Manufactured by:	Document ref. ERMC 003-01	Distributed by:
ELECTRO RANGE MFG CO	**General instructions & guidelines for the use, care, handling and reprocessing of *ERMC SINGLE USE ELECTROSURGICAL FORCEPS, FINGERSWITCHES & ELECTRODES***	BOLTON SURGICAL of SHEFFIELD

Devices	• These instructions apply to the following ranges of electrosurgical devices manufactured by ERMC and distributed by Bolton Surgical Ltd: - All single use monopolar and bi-polar electrosurgical forceps complete with a cable. - All single use monopolar and bi-polar electrosurgical forceps without a cable. - All single use hand control fingerswitch cables. - All single use monopolar electrodes. • These products are manufactured from stainless steel with polymer insulators and coatings.
Intended use	• Intended for single use only in electrosurgery procedures by persons with the required specialist knowledge and training for the purpose of grasping, cutting and coagulation of biological tissues and to control bleeding using high frequency electric current by connection of the instrument to the mono or bipolar output, as appropriate, of an electrosurgical generator unit and control system by means of a specialised cable and connectors.

Devices covered by this IFU are intended for one use, or for use on a single patient during a single procedure.	Device has been sterilised using ethylene oxide.	ERMC single use electrosurgical forceps, cables and accessories are **LATEX FREE**, including their packaging.

Appropriate connecting cables	• For single use forceps supplied with a cable, the cable is an integral part of the instrument and cannot be removed. • For single use monopolar forceps supplied without a cable use a cable with a 4.8 mm UK instrument connector. • For single use bipolar forceps supplied without a cable use a cable with a standard Euro instrument connector. • Single use cables compatible with all ERMC single use electrosurgery forceps and all commonly used electrosurgical generator units are available from Bolton Surgical Ltd**.**
Shelf life	• 2 years minimum from date of supply.
Cautions and Warnings	• These instructions are intended for use only by appropriately qualified persons with the required specialist knowledge and training. • When handling biologically contaminated instruments always handle with care wearing appropriate protective gloves, eyewear and clothing in accordance with local Health & Safety procedures. • Misuse of an instrument for tasks other than those for which it is intended may result in failure of the instrument due to over-stressing as well as unnecessary harm to the patient or user. • Fire risks are associated with improper use and handling of electrosurgical instruments and accessories. Do not place them in contact with or near to flammable or explosive substances (eg. drapes, gauze, and oxygen sources). • When temporarily not in use, a sterile, non-conductive holster or quiver should be used to hold electrosurgical instruments and accessories safely, electrically insulated from the patient. • Activate the electrosurgical current supply only if the contact areas are in full view and the electrosurgical instrument has good contact with the tissue that needs to be treated. Use the lowest possible power setting available to achieve the desired surgical effect. • During use, take care to avoid contact between energised electrosurgical instruments and any other metallic instruments or objects. • Observe the use and safety instructions supplied by the manufacturer of the electrosurgical generator unit and control system to be used. • Do not use the device if a cable connector does not fit securely into the socket on the electrosurgical generator unit or, if there are exposed metal portions of the pins after plugging in (ie the plug is not fully inserted). • Do not use if there is a gap exposing an uninsulated metal portion between an electrode sleeve and the nose of the fingerswitch.
Contra-indications	• Do not use the instrument if, in the opinion of the surgical practitioner, patient safety risks outweigh the benefits. • Before undertaking electrosurgery procedures on patients with pacemakers or other active implants, a cardiologist or appropriate medical specialist must be consulted as special requirements may apply (e.g. low HF-current, patient monitoring).
Preparation for use	• ERMC single use electrosurgical instruments and accessories are supplied sterile and ready for use. • Check that the sterile packaging pouch is still sealed for sterility before use. If there is any damage to the packaging pouch do not use the device. • Check that the sterile packaging is still within its remaining shelf life expiry date. • Ensure the electrosurgical generator is in its 'off' or 'standby' mode before connecting the instrument cable and that the instrument is isolated from the patient or user. • Fingerswitches and electrodes – - Fit the electrode to the fingerswitch before connecting to the electrosurgical generator unit by grasping the insulating sleeve on the electrode. - Ensure that the electrode is fully and securely seated in the nose of the fingerswitch such that approximately 3mm of the insulating sleeve is shrouded by the nose of the fingerswitch.

Storage Conditions	• Ensure instruments are stored in dry, clean conditions • Ambient storage temperature range -10°C to +40°C • Ambient storage relative humidity range 40% to 70%	• Stack boxes carefully to avoid damage • Keep away from direct sunlight and heat sources • Store separately from non-sterile products
Limited Warranty	• ERMC single use electrosurgical forceps, fingerswitches and electrodes are warranted for a single use only until the shelf-life expiry date for the product against failure resulting from defective materials and workmanship, when used in accordance with these instructions by persons with the required specialist knowledge and training, for the purpose for which the device is intended. • Liability is refused for products which have been modified as compared to the originally supplied product, misused, incorrectly handled or, used for a purpose that differs in any way from product's stated Intended Use.	
Returned Goods Policy	• Customers wishing to return goods for any reason must do so in accordance with Bolton Surgical's Returns Policy (document ref. POL 009) a copy of which is supplied with each order or, is available online by visiting www.boltons.co.uk. • Determination of a product defect will be made by Bolton Surgical Ltd on behalf of Electro Range Manufacturing Co.	
Disposal	• Disposal/recycling should be in accordance with local waste management protocols for contaminated/single use devices.	
Incident reporting	• Report any serious incident that has occurred in relation to the use of a device covered by this IFU to the Distributor and the Authorised Representative for the country in which the incident occurred and in accordance with the reporting rules applicable in that country.	

Explanation of symbols used on labels:

Manufacturer	Date of Manufacture	Manufacturer's Product Code	Manufacturer's Batch Code	Use by date	Supplied Latex Free	Caution	Consult Instructions for Use	United Kingdom Responsible Person
Single use Do not re-use.	Do not re-sterilise	Device has been sterilised using ethylene oxide.	Do not use if packaging is damaged	Keep away from heat	Keep dry	Temperature limits during storage & transportation.	Humidity limits during storage & transportation.	European Union Authorised Representative

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UK Distributor:	**Bolton Surgical Ltd.** Churchill House, 16 Churchill Way, Chapeltown, Sheffield, S35 2PY, UK T: +44 (0) 114 240 4400 E: sales@boltons.co.uk W: www.boltons.co.uk		This document is approved for use Sign: Date: 04-04-22
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