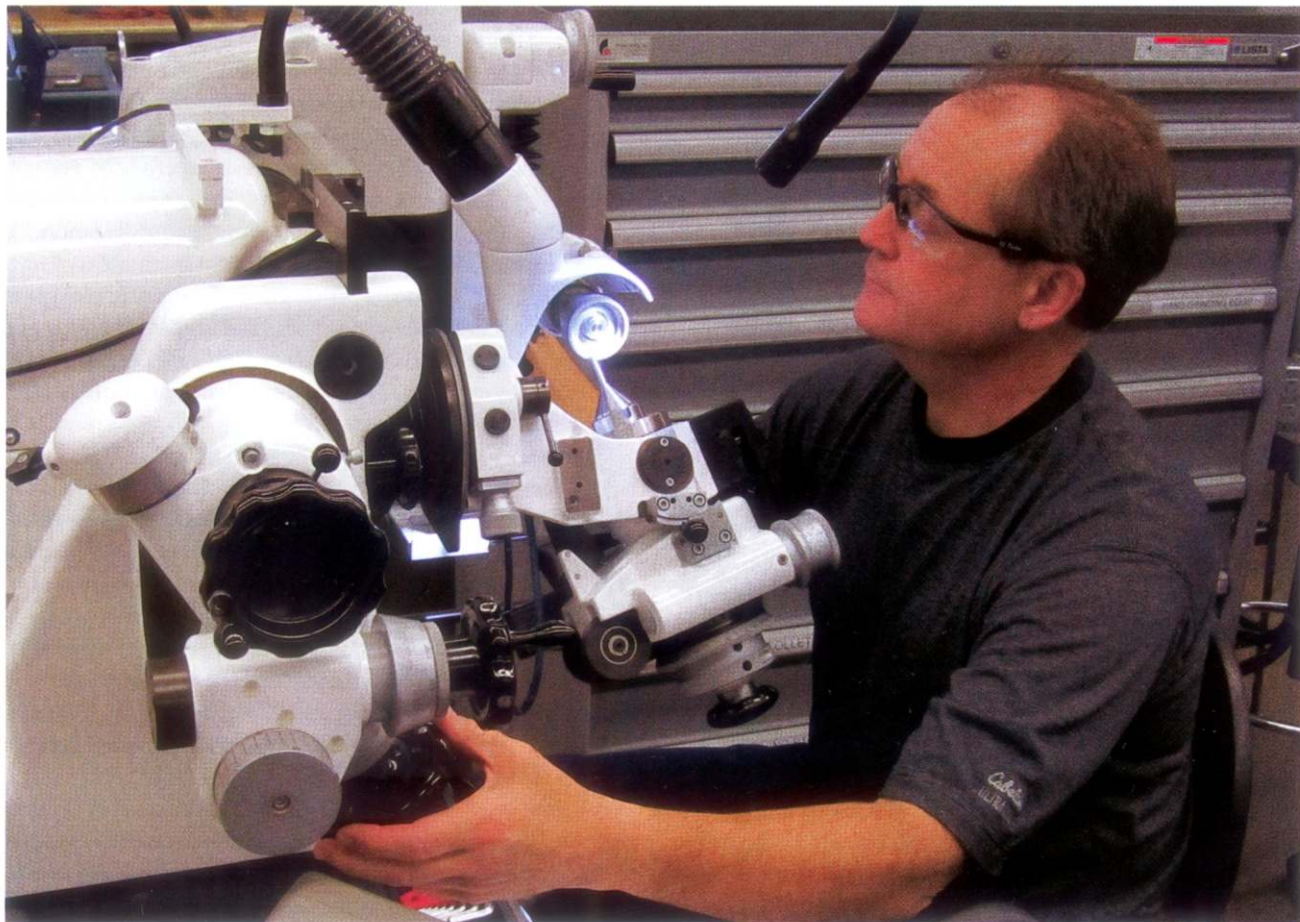


Improving Medical Devices at **Lowell**

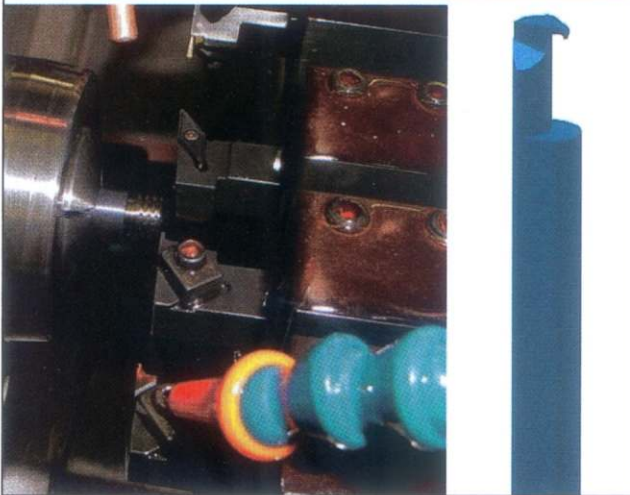
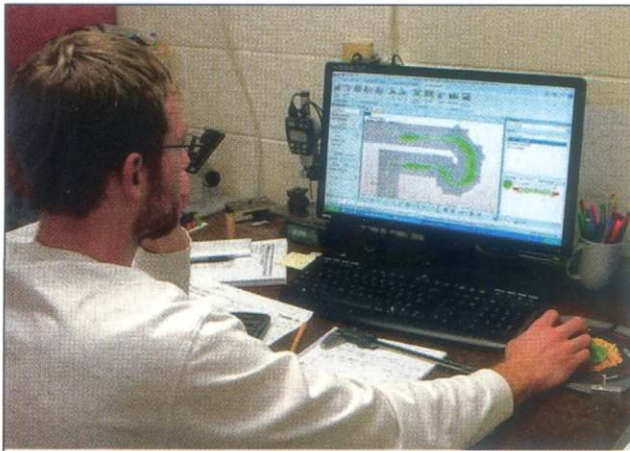
Lowell Inc. (Minneapolis) has been a precision machining contract manufacturer of implantable medical devices for orthopedic and cardiovascular applications for nearly 20 years. Founded in 1964, this private company with 70 employees uses 100 CNC machines to make hundreds of different variations of these critically dimensioned parts that must conform precisely to their design drawings. A key aspect of the process is the custom tooling they use to make the parts. Since the performance of the custom tooling, with their small arc radii and small surface areas, affects the success or failure of every part, getting the fabrication and qualification processes for the tooling under control was very important to Lowell. The company attributes SmartProfile Interactive Fitting and GD&T software for better than 10× improvements in the useful lifetimes of the hundreds of custom tools Lowell uses to make its customers' parts. Tools that used to last for 50 parts now produce thousands.

Custom tooling is verified by precision metrology and software.



A Lowell machinist making a custom tool on the EWAG WS-11 SP grinder.

Like any manufacturer with its focus on the end products they produce, Lowell initially concentrated its energies there and had its tooling made by an outside supplier. These intricate tools have tolerance radii of 0.0008, 0.0005, and 0.0002" (0.02, 0.014, and 0.005 mm) and thickness of the tool profile geometries of 0.015–0.020" (0.38–0.5 mm). Numerous problems with tooling performance, including breakage and inconsistency in production of conforming parts, forced Lowell to bring tooling production in-house.



Top: A Lowell engineer using SmartProfile GD&T Fitting software to assess the quality of a custom tool. Bottom left: Custom tools in place prepared to machine a part. Bottom right: CAD model of a typical custom tool.

The requirement for a new custom tool can come from a number of sources at Lowell. The process starts with a thorough preproduction review of the part and the geometry of its features. Engineering, manufacturing, programming, and tooling departments (the associates in this group possess an average of nearly 30 years of precision machining experience) determine what tooling is needed in order to machine features

