Resolution Med Tech

Instructions for Use

Use, Care, Cleaning and Sterilisation of Orthopaedic Surgical instruments

This guide covers all Resolution Med Tech (RMT) reusable instruments and should be studied carefully.

1 Instrumentation Overview

- Resolution Med Tech (RMT) instrumentation consists of medical devices used in orthopaedic surgical procedures. The range includes Class I surgical instruments (as per TGA Therapeutic Goods (Medical Devices) Regulations 2002).
- Instruments are provided in customised instrument trays except for instruments which are provided to meet surgeon preferences which will be suitably packaged to protect them from damage during transportation.
- RMT instruments must only be used by qualified personnel trained in the use of the surgical instruments and the relevant surgical procedures.

1.1 Intended use and materials

- Instruments developed by RMT are intended for transient use in orthopaedic surgeries.
- The device is manufactured from medical grade metals and plastics and is supplied non-sterile.
- RMT instruments are precision surgical instruments with dimensional accuracy of ±0.5mm unless otherwise stated on individual instrument labelling.

1.2 Contraindications

- Use in Magnetic Resonance (MR) environments.
- Use on patients with known hypersensitivity or allergy to stainless steel, cobalt alloys, or polymer materials.

1.3 Instrumentation use

- Before clinical use, the surgeon must thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation.
- Prior to use, the device must be carefully and completely examined for wear or damage by staff in operating centres prior to surgery. The examination shall include a visual inspection of all functional surfaces and must verify the cleanliness of the device and absence of wear and damage.
- Evidence of damage or wear is included but not limited to: corrosion, discolouration, excessive scratches, flaking, distortion, wear, cracks and loosening of components.
- In the event the device is deemed excessively worn, unrecognisable markings or damage, the devices should not be used.
- The device must undergo regular checks by authorised personnel to ensure that the device remains in good condition and continues to act as intended.
- End of life devices are determined by wear and damage due to surgical use and handling.
- RMT medical devices are not intended for use in MR (Magnetic Resonance) Environments.

1.4 Product handling

- All RMT reusable instruments may be safely and efficiently reprocessed using the instructions outlined in this guide.
- The user/processor should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this guide.
- New and used instruments must be thoroughly processed according to these instructions prior to use.

1.5 Warnings and precautions

- Universal Precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges.
- Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Do not place heavy instruments on top of delicate devices.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilisation steps are facilitated by not allowing blood, body fluid, bone and tissue debris, saline, or disinfectants to dry on used devices.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used. Instruments must not be placed or soaked in Ringers Solution.
- Mineral oil or silicone lubricants should not be used because they coat microorganisms, prevent direct contact of the surface with steam and are difficult to remove.
- Descaling agents should not be used in steam sterilisers as they can cause residues to build up which can cause damage to polyethylene instruments over time.
- Alkaline detergents can stain the stainless-steel instruments; consequently, only neutral pH detergents are recommended.
- Prior to use, consideration should be given to patients with known or suspected hypersensitivity to stainless steel metals or polymer materials. Discontinue use if an adverse reaction is suspected.

1.6 Potential adverse effects, complications and residual risks

- Residual risks, adverse effects and complications that may occur due to instrument usage include:
  - Vessel, nerve and surrounding tissue damage
  - Superficial infection, biological or allergic reaction
  - Breakage, wear, deterioration and disassembly of components leading to surgical delay.
  - Injury to patient or operator

1.7 Limitations and restrictions

- Automated cleaning using a washer/disinfector alone may not be effective for orthopaedic instruments. A thorough, manual cleaning process has been validated and is recommended.
- Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning RMT reusable devices.
- Low foam reagents are recommended to maximise instrument visibility during cleaning.

Note: Instruments must be removed from metal or polymer trays for manual cleaning. Instrument trays, cases and lids must be cleaned separately.

