Vibroplasty™ Couplers
Appendix to the Information for Surgeons
Acknowledgements:
Special thanks to Prof. K.-B. Hüttenbrink from Cologne and Prof. T. Zahnert from Dresden for their commitment during the development of the Vibroplasty Couplers and this manual.
I. Introduction

The purpose of this appendix to the brochure *Information for Surgeons for Incus and Round Window Vibroplasty* for the Vibrant Soundbridge is to serve as a reference guide for the use of the Vibroplasty Couplers. It is designed to assist the surgeon during the installation of the FMT in combination with the Vibroplasty Couplers.
II. Vibroplasty Couplers

Alongside the existing and very successful ways of placing the FMT, such as the Incus or the Round Window Vibroplasty, Vibroplasty Couplers offer additional options of attaching the FMT in the middle ear. This allows even more surgical flexibility in a variety of conditions and anatomies in a more standardized way. Vibroplasty Couplers are attached to the FMT and couple the FMT to various middle ear structures.

There is one standard size of each coupler. On request, the OW-Coupler and the CliP- and Bell-Couplers are also available in three other sizes as shown in the table on the next page.

„FL“ represents the functional length of the coupler and is measured from the point where the coupler touches a vibratory structure to the point where the FMT touches the coupler.

„Σ“ is measured from the point where the coupler touches a vibratory structure to the far end of the FMT.
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<td>Vibroplasty-OW-Coupler</td>
<td>The Vibroplasty-OW-Coupler is intended to be placed on the stapes footplate. For cases where the incus and the stapes superstructure are missing and the footplate is intact and mobile.</td>
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<td>Vibroplasty-Bell-Coupler</td>
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<td>Vibroplasty-RW-Coupler</td>
<td>The Vibroplasty-RW-Coupler is intended to be placed on the round window membrane. For cases where the surgeon decides to place the FMT onto the round window membrane.</td>
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*Other sizes available:*
## Intended use

The Vibroplasty 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-OW-Coupler is intended to be placed on the stapes footplate (oval window) when the stapes superstructure is absent or unsuitable for use.

The Vibroplasty-CliP-Coupler and the Vibroplasty-Bell-Coupler are intended to be placed on the head of the stapes, in between the stapes and the eardrum.

The Vibroplasty-RW-Coupler is intended to be placed on the round window (RW) membrane.

## Surgery

THE PROCEDURES DESCRIBED IN THIS BROCHURE ARE ADDITIONAL WAYS TO PLACE AN FMT IN THE MIDDLE EAR. THIS MEANS THAT THE STEPS 1-6 AND STEPS 8-9 FROM THE BROCHURE “INFORMATION FOR SURGEONS FOR INCUS AND ROUND WINDOW VIBROPLASTY” STILL APPLY, ONLY STEP 7 „FMT PLACEMENT” HAS BEEN APPENDIXED.

### General remarks

The placement of a Vibroplasty-OW-Coupler, a Vibroplasty-Bell-Coupler or a Vibroplasty-CliP-Coupler is similar to the placement of passive middle ear prostheses.

With the Vibroplasty OW-, CliP- and Bell Couplers, the reconstructed tympanic membrane is not needed to transfer sound from the outer to the inner ear, as with passive middle ear prostheses. The cartilage of the reconstruction is only needed to stabilize the Coupler-FMT assembly. Therefore the cartilage can be thicker than in normal passive middle ear prostheses.

For all Vibroplasty Couplers, it is important to know that fibrous tissue growth does not impede the good sound transfer. On the contrary: fibrous tissue growth will most probably promote additional fixation for the FMT-Coupler assembly.

The VORP and the Vibroplasty Couplers should not be removed from the sterile packaging, until the seat for the implant is prepared and the surgeon is ready to place the device(s).
Attaching the FMT to the Coupler

Based on the surgeon’s preference, the FMT’s attachment clip can be removed before attaching any Coupler. Use standard otologic scissors to cut the clip off at the “neck” or base of the attachment (see Figure 1).

First the VORP is placed into the drilled out bed and the demodulator is sutured down. The FMT should then be connected to the Coupler before the complete construction is placed within the patient’s middle ear. This avoids putting excessive pressure on any auditory structure of the middle ear.

Suitable forceps (e.g. VIBRANT MED-EL Forming Forceps) should be used, to lock the FMT in position. Great care should be exercised when using forceps (see Figure 2).

