

CLEANING – DISINFECTION – STERILIZATION

Technologies for hygiene-relevant areas







CLEAN, PURE, STERILE

The Fraunhofer FEP works on innovative solutions for the cleaning, disinfection and sterilization of surfaces, medical devices and materials. Our aim is to transfer these technologies into applications and to offer our customers and partners practical and tailor-made solutions for their hygiene-relevant areas.

By using low-energy electrons, the depth of penetration and the degree of germ elimination can be controlled to a previously unattained degree. This enables manufacturers of brand-new medical instruments, for example, to integrate disinfection and sterilization beside of cleaning directly into their production and development processes. With the help of the know-how and many years of experience of the Fraunhofer FEP, these processes can be used to gently clean and sterilize a variety of materials, sensitive surfaces and instruments in accordance with their areas of application. The Fraunhofer FEP's mission as your partner, e. g. for the development of hardware, technologies and the transfer thereof, always focuses on meeting the requirements of various applications.

In contrast to sterilization via high temperature, aggressive substances or high energy irradiation, these low energy technology can be used for sterilization without damaging in the field of care, implantology, surface and tissue treatment. For this purpose, a suitable cleaning technology can be combined with this innovative sterilization process.

Our service includes the complete range from market analysis, technology development and pilot production to technology transfer and on-site training and consulting.

OUR SERVICES AT A GLANCE

Feasibility and market studies

Simulation

Process development

Component and system development

Prototypes, demonstrator development

Characterization and tests

Pilot production

Process transfer, licensing

Support and consulting



CLEANING

Motivation

Medical technology includes all services associated with the provision of products, devices, software or even services with a medical reference. All products that come into contact with the human body must have an appropriate level of cleanliness up to and including sterility. This must already be guaranteed during the manufacturing of the products. Thus, cleaning in production chains for the manufacture of medical products aims at the process-reliable removal of filmic and particulate contamination. For example, cooling lubricants, cutting and punching oils, preservatives, swarfs, abrasion and other production aids that have to be removed for the next machining step or final use. Of course, current guidelines such as the newly published standard VDI2038 Part 21 are also observed at the Fraunhofer FEP. In medical technology, however, the requirements for cleaning are complex: the materials used, such as shape memory polymers and metals, as well as absorbent and biocompatible materials, often require specific adaptation of the cleaning processes. In addition, in contrast to most other industries, the validation of the processes is essential. Therefore, proof must be provided that all requirements and measures for a process-safe compliance with the residual dirt requirements are fulfilled.

Applications

- Industrial parts cleaning in the manufacture of medical devices
 - implants
 - surgical materials
 - medical instruments and devices
 - sensors, electronics
 - biological tissues
- pharmaceutical raw materials
- disposables
- wound dressings
- dental equipment
- Cleaning in hygiene-relevant areas
- Cleaning in medical and pharmaceutical production plants



Did you know?

