GENICON® REUSABLE PROBES INSTRUCTIONS FOR USE

INTENDED USE/INDICATIONS FOR ALL GENICON® PRODUCTS

GENICON's lines of laparoscopic and endoscopic products are intended for use wherever minimally invasive surgical procedures are indicated. GENICON's products are typically indicated for use in laparoscopic abdominal, gynecological, thoracic, and general procedures, or as noted.

General Contraindications, Warnings, and Precautions for All GENICON® Products

- The use of GENICON laparoscopic and endoscopic products is contraindicated whenever endoscopic surgical techniques are contraindicated for any reason. Contraindications relevant to individual GENICON products are noted in the specific sections.
- 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 failure.
- GENICON disposable products are intended for single patient use only – DO NOT RESTERILIZE. Instructions for sterilization of re-usable devices are noted in the appropriate sections.
- Do not use any pre-sterilized products if the packaging sterile barrier is damaged
- Consult medical literature or country specific regulations for specific techniques, complications, and hazards prior to procedure.
- Care must be taken when using laparoscopic instrumentation to avoid damage to major vessels and other anatomic structures.
- Establish and maintain adequate pneumoperitoneum to reduce the risk of injury to internal structures.
- Properly position the patient and note anatomical landmarks to introduced devices without unintended damage.
- Do not use excessive force or in a manner not consistent with normal instrumentation use.
- A thorough understanding of the principles and techniques involved in laparoscopic electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel, and damage to the device or other surgical instruments.
- Carry out electrosurgical procedures using only non-combustible gases (CO_2).
- Verify that the devices are compatible with other products that will be used in surgery prior to the procedure.
- Store all products safely in a climate controlled environment and handle with care.
- GENICON Suction Irrigation devices are DEHP / Latex free and sterilized using gamma sterilization, except as noted.
- Dispose of all used or damaged products using standard hospital practices for biohazard control.

Potential Complications for All GENICON® Products

Potential complications associated with the use of laparoscopic devices include but are not limited to organ or vessel damage/perforation, hemorrhage, hematoma, trocar site hernia, and septicemia/infection.

GENICON® Reusable Probes

Non-sterile packaged Reusable Suction-Irrigation Probes.

Intended Use/Indications

The GENICON Laparoscopic Suction-Irrigation System and probes are designed to facilitate lavage during laparoscopic surgery.

Contraindications, Warnings, and Precautions

- Use of this device for hysteroscopy or for cavity distention is contraindicated.
- When using the mono-polar probes, verify that the tip is not in contact with a conductive irrigation fluid.
- Sufficient care and distance must be maintained during use to prevent arcing to other instruments.
- Never pass irrigation fluid through the probe during coagulation.

Instructions for Use

Inspect all components carefully for any damage that may have occurred during shipment, or where applicable, routine maintenance.

Follow the steps below for use of the Reusable Electro-Cautery Probes:

1. Check the probe for damage and ensure the tip is securely attached. Dispose of probe if damaged.
2. To remove the probe, twist the probe nut in a counter clockwise motion. To attach/tighten the probe, twist in a clockwise motion. If probe is equipped with a mono-polar post, tighten until post points upward.
3. Insert shaft of probe through a laparoscopic cannula advancing gently to penetrate the cannula valve. Under appropriate visualization, advance until tip is at desired location.
4. When attaching a mono-polar cable to the probe, follow the manufacturer's instructions for use and setup.

Cleaning and Re-sterilizing Re-Usable Lavage or Electro-Cautery Probes:

1. Disinfect by completely submerging the probe into a disinfecting solution using manufacturer's instructions.
2. Remove coagulated residue by soaking in cleaning detergent and using a soft cleaning cloth or brush.
3. Do not remove residue using sharp objects or abrasives. This may damage the contact surfaces or insulation.
4. Completely rinse and dry the probe before sterilization.
5. If sterilisation is to be performed using the fractionated vacuum method, then the 134°C / 3 bar - program is to be used
   - 5.1. Employing a minimum - hold time of 4 minutes
   - 5.2. Drying time: 20 min
   - 5.3. Allow equipment/instruments to cool down to room temperature before renewed use
   - 5.4. After steam sterilisation, store exclusively in suitable containers designated for such purpose
   - 5.5. Performance could be impaired due to excessive autoclaving.
   - 5.6. Thoroughly inspect the probe prior to each use
6. Carefully inspect the insulation on electrocautery probes for damage using an insulation current leakage tester.

This product may be covered by one or more U.S. patents and their foreign counter parts. Other Patents may be pending.
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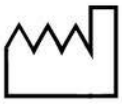
Disclaimer of Warranties on Re-Processing or Re-Sterilizing of Vendor's Disposable (Single-Patient) Products: Any reprocessing or re-sterilizing of disposable single patient devices voids Vendor's warranty. Vendor assumes no liability for reprocessed or re-sterilized products. Vendor warrants that reasonable care has been used in the manufacture of these disposable single patient devices and that they are free from defects in workmanship or materials at the time of shipment from Vendor. Vendor's sole obligation shall therefore be to repair or replace any device which it determines was defective at the time of shipment. Because no product is completely effective under all circumstances, and because the actual use and handling of these devices are beyond Vendor's control, Vendor cannot warrant for a good effect or against a bad effect in the application and use of these disposable single patient devices. The Purchaser therefore assumes all liability resulting from re-sterilization or re-processing of these disposable single patient products. Vendor therefore gives no warranty of merchantability or fitness for a particular purpose. Vendor will not be liable for any direct, indirect, incidental or consequential damages resulting from or related to a disposable product that has been re-sterilized or re-processed. Vendor shall not be liable for incidental or consequential loss, damage or expense resulting from the use or application of these said products. This warranty is in lieu of all other warranties, whether implied, express, oral or written, and no individual or entity has the authority to vary the terms of this warranty.

	EN	Manufacturer		EN	Serial Number
	EN	Latex Free		EN	Authorized Representative in EU
	EN	Manufacture Date		EN	Authorized For Sale or Use by Physician Only
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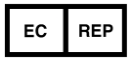

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