INSTRUCTIONS FOR USE English.

CE
0197

Device name: Single Use ophthalmic Corneal Markers.
Sterile: All Single use ophthalmic surgical instrument are supplied sterile.
Item specifics: For use in ophthalmic surgery.
Intended use: Used for Marking the Cornea in Refractive Surgery.
For use by: Only for use by a suitably trained medical professionals.
Only open the sterile packaging in a clinical environment.

SR21	Lasik corneal marker
SR40	CK Lasik marker (target centre)
SR72	Corneal marker 8 lines
SR101	S marker

After Use.

Dispose of Single Use product in a puncture resistant container. Refer to local regulatory guidelines.

Caution

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

Warnings

1. Single use devices.
2. Not intended for reprocessing.
3. Do Not Use if package is damaged (The only symbol Do not use if package is damaged).
4. DO NOT USE IF THE PACKAGING IS BROKEN OR OPENED.
5. Warning used surgical instruments are contaminated. Disease may occur from injury or reuse.
6. After use dispose of Single Use product in a puncture resistant container. Refer to local regulatory guidelines.

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 single use 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.

The images for each instrument are attached to this IFU from page 6 in PDF format.

Inspection & Function

Visually inspect and check:

1. All devices for damage.
2. Check that you cannot see any particles on the device.
3. Marking edges are true and straight with no 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. Device should be stored in a clean, dry environment, away from sunlight.
2. Keep dry.
3. Temperature range (-5°C to 50°C).
4. Only open sterile packaging in a clinical environment.

Symbol explanation

Category	Guidelines
Medical Device Status STERILE EO	These devices are currently placed on the market sterile.
Packaging	Devices are packaged in a double sterile barrier system consisting of wrap or pouches compliant with ISO11607/EN868 as appropriate. Packaging should be checked prior to opening to ensure the packaging is clean and intact.
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
PRC	Date of manufacture. **YYYY/MM/DD.**
EU Representative EC REP	**Advena Limited** Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta Tel: +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	**Swiss AR Services GmbH** Industriestrasse 47 CH-6300 Zug info@swissairservices.ch Tel.: +41 41 480 40 00
	Surgitrac Europe S.A.S. 2 rue Helene Boucher, 35235 Thorigne-Fouillard. France.

Category	Guidelines
Storage  	Keep dry. Keep away from sunlight.
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).
	Do not re-use. Intended for one single use only.
	Do not used if packaging is damaged or compromised.
REF	Model Number.
LOT	Batch/Lot Number.
	Used by date. YYYY/MM/DD.
MD	Medical device.
UDI	Unique device identifier
CE 0197	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

