WFHSS ÖGSV

Sterile Supply Specialist Training Course Level II

MATERIALS USED IN MEDICAL TECHNOLOGY

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Materials Used in Medical Technology

1 Introduction to material sciences

1.1 Foreword

Surgical instruments have been used for millennia for operative interventions to treat people. In the course of history the most diverse basic materials have been employed. These have included materials such as obsidian, ivory, wood, bone or stone since thanks to their material properties it was easy to produce them. But from a hygiene viewpoint, the suitability of such materials was questionable. However, hygiene and the consequences of poor hygiene was a topic that remained unknown for a long time.

With the introduction of asepsis (= absence of microbes) by Sir Joseph Lister in 1867 the bronze or iron entire-metal instruments used in antiquity once again became popular since they met the requirements for disinfection. This was a condition that the materials mentioned above were unable to fulfil because of their porosity.

In modern medicine a number of materials are employed and designed for optimal use in their intended field. Close attention must be paid already to choosing the basic material used to manufacture surgical instruments, because an injudicious combination of different materials must not result in malfunctioning of the instrument. Moreover, the biocompatibility of the materials used, in particular in the medical setting, must be taken into account. Nor should a material react with body fluids (e.g. corrosion of body implants) or toxic substances be released from the materials because of chemical reactions.

If a medical device is designed for reuse, it must lend itself to reprocessing involving, depending on its use, disinfection or sterilisation after cleaning. In such cases the material must be able to tolerate the effects of these procedures without suffering any damage.

This means that, on the one hand, the manufacturer of instrument /parts used in the medical field must have a thorough knowledge of the basic materials. But on the other hand, all the instructions specified by the manufacturer regarding how to care for the instrument must be carefully

observed by medical and technical personnel to prevent failure of the instruments due to inappropriate care measures.

Much work is being conducted in the area of research and development to produce materials that are better able to meet the pertinent requirements and withstand without damage the procedures to which they are exposed when used and reprocessed. This is urgently needed because of changing biological conditions and new insights and, accordingly, the different hygiene demands addressed to the materials.

In addition to an introduction to material sciences, a brief overview of medical devices and implants will be given. In another section a basic knowledge of physics and chemistry will be imparted to promote a better understanding of these subjects. For more detailed information, the reader is advised to consult the specialist literature.

A separate chapter is devoted to the various changes seen in the surfaces of medical devices. This includes information on residues and corrosion as well as on the remedial and protective measures that can be taken in the individual case.

The third most prominent topic addressed in a number of chapters relates to the materials most commonly used in the medical setting and how they respond to corrosion.

This Script concludes with the References to enable the reader to consult further specialist literature on this subject.

1.2 General fundamentals

The requirements governing the properties of the materials used to manufacture reusable medical devices are determined by the intended use and reprocessing method as well as by the manufacturing process. The following factors are taken into account:

- Biocompatibility (EN ISO 10993-1:2003)
  Nature of contact, duration of contact when device is used as intended > biological effect, e.g. cytotoxicity
- Diagnostic properties
  X-ray transparency
- Thermal properties
  Thermal conductivity, thermoforming and temperature resistance
- Chemical properties
  Hydrolysis and chemical resistance during reprocessing (washer-disinfector), stress cracking susceptibility
- Electrical properties
  Insulation properties – breakdown strength, conductivity, surface resistance, etc.
- Optical properties
  Colours, transparency, reflexion, etc.
- UV resistance properties
  Colour fastness, mechanical properties
- Processing properties
  Injection moulding, extrusion, mechanically workable, malleable, rollable, temperable
- Mechanical properties
  Tensile strength, stiffness, toughness, impact resistance, etc.

Based on knowledge of the properties of the materials and their behaviour, when also exposed to the effects generated by the medical device circuit such as temperature, pressure, chemical and mechanical influences, materials are chosen in accordance with their intended purpose from the range of materials available. After verifying the actual properties and only if these specifications are met are the raw materials forwarded to the manufacturing process. The initial inspections conducted to determine suitability include:

- Precise shape and dimensions
- Surface quality (cracks, pores)
- Material analysis (quantitative determination of alloy elements)
- Mechanical and technical properties (hardness, strength)

- Structural condition (grain size, purity degree, evenness)
- Malleability, temperability, corrosion resistance

Preconditions for

production	**value retention**
high-quality materials	used as per intended purpose
safe manufacturing process	gentle reprocessing
selective quality checks	regular care and inspection

of a quality product:

This calls for a functional quality management system for manufacture as well as for use throughout the entire medical device circuit. Manufacturers make enormous efforts to ensure reproducibility of the materials used and of the manufacturing processes. This is a requirement that also has implications for the user so as to, on the one hand, guarantee value retention and, on the other hand, safe use throughout the medical device's service life.

2 Medical devices

The essential requirements governing medical devices have already been outlined. The best possible material to be used for a medical device in any particular case will be determined by its technical design and constructional features. However, under certain circumstances one single material will not be able to meet these requirements. Depending on the required properties, several materials may be combined and therefore in devices composed of many single parts, these individual components will be made of different materials. One such example is a bone chisel equipped with a plastic handle, where its functional part is made of steel and the handle of a synthetic material. In more complex medical devices, such as motor handpieces or endoscopes, the material used in each part is tailored to its specific function. The challenge here is to ensure that the various components will be mutually compatible and not have any adverse effect on the overall functional capability of the device as a result of the stress experienced in the phases of the medical device circuit. This is because different materials behave differently when exposed to thermal, chemical and mechanical influences, e.g. expansion following a rise in temperature.

The requirements addressed to the constructional features, utilisation characteristics and the material used for reusable medical devices include:

- Intended purpose
- Functionality
- Safety aspects
  Insulation, roundings, no jamming
- Reliable manipulation during use
- Ergonomic design
- User friendliness
  Assembly / dismantling
- Good price-performance ratio
  Quality / price / service life
- Little need for repairs
- Easy to repair and service
  Easy replacement of parts subject to wear

- Reusable
  Not prone to ageing, easy to reprocess
- Reliable reprocessing

At the close of the 19th century Sir Robert Abbott Hadfield discovered that noble steels could be rendered resistant to corrosion through the addition of chromium. As from a chromium content of 12%, steel becomes resistant to rust. This protection is afforded through the formation of an oxide layer = passive layer that is formed by the bonding of chromium to oxygen (see Passivation, Chapter 5.1.4).

Today there is a broad variety of different anticorrosion stainless steels that have one common property: a chromium content of at least 12%. However, they differ in terms of their varying content of alloy elements such as e.g. carbon, chromium, nickel, molybdenum, vanadium, etc. Alloys are used to confer certain properties. Depending on the intended use and the associated requirements addressed to the instrument, other alloy elements are added to the underlying material.

Alloy element	**Implications**
Chromium Cr	anticorrosion protection
Carbon C	hardening agent
Molybdenum Mo	anticorrosion protection re. acids + chlorides
Nickel Ni	austenitic agent
Nitrogen N	increases strength properties
Copper Cu	improves cold heading
Manganese Mn	structural stabilisation re. deformation stress
Silicium Si	improves scale resistance
Sulphur S	improves machineability
Titanium Ti	protects against intercrystalline corrosion
Niob Nb	protects against intercrystalline corrosion
Vanadium V	increases thermal resistance

2.1 Materials

The vast range of materials currently employed in medical technology continues to expand since there is a perpetual quest for materials better able to meet the demands made on them. The main groups of materials used at present are listed below:

Steel-iron group of materials

Non-alloy steels	tools, saw blades, equipment components
Low-alloy steels	tools, dental drills, equipment components
High-alloy stainless steels	tools, instruments, equipment components

Pros: well tried and tested manufacturing process, virtually optimal properties thanks to alloys and heat treatment processes

Cons: susceptible to corrosion

Non-iron group of materials

Light metals

Ti + Ti alloys	parts /components for
Al + Al alloys	instruments and equipment, containers
Non-ferrous metals Cu + Cu alloys	parts /components for instruments and equipment

Noble metals e.g. silver, probes, cannulas

Pros: Ti: colourable, very good biocompatibility (implants), resistant to chlorides, no stress corrosion cracking, no pitting corrosion

Al: colourable, easy to work

Cons: Ti: very hard and therefore difficult to work, expensive

Al: soft, gentle treatment needed

Hard metal group of materials

Vacuum cast stellite

Co base + Cr, W, C, Ta, Mn, Fe	parts /components for HM scissors
Sinter metals	parts /components for

WC with Ni binding phase in ratio = 9:1 — HM needle holders, HM forceps

Pros: low wear since essentially harder than steel, used for heavy-duty parts

Cons: difficult to work, must be applied and bonded to carrier material

Special alloys' group of materials

Cobalt underlying material Phynox – ISO 5832/7 — saw blades, probes, vascular clips > jaw regions for application forceps

Nickel underlying material Ni-Basis + Fe, Mn, C, Cu — parts /components for MIS tubular instruments

Pros: properties tailored to respective use requirements

Cons: alloys of certain compositions are difficult to produce

Ceramic group of materials

Aluminium-zirconium oxide Al_2O_3 / ZrO_2 — parts /components for MIS instruments for use in HF surgery

Pros: electrical isolation

Cons: hard → risk of breakage

Synthetic group of materials

<u>Duroplastics</u>

PPSU Polyphenyl sulphone — container components

Harex (trade name) = cotton-reinforced phenol resin — parts / components for instruments

<u>Thermoplastics</u>

PPS Polyphenyl sulphide (GF reinforced) — parts / components for dental instruments

POM Polyoximethylene — implant sets (storage)

PEEK Polyether ether ketone (partly crystalline /anisotropic) — parts / components for instruments

= substitute for Harex

Pros: high dimensional stability, high impact resistance, high hydrolysis resistance

Cons: stress cracking susceptibility / embrittlement due to chemicals (surfactants)

Elastomeres

Silicone rubber	for instruments, equipment and containers (seals), storage purposes

Diamond

Pure carbon. Used for cutting and for knives

Pros: hard, good edge retaining ability

Cons: expensive, difficult to work

2.2 Surgical instruments

Surgical instruments are the most expensive "mobile" capital goods in the hospital and, as such, they play a pivotal role in determining the success of the services rendered, while facing high demands for continuing performance and, at the same time, posing minimal risk to patients and users. Hence they are of paramount importance in ensuring that the hospital can deliver its process: surgery.

In the majority of cases, surgical instruments can meet the demand for high elasticity and impact strength, stiffness, good cutting action and high wear resistance as well as best possible anticorrosion properties only through the use of metals. Hence the materials predominantly used in this setting are stainless, temperable chromium steels with a chromium content of between 12 and 14%. The main emphasis is on the homogeneous structure of the underlying material as well as on even distribution of the alloy elements – this cannot be changed subsequently – to assure the properties of the material across the entire instrument. The requisite properties can be achieved through refinement in the form of annealing or tempering. But the user should note that while these instrument steels listed in the various national (e.g. Austrian) and international (EN and ISO) standards are resistant to the chemical and thermal stresses generally encountered in

medical practitioners' offices and hospitals, they are susceptible to every type of corrosion (see Chapter 4).

In addition to the temperable, stainless chromium steels, non-temperable chromium steels with a modified chromium and carbon content are used, but the use of such steels is confined to certain areas because of the altered mechanical properties.

A surface that is free of cracks and pores, polished to a high degree or given a mat finish in an additional working step will guarantee the effectiveness of any measures taken to meet the hygiene requirements.

2.3 Instruments for minimally invasive surgery (MIS)

In minimally invasive surgical instruments stringent demands are made on the material, construction, manufacture and fine mechanics. To meet the surgical / technical demands made on them, the functional components are extremely delicate and finely structured.

At the time when endoscopic techniques were first introduced to the market, MIS instruments were made entirely of instrument steel. In the meantime MIS instruments are available with isolation facilities to permit the use of high-frequency techniques. Whereas monopolar MIS instruments are supplied only with current that is conducted via the patient's body, bipolar instruments, in which the current is routed into and out of the body to confine this spatially, call for a major investment in construction and precise manufacture to electrically isolate the individual components. The current can only flow via the tissue placed between the jaw regions and thus its effect is exerted at the desired site.

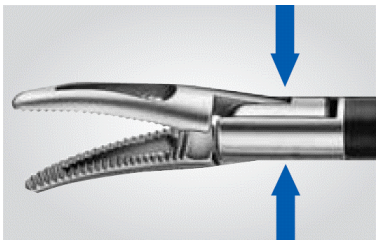


Fig. 1: Monopolar MIS instrument

By virtue of their design, MIS instruments are particularly sensitive to inappropriate mechanical stress during use, transport or reprocessing. It was been identified that the vast majority of instances of damage are

related to mechanical influences. In most case, this damage cannot be reversed. The use of special storage supports is therefore recommended.

2.4 Motor systems

Motor systems are used in medicine to improve the results of surgery, shorten the operating time and facilitate the surgeon's manipulations. Surgical motor systems convert the primary energy first into a rotary movement. Using appropriate handpieces and transformations, this rotation is then converted to the desired type of movement of the implement.

Based on the various requirements addressed to the individual components of the motor system and their construction as well as the different types of drives (pneumatic, electrical with mains operation or internal power source = storage battery) a vast variety of different materials are used. Their various properties as well as the interaction between the material combinations must be taken account of during use and reprocessing, since the different materials behave differently during the individual phases of the instrument circuit e.g. in respect of thermal expansion.

Alloyed stainless and non-alloyed temperable chromium steels for drills, milling tools, saw blades and drive components are used just as are sterilisable plastics for handles, switches, drive components or cables and tubes. Non-alloyed varnished steel plates for housings, varnished colour coding to designate transformation ratios on handpieces or anodised casings from aluminium for hand- and angle pieces as well as storage batteries may require special reprocessing methods. Heavy-duty shafts, bearings and gear units made of stainless steel, but in rare cases too of non-stainless coated steel as well as from brass materials, call for lubrication measures in addition to special reprocessing methods.

Under no circumstances may motor components be immersed in a disinfectant or detergent solution since this would tend to result in a higher load of contaminants being introduced into, rather than removed from, the casing. Any liquids or chemical substances that have entered lumens will generally not be able to escape and in the course of time will lead to failure of components due to material alternations.

Fig 2: Components of a saw handpiece

Automated reprocessing can be carried out without any consequential damage only for motor components that have been manufactured while taking account of special constructional features and when using special storage supports and cleaning programmes. These special supports cover sensitive openings to prevent the direct entry of liquids. Oblique positioning of a device will expel any liquid that entered it during the cleaning process or which was formed as condensate during the sterilisation process.

Motor components with mobile parts must be lubricated with suitable agents before each sterilisation cycle. The manufacturer's reprocessing instructions tailored to the materials or special features of motor systems must be carefully noted and complied with.

