

TORNOS BECOMES IMPORTANT FIXTURE IN THE BACKBONE OF HIGHLY SUCCESSFUL MEDICAL COMPONENTS MANUFACTURER

Structure Medical, headquartered in Naples, Florida in the US, with a second plant in Mooresville NC, manufacturers pedicle screw assemblies and other spinal and extremity implants under contract for ten of the biggest names in medical. They have developed patented production protocols that have made them a top one percent supplier to many global industry leaders. Structure Medical has experienced remarkable growth in the last two years. They attribute their success to a philosophy of continuous improvement and an unbending commitment to buy the latest and greatest equipment available.



Structure Medical Headquarter in Naples, Florida, USA.

The turning point for Structure Medical

Turning centers weren't always important to Structure Medical. In the beginning, they were just necessary equipment to help them manufacture turned components for 5-axis milled medical parts and assemblies. But that all changed when the medical device manufacturer purchased its first Tornos 2-1/2 years ago and began to see just how the top of the line sliding headstock lathe could contribute to their success. LeNoir Zaiser III (who goes by Len), Structure Medical CEO and co-founder, describes the turning point. "I used to say that we were the best anywhere in 5-axis milling. Now all of a sudden we find that we're winning a lot of contracts away from competitors who

have been in the turning industry a long time. And where I used to believe that our turning work was just a supplement to our 5-axis work... now I find that it's unique and puts us in the very top tier." Zaiser adds a frame of reference: "Products for the medical industry are becoming more complicated. No question about it. As the products have become more complicated, we've started to incorporate Tornos machinery. And suddenly we're in a premier space of turning as well as 5-axis milling. The Tornos equipment put us in a league of our own." Zaiser's son, LeNoir Zaiser IV, co-founder and Senior Vice President/General Manager of Structure Medical (who also goes by Len) adds,

Dossier



Pictured left to right: LeNoir Zaiser III, Lenoir Zaiser IV, Victor Georgiev.



Victor Georgiev at the Sigma 20

"It allowed us to do work beyond what we could ever do on the machines we had before."

Work like the percutaneous polyaxial housing part that Structure Medical's lead Tornos programmer/operator, Victor Georgiev, shared with *decomagazine*. It's a complex part, about 140 mm long. The challenge was that it needed a very long hole. The ratio between the diameter and the length of the hole is very large. And there are very deep, long threads at the bottom of the hole. Explains Georgiev, *"We did that in a unique way. But the challenge was not to make that part – the challenge was to make a few hundred of them exactly alike. We all sat down together and decided to use a specially ground Titanium material. And when we designed the protocol we kept in mind that it had to be a stable process. This customer is very demanding; they scrutinize the part to the smallest detail."*

Structure Medical's production protocol is definitely unique – so much so that they require non-disclosure agreements from anyone who spends time out in the shop. The Zaisers could not divulge any particulars about their protocol (and *decomagazine* was asked not to photograph certain setups for the article), but it's clear that their protocol is based on several factors: utilizing multi-axis milling techniques over simpler cutting processes; grouping multiple parts together in single program operations (vs. making one part at a time); and buying the best equipment, cutting tools, oil, and raw material available. Add to this their quality management and inventory services, and Structure

Medical has an edge on their competition that is not likely to be superseded any time soon.

Len, Senior has started and sold several, very successful aerospace defense and medical contract manufacturing companies in his career. In all cases when starting a new company, Zaiser investigated the current technology being used by his competitors and was amazed to learn how far behind they were. Two of his previous companies were started to manufacture critical parts for the wings and warheads for the Sidewinder air-to-air missiles on US fighter jets. In fact, one of his companies won ALL the business making Sidewinder wings for the United States and NATO forces. Zaiser describes how Structure Medical began and why they were able to excel as a top supplier to the major medical companies in such short order.

"I got started in medical to 'get my karma squared around' after doing military stuff all my life. A very good friend of mine was world-renown hand surgeon James Strickland; and he and another gentleman by the name of Bob Ward, retired from Stryker Howmedica took me and Len (Jr.) to some major manufacturers of orthopedic implants and some smaller companies; and we immediately noticed that the industry [like the aerospace facilities he had witnessed years ago that spurred him into action there] was somewhere between 10-15 years behind in technology. So we decided to buy the latest, greatest, finest machine tools we could buy, mostly made in Switzerland and started out mainly in 5 axis high speed milling."

