

STEREOTAXIS' SECOND ACT

A pioneer in endovascular robotics, Stereotaxis hit a wall just over a decade ago and was near extinction soon after. Now, with a new CEO in place, is the company finally poised to realize the potential of its technology?

► DAVID CASSAK

■ Founded in 1990, Stereotaxis developed a robotic platform built around precise, externally-applied magnetic fields to allow for a direct, distal control of devices such as catheters and guidewires used in interventional procedures.

■ The company achieved a modest success early on and reached an installed base of around 100 before a backlash set in in the late 2000s that saw it struggle. A PIPE in 2016 brought not just a saving infusion of cash, but new management to turn the company around.

■ Stereotaxis' focus today is on the guidance of cardiac ablation procedures used in treating complex arrhythmias. A number of collaborations with other companies, including Acutus, should boost the company's new commercial push and illustrates its commitment to an open platform.

St. Louis-based **Stereotaxis Inc.** was founded more than three decades ago, the brainchild of Matthew Hobbs, MD, a neurosurgeon who was, at the time, a graduate student working on a project to develop a magnetic guidance system for neurosurgery. After several years as a research project, the company was launched with an initial investment from venture capital firm Sanderling Ventures and in 1996, the company recruited Bevil Hogg, a former executive at DME/wheelchair company Eversty & Jennings who had prior to Stereotaxis also launched a bicycle company, Trek Bicycles, to be CEO.

Through its first couple of decades or so, Stereotaxis struggled to gain its footing. By the mid-2010s, while **Intuitive Surgical Inc.** was building a powerful position in robotically-assisted surgery, with a stock price appreciation that rivaled the big tech companies, Stereotaxis was going nowhere and headed for extinction.

Stereotaxis' current CEO and Chairman David Fischel had been watching the company for a couple of years at that point. Based at the time in Los Angeles, Fischel was an analyst with DAFNA Capital Management, a healthcare investment firm that funds publicly-traded biotech and medical device companies, focused, says Fischel "on cutting edge medicine, but as passive investors." In 2016, Fischel came across Stereotaxis and was struck by what he calls "this dichotomy between, on the one hand, a company that was nearly going out of business, and, on the other, one with a very elegant technology, the most elegant approach for allowing robotics to improve endovascular intervention."



DAVID FISCHEL

DAFNA made a strategic investment in Stereotaxis in 2016 as part of a PIPE, investing alongside a number of other investors, including a couple of medtech CEOs. With that investment, the company was able to pay off all of its debt and also use some of the money raised for operating capital. Fischel also joined the company's board and four months later switched from his role as investor/board member to become CEO.

Stereotaxis had, in its earliest days, pioneered what Fischel calls "this crazy idea of using precise, externally-applied magnetic fields to allow for a direct, distal control of an interventional device." Using the Stereotaxis robot, interventionalists snake guide wires and place catheters relying on magnets to guide precise manipulation for procedures in the heart. "And the fact that they actually made it work is really a feat," he says. Having received FDA clearance in 2004, the same year it did an initial public offering, the company was somewhat successful in its early commercial efforts, placing about 100 systems between 2005 and 2009. The problem was, customers weren't actually using the systems once installed. "There was a focus on capital sales and not on making sure once they made a sale that physicians were actively using the system and building a successful robotic practice," says Fischel.

That, in turn, created something of what Fischel calls "a backlash" against the company. Between 2009 and 2011, Stereotaxis saw many fewer placements. "And like many start-ups, it had built its team and ramped up expenses, expecting significant growth," he continues. As potential new customers heard reports that other hospitals in their markets weren't using the systems, "they stepped back from the signature page." With sales below expectations, Stereotaxis scrambled to cut expenses and did some dilutive financings. "That caused the stock price to go down," says Fischel, all of which saw the company in "a vicious cycle" and led to the departure of Hoggs, the original CEO.

A Different Kind of Robot

At DAFNA, Fischel had followed Hansen Medical, the structural heart robotics company, launched by robotics pioneer Fred Moll, MD, following his time at Intuitive Surgical and had, in fact, been an investor in Intuitive and Mako Surgical. "We had been circling around many of these companies and so we were aware of what was going on, but didn't really understand [all that Stereotaxis was going through] until we dug into the details," he says.

