INSTRUCTIONS FOR USE
BP105-M, Medtronic/Valleylab™ Compatible
HAND ACTIVATED DISPOSABLE BIPOLAR ELECTROCAUTERY CORD

DO NOT OPERATE THIS DEVICE UNTIL YOU HAVE READ THESE INSTRUCTIONS

WARNING, CAUTION, AND NOTE

These instructions for use utilize the following symbols and special text to emphasize important information.

WARNING: Warnings are intended to alert user with the importance of following the correct operating procedures, where risk of injury to the patient or system user exists.

CAUTION: Cautions are intended to alert user to the importance of following the correct operating procedure to prevent damage to the system.

NOTE: Notes contain information concerning the proper use of the system and/or correct execution of a procedure

Read the Instructions for Use and keep them in a safe place.

WARNING: Failure of the cord could result in unpowered electrosurgical forceps. Failure of the hand switch will result in current always present OR current never present. Non-function of the cord may cause interruption of surgery. A backup cord should be available for use.

WARNING: Pulling on or adjusting the cable fall during surgery may result in the accidental detachment of the cable from the generator output power connections. Reseat cable connections and test for correct output prior to continuing use.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only

CAUTION: This product is disposable and is supplied **STERILE**. Prior to the expiration date, contents are sterile if the package has not been opened or damaged STERILE EO

INDICATIONS FOR USE:

BIPAD® Hand Activated, Disposable Bipolar Electrocautery Cords are intended to connect an electrosurgical device to an electrosurgical generator. They are indicated for use with bipolar forceps during general surgical procedures.

CONTRAINDICATIONS:

The Hand Activated Disposable Bipolar Electrocautery Cord should not be used for laparoscopic procedures.

WARNING: INSPECT instruments and cables for damage prior to use. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator. If any defects are found, discontinue use.

WARNING: INSPECT all cord connections (electrosurgical generator and surgical forceps) before use. Ensure that the accessories function as intended. Improper connection, or intentionally using with incorrect generator, may result in arcs, sparks, susceptibility to electromagnetic disturbance, accessory malfunction, or unintended surgical effects.

WARNING: Potentially hazardous conditions may exist when accessories are not appropriate for the type of generator output used. If unusual operating characteristics develop or are observed during procedures, including electromagnetic disturbance, use of the product should be discontinued.

CAUTION: Electrosurgical leads (active or bipolar) should be positioned so that they cannot come into contact with the patient or other leads.

DEVICE DESCRIPTION:

The Hand Activated Disposable Bipolar Electrocautery Cord is designed to be compatible with the MEDTRONIC / VALLEYLAB™ FORCEX Electrosurgical Generators where a cord or footswitch would typically be utilized in surgical procedures to transmit the electrical current from the generator to the

electrosurgical forceps. Please refer to the generator labeling to determine the intended connections and specific use of the cord.

The BIPAD® Hand Activated Disposable Bipolar Electrocautery Cord is an electrosurgical accessory designed to be universal when used with standard bipolar non-irrigating two-prong connector forceps. When the switch assembly is connected via the power cord to an electrosurgical generator, **depression of the switch button results in the activation of the coagulation output of the generator.** The hand switch is a momentary SPST button switch. Generator current is only delivered while the BIPAD® switch is pressed (on state). The "as delivered" state of the switch is "OFF".

INTENDED USER:

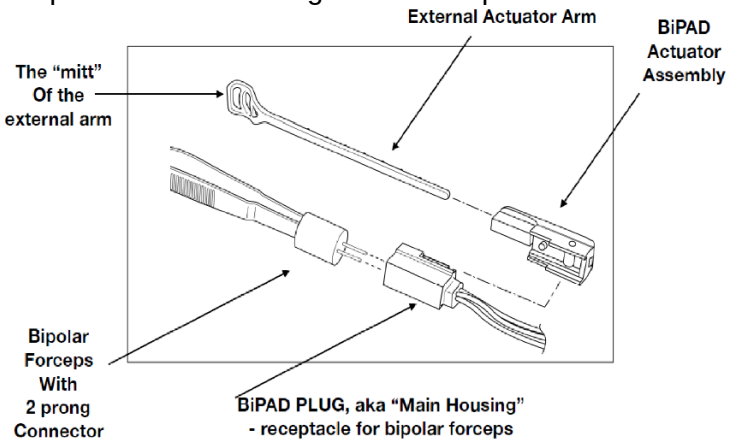
The BIPAD® Hand Activated Disposable Bipolar Electrocautery Cord is intended for use by qualified surgeons and qualified surgical assistants that are familiar with performing traditional open surgical procedures and techniques utilizing electrocautery devices.

