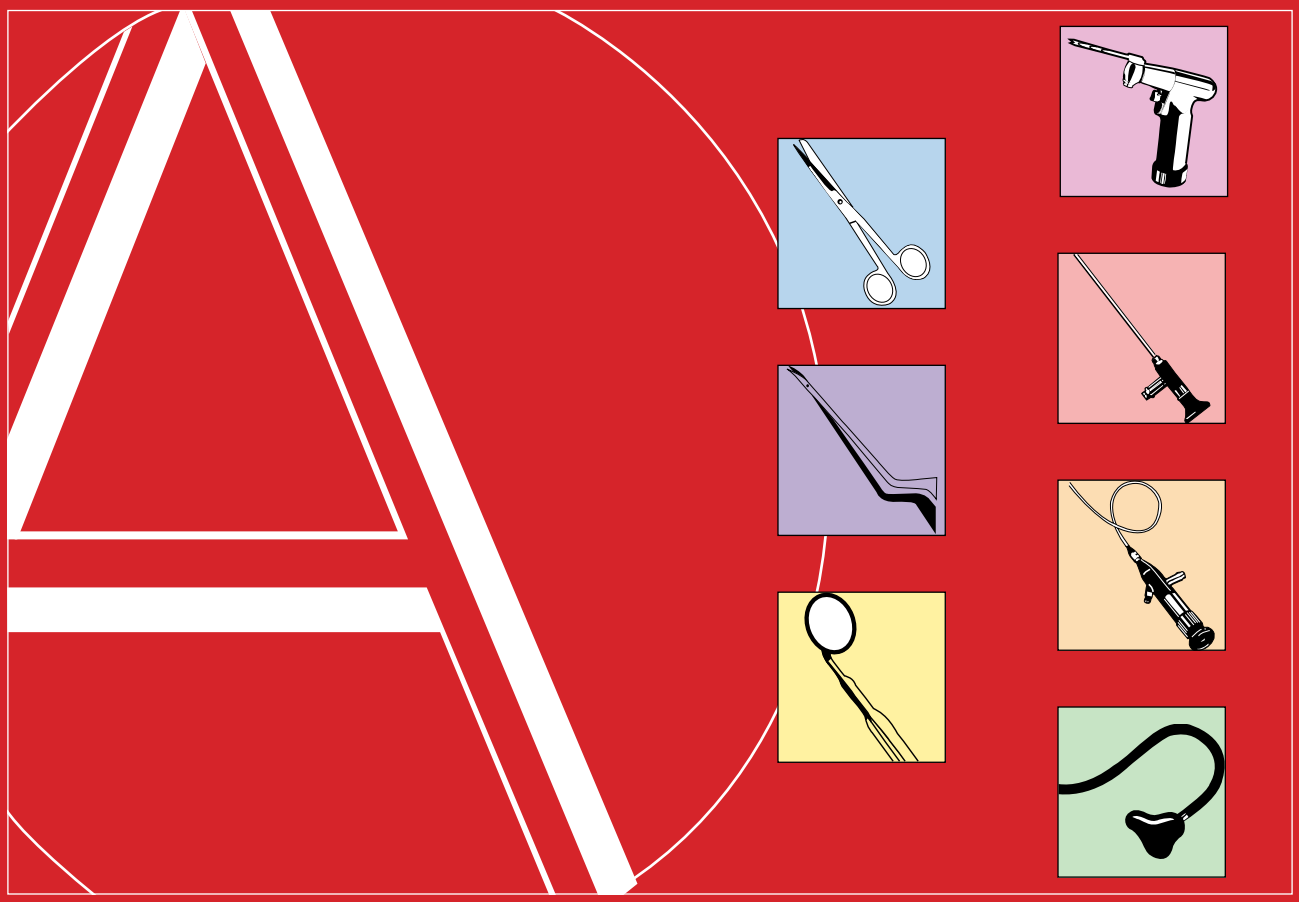
# Instrument Reprocessing

## Reprocessing of Instruments to Retain Value



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Working Group
Instrument Reprocessing

# Reprocessing of Instruments to Retain Value

11th edition 2017
Surgical Instruments
Microsurgical Instruments
Dental Instruments
Motor Systems
Instruments for Minimally Invasive Surgery, Rigid Endoscopes, Robotic Instruments and HF Instruments
Flexible Endoscopes and Accessories
Flexible Instruments and respiration systems

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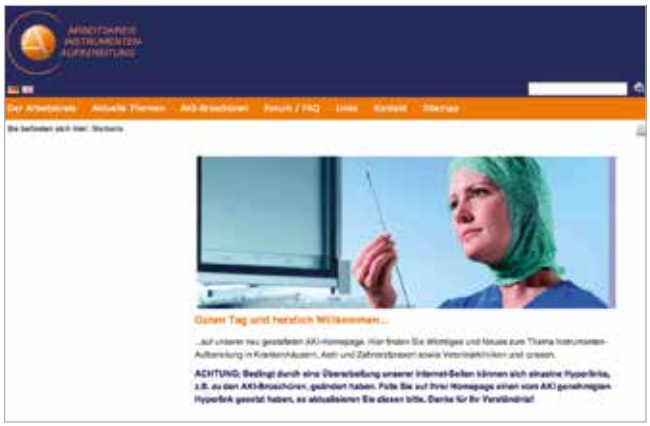

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# Reprocessing of Instruments to Retain Value

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# Preface

The Instrument Reprocessing Working Group (AKI) was founded in 1976 with the aim of developing and publishing expertise and practical information on the safe reprocessing of instruments in healthcare with the aim of retaining their value. Having been established for four years as of 2016, AKI has not only become part of the history of "instrument reprocessing", but also embodies the present, serving as an inspiration for the future of our specialty field as an example of multidisciplinary and interactive cooperation.

Efforts to ensure the independence of the departments for sterile supplies over these past decades, now known as the "Reprocessing Unit for Medical Products (RUMP)", were an important step towards establishing a scientific basis and much improved reprocessing. This was later followed by the industrialization of the department (i.e. viewing the sterile supplies department as an industrial production unit), assisted by the introduction of quality management systems and IT systems.

Today, we have reached the next phase, defined by a more unified perspective of "reprocessing". A sterile medical product is the sum of a series of actions, of which the sterilization process itself is only a part. Sterility is the result of integrity across processes, which also requires "all-inclusive" responsibility to be assumed by the reprocessing department for this overall process. This responsibility no longer ends at the exit door of the Reprocessing Unit for Medical Products – today, it reaches as far as the operating theater, the patient's bed, and the treatment room of the clinic.

AKI's great achievement lies in always having remained within its essence. Its various publications have made a significant contribution to establishing a robust basis for the reprocessing of healthcare instruments, offering practical solutions to everyday problems faced by sterile supplies departments or dental practice. For instance, these may be problems relating to water reprocessing and water quality, to the selection and dosage of cleaning agents, to the structure of programs of various devices, to the quality of the instruments themselves, and also to the organization of work flows, which has a major impact on the quality of the end product and on its long-term value. These are recurring problems for which even the latest apps cannot help to find definitive solutions. Ultimately, they require daily monitoring of the various parameters and timely intervention in the event of significant discrepancies. They require the ongoing vigilance of the staff of the Reprocessing Unit for Medical Products.

The influence that AKI's publications have had and continue to have on modern sterilization is impossible to overestimate. AKI since offers

information through two generations of "sterilization staff", information that, as previously stated, is only becoming more expansive and has lost nothing of its relevance to this day. Additionally, the brochures help to ensure much-needed continuity, especially as the pioneers of sterilization are beginning to leave the field. This ensures that knowledge is not lost, but continuously built upon.

"Reprocessing of Instruments to Retain Value", nicknamed the "red book", is the publication that AKI is best known for. As far as sterilization is concerned, this red book, unlike the other little red book with quotes from Mao Zedong, has contributed to a quiet, progressive and constructive revolution. It has helped to improve reprocessing throughout the world and has doubtlessly saved countless unnamed lives. There is no doubt that its availability in 20 different languages has played a major role in this. The ability to read it in one's own language helps to ensure a better understanding. Understanding is necessary for knowledge. Knowledge is necessary for change and improvement.

Wim Renders

Honorary President, World Federation for Hospital Sterilization Sciences (WFHSS)

# Foreword

Instruments are a major asset and represent a significant share of the total capital spending of a hospital. It is a daily challenge to reprocess these in a manner that is safe and conducive to their long-term use. The practical experience recorded in this booklet, together with a description of fundamental interrelationships, is intended to help users to keep their reusable instruments in good working order and preserve their value for many years, by ensuring proper reprocessing. It should be emphasized that the recommended measures must always be carried out in accordance with the manufacturer's instructions, pertinent national hygiene requirements and official safety-at-work guidelines. In the interest of preserving the value of instruments, it may be advisable to go beyond national standards.
Instrument reprocessing is increasingly subject to medical product legislation and is standardized in many countries.

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

This 11th edition contains extensive updates.
For instance, the booklet now contains information on the reprocessing of instruments used in robot-assisted surgery New knowledge gleaned from both practical experience and laboratory testing have provided the basis for various new sections, and the requirements of updated standards have also been included in the booklet.
The glossary has been expanded to include further terms and definitions.

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 section starts with handling instructions for surgical instruments, including general instructions for the product groups described below. 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*

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


Surgical motor systems


Minimally-invasive surgery instruments, robotic instruments, rigid endoscopes and instruments for high-frequency surgery (HF)

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.

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

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

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, with this booklet addressing those that may be used only under sterile conditions and therefore need to be cleaned and resterilized after use, such as hand-held battery and compressed-air driven devices or handpieces.

Other instrument groups for which special processing instructions are provided in this guide are MIS instruments, robotic instruments, rigid endoscopes, HF instruments, flexible endoscopes and flexible instruments.

Needless to say, users of medical devices expect well-known manufacturers to exercise the greatest of care in both selecting the right materials and manufacturing the product. Because of this, the user can count on medical 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

Medical products should only be reprocessed if the relevant manufacturer has specified that it is appropriate to do so and if the manufacturer has provided instructions to this end.

## General notes and instructions

Basically, the reprocessing of medical devices comprises:

- Preparation (pre-treatment, collecting, pre-cleaning and, where applicable, taking the instruments apart),
- Cleaning, disinfecting, final rinse, drying (if required),
- Visual inspection of cleanliness and condition of material,
- Care and repair where required,
- Functional test,
- Marking,
- Packaging,
- Sterilization,
- Approval,
- Storage.

