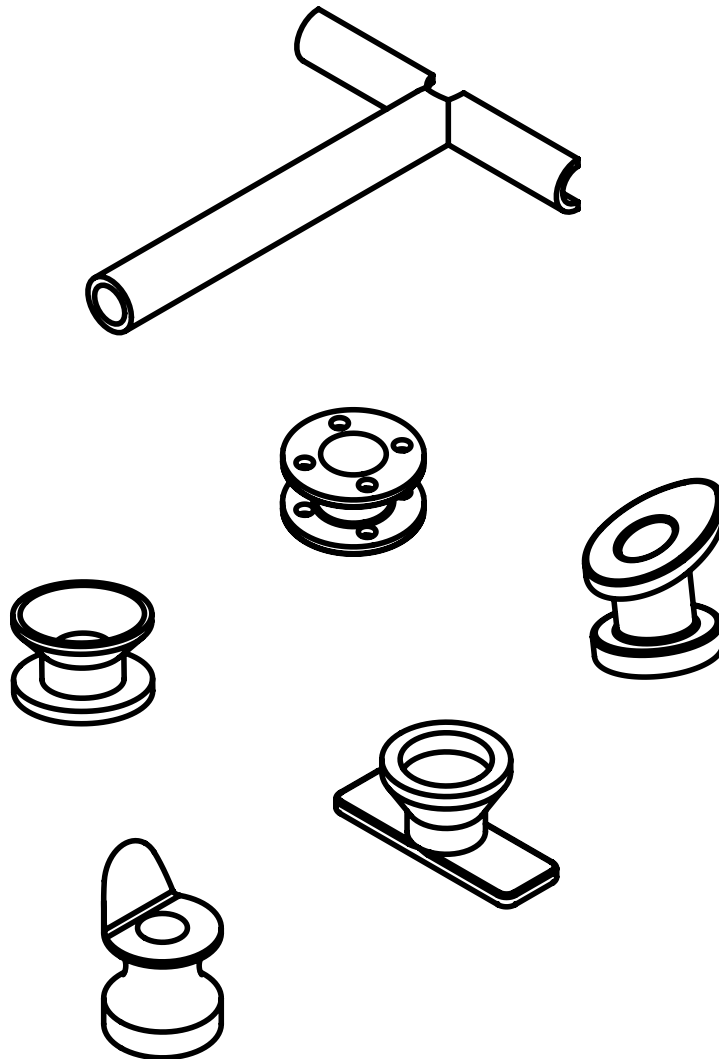


EN **OTOLOGICAL VENTILATION TUBES** PATIENT INFORMATION LEAFLET



OTOLOGICAL VENTILATION TUBES



PRO-000-310, PRO-000-311, PRO-000-410, PRO-000-411, VT-0100-01, VT-0101-01, VT-0102-01, VT-0200-01, VT-0201-01, VT-0202-01, VT-0203-01, VT-0204-01, VT-0300-01, VT-0301-01, VT-0400-01, VT-0401-01, VT-0403-01, VT-0405-01, VT-0406-01, VT-0407-01, VT-0408-01, VT-0409-01, VT-0410-01, VT-0500-01, VT-0501-01, VT-0503-01, VT-0508-01, VT-0602-01, VT-0606-01, VT-0608-01, VT-0700-01, VT-0802-01, VT-0803-01, VT-0901-01, VT-0903-01, VT-1001-01, VT-1002-01, VT-1203-01, VT-1204-01, VT-1231-01, VT-1232-01, VT-1425-01, VT-1602-01

WHAT IS THIS LEAFLET?

This leaflet answers some common questions about Summit Medical, LLC Otolological Ventilation Tubes. It does not contain all the available information. It does not take the place of talking to your surgeon/doctor.

All medical devices and implants have risks and benefits. Your surgeon/clinician weighed the risks of using Otolological Ventilation Tubes against the expected benefits.

Follow your surgeon/clinician's advice even if it differs from what is in this leaflet.

