Reprocessing Manual	
Warnings: Solutions, materials and equipment	
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 ○ Iodine solutions
Corrosion and pitting	• Localized corrosion can be caused by Chloride-bearing solutions such as blood and saline. Avoid prolonged rinsing in saline solutions and use pure water instead. • Periodically check the condition of the Instrument, making sure there is no sign of corrosion. Discard the damaged instruments.
Detergents, Water and lubricant	• Use only detergents that have been CE marked for cleaning medical devices made from stainless steel. • Repeated exposure to strong alkaline solutions may cause discoloration of the device. Take into account the local water hardness levels when selecting the detergent. • Use Pure water i.e. water that has been demineralized, deionized, distilled or processed through reverse osmosis • Water quality may influence the result of the cleaning and disinfection of the instruments. Therefore, use only deionized / distilled water or purified water / high purified water for all the steps that require water. Water with chloride contents may damage or even destroy the instruments. • Tap water contains minerals that may leave stains on the device after processing. Tap water can be used if validated and approved by your facility.

	• Check the hardness of the water used in the autoclave. Too hard water will leave a deposit on the instruments. • If a water softener is used ensure it is at the manufacturer's recommended level. Too much may cause discoloration or pitting. • Never use general – purpose oils for instruments; only water-soluble medical grade lubricants should be used. (if required) • Do not use corrosive cleaning agents. We recommend cleaning solutions and rinses with pH 7.0.
Material and equipment	• Never use abrasives on instruments, as this will spoil the surface finish. This may later cause discoloration, rusting or pitting. • Do not use abrasive cleaners & brushes with hard bristles. • Use only detergents, cleaning materials and equipment that have been CE marked for processing medical devices made from stainless steel, medical grade gold coating and tc.
Warnings: Processing	
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. • When sterilizing instrument(s) in an autoclave cycle ensure that the instructions from sterilizer's manufacturer are followed. • Always check all instructions for use and sterilization of new instruments.
Temperatures	• No part of the process should exceed 140°C. To prevent coagulation of proteinaceous substances, the initial cleaning/rinsing should not exceed 40°C.
Personnel	• Always qualified and experienced personnel should perform (re)processing.

Difficult to clean devices	• 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.
Processing	• Do not leave instruments in cleaning or disinfecting solutions for long terms (over night or weekend), the instruments can be destroyed. • Do NOT mix Surgical Instruments and textiles/linen in the same autoclave load. • All steps of (re)processing must be completed in a sequential manner, moving in one direction only from dirty to clean; as mentioned below. • Never use without sterilization.
Handling	• Always handle all instruments gently. Never overstrain, drop or misuse them. Avoid undue stresses or strains on the devices during processing. • Do not bang or drop devices or knock devices against each other as this may damage their structure. • Never handle instruments by their tips. These should be cleaned by trained personnel only who will ensure the delicate working ends are adequately protected during storage or sterilization. • Do not allow devices to remain wet, store clean and dry. Keep sterilized devices out of direct sunlight and away from moisture. • Never store damp instruments. So, they must be thoroughly dried first. • Never misuse instruments or overstrain joints or racks. • Keep fingers away from sharp tips and edges, use extreme caution when handling sharp devices.
Warnings: Cross Contamination	

High risk patients	• If prions and Creutzfeld-Jakob disease are suspected, special reprocessing requirements must be followed. These procedures have not been described within the scope of these reprocessing instructions. Please refer to Annex 7 of the recommendation "Hygiene requirements for the reprocessing of medical devices" by RKI and BfArM. • 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)
Health and Safety	• Wear protective clothes, gloves and eye wear as specified in your Health and Safety procedures. • Dirty and clean instruments must not come into contact with each other – keep separate to avoid cross-contamination. • Follow hospital/facility approved Health & Safety procedures at all times. • Consult National Infection Control / Prevention Protocols for specific guidance regarding processing of medical devices and always follow recommended best hospital practices and local government Health & Safety procedures and regulatory requirements.
Warnings: Use	

Intended Use	• Ensure instruments are only be used for their intended purpose. • Instrument should always be used in controlled environment i.e. following operation theatre SOP/Law.
Before & After use	• An instrument count should be made before and after surgery to ensure no devices are missing. • Check all instruments for damage before and after use. • Ensure instruments are not caught in soiled linen as these will create an injury hazard at the laundry and may become damaged beyond repair. • Always inspect for rust, pits, crakes, pores, dents and misalignments before use.

Limitations on Reprocessing	
End of Life	Due to the product design and the materials used, no definite limit to the maximum number of performable processing cycles can be specified. Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use. The service life of the medical devices is determined by their function and careful handling. They are then to be disposed of according to best hospital procedure. Do not use any damaged instruments.

