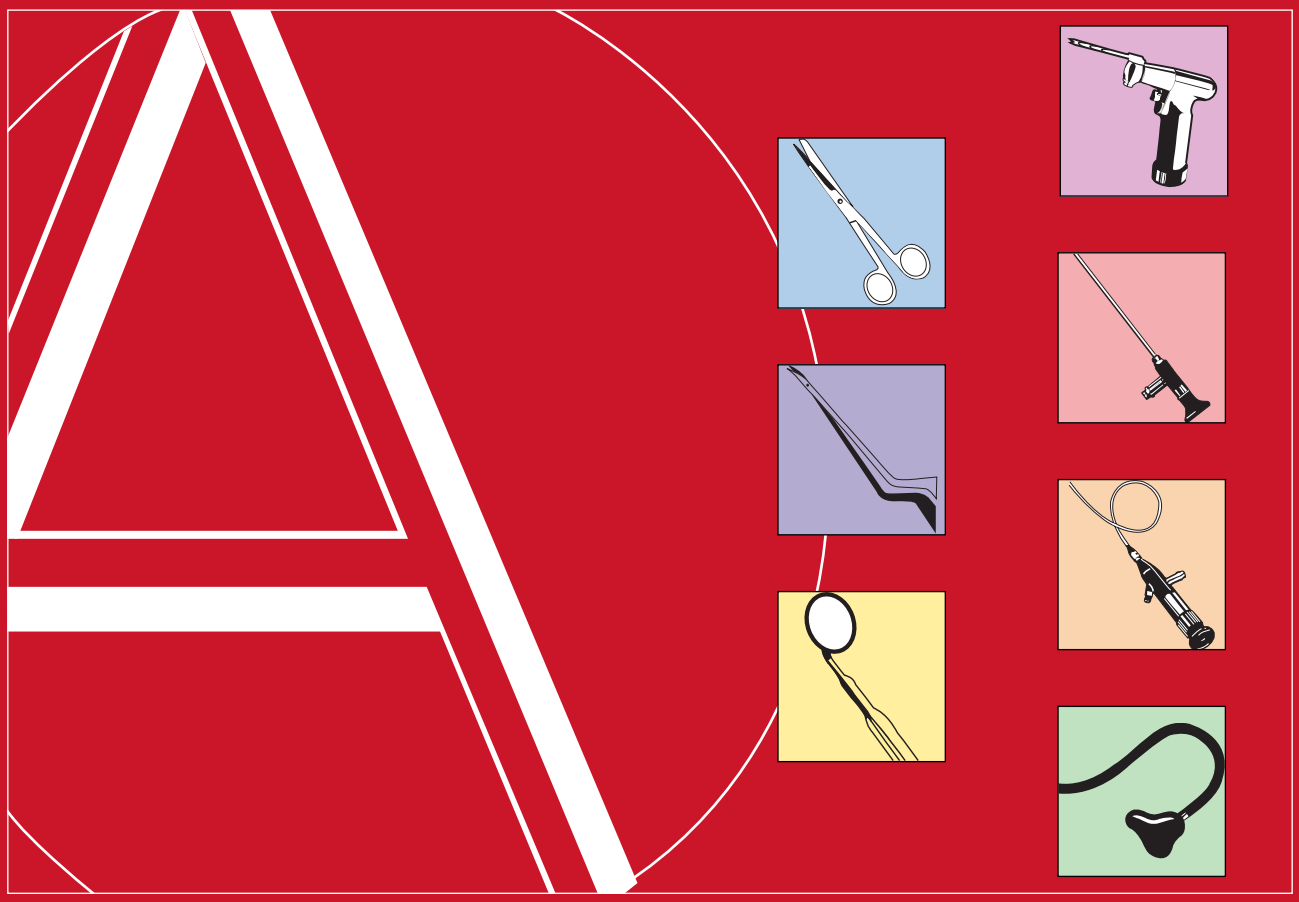
Instrument Reprocessing

Reprocessing of Instruments to Retain Value



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Working Group
Instrument Reprocessing

Reprocessing of Instruments to Retain Value

10th edition 2012
Surgical instruments
Microsurgical instruments
Dental instruments
Surgical motor systems
MIS instruments, rigid endoscopes and HF instruments
Flexible endoscopes and accessories
Flexible instruments and respiration systems

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Reprocessing of Instruments to Retain Value

Table of Contents

Preface

33 years after the appearance of the first edition, this is now the 10th edition of "Reprocessing of Instruments to Retain Value". This new edition is clear proof of its importance, and also of the great interest shown in this "Red booklet".
Its international relevance is reflected in the fact that the previous version has been published in 19 languages, and other language versions are planned.

The first edition appeared in 1979 and must have seemed very advanced then, at a time when the concept of "Central Sterilization" was still in its infancy. Since then reprocessing has undergone major changes.

Instrument reprocessing has developed from a small appendage to the operating room into an independent Central Sterile Supply Department (CSSD)

- a move away from an open area with wildly conflicting different activities and procedures, to a department that is strictly divided into different zones;
- a move away from mainly manual working towards automated instrument and device preparation;
- a move away from the unrestricted and uncontrolled reusing of medical instruments that should be disposed of after use, to responsible reuse of instruments, or even a ban on such reuse;
- a move away from the use of chemical and biological indicators towards physical validation of sterilization processes;
- a move away from a quality check at the end of the sterilization process towards permanent monitoring of each step of the decontamination process; and also
- a move away from untrained staff to highly qualified personnel.

In other words, sterile preparation has developed from a department concentrating on the sterilization process to a department with a wholistic "reprocessing" approach.

However the fact that all these changes have taken place does not mean that there is no room for further improvement. Quite the opposite.
The introduction of traceability and quality systems, centralization of those specialist departments – including outside of the hospital – in combination with more economical and ecologically sustainable methods, as well as the appraisal of a range of measures, poses new challenges.

It is obvious that the CSSD endeavors to provide a highly professional service in the hospital environment, as is expected. Quite rightly, old procedures and working methods are being reassessed. The traditional rules of thumb are no longer acceptable; all our activities should be underpinned by science.

The Instrument Reprocessing Working Group has without doubt made an important contribution to this development of the CSSD into an exemplary department such as we see today.

The aim of this development and the core activity of the CSSD is, and continues to be, to supply medical products of the best possible quality for the healthcare settings and for the patients. This should take place in a reproducible manner.

Although the title of this booklet appears to indicate otherwise, in fact it deals appropriately with every aspect of the reprocessing of surgical instruments. The main benefit is that it concentrates on the important information. Basic facts are discussed and explained clearly, plainly and in practical terms.
As a consequence it takes special account of what actually happens in daily practice.
All this has contributed to the fact that this booklet has become a standard work, frequently consulted within sterilization departments, regardless of the stage of development they might have reached.

The booklet has contributed to solving a wide variety of reprocessing problems, and continues to do so today. Quite rightly, it concentrates on "cleaning" - one of the most important steps in the decontamination process.

Every contribution, however small, that helps to improve the quality of the end product is a step in the right direction. However, in practice instrument reprocessing is a way-marker, pointing the way towards a standardization of processes in sterilization departments throughout the world.

Wim Renders
President, World Forum for Hospital Sterile Supply (WFHSS)

Foreword

Instruments are a major asset and represent a significant share of the total capital investment of a hospital. The practical experience recorded in this booklet, together with a description of fundamental interrelationships, is intended to help users to keep their reusable medical products 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 medical products legislation, and is harmonized in many countries.

In addition, there are direct legal requirements that need to be observed, such as the German "Betreiberverordnung" (Operator Regulations), which implement 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 management system.
This "Red Booklet" is structured according to the procedures applied in reprocessing, and incorporating the provisions of EN ISO 17664. It can therefore be integrated into a process-oriented system.

This 10th edition extensively updates text and photographic content.
In particular, its chapter 2, "Media for Instrument Reprocessing", has been completely revised. The new chapter 13 includes a glossary explaining the key terms used in the booklet.

A cross-check has also been conducted comparing reprocessing procedures focused on retaining the value of instruments against US AAMI* standards. This has resulted in a number of additions the "Red Booklet" at various points.

* Association for the Advancement of Medical Instrumentation

Introduction

Each chapter starts with handling instructions for surgical instruments, and subsequently general instructions for the product groups below are described. Special instructions for these product groups are given under the following symbols.


Surgical instruments


Flexible endoscopes and accessories


Microsurgical instruments


Flexible instruments and respiration systems


Dental instruments*


Surgical motor systems


Minimal invasive surgery instruments, rigid endoscopes and instruments of high-frequency surgery (HF)

* For detailed information relating to preprocessing of dental instruments, please refer to the yellow AKI booklet "Proper Reprocessing of Dental Instrument".

However, one should keep in mind that these product-specific instructions must always be seen in the context of the general instructions given for all instruments in a particular section.

Contrary to the widely held view that stainless steel is indestructible and permanently resilient, it must be stated that it is in fact susceptible to a wide range of potential mechanical, thermal or chemical attacks.

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.

Microsurgical instruments require particularly careful reprocessing.
Due to the requirements of the applications, these instruments are very delicate and incorporate very delicate and fine filigree parts.

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

The same applies to individual components of surgical motor systems, especially those that may be used only under sterile conditions and therefore need to be cleaned and resterilized after use, such as accumulator and compressed-air driven devices or handpieces.

Other instrument groups for which this booklet provides special reprocessing guidance are MIS instruments, rigid endoscopes, HF instruments, flexible endoscopes and elastic instruments.

Needless to say, users of medical products 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 products 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.

Disposal 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 products comprises:

- Preparation (pretreatment, collecting, precleaning and, where applicable, taking the instruments apart).
- Cleaning, disinfecting, rinsing, drying (if required).
- Visual inspection of cleanliness and acceptable 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 products 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 products], 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 (W/D) 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 medical product failure might endanger the patient or third parties. We urge you to consult the manufacturer if you have any doubts.

Automated reprocessing with thermal disinfection and steam sterilization should be preferred to other methods in the case of thermostable medical products.

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

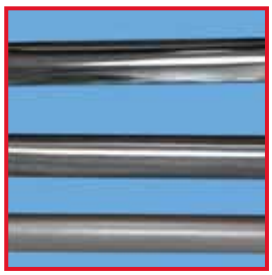
1. Materials and Design

1.1 Materials

When producing medical products, the manufacturer must design them to be fit for their intended use not only in design, manufacture and surface 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

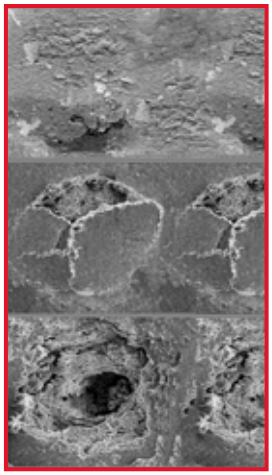


Surface finishes on instruments

The corrosion resistance of stainless steel primarily depends on the quality and thickness of the passive layer. This is a protective layer of iron/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 material/alloy,
- Microstructure of the material, which is influenced by heat treatment (e.g. forging, tempering, annealing, welding, soldering),
- Surface condition, e.g. roughness or cleanliness,
- 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 halogenides (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". 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".

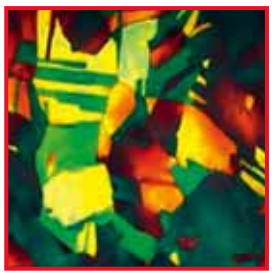
Reactivation salt containing chloride caused massive pitting on the surface of the instrument. Leaking ion-exchanger connection in the W/D.

As a result of chemical passivation by the manufacturers, for example supported by dip processing in a citric acid mixture, and as the service life progresses, the passive layer increases in size. 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 area of the supply).
- Insufficient demineralization of the water used for the final rinse and steam sterilization.
- Reactivation salt carry-over, leakage or spillage from ion exchangers used for water softening.
- Use of agents not permitted for or incorrectly used during reprocessing.
- Isotonic solutions (such as physiological salt solutions), etchants and drug residues.
- Organic residues (body fluids such as blood, chloride content 3,200-3,550 mg/ltr, saliva, sweat) dried on the surfaces.
- Laundry, textiles, packaging materials.

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 processed in the same cycle with older instruments, the reason can probably be found in the instrument reprocessing conditions. In all cases investigated so far, treatment had taken place under conditions that individually or collectively approached or exceeded the limits of process security.



Color etching - austenitic microstructure on rust 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 and EN ISO 16061. Their mechanical properties are limited however, so that the use of these steels is restricted to certain types of instruments.

For instruments used in endoscopy and minimally invasive surgery, a great variety of materials is employed, 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.
- Cobalt-chromium alloys.
- Carbide metals, such as sintered metal, tungsten carbide with nickel binding phase, cobalt-chromium base alloy.
- Non-ferrous heavy metal alloy with surface finishing (e.g. chromium-/nickel-plated brass).
- Coatings (e.g. titanium aluminum nitride, titanium aluminum carbonitride, zirconium nitride and titanium nitride)
- Light metals (e.g. anodized aluminum).
- Non-corrosion-resistant steels (e.g. for coated assemblies and components).
- Glass (for optical systems).
- Ceramics.
- Cements and other adhesives.
- 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 reprocessing treatment apart from standardized instrument reprocessing. These are described in the manufacturer's instructions.

The design and application requirements of flexible instruments and respiration systems also make it necessary to combine a variety of materials (which are more or less identical with those used for endoscopes). Here, the most frequently used materials are rubber and latex (based on natural rubber) and various synthetic materials, especially silicone elastomers (or silicone rubber).

