Altomed Limited – Reprocessing Reusable Stainless Steel and Titanium Devices.

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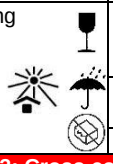
- The following instructions and guidance relate to Altomed Limited reusable stainless steel, titanium and ceramic coated stainless steel instruments. Any separate instructions for use supplied with the device itself should also be followed.
- Instruments with Tungsten Carbide inserts will have a gold coloured handle.
- These procedures should be followed when cleaning and sterilizing the aforementioned Altomed reusable instruments.
- The devices should be monitored, controlled, handled, cleaned and processed by suitably trained and qualified personnel under an approved quality management system such as ISO 9001 or ISO 13485.
- Follow Department of Health and MHRA Guidance where appropriate.
- Processing systems used must be able to sterilize devices to EN 556.
- **The instructions provided below have been validated by Altomed as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed, using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.**
- NOTE: Pure water - Water that has been demineralised, deionised, distilled or processed through reverse osmosis.

If in any doubt as to these instructions, contact the Quality Department at Altomed Limited.

Warnings 1: Solutions and materials and equipment	
1.1 Stainless steel. Avoid contact with:	Strong acids e.g. hydrochloric, aqua regia, dilute sulphuric, carbonic and tartaric.
	Salt solutions e.g. ammonium chloride, mercury salts and stannous chloride.
	Potassium thiocyanate and potassium permanganate.
	Limit contact with iodine solutions to less than 1 hour.
1.2 Titanium. Avoid contact with:	Potassium Perchlorate.
1.3 Tungsten carbide.	Exposure to Benzyl Ammonium Chloride (BAC) may loosen tungsten carbide inserts.
1.4 Corrosion and pitting.	Localised corrosion can be caused by Chloride-bearing solutions such as blood and saline. Avoid prolonged rinsing in saline solutions and use pure water instead.
1.5 Detergents.	Use only detergents that have been CE marked for cleaning stainless steel and titanium instruments. Repeated exposure to strong alkaline solutions may cause discolouration of the device. Take into account local water hardness levels when selecting the detergent.
1.6 Materials and equipment.	Avoid the use of abrasive pads or cleaners. Use only cleaning materials and equipment that have been CE marked for processing stainless steel and titanium medical devices.
Warning 2: Processing	
2.1 Instructions for use.	Follow instructions for use and warnings issued by the detergent manufacturer. Ensure all detergent residues are rinsed off as this may result in spotting or staining
	Follow instructions for use and warnings issued by the ultrasonic/washer/disinfector manufacturer.
2.2 Temperatures.	No part of the process should exceed 137°C. To prevent coagulation of proteinaceous substances, the initial cleaning/rinsing should not exceed 45°C.
2.3 Difficult to clean devices.	Due to the intended use of the device, some instruments may be difficult to clean. Devices with a long narrow lumen should be flushed using a Q-Rinse Machine or syringe with pure water. If still not clean use a chemical brush specifically designed for use on lumen devices e.g. *Ruhof InstruSponge.* Suitable CE marked medical device brushes may be used if needed.
	Devices with complex specifications, e.g. closed pressure jaws, small bowl jaws etc. should be manually cleaned first with a suitable CE marked medical device brush.
2.4 Handling 	Altomed medical devices are ***VERY*** delicate and must be handled with care at all times by suitably trained staff. Do not bang or drop devices or knock devices against each other as this may damage their structure or cutting edges. Avoid undue stresses or strains on the devices during processing.
	Do not allow devices to remain wet, store clean and dry. Keep sterilized devices out of direct sunlight and away from moisture.
	Do not use sterilized medical devices if the packaging has been compromised.
Warnings 3: Cross contamination	
3.1 High risk patients.	Follow hospital/facility approved procedures or recommendations in "Transmissible Spongiform Encephalopathy Agents: Safe Working And The Prevention Of Infection" compiled by the Advisory Committee on Dangerous Pathogens Spongiform Encephalopathy Advisory Committee for processing devices that have been exposed to unconventional slow viruses or prion diseases such as Creutzfeldt Jakob Disease (C.J.D), Kuru, Gerstmann-Straussler-Scheinker Syndrome (G.S.S.), Fatal Familial Insomnia (F.F.I.), Scrapie, Bovine Spongiform Encephalopathy (B.S.E.) etc.
	Segregate instruments used on high risk tissues for patients born after 1st January 1997. See NICE IPG 196 (2006)
3.2 Health and safety	Follow hospital/facility approved Health & Safety procedures at all times (e.g. C.O.S.H.H., P.P.E. etc.). Wear protective clothes, gloves and eye wear as specified in your Health and Safety procedures. Keep fingers away from sharp tips and edges, **use extreme caution when handling sharp devices.**
Warnings 4: Use	
4.1 Intended use	Instruments should only be used for their intended purpose, e.g. clamping, cutting, retracting etc. Do not use scissors for the wrong job as blades may misalign, blunt or chip. Use tissue scissors only for cutting tissue and not sutures, wires etc. Do not use needle holders as pliers. Extra care should be taken with delicate microsurgical instruments; these should be protected when not in use e.g. MicroWash Tray.

