Cleaning, disinfection and sterilization instructions for reusable accessories

Process	• Cleaning • Disinfection • Sterilization with hot steam (DIN EN ISO 17665-1)
Device codes	**Guns**: GUN-01; ASA0130; ASA0310 **Trials for Spacers**: Ref codes for EU market: SPG03; SPG03XL; SPC90Z0; SPC91Z0; SPK03; SPK03Z0; SPS90Z0 Ref codes for US market: SPC90Z1; SPC91Z1; SPC90Z3; SPC91Z3; SPK90Z1; SPK03Z1; SPS90Z1 **Cemex System Container**: ASA0031
Warnings	Devices that are supplied non-sterile are clearly marked with “NON STERILE” and must be cleaned, disinfected and sterilized prior to their use. Devices may only be processed by qualified personnel. Only approved cleaning agents and disinfectants are to be used (pH ≤ 12 for devices made of metal). Devices made from synthetic materials or containing components made from synthetic materials may by no means be sterilized using dry heat.
Restriction regarding reprocessing	Differing instructions and recommendations of the manufacturer must be observed

Instructions	
Location of use	It is advisable to prepare devices for reuse as soon as possible after using them. Remove surface flecks with a disposable towel/paper towel. Devices may be placed into a disinfectant solution or hot water (80°C) immediately after use, in order to make cleaning easier and to reduce the risk of infection.
Preparation for cleaning	Pre-cleaning of device: Completely immerse the device in an enzymatic or alkaline cleaning solution (pH ≤ 12) and soak for 10 minutes. Clean the device with a soft plastic brush. Then rinse the device repeatedly with running water.
Effect of high pH	**Guns**: Cleaning with alkalinic detergents may whiten the oxidized surfaces of the device (the device will appear gray). This does not affect the functioning of the device **Trials**: No specific effect **Cemex System Container**: No specific effect
Automatic cleaning and disinfection	Automatic cleaning is preferable to manual cleaning, if this is an option. The machine should offer a suitable thermal-disinfection programme: A0 value > 3000, or at least 10 minutes at 93°C in older machines. Alternatively, if using a chemical disinfection method, bear in mind the risk of residue being left on the device. When choosing a cleanser, make sure that it is compatible with device materials. Follow manufacturer instructions when loading cleaning machines. Place device in such a way so as to allow complete, thorough rinsing of all ducts and cavities. Use deionised water for the final rinse. Be sure to allow sufficient drying time. Immediately after the programme has finished, remove the device from the machine and, if necessary, dry it with a soft, absorbent, lint-free cloth.
Manual cleaning	Begin by removing major surface contamination from the device using a soft nylon brush or a soft, lint-free cloth, along with either clear running water or a cleaning solution. Never use abrasive cleaning agents or metal brushes. Lay the device in the cleaning solution, following manufacturer‘s instructions as regards concentration, soaking time, and compatibility with the device materials. Be sure that the instrument is completely submerged in the cleaning solution. Be sure to vent all cavities, lumens and openings. Clean lumens and drill holes using appropriate brushes. After cleansing, rinse using deionised water, and dry thoroughly. OPTIONAL: Subsequent ultrasonic cleaning. Be sure that the ultrasonic bath is pre-heated according to device manufacturer or cleaning-agent manufacturer instructions. When loading the bath, make sure that the cleaning solution completely covers the device, and that all cavities, lumens and openings are fully vented. Clean device at 35-40 kHz for five minutes. After UV cleansing has finished, rinse device thoroughly with clear, running water, making sure to flush out cavities, lumens and openings wherever applicable.
Device maintenance	Allow device to cool down to room temperature. **Guns**: OPTIONAL. Oil moving parts lightly with sterilisable, steam-penetrable surgical lubricating oil.
Checking functionality	After each cleaning/disinfection, inspect the device for cleanliness, functionality, and damage (e.g., bent, broken, worn or missing parts). Never use damaged devices.
Cleaning and disinfection empty sieves	Not applicable
Packing	Prior to steam sterilization, cleaned, disinfected devices should be inserted into suitable containers or sterilisation packages (ISO11607-1). **Cemex System Container**: The device shall be kept open (the two halves shall not be screwed in).
Sterilization	Device sterilisation is to be performed using a ISO 17665-1 validated procedure. We recommend a fractionated vacuum method when using a steam steriliser. **Guns & Trials**: The maximum allowable sterilisation temperature is 134°C (273°F) plus tolerances as per ISO 17665-1. Sterilisation time (exposure time at the sterilisation temperature) should be at least 15 minutes at 121°C (250°F) or 4 minutes at 134°C (273°F). The recommended pressure level is 1 or 2 bar, respectively. **Cemex System Container**: The maximum allowable sterilisation temperature is 121°C (250°F) plus tolerances as per ISO 17665-1. Sterilisation time (exposure time at the sterilisation temperature) should be at least 15 minutes at 121°C (250°F). The recommended pressure level is 1 bar.
Storage	After sterilisation, the device must be kept in its sterilisation packaging and stored in a dry, dust-free place.

Preparation instructions in accordance with ISO 17664

The preparer is responsible for ensuring that the preparation procedure actually employed (using the materials, equipment, and personnel available in the preparation facilities) achieves the desired results. Normally, this means that the procedure must be validated and subject to routine monitoring.
Likewise, any deviation from the instructions provided should be carefully evaluated by the preparer to determine its effectiveness and possible negative consequences.
As regards to the preparation procedure, we would also like to point out the vital importance of following the any relevant national regulations.