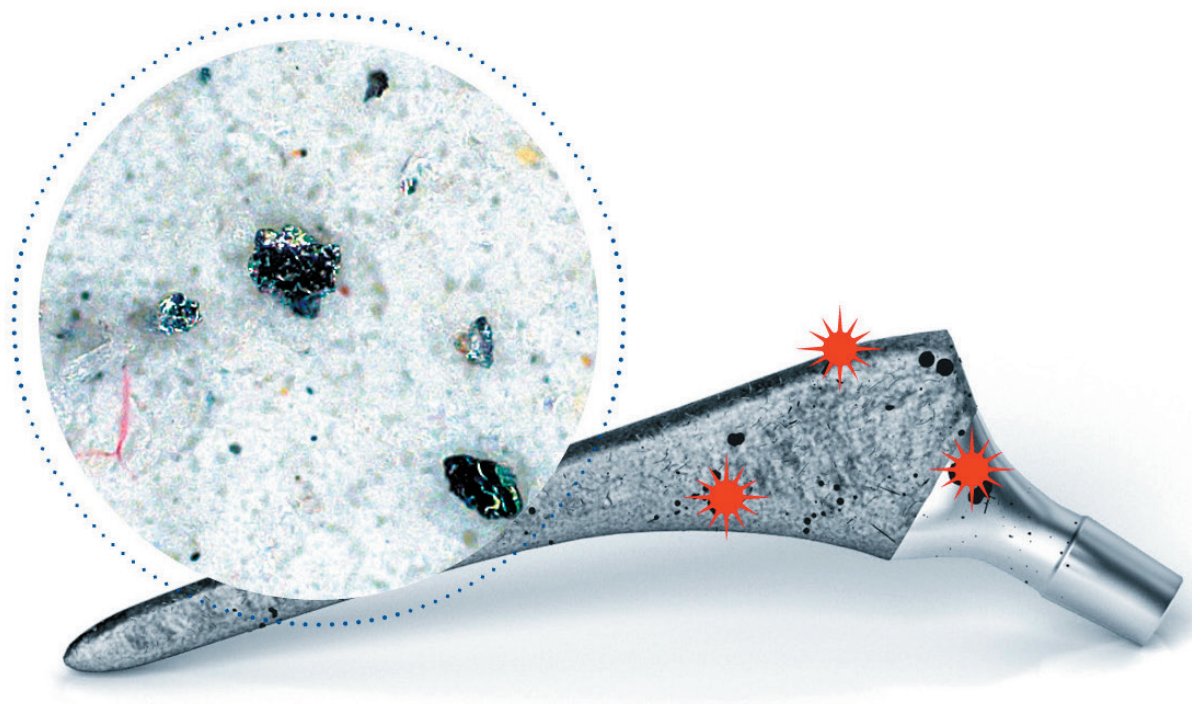


Technical paper

Identify critical particles on medical products

Importance of technical cleanliness in the manufacturing process



ZEISS Medical Industry Solutions

Quality Assurance for the Highest Medical Standards



Seeing beyond

Identify critical particles on medical products

Medical products have a direct impact on peoples' lives, the fitting of a contaminated implant would ultimately pose a high health risk to the patient. To avoid this, medical technology companies need to fulfill stringent regulatory requirements stipulated by various authorities regarding quality. Technical Cleanliness is a key factor for quality in all steps of the manufacturing area, with production processes, the production environment, and the final packaging all having an influence on component cleanliness. ZEISS Technical Cleanliness Solutions are ready for deployment at every step of the production process and help to detect and analyse particulates that should not be present, a mandatory requirement when looking to comply with regulations, whilst improving productivity through reduced scrap or rework.