For surgical motor systems, the full range of materials described in this guide is used, because of the design and manufacturing requirements involved. Stainless, heat-treatable chromium steels, for example, are used for drill bits, cutters, burrs, saw blades and gear components, while sterilizable plastic materials are usually used for handles, switches, gear components or cables and flexible tubes.

Special reprocessing treatment 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). For appropriate treatment recommendations, please refer to the manufacturer's instructions. In addition to special reprocessing treatments, 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 products is of extreme importance for patient and user safety. During the design and development stage of a medical product 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 product can be dismantled as much as possible. But there are limits here too. It is possible to dismantle many medical products only with great difficulty - for example jointed instruments used in minimally invasive surgery with diameters of less than 3 mm, because users are unable to dismantle and reassemble these filigree-thin 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. A further requirement of the materials selected is the alkaline resistance at the places in special applications where prior contamination is possible.

To achieve optimum reprocessing results, close cooperation is essential between all the parties involved: from the medical product manufacturer, the manufacturers of washers/disinfectors and sterilizers, to the manufacturers of process chemicals. When purchasing medical products it is recommended that those responsible for reprocessing instruments are included in the process at an early stage.

2. Media used 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 treatment process, including:

- Dissolving cleaners and other process chemicals.
- Transferring mechanical forces and heat to the instrument surface.
- Dissolving soluble dirt and impurities.
- Flushing process chemicals.
- Thermal disinfection for automated reprocessing.
- Medium for steam sterilization.

Use correct water quality!

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

Water constituents and their influence in reprocessing

While any natural water contains dissolved salts, their types and concentrations in drinking water vary depending on the source area of the water and how it is collected.
The water constituents may cause the following problems:

Minerals causing water hardness (calcium and magnesium salts)	Scaling, lime deposits due to calcium and magnesium salts
Heavy and nonferrous metals, e.g. iron, manganese, copper	Brownish red scaling
Silicates, silicon dioxide	Glaze-like colored appearance, thin scaling
Chlorides	Pitting
Evaporation residue	Spotting and scaling

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.

Aluminum might be attacked by softened water.

Image page right: Corrosion of black anodized instrument surfaces by softened water.

Minerals causing water hardness
Depending on water hardness and temperature, minerals causing water hardness 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.

Heavy and nonferrous metals
Heavy and nonferrous metals and their compounds in the water can lead to colored scaling even at low concentrations.

Silicates
Silicon dioxide and silicates may cause yellowish brown or bluish purple discolorations even at low concentrations.

Chlorides
Chlorides dissolved in the water are particularly critical substances, as they tend to cause pitting even on stainless steel instruments if present in higher concentrations.

Chlorides are dangerous

Pitting induced by chlorides on instrument.

The danger of chloride-induced pitting generally rises with:

- An increase in the chloride content,
- An increase in temperature,
- Decreasing pH value,
- Increasing exposure time,
- Insufficient drying,
- Increasing concentration by evaporation 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.

Evaporation residue

When water evaporates, some substances contained in it remain as visible mineral evaporation residue. These may result in spotting and/or corrosion. Owing to the substances in the water, the natural drinking water cannot be recommended for all reprocessing steps. The drinking water should be softened or demineralized depending on the application. The following methods are applied:

Water treatment methods

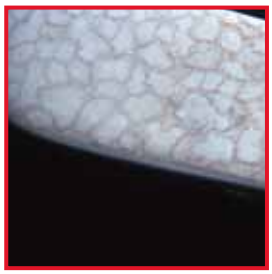
Water softening

In the water softening process, the calcium and magnesium cations, which are the substances causing the water hardness, are replaced by sodium ions. This does not reduce the overall load of evaporation residue in the water however. When using softened water, alkalinity can greatly increase due to the formation of sodium carbonate depending on the temperature, time and carbonate hardness in the initial water.

Full demineralization

In the full demineralization process, all mineral substances are largely removed from the drinking water. The methods used to do this are reverse osmosis as well as cation and anion exchangers, including in combination, and in special cases also distillation.

Substances contained in the water used, such as silicon dioxide, may cause discolorations.



Spotting caused by
silicon dioxide in the steam condensate.

Example of water qualities in comparison:

	Drinking water		Softened water		Demineralized water
Evaporation residue (ppm)	500		530		5
Elec. conductivity (µS/cm)	650		700		3
Total hardness (°d)	14		< 0.1		< 0.1
Sodium salts (mg/l)	20		160		< 1
Chlorides (mg/l)	40		40		< 1
Silicates (ppm SiO_2)	12		12		< 0.1
pH value	6.7		8		5.5

Requirements for water qualities:

Special requirements in terms of water quality may need to be met depending on the reprocessing step being executed (see chapters 6, 7 and 10).

Softened water:

Based on experience in automated instrument reprocessing, the following guide values are recommended:

Total hardness: < 3 °d (< 0.5 mmol CaO/L)
Total salt content: < 500 mg/l
Chloride content: < 100 mg/l
pH value: 5-8

Attention: When using softened water, especially when applying thermal disinfection in the final rinse, anodized aluminum surfaces might be subject to attack due to an increased pH value.

Use fully demineralized water for the final rinse!

Demineralized water:

For steam sterilization, limit values for feed water quality conforming to EN 285 and ISO 17665 are required:

Contamination in the supply water to an assigned steam generator	
Substance/property	**Feed water**
Evaporation residue	≤ 10 mg/l
Silicates (SiO_2)	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Heavy metal residues, except for iron, cadmium, lead	≤ 0.1 mg/l
Chlorides (Cl)	≤ 2 mg/l
Phosphates (P_2O_5)	≤ 0.5 mg/l
Conductivity (at 25 °C)*	≤ 5µS/cm
pH value (degree of acidity)	5 to 7.5
Appearance	colorless, clear, no deposits
Hardness ∑ (of alkaline earth ions)	≤ 0.02 mmol/l

Note: Recognized analytical procedures must be used to ensure compliance.

Source: DIN EN 285 (+A2), Version 2009

* At variance to this table, experience has shown that electrical conductivity of approximately 15 µS/cm can be tolerated.

Since there is currently no specific standard regarding the use of demineralized water in automated reprocessing, we recommend the boiler feed water quality as defined in DIN EN 285, Appendix B also be applied in reprocessing of medical products.

Application guidance:
We recommend using demineralized water for the final rinse for the following reasons:

- No spotting
- No increase in concentration of corrosive constituents, e.g. chlorides
- No dried crystalline residues which could have a negative effect on the downstream sterilization process.
- Protection and stabilization of anodized aluminum surfaces

To optimize the process and to achieve consistent quality of results, we recommend that you use fully demineralized water at all steps of the program.

If ion exchangers are used in the production of fully demineralized water, glaze-like discolorations may occur as a result of silicon dioxide passage (see chapter 12.4).
Quality monitoring of the fully demineralized water by way of monitoring of electrical conductivity is not adequate for identification, as the silicon dioxide does not imbue the water with conductivity.
Practical experience has shown that silicon dioxide passage may occur even at electrical conductivity of approximately 1 µS/cm. To minimize this risk, an inline configuration of two mixed-bed ion exchangers has proved successful. This inline configuration downstream of a reverse osmosis unit optimizes the production of fully demineralized water with no silicon dioxide content.

An expert should be consulted in any case.

In order to meet requirements in terms of the microbiological qualities used in instrument reprocessing, national recommendations should be followed.

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.

- Cleaners, neutralizing agents, rinsing and care agents are classified as class I medical products and are identified by the CE mark on the label.
- Process chemicals exerting a disinfecting effect are classified as class II a for the disinfection of medical products and class II b for the disinfection of invasive medical products. This are linked by a CE mark with a four-digit number identifying 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, disinfecting effectiveness, or the care properties, taking into account compatibility with the materials used (see chapter 1) to manufacture the instruments, as well as the bio-compatibility with any adhering residues in contact with 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 ISO 10993 "Biological Assessment of Medical Devices".

Optimum application properties, material compatibility and bio-compatibility of the process chemicals are assured only under the application conditions recommended by the manufacturer. The manufacturer must describe the application conditions in a relevant document (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 confirmations of material compatibility, effectiveness, ecological properties and bio-compatibility.

The ingredients of various process chemicals may interact. For example, in an automated process the constituents of a detergent can have a negative effect on the effectiveness of a disinfectant if they are entrained into the downstream disinfection step. As this aspect must be taken into consideration by the manufacturers of the process chemicals in testing effectiveness, it is recommended that only inter-coordinated process chemicals from a single manufacturer should be used in a closed automated reprocessing cycle. Constituents of pretreatment agents

can also cause interactions with process chemicals used in a automated process, such as scaling, so manufacturers' directions should be followed.

2.2.1 Types of process chemicals

Pretreatment agents:
Pretreatment agents may be detergents or anti-microbial - e.g. bacteriostatic or disinfectant - products which are applied prior to a manual, or preferentially automated cleaning and disinfection procedure, for example as foam sprays, wet disposal products, etc.

Detergents:
Using detergents restricts contamination of a medical product to a degree necessary for further reprocessing or application. Detergents are employed for both manual and automated reprocessing procedures. A basic distinction is made between:

- pH-neutral detergents with/without enzymes
- mildly alkaline detergents with/without enzymes
- alkaline detergents with/without tensides
- detergents with an anti-microbial effect (combined detergent and disinfectant products).

Disinfectants:
Disinfectants are employed both for manual and - preferentially - automated reprocessing to provide final disinfection for thermolabile medical products, such as flexible endoscopes. Disinfectants contain germ-killing agents and combinations of such agents. They reduce the number of viable micro-organisms on a surface to a level suitable for further handling or use.
Preferred active agents in final disinfectant products are oxidizing substances and aldehydes which act based on chemical reactions with the micro-organisms. These substances have the necessary range of effectiveness to effect final disinfection even at room temperature. Examples of the aldehyde group of substances are formaldehyde, glutaraldehyde or ortho-phthalaldehyde. The key agents in the group of oxidizing substances are hypochlorous acid, chlorine dioxide, hydrogen peroxide as well as peracetic acid and its salts.
Active substances with different action mechnisms do not have the necessary range of effectiveness to effect final disinfection at room temperature. This disadvantage can be compensated in specific cases by increasing the temperature, which results in increased material stresses, particularly of plastics and adhesive compounds. Examples of these agent groups are alcohols, alkylamines, guanidines, or quaternary ammonium compounds.

Neutralizers
Acidic substances based on citric acid or phosphoric acid which can be added to the initial rinsing water in automated reprocessing following alkaline cleaning in order to neutralize alkalinity and enhance rinsing of the detergent.

Rinse aids
Rinse aids are added to the final rinsing water in a automated reprocessing procedure to achieve more effective, faster drying. The active agents in the rinse aids reduce the surface tension of the rinsing water and so minimize adhesive residual moisture.

Care products
Care products for surgical instruments with metallic friction surfaces which need lubrication are made of paraffin oil (paraffinum perliquidum) and emulsifiers. Other care products, such as for anesthesia utensils, may also be silicone oil-based.

2.2.2 Properties and assessment of constituent substances

Caustic alkalis
may be constituents of alkaline detergents (calcium hydroxide, sodium hydroxide) and decompose organic dirt residues by their alkalinity.

Anti-microbial agents
Aldehyde-based disinfectants, such as formaldehyde, glutaraldehyde and ortho-phthalaldehyde, are preferentially used for final disinfection at temperatures up to 60 °C. In this temperature range they are usually highly compatible with instrument materials. Due to their fixing properties on proteins, combined detergents and disinfectants based on these agents are not recommended for cleaning.
Alcohols are used in large quantities in disinfectants as anti-microbial agents, or in smaller quantities as solvents. Most instrument materials are highly compatible with alcohols at room temperature. When using aromatic alcohols, such as phenoxyethanol, at higher temperatures for final disinfection damage to adhesive compounds has been described, especially in the case of flexible endoscopes.

Alkylamines aid cleaning in addition to their anti-microbial effect. As a result, they are particularly well suited for use in combined detergents and disinfectants for pretreatment and cleaning of instruments. In this group of agents material compatibility - particularly with elastomers and adhesive compounds - is heavily influenced by the chemical structure of the agent, which means some products are excluded from the

reprocessing of flexible endoscopes. In the case of silicone elastomers, extended treatment with alkylamine-based disinfectants may lead to hardening.

Chlorine dioxide is used for final disinfection, particularly of flexible endoscopes, in automatic disinfection machines as a two-component system. Depending on the product composition, changes in the material of endoscopes, such as discoloration of the black insertion section, are possible which may be merely of a cosmetic nature. Shortened service lives of plastics and adhesive compounds cannot be ruled out if this agent is used.

Depending on pH value, peracetic acid and its salts can be used both as combined detergents and disinfectants and as final disinfection products. Material compatibility depends heavily on the composition of the disinfectant and on the operating conditions, such as pH value, agent concentration, and temperature. For this reason, the tested and validated instructions of the manufacturers must be strictly observed.

