

GMPS NAVIGATION AND MAPPING IN ABLATION AND CRT PROCEDURE

A black and white close-up photograph of a person's face, likely a patient, wearing a surgical mask and a hood. A medical device, possibly a catheter or probe, is inserted into the patient's mouth. The lighting is dramatic, highlighting the contours of the face and the metallic surfaces of the equipment.

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MEDIGUIDE™ TECHNOLOGY OVERVIEW: NAVIGATING AWAY FROM LIVE X-RAY

MediGuide™ Technology is a unique solution that enables navigation of devices on pre-recorded X-ray images, addressing the needs of physicians to reduce fluoroscopy time and radiation dose, and to improve visualization and navigation in cardiac intervention procedures.

X RAY 0 IS IT POSSIBLE?



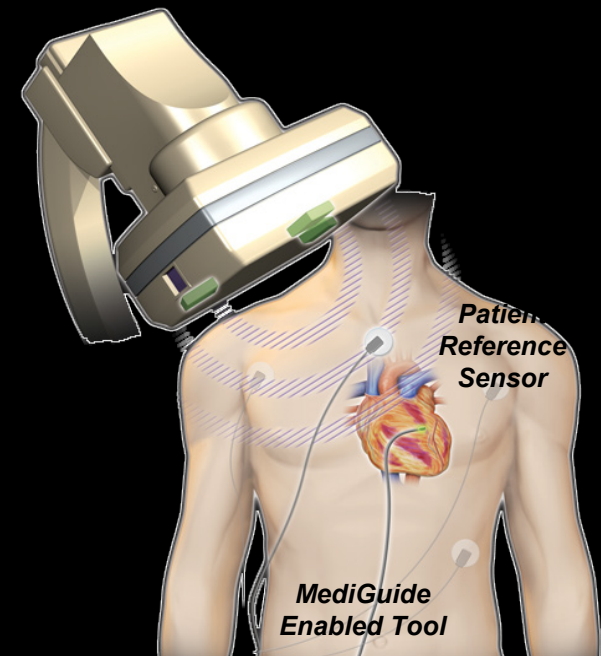
ME AT THE END OF THE DAY....

HOW I WOULDN'T APPEAR.....



MEDIGUIDE™ TECHNOLOGY METHODOLOGY

- MediGuide Technology uses a low-powered electromagnetic field to locate device-based sensors in 3-D space.
- Position and orientation of devices are displayed on the corresponding pre-recorded X-ray images.
- With the use of pre-recorded X-ray images, MediGuide Technology creates a real-time clinical environment that:
 - Adjusts automatically for changes in heart rate, respiratory motion and patient movement
 - Provides bi-plane visualization with uni-plane equipment
 - Adds additional perspective and improves workflow during catheter navigation



COMPONENTS OF MEDIGUIDE™ TECHNOLOGY



MEDIGUIDE™ INTEGRATION WITH ELECTROPHYSIOLOGY PRODUCTS

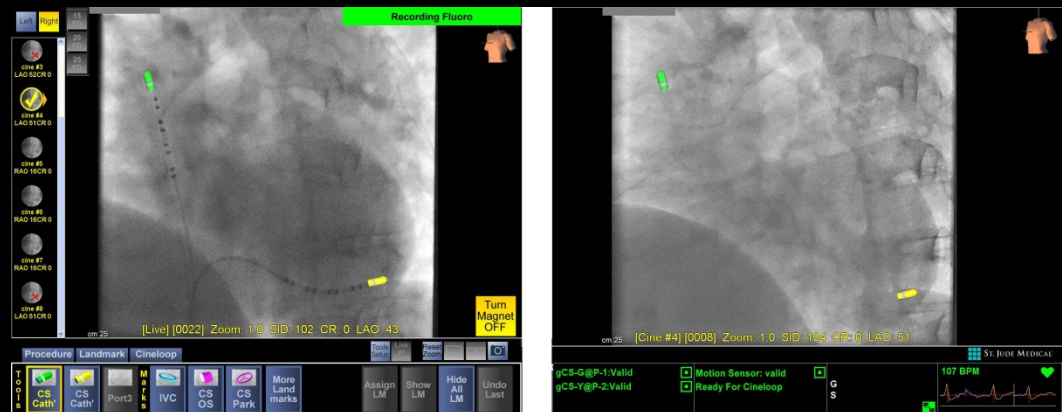
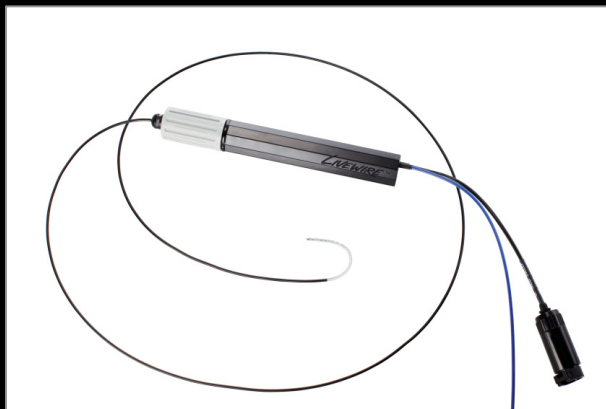
Livewire™ Diagnostic Catheter, MediGuide Enabled™

