Quality Assurance for the Highest Medical Standards

ZEISS Medical Industry Solutions

Orthopedic Implants Application Catalogue

Status: March 2021

ZEISS Medical Industry Solutions
Overcome the hurdles of a regulation-driven industry

Proof of Quality

Guideline Compliance
FDA, MDR, etc.

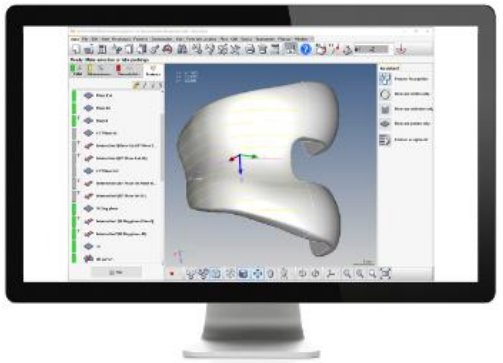
Data Handling Regulation
FDA CFR 21 Part 11

Quality Management Regulation
ISO 13485:2016
FDA CFR 21 Part 820

Connect to Productivity
ZEISS software

- 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

Connect to Productivity
ZEISS software for regulatory demands



ZEISS GUARDUS
MES & CAQ software solution

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

ZEISS CALYPSO
Measurement software

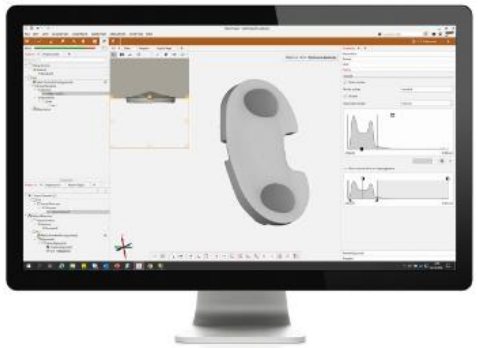
With ZEISS CALYPSO you can measure your workpiece easily, quickly and reliably. In addition to comprehensive identity management (e.g. via LDAP) and the comparison of inspection plan versions, a wide range of functions are available to provide security and increase efficiency.

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.

Connect to Productivity

ZEISS software for Evaluation, Analyses, Reporting and Automation



GOM Volume Inspect

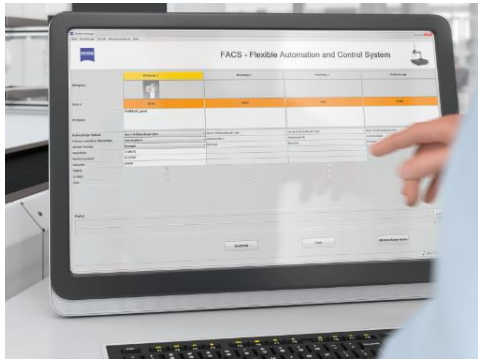
Trend analysis on volume data

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

ZEISS PiWeb

Reporting & Statistical Analysis

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



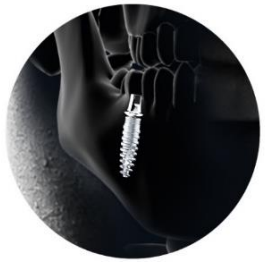
ZEISS FACS

Automation software

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

Quality Solutions

Assure Quality for all types of Implants






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

Metal Working Process
Quality Gates and Solutions

Raw material	Primary Shaping	Processing	Finishing
	Forging / Casting / Additive Manufacturing	Milling / Turning / Grinding	

Metallography	Quality of Raw Parts	Incoming Inspection	In Process Control	Geometric Dimensioning	Surface Analysis

Metal Working Process
Quality Gates and Solutions

Raw material	Primary Shaping	Processing	Finishing
	Forging / Casting / Additive Manufacturing	Milling / Turning / Grinding	

Metallography	Quality of Raw Parts	Incoming Inspection	In Process Control	Geometric Dimensioning	Surface Analysis

Metallography
Analysis of raw material

Challenges

- Quality of material with respect to porosity, voids, cracks, fissures and grain size.
- Identifying common inclusion types found in metal
- Assessing the materials chemical composition.
- Analysis of raw material powder in additive manufacturing.

Quality Solutions

- Industrial Microscopes:
  - ZEISS Axio Zoom V.16
  - ZEISS Axio Imager 2
  - ZEISS Visioner 1

- Scanning Electron Microscopes:
  - EVO

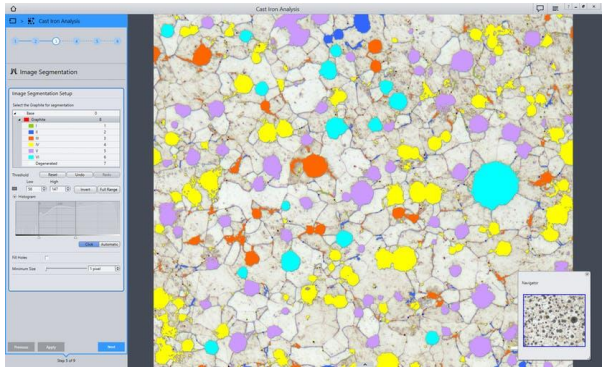
Added value

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

Metallography

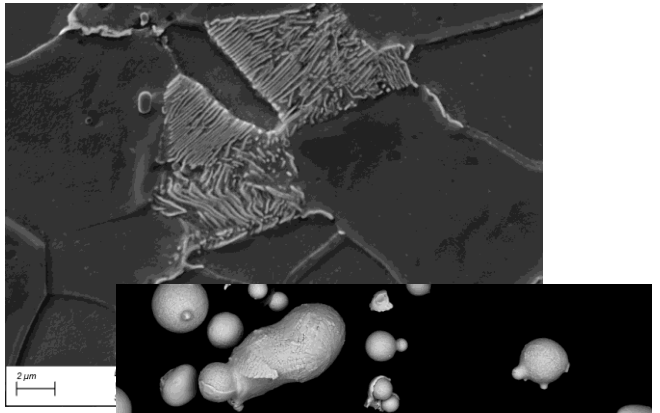
Challenge

- Characterisation and quality assurance of bulk stock material or raw powder



Customer need

- Simple and easy imaging and analysis of stock material to ensure greater material consistency and more reliable product.
- Check the quality of the raw material before processing, adding value and wasting time and resources



Quality solution

- ZEISS Axio Imager 2
- ZEISS EVO with EDS / EBSD
- ZEISS ZEN core with GxP

ZEISS Winning Benefit

✓ Optical and SEM based solutions with a correlative workflow

✓ GxP compliant solution

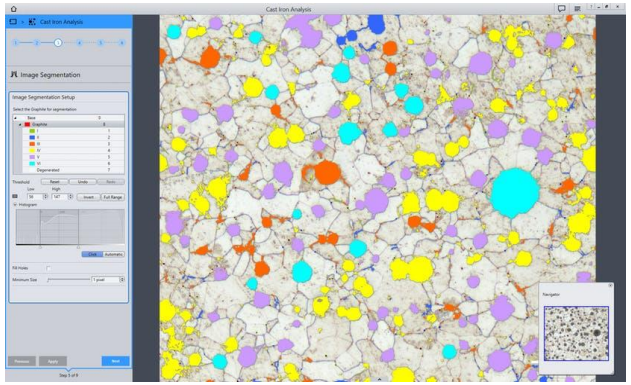
Metallography
Crystaline structure

Challenge

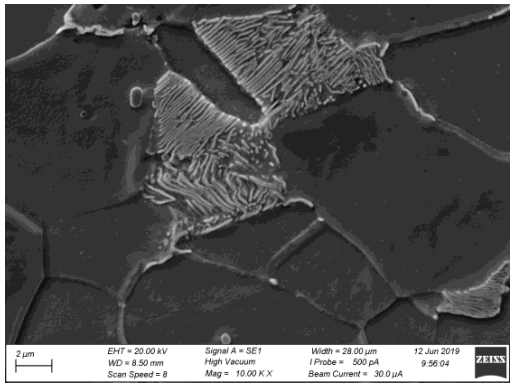
- Characterisation and quality assurance of bulk stock material

Quality solution

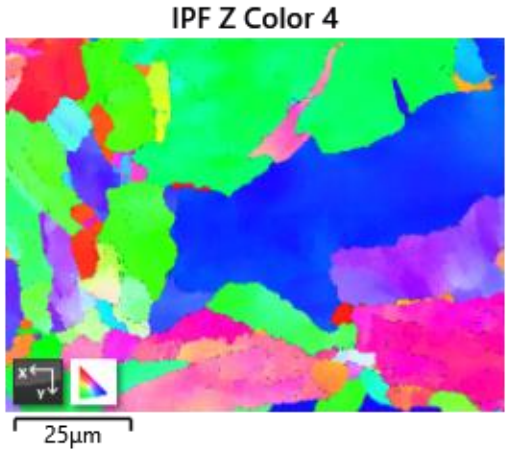
- ZEISS Axio Imager 2
- ZEISS EVO with EDS / EBSD
- ZEISS ZEN core with GxP



- Imaging of polished section using light microscopy
- ZEN Core is then used to segment the image



- Conformation of nano scale features using the SEM
- Elemental analysis on the SEM with EDS



- Further analysis of the grain structure and crystal orientation on the SEM with EBSD

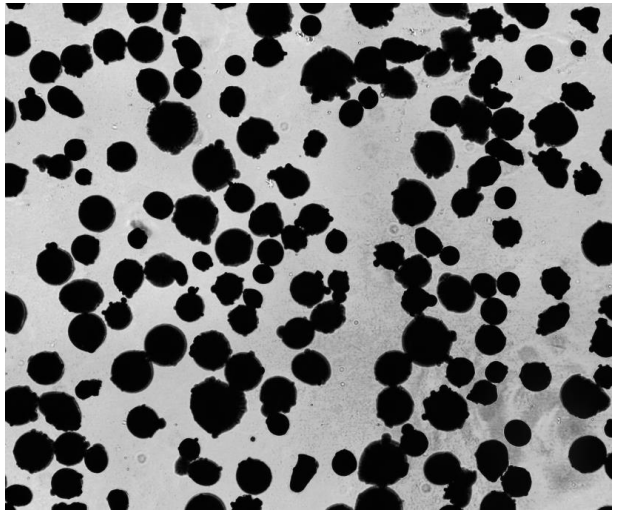
Metallography
AM powder

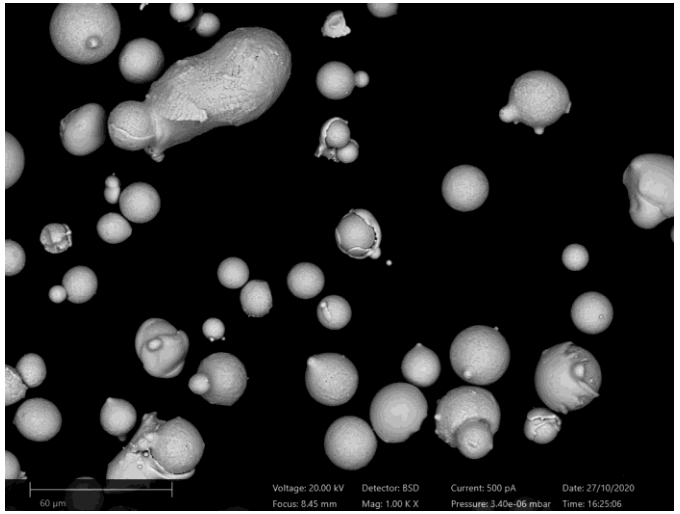
Challenge

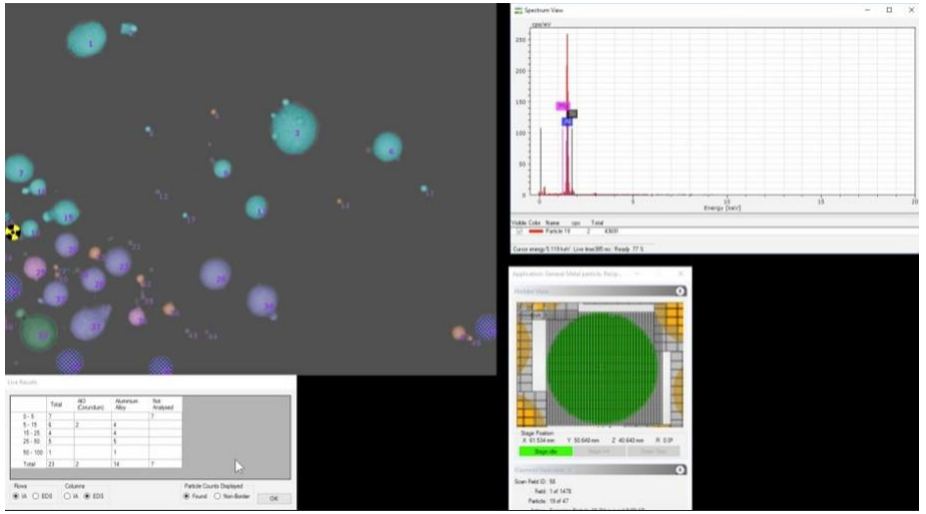
- Characterisation and quality assurance of raw powder

Quality solution

- ZEISS Axio Imager 2
- ZEISS EVO with EDS / EBSD
- ZEISS ZEN core with GxP







Metal Working Process
Quality Gates and Solutions

Raw material	Primary Shaping	Processing	Finishing
	Forging / Casting / Additive Manufacturing	Milling / Turning / Grinding	

Metallography	Quality of Raw Parts	Incoming Inspection	In Process Control	Geometric Dimensioning	Surface Analysis

Quality of Raw Parts
Inspection of primary shape

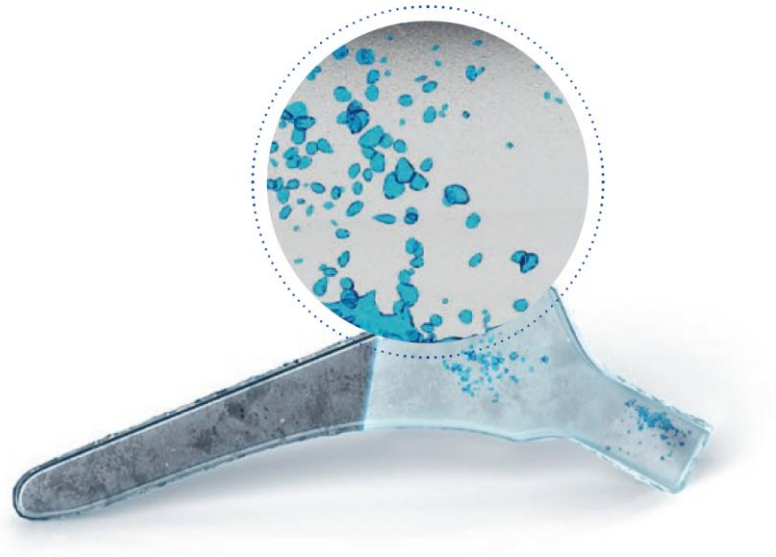
Challenges

- Verifying that the components are produced in a good shape and specified dimensional quality before accepting it
- Check parts for critical defects as voids, cracks and inclusions before further processing
- Rapid location of defects without destroying the component

Quality Solutions

- Void Inspection:
  - SRE MAX from Bosello
  - ZEISS METROTOM 800
  - ZEISS METROTOM 6 scout

- Geometrical Inspection:
  - ATOS Q from GOM



Added value

- Fast inspection of the incoming goods to prevent cost-intensive failures later in the manufacturing process
- Incorrect stock can later not only lead to costs in production but must also be reimbursed by the supplier.

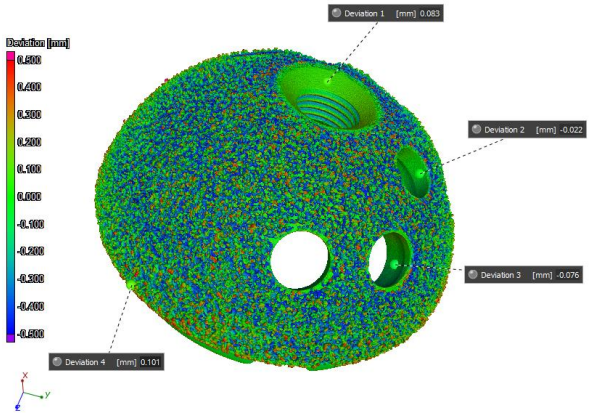
Quality of Raw Parts
Acetabular cup

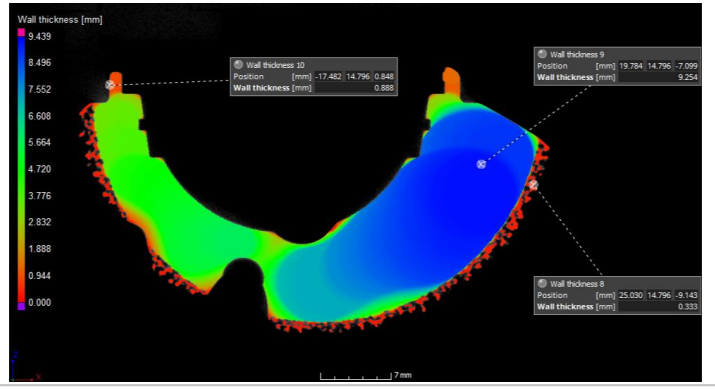
Challenge

- Penetrability of the part
- Porous structure on the surface

Customer need

- Comparison to the CAD model
- Evaluation of the wall thickness on each area of the part





Quality solution

- Hardware: METROTOM M1500 or M800 HR depending on desired voxelvsize/ resolution
- CALYPSO for nominal-actual comparison
- GOM volume inspect for nominal-actual comparison and wall thickness analysis

