Instructions for Use

Speedboat RS2 Instrument

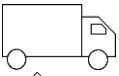
Language: English

For use with the Creo Medical electrosurgical generator and interface cable only.

Explanations of symbols

	General Warning		Do not use if package is damaged
	Blue symbol. Consult accompanying documents		Instrument can be broken or damaged if not handled carefully
	Manufacturer		Keep away from sunlight
	Date of manufacture		Keep dry
	Use by date / Expiration date		Temperature limitation
LOT	Lot number		Humidity limitation
REF	Reference (model) number		Atmospheric pressure limitation
	Do not re-use	STERILE EO	Sterilised using ethylene oxide
	Number of units enclosed in box	EC REP	European Union authorised representative
	MR unsafe	CE 2797	CE 2797 - BSI Certified
	Do not resterilise		Caution
MD	Medical Device		Single sterile barrier with protective packaging inside
	Non-pyrogenic		Single sterile barrier with protective packaging outside
	Recycle		Do not use blade to open

Type BF applied part



Transportation, this symbol appears next to the symbols indicating environment limitations during transportation.

Storage, this symbol appears next to the symbols indicating environment limitations during storage before and between uses.

Safety Instructions

Indications for Use

Speedboat RS2 (Instrument) is intended for use in the cutting and coagulation of soft tissue in the gastrointestinal tract, and the delivery and injection of fluid solutions, as required or encountered in endoscopic procedures.

Refer to specifications at the end of this document concerning injection fluid solution compatibility.

Contraindications and target treatment group

Speedboat RS2 is contraindicated for:

- *Non-endoscopic procedures;*
- *Where endoscopic procedures are contraindicated;*
- *Where electrosurgery is contraindicated;*
- *For any procedure that is not in the GI tract;*
- *For treatment of deep and/or infiltrative cancerous lesions or tumours;*
- *Where the treatment site is not adequately prepared for an endoscopic electrosurgical procedure;*
- *In patients with any of the following conditions:*
    - *Pregnancy;*
    - *Unaddressed adnexal pathology;*
    - *Where there is an unacceptable risk to the patient due to incomplete removal of target tissue;*
- *Where the patient is uncooperative with the endoscopy procedure or the patient is uncontrolled.*

The target treatment group is:

- *Sex: Male and female excepting pregnant women.*
- *Age: Adults, i.e. 18 years old and older. No upper limit for age is identified.*
- *Anatomy: GI tract.*
- *Physiology: No exclusions are identified except where the patient is contraindicated.*
- *Exclusions: Refer to contraindications.*

It is recommended that the Speedboat RS2 is not used in patients who have electronic implants, such as cardiac pacemakers, without first consulting a qualified professional (e.g. cardiologist).

User Qualification

The operator of this Instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic electrosurgical techniques and use of bipolar electrosurgical Instruments. This manual does not explain or discuss clinical endoscopic procedures.

Training in the operation of this Creo Medical surgical instrument and electrosurgical generator is recommended and is available from the manufacturer.

Instructions for Use

This Instructions for Use contains essential information about the Instrument and instructions on how to handle, prepare and use the Instrument in endoscopic procedures. Before using the Instrument, study these Instructions for Use thoroughly and refer to it when needed. If you have any questions regarding these Instructions for Use or the Instrument itself, contact Creo Medical.

Warnings

Indicate a hazardous situation which, if not avoided, may result in death or injury of the patient or user.

Cautions

Indicate a hazardous situation which, if not avoided, may result in damage to the Instrument or minor injury to the patient or user.

Important Safety Warnings

Warnings

Safe and effective endoscopic Electrosurgery is dependent not only on the equipment design but also on factors that are directly under the control of the user. The user should be qualified and experienced in relevant clinical endoscopic electrosurgical techniques. Use this Instrument only for indications specified in this Instructions for Use and operate the Instrument in accordance with the Instructions for Use. Using the Instrument outside its intended use may lead to unintended clinical effects with risk of injury or death to the patient.

This Instrument is intended only for use with a Creo Medical Electrosurgical Generator and connection cable. Do not use with any other electrosurgical generators. Using any other electrosurgical generator or connection cable may result in malfunction of the Instrument posing the risk of injury to patient or user.

Ensure the Instrument is stored and used in the environmental conditions specified on its packaging and in these Instructions for Use. Failure to comply may result in faulty operation or compromised sterility of the Instrument.

