

Surgical Blades - Sterile for single use



Device Name

Surgical Blades

Device 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). Surgical blades are usually made of hardened & tempered steel, stainless steel, or high carbon steel sterilized by Gamma-irradiation as per applicable National / International Standards.

Device Specifications

Blade size	Indication
Small Fitment Surgical Blades	Intended to be used for tissue separation and other procedures that require a sharp blade to puncture or cut.
9, 10, 10A, 10B, 10S, 11, 11K, 11P, 12, 12B, 12D, 12S, 13, 13D, 14, 15, 15A, 15B, 15C, 15T, 16, 17, 17P, 100, SC 40, SC 65, SC 90, SC 110	
Large Fitment Surgical Blades	
18, 19, 20, 21, 22, 22A, 22B, 23, 24, 25, 25A, 26, 27, 36, 36D, 60, 60B, 70, PM40, PM40B	
Miniature Fine Surgical Blades	
61, 62, 63, 64, 65, 65A, 67, 67A, 68, 69, 312, 313, 314, 316	

Intended Use

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

Intended User

It is intended to be used by lawfully authorized, technically knowledgeable, experienced, educated, trained, and well-resourced health practitioners or personnel. The proper surgical technique for the use of the product is the responsibility of the health practitioners or personnel.

Duration of Use

Transient Use

Shelf Life:

Five years after Gamma Sterilization.

Method of sterilization:

The sterile devices are sterilized by Gamma Irradiation

Usage Frequency

Single use; All Surgical Blades supplied in a sterile condition, are NOT intended for reuse.

Sterility State of Device Supplied: Sterile (Sterility achieved by Gamma sterilization)

Medical Indications

Medical Surgeries where dissection incisions are required.

Some of the indications are:

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

Following are the examples of conditions where the specific number of blades can be used but not limited to as #9 and 10 are used to cut the muscle and skin in general surgical procedures whereas, the #20 is for general surgical procedures and orthopedic procedures. Miniature blades such as #61 are generally used for plastic surgery and reconstructive 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. Adverse event may occur if Blade are used after expiry date of product sterility.

How to use

(a) To attach a blade:

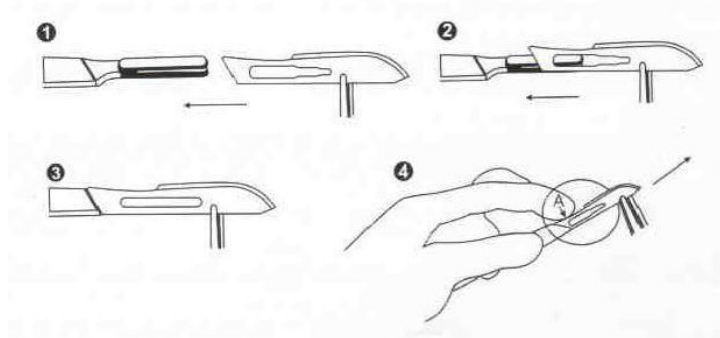
- (i) Grip blade with forceps (or a similar instrument) avoiding contact with cutting edge.
- (ii) Hold handle in left hand with fitting uppermost (Fig.1).
- (iii) Place blade partway over handle fitting and engage slots (Fig.2).
- (iv) Slide the blade until it clicks into position (Fig.3).

(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).



Handling instructions of the device

1. Wear hand gloves before opening the packaging; do NOT open the device packaging with wet hands.
2. Remove the device from the individual pouch following the instructions detailed below:

	<p>Back Foil</p>	<p>Front Foil</p>	
<p>2a. Always peel open the pouch at a 90° angle to ensure smooth and safe removal, as shown in the image</p>	<p>2b. Always peel open from the back foil as shown in image</p>		

3. To mount the surgical blades on the handle, align the blade with the scalpel handle.
4. Place the blade on the groove of the handle and gently slide it towards the scalpel handle.
5. Continue to slide the surgical blades onto the scalpel handle until it locks in place.
6. Before using, check whether the surgical blades were properly fitted to the Scalpel Handle
7. To remove the surgical blades, carefully lift the bottom of the blade until it unlocks from the scalpel handle.
8. Slide the surgical blades off the scalpel handle, moving it away from the handle.

Selection of the handles for the blades:

The device surgical blade is intended to be used with the help of handle. The handle is made up of either stainless steel or plastic material. The handles are reusable however, the blades

are meant to be single use. The numbers allocated for each handle is based on the sizes and type of blades that are compatible with the handle.

For the blades with small fitment ranging from size 9 to 17; handle number 3, 3L, 5 & 7 are compatible.

For the blades with large fitment ranging from size 18 to 36; handle number 4, 4L & 6 are compatible.

For the blades with large fitment ranging from size 60; 8 number handle is more compatible.

These handle numbers are universal and can fit with same size of other blades as well. Apart from these the miniature blades needs to be operated with the help of handles such as 3/4 miniature scalpel handle.

