

Instruction for Use

Toomey Tip Syringe Glass

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 peel-open package. No contact with the body. The configurations available include:

| Family | Volume (ML) |
|-----------------------------|-------------|
| Toomey Tip Syringe (TTS) | 12 |
| | 50 |
| | 70 |
| | 90 |
| | 100 |

Intended Purpose

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

Intended User

This device should be administered to humans only by physicians authorized by the Competent Authority of the country in which the physician is practicing.

Medical conditions to be Treated

Administering irrigation fluid to the bladder for the removal of blood clots, debris, or mucous, aiding in the management of haematuria or post-surgical care

Performance Characteristics of the device

Toomey Tip Syringe Glass 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

Irrigation and evacuation of irrigation solutions

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:

- The intended user of the device must be a Urologist specializing in the treatment of urinary system disorders and related urological procedures authorized by the Competent Authority of the country in which the physician is practicing.
- Confirm the information on the label and that the product has not reached its expiration date and there is no damage to the packaging or device.
- Store the Toomey Tip Syringe Glass at a temperature between 12-35°C and a Humidity range of 30-70%.
- Store in a dry, cool place. Avoid extended exposure to sun light.

Warnings:

- If the package is damaged or possibly opened, do not use. Contact “Manufacturer or Distributor” and replace the product.

Intended Patient Population

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

Shelf-life

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

Sterility

- The Toomey Tip Syringe are supplied non-sterile and can be re-used once thoroughly cleaned by single patient.
- The Toomey Tip Syringes are packed single.

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.

Cleaning Instructions




















- Rinse the device in cool, clean water using a suitable disinfectant after each use.

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.

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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 |  | Unique Device Identifier |  | 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 |  | Humidity Limit |
|  | Sterilized using ethylene oxide |  | Consult Instructions for Use |  | Temperature Limit |  | Do Not Use if Package is Damaged | | |



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Bibliography

- MDCG 2019-15 rev 1- Guidance Notes for Manufacturers of Class I Medical Devices
- EU MDR 2017/745 Regulations
- 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.