Control         Control <t< th=""><th colspan="2">Manufactured by:</th><th colspan="4">Document ref. ERMC 003-01</th><th>Distributed by:</th></t<>	Manufactured by:		Document ref. ERMC 003-01				Distributed by:		
Concerning     Programment     Preparation     Preparatio	ELECTRO RANGE MFG CO		General instructions & guidelines						
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PARCEPS, FINCERSWITCHES & ELECTRODES     Process     Price of the instruction sply to the following ranges of decrosurgical diveces manufactured by UMIC and distributed by Botton Surgical Lts: <ul> <li>All single use monopolar and bipolar decirosurgical diveces manufactured by UMIC and distributed by Botton Surgical Lts:             <ul> <li>All single use monopolar and bipolar decirosurgical diveces manufactured by UMIC and distributed by Botton Surgical Lts:</li></ul></li></ul>							OF SHEFFIELD		
<ul> <li>These instructions apply to the following ranges of electrosurgical devices manufactured by ERMC and distributed by Bolion Sargical Ltd: <ul> <li>All single use monopolar and bip plan electrosurgical devices manufactured by ERMC and distributed by Bolion Sargical Ltd: <ul> <li>All single use monopolar and bip plan electrosurgical devices without a cable.</li> <li>All single use monopolar indevices with the required specialist involving and training for the purpose of pression.</li> <li>These products are manufactured from stainies steel with polymer insulators and coatings.</li> </ul> </li> <li>Intended use <ul> <li>Intended or single use only in electrosurgical torus and is control beleficity using high frequency electric current by connection of the instrument to the mono or bipclar output, a appropriate, of an electrosurgical generator with and control system by means of a prealised coating of the purpose of appealing electrosurgical brance and control beleficity using high frequency electric current by connection of the instrument to the mono or bipclar output, a appropriate, of an electrosurgical generator with and control bystem by means of a prealing coating for the purpose of using the precision of the purpose of a prealing coating and on polar output, a support of the system with the required special to control bystem by means of a prealing coating of the purpose of using the precision of the purpose of a prealing coating of the purpose of the use of the use of the with a list of the instrument and control bystem purpose of a model of the purpose of t</li></ul></li></ul></li></ul>									
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Devices       - All single use monopolar and bi-polar electrosurgical forceps without a cable.         - All single use monopolar electrosurgical forceps without a cable.       - All single use nonopolar electrosurgical sceles.         - Miningle use products are manufactured from stainless stele with polymer insulators and costings.       - Intended use only in electrosurgical procedures by persons with the required specialisk howledge and training for the purpose of proping, tuting and cospublic on blocking attacks and nonnet observing significance with an electrosurgical generator unit and control steleding and costing biological scales and nonnet observing significance with an electrosurgical generator unit and control steleding significance and the policy of the purpose of units of the purpose of units of the purpose of thepurpose of the purpose of the purpose of the p									
Devices       - All single use hand control fingerswitch cables.         - All single use monopolar dectrodes.       - All single use monopolar dectrodes.         Intended use       - Intended for single use only in electrosurgery procedures by persons with the required specialist knowledge and training for the purpose of propring, cuts may anonopolago of biological issues and to control blecking using high requery electic current by connection of the specialistic cable and control system by mouse of a specialistic data and control system by mouse of a specialistic data and control system by mouse of a proprint during a single procedure.         Over the system of the set of the system system of the system of the system of the system of t									
- All single use monopolar electrodes.     - All single use monopolar electrodes.     - These products are manufactured from stainless stel with polymer insultors and costings.	Devices								
<ul> <li>Intended use         <ul> <li>Intended or single use only in electrosurgery procedures by persons with the required specialist knowledge and training for the purpose of grisping, cutting and cogulation of the instrument to the mono of plogical tissues and to control bleeding using high frequency electric current by connection of the instrument to the mono of plogical tissues and to control bleeding using high frequency electric current by connection of the instrument to the mono of plogical tissues and to control bleeding using high frequency electric current by connection of the instrument to the mono of plogical tissues and to control bleeding using high frequency electric current by connection of the instrument during a single procedure.</li> <li>For single use forces supplied with a cable, the cable is an integral part of the instrument and cannot be removed.</li> <li>For single use forces supplied with a cable, the cable is an integral part of the instrument connector.</li> <li>For single use comptible with all EMOC single use electrosurgery forces and all commanty used electrosurgical generator units are available from Bolton Surgical Ltd.</li> <li>Sheff life</li> <li>2 years minimum from date of supply.</li> <li>These instructions are intended for use only by appropriately qualified persons with the required specialist knowledge and training.</li> <li>When handling biologically contaminated instruments always handle with care wearing appropriate protective gloves, eyewear and clothing in accordance with hold with lift as intended for use only by appropriately qualified persons with the required specialist knowledge and training.</li> <li>When handling biologically contaminated instruments always handle with care wearing appropriate protective gloves, eyewear and clothing in accordance with hold with lifts in intended may result in failure of the instrument due to over stressing as well as unnecesary harm to the pati</li></ul></li></ul>									