Quaternary ammonium compounds and guanidine compounds are preferentially used in combined detergents and disinfectants. They exhibit good material compatibility. Agents from this substance group tend to be adsorbed on plastic surfaces, which can result in scaling if surfaces are inadequately rinsed after cleaning. Owing to their range of effects, using only agents from this substance group for final disinfection is not recommended. If these agents are used for final disinfection in combination with aromatic alcohols at higher temperatures, damage to adhesive compounds in endoscopes has been described.
Hypochloride acid is formed in automatic disinfection machines by an electrolysis process and is used for final disinfection, particularly of flexible endoscopes. Material compatibility depends heavily on the pH value of the application solution and on the concentration of the agent. In some cases additional measures (coating) have been recommended to protect plastic components on endoscopes. Depending on the operating conditions, shortened service lives of plastics and adhesive compounds cannot be ruled out if this agent is used.

Hydrogen peroxide is used in isolation or in combination with per-acids in combined detergents and disinfectants, in final disinfection products, and for low-temperature sterilization. At room temperature the agent is highly compatible with instrument materials in the concentrations usually employed. At higher temperatures and under different application conditions, the agent must be classified as sensitive in terms of its material compatibility, owing to its oxidizing properties. For this reason, the tested and validated instructions of the manufacturers must be strictly observed.

Enzymes
such as protase, amylase and lipase are proteins which catalytically decompose dirt, such as protein, carbohydrates and fats under mild application parameters, making them soluble in water.

Complexing agents
deactivate substances causing hardness in the water and support the cleaning effect in detergents.

Oxidation agents
are based on hydrogen peroxide, for example, or on sodium hypochlorite, and are able to decompose particularly stubborn organic dirt residues.

Paraffin oil
A care constituent of instrument care products used to prevent friction corrosion on instruments with metallic friction surfaces.

Phosphates
Phosphates are used to soften water. Their dirt-carrying capacity supports the cleaning process.

Phosphate substitutes
Phosphate substitutes, such as gluconates and phosphonates, complexify water hardness but can only partially substitute for the cleaning-supporting properties of phosphates.

Acids (citric and phosphoric acid)
Citric and phosphoric acid preparations are used as neutralizers, but can also be used as acid-integrated cleaning stages in automated reprocessing treatments.

Silicates
provide corrosion protection, such as for light metals, in alkaline detergents.

Silicone oils
are recommended as care substances for anesthesia utensils.

Tensides
Tensides in detergents reduce the surface and boundary layer tension, and as a result their emulsifying and dispersive effects support cleaning and prevent redeposition. Suitable tensides in machine cleaners evaporate foam, such as is caused by high levels of blood contamination. Moreover, tensides with corresponding biocompatibility as the main constituents of rinsing agents reduce the surface and boundary layer tension of the rinsing water and so improve drying of the medical products being reprocessed.

3. How to Treat Brand-New and Repaired Instruments

Preparation

Brand new instruments, including their instructions for use, and instruments returned from repair must be routed to the CSSD as soon as possible and removed from their transportation packaging before storing and/or introduction into the instrument usage and processing cycle. Any protective caps or foils 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 lubricants) could result in the formation of stains or deposits during sterilization.
Always visually inspect cleaning results. It should be emphasized that the recommended Instruments must be visibly clean.
The passive layer of brand new instruments is usually still thin and these instruments, therefore, tend to be more sensitive to critical reprocessing conditions than used instruments.

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, microsurgical instruments should be stored in suitable racks or retainers right from the start.

Flexible instruments must be stored in their original packaging in a dry, cool and dark place. When restocking your supplies, keep in mind that flexible instruments made of rubber or latex will age even if stored unused. Functional parts of respiration systems frequently incorporate valves or diaphragms which tend to become blocked by internal surfaces sticking together during longer storage periods. Always test valves or diaphragms before using instruments.

4. Procedure Recommendation for Returned Goods

In our context, returned goods are defined as packaged medical products 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 removed implants for scientific investigation or damage analysis, etc.
Return shipments must be carried out promptly, in accordance with the manufacturer's instructions. 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 handling processes.

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

- have been cleaned, disinfected and dried in accordance with the manufacturer's instructions, and have been declared hygienically safe, and/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.

This type of collective declaration (such as the BVMed notice in Germany, see literature reference no. 27) 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.

In addition, the following information on the individual medical product must be included in the accompanying documentation:

- Application of the medical product
- Decontamination method
- Date of reprocessing
- Name of reprocessor
- Reason for return

5. Preparation for Cleaning and Disinfecting

The first steps in a proper reprocessing cycle are taken in the operating theatre. Coarse contamination, residues from hemostatics, skin disinfectants and slip agents, as well as caustic drugs should, wherever possible, be removed before the instruments are set down.

Chlorides are dangerous

Corrosion caused by immersion in physiological salt solution over a period of several hours

Never deposit stainless steel instruments in an isotonic solution (such as physiological salt solution).
This is because prolonged instrument contact with saline solution leads to pitting and stress corrosion cracking.

Careless dropping can also damage instruments. For example, the hardened (tungsten carbide) tips of scissors may come off, or small clamps may be bent. To avoid damage, always put your instruments down carefully after use. Do not overload instrument trays. Waste, skin disinfectant residues, saline solutions etc., may not be put in disposal containers.

Deformation caused by improper handling

In hospitals with a Central Sterile Supply Department (CSSD), (also called Sterile Processing Department - SPD), closed systems are used to transport contaminated medical products from the operating rooms and wards to the CSSD. Wherever possible, so-called "dry disposal" should be preferred.

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.

Avoid long intervals between use and treatment for reuse!

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.

The instruments must be placed into instrument carriers (e.g. trays, racks) that are suitable for automated cleaning procedures.
Effective cleaning requires that hinged instruments (such as scissors, clamps, 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 acoustic or spray shadows.
Complex instruments must be taken apart for cleaning in accordance with the manufacturer's instructions. Instruments not used for surgical intervention must be treated in the same way as instruments that were actually used.

Special racks or appropriate storage fixtures must be used for microsurgical instruments, and where appropriate load carriers using specially adapted spraying technology.

Dental materials adhering to dental instruments (such as filling materials or acid cement removers) must be cleaned away immediately after use. Otherwise, the material will harden on the instrument and/or cause corrosion. Dental cement must preferably be removed with a swab immediately after use at the patient's chair.

Surgical motor systems must be taken apart immediately after use, following the manufacturer's instructions. If the manufacturer's instructions call for special storage systems in readiness for automated reprocessing, such systems must be used.

Simple tools, such as drill bits or saw blades, can be processed in the same way as surgical instruments, provided that they are not categorized as disposable (single-use) medical products.

To avoid damage to fine instruments, they must be transported in suitable containers with retainers. MIS instruments, endoscopes and HF instruments that can be taken apart must be disassembled in accordance with the manufacturer's instructions prior to reprocessing. Optics must be placed in special containers.

Deformation caused by improper handling

Dried-on residues are particularly critical in relation to instruments for operative endoscopy, as dirt residues in tight lumens are difficult to remove and may result in lack of joint function. This is why these instruments should always be reprocessed immediately after use. If the available methods and processes make cleaning problematic, to remove coagulated residues from HF instruments pretreatment with a 3 % hydrogen peroxide solution is recommended. HF instruments for robotics must not be treated with hydrogen peroxide solutions. It is advisable to fill these instruments with enzymatic detergent solution prior to disposal.

Handles and cables for HF surgery can be pre-treated in the same way as surgical instruments.

In the case of flexible endoscopes, the insertion part must be wiped with a lint-free cloth immediately after use. This cloth should be saturated with an instrument-cleaning, cleaner-disinfectant solution which has no protein-fixing effect. To avoid encrustation and clogging, the discharge duct as well as other channels should also be rinsed with the same solution. To rinse the air/water channel, water from the rinsing bottle can be used.

Before entering the next stage of reprocessing, a leak test must first be carried out in accordance with the manufacturer's instructions. This ensures the early detection of leaks and perforations and the prevention of more serious damage (as could be caused by penetrating liquids).
A defective endoscope must be returned to the manufacturer immediately, together with a description of the problem. If it has not been sufficiently cleaned and disinfected, this must be clearly and visibly indicated on the liquid-tight packaging.

Flexible instruments and respiration systems must always be taken apart (in accordance with the manufacturer's instructions) to ensure proper reprocessing for reuse. Make sure to handle cones, sealing surfaces, threaded connections and valve plates carefully, protecting them from mechanical damage.
Prior to reprocessing, absorbers must be checked for respiration deposits (respiratory lime deposits). Any such residue found must be completely removed from the absorbers.

Sensors may only be treated in accordance with the manufacturer's instructions.

When using wet disposal, flexible instruments with lockable cavities (such as larynx masks, certain other masks) must be closed.

6. Manual and Automated Cleaning and Disinfecting

6.1 Manual Cleaning/Disinfecting Cleaning

For manual cleaning, active non-protein-fixing process chemicals with or without anti-microbial 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.

As regards detergents and disinfectants, the manufacturer's instructions concerning concentration, temperature and exposure time should always be strictly observed! When treating non-stainless-steel instruments, the manufacturer's instructions on material compatibility are of particular importance. The cleaning/disinfecting solutions used should be freshly prepared on a daily basis. Where contaminations levels are high, it is advisable to prepare fresh solutions at even shorter intervals.

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 interference).

Hinged instruments must be placed into the solution open, thus minimizing obscured surface area. Narrow-lumened instruments such as flexible tubes and cannulas, and instruments incorporating cavities are always difficult to process. 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 changes and clog narrow instrument channels.

We recommend using soft, lint-free cloths or towels, plastic brushes or cleaning guns for cleaning. For cavity instruments the type and size of brushes recommended by the medical product manufacturer must be used. 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 prevent water spots, use only fully demineralized water, which is microbiologically at a minimum of drinking water quality. The relevant water treatment systems must be serviced in accordance with the manufacturer's instructions. The instruments must be dried thoroughly immediately after rinsing. Compressed air drying is preferred to other drying methods (such as drying with a cloth), because 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 too much force,
- Dropping or bumping of instruments.

Microsurgical instruments are especially prone to mechanical damage.

Dental instruments can usually be treated in the same manner as surgical instruments. For dental instruments requiring special reprocessing, please see the following instructions:
Handpieces and turbines should never be immersed in a solution. Instead their external surfaces should be sprayed with a suitable disinfectant or wiped with a disinfectant. As regards cleaning their internal surfaces, and taking appropriate maintenance and care measures, observe the manufacturer's instructions.

Dental instruments with rotating components not manufactured from stainless steel may be immersed only in special disinfecting and cleaning solutions that are specifically suitable for their materials. To prevent corrosion, a short rinse is followed by immediate drying and treatment with an anticorrosive agent suitable for sterilization. In the case of ceramic or plastic-bonded abrasive tools, check first whether the cleaning agents used are suitable for these instruments. The use of unsuitable cleaners and disinfectants could destroy bonding agents, endangering shaft fixation.

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 which serve to adjust the depth of preparation. If such instruments have colored, anodized handles, do not treat them with alkaline solutions because this would impair or destroy their color-coding function.

Motor systems must be wiped with a cleaning surface disinfectant. Apart from lint-free cloths, soft brushes can also be used for cleaning in these

cases. After spraying the surfaces with a disinfectant and allowing time for the spray to take effect as specified by the manufacturer, the surfaces are wiped clean. Following cleaning and disinfecting, make sure to rinse the surfaces under running water, holding the handles at an angle in order to prevent water from penetrating into the couplings or other components. Never immerse these products in water or other treatment solutions! In the case of accidental ingress of liquids, these must be removed at once.

Avoid ingress of liquids!

In the case of battery-powered machines, be sure to remove the batteries prior to cleaning and disinfecting. Moreover, avoid direct contact between electrical components and the cleaning/disinfecting solution. For potential battery cleaning and disinfecting, refer to the manufacturer's instructions.

When using compressed air to dry machines and handpieces, make sure that you never point the compressed air gun at bearing seats or at the seals, since such action can damage the bearings and seals. Simple reusable tools can be treated like surgical instruments.

MIS instruments and rigid endoscopes are susceptible to mechanical damage.
Systems or components with cavities and channels/ducts must be treated with particular care to ensure effective cleaning.

Minimum requirements include:
- Removal of all gaskets.
- Opening of all stop cocks.
- Disassembly in accordance with the manufacturer's instructions.
- Rinsing of all cavities.

Rinsing forceps with irrigation connection

When immersing such instruments in a cleaning/disinfecting solution, make sure that the cavities are free from air bubbles so that all the inner surfaces are completely wetted. (To check, agitate the item or hold it at an angle). Instrument manufacturers may recommend flushing through at a specified pressure for a defined time.

Cleaning the lens of an endoscope

If non-dismountable instruments with an irrigation connector must be suffieciently flushed with a cleaning or disinfection and cleaning solution. Make sure that the flow towards distal end of the instrument is sufficient.

The glass surfaces of optical systems should be cleaned by rubbing gently with a cotton swab saturated with alcohol. (Use swabs manufactured using a wooden or alcohol-resistant plastic material).

Instruments with coagulation residues that cannot be removed even by intensive cleaning (e.g. with 3% hydrogen peroxide solution, brushes or ultrasound) must be discarded, because their proper functioning and their required sterile condition can no longer be guaranteed.

Remove valves and caps from flexible endoscopes prior to reprocessing. This is the only way to ensure that the channels can be thoroughly cleaned and flushed. Cleaning is effected by immersing the flexible endoscope in a cleaning or disinfection and cleaning solution and wiping external surfaces thoroughly.

The channels are first cleaned with the brush supplied with the system, and are then rinsed with a cleaning or disinfection and cleaning solution. Some manufacturers also offer a hand pump for this purpose. The distal end (optics, Albarran lever, etc.) must be cleaned with particular care.

