L.A. Medical®
Fabricantes de Instrumentos Cirúrgicos Lda.

Reprocessing Instructions
Reusable Medical Devices

General Remarks	The following instructions apply to all reusable medical devices (below referred as devices) manufactured by L.A. Medical, unless stated otherwise with the packaging of the product. These instructions are intended for use only by persons with required specialist knowledge and training. Additional information may be supplied with certain devices regarding disassembling or interaction with other devices. Such information will be enclosed with the specific devices and are supplemental to these instructions. It is processor responsibility to ensure that the reprocessing is performed using adequate equipment and materials, and that the personnel in the facility has the necessary training to ensure that the desire results are achieved. Equipment and processes must be validated by the equipment manufacturer and be routinely monitored. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. All of the stages for the reprocessing of the L.A. Medical devices have been validated.
WARNINGS	Follow instructions and warnings as issued by manufacturers of any disinfectants and cleaning agents used. Whenever possible avoid use of mineral acids and harsh, abrasive agents. Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning. Instruments with aluminum components will be damaged by alkaline solutions. Do not exceed 115ºC during drying. Do not exceed 137ºC during sterilization. L.A. medical does not assume the responsibility due to lack of cleaning and sterilization of its devices, which should be reprocessed by the final user. ***Note**: when reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with Health & Safety procedures implemented.*
Limitations on Reprocessing	Repeated processing has minimal effect on these devices. End life of the device is normally determined by wear and damage due to use. In the point “Inspection and Function Testing” are described the items to evaluate in order to determine the end life of L.A. Medical devices. Any specific limitation on the number of reprocessing cycles shall be made available with the device.

REPROCESSING INSTRUCTIONS	
Point of use	Wherever possible, do not allow blood, debris or body fluids to dry on the devices. For best results and to prolong the life of the device, reprocess immediately after use. If reprocessing cannot be performed immediately, use an enzymatic disinfectant to help prevent soil from drying, removing excess soil from the devices.
Containment and Transportation	If supplied, ensure protective caps and guards are fitted to devices. Ensure that cutting edges are protected.
Preparation for Cleaning	Reprocess all devices as soon as it is reasonably practical following use. Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available with the device. Use a bristled brush so soft not to damage delicate tips, to remove all blood, debris or body fluids.
Cleaning / Disinfection: Automated	Use only CE marked washer-disinfector machines that have been validated by the equipment manufacturer. The cycle of the washer-disinfector machine may include the stages of rinsing, washing, neutralization, thermal disinfection and drying. For the L.A. Medical devices, the program “Instruments” of the washer-disinfector machines should be used. In each different stage the right products should be used: - Washing: alkaline cleaning agents, with non-ionic surfactants, non foaming and biodegradable; - Neutralization: acidic neutralizer; - Drying: anionic surfactant additives, which will activate the drying, enhancing the rinsing. Do not exceed 115ºC during drying. Ensure that soft, freshly distilled or deionised water, which is sterile or controlled for bacterial endotoxins, is used in the final rinse stage. Load devices carefully, with any box joints and hinges open and so that any fenestrations in devices can drain. Place heavy devices with care in the bottom of containers, taking care not to overload wash baskets. Place devices with concave surfaces facing down to prevent pooling of water. Where available, use appropriate flushing adaptor attachments to flush inside devices with lumens or cannulation. Ensure lumens and cannulas have unobstructed flow prior to fitting flushing adaptors to ensure thorough cleaning and disinfection When unloaded the devices, check cannulations, holes, etc., for complete removal of visible soil. If necessary repeat cycle or repeat manual cleaning. ***Note**: Automated cleaning may not be suitable for all lumens and cannulations, in which case clean manually with a water jet gun, if available, and an appropriate brush that reaches the depth of the feature. After manually cleaning, pass all devices through an automated cleaning cycle to achieve disinfection.*

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	***Note**: Different automated cleaning-disinfection systems are available, each one with specific instructions to be observed. The recommendations of the equipment manufacturer must always be followed during cleaning and disinfection, in order to use validated programs and adequate detergents / cleaning agents.*
Cleaning / Disinfection: Manual	Care must be taken not to damage delicate tips on devices by the use of hard brushes, scouring agents or by excessive force. Manual cleaning is not advised if an automated washer-disinfector is available. If this equipment is not available, use the following method: 1. Rinse excess soil form device and proceed for a visual inspection of them. 2. Fully immerse the device into a biodegradable disinfection detergent solution - enzymatic detergent – with a concentration of 0,5 to 1,6%, neutral pH, not exceeding 30ºC, during 5 to 10 minutes (or according to the introductions of the product manufacturer). 3. Using appropriate cleaning accessories, wash and scrub vigorously applying enzymatic detergent solution to all surfaces ensuring that hinged devices are cleaned in both open and closed positions. 4. It is important to ensure that no soil is trapped inside the devices with lumens or cannulations and that the detergent covers all surfaces. These devices should also be flushed through with an enzymatic detergent solution for a minimum of 3 times. 5. After manual cleaning, rinse the device in clean water during 1 to 3 minutes. Ensure that running water passes through cannulations, and blind holes are repeatedly filled and emptied.
Drying	When drying is achieved as part of a washer disinfector cycle, do not exceed 115ºC. In the case of a manual cleaning / disinfection the devices may be dried manually, using a medicinal filtered compressed air (3 – 7 bars) during 1 to 5 minutes, according to the device size. If there is not medicinal filtered compressed air, the drying can be achieved leaving the devices to be dried at ambient temperature during 1 to 6 hours, according to the device size. The evaluation of drying is done with a visual inspection (presence or absence of water).
Maintenance	After the cleaning, disinfection and drying (automated or manual) is necessary to apply a small amount of surgical lubricant in the hinges, before proceeding to sterilization. This lubricant should not contain silicones, should be base on mineral oil and be antibacterial. Discard blunt or damaged devices.
Inspection and Function Testing	Visual inspect and check: - All devices for damage and wear - Cutting edges are free of nicks and present a continuous edge - Jaws and teeth align correctly - All articulated devices have a smooth movement without excess play - Locking mechanisms fasten securely and close easily - Long and slender devices are not distorted - Any component parts fit and assemble correctly with mating components - When devices form part of a larger assembly, check assembly Remove for repair or replacement any blunt, worn out, fractured or damaged devices. If any soil or fluid is still visible, return the device for repeat cleaning and decontamination. ***Note**: if a device is returned to the manufacturer / supplier the device MUST be decontaminated and/or sterilized and be accompanied by the relevant documented evidence.*
Packaging	Singly: A standard packaging material may be used. Ensure that the pack is large enough to contain the device without stressing the seals. In sets: Devices may be loaded into dedicated device trays, or general-purpose sterilization trays. Warp the trays using appropriate method.
Sterilization	The instruments must be sterilized in autoclave: Method: Vacuum Temperature: 134º C (273º F) Exposure time: 3 minutes (minimum) Drying: 20 – 40 minutes Only products that have been cleaned and disinfected can be sterilized. Ensure devices are dry before sterilization. Use only CE marked vacuum autoclave that have been validated by the manufacturer. Always follow the instructions of the equipment manufacturer. When sterilizing multiple devices in one autoclave ensure that the sterilizer's maximum load in not exceeded.
Storage	Ensure devices are dry before storage. Storage instruments in dry and clean conditions at an ambient room temperature.
Manufacturer Contact	For additional information please contact the manufacturer by telephone (234 529 790) or e-mail (lamedical@lamedical.pt)