

TOP TRENDS AND SMART SOLUTIONS

TO GRIND FOR SUCCESS IN THE
MEDICAL INDUSTRY



ANCA
CNC MACHINES

When it comes to language, food, fashion, politics, and so on, people across the globe differ widely. But when it comes to biology, we're each unique in the particulars and nearly uniform in the aggregate. We share the same diseases and maladies. A heart valve for the average German will suit the average Chilean. World-class surgery is world-class surgery everywhere. So it's no surprise that the R&D, marketing, and production of medical devices is international. Your American dentist might be using Korean drills, and the artificial knee keeping your Scottish uncle on the golf course might have come from the US. Thus the smart move for manufacturers is to partner with international players who can deliver a competitive package, no matter the challenge and no matter the locale. With a worldwide team and equally diverse customers, ANCA presents an ideal example.



SURGICAL INSTRUMENTS

The United States remains both a giant consumer of health care and the world leader in developing medical products. Indeed, the top 3 medical device companies are all American: Medtronic, Johnson & Johnson, and Abbot, with others, like Stryker and GE, rounding out the top 10. ANCA's president in the US, Russell Riddiford, observed that these firms "maintain a strong desire to retain manufacturing in the USA," albeit often via 2nd and 3rd tier companies working on a contractual basis. And while ANCA's capabilities stretch into orthopedic implants and beyond, Riddiford added that solid shank surgical cutting tools remain the most common medical application for their machines. Tru-Edge, based in St. Henry, Ohio, USA, illustrates that point.

Founded in 1996, Tru-Edge's vision is to be the leader in custom crafted round tools and re-sharpening programs in several industries, such as aerospace, automotive, and medical. In fact, their motto is to "Simplify Tooling to Deliver Productivity." But beginning in 2007, several big orthopedic customers in the Warsaw, Indiana area contracted them to produce hip broaches, bone rasps, bone graft drills, reamers, and taps—A business that now represents 10% of their total sales. Director of operations Vice

President Brian Hackman recounted that for the first 14 years or so, these were primarily reusable instruments, with the ultimate customer being major hospitals that had the ability to sterilize them.

By optimizing wheels, plus the speeds and feeds on their ANCA TX, MX, and FX machines, Hackman said Tru-Edge was also able to deliver a burr-free finish that virtually eliminated the need for post-processing. This contributed to even more business and an award from the regional manufacturing association in 2018.

Hackman credited their success in part to innovations in ANCA's Toolroom software and the incorporation of linear motors. While Rick Brunswick, engineering manager, pointed to ANCA's in-process wheel dressing capabilities as a key ingredient to maintaining tight form tolerances, especially on medical taps, while also reducing cycle time and the number of operations. He added that they favor ANCA's approach to outfitting a machine with a large (250 mm \varnothing) dressing roll around the work head, rather than the optional side-mounted dresser. "It lasts much longer, because you have more surface area on that diamond dressing roll than you would with a smaller dressing roll that's off to the side."

"They wanted the tools to be as visually appealing as they could possibly be, had a jewel like appearance, due to the highly polished surface finish and complex geometries. The different facets and reliefs we would grind in them would literally sparkle."

- **Brian Hackman**, Vice President, Tru-Edge



AUTOMATION SOLUTIONS

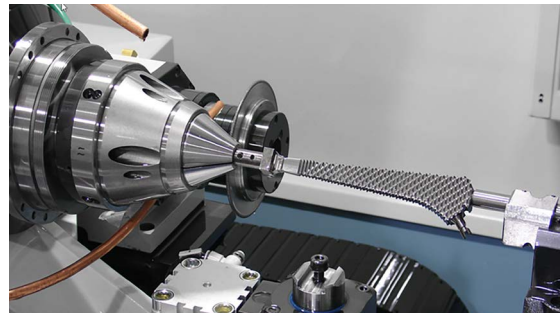
By 2020, reported Hackman, customer requirements started shifting dramatically toward single use instruments, owing to a corresponding explosion in orthopedic surgery occurring in smaller medical centers. These facilities are generally doctor-owned, explained Hackman, and demand a simpler, functional tool at the lowest cost, versus a visual showpiece. Thus, the primary material changed from 17-4 stainless steel to 455, which is "slightly duller. It's also gummier, and tends to produce more burrs. So it takes more time to get burrs off."