Applying a milling mindset to turning

The unique work they are doing on the Tornos is related to their milling roots. Structure Medical often utilizes surface milling processes with a ball mill tool on the Tornos over traditional form tool turning processes. This allows them to achieve perfect blends on the corners of their parts. Georgiev provides a detailed picture of this scenario, *"We use a ball mill and take one cut across and follow the surface based on the CAD model of the part. And then we make a step over... and the step over will be determined by the diameter of the tooling and parameters of the part – but let's say we move 3-4 thousandths of an inch... and then we take another cut. And we repeat that motion. So the tool is driven on the surface of the part. Basically it's like sculpturing."*

Up to now, turning centers weren't meant to do this type of work. But Structure Medical has found that their Tornos Deco Sigma 20's and 32 can do it very accurately without sacrificing cycle time. *"Wherever there are irregular surfaces,"* explains Georgiev, *"I cannot use a form tool — it won't blend really nice when I go around the corner because our parts have a different curvature on both sides. So, that's where the accuracy of Tornos comes into place. Because the machine has minimal thermal expansion, all the blends will be perfect."*

Zaiser Sr. adds: *"Turning is just a small part of what these machines do. One of the key things about Tornos is they seem to run the hardest the longest. The quality of workmanship on the machine, we think, is superior in the industry. They are in a space of their own. And the interface of the barfeeder to the machine is superior to anything we've found so far... very reliable. They also have an extremely good temperature compensation system."*

Georgiev continues Zaiser's thought, *"Tornos has been a very good choice for us. I've always liked Tornos because they're built really well. They are sophisticated machines; yet they are easy to use, program and set up. And they are extremely reliable. We're running 24/7. And we can do very complex parts and pretty unusual applications as well. Our most complex parts are going on the Tornos."*

Says Zaiser Sr., *"The sophistication of the machine is at such a level that we can respond to our customer's most demanding requirements for complex*

VITAL STATISTICS

- 90+ employees.
- A 30,000 sq. ft. facility in Naples, Florida and a 25,000 sq.ft. Mooresville, North Carolina
- Even during recession, grew revenues by 110% in 2009. Projected growth of 60% in 2010
- Cutting medical parts primarily for repair of spinal column and extremity bones. The components include items such as polyaxial and monoaxial pedicle screw assemblies, cervical/lumbar plates and extremity plates.
- Part diameters range from 1 mm up to 32 mm
- Serves ten major customers
- Lot size: 10 pieces to 100's of pieces. Usually families of parts
- Ships about 15,000 components per month for a total of around 400 orders/month
- Cutting 90% titanium, plus Cobalt Chrome, stainless steel, and PEEK
- Average cycle times between 25 seconds and 20 minutes depending on part complexity
- Patented manufacturing protocols to produce complex parts
- ISO 13485 medical devices certification, FDA CGMP compliant
- 60 state of the art machine tools including: (4) Deco Sigma 20s, (1) Deco Sigma 32, (1) Deco 13a, (4) EvoDECO 16s on order



parts. They're really almost overbuilt as far as rigidity. If you do a size-for-size comparison... the Tornos probably weighs twice as much as other machines on the market. The Tornos has twice as much mass. This gives it reliability and precision.

"It's interesting that the highest priced machine in its class in the industry gives us the lowest cost per unit. That has to do with uptime, speeds, precision, and stability."

The program for success

All of the surface milling operations that Structure Medical performs on their Tornos machines result in very long programs. On other turning centers, long programs present a problem when the machine runs out of memory. But the Tornos Deco Sigmas with 31i control allow the use of external memory expansion and can handle these complex programs without a hiccup. This is a vital differentiation and one which Structure Medical comes back to again and again during this interview. It is absolutely critical that their machine tools be able to handle the long programs (with thousands of lines of code) inherent in their complex surface milling processes and on "ganged" parts being cut out of a single piece of raw material. Georgiev finds one other feature key to the control.

"The machine has a look-ahead function that allows us to see what's coming up next. The Sigmas, with the 31i control, let us do what our customers are demanding of us. Most machine shops would like

medical parts to be less sophisticated. We're quite the opposite. We're looking for difficult parts."

