Rocialle Healthcare

INSTRUCTIONS FOR USE

BLADE HANDLES

TF01-IFU-007

REVISION 1

Intended use

Blade Handles are surgical instruments used to hold scalpel blades securely throughout surgical procedures. They help make initial incisions, create access points, and perform delicate dissections They are available in varying tips styles, to accommodate various blade sizes and shapes used during different procedures.

Reuse of Single Use Product

This Product is designated as 'Single Use' ONLY. It should-be used for one-patient, during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient. Along with an increased risk of infection, the safety of the product cannot be guaranteed with multiple use.

<u>Product inspection before use</u>

Inspect device for rust, dents, cracks, pits and pores before use.

Warning

- Do not use if product or sterile barrier system is damaged.
- Products supplied non-sterile must be sterilised before use.
- Please follow our sterilisation instructions prior to use.
- Do not use beyond the expiry date stated on the packaging.

Sterilisation

Instruments can be sterilised using the following methods:

Ethylene Oxide

Concentration: up to 450mg/l

Temperature: 60°C Exposure: up to 6 hours Humidity: up to100%

Irradiation

Dose to be validated by user, up to 70kGy.

Contraindications

Instruments should not be used for anything other than their intended use. They are not to be used on patients who have an allergy or sensitivity to stainless steel, or any other component material e.g. Zinc.

Intended User

Our instruments are designed for use by appropriately qualified clinicians, who will have good knowledge of their features and how they should be used. These products are not intended for use by lay persons.

Disposal:

Used instruments should be disposed of in accordance with Local Clinical Waste Guidance.



