

OTOLOGICAL VENTILATION TUBES

Tympanostomy Tubes

NeoZoline™

INSTRUCTIONS FOR USE

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Safety Information

- Ensure IFU is read before use.
- Application only by trained medical professionals.
- Do not disassemble or modify the product.
- For variants available please refer to page 5.

Cautions

- Do not re-use Ventilation Tubes.
- Do not re-sterilize the Ventilation Tube if the case is opened.
- Complications may include cholesteatoma and granulation tissue.
- Do not implant the Ventilation Tube if the pouch which maintains sterility has been previously opened or damaged.
- After insertion of a Ventilation Tube fluid should be prevented from entering the ear to avoid contamination and infection.
- It is often difficult to determine if complications occurring after insertion of Otological Ventilation Tubes are due to the Ventilation Tube or are due to sequelae of the intrinsic disease. Occasionally Otological Ventilation Tubes may contribute to a number of post-operative complications including secondary infection accompanied by otorrhea through the tube, permanent perforations, dislocation of the tube into the middle ear cavity, tympanosclerosis, and localised or diffuse membrane atrophy.
- US Federal law restricts this device to sale and use by or on the order of a physician. Ventilation Tubes are only to be inserted by qualified personnel.

Warning

Gloves should not be dusted with powder, powderless gloves are recommended as the Ventilation Tubes may have an affinity for particulate matter. Under no circumstances should the Ventilation Tube make contact with powdered gloves, as the glove powder might provoke a foreign body reaction with granulation formation.

Intended Purpose

An Otological Ventilation Tube or Tympanostomy Tube (Grommet) is a device that is intended to be implanted into the tympanic membrane for ventilation and/or drainage of the middle ear. NeoZoline™ Ventilation Tubes are single-use and are sterilized by ethylene oxide.

Indications

- Chronic or recurrent otitis media with persistent effusion (OME).
- Recurrent acute otitis media.
- Acute otitis media with complications.
- Eustachian tube dysfunction resulting in one or more of the following: significant and symptomatic hearing loss, otalgia, vertigo, and tinnitus.
- Hearing loss resulting from bilateral chronic middle ear effusion.

Contraindications

- Patients where drug treatment will suffice.
- Where in the surgeon's opinion surgical incision (myringotomy) of the tympanic membrane or aspiration of middle ear through the tympanic membrane without insertion of Ventilation Tubes will be sufficient.
- Ongoing middle ear infection.
- When adverse effects may be expected.

Risks/Side Effects

- Early extrusion or expulsion of the Ventilation Tube.
- Airborne or water contaminants entering through the Ventilation Tube may result in further infection.
- Ventilation Tube may become clogged or blocked and cease to function.
- Certain Ventilation Tube materials may cause increased tissue irritation due to increased patient allergy or sensitivity.
- Grafting procedures may be required with permanent and/or consistent perforations of the tympanic membrane.

Patient Target Group

The device is intended for use in patients undergoing a tympanostomy procedure, in cases in which they do not meet the criteria outlined in the contra-indications.

Training/Qualifications

- The device should only be used by medical professionals trained in the procedure.
- Read the IFU before use.

Intended User

The device is only intended for use by trained medical professionals.

Info to be supplied to the patient

After insertion of a Ventilation Tube fluid should be prevented from entering the ear to avoid contamination and infection.

Warranty

Adept Medical Ltd shall not be liable for any injury or damage suffered by a patient as a result of:

- Any method of implantation or technique used by the surgeon to implant or use NeoZoline™ products.
- Any selection, prescription or use of NeoZoline™ products for any patient or condition.

Adept Medical Ltd makes no expressed or implied warranties in connection with the sale of its products and specifically disclaims liability upon use or misuse.

Shelf Life

Refer to the product label for expiry.