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

and sterilization processes, supplemented by defined configurations for loading the washers/disinfectors (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 product failure might endanger the patient or third parties. We urge you to consult the manufacturer if you have any doubts.

For thermostable medical products, machine-cleaning with thermal disinfection and steam sterilization are the preferred methods.

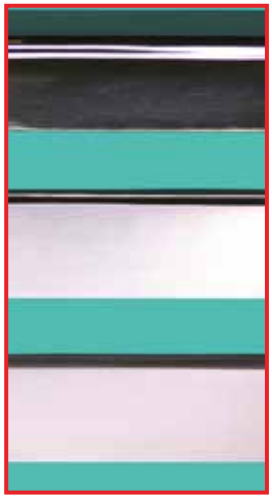
# 1. Materials and Design

## 1.1 Materials

When producing medical devices, the manufacturer must engineer them to be fit for their intended purpose not only in design, manufacture and finish, but also by selecting adequate materials suitable for the intended use, potential reprocessing procedures and process chemicals to be used.

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

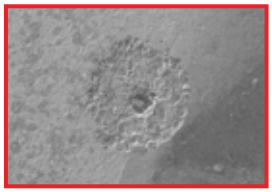



Surface finishes on instruments

The corrosion resistance of stainless steel primarily depends on the formation, thickness and integrity of the passive layer. This natural coating 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, as long as the surface topography of the product (matte or high-gloss) is suitable. In fact, its formation and morphology are influenced by the following factors:

- The material composition, alloy and purity,
- Microstructure of the material, which is influenced by heat treatment (e.g. forging, tempering, annealing, welding, soldering, laser engraving),
- Surface condition, e.g. roughness, topography, flawlessness and cleanliness,
- Handling and reprocessing conditions,
- The service life and number of reprocessing cycles,
- Instrument labeling (e.g. laser engraving, electrochemical markings, embossing).

### Chlorides are dangerous



Scanning electron microscope image, chloride-induced pitting

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

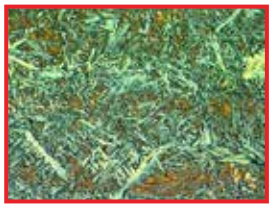
Tweeters in detail: Transition between spring and grip surface.Reactivation salt containing chloride caused massive pitting on the surface of the instrument. Leaking ion-exchanger connection in the W/D.

Technical measures such as chemical passivation implemented by the manufacturers, supported by processes such as dip processing in a citric acid mixture and the natural aging process, ensure that the passive layer becomes more resistant (provides more protection from corrosion). Where there is mechanical damage or wear, this optimized passive layer is also destroyed in certain areas, only to be replaced by a natural passive layer (see page 14) resulting from a form of "self-healing" caused by re-passivating.
Experience has shown that a newly applied technical passive layer is superior to a natural passive layer that has been damaged in certain areas, because it reduces the likelihood of chlorides penetrating it through to the unprotected base material.

Chloride sources in the instrument usage and processing cycle:

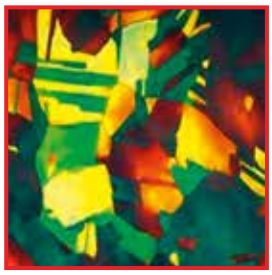
- Fresh-water chloride content (depending on the source of the supply).
- Insufficient demineralization of the water used for the final rinse and steam sterilization.
- Reactivation salt carry-over, leakage or spillage from ion exchangers used for water softening.
- Use of agents not permitted for or 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/l, saliva, sweat) dried on the surfaces.
- Laundry, textiles, packaging materials.

Regardless of whether the instrument has a "matte" or "glossy" surface and how the passive layer is formed, pitting and stress corrosion cracking do not occur (or at most only occur rarely) in environmental conditions with no or little chloride content.
If corrosion occurs on new, high-quality instruments processed in the same cycle with older instruments, the reason was found in all cases investigated so far in the instrument reprocessing conditions, where individual or several treatment steps had taken place under conditions that approached or exceeded the limits of process reliability.



Color etching – martensitic structure (500x magnification)

As well as hardenable martensitic chromium steels, standardized non-hardenable chromium steels with modified chromium contents and rust/acid-resistant chromium-nickel steels, each classified as being of stainless steel quality, 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. The mechanical properties of products made from these also remain unaffected even after any number of reprocessing cycles.



Color etching - austenitic microstructure on rust and acid-resistant instrument steel (500x magnification)

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). However, these are used only rarely today.
- Coatings (e.g. titanium aluminum nitride, titanium aluminum carbonitride, zirconium nitride and titanium nitride,
- Light metals (e.g. anodized aluminum),
- Noble metals (e.g. silver),
- 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. These items may therefore require special treatment that varies from the standardized instrument reprocessing procedure. Such treatment is 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 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 flexible endoscope, combinations of highly flexible polyurethane hoses, adhesives, lenses, optical fibers and more are used.

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 housing made of unalloyed sheet steel, handpieces with colored graduations (indicating gear ratios) or anodized aluminum housings (as used for handpieces and elbows). 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 device it is necessary to consider its capacity for good reprocessing after use. However, the focus must be not only on the capacity for reprocessing, but also on correct functioning. Often, the mechanism required must be 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 only possible to dismantle many medical products with great difficulty, for example articulated instruments used in minimally invasive surgery with diameters of less than 3 mm, because users & reprocessors are unable to dismantle and reassemble these ultra-thin components. Another important point is the choice of materials and joining techniques. Joining methods such as welding and soldering are designed to avoid affecting the mechanical and corrosive properties of the product over the course of its service life.

Because fractional steam sterilization is the most commonly applied sterilization method and is the most damaging for many non-metallic materials, suitable materials must be selected.

To achieve optimum reprocessing results, close cooperation is essential between all the parties involved: from the medical product manufacturer, the manufacturers of automatic 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:

- As a solvent for cleaning agents and other process chemicals,
- Transferring mechanical forces and heat to the instrument surface,
- Dissolving water-soluble dirt and impurities,
- Flushing process chemicals,
- Thermal disinfection for machine-cleaning and disinfection,
- Medium for steam sterilization.

### Use correct water quality!

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

**Water constituents and their influence in reprocessing**

While any natural water contains dissolved salts, The nature and concentrations present in drinking water vay depending on the source 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, corrosion potential |
| Heavy and nonferrous metals, e.g. iron, manganese, copper | Brown-red deposits, secondary rust |
| Silicates, silicic acid | White-grey, 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.

## Chlorides are dangerous

Chloride-induced pitting on instrument.

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. High quantities of iron dissolved in water can cause corrosion on surfaces (secondary rust).

Silicates

Silicic acid and silicates may cause white-gray, 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.

The danger of chloride-induced pitting generally rises with:

- An increase in the chloride content,
- An increase in temperature,
- Declining pH value,
- Increasing exposure time,
- Insufficient drying,
- Concentration of chloride resulting from adherence of dry residues to instrument surfaces after evaporation.

While the causal relationships between the chloride content of the water and pitting are not always predictable, laboratory testing has shown sign of corrosion on instruments after just two hours with a chloride content of 100 mg/l at room temperature. As chloride concentrations increase, the risk of pitting also increases rapidly.

Evaporation residue

When water evaporates, some substances contained in it remain as visible 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. Depending on the application, drinking water should be softened or demineralized by means of reprocessing procedures described in more detail below.

## 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. However, this does not reduce the overall load of evaporation residue (including chloride content) in the water. 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, cation & anion exchangers, and electrode ionization, a combination of the above, and also distillation in special cases.

Substances in water, such as silicic acid, may cause discolorations.

Stain pattern caused by silicic acid in steam condensation.

Comparison of example water qualities:

| | Drinking water | | Softened water | | Demineralized water |
|---|---|---|---|---|---|
| Evaporation residue (mg/l) | 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 machine-based instrument reprocessing, the following guide values are recommended:

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

Attention: When using softened water, especially when applying thermal disinfection, corrosion may develop on instruments and anodized aluminum surfaces might be subject to attack due to an increased pH value.

Attention: Where chloride content exceeds 50 mg/liter and cleaning parameters are unfavorable (low pH value, elevated application temperature and exposure time), the risk of pitting cannot be eliminated for stainless chromium steels.

Use fully demineralized water for the final rinse!

Demineralized water:

Since there is currently no specific standard for demineralized water in machine-based or manual cleaning and disinfection, the application of the boiler feed water quality as defined in DIN EN 285, Appendix B is also recommended for this process step. Despite the requirement specified in EN 285, empirical data has shown that a conductivity value of around 15 µS/cm is sufficient for manual and machine-cleaning and disinfection.

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 surface

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.

For steam sterilization, limit values for feed water quality as specified in 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-) | ≤ 0.5 mg/l |
| Phosphates ($P_2O_5$) | ≤ 0.5 mg/l |
| Conductivity (at 20 °C)* | ≤ 5µS/cm |
| pH value (degree of acidity) | 5 to 7.5 |
| Appearance | colorless, clear, no deposits |
| Hardness (Σ of alkaline earth metal ions) | ≤ 0.02 mmol/l |

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

Source: DIN EN 285: 2016-05 (EN 285:2015, Table B.1)

If ion exchangers are used in the production of fully demineralized water, glaze-like discolorations may occur as a result of silicic acid passage (see chapter 12.4). To ensure that instruments can be reproducibly kept spot-free, the silicate content should be consistently below 0.4 mg/l. Quality monitoring of the fully demineralized water by way of monitoring

of electrical conductivity is not adequate for identification, as the silicic acid does not imbue the water with conductivity. For this reason, it is advisable to periodically measure the silicic acid content using a quick chemical test. Practical experience has shown that silicic acid 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 silicic acid content.

Qualified personnel 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, neutralizers, 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.

Outside of Europe, the relevant national regulations must be observed.

The producers of process chemicals must provide evidence of and document claimed properties such as cleaning, disinfection and care, and also regarding the biocompatibility of residues. This is part of the product documentation that is required to achieve a CE mark.
The producer of the process chemicals must provide evidence of compatibility with materials, if necessary in cooperation with the manufacturer of the corresponding medical instruments. The bio-compatibility of potential process chemical residues must be tested and assessed in accordance with ISO 10993 "Biological Assessment of Medical Devices".

Optimum application properties and the material compatibility of the process chemicals are assured only under the application conditions recommended by the manufacturer. Material compatibility is heavily dependent on temperature and concentration. Attacks are possible, for instance on coatings or anodized surfaces, depending on the reprocessing procedure. The producer must describe the application conditions and product properties in a relevant document in detail (on the label, product information, safety 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 ingredients of various process chemicals may interfere with one another. For example, in a machine process the constituents of a cleaning agent 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 process chemicals designed to be used together from a single manufacturer be used in a self-contained machine-cleaning & disinfection cycle. Ingredients of pretreatment agents may also inferfere with process chemicals used in a machine-based process, potentially resulting in the formation of deposits. It is recommended to take note of the information provided by the producer.

