Grace Medical

Patient Leaflet for Grace Medical Implants

What kind of device do I have?

Grace Medical offers two categories of implants:

- Ossicular Replacement Prostheses
- Stapes Prostheses

What is the intended use of the Grace Medical Implants?

- Ossicular replacement prostheses are surgically implanted into the middle ear as replacements for the malleus, incus, stapes, or a combination of the three function as a mechanical transformer and transmit sound energy from the tympanic membrane to the oval window of the cochlea.
- Stapes replacement prostheses are surgically implanted into the middle ear as replacements for an immobile stapes due to otosclerosis. Piston or Bucket Handle prostheses function as a mechanical trans-former and transmit sound energy from the incus to the oval window of the cochlea.

How do I keep my device safe?

The patient should be advised of the importance of keeping the operative ear clean and dry until healing is complete and dressings are removed. Specific instructions on how to maintain proper hygiene of the operative ear should be given to the patient by the operating physican.

Other information:

Reference the MRI compatibility details on your Patient Information Card if an MRI is needed in the future.

What is the name and model of the device?

Reference your Patient Information Card for the name and model of the device you have. The general description for each model provided by Grace Medical is below:

Grace Medical Ossicular Replacement Prosthses:

- ALTO DESIGNS: All Grace Medical ALTO's are adjustable length type. Each bump on the shaft is .2mm. The ALTO is delivered in an adjuster which allows the surgeon to adjust the length of the prosthesis within the adjuster body. Whenever the proper length of the prosthesis is determined, the excess shaft protruding from the head is trimmed. The prosthesis can then be easily removed from the adjuster body using forceps. All ALTO's are packaged with total and partial disposable sizers. The sizers are used to determine what length prosthesis to use.
- FIXED LENGTH DESIGNS: Fixed length total & partial prostheses are offered as one integrated piece. Fixed length designs are not adjustable. Fixed length designs are offered with a centered shaft, offset shaft, or optional HA head centered shaft.
- HA DESIGNS: HA prostheses are offered with varying head diameters and shaft length. HA prostheses can be trimmed with a diamond bur.
- OTOSIL DESIGNS: Otosil prostheses are offered with varying HA head diameter's and a fixed length otosil shaft that can be trimmed to length using an ordinary scalpel blade.
- FOOTPLATE SHOE DESIGNS: Variations of footplate shoes can complement all of Grace Medicals total prosthesis line. HA and titanium designs are available.
- HA STRUTS: Total and partial styles are available in varying lengths.
- WEDGE INCUS STRUT (Titanium): The Wedge prostheses are offered in adjustable length configurations. The Wedge is delivered in an adjuster which allows the surgeon to adjust the length of the prosthesis within the adjuster body. Whenever the proper length of the prosthesis is determined, the excess shaft protruding from the head is trimmed. The prosthesis can then be easily removed from the adjuster body using forceps.
- WEHRS: Single and double notch available in trimmable designs. The Wehrs prosthesis line are offered with an HA head and trimmable otosil shaft. The prostheses are packaged in a device with a mm scale so as to make trimming the shaft easy and accurate.
- DUO ALTO: When there is a need to convert a Total prosthesis to a Partial prosthesis, Grace Medical offers the DUO ALTO, packaged with a StapesLink Cup. To use the cup, simply remove protective sleeve from the adjuster body. Adjust the ALTO prosthesis to desired length and trim

excess shaft. Remove the implant and insert the base of the ALTO prosthesis into the cup. A small drop of sterile saline into the cup will provide good surface adhesion to the ALTO prosthesis. Remove ALTO prosthesis and cup together from the adjuster.

- FRISBEE: The Frisbee prosthesis designs are available in varying length and intended to be used for myringopexy cases where the distance between the eardrum and stapes head are minimal. Grace offers a choice of HA or titanium material.
- STRASNICK DESIGNS: The Strasnick is offered as a total and a partial. The head is titanium and the shaft otosil which can be easily trimmed using a scalpel. Each is packaged in a device with a mm scale so as to make trimming the shaft easy and accurate.
- BOJRAB UNIVERSAL PROSTHESIS: The Bojrab universal prosthesis can be used as either a total or a partial. The head is HA and the shaft otosil which can be easily trimmed using an ordinary scalpel.
- KRAUS K-HELIX CROWN: The K-Helix crown is intended to be used between an eroded incus and head of the stapes. The coils can be stretched to lengthen or cut to shorten. Optional - the use of cement may be used to adhere the coils to the incus bone.
- NITINOL ISJ PROSTHESIS: The ISJ prosthesis is intended to be placed over the incudal stapedial joint and onto the head of the stapes. The shape memory region of the prosthesis can be closed using an available heat source. The heat source should be applied to the three heating zones located on top of the incus. Each zone closes two of the six tapered nitinol arms that wrap around the incus. Begin heating at zone one which is located most proximal on the incus and end at zone three.