In robotics' early days, it wasn't unusual for robotic companies to struggle in their early commercialization efforts. Nor were reports, whether apocryphal or real, of hospital hallways populated by robotic systems that sat unused, covered by drapes. Even Intuitive faced a decade of relative quiet between

the time of daVinci's regulatory approval and the point at which the company began to take off." (See *"Intuitive Faces the Future of Surgical Robotics,"* MedTech Strategist, January 16, 2019 and *"Intuitive Surgical: As Robotics Heats Up, Can the Market Leader Stay Ahead of the Pack?"* MedTech Strategist, December 19, 2018.)

But Intuitive's great success began just as Stereotaxis faced its backlash, and it was hard to explain away the company's problems by citing the immaturity of the market and the relative newness of robotic technology generally speaking. Stereotaxis faced the further challenge that it isn't a surgical robot per se, but one focused on structural heart and endovascular medicine, an area that, Hansen notwithstanding, was a somewhat new robotic application at the time and with a novel technological hook. "All early adoption is messy," says Fischel. "It doesn't happen in a smooth upward trajectory." Stereotaxis adoption was further hampered by, as noted, low utilization rates. Fischel estimates that by around 2010, Intuitive was doing over 100,000 cases a year; Stereotaxis was around 10,000. "Intuitive had had its own difficulties, particularly in the first few years as it was trying to chase after CABG procedures as a primary focus," says Fischel, before the switch to robotically-assisted prostatectomies that drove its ultimate success. At just the time that Stereotaxis' struggles began, "the majority of the prostatectomies in the US were being done robotically," he recalls. "And hysterectomy as a field was latching onto and adopting daVinci as well."

By the early 2010s, robotically-enabled surgery was making important strides in prostate and general surgery and orthopedics as well. (**Stryker Corp.**'s acquisition of Mako Surgical, a kind of affirmation of the value of robotics in orthopedics, took place in 2012, after a long history of false starts and struggles by Mako as well.) "A lot of people thought, 'Robots are really good for orthopedic or laparoscopic surgery, but maybe it's not suitable for interventional and endovascular applications.'" Indeed, the one other interventional robotic system, Corindus (now part of **Siemens Healthineers**), was something of an outlier as surgical robotic technology caught on. "I think sometimes there's unique individual circumstances that drive adoption," Fischel goes on. "It's not a reflection of the macro suitability of robotics in a field. To some extent, Intuitive Surgical got a little bit lucky. If urologists hadn't taken hold, who knows how the future would have progressed?"

Even Hansen, notwithstanding Moll's role, struggled. While the technology solution in endovascular looked promising, Fischel says, the reality was more complex—developing a robotic solution in endovascular was not like developing one for surgical applications. Speaking generally of the challenge, he explains, "Endovascular surgery requires the safe use of small highly-flexible instruments operating in very delicate anatomy. When

I step back, that's what I saw at Stereotaxis at the time [i.e., of the 2016 investment]—seven or eight years of stress and limited progress but, on the other hand, a very elegant approach that could fundamentally improve endovascular intervention."

A 20-Year Old Start-Up

Though Stereotaxis' sales had slowed, by the mid-2010s, it was still being used in about 100 hospitals and had treated over 100,000 patients. "So we had robust, real world experience that the system actually works in a practical way," Fischel continues. "And the clinical data was as good as it gets." Indeed, having done due diligence on and invested in both Intuitive and Mako, he came to the conclusion that "The clinical data around the use of Stereotaxis' robot in cardiac ablation to treat arrhythmias was much stronger than the clinical data for robots in other fields."

That data was "the foundation" of his belief in Stereotaxis; Fischel came to believe that the company was more of a rebuilding exercise than anything else—in effect, a 20-plus-year old "start-up." "I do think about this more as a start-up because, to some extent, there's been a major rebuilding. Yes, it's on the shoulders and on the foundation of the technology that existed before, but that gives a great advantage to the rebuilding," he says.

That's not to say that part of the challenge isn't to improve the technology. Fischel acknowledges, "Other than slight improvements in control software and motors, the [Stereotaxis] robots that were on the market until very recently were exactly the same robots that launched 15 years ago when adoption of robots really started. There are many aspects of the technology that haven't improved for a long time. That's a weakness and a risk, but it also means there's significant opportunity because over those years, there have been great insight as to how to improve every aspect of the technology to make it better for patient care, better for the physician experience, and better for the hospital."