Beyond the benefits of the control itself, it's also important to Structure Medical that all their Tornos machines share the same control so they can easily swap parts from one machine to another. Due to the small lot sizes in the medical industry, Structure Medical finds they have to do a lot of setups. And short runs mean they need to be very nimble.

Explains Georgiev: *"We have to be flexible. We have four different Sigma models, — four Sigma 20's and one Sigma 32 — but since the machines are nearly identical, we have the flexibility to move parts to whichever machine is available at the time."*

The changing nature of the medical parts industry

Structure Medical has seen major price pressures in recent years in the medical components industry. The industry has become much more demanding.

Zaiser Jr. paints the picture: *"The medical components industry is getting pressure from the FDA to not only control their own shops and to lock down their own processes... but the FDA is also saying... you have got to look at your suppliers too. Driving costs down is expected now. It is expected that the suppliers (like us) will participate in the pressures from the health-care initiatives or reforms."*



But the price pressure being experienced by Structure Medical is not simply due to US healthcare reform, it's also because their customers want to expand into European markets. And the European marketplace won't support US pricing. "You can't get as much for a product in Europe as you do in America," explains Zaiser Sr. "In general, there is more price pressure in Europe than in the U.S. And since our customers are looking at expanding their international business, we've received requests for and have acquiesced to major price concessions."

How will Structure Medical continue to make money with such cost reductions? They are going to, as they put it: do it better and faster without cutting any corners. "We're going to replace some work done on our other turning machines with Tornos," says Zaiser Sr.

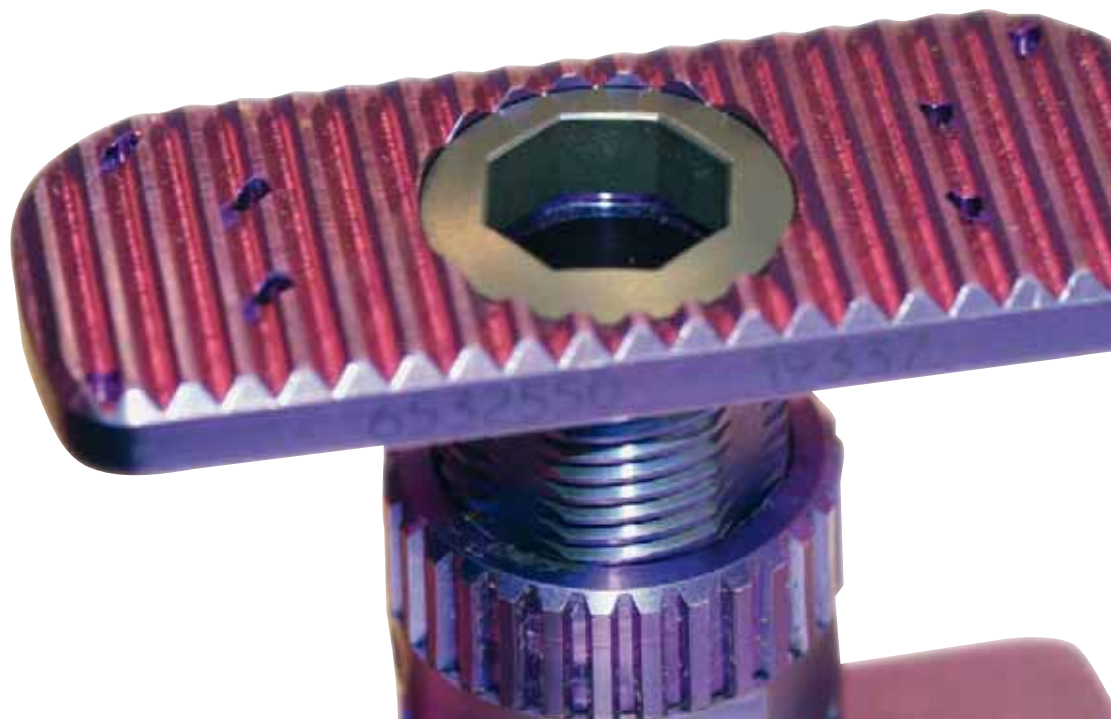
In the last year, Zaiser Sr. estimates that Georgiev probably cut 40-50% of the time cycle out of several jobs by moving from other turning machines to the Tornos. Zaiser explains, "Part of it is Victor's protocol and part of it is the machine itself. We're excited about price pressure deals. Because it's going to drive some competitors out of business.