2.5 Endoscopes

Endoscopes constitute a further group of medical devices which are available in rigid and flexible designs

Endoscopes are precision instruments designed to examine illuminated preformed body cavities such as e.g. the bladder, intestines, abdominal cavity, bronchi, insides of joints or blood vessels. By virtue of their constructional design, various materials are used to manufacture endoscopes and their properties must be taken into account when using and reprocessing the instruments. Special reprocessing methods are also needed

for flexible endoscopes with rubber or plastic sheaths, as used in urology, anaesthesia or gastroenterology.

Here different materials are used depending on the application techniques and the purpose for which the endoscopes are used. The most important of these include:

- stainless chromium steel
- non-ferrous metals with anodised surfaces, such as chromium-coated brass
- light metals (e.g. anodised aluminium)
- glass
- ceramics
- putty and glues
- plastics and rubber

The combination of various materials and especially the different behaviour evinced by them during the different phases of the instrument circuit call for special attention. In particular, because of the stress generated during reprocessing (mechanical, thermal, moisture, pressure), it is important to be aware of the possible consequences of such treatment processes.

For example, the glass used for endoscope lenses has a different thermal expansion profile from that of the surrounding materials. Manipulations or mechanical stress after heat treatment (e.g. disinfection or sterilisation) should be avoided as far as possible since glass is extremely brittle when it is hot.

Special reprocessing methods, which differ from those normally used, may therefore be needed for endoscopes. By now, endoscopes can be sterilised at 134° C / 3 bar, as indicated by the following symbol on the endoscope shaft: 

. However, older optics that cannot be autoclaved still continue to be used. If there are any doubts, the manufacturer's advice should be sought.

2.6 Products for provision of sterile supplies – containers

Medical devices are subjected to the sterilisation process while accommodated inside containers. These are also used to store the supplies, make them available for use in a sterile state and, as such, they must ensure that sterility is preserved following the sterilisation process. Other

products used to this effect are mesh trays, supports, seals to indicate the integrity of the container (i.e. that is has not been tampered with) after undergoing the sterilisation process and other accessories e.g. used for labelling purposes. Because of the manifold nature of the products used for this group – based on the respective task and requirements – the most diverse materials are employed but the majority of them are already known from other fields of medical technology or have been discussed in another section of this Script. Indeed, well-tried and tested materials are used since to a certain extent these products must withstand the same stresses (thermal, chemical), but also other demands (mechanical) during reprocessing and must also meet the pertinent hygiene requirements. One such example is the stainless steel used for trays, the silicone used for knob mats for gentle positioning of delicate instruments or the most diverse synthetic materials used for product-specific storage and for container lids as well as for seals and filters. Whereas in the past chromium-coated brass, stainless steel and plastics have been used for containers, today preference is given to aluminium as a basic material since it confers advantages such as lighter weight but, at the same time, better thermal storage and thermal conductivity. The general requirements governing containers can be consulted in Austrian standard ÖNORM EN 868 Part 8.

While these products are intended only to accommodate the sterile supplies till the time of use, the information outlined above on biocompatibility, release of toxic substances or chemical reactions also applies.

2.7 Implants

Implants are devices that are embedded into the human body, with a distinction being made between short- and long-term implants.

Short-term implants are e.g. catheters. These are made of natural caoutchouc such as rubber or latex or of synthetic materials e.g. silicone elastomer or silicone rubber. In general these devices are left in the body only for a few days. The material employed here appears to be suitable for this indwelling period, hence damage or changes that could adversely affect the device’s functions are rarely manifested.

Long-term implants such as e.g. joint implants are left in the human body for years, often until the end of a person’s life.

2.7.1 Requirements for implants

Implant materials must meet several requirements because of their role as outlined above:

- **Safety**
  - non-carcinogenic
  - non-toxic
  - antigen-free
- **Biological compatibility**
  - no foreign body reaction
  - incorporation into the metabolism of support structures
  - biological stability (absorption stop)
- **Mechanical compatibility**
  - adequate mechanical strength
  - electrochemical stability (corrosion resistance)
  - isoelastic relationship to support tissue
- **Functional capability**
  - aesthetically acceptable
  - amenability to cleaning (oral hygiene)
  - X-ray stability
- **Manipulations**
  - sterilisable
  - removable
  - processable

The safety of implants, i.e. they must neither contain toxic agents nor provoke toxic reactions (antigen-antibody reaction), is something that should be possible to assume. Of paramount importance is also biological compatibility, i.e. no foreign-body reactions. Mechanical strength, electrochemical stability, functional capability and easy manipulation are further characteristics that implants must have.

When selecting implant materials a balance must be struck between the compatibility of the material with the physiological tissue and the mechanical properties of the various systems.

In most cases good bioreactivity comes hand in hand with poor mechanical properties. This means that a compromise has always to be reached where

these properties are concerned. For example, glass ceramics which, while endowed with good biocompatiblity, have poor mechanical stability (brittle).

In general, when it comes to corrosion of implants one has to distinguish between two potential corrosion routes. On the one hand, body fluids attack the material, leading in the long term to failure or even breakage of the implant. On the other hand, the implant must be sterilised before being embedded in the body since the presence of any pathogens on the material must be ruled out. And only through sterilisation can this be assured. In view of the stringent demands, as outlined below, made on materials during steam sterilisation or other sterilisation processes the materials used in implants must also be able to withstand these without suffering any damage.

2.7.2 Implant materials

The most popular implant materials are as follows:

Metals, including stainless steel, alloys based on cobalt and titanium as well as titanium-based alloys, no doubt account for the majority of long-term implants currently used. Other metals such as tantalum, niob, precious metals as well as memory alloys are used in special cases.

Ceramic materials such as aluminium oxide, carbon, calcium-phosphate ceramics as well as glass ceramics are the implant group least susceptible to corrosion.

Polymer materials are used especially for short-term implants. Polyethylene, polymethyl methacrylate, polyurethane and nylon are typical examples of this group.

2.8 Standards

Standardisation denotes the planned activities and tasks undertaken to compile and implement regulations so that material objects and non-material processes will have a uniform character.

Standardisation is employed, in particular, when equivalent or similar objects are used in many different contexts, at different places and by different groups of people. By advocating uniform, standardised procedures and approaches, standardisation is aimed at preventing national and international technical barriers to use within interested groups and at

promoting the exchange of goods and services. Other benefits bestowed by standardisation are rationalisation, compatibility, suitability for use and safety of products and services.

By virtue of their origin, support structures, content and scope standards are vested with the character of recommendations whose observance and application is voluntary. While strictly speaking standards are not legally binding, they can become binding as a result of legal or administrative regulations or contracts stipulating their observance. Often they serve to clarify unclear legal terms such as "the state of the art" and thus acquire a legal significance.

The state of the art in technology = highest level of technical and economic development of a technique, device or operating procedure which, as the best available techniques, lend themselves to practical use.

Generally recognised rules of technology = technical level of a process that has been tested in practical application, whereby the majority of experts working in this area deem this process to be correct and advisable.

Characteristics of standards:

- Technical specifications
- Accessible to everyone
- Compiled in collaboration and with the consensus of all interested parties
- Based on agreed results from industrial, technical and legal settings and from everyday practice
- Aimed at achieving maximum benefits for the common good
- Are adopted by a recognised standardisation body for general and recurring application
- Compliance with them is not mandatory

Standardisation is beneficial because …

- compatibility of products and services are an essential precondition for exchange of goods
- removal of non-tariff barriers to trade at regional, national and international level is a precondition for promoting and intensifying exchange of goods

- standardised communication and information patterns promote understanding, in particular in multilingual settings
- a systematic approach is the basis for rationalisation and is thus indispensable for the viability of enterprises now and in the future
- institutionalised quality assurance of products, persons and services is a prerequisite for assuring equal opportunities worldwide, thus facilitating entry to markets

3 Material alterations

Material alterations can have several causes. The first indication of these are an altered surface, since the change-inducing agent launches its attack here.

The alterations outlined in sections 3.1 and 3.2 are due to ion deposits. These ions may be carried with the cleaning water or the sterilisation steam. However, these changes are only surface deposits, hence after sterilisation the respective devices will meet the customary hygiene requirements.

If these residues or organic deposits (as described in section 3.3) cannot be removed from the instruments, severe damage can be inflicted on the underlying material due to the concentration and effects of different media (heat, moisture. This is elaborated on in detail in Chapter 4 Corrosion.

3.1 Water marks

Water marks can occur on surfaces because of the high concentrations of ions in the cleaning water. Water marks are caused by evaporation of water droplets on the surface. The ions dissolved in the water are unable to evaporate and thus can be seen as a residue. The higher the concentrations of ions in the water, the sooner such marks can be observed.

A characteristic feature of water marks is their sharp margins. Fig. 3 shows typical water marks on medical instruments.

These marks can be normally removed with an acidic detergent. It is important to rinse instruments after cleaning with demineralised water so that there is no trace of the detergent solutions remaining anywhere.

If instruments harbouring water marks are sterilised with moist heat, this can give rise to annealing, i.e. a reaction between the ions and the

underlying material. If such processes continue to be repeated, the instrument surfaces will be irreversibly altered.

To prevent occurrence of water marks, the instruments must be rinsed with demineralised water after cleaning them thoroughly.

Fig. 3: Water marks

3.2 Annealing colours

Unlike water marks that can appear on any cleaned instrument after drying, annealing colours manifest on metallic surfaces only after heat treatment. Typically, this form of heat treatment is moist heat sterilisation.

And as opposed to water marks, annealing colours do not have well-delineated margins. They often appear on medical instruments that have been in use over a long period of time. These colour deposits are caused by ion residues from either heavy metals (e.g. from the cleaning water) or silicate deposits (e.g. from the cleaning solution). In Fig. 4 and Fig. 5 are illustrated such characteristically discoloured instruments.

A conspicuous finding is the presence of a high phosphor and silicium content on the surfaces, in addition to other ions such as sodium, potassium and chloride.

If demineralised water is not used for the final rinse there may be a build-up of residues on the surface (similar to the aforementioned water marks). Ions can also be introduced into the steriliser in sterilisation drapes (cotton

towels), (poor) steam quality or via components of the steriliser itself (e.g. door seals, etc.).

If such an instrument is then sterilised, the ions will be annealed ('burnt') on the surface. In such cases of annealing, the ions react with the underlying material, giving rise to the characteristic bluish brown or rainbow surface discolorations.

Fig. 4: Annealing colours due to silicates

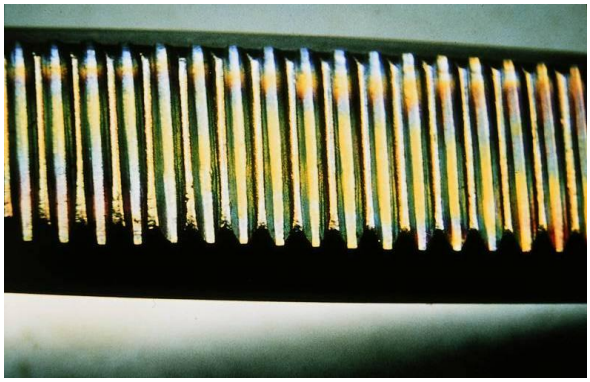


Fig. 5: Rainbow coloured surface alterations due to silicates

These discolorations can be eliminated by cleaning the surface with an acidic detergent, while ensuring that demineralised water is used for the final rinse to prevent the acidic detergent from damaging the underlying material.

While such surface alterations do not pose any major risk to the material, they restrict the scope of visual inspection for cleanliness. Furthermore, there is a risk that damage to the surface will not be detected early on so that the material could be irreversibly damaged e.g. due to corrosion.

Causes: Entrainment of silicone-based detergents in the final rinse because of inadequate intermediate rinsing

Elimination: Basic detergent or mechanical removal – depending on the nature and deposit load

Prevention: Optimise intermediate rinsing (either prolong or use more intermediate rinsing steps), switch to a different detergent (use low-silicate detergent)

Risks: Purely cosmetic effects. Do not pose any risk to patient

3.3 Discoloration due to organic deposits

Protein surgical residues on medical devices can also lead to discolorations. It is possible that incrusted soils (soils harbouring dried residues) are not fully removed during the cleaning process. This can happen e.g. if the surgical instruments have an especially high contamination load and too little detergent was used for such a high level of contamination, or as a result of fixation of protein residues due to too high a precleaning temperature or because cleaning was initiated only after a very long time (soils have been allowed to dry). The subsequent sterilisation process at high temperatures will cause 'caking' (burning) of the residues, giving rise to the formation of dark sites on the surfaces.

Normally these marks can be removed when first noticed by cleaning with an acidic detergent. Here, too, demineralised water must be used to prevent the detergent from inflicting damage on the underlying material. If these marks are not noticed on time, for example if they are hidden beneath labelling tape, the underlying material risks being damaged by corrosion.

Fig. 6: Deposits detected after removal of labelling tape

Fig. 7: Inadequately removed organic deposits

Causes: Surgical residues, water trapped beneath labelling tape, drying, disinfectant-mediated fixation (aldehydes, alcohol), too high a precleaning temperature in WD (> 45° C), poor cleaning performance due to insufficient opening e.g. closed joints / - precleaning / rinse mechanical action / cleaning cycle too short, too much foam formation, spray shadowing, overloading of trays

Elimination: Intense cleaning with brush, if necessary, ultrasonic cleaning backed up by hydrogen peroxide (automated, OxiVario)

Prevention: Avoid use of coding tape, clean instruments as quickly as possible after use, eliminate any effects leading to fixation

Risks: Infection risk, eventually leading to a risk of breakage due to pitting and stress corrosion cracking

3.4 Embrittlement / bleaching

Alterations in synthetic materials caused by embrittlement / stress cracking occur due to use of chemicals, e.g. rinse aids or because of other effects such as UV exposure, pressure or high temperatures and moist heat as arising during the sterilisation process. Oxidising agents can lead to bleaching of synthetic materials, something that is generally accompanied by an increase in surface roughness. The suitability of the chemicals employed must be checked before use and the instructions issued by the manufacturer of the chemical substance carefully observed.

