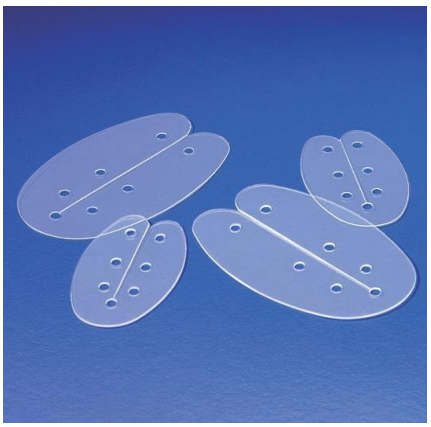
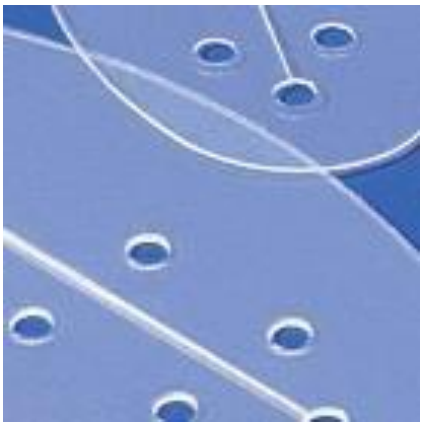
# Fluoroplastic Bivalve Splints Specification Sheet





## Product Overview

The NETWORK ENT® Fluoroplastic Bivalve Splint 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 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

## Fluoroplastic 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 | 490 Micron White Boxboard |

## Intended Use

NETWORK ENT® Fluoroplastic Bivalve 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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