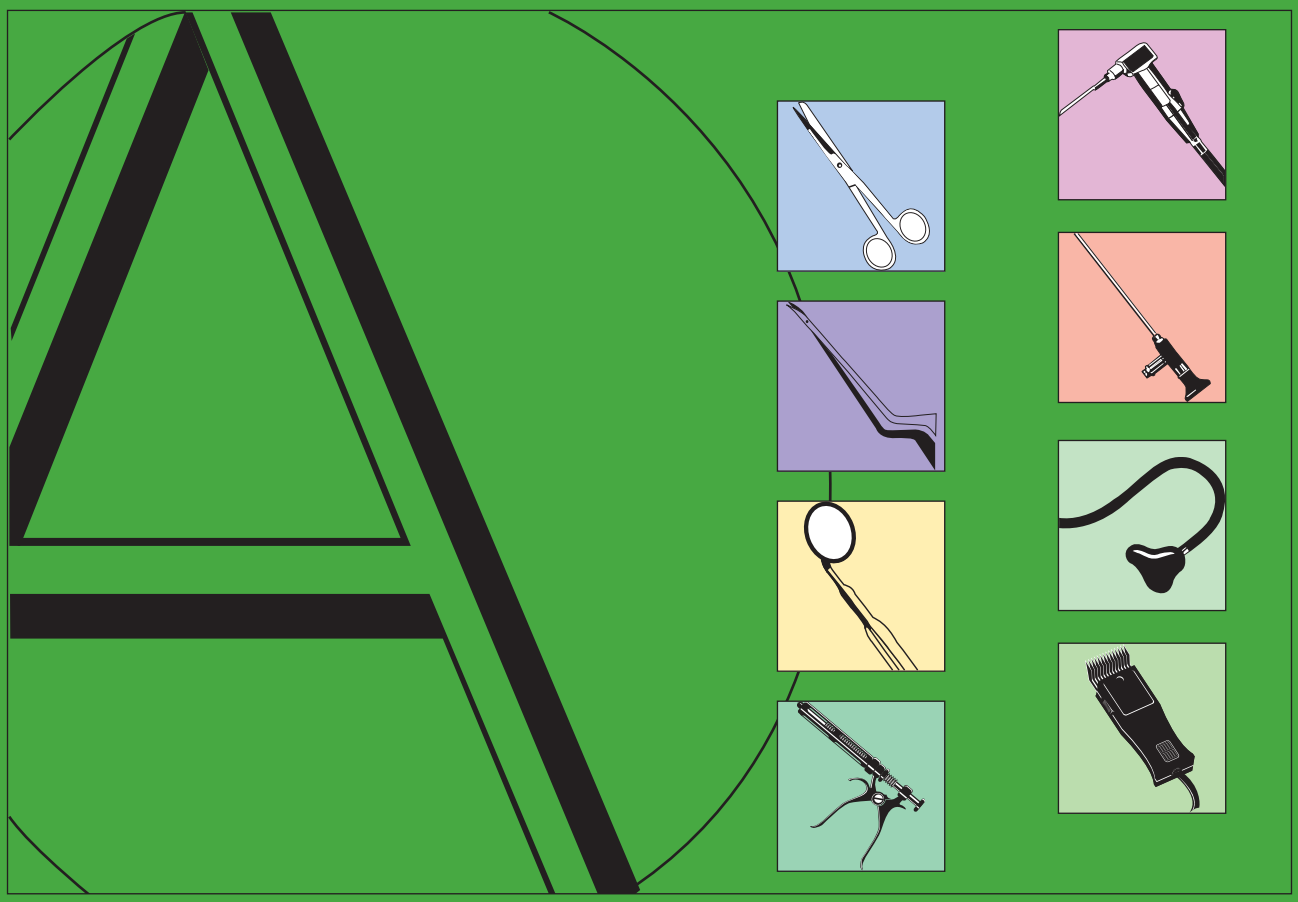
Proper Maintenance of Instruments in Veterinary surgeries



1

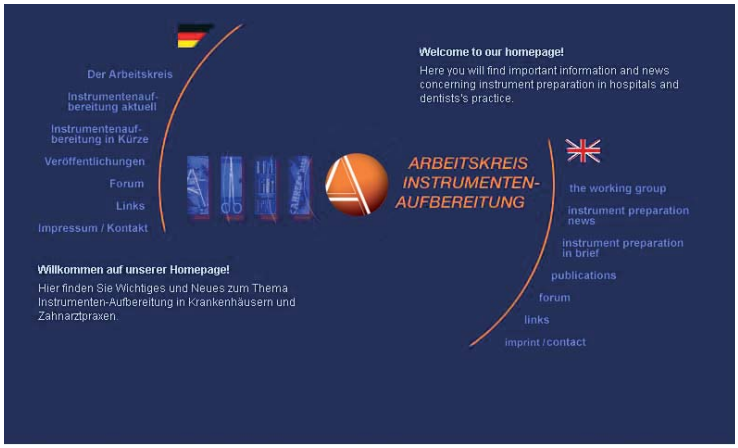
edition

Instrument Preparation
Working Group

Proper Maintenance of Instruments in Veterinary surgeries

1th edition, 2006
Surgical instruments
Microsurgical instruments
Dental instruments
Surgical motor systems
MIS instruments, rigid endoscopes and HF instruments
Flexible endoscopes and accessories
Flexible instruments and respiration systems
Electric clippers
Automatic syringes

Previous German editions:
1st edition, 2005



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We would most sincerely like to thank all former AKI members who are not named here for contributing to the layout and content of and continuous additions to the AKI brochures.

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Proper Maintenance of Instruments in Veterinary surgeries

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Preface

Due to many enquiries from veterinary surgeons regarding the preparation of instruments, the Instrument Preparation Working Group (AKI) decided to become involved in this sector too. A green brochure has been developed in cooperation with veterinary surgeons and the relevant industry alongside the red brochure for human medicine instruments and the yellow brochure for the dental sector. During the revision of the brochure regarding its content it became clear that the recommendations from the human sector could be adapted.
Beyond that, the green brochure also contains references for specific instruments, like e.g. clippers.

The intention is to provide users with a guide containing detailed instructions for the correct handling of instruments. The instruments' value thereby being optimised.

These instructions are intended as a supplement to the recommendations published by the Robert Koch Institute (RKI) and the German Society for Hygiene and Microbiology, as well as relevant accident prevention regulations and the instructions of the manufacturer.

Proper instrument disinfection and sterilization clearly depends on adequate cleaning and care, as well as on selecting the right materials and using suitable cleaning agents and treatment processes in order to maintain the value of the instruments.

Therefore, we have every reason to thank the Instrument Preparation Working Group for publishing this brochure for the veterinary medicine. We can only hope that the AKI gives this topic due consideration in the future too.

(Prof. Dr. med. vet. Martin Kramer, Hospital for small animals, surgery, Justus-Liebig-University Giessen)

Introduction

Instruments are a major asset and represent a significant share of the total capital spending of veterinarian hospitals and practices. The practical experience recorded in this guide, 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 care and maintenance. It should be emphasized that the recommended measures must always be carried out in accordance with the manufacturer's instructions, pertinent hygiene requirements and official safety-at-work guidelines.

For the preparation of instruments within the veterinary sector, no appropriate guidelines yet exist, nor are these instruments covered by the medical procut legislation. However, rules for the prevention of accidents issued by professional associations are valid for both the veterinary and the human sector. Besides, the guidelines of the Robert-Koch Institute (RKI) are already applied within the veterinarian sector.

Unlike human medicine, where validation measures for procedures in the preparation of medical products are explicitly set out, it is the veterinary practitioner's own responsibility to validate the preparation of his equipment.

These measures can be most usefully proven and integrated as a part of a quality management system.

The current green booklet is a process oriented sequence of operations included in the guidelines from EN ISO 17664 "information for the recycling of resterilisable equipment, to be provided by the manufacturer" and therefore can be included in such a system.

Section	Green Booklet	Section	RKI Recommendations	Section	EN ISO 17664: 2004
1	Materials				
2	Water used for instrument processing				
3	Brand-new and repaired instruments				
4	Treatment recommendations for returned goods				
5	Preparation for cleaning and disinfecting	2.1	Processing of non-used medical devices	3.3	Preparation at the place of use
6.1	Manual cleaning and disinfecting	2.2	Processing of used medical devices	3.4	Preparation for cleaning
6.2	Machine-based cleaning and disinfecting			3.5	Cleaning
6.3	Ultrasonic cleaning ans disinfecting	2.2.1	Preparation for processing, cleaning/disinfecting, rinsing and drying	3.6	Disinfecting
7	Final disinfection			3.7	Drying
8	Checks and care	2.2.2	Checking technical-functional safety	3.8	Checks, maintenance, testing
9	Packaging	2.2.3	Packaging	3.9	Packaging
10	Sterilization	2.2.4	Sterilization	3.10	Sterilization
		2.2.5	Marking		
		2.2.6	Release		
		2.2.7	Documentation		
11	Storage	2.2.8	Transportation und Storage	3.11	Storage
12	Surface Changes, Deposits, Corrosion, Ageing, Swelling and Stress Fractures				

Structural comparison between EN ISO 17664, RKI recommendations and the “Green Booklet”

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

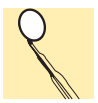
Special instructions for these product groups are given under the following symbols:


Surgical instruments


Flexible endoscopes and accessories


Microsurgical instruments


Supple instruments and respiration systems


Dental instruments


Automatic syringes


Surgical motor systems


Electric clippers


MIS instruments, rigid endoscopes and HF instruments

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 attack - whether mechanical, thermal or chemical.

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

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

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

The same applies to individual components of surgical motor systems, especially those that may be used only under sterile conditions and therefore need to be cleaned and resterilized after use, such as hand-held motors (pneumatic motors and micro-motors).

Other instrument groups for which special processing instructions are provided in this guide are MIS instruments, rigid endoscopes, HF instruments, flexible endoscopes and flexible instruments as well as automatic syringes and clippers.

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

Disposable instruments

Disposable instruments should never be used more than once as the respective declaration of conformity applies to single use only! Consequently, these instruments are not dealt with and no instructions for reprocessing are provided in this guide.

