Instrument reprocessing

In Dental Practices

How To Do It Right

Working Group
Instrument Reprocessing

4
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Instrument reprocessing In Dental Practices
How To Do It Right

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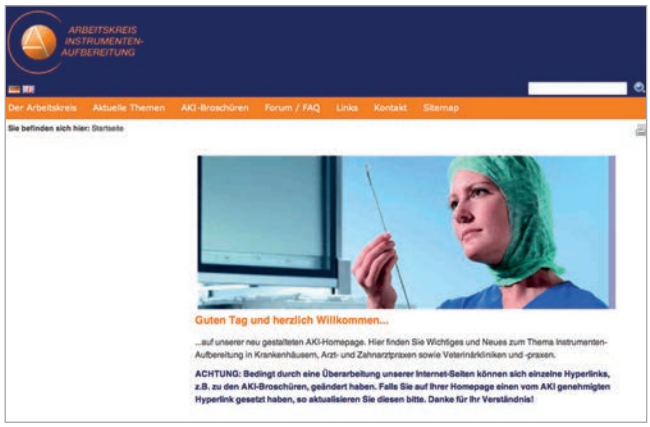

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Instrument reprocessing In Dental Practices; How To Do It Right

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Preface

The Instrument Reprocessing Working Group (AKI) was first set up in 1976 in Germany. Since its inception, its members have devoted themselves to the collection and publication of expertise relating to the safety and value retention of the instruments used in human, dental and veterinary medicine.

Today, in 2016, the AKI is publishing its anniversary brochure to mark its 40-year existence. This brochure, like its predecessors, presents the salient aspects of instrument reprocessing in simple, easy-to-understand terms. This brochure does not profess to present a scientific approach to the subject but rather attempts to provide users with practical tips which are of benefit in their responsible work.The international relevance of the AKI brochure is reflected in the fact that it has already been published in 19 languages with a total circulation of more than 300,000 copies worldwide and is valued in a large number of countries by machine users and trainers alike.

Modified quality assurance regulations for the reprocessing of dental instruments, changed materials and new findings on influences and constraints during their treatment have resulted in a revision of the so-called "Yellow Booklet".

This booklet focuses on retaining the value of instruments, since corrosion and malfunctioning that require either repair work or lead to the complete destruction of instruments can have an enormous economic impact. Proper instrument reprocessing demands numerous chemical and physical factors to prevent the spread of germs. However, the required measures should only be carried out after considering the risks involved. Correct reprocessing combined with long-term value retention of the instruments is only possible with profound knowledge of the material properties, the effectiveness of treatment agents, the influence of various water qualities, and the consequences resulting from unsuitable treatment.

This booklet is, therefore, not simply a guideline about the hygienic aspects of instrument reprocessing. Nonetheless, the current and generally accepted concepts of hygiene are related to their effects on the respective instrument and form the basis for the structure and content of this booklet. The professional revision of this booklet was only possible with the help of specialists who develop and manufacture instruments, chemical agents, and reprocessing devices, as well as experts in the field of hygiene.

Dentists and dental specialists are thus provided with an updated

compendium for the execution of cutting-edge reprocessing measures within the framework of dental practice hygiene. It will hopefully be well accepted and appreciated.

Prof. Dr. Michael Pietsch
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Introduction

Instruments are a major asset and represent a significant share of the total capital spending of a dental practice. The practical experience recorded in this booklet, together with a description of fundamental interrelationships, is intended to help users to keep their reusable instruments in good working order and preserve their value for many years, by ensuring proper reprocessing. It should be emphasized that the recommended measures must always be carried out in accordance with the manufacturer's instructions, pertinent hygiene requirements and official safety-at-work guidelines.

Instrument reprocessing is increasingly subject to legislation (Medical Devices Act, Medical Devices Directive), with a general tendency towards a worldwide harmonization.

In addition, there are direct legal requirements that need to be observed, e.g. the German "Betreiberverordnung" (Operator Regulations), which implements the Medical Devices Directive (MDD). They provide detailed instructions in the form of validation measures that should be carried out by the Central Sterile Supply Department (CSSD). Compliance with such requirements can best be assured and documented within the context of a quality system (QS). As this "Yellow Booklet" has a distinctly process-oriented structure according to the reprocessing procedures and based on the provisions of DIN EN ISO 17664, it can be incorporated directly into a process-oriented system.

Section	Yellow Booklet	Section	National regulations, e.g. RKI guideline	Section	EN ISO 17664: 2007
1	Materials and Design				
2	Media for Instrument Reprocessing				
3	How to Treat Brand New and Repaired Instruments				
4	Treatment Recommendations for Returned Good				
5	Preparation for Cleaning and Disinfecting	2.1	Reprocessing Unused Medical Devices	3.3	Processing at the point of use
6.1	Manual Cleaning/ Disinfecting Cleaning	2.2	Reprocessing Used Medical Devices	3.4	Preparation before the cleaning
6.2	Machine-Based Cleaning and Disinfecting	2.2.1	Preparation for Reprocessing, Cleaning/Disinfecting, Rinsing and Drying	3.5	Disinfecting
6.3	Ultrasound			3.6	Drying process
7	Checks and Care	2.2.2	Checking technical-functional safety	3.8	Checks, maintenance, testing
8	Packaging	2.2.3	Packaging	3.9	Packaging
9	Sterilization	2.2.4	Sterilization	3.10	Sterilization
10	Storage	2.2.5	Labeling	3.11	Storage
		2.2.6	Release		
		2.2.7	Documentation		
		2.2.8	Transport and Storage		
11	Surface Changes, Deposits, Corrosion, Aging, and Stress Cracks				

Comparison of structure Yellow Booklet, RKI recommendation and EN ISO 17664

*Hygiene requirements for the sterile reprocessing of medical devices. Recommendation; Federal Health Gazette 44/2001, 1115-1126 – For other countries, the German example must be modified and adapted in accordance with valid national regulations.

A wide-spread misconception that "high-grade steel" or "stainless steel" are virtually indestructible and extremely durable needs to be corrected: even stainless steel can be adversely affected by a wide range of potential attack - whether mechanical, thermal or chemical.

Nonetheless, as long as you understand the material and its characteristics and know how to handle these products, you will be able to extend the trouble-free life of your stainless steel instruments.

Dental instruments need special care due to their great variety and the particular materials used in each case.

Needless to say, users of medical devices expect well-known manufacturers to exercise the greatest of care in both selecting the right materials and manufacturing the product. Because of this, the user can count on medical devices that are optimally adapted to the intended purpose and provide excellent functionality. However, to retain the value of the instruments in the long run, users must make a significant contribution, i.e. by ensuring correct reprocessing and care. To explain how this is done is the purpose of this booklet.

Disposable instruments

Disposal instruments are intended for single use, because their conformity assessment covers such use only. This is why this booklet contains no instructions on how to reprocess disposal instruments.

General notes and instructions

Basically, the reprocessing of medical devices comprises:

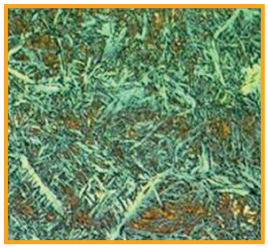
- Preparation (pretreatment, collecting, precleaning and, where applicable, taking the instruments apart)
- Cleaning, disinfecting, final rinse, drying (if required)
- Visual inspection of cleanliness and condition of material
- Care and repair where required
- Functional test
- Marking
- Where applicable, packaging and sterilization, approval for reuse and storage

National regulations, such as the German Operator Regulations relating to medical devices and the recommendations of the Robert Koch Institute (RKI) entitled: "Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten" [Hygiene requirements to be observed when reprocessing medical devices], demand quality control and assurance in these processes. It is the owner's/operator's responsibility to evaluate the risks, to classify the various risk areas, to provide written standard work instructions that clearly define each step in the reprocessing process and to ensure adequate documentation. Validated cleaning, disinfecting and sterilization processes, supplemented by defined configurations for loading the washers/disinfectors (Ws/Ds) and sterilizers, are an indispensable prerequisite for quality assurance.

It is particularly important to follow the manufacturer's instructions in the instruction manual, not only because ignoring them might lead to expensive replacements or repairs, but also because incorrect reprocessing or product failure might endanger the patient or third parties. We urge you to consult the manufacturer if you have any doubts.

For thermostable medical devices, machine-based reprocessing with thermal disinfection and steam sterilization is the preferred method.

Instruments and components which are exclusively provided for single only use must be disposed of after use.



Color etching - martensitic microstructure on corrosion-resistant instrument steel - hardened (magnified 500 times)

1. Materials and Design

1.1 Materials

When producing medical devices, the manufacturer must design them to be fit for their intended purpose not only in design, manufacture and finish, but also by selecting adequate materials. For surgical instruments generally only stainless steel (hardened, non-rusting) can meet the tough requirements in terms of elasticity, tenacity, rigidity, blade characteristics, resistance to wear and maximum corrosion resistance.

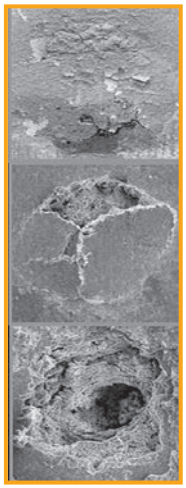
Corrosion resistance/ Passive layer

Surface finishes on instruments

The corrosion resistance of stainless steel primarily depends on the quality and thickness of the passive layer. This passive layer is a layer of chromium oxide that results from the chemical reaction between the chromium in the steel alloy (at least 12%) and oxygen in the ambient air. This layer is not affected by the specific surface finish of the product (matt or high-gloss). In fact, its formation and growth are influenced by the following factors:

- Composition of the alloy
- Microstructure of the material, which is influenced by heat treatment (e.g. forging, tempering, annealing, welding, soldering)
- Surface finish and condition, e.g. roughness or smoothness
- Handling and reprocessing conditions
- The service life and number of reprocessing cycles

Chlorides are dangerous



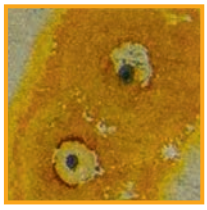
Scanning electron microscope image, chloride-induced pitting

Passive layers are extremely resistant to many chemical substances. Depending on the factors mentioned above, on every passive layer there are areas with a specific crystallographic structure where the passive layer is very susceptible to corrosive attack, particularly when in a damp or aqueous environment. Among the few substances that can attack and destroy this layer are halogen salts (halides), the most common and dangerous of them being chlorides. Chlorides tend to react with the passive layer in a process leading to the well-known, chloride-induced damage called "pitting corrosion". Depending on the concentration of chlorides, the damage caused ranges from a few sparse points of attack (visible as small black dots) to a completely damaged instrument surface covered with large deep holes. Chlorides also cause "stress corrosion cracking".

With increasing service life, the passive layer tends to become thicker. From experience, this causes a decrease in corrosive attack because the probability of chlorides penetrating all the way down to the unprotected base material is reduced.

