

## INSTRUCTIONS FOR THE CARE, HANDLING AND REPROCESSING OF RE-USABLE SURGICAL INSTRUMENTS (Class 1)

**Devices** These instructions are for re-usable medical devices supplied by instruMED. Products covered by this instruction include all stainless-steel instruments, as well as those containing plastic parts, dissimilar metal components or coatings (i.e. Aluminium, Copper, Gold, Hard edging alloys, Tungsten Carbide).

**Intended Use** instruMED's medical devices are intended for use by suitably qualified surgical practitioners to perform specific functions such as cutting, grasping, clamping, dissecting, probing, retracting, draining, aspirating, suturing, ligating, and other similar procedures.

**How Supplied** All instruments and accessories are supplied non-sterile and must be cleaned, disinfected and sterilised prior to use.

### WARNINGS



Follow manufacturer's instructions and warnings regarding use of decontaminants, disinfectants and cleaning agents. Wherever possible avoid use of mineral acids and harsh, abrasive agents.  
Do not exceed 140° C during any part of the process  
Some sensitive material surfaces in some instruments (e.g. Aluminium) may be damaged by high alkaline solutions (pH>10).  
Appropriate protective gloves, eyewear and clothing should be worn when handling biologically contaminated instruments and reprocessing medical devices.

**Limitations** Repeated processing has minimal effect on reusable surgical instruments. End of life is normally determined by wear and damage due to use. Any specific limitations on the number of reprocessing cycles shall be made available with the instrument (e.g. electrosurgery cables). Misuse may result in instrument damage, failure and/or unnecessary stress to the patient. Rongeurs, bone cutting forceps, osteotomes and chisels should never be used to cut wire or pin. Acetel plastics should be inspected for surface chalking and hydrolysis

### INSTRUCTIONS

**Point of Use** Remove excess soil using absorbent wipes.  
Where possible, do not allow blood, surgical debris or bodily fluids to dry on medical instruments.  
For best results and to maximise their service life reprocess instruments immediately after use. If this is not possible, consider covering the instruments with a damp cloth or using an enzymatic foam spray cleaner to help prevent soil from drying. Do not leave instruments soaking in saline or chlorinated solutions.

### Preparation for Cleaning

Disassemble all instruments where required. Retain all parts to facilitate reassembly.

### Automated Cleaning

Equipment: Washer/Disinfector exposure times and temperatures shall comply with ISO 15883. Cleaning agents as per validation study in recommended concentrations shall be used.

1. Load instruments so that hinges are open, and cannulations and holes can drain. place heavy instruments with care into the bottom of containers.
2. Ensure cannulated instruments are attached to specific MIS basket components
3. Run Washer/Disinfector cycle complying with manufacturers' recommendations.
4. When unloading, inspect instruments esp. cannulations, holes etc. for complete removal of visible soil. If soil present repeat process or use manual cleaning.

### Manual Cleaning

If an automatic washer-disinfector is not available, use the following process: 1. Use a double sink system (wash/rinse) dedicated for instrument cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35°C.

2. In the first sink, keeping the instrument submerged, with an autoclavable brush, apply 'CE' marked cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets and hinges, always brushing away from the body and avoiding splashing. Ensure rongeurs and hinged instruments are thoroughly cleaned in both open and closed positions.
3. In the second sink, rinse instruments with soft, high purity water which is controlled for bacterial endotoxins, so that water reaches all parts of the instrument, then carefully hand dry or use a drying cabinet.

Note: Manual cleaning is NOT a disinfection process: when manual cleaning is used it may not be possible to disinfect the device prior to further handling.

### Disinfection

Ensure compliance with ISO 15883, AS/NZS4187 and all manufacturers recommendations.

### Drying

The air used for drying must be filtered. Do not exceed 120°C. If needed, additional manual drying can be performed with a lint free towel. Insufflate lumens of instruments by using sterile compressed air.

### Inspection and Function Testing

All instruments: Visually inspect for damage or wear  
Cutting edges: Check free of nicks and present a continuous sharp edge  
Jaws and Teeth: Ensure correct alignment  
Hinges: Check for smooth movement without excessive "play"  
Locking (ratchet) mechanisms: Check for correct action  
Instruments with long slender or rotating features: Check for distortion  
Device consisting of components: Ensure all components are present and check assembly  
Damaged instruments must be immediately rejected.

<b>Packaging</b>	<p>Ensure all instruments are dry prior to packaging.</p> <p>The sterile barrier system shall conform to ISO 11607-1 and ISO 11607-2.</p> <p>Singly: Ensure that the pack is large enough to contain the instrument without stressing the seals.</p> <p>Sets: Instruments may be loaded into dedicated instrument trays or general-purpose sterilisation trays.</p> <p>Ensure that cutting edges and delicate tips are protected.</p> <p>Do not exceed weight limits advised by steriliser manufacturer.</p> <p>Wrap trays using appropriate method.</p>	<b>Additional Information</b>	<p>Only process chemicals recommended by the manufacturer for cleaning, disinfection and compatibility to the material may be used. Any application specifications as e.g. concerning temperatures, concentration, treatment times etc. are to be strictly adhered to. Further current information on treatment may also be found at <a href="http://www.a-k-i.org">www.a-k-i.org</a></p>
<b>Sterilisation</b>	<p>Use either 'CE' marked or validated vacuum autoclave operating at 134 - 137°C, for a minimum holding time of 3 minutes.</p> <p>Ensure instruments are dry before sterilisation.</p> <p>Sterilisation cases should be loaded just prior to the sterilisation step.</p> <p>When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.</p> <p>Ensure relevant time and temperature parameters and hold times are met as identified in applicable International Standards (ISO11134 &amp; ISO13683) and Steriliser Manufacturers recommendations.</p>	<b>Disposal</b>	<p>End of service life instruments must be decontaminated and sterilised prior to disposal in accordance with local waste management procedures.</p>
<b>General Cleaning Precautions</b>	<p>Automated cleaning methods should be used in preference to manual methods. Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. The quality of the water used for diluting cleaning agents and for rinsing medical devices should be carefully considered. Mineral residues from hard water can result in staining of the device or prevent effective cleaning and decontamination. De-scaling agents, if used, will not harm the devices. If practicable, avoid processing instruments of different metallic composition close together to minimise risk of electrolytic damage.</p> <p>Delicate instruments require special handling to prevent damaging the tips and should be separated from heavy or sharp instruments. Use caution during cleaning and sterilisation.</p> <p>A non-fibrous sponge should be used to wipe off all blood and debris. Do not apply excessive stress or strain at joints.</p> <p>Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning.</p> <p>To preserve the surface coating of ebonised (blackened) instruments, keep them separated from other instruments.</p> <p>Exercise care when handling instruments with sharp cutting edges to prevent personal injury and equipment damage.</p> <p>Avoid mechanical cleaning processes and abrasive cleaners as these can scratch the surface and remove the ebonised coating.</p>	<b>NOTE</b>	<p>It is the responsibility of the processor to ensure that that processing is performed using equipment, materials and qualified personnel in the processing facility to achieve the desired results. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.</p>
<b>Storage</b>	<p>Ensure instruments are dry before storage and stored in dry, clean conditions at an ambient room temperature. Storage requirements as described in AS/NZS4187 shall be met.</p>		
<b>Maintenance and Repair</b>	<p>Apply a small quantity of surgical grade lubricant to hinges as required.</p> <p>Separate blunt or damaged instruments. Do not use damaged instruments.</p> <p>Where required complete repair process as per departmental policies.</p> <p>Instruments sent to Instrumed for repair must be decontaminated and sterilised and accompanied with the relevant documented evidence.</p>		