Do not use in oxygen-rich environments, in the presence of flammable gases (e.g. flammable anaesthetics or gastrointestinal gases), in the presence of flammable liquids or other flammable materials. Ensure that flammable liquids

are not pooled. The Instrument is an ignition source. Using it in oxygen-rich environments or in the presence of flammable gases or liquids poses the risk of explosion or fire.

Do not activate the Electrosurgical Generator while the Instrument or connectors of the Generator connection cable (Creo Medical Interface Cable) are in unintentional contact with tissue or when the Instrument is not in direct view of the endoscopist or surgeon, as this may result in unintended tissue effects.

Full visibility through the endoscope of the treatment site must be maintained during use of the Instrument to ensure treatment is as intended.

Always apply energy for cutting and coagulation purposes at the minimum output power level and for the minimum time necessary to successfully complete the procedure. Excessive energy may result in patient injury, due to excessive penetration and lateral spread of thermal effects.

Excessive tamponade pressure and/or excessive application of energy may result in acute or delayed perforation.

In the event of a malfunction of the Instrument, remove and replace the Instrument. Always have a spare Instrument available.

In the event of a malfunction of the Electrosurgical Generator, immediately cease treatment. Turn the Electrosurgical Generator off using the switch on the rear panel of the generator or by disconnecting the power supply cord from the generator or the wall plug. In emergencies, treatment delivery may also be terminated by disconnecting the Instrument from the Interface Cable.

Do not attempt to modify or repair the Instrument. This poses the risk of faulty operation that may result in injury to the patient or user.

Do not allow conducting (i.e. metallic) parts of the Instrument or Interface Cable to come into contact with users, as there are hazardous voltages present that pose a risk of an electrical shock.

Microwave energy should be not be applied to persons wearing metallic jewellery or clothing containing metallic material. Hearing aids should be removed. Patients with implanted electronic devices and/or electrodes should be excluded from treatment with microwaves and from areas where the microwave equipment is operated. For patients with cardiac pacemakers or other active implants, a possible hazard exists due to interference with the action of pacemaker or the pacemaker may be damaged, and when in doubt, approved qualified advice should be obtained.

The instrument is a potential ignition source, the use of non-flammable agents for cleaning and disinfection are recommended. When flammable agents or solvents are used, these should not be allowed to pool (e.g. in body cavities) and should be allowed to evaporate before use of the Instrument.

Potential Undesirable Effects

The following residual risk could be associated with the use of Speedboat RS2 instrument:

Weakening of the device due to rotation and manipulation in use may result in inability to control the orientation of the instrument which may cause unintended cutting or coagulation and may lead to unintended perforation or bleeding.

Instrument Description

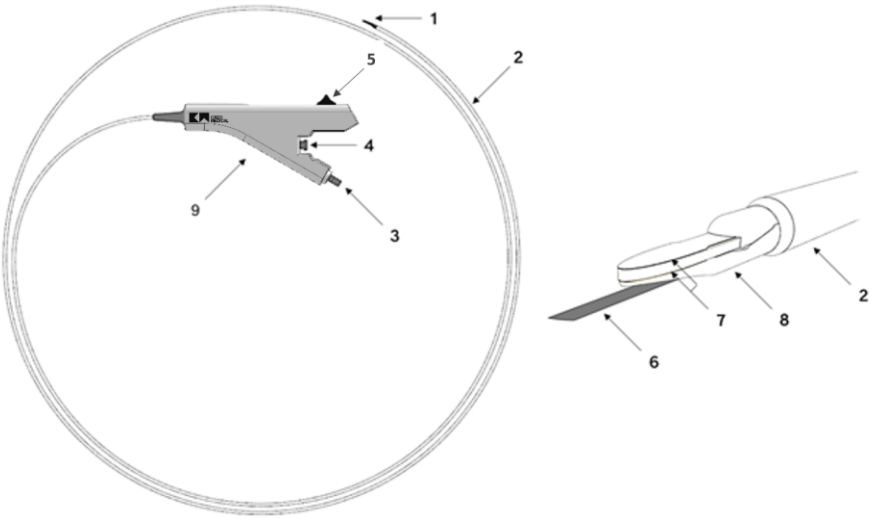
The Instrument is a bipolar device; both Top and Bottom Electrodes (7) must be in contact with tissue for cutting to occur. The Protective Hull (8) is part of the Bottom electrode.