## 2.2.1 Types of process chemicals

**Pretreatment agents**

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

**Detergents**

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

- pH-neutral cleaning agents with/without enzymes,
- mildly alkaline cleaning agents with/without enzymes,
- alkaline detergents with/without tensides.

There are also combined lab cleaning agents that both clean and disinfect. Material compatibility is dependent not only on pH value, but on the overall composition of the cleaning agent and the circumstances under which it is applied. Therefore, all of the specified cleaning agent types may have stated material compatibilities.

**Disinfectants**
Disinfectants are employed both for manual and – preferentially – automated cleaning and disinfection to perform final disinfection (see chapter 7) on heat-sensitive medical products such as flexible endoscopes. Disinfectants contain anti-microbial 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.

**Neutralizers**
Acidic substances based on citric acid or phosphoric acid which can be added to the initial rinsing water in machine-cleaning and disinfection following alkaline cleaning in order to neutralize alkalinity and enhance rinsing of the cleaning agent. Neutralizers may also be used to present spotting and support the formation of passive layers.

**Rinse aids**
Rinsing agents are added to the final rinsing water in a machine-based cleaning & disinfection procedure to achieve more effective, faster drying. The agents in the rinsing agents 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 oiling 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 cleaning agents (calcium hydroxide, sodium hydroxide) and decompose organic dirt residues by their alkalinity.

**Anti-microbial agents**
**Aldehydes** 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 cleaning agents 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 cleaning agents and disinfectants. 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 cannot be used to reprocess 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 disinfectors 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 the usage conditions.

Depending on pH value, **peracetic acid** and its salts can be used both as combined cleaning agents 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 cleaning agents 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. Due 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, especially for flexible endoscopes. Material compatibility depends heavily on the pH value of the application solution and on the concentration of the agent. 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 peracids in combined cleaning agents and disinfectants, in final disinfection products, and for low-temperature sterilization. At room temperature, this agent demonstrates good material compatibility in conventional concentrations, although the special conditions of low-temperature sterilization processes (temperature & concentration) may affect material compatibility.

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

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

**Oxidation agents**
are based on hydrogen peroxide or on sodium hypochlorite, for example, and are able to decompose particularly stubborn organic contaminant 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 contaminant-carrying capacity supports the cleaning process.

**Phosphate substitutes**
Phosphate substitutes such as gluconates and phosphonates absorb water-based minerals but can only partially substitute the assistance that phosphates provide in cleaning.

**Acids (citric or phosphoric acid)**
Citric and phosphoric acid preparations are used as neutralizers, but can also be used as complete acidic cleaning components in machine-based reprocessing procedures.

**Silicates**
provide corrosion protection, such as for light metals, in alkaline cleaning agents.

**Silicone oils**
are recommended as care substances for anesthesia utensils.

**Tensides**
Tensides in detergents reduce the interfacial and surface tension of water, assist cleaning with their emulsive and dispersive effects, and prevent redeposition of contaminants. Suitable tensides in machine cleaning agents inhibit form formation, which may occur for instance when high amounts of blood are present. Tensides are also a major component of rinsing agents to reduce interfacial and surface tension, which ensures that water runs off better, thereby improving the drying of the rinsed product.

# 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 Reprocessing Unit for Medical Products as soon as possible and removed from their transportation packaging before storage 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. The number of cycles is dependent on the manufacturer specifications.

## Cleaning is mandatory!

This cleaning step should never be skipped, because residues on instruments (e.g. from packing materials or care agents) may result in the formation of stains or deposits during sterilization.
Always visually inspect cleaning results. As a rule, the instruments should be visibly clean after the cleaning stage.
Where the passive layer of brand-new instruments is still thin, these instruments may be more sensitive to critical reprocessing conditions than older, used instruments. Some manufacturers recommend that they undergo cleaning and disinfection (washing) several times.

## 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 holders, even after being reprocessed for the first time.

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 Recommendations for Returned Goods

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

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

- they have been cleaned, disinfected and dried in accordance with the manufacturer's instructions, and have been declared hygienically safe, or
- they 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 if they were undergoing their normal cycle. This prevents subsequent damage to the instrument (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. 31) 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(s),
- Reason for return.

# 5. Preparation for Cleaning and Disinfecting

The first steps in a proper reprocessing cycle are taken in the operating theater. Coarse contaminants, residues from hemostatics, skin disinfectants and lubricants, 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 immerse stainless steel instruments in an isotonic solution (such as physiological saline 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 Reprocessing Unit for Medical Products, self-contained systems are used to transport contaminated medical products from the operating theaters and wards to the unit. Dry disposal always preferable as a more conservative method aimed at retaining value.

Wet disposal involves damp cloths being placed on the instrument trays during transport or the use of an appropriate foam spray. The damp conditions increase the risk of corrosion and may encourage the growth of microorganisms.

When using wet disposal, it is advisable to immerse the instruments in a cleaning agent or combined cleaning agent 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 specifications should be noted at all times.

## Avoid long intervals between use and treatment for reuse!

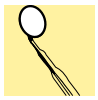
Because of the corrosion risk and the cleaning factors, long intervals between instrument use and reprocessing (e.g. overnight or over the weekend) should be avoided. Field experience has shown that in the case of dry disposal, intervals of up to 6 hours pose no problem. Contamination and pre-cleaning are factors that have a critical impact here.

For certain instruments, it is recommended that reprocessing commence immediately, for instance for flexible endoscopes and robotic surgery instruments.

The instruments must be placed into instrument carriers (e.g. trays, racks) that are suitable for machine-based cleaning procedures.
Effective cleaning requires that articulated 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 washers/disinfectors will not be hampered by acoustic or spray shadows.
Complex instruments must be taken apart for cleaning in accordance with the manufacturer's specifications.

Instruments not used for surgical intervention must be treated in the same way as instruments that have actually been used.

Special racks, suitable storage holders and load carriers with special rinsing equipment must be used for microsurgical instruments.

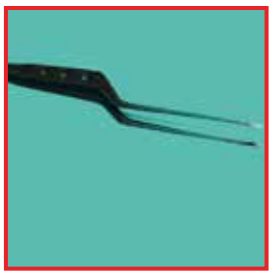


Dental materials adhering to dental instruments (such as filling materials or acid cement removers) must be cleaned away immediately after use. Otherwise, the material will harden on the instrument and/or cause corrosion. Dental cements and composites should ideally be removed directly after application, for instance with a swab.

Surgical motor systems must be taken apart immediately after use in accordance with the manufacturer's specifications. If the manufacturer's specifications call for special storage systems for automated cleaning and disinfection, such systems must be used. Batteries not suited to reprocessing must be removed from the motor systems.

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 sensitive instruments, they must be transported in containers designated for this purpose with restraints. Shaft-based robotic instruments are pre-filled with water or cleaning agent and immediately transported for reprocessing. MIS instruments, endoscopes and HF instruments that can be taken apart must be disassembled in accordance with the manufacturer's specifications prior to reprocessing. Optics must be placed in special containers.



Deformation caused by improper handling

Dried-on residues are particularly critical in the case of instruments used in surgical endoscopy, because such deposits are difficult to remove from small lumens, and may impair or destroy the functionality of joints. This is why these instruments should always be processed immediately after use. Where cleaning proves to be difficult using the available methods or procedures, we recommend that HF instruments be pre-treated with a hydrogen peroxide solution in order to remove any coagulated residues. HF instruments for robotics must not be treated with hydrogen peroxide solutions. It is advisable to fill these instruments with enzymatic cleaning agent 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 or 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 specifications. 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 respiratory systems must always be taken apart (in accordance with the manufacturer's specifications) to ensure that they are properly reprocessed 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 soda lime. 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 and Disinfecting

**Cleaning**

For manual cleaning, active non-protein-fixing process chemicals with or without anti-microbial effect and with or without enzymes are used.

When using cleaning agents, the manufacturer's specifications, especially those regarding concentration and temperature, must be observed. The cleaning/disinfecting solutions used should be freshly prepared on a daily basis. If it becomes visibly contaminated, it is advisable to prepare fresh solutions at even shorter intervals.

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

- Reduced cleaning performance due to increased reintroduction of contaminants.
- Risk of corrosion due to contamination and due to increased concentrations caused by evaporation.
- Microbial development in the cleaning agent solution, thereby potentially putting personnel at risk.

**Disinfecting cleaning**

When performing disinfecting cleaning, please also note that the disinfecting capability should have been proven under "dirty conditions" (high protein load) in accordance with European (EN) standards or corresponding national regulations. When using disinfecting cleaning agents, the producer's specifications regarding concentration, temperature, exposure time and material compatibility must be observed. The cleaning/disinfecting solutions used should be freshly prepared on a daily basis. If it becomes visibly contaminated, it is advisable to prepare fresh solutions at even shorter intervals.

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

- Reduced cleaning performance due to increased reintroduction of contaminants.
- Risk of corrosion due to contamination and due to increased concentrations caused by evaporation.

**Disinfection**

In some countries, medical products are disinfected before sterilization for occupational health & safety reasons (see chapter 15). In such cases, disinfectants with proven disinfection effects are used. The disinfection effect must at least have been proven under "clean conditions" (low protein load) in accordance with European (EN) standards or corresponding national regulations.

The disinfectant solution must be replaced as specified by the producer.

Dissolve powders completely!

If powdered products are used, the powder must be fully dissolved in the water in accordance with producer specifications before use. Only then are the instruments placed in the solution. Suitable measures should be taken to mitigate the risk of contact between undissolved particles and instruments (e.g. disinfectant bath with sieve) to prevent changes to the surfaces or blockages of narrow-lumened instruments.

Stains caused by high salt content of rinse water

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 procedure removes contaminant residues that may still adhere to the surfaces of the instruments.

Water must be used to rinse the instruments, and must be at least consistent with the microbiological quality of drinking water. For the final rinse, fully demineralized water is recommended to prevent spotting. The relevant water reprocessing systems must be serviced in accordance with the manufacturer's instructions. The instruments must be dried thoroughly immediately after rinsing. Drying using oil-free compressed air is especially conservative and effective, which is why it should be preferred over other drying methods such as drying with a cloth.

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.

Articulated 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 require greater attention to process. It is important to make sure that the internal surfaces are thoroughly and completely in contact with the solution.