As you might expect, the switch to single use instruments also flipped production volumes. As Hackman summarized it, "ten years ago we were doing six, eight, and ten piece orders. We had an 11,000 piece order last July...We still have the technology, the innovation, and the knowhow to provide a burr-free, beautifully finished part. But now we have to do them by the thousands, instead of by the fives and sixes."



Here again, ANCA fit the need. For example, with robot loaders and automatic wheel changing from a 6-position carousel on their MX machines, Tru-Edge is able to run lights-out. Another contributor is the traveling steadyrest, riding on what ANCA calls the P-axis. As Brunswick explained, long, thin surgical cutting tools tend to bow. But Tru-Edge developed part-specific bushings that, in conjunction with the steadyrest, force the tool into a perfectly straight setup for the grind. As such, Hackman said a single MX can produce 5,000 small diameter surgical drills per month.

Automating femoral rasp production typically involves both an automatic collet chuck and a swing-out tailstock to secure the other end. As Hackman put it, these rasps vary widely. "Some are long, skinny, and nicely straight. Others are crooked like a dog's leg. So we had to develop part specific tailstock fixturing to allow different shapes to be held on center."



These parts are typically designed in Siemens NX, and ANCA provides a post-processor to create the necessary machine motions. After importing this file, ANCAam gives the operator the ability to manage specific process parameters, like speeds and feeds, offsets, and wheel selection, and dressing cycles. While ANCA's CIM3D package offers a full simulation to verify the grinding motion and to compare the expected part with the original model.

THE EUROPEAN ANGLE

Headquartered near Germany's center of medical technology between the Black Forest and Lake Constance, Mahe Medical opens a window into the vibrant European production scene. In addition to a full line of surgical cutting tools, Mahe also manufactures orthopedic implants, power tools, and rinsing systems. They even make instruments to remove spinal implants without injury to the patient, a system they developed in close cooperation with doctors and scientists.

Echoing Tru-Edge's experience, Klaus Stehle, Mahe's quality management and projects leader, said they also worked with ANCA on clamping and support solutions to meet the challenge of grinding long, thin instruments. He also added the importance of being able to vary the probing position depending on the blank, plus the ability simulate the grind in ANCA's software. Like Tru-edge, Stehle said they have to handle batch sizes for these parts ranging from 20 to 1,000 or more.

According to Stehle, Mahe was an early adopter of ANCA machines, buying the RGX back in the mid-90s. "At that time, software and simulation were decisive factors in the purchase decision. New, more flexible, more precise geometries were possible."

Stehle also cited ANCA's applications support as critical to producing rasps, given their odd shape and the related challenge of holding them. He added that these parts are often produced in small quantities, making efficient programming and fast changeover decisive in ensuring profitability. Finally, said Stehle, ANCA's international support helped them establish production facilities in Thailand in 2012.

ANCA's general manager for Europe, Africa, and the Middle East, Martin Winterstein, described the medical market as highly international, while also culturally and linguistically diverse. From range of surgical and dental cutting tools to various types of implants, he said ANCA machines are proving their worth across the region, be it in Spain, Ireland, the UK or Poland. At the same time, he said, addressing the needs of the market has ANCA expanding their physical presence beyond their tech center in Coventry, in the UK (focused on orthopedic implants), and their German hub (focused on round tools). "We're looking at locations in Italy, Turkey, Israel, Spain, and elsewhere," said Winterstein. "Medical manufacturing has picked up considerably since the pandemic, and ANCA is committed to supporting customers wherever needed, across the full range of applications."

"At that time, software and simulation were decisive factors in the purchase decision. New, more flexible, more precise geometries were possible."