Carefully attach the Coupler to the FMT in such a way, that the side of the cut-off FMT clip is facing away from the Coupler and that the conductor link is between two of the three legs of the Coupler.

- Be sure to attach the Coupler–FMT assembly to an auditory structure that will endure the mechanical stress for the lifespan of the components. Selecting an unsuitable structure may result in an inadequate benefit, a reduction or total loss of residual hearing and may necessitate further surgery.

- The size of the Coupler chosen should be as short as possible in order to reduce the lateral lever torque.

- Take care not to bend the three FMT holding clips when connecting the Coupler with the FMT. These clips should not be modified unless the connection seems loose or insecure. Avoid inserting the FMT into the holding clips of the Coupler more than once.
Installation of the FMT and the Vibroplasty-OW-Coupler

1. Use a full thickness piece of cartilage and remove any perichondrium.

2. Use the „Kurz“ cartilage punch to produce a 3.5 mm by 2.5 mm oval cartilage disc with a central perforation. The opening corresponds to the diameter of the stem end of the Vibroplasty-OW-Coupler.

3. Free the stapes footplate from granulation tissue and install the cartilage on it. If possible, use two pieces of cartilage disc in order to fill the OW niche.

4. In case rudiments of the crura are above the level of the footplate, the oval cartilage disc can be reduced to a quadrangular shape with a scalpel in order to fit the footplate.

5. Determine which size of Coupler you need and open the appropriate sterile Coupler package.

6. Use the suitable forceps (e.g. VIBRANT MED-EL Forming Forceps) to carefully hold the FMT in place and attach the Coupler to the FMT (see Figure 2). Attach the coupler to the side of the FMT where the attachment clip has been removed.

7. Position the conductor link by gently bending it to contour along the floor of the middle ear space. Bone paté may be used to secure the conductor link into position. The stiffness of the conductor link can be used in such a way that is serves as an additional fixation.

8. Place the Coupler–FMT assembly into the central perforation of the cartilage disc(s).

9. Place further cartilage fragments cut with a scalpel into the OW niche around the central perforation to provide additional guidance and fixation.

10. Use fibrin glue in order to additionally stabilize the prosthesis and the cartilage.
11. Palpate the entire assembly in order to ensure its stability.

12. 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 is not needed to transfer sound but to stabilize the FMT and should therefore be thicker (approx. 1 mm).

13. Additional pieces of cartilage can be inserted into the middle ear for increased stability of the assembly. Fibrin glue can be added.
Installation of the FMT and the Vibroplasty-CliP-Coupler

1. Clean the head of the stapes of scars and granulation tissue.

2. Determine which size of Coupler you need and open the appropriate sterile Coupler package.

3. Use the suitable forceps (e.g. VIBRANT MED-EL Forming Forceps) to carefully hold the FMT in place and attach the Coupler to the FMT (see Figure 2). The stiffness of the conductor link can be used in such a way that it serves as an additional fixation.

4. Position the conductor link by gently bending it to contour along the floor of the middle ear space. Bone paté may be used to secure the conductor link into position.

5. Place the Coupler–FMT assembly onto the head of the stapes.

6. Palpate the entire assembly in order to ensure its stability.

7. Use fascia and cartilage in order to give additional stability to the Coupler–FMT assembly.

8. 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 is not needed to transfer sound but to stabilize the FMT and should therefore be thicker (approx. 1 mm).

IF THE CONNECTION SEEMS LOOSE:

• REMOVE THE COUPLER–FMT ASSEMBLY FROM THE STAPES.
• CAREFULLY BEND THE CLIPS 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.
Installation of the FMT and the Vibroplasty-Bell-Coupler

1. Clean the head of the stapes of scars and granulation tissue.

2. Determine which size of Coupler you need and open the appropriate sterile Coupler package.

3. Use suitable forceps (e.g. VIBRANT MED-EL Forming Forceps) to carefully hold the FMT in place and attach the Coupler to the FMT (see Figure 2). The stiffness of the conductor link can be used in such a way that it serves as an additional fixation.

4. Position the conductor link by gently bending it to contour along the floor of the middle ear space. Bone paté may be used to secure the conductor link into position.

