







## Always on Hand to Help with Hygiene – in Europe and Around the World.





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Dr. Weigert Management System - Certified according to DIN EN ISO 9001/13485/14001

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## Always on the Safe Side.

neodisher<sup>®</sup> – Reprocessing of Medical Devices.

## neodisher<sup>®</sup> – for Reliable and Reproducible Reprocessing

of Medical Devices.

## Hygiene Safety

... has top priority! Anyone involved in the reprocessing of medical devices knows the quality requirements that the process and results have to meet – put your trust in our experience and our service!

Cleaning and disinfecting processes must achieve reproducible results of the highest level. For this reason, validated and documentable processes must be used.

Make use of Dr. Weigert's expertise to perform hygiene processes with an optimum balance of efficiency, safety and economy.

## **Perfect Solutions!**

In cleaning and disinfection, hygiene safety and maintaining the condition of sensitive materials are paramount. neodisher® concepts are an ideal solution for achieving these objectives. Right from the product development stage, the effectiveness, cleaning performance and resistance of the most diverse materials are comprehensively tested under practice-relevant conditions – for the safe reprocessing and long service life of high-quality instruments.

Instrument reprocessing starts with the proper disposal of the instruments in the operating theatre in suitable containers and the correct loading of the washer disinfector. It ends with sterilisation and documented release for re-use.

If there are changes in materials, the entire instrument cycle has to be checked. After automated cleaning and disinfection, surface changes may be visible on reprocessed medical devices, such as surgical instruments, caused by steam sterilisation or disposal in the operating theatre, for example.

We determine the causes of the material changes and, in addition to microscopic surface analyses, we also carry out systematic investigations. Analyses of the various process waters, steam condensates, the boiler feed and boiler water as well as the sterilisation packaging provide important information.

On the basis of this, we give practical recommendations for avoiding the recurrence of discoloration, etc. – for consistent first-class results.



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## Our Experience for Your Safety.



### **The Requirements**

...to be met by the cleaning and disinfection of medical devices are defined in standards and in Germany also in the KRINKO<sup>1</sup> and BfArM<sup>2</sup> recommendations. The standard DIN EN ISO 15883 specifies the requirements for washer disinfectors for surgical instruments, anaesthetic equipment, receptacles, utensils, glassware, human waste containers and thermolabile endoscopes. In order to achieve maximum process reliability, automated and validated procedures are required.

**Medical Devices Directive:** The EU Medical Devices Directive (93/42 EG) is the reference for all EU member states as the legal basis for producing medical devices and their accessories as well as for putting them into circulation. The directive guarantees that medical devices have the promised properties and that they are safe for patients, users and third parties.

National Acts and Regulations: The EU member states turn the Medical Devices Directive into national acts, e.g. as "Medizinproduktegesetz" and "Medizinprodukte-Betreiberverordnung" in Germany, as "Loi relative à la santé publique et à la protection sociale", "Décret relatif aux dispositifs médicaux", "Décret relatif à la matériovigilance exercée sur le dispositifs médicaux" in France or as "Besluit medische hulpmiddelen" in the Netherlands. National acts describe the correct dealing with medical devices and apply to all employees who are involved in cleaning and disinfecting medical devices in the CSSD (Central Sterile Supply Department), on wards or other divisions. Some national directives and regulations demand that cleaning, disinfecting and sterilisation must be carried out by using validated processes.



**Standards and National Guidelines:** Standards represent the state of the art, guidelines the state of science. Processes in accordance with guidelines and relevant standards, as for example DIN EN ISO 15883, therefore give the user the necessary legal safety. Hygiene guidelines describe the requirements, sequences and necessary steps for cleaning and disinfecting medical devices correctly. Automated processes are to be preferred since they can be standardised and offer better protection for employees.

Validation: Validation provides proof of the effectiveness and reproducibility of the processes and is an important element in quality assurance. The aim of a process validation, as required by the regulations, is to achieve a high safety standard and minimise all risks in order to protect patients, users and other persons and to legally protect the operator. All important steps in the reprocessing processes must be comprehensible and documented.

**Practice-orientated process concepts:** The selection of process chemicals is crucial in automated reprocessing. However, consistently reliable results are achieved only if automated dosing and concentration monitoring are tailored to the process. Dr. Weigert offers tailor-made dosing technology solutions to ensure the reliable operation of washer disinfectors – if required, also with modules for precise recording and documentation of quantities consumed.