- **Klaus Stehle**, *Quality Management and Projects Leader, Mahe*



mahemedical

DENTAL DRILLS AND THE ASIAN SCENE

While medical manufacturing remains strong in the US and Europe, many firms take advantage of lower wages in Asia, either directly (like Mahe) or by subcontracting production to Asian firms. Jake Farragher, ANCA's general manager for Asia, identified dental drill manufacturing in Korea as a prime example. "Almost all of it is for export, including destinations far beyond Asia," he explained.

ENG-K, established in 2014, is a Korean success story in this area, with a dozen ANCA FX machines and an annual growth rate of 30%. They actively participate in their client's research and development of new instruments, thereby "satisfying the customer's needs as much as possible by reflecting the function and structure in the production," as president Dae-Seong Kwak put it.

Jake explained that manufacturing dental drills presents several unique challenges. The drills have a smaller diameter, complex geometry, and they are made of special materials. To address these challenges, the FX machine is well-suited for the task. "We have incorporated a pressure-reducing gripper system into our auto loader as the material is softer than conventional cutting tools." Mr. Kwak reported.

He further emphasized that ANCA's drill loading system improved efficiency by increasing productivity and significantly reducing operator fatigue. Mr. Kwak attributed the production of high-quality tool radius and profile to ANCA's latest software release, which in turn made them more competitive in the market.

ANCA's Greater China general manager, Denny Zheng, tells a somewhat different story. There is less subcontracting for export and more production for internal consumption. For example, giants like Zimmer Biomet have plants in China to make femoral knees mainly for the Chinese market, he explained. And companies are "experimenting with 3D printing of stainless steel femoral knee implants, customizing the shape for each person. They say that will be the future of the product." He added that testing already includes human patients, and while the parts must be polished after they're printed, they don't need to be ground. It's not clear if this approach has extended to cobalt chromium, which is the preferred material in the US and elsewhere.

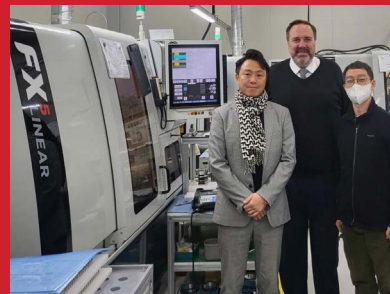


According to Zheng, the expense of getting the required certifications to export medical products has limited most of the smaller manufacturers to the local market. At the same time, he said, procedures like dental surgery are very expensive and “high status,” with doctors and patients actually seeking the cachet of imported tools. Only recently has dental work become more common, with a drive to lower costs resulting in more local production. Even then, he said, it’s difficult to source the proper medical grade stainless steel in China.

On the other hand, the long term prospects are excellent. “Ten years ago there were probably less than ten dental clinics in Shanghai, apart from the government one,” recounted Zheng. “Now there are hundreds.” Likewise, a few years ago, elderly Chinese just accepted the fact that they were unable to walk well. “But people are getting a bit richer. And we are telling them, if they replace their knees, they can throw away their stick and walk normally. So it’s just started.”

“The automatic warm-up routine is another upgrade. As a result, size deviations are smaller and the platform is very stable, so the defect rate is reduced and process reliability is assured. In addition, ANCA’s team in Korea has always managed to minimize production disruptions with friendly explanations and quick action. We’re very thankful.”

- *Dae-Seong Kwak, President, ENG-K*



SOPHISTICATED DENTAL BURRS

Sometimes a creative medical professional partners with manufacturing engineers to produce a unique solution in one place that wins converts around the globe. That's the case with Dr. Salah Huwais and his team at Versah, based in Jackson, Michigan, USA. Their patented dental burr returns all the bone back into the jaw as the periodontist cuts the hole needed for the planned implant. According to Aaron Beach, director of manufacturing and product development, this usually enables the surgeon to immediately place the permanent implant, versus waiting 6 to 12 months for the bone to heal, as is required when using a traditional burr.

