

RiBBEL[®] SURGICAL BLADES

Sterile, for Single Use

Please read instructions carefully before use



PRODUCT DESCRIPTION

A surgical blade forms a part of Surgical Scalpel which consists of two parts, a blade and a handle. The handles are reusable, with the blades being replaceable. In medical applications, each blade is only used once (even if just for a single, small cut). Scalpel blades are usually made of hardened & tempered steel, stainless steel, or high carbon steel sterilized by Gamma-irradiation as per applicable National / International Standards.

S. No.	Product Categories		Applicable Blade Size No. (if any)	Intended Use	MDD Class (Rule 6)
i	Disposable Surgical Blades	Small Fitting (i.e. Fitment #3) type Surgical Blades <i>[fit handle numbers 3, 3L, 5 & 7]</i>	9, 10, 10A, 10B, 10S, 11, 11K, 11P, 12, 12B, 12D, 13, 14, 15, 15A, 15B, 15C, 15T, 16 & 17	Intended to be used for tissue separation and other procedures that require a sharp blade to puncture or cut	IIa
		Large Fitting (i.e. Fitment #4) type Surgical Blades <i>[fit handle numbers 4, 4L & 6]</i>	18, 19, 20, 21, 22, 22A, 22B, 23, 24, 25, 25A, 26, 27, 36 & 36D		
		Large Fitting (i.e. Fitment #8) type Surgical Blades <i>[fit handle number 8]</i>	60, 60B, 70		
		<i>fit the 'FINE' range of special handles</i>	61, 62, 63, 64, 65, 65A, 67, 67A, 68 & 69		
		<i>Long angled stainless steel blade with short cutting edges at tip for both up & down cutting fits the 'FINE' range of handles</i>	Myringotomy Blades		

INDICATIONS FOR USE

Ribbel Surgical Blades are designed to be used for surgery. For use by, or as directed by, a qualified surgeon. The proper surgical technique for the use of the product is the responsibility of the surgeon. Some of the indications are:

- Cricothyrotomy
- Endotracheal intubation
- Tracheostomy
- Gynaecology related surgeries
- Orthopaedic surgeries
- Dermatological procedures
- Augmentations
- Plastic surgeries



CONTRAINDICATIONS

The products should not be used for anything other than their intended use. Re-use is not recommended as the product is not designed to be cleaned, disinfected or sterilized after single use.

STORAGE AND HANDLING

Store at a temperature 5°C to 50 °C in the original packing in a dry place preferably away from direct and indirect sources of light and heat.

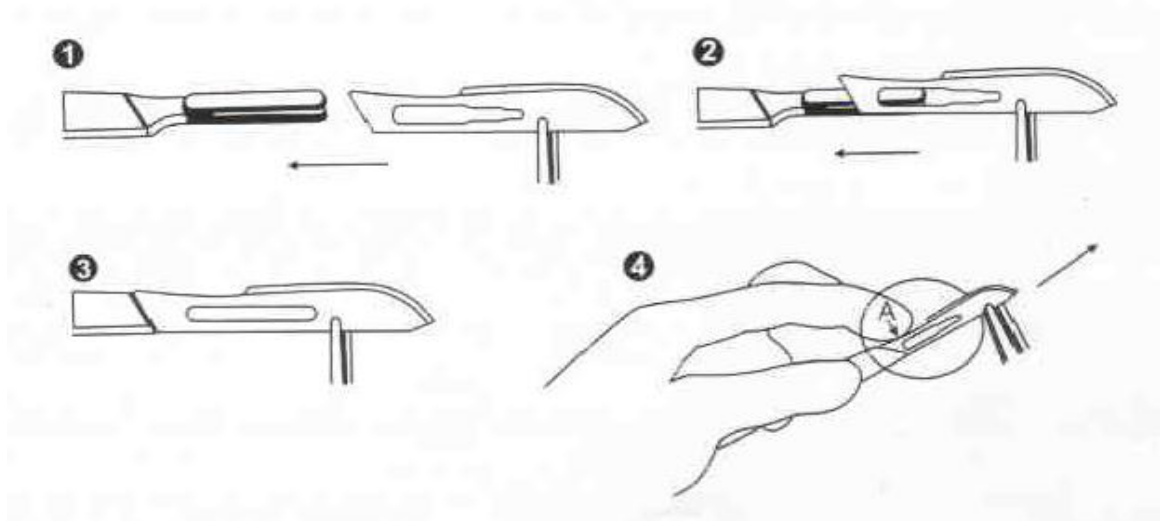
HOW TO USE

(a) To attach a blade:

- (i) Grip blade with forceps (or a similar instrument) avoiding contact with cutting edge.
- (ii) Hold handle in left hand with fitting uppermost (Fig.1).
- (iii) Place blade partway over handle fitting and engage slots (Fig.2).
- (iv) Slide the blade until it clicks into position (Fig.3)
(For better assembly, flex blade slightly upwards when sliding onto handle).

(b) To remove a blade:

- (i) Grip blade with forceps (or a similar instrument).
- (ii) 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).



PRECAUTIONS / CAUTIONS / WARNINGS

The device will perform as intended when the instructions are followed accordingly: -







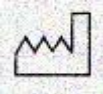

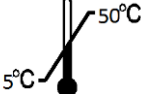








- The way in which a surgical blade is handled prior to use can affect the performance of the blade during use. Take care to ensure that the cutting edge of the blade does not become damaged once removed from its packaging including dropping the blade into a metal bowl or other container that could potentially make the blade dull and also gripping the blade with a forceps or needle clamp across the cutting of the blade.
- Examine individual package for integrity of packaging prior to use. If packaging has been torn, do not use as the sterility of the products is NOT guaranteed if packaging is damaged or open. Do NOT use this product after expiration date printed on the label.
- Avoid twisting, bending or putting excessive force or strain on the blade in order to help prevent breakage. Since the surgical blades are sharp instruments, take proper precautions in handling the blade so as not to injure yourself or others before, during, or after use. The use of these products is restricted to a qualified surgeon or paramedic and it is their responsibility to ensure that they are trained to operate or use these medical devices.
- Re-use of the product intended for single use only may result in degraded performance or a loss of functionality. Any used blade is considered contaminated and should be disposed off after use in a puncture free container, preferably of steel / hard plastic (i.e. in accordance with hospital policy for biohazards). **DO NOT RESTERILIZE**. Re-use may result in exposure to viral, bacterial, fungal or prionic pathogens. Validated cleaning & sterilization method after single use and instructions for reprocessing to the original specifications are not available for these medical devices.
- Before use, all handles should be checked and inspected thoroughly for their cleanliness, sterilization & any damage or wear within the grooves of the bayonet and it should be ensured that the blade is attached to the handle correctly and securely. Handles that have become worn and damaged should not be used.
- The surgical blade is intended to be used for limited contract duration, less than 24 hours. If the blade gets damaged (becomes dull or breaks), dispose and replace it.

DISPOSAL METHOD AFTER USE

The surgical blade, after the completion of the procedure, is to be disposed off in a puncture resist container line with the institutional and local regulatory guidelines for bio-hazardous medical waste disposal.



EXPLANATION OF SYMBOLS:

Symbol	Title / Meaning	Symbol	Title / Meaning	Symbol	Title / Meaning
	Manufacturer		Sterilized using irradiation		Keep away from sunlight
	Symbol for European Authorized Representative		Do not re-sterilize		Keep away from rain
	Date of manufacture		Do not use if package is damaged		Storage Temp. limits
	Use by date		Do not re-use		This side up
	Batch code		Caution		Consult instructions for use
	Catalogue number		Non-sterile		