Instructions for Reprocessing

- 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.
- Processing systems used must be able to sterilize devices to EN 556.
- 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.	
Preparation at point of use before processing	
Remove Contamination	○ Wherever possible do not allow debris (e.g. blood or other bodily fluids) to dry on the devices. For best results and to maximize instrument life, process as soon as is reasonably practical after use. ○ Ensure all instruments exposed during the surgical procedures are reprocessed, even if they were not used as they may have been inadvertently contaminated. ○ Remove excess soil by rinsing in pure water (below 40°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 i.e. remove gross soiling with disposable low–linting cloth/paper wipe from the instruments directly after application. Do not use fixating agents or hot water (>40°C), as this causes fixation of residues and can impair successful cleaning. In order to avoid contamination drying on, soak the used instruments in a disinfectant bath.
Containment & transportation	○ Pack the device in a closed suitable container and transport of the instruments to the processing location, in order to avoid unwanted movement and damage to instruments and environmental contamination. ○ It is recommended that these instruments are processed as soon as is reasonably practical following use. ○ Care must be taken to prevent unwanted contamination. Follow hospital/facility approved procedures using trained staff for transporting contaminated devices.
Preparation at processing facility	

Preparation for Decontamination	No particular requirements.
Preparing before cleaning	o Keep working ends open for cleaning. o Ensure staff who will be processing the devices are trained in handling the devices due to their delicate nature.
A. Manual Cleaning / Disinfection	
Cleaning: Manual	Equipment: Neutral pH Detergent (The ideal cleaning agent is nonabrasive, low-foaming and free-rinsing), CE marked soft bristled brush, pure running water method, CE marked instrument wipe, hospital approved tissue paper, hot air dryer, drying cabinet or air gun. 1- Rinse gross soil from instrument. 2- Remove any obvious debris accumulated during use from the instrument with a soft, non-metallic instrument cleaning brush plus mild detergent and sterile purified water solution. Using brush, apply detergent solution to all surfaces ensuring that hinged instruments are cleaned in both open and closed positions. o During manual cleaning, never use steel wool, wire brushes, scalpel blades or highly abrasive detergent or cleansers to remove soil from Surgical Instruments. These will damage the instruments' protective surface and lead to corrosion. Use a clean soft bristled brush to clean instruments with an accessible channel. 3- Rinse thoroughly with sterile, purified water until free of detergent residual and debris. Always follow best hospital practices / recommended procedure for cleaning and follow detergent manufacturer's instructions for use for the concentration, temperature and contact time.

	Inspect instruments for good cleaning result and repeat procedure if necessary. The best effects are achieved by cleaning and rinsing the instruments immediately after each application.
Disinfection: Manual	Instruments should be disinfected with recommended disinfectant solution (RKI– and VAH– listed disinfectant) and make sure there should be no contact between the instruments. Pay close attention to the correct dosages and exposure times according to disinfectant solution manufacturer's instructions for use for the correct dosage and contact time. It shall be guaranteed that the disinfectant reaches all the areas of the disinfected device (move parts in the disinfection bath and rinse any covered surfaces with a syringe - without a cannula - with the disinfecting agent). An overdose of the cleaning/disinfection solution is to be avoided. Then rinse instruments thoroughly with water.
Manual Drying	Thoroughly dry using low-linting sterile wipes before sterilization. Medical grade, sterile, oil free compressed air may be used to aid the drying process in order to avoid as much water residues in cavities as possible. • Ensure all instruments are thoroughly dried before being stored.
Automatic Cleaning / Disinfection process	
Automated Cleaning	Recommended Equipment: Suitable sized CE marked processing trays, CE marked and validated washer / disinfector machine to EN ISO 15883, CE marked endozyme or alkaline detergent, which is a liquid, low foaming, free rinsing and non-abrasive, biodegradable. Detergents should not contain artificial colouring agents; optical brighteners; perfumes; halides at an in-use concentration greater than 120 mg/L; fatty soaps, glycerine or lanolin; or leave a toxic residue.

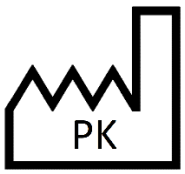
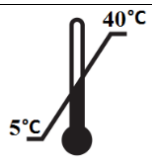
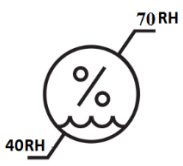
	1. Initial – rinse / Pre – wash: with cold filtered water: > 1 min., temp. < 40°C. 2. Drain 3. Repeated pre-rinse with cold water: 3 min. (temp. < 40°C) 4. Emptying 5. Detergent wash i.e. cleaning with 0.5% alkaline detergent: > 5 min. at 55°C 6. Drain 7. Neutralize with warm water: approx. 40°C, 3 min., neutralizing agent 8. Draining 9. Rinsing with deionized water: 3 min. temp. approx. 40°C 10. Emptying 11. Thermal disinfection: > 90° C for 5 min. 12. Drying with 15-25 min. at 90 – 110°C. The program of the WD must include an appropriate drying phase. When drying is achieved as part of a washer-disinfector cycle do not exceed 120°C. 13. Open the machine and allow any remaining water vapor to escape. Remove the product from the WD after the end of the program and cooling to room temperature. If necessary, blow out the product additionally with medical compressed air until it is completely dry.
Maintenance, inspection and testing	
Lubrication	• Apply a small quantity of surgical grade lubrication oil to hinges. Discard blunt or damaged instruments. • Always lubricate after cleaning with a proprietary water-soluble instrument lubricant.

