GENICON SINGLE USE MONOPOLAR X-SURGE SHAFT
INSTRUCTIONS FOR USE

Including sterile packaged Single-Use Monopolar shafts with Dissectors, Scissors and Graspers. Handle not included.

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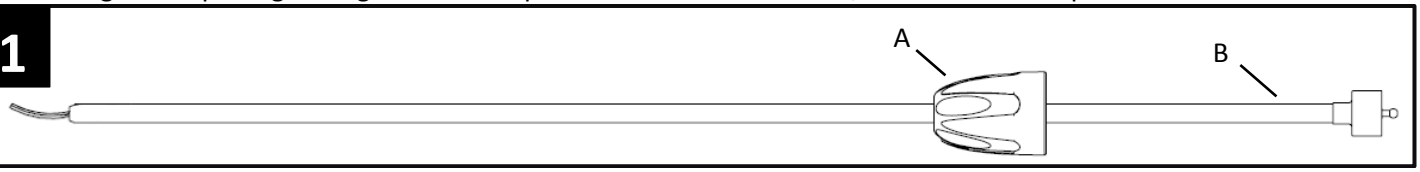

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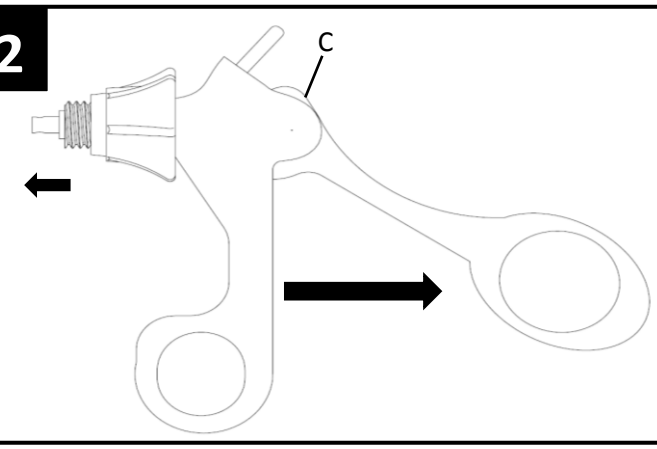

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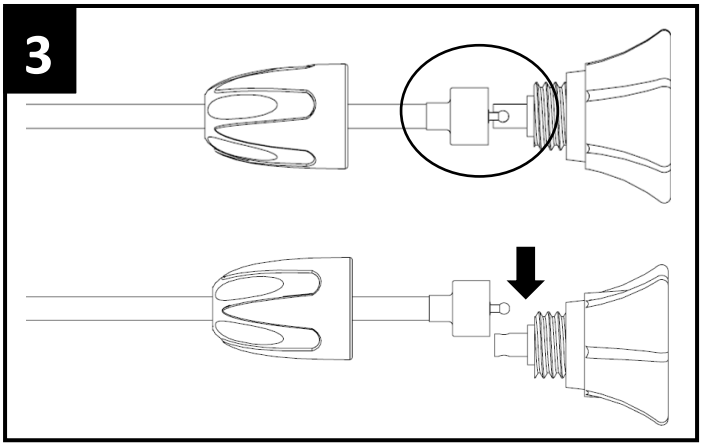

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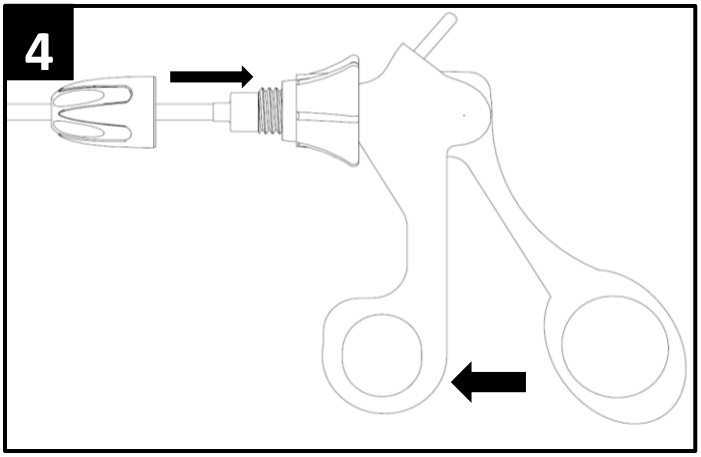

