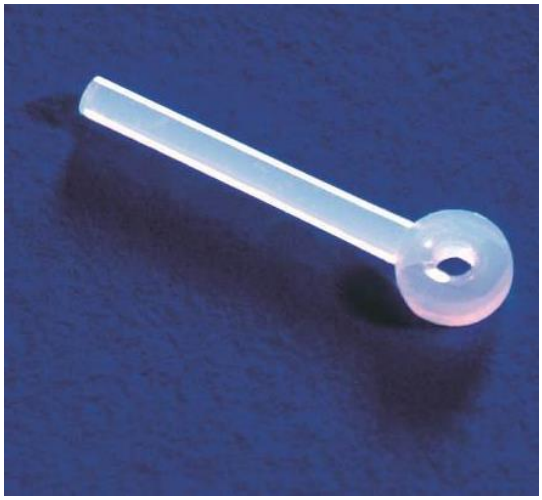
NETWORK ENT PRODUCTS

Stapes Piston Range Specification Sheet



Product Overview

The NETWORK ENT® Stapes Piston range has been specifically designed to restore hearing after the removal of the ossicular structures of the middle ear. The range includes a variety of sizes, and each Stapes Piston can be trimmed to length.

- Constructed from biocompatible 100% medical grade PTFE (Fluoroplastic)
- Suitable for partial or total replacements depending on port/torp surgery requirements
- Supplied sterile, single use only, one per box, declared 5 year shelf life
- Manufactured in the UK

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Stapes Piston Size Options

Shaft Diameter	Loop Diameter	Length	Product Code
0.4 mm	0.6 mm	6.0 mm	71-400
0.4 mm	0.6 mm	5.0 mm	71-401
0.4 mm	0.6 mm	4.5 mm	71-402
0.4 mm	0.6 mm	4.0 mm	71-403
0.4 mm	0.6 mm	3.5 mm	71-404
0.6 mm	0.6 mm	6.0 mm	71-405
0.6 mm	0.6 mm	5.0 mm	71-406
0.6 mm	0.6 mm	4.5 mm	71-407
0.6 mm	0.6 mm	4.0 mm	71-408
0.6 mm	0.6 mm	3.5 mm	71-409
0.8 mm	0.6 mm	6.0 mm	71-410
0.8 mm	0.6 mm	5.0 mm	71-411
0.8 mm	0.6 mm	4.5 mm	71-412
0.8 mm	0.6 mm	4.0 mm	71-413
0.8 mm	0.6 mm	3.5 mm	71-414

Material Specification

Product Component	Specification
Piston	100% medical grade PTFE (Fluoroplastic)
Pouch Packaging	Tyvek/Film
Outer Box/Carton Packaging	500 Micron White Boxboard

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Intended Use

Stapes pistons are fitted into the middle ear cavity following stapedectomy or tympanoplasty procedures. The usual reason for the replacement of the ossicles is conductive hearing loss where the ossicles have become fixed or lose continuity. The ossicles may be eroded by a mass or inflammatory process or they may be congenitally malformed.

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.

Sterilisation

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

Conformity to the European Directives

Implantable device intended for long term use. Classification IIb according Rule 8 of Annex IX of the 93/42/EEC Medical Devices Directive.

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