

Descrizione Del Dispositivo

Esistono molti tipi di tubi timpanostomici, disponibili in una varietà di materiali diversi, come la fluoroplastica, il silicone, l'acciaio inossidabile, il titanio e il polietilene. La disponibilità di una così vasta gamma di modelli e di materiali fornisce ampia flessibilità per quanto riguarda i metodi di incisione per miringotomia, l'inserimento dei tubi e il quadrante di posizionamento del tubo e da fattori quali la risposta fisiologica del paziente e la rimozione chirurgica.

I tubi timpanostomici con rivestimento in Hydromer™ sono realizzati in titanio. Il rivestimento idrofilo in Hydromer è concepito per ridurre l'incidenza dell'occlusione del lume del tubo stesso, nonché per facilitarne lo sturamento in caso di necessità.

Uso Previsto

Lo scopo dell'inserimento dei tubi timpanostomici nella membrana timpanica è di ventilare l'orocchio medio a seguito di episodi di otite media. La collocazione del tubo nella membrana timpanica consente di eliminare il fluido accumulatosi nell'orecchio medio e crea nel contempo un canale per il passaggio dell'aria atto ad equilibrare la pressione su entrambi i lati del timpano.

Indicazioni

- A. Otite media cronica con suppurazione (sierosa, mucosa o purulenta).
- B. Episodi ricorrenti di otite media acuta nonostante il trattamento medico convenzionale.
- C. Anamnesi di alta pressione negativa nell'orecchio medio associata a uno o più dei seguenti sintomi:
  1. perdita sintomatica dell'udito di conduzione;
  2. otalgia persistente o ricorrente;
  3. vertigini e/o tinnito ricorrenti.
- D. Tasca di retrazione della membrana timpanica.

Controindicazioni

Le controindicazioni possono essere relative o assolute, e vanno ponderate attentamente in rapporto al quadro clinico globale del paziente.  
 A. Casi in cui il trattamento farmacologico risulti efficace.  
 B. Casi in cui la miringotomia (incisione chirurgica della membrana timpanica) o la timpanocentesi (ago aspirato dell'orecchio medio attraverso la membrana timpanica), a parere del chirurgo, siano in grado di alleviare la condizione particolare del paziente.

Precazioni

Una volta che il tubo timpanostomico è stato inserito nella membrana timpanica, bisogna prendere le necessarie precauzioni al fine di evitare l'entrata di acqua nell'orecchio che potrebbe causare la contaminazione dell'orecchio medio.

Possibili Effetti Collaterali

- I potenziali effetti collaterali noti includono i seguenti.
1. Il tubo timpanostomico può occludersi e di conseguenza cessare di funzionare correttamente.
  2. si può verificare l'estrusione precoce del tubo.
  3. Possono insorgere ulteriori infezioni dovute ad agenti contaminanti presenti nell'aria o nell'acqua infiltrarsi nell'orecchio medio attraverso il tubo.
  4. Possono verificarsi perforazioni persistenti o permanenti, chi potrebbero richiedere la chiusura mediante innesto.
  5. Una reazione allergica o la sensibilità del paziente a determinati materiali possono causare l'irritazione dei tessuti.

Attivazione del Rivestimento in Hydromer













Per attivare il rivestimento in Hydromer del lume e delle flange, i tubi timpanostomici con rivestimento in Hydromer possono essere immersi in acqua sterile o in soluzione fisiologica sterile prima dell'inserimento. NON immergere i tubi timpanostomici in alcool, soluzioni a base di alcool o solventi di qualsiasi natura.

Confezionamento

I tubi timpanostomici della Smith & Nephew vengono forniti in condizioni sterili. ATTENZIONE: prima dell'apertura, esaminare attentamente le confezioni per rilevare l'eventuale presenza di fori o l'evidenza di contaminazione garantisca la sterilità del prodotto.

Esclusivamente monouso. Non riutilizzare.

\*Hydromer è un marchio di fabbrica della Hydromer, Inc.

