Work instruction for the reprocessing of re-sterilisable instruments according to DIN EN ISO 17664:2004

Manufacturer:
CARL MARTIN GmbH, Neuenkamper Str. 80-86, 42657 Solingen, Germany

Processing procedure:
manual pre-cleaning + automated in a washer-disinfector (WD)

Products:
Carl Martin medical devices of Class I – all reusable dental instruments supplied by Carl Martin with readily accessible hinges and screws as well as instruments which can be disassembled**.**

Limitations for reprocessing:
frequent reprocessing has little effect on these instruments. The end of the product's service life is normally determined by the wear and damage during use.

1.) General notes

1.1 Scope

This Work Instruction applies to all reusable instruments of Class I which

- are single-component
- have simple joints, if applicable, or
- contain simple moving parts
- if applicable, are composed of several changeable parts (e.g. handle and various attachments)

1.2 Use as intended

This Work Instruction cannot be a substitute for training, diligence and state-of-the-art technology at the user's. For this reason we take it for granted that the appropriate legal requirements, standards and guidelines are known.
Carl Martin instruments may only be used according to their intended purpose in the specialist medical fields and by appropriately trained and qualified specialist personnel. Inappropriate or misappropriate use can lead to premature wear of the instruments. The treating clinician or user is responsible for selecting the instruments for specific applications and their operational use, for appropriate training and information and adequate experience for handling the instruments.

1.3 General warnings

Carl Martin GmbH instruments are not supplied sterile. These must be cleaned, disinfected and sterilised prior to any use. The user is responsible for the sterility of the instruments. Please ensure that only validated processes are employed for cleaning, disinfection and sterilisation. Furthermore, the sterilisation equipment must be serviced and checked regularly. After receipt of the instruments, check their identity, completeness, integrity and function before processing the instruments. Prior to every use, the instruments are to be checked for fractures, cracks, deformation, damage and functionality. Areas such as blades, locks, tips and all moveable parts are to be checked in particular. Worn, corroded, deformed, porous or otherwise damaged instruments must

be disposed of. If an instrument was disassembled for processing, check for perfect functioning after assembly.

1.4 Warranty

The responsibility for the proper cleaning, disinfection and sterilisation of instruments lies with the user. It is essential to observe national regulations. Carl Martin GmbH excludes any warranty claims and shall not be liable for indirect damages or subsequent damages arising from:

- misappropriate use, application or handling
- improper processing and sterilisation
- improper use, application or handling
- improper repairs
- non-compliance with this Work Instruction
- Individual parts may not be replaced with parts from other manufacturers

1.5 Returns and repairs

Do not carry out repairs yourself. Servicing and repairs should only be carried out by specialist personnel. Non-compliance will result in the exclusion of any warranty claims whatsoever. Faulty products must have visibly passed through the entire reprocessing procedure before being returned for repairs. Contaminated instruments are excluded from return or repair. Third party products are also excluded from repairs as well as the grinding services we offer.

2. Information on processing

- Basic cleaning must be performed as a matter of principle prior to first use and sterilisation of the instruments
- Brand new instruments and instruments returned from repair are to be processed as used instruments prior to first use
- The protective shipping packaging, protective caps, etc. are not suitable for sterilisation
- Instruments which can be disassembled must be disassembled prior to processing
- Instruments with joints must be cleaned in an opened condition
- Avoid overfilling of instrument sieves and wash trays

3. Automated reprocessing

3.1 Pre-treatment

When using the instruments, these come into contact with blood, tissue residues and saline solution. The contained chlorides attack the surfaces of the instruments. It is therefore of benefit to process contaminated instruments quickly after use in order to avoid drying out of any contamination. Coarse contamination must be removed within a maximum period of 2 hours after use. No fixating detergents or hot water (>40 °C) may be used as this can negatively affect the cleaning result. Please only use a soft brush for the manual removal of coarse contamination. No metal brushes or steel wool may be used under any circumstances.

3.2 Transport

Safe storage in a closed container and transport of the instruments to the processing site to avoid damage to the instruments and environmental contamination.

