# INSTRUCTIONS FOR USE

**Technical Name:** NASAL MODELER

**Commercial name:** TRAUMEC INTERNAL NASAL SPLINT

**Fabricante**: TRAUMEC - Tecnologia e Implantes Ortopédicos Importação e Exportação Ltda

**MEDICAL USE PRODUCT**
**STERILE PRODUCT**

**WARNING:** Please read carefully all instructions before use. Follow all warnings and precautions mentioned in this instruction. Disregarding these points may lead to occurrence of complications.

## 1. Product Identification.

Traumec Internal Nasal Splint is indicated for nasal surgeries in general (septoplasties, sinusectomies, rhinoplasties, tubinectomies, epistaxis surgeries and pituitary surgeries). The Traumec Internal Nasal Splint consists of a silicone tube that is positioned near the nasal septum at the end of the surgery. The function of the Traumec Internal Nasal Splint is to ensure good healing of the septum, avoiding synechiae, and assist in nasal ventilation. The splint should be removed within approximately seven days after surgery.

Traumec Internal Nasal Splint is supplied STERILE
by Ethylene Oxide - ETO.

## 2. Specifications and Technical Characteristics.

Traumec Internal Nasal Splint are made of silicone.

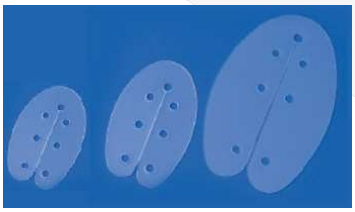
The table below shows the products in this registration process.



traumec.com.br
+55 (19) 3522.1177
Rua 1A JC, 138, Jd. Centenário, 13503-510, Rio Claro/SP - Brasil
CNPJ: 09.123.223/0001-10 • IE: 587.293.570-117

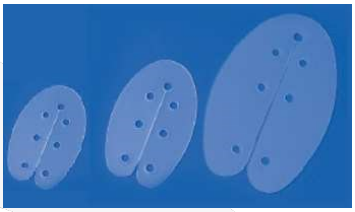
| CODE | DESCRIPTION | FUNCTION | SPECIFICATION | ILLUSTRATION |
|---|---|---|---|---|
| PA.02.24.0001 | Internal Nasal Splint with cannula – Standard | Ensure good healing of the septum, help in nasal ventilation and avoid the formation of nasal synechiae. | Silicone |  |
| PA.02.24.0002 | Internal Nasal Splint with cannula - P | | | |
| PA.02.24.0003 | Internal Nasal Splint with cannula - M | | | |
| PA.02.24.0004 | Internal Nasal Splint with cannula - G | | | |

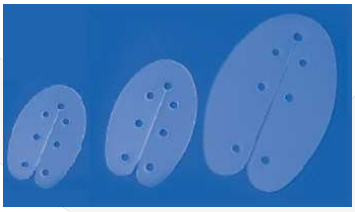
| CODE | DESCRIPTION | FUNCTION | SPECIFICATION | ILLUSTRATION |
|---|---|---|---|---|
| PA.02.24.0005 | Internal Nasal Splint Straight – Standard | Ensure good healing of the septum, help in nasal ventilation and avoid the formation of nasal synechiae. | Silicone |  |
| PA.02.24.0006 | Internal Nasal Splint Straight - P | | | |
| PA.02.24.0007 | Internal Nasal Splint Straight - M | | | |
| PA.02.24.0008 | Internal Nasal Splint Straight - G | | | |

| CODE | DESCRIPTION | FUNCTION | SPECIFICATION | ILLUSTRATION |
|---|---|---|---|---|
| PA.02.24.0009 | Internal Nasal Splint P - thickness 0,25mm | Ensure good healing of the septum, help in nasal ventilation and avoid the formation of nasal synechiae. | Silicone |  |
| PA.02.24.0010 | Internal Nasal Splint M - thickness 0,25mm | | | |
| PA.02.24.0011 | Internal Nasal Splint G - thickness 0,25mm | | | |



traumec.com.br
+55 (19) 3522.1177
Rua 1A JC, 138, Jd. Centenário, 13503-510, Rio Claro/SP - Brasil
CNPJ: 09.123.223/0001-10 • IE: 587.293.570-117

| CODE | DESCRIPTION | FUNCTION | SPECIFICATION | ILLUSTRATION |
|---|---|---|---|---|
| PA.02.24.0012 | Internal Nasal Splint P - thickness 0,50mm | Ensure good healing of the septum, help in nasal ventilation and avoid the formation of nasal synechiae. | Silicone |  |
| PA.02.24.0013 | Internal Nasal Splint M - thickness 0,50mm | | | |
| PA.02.24.0014 | Internal Nasal Splint G - thickness 0,50mm | | | |

| CODE | DESCRIPTION | FUNCTION | SPECIFICATION | ILLUSTRATION |
|---|---|---|---|---|
| PA.02.24.0015 | Internal Nasal Splint P - thickness 1,0mm | Ensure good healing of the septum, help in nasal ventilation and avoid the formation of nasal synechiae. | Silicone |  |
| PA.02.24.0016 | Internal Nasal Splint M - thickness 1,0mm | | | |
| PA.02.24.0017 | Internal Nasal Splint G - thickness 1,0mm | | | |

**Note:** illustrative images

### 3. Principle of Operation

Traumec Internal Nasal Splint were developed to aid in the healing process in septum surgeries, avoiding complications such as nasal synechia and assisting in nasal ventilation. Its use depends on the technique of the professional, but always on support activity.



traumec.com.br
+55 (19) 3522.1177
Rua 1A JC, 138, Jd. Centenário, 13503-510, Rio Claro/SP - Brasil
CNPJ: 09.123.223/0001-10 • IE: 587.293.570-117

## 4. How to Use

The selection of the splint that best fits the patient's anatomy is an integral part of the post-surgical planning and should be performed by the physician responsible for the procedure. It is very important to perform a thorough inspection on each component paying attention to the conditions of use and integrity of the sterile package.