NOTE: This product is designed for use with MEDTRONIC/VALLEYLAB™ FORCEX Electrosurgical generators only. No additional accessories or items are needed for this connection.

WARNING: CORD IS SUPPLIED STERILE AND IS INTENDED FOR SINGLE USE ONLY. DO NOT clean or re-sterilize. After one use - DISCARD immediately!

WARNING: DO NOT USE THIS PRODUCT IF STERILE PACKAGE IS DAMAGED OR SEAL IS BROKEN IN ANY WAY.

NOTE: Can be used with or without hand switch. If the hand switch is not used, a foot switch (foot pedal) is required to control the generator output. See Instructions for Use for the generator.



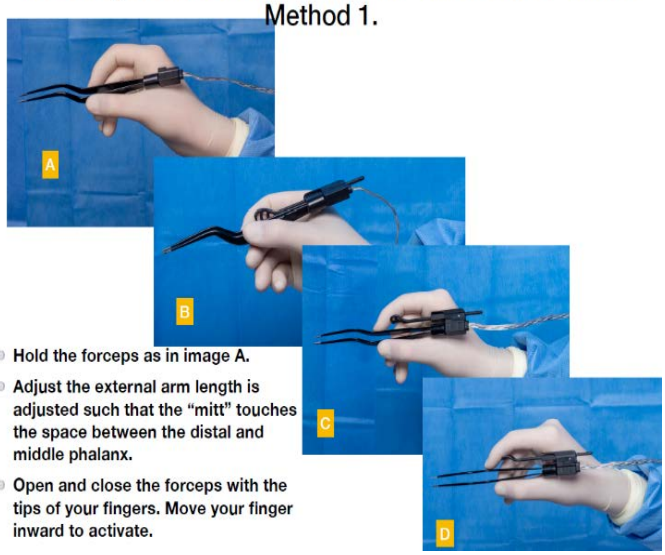
The BIPAD® Hand Activated Disposable Bipolar Electrocautery Cord has a hand switch integrated into the actuator assembly of the cord (see below). The ergonomically designed actuator arm fits the inner curve of the surgeon's finger allowing the surgeon to hold the forceps in their usual, preferred manner. The external arm is used to activate the hand switch. **To stop the coagulating output of the generator, release pressure on the actuator arm (or release foot switch pedal).**

The "mitt" at the top of the external arm is usually positioned facing the forceps (as shown).

NOTE: The forceps can be attached in either direction to accommodate right or left-handed use.

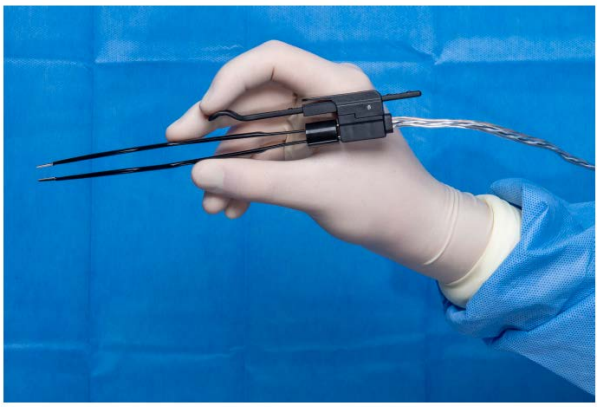
Two ways to hold and activate the BiPAD hand switch.

Method 1.



- Hold the forceps as in image A.
- Adjust the external arm length is adjusted such that the "mitt" touches the space between the distal and middle phalanx.
- Open and close the forceps with the tips of your fingers. Move your finger inward to activate.

Method 2.



- Hold the forceps as above.
- Use your forefinger to activate the BiPAD switch.

ATTACHING THE FORCEPS

If you are RIGHT-handed, hold the BIPAD® plug with the actuator assembly to your RIGHT and insert the 2-prong forceps.
If you are LEFT-handed, hold the BIPAD® plug with the actuator assembly to your left and insert the forceps