Cutting will occur along the edge of the Top Electrode that is in contact with tissue.

Coagulation should be performed when both Top and Bottom Electrodes are in contact with target tissue; the Distal Tip can be used to tamponade.

The Needle (6) must be retracted before applying cutting or coagulation energy.

Speedboat RS2



1. Distal Tip
2. Shaft
3. Interface Cable Connector
4. Syringe Connector (Luer lock fitting)
5. Needle Slider
6. Needle
7. Top and Bottom Electrodes
8. Protective Hull
9. Handle

Normal Use

Warnings

Do not use this Instrument beyond its expiration (expiry) date as marked on its packaging. Doing so may pose infection control risk.

This Instrument is a single-use, disposable endoscopic Instrument that is delivered in a sterile condition. Do not sterilise before use or re-sterilise. Sterilisation by the user will damage the Instrument resulting in faulty operation.

Do not re-use. Reusing the Instrument may result in faulty operation or cross-contamination.

The recommended operational life of the instrument may be up to 3 hours, dependent upon lesion size and complexity. A second device may be required if the lesion diameter size is greater than 6 cm or in the event of clinical complexity extending the time of the procedure.

Inspection and Removal from Packaging

Warnings

Do not use the Instrument if the packaging is damaged, the Instrument is dropped or becomes otherwise contaminated, as this poses the risk of injury or death to the patient due to contamination.

Do not use or continue to use the Instrument if it appears to have had a loss of performance or appears damaged in any way, as this may pose a serious risk of injury to the patient or user.

Cautions

Do not use excessive force when removing the Instrument from packaging as this may damage the Instrument.

Inspect the sterile pouch for tears, water damage and broken seals. If the sterile package shows any irregularities, do not use the Instrument as the sterile condition of the Instrument might be compromised.

Using standard sterile technique, gently remove the Instrument from the packaging. Slowly remove the Instrument from the protective tubing by carefully pulling it by the Handle (9). Prevent the Instrument tip from touching the floor by coiling the Instrument as it is removed from the protective tubing. Once the Instrument is removed, the protective tubing can be disposed.

Before connecting the Instrument to the Interface Cable for use, inspect the Instrument and ensure that:

- no parts of the Instrument have become loose
- the Distal Tip (1) is free from cracks or any other damage
- the Shaft (2) is free from bends or other deformation
- the Handle (9) is free from any cracks or other damage
- the Needle (6) is moving freely when the Needle Slider (5) is moved back and forth

To prevent the liquid to be used for delivery/ injection with the Instrument from accidentally entering the Interface Cable Connection socket (3), it is recommended to connect the Creo Medical Interface Cable (provided separately) to the Instrument before connection of a fluid-filled syringe to the Syringe Connector (4).

Connection of Interface Cable, Creo Medical reference 2-RS2-210

Warnings

Do not attempt to connect or disconnect the Creo Medical Interface Cable when the Instrument is positioned for treatment, as this may cause unintended movement of the Instrument.

Cautions

Ensure that the Interface Cable is securely connected to the Electrosurgical Generator and the Instrument before activating the output of the Electrosurgical Generator. Incorrect connections pose the risk of the user being exposed to high voltages or degradation of delivered power and unintended tissue effects.

Do not use excessive force when connecting the Interface Cable to the Instrument or Electrosurgical Generator. Doing so poses the risk of damage to the Instrument.

Always ensure a sterile disposable cover is fitted to the distal end of the Interface Cable reference 2-RS2-210 before connection of the cable to Speedboat RS2, refer to the Interface Cable instructions for use for further information. Connect the Interface Cable to the Interface Cable Connector (3) on the Instrument and confirm that it clicks into place.

Selection of Instrument on Generator

Warnings

Ensure the correct Instrument (Speedboat RS2) is selected from the displayed options on the Generator.

Refer to the instructions of use of the Creo Medical Electrosurgical Generator.

Insertion of Instrument into Endoscope

Warnings

The Instrument is for use in an endoscope working channel with minimum diameter of 3.7 mm. Do not attempt to use the Instrument with an incompatible or damaged endoscope as this may result in damage to the Instrument. Should damage occur replace the Instrument and use with an undamaged and compatible endoscope.

Do not allow the Shaft (2) of the Instrument to be bent sharply or to become kinked as this poses the risk of faulty operation which may result in injury to the patient or user.