Chloride sources in the instrument usage and processing cycle:

- Fresh-water chloride content (depending on the source of the supply)
- Insufficient demineralization of the water used for the final rinse and steam sterilization
- Regeneration salt carryover, leakage or spillage from ion exchangers used for water softening
- Use of agents not permitted for or incorrectly used during reprocessing
- Isotonic solutions (e.g. a physiological salt solution), etchants and drug residues
- Organic residues (body fluids such as blood, chloride content 3200-3550 mg/ltr, saliva, sweat) dried on the surfaces
- Laundry, textiles, packaging materials



Regenerating salt containing chloride caused massive pitting on the surface of the instrument. Cause: Leaking ion-exchanger connection in the W/D.

Pitting and stress corrosion cracking are seldom or never observed in a chloride-free or low-chloride environment irrespective of the degree of gloss and the given passive layer of the instrument surface.
If corrosion only occurs on new, high-quality instruments reprocessed in the same cycle as older instruments, the reason can probably be found in the instrument reprocessing conditions. In all cases investigated so far, reprocessing had taken place under conditions that individually or collectively approached or exceeded the limits of process security.

Color etching - austenitic microstructure on corrosion and acid-resistant instrument steel (magnified 500 times)

As well as heat-treatable chromium steels, standardized non-hardenable chromium steels with modified chromium contents and rust/acid-resistant chromium-nickel steels are also used to make instruments in accordance with EN ISO 7153-1. Their mechanical properties are limited however, so that the use of these steels is restricted to certain types of instruments.

A great variety of materials is employed for instruments, depending on the given application technique and the particular instrument design. The most important of these are:

- Rust/Acid-proof chromium-nickel steels (also as welding filler)
- Pure titanium or titanium alloy
- Non-ferrous heavy metal alloys with surface finishing (e.g. chrome/nickel-plated brass)
- Light metals (e.g. anodized aluminum)
- Non corrosion-resistant steels and components

- Glass (for optical systems)
- Ceramics
- Cements and other bonding agents
- Solder
- Plastics and rubber

Special processes may be required depending on the material combination used.

The combination of these very different materials in a particular instrument places restrictions on reprocessing. In other words, these items may require special treatment apart from standardized instrument reprocessing. These are described in the manufacturer's instructions.

Special reprocessing methods may be necessary for varnished housings made of unalloyed sheet steel, handpieces with colored graduations (indicating gear ratios), or anodized aluminum housings (as used for handpieces and angle pieces). For appropriate treatment recommendations, please refer to the manufacturer's instructions. In addition to special reprocessing requirements, lubrication is also essential for heavy-duty shafts as well as for bearing and gear components made of stainless steel (and in some cases, also for those made of non-stainless quenched and tempered steels or bronze materials).

1.2 Design

The capacity for reprocessing medical devices is of extreme importance for patient and user safety. During the design and development stage of a medical device it is necessary to consider its capacity for good reprocessing after use. However, the focus must also be on correct functioning and the capacity for reprocessing. Often the mechanism required is accommodated in the tiniest of spaces in order to avoid patient discomfort.

Optimum cleaning results can be achieved if the medical device can be dismantled as much as possible. But there are limits here too. It is possible to dismantle many medical devices only with great difficulty, e.g. a turbine head, since users are unable to disassemble and reassemble these delicate components. Another important point is the choice of materials and joining techniques. Since at 134 °C steam sterilization represents the most important sterilization method, the materials used must be temperature-resistant.

In order to achieve optimum reprocessing results, everyone involved needs to cooperate closely: from the medical device manufacturer, the manufacturers of automatic washers/disinfectors and sterilizers to the manufacturers of process chemicals. When purchasing medical devices, it is recommended that the aspects of instrument reprocessing are considered at an early stage.

2. Media for Instrument Reprocessing

2.1 Water

The quality of water used for instrument reprocessing has a considerable influence on value retention.

Water fulfills a variety of functions in the reprocessing process, e.g.:

- Dissolving detergents and other treatment agents
- Transferring mechanical forces and heat to the surface of the items to be washed
- Dissolving soluble dirt and impurities
- Flushing away cleaning and treatment solutions
- Thermal disinfection for machine-based reprocessing
- Application for steam sterilization

Stains on instruments. Cause: Dried water with high salt content

Unfavorable water composition can have an adverse effect both on the reprocessing process and on the appearance of the instruments and materials. This is why water quality in sufficient quantity is already important when planning on-site plumbing installations.

While any natural water contains dissolved salts, concentrations vary depending on the source of the water and how it is collected.

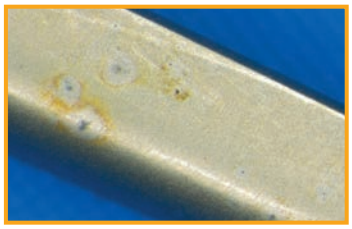
Depending on water hardness and temperature, the fresh water used can lead to the formation of a hard layer (lime deposits, scale) that is difficult to dissolve. It is even possible for corrosion to occur underneath such deposits.

Scale is acid-soluble and can thus be removed with an acid-based detergent. However, make sure to observe the detergent manufacturer’s instructions regarding material compatibility.

Aluminum might be attacked by softened water.

Left: Original
Right: Optical changes to color anodized aluminum

Chlorides are dangerous



Pitting induced by chlorides on instrument

In softened water, the above-mentioned "hardeners" have been replaced by sodium salts. However, this does not reduce the total load of substances contained in the water.

When using softened water, alkalinity can greatly increase depending on the temperature and exposure. Especially when thermal disinfection is used in the final rinse, aluminum surfaces might be subject to attack.

When water evaporates, some substances contained in it remain as visible mineral residues. Chlorides dissolved in water are particularly critical substances, as they tend to cause pitting even on stainless steel instruments if present in higher concentrations.

Generally speaking, the danger of chloride-induced pitting rises with:

- an increase in the chloride content
- an increase in temperature
- a decrease in the pH-value
- an increase in the exposure time
- insufficient drying
- concentration of chloride resulting from adherence of dry residues to instrument surfaces after evaporation

While the causal relationships between the chloride content of the water and pitting are not always predictable, experience shows that the probability of pitting is low as long as the chloride content does not exceed a level of approx. 120 mg/l (equivalent to 200 mg/l NaCl) at room temperature. However, with increasing chloride concentrations the risk of pitting also increases rapidly. It should also be noted that when water evaporates during the drying process, the chloride content of water droplets may drastically exceed the limit of 120 mg/l.

To prevent excessive chloride concentrations and subsequent pitting, we recommend using fully demineralized water for the final rinse.

Other substances may cause brownish, bluish, gray-black or iridescent discolourations, even when present in small quantities. Such discolourations may be caused by silicates/silicic acids contained in the water, or by compounds containing iron, copper or manganese. As a rule, however, such discolourations are harmless, constituting very thin residual layers that do not cause or facilitate corrosion.

Apart from its natural constituents, drinking water sometimes contains rust, generally flushed from corroded pipework. During the reprocessing cycle this rust tends to adhere to instruments, causing rust spots (extraneous rust) and subsequent corrosion.

Discolored surfaces on scalpel handle

Use fully demineralized water for the final rinse!

The use of fully demineralized water in the final rinse is not only recommended for the reasons described above (i.e. preventing chloride-induced corrosion), but also because it helps to keep the surfaces of the instruments free from stains and discolourations, and stabilizes anodized aluminum surfaces. Fully demineralized water for the final rinse does not leave dried crystalline residues, which could have a negative effect on any later sterilization procedures.

Since there is currently no specific standard regarding the use of fully demineralized water for machine-based reprocessing, we recommend the following quality based on experience in the reprocessing of medical devices within the dental industry:

Conductivity value (at 25 °C) < 20 µS/cm
Chloride < 5 mg/l
Silicate < 2 mg/l

If ion exchangers are used in the production of fully demineralized water, glaze-like discolourations may occur as a result of the specific behavior of silicic acid. This cannot be controlled through the conductivity value in the regeneration process! Make sure to consult an expert in this case.

2.2 Process chemicals

Process chemicals used to reprocess medical instruments must be developed, tested and manufactured in Europe in accordance with the European Medical Devices Directive [20].

- Cleaners, neutralizing agents, rinsing and care agents are classified as class I medical devices and are identified by the CE mark on the label.
- Process chemicals with anti-microbial effect that are used for disinfecting cleaning or manual/automatic final disinfection at room temperature or raised temperature are classified in Europe as class II medical devices and identified by the CE mark and a four-digit number indicating the responsible notified body.

When developing the product, the manufacturer of the process chemicals must ensure that the composition of the products is optimized with regard to the desired effects of application, such as cleaning efficiency, anti-microbial effectiveness, or the care properties, taking into account compatibility with the materials used to manufacture the instruments, as well as the bio-compatibility with any adhering residues containing human tissue at the place where the instrument is to be used. The manufacturer of the process chemicals must provide evidence of the compatibility of the materials, if necessary in cooperation with the manufacturer of the corresponding medical instruments. The bio-compatibility must be tested and assessed in accordance with EN ISO 10093-1 "Biological Assessment of Medical Devices"

Optimum application properties, material compatibility and bio-compatibility of the process chemicals are achieved only under the application conditions recommended by the manufacturer. The manufacturer must describe in detail the application conditions (on the label, technical data sheet) and users must observe these instructions. Special attention must be paid to the concentrations of the process chemicals in the application solutions and to the temperature and exposure time. The process chemical documents are supplemented by safety data sheets and, upon request from the user, by expert's reports on material compatibility, effectiveness, ecological properties and bio-compatibility.

The ingredients of various process chemicals may not be compatible. For example, the constituents of a detergent can have a negative effect on the effectiveness of a disinfectant if small quantities of the detergent enter the disinfectant solution. For this reason, it is recommended that only inter-coordinated process chemicals from a single manufacturer should be used in a closed reprocessing cycle.

3. How to Treat Brand New and Repaired Instruments

Preparation

Brand new instruments and those returned from repair must be removed from their transportation packaging before storing and/or inclusion in the instrument usage and processing cycle. Any protective caps or film must also be removed.

Before using brand new and repaired instruments, they must be sent through the entire reprocessing cycle in the same manner as used instruments.

Cleaning is mandatory!

The cleaning step should never be skipped because residues (e.g. from packing materials or care agents) could result in the formation of stains or deposits during sterilization. Always visually inspect cleaning results. As a rule, the instruments should be visibly clean after the cleaning stage. The passive layer of brand new instruments is usually still thin and these instruments, therefore, tend to be more sensitive to critical reprocessing conditions.

Storage

Brand new instruments and instruments returned from repair must be stored only at room temperature in dry rooms or cabinets. Otherwise condensate may build up inside plastic packages as a result of temperature fluctuations. This may cause subsequent corrosion damage. Instruments should never be stored near chemicals, such as active chlorine, which emit corrosive vapors.

To avoid mechanical damage during reprocessing, easily damaged instruments should be stored in suitable racks or retainers right from the start.

