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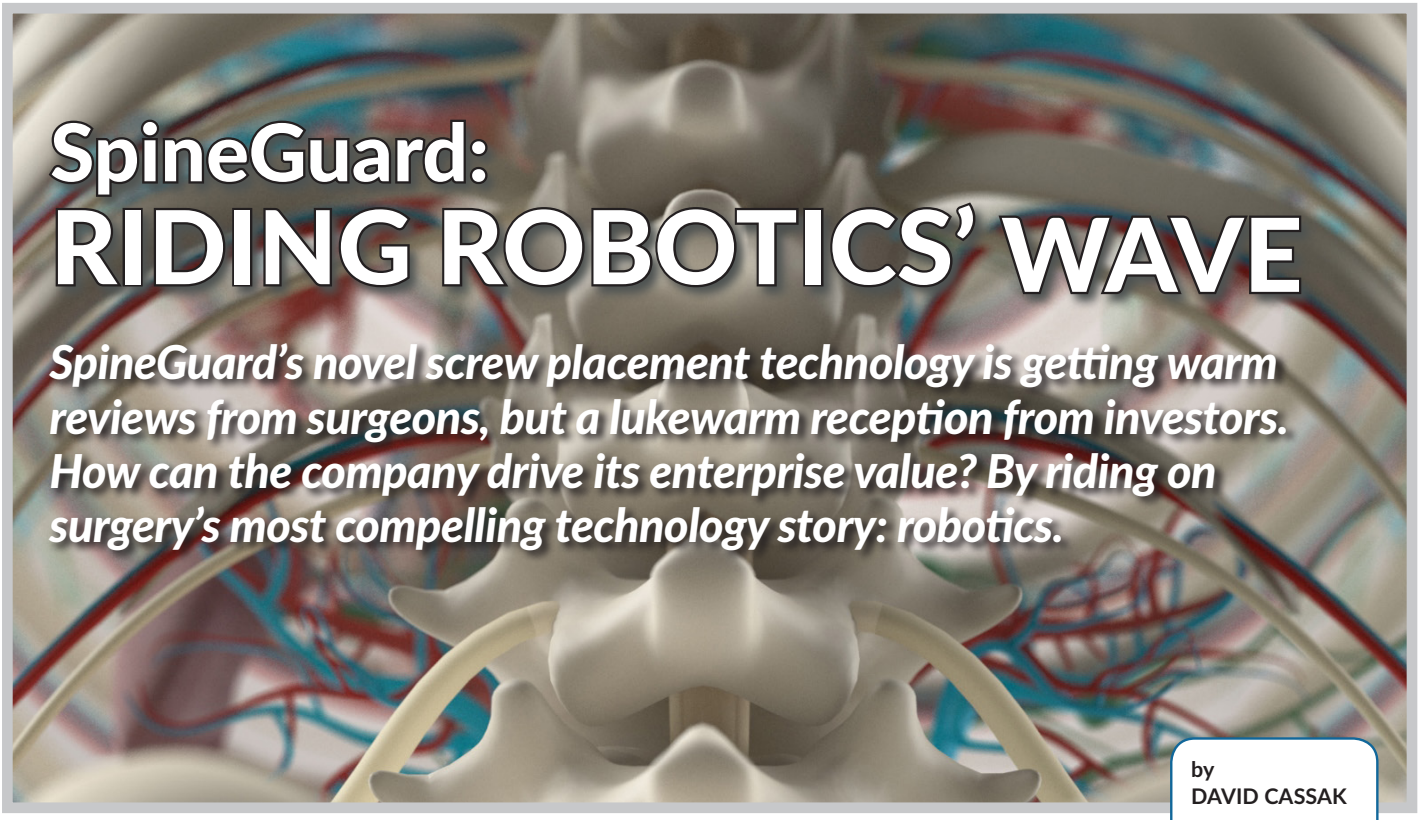


SpineGuard: RIDING ROBOTICS' WAVE

SpineGuard's novel screw placement technology is getting warm reviews from surgeons, but a lukewarm reception from investors. How can the company drive its enterprise value? By riding on surgery's most compelling technology story: robotics.

by
DAVID CASSAK

KEY POINTS

- A spin off from an earlier French spine company, SpineGuard has developed a novel, smart technology that enables surgeons to navigate the often tricky task of placing pedicle screws.
- While adoption is going well, particularly at academic medical centers in the US and France, investors have been slower to respond, and SpineGuard, which went public several years ago, has seen its share price drop.
- Well-established in total joint replacement, surgical robots are just now beginning to catch on in spine surgery.
- By getting in early, SpineGuard executives hope that robotics can be key to the company's long-term strategy, and that its technology can provide a solution to the limitations of robotics as deployed in spine surgery.

