Grace Medical

Patient Leaflet for Grace Medical Tympanostomy Tubes

What kind of device do I have?
Grace Medical ventilation tubes

What is the intended use of the Grace Medical Tympanostomy Tubes?
Tympanostomy tube insertion procedure is to aspirate or ventilate the middle ear subsequent to acute otitis media. The placement of the tube in the tympanic membrane provides the means for drainage of any fluid buildup in the middle ear while creating an avenue for the passage of air to equalize pressure on either side of the tympanic membrane.

How do I keep my device safe?
Once a tube is inserted into the tympanic membrane, care should be taken to avoid environments which could cause contamination of the middle ear.

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 Tympanostomy Tubes is below:

- Grace Medical, Inc's tympanostomy (myringotomy, vent tubes) tubes are produced from a variety of biocompatible materials which include silicone elastomer, polytetrafluoroethylene (also known as PTFE or Fluoroplastic), stainless steel, and Titanium. Various configurations are available to suit the physician's preference for short or long term ventilation.

Grace Medical Tympanostomy Tubes are not specific to a target patient population.

Are there any special operating instructions for the patients to use with the Grace Medical Tympanostomy Tubes?
Once a tube is inserted into the tympanic membrane, care should be taken to avoid environments which could cause contamination of the middle ear.

What is the intended performance of Grace Medical Tympanostomy Tubes?
Grace Medical Tympanostomy Tubes 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?
The following are Possible Adverse Effects of Grace Medical Tympanostomy Tubes:

- The following are Possible Adverse Effects of Grace Medical Tympanostomy Tubes:
- Ventilation tube could become clogged and cease to function properly.
- Early extrusion of the ventilation tube may occur.
- Additional infection from airborne or aqueous contaminants entering through the tube may occur.
- Persistent or permanent perforation may occur which may require a grafting procedure to close.
- Patient allergy or sensitivity to certain materials may result in tissue irritation.
- Longer term tubes, such as T-tubes, and tubes with larger flanges may require a second surgical procedure to remove the tube.

Are there any residual risks of Grace Medical Tympanostomy Tubes?
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?

- Ear Pain
- Drainage
- Other signs of infection

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

Contact your physician.

What is the expected LIfetime of Grace Medical Tympanostomy Tubes?

Up to 3 years

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

Contact your physician

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 Tympanostomy Tubes?

Contact your physician

What Materials or Substances are included in the devices?

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

- Grace Medical Tympanostomy Tubes are made from a variety of biocompatible materials which include silicone elastomer, polytetrafluoroethylene (also known as PTFE or Fluoroplastic), stainless steel, and Titanium.

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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