MYSORE WIFILTRONICS

INSTRUCTIONS FOR USE
HF BIPOLAR UROLOGY ELECTRODES

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Read all instructions prior to use.

DESCRIPTION OF SYMBOLS USED	
Symbol	**Description**
	Manufacturer
	Date of Manufacture
	Use-by date
STERILE EO	Sterilized using Ethylene Oxide
	Do not re-use
	Do not resterilize
LOT	Batch Code
	Keep away from sunlight
	Keep dry
	Caution
	Type BF applied parts
	Do not use if package is damaged and consult instructions for use
REF	Catalogue Number
	Consult instructions for use
MD	Medical Device
	Single sterile barrier system with protective packaging inside

Manufactured in India
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INTENDED USE:
The HF Electrodes are single use electrosurgical electrodes designed and intended for use in endoscopic resection / surgical procedures for the resection, ablation, vaporization, enucleation or removal of soft tissue and coagulation where hemostasis is required in combination with a compatible surgical instrument and an electrosurgical generator.

DESCRIPTION:
HF Bipolar Urology Electrodes are High Frequency, Electrosurgical, Active, Non-implantable Bipolar Electrode for endoscopic Urogenital procedures. The electrodes consist of a Loop head (active tip) made of Tungsten, Tungsten Alloy or Stainless steel. PTFE Tubes and Ceramic Tube for insulation. Guide, SS tubes and Boot for guiding, locking purpose to respective resectoscope. The active tip has a variant that consists of Loops, Balls, Bands, Needles, Rollers, Collins Knife, Buttons etc.

MATERIALS:
The electrodes are manufactured from Bio compatible Tungsten, Tungsten Alloy, Alumina Oxide, medical grade Stainless steel and Polytetrafluoroethylene (PTFE).

INDICATIONS FOR USE:
The Electrodes are indicated for use in the prostate, bladder, bladder neck, for the treatment of Benign prostate hyperplasia (BPH), Bladder tumor, and Bladder neoplasms. The procedures for which the devices can be used include Transurethral Resection in Saline (TURiS), Transurethral Resection of the Prostate (TURP), Transurethral Vaporization of the Prostate (TUVP, TUVRP, TUVIS), Transurethral Enucleation of the Prostate (TUEP), Transurethral Incision of the Prostate (TUIP), Transurethral Resection of Bladder Tumors (TURBT). These devices are intended to be used in an irrigated environment (0.9% NaCl).

CONTRAINDICATIONS:
There are no known contraindications. The use of electro surgical instruments is contraindicated when, in the judgment of the physician, their use would be contrary to the best interest of patient.

DEVICES APPLICABLE:
HF Bipolar Urology Electrode variants as mentioned
- Bipolar Single Stem & Double stem- Compatible to Storz resectoscopes
- Bipolar-Compatible to Olympus resectoscope
- Bipolar- Compatible to Wolf resectoscope
- Bipolar- Compatible to Gyrus Acmi resectoscope.

CLINICAL BENEFITS:
- Improves urinary flow and lower urinary tract symptoms.
- Enables effective hemostasis.
- Effective bladder tumor resection with comparable oncological outcomes.
- Minimal obturator nerve reflex.
- Minimises the risk of fluid overload and postoperative hyponatraemia.

PERFORMANCE CHARACTERISTICS:
- Delivers high-frequency energy between closely spaced electrodes.
- Confines current to the target tissue only.
- Compatible with isotonic saline irrigation.
- Enables controlled cutting and coagulation.
- Minimises lateral thermal spread.

INTENDED PATIENT POPULATION:
HF Electrodes Bipolar Urology are intended for use in adult male patients undergoing transurethral urological endoscopic procedures.

INTENDED USERS:
HF Electrodes Bipolar Urology are intended to be used by trained and qualified healthcare professionals, specifically urologists, during urological procedures.