Instructions for Insertion

- The pouch containing the Ventilation Tube case should be opened aseptically.
- Because the Ventilation Tube packaging materials are plastic, the Ventilation Tube may pick up an electrostatic charge. Upon opening the package, the Ventilation Tube should be carefully examined to ensure that particles have not been attracted to it.
- Using a suitable inserter instrument, insert the Ventilation Tube into the tympanic membrane in the appropriate location.
- Ensure the orientation of the Ventilation Tube is correct as outlined in the specification table.

Aftercare/Removal

Follow-ups as indicated by the treating physician.

Disposal

Used Ventilation Tubes are a biohazard, please ensure these are disposed according to biohazard waste procedures at your clinic and in accordance with local regulations.

Serious Incidents

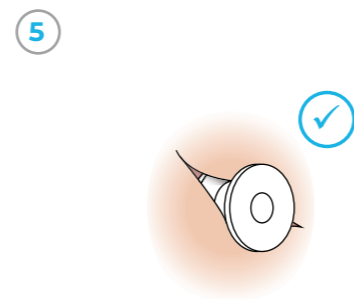
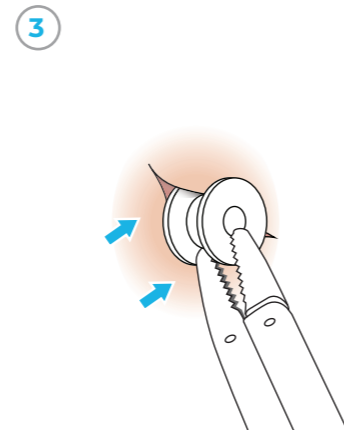
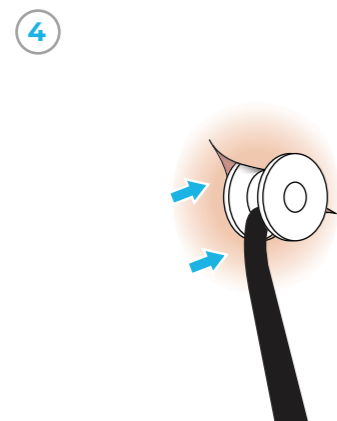
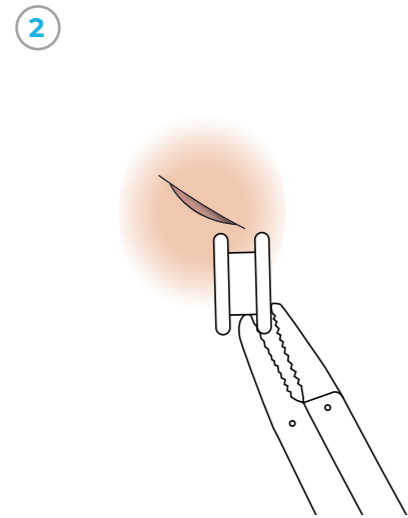
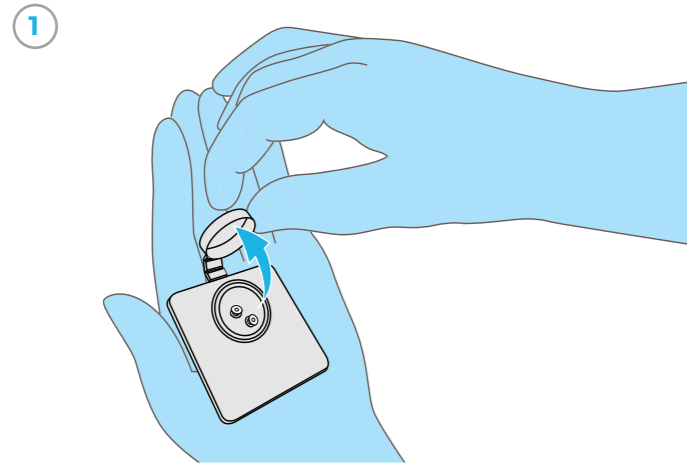
Any serious incident which occurs in relation to the device should be reported immediately to:

- The Competent Authority of the applicable Member State.
- The Manufacturer using the Serious Incident Reporting Form found on the Adept Medical Website.

