Instructions For Use

maxill Hand Instruments and Accessories

SPAULDING CLASSIFICATION: CRITICAL Equipment/Device. Equipment/device that enters sterile tissues, including the vascular system. Cleaning followed by sterilization.

OVERVIEW: All instruments must be cleaned and sterilized prior to each use, including the first use of non-sterile instruments after removal from the protective packaging. Effective cleaning is an indispensable requirement for proper instrument sterilization.

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.

MATERIALS: Medical grade silicone, Stainless steel.

STEPS FOR INSTRUMENT REPROCESSING

CLEANING

Basics:
If possible, an automatic procedure in dental instrument washer or ultrasonic bath should be used for cleaning of the instruments.

A manual procedure, such as hand scrubbing, should only be used is an automatic procedure is not available, if debris is remaining after automated cleaning, or if such a method is not compatible with specific materials. 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.

All assembled instruments must be disassembled before reprocessing.

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

Use an enzymatic cleaner or a precleaning product. When using an enzymatic cleaner, pre-soak for 3-5 minutes at 89.6°F (32°C). For other cleaning agents and disinfectants the instructions of the manufacturer must be observed.
For manual removal of coarse impurities, use only a soft brush or a long handled soft brush. Never use metal brushes or steel wool.

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Automatic Washer Disinfector:

Items to consider when using an automated washer disinfector:

- fundamentally approved efficiency of the washer disinfector
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post rinse only with low contaminated deionized water (max. 10 germs/ml, max. 0.25 endotoxin units/ml) for example purified water
- only use filtered air for drying
- regular maintenance and inspection/calibration of the washer disinfector

Items to consider for the selection of detergents to be used with the automated washer disinfector:

- fundamental suitability for cleaning of instruments
- additional application
- if instruments are not compatible with the automated washer, please follow the recommended instructions for the manual cleaning
- compatibility of the detergents with the instruments

The use of a cassette system is recommended. Consider the instructions of the detergent manufacturers regarding concentration and soaking time.

PROCEDURE:

1. Completely disassemble instruments if applicable
2. Place the disassembled instrument in a cassette or any other tray system suitable for the instrument, and place it in the automated washer disinfector)no contact between the instruments). If applicable, connect the instruments by suitable rinsing adaptor to the rinsing port of the automated washer disinfector.
3. Start the cycle
4. Remove the instruments from the automated washer disinfector after end of the cycle.
5. Inspect and package the instruments immediately after removal. If necessary, allow post drying step in a clean place.

MANUAL AND ULTRASONIC CLEANING

GENERAL INFORMATION

Consider the following items during selection of the cleaning detergents:

- fundamental suitability for the cleaning of dental 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., purified water, and filtered air for drying, respectively.

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MANUAL CLEANING PROCEDURE:

1. Completely disassemble the instruments, if applicable
2. Soak the disassembled instruments for the recommended soaking time in the cleaning solution, and make sure that the instruments are sufficiently immersed.
3. Remove the instruments from the cleaning solution and post rinse them extensively with low contaminated and deionized water (i.e., purified water).
4. Inspect the instruments for proper cleaning.
5. Thoroughly dry prior to packaging for sterilization.

ULTRASONIC CLEANING PROCEDURE:

1. Completely disassemble the instruments if applicable. Soak the disassembled 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. Note: There should not be any contact between instruments.
2. If you are using a cassette system, the ultrasonic cleaning time has to be a minimum of **16 minutes,** unless a longer exposure time is required by the manufacturer of the detergent. Do not overload the ultrasonic cleaning unit. Use “sweep mode” if available.
3. Remove the instruments from the cleaning solution and post rinse them intensively with a low contaminated and deionized water (i.e., purified water) for best results.
4. Inspect the instruments for proper cleaning
5. Thoroughly dry prior to packaging for sterilization.

INSPECTION

Inspect all instruments after the cleaning and rinsing step for corrosion, damaged surfaces, and impurities. Do not further use damaged instruments. If instruments are visibly soiled, clean again. Sharpen instruments if necessary Completely remove any residues from the sharpening process, such as metal residue or sharpening oil. In case sharpening is done, remember to repeat the cleaning and sterilization process.

MAINTENANCE

Light corrosion on the surface can be removed with low-viscosity, penetrating oil. If the corrosion cannot be completely eliminated, the instruments should be removed from use. Otherwise, such corrosion could damage other instruments. After treating an instrument with penetrating oil, the instrument must be cleaned and sterilized once more.

Hinged instruments should be lubricated with a lubricant suitable for steam sterilization.

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PACKAGING:

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

- FDA/Health Canada approved
- suitable for steam sterilization (temperature resistant 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 manufacturers instructions
- make sure the devices are completely dry before packaging

STERILIZATION

Please use only the recommended sterilization procedures listed below. Other sterilization methods are the responsibility of the user. maxill recommends a minimum 30-minute dry time; however, defer to the manufacturers instructions for the equipment used.

STEAM STERILIZATION

- fractionated vacuum or gravity procedure
- sufficient product drying must be ensured after sterilization and before handling
- steam sterilizer according to or AAME/ANSI ST55 and AAMI/ANSI ST8
- validated according to or ANSI/AAMI ST 79 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))

Minimum cycle times for GRAVITY-DISPLACEMENT steam sterilization cycles

ITEM	Exposure time at 250ºF (121ºC)	Drying Time
Wrapped Instruments	30 Minutes	Minimum 30 Minutes

Minimum cycle times for DYNAMIC-AIR-REMOVAL steam sterilization cycles

ITEM	Exposure time at 270ºF (132ºC)	Drying Time
Wrapped Instruments	5 Minutes	Minimum 30 Minutes

NOTE: These tables represent the variation in sterilizer manufacturers recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturers recommendations.

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INSPECTION AND MAINTENANCE RECOMMENDATIONS FOR STEAM STERILIZER

- The manufacturer's instructions regarding routine inspection and the regular maintenance of the sterilizer must be observed.
- The sterilizer must be cleaned regularly
- Only low-contaminated and deionized water (i.e., purified water) should be used.
- The sterilized items must be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

RESTRICTIONS

- Immediate sterilization (flash sterilization) should **NOT** be a facility's primary source of sterilization. When used follow manufacturer's instructions for use.
- Do not use radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization, or plasma sterilization
- The application of dry heat sterilization is the responsibility of the user. For some products, the dry heat sterilization procedure has been explicitly excluded.

STORAGE

Please store the instruments after sterilization in a dry and dust-free place in the clean section of the instrument processing area or instrument storage area. Sterilization can only be maintained if the instrument remains packaged or wrapped - impermeable to microorganisms - following validated standards. 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.

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.

Water quality may influence the result of the cleaning 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 the area. With the use of completely deionized or distilled water, most water quality problems can be avoided beforehand.

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REUSABILITY

The instruments can be reused, unless indicated otherwise. The lifetime of instruments depends on the frequency of use, the care of the use, 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). Sharpen instruments if necessary. Completely remove any residues from the sharpening process, such as metal residue or sharpening oil. In case sharpening is done, remember to repeat the cleaning and sterilization process.

SINGLE-USE INSTRUMENTS

Single-use instruments are intended and manufactured for one use only. they **MUST NOT** be reprocessed.

***Acceptance for North American Healthcare Facilities**

Symbol	Symbol Title	Explanation
	Medical Device	Indicates the item is a medical device.
	CE marking	'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.
	Caution	To indicate that caution is necessary when operating the device.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.

Spaulding's Classifications

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