WARNINGS:
1. These devices are for single use ONLY. Discard after single use.
2. Do not reuse, reprocess, or re-sterilize. Reuse, Reprocessing or Re-sterilization may compromise the performance and safety of the loop. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
3. Never reuse any electrode even if it appears unmarked or undamaged. Reuse of the electrodes may result in reduced mechanical performance, malfunction, or failure of the device. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Any electrode that has been used/ opened must be discarded. Use only new electrodes for each procedure.
4. The electrodes are provided terminally sterile using an Ethylene Oxide (EO) sterilization process. Do not use if the package is opened or damaged when received. Prior to use, inspect for damage. Do not use if components show signs of damage.
5. Store the device in its original unopened package in dry and clean conditions at room temperature and only open the package immediately before use. Avoid direct contact with sunlight, high temperature, and high humidity.
6. Use the device within the expiry date as mentioned in the label.
7. Use of this device for any other purpose other than the stated intended use is neither advised nor recommended.
8. Always refer to the applicable operating and maintenance manual for the resectoscope and electrosurgical system operator's manual for proper use and setup. Ensure all manufacturers' precautions have been observed. The inspection, handling, and use of electrosurgical devices are the user's responsibility.
9. Never Install and operate the equipment where there is a risk of flammable gasses. Do not perform electro surgery in the presence of flammable anaesthetics or other flammable gasses, near flammable fluids or objects, or in the presence of oxidising agents, as it could result in fire.
10. Dispose of this device according to standard institutional guidelines and norms for bio-hazardous medical waste, in conformance with state/national laws and regulations.

CAUTIONS AND PRECAUTIONS:
1. All medical staff must review instructions before use. Inappropriate use of the device may adversely affect the procedure or may cause injury to the patient and / or surgeon.
2. Follow standard operation room procedures while using these devices.
3. This medical device should only be used by a qualified surgeon, who are familiar with the use of these electrosurgical instruments, devices, and electrosurgical generators. Consult the medical literature regarding techniques, complications, and hazards before any endoscopic procedure
4. Proper care and maintenance is very important for efficient and safe operation of surgical equipment, instruments used with device.

5. Select the appropriate variant of electrode based on the surgery requirements
6. Prolonged use or usage more than necessary for treatment may compromise patient safety.
7. Although most modern cardiac pacemakers are resistant to interference by extraneous electromagnetic signals, several incidences of asystole and cardiac arrest have been reported when electrosurgery is used in patients with pacemakers. Implanted pacemaker function can be disrupted. Consult pacemaker manufacturer's literature before using HF equipment.
8. Use compatible Resectoscopes. Failure to use the correct Resectoscope working unit with the correct HF generator may cause injury to the user or patient or damage to instruments.
9. Alteration to the distal tip may result in contact with the resectoscope working unit resulting in current leakage, burns and damage to user, patient or equipment.
10. The loop is a delicate device and should be handled carefully at all times.
11. Do not bend or change the angle of the loops. Never try to bend irregular cutting loops or other electrodes into shape. Care should be taken to avoid severe impacts, side stresses or bends at sharp angles.
12. Immediately discontinue use if wear and tear is observed, or if there is a break or fracture in the device. If the instrument is damaged or does not function properly, replace it.
13. Cables conduction plugs & connectors should be regularly checked for damage. If damaged, replace before use.
14. Poor electrical conduction and loose connections in the instrument and HF Generator may result in poor performance, damage to device & instrument, and injury to patient or surgeon.
15. Connect accessories to electrosurgical unit (ESU) as recommended in the (ESU) instructions for use. Never connect accessories or disconnect accessories from an (ESU) while the system is activated. Failure to observe this precaution or handling of these connections while the system is activated may result in injury or electrical shock to the patient or operating room personnel.
16. Do not connect any applicable RF Bipolar Cable to an A/C power source; connection of exposed pins to an A/C power source may pose a risk of serious injury or death. Only connect to an Electro Surgical Unit (ESU) that has been cleared for medical use for procedures.
17. Use of separate settings for cutting and coagulation will result in better performance.
18. Compatible generators to any of the electrodes include generators with output specifications that meet the following criteria: 100-120/220-240 V, ~50-60 Hz / 1000VA, 10-12 A, Int 10s/30s, with output frequency 310-380 KHz.
19. Use of the device with a damaged insulation may cause unintended electrosurgical burns.
20. Place active electrodes in a non-conductive dedicated instrument holder or in a clean, dry, non-conductive area away from the patient when not in use. Inadvertent contact with the patient may result in burns. Contact with drapes may cause a fire.
21. To prevent burns caused by HF current, use conductive irrigation fluid (0.9% NaCl) and conductive lubricant only. Continuous irrigation throughout the procedure is needed to prevent burns and provide a medium for which to operate providing both adequate visualization and operative conditions in which the electrodes may fire.
22. Ensure that the distal tip of the device must be immersed in distension media - saline solution and should be kept in view during the procedure.
23. The risk of injury to the patient and/or user. Do not activate the release electrode button when operating the instrument. If HF current is activated, spark discharge may occur, and the instrument may be damaged.
24. There is a risk of damaging the electrode / instrument when attaching / removing the electrode into the instrument. Ensure proper methodology of the instrument and do not to

