



Electronic version : Available on www.jaisurgical.com

Product Information, Intended Use, Safety and Performance Guidelines.

Device Name:

Biopsy Punches (Sterile)
Biopsie-hautstanze
Emporte-pièce pour biopsie dermique
Punzon para biopsia dermica
Punzone per biopsia dermica
Punção para biopsia dérmica

Description: Single-use, sterile medical device with a stainless-steel blade and plastic handle, designed to extract small tissue samples for histological examination. The removable blade guard prevents damage to blade.

Intended Use: Removes skin layers (epidermis, dermis, and superficial fat) for histological analysis.

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 groups requiring skin biopsy.

Contraindications:

- Do not re-use. Single-use only.
- Do not use if packaging is opened, damaged or after expiry date.
- Do not use if allergic to nickel and chromium metals.
- Prevent contact with hard surfaces to avoid blade dulling.

Performance: Provides precise tissue removal for accurate histology. Ready-to-use sterile device requiring no further sterilization or maintenance.

Handling & Storage:

- Use 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/expiry 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.

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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 manufacturer is not responsible for improper or off-label 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.	

**Product Information, Intended Use, Safety and Performance Guidelines-
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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		Manufacturer Country code	IN
Single sterile barrier system		Date of manufacture	
Handle with care freight		This Way Up	
Model number		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:

Advena Limited
Tower Business Centre,
2nd Flr., Tower Street,
Swatar, BKR 4013 Malta.
Website: www.advenamedical.co