

SIS ALMANAC ONLINE:

STEREOTAXIS

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INTRODUCTION

Advances in Interventional Cardiology have occurred at lightning pace over the past decade. Indeed, few other medical specialties have evolved as swiftly. One of the most promising technologies to date is in the realm of magnetic navigation (MN). MN is an interaction between a magnetic field of specified direction and magnitude, positioned externally to the patient and a tiny magnet in the tip of an interventional device. The end result is alignment of the distal tip of the magnet on the interventional device with the field direction of the external magnet, literally steering catheters and guidewires through the complex pathways within the heart and the coronary vasculature.

There are a number of traditionally invasive procedures, interventional and electrophysiology challenges that will potentially benefit from this modality, including atrial fibrillation ablation, chronic total occlusion, complex and tortuous coronary anatomy, angiogenesis, percutaneous cardiac bypass graft, and percutaneous mitral valve repair.

Stereotaxis, Inc.'s Niobe™ System is the world's first digital, magnetic navigation system of its kind that permits the operator to digitally navigate catheter and guidewire-based devices along the complex paths of the heart and vasculature. The system is comprised of the following components that are fully integrated into the cardiac catheterization laboratory:

- 1) Niobe™ magnetic navigation system (MNS)
- 2) AXIOM Artis dFC™ (Siemens flat-detector fluoroscopic imaging technology system)
- 3) Digital control station with operator interface

This technology platform combines high-resolution image quality with the potential for more precisely guided catheters. In effect, the system integrates useful information with the ability to navigate interventional devices with more accuracy and speed.

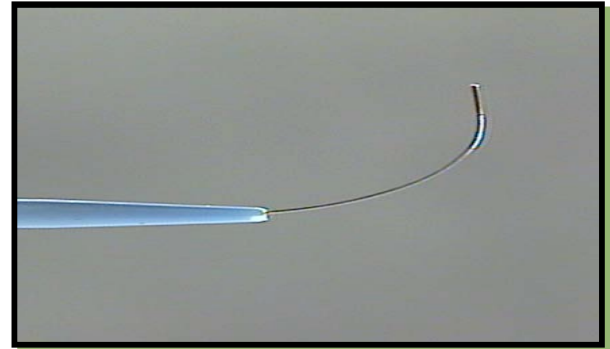
BACKGROUND

The Stereotaxis Niobe™ MNS consists of two computer controlled permanent magnets positioned and aligned externally to each side of the patient and is controlled via an integrated navigation software (Stereotaxis' Navigant™ software). The magnets create a relatively uniform (.08 Tesla) magnetic field of approximately 15 cm in diameter inside the chest of the patient. This magnetic field volume can be steered in any direction.



The tips of the special Stereotaxis guidewires (Cronus® 0.014 inch guidewire) and catheters contain small magnets with pulses interacting with an external 15cm magnetic field causing the tip to deflect when both energy fields are not in alignment. The steering within three-dimensional space is controlled by the operator thru a navigation software console located at the table and in the control room.

With commands given from the console, the outer magnets reorient the direction of the external field which results in a predictable amount of tip deflection in the catheter or guidewire. This approach allows for 360-degree rotation of the guidewire or catheter and can provide greater precision, deflection and control than with manual conventional methods.



