Work instruction for the reprocessing

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

The instruments from Carl Martin GmbH are not delivered low in germs or sterile. These must be cleaned, disinfected and if need be 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. In addition, the sterilization and cleaning and disinfection devices must be regularly serviced and checked. 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.

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. Flush through cavities and threaded channels for at least 10 seconds with a syringe.

Please note that pre-cleaning is mandatory.

3.4 Automated cleaning in a washer-disinfector

Washer-disinfectors, type-tested in accordance with DIN EN ISO 15883-1, provide corresponding cleaning results even if the holding times for the process phases pre-rinse, intermediate rinse 1 and intermediate rinse 2 differ. If necessary, an intermediate rinsing step can be omitted and / or the use of a neutralizer can be dispensed with if it is ensured that no residues of alkaline solution remain on the instrument after disinfection.

Pre-rinse: 4 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

Washer-disinfectors, type-tested in accordance with DIN EN ISO 15883-1, provide a corresponding disinfection performance even with different holding times for disinfection. Depending on the washer-disinfector, the holding time A0 value is controlled and therefore variable and dependent on the heat absorption of the load.

5 minutes at 90°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 oil free medical air.

3.7 Inspection and functional testing

Disassembled instruments must now be reassembled.
All instruments must be checked for corrosion, damaged surfaces and contamination after the cleaning and disinfection process. Damaged instruments must be returned to the repair cycle or disposed of. Instruments with existing contamination must be returned to the reprocessing cycle. Cutting instruments (especially scalers and curettes) must be re-sharpened if necessary. After sharpening, all residues (oil) must be removed.

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 Packaging

Packaging according to DIN EN ISO 11607-1:2020 must be selected that is suitable for the instrument and the sterilization process. The packaging must be large enough that the seal is not under tension.

3.10 Sterilisation

Make sure that only sterilization processes using moist heat (steam sterilization) are used with which a validated sterilization process according to the specifications of DIN EN ISO 17665-1: 2006 is possible.
Processes in small steam sterilizers in accordance with DIN EN 13060 and Procedure in large sterilizers according to EN 285.

Ventilation: Fractionated fore-vacuum
Sterilization: 134 ° C for 5 minutes
Drying: min. 15 minutes

Please observe the specific instructions of the sterilisation device's manufacturer.

3.11 Storing

In terms of optimal didactic preparation for various surgical interventions (osteotomy, periodontal surgery, apical resection, 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. Information on the validation of processing

The following materials and machines were used for validation:

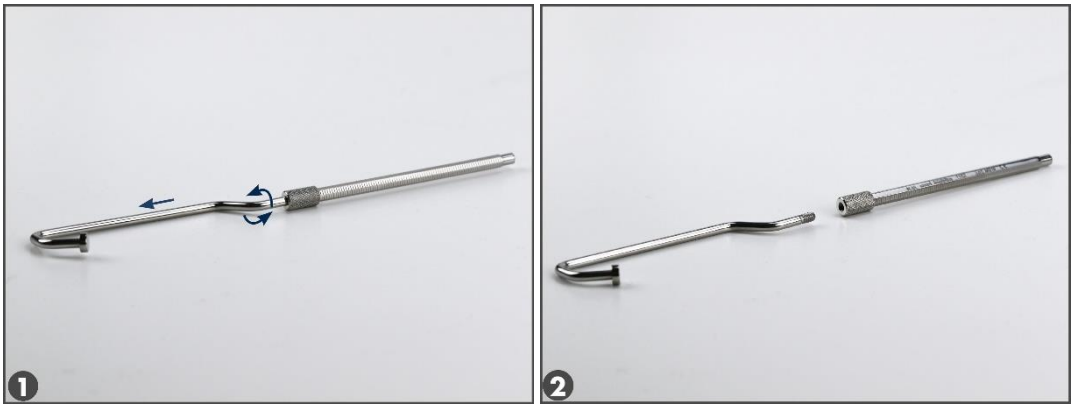
Thermal disinfector:	Melag Melatherm 10 DTA
Detergents:	Dr. Weigert GmbH & Co. KG – neodisher MediClean Dental
Neutraliser:	Dr. Weigert GmbH & Co. KG – neodisher Z Dental

Validation of the processing by solgiene oHG (in cooperation with biocheck Hygienetechnisches Labor GmbH - accredited according to DIN EN ISO / IEC 17025: 2005 by the German accreditation body).
The validation proves that the instruments can be processed in accordance with the standard using a standard, validated machine cleaning and disinfection process in accordance with DIN EN ISO 15883, a validated sterilization process in accordance with DIN EN ISO 17665-1: 2006 and the packaging in accordance with DIN EN ISO 11607-1: 2020.

