Technical paper

Geometric dimensioning of a femoral implant

ZEISS Medical Industry Solutions

Quality Assurance for the Highest Medical Standards

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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 femur implant, the following section describes geometric dimensioning performed using ZEISS CONTURA or ZEISS PRISMO – equipped with ZEISS DotScan – or our multi-sensor CMM 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

Femoral knee implants: Optical analysis for optimum quality

As femoral knee implants comprise rough and polished surfaces, the key challenge in assuring their quality is the ability to measure both such surfaces in contact and non-contact modes respectively. This makes it necessary to move beyond merely tactile solutions and turn to optical innovations. ZEISS DotScan is a key driver of this development. In performing non-contact measurements of polished surfaces, it is able to handle tight profile tolerances while avoiding scratches. When combined with the new-generation rotary table, it offers precision 4-axis scanning capability. Furthermore, with the support of additional tools such as ZEISS CALYPSO, users can take their quality control to the next level via the creation of elements, freeform surfaces, and protocols.

Equipped with ZEISS Multi Application Sensor System (mass) technology, the new ZEISS CONTURA CMM marries the tactile and optical approaches within a single overall process. This makes it particularly suitable for use with femoral knee implants, as its non-contact concept eliminates the risk of surface damage, its scanning technology is ideal for highly reflective surfaces, and its 4-axis scans are perfect for analyzing curves. With customizable measuring plans, adjustable strategies, and precision protocols generated via ZEISS PiWeb, users of ZEISS CALYPSO can ensure optimum quality through groundbreaking optical analysis of femoral knee implants.

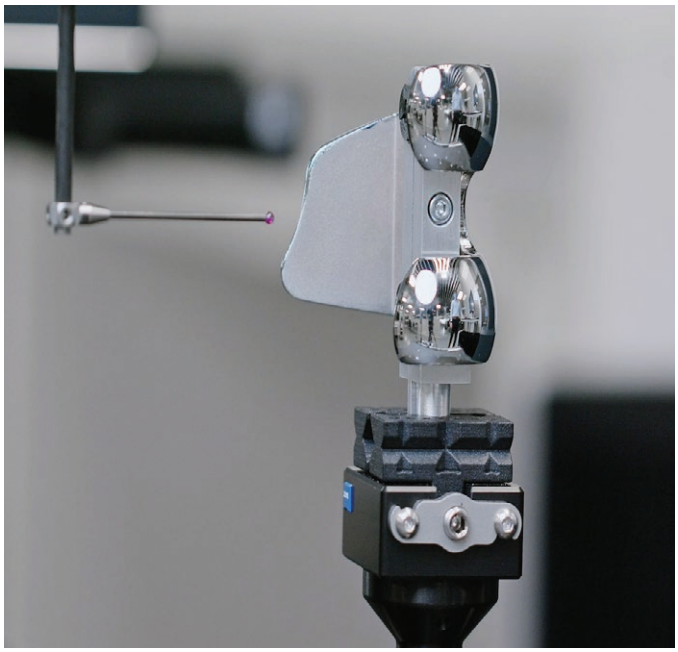
Femoral knee implant featuring rough and polished surfaces

Adjustable strategies for enhanced workpiece alignment

For this process, ZEISS CALYPSO users must note that ZEISS DotScan requires an additional reference sphere and that rotary table access must also be checked regularly with the principal reference sphere. This extra equipment ultimately makes it possible to adjust and execute a tailored measurement strategy.

The first step is to program the base alignment using a classic tactile sensor such as the ZEISS VAST XXT. Having defined the plane, line, and symmetry point, users can complete this stage by instructing ZEISS CALYPSO to keep the original alignment from the CAD model. Users can then program the clearance plane simply by defining the respective edge distance. Before moving on to the adjustment process, the user must remember to activate the rotary table for the measurement plan in question.

One example of an adjustment that can be made is the creation of a polyline either on the basis of the CAD model itself or through manual data input. Users can then further boost the scan speed by having ZEISS CALYPSO transform three interlinked points into a curve. As this program additionally supports the use of an automatic basic alignment axis for the rotary table, it ensures that parts are rotated perpendicular or parallel to the axis so as to avoid shaft probing. Once an alignment has been executed, ZEISS CALYPSO will automatically prompt the user to recalculate the existing base alignment as it now knows the position of the measured workpiece.