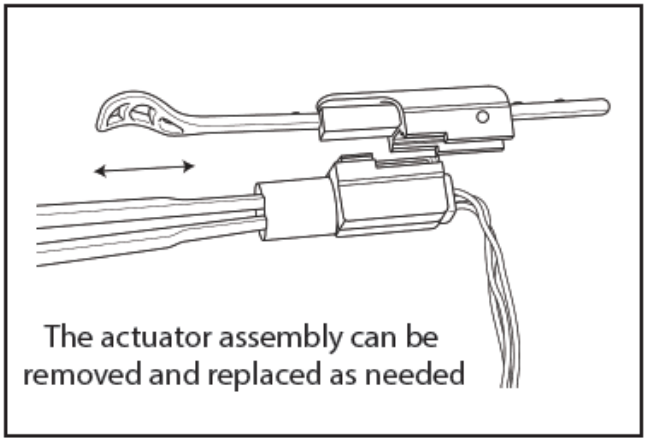
ADJUSTING FIT

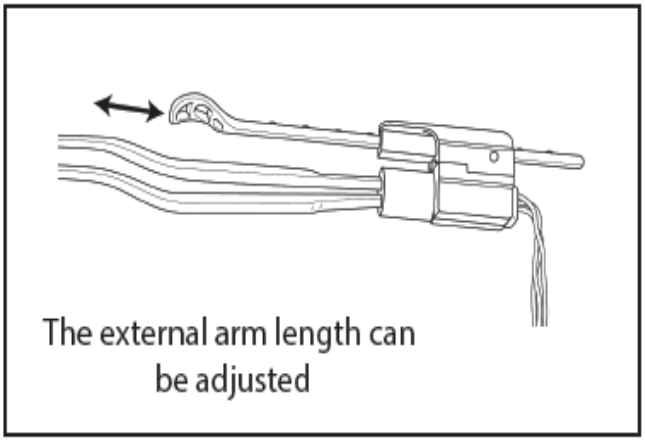
The angle of the external arm can be changed by grasping both ends of the arm (if disengaged from the housing) or grasping the mitt end and bending as desired up to a maximum of 90° to fit user hand morphology or preferred hold on the forceps. Up to two bends (up to 90°) can be accomplished without damaging the external actuator arm.

⚠ **WARNING:** DO NOT USE ANY PART THAT APPEARS DEFECTIVE. Replace if the actuator arm breaks or bends excessively in use.

The external arm length can be adjusted by pushing/pulling the external arm through the actuator housing.
-Hold the BIPAD® plug with one hand and the external actuator arm with the other.
-Slide the arm into the BIPAD® actuator assembly to shorten, or outward to lengthen or remove.
An auditory click will be heard as the arm is moved. Wiggle the actuator arm (front to back) to ensure the arm is fully seated after adjusting and prior to use.

⚠ **WARNING:** When removing the actuator assembly from the cord ensure that you are facing away from the patient.





⚠ **CAUTION:** Avoid kinking or sharply bending the cables or damaging the insulation. Failure to do so may result in broken wires causing cable failure, electrical shock, or susceptibility to electromagnetic disturbance.

⚠ **CAUTION**: The connectors of this cord are susceptible to ingress of liquids. At switch end, the cord could suffer damage and/or harmful effects if immersed (CODE IP20).

⚠ **CAUTION**: Do not wrap the Hand Activated Disposable Bipolar Electrocautery around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

⚠ **CAUTION**: Dropping, dropping other items onto, mishandling, or mistreatment of the cord (packaged or unpackaged) could result in damage to the cord, switch, actuator assembly, or power connectors.

SETUP THE BIPAD® CORD DURING SURGERY:

⚠ **WARNING**: Connect adaptors and accessories (including this sterile cable and Y-connector) to the electrosurgical generator only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room staff.

1. Connect the NON-IRRIGATING Cord plug to the bipolar forceps ensuring that the forceps pins are fully seated into the cable receptacles
2. Insert the BIPAD® Medtronic/Valleylab™ compatible plug into the Medtronic/Valleylab™ bipolar generator.
3. The RF generator should be in close enough proximity to the surgeon that there is no risk of the cable connections being pulled out of the generator when the cable is fully extended during normal operation.

To activate the Bipolar mode from the generator, depress the hand switch on the Hand Activated Disposable Bipolar Electrocautery Cord, or depress the appropriate pedal on the bipolar footswitch.

WARNING: Connect Bipolar accessories to the Bipolar receptacle only, and Monopolar accessories into the Monopolar receptacle. Improper connection of accessories may result in inadvertent accessory activation or other potentially hazardous conditions.

WARNING: Accommodates only 2-prong standard surgical forceps. These forceps will insert into the BiPAD receptacle with minimal force. Do not insert non-compatible forceps into the BIPAD® receptacle.

WARNING: The forceps are considered an applied part (Type BF) when connected as directed. Refer to Forceps Instructions for use for applicable rating.

WARNING: Do not reuse or re-sterilize. Patient cross contamination and/or product malfunction may occur.

CAUTION: Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.

NOTE: BIPAD® Surgical disclaims any and all responsibility and liability concerning the use of this product or any component herein, if it is reused, abused, misused, damaged, or used contrary to the Instructions contained herein.

