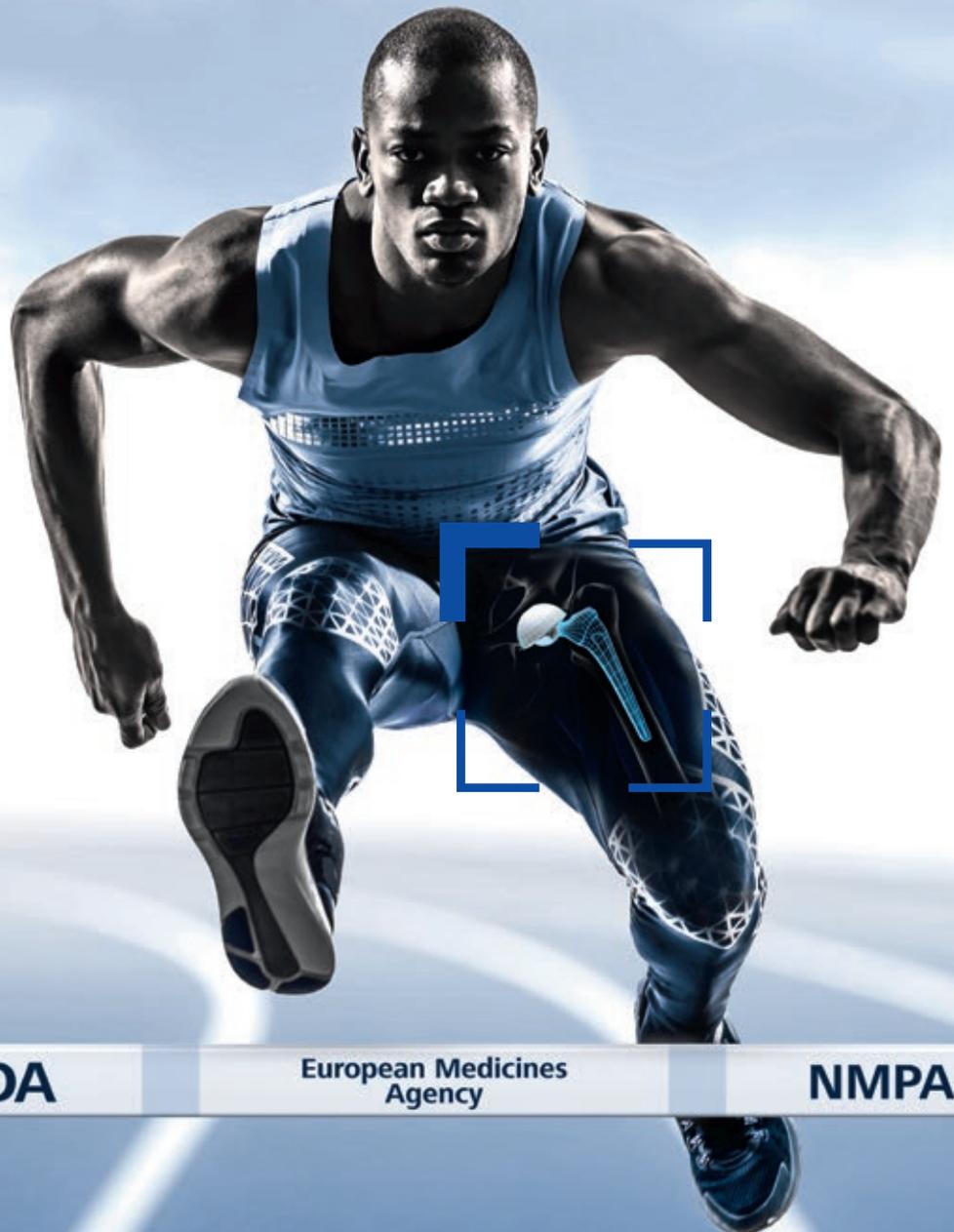


# Quality Assurance for the highest medical standards.



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

### Proof of Quality

Authorities and patients demand a complete and provable correctness of the quality assurance results in the medical industry and their application. However, the large number of different medical technology components – made from various materials and in diverse shapes – from small plastic parts in insulin pumps 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 Regulations). In the USA, the Food and Drug Administration (FDA) is the relevant regulative body. Additionally, China, Canada, South America etc. have their own guidelines.

