The purpose of this document is to provide detailed instructions to guarantee the correct management of Asa Dental reusable instruments, a set of guidelines commonly referred to as reprocessing.

Reprocessing procedures have two main objectives: 1) patient and operator safety and 2) instrument integrity for effective reuse.

Reprocessing in fact involves chemical, thermal and mechanical stress necessary to guarantee that instruments can be safely reused but also capable of altering instruments effectiveness.

Reprocessing applies to all non-disposable medical instruments designed to be reused over time on many different patients. The involved operations are subject to international guidelines for sterilization and to manufacturer’s instructions for use regarding material, shape and application.

For this reason all Asa Dental instruments must be cleaned and sterilized before every use, including the first one.

The complete reprocessing procedure involves different steps including decontamination, cleaning, disinfection, sterilization and storage, all equally important for the final results.

Different factors contribute to reprocessing effectiveness including operator’s proficiency, equipment quality and maintenance, chemical products, physical environment and procedures compliance. Involved operators must guarantee that all the necessary reprocessing steps are correctly and safely implemented.

International or country regulations conflicting with this document have priority and Asa Dental recommends to follow them.

PRELIMINARY NOTES

Staff training
Everyone involved with reprocessing procedures must be trained and qualified beforehand. Training must include cleaning, disinfection, sterilization, and infection prevention & control procedures.

Safe area
Reprocessing protocol demands for a dedicated space separate from patient treatment areas and from non medical staff.

Size of the area depends on the type of dental practice, but its characteristics are general:
• Large enough to run operations
• Separation between operations and storage
• Dedicated hand-washing area
• Surfaces, walls and floors easy to clean and disinfect
• Room controls (i.e. temperature, humidity, ventilation, etc)
• Limited personnel access

Equipment and chemicals
The practice should be equipped with instruments and chemicals necessary for cleaning, disinfection and sterilization of instruments, all compliant with international regulations and well maintained in accordance with manufacturer’s instructions.

RECOMMENDATIONS

For correct instrument handling
• All brand new hinged instruments (scissors, hemostats, pliers, extracting forceps, etc.) must be articulated at least 20 times immediately after opening the package. Extra lubricating oil must then be removed
• Following the previous operation, if applicable, proceed with instrument sterilization before use
• Used/contaminated instruments must be moved from use area to reprocessing area with appropriate containers in order to avoid any contacts with the operator and with the environment
• We strongly recommend to always apply a preliminary disinfection/decontamination to prevent operator and environment contamination that may happen during cleaning, especially when washing instruments under running water
• We strongly recommend a very accurate rinsing after any steps where the instruments has been exposed to chemical agents for cleaning and disinfecting purposes in order to remove residuals

WORKFLOW

1 DECONTAMINATION
2 CLEANING
   2A Automatic cleaning
       Drying
   2B Manual cleaning | Ultrasonic cleaning
       Disinfection
       Drying
3 INSPECTION
   Visual check
   Maintenance
4 PACKAGING
   Packaging
   Traceability
5 STERILIZATION
6 STORAGE

1 DECONTAMINATION

Equipment
Purified or sterile water: max 100 CFU/ml e 0.5 EU/ml, as residues of hard water or water with higher contamination (microorganism and endotoxins) can cause staining of the instruments or prevent effective decontamination.
Disinfectant intended for manual disinfection, applied in accordance to the manufacturer’s guidelines concerning time and concentrations.

Procedure
1. If it applies, disassemble the instrument (i.e. mirrors)
2. Immediately after proceed removing gross organic and material residuals using soft disposable wipes and immerse instruments in a decontamination bath with a cleaning/decontaminating agent to avoid solidification of composites, cements and glass ionomers
3. Instruments should be immersed in the decontamination bath using a sterilization cassette, depending on availability and type of instruments

Notes
We strongly recommend to carefully place the instruments to prevent 1) injuries to operators and/or damages to sharp instruments that may affect their effective use.
The guidelines provided by the cleaning/decontaminating agent manufacturer regarding concentrations and time should be strictly followed.
2A  CLEANING | Automatic cleaning + Drying  

**Equipment**  
Washer-disinfector  
One or more cassettes of appropriate size.  

Cleaning agent intended for use in a washer-disinfector; selected depending on the material of the instrument, and used following the manufacturer’s guidelines concerning time and concentrations; avoid cleaning agents with high pH (>8.5) in order to prevent damages to polymers and aluminum instruments. Refer to SPECIAL PROCEDURES section of this document to verify compatibility with some Asa Dental instruments with specific requirements.

