

For the Good of the Patient

Multisensor Measuring Technology for Surgical Instruments and Implants

No other industry is subject to as much regulation or high customer expectations as the field of medical technology. In order to meet all of the quality requirements, Gebr. Brasseler uses the latest measurement technology, which feeds the company's digital process chain on the software side. By networking with CAD, CAM, and CAQ, the medical technology manufacturer is able to produce top quality and still get to market quickly.

Gebr. Brasseler is an international medical technology company with over 1,000 employees at its headquarters and main production facility in Lemgo, Germany. For over 90 years, the brand name Komet has stood for high-quality dental drills. With these rotating instruments and other dental tools, the company became a global leader in innovation and quality. From this strong position, Gebr. Brasseler developed Komet Medical, a division that manufactures rotating instruments, saw blades, immobilization and navigation pins, and other products for orthopedics, ENT, and neurosurgery, in the

1990s. Starting in the fourth quarter of 2017, the scope of manufacturing technology has expanded to include the spinal implant product group. Komet Medical will only be a contract manufacturer in this area, however.

While Komet Medical branded products are sold as catalog items by distributors all over the world, the division, which has been managed as a separate business unit since 2013, is also a production partner for numerous PLMs (private label manufacturers). Jens Haverkamp, General Manager of Komet Medical, explains, "For some PLMs, we now deliver complete sterile-packaged

products bearing their label. This is a sign that our quality is truly first-class and that customers trust our entire process chain."

No wonder, as Brasseler works according to a comprehensive quality management system certified to the EN ISO 9001 and EN ISO 13485 standards. Regulatory requirements, however, have grown tremendously in recent years. In order to reliably meet all the specifications, the development process often takes up to a year, starting with a risk analysis per DIN EN ISO 14791. "This places tremendous pressure on project and product management," says Jens Haverkamp. "Ultimately, product

launch times should be as soon as possible for cost reasons.”

Optimized Processes Under Industry 4.0

Gebr. Brasseler reacted several years ago and optimized the entire process, from product development to shipment of finished parts. The term Industry 4.0, familiar throughout Germany, describes production that is self-organized and monitored to the greatest extent possible. Investments in new hardware and software were combined with the development of optimized design methods and digital data flows.

The optimization process also included quality assurance and measurement technology, which in Jens Haverkamp's view will take over a large portion of the manufacturing process in the future (Figure 1). “In order to meet all the specifications, we need traceable and reproducible processes at all times. This can only work with high-precision measurement technology that covers the entire process and is integrated in our digital network.”

For a long time now, Brasseler has partnered with Werth Messtechnik, a leading company in coordinate measuring technology with optical sensors, multisensor systems, and X-ray tomography. Many ScopeCheck and VideoCheck multisensor coordinate measuring machines are in use in the Lemgo facility. Jens Haverkamp explains why, “Multisensor systems are indispensable, especially for our rotating and oscillating instruments. In order to capture various different features, we need optical image processing sensors and lasers, as well as various probes.”

Komet Medical, where such sophisticated instruments as the high-speed drills



Figure 1. Using modern measurement technology, even the strict requirements for the medical industry are met. (© Gebr. Brasseler/Werth Messtechnik)

for neurosurgery and the new spinal implants are produced, uses the Werth VideoCheck FB DZ, a high-precision multisensor coordinate measuring machine with a fixed bridge design and air-bearing technology. In order to use sensors flexibly, it also has a rotary/tilt axis, in addition to the three linear axes. Besides an image processing sensor with a fixed magnification, the patented Werth Zoom is equipped with an integrated Werth Laser Probe (WLP) optical distance sensor. The Werth Fiber Probe (WFP), also patented, makes it possible to measure extremely small geometries with high tactile accuracy. Metrologists at Komet Medical use it to check a pedicle screw that helps to stabilize vertebral bodies. To find the core diameter of a twist drill, they use the patented Werth Contour Probe (WCP). The tactile-optical WCP can be used to perform profile and roughness measurements as well.

Axel Pieper, Group Lead for Quality Engineering, explains, “We derive the need for measurement systems from the required measurement tasks in each case.

When highly accurate measurements or multisensor systems are required, we typically use Werth VideoCheck or ScopeCheck machines for both process-integrated measurements and final inspections.” For the saw blades product group (Figure 2), which has entirely different measurement tasks, the quality assurance team at Komet Medical uses the latest machines in the Werth FlatScope series. “The Werth FlatScope was the only measurement device that was able to meet our requirements,” says Axel Pieper.

