Boston Scientific
Advancing science for life™

NAV-ENABLED ABLATION CATHETERS

NAV-ENABLED ABLATION CATHETERS

Select from these topics

RHYTHMIA HDx™ Mapping System

The RHYTHMIA HDx Mapping System's cutting-edge technology sets the standard of performance in high-definition mapping.

RHYTHMIA's automated rapid acquisition of high-density, high-resolution maps provides unparalleled clarity so that you can efficiently identify the ablation target even in the most complex substrate.

Only the combination of advanced noise-filtering hardware, a novel software algorithm that can process unlimited data and a high-resolution mapping catheter working together can achieve true high-definition mapping.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- ○ RHYTHMIA HDx™ Mapping System
- ● RHYTHMIA Catheter Portfolio
- ○ INTELLAMAP ORION Mapping Catheter
- ○ RHYTHMIA and INTELLANAV

RHYTHMIA™ Versatile Catheter Portfolio

The Boston Scientific nav-enabled catheter portfolio is a versatile suite of catheter tip technology combined with magnetic tracking for accuracy and efficiency. This offering is optimized for use with the high-resolution cardiac mapping system, RHYTHMIA HDx, giving you clarity for any complexity.

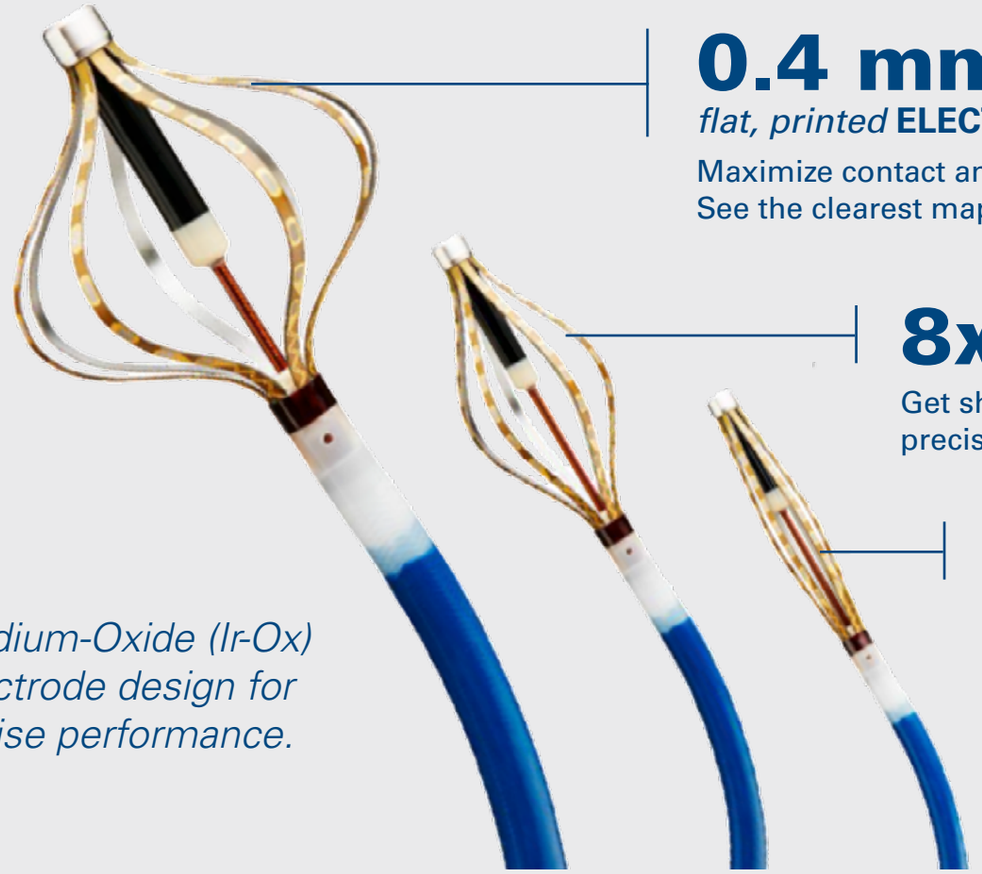
NAV-ENABLED ABLATION CATHETERS

Select from these topics

- RHYTHMIA HDx™ Mapping System
- RHYTHMIA Catheter Portfolio
- INTELLAMAP ORION Mapping Catheter
- RHYTHMIA and INTELLANAV

INTELLAMAP ORION™ High-Resolution Mapping Catheter

The world's first variable deployment basket catheter (3-22mm)



0.4 mm²
flat, printed **ELECTRODES**
Maximize contact and minimize far field.
See the clearest map possible.

8x *smaller* **ELECTRODES**[1]
Get sharper, better-quality signals for precise localization of arrhythmias.

3x *more* **ELECTRODES**
Collect more data more rapidly with 64 electrodes.

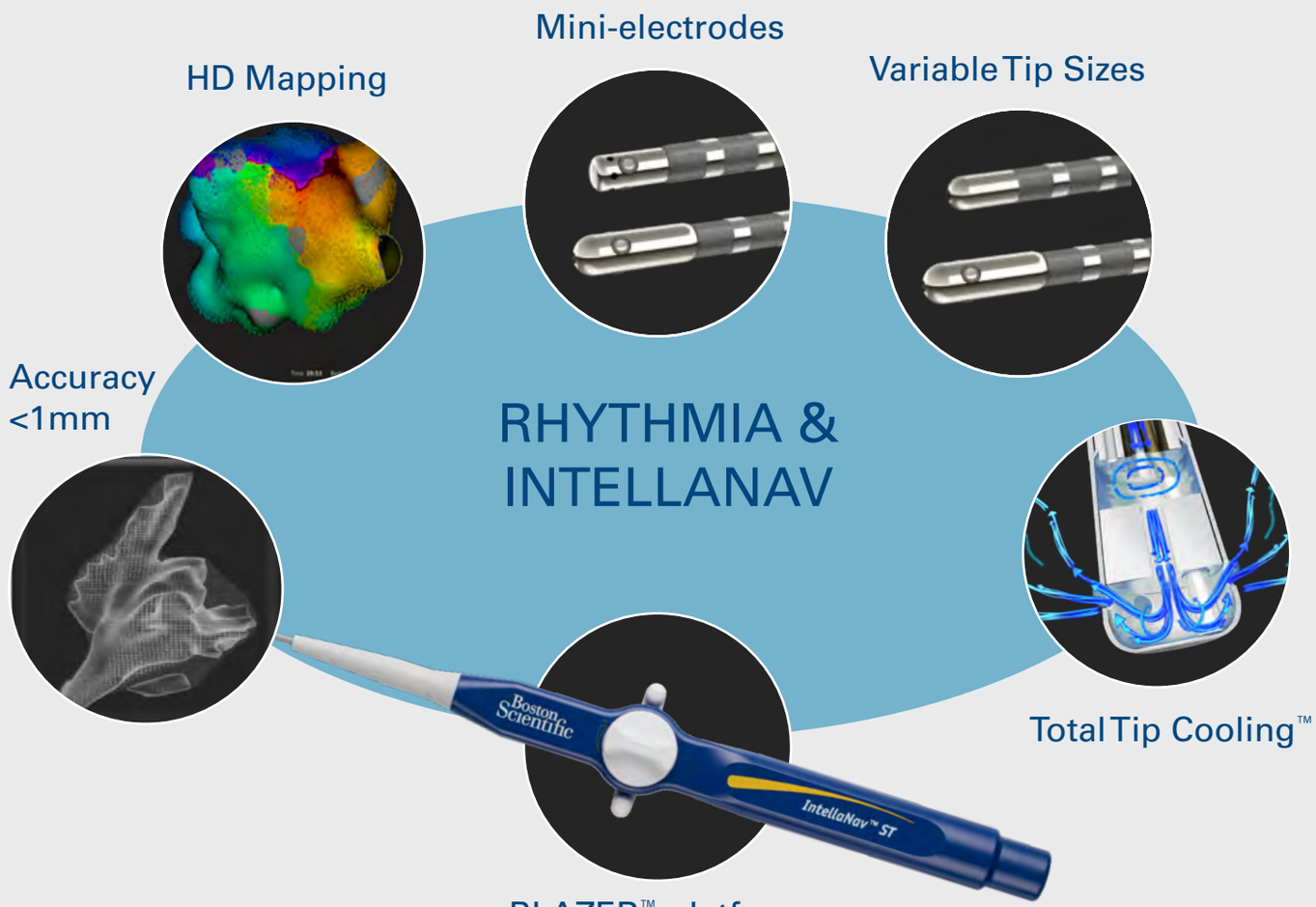
Unique, Iridium-Oxide (Ir-Ox) coated electrode design for optimal noise performance.

1. Calculation utilizes labeled size of electrodes on one commercially available electrophysiology mapping catheter.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

RHYTHMIA™ and INTELLANAV™



NAV-ENABLED ABLATION CATHETERS

Select from these topics

Unparalleled Clarity
Cool Performance
Confident Navigation

Cool Performance
Confident Navigation

Unparalleled Clarity
Performance
Accuracy

Familiarity
Performance
Accuracy

NAV-ENABLED ABLATION CATHETERS

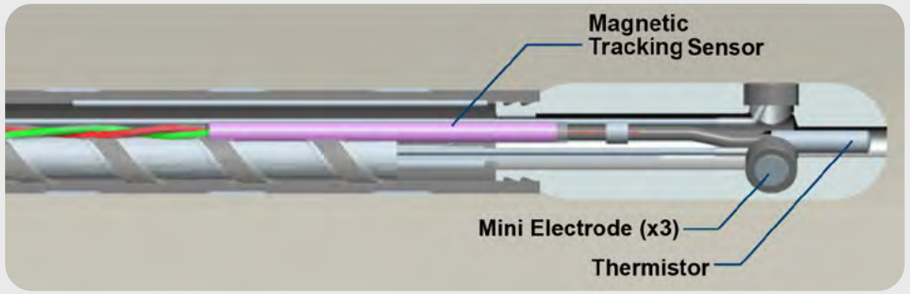
Magnetic Sensor

Embedded magnetic sensors delivered tracking accuracy of better than 1mm[1]

Leverages hybrid tracking system: simultaneously creates impedance field maps while mapping

INTELLANAV MIFI™ XP EXAMPLE
External View

Internal View



1. Bench data on file.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Enables Mapping Creation with RHYTHMIA™

Map Creation with INTELLANAV MIFI™ XP

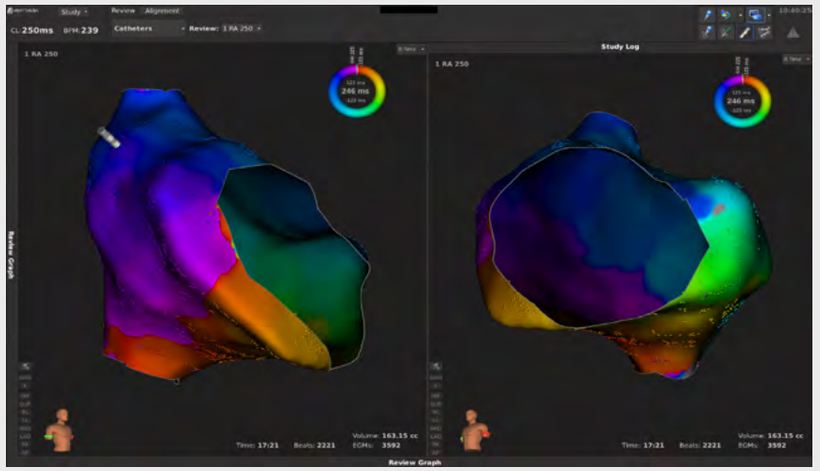
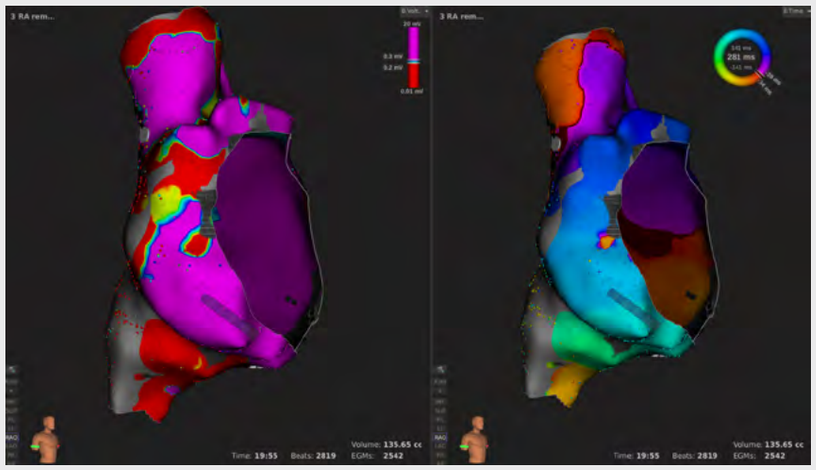


Image courtesy of Matt Ostrom, MD, Torrance Memorial Hospital, Torrance, CA.

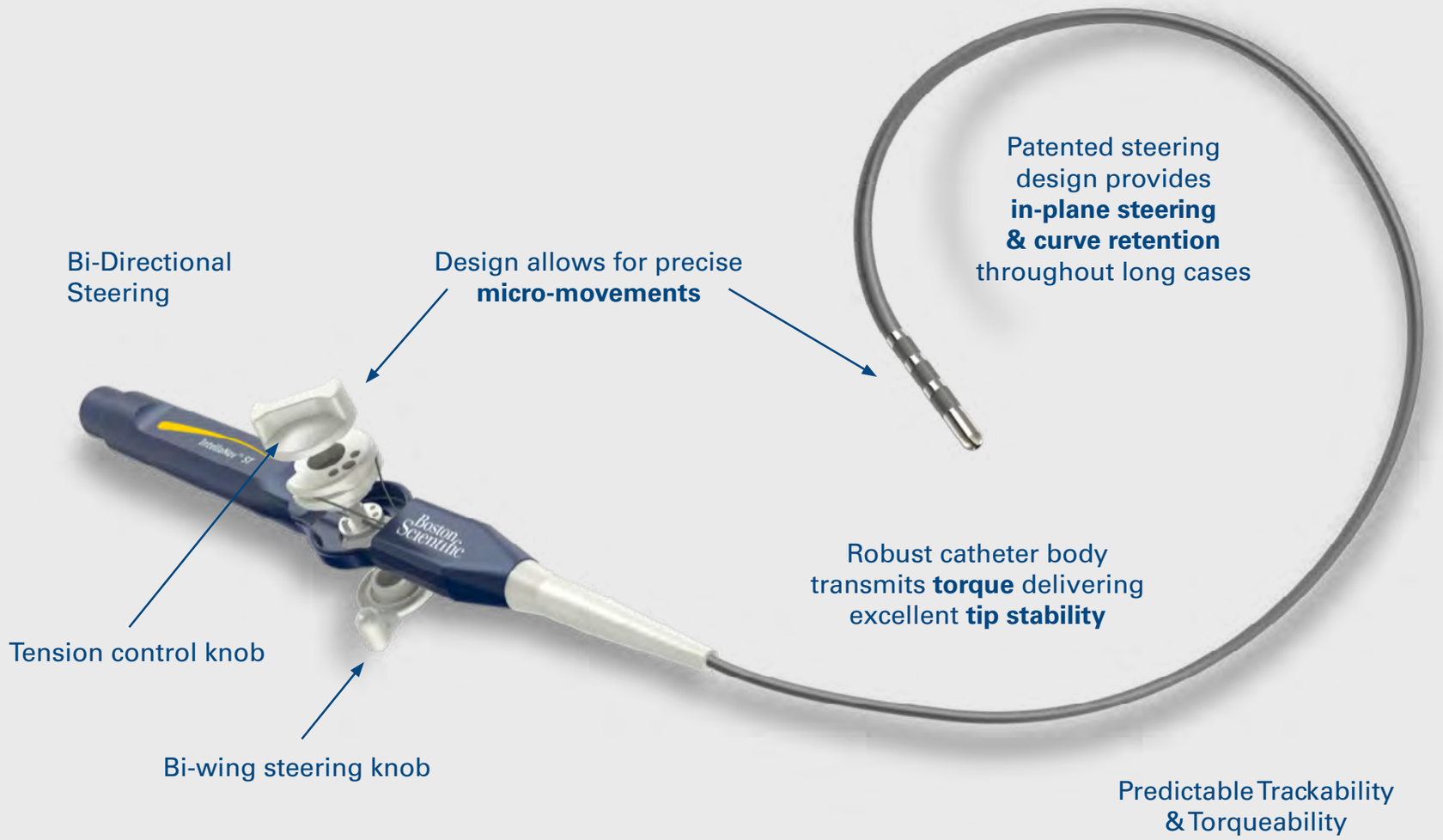
Map Creation with INTELLANAV™ OI



NAV-ENABLED ABLATION CATHETERS

Select from these topics

Proven BLAZER™ Mechanical Design



NAV-ENABLED ABLATION CATHETERS

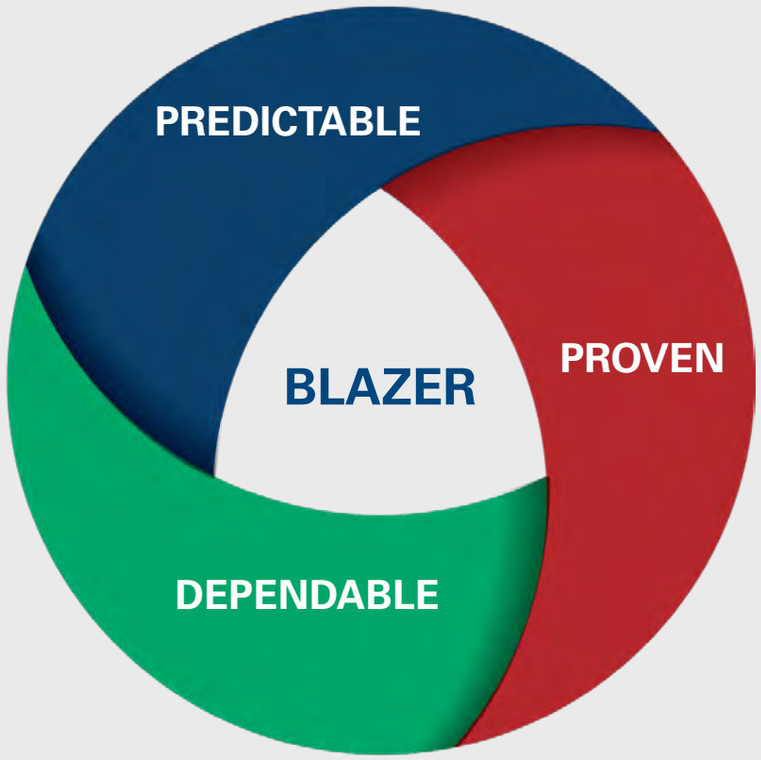
Select from these topics

Built from the BLAZER™ Platform - *Now with Navigation*

Predictable Handling
Designed for consistent handling – whether mapping or delivering therapy.
- Precise micro-movements
- Torqueability
- In-plane steering
- Tip stability

Dependable Performance
Catheter can be relied upon to perform consistently throughout long cases.
- Curve retention

Proven Results
One of the top-selling therapeutic catheters.
- Over 1 million catheters sold globally



NAV-ENABLED ABLATION CATHETERS

Construction - Conventional Catheters

INTELLANAV™ ST & INTELLANAV MIFI™ XP are most similar to the BLAZER™ II HTD / BLAZER II XP handling

Catheter	Distal Shaft Material	Distal Shaft Durability	Pushability
BLAZER II	Single layer Pellethane™	Standard	Standard
BLAZER II HTD BLAZER II XP	Single layer Pebax™	Standard	Standard
BLAZER PRIME	Two layer Pebax	Fiber reinforced	Support mandrel
INTELLATIP MIFI XP	Two layer Pebax	Fiber reinforced	Standard
INTELLANAV ST **INTELLANAV MIFI XP**	Two layer Pebax	Fiber reinforced	Standard

NAV-ENABLED ABLATION CATHETERS

Construction - Open-Irrigated

INTELLANAV™ OI is most similar to BLAZER™ II Standard handling
INTELLANAV MIFI™ OI is most similar to BLAZER II HTD handling

Catheter	Distal Shaft Material	Distal Shaft Durability	Pushability
BLAZER II STD	Single layer Pellethane™	Standard	Standard
BLAZER II HTD	Single layer Pebax™	Standard	Standard
BLAZER PRIME	Two layer Pebax	Fiber reinforced	Support mandrel
BLAZER OI **INTELLANAV OI**	Single layer Pellethane	Standard	Standard
INTELLATIP MIFI OI **INTELLANAV MIFI OI**	Two layer Pebax	Fiber reinforced	Standard

NAV-ENABLED ABLATION CATHETERS

INTELLANAV™ Specification Summary

INTELLANAV Ablation Catheters

	INTELLANAV ST	INTELLANAV MIFI XP	INTELLNAV OI	INTELLNAV MIFI OI
Suffix	Small Tip	Micro Fidelity & Extra Power	Open-Irrigated	Micro Fidelity & Open-Irrigated
Tip Length/Size	4mm/7F	8mm/8F	4mm/7F	4.5mm/7.5F
Shaft Size	7F	7F	7.5F	7.5F
Compatible Sheath	8F	8.5F	8F	8F
Curves	Standard, Large	Standard, Large, Asymmetric	Standard, Large, Asymmetric	Standard, Large, Asymmetric
RHYTHMIA Navigation Enabled	◆	◆	◆	◆
Open-Irrigated	–	–	◆	◆
Mini-Electrodes	–	◆	–	◆
Connection Cable	M004 RARC010	M004 RARC010	M004 RARC010	M004 RARC010

NAV-ENABLED ABLATION CATHETERS

INTELLANAV™ Specification Summary

A Versatile Portfolio for Customized Ablation Strategy with RHYTHMIA HDx™

- Tracking accuracy
- Map creation
- Ablation tip technology
  - Open-irrigation
  - Mini-electrodes
  - Tip lengths
- Familiarity of BLAZER™

BETTER THAN
1mm *tracking* ACCURACY
IN RHYTHMIA™ MAPPING SYSTEM CASES.[1]

1. Bench data on file.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- Nav-Enabled Portfolio
- IntellaNav MiFi OI
  - Catheter Overview
  - Technical Specs
- IntellaNav OI
- IntellaNav MiFi XP
- IntellaNav ST

Catheter Overview

Unparalleled Clarity. Cool Performance. Confident Navigation.