GOM Inspect Professional

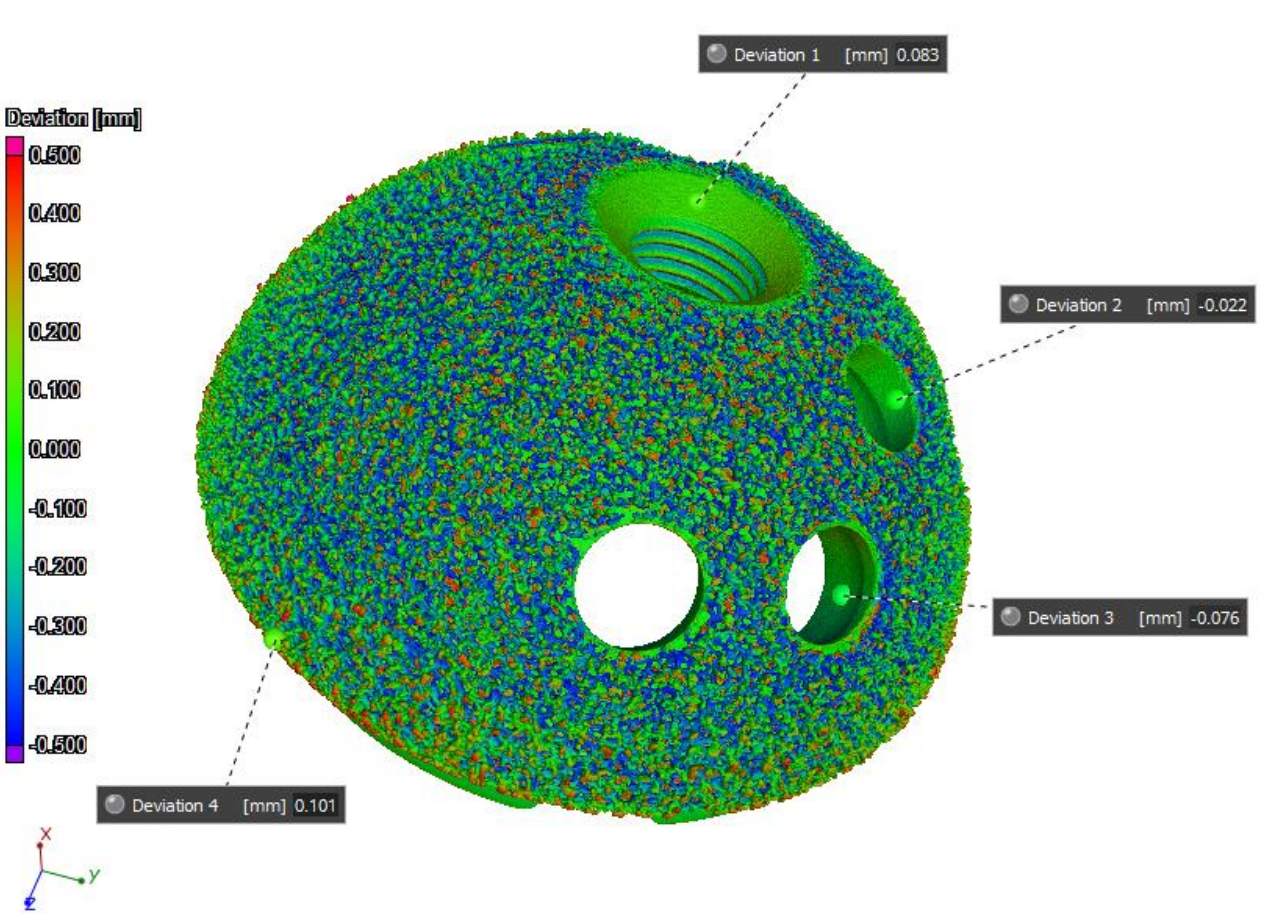
ZEISS Winning Benefit

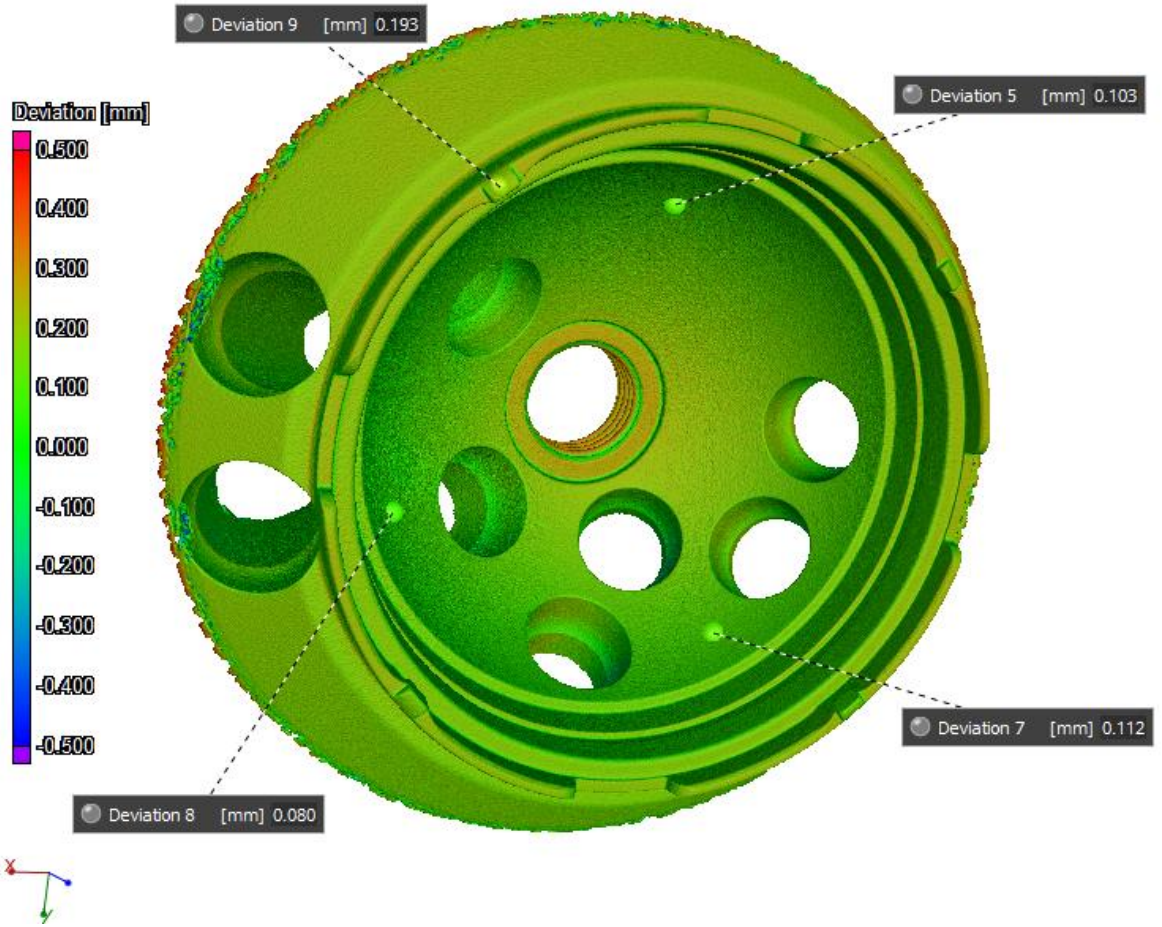
- ✓ Visualization of the deviations to the CAD model on each area also on hidden features
- ✓ Calculation of the thickness for the whole part. Labels can be created to show the values on special points of interest

Quality of Raw Parts

Nominal-actual comparison

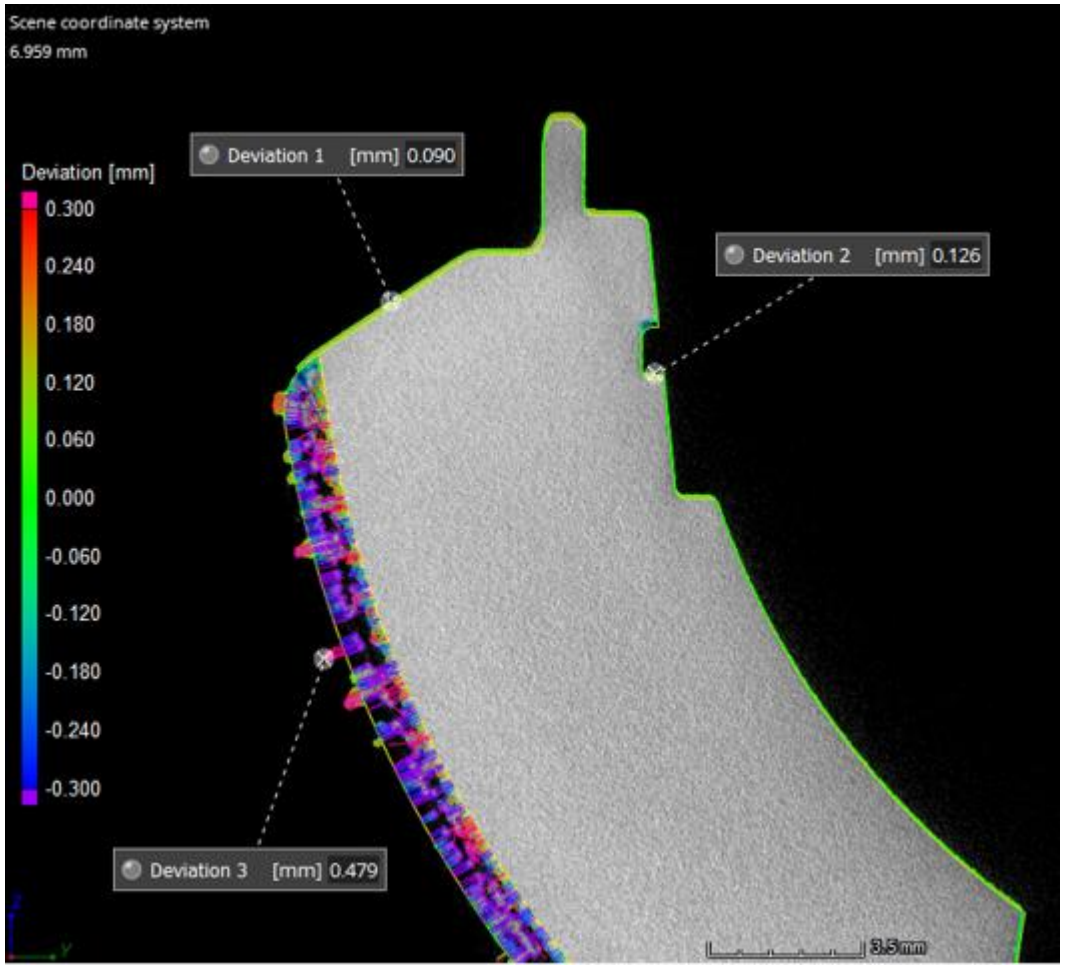
Surface deviation in colors –3D view

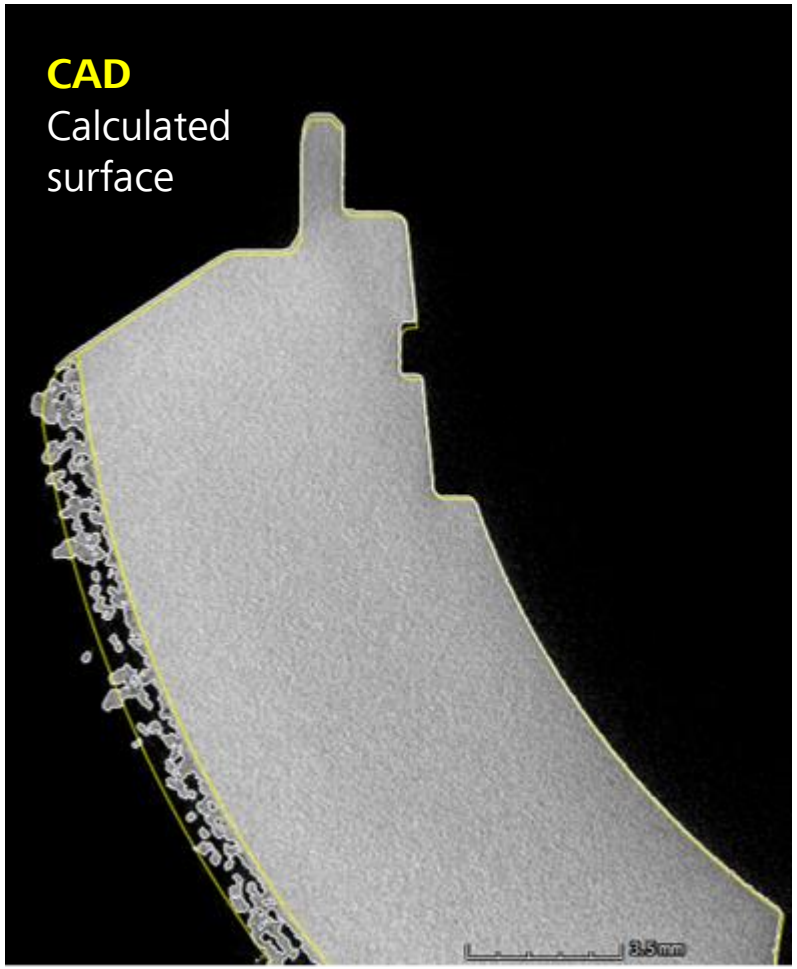




Quality of Raw Parts

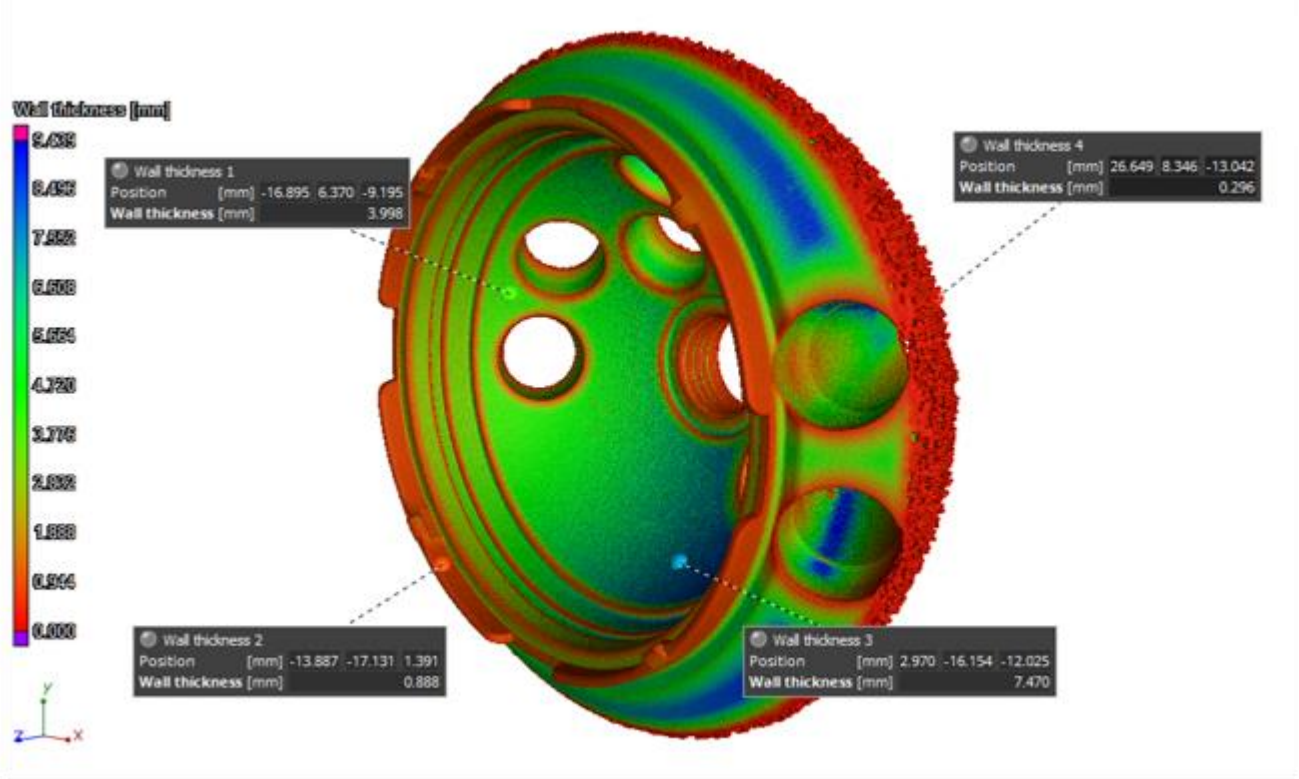
Nominal-actual comparison
Surface deviation in colors – 2D view

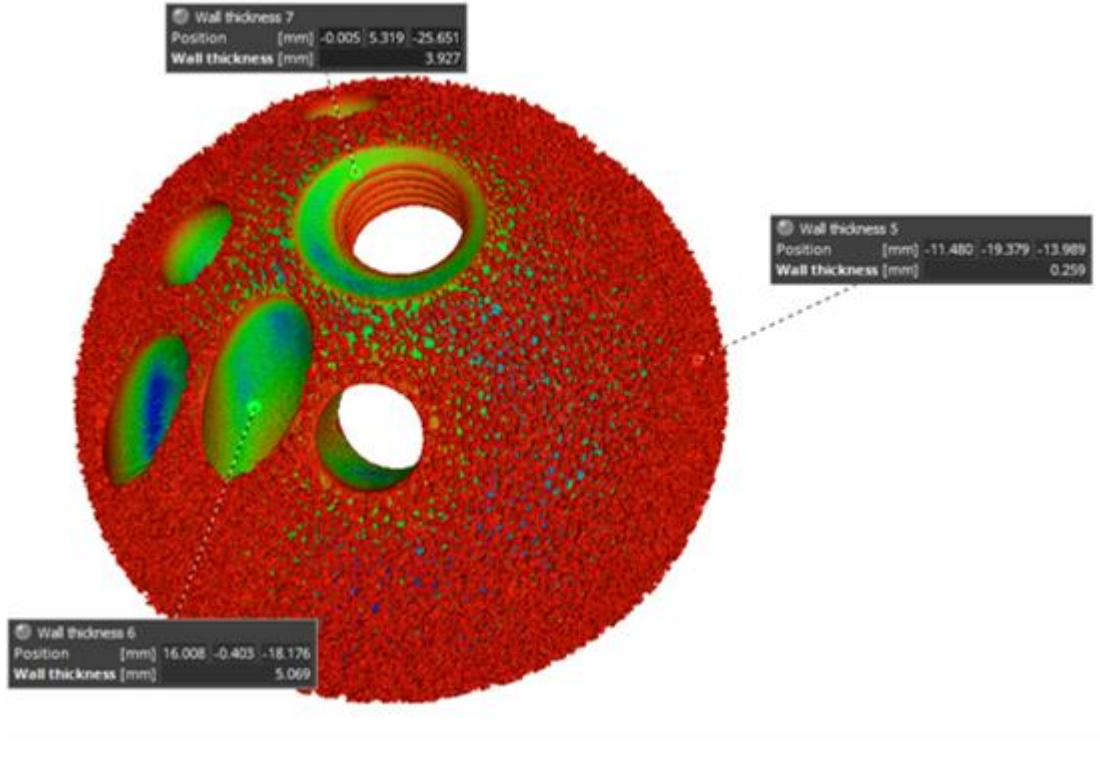




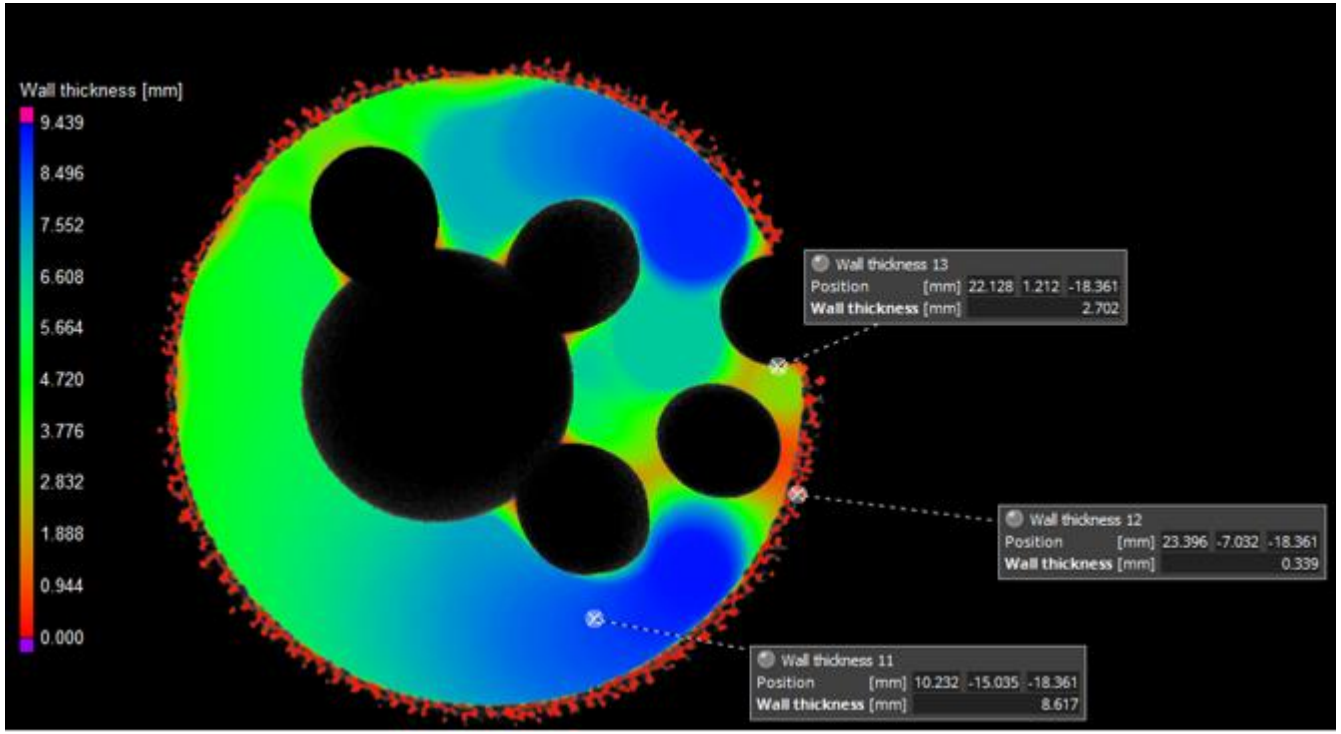
The deviation table can be flexible customized. Also, the deviation flags can be positioned on each area of interest. It is also possible to calculate the nominal-actual comparisons in different alignments.