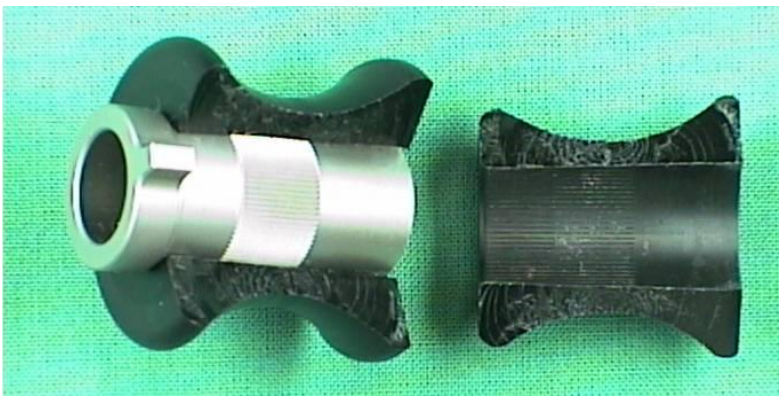


Fig. 8: Material breakage due to cracking / embrittlement

Fig 9: Embrittlement, bleaching

Causes: Surfactants in process chemicals, accentuated in combination with material stress (shrinkage fit, as in Fig. 8) or following use of the oxidising agent H_2O_2 (mainly accompanied by bleaching and increase in surface roughness as in Fig. 9)

Removal: Not possible

Prevention: Avoid using process chemicals containing surfactants (rinse aids) to reprocess synthetic devices, before drying use demineralised water to rinse off all surfactant residues, do not use any special cleaning programmes with addition of an oxidising agent to reinforce the cleaning performance

Risks: Hazard to patient because of potential risk of breakage during use if the fault is not detected in the course of visual inspection or functional testing. If embrittlement is confined to the surface (depending on the material), surface roughness will increase → hygiene problem!

3.5 Other discolorations

3.5.1 Discoloration due to detergent residues

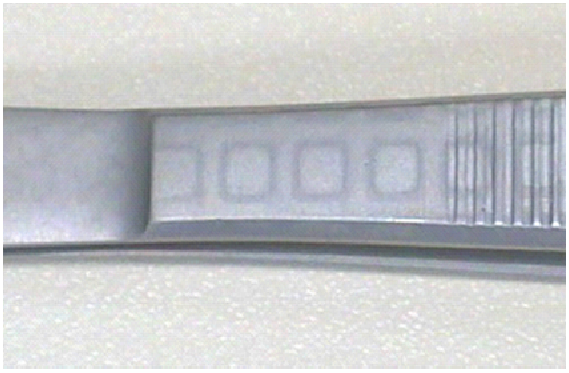


Fig. 10: Discoloration due to detergent residues

Cause: Process chemicals not properly removed in intermediate or final rinse in WD, possibly spray shadowing

Elimination: Can generally be removed by washing repeatedly while using a neutralising agent or acidic rinse aid (note manufacturer's instructions!)

Prevention: Thorough intermediate / final rinse with demineralised water, avoid any spray shadowing

Risks: Hazard to patient due to potential risk of corrosion from alkaline residues on ophthalmologic instruments

3.5.2 Discoloration due to acidic chemicals – basic detergent

Fig. 11: Discoloration due to acidic chemicals – basic detergent

Cause: Inappropriate use of basic detergents

Elimination: Only mechanically, but absolutely necessary because of corrosion risk

Prevention: If necessary, optimise dosage for basic cleaning and in WD. If necessary, switch to citric acid neutralising agent

Risks: Sort out any instruments implicated immediately because of risk of damage from secondary corrosion. Crush any jointed instruments because of risk of stress corrosion cracking.

3.5.3 Discoloration due to acidic chemicals – neutralising agent

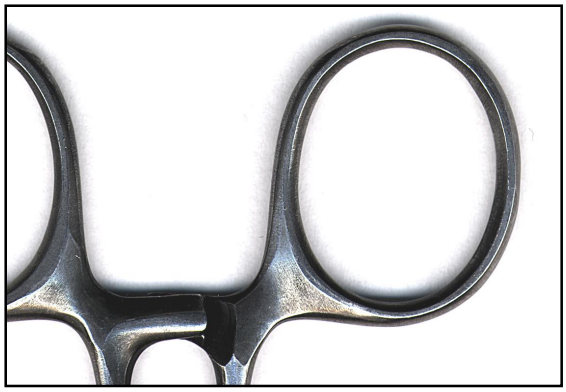


Fig. 12: Discoloration due to acidic chemicals - neutralising agent

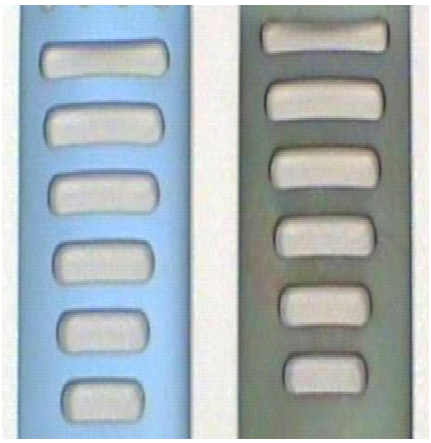
Cause: Overdosage of phosphor acid neutralising agents and / or inadequate rinsing after neutralisation

Elimination: Only mechanically, perfect corrosion protection

Prevention: Optimise dosage, if necessary, switch to citric acid neutralising agent

Risks: Purely cosmetic effect. No risk to patient or instruments, but does impede visual inspection

3.5.4 Discoloration due to oxidising agents



before after

Fig. 13: Discoloration due to oxidising agents

before after

Fig. 14: Discoloration due to oxidising agents

Cause: Process chemicals used, reinforced effect if oxidising agents used additionally

Elimination: Chemically, mechanically by manufacturer

Prevention: No special cleaning programmes with addition of an oxidising agent

Risks: Loss of coding function which have may safety implications, e. g. in aneurysm clips otherwise purely cosmetic effect

3.5.5 Discoloration due to hydrogen peroxide

This surface alternations are seen in the case of black titanium aluminium nitride (TiAlN) and titanium aluminium carbon nitride (TiAlCN) layers as well as instruments and components originally coated with yellow gold zirconium nitride (ZrN) or titanium nitride (TiN).

Fig. 15: TiAlN coating: discoloured

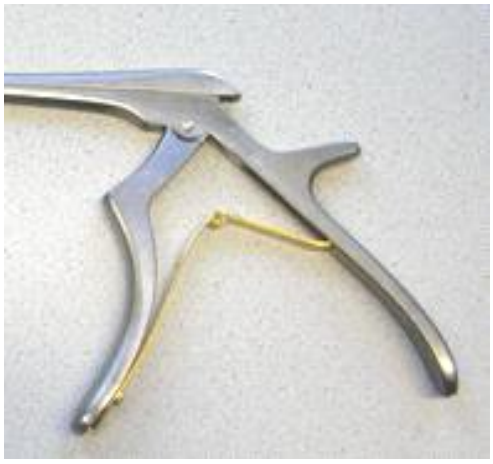


Fig. 16: TaAlN layer: completely bleached

Cause: Special cleaning process: surface reaction with cleaning solutions to which hydrogen peroxide has been added and / or highly alkaline cleaning solutions with a pH value > 10 at temperatures of 80 - 90° C

Elimination: Repair / new coating

Prevention: Use neutral / mildly alkaline detergents; for alkaline detergents do not exceed temperature of 60° C

Risks: Loss of original use properties related to low glare and wear, needs more care, otherwise scuffing tendency and risk of fretting corrosion

4 Corrosion

In the cases described so far, thin layers of coloured oxide films can be formed on the instruments. In general, it is possible to remove these deposits once again, but if they react with the underlying material, as can happen due to high temperatures during sterilisation, the underlying material can be severely damaged. This state is known as corrosion.

Hence corrosion involves destruction of metals, originating on the surface. This destruction may involve chemical, but in many cases also, electrochemical reactions.

Depending on the nature of the damage, several different types of corrosion can be distinguished. An overview of the principle forms is given in Fig. 17.

Damage to the surface, as well as to the underlying material, can be inflicted during use.

The volume spectrum of action, which inter alia includes embrittlement, ductile fractures, etc. will not be addressed here.

The surface of a device / component can be damaged mechanically or due to corrosion.

Mechanical damage is generally manifested in the form of wear or erosion. By choosing suitable materials (e.g. harder steel varieties) this type of failure can be minimised.

Chemical corrosion occurs in particular at high temperatures, hence it tends to be rarely seen in the medical setting.

But things are different when it comes to electrochemical damage. This type of corrosion is the commonest cause of damage seen in the medical domain, both in the presence or absence of mechanical stress.

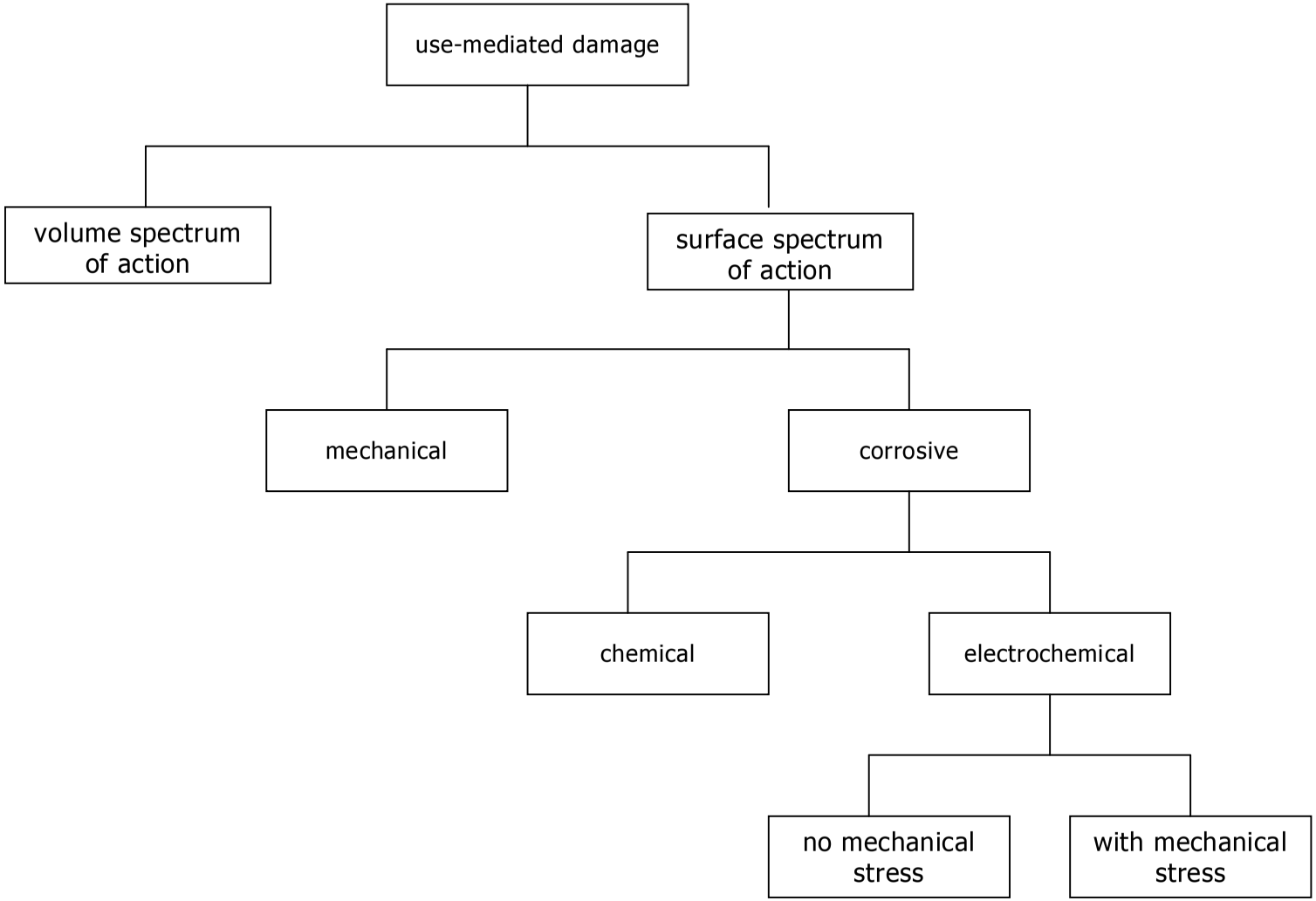


Fig. 17: Overview of different types of corrosion

The major implications of corrosion are not confined exclusively to loss of the metal since often even relatively minor loss of material results in massive damage to the instrument. Despite the manifold nature of corrosion manifestations the cause of corrosion is the same in all cases.

Hence the physical underlying causes of corrosion shall be briefly discussed here.

4.1 Fundamentals

Most metals do not occur in pure form in nature but rather in the form of compounds. These compounds represent the lowest energy state and are thus most stable. By means of technical processes that require a high energy input, metals of a pure form are produced from these compounds. Hence the metals exist in a strained condition which they try to abandon by reacting with their environment.

Essentially, metals revert to their original state in two steps:

The first step entails bonding of the metal with oxygen from the air, giving rise to metal oxides. However, in compact materials this oxidation is confined to the formation of a thin oxide film, possibly comprising only a few atom layers. The less precious a metal, the easier it will be for a metal oxide to form and the stronger the latter will be. But the use of top layers or coatings means that metals will exhibit a more favourable behaviour (→ Chapter 4.1.4 Passivation), hence metals can be used in this way for technical purposes.

The second step constitutes the basic process unfolding in most cases of corrosion, whereby in the presence of water metals form local elements.

4.1.1 Local element formation

The basic process underlying corrosion manifestations involves in most cases formation of a local element. A local element, also known as galvanic element, is formed when metals and water come together. In this galvanic element the metal is dissolved (anodic process) and water components released (cathodic process). Fig. 18 shows a schematic overview of such a local element.

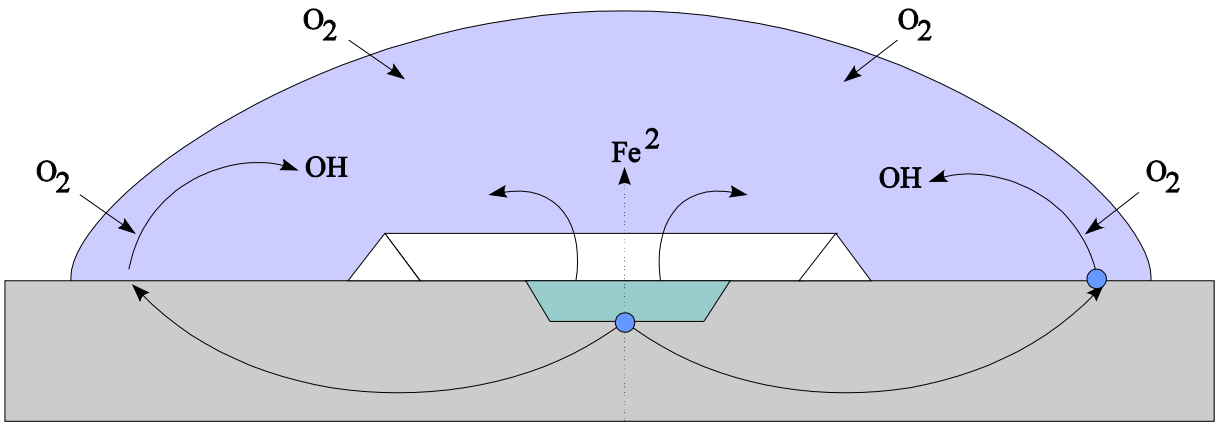


Fig. 18: Local element formation

In practice what happens differs from this simple local element process in that the hydrogen does not escape but is oxidised by an oxidising agent (mainly oxygen from the air). This process is also known as depolarisation.

