

Решения по обеспечению качества для медицинской промышленности в ортопедических имплантатах, медицинском пластике, криминалистике, для выполнения нормативных требований медицинского рынка, в исследовании и разработках

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Quality Assurance for the Highest Medical Standards.

ZEISS Medical Industry Solutions



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

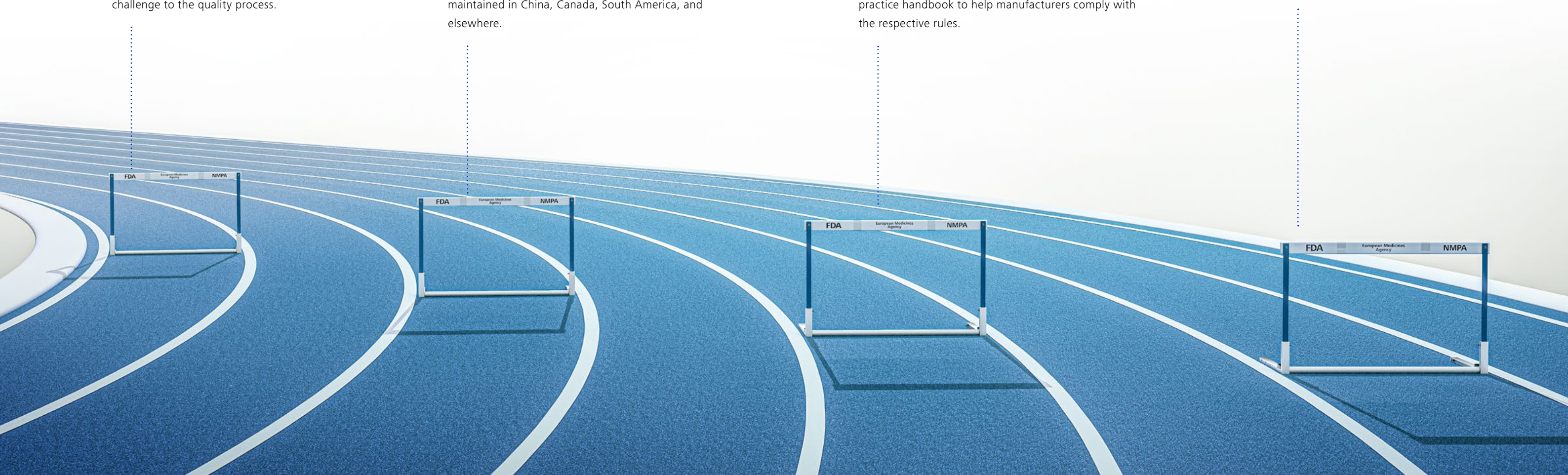
Global companies need to fulfill the regulations of various authorities. In Europe, for example, these rules are defined in different EC directives (regulations and guidelines of the European Communities) and summarized in the MDR (Medical Device Regulation). In the USA, the Food and Drug Administration (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.

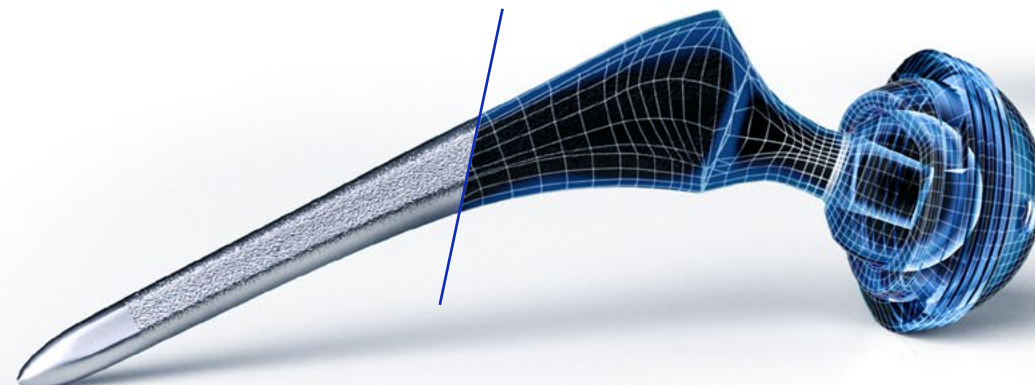
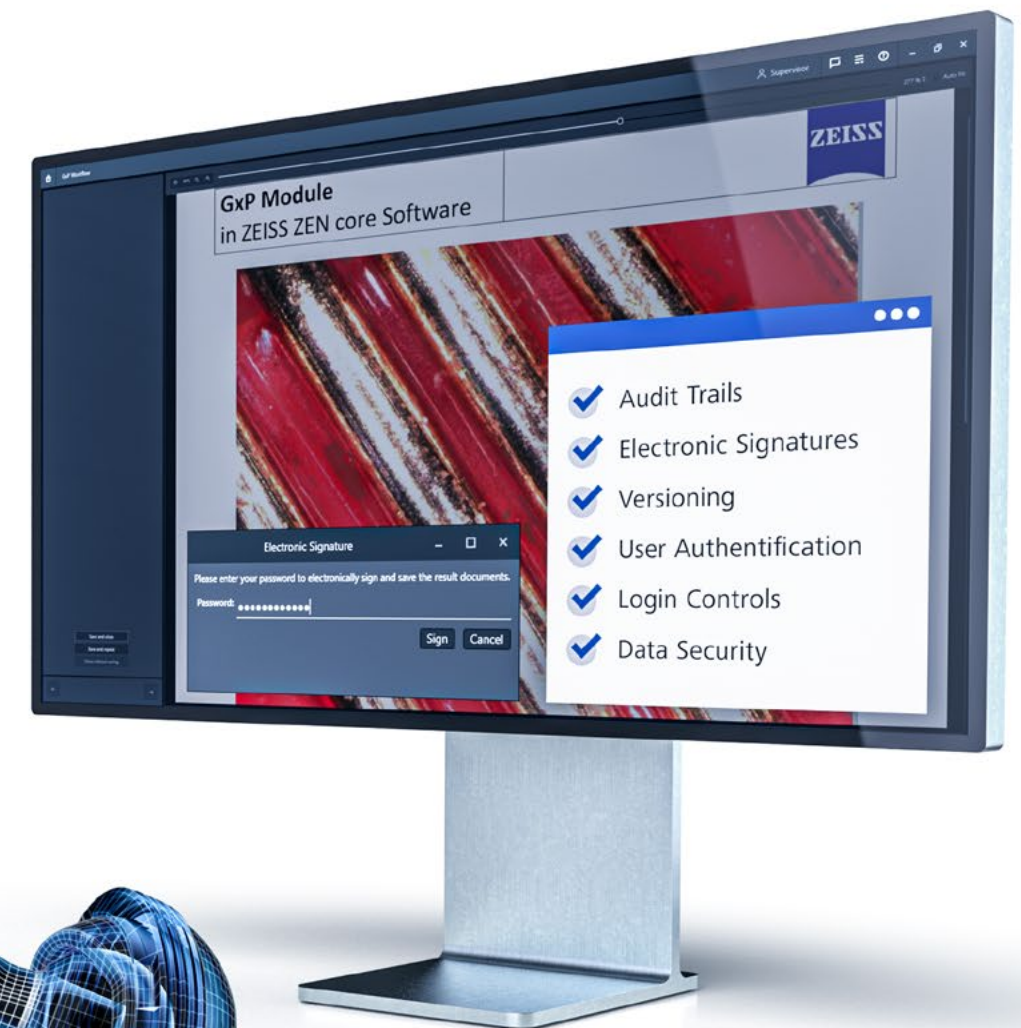
ZEISS offers a comprehensive and connected portfolio of hardware solutions that includes tactile and optical coordinate measuring machines (CMMs), 3D scanners, microscopes as well as CT and X-ray solutions. Our customers benefit from class-leading resolution, accuracy, measurement speed and powerful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

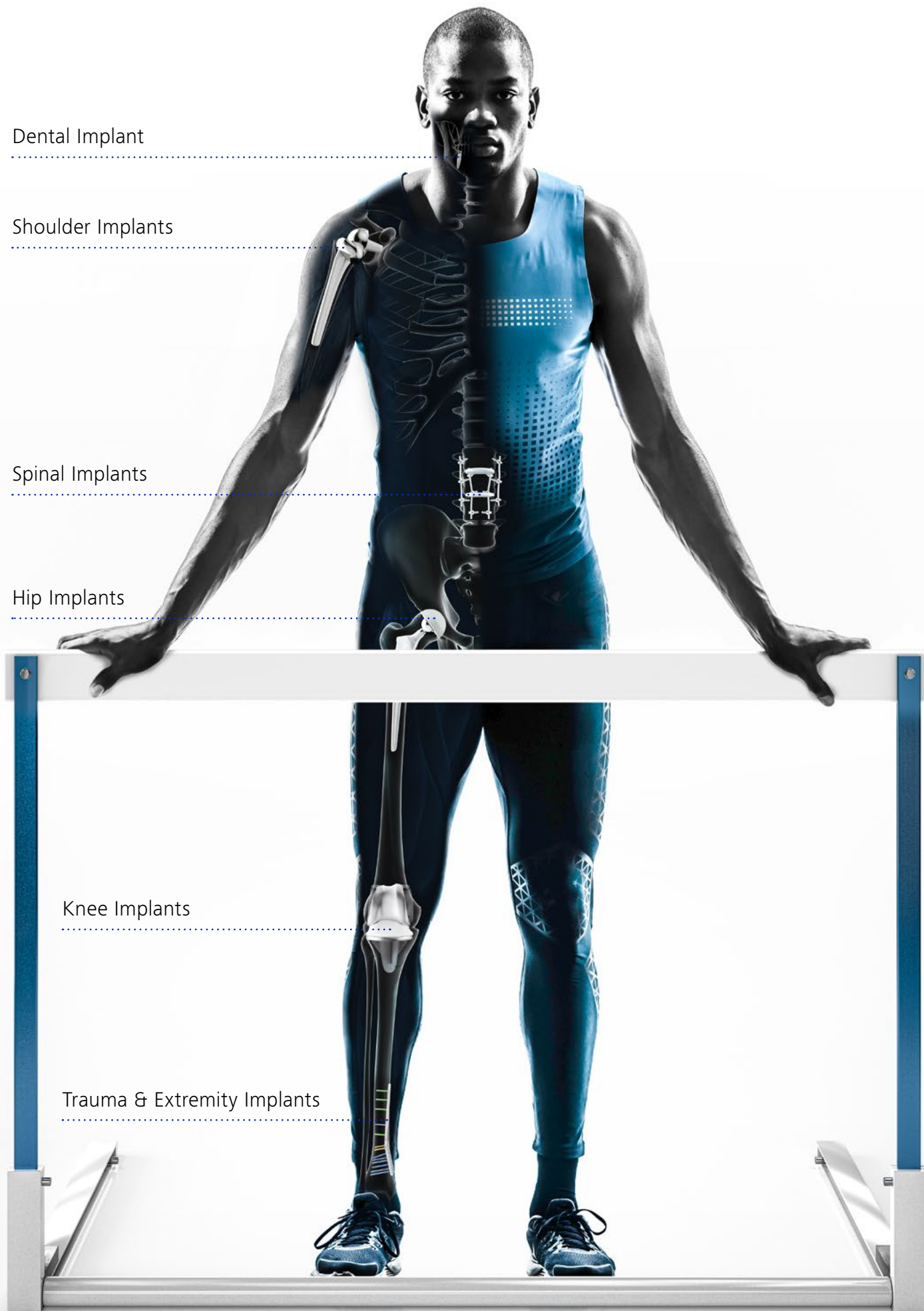
The key for regulatory compliance however lies in the ZEISS software that fits the hardware perfectly and supports manufacturers in fulfilling their required step-by-step processes. For example, we offer a GxP module for our microscopes and their unified ZEISS ZEN core software.

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

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.

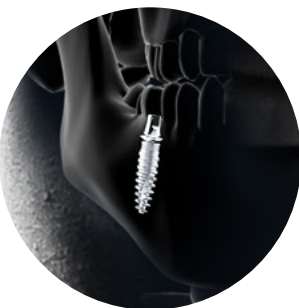










For example, ensuring biocompatibility is essential – the implant must not trigger an immune response. It is also important that the implant functions mechanically, withstands stress, and is durable. The most stringent regulatory requirements, such as FDA Class II or III and FDA 21 CFR Part 820, must 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 |
|--------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
|  |  |  |
|  <div>Implant</div> |  <div>Peripheral Screws</div> |  <div>Monoaxial Pedicle Screw</div> |
| |  <div>Glenosphere</div> |  <div>Spinal Rods</div> |
| |  <div>Glenoid Implant</div> | |
| |  <div>Humeral Stem</div> |  <div>Intervertebral Disc</div> |

| Hip Implants | Knee Implants | Trauma & Extremities | Manufacturing Process |
|---------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-------------------------|
|  |  |  | |
| | |  <div>Bone Screws</div> | Metal Working |
|  <div>Acetabular Cup</div> |  <div>Femoral Implant</div> | | Metal Working |
|  <div>Polyethylene Liner</div> |  <div>Tibial Insert</div> | | Plastic |
|  <div>Femoral Head</div> | | | Ceramic & Metal Working |
|  <div>Femoral Stem</div> |  <div>Tibial Tray</div> |  <div>Bone Plate</div> | Metal Working |

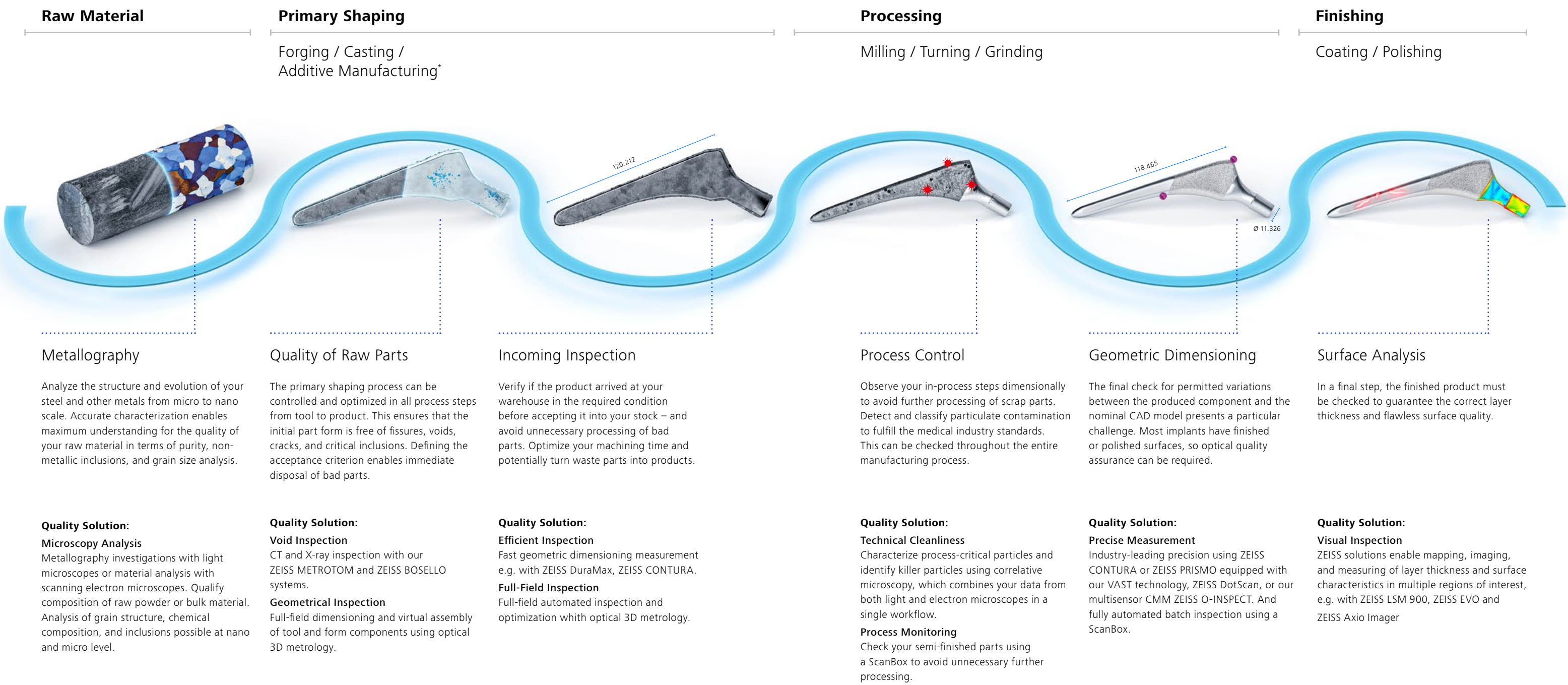
Metal Working Process



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



Solutions

For quality gates

Metallography

Analysis of raw material

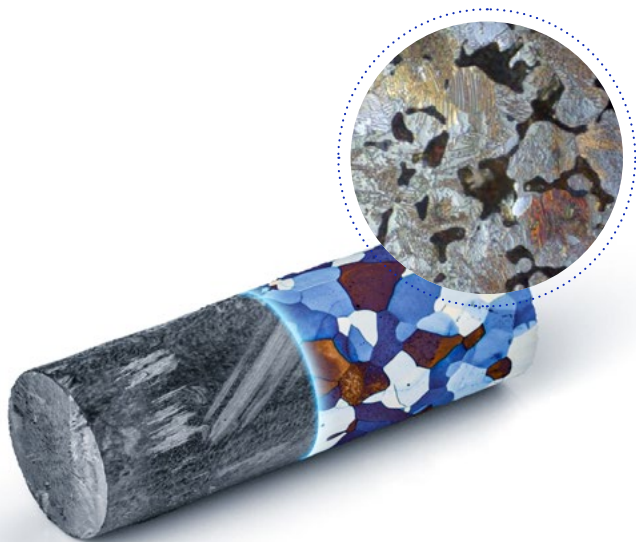
Challenge:

- 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

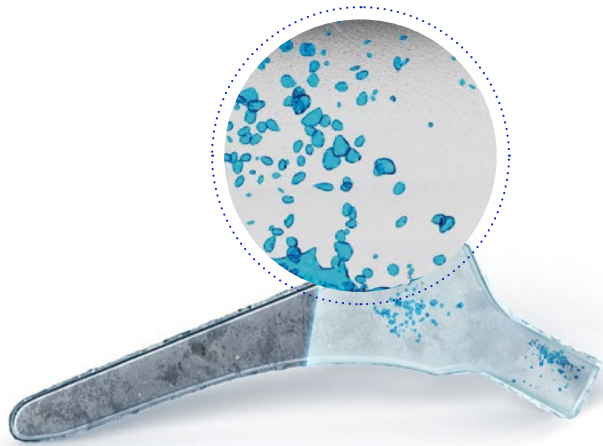
Quality Solution:

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

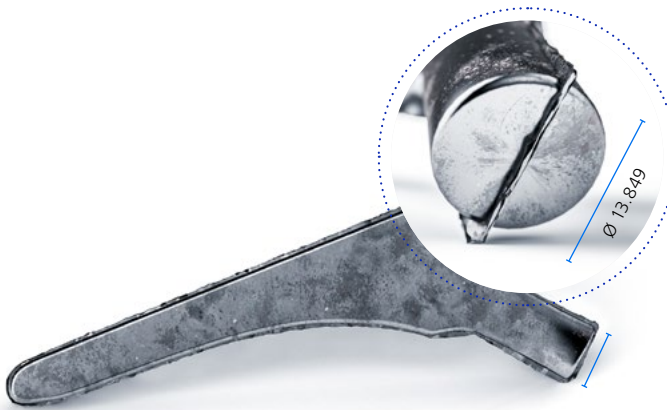
Full-Field Inspection

- 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

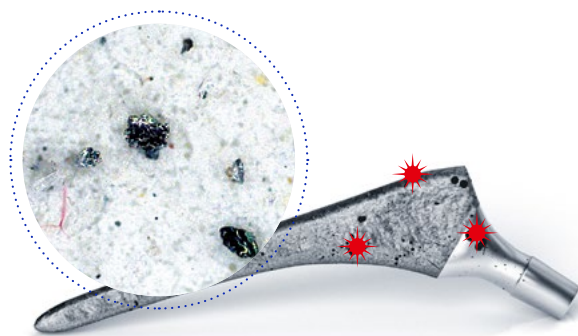
Quality Solution:

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

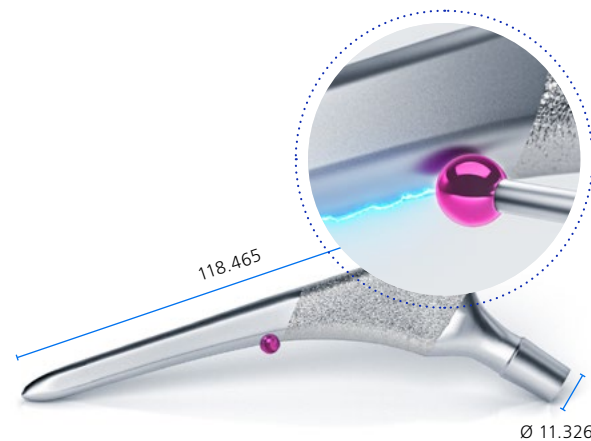
Challenge:

- 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

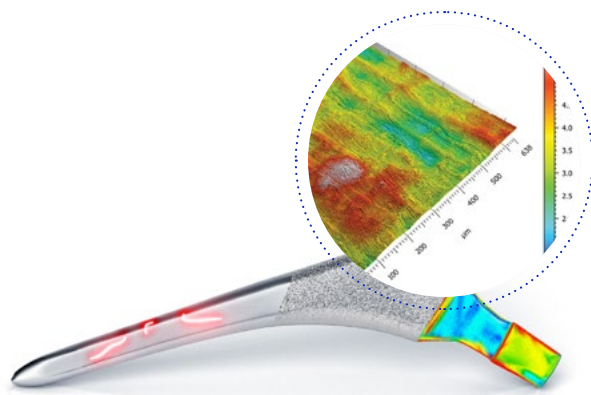
Challenge:

- 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

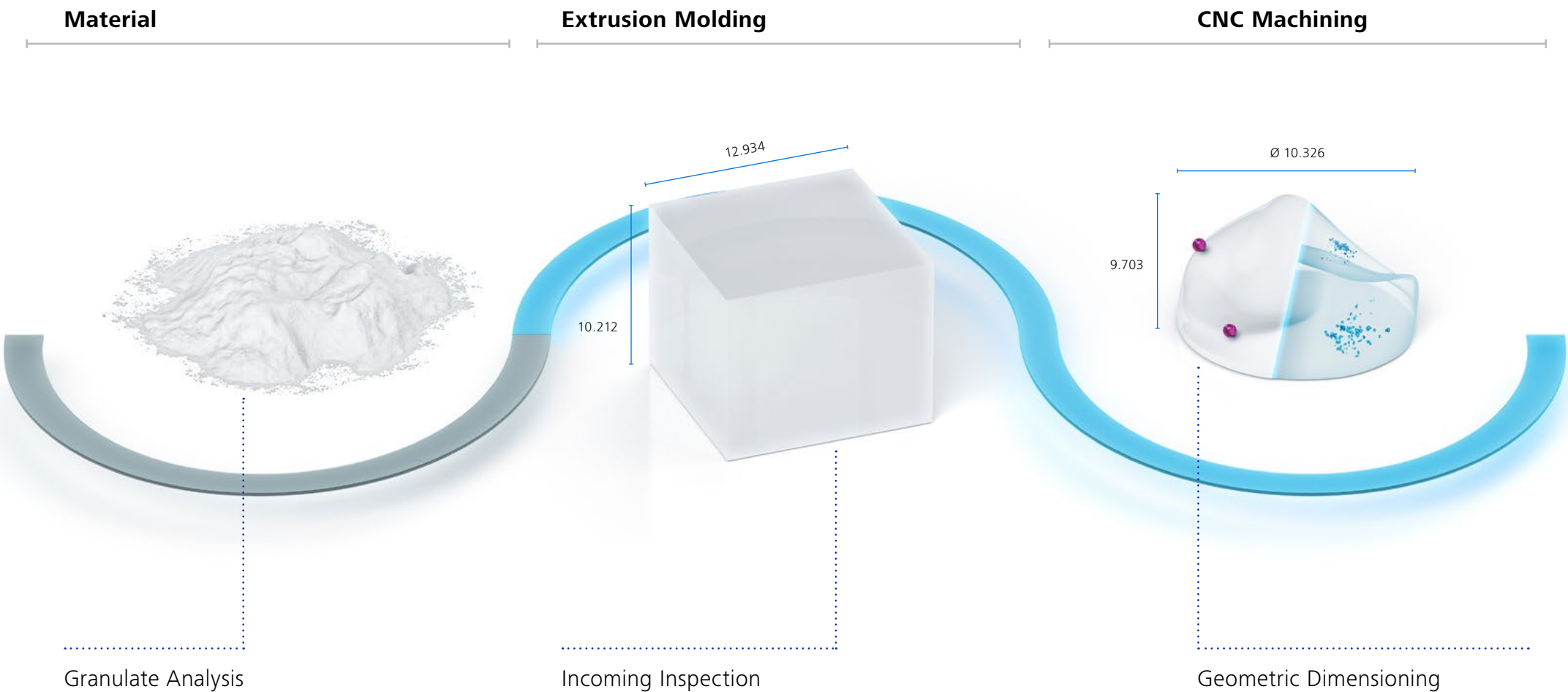
Plastic Manufacturing Process



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



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

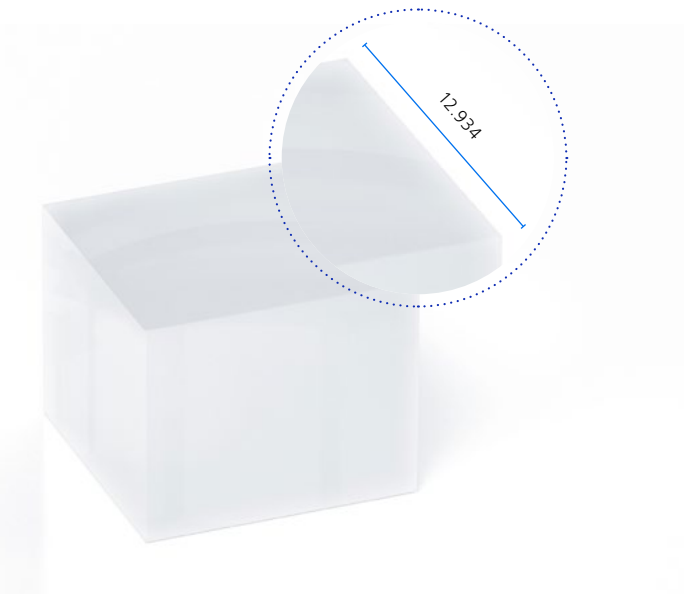
For quality gates

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

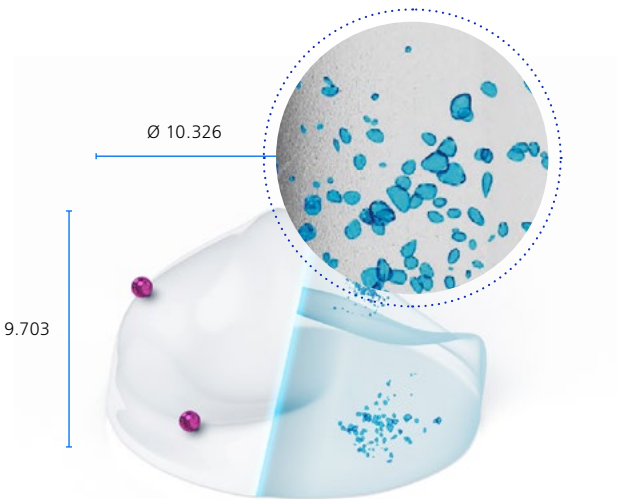
Geometric Dimensioning

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

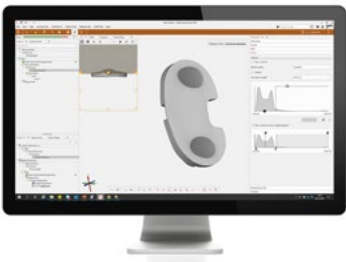
Scalable reporting and statistical analysis software that helps you transform quality data into meaningful results.



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!



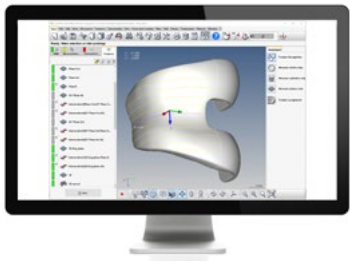
Software for Regulatory Demands



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.



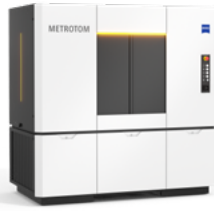
ZEISS BOSELLO MAX
2D X-ray inspection

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.

Quality Assurance for the Highest Medical Standards.

ZEISS Medical Industry Solutions

ZEISS Medical Industry Solutions:

Overcome the hurdles of a
regulation-driven industry

High Precision Injection Molding for Medical Plastics

Overcome the hurdles of a regulation-driven industry. Our connected quality intelligence portfolio features 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.

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

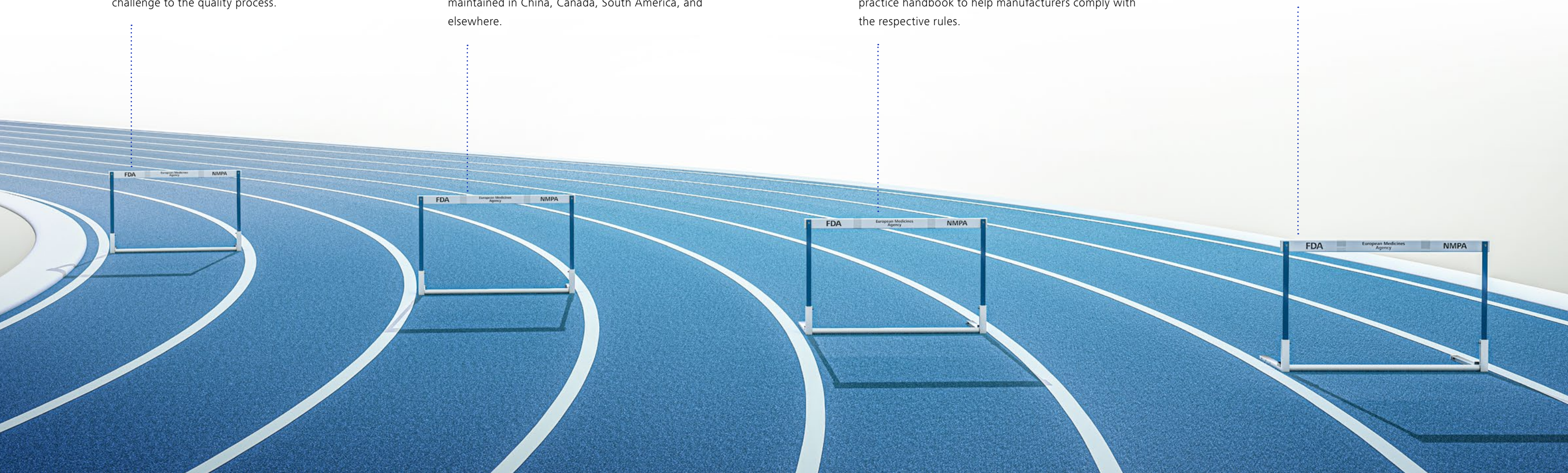
Global companies need to fulfill the regulations of various authorities. In Europe, for example, these rules are defined in different EC directives (regulations and guidelines of the European Communities) and summarized in the MDR (Medical Device Regulation). In the USA, the Food and Drug Administration (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, and CT and X-ray solutions. Our customers benefit from class-leading resolution, accuracy, and measurement speed, along with powerful automation functions.

The key to regulatory compliance lies in the ZEISS software, as this perfectly complements the hardware and supports manufacturers in fulfilling their required step-by-step processes. We offer a GxP module for our microscopes and their unified ZEISS ZEN core software.

Thanks to our 100-plus years of experience in metrology and quality assurance solutions, coupled with our great knowledge of global regulation requirements, ZEISS is a trusted one-stop solution provider that helps manufacturers 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 Assurance

For all types of medical plastics

As engineered systems and technologies that deliver a pharmaceutical compound to its target site, medical plastics are vital to human health in everyday life. They must therefore guarantee functionality and achieve their desired therapeutic effect – such as by determining the exact amount of a drug to administer. Yet while the understandably tough regulations governing these products may at first appear prohibitively stringent, ZEISS quality solutions help you thrive in this demanding sector.



Ensuring Regulatory Compliance

The substantial responsibility imposed on manufacturers by these regulations is a hurdle that must be cleared in order to enable the production of medical plastics. Since such products have a direct impact on the condition and health of users, traceability and reproducibility within the testing and manufacturing processes are key to satisfying the requirements of the authorities. In ensuring proper production and complying with a variety of industry norms, you have to perform quality control on large volumes, process small features and non-standard geometries, and correctly handle plastics that may be transparent, sensitive, or prone to bending. Only in this way can you reliably avoid serious issues that affect precision injection molding, including degradation and misalignment of molds or the presence of inclusions, voids, and cracks in the material. ZEISS Medical Industry Solutions inspire a virtuous circle whereby the drive to meet medical industry standards propels your quality assurance to new heights.

Next-Level Manufacturing Process

Quality assurance is intrinsically important to manufacturing as it establishes a traceable process for constant productivity and the creation of exactly the right finished product. Also known as medical combination products, medical plastics either comprise multiple components, combine multiple products, or may only be used together with a specific separate drug or device. ZEISS therefore helps you run fast checks on multiple components simultaneously, undertake multisensory inspections of flexible and soft parts, and perform freeform analysis to achieve optimum function and design of assemblies. These solutions boost precision and functionality while reducing costs and wastage. In offering design and product quality verification according to individual requirements, they successfully cut the number of production iterations and time to market. Enjoy the benefits of a holistic manufacturing process that is cost-effective, sustainable, reliable – and more than ready for the requirements of the medical industry.



Challenges for Medical Plastic Components

Process classification overview

Requirements for the manufacturing process

Drug delivery systems are mostly assembled products comprising various components. The main components are plastic parts that are assembled around springs, metal inserts, actuators, and electronic components to enable a specific function.



Tool Manufacturing Process



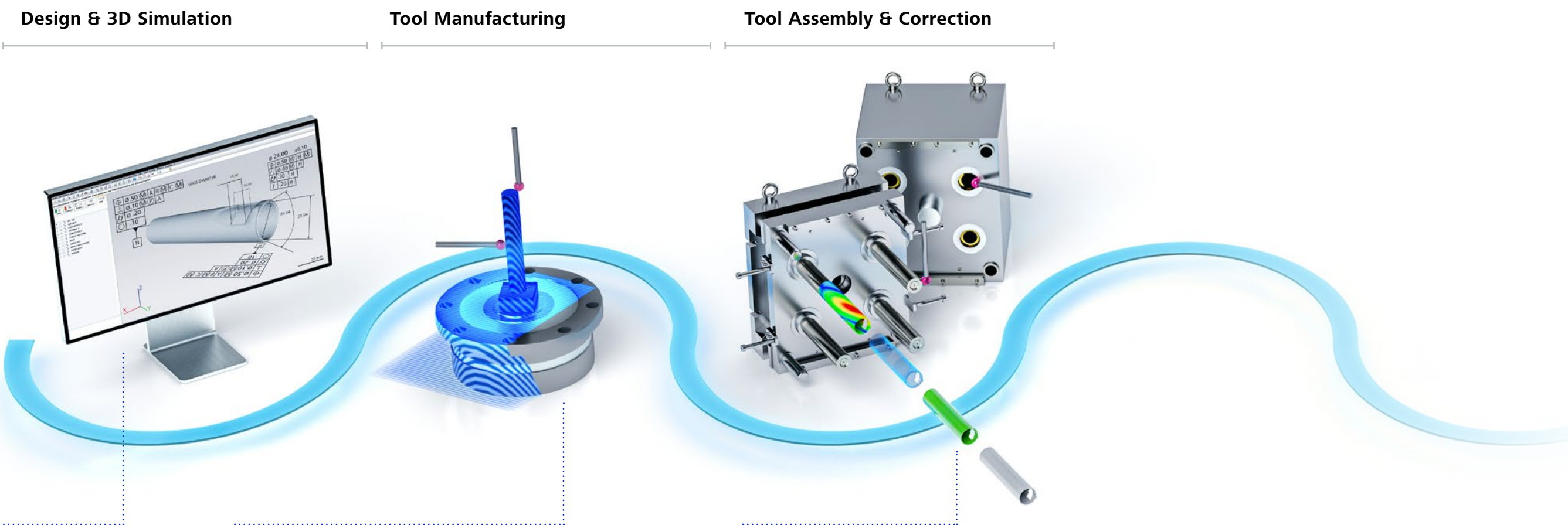
High precision is vital to perfect functionality in the field of medical plastics. Manufacturers must boast in-depth knowledge of the plastic materials featured in their parts and how these function with or respond to specific drugs. After all, such systems are intended for administering a pharmaceutical product to a patient.

Tool manufacturing should involve as few iteration loops as possible while ensuring accuracy and minimizing waste. Beginning with PMI-based inspection plans and extending through to the comparison of CAD models, this workflow has to ensure flawless handling of external influences such as electrodes.

By promoting much faster and more cost-effective correction of high-precision tools, ZEISS solutions enable you to optimize your operations accordingly.

From Design to Tool Correction

Quality gates and solutions in the tool shop



Fit for Use Metrology

Suitable inspection plans must be created as part of a well-coordinated workflow. By importing all inspection data directly from CAD (PMI / FTA), you can save time and costs while also achieving maximum inspection efficiency.

Quality Solution:
PMI-Based Inspection Plans

CAD model with PMI specified by the designer is imported from the CAD software to the inspection software. This transfer enables the creation of streamlined inspection plans composed exclusively of essential inspection data – so there is no need for any data reconstruction and no risk of manual input errors by the operator.

Determination of Electrode Offset and Geometry

Eroding, manual alignment of electrodes, and performing measurements directly on the EDM machine can make this a very time-consuming step. Automation solutions from ZEISS can help avoid issues such as extended machine downtime, longer setup times, inaccurate results, and inefficient processes.

Quality Solution:
Electrode Inspection on CMM

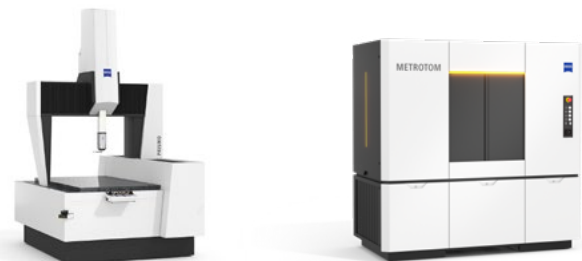
Use a ZEISS CMM or an ATOS 3D scanner to determine the electrode offset. Take your operations to the next level with shorter machine setup times, higher accuracy, and much higher productivity. ZEISS ScanBox RC also enables the automatic measurement of entire batches of electrodes.

Inspection for Tool Correction and First Article Inspection

A tool correction process with fewer iterations saves time, boosts efficiency, and lends a competitive edge. Kick off your production process sooner with an automated data transfer solution that cuts out at least 50% of the iteration loops involved in tool correction.

Quality Solution:
CAD Model Comparison

If parts become twisted due to warpage and shrinkage, it is easy to obtain corrected tool data with ZEISS Reverse Engineering by creating a morphed CAD file using actual measurement data or simulation information. After you perform a scan with one of various hardware options including ATOS Q, ZEISS LineScan (on a CMM), ZEISS METROTOM, or even a third-party machine, you can send the tool data to ZRE for high-precision CAD processing.



Solutions

For quality gates

Fit for Use Metrology

Tailored plans for efficient inspection

Challenge:

- Creation and implementation of inspection plans must be made less costly and time-consuming
- Inspection plans should be crafted for maximum efficiency, as the inclusion of unnecessary aspects needlessly slows down inspection
- Ensure good coordination between designer and inspector throughout process
- Avoid potential errors and lost time caused by transferring dimensions from the drawing to the inspection software via manual copying

Quality Solution:

PMI-Based Inspection Plans

- Straightforward import of relevant PMI data such as measurement elements, alignments, tolerances, datum references, form, orientation, and position, plus automatic assignment of measuring principles
- This PMI data sourced from the CAD software can be used to generate inspection plans quickly and easily
- PMI function in ZEISS CALYPSO can automatically implement size, form, position, and orientation tolerances as an inspection plan to reduce the user workload
- Our metrology software features direct import function, comparison of actual data with nominal data, and auto-generation of inspection plans – with all unnecessary characteristics excluded



Added Value

- Transfer PMI characteristics from CAD software to inspection software
- Use of targeted and specific data for superior efficiency
- Spend less time and money on inspection plan and inspection process

Determination of Electrode Offset and Geometry

Efficient and exact electrode and workpiece presetting

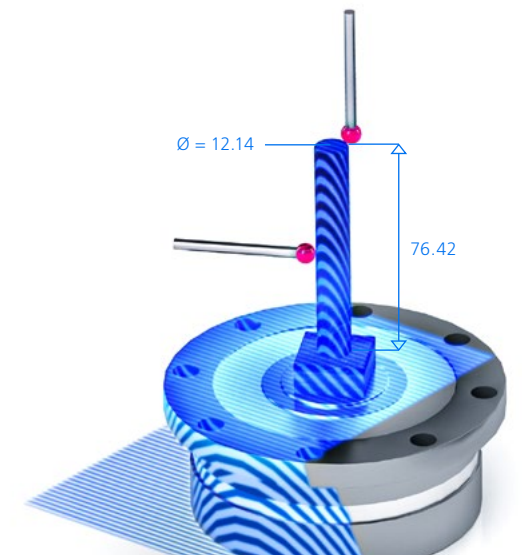
Challenge:

- Accurate alignment of electrode with tooling mold
- Establish automated process to reduce reliance on user ability
- Reduce downtime of EDM machines: zero-point correction for aligning current EDM process with previous steps
- Make EDM machine produce workpieces instead of measuring them

Quality Solution:

Electrode Inspection

- ZEISS CMM (such as DuraMax) enables electrode and workpiece measurement with features including alignment (offset) correction, shape inspection, and spark gap calculation
- ZEISS CALYPSO preset compares nominal and actual values
- The preset module makes the process easy to understand with the help of macros – select from the macro library or create your own
- Zero-point clamping means the same reference system is used for electrodes and workpieces, enabling easy transfer of these between the CMM and EDM machine
- As ZEISS CALYPSO preset sends the electrode offset data directly, the EDM machine does not have to perform measurement itself and is freed up for greater utilization



Added Value

- **50-90%** reduction in machine setup times, **3x increase** in machine running times
- Enables 24/7 production and cost savings
- Production process involves almost no manual tasks
- Automatic alignment and measurement for increased accuracy

Inspection for Tool Correction and First Article Inspection

Highly efficient modeling

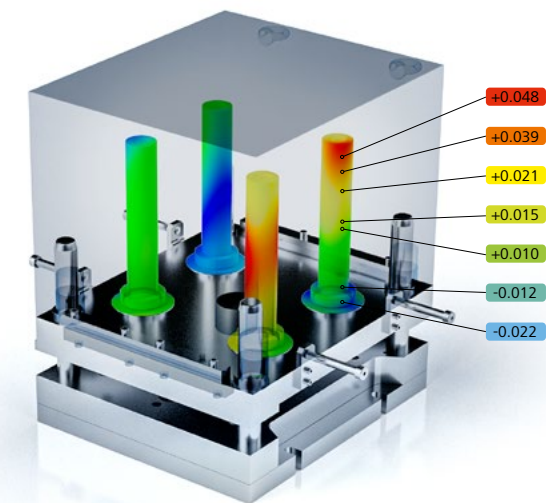
Challenge:

- Tool correction process was previously known for being time-consuming, unreliable, and heavily dependent on expertise of individual user
- Corrections then required multiple iterations
- Users need to be able to implement corrections based on comparison with the CAD model
- Ensure alignment of mold halves to reduce flashing

Quality Solution:

CAD Model Comparison

- ZEISS Reverse Engineering (ZRE) can process tool scans from a wide range of hardware, e.g. ATOS Q, ZEISS LineScan, ZEISS METROTOM, and third-party machines
- Imported point clouds (ASCII) or polygon meshes (STL) are used to compare the CAD model to the standard CAD format
- The CT software Volume Inspect ensures perfect fit through data preparation and surface reconstruction features such as virtual assembly, virtual touching, and virtual tensioning
- Enables corrections to be made with remarkable ease – not only to individual measuring points of tool, but even its entire surface
- Having received step-by-step guidance throughout, users can create and export CAD models in numerous formats (IGES, STEP, SAT)
- Combination of hardware and software achieves perfect molds 50% faster than with traditional tool iterations
- ZEISS metrology software can also be used to compare nominal and actual values



Added Value

- Excellent usability reduces need for intervention by tool and mold experts
- Wide range of hardware compatible with ZEISS Reverse Engineering
- Use of CAD modeling generates superlative molds
- Shorter route to production launch means faster time to market

Precision Injection Molding Process



The structure of the manufacturing process enables highly efficient production of plastic components in large batches. Part design and requirements may vary considerably, however, with rotation capacity, elasticity, and compatibility with materials such as metal just some of the potential factors.

It is of course essential to assess the raw material properties at the start of the process, both to detect impurities and to safeguard the desired product performance. And through the use of ultra-modern machines and systems based on optical technologies and computed tomography, it is now possible for very small parts featuring complex geometries to be manufactured with great precision – and evaluated via non-destructive checks.

Quality gates and solutions in part manufacturing

Drug Delivery Filling Process



Incoming Goods Inspection

Once the device has been fully assembled, non-destructive checks have to be performed on aspects such as mating surface contact, adhesion of components, and internal surfaces. Suitable identification of errors is essential, as is the ability to assess the functionality of the overall assembly.

Quality Solution:

Non-Destructive CT Checks

Various computed tomography (CT) hardware options including ZEISS METROTOM and ZEISS VoluMax enable you to see inside parts, even down to the powder or medication packaged within a given device. Their non-destructive approach is quick and holistic, making it possible to perform full-scale inspections and pinpoint any potential errors.

within a given device. Their non-destructive

approach is quick and holistic, making it possible to perform full-scale inspections and pinpoint any potential errors.



Solutions

For quality gates

Granulate Analysis

Pre-processing quality checks

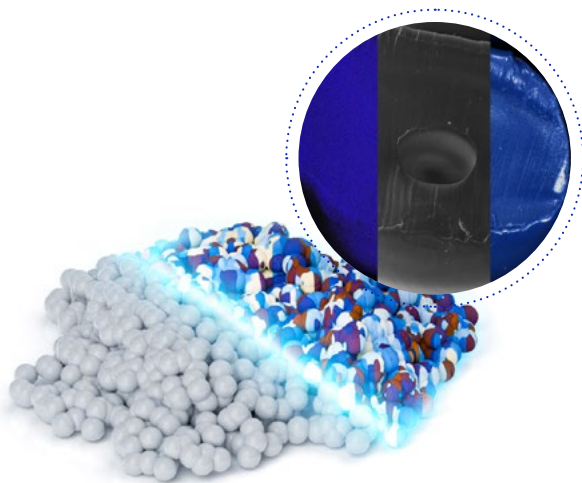
Challenge:

- Perform quick and easy imaging and analysis of stock before production begins
- Check raw material characteristics to achieve added quality assurance
- Ensure greater material consistency and a more reliable product

Quality Solution:

Impurity Detection and Classification

- ZEISS Visioner 1 (with MALS technology) enables quick and easy optical inspection with a large depth of focus and digital image capture
- Scanning electron microscopy solution ZEISS EVO and ZEISS Sigma images the raw material to identify compositional distribution and potential contaminants at the nano and micro level
- SEM can be paired with energy dispersive spectroscopy (EDS) for surface analysis to assess the elemental composition
- Light and electron microscopy imaging of fracture surfaces in failed components can help with identifying the cause of failure
- Images can be captured in ZEISS ZEN core, which features a GxP module to establish an auditable trail for each product or batch



Added Value



- GxP-compliant solution for traceability of parts and batches
- Use of confirmed high-quality raw materials helps save time and resources
- Correlative workflow for LM- and SEM-based solutions

Geometric Dimensioning and Quality Inspection

Material-friendly measurement

Challenge:

- High inspection quota, high volume throughput, fast cycle times
- Exceed traditional capabilities with inspection of multiple parts
- No bending of plastic during measurement
- Avoid expensive recalls through holistic and accurate inspection
- Analysis of parts relevant to health and safety, including small, hidden, and internal features

Quality Solution:

Optical 3D Scan

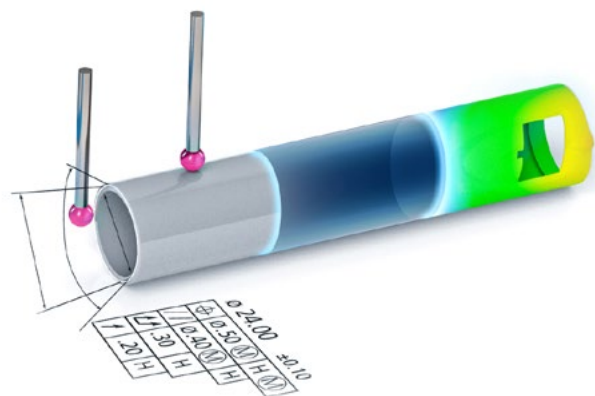
- ATOS for non-transparent workpieces. Measure up to 12 million 3D points in less than a second. Scan one part in high resolution or scan multiple parts at the same time

Optical Component Scan

- ZEISS O-INSPECT: Excellent accuracy for far shorter measuring time
- High-resolution hardware performs geometry analysis of very small parts, inspects assembly, and checks volume
- ZEISS CALYPSO VAST probing cuts measuring time by up to 25% without leaving any marks or bending soft material
- ZEISS CALYPSO Pallet Optimizer replaces traditional probe-by-probe approach with feature-by-feature scanning of entire pallet
- ZEISS CALYPSO AutoRun automation interface supports creation and implementation of pallet and batch measurements
- ZEISS PiWeb reporting provides clear visuals and information on how materials combine to form single component

CT Component Scan

- ZEISS METROTOM measurement process is automated and traceable, with scan parameters selected to ensure consistent results
- Maximized throughput with scanning of multiple parts at once
- Multi-material inspection generates adjustable surface for each material
- Measurement data is aligned with CAD automatically by software, supporting alignment of rotationally symmetrical parts
- Comparison of nominal values and computed actual values
- Full measuring summary and visualization of faulty part locations



Quality inspection of parts with the Visioner 1 prior to assembly enables checking of precision plastic components for burrs, scratches, and flash. This can also be documented to monitor tooling issues. Perfect for when CT is just “too much” for the process.

Added Value



- Broad range of optical and CT solutions to suit manufacturing needs
- Both inspection methods are ideal for complex multidimensional components
- Fast cycle times via ZEISS CALYPSO VAST probing and Pallet Optimizer or automated CT solutions

Solutions

For quality gates

Particle Contamination

Twin approaches to effective analysis

Challenge:

- Detect particle contamination in line with the exacting standards of the medical industry
- Achieve high-quality itemization and classification of particles
- Improve productivity and simplify the technical cleanliness process by combining LM and EM data in a correlative solution
- Minimize maintenance costs via swift measurement and analysis of critical particles

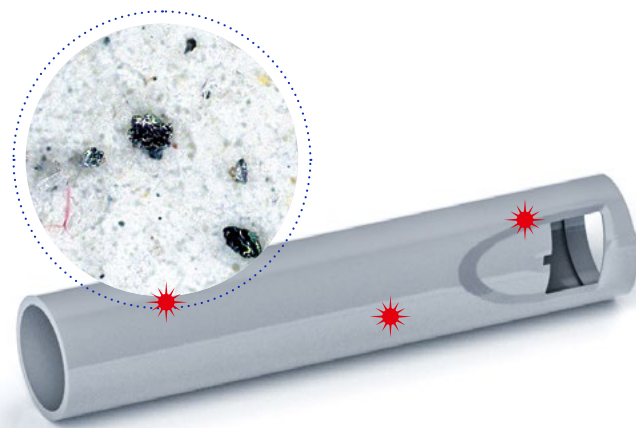
Quality Solution:

ZEISS Technical Cleanliness Analysis (TCA)

- Workflow can be adapted to suit every routine, with analysis, reporting, and archiving all available in just a few clicks
- ZEISS ZEN core TCA module delivers reliable and reproducible results while ensuring high productivity
- Display of all size classifications and cleanliness levels at a glance, plus quick overview of particles by type: metallic, non-metallic, and fibers
- Reclassification and editing made easy with the convenient revision mode

Correlative Solutions for Technical Cleanliness

- Correlative particle analysis combines LM and EM data in a single process: After the light microscope classifies reflecting (i.e. metallic) and non-reflecting particles by size and identifies fibers, the electron microscope relocates the particles
- Fully automated EDS analysis then establishes the elemental composition, with all results from LM and EM being pooled in a single report for clarity
- Correlative particle analysis workflow supports the particle analysis standards ISO 16232 and VDA 19



Added Value ✓

- TCA: One-scan workflow identifies root cause for faster decision-making
- Correlative particle analysis: early detection saves resources and cuts downtime while meeting tough medical industry standards
- Correlative microscopy: High-resolution ZEISS bundles are unique – no other manufacturer can offer correlative solutions without the use of competitor products
- Higher Productivity: Correlative LM & EM options deliver results up to 10 times higher

Inspection of Assembly

Making the invisible visible

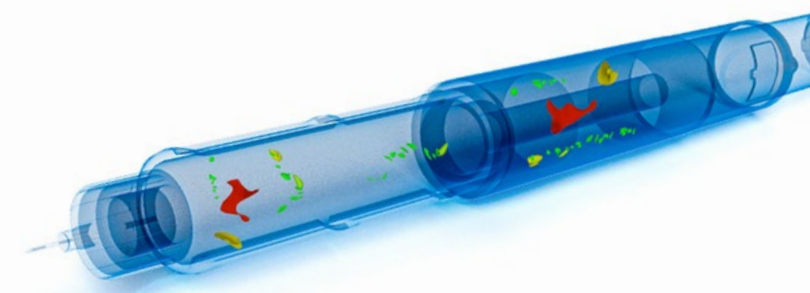
Challenge:

- 24/7 inspection capability that delivers fast cycle times, high performance, and accuracy
- Measurement of small features with tight tolerances
- Simultaneous scanning of multiple parts
- Functional inspection of full assembly

Quality Solution:

Non-Destructive CT Checks

- ZEISS METROTOM offers 3D X-ray inspection that helps reduce scan time by up to 75%
- Numerous characteristics can be checked in a single run, all as part of a precise and traceable process
- ZEISS VoluMax performs speedy CT inspection of multiple components for high throughput
- Improved internal scanning, large sample quantities, and automatic evaluation
- ZEISS metrology software is suitable for all-in-one processing of results



Added Value ✓

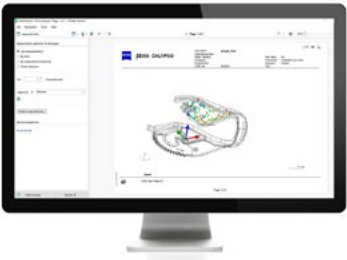
- Quick and holistic solutions via non-destructive technology
- Makes CT accessible to beginners
- High throughput and scanning of multiple components boosts productivity
- Error identification made easy, e.g. via color mapping
- Inspection of fully assembled workpiece / part is key for critical medical devices such as injectors

ZEISS Portfolio

Our propositions for the medical industry



Software for Automation & Reporting



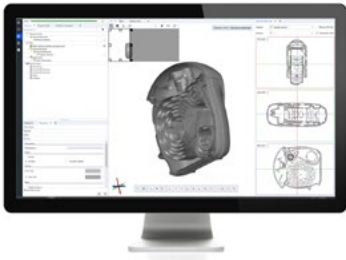
ZEISS PiWeb
Reporting & statistical analysis

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.



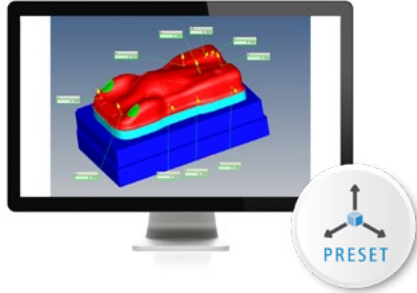
ZEISS CALYPSO
Metrology software

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.



ZEISS REVERSE ENGINEERING
Tool correction

ZEISS REVERSE ENGINEERING includes options for reverse engineering and tool correction.



ZEISS CALYPSO preset
From an EDM machine to an automated cell

Simple offset and quality measurement, from the electrode to the workpiece and the clamping system.



ZEISS CALYPSO PMI
For design & 3D simulation

When using appropriate CAD interfaces with ZEISS CALYPSO PMI, size, form, and position tolerances contained as PMI in the CAD model can be implemented automatically in the form of measurement plans. This considerably reduces the user's workload.

ZEISS Portfolio

Our propositions for the medical industry



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 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.



Electron Microscopy System



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 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.



CT and X-Ray Systems



ZEISS METROTOM 1

The new simplicity of non-destructive inspection of components

With ZEISS METROTOM 1, ZEISS is introducing an entry-level solution for the non-destructive inspection of parts. This compact computed tomography system delivers precise results, but is nevertheless easy to operate.



ZEISS METROTOM 800 130 kV

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.



Coordinate Measuring Machines



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.



Manual and Automated Scanning



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 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.

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

Quality Assurance for the Highest Medical Standards.

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.

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.



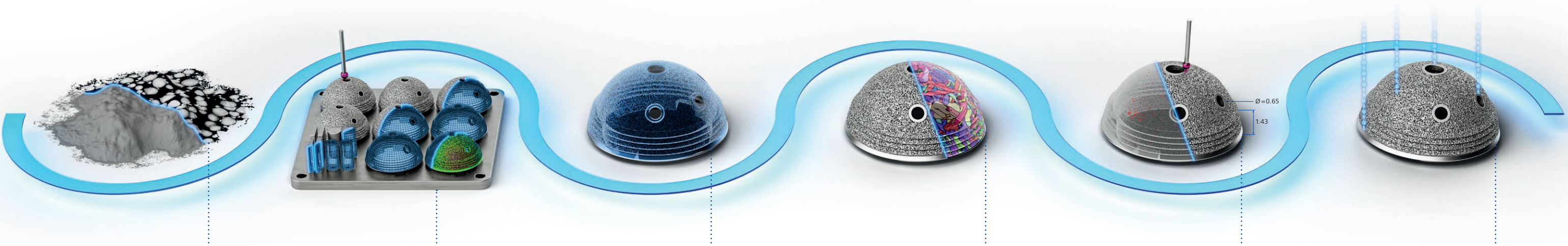
From Raw Material to Finished Parts

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.

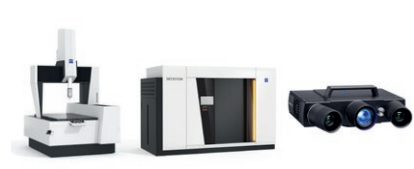
Quality Solutions:
CMMs, Industrial CT, 3D Scanning
ZEISS PRISMO CMM performs fast and accurate part measurement, while ZEISS METROTOM industrial CT simultaneously measures interior and exterior features. Automatic batch inspection is implemented across the entire ZEISS portfolio.

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

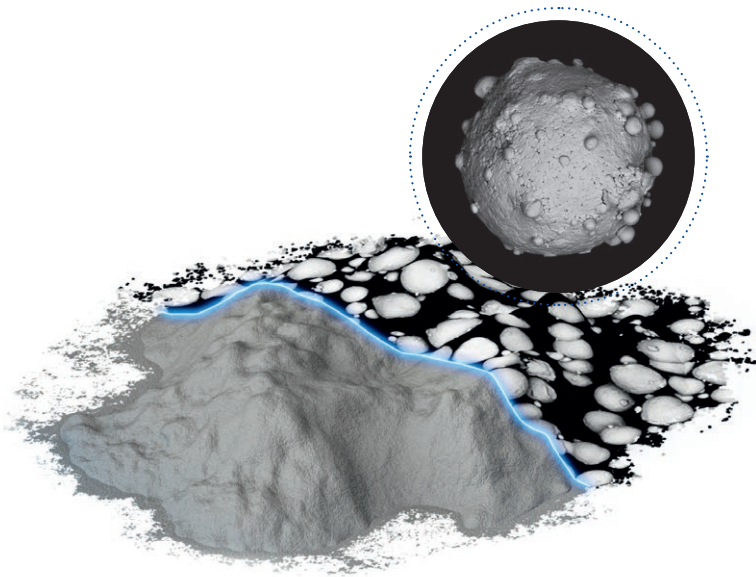
Challenges:

- 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

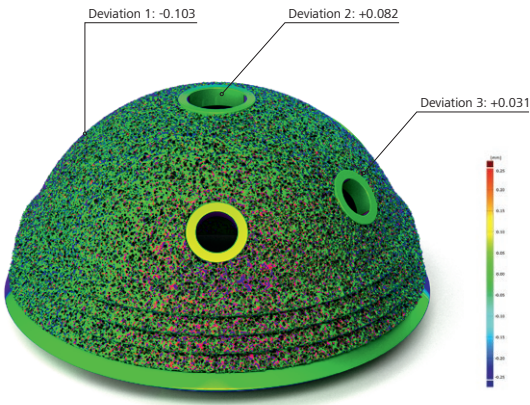
Challenges:

- 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

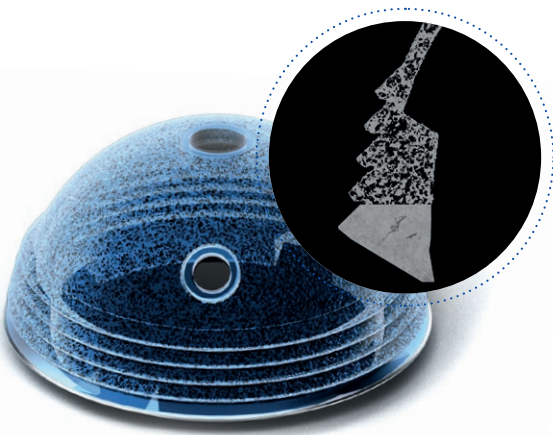
Challenges:

- 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

Dimensional Inspection

Final analysis

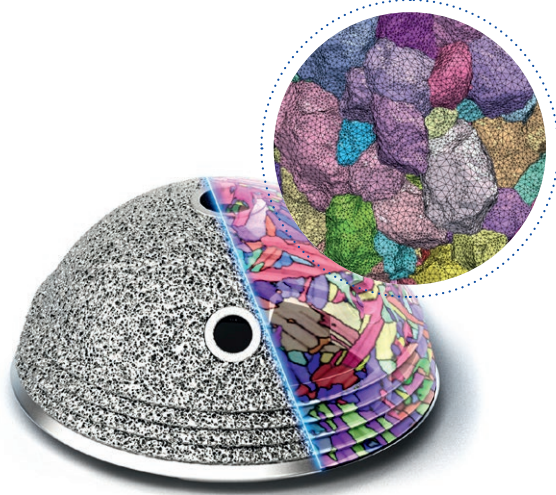
Challenges:

- 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

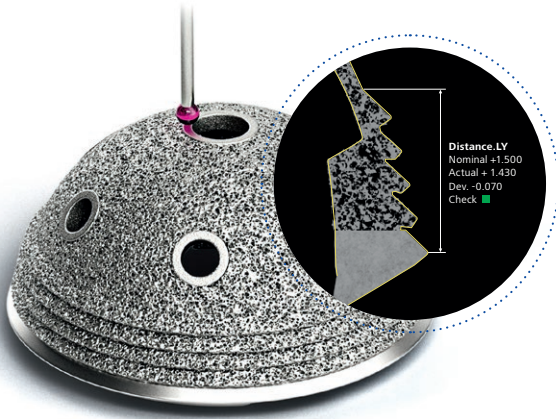
- Part measurement with CMMs means no compromise on speed or accuracy
- Simultaneous measurement of internal and external features with industrial CT
- Automatic batch inspection is implemented across the entire ZEISS portfolio
- Complete dimensioning and evaluation of characteristics in report



Added Value



- 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



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

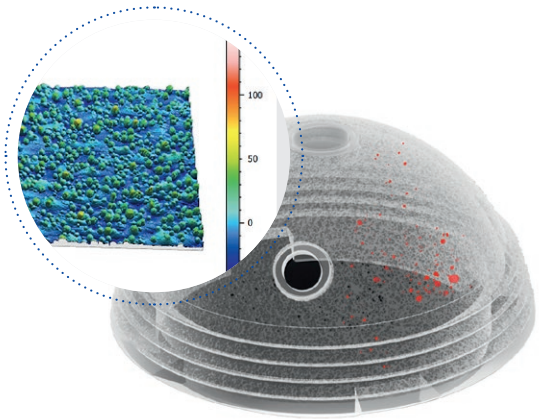
Challenges:

- 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

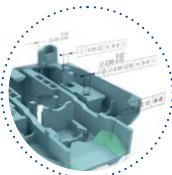
Coordinate Measurement Solutions



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.



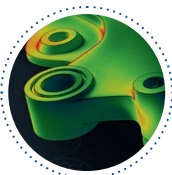
Optical Solutions



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.



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.



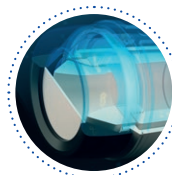
CT and X-Ray Solutions



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.



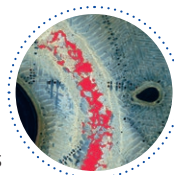
Microscopy Solutions



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

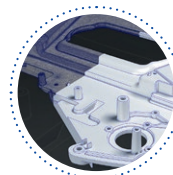
ZEISS ZEN core

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



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.





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