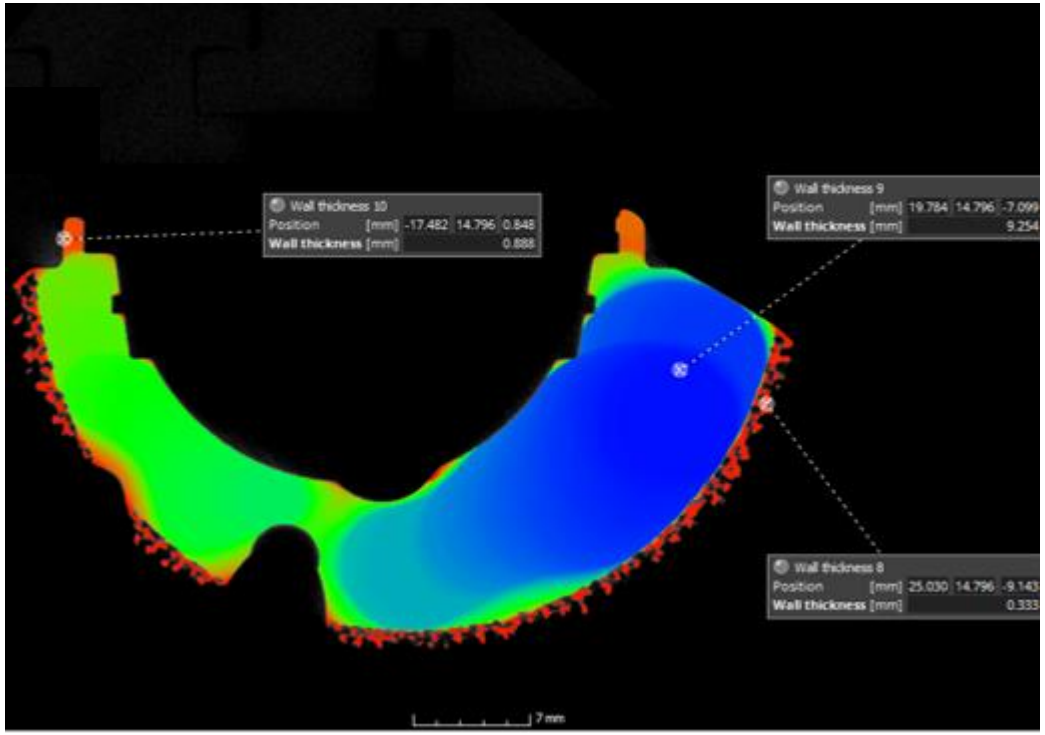
Quality of Raw Parts
Wall thickness evaluation
3D-visualization





Quality of Raw Parts
Wall thickness evaluation
2D-visualization





Quality of Raw Parts
Femoral implant

Challenge

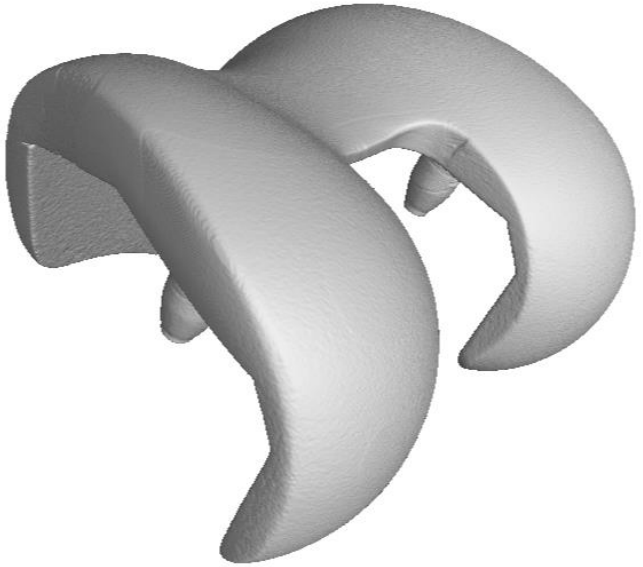
- Penetrability of the part
- high scanning quality for detection of inner defects

Customer need

- Visual inspection of the whole part
- Detection of defects (air inclusions, cracks, porous structure…)
- Information defect size, position

Quality solution

- Hardware: METROTOM M1500 or M800 HR depending on desired voxel size/ resolution
- GOM volume/ inspect for visual inspection of the part
- Automatic defect detection

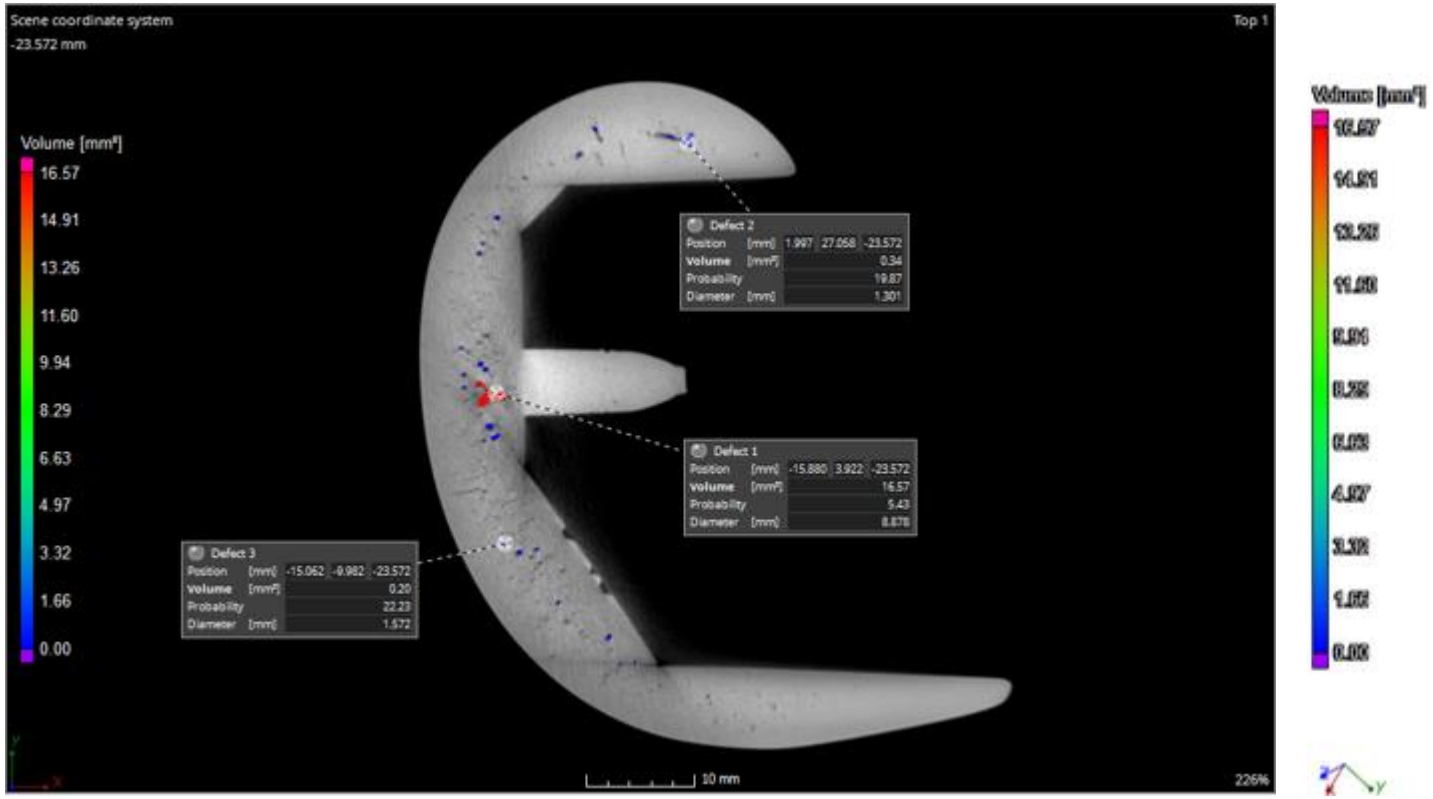


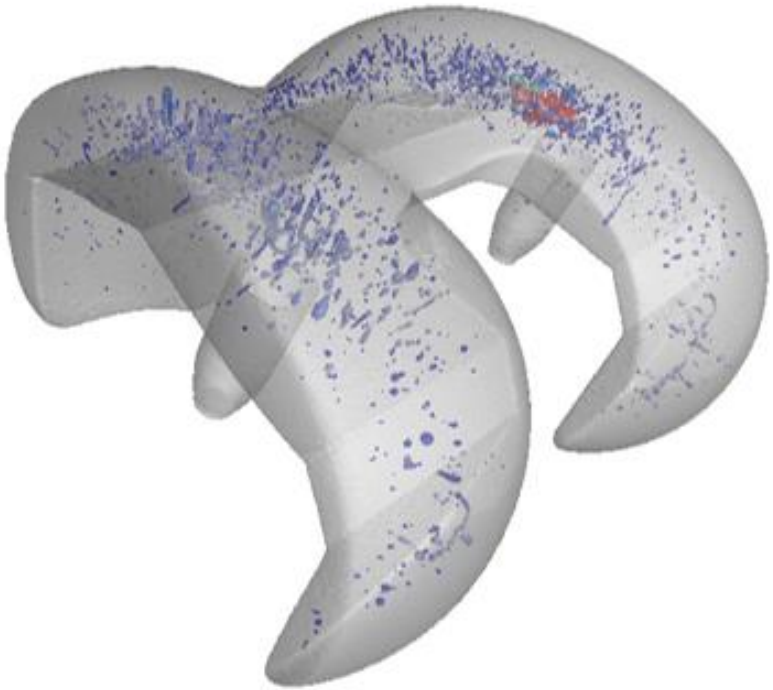
GOM Inspect Professional

ZEISS Winning Benefit

- ✓ Visualization of defects, which can't be seen without destroying the part
- ✓ Evaluation of the part quality e.g. high risks of existing cracks
- ✓ Evaluation of the production process by analyzing appearing defects

Quality of Raw Parts
Defect evaluation





Metal Working Process
Quality Gates and Solutions

Raw material	Primary Shaping	Processing	Finishing
	Forging / Casting / Additive Manufacturing	Milling / Turning / Grinding	

Metallography

Quality of Raw Parts

Incoming Inspection

In Process Control

Geometric Dimensioning

Surface Analysis

Incoming Inspection
Efficient verification of supplied parts

Challenges

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

Quality Solutions

- Efficient Inspection:
  - ZEISS DuraMax
  - ZEISS CONTURA
  - ZEISS LineScan

- Geometrical Inspection:
  - ATOS ScanBox from GOM

Added value

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

Incoming Inspection
Hip stem forging

Challenge

- High quantity of parts
- Must have enough stock material on 100% of part
- Made with dimensions close to final to reduce processing time

Customer need

- Fast incoming inspection either optical systems or tactile CMM's in shop floor.
- Simple nominal actual comparison for stock material.

Quality solution

- ZEISS DuraMax
- ZEISS CONTURA
- ZEISS LineScan
- GOM Atos Q
- ZEISS CALYPSO
- ZEISS PiWeb
- GOM Inspect

ZEISS Winning Benefit
- ✓ Complete Surface scanning to CAD comparison possible
- ✓ Simple Go / No-Go Quality gate

Incoming Inspection
Hip stem forging

Challenge

- Simple Go / No-Go Quality gate
- Fast incoming inspection either optical systems or tactile CMM's in shop floor.
- Guarantee to have enough stock material on 100% of part

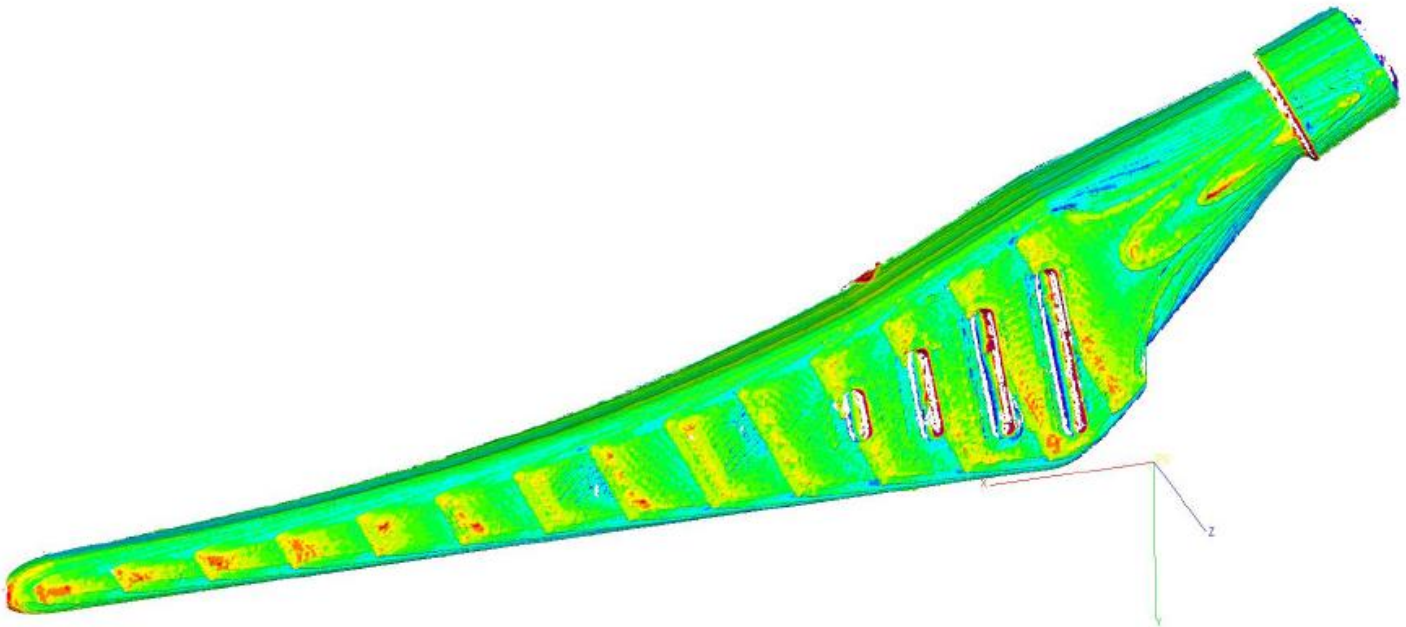
Quality solution

- ZEISS DuraMax
- ZEISS CONTURA
- ZEISS CALYPSO
- ZEISS PiWeb

Incoming inspection
Hip stem forging

Challenge

- 3D PointCloud solution for full comparison
- LineScan and CALYPSO
- GOM and ATOS Q
- Simple nominal actual comparison for stock material.



Quality solution

- ZEISS CONTURA
- ZEISS LineScan
- GOM Atos Q
- CALYPSO
- PiWeb
- GOM Inspect

Incoming Inspection
Femoral knee 3D print

Challenge

- High quantity of parts
- Must have enough stock material on 100% of part
- Parts printed in stacks/pairs
- Printed in large groups that need to me measured simultaneously in lots
- Not all features accessible due to supporting structure

Customer need

- Fast inspection either optical systems or tactile CMM's in shop floor.
- Simple nominal actual comparison for stock material.
- Directly comparable to inspection cycle times on tactile inspections

Quality solution

- ZEISS DuraMax
- ZEISS CONTURA
- ZEISS LineScan
- GOM Atos Q
- ZEISS CALYPSO
- ZEISS PiWeb
- GOM Inspect

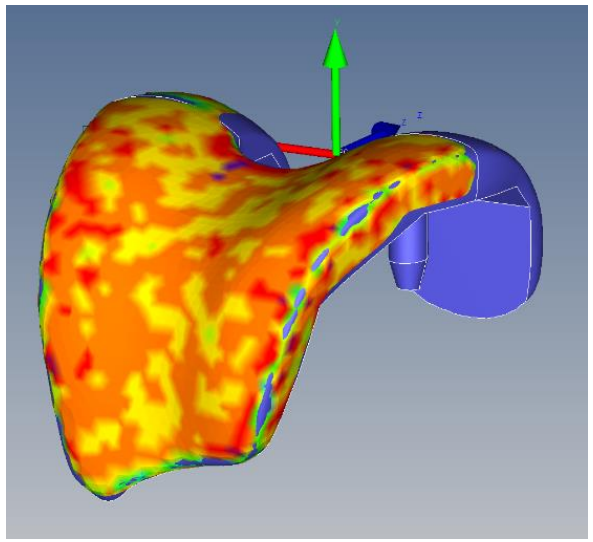
ZEISS Winning Benefit

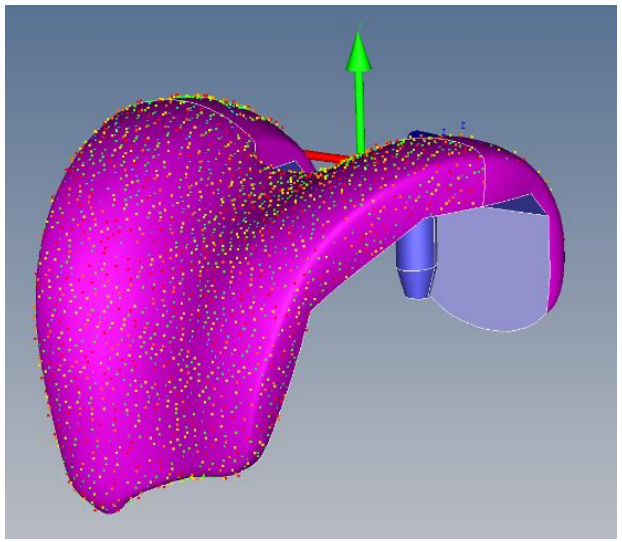
- ✓ Point cloud to CAD model comparison and visualization of stock material possible
- ✓ Complete lot inspection possible and can be automated

Incoming Inspection
Femoral knee 3D print

Challenge

- Must have enough stock material on 100% of part





Quality solution

- 3D point cloud analysis
- Should be done on rough surface to avoid structured light scatter
- With a few angles a pallet run can be done
- ZEISS LineScan and ZEISS CALYPSO / GOM and ATOS Q

Incoming Inspection
Custom parts 3D printed

Challenge

- Unique parts with complex structure
- Must have enough stock material on 100% of part
- Quick turnaround time needed
- Not all features accessible due to supporting structure

Customer need

- Fast and simple inspection solution that fits all custom parts
- Simple nominal actual comparison for stock material.

Quality solution

- ZEISS CONTURA
- ZEISS LineScan
- GOM Atos Q
- ZEISS CALYPSO
- ZEISS PiWeb
- GOM Inspect

3D point cloud analysis: Scan as seen here done with LineScan 2-50 took less than 90 Seconds to measure

Generic program can be created to scan almost any structure that fits within the scan volume of program.