Flexible instruments with lockable cavities (e.g. larynx masks with balloons, or respiration/resuscitation masks) must be cleaned and disinfected in closed condition to protect the cavities from ingress of liquids. Rubber and flexible instruments may require a longer rinsing. Appropriate drying must be carried out to ensure sufficient drying.

6.2 Automated Cleaning and Disinfecting

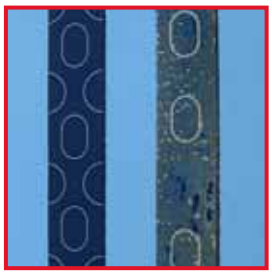
Cleaning and disinfecting can best be standardized when using automated processes. Always keep in mind that proper cleaning during instrument reprocessing is essential for retaining the value of your instruments as well as for successful sterilization. The International standards series (EN ISO 15883) and/or the national versions of those standards (e.g. DIN EN ISO 15883), and national guidelines state that only validated automated cleaning and disinfecting procedures should be used. The general requirements of washer/disinfectors (W/D) are stipulated in Part 1 of EN ISO 15883, the requirements apply both to single-chamber W/D and to multi-chamber W/D (indexing belt conveyor systems).

Automated reprocessing should preferably be preceded by dry disposal. In the case of wet disposal, either suitable low-foam cleaners and disinfectants must be used, or the items must first be thoroughly rinsed. This is because foam significantly impairs the spray pressure in automated cleaning processes and can affect the result.
This also applies if heavily soiled instruments (problematic encrustations on HF instruments, filling-material residues adhering to dental instruments, etc.) have been pre-treated manually or with an ultrasonic bath.

Ensure correct loading!

When using automated processes (in a washer/disinfector), the following should be observed (see also chapter 6.2.3):

- To ensure effective automated reprocessing, all trays, inserts, holders, etc., must be loaded correctly. Hinged 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 employ the load pattern established with validation.
- When placing large instruments on trays, make sure that they do not obscure other instruments and create spray shadows, thus preventing proper cleaning.
- Instruments with cavities or hollow spaces (such as turbines, trocar sleeves, respiration systems) need careful cleaning and rinsing on the inside as well. For this purpose, special (instrument-specific) inserts with appropriate irrigation facilities should be used.
- The instruments must be arranged in such a way as to prevent mechanical damage through contact.



Visual changes to color anodized aluminum occurs even in mildly alkaline solutions

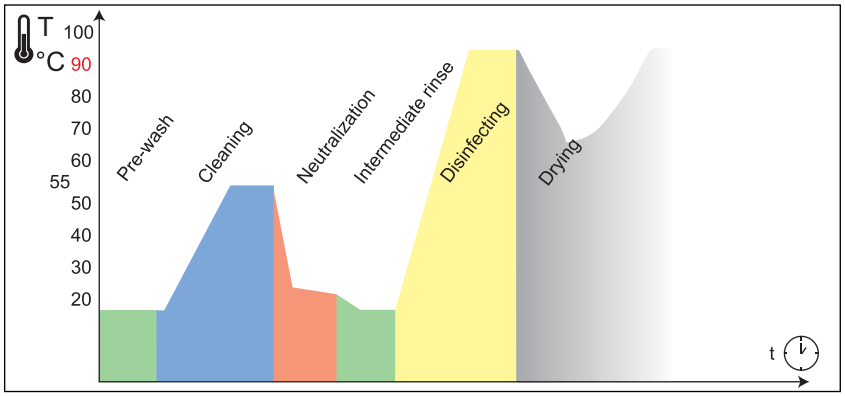
Colored, anodized aluminum parts may fade as a result of automated cleaning, thereby losing their coding function. However, if neutral-pH detergents are used and fully demineralized water is employed for the final rinse (and for thermal disinfection as well), such instruments can be cleaned and disinfected together with other items to be processed.

The items to be processed 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 automated reprocessing, both thermal and chemo-thermal disinfection options are available. As a rule, thermal disinfection is the better choice. Therefore, you should take the suitability of medical products for automated reprocessing with thermal disinfection into account at the purchasing stage.

6.2.1 Automated Cleaning and Thermal Disinfection

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 A_0 value has been introduced (DIN EN ISO 15883-1*, Appendix A). It determines the temperature-time relation as a dependent on microbial contamination and the intended purpose of the medical products involved (e.g. A_0 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 processed. A automated reprocessing program with thermal disinfection typically includes the following steps or stages:



Cleaning program with thermal disinfection

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

2. Cleaning
Hot or cold water (fully demineralized if possible); cleaning is usually carried out at temperatures of 40-60 °C depending on the load, for at least 5 minutes.

Use a suitable cleaning agents!

Suitable neutral-pH or alkaline products added or dispended to in cold to lukewarm water can be used for cleaning.
The choice of cleaning agents 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).
Increased chloride concentrations (natural levels, isotonic solutions) in the water used could cause pitting or stress corrosion cracking. Such hazards can be avoided by using alkaline cleaning agents and/or fully demineralized water.

Carry-over of cleaning agent residues due to insufficient rinsing

3. First intermediate rinse
With hot or cold water. Adding an acidic neutralizer facilitates the removal of alkaline cleaning agents 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).

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

5. Thermal disinfection/Final rinse
Fully demineralized water, thermal disinfecting takes place at temperatures of 80-95 °C and for the corresponding exposure time as per the A_0 concept, EN ISO 15883.
Using fully demineralized water prevents spotting, stains, deposits and corrosion on the surfaces of the items to be processed. It also prevents the formation of crystals which can interfere with the sterilization process.
If you add a final rinse aid to shorten the drying period, make sure to check the material compatibility of the items to be processed.

6. Drying
Sufficient drying must be ensured either through the washer/disinfector or by taking other appropriate measures.

Observe the manufacturer's instructions!

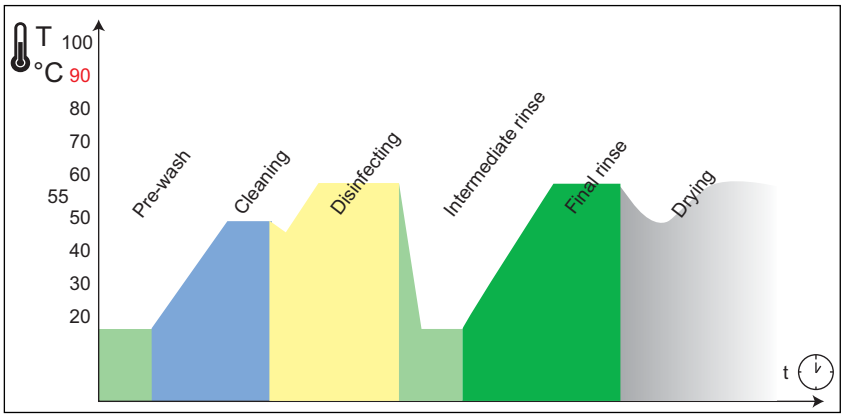
With regard to the process chemicals used, the manufacturer's instructions concerning concentration, temperature and exposure time should always be observed. This guarantees good results and keeps the instrument materials intact to the greatest possible degree. It must be possible to verify the automatic dosing of process chemicals.

6.2.2 Automated Cleaning and Chemo-thermal Disinfection

Thermally sensitive medical products are treated chemo-thermally. This means that a disinfectant especially suitable for automated disinfection is used after the cleaning stage. The temperature must be limited in all rinsing phases as well as during drying.

In chemo-thermal processes (as per EN ISO 15883-4), cleaning is carried out at defined temperatures generally <65 °C, for flexible endoscopes < 60 °C) and for disinfecting a special disinfectant suitable for machine treatment is added in corresponding concentration for specified exposure times.

Example of a cleaning program with chemo-thermal disinfection:



Cleaning program with chemo-thermal disinfection

1. Pre-wash

Cold water without any additives, to remove coarse dirt and foaming substances (such as residues from pre-treatment).

2. Cleaning

Hot or cold water (fully demineralized if possible); cleaning takes place at temperatures of 40-60°C for at least 5 minutes, depending on the items to be processed.

Suitable neutral-pH or alkaline products can be used as cleaning agents. The choice of cleaning agent depends on the materials and properties of the instruments to be treated and on the required cleaning efficiency.

3. Chemo-thermal disinfection

Hot or cold water (fully demineralized if possible). Chemo-thermal disinfection takes place at (≤ 60°C, using a special disinfectant with proven effectiveness and suitable for automated disinfection.

4. Intermediate rinse

Hot or cold water (if appropriate fully demineralized water) with no additive (if appropriate additional intermediate rinses to ensure that the disinfectant has been sufficiently well rinsed away to ensure non-toxicity).

5. Final rinse

Using fully demineralized water, final rinsing at max. 60 °C. This prevents spotting, stains, deposits and corrosion on the surfaces of the items to be processed. If a rinse aid is added to shorten the drying period the material compatibility has to be checked.

6. Drying

Sufficient drying must be ensured either through the washer/disinfector or by taking other appropriate measures. The drying temperature should be set to suit the temperature stability of the items to be processed (e.g. 65 °C).

Observe the manufacturer's instructions!

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 dosing of liquid process chemicals.

6.2.3 Instrument Groups Requiring Special Treatment

Microsurgical instruments can be machine-reprocessed and disinfected in the same manner as other surgical instruments, provided the instruments are safely held in place (e.g. by using racks or other suitable supports) and an effective rinsing method is used.

Dental instruments can also be machine-reprocessed in the same way as surgical instruments. However, the following specific points need to be observed:

- Probes and other easily damaged instruments must be placed on racks or special holding devices for protection.
- Rotating instruments such as drill bits, cutters, burrs or abrasive tools are only conditionally suitable for automated reprocessing. It may be necessary to carry out an additional pre-treatment by ultrasound.
- Instruments for root-canal treatment may only be processed in a W/D if each item is held in place securely and safely by appropriate supports. Otherwise, ultrasonic bath treatment is preferable.
- Handpieces can be machine-reprocessed where this is permitted by the manufacturer, and special irrigation fixtures are available for rinsing spray, air channel infeed as well as air refeed of the turbine drive.
- Mouth mirrors are subject to wear. For example, silver-backed glass mirrors may become dull as a result of automated reprocessing; rhodium-metalized mirrors, in contrast, are more resistant, but are easily damaged by mechanical impact.

Surgical motor systems may only be machine-reprocessed if the manufacturer allows such treatment in connection with aids and facilities. Tools approved for use in medical applications can be machine-reprocessed in the same way as surgical instruments, though most require additional pretreatment in an ultrasonic bath.

Ensure internal rinse!

MIS instruments, rigid endoscopes and HF instruments must be disassembled and removed for automated reprocessing in accordance with the manufacturer's instructions. All seals/gaskets must be removed and all stop cocks opened or removed as appropriate. Use automated reprocessing only where approved by the manufacturer of the product. To avoid damage, fix the items securely in place. The machine and load carriers used must have appropriate facilities that allow sufficient and reliable internal rinsing in the case of hollow instruments as well.

Discard!

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

Robotics instruments

Robotics instruments cannot be dismantled - or can be dismantled only to a limited extent - so special recommendations for their reprocessing need to be followed. Proper preparation for automated reprocessing must be ensured in particular.
To achieve perfect cleaning and rinsing results, fully demineralized water needs to be used in all process stages.

Flexible endoscopes may only be machine-reprocessed if special washer-disinfectors are used. If endoscopes are pretreated manually prior to automated cleaning and disinfection, all detergents and disinfectants used must be compatible with each other. This prevents poor results as well as endoscope surface changes and excessive foaming inside the machine.

Manual leakage test on flexible endoscope

Prior to automated reprocessing, a leak test must be carried out in accordance with the manufacturer's instructions. This ensures the early detection of leaks and perforations in order to avoid subsequent more serious damage (e.g. caused by penetrating liquids). Some W/D's can carry out a leak test automatically, either before the program starts, or while it is running. Defective endoscopes must be returned to the manufacturer, together with a description of the problem.

Alkaline process chemicals may damage endoscopes, so it is important to use only special cleaners and disinfectants suitable for the automated reprocessing of flexible endoscopes. Throughout the cleaning and disinfecting cycles the maximum temperature of 60°C may never be exceeded. Moreover, the instructions provided by the endoscope manufacturer must always be carefully observed.

During automated reprocessing, the endoscope must be securely kept in place inside the machine. Use appropriate devices to ensure that all external surfaces as well as the inside of all channels/ducts are thoroughly and reliably cleaned and flushed.

Suitable technical processes must be employed to ensure that the water used for the final rinse is of a quality that prevents renewed germ growth on disinfected endoscopes.
Prior to storing endoscopes for later use, proper drying is necessary to prevent the growth of microorganisms. Drying can be done in an automatic washer-disinfector or by using a suitable drying cabinet.

Flexible instruments with lockable cavities (such as tubes with balloons, respiration/resuscitation masks, etc.) must be cleaned and disinfected in their closed condition so that no liquid enters the cavities. To prevent the mask bulge from being overstretched, discharge some of the air prior to reprocessing (remove the plug, squeeze out some air, then replace the plug).

It is necessary to be extra careful when processing rubber instruments, because detergent or disinfectant residues can cause irreversible damage during subsequent drying or sterilization. This is due to the fact that such residues may damage the surface of the material and so cause it to become sticky. Latex coatings tend to blister off.

Ensure complete drying!

