

# 100 percent measurements on implants thanks to automation

## Quality assurance of bone implants

In order to be able to produce titanium bone implant systems cost-effectively in Switzerland, the manufacturer Genostis relies on automation. An important feature of the process chain is a CT machine from Werth, which automatically measures all implants.

The Swiss company Genostis AG, based in Burgdorf in the canton of Berne, manufactures bone implants based on known and now patent-free designs. Thanks to the principle known as "generic", the costs for research and development are marginal. "Our plates and screws are based on designs that have been tried and tested over decades," explains Genostis CEO Lorenzo Zoccoletti. "In an in-house reengineering process, we optimize them in line with today's requirements for patient-friendly application and efficient production."

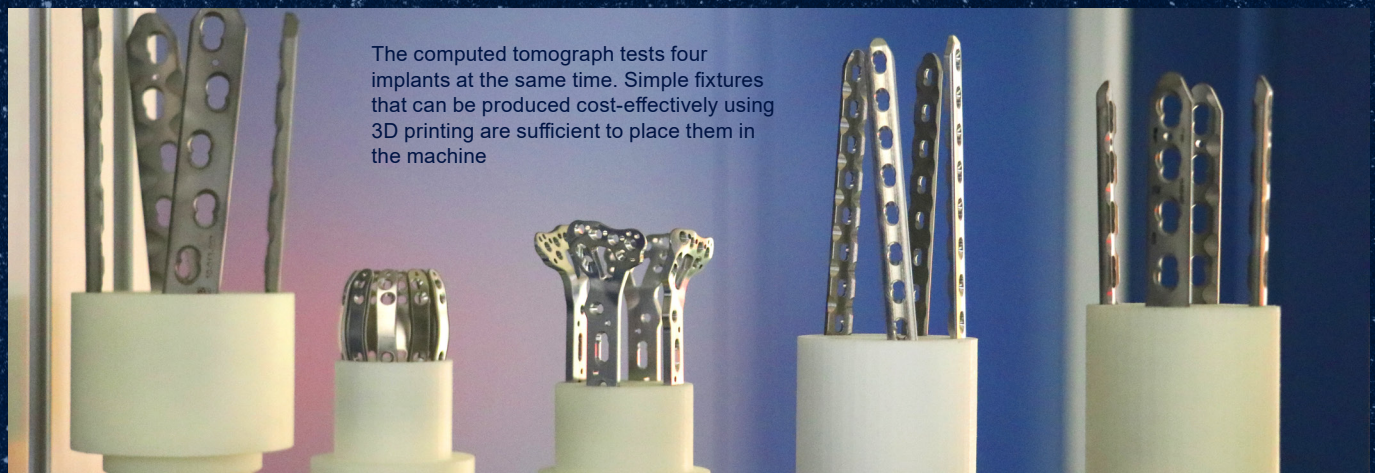
The prices for such implants are significantly lower than those of other well-known suppliers. According to Zoccoletti, 100% of the high-quality systems are produced in Switzerland. As the largest cost block is in production, those responsible there pay attention to very high efficiency. "We have very high labor costs here in Switzerland," says Carmelo Blandini, COO of

Genostis. "That's why maximally automated production processes and the intelligent use of innovative production equipment are crucial to our success."

## Automated metrology as the basis for MDR certification

A core element here is metrology. "All of our implants must meet the strict legal requirements for medical devices, including the applicable EU Medical Device Regulation MDR 2017/745," explains Zoccoletti. In order to use the CE mark to market an implant in the EU, various proofs must be provided and tested by a certification company.

In addition to validation measures, some measurement tasks are also unavoidable, such as initial sample testing of the individual products. In addition, measure-



The computed tomograph tests four implants at the same time. Simple fixtures that can be produced cost-effectively using 3D printing are sufficient to place them in the machine

ments close to production are required, which Genostis has integrated automatically into the production process.

"Computed tomography seemed to us to be the most suitable measurement technology for our concept," explains Genostis COO Blandini. He ruled out conventional tactile 3D coordinate metrology for various reasons: The time and costs involved for the required clamping devices and measurements were enormous, and the test specimens also had to be placed manually. An industrial CT machine offered better conditions for achieving the desired high level of automation.

The Genostis managers opted for the TomoScope® XS Plus 160 from Werth Messtechnik GmbH in Giessen. "We were familiar with Werth as a renowned metrology provider that has been offering coordinate measuring systems for industrial computed tomography for a long time," says Blandini. The selected TomoScope® XS Plus 160 enables the scanning of small and medium-sized workpieces up to around 300 mm in diameter and 450 mm in length. A core element is the transmission tube in monoblock design, which enables a small focal spot even with high tube power, so that fast measurements with high resolution can be carried out.

The maximum voltage of the machine is 160 kV. This means that workpieces with longer radiographic lengths, as well as denser materials, can also be measured. "As we need to capture the geometries of plates and screws made of titanium, this was an important decision criterion," explains Blandini. However, he also points out that the short cycle time required for production control was a challenge. "We had to invest some time until we had built up the necessary experience with the CT sensor."

Genostis wanted to scan the titanium workpieces in multiple clamping, for example. "As the measuring objects influence each other during the measurement and this can result in image errors, so-called artifacts, we ran many tests regarding the number of parts and their positioning in relation to each other in order to get good results," explains Dusan Mirkovic, Head of Production and Automation. "The CT specialists from Werth actively supported us with their expertise, so that we were able to develop a great deal of know-how and ultimately measurement strategies that fit our products perfectly."

As a result, Genostis has succeeded in reducing scanning times from an average of around 20 minutes to 2 to 5 minutes per titanium workpiece. "These values depend on the products, their size, the required resolution and the sizes to be captured," explains the production manager. On average, ten to twelve critical geometrical characteristics have to be captured during a

measurement. The TomoScope® XS Plus 160 provides the complete three-dimensional workpiece volume as a measurement result. The user can set the resolution to almost any value up to 60 billion voxels.



The TomoScope® XS Plus 160 scans four titanium implants in around ten minutes

"The 3D nominal-to-part variation analysis is very good," praises Mirkovic. "We read in the 3D CAD model and compare it with the measured point cloud in STL format." The color-coded deviation plot quickly shows whether the workpiece is within tolerance. "If we then determine a few critical geometrical characteristics, the values of which are also automatically stored in the measurement log, we can release the medical device for use within seconds."

### **All measurement results are reliable and traceable**

Manual measurements are completely eliminated. And: the manufacturer has 100% documentation of the measurement results. Mirkovic adds: "It is important for our use in medical technology that the measurement results are reliable and traceable. Werth Messtechnik guarantees this through standard-compliant calibration, including with a DAkkS certificate." Programming, control and evaluation of the entire measuring process take place in the WinWerth® measurement software. Genostis uses it not only on the TomoScope® itself, but also on two additional workstations that are used for programming and evaluation. "This way, we never block the measuring machine with other tasks," says Mirkovic. The TomoScope® XS Plus is very easy to automate. Genostis, for example, installed a measuring cell with a robot and a racking system with 135 places.

At the moment, Genostis mainly measures plates and screws. After further expansion of production, the TomoScope® XS Plus 160 will also increasingly be used for validation and initial sample inspection. Blandini sums up: "As things stand today, we are very satisfied with our CT coordinate measuring system."