MediGuide™ Technology: Navigating Away from Live X-Ray

Clinical Compendium

MediGuide™ technology is the first and only solution to enable navigation of devices on pre-recorded X-ray images, allowing the physician to reduce the duration of live X-ray during a procedure. The ability to use pre-recorded X-ray images, instead of live X-ray during a procedure, is consistent with the radiation principle, As Low As Reasonably Achievable (ALARA). MediGuide technology addresses both the principle to reduce radiation exposure and the need to improve visualization and navigation in cardiac intervention procedures. This compendium outlines the latest clinical research and evidence generated using MediGuide technology to facilitate complex cardiac resynchronization therapy and electrophysiology procedures.
Enhanced Features Facilitate Electrophysiology Procedures

MediGuide™ technology integrates nonfluoroscopic catheter navigation into the environment of pre-recorded conventional 2D fluoroscopy. The system allows for precise, real-time catheter tracking within the cardiac chamber on pre-recorded X-ray images. The following studies build on the clinical evidence supporting the use of the MediGuide technology system to facilitate electrophysiology procedures.

MediGuide™ Technology Robustly and Accurately Tracks Catheter Location

- Swine were used to test the accuracy of the MediGuide system (n=4).
- After obtaining baseline cines, diagnostic and ablation catheters with MediGuide sensors were positioned in several locations within the heart.
- Key takeaway: Results showed that MediGuide technology accurately tracks real-time catheter location even when real-time heart and respiratory rates have changed.

First-in-man (FIM) Experience with the Magnetic Medical Positioning System (MPS) for Intracoronary Navigation

- This study investigated the safety and feasibility of the MediGuide™ system for intracoronary tracking (n=20).
- Performance was evaluated on a scale of 1 to 5; 5 indicated excellent superimposition with the vessel, while a score of 1 was given to assessments that had unacceptable performance.
- The mean score for tracking by projection on live fluoroscopy was 4.89 versus 3.58 by projection on recorded cine-loop.
- Key takeaways:
  - Length measurement of a 20 mm distance was significantly better with the MediGuide system (mean deviation of 0.6 mm=3%) versus standard tracking system (1.5 mm = 8%, p < 0.05).
  - No adverse events occurred; 3D reconstruction was possible in 13 out of 20 cases (65%) with an average score of 4.68.

Nonfluoroscopic Sensor-Guided Navigation of Intracardiac Electrophysiology Catheters within Prerecorded Cine Loops

- This study reported on the first-in-human application of the MediGuide system for 3D EP catheter tracking in full integration with conventional fluoroscopy imaging (n=1).
- The study tested clinical feasibility, stability and accuracy of the guided medical positioning system to perform nonfluoroscopic right and/or left atrial catheter positioning in patients presenting for diagnostic EP procedures and supraventricular tachycardia ablation.
- Key takeaways:
  - All catheters were positioned entirely nonfluoroscopically at the intracardiac location.
  - Total fluoroscopy time was 30 seconds; radiography was only used for initial cine loop acquisition and for confirmation of catheter position.

Initial Experience in Ablation of Typical Atrial Flutter Using a Novel Three-Dimensional Catheter Tracking System

- This study reported on the first clinical experience for ablation of cavo-tricuspid isthmus (CTI) dependent flutter using MediGuide technology (n=10).
- Coronary sinus cannulation was performed using two steerable diagnostic EP catheters and cavotricuspidal isthmus reconstruction was performed with the EnSite™ Velocity™ System.
- Ablation was performed with a conventional 8 mm tip ablation catheter.
- In 10 out of 10 (100%) patients, both sensor-equipped catheters could be tracked nonfluoroscopically.
In 9 out of 10 (90%) patients, the CS cannulation was performed using the MediGuide technology only.

**Key takeaways:**
- Complete isthmus block was achieved in all patients (100%).
- Mean fluoroscopy time was 2.5 ± 2 min with four patients (40%) obtaining fluoroscopy times of < 60 seconds. Mean procedure time was 55 ± 9 min.

**Atrial Flutter Ablation using MediGuide™ Nonfluoroscopic Catheter Tracking System: A Novel Technology to Reduce Radiation Exposure**


- This case report described the first use of MediGuide technology for the ablation of a typical right atrial flutter in North America (n=1).

**Key takeaways:**
- Total fluoroscopy time was 3 minutes.
- The patient tolerated the procedure well and was discharged the next day.

“Conventional” Isthmus Ablation without Fluoroscopy


- This case report presented the University of Leipzig’s first experience in atrial flutter ablation using MediGuide Enabled™ ablation catheters.
- A 69-year-old male was admitted with typical atrial flutter for isthmus ablation.
- Total procedure time from acquisition of the cine loops to withdrawal of the sheaths was 45 minutes, with an overall fluoroscopy time of 6 s and a radiation dose of 32 cGy/cm².
- No further fluoroscopic support was used following the acquisition of the two cine loops.