Today, Stereotaxis "is in the midst" of what Fischel calls "a very significant innovation effort to really improve every aspect of the technology, and I think that improves both its performance in the real world and the strategic and financial foundation of Stereotaxis as a company."

More than just software or hardware enhancements, Stereotaxis' improvement effort is focused on every aspect of the robotic experience. "When we think about innovation, we think about the robot, the interventional devices used with the robot, and the ancillary technology around the robot," Fischel says. "We also think about the software and how to provide meaningful insights to the physician during the procedure, how to integrate data, including various patient-specific information during the

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performance, how to enable telemedicine during the procedure and create automation capabilities in the system to assist physicians during the procedure."

Taking a step back, Stereotaxis "looks at interventional medicine as a whole," Fischel says. For example, why does it make sense to want a robotic system in an interventional procedure in the first place? In open procedures, surgeons have direct, tactile experience of the operating theater, whereas interventional procedures by definition represent a totally different experience for the physician. "In all of these procedures," he says, "a physician has control of one end of the interventional device while the procedure takes place at the other end, two, three, four feet away." Much different from the experience of the surgeon, interventional procedures are all about gaining and maintaining control of the distal end of a catheter or guide wire where the therapeutic effect of the procedure is realized, Fischel explains.

Whether you're talking about a catheter or a guide wire, "you're still translating control from one end, from the handle to the tip because the procedure happens at the tip, but [physicians] only have control of the handles." As a result, they often experience limited stability and precision at the tip, and there is, as well, a limited amount of deflection available at the tip to navigate the twists and turns of tortuous anatomy.

In non-robotic interventional medicine, Fischel notes, "the fact that you need to translate control from handle to tip means

you need rigidity all along the shaft. That rigidity introduces risk in delicate anatomy," which in turn points to "some of the weaknesses of the mechanism of action of modern-day endovascular intervention." It also, implicitly or explicitly, argues for the role of robotically-assisted procedures, as much as or perhaps even more so than in surgical robotics.

Stereotaxis' solution: to make the body of the interventional device soft and flexible, with magnets at the tip, and then using very precise, computer-controlled external magnetic fields, to take control of the interventional tool directly from the tip. "The magnetic fields can almost be viewed as invisible fingers exercising direct control over the tip," Fischel explains. "You can hold [the device] very steady in a specific space. You can also do all sorts of bends and twists and turns that are otherwise impossible, all with a very safe, gentle device."

Key to Stereotaxis' Genesis robot is its proprietary magnet technology. Positioned in the operating room on both sides of the patient, near his or her shoulders, "the magnets on robotic arms are designed and shaped to create this highly precise, highly controllable magnetic field in the area of the operation," Fischel says (see Figure 1). The magnets are held on mechanical motors, controlled by software, to adjust their orientation and tilt. User interface software allows the physicians to adjust the magnets intuitively to create the right magnetic field to move the interventional device in the direction it needs to go. "There's a lot more than just magnets in terms of mechanical engineering, electrical engineering, software on both the back end and the front end, as well as design of the interventional devices themselves within the magnetic field," he adds. "But

our expertise and specialty, which is unique among robotic companies, is our knowledge of magnets."

There is a small learning curve for physicians in adopting the technology; EPs who have long used conventional ablation techniques almost have to unlearn or forget what they know, says Fischel, though he adds "overall, it's more intuitive to navigate a catheter by pointing where you want it to go with a mouse on a screen than having to move your hands and arms in this delicate dance to get a catheter where you want it." Stereotaxis has made it easier for physicians to master the learning curve through the use of simulators as training tools. It has also put in place a fellowship program for EPs that helps younger physicians become proficient in navigation.

The Four Ps

Broadly speaking, that magnet technology is how Stereotaxis' system "improves catheter precision, stability, reach, and safety, and allows physicians to overcome the otherwise inherent limitations and weakness of current endovascular interventions." And in that context, Stereotaxis is focused on one specific application: cardiac ablation to treat heart arrhythmias, which entails sending a catheter into the chamber of the heart in order to burn specific parts of the heart muscle that are not performing as they should. The ablation arrests the arrhythmia and puts the patient into normal heart rhythm.

