
INSTRUCTIONS FOR USE [English](#).



0197

Device name: Single Use ophthalmic Castroviejo Adjustable Calliper.

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

Item specifics: For use in ophthalmic surgery.

Intended use: Used to measure ocular tissue.

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

Only open the sterile packaging in a clinical environment.

SGO5	Castroviejo adjustable calliper
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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 instrument 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 measure ocular tissue with the aid of an ocular ruler.
- 2 Cataract, vitreoretinal, lid surgery, strabismus and Glaucoma.
- 2 Blurred or poor vision, refractive error.

Clinical benefit,

- 1 Better visual outcome from the surgery.

Performance characteristics,

- 1 The calliper needs to mark the surgical site accurately, so the increments need to be accurate.

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 always taken when handling these devices to avoid damage.
4. Surgitrac recommend an ophthalmic ruler is used to check the accuracy of the calliper and measure twice before cutting tissue.

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. The measuring gauge must be clearly defined.
4. All articulated devices have a smooth movement without excess play.
5. The tips should be straight and level.

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 	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. No75 Kaifa Avenue, Economic Development Zone, Sihong County. Suqian City, 223900, Jiangsu, P.R. China. www.surgitrac.com info@surgitrac.com
	Date of manufacture. YYYY/MM/DD.
EU Representative 	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
	Swiss AR Services GmbH Industriestrasse 47 CH-6300 Zug info@swissairservices.ch Tel.: +41 41 480 40 00
	Surgitrac Europe Limited 2 Helene Boucher, 35235 Thorigne-Foulillard.

Renne.
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.
	Model Number.
	Batch/Lot Number.
	Used by date. YYYY/MM/DD.
	Medical device.
	Unique device identifier
	EU Medical Device Notified body number (TUV Nord).
0197	

Customer Contract Information

Surgitrac Instruments UK Limited

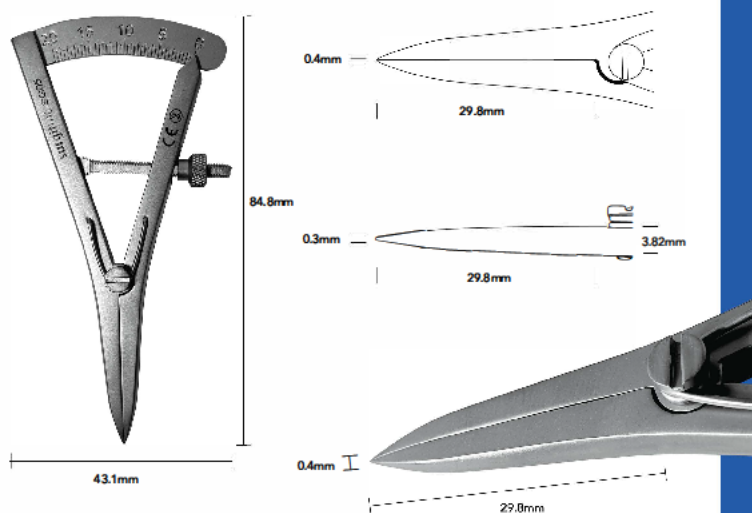
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SGO5 Castroviejo adjustable caliper.



Overall Length: 84.8mm | Overall Width: 43.1mm | All Measurements +/- 0.05mm