push / pull the electrode too forcefully in the working element.

POTENTIAL COMPLICATIONS:

1. Complications include infection, thermal damage, and perforation, patient discomfort during or after energy application.
2. Undesirable side-effects include post-operative urinary retention, Transient urinary incontinence and Hematuria.
3. During TURBT, there exists a potential complication of bladder explosion due to presence of combustible gasses, from anaesthetics, alcohol or use of other inflammable substance based disinfectants, improper use of evacuators which results in excessive air bubble accumulation and entry of atmospheric oxygen or bowel gas.
4. Interference with pacemakers and monitors, neuromuscular stimulation including ventricular fibrillation, accidental burns, and the potential for the transmission of infection.
5. Other mechanisms of skin burns involve the ignition of paper drapes or antiseptic solutions, particularly alcohol, used in skin preparation. If alcohol is used to prepare the skin prior to surgery, time should be allowed to ensure that it has fully evaporated prior to draping the patient
6. Immediately after use reprocess the resectoscope working element following the manufacturer's instructions. Improper or incomplete reprocessing can cause infection of the patient or medical personnel.

INSTRUCTIONS FOR USE:

1. Check the cables and connections for electrical conduction. Contacts of cables which have been immersed in disinfectants should be wiped clean.
2. Cables, conduction plugs and connectors should be regularly checked for damage. If damaged, replace before use.
3. Internal contacts such as locking mechanism of the resectoscope should be free of debris, foreign objects, and moisture. These contacts should be cleaned with a sterile swab and air dried. Failure to do so may result in current leakage, damage to device and instrument, injury to patient or surgeon.
4. Carefully remove the Electrode from the package and inspect for damage. Visually inspect the instrument prior to use. Electrodes are delicate devices and should be handled carefully at all times without deforming any part of it. Warped electrodes, defective insulation and broken, cracked, or irregular cutting loops represent a danger for both the patient and the surgeon and must not be used.
5. Following the instruction of the resectoscope manufacturer, assemble the resectoscope lens and the working element.
6. Insert the electrode. Introduce the electrode's proximal end into the distal opening of the working element's electrode guiding tube. Advance the electrode into the working element until it comes to a stop. Make sure that the telescope is guided through the electrode's guide tube. The electrode clicks into position. Ensure the electrode is properly fitted and that the distal end is not touching any metal parts of the resectoscope unit.
7. Check locking of the electrode. Grasp the electrode at the guide tube. Pull in the distal direction. The electrode must be securely fixed.
8. Attach an electrosurgical cord to the connector end of the working element until the cord receptacle sleeve connects securely against the connector cup on the compatible working element.
9. Connect the foot switch to the ESU using proper cable connector
10. Confirm that the Electrode is firmly in place by gently pulling the barrel of the electrode, and by actuating the working element to its full length, and relaxing back emulating one full resection motion. If the electrode fails to return properly, check the connection, and try again.
11. Use saline (0.9% NaCl) as the irrigant for Urological Bipolar applications.
12. Activate the current, by pressing the footswitch, only when the element is completely engaged in the sheath and the electrode is in contact with the tissue. If there is little or no tissue effect, check the irrigant and ensure that it is a conductive solution such as Sodium Chloride (0.9%NaCl), electrosurgical unit (ESU) connection, working element cable connection plugs for electrical conduction, power cables and the device is not covered with tissue or by a calcification.
13. As a general guideline, start with a lower power setting and gradually increase to achieve the desired effect. Operate the loop at the lowest satisfactory HF Generator settings. The user should only activate the device when it is in contact with the target tissue or is in a position to deliver energy to target tissue by fulguration.
14. During the procedure, periodically check the distal tip insulation. Burnt, worn or damaged insulation may result in current leakage.

