OC-PRO-003 WI-001 Revision 5 Date of Issue: 13-Sep-2023	**Cleaning Instructions** **For Ortho-Care Stainless Steel Reusable Instruments**	ORTHO CARE (UK) Limited

- The following instructions and guidance relate to Ortho-Care (UK) Ltd. reusable stainless instruments. Any separate instructions for use supplied with the device itself should also be followed.
- These procedures should be followed when cleaning and sterilizing Ortho-Care 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 Ortho-Care 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 to 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 how to follow these instructions, contact quality@orthocare.co.uk

Product Description
Dental and orthodontic instructions are a group of devices used in dentistry in dental examination and various dental procedures. In orthodontics, the instruments are primarily used in the oral cavity to apply and remove the orthodontic appliances.

1. WARNINGS: SOLUTIONS AND MATERIALS AND EQUIPMENT	
1.1 Avoid contact of stainless steel instruments 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 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.
1.3 Detergents	Use only detergents that have been CE marked for cleaning stainless steel instruments. Repeated exposure to strong alkaline solutions may cause discolouration of the device. Take into account local water hardness levels when selecting the detergent.
1.4 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.
2. WARNING: 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	Devices with complex specifications, e.g., small bowl jaws etc. should be manually cleaned first with a suitable CE marked medical device brush.
2.4 Handling	Ortho-Care medical devices are 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.
	When processing, use in a well-ventilated area and use local exhaust ventilation. Avoid inhaling dust and fumes.
3. WARNINGS: 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.
	Where instruments have been used on high risk patients, segregate and keep the devices moist, prior to cleaning, disinfection and sterilisation of the instruments. See NICE IPG 666 (2020).
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.**
4. USE	
4.1 Intended use	Instruments should only be used for their intended purpose, e.g., clamping, cutting, etc. Do not use scissors for the wrong purpose as blades may misalign, blunt or chip. Extra care should be taken with delicate microsurgical instruments; these should be protected when not in use e.g., sterilisation 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.
4.3 Contraindications	The improper use of an instrument during handling, use or reprocessing, for which they are not indicated may result in damaged or broken instruments.
5. LIMITATIONS ON REPROCESSING	
5.1 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 are identified on the product labelling or instruction sheet provided with the device.

	If stored, handled and reprocessed appropriately Ortho-Care Class I products have a 2-year shelf life from the date of purchase, unless an expiry date is specified on the product label.				
	Devices should be inspected (under a microscope if necessary) and tested to ensure they have not been damaged and function correctly. See Maintenance, Inspection and Testing below. If the device fails, it should be segregated and disposed of following Good Clinical Practice e.g., sharps bin or clinical waste etc.				
5.2 Reprocessing single use devices	If the Ortho-Care 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 Good Clinical Practices, 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 end to tips.				
6.2 Containment and transportation	Care must be taken to prevent unwanted contamination and any damage due to transportation. 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.				
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. Instrument sponge. Low foaming, free rinsing, CE marked, pH neutral endozyme detergent and pure water. Water gun or syringe. CE marked instrument wipe, hospital approved tissue paper, hot air dryer, drying cabinet or air gun.			
		Temperature range	<35°C		
		Time	Minimum 2 minutes		
		Dilution ratio	Use in accordance with instructions specified by the detergent manufacturer.		
	Use a double sink system dedicated only for cleaning instruments - DO NOT use a hand wash basin. Use warm water (<35°C). Use a hospital/facility approved and CE marked detergent to the manufacturer's guidelines in the first sink and pure water in the second.				
	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.				
	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.				
9. PROCESSING 5: CLEANING – WASHER/DISINFECTOR					
9.1 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, non-ionising cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles.			
	Validated	Washer / Disinfector, Sterilisation Tray, HAMO Liquid 52 Neutral Enzymatic detergent and pure water.			
		Stage	Temperature	Format	Time
		Initial pre rinse / Pre-wash	<35°C	Filtered water	5 minutes
		2nd rinse / Pre-wash	<35°C	Filtered water	5 minutes
		Detergent wash	60°C	Detergent as per manufacturer instructions	15 minutes
		Disinfection cycle	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.	20 minutes
	Ensure any handwashing has been carried out if specified on the device manufacturers instructions for use.				
	Place instruments into a suitable container (e.g., sterilisation tray) that has been validated for use with the washer/disinfector to protect devices from handling damage that can occur during processing.				
	If no sterilisation 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, 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 sterilisation tray plan.				
	Run a cycle that has been approved and validated by the hospital/facility. The initial two rinses should be at or below 35°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 and HTM 01-01 part D: Washer Disinfectors).				
	When unloading check devices for complete removal of visible soil. 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 sterilisation tray or specially designed sterilization tray to prevent any damage, especially to tips. wrap the sterilisation tray or sterilization tray in a hospital approved wrap or in a peel pouch as specified by under local protocols. Ortho-Care 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 (HTM 01-01 Part C: Steam Sterilization). Ortho-Care 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.				
	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.				
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.				
	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, joints and holes 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.				
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 Ortho-Care at quality@orthocare.co.uk				
	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. 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.			
	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 close 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/parts	Any serrations and interlocking parts should mesh when in the closed position.
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 Ortho-Care for repair along with the signed Decontamination Certificate, or disposed of following hospital/facility approved procedures, e.g., Sharps Bin or Clinical Waste etc..	
12.6 Corrosion or Discolouration	Ortho-Care instruments are made with high quality surgical grade stainless steel, which protect instruments from rust, however care is the key factor for the long life of instruments and protection from rust or oxidation. Corrosion problems can be avoided by properly following all the recommendations below:- • Clean and dry instrument thoroughly after sterilization, and store in a dry place. Failing to do this is likely to result in brown or yellow stains. • When instruments are not being used, they must be stored in a protective case, capable of keeping the instrument dry. • Instruments showing any sign of corrosion beyond surface discolouration should not be used. • Discoloured or corroded instruments must not be mixed with other instruments (during cleaning, sterilizing or storage), as this could cause other instruments to become contaminated and to corrode as well.	
13. OTHER		
13.1 Manufacturer	Ortho-Care(UK) Limited, 1 Riverside Estate, Saltaire, West Yorkshire, England, BD17 7DR, UK. Tel: 01274 533233 Email: info@orthocare.co.uk Web: www.orthocare.co.uk	
13.2 EU Rep	EC REP Advena Limited, Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, Malta	
13.3 Other symbols	https://www.orthocare.co.uk/acatalog/resources.html MD CE UKCA (UKCA Mark)	
13.2 Manufacturer warranty	If stored, handled and reprocessed appropriately Ortho-Care Class I products have a 2-year shelf life from the date of purchase, unless an expiry date is specified on the product label.	
13.3 Storage	Store away from acids.	
13.4 Disposal	Place in suitable container for disposal and dispose of waste materials in accordance with all federal, state and local regulations. Avoid release to waterways.	
13.5 Performance characteristics and clinical benefits	No new risks, and/or increase in trend of known risks, and/or ambiguity of long-term clinical performance that may impact the benefit/risk ratio have been identified for these instruments. Medium/long-term safety and clinical performance is already known from the considerable time it has been on the market.	
13.6 Reporting serious incidents	Any serious incident that has occurred in relation to use of this product should be reported without undue delay to Ortho-Care and the competent authority for the country in which the incident occurred.	

Note. Please ensure that all joints are lubricated sufficiently as this will reduce the risk of damage to the instruments and increase the life span significantly.