Besides the Technology, the Overall Concept is Critical

At Brasseler, the required measuring equipment is always discussed with the team (Figure 3). For new acquisitions, the decision is made unbiasedly using defined key factors, one of which is a suitable overall concept. Quality expert Pieper explains, “The measuring machines and their software need to be able to be integrated in our structures, including the digital ones. For example, we need to have the superstructure of a software system with an offline programming option. It also has to be able to exchange data with our various systems.”

This is because the decision-makers at Gebr. Brasseler have designed the process chain to be completely digital in order to reduce time to market. A 3D volume model is created in the CAD system, from which the NC programs required for machining are derived in the CAM system. In parallel, the volume model is used to program the measurement sequence offline in the WinWerth software. The measurement techni-

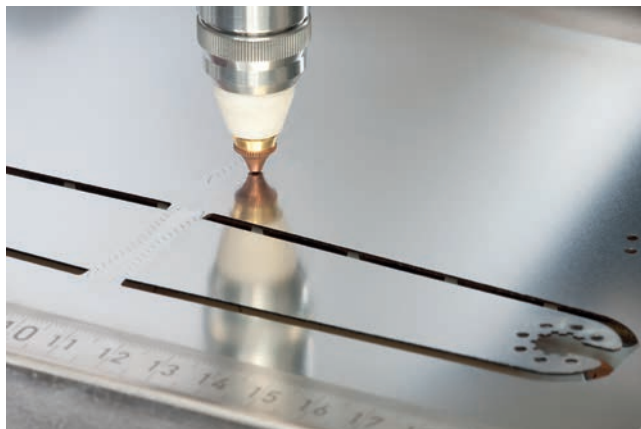


Figure 2. Demonstrable high quality is critical to the continued market success of Komet Medical saw blades. (© Gebr. Brasseler/Werth Messtechnik)

cians at Komet Medical are thus able to create a measurement program for a new product before a single workpiece has come off the machine. Offline programming thus speeds up production starts and keeps the measuring machine free for other tasks.

The WinWerth measurement software includes a CAD as well as a CAQ interface. Werth Messtechnik has a special projects department that takes care of customer-specific interface adaptations. "The data exchange with CAQ software means that we can use part of the measurement program to create the inspection plan. It defines the inspection sequence, when



Figure 3. Jens Haverkamp (left) and Axel Pieper agree, "We need reliable, long-term partners like Werth Messtechnik to provide quality products, which can be integrated into our digital network."

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INFORMATION & SERVICE

INSTRUMENTS FOR DENTISTS AND SURGEONS

The medical technology company Gebr. Brasseler in Lemgo, Germany was founded in 1923 and is still family-owned today. The Komet brand of products has been in existence nearly as long. Today, Gebr. Brasseler is an international company with 1,200 employees around the world. Besides the Dental division, other business areas have been defined: Medical, Custom Made (contract manufacturing for dental implants), and Jewelry, which also operate successfully on a global scale.

With medical instruments for bone cutting in the mouth, jaw, and facial areas, as well as for ENT, neurosurgery, and orthopedics, the Komet Medical business unit has become a solid pillar within the Brasseler Group. The product range of Komet Medical includes saw blades, twist drills, high-speed drills for neurosurgery, immobilization and navigation pins, and in the future, spinal implants as well.

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each feature is measured, and at what frequency the inspection needs to be performed. The dimensions and tolerances are taken from the measurement program," explains Pieper.

When the programs support process-integrated measurement, the measurement results flow directly into a modern CAQ / SPC software system that performs statistical analysis and gives appropriate feedback. The result is a data bundle that extends across all process stages. Axel Pieper sums it up, "In the end we benefit from faster processes and increased reliability. Manual entry is completely eliminated as a potential source of errors."

Data Exchange Defines the Future

Komet Medical General Manager Jens Haverkamp considers this cooperation with Werth Messtechnik to be the way of the future. "We need reliable, long-term partners like Werth to provide quality products, which can be integrated into our digital network." He especially prizes the willingness of his measurement technology partner to work closely with Brasseler as an end user, as well as with grinding system manufacturers and CAQ software providers.

Cross-company partnerships will increase in the future, in his opinion. The reason for this, in Haverkamp's view, is that projects take much longer due to regulatory requirements, especially with large partners in medical technology. This produces

close partnerships that last many years and often lead to identical measurement technologies being purchased and used. "Unlike in previous times, data exchange is often much more open, which strengthens both partners in the end," asserts Haverkamp confidently. For him and for Komet, this already means, "Our customers know what machines we work with and what we measure. We share measurement programs with our project partners in order to reduce costs and also build a secure basis to guarantee that measurements are correct." This eliminates incorrect measurement strategies, so the measured values and results can be discussed immediately. ■

Translated by Werth Messtechnik GmbH