

Tx360[®] Nasal Applicator

INSTRUCTIONS FOR USE

The Tx360[®] 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 Tx360[®] Nasal Applicator. Failure to do so may result in patient injury.

Rx Only

INTRODUCTION

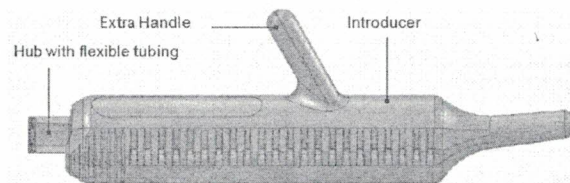
INTENDED USE

The Tx360[®] Nasal Applicator is a sterile device intended for use in adults to deliver small amounts of fluid (\leq 1cc, luer lock) selected by a healthcare professional to the nasal pathway, including the area of the inferior turbinate, superior turbinate, sphenopalatine foramen, etc. It is intended for use on adult patients with intact nasal mucosa.

TX360[®] NASAL APPLICATOR PRODUCT DESCRIPTION

Tian Medical Inc. provides a simple and convenient nasal applicator for delivery of fluid (drugs or solutions) to the nasal cavity. The Tx360[®] 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 Tx360[®] 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 that 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
Tx360[®] Nasal Applicator



THE TX360[®] NASAL APPLICATOR PROVIDES

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

USE AND STORAGE

- The Tx360[®] 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 Inc. Customer Service at 630-426-9605.
- Single Use Only.
- Do not store at extreme temperatures and humidity.

DO NOT USE THE TX360[®] NASAL APPLICATOR IN THE FOLLOWING CONDITIONS (CONTRAINDICATIONS):

- If the patient has a nasalseptal deformity such as the following: malformed facial or nasal passages such as cleft lip and palate, choanal atresia (narrowed nasal passages), atrophic rhinitis, rhinitis medicamentosa, septal perforation, nasal/midface trauma or he or she has recently had nasal/sinus surgery.
- Potential for injury may occur, such as 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 airway 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 mucus is an abnormal color.

DO NOT USE THE TX360[®] NASAL APPLICATOR IF:

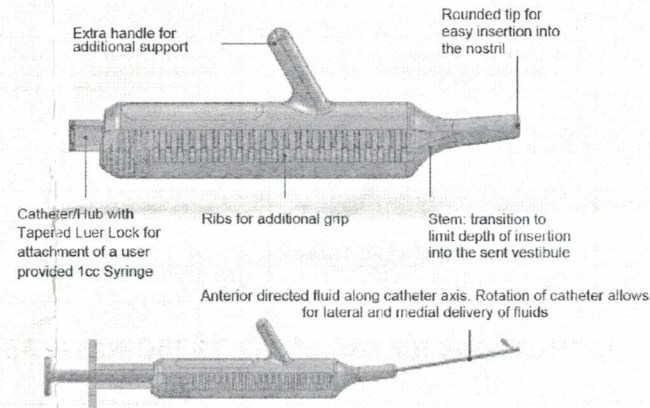
- The skin around and inside the nasal passage is dry, cracked, oozing, or bleeding.
- The patient experiences recurrent nose bleeds.
- The patient has a nasal or facial fracture
- The Tx360[®] Nasal Applicator may cause nose bleeding and additional nasal trauma and irritation.

WARNING AND PRECAUTIONS

The Tx360[®] 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 Tx360[®] Nasal Applicator.
- Nose bleeding. Do not force the tip of the Tx360[®] Nasal Applicator into the nose. Insert the device slowly and carefully following the step by step instructions described on back. If bleeding occurs, immediately stop using the device and apply pressure on the nose to stop bleeding.
- The Tx360[®] Nasal Applicator is a disposable device for Single Use Only. Not To Be Reused.
- Discard appropriately after use.
- Reuse of the Tx360[®] 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



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

Instructions for use of the Tx360 Nasal Applicator (Right)

- 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 0.5cc.

This is a one time use device for both nostrils only. Looking at the Tx360® device inferiorly, notice the two tracks at the bottom of the Tx360®.

Side View

Inferior View
- Remove the u-shaped clip at the base of the push rod. Gently rotate the syringe onto the Tx360® device until a click so that syringe is locked onto the Tx360® device. Push gently until lure lock is secured as it clicks into place.
- Hold the body of the syringe and advance it slightly into the device past the "Engaged" position.

Inferior View

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

Inferior View

Back View
- Using the non-dominant hand, hold the Tx360® device firmly as shown.

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 laper 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.
- Using the non-dominant hand, hold the Tx360® 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 laper 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.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.

Instructions for use of the Tx360 Nasal Applicator (Left)

- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.
- Using the non-dominant hand, hold the Tx360® 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 tension limits further advance of the device.

CONTACT INFORMATION

WARNING: If you observe a defect or experience a problem with use of the device, call Tian Medical, Inc. Technical support at 408-465-9145. Voice: 530-426-9005. Email: sales@tbiomedical.com. Website: www.tbiomedical.com.

Manufactured for Tian Medical, LLC
388 E. Bekdere Road, Ste 212
Graylake, IL 60030

ndi Europa GmbH
Langenhagener Strasse 71
D-30855 Langenhagen