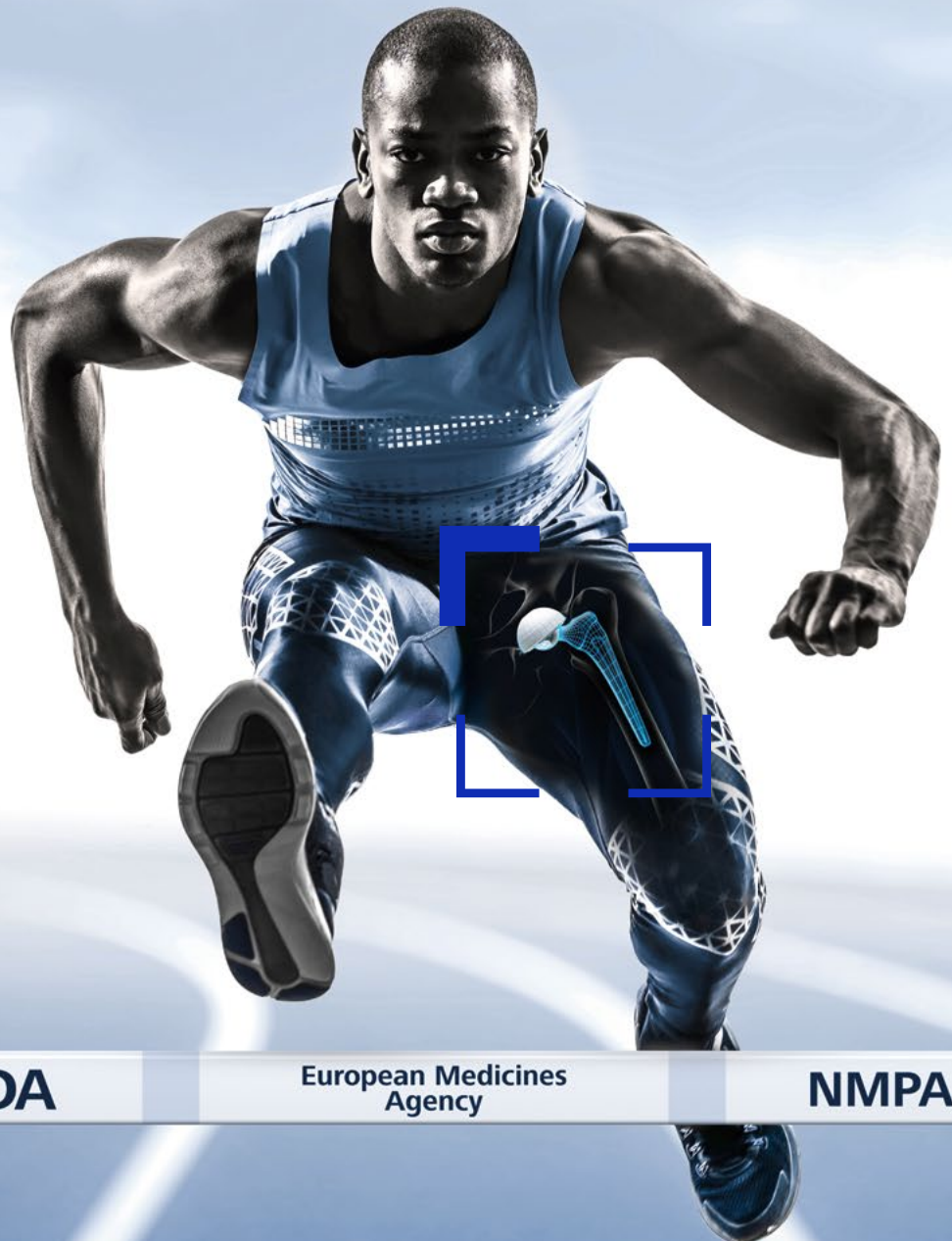


Quality Assurance for the Highest Medical Standards.



Seeing beyond

ZEISS Medical Industry Solutions



FDA

European Medicines
Agency

NMPA

ZEISS Medical Industry Solutions:

Overcome the hurdles of a
regulation-driven industry



Quality and Compliance

The hurdles of the medical industry

ZEISS understands your challenges

With its high regulatory requirements and a large number of products that have a direct impact on the quality of people's lives, the medical technology industry depends on reliable quality assurance systems.

ZEISS understands the regulations, requirements, and the challenges faced by manufacturers and their quality departments. Our connected quality intelligence portfolio offers tailored hardware and software solutions that fulfill industry standards and work as a coherent system, granting manufacturers the certainty they need to achieve the productivity they desire.

Proof of Quality

Authorities and patients demand the proper application of quality assurance results that are verifiably 100% correct. However, the large number of different medical technology components made from a range of materials and featuring diverse shapes – from small plastic parts in insulin pumps through to implants made of ceramics and metals – represents a direct challenge to the quality process.

Guideline Compliance

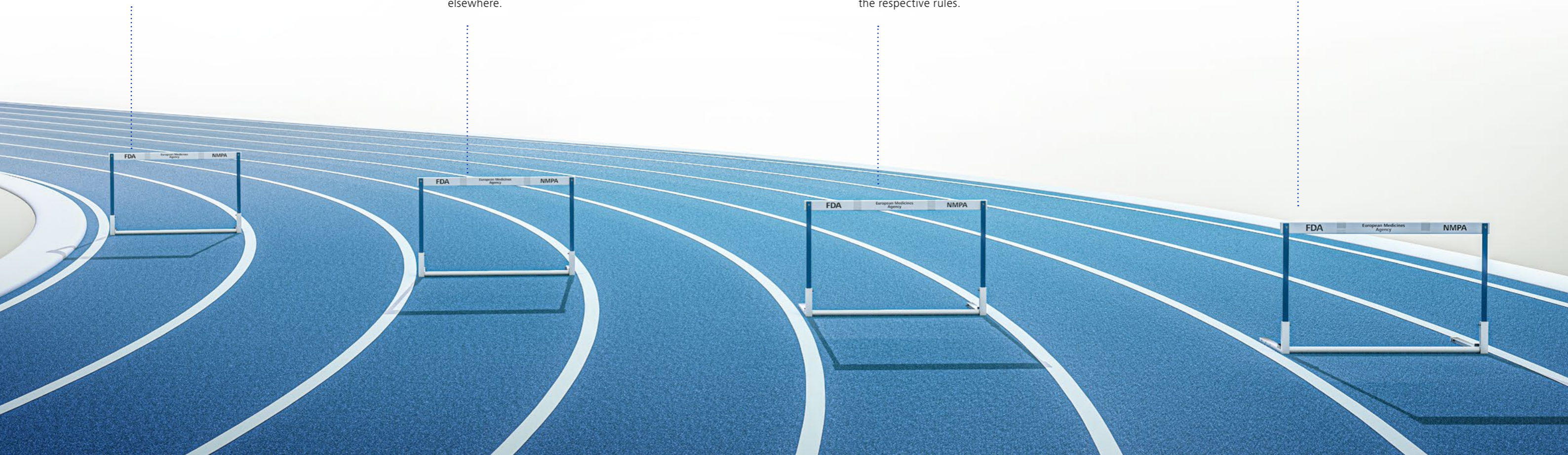
Global companies need to fulfill the regulations of various authorities. In Europe, for example, these rules are defined in different EC directives (regulations and guidelines of the European Communities) and summarized in the MDR (Medical Device Regulation). In the USA, the Food and Drug Administration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

Data Handling Regulations

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. It requires companies in the medical industry to implement controls for software and systems that are used to process electronic data regulated by the FDA. The GxP (Good 'X' Practice) guidelines serve as a best practice handbook to help manufacturers comply with the respective rules.

