

Electronic version : Availbel on www.jaisurgicals.com

Product information, Intended Use, Safety and performance Guidelines

Device Name:

Stitch Cutter Blades Long Carbon Steel
Lame Coupe-fils, version longue, acier au carbone
Hojas Quitapuntos, versión larga, acero al carbono
Lame Singole Tagliapunti, versione lunga, acciaio di carbonio
Lâminas Corta Suturas, versão longa, aço carbonico
Chirurgische Fadenschneiderklingen, lange Ausführung, Karbonstahl

Standard Stitch Cutter Blades Carbon Steel
Lames coupe-fils standard en acier au carbone
Hojas de bisturí corto-punzantes estándar en acero al carbono
Lame Standard per la Rimozione dei Punti di Sutura. Acciaio al Carbonio
Lâminas Corta Pontos Standard. Em Aço de Carbono
Fadenschneider "Standard" Kohlenstoffstahl

Safety Retractable Stitch Cutters with Disposal Lock Stainless Steel
Lames coupe-fils retractable avec dispositif de sécurité. Lame en acier inoxydable
Hojas de bisturí corto-punzantes de acero inoxidable retraíbles de seguridad con cierre para descartar
Bisturi di Sicurezza per la Rimozione dei Punti di Sutura con Lama Retrattile e Blocco Irreversibile. Lama in Acciaio Inossidabile
Corta Pontos Retrátíl de Segurança com Sistema de Descarte. Lâmina em Aço Inoxidável
Sicherheitsfadenschneider mit zurückziehbarer gesicherter rostfreier Klinge

Disposable Long Stitch Cutters with Blade Guard Stainless Steel Blade
Coupe-fils à usage unique long. Lame en acier inoxydable sertie sur manche plastique.
Capuchon protecteur.
Quitapuntos desechable, larga. Hoja de acero inoxidable montada en un mango de plástico.
Funda protectora de la hoja.
Falcetto Tagliapunti Monouso. Lama Acciaio Inox inserta su di un Manico di Plastica.
Protezione della Lama.
Corta Suturas Longo Descartável. Lamina em Aço Inoxidável montada num Cabo de Plástico.
Guarda Lamina.
Chirurgischer Einmal-fadenschneider (lang). Rostfreie, an einem Plastikgriff befestigte Klinge.
Mit Klingenschutz

Description: Stitch Cutter blades made of high-grade carbon steel or stainless steel alloy and is used as a instrument to cut the surgical sutures.

Intended use: Suture removal by cutting the suture stitches.



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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 by cutting the suture stitches.

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 Suture /Stitches removal for accurate. 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.
- 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.

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

Shelf Life : Five (5) years

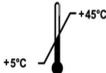
Sterilization : Gamma Irradiation (min 25 kGy). Do not autoclave.

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	
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	

**Product Information, Intended Use, Safety and Performance Guidelines-
Stitch Cutter (Sterile) :**

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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



EC Representative:

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Tower Business Centre,
2nd Flr., Tower Street,
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