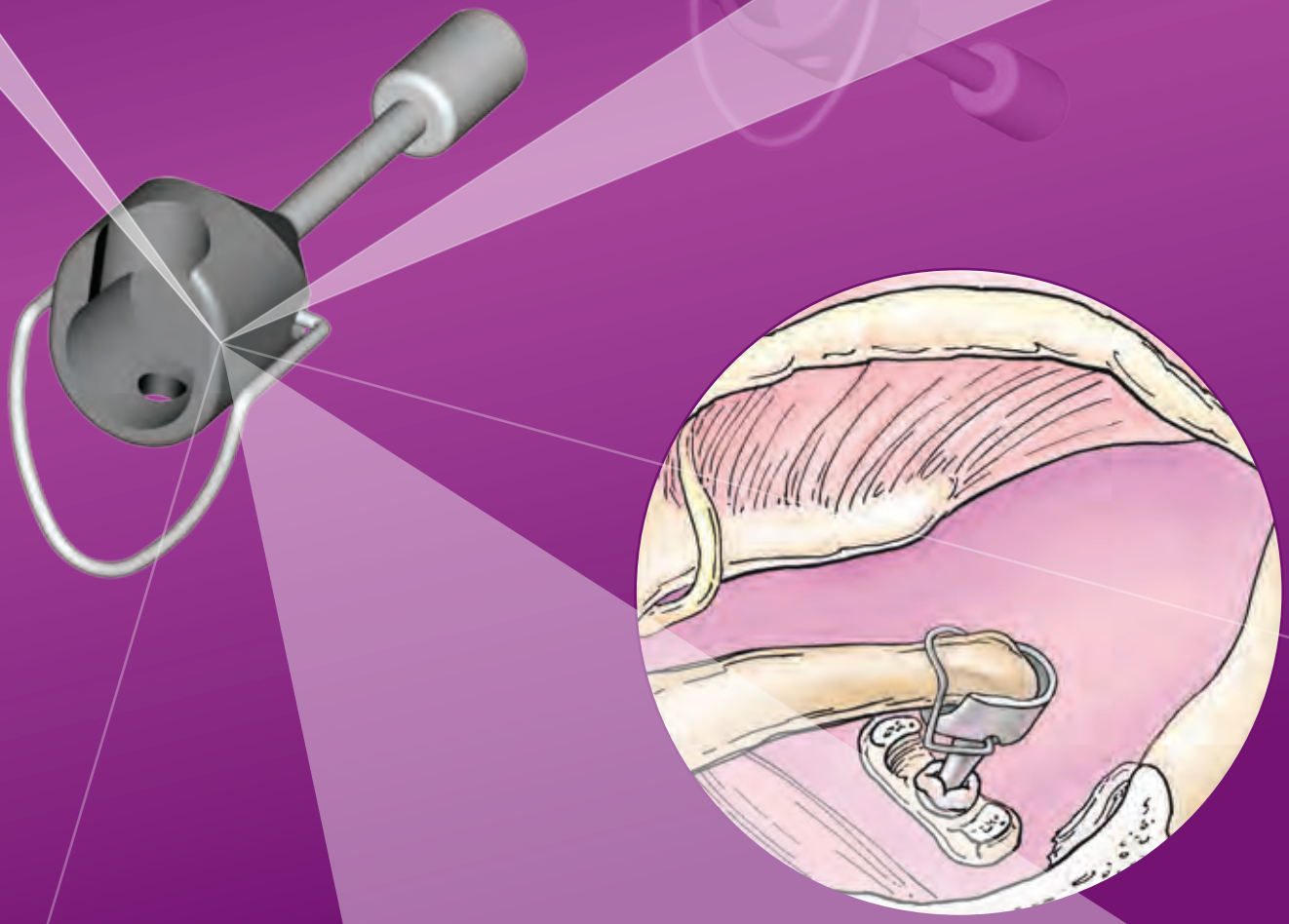
Medtronic

The Roberson Stapes Prosthesis

SURGICAL TECHNIQUE

Lightweight, titanium design for stapes surgery



Developed in conjunction with Joseph Roberson Jr., M.D.

