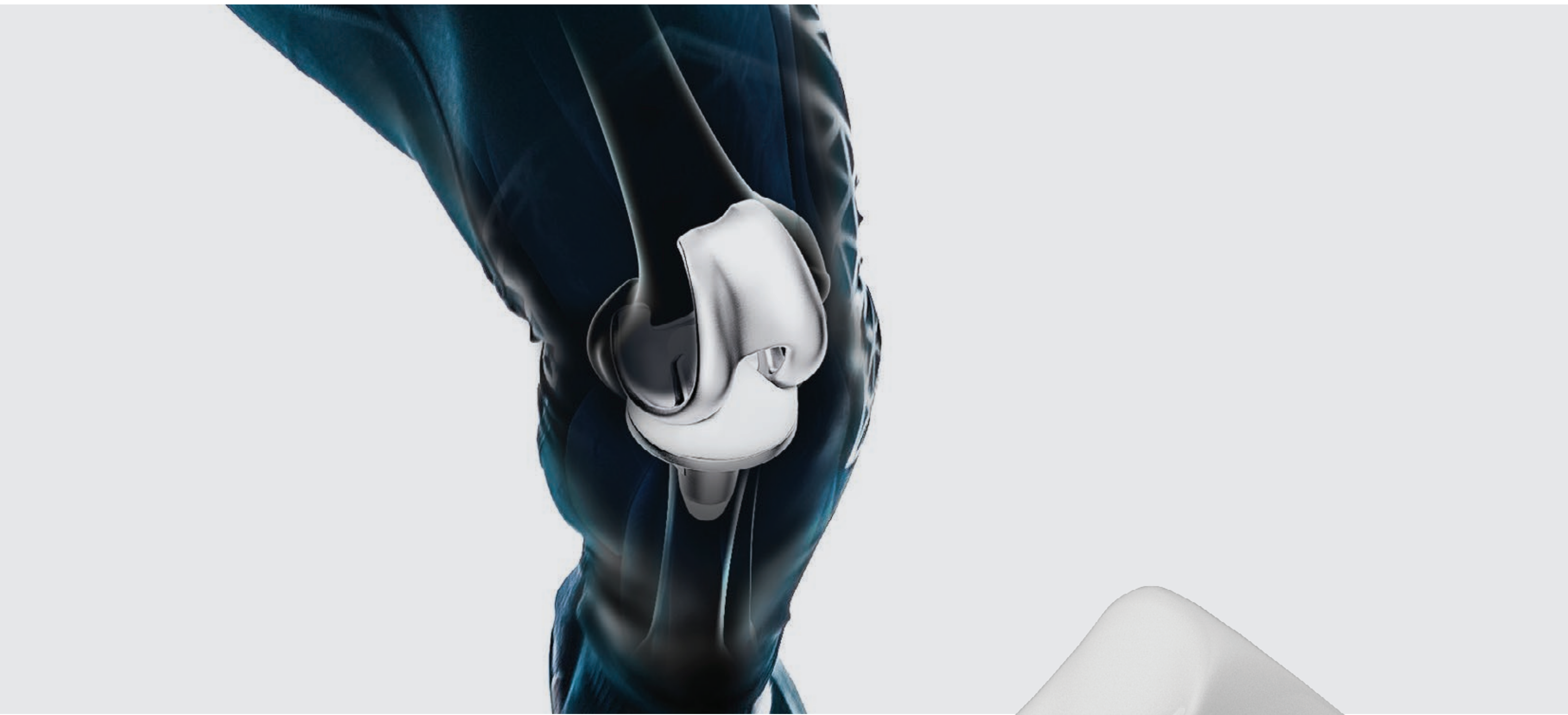
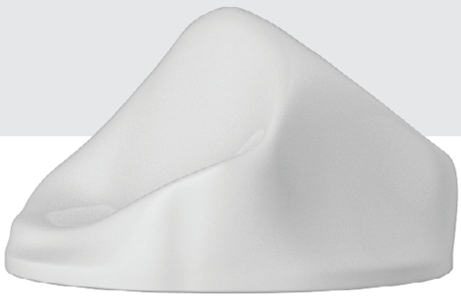
Technical paper
Geometric dimensioning
of a tibial insert