ZEISS Winning Benefit
- ✓ Fully encompassing solution for custom parts that fits with general production
- ✓ Increase in inspection versatility

Incoming Inspection
Cast femoral knee

Challenge

- High quantity of parts
- Must have enough stock material on 100% of part
- Made with dimensions close to final to reduce processing time
- Datum and alignment features need to be tightly controlled

Customer need

- Fast incoming inspection either optical systems or tactile CMM's in shop floor
- Stock material measured and compared to datums

Quality solution

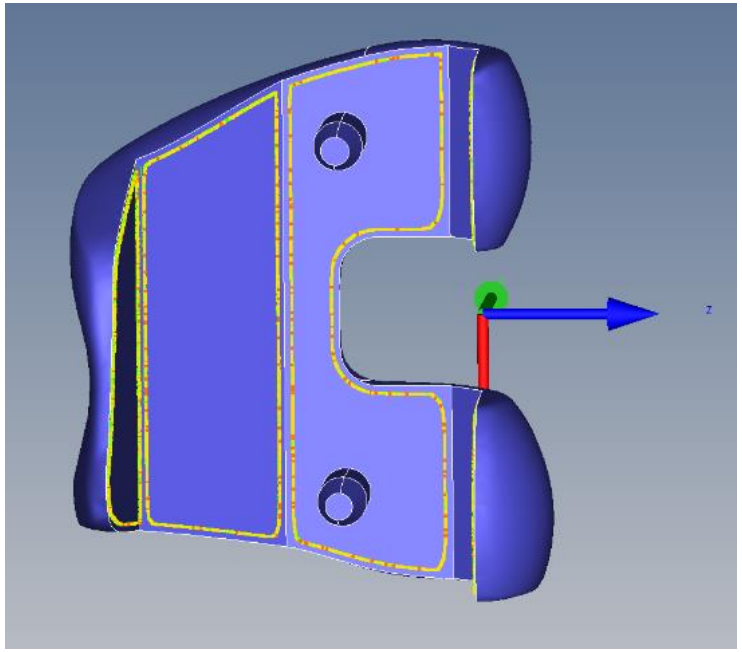
- ZEISS CONTURA
- ZEISS DuraMax
- ZEISS CALYPSO
- ZEISS PiWeb

ZEISS Winning Benefit
✓ Fast shop floor inspection
✓ Pallet and automatic loading capable

Incoming Inspection
Cast femoral knee

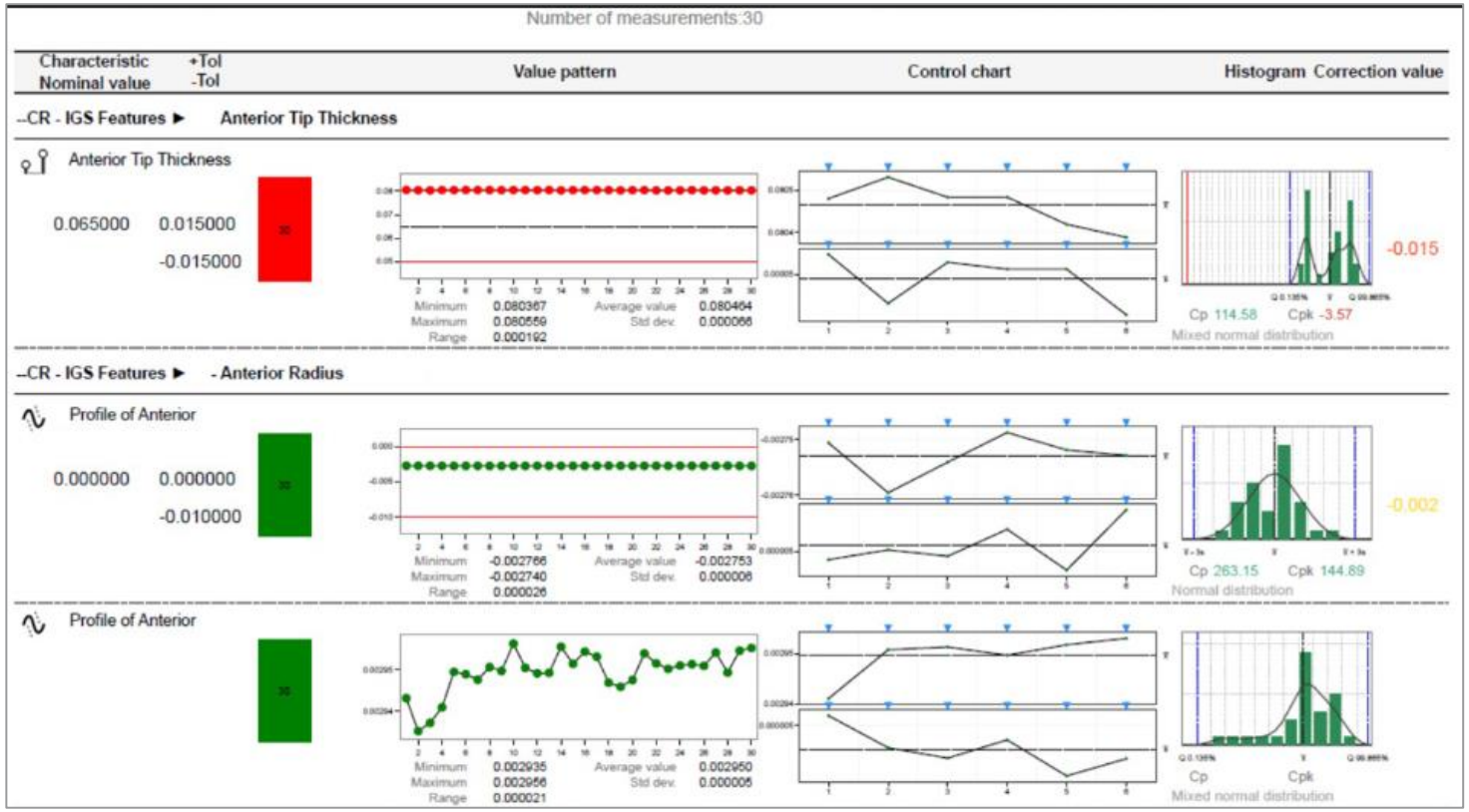
Challenge

- Fast incoming inspection either optical systems or tactile CMM's in shop floor



Quality solution

- Active Scanning
- Quick measuring time with VAST head (4:30) with great repeatability
- Shop floor scans with the DuraMax



Incoming Inspection
Bone plate

Challenge

- Large number of part families and sizes
- Few standard geometries present
- Small intricate splines with tight tolerances
- Bores in multiple complex angles

Customer need

- Full solution for a deep catalogue of parts
- Capability for 100% inspection

Quality solution

- ZEISS CONTURA
- ZEISS PRISMO
- ZEISS ZAS
- Rotary Table
- ZEISS ViScan
- ZEISS METROTOM
- ZEISS O-INSPECT
- ZEISS CALYPSO
- ZEISS PiWeb

ZEISS Winning Benefit
- ✓ 5 axis scanning possible with ZAS + RT
- ✓ Quick scanning of splines at any angle with ZEISS ViScan

Metal Working Process
Quality Gates and Solutions

Raw material	Primary Shaping	Processing	Finishing
	Forging / Casting / Additive Manufacturing	Milling / Turning / Grinding	

Metallography

Quality of Raw Parts

Incoming Inspection

In Process Control

Geometric Dimensioning

Surface Analysis

In Process Control
Observation of processing quality

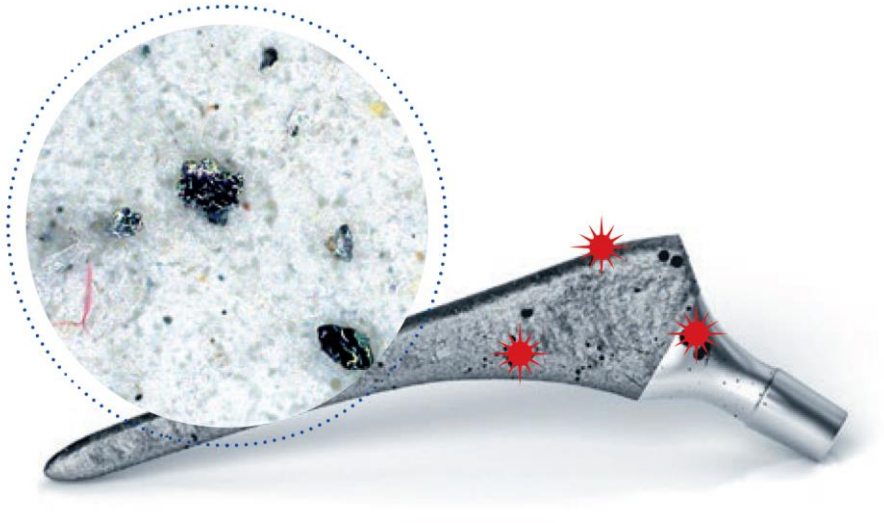
Challenges

- Detect and classify particulate contamination to fulfill the medical industry standards along the entire production process
- Manufacturing processes vary. Inspection vary of manufacturing process to control the processing and avoiding unnecessary further scrap

Quality Solutions

- Technical Cleanliness:
  - ZEISS Axio Imager 2
  - ZEISS EVO
  - ZEISS ZenCore with GxP
  - ZEISS TCA/ CAPA

- Process Monitoring:
  - ZEISS DuraMax
  - ZEISS CONTURA
  - ATOS Q from GOM



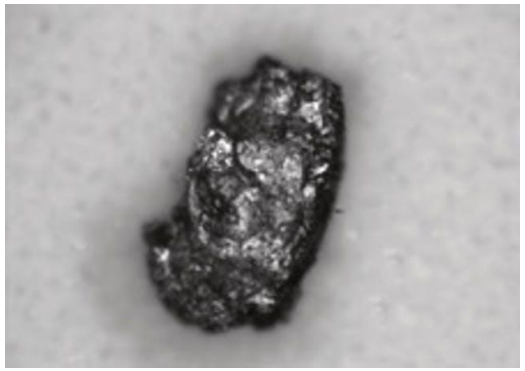
Added value

- Automated Particle Analysis with Light and Electron Microscopes: detect and classify particulate contamination to fulfill industry standards and GxP regulations
- Avoid scrap parts or even turn those into final products
- Reduce machining time

In Process Control
Technical Cleanliness

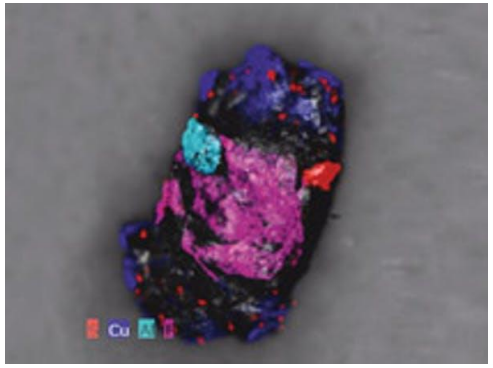
Challenge

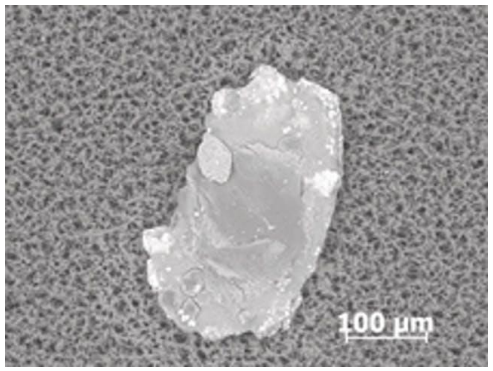
- Particulate contamination is the enemy of any product's efficiency, functionality and longevity



Customer need

- Conformation of component cleanliness conforming to VDI 2083
- To identify the root cause of contamination





Quality solution

- ZEISS AXIO Imager 2
- ZEISS EVO
- ZEISS TCA / CAPA
- ZEISS ZEN Core with GxP
- ZEISS Smart PI

ZEISS Winning Benefit
✓ Correlative capabilities
✓ GxP and VDI compliance

Metal Working Process
Quality Gates and Solutions

Raw material	Primary Shaping	Processing	Finishing
	Forging / Casting / Additive Manufacturing	Milling / Turning / Grinding	

Metallography

Quality of Raw parts

Incoming Inspection

In Process Control

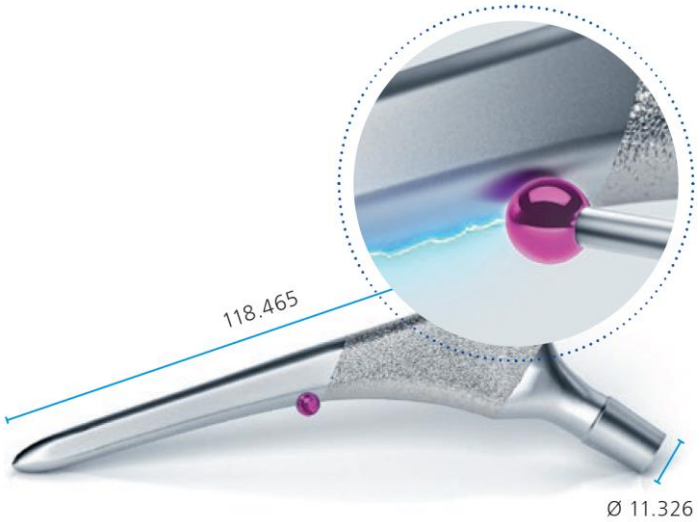
Geometric Dimensioning

Surface Analysis

Geometric Dimensioning
Final dimensioning

Challenges

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



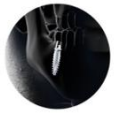
Quality Solutions

- ZEISS PRISMO
- ZEISS CONTURA
- ZEISS O-INSPECT
- ZEISS DotScan
- ZEISS METROTOM800 225kV HR
- ATOS ScanBox from GOM

Added value

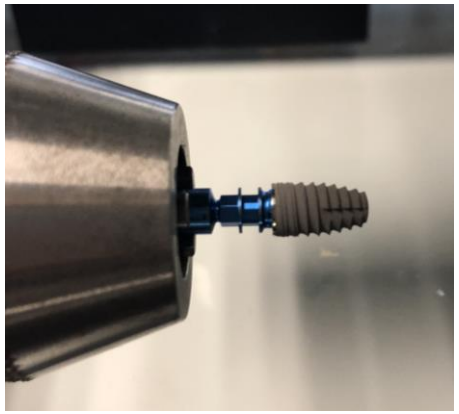
- Increase usable acceptance range by decreasing measurement uncertainty
- Reduce operator influence and need time for manual inspection by using CNC-inspection
- Fast and Accurate 100% inspection

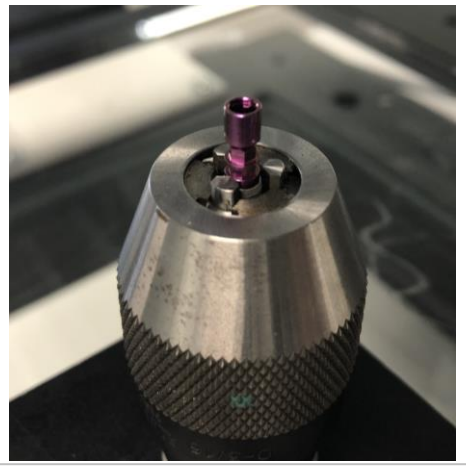
Geometric Dimensioning
Dental implant



Challenge

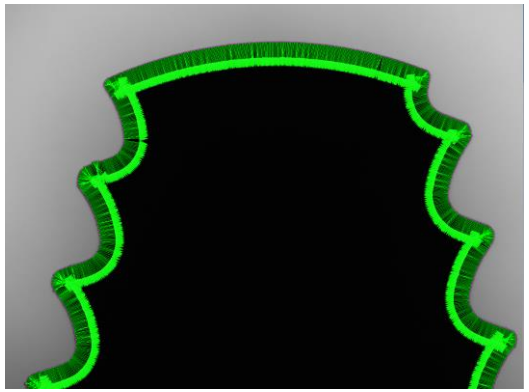
- Small structures
- Small tolerances

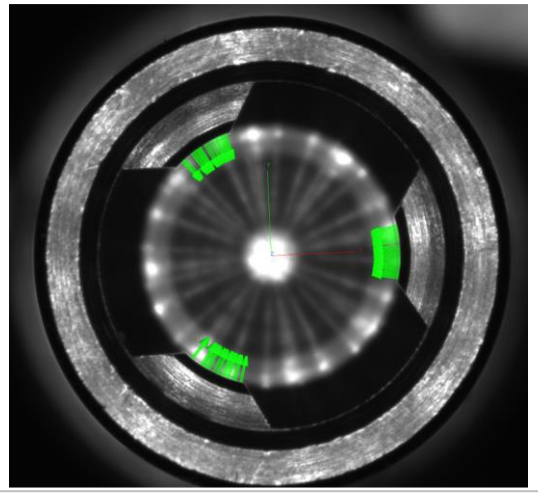




Customer need

- fast cycle times
- reliable results





Quality solution

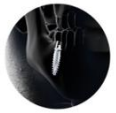
- ZEISS O-INSPECT
- ZEISS VAST XXT
- Rotary table

ZEISS Winning Benefit

✓ Micro stylus systems allow to measure tiny structures

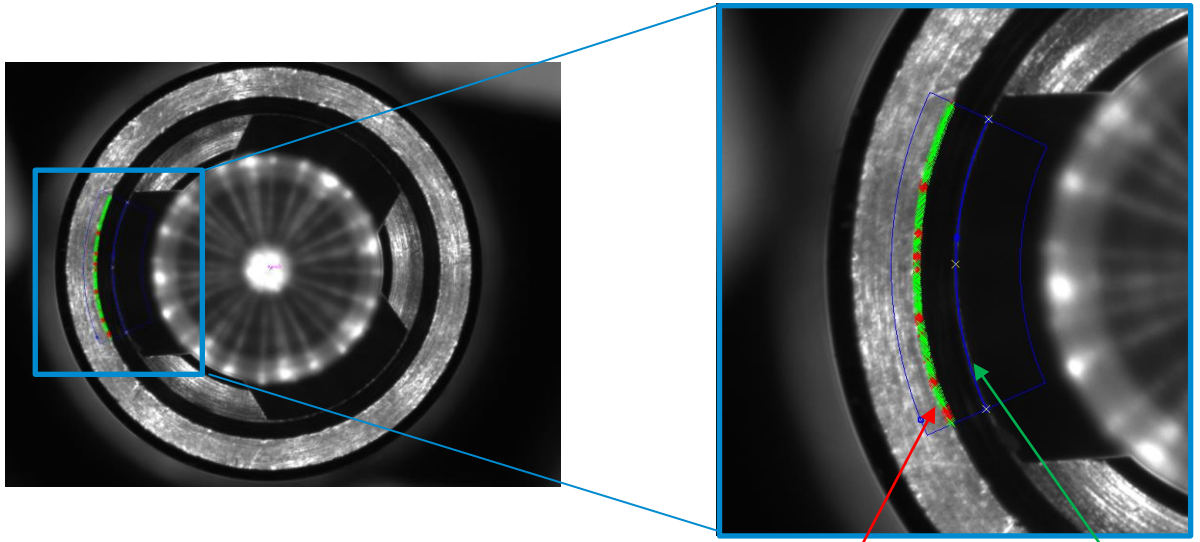
✓ Palette Optimizer leads to fast cycle times