4. Treatment Recommendations for Returned Goods

In our context, returned goods are defined as packaged medical devices which, irrespective of whether they have been used or not, are returned to the manufacturer. The reasons for return can be manifold: necessary repairs or servicing, return of leased instruments, for checks to be carried out on products that are being clinically tested, in the case of complaints, return of explants for scientific investigation or damage analysis, etc. Note that there is a risk of infection for anyone dealing with products actually or potentially contaminated. It is most important to minimize this risk by implementing adequate and reliable treatment processes.

The above guideline implies that goods may be returned only if they:

- have been properly disinfected and declared hygienically safe, or
- are visibly marked as "non-decontaminated" and delivered in sufficiently safe packaging

The decontamination of products to be returned should be carried out as soon as possible after use, as in the normal supply and reprocessing cycle. This prevents subsequent damage (e.g. pitting caused by blood chlorides).

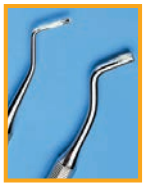
However, decontamination is not indicated where such treatment would alter or destroy the product, prevent proper analysis, or distort its results. If in doubt, consult the manufacturer of the product.

Possible procedural options include the enclosure of an individual or collective declaration containing all the information required (see, for example, the BVMed). This type of collective declaration given to the manufacturer or other receiving or processing entity should at least contain the following information:

- Date of manufacture/validity
- Confirmation that from that date onwards all goods returned can be considered hygienically safe unless clearly and visibly marked otherwise.
- Contact details to enable the clarification of any questions concerning the goods and the receipt of returns.

5. Preparation for Cleaning and Disinfecting

Immediately clean instruments with filling materials and caustic agents

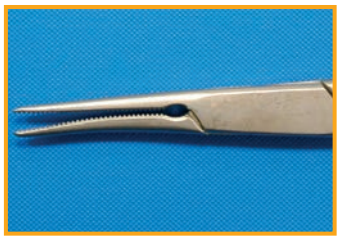


Filling instruments with adherent composite material. Cause: Lack of immediate reprocessing

The first steps in a proper reprocessing cycle are taken in the treatment room. Dental materials adhering to instruments (such as filling materials or phosphoric acid-based cement removers) must be removed immediately after use. Otherwise, the material will harden on the instrument and/or cause corrosion. Dental cement must preferably be removed with a swab or cellulose cloth immediately after use at the patient's chair. Residues from isotonic solutions (e.g. a physiological salt solution), hemostatics and caustic drugs must be removed before the instruments are set down. Cleaning and disinfecting in an ultrasonic bath is recommended for instruments with filling materials adhering to them. The suitability of the instrument for treatment in an ultrasonic bath must be taken into account (see section 6.3 Ultrasound).

Load instruments carefully, do not throw

Scissors with broken tip. Cause: Incorrect loading



Deformation caused by improper handling

Disinfection container (Fräsator)

Machine-based reprocessing should be preferably used for instruments. After use, they are carefully placed on a suitable tray or in an instrument cassette (dry disposal) and undergo machine-based cleaning and disinfecting as soon as possible. Always observe the manufacturer's instructions! Improper handling may damage the instruments. This applies, in particular, to instruments with delicate working ends, e.g. forceps, probes, scissors, especially with carbide inserts, needle holders, periodontal (PA) instruments.

When using wet disposal, it is advisable to immerse the instruments in a combined detergent and disinfectant that has no protein-fixing effect. Disinfectants containing aldehyde should be avoided, as they have a fixing effect. As regards concentration and exposure time, as well as the addition of cleaning intensifiers, the manufacturer’s instructions should be followed at all times.

Because of the corrosion risk and the cleaning factors, long intervals between instrument use and reprocessing (e.g. overnight or over the weekend) should be avoided, irrespective of the disposal method being used (i.e. wet or dry disposal). Field experience has shown that in the case of dry disposal, intervals of up to 6 hours pose no problem. Wherever possible, "dry disposal" should be preferred.

Instruments with rotating components must be processed using wet disposal or initially cleaned with a brush under running water. If these instruments can be reprocessed in a washer/disinfector, it is a prerequisite that they can be placed in machine-suitable stands (racks). During manual reprocessing, instruments with rotating components should be placed in a suitable container (disinfection container) for disinfecting and subsequently be cleaned. The same applies to root canal instruments.

Handpieces, angle pieces and turbines should be placed separately and preferably machine reprocessed in accordance with the manufacturer's instructions.

Effective cleaning requires that articulated instruments (such as scissors and forceps) be processed in the open position to minimize surface overlapping. The trays, racks, holders, supports, etc., must be such that subsequent cleaning in ultrasound basins or washer/disinfectors will not be hampered by areas inaccessible to ultrasound or water. Unused instruments on the dental instrument table must be treated in the same manner as used instruments during processing.

Special racks or appropriate storage fixtures must be used for easily damaged instruments.

Do not reprocess disposable instruments

To avoid damage to fine instruments, they must be transported in suitable containers with retainers.

Disposal instruments, e.g. polishers with lamellae, polishing brushes, should not be reprocessed. These instruments must be treated as dental practice waste in accordance with relevant regulations and guidelines.

6. Manual and Machine-Based Cleaning and Disinfecting

6.1 Manual Cleaning/Disinfecting Cleaning

Instruments in a combined detergent and disinfectant solution

For manual reprocessing, the instruments are placed in a solution of a combined detergent and disinfectant with proven disinfecting capability.

- Correct concentration
- Correct exposure time
- Correct temperature

For manual cleaning, active non-protein-fixing detergents with or without antimicrobial effect and/or enzymes are used. If disinfecting cleaning is required, the disinfecting capability should be proven under "dirty conditions" (high protein load) in accordance with European (EN) standards or corresponding national regulations.

Choose suitable detergent and disinfectant

As regards the detergent and disinfectant, the manufacturer’s instructions concerning concentration, temperature, and exposure time, as well as shelf life of the solution should be strictly observed. When treating non-stainless-steel instruments, the manufacturer’s instructions on material compatibility are of particular importance.

Observe material compatibility!

Material compatibility depends on the instrument material, the composition of the disinfectant, the temperature, the exposure time, the concentration, and the pH-value of the solution being used. Regards organic peroxo compounds, particularly disinfectants containing peracetic acid, compatibility greatly depends on the composition of the disinfectant and the specific conditions of use. When using disinfectants containing alkylamines, the chemical structure of the agent strongly influences material compatibility with regard to elastomers and adhesive/glued joints. In the case of silicone elastomers, extended treatment with alkylamine-based disinfectants may lead to hardening.

Disinfectants based on organic peroxo compounds or alkylamines must be categorized as "sensitive" in terms of instrument material compatibility. For this reason, the tested and validated instructions of disinfectant manufacturers must be strictly observed.

Incorrect concentrations and excessive exposure times may result in material damage.

If solutions are used for too long, the following problems may occur:

- Corrosion risk due to contamination levels
- Corrosion risk due to increased concentration of cleaning/ disinfecting solution as a result of evaporation
- Insufficient disinfection due to accumulated contamination (loss of active agent/protein effect)

Open articulated instruments

Articulated instruments must be placed into the solution open, thus minimizing obscured surface area.

Avoid air bubbles in hollow bodies

Narrow-lumened instruments such as flexible tubes and cannulas, and instruments incorporating cavities are always difficult to reprocess. This is why it is important to make sure that the internal surfaces are thoroughly and completely in contact with the solution.

Dissolve powders completely!

If powdery products are used, the powder must be fully dissolved in the water before immersing the instruments. Undissolved particles may cause surface damage and clog narrow instrument channels.

Immerse instruments completely

The instruments must be completely covered by the solution. Immersion baths should, therefore, not be overloaded.

We recommend using soft, lint-free cloths or towels, plastic brushes or cleaning guns for cleaning. Following manual cleaning or disinfection and cleaning, make sure to rinse instruments adequately and thoroughly with clear running water. This manual procedure removes dirt residues that may still adhere to the surfaces of the instruments.

Stains caused by high salt content of rinse water

To avoid water spots, use only fully demineralized water. The instruments must be dried carefully immediately after this procedure. Compressed air drying is preferred to other methods (such as drying with a cloth), as it is not only a very gentle, but also highly effective technique.

The main reasons for mechanical damage during manual reprocessing include:

- Use of metal brushes
- Use of coarse scouring agents
- Use of excessive force
- Dropping or bumping of instruments

Easily damaged instruments are especially prone to mechanical damage.

Treatment instruments, such as handpieces, angle pieces, and turbines, should never be immersed in a solution. They can be cleaned under running water with a brush and their external surfaces sprayed with a suitable disinfectant or wiped with a disinfectant. As regards cleaning their internal surfaces and taking appropriate reprocessing measures, please observe the manufacturer's instructions. Machine-based reprocessing methods are preferable.

Stand with instruments for root canal treatment

Instruments with rotating components are placed in an appropriate instrument rack and then immersed in a suitable cleaning and disinfecting solution. In the case of polishing, ceramic, or plastic-bonded abrasive tools, check first whether the agents used are suitable for these instruments. The use of unsuitable agents, e.g. alcohol-based formulations, could destroy bonding agents, endangering shaft fixation. Sonic tips are difficult to reprocess. Use a suitable tool, e.g. cleaning wire, to ensure patency (free passage, no obstructions). Further reprocessing must be carried out in accordance with the manufacturer's instructions.

Instruments for root canal treatment are highly susceptible to mechanical damage and should therefore be reprocessed separately and placed in special stands for handling purposes. For cleaning and disinfecting, remove the silicon stoppers in order to adjust the depth of preparation. If instruments for root canal treatment have colored, anodized handles, do not treat them with alkaline solutions, as this would impair or destroy their color-coding function.

6.2 Machine-Based Cleaning and Disinfecting

Cleaning and disinfecting can best be standardized when using machine-based processes. Always keep in mind that proper cleaning during instrument reprocessing is essential for retaining the value of your instruments as well as for successful sterilization. The International Standard (EN ISO 15883) and/or the national versions of that standard (e.g. DIN EN ISO 15883), and national guidelines state that only validated machine-based cleaning and disinfecting procedures should be used. The general requirements of washers/disinfectors (Ws/Ds) are stipulated in Part 1 of EN ISO 15883.

Machine-based reprocessing should preferably be preceded by dry disposal. With wet disposal (e.g. instruments with rotating components), the applied foam active detergent and disinfectant must be fully rinsed off. Foam can significantly reduce the rinse pressure during machine-based cleaning, thus impairing the result.

This also applies if heavily soiled instruments (filling material residues adhering to dental instruments, etc.) have been pre-treated manually or with ultrasound.

Ensure correct loading!

When using machine-based reprocessing, the following should be observed:

- To ensure effective machine-based reprocessing, all trays, inserts, holders, etc., must be loaded correctly.
- Articulated instruments must be opened for loading.
- Avoid overloading trays to ensure that all instrument surfaces can be readily accessed by the cleaning/disinfecting solutions. Always consult the established loading templates for validation purposes.
- When placing large instruments on trays, make sure that they do not obscure other instruments, thus preventing proper cleaning.
- Instruments with cavities or hollow spaces (e.g. turbines) need careful cleaning and rinsing on the inside as well. For this purpose, special (instrument-specific) inserts with appropriate rinsing facilities should be used.
- The instruments must be arranged in such a way as to prevent mechanical damage through contact.