Naturally, Versah does not want to publicize all the secrets that go into making these tools, except to say that they are ground to "extremely tight tolerances" on ANCA MX and FX machines, where the biggest challenge is accounting for wear in the steadyrest and the grinding wheels, said Beach. But the CBN wheels hold up well enough that they don't require in-process dressing, he reported.

In terms of workholding and part handling, all jobs are fully automated, with a typical batch size of 1,000 burrs. "We inspect parts with a vision system every 30 minutes, and document the inspections every 2 hours, to maintain quality," added Beach.

Another important point Beach made is that although he had manufacturing knowledge when starting this project in 2015, he had no grinding experience. Versah jumped in with a fully equipped ANCA MX5 and then a number of FX machines. As Beach recalled, "I did some Solidworks programming in the past that helped. But I didn't know anything about ANCA's iGrind software or anything related to grinding. The fact that you're able to watch the part unfold in the software, to watch the changes happen right in front of you on the machine, makes it very, very user friendly.

Beach lauded ANCA's customer service and reliability. "We run these machines around the clock, six to seven days a week. So, they've gotten a lot of use, which obviously calls for maintenance and support. But we find them to be very low maintenance."

"The software is also educational. New people coming in, or even our team in the offices with no manufacturing background, can click on different items, leave some highlighted, and it walks them through how that part's being ground, and shows how each part of the program is connected with each tool feature. It's really simple. I have hired a few people on these grinders that had zero experience with them and they've picked it up quickly. "

- **Aaron Beach**, Director of Manufacturing and Product Development, Versah



ORTHOPEDIC IMPLANTS

It's no secret that demographic and dietary changes, coupled with increasing wealth, are driving worldwide demand for knee and hip replacements. And given the required materials, surface finishes, and dimensional tolerances, these are difficult parts to manufacture, especially if you want to automate the process as much as possible to increase both throughput and profitability.

Jake observed that customers appreciate ANCA's organizational flexibility and technical adaptability, two crucial factors in tackling the diverse challenges of manufacturing orthopedic implants. For example, according to ANCA special projects manager, Duncan Thompson, the same machine that can grind femoral heads can be retooled to grind a femoral rasp or a rotary cutting tool.

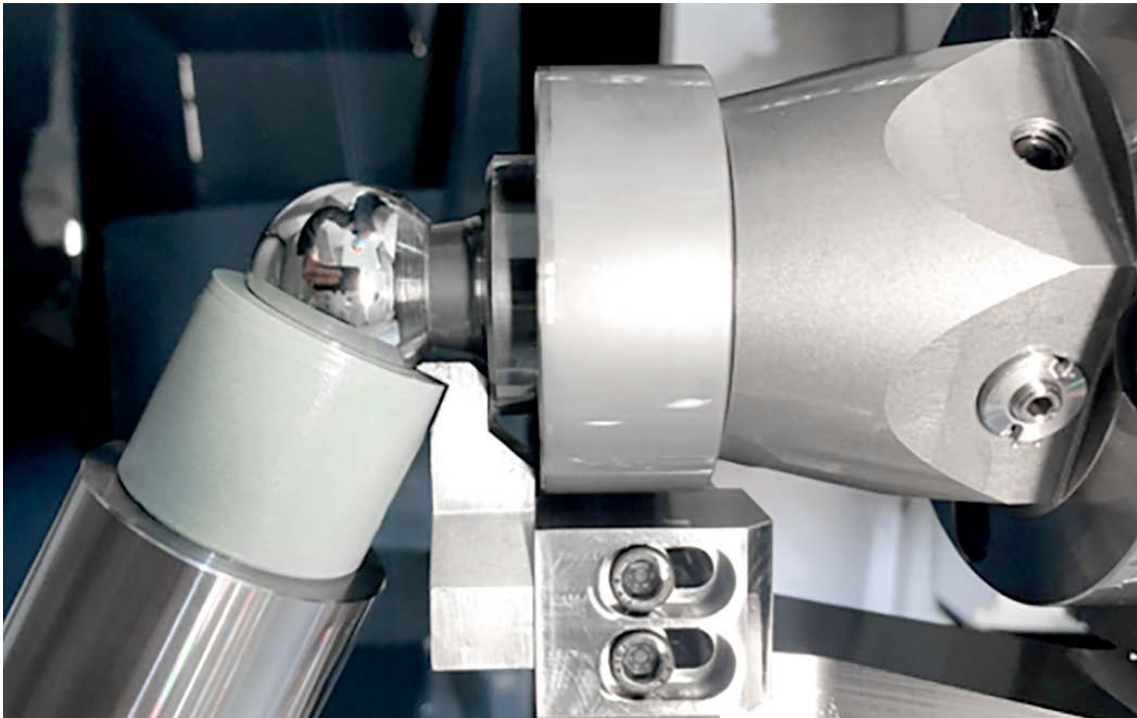
Likewise, automation options abound. For a femoral ball with an internal Morse taper, ANCA can provide an automatic expanding mandrel matched to the taper, with the ability to dial out the runout to within a few microns. What's more, the same workholding could easily be switched to rotary cutting tools, if needed.

