PROGRESSIVE MEDICAL

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# PMI LAPSYSTEM™

## INSTRUCTIONS FOR USE

## REPOSABLE 5MM MONOPOLAR INSTRUMENTATION

**IMPORTANT INFORMATION – PLEASE READ BEFORE USE!**

Please read all information contained in this insert. The use of an instrument for a task other than that for which it is intended, incorrect handling, improper care, failure to adhere to all warning and precautions and misuse can lead to premature wear and/or have serious clinical consequences to the user or patient, such as injury, contamination, cross-infection, or death. Federal (USA) law restricts this device to sale by or on the order of a physician.

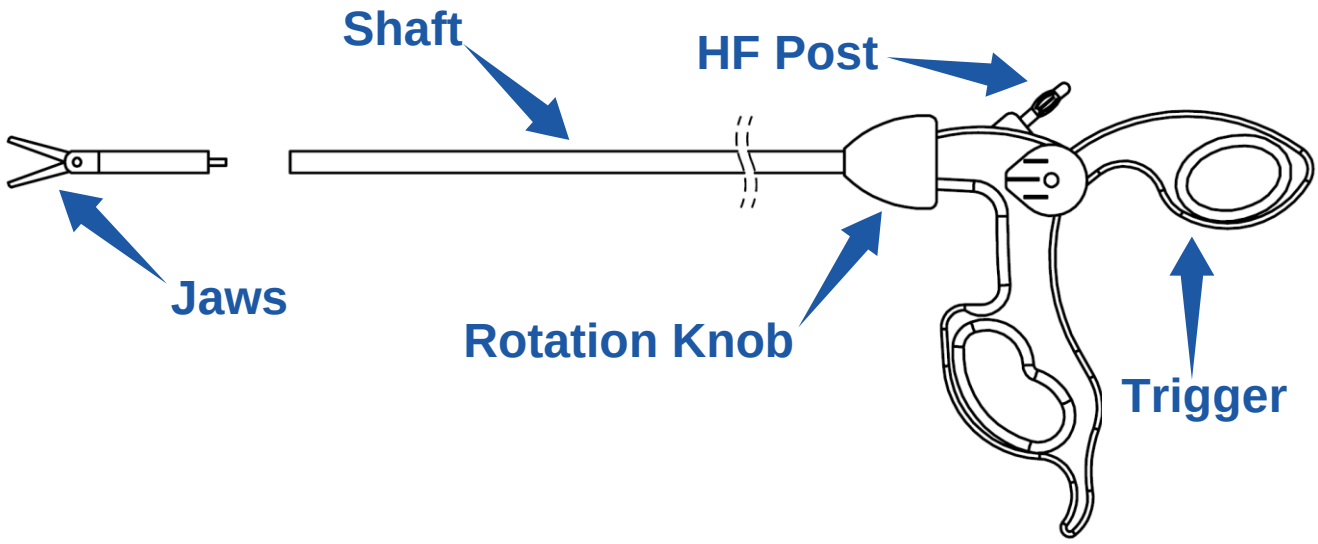
Before using, read the following information thoroughly. This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

### INDICATIONS FOR USE

The Disposable Monopolar Laparoscopic Tips and Reusable Handles are designed to cut, dissect, manipulate and/or cauterize various tissues during endoscopic/laparoscopic, general surgical procedures.

### DESCRIPTION

The Disposable Monopolar Laparoscopic Tips and Reusable Handles are sterile packaged single use monopolar attachments intended for use in combination with the Reusable Handle. Attachments include graspers, dissectors, and scissors designed to cut, dissect, manipulate and/or cauterize various tissues during endoscopic/laparoscopic, general surgical procedures. Devices are not made with natural rubber latex.



## CONTRAINDICATIONS

The use of laparoscopic and endoscopic products is contraindicated whenever endoscopic surgical techniques are contraindicated for any reason.

The Disposable Monopolar Laparoscopic Tips and Reusable Handles are NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transaction of the fallopian tube.