Warnings

- Read the Instructions for Use (IFU) carefully, prior to use of the device.
- The product should be used only by lawfully authorized, technically knowledgeable, experienced, educated, trained, and well-resourced health practitioners or personnel.
- Always check for the integrity of the product and packing along with expiry date before use.
- Surgical blades are extremely SHARP. Always hold the back of the blade while handling the device.
- Never apply excess force on the blade; a clinical failure may occur during the use of the device due to sudden bending, breakage of the blade, if excess force is applied on the scalpel. The breakage of the blade may be prevented by handling the surgical blade with controlled stronger grip, angular incisions, maximizing the contact of blade's cutting surface with tissue and application of pressure only applied by palm and fingers.
- Before using, check whether the blade was properly fitted to the Scalpel Handle
- If the Surgical blades get stuck on the handle, use a pair of pliers to securely remove the blade.
- For SINGLE USE ONLY, if re-used, the device may act as a carrier for communicable and contagious diseases, including STDs (HIV, Hepatitis, etc.)
- Use the product immediately after opening the pack.
- Dimeda is NOT responsible for any possible consequences resulting from improper and/or off-label use.

- Dimeda does NOT hold any responsibility or liability for all the dangers that arise if the device is re-used or re-sterilized.
- Sterility of product is NOT guaranteed if the packaging is broken/torn.
- Keep out of the reach of children.
- After the use of surgical blades, the contaminated blade shall be disposed of in a puncture resist container in line with the institutional and local regulatory guidelines for bio-hazardous medical waste disposal. For disposal the recommended procedure is described as follows mentioned in the product IFU.
- The device does NOT include any measuring functions. The scale provided on the handle of the device is ONLY FOR INDICATIVE PURPOSES and the device does NOT possess any measuring functions.
- The device may cause an allergic reaction due to the material of construction.
- To remove the device from the individual pouch, always follows the handling instructions.

Precautions

- This device must be used by lawfully authorized, technically knowledgeable, experienced, educated, trained, and well-resourced health practitioners or personnel.
- Care must be taken so that the pouch is NOT opened in an unsterile area. Otherwise, the blade which has already been sterilized will become unsterile.
- Do NOT use it if the product or pouch appears to be damaged.
- AVOID twisting, bending, or putting excessive force or strain on the blade during use of the device to prevent breakage.
- Always open the pouch in a peel-apart direction to avoid injury.
- Device is extremely SHARP, handle it with care.
- Appropriate procedures must be followed as applicable for handling of any sterile product.
- If the blade is dull or breaks during use, then dispose and replace with new product.
- Care must be taken during disposal of the device to avoid any contact/injury due to the sharp nature of the device.
- In case of any changes/deviations in the performance of the device as per the intended use is observed, replace the defective device with a new one in order to fulfill the required application.
- DO NOT RESTERILIZE OR RE-USE. Re-use may result in exposure to viral, bacterial, fungal or preonic pathogens. Validated cleaning & sterilization method after single use and instructions for reprocessing to the original specifications are not available for these medical devices.
- The Surgical Blades are intended to be used for transient duration, less than 60 minutes (this includes the entire duration of use of the same device without regards to temporary interruption of use during a procedure). If the blade gets damaged (becomes dull or breaks), dispose, and replace it.

Storage and Handling

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

Clinical Benefits

- Making skin incisions and tissue dissections during a variety of surgical approaches
- Can be used in all patient populations.
- Biocompatible products
- As the devices are sold in sterile conditions as well, those devices can be directly used on the patients.

Performance Characteristics of device

The device is a very sharp instrument and comes in various sizes for different types of cuts and surgeries.

Possible Adverse events/Side effects

- Allergic reaction due to the material of construction.
- Pain as a symptom of soreness and tenderness at the site-of-use.
- Scarring of tissue.
- Infection of improperly managed wounds
- Breakage of the blade due to excessive mechanical force

Notice to Users and/or Patients.

If any serious incident that has occurred while using the device, the user or patient should REPORTED to Dimeda AND the competent authority of the Member State in which the user and/or patient is established.

Disposal Instructions

The surgical blades, after the use of surgical blades, the contaminated blade shall be shall be disposed off in a puncture resist container in line with the institutional and local regulatory guidelines for bio-hazardous medical waste disposal. For disposal recommended procedure is described as follows mentioned in the product IFU.

General Symbols:

Description	Symbol	Description	Symbol	Description	Symbol	Description	Symbol
Medical Device		CE Marking		Manufacturing Country		Caution - Sharp Blades	
Lot No.		Temperature Limitation		Manufacturer		Units in a pack	
Date of Manufacture		Do not Use if Package is damaged		Authorized Representative in the European Community		UDI	
Use by		Sterilized Using Gamma Irradiation		Catalogue No.		Single sterile barrier system	
Consult Instruction for use		This side up		Caution		Importer	
Do not reuse		Keep Dry		Latex free			
Do not Re-sterile		Keep away from sunlight		Phthalate and DEHP free			
Model Number		Non-pyrogenic		Distributor			

 Obelis S.A. Bd. Général Wahis, 53 1030 Brussels, Belgium Tel.: +32 27325954 Fax.: +32 2732600	 Ribbel International Limited 20th Mile, Jatheri Road, P.O. Rai Sonapat, Haryana (INDIA) 131029 Web.: www.ribbel.com Cell No.: +91-130-2368063, 3204399
--	--