Quality Management Regulations

ISO 13485:2016 is a comprehensive management system that specifically addresses the production of medical devices. The FDA's equivalent is 21 CFR Part 820, a quality system regulation for all finished products and devices intended for human use. Manufacturers need to ensure that these norms are met by their quality management processes and by all of their suppliers.



Clearing all Hurdles

With the connected ZEISS portfolio

To fulfill the regulatory demands of medical technology authorities, manufacturers must go beyond the usual requirements in quality assurance. Not only must industry-specific workflows be correctly set up, manufacturers must be able to document and validate that these workflows are consistently followed. To this end, quality assurance hardware and software must work hand in hand to provide appropriate functionality.

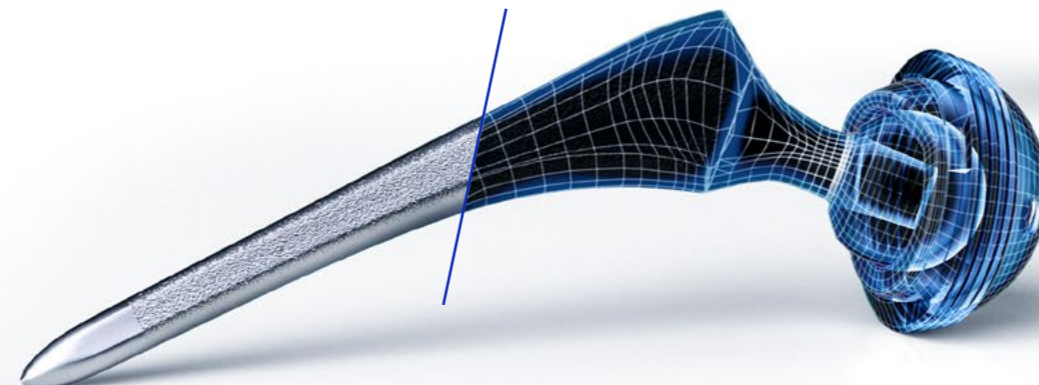
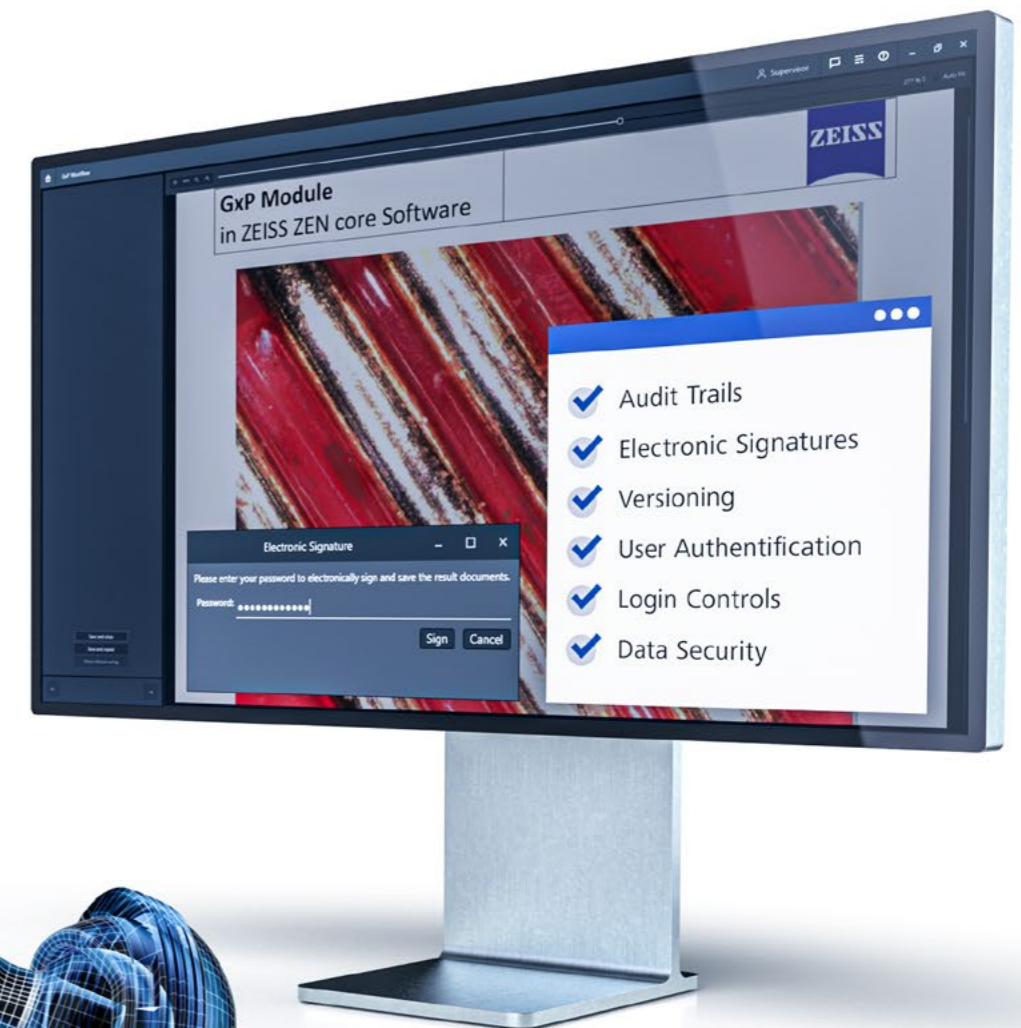
ZEISS offers a comprehensive and connected portfolio of hardware solutions that includes tactile and optical coordinate measuring machines (CMMs), 3D scanners, microscopes as well as CT and X-ray solutions. Our customers benefit from class-leading resolution, accuracy, measurement speed and powerful automation functions.

The key for regulatory compliance however lies in the ZEISS software that fits the hardware perfectly and supports manufacturers in fulfilling their required step-by-step processes. For example, we offer a GxP module for our microscopes and their unified ZEISS ZEN core software.