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, elbows and drive systems that cannot be submerged in an immersion bath undergo disinfection by wiping from the outside (e.g. using a suitable surface cleaner-disinfectant). As regards cleaning their internal surfaces, and taking appropriate maintenance and care measures, observe the manufacturer's specifications.

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.

Instruments for root canal treatment are highly susceptible to mechanical damage and should therefore be reprocessed separately and placed in special stands for handling purposes. For cleaning and disinfecting remove the silicon stoppers in order to adjust the depth of preparation. Alkaline solutions may attack instruments used for root canal treatment with colored, anodized handles and may 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, Operating instructions must be noted to allow the entry or liquids, cleaning agents or disinfectants into lumens and cavities.

Avoid ingress of liquids!

For battery-powered devices, check whether the manufacturer's specifications require and allow cleaning and disinfection of the batteries. Contact between the battery's contact and electrically conductive objects (instruments, sieve baskets) or liquids must be avoided.

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.

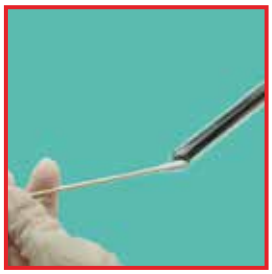
MIS instruments and rigid endoscopes are susceptible to mechanical damage.
Systems or components with cavities and channels/ducts must be treated with particular care to ensure effective cleaning.

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

Rinsing forceps with irrigation connection

When immersing such instruments in a cleaning or disinfecting solution, make sure that the cavities are free of 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.

If instruments with an irrigation connector cannot be taken apart, they must be sufficiently flushed with a cleaning or disinfectant solution. Make sure that the distal end of the instrument is adequately flushed as well. Manufacturers recommend that robotic instruments be cleaned using enzymatic cleaning solutions. When rinsing, the manufacturer's pressure and time specifications must be observed.



Cleaning the lens of an endoscope

The glass surfaces of optical systems should be treated 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 hydrogen peroxide solution, brushes or ultrasound) must be discarded, because their proper function and their required sterile condition can no longer be guaranteed.

Remove valves and caps from flexible endoscopes prior to processing. Suitable protective caps must be applied in accordance with manufacturer specifications. This is the only way to ensure that the channels can be thoroughly cleaned and flushed. Cleaning is performed by immersing the flexible endoscope in a bath with a cleaning or cleaner-disinfectant solution and wiping external surfaces thoroughly.

The channels are first cleaned with the brush supplied with the system, then rinsed with a cleaning or cleaner-disinfectant 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 final rinse. 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 machine-based processes. Always keep in mind that proper cleaning during instrument reprocessing is essential for retaining the value of your instruments as well as for successful disinfection and sterilization. The international standards series (EN ISO 15883), the national versions of those standards (e.g. DIN EN ISO 15883) and national guidelines state that only validated machine-based cleaning and disinfecting procedures should be used. The requirements imposed upon washers and disinfectors are described in the EN ISO 15883 series of standards.

Automated cleaning and disinfection should ideally be preceded by dry disposal. When performing 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 water flow in machine-based cleaning processes and can affect the result.
This also applies if heavily soiled instruments (problematic encrustations on HF instruments, filler residues adhering to dental instruments, etc.) have been pre-treated manually or with an ultrasonic bath.

### Ensure correct loading!

When using machine-cleaning and disinfection, there are a number of points that should be observed in particular (see also chapter 6.2.3):

- To ensure effective automated cleaning and disinfection, all trays, inserts, holders, etc., must be loaded correctly to ensure proper rinsing. Articulated instruments must be opened for loading.
- Avoid overloading trays to ensure that all instrument surfaces can be readily accessed by the cleaning/disinfecting solutions. Always consult the established loading templates for validation purposes.
- When placing large instruments on trays, make sure that they do not obscure other instruments and create spray shadows, thus preventing proper cleaning.
- Any instruments with cavities or hollow spaces (such as drives, trocar sleeves, respiratory systems) need careful cleaning and rinsing on the inside as well. For this purpose, special (instrument-specific) load carriers with appropriate rinsing 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

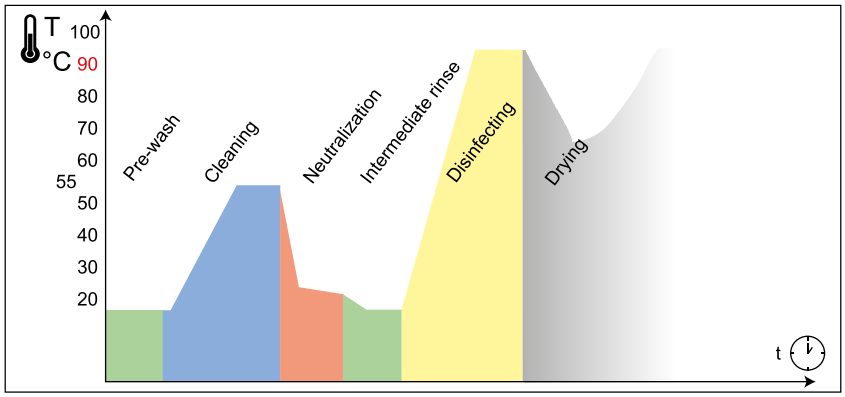
Instruments used for root canal treatment with colored, anodized handles may fade when using machine-based cleaning processes, potentially destroying their color-coding function. The use of pH-neutral or mildly alkaline cleaners and demineralized water for rinsing (also for thermal disinfection) can improve material compatibility.

The items to be rinsed should be removed from the machine immediately upon completion of the program. If they are left in the self-contained machine for a longer period of time, 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 cleaning and disinfection, both thermal and chemo-thermal disinfection options are available. As a rule, thermal disinfection is the better choice.

### 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. The A0 value has been introduced as a measure of disinfectant capability (DIN EN ISO 15883-1*, Appendix A). It determines the relationship between temperature and time as a function of microbiological 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 treated. A machine-based reprocessing program with thermal disinfection may includes the following steps or stages, for instance:




Cleaning program with thermal disinfection

**1. Pre-wash**
Cold water without any additives, to remove coarse dirt and foaming substances from previous process steps. A second pre-rinsing stage may be necessary.

**2. Cleaning**
Hot or cold soft water (ideally fully demineralized); cleaning is usually carried out at temperatures of 40-60 °C for at least 5 minutes.

Use a suitable cleaning agent!

Suitable pH-neutral or alkaline products added to 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 may 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**
Hot or cold soft water (ideally fully demineralized). Adding an acidic neutralizer facilitates the removal of residual alkaline cleaning agents. Even when using neutral cleaning agents, it may be advisable to add a neutralizer if the water is not of ideal quality (e.g. in cases where the water used has a high salt content), in order to prevent deposits and/or corrosion.

**4. Second intermediate rinse**
Hot or cold soft water (ideally fully demineralized). 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 take place.

**5. Thermal disinfection/Final rinse**
Fully demineralized water, thermal disinfection takes place at temperatures of 80-95 °C and for the corresponding exposure time as per $A_0$-Konzept, 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 agent 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.

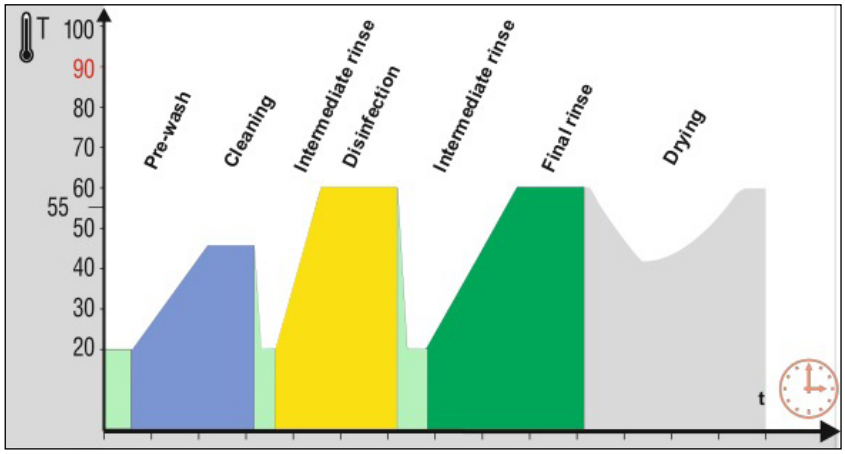
Note the specifications of the process chemicals producer

With regard to the process chemicals used, the manufacturer's specifications concerning concentration, temperature and exposure time should always be observed. This is the only way to guarantee good results and keep the instrument materials intact to the greatest possible degree. It must be possible to verify the automatic dosing of process chemicals. For instruments containing plastics and adhesives, chemical drying aids (rinsing agents) should only be used in accordance with the instructions of the manfacturer of the medical product.

## 6.2.2 Automated Cleaning and Chemo-thermal Disinfection

Heat-sensitive medical products are treated chemo-thermally. This means that a disinfectant especially suitable for machine-based 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), cleaning is carried out at defined temperatures (normally < 65 °C, for flexible endoscopes < 60 °C), and for disinfection, a disinfectant suited to the machine is added for the appropriate concentration and specified exposure times.
Example of a cleaning program with chemo-thermal disinfection:




Cleaning program with chemo-thermal disinfection for heat-sensitive endoscopes

**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 soft water (ideally fully demineralized); cleaning is usually carried out at temperatures of 40-60 °C for at least 5 minutes.
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. Intermediate rinse**
Hot or cold soft water (ideally fully demineralized).

**4. Chemo-thermal disinfection**
Hot or cold soft water (ideally fully demineralized). A special disinfectant with proven effectiveness and suitable for machine-disinfection is used. Chemo-thermal disinfection is performed under the conditions specified by the producer of the process chemicals (concentration, temperature, time).

**5. Intermediate rinse**
Hot or cold soft water (ideally fully demineralized water) with no additive (if appropriate, additional intermediate rinses to ensure that the disinfectant has been sufficiently rinsed away to ensure non-toxicity).

**6. Final rinse**
Fully demineralized water, final rinsing at higher temperature, at less than 60 °C for endoscopes. The use of demineralized water prevents spotting, deposits and corrosion on the surfaces of the items to be rinsed. For instruments containing plastics and adhesives, chemical drying aids (rinsing agents) should only be used in accordance with the instructions of the manfacturer of the medical product.