Residues adhering to functional parts of respiration systems are particularly problematic. It is also vital that all such parts are completely dried, as even very small amounts of moisture may cause malfunctioning. Functional parts of respiration systems of anesthesia machines have been specifically designed by the manufacturer, and therefore must be processed in accordance with the manufacturer's instructions.

Flexible thermolabile instruments (e.g. PVC products) must never be processed (disinfected, cleaned or dried) at temperatures above 60°C. Flexible instruments such as rubber/latex instruments made from natural rubber, may not be dried at temperatures above 95°C, as higher temperatures would greatly reduce their useful lives. The recommended temperature range for drying here is 70-80 °C.

6.3 Ultrasonic Cleaning and Disinfecting

Ultrasonic treatment is a very good choice to help with cleaning instruments made of stainless steel or hard plastic materials (except elastomers). Instruments sensitive to mechanical impact (e.g. microsurgical or dental instruments) can in particular be gently and thoroughly cleaned and disinfected in one operation with the help of ultrasound. Powerful ultrasonic devices are able to dissolve encrustations in places that are difficult to access otherwise.

Ultrasound unit installed in work area

Ultrasonic cleaning is used:

- as an effective mechanical method supporting manual cleaning processes.
- for removing tenacious encrustations before or after automated reprocessing.
- as an integral part of automated reprocessing treatments, thus supporting other measures for improved cleaning results.
- for time-saving disinfection while providing intensive cleaning.

To secure optimal cleaning results when using ultrasound, observe the following:

- Fill the bath in accordance with the manufacturer's instructions.
- Add a suitable cleaning agent or a combined cleaner-disinfectant.
- When using both disinfectant and cleaning agents, the concentration, temperature and ultrasound treatment/exposure time must be chosen in accordance with the manufacturer's instructions to ensure compatibility.
- We recommend filling the bath with water at room temperature.
- Water temperatures above 50°C can lead to encrustations due to protein denaturation.
- Freshly prepared disinfection or cleaning solutions require degassing before their first use.
- The efficacy of the ultrasonic bath can be verified by the foil test to IEC/TR 60886: 1987. On completion of the test the ultrasonic bath should be thoroughly rinsed so as to prevent dissolved aluminum particles from being deposited on instruments.

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

- The items to be treated must be fully immersed in the liquid.
- Hinged instruments, scissors etc. must be opened in order to minimize the obscured surface areas.
- Use only suitable trays (e.g. wire or perforated plate trays) that do not obstruct the ultrasonic cleaning process. Insert instruments next to each other; do not stack them.
- Insert instruments next to each other; do not stack them.

- Large-surface, bulky instruments must be stored so that they do not create acoustic shadows. Such items should be placed vertically.
- Do not overload trays.
- Ultrasonic baths should be refilled each day. Disinfectant solutions can have long lives provided they are duly certified, taking care to observe national guidelines as well as the manufacturer's instructions. As high contamination levels impair ultrasonic cleaning and promote corrosion, more frequent replacement of ultrasound solution may be necessary, depending on the requirements of specific cases.
- Given efficient modern equipment, ultrasonic treatment times of approx. 3 minutes at frequencies of around 35 kHz should be sufficient.
- If disinfection and cleaning are carried out simultaneously, make sure to use suitable products, paying attention to concentration and exposure time requirements.

If shorter exposure times and/or lower concentrations for disinfection are recommended when using cleaners and disinfectants with ultrasound, such values must always be checked and corroborated by microbiological examinations (expert opinions), taking account of temperature, frequency range and germ spectrum.
Following ultrasonic treatment, the instruments must be thoroughly rinsed manually. 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.

Microsurgical instruments must be stored on special racks in order to prevent damage.

Acidic cement removers and basic cleaners should be used in accordance with manufacturers' instructions in the ultrasonic bath.

Handpieces and turbines should never be treated in an ultrasonic bath. With the exception of simple tools and accessories, motor systems should never be treated in an ultrasonic bath.

Due to the materials used in their construction, rotating dental instruments must be treated often with special disinfectants and cleaning agents. Prior to ultrasonic treatment, they should be mounted on special stands to prevent the instruments from being damaged by contact with each other (e.g. by sharp cutting edges, or diamond grain). After a quick rinse under running water followed by immediate drying, rotating dental instruments must be treated with a sterilization-stable anticorrosive agent. Polishing and flexible instruments cannot be processed in the ultrasonic bath, because the elasticity absorbs the ultrasound.
Mouth mirrors may be damaged by ultrasonic bath treatment.

Only MIS instruments, endoscope accessories and HF instruments which are suitable according to the manufacturer's specification may be treated in an ultrasonic bath.

Camera systems and optical cables may never be cleaned in an ultrasonic bath.

Flexible endoscopes must never be treated in an ultrasonic bath. However their accessories (such as valves, caps, biting rings or forceps) can be treated in this way.
Elastic instruments do not respond well to ultrasonic processing, as ultrasonic waves have only a limited effect on them.

Functional parts of respiration systems may not be processed in an ultrasonic bath.

7. Final Disinfection

A final disinfection is carried out for instruments that cannot be sterilized or where sterilization is not required. In most cases, this applies to thermolabile instruments such as flexible endoscopes or equipment used in anesthetics.

Final disinfection can be performed either manually or mechanically at room temperature, or mechanically at higher temperatures using a chemo-thermal or thermal process. For automated thermal and chemo-thermal disinfecting processes with integrated cleaning stage, refer to chapter 6.2. When using chemical processes for final disinfection, aldehydes, organic peroxo compounds or alkylamines are primarily used as microbicidal agents (either alone or in combination with cleaning components and/or corrosion inhibitors and additives). The effectiveness of the disinfectants used should be proven under clean conditions (no contamination) in accordance with European (EN) 14885 standards or equivalent local guidelines.

Observe material compatibility!

Material compatibility is dependent on the type of agent, the composition of the disinfectant, temperature, exposure time, concentration, and the pH-value of the solution used. See also chapter 2.2.

Inasmuch as the same products are used for disinfection and cleaning and the final disinfection, separate solutions must be employed for the two steps. If products based on different agents are used, product compatibility must be ensured (to prevent the formation of deposits, for example).

Ensure complete wetting!

In chemical final disinfection, it is important to ensure that all surfaces to be disinfected are completely covered by the solution, including the gaps in hinged instruments, and any channels or cavities.

Following disinfection, the instruments must be rinsed thoroughly with sterile, fully demineralized water to completely remove any residues, and must then be dried immediately. If compressed air is used for drying, the air must be passed through a sterilizing filter. We recommend using disinfecting solutions for no longer than one day. If the manufacturer recommends or allows longer use, the agent concentration should be checked regularly (at least daily), because losses can occur either during the introduction and removal of instruments, or due to chemical reactions. The solution should be disposed of as soon as the concentration limit value - up to which the manufacturer guarantees the action spectrum expected by the user - is reached. For suitable methods for checking concentration, consult the manufacturer of the product.

Flexible endoscopes are sufficiently rinsed externally as well as internally with water in accordance with the cleaning instructions given in chapter 6.1, and are then immersed in a disinfecting solution. It is important to ensure that the endoscope is completely covered by the solution and that all channels are completely filled or wetted by the solution flowing through them.

In the case of flexible endoscopes, this can be done with a hand pump or by using a program-controlled automatic pump system. Make sure to disinfect the discharge ducts as well! Following chemical disinfection, external surfaces and all channels of the endoscope must be thoroughly rinsed to remove any residues. To avoid water spots, use only fully demineralized water. Additional sterile filtration prevents unwelcome recontamination.
To dry the external surfaces of flexible endoscopes, use a virtually lint-free cloth. The channels should be dried with a hand or discharge pump or with compressed air at max. 0.5 bar, depending on the manufacturer's instructions. The use of sterile (filtered) compressed air prevents unwelcome recontamination.

In the case of flexible instruments made of plastic or rubber, white spots are caused by the penetration of water into the instrument's surface. Such spots can only be removed by drying.

To prevent diaphragm damage in functional parts of respiration systems, do not use compressed air for drying.

8. Checks and Care

Cleanness

Sufficient cleaning standards are absolutely vital for successful sterilization. Instruments must be checked visually - tactile and 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 (particularly atraumatic toothing) require especially careful checking.

It is advisable to use working lights, such as light magnifying glasses with lenses of 3 to 6 diopters when checking filigree working ends. 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.

Biopsy forceps damaged by sheer force

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 (as described below) and then rinsed sufficiently:

- Manual cleaning, if necessary with ultrasound (see chapter 6).
- Immersion in a 3% H_2O_2 solution (for approx. 5 minutes; note exceptions!)

Integrity

To prevent damage and consequential corrosion (rust) due to metal abrasion, never use metal brushes or metal sponges for removing stains.

Surface changes

Instruments with hairline cracks in the joint areas, as well those that are damaged, distorted or otherwise worn, must be replaced because their functionality can no longer be fully guaranteed.

Stress cracks next to scissor hinge

Instruments with corrosion residues or damaged nickel-chromium coating need special processing. Such treatment is not mandatory, however, in the case of discolorations and/or stains.

For detailed information and recommendations on this topic, please refer to chapter 12.

Care

Targeted joint cleaning

Corrosion due to insufficient use of care products

Maintenance and care measures are usually carried out prior to the functional check.

Maintenance or care means targeted application of a lubricant milk to the joints, hinges, locks, threads or friction surfaces of instruments such as clamps, scissors or punches, after they have been carefully cleaned and disinfected.
This prevents metal-on-metal friction and therefore constitutes a preventive measure against friction corrosion. In this way, the instruments are kept functional and hinge action maintained.

Requirements for care agents for surgical instruments:

- Paraffin/white oil based, in accordance with the current European or United States Pharmacopeia
- Biocompatible
- 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 as well.

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 lubricant must be applied manually and accurately to joints, threads and friction surfaces. This applies in particular to hinged instruments treated in special cleaning procedures using a hydrogen peroxide additive. The care agent must be distributed evenly by operating the joints/slide surface. Any excess care agent must be removed with a lint-free cloth.

Spraying the instruments or applying the lubricant mechanically is not sufficient, nor does it provide additional corrosion protection. Immersion baths should not be used because of the microbial infestation hazard.

Never process plastic surfaces with instrument lubricants.

Function

As surgical 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.

Hinged and threaded instruments must be targeted lubricated before subjecting them to a functional test (aerosol can with nozzle, oil pen, squirt oiler) or through targeted application of drops of oil.

The proper functioning of the instruments must be assured by testing. Such a test must always be carried out on the fully assembled instrument. The item should be taken apart again for sterilization after successful testing as necessary. Make sure you proceed in accordance with the manufacturer's instructions when assembling and disassembling the instrument.

Medical products due for repair must be sent through the entire reprocessing cycle to fulfill the requirements of hygiene.

After the check, microsurgical instruments must be stored in the special racks designed for them that prevent transportation damage. If indicated, suitable facilities should be employed to secure them against dislocation.

Care

Dental instruments are usually serviced in the same manner as surgical instruments. However, there are some exceptions:

- A few rotating dental instruments with rotating components (drill bits, cutters, burrs, reamers) must be treated with an anti-corrosion agent which is suitable for use with sterilizing media such as steam or hot air, immediately after drying.
- Handpieces and turbines must be treated with special agents in accordance with the manufacturer's instructions due to their complicated internal design.

Care

As proper lubrication and care is a vital factor for long-term value retention in the case of motor systems, the manufacturer's instructions should be carefully followed. For non-sealed handpieces, e.g. many micro-handpieces with a motor connection according to DIN 13940/ISO 3964, a special spray must be used for lubrication.

A few drops of special oil are applied to the air intake duct of compressed air motors. To facilitate the distribution of the oil inside, the motor is run with compressed air for a few seconds.
This excludes maintenance-free compressed air motors, labeled accordingly. As a rule, all movable external parts, such as pushbuttons or tool couplings, should be properly lubricated, unless expressly forbidden by the manufacturer. Make sure to use only lubricants approved by the manufacturer.

Function

Before sterilization, surgical motors and their accessories must be subjected to a functional test, in accordance with the manufacturer's instructions. All compressed air components must in addition be subjected to a leak test and be visually inspected for potential defects, especially the compressed air hoses and motors.
To check the air intake duct, it is necessary to connect the air hose to the compressed air connector. Leaks can then be detected either acoustically or by submerging the hose in water.
To check the air discharge duct, the compressed air motor must also be connected to the compressed air hose. After starting the motor, leaks can best be detected by submerging the hose in water.

Simple tools must be checked in accordance with the instructions for general surgical instruments. To prevent transportation damage, tools should be stored in special fixtures and secured against slipping.

Cleanness

Residues on endoscope glass surfaces, optical fiber cables and camera heads can be removed with a swab soaked in alcohol.
For this purpose swabs made of wood or alcohol-resistant plastic should be used. Swabs including metal should be avoided as they may scratch glass surfaces. Note also that alcohol is not suitable for removing blood residues.

Glass surfaces with stubborn deposits (e.g. in the case of oculars, lenses or light connectors) can be treated with a detergent or cleaning procedure recommended by the manufacturer.
If deposits or tarnish cannot be removed in this way, the instrument must be sent back to the manufacturer for inspection.

Integrity

Worn parts, defective components, gaskets and sealing rings must be checked for integrity before each sterilization cycle. If damaged, they must be replaced at once.
Damaged, blunt and/or distorted cannulas must be taken out and discarded.

Damaged insulation on HF instrument

Instruments with damaged insulation must be replaced immediately because they would pose a risk to patients, users and third parties.