MiFi – Mini-electrode technology

Total Tip Cooling™ Design

Dual cooling chambers uniformly cool the entire tip internally

Optimized flow pattern actively washes entire tip electrode externally

Consistent cooling throughout RF delivery

BLAZER™ Platform Design

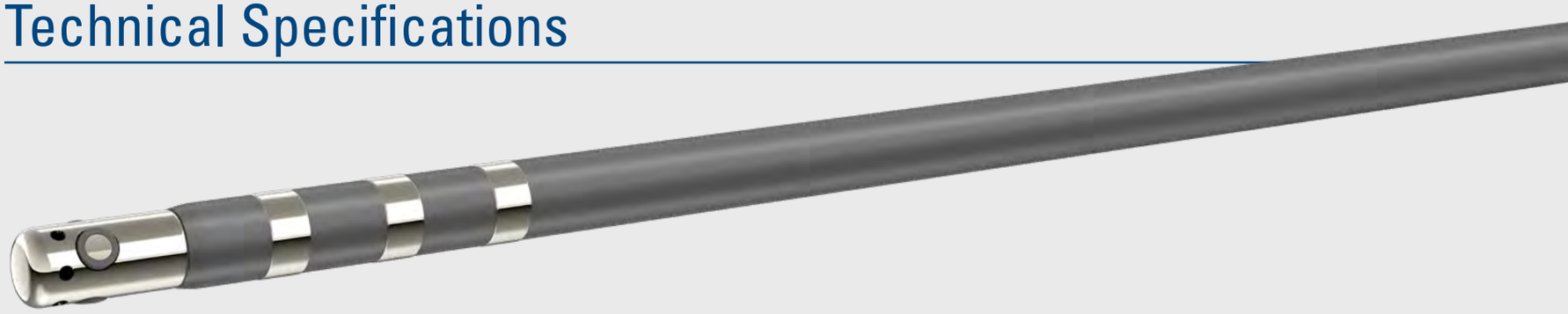
Dependable performance

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- Nav-Enabled Portfolio
- IntellaNav MiFi OI
  - Catheter Overview
  - Technical Specs
- IntellaNav OI
- IntellaNav MiFi XP
- IntellaNav ST

Technical Specifications



Platform
Built on the bidirectional BLAZER™ Catheter Platform

Compatibility
Compatible with the RHYTHMIA™ Mapping System, MAESTRO 4000™ Cardiac Ablation System and METRIQ™ Pump

Tip Design
Open-irrigated with 6 irrigation holes, dual internal cooling chambers and 3 mini-electrodes (4.5mm/7F)

Shaft Size
7.5F

Compatible Sheath
8F

Curves
Standard, Large & Asymmetric

Electrode Spacing
Quadripolar 2.5/2.5/2.5mm

Shaft Length
110cm

Proximal Shaft Material
Metallic braided Pebax™

Distal Shaft Material
Fiber reinforced braided Pebax

Electrodes
Pt/Ir 10%

Maximum Wattage
50 W

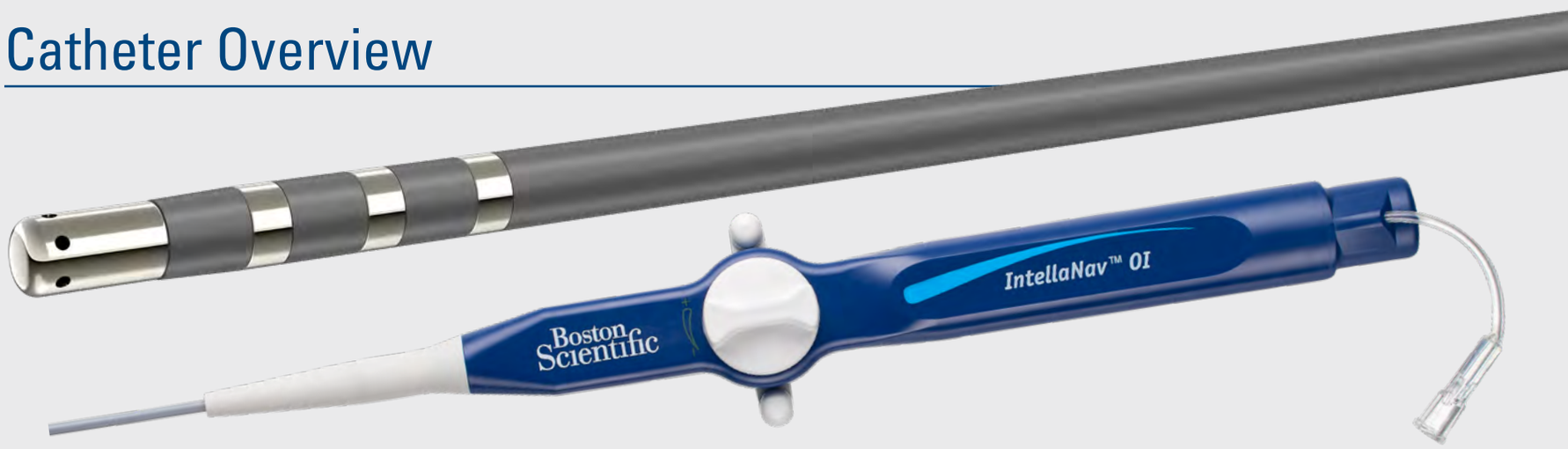
Generator Control Mode
Power

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- Nav-Enabled Portfolio
- IntellaNav MiFi OI
- IntellaNav OI
  - Catheter Overview
  - Technical Specs
- IntellaNav MiFi XP
- IntellaNav ST

Catheter Overview



Cool Performance. Confident Navigation.

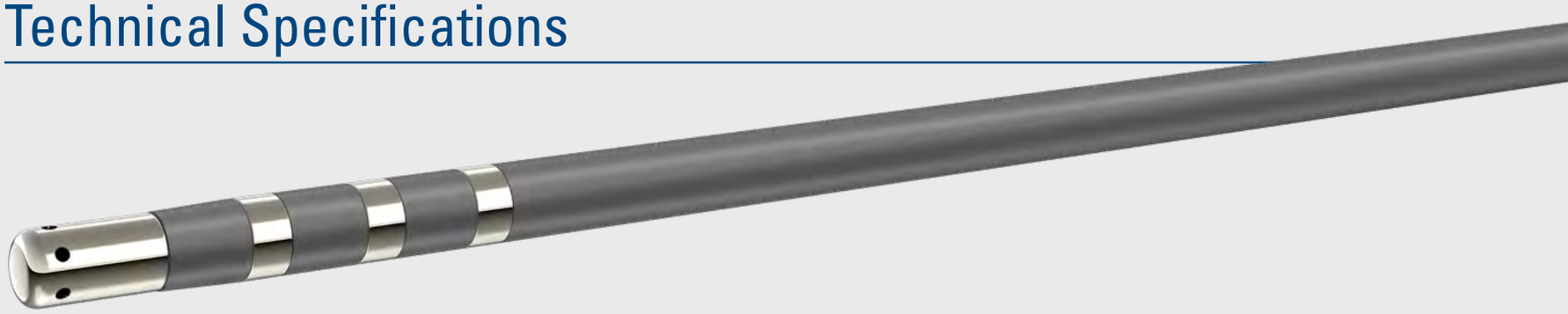
- Total Tip Cooling™ Design
- Dual cooling chambers uniformly cool the entire tip internally
- Optimized flow pattern actively washes entire tip electrode externally
- Consistent cooling throughout RF delivery
- BLAZER™ Platform Design
- Dependable performance

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- Nav-Enabled Portfolio
- IntellaNav MiFi OI
- IntellaNav OI
  - Catheter Overview
  - Technical Specs
- IntellaNav MiFi XP
- IntellaNav ST

Technical Specifications



Platform
Built on the bidirectional BLAZER™ Catheter Platform

Compatibility
Compatible with the RHYTHMIA™ Mapping System, MAESTRO 4000™ Cardiac Ablation System and METRIQ™ Pump

Tip Design
Open-irrigated with 6 irrigation holes and dual internal cooling chambers (4mm/7F)

Shaft Size
7.5F

Compatible Sheath
8F

Curves
Standard, Large & Asymmetric

Electrode Spacing
Quadripolar 2.5/2.5/2.5mm

Shaft Length
110cm

Proximal Shaft Material
Metallic braided Pebax™

Distal Shaft Material
Pellethane™

Electrodes
Pt/Ir 10%

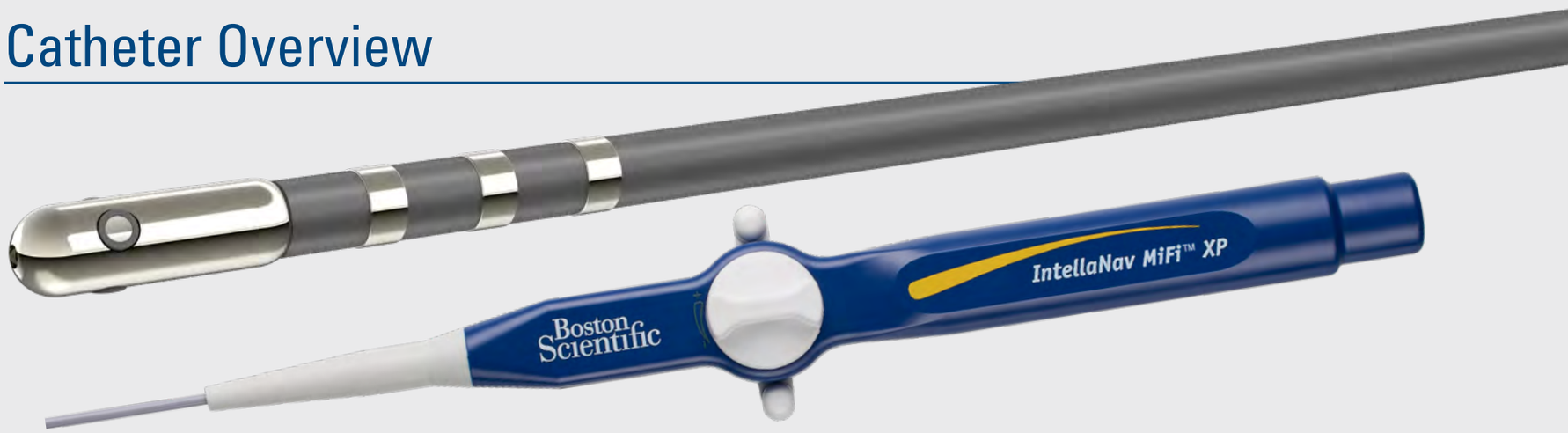
Maximum Wattage
50 W

Generator Control Mode
Power

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Catheter Overview

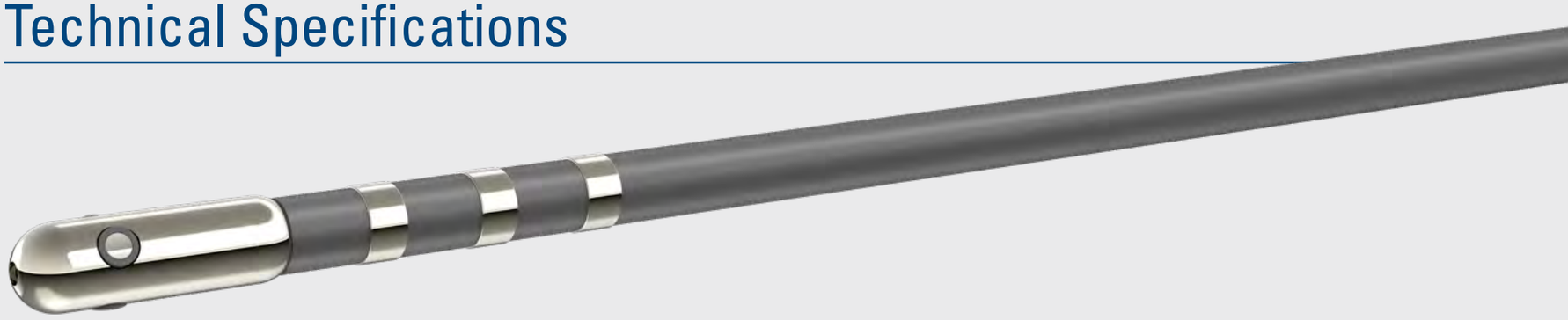


Unparalleled Clarity. Performance. Accuracy.

- MiFi – Mini-Electrode Technology
- Trusted BLAZER™ Platform
- Torqueability (1:1 movements)
- Synergy with RHYTHMIA™ High Definition Mapping
- Bi-Directional Steering
- Fine Micro-movements

NAV-ENABLED ABLATION CATHETERS

Technical Specifications



Platform
Built on the bidirectional BLAZER™
Catheter Platform

Compatibility
Compatible with the RHYTHMIA™ Mapping System,
MAESTRO 3000 & 4000™ Cardiac Ablation System

Tip Design
Solid tip with 3 mini-electrodes (8mm/8F)

Shaft Size
7F

Compatible Sheath
8.5F

Curves
Standard, Large & Asymmetric

Electrode Spacing
Quadripolar 2.5/2.5/2.5mm

Shaft Length
110cm

Proximal Shaft Material
Metallic braided Pebax™

Distal Shaft Material
Fiber reinforced braided Pebax

Electrodes
Pt/Ir 10%

Maximum Wattage
100 W

Generator Control Mode
Temperature or Power

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Catheter Overview

Familiarity. Performance. Accuracy.

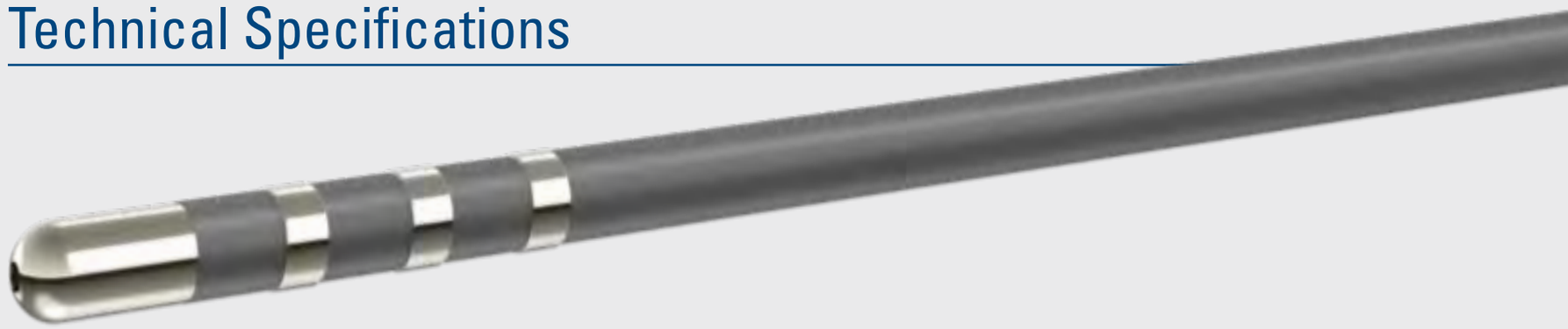
- Historical performance meets HD mapping
- Trusted BLAZER™ Platform
- Torqueability (1:1 movements)
- Pushability
- Fine Micro-movements
- In-plane Steering
- Bi-Directional Curves
- Precision of small ablation tip

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- Nav-Enabled Portfolio
- IntellaNav MiFi OI
- IntellaNav OI
- IntellaNav MiFi XP
- IntellaNav ST
- Catheter Overview
- Technical Specs

Technical Specifications



Platform
Built on the bidirectional BLAZER™ Catheter Platform

Compatibility
Compatible with the RHYTHMIA™ Mapping System, MAESTRO 3000 & 4000™ Cardiac Ablation System

Tip Design
Solid tip (4mm/7F)

Shaft Size
7F

Compatible Sheath
8F

Curves
Standard & Large

Electrode Spacing
Quadripolar 2.5/2.5/2.5mm

Shaft Length
110cm

Proximal Shaft Material
Metallic braided Pebax™

Distal Shaft Material
Fiber reinforced braided Pebax

Electrodes
Pt/Ir 10%

Maximum Wattage
50 W

Generator Control Mode
Temperature or Power

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- Cool Performance
- Clinical Science
- Open-Irrigated System