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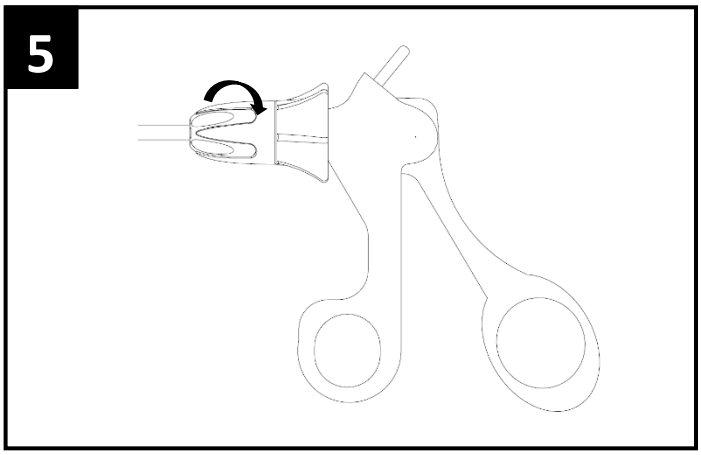

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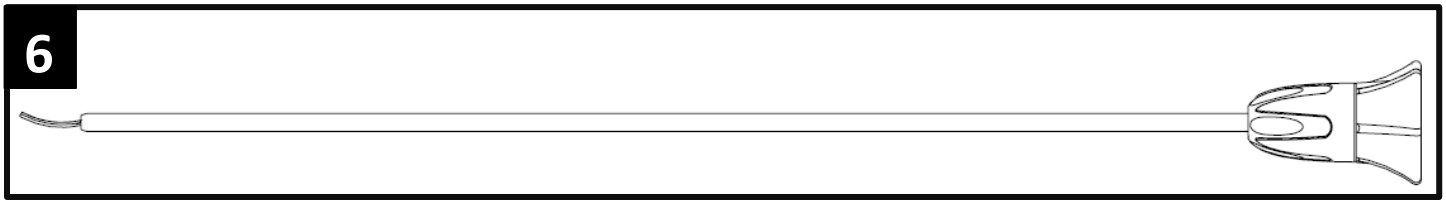

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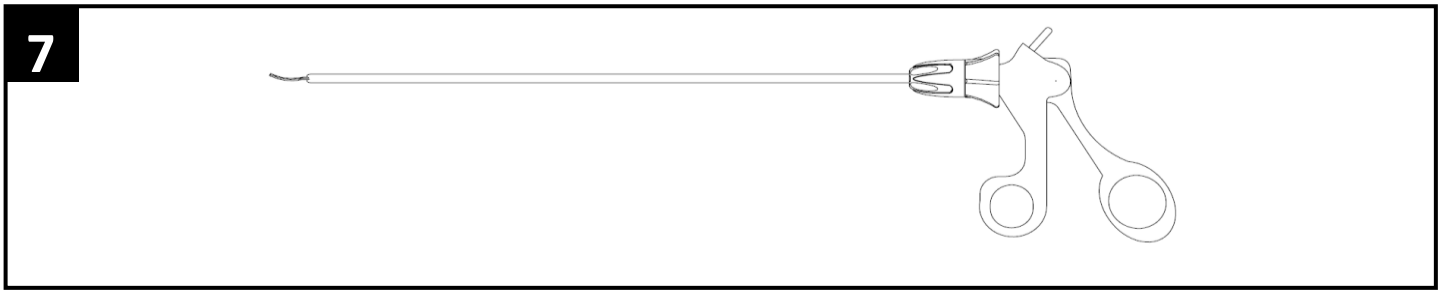

