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INSTRUCTIONS FOR USE [English](#).



0197

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**Device name:** Single Use ophthalmic Scleral Depressors.

**Sterile:** All Single use ophthalmic surgical instrument are supplied sterile.

**Item specifics:** For use in ophthalmic surgery.

**Intended use:** Used to tamponade or indent the globe for observation purposes.

**For use by:** Only for use by a suitably trained medical professionals.

Only open the sterile packaging in a clinical environment.

|      |                                |
|------|--------------------------------|
| SC23 | Scleral depressor bulbous end  |
| SC24 | Scleral depressor hammer shape |
| SC25 | Scleral depressor double ended |

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 to tamponade or indent the globe for observation purposes (to examine the fundus).
- 2 Used for vitreoretinal and retinopathy of prematurity.
- 3 Blurred or poor vision, refractive error.

### Clinical benefit,

1. Better visual outcome from the surgery.
2. In the case of premature babies ROP without the examination they could be blind.

### Performance characteristics,

1. These instruments do not have performance characteristics.

### , 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. Hammer and bulbous ends must be smooth and free from burrs.
7. 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 Operating theatre.

## Symbol explanation

| Category                                                                                                           | Guidelines                                                                                                                                                                                                                                                                         |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Medical Device Status</b><br>   | These devices are currently placed on the market sterile.                                                                                                                                                                                                                          |
| <b>Packaging</b><br>               | The devices are packaged in a single blister sterile barrier system consisting of blister pouch and paper seal compliant with ISO11607/EN868 as appropriate. Packaging should be checked prior to opening to ensure the packaging is clean and intact.                             |
| <b>Manufacturer</b><br>            | <b>Surgitrac Instruments China Limited,</b><br>No.75 Kaifa Avenue, Economic Development Zone, Sihong county, Suqian city,<br>223900 Jiangsu, P.R. China.<br><a href="http://www.surgitrac.com">www.surgitrac.com</a><br><a href="mailto:info@surgitrac.com">info@surgitrac.com</a> |
|                                    | Date of manufacture.<br>YYYY/MM/DD.                                                                                                                                                                                                                                                |
| <b>EU Representative</b><br>       | <b>Advena Limited</b><br>Tower Business Centre, 2nd Floor,<br>Tower Street,<br>Swatar,<br>BKR 4013,<br>Malta<br>Tel: +44 (0) 192 680 0153                                                                                                                                          |
| <b>UK Responsible Person</b><br> | <b>Steve Bourne</b><br>Surgitrac Instruments UK Limited,<br>10 Wharfside Business Park,<br>Irlam Wharf Road,<br>Irlam,<br>Manchester,<br>M44 5PN<br>Tel: +44 (0) 161 776 7626                                                                                                      |
|                                  | <b>Swiss AR Services GmbH</b><br>Industriestrasse 47<br>CH-6300 Zug<br><a href="mailto:info@swissairservices.ch">info@swissairservices.ch</a><br>Tel.: +41 41 480 40 00                                                                                                            |
|                                  |                                                                                                                                                                                                                                                                                    |
|                                  | <b>Surgitrac Europe S.A.S.</b><br>2 rue Helene Boucher,<br>35235 Thorigne-Fouillard.<br>France.                                                                                                                                                                                    |

| Category                                                                           | Guidelines                                                                                                                                                                     |
|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Storage                                                                            |                                                                                                                                                                                |
|    | Keep dry.                                                                                                                                                                      |
|    | Keep away from sunlight.                                                                                                                                                       |
| IFU                                                                                | Consult instructions for use.<br>Electronic version available at <a href="http://www.surgitrac.com">www.surgitrac.com</a> , then go to:<br>About us – Quality and Credentials. |
|    | Instructions are available in PDF version. An internet connection and PDF reader is required.<br>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.                                                                                                                            |
|  | Model Number.                                                                                                                                                                  |
|  | Batch/Lot Number.                                                                                                                                                              |
|  | Used by date.<br>YYYY/MM/DD.                                                                                                                                                   |
|  | Medical device.                                                                                                                                                                |
|  | Unique device identifier                                                                                                                                                       |
|  | EU Medical Device Notified body number (TUV Nord).                                                                                                                             |
| 0197                                                                               |                                                                                                                                                                                |