**7. 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. for heat-sensitive endoscopes < 60 °C).

Note the manufacturer's specifications

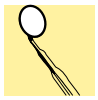
With regard to the process chemicals used, the manufacturer's instructions concerning concentration, temperature and exposure time should always be observed. This guarantees good results and keeps the instrument materials intact to the greatest possible degree. It must be possible to verify the automatic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

### 6.2.3 Instrument Groups Requiring Special Treatment

Microfilters used in the load carrier to protect medical products with fine channels, complex structures or sensitive drives must be regularly cleaned or replaced in a controlled fashion in accordance with manufacturer specifications.

Microsurgical instruments can be reprocessed and disinfected using machinery in the same manner as other surgical instruments, provided the instruments are safely held in place (e.g. by using racks) and the rinsing method is adapted accordingly.

Ophthalmic instruments: With these instruments, it may be necessary to measure the pH value, to check that the instruments are clear and possibly to manually dry them after cleaning and disinfection, if the result of drying is not satisfactory after machine-based reprocessing.



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

- Probes and other sensitive instruments must be placed on special holding devices for protection.
- Instruments with rotating components such as drill bits, cutters, burrs or abrasive tools are only suitable to a limited degree for machine-cleaning and reprocessing. It may be necessary to carry out an additional pre-treatment by ultrasound.
- Instruments for root-canal treatment may only be machine-treated if each item is held in place securely and safely by appropriate supports. Otherwise, ultrasonic bath treatment is preferable.
- Handpieces and elbows can be machine-cleaned and disinfected where permitted by the manufacturer, and if special rinsing fixtures are available for rinsing the turbine drive's spray, air channel or air infeed & recirculation system. The instruments must be removed from the washer/disinfector immediately after the process is complete. It may be necessary to dry them again once removed from the washer/disinfector.
- Mouth mirrors are subject to wear. Silver-backed glass mirrors may become dull as a result of machine-cleaning and disinfection; rhodium-plated mirrors are more resistant, on the other hand. but are easily damaged by mechanical impact.

Motor systems may only be machine-cleaned and disinfected if the manufacturer allows such treatment using such substances and machinery. Reusable tools approved for use in surgical applications can be machine-cleaned and disinfected in the same way as surgical instruments, although most require additional pre-treatment in an ultrasonic bath.

Ensure internal rinse!

MIS instruments, rigid endoscopes and HF instruments must be disassembled for machine-cleaning and disinfection in accordance with the manufacturer's specifications. All seals/gaskets must be removed and all stop cocks opened or removed as appropriate. Such parts may only be machine-cleaned and disinfected if approved by the manufacturer. To avoid damage, fix the items securely in place. The machine and loading trays 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. hydrogen peroxide solution, with a brush or ultrasound) must be discarded as their proper function and sterility can no longer be guaranteed.

## Robotic instruments

Robotic 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 machine-based cleaning and disinfection 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 can only be machine-cleaned and disinfected in special washers/disinfectors. If endoscopes are pretreated manually prior to machine-based reprocessing and disinfection, all cleaning agents 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 leak test on flexible endoscope

Prior to machine-cleaning and disinfection, a leak test must be carried out in accordance with the manufacturer's specifications. This ensures the early detection of leaks and perforations in order to avoid subsequent damage caused by penetrating liquids. Some washers/disinfectors 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 (see chapter 4).

Alkaline process chemicals may damage endoscopes, so it is important to use only special cleaners and disinfectants suitable for the machine-based 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 cleaning and disinfection, 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 measures must be taken to ensure that the water used for the final rinse is treated in such a way that prevents renewed microbial development on disinfected endoscopes.
Prior to storing endoscopes for later use, proper drying is necessary to prevent the development of microorganisms. This can be done either in the washer/disinfector or in a suitable storage cabinet with controlled

environmental conditions for reprocessed, heat-sensitive endoscopes (in accordance with DIN EN 16442).

Flexible instruments with sealable cavities (such as tubes with balloons, respiration/resuscitation masks, etc.) must be cleaned and disinfected while sealed 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 cleaning agent 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 respiratory systems are particularly problematic. It is also vital that all such parts are completely dried, as even very small amounts of moisture may cause malfunctions. 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 heat-sensitive 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 conservatively 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.
- to remove stubborn residues.
- as an integral part of machine-based reprocessing treatments, thus supporting other measures for improved cleaning results.

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 45°C can lead to encrustations due to protein denaturation.
- Freshly prepared disinfectant 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. Upon completion of the test, the ultrasonic bath should be thoroughly rinsed in order to prevent dissolved aluminum particles from being deposited on instruments.

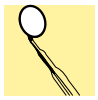
Apart from a properly prepared bath, the following basic rules should always be observed to ensure good cleaning results:

- The items to be treated must be fully immersed in the liquid.
- Articulated instruments, scissors etc. must be opened in order to minimize the obscured surface areas. Insert instruments next to each other; do not stack them.
- Use only suitable trays (e.g. wire or perforated plate trays) that do not obstruct the ultrasonic cleaning process.
- Large-surface, bulky instruments must be placed 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 manufacturer specifications. As high contamination levels impair ultrasonic cleaning and promote corrosion, more frequent replacement of the ultrasound solution may be necessary, depending on the requirements of specific cases.
- Given powerful 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 than without ultrasound, such values must always be checked and corroborated by microbiological examinations (expert opinions), taking into account temperature, frequency range and germ spectrum, and also monitored in the course of practical application.

Following ultrasonic treatment, the instruments must be thoroughly rinsed manually. The manual final rinse can be carried out with fresh tap water, taking care that all cleaning agent 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 holders in order to prevent damage.



Acidic cement removers and basic cleaners should be used in accordance with manufacturers' specifications in the ultrasonic bath. The bath container must be material-compatible.

Handpieces, elbows 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, dental instruments with rotating components must often be treated with special disinfectants and cleaning agents. Prior to ultrasound treatment, they should be placed in special stands to avoid any contact damage between the instruments (e.g. via sharp cutting edges, diamond grains). After a quick rinse under running water followed by immediate drying, dental instruments with rotating components must be treated with a sterilization-stable anticorrosive agent. Polishing and flexible instruments cannot be processed in the ultrasonic bath, because the flexibility absorbs the ultrasound.
Mouth mirrors may be damaged by ultrasonic bath treatment.

MIS instruments, robotic instruments, endoscope accessories and HF instruments which are suitable according to the manufacturer's specifications may be treated in an ultrasonic bath. The rinsing and agitation of special instrument components during ultrasonic exposure supports the cleaning effect.

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

Flexible endoscopes must never be processed 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 respiratory 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 heat-sensitive instruments such as flexible endoscopes or equipment used in anesthetics. In many regions, this step is referred to as "high-level disinfection" (HLD).
Agents must be used in this disinfection step that have at least proven bactericidal, mycobactericidal, fungicidal, and virucidal effects. National regulations may require difficult ranges of effects.

Final disinfection can be performed either manually or using a machine at room temperature, or using a machine at higher temperatures with a chemo-thermal or thermal process. For machine-based thermal and chemo-thermal disinfecting processes with integrated cleaning stage, refer to section 6.2.
For final chemical disinfection, aldehyde and peroxide compounds are primarily used as microbicidal agents. The disinfection effect of the disinfectant should have been proven under "clean conditions" (no contamination) in accordance with EN 14885 or equivalent national guidelines.

## Observe material compatibility!

Material compatibility depends on the instrument material, the composition of the disinfectant, the temperature, the exposure time, the concentration, and the pH-value of the solution being used (see also chapter 2.2).

If the same products are used for disinfection & cleaning as for final disinfection, separate solutions must be used 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 the final chemical disinfection, it is important to ensure that all surfaces to be disinfected are completely covered by the solution, including the gaps in articulated instruments, and any channels or cavities.

We recommend using disinfecting solutions for no longer than one day. Some producers claim longer usage times, in which case 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.

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 disinfectant 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. To prevent recontamination, sterile or low-germ water should be used.
To dry the external surfaces of flexible endoscopes, use a virtually lint-free cloth. The channels should be dried with a hand or suction pump or with compressed air at max. 0.5 bar, depending on the manufacturer's specifications. The use of oil-free, low-germ 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 to be sterilized must be checked visually and by touch, and must be macroscopically clean, i.e. free from visible residues. This is checked by visual inspection. Critical areas such as handle structures, joints or jaw serration (particularly atraumatic toothing) require especially careful checking.

It is advisable to use working lights, such as light magnifying glasses with lenses of 3 diopters when checking the fine tips of instruments. If there is any doubt as to the level of cleanliness, particularly in the case of instruments with cavities, chemical tests for protein and blood must be carried out, for instance with 1% sodium dodecyl sulfate solution (pH 11) after intensive elution/extraction.

All instruments with lumens, such as cannulas, etc., must be checked for blockages, for instance with a suitable cleaning brush. 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 secondary corrosion due to metal abrasion, never use metal brushes or metal sponges to remove 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 function can no longer be fully or adequately guaranteed.

Stress cracks next to scissor hinge

Instruments with corrosion residues or damaged nickel-chromium coating need special treatment. 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

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

Maintenance or care means targeted application of instrument 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 imposed upon 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.

Targeted joint cleaning

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

**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.

Corrosion due to insufficient use of care products

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

Spraying the instruments or applying the care agent mechanically is not sufficient, nor does it provide additional corrosion protection.

Never process plastic surfaces with instrument care agents.

## Function

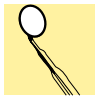
As surgical instruments are made for specific application purposes, the functional tests must be carried out so that items that fail to serve their intended purpose are reliably recognized and discarded. If in doubt, consult the instrument manufacturer for suitable testing methods.

Articulated and threaded instruments must be lubricated before subjecting them to a functional test using a squirt oiler, an oil pen, 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.

For medical products submitted for repair, please note the information in chapter 4.

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 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, elbows 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. Motors and handpieces may be engineered to be sealed or not sealed. In the latter case, a care spray must be applied after each reprocessing.

Compressed air motors must be lubricated using a special care spray or oil (the motor may need to be run afterwards, see manufacturer specifications).
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 function test in accordance with the manufacturer's instructions. All compressed air components must also 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 cleaning agent 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.
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 optical mechanism to fail.

## Care

Care agents should not be applied manually or automatically to optical systems, gaskets or current-carrying components, because this could cause significant problems and lead to loss of function.

Joints, threads and friction surfaces, as well as connections subject to regular servicing on rigid endoscopes must be treated with instrument oil in accordance with the manufacturer's instructions. Alternatively, a special-purpose grease 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 assembling and disassembling the instrument.

## Cleanness

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

Respiratory systems must be checked in accordance with the manufacturer's specifications to ensure that they are undamaged and functioning properly. (The channels must be checked for blockages during or before machine-based reprocessing and immediately before procedures).