BEFORE USING THIS PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT!
1. This booklet is designed to assist using this product. It is not a reference to surgical techniques
2. This device was designed, tested and manufactured for single use patient use only
3. Reuse of this device may lead to its failure and subsequent patient injury
4. Reprocessing and/or resterilization of this device may create risk of contamination and patient infection
5. Do not reuse, reprocess or resterilize this device

DESCRIPTION
The GENICON X-Surge Monopolar Laparoscopic Instruments are sterile packaged single-use monopolar attachments intended for use in combination with a compatible handle (*supplied separately*). It includes graspers, dissectors, and scissors, intended to grasp, manipulate, cut, and cauterize soft tissue (*handle required*).

INDICATIONS FOR USE-
Endoscopic surgical procedures, it is a family of instruments which include graspers, dissectors, and scissors, intended to grasp, manipulate, cut, and cauterize soft tissue.

CONTRAINDICATIONS
1. The GENICON monopolar Laparoscopic X-Surge single use instruments are NOT intended for contraceptive coagulation of fallopian tissue, but may be used to achieve hemostasis following transaction of the fallopian tube.
2. These devices are intended for use only as indicated.

WARNINGS AND PRECAUTIONS
1. 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.
2. 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.
3. 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.
4. This device is provided STERILE and is intended for SINGLE procedure ONLY. DISCARD AFTER USE. DO NOT RESTERILZE.
5. Do not use any pre-sterilized products if the packaging sterile barrier is damaged.
6. Select a generator with necessary safety mechanisms to eliminate interference with other electrical equipment.
7. Do not loop electrocautery cable or place directly on patient's skin.
8. Do not place electrocautery cable on camera cable to avoid monitor display interference.
9. 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.
10. Single Use devices may not be repaired, modified or re-processed.
11. Introduce the instrument through the cannula carefully to avoid damaging the working tip.
12. Store all products safely in a climate controlled environment and handle with care.
13. A risk of injury may arise from any sparks or ignition of combustible gases. Be sure to follow the safety information in the operating instructions of the HF generator.
14. Adjust the HF-output power to match with the intended procedure. Voltage/power levels should be set as low as possible to achieve the desired effects. This will reduce the potential for capacitive coupling and/or inadvertent burning of tissues.
15. Do not use power settings that may result in more than 120W being delivered to the GENICON X-Surge Shaft monopolar laparoscopic instruments. Excessive power levels may result in instrument malfunction and possible patient or user injury.
16. Prior to use, ensure the jaws are in the closed position and connect to a compatible handle. Compatibility of parts from different manufacturers must be verified prior to conducting the procedure.
17. The GENICON X-Surge 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.
18. 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.
19. Damage to instrument may occur if attempting to cut staples, clips, or other non-tissue based materials.
20. Use appropriate technique to achieve hemostasis if not present after removal of instrument.
21. Ensure that the energized tip is not in contact with a conductive irrigation fluid, staples, clips, or other conductive device. Users are cautioned that activating the mono-polar device simultaneously with suction/irrigation devices may alter the path of the electrical energy away from the target tissue.
22. Mono-polar devices used in conjunction with a laser/Argon beam may create the potential for the development of a gas embolism.
23. Capacitive coupling may occur if the device is activated and not in position to deliver energy to the target tissue.
24. Electrosurgical generators may cause unintended destruction of tissue and are dangerous if operated improperly. Follow all instructions for use required by the generator manufacturer.
25. Keep the contact surface of the instrument clean during the operation. Wipe off any dried residue.
26. The jaw 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.
27. Mono-polar products should be connected ONLY to a mono-polar power connection on the generator

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.