Safire™ Duo Ablation Catheter, MediGuide Enabled™

Cool Path™ Duo Ablation Catheter, MediGuide Enabled™

Flex ability SE

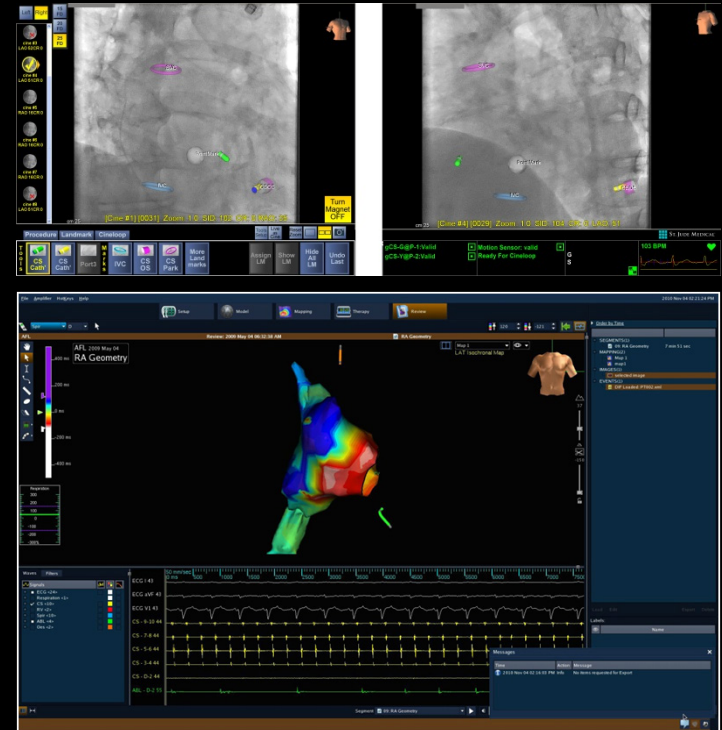
- Miniature sensors allow the position and orientation of the device to be visualized in real-time on both live and pre-recorded fluoroscopy.
- Catheter location is accurately tracked within 1 mm and 1 degree.
- Catheter features include automatic steering lock, a wide range of tip deflection and predictable handling characteristics.



INTEGRATION WITH ENSITE™ VELOCITY™ CARDIAC MAPPING SYSTEM

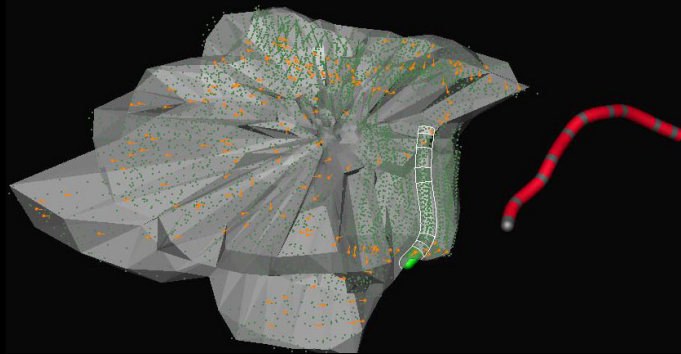
MediGuide™ Technology Interface Module

- Easily integrates with the EnSite Velocity system and maintains existing workflow
- Displays the position and orientation of MediGuide Enabled™ devices in both systems simultaneously
- Automatically detects and adjusts for movement of the internal system reference
- Updates the EnSite Velocity system chamber model based on the MediGuide Technology coordinate system

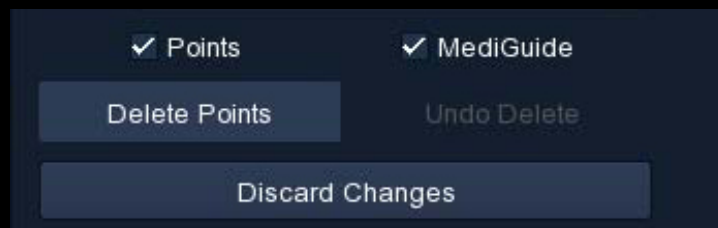


MEDIGUIDE™ TECHNOLOGY AND ENSITE™ NAVX™ TECHNOLOGY MODEL POINTS

Velocity™ System will collect both EnSite™ NavX™ Technology (green) and MediGuide™ Technology (orange) points



Note: If orange MediGuide Technology points are not being displayed, verify that the status indicators are displaying valid and verify the MediGuide Technology points box is checked



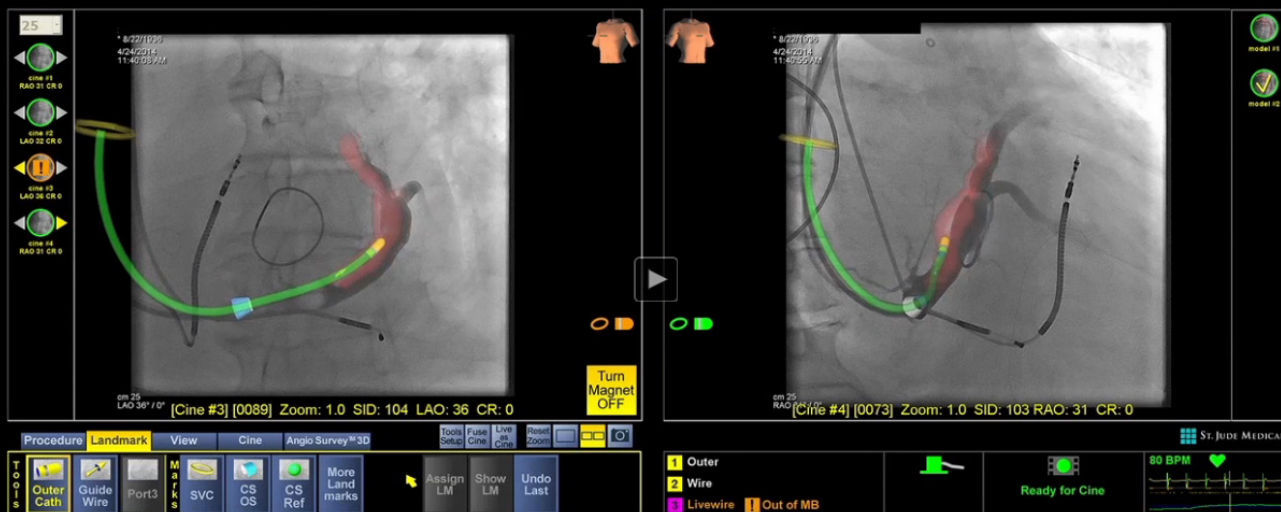
MEDIGUIDE™ INTEGRATION FOR CRT PROCEDURES

