 <p>Aditya Dispomed Products Pvt. Ltd. Plot No 19, Sector 6 IMT Manesar, Haryana 122050 India T: +91 124 2291406/7 www.adityadispomed.com</p>	<p>Document IFU 01 Revision 15 Date 01-04-2023 Approval No 5124/(EN)</p>
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INSTRUCTIONS FOR USE

STERILE SURGICAL BLADES

DESCRIPTION:

Surgical Blades are made of Carbon steel / Stainless Steel. They are packed in Peel Apart foil pouches. Each blade is individually packed in a foil pack to prevent the edge from getting damaged in contact with another blade. Carbon steel have a protective VCI liner.

Labelling and Marking of blades is fully compliant with the requirements of MDD93/42/EEC MDR 2017/745, EN 1041, BS 2982:1992. & EN ISO 15223:2021.

INTENDED USE:

These are used for surgery after mounting on Metal B.P. Handles
Device is Gamma Irradiation for single use and for all age patient groups.

INDICATION:

- Dissection incision
- Different size for different thickness of tissue and site.
- Removal of extra tissues from operating area.

INTENDED USER

This device must be used by surgeons who are trained and qualified in the appropriate surgical techniques.

CONTRAINDICATIONS:

- Re-use of blade can work as carrier for communicable disease to patient and/or user
- Adverse event may be happen if blade use after expiry date as expiry date of product sterility

STORAGE CONDITION:

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

SHELF-LIFE:



- 5 Years (60 months) from the date of manufacturing.

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 by Gamma radiation will become unsterile.
- Don't use if product or pouch appear to be damaged
- For single patient use only content supplied sterile
- 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.
- Proper care must be taken while fitment of blade with respective handle to avoid any injury or accident
- In case of changes in the performance of device for intended use replace the defective device by new to full fill the required application

USE

- It is recommended that the foil pouch is peeled apart half in a sterile area allowing the blade to be exposed. There is no need to drop the blade from the pack.
- Blade shall be used with Fitment# 3 and Fitment# 4 handles conforming to EN ISO 27740.
- The blade can be either directly fitted on to 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 with a forceps and fitted on the handle as shown in the attached sketch.

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DISPOSAL: Discard the Surgical Blades in proper waste container & dispose off the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste



WARNING

- **Use according to the instruction**
- 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,**
- **Do not reuse the device in any circumstances**
- **Do not Resterile the device**
- Use product immediately after opening the pack
- 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.
- Sterility of product is not guaranteed if packet is broken/torn.
- Keep out of reach of children.
- After use of products must be disposed off as per country law of bio-waste handling rule

KNOWN CHARACTERISTICS OF DEVICE & TECHNICAL FACTOR FOR THE RISK IN CASE OF RE-USE

- Difficult to cut at incision site during reuse.
- Any infectious disease can transfer.
- In case of reuse of device may cause communicable and transferable disease from the device.

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 as soon as possible after 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 separated with proper identification of damaged goods.

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 and customer complaint contact T: +91 124 2291406/7.

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.

SYMBOLS

	Batch code		Catalogue number		Use by date
	Do not re-use		Cation, consult instruction for use		Don't use if package is broken
	Keep dry		Keep away from		Don't Resterile
	Sterilized using Irradiation		Temperature Limitation		Manufacturer
	Consult instruction for use		Authorized representative in the European community		CE Mark with NB Number
	Non-pyrogenic				

The same IFU is available on our web site



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

PEEL OFF BLADE PACKING

<p>1- PACKED SAMPLE</p>	<p>2- HOLD IT IN HAND</p>	<p>3- PEEL OPEN POSITION</p>
<p>4- POSITION OF BLADE</p>	<p>5. HOLD IT IN THIS POSITION TO AVOID FALLING OF BLADE</p>	

ATTACHMENT & REMOVAL OF BLADES

<p>To attach blade</p> <p>Grip blade with forceps, or similar, avoiding contact with cutting edge.</p> <ul style="list-style-type: none"> • 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). 	
<p>To remove a blade</p> <p>Grip 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).</p>	

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