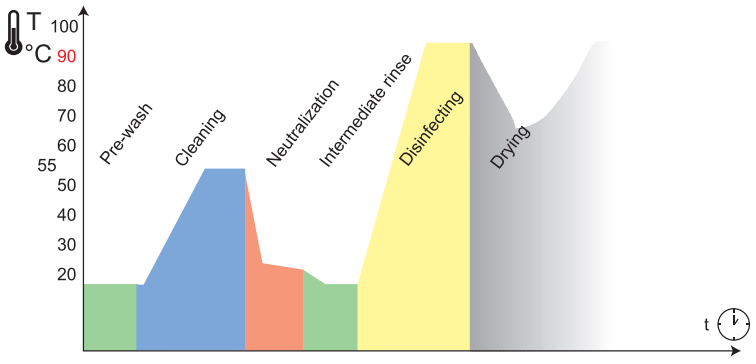
Severely attacked anodized aluminum stand

For instruments with rotating components made of carbide or stainless steel, it is recommended to carry out reprocessing in special stands (racks) to prevent damage to the blades.
Colored, anodized aluminum parts may fade as a result of machine-based cleaning, thereby losing their coding function (see section 11.10). However, if special detergents are used and fully demineralized water is employed for the final rinse (and for thermal disinfection), such instruments can be reprocessed and disinfected together with other instruments.

The items should be removed from the machine immediately upon completion of the program. If they are left in the closed machine, the residual moisture may cause corrosion.

As a rule, it is advisable to use processes where cleaning is carried out at a separate stage prior to disinfection. For machine-based reprocessing, both thermal and chemothermal disinfection options are available. As a rule, thermal disinfection is the better choice. Therefore, you should take the suitability of medical devices for machine-based reprocessing with thermal disinfection into account at the purchasing stage.

In thermal processes, disinfecting is carried out at temperatures above 65 °C for the corresponding exposure time. As a measure of the disinfecting capability, the Ao value has been introduced (EN ISO 15883-1, Appendix A). It determines the temperature-time relation as a function of microbiological contamination and the intended purpose of the medical devices involved (e.g. Ao = 3000 = 90 °C and 5 minutes exposure time). The program structure depends on the outcome requirements for cleaning, disinfecting, and rinse quality, and on the items to be treated. A machine-based reprocessing program with thermal disinfection typically includes the following steps or stages:



Use a suitable detergent!

1. Pre-wash
Cold water without any additives, to remove coarse dirt and foaming substances.

2. Cleaning
Hot or cold water; cleaning is usually carried out at temperatures of 40-55 °C for at least 5 minutes. Suitable, more or less alkaline products can be used for cleaning. The choice of detergent depends on the materials and properties of the instruments to be treated, the necessary cleaning efficiency, and on national guidelines and recommendations (e.g. as issued by the Robert Koch Institute in Germany).

3. First intermediate rinse
With hot or cold water. Adding an acidic neutralizer facilitates the removal of alkaline detergent residues. Even when using neutral detergents, it may be advisable to add an acidic neutralizer in order to prevent deposits (e.g. in cases where the water used has a high salt content).

Carry-over of detergent residues due to insufficient rinsing

4. Second intermediate rinse
With hot or cold water, no additives (use fully demineralized water if possible). Depending on the items to be processed and on the rinsing quality and safety level required, several intermediate rinses without additives will take place.

5. Thermal disinfection/Final rinse
Using fully demineralized water prevents spotting, stains, deposits and corrosion on the surfaces of the instruments. It also prevents the formation of crystals which can interfere with the sterilization process. If you add a final rinse agent to shorten the drying period, make sure to check the material compatibility of the processed items.

6. Drying
Sufficient drying must be ensured either through the washer/disinfector or by taking other appropriate measures. With regard to the process chemicals used, the manufacturer's instructions concerning concentration, temperature and exposure time should always be observed. This guarantees good results and keeps the instrument materials intact to the greatest possible degree. It must be possible to verify the automatic volume dosing of liquid process chemicals.

Instruments Requiring Special Treatment

Easily damaged instruments can undergo machine-based reprocessing, provided the instruments are safely held in place (e.g. by using stands or other suitable supports) and an effective rinsing method is used.

The following specific points need to be observed for certain instruments:

Drill bit stand

- Probes, periodontal (PA) and other easily damaged instruments must be placed in special holding devices for protection.
- Instruments with rotating components, such as drill bits, cutters, burrs or abrasive tools, are only suitable for machine-based reprocessing if it is expressly permitted by the manufacturer. They should be placed in special instrument stands that are suitable for rinsing. It may be necessary to carry out an additional pre-treatment by ultrasound.
- Instruments for root canal treatment should always be reprocessed in suitable instrument stands to prevent damage to delicate parts and to minimize the risk of injuries.
- Ultrasound and sonic tips with lumen for internal cooling must be connected to special rinsing adapters to ensure internal rinsing. To prevent corrosion, use fully demineralized water for the final rinse.

Handpieces and angle pieces

- Handpieces, angle pieces, and turbines can undergo machine-based reprocessing if it is expressly permitted by the manufacturer, the manufacturer's instructions are observed, and special rinsing fixtures are available for rinsing the turbine drive's spray, air channel and air infeed recirculation system. The same applies for spray channels (air and water) and the drive duct of motorized treatment instruments. For these instruments, there are also special devices with process-combined cleaning, care and disinfection.
- Mouth mirrors are subject to wear. For example, silver-backed glass mirrors may become dull as a result of machine-based reprocessing; rhodium-metalized mirrors, in contrast, are more resistant, but are easily damaged by mechanical impact.

Instruments with stubborn coagulation residues that cannot be removed by additional intensive cleaning (e.g. 3% hydrogen peroxide solution, brushes, ultrasonic bath) must be discarded, as proper functioning and hygiene can no longer be guaranteed.

6.3 Ultrasound

Ultrasonic device

Ultrasonic treatment is a very good choice to help with cleaning instruments made of stainless steel or hard plastic materials. Instruments sensitive to mechanical impact can likewise be gently and thoroughly cleaned and disinfected with the help of ultrasound. Powerful ultrasonic devices are able to dissolve encrustations in places that are difficult to access otherwise.

In principle, the same requirements apply for preparing the bath as for manual cleaning and disinfecting in an immersion bath. However, the following special conditions must be observed:

Filling level
The bath must be filled to the line

Suitable detergents and/or disinfectants
A suitable detergent or disinfectant must be added to the water.

Temperatures of 50 °C should not be exceeded, as it could result in blood encrustations.
Temperatures of between 40 °C and 50 °C support the cleaning efficiency. Depending on the used product, always pay attention to the manufacturer's instructions as regard concentration, exposure time, and temperature when cleaning and disinfecting.

Degassing
The freshly prepared disinfecting or cleaning solution requires degassing before initial use.

Timely replacement of the cleaning/disinfecting solution
A high level of contamination in the ultrasound basin impairs the cleaning capacity and increases the risk of corrosion. Depending on the specific conditions of use, the solution must be replaced at regular intervals in accordance with the manufacturer's instructions.

Preparing the bath

Apart from a properly prepared bath, the following basic rules should always be observed to ensure good cleaning results:

- The instruments should only be placed in suitable holders or baskets to ensure the effectiveness of the ultrasonic bath.
- The items to be treated must be fully immersed in the cleaning solution.
- Articulated instruments, scissors etc. must be opened in order to minimize the obscured surface areas.

- Do not overload trays.
- Hollow body instruments, such as suction tubes, must be placed in the ultrasonic bath at an angle to ensure any trapped air is removed, as it would otherwise reduce the cleaning efficiency.
- Blades should not have contact with metal parts.

Very important: Thorough rinsing!

After ultrasonic treatment, the instruments are either thoroughly manually rinsed or undergo machine-based reprocessing. The manual rinse can be carried out with fresh tap water, taking care that all detergent and disinfectant residues are completely removed in the process. To avoid water spots, we recommend using fully demineralized water for the final rinse.

Instructions for certain dental instruments

Handpieces, angle pieces, turbines, and other drives

Handpieces, angle pieces, turbines, and other drives should not be treated in an immersion or ultrasonic bath.

Instruments with rotating and oscillating components

Dental instruments with rotating components should only be treated with suitable detergents and disinfectants. Prior to ultrasound treatment they should be placed in special stands to avoid any contact damage between the instruments (e.g. via sharp cutting edges, diamond grains). The cleaning efficiency of an ultrasonic bath is limited for polishing and flexible instruments (polishing brushes, polishers), as the elasticity absorbs the ultrasound.

Instruments for root canal treatment

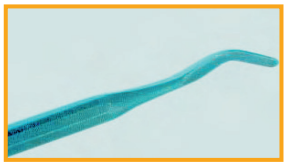
Instruments for root canal treatment with colored, anodized aluminum handles should not be treated in an alkaline solution, since their color coding function would be impaired or lost.

Chrome-plated instruments and aluminum instruments

Instrument stands or trays which are not made of stainless steel, but, e.g., of chrome-plated brass, anodized aluminum, or plastic, should only be used with suitable detergents and disinfectants.

Mouth mirror

Mouth mirrors can be damaged in an ultrasonic bath.



Corroded filling spatula. Cause: Material attacked by acidic cement remover

Acid detergents, e.g. cement removers, should only be used when absolutely necessary, as they cause corrosion on surfaces and at soldered seams.

7. Checks and Care

Blood residues on the grip of an instrument. Cause: Insufficient cleaning

Sufficient cleaning standards are absolutely vital for successful sterilization. Instruments to be sterilized must be macroscopically clean, i.e. free from visible residues. This is checked by visual inspection. Critical areas, such as handle structures, joints or jaw serration, require especially careful checking. It is advisable to use working lights with magnifying lenses when checking instruments. If there is doubt as to the level of cleanliness, particularly in the case of instruments with hollow areas, chemical tests for protein and blood must be carried out.

All instruments with lumens, such as cannulas, etc., must be checked for patency (free passage, no obstructions). Clogged instruments must be reprocessed. If this does not help, such instruments must be replaced.

Poorly cleaned instruments must be recleaned, disinfected, and then rinsed sufficiently.

Instruments with metallic friction surfaces, e.g. articulated instruments, must be lubricated before subjecting them to a functional test using a squirt oiler or via the precise application of drops of oil.

Maintenance or care means the targeted application of care agent to the joints, hinges, locks, threads or friction surfaces of instruments, such as clamps and scissors, after they have been carefully cleaned and disinfected. This minimizes metal-on-metal friction and therefore constitutes a preventive measure against corrosion caused by chafing.

Lubricating instruments with a spray can or drops of oil

This ensures the instruments are kept functional and the hinge action maintained.