Alignment process on rotary table

From tactile to optical with ZEISS DotScan

Following alignment, the next task is to create a curve by cutting the CAD model via planes. Users can set the number of desired nominal points to suit their needs and even delete individual points within a segment as required. The benefit of this latter option is that it enables more tailored measurements compared with a basic edge-to-edge approach.

This marks the moment in the process where a tactile solution such as the ZEISS VAST XXT makes way for the optical ZEISS DotScan, which is then selected as the sensor for the element undergoing measurement. To scan the desired segment using the rotary table in combination with ZEISS DotScan, it is first necessary to define the position of the rotary table itself.

When the user instructs ZEISS CALYPSO to execute a curve via a 4-axis measurement, it will first rotate the rotary table to the required position. The ZEISS DotScan then moves during the scan, maintaining a perpendicular direction to the surface and thereby ensuring that the measurement is as precise as possible.

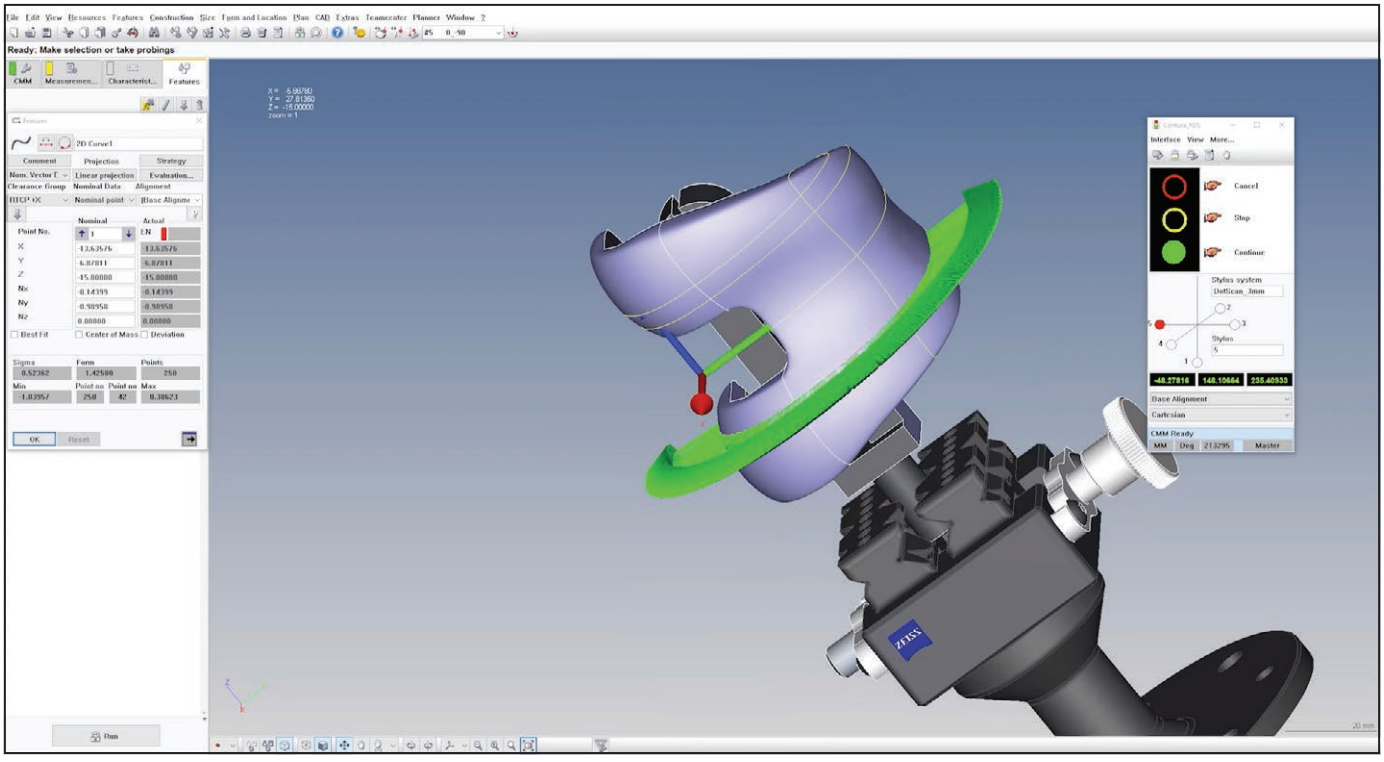
ZEISS DotScan prepares to perform a measurement

