

# Tx360<sup>®</sup> Nasal Applicator

## INSTRUCTIONS FOR USE

The Tx360EU Nasal Applicator is for Single Use Only. Not To Be Reused. Discard appropriately after single use. NOTICE: Please read the complete instructions for use prior to using the Tx360EU Nasal Applicator. Failure to do so may result in patient injury.

Rx Only

EN

## INTRODUCTION

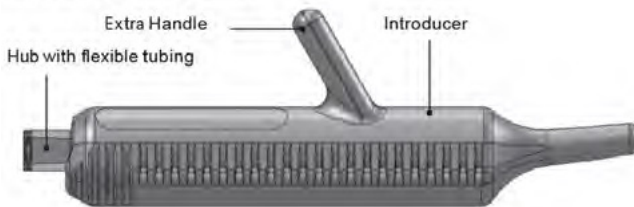
### Tx360EU INTENDED USE

The Tx360EU nasal applicator device is intended to deliver fluids, selected by a healthcare professional, to the mucous membrane covering structures of the nasal pathway, such as the inferior turbinate, middle turbinate, superior turbinate, sphenopalatine foramen, nasal septum, etc. The Tx360EU provides an aid to physicians in the delivery of drugs used as nerve block agents when performing sphenopalatine ganglion nerve block for the purpose of treating headaches.

### TX360EU NASAL APPLICATOR PRODUCT DESCRIPTION

Tian Medical LLC provides a simple and convenient nasal applicator for delivery of fluid (drugs and solutions) to the nasal cavity. The Tx360EU device is compatible with aqueous and light oil solutions. The healthcare professional controls the type and amount of solution, the location, and the rate of delivery. The healthcare professional controls the rate of delivery by the pressure exerted on the plunger of the 1cc syringe. The Tx360EU attaches to a provided luer lock 1cc disposable syringe allowing the healthcare professional to deliver small and measured amounts of fluid to areas along the nasal pathway. A hub with a small length of flexible, thin tubing is connected to the top of the delivery system. It has a soft rounded tip which has a single small opening to deliver the solution in a gentle stream to the desired region of the nasal pathway. All components are latex-free. The device has been designed with a slightly flared stem to assure the device cannot be placed too high in the nasal pathway. Its small flexible tip is designed to help reduce irritation to the nasal lining. Figure 1 below illustrates the device and its components.

**FIGURE 1**  
**Tx360EU Nasal Applicator**



### TX360EU NASAL APPLICATOR PRODUCT DESCRIPTION

- An easy-to-use, disposable nasal applicator for Single Use Only. Not To Be Reused.
- Latex-free component.
- An extra handle for user convenience.
- Suitability for use in both right and left pathway.
- A selected volume delivered from the provided disposable 1cc syringe provides an efficient fluid stream.
- Hand-held portability.
- A guide that locks to the syringe and provides a convenient method to access the desired nasal area.

### TX360EU USE AND STORAGE

- The Tx360EU Nasal Applicator must be used only as directed. Please read all instructions before use.
- If you have any questions about the use of this product, contact Tian Medical LLC. Customer service at 630-426-9605.
- Single use only.

### DO NOT USE THE TX360EU NASAL APPLICATOR IN THE FOLLOWING CONDITIONS (CONTRAINDICATIONS):

- If the patient has a nasal septal deformity such as the following: malformed facial or nasal passages such as cleft lip, choanal atresia (narrowed nasal passages), atrophic rhinitis, rhinitis medical mentosa, septal perforation, nasal/midface trauma or he or she has recently had nasal/sinus surgery.
- Potential for injury may occur, such as a nasal passage obstruction and nasal trauma and irritation.
- If the patient has a bleeding disorder such as Von Willebrand's disease or hemophilia, uncontrolled bleeding may occur.
- If the patient has severe respiratory distress.
- Further irritation of nasal airways may worsen respiratory distress.
- If the patient has a Neoplasm including, but not limited to: Angiofibroma, sinus tumors, Granuloma.
- Congestion has been present for more than 10 days, there is a high fever, and the nasal mucous is an abnormal color.

### DO NOT USE THE TX360EU NASAL APPLICATOR IF:

- The skin around and inside the nasal passage is dry, cracked, oozing, or bleeding.
- The patient experiences recurrent nose bleeds.
- The patient has a nasal or facial fracture.
- The Tx360EU Nasal Applicator may cause nose bleeding and additional nasal trauma and irritation.