But since oxygen has at the same time the tendency to coat the metal surface with a protective oxide layer, in such a case the same substance can exert a corrosive or anticorrosive effect.

Fig. 18 shows such an instance of local element corrosion with oxygen depolarisation, illustrating corrosion of iron due to water drops. The zone situated at the outer margin of the drop is transformed into an oxide film due to the good oxygen supply and is now protected against damage and functions as a local element cathode. In the middle of the drop, where oxygen supply is lowest, iron is anodically dissolved. The electrons released through the formation of iron ions can either discharge hydrogen ions on the noble cathodic oxide film or form water-hydroxde ions (OH^- ions) from oxygen. Between the anode and cathode space a ring of rust has formed because here the anodically formed iron salt has been precipitated by the cathodically formed OH^-ions as a brown iron oxide or iron hydroxide. The end product of the reaction between oxygen and water consists more or less of water-based oxides or hydroxides (rust).

4.1.2 Hydrogen corrosion

The dissolution of iron is associated with electron transport. Electron transport gives rise to the electrical potential which is characteristic of every metal. If this potential is measured for different metals against a

standard electrode, the value obtained is known as the standard potential of the respective metal. (In practice, this potential is measured against standard hydrogen electrode).

Tab. 1 shows the electrochemical series for selected materials.

	Metal		**E_0 (Volt)**
Al	Aluminium	Al/Al^{3+}	-1.69
Mn	Manganese	Mn/Mn^{2+}	-1.10
Zn	Zinc	Zn/Zn^{2+}	-0.76
Cr	Chromium	Cr/Cr^{2+}	-0.51
Fe	Iron	Fe/Fe^{2+}	-0.44
Co	Cobalt	Co/Co^{2+}	-0.29
Ni	Nickel	Ni/Ni^{2+}	-0.25
Sn	Tin	Sn/Sn^{2+}	-0.16
Pb	Lead	Pb/Pb^{2+}	-0.13
H_2	**Hydrogen**	**H_2/H_30^+**	**-0.00**
Cu	Copper	Cu/Cu^{2+}	+0.35
Ag	Silver	Ag/Ag^{+}	+0.81
Hg	Mercury	Hg/Hg^{2+}	+0.86
Au	Gold	Au/Au^{2+}	+1.38
Pt	Platinum	Pt/Pt^{2+}	+1.60

Tab. 1: Electrochemical series

Metals are listed in the electrochemical series table in the order of their potential. Metals with a negative standard potential are designated as non-precious (non-precious), while those with a positive sign are known as precious (noble) metals.

Based on the electrochemical series of metals and the effect of oxygen from the air, the following corrosion profiles can be roughly predicted for the various metals:

Metals that are less precious than hydrogen (e.g. aluminium, manganese, zinc, iron, etc.) endeavour to dissolve in acids by means of hydrogen evolution.

In the absence of oxygen metal attack thus occurs only if direct hydrogen evolution is possible. This behaviour is known as hydrogen corrosion.

This leads, e.g. in the case of iron, to metal dissolution as from a pH value < 4.

In reality, in addition to the electrochemical series, one must also take account of the overvoltage for hydrogen evolution. This involves inhibition of hydrogen evolution (e.g. because of impeded discharge of hydrogen ions).

This form of corrosion needs the presence of a chemically strong attack agent.

4.1.3 Oxygen corrosion

Hydrogen corrosion described above occurs only rarely in practice since it presupposes the complete absence of air in the attack solution.

The corrosion process illustrated in Fig. 18 for a water drop on iron (local element) shows how oxygen corrosion occurs. In all cases it involves the flow of local currents between the noble oxide film and the non-precious underlying material.

The difference between this and hydrogen corrosion resides in the fact that, under the conditions prevailing in oxygen corrosion, hydrogen cannot evolve in gaseous form since the attack solution is not sufficiently acidic and the corroding metal is not sufficiently non-precious. This applies to corrosion of the most important metals used, e.g. iron, zinc and lead in neutral, low acidic and low alkaline solutions, i.e. corrosion in contact with natural types of water (sea water, industrial water, river water, rain water).

The main forms of corrosion encountered in practice are thus of the oxygen corrosion type. The principle characteristic underlying this is that the amount of metal destroyed is determined by the amount of oxygen reaching the surface of the metal. This means that unlike hydrogen corrosion it is not primarily the composition of the metal that is decisive but the composition of the attack agent. Here the material composition of the corroding metal plays only a minor, if indeed any, role.

Hence oxygen corrosion entails a reduction process which unfolds in areas on the corroding metal surface composed of oxide films.

4.1.4 Passivation

The corrosion reactions described hitherto call for an active, i.e. largely polished metal surface. As already mentioned, metals exist in a strained condition from which they try to escape by forming compounds. This thus gives rise to formation of surface oxide layers that also have a protective character. As the thickness of the layer increases, so the porosity declines and the protective effect increases. Porous layers do not confer any protection.

In addition to the macroscopic protective film, there are a number of metals that form an optical invisible oxide film. Formation of such an oxide film is known as metal passivation. Passivation, which can be tracked electrochemicallly, bestows better stability on most metals.

Passivation can be artificially expedited or generated. In the case of aluminium this can be achieved e.g. through anodic (electrolytic oxidation of aluminium = eloxal) or chemical oxidation. In chromium steel the formation of this oxide layer can be promoted through chemical passivation, e.g. treatment with citric, nitric or phosphor acid.

Conscientious manufacturers effect such passivation at the end of the production process, but the passivation layer in a new medical device is very thin. This continues to increase the longer the instrument is used and is based, first, on an ongoing = oxygen bonding and, second, on the neutralising agents employed in the cleaning process. Since their passive layer is still very thin, new instruments are inherently more susceptible to surface changes and to corrosion because of mechanical and chemical influences.

4.2 Manifestations of electrolytic corrosion

The types of corrosion most commonly encountered in the medical setting are briefly discussed below, while giving an example in each case.

4.2.1 Surface corrosion

Surface corrosion is the corrosion form that is easiest to control. It occurs as even or uneven surface corrosion.

In the even form of surface corrosion there is homogeneous erosion across the entire surface of the material.

The term uneven surface corrosion, or crevice corrosion, is used to denote the situation where erosion varies from one site to another. This is caused by the presence of several corrosive elements.

A common feature of both types is that the surface expansion of these regions is mainly greater than the depth of erosion. Fig. 19 shows a schematic diagram of surface corrosion.

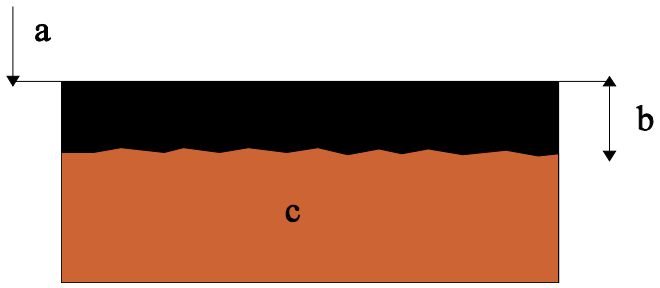


Fig. 19: Surface corrosion

In this figure "c" denotes the underlying material. From the original height "a" section "b" has been eroded through corrosion in the course of time.

Surface corrosion occurs in the medical setting if the passive layer is destroyed or if non-coated steel is used, which as illustrated in Fig. 20 does not lend itself to reprocessing. This form of destruction can be attributed to the effects of heavy metals or to highly acidic or alkaline agents. Fig. 21 depicts an instrument corroded by an excessively concentrated detergent solution.

Fig. 20: Surface corrosion of surgical blades

Fig. 21: Surface corrosion due to detergent

Cause: Chemical, e.g. acidic or alkaline agents, in carbon steels (e.g. disposable surgical blades), anodised aluminium, too high a pH value of cleaning solution because of alkaline detergent and / or use of softened water for thermal disinfection

Elimination: Generally not possible, a "self-healing effect" unfolds on aluminium surfaces if damage is slight; possibly use eloxal cleaner

Prevention: Use chemical substances suited to aluminium as well as demineralised water for the final rinse, see also EN 17664

Risks: Functional problems in bonding elements, potential hygiene problems because of cavities; remove affected instruments since intact instruments risk damage from secondary corrosion

4.2.2 Pitting corrosion

Pitting corrosion is the most common form of corrosion encountered in the case of medical devices. Pitting corrosion entails formation of crater-like recesses undercutting the surface. A typical feature is the absence of erosion outside those sites affected by pitting corrosion. Normally the depth of the area affected by pitting corrosion is generally equal to or greater than its diameter.

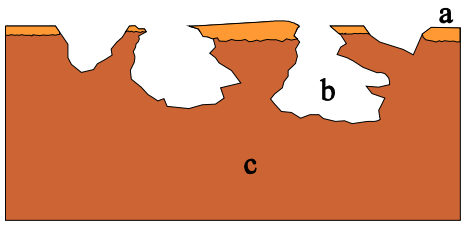


Fig. 22: Pitting corrosion

The figure above depicts the various manifestations, whereby "c" denotes the underlying material and "a" the coating. Prolonged exposure time will result in erosion of “b” areas.

Pitting corrosion of a chisel caused by chloride ions:

Fig. 23: Macroscopic general image

Fig. 24: Microscopic detailed view, with 20-fold magnification

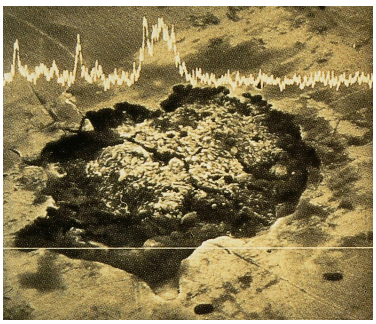


Fig. 25: Electron microscope image of a corrosion pit using 2,000-fold magnification and showing integrated chloride measuring curve

Pitting corrosion can only occur if there is an anticorrosion protective layer = passive layer on the material surface. Damage to this protective layer leads to formation of an electrochemical local element via which erosion then occurs. Destruction of this protective layer normally involves a reaction taking place after contact with various chemicals, as a consequence of mechanical influences inflicting damage on the passive layer. In principle, both attack parameters and material-related parameters play a role in pitting corrosion. The attack parameters include e.g. the medium (agent), ion concentration and temperature. Of importance here is chloride which, even in low concentrations, can lead to pitting corrosion. Moreover, pitting corrosion is reinforced at high temperatures (e.g. in a steam steriliser).

The chief material parameters are structural homogeneity, alloy elements as well as surface composition. Rolling faces, i.e. surfaces running parallel

to the deforming direction are less susceptible to pitting corrosion than are vertically arranged faces. Pitting corrosion is also promoted by contaminants in the structure as well as by a rough surface, since the formation of ridges affects the erosion rate. As regards the influences exerted by alloy elements, it has been noted that a high chromium and molybdenum content in the steel increases the material's resistance to pitting corrosion.

Table 2 gives a summary of the pitting corrosion parameters for austenitic chromium nickel steels.

Promotes pitting corrosion	**Inhibits pitting corrosion**
material parameters	
rough surface	polished surface
non-homogeneous structure	homogeneous structure
attack agent parameters	
high chlorine ion concentration	low chlorine ion concentration
high temperature	low temperature
low pH value	high pH value
resting attack agent	high flow velocities
Alloy-related measures	
low chromium content	high chromium content
low molybdenum content	high molybdenum content

Tab. 2: Parameters of pitting corrosion of austenitic chromium-nickel steels

However, pitting corrosion is not confined exclusively to stainless steel. This group also includes other metals used in a passivated state, such as aluminium and its alloys, as well as non-alloys that are amenable to passivation and titanium.

Causes: e.g. prolonged contact with surgical residues, tinctures, drugs, saline solution, water constituents, detergents/

disinfectants, regeneration salt, laundry, packing towels / packaging material

Elimination: If necessary, this can be done only mechanically

Prevention: Wipe off highly "contaminated" instruments only with a compress impregnated in sterile water, connect demineralisation cartridge properly and rinse thoroughly with pure water after the regeneration process

Risks: Patient at risk because of inadequate hygiene and risk of instrument breakage

4.2.3 Stress corrosion cracking

In general stress corrosion cracking occurs only on rust-free instrument steel. Several criteria must be met before occurrence of stress corrosion cracking, which makes an instrument unsuitable for further use: apart from any material stress (example caused by riveting the instrument), force (tensile stress, inherent stress) must be applied to the instrument and an attack agent must be present. Instruments with ratchets that are sterilised in a closed state are subjected to stress because of the physical phenomena unfolding during the sterilisation process. The attack agent is the chlorides found in various agents and thus exerting an effect on the instrument.

Possible attack agents:

- physiological saline solution
- blood, saliva, sweat
- drugs containing chlorides
- chlorides in the water or steriliser steam
- entrained regeneration salt
- inappropriately used treatment agents
- residues in textile towels, laundry or packaging materials

This type of corrosion can be recognised from the, often very rapid, appearance of cracks, and always at the site of maximum stress. If the surface is damaged and subjected to stress, a crack can develop in the underlying material. Fig. 26 shows a schematic diagram.

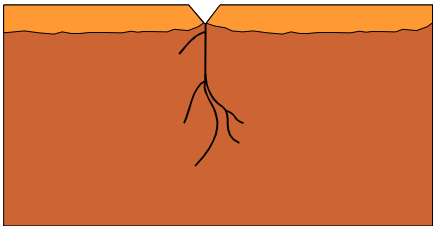


Fig. 26: Stress corrosion cracking

Fig. 27: Stress corrosion cracking of a scissors and forceps

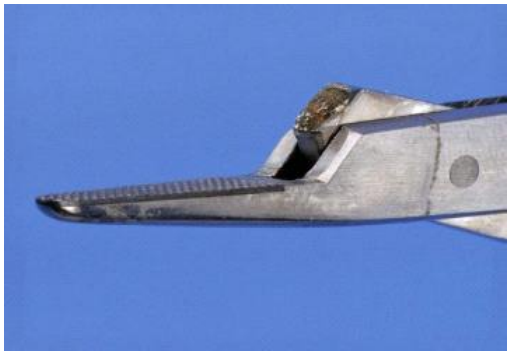


Fig. 28: Stress corrosion cracking of a needle holder

Cause: The use of water with high Cl load in WD. Critical as from 120 mg/l. Occurs only in temperable chromium steel with concomitant exposure to temperatures > 60° C and high material stress e.g. closed ratchet and a corrosive agent

Elimination: Not possible

Prevention: Reduce chloride load, if necessary, optimise cleaning, if necessary, mix water with demineralised water, thermal disinfection with demineralised water, sterilise instruments with the ratchet open or ensure standard instruments are engaged by at most the 1st notch

Risks: Patient at risk because of inadequate hygiene and risk of instrument breakage, crush instruments affected

4.2.4 Gap corrosion

Gap corrosion is understood to mean occurrence of a higher rate of corrosion in gaps. The oxygen supply inside a gap is insufficient, resulting in turn in the electrolyte being deprived of oxygen. This can lead to the passive layer of the material "breaking open". Chemical reactions take place because of the local element now formed, leading in turn to more attacks. The situation is further compounded by chemical reactions and the attack progresses ever more rapidly.

