INSTRUCTIONS FOR USE English.

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INSTRUCTIONS FOR USE (IFU) – UK

Device name: Reusable ophthalmic Corneal Marker
Sterile: Supplied non-sterile
Item specifics: For use in ophthalmic surgery.
Intended use: Used for marking the cornea during refractive surgery.
For use by: Only for use by a suitably trained medical professionals.

RUR101	S Marker

Table 1: Reusable Ophthalmic corneal marker

Caution

1. These instruments are intended for use only by suitably trained medical professionals.

Cautions and warnings

1.Reusable instruments require decontamination and reprocessing before reuse.
2.Reusable instruments are sterilised using irradiation, ETO or steam sterilisation.
3.Reusable instruments products have a one-year warranty.

Intended purpose and indications,

1. Used for marking the cornea in refractive surgery.
2. For refractive error, Astigmatism and Fuchs dystrophy.
3. Blurred or poor vision, refractive error.

Clinical Benefit,

1 Better visual outcome from the surgical procedure.

Performance characteristics,

1 The marking surfaces have to be smooth and the angles of the marking surfaces have to be accurate.

2. The S shape of the S marker needs to be well defined and the front edge smooth.

Risks, contradictions, precautions and side effects

1. Incorrect use may cause blindness.
2. Surgitrac reusable devices are precision surgical devices.
3. The utmost care must be taken at all times when handling these devices to avoid damage.

Medical Device Reporting

Any serious incident occurring as a result of use of the medical device must be reported to the Surgitrac Instruments UK Limited as soon as the User becomes aware of the incident. The incident must also be reported to the authority having jurisdiction in the locale of use.

Inspection & Function

Visually inspect and check:

1. All devices for damage.
2. Check that you cannot see any particles on the device.
3. Check the base of the S is smooth and free from burrs.
4. Long, slender devices are not distorted

Report any issues to Surgitrac – See contact information at end of IFU

Storage, transport, and Operation condition

1. Temperature range (-5°C to +50°C)

Symbol explanation

Category	
Medical Device Status	
	These devices are currently placed on the market Non-sterile.
Packaging	Packaging for reusable non-sterile devices is boxed and labelled.
	Date of manufacture. YYYY/MM/DD.
EU Representative EC REP	**Advena Limited** Tower Business Centre, 2nd Floor Tower Street Swatar BKR 4013 Malta +44 (0) 192 680 0153
UK Responsible Person	**Steve Bourne** Surgitrac Instruments UK Limited, 10 Wharfside Business Park Irlam Wharf Road, Irlam Manchester, M44 5PN Tel: +44 (0) 161 776 7626
CH Rep CH REP	**Swiss AR Services GmbH,** **Industriestrasse 47** **CH-63900 Zug.** Info@swissarservices.ch **Tel. +41 41480 40 00**
	**Name and Address of EU distributor.**
	**Name and Address of EU Importer.** Surgitrac Europe S.A.S. 2 rue Helene Boucher, 35235 Thorigne-Fouillard, France.

Symbol explanation

Category	Guidelines
IFU 	Consult instructions for use. Electronic version available at www.surgitrac.com, then go to: About us – Quality and Credentials. Instructions are available in PDF version. An internet connection and PDF reader is required. The IFU is available in English, French, Spanish German and Italian
	Indicates the temperature limits to which the medical device can safely be exposed. (-5°C to 50°C)
	Check the instrument for damage if the box is damaged.
REF	Model Number
Manufacturer. 	**Surgitrac Instruments China Limited,** No.75 Kaifa Avenue, Economic Development Zone, Sihong county, Suqian city, 223900, Jiangsu, P.R.China. www.surgitrac.com info@surgitrac.com
MD	Medical device
UDI	Unique device identifier
CE	EU Medical Device Notified body number (TUV Nord)

