

---

INSTRUCTIONS FOR USE [English](#).



0197

---

**Device name:** Single Use ophthalmic Punctal Dilators.

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

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

**Intended use:** Used to Dilate the Punctum or clear Lacrimal Duct.

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

Only open the sterile packaging in a clinical environment.

|             |                                                 |
|-------------|-------------------------------------------------|
| <b>PD01</b> | Punctal dilator sharp                           |
| <b>PD02</b> | Punctal dilator blunt                           |
| <b>PD03</b> | Punctal dilator double ended                    |
| <b>PD05</b> | Bowmans probe oo-o                              |
| <b>PD06</b> | Bowmans probe oo-ooo                            |
| <b>PD07</b> | Punctal dilator and lacrimal probe double ended |
| <b>PD08</b> | Lacrimal probe                                  |

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 persons with the required specialist knowledge and training.

**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 dilate the punctum and clear the lacrimal duct.
- 2 Dry eye syndrome.
- 3 Blurred or poor vision.

**Clinical benefit,**

- 1 Better visual outcome from the surgical procedure.

**Performance characteristics,**

- 1 These devices do not have performance characteristics.

**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:

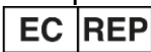
1. All devices for damage.
2. Check that you cannot see any particles on the device.
3. Tips and shafts should be burr free.
4. Long, slender devices are not distorted.

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                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Medical Device Status</b><br>   | These devices are currently placed on the market sterile.                                                                                                                                                                                                                           |
| <b>Packaging</b><br>               | 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.                                                       |
| <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><b>YYYY/MM/DD</b>                                                                                                                                                                                                                                           |
| <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

##### Surgitrac Instruments UK Limited

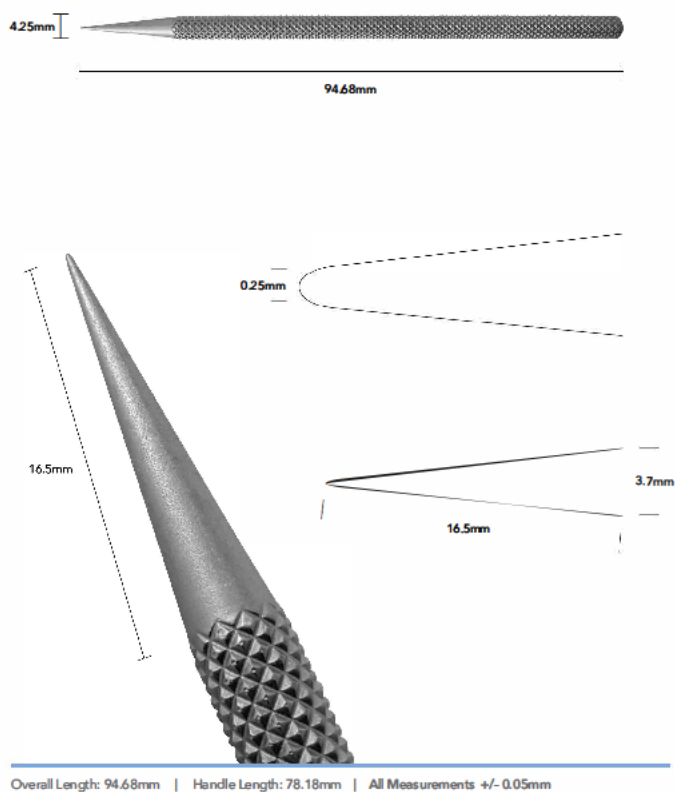
Unit 10 Wharfside Business Park,  
Irlam Wharf Rd,  
Irlam,  
M44 5PN  
UK  
Tel: 0161 7767626

[www.surgitrac.com](http://www.surgitrac.com)

[info@surgitrac.com](mailto:info@surgitrac.com)

