INSTRUCTIONS FOR USE (IFU)

STERILE SURGICAL BLADES

1. DEVICE DESCRIPTION:

Sterile surgical blades are manufactured from high-quality carbon steel or stainless steel and are designed for precision surgical cutting. Each blade is individually packaged in a peel-apart foil pouch to protect the cutting edge from damage and maintain sterility until use. Carbon steel blades have a protective VCI (Volatile Corrosion Inhibitor) liner to prevent corrosion during storage.

The device is intended for single use only and is sterilized using validated gamma irradiation. The device must not be used if the sterile barrier is damaged or opened.

Labelling and markings on the product and packaging comply with the applicable requirements of **Directive 93/42/EEC (MDD)** and relevant provisions of **EU Regulation 2017/745 (MDR)**, as well as **EN ISO 20417:2021**, **EN ISO 15223-1:2021**, and **BS 2982:1992**.

2. INTENDED PURPOSE:

The sterile surgical blade is intended to be used by trained healthcare professionals to make surgical incisions and cut tissue during surgical procedures. The blade is designed for single use and must be mounted on compatible Bard-Parker type scalpel handles. Different blade sizes allow selection appropriate to the surgical procedure and tissue characteristics.

3. INTENDED USER:

The device is intended for use by qualified healthcare professionals, including surgeons, physicians, or trained emergency medical personnel, who are experienced in appropriate surgical techniques.

4. INDICATIONS FOR USE:

The surgical blade is intended for use by trained healthcare professionals to make surgical incisions and cut tissue during surgical procedures. Different blade sizes allow selection appropriate to the surgical procedure and tissue characteristics.

5. PATIENT TARGET GROUP:

Suitable for use in patients of all ages where surgical incision is clinically indicated.

6. CONTRAINDICATIONS:

- Do not reuse the device. Reuse may result in infection transmission between patients or users and may compromise device performance.
- Do not use the device after the expiry date, as sterility and performance cannot be guaranteed.
- Do not use the device if the sterile packaging is damaged or opened.

7. STORAGE CONDITIONS:

The device should be stored in a clean, dry environment within a temperature range of **5°C to 45°C** and protected from direct sunlight and moisture.

This is indicated on the product using symbols as defined in ISO 15223-1. Please refer to Page 3 for the actual symbol.

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8. SHELF-LIFE:

Sterility is guaranteed until the expiry date provided packaging remains intact and stored as recommended.

9. PRECAUTIONS:

- This device must only be used by trained healthcare professionals experienced in surgical techniques.
- Do not use the device if the product or pouch appears damaged.
- The device is supplied sterile and is intended for single use only.
- Avoid twisting, bending, or applying excessive force on the blade to prevent breakage.
- Always open the pouch from the peel-apart direction to avoid injury.
- The blade is extremely sharp; handle with care.
- Ensure proper fitment of the blade to the handle to avoid injury.
- If the device does not perform as intended, replace it with a new sterile blade.

10. INSTRUCTIONS FOR USE:

- It is recommended that the foil pouch is partially peeled open in a sterile area to expose the blade.
- Do not drop the blade from the pack as this may damage the edge.
- The blade shall be used with Fitment No. 3 and Fitment No. 4 scalpel handles conforming to EN ISO 27740.
- The blade can be either directly mounted on the metal handle by sliding the handle in the slot made on the blade before removing the blade from the pouch or the blade can be removed from the pouch using forceps and fitted onto the handle.
- Verify that the blade is securely seated in the handle before incision.

11. ⚠ WARNING

- Use the device only according to these instructions.
- The device must be used only by qualified healthcare professionals.
- Verify packaging integrity and expiry date before use.
- For single use only. Do not reuse the device.
- Do not re-sterilize the device.
- Use the device immediately after opening the sterile package.
- Sterility cannot be guaranteed if the package is damaged or opened.

12. RISKS ASSOCIATED WITH REUSE:

- Reduced cutting performance at the incision site.
- Transmission of infectious diseases.
- Cross-contamination between patients or users.

13. RETURN OF DEVICE:

If a defective product is identified, it must not be used. The product should be segregated and clearly identified as defective. Contact the manufacturer for instructions regarding return of the device.

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14. NOTICE TO THE USER:

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to 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 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.

15. SYMBOL:

LOT	Batch code	REF	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	STERILIZE	Do not resterilize
STERILE R	Sterilized using Irradiation	45 °C 5 °C	Temperature Limitation		Manufacturer
	Consult instruction for use	EC REP	Authorized representative in the European Union	CE 2460	CE Mark with NB Number
	Non-pyrogenic	IN	Country of Manufacture	MD	Medical Device
	Single Sterile Barrier system		Manufacturing Date	CH REP	Authorized Representative in Switzerland
STERILE R	Single-barrier system Sterilized by irradiation	EU REP	Authorized Representative in the European Community		

The same IFU is available on our web site

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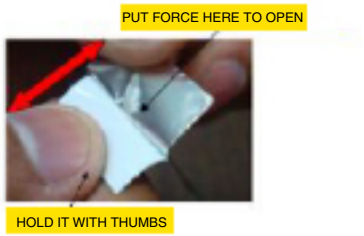
RECOMMENDED PROCEDURE FOR PEELING OFF BLADE PACKING, ATTACHMENT & REMOVAL OF BLADES

PEEL OFF BLADE PACKING

1. PACKED SAMPLE

2. HOLD IT IN HAND

3. PEEL OPEN POSITION



4-POSITION OF BLADE

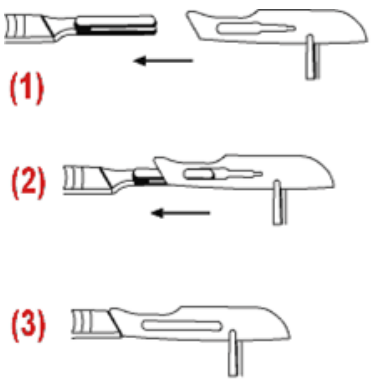
5. HOLD IT IN THIS POSITION TO AVOID FALLING OF BLADE

ATTACHMENT & REMOVAL OF BLADES

To attach blade

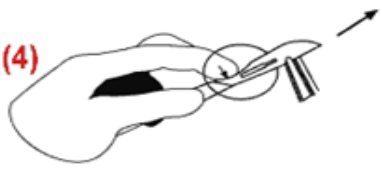
Grip blade with forceps, or similar, avoiding contact with cutting edge.

- Hold handle in left hand with fitting uppermost (fig 1).
- Place blade partway over handle fitting and engage slots (fig 2).
- Slide blade until it clicks into position. (fig 3).



To remove a blade

Grip the blade with forceps, or similar.
Lift heel of blade at point 'A' with tip of index finger, avoiding contact with cutting edge, and slide away from handle carefully (fig 4).



DISPOSAL:

Discard used surgical blades in an approved sharps container and dispose of them in accordance with accepted medical practice and applicable local, state, and national regulations governing biomedical waste.

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