**Procedure**  
1. Place the instruments in the cassette avoiding contact to avoid damages during the procedure and ensure proper washing. Arrange instruments so that those with cannulations are not horizontal and the those with blind holes are downwards to assist cleaning and drainage
2. Load the washer
3. Connect cannulations to the rinsing ports
4. Activate an approved thermal disinfection program (time, temperature, rinsing steps)
5. Wait for the program to finish and unload the device
6. Visually inspect the instruments immediately after the cleaning for residuals and, if necessary, repeat the program
7. Dry using filtered, compressed air device or clean, lint-free wipes
8. In case additional drying is required proceed arranging instrument on a clean surface or heat in oven (max temperature 110°C)

**Notes**  
- Ensure that the washer-disinfector is valid for the purpose (CE mark, FDA approval in accordance to ISO15883), properly installed and regularly maintained and tested
- We do not recommend chemical disinfection programs as they may result in residuals that interfere with the sterilization phase

2B  CLEANING | Manual cleaning  

**Equipment**  
Purified or sterile water: max 100 CFU/ml e 0.5 EU/ml, and the use of a syringe in case of instruments with hollow parts and cannulations to ensure that the cleaning solution reaches all parts.

Cleaning agents: depending on the material of the instrument, follow the manufacturer’s guidelines concerning time and concentrations; avoid cleaning agents with high pH (>8.5). Refer to SPECIAL PROCEDURES section of this document to verify compatibility with some Asa Dental instruments with specific requirements. Bath large enough to allow complete immersion of instruments.

**Procedure**  
1. Prepare the bath and completely immerse the instrument and all its parts
2. In case of hollow parts and cannulations use a syringe (up to 50ml) and tilt the instrument to make sure that the cleaning agent reaches all its parts especially blind holes, hinges and joints
3. Keep the instrument in the solution for at least the time specified by the detergent manufacturer’s instructions
4. Rinse the instrument at least 1 minute in running water and ensure that all traces of detergent solution are removed
5. Inspect instrument, especially in case of blind holes, cavities and cannulations and, if necessary, repeat the cleaning procedure from the beginning

**Notes**  
WARNING: automatic cleaning is always to be preferred to manual cleaning, even in case of manual cleaning with an ultrasonic device. Manual cleaning should be used only when the instrument properties are not compatible with automatic cleaning. Never use metal brushes or other tools that may damage the instrument.

**CLEANING | Ultrasonic cleaning**

**Equipment**  
Cleaning agent: choose the detergent depending on the instrument material and follow manufacturer’s guidelines concerning time and concentration of the cleaning agent.

Ultrasonic bath: must be large enough to allow complete immersion of the instrument and work in a 25 - 50 kHz frequency range, without exceeding temperatures stated by the detergent manufacturer’s instructions.

**Procedure**  
1. Completely immerse the instrument and all its parts
2. In case of hollow parts and cannulations use a syringe (up to 50ml) and tilt the instrument to make sure that the cleaning agent reaches all its parts especially blind holes, hinges and joints
3. Activate the bath for minimum of 15 minutes or the time recommended by the detergent’s manufacturer
4. Rinse the instrument at least 1 minute in running water and ensure that all traces of detergent solution are removed
5. Inspect instrument, especially in case of blind holes, cavities and cannulations and, if necessary, repeat the cleaning procedure from the beginning

**Notes**  
WARNING: automatic cleaning is always to be preferred to manual cleaning, even in case of manual cleaning with an ultrasonic device. Manual cleaning should be used only when the instrument properties are not compatible with automatic cleaning. Never use metal brushes or other tools that may damage the instrument.

3  INSPECTION | Visual check  

**Equipment**  
Magnifying tool and proper lighting conditions.

**Procedure**  
1. Visually inspect all the instruments
2. Carefully check cavities, cannulations, blind holes, hinges, joints and textured surfaces (i.e. extracting forceps handles)
3. Repeat the cleaning procedure in case of impurities, chemical residuals or other materials discovered on the instrument
4. In case of corrosion, alteration, wear or any other modifications that may compromise or limit instrument functionality, it is mandatory to proceed with maintenance procedures

**Notes**  
All instruments should be inspected before proceeding with sterilization.

**INSPECTION | Maintenance**

**Equipment**  
Magnifying tool and proper lighting conditions.

Anticorrosion oil and lubricating oil for stainless steel and for aluminum to protect joints and hinges.

Sharpening accessories for blades and tips.