INSTRUCTIONS FOR USE
1. Open the package by using standard sterile technique
2. Inspect the unit for defects– do not use if unit is defective. **Refer to picture 1 & 2**
    A. Locking Knob

B. Shaft
C. Compatible Handle (*supplied separately*)

3. Open the handle to fully to extend the center attachment rod. **Refer to picture 2**
4. Align the ball extension of GENICON X-Surge shaft and insert into the socket of the exposed center rod on the handle with the shaft parallel to the working length of the handle **Refer to picture 3**
5. Close handle to temporarily secure the shaft in place, and bring Locking Knob to the proximal end of the handle. **Refer to picture 4**
6. Rotate the Locking Knob clockwise until tightened to handle, ensure fit is secure. **Refer to picture 5**

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 DE DK ES FI FR IT NO SV 英语	Manufacturer Hersteller Producent Fabricante Valmistaja Fabricant Produttore Produsent Tillverkare 制造商		EN DE DK ES FI FR IT NO SV 英语	Single Patient Use Only Nur zum einmaligen Gebrauch Kun til brug til en enkelt patient Para uso exclusivo de un sólo paciente Käyttöön vain yhden potilaalla Utilisation pour un seul patient Monouso For bruk på bare én pasient Endast för enpatientsbruk 限于单个病人使用
	EN DE DK ES FI FR IT NO SV 英语	Not Made with Natural Rubber Latex Nicht mit Naturkautschuklatex hergestellt Ikke fremstillet af naturgummi latex No hecho con látex de caucho natural valmistettu ilman luonnonkumilateksia sans latex de caoutchouc naturel non fatta con lattice di gomma naturale Ikke laget med naturlig gummilateks ej tillverkad av naturgummilatex 不是用天然胶乳制成		EN DE DK ES FI FR IT NO SV 英语	Sterilized By Ethylene Oxide/EO/EtO Durch Ethylenoxid sterilisiert/EO/EtO Steriliseret med ethylenoxid /EO/EtO Esterilizado con óxido de etileno/OE/ OEt Steriloitu etyleenioksidilla/EO/EtO Stérilisé par l'oxyde d'éthylène/EO/EtO Sterilizzato con ossido di etilene/OE/ OEt Sterilisert med etylenoksid/EO/EtO Steriliserad med etylenoxid 用环氧乙烷/EO/EtO灭菌
	EN DE DK ES FI FR IT NO SV 英语	Do Not Re-Sterilize Nicht resterilisieren Må ikke resteriliseres No volver a esterilizar Älä steriloi uudelleen Ne pas ré-stériliser Non risterilizzare Må ikke resteriliseres Får ej återsteriliseras 不得重新消毒		EN DE DK ES FI FR IT NO SV 英语	Authorized Representative in EU Bevollmächtigter Vertreter in der EU Autoriseret forhandler i EU Representante autorizado en la Unión Europea Valtuutettu edustaja EU:ssa Représentant autorisé en UE Rappresentante autorizzato UE Autorisert representant i EU Auktoriserad representant inom EU 欧盟授权代表
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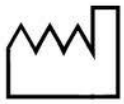
	EN DE DK ES FI FR IT NO SV 英语	Type BF Applied Part Anwendungsteil Typ BF Type BF Anvendt Del Pieza de contacto directo con el paciente de tipo BF Tyypin BF sovellettu osa Partie appliquée de type B Parte applicata di tipo BF Type BF-komponent Typ BF, gällande del 型应用部分		EN DE DK ES FI FR IT NO SV 英语	Do not Use if Package is Damaged Nicht verwenden, wenn die Verpackung beschädigt ist Må ikke anvendes, hvis pakken er beskadiget No usar si el envoltorio está dañado Älä käytä, jos pakkaus on vaurioitunut Ne pas utiliser si le paquet est endommagé Non utilizzare se l'imballaggio è danneggiato Må ikke brukes dersom emballasjen er skadet Får ej användas om förpackningen är skadad 包装损坏后不得使用
	EN DE DK ES FI FR IT NO SV 英语	Caution Vorsicht Forsigtig Cuidado Huomio Mise en garde Cautela Forsiktig Observera! 慎重		EN DE DK ES FI FR IT NO SV 英语	Manufacture Date Herstellungsdatum Produktionsdato Fecha de fabricacion Valmistuspäivä Date de fabrication Data di prduzione Produksjonsdato Tillverkningsdatum 生产日期

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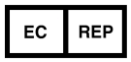

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