

Instruction for Use

Toomey Tip Syringe

Device Description

Toomey Syringe is a multi- purpose syringe suitable for TURP procedure and Bladder Irrigation compatible with-Storz, wolf, cystoscope and resectoscope. Delivered in sterile peel-open package. Intended for single use. No contact with the body. The configurations available include:

Family	Volume (cc)	Variants	Catalogue Number
Toomey Tip Syringe (TTS)	70	Glass Plastic	AMPLGP007

Intended Purpose

Toomey Tip syringe is intended for use in irrigation and evacuation during Trans Urethral Resection of Prostate.

Performance Characteristics of the device

Toomey Tip Syringe can fit cystoscopes and resectoscopes for versatile use. Made with a thumb ring plunger and smooth piston action. This 70cc Toomey syringe is great for one- handed use. Toomey Tip syringe comes with a luer adapter tip and a catheter adapter tip for easy irrigation of Foley catheters and the inflation of Foley balloons. It also has a double- flanged plunger tip to ensure superior vacuum properties.

Indications

A Toomey syringe is used to irrigate and evacuate during medical treatments

Contraindications

No known Contraindications.

Precautions & Warnings

Carefully read all instructions for use and product labeling. The device shall only be applied for its intended use and in accordance with these instructions. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Precautions:

- All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.
- The Intended User of the device must be a urologist specializing in the treatment of Urinary system disorders and related urological procedures.
- Do not use the device if there is any indication that the sterility of the device has been compromised.

Warnings:

- The device is for single use only.
- The product must not be re-used. Reusing single-use devices can lead to potentially serious consequences for the patient: Bio-contamination due to release of infectious agents from device into the body which further may result in Infections.
- This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Intended Patient Population

The device can be used by patients of all age groups when evacuation or bladder irrigation is required.

Shelf-life and Storage condition of the Product

The shelf life of the Toomey Tip Syringe is 3 years (Indicated on product label with the following use-by symbol).

Store the Toomey Tip Syringe at a temperature between 12°-35°C and a Humidity range of 30%-75%.

Store in a dry, cool place. Avoid extended exposure to sun light.

Sterility – This product is Sterile unless the package has been opened or damaged

- The Toomey Tip Syringes have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change colour from blue to brown after ethylene oxide exposure. Do not use the product unless the sterility indicators are the correct color.
- Exposure to high levels of Ethylene Oxide may result in presence of residual ETO which leads to Toxic Reaction in the body resulting in tissue damage in the Urinary System.
- If the sterile package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.
- The Toomey Tip Syringes are packed single. Product in each pack must be utilized immediately when opened. Product should not be re- sterilized.

Directions for Use

- Open the package at the Chevron Side (‘V’ Notch) of the pouch.
- Suggested instructions for using Toomey Tip Syringes:
- Remove the device from the package.
- Attach the desired adapter (Luer adapter or catheter adapter) into the tip of the syringe. While connecting the adapter, applying excessive pressure may cause damaging adapter or syringe tip.
- No contact with the body.


















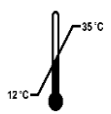


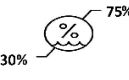
Disposal Instructions

Dispose of all equipment, including the extension set, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Instruction for Use

Toomey Tip Syringe

Explanation of symbols used on label

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
	Catalogue Number		CE Mark		Do not Re sterilize		Country of Manufacture		Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use		Unique Device Identifier
	Sterilized using ethylene oxide		Consult Instructions for Use		Temperature Limit		Do Not Use if Package is Damaged		Authorized Representative in the European community
	Humidity Limit								



Aster Medispro Pvt. Ltd
 S.P.181, 10th Main, 1st Stage,
 DR.B.R.Ambedkar Industrial Estate (KSSIDC)
 Jigani Industrial area, Jigani,
 Bangalore - 560105, Karnataka, India.
 Tel: +91 80-42062716
 Email: info@astermedispro.net
 Web: www.astermedispro.net



M/sCMC Medical Devices & Drugs S.L.
 located in C/Horacio Lengo N° 18, CP29006,
 Málaga, Spain
 Tel : +34951214054, Fax: +34952330100
 E-mail : mmateos@cmcmedicaldevices.com
 Web : www.cmcmedicaldevices.com

Bibliography

- Single Use Medical Device
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/956268/Single_use_medical_devices.pdf
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements
- EN ISO 20417:2020 – Medical Devices- Information to be supplied by the manufacturer.