Requirements for care agents for surgical instruments:

- Paraffin/White oil basis
- Biocompatible in accordance with the current European or United States Pharmacopeia
- Suitable for steam sterilization and vapor-permeable

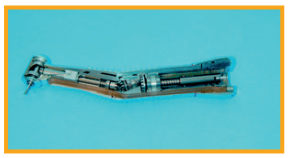
Instruments must not be treated with care agents containing silicone oil. This can adversely affect the instrument's functionality and also the steam sterilization results.

Proper performance of care measures:
Allow the instruments to cool down to room temperature before opening and closing the instruments, as otherwise metal abrasion might occur when the parts rub against each other. Such "fretting" would impair the instrument's ease of movement or even destroy its functionality altogether.
The care agent must be distributed evenly by operating the joints/ friction surfaces. Any excess care agent must be removed with a lint-free cloth.

Spraying the instruments or applying the care agent mechanically is neither sufficient, nor does it provide additional corrosion protection. Immersion baths should not be used because of the germ infestation hazard.

Never process plastic surfaces with instrument care agents.

However, there are some exceptions:



Internal design of handpiece and angle piece

- Handpieces, angle pieces, and turbines must be treated with special agents in accordance with the manufacturer's instructions due to their complicated internal design.
- As the various instruments are made for specific application purposes, the functional tests must be carried out so that items that fail to serve their intended purpose are reliably recognized and discarded. If in doubt, consult the instrument manufacturer for suitable testing methods.

Special storage of easily damaged components

- After the check, easily damaged instruments must be stored in special cassettes designed to prevent transportation damage. If indicated, suitable facilities should be employed to secure them against dislocation.
- Cutting instruments (periodontal instruments, excavators, gingival margin trimmers, sharp curette) must be resharpened at regular intervals. To ensure the correct sharpness and functioning, it is advantageous to resharpen the instruments after each use.

Resharpen cutting instruments

Regular resharpening can, however, cause a weakening of the material (reduced cross section). If there is a risk of these instruments bending or breaking under normal working pressure, they must be removed and discarded.

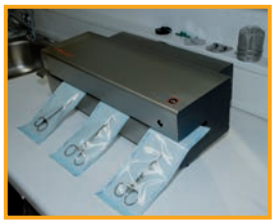
Blunt periodontal instrument

8. Packaging

International standard EN ISO 11607 Parts 1 and 2 apply to packed items requiring sterilization. The standard stipulates the packaging material (Part 1) and the validation of the packaging process (Part 2).

Sterile barrier system

The packaging for items for sterilization must be of a type representing a sterile barrier system. Its task is to prevent micro-organisms from entering the packaging and to enable removal under aseptic conditions. It must also be possible to open the package easily under aseptic conditions. The sterile barrier system represents a microbial barrier which prevents recontamination under specified conditions. Such conditions include:



Sealing sterile packaging with a sealer.

- Temperature
- Pressure
- Humidity
- Sunlight
- Cleanliness
- Pathogen contamination

Protective packaging

The protective packaging is additional packing designed to prevent damage from occurring to the sterile barrier system from the moment it is put together until the moment of use.

The sterile barrier system can be a reusable system (sterilizing container) or a disposal product (non-woven fabric, paper, transparent bag).

Containers and storage systems help to retain the value of instruments.

The packaging has a considerable effect on sterilization results. Therefore, the packaging system (sterile barrier system and protective packaging) must be compatible with the sterilization procedure. The packaging material must not absorb the sterilizing agent beyond a reasonable limit, and must not cause any alterations in the sterilizing agent. The sterilization process validation also investigates the suitability of the packaging. The processes involved in forming the pack, seal and composition that previously took place must also be validated. Whenever new materials are used that have not yet been properly validated, the performance assessment (validation) must be repeated.

Drying

To retain the value of the instruments, it is also important that they are sufficiently dried, because residual humidity can cause corrosion damage. If non-woven fabric is used, care should be taken to ensure that it does not interfere with the drying process.

Marking

It must be possible to mark and identify the package with information such as:

- Sterilization date
- Packer
- Expiry or "use before" date (if date has been defined)
- Contents

9. Sterilization

Within the scope of European (EN) standards, the application of sterile instruments on or in the patient requires proper cleaning and disinfecting, followed, if necessary, by sterilization in approved packaging, on the basis of a validated sterilization process. Following such treatment, the sterile items must be stored in accordance with the rules and provisions governing sterile supplies. Consequently, it is important to only use sterilization methods and sterilizers that allow validated sterilization processes. Sterilization accessories and packaging materials must be selected in accordance with the items to be sterilized as well as with the sterilization method being used. In this context, the user instructions for the sterilizer used must be strictly observed. In dental practices, steam sterilization is the method of choice!

9.1 Steam Sterilization

Checking the suitability and functionality of the sterilizer

Small steam sterilizer

Steam sterilization is performed with saturated steam, usually at 134 °C.

The sterilizer and the sterilization method must correspond to current standards and regulations.

Sterilizer types are divided into 3 categories in accordance with EN 13060 (European standard on small steam sterilizers):

Type B for wrapped, solid, hollow load and porous products
Type N for non-wrapped, solid instruments
Type S for products specified by the manufacturer of the small sterilizers

Note:
Type B for universal application
A **type B** sterilizer is recommended for universal application in dental practices. The following restrictions apply to the other types:

- **Type N** small sterilizers are not suitable for wrapped products and are, therefore, not usually appropriate for reprocessing items to be sterilized.
- **Type S** sterilizers are suitable for specific products, e.g. treatment instruments.

Stains on tweezers: Cause: Insufficient steam quality

Always adhere to the specified routine checks and maintenance regulations. The manufacturer's instructions must be observed.

Only use fully demineralized or distilled water in the steam sterilizer. The use of tap water will result in deposits and corrosion on the instruments and the sterilizer.

Stain formation due to "running" chemoindicators

If chemoindicators are used in large numbers in a sterilization batch, it may lead to stains on instrument surfaces, especially if there is direct contact between instruments. This particularly applies to silver products or products with silver-plated surfaces.

Ensure steam quality in accordance with EN 285 or EN 13060

If validated steam sterilization processes are used in accordance with ISO 17665 (or DIN 58946 Part 6 in Germany) and all process-relevant parameters, such as pressure, temperature and the proportion of non-condensable gases in the steam, are being documented, it is a good idea to use chemoindicators to detect sterilization. The sterilization steam used must be free from impurities and should neither impair the sterilization process nor damage the sterilizer or the items to be sterilized. To ensure this, the tolerances specified in the table of EN 13060, Appendix C, relating to the quality of the boiler feed water and the condensate should not be exceeded. Otherwise corrosion may result from contaminants, such as rust particles in the piping system, or discolouration caused by excessive silicic acid levels may appear on instrument surfaces.

Marbling caused by impurities in steam condensate

Contamination in the condensate of a steam supply for sterilizers, measured at the sterilizer supply line	
Substance/Property	**Condensate**
Silicates (SiO_2)	≤ 0.1 mg/l
Iron	≤ 0.1 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Heavy metal residues, except for iron, cadmium, lead	≤ 0.1 mg/l
Chloride (Cl-)	≤ 0.1 mg/l
Phosphate (P_2O_5)	≤ 0.1 mg/l
Conductivity (at 25 °C)	≤ 3 µS/cm
pH value (degree of acidity)	5 to 7
Appearance	colorless, clear, no deposits
Hardness ∑ (of alkaline earth ions)	≤ 0.02 mmol/l

Note: See 22.4 for the procedure for taking condensate samples.

Source: EN 13060, Appendix C, updated 2009

If the feed water contains large quantities of bicarbonate hardness, it increases the inert gas content of the sterilization steam and may adversely affect the sterilization result.

Corrosion hazards due to residual humidity/dampness!

Damp or wet containers pose instrument corrosion hazards. Poor and insufficient drying is frequently caused by incorrectly organized loading and the use of less suitable types of non-woven fabrics for drying. In principal, heavy sieves should be placed at the lowest level, so that the majority of the accumulated condensate can drain off directly.

In practice, residual moisture in the form of a few drops of water capable of evaporating within 15 minutes is tolerated, but actual pools of water are not acceptable. Even so, a few drops of water may cause some spotting. To prevent residual moisture altogether, consult the manufacturer of your sterilizer for relevant procedures.

Should separate treatment be required for dental instruments, the following instructions apply for steam sterilization:

- Instruments with rotating components (e.g. drill bits or burrs) can be steam sterilized.
- Handpieces, angle pieces, and turbines should be steam sterilized at 134 °C wherever possible to keep treatment time to a minimum.
- Mouth mirrors can be steam sterilized, but being subject to wear, will soon become dull as a result of the ingress of moisture. This is possible because of the different expansion coefficients of various materials.

9.2 Hot Air Sterilization

Although hot air sterilization no longer represents the state of the art, it is still being used in isolated cases. If sterilization is still carried out with a hot air sterilizer, the following instructions continue to be effective and must be observed:

At temperatures above 185 °C, paraffin oil will resinify. This destroys its lubricating properties and thus reduces the instrument's functionality.

Prescribed temperature should not be exceeded!

If the specified temperature is significantly exceeded, there is a corrosion hazard as well as the risk of loss of hardness. Consequently, functionality is compromised, making instruments useless in many cases. Similarly, plastics such as color rings may be adversely affected or even destroyed at higher temperatures.

To ensure uniform heat distribution in the sterilization chamber, and thus in the items to be treated, the sterilizer loading instructions must be strictly observed! Treatment instruments should never be hot air sterilized.

10. Storage

10.1 Storing Non-Sterile Instruments

Instruments stored in poor conditions can corrode. To prevent this they should be stored in dry and dust-free conditions. Major temperature fluctuations should be avoided to prevent the accumulation of moisture (condensate) on instrument surfaces. Chemicals may destroy metals when in direct contact with them, or may emit corrosive vapors. Never store your instruments near chemicals!

The storage of instruments must be organized in such a way that they cannot damage one another. Appropriate systems must be used to ensure this; such systems improve overall clarity of the organization, while also reducing the risk of injury to users. Closed storage systems are preferable in order to ensure additional protection against pathogens.

10.2 Storing Sterile Instruments

To guarantee the sterility of instruments until they are used on/in the patient, germ-tight packaging is absolutely essential. Further requirements for the protected storage of sterile supplies and the prevention of corrosion damage include a dust-free and dry environment and the prevention of temperature fluctuations. These conditions allow items to be stored for six months (or more). See DIN EN 868 and Table 1 of the German standard DIN 58 953, Part 9, for further details.

11. Surface Changes, Deposits, Corrosion, Aging, and Stress Cracks

11.1 Metal/Deposits – Organic Residues

During daily use and over time many medical devices are subject to surface changes due to chemical, thermal and/or physical impacts. If not directly caused by normal usage, the origin of such changes can usually be found in the reprocessing conditions. If surface changes occur, it is advisable to proceed systematically in the following order in order to remove and avoid surface damage:

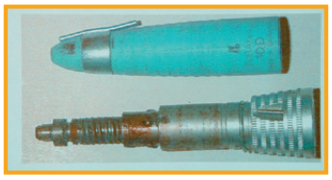
- Determine the nature, origin and cause
- Estimate the risks
- If necessary, process/treat the items in accordance with the manufacturer's recommendations to correct the changes
- Take appropriate measures to prevent re-occurrence, then validate your entire instrument reprocessing process

Reworking or repair of affected products only makes sense if the causes of the surface changes have been determined and eliminated. All examples given below are based on the systematic 4-step approach outlined above. These examples cover the most frequent surface changes in metallic instruments made of stainless steels and/or plastic products.

