Otological
Ventilation Tubes

Description

Anthony Products, Inc. Otological Ventilation Tubes are designed for placement through the tympanic membrane to ventilate the middle ear space, and if present, drain accumulations of fluid from the middle ear.

These tubes act as ventilation devices, allowing a free exchange of air between the outer ear and middle ear space, equalizing the air pressure on both sides. When fluid is present, the ventilation tubes can also act as drain devices allowing fluid to drain from the middle ear space to the external auditory canal.

These tubes are available in a variety of designs and materials. The design and material selected by the surgeon is a matter of individual preference. The materials used to manufacturer ventilation tubes are Teflon®, Polyethylene, Silicone, Carbon and Stainless Steel. These materials have a long history of use as implanted medical devices and are well tolerated by body tissue for both long and short term durations. Each lot of material is tested for biocompatibilty by an independent laboratory.

Indications

Where chronic eustachian tube dysfunction fails to respond to conventional therapy.

Contraindications

There are no known contraindications to the use of an otological ventilation tube.

Precautions

Water should be prevented from entering an ear in which a ventilation tube has been inserted. Water could possibly cause contamination, or create a stinging sensation in the middle ear. Measures should be taken to prevent entry of water by providing the patient with ear molds or protective ear devices.

Package

Ventilation tubes are supplied in a sterile package with product identification marked on the primary package label. The primary package consists of a specially designed polypropylene case which holds the tubes.

The secondary package is a sealed pouch made from uncoated Tyvek paper and poly mylar film. These packages are stored and shipped in a small box designed to accommodate and protect the packages.

To Open

1. Remove secondary package from box and peel open package under clean aseptic conditions by accepted sterile technique. Remove inner, primary package.
2. Working in a sterile field, carefully snap open lid of primary package using a sterile instrument.
3. Remove tube from primary package using sterile instrument.

To Reclean

If the product becomes contaminated, wash thoroughly in a hot water and mild, non-oily soap solution. Do not use synthetic detergents or oil based soaps. Rinse thoroughly in hot water followed by distilled water. Place tube in a sterilizable case such as the original package supplied by API and place in a lint free pouch. Sterilize by one of the following methods:

- **High Speed (Flash) Instrument Sterilization**
  Sterilize a minimum of 10 minutes at 270°F, 30psi (132° C, Kg/cm^2).
- **Standard Gravity Sterilization**
  Sterilize a minimum of 30 minutes at 250°F, 15psi (121°C, Kg/cm^2).

Surgical Procedure

Proper surgical procedures and techniques are the responsibility of the medical profession. Each surgeon must evaluate the appropriateness of the procedure based upon current accepted techniques, medical judgement and experience. The following surgical procedures by Joseph R. DiBartolomeo, M.D.* is provided for th e purpose of general information only.

The surgical procedure is usually carried out under local anesthesia. The ear canal is prepped and the largest speculum that can be accommodated by the ear canal is inserted. Too large a speculum my result in bleeding which will interfere with the surgeon's view.

A conventional myringotomy is preformed using either a flat or slit incision. Middle ear fluid, if present, is removed using suction techniques. This fluid is diluted by saline, the middle ear is again suctioned clear of its fluid. The length of the slit incision should be kept to a minimum.

Tube Insertion

Ventilation tubes may be inserted using either a conventional tube inserter or small alligator type forceps. Grommet-type silicone tubes may be inserted using forceps, squeezing together allows the tube to be inserted through an incision smaller than the outside diameter of the inner flange. On releasing the tube, the outer flange springs into place lateral to the tympanic membrane. Tabs provided on certain tube styles

can also act as an aid in insertion and positioning of the tube in the tympanic membrane.

Current literature suggests that the ventilation tube be left in place until the eusthachin tube regains its normal function. Depending on the etiology, the eustachian tube may normalize within a few days or remain indefinitely impaired. If the condition has normalized, the tube may be removed by the surgeon, or left until self-extruded.

If extruded before the eustachian tube becomes patent, a new ventilation tube may be reinserted. Based on physician experience and training, the ear should be examined periodically and the condition reappraised as to removal or reinsertion of the tube.

Tube Removal

It is seldom necessary to remove a tube. Should a postoperative infection or prolonged drainage occur, a culture of the drainage and sensitivity of the organism should be obtained. If conservative therapy is not effective in eradicating the infections of eliminating the drainage, removal should be considered. Grommet-type tubes can be removed by grasping the outer flange with small forceps and pulling the tube straight out. Tubes supplied with intergral removal tabs assist grasping and removal of the tube. Attachment wires, provided on certain tube designs lie in the external auditory canal and provide an excellent removal ad.

*** Joseph R. DiBartoloneo, M.D. 2429 Castillo Street, Santa Barbara, CA 93105**

Caution

United States Federal Law restricts this device to sale by or on the order of a licensed physician.

Warranty

API warrants that reasonable care was used in the manufacture of this product, and will replace at no charge any product that API feels was defective at time of shipment.

anthony products, inc.

7740 Records Street
Indianapolis, IN 46226
800-428-1610 • Fax (317) 543-3289
www.anthonyproducts.com

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