Duncan explains the MX7 Linear is ideally suited to the production of femoral balls that require surface finish under 0.01 $\mu\text{m Ra}$. MX7 Linear features both linear motors and a 6-station wheel changer, enabling the machine to apply progressively finer honing wheels with extreme precision. A final polishing cycle which includes automatic application of lapping paste means surface finish between 0.006 and 0.008 $\mu\text{m Ra}$ (0.2-0.3 $\mu\text{in.}$) is possible, with a diameter accuracy within 5 μm (0.0002") from part to part, and sphericity <3 μm (0.0001"). Getting those results also requires in-process wheel dressing, applying constant force between the wheel and the ball during honing, and a wheel probing between cycles to account for wear, all of which the machine juggles automatically.



For knees, Duncan said their TX platform is generally best, because it can be configured to handle two implants in one clamping, with automatic changing of up to 24 wheels or tools. Thus the machine can be configured to both grind and mill the entire surface of the casting, as desired. In the TX, two knees can be ground simultaneously, starting with a plated wheel for rough grinding of the gates left from the casting process. This is followed by grinding of the full external surface profile (condyle and patella) with vitrified CBN. Milling operations are also included in the process to finish the knee surfaces, such as the cruciate slot and tie bar, not accessible by the grinding wheel. The same robot used to change grinding wheels or milling tools can also be utilized to automatically change out the knee and fixture making unattended long production runs possible. Duncan added that in his experience a final polishing pass on the grinder is also able to reduce the need for finishing, a big benefit.

As mentioned on other applications, the machine can be equipped with a 250 mm diameter dressing wheel to recondition the vitrified bond CBN wheels. And since redressing the wheel does not require reposting the grinding program, this again is an automated function enabling long part runs. An optional acoustic sensor ensures an optimal dressing cycle. Finally, said Duncan, you can equip the machine with a laser measuring device to eliminate the need to preset the milling tools offline.



CUTTING TOOLS FOR MACHINING MEDICAL COMPONENTS

As referenced above in covering orthopedic implants, making medical components often requires cutting tools. And truly optimizing medical machining often requires specialized cutters. So our review would be incomplete without covering the design and grinding that goes into making them, and there's no better model than ARCH Cutting Tools, headquartered in Bloomfield Hills, Michigan, USA.

Take the task of machining a polyethylene tibial insert. As ARCH's Northeastern regional director of operations, Jim Gray, spelled out, this has almost always been done with a single, flat blade mounted in a holder so as to maximize the shear angle. But, said Gray, this design often produces lines on the surface, or an "orange peel" effect, due to burning, as it doesn't cut the polyethylene as cleanly as desired. A straight flute design also impacts the part with a lot of force on each rotation.