Resection of Bladder Tumors:

1. Use only electrodes with wire size of 180µ for resection of Bladder Tumors
2. Adjust the cutting current accordingly and move the electrode slowly.

Vaporization of the prostate:

1. Use only electrodes compatible with vaporization. Adjust the cutting current for Vaporization and move the electrode slowly, which will result in a smooth surface of the vaporized tissue. Place the patient's head in a slightly elevated position. This will prevent the collection of air bubbles in front of the resectoscope.
2. As current is passed using a bipolar generator, a voltage gradient is created between the bipolar electrode active and return components that vaporize the sodium chloride solution resulting in small ionized bubbles that produce plasma. This plasma of activated sodium ions is visible as a bright glow on the loop.
3. The energy of the plasma transfers to the tissue causing locally restricted vaporization and the loop resects the tissue.
4. After use, remove the electrode from the working element.
5. Handle and dispose of the device following standard acceptable practices and state laws and regulations.

STERILITY:

Product supplied either sterile or unsterile. Check Indicator on Tyvek pouch for Sterility status. Recommended to carry out EO Sterilization before use if supplied as unsterile. Autoclave, Gamma Radiation and other methods of sterilization are not Recommended.

SUPPLY:

One product per pouch

STORAGE:

Store in a cool, dry and clean environment.

DISPOSAL:

This device has been designed for single use only. Dispose of this device according to standard institutional guidelines and norms for bio-hazardous medical waste, in conformance with state/national laws and regulations

PRODUCT COMPLAINTS:

Communicate suspected defect in product quality, identity, durability, reliability, safety, effectiveness and/ or performance directly to Mysore Wifiltronics Pvt Ltd. e-mail: qa@wifiltronics.com, commercial@wifiltronics.com When filing a complaint, please provide the device name(s), catalogue number(s), lot number(s), your name and address, the nature of the complaint, and patient case number. Sterilize and return all device(s) to Mysore Wifiltronics Pvt Ltd distributor.

COMPETENT AUTHORITY:

State Agency of Medicines, Department of Medical Devices
Nooruse, 1, Tartu, Estonia
Email: mso@ravimiamet.ee
Telephone: +372 737 4140

Note: Any serious incident that has occurred in relation to the device should be reported to Mysore Wifiltronics Pvt Ltd and to the competent authority of the Member State in which the user and/or the patient is established. List of competent authorities.

FURTHER INFORMATION:

For any additional information, technical help or customer service contact Mysore Wifiltronics Pvt Ltd email: info@wifiltronics.com, Mob No: +918431436155.

WARRANTY:

Mysore Wifiltronics Pvt Ltd warrants that highest reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient diagnosis, treatment, surgical procedures, and other matters beyond manufacturer's obligation under this warranty is limited to the repair or replacement of this instrument and shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. Mysore Wifiltronics Pvt Ltd neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Authorized Representatives of Mysore Wifiltronics Pvt Ltd or its distributors are not allowed to change the conditions mentioned before to extend liability or to assume any additional product related obligations. Product is subject to change without notice. No person has the authority to bind Mysore Wifiltronics Pvt Ltd to any representation or warranty except as specifically set forth herein. Mysore Wifiltronics Pvt Ltd will not be responsible for any direct, incidental or consequential damage resulting from re-use of the product.

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