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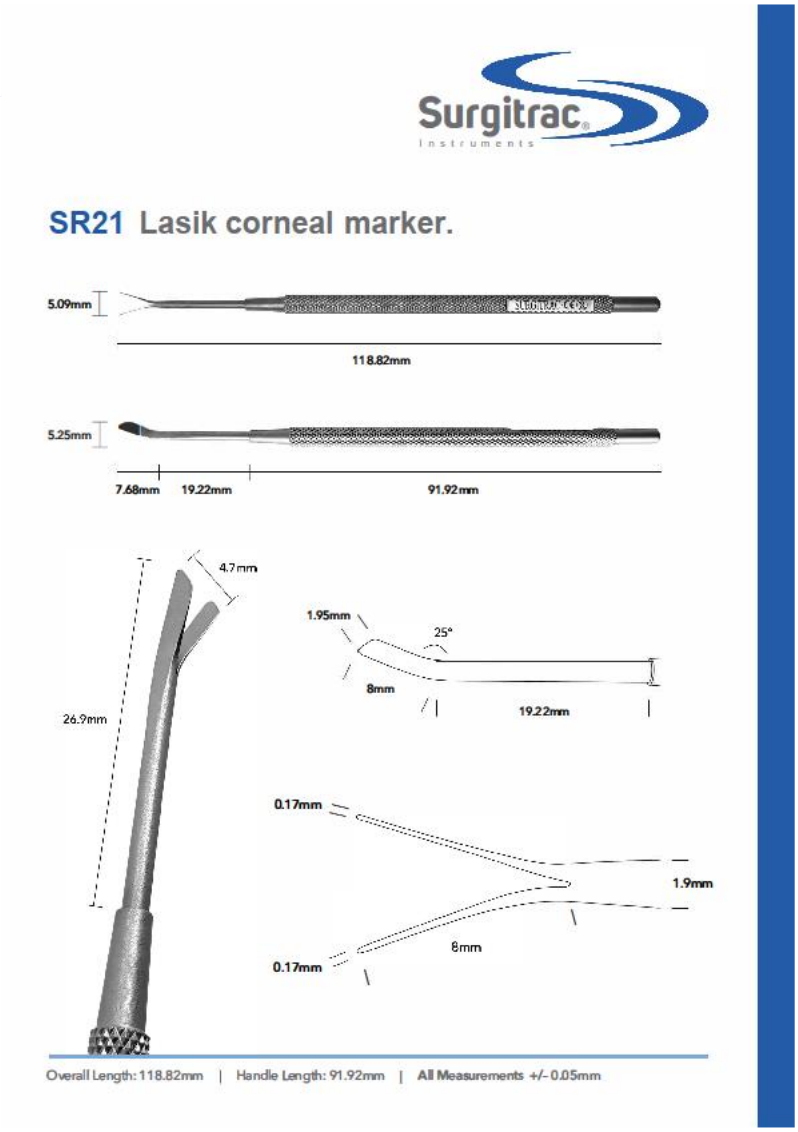
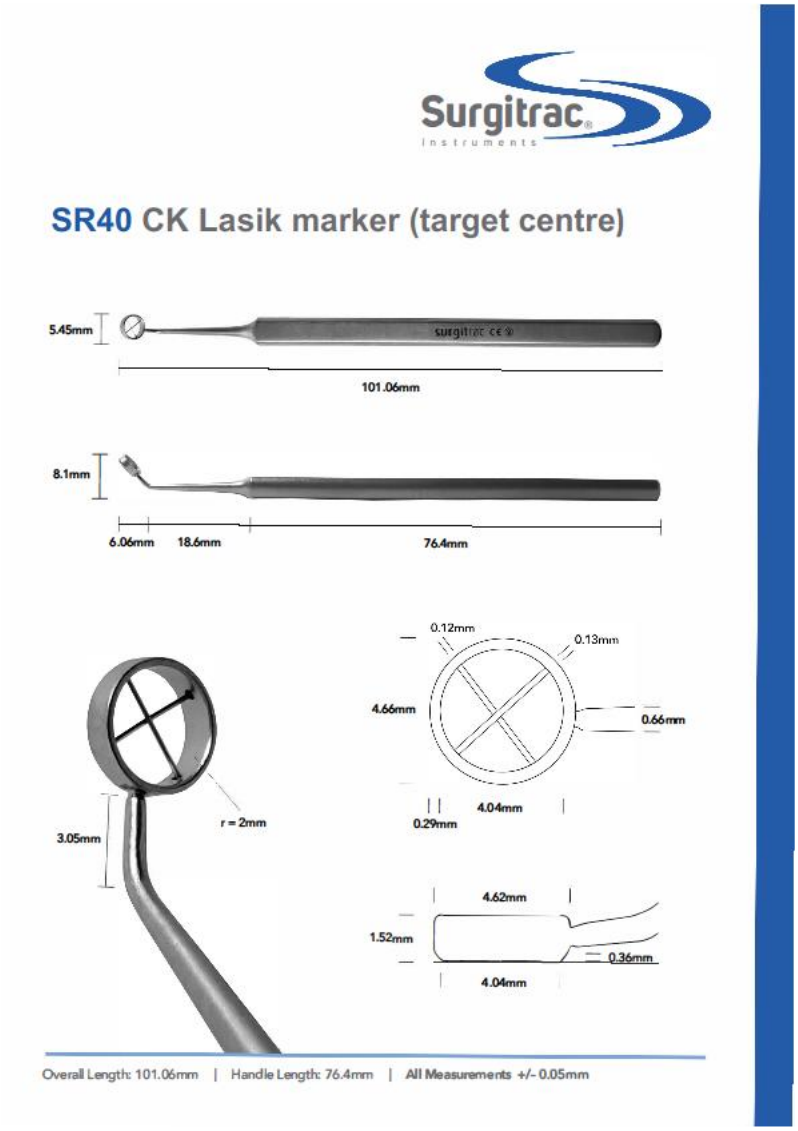
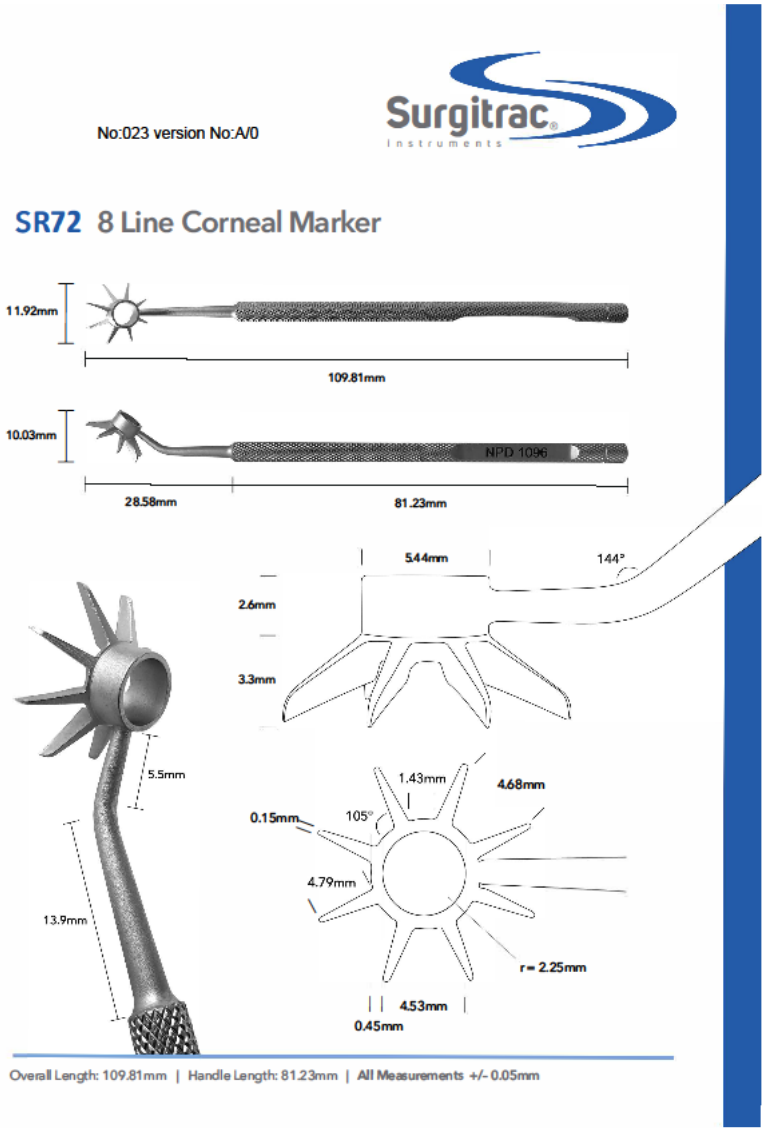
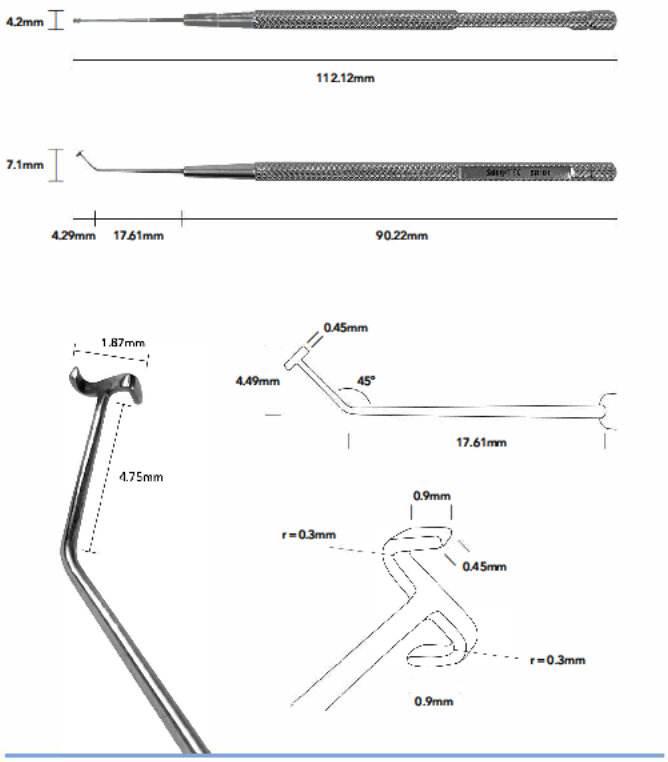
info@surgitrac.com