Geometric Dimensioning
Dental implant



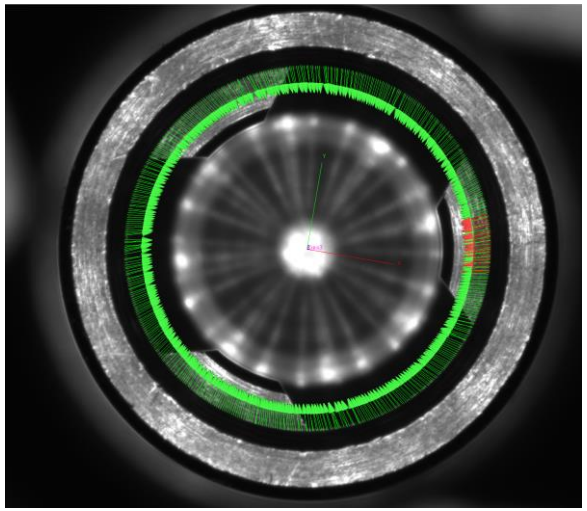
Challenge

- Limits of optical measurement
- Some edges aren't possible to measure optically



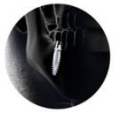
Solution I

ZEISS VAST XXT allows micro stylus systems with probe diameter of 0,1 - 0,3 mm



Tactile measurement points, shown in camera view

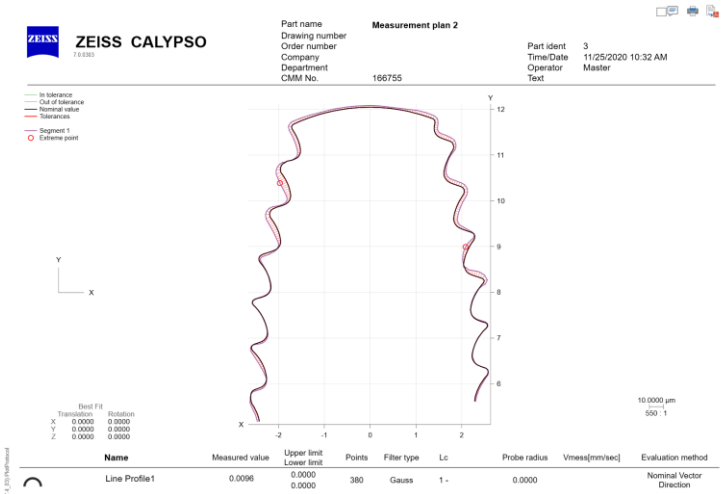
Geometric Dimensioning
Dental implant

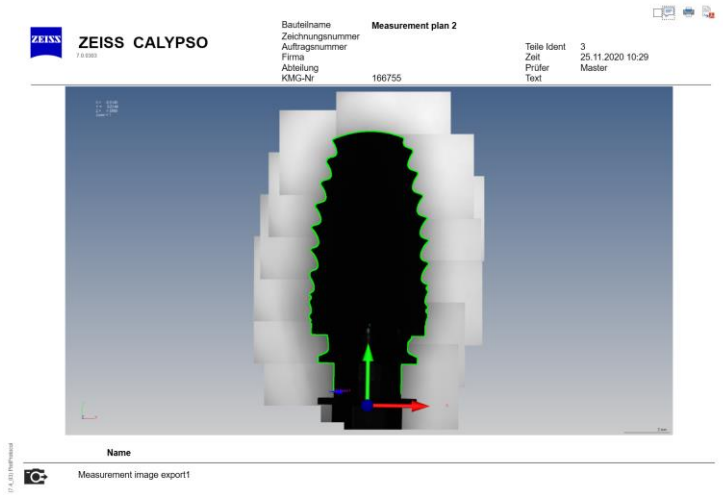


Customer need

- Reliable and repeatable results:
  Measuring range of < 1µm
- Visulization of results with ZEISS PiWeb

Characteristic Nominal value	+Tol -Tol	Value pattern	Control chart	Histogram	Correction value
A_2,7_tactile on the bottom					
A_2,7_1_tactile					
2.7000	0.0050 -0.0100	Minimum 2.6938 Average value 2.6941 Maximum 2.6944 Std dev. 0.0002 Range 0.0006		Cp 15.92 Cpk 9.17 Mixed normal distribution	0.003
A_2,7_2_tactile					
2.7000	0.0050 -0.0100	Minimum 2.6938 Average value 2.6940 Maximum 2.6943 Std dev. 0.0001 Range 0.0005		Cp 24.20 Cpk 13.28 Mixed normal distribution	0.003
A_2,7_3_tactile					
2.7000	0.0050 -0.0100	Minimum 2.6930 Average value 2.6933 Maximum 2.6937 Std dev. 0.0002 Range 0.0007		Cp 15.16 Cpk 7.25 Mixed normal distribution	0.004
Ø B_Ø4,11					
4.1100	0.0100 -0.0100	Minimum 4.1079 Average value 4.1080 Maximum 4.1083 Std dev. 0.0001 Range 0.0004		Cp 39.91 Cpk 38.59 Mixed normal distribution	0.002





Geometric Dimensioning
Implant Screw

Challenge

- Small structures
- Small tolerances
- Shiny surfaces

Customer need

- fast cycle times
- reliable results

Quality solution

- ZEISS O-DETECT with different illuminations
- ZEISS CALYPSO

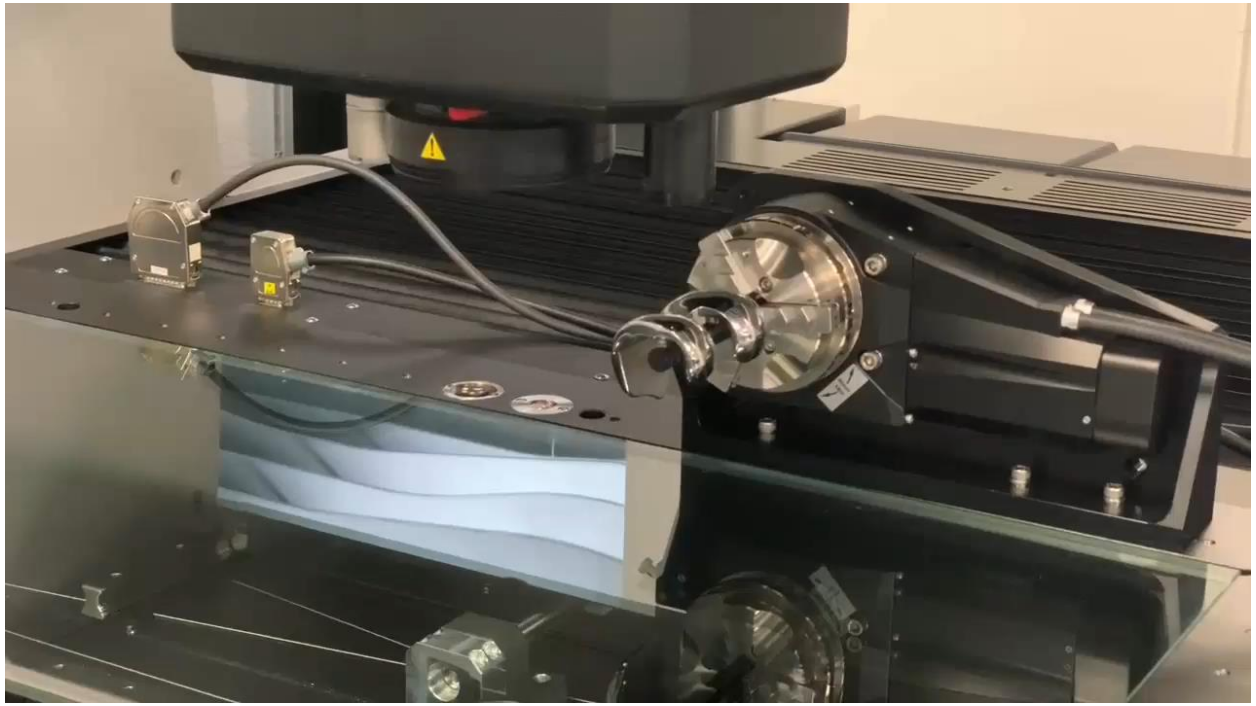
ZEISS Winning Benefit

✓ Different Illumination sources for perfect images
✓ CALYPSO for rotating alignment and palette measurement

Geometric Dimensioning
Femoral implant

Challenge

- No possibility to touch the polished surface due to the risk of micro scratches
- High polished surface difficult to measure with optical sensors
- Accessing parts
- Multifamily fixturing



Customer need

- Nondestructive measurements only
- Short cycle time
- Repeatability measurement

Quality solution

- ZEISS O-INSPECT
- ZEISS CONTURA with VAST XT
- ZEISS DotScan
- Rotary Table

ZEISS Winning Benefit

✓ Contactless measurement of the sensitive surface with ZEISS DotScan

✓ Accessibility to bearing and mating surface

Geometric Dimensioning
Femoral implant

Challenge

- Risk of micro scratches by tactile measurement
- High polished surface difficult to measure with optical sensors
- Accessing parts
- Multifamily fixturing

Customer need

- Nondestructive measurement required
- Short cycle time
- Repeatability measurement

Quality solution

- ZEISS CONTURA with RDS
- ZEISS VAST XXT
- ZEISS DotScan
- Rotary Table

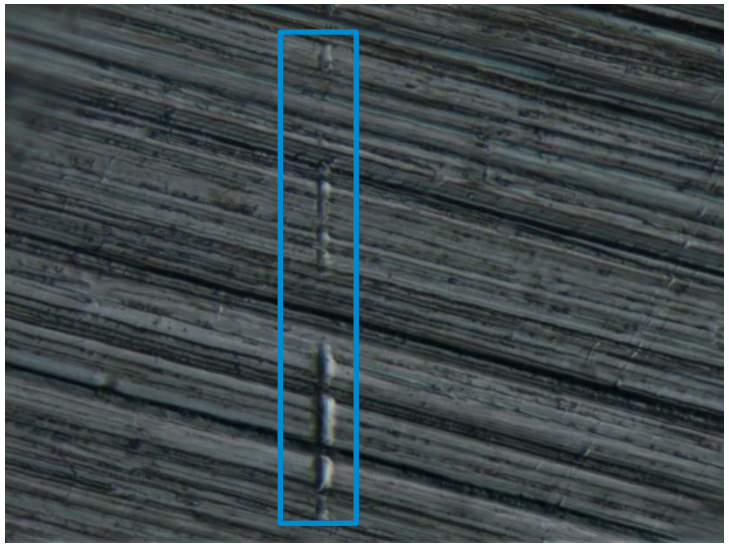
ZEISS Winning Benefit

- ✓ Contactless measurement of the sensitive surface with ZEISS DotScan
- ✓ Accessibility to bearing and mating surface

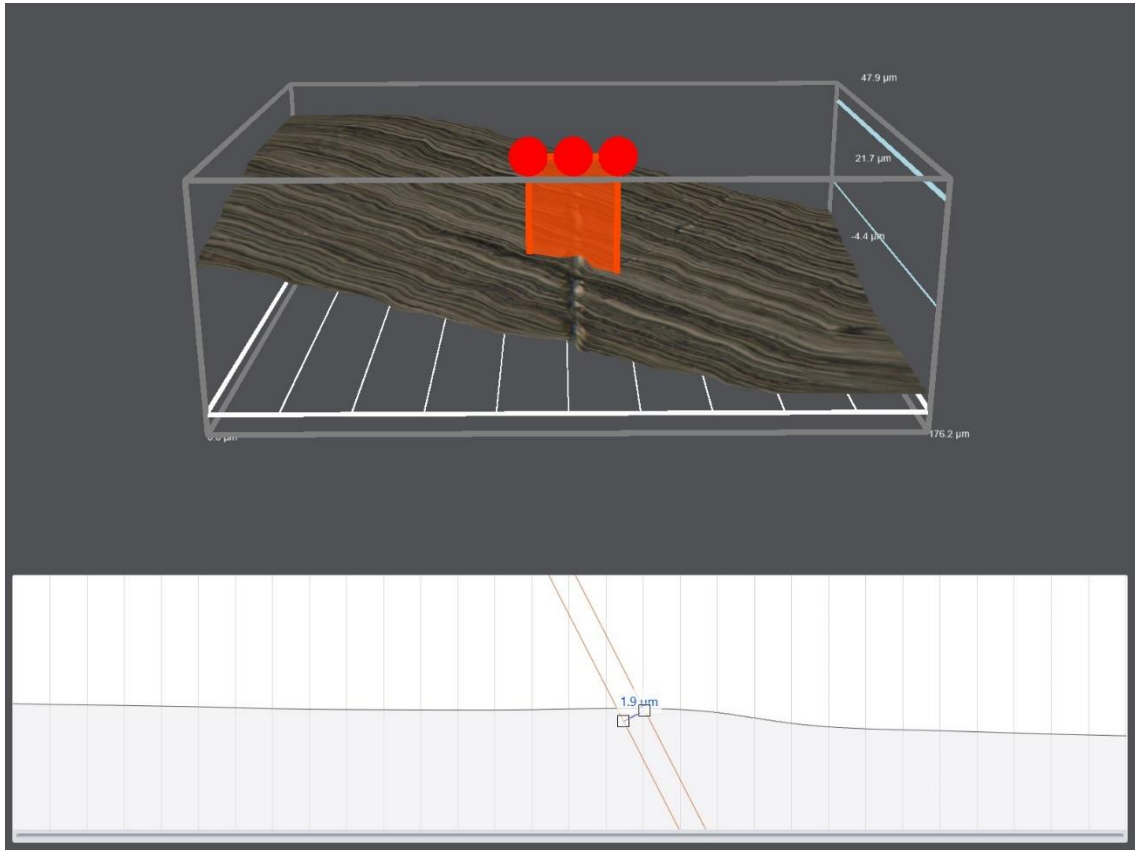
Geometric Dimensioning
Femoral implant – risk of micro scratches

Challenge

- High polished surface
- No possibility to touch the surface due to the risk of micro scratches.

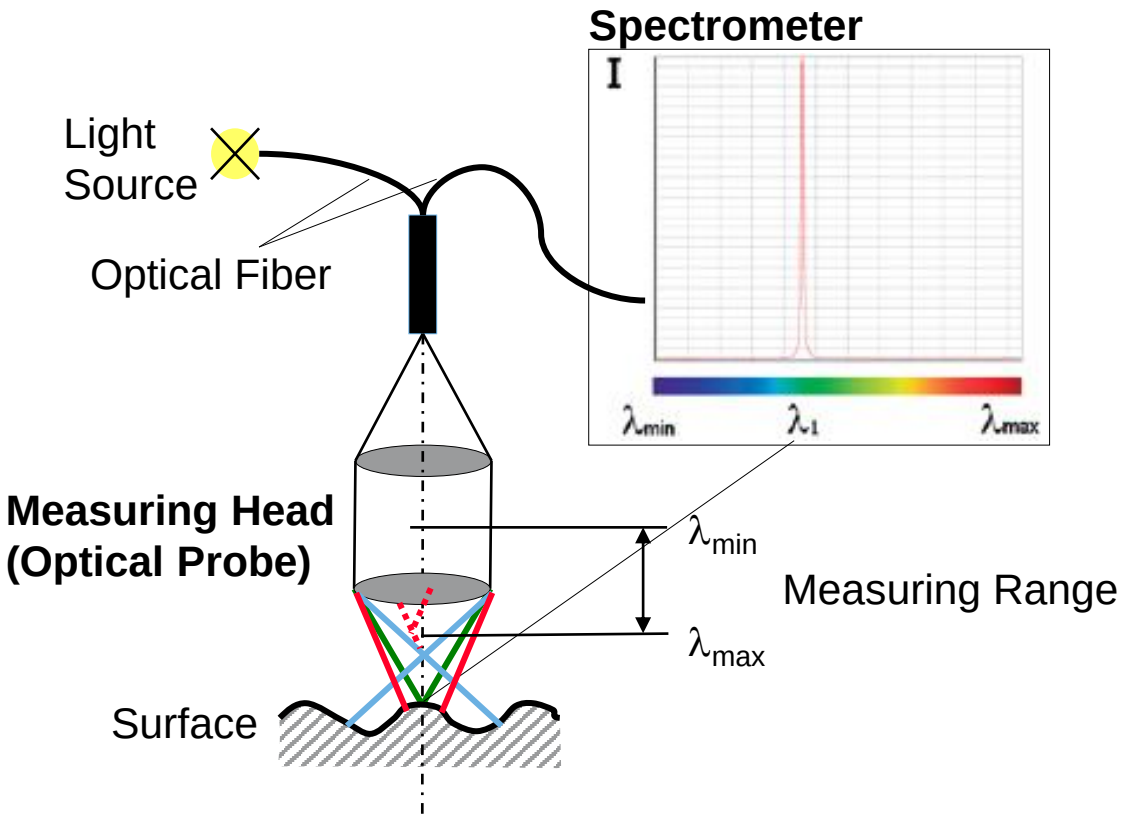


10 times scanned surface with VAST XT and stylus Ø6 mm with standard (200 mN) force



SmartZoom analyze with 2000x magnification

Geometric Dimensioning
Femoral implant – contactless measurement



Quality solution

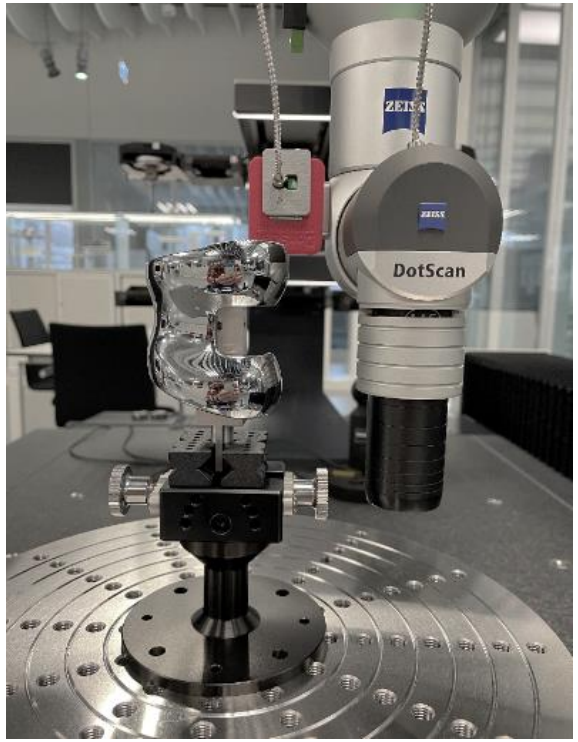
- ZEISS DotScan

Source: Michelt, B., Schulze, J.: Die Spektralfarben des Nanometers, chromatisch codierte Distanzmessung, in: Mikroproduktion, Carl Hanser Verlag, 2/2005, S. 39-41

Geometric Dimensioning
Femoral implant – fixturing concept

Challenge

- Accessing parts
- Multi family fixturing



Custom-made fixture (without Rotary table):

- Tactile solution
- Optimal using measuring volume
- Multisize

Part specified 3D printed fixture:

- Easy to construct
- Low print or milling coast

Geometric Dimensioning
Femoral implant

Challenge

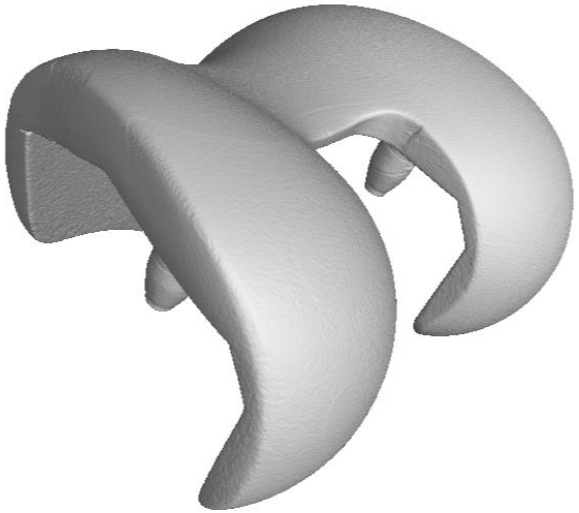
- Penetrability of the part
- high scanning quality for metrological evaluation vs. requirement of short scanning time