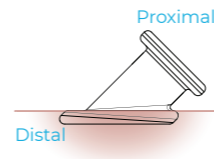
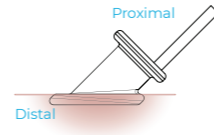
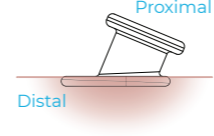
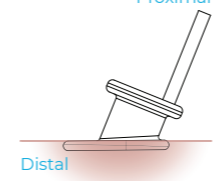
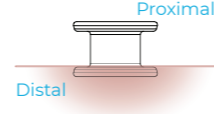
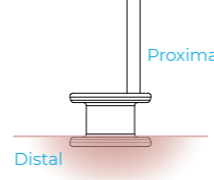
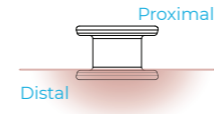


Serious Incident Reporting Form:
qrco.de/seriousincform

Tube Insertion Guide



Product Specifications

	Product	Product Code	Material	Internal Diameter	Outer Flange Diameter	Length
	Armstrong (1.14mm)	NZ3121	Fluoroplastic	1.14mm	2.5mm	3.79mm
	Armstrong (1.14mm) with tail	NZ3122	Fluoroplastic	1.14mm	2.5mm	6.79mm
	Modified Armstrong (1.14mm)	NZ3123	Fluoroplastic	1.14mm	2.5mm	2.59mm
	Modified Armstrong (1.14mm) with tail	NZ3124	Fluoroplastic	1.14mm	2.5mm	5.59mm
	Collar Button (1.14mm)	NZ3211	Fluoroplastic	1.14mm	2.6mm	1.71mm
	Collar Button (1.14mm) with tail	NZ3212	Fluoroplastic	1.14mm	2.6mm	4.81mm
	Collar Button (1.27mm)	NZ3111	Fluoroplastic	1.27mm	3mm	2.22mm

	Product	Product Code	Material	Internal Diameter	Outer Flange Diameter	Length
	Collar Button (1.27mm) with tail	NZ3112	Fluoroplastic	1.27mm	3mm	5.22mm
	Shepard (1.14mm)	NZ3213	Fluoroplastic	1.14mm	2.4mm	2.2mm
	Shepard (1.14mm) with tail	NZ3214	Fluoroplastic	1.14mm	2.4mm	4.9mm
	Shah Mini (0.76mm)	NZ3223	Fluoroplastic	0.76mm	1.54mm	1.50mm
	Shah Mini with tail (0.76mm)	NZ3226	Fluoroplastic	0.76mm	1.54mm	4.50mm
	Shah (1.14mm)	NZ3224	Fluoroplastic	1.14mm	2.34mm	2.41mm
	Shah with tail (1.14mm)	NZ3227	Fluoroplastic	1.14mm	2.34mm	5.41mm

	Product	Product Code	Material	Internal Diameter	Outer Flange Diameter	Length
	T-Tube Silicone (6mm) length	NZ3306	Silicone	1.3mm	1.7mm	6mm
	T-Tube Silicone (9mm) length	NZ3309	Silicone	1.3mm	1.7mm	9mm
	T-Tube Silicone (12mm) length	NZ3312	Silicone	1.3mm	1.7mm	12mm
	Straight Tube (1.14mm) white	NZ3151	Fluoroplastic	1.14mm	2.7mm	7mm
	Bevel Bobbin (1.14mm) white	NZ3141	Fluoroplastic	1.14mm	2.8mm	1.7mm
	Donaldson (1.1mm) Blue	NZ3321Blue	Silicone	1.1mm	2.3mm	2.20mm

| Glossary of Symbols



Manufacturer



Date of Manufacture



Authorised representative in the European Community



Sterilised using ethylene oxide



Medical Device



Batch code



Do not re-use



Do not re-sterilise



Keep dry



Use-by date



Do not use if package is damaged



Keep away from heat



Caution – consult IFU prior to use

| Terminology

- **Distal:** from the surgeons' view further away.
- **Proximal:** from the surgeons' view closer.



Medical
Supporting you



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