General notes and instructions

Basically, the reprocessing of medical devices comprises:

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

In human Medicine, 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 process, and to ensure adequate documentation.Validated cleaning, disinfecting and sterilization processes, supplemented by defined configurations for loading the washer-disinfectors (W/Ds) and sterilizers, are an indispensable prerequisite for quality assurance. Other requirements result from GVP.
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.

Machine-based reprocessing with thermal disinfection and steam sterilization are the preferred methods.

1. Materials

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

Corrosion resistance/ passive layer

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

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

Chlorides are dangerous!

Passive layers are extremely resistant to many chemical substances. Among the few substances that can attack and destroy this layer are halogen salts (halides), the most common and dangerous of them being chlorides. Chlorides tend to react with the passive layer in a process leading to the well-known, chloride-induced damage called “pitting corrosion”. Depending on the concentration of chlorides, the damage caused ranges from a few sparse points of attack (visible as small black dots), to a completely damaged instrument surface covered with large deep holes.

Chlorides are usually the cause of “stress corrosion cracking”. 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.

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

Corrosion on chisel

Possible Chloride sources in the instrument usage and processing cycle:

- Fresh-water chloride content (depending on the source of the supply)
- Insufficient demineralization of the water used for the final rinse and steam sterilization
- Regeneration salt carryover, leakage or spillage from ion exchangers used for water softening
- Use of agents not permitted for or improperly used in the treatment of surgical instruments
- Physiological salt solutions, etchants and drug residues
- Organic residues (body fluids such as blood, saliva, sweat) dried on the surfaces
- Laundry, textiles, packaging materials

Deposits on instrument formed by substance containing chloride

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

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

For instruments used in endoscopy and minimally invasive surgery, a great variety of materials is employed, depending on the given application technique and the particular instrument design. The most important materials are:

- Rust-/acid-proof chromium-nickel steels (also as welding filler)
- Pure titanium or titanium alloy
- Non-ferrous heavy metal alloys with surface finishing (e.g. chromium-/nickel-plated brass)
- Light metals (e.g. anodized aluminum)
- Non-corrosion-resistant steels (e.g. for coated assemblies and components)
- Glass (for optical systems)
- Ceramics

- Cements and other bonding agents
- Solder
- Plastics and rubber

Special processes may be required depending on the material combination used

Combination of these very different materials in a particular instrument places restrictions on the treatment processes. In other words, these items may require special treatment apart from standardized instrument processing. If in doubt in a given case, and no treatment recommendations are given in the instruction manual for the instrument, contact the manufacturer for advice.

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

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

One should refrain from using general tool drives (e.g. from DIY hypermarkets) not only for reasons of liability but also because of lack of service (with cheap products). These drives are usually without any casing and in most cases are not sealed. Thus humidity and residues from operations can get into the machinery. Gratings and lubricants can leak from the machine and reach the place of operation via the air vents or the fan. The data mentioned are not only causes of malfunctions, but are also a danger for users and patient (animal). Due to non-corrosion resistant components of machine tools transfer of rust particles onto other instuments is also possible.

Special 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, refer to the manufacturer's instructions. In addition to special processing requirements, lubrication is also essential for heavy-duty shafts as well as for bearing and gear components made of stainless steel (and in some cases, also for those made of non-stainless quenched and tempered steels or bronze materials).

Most shearing heads of hair clippers are made of unalloyed steel with a high carbon content, in order to achieve maximum cutting stability. Due to the material type these cannot be classed as stainless products. This should always be considered during preparation.

2. Water Used for Instrument Processing

The quality of water used for instrument processing has a considerable influence on depreciation in value.

Water fulfils a variety of functions in the treatment process, including:

- Dissolves cleaners and other treatment agents
- Transmission of mechanical forces and transfer of heat to the surface of the items to be washed
- Dissolves soluble dirt and impurities
- Flushes away cleaning and treatment solutions
- Is used for steam sterilization

Use correct water quality!

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

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

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

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

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

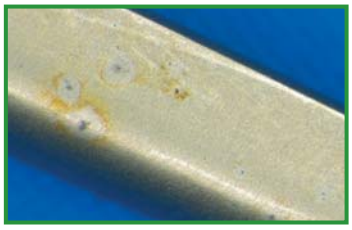
Aluminum might be attacked by alkaline solutions.

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

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

Chlorides are dangerous!

While the causal relationships between the chloride content of the water and pitting are not always predictable.



Pitting induced by chlorides on instrument

The danger of chloride-induced pitting generally rises with:

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

Experience shows that the probability of pitting is low as long as the chloride content does not exceed a level of approx. 120 mg/l (equivalent to 200 mg/l NaCl) at room temperature. With increasing chloride concentrations however, the risk of pitting will increase rapidly, too. It should also be noted that when water evaporates in the drying process, the chloride content of water droplets may drastically exceed the limit of 120 mg/l.

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

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

Instruments discoloured by silicic acid

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

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

Use fully demineralized water for the final rinse!

The use of fully demineralised water from water treatment units can be recommended for the final rinse not just, as described above, to avoid corrosion by chlorides in the final rinse water but also to assist in spotlessness and stabilising the anodised aluminium surfaces.

Extract from Table B.1: Feed Water Impurities	
	Feed Water
Evaporation residues	≤ 10 mg/l
Silicon dioxide, SiO_2	≤ 1 mg/l
Iron	≤ 0,2 mg/l
Lead	≤ 0,005 mg/l
Traces of heavy metals, except iron, cadmium, lead	≤ 0,1 mg/l
Chlorides (Ci')	≤ 2 mg/l
Phosphates (P_2O_5)	≤ 0,5 mg/l
Conductivity (at 20°C)*	≤ 15µS/cm
pH-value (degree of acidity)	5 bis 7
Color	colorless clear no residues
Hardness ∑ (alkaline earth ions)	≤ 0,02 mmol/l

Note: Using feed water or steam containing substances above the limit values indicated in table B1 can significantly reduce the service life of the sterilizer and the items to be sterilized, and may void the manufacturer's warranty or guaranty.

* In some national standards, this requirement has already been raised to ≤ 5 µS/cm.

Source: EN 285, steam sterilizers, version 1996

Since there is currently no specific standard regarding the use of fully demineralized water in machine-based treatment processes, we recommend the use of water of boiler feed quality for washer-disinfectors in which medical devices are treated (as defined in EN 285, Appendix B).

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

To optimize the pre-wash and main wash stages of machine-based treatment processes, we recommend using fully demineralized water or at the very least softened water. Experiments have shown that blood removal tends to become more difficult as the hardness of the water used in cold-water pre-washes and in the main wash increases.

3. How to Treat Brand-New and Repaired Instruments

Preparation

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

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

Cleaning is mandatory!

The cleaning step should never be skipped because residues (e.g. from packing materials or care agents) could lead to the formation of stains or deposits during sterilization.

Always check cleaning results by visual inspection. As a rule, the instruments should be visibly clean after the cleaning stage.

Electric clippers do not need to be prepared before first use.
The passive layer of brand-new instruments is necessarily still thin, and so these instruments tend to be more sensitive to critical treatment conditions than are older used instruments.

Storage

Brand-new instruments and instruments returned from repair may only be stored 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 processing, microsurgical instruments should be stored in suitable racks or retainers right from the start.

Flexible instruments must be stored in their original packaging in a dry, cool and dark place. When restocking your supplies, keep in mind that flexible instruments made of rubber or latex will age even if stored unused.

Functional parts of respiration systems frequently incorporate valves or diaphragms which tend to become blocked by internal surfaces sticking together during longer storage periods. Always check and test valves or diaphragms before using instruments.

Store the electric clippers only with oiled shearing heads and oiled shearing head fastener and keep in a dry place.

4. Treatment Recommendations for Returned Goods

In our context, returned goods are defined as packaged medical devices which, irrespective of whether they have been used or not, are returned to the manufacturer.

The reasons for return can be manifold: necessary repair or servicing; return of leased instruments; for checks to be carried out on products that are being clinically tested; in the case of complaints; return of explants for scientific investigation or damage analysis, etc.
Note that an infection risk exists for any person dealing with products actually or potentially contaminated. It is most important to minimize this risk by implementing adequate and reliable treatment processes.

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

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

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

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

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

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

5. Preparation for Cleaning and Disinfecting

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

The first steps in a proper reprocessing cycle are taken in the operating theatre. Before laying instruments aside for disposal, any residues from hemostatics, skin disinfectants, lubricants and caustic drugs should, wherever possible, be removed.

Never immerse stainless steel instruments in a physiological salt (NaCl) solution. This is because prolonged instrument contact with saline solution leads to pitting and stress corrosion cracking.

Deformation caused by improper handling

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. Disposal containers should also be kept closed, to prevent possible residues drying onto the instruments.

Medical products should ideally be transported in a dry state.

Avoid long intervals between use and treatment for reuse!

When using “wet disposal”, it is advisable to immerse the instruments in a detergent-disinfectant solution that has no protein-fixing effect. This requirement makes aldehyde-containing disinfectants (which have such an effect) unsuitable.

As regards concentration and exposure time, as well as the addition of cleaning intensifiers, the manufacturer’s instructions should be followed under all circumstances.

Because of the corrosion risk, long intervals between instrument use and processing for reuse (e.g. overnight or over the weekend) should be avoided, irrespective of the disposal method used (i.e., wet or dry). Experience shows that waiting times exceeding six hours should be avoided with dry disposal.

The instruments should be placed on instrument carriers (trays) suitable for machine-based cleaning processes, thereby helping to ensure that they will be properly washed and rinsed. Effective cleaning requires that articulated instruments (such as scissors, clamps, forceps) be processed in the open position to minimize surface overlapping. The trays, racks, mats, holders, supports, etc., must be such that subsequent cleaning in ultrasound basins or washer-disinfectors will not be hampered by areas inaccessible to ultrasound or water. Complex instruments must be taken apart for cleaning in accordance with the manufacturer’s instructions.

For microsurgical instruments, special racks or suitable fixing devices/supports should be used.

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.

Surgical motor systems must be taken apart immediately after use, following the manufacturer's instructions.

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 devices.

Hose/tubing sets used for cooling liquids or spray nozzles must be rinsed with water from the rinsing bottle immediately after disconnection, and then be checked for leaks (visual inspection; see section 8).

MIS instruments, endoscopes and HF instruments that can be taken apart, must be disassembled in accordance with the manufacturer's instructions prior to cleaning. Optics must be placed in special containers. Disposable items or components must be disposed of accordingly.