4.2 After use	An instrument count should be made before and after surgery to ensure no devices are missing. Ensure instruments are not caught in soiled linen as these will create an injury hazard at the laundry and may become damaged beyond repair.

5. Limitations on Reprocessing	
5.1 Shelf Life 	For reusable devices that have been presented for use in a sterile condition, ensure the use by date has not been exceeded. The use by date is in the format of Year/Month/Day and is displayed next to the hour glass symbol.
5.2 End of life	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and tear and damage due to use, processing or handling. Any specific limitations on the number of processing cycles is identified on the product labelling or instruction sheet provided with the device. Devices will withstand over 20 autoclave cycles unless specified elsewhere on the label.
	Devices should be inspected (under a microscope if necessary) and tested to ensure they have not been damaged and function correctly. See Inspection and Testing below. If the device fails, it should be segregated, identified accordingly and decontaminated. It should then be either sent back to Altomed for repair along with the signed Decontamination Certificate, or disposed of following hospital approved procedures, e.g. Sharps Bin or Clinical Waste etc..
5.3 Reprocessing single use devices 	If the Altomed device or packaging is labelled with a single use symbol, then this device is intended to be used only once. **Single use devices must not be reprocessed** but disposed of after use following hospital approved procedures, e.g. decontamination, sharps bin, clinical waste bin etc.

6. Processing 1: Preparation at point of use	
6.1 Point of use	Wherever possible do not allow debris (e.g. blood or other bodily fluids) to dry on the devices. For best results and to maximise instrument life, process as soon as is reasonably practical after use.
	Follow any separate instructions for use supplied with the device in question.
	Ensure all instruments exposed during the surgery are reprocessed, even if they were not used as they may have been inadvertently contaminated.
	Remove excess soil by rinsing in pure water (below 45°C) as soon as possible after use. If necessary use a CE marked soft bristled brush or instrument wipe to remove stubborn contaminants, brush carefully from stock to tips.
	If the devices cannot be processed immediately after use, Altomed recommend the use of an Enzymatic preparation solution such as Ruhof Prepzyme XF to keep debris moist. Ensure all surface areas of the device including any lumen, are fully coated in the solution.
6.2 Containment and transportation	Pack the devices in a suitable container such as an Altomed MicroWash Tray, to prevent unwanted movement and damage to the instruments during transportation and processing.
	Care must be taken to prevent unwanted contamination. Follow hospital/facility approved procedures using trained staff for transporting contaminated devices.
7. Processing 2: Preparation at processing facility	
7.1 Preparation for cleaning	Ensure staff who will be processing the devices are trained in handling the devices due to their delicate nature.
	Disassemble the device when the instructions for use supplied with the device specify this. Only use tools that have been recommended in the specific device's instruction sheet for disassembly.
	Flush any devices with a lumen using a Q-Rinse Machine, syringe or water jet gun as available to ensure they are free flowing. Use pure water. If necessary, use a chemical brush designed for lumens; Altomed recommend the Ruhof InstruSponge. Select the correct diameter brush to use and one which is long enough to reach the depth of the feature. Rinse thoroughly in pure water.
	Rinse off any enzyme preparation solution using pure water (<45°C).
8. Processing 3: Cleaning – Manual	
8.1 Manual cleaning	Due to the nature of some medical devices it may be necessary to manually clean these before processing through the automated process. Instructions for use supplied with the device will specify if manual cleaning is needed.
	Required equipment: Double sink dedicated for cleaning instruments. CE marked soft bristled brush. Ruhof InstruSponge. Low foaming, free rinsing, CE marked, pH neutral endozyme detergent and pure water. MicroWash Q-Rinse Machine, water gun or syringe. CE marked instrument wipe, hospital approved tissue paper, hot air dryer, drying cabinet or air gun.
	Altomed used: Double sink dedicated for cleaning instruments. Altomed A11076 CE marked soft bristled brush. Ruhof InstruSponge. MicroWash Q-Rinse Machine. Ruhof Endozyme AW Plus detergent and pure water.
	Temperature range: 10°C to 45°C
	Time: Minimum 2 minutes
	Dilution ratio: 17 millilitres detergent / 4 litres of water
	Use a double sink system dedicated only for cleaning instruments - DO NOT use a hand wash basin. Use warm water (10°C to maximum 45°C). Use a hospital/facility approved and CE marked detergent to the manufacturers guidelines in the first sink and pure water in the second.
	Flush any devices with a lumen using a Q-Rinse Machine, syringe or water jet gun as available to ensure they are free flowing. Use pure water. If necessary, use a chemical brush designed for lumens; Altomed recommend the Ruhof InstruSponge. Select the correct diameter brush to use and one which is long enough to reach the depth of the feature.
	Carefully immerse the device in the detergent solution and displace any trapped air. Ensure solution reaches all areas of the device.
	Keeping the device fully immersed in the solution, brush, wipe and agitate the item to dislodge any visible dirt. Pay particular attention to any serrations, teeth, ratchets, hinges or other difficult to clean areas. Always brush away from the body and avoid splashing.
	Ensure the device is thoroughly cleaned in both the open and closed positions.

