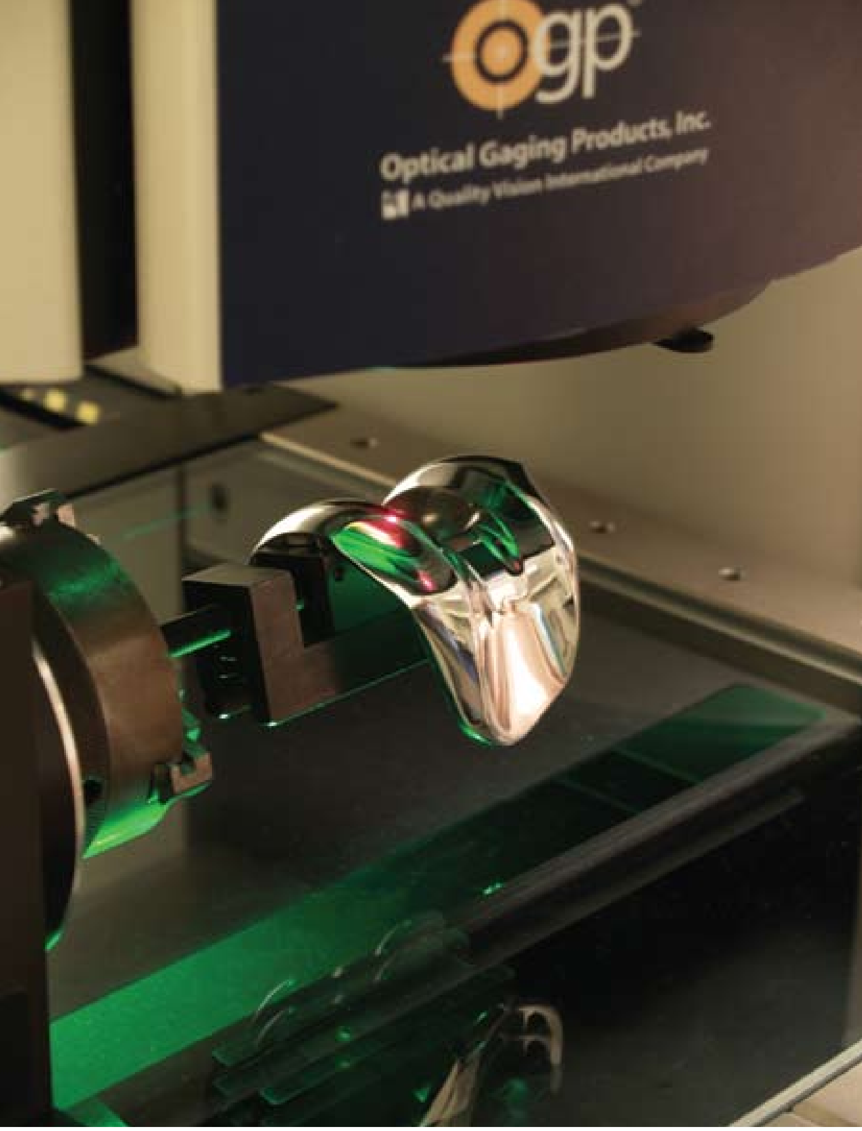


OGP's SmartScope Specialist 300 delivers area accuracy of (1.5 μm + 5L/1000) with options that include scanning and touch-trigger probes, TTL lasers, microprobes, and rotary tables for additional axes of movement. Here, a prosthetic knee mounted on a rotary indexer is measured with a laser sensor on an OGP SmartScope Flash 302.

Medical Metrology

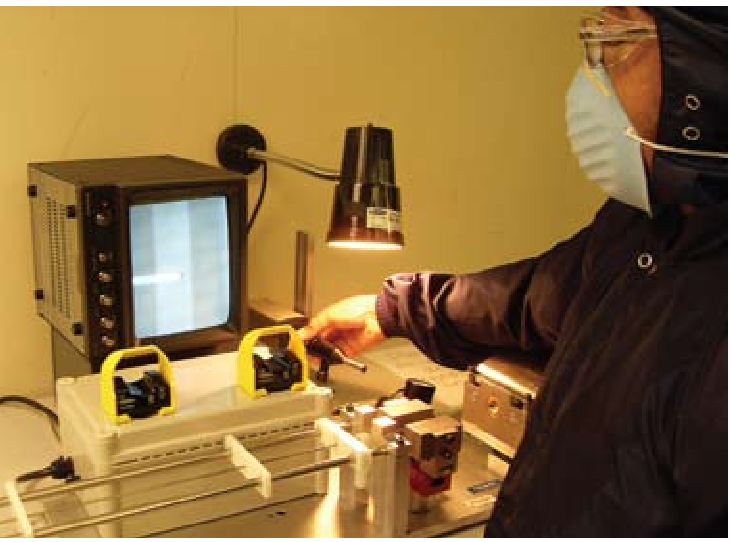
AS PART OF THE WHOLE

As in other industries, advanced metrology technology is finding a place closer to the medical-device production line