## WARNINGS & PRECAUTIONS

1. Endoscopic surgery should be performed only by physicians who are thoroughly trained in endoscopic techniques and failure modes, precautions, and corrective actions in the event of a failure. Consult medical literature and country specific regulations for specific techniques, complications, and hazards prior to the procedure.
2. Single-use (disposable) products are intended for single patient use only and may not be repaired, modified or re-processed – DO NOT RESTERILIZE.
3. Reusable products are provided NON-STERILE and must be cleaned and sterilized prior to and after each use. Cleaning and sterilization using any other method then specified may result in damage to the device and possible patient injury.
4. Failure to follow all transport, storage and handling instructions may lead to damage to the device or packaging.
5. Prior to use, carefully examine the packaging and instrument for damage. Do NOT use damaged instruments. Do NOT use the instrument when the sterile package is damaged.
6. Care must be taken when using laparoscopic instrumentation to avoid damage to major vessels and other anatomic structures.
7. Establish and maintain adequate pneumoperitoneum to reduce the risk of injury to internal structures.
8. Verify that the devices are compatible with other products that will be used in surgery prior to the procedure.
9. Safely dispose of all used or damaged products using hospital protocols and local regulations for biohazard materials.
10. A thorough understanding of the principles and techniques involved in electrosurgical procedures is necessary to avoid shock and burn to both patient and operator. Verify compatibility of instrumentation, and ensure that electrical insulation or grounding is not compromised.
11. Utilize available technology (tissue response generator, active electrode monitoring) to further eliminate concerns about insulation failure, capacitive coupling and interference with other electrical equipment.
12. The PMI Disposable Monopolar Laparoscopic Instruments are NOT intended for contraceptive coagulation of fallopian tissue but may be used to achieve hemostasis following transaction of the fallopian tube.
13. Cords should not be bundled, wrapped around metal instruments affixed to the patient or placed directly on patient's skin. Antenna coupling may occur when running the electrosurgical cord parallel to other patient or user contact cords or leads.
14. Do not place electrocautery cable on camera cable to avoid monitor display interference.
15. Do not use a damaged or faulty instrument. Check the instrument for bent, broken, cracked, worn, or separated parts prior to use. Do not use if inspection or current leakage tests indicate damage. Insulation failures may result in burns or other injuries to the patient or operator.
16. Introduce the instrument through the cannula carefully to avoid damaging the working tip.

17. DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
18. Adjust the HF-output power to match with the intended procedure. Use the lowest possible power setting that will achieve the desired surgical effect. Such as the low-voltage waveform (cut) and brief intermittent activation. This will reduce the potential for capacitive coupling and/or inadvertent burning of tissues.
19. Excessive power levels may result in instrument malfunction and possible patient or user injury. The rated voltage for these devices is 3800 $V_{pk}$.
20. Monopolar laparoscopic instruments are intended for use with electrosurgical generators and accessories in compliance with safety standards IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2 including applicable national/regional differences. Refer to the electrosurgical generator manual to verify compatibility and corresponding settings. Follow all safety precautions.
    a. Compatible generator manufacturers include. Olympus, Valleylab, Aesculap, Berchtold, Inheritance, KLS/Martin and Siemens
    b. Output Voltage should not exceed 3800 $V_{pk}$
    c. Operating frequency of 300 to 2000 kHz
    d. Operating Current of 0.8$A_{rms}$
21. Ensure device grasping or cutting surfaces are fully visible prior to engaging the electrical current to avoid unintended results. Keep the working-end under full and unobstructed visualization during use.
22. Damage to instrument may occur if attempting to cut staples, clips, or other non-tissue based materials.
23. Use appropriate technique to achieve hemostasis if not present after removal of instrument.
24. Do not activate in close proximity or direct contact with another instrument, such as clips, staple, laparoscope, etc. Do not active the instruments in contact with, in close proximity to, or in conjunction with conductive fluids (e.g. blood or saline). This may alter the electrical path and cause unintended tissue damage.
25. Electrosurgical devices used in conjunction with a laser/Argon beam may create the potential for the development of a gas embolism.
26. 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 or cause damage to the device.
27. Electrosurgical generators may cause unintended destruction of tissue and are dangerous if operated improperly. Follow all instructions for use required by the generator manufacturer.
28. Monopolar products should be connected ONLY to a monopolar power connection on the generator.
29. Do not use excessive force or in a manner not consistent with normal instrument use.
30. 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.
31. The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.
32. 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 both open and laparoscopic procedures.
33. 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.
34. When the active electrode is not being used, it should be placed in an insulated holster. Do not place instrument on the patient or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire or patient burns.