Surgitrac
Instruments
SR21 Lasik corneal marker.
5.09mm
118.82mm
5.25mm
7.68mm
19.22mm
91.92mm
4.7mm
26.9mm
1.95mm
25°
8mm
19.22mm
0.17mm
1.9mm
8mm
0.17mm
Overall Length: 118.82mm | Handle Length: 91.92mm | All Measurements +/- 0.05mm


Surgitrac
Instruments
SR40 CK Lasik marker (target centre)
5.45mm
surgitrac ce
101.06mm
8.1mm
6.06mm
18.6mm
76.4mm
0.12mm
0.13mm
4.66mm
0.66mm
0.29mm
4.04mm
3.05mm
r = 2mm
4.62mm
1.52mm
0.36mm
4.04mm
Overall Length: 101.06mm | Handle Length: 76.4mm | All Measurements +/- 0.05mm


No:023 version No:A/0
Surgitrac
Instruments
SR72 8 Line Corneal Marker
11.92mm
109.81mm
10.03mm
NPD 1096
28.58mm
81.23mm
5.44mm
144°
2.6mm
3.3mm
5.5mm
13.9mm
1.43mm
4.68mm
0.15mm
105°
4.79mm
r = 2.25mm
4.53mm
0.45mm
Overall Length: 109.81mm | Handle Length: 81.23mm | All Measurements +/- 0.05mm

SR101 S marker.



Overall Length: 112.12mm | Handle Length: 90.22mm | All Measurements +/- 0.05mm