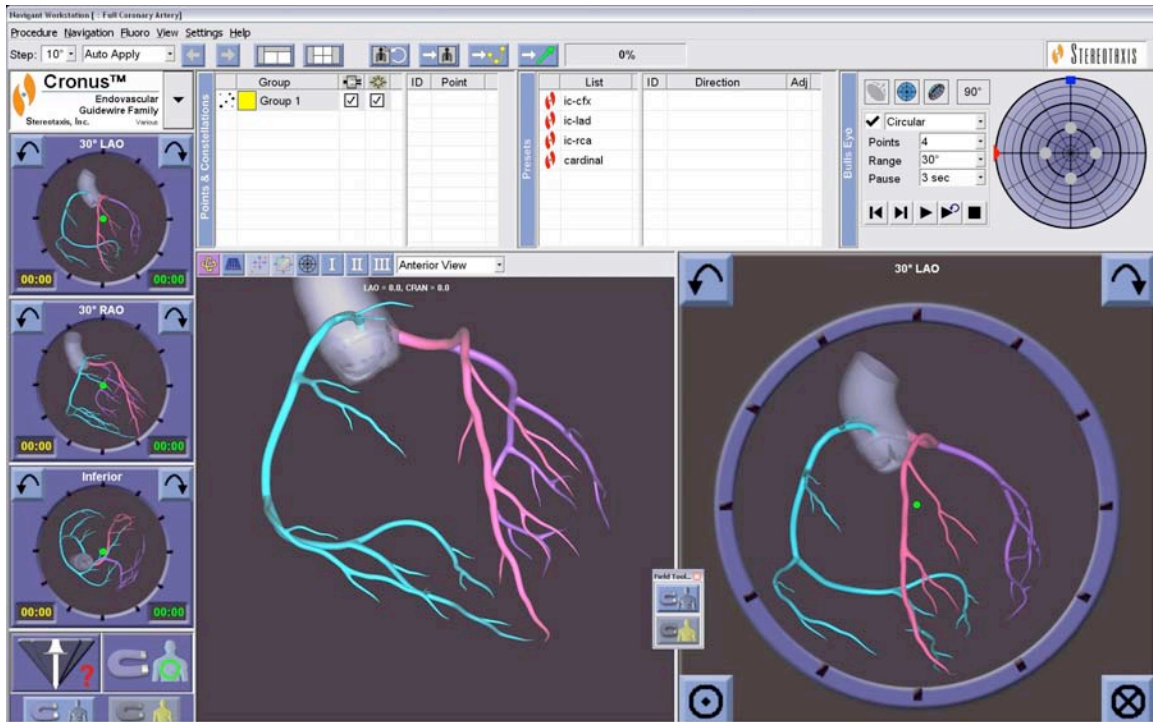
Stereotaxis Cronus 0.014" guidewire

The Niobe® System's Navigant™ software permits the operator to select the vessel of interest and initiate guidewire or catheter-tip orientation changes via a pre-set vessel navigation schematic that recommends vessel direction parameters.

If difficulty is encountered, the operator can make fine-tuning angulation adjustments using a “bull’s-eye” or transverse plane control. Three-dimensional target vessel schematics can also be utilized to create a path for a patient’s individual target vessel navigation.

For managing chronic total occlusions, the navigation software includes a “bull’s-eye” method for guiding the magnetic-tipped guidewire. This feature allows the cardiologist to very precisely manipulate the distal tip of the wire within any vessel into very eccentric or small microchannels of occlusions as well as to navigate after crossing the distal cap of the vessel.

Lastly, the navigation software offers the opportunity for storage of directions for later recall (e.g., wire angulation positions), enabling the physician to re-navigate the wires and catheters to their exact previous position.



Within interventional cardiology, magnetic-assisted navigation provides the opportunity to quickly and precisely traverse highly angulated, tortuous vessels.

The Stereotaxis magnetic navigation system can overcome vessel turns greater than 90 degrees. Extreme angulations are difficult to navigate with conventional guidewires due to their tendency to prolapse at the vessel's angle.

Additionally, the system has demonstrated effectiveness in traversing tortuous anatomy involving multiple tight turns with a single magnetically deflectable guidewire. It does this without the need to change wires or withdraw the guidewire to adjust the curvature of the tip.

Stereotaxis also offers a technology software platform designed for electrophysiology challenges.

Special guidewires (i.e., Cronus® 0.014" guidewire, available for both magnetically navigated interventional cardiology and electrophysiology applications) and catheters (i.e., Tangent™ Electrophysiology mapping catheter which uses magnetic torque to maintain contact with targeted endocardial tissue throughout the cardiac cycle) are available for these purposes.

The development of "retrograde" and "target-based" navigation tools to further improve electrophysiology navigation is currently under way.

Two clinical investigations involving magnetic navigation technology are currently being reviewed as U.S. FDA-approved Investigational Device Exemptions (IDEs). The Helios™ catheter is a magnetic cardiac ablation catheter designed for the diagnosis and treatment of supraventricular tachycardia and the Iliad® interventional guidewire is used in the treatment of patients undergoing neurovascular procedures.

Magnetic assisted intervention is an emerging technology that may enable the interventional cardiologist to more successfully perform various complex interventional procedures. The continued evolution of this technology, along with the anticipated importation of computed tomography and magnetic resonance imaging images and the availability of additional magnetically enabled delivery systems, has the potential to further enhance and accelerate new therapeutic developments within interventional cardiology.

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