## 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.
Endoscopes with damaged feed and/or elbow tubing, or other defects, must be taken out and sent for repair.

## Care

Swelling at distal end of fiberscope

In the case of flexible endoscopes, always check whether the valves (if incorporated) need treating with an care agent recommended by the manufacturer before use.

Note that the endoscope surface must not be sprayed because spray propellants damage these instruments. Vaseline, silicone oil or care agents containing paraffin cause swelling or softening in plastic components (see also chapter "Surface Changes"!).
Only suitable grease-free gels may be used as lubricants in accordance with the manufacturer's specifications.
Immediately after an endoscopic procedure, all functions of the instrument must be checked or tested in accordance with the manufacturer's specifications.

## Function

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 purpose. The most important checks and tests include:

- Checking the integrity of balloons.
- Checking balloon filling systems for leaks.
- 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.

## Integrity

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

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

- temperature
- pressure
- humidity
- sunlight
- cleanness
- microbial contamination.

Sterile items container

## Protective packaging

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

## Packaging types

The sterile barrier system can be a reusable system (sterilising 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 materials are used that have not yet been properly validated, the performance assessment (validation) must be repeated.

### Drying

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

### Marking

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

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

## 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 for the specific instruments group that only use sterilization methods and sterilizers be used that allow validated sterilization processes. During validation, it must be confirmed that the sterilization method used in the reprocessor is suitable for the products to be sterilized and that the results are reproducible.

Sterilization accessories and packaging materials must be selected in line 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 / 132 °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 (or DIN 58946 Part 7 in Germany) and all process-related parameters such as pressure, temperature and the proportion of non-condensible gases in steam are documented, it is possible to forgo chemoindicators or bioindicators for batch control, provided that the three parameters relevant to the procedure are consistently monitored.

### Ensure steam quality in accordance with EN 285!

The sterilization steam used must be free of impurities and should not impair the sterilization process, nor should it 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 silicic acid levels may appear on instrument surfaces.

Marbling caused by impurities in steam condensate

Contamination in the condensate of a steam supply for sterilizers, measured at the sterilizer supply line

| Substance/Property | Condensate |
|---|---|
| Silicates ($SiO_2$) | ≤ 0.1 mg/l |
| Iron | ≤ 0.1 mg/l |
| Cadmium | ≤ 0.005 mg/l |
| Lead | ≤ 0.05 mg/l |
| Heavy metal residues, except for iron, cadmium, lead | ≤ 0.1 mg/l |
| Chlorides ($Cl^-$) | ≤ 0.1 mg/l |
| Phosphates ($P_2O_5$) | ≤ 0.1 mg/l |
| Conductivity (at 20 °C) | ≤ 4.3 µS/cm |
| pH value (degree of acidity) | 5 to 7 |
| Appearance | colorless, clear, no deposits |
| Hardness (Σ of alkaline earth metal ions) | ≤ 0.02 mmol/l |

Source: EN 285: 2015, Table 4

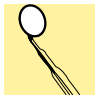
Note: A method for extracting a condensation sample is specified in chapter 21.4.

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 the improper arrangement of loads, the use of less suitable types of non-woven fabrics for drying, and plastic dishes for instrument sets. In principal, heavy sieves 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 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 and elbows should be sterilized at 134 / 132 °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.

Any motor systems used under sterile conditions can be steam-sterilized at 134 / 132°C.
Make sure the manufacturer's specifications are observed (e.g. regarding securing) 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. They must be positioned in the sterilization trays so that the permitted bending radii is observed and condensation can run off.

As regards battery-powered systems, make sure to strictly observe the manufacturer's instructions for sterilizing batteries.

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 / 132 °C rather than at 121 °C, due to the shorter exposure time (and correspondingly lower thermal stress). Alternatively, a suitable low-temperature sterilization process can be used to completely avoid 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 process must therefore be used for these 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 / 132 °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 respiratory systems can be steam-sterilized at 134 / 132 °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 impairs the instrument's function.

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 must never be sterilized with hot air.

## 10.3 Low-Temperature Sterilization

Low-temperature sterilization methods include gas sterilization and gas (plasma) sterilization. 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 and in the interest of patient and personnel safety, low-temperature sterilization 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.

Rigid optical systems that cannot be steam-sterilized are sterilized at low temperatures in accordance with the manufacturer's specifications.

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), please note 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 that are used in a disinfected state should ideally be stored in a designated storage cabinet with controlled environmental conditions in accordance with EN 16442. They should be stored in a hanging position in sterile, dry, low-dust and well-ventilated conditions. Endoscopes must be sufficiently dry before storage. Valves and caps must be removed and stored separately, under dry and dust-free conditions. Flexible endoscopes must not be stored in transportation cases.

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, anti-microbial 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 that they be kept with the shaft unkinked and/or laid out in a sufficiently large loop.

# 12. Surface Changes: Deposits, Discoloration, Corrosion, Aging, Swelling and Stress Cracks

In practice, many medical products are subject to surface changes over time 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.

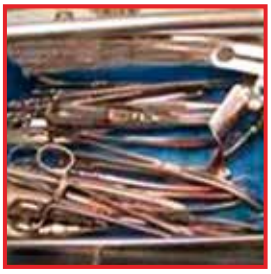
- Determine the nature, origin and cause.
- Estimate the risks.
- If necessary, process/treat the items in accordance with the manufacturer's recommendations to correct the changes.
- Take appropriate measures to prevent re-occurrence, then validate your entire instrument reprocessing process.

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, as a result of surgical residues (blood, protein), salt residues, drug residues.

- Dry residue because the interval between use and reprocessing is too long.
- Protein fixing, e.g. by disinfectants containing aldehyde.
- Transferred by contaminated cleaning agents and disinfectants.
- Insufficient rinsing after cleaning.
- Insufficient cleaning efficiency due to acoustic shadows in ultrasonic cleaning.
- Inadequate maintenance of the washer/disinfector.
- Possible protein fixing caused by excessive water feed temperature (> 50 °C) in first rinsing 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 cleaning agent 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.

Overloading

### Treatment recommendations

- Recleaning with ultrasound.
- Targeted manual recleaning.
- Immersion in 3 % $H_2O_2$ solution (approx. 5 min.).

### Preventive measures

- Remove all coarse contamination, especially salt saline 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 pre-rinse with cold water.
- Program sequence correction 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 condition, bright to dark gray deposits / discoloration may appear in various sizes. This may become even more apparent following sterilization.

### Type of surface change

Surface with visible residues

Suitable load carrier 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 low-lint cloth.
- Acid-based cleaning with special cleaning agents as recommended by the instrument manufacturer.

### Preventive measures

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

### Risk assessment

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

## 12.3 Metal/Deposits – Spotting Caused by Lime

### Type of surface change

Rinsing chamber with heavy limescale deposits

Consequence: Instruments have 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

- To be wiped off with a clean, low-lint cloth.
- Acid-based cleaning with special cleaning agents as recommended by the instrument manufacturer.

### Preventive measures

- Cleaning and intermediate rinses (as appropriate) with demineralized water.
- Use of fully demineralized water for the final rinse to prevent stain formation during machine-based reprocessing.

### Risk assessment

- Corrosion may developed as a result (see chapter 2).

## 12.4 Metal/Discoloration – Caused by Titanium Oxide or Silicates

### Type of surface change

Discoloration caused by silicates occurs occasionally during instrument reprocessing in the form of titanium oxide, more frequently in the form of silicic acid. Such discoloration is especially visible on new and repaired instrumented, storage systems, washers/disinfectors and sterilization chambers.

The severity of the discoloration is in part dependent on the surface finish, any deposits of metal ions (e.g. copper from fittings or the pipe system), the weight and the positioning of the instruments

Titanium oxide discoloration occurs mostly on reflective surfaces over large surfaces, yellow-brown to blue-violet, sometimes with a shimmering appearance, in the wash chamber or over the entire surface of the instrument during machine-cleaning.

Typical silicate discoloration occurs, regardless of the nature of the surface, over large surfaces, yellow-brown to blue-violet in the cleaning & disinfection process, or in spots, droplet-shaped with pronounced condensation stain-like appearance during the steam sterilization process.

## Origin and causes

- Silicate discoloration: During the production of fully demineralized water, silicic acid is passed as a result of the use of ion exchangers and reverse-osmosis water reprocessing equipment.
- Silicate discoloration: Silicate-based cleaning agents are carried over into the final rinse process of machine-based reprocessing due to insufficient intermediate rinsing or dried cleaning agent solution deposits.
- Silicate discoloration: Increased concentration of silicates in steam generators, which is carried over to the sterilization steam.
- Titanium oxide discoloration: Silicate-based cleaning agents containing small (trace) quantities of titanium oxide compounds as a substance present naturally in the silicates are carried over in the final rinse process due to inadequate intermediate rinsing or dried cleaning agent solution deposits.

## Treatment recommendations

- Silicate deposits can be removed by means of acid-based cleaning using special cleaning agents as recommended by the manufacturer. Stubborn deposits can be removed with agents containing hydrofluoric acid.
- Titanium oxides are especially stubborn and cannot be removed (or at best, cannot be removed completely) using common acid-based cleaning processes.
- Have the surface mechanically treated by the manufacturer or a qualified repair service.

## Preventive measures

Use silicic acid-free, fully demineralized water for the final rinsing during machine-based reprocessing. Prevent cleaning agent 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 machine-based reprocessing.
- For steam sterilization, use water and steam quality as specified in EN 285 (Appendix B, Table B1.) or DIN 58946 Part 6.

### Risk assessment

- No corrosion – only aesthetic effect. There are no findings indicating a patient risk.
- Discoloration may make visual inspection difficult (e.g. to detect 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/Discoloration – Caused by 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.

Clamp in detail: Lock and ring area

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

The change in color is generally even. However it can also occur in patches.

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 non-cutting 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

In the case of the above stainless steels, the passive layer is formed during automated cleaning as a result of the neutralizer carried during the final rinsing and/or by other as-yet unidentified factors forming passive layers. 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

Repair of the damage by the user is not recommended due to the properties of the deposit, but may be carried out by the manufacturer or a qualified repair service if necessary. In both cases, appropriate surface treatment is required (mechanical in the case of steel, chemical in the case of titanium). In the case of stainless steels, removing the deposit with a basic cleaning agent 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 – aesthetic 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/Discoloration – Caused by Stripping of Colored Plasma Layers

### Type of surface change

Example: black, TiAlN coated punch. The partial erosion of the layer has caused bright, colorful discoloration or complete removal of the layer with undamaged gold-plated components.
Right Punch: as new

### Origin and cause

Surface reaction caused by cleaning solutions to which hydrogen peroxide has been added, and/or wash solutions such as 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 products/components coated with originally goldish-yellow zirconium nitride (ZrN) and titanium nitride (TiN).