Unintentional movement of the Instrument Handle (9) and Shaft must be avoided as it results in movement of the Instrument Distal Tip (1) which may result in injury to the patient.

Cautions

Do not use excessive force or activate the output when the Instrument is being removed from or inserted into the endoscope as this poses the risk of damage to the Instrument or endoscope.

When, prior to or during a procedure, the Instrument is not deployed in the endoscope, store the Instrument in a location isolated from the patient.

Before inserting the Instrument into the endoscope, ensure that the Needle (6) is fully retracted. During insertion, pull back the Needle Slider (5) in the direction away from the Distal Tip to keep the needle fully retracted; then slowly insert the Instrument into the working channel of the endoscope.

Avoid bending the Shaft of the Instrument at all times.

Ensure that the endoscope is in the correct position for the procedure and that endoscopic field of view is clear before extending the Distal Tip of the Instrument from the endoscope into the field of view.

Rotation

Warnings

Do not use excessive force or speed when rotating the Instrument. Excessive force may damage the Instrument.

Ensure rotation has stopped before applying electrosurgical energy.

Rotation of the Distal Tip (1) may be affected when the endoscope is in difficult endoscope positions.

Rotation of the Distal Tip is required to correctly orientate the Electrodes to target tissue. The Protective Hull (8) should be positioned towards non-target tissue. Rotation of the Distal Tip is performed by slowly rotating the Handle (9) around the axis of the Shaft (2) or by rotating the endoscope. Rotation should be performed only when there is satisfactory visualization of the Distal Tip of the Instrument.

Fluid Delivery and Injection

Warnings

Do not activate the output of the Creo Medical Electrosurgical Generator when fluid is being delivered to tissue, as this may cause unintended tissue effects.

Any fluid that is used with this Instrument for the purposes of flushing or injection must be appropriate and supplied in a suatable condition for the intended purpose. Fluids intended for use with this Instrument are specified in the final section of these Instructions for Use. Using inappropriate fluids can cause serious injury or death to the patient.

Do not inject a flammable liquid as there is a risk of fire when activating the Instrument in proximity to flammable liquids.

Do not inject air into tissue. Ensure the injection liquid fills the Instrument and confirm there is uninterrupted liquid flowing from the Needle tip prior to injection in to tissue. Injecting air poses the risk of injury or death to the patient.

It is essential that the actions of the user and assistant (if applicable) prevent uncontrolled and unexpected movement of the Instrument ’s Distal Tip when the Needle is extended and when delivering fluid. For example, movement of the Instrument Handle or proximal Shaft that results in any movement of the Distal Tip and therefore should be avoided. Uncontrolled movement of the Instrument ’s Distal Tip poses the risk of injury to the patient.

Deliver the fluid using a syringe only with a steady and controlled pressure. Do not use excessive pressure or a fluid pump, as these pose the risk of patient injury or Instrument damage.

Ensure that the Needle is fully retracted at all times other than for intra-procedural fluid delivery or injection to avoid patient injury caused by the Needle. Do not activate the output while the Needle is extended.

Do not use the Needle for blunt dissection and do not apply a sideways force to the Needle. The Needle may be become bent and this will prevent retraction.

Should it not be possible to retract the Needle ensure that care is taken when removing and when disposing of the Instrument to prevent injury to personnel and damage to the endoscope.

Cautions

Ensure the syringe has an outlet Luer-lock type connector that is centrally located; otherwise the syringe may not connect to Instrument correctly. Use 5 ml or 10 ml capacity syringes only. Screw the required pre-filled fluid syringe to the Syringe Connector (4) on the Instrument and ensure the connection is secure. Do not use a syringe that cannot be fitted securely.

Connect a pre-filled 5 ml or 10 ml syringe to the Syringe Connector and ensure that the connection is secure. Prior to delivery of fluid, completely flush the liquid to be used through the Instrument to remove any air.

Position the tip of the Instrument in proximity to the target tissue and make sure that the Needle can be seen when extended. Slowly extend the needle to the desired length by moving the Needle Slider (5) forward on the Instrument handle. Hold the Needle Slider in this position while carefully inserting the Needle into the tissue for injection.

Under direct visualisation, inject the fluid. Avoid any movement of the endoscope or Instrument during injection as this may result in tearing of the tissue.