With over 100 years of experience in metrology and quality assurance solutions and our longstanding experience as a global supplier that knows the global regulation requirements, manufacturers find in ZEISS a trusted one-stop solution provider that helps them achieve their quality, efficiency and compliance goals.

ZEISS software solutions include:

- Compliance with the requirements of DIN EN ISO 13485 and FDA 21 CFR Part 11
- Secure user management
- Integration of audit trail and release management
- Automated creation of certificates and manufacturer test certificates
- Continuous validation
- Versioning of documents and protection from modification
- Detailed authorization concepts including electronic signatures
- Disaster recovery
- Company-wide online performance indicators and key performance indicators



Quality Solutions

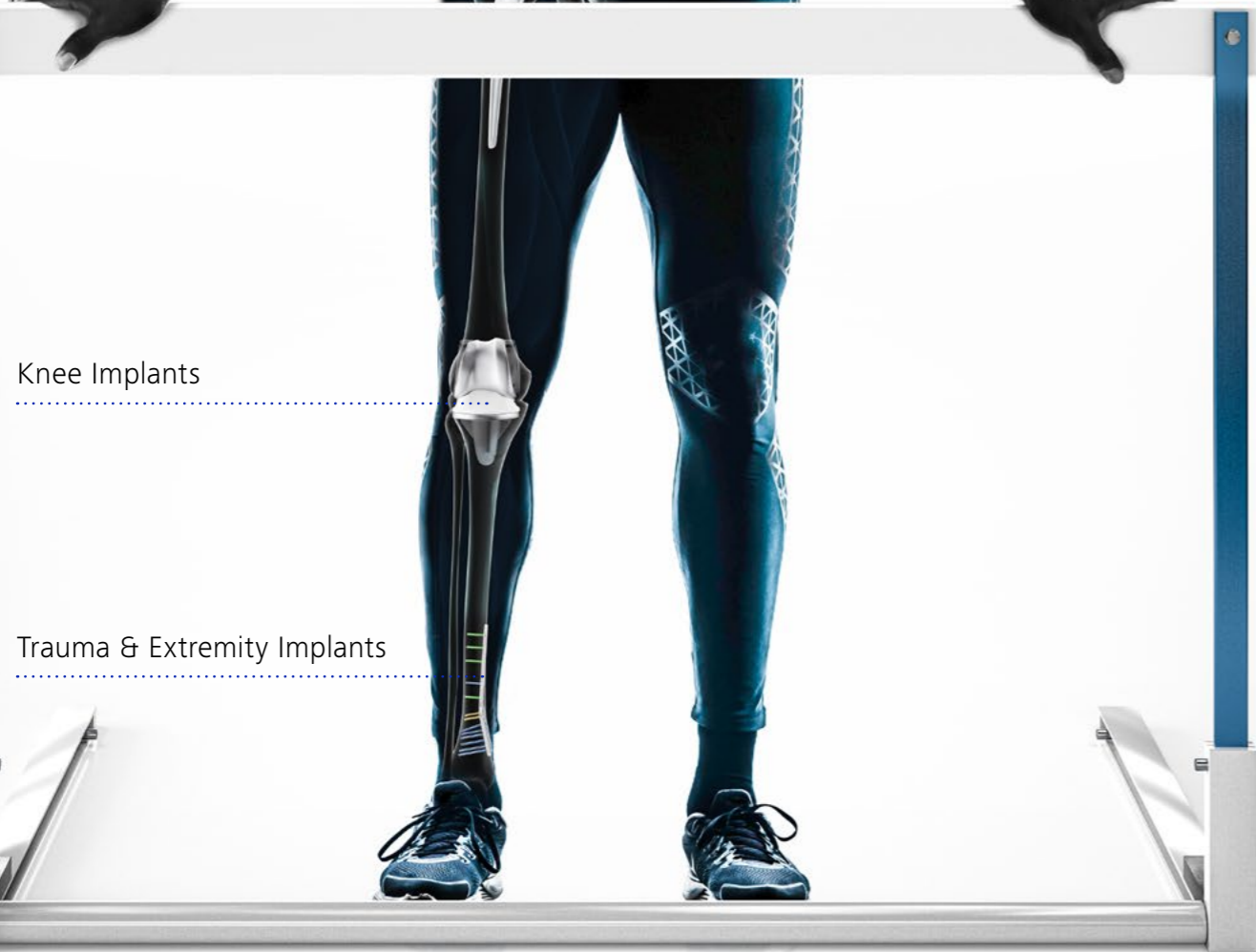
For all types of implants

Dental Implant

Shoulder Implants

Spinal Implants

Hip Implants



Knee Implants

Trauma & Extremity Implants

Implants remain in the human body for years or decades and must function flawlessly in terms of mechanics and biology. This leads to exceptionally high quality requirements and an enormous responsibility on the part of manufacturers to fulfill them.

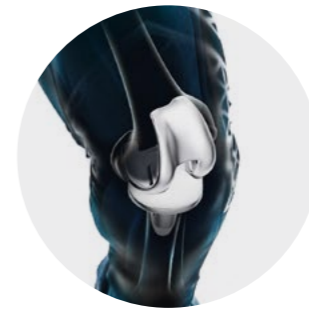
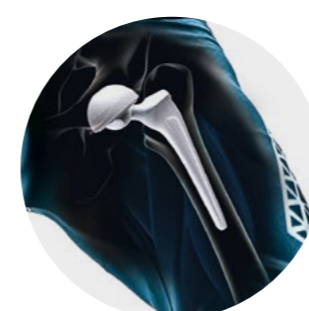
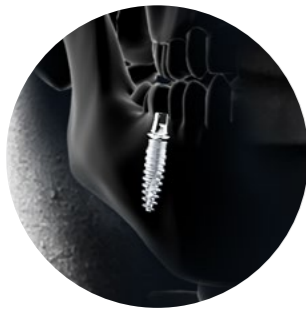
For example, ensuring biocompatibility is essential – the implant must not trigger an immune response. It is also important that the implant functions mechanically, withstands stress, and is durable. The most stringent regulatory requirements, such as FDA Class II or III and FDA 21 CFR Part 820, must be met. A diverse range of materials is therefore used in implants today, ranging from plastic (polyethylene, PEEK, UHMWP, etc.) to various metal alloys (stainless steel, titanium alloy, etc.). Each manufacturing process has its specific quality challenges that require specialized equipment and processes. ZEISS delivers a connected quality control solution portfolio for all types of implants and every quality gate in their respective manufacturing processes.


