Product Features

Material

- 44 percent lighter than stainless steel designs allows improved high-frequency sound transmission.
- Titanium alleviates ferro-magnetic concerns for MRI compatibility, improves biocompatibility with potential for tissue in-growth, and provides long-term stability and sound conduction.
- Smaller signal void surrounding the titanium material allows for future MR imaging of inner ear structures on the surgical side.

Easier to Use

- Lighter design reduces "top-heavy" characteristics of standard stainless steel bucket prostheses.
- Narrow design and malleable shaft accommodates the narrow oval window niche/ dehiscent facial nerve space.
- Textured bucket surface eliminates glare from microscope light reflection.
- Piston depth gauge allows enhanced depth judgment for stapedotomy insertion.

Improved Stability

- Deep bucket construction allows better seating of the incus in the prosthesis platform.
- Longer incus interface platform reduces risk of incus erosion and increases stability.
- Design reduces the exposure to lenticular-distal incus erosion compared to standard crimped prostheses.
- Improved incus interface and bail wire configuration increase prosthesis stability which reduces the potential for postoperative displacement.
- Enhanced stability with malleable bail wire placement preventing the bail wire from displacement.

Ordering Information

Roberson Stapes Prosthesis

Product	Shaft Diameter	Well Diameter	Length	Quantity
1133061	0.6 mm	0.9 mm	4.00 mm	1
1133065	0.6 mm	0.9 mm	4.25 mm	1
1133062	0.6 mm	0.9 mm	4.50 mm	1
1133063	0.6 mm	1.0 mm	4.00 mm	1
1133066	0.6 mm	1.0 mm	4.25 mm	1
1133064	0.6 mm	1.0 mm	4.50 mm	1

Figure 1

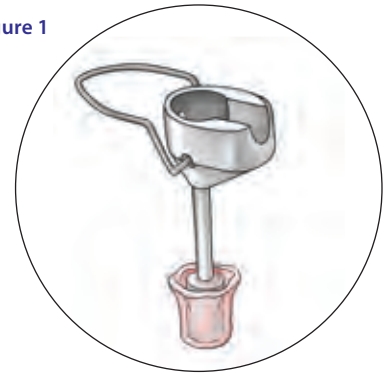


Figure 2

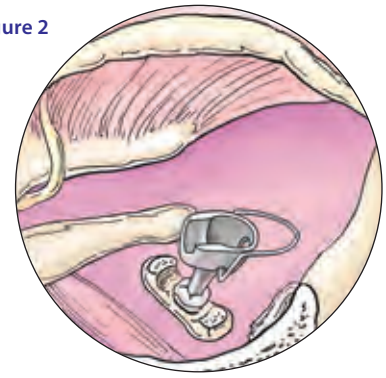
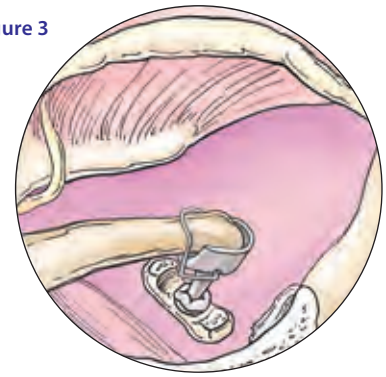


Figure 3



Stapedotomy - Roberson Surgical Technique

Following elevation of the tympano-meatal flap, curetting the posterior bony canal wall, removal of the stapes superstructure and making measurements to select prosthesis length, the prosthesis is prepared as follows:

- An incision is made over a dorsal vein on the back of the hand ipsilateral to the surgical side. Adventitia is removed from the vein, which is slit lengthwise, to be positioned over a pre-drilled 0.8 mm well in a surgical block.
- The vein is trimmed on the block with a 15 blade under the microscope to a circular diameter of approximately 3.0 mm.
- With the vein centered adventitia side down over the 0.8 mm well, the prosthesis is pushed into the well, causing the vein to clad itself to the stapedotomy end of the prosthesis. Approximately half of the 1.0 mm stapedotomy end of the prosthesis should be clad with the vein.
- After drying for a short time, the vein-clad prosthesis is removed from the well of the surgical block (Figure 1) and loaded on self-retaining alligator forceps.