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. In the case of HF instruments, a 3% hydrogen peroxide solution is recommended for pre-treatment to remove any coagulating residues adhering to instruments after operations.

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

To avoid damage, delicate instruments should always be transported in containers or holders specially designed for this purpose.

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 that 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 the treatment process, a leak test must first be carried out in accordance with the manufacturer's instructions. This ensures the early detection of leaks and perforations and the prevention of more serious damage (as could be caused by penetrating liquids).

A defective endoscope must be returned to the manufacturer immediately, together with a description of the problem. If it has not been sufficiently cleaned and disinfected, this must be clearly and visibly indicated on the liquid-tight packaging.

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

Sensors may only be treated in accordance with the manufacturer's instructions.
When using wet disposal, flexible instruments with lockable cavities (such as tubes with balloons, or some masks) must be closed.

Before cleaning the shearing heads of the hair clippers these must be taken apart. When taking them apart, take careful consideration of the manufacturer's instructions as the adjustment of the shearing heads may otherwise be affected.

6. Manual and Machine-Based Cleaning and Disinfecting

6.1 Manual Cleaning/Disinfecting Cleaning

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

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

If solutions are used for too long, the following problems may occur:
- Corrosion risk due to contamination levels
- Corrosion risk due to increased concentration of cleaning/disinfecting solution as a result of evaporation

- Insufficient disinfection due to accumulated contamination (protein effect)

Narrow-lumened instruments such as flexible tubes and cannulas and instruments incorporating cavities are always difficult to process. This is why it is important to make sure that all external and internal surfaces are completely wetted by the cleaning or disinfecting solution.

Dissolve powders completely!

If powdery products (cleaning agents or disinfectants) are used, make sure you dissolve the powder completely in water before immersing the instruments. Undissolved particles may cause surface damage and clog narrow instrument channels.

We recommend using soft, lint-free cloths or towels, plastic brushes or cleaning guns for cleaning. Following manual cleaning or disinfection and cleaning, make sure to rinse instruments adequately and thoroughly with clear running water. This manual procedure removes dirt residues that may still adhere to the surfaces of the instruments.
To prevent water spots (spotting), a final rinse using fully demineralized water is recommended. After this the instruments must be dried carefully immediately. Compressed air drying is the drying method of choice, because it is not only a very gentle but also highly effective technique.

Stains caused by high salt content of rinse water

The main reasons for mechanical damage in manual treatment processes include:

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

Microsurgical instruments are especially prone to mechanical damage.

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

Dental instruments with rotating components may be immersed only in special disinfecting and cleaning solutions that are specifically suit-

able 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 agents used are suitable for these instruments. The use of unsuitable cleaners and disinfectants could destroy bonding agents, endangering shaft fixation!

Instruments for root-canal treatment are highly susceptible to mechanical damage and therefore should be processed separately. If such instruments have colored, anodized handles, do not treat them with alkaline solutions because this would impair or destroy their color-coding function.

Always clean motor systems by wiping their external surfaces with a cloth soaked in cleaner-disinfectant solution. Apart from lint-free cloths, soft brushes can also be used for cleaning in these cases. After spraying the surfaces with a disinfectant and allowing time for the spray to take effect as specified by the manufacturer, the surfaces are wiped clean. Following cleaning and disinfecting, make sure to rinse the surfaces under running water, holding the handles at an angle in order to prevent water from penetrating into the couplings or other components. Never immerse these products in water or other treatment solutions! In the case of accidental ingress of liquids, these must be removed at once.

Avoid ingress of liquids!

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

When immersing such instruments in a cleaning/disinfecting solution, make sure that the cavities are free from air bubbles so that all surfaces are completely wetted. (To check, agitate the item or hold it at an angle).

Rinsing forceps with irrigation connection

Cleaning the lens of an endoscope

If instruments with an irrigation connector cannot be taken apart, they must be sufficiently flushed with a cleaning or disinfection and cleaning solution. Make sure that the distal end of the instrument is adequately flushed as well.

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

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

In the case of flexible endoscopes, all valves and caps must be removed prior to treatment to ensure thorough cleaning and flushing of all channels. Cleaning is effected by immersing the flexible endoscope in a cleaning or disinfection and cleaning solution and wiping external surfaces thoroughly.

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

Flexible instruments with lockable cavities (e.g. tubes 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.

Shearing heads are to be cleaned regularly according to the instructions of the manufacturer. To this end the shearing heads need to be taken apart and cleaned carefully with a soft cloth or brush especially between the teeth.

When disinfecting shearing heads, they must be neutralized afterwards and dried and oiled very carefully, otherwise rust infestation can occur. The disinfectants must be material compatible (carbon steel), the impact times and concentrations data are to be observed according to the instructions of the manufacturer.

6.2 Machine-Based Cleaning and Disinfecting

Cleaning and disinfecting can best be standardized when using machine-based processes. Always keep in mind that proper cleaning is essential for retaining the value of your instruments as well as for successful sterilization. As specified by international standards (EN ISO 15883) and national guidelines, only validated machine cleaning and disinfecting processes should be used.

Machine processing should preferably be preceded by dry disposal. In the case of wet disposal, either suitable low-foam cleaners and disinfectants must be used, or the items must first be thoroughly rinsed. This is because foam impairs the cleaning and disinfecting results in machine-based processes. This also applies if heavily soiled instruments (problematic encrustations on HF instruments, filling-material residues adhering to dental instruments, etc.) have been pre-treated manually or with ultrasound.

When using machine-based processes (in a washer/disinfector), the following should be observed:

Ensure correct loading!

- To ensure effective cleaning, all trays, inserts, holders, etc., must be loaded correctly.
  For the same reason, all articulated instruments must be placed into the washer in the open position.
- Avoid overloading trays to ensure that all instrument surfaces can be readily accessed by the cleaning/disinfecting solutions.
- When placing large instruments on trays, make sure that they do not obscure other instruments, thus preventing proper cleaning.
- Instruments with cavities or hollow spaces (such as shafts, tubing, hoses, respiration systems) need careful cleaning and rinsing on the inside as well. For this purpose, special (instrument-specific) inserts with appropriate rinsing facilities should be used.
- The instruments must be arranged in such a way as to prevent mechanical damage through contact.

Optical changes to colour anodised aluminium occurs even in mildly alkaline solutions

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

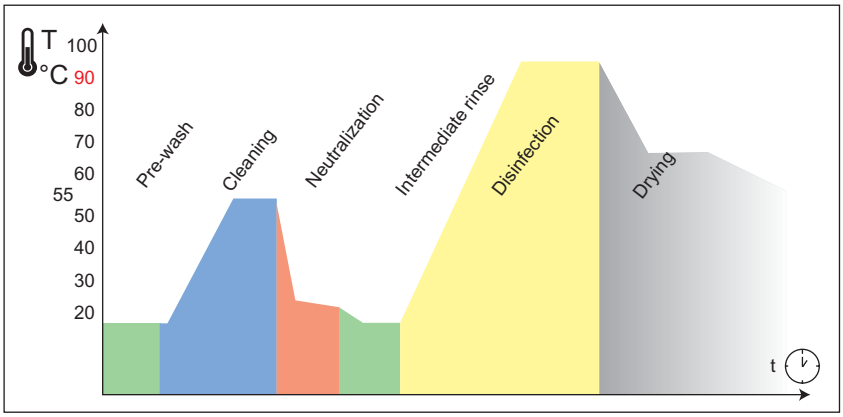
The items should be removed from the machine immediately upon completion of the program. If they are left in the closed machine, the residual moisture may cause corrosion.

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

6.2.1 Machine-Based Cleaning and Thermal Disinfection

In thermal processes, disinfection is carried out at higher temperatures with corresponding exposure times. As a measure of the disinfecting capability, the A_0 value has been introduced (EN ISO 15883-1, Appendix A). It determines the temperature-time relation as a function of microbiological contamination and the intended purpose of the medical devices involved.

Basically, the program structure depends on outcome (such as hygienic) requirements and on the type of items to be treated.
A machine-based treatment program with thermal disinfection typically includes the following steps or stages:



Cleaning programme with thermal disinfection

1. Pre-wash
Cold water (fully demineralized if necessary) without any additives, to remove coarse dirt and foaming substances.

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

Use suitable cleaning agents!

Suitable neutral-pH or alkaline products can be used for cleaning. Cleaning agent selection depends on the materials and properties of the instruments to be treated. National guidelines and recommendations as issued, for example, by the German Robert Koch Institute, must be observed as well.

Increased chloride concentrations in the water used could cause pitting or stress corrosion cracking. Such hazards can be minimized by using alkaline cleaning agents or fully demineralized water.

Carry-over of cleaning agent residues due to insufficient rinsing

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

4. Second intermediate rinse
With hot or cold water, no additives (use fully demineralized water if possible)

5. Thermal disinfection/final rinse
Use fully demineralized water. Thermal disinfection takes place at temperatures of 80-95°C with appropriate exposure times in accordance with the A_0 concept (see EN ISO 15883).

Using fully demineralized water prevents spotting, stains, deposits and corrosion on the surfaces of the instruments.

If you add a surfactant to shorten the drying period, be sure to check material compatibility as well as biocompatibility.

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

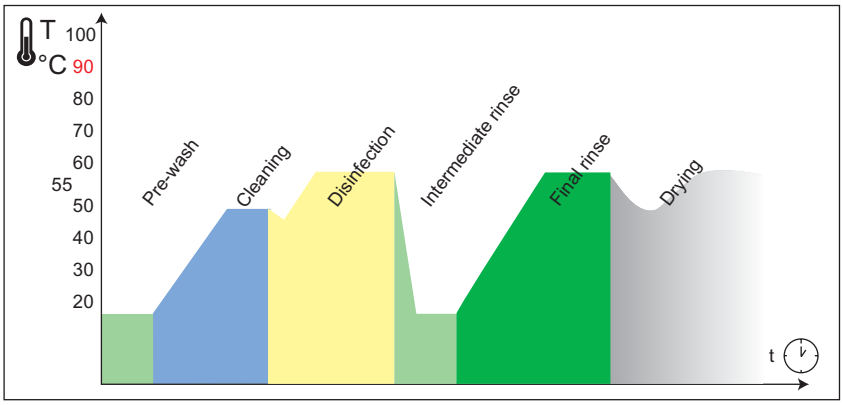
Observe the manufacture´s instructions!

