ASTER MEDISPRO PRIVATE LIMITED

Instruction for Use

TURP Electrode

Device Description

A TURP electrode is a specialized instrument used for the ablation and coagulation of prostate tissue during transurethral resection. The configurations available include:

Family	Channels	Degrees	Types	Length (CM)	variants	For Manuf.
TURP Electrode (TE)	24 27	30	Monopolar Bipolar	30bg q	Single Stem (SS) Double Stem(DS)	Storz (S) Wolf (W) Olympus (O)

Intended Purpose

TURP Electrodes are indicated for the ablation/coagulation of soft tissue and is intended for use with compatible resectoscope. This device is a monopolar electrode designed to deliver radio frequency energy that is supplied by an electrosurgical generator cleared for medical use.

Intended User

This device is intended for the coagulation of soft tissue during surgical procedures. It must be used only by qualified urologists trained in surgical techniques and authorized by the Competent Authority in the country where they practice. The device is for professional use only in controlled clinical or surgical environments.

Medical Conditions to be Treated

- Ablation and coagulation of soft tissue in the prostate
- Surgical management of benign prostatic hyperplasia (BPH)
- Relief of urinary obstruction caused by prostatic tissue overgrowth
- Restoration of normal urinary flow in patients with lower urinary tract symptoms (LUTS) associated with BPH

Performance Characteristics of the Device

The TURP Electrode is a monopolar electrode intended for use with a compatible resectoscope, and an electrosurgical generator cleared for medical use. It delivers radiofrequency energy to perform cutting and coagulation of prostatic tissue during transurethral resection of the prostate (TURP). The electrode is designed to provide precise energy delivery, ensuring effective tissue resection and haemostasis while minimizing collateral damage. Its construction supports consistent performance, surgical control, and enhanced safety throughout the procedure.

Indication

Persistent lower urinary tract symptoms (LUTS) or bladder outlet obstruction (BOO) not relieved by medications. Requiring drainage, especially if accessible via the urethra. Associated with obstruction

Contraindications

Contraindicated in patients with active local/systemic infection, uncorrected coagulopathy, or conditions where electrosurgery is inadvisable. Potential complications include thermal injury, hematoma, dissection, perforation, or patient discomfort.

Precautions, Warnings & Complications

- Carefully read all instructions for use and product labelling. The device shall only be applied for its intended use and in accordance with these instructions.

Caution: 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.

Warning: All components of the TURP Electrodes are for single use only.

Caution: Do not use the device if there is any indication that the sterility of the device has been compromised.

Warning: All medical staff should carefully review product labelling and instruction sheets before using this device. Inappropriate use of the instrument could adversely affect the procedure or cause injury to the patient and/or surgeon.

- Refer to the applicable operating and maintenance manual for the resectoscope and electrosurgical generator being used.
- This device should only be used by a physician who is familiar with the use of electrosurgical instruments, devices and power generators. Consult the medical literature regarding techniques, complications and hazards prior to any endoscopic procedure.
- Do not bend or change the angle or shape of the distal end. Doing so may cause poor function, damage to the resectoscope and injury to the physician and/or the patient.
- Power settings vary greatly depending on the surgeon's preferences, technique, type of electrosurgical generator used and tip style. The maximum rated voltage for this device is 3000 Vp-p (AC). As a general guideline, the following power settings can be used.
- In the "cut" mode, the power settings should be started low and increases gradually until the desired electrosurgical effect is achieved. Never exceed 280 watts.
- In the "coagulation" mode, the power setting should be started low and increased gradually until the desired electrosurgical effect is achieved. Never exceed 200 watts. Caution must be taken to prevent arcing on high coagulation settings.
- If there is little or no tissue effect, check the generator, power cables, patient ground and the device.

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- Constant irrigation is required throughout the procedure. The distal tip of the device should be kept in view and submerged in the irritant at all times
- CAUTION - Only non-conductive irrigants should be used.
- Immediately discontinue use if breaks or fractures appear in the device. These conditions may allow undirected emission of electrical energy, rendering the device useless and potentially causing harm to surrounding tissues.
- Do not use electrode if there are breaks, scratches, and cracks in the insulation on the electrode. Use of the electrode with damaged insulation may cause unintended electro surgical burns.
- Care should be taken to avoid severe impacts, side stresses or bends at sharp angles.
- When endoscopic device are used together, ensure that any isolation or ground is not violated.

Intended Patient Population

The TURP Electrodes can be used in patients of all age groups based on doctors' decision.

Shelf-life of the Product

The shelf life of the TURP Electrodes is 3 years (Indicated on product label with the use-by symbol and date). Store the TURP Electrodes at dry, cool place at 12-35°C. Avoid extended exposure to light.

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

- The TURP Electrodes 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 colour.
- If the sterile package is damaged or possibly opened, do not use. Contact "Distributor" and replace the product.
- The TURP Electrodes are packed single. Product in each pack must be utilized immediately when opened. Product should not be re-sterilized.

Directions for Use

- Suggested instructions for using TURP Electrodes:
  - Remove the device from the package and Open at the v notch/Open here position & examine it for damage. Do not use if there are visible signs of damage, or if insulation is not intact.
  - Assemble the working element and resectoscope.
  - Insert the device into the working channel of the resectoscope.
  - Ensure that the electrode is securely locked in to position by pulling carefully on the electrode stabilizer sleeve (if applicable). Do not squeeze the stabilizer sleeve.
  - Attach resectoscope to the electrosurgical generator.
  - Insert combined assembly into the resectoscope sheath and position at the point where initial application of electrical energy will be delivered.
  - The electrosurgical generator should be set at power levels consistent with standard ablation/ resection procedures.
  - Maintain constant irrigation through the resectoscope using sterile irrigant. Keep the distal tip of the device in view and submerged in the irrigant at all times.
  - If tissue adheres to the working end, cleaning can be accomplished by switching to a coagulating setting of 200 watts maximum and engaging current without tissue contact. The working end needs to be fully submerged in irrigation solution.
  - Duration of contact with the body is 1 day.

Removal Instructions

Retrieve cystoscopically by gently pulling on electrodes or retrieval line with grasping forceps or equivalent. If resistance is encountered during removal of the electrodes, 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 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
REF	Catalogue Number	UDI	Unique Device Identifier	2 STERILIZE	Do not re sterilize	CC	Country of Manufacture	MD	Medical Device
	Manufacturer		Date of manufacture		Keep Dry		Caution		Single Sterile barrier system with protective packaging inside
LOT	Batch Code		Use by Date		Keep Away from Sunlight		Do not re-use	75% 30%	Humidity Limit
STERILE EO	Sterilized using ethylene oxide		Consult Instructions for Use	35 °C 12 °C	Temperature Limit		Do Not Use if Package is Damaged		

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Bibliography

- Indications: https://www.ncbi.nlm.nih.gov/books/NBK560884/
- 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.