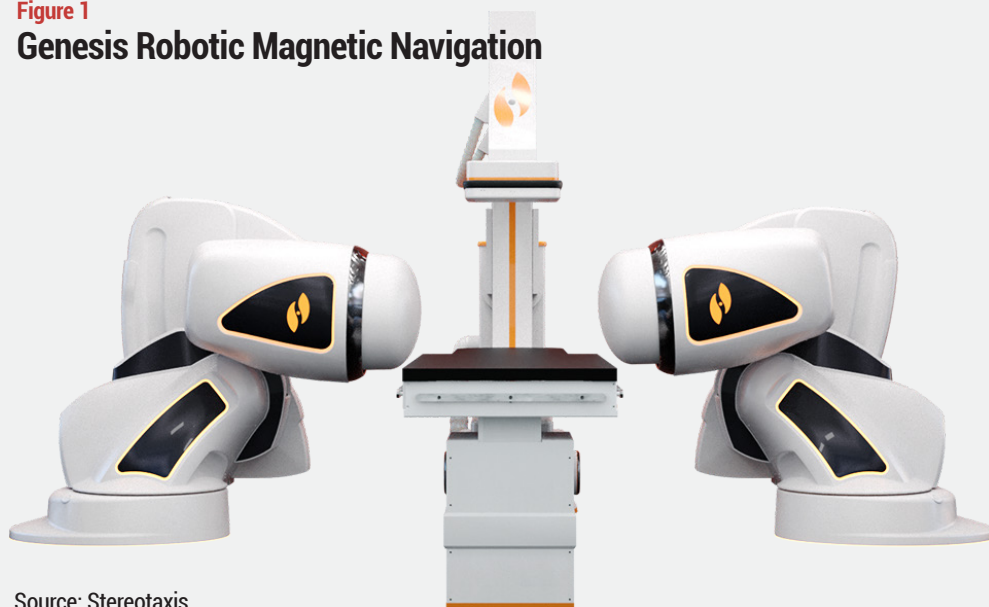
Fischel notes that there are about 1.1 million cardiac ablations performed each year, worldwide, creating a market that is around \$6 billion. "The procedure helps more than a million

patients a year, and the benefits of stability and precision and safety are enhanced because you're working in the chamber of a beating heart," he goes on. "Holding a catheter steady against the tissue is impossible with a manual catheter because you have to push very hard and when you push hard, you risk perforating the heart." Stereotaxis is working on other applications of its robotic system, but right now, he says, the company is focused on making cardiac ablation "both safer and more precise."

As noted, Stereotaxis has an installed base of about 100 hospitals and an annual procedure volume just under

Figure 1

Genesis Robotic Magnetic Navigation



Source: Stereotaxis

10,000, all doing cardiac ablation, with a target customer of the EP. And like most robotic companies, Stereotaxis argues that the shift from traditional cardiac ablation to robotically-assisted holds benefits for all of the constituents of a procedure: patients, physicians, payors, and providers or hospital systems—the Four Ps, as Fischel calls them.

From the patient's perspective, the robot is all about safety and outcomes, he says—did the procedure achieve the therapeutic effect desired and did the patient come out of it safely? "There's a substantial body of clinical evidence now—over 400 publications—that consistently shows a fairly dramatic reduction in major adverse events when you do a procedure robotically versus manually with hand-held catheters," Fischel says. "And I think that's driven by the fact that the catheter can be designed to be very soft and gentle. You don't need a rigid catheter because you don't need to translate any control from the handle to the tip, and the data is fairly dramatic." Indeed, data show that major adverse events are reduced around 70% and perforations around 80% of the time. "That's dramatic," he says. "I don't know of any other robotic technology which has shown that type of huge reduction in adverse events."

Efficacy, too, is supported by the data, though perhaps not quite so dramatically. The evidence "is more modest, but you see a relatively consistent trend towards improved efficacy," he adds. Fischel notes that as an investor looking at investing in Stereotaxis five or so years ago, "the first question we always asked is what, if, God forbid, someone in our family had the disease, would we want them treated with this technology? And all of us [at DAFNA] resoundingly said yes, which was not always the case with robots in other clinical specialties."