Assure Quality

Overview of orthopedic implants

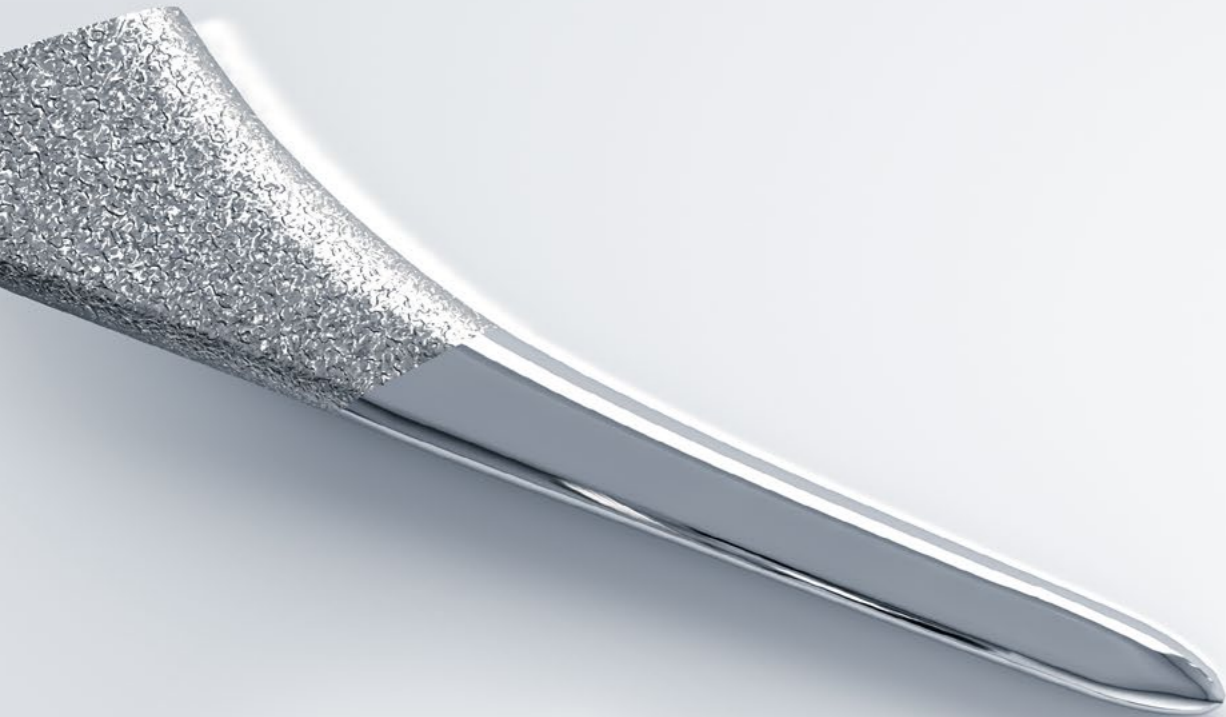
Different implants, same manufacturing processes

Despite the diverse range of implants, fixation options, and solutions, the manufacturing processes of the individual components remain similar. Due to their material properties, orthopedic implants can be classified according to the manufacturing processes. This enables us to offer tailored quality solutions in the individual segments, which boosts productivity in your process. The following sections introduce our solutions for the metal and plastic processes, including the relevant quality gates along the entire production chain.



Dental Implant	Shoulder Implants	Spinal Implants	Hip Implants	Knee Implants	Trauma & Extremities	Manufacturing Process
 Implant	 Peripheral Screws	 Monoaxial Pedicle Screw			 Bone Screws	Metal Working
	 Glenosphere	 Spinal Rods	 Acetabular Cup	 Femoral Implant		Metal Working
	 Glenoid Implant		 Polyethylene Liner	 Tibial Insert		Plastic
			 Femoral Head			Ceramic & Metal Working
	 Humeral Stem	 Intervertebral Disc	 Femoral Stem	 Tibial Tray	 Bone Plate	Metal Working

Metal Working Process



Orthopedic implants must function flawlessly even under the demanding physiological conditions in the human body. This makes it a central requirement for manufacturers to gain a deep understanding of orthopedic materials – metallic compounds, ceramic, and polymers – and the resulting organic reaction. One of the most important steps in the metal working process is assessing the raw material properties to ensure the performance of the product. Other important challenges are the geometric dimensioning, technical cleanliness during the manufacturing process, and efficiency gains through minimizing waste.

From Raw Material to Finished Parts

Quality gates and solutions

Raw Material

Primary Shaping

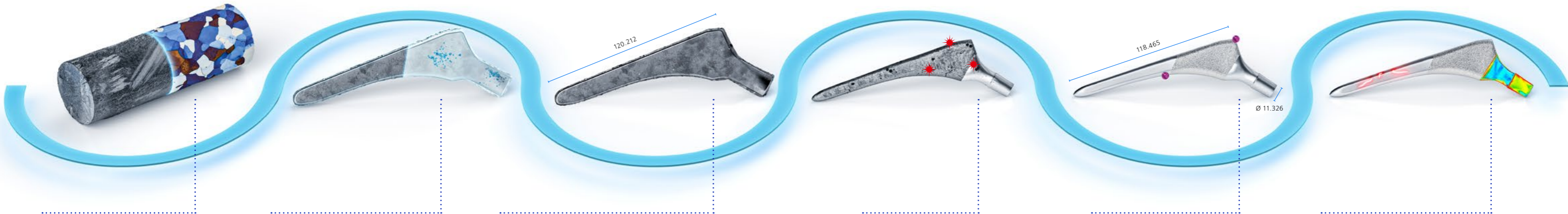
Forging / Casting / Additive Manufacturing*

Processing

Milling / Turning / Grinding

Finishing

Coating / Polishing



Metallography

Analyze the structure and evolution of your steel and other metals from micro to nano scale. Accurate characterization enables maximum understanding for the quality of your raw material in terms of purity, non-metallic inclusions, and grain size analysis.

Quality Solution:

Microscopy Analysis

Metallography investigations with light microscopes or material analysis with scanning electron microscopes. Qualify composition of raw powder or bulk material. Analysis of grain structure, chemical composition, and inclusions possible at nano and micro level.

Quality of Raw Parts

The primary shaping process can be controlled and optimized in all process steps from tool to product. This ensures that the initial part form is free of fissures, voids, cracks, and critical inclusions. Defining the acceptance criterion enables immediate disposal of bad parts.

Quality Solution:

Void Inspection

CT and X-ray inspection with our ZEISS METROTOM and ZEISS BOSELLO systems.

Geometrical Inspection

Full-field dimensioning and virtual assembly of tool and form components using optical 3D metrology.

Incoming Inspection

Verify if the product arrived at your warehouse in the required condition before accepting it into your stock – and avoid unnecessary processing of bad parts. Optimize your machining time and potentially turn waste parts into products.

Quality Solution:

Efficient Inspection

Fast geometric dimensioning measurement e.g. with ZEISS DuraMax, ZEISS CONTURA.

Full-Field Inspection

Full-field automated inspection and optimization with optical 3D metrology.

Process Control

Observe your in-process steps dimensionally to avoid further processing of scrap parts. Detect and classify particulate contamination to fulfill the medical industry standards. This can be checked throughout the entire manufacturing process.