CPS Direct™ Slittable Outer Guide Catheter, MediGuide Enabled™

CPS Aim™ Slittable Inner Catheter, MediGuide Enabled™

CPS Excel™ Guidewire, MediGuide Enabled™

- Slittable, non-steerable 8 F outer catheter facilitates CS cannulation and LV lead delivery.
- Slittable, nonsteerable 5.9 F inner catheter allows for the sub-selection of target branches and delivery of a 4 F LV lead.
- Sensor-embedded 0.36 mm PCI guidewire can be used for target vein access and over-the-wire lead deployment.



SUMMARY OF CLINICAL EVIDENCE USING MEDIGUIDE™ TECHNOLOGY TO FACILITATE EP PROCEDURES WITH REDUCED FLUOROSCOPY

Study, Year	Procedure Type(s)	Fluoroscopy Time (no. of patients per group)			Radiation Dose		
		MediGuide	Conventional	P-value	MediGuide	Conventional	P-value
<u>Mansour, 2015¹</u>	TS puncture (N = 32)	0.48 min (n = 16)	5.9 min (n = 16)	< 0.0001	13.8 mGy	390 mGy	< 0.001
<u>Malliet, 2015²</u>	AF ablation (n = 44)	12.5 min (n = 22)	21.5 min (n = 22)	< 0.0001	1107 µGy·m²	2835 µGy·m ²	0.0001
	AFL ablation (n = 90)	0.8 min (n = 48)	9.9 min (n = 42)	< 0.0001	161 µGy·m²	1651 µGy·m ²	< 0.0001
<u>Schoene, 2015³</u>	AFL ablation (N = 40)	0.3 min (n = 20)	5.7 min (n = 20)	< 0.001	17.4 cGy·cm²	418 cGy·cm ²	< 0.001
<u>Sommer, 2014⁴</u>	AF ablation (n = 375)	2.8 min (N = 375)	NA	NA	789 cGy·cm²	NA	NA
<u>Vallakati, 2013⁵</u>	SVT ablation (N = 90)	8.3 min (n = 45)	21.2 min (n = 45)	< 0.001	685 mGy	1782 mGy	< 0.001
<u>Rolf, 2013⁶</u>	AF ablation (N = 80)	4.4 min (N = 80)	NA	NA	2115 cGy·cm²	NA	NA
<u>Sommer, 2013⁷</u>	SVT ablations (N = 1889)	0.5 min (n = 24)	10.2 min (n = 1865)	< 0.001	187 cGy·cm²	996 cGy·cm ²	< 0.05
<u>Sommer, 2013⁸</u>	AFL ablation (n = 10)	2.5 min (N = 10)	NA	NA	1355 cGy·cm²	NA	NA
<u>Rolf, 2012⁹</u>	AF ablation (N = 98)	16 min (n = 49)	31 min (n = 49)	< 0.001	7363 cGy·cm²	14,453 cGy·cm ²	< 0.001

Right click on underlined author, year and select "Open Hyperlink" to go directly to the summary slide for the study

MEDIGUIDE™ SYSTEM USE DURING AF AND AFL ABLATION ASSOCIATED WITH SIGNIFICANT RADIATION EXPOSURE REDUCTION

- Prospective study using the MediGuide System versus conventional fluoroscopic guidance in patients undergoing ablation for atrial fibrillation (N = 44) or atrial flutter (N = 90).
- The use of the MediGuide System was associated with significant reductions in fluoroscopy, and reduced radiation exposure by 60% during AF ablation and 90% during AFL ablation procedures when compared to conventional guidance.

AF Ablation Procedures	MediGuide (N = 22)	Conventional (N = 22)	P-value
Procedure Duration (min)	168.5 [135.8, 180.0]	159.5 [136.5, 184.3]	p = 0.9954
Total Fluoroscopy time (min)	12.5 [7.6, 17.4]	21.5 [15.3, 23.0]	p < 0.0001
Radiation dose (μGy·m ²)	1107 [9.6, 2033]	2835 [1688, 3855]	p = 0.0001
AFL Ablation Procedures	MediGuide (N = 48)	Conventional (N = 42)	P-value
Procedure Duration (min)	89.5 [71.7, 110.3]	82.5 [65.0, 111.5]	p = 0.4286
Total Fluoroscopy time (min)	0.8 [0.4, 2.5]	9.9 [5.1, 22.5]	p < 0.0001
Radiation dose (μGy·m ²)	161 [65, 537]	1651 [796, 4569]	p < 0.0001

RANDOMIZED STUDY SHOWS SIGNIFICANT REDUCTION IN RADIATION EXPOSURE DURING AFL ABLATION WITH MEDIGUIDE™ SYSTEM

- The use of the MediGuide System was associated with significant reductions in fluoroscopy time and radiation dose versus conventional fluoroscopic guidance in this first prospective randomized study in patients undergoing typical atrial flutter ablation procedures (N = 20 patients per group).
- Freedom from atrial flutter at 6 months was similar between the two groups: 19/20 (95%) in the MediGuide and 18/20 (90%) in the conventional group.
- This study supports the incorporation of non-fluoroscopic catheter tracking with MediGuide Technology in routine