For a long time, most innovation in medical devices was incremental—second generation technology and tools designed to further or enhance an earlier innovation. Companies and their investors were well-rewarded for those incremental advances with strong adoption and premium prices. More recently and for a lot of reasons— continuing cost pressures on health systems, the changing role of physicians in product selection and a more rigorous selection process at hospitals, and skepticism about the real value of incremental innovation, to name just three—even companies with clinically valuable niche technology can find the path to market adoption difficult.

In turn, those challenges have left their mark on investors who are becoming more and more wary about where to place bets in medical devices. As the game gets harder, investors, both private and public, are turning away from incremental technology enhancements in search of big hits from disruptive technology. If it's going to take longer and cost more to get a product to market, why not place your bets on those technologies that seem to promise blockbuster returns rather than small value enhancements?

Medtech companies just starting out can adjust their game plans accordingly— for example, by finding a digital play to further their technology. But what if you're an older company, perhaps one that went public in more accommodating times, and find investors simply are no longer interested? That, arguably, is the plight

of **SpineGuard SA**, a Paris-born, San Francisco-based spine company with an innovative technology to help spine and neurosurgeons with the tricky task of screw placement. While surgeon adoption continues to ramp up, investor support for SpineGuard has lagged. SpineGuard's solution: tie your (technology) horse to arguably the hottest technology in spine today: surgical robotics.

A Spin-Off

Development of SpineGuard's *Dynamic Surgical Guidance* (*DSG*) technology and derived *PediGuard* devices was begun under SpineVision, a Paris-based spinal implant company launched in the late 1990s. When SpineVision ran into troubles in the mid- to late 2000s—a severe cash crunch and restive investors with different agendas and misaligned interests—company executives pursued a number of options. One included the sale of its emerging *PediGuard* line of products, which SpineVision executives saw as something of an outlier in the company's portfolio anyway.

SpineVision found an interested party in one of the pure-play spine companies at the time. But before that deal could be done, two SpineVision executives, Pierre Jerome, SpineVision's head of Sales and Marketing at the time, and Stephane Bette, head of the company's US subsidiary and former head of R&D, raised sufficient capital to compete with the other bid and close the deal. "In addition to purchasing the assets, we offered to transfer key employees whose jobs were at stake," says Jerome, a former Boston Scientific and Sofamor Danek executive and, at its launch, SpineGuard's CEO. (Jerome now serves as SpineGuard Chairman of the board). "We felt that technology was the gem."

SpineGuard officially launched in January of 2009 and, given the development work on the *DSG* technology that had been done under SpineVision, the company was shipping *PediGuard* devices by the spring of that year. Joining Jerome and Bette were the device's co-inventors Maurice Bourlion, PhD, currently a member of both the Board of Directors and SAB at SpineGuard, and Irish neurosurgeon Ciaran Bolger, MD, PhD. The first investors, participants in an €11 million Series A round raised to acquire the *PediGuard* assets and a San Francisco-based subsidiary SpineVision had launched, included then-Credit Agricole Private Equity, a Paris-based investor now known as Omnes, as well as Paris-based A Plus, Irish venture firm Delta, and IPSA, formerly Innoven, the one holdover from the original SpineVision investors. (SpineGuard's founders wanted one SpineVision but only one, concerned that there be a clear separation between the two companies.)

A Smart Screw

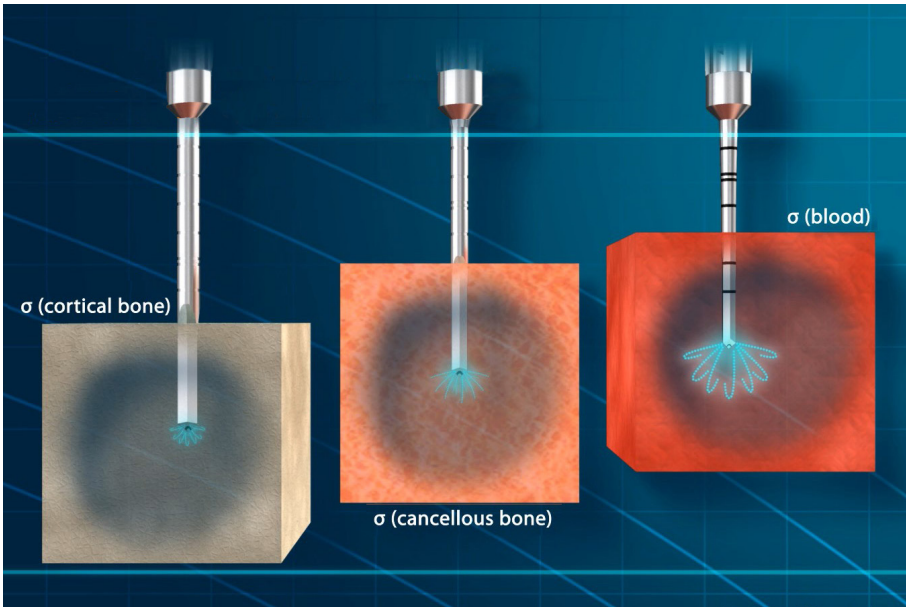
DSG (Dynamic Surgical Guidance) is a screw placement technology that allows surgeons to place pedicle screws safely by detecting the presence of different types of bone and tissue during surgery. The system operates on the principle that the electrical conductivity of tissue in the spine varies by the type of tissue; thus, cortical bone has low conductivity, while cancellous bone has medium conductivity, and periosteum and blood have high conductivity (*see Figure 1*). Assessing the different levels of conductivity can be helpful in determining where the surgeon is when drilling to place a pedicle screw and whether he or she is on target for an appropriate placement or a problematic one.