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Operation         Design of the part of the pa				STERILEEO		(LATEX)	-		
Appropriate contexting <ul> <li>For single use biploar forceps supplied without a cable use a cable with a 4.8 mm UK instrument connector.</li> <li>For single use biploar forceps supplied without a cable use a cable with a standard Euro instrument connector.</li> <li>Single use cables compatible with all ERMC single use electrosurgery forceps and all commonly used electrosurgical generator units are available from Boton Surgical 1td.</li> </ul> <li>Shelf life         <ul> <li>2 years minimum from date of supply.</li> <li>These instructions are intended for use only by appropriately qualified persons with the required specialist knowledge and training.</li> <li>When handling biologically contaminated instruments always handle with care wearing appropriate protective gloves, eyewear and clothing in accordance with local Health &amp; Safety procedures.</li> <li>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.</li> <li>Fire risks are associated with improper use and handling of electrosurgical instruments and accessories. Do not place them in contact with or near to fammable or explosive subtances (e.g. grapes, gaue, and oxygen sources).</li> <li>When themporarily not in use, a stellic, non-conductive holster or quiver should be used to hold electrosurgical instruments and accessories safely, electrically insulated from the patient.</li> <li>Activate the electrosurgical current supply only if the contact areas are in full wey and the electrosurgical instruments and control system to be used.</li> <li>Ob ont use the divice if a cable connector dees not fit scureely instructions supplied by the manufacture of the electrosurgical generator unit or, if there are exposed metal porti</li></ul></li>			-		using ethylene oxide.	XX	including their pa	ckaging.	
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<ul> <li>For single use bipolar forceps supplied without a cable use a cable with a standard Euro instrument connector.</li> <li>Single use cables compatible with all ERMC single use electrosurgery forceps and all commonly used electrosurgical generator units are available from Botton Surgical Ltd.</li> <li>Shelf life         <ul> <li>2 years minimum from date of supply.</li> <li>These instructions are intended for use only by appropriately qualified persons with the required specialist knowledge and training.</li> <li>When handing biologically contaminated instruments always handle with care wearing appropriate protective gloves, eyewear and clothing in accordance with local Health &amp; Safety procedures.</li> <li>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.</li> <li>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).</li> <li>When temporarily not in use, a sterile, non-conductive holster or quiver should be used to hold electrosurgical instruments and accessories safely, electrically insulated for the better.</li> <li>During use, take care to avoid contact between energised electrosurgical instruments and any other metallic instruments or objects.</li> <li>Observe the use and safety instructions supplied by the manufacture of the electrosurgical generator unit or, if there are exposed metal portion between an electrode sieeve and the nose of the fingerswitch.</li> </ul> </li> <li>Do not use if there is a gap exposing an uninsulated metal portion between an electrode sieeve and the nose of the fingerswitch.</li> <li>Do not use the electrosurgical practitioner, patient safety</li></ul>	Appropriate								
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Cautions and Warnings       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.         • Do not use if there is a gap exposing an uninsulated metal portion between an electrode sleeve and the nose of the fingerswitch.         • Do not use the instrument if, in the opinion of the surgical practitioner, patient safety risks outweigh the benefits.         • Before undertaking 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'	/!\								
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	Ensure instruments are stored in dry, clean conditions     Stack boxes carefully to avoid damage							
Storage Conditions	<ul> <li>Ambient storage temperature range -10°C to +40°C</li> </ul>	nt and heat sources						
	Ambient storage relative humidity range 40% to 70%	erile products						
Limited Warranty	<ul> <li>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.</li> <li>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.</li> </ul>							
Returned Goods Policy	<ul> <li>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 <u>www.boltons.co.uk</u>.</li> <li>Determination of a product defect will be made by Bolton Surgical Ltd on behalf of Electro Range Manufacturing Co.</li> </ul>							
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 Manufacturer's Product Code Datch Code		Consult Instructions for Use UK REP United Kingdom Responsible Person					
	Single use Do not re-use. Do not re-sterilise Do not re-sterilise	limits during	40% Humidity limits during storage & transportation.					
	Electro Range Mfg Co.       250M Daska Road Ghuinke 51040, Sialkot, Pakistan.       Manufactured and Distribute         T: +92 (0) 321 610 0080       E-mail: info@electrorange.com       I639							
UK Distributor:	Bolton Surgical Ltd.       Churchill House, 16 Churchill Way, Chapeltown, Sheffield, S35 2PY, UK       This document is approximately a series of the							
EC REP	European Healthcare & Device Solutions Ltd. Stratton House, Bishopstown Road, Bishopstown, Cork, T12 Y9 T: +353 (86) 228 0846 E: info@europeandevicesolutions.eu W: www	Sign:						
UK REP	European Device Solutions 15 Coanwood Drive, Whitley Bay, Tyne & T: +44 (0) 754 559 5464 E: info@europeandevicesolutions.co.uk W: w	Date: 94-04-22						