	Transfer item to the second sink. Ensure the device is fully immersed and rinse thoroughly with the pure water to remove any residues in both open and closed positions. Flush any lumen with a MicroWash Q-Rinse Machine and pure water to ensure correct flow rates.				
	Carefully hand dry using instrument wipe or hospital approved tissue paper, an industrial hot air dryer, drying cabinet or filtered air gun can also be used. If necessary, use medical grade compressed air to dry any cannulated devices.				
9. Processing 4: Cleaning – Ultrasonics					
9.1 Ultrasonic cleaning	If specified in the Altomed instructions for use supplied with the device or elsewhere in these procedures, ultrasonically clean the instrument.				
	Warning! Do not process plated instruments (e.g. Lang Speculum) or ceramic coated devices in the ultrasonic as this may crack or rupture the surface.				
	Required equipment	CE marked and validated Ultrasonic bath and basket, suitable sized CE marked processing trays such as MicroWash Tray, pure water. CE marked endozyme detergent, which is a liquid, low foaming, free rinsing, non-abrasive and biodegradable. It should not contain artificial colours, optical brighteners, perfumes, halides at an in concentration >120mg/L, fatty soaps, glycerine or lanolin or leave a toxic residue.			
	Altomed used	Ultrasonic bath, MicroWash Tray, Ruhof Endozyme AW Plus detergent and pure water.			
		Temperature range	20°C to 45°C		
		Time	Minimum 2 minutes		
		Dilution ratio	17 millilitres detergent / 4 litres of water		
	Ensure the Ultrasonic Machine is clean, empty and dry and has been approved for use.				
	Fill fluid reservoir with solution of detergent and water to ensure complete immersion of device. Follow the Detergent and Ultrasonic Cleaner Manufacturer's instructions for use. Acidic or alkaline products with >2% available alkalinity is not recommended as they cannot be properly neutralised.				
	Degas the solution by following the machine manufacturer's instructions for use. Set and wait until the temperature is at the required level as specified in the detergent manufacturer's instructions.				
	Protect the devices by packing them in MicroWash Trays, Ultrasonic trays or cassettes, on finger matting or specially made holders to prevent them touching each other or the sides and bottom of the Ultrasonic bath.				
	Ensure loading pattern has been validated and is as the machine manufacturer's instructions. Ensure all box locks and jaws are open, lumen and holes are set at an angle to drain, do not allow instruments to touch each other.				
	Carefully place items into the solution using the machine basket. Ensure items are fully immersed and that any air contained in the device is displaced. Replace lid and leave for the time required.				
	When the cycle is finished, switch off the cleaner, remove the instruments and drain them. Rinse thoroughly in pure water to remove any residues; NOTE: ensure any lumen are flushed thoroughly. The Ruhof Endozyme has been clinically tested to be free rinsing.				
	Carefully hand dry using absorbent non-shedding cloth, alcohol wipe, industrial hot air dryer or drying cabinet. If hand drying, dry from the stock of the device to the tips, ensure care is taken so that delicate items such as tips, probes, hooks, dilators etc. are not damaged. If necessary, use medical grade compressed air to dry any cannulated devices. Inspect and test prior to further processing.				
10. Processing 5: Cleaning – Washer / Disinfector					
10.1 Automated cleaning	Recommended equipment	Suitable sized CE marked processing trays - Do not use Radel (plastic) sterilization trays in the washer / disinfector as they do not permit correct exposure to the process. CE marked and validated washer / disinfector machine to ISO15883 CE marked detergent which is a liquid, low foaming, free rinsing, biodegradable and non-abrasive. It should not contain artificial colours, optical brighteners, perfumes, halides at an in concentration >120mg/L, fatty soaps, glycerine or lanolin or leave a toxic residue.			
	Validated	Washer / Disinfector, MicroWash Tray, either (1) HAMO Liquid 52 Neutral Enzymatic; or, (2) Prolystica 2X Alkaline detergent and pure water.			
		Stage	Temperature	Format	Time
		Initial rinse / Pre-wash	(1) <45°C (2) <20°C	Filtered water	2 minutes
		Detergent wash	60°C	((1) 60ml per cycle ((2) 2.0ml/L	6 minutes
		Detergent rinse	<45°C	Pure water, soft high purity water controlled for bacterial endotoxins	15 seconds
		Disinfection cycle	Min. 90°C	Heat	1 minute
		Drying cycle	Sufficient to remove all remaining surface moisture	Hot clean air that does not introduce microbial contamination or impair the cleanliness of the device.	>12 minutes
	Ensure any handwashing or Ultrasonic Cleaning has been carried out if specified on the device manufacturers instructions for use.				
	Place instruments into a suitable container (e.g. MicroWash Tray) that has been validated for use with the washer / disinfector to protect devices from handling damage that can occur during processing. Especially ceramic coated devices! Ensure instruments are in their correct location in the MicroWash Tray and that the lid is on the correct way around and locked closed if applicable.				
	If no MicroWash Tray is used, load instruments so that as much contaminated surface area is exposed as possible, e.g. open jaws, hinges etc. Place any devices with holes, lumen, concave				