AFL Ablation Procedures	MediGuide (N = 20)	Conventional (N = 20)	P-value
Procedure Duration (min)	49.5 [37, 65]	33.5 [26.3, 55.5]	p = 0.053
Total Fluoroscopy time (min)	0.3 [0.2, 0.48]	5.7 [4.2, 11.5]	p < 0.001
Radiation dose (cGy·cm ²)	17.4 [11, 206.6]	418.4 [277, 812.2]	p < 0.001

EXPERIENCE WITH MEDIGUIDE™ SYSTEM SIGNIFICANTLY IMPACTS REDUCTION IN FLUOROSCOPY EXPOSURE DURING EP PROCEDURES

- Largest study to date that reports on the safety of the MediGuide System in PVI procedures (n = 375).
- Data suggest that significant decreases in procedure time, fluoroscopy time and radiation dose could be associated with the operator's increased familiarity with the system over time.

PVI Procedures	Group I (first 50 cases)	Group II (last 50 cases)	P-value
Procedure time (min)	169 ± 49	128 ± 39	p < 0.001
Fluoroscopy time (min)	6.0 [4.1, 10.3]	1.1 [0.7, 1.5]	p < 0.001
Fluoroscopy dose (cGy·cm ²)	2363 [1413, 3475]	490 [230, 654]	p < 0.001

MEDIGUIDE™ SYSTEM REDUCES FLUOROSCOPY EXPOSURE DURING RF ABLATION AND MAPPING PROCEDURES (LESS-RADS REGISTRY)

- Prospective observational study evaluated the impact of MediGuide System vs. conventional mapping technologies in a variety of EP procedures, including RF ablation for atrial flutter, AVNRT and WPW, and EP studies with no ablation (n = 90).
- A significant 61% decrease in fluoroscopy duration was seen, with both experienced and less experienced MediGuide Technology operators.
- Procedure duration was also significantly reduced by 27% in this study with MediGuide Technology in comparison to conventional technology.

SVT RF Ablation Procedures	MediGuide (N = 45)	Conventional (N = 45)	P-value
Procedure time (min)	103.8 ± 25.3	142 ± 55.8	p = 0.03
Fluoroscopy time (min)	8.25 ± 4.9	21.2 ± 14.8	p < 0.001
Fluoroscopy density (μGy·m ²)	7079 ± 7072	18857 ± 33647	p < 0.001
Fluoroscopy quantity (mGy)	685 ± 751	1782 ± 5153	p < 0.001

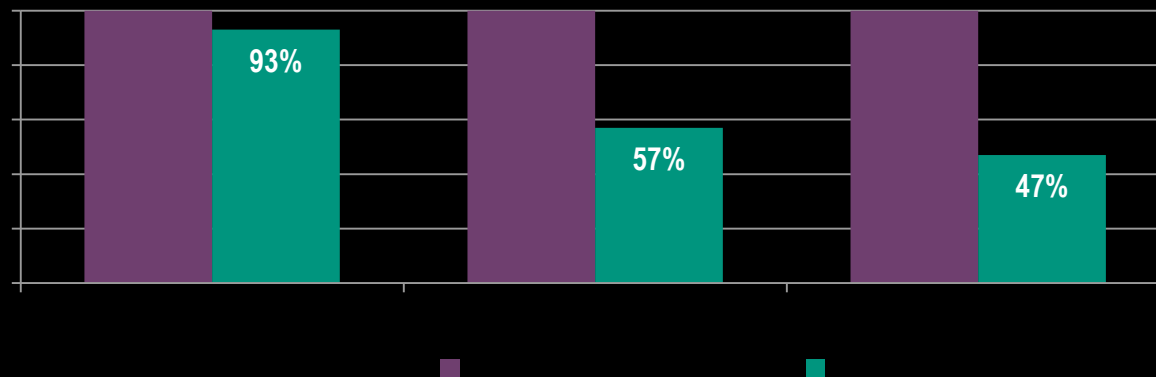
MEDIGUIDE™ SYSTEM INITIAL EXPERIENCE IN PEDIATRIC SUPRAVENTRICULAR TACHYCARDIA ABLATION

- First pediatric ablation series using MediGuide Technology integrated into the EnSite™ Velocity™ 3-D mapping system.
 - MediGuide Technology required minimal radiation exposure (comparable to “non-fluoroscopic” ablation with the EnSite Velocity system) and resulted in a substantial reduction in radiation exposure compared to conventional fluoroscopic ablation.
 - MediGuide Technology improves accuracy of the EnSite Velocity 3D mapping system, resulting in fewer test ablations

Pediatric SVT Ablation Procedures	MediGuide with EnSite (N = 38)	Fluoro with EnSite (N = 134)	P-value vs. MediGuide	Non-fluoro with EnSite (N = 168)	P-value vs. MediGuide
Median Total Procedure time (min)	154	164	P = 0.5	175	P = 0.5
Median Fluoroscopy Time (min)	0.4	10.4	p < 0.001	0	P = 0.04
Median Radiation Dose (μGy·m ²)	40	303	p < 0.001	0	p < 0.001
Median Mapping Time (min)	18	34	p < 0.003	23	P = 0.2
Median Number of Test Lesions	1	4	p < 0.004	2	P = 0.03

