

INSTRUCTIONS FOR USE

The following instructions are for all surgical instruments supplied by Precision Surgical Ltd., unless stated otherwise with the packaging of the product. These instructions are intended for use only by persons with the required knowledge and training in a health care facility.

The surgical instrument must be inspected, cleaned and sterilised before each surgical procedure.

INTENDED USE

Surgical Instruments are intended for use in the surgical setting for clamping, cutting, dissecting, grasping, probing, retracting and suturing.

CONTRAINDICATIONS

The improper use of a surgical instrument during handling, surgical use or reprocessing, for which they are indicated, may result in damaged or broken instruments.

PRECAUTIONS

When reprocessing surgical instruments - Always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures. Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the metals resulting in pitting and rusting of stainless steel instruments.

Delicate surgical instruments require special handling to prevent damage to the tips.

Use caution during cleaning and sterilisation. A non-fibrous sponge should be used to wipe off all blood and debris.

Do not use excessive stress or strain at joints; misuse will result in misalignment or cracks at the box-joint or jaws

LIMITATIONS ON REPROCESSING

Repeated processing has minimal effect on the instrument life.

End of useful life for metal surgical instruments is normally determined by wear and damage due to the intended surgical use.

Always inspect instruments between uses to confirm proper functioning.

Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.

result in misalignment or cracks at the box joints or jaws. Aluminum and titanium instruments that are colour anodised may lose their colour over time through normal use and reprocessing.

FROM POINT OF USE

Wherever possible, do not allow blood, debris, or body fluids to dry on instruments. For best results and to prolong the life of the surgical instrument reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.

PREPARATION FOR DECONTAMINATION

~ Reprocess all instruments as soon as it is reasonably practical following use.

~ Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.

~ Do not use high acid (pH 4.0 or lower) or high alkaline (pH 12 or higher) products for disinfection. Neutral pH detergents are preferred range of 8.0-11.0 pH

~ If appropriate, disassemble prior to cleaning and sterilisation, without the use of tools unless specifically provided by the manufacturer. Additional instructions required for disassembly will be made available with the product or the manufacturer.

~ Remove gross contaminants with a steady stream of lukewarm/cool water, not to exceed 35° C (95° F). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.

CLEANING: AUTOMATED (Washer Disinfectant)

~ Use only either CE marked or validated washer-disinfectant machines and low-foaming, non-ionising cleaning agents and detergents following the manufacturer's instructions for use, warnings, concentrations, and recommended cycles.

~ Load instruments carefully, leaving box joints and hinges open, allowing the instrument to drain.

~ Place heavy instruments on the bottom of containers, taking care not to place on delicate instruments or overload wash baskets.

~ Place instruments with curved surfaces facing down to prevent pooling of water.

~ Where available, use appropriate cleaning accessories to Flush instruments with channels or lumens.

~ Ensure that soft, high purified water that is controlled for bacterial endotoxins is used in the final rinse stage.

Note: Automated cleaning may not be suitable for all lumens and channels, in which case clean manually with a water jet, if available, and an appropriate brush (and stilette if provided) that reaches the depth of the feature. After manually cleaning, pass all instruments through an automatic cleaning cycle to achieve disinfection.

Note: These instruments should be processed using washer disinfectant cycle validated to:

-ISO 15883-2:2006 Requirements and tests for washer disinfectors employing thermal disinfection for surgical instruments.

-Adhering to:HTM 01-01: Management & decontamination of surgical instruments: Part D – Washer disinfectors.

Cycle Stage	Temperature(°C)	Hold Time(secs)
Pre-Wash	<40	120
Wash	60	360
Rinse	N/A	60
Thermal Disinfection	90	60
Drying	100	900

CLEANING: MANUAL

~ Manual cleaning is not advised if an automatic washer-disinfectant is available. If this equipment is not available, use the following process for manual cleaning:

~ 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 (95° F).

~ In the first sink, keeping the instrument totally immersed, with an appropriately sized autoclavable soft nylon brush, apply validated cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets, box locks 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.

Use a large syringe or water jet to thoroughly flush all channels and lumens with cleaning solution to remove debris.

~ In the second sink, rinse instruments thoroughly with soft, high purified water, which is controlled for bacterial endotoxins, so that the water reaches all parts of the instrument, then carefully hand dry or use a drying cabinet.

CLEANING: INSPECTION

After cleaning, visually inspect all surfaces, ratchets, box joints, holes, channels and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.

DRYING

Instruments must be thoroughly dried and all residual moisture must be removed before they are sterilised. Use a soft absorbent towel or cloth to dry external surfaces.

LUBRICATION / MAINTENANCE

Apply surgical grade (non-silicone, water soluble) lubricants to hinges, box joints and moving parts as per the lubricant manufacturer's instructions.

INSPECTION AND FUNCTION TESTING

~ Visually inspect and check all instruments for damage and wear: cutting edges are free of nicks and present a continuous edge; jaws and teeth align correctly; all articulated instruments have a smooth movement without excess play; locking mechanisms (such as ratchets) fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components.

~ Close instruments with a ratchet lock in the first ratchet position before sterilisation to avoid temperature-induced stress cracks in the box joints.

~ Consider removing for repair or replacement any blunt, worn out, flaking, fractured, corroded, stained, discoloured, or damaged instruments.

Note: If an instrument is returned to the manufacturer / supplier, the instrument must be decontaminated and sterilised and be accompanied with the relevant documented evidence.

PACKAGING

All instruments to be wrapped or packaged following local procedures; in accordance with ISO 11607-1 – Examples described in ANSI/AAMI ST79

STERILISATION

Autoclaves should comply with the requirements of, and be validated and maintained in accordance with EN285, EN13060 and ENISO 17665

~ Either CE marked or validated vacuum autoclave operating at 134-137° C for a minimum holding time of 3 minutes - always following the instructions of the machine manufacturer.

~ When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded

~ Ensure instruments dry before sterilisation/storage

~ Place heaviest items on bottom of set

STORAGE

Non-sterile instruments or sterile wrapped instruments should be stored in dry, clean conditions at an ambient room temperature.

ADDITIONAL INFORMATION

Other forms of **cleaning** (i.e., ultrasonic) and **sterilisation** (i.e., Low temperature steam and Formaldehyde, Ethylene Oxide and Gas Plasma) are available. However, *always* follow the instructions for use as issued by the manufacturer and *always* consult with them if in any doubt over the suitability of any process used.

Standards and guidelines are available – Refer to: - HTM0101/WHTM/SHTM BS EN

ISO 15883-2:2006 Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments. • Adhering to: HTM 01-01: Management and decontamination of surgical instruments: Part C: Steam Sterilisation Part D - Washer-disinfectors

NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING, AS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY, ACHIEVE THE DESIRED RESULT. THIS REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKEWISE, ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.