INTELLANAV™ OI

INTELLANAV MIFI™ OI

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Cool Performance

Total Tip Cooling™ Technology

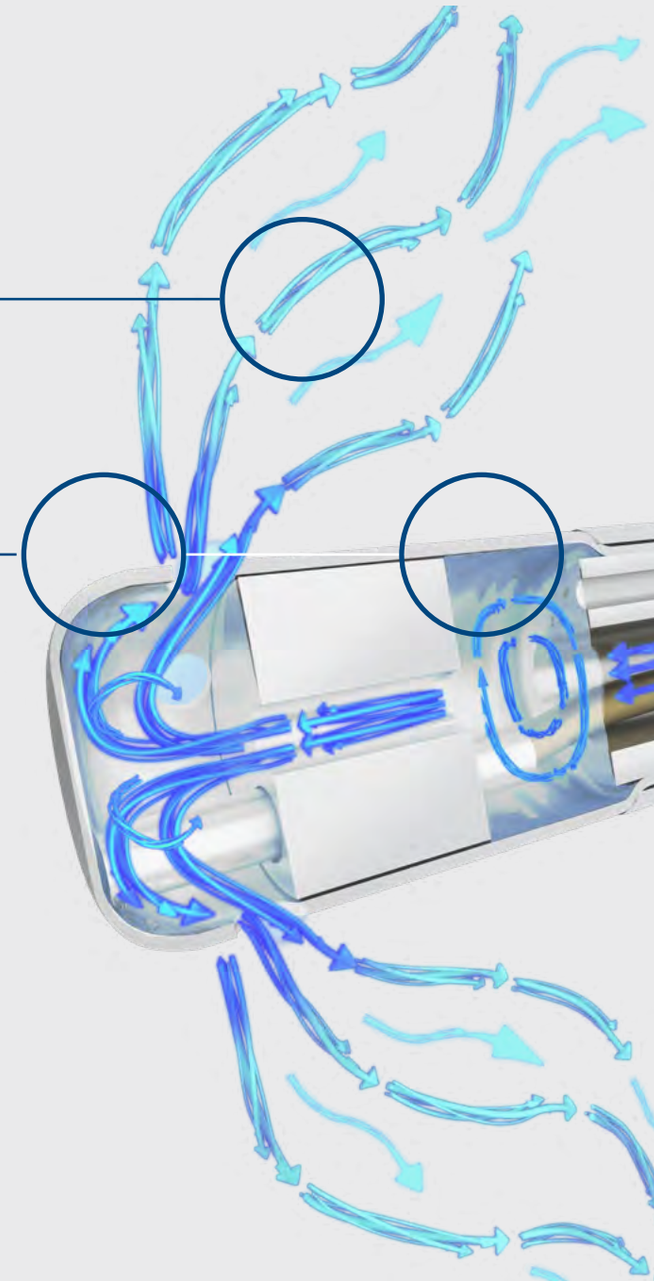
Designed to reduce potential of char, coagulum and thrombus

Dynamic external cooling

Proximally directed exit flow actively cools the entire tip electrode

Active internal cooling

Dynamic saline flow fills two chambers to cool areas prone to hot spots from within

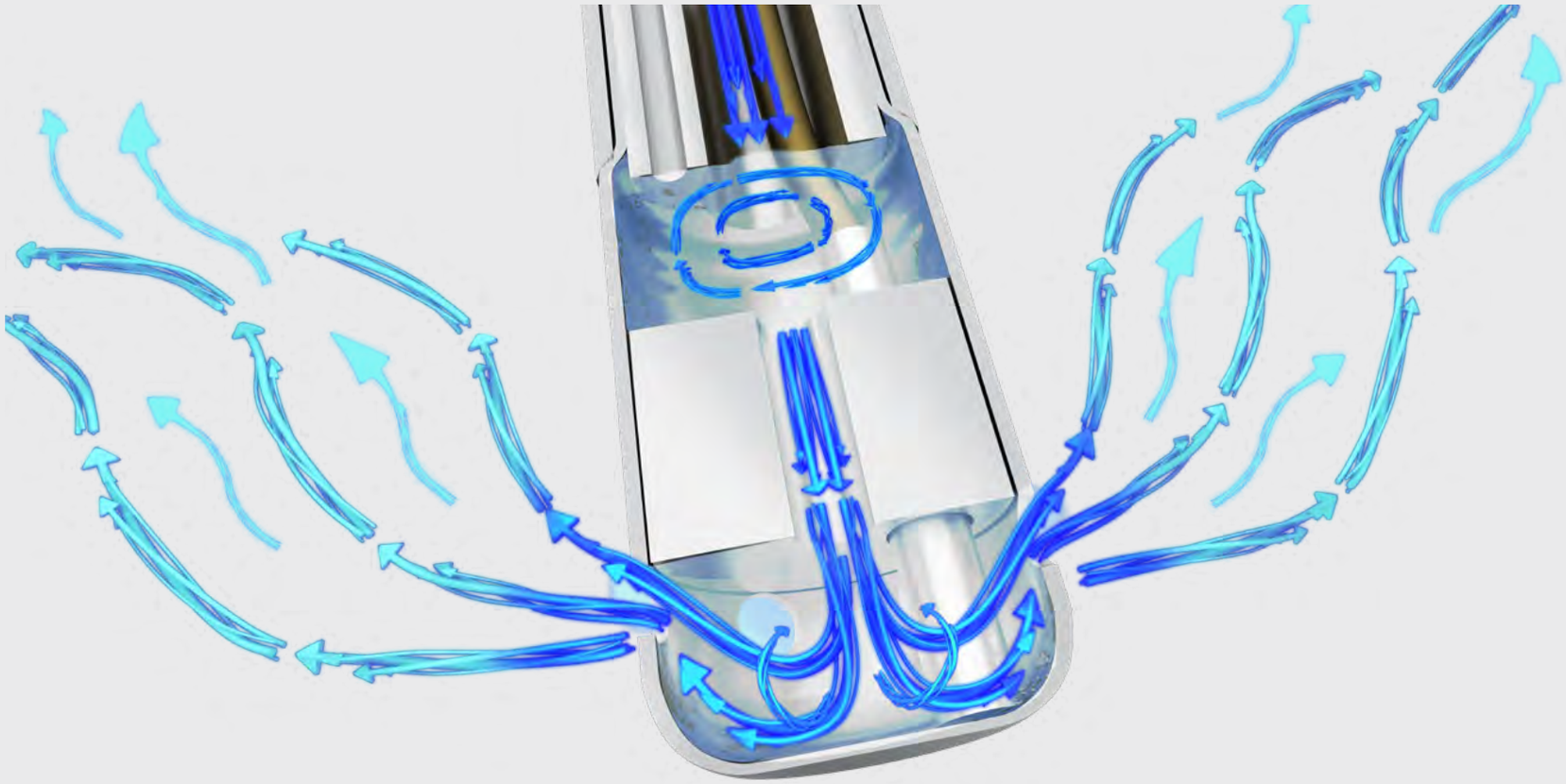


Product illustration, not actual photograph.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Total Tip Cooling™ Design



Dual Cooling Chambers | **Targeted Proximal Cooling** | **Exit Flow Directed Proximally** | **Central Cooling Lumen**

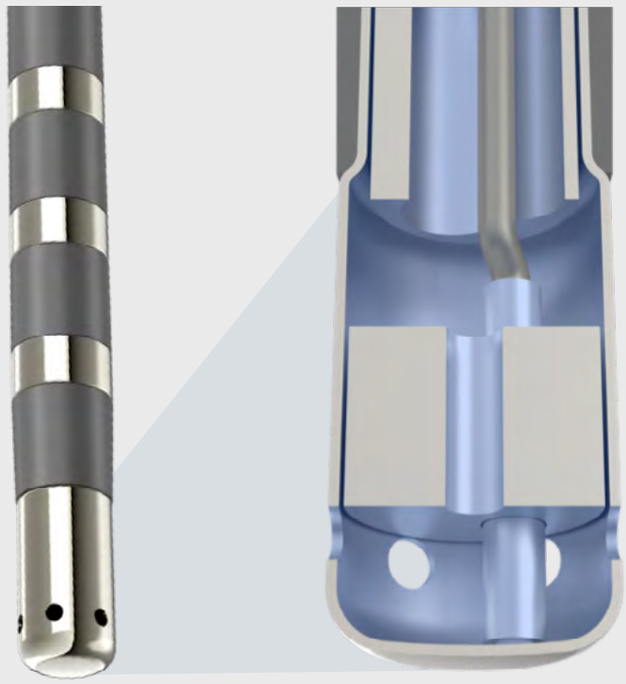
Product illustration, not actual photograph.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

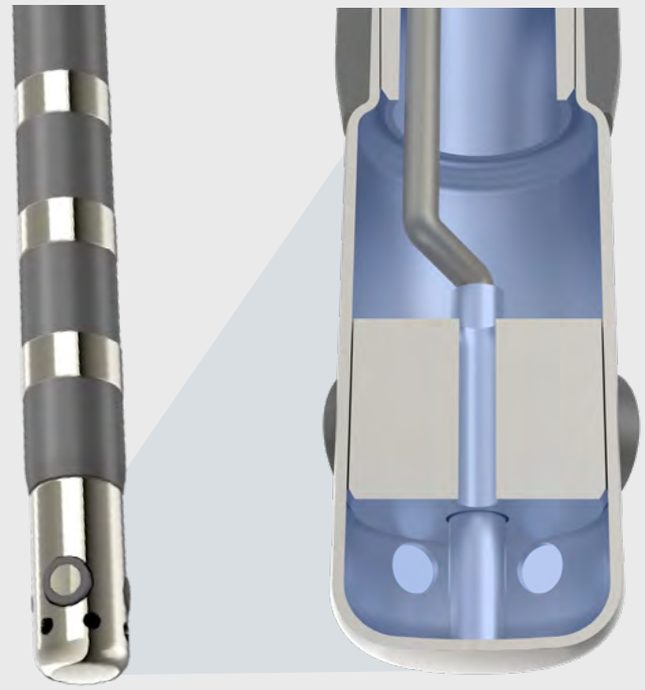
Same Internal Open-Irrigated Design

INTELLANAV™ OI



Same design as BLAZER™ OI

INTELLANAV MIFI™ OI



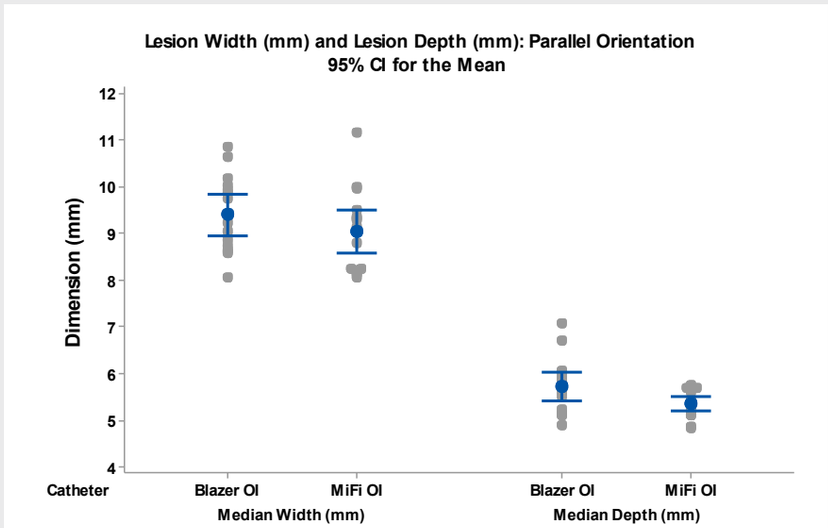
Same design as INTELLATIP MIFI™ OI

NAV-ENABLED ABLATION CATHETERS

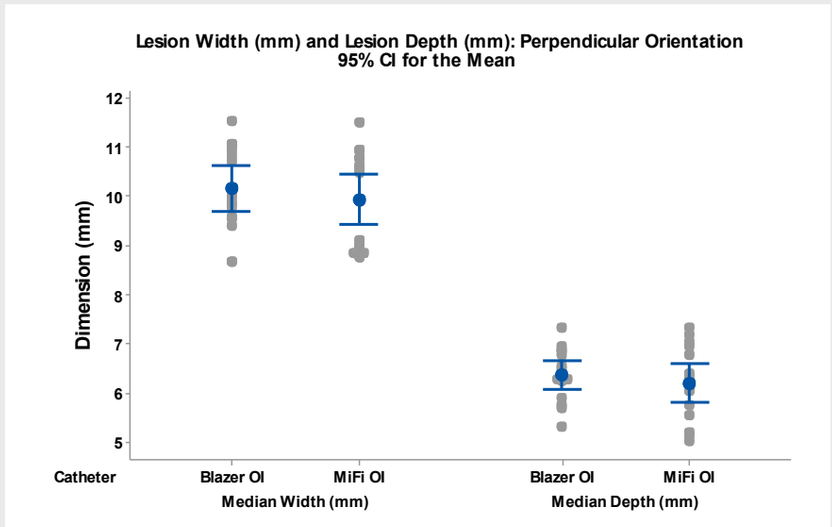
Demonstrating Performance Equivalency: Lesions

BLAZER™ OI VS. INTELLATIP MIFI™ OI RESULTS

(16 lesion samples per catheter per orientation)



Individual standard deviations were used to calculate the intervals.



Individual standard deviations were used to calculate the intervals.

BLAZER™ OI & INTELLATIP MIFI™ OI

Lesion dimensions (width & depth) are not clinically different.

Statistical Analysis was performed using Minitab software. Maximum likelihood estimates were obtained from the regression with life data function.

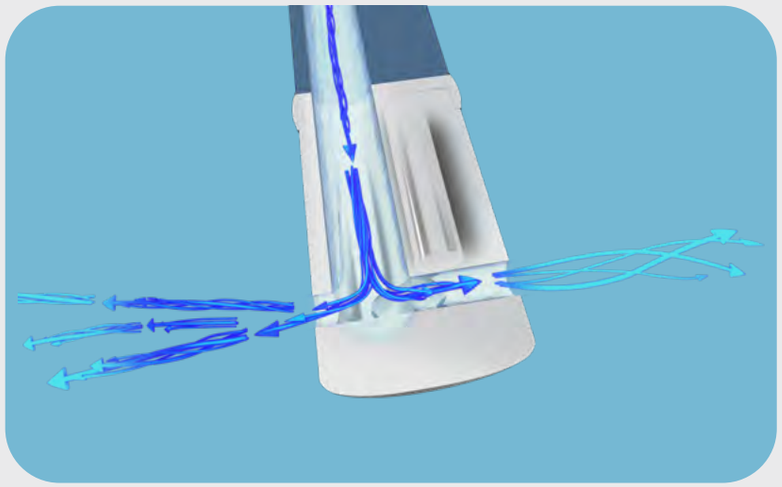
NAV-ENABLED ABLATION CATHETERS

Why open-irrigated design matters

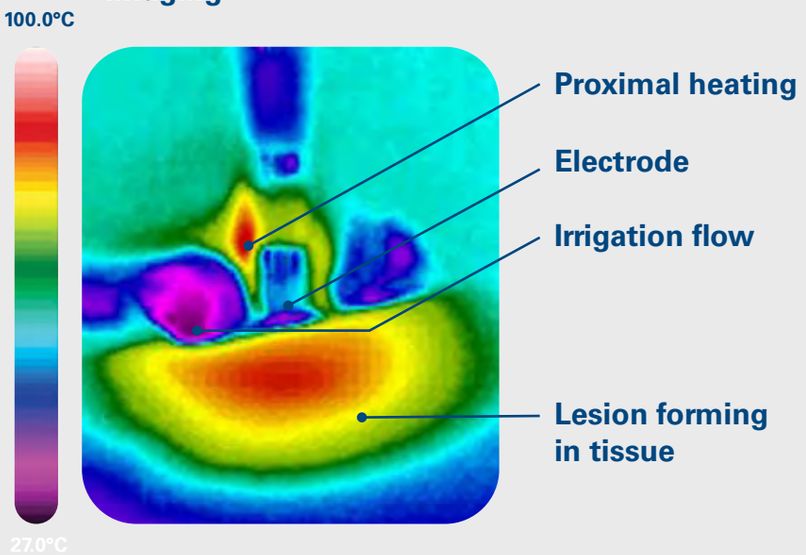
Conventional open-irrigated catheters are designed to **reduce tip temperature** and enable delivery of higher power

But, tip cooling is **not uniform**, which can result in formation of **proximal hot spots**[1]

Cross Section of Conventional Open-Irrigated Catheter



Infrared Imaging



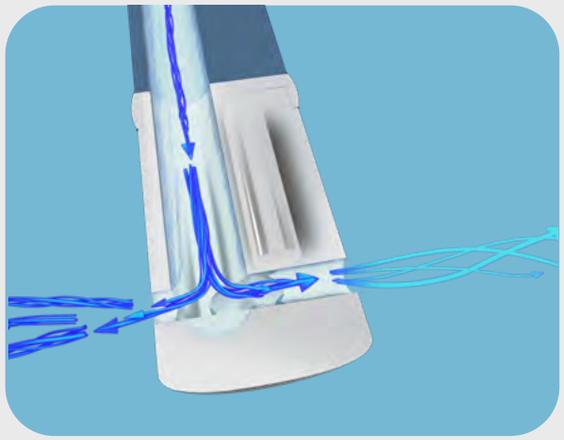
1. Bench testing completed by Boston Scientific. n = 1. Data on File. This image is of a single catheter and may not be fully representative of all catheters. Product illustration, not actual photograph. Bench test results are not necessarily predictive of clinical performance.

NAV-ENABLED ABLATION CATHETERS

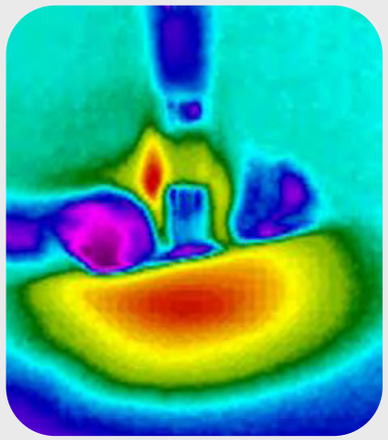
Select from these topics

Total Tip Cooling™ Visualization

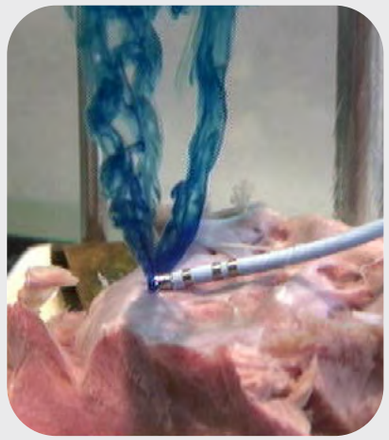
Cross Section of Conventional Open-Irrigated Ablation Catheter



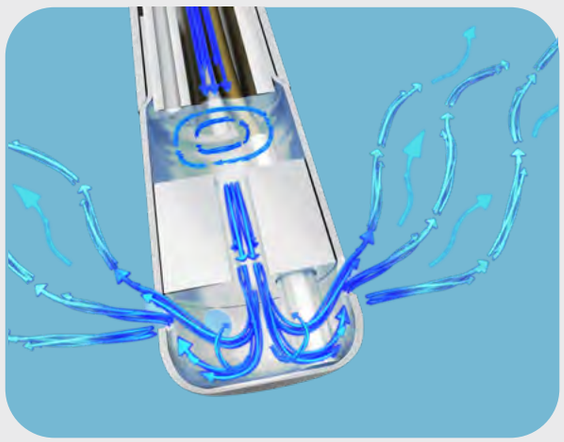
Infrared Imaging
(20W, ~30 seconds)



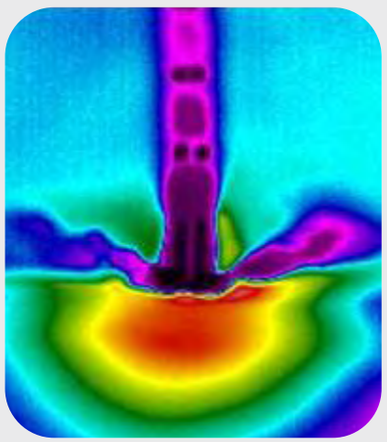
External Flow Visualization
(17 ml/min)



Cross Section of BLAZER™ Open-Irrigated Ablation Catheter



Infrared Imaging
(20W, ~30 seconds)



External Flow Visualization
(17 ml/min)

Thermal camera testing and external flow visualization completed by Boston Scientific. n = 1. Data on File. These thermal camera images are of a single catheter and may not be fully representative of all catheters. Product illustrations, not actual photographs.