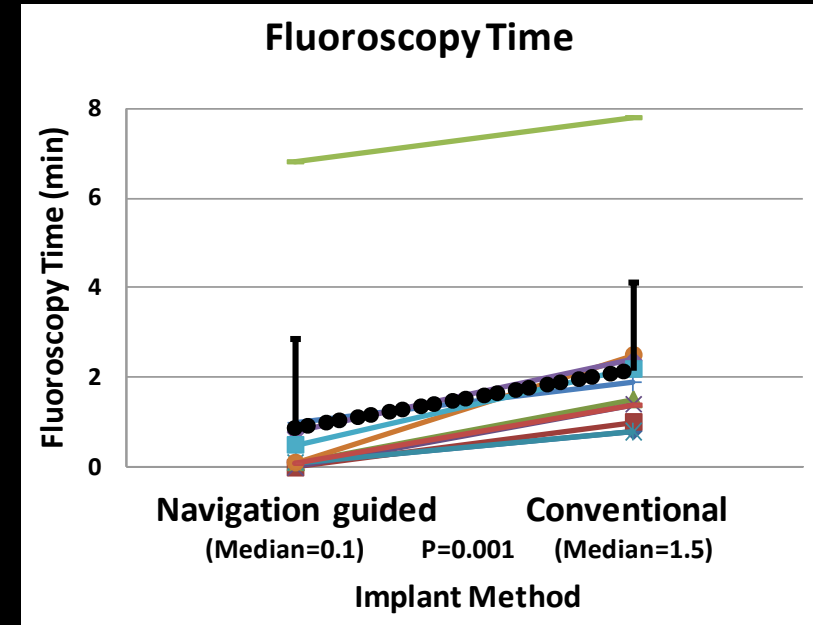
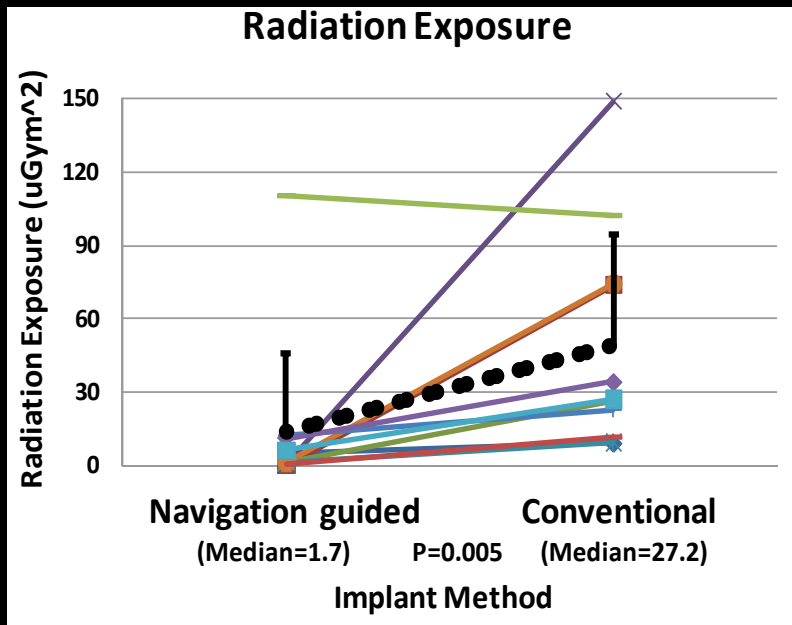
MEDIGUIDE™ SYSTEM SAFETY AND FEASIBILITY FOR RADIATION REDUCTION IN VENTRICULAR TACHYCARDIA ABLATION

- Retrospective 2:1 case-matched comparison of MediGuide System (n = 21 patients) vs. conventional 3-D system (n = 42 patients) for RF ablation of VT
 - Mean fluoroscopy time (15 ± 8.39 vs. 8.6 ± 3.83 minutes, $p = 0.0001$) and radiation dose ($3,733 \pm 3,429$ vs. $1,747 \pm 1,770$ $\mu\text{Gy}\cdot\text{m}^2$, $p = 0.008$) were significantly reduced by the use of MediGuide Technology when compared to conventional VT ablation procedures.
 - Mean procedure duration using MediGuide Technology was reduced by 16 minutes.
- The use of the MediGuide System is feasible and safe in VT ablation, significantly reducing fluoro time and radiation



Preclinical Study: MediGuide™ reduces fluoroscopy time / radiation exposure in LV lead placement

- LV lead placement was performed by three operators using both Conventional and MediGuide™ approaches in random order
- Total fluoroscopy time, radiation exposure and lead delivery time were recorded from the time of CS cannulation to the time of final LV lead placement



Legend:
- Each line represents a CS branch
- Dotted black line with vertical bars represents mean+SD

