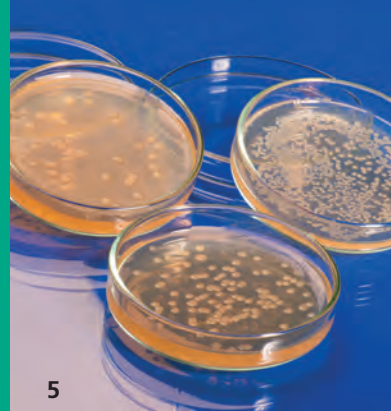


FROM THE IDEA TO THE PRODUCT:
DO NOT FORGET STERILIZATION!



5



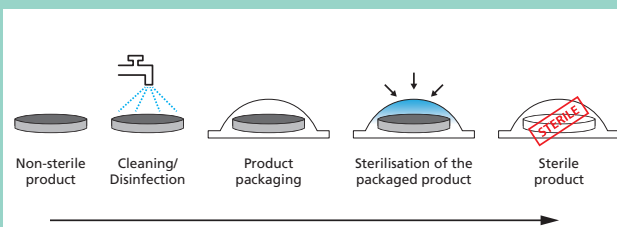
6

OUR OFFER

- End-of-pipe sterilization by means of accelerated electrons
- Proof-of-concept of sterilization
- Individual development and conception of the appropriate sterilization solution in our 3D test facility
- Planning of the customer-specific sterilization plant in your production environment
- Preparation of the legally required sterilization instructions according to DIN ISO 17664
- Verified microbiological test laboratory
- Closed development chains incl. clinical studies through existing collaborations

We see ourselves not only as a service provider, but rather as a partner who can contribute to the success of your medical device during the development phase with our expertise in the field of sterilization and disinfection.

7 Sterilization process chain



CONTACT

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COVER *Packaging of a lens to measure
intraocular pressure prior to sterilization*

- 1 Packaged sterilized microdisplay
- 2 Sterilized biological tissue
- 3 Sterilized cardiac valve
- 4 Hip implant during sterilization
- 5 Bacteria growth on culture agar
- 6 Schematic illustration of an on-site sterilizer

(© Fraunhofer IBMT)