NAV-ENABLED ABLATION CATHETERS

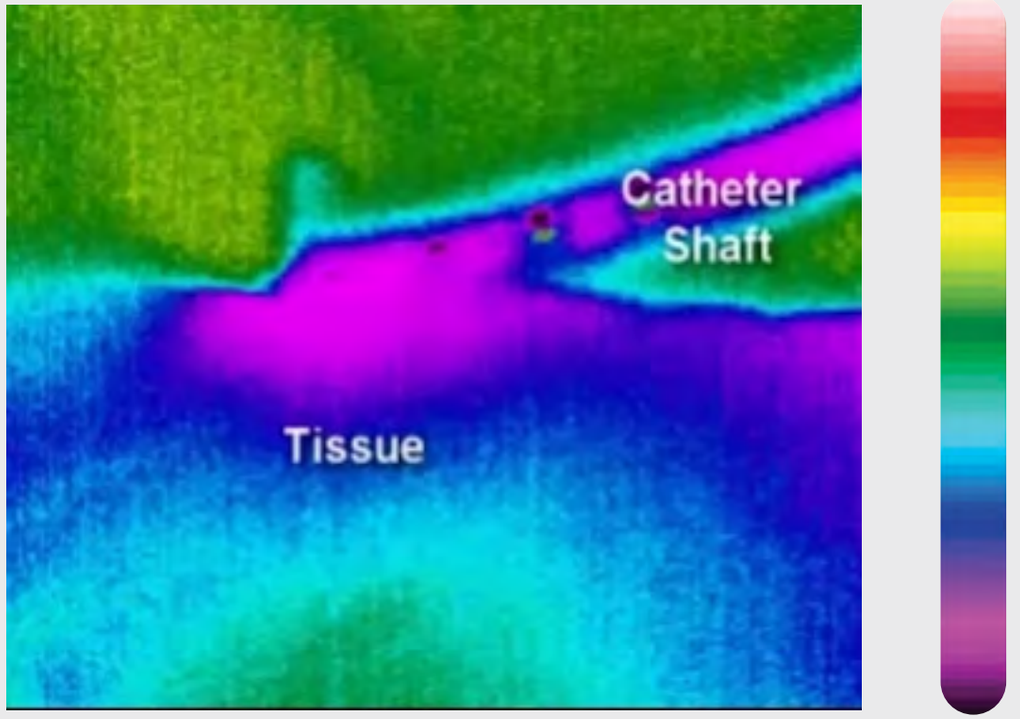
Cooling Profile of BLAZER™ OPEN-IRRIGATED Catheter

Design Goals

- Uniform cooling of tip electrode
- Cooling fluid actively washes tip electrode

IR Thermography

(25W, 17 ml/min irrigation)



Testing completed by Boston Scientific. n = 1. Data on File. This video is of a single catheter and may not be fully representative of all catheters. Bench test results are not necessarily predictive of clinical performance.

NAV-ENABLED ABLATION CATHETERS

Total Tip Cooling™ Technology for Effective Power Delivery

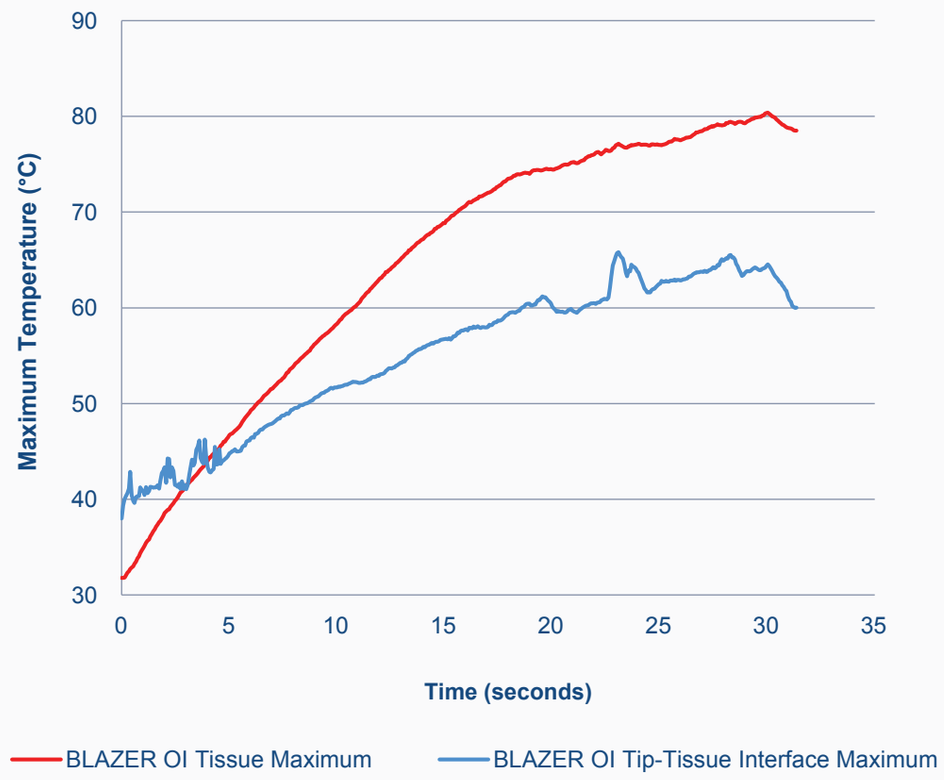
Efficient Tissue/Tip Interface Cooling

Promotes lesion creation while avoiding rapid tissue temperature rise

BLAZER™ OI

Effective power delivery with steady tissue temperature rise

Bench Testing: Temperature during Ablation (20W Power Control) BLAZER™ OPEN-IRRIGATED Catheter



Note: Bench testing performed by Boston Scientific. Data on file. Bench test results may not necessarily be indicative of clinical performance.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Competitive Landscape

ThermoCool™ 1st Generation vs. ThermoCool™ SF @30 seconds[1]

BLAZER™ OPEN-IRRIGATED vs. ThermoCool™ SF @30 seconds[1]

Data based on bench testing conducted by Boston Scientific.

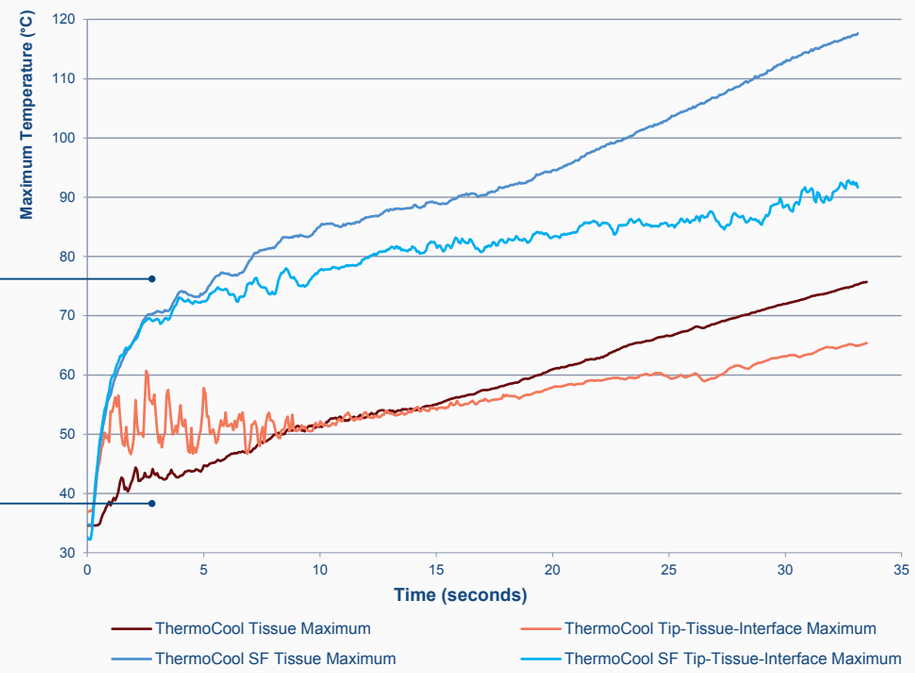
Maximum Temperature during Ablation
(20W Power Control)

ThermoCool SF

Bench testing showed rapid internal tissue temperature rise

ThermoCool

Bench testing showed power delivery with steady tissue temperature rise



1. Bench testing completed by Boston Scientific. n = 1. Data on File. The image is of a single catheter and may not be fully representative of all catheters. Bench test results are not necessarily predictive of clinical performance. All other trademarks are property of their respective owners.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Competitive Landscape

ThermoCool™ 1st Generation vs. ThermoCool™ SF @30 seconds[1]

BLAZER™ OPEN-IRRIGATED vs. ThermoCool™ SF @30 seconds[1]

Data based on bench testing conducted by Boston Scientific.

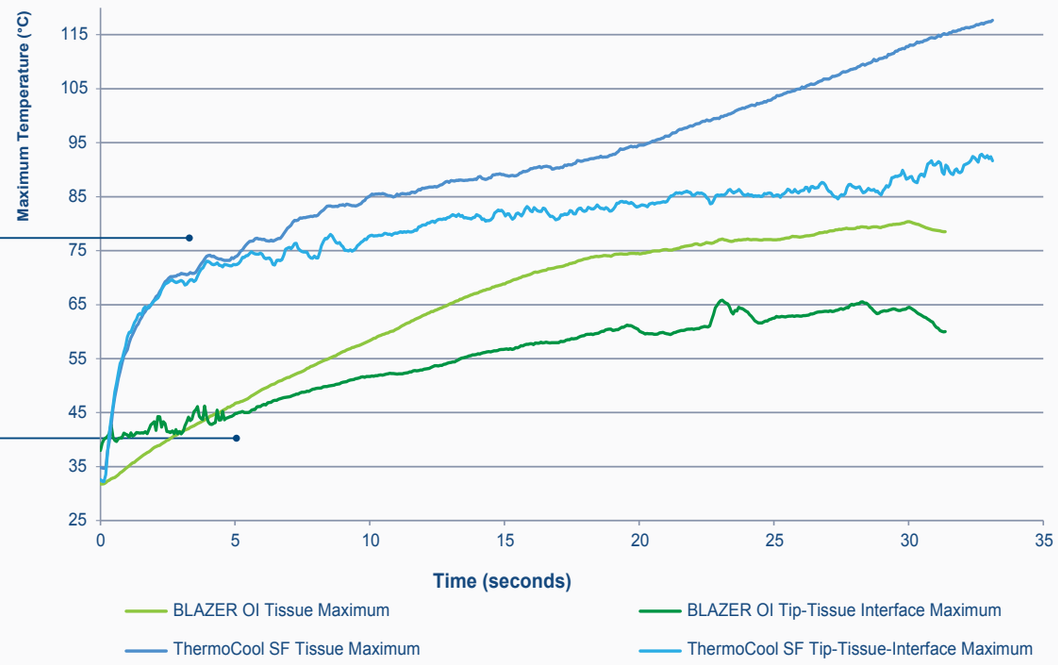
Maximum Temperature during Ablation
(20W Power Control)

ThermoCool SF

Bench testing showed rapid internal tissue temperature rise

BLAZER OI

Bench testing showed power delivery with steady tissue temperature rise



1. Bench testing completed by Boston Scientific. n = 1. Data on File. The image is of a single catheter and may not be fully representative of all catheters. Bench test results are not necessarily predictive of clinical performance. All other trademarks are property of their respective owners.

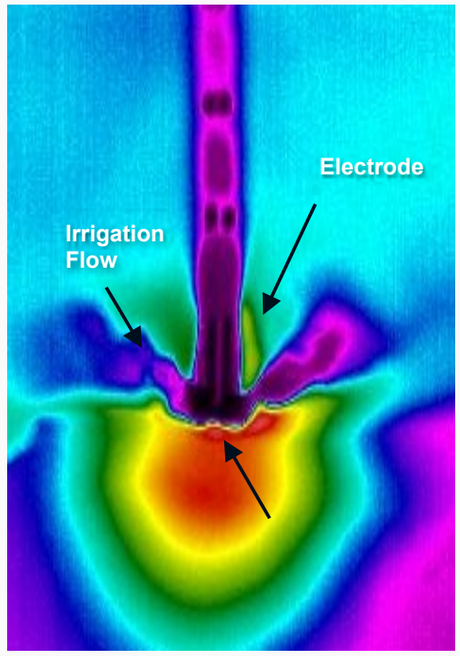
NAV-ENABLED ABLATION CATHETERS

Thermal Testing | No compromise to cooling or power delivery

Data based on bench testing conducted by Boston Scientific.

BLAZER™ OPEN-IRRIGATED Catheter vs. Competitive Catheters @30 seconds[1]

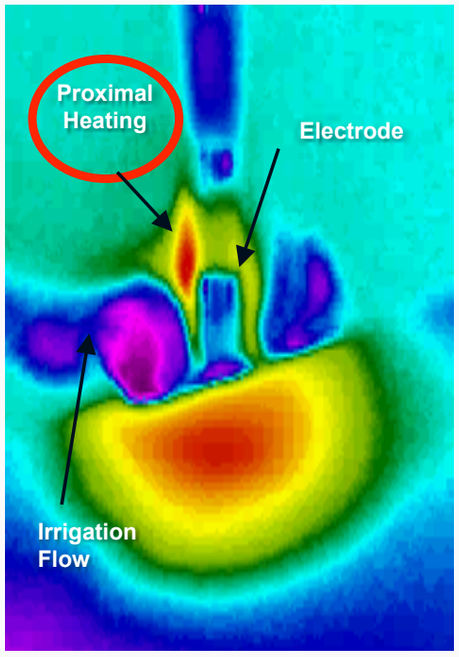
BLAZER OPEN-IRRIGATED Catheter



Saw total tip cooling with no hotspots

Power delivery without rapid tissue temperature rise

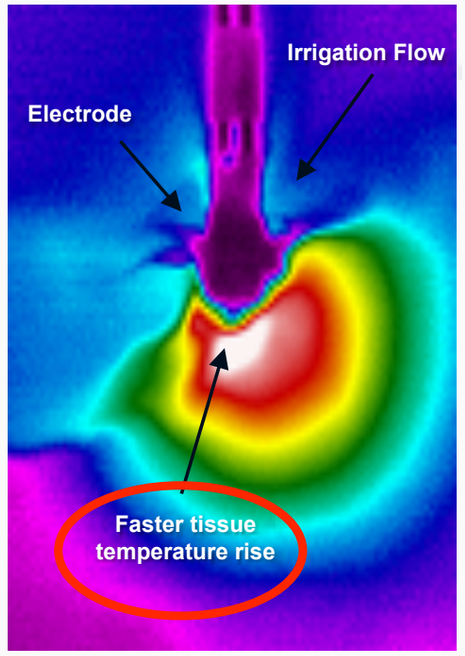
ThermoCool™ Catheter



Tip cooling was not uniform, which can result in the formation of proximal hotspots

Power delivery without rapid tissue temperature rise

ThermoCool™ SF Low Flow Catheter



Efficient tip cooling for no hot spots

Saw rapid tissue temperature rise

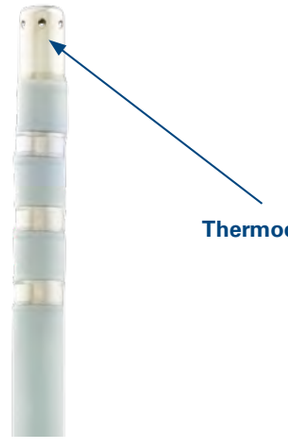
1. Infrared Thermal Camera (20W, ~30sec) — 17ml/min for 1st Generation ThermoCool (conventional catheter) & BLAZER OI — 8 ml/min for ThermoCool SF (conventional low flow catheter). Bench testing completed by Boston Scientific. n = 1. Data on File. The image is of a single catheter and may not be fully representative of all catheters. Bench test results are not necessarily predictive of clinical performance.

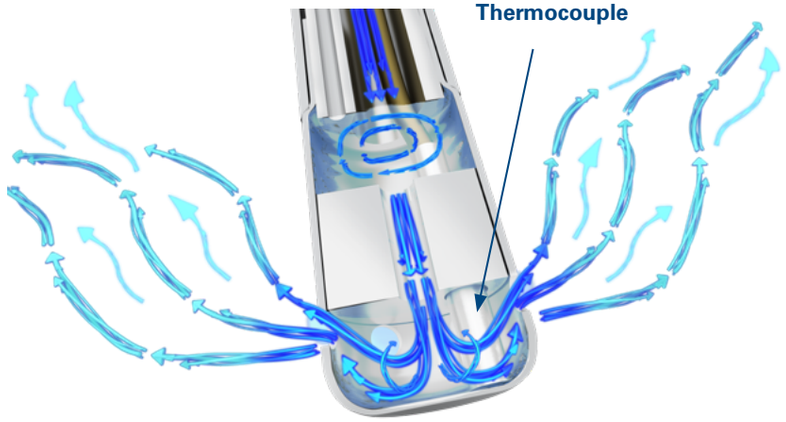
NAV-ENABLED ABLATION CATHETERS

Select from these topics

Temperature Sensing

- INTELLANAV™ OI uses the same thermocouple and distal tip design as BLAZER™ OI
- The thermocouple is located in the distal tip and it is slightly offset with respect to the central axis of the catheter
- Physicians may notice a lower temperature during ablation
- Temperature reading is not indicative of effective ablation





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NAV-ENABLED ABLATION CATHETERS

Moreno et al. Thermodynamic Evaluation of 4 Open-Irrigated Catheters[1]

This study was an experimental assessment of four open-irrigated catheters comparing lesion size, safety and heat transfer. The thigh lesion model was performed on six anesthetized pigs.

Thermodynamic comparison of four Open-Irrigated Catheters

- ThermoCool™
- ThermoCool™ SF
- BLAZER™ OPEN-IRRIGATED
- CoolFlex™

Porcine thigh model

- 30W (60 sec) - assessing lesion morphology both perpendicularly and tangentially
- 50W (180 sec) – evaluating the propensity for deep-tissue overheating to compare "pop" rates
- Thermal assessment of lesion generation (20W, 60 sec)

Results

- Newer catheters showed lower temp readings compared to ThermoCool
- ThermoCool SF pushed maximum thermal effect deeper, created largest lesions at 8mL/min (perpendicular)
- CoolFlex readily induced steam pops at 50W (perpendicular)
- No major differences found between BLAZER OI and ThermoCool (perpendicular)

LEARN MORE

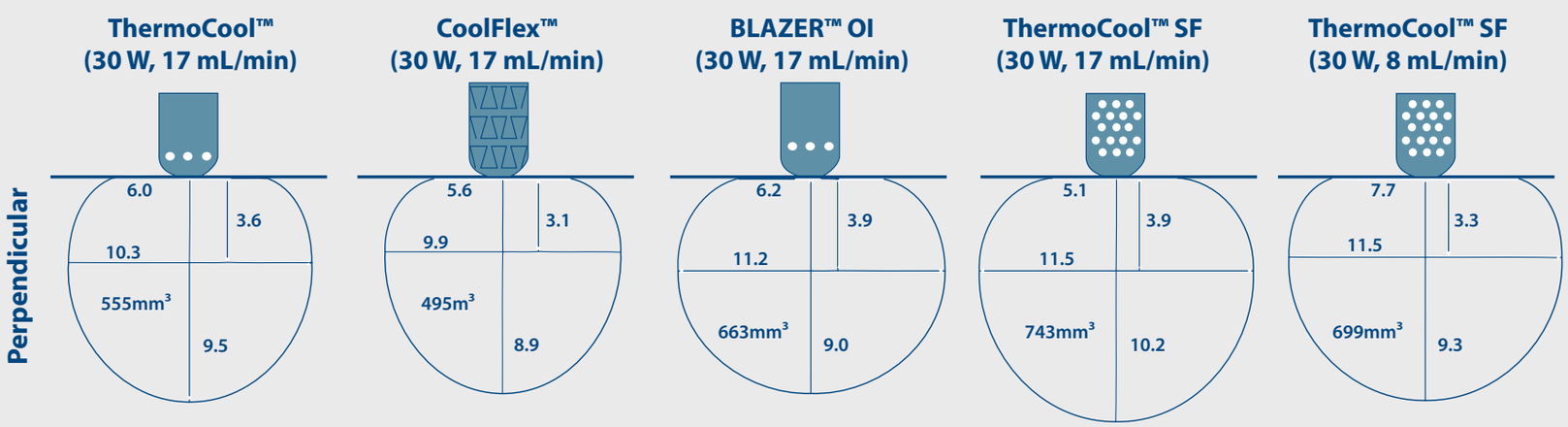
1. Moreno J, Quintanilla JG, Molina-Morúa R, et al. Thermodynamic evaluation of 4 open-irrigated catheters. *J Cardiovasc Electrophysiol.* 2014 Dec;25(12):1391-9.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Moreno et al. Thermodynamic Evaluation of 4 Open-Irrigated Catheters[1]

30W, 60 second lesions



- No major differences were seen in maximum depth of lesions.
- CoolFlex showed a trend to lower volume lesions compared with BLAZER OI (P=0.09).
- No coagulum formation or thrombus occurred in any application.
- No differences seen in tangential (parallel) orientation (not shown).

