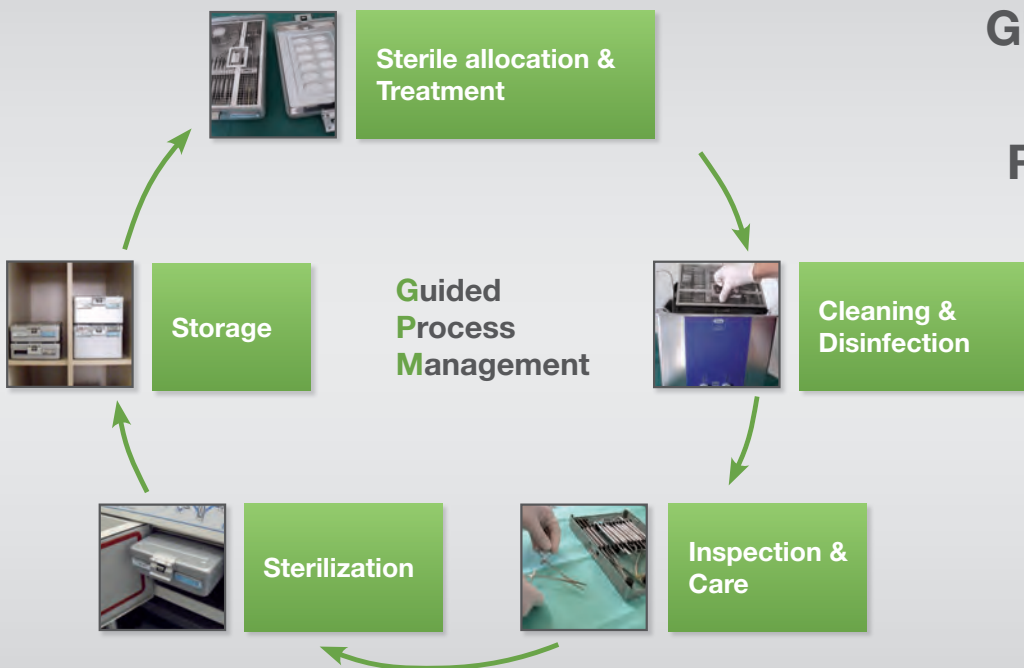


... makes the difference

GUIDELINES FOR INSTRUMENT REPROCESSING



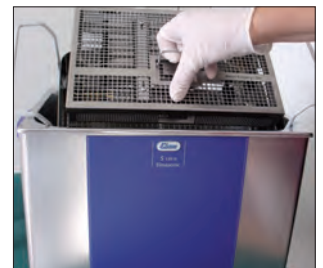
REPROCESSING AND CLEANING INSTRUCTIONS

The instruments are delivered unsterile and have to be subjected to complete reprocessing before their initial use, as well as after every use. That means cleaning by hand in a disinfectant solution and/or in an ultrasonic cleaning system, or rather in a thermo-disinfector. For this, protecting caps and lamination sheets have to be completely removed.

When reprocessing, delicate instruments (e.g. root canal instruments) have to be put into special trays, racks or holding devices. Instruments or trays which are not made from stainless steel, but from e.g. chromed brass, anodized aluminium or plastic, have to be treated only with adjusted cleansers and disinfectants. Acidic cleansers, like cement removers, should only be used if absolutely necessary, as the use of such cleansers will cause corrosion on the surfaces and soldering seams. Cleansers with chloric substances, as well as corresponding compounds of the other halogens (fluoric, iodine, bromine), may not be used.

Instruments may only be reprocessed by persons who have the necessary expert knowledge and education. They have to evaluate the arising risks with their corresponding effects. Contaminated instruments must always be handled with protective gloves when preparing them for reprocessing.

Improper execution and care, as well as use for other purposes than intended can effect an untimely wear. In addition, sterilizers continuously have to be cared for and examined.



REDUCTION OF REPROCESSING

Due to the product design and the used materials it is not possible to appoint a defined limit of maximal operable reprocessing cycles. The life time of the medical devices depends on their function and their gentle handling. In general, products should be disinfected and cleaned immediately after use to prevent drying up of blood residues, which are much more difficult to clean. Blood residues can transmit the Creutzfeld-Jacob disease.

Defective products have to pass through the complete reprocessing cycle before being returned. If these instruments cannot be repaired, they should be disposed of according to the hospital's guidelines.

