

OTOLOGICAL VENTILATION TUBES

Tympanostomy Tubes

NeoZoline™

PATIENT INFORMATION

Issue Date: 11/2023

Revision: C



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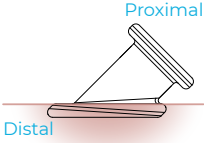
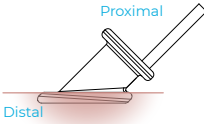
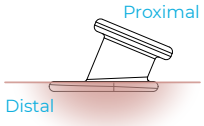
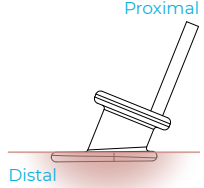
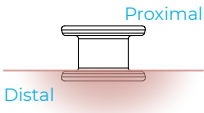
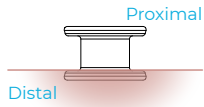
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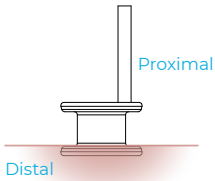
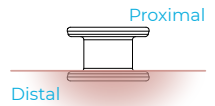
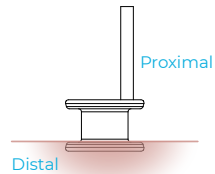
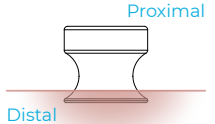
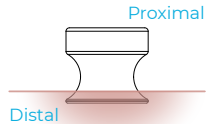
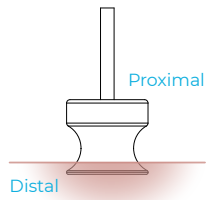
Serious Incidents

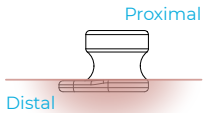
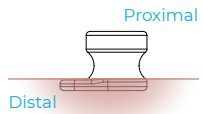
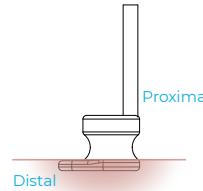
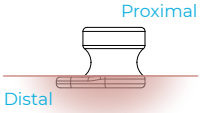
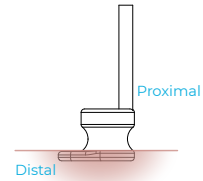
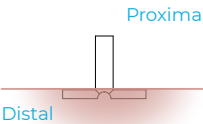
Reporting Serious Incidents to Manufacturer

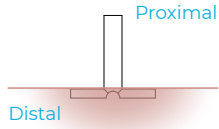
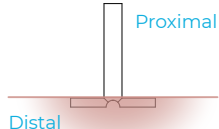
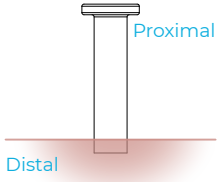
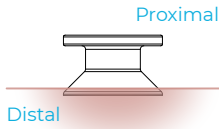
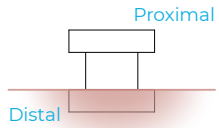
Information

Device Overview

	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) blue	NZ3211Blue	Fluoroplastic	1.14mm	2.6mm	1.71mm

	Product	Product Code	Material	Internal Diameter	Outer Flange Diameter	Length
	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
	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) blue	NZ3213Blue	Fluoroplastic	1.14mm	2.4mm	2.2mm
	Shepard (1.14mm) with tail	NZ3214	Fluoroplastic	1.14mm	2.4mm	4.9mm

	Product	Product Code	Material	Internal Diameter	Outer Flange Diameter	Length
	Shah Mini (0.76mm)	NZ3223	Fluoroplastic	0.76mm	1.54mm	1.50mm
	Shah Mini blue (0.76mm)	NZ3223Blue	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
	T-Tube Silicone (6mm) length	NZ3306	Silicone	1.3mm	1.7mm	6mm

	Product	Product Code	Material	Internal Diameter	Outer Flange Diameter	Length
	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

Intended Purpose

Otological Ventilation Tubes (also commonly known as grommets or tympanostomy tubes) are small plastic tubes designed to be placed in the ear drum and are used to treat infection by allowing fresh air to pass into the middle ear, reducing fluid build-up.

Patient Target Group

The device is intended for use in patients undergoing a tympanostomy procedure.

Warnings and Cautions

Side Effects & Risks

- The ventilation tube falls out early.
- Further infection from contaminants entering through the ventilation tube.
- Ventilation tube may become clogged or blocked, affecting its functionality.
- Certain ventilation tube materials may cause irritation due to patient allergy or sensitivity.
- Grafting procedures may be required, causing permanent damage to the ear drum.

