



PIONEERS OF ROBOTICS IN INTERVENTIONAL ENDOVASCULAR MEDICINE

Today, Stereotaxis is the leader in robotics in interventional cardiology. Since its creation, the company has developed robotic magnetic navigation systems with all the sophisticated advantages associated with robotic technology, enabling safer and more efficient cardiac ablation procedures. Hundreds of doctors have used this technology in more than a hundred hospitals worldwide and have treated over 100,000 patients to date

Présentation avec **David Fischel**, Chairman & CEO, Stereotaxis



Can you tell us the history of Stereotaxis and how you became the leader in robotics for interventional cardiology today?

David Fischel: Stereotaxis was originally founded with the goal of delivering precise therapy to difficult-to-reach areas of the brain. The concept of using computer-controlled magnetic fields was daring in its technical challenges, but attractive since magnetic fields could allow for direct control of devices, irrespective of their location in a patient's anatomy. After initial exploration into various clinical applications, we began to focus on interventional cardiology as a particularly large field of medicine where traditional endovascular catheters have significant limitations. The mechanism of action of traditional catheters requires control at the catheter handle to be

translated into movement of the catheter tip. This is accomplished due to the rigid plastic of the catheter and pull-wires, but the mechanism leads to poor precision at the tip, low stability, an inability to reach certain areas, and risk of damage to delicate anatomy. Using precise computer-controlled magnetic fields, a physician can navigate a very gentle catheter with direct control of the catheter tip, overcoming these limitations. Over the last 15 years we have seen increased adoption of our technology in electrophysiology and are continuing to advance the technology with the goal of expanding the benefits of interventional medicine. Stereotaxis has proven to be a very reliable partner in innovating electrophysiology labs.



How do you explain that Stereotaxis is the only company to have successfully developed a functional robotic magnetic navigation system, when several other companies have entered the race?

It is challenging to develop medical technologies that provide clinical value, can be manufactured in a cost effective fashion, and perform reliably in the demanding clinical setting. Developing high-technology surgical robots is particularly challenging, as the technology requires macro mechanical systems, micro instruments, electrical systems, control software and user-interface software to all work seamlessly together. Very few companies globally have developed robust robotic surgical systems that can withstand the daily rigor of clinical use at the best medical institutions. We are proud that we have pioneered robotics for interventional medicine and been able to overcome these challenges with a technology that has already treated over 130,000 patients at over 100 hospitals globally.

Most heart surgeries are still performed manually using manual catheters. How can we make this technology more accessible today in order to advance robotic interventional medicine?

Ensuring that the best healthcare is broadly accessible and affordable to patients is a key goal for Stereotaxis. We are proud of the robust clinical validation of our technology and its ability to improve patient care but also recognize that, historically, establishing a robotic interventional practice was expensive and challenging. With the development of our newest Genesis Robotic Magnetic Navigation System we endeavored to make the installation process and financial burden for hospitals much lower. We accomplished this by significantly reducing

the weight and size of the systems, and by including a tightly-integrated fluoroscopy system with our robot such that a fully functional robotic interventional laboratory could be acquired for a similar cost of a manual bi-plane system. We continue to be motivated to improve access and affordability of robotics through innovation with an expectation that in the future every hospital and patient will be able to benefit from the technology.

In your opinion, to what extent will augmented medicine, artificial intelligence and telemedicine impact and revolutionize interventional practices?

This is a fascinating topic for discussion! When we speak today about the benefits of Stereotaxis' robotic technology we mainly discuss the mechanistic benefits: improved precision, improved catheter stability, enhanced reach, and the highest levels of safety. These are all true and important, but robotics is a critical and necessary foundation on which to advance the concept of digital surgery. We view digital surgery as encompassing four key topics: telemedicine, automation, image guided therapy, and big data insights. As these are advanced, we are confident they will have a transformational positive effect on interventional medicine by improving connectivity in the operating room, ensuring the full array of patient data is available to support procedure decision making, and to learn in a scientific fashion from the accumulated wisdom of thousands of previous procedures. I am certain that in the next couple of decades surgeries will not be performed without the benefit of digital surgery. We are grateful for the collaboration we have had to date with Dr. Gabriel Latcu in advancing telemedicine at Centre Hospitalier Princesse Grace de Monaco and look forward to continued collaboration on these exciting topics.





How does Stereotaxis fit into this revolution in augmented medicine to provide practitioners and surgeons with the tools they will need in the operating rooms of the future, both in cardiology and in other areas of interventional medicine?