ZEISS Medical Industry Solutions
Quality Assurance for the Highest Medical Standards

Seeing beyond

Quality solutions for all types of implants: Metal – Plastic – Ceramic

Orthopedic implants must function flawlessly even under the most demanding physiological conditions in the human body. It is therefore essential for manufacturers to develop a comprehensive understanding of the materials used (metallic compounds, ceramic, and polymers) and the various biological defense responses that result. One of the most important steps in the metal manufacturing process is assessing the size, form, and location. Other important challenges include technical cleanliness during the manufacturing process, the assessment of material properties, and efficiency gains through minimizing waste.
A particularly exacting aspect is the final check to establish the permissibility of the deviations from the nominal CAD geometry within the manufactured component. As most implants feature finished or polished surfaces, it is necessary to perform a visual quality inspection.

Based on the example of a tibial insert, the following section describes geometric dimensioning performed using X-ray and multisensor CMMs from ZEISS like ZEISS METROTOM, GOM Volume Inspect, and ZEISS O-INSPECT.

From material to finished product.
Your product must prove its quality in various ways during the metal working process – and versatile tailored quality solutions from ZEISS are ready for deployment at every step of the production chain.

- **Metallography**
  for material analysis
- **Quality testing**
  of raw parts
- **Incoming goods check**
  for efficient inspection of supplied parts
- **In-process inspection**
  for monitoring the processing quality
  and technical cleanliness
- **Testing of size, form, and location**
  for final dimensioning
- **Surface analysis**
  for final visual check

Dental Implant

Shoulder Implants
Peripheral Screws
Glenosphere
Glenoid Implant
Humeral Stem

Spinal Implants
Monoaxial Pedicle Screws
Spinal Rods
Intervertebral Disc

Hip Implants
Acetabular Cup
Polyethylene Liner
Femoral Head
Femoral Stem

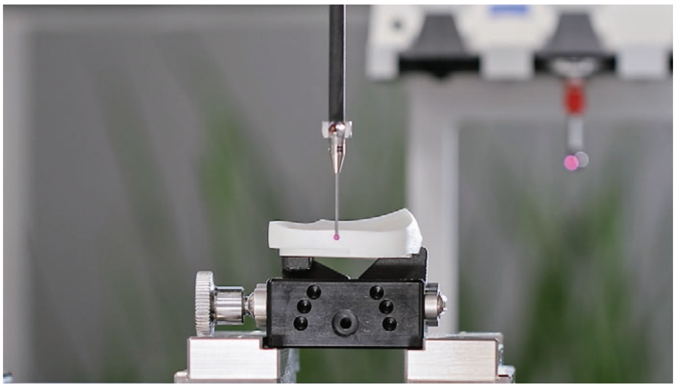
Knee Implants
Femoral Implant
Tibial Insert
Tibial Tray

Trauma & Extremities
Bone Plate
Bone Screws

Tibial insert:
Twin approaches to quality assurance

As the tibial insert is the only one of the three components in a knee implant to be made of plastic rather than metal, it presents a quite different set of quality assurance requirements. The tibial insert can be handled by a combination of tactile and optical solutions, namely ZEISS O-INSPECT and ZEISS DotScan respectively, or an approach based entirely on computed tomography tools including ZEISS METROTOM, GOM CT Professional, and GOM Volume Inspect. Whatever the route taken, the goal is the same – and while abrasion affecting plastic parts cannot be eliminated entirely, it can be significantly reduced through optimized design and high component quality. Thanks to innovations such as pallet-by-pallet measurement with ZEISS O-INSPECT and simultaneous scanning of multiple components with ZEISS METROTOM, users also spend less time checking each individual part.