An Appeal for Physicians

Physicians, too, benefit, Fischel argues. Indeed, historically, the appeal of robots in interventional medicine was largely directed at physicians. Even if patient outcomes were equal, robotic companies argued, interventionalists benefited enormously from improved ergonomics because they no longer had to stand hunched over patients, wearing heavy protective aprons, risking back and neck injuries long-term, or face the risk of radiation exposure. With the Stereotaxis robot, "instead

of doing the procedure standing by the bedside, wearing a 25-pound protective lead vest and getting exposed to radiation, they do the procedure seated, unscrubbed, and fully protected from radiation," he says.

EPs also gain a greater control over the procedure using a robot. In conventional cardiac ablation, the physician is assisted by a team who helps assess whether the ablation is going properly and makes adjustments when it's not. In that procedure, "the physician is standing by the bedside with the device in hand and has to be very conscious about their body position and how they're holding the device. And whenever they need an adjustment in the information on the screen, they have to shout out commands to others who will make those changes, taking points and drawing lines, and adjusting the orientation so they see the anatomy of the patient from different angles," Fischel explains. Sitting in the Stereotaxis cockpit in a room adjacent to where the procedure is taking place, the physician has all of the information he needs on a large screen in front of him (see Figure 2). "And with a single mouse, they have control over all of the different information," he says. "That allows them to focus on the cognitive aspect of the procedure rather than the mechanical aspect."

How compelling the appeal to physician comfort and ergonomics is—less physical stress and radiation exposure in the short term, fewer long-term back and spine problems—depends on the physicians and, to some degree, on the hospital administration's willingness to accommodate such concerns and make its EPs happy, says Fischel. "There are some where that's very important and others on the opposite end," he says. Some physicians also prefer the tactile feel of holding a device in his or



Comfort and ease of use “are an important part [of the Stereotaxis appeal] but I don’t think that’s the core driver of adoption.” Rather Fischel believes that Stereotaxis’ appeal lies in the kinds of evidence of improved outcomes that drives most medical technology.

her hand and look down on physicians who’d prefer to sit at a console. “There’s a full spectrum,” he goes on. “I don’t think the adoption of the robotics, predicated on offering the physician a more comfortable work environment, is sufficient to allow for wide-scale adoption.” Perhaps more importantly, ergonomically-focused robots don’t provide the kinds of clinical or outcomes-oriented benefits that Stereotaxis’ system does. Comfort and ease of use “are an important part [of the Stereotaxis appeal] but I don’t think that’s the core driver of adoption,” says Fischel.

Rather he believes that Stereotaxis’ appeal lies in the kinds of evidence of improved outcomes that drives most medical technology. “We did a comprehensive review of every head-to-head publication, looking at hospitals where the same physician at the same hospital treated patients manually and robotically,” he says. “In just the ones over the last 10 years that have had 50 or more comparable cases, there were about a dozen studies with almost 5,000 patients that showed a 72% reduction in major adverse events,” says Fischel. “That type of consistency and dramatic reduction is, I think, very meaningful.”

Of course, questions about clinical efficacy seem to pursue robotics companies in a way that doesn’t happen with most medical device technologies. Even today, for all of its success, even Intuitive faces the occasional skeptic who argues that the clinical benefit of robotically-assisted surgery hasn’t been proven. Stereotaxis faces the same skepticism, perhaps more so because cardiac ablation is a much more complex and difficult

procedure than, say, a prostatectomy. “If you don’t have a robot and don’t want to change your thinking, you push back and say, ‘Well, none of these are prospective, randomized controlled studies,’” he says. “The challenge in procedural medicine, and Intuitive faced the same difficulty, is that there is so much variability by physician, by center, and even by patient, that it’s hard to structure good, prospective trials.”

Well-controlled randomized trials work well with some devices and, in particular, drugs, he goes on. “But in procedural medicine you rarely have that type of data, and people can always use that as a way to push back.” Trials for atrial fibrillation (AF) technology may not be “of the highest quality,” Fischel concedes, “but you look for consistency, and when there’s consistency of data across many different physicians at different centers with different types of arrhythmias in thousands of patients—when you see the same results in every study and you’re not cherry-picking the studies, you start to say, ‘yeah, there’s probably something to it.’”