Disassembling of the instruments

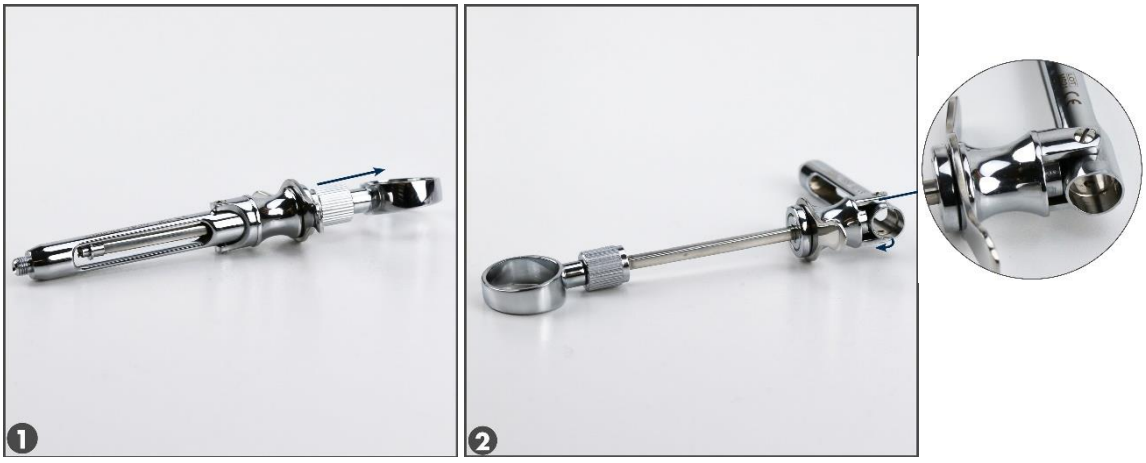
Crown remover (Example Ref. 1108)

Crown remover (Example Ref. 1162)



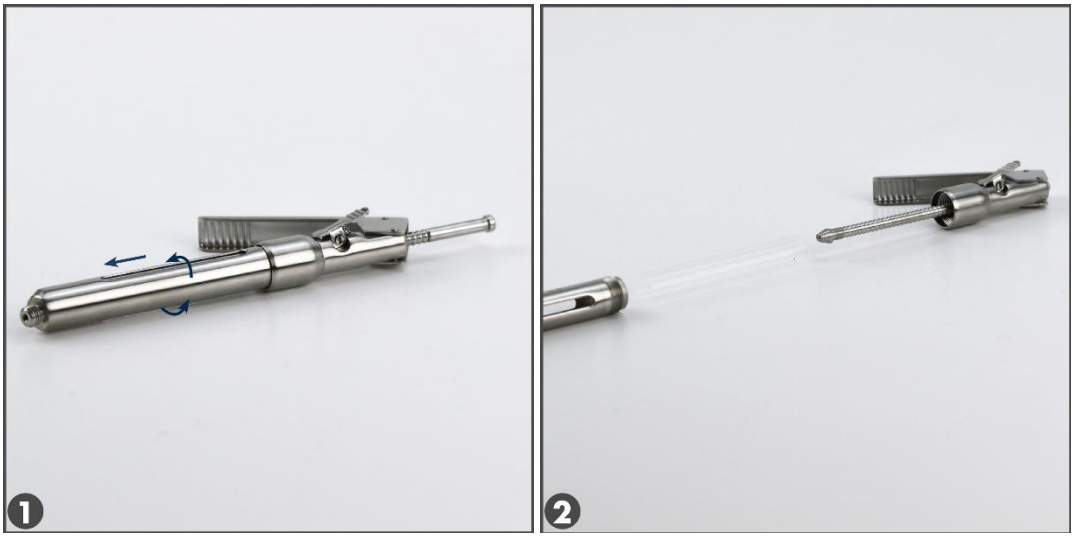
Syndesmotome (Example Ref. 1809)