Medical technology depends on reliable quality assurance systems, not only in order to meet demanding industry requirements but also because such parts have a major impact on quality of life. It is essential for a tibial insert to work flawlessly for as long as possible, thus avoiding the need for replacement or revision: After all, abrasion of the plastic surface can lead to problems as serious as bacterial infection of the knee joint. Tibial inserts must therefore undergo geometrical evaluation and defect inspection as part of a non-destructive approach that delivers fast cycle times and reliable results even in the context of tight profile tolerances. Read on to discover just how ZEISS O-INSPECT and ZEISS METROTOM meet all these requirements and more.



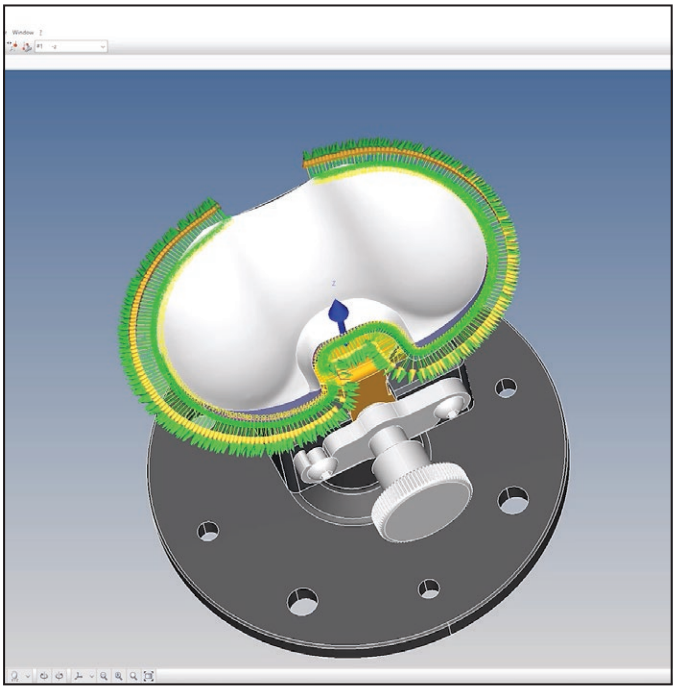
Tactile scan of a tibial insert with ZEISS O-INSPECT

Tactile measurement using the ZEISS VAST XXT sensor

Available in three different sizes, the ZEISS O-INSPECT multisensor measuring machine enables optimum handling of each characteristic via tactile or optical measurements. The former approach requires the combination of a camera sensor and the ZEISS VAST XXT tactile sensor, with processing performed in the software solutions ZEISS CALYPSO and ZEISS PiWeb.

Having placed your part on ZEISS O-INSPECT, you must create a base system in ZEISS CALYPSO. Always remember that you can tailor the settings to your needs by adjusting the speed as desired and deleting any nominal points of your choice to ensure a more focused scan. In addition to modifying the nominal points of the curve after performing a scan, you can also adjust both the speed and the increment.

You will then need to create a characteristic in order to create a line profile, taking advantage of the automatic best fit setting in the process. The software uses the information to generate a ZEISS PiWeb protocol showing this best fit: Not only is the position translated into X and Y values, there is also a clear overview of the tolerances, nominal values, scan speed, and additional general data such as the user name and scan date. You can even preview your protocol, save it as a PDF, or send it to a printer to share your findings.



Post-scan display of nominal and actual points

Swift optical measurement with ZEISS DotScan

While ZEISS O-INSPECT operators who wish to perform a non-contact measurement can of course use a ZEISS zoom lens camera such as the Discovery. V12, we will focus here on the optical capabilities of ZEISS DotScan. This innovation performs white light scans to determine the distance between the sensor and the surface. It is also much faster than tactile approaches, meaning that the scan speed can be set several times higher.