The *PediGuard* probes are what SpineGuard calls "smart drilling single-use devices" featuring the *DSG* sensing technology. They have a bipolar sensor embedded in the tip; as a low frequency and low voltage current is run through the sensor,

Figure 1

PediGuard Probes React to Local Conductivity

Probes emit low pitch in cortical bone, medium pitch in cancellous bone, high pitch in blood



Source: SpineGuard

the surgeon can tell what kind of tissue he or she is encountering at the tip. The information is helpful in avoiding a cortical breach, as changes in the pitch and cadence of an audio signal warn when the probe has moved into different tissue. Audible beeps alert surgeons when they are moving beyond bone and into sensitive tissues, getting too close to the spinal cord or vascular structures such as the aorta. A flashing light also alerts the surgeon if he or she has moved out of a safe zone. In addition to a straight *PediGuard* instrument available in three sizes, SpineGuard also offers two curved devices, a threaded device, and a cannulated version for percutaneous procedures, all embedding the *DSG* sensing technology.

The *DSG* integration module, the latest iteration of its spinal screw placement technology, was introduced last year and consists of sensing components that turn a classic cannulated pedicle screw system into an active sensing system where the sensor is embedded at the tip of the screw itself, allowing for direct insertion, placement accuracy, reduced operative time, and decreased usage of x-ray imaging. SpineGuard calls it the "smart" screw.

Today, the company markets its full line of *DSG* equipped devices in all segments of the spine and to treat a range of spine problems, including degenerative disease, trauma, tumors, and deformities. And with products approved around the globe, SpineGuard has begun to drive adoption particularly in academic centers, with high penetration rates, in particular, in France and the US.

In many respects, SpineGuard is a classic medtech company, with an innovative device designed to address important problems surgeons face in day-to-day practice. CEO Stephane Bette argues that SpineGuard has played a key role in creating awareness around two critical issues for spine surgeons: what he calls "the delicacy of the placement of the implant" and problems associated with radiation overexposure. "There is more awareness and more solutions associated with safety," says Bette. "And we're part of that."

In particular, Bette notes that incorrect placement of pedicle screws can lead to "neurological and hemorrhagic complications that can be quite dramatic." In addition, in developed and developing countries, healthcare systems are facing accountability issues, with real economic consequences associated with complications. Surgeons and providers, of course, always want to provide the best care possible to patients; today, however, governments and regulators "are requiring repeatable outcomes and optimized cost for every procedure," Bette goes on. "That's become a constant around the globe."

All of which places a premium on devices like *PediGuard* that can help surgeons place pedicle screws quickly and with greater accuracy. And where radiation exposure is concerned, the growth of advanced imaging and navigation systems over the years has increased risks of radiation exposure for both surgeons and patients. As awareness of those risks has led to a search for solutions, SpineGuard "wants to be part of that," says Bette.

Jumping on the Robotics Bandwagon

DSG is what Bette calls "an enabling technology," and he notes that most of the major orthopedic players "are now putting a lot of importance on" such technologies. But another way of thinking about enabling technologies like SpineGuard's is that they are niche or adjunct technologies, valuable to be sure, but addressing one aspect of a procedure. For many medtech companies—and there are hundreds if not thousands of them—the challenge with niche technologies is not so much creating clinical value but rather creating enterprise value.