**Key takeaway:** MediGuide technology seamlessly allows for nonfluoroscopic catheter visualization within the workflow of conventional invasive electrophysiology procedures.
**MediGuide™ Technology Accurately and Reliably Tracks Sensor-enabled Tools for LV Lead Placements**

The MediGuide™ technology is an electro-magnetically guided navigation system that is used as an adjunct to fluoroscopy. It uses a pre-recorded cine loop and reduces the fluoroscopy time and exposure to patients, physicians and staff. The following studies build on the clinical evidence to support the use of MediGuide technology to reduce fluoroscopy times and facilitate LV lead placements in CRT procedures.

### 3D Cardiovascular Navigation System: Accuracy and Reduction in Radiation Exposure in Left Ventricular Lead Implant


- This was a preclinical study involving six canines; data were collected by three different implanters in three standard fluoroscopic projections (RAO, LAO, AP) and at three different heart rates (60-140 bpm).
- There was no significant difference in LV lead delivery time between the implants guided by the MediGuide system and conventional implants (233 ± 195 vs. 186 ± 177 seconds, p=0.27)
- Mean fluoroscopy time and radiation exposure were significantly lower for implants guided by the MediGuide System compared to conventional implants:
  - ~ 60% less fluoroscopy time: 52 ± 120 vs. 129 ±118 seconds, p<0.001
  - ~ 72% reduced radiation exposure: 13.8 ± 32.4 vs. 49.2 ± 45.3 μGy/m2, p=0.03
- Overall median displacement accuracy was 0.48 ± 0.94 mm from the target branch; median separation was 0.00 mm.
  - System accuracy was not affected by various C-arm angulations. RAO was 0.36 ± 0.82 mm, LAO was 0.48 ± 0.93 mm, and AP was 0.59 ± 1.04 mm.
  - System accuracy was also unaffected by heart rate variations up to ±30 bpm from the original heart rate that was used to acquire the CS venogram.
- **Key takeaway:** This article demonstrates the accuracy of MediGuide technology in a lab environment to successfully guide and place LV leads with a significant reduction of fluoroscopy and no impact on procedure times.

### Dynamic 3D Model of Coronary Sinus Anatomy Utilizing 3D Cardiovascular Navigation System


- This study reported on the use of MediGuide™ technology to accurately model CS anatomy by performing contrast enhanced venography at four C-arm orientations on a sedated canine (n=1).
- Automatic computation of dynamic 3D models over a cardiac cycle using the MediGuide AngioSurvey™ feature from both LAO and AP views were performed.
- **Key takeaway:** Results showed that differences between the MediGuide AngioSurvey 3D feature CS model vs. reference venogram did not exceed 0.5 mm. LAO 40 was 0.1 ± 0.06 mm while AP was 0.2 ± 0.14 mm, confirming that the AngioSurvey 3D feature allows for sub-millimeter accurate construction of CS models.
Left Ventricular Lead Implantation Guided by Sensor-based Electromagnetic Navigation in a Patient with L-transposition of the Great Arteries


- The authors reported on the use of MediGuide technology to guide LV lead placement in a 31-year-old male with a congenital heart defect (n=1).
- Echocardiography revealed dilatation of the systemic RV, reduced RV ejection fraction (45%), moderate tricuspid regurgitation and signs of ventricular dyssynchrony.
- The patient was upgraded from a dual-chamber pacemaker to an implantable ICD with biventricular pacing; nonfluoroscopic intubation of the coronary sinus and subselection of the target vein was achieved with MediGuide technology.
- **Key takeaway:** MediGuide technology helps guide LV lead placement and increases spatial anatomic orientation during CRT procedures in patients with complex cardiac and CS venous anatomy.

CRT Implant Using a New Sensor-based Navigation System Results from the First Human Use (FHU) Study


- This study reported the initial results of the first human clinical study evaluating MediGuide technology in CRT implantation (n=15).
- A total of 15 patients (average age of 66 ± 8 years, with 53% of the patient's male) with an indication for CRT were implanted using the MediGuide system and followed for 4 weeks, with fluoroscopy time for LV lead deployment measured from CS cannulation to withdrawal of CS sheath.
- Results from this initial study showed that the CRT system was successfully implanted with a lateral LV lead position in all patients without severe adverse events. Total procedure time was 98 minutes, total fluoroscopy time (skin to skin) was 5.2 minutes, while fluoroscopy time for LV lead deployment was 2.9 minutes.
- **Key takeaway:** This first human study using the MediGuide system for CRT implantation showed the safe and successful LV lead placement with an indication for substantially reduced fluoroscopy time.
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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