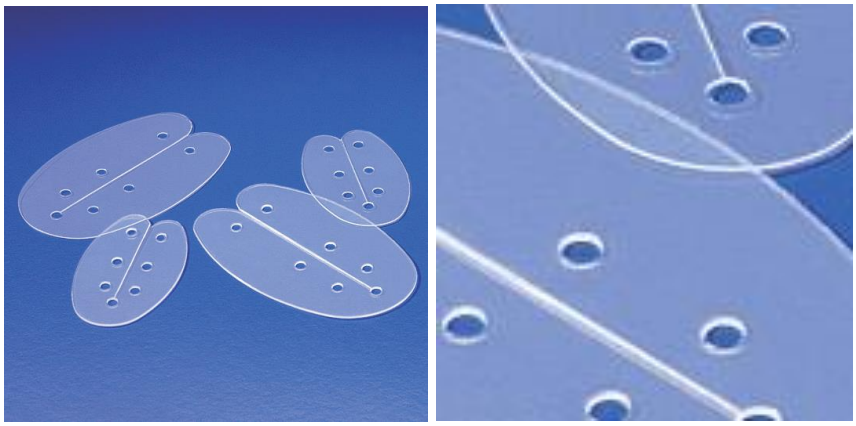
NETWORK ENT PRODUCTS

Fluoroplastic Bivalve Splints Specification Sheet



Product Overview

The NETWORK ENT® Fluoroplastic Bivalve Splint are ideal for providing septal support post procedure and reducing adhesion between the septum and lateral nasal wall.

- Constructed of biocompatible 100% medical grade fluoroplastic
- Integral suture holes
- Can be trimmed prior to insertion
- Clear colour for maximum visualisation
- Supplied sterile, single use only, declared 5 year shelf life
- Manufactured in the UK

Fluroplastic Bivalve Splint

Product	Pack Size	Product Code
Standard Thin	10	72-3032
Standard Thick	10	72-3033
Large Thin	10	72-3034
Large Thick	10	72-3035

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Material Specification

Product Component	Specification
Splint	100% Medical Grade Fluoroplastic
Pouch Packaging	Tyvek/Film
Outer Box/Carton Packaging	500 Micron White Boxboard

Intended Use

Airway Splints are intended for use after reconstructive nasal and septal surgery.

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 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.

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