



INSTRUCTIONS FOR USE: Operating Scissor

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Manufacturer	EU Authorised Representative (EC REP)
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CRITICAL SAFETY DATA

- **STERILITY:** Supplied NON-STERILE. These instruments must be cleaned and sterilized before first use and all subsequent uses.
- Material Medicalgrade stainless steel AISI 420

LIMITATION: These scissors are for external use only. NOT for use on living tissue or surgical incisions.



1. TECHNICAL SPECIFICATIONS

Intended Use: Precise cutting and blunt dissection of soft tissues during general, gynecologic, vascular, and plastic surgical procedures. Intended Users: Qualified healthcare professionals only.

Storage Conditions: Store in a dry, clean environment

2. REPROCESSING (CLEANING & DISINFECTION)

2.1 Automated Cleaning (Preferred)

1. Load scissors in an OPEN position on a dedicated instrument stringer or mesh tray to prevent blade damage from contact with other heavy instruments
2. TC BLADE WARNING (If Applicable): Limit ultrasonic cleaning phase to ≤ 5 minutes. Prolonged ultrasonic cavitation may dislodge Tungsten Carbide inserts from the steel blade.
3. Thermal Disinfection: Validated cycle achieving $A_0 \geq 3000$ (ISO 15883)
4. Use a validated thermal disinfection cycle (ISO 15883).
5. Cleaning Phase: 55°C for 5 minutes using a pH-neutral enzymatic detergent (pH 7.0–9.5).
6. Thermal Disinfection: 93°C for at least 5 minutes ($A_0 \geq 3000$).

2.2 Manual Cleaning (Alternative)

- Soak in 0.5% enzymatic solution (35–40°C) for 5 minutes.
- Using a soft nylon brush, scrub box lock hinge, serrations (if present), and blade edges. Brush direction: Brush AWAY from the sharp edge. Brushing along the edge causes lacerations..
- Rinse thoroughly with demineralized water (conductivity < 10 $\mu\text{S}/\text{cm}$)
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3. MAINTENANCE & STERILIZATION

- Lubrication: Apply a water-soluble surgical grade lubricant to the hinge after cleaning. Do not use silicone-based oils.
- Validated steam sterilization process per ISO 17665

Cycle Type	Temperature	Hold Time
Pre-vacuum	134°C ($\pm 2^\circ\text{C}$)	4 Minutes



4. MANDATORY PRE-USE INSPECTION

Discard the instrument if it fails any of the following Blade Sharpness and Edge Integrity Test

- Material: Use a standard latex surgical glove or 0.1 mm thick latex sheet.
- Procedure: Hold the glove taut. Using the distal half of the blade, make a single, smooth cutting stroke.
- PASS: The latex is cut cleanly and effortlessly with no dragging, snagging, or tearing of the material.
- FAIL: The latex stretches, tears irregularly, or requires sawing motion. DISCARD. (Dull blade = tissue crush injury).
- PASS: Blades meet at the very tips first with a slight, even gap near the hinge (proximal opening). This ensures the cutting action shears from tip to hinge
- FAIL: Blades overlap (scissoring) or meet at the hinge before the tips (gap at tip). DISCARD
- Any orange/brown pitting or staining, particularly within the hinge mechanism or along the cutting edge = DISCARD. Pitting on the cutting edge acts as a stress riser and will cause the blade to chip or fracture during use.

5. LIFECYCLE & DISPOSAL

- Service Life: Replace instrument immediately if hinge becomes loose, performance degrades (fails Section 4 cut test), or corrosion is observed
- Disposal: Deface or bend the instrument to prevent reuse and discard in a sharps container per local clinical guidelines.

6. REPORTING & VIGILANCE

Serious incidents must be reported to Kopek International and the relevant Competent Authority in accordance with EU MDR 2017/745 Article 87.

7. DOCUMENT CONTROL

Rev	Date	Author	Summary of Changes
V3	2026-04-16	Regulatory Affairs	Made necessary changes; content removed; Kopek Brand Guidelines applied.