## Automated Cleaning and Disinfection

Successful cleaning is of paramount importance. It is a prerequisite for the effectiveness of the subsequent disinfection and sterilisation. Thermal processes are preferred for disinfecting. It is important to ensure that the necessary minimum temperature is maintained on all surfaces of the charge and the chamber over the specified disinfecting time (A value). This can be checked using temperature sensors, for example. With thermolabile instruments, chemical disinfection is necessary. In this case, the conditions as per the process certificates of the disinfectant manufacturer should be observed. Adherent detergent and disinfectant residues must be washed off in the "rinsing phase" until they are considered safe. We provide these safe limits and the detection method for determining the remaining residual concentration.

## **Validation in Practise**

Validation is a check of the cleaning and disinfection process and serves as proof that the process meets the requirements in a reproducible manner. It must be carried out by the operator of the washer disinfector. Based on the information and data obtained, e.g. during validation, routine tests must be specified. These should show that the process always proceeds within the set limits and achieves the required results. Among other things, such tests may include a visual check for cleanliness, a thermoelectric test of the disinfection temperature and a test to check for the correct dosage of the process chemicals.

## **Dosage and Data Collection**

The precise dosage of detergent and disinfectant, the automated monitoring of concentration and the collection of important process data are a prerequisite for process validation. Central dosage and control systems for supplying several washer disinfectors have numerous advantages. The integration of important quality elements is new. Thus, all relevant data, such as running times of the washer disinfectors and quantities of process chemicals consumed can be continually collected and documented by the memory unit: clearly displayed on the PC or the touch panel and can be viewed and assessed from the desk and analysed and evaluated locally or via the Internet. This guarantees maximum operating efficiency and early detection of errors and malfunctions – a "must" for all validated processes and for optimum process reliability.

A DR.WEIGERT

## Optimising Process Reliability

Outstanding cleaning results and maximum process reliability are achieved through the optimum dosage of process chemicals using weigomatic<sup>®</sup> control systems plus data collection and data management. System solutions, from the simple dosing station for single-tank washer disinfectors to complex systems to cope with the highest demands, should therefore be an integral component of the planning of new and restructured plants. Design and installation require a high level of experience - Dr. Weigert has been doing this for many years!



## Competence through the **Entire** Instrument Cycle.



For Over 30 Years

high-quality materials.

of instruments and has been setting new standards.

even the most difficult tasks. Competence you can trust.



## **The Instrument Cycle**

#### **Operating Theatre**

The instrument cycle starts in the operating theatre. Here, the instruments are disposed of correctly after use and, if necessary, disassembled. Major contamination is removed and the instruments are placed in mesh trays. Long drying times should be avoided.

#### Automated reprocessing

Automated reprocessing encompasses the sub-steps cleaning, disinfecting, rinsing and drying. Effective cleaning of all surfaces is a prerequisite for the subsequent disinfection and sterilisation. Modern process chemicals such as neodisher® MediClean forte. neodisher® SeptoClean, neodisher® MediKlar and the neodisher® system ALPHA component dosing system offer maximum process safety and efficacy with excellent material compatibility. The use of water of optimum quality, such as demineralised water, for the final rinse contributes to process reliability.



#### Control, Care, Packaging

Sterilisation

steam condensate.

Sterile product storage

place that is as dark and cool as possible.

The extent and nature of the testing must be defined and documented, e.g. in a standard operating instruction. Jointed instruments are specifically treated using **neodisher® IP Spray** in order to prevent frictional corrosion. This will not affect the subsequent steam sterilisation. The packaging must be tailored to the sterilisation process, the properties of the medical device and the storage and transport.

The sterilisation process must be tested for suitability and be effective and validated. Thermal processes using steam are preferred for thermostable medical devices. To avoid discoloration or corrosion of the sterilised product, EN 285 and DIN 58946 should be taken into account in respect of the quality of the boiler feed water, boiler water and

The properties of the reprocessed medical devices must not be negatively affected by storage. They are stored in suitable sterile packaging, protected from dust in a dry



#### **DR.WEIGERT**





... neodisher® has kept pace with technological developments in the reprocessing

neodisher® concepts guarantee first-class results and the long service life of

Our specialist expertise in hygienically sensitive areas provides solutions for



## Solutions Tailored

Different Materials.





## **Safety and Value Preservation.**

#### Surgical and Micro-Surgical Instruments

... are usually made of stainless steel and other metallic materials, such as carbide, titanium and gold-plated surfaces. To preserve their value, suitable qualities of water and sterilisation steam must be used, in addition to material-compatible neodisher® process chemicals, in optimised programme cycles.

#### MIC Instruments and Rigid Endoscopes

... are of complex design and made of different materials, such as stainless steel, soldered and adhesive joints, optics and plastic coatings. The penetration of secretions and the difficulty of accessing the internal surfaces place particularly high demands on reprocessing. It must be ensured that the external and internal surfaces can be cleaned either by disassembling the instruments or by using suitable rinsing adapters.