#### Customer Contract Information

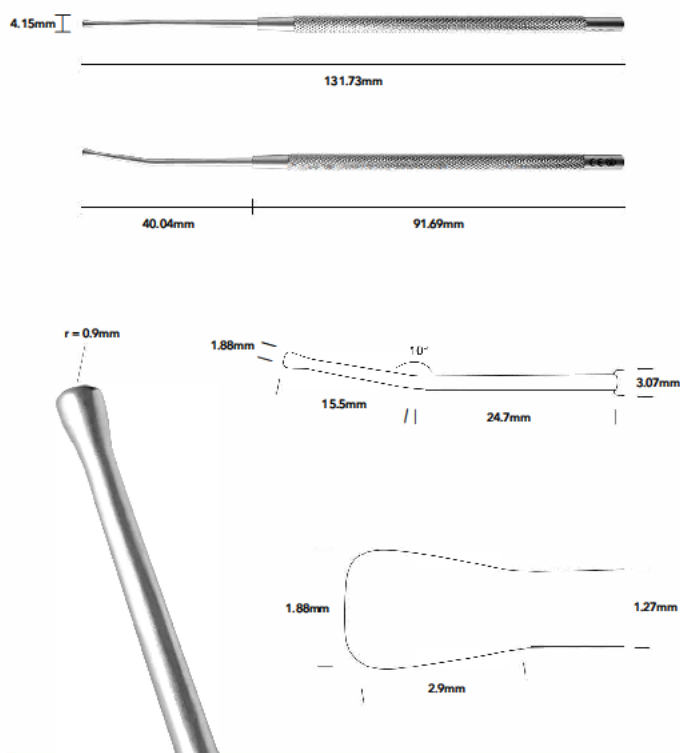
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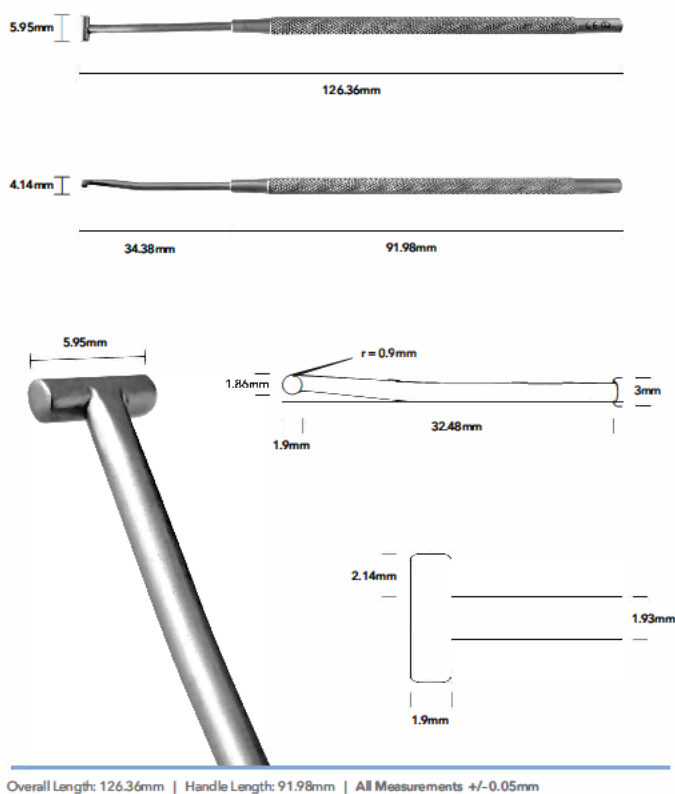
## SC23 Scleral depressor bulbous end.



Overall Length: 131.73mm | Handle Length: 91.69mm | All Measurements +/- 0.05mm



## SC24 Scleral depressor hammer shape.





## SC25 Scleral Depressor doble ended.

