Quality Assurance for the Highest Medical Standards.

ZEISS

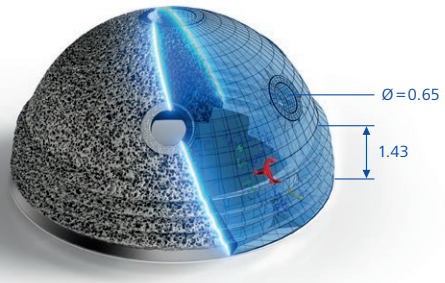
Seeing beyond

ZEISS Medical Industry Solutions

Additively Manufactured Implants

Overcome the hurdles of this dynamic manufacturing process within a regulated industry. Our tailored hardware and software solutions fulfill industry standards and work as a coherent system, granting manufacturers the certainty they need to achieve the productivity they desire.

zeiss.com/metrology/medical



ZEISS Medical Industry Solutions: Overcome the hurdles of a regulated industry

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. Quality assurance hardware and software must work hand in hand to provide appropriate functionality.

The exciting potential of additive manufacturing is leading medical manufacturers to reconsider their production processes. From hips and knees to spine parts and from trauma components to patient-specific products (PSPs), the customizable layer-by-layer approach is ideal for a wide variety of orthopedic implants that are crucial to improving users' quality of life.

However, manufacturers must implement appropriate quality assurance processes to handle the new steps involved in this novel production method. This will enable them to generate safe and effective solutions while demonstrating their ongoing compliance with medical regulations.

Quality Assurance
for additively manufactured medical implants

In order for customized, high-precision, reproducible, and FDA-compliant implants to be produced via additive manufacturing, this novel method must fulfill rigorous quality assurance requirements. Since these products are fitted in the human body, they have a significant impact on the condition and health of users. ZEISS has responded with a holistic and innovative approach to ensure medical implant quality.

Ensuring Regulatory Compliance
For proper production and compliance with strict industry standards, manufacturers must perform quality control adapted to one-of-a-kind customized implants and large component volumes alike. They must also ensure traceability and reproducibility within their testing and manufacturing processes for these highly customizable products. This represents the only way to reliably avoid serious issues when combining the thousands of melted metal layers that form additively manufactured implants.

ZEISS Medical Industry Solutions focuses on establishing safe and stable processes with holistic data integrity. Our portfolio of hardware and software solutions inspires a virtuous circle whereby the drive to meet medical industry standards propels your quality assurance to new heights.

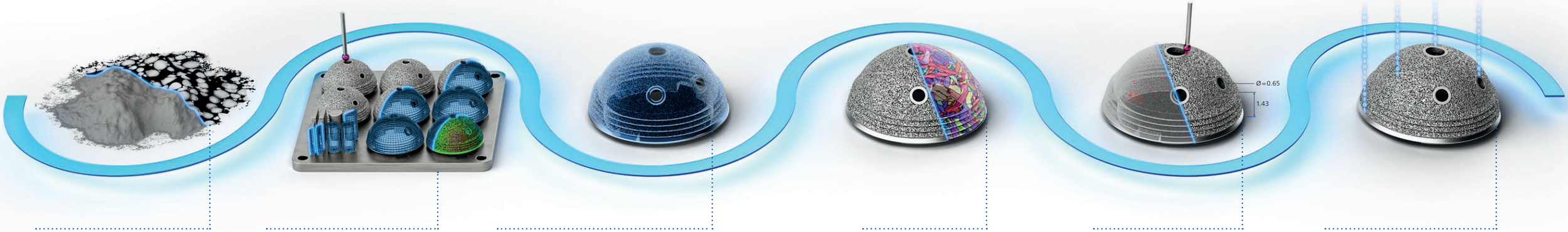
Next-Level Manufacturing Process
All steps must be tested and be shown to function correctly. One key concern in this regard is that while additive manufacturing offers the benefit of faster production, its speed means that defects can also be generated more quickly. ZEISS solutions target early defect detection, significantly reducing the amount of time and money that would otherwise be lost on the further processing of defective parts.

ZEISS has worked with customers to identify their needs at every stage, from feasibility testing with coupons through to non-destructive inspection of the final product tolerances. This establishes a seamless link between pre-development and series production. We help manufacturers keep pace with the evolving challenges and fast-developing technology in this field, giving them the confidence they need to commit to cost-effective additive manufacturing in their implant production.

From Raw Material to Finished Parts

Quality gates and solutions

Raw Material | **Production Process** | **Analytics**



Powder and Material Characterization

Powder characteristics are highly important within the additive manufacturing sector, since they influence spreadability and the formation of possible defects.

Quality Solutions:

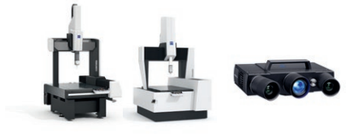
Microscopy Analysis
ZEISS Axio Imager and ZEISS Axioscope light microscopes featuring a motorized stage can capture a large sample size, which is then processed with ZEISS ZEN core software suite. ZEISS EVO and ZEISS Sigma scanning electron microscopes (SEMs) are combined with ZEISS SmartPI software for electron microscopy analysis. Powder particles can be processed with ZEISS X-ray microscopy for subsequent evaluation in 3D software.

Post-Print Heat Treatment and Part Removal

Post-processing treatments ensure dimensional accuracy and optimal material properties. Heat-treating after printing relieves stress, with some parts then heat-treated again to address microstructure changes. A CMM or optical 3D scanners can help with understanding how these processes influence final accuracy.

Quality Solutions:

Optical Scanners and CMMs
ZEISS CONTURA and ZEISS PRISMO verify post-print compliance with part tolerances. Geometrical analysis identifies distortions with ZEISS #HandsOnMetrology and the automated optical portfolio. Dedicated software uses model compensation to ensure tolerances are met.



Internal Defect and Structural Inspection

The part must be inspected in order to detect the presence of voids, cracks, and any other issues affecting the internal structure. This is done destructively and non-destructively using light or electron microscopy as well as high-resolution CT and X-ray systems.

Quality Solutions:

CT and Light/Electron Microscopy
The light microscopy solutions ZEISS Axio Imager, ZEISS EVO, and ZEISS LSM 900 are used to evaluate weld pool characteristics. Volumetric part scans can be performed with ZEISS METROTOM industrial CT systems and the X-ray microscope ZEISS Xradia Versa. ZEISS scatterControl hardware module and our software innovations such as AI-based ZEISS Automated Defect Detection (ZADD) offer numerous powerful features that boost efficiency and performance.

Post-Print Material Quality Inspection

The additive manufacturing process greatly influences the crystallography and therefore the part properties. Part quality inspection can be performed with light microscopy, electron microscopy, CT, and X-ray systems.

Quality Solutions:

Microscopy Analysis
The light microscopy solutions ZEISS Axio Imager, ZEISS EVO, and ZEISS LSM 900 reveal the etched surface microstructure. Electron backscatter diffraction (EBSD) in an electron microscope and laboratory diffraction contrast (LabDCT) in ZEISS Xradia Versa handle grain types and orientations in 2D and 3D respectively. Energy-dispersive X-ray spectroscopy (EDX) detects intermetallic phases and segregations.

Optical Scanners
The 3D camera system ZEISS ARAMIS promotes understanding of 3D material characteristics, 3D deformations, and surface strains.

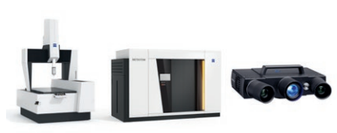
Dimensional Inspection and Surface Quality Inspection

CMMs and optical 3D systems can be used to measure the shape, size, and topography of the external surface. Internal structures are inspected and measured via CT, X-ray systems, and light microscopy.

Quality Solutions:

CMMs, Industrial CT, 3D Scanning
ZEISS PRISMO CMM performs fast and accurate part measurement, while ZEISS METROTOM industrial CT simultaneously measures interior and exterior features. Automatic batch inspection is implemented across the entire ZEISS portfolio.

Industrial Microscopy, CT, XRM
Complex requirements relating to the external surfaces can be handled with the light microscopy solutions ZEISS Axio Imager, ZEISS EVO, and ZEISS LSM 900. ZEISS Xradia Versa XRM and ZEISS METROTOM industrial CT systems cater to hidden internal surfaces.



Process Data Statistics and Analytics

Data is gathered from the entire process chain for fast analysis and visualization. This provides an efficient means of resolving issues using the software solution ZEISS PiWeb.

Quality Solutions:

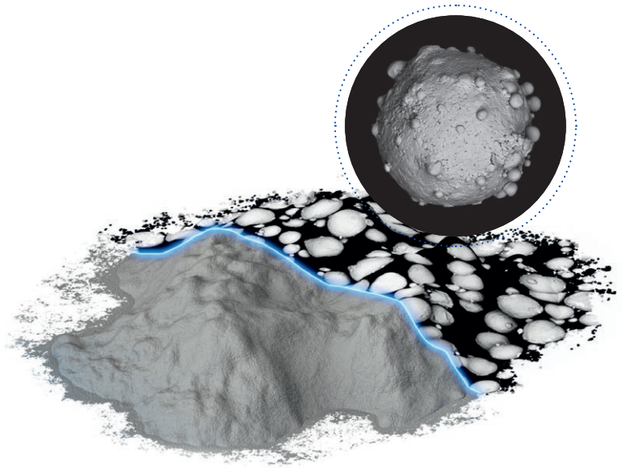
Data Aggregation and Evaluation
ZEISS software supports central data collection and calculation of metrics. ZEISS ZEN Data Storage enables centralized management of data, reports, and more for light and electron microscopy. The GxP module guarantees traceable analyses for compliance with regulation and certification requirements, while ZEISS arivis Cloud infrastructure promotes easy collaboration and access to AI image analysis tools.

Solutions
for quality gates

Powder and Material Characterization
Analysis of raw material

Challenges:
- Particle size distribution and material chemical composition must be precisely monitored
- Contaminant analysis is needed to ensure quality and safety
- Material degradation can impair performance and must be detected

Quality Solutions:
Microscopy Analysis
- Capture large sample size with powder particle analysis using light microscopy
- Segmentation and automated evaluation of powder particle images based on a pre-defined job template
- Automated EDX measurements reveal material chemical composition via electron microscopy analysis
- 3D software evaluation of powder particles following inspection with X-ray microscopy



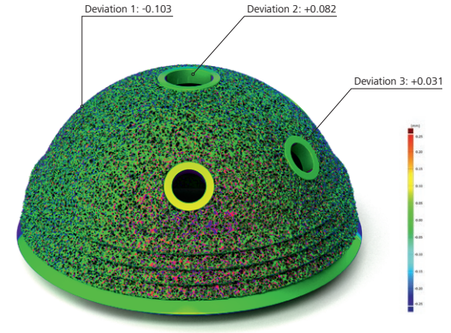
Added Value ✓

- Consistent quality of material feedstock, e.g. via early detection of fluctuations in powder particle size or shape
- Ensure part quality by avoiding contaminants and any large variations in elemental composition
- Improved monitoring of material recycling and re-use strategies

Post-Print Heat Treatment and Part Removal
Analysis after print

Challenges:
- Warping of parts due to different cooling rates within the build
- Need to compensate for build and/or heat treatment with reverse engineering tools
- Functional parts must undergo proper testing

Quality Solutions:
Optical Scanners and CMMs
- After printing and stress relief treatment, use CMMs to verify compliance with part tolerances
- 3D scanning enables detailed examination of critical geometries that are prone to distortion or high internal stresses
- To ensure medical parts are printed within the correct tolerances, implement model compensation via reverse engineering



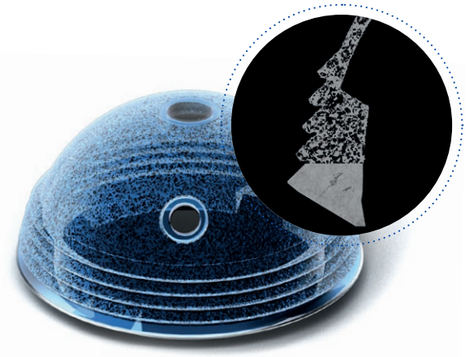
Added Value ✓

- Reliably meet part tolerances once printing and stress relief treatment are complete
- Improved process control reduces cycle times and number of non-compliant parts

Internal Defect and Structural Inspection
Structural integrity of the part

Challenges:
- Defects (such as pores and cracks) above a critical size must be eliminated to meet static or fatigue performance requirements
- Inclusions of different materials can lead to higher levels of localized brittleness in the part
- Monitoring of process stability is essential for ensuring consistent quality of produced parts

Quality Solutions:
CT and Light/Electron Microscopy
- Weld pool characteristics with direct impact on mechanical properties can be evaluated using light microscopy
- Perform volumetric scans of parts with X-ray microscopy and industrial CT
- Segmentation of pores and detection of foreign metal inclusions in the melted material using metrology software
- Reduce scattering artifacts of high-density materials with dedicated software module
- Guided inspection via higher-resolution detailed scans of critical part regions



Added Value ✓

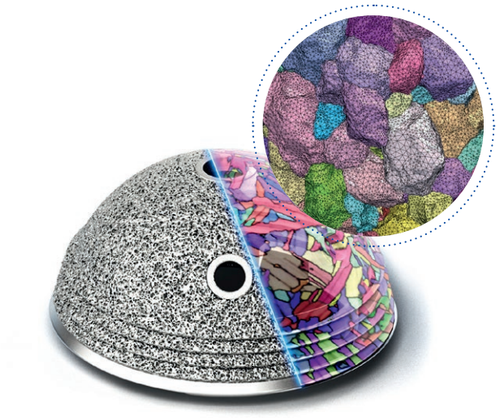
- Easily and accurately compute the volumetric density of parts
- Determine pore location, size, and shape to estimate impact on mechanical performance
- Monitor process cleanliness by calculating the number of inclusions
- Perform metrology measurements (such as 3D porosity) on trabecular structures
- Enables build qualification and process parameter optimization based on part geometry

Post-Print Material Quality Inspection
Analysis before final processing

Challenges:
- Processing parameters have a major influence on the grain structure for medical alloys
- Need to evaluate and understand the relationship between grain structure and mechanical properties of medical implants
- 3D displacement and surface strains must be analyzed while implant is under working load

Quality Solutions:
Microscopy Analysis
- Analyze etched surface with light microscopy to reveal microstructure
- Perform electron backscatter diffraction (EBSD) measurements to reveal grain types and orientation
- Detect intermetallic phases or segregations with energy-dispersive X-ray spectroscopy (EDX) measurements

Optical Scanners
- Explore material characteristics such as 3D displacement with ARAMIS 3D camera systems
- Gain the necessary further understanding of mechanical properties in functional parts

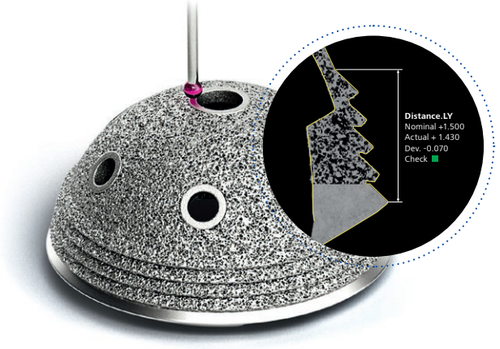


Added Value
- Ensure desired time and temperature for heat treatment of complex medical parts
- Fine-tune the grain size via microstructure validation in 2D or 3D
- Study polycrystalline materials via EBSD (2D) and LabDCT (3D)
- Understand 3D deformation in built and heat-treated parts with ARAMIS

Dimensional Inspection
Final analysis

Challenges:
- Dimensional control of highly complex 3D external geometries and internal structures/features
- Demanding fixturing requirements due to complex 3D geometry
- Printed part quality must be assessed to enable problem-free subtractive processing
- Real-time corrections based on part quality evaluations

Quality Solutions:
CMMs, Industrial CT, 3D Scanning
- Part measurement with CMMs means no compromise on speed or accuracy
- Simultaneous measurement of internal and external features with industrial CT
- Automatic batch inspection is implemented across the entire ZEISS portfolio
- Complete dimensioning and evaluation of characteristics in report

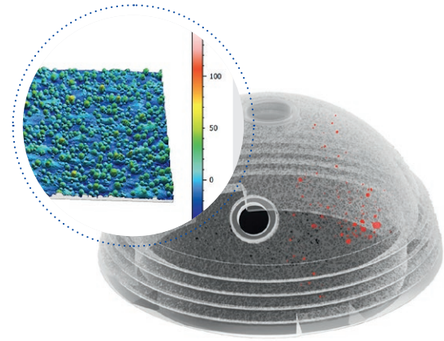


Added Value
- Verification of critical dimensions is key to validating build quality
- Accurate alignment of actual data with nominal information in areas requiring correction
- Fast and accurate dimensional assessment of complex internal features
- Full digital twin data acquisition via blue light optical inspection
- Perform non-destructive inspection required for trabecular structure

Surface Quality Inspection
Final analysis

Challenges:
- Additively manufactured medical implants can be extremely complex
- Topography checks must be performed on their hidden inner surfaces
- Non-contact inspection is a requirement for topography evaluation of surfaces

Quality Solutions:
Industrial Microscopy, CT, XRM
- Manage external surface requirements with light microscopy solutions
- Handle complex hidden inner surfaces via X-ray microscopy (XRM) and industrial CT



Added Value
- Inspect internal features in line with surface topography requirements
- Efficient data acquisition in regions of interest after surface processing of 3D printed implants
- Non-contact inspection removes need for part marking as found in traditional methods

Process Data Statistics and Analysis
Process stability

Challenges:
- Implement process monitoring of additively manufactured parts
- Seamless approach must link all phases of component life cycle
- Multimodal data can be drawn from various sources including microscopy, CT, CMMs, and optical scanners
- Specific medical solutions are required for compliance with FDA 21 CFR Part 11

Quality Solutions:
Data Aggregation and Evaluation
- Central data collection and calculation of metrics with quality and reporting software
- Centralized data management solution for light and electron microscopy
- GxP module for traceable microscopy workflows that comply with strict standards
- Cloud-based collaboration tool for coding-free AI image analysis

Added Value
- Reduce production downtime by detecting process deviations
- Data analysis shows how process changes may correlate with various properties
- More efficient printing strategy development via clear visualization and correlation of results

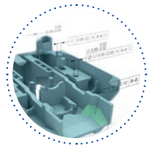
ZEISS Portfolio

Want to explore all hardware and software solutions across the entire ZEISS portfolio? Visit us at **zeiss.com/metrology**

Coordinate Measurement Solutions

ZEISS CMMs deliver stunning speed, accuracy, and flexibility, while ZEISS VMMs offer outstanding point density for fast optical measurement results.

ZEISS CALYPSO
ZEISS CALYPSO is your dimensional metrology software solution for CMMs.

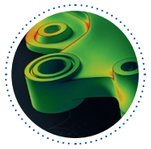


ZEISS Smart Services
ZEISS Smart Services boost safety, availability, and productivity.

Optical Solutions

ZEISS manual and automatic scanning delivers fast high-resolution results for small to medium components. ZEISS optical solutions enable dynamic object measurement to test for deformation or movement.

ZEISS INSPECT
ZEISS INSPECT Optical 3D software takes inspection and evaluation to a whole new level with features such as full-field data acquisition and trend analysis.



CT and X-Ray Solutions

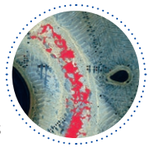
2D and 3D X-ray from ZEISS are ideal for fast and non-destructive scanning. ZEISS industrial CT performs measurement and defect analysis in a single X-ray scan, supporting fast handling even of more dense parts.

ZEISS INSPECT
ZEISS INSPECT X-Ray software performs in-depth visualization using the data generated with industrial CT.

Microscopy Solutions

ZEISS offers precision solutions in light, digital, electron, and X-ray microscopy, from specific surface inspection to general material characterization.

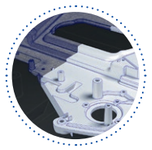
ZEISS ZEN core
The powerful imaging and connectivity software ZEISS ZEN core enables traceable analysis and ensures compliance with regulatory demands.



Supporting software

Data Management
ZEISS PiWeb scalable reporting and quality management software combines metrology results from different measuring technologies for efficient tracking of production quality. Its powerful features and intuitive templates handle huge amounts of data and provide immediate results.

Reverse Engineering
ZEISS REVERSE ENGINEERING surface reconstruction software promotes the automated, interactive, and highly precise creation of CAD models. The additional tool correction option helps improve CAD data quality.



Your Global Partner –
Present in all regions

32
Sales & Service Organizations

63
ZEISS Quality Excellence Centers

100
Business Partners

10
Production Sites

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.

medical.metrology@zeiss.com

Carl Zeiss IQS Deutschland GmbH
Carl-Zeiss-Straße 22
73447 Oberkochen

Vertrieb
Telefon: +49 7364 20 6337
E-Mail: sales.metrology.de@zeiss.com

Service
Telefon: +49 7364 20 6337
E-Mail: info.metrology.de@zeiss.com

www.zeiss.de/imt

Carl Zeiss Industrial Quality Solutions, LLC
6250 Sycamore Lane North
Maple Grove, MN 55369, USA

Phone: +1 800 327-9735
Fax: +1 763 533-0219
Email: info.metrology.us@zeiss.com

www.zeiss.com/metrology

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