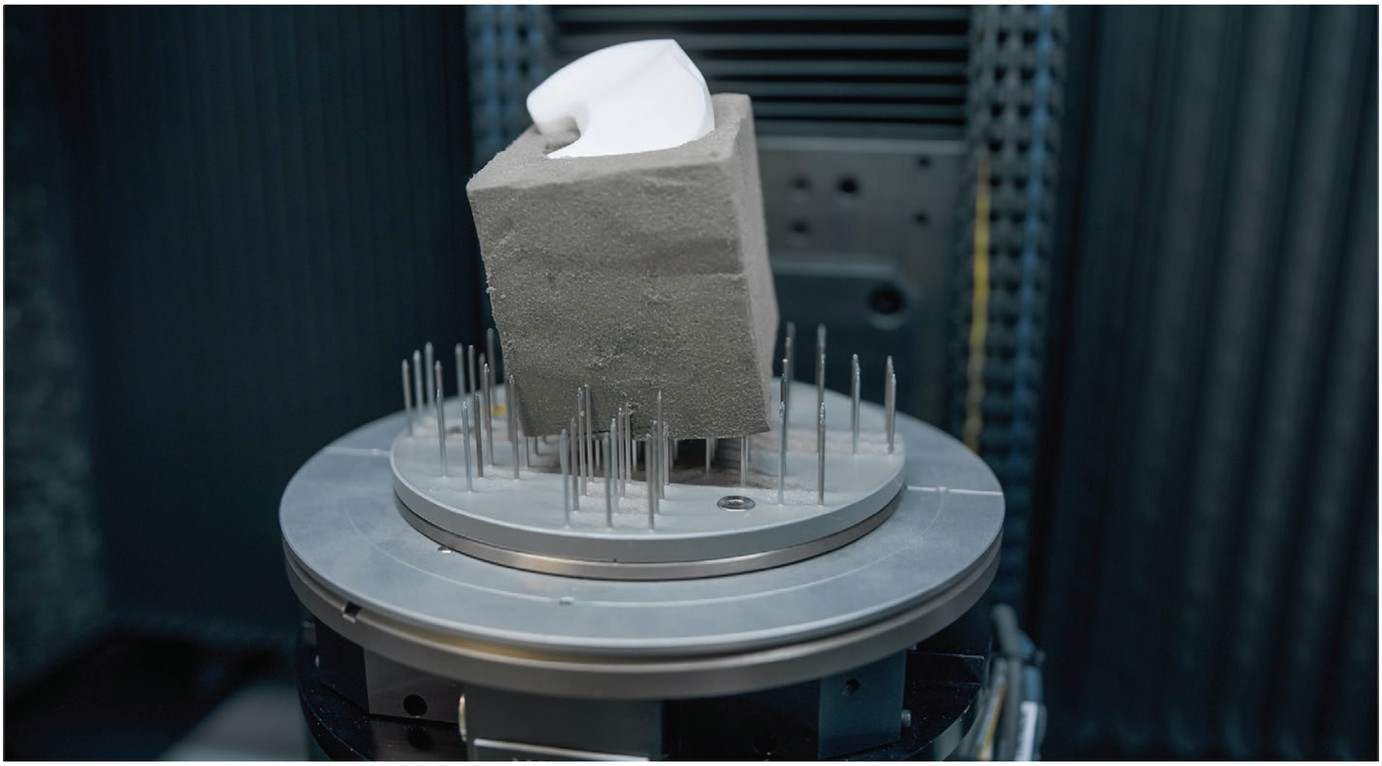
After performing a contactless measurement with ZEISS DotScan, it is once again possible to adjust the tolerance as required and make use of the automatic best fit setting. You can then superimpose your scan results on the CAD model as part of a color-coded display that helps you assess particular features of the surface.
Complete the process by generating a ZEISS PiWeb protocol as before: This will feature additional information on deviations that has been gathered by the optical ZEISS DotScan technology.

