

Falcon® STERILIZATION, CARE AND MAINTENANCE INSTRUCTIONS



Consult Instructions



Safety First!

Processing Regulations

Reprocessing Limitations and Warranty

- ▶ You have bought a quality instrument, for best results, please observe the following instructions.
- ▶ The following instructions are for all reusable medical devices supplied by Falcon, unless otherwise stated on packaging of the product.

- ▶ Special care must be taken to ensure personal safety.
- ▶ Only fully trained personnel must perform these procedures.
- ▶ Protective clothing, gloves and eyewear must be worn in accordance with local health and safety standards.
- ▶ Sharp instruments must be handled separately in baskets or cassettes.
- ▶ Manufacturers' instructions and guidelines must be followed.

- ▶ These instructions offer general guidelines, in addition to these please observe national regulations and standards.
- ▶ For patients with CJD, HIV, Hepatitis or any other contagious diseases, observe the relevant national regulations concerning the reprocessing of the products.
- ▶ Always follow the instructions of cleaning agent, disinfectant and equipment manufacturer.
- ▶ The operator is solely responsible for the success of the selected procedure and validation of its effectiveness.

- ▶ Repeated processing can have minimal effect on instruments, end of instrument life is normally determined by wear and damage in use. Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.
- ▶ All Falcon's re-usable and sterilizable instruments are fully guaranteed to withstand repeated processing if these instructions are observed.

Note: Corrosion and Surface pits, if not occurred after first Sterilization, are almost always due to improper care by relevant personnel. All Product Complaints will be handled according to this Rule!



Unless otherwise stated on product label, all instruments are supplied NON-STERILE.

Process	Instructions	Process	Instructions
	<p>New Instruments: All instruments are supplied non-sterile unless otherwise stated on label. Remove all packaging including plastic protection sleeves on instrument tips. Clean the new product either manually or mechanically prior to the initial sterilization.</p> <p>Used Instruments: Wherever possible, do not allow blood debris or bodily fluids to dry on instruments. For best result and to prolong the life of the medical device reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.</p> <p>Preparation for decontamination: Reprocess all instruments as soon as it is reasonably practical following use.</p>		<p>Inspection and Maintenance</p> <p>After cleaning, visually inspect all surfaces, cannulation, ratchets, joints, holes and lumens for complete removal of soil and fluids. If ANY soil or fluid is still visible, return the instrument for repeat decontamination.</p> <p>Lubrication: Apply surgical grade lubricants to hinges, joints and moving parts as per the lubricant manufacturer's instructions. Use only a non-silicon water-soluble lubricant, not industrial type.</p> <p>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.</p> <p>Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged instruments.</p> <p>Note: if an instrument is returned to the manufacturer / supplier, the instrument must be decontaminated and sterilized and be accompanied with the relevant documented evidence.</p> <p>Packaging: All instruments to be packed according to method of sterilization used following national and international standards.</p>
1	Cleaning	2	Cold Disinfection
1.1	<p>Ultrasonic Cleaning</p> <ul style="list-style-type: none"> ▶ Use only validated and CE marked equipment. Always follow manufacturer's instructions for use. ▶ Do not over-clean maximum immersion time of 10 minutes is recommended. ▶ Avoid over-crowding of instruments. Place heavier instruments at the bottom of the basket. ▶ Handle 'sharps' (scissors, knives, chisels etc.) separately. ▶ Keep joints open and ratchets unlocked. ▶ Rinse instruments with water to remove cleaning solution. 		<ul style="list-style-type: none"> ▶ Use only CE marked products. ▶ Do not use bleach (sodium hypochlorite). ▶ Follow all manufacturers instructions and warnings. ▶ Rinse thoroughly after disinfection under running water. <p>Note: Disinfection is not an alternative to Sterilization</p>
1.2	<p>Automatic Washer / Disinfectant</p> <ul style="list-style-type: none"> ▶ Use only CE marked and validated washer-disinfectant machines and low-foaming, non ionizing cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles. ▶ Load instruments carefully, with any box joints and hinges open and so that any fenestrations in instruments can drain. ▶ Place heavy instruments with care at the bottom of containers, taking care not to overload wash baskets. ▶ Place instruments with concave surfaces facing down to prevent pooling of water. ▶ Where available, use appropriate attachments to flush inside reamers and devices with lumens or cannula. ▶ Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage. <p>Note: Automated cleaning may not be suitable for all lumens and cannula, in which case clean manually with a water jet gun, if available, and an appropriate brush (and stilette if provided) that reaches the depth of the feature. After manually cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.</p> <p>Note: These instructions have been validated using a washer-disinfectant cycle validated to include two cold rinses at <30°C, a detergent cycle and a rinse cycle both at >50°C, a disinfection cycle operating at a temperature of between 80°C and 87°C for a minimum holding time of 1 minute (actual holding time in excess of 2 minutes 50 seconds) and a 20 minute drying cycle. The detergent used was a low foaming, non-ionising spray wash detergent cleaner (max 12 pH) and the rinse aid a neutral PH low foaming, non-ionic surfactant with isopropyl alcohol.</p>	3	Sterilization
		3.1	<p>Steam Sterilization</p> <ul style="list-style-type: none"> ▶ Use only CE marked and validated vacuum autoclaves ▶ Always follow manufacturer's instructions for use. ▶ Ensure instruments are fully clean, dried and lubricated. ▶ Use packaging materials as specified by EN 868 and ISO 11607. ▶ Do not exceed manufacturer's stated load. ▶ Recommended temperature and time: 134° C - 137° C 2.25 bar for minimum 3 minutes Do not exceed 140° C
1.3	<p>Manual Cleaning</p> <ul style="list-style-type: none"> ▶ Use a double sink system (Wash/rinse) dedicated for instruments cleaning (not used for hand washing). ▶ In the first sink (Wash), keeping the instrument submerged, with an autoclavable brush, apply CE marked cleaning solution to all surfaces until all soil has been removed. ▶ In the second sink (Rinse), rinse instruments thoroughly with soft, high purity water which is controlled for bacterial endotoxins, so that the water reaches all parts of the instrument, then carefully dry or use a drying cabinet. ▶ Ensure that the water temperature does not exceed 35° C ▶ Always brush away from the body and avoid splashing ▶ Pay particular attention to serrations, knurling, hinges, ratchets and tubes. Ensure hinged instruments are thoroughly cleaned in both open and closed position. ▶ Clean delicate instruments separately to avoid damage. ▶ Do not use steel wool or steel wire brushes. ▶ Use only CE Marked detergents with neutral pH (7). <p>Note: Manual cleaning is NOT a disinfection process.</p>	3.2	<p>Dry Heat Sterilization</p> <ul style="list-style-type: none"> ▶ Use only CE approved dry heat sterilizers. ▶ Always follow manufacturer's instructions for use. ▶ Recommended temperature: 160° C do not exceed 180° C <p>Note: Other forms of sterilization (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.</p>
			<p>Storage</p> <p>Ensure instruments are dry before storage, and stored in dry, clean conditions at an ambient room temperature</p> <p>NOTE: IT IS THE RESPONSIBILITY OF THE PREPROCESSOR 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 PREPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.</p>