With regard to the process chemicals used, the manufacturer's instructions concerning concentration, temperature and exposure time should always be observed. This guarantees good results and keeps the instrument materials intact to the greatest possible extent. Automatic liquid dispensing devices must be controllable.

6.2.2 Machine-Based Cleaning and Chemothermal Disinfection

Thermally sensitive medical devices are treated chemothermally. 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 chemothermal processes, cleaning is carried out at defined temperatures generally (60 °C) and a special disinfectant suitable for machine treatment is added in corresponding concentration for specified exposure times.
Example of a cleaning program with chemothermal disinfection:



Cleaning programme with chemo thermal disinfection

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

2. Cleaning
Hot or cold water (fully demineralized if possible); cleaning takes place at temperatures of 40-60°C for at least 5 minutes.

Suitable neutral-pH or alkaline products can be used as cleaning agents. Cleaning agent selection depends on the materials and properties of the instruments to be treated and also on national guidelines and recommendations.

3. Chemothermal disinfection
Hot or cold water (fully demineralized if possible).
Chemothermal disinfection takes place at 60°C, using a special disinfectant with proven effectiveness and suitable for machine-based disinfection.

4. Intermediate rinse
Hot or cold water (fully demineralized if possible), no additives.

5. Final rinse
Use fully demineralized water. The final rinse is carried out at max. 60°C.

Using fully demineralized water prevents spotting, stains, deposits and corrosion on the surfaces of the instruments.

If you add a final rinse agent to shorten the drying period, make sure to check material compatibility as well as bio-compatibility.

6. Drying
Sufficient drying must be ensured either through the washer-disinfector or by taking other appropriate measures. Drying is carried out at max. 60°C, depending on the products to be treated.

Observe the manufacturer's instructions!

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

6.2.3 Instrument Groups Requiring Special Treatment

Nickel and/or chrome-coated instruments, e.g. castration pliers must not be prepared machine-processed.

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

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

- Probes and other easily damaged instruments must be placed on racks or special holding devices for protection.
- Instruments with rotating components such as drill bits, cutters, burrs or abrasive tools are only conditionally suitable for machine treatment. As a rule, ultrasonic bath treatment is preferable.
- Instruments for root-canal treatment may only be machine-processed 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-processed, provided the manufacturer has certified the products for the process.
- Specula are subject to wear. For example, silver-backed glass mirrors may become dull as a result of machine treatment. Rhodium-metallized mirrors, in contrast, are more resistant to thermal and chemical influences but are easily damaged by mechanical impact.

Surgical motor systems may only be machine-processed if the manufacturer allows such treatment in connection with special processes, aids and facilities. Tools approved for use can be machine-treated in the same way as surgical instruments.

MIS instruments, rigid endoscopes and HF instruments must be disassembled for machine processing in accordance with the manufacturer's instructions. All seals/gaskets must be removed and all orifices opened.

Ensure internal rinse!

Use machine-based processes only where approved by the manufacturer of the product. To avoid damage, fix the items securely in place. The machine and machine inserts 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. with a brush or ultrasound) must be discarded as proper functioning and hygienic can no longer be guaranteed.

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

Manual leakage test on flexible endoscope

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

Alkaline detergents may damage endoscopes, so it is important to use only special cleaners and disinfectants suitable for the machine treatment 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 the process, the endoscope must be securely kept in place inside the machine. Use appropriate devices to ensure that all external surfaces as well as the inside of all channels/ducts are thoroughly and reliably cleaned and flushed.

Suitable technical processes must be employed to ensure that the water used for the final rinse is of a quality that prevents renewed germ growth on disinfected endoscopes.

Prior to storing endoscopes for later use, proper drying is necessary to prevent the growth of microorganisms. Drying can be done in an automatic washer-disinfector or by using a suitable drying cabinet.

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

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

Ensure complete drying!

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

Flexible instruments having a low resistance to heat (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.

Electric clippers must not be reprocessed using machines.

6.3 Ultrasonic Cleaning and Disinfecting

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

Ultrasonic cleaning is used:

- as an effective mechanical method supporting manual cleaning processes
- for removing tenacious encrustations before or after machine treatment
- as an integral part of machine-based processing cycles, thus supporting other measures for improved cleaning results
- for time-saving disinfection while providing intensive cleaning

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

- Fill the bath in accordance with the manufacturer's instructions.
- Add a suitable cleaning agent or a combined cleaner-disinfectant.
- When using both disinfectant and cleaning agents, the concentration, temperature and ultrasound treatment/exposure time must be chosen in accordance with the manufacturer's instructions to ensure compatibility.
- We recommend using warm water for the bath as follows.
- Water temperatures above 50°C can lead to blood encrustations.
- Freshly prepared disinfection or cleaning solutions require degassing before their first use.

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 cleaning solution.
- Articulated instruments (e.g. scissors) must remain open during treatment.
- Use only suitable trays (e.g. wire trays) that do not obstruct the ultrasonic cleaning process.
- Large-surface, bulky instruments such as lead hands, or kidney-shaped bowls, must be stored so that they do not obstruct the passage of sound waves or create anechoic zones.
- Do not overload trays.
- Ultrasound baths should be prepared freshly each day, taking care to observe national guidelines as well as the manufacturer's instructions. As high contamination levels impair ultrasonic cleaning and promote corrosion, more frequent replacement of ultrasound solution may be necessary, depending on the requirements of specific cases.
- Given efficient modern equipment, ultrasonic treatment times of approx. 3 minutes at frequencies of around 35 kHz should be sufficient.
- If disinfection and cleaning are carried out simultaneously, make sure to use suitable products, paying attention to concentration and exposure time requirements.

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

Following ultrasonic treatment, the instruments must be thoroughly rinsed manually. The manual rinse can be carried out with fresh tap

water, taking care that all cleaner and disinfectant residues are completely removed in the process. To avoid water spots, we recommend using fully demineralized water for the final rinse.

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

To prevent surface and soldering seam damage on dental instruments, never add acid cement remover to the ultrasonic bath.

Handpieces, elbows and turbines should never be treated by immersion in an ultrasonic bath.

Due to the materials used in their construction, dental instruments with rotating components must be treated with special disinfectants and cleaning agents. Prior to ultrasonic treatment, they should be placed on special racks to avoid contact damage among the instruments (e.g. by sharp cutting edges). 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.

Specula may be damaged by ultrasonic bath treatment.

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

In the case of MIS instruments, rigid endoscopes and HF instruments, ultrasonic bath treatment is allowed only for those parts for which the manufacturer has given his explicit approval.

No ultrasonic cleaning!

Optics, camera units, shearing heads and optical cables may never be cleaned in an ultrasound bath.

In the case of instruments used in HF surgery, a 3% H_2O_2 solution speeds up the removal of encrustations.

Flexible endoscopes must never be treated in an ultrasonic bath. However their accessories (such as valves, caps, biting rings or forceps) can be treated in this way.

Elastic instruments do not respond well to ultrasonic processing, as ultrasonic waves have only a limited effect on them.

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

7. Final Disinfection

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

Final disinfection can be performed either manually or mechanically at room temperature, or mechanically at higher temperatures using a chemothermal or thermal process. For machine-based thermal and chemothermal disinfecting processes with integrated cleaning stage, refer to section 6.2.

When using chemical processes for final disinfection, aldehydes, organic peroxo compounds or alkylamines are primarily used as microbicidal agents (either alone or in combination with cleaning components and/or corrosion inhibitors and additives). The effectiveness of the disinfectants used should be proven under “clean conditions” (no contamination) in accordance with European (EN) standards or equivalent local guidelines.

Observe material compatibility!

Material compatibility is a function of the instrument material, the composition of the disinfectant, temperature, exposure time, concentration, and the pH-value of the solution used.

Aldehyde-based disinfectants are usually highly compatible with instrument materials.
Regarding organic peroxo compounds, particularly disinfectants containing peracetic acid, compatibility greatly depends on the composition of the disinfectant and the specific conditions of use.

When using disinfectants containing alkylamines, the chemical structure of this agent strongly influences material compatibility with regard to elastomers and adhesive/glued joints. In the case of silicone elastomers, extended treatment with alkylamine-based disinfectants may lead to hardening.

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

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

Ensure complete wetting!

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

Following disinfection, the instruments must be rinsed thoroughly with sterile, fully demineralized water to completely remove any residues, and must then be dried immediately. If compressed air is used for drying, the air must be passed through a sterilizing filter.

We recommend using disinfecting solutions for no longer than one day. If the manufacturer recommends or allows longer use, the agent concentration should be checked regularly (at least daily), because losses can occur either during the introduction and removal of instruments, or due to chemical reactions. The solution should be disposed of as soon as the concentration limit value - up to which the manufacturer guarantees the action spectrum expected by the user - is reached. For suitable methods for checking concentration, consult the manufacturer of the product.

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

In the case of flexible endoscopes, this can be done with a hand pump or by using a program-controlled automatic pump system. Make sure to disinfect the discharge ducts as well! Following chemical disinfection, external surfaces and all channels of the endoscope must be thoroughly rinsed to remove any residues. To avoid water spots, use only fully demineralized water. Additional sterile filtration prevents unwelcome recontamination.

To dry the external surfaces of flexible endoscopes, use a lint-free cloth. The channels should be dried with a hand or discharge pump or with compressed air at max. 0.5 bar, depending on the manufacturer's instructions. The use of sterile (filtered) compressed air prevents unwelcome recontamination.

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

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

8. Checks and Care

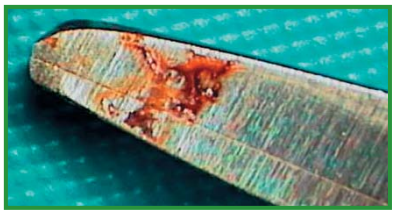
Cleanness

Sufficient cleaning standards are absolutely vital for successful sterilization. Instruments to be sterilized must be macroscopically clean, i.e. free from visible residues. This is checked by visual inspection.

Blood residues

Critical areas such as handle structures, joints or jaw serration (particularly atraumatic toothing) require especially careful checking.

It is advisable to use working lights with magnifying lenses of 3 to 6 diopters when checking filigree working ends.



