check

Before closing the wound, you can test the integrity of the implant with the VSB QuickCheck 2. You will get a result wirelessly in a couple of seconds.

Figure 34: VSB QuickCheck 2 for implant integrity testing

Information on Use

1. Put the VSB QuickCheck 2 into a sterile sleeve.
2. Press the button to switch the VSB QuickCheck 2 on.
3. Select the implant model VORP 503 by pushing the button.



4. Perform an integrity check by positioning the transmitter section of the VSB QuickCheck 2 exactly on top of the internal receiver coil of the implant (magnetic attraction will help you to find the right position).

For further information refer to the VSB QuickCheck 2 instructions for use or the Quick Guide.

STEP 11: Closure

CAUTION

Monopolar electrocautery shall 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 and as close as possible to the stapes. The FMT must not touch 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 is placed behind the FMT to give it a prestress. Tissue is used to cover the FMT.

It is also important that there is a bit of a slack in the conductor link so that fibrous tissue will not pull the FMT out of the RW niche over time.

Before closing the wound it is important to rinse the middle ear thoroughly with saline solution to remove all bone dust.
Close the scalp wound in layers. Clean the incision site and apply a pressure dressing to the wound.

Key Points

Preserve Residual Hearing and Middle Ear Structures
Do not touch 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 Vibroplasty Couplers
Take care that the Coupler is not bent during removal from its package.

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 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 using the screws and the screwdriver provided in the 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 positioning 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 touch 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 stabilizing the FMT.

Attach one of the RW-Soft-Couplers onto the FMT Sizer and use the assembly to ensure that the FMT Coupler assembly will fit in the round window niche without touching the bony overhang and 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. Bone paté is used to fixate the conductor link and, in addition, cartilage and fascia should be placed on top of the bone paté to cover the conductor link and to avoid extrusions.

Positioning the FMT: Stapes Vibroplasty
The Stapes-SH-Coupler and the Vibroplasty-CliP-Coupler can be used independently from middle ear ventilation.

To place the FMT Stapes-SH-Coupler assembly onto the head of the stapes, first place it laterally to the stapes in a tilted manner. Then arrange it in an upright position and gently push it down on the head of the stapes. If possible, try to close the gap between the Coupler and the head of the stapes.

The Vibroplasty-CliP-Coupler is placed on the head of the stapes with the longer legs parallel to the stapes and the shorter legs over the stapedial tendon.

Ensure Proper Skin Flap Thickness
The skin flap including the temporalis fascia is 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.

Registration Form
The VORP 503 registration form, contained in the packaging, should be completed and returned promptly to MED-EL. The peel-off label of the Coupler used should be placed onto the registration form.

Initial Activation
Eight weeks following surgery, the patient returns for medical clearance and initial activation of the audio processor.

MED-EL Elektromedizinische Geräte GmbH
Fürstenweg 77a, 6020 Innsbruck, Austria
office@medel.com