













 MYSORE WIFILTRONICS
INSTRUCTIONS FOR USE ELECTRODES- BIPOLAR GYNEACOLOGY
Doc No: D-MKT-HG-IFU-01 Rev : C Prepared Date: 17-10-24

Read all instructions prior to use.

EXPLANATION OF SYMBOLS	
Symbol	Explanation
	Manufacturer
	Date of Manufacture
	Use-by date
	Sterilized using Ethylene Oxide
	Do not re- use
	Do not re-sterilize
	Batch Code
	Keep away from sunlight
	Keep dry
	Warning
	Type BF applied parts
	Don't use if packing is damaged
	Catalogue Number
	Refer instruction manual

Manufactured in India
MYSORE WIFILTRONICS PVT.LTD
 1-FA Hootagalli Industrial Area,
 Mysore, Karnataka - 570 018
 Email: info@wifiltronics.com
 Website: www.wifiltronics.com
 Mfg License-MFG/MD/2021/000220
 Endorsement No-1



INTENDED USE:

The HF Bipolar Gyneacology Electrodes are single use electrosurgical electrodes designed and intended for use in Gyneacological surgical procedures for the resection, ablation, or removal of soft tissue and coagulation where hemostasis is required, for use in the uterus and cervix, in combination with a compatible Hysteroscope and a electrosurgical generator.

DESCRIPTION:

HF Bipolar Gyneacology Electrodes are High Frequency, Electrosurgical, Active, Non-implantable Bipolar Electrode for endoscopic Gyneacological procedures. The electrodes consists of a Loop head (active tip). PTFE Tubes for insulation. Guide, SS tubes and Boot for guiding, and locking purpose to respective hysteroscope. The active tip has variants that consists of Loops, Needles, Ball etc.

MATERIALS:

The electrodes are manufactured from Bio compatible Tungsten, medical grade Stainless steel and Polytetrafluoroethylene (PTFE).

INDICATIONS:

The specific gyneacological indications include use in the Uterus and cervix. The specific treatment indications include use for Uterine septum dissection, Synechia, Polypectomy and myomectomy (especially pedunculated myoma), Adhesiolysis, and coagulating minor bleeding, coagulating endometriotic lesions, fibroids. The procedures for which the devices can be used Hysteroscopy and Transvaginal Endoscopy (TVE). These devices are intended to be used in an irrigated environment (0.9% NaCl).

CONTRA INDICATIONS:

There are no, known contra indications. The use of electro surgical instruments is contra indicated when, in the judgment of the physician; their use would be contrary to the best interest of patient.

DEVICES APPLICABLE:

HF Bipolar Gynecology Electrode variants as mentioned

- Bipolar Hysteroscopy electrodes compatible with respective hysteroscopes.

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 re-sterilization 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 re-sterilization 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 it if the package is opened or damaged when received. Prior to use, inspect for damage. Do not use components if 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 dates 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 Hysteroscope and electrosurgical system

operator's manual for proper use and setup. Ensure all manufacturer's 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 many 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 Hysteroscopes. Failure to use the correct Hysteroscope 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 Hysteroscope working unit resulting in current leakage, burns and damage to user, patient or equipment.
10. The loop is a delicate device and should be always handled carefully.
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, 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 instrument when attaching the electrode, make sure not to push it too forcefully into the working element. Otherwise, the electrode may be damaged.

POTENTIAL COMPLICATIONS:

1. Complications include infection, thermal damage, dissection and perforation, patient discomfort during or after energy application.
2. The potential for the explosion of combustible gasses, anaesthetics or bowel gas, interference with pacemakers and monitors, neuromuscular stimulation including ventricular fibrillation, accidental burns, and the potential for the transmission of infection.
3. 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
4. Immediately after use reprocess the Hysteroscope working element following the manufacturer's instructions. Improper or incomplete reprocessing can cause infection of the patient or medical personnel.

INSTRUCTION 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 Hysteroscope 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 Hysteroscope manufacturer, assemble the Hysteroscope 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 Hysteroscope 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 Gyneacology 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.
15. After use, remove the electrode from the working element.
16. Handle and dispose of the device following standard acceptable practices and state laws and regulations.

STERILITY:

Product supplied EO sterile

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. Notify Mysore Wifiltronics Pvt Ltd immediately of an incident resulting in patient death or serious injury.

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. Distributors of Mysore Wifiltronics Pvt Ltd 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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