LEARN MORE

1. Moreno J, Quintanilla JG, Molina-Morúa R, et al. Thermodynamic evaluation of 4 open-irrigated catheters. *J Cardiovasc Electrophysiol.* 2014 Dec;25(12):1391-9.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Moreno et al. Thermodynamic Evaluation of 4 Open-Irrigated Catheters[1]

Time-To-Pop Assessment (50 W, up to 180 seconds)

	50W, 30 mL/min				50W, 15 mL/min	Global
Perpendicular	BW ThermoCool™	SJM CoolFlex™	BSC BLAZER™ OI	BW SF-30	BW SF-15	P Value
Tip Temperature (°C) Mean	38.4 ± 3.2	41.2 ± 6.5	34.8 ± 2.5	33 ± 1.4	33.4 ± 0.8	<0.001
Tip Temperature (°C) Maximum	43.9 ± 4.8	48.2 ± 14.6	42 ± 11.8	37.9 ± 1.8	36.8 ± 1.2	0.008
Pop before 30s	1 (8%)	8 (67%)	0 (0%)	2 (17%)	3 (25%)	
Pop before 60s	3 (25%)	12 (100%)	4 (33%)	2 (17%)	6 (50%)	
Pop before 90s	9 (75%)	12 (100%)	9 (75%)	8 (67%)	8 (67%)	
Pop before 180s	12 (100%)	12 (100%)	12 (100%)	9 (75%)	11 (91%)	

CoolFlex performed significantly worse than other catheters, invariably inducing steam pops after 60 seconds of RF

BLAZER OI did not induce any steam pops in the first 30 seconds

Mean and Maximum tip temperature readings were significantly lower with the BLAZER OI and the SF catheter at a standard flow (17 ml/min)

CoolFlex and ThermoCool were associated with significantly higher mean and maximum tip temperatures than the other catheters

1. Moreno J, Quintanilla JG, Molina-Morúa R, et al. Thermodynamic evaluation of 4 open-irrigated catheters. *J Cardiovasc Electrophysiol.* 2014 Dec;25(12):1391-9.

NAV-ENABLED ABLATION CATHETERS

Guerra et al. In Vitro Comparison of 6 Open-Irrigated Catheters[1]

The purpose of this study was to compare the lesion size and potential complications produced by commercially available open-irrigated catheters in an in vitro porcine heart model.

- Catheters tested include: ThermoCool™, BLAZER™ OI, Therapy™ Cool Path™, Therapy™ Cool Path Duo™, ThermoCool™ SF and Therapy™ Cool Flex™

Total of 601 lesions were made in 26 in vitro preparations

- 20 & 35 W, 30 & 60 sec
- Static flow rate of 13mL/min for all catheters

Tip Temperature profile showed significant differences between the catheters ($p < 0.001$) with ThermoCool registering the lowest

Lesion Volume

- No significant differences between catheters found, regardless of power and flow conditions

Complications

- Char mostly occurred at low-flow conditions
- Steam pops only occurred in the 35W, 60-second setting, being highest with Therapy Cool Path and ThermoCool SF

LEARN MORE

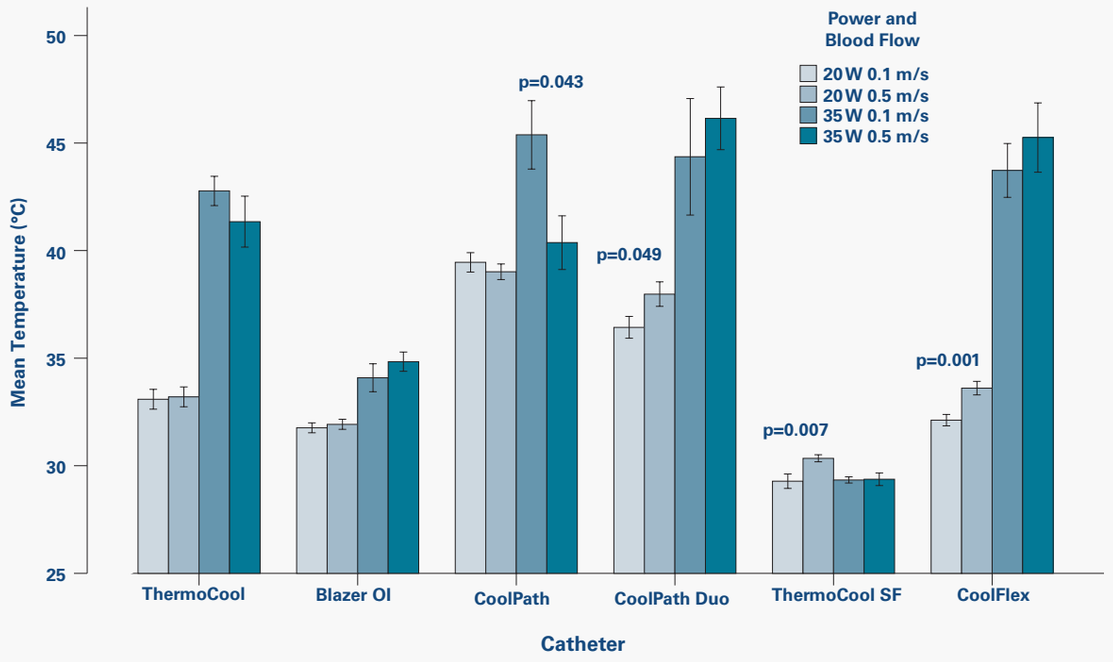
1. Guerra JM, Jorge E, Raga S, et al. Effects of open-irrigated radiofrequency ablation catheter design on lesion formation and complications: in vitro comparison of 6 different devices. *J Cardiovasc Electrophysiol*. 2013 Oct;24(10):1157-62.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Guerra et al. In Vitro Comparison of 6 Open-Irrigated Catheters[1]

Mean catheter tip temperature during the RF applications at the 2 tested powers and blood flow conditions. Bars represent: ± SEM.



At 20 W, when the blood flow increased a paradoxical response with an increase in tip temperature was seen with both ThermoCool™ SF and CoolFlex™.

- Because cooling effect is more homogenous, local fluid output per hole is lower, and, as a result, the irrigating saline flow is not able to counteract the higher blood flow.

1. Guerra JM, Jorge E, Raga S, et al. Effects of open-irrigated radiofrequency ablation catheter design on lesion formation and complications: in vitro comparison of 6 different devices. *J Cardiovasc Electrophysiol*. 2013 Oct;24(10):1157-62.

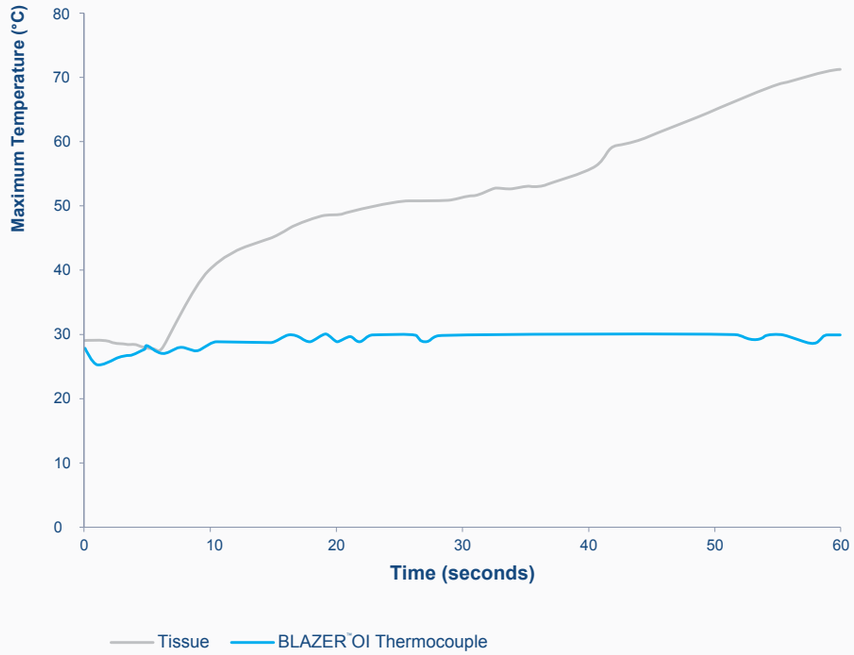
NAV-ENABLED ABLATION CATHETERS

Select from these topics

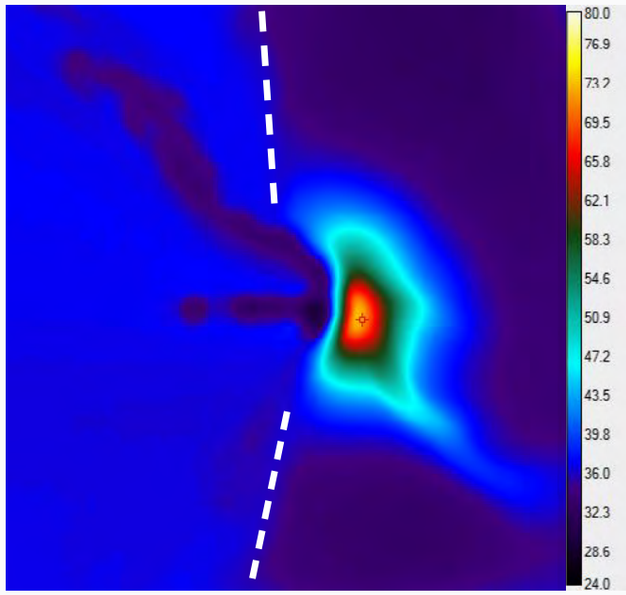
- Cool Performance
- Clinical Science
  - Moreno et al.
  - Guerra et al.
  - Tip Temperature
  - Key Takeaways
- Open-Irrigated System

Importance of Tip Temperature

Bench Testing



20 Watts, 60 sec, 17mL/min



Bench testing found, BLAZER™ OI had a consistently cool tip throughout RF delivery with steady tissue temperature rise

Note: Bench testing performed by Boston Scientific. Data on file. Bench test results may not necessarily be indicative of clinical performance.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- Cool Performance
- Clinical Science
  - Moreno et al.
  - Guerra et al.
  - Tip Temperature
  - Key Takeaways
- Open-Irrigated System

Key Takeaways:

Moreno et al.[1]

- Catheter design has impacts on lesion creation and safety profile
- CoolFlex™ induced steam pops at higher powers
- ThermoCool™ SF pushed thermal effect deeper, creating larger lesions
- BLAZER™ OI did not induce any steam pops at 30 seconds

Guerra et al.[2]

- Tip temperature profiles were statistically different
- No lesion creation difference seen among catheters
- Char occurred mostly in low flow conditions
- Newer “low flow” catheters saw an increase in temp in high blood flow
- BLAZER OI demonstrated a consistent cooling profile

Note: Animal models only

1. Moreno J, Quintanilla JG, Molina-Morúa R, et al. Thermodynamic evaluation of 4 open-irrigated catheters. *J Cardiovasc Electrophysiol.* 2014 Dec;25(12):1391-9.
2. Guerra JM, Jorge E, Raga S, et al. Effects of open-irrigated radiofrequency ablation catheter design on lesion formation and complications: in vitro comparison of 6 different devices. *J Cardiovasc Electrophysiol.* 2013 Oct;24(10):1157-62.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Introducing the MAESTRO 4000™ & METRIQ™ Pump

Empowered Irrigated Ablation Procedures

Efficiency. Performance. Integration.

NAV-ENABLED ABLATION CATHETERS

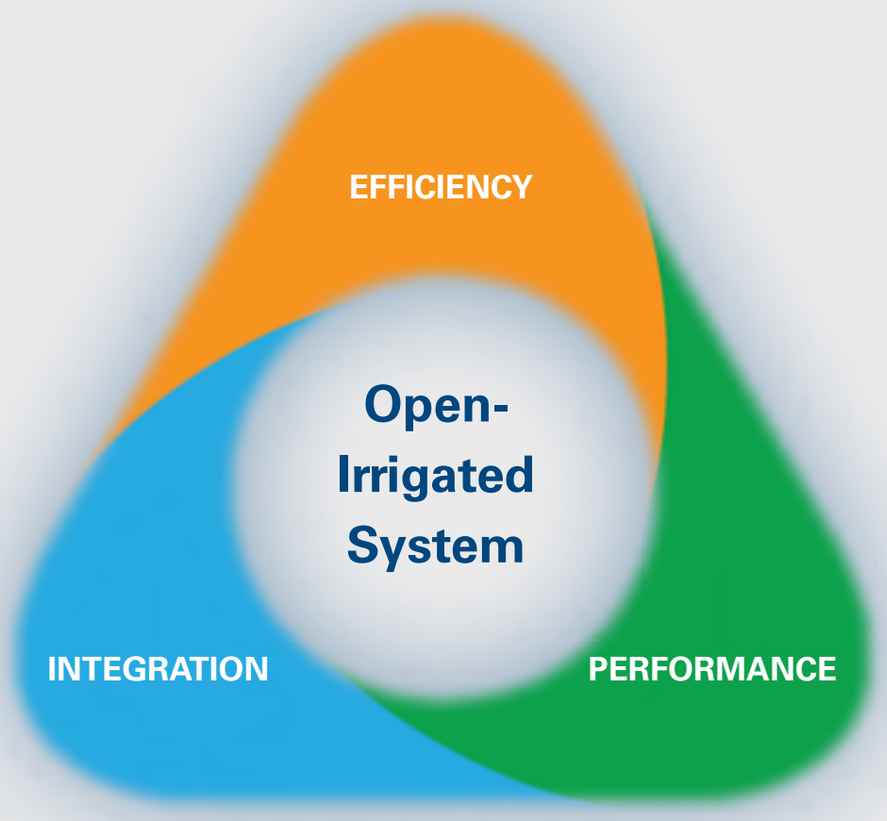
Select from these topics

Open-Irrigated System

Empower Efficiency
- Intelligent User Interface
- IntellaSight™ Infusion Monitoring
- Customizable Memory Buttons

Empower Performance
- Bubble and Occlusion Detection
- Automatic Titration

Empower Integration
- Cutting-Edge Catheter Portfolio
- Boston Scientific EP Lab



NAV-ENABLED ABLATION CATHETERS

Open-Irrigated System Components I MAESTRO 4000™ Cardiac Ablation System

Seamless, automatic communication

- Flexible setup and easy operation
- Accurate, clear diagnostic message display
- Compatible with Boston Scientific's full portfolio of therapeutic and diagnostic catheters

NAV-ENABLED ABLATION CATHETERS

Open-Irrigated System Components | METRIQ™ Irrigation Pump

Vital, real-time procedure information

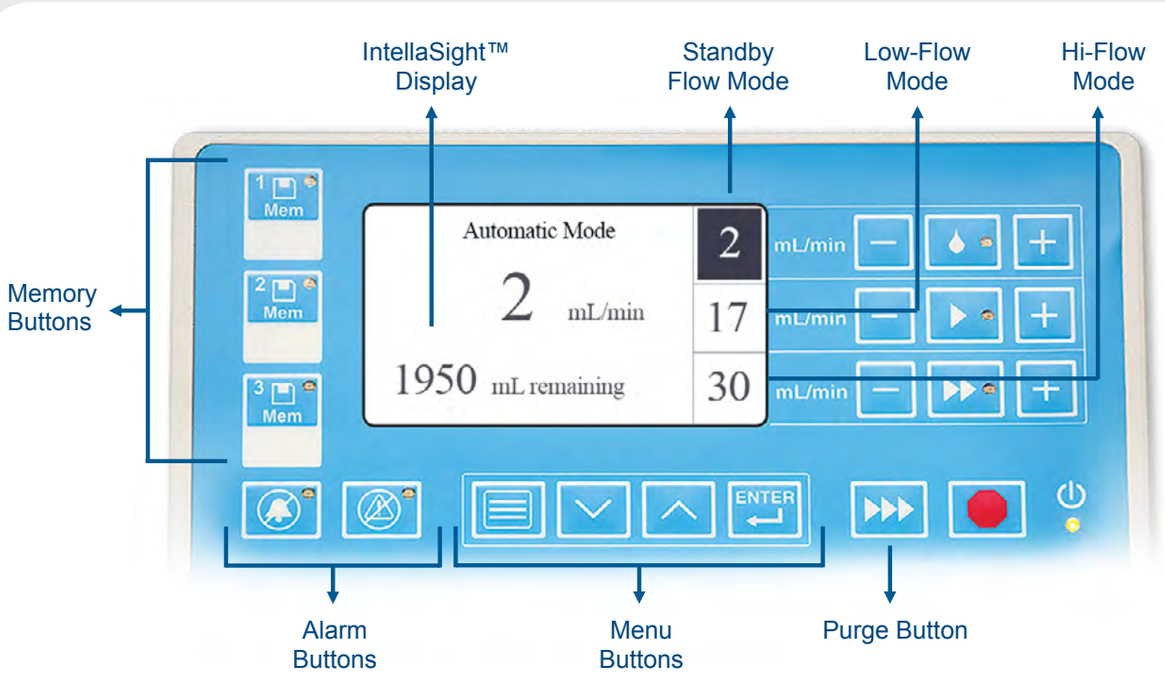
- Large, easy-to-read display screen with intelligent user interface
- Intuitive, easy-to-interpret diagnostic messages
- Bubble and occlusion detection

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Intelligent User Interface

- Comprehensive, real-time diagnostic information on one screen
- Large, easy-to-read display can be viewed from a distance
- Quick, intuitive menu navigation



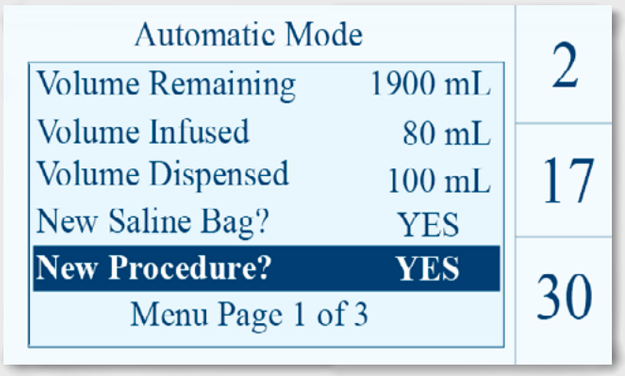
IntellaSight™ Infusion Monitoring | Customizable Memory Buttons