Encrusted blood residues

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

Forceps

Poorly cleaned instruments must be recleaned (as described below) and then rinsed sufficiently:

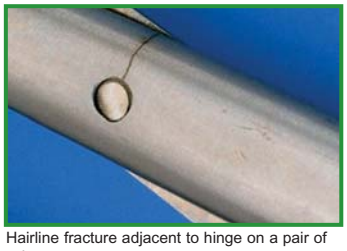
- Manual cleaning, if necessary with ultrasound (see section 6)
- Immersion in a 3 % H_2O_2 solution (for approx. 5 minutes)

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

Integrity

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

Biopsy forceps damaged by sheer force



Hairline fracture adjacent to hinge on a pair of scissors

Surface changes

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

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

Care

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

Fretting corrosion due to inadequate lubrication

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 corrosion caused by chafing.

In this way, the instruments are kept functional and hinge action maintained.

Requirements for care agents for surgical instruments:

- Paraffin/white oil basis,
- Biocompatible in accordance with the current European or United States Pharmacopoeia
- Suitable for steam sterilization and vapor-permeable.

Never process instruments with care agents containing silicone oil because they might not only adversely affect the instrument's functionality (ease of movement) but also the steam sterilization results as well.

Proper performance of care measures:
Allow the instruments to cool down to room temperature before opening and closing the instruments because otherwise metal abrasion might occur when the parts rub against each other. Such "fretting" would impair the instrument's ease of movement or even destroy its functionality altogether.

The care agent must be applied manually and accurately to joints, threads and friction surfaces and should then be distributed evenly by operating the respective joints. Any excess care agent must be removed with a lint-free cloth.

Spraying the instruments or applying the care agent mechanically is not sufficient, nor does it provide additional corrosion protection. Dipping baths should not be used because of the germ infestation hazard.
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 or through targeted application of drops of oil.

Separable instruments are tested in their assembled condition.

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

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

Care

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

- All 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.

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

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

Function

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

To check the air discharge duct, the compressed air motor must also be connected to the compressed air hose. After starting the motor, leaks can best be detected by submerging the hose in water.

Simple tools must be checked in accordance with the instructions for general surgical instruments. To prevent transportation damage, tools should be stored in special racks or secured using appropriate devices.

The flexible tube sets used for cooling liquids can be checked for leakage with a clamp and large-volume syringe. The tubing is filled with water, and a clamp applied to one end. Then water is injected by syringe at the other end.

Cleanness

Residues on endoscope glass surfaces, optical fiber cables and camera heads can be removed with a swab soaked in alcohol.

For this purpose swabs made of wood or alcohol-resistant plastic should be used. Swabs including metal should be avoided as they may scratch glass surfaces. Note also that alcohol is not suitable for removing blood residues.

Glass surfaces with stubborn deposits (e.g. in the case of oculars, lenses or light connectors) can be treated with a detergent or cleaning procedure recommended by the manufacturer.

If deposits or tarnish cannot be removed in this way, the instrument must be sent back to the manufacturer for inspection.

Integrity

Worn parts, defective components, gaskets and sealing rings must be checked for integrity before each sterilization cycle. If damaged, they must be replaced at once.

Damaged, blunt and/or distorted cannulas must be taken out and discarded.

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

Damaged insulation on HF instrument

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.

Care

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

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

Function

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

The instrument channels of flexible endoscopes must be checked for free passage (no obstructions).

Cleanness

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

Integrity

Gaskets, sealing rings, valves, caps and other parts which wear out, must be checked for integrity after each treatment cycle. If damaged or worn, they must be replaced at once.

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

Care

Swelling at distal end of fiberscope

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

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

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

Function/Integrity

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

Respiration systems must be checked in accordance with the manufacturer's instructions, to ensure that they are in proper working order, and are functioning properly.
Flexible instruments must be checked for proper functioning in accordance with their intended purpose. The most important checks and tests include:

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

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

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

Care

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

Never use silicone oil!

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

Cleanness

Electric clippers can only cut well and precisely if there are no hairs, dust particles or similar between the cutting plates. Before assembly the flat surfaces of the shearing heads must therefore be free from such impurities. To this end rubbing off with the ball of the thumb is to be recommended.

Care

The cutting plates are to be oiled before each use with the shearing head fully assembled, using the oil recommended by the manufacturer.

Function

After assembling the shearing head a test cut should be carried out. Badly cutting shearing heads are to be segregated and must be sharpened professionally.

9. Packaging

All sterilized products which need to be stored, transported or relocated for new storage until they are used, must be sterilized in suitable packaging. (DIN 58946, part 6, section 6.4. Routine Operation: items requiring sterilization must be wrapped in a suitable sterilization packaging which ensures that the ensuing process steps (cooling, transportation, storage, transportation, use) do not allow any recontamination. Theoretically only such items do not require any packaging which are sterilized in a room where immediately after sterilization they are used on the patient. This however is not the case with medical products which are reprocessed and sterilized in a central reprocessing facility.

The General Requirements for packaging sterile supplies include:

- Suitability for the sterilization method used
- Effective protection of the sterile contents during transportation and storage.

According to EN 868, Part 1, the following types of packaging must be distinguished:

Final packaging:

The outer packing in which the medical device is sterilized.

Primary packaging:

The sealed or closed and germ-tight packaging system that encloses the medical device.

Transportation packaging:

Packaging intended to provide adequate protection during transportation and storage.

In addition, there is the wrapping used for sterile supplies inside a container.

The type of packaging used has a significant influence on sterilization results. The sterile supply packaging must be sufficiently permeable to air and to the sterilizing agent used, in order to ensure the required sterilization

conditions. 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 packaging materials for the intended sterilization result is checked in the context of sterilization process validation. Whenever new materials are used that have not yet been properly validated, the performance assessment (validation) must be repeated.

Corrosion hazard due to residual humidity!

The drying process can be facilitated by wrapping the perforated trays with a towel or cloth inside the sterilization container, or inside the outer paper wrapping. A polycotton fabric has proved to be the best choice, due to the absence of lint. Coated fleece, in contrast, may result in insufficient drying. As always, the material's suitability as internal packaging must be tested in the context of process validation.

Basically, the effectiveness of the sterile supply packaging used is determined by its ability to provide an impermeable barrier to microorganisms, from the time of sterilization up to the time of use of the instruments. In practical terms, maintaining sterility greatly depends on proper handling and storage.

Deposits or corrosion due to chemical substances!

The sterile supply packing materials must not have any adverse effect on the items packaged! In other words, no chemical substances (indicator or dyes, etc.) may be released either during the sterilization process or subsequent storage, because any such action would lead to changes (deposits, stains or corrosion) on the instrument surfaces.

The following packaging materials or systems are considered suitable, depending on the sterilization method used:

Saturated steam

Reusable sterilization containers, transparent pouches and tubes (tubular film), sterilizing paper, paper bags, etc.

Ethylene oxide/formaldehyde

Transparent pouches, transparent tubes

H_2O_2-gas plasma

PE transparent pouches, e.g. TYVEK products (except "self-sealing" type). When using heat-sealing devices, different temperature setting requirements should be observed (e.g. TYVEK).
Additional packaging requirements:
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

It must also be possible to open the package easily under aseptic conditions.

10. Sterilization

Within the scope of European (EN) standards, the application of sterile instruments on or in the patient requires proper cleaning and disinfecting, followed by sterilization in approved packaging, on the basis of a validated sterilization process. Following such treatment, the sterile items must be stored in accordance with the rules and provisions governing sterile supplies. Consequently, it is important to use only sterilization methods and sterilizers that allow validated sterilization processes.

Sterilization accessories and packaging materials must be selected in accordance with the items to be sterilized as well as with the sterilization method used.

In this context, the user instructions for the sterilizer used must be strictly observed.

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

10.1 Steam Sterilization

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

When using small sterilization units ensure that class S equipment is used for everything to be sterilized which has hollow parts.

Stain formation due to "running" chemo-indicators!

If chemoindicators are used in large numbers in a sterilization batch, this 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.

Table B1: Condensate impurities

	Condensate
Evaporation	≤ 1,0 mg/kg
Silicon diowide, SiO_2	≤ 0,1 mg/kg
Iron	≤ 0,1 mg/kg
Cadmium	≤ 0,005 mg/kg
Lead	≤ 0,05 mg/kg
Heavy-metal traces (except iron, cadmium, lead)	≤ 0,1 mg/kg
Chlorides (Cl)	≤ 0,1 mg/kg
Phosphates (P_2O_5)	≤ 0,1 mg/kg
Conductivity (at 20°C)	≤ 3 µS/cm
ph-value (degree of acidity)	5 to 7
Color	colorless clear no residues
Hardness (∑ alkaline earth ions)	≤ 0,02 mmol/l

Remark: If feed water or steam containing constituents above the levels indicated in table B1, the service life of the sterilizer and the sterile supplies may be reduced and the guaranty or warranty of the manufacturer may become void.

* some national standards already require ≤ 5 µS/cm

Source: EN 285, steam sterilizers, table section B, version 1996

If validated steam sterilization processes are used in accordance with EN 554 provisions (or DIN 58946, Part 6, in Germany), then all process-relevant parameters such as pressure, temperature and inert gases have been validated, and are being monitored and documented. Thus there is no need to use chemoindicators or bioindicators for batch control.

Ensure steam quality in accordance with EN 285!

The sterilization steam used must be free from impurities and should neither impair the sterilization process nor damage the sterilizer or the items to be sterilized. To ensure this, the tolerances specified in EN 285, Table B.1, relating to the quality of the boiler feed water and the condensate may not be exceeded. Otherwise corrosion may be result from contaminants such as rust particles from the piping system, or discolorations on instrument surface may be caused by an excessive silicic acid levels.

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

Marbling caused by impurities in steam condensate

Corrosion hazards due to residual humidity!

Damp or wet containers pose instrument corrosion hazards. 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, 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 steam-sterilized at 134°C wherever possible to keep treatment time to a minimum.
- In the case of drive systems, consult the manufacturer's instructions to determine whether or not steam sterilization is permitted.
- Specula can be steam-sterilized, but being subject to wear, will soon become dull as a result of the ingress of moisture. This is possible because of the different expansion coefficients of different materials.

All surgical motor systems used under sterile conditions can be steam-sterilized at 134°C.

Make sure the manufacturer's instructions are observed, e.g. on fixing during sterilization.

Kinking reduces service life and impairs the functionality!

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

As regards battery-powered systems, make sure to strictly observe the manufacturer's instructions concerning compatibility.