Syringe (Example Ref. 1950)



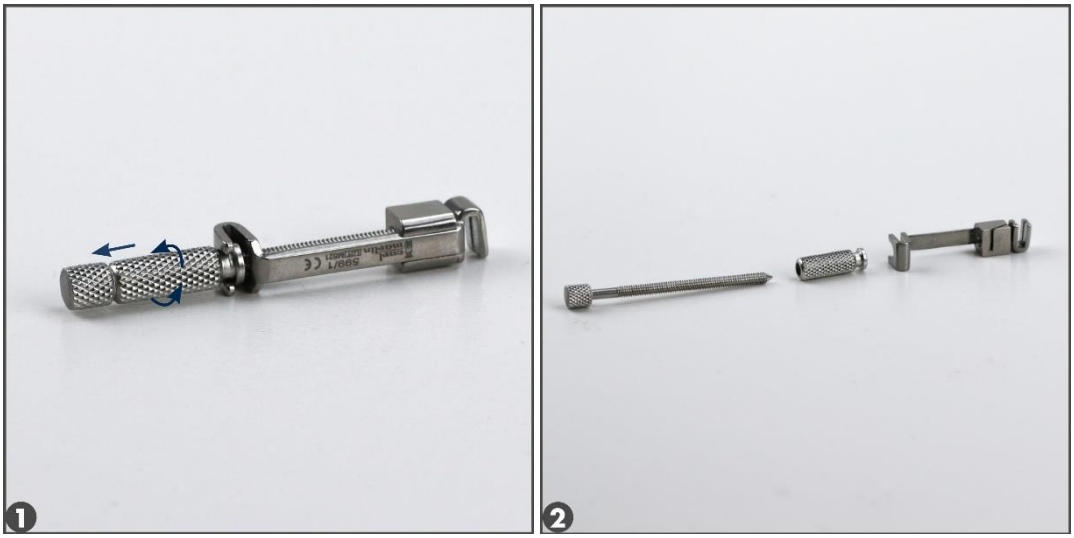
Syringe (Example Ref. 1953)

Syringe (Example Ref. 1955)