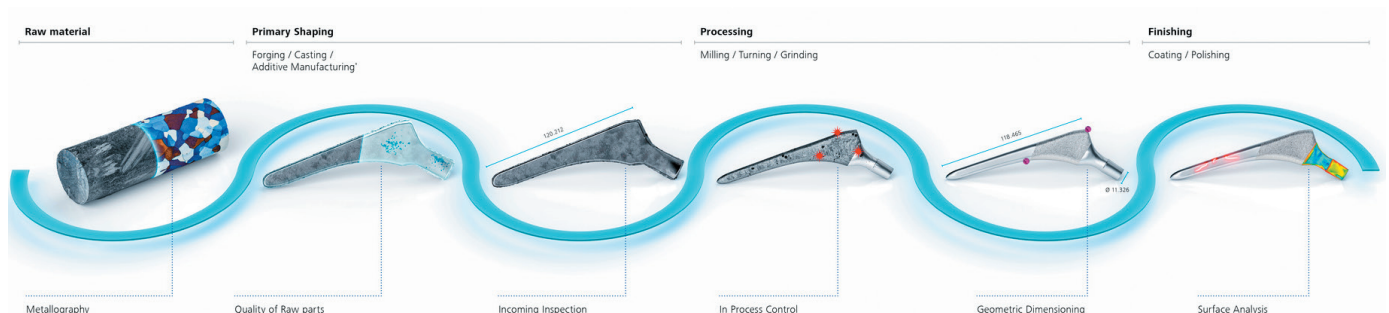
manufacturing. Various influences such as personnel, process equipment and process media can introduce contaminants into the manufacturing environment. Cleanroom personnel contribute a large percentage of all contamination found within the cleanroom. In this way medical products can also be contaminated in the production process. It is important to identify particle contamination as soon as possible, if not it is possible that the contamination leads to a stopping of the manufacturing process. Therefore, medical companies need to observe their in-process steps for part cleanliness. For the whole process it is crucial to combine particle detection and classification in a highly efficient workflow that not only finds particles, but also helps classify them by contamination or wear origin.

Importance of Technical Cleanliness in the manufacturing process

Particle contamination can cause critical medical influences if not found and dealt with. Particulate cleanliness has been a fundamental requirement in the medical technology sector for many decades, but problems linked to insufficient levels of cleanliness still tend to arise.

Total cleanliness cannot be fully reached despite the application of established cleanroom technologies. The residual risk of a clean room can always lead to critical contamination during

The quality gates in the production process from raw material to finished medical parts

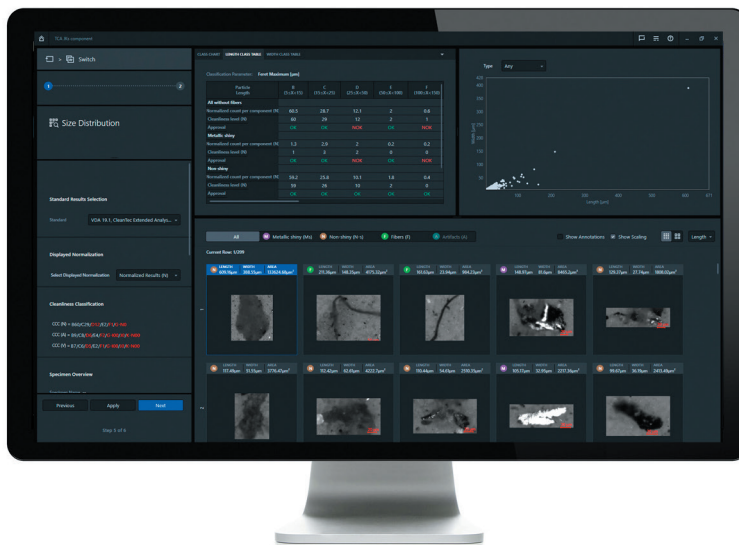


Increase your productivity with ZEISS Technical Cleanliness Solutions

In the Technical Cleanliness process, particles are removed from the medical component in the cleaning cabinet by water, air or ultrasound. During the process, the fluid flows through a filter whereby the particles are captured ready for analysis under the microscope.