	surfaces, box joints etc. so that they can drain freely. Load the machine as specified in the machine manufacturer's instructions so that the load configuration does not impede the cleaning process.
	Keep heavy objects at the bottom of trays, do not overload baskets and do not let instruments touch each other. Load as described in hospital/facility procedures or as in the MicroWash Tray Plan.
	Where available use machine attachments to flush the lumen of any cannulated devices.
	Run a cycle that has been approved and validated by the hospital/facility. The initial rinse should be at or below 45°C. The hot water disinfection rinse should ensure the surface of the device reaches 90°C for a minimum of 1 minute (see also ISO 15883-1).
	When unloading check devices, including cannulations and holes etc. for complete removal of visible soil. If necessary, test lumen flow rates using a Quickrinse Machine or syringe and pure water. If necessary, repeat cycle or carry out manual cleaning.
	Ensure instruments are dry, if not they should be reprocessed.

11. Sterilization			
11.1 Packaging	All delicate devices must be packed in a suitable MicroWash Tray or specially designed Sterilization Tray to prevent any damage, especially to tips. Wrap the MicroWash Tray or Sterilization Tray in a hospital approved wrap or in a peel pouch as specified by under local protocols. Altomed recommend the use of wraps or pouches that meet the requirements of the current harmonised standards (E.g. BS, EN, ISO.).		
11.2 Sterilization	Follow local protocols to Department of Health Guidance for autoclave sterilization. Altomed have validated the following autoclave protocol as shown below:		
	Autoclave	Vacuum Autoclave	CE marked and maintained to Department of Health Guidance
		Water	Pure water
		Holding Time (E.g. Sterilization time)	3 to 3½ minutes
		Sterilization temperature	134°C to 137°C
	Load the autoclave as described in the autoclave manufacturer's instructions for use, do not overload.		
Label device once sterilized with "sterile" symbol 	Ensure the autoclave has fully finished the cycle before opening the door. Failure to do so may result in wet product. All product and packaging must be dry when the autoclave cycle has finished. If not, they should be reprocessed and the autoclave reviewed for suitability. Label device as sterile.		
	Other forms of sterilization are available such as ethylene oxide and gamma etc., please contact the Altomed Quality Department at quality@altomed.com for further details.		