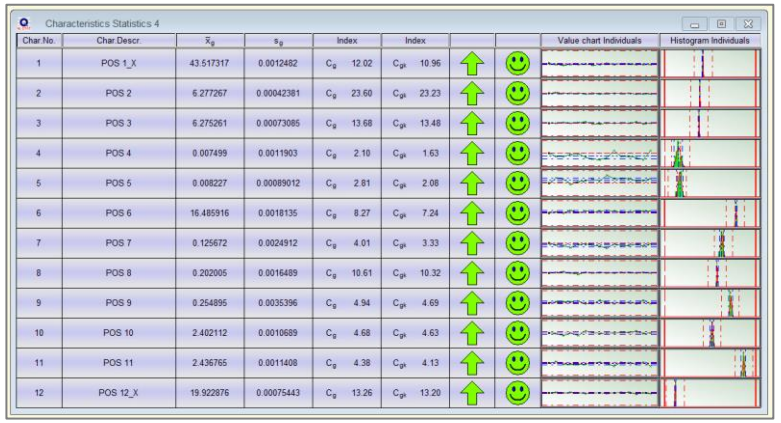
Customer need

- Metrological evaluation
- Requirements for evaluation/ scanning time

Quality solution

- Hardware: ZEISS METROTOM M1500 or M800 HR depending on desired voxel size/ resolution
- ZEISS CALYPSO for metrological evaluation



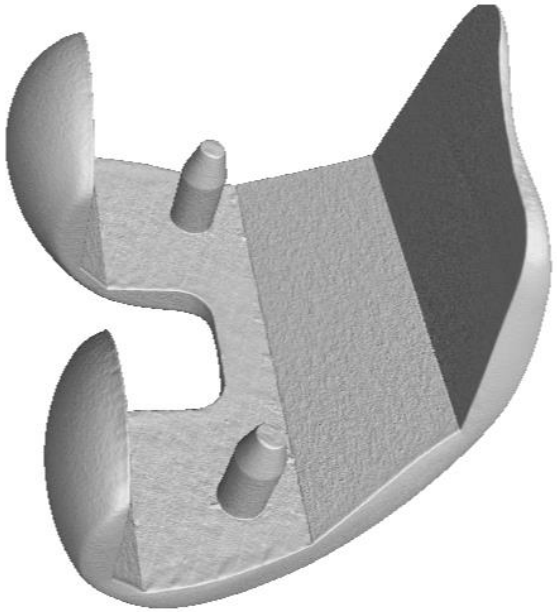


CALYPSO 2020

ZEISS Winning Benefit

✓ Metrological evaluation of the part on each position; no restrictions of fixture

Geometric Dimensioning
Metrological evaluation in CALYPSO MSA



Characteristics Statistics 4

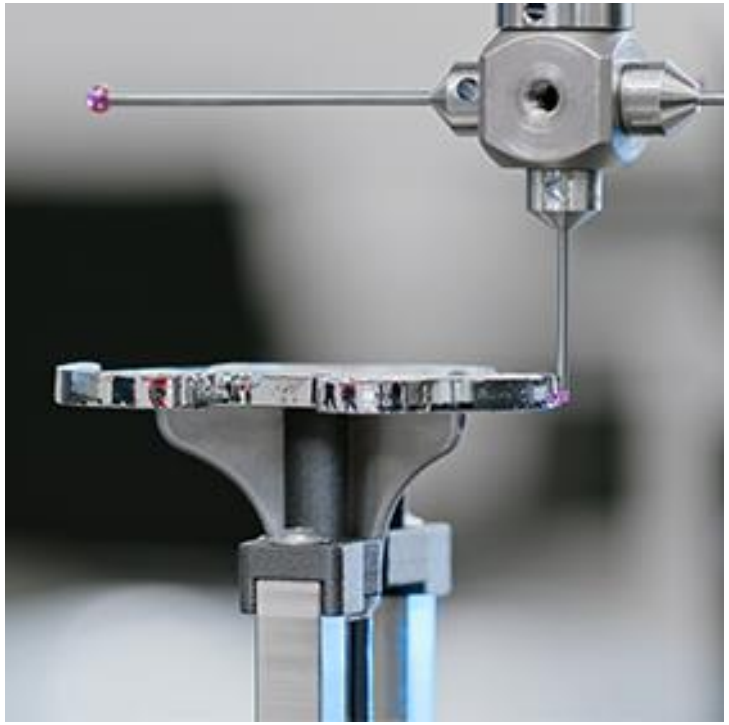
Char.No.	Char.Descr.	$\bar{x}_g$	s_g	Index	Index			Value chart Individuals	Histogram Individuals
1	POS 1_X	43.517317	0.0012482	C_g 12.02	C_{gk} 10.96				
2	POS 2	6.277267	0.00042381	C_g 23.60	C_{gk} 23.23				
3	POS 3	6.275261	0.00073085	C_g 13.68	C_{gk} 13.48				
4	POS 4	0.007499	0.0011903	C_g 2.10	C_{gk} 1.63				
5	POS 5	0.008227	0.00089012	C_g 2.81	C_{gk} 2.08				
6	POS 6	16.485916	0.0018135	C_g 8.27	C_{gk} 7.24				
7	POS 7	0.125672	0.0024912	C_g 4.01	C_{gk} 3.33				
8	POS 8	0.202005	0.0016489	C_g 10.61	C_{gk} 10.32				
9	POS 9	0.254895	0.0035396	C_g 4.94	C_{gk} 4.69				
10	POS 10	2.402112	0.0010689	C_g 4.68	C_{gk} 4.63				
11	POS 11	2.436765	0.0011408	C_g 4.38	C_{gk} 4.13				
12	POS 12_X	19.922876	0.00075443	C_g 13.26	C_{gk} 13.20				

Capable evaluation dependents on the tolerances and the quality of the scans

Geometric Dimensioning
Tibial baseplate

Challenge

- Large parts value
- Accessing parts
- Multifamily fixturing
- Difficult to reach undercuts



Quality solution

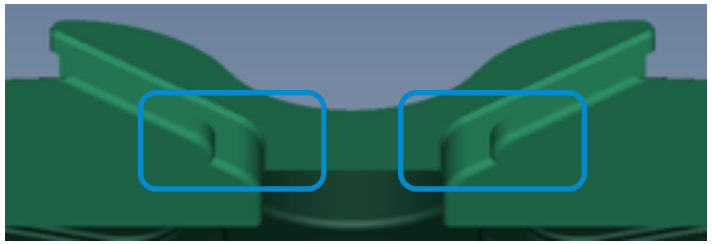
- ZEISS CONTURA
- ZEISS VAST XT or XTR
- ZEISS 3D Fixture

ZEISS Winning Benefit
- ✓ Fast cycling time
- ✓ One stop solution

Geometric Dimensioning
Tibial baseplate - undercuts approach

Challenge

- Accessing parts
- Fewer stylus changes



Quality solution

- ZEISS L-Stylus - Undercuts

Geometric Dimensioning
Hip cup

Challenge

- Bores with multiple axis in different orientations

Customer need

- Short cycle time
- Repeatability measurement
- Simple stylus system
- Quick CMM preparation
- Pallet measurement

Quality solution

- ZEISS PRISMO
- ZEISS Articulating stylus
- ZEISS Rotary table

ZEISS Winning Benefit

✓ Pallet measurement with rotary table possible

✓ Reducing stylus change and consumable cost per measured component

Geometric Dimensioning
Hip cup

Challenge

- Large number of parts
- Pallet fixturing solution

Customer need

- Short cycle time
- Repeatability measurement
- Quick CMM preparation
- Pallet measurement

Quality solution

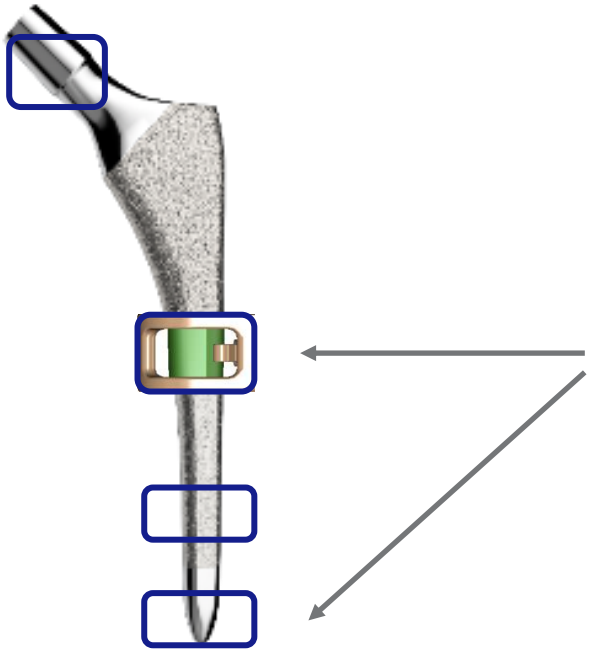
- ZEISS CONTURA

ZEISS Winning Benefit
- ✓ Pallet measurement
- ✓ Fast cycle time

Geometric Dimensioning
Stem implant – fixturing concept

Challenge

- Accessing parts
- Multi family and size fixturing
- Large parts value

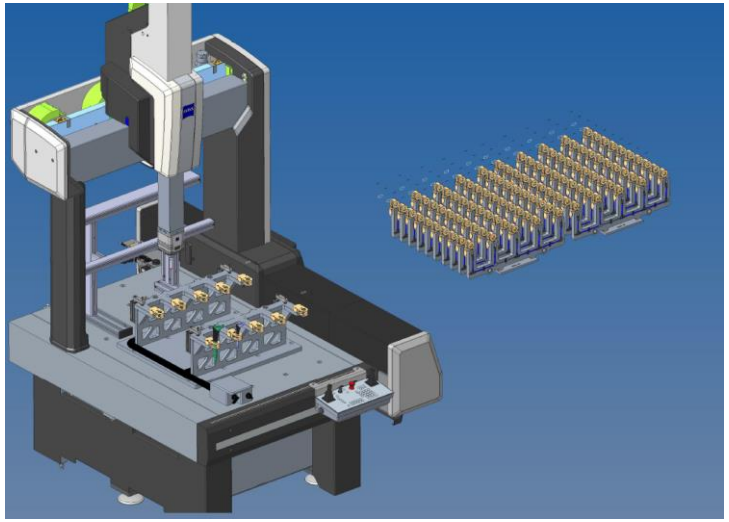


Critical measuring locations

3D custom-made fixture

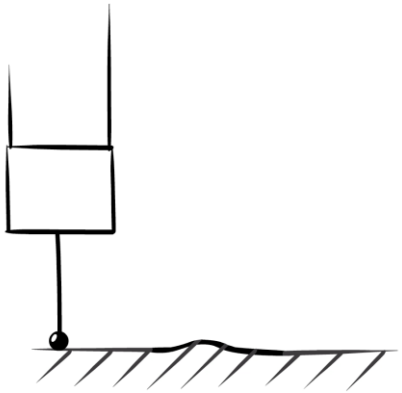
Quality solution

- Quick change fixtures allows using one CMM for all part sizes.
- Maximising the useable measuring volume (maximale Anzahl an Aufspannvorrichtungen pro KMG)
- 3D bespoke (custom-made, maßgeschneidert) fixture

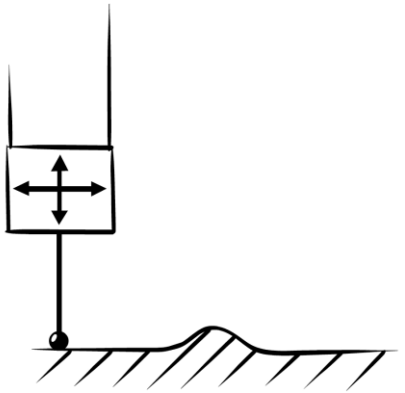


Geometric Dimensioning
High scanning speed with active sensor (VAST XT)

Scanning without ZEISS VAST XT



Scanning with ZEISS VAST XT



Metal Working Process
Quality Gates and Solutions

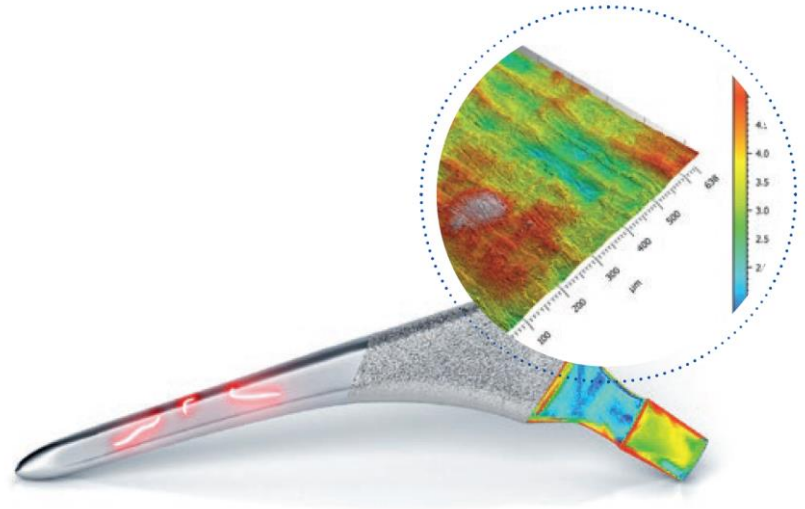
Raw material	Primary Shaping	Processing	Finishing
	Forging / Casting / Additive Manufacturing	Milling / Turning / Grinding	

Metallography	Quality of Raw parts	Incoming Inspection	In Process Control	Geometric Dimensioning	Surface Analysis

Surface Analysis
Final visual inspection

Challenges

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



Quality Solutions

- ZEISS Smartproof 5
- ZEISS SurfMax
- ZEISS SURFCOM NEX

Added value

- Fast contactless evaluation of roughness
- Reproducible and fast results in final Inspection
- Highspeed performance for visual defect detection and classification

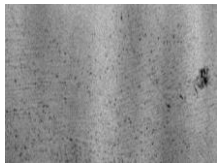
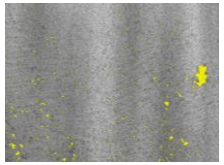
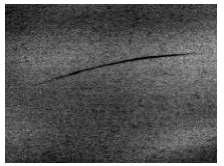
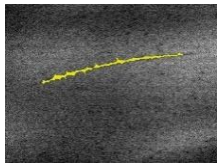
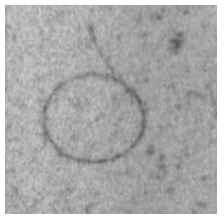
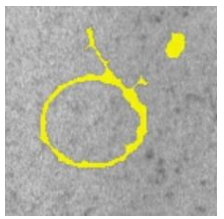
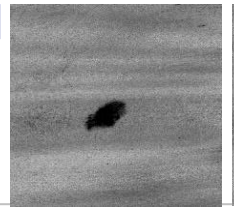
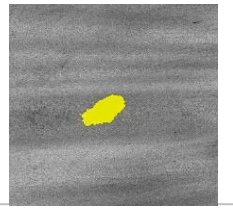
Surface Analysis

Challenge

- Inspection of polished components
- Optical imaging and defect detection of surface defects

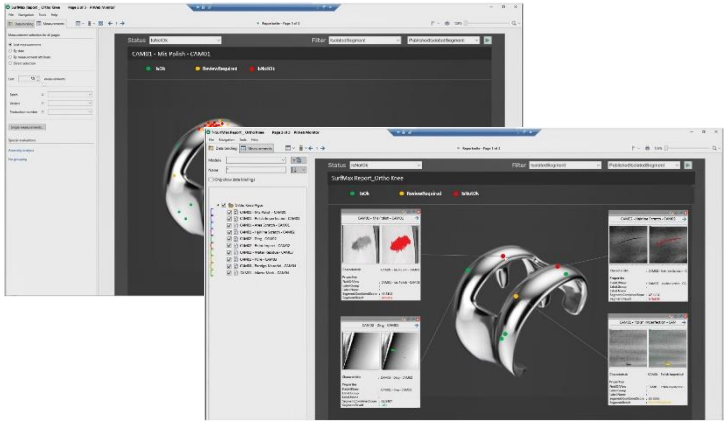
Customer need

- Identification and classification (by type and severity) of surface defects
- Process control to identify cause of defects

Defect Example	Gloss Image	Detection
Polishing Imperfection		
Hairline Scratch		
Residue		
Matte Area		

Quality solution

- ZEISS SurfMax



ZEISS Winning Benefit

- ✓ Improved reliability & accuracy resulting in reduction of overkill and escapes
- ✓ Traceable documentation and batch run analysis with ZEISS PiWeb

Surface Analysis

Challenge

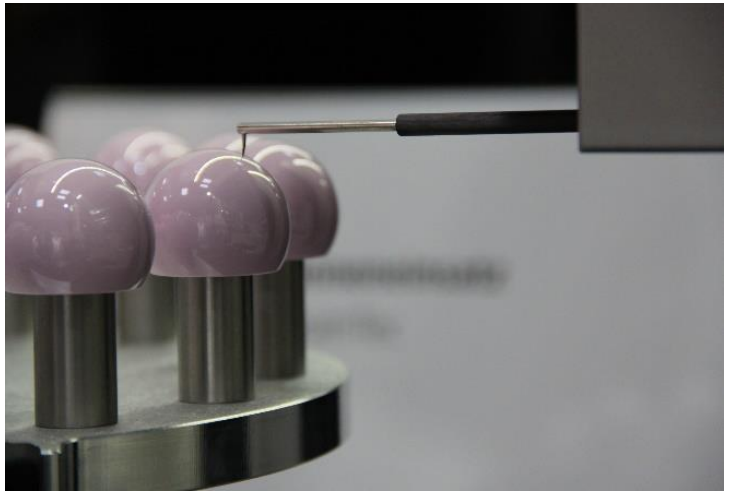
- Inspection of polished components
- Optical imaging and dimensioning of scratches or surface defects

Customer need

- Identification and classification of surface defects
- Cause identification of defects

Quality solution

- ZEISS SURFCOM NEX



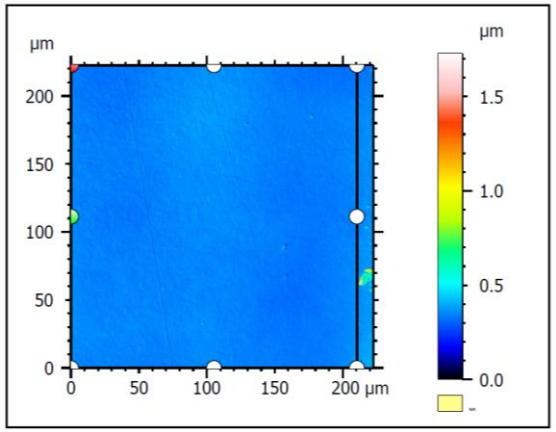
ZEISS Winning Benefit

- ✓ Full flexibility on roughness and contour measurements
- ✓ Pallet measurement

Surface Analysis
Smartproof 5

Challenge

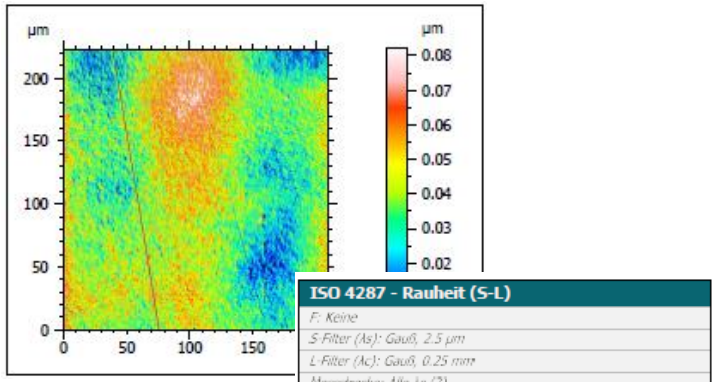
- Inspection of polished components
- Optical imaging and dimensioning of scratches or surface defects



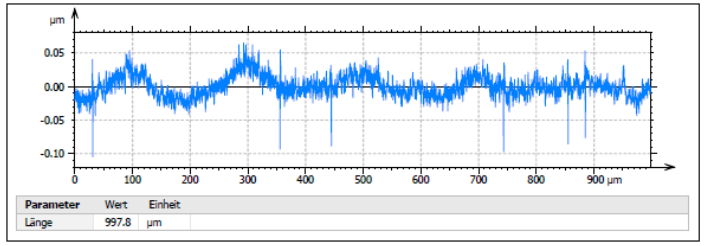
ISO 25178 - Rauheit (S-L)		
F: [Analyseablauf] Form entfernt (LS-Poly 2)		
S-Filter (λs): Gauß, 2.5 µm		
L-Filter (λc): Gauß, 0.2 mm		
Höhen-Parameter		
Sq	0.009836	µm
Ssk	0.1885	
Sku	3.807	
Sp	0.1047	µm
Sv	0.07364	µm
Sz	0.1783	µm
Sa	0.007738	µm
Information		
Das Studienobjekt enthält nicht-gemessene Punkte. Die Ergebnis...		