Optical fiber cables and endoscopes must be checked for fiber breakage by holding the distal end against a light source and looking into the cable at the other end (the connector side of optic). Fiber breakage is indicated by black spots in the waveguide. If more than about 30% of the fibers are broken, the light output at the distal end is no longer adequate. If this is the case, the cables or endoscopes must be returned to the manufacturer for repair. Check endoscope cover glasses for relevant scratch marks and/or cracks. These can result in leaks, causing the optic to fail.

Care

Application of care agents, either manual or mechanical, should be avoided with optical systems, gaskets and current-carrying components because this could cause significant problems and lead to loss of function.

Joints, threads and friction surfaces, as well as non-maintenance-free connections on rigid endoscopes must be treated with instrument oil in accordance with the manufacturer's instructions. Alternatively, lubricating milk can be used if permitted by the manufacturer.

Function

A function test ensures the proper functioning of MIS instruments and rigid endoscopes. Such a test must always be carried out on the fully assembled instrument. The item must subsequently be taken apart again if sterilization is necessary. Make sure you proceed in accordance with the manufacturer's instructions when disassembling and assembling the instrument.

Channels of flexible endoscopes must be checked for free passage (no obstructions).

Cleanness

Glass surfaces of flexible endoscopes (lenses, oculars and light entry/exit surfaces) must be checked for cleanness in the same way as for rigid endoscopes.

Integrity

Gaskets, sealing rings, valves, caps and other parts which wear out, must be checked for integrity after each reprocessing cycle. If damaged or worn, they must be replaced at once.
Endoscopes with damaged feed and/or elbow tubing, or other defects, must be taken out and sent for repair.

Care

In the case of flexible endoscopes, always check whether the valves (if incorporated) need treatment with an instrument care agent before use.

Swelling at distal end of fiberscope

Note that the endoscope surface must not be sprayed because spray propellants damage these instruments.

Only grease-free gels may be used as slip agents, in accordance with the manufacturer's instructions. Vaseline or agents containing paraffin cause swelling or softening in plastic components (see also chapter "Surface Changes"!).

Function/integrity

Immediately after an endoscopic operation all functions of the instrument must be checked or tested in accordance with the manufacturer's instructions.

Respiration systems must be checked in accordance with the manufacturer's instructions to ensure that they are in proper working order and are functioning properly.

Flexible instruments must be checked for proper functioning in accordance with their intended use. The most important checks and tests include:

- Checking the integrity of balloons.
- Checking balloon filling systems for non-leaking.
- Checking instrument lumens for obstructions.
- Testing connectors for functional safety.
- Inspecting tracheal tubes for distortion, e.g. radii.
- Checking polysulphone connectors and similar products for stress cracks.

Make sure to remove and discard any damaged or defective instruments! Frequent damage includes:

- Blistering, scaling.
- Surface cracks (e.g. ozone cracks; crazing/orange-peel effect, i.e. network of directionless micro-cracks); stress cracks in plastic components.
- Sticky surfaces.
- Hardening.
- Porous surfaces.

Care

Flexible instruments and respiration systems may never be treated with lubricants or care agents before sterilization. Where required, special servicing and care measures are always indicated by the manufacturer.

Never use silicone oil!

Flexible instruments made of silicone rubber must not be treated with silicone oil because it may cause swelling, thus destroying the instrument's functionality. To prevent swelling in rubber and latex instruments never use agents containing paraffin.

Repair

Damaged medical products or products that are no longer functioning properly must be sent for repair or scrapped.

Maintenance

Always send medical products to the manufacturer for servicing as per the maintenance schedule.

9. 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. It's 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:

- temperature
- pressure
- humidity
- sunlight
- cleanness
- pathogen contamination

Sterile items container

Protective packaging

The protective packaging is additional packing designed to prevent damage from the sterile barrier system. The protection starts with the packaging process and ends with the moment of use.

Packaging types

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 suitability of the packaging, including its sealing and composition, is verified in the course of validating the sterilization process.
Whenever new packages 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.

10. Sterilization

Within the scope of European (EN) standards, the application of sterile instruments on or in the patient requires proper cleaning and disinfecting, followed 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.

For thermostable products, steam sterilization is the method of choice!

10.1 Steam Sterilization

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

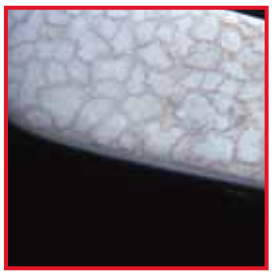
Stain formation due to "running" chemoindicators

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.

If validated steam sterilization processes are used in accordance with ISO 17665, EN 554 (or DIN 58946 Part 6 in Germany) and all process-relevant parameters such as pressure, temperature and the proportion of non-condensable gases in steam are being documented it is possible to do without chemoindicators or bioindicators for batch control, provided that the three parameters relevant to the procedure are permanently monitored.

Ensure steam quality in accordance with EN 285!

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 EN 285, Table B.1, relating to the quality of the boiler feed water and the condensate may not be exceeded. Otherwise corrosion may result from contaminants, such as rust particles in the piping system, or discoloration caused by excessive silicon dioxide 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
Chlorides (Cl)	≤ 0.1 mg/l
Phosphates (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

Source: EN 285 (+A2), version 2009

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

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 items should be placed at the lowest level, so that the majority of the accumulated condensate can drain off directly. Special drying measures must be adopted when validating items weighing more

than 10 kg (according to EN 868) per sterilizing unit (30x30x60cm). 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.

Dental instruments can usually be steam-sterilized in the same way as surgical instruments. Should separate treatment be required for dental instruments, the following instructions apply for steam sterilization:

- Dental instruments with rotating components (e.g. drill bits or burrs) are steam-sterilizable.
- Handpieces should be steam-sterilized at 134°C wherever possible to keep treatment time to a minimum.
- In the case of drive systems, consult the manufacturer's instructions to determine whether or not steam sterilization is permitted.
- 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 thermal expansion coefficients of different materials.

All surgical motor systems used under sterile conditions can be steam-sterilized at 134°C.
Make sure the manufacturer's instructions are observed, e.g. on fixing during sterilization.

Kinking reduces service life and impairs the functionality.

Compressed air hoses need to be protected against mechanical damage (such as compression or kinking) during sterilization. The permitted bending radii should therefore be observed when storing such items in sterilization trays.

As regards battery-powered systems, make sure to strictly observe the manufacturer's instructions for sterilizing batteries. Long exposure to the effects of temperature considerably reduces the state of charge.

MIS instruments, rigid endoscopes, optical fiber cables and HF instruments can usually be sterilized in the same manner as surgical instruments. Steam-sterilizable optical systems should be sterilized at 134°C rather than at 121°C, due to the shorter exposure time (and correspondingly lower thermal stress). Alternatively the H_2O_2 gas-plasma sterilization process can be used. This completely avoids thermal stress. To avoid mechanical damage, optical systems should always be stored securely in accordance with the manufacturer's instructions during sterilization.

Flexible endoscopes are not steam-sterilizable due to their limited heat stability. A low-temperature sterilization method must therefore be used in cases where sterilization is required. However, all items used endoscopically (such as forceps, catheters, etc.) must be steam-sterilized.

Flexible instruments made of silicone elastomer or natural rubber or latex, with and without a balloon, can be steam-sterilized. Due to the lower thermal stress tolerance, it is preferable to sterilize them at 134°C. Items made of temperature-sensitive materials (e.g. plastics) are only steam-sterilizable if they are marked as such, or if such treatment is expressly permitted by the manufacturer.

When steam-sterilizing flexible instruments, all cavities e.g. bulge of mask, balloon, must remain open during sterilization, to prevent damage caused by pressure variations.
Cavities locked with a valve must be completely emptied i.e. made water- and air-free, with a syringe before sterilization.

Functional parts of respiration systems can be steam-sterilized at 134°C. Cavities must remain open to prevent valve damage.

10.2 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!
MIS instruments and endoscopes may never be sterilized with hot air.

10.3 Low-Temperature Sterilization

Gas sterilization and gas plasma systems are Low-Temperature Sterilization procedures. All these procedures work with chemical agents at temperatures between 37 and 75 °C.

When choosing the low-temperature sterilization procedure please take particular notice of the reprocessing instructions specified by the manufacturer of the medical product.

It is possible that the concentrations of agents will differ depending on the type, procedure and year of manufacture of the sterilizers used, and errors would cause various amounts of damage to the processed products.

Due to the possibility of harmful interactions a medical product should always be sterilized in a low-temperature sterilization process!

Depending on the sterilization procedure different kinds of packaging are permitted. In general, containers used for steam sterilization are not suitable. For environmental reasons as well as patient- and personnel-related safety reasons, these methods should only be used for items that cannot be steam-sterilized!

Items sterilized with ethylene oxide require adequate aeration following sterilization (and before reuse). Aeration times may vary considerably, depending on ventilation conditions and the product treated. For reliable aeration times, always consult the instrument manufacturer and/or observe the corresponding instructions.
Sterilization with EO gas may only be used for motor systems if expressly specified by the manufacturer.

Non-steam-sterilizable rigid optical systems (telescopes) can be sterilized at low temperatures in accordance with the manufacturer's instructions.

Flexible endoscopes can be sterilized up to a maximum temperature of 60°C, using a sterilization method permitted by the manufacturer.

For sterilization the flexible endoscope must be packed in a transparent tube, in the extended condition wherever possible. Make sure the aeration cap is placed on the inlet connector, otherwise the instrument could be irreversibly damaged.

To ensure protection against mechanical damage, the sealed-in flexible endoscope must be held securely on the sterilizer tray. Make sure that the loop diameter is no less than 30 cm.

Following sterilization and adequate aeration (if required), flexible endoscopes must always be stored in their extended state to avoid deformation and kinks.

Flexible instruments made of heat-sensitive plastic are not steam-sterilizable, but are sterilized using one of the methods indicated by the manufacturer.
Cavities locked with a valve must be fully evacuated and all water removed with a syringe prior to sterilization.

Flexible instruments made of rubber, as well as functional parts of respiration systems, should not be gas-sterilized, as they can more effectively be steam-sterilized.

When sterilizing medical products incorporating a battery (such as cardiac pacemakers or implantable defibrillators), bear in mind that the battery charge may be reduced during the process, depending on temperature and treatment time.

11. Storage

11.1 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.

Flexible endoscopes must not be stored in transportation cases. They should be stored under dry and dark conditions. Endoscopes must be sufficiently dry before storage. Valves and caps must be removed and stored separately, under dry and dust-free conditions. It is advisable to hang up endoscopes during storage, using special cabinets that should be located near the place of use.

To prevent premature failure of flexible instruments, avoid kinking or overstretching during storage (use only suitable connectors!).

11.2 Storing Sterile Instruments

Sterile items store

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). For details, refer to DIN EN 868 and Table 1 of the German standard DIN 58 953, Part 9.

Proper storage of sterilized endoscopes requires storing them with the shaft unkinked and/or laid out in a sufficiently large loop. Following degassing, such items should be stored in a closed cabinet so as to be protected against contamination.

12. Surface changes, deposits, corrosion, aging, swelling and stress cracks

During daily use and over time many medical products 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 approach outlined above. These examples cover the most frequent surface changes in metallic instruments made of stainless steels and/or plastic or rubber products.

12.1 Metal/Deposits – Organic Residues

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.

Rust and/or blood-colored deposits can often be seen.

Origin and causes

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.
- Protein fixing, e.g. by aldehyde-containing disinfectants.
- Transferred by contaminated detergents and disinfectants.
- Insufficient rinsing after cleaning.
- Insufficient cleaning efficiency due to acoustic shadows in ultrasonic cleaning.
- Inadequate maintenance/servicing of the washer/disinfector.
- Possible protein fixing caused by water feed temperature being too high (> 50 °C) in first rinse phase.
- Ineffective rinsing (insufficient water flow through or around the instruments, insufficient rinse pressure, spray shadows).
- 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.

Overload

Treatment recommendations

- Recleaning with ultrasound.
- Targeted manual recleaning.
- Immersion in 3 % H_2O_2solution (approx. 5 min.).

Preventive measures

- Remove all coarse contamination, especially salt solutions immediately after the operation.
- Factors causing drying or fixing exclude: 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 because blood, for example, contains chloride ions. If present in higher concentrations, these ions cause pitting and/or stress-crack corrosion.

12.2 Metal/Deposits – Process Chemical Residues

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

Type of surface change

Hollow handle with visible residues

Suitable load carrier with injectors for cleaning and rinsing ophthalmic instruments

Incorrect loading/tipped kidney-shaped bowls

Origin and causes

Process chemicals that have not been removed sufficiently (spray shadows, 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!

No influence on material properties.
A risk to the patient cannot be ruled out if the process chemical residues in the final rinse water exceed the manufacturer's specifications.

Risk assessment

The safety of the final rinse water must be tested and confirmed in the course of validation.

Particularly in the case of ophthalmic instruments patients could be exposed to risk of chemical burns caused by alkali and tenside residues.

12.3 Metal/Deposits – Spotting Caused by Lime

Type of surface change

Rinsing chamber with heavy lime scale deposits

Consequence: Instruments with limescale residues

Stains/Discolorations 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 and 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 as necessary intermediate rinses with demineralized water.
- Use of fully demineralized water for the final rinse to prevent stain formation during automated reprocessing.

Risk assessment

- No corrosion, only cosmetic effect.

12.4 Metal/Deposits – Silicates

Silicate deposits occur most frequently in instrument reprocessing.