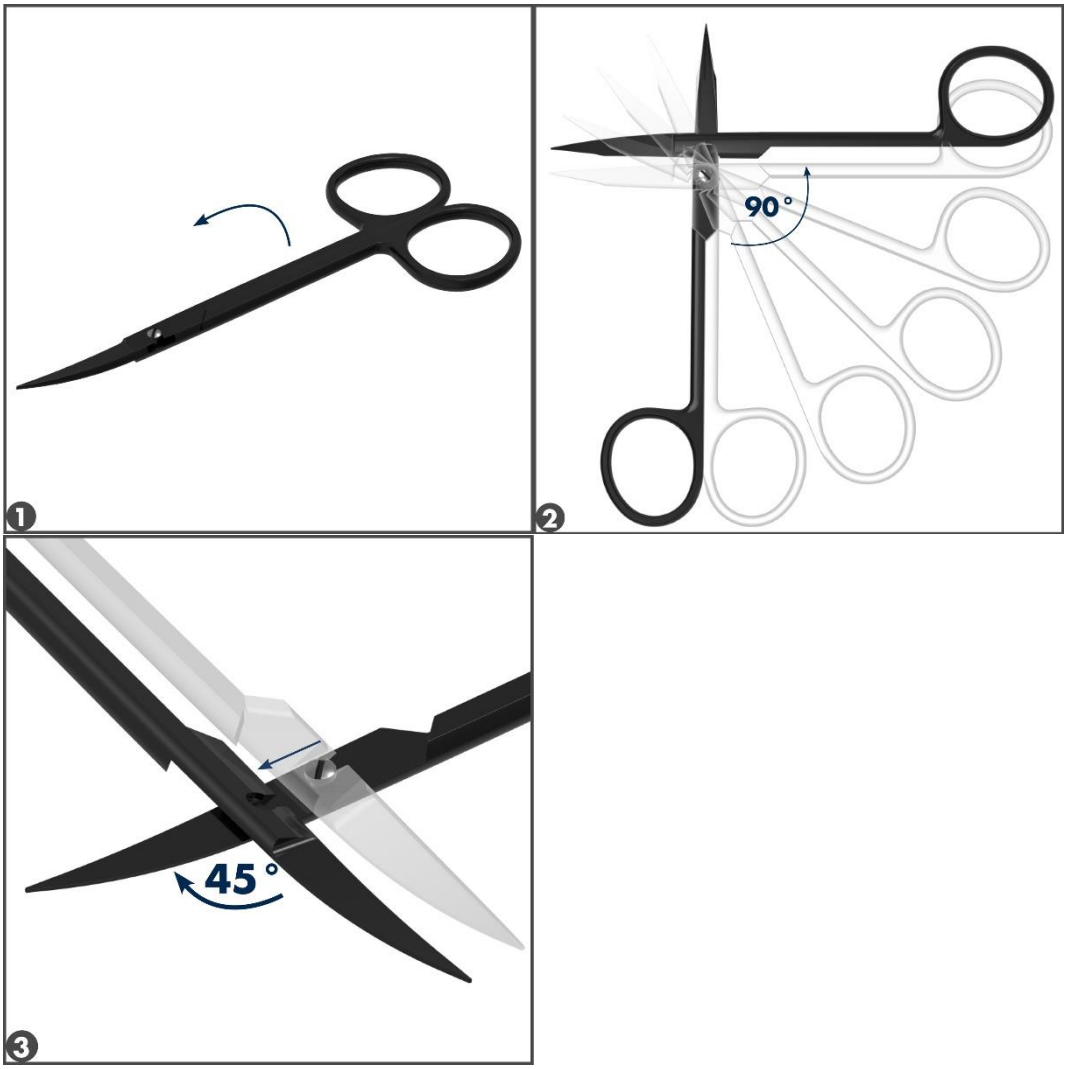


Syringe (Example Ref. 1956)

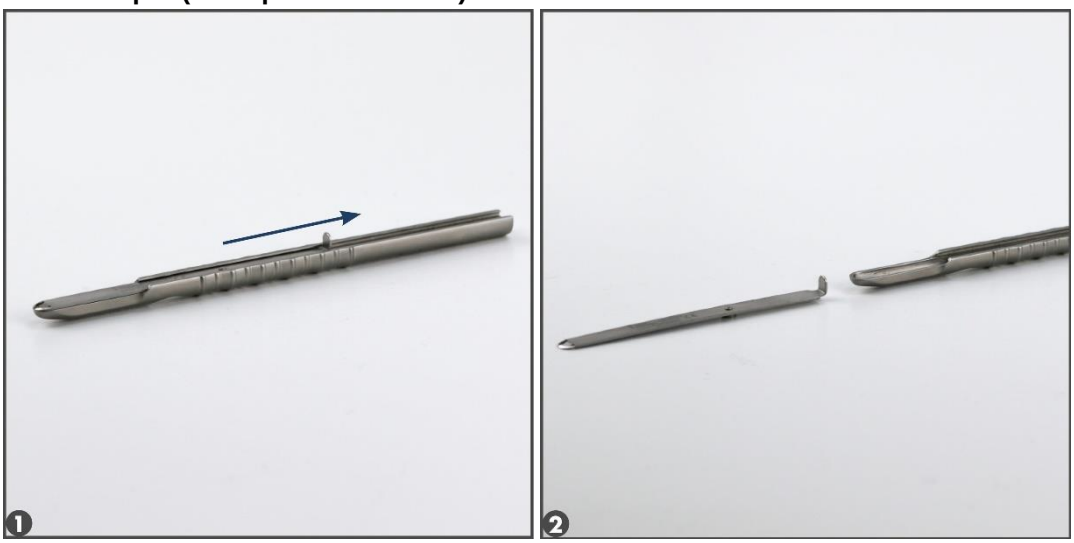
Matrix retainer (Example Ref. 599/1)



