



Electronic version : Availbel on [www.jaisurgical.com](http://www.jaisurgical.com)

**Product information, Intended Use, Safety and performance Guidelines.**

**Device Name**

Disposable Scalpels with Blade Guard Stainless Steel Blade  
Scalpels jetables avec couvre lame. Lame en acier inoxydable  
Escalpelos desechables con hoja protegida. Hoja de acero inoxidable  
Bisturi Monouso con Cappuccio Coprilama. Lama in Acciaio Inossidabile  
Bisturis descartáveis com protector de lâmina. Lâmina em aço inoxidável  
Einmalskalpelle mit Klingenschutz und rostfreien Klängen

Safety Retractable Scalpels with Disposal Lock. Stainless Steel blade  
Bistouri sécurisé à lame rétractable avec bouton poussoir. Lame en acier inoxydable  
Escapelo (bisturi) retráctil de seguridad con cierre desechable. Hoja de acero inoxidable  
Bisturi di sicurezza con lama retrattile in acciaio inox autobloccante  
Bisturi de segurança com lâmina retráctil e dispositivo de bloqueio para descarte. Lâmina em aço inoxidável  
Skalpell mit einziehbarer Klinge und Sicherheitsverriegelung. Klinge aus Edelstahl

Safety Protective Shield Scalpels with Disposal Lock Stainless Steel Blade  
Bistouri de sécurité à enveloppe protectrice avec verrou de blocage. Lame en acier inoxydable  
Escudo (funda) protectora de seguridad con cierre desechable. Hoja de acero inoxidable  
Bisturi di sicurezza con coprilama autobloccante. Lama in Acciaio Inossidabile  
Bisturi de segurança com escudo protector e dispositivo de bloqueio para descarte. Lâmina em aço inoxidável  
Sicherheit Schutzschild Skalpell mit Entsorgungsverschluss. Klinge aus Edelstahl

**Description:**

**Disposable Scalpels:** Stainless-Steel blades, pre-fit on a plastic handle with a blade guard. The blade guard is intended to protect the blade from damage.

**Safety Scalpel are two types:**

**Retractable Safety Scalpels with Steadfast Disposal Lock**, the blades are made with stainless steel, pre-fit on the plastic carrier, inside the housing component of safety scalpel, enabled with retractable safety mechanism through which the blades come out from housing for use and after use can be pushed back for disposal lock and disposal of the device. Safety Scalpels do not have removable blade guards.

**Protective Shield Safety Scalpels with Steadfast Disposable Lock**, the blades are made with stainless steel, pre-fit on the plastic handle and covered with plastic shield, enabled with Protective safety mechanism through which the blades come out from handle for use and after use can be pushed forward for disposal lock and disposal of the device. Safety Scalpels do not have removable blade guards.

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

**Product Information, Intended Use, Safety and Performance Guidelines- Disposable Scalpel Including Safety types (Sterile)**



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**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 with hard surfaces to avoid blade dulling.

**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.

**System Preparation:**

- Check manufacture/expire dates before use.
- Do not use if packaging is opened, damaged or after expiry date.
- Carefully remove blade guard. Do not recap guard.
- 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.
- Do not recap guard.

**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.**

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**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	
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	

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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	



**Manufacturer:**

Jai Surgicals Limited  
H.O- B-3, Infocity, Sector 33-34, Gurgaon,  
122 001, India (IN)  
Work - SP-146 (L), Riico Industrial Area  
Bhiwadi, 301019, India (IN)  
Website: [www.jaisurgicals.com](http://www.jaisurgicals.com)



**EC Representative:**

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Swatar, BKR 4013 Malta.  
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