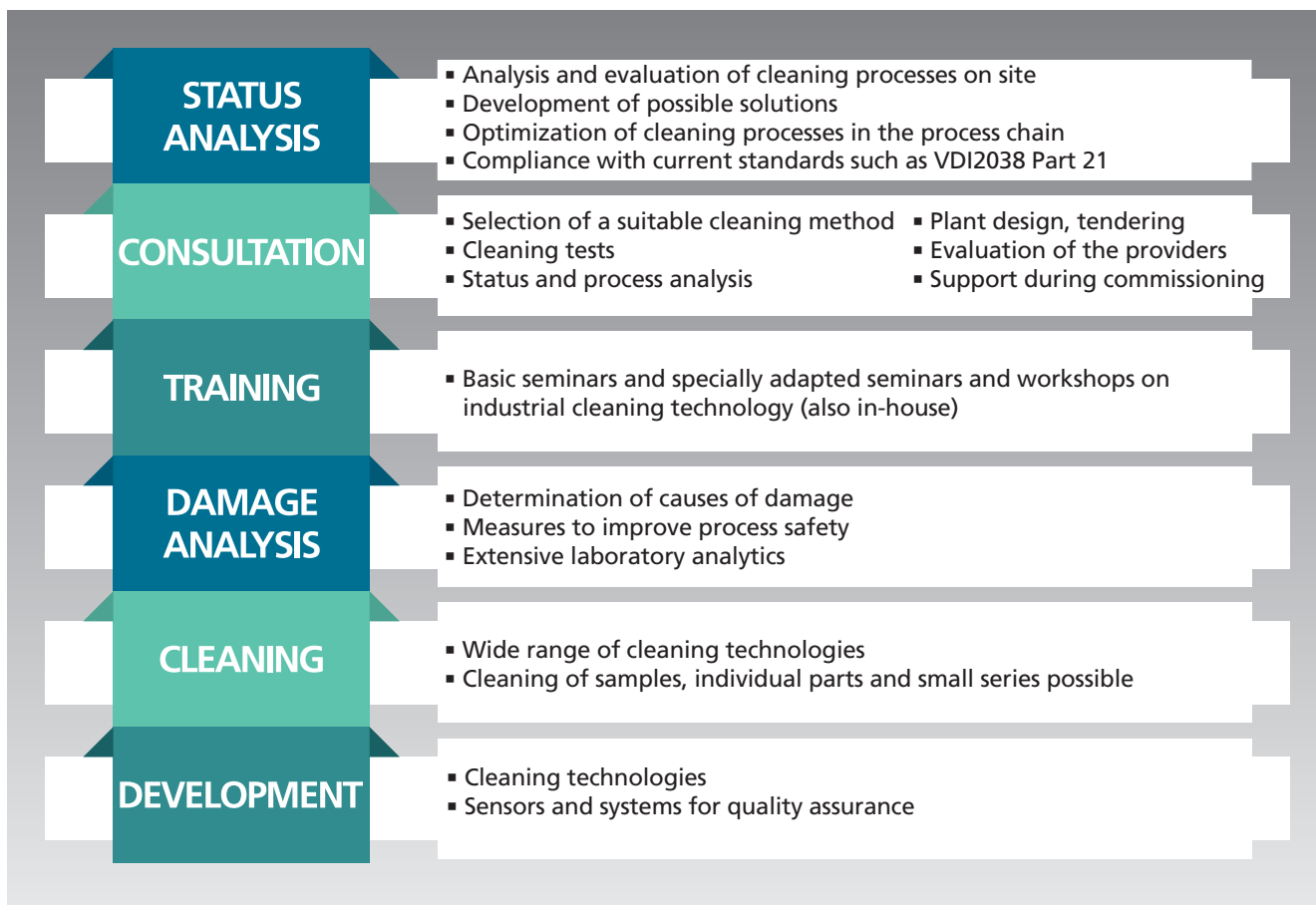
- ➔ Dishcloths and sponges often top the lists of everyday objects contaminated with germs, but 11.4 million germs per cm² also swarm in an average private refrigerator. At the same time, smartphone displays are pure bacteria biotopes with around 3895 bacteria per cm².
- ➔ Handbags are 15 times more contaminated with germs than a toilet seat.
- ➔ The toothbrush is a cleaning device for a hygiene-relevant area, yet studies have found high numbers of fecal bacteria, intestinal bacteria and herpes viruses.
- ➔ Sales of detergents, cleaning agents and cleaning products for private consumers only in Germany will amount to approximately 4.4 million euros in 2020 with a predicted sales growth of 0.9% until 2023.
- ➔ In 2018, 1.27 million people aged 14 and over in the German-speaking population used disinfectants daily.