"Victor's goal is not squeezing the last second out of a cycle time. It's squeezing the most runtime without intervention. If you can get a one minute time cycle where you change tools every hour and a half, vs. a 2-minute time cycle where you change the tool once a day, we'll go with the 2-minute time cycles. We are mainly concerned with how many parts we have in the bucket at the end of the week."

Georgiev agrees. "That's true. Cycle time alone for us is not an indication of whether we're doing a good job or not. The process needs to be stable. And we start from there. We're not a big fan of making the part in one setup. Sometimes, we find that if we break that part into different operations it's more efficient for us."

Zaiser explains further: "We'll come up with some better methods to do primary operations on products to save time. I lay awake all night figuring ways to do it faster. I don't count sheep and I don't play golf. We start with the raw materials and go down to the process. I can say to Victor... take the part out there that you're running now – the one for which you think you've got the best time cycle that you'll ever have – go take 10% out of it and let's sit down and talk about it." Zaiser quips, "Would we do it? ALWAYS!" "ALWAYS," Georgiev mirrors Zaiser; and then clarifies. "It's usually more than 10%. But that's why the company is so successful – because we can communicate very well and we can make decisions on how to improve the processes. It's a constant thing."

Zaiser Jr. adds: "Our corporate culture is this: there's always room for improvement. There's always room to come up with a better process. Just because it's working doesn't mean that it's good enough. It's very difficult for many people to understand, especially if they've been making money on a project for a while... they think... why do we need to change it? Why are we going to start from the beginning? Let's just let it run. By the time we fix it from the start;



it's not going to matter. But that's not my Dad's philosophy. His philosophy is always: rethink."

Georgiev adds: *"But never sacrifice the work and the quality."*

Zaiser agrees and adds, *"That's where this industry is going."*

Measuring cost reduction pressure from every angle

Bringing the cost of parts down is not the only pressure being faced by those in the medical industry. There is also the pressure of implementing and adhering to a quality management system. And we're not talking about the quality of the parts – part quality is a given when you have a Tornos. We're talking about validation protocols, training, auditing and monitoring of quality processes.

In the quality management arena, Structure Medical was proactive early on. And their commitment to quality is evident in the fact that two of their six management offices in their Naples headquarters are occupied by quality managers. *"Our quality engineer sits in the corner office,"* notes Zaiser Sr. *"And next to him is our ISO Director of Quality. So, of the four offices, two of them are quality related."*

Says Zaiser Jr., *"We started a couple years ago on this initiative – on our quality management system – because we saw it coming down the pike. We put a team in place and we got out ahead of everybody on the validation of the machinery. We got ahead of everybody on controlling the process flow of how these parts are manufactured. We got ahead of everybody on auditing our suppliers. We got ahead of everybody on training our employees. We spend a lot of money and a lot of time and effort training our employees on the quality management system. And we have been rewarded for all those*

efforts. As painful as it's been – and we can all tell you it's been painful – we have been rewarded for those efforts because we have been recognized as preferred vendors or top tier suppliers for major customers. And it's not only because of the quality of our products... it's because they're comfortable that we have this quality management system under control."

Beyond cost cutting pressures and the responsibility of quality management, there is one more expensive aspect to running a medical parts business: inventory management. Structure Medical is contractually obligated to have a three-months supply of finished parts ready to ship within 24 hours for some customers. Explains Zaiser Jr. *"Although this is an industry where you do a lot of small runs, we do have programs where we'll run maybe 3-4 times more parts than ordered and then stick them on our shelves and hold them as inventory for our customers. We manage the inventory."*

Zaiser Sr. adds, *"It creates an inventory cost. That's all our money on those shelves."* Smaller, less successful medical device contract manufacturers may have a difficult time fulfilling this contractual obligation, but for Structure Medical, it's no problem.

The best way to control costs is to buy the latest (and most expensive) equipment?

"When our machines are 5 to 10 years old," says Zaiser Sr., *"we start to look for a home for them and replace them with new. We'll probably run Tornos longer than that. But when we replace a machine at the end of 5 years, it's not because of wear or precision. It's because of capability. We buy the finest machines out there and are still finding that every 5 years we can swap them for new and gain 20-25% productivity. Our 5-year old machines are exactly as the day we bought them. There's no difference."* So, it's not





that Structure Medical's machines are wearing out and losing productivity. This "buy new" philosophy stems from Zaiser's understanding that machine tool manufacturers are continuously improving technology just like he is and he wants to take advantage of those new capabilities. After all, it was the new Tornos machines he purchased a couple years ago that propelled Structure Medical into the top tier of turning work.