	• Unless otherwise directed; instruments should be inspected, cleaned, rinsed and lubricated (if required) before being put into service.
Inspection and function testing	Hinged instruments: Check for smooth movement of hinge without excessive "play". Locking (ratchet) mechanisms should be checked for action. All instruments: Visually inspect for damage and wear. Cutting edges should be free of nicks and present a continuous edge. Check instruments with long slender features (particularly rotating instruments) for distortion. Where instruments form part of a larger assembly, check assembly with mating components Prior to use, visually inspect the instrument for bent, broken, cracked, worn, or missing component(s). Edges and surface should be free of nicks. Do not use the instrument if it is damaged or defective. Sharpen, service or replace instruments, if necessary. If instruments are still dirty, repeat cleaning and disinfection procedures. After manual cleaning / disinfection, check visible surfaces visually for residues.
Packaging:	Pack serviced and cleaned instruments for sterilization. A standard sterile barrier system may be used. Standard packaging of instruments for sterilization according to ISO 11607 and EN 868. Ensure that the pack is large enough to contain the instrument without stressing the seals. When used as intended, these instruments do not need an outer wrap or additional protection. In sets: Instruments may be loaded into dedicated instrument trays, or general-purpose sterilization trays. Ensure that cutting edges are protected. Wrap the trays using appropriate method.

	When sterilizing reusable instruments in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded. Always use protective caps for packaging / storage of clean instruments, where needed. • Pack instruments carefully with the heavier ones lying on a piece of cloth or towel at the bottom. • Never pack instruments with other heavier instruments without care. Remember always – heavy instruments on the bottom and light instruments on the top.
Sterilization	Steam sterilization (autoclave) of instruments: 3 pre-vacuum phases Heat up to a sterilization temperature of 134°C Moreover, it is recommended that sterilization temperatures should not exceed 280°F (137°C). Shortest hold time: 5 min Drying time: at least 20 min Note: Ensure steam quality in accordance with EN 285! Dry times may be highly variable due to the differences in packaging materials (e.g. non-woven wraps), environmental conditions, steam quality, device materials, total mass, sterilizer performance and varying cool down time. The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. Always follow recommended local government Health & Safety procedures and regulatory requirements for Sterilization of the instruments.

Storage	Store packaged device in dry / clean place and dust free environment at moderate conditions as per Hospital best practices to allow device to remain clean, dry, and ready for service.
Stability / Shelf life	5 years
Calibaration	The products do not require calibration.
Disposal	No special decomposition or disposal required for pertinent product(s) as they don't contain any toxic or hazardous material; when recycling medical devices please follow your local government Health & Safety procedures and regulatory requirements.
Warranty	This product is guaranteed to be free from defects in material or workmanship. The warranty is null and void should product damage occur as a result of mis-handling or mis-use. Modifications carried out on devise may also result in loss of guarantee / warranty rights. Care must be taken in the use handling and use of this product.
Return	In case of damage or faulty, please return to supplier with same packaging and event description.
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 manufacturer for repair along with the signed Decontamination Certificate, or disposed of following hospital approved procedures, e.g. Sharps Bin or Clinical Waste etc.
Serious Incident	Report to the manufacturer / authorized representative and the competent authority of the member state in which user and/or patient is established; about any serious incident that has occurred in relation to the device.
Complications	The complications related to the use of instruments are dependent on procedure adopted, no complications are associated with instruments.

Legends	
	**Ray Bright Industries** New Asghar Awan Attari, Marjan Road, Ugoki, Sialkot – Pakistan
	**CMC MEDICAL DEVICES & DRUGS, S.L** C/ Horacio Lengo n18 C. P 29006 Málaga-Spain Phone+34 951 214 054 Email: info@cmcmedicaldevices.com
Importer **SRN**	**MA Dental ApS** Produktionsvej 24 Glostrup 2600 Denmark DK-IM-000004132
	Medical Device
	Manufacturer
	EU Authorized Representative
	Catalogue Number
	Batch code
	

	
	Instrument are non-sterilized
	Manufacturing Date with country code (Pakistan)
	Use-by date
	Number of pieces contained
	Instrument is sterilizable in steam sterilization (autoclave)
	Fragile, handle with care
	Temperature limitations: Transport and store between 5°C to 40°C
	Humidity limitations: Transport and store between 40% RH to 70%RH

	Keep away from Sunlight
	Keep dry
	Caution, consult accompanying documents
	Latex free
	Lead free
	The device complies with EU MDR 2017/745 as amended by 2020/561
MADE IN PAKISTAN	