12. Maintenance, inspection and testing.		
12.1 Reassembly	Reassemble any devices where necessary if the instructions supplied with the device specify this. Follow the instructions supplied with the device to assemble correctly. If applicable, ensure any sharp tips have a protective cover to prevent puncturing sterilization pouches.	
12.2 Lubrication	After washing and before sterilization, lubrication should be applied to moving parts or joints for example screw threads, hinges, moving blades, moving platforms, moving arms etc.	
	Follow the Lubricant Manufacturer's instructions. Any lubricants used must be water soluble and specifically designed, CE marked and labelled for use with medical devices. Altomed recommend Ruhof Premix-Slip.	
	Oil-based lubricants should not be used. They deliberately cause contamination over the entire cleaned surface. Mineral oils have poor biocompatibility and may inhibit the penetration of steam or sterilant gases on terminally sterilized product.	
12.3 Inspection	Visually inspect all surfaces, cannulations, ratchets, joints, holes and lumens for complete removal of any debris such as organic matter and any chemical residues. If devices are not visibly clean, reprocess using manual cleaning or automated cleaning as necessary. Use a microscope if necessary to see tips etc.	
	If unsure about the integrity of cannulated device flush with pure water and check the flow rate.	
12.4 Testing	See also ISO 7151 and BS 5194 Parts 2, 3 and 4. If applicable follow any additional inspection and testing as specified on the device's instructions for use. If you have any questions on device testing, please contact Altomed Quality Department on quality@altomed.com.	
	Alignment	All jaws, teeth, arms etc. should be correctly aligned and interlock where appropriate.
	Finish	Device should be clean with no staining, chemical or cleaning residues or body fluids or debris. Any markings should be clear and easily visible. Staining may be removed by using a specially designed cleaning agent such as Ruhof Surgi-Stain. Follow cleaning agent instructions for use. Re-clean where applicable.
	Structure	No scratches, bends, distortions, chips, cracks, flaking, grinding marks, pitting or other signs of physical or handling damage. Sharp edges should only be where designed, e.g. blades. Check also for any cracks in box locks and hinges and excessive wear. Ensure any ceramic coated devices have not become chipped or cracked and any lockable platforms have not been bent out of shape.
	Movement	Smooth without grating, scratching, jerking or excessive play unless designed to be otherwise. Should be easy to open and close with two fingers without catching. Screw actions should be smooth without any gritty action. Moveable fixation rings should move easily under pressure yet remain stationary when not.
	Locking Mechanisms	Should open and closed easily. Should hold jaws in the position required securely when in the locked position.
	Tips and teeth	Check the integrity of any delicate parts on probes, hooks, dilators etc. Ensure any tips or teeth are not bent, snapped, missing or otherwise damaged (see also alignment). Teeth and prongs should be appropriately sharp and equally shaped where applicable with no resistance when reopening. Any tips normally held under

		pressure in a closed position, should interlock and remain closed unless operated. These tips should open correctly with pressure applied by two fingers.
	Assemblies	All interlocking and detachable parts should fit easily and correctly without the need to apply any excessive force
	Cutting edges	Should give a clean cut from the tip down to two-thirds of the blade. Test by cutting moist tissue paper in a single continuous movement, do not apply lateral pressure. Cut should be clean and not pull tissue fibres when the closed blades are retracted from the paper.
	Interlocking arms or platforms	Any serrations and interlocking parts should mesh when in the closed position. Bulldog clip jaws and needle holder jaws should apply sufficient pressure to securely hold a suture. DCR punch arms should be correctly connected to ensure smooth movement. Ball and socket towel clip ends should fit each other. Tungsten carbide platforms should be securely attached with no gaps around the join.
12.5 Failed devices	If the device fails any of the quality inspection criteria above it should be segregated, identified accordingly and decontaminated. It should then be either sent back to Altomed for repair along with the signed Decontamination Certificate, or disposed of following hospital approved procedures, e.g. Sharps Bin or Clinical Waste etc..	

13. Other	
13.1 Manufacturer	Altomed Limited. 2 Witney Way, Boldon, Tyne/Wear, England. NE35 9PE. Tel: 0191 519 0111, Fax: 01981 519 0283 E-Mail: admin@altomed.com or quality@altomed.com

Symbols Used to BS EN ISO 15223-1 and ASTM F 2503:


If this symbol is on the device label do not reprocess or reuse – Single use


Keep away from direct sunlight and store dry

These reusable devices are non-sterile Sterilize before use


Fragile handle with care


Do not use if packaging has been damaged


Date of manufacture


Name of manufacturer

Lot number

Product code number


Use by Date


Follow instructions for use (IFU)


Caution see IFU warnings


Meet requirements for CE marking in the EU

The product is sterile if this symbol is on product label

US Statement.

Caution: Federal law restricts this device to sale, distribution and use by or on the order of a Physician trained and/or experienced in the use of this device.