Monitoring and Maintenance

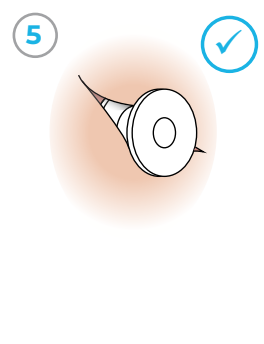
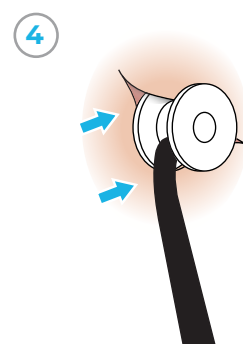
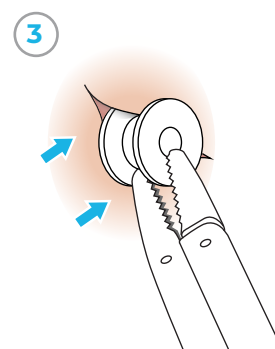
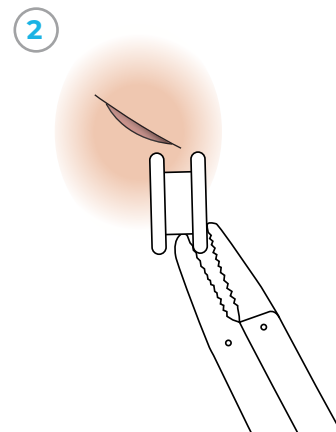
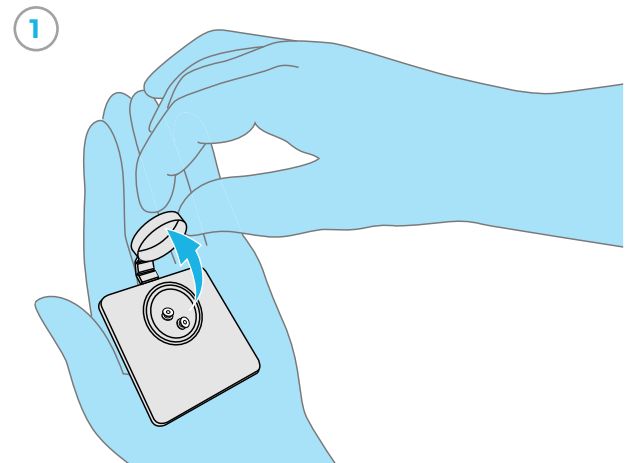
It is important to attend any outpatient appointments that are requested, as indicated by the clinician. It is important to check the ear is healthy at this stage, and that the ears return to normal when the tubes fall out with no further treatment needed.

Symptom Management

Ventilation tubes can become blocked by wax, blood, discharge, or foreign bodies which will restrict airflow. Blocked ventilation tubes can cause persistent drainage from the ear, pain, infection, hearing difficulties and a feeling of fullness in the ear.

If you believe you are experiencing symptoms of infection or device malfunction, contact your clinician/health professional to discuss further treatment.

Grommet Insertion



Post-operative Information

Precautions

It is important to follow post-operative care instructions provided by your clinician.

Ensure contaminated or soapy water does not encounter the treated ears, as this could cause a risk of infection. Swimming is not recommended until one-month post-surgery.

For any sign of infection or adverse symptoms, contact your clinician.

Expected Device Lifetime

Usually, a ventilation tube will stay in place for six to twelve months and will naturally fall out on its own. However, this time can vary due to many factors, including the type of ventilation tube used. In some cases, the ventilation tube will need to be removed by the clinician.

Factors Affecting Device Lifetime

In some cases, the ventilation tube will fall out early. In this instance, further treatment may be required.

Precautions to Be Taken Near End of Expected Device Lifetime

Monitor symptoms to ensure the device is serving its intended purpose, and no symptoms of device malfunction are present.

Necessary Follow Up

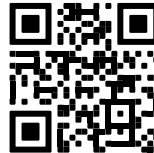
It is important to attend any outpatient appointments that are requested, as indicated by the clinician to ensure the device is serving its intended purpose.

Serious Incidents

Reporting Serious Incidents to Manufacturer

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

- The Competent Authority of the applicable Member State.
- Any occurrence of serious incidents in Australia should also be reported to TGA, via <https://www.tga.gov.au/>.
- The Manufacturer using the Serious Incident Reporting Form found on the Adept Medical Website.



Serious Incident Reporting Form:
qrco.de/seriousincform



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Supporting you



Manufacturer

Adept Medical Ltd
2-6 McDonald St,
Morningside
Auckland 1025, New Zealand

