

## Instructions for Sterilization

Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user.

### 1. Fundamental points

All instruments are to be cleaned and sterilized prior to each use. In addition, cleaning and sterilization is also required for the first use of non-sterile instruments after removal from the protective packaging. The user is responsible for the sterility of the instruments. Therefore, please ensure that only validated procedures are used for cleaning and sterilization. The sterilization equipment must also be maintained and checked regularly, as well as the validated parameters applied to each cleaning and sterilization cycle.

Additionally, consider the legal provisions valid for your country as well as to the hygienic instructions of the doctor's practice or hospital.

### 2. Instrument Reprocessing Steps

#### 2.1 Cleaning

If possible, an automatic procedure instrument washer unit should be used for cleaning of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automatic procedure is not available. In this case, the significantly lower efficiency of a manual procedure must be considered.

The pre-treatment step is to be performed in both cases.

##### a) Pre-treatment

Before processing the instruments single or in a tray or cassette system, remove coarse impurities on the instruments immediately after application (within a maximum of 2 h). Instruments with impurities have to be pre-treated within two hours from the application.

##### b) Automatic Cleaning in an automated washer unit

Consider the following items, when using an automated washer unit:

- fundamentally approved efficiency of the unit
- possibility for an approved program for thermal disinfection (A 0 >3000 or in case of older devices at least 10 min at 93°C and must follow equipment manufacturers guidelines). In the case of chemical disinfection there is a danger of remnants of the disinfectant on instruments.
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post rinse only with low contaminated and deionized water (max. 10 germs/ml, max. 0.25 endotoxin units/ml) for example aqua purificata (highly purified water acc. Pharmacopeia).
- only use filtered air for drying
- regular maintenance and inspection/calibration of the unit.

For the selection of detergents to be used with the automated washer unit, consider the following items:

- fundamental suitability for cleaning of instruments
- compatibility of the detergents with the instruments

Consider the instructions of the detergent manufacturers regarding concentration and soaking time.

#### Procedure:

1. Place the instruments in a cassette or any other tray system suitable for the instrument 3. Start the program.
2. Remove the instruments from the automated washer unit after end of the program.
5. Inspect and package the instruments immediately after removal.

##### c) General information

Consider the following items during selection of the cleaning detergents:

- fundamental suitability for the cleaning of the instruments
- compatibility of the detergents used with the instruments
- Powder based cleaners have to be dissolved completely in water before immersing the instruments into the solution.
- Observe the instructions of the manufacturer with respect to the concentration of the cleaning solution, the time of exposure and the temperature.

Consider the instructions of the detergent manufacturers regarding concentration and soaking time. Please use only freshly prepared solutions as well as only low contaminated and deionized water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), i.e. aqua purificata (highly purified water acc. Pharmacopeia), and filtered air for drying, respectively.

##### d) Manual Cleaning

1. make sure that the instruments are sufficiently immersed. Time of immersion has to be sufficient.
2. Remove the instruments from the cleaning solution and post rinse them intensively with low contaminated and deionized water (aqua purificata).
3. Inspect the instruments for proper cleaning.

##### e) Ultrasonic Cleaning

1. Soak the instruments for the recommended soaking time in the cleaning solution, and make sure that the instruments are sufficiently immersed. Use the processing time recommended by the manufacturer of the detergent and/or the cassette system.

2. If you are using the IMS Cassette System, the ultrasonic cleaning time has to be at least 16 minutes, unless a longer exposure time is required by the manufacturer of the detergent. Do not overload the Ultrasonic Cleaning unit. Use "Sweep modus" if available.

3. Remove the instruments from the cleaning solution and post rinse them intensively with low contaminated and deionized water (i.e. aquapurificata)

### 2.2 Inspection

Inspect all instruments after the cleaning and rinsing step for corrosion, damaged surfaces, and impurities. Do not further use damaged instruments

### 2.3 Packaging

We recommend the use of a cassette system or suitable sterilization containers, if the following requirements are fulfilled:

- FDA or CE approved (depends on the country)
- suitable for steam sterilization (temperature resistance up to at least 141 °C (286 °F), sufficient steam permeability)
- sufficient protection of the instruments and the sterilization packaging against mechanical damage
- regular maintenance according to the manufacturer's instructions (Sterilization Containers: limitations also see 4.0 Special Procedures section)

### 2.4 Sterilization

Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user. We recommend a 30 minute dry time; however defer to the manufacturer's instructions for the equipment used.

#### a) Steam sterilization (Device according to the standard EN 13060, class B)

- fractionated vacuum or gravity procedure ( 4 times)
- Sufficient product drying must be ensured after sterilization and before handling.
- Steam sterilizer according to or AAMI/ANSI ST55 and AAMI/ANSI ST8
- Validated according to or ANSI/AAMI ST 79 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ)
- For a specific sterilizer, consult only that manufacturer's recommendations.

Exposure time at 121°C (250°F) Drying times: Wrapped instruments = 30 minutes

Exposure time at 134°C (270°F) Drying times: Wrapped instruments = 4 - 30 minutes

#### b) Inspection and Maintenance Recommendations for Steam Sterilizers:

- The manufacturers' instructions with respect to routine inspection and the regular maintenance of the Sterilizer must be observed.
- The sterilizer must be cleaned on a regular basis.
- Only low contaminated and deionized water (i.e. aqua purificata) should be used.
- The sterilized items have to be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

#### c) Restrictions:

- The flash sterilization procedure must not be used.
- Do not use radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization, or plasma sterilization.
- Application of dry heat sterilization is the responsibility of the user.

### 2.5 Storage

Please store the instruments after sterilization in a dry and dust free place in the clean section of the instrument processing area. Sterilization can only be maintained, if the instruments remain packaged or wrapped - impermeable to micro-organisms. The status of the sterilization has to be clearly indicated on the wrapped packages or the containers. For safety reasons, keep sterile and non-sterile instruments strictly apart.

### 2.6 Material resistance

Detergents or disinfectants containing the following substances must not be used:

- strong alkalines (> pH 9), strong acids (< pH 4), phenols or iodophors, - interhalogenic agents/halogenic hydrocarbons/ iodophors, strong oxidizing agents/peroxides, organic solvents

Do not clean any instruments, sterilization trays or sterilization containers using metal brushes or steel wool.

Do not expose any instruments, cassettes, trays or sterilization containers to temperatures higher than 141 °C (286 °F).

Exposure to higher temperatures is the responsibility of the user.

Water quality may influence the result of the cleaning and disinfection of the instruments. Corrosion could be caused by high contents of chloride or other minerals in the tap water. If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in your area. With the use of completely deionized or distilled water most water quality problems can be avoided beforehand.

### 2.7 Reusability

The instruments can be reused. The life time of instruments depends on the frequency of use, the care of the user and proper reprocessing methods. The user is responsible for inspecting instruments prior to each use, and for the use of damaged and dirty instruments (no liability in case of disregard).