In SpineGuard's case, the company has done well in gaining acceptance for its technology, but investors have been slower to catch on. Since going public in late 2013 at just under €7 a share, the company's stock peaked at around €12 a year or so later and has slowly declined, and now is trading at around €2. In other words, while surgeon interest and adoption are rising and sales are growing, investor enthusiasm is lagging. How, then, does a company with a promising niche technology position itself to investors who are more interested in bigger, sexier technologies? For SpineGuard, the answer is: jump on the robotics bandwagon—if not by developing its own robotic system, then by positioning *DSG* for what company officials believe is a coming wave of robotic surgery in spine.

Interest in robotics in orthopedics, if not spine specifically, is soaring. Starting with **Stryker Corp.**'s 2012 acquisition of Mako, the last several years has seen a wave of acquisitions of robotic companies by orthopedic companies: **Zimmer Biomet Inc.**'s acquisition last year of Medtech, developers of the *Rosa* system, **Smith & Nephew PLC**'s deal for BlueBelt, **Globus Medical Inc.**'s acquisition of Lausanne-based KB Medical, and, earlier this year, **Johnson & Johnson** operating company **DePuy Synthes**' play for French company Orthotaxy. In addition, Israeli robotic company **Mazor Robotics Ltd.** has had a collaboration with **Medtronic plc** for the past several years and in September was acquired by Medtronic for $1.6 billion. Globus last year received clearance of its robotic/navigation system *Excelsius* and Chinese robotics company, **Tinavi Medical Technology Co. Ltd.** has also launched a robot for spine surgery. (*See, "Technologies to Watch, Surgical Robotics: The Future is Now,"* MedTech Strategist, April 20, 2018 *and "Under the Lens: Mazor Robotics Bets on Million-Dollar Spine Robots," MedTech Strategist, February 13, 2015*).

Solving a Problem with Robots

Jumping on the robotics bandwagon may not be a fair way of characterizing SpineGuard's interest in this hot new technology. Maurice Bourlion, who was involved early in the development of *DSG* and *PediGuard*, early on saw the potential

of robotics and robotic-like technology in spine surgery. In some ways, robots are a natural extension of the surgical navigation systems that have been around for years. "The robot is an arm guided by surgical navigation," says Bourlion. "It's a matter of having virtual images that you plug into a machine that will follow and be guided by virtual images." If surgical navigation systems provide guidance and positioning to the surgeon based on pre-operative images, the robot is the tool that will act on those images.

Today, SpineGuard is working on robotic applications of its *DSG* technology, in the robotics lab on the campus of the University of Science in Paris, including the incorporation of Bluetooth technologies. But even if one concedes that robotic technology represents an important new contribution to surgery and is attracting robust valuations today, what does that have to do with SpineGuard and its novel screw placement technology?

For one thing, as robotics catches on, advocates for the technology envision a surgical suite increasingly populated by advanced technology that includes and integrates a wide range of equipment and devices: robotics, navigation systems, 3D printing, and tech-oriented capabilities like advanced analytics, machine learning, and artificial intelligence. To power an operating room with such advanced technology and continue to use what might be called dumb screws makes no sense, says SpineGuard. Its sensor-based device fits nicely with the technologies that are at the heart of these other devices.

Even more importantly, SpineGuard argues that its *DSG* system addresses an important shortcoming of most robotic systems today. Stephane Bette argues by analogy. "Consider a self-driving car," he says. Beyond a motor, tires, and steering wheel and brakes, driverless cars need other technologies that regular cars don't: navigation technology to get the car from one destination to another, sensors to manage turns and avoid pedestrians and other obstacles, and special failsafe technology to allow for human intervention should something go wrong. Robotic surgery, similarly, requires technology not called for in regular surgeries, including, among others, they argue, the navigation capabilities inherent in *DSG*.

"The problem with the robotic technology in the surgical field today is that the robots are blind," says Bette. "The only way the robot can see is through virtual reality which is a reconstructed, navigated reality." *DSG* isn't just a cool new screw system; it is, in effect, a navigation system itself, helping spine surgeons place screws precisely in a difficult anatomy while doing so with less than perfect visualization. Without *DSG*, a lot can happen in the OR that results either in misaligned screw placement or trauma during surgery due to an inadvertent movement of the patient, of the optical markers used by the navigation technology, or due to an excessive distance between the operated level and the level where these markers are placed. "How can a robot tell in real time if something is moving or the screw isn't being placed right?" Betts asks. "What we are saying is that our technology at the tip of the robotic arm is one of the very few existing technologies that can give the robot a refined feedback coming straight from the tissue and the end of the robotic arm, in real time."

In addition, like the failsafe features of a self-driving car, the *DSG* system can help the surgeon prevent any problems that might arise when performing a procedure with a robot. "It's the responsibility of the surgeon to detect any problem and to interrupt the procedure and reposition the tools if necessary," Bette says. And that's precisely what *DSG* enables the surgeon to do. Haptic feedback in current robotic technology does something similar, he goes on, but it's much less reliable, particularly as the surgeon encounters the bone of the spine. "Changes in bone mechanical resistance are too subtle" for most haptic feedback systems, he says. *DSG* represents a better approach because it measures the conductivity levels of the different kinds of tissue in a way that robots can't.

