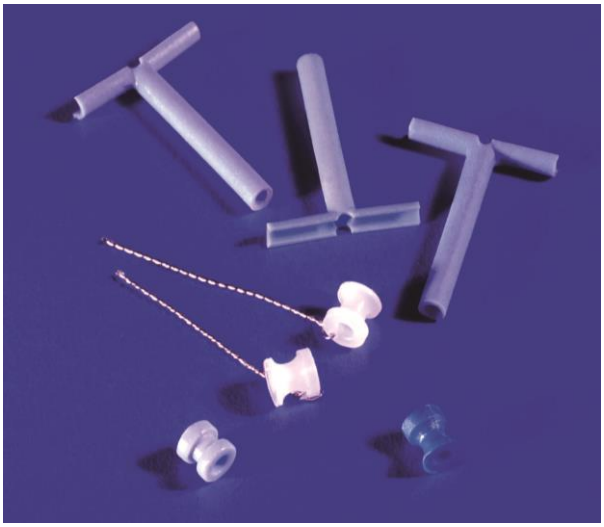
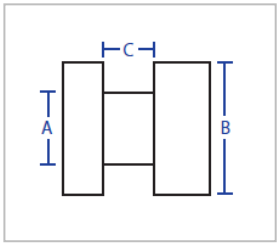
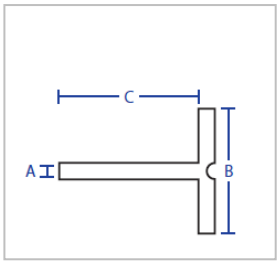
NETWORK ENT PRODUCTS

Ventilation Tubes Specification Sheet







Product Overview

The NETWORK ENT® Ventilation Tubes are designed for easy placement through the tympanic membrane to ventilate the middle ear space, and, if present, drain accumulations of fluid from the middle ear.

- Constructed form 100% medical grade biocompatible silicone/ Fluoroplastic
- Available in a wide range of designs, sizes and materials to best meet surgeon's preference
- Supplied sterile, single use only, declared 5 year shelf life
- Manufactured in the UK

T-Tube Size Options

Product	Material	Dimensions	Pack Size	Product Code
T-Tube (12mm)	Silicone	1.1 X 9.0 X 12.0 mm	10	74-100
T-Tube (9mm)	Silicone	1.1 X 9.0 X 9.0 mm	10	74-101
T-Tube (6mm)	Silicone	1.1 X 9.0 X 6.0 mm	10	74-102

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Paparella Tube Size Options

Product	Material	Dimensions	Pack Size	Product Code
Paparella Tube II	Silicone	1.5 x 4.5 x 1.1 mm	10	74-103
Papareallа Tube I	Silicone	1.0 x 2.1 x 1.1 mm	10	74-104

Shepard Grommets Size Options

Product	Material	Dimensions	Pack Size	Product Code
Sheppard Grommet with wire	Fluoroplastic	1.1 x 2.3 x 1.5 mm	10	74-106
Sheppard Grommet with wire	Fluoroplastic	1.1 x 2.3 x 1.5 mm	2 per pouch/ 20 pouches	74-107
Shepperd Grommet	White ETFE Fluoroplastic	1.14mm Lumen	Box of 10	VT-0202-01

Donaldson Size Options

Product	Material	Dimensions	Pack Size	Product Code
Donaldson	Silicone	1.1 x 2.4 x 0.8 mm	10	74-108
Donaldson	Fluoroplastic	1.1 x 2.3 x 0.8 mm	10	74-120

Shah Size Options

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Product	Material	Dimensions	Pack Size	Product Code
Shah Grommet with Tab	White PTFE Fluoroplastic	1.14mm Lumen	Box of 10	VT-0802-01

Armstrong Size Options

Product	Material	Dimensions	Pack Size	Product Code
Armstrong	Fluoroplastic	1.1 x 2.6 x 4.0 mm	10	74-115

Reuter Bobbin Size Options

Product	Material	Dimensions	Pack Size	Product Code
Reuter Bobbin	Fluoroplastic	1.0 x 2.5 x 0.9 mm	10	74-121

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Material Specification

Product Component	Specification
Ventilation tube	As detailed above.
Pouch Packaging	Tyvek/Film
Outer Box/Carton Packaging	500 Micron White Boxboard

Intended Use

Ventilation tubes are indicated for the treatment of chronic otitis media with effusion, recurrent acute otitis media, tympanic membrane atelectasis and complications of acute otitis media in children. The tubes which are surgically inserted through an incision made in the tympanic membrane, act as ventilation devices allowing a free exchange of air between the outer ear and the middle ear space equalizing the pressure on both sides of the membrane. When fluid is presenting in the middle ear, the ventilation tube can also act as a drain, allowing fluid to drain from the middle ear space to the external auditory canal.

The shape and design of the tube is important in determining its function. Large inner flanges increase the duration of the middle ear ventilation. Tubes with a large lumen and short length are less likely to occlude but may allow easier passage of water. Short term tubes, with an average duration of ventilation of 10 months are shaped like grommets, are easy to insert and have a low rate of obstruction and permanent perforation. Long term ventilation tubes, with an average duration of ventilation of 30 months, have the opposite characteristics, and are typically T-shaped.

Sterilisation

Products are sterilised by Ethylene Oxide (EO) according to a validated cycle and the requirements of BS EN ISO 11135-1(current).

Instructions for Use

The instructions for use and suggested surgical technique are supplied in the form of a multi-lingual leaflet with instructions given in diagram form where appropriate. The international symbols used on the packaging are explained in each language. A leaflet is supplied with each product.

Conformity to the European Directives

The Network range of Ventilation tubes are intended for implantation and continuous use for more than 30 days. Therefore the classification is Class IIb (rule 8, Annex IX, 93/42/EEC Medical Device Directive).

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