Customer Contract Information

Surgitrac Instruments UK Limited
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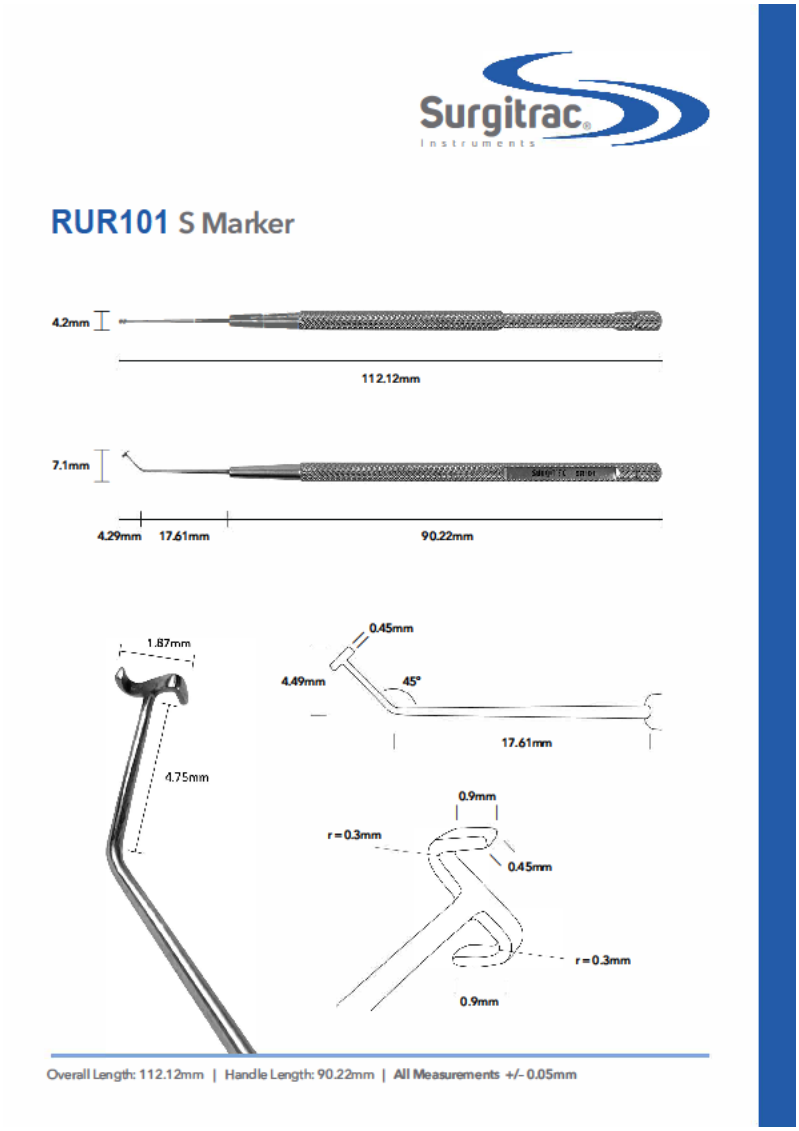
Irlam Wharf Rd
Irlam
M44 5PN
UK
Tel: 0161 7767626

www.surgitrac.com info@surgitrac.com

Appendix A	Technical Drawings
Appendix B	Reprocessing Guidelines.

Appendix A.


Surgitrac
Instruments
RUR101 S Marker
4.2mm
112.12mm
7.1mm
4.29mm
17.61mm
90.22mm
1.87mm
4.75mm
0.45mm
4.49mm
45°
17.61mm
0.9mm
r = 0.3mm
0.45mm
r = 0.3mm
0.9mm
Overall Length: 112.12mm | Handle Length: 90.22mm | All Measurements +/- 0.05mm

Appendix B

Reprocessing Guidelines.

The following information is provided to give general guidance on how metal (316 grade stainless steel) surgical tools supplied by Surgitrac instruments ltd. may be processed to prepare them for use. They must be sterilized prior to use. Equipment, operators, cleaning agents and procedures all contribute to the efficacy of the processing and the healthcare facility should ensure that the surgical tools are always safe for use.

The following are guidelines provided to give general guidance on how metal (316 grade stainless steel) reusable medical devices supplied by Surgitrac Instruments Limited may be processed to prepare them for use. Equipment, operators, cleaning agents and procedures all contribute to the efficacy of the processing and the healthcare facility should ensure that the surgical instruments are always safe for use.

These instructions are intended for use only by persons with the required specialist knowledge and training.

The following instructions have been validated by Surgitrac as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing performed, using equipment, materials and personnel in the facility, achieve the desired results. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. All cleaning and sterilisation processes require validation at the point of use. Their effectiveness will depend on many factors and it is only possible to provide general guidance on proper device cleaning, disinfection and sterilisation.

Category	Guidelines
Warnings	Re-usable devices supplied by Surgitrac are non-sterile. Never use reusable instruments that have not been cleaned, disinfected and sterilised first. Used surgical instruments are contaminated. Disease may occur from injury. Dispose of in a puncture resistant container. Refer to local regulatory guidelines. These devices are designed for use by appropriately trained, qualified and competent personnel. When reprocessing medical devices always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures.

	Always follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents. Surgitrac reusable devices are precision surgical devices. The utmost care must be taken at all times when handling these devices to avoid damage. Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning. No part of the process shall exceed 137°C Avoid the use of mineral acids and harsh, abrasive agents. **Risks, contradictions, precautions and side effects -** Incorrect use may cause blindness. DO NOT apply an ultra-sonic cycle to devices with fine delicate tips, such as hooks and probes.
Medical Device Status	These devices are currently placed on the market. Provided non-sterile. Refer to reprocessing guidelines.
Limitations on reprocessing:	Repeated processing has minimal effect on these devices. End of life is normally determined by wear and damage due to use. Wherever possible, do not allow blood, debris or bodily fluids to dry on devices. For best results, and to prolong the life of the device, reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying, removing excess soil with disposable cloth/paper wipe. If supplied, ensure protective caps and guards are fitted to devices. The warranty provided on reusable devices is 2 years.
Preparation for cleaning	Reprocess all devices as soon as it is reasonably practical following use. Remove any gross contaminants with a steady stream of lukewarm water (below 95°F / 35°C). Rinse each Surgical instrument thoroughly. Using a bristled brush so soft not to damage delicate tips, remove all blood, debris or bodily fluids. **Cleaning Precautions** Avoid mechanical damage during transportation to the process area. Transport to the processing area as soon as possible. Do not soak Surgical instruments in water >35°C, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not use steel wool, wire brushes, pipe cleaners or other abrasive cleaners. **Manual Cleaning**

	Manual cleaning is not a validated process and is therefore not recommended. Surgitrac recommend always processing Surgical instruments through a validated washer disinfector.