A Solution to a Solution

As noted, Maurice Bourlion had been thinking about the implications of robotic surgery for *DSG* almost from the beginning. But SpineGuard's efforts in the space started to move forward only recently, driven in large part by surgeons who had approached the company about a potential role for *DSG* in the next generation of robotic surgery. Says Pierre Jerome, "The ones who made it clear to us were the physicians who designed the spine applications for the robots and had the first clinical experience. They came to us and said, 'We have problems you might be able to help us solve," and introduced us to the robotic companies."

Twenty years ago, robots like **Intuitive Surgical Inc.**'s *DaVinci* established themselves clinically by providing a solution to the device-related problems raised by the advent of minimally-invasive surgery (MIS)—a solution to the rigid, uncomfortable instrumentation that surgeons found difficult to use in the closed spaces of portal-driven surgery. As robotic surgery begins to gain adoption in spine surgery, SpineGuard, albeit in a more limited sense, wants to be a solution to the limitations of robotics as deployed in spine surgery.

Specifically, the surgeons who approached SpineGuard wanted to use *DSG* inside the robot "to make sure nothing bad happens and any mistakes would be detected," Stephane Bette says. KOLs who were working with the leading robotic companies in spine, including Mazor, MedTech (acquired by Zimmer Biomet), and Globus, came to SpineGuard to talk about the challenge of navigation in robotically-enabled surgery and how DSG could help. (*See sidebar, "The Learning Curve is Key."*)

Losing Control

SpineGuard sees its role in enhancing current robotics technology rolling out in two phases. First, says Bette, is the current need "to prevent mistakes and help the surgeon avoid problems" associated with poor screw placement. In this first phase of development, *DSG* technology integrated with a robot would feature an automatic stop that would itself detect when something was going wrong, independent of the judgment of the surgeon, and shut down the robot. (As noted, under the current *DSG* system, the surgeon is alerted to problems by an audible signal.)

In this phase, says Bette, "we have taught the robot when to detect a problem. But in the future, we can do more." In phase two, software developed by SpineGuard would enable the robot to actually do placement of the screw itself—much like a driverless car drives without human interaction. "In our conversations with surgeons," he says, "a number of them tell us that as much as they like to be the brains behind the procedure and to diagnose and assess the best treatment plan, they could envision a platform where all they would have to do is to push a button" to place a pedicle screw. Indeed, in the more complex and difficult surgeries that spine often presents, Maurice Bourlion argues, surgeons will all the more readily embrace robots. Robots will catch on, he says, because spine surgery is so difficult. "Because it's an uneasy surgery, the robot has its place. It will help the surgeon reproduce the correct gesture. Ultimately, I think the surgeon will be happy to have this help."

At the same time, even in this second phase, SpineGuard executives are careful to make sure that *DSG* doesn't trigger one of the major concerns surgeons have with robots: fear of losing control of the procedure. *DSG* is an important tool, but only a tool. Even if our technology evolves to the point where the robot itself places the screw, says Bourlion, "The surgeon will always have to plan the surgery. He will never be replaced; he will be helped by the robot. And at the end of the day, the surgeon remains in control because he or she

The Learning Curve is Key

Andrew Cannestra, MD, PhD is a neuro- and spine surgeon at Baptist Memorial in Jacksonville, FL, heading one of the leading robotic spine surgery centers in the US. Baptist purchased its first robot, a first-generation Mazor *Renaissance*, in 2013 and he's been an advocate ever since. (The robot has been so eagerly adopted at his hospital that Baptist purchased a second robot a couple of years ago.)

Cannestra notes that the biggest obstacle initially was speed. "For a long time, it was just too slow and would slow down procedures," he notes. But refinements and advances to the Mazor technology have largely solved that problem, he goes on, and "since 2013, we've seen a growing acceptance of the robot by both neuro and spine surgeons."

Cannestra points to the rapid development of robots by Mazor, now on its second-generation robot, as well as other spine companies and argues that "robotics are here to stay." He distinguishes between two types of robots, navigation, and anatomy robots, the latter which attaches to the patient's body. "Companies are blurring navigation and robotics into a single tool," he goes on. To date, he says, robots are most often used in placing implants, mostly screws, and much less so in cranial cases and biopsies and in procedures such as placing cages and non-implant cases. "I'm not aware of anyone doing cages" with a robot, he says, though it's likely that steps will be taken in those directions.

