



Electronic version : Availble on www.jaisurgical.com

Product Information, Intended Use, Safety and Performance Guidelines

Device Name:

Dermal Curette (Sterile)

Curette dermique jetable. Lame en acier inoxydable

Cureta dermatológica desechable. Hoja de acero inoxidable

Curetta dermica monouso. Lama in Acciaio Inossidabile

Cureta dérmica descartável. Lâmina de aço inoxidável

Einweg-Hautkürette. Klinge aus Edelstahl

Description: Single-use, sterile medical device with a stainless steel blade and plastic handle, designed to to make surgical scrapings or debridement of biological tissue required during surgical and other minor procedures. The removable blade guard prevents damage to blade.

Intended Use: The intended purpose of Dermal curette is to make surgical scrapings or debridement of biological tissue 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 groups requiring skin Curette.

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 surgical scrapings or debridement of biological 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.



Electronic version : Available on www.jaisurgical.com

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-
Dermal Curette (Sterile):**

Electronic version : Available on www.jaisurgical.com

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	
Single sterile barrier system		Date of manufacture	
Manufacturer		Model number	
Manufacturer Country code	IN	Handle with care freight	
Corrugated cardboard Recycling Code		This Way Up	
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.jaisurgical.com



EC Representative:

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