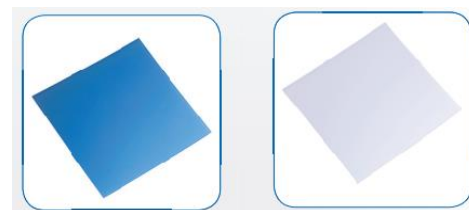
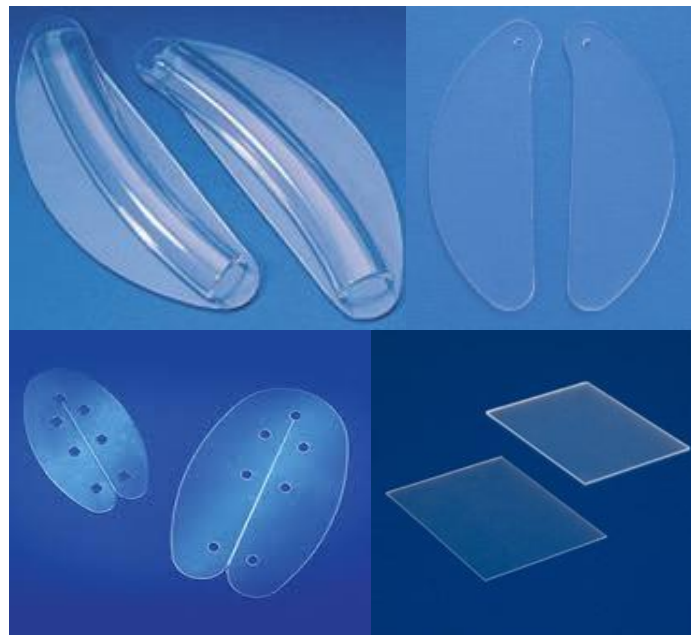


Products Name: Internal Nasal Splint
Variants:

F3147S	Nasal Airway Splint Standard
F3147L	Nasal Airway Splint Large
F3147P	Nasal Airway Splint Pre-cut
F3146S	Silicone Sheets (Thickness: 3.00mm)
F3146T	Silicone Sheets (Thickness: 5.00mm)
F3146UUS	Silicone Sheets (Thickness: 0.13mm)
F3146US	Silicone Sheets (Thickness: 0.25mm)
F3146MS	Silicone Sheets (Thickness: 0.50mm)
F3146NS	Silicone Sheets (Thickness: 1.00mm)
F3146BS	Silicone Block (5cm x 3cm x 1cm)
F3146BM	Silicone Block (6cm x 4cm x 1.5cm)
F3146BL	Silicone Block (7cm x 5cm x 2cm)
F3148SS	Internal Nasal Bi-valve Splint - Standard
F3148ST	Internal Nasal Bi-valve Splint - Thick
F3146UUS-1515C	Silicone Sheeting Clear Folios, 0.13x15x15mm
F3146UUS-206B	Silicone Sheeting Blue Folios, 0.13x20x6mm
F3146UUS-206C	Silicone Sheeting Clear Folios, 0.13x20x6mm
F3146UUS-406B	Silicone Sheeting Blue Folios, 0.13x40x6mm
F3146UUS-406C	Silicone Sheeting Clear Folios, 0.13x40x6mm


Intended use:

Internal Nasal Splint enhances patient comfort by allowing nasal breathing while providing support of nasal Septal structure.

Raw Material: Medical Grade Silicone

Sterilization:

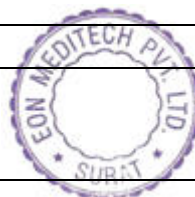
Internal Nasal Splint is sterilized by Ethylene Oxide.

Analysis certificate:

We EON Meditech Pvt. Ltd., the manufacturer declare that the analysis done on the finished Product is according to Biological Evolution following standard EN ISO 10993-1:2018

Issued & Approved By:

Sign & Date : Mr. Nirav Khunt
Technical Director
01/02/2024

TECHNICAL FILE
Doc. No.: EM/TCF/INS/01
Date: 01/02/2024
Rev. No.: 03
Section: 01

Tests	Acceptance Criteria	Result
In vitro Cytotoxicity	ISO 10993-5 : 2009	Complies
Intracutaneous reactivity	ISO 10993- 10 : 2010	Complies
Acute systemic toxicity	ISO 10993-11 : 2006	Complies
Bacterial Reverse Mutation (AMES)	ISO 10993-3 : 2014	Complies
Implantation	ISO 10993- 6 : 2016	Complies
Skin Sensitization	ISO 10993-10 : 2010	Complies
Clinical Evaluation of Medical Device	ISO 14155 : 2020	Complies
Risk Analysis	ISO 14971 : 2019	Complies

Sterility Test:

Tests	Acceptance Criteria	Result
Ethylene Oxide sterilization	ISO 11135-1:2014	Complies
Sterility	ISO 11737-2 : 2019	Complies

Packaging:

Internal Nasal Splint is packed in peel pouch made of Tyvek material grade: 1073 B. Packaging system is as per EN ISO 11607 1:2019. Package labeling as per ISO 15223 1:2021.

Storage conditions:

Store in a cool dry conditions away from heat and direct light.

Issued & Approved By:
Sign & Date : Mr. Nirav Khunt
Technical Director
01/02/2024

