



## INSTRUCTIONS FOR USE (IFU)

### STERILE FINE / MICROSURGERY BLADES

#### 1. DEVICE DESCRIPTION

Fine surgical blades are sterile, single-use medical devices intended for precision surgical procedures. The blades are manufactured from medical-grade stainless steel and are designed to be mounted on compatible collet-type surgical handles.

Each blade is individually packed in an easy-peel foil pouch, supplied sterile and non-pyrogenic, and intended for single use only. The device is manufactured to deliver controlled and predictable cutting performance when used in accordance with these instructions.

Labelling and Marking of blades is fully compliant with the requirements of MDD/93/42/EEC, EU MDR 2017/745, BS 2982:1992, EN ISO 20417:2021 & EN ISO 15223-1:2021.

#### 2. INTENDED USE:

Fine surgical blades are intended for controlled surgical incisions and tissue dissection when mounted on a compatible surgical handle.

#### 3. INDICATION:

Fine surgical blades are indicated for procedures requiring high precision and controlled incisions, including but not limited to ophthalmic procedures, reconstructive surgery, dental surgery, podiatry, cosmetic and other precision surgical disciplines. Selection of blade size and geometry should be based on the specific surgical application and tissue type.

#### 4. INTENDED USER

This device is intended for use by trained healthcare professionals, including surgeons and medical practitioners, who are qualified to perform surgical procedures requiring fine or microsurgical blades.

#### 5. PATIENT TARGET GROUP

The device is intended for use on human patients requiring surgical procedures involving controlled and precise incisions. There are no specific patient population restrictions when the device is used as intended.

#### 6. CONTRAINDICATIONS:

- Re-use of Scalpel can work as carrier for communicable disease to patient and/or user.
- Adverse event may occur if blade is used after expiry date as expiry date impacts product sterility.

#### 7. WARNING:

- Read instructions for use.
- The product should be used only by a qualified surgeon, Doctor or paramedic.
- Before use always check integrity of product and packing along with expiry date.
- For single use only, If re-used this can work as carrier for communicable disease, HIV, Hepatitis, contagious diseases, undue diseases to patient and/or user.
- Sterility of product is not guaranteed if packet is broken/torn. Use product immediately after opening the pack
- Do not attempt to bend, reshape, or modify the blade.
- Use only with compatible surgical handles.

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- ADPPL is not responsible for any possible consequences resulting from improper use.
- ADPPL do not hold any responsibility if device re-used or re-sterile.
- After use of products must be disposed off as per country law of bio-waste handling rule.

### 8. PRECAUTIONS:

- This device must only be used by surgeons who are trained & qualified in the appropriate skills.
- Care must be taken so that the pouch is not opened in an unsterile area otherwise the blade which has already been sterilized may become unsterile.
- Don't use if product or pouch appear to be damaged.
- For single patient use only as content is supplied sterile.
- Ensure the blade is securely mounted on the handle before use.
- During use avoid twisting, bending or putting excessive force or strain on the blade in order to prevent breakage.
- Always open the pouch from peel apart direction to avoid injury.
- Devices are extremely sharp, use care while handling.
- Proper procedures must be used as applicable for handling any sterile product.
- Care must be taken during disposal of device to avoid any contact or injury due to the sharp nature of the device.
- In case of changes in the performance of device for intended use, replace the defective device by new to full fill the required application.
- Follow standard surgical sharps handling procedures at all times.

### 9. KNOWN EFFECTS OF REUSE

Reuse of the blade may lead to degradation of the cutting edge and inconsistent cutting performance, and an increased risk of cross-contamination or infection.

### 10. STERILIZATION

The device is sterilised by gamma irradiation at a validated minimum dose of 2.5 Mrads and is supplied sterile for single use.

### 11. USE

- Open the peel-apart foil pouch partially within a sterile field.
- Carefully expose the blade without allowing it to drop from the pouch.
- Slide the blade onto a compatible collet-type surgical handle using appropriate technique.
- Confirm that the blade is securely mounted before use.

### 12. STORAGE CONDITION:

- Keep away from direct sunlight.
- Keep away from rain.
- Storage temperature should be 5°C to 45°C.
- Keep away from children.
- Store in cool and dry place.

### 13. SHELF-LIFE:

The shelf life of the device is 5 years (60 months) from the date of manufacture, when stored under the recommended conditions.

### 14. DISPOSAL:

Dispose of the blade immediately after use in an approved sharps container, in accordance with applicable local, national and international biomedical waste regulations.

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### 15. RETURN OF DEVICE





















The documents & papers required for return of defective device and in compliance of law of the land for origin and destination shall be provided to ADPPL within a week (subject to any natural calamity) of receipt of the product along with the photograph & inspection report as an evidence of damaged product and the product shall not be used under any circumstances & it should be separately with proper identification of damaged goods.

### 16. NOTICE TO THE USER

Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. The details for the notice to the manufacturer of any serious incident can be reported through our web site [www.adityadispomed.com](http://www.adityadispomed.com) and customer complaint contact T: **+91 124 4764900**.