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

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

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

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

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

Shearing heads must never be sterilized with steam and hot air.

10.2 Hot-Air Sterilization

Hot air sterilization is sterilizing with dry heat. This procedure holds a number of uncertainties:

- Using dry heat the heat transfer onto the object to be sterilized is relatively slow.
- The sterilization success may be impaired by the formation of cold spots.
- Procedure validation is not possible.

Should the procedure in spite of the afore mentioned uncertainties be use, a temperature of 180°C should be maintained for at least 30 minutes.

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

Prescribed temperature should not be exceeded!

If the specified temperature is significantly exceeded, there is a corrosion hazard, in addition to a 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!

Dental instruments can generally be sterilized using dry heat just like surgical instruments. For dental instruments to be treated separately please find the following tips for hot-air sterilization:

- Grips and contra-angles, as well as turbines are not suitable for the hot air sterilization.
- With drills and cutters a temperature of 180°C is to be kept to as exactly as possible as a decrease in hardness even at this temperature begins.
- Stomatoscopes are consumable items which in time become clouded during preparation because of the differing thermal expansion.

The components of the drive systems are only partly suitable for the hot-air sterilization due to the materials used. Instructions of the manufacturer are to be considered.

MIS instruments and endoscopes may never be sterilized with hot air on account of the high temperatures reached!

For flexible endoscopes hot-air sterilization is not applicable.

For flexible instruments hot-air sterilization is not applicable.

For respiration systems hot-air sterilization is not applicable.

Shearing heads must never be steam and hot air-sterilized.

10.3 Low-Temperature Sterilization

Low-temperature sterilization methods include gas sterilization using ethylene oxide or formalin, and gas plasma sterilization using hydrogen peroxide.

For environmental reasons as well as patient- and personnel-related safety reasons, these methods should only be used for items that cannot be steam-sterilized!

Items sterilized with ethylene oxide require adequate aeration following sterilization (and before reuse). Aeration times may vary considerably, depending on ventilation conditions and the product treated. For reliable aeration times, always consult the instrument manufacturer and/or observe the corresponding instructions.

Sterilization with EO gas may only be used for motor systems if expressly specified by the manufacturer.

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

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

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

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

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

Flexible instruments made of heat-sensitive plastic are not steam-sterilizable, but are sterilized using one of the methods indicated by the manufacturer.

Cavities locked with a valve must be fully evacuated and all water removed with a syringe prior to sterilization.

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

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

11. Storage

11.1 Storing Non-Sterile Instruments

Instruments may corrode as a result of adverse storage conditions. To prevent this they should be stored in dry and dust-free conditions. Major temperature fluctuations should be avoided in order to prevent 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!

Proper storage requires suitable structured systems that have been carefully considered to allow safe instrument storage. This prevents contact damage and reduces the risk of injuries.

Closed stacking/storage systems are preferable because they provide additional protection against biological recontamination.

Flexible endoscopes must never be stored in transportation cases, because these do not provide the essential low-germ, dry, dust-free and well ventilated storage conditions required. Endoscopes must be sufficiently dry before storage. Valves and caps must be removed and stored separately, under dry and dust-free conditions. It is advisable to hang up endoscopes during storage, using special cabinets that should be located near the place of use.

To prevent premature failure of flexible instruments, avoid kinking or overstretching during storage (use only suitable connectors!). They should be stored under dry and dark conditions.

Store the clippers only with oiled shearing heads and oiled shearing head fastener and keep at a dry place.

11.2 Storing Sterile Instruments

To guarantee instrument sterility up to the time of use on the patient, germ-tight packaging is absolutely essential.

Further requirements for protected storage of sterile supplies and prevention of corrosion damage include a dust-free and dry environment and the prevention of temperature fluctuations. Such conditions permit storage for six months (or more). For details, refer to EN 868 and Table 1 of the German standard DIN 58 953, Part 9.

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

12. Surface Changes, Deposits, Corrosion, Ageing, Swelling and Stress Fractures

In daily practice many medical devices are subject to surface changes due to chemical and/or physical impact. 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:

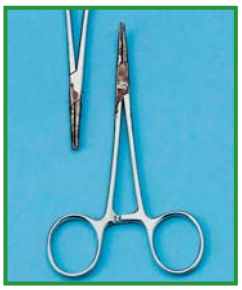
- Determine nature, origin and cause
- Assess risks
- Process/treat the items in accordance with the manufacturer's recommendations to correct changes where necessary
- Take appropriate measures to prevent reoccurrence, then validate your entire instrument treatment processes

Reworking or repair of affected products makes sense only if the causes of the surface changes have been determined and eliminated.

All examples given below are based on the systematic 4-step approach outlined above. These examples cover the most frequent surface changes in metallic instruments made of stainless steels and/or plastic or rubber products.

Metal/Deposits – Organic Residues

Type of surface change



Clamps

Tweezers

Close-up of scissor hinge area

Colored deposits consisting of blood, proteins, drug residues

Origin & causes

In manual processing and ultrasonic cleaning:

- Long interval between use and reprocessing
- Use of unsuitable instrument disinfectants
- Use of contaminated cleaners and disinfectants
- Insufficient rinsing after treatment
- Presence of inaccessible areas (ultrasonic cleaning)

In machine-based processing:

- Long interval between use and reprocessing
- Water feed temperature too high (exceeding 45°C) in first water intake cycle
- Ineffective rinsing (insufficient water flow through or around the instruments, insufficient rinse pressure, inaccessible areas)
- Inadequate maintenance/servicing of the cleaning and disinfecting unit
- Foam formation due to cleaner or disinfectant residues carried over from the ultrasonic or immersion bath
- Improper loading due to use of wrong instrument trolley/trays or overloading
- Leaving instruments fully assembled, processing hinged instruments in closed condition.

Treatment recommendations

- Recleaning with ultrasound
- Targeted manual recleaning
- Submersion in 3% H_20_2 solution (approx. 5 min.)

Preventive measures

- Remove coarse contamination immediately (see RKI recommendations in Hygiene requirements for the sterile processing of medical devices, item 2.2.1).
- Shorten the interval between instrument use and reprocessing (<6 hours).
- Use combined detergent/disinfectants for wet disposal
- Water inlet temperature in machine processing <45°C
- Correction program sequence in cleaning and disinfecting units.

Risk assessment

- 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.

Metal/Deposits – Spotting Caused by Lime

Type of surface change

Various instruments

Washer-disinfector cabinet

Instrument surface with insert mesh contact pattern

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 & causes

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

Treatment recommendations

- Wipe-off with a fuzz-free cloth
- Acid-based cleaning with special cleaners as recommended by the instrument manufacturer

Preventive measures

- Cleaning and as necessary intermediate rinses with demineralized water
- Use of fully demineralized water for the final rinse, to prevent stain formation in machine-based reprocessing

Risk assessment

- No corrosion, only aesthetic significance

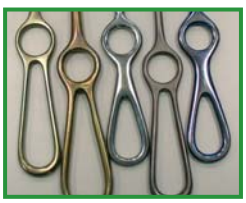
Metal/Deposits – Silicates and Other Mineral Compounds

Type of surface change

Stained, discoloured instruments

Various discoloured instruments

Instrument surface with drip-like discolouration



Various discoloured instruments

Discoloured cabinet

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

Origin & causes

- Silicic acid leakage in the production of fully demineralized water when using ion exchangers and reverse-osmosis water treatment equipment.
- Carry-over of cleaner residues containing silicates into the final rinse in machine treatment processes, due to insufficient intermediate rinsing.
- Other mineral substances contained in the final rinse water of machine-based cleaning processes or in the steam condensate, e.g. copper from the pipework system.

Treatment recommendations

- Mineral deposits can be removed by acid-based cleaning using special detergents as recommended by the manufacturer:
- Stubborn deposits (silicate build-up) can be removed with agents containing hydrofluoric acid.
- Mechanical surface treatment by the manufacturer or
- Implementation of repair by a qualified repair service agent.

Preventive measures

Use silicic acid-free, fully demineralized water for final rinse in machine processing. Prevent cleaner carry-over by:

- Correct tray loading and proper positioning/fixation of items with hollow spaces in which liquids can accumulate (e.g. kidney-shaped bowls).
- Ensure correct functioning of dispensing equipment.
- Ensure sufficient neutralization and intermediate rinsing in machine-based cleaning processes.
- Use water quality as specified in EN 285 (Appendix B, Table B.1) or DIN 58946, Part 6, for steam sterilization.

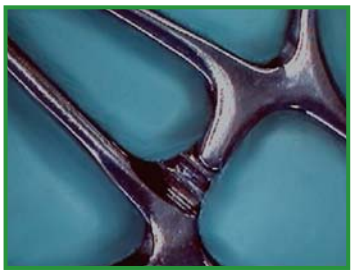
Risk assessment

- No corrosion, only aesthetic effect; no hygienic hazards
- 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.

Metal/Deposits – Discoloration Due to Oxidation

Type of surface change

Surgical hook with shaft made of hardened Cr-steel showing black discoloration and handle that has remained bright and blade made of non-hardened CrNi steel



Detail of forceps: lock and ring area

Left valve: brand new - uniformly green
Right valve: machine-cleaned - strongly discolored

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

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

Origin & causes

In the case of the above steels, in the case of machine cleaning by the neutralizer carried away in the last rinsing stage and/or by other factors forming passive layers are not yet identified. 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 chromium content/carbon content, alongside the influences of the material composition referred to above. In practice, this means that the higher the carbon content, the faster a gray-black discoloration may become visible.

In the case of titanium materials, damp heat and/or cleaning chemicals used in the various reprocessing stages may lead to oxidation of the surface and hence to discoloration of the surface.

Titanium oxide deposits may be transparent or multicolored/colored depending on the composition, density and thickness.

Treatment recommendations

Not recommended due to the properties of the deposit, but may be carried out at the manufacturer or a qualified repair service as necessary in both cases only by appropriate surface treatment (mechanical in the case of steel, chemical in the case of titanium). In the case of stainless steels, removing the deposit with a basic cleaner 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, because the nature of the material means it always reacts with the surface more or less visibly as a result of the ambient conditions prevailing during reprocessing (temperature, chemicals, humidity).