Gap corrosion is a function of gap geometry, whereby gap widths of less than 1 mm are deemed to be particularly critical. These areas are generally poorly accessible, hence residues from the cleaning water or soil residues can build up here. These then function as an agent and lead to damage of the surfaces.

The following figure shows a schematic diagram of gap corrosion. The dark area has been already eroded by corrosion, but the surface coating remains intact.

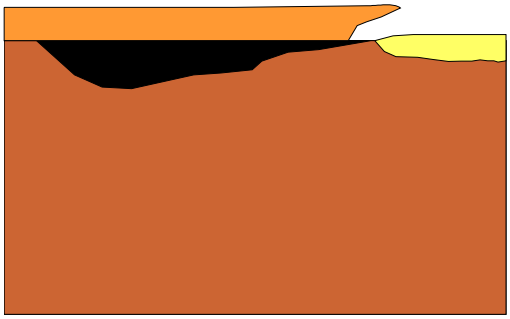


Fig. 29: Gap corrosion

Fig. 30: Gap corrosion of forceps

Causes: Residual moisture and unfavourable dimensional ratio of gap width to gap surface area

Elimination: Chemically with low-dose basic detergent, citric acid neutralisation (passivation effect), mechanically

Prevention: Improve drying conditions in WD, lubricate jointed gaps or other metallic sliding surfaces before sterilisation

Risks: Sort out any instruments implicated immediately because of risk of damage from secondary corrosion.

4.2.5 Fretting corrosion

Metallic abrasion occurs when mobile instruments components that rub against each other are not, or not properly, lubricated. This damages the passive layer, giving rise to corrosion.

Fig. 31: Fretting corrosion of inner surfaces of scissors

Regular lubrication with instrument oil, which must meet the following criteria, helps here:

- it must not adversely affect the sterilisation performance, i.e. it must be permeable to steam
- it must be physiologically safe
- no negative effect on patients or personnel
- silicone free
- based on paraffin oil

It must be free of silicone because silicone

- is not broken down in the human organism
- is not fully removed during reprocessing
- silicone deposits have adverse effect on functional capabilities and sterilisation

Devices are treated with instrument oil after cleaning and before sterilisation. Functional testing must only be performed after lubrication as otherwise the friction would lead to roughening of the surface and in turn to fretting corrosion. If instruments are not, or not properly, lubricated, their surfaces will be continuously and irreversibly damaged by the roughness.

Causes: Inadequate lubrication of metallic sliding surfaces, the use of a care agent in the WD is no substitute for lubrication!

Elimination: Chemically with low dose basic detergent, citric acid neutralisation / rinse aid (passivation effect) or mechanically

Remedy: Regular lubrication with oil that is compatible with steam sterilisation (paraffin oil)

Risks: Sort out any instruments implicated immediately because of risk of damage from secondary corrosion.

4.2.6 Contact corrosion

Contact corrosion occurs when metals that are composed of different materials come into contact with each other. Exposure to a moist medium will give rise to formation of a local element (→ Chapter 4.1.1) and in turn to dissolution of the non-noble component. Particularly pronounced contact corrosion occurs when stainless steel instruments come into contact with instruments whose surface layer is damaged and whose underlying layer is not made of uncoated steel. Examples of this include chromium-coated instrument steel whose chromium or nickel layer is damaged. Fig. 32 illustrates contact corrosion.

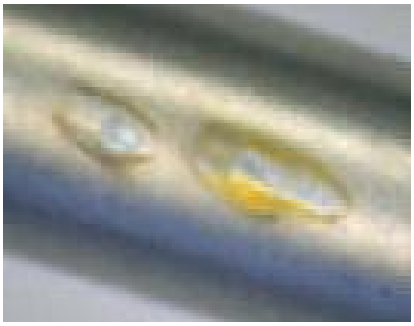


Fig. 32: Contact corrosion

Causes: Typically due to various precious materials (brass with detached Cr layer / NR steel) or in NR steel / NR steel due to micro-friction

Removal: Chemically with low dose basic detergent, citric acid neutralisation / rinse aid (passivation effect) or mechanically

Elimination: Replace old instruments, rule out vibration and micro-friction in WD, reprocess separately

Risks: Sort out any instruments implicated immediately because of risk of damage from secondary corrosion

4.2.7 Extraneous rust

Non-rust-resistant supply pipes, or also pipes, can give rise to release of rust particles, which are then distributed via a specific medium (water, steam, etc.). Signs of extraneous rust include e.g. deposits on the steriliser chamber, sterile packaging or container filters. If not fully removed, this extraneous rust can result in secondary rust.

Fig. 33: Corroded sterilisation chamber as trigger of extraneous rust

Causes: Material chosen ("Black systems" – cast iron) - steam supply system that is more susceptible to corrosion

Elimination: Not possible for devices made of normal steel. For NR steel instruments through use of low dose basic detergent or mechanically

Remedy: Replace critical components with NR steel, make sure steam is supplied at constant rate, add corrosion inhibitors that pose no hygiene risk to the steam mixture

Risks: Sort out any instruments implicated immediately because of risk of damage from secondary corrosion

4.2.8 Rust film, secondary rust

Deposits known as a rust film are spread by devices that are already corroded. For example, if corroded medical devices are not completely withdrawn from circulation, they will give rise to increased corrosion of the instrument concerned and, on the other hand, the rust can be spread to other instruments during various cleaning or sterilisation cycles, giving rise to secondary rust.

Fig. 34: Corrosion signs on saw blade – trigger of rust film

Causes: e.g. due to reprocessing of single-use devices made of normal steel, damaged galvanic coatings in instruments made of normal steel. Highly corroded NR steel instruments (e.g. due to widespread damage from pitting corrosion)

Elimination: Depending on intensity, possibly chemically with low dose basic detergent, citric acid neutralisation / rinse aid (passivation effect) or mechanically

Prevention: Sort out any normal steel instruments whose coating is damaged: VISUAL INSPECTION!

Risks: Sort out any instruments implicated immediately because of risk of damage from secondary corrosion

4.3 Corrosion protection

The best way to protect against corrosion is to, in the first place, use appropriate materials. This may mean having to use expensive and, in a mechanical sense, not satisfactory materials in cases where the materials are exposed to high levels of stress because of corrosive media.

As already stated, there is no such thing as an optimal material for use in the medical setting. Therefore one has to always make compromises when it comes to choosing suitable materials.

One way to protect materials against corrosion is to coat them. These coatings together with the underlying material create what is known as a composite system. The main function of such a system is discharged by an inexpensive underlying material endowed with good mechanical properties, while corrosion protection is assured by the coating, which is often present as a very thin layer.

To render coatings suitable for use in the medical setting several chemical as well as physical requirements must be met.

In the case of metallic coatings one must ensure that the metal coating will as far as possible have the same potential as the underlying material. A large difference in potential promotes formation of local elements and, in turn, onset of corrosion.

Before applying a coating, the surface of the underlying material must be smooth and free of sink holes, cracks, enclosures, etc. This means that there must only be minimal roughness depth and that can be accomplished through smooth filing and polishing. It must also be borne in mind that instruments to which a coating has already been applied cannot be worked on again. Therefore coatings must always be applied as the last step of the manufacturing process.

The coatings themselves must be

- impervious
- endowed with good adhesive strength
- even
- and possess good mechanical properties.

The imperviousness of a coating is understood to mean its porosity. Every coating will have pores derived from the manufacturing process. In general the thicker a coating, the lower its porosity. Hence the aim is to achieve an optimal thickness that will ensure that the coating is impervious. From the above one can easily conclude that corrosion always starts from the pores of a coating.

The strength of a coating is especially important. Obviously a coating with a poor adhesion profile will result in more corrosion. Poor adhesion can be caused by, inter alia, inadequately cleaned underlying materials that still harbour soils or manufacturing residues from metal-cutting processes such as polishing. The choice of underlying material is also of paramount importance.

The third requirement to be met by a coating is its evenness. An attack will always start at the thinnest site of a coating, i.e. at its weakest link.

When choosing the type of coating to be used the mechanical properties such as hardness, tensile strength, etc. also play a role since they are the chief determinants of the intended use.

5 Investigation methodology

If discolorations, alterations or corrosion are detected on the surfaces of medical devices, equipment or systems, the reasons for these must be investigated to ensure that such problems will not be spread to other devices or equipment.

As a first step it is advisable to check whether the respective manifestation is a deposit or represents an attack on the underlying material. In general, deposits can be removed using any basic agent, whereas corrosion can be eliminated only by mechanically processing the surface. Initial inspection with optical magnifying devices e.g. magnifying glass or light microscope will, provide insights into the composition of the surface change.

If there is a visible deposit, its composition must always be analysed. Since deposits are very thin layers it is advisable to examine these with a scanning electron microscope to which an energy dispersive analysis system has been connected. From the chemical composition of such traces, one can generally get an idea about their origin.

If these "marks" are widespread it is advisable to check the water quality used for moist heat sterilisation since there is reason to believe that these surface alternations are caused by the entrainment of ions from that source. If the tests reveal that the requisite purity level is not assured one must investigate how ion entrainment occurred. Because of the complex and manifold nature of ion entrainment into the system, often it is only by engaging the services of a professional test institute that this matter can be clarified.

One possible cause is inadequate water treatment. Several types of systems are used for water treatment (complete demineralisation using ion exchangers, reverse osmosis systems, etc.). The "contamination" could be due to a fault.

The standard EN 285 stipulates the maximum permissible concentrations of certain ions. Table 3 shows an excerpt from that standard.

Parameters	**Condensate**	**Feedwater**
Evaporation residues	≤ 1.0 mg/kg	≤ 10 mg/l
Silicium, SiO_2	≤ 0.1 mg/kg	≤ 1 mg/l
Iron	≤ 0.1 mg/kg	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/kg	≤ 0.005 mg/l
Lead	≤ 0.05 mg/kg	≤ 0.05 mg/l
Heavy metals apart from iron, cadmium, lead	≤ 0.1 mg/kg	≤ 0.1 mg/l
Chlorides	≤ 0.1 mg/kg	≤ 2 mg/l
Phosphates	≤ 0.1 mg/kg	≤ 0.5 mg/l
Conductivity at 20° C	≤ 3 µS/cm	≤ 5 µS/cm
pH value	5 to 8	5 to 8
Colour	colourless, clear, no residues	colourless, clear, no residues
Hardness	≤ 0.02 mmol/l	≤ 0.02 mmol/l

Tab. 3: Excerpt from standard EN 285

Another possibility is entrained detergent residues, possibly because of inadequately rinsed medical devices. These are commonly seen in utensils with dead volumes. One must ensure that such vessels are completely empty before sterilisation.

Entrainment (e.g. of detergents) from cotton towels used to wrap surgical instruments for sterilisation represents a further source of contamination.

6 Changes in properties

In the course of use and because of the influences exerted in the medical device circuit such as temperature, pressure, mechanical action and chemical substances – individually or cumulatively – changes occur in the properties of the various materials. While the alterations summarised in Chapter 3 generally do not give rise to any changes in the properties of materials (with the exception of embrittlement), corrosion certainly does so. In general, a distinction must be made between changes in properties of inorganic materials (stainless steel, alloys, etc.) and organic materials (synthetics, rubber, latex, etc.).

6.1 Inorganic materials

In the case of metals, prolonged use leads to embrittlement. Mechanical effects on the surface will increase roughness and a polished surface can lose its shine and become dull. Corrosion can lead to malfunctioning of the components / instruments affected.

Ceramics and glass become brittle in normal use. Prolonged use and repeated exposure to high temperature can lead to loss of brightness of glazing. Glasses often become dull after prolonged use. This is generally due to small cracks. Detergent additives (scouring milk), hard residues on surfaces, which must be mechanically removed, as well as mechanical influences can cause such cracks.

6.2 Organic materials

The term ageing is mainly used for rubber and latex or natural cauotchouc, i.e. materials used for flexible instruments as well as for endoscopes and respiratory systems. Ageing is a slow, natural process that inevitably

occurs even during storage. The ageing process is expedited by the effects of dry heat at temperatures above 80° C, extension and overextension as well as by light (e.g. UV rays). Ageing manifests in rubber as discoloration (brown discoloration) and embrittlement (formation of surface cracks). Plastics are also subject to ageing: they become yellow and hard. Conversely, silicone rubber, also known as silicone elastomer, does not age.

Swelling is another alteration seen for rubber, latex and synthetic materials. It is caused by penetration of liquids or gases into the surface. Swelling may be reversible and is manifested only temporarily following exposure to volatile solvents or spray propellant gases. This also applies if rubber and certain synthetic materials come into contact with narcosis gases such as halothane. Conversely, irreversible swelling is caused by contact with non-volatile oils (paraffin oil), Vaseline and inappropriate disinfectants (e.g. phenol derivatives). Silicone rubber undergoes a reversible reaction to spray propellant gases and narcosis gases – but an irreversible reaction to silicone oils and solvents.

Typical features of swelling are bleached, sticky surfaces as well as destruction of thin-walled instrument components.

Embrittlement can occur after prolonged use of organic materials. This embrittlement can be caused by either release of softeners or may derive from the structure of synthetic materials (breakage of networks structures due to UV radiation, aggressive media, temperature, etc.). Embrittlement reduces elasticity and can lead to cracking and loss of imperviousness of the materials concerned. It is important to bear in mind that ions are increasingly retained in the cracks and this can later lead to different forms of corrosion of the materials concerned.

A critical aspect of these material changes is that there is no closed surface. They also pose a risk to patients since the brittle material could break and, furthermore, reprocessing in line with hygiene requirements is no longer possible (deposits of contaminants in cavities of porous surfaces).

7 Practical tips

7.1 Handling brand new instruments

New instruments straight from the factory and instruments returned after repair must be removed from the transport packaging before they are stored and / or introduced into the instrument circuit. Remove any protective caps or protective foil. Furthermore, before they are first used they must be put through the entire reprocessing circuit used for routine instruments. The cleaning step must under no circumstances be omitted since residues on instruments, e.g. from packaging materials or excess care agents could lead to formation of marks and deposits during sterilisation. Visual inspection of the cleaning results is needed. Instruments must be visually clean. Brand new instruments with a thin passive layer could react more sensitively to critical reprocessing conditions than older, already used instruments.