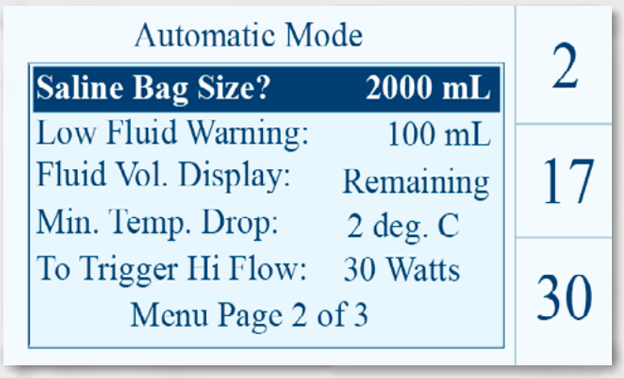
NAV-ENABLED ABLATION CATHETERS

IntellaSight™ Infusion Monitoring

Provides real-time feedback on five different saline assessments

	Item	Description
1	Volume Remaining	Total fluid left in bag
2	Volume Infused	Total fluid dispensed while catheter is in patient
3	Volume Dispensed	Total fluid flow since start of procedure
4	New Saline Bag	Standard saline bag sizes from 500 mL to 2000 mL
5	Low Fluid Warning	Set alert message to display at 100 mL to 500 mL remaining





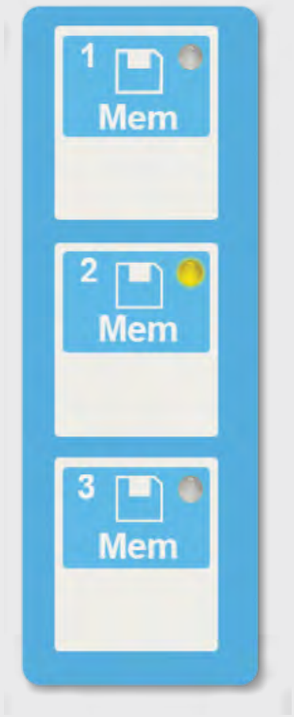
NAV-ENABLED ABLATION CATHETERS

Select from these topics

- Cool Performance
- Clinical Science
- Open-Irrigated System
  - Systems
  - Overview
  - MAESTRO 4000
  - METRIQ
  - User Interface
  - Detection
  - Titration

Customizable Memory Buttons

- Programmable flow and menu settings can be quickly accessed for future procedures
- Store and retrieve procedure parameters for up to three different scenarios



To store flow and menu settings

- Press and hold button for more than two seconds
- Pump will sound a short beep when button is pressed and a long beep when settings are stored
- LED will flash

To retrieve flow and menu settings

- Press and then release button
- Pump sounds a short beep and the stored parameter will display

White space can be used to label button

IntellaSight™ Infusion Monitoring | Customizable Memory Buttons

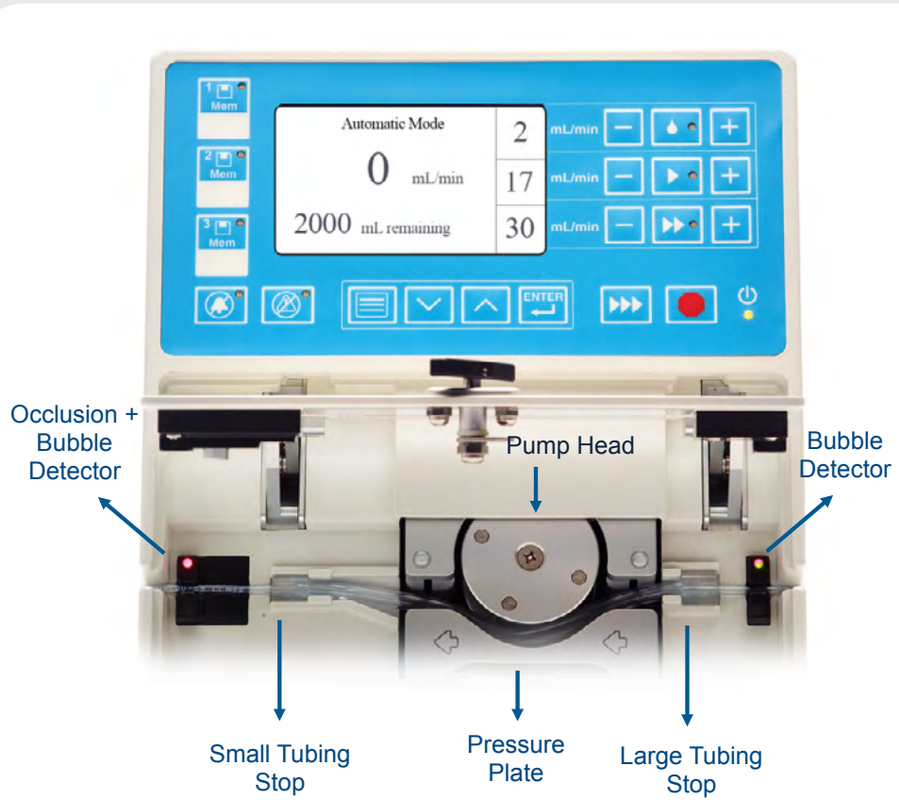
NAV-ENABLED ABLATION CATHETERS

Select from these topics

- Cool Performance
- Clinical Science
- Open-Irrigated System
  - Systems
  - Overview
  - MAESTRO 4000
  - METRIQ
  - User Interface
  - Detection
  - Titration

Bubble and Occlusion Detection

- Reliable sensor technology designed to prevent air infusion and occlusion
- Simple placement process to ensure accurate tubing alignment
- Smaller tubing designed to effectively clear bubbles and increase flow



NAV-ENABLED ABLATION CATHETERS

Automatic Titration

- Intelligent, automatic titration ensures optimal power-to-fluid control
- Instant, clear display of titration status

Example Scenario: METRIQ™ Pump delivers saline at hi-flow (30 mL/min) when the MAESTRO 4000™ Controller power level is set to 30 Watts

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- MiFi Mini-Electrodes
- True Tip Location
- True Tissue Assessment
- True Ablation Feedback

INTELLANAV MIFI™ XP

INTELLANAV MIFI™ OI

NAV-ENABLED ABLATION CATHETERS

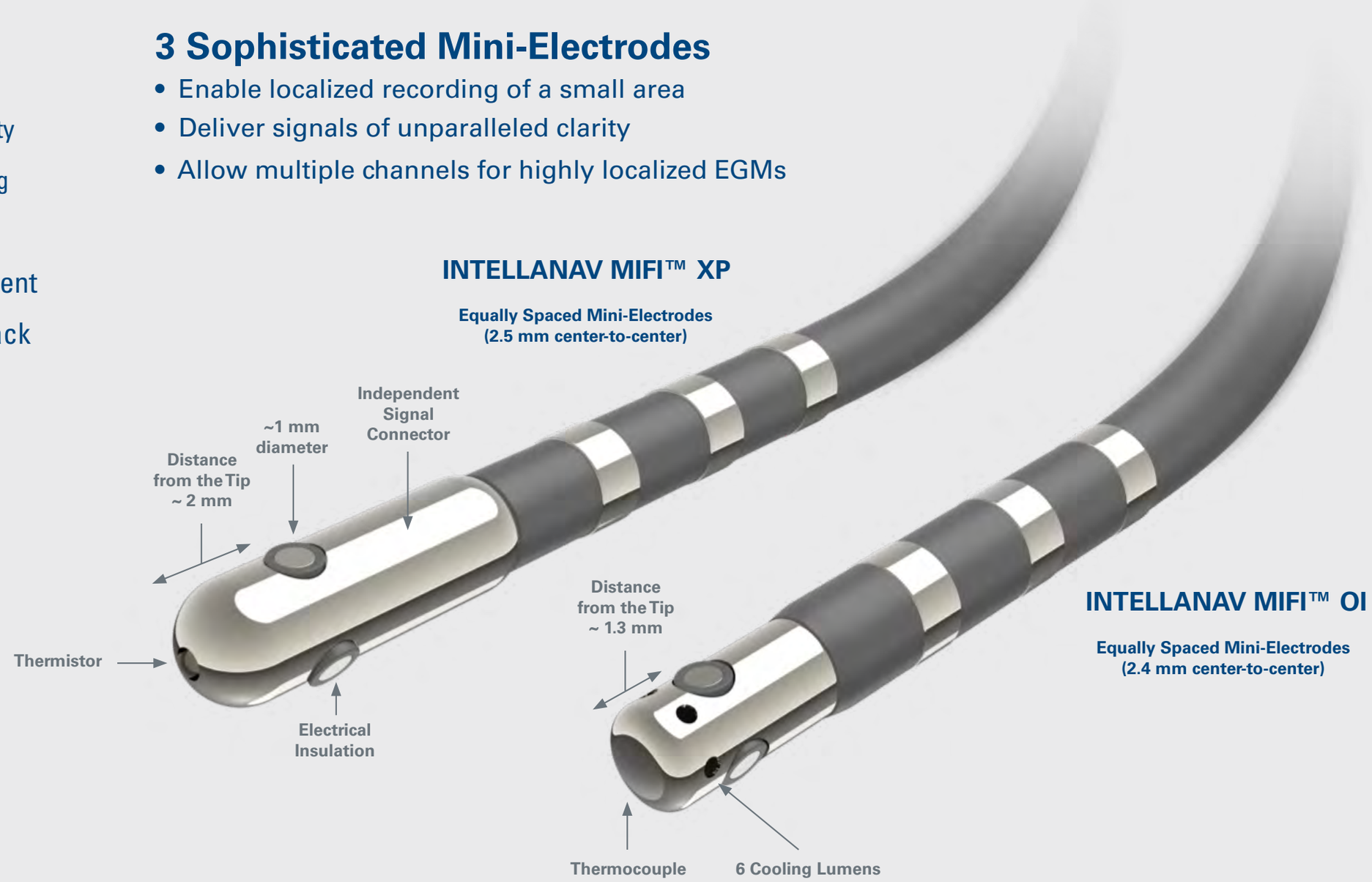
Select from these topics

- MiFi Mini-Electrodes
  - Unique Design
  - Unparalleled Clarity
  - Seeing Is Believing
- True Tip Location
- True Tissue Assessment
- True Ablation Feedback

Unique Catheter Design

3 Sophisticated Mini-Electrodes

- Enable localized recording of a small area
- Deliver signals of unparalleled clarity
- Allow multiple channels for highly localized EGMs

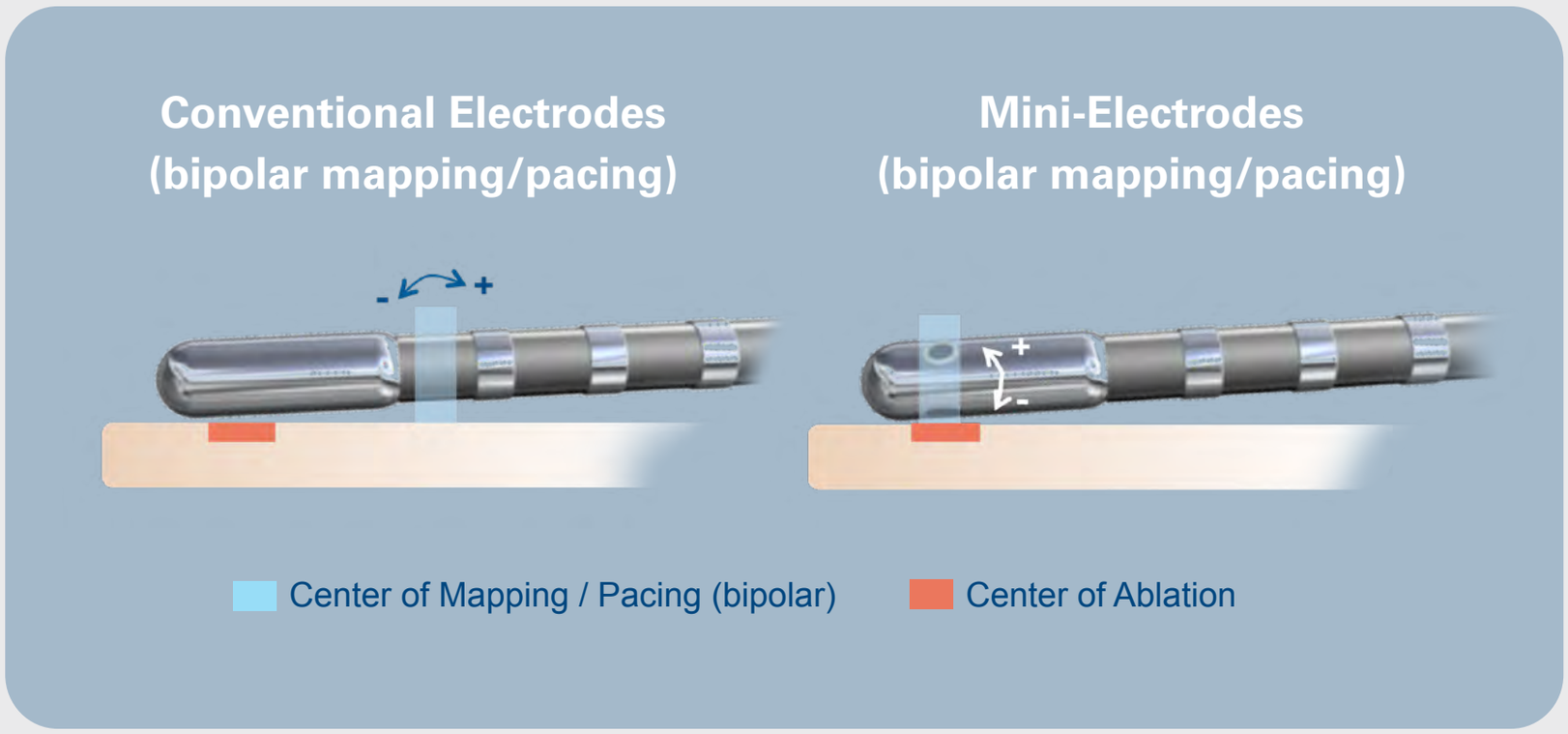


NAV-ENABLED ABLATION CATHETERS

Select from these topics

- MiFi Mini-Electrodes
  - Unique Design
  - Unparalleled Clarity
  - Seeing Is Believing
- True Tip Location
- True Tissue Assessment
- True Ablation Feedback

Unparalleled Clarity | The Truth with MicroFidelity



NAV-ENABLED ABLATION CATHETERS

Select from these topics

- MiFi Mini-Electrodes
  - Unique Design
  - Unparalleled Clarity
  - Seeing Is Believing
- True Tip Location
- True Tissue Assessment
- True Ablation Feedback

Map creation with INTELLANAV MIFI™ XP

True Tip Location

MiFi sensitivity can show contact via EGMs

- Example 1 – concept animation
- Example 2 – EGM strip

MiFi can show when the catheter tip is:

- In the ventricle
- In the atrium

Tip location in relation to a line of block

True Tissue Assessment

- Viable or Non Viable Tissue
- vMap™ to assess block on the CTI
- Map double potentials
- Look for gaps
- Pacing thresholds to assess tissue

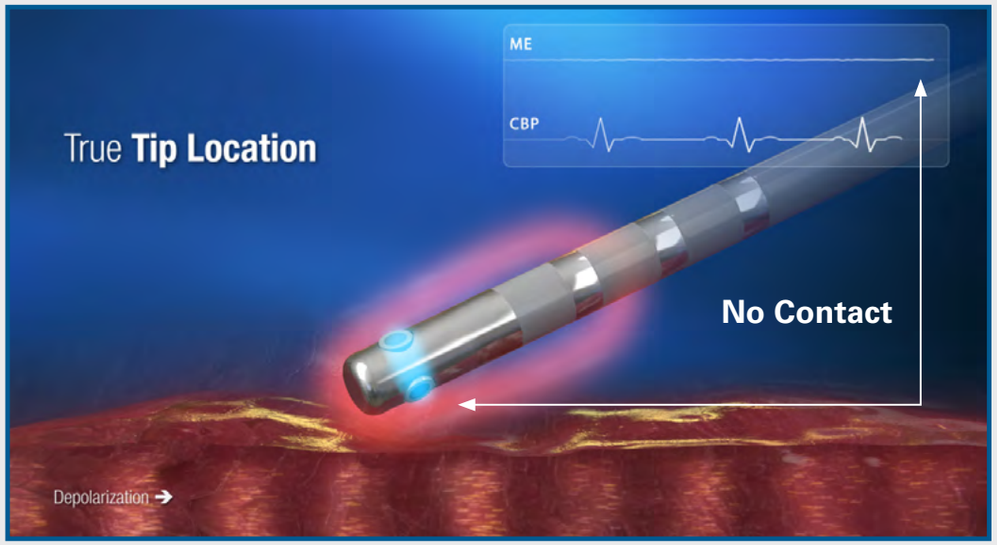
True Ablation Feedback

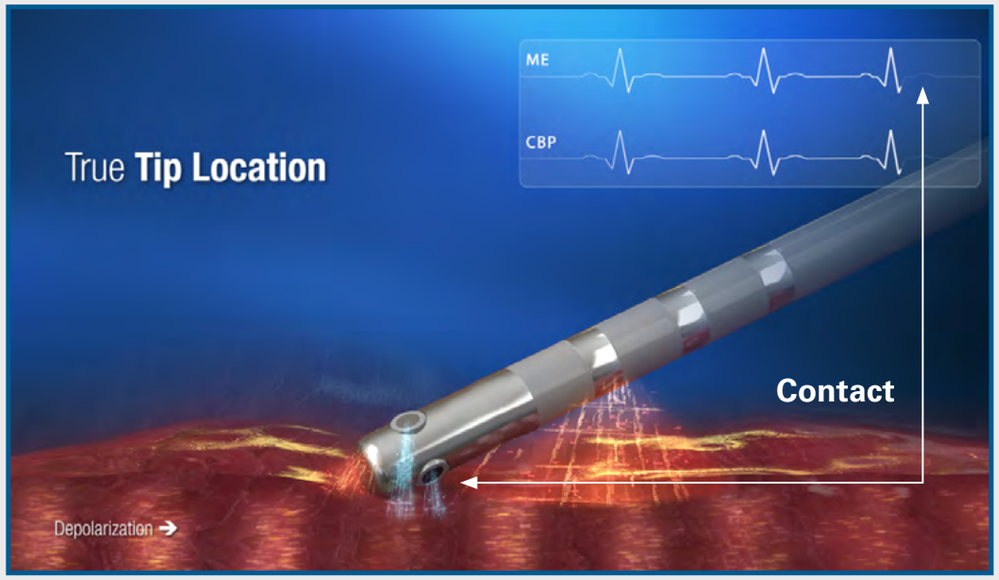
- EGM attenuation
- Amplitude reduction greater than common bi-pole

NAV-ENABLED ABLATION CATHETERS

Select from these topics

True Tip Location



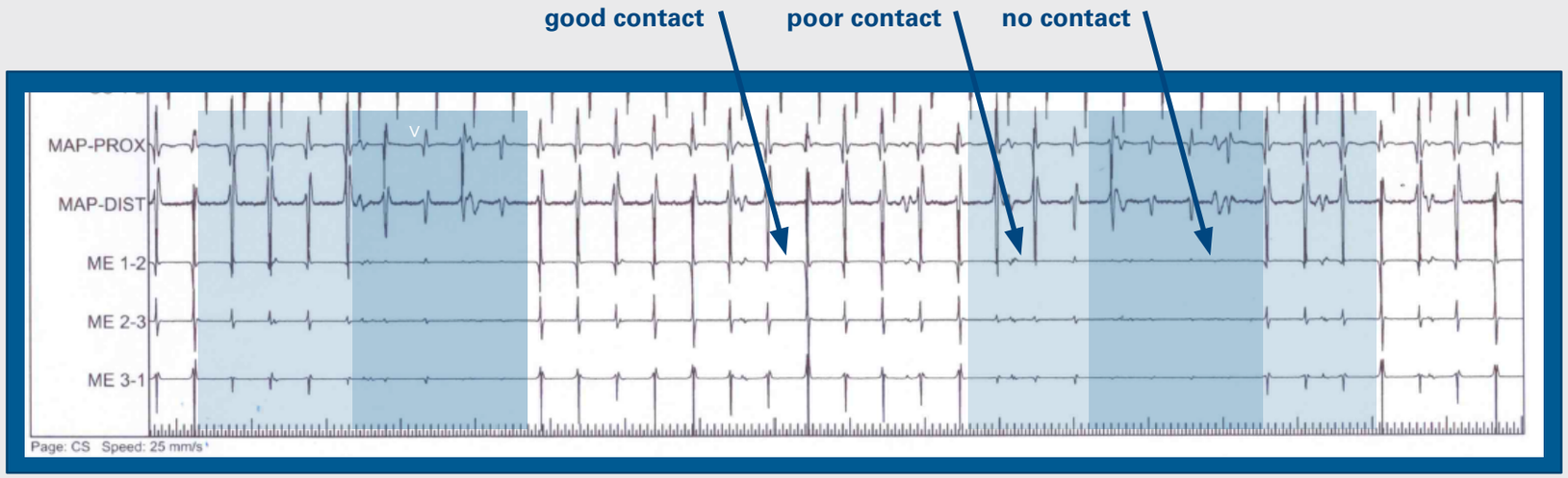


NAV-ENABLED ABLATION CATHETERS

True Tip Location | Contact assessment with MiFi electrograms

Distinguishing varying degrees of contact

- Tracing below shows respiratory movement leading to intermittent contact
- MiFis show not only “no contact” but also the transition from “good contact” to “no contact”
- Conventional bipoles (MAP-PROX and MAP-DIST) are dominated by far-field activity and suggest adequate contact throughout the recording.