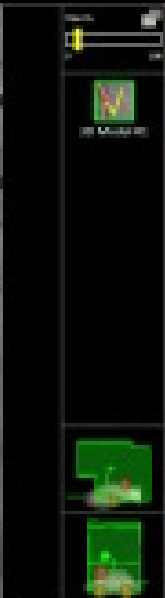
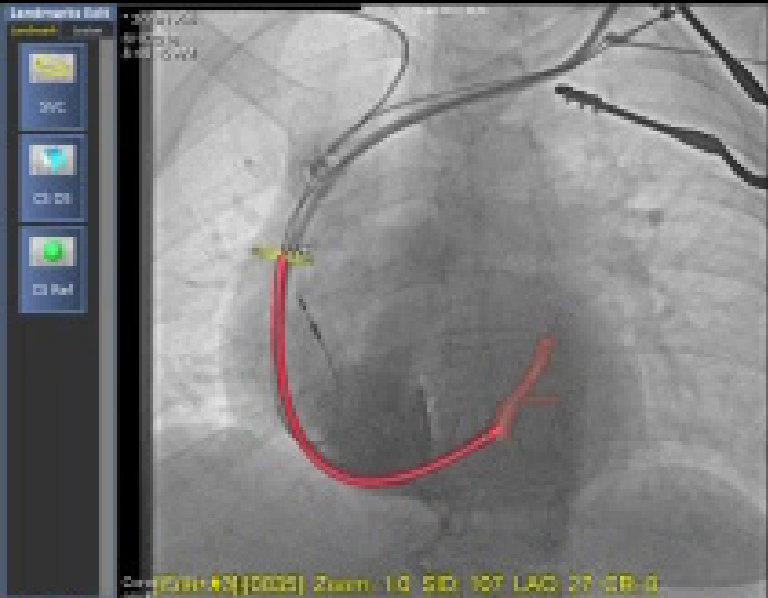
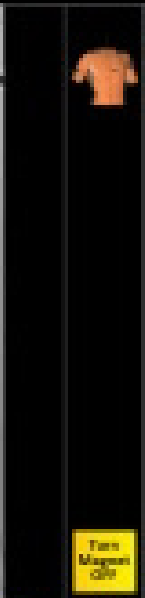


The MediGuide™ system resulted in a 93% reduction in median values of fluoroscopy time and a 94% reduction in median values of radiation exposure

OUR EXPERIENCE CRT

Incannulation of coronary sinus without x ray





Procedure: **Tablomat** View Case

Buttons: **CPA Wire** **Outer** **Leadwire** **Port4** **Port5** **Port6** **Hide All List** **Hide All LM text**

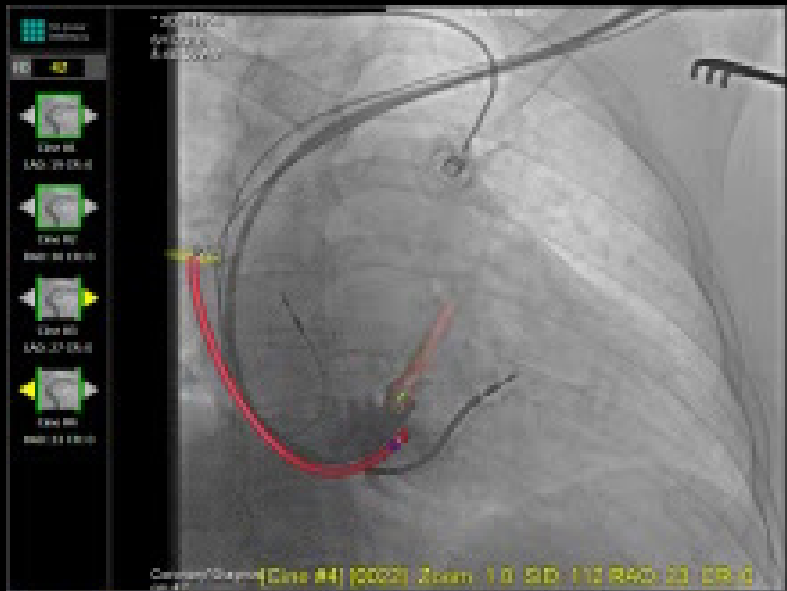
CPA Wire **Out of MB**

Outer **Out of MB**

Leadwire **Out of MB**

Ready for cine

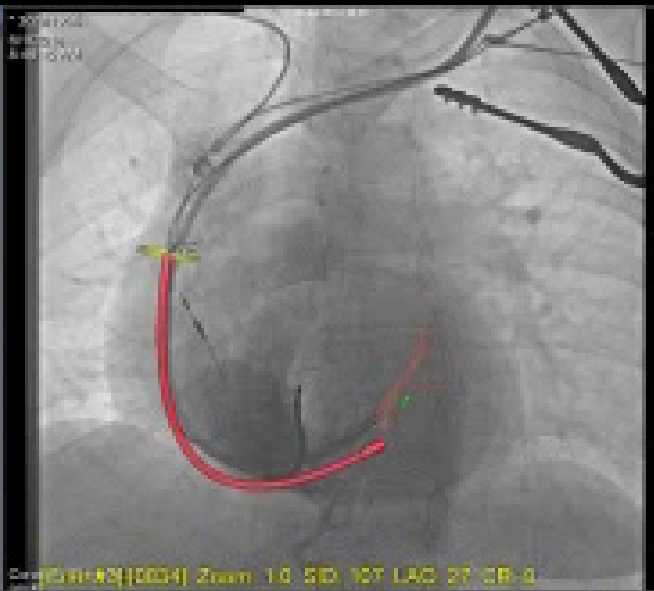




Landmarks Edit

- APC
- CI CR
- CI Ref

Turn Magnet On



ECG (M) (M)

ECG (M) (M)