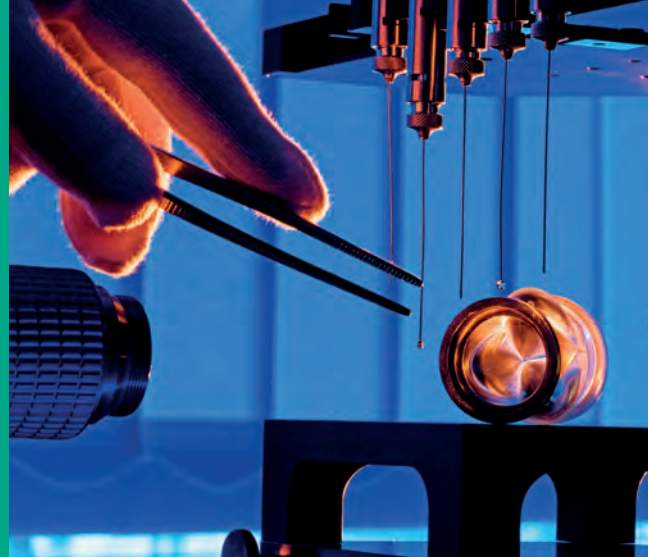


Technology

- Wet chemical fine cleaning for metallic components
- Wet chemical precision cleaning for precision parts made of glass and plastic
- High-rate plasma cleaning for metal and plastic components in vacuum
- Local functional surface cleaning with the electron beam in vacuum
- Sterilization, disinfection and inactivation with accelerated electrons
- Further processes are available within Fraunhofer Cleaning

Services





DISINFECTION AND STERILIZATION

Definition and solutions

Disinfection is a form of decontamination in which the number of infectious agents is reduced to such a degree that transmission or infection is no longer possible. However, there is no 100% reduction of germs.

Sterilization is of great importance not only in medicine but also in entire process chains. Novel high-tech products and materials increasingly pose a great challenge to traditional sterilization processes. temperature sensitive materials, bioactive ingredients and coatings as well as integrated electronic components such as microchips and sensors undergo material changes or even loss of function when sterilized with thermal, chemical or high-energy ionizing processes.

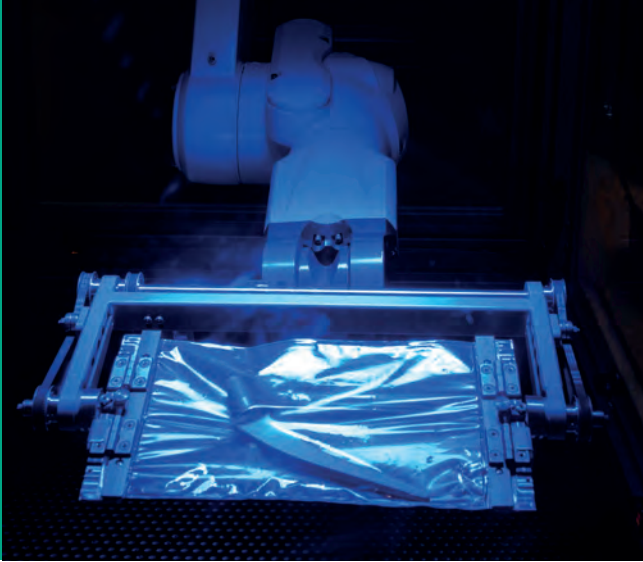
However, in Germany it is essential for a product to be sterilized before it can be released as a medical device. If sterilization is not possible with traditional methods, expensive further or new developments are necessary. In the worst case, approval as a medical device can be prohibited. For this purpose, the Fraunhofer FEP develops solutions for gentle sterilization and disinfection.

Technology

- Low-energy accelerated electrons
 - efficient disinfection and sterilization of sensitive materials and products within seconds
 - treatment in ambient atmosphere while maintaining the product-specific properties
 - sterilization of the product surface also within the packaging by means of accelerated electrons
 - only basic, local radiation shielding up to max. 150 keV required
 - compact and easily integrable into existing process chains in-line, online process monitoring
- UV treatment
- Plasma-based processes
- X-ray

Anwendungen

- Implants
- Surgical materials
- Medical instruments and devices
- Medical sensor technology
- Electronics
- Biological tissues
- Pharmaceutical raw materials
- Individualized medical products e.g. from 3D printing
- Disposables
- Wound dressings
- Dental equipment
- High-tech materials and material alloys
- Textiles and textile surfaces
- Metallic and polymeric surfaces, structured and smooth



Did you know?

