



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

## **Product Information, Intended Use, Safety and Performance Guidelines**

### **Device Name:**

Reusable Handle (Non-Sterile)

**Description:** Reusable Handle are made up of stainless steel with different sizes as per International standards like Fitment #3, and Fitment #4. Reusable Handle are supplied in a non-sterile condition.

**Intended use:** Reusable Handle is intended for use as a scalpel handle on which a compatible surgical blade is fitted to perform surgical procedures and incisions.

**Intended User:** 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 surgical procedure.

### **Contraindications**

- None

**Performance:** Reusable Handle is intended for use as a scalpel handle on which of a compatible surgical blade is fitted to perform surgical procedures and incisions.

### **Handling & Storage:**

- Instruments must be dry before storage and stored in dry, clean conditions at an ambient room temperature, Discard the Reusable Handle in proper waste container & dispose of the product in accordance with accepted medical practice and applicable local, state and country laws and regulations for handling of bio-medical waste.

### **System Preparation:**

- Check manufacture/expire dates before use.

### **Re-use Risk:**

- Re-use can lead to cross-infection.

### **Warnings:**

- The reusable scalpel handle is a delicate precision instrument and requires the utmost care and caution whilst handling and reprocessing to prevent damage and misalignment of parts and injury to personnel. The SAFhandle™ reusable scalpel handle is not compatible with reinforced-back blades. The SAFhandle™ reusable scalpel handle is protected during transportation with a plastic guard which must be removed.

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

**Shelf Life:** Five years

**DOC. NO. F 4.2.3-6A (Reusable Handle Non-Sterile)**

**REV. NO. 00 REV. DATE 22.10.2024**

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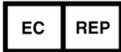
**Usage Frequency:** All Reusable Handle supplied in an unsterile condition, are intended for reuse

**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		Catalogue Number	
Lot No./ Batch No.		UDI	
Keep away from sunlight		Keep Dry	
Caution		CE mark	
Non-Sterile	 Sterile before use	EU Representative, if applicable	
Units in a pack		Model number	
Temperature Limit		Manufacturer	
Manufacturer Country code	IN	Handle with care freight	
Corrugated cardboard Recycling Code		This Way Up	

**Product Information, Intended Use, Safety and Performance Guidelines- Reusable Handle (Sterile) :**

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<b>Distributor</b>		<b>Importer</b>	
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**Manufacturer:**

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