Take a closer look with in-depth analysis

Having performed a 4-axis measurement to create a curve scan, ZEISS CALYPSO users can subsequently employ a host of options to zero in on the most important data. For instance, the scan can be displayed with greater clarity by deactivating outlines, eliminating outliers, and hiding nominal points while showing newly measured data. This ensures a neater and more focused layout that provides the ideal foundation for more detailed processing and analysis.

A number of further characteristics including roundness, flatness, waviness, and straightness can then be added to the measurement plan. On top of this, users can incorporate highly effective analysis features – in the case of symmetry points, simply by selecting two desired points within the curve scan.

Of course, no measurement strategy or analysis procedure is complete without a protocol. And thanks to the ZEISS PiWeb functionality included as standard in the ZEISS CALYPSO package, the curve scan created by the user is flawlessly transformed into a protocol containing a technical drawing of the plot line profile.



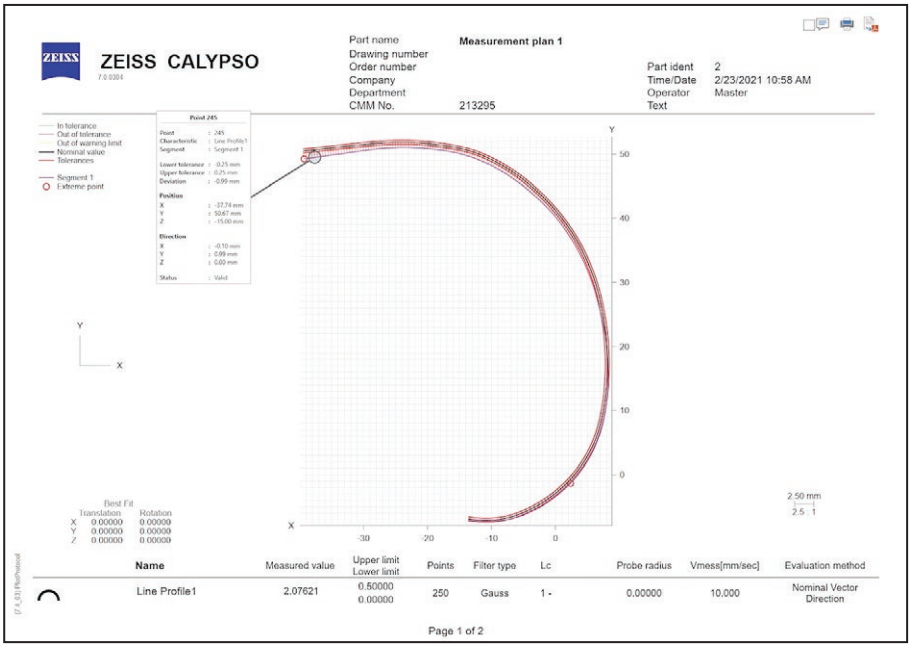
Tailored display of curve scan

Precision protocols with ZEISS PiWeb

These ZEISS PiWeb reports also feature key data visualization including points outside of the tolerances, points outside of the warning limit, the nominal value, and the tolerances themselves. Further information including the company name, operator name, responsible department, and report generation time is also shown in a clear overview.
This delivers a substantial boost in terms of quality assurance: Not only can users increase error scaling in reports so as to better detect deviations from the nominal value, they can also select any individual point in the drawing to immediately view detailed point-specific data and check compliance with requirements. It is also possible to “clip” any of the points within a drawing, thereby making it easier to identify specific scan regions if required.

Together with a sizable variety of protocol types on offer in the program, users are free to generate a number of different protocols for inclusion in a single report.

Whatever form the final protocol takes, it can easily be previewed, saved as a PDF, or sent directly to a printer. Precision protocols, perfectly portable.



Clipping a point within a protocol

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