## OPERATING INFORMATION

1. Inspect the sterile packaging and device for any damage or defects. **DO NOT USE IF THE DEVICE OR PACKAGING IS DAMAGED.**
2. Ensure the Reusable Handle has been cleaned and sterilized in accordance with below procedure prior to use.
3. Open the sterile pouch and remove the Disposable Monopolar Laparoscopic Tip(s) and Reusable Handle(s) using proper sterile technique
4. Inspect the device(s) for defects or damage. **DO NOT USE IF THE INSTRUMENT IS DAMAGED.**
5. With the handle in the close position, grasp the tip protector and screw the tip onto the shaft until finger tight and remove the tip protector.
   **Note:** The tip protector should not rotate relative to the tip during assembly. Over tightening the tip in this manner may damage the instrument jaws or tip protector and lead to device contamination and/or malfunction.
6. Prior to use, operate the handle to open the tip to full aperture and verify proper assembly and working condition.
7. Use an electrosurgical cable that has a 4mm female connector when attaching a monopolar generator cable to the cautery connector located on the top of the instrument and follow the generator manufacturer's instructions for use and setup.
8. Keep the contact surface of the instrument clean during the operation. Wipe off any dried residue.
9. The tip mechanism is designed to open and close smoothly. Care should be taken not to forcibly open the jaws wider as undue stress may damage the insulation, or jaw components.
10. Upon completion of the procedure, detach the tip and dispose in accordance with hospital protocols and local regulations for biohazard materials. Follow the below instructions to clean and sterilize the Reusable Handle.

## THERMAL EFFECTS ON TISSUE TYPES

The following information is provided to aid the user in understanding the thermal performance of these devices at various power levels and tissue types.

**Table 1 – Thermal Damage on Kidney Tissue**

| Power Level | Thermal Damage Width ($\bar{X}$ ±SD, mm) | Thermal Damage Depth ($\bar{X}$ ±SD, mm) |
|---|---|---|
| 30W | 0.42 ±0.26 | 3.05 ±2.10 |
| 50W | 0.28 ±0.30 | 2.69 ±0.47 |
| 90W | 0.47 ±0.36 | 4.43 ±1.42 |

**Table 2 – Thermal Damage on Liver Tissue**

| Power Level | Thermal Damage Width ($\bar{X}$ ±SD, mm) | Thermal Damage Depth ($\bar{X}$ ±SD, mm) |
|---|---|---|
| 30W | 0.46 ±0.15 | 3.11 ±0.80 |
| 50W | 1.41 ±1.06 | 4.48 ±0.53 |
| 90W | 1.40 ±1.36 | 4.02 ±0.14 |

**Table 3 – Thermal Damage on Muscle Tissue**

| Power Level | Thermal Damage Width ($\bar{X}$ ±SD, mm) | Thermal Damage Depth ($\bar{X}$ ±SD, mm) |
|---|---|---|
| 30W | 1.28 ±0.58 | 2.62 ±0.20 |
| 50W | 1.51 ±0.65 | 3.26 ±0.32 |
| 90W | 1.20 ±0.85 | 2.82 ±0.37 |

## CLEANING & STERILIZATION (REUSABLE HANDLES ONLY)

**WARNING:** Failure to following the below instruction or the use of other cleaning/disinfecting agents, settings, methods, or material other than specified may result in incomplete cleaning and/or sterilization and may cause degradation of the instrument material resulting in premature failure of the device.