New instruments straight from the factory and instruments returned after repair must only be stored in dry rooms / cabinets at room temperature. Otherwise corrosion damage could be inflicted, e.g. because of condensate formation due to temperature fluctuations inside synthetic packaging. Under no circumstances may instruments be stored in the immediate vicinity of chemical substances since they could release corrosive vapours (e.g. activated chlorine) because of their ingredients.

Microsurgical instruments must be placed in the intended racks or fittings to prevent damage also when first reprocessed.

Elastic instruments must be stored in the original packaging under cool, dark and dry conditions. When stockpiling instruments, bare in mind that elastic instruments made of rubber or latex are subject to wear even while stored. The functional components of respiratory systems often have valves or membranes that could become sticky after prolonged storage. The functional capabilities of such valves or membranes must definitely be checked before use.

7.2 Using ultrasound

Ultrasound is particularly suitable as an adjunct for cleaning stainless steel instruments and hard synthetic materials. Mechanically sensitive instruments (microsurgery, dental instruments) can be gently and thoroughly cleaned and disinfected using ultrasound to underpin this process. High-performance ultrasonic equipment is able to detach dried soils even on inaccessible sites.

To derive maximum benefit from ultrasound, the following points must be borne in mind:

- The basin must be filled in accordance with the manufacturer's instructions.
- A suitable detergent or combined disinfectant/detergent must be added to the water.
- When using disinfectants and detergents, the concentration, temperature and sonication time must be tailored to each other as per the manufacturer's instructions.
- Filling the basin with warm water is recommended.
- Temperatures above 50 °C can lead to blood incrustation because of protein denaturation.
- The freshly prepared disinfectant or detergent solution must be degassed before it is first used.

Even if the basin is prepared as per the specifications, a number of basic measures should be taken to avoid mistakes:

- The instruments must be completely immersed in the cleaning solution.
- Jointed instruments and scissors must be opened before ultrasonic treatment to minimise covered surface areas.
- Instruments must be placed only on trays that do not impede ultrasound performance (e.g. wire mesh trays).
- Instruments / components with large surface areas must be positioned such that they do not give rise to spray shadowing or to zones where

no sonication will take place. These must be positioned vertically or placed on top of other instruments.

- Trays must not be overloaded.
- Since a high contamination load will adversely affect performance and promote corrosion, it may be advisable to frequently replenish the basin contents in line with the use conditions.
- For high-performance ultrasonic equipment cleaning times of around 3 minutes at frequencies of 35 kHz suffice.
- For concomitant disinfection and cleaning, use suitable products while observing the recommended concentration and exposure time.

Flexible endoscopes must not be treated in an ultrasonic basin. Accessories (valves, caps, bite guards, forceps) can be cleaned in an ultrasonic basin. The effectiveness of ultrasound is limited in the case of elastic instruments. The functional components of respiratory systems must not be reprocessed in an ultrasonic basin.

Problems occurring after prolonged treatment times:

- Friction sites on surface
- Damage to solder seals
- Loosening of screws
- Breakage of cutting edges, in particular in the case of hard metal inserts
- Possibly cracks and breaks

7.3 Reprocessing with respect to CJD

In special cases (patient with suspected Creutzfeld-Jacob disease (CJD), "anti-prion" reprocessing of medical devices is recommended in some countries (e.g. immersion in 1 M sodium hydroxide solution).

Standard surgical instruments made of instrument steel can be safely disinfected with sodium hydroxide solution (NaOH). Other materials respond as follows to treatment with NaOH:

Aluminium (e.g. hammers) corrosion attack

LCP (e.g. chisel handle)	no problem (sensitivity to indentation increases)
Hardboard (e.g. chisel handle)	no problem
Titanium	changes in oxidation colour, become black
Silicone	become brittle
PEEK (e.g. MIS components)	no problem
Chromium-coated instruments	no problem, with undamaged coating (!)
Silver (e.g. probes, cannulas)	no problem
Tin (e.g. probes)	no problem at pH values < 12.5
	with sodium hydroxide solution pH ~ 14
corrosion	
Coating on HF forceps	no problem
TiAlN coating	detachment of coating

The evaluation "No problem" means that the normal service life is not significantly affected. Devices with soft / hard solders, adhesive sites and glass are more or less affected and must be replaced depending on the extent of damage. Meticulous visual inspection and functional testing are needed to identify any changes.

An extended holding time during steam sterilisation will not give rise to any changes in instrument materials.

7.4 Examples of damage to surgical instruments

Peeled off coating

Fig. 35 shows a chromium-plated instrument from which parts of the coating are already missing. One can clearly see that peeling has occurred in different stages, with earlier (dark sites) and more recent (bright sites) evidence of detachment. If the coating is broken open at any site, the influences exerted in the instrument circuit can infiltrate the coating and thus lead to further detachment of this layer. This poses a major risk since it occurs, inter alia, intraoperatively. Nor is the requisite standard of hygiene assured.

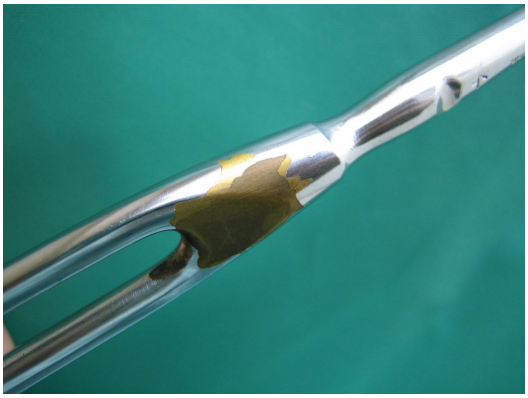


Fig. 35: Chromium-coated instrument with some of the coating missing

Engraving

The passive layer has been penetrated by the engraving. Engraving is not a suitable identification method.

Fig. 36: Engraved instrument

Incipient corrosion must be identified through meticulous visual inspection, even at sites that hardly lend themselves to visual inspection.

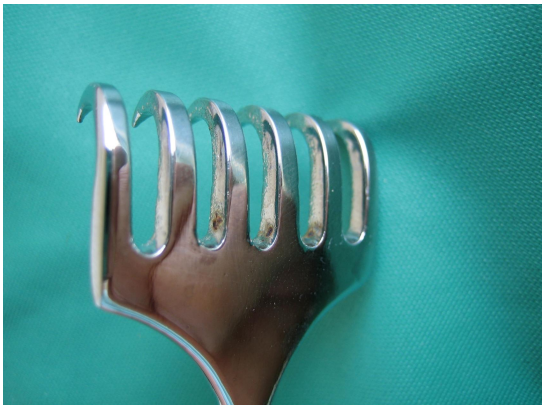


Fig. 37: Corrosion of a rake prong

Fig. 38: Corrosion of a ratchet

Use only medical devices

By reprocessing a non-medical device the reprocessor assumes the role of manufacturer pursuant to valid legislation.

Fig. 39 shows safety pins, which are not medical devices, following reprocessing. Corrosion-mediated changes can be clearly recognised!

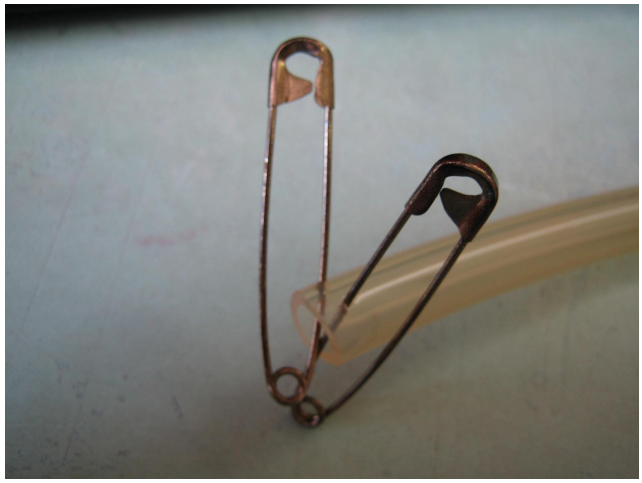
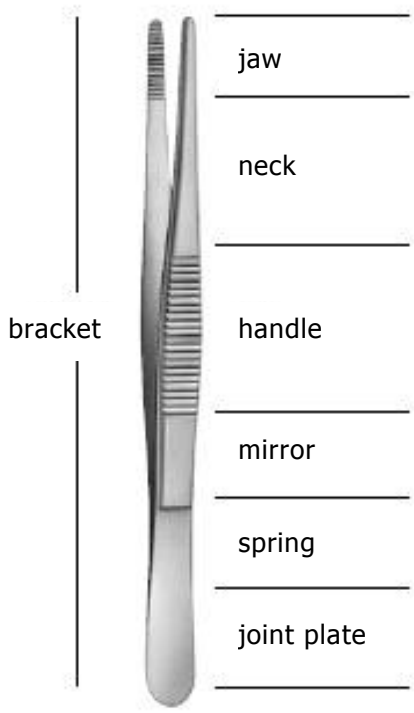


Fig. 39: Rusty safety pins

7.5 Testing of surgical instruments as a mean for decision in procurement

7.5.1 Test criteria Straight forceps



Administrative part – to be confirmed by the manufacturer

Qualitiy of steel: fulfilled

steel grade acc. ISO 7153-1

Chemical consistence equates to

X15Cr13 Material-Nr.:1.4024 ❒

X20Cr13 Material-Nr.:1.4021 ❒

Resistance to corrosion acc. EN ISO 13402 ❒

After deadening a verifiable effective chemical passivation acc. to ASTM Designation: A 380-06 has been carried out ❒

Practical part – to be proved by the user

Surface:

The whole surface has to be free from burrs, pinholes, draughts, cracks, folds, grooves, forging scales, charring of the surface, acidic grease and remains of abrading and polishing media. ❒

Examples for draughts and folds:

The whole surface of the instrument, including the functional surface, has to show an even appearance. ❒

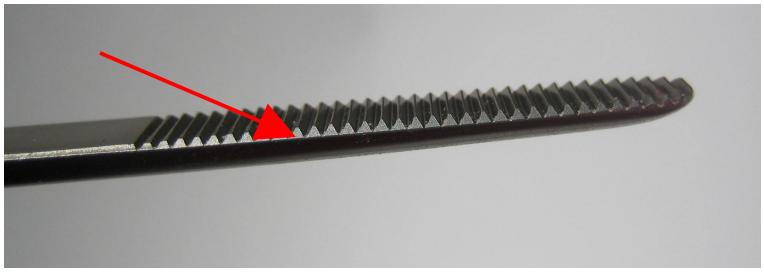
Labelling:

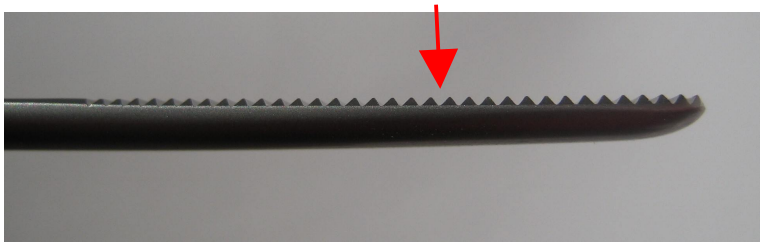
Resistant to corrosion, abrasion-proof and good readable. ❒

Shape:

The uniformity must be warranted, so that with each instrument the operation purpose is secured. ❒

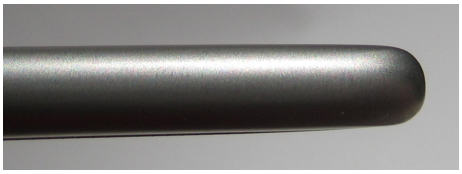
The edges of the jaw are burr-free broken up to the ground of teeth. ❒



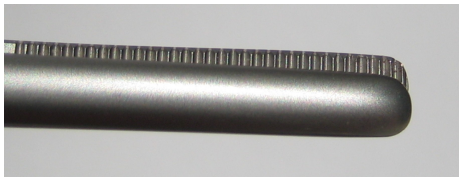


Points of jaw are symmetrical, are closing evenly and cover each other at the side. ❒

Correct:



Wrong:

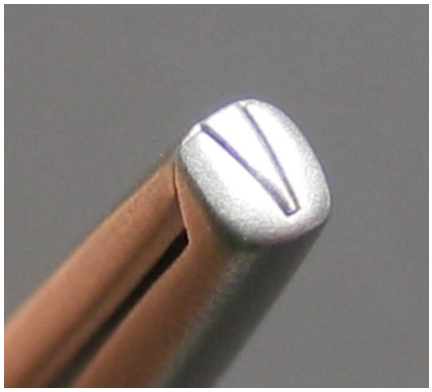


Joint plate welded without crevice. ❒

Surgical forceps:

In closed condition completely closed front, the teeth gear into each other without a remaining space between. ❒

Correct:



Wrong:

Even curving oft the jaws. ❒

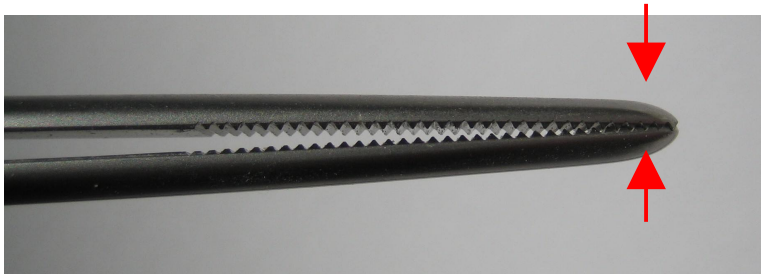
In closed condition no edges. ❒

Teeth don’t hook or stick while opening or closing. ❒

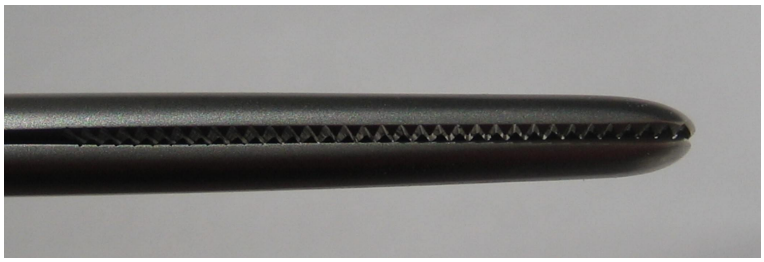
Function:

Forceps is closing elastic, beginning at the point over the whole tooth profile. ❒