Zaiser Sr. points out that they take very good care of their machine tools and don't skimp on anything related to equipment. "Our machines are just like new no matter how old they are. We do all the calibrations and maintenance and everything. And we use the highest quality oil (Motorex) even in our toolroom for two reasons: one, the finish at the end of the day is superior; and two, machine tool life is exponentially increased."

Georgiev interjects, "It's important to make a point that we always buy the best machine tools. But we are also using the best cutting tools. When we select a tool, we're not looking at cost. Our goal is to buy the best possible tool to do the job. We've found that a lot of companies will spend money on the best machines but then they won't spend the money on the tooling."

"And," Zaiser Jr. adds, "instead of getting standard stock (Structure Medical makes parts from titanium,

cobalt chrome, and stainless on their turning centers), we might pay more for super precision ground stock."

Zaiser Sr. articulates, "We made the corporate decision to go to considerably more costly, very high precision ground stock for our sliding headstock machines because it improves productivity at the end of the week and it improves precision and tool life. If the stock is rattling around in the guide bushing... if it's moving around one thousandths of an inch, it's going to cause loss of precision and tool wear. That's all part of the formula."

The prototype for winning medical parts contracts

Zaiser Jr. brings up a new topic of interest, "I think another thing that makes us unique is we don't have a prototype shop. Yet we do a lot of prototype work. Our philosophy is, do the prototype job on production machines so we can fully understand what the final result is going to be. It's more costly. But in the long run, we have much better control over what the true cost is going to be in the future."

Zaiser Sr. adds, "And our customers have a better idea of what the product is going to look like coming out of the machine. Then, if we like it and want more... we press the button."

"We actually are completely vertically integrated," states Zaiser Jr.

"The only thing we outsource is anodizing and passivation. All our secondary processing; even complex secondary processes are done in-house. So are our assemblies. We like to control all the processes."



Cost containment as a business model has made Structure Medical financially strong

Structure Medical grew 110% in 2009 and another 60% in 2010. But Zaiser Sr. points out, as they were growing exponentially, the financial industry was going the other direction. In the US, the banks stopped supporting small businesses during the economic recession. Structure Medical had no financial problems: they were paying their bills on time and even bought 6 million dollars in capital equipment in '09. But when small business loans dried up in the US, the Zaisers became concerned that they couldn't continue to buy the high-end equipment they needed. They estimated they would need about \$3 million to boost supply to their biggest customers. "Our customers were growing with us so fast. If we had to go



back and tell them, 'gee, we really can't take more of that,' they would find someone else to do it. We were very fortunate and proud to say that we never went out looking for an acquirer," Zaiser Sr. pauses to set up the next very impressive fact. "We had numerous unsolicited offers to buy the company. Ultimately we decided to sell the company to an organization called Squadron Capital founded by the Pritzker family out of Chicago. And what it has done is it has made us a very strong company financially. We're one of the few in our space with no debt."

"We're buying unequivocally the finest machine tools available in their field," Zaiser Sr. points out... clearly happy that he can continue his successful path thanks to the private investors. Then he indicates one more key to Structure Medical's success: "I'd say 80% of our capital equipment is made in Switzerland."

"We have ten major customers," says Zaiser Jr. "And we're close partners with all ten of them. We make exclusively some of the products for each customer.

So there's a big commitment to them. They want to be sure that we're strong and can continue because we're the only source for some of their products."

Zaiser Sr. sums up, "The new ownership arrangement has given us the strength to continue to buy capital equipment when a new project comes along."

"It creates next year's growth," Zaiser Jr. states.

And next year, Structure Medical will be proud to take delivery of four new Swiss turning machines – Tornos' newest top to the line EvoDECO machines. We'll be sure to check back in with them and let you know how they like them.

Decomagazine would like to thank the Zaisers, Len Sr. and Len Jr., and Victor Georgiev for their participation in this article. We wish them continued extraordinary success.

Structure Medical

9935 Business Circle
Naples, Florida 34112 (USA)
www.structuremedical.com
00 1 239 262 5551
lzaiser@structuremedical.com