Quality Solution:

Technical Cleanliness

Characterize process-critical particles and identify killer particles using correlative microscopy, which combines your data from both light and electron microscopes in a single workflow.

Process Monitoring

Check your semi-finished parts using a ScanBox to avoid unnecessary further processing.

Geometric Dimensioning

The final check for permitted variations between the produced component and the nominal CAD model presents a particular challenge. Most implants have finished or polished surfaces, so optical quality assurance can be required.

Quality Solution:

Precise Measurement

Industry-leading precision using ZEISS CONTURA or ZEISS PRISMO equipped with our VAST technology, ZEISS DotScan, or our multisensor CMM ZEISS O-INSPECT. And fully automated batch inspection using a ScanBox.

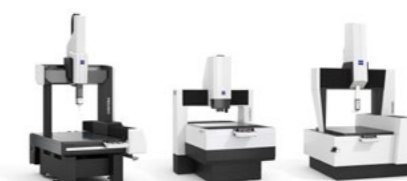
Surface Analysis

In a final step, the finished product must be checked to guarantee the correct layer thickness and flawless surface quality.

Quality Solution:

Visual Inspection

ZEISS solutions enable mapping, imaging, and measuring of layer thickness and surface characteristics in multiple regions of interest, e.g. with ZEISS LSM 900, ZEISS EVO and ZEISS Axio Imager



Solutions

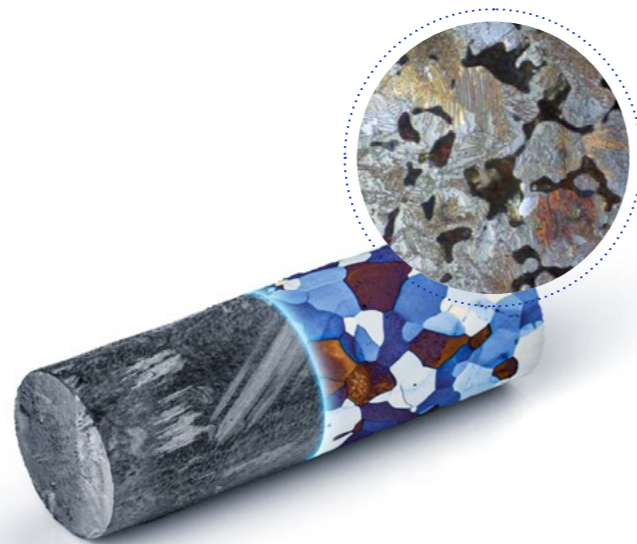
For quality gates

Metallography

Analysis of raw material

Challenge:

- Assure constant quality of material, e.g. with respect to porosity, voids, cracks, fissures, and grain size
- Rapidly identifying common inclusion types found in metal
- Assessing the material further by determining its chemical composition
- The phase of the titanium (Ti) alloys can affect the strength and elasticity of the final component. Different Ti alloys will have different phases – this may depend on the other elements present and the heat treatment undergone by the component
- Identifying the source of failure via insights relating to the macro, micro, and nano structure



Quality Solution:

Microscopy Analysis

- A portfolio of connected and correlative solutions for quantifying the chemistry, crystallography, topography, and tomography of cracks, fissures, and deformations in your metallic samples
- Optical, electron, and X-ray imaging, plus energy dispersive X-ray spectroscopy, electron backscatter diffraction, and focused ion beam milling techniques including non-destructive large-volume techniques using X-ray microscopy
- Software solutions designed around the user to quickly generate actionable information for solving and preventing recurrence of failures

Added Value

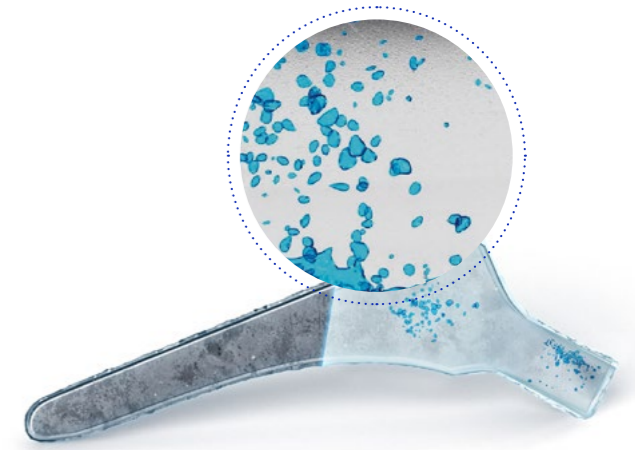
- Confirm that the manufacturing processes, the product grade and quality, and the material characteristics meet the strict specifications
- Assess minor impurities or defects that can cause a component to fail
- Determine the root cause of failure to improve overall reliability

Quality of Raw Parts

Inspection of primary shape

Challenge:

- Verifying that the components feature a good shape and specified dimensional quality prior to acceptance
- Checking parts for critical defects such as voids, cracks, and inclusions before further processing
- Gathering information on the number, type (inclusion, crack, void), size (dimensions, volume), position (e.g. distance to outer surface), and distribution of defects



Quality Solution:

Void Inspection

- Visual inspection of your incoming goods
- All defects inside the part can be detected
- Rapid location of defects without destroying the component
- Bosello systems for fast and automated 2D inspections
- ZEISS METROTOM systems for high-precision 3D inspection
- ZEISS Xradia systems for high-resolution 3D analysis and inspection

Geometrical Inspection

- Inspection of complete shape and assembly of process tools
- Validation of unfinished products to reduce waste
- ATOS sensors for full digitization of components

Incoming Inspection

Efficient verification of supplied parts

Challenge:

- Ensuring supplied parts are within the margins for machining and processing
- Verifying the allowance on machining areas
- Fast inspection cycle times to reduce probability of bottlenecking
- Tracking warping or bending that happens after heat treating

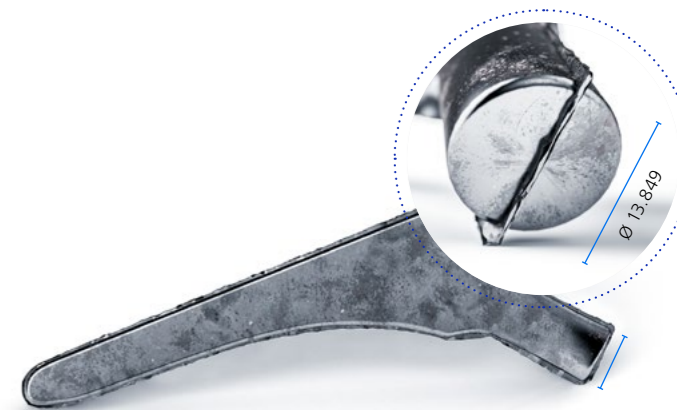
Quality Solution:

Efficient Inspection

- CMMs (ZEISS DuraMax, ZEISS CONTURA) inspect forged part surfaces with the highest possible accuracy – results can be trusted, changes to the die or forging process are traceable
- Fringe projection sensors (e.g. ATOS Q) allow a complete evaluation of the forged part surface by comparing it to the CAD data

Full-Field Inspection

- Verification of material allowance on entire part
- Alignment on milling machine for machine time reduction
- Creating a geometrical digital twin using optical 3D metrology



Added Value

- Fast inspection of the incoming goods to prevent cost-intensive failures later in the manufacturing process
- Incorrect stock can lead to subsequent additional production costs that must be reimbursed by the supplier. A careful inspection of incoming goods can prevent this, ensuring that only the correct quality is used in the production process

Added Value

- Programmable inspection plans that can be executed in CNC
- Quality control during production allows elimination of existing defects prior to further processing
- Cost-intensive rejects and complicated repairs can be avoided

Solutions

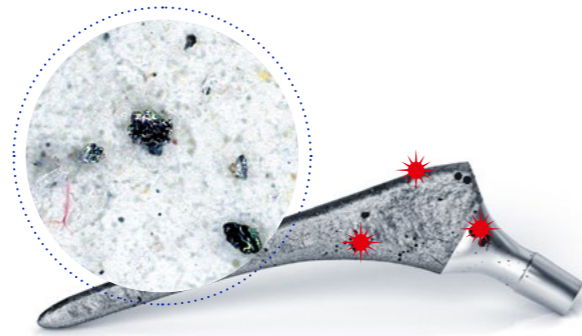
For quality gates

In-Process Control

Observation of processing quality

Challenge:

- Suppliers, manufacturers, and end users demand ever-increasing quality standards, so an advanced technical cleanliness program is fundamental to eradicating contamination of manufactured parts and components along the entire production process
- Manufacturing processes vary. Inspection of in-process steps is required to monitor processing and avoid unnecessary additional scrap



Quality Solution:

Technical Cleanliness

- Automated Particle Analysis with light and electron microscopes: Detect and classify particulate contamination to fulfill industry standards and GxP regulations
- ZEISS Technical Cleanliness Analysis (TCA) with medical standards (VDI 2083 Part 21: Cleanliness of medical devices in the manufacturing process, GxP compliance & traceability of workflows for medical companies)

Process Monitoring

- Using optical 3D metrology for manual or automated inspection of any process step to avoid further processing of scrap parts

Added Value

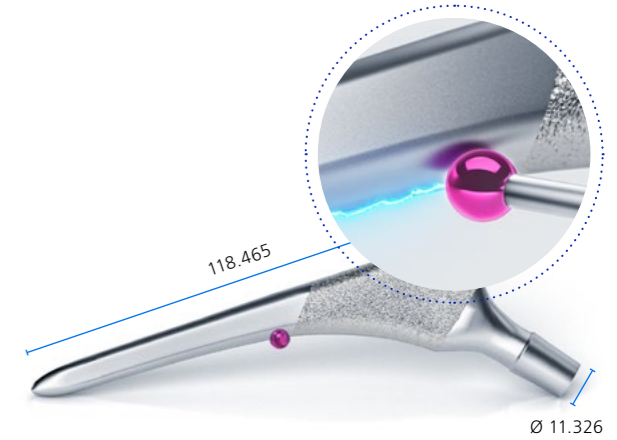
- Quantify particulate contamination according to medical standards
- Combine particle detection and classification in a highly efficient workflow that not only finds particles, but also helps classify them by contamination or wear origin
- Avoid scrap parts or even turn these into finished products
- Reduce machining time

Geometric Dimensioning

Final dimensioning

Challenge:

- Critical factors for quality assurance are cycle time and the reliability of results
- Expensive material and difficult machining drive require manufacturers to make the forged part small with minimal material removal
- An optical inspection may be required if the parts have highly polished sections and cannot be touched due to the risk of micro scratches
- Tight profile tolerances on polished surfaces are a challenge for traditional inspection methods



Quality Solution:

Precise Measurement

- ZEISS PRISMO inspects parts without compromising on speed or accuracy
- ZEISS CONTURA with ZEISS LineScan can quickly scan the hip stems and produce comprehensive false color maps of the deviations
- ZEISS O-INSPECT with its multisensor array allows ease of use moving between tactile and optical sensors
- ZEISS DotScan enables the possibility of measuring tight profiles on polished surfaces
- ZEISS METROTOM can measure interior and exterior features simultaneously
- Manual and automated ATOS systems automatically inspect batches of parts
- Complete dimensioning and evaluation of the characteristics included in the report

Added Value

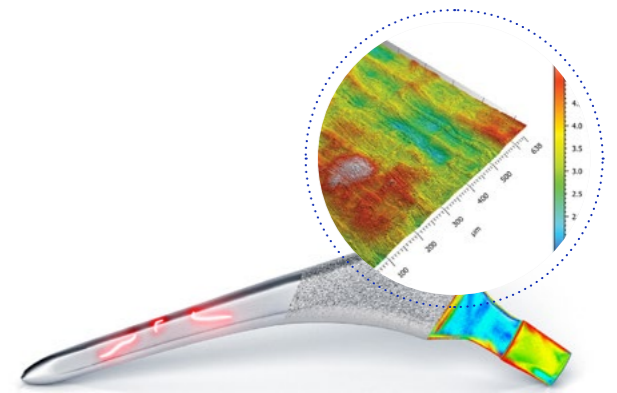
- Increase usable acceptance range by decreasing measurement uncertainty
- Reduce operator influence and needed time for manual inspection by using CNC inspection

Surface Analysis

Final visual inspection

Challenge:

- Polishing results in a mirror-like finish that poses challenges for optical inspection
- Check surface morphology on critical surfaces
- Final inspection without operator influence



Quality Solution:

Visual Inspection

- ZEISS Axio Imager, ZEISS EVO, and ZEISS LSM 900 can provide morphological results on highly reflective surfaces by optical means

Added Value

- Fast contactless evaluation of roughness
- Reproducible and fast results in final inspection

