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# GENERAL TREATMENT AND PREPARATION GUIDE FOR SURGICAL INSTRUMENTS<sup>®</sup>



**important  
to note!!**

## Quality- Management- Manual

Erstellt / geändert von  
Jochen Zepf  
Erstelldatum  
2010-04-01

## 1. General instructions



Responsibility for professional treatment and preparation lies with the operator of the respective central sterile supply department and his or her assistants.



The treatment and preparation of medical products which, in accordance with regulations, are to be used in a low-bacteria or sterile condition should be realised employing suitably validated procedures and taking manufacturer specifications into consideration in a manner that guarantees the verifiable success of the procedure and ensures that the safety and health of patients, users or third parties are not endangered. Evidence of compliance should be compiled of treatment and preparation.



Manufacturer specifications regarding the concentration, temperature, exposure, etc. of respective cleaning and disinfecting agents should be adhered to during treatment and preparation.



Only chemicals suitable and approved for the treatment and preparation of instruments should be used.



Excessive concentrations of chemicals can lead to damage on instruments and contribute to rendering the laser engraving or etching illegible.



Treatment and preparation of instruments should be realised as timely as possible to avoid damage to the instrumentarium.



Professional treatment and preparation of surgical instruments begins on the operating table.



New and repaired instruments should pass through the complete treatment and preparation cycle prior to use!



Instruments exhibiting visible damage should be professionally repaired.



Damaged instruments can jeopardise the success of an operation!



Implants which come into contact with bodily secretions should not be used again.



Implants which no longer correspond in their appearance to their delivery condition should not be used.



Instruments which require special treatment and preparation are delivered with separate treatment and preparation instructions.

## 2. Handling brand-new instruments



Instruments newly arriving from production and which have now been delivered to you require particular attention when it comes to treatment and preparation / storage.

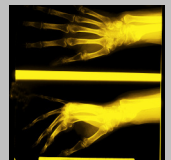


Staining and discolouring may occur in the vicinity of the inscription (laser engraving) following cleaning and disinfecting in the cleaning and disinfecting unit. Instruments which have been cleaned in the same cleaning and disinfecting unit and have been in circulation for a longer period do not exhibit these changes.

This can be a consequence of the still very thin passivated layer on the new instruments.



The following instructions should be heeded to avoid problems of this nature.



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Always remove new instruments from the transportation packaging (closed plastic packaging can lead to the formation of condensation if exposed to temperature fluctuations, thus considerably increasing the risk of corrosion.)

- ① New instruments should be included in at least three cleaning and disinfecting batches prior to initial sterilisation
- ② to completely remove any manufacturer residues present
- ③ to avoid discolouring in the vicinity of the inscription(s)
- ④ to strengthen the still extremely thin passivated layer.



New instruments should be stored in indoor air without protective packaging in a closed cabinet / drawer. It is important to ensure that pertinent hygienic regulations are adhered to in each case

- ① to avoid unnecessary dust deposits
- ② to avoid corrosion
- ③ New instruments should not be stored in the immediate vicinity of chemicals (chemical vapours can trigger corrosion on the instruments).
- ④ In the case of new instruments which are to be stored for a longer period of time, we recommend treatment with a maintenance oil approved for sterilisation, as this considerably reduces the risk of corrosion

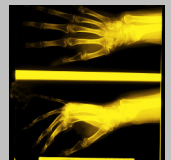


The following procedure should be chosen in the case of discolouring in the vicinity of the inscription:

- ① Discolouring should be removed with the aid of an instrument eraser (e.g. Instruflex W4) or a steam cleaner (Dreamsteam)
- ② Immerse the instrument in, for example, "neodisher IR" from Dr. Weigert (please observe the chemical manufacturer's specifications).
- ③ Rinse off the instrument thoroughly with demineralised water.
- ④ Subject the instrument to renewed cleaning and disinfecting in the cleaning and disinfecting unit.



Please contact our Service Department if, despite several cleaning and disinfecting operations (< 5 batches) in the cleaning and disinfecting unit, discolouring is still evident in the vicinity of the inscription.



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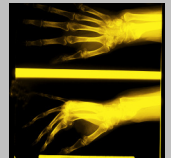
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### 3. Preliminary work for treatment and preparation Only clean instruments can be sterilised!