ZEISS DotScan executing an optical scan

CT-based internal evaluation with ZEISS METROTOM

The computed tomography (CT) system ZEISS METROTOM 6 scout boasts a powerful X-ray detector for high-resolution image quality, a 5-axis kinematic positioning system, and the ability to scan parts measuring as much as 400 mm. This entirely contactless technology is particularly suitable for viewing the inside of plastic parts such as tibial inserts, which are highly sensitive and often at risk of abrasion. In terms of software, scans can be performed with the help of GOM CT Professional and subsequently evaluated using GOM Volume Inspect.
Once ZEISS METROTOM 6 scout has been warmed up, the user can place the part in the CT system. Automatic positioning is performed by creating a projection, then using the click-and-drag functionality to select the area in which the part is located. The software will then calculate perfect central positioning of the part relative to the detector, thereby ensuring the best possible magnification.

In a further boost to accuracy and efficiency even with less experienced operators at the controls, the software can automatically define the scanning parameters. The operator does not have to be entirely passive, however, as they are able to adjust the resolution quality and apply a prefilter if desired. Scans can then be evaluated using the software GOM Volume Inspect, which offers full metrology capability and can look inside the part in question. Detailed analysis can also be undertaken in the form of defect detection.

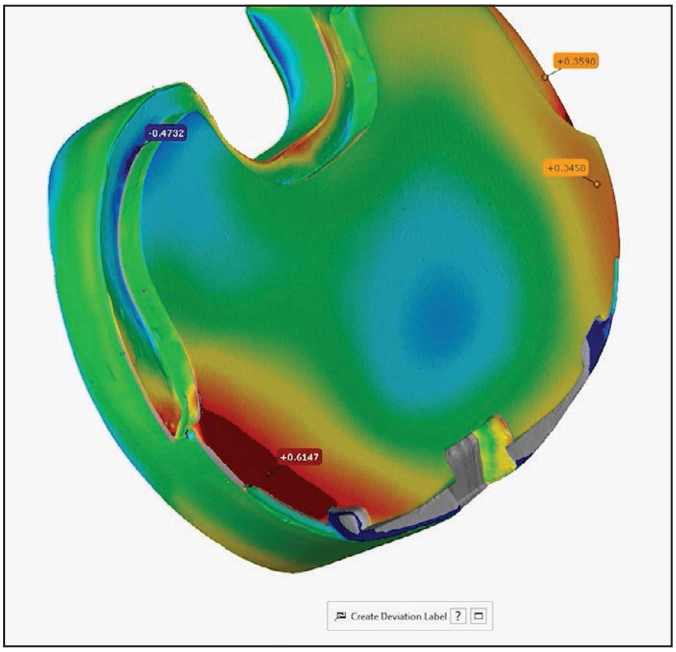


The part is placed in ZEISS METROTOM for scanning

GOM Volume Inspect for in-depth data inspection

Start by loading the existing CAD model and volume data to display the imported volume, which you can then polygonize. GOM Volume Inspect will automatically search for material peaks and calculate the complete surface of the volume. The CAD model and STL data can be aligned in different ways prior to part evaluation, with options including local best fit based on your choice of reference – such as geometric elements or coordinate systems.
Inspection plans can be further expanded with additional evaluations like the nominal-actual comparison – a color-coded visualization that highlights the extent of deviations between the nominal and actual values. This deviation view can also be restricted to a user-defined inspection section for greater focus and efficiency. You can then click on any individual area to generate a label clearly stating the specific deviation at that point. It is also possible to define the distance between two planes and calculate the flatness of a given plane simply by selecting the relevant characteristics in the software.

The data relating to deviations in flatness can likewise be color-coded with reference to the tolerances for easier comprehension. Thanks to the high-resolution scanning capacity, you will be able to identify even small indentations and cracks on the surface. And of course, any screenshots you create at any time during inspection will automatically be saved in the reports section for editing, adjustment, and PDF export to guarantee maximum portability.



Color-coded nominal-actual comparison marked with deviation labels

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EN_60_012_0023I Created in Germany CZ-IX/2021