As described before, the full potential of augmented medicine is only possible when the procedure is digitized. Robotic systems are necessary foundations for the digitalization of interventional medicine and without robotics there can never be the full revolution of digitization of the operating room. As the global leader in robotics for interventional medicine, we play an important role in advancing this vision. We are glad to collaborate with many companies that develop innovative technologies that support this future, and are committed to an open-ecosystem around our robotic technology to ensure more rapid, cost-effective and democratic progress of this vision. Stereotaxis plays a central role in bringing together an attractive ecosystem for the benefit of patients and physicians.





“ROBOTIC NAVIGATION FOR THE TREATMENT OF ARRHYTHMIAS”

“The acquisition of robotic technology reflects the desire of a modern hospital to provide the necessary means to offer the best quality of care to its patients”

Propos recueillis auprès de **Laurent Josseume**, Capital Sales & Adoption Manager

What is your role within Stereotaxis?

Laurent Josseume: My primary role within Stereotaxis is to support the clinical adoption of our robotic platform and to ensure that hospitals are well equipped and trained to maximize the success of their clinical program and customer experience using our technology. Additionally, we aim to develop Centers of Excellence to educate the electrophysiology community. Another interesting part of my job is to lead projects in collaboration with physicians, biomedical engineers and hospital executives.

I enjoy the complexity of my work, making the latest robotic technology available to hospitals, clinicians and patients.

The primary therapies prescribed to arrhythmia patients include pharmaceuticals, implanted devices, and cardiac ablation procedures...

Laurent Josseume: Cardiac ablation is a well-established treatment for arrhythmias, with nearly one million procedures performed each year. This minimally invasive procedure involves navigating a catheter through the blood vessels into

the heart. The catheter delivers energy to precise parts of the heart muscle, normalizing the electrical signals and returning the heart to a normal healthy rhythm.

In traditional cardiac ablation procedures, a physician manually manipulates a catheter by hand. Controlling the catheter tip by holding on to the opposite end (over one meter away!) while trying to perform precise movements within the delicate heart is not easy. The challenge could be compared to signing your name while holding a long pencil by its eraser.

Robotic magnetic navigation (RMN) is designed to address the inherent limitations, challenges, and risks of manual interventional medicine. RMN fundamentally transforms catheter navigation using magnetic fields and robotic precision to navigate a magnetic catheter directly from the tip. The technology consists of two robotically controlled magnets next to the operating table. During the procedure, a physician uses an intuitive computer interface to adjust the magnetic field around the patient. This allows a physician to precisely direct and steer a cardiac ablation catheter that has a magnet embedded in its tip.



What are the advantages of this navigation system based on the use of an electromagnetic field for patients but also for practitioners?

L.J.: Unlike the traditional technique of manipulating catheters by hand, Stereotaxis offers a robotic approach with different catheters on which we can apply a force delivered by a magnetic field. This technique offers greater precision and allows working with more flexible instruments, which increases patient safety. The various scientific publications are unanimous, we offer the safest solution on the market today. In addition to better safety, we see better results on several pathologies than our competitors thanks to the flexibility and maneuverability of magnetic catheters.

Our technology also offers advantages for operators. Since the machine which generates the magnetic field is controlled by a computer, the doctor does not need to be in the direct vicinity of the patient and be exposed to X-ray. Radiation is a real issue, operators must wear a lead apron to protect themselves from dangerous ionizing radiation, a burden that causes back problems for interventional cardiologists.

To what extent did Stereotaxis participate in the democratization of this technique?

L.J.: The first generation of our equipment was developed in 2003 and, very quickly, we equipped our first centers in Europe and the United States of America. Actually, Monaco, Princesse Grace Hospital was amongst the first five centers in the world to acquire a robotic system. We developed many generations, put a lot of resources in R&D to improve and to further develop robotics. We partnered with leading electrophysiology teams around the world and are now the leader in robotics for interventional cardiology. A key part of our efforts has been to democratize access to the best therapy and to make it possible for every hospital to benefit from our technology. We are proud that Princesse Grace Hospital is working closely with us to advance our latest technologies.

You are therefore driving major innovation in interventional cardiology ...

L.J.: Yes! Robotics and the digitization of surgery is at the cutting edge of many fields of medicine and we are confident it will positively transform interventional cardiology in the coming years.

As always when developing innovative technologies, we want to solve an existing problem; in the first place the difficulty of manipulating instruments remotely in the patient's heart with a high level of precision and safety. The operator must control the tip of a one-meter-long catheter in a beating heart with millimeter precision, which presents an immense challenge. Robotic Magnetic Navigation elegantly addresses that problem.

Moreover, by innovating computer controlled magnetic navigation system, we improve safety, comfort and maneuverability of the catheter and maximize clinical outcomes for the patient.