-  Coarse impurities should be cleaned off instruments on the operating table.
-  Instruments should be laid on a disposal tray in a manner that ensures that no parts are left unrinsed!
-  Instruments with joints or hinges should be opened before depositing.
-  Instruments which consist of several parts should be dismantled!
-  All instruments should be disposed of in a manner which ensures that unauthorised third parties have no access to them and their renewed use is impossible.
-  Instruments with cavities (cannulae, bore sleeves, etc.) should be rinsed through with water on the operating table.
-  Micro instruments should be disposed of on a separate tray

### 4. Manual cleaning and disinfecting

-  Immerse the instrument completely in a cleaning and disinfecting agent.
-  Ensure that all instruments are totally immersed so that they are completely covered with cleaning and disinfecting agent.
-  Scrub off the instruments with a soft brush following the prescribed exposure time.
-  Brush through instruments with cavities using a suitable round brush.
-  Check the instrument for residual dirt and scrub and brush through again if necessary.
-  Following cleaning and disinfecting, the instrument should be rinsed with demineralised water until all cleaning and disinfecting agent residue has been completely removed.
-  Dry the instrument with a lint-free cloth or with the aid of medical compressed air.
-  Respective manufacturer specifications regarding concentration of and exposure to the cleaning and disinfecting agent should be observed.
-  Appropriate personnel protection must be assured.
-  Only brushes with soft synthetic bristles should be used to avoid damage to the instrument.
-  Use of cleaning brushes consisting of metal and lubricant gel (tip cleaner) can lead to corrosion and damage.



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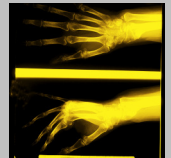
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### 5. Cleaning or preliminary cleaning in the ultrasonic bath

-  Only cleaning and disinfecting agents should be used in the ultrasonic bath which are approved for use in the ultrasonic tank.
-  The prescribed maximum sonic exposure for the respective instrument should be observed (see manufacturer specifications).
-  Following cleaning in the ultrasonic tank, the instrumentarium should be rinsed with demineralised water to avoid foaming in the cleaning and disinfecting unit (foaming error).
-  Instruments should be cleaned and disinfected again in a cleaning and disinfecting unit following treatment in the ultrasonic tank to achieve optimum cleaning results.
-  Choose a concentration and exposure conforming to the chemical manufacturer's specifications.
-  The length of sonic exposure depends on the specifications of the instrument manufacturer.
-  The ultrasonic tank should be covered with a lid during use.
-  Do not reach into the ultrasonic tank during use.
-  Sensitive instruments such as scopes or motor systems should not be cleaned in the ultrasonic bath (instrument and manufacturer specifications should be heeded).

### 6. Machine treatment and preparation in the cleaning and disinfecting unit

-  Instruments should be laid on a cleaning tray in a manner that ensures that no parts are left unrinsed.
-  Bowls and pots should, where possible, be laid on a separate tray.
-  Hollow instruments and instruments which are difficult to clean can be cleaned in advance in the ultrasonic unit to aid cleaning.
-  Hollow instruments should be evenly distributed on the charging trolley of the cleaning and disinfecting unit so that they are completely rinsed out in compliance with validation specifications.
-  Cleaning and disinfecting should be realised with appropriate validated procedures to ensure that success can be verified (see DIN EN ISO 15883 in this respect).
-  Individual process steps should be determined in the validation procedure in the respective central sterile supply department.
-  The chemical manufacturer should be consulted when determining process parameters such as dosing quantity and dosing temperature to achieve an optimum cleaning result.
-  Instruments should be visually inspected following cleaning to ensure that they are clean.
-  Instruments which are not clean should be subjected to cleaning once again (manual preliminary cleaning should be realised where necessary).