Procedure Landmark View Case

Angio Suite™ 3D Imaging Workstation

ECG Print Outlines Front Front Front

Hide All List Hide All LM List

CPS follow

Center

Ultrasonic

Out of MR

Ready for cine



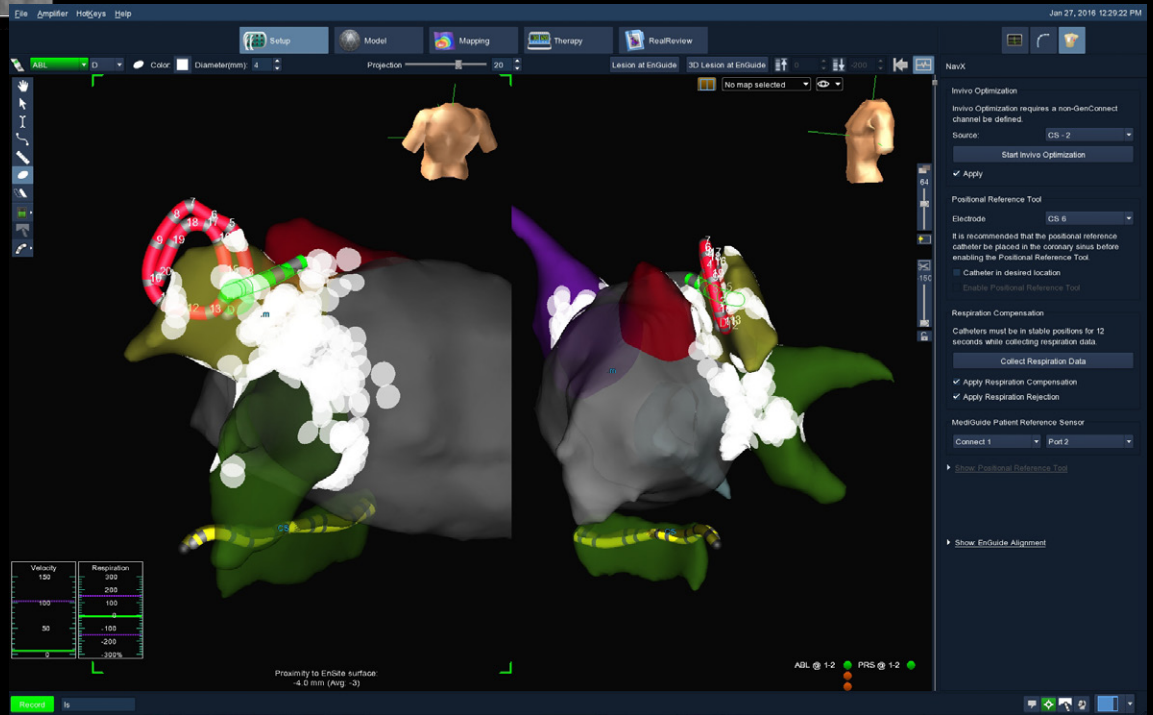
AF ABLATION : OUR EXPERIENCE

The screenshot displays a 3D anatomical map of the heart's left atrium. Key features include:

- LAO 35 CR 0**: Good
- RAO 27 CR 0**: Good
- tsp2 RAO 0 CR 0**
- Abi RSPV RAO 0 CR 0**
- Abi LIPV RAO 0 CR 0**
- Abi LSPV RAO 0 CR 0**

Labels on the map include: **RSPV**, **RIPV**, **LSPV**, **PointMark**, **OS**, and **LIPV**. A catheter is shown in a blue and green position. A small human torso icon is visible in the top right corner. A yellow button labeled **Turn Magnet OFF** is in the bottom right. At the bottom, a toolbar contains buttons for **Tools Setup**, **Live as Cine**, **Reset Zoom**, **Un-Crop**, **Port1**, **Abi Cath'**, **Port3**, **Marks**, **IVC**, **CS OS**, **CS Park**, **More LM**, **Assign LM**, **Show LM**, **Hide All LM**, and **Undo Last**. The status bar at the bottom reads: **[Cine #33] [0028] Zoom: 2.1 SID: 105 RAO: 0 CR: 0**.