Bruce Morey
Contributing Editor

For those who manufacture medical devices, the thinking is personal. "We have the attitude that any of our parts could go into any of our children, or our mothers, tomorrow," explains Jeff Corey, senior calibrations technician for ATEK Medical (Grand Rapids, MI). ATEK is a Tier 1 medical device manufacturer with experience in clinical disciplines including cardiovascular, gynecologic, orthopedic, and spinal. Medical devices manufactured at the Grand Rapids facility range from plastic parts used in delicate heart surgeries to machined plates and screws made of bioresorbable protein for repairing skull and bone fractures.

Such devices require precision measurements to ensure accuracy. Corey notes that the typical dimensional tolerances for most of his parts range from ±0.0005 to ±0.00025" (±0.013 to ±0.0064 mm). Measurements often called out include concentricity, flatness, hole diameters, and lengths. Many of the parts they measure are flexible plastic—a challenging material to measure repeatably and reliably with typical contact devices. "We are in a field where depth gages, micrometers, and rulers are giving way to 3-D laser technologies and CMMs equipped with vision," remarks Corey, though he cautions that the industry will never completely eliminate using hand-held measurement tools or more traditional contact sensors. "Using progressive technologies means you can do more with less. Automated metrology tools are more repeatable and enable 24/7 operation, and results are not operator-dependent," explains Corey. Variety is a hallmark as well as demanding precision. ATEK produces over 1000 separate products. "The ability of a single system to replace multiple gadgets eliminates calibration time, processing cost, and redundant capital expense," he remarks.



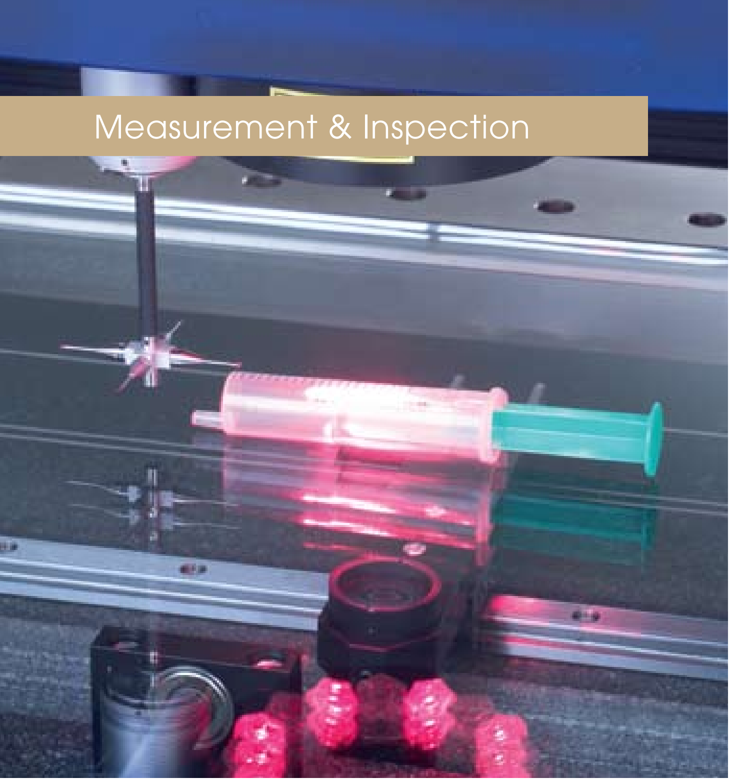
Inspecting product for conformance with a Video Scope at ATEK Medical. Typical calibration accuracy ratio is 4:1 from standard to test unit at this company.

Another potential key driver in the use of more advanced metrology, he notes, is how the industry is increasingly certifying vendors and their manufacturing processes, rather than their parts. "Certified vendors provide us components that, in turn, give us confidence in what we provide to our customers. Certification reduces the amount of inspection needed," he explains. Instead of checking incoming components from these certified suppliers, ATEK measures critical dimensions and functions as a normal part of the manufacturing process.

