

Aditva Dispomed Products Pvt. Ltd

Plot No.19 Sector 6 I.M.T. Manesar Gurgaon Haryana 122 050 India www.adityadispomed.com

MADE IN INDIA

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

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24-02-2018

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.

INTENDED USE:

Intended for tissue separation and other procedures that require a sharp blade to puncture or cut

CONTRADICTIONS:

Not known

ADVERSE EFFECT:

Not known

PRECAUTIONS

- This device must only be used by surgeons who are trained & qualified in the appropriate surgical skills.
- Don't use if the 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 help prevent breakage.

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 & Fitment # 4 handles conforming to EN ISO 27740.
- The blade can be either directly fitted on to 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 removed from the pouch with a forceps and fitted on the handle as shown in the attached sketch.

STORAGE CONDITION:

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

Disposal: Proper care must be taken during disposal to avoid any contact or injury due to the sharp nature of the object. Suggest dispose in an approved sharps container.

WARNING .

Blade is extremely sharp. Handle with care. Used sharps are contaminated. Disease may occur from injury. Refer to AORN,CDC,OSHA or other local standards setting organization guidelines for handling and disposal of sharps

SYMBOLS

LOT	Batch code	REF	Catalogue number	2	Use-by date
2	Do not re-use	$\overline{\mathbb{V}}$	Caution	®	Do not use if package is damaged
†	Keep dry	*	Keep away from sunlight	STERBLIZE	Do not resterilize
STERILE R	Sterilized using Irradiation	+5°C +45°C	Temperature limit	<u>l</u>	Manufacturer
[]i	Consult instructions for use	EC REP	Authorized representative in the European Community		



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RECOMMENDED PROCEDURES FOR ATTACHMENT & REMOVAL OF BLADES

TO ATTACH BLADE

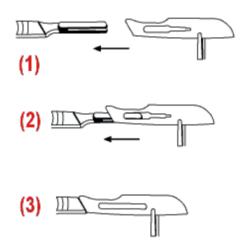
Take Fitment # 3 / Fitment # 4 handle as per Blade Fitment

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 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).