WHAT IS A VENTILATION TUBE?

Otolological Ventilation Tubes, also referred to as vent tubes, are small tubular implants available in a variety of materials, designs, and sizes. They are surgically implanted into the eardrum to create an opening to the middle ear which provides ventilation.

WHO USES VENTILATION TUBES?

A surgeon/clinician may suggest a ventilation tube if they consider ventilating and/or draining fluid from the middle ear or equalizing the air pressure between the outer ear and middle ear to be beneficial. Conditions include:

- Eustachian Tube Dysfunction
- Chronic Otitis media with Effusion that is serous, mucoid, or purulent
- Recurrent Acute Otitis Media that fails to respond to other treatment options

HOW DO VENTILATION TUBES WORK?

A small incision is made to the eardrum, then a vent tube is placed within the incision. Once the vent tube is surgically inserted, it acts as a passageway for air movement between the auditory canal and the middle ear, providing ventilation. The ventilation provided by a vent tube prevents fluid accumulation that can inflame or infect the middle ear and equalizes air pressure between the outer ear and the middle ear.

HOW LONG WILL THE VENTILATION TUBE REMAIN IMPLANTED?

The vent tube will fall out on its own or be removed by a physician within 24 months of insertion. It is recommended that the tubes should be used for no longer than 24 months. A physician may remove the vent tube if they feel it is no longer necessary.

WHAT IS A VENTILATION TUBE MADE OF?

Summit Medical vent tubes are made from silicone, ETFE (Ethylene Tetrafluoroethylene), PTFE (polytetrafluoroethylene), or titanium. Some vent tubes come with a stainless-steel wire attached, which is used to insert the tube.

IS IT SAFE TO HAVE AN MRI SCAN WHILE THE VENTILATION TUBE IS IMPLANTED?

If a patient needs an MRI scan while a vent tube is implanted, refer to the implant card you received from your surgeon/clinician.

Show your patient implant card to your healthcare professional before undergoing an MRI and direct them to the Instructions for Use Manual on summitmedicalusa.com/ifu/documents/20989-vent-tubes-ifu/.



Titanium (denoted TI) vent tubes and Fluoroplastic vent tubes with attached stainless steel wires are MR-conditional. This means your healthcare professional will need to verify the specific conditions are safe for scanning.



Silicone (denoted SI) and Fluoroplastic (denoted FL) vent tubes (without wire) are safe to use with an MRI scan.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS?

- If the ventilation tube becomes contaminated by fluid or airborne pathogens entering the ear, a secondary infection may occur.
- An upper respiratory tract infection may develop.
- The middle ear may become inflamed, or a secondary infection may develop.
- Allergic reactions occur such as hair loss or skin irritations like eczema or rashes may occur if sensitive or allergic to the device materials.
- Earaches.
- Ear discharge.
- Loss of hearing or ringing in the ears (tinnitus)
- Clogging of the ventilation tube.
- The ventilation tube may fall out earlier than expected; medical intervention will be needed for removal if it is late falling out.
- The ventilation tube may get dislodged into the middle ear space.
- The eardrum may be perforated after the ventilation tube is extruded.
- Tympanosclerosis, myringosclerosis, granulomatosis, eardrum atrophy, deep retraction pockets, cholesteatoma, and atelectasis could develop and be diagnosed upon middle ear inspection.

WHEN TO CONTACT A HEALTHCARE PROVIDER?

See a physician if you experience any side effects/risks. If initial symptoms persist, device may require attention from a physician.

HOW TO REPORT ADVERSE EFFECTS?

If you wish to report any adverse effects you believe are a result of Otolological Ventilation Tubes, please report the information to Summit Medical at customerservice@innoviamedical.com.

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the FDA or the competent authority of the Member State in which the user and/or patient is established.

Reports may also be made directly to the appropriate Government Health Authority where you are based, including:

Australia: Therapeutic Goods Administration via the website: <https://www.tga.gov.au/reporting-adverse-events>



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