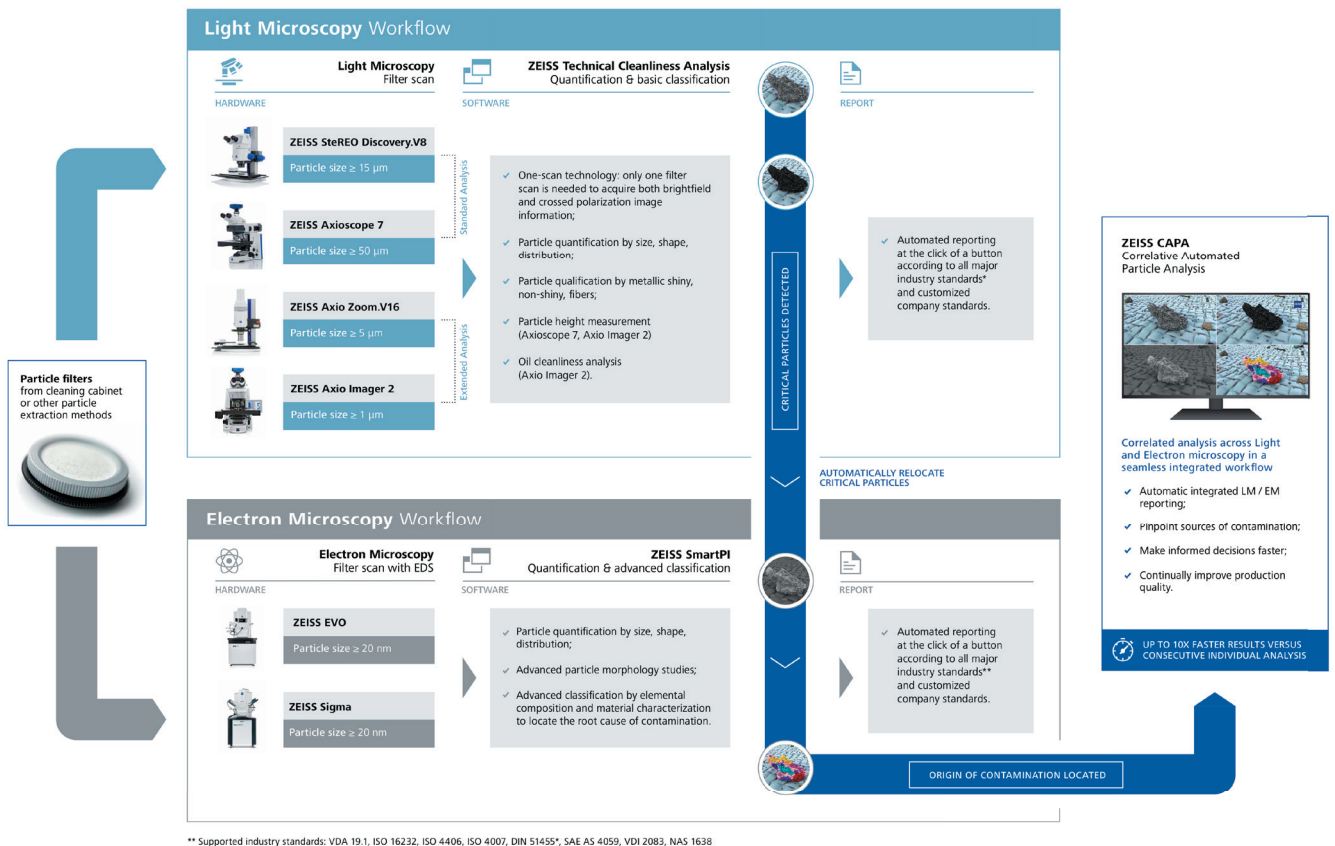
This filter, once dried, is placed under a ZEISS light microscope (e.g., ZEISS Axio Imager 2, ZEISS Axio Zoom V16) to detect all the non-metallic and metallic particles on the filter. The intuitive ZEISS ZEN core software then provides a guided workflow to analyze the particles that are on the filter. It lists all particles in a table and categorize them accordingly. There is no need to be an expert in microscopes or software operation due to the intuitive user interface as well as the guidance provided to the user when going through the application and workflow. The support by defined microscope hardware and software settings makes complex analysis processes much easier to perform and more reliable. The data is stored by the system and exported if required. In addition, the software is also capable of generating a report in accordance with the relevant standards. The software feature ZEISS ZEN Connect also connects this data to electron microscopy solutions, generating a seamless workflow for switching between these technologies. The new directive VDI 2083 sheet 21 gives manufacturers and users options to control the risk for patients due to contamination on medical devices.

A consistent implementation of regular quality controls for medical products, especially in the critical area of particulate cleanliness, which has not been consistently observed up to now, is therefore recommended. The additional work required for these tests is straightforward, but the safety benefit for users and patients is considerable. The ZEISS software for Technical Cleanliness Analysis already contains the VDI 2083 standard, sheet 21.