Grace Medical Stapes Prostheses:

- CRIMP STYLE PISTONS: Crimp style pistons are available either with round wire, flat ribbon, or fluoroplastic loops in diameters of 0.4mm, 0.5mm, 0.6mm, and 0.8mm. Most are offered in fixed length increments of 0.25mm, with some fluoroplastic designs capable of being trimmed to the desired length.
- NON-CRIMP PISTONS: Shape memory nitinol styles are offered in 0.4mm, 0.5mm and 0.6mm diameters, most in fixed length increments of .25mm. The shape memory nitinol pistons are intended to be placed over the incus and closed using an available heat source. The heat source should be applied to the shape memory zone which ranges from the 12 o'clock position of the loop anteriorly (towards the opening of the loop). For proper closure, heat should not be applied to the posterior section of the loop.
- BUCKET HANDLE PROSTHESES: Bucket handle prostheses are available in 0.4mm, 0.6mm and 0.8mm diameters. Most are offered in fixed length increments of .25mm with the option of notched or regular bucket style.
- BARTELS BUCKET HANDLE: The Bartels bucket handle prosthesis features an adjustable diameter bucket to fit varying incus diameters.
- KRAUS K-HELIX PISTON: The K-Helix piston is intended to be used in stapes revision surgery where a previous piston has eroded the incus bone. Optional - the use of cement may be used to adhere the coils to the incus bone.
- MEGERIAN NITINOL SRP: The Megerian SRP Piston is intended to be used in stapes revision procedures where the incus has undergone necrosis. The nitinol arms can be closed using an available heat source. The heat source should be applied to the three heating zones located on top of the incus. Each zone closes two of the six tapered nitinol arms that wrap around the incus. Begin heating at zone one which is located most proximal on the incus and end at zone three.
- ECLIPSE MALLEUS PISTON: The Eclipse Malleus Piston is intended to be used in malleo-vestibulpexy procedures. The nitinol loop can be closed using an available heat source. The heat source should be applied to the shape memory zone which ranges from the 12 o'clock position of the loop moving anteriorly (towards the opening of the loop). For proper closure, heat should not be applied to the posterior section of the loop.

Grace Medical implants are not specific to a target patient population.

There are no special operating instructions for the patients to use the Grace Medical Implants.

What is the intended performance of Grace Medical Implants?

Grace Medical Implants are intended to transmit sound energy from the ear drum to the inner ear which results in improved hearing of the patient.

Are there any side effects?

Serious complications may arise either during or after surgery which may result in irreparable damage to the otologic structures which could lead to a partial or total loss of hearing. Complications which may occur include but are not limited to:

- Sensorineural deafness due to trauma during surgery
- Granuloma and perilymph fistula
- Post-surgery displacement of the implant due to the development of scar tissue
- Recurrence of oval window fixation
- Vertigo
- Incus necrosis
- Round window closure
- Labyrinthitis
- Otitis media

Are there any residual risks of Grace Medical Implants?

As with all medical devices, packaging risks, mechanical risks, cleaning risks, sterilization risks, and biocompatibility risks are all present. All of the previously mentioned risks have all been reduced as far as possible through thorough testing and validation procedures.

Are there warnings about interactions with the device and other equipment?

Please reference your Patient Information Card or www.gracemedical.com for specific MRI information.

Is there Preventative Examination / Monitoring / Maintenance of the device?

Please follow any instructions prescribed by your physician.

What symptoms could indicate the device is malfunctioning?

- Hearing loss
- Dizziness
- Vertigo
- Imbalance

What precautions do I take if any of the symptoms above arise?

Contact your physician.

What is the expected LIfetime of Grace Medical Implants?

15 years.

Is there anything that could shorten or lengthen the device lifetime?

Extrusion of the implant through the ear drum

Are there any precautions to take near the end of the expected device lifetime?

Contact your physician

What other circumstances should the patient contact their physician in relation to the operation of Grace Medical Implants?

Ear pain, drainage, or any sign of infection

What Materials or Substances are included in the devices?

Please reference your Patient Information Card for your devices specific material(s).

Grace Medical Ossicular Replacement Prostheses

- Composite ossicular replacement prostheses can be made of any combination of titanium, platinum, stainless steel, hydroxylapatite (HA), silicone, nitinol (nickel & titanium), otosil (barium sulfate & silicone), fluoroplastic, and medical grade epoxy.
- Non-composite ossicular replacement implants can be made of titanium, hydroxylapatite (HA), nitinol and fluoroplastic.

Grace Medical Stapes Prostheses

- Composite Pistons made of fluoroplastic, titanium, platinum, stainless steel, & nitinol.
- Non-composite Pistons can be made entirely of fluoroplastic, titanium, platinum, stainless steel, & nitinol.
- Bucket Handle prostheses are made of titanium or nitinol.

Are there any manufacturing residuals that could pose a risk to the patient?

No

Any serious incident that occurs in relation to the device should be reported to Grace Medial Inc. and, if the patient lives in Australia, to the Therapeutic Goods Administration.

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