MiFi electrograms reveal more information than just contact or no contact. They also reveal stability of contact.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

True Tip Location I All V on MiFi

Mini-Electrode EGMs clearly demonstrate when the catheter tip is in the ventricle

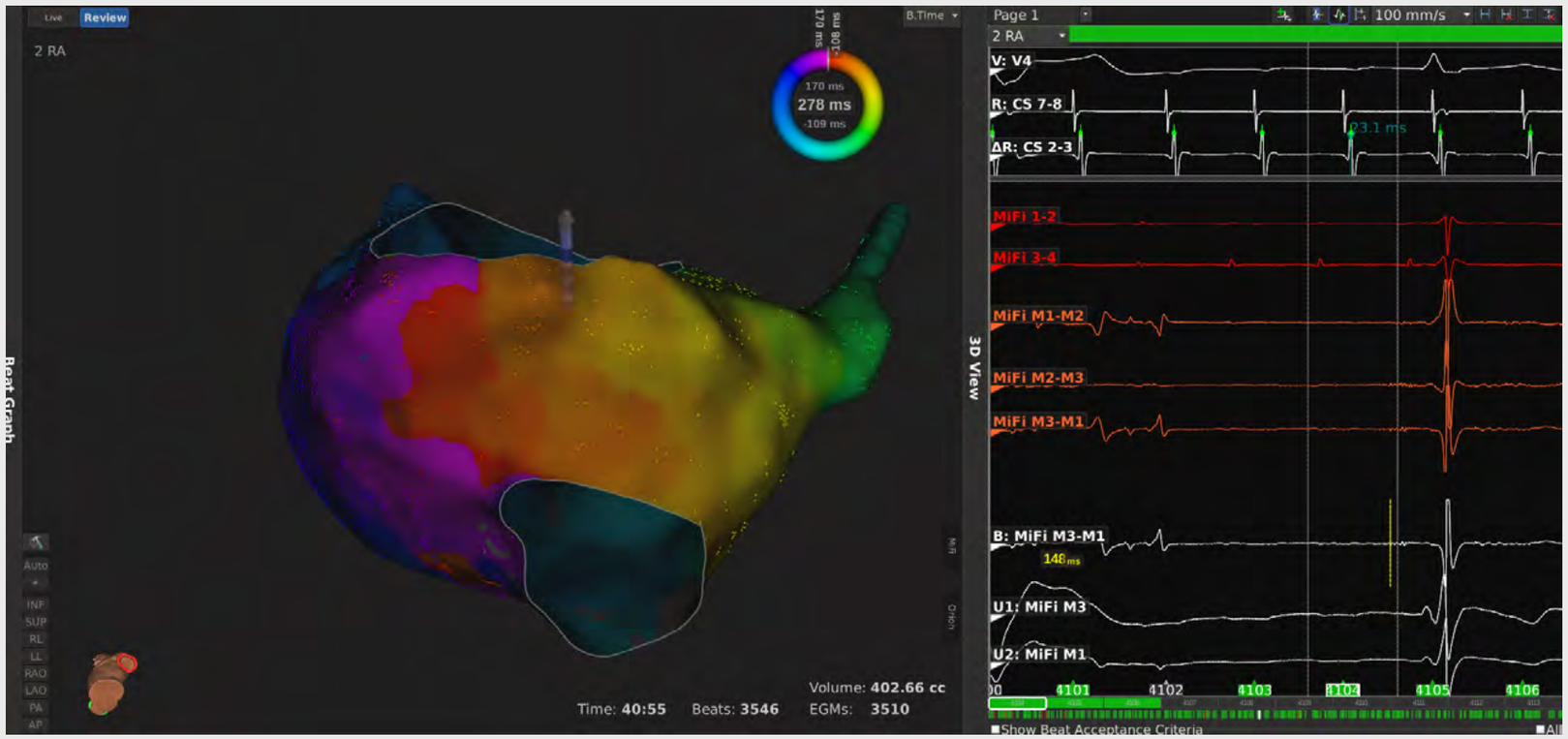


Image courtesy of Kevin Makati, MD, St. Joseph's Hospital, Tampa, FL.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

True Tip Location I A & V on MiFi

Mini-Electrode EGMs clearly demonstrate when the catheter tip is entering the atrium

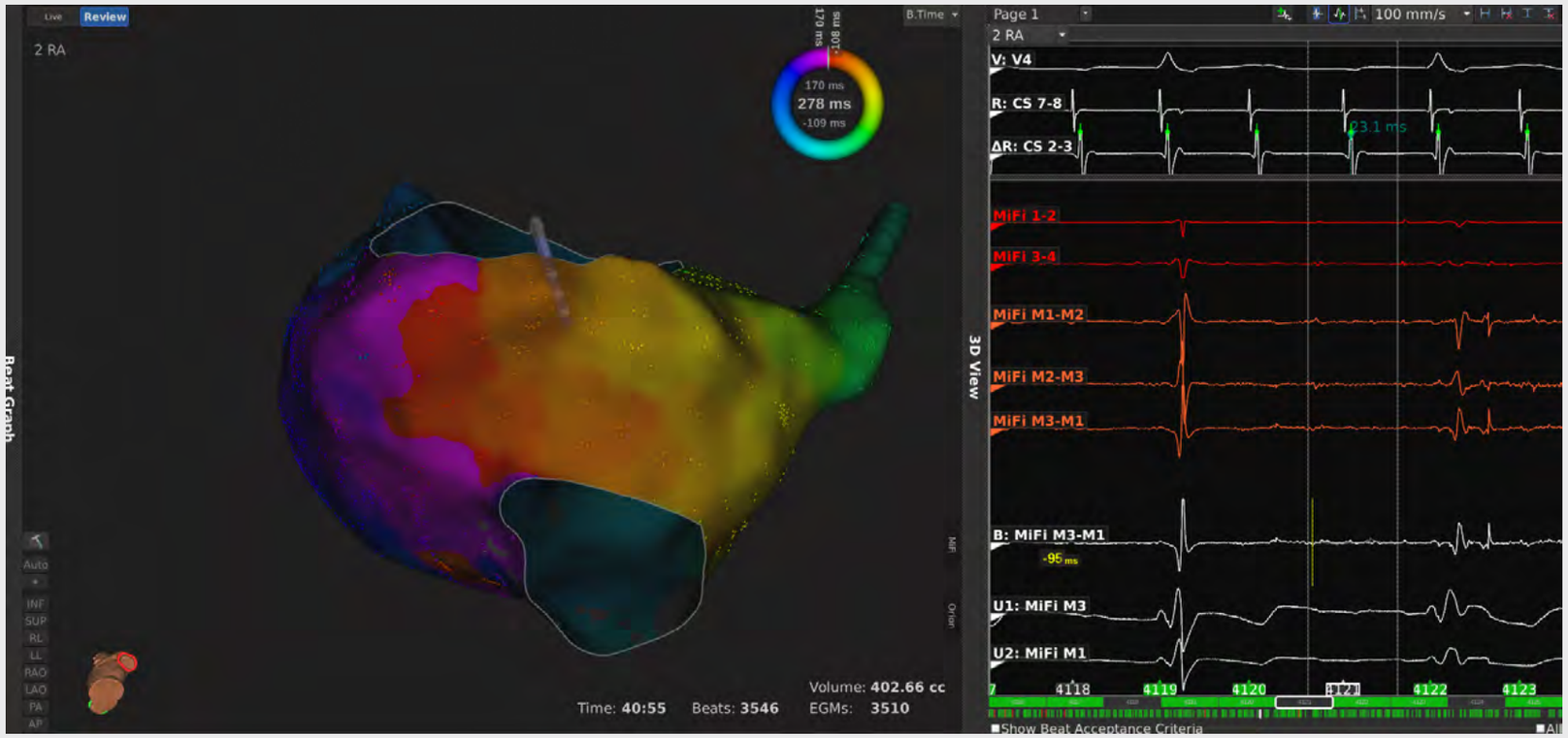


Image courtesy of Kevin Makati, MD, St. Joseph's Hospital, Tampa, FL.

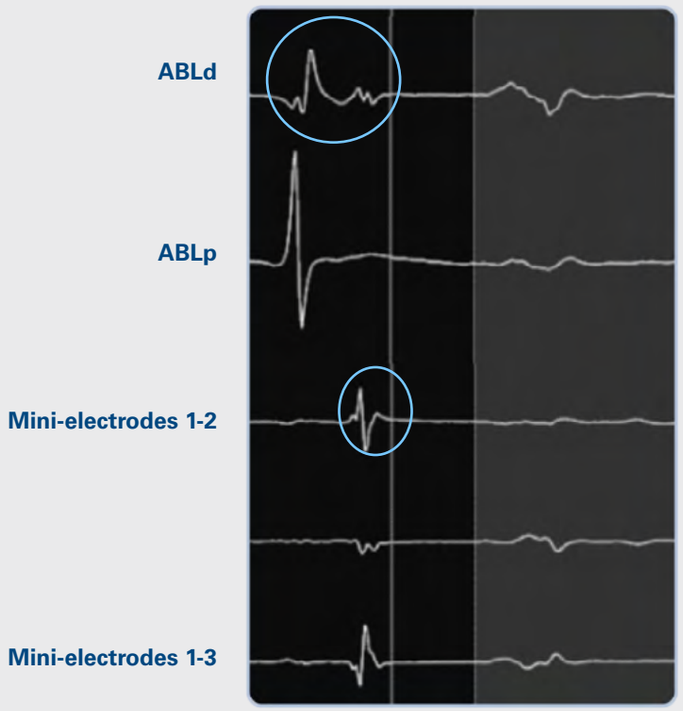
NAV-ENABLED ABLATION CATHETERS

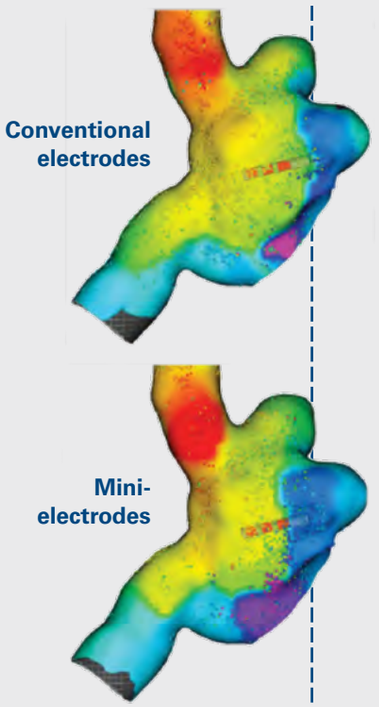
Select from these topics

- ○ MiFi Mini-Electrodes
- ● True Tip Location
  - ○ Visual
  - ○ Electrograms
  - ○ All V on MIFI
  - ○ A & V on MIFI
  - ● High Resolution Mapping
- ○ True Tissue Assessment
- ○ True Ablation Feedback

Accurate High-Resolution Mapping

Maps generated with the mini-electrodes provide accurate information of tip location in relation to the line of block





Conventional electrode recordings suggest the tip electrode is located on the proximal side of the line of block (first potential of double potentials), but the mini-electrode recording shows that the tip electrode is actually located on the distal side (second potential of double potentials).

Nakagawa H, Harlev D, Koblish J, et al. Mini recording electrodes within a conventional 4.5 mm tip electrode improves ablation catheter mapping resolution. Poster session PO06-72 presented at 2012 Heart Rhythm Society, Boston, MA. (Right Atrial canine model, n=4. Operator utilized RHYTHMIA Mapping System with 4.5 mm Open-Irrigated IntellaTip MiFi catheter). Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- MiFi Mini-Electrodes
- True Tip Location
- True Tissue Assessment
  - Tissue Substrate Identification
  - INTELLENAV MIFI & vMap
  - Mapping Double Potentials
  - Gap Identification
  - True Tissue Assessment
- True Ablation Feedback

Tissue Substrate Identification

INTELLANAV MIFI™ XP technology provided higher specificity and sensitivity in predicting atrial fibrosis and identifying abnormal substrate

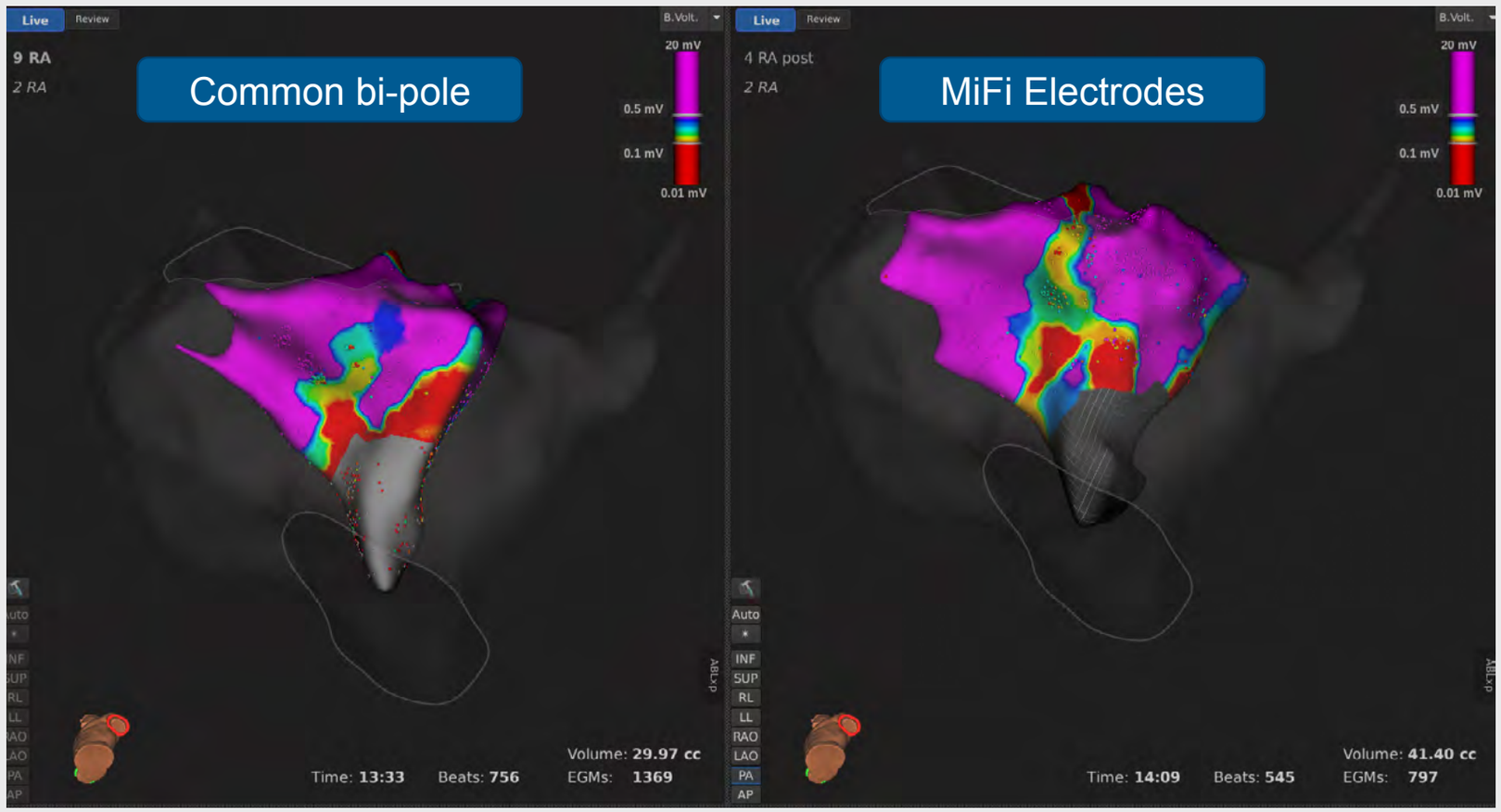


Image courtesy of Kevin Makati, MD, St. Joseph's Hospital, Tampa, FL.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

- MiFi Mini-Electrodes
- True Tip Location
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  - Gap Identification
  - True Tissue Assessment
- True Ablation Feedback

INTELLANAV MIFI™ XP & vMap™

INTELLANAV MIFI XP provided clarity and accuracy to quickly vMap and assess bi-directional block

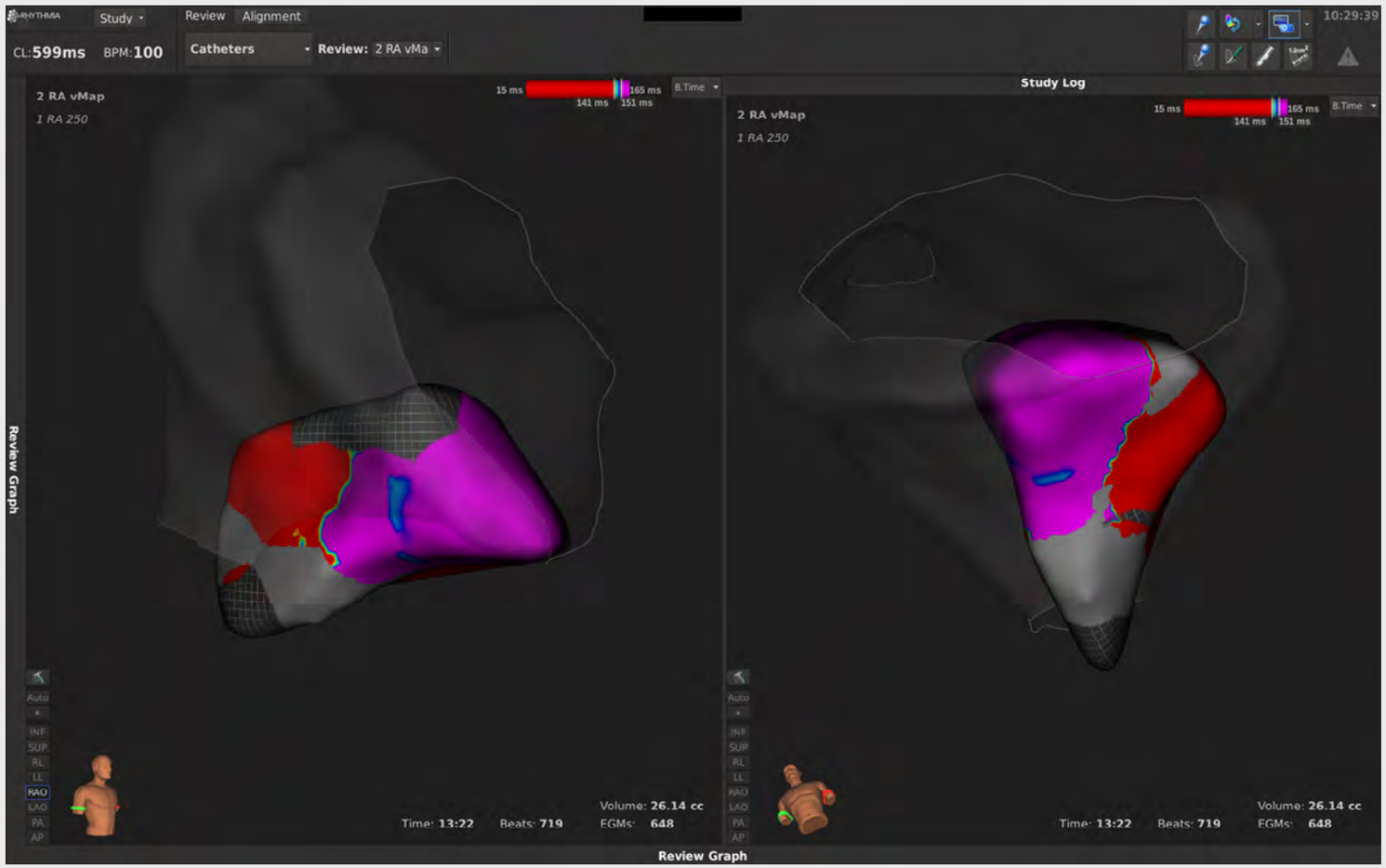

Image courtesy of Matt Ostrom, MD, Torrance Memorial Hospital, Torrance, CA.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