Type of surface change

Typical silicate discoloration in the washer-disinfector chamber and on the surface of the instrument caused by a detergent containing silicate, or excessive levels of silicon dioxide in the water.

Typical silicate discoloration on the surface of the instrument after steam sterilization caused by excessive silicon dioxide levels in the demineralized water.

Yellowish-brown to blue-violet discolorations 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 and causes

- Passage of silicon dioxide in 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 automated reprocessing due to insufficient intermediate rinsing.

Treatment recommendations

- Silicate deposits can be removed via acid-based cleaning using special detergents as recommended by the manufacturer. Stubborn deposits can be removed with agents containing hydrofluoric acid.
- Arrange mechanical surface treatment by the manufacturer or a qualified repair service.

Preventive measures

Use silicon dioxide-free, fully demineralized water for final rinse during automated reprocessing. Prevent detergent carry-over by:

- Correct tray loading and proper positioning/fixation of items to be processed 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 automated reprocessing.
- For steam sterilization use water quality as specified in EN 285 (Appendix B, Table B1.) or DIN 58946 Part 6.

Risk assessment

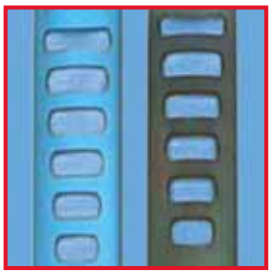
- No corrosion – cosmetic effect. There are no findings indicating a patient risk.
- Discoloration may make visual inspection difficult (such as detecting dirt residues).
- The laser-lettered labels of instruments may be adversely affected (bleached) when treating them with acid-based cleaners. This may result in poor legibility, thus impairing or even destroying their coding function.

12.5 Metal/Deposits – Discoloration Due to Oxidation

Type of surface change

Retractors with discolored 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



Section - titan valves: Left-hand valve – brand new. Right-hand valve – machine-cleaned.

The change in color is generally homogenous. However it can also occur in patches or multi-colored.

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

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

Origin and causes

For the above mentioned hardenable stainless steels, in the case of automated 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 discoloration 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 discoloration of the surface.
Titanium oxide deposits may be transparent or multicolored/colored depending on the composition, density, and thickness.

Treatment recommendations

Not recommended due to the properties of the deposit, but may be carried out by the manufacturer or a qualified repair service as necessary in both cases only by appropriate surface treatment (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, process chemicals, humidity).

Risk assessment

No corrosion – cosmetic effect.
If, in the case of titanium materials, any identification/coding function lost as a result of discolorations, e.g. color coding of the blade width in the case of valves (see picture), does not present a safety risk, color changes due to the formation of different properties of oxide layers is completely unproblematic. That is to say, there are no restrictions with regard to biocompatibility, hygiene, function or lifetime.
Discoloration may make visual inspection difficult (such as detecting dirt residues).

12.6 Metal/Deposits – Discoloration/Loss of color in colored plasma layers

Type of surface change

Example: black, TiAlN coated punch. Inside colors, or coat complete removed with undamaged, gilded components (end screw, springs).

Punch: as new

Origin and cause

Surface reaction from cleaning solutions to which hydrogen peroxide has been added, and/or wash solutions, for example those with high alkalinity at pH > 10, combined with temperatures of above 70 °C. This affects black titanium aluminum nitride (TiAlN) and titanium aluminum carbonitride (TiAlCN) layers as well as originally goldish-yellow zirconium nitride (ZrN) and titanium nitride (TiN), titanium aluminum nitride (TiAlN) and

titan aluminum carbonitride (TiAlCN) layers as well as originally goldish-yellow zirconium nitride (ZrN) and titanium nitride (TiN) coated products/components.

Treatment recommendations

As a result of repair, recoat.

Preventive measures

Use only neutral or mild-alkaline cleaner. Do not exceed a temperature of 70 °C when using alkaline cleaners.

Risk assessment

Reduced wearing properties and increased reflection.
Note: Because of the extremely strong cleaning effect of such special cleaning programs the friction surfaces of metal instruments must be oiled following each step of cleaning. Otherwise there is a high risk of "metal pitting" or friction corrosion.

12.7 Metal/Corrosion – Pitting

Type of surface change


Scissors with pitting


Example of pitting

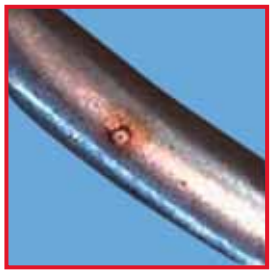

Example of pitting


Example of pitting


Example of pitting


Example of pitting


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



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

Origin and causes

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.).

- 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 chapter 12.1 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 be largely prevented by using low-chloride water qualities, by minimizing organic residues or other effects of chloride-containing liquids, such as physiological cooking salt solution, on instrument steel.

Risk assessment

- Severely 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 must be eliminated.
- Corrosion holes can pose a hygienic hazard and may lead to stress corrosion cracking as well.

12.8 Metal/Corrosion – Wear Friction Corrosion

Type of surface change

Hinge area (scissors)

Bone punch, friction surface on sliding section indicates onset of friction corrosion.

Prevention: Careful treatment with instrument oil

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

Origin and 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 where 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 care products to the instrument prior to performing the functional check.
- Manually apply the care product directly to the joint area (using drops or spray).
- Distribute the care product uniformly in the joint by opening and closing the instrument in the joint area several times.

Requirements for instrument care products:

- Basis of care product: liquid paraffin (paraffin oil)/white oil.
- Must conform to currently valid pharmacopeia.
- Must 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.

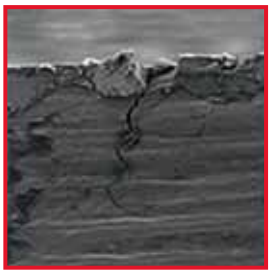
Risk assessment

Do not use lubricants on rubber and latex articles, as this leads to swelling.

Friction corrosion impairs or completely destroys the instrument's functionality. Friction corrosion may lead to pitting.

12.9 Metal/Corrosion – Stress Corrosion

Type of surface change



Detail: Scissors hinge joint with typical intercrystalline crack.

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

Origin and causes

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).

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.
- 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 corrosion cause is water containing chlorides, but surgical residues, drugs and the like 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 (for example, reduce surgical and drug residues; use only suitable water for reprocessing, final rinse and sterilization).
- Avoid improper handling that could lead to overstressing.
- Have your instruments repaired only by the manufacturer or a qualified and specially authorized repair service provider.

Risk assessment

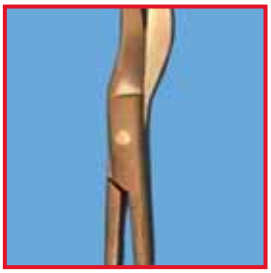
- Corroded instruments should be immediately withdrawn from service (and the instrument processing cycle) for reasons of patient and user safety.
- To retain the value of your instruments, eliminate the cause of corrosion.

12.10 Metal/Corrosion – Surface Corrosion

Type of surface change

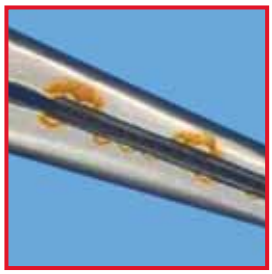
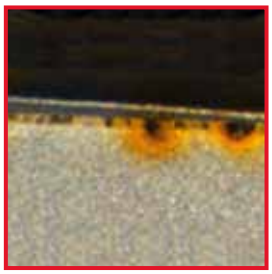
Surface of blade affected due to humidity. Cause: Composition of materials, normal steel, so disposable product.

Material affected at partially defective chrome coating. Cause: Humidity causes corrosion to form on unprotected carrier material (normal steel)



Etching effect on surface of instrument. Cause: Effects of over-dosed acids.

Partial etching effect and deposits of an etching agent causing hemostasis on the surface of the instrument. Cause: contact time too long

Etching effect on soldered seams. On carbide metal scissors, carbide tweezers and needle holders
Cause: Effects of acid due to over-dosing of neutralizing chemicals or due to using acid-based cleaners.

Material affected at aluminum handle. Cause: Unsuitable alkaline cleaner

Detail - optical fiber cable material affected.
Cause: Alkaline effect due to non-compliance with the manufacturer's instructions to use a neutral cleaner.


Material affected on natural/ colored anodized aluminum surface of containers. Cause: alkaline washer solution above permitted level

- On stainless steel mostly a uniform, flat-gray surface attack that quite often leads to subsequent damage in the form of corrosive deposits.
- In non-stainless steel products (e.g. disposable products such as scalpel blades, or old instruments not made of stainless steel, typically with damaged or peeled-off chromium surface layers), usually extreme corrosion on a matt black surface.
- In naturally anodized surfaces, whitish-gray corrosion products, with crater formation in cases of strong attack.
- In colored, anodized surfaces, color partially or completely faded, with discoloration and material erosion in cases of strong attack.
- Dark staining and material erosion at soldering points.

Origin and causes

- Chemical and electrochemical influences only in connection with an excessive acid content in case of
  - stainless steel,
  - soldering points.
- Long-term impact of water/condensate in the case of stainless steel.
- Effect of acids or too high alkalinity in anodized surfaces, adhesives and optical fiber cables.

Treatment recommendations

- Rust removal through acid-based cleaning in the case of stainless steel if the damage is still superficial, and/or mechanical treatment of soldering points (if applicable) by the instrument manufacturer or a qualified repair service provider.
- If anodized or sintered tungsten carbide metal or cobalt is affected (WC/CO at a mix ratio of 9:1), the damage is irreparable.

Preventive measures

- In the case of soldered instruments always observe the application recommendations when using acid cleaners and neutralizing agents.
- Remove and discard disposable products made of steel or old steel instruments with damaged surfaces, and replace them with stainless steel products.
- Avoid long-term exposure to moisture (condensate).
- Treat instruments with anodized surfaces in a neutral-pH/mildly alkaline environment.

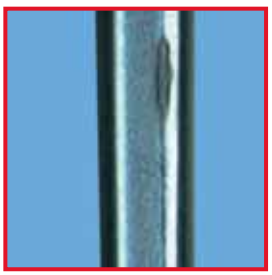
Risk assessment

- If surface treatment proves ineffective, replace the affected instruments with new ones (otherwise there is a risk of subsequent rust formation or film rust).
- Loss of color-coding function in anodized instruments.

12.11 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 discolorations 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 and 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 automated cleaning 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 accelerate 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. ultrasound treatment, automated reprocessing) stainless steel instruments (e.g. by ensuring that the cleaning/disinfecting apparatus, or W/D, 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.

12.12 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

- Individual, irregularly dispersed rust particles.
- Brown, mostly locally limited corrosion deposits (rust formation).
- In the event of direct, wide-area contact with very rusty products, subsequent rust damage may occur in the area of the contact surfaces.

Origin and causes

- 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 such as scalpel blades, 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 (reprocessed) by the manufacturer or a qualified repair service provider.

Preventive measures

- Disposable items made of steel must not be reprocessed.
- Discard, or treat separately, any non-stainless instruments and materials.
- Avoid using low-value, unapproved 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.

12.13 Metal/Corrosion – Crevice Corrosion

Type of surface change

Hinge area - clamp

Joined area - tweezers ends

- 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 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 and 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

- Treat affected instruments in accordance with the manufacturer's directions.
- Mechanical treatment (reprocessing) of the instrument by the manufacturer or an authorized repair service.

Preventive measures

- Remove coarse dirt immediately (RKI recommendation: "The single most important measure for preventing this type of corrosion is the adequate drying of narrow joint crevices").
- Use rinsing water with a low salt content (preferably fully demineralized water).

Risk assessment

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").

12.14 Plastic/Rubber – Aging

Type of surface change

Aging tears in a breathing mask

- Brown stains/discolorations, and possible crack formation, in rubber and latex products.
- Softening or hardening.
- Many plastic materials turn yellow or become brittle.
- Silicone elastomers are extremely resistant to aging but tend to turn yellow.

Origin and causes

- Dry heat impact.
- Straining and overstretching during storage.
- Sunlight, UV radiation.
- Oxygen impact (oxidation, true aging).
- Ozone impact.

Treatment recommendations

None (cannot be corrected)

Preventive measures

If possible store instruments in dark and cool conditions.

Risk assessment

If the changes are application- and/or risk-relevant, withdraw affected instruments (depending on aging condition).

12.15 Plastic / Rubber – Swelling

Type of surface change

Swollen insertion tube caused by using unsuitable care agent.

Right: Swollen seals caused by incorrectly applied instrument oil.
Left: New seals

Right: Leaking flap valve on a trocar caused by the seal swelling as a consequence of contact with oil.
Left: New flap valve

- Swollen, softened, sticky surfaces of plastic, rubber or latex products.
- Thin-walled parts can split open or burst.
- Material becomes brittle and hardens.

Origin and causes

Penetration of gases or liquids into the surface. Swelling can be reversible and temporary if due to the impact of volatile spray solvents or propellants. The same symptom can also occur if rubber or certain plastics come into contact with gaseous anesthetics.
However, irreversible swelling can be caused by contact with oils (paraffin oil), Vaseline and unsuitable disinfectants (e.g. phenol derivatives). Silicone rubber shows a reversible reaction to spray propellants and gaseous anesthetics, but irreversible damage is caused by silicone oils, solvents and some disinfecting agents (e.g. amines).

Treatment recommendations

None (cannot be corrected)

Preventive measures

Avoid contact/exposure, depending on material (see "Origin and causes").