"Medical-device manufacturing, globally, is a growing market segment for us," states Chris Bomgaars of Carl Zeiss Industrial Metrology LLC (Brighton, MI). He notes that the company offers metrology systems designed for measuring medical devices on the shop floor. One is the DuraMax CMM gage, a CMM equipped with a scanning tactile probe that does not need a special enclosure or room. The other is the O-Inspect multisensor system that combines vision and tactile probes. "Some medical device-companies have many of their metrology machines in their manufacturing cells, while others are certainly moving that way," explains Bomgaars. "That is the trend in all industries, not just medical; to move measuring onto the shop floor to reduce the time needed to gage a part."

Interestingly, for medical manufacturing he also sees that the abilities of their hardware to deliver measuring uncertainties are no more difficult than those encountered in production of many other precision goods. "There is a never-ending arms race to deliver ever-decreasing measuring uncertainties," he says. Medical-device manufacturing is perhaps unique in the level of documentation required for each part. "They need to track the version control of the parts programs and archive parts programs so they can be called up at any time," Bomgaars observes. To meet these needs, Carl Zeiss developed the Master Control Center package. "Once we understood the level of capability companies were going to need to document their process, that was a catalyst for creating the MCC software. The MCC controls version levels, and only released versions can run on the measuring machines. There is also a tool available to archive every run by, say, serial number or other unique identifier. This software also tracks machine utilization and predictive maintenance."

Three-axis vision-based metrology systems are also well-suited for a number of medical parts, notes Allen Cius, product specialist for vision systems for Mitutoyo (Aurora, IL). He lists such products as multilumen tubing, medical packaging, dental components, cardiac components, and orthopedic knees. Mitutoyo offers their multisensor QuickVision systems with an accuracy of 1.5 µm. Their QuickVision ULTRA system measures to 250 nm of accuracy in the *X* and *Y*-axes and 1.5 µm in *Z*. "Our systems support process control, and are placed near production cells as well as used in more off-line, intensive QC tasks," he says. In critical cases, where 100% inspection



Carl Zeiss IMT's O-Inspect multisensor system with a typical medical device.

is required of components such as balloon catheters used in angioplasty, robots feed parts to a QuickVision system. "The advantage to the user is that a multivision system is capable of both first-article inspection—a much more lengthy process—and subsequent process control," explains Cius.

Like any other industries, medical manufacturing strives to produce quality parts at lower cost and with faster processing times. Cius points to the QV Stream vision-based system for high-throughput applications. While it offers 1.5-μm accuracy, what is unique is that the system uses stroboscopic illumination and a progressive scan camera to boost speed up to five times when compared to conventional processing, according to the company. "This system never stops moving," explains Cius, while conventional systems move, stop, collect data, and move again. "This capability would be especially useful in products like multilumen tubings or medical packaging—soft parts where noncontact measurement is needed and the parts are made in high volume," he observes. New in 2010 for the QV Stream System was improved concurrent-image processing that can measure nonlinear data points through an interpolated path. "This makes it more useful for a wider array of medical parts," says Cius. "Medical device parts are getting smaller to be less invasive in the body. As they shrink, we need to measure ever-smaller parts and tolerances."

A tool frequently used for near-process measurements in manufacturing cells are optical comparators. These devices project a magnified silhouette of a part on a screen. Operators check the dimensions and geometry of the part against limits, using Mylar overlays. Generally easy to use by shop-floor personnel, and relatively easy on the capital budget, they are popular metrology tools for manufacturers of irregular parts, according to Patrick Beauchemin, an engineer with VISIONx (Pointe-Claire, Quebec, Canada). These components include orthopedic replacement knees, hips, bonescrews, and craniomaxialfacial implants. Handling the overlays, making sure the part number is at the right revision level, and accounting for operator differences are known issues with these devices.

"A few of our medical device manufacturers urged us to adapt our vision systems and software to create a digital optical comparator," explains Beauchemin. Enter the VisionGauge digital optical comparator. Using machine vision instead of optics, the system has the look and feel of an optical comparator, but compares images of parts directly with CAD data in DXF format, eliminating a hard overlay. Images are stored and deviations recorded digitally, without human intervention. A full range of magnifications is possible—5, 10, 20, 50 and 100×—for a range of accuracies. "For example, at 50× magnification, we can deliver 0.0001" [0.003 mm] measurement uncertainty," explains Beauchemin.

The development of this device by VISIONx illustrates how new technology may best be served by putting it in a familiar form. The company's previous experience is primarily automated imaging, visual inspection, and high-accuracy measurement solutions. It does not offer traditional optical comparators in its product lineup. "We 'back-fitted' this new technology into something they are familiar with," remarks Beauchemin. He also points out that it offers many new possibilities, such as an automatic pass/fail capability. VisionGauge products are marketed, demonstrated, and exclusively sold, distributed, and supported throughout North America by Methods Machine Tools Inc. (Sudbury, MA).