Cleaning: Automated	**Equipment Required** Validated washer/disinfector Cleaning/rinsing agents as required by washer/disinfector **Automated Cleaning** Use only validated washer-disinfector machines compliant with HTM01-01 or equivalent guidance and low-foaming, non-ionizing cleaning agents and detergents following the manufacturer's instructions for use, warnings, concentrations and recommended cycles. It is recommended to disinfect thermally (at least 1 minute at 90-95°C). Detergent solution must be used in accordance with label instructions of the detergent manufacturer. When preparing the devices for cleaning, ensure that they do not touch each other and the devices are in a relaxed state. Locks and hinges should be open. Take care not to overload wash baskets. Place devices with concave surfaces, for example curette's, facing down to prevent pooling of water. Where available, use appropriate flushing adaptor attachments to flush inside devices with lumens or cannulations. Ensure lumens and cannulas have unobstructed flow prior to fitting flushing adaptors to ensure thorough cleaning and disinfection. The above has been validated using a washer disinfector cycle to include: 1. One pre-wash stage below 35°C 2. One wash stage at <60°C 3. One rinse cycles at <60°C 4. A final disinfectant rinse stage at >90°C for a minimum holding time of one minute and a minimum drying stage of thirty minutes. Use a wash detergent cleaner with a maximum of 12.2pH and use reverse osmosis water which is controlled for bacterial endotoxins for the rinse. When unloading check cannulations, holes etc for complete removal of visible soil. If necessary, repeat cycle.
Cleaning: Manual **WARNING!**	Care must be taken not to damage delicate tips on devices by the use of hard brushes, scouring agents or excessive force. Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, the reprocessing service must validate their own processes accordingly.

Packaging	Devices should be packaged in wrap or pouches compliant with ISO11607/EN868 as appropriate. Tip protectors should be used for delicate/sharp devices. During the packing process, devices should be visually checked for damage, material degradation and remaining contamination. Contaminated devices must be reprocessed through the wash process again. Damaged items or those where material degradation is identified should be disposed of. Packing processes should take place in a monitored clean room environment.
Drying	When drying is achieved as part of a washer disinfector cycle, do not exceed 137°C.
Sterilisation	Instruments can be sterilized using steam at 134-137°C for 3 – 3 ½ minutes. Steam sterilisers should be compliant with HTM01-01 or equivalent guidance in the Country of use. The three minutes is for exposure, it does not include ramp up times or dry cycle times needed. If other sterilization methods are to be used, the User will validate the sterilization method before routine use. Note: The final responsibility for validation of sterilization techniques and equipment lies directly with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.
Maintenance/Testing	Apply a small quantity of surgical lubrication oil to hinges. Discard blunt or damaged devices.
Inspection & Function	Visually inspect and check: • All devices for damage and wear. • Cutting edges are free of nicks and present a continuous edge. • Jaws and teeth align correctly. • All articulated devices have a smooth movement without excess play. • Locking mechanisms (such as ratchets) fasten securely and close easily. • Long, slender devices are not distorted. Remove for repair or replacement any blunt, worn out, fractured or damaged devices. If any soil or fluid is still visible, return the device for repeat decontamination. Note: if a device is returned to the manufacturer / supplier, the device MUST be decontaminated and sterilised and be accompanied by the relevant Declaration of Decontamination. Any device with a measuring function should be checked prior to first use using a micrometer which is calibrated, traceable to national standards.

	Other forms of cleaning (i.e. ultrasonic) and sterilisation (i.e. low temperature steam and formaldehyde, ethylene oxide and gas plasma) are available. However, always follow the instructions for use as issued by the processing equipment manufacturer and always consult with them if in any doubt over the suitability of any process used. Validate the process prior to use.
Storage	Once sterile, packs should be stored in accordance with the packaging manufacturer's instructions and relevant standards. Always store sterile instruments in a clean, dry environment, away from sunlight. The shelf life is dependent on the sterile barrier employed, storage, environmental and handling conditions. A maximum shelf life for sterilized medical devices before use should be defined by the healthcare facility.
Transport	Products returned to the manufacturer after use must have a decontamination certificate which testifies that each Surgical instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a delay in your enquiry being processed. Contaminated items must be treated as dangerous goods.
Additional Information	Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.
Reporting of Incidents	Any serious incident occurring as a result of use of the medical device must be reported to the Surgitrac Instruments UK Limited as soon as the User becomes aware of the incident. The incident must also be reported to the authority having jurisdiction in the locale of use.