POWER

No power source or battery is provided with this device. Must be connected to a compatible high frequency surgical generator.
Cable voltage rating: 550 Vpeak (1100 Vp-p)
Duty Cycle: 6%
Rated Frequency: 400-470 KHz.

GENERATOR COMPATIBILITY

The subject device has been fully tested and are compatible with FDA cleared and marketed Electrosurgical Generators which will accommodate the standardized Medtronic style molded bipolar lead connector. These generators share the following characteristics of bipolar operations:

-Patient Circuit Isolated from Earth Ground

-**Electrical properties:**

- Nominal Operating Voltage: 100 – 240 VAC
- Nominal Operating Frequency: 50-60 Hz
- Output Power Variation (as a function of input variation) ≤8%

-**Output Characteristics**

- Mode: Bipolar
- Max Power (Watts): 50-80 W
- Output Tolerance: ≤20%
- Rated Load Ohms :100 Ohms
- Maximum Open Circuit Voltage Vp-p: ≤ 760 Vp-p
- Operating Frequency kHz: 400kHz - 495kHz
- Crest Factor Nominal @ Rated Load: 1.4 – 1.8

-**Power Consumption Maximum mains current** (100-120 VAC): Bipolar 1.3A-1.4A

CAUTION: Because of the variability of output voltages and modes form generator to generator, DO NOT USE the Hand Activated Disposable Bipolar Electrocautery Cord with generators having output voltages that exceed 1100Vp-p. Refer to the appropriate electrosurgical generator manual for indications and instructions on output characteristics to ensure that all safety precautions are followed.

CAUTION: Start at the lowest power setting and increase as necessary to achieve the desired effect.

Power setting guidelines may vary due to differences in surgical techniques, patients, electrodes, and surgical setup. Start at the lowest power setting and increase as necessary to achieve the desired effect. At the lowest power setting, test the forceps by pressing the generator's activating switch. If the generator fails to activate, check the forceps connection with the cable.

ELECTROSURGERY PRECAUTIONS

Refer to your electrosurgical system operator's manual for proper use and set-up. Ensure that all manufacturers' precautions have been observed. The inspection, handling and use of electro-surgical devices are the responsibility of the user.

WARNING: DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

WARNING: DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as ether and alcohol), as explosion may occur.

When using instruments in electrosurgery, keep the voltage/power as low as possible to achieve the desired effect.

WARNING: DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.

WARNING: When not using instruments place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

WARNING: Damage caused by misuse, overuse, or mishandling or wear may cause electrical shocks or burns to patient and/or user. If there is a break in the cable wire or the cable becomes otherwise electrically discontinuous, electrical shock may occur and may burn the patient/user or create a fire.

WARNING: If using irrigation near cable, care should be taken to ensure that the liquid does not enter the connection between the electrosurgical fitting and the cable. There is a high risk of electrical shock if liquid enters the fitting.

CAUTION: PROPER DISPOSAL of the Hand Activated Disposable Bipolar Electrocautery Cord possibly contaminated with blood, tissue, or other potentially infectious material presents a biological risk and must be discarded in a closable, leak-proof, puncture-resistant receptacle, that is adequately labeled (e.g., color coding or symbology) for easy identification as biohazard waste.

ADVERSE REACTIONS

Adverse events reported while using bipolar electrosurgical devices include inadvertent activation with resultant tissue damage at the wrong site and/or equipment damage.

WARNING: DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.

WARNING: The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.

WARNING: Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in open procedures.

ENVIRONMENTAL RECOMMENDATIONS

The equipment shall be operated, stored and transported under the following parameters and environmental requirements.

Conditions / Parameters	Operation	Storage	Transportation
Environment temperature	+16℃-+40℃	5℃-+40℃	-10℃-+55℃
Relative humidity	15%-80% Non-condensing	<90% Non-condensing	<90% Non-condensing

NOTE: Store in a dry, clean, relatively dust-free environment at a moderate temperature.

WARNING: Protect from long exposure to direct UV light and heat to maintain the sterile barrier.

NOTE: Device is intended to be used in a hospital, clinical, or outpatient surgical setting.

EMC COMPLIANCE

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Hand Activated Disposable Bipolar Electrocautery Cord. Otherwise, degradation of the performance of this equipment could result.

CAUTION: The Hand Activated Disposable Bipolar Electrocautery Cord has been tested and found not susceptible to typical electromagnetic disturbances for EM equipment. However, if power is lost or degraded due to extreme EM Disturbances discontinue use immediately.