Type of surface change

Blood residues in the closed joint area. Cause: Instrument was closed for cleaning.

Clean in closed joint area
Reason: Instrument was open for cleaning.



Organic residues

Origin & causes

Rust and/or blood-colored deposits can often be seen. Immediately after the operation caused by operational residues (blood, protein) due to salt residues, due to drug residues.

- Dry residue because the interval between use and reprocessing is too long.
- Use of unsuitable instrument disinfectants.
- Transferred by contaminated detergents and disinfectants.
- Insufficient rinsing after cleaning.
- Insufficient cleaning efficiency caused by areas inaccessible to ultrasound when ultrasonic cleaning.
- Inadequate maintenance/servicing of the washer/disinfector.
- Fixing caused by water feed temperature being too high (exceeding 45 °C) in first water intake cycle.
- Ineffective rinsing (insufficient water flow through or around the instruments, insufficient rinse pressure, inaccessible areas)
- Insufficient cleaning efficiency due to foam formation, for example due to high amounts of blood or detergent and disinfectant residues carried over from the ultrasonic or immersion bath.
- Improper loading due to use of wrong instrument trolley/trays or overloading
- Insufficient cleaning efficiency, because the instruments/devices were not open and/or badly positioned.

Treatment recommendations

- Sufficient cleaning
- Regular replacement of immersion baths
- Recleaning with ultrasound
- Targeted manual recleaning
- Immersion in 3% H_2O_2 solution (approx. 5 minutes)

Preventive measures

- Remove all coarse contamination, especially salt solutions, immediately after treatment.
- Exclude factors that cause drying or fixing.
- Minimize drying by reducing the period between use and reprocessing (under 6 hours).
- The use of suitable aldehyde and alcohol-free disinfectants for wet disposal.
- Ensure cold water pre-rinse.
- Correction program sequence in washers/disinfectors.

Risk assessment

- Hygiene risk – danger of infection for patients. Can lead to corrosion even with stainless steel, as blood, for example, contains chloride ions. If present in higher concentrations, these ions cause pitting and/or stress-crack corrosion.

11.2 Metal/Deposits – Process Chemical Residues

Depending on the extent of the residues, instrument type, and surface quality, various sizes of bright-to-dark gray deposits / discolouration may appear. The ability to detect this can be reinforced even further by sterilization.

Type of surface change

Hollow handle with visible residues

Incorrect loading of a washer/disinfector

Origin & causes

Process chemicals that have not been removed sufficiently (inaccessible areas, incorrect loading) during the intermediate and/or final rinses.

Treatment recommendations

- Wipe off with a lint-free cloth.
- Acid-based cleaning with special detergents as recommended by the instrument manufacturer.

Preventive measures

Ensure sufficient intermediate and/or final rinsing with fully demineralized water or correct the loading. The manufacturer's instructions regarding disassembly and cleaning must be followed strictly!

Risk assessment

Discolored surfaces can also be caused by residues of process chemicals, as described in other sections.

11.3 Metal/Deposits – Spotting Caused by Lime

Type of surface change

Rinsing chamber with heavy lime scale deposits

Consequence: Instruments have lime scale residues

Stains/Discolourations of a milky white to gray color. Depending on specific conditions, these changes may extend across a larger surface or take the form of irregular spots with sharply defined borders, distributed across the instrument's surface (and/or the washer/disinfector's internal surfaces).

Origin & causes

Excessive lime in the water used for the cleaning stage or at the final rinse.

Treatment recommendations

- Wipe-off with a lint-free cloth.
- Acid-based cleaning with special detergents as recommended by the instrument manufacturer.

Preventive measures

- Cleaning and, if necessary, intermediate rinse with demineralized water.
- Use of fully demineralized water for the final rinse to prevent stain formation during machine-based reprocessing.

Risk assessment

- No corrosion, only aesthetic significance.

11.4 Metal/Deposits – Silicates and Other Mineral Compounds

Type of surface change

Typical silicate discolouration in the rinsing chamber and on the surface of the instrument caused by a detergent containing silicate, or excessive levels of silicic acid in the water.

Typical silicate discolouration on the surface of the instrument after steam sterilization caused by excessive silicic acid levels in the demineralized water.

Yellowish-brown to blue-violet discolourations of various forms, ranging from extended and rainbow-like tarnish to colored spots or droplet-shaped stains on instruments, washer/disinfectors and sterilization chambers.

Origin & causes

Silicic acid leakage during the production of fully demineralized water when using ion exchangers and reverse-osmosis water treatment equipment.

- Carry-over of detergent residues containing silicates into the final rinse of machine-based reprocessing due to insufficient intermediate rinsing.
- Other mineral substances contained in the final rinse water of machine-based reprocessing or in the steam condensate, e.g. copper from the pipework.
- Mineral deposits can be removed via acid-based cleaning using special detergents as recommended by the manufacturer.

Treatment recommendations

- Stubborn deposits (silicate build-up) can be removed with agents containing hydrofluoric acid.
- Mechanical surface treatment by the manufacturer.
- Implementation of repair work by a qualified repair service agent.

Preventive measures

Use silicic acid-free, fully demineralized water for final rinse during machine-based reprocessing. Prevent detergent carry-over by:

- Correct tray loading and proper positioning/fixation of items with hollow spaces in which liquids can accumulate (e.g. kidney-shaped bowls).
- Ensure correct functioning of dispensing equipment.
- Ensure sufficient neutralization and intermediate rinsing during machine-based reprocessing.
- Use water quality as specified in EN 285 (Appendix B, Table B1.) or EN 13060, Appendix C, for steam sterilization.

Risk assessment

No corrosion, only aesthetic effect; no hygiene risk.
The laser-lettered labels on instruments may be adversely affected (bleached) when treating them with acid-based detergents. The coding function may become illegible or even completely lost.

11.5 Metal/Deposits – Discolouration Due to Oxidation

Type of surface change

Retractors with dis-colored black shaft in hardened Cr-steel with the handle and blade remaining bright, made from non-hardenable CrNI steel.

Details of clamp: Lock and ring area

Discolored instrument handle made of titanium

A shiny, gray-black passive chromium oxide layer is only formed in the case of hardenable stainless steels, frequently initially identifiable with cutting instruments (e.g. scissors), but also in the case of blunt instruments (e.g. forceps, tweezers).

Origin & causes

In the case of titanium materials (pure titanium or alloys), surface discolouration may be formed with uniform varying coloration (e.g. gray, blue, violet, red, golden yellow, green) or with blotchy multicolor discolouration.

For the above mentioned hardenable stainless steels, in the case of machine-based cleaning by the neutralizer carried away in the last rinsing stage, and/or by other passive layer forming factors that have not yet been identified in the cleaning process. Passive layers may be transparent (is usual) to black in the case of stainless steels, depending on the composition, density and thickness. The tendency to form gray-black chromium oxide passive layers depends, in particular, on the ratio of chromium content/carbon content, alongside the influences of the material composition referred to above. In practice, this means that the higher the carbon content, the faster a gray-black discolouration may become visible.

In the case of titanium materials, damp heat and/or cleaning chemicals used in the various reprocessing stages may lead to oxidation of the surface and hence to discolouration of the surface. Titanium oxide deposits may be transparent or multicolored/colored depending on the composition, density, and thickness.

Treatment recommendations

Elimination of the problem is not recommended due to the properties of the deposit, but may be carried out by the manufacturer or a qualified repair service if necessary. In both cases, appropriate surface treatment is required (mechanical in the case of steel, chemical in the case of titanium). In the case of stainless steels,

removing the deposit with a basic detergent has no effect on account of significantly increased resistance to corrosion.

Preventive measures

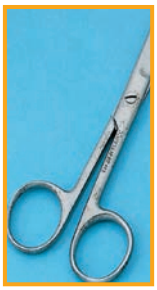
In the case of stainless steels, ensure precise dosing of the neutralizer. Exclude carry over of the neutralizer with adequate final rinsing. In the case of titanium materials, virtually unavoidable or not avoidable, since the nature of the material means it always reacts with the surface more or less visibly as a result of the ambient conditions prevailing during reprocessing (temperature, chemicals, humidity).

Risk assessment

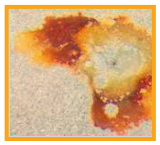
No corrosion – aesthetic effect If, in the case of titanium materials, any identification/coding function lost as a result of discolourations, e.g. color coding of the size of the medical device, does not present a safety risk, color changes due
to the formation of different properties of oxide layers is completely unproblematic. This means there are no restrictions as regards bio-compatibility, hygiene, functioning or service life.

11.6 Metal/Corrosion – Pitting Corrosion

Type of surface change



Scissors with pitting



Pitting on tweezers. Cause: Over-aging of color-coding band allows harmful substances containing chloride to infiltrate.

Examples of pitting

Pitting - seen under a scanning electron microscope - magnified 200 times

Pinprick-like corrosion holes in stainless steel, frequently microscopically small, surrounded by sparkling, reddish-brown or multi-colored corrosion spots, often associated with circular corrosion deposits around the corrosion hole. (Not to be confused with material-specific cavities or foreign-matter inclusions that may occur in low-quality instrument steels or with contact corrosion symptoms when only stainless steel instruments are used.)

Origin & causes

- In stainless steel, caused by exposure to halide ions (bromides, iodides and chlorides), but especially chlorides, that locally break through the passive layer of instrument steel, thus causing pitting.
- Dried-on organic residues, e.g. blood, pus, secretions (see section 11.1 Metal/Deposits - Organic Residues)
- Frequent pitting is due to the use of liquids with a high chloride content, or more specifically, due to dry residues of such liquids adhering to the instrument surfaces, e.g. if the concentration of chlorides in the final rinse water is too high or if residues of physiological salt solutions remain on the instruments.
- Brand new instruments are particularly susceptible to attack by media containing chlorides due to their still thin passive layer. Instruments that have been in use for some time are more resistant to chloride attack, because they have developed a thicker passive layer.

Treatment recommendations

Corrosion products can be dissolved with an acid-based detergent used in accordance with the manufacturer's instructions. The remaining corrosion holes may be treated mechanically (reworking either by the manufacturer or by a qualified repair service provider).