- Repeated processing, according to the instructions in this manual has minimal effect on RMT reusable manual instruments unless otherwise noted. End of life for stainless steel or other metal surgical instruments is normally determined by wear and damage due to the intended surgical use and not to reprocessing.
- Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instruments. One or more of the following processes may be used to purify water: ultra-filter (UF), reverse osmosis (RO), deionised (DI), distilled water, or equivalent.
- Ethylene oxide (EO), gas plasma and dry heat sterilisation methods are not recommended for sterilisation of RMT reusable instruments.
- Steam (moist heat) is the recommended & validated sterilisation method for RMT instruments.

2 Instructions

2.1 Point of use

- Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.
- Instruments should be cleaned within 30 minutes of use to minimise the potential for drying prior to cleaning.
- Flush the instrument in running water, within the temperature range 15°C to 30°C, to remove gross visible blood and body substances.

2.2 Preparation for decontamination

- Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
- Where applicable, multi-component instruments should be disassembled for appropriate cleaning. Disassembly, where necessary is generally self-evident. Care should be exercised to avoid losing small screws and components.
- All cleaning agents should be prepared in accordance with the instructions of the reagent manufacturer as the use of recommended temperatures and dilutions are important for optimal performance of cleaning agents. Softened tap water may be used to prepare cleaning agents.

Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

2.3 Manual cleaning and disinfection

Description: Enzymatic soak and scrub followed by sonication.

Step 1: Completely submerge instruments in enzyme solution and allow to soak for 20 minutes. Scrub using a soft-bristled, nylon brush (crevices, lumens, mated surfaces and other hard to clean areas should be attended) until all visible soil has been removed. Hold the items low in the sink to limit the generation of aerosols during scrubbing.

Note: Clean cannulations and holes using an appropriate brush ensuring that the full depth of the feature is reached. Manoeuvre any movable parts repeatedly under running water to loosen any trapped debris.

Step 2: Remove the device from solution and rinse in purified water (from one or any combination of the following: ultra-filter, reverse osmosis, deionised or distilled) for a minimum of 3 minutes. Thoroughly flush holes and other difficult to reach areas. Ensure that running water passes through the cannulations, and

that blind holes are repeatedly filled and emptied. Manoeuvre any movable parts repeatedly under running water to loosen any trapped debris.

Step 3: Pour the freshly prepared neutral pH cleaning solution into a sonication unit and completely submerge the device in the solution and sonicate for 10 minutes at 40-50 kHz.

Step 4: Rinse instrument in purified water for at least 3 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.

Step 5: Repeat the sonication and rinse steps above.

Step 6: Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse these devices. Acidic, anti-corrosion agents should only be used on an as needed basis. Any cutting edges should be carefully inspected after use.

2.4 Maintenance, inspection and testing

- Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning and disinfection process.
- Check the action of moving parts (e.g. hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Where instruments form part of a larger assembly, check that devices assemble readily with mating components.
- Hinged, rotating, or articulating instruments should be lubricated with a medical-grade, moist-heat compatible lubricant product (e.g. Aesculap Sterilit® I Lubricant or acceptable equivalent) intended for surgical instruments that must be sterilised. Manufacturer's expiration dates should be adhered to for both stock and use-dilution concentrations.

2.5 Packaging and testing

- Trays shall be wrapped in standard medical grade, steam sterilisation wrap using the AAMI double wrap method or equivalent.
- The customised trays supplied by RMT contain areas designated for specific instruments. Hospital staff must ensure that instruments are placed in the appropriate designated areas.
- Where specialised instruments are provided by RMT to meet surgeon preferences they may not be provided in a tray. The hospital shall ensure that such Instrument sets are properly prepared and packaged in trays that will allow steam to penetrate and make direct contact with all surfaces.
- The user must ensure that the instrument tray is not tipped or the contents shifted once the devices are arranged in the tray.
- The instruments must not be stacked or placed in close contact and must be disassembled where possible prior to packaging.

2.6 Sterilisation

Disinfection is only acceptable as a precursor to full sterilisation for reusable surgical instruments. Refer to Table 1 for recommended minimum sterilisation parameters that have been validated to provide a 10^{-6} sterility assurance level (SAL).

- The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned. Instruments must be disassembled and packaged in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.
- Moist heat/steam sterilisation is the recommended and validated method for RMT orthopaedic instrument sets.
- The sterilising unit manufacturer's recommendations should always be followed. When sterilising multiple instrument sets in one sterilisation cycle, ensure that the manufacturer's maximum load is not exceeded.
- Instrument sets must be properly prepared and packaged in trays that will allow steam to penetrate and make direct contact with all surfaces.
- Ethylene oxide or gas plasma sterilisation methods should not be used.
- Gravity displacement sterilisation cycles are not recommended because cycle times are too long to be practical.
- Do not stack instrument trays during sterilisation

Table 1: Recommended steam sterilisation parameters

Cycle type	Temperature	Pressure	Exposure Time	Dry Time
Prevacuum	134°C	3.05 bar 44.3 psi	4 minutes	30 minutes

1. Local or national specifications may be followed where steam sterilisation requirements are stricter or more conservative than those listed in this table. However, it is then the responsibility of the user to validate the specification.
2. Steam sterilisation cycles with longer times than those listed are also acceptable.
3. Drying times may vary according to load size and should be increased for larger loads. In the event the device is found to have water left after sterilisation, the sterilisation should be repeated.
4. The pressure value represents the minimum pressure recorded during sterilisation validation testing. Temperature and exposure time are the controlled sterilisation parameters

Note: The Steriliser manufacturer's instructions for operation and load configuration should be followed explicitly.

2.7 Storage

- Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

2.8 Disposal

- Disposal of the device should be in accordance with the health care facilities procedures, ensuring protection from physical hazards such as exposed edges. Used devices should be decontaminated prior to disposal, otherwise disposed of as infectious waste.
- Devices should be destroyed in a manner that prevents potential reuse.

2.9 Complaints

- Any health care professional with a complaint or dissatisfaction related to; quality, durability, reliability, safety, effectiveness and performance of the device should notify their RMT representative immediately. If the device has malfunctioned or suspected to malfunction, the RMT representative must be immediately advised.
- In the event the RMT device causes or contributes to a serious incident, serious injury or death, notify the Therapeutic Goods Administration (TGA) and an RMT representative in writing.
- For all complaints, please include the device name, catalogue number, full description of markings, contact name and address, and description of the issue. Please ensure the device is retained for investigative purposes.

2.10 Additional information

- Loan sets must undergo all steps of decontamination, cleaning, disinfection, inspection, and terminal sterilisation before being returned to RMT. Documentation of decontamination must be provided with instruments being returned to RMT.
- The instructions provided in this User Guide have been validated as being capable of preparing orthopaedic devices for use. It is the responsibility of the Hospital to ensure that reprocessing is performed using the appropriate equipment and materials, and that personnel in the reprocessing facility have been adequately trained to achieve the desired result. Equipment and processes should be validated and routinely monitored. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.
- This User Guide has been developed in accordance with ISO 17664, ISO 17665-1 and AS 4187.

2.11 Important statements

- RMT validated reprocessing instructions are not applicable to RMT instrument trays that include devices that are not manufactured and/or distributed by RMT, or which are not packed in accordance with RMT specifications.
- It is strictly prohibited to carry out any modification whatsoever on a RMT instrument. Only RMT has the competence to carry out such work. If this recommendation is not followed, RMT disclaims any liability for any such consequences.
- The nature of microbiological death is exponential and the presence of microorganisms on any item can only be expressed as a probability that can be reduced but never to zero, and that this probability can only be assured for validated processes.

2.12 Manufacturer contact information

Resolution Med Tech Pty Ltd
10 Resolution Drive,
Unanderra, NSW, 2526
Phone: 1300 844 600

2.13 Symbol interpretation

MD	Medical Device		Consult Instructions for Use
	Manufacturer		Date of Manufacture
REF	Catalogue Number	NON STERILE	Parts Supplied Non-Sterile
LOT	Batch Code	MR	Not MR Safe