Risk assessment

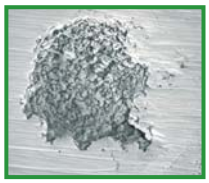
No corrosion – aesthetic effect
If, in the case of titanium materials, any identification/coding function lost as a result of discolorations, e.g. color coding of the blade width in the case of valves (see picture), does not present a safety risk, color changes due to the formation of different properties of oxide layers is completely unproblematic. I.e. there are no restrictions relating to toxicity, hygiene, function or lifetime.

Metal/Corrosion – Pitting Corrosion

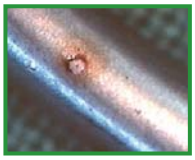
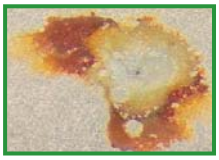
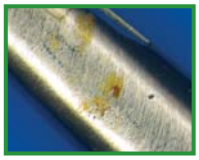
Type of surface change


General view


Magnified section


Microscopically magnified (200x) corrosion hole


Castration pliers

Examples of pitting

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 lo-quality instrument steels, or with contact corrosion symptoms when only stainless steel instruments are used.)

Origin & causes

- In stainless steel, caused by exposure to halide ions (bromides, iodides and chlorides), but especially chlorides, that locally break through the passive layer of instrument steel, thus causing pitting.
- Dried-on organic residue, e.g. blood, pus, secretions

- Frequently pitting is due to the use of liquids with a high chloride content, or more specifically, 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. Ins-truments that have been in use for some time are more resis-tant to chloride attack, because they have developed a thicker passive layer.

Treatment recommendations

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

Preventive measures

Chloride-induced pitting can usually be prevented by using low-chloride concentrations in the water used for reprocessing, and minimizing ins-trument exposure to other liquids containing chlorides, such as physiological salt solutions.

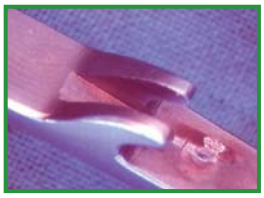
Risk assessment

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

Metal/Corrosion – Fretting Corrosion

Type of surface change

Scissor hinge area



Suture holder with spring abrasion

Castration pliers hinge area

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

Origin & causes

Insufficient lubrication leads to corrosion of the metallic friction surfaces that move relative to each other (especially in locks/joints and sliding paths of for example, punching instruments). Microabrasion occurs in such cases, and destroys the passive layer. In these sensitized areas, humidity and 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: Apply a lubricant to the instrument in the joint area prior to performing the functional check
- Manually apply the lubricant directly to the joint area (using drops or spray)
- Distribute the lubricant uniformly in the joint by opening and closing the instrument several times

Lubricants suitable for instrument care must:

- be based on, for example, liquid paraffin (paraffin oil)/white oil,
- be in conformity with the currently valid pharmacopoeia,
- be physiologically safe as specified by the German Pharmacopoeia (DAB) and Article 31 of the LMBG (German Food and Commodities Act) (or corresponding local regulations)
- be vapor-permeable/sterilizable
- Jamming of the joints due to accumulated lubricant must be prevented.

Do not use lubricants with rubber and latex items, as this leads to swelling and surface destruction.

Risk assessment

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

Metal/Corrosion – Stress Corrosion Cracking

Type of surface change

Scissors with breakage around hinge

Breakage at countersunk screwhead

Fracture at hinge pin

Jaw breakage

Fracture at hinge

Jaw breakage on suture holder

The so-called electrolytic/anodic stress-crack corrosion (or stress corrosion cracking) usually leads to visible cracks and fractures.

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

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

Origin & causes

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

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

Treatment recommendations

None (cannot be corrected)

Preventive measures

- Clean jointed instruments in open position and sterilize them with the ratchet locked in the first tooth at the farthest.
- Reduce the chloride load to a minimum (for example, reduce surgical and drug residues; use only suitable water for cleaning, 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

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

Metal/Corrosion – Surface Corrosion

Type of surface change

Stainless steel instrument with acid attack (brown tarnishing).
Cause: Overdispensing.

Rust formation on a scalpel blade.
Cause: Not stainless steel as this is a disposable product.

Rust formation on a chromium-plated saw blade made of carbon steel.
Cause:
Defects in chromium layer.

Material attack.
Cause: Alkaline cleaner

Damage to aluminum handle only.
Cause: Use of highly alkaline detergent

Aluminium surface damage due to use of highly alkaline cleaner

Damage to aluminium components only.
Cause: use of highly alkaline detergent

Acid attack on welds and hard metal inserts, with consequential damage in the form of extensive wear
Cause: Overdispensing

Discoloration by pickling on aluminum

Chrome plate castrations forceps. Damage to chrome parts lead to corrosion films. Danger of transfer of rust onto stainless instruments.

Chrome plate pliers from DIY store. Non-chrome parts (e.g. joint) lead to corrosion films. –> Danger of transfer of rust onto stainless instruments.

Standard chrome plate handicraft crochet hook – Chrome plate is not able to withstand reprocessing.

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

- Material erosion on sintered carbide inserts made of cobalt-bonded tungsten carbide (= TC/Co) and at welds.

Origin & causes

- Chemical and electrochemical influences only in connection with an excessive acid content on
  - Stainless steel
  - Sintered carbide metals (TC/Co)
  - Soldered connections
- Long-term impact of water/condensate in the case of stainless steel.
- Impact of acid or alkaline agents in the case of anodized surfaces.

Treatment recommendations

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

Preventive measures

- Observe application recommendations for acid cleaners and neutralizers when treating instruments made of stainless steel or sintered carbide (TC/Co), or items incorporating soldered connections
- Remove and discard disposable products made of steel or old steel instruments with damaged surfaces, and replace them with stainless steel products
- Avoid long-term exposure to moisture (condensate)
- Treat instruments with anodized surfaces in a neutral-pH/mildly alkaline environment

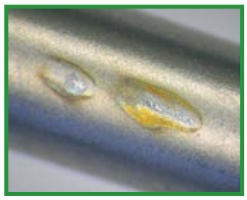
Risk assessment

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

Metal/Corrosion – Contact Corrosion

Type of surface change

Contact corrosion between two instruments both made of stainless steel



Contact corrosion

Contact corrosion through contact of stainless steel and brass

Contact corrosion

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

Origin & causes

The classic variant of contact corrosion occurs in a material combination involving stainless steel and non-ferrous metals (German silver, brass, copper). Depending on the ambient conditions, e.g. humidity, this generally also leads to corrosion deposits in the contact areas and usually beyond them as well.

When using only stainless steel instruments, contact corrosion has so far been observed only after the machine washing cycle. Microfriction at the contact points leads to partial abrasion of the passive layer. Thus the corrosion protection is temporarily removed in these places, which in turn leads to the surface changes described above. (This surface change could also easily be classified as “fretting corrosion”).

In the classic material combination stainless steel/brass, when the instrument stock typically contains old and new instruments (old/chromium-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 hollow handles or retractors).

Treatment recommendations

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

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

Preventive measures

Avoid vibration when cleaning (e.g. ultrasound treatment, machine reprocessing) stainless steel instruments (e.g. by ensuring that the cleaning/disinfecting apparatus, or washer-disinfector, stands firmly on level ground).

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

Risk assessment

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

Metal/Corrosion – Extraneous and Film Rust/Subsequent Rust

Type of surface change


Container filter holder


Ratchet


Scalpel blade holder

- Individual, irregularly dispersed rust particles
- Brown, mostly locally limited corrosion deposits (rust formation)
- Given large-surface contact with very rusty products, subsequent damage in the form of “instrument impressions” may occur.

Origin & 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
- Continued use and reprocessing of non-corrosion-resistant steels (often old instruments) whose protective layer has been damaged or completely dislodged

Treatment recommendations

Given a slight and only superficial attack, removal of the deposits with acid-based cleaning may be an option (only for stainless steels), but it is necessary to check afterwards whether the instrument surface is still intact.

Provided the damage is still superficial, it may be possible for the instrument to be treated mechanically (reworked) by the manufacturer or a qualified repair service provider.

Preventive measures

- Disposable items made of steel must not be reprocessed. (no reuse!)
- Discard, or treat separately, any non-stainless instruments and materials
- Avoid using cheap products (e.g. accessories available in do-it-yourself chains)
- Carry out effective construction measures to prevent pipework rust particles from entering the cleaning and sterilization stages (e.g. by filtering the feed water mechanically before it enters the washer or sterilizer)

Risk assessment

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

Metal/Corrosion – Crevice Corrosion

Type of surface change

Forcep hinge

MIS instrument hinge

Tweezers

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

Origin & causes

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

Treatment recommendations

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

Preventive measures

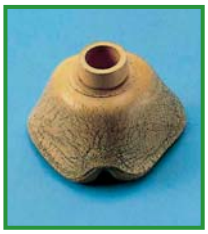
- Remove coarse dirt immediately (RKI recommendation: "The single most important measure for preventing this type of corrosion is the adequate drying of narrow joint crevices".
- Use rinsing water with a low salt content (preferably fully demineralized water).

Risk assessment

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

Plastic/Rubber – Ageing

Type of surface change



Cracks caused by ageing on breathing mask

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

Origin & causes

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

Treatment recommendations

None (cannot be corrected)

Preventive measures

If possible store instruments in dark and cool conditions.

Risk assessment

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

Plastic / Rubber – Swelling

Type of surface change

Swelling in a flexible insertion tube due to use of an unsuitable care agent.

Swollen gaskets as a result of non-targeted instrument oil application.

Leaky trocar flap valve due to gasket swelling as a result of oil contact.

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

Origin & causes

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

Treatment recommendations

None (cannot be corrected).

Preventive measures

Avoid contact/exposure, depending on material (see “Origin & causes”).

Risk assessment

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

Plastic – Stress Cracks

Type of surface change

Stress crack

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

Origin & causes

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

Under specific instrument processing 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

Adequate tempering as part of the manufacturing process can minimize internal stress (e.g. in polysulphone products). The manufacturer's cleaning/processing instructions should always be followed.

Risk assessment

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

13. List of abbreviations

BVMed
Federal Association of Medicine Technology, Berlin
The BVMed represents appoximately 200 industrial and commercial ventures of the medicine technology industry as a trade association

DIN
German Insitute for standardization

DNA
German standardization committee
In a joint venture of German producers and consumers, regulations and guidelines for the standardization of
- Building and machine parts
- Materials
- Measurements
- Procedure etc.

are set up which are constantly being scrutinized and supplemented by practical experience.

