

# INSTRUCTIONS FOR USE: NASOTRACHEAL TUBE IMMOBILIZER

**BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.**

## DESCRIPTION

The Nasotracheal Tube Immobilizer (NTI) is a single use device used in surgical procedures. The intended use of the NTI is to secure and immobilize the nasotracheal tube during and after the intubation process to avoid device-related injury and ensure safe high-quality care of the patient.

## INDICATIONS

The NTI is a single use, non-sterile device to be used during and after the intubation process to avoid device-related injury and ensure safe high-quality care of the patient.

## INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals only.

## CONTRADICTIONS

This device is not designed, sold, or intended for use except as indicated.

## KNOWLEDGE AND USE

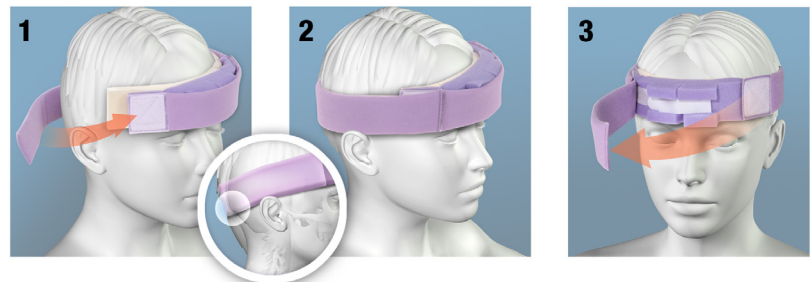
Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

## CLINICAL BENEFITS

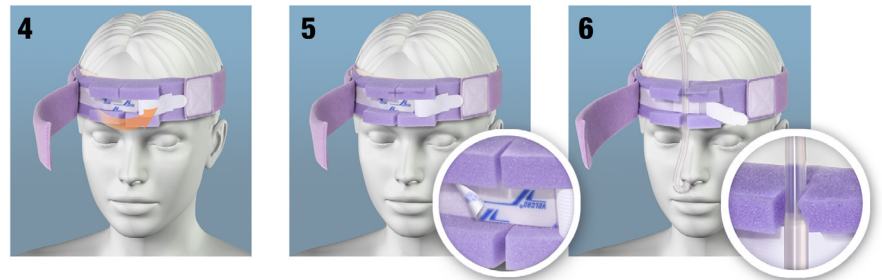
Provides immobilization of an intubation tube on the patient during surgical procedures.

## PREPARATION AND USE

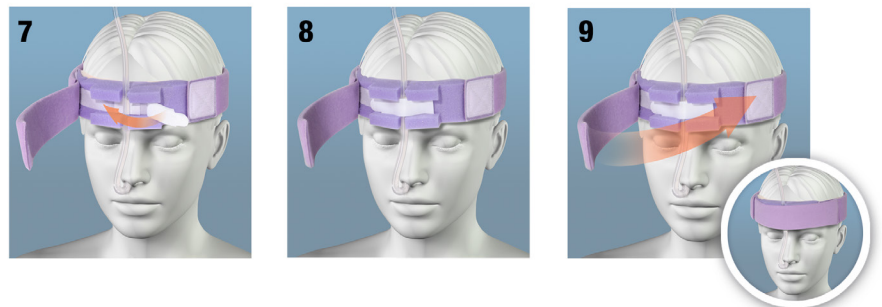
- 1-2** Position the NTI™ on patient inferior to the external occipital protuberance and secure by attaching strap to velcro square (*see inset*).
- 3** Open outer tube retaining strap by peeling it away from the velcro to reveal tube securement measures.



- 4** Open inner tube retaining velcro strap to reveal adhesive tab.
- 5** Peel off plastic liner to expose adhesive (*see inset*).
- 6** Insert tube into slit in foam block and press firmly against adhesive to affix (*see inset*).



- 7** Secure tube with inner tube retaining velcro strap.
- 8** Tube is now secured in the NTI™.
- 9** Close outer tube retaining strap by securing it to the velcro square. Ensure NTI™ is positioned above and not entrapping the ears and make any final adjustments (*see inset*).



## DISPOSAL

- After use, the NTI should be disposed of in accordance with hospital policy.

## WARNINGS

- This device was designed, test and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure or subsequent injury.
- Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection
- Do not reuse or reprocess this device.
- After use, the NTI should be disposed of in accordance with hospital policy.
- The NTI should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.

## PRECAUTIONS

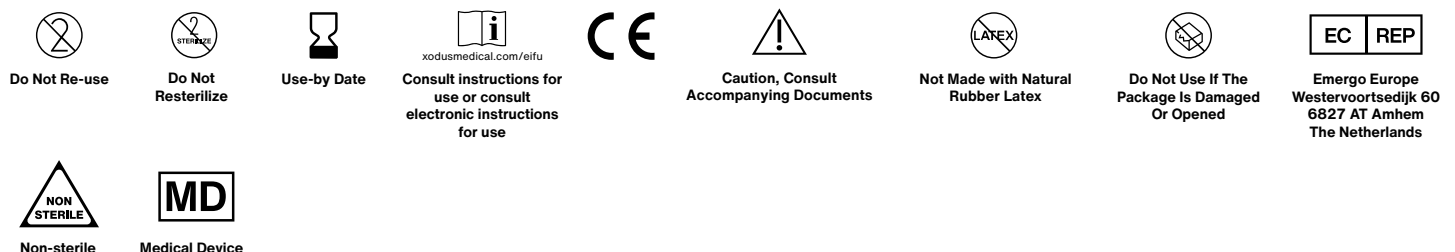
- The NTI should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturer of the associated instrument.
- Notice to the User and/or patient that any serious incident that has occurred in relation to the device should be reported and the competent authority of the Member State in which the user and/or patient is established, as well as, Xodus Medical and its Authorized Representative.

## TECHNICAL SPECIFICATIONS

- Materials of manufacture include:
  - » Polyurethane foam, synthetic adhesive, nylon strap
- Shelf Life – indefinite

## STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

- NTI should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.



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FDA REGISTERED  
ISO 13485 CERTIFIED

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