	Manufacturer: Indicates the medical device manufacturer, as defined in EU directives 90/385/EEC, 93/42/EEC, and 98/79/EC.
	Authorized representatives in the European Community. This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.
	Use by date: Indicates the date after which the medical device is not to be used.
	Batch code: Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog Number: Indicates the manufacturer's catalog number so that the medical device can be identified.
	Sterilized using ethylene oxide: Indicates a medical device that has been sterilized using ethylene oxide.
	Do not re-sterilize: Indicates a medical device that is not to be re-sterilized.
	Do not use if package is damaged: Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not re-use: Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Consult instructions for use: Indicates the need for the user to consult instructions for use.
	Caution: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Medical Device Indicated

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General handling

Any contamination of the product must be avoided. The product must be kept in its sealed protective packaging. Examine packaging for damage before opening since damaged packaging may impair the sterility of the product. Do not open the protective packaging until just before implantation of the product. In addition, the product must be visually checked for damage. This product is intended for single use only. Once the seal of the sterile packaging has been torn open its contents will not be taken back by the manufacturer.

Packaging and sterility

The packaging of the product consists of Sterile packaging (primary packaging). The packaging meets the provisions of the European Standards. Intact packaging protects the product from environmental influences and ensures sterile storage.

Handling of sterile packaging

Please ensure that the relevant aseptic instructions are complied with when removing the product from the packaging.

Re-sterilization

Re-sterilization after expiry of the use-by date as well as re-sterilization of unsterile uncontaminated products is prohibited. Manufacturer and distributor will assume no liability for products that have been re-sterilized by the user.

Storage

Store in a dry environment at room temperature. After expiry of the use-by date the product may no longer be used.

Warranty

Invotec International, Inc. warrants that the product is free from defects in material and workmanship. Invotec will replace or provide a refund for any product found to be defective so long as the product is returned according to the Returned Goods instructions in the Sales Policy. Invotec shall not be liable for any consequential loss, damage or expense directly or indirectly arising from the use of, or inability to use, this product.

THE FOREGOING WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, HOWEVER ARISING, INCLUDING MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AGAINST INFRINGEMENT OR OTHERWISE.

Invotec International neither assumes, nor authorizes any person to assume for it, any other additional liability or responsibility with respect to this product.

Product description

Ventilation tube for ventilation of the middle ear. The tube should be implanted via a small incision in the eardrum (myringotomy). The tube has a central lumen of varying diameter. The actual size to used should be decided by the surgeon based on the respective indication. The tube facilitates the removal of secretions (middle ear effusion) and relieving the auditory tube (Eustachian tube).

Indications

- Tympanum (Middle Ear) effusion (secretory otitis media, glue ear)
- Chronic Eustachian tube related middle ear ventilation problems

Contraindications

Allergic reactions to the material used.

Side-Effects

1. In rare cases otitis media is possible after myringotomy; in such cases the patient can be treated with either a topical or systemic antibiotic.
2. Insertion of an otologic ventilation tube very rarely results in a potentially permanent eardrum perforation in which in turn can be closed through tympanoplastic surgery, if necessary.
3. The tube may also fall into the middle ear. In this case the tube can be surgically removed.
4. Usually the tube will migrate spontaneously after a prolonged period, when it simply falls out onto the outer ear. If this does not occur then the tube can be surgically removed, though this is not normally required.
5. If strong viscid secretions are produced (secretory otitis media) the tube may become clogged. If it is not possible to free the tube from these clogging secretions then the clogged tube can be removed and replaced by a new tube.
6. Premature migration of the ventilation tube may occur. If this occurs, new otologic ventilation tube may have to be inserted after the reasons for the early migration have been identified.
7. There is the possibility of hyalinization and subsequent calcification (myringosclerosis / tympanosclerosis of the ear drum).
8. Improper insertion may cause subluxation of the ossicular chain.
9. The existence of anatomical anomalies may lead to injury injury of other middle ear structures including the facial nerve, tensor tympani or stapedius muscles, or temporal bone related vital structures such as the middle ear, carotid artery or jugular vein.

Precautions

While the tube remains inserted in the eardrum the patient need be advised that water or contaminated fluid can flow through the tube into the middle ear, since this may result in a secondary infection. This can occur as a result of bathing, washing the hair, swimming, etc. To avoid such infection the use of tight fitting ear plugs is recommended. The patient needs to be aware that significant pressure variations while the tube remains in situ, e.g. from deep water diving, may result in injured ear and possibly hearing injury. All ventilation tubes from Invotec International are MRI compatible to 4.5T.

