
INSTRUCTIONS FOR USE [English](#).



0197

Device name: Single Use ophthalmic Curettes.

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

Item specifics: For use in ophthalmic surgery.

Intended use: Used in Meibomian Cyst Surgery.

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

Only open the sterile packaging in a clinical environment.

CR01	Curette small
CR02	Curette medium
CR03	Curette large
CR05	Curette double ended M & L

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 suitable 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 in meimobium cyst surgery to scoop out the debris from the cyst.
- 2 Meimobium cyst on eye lid.
- 3 Blurred or poor vision and lump on eye lid.

Clinical benefit,

- 1 Lid lump removed taking pressure of the eye giving better visual outcome from the surgery.

Performance characteristics,

- 1 The cup size and shape needs to be correct for the size of cyst.

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. Check the scoop edges for burrs or sharpness.
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 	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
	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 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.
	Model Number.
	Batch/Lot Number.
	Used by date. YYYY/MM/DD.
	Medical device.
	Unique device identifier
 0197	EU Medical Device Notified body number (TUV Nord).

Customer Contract Information

Surgitrac Instruments UK Limited

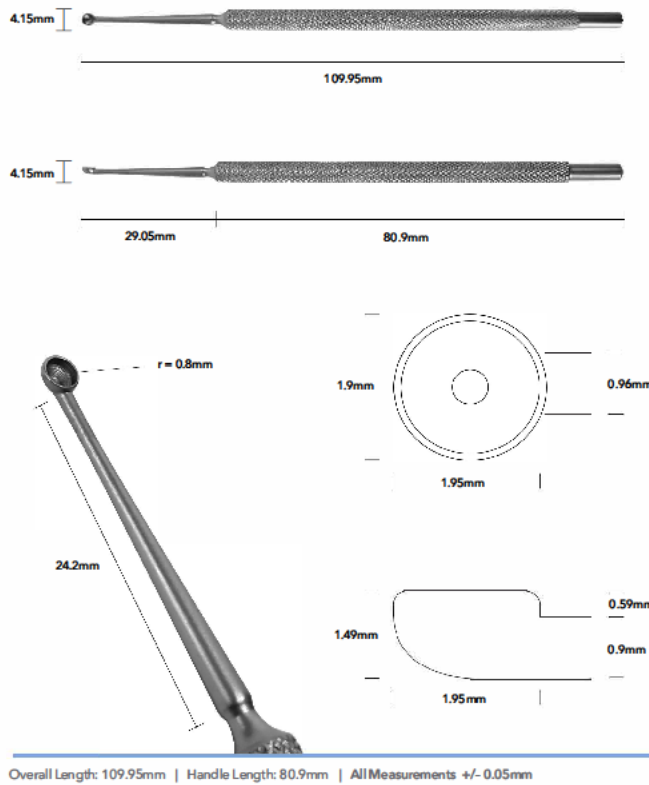
Unit 10 Wharfside Business Park,
Irlam Wharf Rd,
Irlam,
M44 5PN
UK
Tel: 0161 7767626

www.surgitrac.com
info@surgitrac.com

Appendix A

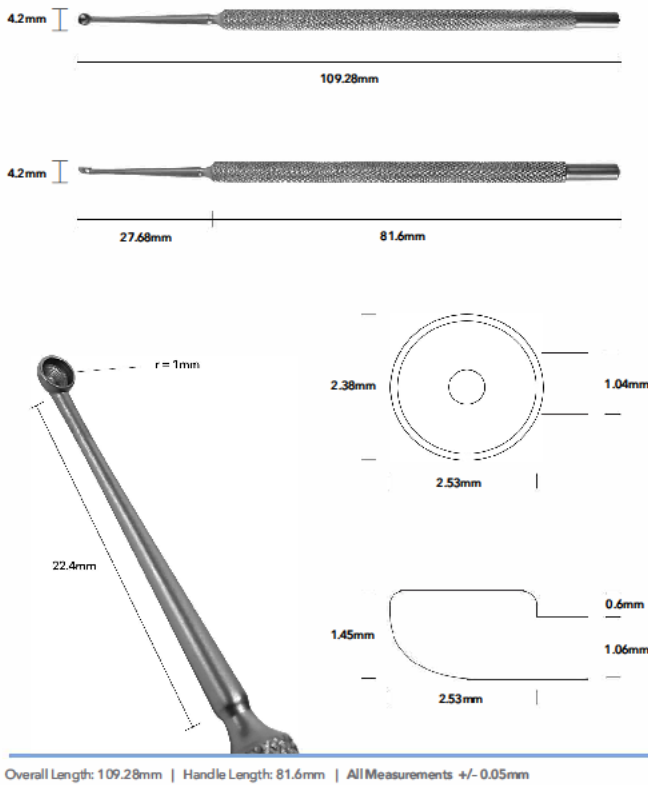


CR01 Curette small



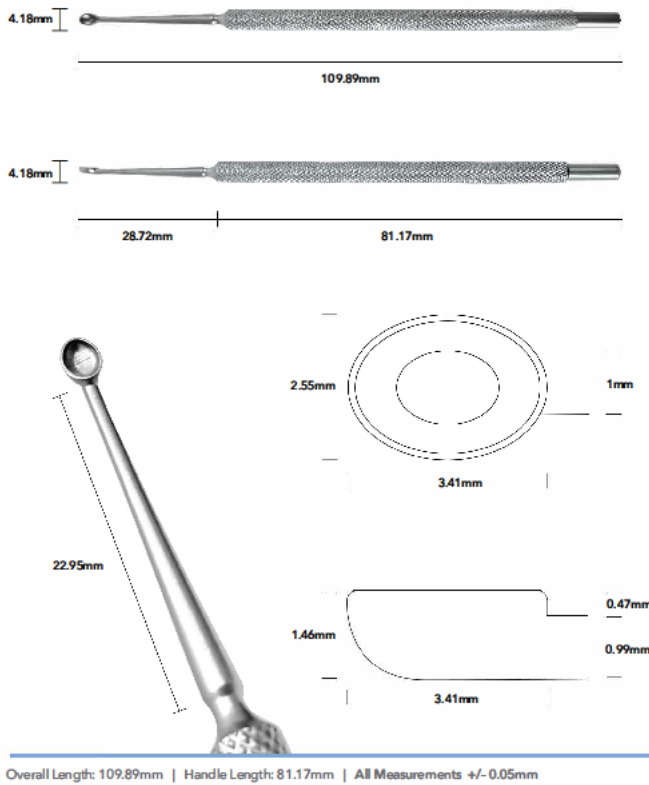


CR02 Curette medium.



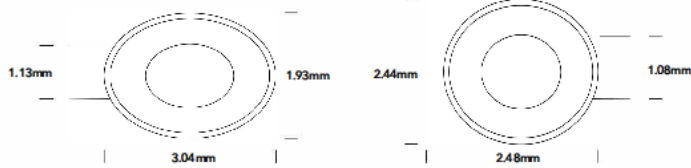
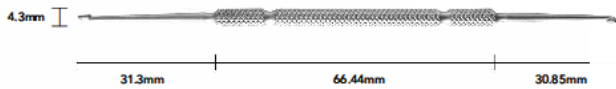
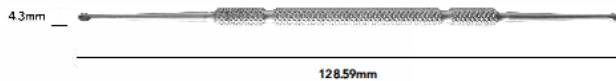


CR03 Curette large.





CROS Curette double ended medium and large.



Overall Length: 128.59mm | Handle Length: 66.44mm | All Measurements +/- 0.05mm