The intuitive ZEISS ZEN core software lists all particles in a table and categorize them accordingly

ZEISS Correlative Particle Analysis Workflow



Identify the root cause, make the right decision faster

The functionality of the direct retrieval of highlighted particles from a light microscope to an electron microscope boosts productivity and efficiency by providing immediate access to the dedicated analysis view in the high-resolution electron microscope.

To find out more about the particles, the filter is placed in an electron microscope such as ZEISS EVO or ZEISS Sigma. Its connected system makes it easy to find the individual particles with the support of ZEISS SmartPI SEM Software. The use of a uniform portfolio uniquely enables the user to save the coordinates of critical particles on the filter and therefore identify the particle type with the ZEISS SmartPI software. The system then analyses the material, how it is built up, and can assist the user to determine where the contamination has potentially come from. After all, the chemical composition of the particles is determined by EDS measurement to determine their origin.

ZEISS SmartPI provides much more than size, shape, distribution, and corresponding particle morphology. It also provides chemical composition and material characterization. Thereby enabling the user to locate the root cause of contamination.

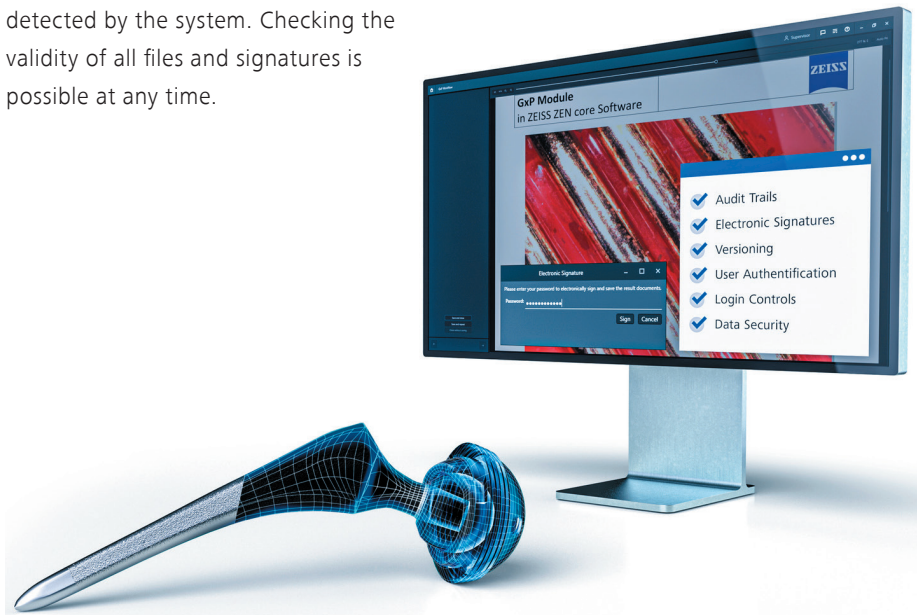
Medical Quality Management Regulation

Global companies need to fulfill the regulations of various authorities. In Europe for example, these rules are defined in different EC directives (regulations and guidelines of the European Communities) and summarized in the MDR (Medical Device Regulation). In the USA, the Food and Drug Administration (FDA) is the relevant regulative body. Additionally, China, Canada, South America etc. have their own guidelines.

21 CFR Part 11 in the FDA's Code of Federal Regulations defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records. Companies in the medical industry are required to implement procedures for software and systems that are used to process electronic data regulated by the FDA.

With the new GxP function, it is possible to trace every work step without gaps. The laboratory manager defines the workflows, where he can use ZEISS ZEN core modules specified by the software. Data is stored in the database (cloud or

on premise) and each result is signed, which protects against subsequent manipulation. Every change is precisely recorded. Any incorrect result or deviation from the specified steps is detected by the system. Checking the validity of all files and signatures is possible at any time.



Services from ZEISS Industrial Quality Solutions

Technical Cleanliness is rapidly growing in importance within the medical industry. At ZEISS, we help professionals understand our systems and bring them closer to the handling of our machines.

We provide assistance for everything from construction, service, and repair to employee training on correct use of the equipment. We are always available and at your side every step of the way. Our Demo Center is fully equipped to prepare you for every aspect of our machines.

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