

The methods and instructions for application of the detergents from the manufacturer must get adhered.

**Chlorides have a negative effect on your products!**

**Frequent reprocessing has only minor effects on our products**

**The end of the durability usually gets determined by wear/abrasion from the general use of the products.**

**After use**

Wet storage (wet disposal )	Not recommended for our products. Select a suitable detergent. Recommended: <b>Dr. Weigert- Neodisher Septo PreClean</b> The operator is responsible for the process qualification/ validation.
Dry storage (dry disposal )	Directly after use, pre-cleaning with a soft cloth or soft brush. Controlled depositing/ storage in suitable containers or holders. <b>!! Uncontrolled storage/disposal can cause mechanical damage !!</b> Keep storage times as low as possible, max 5 hours.

**Ultrasonic cleaning ( not validated )**

Cleaning	Make sure that the devices are completely submerged in the solution. Cleaning solution can get added. The compability of these detergents with the products must be ensured. Recommended detergent: <b>Dr. Weigert- Neodisher Septo PreClean or Septo Plus</b> Make sure, that the temperature will stay below 50° C / 122° F all the time. There is the risk of thermal protein denaturation. Adhere the recommend time setting of the manufacturer of the ultrasonic machine and of the of the detergent manufacturer. Hard residues in the process water can cause scratchings.
Rinsing	Rinse the products with tap water. The use of demineralized water is recommended.
Control	Check the products thoroughly for damages/ residues/ soils.

**Manual reprocessing instructions for cleaning and disinfection ( Not validated )**

Cleaning	Soak products completely into the detergent Recommended detergent: <b>Dr. Weigert- Neodisher Septo PreClean</b> Clean the products with a soft cloth or a soft brush. <b>Don't use galling solutions or equipment.</b>
Rinsing	Rinse the products with tap water thoroughly. Let the water drain off, otherwise the disinfection solution could get diluted.
Disinfection	Soak products completely into the disinfection solution for the specified period. Recommended detergent: <b>Dr. Weigert- Neodisher Septo PreClean</b> The use of demineralized water is recommended.
Final rinsing	Rinse the products under demineralised running water for at least 5 seconds.
Drying	Towel the products with a soft, lint-free, absorbing cloth. Use of pressurized air is possible. Quality: ISO 8573-1, minimum class 2 . The operator has the responsibility for the air quality and the process quality. <b>( There is the danger of contamination from the pressurized air! The use of steril-filtered air is recommended by us. )</b>
Control	Check the products thoroughly for damages/ residues/ soils.

**Automatic process for cleaning and disinfection. ( Validated )**

**! No chemical disinfection is allowed !**

Process qualification	DIN EN ISO 15883
Cleaning	<p>The use of an enzymatic ph- value neutral detergent is recommend from us and furthermore is best suited for the durability of your instruments. The instruction of the detergent manufacturer must get adhered. Recommendation: Use only demineralised water. Recommendation: <b>Dr. Weigert- Neodisher MediZym</b>, at 40- 50°C/ 104-122° F for approx. 10min.</p> <p>The use of mild-alkaline detergents can get considered ( ph value ≤ 10,5 ) Recommendation: <b>Dr. Weigert- Neodisher MediClean</b> at 50 – 60°C/ 122-140°F for 5 min- 10 min.</p> <p><b>Alkaline detergents are not recommended from us, because they have a negative effect on the functionality of the products and on the environment. The operator is responsible for the conformity of the detergent with the products. ( long-time effect on the products )</b></p>
Neutralisation	Neutralisation is not a must when using the recommended detergents and water quality. Please follow the instruction of the detergent manufacturer.
Final rinsing	It is possible to use <b>Dr. Weigert- Neodisher MediKlar</b> as an additive for the final rinsing. Use only demineralised water.
Disinfection	for 5 minutes time at temperature >90°C/194°F ; A <sub>0</sub> level = 3000
Drying	In case of residual moisture on the products, final drying must get carried out again. The necessity of a reconfirmation of the performance evaluation has to be considered.
Control	Check the products thoroughly for damages/residues/soils.

**Sterile- Barrier- Packing**

Material qualification	Materials for the sterile-barrier-system must get qualified according to the DIN EN ISO 11607-1.
Process qualification	The processes for the forming and the sealing must get qualified according to the DIN EN ISO 11607-2.
Sterile-Barrier-System	<p>Choose a size of the packing which gives enough space for the products. The packing must have enough space to work during the sterilisation process. If the packing is not designed big enough, there is the risk, that the seals will get damaged. We recommend a filling level of not more than 75 % with at least 3 cm distance of the products to the seals. <b>Pressure filling of the packing must be avoided.</b></p>

**Steam sterilisation only! ( Validated )**

**Hot air sterilisation is not allowed! Other techniques/ methods are not validated.**

Sterilizer qualification	DIN EN ISO 285 or DIN EN ISO 13060
Process qualification	DIN EN ISO 17665
Boiler water/ condensate	DIN EN ISO 285, Annex B or DIN EN ISO 13060, Annex C
Process parameter	<p>Fractional- pre- vacuum steam sterilisation, with a minimum of 3 minutes holding time at 134°C/273,2°F. Please be aware, that the selected packing system must be a part of the process validation and of the periodical performance evaluation.</p>
Sterilisation	<p>When the sterilizer gets loaded, please make sure, that the poly-sides will not be the down side of the packing ( puddle –building! ). Please make sure, that the packed products are not packed to tightly inside the chamber. During vacuum-periods, the packing will balloon.</p>

### **Storage**

The storage time und the conditions under which the sterile packed products can get stored are depending on the chosen packing system. We can't give advices to this subject. These information can get obtained from the producer of the packing material as far as they are not part of the validation according to the DIN EN ISO 11607.