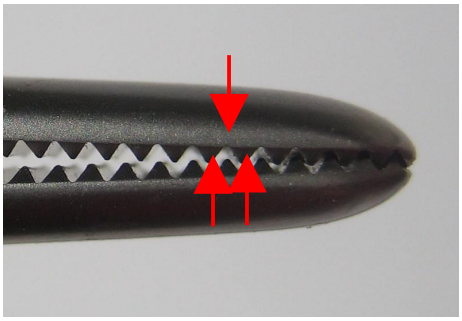
Correct:



Wrong:

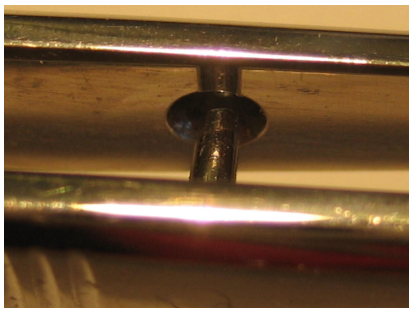


The tooth profiles are symmetrical and fit together. ❒



Guide pin:

An optionally existing guide pin is rounded, glides centrical in the guidance hole and does not grip or stick by closing or opening of the forceps. ❒

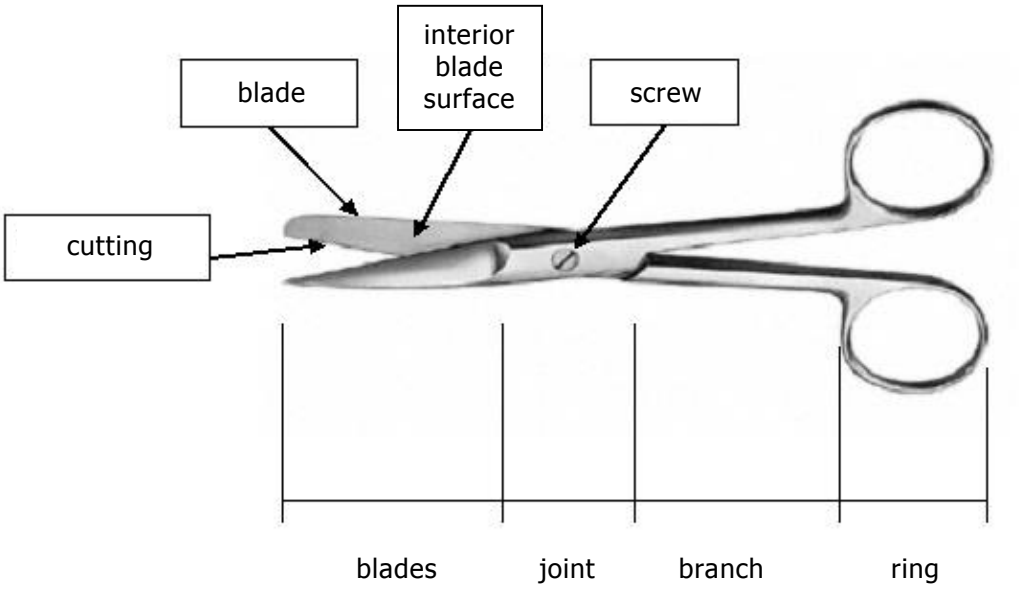


An evenly function of the forceps is achieved by tolerance of the thickness of the jaws, the range of the jaw opening and the tolerance of the closing force. This is guaranteed by the compliance of the following data, shown in the table:

Length	Length of jaw	Width of jaw	Thickness of jaw	Opening of jaw	Closing force	fulfilled
mm	mm	mm	mm	mm	Gramm	
130	13 +/- 0,8	2	1,3	16 +/- 1	205 +/- 20	❒
130	13 +/- 0,8	3,5	1,2	16 +/- 1	330 +/- 40	❒
145	15 +/- 1	2,3	1,3	18 +/- 1,5	205 +/- 20	❒
160	16 +/- 1	3,4	1,6	19 +/- 1,5	330 +/- 40	❒
180	18 +/- 1	3,9	1,7	21 +/- 1,5	380 +/- 40	❒
200	18 +/- 2	3,2	1,7	24 +/- 3	265 +/- 30	❒
200	20 +/- 1	3,9	1,7	23 +/- 1,5	420 +/- 50	❒
250	25 +/- 1	4,1	1,7	26 +/- 2	420 +/- 50	❒
300	30 +/- 1	4,8	2	30 +/- 2	420 +/- 50	❒

Checking of the closing force by use of scales.

7.5.2 Test criteria Surgical scissors



Administrative part – to be confirmed by the manufacturer

Qualitiy of steel: fulfilled

steel grad acc. ISO 7153-1

Chemical consistence equates to

X50CrMoV15 Material-Nr.:1.4116 ❒

Resistance to corrosion acc. EN ISO 13402 ❒

After deadening a verifiable effective chemical passivation acc. to ASTM Designation: A 380-06 has been carried out ❒

Practical part – to be proved by the user

Surface:
The whole surface has to be free from burrs, pinholes, draughts, cracks, folds, grooves, forging scales, charring of the surface, acidic grease and remain of abrading and polishing media. ❒

Examples for draughts and folds:

The whole surface of the instrument, including the functional surface, has to show an even appearance. ❒

Labelling:

Resistant to corrosion, abrasion-proof and good readable. ❒

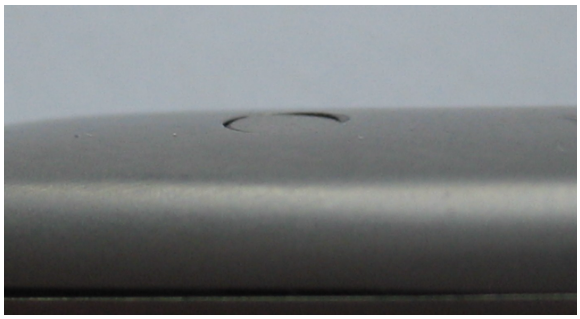
Shape:
The uniformity must be warranted, so that with each instrument the operation purpose is secured. ❒

When the scissors are closed, i. e. when the internal surfaces of the branches touch fully, the tips oft the blade are congruent (blades have the same length). ❒

The screw fits tightly during any movement of the scissors. ❒

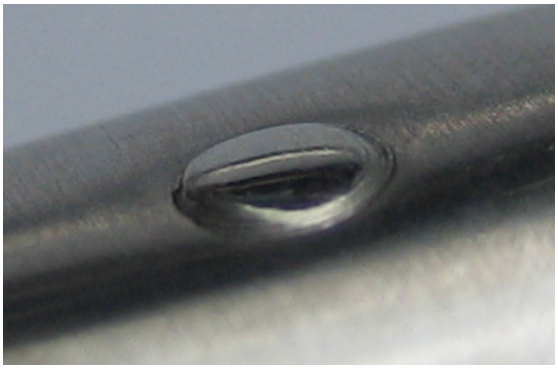
Screw head and thread dome are aligned to the shape of the joint area, are not too short, too long or are too sharp. ❒

wrong:

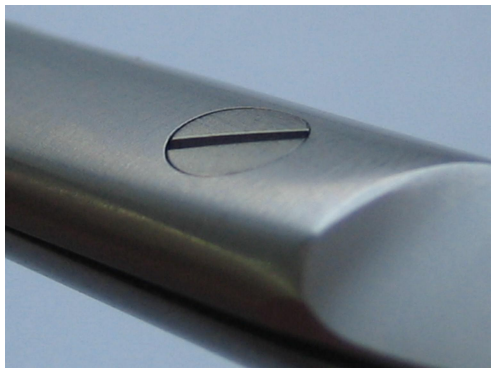


wrong:

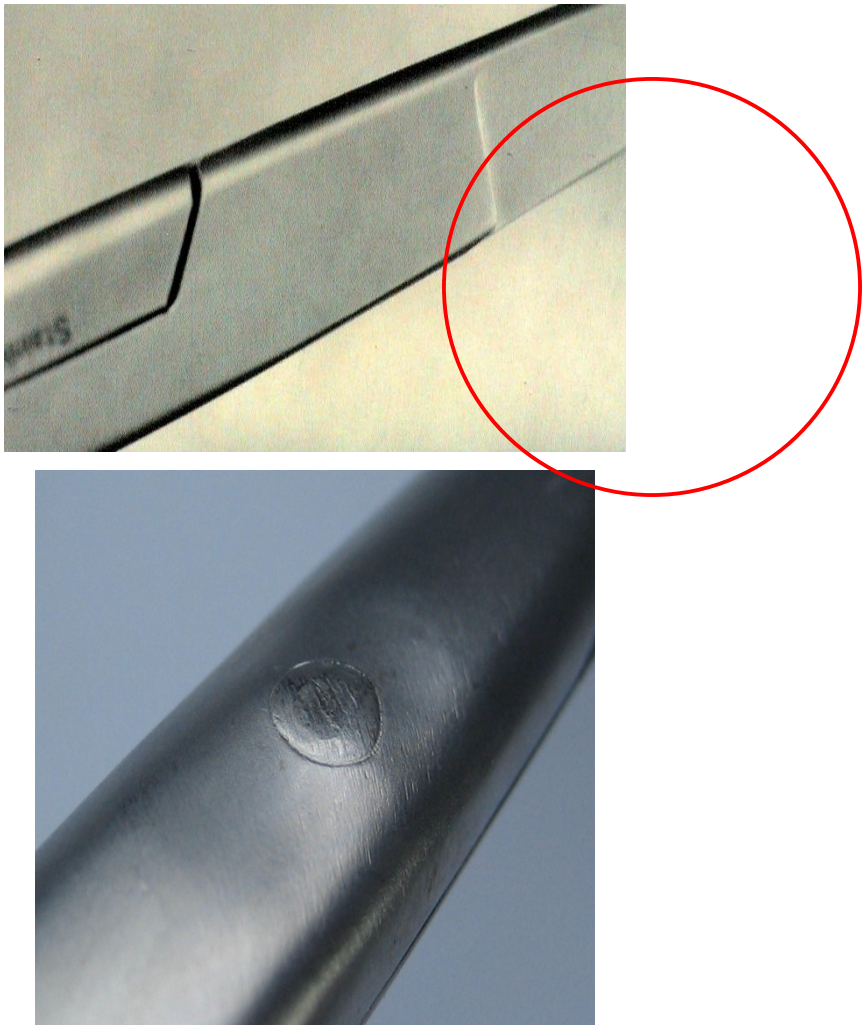
correct:



correct:

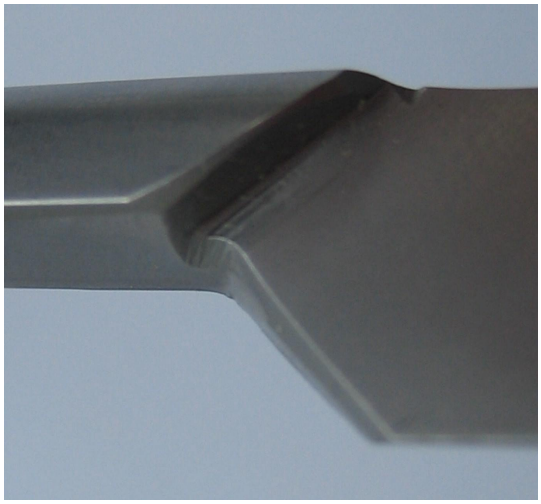


The joint screw is not rivetted. ❒

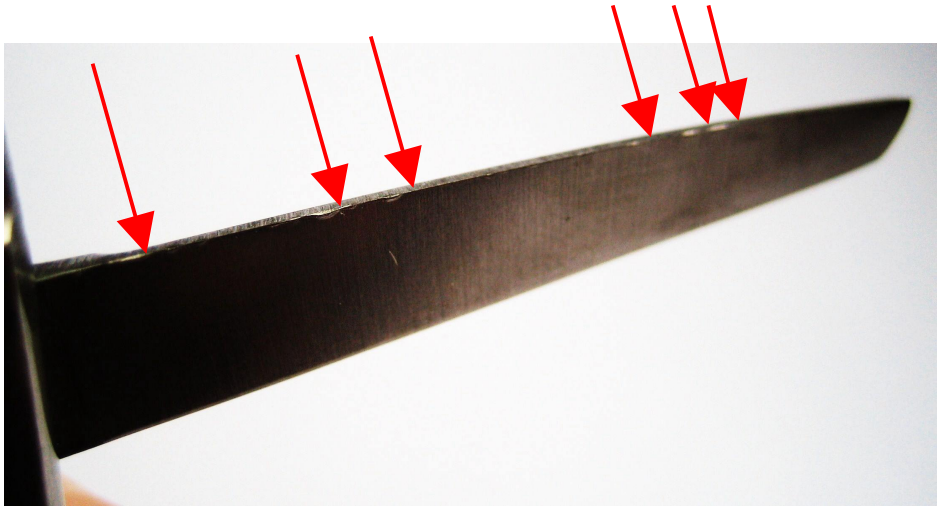


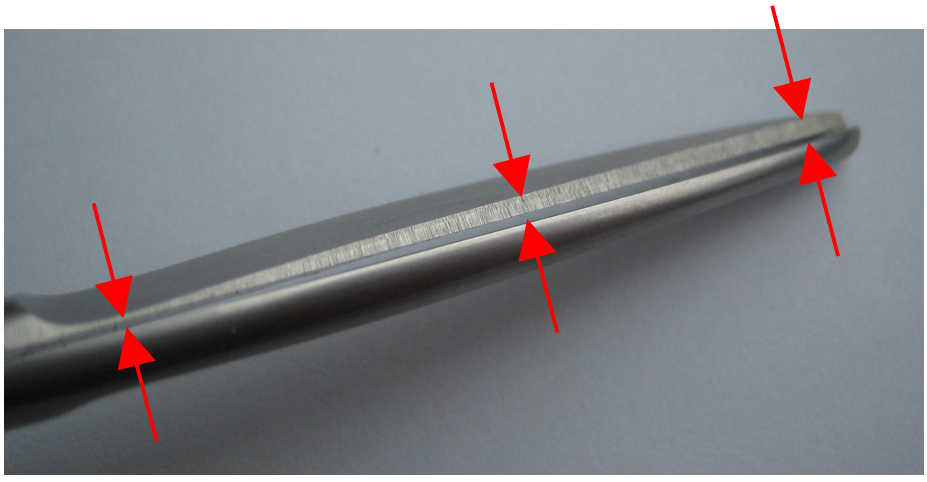
The joint screw is in the centre. ❒

The edges in the joint area are chamfered. ❒



The cutting edges are straight without outbursts, nickings or deformations. ❒



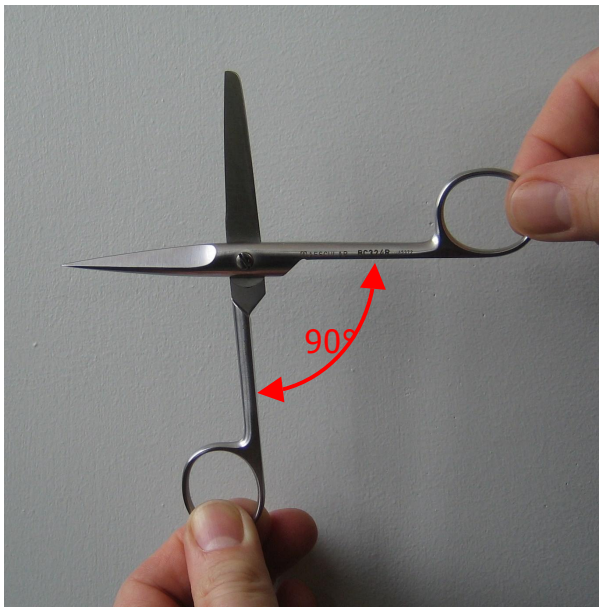


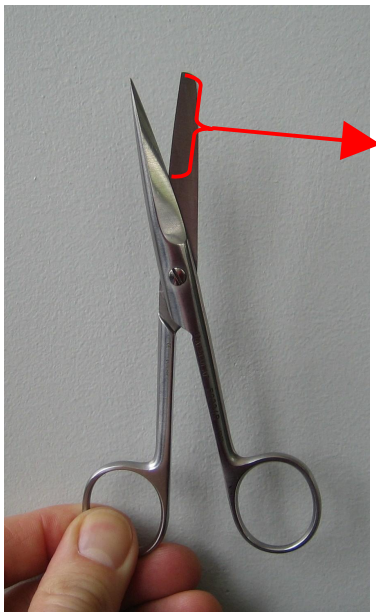
Functional testing:

The movement (without any tensile forces or pressure being laterally transmitted via the branches) starts at approx. 1/3 of the blade neither too loose or too tight and in any case even. ❒

Closing performance:

Open branches up to 90°
Drop horizontal branch
Remaining jaw opening shows, where the scissors start to cut.





