



Instructions for Use

According to EU Medical Device Regulation 2017/745

Doc# KNSIFU-423-05

KN Surgicals

SURGICAL SCALPELS
REUSABLE INSTRUMENTS
IFU#IFU-SSCA-003



KN SURGICALS

Usman Centre, Khadim Ali Road, Sialkot-
51310, Pakistan

Phone:+92-52-3553725

Email: info@knsurgicals.com



KHANG BAOINTERNATIONAL KFT
Budapest, Auróra utca, 13. al. 1
1084 BUDAPEST, Hungary

Phone:+36707197778

Email: info@kb-intl.com

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Category	Instructions
Intended Use	Reusable surgical scalpels are intended for making precise incisions and cutting tissues during surgical procedures.
Intended User	These scalpels are intended for use by trained and licensed healthcare professionals only.
Return/Warranty	In case of damage or faulty, please return to supplier with same packaging and event description.
Shelf Life	The shelf life of surgical scalpels is typically 5 years if stored and maintained properly.
Limitations on Reprocessing	Repeated processing has a minimal impact on these instruments. There are no specific guidelines on the maximum number of sterilization cycles, as this largely depends on the condition of the instrument. Any instruments showing signs of corrosion should be discarded immediately.
Expected Patient Age Group	Suitable for patients of all age groups, depending on the specific procedure and healthcare provider's discretion.
Cleaning	1. Rinse under warm running water immediately after use. 2. Use a soft brush and pH-neutral detergent to clean thoroughly as per hospital practice. 3. Rinse with deionized or distilled water. 4. Dry with a lint-free cloth or air dryer.
Disinfection	1. Immerse in an EU-approved disinfectant solution. 2. Follow recommended contact time and concentration. 3. Rinse with sterile water to remove chemical residues.



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- Follow approved cleaning procedure of hospital.
- Do not use abrasive cleaners & brushes with hard bristles
- Water with chloride contents may damage or even destroy the instruments
- Do not leave instruments in cleaning or disinfecting solutions for long terms (over night or weekend), the instruments can be destroyed.
- Handle all instruments gently. Never overstrain, drop or misuse them.
- Never use abrasives on instruments, as this will spoil the surface finish. This may later cause discoloration, rusting or pitting.



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- Also make sure that the product does not come into contact with acids or other aggressive disinfectants that could corrode it.

Sterilization (Moist Heat)

Before performing sterilization described below, the instrument should be cleaned as described in the cleaning Procedure and Disinfection. The recommended method of sterilization is that of autoclave steam.

2. Sterilize in a steam autoclave at 134°C (273°F) for a minimum of 3 minutes or according to autoclave guidelines.

3. Ensure scalpels are dry before removal (drying time 20 mint).

- It is recommended that sterilization temperatures should not exceed 275°F (135°C) to avoid damage to the product.
- The process of steam sterilization must take place in accordance with **EN ISO 17664**.
- Sterilization solution must have the pH near to 6.0/7.0
- Don't sterilize the instruments having the solution with chloride ions
- Check the hardness of the water used in the autoclave. Too hard water will leave a deposit on the instruments.
- If a water softener is used ensure it is at the manufacturer's recommended level. Too much may cause discoloration or pitting.

Storage Condition

- Store in a clean, dry, and controlled environment.
- Keep in a sterilization pouch until use.
- Storage temperature max 45°C



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Storage Humidity

The humidity limits for storing reusable surgical instruments should ideally be kept between 20% and 60%. This range helps prevent corrosion and other damage to the instruments, ensuring they remain in optimal condition for use. It is also important to store the instruments in a dry and controlled environment to maintain their sterility and functionality.



- Never handle instruments by their tips. These should be cleaned by trained personnel only who will ensure the delicate working ends are adequately protected during storage or sterilization
- Pack instruments with other heavier instruments with care. Remember always -



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heavy instruments on the bottom and light instruments on the top.

Routine Maintenance

1. Inspect for damage, wear, or corrosion before each use.

2. Lubricate hinges if necessary.



- Use protective gloves and wash the hand with anti-germs and anti-bacterial soap before operating any medical operation.
- If the instrument has rusted then don't use it.
- Avoid placing the instrument for a longer time in ordinary water or in contact with blood or in salty or humid atmosphere.
- Only use one type material during sterilization process.

Precaution use:

- before
- Always perform a visual inspection for damage or signs of wear
 - Sharp edges must be free of dents and with continuous edges
 - There should be no distortion of instruments with long parts
 - The instruments that are part of a larger assembly, must be checked together with other assembly components
 - Always check the rotating movement of hinges, which must not have excessive play (if applicable)
 - Always check that the locking systems are working (if applicable)
 - Always check the function of the instrument

Handling

1. Handle with clean, dry hands or sterile gloves.
2. Avoid dropping or applying excessive force.

Warnings

1. Do not use if damaged, dull, or corroded.
2. Follow manufacturer's cleaning and sterilization instructions.



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Calibration (if applicable)

3. Ensure proper sterilization before use to prevent infection.

Not applicable for surgical scalpels.

Contraindications

No reported contraindications.



Incident Reporting

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer, our authorized representative and competent authority of the member state where your registered office is located.



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Disposal:

No special decomposition or disposal required for Surgical Instruments as they don't contain any toxic or hazardous material; the material stainless steel is recyclable in ordinary steel manufacturing units.

Symbols	Symbol Meaning
	Manufacturer
	Product code
	Lot number
	Caution: read instructions (warnings) carefully
	Keep in a cool, dry place
	Medical Device complies with Regulation MDR 2017/745 as amended by 2020/561
	Keep away from sunlight



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	Date of manufacture
	Consult instructions for use
	Medical device



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	Instrument are non-sterilized
	
	
MADE IN PAKISTAN	



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