Information on Processing of Medical Devices

Please observe the following processing instructions, which relate to cleaning, disinfection and sterilization. This is important information also for retaining the value of your instruments, implants and other devices. While there are many processing options available, the correct choice depends on the material of the item at hand (i.e. its compatibility with the selected procedure). Note that the operator is solely responsible for the success of the selected procedure. Be sure to observe and follow also the recommendations and provisions contained in the relevant national/legal standards and instructions for use.

Preparation at place of use	
dry / wet	It is assumed that commercially available products approved for the intended application are used and that the user complies with recommended concentrations, exposure times and temperatures. It must be guaranteed also that no residues remain on the products. Fully demineralized water must be used for the final rinse.
Cleaning and disinfection	
Manual or machine processing with/without ultrasonic treatment.	
Chemicals and temperatures to be used for cleaning and disinfecting	
Acid/neutral/alkaline with/without addition of tensides, chemically at max. 60°C/140°F or with fully demineralized water, thermally at max. 93°C/199°F	It is assumed that commercially available products approved for the intended application are used and that the user complies with recommended concentrations, exposure times and temperatures. It must be guaranteed also that no residues remain on the products. Fully demineralized water must be used for the final rinse.
Drying	
Max. 100°C / 212°F	
Checks, maintenance / care and inspection	
Inspection for usability and surface integrity.	
Packaging	
Packaging materials as specified by EN 868 and ISO 11607 standard series and approved by the manufacturer for the specified sterilization method.	
Sterilization	
One or several procedures available: Validated steam sterilization process, 134°C (273°F) / 2-bar program, or validated steam sterilization process, 121°C (250°F) / 1-bar program	Sterilization and holding times are subject to national regulations and guidelines and therefore cannot be set universally. It is the operator's responsibility to ensure that the intended results are actually achieved with the processing and sterilization methods, equipment, materials and personnel used. This, in turn, requires validation and routine monitoring of all relevant processes.
Alternative sterilization methods*	***Notes on alternative sterilization methods:** Steam sterilization has established itself worldwide as a very safe and highly reliable sterilization method and, therefore, represents the method of choice with regard to temperature- and humidity-insensitive goods. As a rule, steam sterilization in the form of a validated process is required (see also DIN EN 554). Therefore, it is not necessary to use alternative sterilization methods – such as low-temperature plasma sterilization (LTP), formaldehyde or ethylene oxide for steam-sterilizable medical devices. Since there is controversy among experts regarding the effectiveness of plasma sterilization in cavities and lumens, WEINMANN GmbH does not validate sterilization processes using gas/plasma sterilizers for steam-sterilizable medical devices. Nonetheless, sterilizer operators are free to validate sterilization processes using alternative methods for sterilizing their products.
Storage	
No special requirements.	Please observe all basic rules and standard requirements when dealing with sterile supplies and packaging.

Additional information

- Instruments with a joint or lock box (such as scissors and forceps, etc.) or with metallic gliding surfaces (such as rib shears, punches, etc.) must be treated with steam-sterilizable, paraffin oil-based care agents. The paraffin oil used must comply with the currently valid pharmacopoeia. These care agents prevent metal-on-metal friction and ensure the instruments' ease of movement. The lettering of laser-lettered products may fade if treated with intensive cleaners containing phosphoric or hydrofluoric acid. This may impair or destroy the coding function.
- Please note that products to be returned to WEINMANN GmbH (or a WEINMANN GmbH-authorized service provider) for maintenance or repair must first be properly cleaned and sterilized!
- The processing information given herein cannot replace detailed process descriptions because it is not possible to give a detailed account of the numerous processing methods used all over the world. All information is given without guarantee.

All information is provided without guarantee. WEINMANN GmbH reserves the right to make changes without prior notice.

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