With consequent digitalization, we have developed the concept of TeleRobotics, combining telemedicine and robotics to improve patient care, enhance physician education and efficiency, and expand access to high-quality therapy. Telerobotics allows remote clinical and technical support of procedures, peer-to-peer training and proctoring, and remote surgery

What are the structural and organizational constraints to install a Stereotaxis robotic room?

L.J.: The constraints are the same as for all heavy and large equipment, like MRI's and CT-scanners, for example. Our magnetic fields are 15-30 times weaker than those of an MRI, but they still require the room to be located away from other sensitive magnetic equipment. We provide all necessary support for the successful planning, construction and installation of a robotic lab.



What are the specifications required for a cardiology department to acquire such technology?

L.J.: Any facility with an existing or future electrophysiology program can successfully implement Stereotaxis technology. Like with every new technology, operators go through a learning curve. They need a certain number of procedures to develop and maintain their expertise and skills to take full advantage of the benefits of a robotic system. Robotics are designed to assist and amplify the human skills, not to replace the physician. For a robotic system, an additional investment is needed which is justified by its benefits, better patient outcomes, less complications, higher patient volume, innovative image of the center etc. The acquisition of our technology allows a hospital to build a new program and strengthen its leadership in a very competitive environment. The acquisition of robotic technology reflects the desire of a modern hospital to provide the necessary means to offer the best quality of care to its patients.

How is Europe positioned in the development of your technology?

L.J.: Europe is playing a leading role in the development of our technology; often new technology is first introduced in the European market. Europe, together with North America, are the most important markets for Stereotaxis. Lately our new robotic system, Genesis® has been first installed in Europe and Monaco, Princesse Grace Hospital, is one of the first in the world.

How important is staff training to the use of your systems?

L.J.: The successful adoption of our technology is our highest priority. Staff training is a very important component in this effort as the staff play a key role in the treatment of patients and in maintaining an efficient operating room. We are well experienced in training teams successfully to become independent daily users of our system. With more than 130.000 procedures performed, we have developed a very comprehensive education program including simulator training and innovative TeleRobotic sessions. Our staff training is tailored to all stakeholders like physicians, fellows, technicians and nurses.

What are the main characteristics of your 4th generation robot?

L.J.: The Genesis system is actually the first major architectural change to our robot since its initial launch. We have managed to speed up the movements of the machine significantly to optimize its efficiency, making it more user-friendly and faster. This system allows us to further develop automation and use of artificial intelligence. The system is also much smaller and lighter and therefore easier to install. As a very interesting innovation, we have fully integrated imaging system with our robot, specifically designed for electrophysiology. Our Genesis® robotic system will also serve as a platform for future endovascular applications beyond electrophysiology.

Which institutions will benefit from this latest generation system?

L.J.: The institutions that will potentially acquire the system have not changed, we have made it easier to establish a robotic program. This new generation is not more expensive than the previous generation and the installation constraints have been simplified. Stereotaxis provides integrated service and maintenance for the entire robotic system including imaging. Our desire has always been to allow the acquisition of the system to as many people as possible. We strongly believe that in the future every electrophysiology department will offer robotic technology as a standard of care. Hospital Princess Grace is a long-term partner of Stereotaxis and has always been a pioneer in robotic magnetic navigation. Now, being one of the first ones in the world to acquire the new Genesis® robotic system, the cardiology department of Professor Atul Pathak with Dr. Gabriel Latcu, Head of EP department, will demonstrate again its leadership in the electrophysiology community.

How will this technology make it possible to further democratize telerobotics and remote collaborations between institutions?

L.J.: The digitization of the interface allows to monitor and take control remotely. This is already the case within the hospital since the operator is located about ten meters from the patient during the operation. Then the technology can be used anywhere if you have stable VPN internet connection and does not require any special equipment. During the TeleRobotic Surgery Virtual Symposium in 2020, physicians demonstrated our powerful remote capabilities with physician collaboration and remote procedures taking place between Lisbon and Milan. Telemedicine can be attractive in areas where the financial resources are present to acquire the equipment but not necessarily the human resources to use it. This allows these institutions to treat their patients with an expert working remotely, pending regulatory approval.

How are you supporting healthcare institutions in this transition to telerobotics?

L.J.: As strongly as we feel about establishing robotic technology in every electrophysiology lab, our vision is to enable remote support as a new standard of care. We offer a variety of TeleRobotic educational events and work with every hospital so they can benefit from the new technology.

To what extent do you combine the experience and expertise of the most seasoned operators to benefit as many people as possible?

L.J.: We share this experience and expertise when we invite doctors to visit Centers of Excellence during their training phase - physically or remotely - or when they need special advice. In these Centers of Excellence, expert operators have developed an exemplary practice. These physicians have contributed to improving user satisfaction and clinical outcomes through practice and research. The Stereotaxis training and education program is built on best practice experience of thousands of procedures.