It is the responsibility of the user to make sure, that the reprocessing cycle (including resources, material, staff) is able to attain the necessary results.

INSTRUMENT TRAYS – TRAY CONTAINER SYSTEM

For an optimal and didactical preparation it is recommended that the instruments are stored in an appropriate tray. These trays can be shrink-wrapped and sterilized and are superposable for up to 6 months, according to the valid legal guidelines. Therefore, the individual shrink-wrapping of many single instruments is not necessary, which in turn saves time and reduce the costs of the sterile materials.

Single trays can be led to sterilization in various dental containers without shrink-wraping. In this case, they are sterile for up to 6 months.

The tray container system is the ideal solution to preposition the instruments clearly and process-oriented. Efficient cleaning, disinfection, sterilization and storage are all optimally achieved.



PREPARATION

Stains on the surface have to be removed with paper towel.

Raw contamination should immediately be removed after use (within 30 minutes, max.) before they are processed individually or in a tray container system.

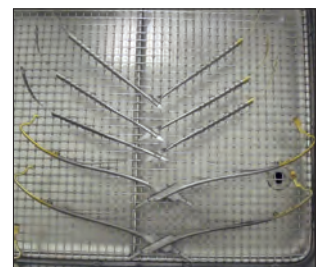
Don't use fixing materials or hot water (> 40° C), which can lead to residues and can influence the success of the cleaning.

The instruments must be demounted or preferably opened. They have to be laid into cold water for 5 minutes.

For the manual removal of raw contamination only use a soft brush. (no metal brush or steel wool). No visible residue should remain.

Box sections, drill-holes, and thread turns should be press-cleaned with a squirt gun 10 seconds minimally. (pulsated mode)

If the instruments are cleaned with a disinfectant liquid before mechanical reprocessing, it is recommended, to use a low foaming product. If foaming products are used, residues must be rinsed thoroughly before mechanical reprocessing. This advice also applies for extremely contaminated instruments, which due to skin, dry blood and secretion, or residues of filling material, have to be preprocessed in an ultrasonic or steep bath.



MANUAL DISINFECTION AND CLEANING

For manual reprocessing, the instruments are placed into a liquid of combined cleanser and disinfectant with a verified value of disinfection.

IMPORTANT: correct concentration
 correct exposure time
 correct temperature

The manufacturers' instructions have to be followed completely when applying the compounds. The wrong concentration or an over-exposure time can result in damage to the materials e.g. hazard of corrosion, discolouration (ranging from grey to black). Soaking the instruments overnight or over the weekend should be strictly avoided.

Fresh cleanser and disinfectant have to be used daily. Instruments with joints/hinges have to be opened before insertion and must be completely covered by the dilution. (Do not overload steep baths)



CLEANING IN ULTRASONIC

Basically, there are the same standards for the preparation of the dip as for the manual cleaning and disinfection in a steep bath.

Temperatures between 40° C and 50° C optimise the Ultrasonic cleaning process.

Temperatures of more than 50° C can cause blood crusting. Heavy dirt contamination of the ultrasonic bowl reduces the effect and increases the danger of corrosion. Therefore, the dip has to be replaced continuously, according to the usage conditions – but at least once a day.

For the cleaning of light contamination, treatment times of a minimum of 3 minutes, at frequencies of 35 KHz have proved successful. For steadfast contamination, the ultrasonic exposure time has to be increased.

Instruments may only be placed into special holders or racks. Instruments with hollow spaces have to be inserted diagonally.

Thorough rinsing washing-up of the instruments is very important. To remove the remainders of from cleanser and disinfectant, it is recommended to only use demineralized water.



MECHANICAL CLEANING/THERMO DISINFECTOR

Mechanical cleaning requires the safe fastening of the instruments in the thermo disinfecter (i.e. storage and fixation in special wash-trays-cassettes). Instruments with joints or hinges always have to be opened. Instruments with long or narrow hollow spaces, such as tubes or cannulas, should be placed into special racks.

A cold water supply is recommended, as cold water already has proteins removed. The temperature of the inlet water should not exceed 45° C. Higher temperatures will cause protein to coagulate, which results in problems with the cleaning.

Use only an appropriate cleanser. The dosage has to be followed according to the manufacturers' instructions.

Any residues from the cleaning process must be reliably removed in subsequent rinsing cycles, otherwise stains and/or discoloration will occur on the instruments. Therefore it is recommended, to execute the final rinsing with fully desalinated and demineralized water.