3.3 Pre-cleaning

The instruments must be placed in cold water for at least 5 minutes and cleaned with a soft brush until any residues are no longer visible. Pressure-rinse cavities and threaded channels for at least 10 seconds with a water gun.

3.4 Automated cleaning in a washer-disinfector

Pre-rinse: 3 minutes
Cleaning: 10 minutes at 55 °C with 0.5% alkaline detergent (cleaning time corresponds to manufacturer's recommendations)

Intermediate rinse 1: 1 minute
Intermediate rinse 2: 1 minute with 0.2% neutraliser

Please observe the specific instructions of the cleaning system's manufacturer.

3.5 Disinfection

5 minutes at 93 °C, A0 value >3000

Automated thermal disinfection is to be performed under consideration of the national requirements relating to the A0 value.

3.6 Drying

According to the automated drying process of the washer-disinfector. If necessary, additional manual drying can be achieved using a lint-free cloth. Instruments with cavities can be dried with compressed sterile air.

3.7 Inspection and functional testing

All instruments must be checked for corrosion, damaged surfaces and contamination after the washing and disinfection process. Damaged instruments must be disposed of. Contaminated instruments must be cleaned and disinfected again. Cutting instruments (in particular scalers and curettes) must be re-sharpened if necessary. All residues (oil) must be removed after sharpening.

3.8 Care/maintenance

Instruments with moving parts (forceps, scissors, etc.) should be treated with a silicone-free cleanser (oil) prior to sterilisation if necessary. To this purpose we recommend our special oil-pen for instrument care – Art.-No. 990, which is approved according to USDA, FDA and DAB. The oil is suitable for all sterilisation methods. It is transparent, odour-free and toxicologically safe. This allows precise use for oiling and preservation. Use of the oil minimises friction between metals and thus represents a preventive measure against frictional corrosion.
Please do not use any silicone-containing care products. These can lead to stiffness and question the efficacy of steam sterilisation. Appropriate instructions for care can be requested from Carl Martin GmbH or downloaded from the download section on the Internet homepage.

3.9 Sterilisation

Ensure that only sterilisation methods/sterilisers are used with which a validated sterilisation process is possible.
Steam sterilisation at a temperature between 132 °C and 137 °C is recommended.
Please observe the specific instructions of the sterilisation device's manufacturer.

3.10 Packaging

Select packaging suitable for the instrument and the sterilisation method. The packaging must be large enough to avoid the seal being under tension.

3.11 Storage

In terms of optimal didactic preparation for various surgical interventions (osteotomy, PAR surgery, WSR, etc.), we recommend keeping the instruments in a suitable tray. These trays can be sealed and sterilised accordingly and can be stored for up to 6 months in accordance with the applicable legal guidelines. A dry and dust-free environment is a precondition here. Sterile products must be stored in a dry, clean and dust-free environment at temperatures between 5 °C and 40 °C.

4. Exceptions

Please note the instructions of sterilization for the following listing:

Due to technical reasons the instruments mentioned below are partly manufactured of chrome-plated parts. Therefore please do not put them in the washer-disinfector (WD) or in the ultrasonic bath and use only an appropriated disinfectant.

Ref. 1950 - cartridge syringe
Mouth mirrors
Ref. 1092 ½ - amalgam carrier
Ref. 485CH - mouth mirror handle
Ref. 623A CH - napkin holders

5. Information on the validation of processing

The following materials and machines were used for validation:

Thermal disinfector:	MIELE PG 8582
Detergents:	Dr. Weigert GmbH & Co. KG – neodisher MediClean forte
Neutraliser:	Dr. Weigert GmbH & Co. KG – neodisher Z

Validation of processing according to DIN 17664 by ValiTech GmbH & Co. KG (accredited according to DIN EN ISO/IEC 17025:2005 by the German Accreditation Body)
Validation confirms that the instruments can be processed standard-complaint with a standard washer-disinfector according to DIN EN ISO 15883.

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