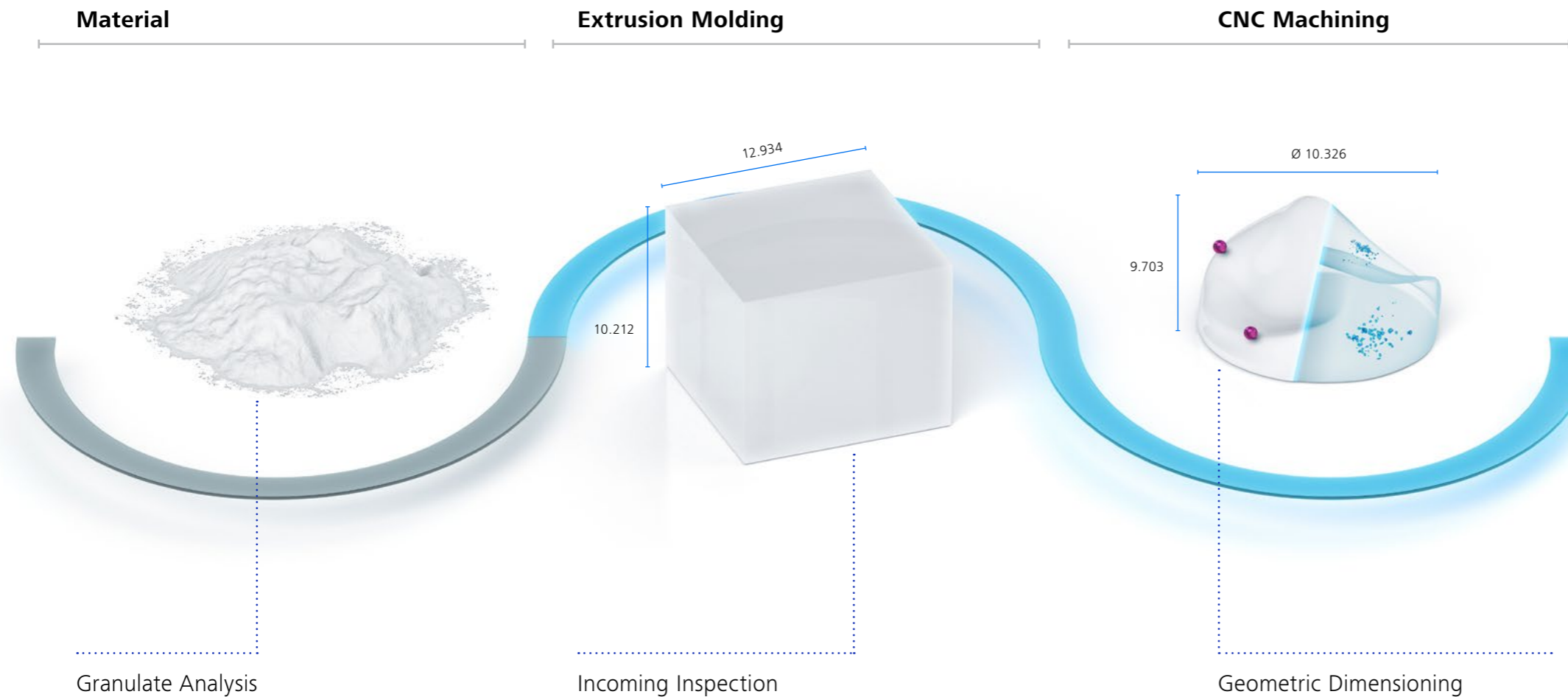
Plastic Manufacturing Process



The manufacturing process enables highly efficient production of plastic implants, either in large batches or individually. In some cases, these are individual parts that have been specifically manufactured for the patient. This is because the great advantage of plastics in medicine is that they can be shaped in a variety of ways and can therefore be ideally adapted to the respective needs of the patient. Ultra-high-molecular-weight polyethylene (UHMWPE) has enjoyed particular success in medical implant applications due to its high abrasion resistance, toughness, and biochemical inertness. The precise manufacture of these parts, which feature complex geometries and are sometimes very small, is now technologically possible thanks to ultra-modern machines and systems.

From Raw Material to Machined Parts

Quality gates and solutions



Granulate Analysis

Incoming Inspection

Geometric Dimensioning

Verify if the product arrived at your warehouse in the required condition before accepting it into your stock – and avoid unnecessary processing of bad parts. Securing high level of technical cleanliness for incoming components

Quality Solution:

Efficient Inspection

Fast geometric dimensioning measurement e.g. with ZEISS DuraMax.



The final check for permitted variations between the produced component and the nominal CAD model presents a particular challenge. Most implants have finished or polished surfaces, so optical quality assurance may be required.

Quality Solution:

Precise Measurement

Industry-leading precision using ZEISS CONUTRA equipped with our VAST technology, ZEISS DotScan, or our multisensor CMM ZEISS O-INSPECT.

Shape and Dimensional Inspection

Performed with ATOS systems.

ZEISS METROTOM 6 scout can additionally be used for internal defects.



Solutions

For quality gates

Incoming Inspection

Efficient verification of stock

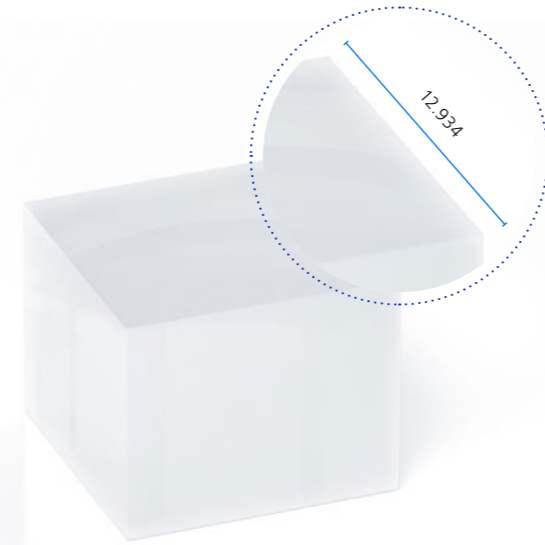
Challenge:

- Ensuring stock material is within the margins for machining and processing
- Fast inspection cycle times to reduce probability of bottlenecking

Quality Solution:

Efficient Inspection

- CMMs (ZEISS DuraMax, ZEISS CONTURA) inspect part surfaces with the highest possible accuracy
- Fringe projection sensors (e.g. ATOS Q) allow a complete evaluation of the forged part surface by comparing it to the CAD data



Added Value



- Programmable execution plans that can be executed in CNC
- Quality control during production allows elimination of existing defects prior to further processing
- Cost-intensive rejects and complicated repairs can be avoided

Geometric Dimensioning

Final dimensioning

Challenge:

- Critical factors for quality assurance are cycle time and the reliability of results
- An optical inspection may be required if the parts have highly polished sections and cannot be touched due to the risk of micro scratches
- Tight profile tolerances on polished surfaces are a challenge for traditional inspection methods

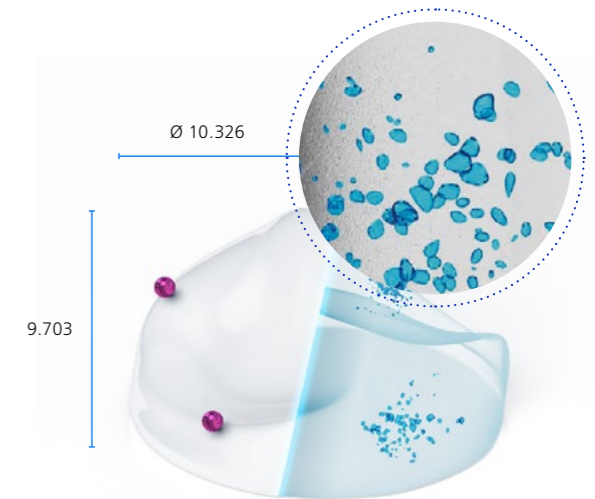
Quality Solution:

Precise Measurement

- ZEISS PRISMO inspects parts without compromising on speed or accuracy
- ZEISS CONTURA with ZEISS LineScan can quickly scan the hip stems and produce comprehensive false color maps of the deviations
- ZEISS O-INSPECT with its multisensor array allows ease of use moving between tactile and optical sensors
- ZEISS DotScan enables the possibility of measuring tight profiles on polished surfaces
- ZEISS METROTOM can measure interior and exterior features simultaneously
- Complete dimensioning and evaluation of the characteristics included in the report

Shape and Dimensional Inspection

- ATOS systems to inspect the digital twin of the component
- ZEISS METROTOM 6 scout to measure interior and exterior features simultaneously



Added Value



- Increase usable acceptance range by decreasing measurement uncertainty
- Reduce operator influence and needed time for manual inspection by using CNC inspection

ZEISS Portfolio

Our propositions for the medical industry



Software for Automation & Reporting



ZEISS PiWeb

Reporting & statistical analysis

Scalable reporting and statistical analysis software that helps you transform quality data into meaningful results.



ZEISS FACS

Automation software

Flexible automation software that boosts productivity by incorporating loading systems into fully automated measuring processes.



Volume Inspect

Trend analysis for volume data

With Volume Inspect, you can look inside your part and analyze geometries, voids, internal structures, and assembly situations. Intuitive operation, high performance: CT data analysis has never been easier!



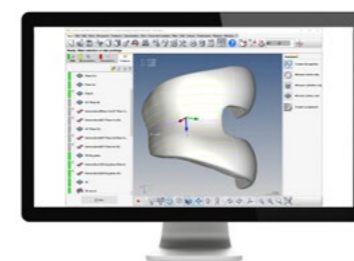
Software for Regulatory Demands



ZEISS ZEN core with GxP Module

Microscopy software suite

ZEN core is the most comprehensive suite of imaging, analysis, and connectivity tools for multi-modal microscopy in connected material laboratories. The GxP module makes all your analyses traceable and therefore compliant with regulation and certification requirements.



ZEISS CALYPSO

Metrology software

With ZEISS CALYPSO, you can measure your workpiece easily, quickly, and reliably. In addition to comprehensive identity management (e.g. via LDAP) and the comparison of inspection plan versions, a wide range of functions provide security and increase efficiency.



Light Microscopy System



ZEISS Visioner 1

Visual inspection

Digital microscope with real-time all-in-focus visualization for even the most comprehensive inspection tasks and corresponding documentation.



ZEISS Axio Zoom V.16

Automated inspection and analysis

Perform accurate and repeatable analyses with this fully automated digital zoom microscope that supports rapid large-field scanning and extended analyses requirements.



ZEISS Axio Imager 2

High-resolution analysis

Meet your high-resolution optical analysis requirements with this fully automated microscope for fast and precise measurement of various applications.

ZEISS Portfolio

Our propositions for medical industry



ZEISS EVO
C-SEM with EDS

Utilize this SEM/EDS system for routine failure or particle analysis applications. ZEISS EVO enables imaging and analysis of non-conductive samples, such as particle filter membranes.



ZEISS LSM 900
Surface characterization

The ZEISS LSM 900 confocal laser scanning microscope is the ideal instrument for your material analysis: It allows you to characterize the surface topography of 3D microstructures.



ZEISS Sigma
FE-SEM

The field emission SEM for high quality imaging and advanced analytical microscopy. The ZEISS Sigma family combines field emission scanning electron microscope (FE-SEM) technology with an excellent user experience.



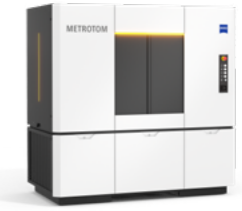
ZEISS BOSELLO MAX
2D X-ray inspection

Fast, non-destructive 2D scans of safety-relevant parts. Equipped with X-ray sources from 160 kV up to 450 kV or micro-focus sources up to 150 kV.



ZEISS METROTOM 800
225 kV HR
Measure and inspect inner structures

With an industrial CT system from ZEISS, you can perform complete measuring and defect analysis via a single X-ray scan. Suitable for fast scanning even of more dense parts.



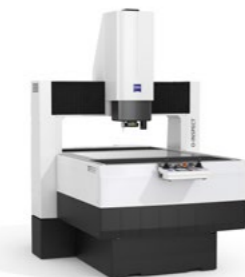
ZEISS METROTOM 6 scout
The powerhouse of resolution for CT inspection and metrology

ZEISS METROTOM 6 scout digitizes complex parts including the internal geometries at the finest level of detail. You get a complete 3D image for GD&T analyses or nominal-actual comparisons. The metrology CT excels at digitizing small plastic parts in particular.



ZEISS DuraMax
Shop floor inspection

Stable scanning measurements across a large temperature range. Featuring a space-saving design and not requiring any compressed air, the DuraMax can go anywhere along the production line.



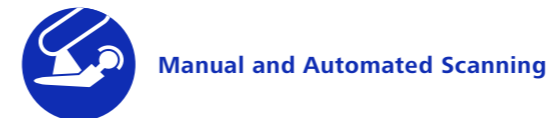
ZEISS O-INSPECT
Multisensor CMMs

Suitable for components where tactile precision is needed, but also where an optical solution is required for surface-sensitive sections. For optimum measuring of every characteristic, every time.



ZEISS CONTURA
Bridge-type CMMs

Measurement results with high accuracy are particularly important for quality assurance. Bridge-type coordinate measuring machines from ZEISS ensure you are prepared today for the measuring requirements of tomorrow. The various solutions and systems can be tailored directly to individual requirements.



ATOS Q
ATOS compact class

This industrial, non-contact, structured 3D light scanner delivers precise scans with detailed resolution at high speed. The light and flexible 3D scanner ATOS Q is ideal for small to medium-sized components.



ScanBox
Measurement of small complex components

Fully automated digitization and inspection to ensure an operator-independent measurement process. Combination with ATOS sensors ensures high-accuracy handling of even the smallest details.

Your Global Partner – Present in all regions

32

Sales & Service
Organizations

10

Production Sites

63

ZEISS Quality
Excellence Centers

100

Business Partners

As medical parts are rarely produced in a single location, measurement and inspection issues can occur in any country and at any supplier. Our global network of application engineers and service technicians provide quality assurance solutions to help you keep traceability and quality at a consistently high level.

Want to know which solution
is perfect for you?

**Get in contact with our
global medical experts.**



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