Customer need

- Identification and classification of surface defects
- Cause identification of defects



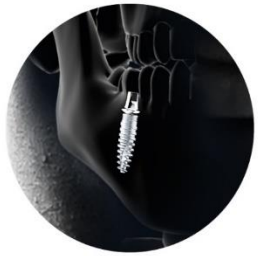
ISO 4287 - Rauheit (S-L)			
F: Keine			
S-Filter (λs): Gauß, 2.5 µm			
L-Filter (λc): Gauß, 0.25 mm			
Messstrecke: Alle λc (3)			
Amplituden-Parameter			
Rp	0.03423	µm	
Rv	0.02602	µm	
Rz	0.06025	µm	
Rc	0.0204	µm	*Keine Durchschnittsberechnung (Ei...*
Rt	0.06493	µm	
Ra	0.009249	µm	
Rq	0.01131	µm	
Rsk	0.4937		
Rku	2.725		



Quality solution

- ZEISS SurfMax
- ZEISS Smartproof 5
- ZEISS EVO with EDS
- ZEISS ZEN Core GxP

ZEISS Winning Benefit
- ✓ Non-contact solutions
- ✓ Inline rapid optical inspection

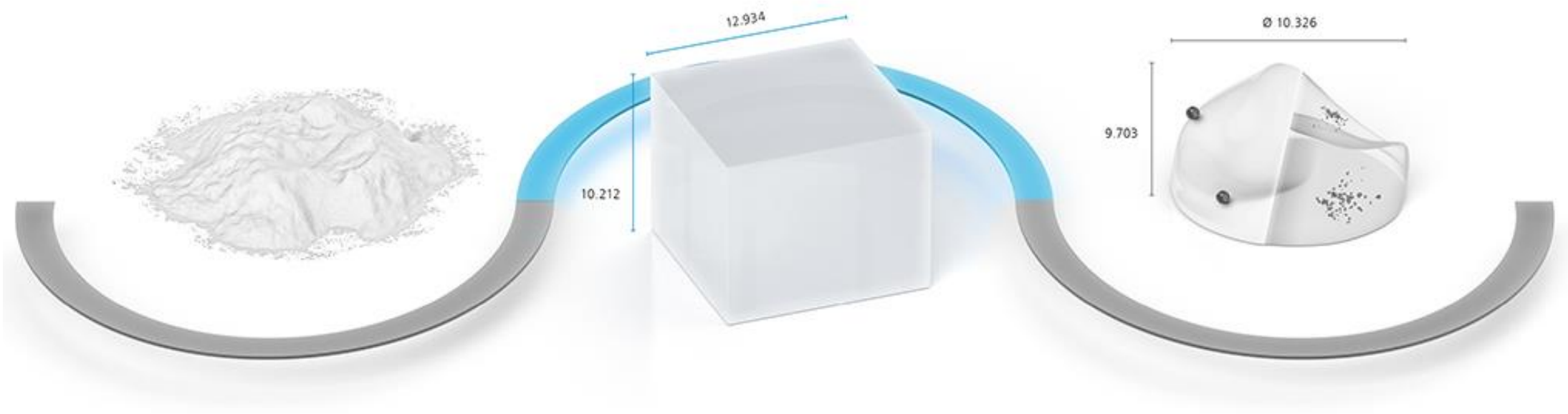





Dental Implant	Shoulder Implants	Spinal Implant	Hip Implants	Knee Implants	Trauma & Extremities	Manufacturing Process
 Implant	 Peripheral Screws	 Monoaxial pedicle Screw			 Bone Screws	Metal Working
	 Glenosphere	 Spinal Rods	 Acetabular Cup	 Femoral Implant		Metal Working
	 Glenoid implant		 Polyethylene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

Plastic manufacturing Process
Quality Gates and Solutions

Material	Extrusion Molding	CNC Machining

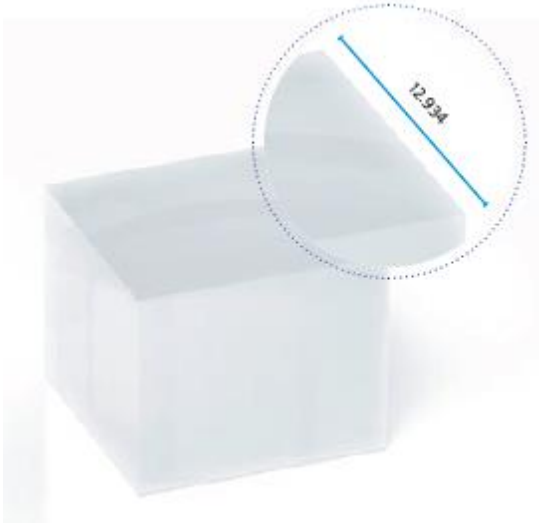


Granulate Analysis	Incoming Inspection	Geometric Dimensioning

Incoming Inspection
Efficient verification of supplied parts

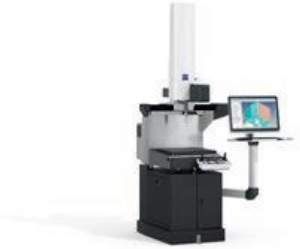
Challenges

- Ensuring supplied parts are within the margins for machining and processing
- Verifying the allowance on machining areas
- Fast inspection cycle times to reduce probability of bottlenecking



Quality Solutions

- Efficient Inspection:
  - ZEISS DuraMax



- Geometrical Inspection:
  - ATOS Q from GOM

Added value

- Quality control during production allows sorting out existing defects before further processing occurs
- Reduce operator influence and need time for manual inspection by using CNC-inspection

Incoming Inspection

Challenge

- Fast cycle times
- Easy to handle
- Trustable results under difficult environmental conditions

Customer need

- Short cycle time
- Repeatability measurement

Quality solution

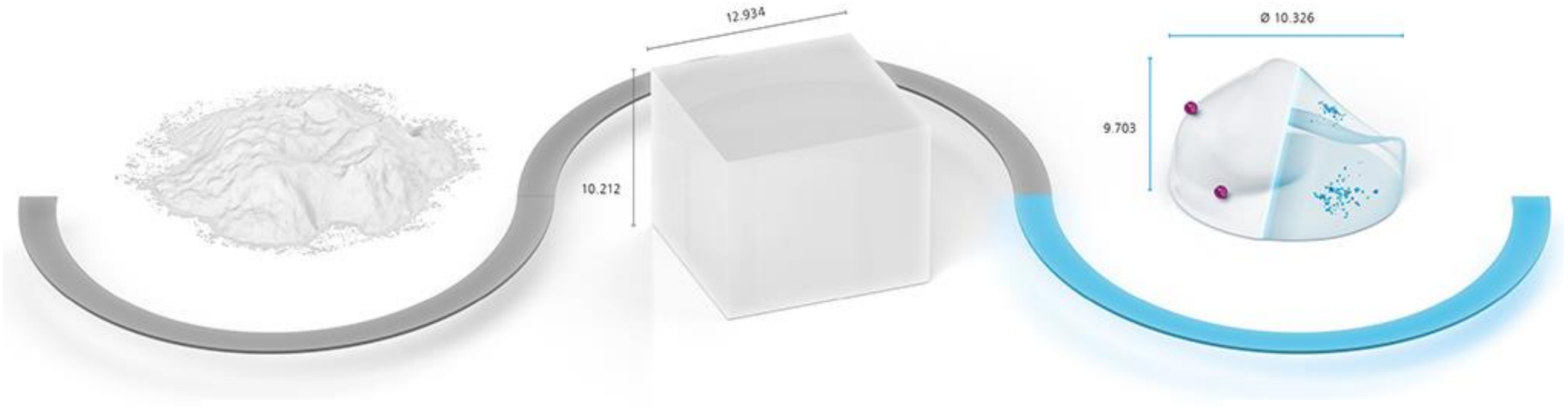
- ZEISS DuraMax
- ZEISS CONTURA
- GOM ATOS Q

ZEISS Winning Benefit

✓ Shop floor usable CMM (DuraMax)
✓ CNC inspection plans (CONTURA & DuraMax)
✓ Reduced operator influence

Plastic manufacturing Process
Quality Gates and Solutions

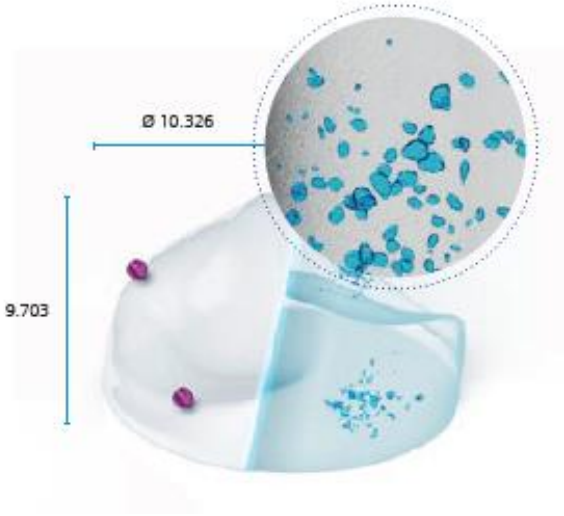
Material	Extrusion Molding	CNC Machining
Granulate Analysis	Incoming Inspection	Geometric Dimensioning



Geometric Dimensioning
Final dimensioning

Challenges

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



Quality Solutions

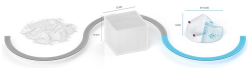
- ZEISS PRISMO
- ZEISS CONTURA
- ZEISS O-INSPECT
- ZEISS DotScan
- ZEISS METROTOM 6 Scout
- ATOS Q from GOM

Added value

- Increase usable acceptance range by decreasing measurement uncertainty
- Reduce operator influence and need time for manual inspection by using CNC-inspection
- Fast and Accurate 100% inspection

Geometric Dimensioning





Challenge

- Fast cycle times
- Sensitive surfaces
- Tight profile tolerances

Customer need

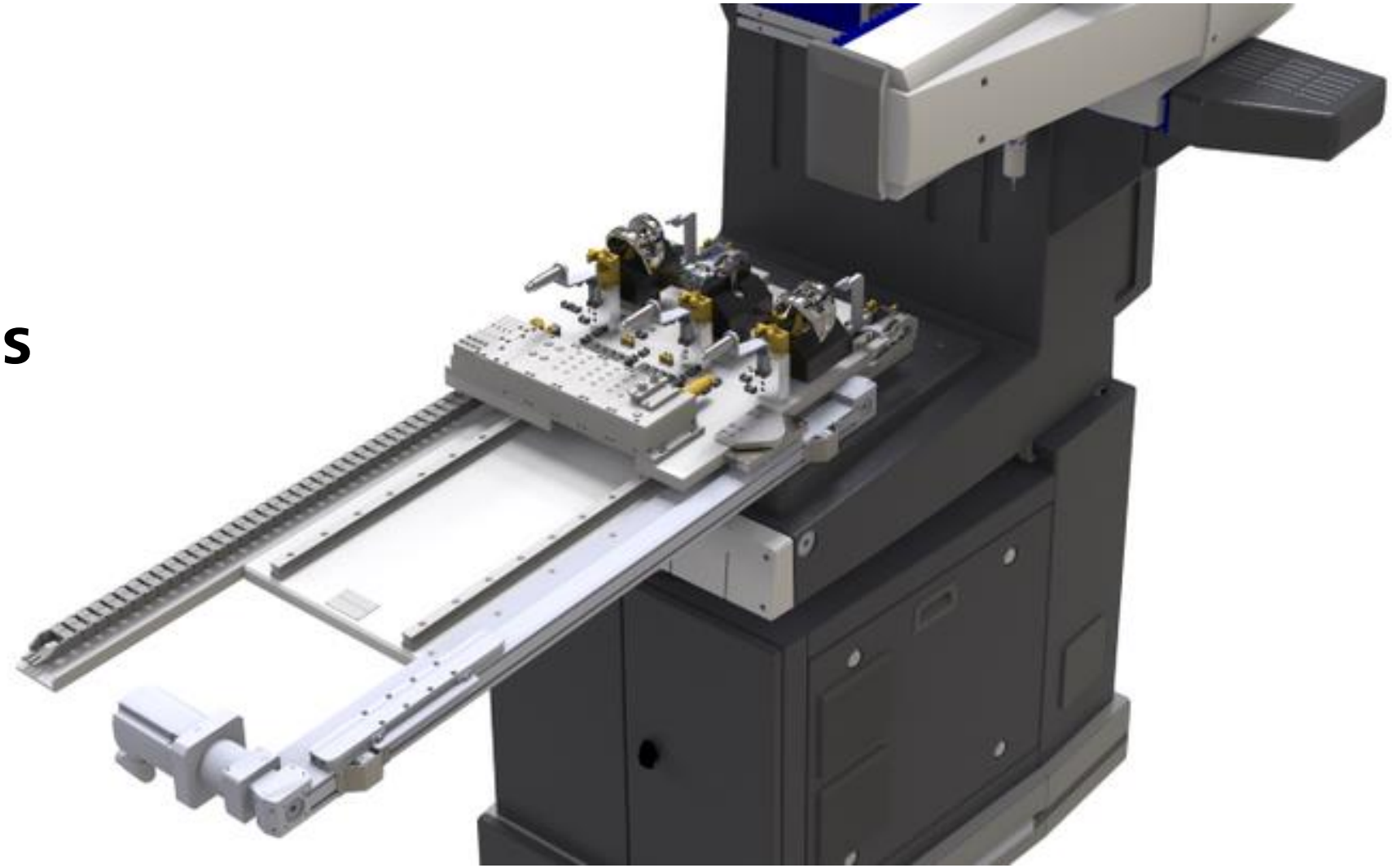
- Short cycle time
- Repeatability measurement
- Nondestructive measurements only

Quality solution

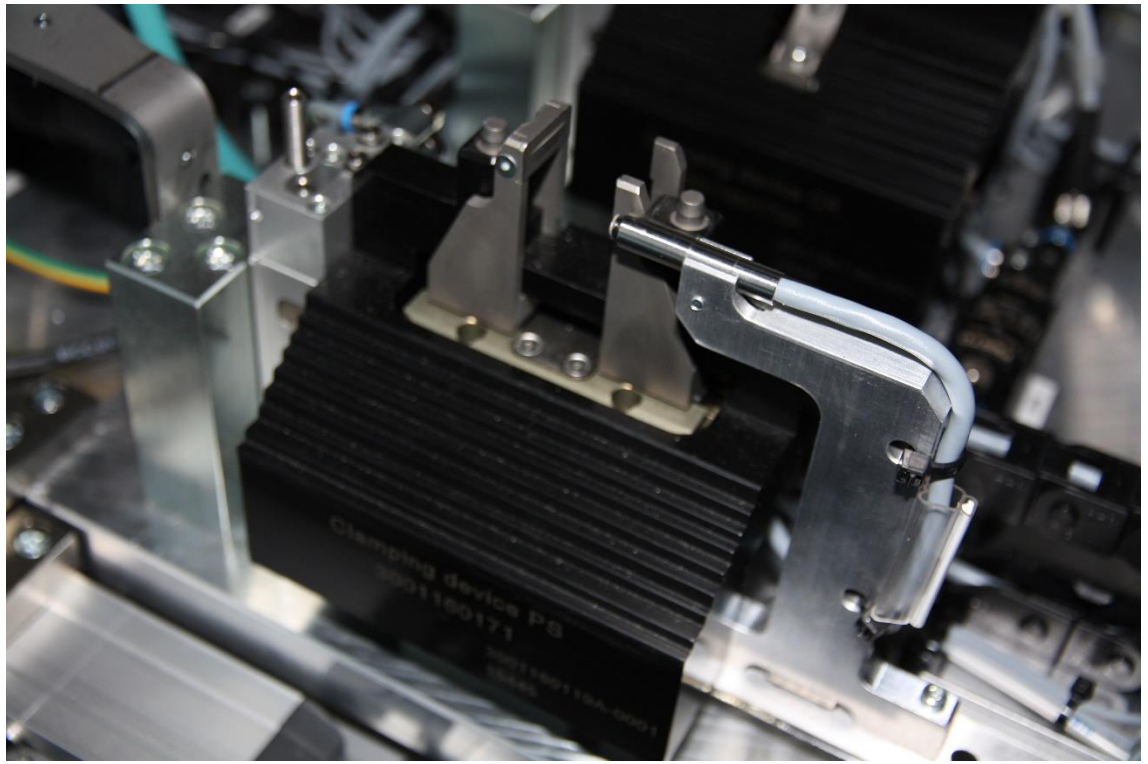
- ZEISS PRISMO
- ZEISS CONTURA
- ZEISS VAST XT
- ZEISS METROTOM
- ZEISS O-INSPECT
- ZEISS DotScan