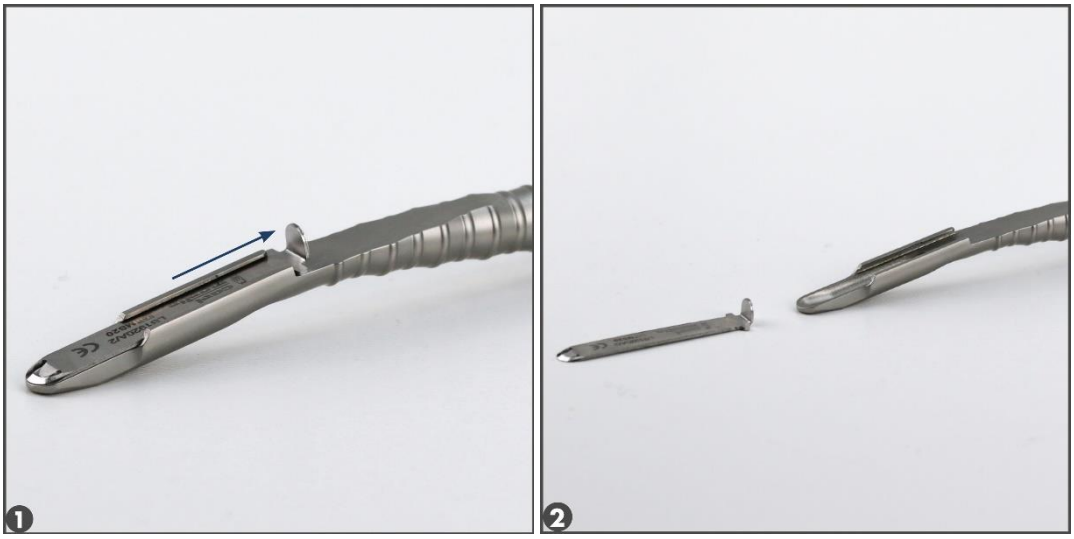
Scissors (Example Ref. 802/12-EC)



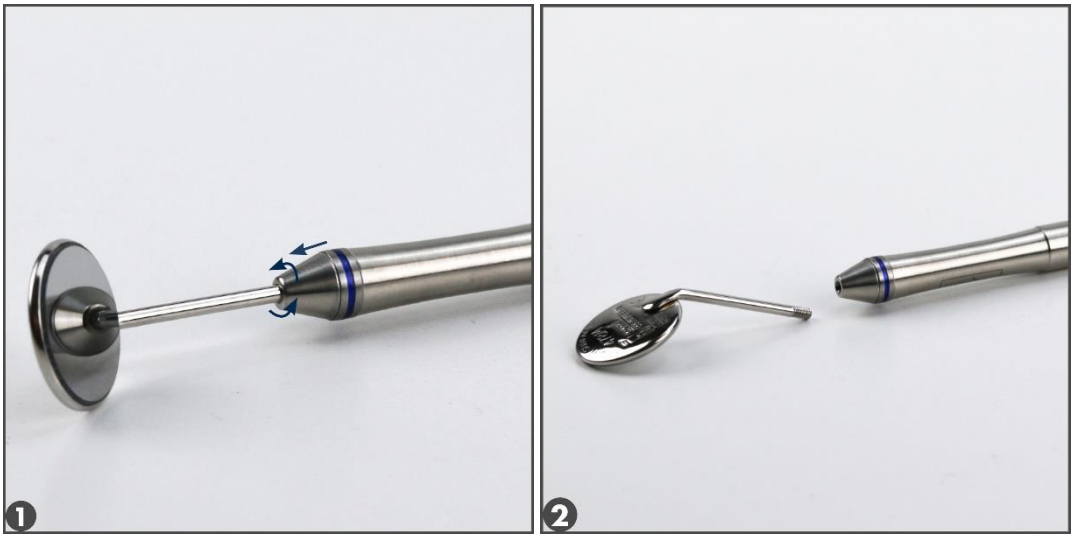
Bone scraper (Example Ref. LS1920)