Preventive measures

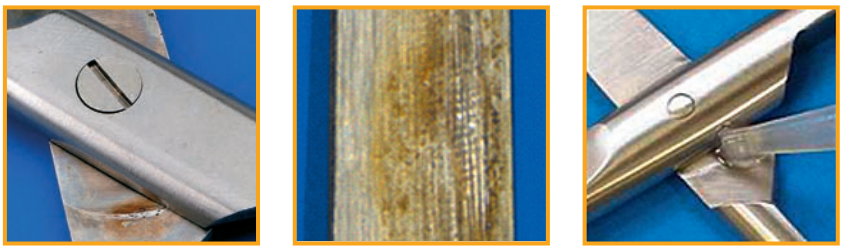
Chloride-induced pitting can usually be prevented by using low-chloride concentrations in the water used for processing, and by minimizing instrument exposure to other liquids containing chlorides, e.g. physiological salt solutions.

Risk assessment

- Heavily corroded instruments should be immediately withdrawn from service (and the instrument processing cycle) for reasons of patient and user safety.
- To retain the value of instruments, the causes of pitting corrosion must be eliminated.
- Corrosion holes can pose a hygienic hazard and may lead to stress corrosion cracking as well.

11.7 Metal/Corrosion – Wear Friction Corrosion

Type of surface change



Hinge area (scissors)

Brown stains/discolourations or rust formation around an area that has been chafed.

Origin & causes

Insufficient lubrication and/or foreign bodies lead to corrosion of the metallic friction surfaces that move relative to each other (especially in locks/joints and sliding paths of, e.g., punching instruments). This forms micro-abrasion, which can make the surface extremely rough and destroys the passive layer. In these sensitized areas, humidity or deposits (e.g. blood residues) can easily accumulate - a process that usually leads to corrosion.

Treatment recommendations

- Discard defective instruments or have them repaired if possible.
- Regrinding and/or polishing can usually repair corrosion damage.
- Repeated reworking affects the handling/controllability and thus the functionality of the instrument, making it useless.

Preventive measures

- Allow the instruments to cool down to room temperature.
- Proper instrument care and servicing = accurately applying a lubricant to the instrument prior to performing the functional check.
- Manually apply the lubricant directly to the joint area (using drops or spray).
- Distribute the lubricant uniformly in the joint by opening and closing the instrument in the joint area several times.

- Lubricants suitable for instrument care must:
- be based on, for example, liquid paraffin (paraffin oil)/white oil.
- conform to currently valid pharmacopeia.
- be vapor-permeable/suitable for steam sterilization at the boundary surface between the material and the oil film.
- Jamming of the joints due to accumulated lubricant must be prevented.

Risk assessment

Impairs or completely destroys the instrument's functionality. Fretting corrosion may lead to pitting.

11.8 Metal/Corrosion – Stress Corrosion Cracking

Type of surface change

Detail: Scissors hinge joint with typical intercrystalline crack.

Detail: Jaw clamp with typical grainy, intercrystalline fractured structure.

Electrolytic/Anodic stress-crack corrosion (or stress corrosion cracking) usually leads to visible cracks and fractures.

In some cases, crack formation is not visible because its origin is hidden according to circumstances (e.g. in the joint of a pair of scissors), possibly with crack propagation to fracture.

Very frequently, the non-deformed and possibly hidden fracture surfaces are indicative of the growth of the crack (typically associated with corrosion products).

Origin & causes

This type of corrosion often affects areas or components subject to high tensile stress

- due to design and/or manufacturing reasons (such as rivet or screw connections, welded or soldered connections or so-called press fit connections)
- Stress corrosion cracking can also be caused by improper repair work (e.g. application of inadmissibly high straightening forces)
- Cleaning/Reprocessing the item in a state of high tension (e.g. when the ratchet is fully closed).
- Processing overstressed or strained instruments in a corrosion-promoting environment, especially at higher temperatures.
  The main cause of corrosion is water containing chlorides, but treatment residues, sodium chloride, and drugs, etc. must also be taken into account.

Treatment recommendations

- None (cannot be corrected)

Preventive measures

- Clean jointed instruments in an open position and sterilize them with the ratchet locked in the first tooth.
- Reduce the chloride load to a minimum (e.g. reduce blood and drug residues; use only suitable water for reprocessing, final rinsing, and sterilizing).
- Overstressing due to improper handling.
- Have your instruments repaired only by the manufacturer or a qualified and specially authorized repair service provider.

Risk assessment

- For reasons of patient and user safety, withdraw affected instruments from service and from the instrument processing cycle at once!
- To retain the value of your instruments, eliminate the cause of corrosion.

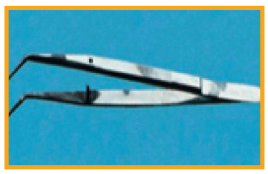
11.9 Metal/Corrosion – Surface Corrosion

Type of surface change

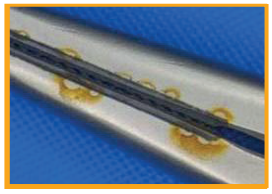
Corroded drill bit made of tool steel. Cause: Material is not suitable for machine-based cleaning without a corrosion protection layer.

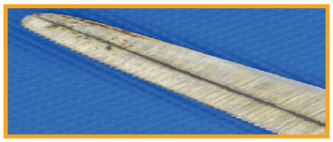
Corroded scissors made of stainless steel. Cause: Subsequent damage due to an acid attack caused by overdosing of the basic detergent.

Corroded, worn out carbide drill head made of TC/CO. Cause: Application of an acid detergent.



Left: Partial material attack due to acidic cement remover, and on the right due to a hemostatic agent. Cause: Excessive contact period or insufficient removal after use.





Corroded soldered seam on a carbide needle holder and carbide scissors. Cause: Phosphoric acid attack caused by overdosing the neutralization agent.

Severe material attack on the natural and color anodized aluminum surfaces of an instrument stand and containers. Cause: Overdosing of the otherwise material-compatible alkaline wash solution.

- On stainless steel there is usually a uniform, matt-gray surface attack that quite often leads to subsequent damage in the form of corrosive deposits.
- A matt-black surface forms on products made of unalloyed steel or tool steel, e.g. old instruments with a dislodged or damaged galvanized protective layer (chrome/nickel-plated) or drill bits. This also leads to subsequent damage in the form of corrosive deposits. Tools with sintered carbide drill heads made of cobalt bonded

tungsten carbide (TC/CO) are discolored black and become worn extremely quickly. Soldered connections at instruments with carbide inserts turn dark and rust-brown corrosion products can build up on surfaces.

- In naturally anodized surfaces, whitish-gray/powdery corrosion products initially form, caused by the dislodged anodized surface.
- In color anodized surfaces, there is a uniform/partial loss of color intensity. This can result in crater formation in cases of strong attack.

Origin & causes

Chemical and electrochemical influences only in connection with an excessive acid content with:

- stainless steel
- soldered connections
- TC/CO sintered carbide tools
- a long-term impact of water/moisture (condensate) in the case of stainless steel, tool steel, and unalloyed steel
- an excessive load due to acids or alkalinity with anodized aluminum (natural/color anodized surfaces).

Treatment recommendations

- Mechanical reworking of stainless steel surfaces without/with soldered connections by a qualified repair service provider if the damage is not application or safety relevant.
- Not possible for TC/CO or anodized carbide tools.

Preventive measures

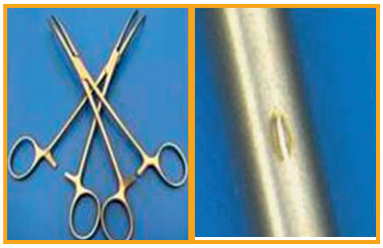
- When using stainless steel instruments without/with soldered connections, always observe the application recommendations for acid detergents and neutralizing agents. When using soldered instruments, always observe the application recommendations for acid detergents and neutralizing agents.
- Discard disposable products or old instruments with a damaged or dislodged unalloyed steel corrosion layer and drill bits made of tool steel and, if necessary, replace them with stainless steel products.

Risk assessment

- Affected instruments or irreparable instruments must be discarded due to the risk of transfer (subsequent rust/extraneous rust) to intact instruments. Immediately scrap affected TC/CO carbide drill bits, as there is a risk of metal abrasion in the oral cavity.
- The decorative appearance and the abrasion resistance of anodized surfaces change, resulting in increased wear.

11.10 Metal/Corrosion – Contact Corrosion

Type of surface change



Contact corrosion: Stainless steel/Stainless steel

Contact corrosion: Stainless steel/Brass

When using only stainless steel instruments, small dot or ring-shaped, brownish-blue discolourations with slight corrosion in the contact areas can occur. This type of contact corrosion is frequently mistaken for pitting. Upon closer examination however, it becomes clear that there is no hole in the center of the corrosion spot. Rather, the surface structure is slightly rubbed smooth in these areas.

Origin & causes

The classic variant of contact corrosion occurs in a material combination involving stainless steel and non-ferrous metals (German silver, brass, copper). Depending on the ambient conditions, e.g. humidity, this generally also leads to corrosion deposits in the contact areas and usually beyond them as well. When using only stainless steel instruments, contact corrosion has so far been observed only after the machine washing cycle. Microfriction at the contact points leads to partial abrasion of the passive layer. Thus the corrosion protection is temporarily removed in these places, which in turn leads to the surface changes described above.

Treatment recommendations

In the classic material combination stainless steel/brass, when the instrument stock typically contains old and new instruments (old/chrome-plated and new/stainless steel instruments), this type of corrosion occurs during cleaning as well as during sterilization, due to a damaged and/or incomplete chromium or nickel layer (e.g. in the case of sharp curettes with hollow handles or retractors).

When only stainless steel instruments are used, there is no need to remove contact corrosion symptoms, because such surface changes, due to their low severity (i.e. quantity of deposits involved), pose no risk either to the affected instruments or to other, unaffected items. Experience shows that such surface symptoms usually disappear after a few reprocessing cycles. Acid media (neutralizing agents) usually dissolve these deposits at once, which in turn accelerates the passivation process.

If contact corrosion occurs as a result of protective layer damage in nickel or chrome-plated instruments, there is usually no remedy. If in doubt, contact the instrument manufacturer.

Preventive measures

Avoid vibration when cleaning (e.g. ultrasonic treatment, machine-based reprocessing) stainless steel instruments (e.g. by ensuring that the cleaning/disinfecting apparatus, or washer/disinfector, stands firmly on level ground).
Replace nickel or chrome-plated instruments which have damaged (scaly, peeled-off) protective layers with stainless steel instruments.

Risk assessment

As experience shows, there is no risk for affected or unaffected items when only stainless steel instruments are used, since the low amount of deposits is insufficient to cause damage. Nor is there a patient hazard in this case. However, when both stainless steel and non-ferrous instruments are used, considerable damage can be caused to intact instruments, depending on the extent of the protective layer damage involved.

11.11 Metal/Corrosion – Extraneous and Film Rust/Subsequent Rust

Type of surface change

Left-hand filter holder showing particulate corrosion. Cause: Heavy corrosion on sterilizing chamber results in light and subsequent corrosion damage

Ruts on drill bits.
Cause: Reprocessing of a disposable instrument

Origin & causes

- Individual, irregularly dispersed rust particles.
- Brown, mostly locally limited corrosion deposits (rust formation).
- Given large-surface contact with very rusty products, subsequent damage in the form of "instrument impressions" may occur.
- Rust particles carried over from the pipework.
- Use of water containing iron or rust, or use of steam containing rust particles.