Once injection is completed, slowly retract the Needle by moving the Needle Slider backwards. Always retract the Needle as far as possible.

If there is a loss of control of the movement of the Needle using the Needle Slider, remove the Instrument from the endoscope and reintroduce the Instrument as this may enable the Needle Slider to regain control of the Needle movement. If this action does not re-establish the ability to control

needle movement, discontinue the use of the Needle or replace the Instrument.

Cut and Coagulate

Warnings

Do not activate the output when the Instrument is in contact with or close proximity to metallic objects or other medical devices. Do not activate in combination with other electrosurgical generators. Contact to other medical devices and Instrument s may cause burns to the patient or user.

Always apply energy for cutting and coagulation purposes at the minimum output power level and for the minimum time necessary to successfully complete the procedure. Excessive output may result in patient injury, due to excessive penetration and lateral spread of thermal effects.

Cutting or coagulating can occur on both sides of the Top and Bottom Electrodes (7), ensure only target tissue is contacting the Electrodes.

In the event of failure of the Electrosurgical Generator, there is a risk of undesirable rise in output power which might cause unintended tissue effects.

Aspirate fluids from the target area. Attempting delivery of cutting or coagulation energy into pools of fluid will result in reduced cutting and hemostasis effects.

Use of radio frequency energy particularly when cutting tissue may result in neuromuscular stimulation resulting in unintended movement of target tissue.

Cautions

During activation of the cut output, momentary interference with the endoscope visualisation may occur. Cutting should be performed only when there is satisfactory visualisation.

The following settings are recommended for the Creo Medical Electrosurgical Generator for use with this Instrument:

Cut: 25 – 35
Coag: 06 – 10

The recommended settings are selected to the best knowledge of Creo Medical.

Use at a too-low power setting may result in poor cutting performance and excessive coagulation, or extended time required to achieve coagulation.

The Instrument is a bipolar device, both Top and Bottom Electrodes (7) must be in contact with tissue for cutting to occur. The Protective Hull (8) is part of the bottom electrode.

Cutting will occur along the length of the edge of the Top Electrode that is in contact with tissue.

Rotate the Protective Hull (8) towards non-target tissue for cutting / dissection.

Coagulation should be performed with both Top and Bottom Electrodes in contact with tissue. The Distal Tip (1) can be used as a tamponade before and during coagulation for hemostasis.

After 10 seconds of continuous coagulation, the Creo Medical Electrosurgical Generator will automatically deactivate the output. To restore the delivery of energy for coagulation, the user must release and then re-press the footswitch.

Prolonged and frequent activation of the coagulation output may result in heating of the proximal region of the Instrument Shaft.

When monitoring electrodes are used simultaneously, these should be placed as afar as possible from the location that the Instrument is applied. Use of needle monitoring electrodes is not recommended. It is recommended that monitoring systems are used that incorporate high-frequency current limiting devices.

The generator output should not be activated when the Instrument is being positioned for treatment.

During electrosurgery smoke may be produced, use of smoke-plume extraction is advised if this occurs.

Warnings

Build-up of eschar and other material on the Distal Tip of the Instrument will result in reduced cutting and coagulation performance. Do not attempt to overcome loss of performance by increasing the power level or prolonging activation. Always clean the Distal Tip before excessive build-up occurs and in accordance with the instructions provided below.

Cautions

Do not use a sharp implement or abrasive material to clean the Distal Tip as this may result in severe damage to Instrument and may result in the formation of sharp edges.

If eschar builds up on the Instrument Distal Tip and effects the functionality, remove the Instrument from the endoscope and carefully clean the Distal Tip with a saline soaked swab. If the functionality degrades despite cleaning the Distal Tip, the Instrument should be replaced.

Removing the Instrument from Endoscope

Warnings

Should degradation or damage occur to the Instrument such that it is not possible to move the Instrument within the endoscope, or remove it from the endoscope, or such that it is in a frozen position protruding from the endoscope, care must be taken while removing the endoscope from the patient as not to injure the patient due to stabbing, snagging or tearing of tissue by the Instrument.

Using standard sterile technique, gently remove the Instrument from the Endoscope. Slowly remove the Instrument from the Endoscope by carefully pulling it by the Handle (9). Prevent the Instrument tip from touching the floor by coiling the Instrument as it is removed from the Endoscope.