A Positive Financial Impact

Closing the loop, Fischel explains the benefits to providers for whom cost concerns are always a factor, perhaps the largest factor. Indeed, while the trend in recent years has been to scale back on robotic systems and offer one with a lower price tag, a kind of “sticker shock” and protests against the cost of the systems were a major part of the early debates around adoption. “We get the same [pushback],” says Fischel, who notes that for all of the cost concerns, Intuitive “has overcome those challenges better than anyone could have imagined.”

Questions of whether the costs of a robotic system are both affordable and justifiable come naturally to hospital administrators. Fischel counters by arguing that “it’s actually a very easy return on investment if the hospital is able to step back and not think only in terms of price.”

Hospital administrators should take into account the kinds of clinically-oriented patient and physician benefits mentioned above in assessing the value of a robot, he says. In addition, those benefits also implicate the cost argument. “At the end of the day, if you have a complication with one of your patients, that’s a negative mark on the hospital, both reputationally and financially,” he argues.

In Stereotaxis’ case, Fischel insists there’s even an argument to be made for a positive cost impact. “One of the benefits of our robot is that we enable the treatment of complex arrhythmias that otherwise wouldn’t be treated at all,” most notably ventricular arrhythmias that, he says, “are dramatically undertreated.” “We have many examples of hospitals that have adopted our robot and built very significant business

lines, treating these types of arrhythmias. If you look at the reimbursement of cardiac ablation in the US and model even very modest assumptions for blended reimbursement for a procedure and for the number of incremental patients that you can treat because you have a robot, you can have IRRs that are very nice and pay-back periods of one to two years and very attractive financial returns." Fischel estimates that even a modest assumption of two additional patients/procedures a month made possible by installing a robot can generate an IRR of 50% even with what he calls "a very conservative assumption on the reimbursement [the hospital] will receive."

Fischel says Stereotaxis has customers that were able to build up their patient volume "significantly" with the adoption of the robot. "I think the primary financial value for a hospital is the ability to treat underserved patients, whether they're complex arrhythmias or particularly frail patients," he continues. "We have hospitals that have used our technology to treat pregnant women because you obviously don't want to expose them to radiation and you can do procedures with our system more safely without the use of radiation." All of which, he says, "allows for a very, very easy financial return on investment for the hospital."

Finally, Fischel argues that payors benefit and notes that "cardiac ablation has demonstrated across several broader industry studies a benefit versus drug management of arrhythmias in terms of reduced risk of stroke, reduced hospitalizations, and other complications that are significant drivers of overall healthcare spending." He also argues that by enabling cardiac ablation therapy for complex arrhythmias that would otherwise not be good candidates for treatment and by allowing for improved efficacy and safety, Stereotaxis is "a constructive partner to payors."

A Halo Effect

So confident is Stereotaxis of the clinical and financial benefit of its robotic system that its commercial effort is predicated on the notion that every hospital should have one, rather than a more limited, center-of-excellence approach. Fischel points to data that shows that 85% of prostatectomies in the US are now done on the daVinci platform and says "the clinical data would justify very much the same type of change taking place in the cardiac ablation field. That's our overall goal."

In the nearer term, Stereotaxis' "low-hanging fruit" will consist of those hospitals committed to treat complex patients. But even so, there are so many of them, that doesn't necessarily mean one center in various major metropolitan areas. "We have markets where we have multiple systems in the same broader metropolitan area, and they're all doing very well and able to attract patients," says Fischel. "Unfortunately, arrhythmias are very common, and cardiac ablation has proven more and

more to be a very good form of therapy for a broad range of arrhythmias. It's not a field lacking of opportunity."

More, the adoption of a Stereotaxis system in a market often spurs installations by other institutions. "As we've seen with robots in other clinical specialties, there's a feeling that when one [hospital] adopts, others need to do so also in order to compete and match that type of capability in the marketplace," says Fischel, especially when the perceived benefits revolve around clinical outcomes. "And while we're disproportionately used in treating complex arrhythmias, we're also being used to treat arrhythmias across the spectrum."