**Surgical Technique:**

1. To facilitate insertion of the splint into the nasal cavity, moisten the sterilized splint with sterile saline or nasal ointment.
2. Once the cartilaginous septum has been sufficiently secured, attach the splint to both sides of the septum for additional support.
3. The narrower side of the splint faces the nasal vestibule while the flat side is in contact with the septum. The tube-shaped arch lies beneath the middle turbinate.
4. The ventilation tube should not be damaged by sutures.
5. If necessary, careful tamping around the splint can be used.

Removal of the splint should be performed approximately 7 days after surgery, or at the discretion of the attending physician.

## 5. Storage Conditions

Traumec Internal Nasal Splint should be stored in a clean, dry place, away from heat and under direct light and in its original packaging, under + 10 ° to + 40 ° C (50°F – 104°F). Relative Humidity: 30 to 85%. Special conditions for storage, handling and maintenance of the product should be followed to ensure the components remain intact for the surgical procedure. Care in receiving, storing, transporting, cleaning and maintaining batch references must be adopted in conjunction with good practices for storage and distribution of medical products.

## 6. Transport and Handling Conditions

Traumec Internal Nasal Splint should be transported and handled in a clean, dry place, away from heat and direct light and in its original packaging under Temperature: + 10 ° to + 40 ° C (50°F – 104°F) - Relative Humidity: 30 to 85% in order to prevent any damage or change in its characteristics.

**Note:** Any product that has been damaged in its original packaging must be segregated.



traumec.com.br
+55 (19) 3522.1177
Rua 1A JC, 138, Jd. Centenário, 13503-510, Rio Claro/SP - Brasil
CNPJ: 09.123.223/0001-10 • IE: 587.293.570-117

## 7. Warnings

- Do not use the product if the package is open or damaged.
- Single Use Product, Do Not Reuse.
- Product to be used only by a qualified professional.
- Prior to initiating the procedure, the anatomical structures of the patient must be identified to ensure that the splints are fitting correctly.
- Do not exert excessive force in the handling of splints, as excessive pressure can cause damage to anatomical structures and adjacent tissues.
- Re-use and reprocessing may cause cross-contamination and damage the device, which may result in injury to the patient.
- The splint is not designed to prevent bleeding. In the case of bleeding during splint placement, identify the source of the hemorrhage and, if necessary, check and correct the buffer.

**ATTENTION:** The product has been designed for a single use, in a single patient. The manufacturer has not designed the product for reprocessing. The reuse of this device is the responsibility of the Health Care Institution.

## LABELING MODEL

**Technical Name:** NASAL MODELER

**Commercial name:** TRAUMEC INTERNAL NASAL SPLINT

**Commercial Model:** INTERNAL NASAL SPLINT WITH CANNULA – STANDARD

**Code:** PA.02.24.0001

**Lot/batch code:** XXXXXX

**Quantity:** 1 box

**ANVISA Registration n. º:** 80455630079

**Sterilized by:** Ethylene oxide - ETO

**Manufacture date:** XX/XX/XXXX

**Expiration date:** XX/XX/XXXX

**Material:** XXXXXXXXXX



traumec.com.br
+55 (19) 3522.1177
Rua 1A JC, 138, Jd. Centenário, 13503-510, Rio Claro/SP - Brasil
CNPJ: 09.123.223/0001-10 • IE: 587.293.570-117

**Technician Responsible:** José Luiz Caritá **-** CREA–SP – 0685038754

**SINGLE USE PRODUCT - PROHIBITED TO REUSE**

**STERILE PRODUCT - REPROCESSING PROHIBITED**

SPECIAL CONDITIONS OF STORAGE, CONSERVATION, HANDLING OF MEDICAL PRODUCT:

**SEE INSTRUCTIONS FOR USE.**

**ANVISA Registration n. º 80455630077**

TRAUMEC TECNOLOGIA E IMPLANTES IMPORTAÇÃO E EXPORTAÇÃO LTDA
**Address:** Rua 1A JC, nº138, Jardim Centenário.
**City:** Rio Claro – State of São Paulo - CEP: 13503-510
**CNPJ: 09.123.223/0001-10**
**Customer Service -** Phone: 55(19) 3522-1177 / Fax: 55(19) 3522-1174 **Email: sac@traumec.com.br**
www.traumec.com.br
Rev.:01

TRADUKO
TRADUÇÃO DE DOCUMENTOS
Referência 201706 Profissional TSM

TRADUKO
REVISÃO DE DOCUMENTOS
Referência 201701 Profissional JHS