Though spine robots tend to be smaller and less expensive, cost "is always an issue," says Cannestra. "It was in 2013 and is even more so in 2018." Surgeons, working closely with hospital administration, have to explore the value of the robot in terms of "clinical excellence, marketing opportunities, and financial impact," he says, noting the he's worked closely with Baptist executives to find and prove the value. "We looked at all of these things and worked in partnership with the hospital," he says, adding, "The fact that we bought a second robot," indicates that they were able to prove to administration's satisfaction the value of the robot.

For Cannestra, the argument for clinical value surpasses all: "As a neurosurgeon, I'm very much a perfectionist about my outcomes," he says. He concedes that there may be some surgeons concerned that the robot takes away some measure of control. "But that's the whole point," he counters. Robots provide "an extra measure" of control or precision, especially in the placement of hardware. The key is the adoption learning curve. Robots may not be right for all procedures and it takes time for surgeons both to learn how to use robots and when they're the right tool to use. "It's a great tool but whether you're talking about a hammer or a complex robot, you have to go through the learning curve. And that's the surgeons' job."

knows which implant will work best and where to place it, even if the robot will do it for him or her." In fact, in in those cases where control is an issue for a surgeon, SpineGuard's *DSG*, if anything, serves just the opposite role: a valuable navigation tool without any more ambitious claim for the technology. "One of the most intriguing pieces of feedback we've gotten is that senior surgeons teaching younger surgeons want to make sure that they [i.e., younger surgeons] are capable of operating without [a robot], so they're not completely dependent on it," says Bette. "That would be scary."

Fighting for Market Share

SpineGuard executives are, in turn, banking on a growing adoption of robotics on the part of surgeons to accelerate interest in *DSG* on the part of the leading spine implant companies. How to work with them is the question for SpineGuard. The company could do a licensing or some other form of contractual relationship with several or all of the major implant companies, at once leveraging its own customer base on behalf of its partners and expanding it via those of its partners. Such an approach would give *DSG* a broader reach into the marketplace but wouldn't, after a while, lead to much differentiation for the large orthopedic companies since a lot of companies would have access to the technology, except in comparison with less sophisticated robots, both their own and those of their competitors.

More likely is that SpineGuard will try to form relationships with a limited number of companies in part, says Pierre Jerome, because it doesn't think that big companies will want non-exclusive arrangements. Jerome sees two dynamics driving what SpineGuard hopes will be interest on the part of the major spine companies. First, a need to further differentiate their robotic systems. Right now, he notes, "they are all in a market development phase with the robotic technology they've just acquired. A rising tide is lifting all boats so they don't yet see an urgent need to differentiate themselves but it won't be long before the market environment becomes much more competitive," he says. "And in that environment, they're going to want to differentiate themselves."

Second, he says, niche enabling technologies can help robotics companies expand the market. "The more they penetrate the market with their robots, the more they're going to convert less skilled surgeons to robots," says Jerome. As those less skilled surgeons try their hands at robotic procedures, "there's a greater risk for bad cases." SpineGuard can help, not only by protecting against the downside risk associated with poor screw placement by less skilled surgeons, but also by giving less skilled surgeons confidence that they can use a robot without compromising outcomes or, in the process, risking a law suit.

Moreover, says Bette, orthopedic companies are showing now that they're looking at robotic systems not just as products in their own right, but as important strategies to place proprietary implants—one key to success, for example, for Stryker in its knee implant business in positioning Mako. SpineGuard expects Stryker to follow the same strategy as it looks to take Mako into spine, and Bette believes such a strategy will drive other companies as well. "I guarantee they're going to use their robotic technology to push their own brands," he says. In such a scenario, closer, more defined relationships are valued over simple access to new technology.

Even in this second phase, SpineGuard executives are careful to make sure that DSG doesn't trigger one of the major concerns surgeons have with robots: fear of losing control of the procedure. DSG is an important tool, but only a tool.

Cost Issues

While SpineGuard executives are betting on a greater role for robotics in spine surgery, strictly speaking, *DSG* doesn't need robotic-enabled surgery to gain adoption. Thus, one calculation for SpineGuard as it prioritizes and pursues its robotics-related strategy is how quickly it thinks robotic penetration will come. Maurice Bourlion says that the question is difficult to answer, but he notes that virtually all of the major spine companies—from Medtronic to Globus, Stryker to DePuy/Synthes—are currently incorporating robots into their offering, which he believes will give the technology a boost. "That's a big force that is going to feed the market," he says. The conversations SpineGuard executives themselves have had with the big implant companies have left them convinced that their intentions are serious.