### ZEISS understands your challenges

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

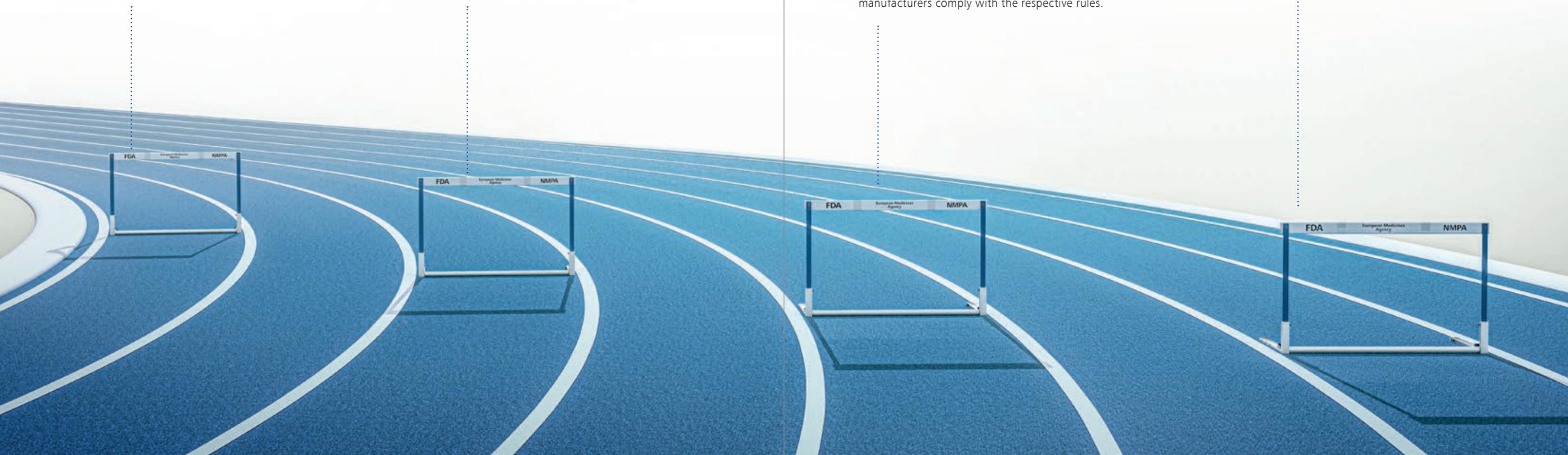
ZEISS understands the regulations, their requirements and the challenges faced by manufacturers and their quality departments. Our connected quality intelligence portfolio offers tailored hardware and software solutions that support industry standards and work as a coherent system to give the manufacturers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

### 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 used to process electronic data regulated by the FDA. The GxP (Good 'X' Practice) guidelines serve as a best practices handbook that helps manufacturers comply with the respective rules.

### Quality Management Regulations

ISO 13485:2016 is a comprehensive management system specifically directed towards 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 their quality management processes fulfill those norms, including 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, the quality assurance hardware and software must work hand in hand and provide the 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.

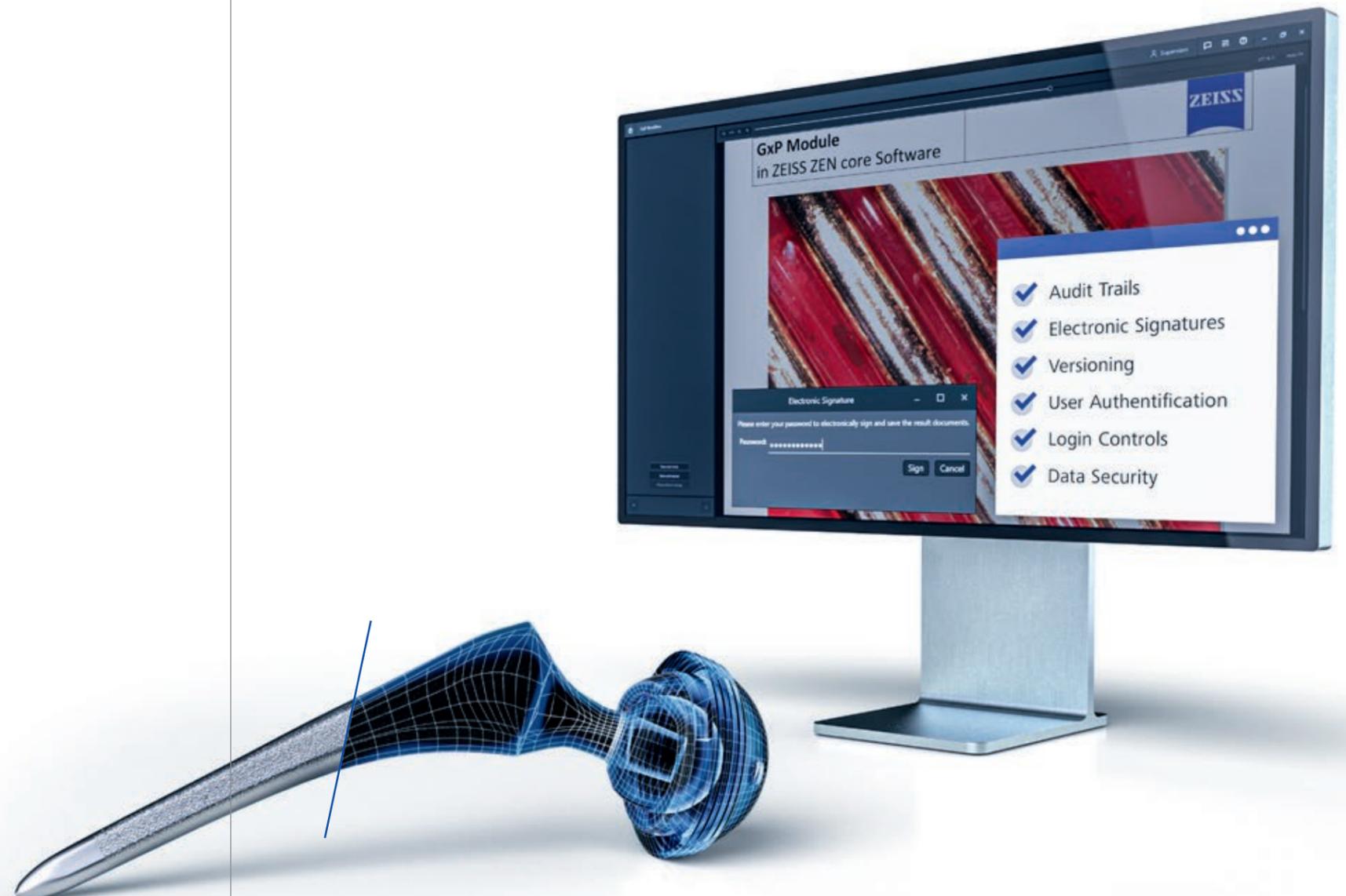
The key for regulatory compliance however lies in the ZEISS software that fits the hardware perfectly and supports manufacturers in fulfilling their required step-by-step processes. For our microscopes and their unified ZEISS ZEN core software, we offer a GxP module. For every other device the ZEISS GUARDUS MES (Manufacturing Execution System) system\* is available, enabling fully traceable workflows through all stages of production starting with the raw material all the way to the finished product.

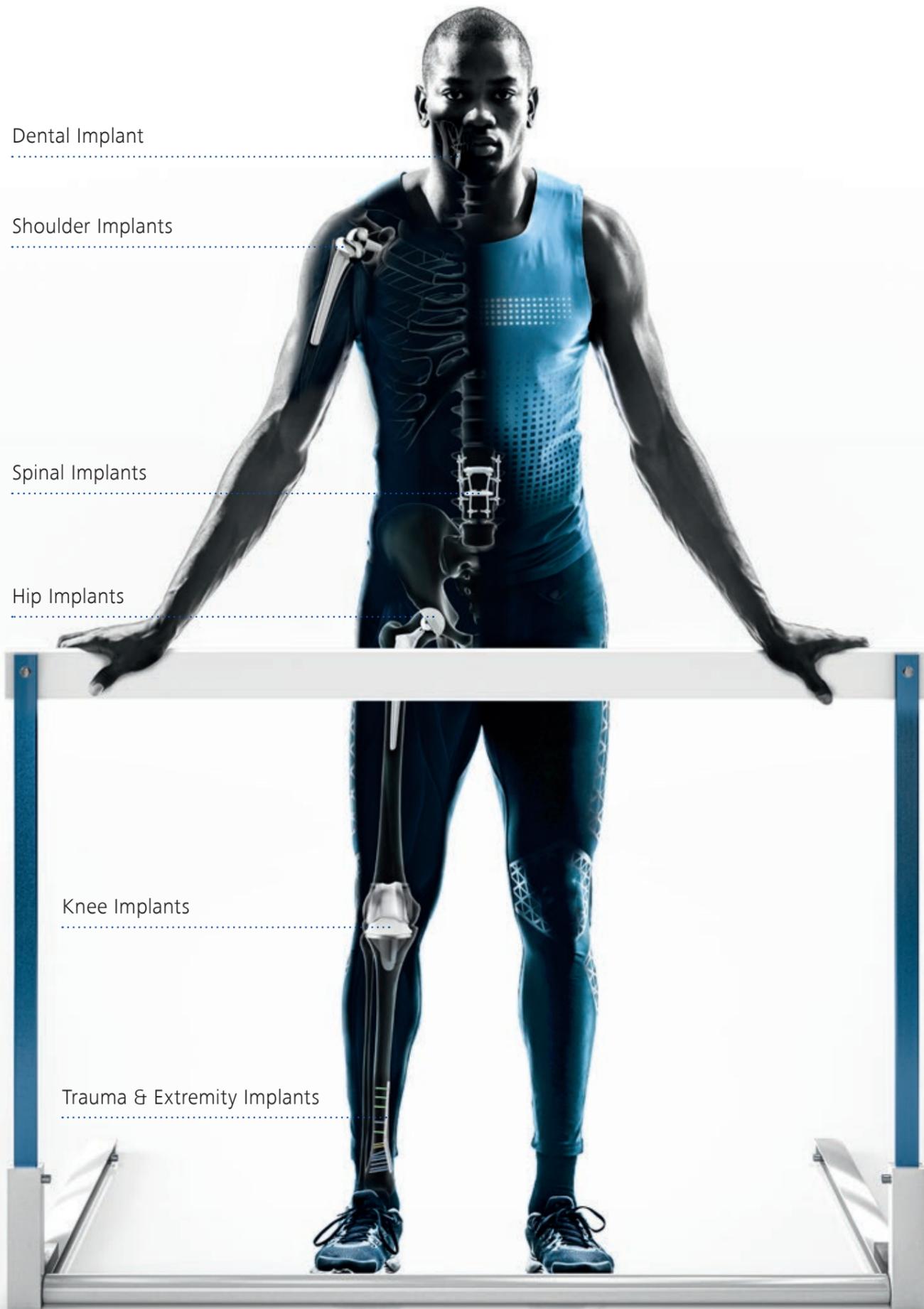
With over 100 years of experience in metrology and quality assurance solutions and our longstanding experience as a global supplier that knows the global regulation requirements, manufacturers find in ZEISS a trusted one-stop solution provider that helps them achieve their quality, efficiency and compliance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

\* currently available only in specific regions

### 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





Dental Implant

Shoulder Implants

Spinal Implants

Hip Implants

Knee Implants

Trauma & Extremity Implants

# Quality Solutions

## For all types of 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 of manufacturers to fulfill them.

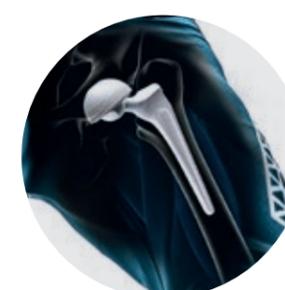
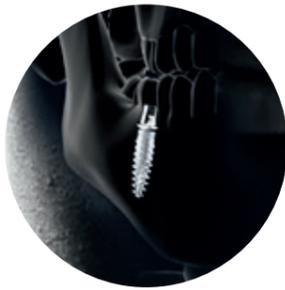
For example, ensuring biocompatibility is essential – the implant must not trigger an immune response. It is also important that the implant functions mechanically, withstands stress and is durable. To this end, the highest regulatory requirements, such as FDA Class II or III and FDA 21 CFR Part 820 must be met. Consequently, the materials used for implants are diverse today. They range 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 individual manufacturing process.

# Assure Quality

## Overview of orthopedic implants

### Different implants, same manufacturing processes

While many different implants and fixation philosophies exist, and the solutions are diverse, 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 leads to an increase in productivity in your process. In the following sections we will introduce you to our solutions for the metal and plastic processes, where you will find necessary quality gates along the entire production chain.



Dental Implant	Shoulder Implants	Spinal Implants
 Implant	 Peripheral Screws	 Monoaxial pedicle Screw
	 Glenosphere	 Spinal Rods
	 Glenoid implant	
	 Humeral Stem	 Intervertebral Disc

Hip Implants	Knee Implants	Trauma & Extremities	Manufacturing Process
		 Bone Screws	Metal Working
 Acetabular Cup	 Femoral Implant		Metal Working
 Polyethylene Liner	 Tibial insert		Plastic
 Femoral Head			Ceramic & Metal Working
 Femoral Stem	 Tibial tray	 Bone Plate	Metal Working

# Metal working process

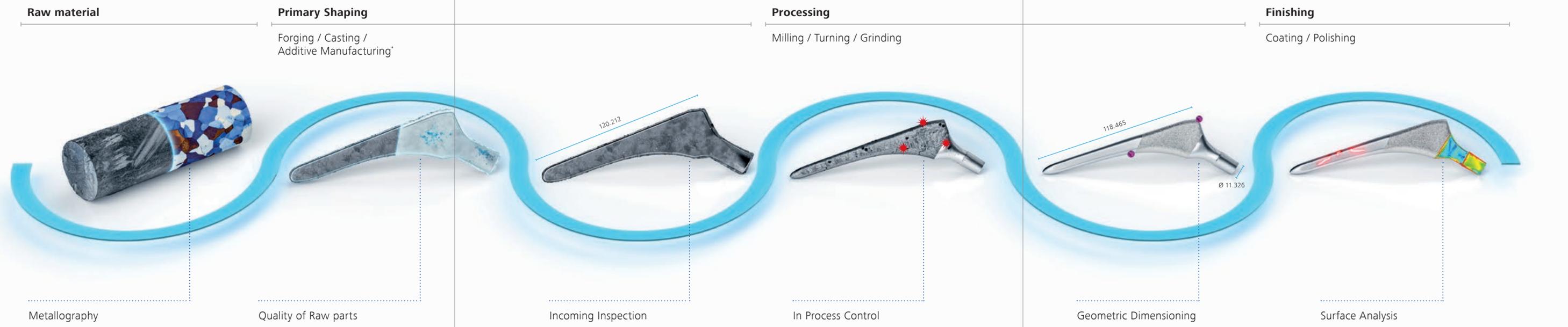


Orthopedic implants must function flawlessly even under the demanding physiological conditions in the human body. This makes it a central requirement for manufacturers to gain a deep understanding of orthopedic materials - metallic compounds, ceramic, and polymers - and the resulting organic reaction. One of the most important steps in the metal working process is assessing the raw materials 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 Part

## Quality Gates and Solutions



### Metallography

Analyze the structure and evolution of your steel and other metals from a micro to nano scale. An accurate characterization will enable maximum understanding for the quality of your raw material in terms of purity, non-metallic inclusions or 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. Ensuring initial part form is without fissures voids, cracks or critical inclusions. By defining acceptance criterion, bad parts can be directly disposed.

#### 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 ATOS Q from GOM.



### Incoming Inspection

Verify if the product arrived in required condition at your warehouse before accepting it into your stock to 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 with e. g. ZEISS DuraMax, ZEISS CONTURA.

##### Full-field Inspection

Full-field automated inspection and optimization with ATOS Q from GOM.



### In 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 along the entire manufacturing process.

#### Quality Solution:

##### Technical Cleanliness

Characterize process-critical particles and identify killer particles using Correlative Automated Particle Analysis (CAPA), which combines your data from both light and electron microscopes in a single workflow.

##### Process Monitoring

Check your semi-finished parts before further processing them to avoid unnecessary further processing using ATOS ScanBox from GOM.



### Geometric Dimensioning

A special challenge is the final check for allowed variations of the produced component to the nominal CAD model. 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 ATOS ScanBox from GOM.



### Surface Analysis

Finally the finished product has to be checked to guarantee the correct layer thickness and a flawless surface quality.

#### Quality Solution:

##### Visual Inspection

With ZEISS solutions we can map, image and measure layer thickness and surface characteristics at multiple regions of interest by using e. g. ZEISS SmartProof 5, ZEISS AxioImager 2, ZEISS SurfMax.



\*see ZEISS 3D ManuFACT Solutions



# Solutions for Quality Gates

## Metallography

### Analysis of Raw Material

#### Challenges

- Assure constant quality of material with respect to e.g. 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 and this can be dependent on the other elements present and what heat treatment the component has gone through
- Finding the source of failure through an insight on a macro, micro and nano structure



#### Quality Solution:

##### Microscopy Analysis

- A portfolio of connected and correlated solutions for quantifying the chemistry, crystallography, topography and tomography of cracks, fissures and deformations in your metallic samples
- Optical, electron and X-ray imaging, as well as energy dispersive X-ray spectroscopy, electron backscatter diffraction, 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, to solve and prevent recurrence of failures

#### Added value

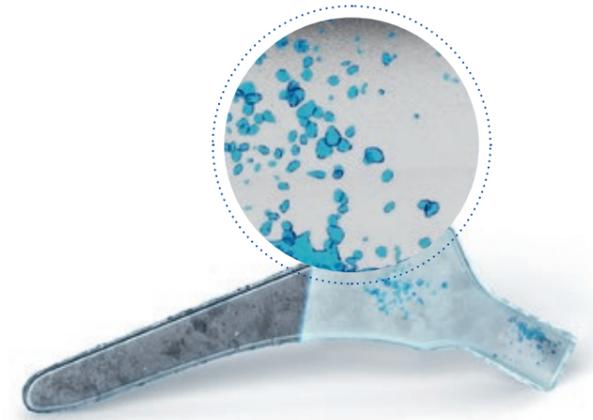
- Confirm that manufacturing processes, grade and quality of the product and the characteristics of its materials meet the strict specifications
- Assess minor impurities or defects that can cause a component to fail
- Determine the root cause of failure to improve overall reliability

## Quality of Raw parts

### Inspection of Primary Shape

#### Challenges

- Verifying that the components are produced in a good shape and specified dimensional quality before accepting it
- Check parts for critical defects as voids, cracks and inclusions before further processing
- Gaining information of defect number, type (inclusion, crack, void), size (dimensions, volume), position (e.g. distance to outer surface) and distribution



#### 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 from GOM for full digitization of components

## Incoming Inspection

### Efficient Verification of supplied parts

#### Challenges

- 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 bottlenecks
- Tracking warping or bending that happens after heat treating

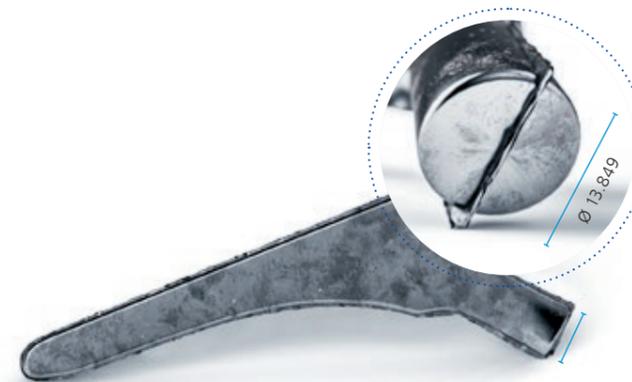
#### Quality Solution:

##### 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 trackable
- Fringe projection sensors (ZEISS DuraMax, ZEISS CONTURA) 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 digital twin using ATOS ScanBox from GOM



#### Added value

- Fast inspection of the incoming goods to prevent cost-intensive failures later in the manufacturing process
- Incorrect stock can later not only lead to costs in production, but must also be reimbursed by the supplier. A careful inspection of incoming goods can prevent this and ensure that only the correct quality is used in the production process

#### Added value

- Programmable inspection plans, which are executable in CNC
- Quality control during production allows sorting out existing defects before further processing occurs
- Cost-intensive rejects and complicated repairs can be avoided

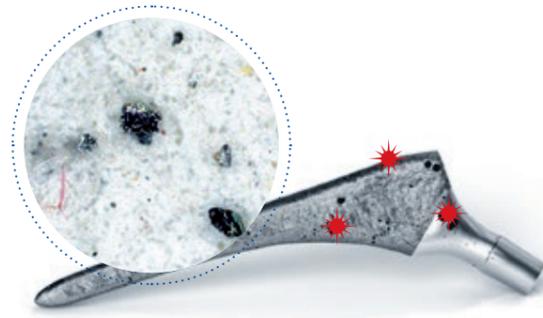
# Solutions for Quality Gates

## In Process Control

Observation of processing quality

### Challenges

- 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. A inspection of in process steps is necessary to control the processing and avoiding unnecessary further 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 products in the manufacturing process, GxP compliance & traceability of workflows for medical companies)

#### Process Monitoring

- Manual or automated inspection, using ATOS from GOM systems, 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 those into final products
- Reduce machining time

## Geometric Dimensioning

Final Dimensioning

### Challenges

- 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 can be required, if the parts have highly polished sections and cannot be touched due to the risk of micro scratches
- Tight profile tolerance on polished surfaces are a challenge for traditional inspection methods



### Quality Solution:

#### Precise Measurement

- ZEISS PRISMO inspects parts without compromising 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 between tactile and optical sensors
- ZEISS DotScan enables the possibility to measure 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
- ATOS ScanBox from GOM to inspect automatically batches of parts

#### Added value

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

## Surface Analysis

Final Visual Inspection

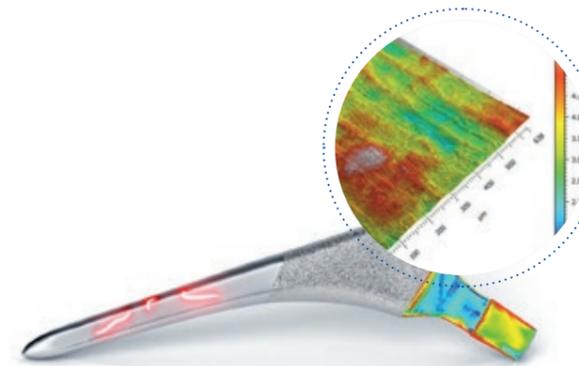
### Challenges

- 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 Smartproof 5 can provide morphological results on highly reflective surfaces optically
- ZEISS SurfMax enables detection of scratches and blemishes consistently



#### Added value

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

# Plastic manufacturing process

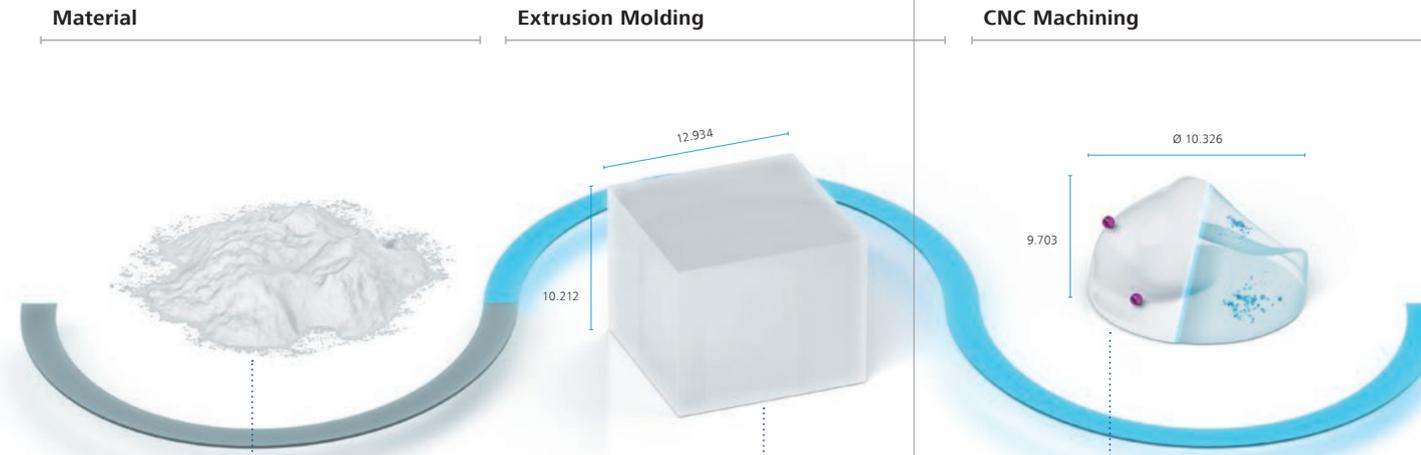


Due to the manufacturing process, plastic implants can be produced very efficiently as large batches, but also individually. Sometimes these are individual parts that have been specifically manufactured for the patient.

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 adapted well to the respective needs of the patient. Especially ultra high molecular weight polyethylene (UHMWPE) has seen great successes in medical implant applications due to its high abrasion resistance, high toughness, and great biochemical inertness. The precise manufacture of the sometimes very small parts with complex geometries is now technologically possible thanks to ultra-modern machines and systems.

## From Raw Material to Machined Part

### Quality Gates and Solutions



Granulate Analysis

Incoming Inspection

Geometric Dimensioning

Verify if the product arrived in required condition at your warehouse before accepting it into your stock to avoid unnecessary processing of bad parts.

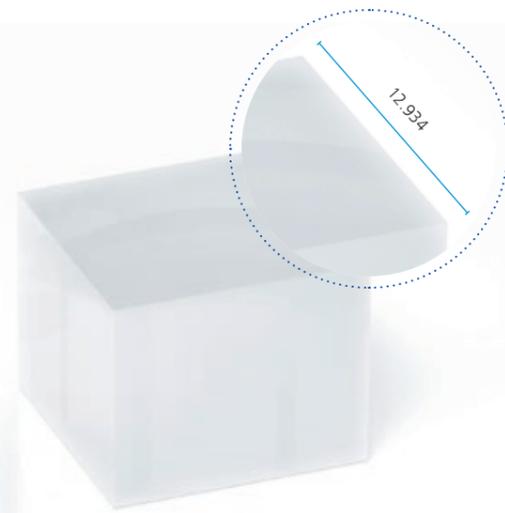
A special challenge is the final check for allowed variations of the produced component to the nominal CAD model. Most implants have finished or polished surfaces, so optical quality assurance can be required.

**Quality Solution:**  
**Efficient Inspection**  
 Fast geometric dimensioning measurement with e. g. ZEISS DuraMax.

**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**  
 Using ATOS systems from GOM or additionally internal failures using ZEISS METROTOM 6 scout.



# Solutions for Quality Gates



## Incoming Inspection Efficient Verification of Stock

### Challenges

- 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 forged part surfaces with the highest possible accuracy – results can be trusted, changes to the die or forging process are trackable
- Fringe projection sensors (ATOS Q from GOM) allow a complete evaluation of the forged part surface by comparing it to the CAD data

### Added value



- Programable inspection plans, which are executable in CNC
- Quality control during production allows sorting out existing defects before further processing occurs
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## Geometric Dimensioning Final Dimensioning

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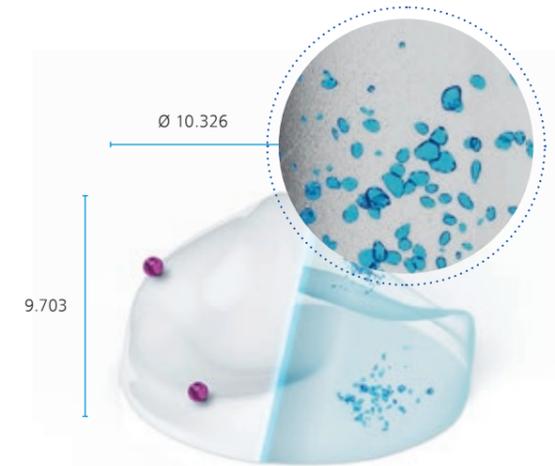
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#### Precise Measurement

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- ZEISS DotScan enables the possibility to measure 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 from GOM 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 Medical Industry



### Software for regulatory demands



#### **ZEISS GUARDUS** MES & CAQ software solution

Standards such as DIN EN ISO 13485 or FDA 21 CFR Part 11 provide clear guidelines what IT systems have to achieve. In addition to the comprehensive MES functionalities, ZEISS GUARDUS supports these requirements.



#### **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** Measurement 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 are available to provide security and increase efficiency.



### Software for Automation & Reporting



#### **ZEISS PiWeb** Reporting & Statistical Analysis

ZEISS PiWeb is a scalable reporting and statistical analysis software that helps you to transform measurement data into meaningful results.



#### **ZEISS FACS** Automation software

ZEISS FACS is the flexible automation software for increasing productivity by connecting loading systems up to full automation of your measuring process.



#### **GOM Volume Inspect** Trend analysis on volume data

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



### Light Microscopy System



#### **ZEISS Visioner 1** Visual Inspection

Digital Microscope with real-time all-in-focus visualization, for the most comprehensive inspection task with 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 analyses applications. ZEISS EVO enables imaging and analysis of non-conductive samples, such as particle filters membranes.



## ZEISS Smartproof 5 Surface Characterization

Combination of fast confocal technology for roughness and topography measurements of sensitive surfaces with light microscopy imaging and documentation functions.



## ZEISS SurfMax Reliable High-Speed Visual Defect Detection

ZEISS SurfMax provides the most consistent feedback and high-speed performance for visual defect detection and classification through manufacturing process steps.



## 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 with only one X-ray scan. Scan fast and denser parts.



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

ZEISS METROTOM 6 scout (GOM CT) 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 particularly excels in digitizing small plastic parts.



## ZEISS DuraMax Shopfloor Inspection

Stable scanning measurements over a large temperature range. With a space saving design and no compressed air required 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. Optimally measure each 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 enable you to be 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

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.



## ATOS ScanBox Measurement of Small Complex Components

Fully automated digitizing and inspection process to ensure an operator independent measurement process. Combined with ATOS sensors smallest details with high accuracy are provided.

# Your Global Partner – Present in all regions

# 32

Sales & Service  
Organizations

# 10

Production Sites

Medical parts are rarely produced in a single location. Yet measurement and inspection issues can pop up in any country and at any supplier. Our global network of application engineers and service are here to help solve your quality-assurance challenges so you can keep traceability and quality at a consistently high level.

# 63

ZEISS Quality  
Excellence Centers

# 100

Business Partners

You directly want to discover  
your perfect solution?  
**Get in contact with our  
global medical experts.**



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