EN
European Standard
In the context of the EEC the European standardization committee matches the national standards and, if necessary provides new standards (e.g. also in the food sector = defaults for the production of beer or wine)

ISO
International organization for Standardisation
The international standardization committee tries to match the national standards and compiles internationally valid standards. For instruments and implants in the future the European medicine product guideline will make Europe wide valid demands regarding ist quality. GMP standards will prescribe for the manufacturers, how to guarantee that the quality of products remains the same. In addition quality assurance systems must be put in place, which are to be certified by independent examining bodies.

GLP
Good Laboratory Practice
GLP is the formal framework for the execution of safety examinations of chemical products. In many countries the GLP is legally prescribed. The GLP specifies the organizational operational sequence and the conditions, on which laboratory tests are planned, accomplished and supervised.

GMP
Good Manufaturing Practice
GMP are guidelines for the quality assurance of operational sequences and - environment in the production of medicine and active substances. In the pharmaceutical production the quality assurance plays a central role, since variations in quality can have direct effects on the health of the consumers. A quality management system true to GMP principles provides the guarantee of the product quality and fulfilment of the requirements of the health authorities which is obligatory for marketing.

H_2O_2
Hydrogen peroxide

HF-Instruments
High frequency surgical instruments

MIC-Instruments
Micro-surgical instruments

MPG
Medical Device Directive

pH value
A unit, with which the hydrogen ion concentration of a solution can be determined. It is indicated as a number that expresses, to what extent a solid or liquid substance has the characteristics of an acid or a base. Thus the pH value states whether a solution is acidic (pH between 1 and 7, example: vinegar), neutral (pH 7, example: pure water) or alkaline (pH between 7 and 14, example: soap solution).

PE
Polyethylene

PVC
Polyvinylchloride

RDG
Washer-disinfector

RKI
Robert-Koch Institute, Berlin
Robert-Koch Institute (RKI) is the central institution of the Federal Government on the area of disease monitoring and - prevention and concomitantly the central institution of the federation in the area of application and measure-oriented biomedical research. The core tasks of the RKI are recognition, prevention and combat against diseases, in particular infections.

VE-Water
Completely demineralized water

GVP Code of Conduct
Good veterinary practice
GVP is a qualtity assurance system of the Federal association of practicing veterinary surgeons e.V., which developed this on behalf the federal veterinary surgeon chamber. The GVP Kodex offers systematics, with whose assistance all capacity ranges and operational squences in veterinary practice and hospital can be strucured comprehensibly and can be better organized.

14. References

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   Reinigungs-/Desinfektionsgeräte
   Anforderungen, Definitionen, Prüfmethoden
   [Washer-disinfectors - Requirements, definitions and test methods]

2. EN 285: 1996
   Sterilisation
   Dampfsterilisatoren, Groß-Sterilisatoren
   [Sterilization - Steam sterilizers, large sterilizers]

3. EN 550: 1994
   Sterilisation von Medizinprodukten
   Validierung und Routineüberwachung für die Sterilisation mit Ethylenoxid [Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization]

4. EN 554: 1994
   Sterilisation von Medizinprodukten
   Validierung und Routineüberwachung für die Sterilisation mit feuchter Hitze [Sterilization of medical devices - Validation and routine control of damp heat sterilization]

5. EN 868; Teile 1 bis 10 (unterschiedliche Erscheinungsjahre der einzelnen Teile): Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte
   [Parts 1-10 (various parts published in different years): Packaging materials and systems for sterilizable medical devices]

6. DIN 58946 - Teil 6: 2002
   Sterilisation - Dampf-Sterilisatoren
   Teil 6: Betrieb von Groß-Sterilisatoren im Gesundheitswesen
   [Sterilization - Steam sterilizers - Part 6: Operation of large sterilizers in health care facilities]

7. DIN 58947, Teile 1, 3, 5, 6 (Teil 1: 1986, Teile 3/5/6: 1990)
   Sterilisation - Heißluft-Sterilisatoren
   [Parts 1, 3, 5, 6 (Part 1: 1986, Parts 3/5/6: 1990)
   Sterilization - Hot-air sterilizers]

8. DIN 58948, Teile 6, 7, 16, 17 (Teil 6: 2003, Teil 7/17: 2001, Teil 16: 2002)
   Sterilisation - Niedertemperatur-Sterilisatoren
   [Parts 6, 7, 16, 17 (Part 6: 2003, Part 7/17: 2001, Part 16: 2002)
   Sterilization - Low-temperature sterilizers]

9. DIN 58952; Teile 2, 3: 1977
   Sterilisation - Packmittel für Sterilisiergut
   [Parts 2, 3: 1977,
   Sterilization - Packaging materials for sterilizable items]

10. DIN 58953, Teile 1, 6, 7 to 9 (unterschiedliche Erscheinungsjahre der einzelnen Teile):
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11. EN 10088, Teile 1 bis 3 (unterschiedliche Erscheinungsjahre der einzelnen Teile): Nichtrostende Stähle
    [Parts 1 to 3 (various parts published in different years): Stainless steels]
    DIN 17440: 2001
    Nichtrostende Stähle - Technische Lieferbedingungen für gezogenen Draht [Stainless steels - Technical delivery conditions for drawn wire]

12. EN ISO 7153-1: 2000
    Chirurgische Instrumente - Metallische Werkstoffe
    Teil 1: Nichtrostender Stahl
    [Surgical instruments - Metallic materials
    Part 1: Stainless steel]

13. ISO 13402: 1995
    Chirurgische und zahnärztliche Handinstrumente
    Bestimmung der Beständigkeit gegenüber Sterilisation, Korrosion und Wärmebehandlung
    [Surgical and dental hand instruments - Determination of resistance to autoclaving, corrosion and thermal exposure]

14. ISO 7151: 1988
    Chirurgische Instrumente; nichtschneidende, bewegliche Instrumente (mit Schlüssen): Allgemeine Anforderungen und Prüfmethoden
    [Surgical instruments; non-cutting, articulated instruments: General requirements and test methods]

15. ISO 7741: 1986
    Chirurgische Instrumente: Scheren; Allgemeine Anforderungen und Prüfmethoden
    [Instruments for surgery: Scissors and shears; General requirements and test methods]

16. ASTM A 380 - 99
    Richtlinie für die Reinigung, Passivierung und Entzunderung von Teilen, Geräten und Anlagen aus nichtrostendem Stahl
    [Standard practice for cleaning, descaling and passivation of stainless steel parts, equipment, and systems]

17. EN ISO 17664: 2004
    Vom Hersteller bereitzustellende Informationen für die Wiederaufbereitung von resterilisierbaren Geräten
    [Sterilization of medical devices - Information to be provided by the manufacturer for the reprocessing of resterilizable devices]

18. ISO 14937: 2000
    Sterilisation von Medizinprodukten: Sterilisation von Produkten für die Gesundheitsfürsorge – Allgemeine Anforderungen an die Charakterisierung eines Sterilisiermittels und an die Entwicklung, Validierung und Routineüberwachung eines Sterilisationsverfahrens für Medizinprodukte
    [Sterilization of medical devices: Sterilization of health care products - General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices]

19. DIN Taschenbuch 100: 1990-2002
Medizinische Instrumente
[DIN paperback 100: 1990-2002
Medical instruments]

20. Directive 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte
Amtsblatt der Europäische Gemeinschaften
L 169, 36. Jahrgang, 12. Juli 1993
[Council Directive 93/42/EEC dated 14 June 1993 relating to medical devices,
Official Journal of the European Communities,
L 169, 36th volume, 12 July 1993]

21. UVV BGV A1 und Berufsgenossenschaftliche Regeln e.g. BGR 250, BGR 206 der Berufsgenosschenschaft für Gesundheitsdienst und Wohlfahrtspflege
[Regulations e.g. 250, 206 of the Employers' Liability Insurance Association for (Private) Health and Welfare Services]

22. Desinfektionsmittel-Liste der DGHM in der jeweils gültigen Fassung;
Liste der nach den Richtlinien für die Prüfung chemischer Desinfektionsmittel geprüften und von der Deutschen Gesellschaft für Hygiene und Mikrobiologie als wirksam befundenen Desinfektionsverfahren (inkl. Verfahren zur Händedekontamination und hygienische Händewaschung).
[Current DGHM disinfectants list;
List of disinfecting procedures tested in accordance with the guidelines for testing chemical disinfectants and considered effective by the German Society for Hygiene and Microbiology (including hand decontamination and hygienic hand washing procedures).]

23. Liste der vom Robert-Koch-Institut geprüften und anerkannten Desinfektionsmittel und -verfahren
14. Ausgabe; Stand vom 31.05.2003
[List of disinfectants and disinfecting methods tested and approved by the Robert Kost Institute;
14th edition; as of 31 May 2003]

24. Europäische Pharmakopöe
[European Pharmacopoeia]

25. Graue Broschüre
„Versuchsreihen und Stellungnahmen“
Veröffentlichungen des AKI
[Gray Booklet: “Test series and bulletins” - AKI publications]

26. Retouren in medizinischen Einrichtungen, Merkblatt Handlungsempfehlungen, BVMed
[Returned goods in medical institutions, Bulletin Treatment recommendations according to Operator Regulation relating to medical devices]

27. RKI (Robert Koch Institute)
- Krankenhausversorgung und Instrumentensterilisation bei CJK-Patienten und CJK-Verdachtsfällen,
Bundesgesundheitsblatt 7/1998, 279-285
[Hospital supplies and instrument sterilization in light of CJD patients and suspected CJD cases,
Federal Health Gazette 7/1998, 279-285]
- Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Empfehlung; Bundesgesundheitsblatt 44/2001, 1115-1126
[General criteria of hygiene for the processing of medical devices. Recommendation; Federal Health Gazette 44/2001, 1115-1126]
- Die Variante der Creutzfeldt-Jakob-Krankheit (vCJK)
Bundesgesundheitsblatt 45/2002, 376-394
[The Creutzfeldt Jakob disease variant (vCJD),
Federal Health Gazette 45/2002, 376-394]

28. GVP (Gute Veterinärmedizinische Praxis)
BPT (Bundesverband Praktizierender Tierärzte e.V.)
[Good veterinary practice,
Federal association of practicing veterinary surgeons e.V.]

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