Risk assessment

Depending on degree of swelling, stop using affected instruments if existing surface changes are application- and/or risk-relevant.

12.16 Plastic – Stress Cracks

Type of surface change

Stress crack

Stress-crack corrosion, e.g. in polysulphone, leads to visible cracks or fractures.

Origin and causes

Stress cracks tend to occur in those areas of a medical product in which increased internal stresses are present for manufacturing reasons.

Under specific instrument reprocessing conditions (e.g. insufficient rinsing, high temperatures, presence of certain surface-active chemicals), cracks tend to develop in these areas.

Treatment recommendations

None (cannot be corrected)

Preventive measures

Do not use process chemicals that favor the formation of stress corrosion cracking. Ensure a sufficient final rinse with demineralized water. The manufacturer's reprocessing instructions must always be followed.

Risk assessment

Affected instruments should be withdrawn from service (and the instrument processing cycle) at once for reasons of patient and user safety!

13. Glossary

A_0 value	**The A_0 value concept** The A_0 value of a disinfection process using moist heat expresses lethality as a time equivalent in seconds at a heat transfer temperature of 80°C, with reference to micro-organisms for which the $_z$ value is 10°C.
Evaporation residue	The non-volatile components in water (e.g. mineral salts) in mg/l which remain behind after a pre-determined drying process.
Anion exchanger	Equipment containing resin to replace negatively charged ions (anions) dissolved in water such as chlorides, sulphates and nitrates through full demineralization using cation and anion exchangers.
Anti-microbial	Effective against micro-organisms. This is a more general term which provides no indication as to the type and extent of deactivating action.
Aseptic	Measures to prevent infection or contamination
Reprocessing	Measures taken to render medical products and accessories safe for use for a specific purpose.
Bacteriostatic	Preventing bacterial growth
Notified Body	A body designated by an authority or institution to certify quality assurance systems and medical products on the basis of the Medical Device Directive.
CE mark of conformity/ medical product	Confirmation that the manufacturer of a product has performed a conformity assessment according to EU Directive 93/42/EEC.
Chemo-thermal process	A process in a washer-disinfector designed for goods which do not tolerate heat, allowing only reprocessing at defined temperatures up to 65°C combined with the use of a disinfectant in a specified concentration over a defined exposure time.
Chlorides	Salts of hydrochloric acid, often occurring as sodium chloride or potassium chloride dissolved for example in water or blood. Table salt and reactivation salt consists of sodium chloride which is also a constituent of physiological salt solution.
Steam sterilization	A validated process to eliminate micro-organisms on products using saturated steam (according to ISO 17665).
Decontamination	Process to dilute contamination and deactivate pathogens in the instrument reprocessing cycle.
Disinfection	Process to reduce the bacterial titer count to a predetermined level suitable for handling or use.
Dispersion	Suspension of insoluble solids in a detergent solution for removal.
Distal end	The distal end of an instrument is the end closest to the patient, e.g. the jaws of forceps.
Protein interference	The capacity of proteinaceous soil to reduce the efficacy of certain disinfectants.
Electrical conductivity	Used in water analyses to measure the total content of dissolved and electrically conductive mineral salts.
Anodized	A surface finish used on aluminum. The anodized layer ($Al_2O_3 \cdot H_2O$ aluminum oxide hydrate) is silver-gray in color and is created by electrolytic oxidation to protect products against wear and corrosion. Dyes can be added to give a variety of colors.
Emulsification	Suspension of insoluble liquids in a detergent solution for removal.

Water softening	Water treatment process in which cation exchangers are used to remove the hardness (calcium and magnesium ions) from water by replacing these with sodium ions.
Color anodized	Signifies the decorative coloring of aluminum, such as by immersion coating. Standard colors include gold, blue, red, black, etc.
Micro-structure	A micro-structure is the internal structure of a material. In metals, this generally refers to the crystalline or grain structure which results from the production process or subjection to heat. In the case of stainless steels, the micro-structure determines a material's properties, for instance hardness or elasticity or its tendency to wear or corrode.
Slip agents	Slip agents are used when introducing probes, endoscopes and ultra-sound devices in order to prevent irritation to the skin and mucous membranes.
Surface tension	Characteristic of water and fluids as a result of the polarity of water molecules.
Minerals causing water hardness	Calcium and magnesium salts dissolved in water
Halogenides	Collective term for chlorides, iodides and bromides with similar chemical properties
Carbide metal	Carbide metals produced in a sintering or casting process which are extremely hard and impervious to wear.
Inert gases	Inert gases are non-condensable gases (NCGs).
H_2O_2 gas-plasma sterilization	Process used to sterilize thermally sensitive materials using hydrogen peroxide.
Contamination	Undesirable substances including micro-organisms
Corrosion	In general terms, corrosion is construed as the degradation of surfaces through environmental influences, e.g. substances with a critical chloride content (blood, salt solution, etc.) on stainless steels.
Ion exchanger	Collective term for cation, anion and mixed-bed ion exchangers
Cation exchanger	Device containing resin to demineralize water by replacing dissolved, positively charged ions (cations) such as calcium and magnesium ions with sodium ions or hydrogen ions.
Boiler feed water	Water used to produce steam in a boiler.
Silicon dioxide	Acid contained in water which is in the acidic range. The salts of this acid are referred to as silicates.
Passage of silicon dioxide	Problem relating to the full demineralization of water using ion exchangers. Silicon dioxide passes through an ion exchanger without increasing the electrical conductivity of demineralized water.
Lumen	Passageway in hollow instruments.
Martensitic	Term used to describe the micro-structure of materials which occurs when steel is hardened through quenching.
Mixed-bed ion exchanger	Combination of cation and anion exchanger used in the full demineralization of water.
Surface tension	Characteristic of water and fluids as a result of the polarity of water molecules. The surface of water appears to form a skin.
Organic residue	Residues such as blood, protein and tissue, mainly from the human body.

pH value	The pH value is a measure of the acidity or alkalinity of aqueous solutions. pH < 7 = acidic pH = 7 = neutral pH > 7 = alkaline
Pharmacopeia	Official listing of medications
PVC	Polyvinyl chloride - Type of plastic frequently used in medical technology.
Protein fixation	Process which changes the structure of proteins. Proteins modified through chemical influences or heat are more difficult to remove from surfaces.
Process chemicals	Collective term for the chemicals such as detergents, disinfectants, neutralizing agents, surfactants and instrument milk used in instrument reprocessing.
Prions	Protein folding error causing transmissible spongiform encephalopathies (TSE) such as BSE, CJD and vCJD.
Denaturation of proteins	Modification of protein structures through chemical influences or heat.
Redeposition	The process in which soil already removed from a surface resettles.
Reactivation salt	Salt used to reactivate water softeners operating on the cation exchange principle. Consists mainly of sodium chloride.
Cleaning	Removal of contamination from an object to a degree which renders the item fit for further reprocessing or its intended use.
Rhodium	A metal with a silver-gray sheen.
Rust	Rust is the product of corrosion on iron, steel and steel alloys as a result of oxidation, a reaction with oxygen in an atmosphere containing water.
Saturated steam	Steam in a state of equilibrium between condensation and evaporation.
Acoustic shadows	Acoustic shadows occur for example in an ultrasonic bath behind objects which stand in the direct path, obstructing the source of sound.
Washer-disinfector load	Collective term for medical products and accessories which require cleaning and disinfection.
Sterile filtration	Filtration of liquids, e.g. the water used in a final rinse, using a filter which prevents the passage of bacteria (pore size <= 0.2 µm).
Spray shadows	Spray shadows are areas within a washer-disinfector shielded by large and improperly positioned items, preventing water jets from accessing the load direct.
Sterilization	A process to remove all micro-organisms from a product.
Tactile	Referring to the sense of touch.
Thermal process	Process in a washer-disinfector using damp heat as the disinfecting agent.
Thermolabile instruments	Medical products and accessories which cannot be thermally disinfected or sterilized using steam.
Heat-resistant instruments	Medical products and accessories which can be thermally disinfected and sterilized using steam.
Non-wovens	Sterile barrier system (SBS), usually as composite material made from textile or non-textile fibers (EN 868-2:2009).
z value	Temperature change in K required to achieve a tenfold change in the microbiological deactivation rate in a disinfection process using moist heat. Source: ISO 15883:2006-07

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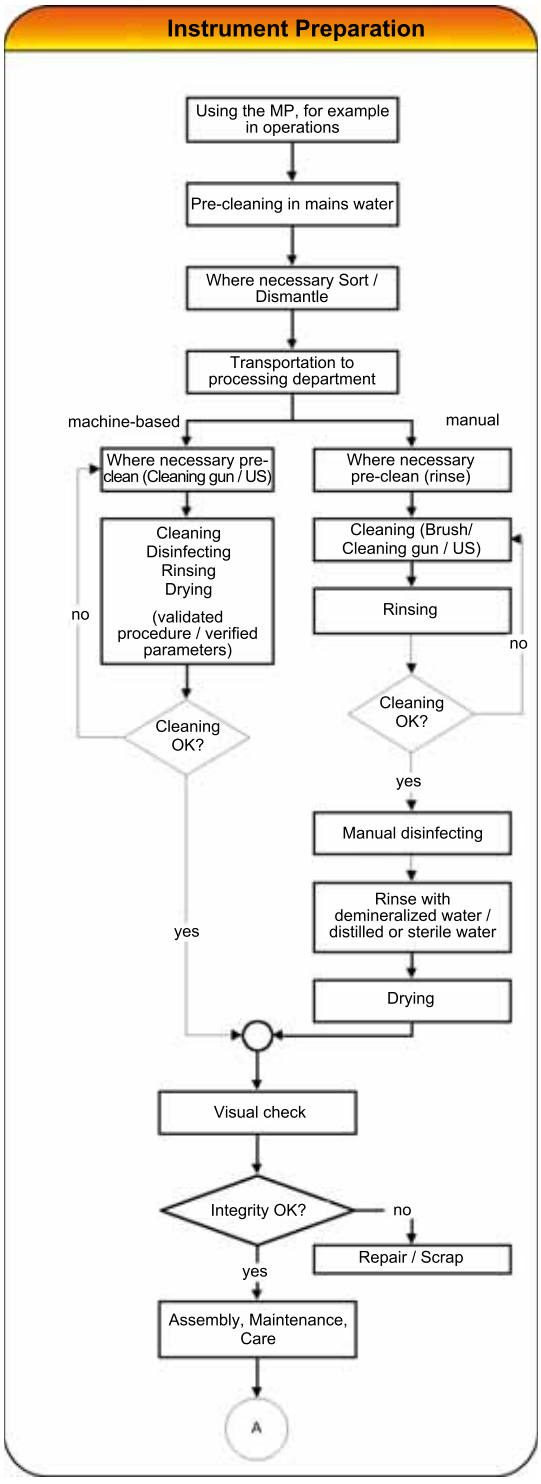

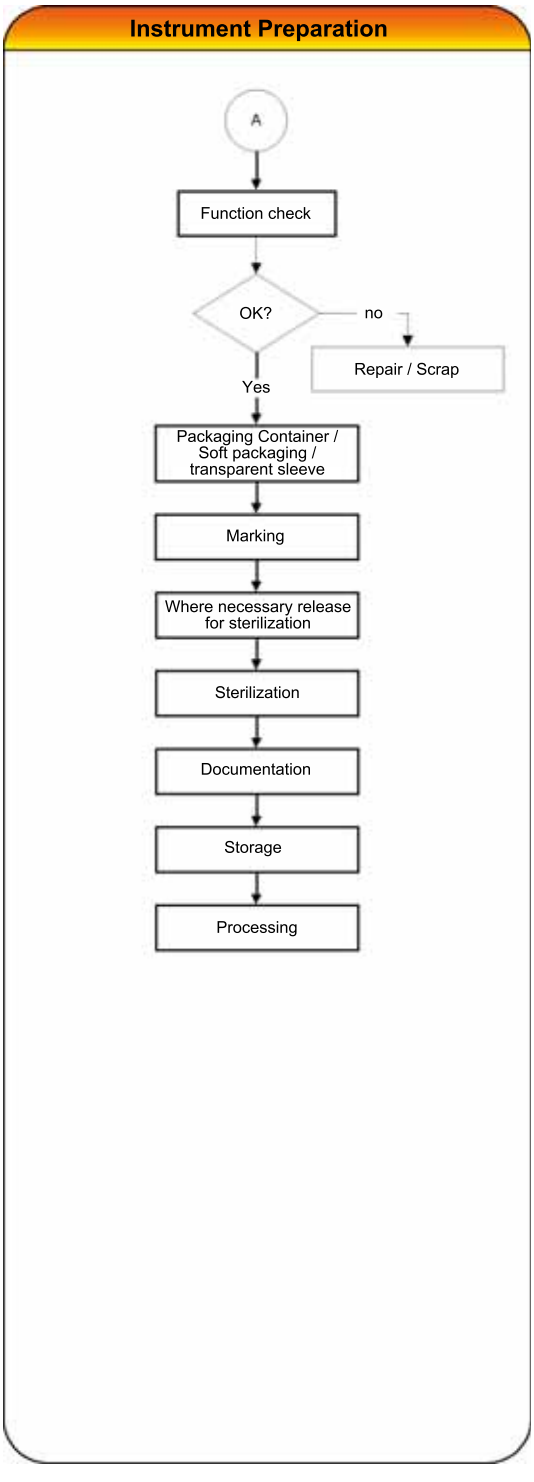

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