5. Place the Coupler–FMT assembly onto the head of the stapes.

6. Carefully close the Coupler’s holding cups with a suitable forceps.

7. Palpate the entire assembly in order to ensure its stability.

8. Use fascia and cartilage in order to give additional stability to the Coupler–FMT assembly.

9. 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 is not needed to transfer sound but to stabilize the FMT and should therefore be thicker (approx. 1 mm).

IF THE CONNECTION SEEMS LOOSE:

- CAREFULLY CLOSE THE COUPLER’S HOLDING CUPS WITH SUITABLE FORCEPS AS NECESSARY, TO MAKE THE CONNECTION STABLE.
- BE CAREFUL NOT TO DAMAGE THE STAPES BY MAKING THE CUPS TOO TIGHT.

Figure 5: The Vibroplasty-Bell-Coupler with FMT placed on the head of the stapes and separated from tympanic membrane by cartilage.
Installation of the FMT and the Vibroplasty-RW-Coupler

1. Use a 1.0 mm diamond burr to enlarge the round window niche, starting anteriorly to the RW membrane and moving to the superior section of the niche. Drilling should be performed with a diamond burr and at a low speed to avoid RW membrane damage. Carefully remove bone in the hypotympanum so that the FMT will be positioned at a perpendicular angle to the RW membrane.

2. Open the sterile Vibroplasty-RW-Coupler package.

3. Use the suitable forceps (e.g. VIBRANT MED-EL Forming Forceps) to carefully hold the FMT in place and attach the Coupler to the FMT (see Figure 2).

4. Prepare a 2 mm diameter (or larger) and 0.1 to 0.2 mm thick perichondrium tissue disc (or artificial fascia). Position the tissue over the RW membrane.

5. Advance the Coupler–FMT assembly into the middle ear with smooth alligator forceps. Avoid grasping the FMT where it connects to the conductor link.

6. Position the conductor link by gently bending it to contour along the floor of the middle ear space. Bone paté may be used to secure the conductor link into position.

7. The Coupler–FMT assembly is placed in contact with the perichondrium (or artificial fascia) covering the RW membrane.

8. Palpate the entire structure in order to confirm that its movement is not impeded.

9. Cartilage and tissue are placed behind the FMT. The cartilage should give the FMT a prestress so that good contact is made to the RW membrane.

10. Place a piece of perichondrium (or artificial fascia) over the FMT in order to promote additional fixation from fibrous tissue growth.

CLOSURE

Once the Vibroplasty Coupler and the VORP are in place, the wound is closed as described in the brochure Information for Surgeons for Incus and Round Window Vibroplasty.
Key Points

ATTACHMENT OF FMT TO COUPLER
• The FMT is connected to the Coupler outside of the patient's middle ear. This avoids excessive pressure on the middle ear structure.

CONDUCTOR LINK
• The stiffness of the conductor link can be used in such a way that it serves as an additional fixation.

CARTILAGE
• The Vibroplasty Couplers are not passive middle ear prostheses and therefore don't need a reconstructed tympanic membrane for sound transfer. Rather the reconstructed tympanic membrane helps to stabilize or to give pre-stress to the FMT-Coupler assembly.

VIBROPLASTY-OW-COUPLER
• The Vibroplasty-OW-Coupler is intended to be placed on the stapes footplate, when the stapes superstructure is absent or unsuitable for use and the footplate is intact and mobile.
• While the stem of the Vibroplasty-OW-Coupler is placed into a cartilage shoe with a central perforation, the upper part of the FMT is placed against a reconstructed tympanic membrane of approximately 1 mm thickness.

VIBROPLASTY-Clip-COUPLER
• The Vibroplasty-Clip-Coupler is intended to be placed on the head of the stapes, when the stapes is attached to the stapes footplate and the footplate is mobile.
• While the clip of the coupler is placed on the stapes head, the upper part of the FMT is placed against a reconstructed tympanic membrane of approximately 1 mm thickness.

VIBROPLASTY-Bell-COUPLER
• The Vibroplasty-Bell-Coupler is intended to be placed on the head of the stapes, when the stapes is attached to the stapes footplate and the footplate is mobile.
• While the bell of the coupler is placed on the stapes head, the upper part of the FMT is placed against a reconstructed tympanic membrane of approximately 1 mm thickness.

VIBROPLASTY-RW-COUPLER
• The Vibroplasty-RW-Coupler is intended to be placed on the round window membrane.
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