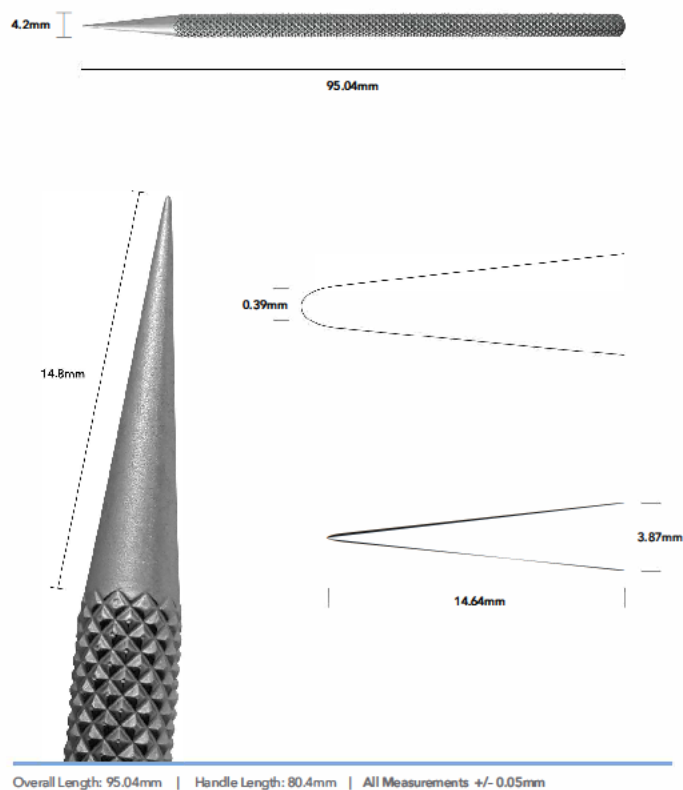


## PD01 Punctal dilator sharp.



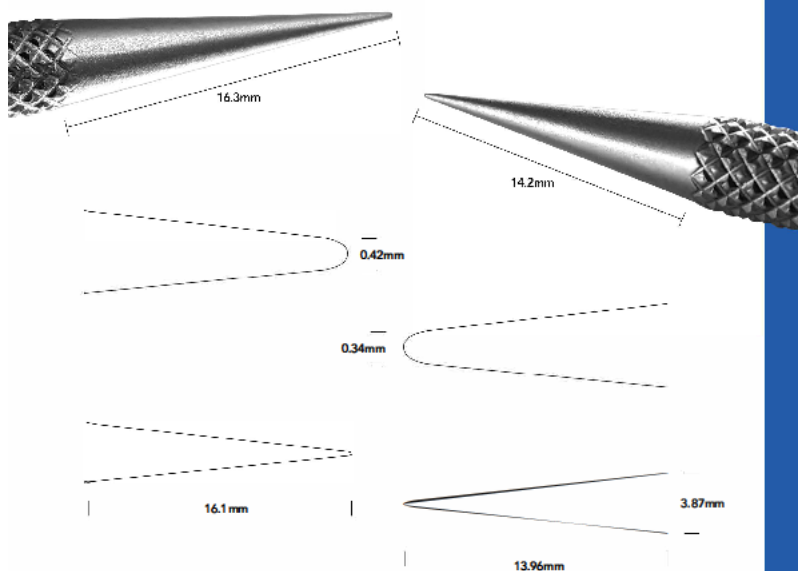
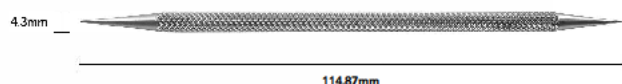


## PD02 Punctal dilator.





## PD03 Punctal dilator double ended.

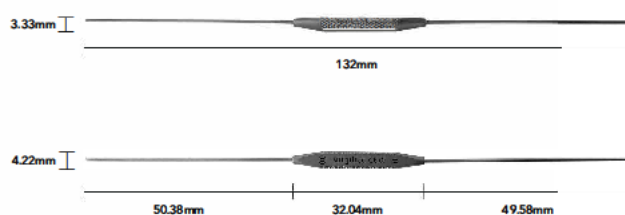


Overall Length: 114.87mm | Handle Length: 84.81mm | All Measurements +/- 0.05mm





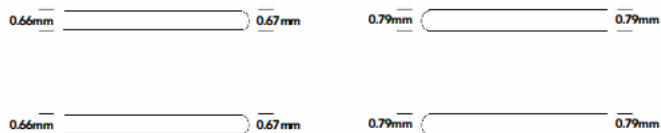
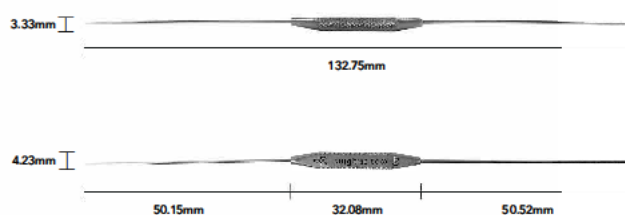
## PD05 Bowmans probe size 00-0.



Overall Length: 132mm | Handle Length: 32.04mm | All Measurements +/- 0.05mm



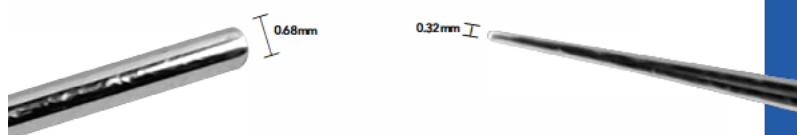
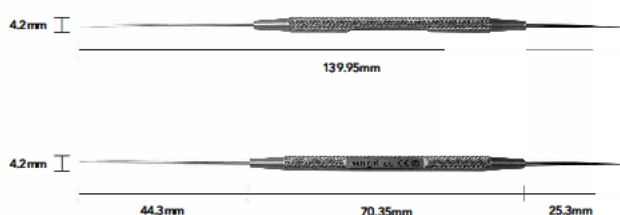
**PD06** Bowmans probe size 000-00.



Overall Length: 132.75mm | Handle Length: 32.08mm | All Measurements +/- 0.05mm



## PD07 Punctal dilator and lacrimal probe double ended.



Overall Length: 139.95mm | Handle Length: 70.35mm | All Measurements +/- 0.05mm



## PD08 Lacrimal probe.