that conform to print. If a standard tool can do the trick it is selected from inventory or an order is placed with a supplier. If a custom tool is required, the engineering team creates a detailed solid model drawing in their CAD software package. The tooling manager and tooling machinist or toolmaker act as interfaces between manufacturing, engineering and programming. Ideas go back and forth until a final design is committed to and confirmed. Before Lowell developed its in-house expertise, the receipt of a custom tool could take weeks. If the tool was wrong or modifications were required even more time could be lost. Now with the process in-house, if a redesign or a tweak is needed, the tool can be reground in a matter of hours. This has been an enormous savings to Lowell in time and manpower. Most importantly, its customers benefit from faster turnarounds and parts that conform to print.

The Importance of Metrology

Since Lowell determined that paying more attention to its tooling directly affected the quality and quantity of the devices it manufactured, the investment in better equipment and personnel for making the tooling seems rather obvious. The first step was an investment in a high end Swiss-made Ewag WS11-SP custom tool grinder. The WS11-SP can precisely grind tooling in carbide, tungsten, steel, and other materials. It even allows for the grinding and measuring of cylindrical and tapered tools in a single clamping. Next, the company needed to find an associate to operate this extremely complex and precise grinder. Fortunately Lowell has an experienced and talented workforce to draw from. The Ewag is operated by an associate who spent 31 years as a machinist at Lowell before taking the rigorous training required to run it.

Finally, Lowell needed a process to determine if the custom tools conform to the design specifications—that is, to properly measure them. This is where the Lowell experience is different than might be expected. They do more than simply measure the tooling.

Lowell uses a variety of measurement systems and gages, but the most important of them are for the inspection of the custom tooling. One is an Avant ZIP 400 video measuring machine from Optical Gaging Products (OGP), and the others are a Leitz Model PMM-C 700 12-10-7 laboratory-grade scanning CMM, and a Brown & Sharpe EXCEL 7-10-7 CMM. The OGP machine uses analysis of magnified images of part details to accurately measure dimensions, angles, and radii without contact. The CMMs measure larger features via touch probing. Together the systems provide the necessary measurements to confirm tool designs. Initially, however, the interpretation of the measured data points was inconsistent. It required a skilled engineer to interpret the large number of individual measurement results for each tool. The engineer could recognize which of those measured values was important and to what magnitude, but it is the cumulative relationships of all the measurements

that's important. So Lowell sought out an interpretive software package that could make complete use of the measure data. This is where the investment in SmartProfile software comes into play. It does more with the measurement data, making it easier to validate tooling against the solid CAD model.