CAUTION: The Hand Activated Disposable Bipolar Electrocautery Cord is a single cable. It is intended to be the only cable connecting the surgical forceps with the electrosurgical generator. No other accessories are intended to be connected or used in conjunction with this cord. Replace with other BIPAD® Surgical Hand Activated Disposable Bipolar Electrocautery Cords. Otherwise, an increase in electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Applicable Standards and Methods

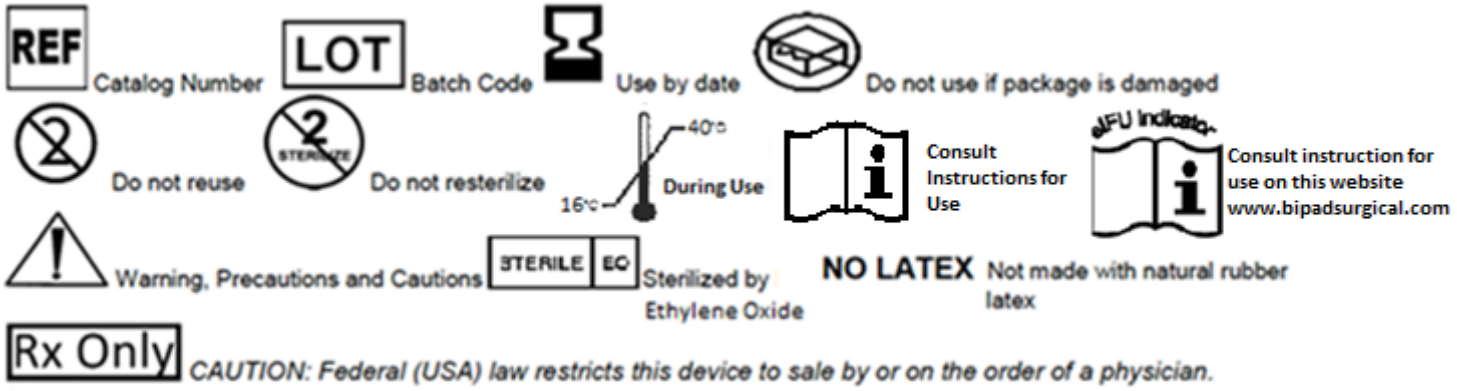
Standard	Method
IEC 60601-1-2 ed4.0 (2014-02)	CISPR 16
IEC 60601-2-2 ed6.0 (2017-03)	CISPR 16

Emissions and Immunity Test Levels

Immunity Type	Regulatory Acceptable Level	Power Input Voltage/Frequency (Configured for US/CA/EU)	EMC Environment
CISPR 11, Radiated Emissions	GISPR 11, Group 1, Class A	120VAC 60Hz, 230VAC 50Hz Mode: Standby Ready	This system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: ⚠ **WARNING:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals only.
IEC61000-4-2, Static Discharge (ESD)	±8kV Contact ±15kVAir	230VAC 50Hz Mode: Operating	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Mains power quality should be that of a typical commercial and/or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the system be powered from a UPS or a battery. NOTE: UT is the AC. mains voltage prior to application of the test level. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment. Separation distance to radio communication equipment must be maintained as indicated. Interference may occur in the vicinity of equipment marked with the symbol: There is no known performance degradation or interference due to conducted RF noise on the cord.
IEC61000-4-3, Radiated RF	3V/m 80-2700MHZ 1kHz 80% AM	230VAC 50Hz Mode: Operating	
IEC61000-4-4, Electrical Fast Transient/Burst	±1 kV Accessory (length is 3m or more)	230VAC 50Hz Mode: Operating	
IEC61000-4-6, Conducted RF	3Vrms 150kHz-80MHz 1 kHz 80% AM (6Vrms ISM) Accessory Only	230VAC 50Hz Mode: Operating	
Immunity to proximity fields	IEC 60601-1-2 Clause 8.10, Per Table 9	230VAC 50Hz Mode: Operating	
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

SYMBOLS USED in the IFU



REORDERING / CONTACT INFORMATION

To reorder or to obtain support for this product please use the following information

BIPAD® Surgical 110 Ocean Blvd Point Lookout, NY, USA 11569	Phone: 1-888-635-6381 www.BiPadSurgical.com
Technical Support	Support@BiPadSurgical.com
Ordering/Feedback	Support@BiPadSurgical.com

This product may be covered by one or more of the following patents: U.S. Pat. No. 9,433,460; U.S. Pat. No. 10,456,192; U.S. Pat. No. D778,442. Other U.S. and foreign patents pending. Patent: www.bipadsurgical.com/patents