When the program has been completed, the door of the machine should be opened immediately, to provide adequate exchange of air. This will make optimum use of the instrument's intrinsic heat and avoid the formation of condensation that promotes corrosion.

Instruments may not be left in the closed machine overnight.



CHECKING, MAINTENANCE AND CARE, PACKAGING

Optically check for cleanliness. According to their separate instruction manuals, rebuild the instruments and test for function.

If necessary, repeat the reprocessing, until the instrument is optically clean.

Instruments with joints have to be lubricated with a silicone-free oil (our item no. 150) according DAB. Joints have to be checked with respect to free movement.

If corrosion spots on the instruments can't be removed, they should not be used anymore.



STERILIZATION

As a safe method of sterilization, we solely recommend steam sterilization with a maximum temperature of 134° C (273.2° F). The doctor accepts full liability if any other method is applied. However, if hot air sterilization is used, it is important, that a temperature of 180° C is not exceeded, as it is then not possible, to remove any discolorations. In addition, the hardness may be reduced. Products with plastic parts should not be sterilized with hot air.

During the sterilization process, stainless steel instruments may not be put together with other metals or materials. If this instruction is not followed, oxidation spots can occur.

Only absolutely dry and correct instruments may be put into the sterilizer.

For sterilization, only completely desalinated and demineralized water should be used. The use of tap water causes covering and corrosion damage on the instruments and sterilizer.

After sterilization, the packaging of the sterilized instrument has to be checked. The date of sterilization (or rather sterile LOT) is documented on the package.



STORAGE

Sterilized instruments should be stored in a dry, dust-free and clean environment at moderate temperatures between 5° C and 40° C (table 1 of DIN 58 953 – part 9) and must not be stored together with chemicals.

CAUTION:

Unpackaged instruments are unsterile. Due to security reasons, sterile and unsterile products should not be stored together.

All validated processes must be in accordance to national guidelines and technological standards.



PROBLEMS, THEIR CAUSES AND PREVENTION

Stains, temper colours, iridescent surface discolorations

Problems

- Inadequate manual or mechanical cleaning
- Local nature of water (e.g. too high content of chloride) can cause stains and damages
- Usage of tap water or distilled water with minor quality or with a too high concentration of mineral compounds, heavy metal ions or silicate, can cause discoloration on the instrument

THEREFORE: ONLY USE DISTILLED WATER

CAUTION:

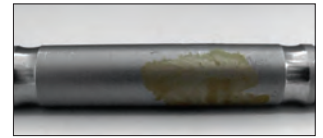
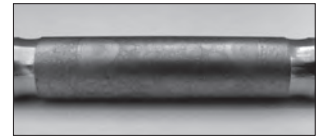
Most problems can be prevented, if only distilled water is used



PROBLEMS, THEIR CAUSES AND PREVENTION

Causes

- Improper cleanser, disinfectant and care products
 - Dosage not observed
 - Drug residues
 - Residues in the water tank of the autoclave break off into the sterilization cycle of the instruments.
- CAUTION:** Due to the high temperature, these residues stove into the material. This can cause pitting corrosion
- Oil desposition: brownish “gumming” can arise, particularly on instruments with joints. This often appears with new instruments, with the oil used in production and with grease residues



Corrosion, external corrosion

- Immediately sort out old (chrome-plated) and damaged instruments (danger of flash rust)
- Can also arise through rusty water at cleaning or in autoclave
- Be sure to clean new autoclaves before initial use



How to find a fast remedy?

- Most surface changes can be removed with a dry cloth if they are recognized in time (if appropriate, apply citric acid on the cloth)
- It is recommended to use a polish (for chrome-nickel finishes), to remove adhesive residues
- Instruments which cannot be cleaned anymore should be removed from the cycle



GUARANTEE

Our products are made from high class materials and are subjected to quality controls before their delivery.

However, if there are any faults, please contact our service department.

devedmed GmbH does not accept any responsibility and cannot be held liable for any casual or resulting damages if the instruments are not used for their respective purpose.

The guarantee becomes invalid if proven that the instructions and guidelines of this manual have not been followed.

CAUTION:

In the case of the instruments being used on patients with the Creutzfeld-Jakob disease or HIV disease, we decline any responsibility for their reuse.



... makes the difference

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