With the prosthesis prepared and loaded, the surgeon performs the stapedotomy using his/her technique of choice resulting in a stapedotomy of 0.9-1.0 mm. With hemostasis present, the following steps are completed:

- With the self-retaining forceps/vein-clad prosthesis in the dominant hand and a #24 suction in the other, take the prosthesis into the middle ear.
- Place the prosthesis on the footplate posterior to or over the stapedotomy with the incus platform positioned toward the lenticular process. Proper grasping position of the prosthesis with the self-retaining forceps greatly facilitates smooth, effective placement. The prosthesis is designed to be grasped either on the bucket edge or by the bail as it is placed into position.
- Change instruments in the dominant hand to a small pick, such as a 30-degree, and continue to use a #24 suction. Gently move the prosthesis over the stapedotomy on top of the vein. Fluid from the vestibule will rehydrate the vein, which fuses with the raw margins of the stapedotomy.
- Move the prosthesis into the stapedotomy and compress it gently into the stapedotomy (Figure 2). The prosthesis should not enter the vestibule more than 0.75 mm. The vein-clad arrangement provides a counterforce to this movement.
- Position the prosthesis with the lenticular process of the incus within the well, leaving the long process of the incus resting in the incus bridge of the prosthesis. This is most readily accomplished by simultaneously advancing and rotating the prosthesis onto the incus as the lenticular process slides along the incus bridge portion of the bucket into the well (counter-clockwise direction in a right ear and clockwise in a left ear). The hole placed in the side of the prosthesis at the well is designed to aid this maneuver.
- Rotate the angled bail wire up and over the incus (Figure 3). Design factors markedly improve stability after placement and the bail may be left as is. If desired, the bail may be secured with vein fragments, or crimped to aid in its stability.

Technical Notes

1. Using a suction or small pick with the non-dominant hand, slight lateral elevation of the incus during prosthesis placement may be accomplished as an aid to the positioning of the prosthesis on the incus.
2. Anterior pressure on the prosthesis will displace too short of a prosthesis from the stapedotomy when the prosthesis is in the final position.
3. Gentle downward pressure on the lateral surface of the incus following prosthesis placement gives the surgeon a sense of normal movement or "ballotment" within the stapedotomy.
4. Lack of an intact lenticular process should prompt the observant surgeon to use another type of prosthesis, as prosthesis stability is dependent on it.
5. Proper length is present as the prosthesis is retained between counterforces: the incus creating a force toward the vestibule and the vein at the stapedotomy creating a force away from the vestibule. Half of the stapedotomy end of the prosthesis should be visible under the microscope outside the stapedotomy, indicating vestibular penetration medial to the footplate of 0.5 mm.
6. Care should be taken to prevent interruption of the surface vasculature of the distal portion of the incus. The prosthesis is manufactured with the most biocompatible substances available, avoiding circumferential crimp or position in order to reduce the chance interruption of these vessels and of future incus erosion.

Nota Bene: The technique description herein and the use of instructions for the related procedures are made available by Medtronic ENT to the healthcare professional to illustrate the author's suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which, in the healthcare professional's judgement, addresses the needs of the individual patient.

For further information, please call Medtronic ENT at 800.874.5797 or 904.296.9600. You may also consult our website at **www.MedtronicENT.com**.

Medtronic ENT
Medtronic USA, Inc.
6743 Southpoint Drive N
Jacksonville, FL 32216
USA
www.MedtronicENT.com
Toll free: (800) 874-5797
Fax: (800) 678-3995

International Telephone Numbers

Adriatic Region 385-1-488-1120
Australia 1-800-668-670
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