Cutting-

Cutting Test:

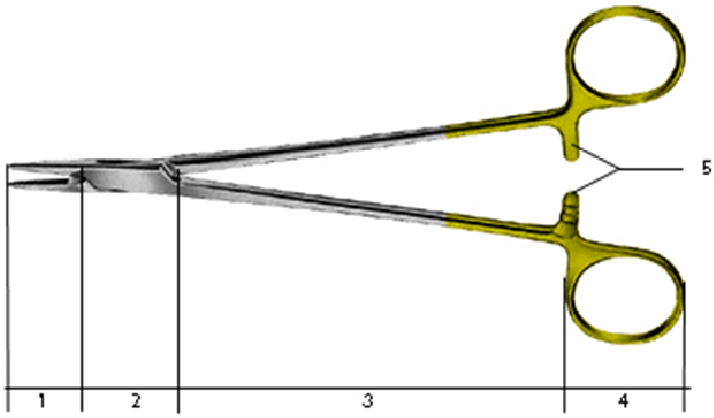
Select the test materials to match the design of the scissors

testing material	number of layers	designation
gauze dressing made of cotton or tissue or jersey	1	microscissors and feather scissors
	2	fine vascular or tissue scissors
	5	dissecting and surgical scissors
	8	dressing, GI and bone scissors

Do not exercise any natural pressure or tension via the branches on the blades during the cutting or movement test („left-handes problem"). Perform uninterrupted cuts in an oblique direction and across the weaving direction of the fabric. The scissors must not stuck.

The cutting test has been passed if at least two thirds of the length of the edge, starting at the tip, were cut evenly without tearing, jamming, pulling or pushing.

7.5.3 Test criteria Needle holder with tungsten carbide inserts

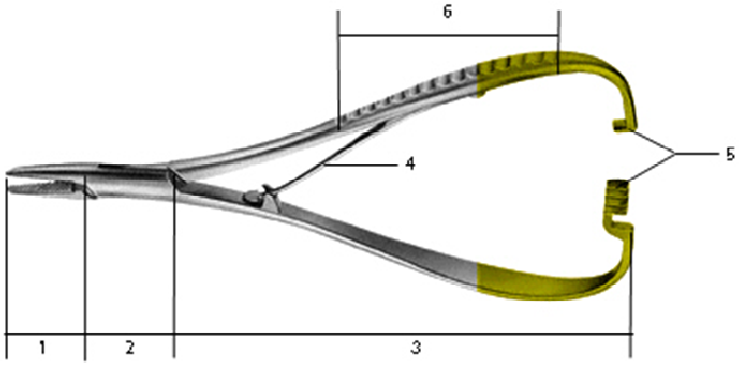


1 Jaws

2 Box lock

3 Shanks / bars

4 Rings



1 Jaws

2 Box lock

3 Shanks / bars

4 Feather

5 Ratchet

Administrativ part – to be confirmed by the manufacturer

Qualitiy of steel (not applicable to the tungsten carbide insert): fulfilled

steel grad acc. ISO 7153-1

Chemical consistence equates to

X20Cr13 Material-Nr.: 1.4021 ❒

Resistance to corrosion acc. EN ISO 13402 ❒

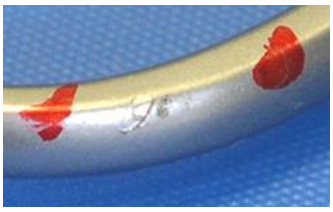
After deadening a verifiable effective chemical passivation acc. to ASTM Designation: A 380-06 has been carried out ❒

Practical part – to be proved by the user

Surface:

The whole surface has to be free from burrs, pinholes, drafts, cracks, folds, grooves, forging scales, charring of the surface, acidic grease and remain of abrading and polishing media. ❒

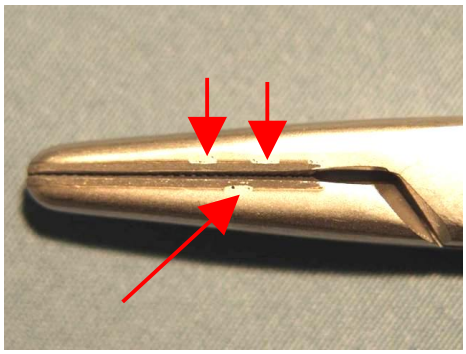
Examples for drafts and folds:

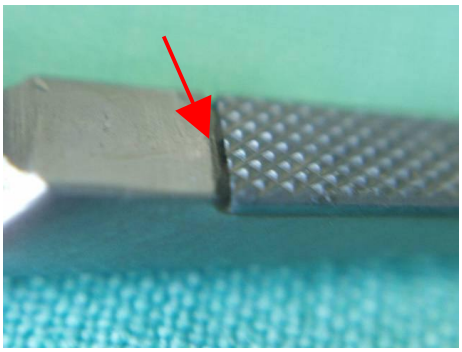
The whole surface of the instrument, including the functional surface, has to show an even appearance. ❒

The soldered seam is continuous closed, free of pinholes, spots and stains, the inner surface free of soldering metal. ❒

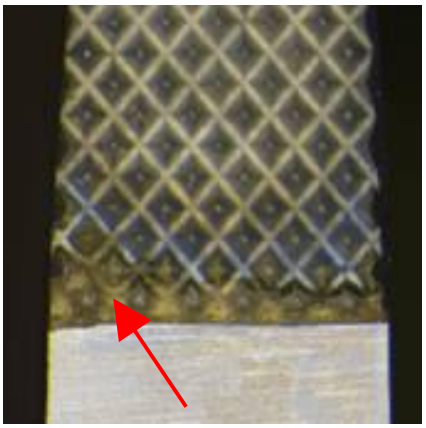
wrong:



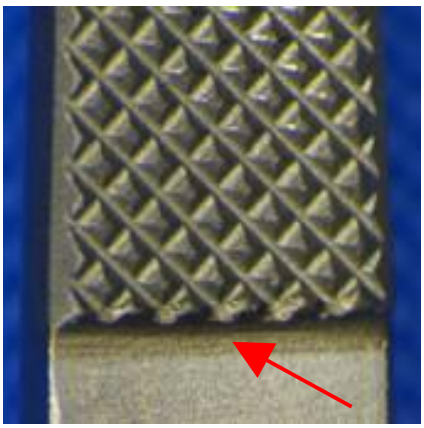
wrong:



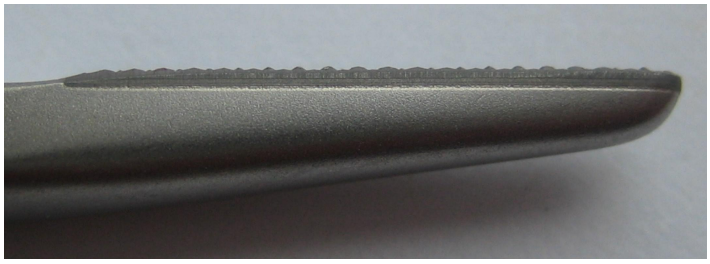
wrong:



correct:



correct:



The gold plating for identification of hard metal inserts is even and free of pinholes. ❒

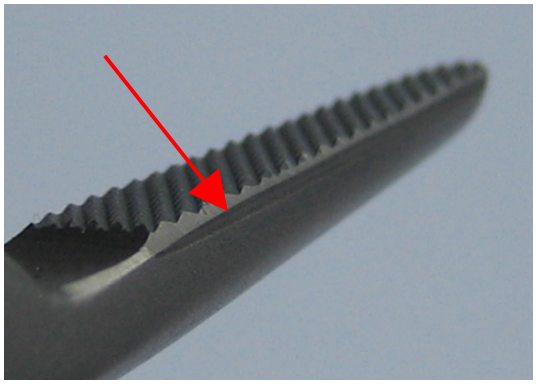
Labelling:

Resistant to corrosion, abrasion-proof and good readable. ❒

Shape:

The uniformity must be warranted, so that with each instrument the operation purpose is secured. ❒

The edges of the jaw are burr-free broken up to the ground of teeth. ❒



The profiles are symmetrical and have a uniform closing. ❒

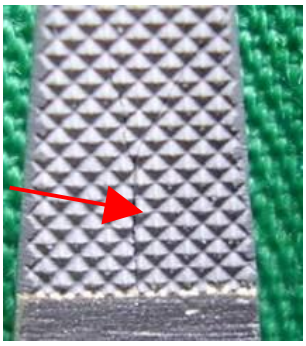
The jaw tips, jaw edges, jaw necks and profile are rounded inwards (visual and tactile inspection to ensure no clasping or pulling at the skin). ❒

Function:

The jaw parts meet at the tip first (without closing pressure). ❒

The jaws close in a spring-like manner at least 2/3 of the jaw length with the ratchet pushed together to the last click. ❒

The profile of the inserts is even and without cracks. ❒

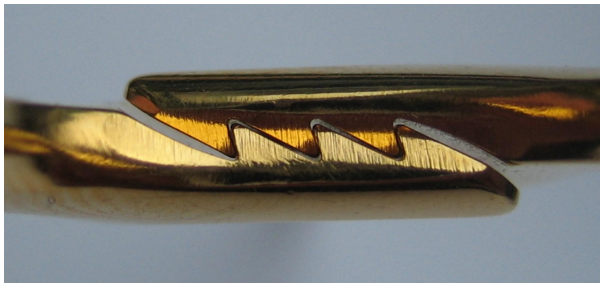


The pyramid tips of tungsten carbide inserts fully engage with each other when close. ❒

The jaw parts are symmetrical and cover each other completely. ❒

The jaw parts meet at the tip when ratchet parts meets without pressure. There must not be a gap at the jaw tips. ❒

The ratchets are fully aligned when closed, the serrations engage fully with each other to guarantee an opening of the ratchet of ring-needle holders by exerting slight pressure without any hook formation. ❒



Checking the position of the shafts and rings by placing on an even surface:
Parallel position of the rings. ❒

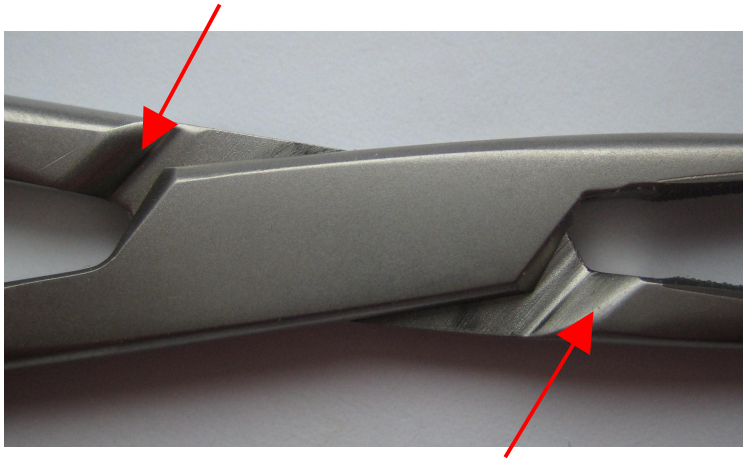
Shafts and rings must not be bent (securing that the needle holder cannot be opened inadvertently). ❒

Box lock:

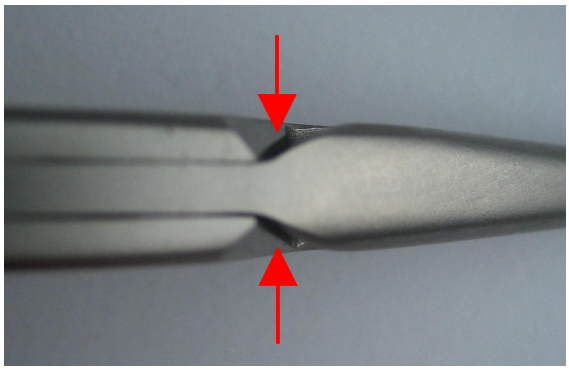
No rocking and slackening in any position (checking by moving the shafts upwards and downwards against each other). ❒

Suction movement (needle holder must not close by it´s self-weight)
in each position. ❒

Needle holder with box lock: open lock with a chamfer of an angle of 45° to the shafts and the jaws ❒



Triangle shaped chamfer on both sides of the box. ❒



8 Author

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The script has been proof read and authorized by the wfhss education group

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11 Learning objectives

The aim of this Script is to enable the student to be able to detect and describe the changes occurring on the surface of medical devices. Furthermore, the student should learn how to classify deposits, discolorations and corrosion types, understand what causes these and thus prevent such occurrences in the medical setting.

The aim is also to acquire basic knowledge so that, in the event of such manifestations, a timely and targeted response is shown, in line with the respective cause, and danger to the patient and other medical devices can be prevented.

The student should

- be able to identify the most important groups of materials
- be able to identify critical materials
- be able to name surface and material changes and explain why they occur
- be able to identify corrosion types and explain why they occur
- be able to name ways to protect against corrosion
- be able to name the most important types of steel and where they are used
- be able to name changes in properties and their potential implications for various materials