NAV-ENABLED ABLATION CATHETERS

Select from these topics

Mapping Double Potentials Along the CTI Ablation Line

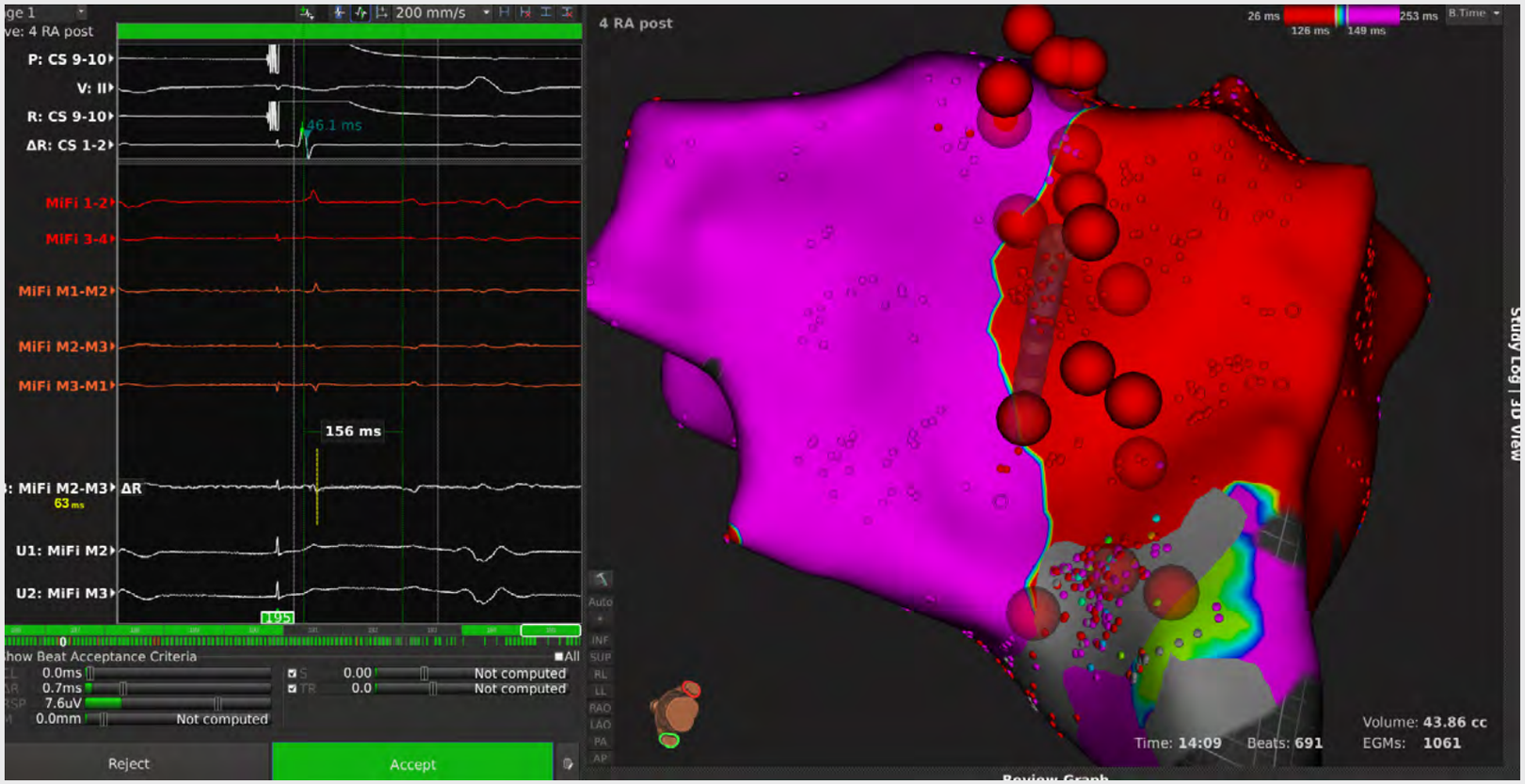

Image courtesy of Kevin Makati, MD, St. Joseph's Hospital, Tampa, FL.

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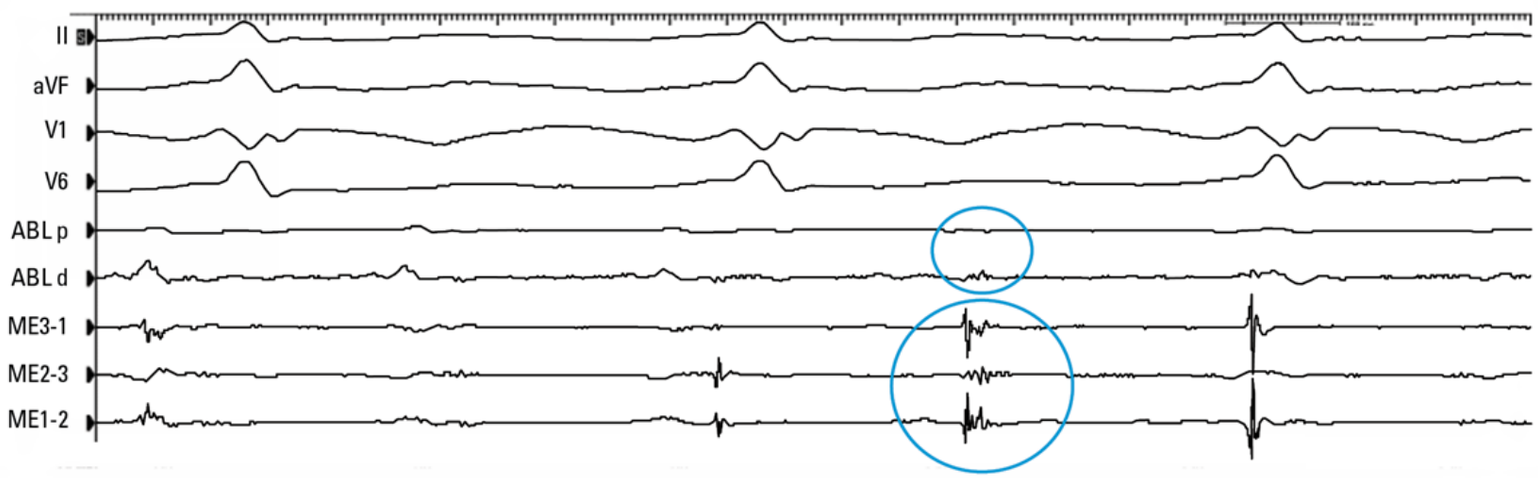
NAV-ENABLED ABLATION CATHETERS

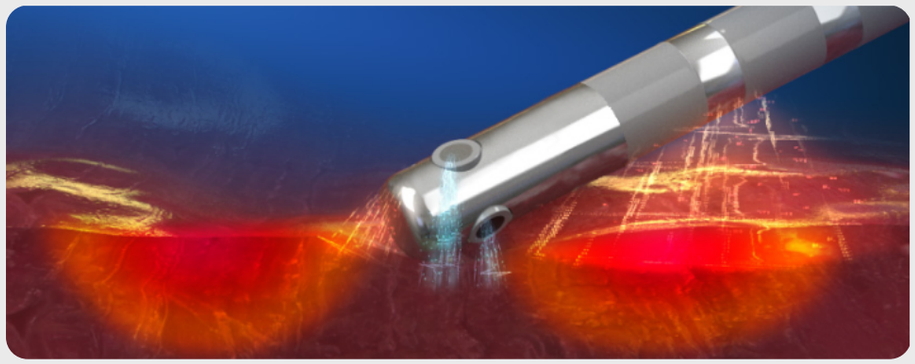
Select from these topics

- MiFi Mini-Electrodes
- True Tip Location
- True Tissue Assessment
  - Tissue Substrate Identification
  - INTELLENAV MIFI & vMap
  - Mapping Double Potentials
  - Gap Identification
  - True Tissue Assessment
- True Ablation Feedback

Gap Identification

High-resolution recording provided the sensitivity needed for quick and accurate detection of viable tissue





1. Maddox W. The IntellaTip MiFi XP Ablation Catheter: Thoughts from a young electrophysiologist. Presented at 2013 Boston Scientific National Sales Meeting, Orlando FL. EP-222201-AA. Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

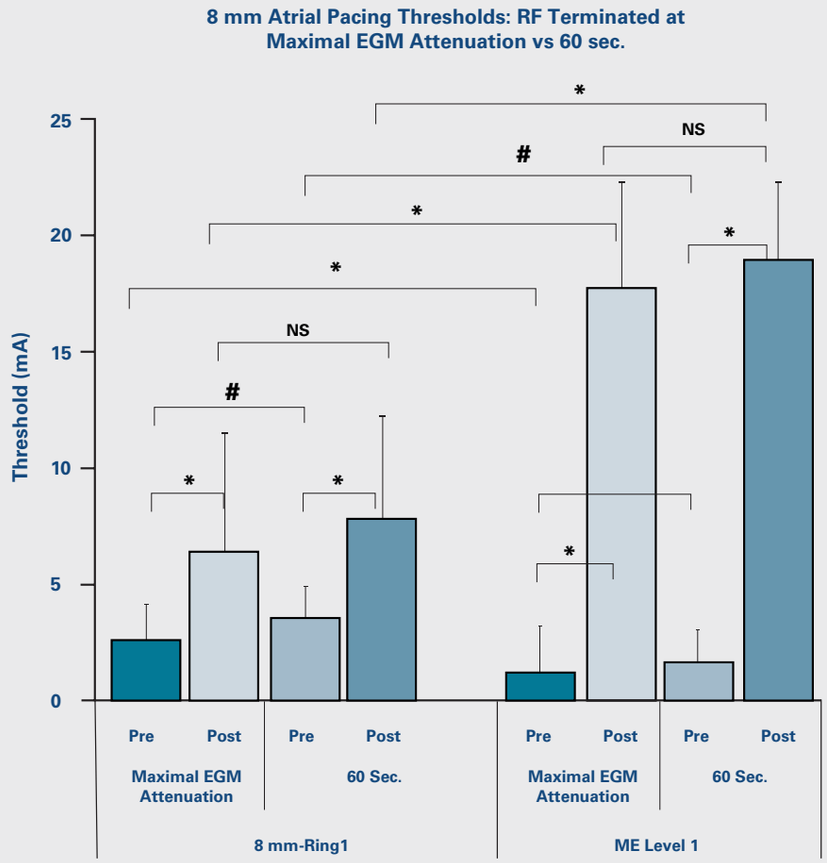
NAV-ENABLED ABLATION CATHETERS

Select from these topics

True Tissue Assessment

- Mini-electrodes exhibited marked threshold and EGM changes in the presence of transmural lesions in the atria
- The smaller surface area of the mini-electrodes compared to the 4.5-mm or 8-mm tip electrode yielded higher current density depolarizing a smaller tissue mass, leading to a lower pacing threshold

ME Pacing can help assess viable vs non-viable tissue



Avitall B, Horbal P, Vance D, et al. Maximal electrogram attenuation recorded from mini electrodes embedded on 4.5-mm irrigated and 8-mm nonirrigated catheters signifies lesion maturation. *J Cardiovasc Electrophysiol.* 2015 Feb;26(2):192-202.
Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

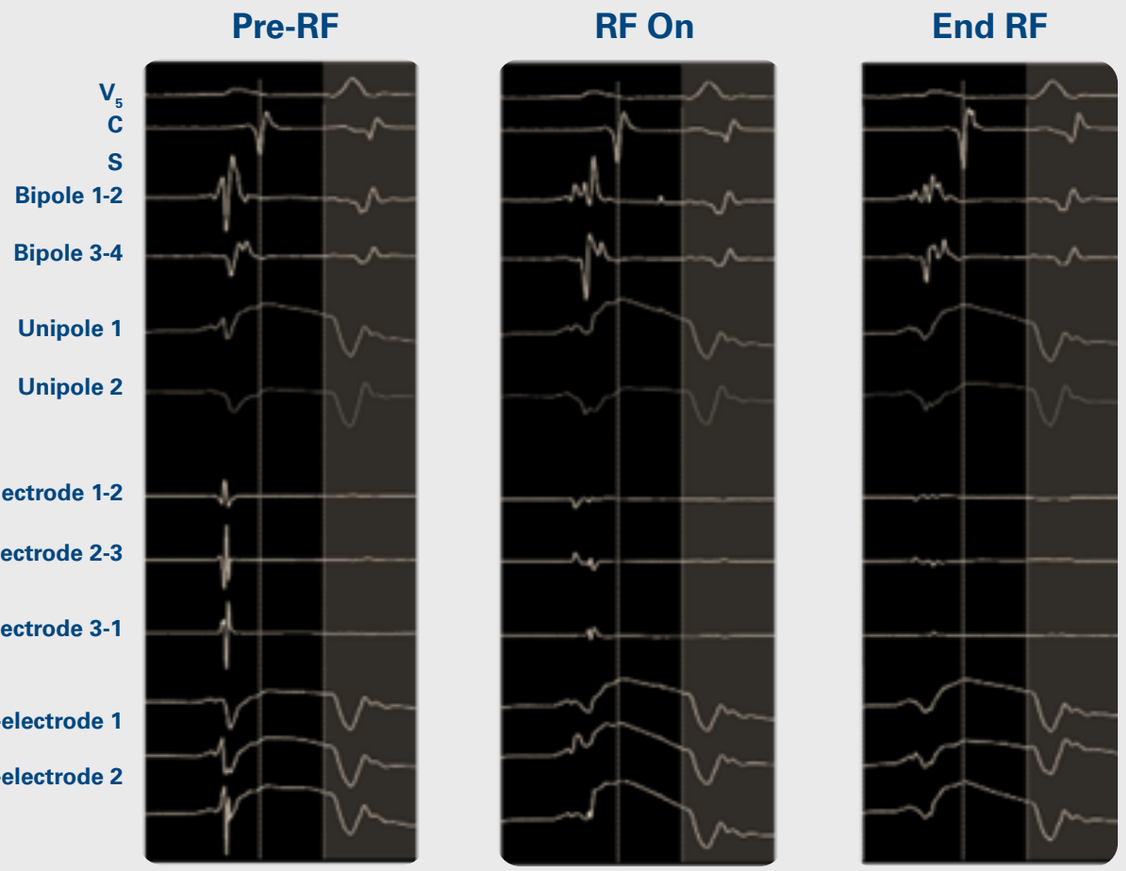
NAV-ENABLED ABLATION CATHETERS

Select from these topics

- MiFi Mini-Electrodes
- True Tip Location
- True Tissue Assessment
- True Ablation Feedback
  - Clarity in EGM Attenuation
  - Lesion Maturation

Clarity in EGM Attenuation

Mini-electrodes demonstrated significant amplitude reduction and signal clarity during ablation as compared to unipolar and bipolar signals



Case images courtesy of W. Jackman, MD, University of Oklahoma Health Sciences Center. Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

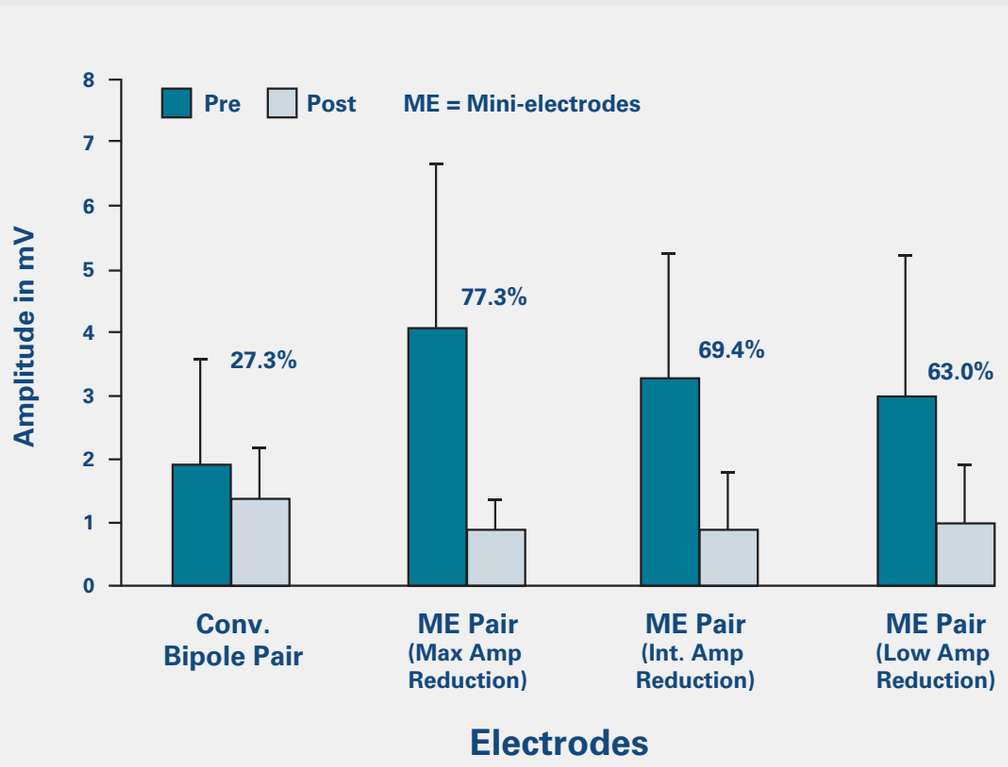
NAV-ENABLED ABLATION CATHETERS

Select from these topics

- MiFi Mini-Electrodes
- True Tip Location
- True Tissue Assessment
- True Ablation Feedback
  - Clarity in EGM Attenuation
  - Lesion Maturation

Lesion Maturation

- **EGM amplitude reduction, post ablation, was greater when measured with mini-electrodes compared to conventional 8 mm tip[1]**
- **EGM amplitude reduction on the mini-electrodes, post ablation, was correlated to transmurality[1]**



1. Price A, Leshen Z, Hansen J, et al. Novel ablation catheter technology that improves mapping resolution and monitoring of lesion maturation. *J Innovat Cardiac Rhythm Manag.* 2012;3:599-609. (Canine model, n=7). Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

NAV-ENABLED ABLATION CATHETERS

7F = 2.33mm | 7.5F = 2.5 mm | 8F = 2.6mm | 8.5F = 2.33 mm