With, as noted, about 100 hospitals currently using the Stereotaxis robotic system, the company has a long way to go before there's widespread adoption, which in a way gives those early adopters a short-term marketing edge precisely because of the low penetration rates. Fischel notes that for early-adopter hospitals, Stereotaxis has, over the past three years, put in place "infrastructure, materials, and resources so the hospital can showcase their leadership in the community. We've made that a bigger part of our effort." Such programs, he says, are more easily conducted with new customers than those that purchased a Stereotaxis system a dozen or more years ago. "It's harder when a hospital has had a system for 10 years," he says. "We've been working more closely with new hospitals to showcase themselves in the community, to make sure they get press and they have the materials to approach referral physicians and address the patient population. We're just in the early stages of doing that, but we've tried to make that more tangible."

Last year, as part of its commercialization strategy, Stereotaxis signed a deal with **Acutus Medical Inc.** to integrate its advanced diagnostic mapping system and enable use of its MedFact magnetic catheter on the Stereotaxis robot.

Though it wasn't a driver of the deal, there are interesting similarities or parallels between the two companies, aside from their common interest in treating complex arrhythmias. Both companies had been around for a long time, working on advanced technologies, before gaining new CEOs around 2016/2017, and both CEOs had come out of the investment world of Southern California to take the helm. Fischel as noted, from DAFNA, Acutus CEO Vince Burgess from Orbimed. And both companies were, says Fischel, turnaround projects to one degree or another.

For its part, through its relationship with Stereotaxis, Acutus executives claim to be taking leadership in integrating state of the art mapping technology with an EP lab robot; now available for integration with the 100 or so Sterotaxis robots around the world and used actively across multiple hospitals. Acutus has called the agreement, "a hunting ground for us to get as many

of our mapping systems into those centers as possible.” And while Acutus’ ambitions are greater than robotically-assisted cardiac ablation, Acutus’ Vince Burgess told *MedTech Strategist* last year, “It’s really slick... I personally believe the Stereotaxis system represents the single most compelling clinical use of a robot in the body.” (See “*Acutus: Building an Open System, Pure Play in EP*,” *MedTech Strategist*, November 5, 2020.)

“If you step back and think about it, there are two important aspects to treating a patient,” says Fischel. The first is the diagnostic part, understanding the patient condition to determine how best to apply a therapy; the second is the actual treatment itself, getting the ablation just right. “I think our robotic mechanism improves significantly on the traditional way of treating the patient [because] you can move the catheter in a much more intuitive way and with stability, precision, and safety.” Acutus, he goes on, has developed a better way to identify and diagnose arrhythmias, where they are and how best to treat them. The collaboration between Acutus and Stereotaxis represents the combination of these advances in diagnostics and therapy.

“There’s a natural beauty to the use of the technologies together,” Fischel goes on, “because each of us is approaching the improvement of patient care in EP from a different vantage point. They come about the diagnostic aspect in a very attractive, novel way, and we come at the therapeutic aspect, again, in our own way, improving that.”

In addition, and consistent with Acutus’ larger strategy, Stereotaxis’ vision is “to build a collaborative, open ecosystem around robotics,” Fischel says. Physicians “want the benefits of robotic magnetic navigation, such as precision, stability, reach, safety, to be paired broadly with a host of diagnostic and therapeutic technologies. And that really is, I think, the best way to build the business—it’s the best way for patients and the best way for physicians to have an open ecosystem around the technology.” Acutus was the first AF company to implement an open mapping software architecture to fully integrate with the Stereotaxis platform. “With that, we’ve now been able to go to customers jointly and share our combined experiences,” he says.

The collaboration “extends itself in how both companies approach customers,” says Fischel, who adds, “We do see that the technologies when used together have benefit and are elegant together. So we support each other and try to generate the joint use of the technology.” Whether the collaboration, which has been in place less than a year, has yet made a material contribution on Stereotaxis’ sales is another matter. “It’s just now that we’re starting to see some impact,” he says. “We haven’t yet seen a dramatic impact but we do see the benefit commercially of working together. Stereotaxis itself only received FDA approval of its new robotic system in March of 2020, just as the pandemic hit. “And as you can guess, there was significant macro pressure

disrupting commercialization for the first few months,” he adds. “We’re just in the earliest innings of commercializing our robotic system to new customers; so is Acutus. We are seeing increasing use of our systems together and positive halo effect on each other through our collaboration.”