The Software

SmartProfile is a 2-D/3-D interactive best fitting-software application that is used in a GD&T environment where part acceptance or rejection is required. Fully compliant with ASME

Y14.5/1994 and ISO 1101 standards, it takes point clouds of data from part measurements performed on any measurement system, merges that data with the nominal CAD model of the part with its GD&T tolerances, and automatically performs a results evaluation based on those tolerances.

As part of its project to improve its custom tooling, Lowell engineers created detailed solid model CAD files of the tooling. As part of its evaluation process, SmartProfile can import any number of popular CAD formats, including IGES, STEP, VDA, STL, and DXF files. Since it accepts measurement data from virtually any measurement system—in Lowell's case, OGP ZIP 400, the Leitz PMM and the Brown and Sharp CMM—SmartProfile readily fits into its custom tooling process.

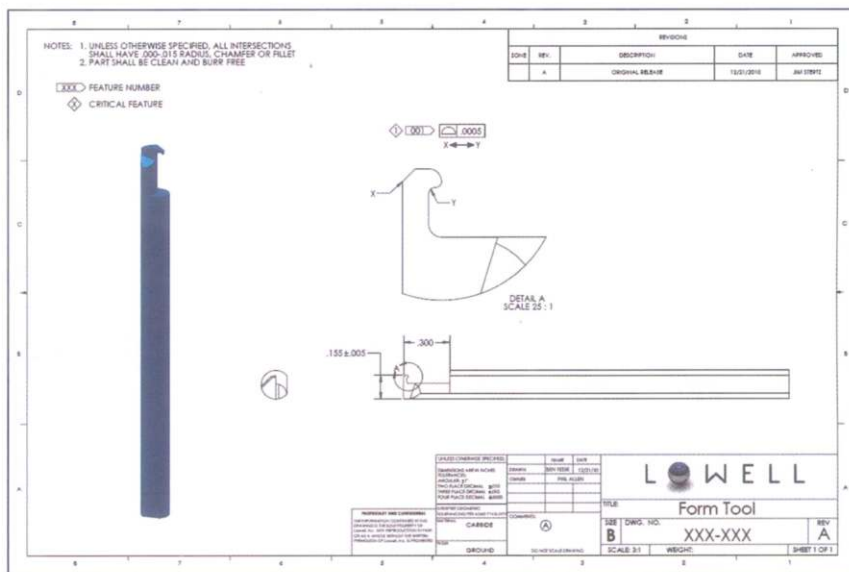
A Lowell engineer at a computer workstation uses SmartProfile to dimension the CAD model, define data, and apply GD&T tolerances. Measured data from the OGP ZIP 400 video measuring system is imported and overlaid on the model. The imported data points may be aligned to the model manually or automatically. SmartProfile then compares the measured data with the nominal model and determines whether measured features are within tolerance. Colorful graphic displays with whisker plots confirm tool quality at a glance. The key advantage of SmartProfile for Lowell is that it can evaluate surface profiles or geometric tolerances against Datum Reference Frames, with compound data, pattern data, data at MMC/LLC, and composite tolerance zones. These extensive analyses are very important to Lowell since their intricate custom tools have numerous exacting profile tolerances for their extremely small and complex geometries. "Accurate confirmation of the tools is key to what this program provides," says

Jim Stertz, Quality Assurance Manager at Lowell. "Now the toolmaker gets confirmation of what he is making. Without SmartProfile we'd still be guessing." Stertz learned about SmartProfile from Productivity Quality (PQI), the local OGP representative in Minneapolis. During the course of assessing Lowell's requirements, PQI performed several demonstrations. "Seeing the first demonstrations of SmartProfile by PQI on site—right then and there I knew we had to get it. There was no decision-making beyond that. I could see its value." At the same time, Lowell staff learned more

"Accurate confirmation of the tools is key to what this program provides."

about GD&T and what it could do for their processes. Since SmartProfile compares measured data to the part CAD file, Lowell simultaneously updated its design drawings to incorporate GD&T. The tooling design and new inspection processes, as well as the new tool grinder and toolmaker, were implemented in parallel so they came into use at the same time.

SmartProfile is now a critical part of Lowell's custom tooling process. Before implementing SmartProfile, only two highly trained people could evaluate the raw measurement data for every part. Today, inspections take half the time with more accuracy and are completed by a broader range of skilled



Engineering drawing of a typical custom tool.

and less-skilled employees. Needless to say, Lowell is pleased with its investment in custom tooling and the software and systems to verify compliance. Stertz adds, "Lowell is a leader in the precision machining and assembly of medical devices. Our commitment to custom tooling leads to conforming parts. Our customers benefit and we benefit." ☑