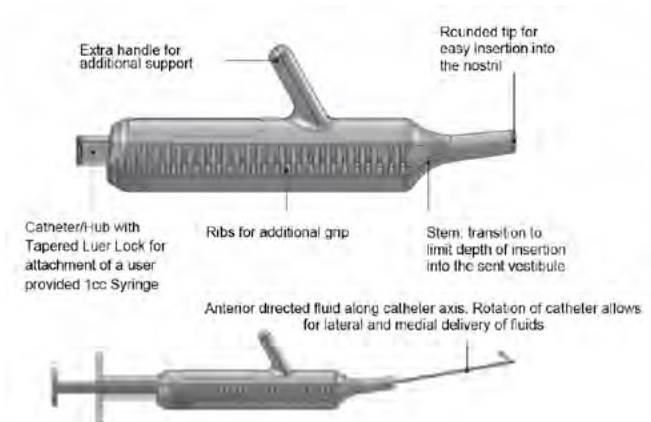
### WARNING AND PRECAUTIONS

The Tx360EU Nasal Applicator should be used with care by healthcare professionals.

Complications may include:

- Nasal passage irritation. Putting anything in the nose may irritate the lining of the nose. To help avoid irritation, use the device for only a short duration. Do not use for more than one application. If the tissue is bright red, appears to be irritated, or if the patient is experiencing pain, immediately discontinue using the Tx360EU Nasal Applicator.
- Nose Bleeding. Do not force the tip of the Tx360EU into the nose. Insert the device slowly and carefully following the step by step instructions described on next page. If bleeding occurs, immediately stop using the device and apply pressure on the nose to stop bleeding.
- The Tx360EU Nasal Applicator is a disposable device for Single Use Only. Not To Be Reused.
- Discard appropriately after use.
- Reuse of the Tx360EU Nasal Applicator and provided 1cc syringe may cause serious infections and introduction of bacteria, including VRE (Vancomycin-Resistant Enterococcus) or MSA (Methicillin-Resistant Staphylococcus Aureus), and other serious bacteria.

### DEVICE FEATURES



Rx Only

Rx Only

EC REP

Authorized representative in the European community



Manufacturer



Do not use if package is damaged

REF

Catalog Number

STERILE R

Sterilized using irradiator



Caution / Instructions for use

LOT

Batch Code



Do not reuse



Use by date



No latex




Instructions for use

**1** Draw the desired solution into the provided syringe. Tap out excess air and draw more fluid to fill the syringe up to its capacity of 0.6cc.

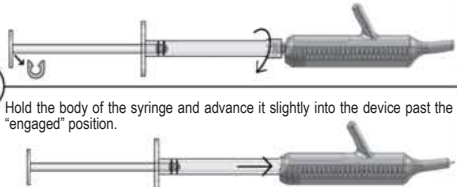
This is a one time use device for both nostrils only. Looking at the Tx360EU device inferiorly, notice the two tracks at the bottom of the Tx360EU.

Side View  
Inferior View



**2** Remove the u-shaped clip at the base of the push rod. Gently rotate the syringe onto the Tx360EU device until a click so that syringe is locked onto the Tx360EU device. Push gently until luer lock is secured as it clicks into place.

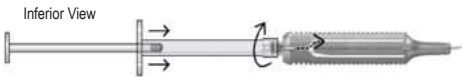
**3** Hold the body of the syringe and advance it slightly into the device past the "engaged" position.




### Instructions for use of the Tx360EU Nasal Applicator (Right)

**4** Gently turn and advance the syringe counterclockwise (or to the patient's right) onto the track for the right nostril. The tip of the catheter should slightly protrude out of the device.