In case of reporting to regulatory authority/competent authority of the member state as per law of the land for reporting of such incidents as per the regulation where the user is established.

### 17. SYMBOLS

|   |                               |   |   |   |   |
|---|-------------------------------|---|---|---|---|
|   | Batch code                    |   | Catalogue number                                    |   | Use by date   |
|  | Do not re-use                 |  | Caution, consult instruction for use                |  | Do not use if package is damaged and consult instructions for use |
|  | Keep dry                      |  | Keep away from Sunlight                             |  | Do not resterilize  |
|  | Sterilized using Irradiation  |  | Temperature Limitation                              |  | Manufacturer  |
|  | Consult instruction for use   |  | Authorized representative in the European Community |  | CE Mark with NB Number  |
|  | Non-pyrogenic                 |  | Country of Manufacturer                             |  | Medical Device  |
|  | Single Sterile Barrier system |  | Manufacturing Date                                  |   |   |

The same IFU is available on our web site

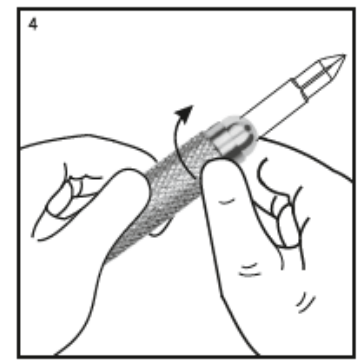
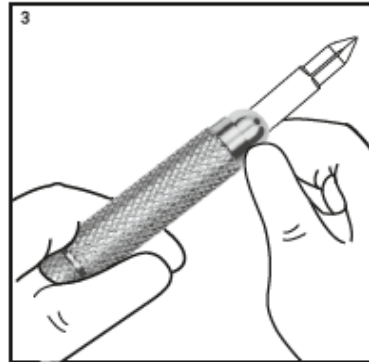
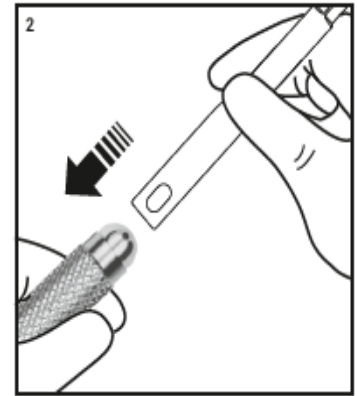
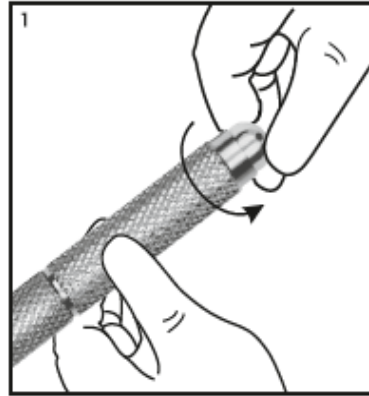
# INSTRUCTIONS FOR USE (IFU)

## RECOMMENDED PROCEDURES FOR ATTACHMENT & REMOVAL OF FINE SURGICAL BLADES ON HANDLE

**⚠ Warning:** Surgical blades are extremely sharp. Handle with care. Use appropriate personal protective equipment (PPE). Avoid direct contact with the cutting edge.

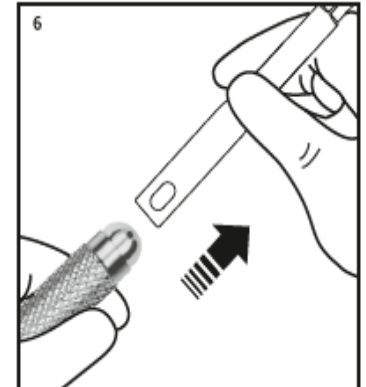
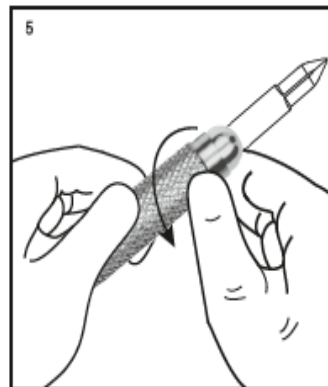
### 1. Blade Attachment (Collet-Type Handle):

1. Ensure the handle is clean, undamaged, and compatible with fine surgical blades.
2. Loosen the collet by rotating the handle grip counter-clockwise.
3. Using a blade holder or sterile forceps, align the blade slot with the collet tongue.
4. Slide the blade fully onto the collet until securely seated.
5. Tighten the collet by rotating the handle grip clockwise until the blade is firmly locked.
6. Gently verify blade fixation before use.



### 2. Blade Attachment (Collet-Type Handle):

1. Hold the handle securely, keeping fingers away from the cutting edge.
2. Loosen the collet by rotating the handle grip counter-clockwise.
3. Using a blade holder or sterile forceps, carefully slide the blade off the collet.
4. Dispose of the used blade immediately in an approved sharps container.



### DISPOSAL:

Dispose of the blade immediately after use in an approved sharps container, in accordance with applicable local, national and international biomedical waste regulations.