But they also believe it may take a while. Stephane Bette argues that "robotics will develop as an overwhelming technology in two decades, maybe one, because of the value to both patients and providers, especially hospitals." Robots will help to drive more consistent and higher quality of care because their ability to deliver a kind of standardization of care at higher levels.

But, he goes on, "I think it will take time because there will be issues." Cost is a major one, both the cost of the robots themselves and also, in a kind of countervailing sense, economic pressures that are pushing more and more procedures, particularly simpler cases, into lower acuity settings like ambulatory surgery centers, "which is the other big wave that we see coming in spine," adds Pierre Jerome.

Those countervailing pressures give SpineGuard "an interesting play on both fronts," says Bette since the *DSG* system can not

only help surgeons who want to embrace robots, but also those who are moving care to outpatient settings. Even as the company prepares for the robotic revolution, Bette points out that up next, from a technology standpoint, for SpineGuard will be the ability to transmit the *DSG* signal to a tablet to enable "a simple set up."

In fact, the cost issue is an interesting one for SpineGuard. Concerns about high price tags for robots are still widely voiced among providers, even as the robotic wave gains steam; that's why so many next-generation robotic companies today talk not just about the capabilities of their technology, but also about their lower price tags and smaller footprints. But independent of the play in robots, SpineGuard executives have long argued for a cost-savings benefit of their technology. As cost pressures push more and more care into lower cost settings, the value of *DSG* increases and the technology, they argue, goes from being enabling to close to essential. Lower acuity settings, lacking the back-up support and sophisticated technology of tertiary care hospitals, have an even more pressing need for devices that help prevent the kinds of mistakes that *DSG* addresses. In this light, *DSG* becomes not simply a novel adjunct technology to the robotic revolution, but a valuable technology that helps surgeons and hospitals protect themselves from potential risks inherent in those cost-savings efforts. In the end, says Pierre Jerome, SpineGuard's technology "is about liability, reproducibility, and an autonomous solution that is easy to implement anywhere in the world. But it's also about a very compelling complement to the most advanced technologies like robotics and navigation," novel technologies that "propose the trajectory but don't provide real-time information as the surgeon progresses into the bone."

Some robotics companies, like **Verb Surgical Inc.**, talk about the democratization that robots will bring, pushing the technology out to more and more patients around the world, and argue that robots can be a solution to the broader cost problems that plague healthcare systems around the globe, (*See "Verb Surgical—Surgery in the Digital Age,"* MedTech Strategist*, May 13, 2017*).

Figure 2

Clinical Data on PediGuard Probes

97%
Screw placement accuracy
(Defino 2015, Heimen 2014, Bai 2013, Chaput 2012, Chang 2009, Bocquet 2006)

98%
Breach detection
(Bolger 2007)

100%
Pedicle breach anticipation
AND
87%
Breach anticipation overall
(Williams 2014)

58%
Breach rate reduction when used by residents
(Sandhu 2014)

3x
Fewer pedicle perforations than with free-hand technique
(Bai 2013)

3-fold
Reduction in neuro-monitoring alarms
(Ovadia 2011)

25%-54%
Reduction in radiation exposure during pedicle screw placement
(Chaput 2012, Bai 2013, Defino 2015)

15%
Surgical time savings during screw placement
(Bai 2013)

Source: SpineGuard

But SpineGuard executives are hedging their bets; robotics represents an important opportunity, but not the whole opportunity. "For sure, not all hospitals, even in the US, will be able to afford the redundancy of safety," says Jerome. "In the first phase, we think there will be a select group of institutions that will be able to afford [a robot]."

Three Paths

In fact, SpineGuard is pursuing three paths at once. The first is the core, stand-alone *PediGuard* probes, backed, Stephane Bette points out, by peer-reviewed articles and clinical trials featuring more than 60,000 surgeries worldwide (*see Figure 2*). Last year, SpineGuard saw revenues of €8.2 million, on products that are seeing double-digit growth and have a gross margin of 85%. One important key to that growth: the global launch of the system, with approvals around the world and, in China, the signing of a distribution agreement with a distributor, **Xinrong**. Though the company does around 80% of its sales in the US, *PediGuard* is currently approved in Europe, Japan, China, India, Russia, Brazil, Mexico and Saudi Arabia as well. (In the US, the company has a penetration rate of around 2.5%, though in selected target markets, the penetration rate is closer to 10%. Around one-third of US teaching hospitals now use its devices, and around half of all French academic centers.)