### 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 light 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
- 200x magnification

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 by-products can be dissolved with an acid-based cleaning agent used in accordance with the manufacturer's specifications. The remaining corrosion holes may be treated mechanically (reworking either by the manufacturer or by a qualified repair service provider). If pitting is deeper, long-term repair is often no longer possible. The instrument must be replaced.

### 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 saline solution on instrument steel.

### Risk assessment

- Corroded instruments should be immediately withdrawn from service (and the instrument processing cycle) in the interest 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/instrument components that move relative to each other (especially in ends/joints and sliding rails, e.g. with punches). 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.

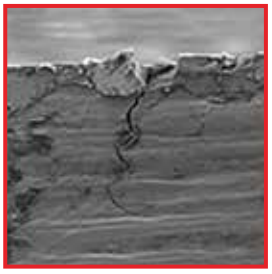
### Risk assessment

Do not use lubricants on rubber or latex products, as this leads to swelling.

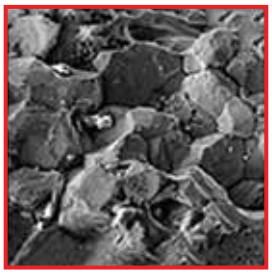
Friction corrosion impairs or completely destroys the instrument's functionality. Friction corrosion may lead to pitting.

## 12.9 Metal/Corrosion – Stress Corrosion Cracking

### Type of surface change



Detail: Scissors hinge joint with typical intercrystalline crack.



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

## Origin and causes

Stress corrosion cracking usually leads to visible cracks and fractures.
In some cases, crack formation is not visible because its origin is hidden by design (e.g. in the joint of a pair of scissors), and the crack may propagate until failure.

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 that

- are 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).
- exhibit excessive stress caused by improper repair work (e.g. poorly performed repairs) or
- have been reprocessed under high stress (e.g. when the ratchet is fully closed) or.
- 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

No remedial measures can be named. The damage is irreparable.

## Preventive measures

- Clean articulated 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) in the interest of patient and user safety.
- To retain the value of your instruments, eliminate the cause of corrosion.

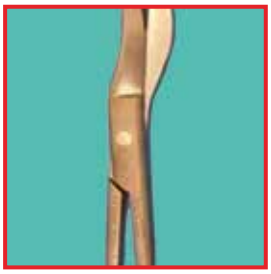
## 12.10 Metal/Corrosion – Surface Corrosion

## 12.10.1 Stainless Steels

### Type of surface change

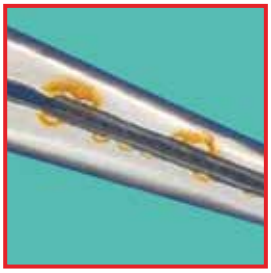
Surface of blade affected due to humidity. Cause: Composition of materials, normal steel, so disposable product.

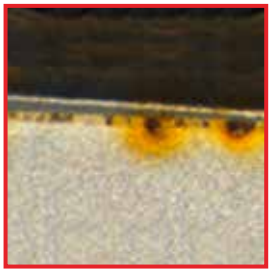
Material affected at partially defective chrome coating. Cause: Humidity causes corrosion to form on unprotected carrier material (normal steel)



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.

- 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.
- Discoloration and erosion of materials at solder points and sintered carbide inserts made of tungsten carbide and cobalt (TC/CO mixing ratio 9:1).

### Origin and causes

- Chemical and electrochemical effects only in connection with an excessive acid content with
  - stainless steel,
  - soldering points.

- Long-term impact of water/condensate in the case of stainless steel.

**Treatment recommendations**

- Rust removal by means of acid-based cleaning in the case of stainless steel if the damage is still superficial and/or mechanical treatment of soldering points (if appropriate) by the instrument manufacturer or a qualified repair service provider.
- If sintered carbide (TC/CO) surfaces are affected, the damage is irreparable.

**Preventive measures**

- In the case of soldered instruments, always observe the application recommendations when using acid cleaners and neutralizers.
- Discard disposable products made of steel or old steel instruments with damaged coatings and replace with stainless steel products.
- Avoid long-term exposure to moisture (condensate).

**Risk assessment**

- If surface treatment proves ineffective, replace the affected instruments with new ones (otherwise there is a risk of secondary rust formation or extraneous rust).

## 12.10.2 Anodized Aluminum

**Type of surface change**

Material affected at aluminum handle. Cause: Unsuitable alkaline cleaner

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

- 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.

Aluminum corrosion is characterized by the discoloration of the surface and the presence of a white, powder-like coating.

**Origin and causes**

- Effect of acids or too high alkalinity in anodized surfaces.

**Treatment recommendations**

- No longer reparable.

## Preventive measures

- Treat in neutral/mild alkaline pH environment.

## Risk assessment

- Loss of color-coding function.

## 12.11 Metal/Corrosion – Contact Corrosion

## Type of surface change

Contact corrosion:
Stainless steel/Stainless steel

## 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. This combination only occurs rarely in practice, as there are problems with non-ferrous metals regarding biocompatibility.

## 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).

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

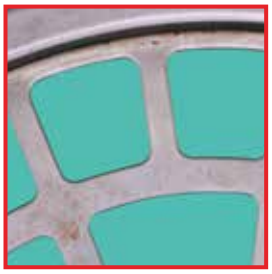
Replace nickel or chrome-plated instruments which have damaged (scaly, peeled-off) protective layers with stainless steel instruments.

## Risk assessment

However, when both stainless steel and non-ferrous metals are combined, considerable rust damage can be caused to intact instruments, depending on the extent of the damage involved.

## 12.12 Metal/Corrosion – Extraneous and Film Rust/Subsequent Rust

### Type of surface change



Filter holder with corrosion in the form of particulate

- Individual, irregularly dispersed rust particles.
- Brown, mostly localized corrosion deposits/rust.
- 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

- Rust deposit on instruments or device components including accessories may give rise to secondary rust on instruments that have previously not been affected. The effect is dependent on the quantity present beforehand, the proximity of the instruments to one another and time.

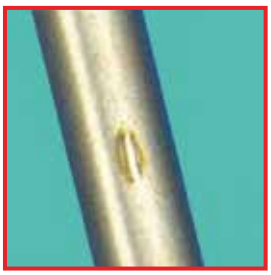
- If rust particles are carried over from the pipework, many of the instruments processed may be affected and thus lose value.

## 12.13 Metal/Corrosion – Crevice Corrosion

### Type of surface change

Joint gap - forceps


Joint area - tweezers ends


Contact area - forceps

- 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 the tips 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.
- With crevice corrosion that has developed as a result of storage, small dot or ring-shaped, brownish-blue discolorations with slight corrosion in the contact areas can occur. This type of crevice 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. In specific cases, the surface structure may be rubbed slightly smooth in these areas as a result of vibration.

### Origin and causes

- Crevice corrosion tends to occur in gaps of critical width if the prevailing ambient conditions favor it (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.
- Crevice corrosion developing as a result of storage has only been observed following machine-cleaning to date. 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

- Treat affected instruments in accordance with the manufacturer's specifications.
- Mechanical treatment (reprocessing) of the instrument by the manufacturer or an authorized repair service.
- Experience has shown that storage-related crevice corrosion disappears after just a few reprocessing cycles. Acidic media (neutralizers) usually dissolve these deposits at once, while also accelerating the passivation process.

## Preventive measures

- Remove coarse contaminants immediately.
- Use rinsing water with a low salt content (preferably fully demineralized water).
- Dry joints or gaps adequately.
- Avoid vibration when cleaning stainless steel instruments (e.g. ultrasound treatment, machine-based reprocessing) to prevent storage-related crevice corrosion (e.g. by ensuring that the cleaning/disinfecting apparatus, or W/D, stands firmly on level ground).

## Risk assessment

Rust cannot spread to other instruments in most cases. 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").

With storage-related crevice corrosion, experience has shown that there is no danger to the affected instruments or to unaffected instruments, because the minor deposit volume is not sufficient to cause damage, unless the phenomenon cannot be eliminated by further reprocessing using acidic media.

# 12.14 Plastic/Rubber – Aging

## Type of surface change

Aging tears in a breathing mask

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

## Origin and causes

- Impact of dry heat.
- Straining and overstretching during storage.

- Sunlight, UV radiation.
- Effect of oxygen (oxidation, true aging).
- Effect of ozone.
- Maximum time between applications/reprocessing exceeded.

**Treatment recommendations**

None (cannot be corrected)

**Preventive measures**

If possible store instruments in dark and cool conditions

**Risk assessment**

If the changes affect applications or risk, discard 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**

Swelling is caused by the 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 "inherent" stresses are present as a result of the manufacturing method.

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 favour the formation of stress corrosion cracking. Ensure a sufficient final rinse with demineralized water. The manufacturer's specifications regarding reprocessing must always be observed.