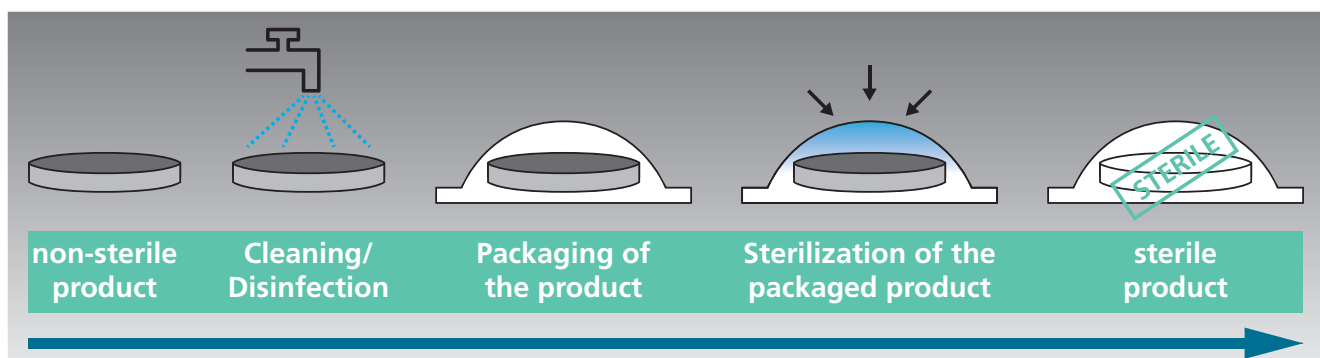
Look into the past

The mortality rate in hospitals was extremely high in the 18th & 19th centuries due to infectious diseases, about 80% of patients died during amputations. The reason for this was lack of hygiene. Surgical instruments were not cleaned between operations, doctors did not wash their hands between examinations of patients and postmortem sections and wearing street clothes was common.

- ➔ 1878 – 1884 Robert Koch cultivated the first bacteria and established the connection between germs and disease transmission
- ➔ At the end of the 19th century Louis Pasteur developed the processes of disinfection, sterilization and pasteurization
- ➔ 1879 the first steam sterilizer (autoclave) was invented by microbiologist Charles Chamber

Services

- Determination of the actual condition, contamination level of the product or the relevant surface areas
- Bioburden test and derivation of the necessary disinfection and sterilization process
- End-of-pipe sterilization
- Proof of concept of the sterilization
- Individual development and conception of the suitable sterilization solution in our 3D pilot plant
- Planning of the customer-specific sterilization plant in your production environment
- Creation of the legally required sterilization instructions according to DIN ISO 17664 and 11737
- Verified microbiological test laboratory
- Closed development chains including clinical studies through existing cooperations
- Evaluation of the biocompatibility of the sterilized products in our own cell biology laboratories
- Studies on the application of new disinfection and sterilization methods
- Development of application-specific investigation regimes





DETECTION AND SENSOR TECHNOLOGY

Motivation

Contamination is a problem in all production areas. To prevent contamination, fast detection is of great importance. Biofilms in particular can form on any surface and are very persistent, making them a previously unsolved problem in many areas of daily life but also in production processes. A biofilm has numerous advantages for the bacteria: they are protected from chemical substances such as cleaning agents and disinfectants and prove to be much more resistant to mechanical impact. All other types of contamination such as particulate deposits or (in)organic film formation also present the challenge of targeted detection. Up to now, there is no procedure with which biofilms can be effectively prevented or specifically inactivated. The Fraunhofer FEP is therefore dedicated to the development of solutions for the effective detection of surface contaminations with the help of the institute's various technologies. Among other things, we rely on the real-time detection of biofilms and other contaminants using bidirectional display technology. Furthermore, organic photodiodes as well as sensors are suitable for the detection and evaluation of surfaces and their contamination in numerous areas such as production processes with pipelines and various liquid-bearing systems.

