Manufacturer: Scala Surgical Ltd	Tel: 0208 997 0077	Address: Unit 6 – Innovation Park, 89 Manor Farm Road, Alperton, Middx, HA0 1BA

Device(s): The following instructions are for Class I reusable surgical instruments and sterilisation baskets supplied by **Scala Surgical Ltd**, unless stated otherwise on the packaging of the product. These instructions are intended for use only by persons with the required specialist knowledge and training.

WARNINGS	• 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. • No part of the process shall exceed 140° C. • Some sensitive materials (e.g.: Aluminium) are damaged by high alkaline solutions (pH >10). • Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning. • **Note: when reprocessing medical devices, always handle with care, wearing protective clothing, gloves, and eyewear in accordance with local Health & Safety procedures.**
LIMITATIONS ON REPROCESSING	• Repeated processing has minimal effect on these instruments. • End of 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.
FROM POINT OF USE	• Wherever possible, do not allow blood, debris, or bodily fluids to dry on instruments. For best results 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.
PREPARATION FOR DECONTAMINATION	• Reprocess all instruments as soon as it is reasonably practical following use. • Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer.
CLEANING: AUTOMATED	• **Use only either CE marked or validated washer-disinfector machines and low-foaming, non-ionising 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 in 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. • **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. • **Note:** these instructions have been validated using a washer-disinfector cycle validated to include two cold rinses at <35°C, a detergent cycle and a rinse cycle both at >50°C, a disinfection cycle operating at a temperature of between 80°C and 95°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.
CLEANING: MANUAL	• **Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment 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 thoroughly with soft, high purity 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. • **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.*
CLEANING: INSPECTION	• After cleaning, visually inspect all surfaces, cannulations, 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.
MAINTENANCE	• Apply surgical grade lubricants to hinges, 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. • ***Remove for repair or replacement any blunt, worn out, flaking, fractured 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 packed following local protocol in accordance with BS standards.
STERILISATION	• **Either CE marked or validated vacuum autoclave operating between 134°C - 137°C at 2.25 bar 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 are dry before sterilisation.
STORAGE	• Ensure instruments are dry before storage, and 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. • Cleaning and sterilising guidelines are available in HTM 2030 and HTM 2010.
MANUFACTURER	• See brochure for telephone and address of local representative or telephone **0208 997 0077**

Important Notice to Reprocessor:

- It is crucial for the reprocessor to guarantee that the actual reprocessing, as conducted, achieves the intended outcomes using the equipment, materials, and personnel within the reprocessing facility. This necessitates:
  1. Validation: Regular confirmation of the effectiveness of the reprocessing method.
  2. Routine Monitoring: Ongoing observation to ensure the process is operating correctly and achieving the desired results.
- Additionally, should there be any deviations from the provided instructions by the reprocessor, a thorough assessment must be conducted to evaluate:
  A. Effectiveness: Ensure the altered approach maintains its efficacy.
  B. Potential Adverse Consequences: Analyse if the deviation might lead to unintended and harmful results.
- Every deviation should be evaluated rigorously to ensure safety and effectiveness in the reprocessing procedure.

Please refer to the table below for definitions of the symbols used within the labelling.

Symbol	Meaning
h	Indicates the manufacturer's catalogue number so that the medical device can be identified.
g	Indicates the manufacturer's batch code so that the batch or lot can be identified.
N	Indicates the date when the medical device was manufactured.
M	Indicates the medical device manufacturer.
P	Indicates the authorized representative in the European Community
UK CA	Indicates the medical device UKCA marking
NON STERILE	Indicates a medical device that has not been subjected to a sterilisation process.
	Indicates a medical device that needs protection from light sources.
	Indicates a medical device that needs to be protected from moisture.
	Indicates the need for the user to consult the instructions for use.
	Indicates the need for the user to consult the instructions for use for important cautionary information.
MD	Indicates a Medical Device.
UDI	Indicates Unique Device Identifier.