### Risk assessment

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

# Notes:

# 13. Glossary

| | |
|---|---|
| $A_0$ value | **The $A_0$-value concept**<br>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. |
| Acidic cleaner | Acidic cleaners are either based on phosphoric acid for the removal of organic residues, limescale or rust caused by dip processing, or on inhibited hydrofluoric acid for the removal of silicate discoloration. When applying these, the application and safety information provided by the manufacturer must always be heeded. |
| Acoustic shadows | Acoustic shadows occur for example in an ultrasonic bath behind objects which stand in the direct path, obstructing the source of sound. |
| Anion exchanger | Equipment to replace negatively charged ions (anions) dissolved in water such as chlorides, sulfates and nitrates against hydroxide ions by way of full demineralization. |
| Anodized | A surface finish used on aluminum. The "anodized" layer (Al2O2 • H2O aluminum oxide hydrate) is silver-gray in color and is created by electrolytic passivation (anodizing) to protect products against wear and corrosion. Dyes can be added to give a variety of colors. |
| 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. |
| Bacteriostatic | Preventing bacterial growth. |
| Boiler feed water | Water used to produce steam in a boiler. |
| Carbide metal | Carbide metals produced in a sintering or casting process which are extremely hard and impervious to wear. |
| Cation exchanger | Equipment to replace positively charged ions (cations) dissolved in water such as calcium and magnesium cations against sodium cations by way of partial demineralization or hydrogen ions by way of full demineralization. |
| CE mark/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 heat-sensitive products, 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.<br>Table salt and reactivation salt consists of sodium chloride which is also a constituent of physiological salt solution. |
| Cleaning | Removal of contamination from an object to a degree which renders the item fit for further reprocessing or its intended use. |
| Color anodized | Signifies the use of dyes in anodizing or the decorative coloring of aluminum, for instance by means of immersion coating. Standard colors include gold, blue, red, black, etc. |
| Contamination | Contamination with undesirable substances including micro-organisms. |
| Corrosion | In general terms, corrosion refers to the degradation of surfaces as a result of environmental influences, e.g. substances with a critical chloride content (blood, salt solution, etc.) on stainless steels. |
| Decontamination | Process to dilute contamination and deactivate pathogens in the instrument reprocessing cycle. |

| | |
|---|---|
| Denaturation of proteins | Modification of natural protein structures by chemical influences or heat. |
| Disinfection | Process to reduce the bacterial titer count to a predetermined level suitable for handling or use. |
| Dispersion | Stable homogeneous distribution of water-insoluble contaminant particulates in a cleaning agent solution (contaminant carrying capacity). |
| Distal end | The distal end of an instrument is the end closest to the patient, e.g. the jaws of forceps. |
| Electrical conductivity | Used in water analyses to measure the total content of dissolved and electrically conductive mineral salts. |
| Emulsification | Suspension of insoluble liquids in a cleaning agent solution for removal. |
| Evaporation residue | The non-volatile components in water (e.g. mineral salts) in mg/l which remain behind after a pre-determined drying process. |
| Flaws | Exposed surface defects caused by material (e.g. purity) or production process (e.g. folds, cracks, pores). |
| Halides | Collective term for chlorides, iodides and bromides with similar chemical properties. |
| Heat-resistant instruments | Medical products and accessories which can be thermally disinfected and sterilized using steam. |
| HF instruments | Instruments for high-frequency surgery (HF). |
| Inert gases | Non-condensing gases used in steam sterilization are referred to as inert gases. These include carbon dioxide or oxygen. |
| Interfacial tension | Forces that occur on the contact surfaces between two phases. Between liquid and gas phases, these are referred to as surface tension. |
| Ion exchanger | Collective term for cation, anion and mixed-bed ion exchangers. |
| Lumen | Passageway in hollow instruments. |
| Martensitic | The term used to describe the micro-structure of materials which develops when steel is hardened through quenching. |
| 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 heat treatment. 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. |
| Minerals causing water hardness | Calcium and magnesium salts dissolved in water. |
| MIS instruments | MIS instruments are instruments used in minimally-invasive surgery. |
| Mixed-bed ion exchanger | Combination of cation and anion exchanger used in the full demineralization of water. |
| Morphology | Morphology significantly defines the functional properties of an instrument's surface. Put simply, it refers to the micro-structures on the surface or directly around the surface |
| Non-wovens | In this context, can refer to a non-woven composite fiber fabric used for sterile barrier systems (SBS) made from textile or non-textile fibers (EN 868-2:2009). |
| 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. |

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|---|---|
| Organic residue | Residues such as blood, protein and tissue, mainly from the human body. |
| Oxidation | A chemical reaction of a substance with oxygen. |
| Passage of silicic acid | Problem relating to the full demineralization of water using ion exchangers. Silicic acid passes through an ion exchanger without increasing the electrical conductivity of demineralized water. |
| pH value | The pH value is a measure of the acidity or alkalinity of aqueous solutions.<br>pH < 7 = acidic<br>pH = 7 = neutral<br>pH > 7 = alkaline |
| Pharmacopeia | Official listing of medications. |
| Prions | Protein folding error causing transmissible spongiform encephalopathies (TSE) such as BSE, CJD and vCJD. |
| Process chemicals | Collective term for the chemicals such as detergents, disinfectants, neutralizers, surfactants and instrument milk used in instrument reprocessing. |
| Protein fixation | Process which changes the structure of proteins, resulting in more difficulty in cleaning. Proteins modified through chemical influences or heat are more difficult to remove from surfaces. |
| Protein interference | The degradation/deactivation of certain disinfectants (e.g. active chlorine) when coming into contact with proteinaceous contaminants. |
| PVC | Polyvinyl chloride - Type of plastic frequently used in medical technology. |
| Reactivation salt | Salt used to reactivate water softeners operating on the cation exchange principle. Consists mainly of sodium chloride. |
| Redeposition | The process in which soil already removed from a surface resettles. |
| Reprocessing | Measures taken to render medical products and accessories safe for use for a specific purpose. |
| Rhodium | A metal with a silver-gray sheen. |
| Roughness | Refers to the unevenness of a surface. |
| RUMP | Reprocessing Unit for Medical Products. |
| 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. |
| Silicic acid | Acid contained in water which is in the acidic range. The salts of this acid are referred to as silicates. |
| 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. |
| Spray shadows | Spray shadows are areas within a washer/disinfector shielded by large and improperly positioned items, preventing water jets from accessing the load directly. |
| Stainless steel/high-grade steel | According to DIN EN 10020, high-grade steel refers to alloyed and unalloyed steels that exhibit a special/higher level of purity due to their production process. This is the case if its sulfur and phosphorus content does not exceed 0.025%. High-grade steel does not necessarily satisfy the specifications of stainless steel, for which there must be minimum amount of chrome present, see 1.1 Material Selection. |
| Steam sterilization | A validated process to eliminate micro-organisms on products using saturated steam (according to ISO 17665). |

| | |
|---|---|
| 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). |
| Sterilization | A process to remove all micro-organisms from a product. |
| Surface tension | Property of water and aqueous solutions in contact a gas phase (atmosphere), caused by the polarity of the water molecules. The surface of water appears to form a skin. |
| 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. |
| Topography | Also referred to as a surface texture, describes the geometric form of technical surfaces or micro-structures. |
| Washer-disinfector load | Collective term for medical products and accessories which require cleaning and disinfection. |
| Water softening | Water reprocessing procedure in which cation exchangers are used to remove the hardness (calcium and magnesium ions) from water by replacing these with sodium ions. |
| 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. |

# 14. Bibliography

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   Part 4, 2009
   Part 6, 2015
   Part 7, 2016
   Cleaning/Disinfecting units

2. EN 16442, 2015
   Storage cabinet with controlled environmental conditions for reprocessed, heat-sensitive endoscopes

3. EN 285: 2015
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26. BGV A1 and Safety Organization Rules of the Statutory Employer's Accident Insurers, such as BGR 250, BGR 206 issued by the Berufsgenossenschaft für Gesundheitsdienst und Wohlfahrtspflege (Statutory Accident Insurer for Healthcare and Welfare Employers)

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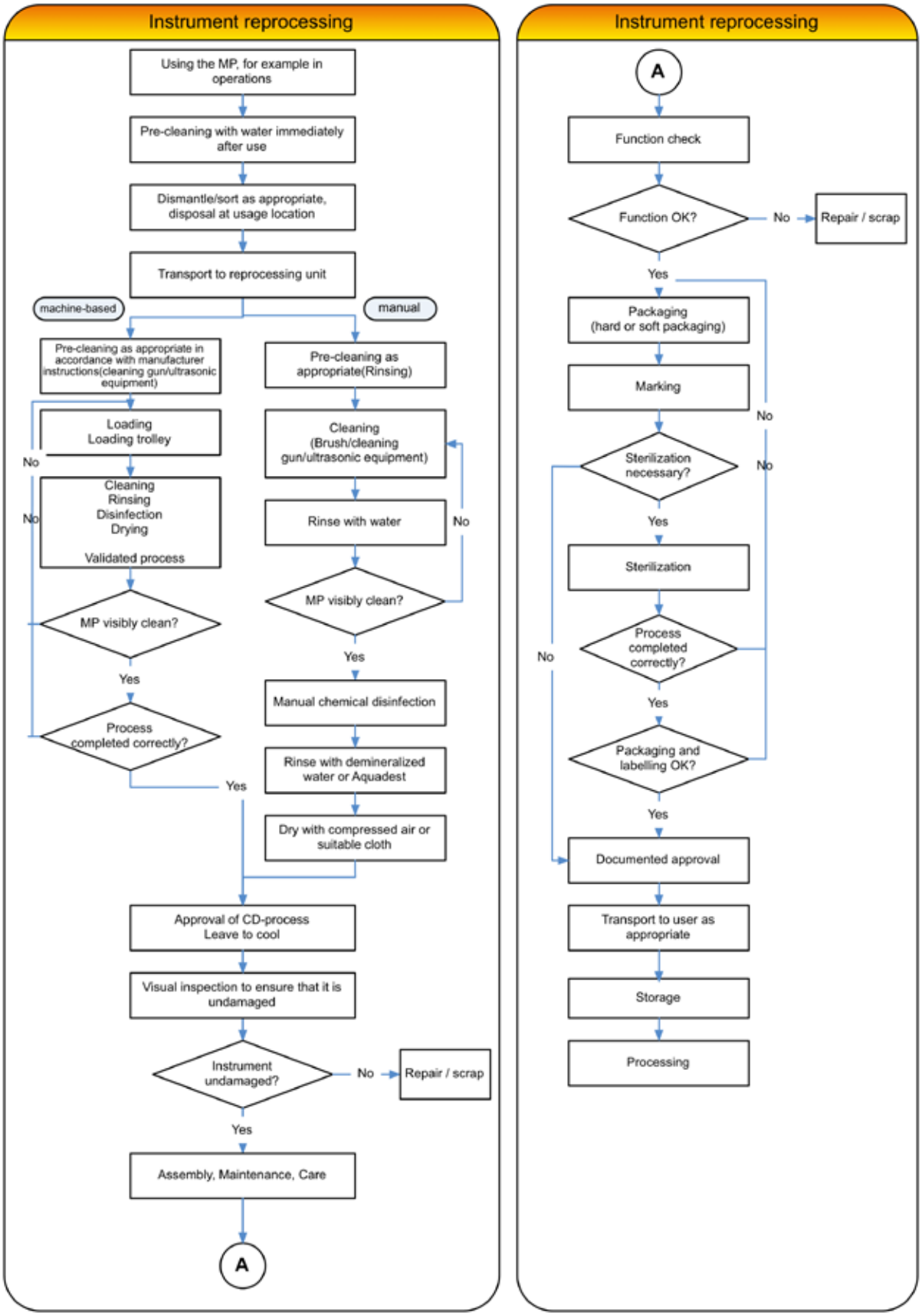
# 15. Schematic Flow Chart as per EN ISO 17664



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