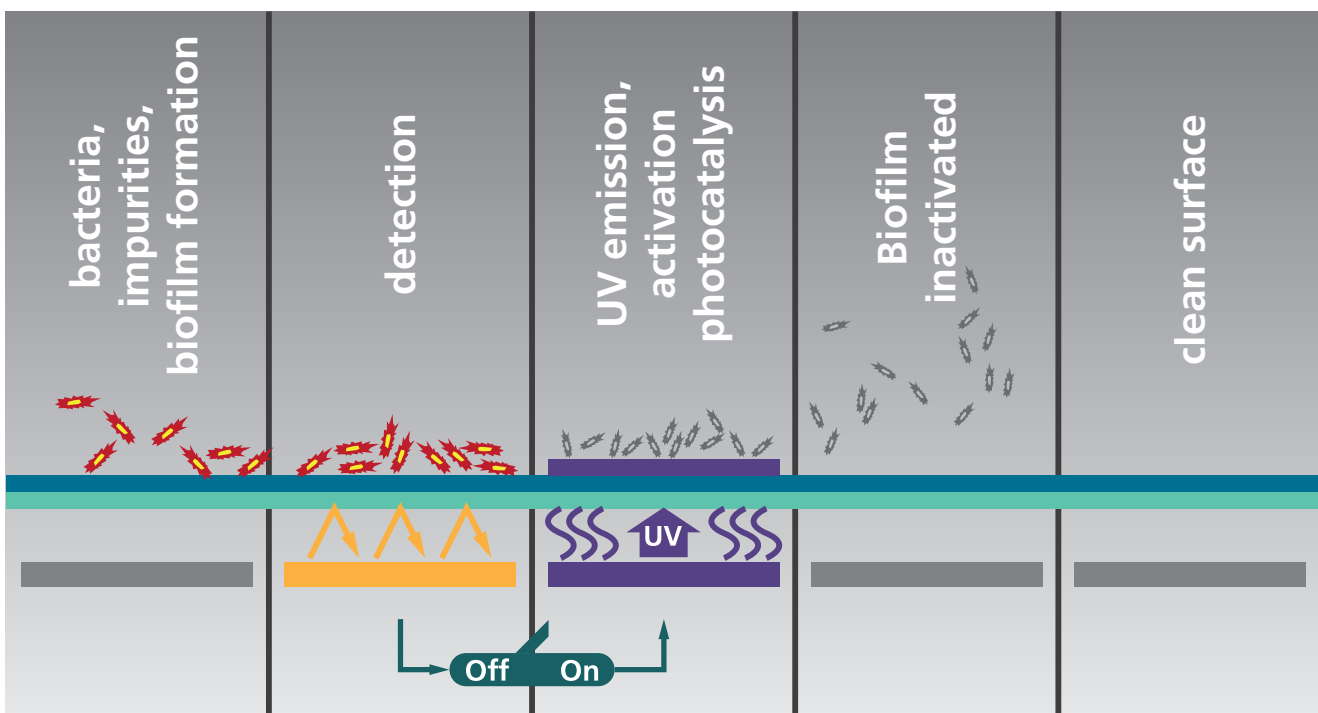
Applications

- Fingerprint sensors
- Solar and photovoltaic systems
- Biofilm inactivation on catheters
- in-vivo infection detection or treatment
- Cleaning of drinking water pipes and liquid-bearing systems
- Lab-on-chip systems
- Interactive monitoring of production processes



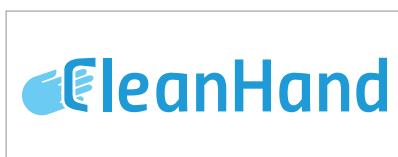
Technology on the example of biofilm detection

- Bidirectional displays emit and detect light via display pixels and integrated photodiodes
- Evaluation via display chip
- Integrated bidirectional display monitors the surface condition and detects biofilm formation
- Cleaning intervals can be triggered automatically depending on the degree of contamination
- Cleaning of the surface by light from the display using coating technologies for easy to clean surfaces





NETWORKS



Innovation Network CleanHand

New technologies for the disinfection of objects to improve the hygienic conditions
www.cleanhand.de



Forum MedTech Pharma

Network for innovations
www.medtech-pharma.de



Fraunhofer Business Area Cleaning

Bundled Fraunhofer expertise in industrial cleaning, pretreatment and surface technology
www.cleaning.fraunhofer.de



Innovation Cluster Sensorik Sachsen SenSa

Innovation cluster to promote the digital networking of sensor technology players active in Saxony
www.sensorik-sachsen.de



CEPI – New vaccines for a safer world

A global alliance financing and coordinating the development of vaccines against infectious diseases
www.cepi.net



ZIM – Central Innovation Programme for small and medium-sized enterprises

Biocompatible IoT solutions for biotechnology and medical technology
www.zim.de



International Irradiation Association

A not-for-profit organization which aims to support the global irradiation industry and scientific community.
www.iia-global.com



FIT – Fachverband industrielle Teilereinigung

Interface between research, development and application
www.fit-online.org



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and the ISO 9001.*