Gray's team instead used their knowledge and ANCA's programming software to create a unique 1½" (38.1 mm) diameter 3-flute carbide helical cutter with high shear and multiple radii along the profile. They grind it on an MX machine, using a dozen wheels to

create a mirror finish and a cutting edge "sharper than a razor blade," as Gray described it. Gray added that their helical design also distributes the cutting forces, in contrast to a straight flute. In sum, the ARCH solution delivers an outstanding part finish, higher throughput, and longer tool life.

Gray also pointed out that in addition to the tool design assistance derived from ANCA's programming software, which includes full 3D simulation, the ToolDraft feature enables detailed documentation for process control. "Instead of relying on 2D drawings on the shop floor," Gray expounded, "ToolDraft gives us the ability lay out every aspect of the tool and the required grinding wheels. One page covers the gullet shape, with the roughing wheel, the finishing wheels, and any information related to fluting. The next page covers profiling, again with all the wheel shapes and data, and the required clearance angles, land width, and other tool geometries. And so forth for the end face. We've promised our customers that no matter what person and what machine grinds their tool, they'll get the same tool every time. And the only way we can keep that promise is with the documentation we've created with ToolDraft."

"You need a very sharp edge to cut the plastic perfectly cleanly. Even a diamond grain that goes through cutting edge, leaving a tiny chip, will show up in the insert. We inspect these tools under a microscope to confirm the edge is crisp and clean."

- **Jim Gray**, Northeastern Regional Director of Operations, ARCH



Moving on to hip stems, Gray said machining up and over these parts requires ball nose end mills in which the radius and its transition to the OD must be perfect. The end face gashing must also meet exactly at the center. "Any mismatch in the center of the ball nose will put a line in the hip stem, and that's not acceptable." Any error in the radius will create geometrical distortion in the part profile, he added. "We scan that whole radius to ensure it's correct."

Hip stems have generally been made of titanium and cobalt chromium, Gray explained. These materials are challenging enough, but Gray said the new 3D printed titanium alloys from Zimmer Biomet and Stryker are even more difficult to machine. They're porous, to facilitate integration with the patient's bone, which essentially guarantees an interrupted cut. The material is also highly abrasive. Thus, minimizing tool changes and increasing manufacturing speed to achieve an acceptable level of efficiency requires an engineered solution from the likes of ARCH.



In another example of ARCH coming to the rescue, a customer suddenly ran out of an imported, replaceable head, keyseat cutter during production. ARCH delivered a custom engineered, solid carbide version, with coating, in under 48 hours. In another case, ARCH created a multi-step counterbore that combined 6 different operations in one tool for machining titanium and superalloys. Both examples again point to the power of combining experienced grinding professionals with ANCA's software and machines to produce high quality medical devices that improve a person's life.

Regrinding is yet another such area. Not only does ARCH reliably return used tools to new condition, Gray said there are numerous cases in which they've actually improved upon the original tool. "One of our bigger medical customers was buying a faceted drill from one of the world leaders in cutting tools," recalled Gray. "The drill was being used on titanium, and we put a roll point on it and made some other changes to the geometry that made the reground drill run better than the new tools." In this context, Gray praised ANCA's integrated laser to automatically check for and correct errors in tool runout, and ANCA's probing capability. In addition to probing coolant holes to ensure proper tool orientation for a regrind, Gray said ANCA makes it easy to probe the entire point profile to enable K-land grinding, a notoriously fiendish task.

WHY CHOOSE ANCA?

Founded in 1974, ANCA is a world-leading manufacturer of CNC grinding machines, motion controls and sheet metal solutions, with over 1,000 employees worldwide.

We're pleased to have been recognized with more than 25 industry and business awards, including our induction into the Australian Export Award Hall of Fame. The Australian Financial Review recognized us as one of Australia and New Zealand's most innovative companies. We hold patents for many products, processes and components, from pulse and gap control for electrical discharge machining equipment to collet adaptors and clamping devices.

With global headquarters in Melbourne, Australia, ANCA exports 99% of products to customers across the globe, servicing 45 countries and delivering leading solutions from offices in the UK, Germany, China, Thailand, India, Japan, Brazil, Mexico and the USA.



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