- Corrosion products (rust) that adhere to non-corrosion-resistant disposable products made of steel, such as drill bits, may be dislodged during the sterilization process and dispersed over other instruments.
- Reprocessing of non-corrosion-resistant steels (often old instruments) whose protective layer has been damaged or completely dislodged.

Treatment recommendations

Given a slight and only superficial attack, removal of the deposits with acid-based cleaning may be an option (only for stainless steels), but it is necessary to check afterwards whether the instrument surface is still intact. Provided the damage is still superficial, it may be possible for the instrument to be treated mechanically (reworked) by the manufacturer or a qualified repair service provider.

Preventive measures

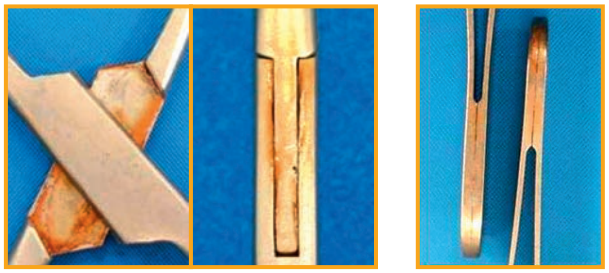
- Disposable items made of steel must not be reconditioned.
- Discard, or treat separately, any non-stainless instruments and materials.
- Avoid using cheap products (e.g. accessories available in DIY stores).
- Carry out effective construction measures to prevent pipework rust particles from entering the cleaning and sterilization stages. (For example, by filtering the feed water mechanically before it enters the washer/disinfector or sterilizer).

Risk assessment

- A single rusty instrument may be enough to cause subsequent corrosive damage in all of the instruments contained in the tray.
- If rust particles are carried over from the pipework, many of the instruments processed may be affected and thus lose value.

11.12 Metal/Corrosion – Crevice Corrosion

Type of surface change



Joint area - Clamp hinge area - Ends of tweezers

Since crevice corrosion is a locally-accelerated type of corrosion, it leads to corrosion deposits only in crevice areas; (e.g. in the joint crevice of the two halves of a pair of forceps, in joint gaps, or in pressed-in or screwed-in working ends, as in the case of probes, for example). Crevice corrosion can also occur in gaps between metal and other materials.

Frequently residues (particularly organic ones) are mistaken for crevice corrosion.

Origin & causes

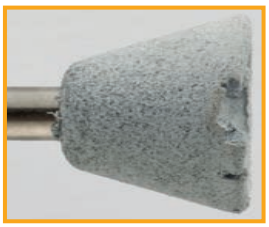
Crevice corrosion tends to occur in gaps of critical width if the prevailing ambient conditions are favorable (e.g. insufficient drying). Under these conditions the passive layer is vulnerable to attack. It can no longer regenerate, as the oxygen supply to the metal surfaces is impeded. The rust then works its way out of the gap or crevice. Rust formation occurs in the presence of humidity and higher salt concentrations.

Treatment recommendations

The spread of rust to other instruments is usually excluded. In severe cases, however, the rust might affect intact instruments and cause subsequent damage there as well (also see "Extraneous and Film Rust/Subsequent rust").

11.13 Rubber/Embrittlement

Type of surface change



Polisher chipped at the distal end

Origin & causes

Rubber compounds may be attacked when using unsuitable detergents and disinfectants. This reduces the elasticity and damages the composite materials, resulting in premature wear/defects.

Treatment recommendations

None (cannot be corrected)

Preventive measures

Application of suitable process chemicals in accordance with the manufacturer's instructions.

Risk assessment

Discard the affected product if it no longer fulfills its intended purpose efficiently and safely.

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    Sterilization of health care products

13. ASTM A 380 – 06
    Standard practice for cleaning, descaling, and passivation of stainless steel parts, equipment, and systems

14. EN ISO 17664: 2007
    Information to be provided by the manufacturer for the reprocessing of resterilizable medical devices

15. ISO 14937: 2000
    Sterilization of health care products - General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

16. DIN 13940-1: 1990-04
    Dentistry, dental handpieces; coupling dimensions

17. ISO 3964: 1982-12
    Dental (drill) handpieces; coupling dimensions (for connection to drive)

18. DIN Pocket book 100: 2009
    Medical Instruments

19. DIN Pocket book 169: 2008
    Sterilizers, Requirements of devices

20. 93/42/EEC Council directive dated 14 June 1993 on medical devices Gazette of the European Communities L 169, 36th year, 12 July 1993

21. UW BGV A1 and Government Safety Organization Rules, such as BGR 250, BGR 206 issued by the Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege (Government Agency for the Prevention of Occupational Risks in Health Services)

22. Current version of the VAH list of disinfectants tested in accordance with the guidelines for testing chemical disinfectants, and approved by the German Association of Hygiene and Microbiology as being effective disinfecting procedures (including hand decontamination and hygienic hand-washing procedures).

23. Current version of the list of disinfectants and procedures tested and recognized by the Robert Koch Institute

24. European Pharmacopeia

25. Gray booklet "Trials and Statements" publication of AKI, 1999

26. Returned goods at medical Institutions, facts sheet Treatment Recommendations, BVMed

27. RKI recommendation
    Hygiene requirements for the sterile reprocessing of medical devices. Recommendation; Federal Health Gazette, 44/2001, 1115-1126

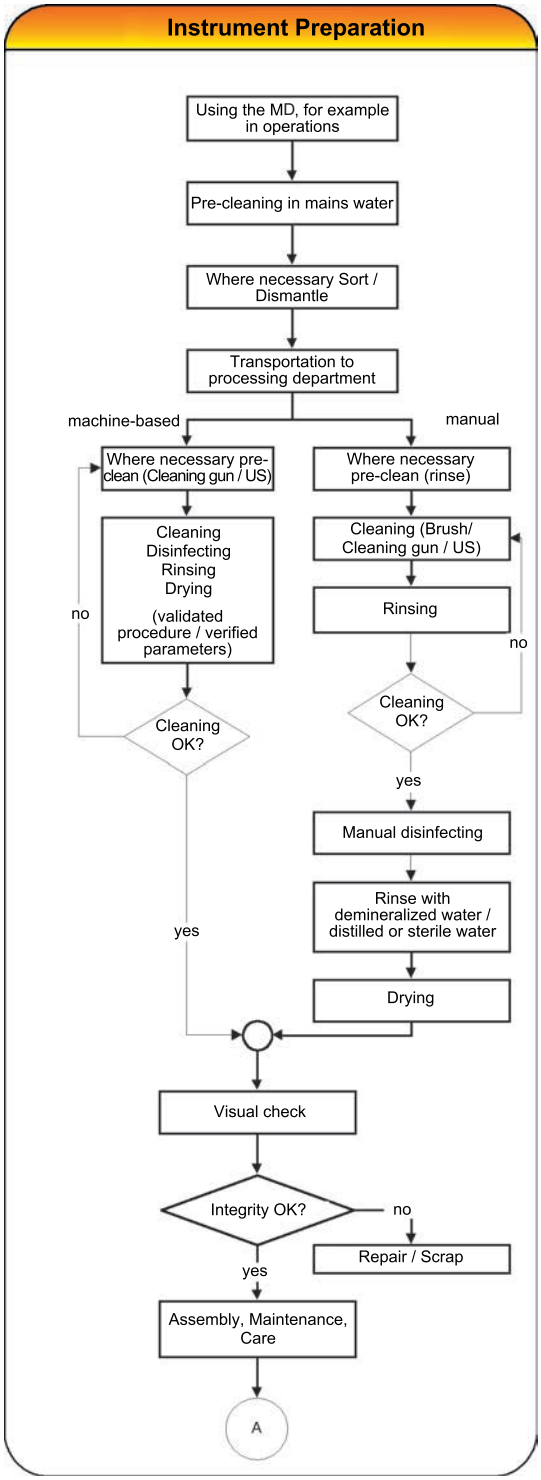
28. EN ISO 10993-1, 2009-03
    Biological evaluation of medical devices

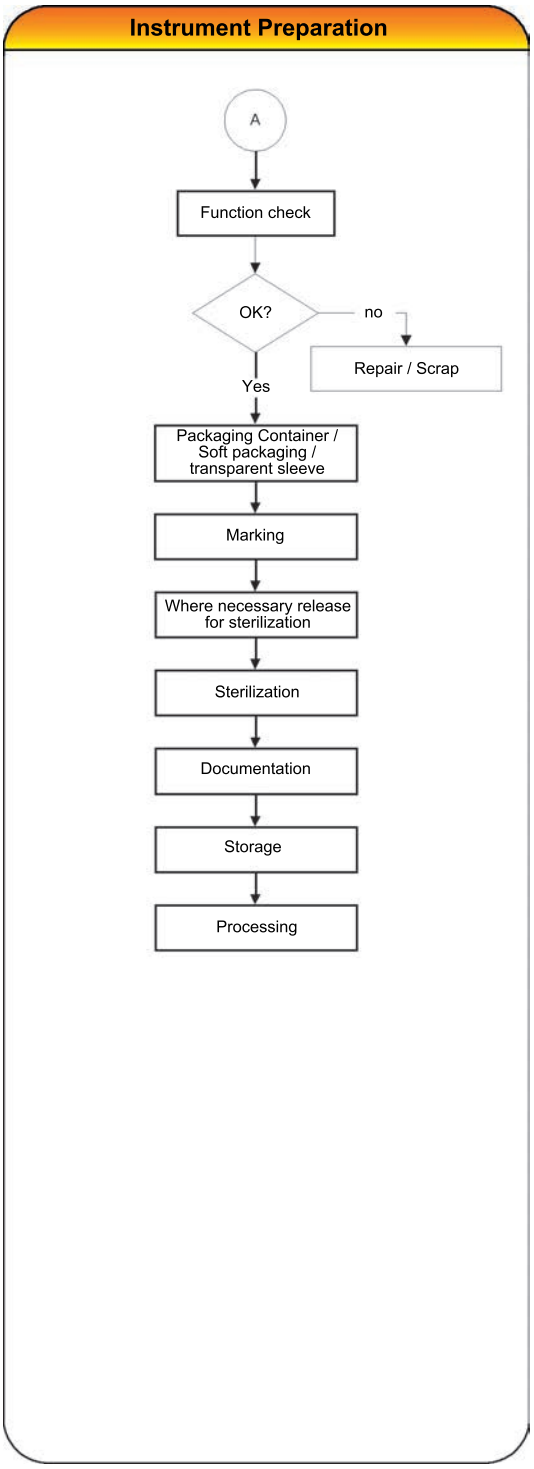
29. EN 14885, 2007-03
    Chemical disinfectants and antiseptics

30. DIN 58946, Sterilization - Steam sterilizers -
    Part 6: Operation of large sterilizers at healthcare facilities

31. EN 285: 2006 Sterilization
    Steam sterilizers, Large sterilizers

13. Schematic flow chart as per EN ISO 17664





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Notes: