Quality Assurance for the Highest Medical Standards.



ZEISS Medical Industry Solutions



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.

zeiss.com/metrology/medical



Quality and Compliance

The hurdles of the medical industry

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.

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.

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.

Prescription Me BITESSA-65108 NORRASE AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS BY MOUTH TWEE FOR PREVENTION OF SWIP STATES AS DIRECTED NI TABLETS AS DIRECTED N

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

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.

Plastic design element

Quality Challenge:

Special focus on freeform analysis for function and design, plus GD&T and assembly analysis.

Plastic part with mechanical function

Quality Challenge:

Function of e.g. thread to be checked. Complex GD&T and assembly analysis.

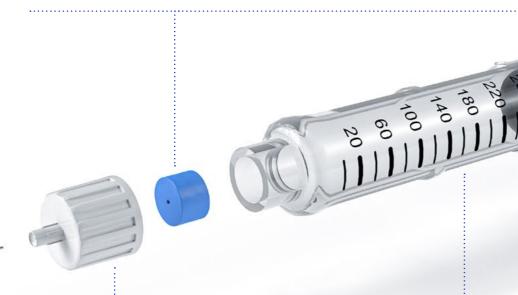
Elastic rubber part

Contactless measurement needed for of incoming goods and GD&T required.



process failure:

Accuracy of fit



High-precision plastic part

Quality solutions for injection molding needed.

Flash

Quality Challenge:

Quality Challenge:

flexible and soft parts. Defect inspection

Overmolded metal insert

Quality Challenge:

.....:

Design & function to be checked. Complex GD&T and assembly analysis. Inspection of finishing.

Possible process failure:

10



Scratch

Possible process failures:



Sink marks / warpage / shrinkage

Black spots

Plastic part with scale

Quality Challenge:

failures:

Inspection of inner volume and verification of printed scale.











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.

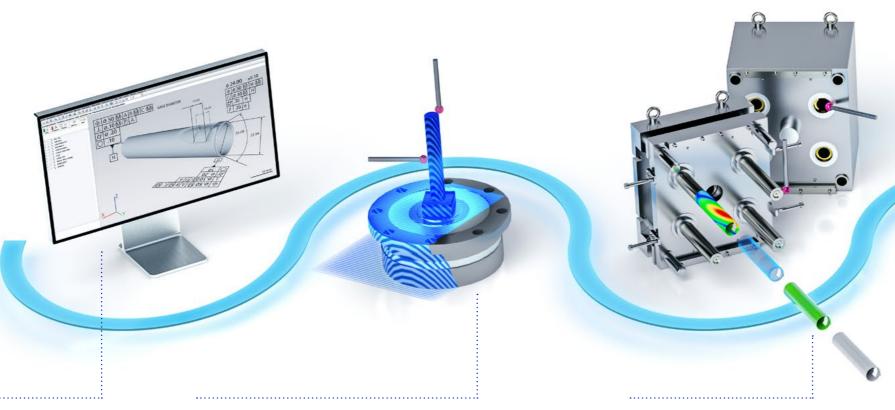
From Design to Tool Correction

Quality gates and solutions in the tool shop

Design & 3D Simulation

Tool Manufacturing

Tool Assembly & Correction



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.













SolutionsFor 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

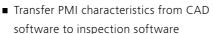
Quality Solution:

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 autogeneration of inspection plans – with all unnecessary characteristics excluded



Added Value



- 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

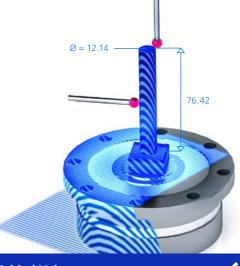
Challenge:

- 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

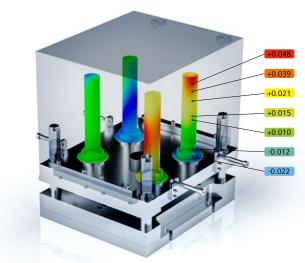
Challenge

- 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
- \blacksquare 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



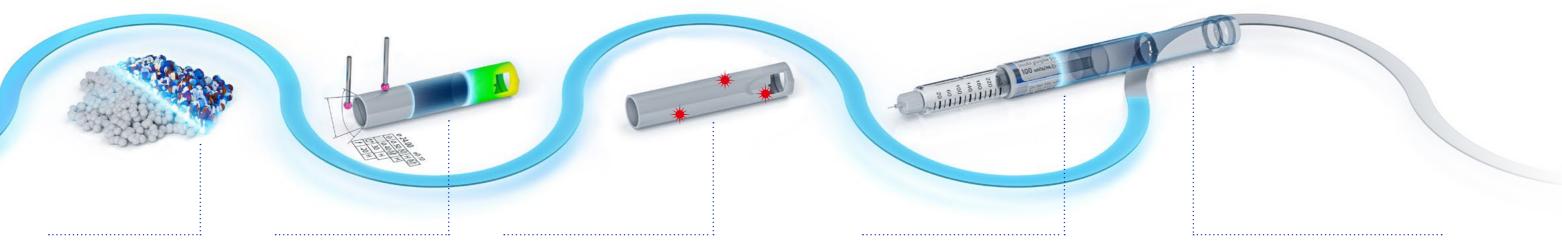
The structure of the manufacturing process enables highly efficient production of plastic components in large batches. Part design and requirements may vary considerably, however, with rotation capacity, elasticity, and compatibility with materials such as metal just some of the potential factors.

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.

From Raw Material to Finished Parts

Quality gates and solutions in part manufacturing

Raw Material Precision Injection Molding Assembly Drug Delivery Filling Process



Granulated Plastics

In the manufacture of medical plastic components, it is extremely important to understand and characterize the raw material. Quality assurance checks provide confidence that the correct material is being used, which will minimize the risk of errors within production and failure in the field.

Quality Solution:

Impurity Detection and Classification

Characterization of materials is conducted by visual inspection using light microscopes to identify granulate size and bulk characteristics. If required, further analysis performed with a scanning electron microscope can identify composite distribution and enable elemental analysis. ZEISS provides solutions such as the AXIO Imager 2 (light microscope) and EVO (scanning electron microscope) to support these examinations.

Geometric Dimensioning and Quality Inspection

A final check has to be performed on produced parts to ensure accuracy of dimensions and tolerances so that individual components fit together seamlessly in the assembly. As the surface of plastic components is particularly sensitive to tactile measurement, optical solutions and CT solutions are preferred for this purpose.

Quality Solution:

Optical Component Scan

The ZEISS O-INSPECT family of multisensory measuring machines can perform a wide range of inspection procedures tailored to the specific material and tolerance. This hardware can be combined with ZEISS CALYPSO VAST probing, Pallet Optimizer, and AutoRun to ensure faster measurements as part of a highly efficient pallet-based approach.

CT Component Scan

Non-destructive computed tomography technologies such as ZEISS METROTOM 6 scout enable 3D scanning of parts in stunning detail. They are even able to perform multi-material inspection for detailed quality analysis of different materials within a single component.

Particle Contamination

You need to monitor particle contamination in order to avoid wasting resources on what will ultimately be unusable parts. Proper detection and classification of such particles is also essential for ensuring compliance with medical industry standards and can be performed at every stage of the manufacturing process.

Quality Solution:

ZEISS Technical Cleanliness Analysis (TCA)

This solution for light microscopes ensures that important settings are always correct and supports automatic image analysis in ZEISS ZEN core. Productivity-boosting one-scan technology saves time and money while guaranteeing reliable and reproducible results.

Correlative Solutions for Technical Cleanliness

Correlative particle analysis is combining your data from both light and electron microscopes in a single workflow. This approach enables you to characterize process-critical particles and identify contaminating particles in next to no time

Inspection of Assembly

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.

Incoming Goods Inspection









Solutions

For quality gates

Granulate Analysis

Pre-processing quality checks

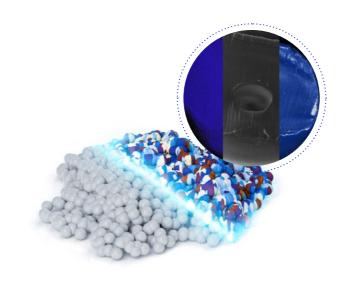
Challenge:

- 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



- Use of confirmed high-quality raw materials helps save time and resources
- Correlative workflow for LM- and SEMbased 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

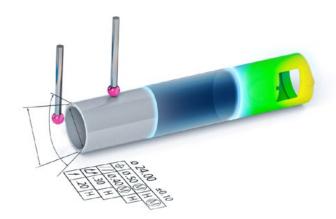
ATOS for non-transparent workpieces. Measure up to
 12 million 3D points in less than a second. Scan one part in high resolution or scan multiple parts at the same time

Optical Component Scan

- \blacksquare 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-byprobe 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

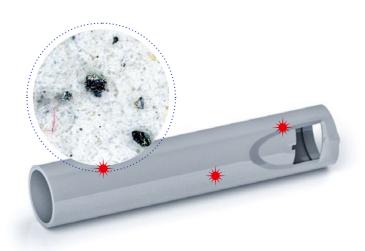
Quality Solution:

ZEISS Technical Cleanliness Analysis (TCA)

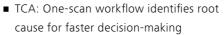
- Workflow can be adapted to suit every routine, with analysis, reporting, and archiving all available in just a few clicks
- ZEISS ZEN core TCA module delivers reliable and reproducible results while ensuring high productivity
- Display of all size classifications and cleanliness levels at a glance, 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 relocalizes 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



- 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



- 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







ZEISS PiWeb

Reporting & statistical analysis

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

ZEISS FACS Automation software

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

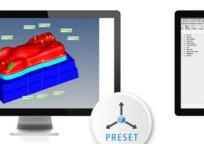
Volume Inspect

geometries, voids, internal structures, operation, high performance: CT data









Trend analysis for volume data With Volume Inspect you can look

inside your part and analyze and assembly situations. Intuitive analysis has never been easier!

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

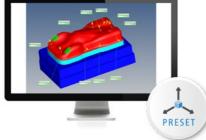
Metrology software

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

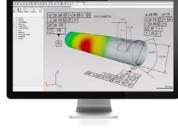
Tool correction

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





ZEISS Visioner 1 Visual inspection

Digital microscope with realtime 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.





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.





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.

Manual and Automated Scanning



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 nominalactual 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 mediumsized 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.

Your Global Partner – Present in all regions

32
Sales & Service
Organizations

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.

63ZEISS Quality

Excellence Centers

100
Business Partners

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