Inferior View

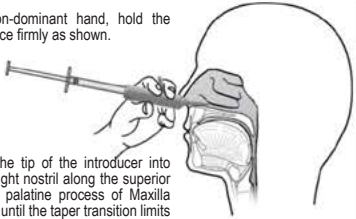


Back View

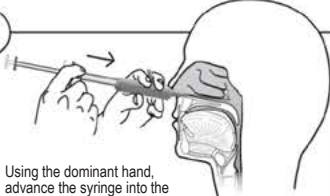


**5** Using the non-dominant hand, hold the Tx360EU device firmly as shown.

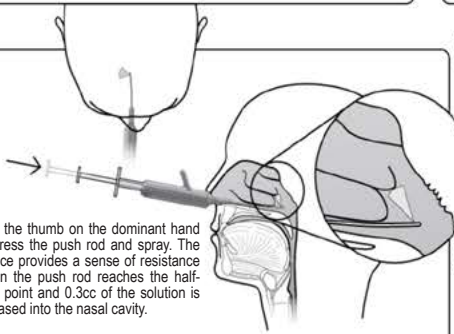
Then, insert the tip of the introducer into the patient's right nostril along the superior aspect of the palatine process of Maxilla (floor of nose) until the taper transition limits further advance of the device.



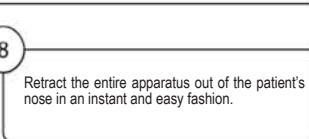
**6** Using the dominant hand, advance the syringe into the device as the tip of the catheter further protrudes out of the introducer until limit. You may feel a small bump indicating the limit. The device is able to administer fluid immediately upon exiting the introducer.



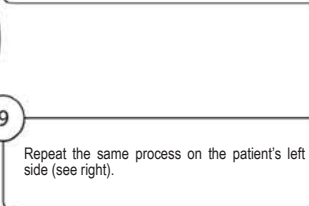
**7** Use the thumb on the dominant hand to press the push rod and spray. The device provides a sense of resistance when the push rod reaches the half-way point and 0.3cc of the solution is released into the nasal cavity.



**8** Retract the entire apparatus out of the patient's nose in an instant and easy fashion.




**9** Repeat the same process on the patient's left side (see right).



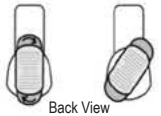
### Instructions for use of the Tx360EU Nasal Applicator (Left)

**10** Gently turn and advance the syringe clockwise (or to the patient's left) onto the track for the left nostril. The tip of the catheter should slightly protrude out of the device.

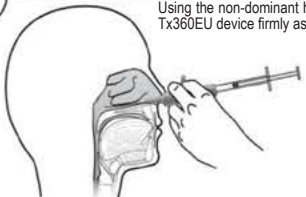
Inferior View



Back View

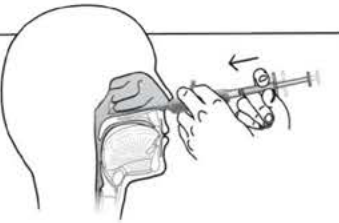


**11** Using the non-dominant hand, hold the Tx360EU device firmly as shown.

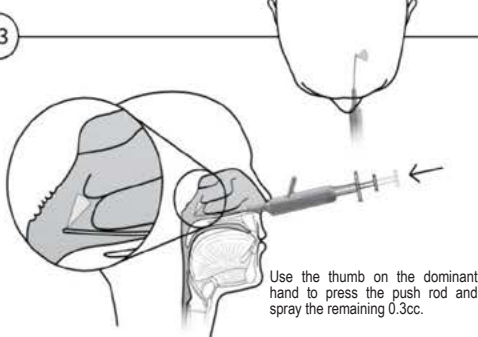


**12** Then, insert the tip of the introducer into the patient's left nostril along the superior aspect of the palatine process of Maxilla (floor of nose) until the taper transition limits further advance of the device.

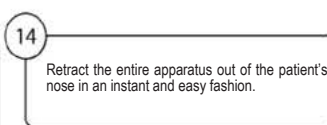
Using the dominant hand, advance the syringe into the device as the tip of the catheter further protrudes out of the introducer until limit. You may feel a small bump indicating the limit. The device is able to administer fluid immediately upon exiting the introducer.



**13** Use the thumb on the dominant hand to press the push rod and spray the remaining 0.3cc.



**14** Retract the entire apparatus out of the patient's nose in an instant and easy fashion.



**CONTACT INFORMATION**

WARNING: If you observe a defect or experience a problem with use of this device, call Tian Medical, LLC.  
 Technical Support at 855-338-0042  
 Customer Service: 630-426-9605  
 Email: sales@tianmedical.com  
 Website: www.europe.tianmedical.com

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