#### Flexible Endoscopes

... are made of sensitive thermolabile materials. During reprocessing it must be ensured that all narrow-lumened channels are flushed. As flexible endoscopes are used in a disinfected condition and because thermolabile materials cannot be disinfected thermally, a chemo-thermal disinfection must be carried out instead. After disinfection, a rinsing step with sterile water follows to prevent recontamination. **neodisher endo**<sup>®</sup> products guarantee reliable reprocessing and a long service life of flexible endoscopes.



#### **DR.WEIGERT**

#### **Anaesthetic and Intensive Care Utensils**

... are made of different elastomers and plastics. Ageing of these materials, which starts as soon as brand-new medical devices are stored, must be minimised by using material-compatible reprocessing processes. Anaesthetic and intensive care utensils can usually be reprocessed using automated thermal processes. However, the drying temperature must not be set too high. With respiratory system function components in particular it must be ensured that no process chemical residues remain after rinsing.

#### **Containers, Bed Frames and Trolleys**

... are hygienically cleaned and disinfected in large-scale washer disinfectors in accordance with DIN 15883. neodisher® decontamination agents and rinsing aids ensure a safe, efficient process while providing optimum material compatibility of the different metal and plastic surfaces, even with particularly sensitive anodised aluminium.

#### **Bedpans**

... are reprocessed in a bedpan washer, preferably using a thermal disinfection programme or a chemo-thermal disinfection process. neodisher® detergents, lime complexing agents and rinsing aids increase process safety. They prevent the formation of limescale in the steam generator, improve the drying of bedpans and urine bottles and keep them stain-free and optimise the cleaning step.



### Leading through Innovation

In product and process development, neodisher<sup>®</sup> is always one step ahead. Close cooperation with the manufacturers of instruments and other medical devices is the basis for the development of innovative process chemicals and the design of new processes. Tailor-made solutions for practical applications – for safety and maintaining the value of the devices!

#### Impressing Customers

with

# Our **Expertise**.



## **Our High-Performance Team**

Reliable instrument reprocessing with first-class results requires a wide range of expertise from various different fields. With our specialist divisions, Dr. Weigert combines concentrated expert knowledge to enable us to pass on our integrated hygiene expertise to our customers.

#### **Research & Development**

We are constantly working on new and improved formulations in order to meet all the requirements of practical applications. The satisfaction of users is at the centre of our business. Research and development in our own laboratories are part of our everyday activities at Dr. Weigert – that is the only way we can ensure progress in the long term and continue to increase the value we provide to customers. We do not only carry out research in the laboratory, however, but also on site in order to obtain practice-orientated solutions.

#### **Application Technology**

Market proximity is the basis for practice-orientated product development and process optimisation. Decades of experience, excellent specialist knowledge and close cooperation with manufacturers of medical devices and washer disinfectors enable us to find the right answers to any questions quickly.

#### Analysis

Numerous elements are involved in obtaining an optimum cleaning result. Each year we analyse over 1,500 water samples from our customers in 22,500 individual tests in our DIN EN/IEC 17025 accredited water analysis, as well as deposits and residues. Experience and know-how are the basis for our sound neodisher<sup>®</sup> application recommendations.

#### Hygiene & Microbiology

Our main objective is to ensure hygiene standards are maintained through reliable processes. Every day the specialists in our Hygiene & Microbiology division evaluate samples, compile application recommendations, conduct customer training courses and seminars, support the work of our technical advisers and find new formulations for groundbreaking cleaning and disinfection concepts.



#### **Dosing Systems Solutions**

We develop practice-orientated solutions to supply the process chemicals to the washer disinfectors. Modern systems allow the recording of quantities consumed and control of the flow. They also enable the remote transmission of data for process monitoring and batch documentation in the quality management system.

#### **Service & Consultation**

Our slogan is: "integrated hygiene expertise" – we have a contact on site who is responsible for answering any queries. The excellent training that our specialists undergo guarantees that you receive comprehensive hygiene advice and reliable processes. We will not leave you to deal with queries or problems regarding hygiene on your own – our neodisher® technical adviser is always there for you.





**DR.WEIGERT** 

### **Know-how**

For first-class results, knowledge of the whole process and the parameters that influence it is necessary. Dr. Weigert possesses this expertise and has an in-depth knowledge of all the equipment on the market.

### Consultation

Consultation is one of our most important tasks: we give our customers the service they expect and find solutions for individual questions. The expertise of our advisers is a compelling reason for choosing Dr. Weigert.

### **System Service**

System service involves continuous support to ensure that first-class results are consistently achieved. Dosing systems are regularly maintained. Microbiological tests monitor and document compliance with hygiene requirements. Our standard service includes the creation of cleaning and disinfection plans. We train your staff and establish the conditions necessary for reliable processes.