Another category of devices that might see more of a future in medical manufacturing is laser scanners. Traditionally, their speed advantage was offset by less accuracy and the need to coat or treat reflective surfaces. "The biggest shift we've seen is that, as laser technology matures, we are more capable of scanning shiny surfaces, such as those typical in orthopedic replacement parts, such as knees and hips," comments Alex Lucas, business development manager of scanning products for Nikon Metrology (Brighton, MI). Medical manufacturers and the FDA frown on unnecessary chemical treatments on parts going into a human body. Lucas points to the Nikon

LC60Dx as a device with an upgraded capability to collect data from shiny and other challenging surfaces.

The VisionGauge optical digital comparator can be fully automated if desired, according to VISIONx, reducing operator variability and speeding throughput.

Even so, a scanner is not as accurate as a typical tactile probe, a fact Lucas himself points out. “Speed is its best attribute, and a lot of our customers are getting comfortable scanning 100% of a part or parts to, say, 75% of their desired accuracy specification,” explains Lucas. What are the advantages of more, fast measurement made less accurately? “That volume of data allows them to do trend analysis and macro analysis of their parts,” he says. “They then can follow-up on specific parts with tactile probes on a few parts with higher accuracy,” based on the trends identified. He notes that he sees many customers choosing to upgrade existing tactile probe CMMs with an additional laser scanner.

Equipment for measuring is one thing, reporting and documenting results is another. Optical Gaging Products (OGP; Rochester, NY) is another supplier of multisensor systems as well as advanced hybrid digital/optical comparators, specifically tailored for the medical market. Because the market is growing, a number of smaller shops that once made only automotive or aerospace parts are now making a transition to producing medical parts, according to Nate Rose, chief application engineer for OGP. “I think one of the biggest challenges in medical device metrology is meeting FDA requirements,” he states. “For example, in manufacturing environments outside of medical, they may not give a second thought to fine-tuning an inspection routine at any time. When the FDA is an overseer, even minor program changes are a big no-no. Once a process is validated and they are using it to make parts, even a small change requires revalidating it.” OGP, recognizing this situation, invested in developing software specifically aimed at helping manufacturers with FDA compliance. OGP offers the ability to run subsets of validated inspection routines, so manufacturers can test specific features without the need to run the entire routine or to modify the validated routine in any way. Rose goes on to note that: “This allows the ability to work from a validated first-article inspection routine and run smaller batch-style inspections consistent with critical dimensions.” While developing new sensor technology, OGP has also grown its offerings in software solutions for processing measurement data with its SmartProfile software. “Conventional measurement involves widths, distances, diameters, etc. On spines and knees, however, those kinds of dimensions are nonexistent,” says Rose. Using point clouds from the measuring machine as basic input, SmartProfile analyzes the dimensional measurement data for conformance of 3-D shape, form, and dimensions of rigid parts to a CAD model, relative to the ASME Y-14.5 GD&T standard. “Demonstrating that you meet that standard is especially important in the medical community right now,” explains Rose.

Nikon Metrology’s LC60Dx collects up to 75,000 points/sec to a measuring uncertainty of 9 µm (0.0004") at 1 sigma with measured results often as low as 7 µm (0.0003") at 1 sigma.

Compared to many other industries, medical-device manufacturing has unique concerns about patient welfare, with lingering thoughts of liability. “These concerns drive extreme process control,” explains Frank Powell, product manager for Marposs (Auburn Hills, MI), a provider of in-process gaging and measurement equipment. “We have installed systems that use a 2-D bar code on each part to relate gaging data, what operation it was measured on, what the measurements were, and even which machine it was made on and who was the operator at the time," he says.

Another example of the extreme care sometimes needed in medical-device manufacturing was the company's experience in developing a mark-free measuring system for titanium hip joints. The ball and socket have to mate perfectly, requiring a superfinish for a nearly friction-free range of motion. Specialized machine tools create the superfinish. In-process gages monitor and control these machines. The problem is that titanium is a highly reactive metal that attaches readily to carbon-based materials, such as the diamond commonly used for precision gage contacts. The buildup on the carbon-based contacts led to inaccuracies. Modern ceramics provide the best wear characteristics. Machining processes using contact gages can leave a mark on the workpiece. In most cases, it would not affect the functional performance of the artificial joint. As Powell points out, however: "Surgeons are not metrologists." If they see a mark, concerns over patient welfare will lead them to reject and scrap the part. In response, Marposs works with process engineers and machine builders to fine-tune the grinding process to prevent visible marks. Powell concludes that more inspection systems will be needed to control quality in the future. **ME**