Disconnecting the Interface Cable

Warnings

Do not disconnect the Instrument from the Interface Cable or the Interface Cable from the Creo Medical electrosurgical generator when the output is active except during an emergency. Energized, exposed connectors of the Interface Cable could cause burns to medical personnel or the Instrument could be damaged.

Do not attempt to connect or disconnect the Interface Cable when the Instrument is positioned for treatment as this may cause unintended movement of the Instrument.

Disconnect the Instrument from the Interface Cable by pulling the connector of the Interface Cable away from the handle of the Instrument.

Specifications

Technical details

Length:	2.3 m
Instrument diameter:	Minimum 3.7 mm working channel
Needle gauge:	0.45 mm OD (26 gauge)
Syringe size:	5 ml, 10 ml
Operating frequency and maximum input voltage:	
Cut:	400 kHz, 460 V peak
Coagulation:	5,800 MHz. 75 V peak
Patient circuit:	Compatible with Type BF
Classification:	USA Class II, EU Class IIb

Electrosurgical system compatibility

Electrosurgical Generator, reference number 7-EMR-050.

Interface Cable: reference number 2-RS2-210 (to be fitted with sterile disposable cover, refer to Interface Cable instructions for use).

Endoscope compatibility

This Instrument is specified to be used with endoscopes with a working channel diameter of 3.7 mm or larger.

Injection fluids

Creo Medical Speedboat RS2 is designed to be used in conjunction with EMR (Endoscopic Mucosal Resection) and ESD (Endoscopic Submucosal Dissection) injection fluid solutions. The choice and application of the fluid solution(s) used is the responsibility of the physician.

The following have been assessed and determined to be compatible with Speedboat RS2. Sigmavisc™ should be diluted with saline as indicated below to ensure adequate flow through Speedboat RS2 without application of excessive pressure.

- Normal saline.
  Normal saline with epinephrine (concentration 1:100,000 or 1: 200,000) and 1 to 2 drops (1 drop = 1/20 ml) of indigo carmine or methylene blue dye per 50 ml of solution.
  Sigmavisc™ (0.4 % Sodium Hyaluronate, Hyaltech Ltd, Livingston UK) diluted 1-part Sigmavisc™ to 3 parts normal saline and 1 to 2 drops (1 drop = 1/20 ml) of indigo carmine or methylene blue dye per 50 ml of solution.

Other fluids have not been assessed for compatibility with the materials and construction of the fluid delivery channel within instrument.

Shelf life

Shelf life is 12 months from the date of manufacture. Expiration date is stated on the Instrument packaging label.

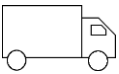
Environment for hospital/clinic storage prior to use

Store at room temperature in a clean and dry environment out of direct sunlight.

Temperature:	+10 °C to +30 °C (+50 °F to +86 °F)
Relative Humidity:	20 % to 90 % (noncondensing)
Atmospheric pressure	69 kPa to 106 kPa

Environment for operation

Temperature:	+10 °C to +30 °C (+50 °F to +86 °F)
Relative Humidity:	20 % to 90 % (noncondensing)
Atmospheric pressure	69 kPa to 106 kPa



Environment for transportation

Temperature:	-10 °C to +55 °C (+14 °F to +131 °F)
Relative Humidity:	20 % to 90 % (noncondensing)
Atmospheric pressure	69 kPa to 106 kPa

Disposal

Speedboat RS2 is a single-use device. Used Speedboat RS2 instruments should be treated as hazardous waste and disposed of in accordance with the hospital or clinical practice clinical waste disposal policy. Speedboat RS2 does not contain batteries.

Serious incidents

In the event of a serious incident involving the product, please inform the manufacturer or its authorised representative and the competent authority of the country in which the user and/or patient is established.

CE marking first applied 25 May 2017

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	Creo Medical Ltd Creo House Unit 2 Beaufort Park Beaufort Park Way Chepstow, NP16 5UH, UK Tel: +44 (0) 1291 637300 Fax: +44 (0) 1291 606015 E-mail: customerservice@creomedical.com Website: creomedical.com	Document Number: IFU-RS4-001 ver. 1 Revision Date: JUNE 2023
EC REP	Creo Medical, S.L. Pol. Ind. Cordovilla D, n°1, 31191 Cordovilla (Navarra), Spain Tel.: +34 948 29 33 24 Fax: +34 948 29 34 18 E-Mail: info.es@creomedical.com	