



Electronic version : Availbel on www.jaisurgical.com

Product information, Intended Use, Safety and performance Guidelines

Device Name:

Scalpel Blades Stainless Steel
Lames de bistouri en acier inoxydable
Hojas de bisturí de acero inoxidable
Lame da bisturi in acciaio inox
Lâminas de bisturí de aço inoxidável
Skalpellsklingen rostfrei

Scalpel Blades Carbon Steel
Lames de bistouri en acier au carbone
Hojas de bisturí de acero al carbono
Lame da bisturi in acciaio al carbonio
Lâminas de bisturí de aço carbônico
Skalpellsklingen aus Kohlenstoffstahl

Description: Surgical Blades (Scalpel Blades) are interchangeable device designed to mount on compatible handle and function as the cutting edge of a scalpel. They are made of high-grade carbon steel or stainless steel alloy and is used as a surgical instrument to cut and dissect tissues.

Intended use: Surgical incisions, cutting, and scraping required during surgical and other minor procedures.

Intended Users: For use by trained healthcare professionals. They are intended for use by lawfully authorized, technically knowledgeable, experienced, educated, trained, and well-resourced health practitioners or personnel

Intended Population: Safe for all age group requiring surgical procedure to make surgical incision cutting or scrapping.

Contraindications:

- Do not re-use. Single- use only.
- Do not use if the if packaging is opened, damaged or after expiry date.
- Do not use if allergic to nickel and chromium matels.
- Prevent contact of delicate blades with hard surfaces or other instruments which will result in loss of sharpness.

Performance: Provides precise surgical incision, cutting and scraping. Ready-to use sterile device requiring no further sterilization or maintenance.

Handling & Storage

- Use an aseptic technique; open carefully to avoid injury.
- Dispose of in a sharps container.
- Store in a clean, cool, dry area away from sunlight.

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System Preparation:

- Check manufacture/expire dates before use.
- Do not use if packaging is opened, damaged or after expiry date.
- Single-use only

Re-use Risk

- Re-use can lead to cross-infection and reduced performance.

Safety Precautions:

- Handle sharp blades with care.
- Avoid excessive force to prevent blade damage.

Warnings:

- Read instructions before use.
- Inspect device and packaging for damage.
- Do not re-use to prevent contamination and infection.
- Use immediately after opening
- Dispose of properly according to local regulations.
- Sterility not guaranteed if packaging is damaged or opened.
- The device may cause allergic reactions in individuals with metal allergies.

Disclaimer: The manufacture is not responsible for improper or off-lable use.

Shelf Life : Five (5) years

Sterilization : Gamma Irradiation (min 25 kGy). Do not autoclave.

Notice to Users and/or Patients in EU:

Any serious incident that has occurred 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.

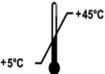
General Symbols provided on the packaging Labels/Artworks in reference to EN ISO 15223-1& EN ISO 20417:

The following applicable symbols for medical devices are labelled as per Section 23 of Annex 1. As well as the symbols as per EN ISO 15223-1:2021.

Description	Symbol	Description	Symbol
Medical Device		Don't use if package is Opened or damage	

Product Information, Intended Use, Safety and Performance Guidelines- Surgical Blades (Sterile) :

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Catalogue Number		UDI	
Use by date		Lot No./ Batch No.	
Keep away from sunlight		Do not re-sterilize	
Keep Dry		Caution Sharp Blade	
Temperature Limit		CE mark	
Sterile		EU Representative, if applicable	
Single Use/Do not reuse		Units in a pack	
Manufacturer		Model number	
Date of manufacture		Single sterile barrier system	
Manufacturer Country code	IN	This Way Up	
Handle with care freight		Corrugated cardboard Recycling Code	
Distributor		Importer	

**Product Information, Intended Use, Safety and Performance Guidelines-
Surgical Blades (Sterile) :**

Electronic version : Availbel on www.jaisurgicals.com



Manufacturer:

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Work - SP-146 (L), Riico Industrial Area
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EC Representative:

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