AF ABLATION : OUR EXPERIENCE



RVOT MAPPING

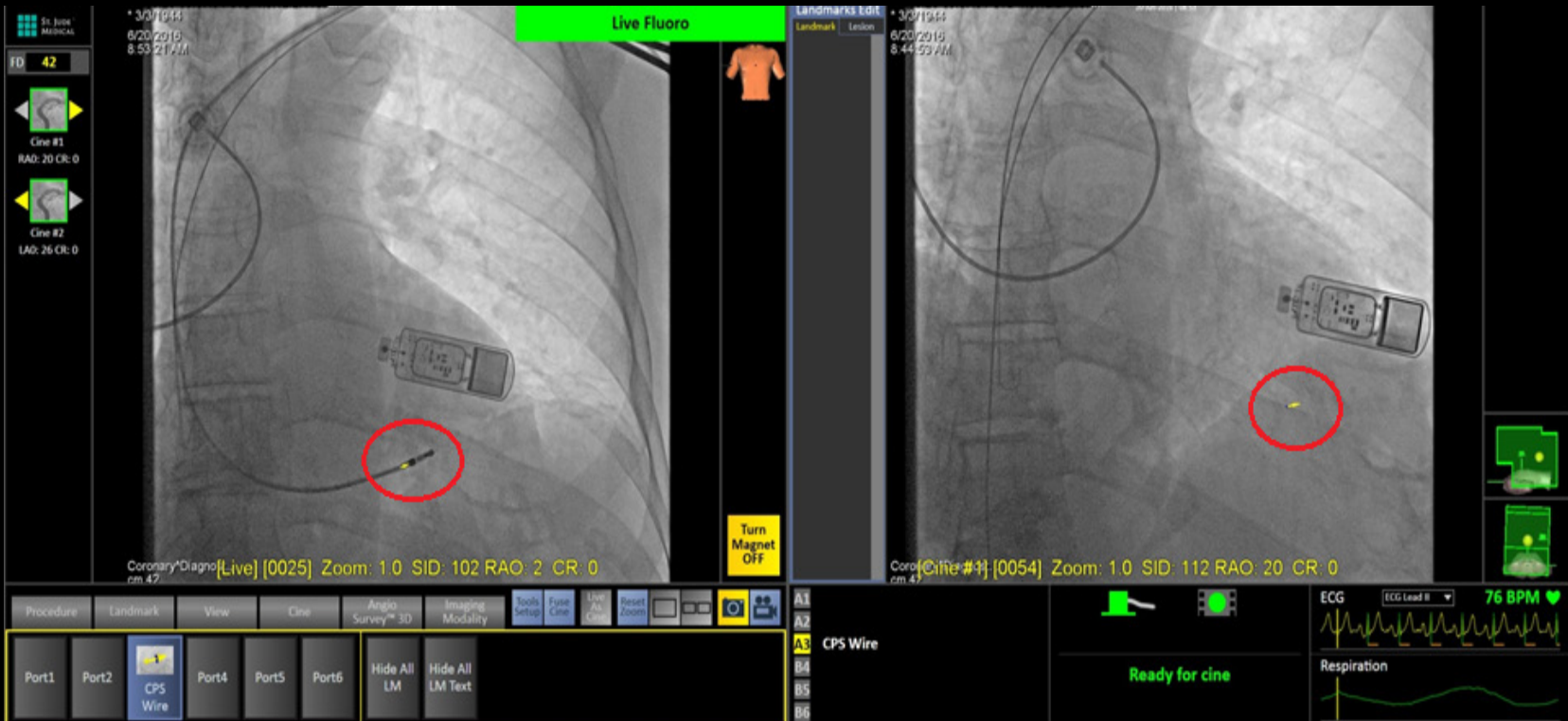


The Future

NEXT EXIT 

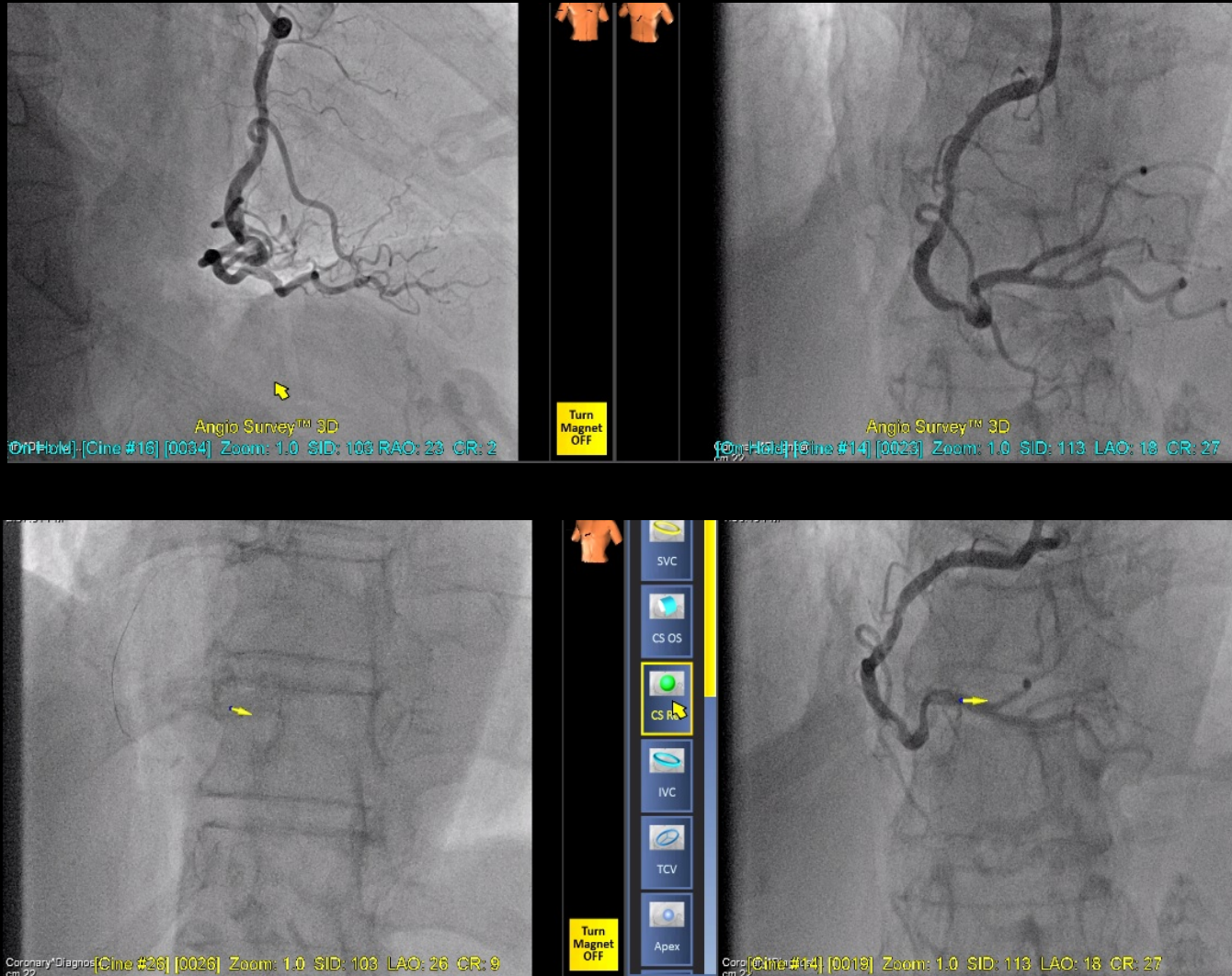
PM IMPLANT

Pacemaker implant with magnetic positioning of the lead: a feasibility case



INTERVENTIONAL CARDIOLOGY

Magnetic Positioning System for intracoronary navigation approach: a First-in-man (FIM) Prospective Experience



INTERVENTIONAL CARDIOLOGY

Magnetic Positioning System for intracoronary navigation approach: a First-in-man (FIM) Prospective Experience



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FROM ALL OF US



THANK YOU!!