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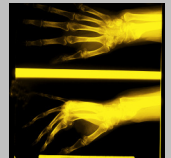
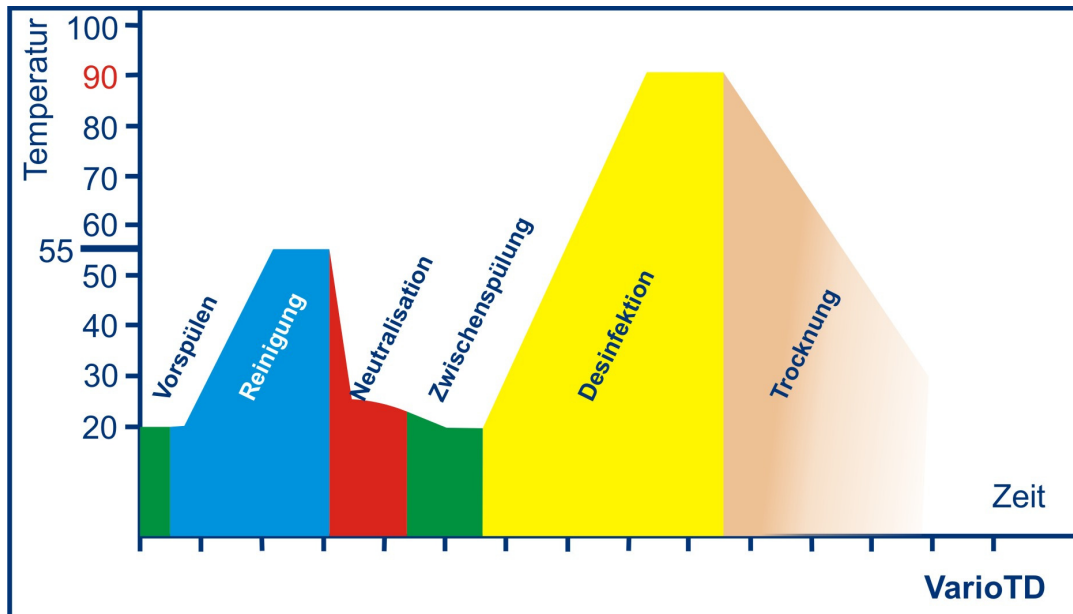
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➔ ZEPF Medical Instruments GmbH recommends the following pH values during cleaning:

Stainless steel	7	➔	10.5
Aluminium	6	➔	9.5
Titanium alloys	6	➔	9.5
Plastics	4	➔	9.5

➔ An excessive pH value during cleaning can lead to damage to the instrumentarium.

➔ We recommend the Vario TD programme for cleaning and disinfecting.



## 7. Care, functional inspection and packing

➔ Individual instrument parts should be inspected for damage prior to assembling instruments.

➔ Instruments with joints, hinges and moving parts should be lubricated with an approved instrument maintenance oil prior to functional testing.

➔ Only maintenance oils approved for sterilisation should be used.

➔ A functional test pursuant to manufacturer specifications should be conducted prior to reuse.

➔ Defective and non-functional instruments should be repaired or replaced.

➔ Instruments should be packed in a packaging system approved by the respective standard (DIN/EN/ISO 868, DIN/EN/ISO 11607).

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### 8. Sterilisation

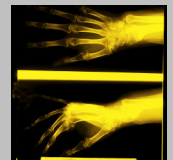
- ☞ Sterilisation should be realised with appropriate validated procedures to ensure that success can be verified. The sterilisation processes should be documented.
- ☞ We recommend a fractionated vacuum process with saturated steam.
- ☞ The sterilisation temperature should lie between 134°C and 137°C for a holding time of 5 min. / 18 min. (Creutzfeld Jakob disease variant) and < 3050 Mbar.
- ☞ Instruments should not be sterilised in the protective packaging sent with the delivery.
- ☞ Responsibility for correct sterilisation lies with the operator of the respective central sterile supply department.
- ☞ The standards DIN/EN/ISO 17665 and DIN/EN/ISO 285 should be observed.
- ☞ National and international sterilisation directives should be heeded.
- ☞ Sterilisation using other sterilisation procedures (e.g. gas or plasma sterilisation) has not been tested.
- ☞ In the event of other sterilisation procedures being employed, ZEPF MEDICAL Instruments GmbH shall bear no liability in these cases. Liability is borne exclusively by the operator of the central sterile supply department.
- ☞ The following temperatures should not be exceeded:

Stainless steel	150 °C
Aluminium	150 °C
Titanium alloys	150 °C
Plastics	150 °C

### 9. Disclaimer

- ➔ ZEPF MEDICAL Instruments GmbH assumes no liability for direct or consequential damage caused by improper use, handling or incorrect treatment and preparation, sterilisation and maintenance. Failure to heed instructions, incorrect handling or incorrect use of products supplied by ZEPF MEDICAL Instruments GmbH shall result in the exclusion of all warranty claims.
- ➔ ZEPF MEDICAL Instruments GmbH cannot be held responsible for damage resulting from the above.

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