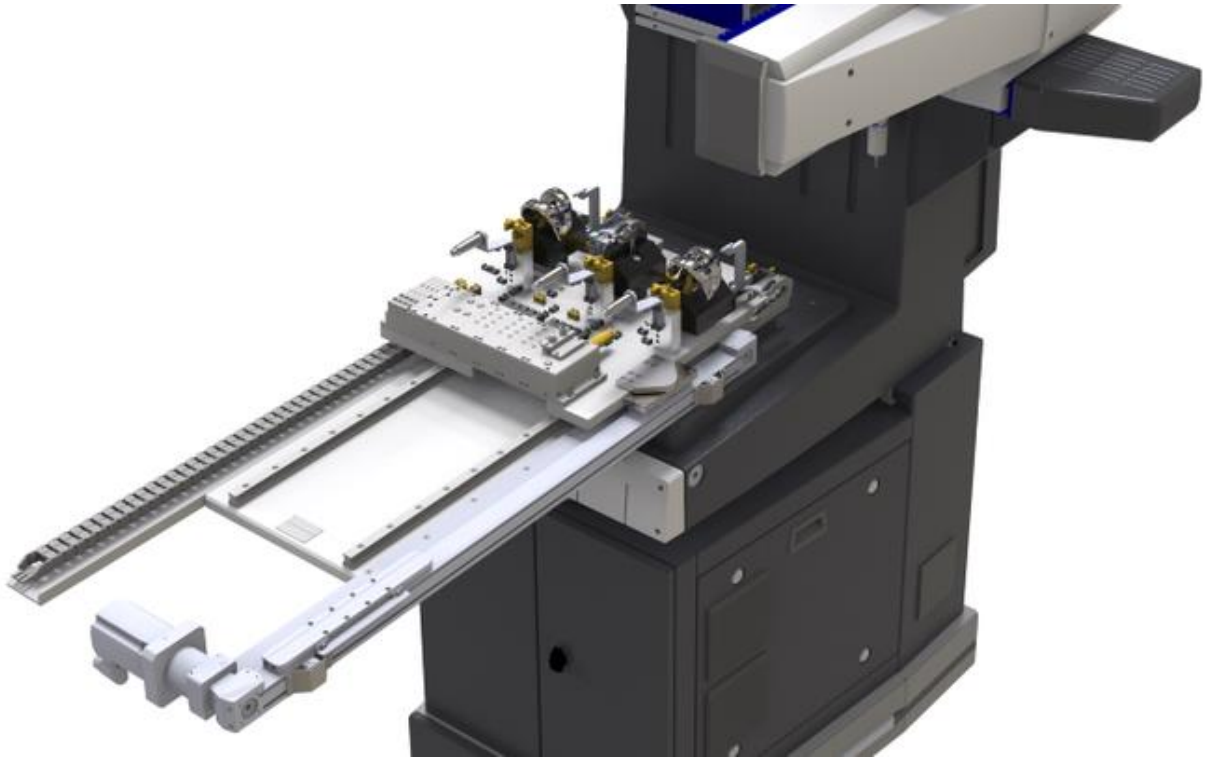
ZEISS Winning Benefit
✓ Contactless measurement possible
✓ Fast Scanning with VAST XT

Fixture Examples

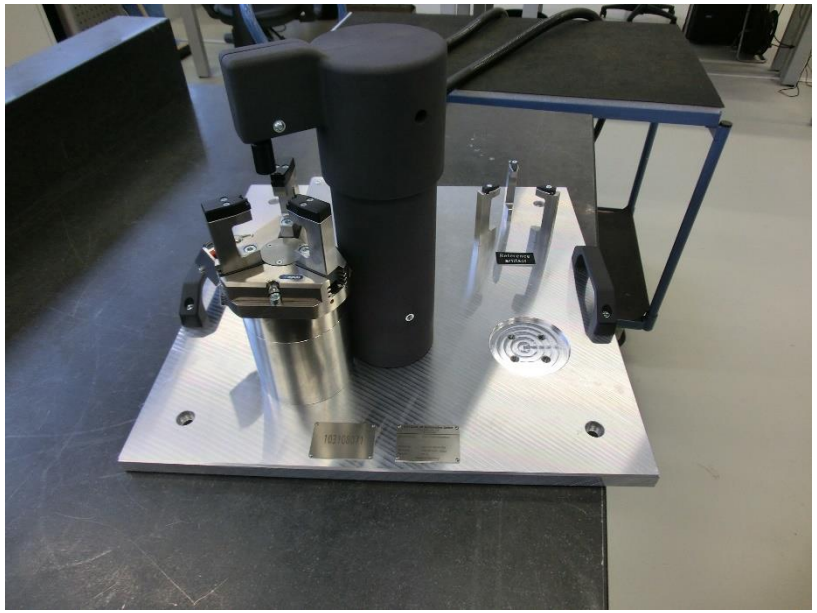


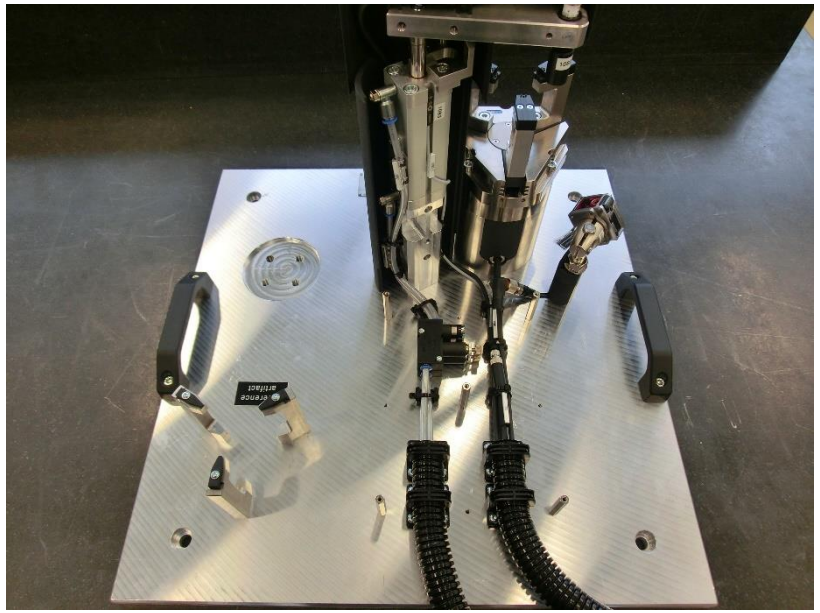
Fixture Examples
Knee Implants – femoral implants

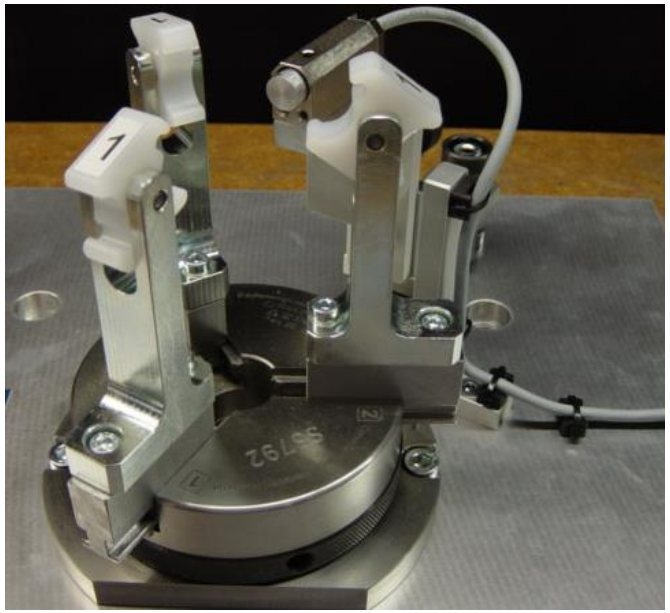




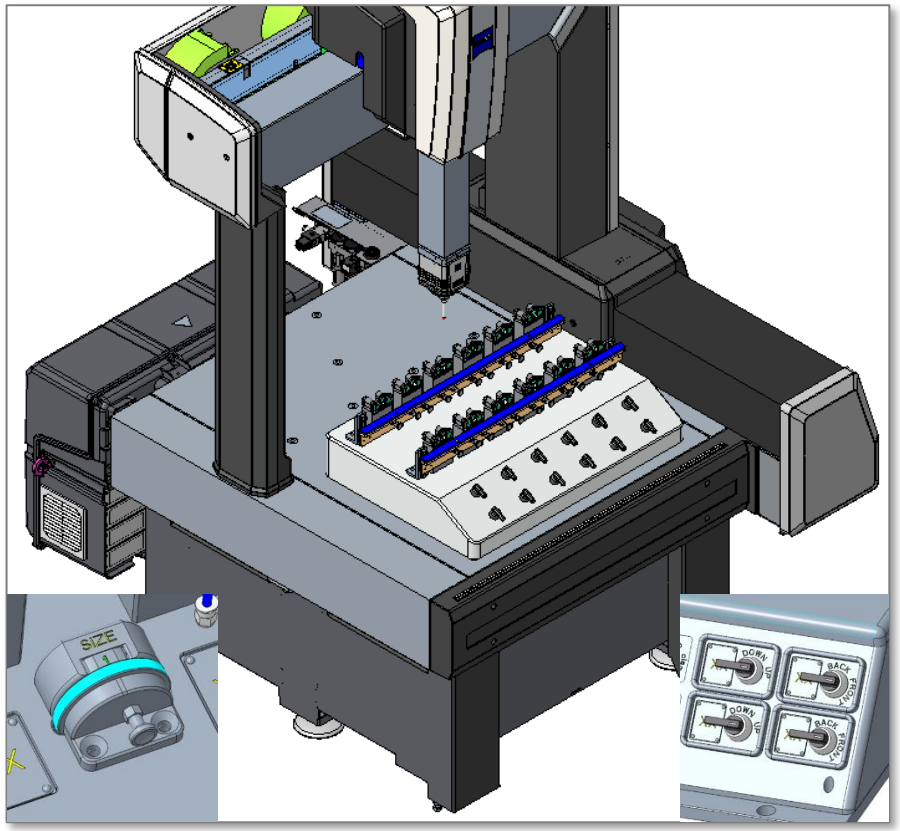
Fixture Examples
Knee Implants - polyethylene liner

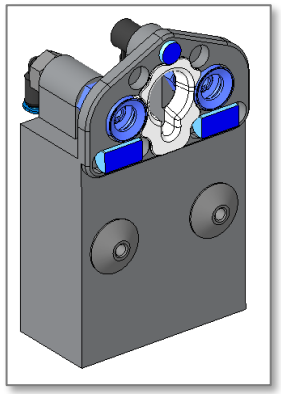


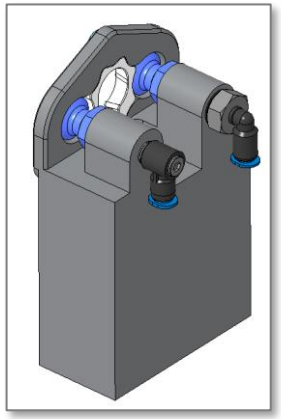




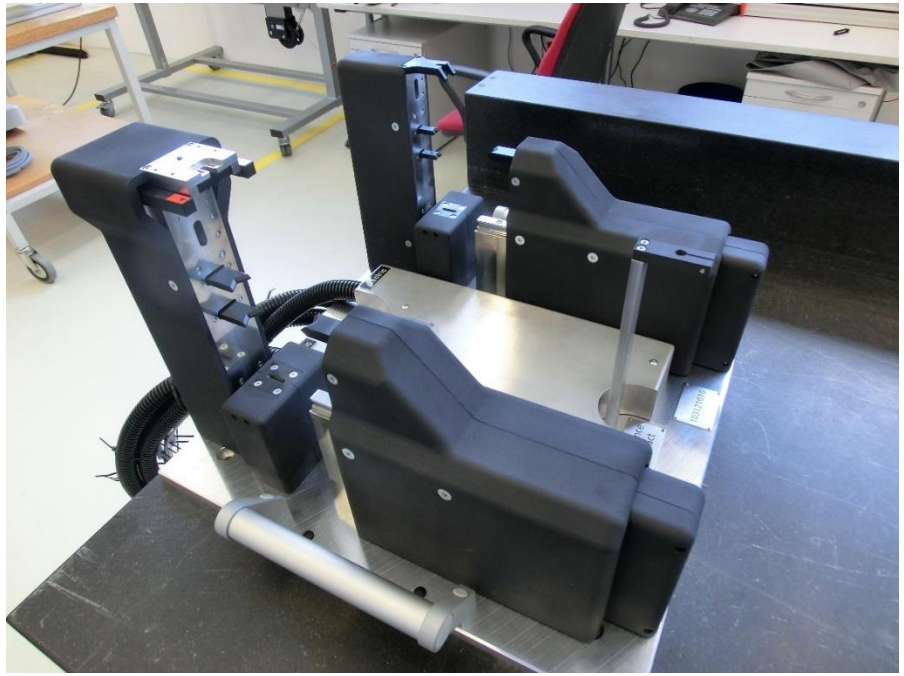
Fixture Examples
Knee implants – tibial insert

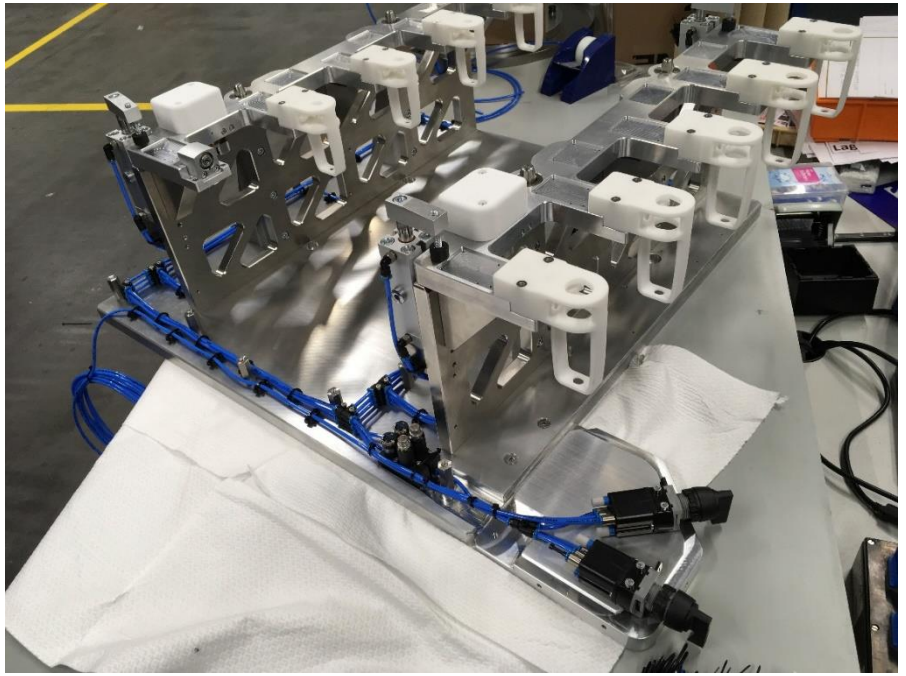






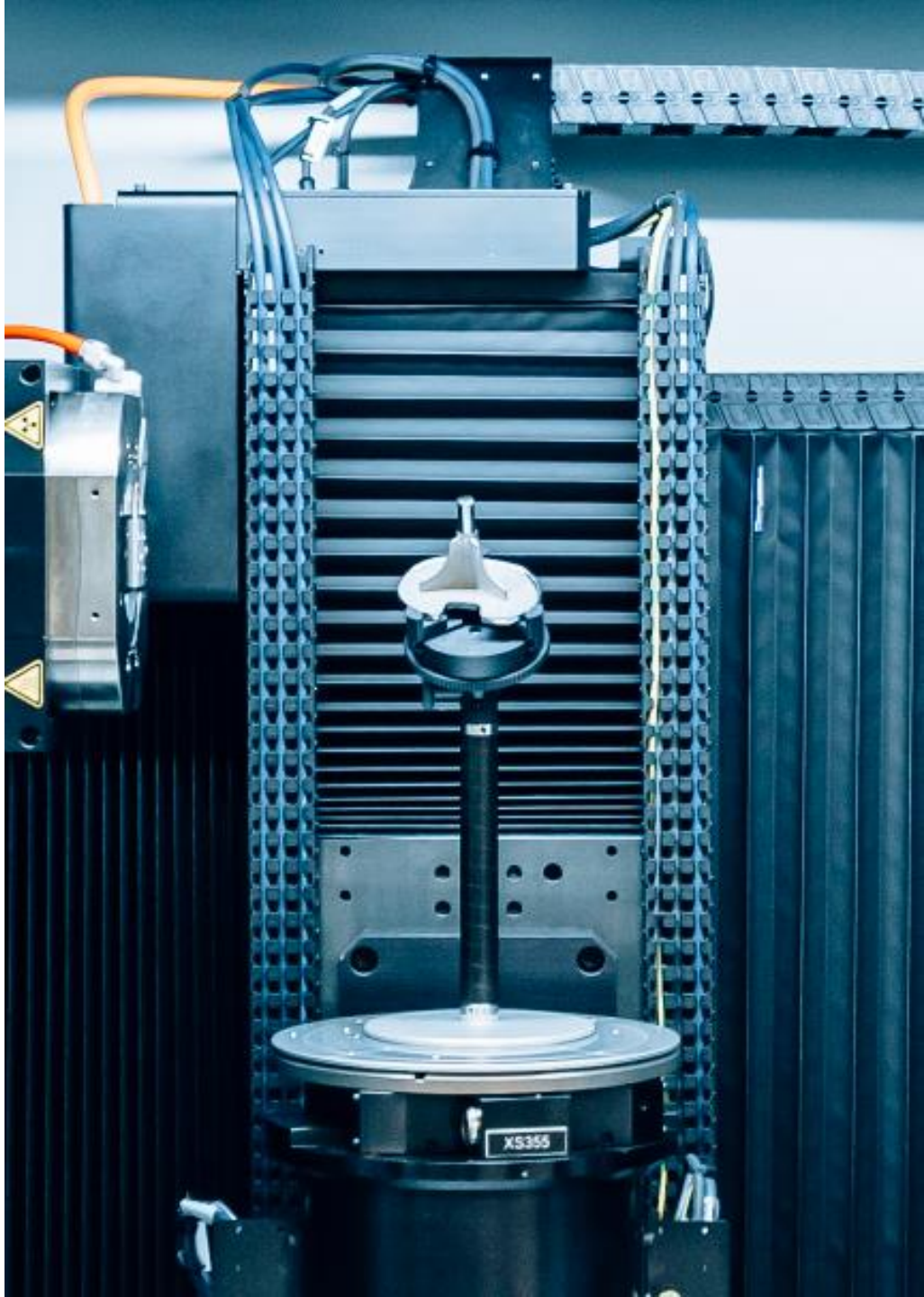
Fixture Examples
Hip implant – femoral stem





ZEISS Portfolio

Our propositions for Medical Industry



ZEISS Visioner 1

Visual Inspection

Digital Microscope with real-time all-in-focus visualization, for the most comprehensive inspection task with documentation.

ZEISS Axio Zoom V.16

Automated Inspection & 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 EVO

C-SEM with EDS

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

ZEISS Medical Industry Solutions
Surface Inspection & Characterization

ZEISS Smartproof 5
Surface Characterization

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

ZEISS SurfMax
Reliable High-Speed Visual Defect Detection

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

ZEISS Medical Industry Solutions
Manual and automated scanning from GOM

ATOS Q
ATOS Compact Class

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

ATOS ScanBox
Measurement of Small Comple Components

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

ZEISS Medical Industry Solutions
CT- and X-Ray Systems

SRE MAX from Bosello
2D X-Ray Inspection

Fast, non-destructive 2Dscans of safety relevant parts. Equipped with X-Ray sources from 160kV up to 450 kV or Micro – focus sources up to 150kV.

ZEISS METROTOM 800 225kV HR
Measure and inspect inner structures

With an industrial CT system from ZEISS, you can perform complete measuring and defect analysis with only one X-ray scan. Scan fast and denser parts.

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

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

ZEISS Medical Industry Solutions
Coordinate Measuring Machines

ZEISS DuraMax
Shopfloor Inspection

Stable scanning measurements over a large temperature range. With a space saving design and no compressed air required the DuraMax can go anywhere
along the production line.

ZEISS O-INSPECT
Multisensor CMMs

Suitable for components where tactile precision is needed, but also where an optical solution is required for surfacesensitive
sections. Optimally measure
each characteristic every time.

ZEISS CONTURA
Bridge Type CMMs

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

Incoming Inspection & Geometric Dimensioning
Application & Fixture Examples

Demo Kit – knee implant

- Femoral Implant
- Tibial Insert
- Tibial Tray

Seeing beyond