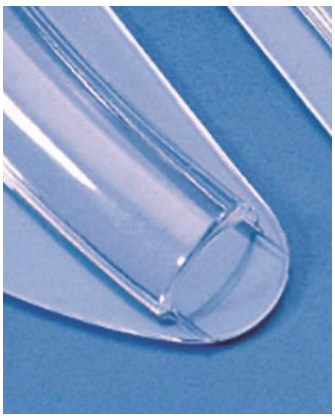
NETWORK ENT PRODUCTS

Silicone Airway Nasal Splints Specification Sheet



Product Overview

The NETWORK ENT® Silicone Airway Splints are used postoperatively to reduce postoperative complication rates associated with septal surgery, such as adhesion, hematoma, and synechiae formation.

- Constructed of biocompatible 100% medical grade silicone
- Pre-punched hole in anterior tip for easier suturing to prevent migration and/or dislodgement.
- Supplied as a pair of left and right
- Supplied sterile, single use only, declared 5 year shelf life
- Manufactured in the UK

Silicone Airway Nasal Splint

Product	Pack Size	Product Code
Left and Right Silicone Airway Splint	10 pairs per pack	72-3030

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Material Specification

Product Component	Specification
Splint	100% Medical Grade Silicone
Pouch Packaging	Tyvek/Film
Outer Box/Carton Packaging	490 Micron White Boxboard

Intended Use

NETWORK ENT® Silicone Airway Splints are intended to be used postoperatively on septal surgery patients to reduce complication rates, such as adhesion, hematoma, and synechiae formation.

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

Classification Rule
The NETWORK family of Internal Nasal Splints are invasive devices with respect to body orifices for short term use in the nasal cavity supplied and are classified as Class I STERILE devices according to Annex IX, Rule 5, of the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC.

Route to Conformity
Annex V

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