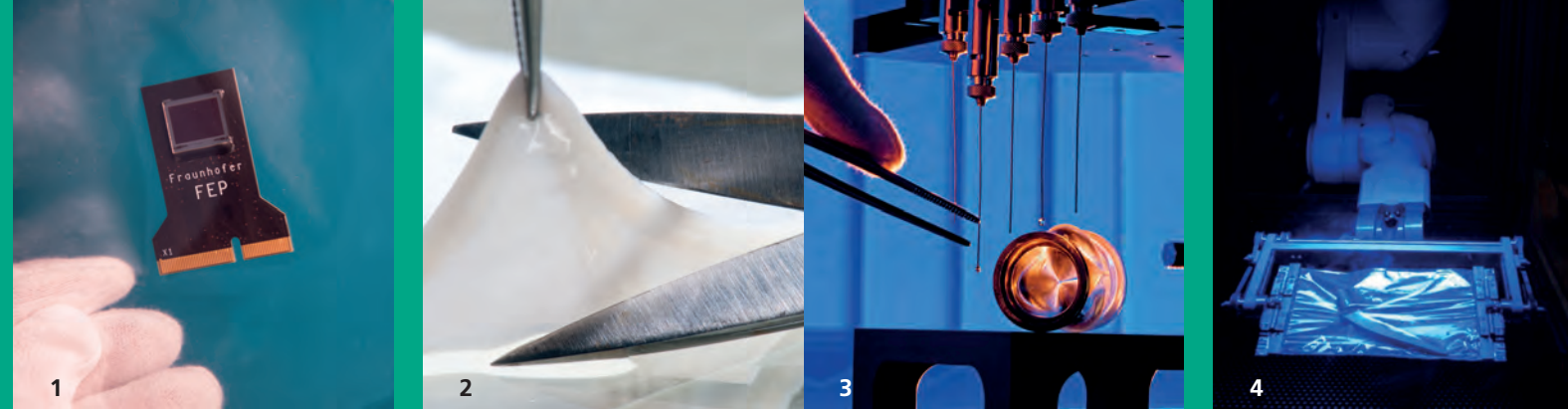
*We focus on quality
and the ISO 9001.*

STERILIZATION OF MEDICAL PRODUCTS

gentle – fast – process-integrated



**FROM THE IDEA TO THE PRODUCT:
DO NOT FORGET STERILIZATION!**



Before a medical product or application is approved in the market, sterilization is a process that is mandatory for the majority of medical devices. Sterilization results in the destruction of all forms of microbial life that cannot be eliminated by regular cleaning procedures.

Sterilization is categorized into different classes such as high temperature/pressure sterilization, chemical sterilization and radiation sterilization. Actually, sterilization techniques are known since 120 years – since the invention of the steam autoclave by Charles Chamberland in 1879. There is no single sterilization process that is suitable for all of the different needs derived by the vast range of products.

One possible side effect - sterilization can modify the bulk and surface properties of products. As an example heat sterilization, whether by dry heat or by steam, can cause thermal degradation of many plastics leading to physical and optical property changes. If the incorrect method is selected, the consequences for the medical device, patient and time to market can be catastrophic.

Sterilization of medical implants is of great importance in medicine. New technologies and electronic components in implant technology require continuously improved sterilization procedures.

The Fraunhofer FEP has developed a solution for the gentle sterilization of medical products. By means of low-energy electron beam treatment, the surface of the product to be processed is gently sterilized without damaging it. With this technology, it is even possible to safely sterilize extremely sensitive objects such as microchips, electronics, battery systems or even polymers up to biological tissue

or protein coatings. All functions are retained and information (e.g. in microchips) is not destroyed. Together with our industrial partners, we support our customers from the feasibility study through the biological and technical testing of your product up to the conception and integration of the systems into existing process chains.

APPLICATIONS

- Implants
- Surgical materials
- Medical instruments and devices
- Medical Sensors
- Electronics
- Biological tissues
- Pharmaceutical raw materials
- Disposables
- Dressing materials
- Dental material

TECHNOLOGY

Low-energy accelerated electrons can also be used to sterilize the surfaces of medical devices or packaging. Sensitive materials and products can be efficiently disinfected or sterilized within seconds using the environmentally friendly and material-friendly technology. The samples can be processed under atmospheric pressure and retain their product-specific properties. The accelerated electrons can also sterilize the product surface through packaging. In contrast to other sterilization processes that work with irradiation, sterilization with electrons up to 150 keV requires only simple, local radiation shielding. This makes the technology compact and easy to integrate into existing in-line process chains.

ADVANTAGES

Gentle	<ul style="list-style-type: none"> ▪ Defined penetration depth <200 µm ▪ Material-friendly conditions
Fast	<ul style="list-style-type: none"> ▪ Treatment time ms to s ▪ No preparation and postprocessing times
Simple	<ul style="list-style-type: none"> ▪ Sterilization directly within in the packaging ▪ Working under normal pressure/atmosphere
On-site	<ul style="list-style-type: none"> ▪ Low equipment costs ▪ Miniaturized system in planning
Safe	<ul style="list-style-type: none"> ▪ No use of toxic chemicals ▪ No radiation
Cheap	<ul style="list-style-type: none"> ▪ Low operating costs (electric current only)
Guaranteed	<ul style="list-style-type: none"> ▪ Destruction of all microorganisms (also viruses and spores) ▪ No known resistances
Efficient	<ul style="list-style-type: none"> ▪ Low energy consumption, max. 150 kV
Convenient	<ul style="list-style-type: none"> ▪ Fully automatic process, few parameters required for control
Verifiable	<ul style="list-style-type: none"> ▪ Validatable procedure according to DIN EN ISO 11137

→ Sterile products without influencing the material properties / functionality