One of the challenges the company faces is reimbursement: because *PediGuard* is a tool used in an existing procedure, there's no separate code for its use. Notes Pierre Jerome, "We can't claim a new reimbursement because we're not creating a new technique or new procedure; we're facilitating an existing one with a fixed reimbursement." In conventional spine surgery, SpineGuard argues that reducing or eliminating the risk of complications

can generate significant savings. "That's how we convince hospitals to pay for it," says Jerome. Furthermore, with the smart *DSG* embedded pedicle screw, Jerome argues, "the value proposition gets even better with the cost of *DSG* being part of the cost of a usually reimbursed implant system."

SpineGuard's second path will be to ride along with the coming robotic revolution, and there, company officials believe their cost argument is even stronger. Reducing the risk associated with expensive robotic systems in which the hospital has just made a huge investment should, SpineGuard hopes, makes for a more compelling case to hospitals. *DSG* "may eventually cost a bit more per procedure," says Jerome, "but you reduce the risk for a revision, so ultimately it's more cost-effective."

Finally, a third path will take SpineGuard for the first time outside of spine. The company has recently signed an agreement with an Israeli company to pursue applications in a number of dental procedures, including sinus lift, lower jaw implant, and zygomatic implant fixation, and will do so not just in Israel but around the globe. These dental procedures benefit from the same kind of distinction *DSG* makes between hard and soft bone in the spine and require the same kind of more precise drilling. Stephane Bette notes that the number of dental procedures targeted by its Israeli partner is eight times larger than the spine market the company has historically targeted.

SpineGuard is looking at other non-spine opportunities as well, most notably in trauma and total joint reconstruction in orthopedics, particularly in more complex cases, to help with the placement of screws used to position bone plates, helping the surgeon to avoid nerves, vessels, and tissues while also reducing radiation exposure for the surgeon. Pierre Jerome notes that one of the changes that robotic surgery brings to spine is the use of power drills to create the holes used in screw placement. In non-robotic spine procedures, he says, "for the most part, [surgeons] prepare the hole and implant the screw manually," because of concerns about touching nerves and other sensitive anatomies; for spine surgeons accustomed to manual techniques, *DSG* represents a new approach. In the rest of orthopedics, however, the use of power tools to drill holes is more common and so the receptivity of technology like *DSG* is arguably already established.

Further out, SpineGuard is working on new technology horizons that, for example, would go beyond guidance and use its sensing technology to measure the quality of the bone. Stephane Bette notes that there is "a very strong link" between the kind of electrical conductivity *DSG* currently detects and bone density. "We think our technology can assess the quality of the bone in a very accurate manner and very precise location," he says. The company has been conducting experiments on detecting bone density; if they can prove its technology works in this area it could be an important tool in detecting bone fragility in osteoporosis patients. Says Stephane Bette, "The associated costs of hip fractures are very high, and the question is, can we prophylactically identify weak bone so it can be treated with bone substitutes or bone enhancement parts?"

Opportunities Beyond Spine

- Dental
- Orthopedic trauma
- Total joint reconstruction
- Bone density measurement
- Alternative to x-ray for surgical navigation

A second project would use *DSG* in conjunction with ultrasound to reduce or eliminate the use of x-ray in surgical navigation. SpineGuard is exploring whether "we can obtain a complete, comprehensive solution to navigation without x-ray or at least much less of it," says Bette. This evolution would expand and extend *DSG*'s role in a spine procedure, before the drilling instrument has been introduced to the bone. It would also make SpineGuard a competitive alternative to existing navigation systems, which are CT-Scanner (ie: intensive x-ray) based. Says Bette, "The idea is to combine ultrasound with *DSG* to enhance navigation."

In many ways, the robotics revolution started two decades ago as an effort to find a solution to an earlier technology-driven revolution, minimally-invasive surgery. The advent of new surgical tools to operate in the closed spaces of MIS was a boon to patients and payors and ushered in a fundamentally new way to do surgery, one that produced less trauma in patients and faster returns to function, which benefits employers and payors as well. But the MIS revolution stalled in many cases because surgeons found the instruments used in closed surgery—many of them rigid and difficult to control and manipulate—problematic. Bringing a degree of articulation and control to tasks performed in closed settings, robots promised to solve the technology challenges that left surgeons unhappy.

And in many cases they did—but not all. For all of his enthusiasm for surgical robotics in spine, neurosurgeon Andrew Cannestra notes that there are some challenges robots still don't solve. Cannestra uses the robot mostly to place hardware like screws. "The robot doesn't provide feedback," he says. "When you're drilling into bone, you don't always know how you're doing. *DSG* provides that." That's the bet that SpineGuard is making—that its novel *DSG* technology, rather than being bypassed or overshadowed by spine surgery's next revolution, will in fact get a boost as robotically-inclined surgeons find in DSG the final piece to the puzzle. If that happens, SpineGuard may finally see investors joining surgeons in their enthusiasm for the technology.