**LIMITATIONS ON PROCESSING:** Repeated processing according to the below instructions has minimal effect on these devices. End of life is normally determined by wear and damage due to use as determined by inspection and functional testing. Evidence of damage and wear on a device may include but is not limited to signs of excessive surface damage (i.e. crazing, cracks, flaking, scratches, discoloration, delamination), broken or damaged parts (i.e. distorted, warped, bent), corrosion of the metallic components (i.e. rust or pitting), missing or removed (buffed off) part numbers/identifiers, failure to pass electrical safety testing, and binding of movable parts (i.e. excessive friction, grinding, freezing). Devices that do not meet the inspection and function testing should not be used.

| **INSTRUCTIONS** | |
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| **Initial treatment at the point of use** | 1. Immediately after a procedure, remove gross/heavy soiling from the device using a soft brush or lint-free cloth and rinse with tap water. To ensure adequate cleaning, it is imperative that the instrument not be allowed to dry soiled.<br>2. Remove and discard the insert if attached.<br>3. Contain and transport the instrument to the decontamination area for cleaning. |
| **Preparation before cleaning** | The insert must be removed and discarded prior to cleaning. |
| **Cleaning: Automated** | **WARNING:** Use of automated cleaning equipment is NOT recommended for these instruments. |
| **Cleaning: Manual** | **WARNING:** Wear personal protective equipment such as protective gloves, clothing and face masks during cleaning and drying of contaminated instruments to reduce the risk of infection or personal injury.<br>1. Thoroughly rinse the instrument to remove all gross debris.<br>2. Completely immerse the instrument in a mild/neutral pH enzymatic cleaning solution (e.g. Enzol) and scrub thoroughly using a soft brush to remove any residual blood, protein material and contaminants from the instrument. Follow the cleaning solution manufacturer's instructions for concentration, temperature and contact time.<br>**NOTE:** Cleaning brushes should be cleaned and disinfected/sterilized after each use to prevent cross contamination<br>3. Thoroughly rinse the instrument using distilled or demineralized water until any debris or detergent which could interfere with sterilization is removed. |
| **Disinfection** | **WARNING:** Use of high-level disinfection is NOT recommended for these instruments. |
| **Drying** | Dry the device using an absorbent lint-free cloth until visible moisture is removed. |
| **Maintenance, Inspection and Testing** | After cleaning, but prior to sterilization, inspect the instrument for cleanliness and damage. Lubricate all moving parts of the device with a water-soluble lubricant such as instrument lubrication milk. |

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| **Packaging** | After inspection and lubrication, the device should be appropriately packaged for sterilization using only materials indicated for the sterilization process detailed below. |
| **Sterilization** | Sterilize devices using the following steam sterilization cycle:<br>**Temperature** 121 °C<br>**Steam/Hold Time** 30 minutes<br>At the completion of the sterilization cycle, all instruments should remain untouched until adequately cooled. |
| **Storage** | Store all sterile devices in a dry, clean and dust free environment as specified in the above section. |
| **Additional Information** | The instructions provided above have been validated as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. |

**TRANSPORTATION & STORAGE**

During transportation, avoid shaking, striking or dropping the devices or packaging or getting them wet.

Devices must be stored in a clean, dry, moisture free environment, without direct sunlight or corrosive gases. The instruments should be stored individually in their shelf box or in a protective tray with partitions.

**SYMBOLS**

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|---|---|---|---|
|  | Caution |  | Consult Instructions for Use |
|   | Catalog Number |   | Authorized for sale or use by physician only |
|  | Expiration Date |  | Manufacture Date |
|   | Lot Number |   | Sterilized by Ethylene Oxide (EO) |
|  | Single Patient User Only |   | Do Not Re-Sterilize |
|   | Serial Number |   | Non-Sterile |
|  | Do Not Use if Package is Damaged | Intentionally left blank | |