

Instruction for Use

TUR Set

Device Description

It is a Y-shaped Set for endoscopic irrigation during trans urethral resection of prostate gland. Delivered in sterile peel-open package. TUR SET is made of nontoxic, nonirritant materials. Intended for single use. Intended duration of use is 1 day. The configurations available include:

Family	PVC Tube Length (Cm)	Silicon Tube(mm)	Spike Needle (mm)	Catalogue Number
Transurethral Resection Set (TUR Set)	162	54	134.5	AMPLGP008

Intended Use

TRANS URETHRAL RESECTION Set (TUR Set) is used for Endoscopic irrigation during the Trans Urethral Resection of Prostate gland and offers continuous irrigation during transurethral resection.

Performance Characteristics of the device

The device consists of thumb operated clamps that enable quick and smooth change of bottles. Flexible silicon tube at proximal end for easy connection to Endoscope.

Indications

Endoscopic irrigation during Trans urethral Resection of Prostate Gland

Contraindications

- Anticoagulation
- Active untreated Urinary Tract Infection
- Bleeding Diathesis

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:

- Each physician is responsible for using the appropriate technique and deciding on the indication for use of this device based on his own experience, training and medical judgement. 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.
- Dispose of all components as infectious waste. Users of this device have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.
- 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 Urinary 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

TURSET is used in patients diagnosed with Urinary Retention/ Obstruction and Acute prostatic infection. The device can be used in patients of all age groups.

Shelf-life and Storage condition of the Product

The shelf life of TUR Set is 3 years (Indicated on product label with the following use-by symbol). Store the TUR Set 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 TURSETs have been sterilized by Exposure to Ethylene Oxide. Sterility indicators are on each package. The imprinted label will change color 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 TURSETs 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 TUR Set are:
- Y shaped set for Endoscopic irrigation during Trans Urethral Resection of prostate gland.
- Thumb operated clamps, help quick and smooth change of bottles.
- Proximal end fitted with flexible tubing for easy connection to Endoscope.
- Duration of contact with the body is 1 day.

Removal Instructions

Retrieve by gently pulling on the device. If resistance is encountered during removal, stop and determine cause of resistance before proceeding.

Disposal Instructions


















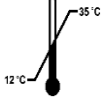



Dispose of all equipment, in appropriate containers. After use, this product may be a potential biohazard. Handle and dispose of in accordance with

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accepted medical practice and applicable local, state and federal laws and regulations.

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								

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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.