**Procedure**  
1. Visually inspect instruments to identify parts showing evidence of corrosion, wear, alteration or other defects that may alter instrument functionality
2. In case of corrosion apply a small quantity of anticorrosion oil
3. In case of hinged instruments like pliers, scissors and forceps, apply a small quantity of lubricating oil
4. In case of damaged cutting edges, proceed with sharpening
5. Always check the effectiveness of the maintenance intervention and if necessary (negative or non acceptable results) proceed with instrument scrapping and replacement
6. After any of the above action, repeat cleaning/disinfecting procedures to remove residuals of maintenance

**Notes**  
Maintenance operations are strongly recommended as they have serious consequences on operators and patient safety.
STERILIZATION Equipment
Asa Dental suggests class B steam sterilizer: dimensions and features compatible with dental studio requirements, equipped with vacuum pump to remove air from the chamber and ensure sterilization of porous materials, wrapped items and instruments with cavities. The device must be compliant with the following regulations: EN285, EN13060, EN ISO17665 e ANSI/AAMI ST79. The same regulations describe also maintenance procedures and sterilization protocols regarding time and temperature. Check SPECIAL PROCEDURES section of this document for more information about care instruction of some Asa Dental products.

Procedure
1. Place wrapped cassettes in the sterilizer
2. Select the sterilization program according to the protocols described below making sure to select the pre-vacuum option and wait for entire program duration:
   (1) Period for which the load and entire chamber is maintained at the sterilization temperature
   (2) Period during which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. The drying time varies due to load configuration, wrapping method, and material

Notes
Do not use flash or chemical sterilization with substances like formaldehyde and ethyleneoxide. Longer exposure time and higher temperature can be used with a potentially negative impact on instrument lifetime. We strongly recommend the use of purified or deionized water. Depending on construction materials, sterilization temperatures can vary: i.e. Magic Color instruments should not be exposed to temperatures above 130°C/260°F. In order to ensure the correct working conditions for the sterilizers we recommend to refer to manufacturer’s instruction manual. Follow above mentioned regulation guidelines for periodic care and maintenance.

STORAGE Equipment
After sterilization, reusable instruments should be stored in the sterilization wrap or rigid container in a dry and dust-free place. The shelf life is dependent on the sterile barrier employed, storage manner, environmental conditions, and handling.

Procedure
1. Store sterilized material in the dedicated storage area
2. Ensure the necessary separation between sterile and non-sterile packages
3. Make sure that storage area meets humidity, temperature and hygienic storage conditions
4. Follow the protocol that implements a sterile barrier between the storage area and other areas
5. Always check labels, indicators and packaging integrity before using stored instruments

Notes
Asa Dental recommends storage conditions in accordance with international guidelines: EP (European Pharmacopoeia), USP (United States Pharmacopoeia) and JP (Japanese Pharmacopoeia). Sterile conditions are guaranteed only when the certified medical wrapping paper is used and the packaging is preserved unopened and undamaged.
SPECIAL PROCEDURES

Aluminum instruments

Such as:
• Matrix retainers
• Aluminum trays
• Aluminum impression trays
• Aluminum handles

WARNING: use only automatic or manual cleaning, avoiding ultrasound cleaning. Use chemical agents following manufacturer’s instructions. Chemical interaction between aluminum and stainless steel instruments processed concurrently should be carefully monitored.

Nylon instruments

Such as:
• Magic Color handles

WARNING: for these instruments sterilization temperature should not exceed 130°C/260°F, and sterilization cycles should be as short as possible.

Poly carbonate instruments

Such as:
• Parts of some aspirators
• Some impression trays
• Color tabs (impression trays)
• Some accessories for orthodontics

WARNING: polycarbonate is a material extremely versatile for dental care applications. Anyway its mechanical structure suffers from temperatures above 130°C (266°F), hence re-processing procedure should not exceed this threshold. The same applies to chemical agents that must be carefully selected for compatibility to prevent any damages.

Special materials

Some instruments have parts or coating made of special materials, such as PTFE, Teflon, Xlayer. These materials enhance performances and resistances against mechanical stress but they require a special care. The following products belong to this category:
• Mallets (parts)
• Clamps (Vision)

INTERNATIONAL REGULATION AND REFERENCES

AAMI TIR 12: Design, testing and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for medical device manufacturers
AAMI TIR 30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
AAMI TIR 55: Human factors engineering for processing medical devices
ANSI/AAMI ST 77: Containment devices for reusable medical device sterilization
ANSI/AAMI ST 79: Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities
EN 285: Sterilization - Steam sterilizers - Large sterilizers
EN 13060: Small steam sterilizers
ISO 1138-3: Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
ISO 1140-1: Sterilization of healthcare products - Chemical indicators - Part 1: General requirements
ISO 1607-1: Packaging for terminally sterilized medical devices
Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 15883-1: Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
ISO 17664: Sterilization of re-usable instruments - Information to be provided by the manufacturer for the processing of re-usable instruments
ISO 17665-1: Sterilization of healthcare products, moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 17665-2: Sterilization of health care products, moist heat - Part 2: Guidance on the application of ISO 17665-1
United States Pharmacopoeia (USP)
European Pharmacopoeia (EP)
Japanese Pharmacopoeia (JP)
HTM-01-01: Decontamination of surgical instruments