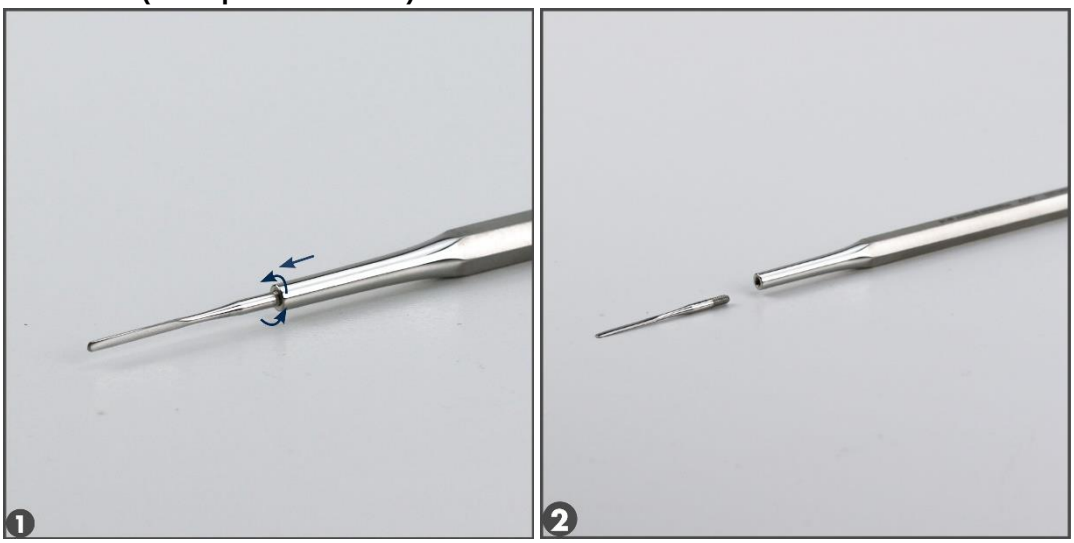
Bone scraper (Example Ref. LS1920A)



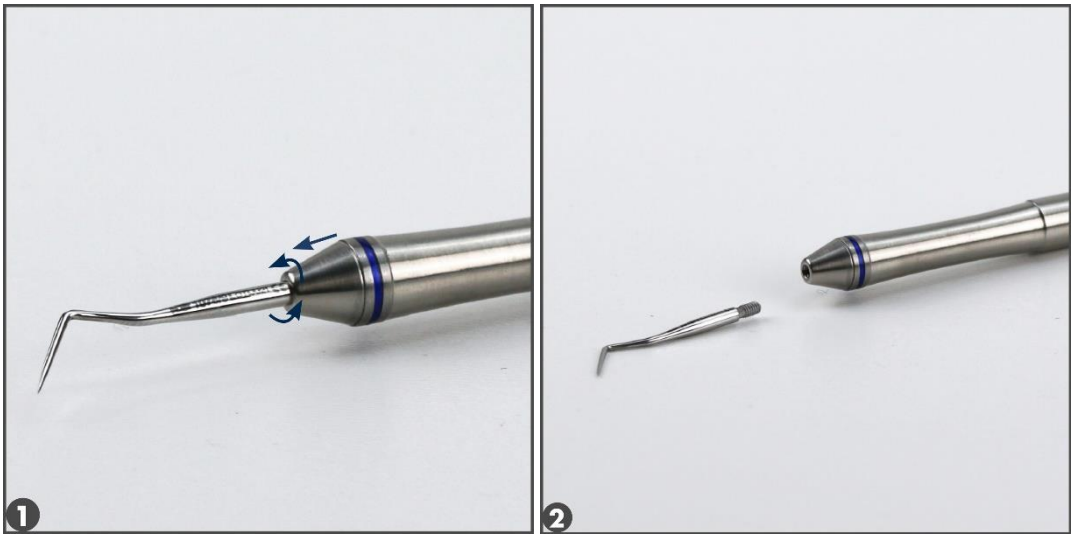
Mirror handle (Example Ref. LS482)



Periotome (Example Ref. 1806/1)



Tip for probe (Example Ref. 1078/9)



CE