Moreover, Stereotaxis is exploring collaborations with other AF companies, including several that do pre-operative MRI and CT scanning specifically for EP procedures including **ADAS3D Medical**, **inHEART**, and **Catheter Precision Inc.** Says Fischel, “we’re committed to an open ecosystem.”

A Play in Telemedicine

Having, in effect, re-launched with the infusion of new capital three years earlier, Stereotaxis was preparing to take its new system to a new set of customers early last year when COVID-19 hit, essentially freezing for a quarter or so many elective procedures. Short-term, the pandemic was a negative for the company, but says Fischel, longer-term, however, it could prove to be a benefit.

“Short-term, hospitals weren’t doing any procedures and they weren’t buying new systems,” he explains. Longer-term, Stereotaxis has attracted interest from potential new customers because of the system’s telemedicine capabilities. Stereotaxis’ technology has long enabled remote collaboration between facilities doing procedures. But for a long time, Stereotaxis put little emphasis on those capabilities. “As you can guess, that became much more interesting over the last year,” he says. “Now, we’re supporting procedures using our remote capability every day. It’s also spurred us to explore additional innovations in that realm,” not yet ready for public discussion. “So overall [the pandemic] has definitely had a silver lining.” As the pandemic has reshaped customer behavior and practices, “there’s a broader acceptance that technological innovation is coming and acceptance that the world does change,” he adds.

More broadly, Fischel notes a natural tendency on the part of people to resist change, “even when we know it’s good for us.” While robotics is attracting a lot of attention right now, penetration rates generally are still low. Crises like the pandemic will, he argues, make people “more open to saying, if something is better, let’s just bite the bullet. That psychological shift has positive implications.”

The Robotics Wave


Given all of the buzz around robotics today and the dominant position of one player, Intuitive Surgical, it’s easy to forget that there was a time, 25 years ago, when interest in robotics was almost as great as it is now—a time when Intuitive was just one of several companies trying to launch the robotics

revolution, including Computer Motion and Transenterix (now **Asensus Surgical**), as well as a host of orthopedic players such as Robodoc—and, of course, Stereotaxis itself.

Today, three decades after its start, Stereotaxis is a lot of things: A pioneer in endovascular robotics, Fischel says the company has a start-up mentality if it's not technically one. Perhaps re-start is a better description and, at the same time, it's a publicly-traded company that has been public for more than half of its 31 years. Asked if Stereotaxis' publicly-traded status is an issue as the company re-starts, Fischel says the question is almost "theoretical": "We are public, so we enjoy being public because we are." Public companies have to be more transparent—"every move becomes public, and there's a challenge there," he says. But "public companies are held to a higher standard and there's pressure to perform better. It forces us to do things with higher quality and professionalism that otherwise might slip through the cracks."

As Stereotaxis positions itself for a kind of second act in life, does the current interest in and enthusiasm around robotics help or hurt? Does the interest direct new eyes at the company, bringing into the picture physicians who might have viewed robotics skeptically when the company first launched? Or is Stereotaxis perceived as an old story, a company that has been lost or left behind in the larger picture drawn by the many dozens of new companies rushing into the space?

Fischel hears whispers of both. "On the one hand, there's a positive halo effect because people recognize that robotics is transforming medicine," he says. "On the other hand, there's a lot of confusion and messiness. My guess is that most stakeholders, whether at the hospital or in the investment community or at other companies, sometimes confuse one robot for another and don't really understand the differences among them. And so we sometimes get lumped in with this big heap of robots even though there's really no one, other than Corindus, that's doing anything in endovascular intervention—and even then, we're very different from Corindus, with an entirely different robotic mechanism of action, and don't really compete with them."

But Fischel also believes that as robotics becomes a standard of care, that confusion will fade. "Twenty years from now, I think robotics will be as ubiquitous in endovascular intervention as it is now in laparoscopic surgery. That will be of enormous benefit to patients and, to some extent, if we aren't the ones pushing this, no one will. It's an exciting position to be in when you can have that type of impact on the evolution of medicine." 

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