Boston Scientific
Advancing science for life™

FARAPULSE™

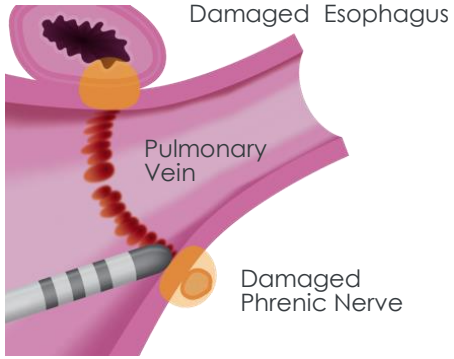
Pulsed Field Ablation System

Safety Profile to Adjacent Structures

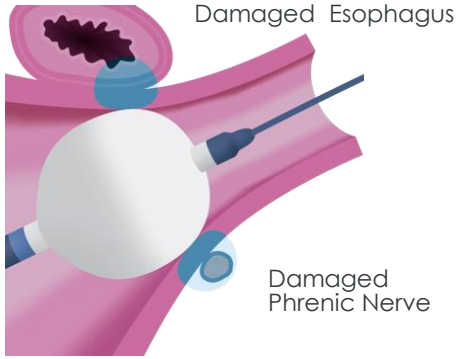
Thermal Energy Can't Differentiate; PFA is Tissue Selective

Thermal lesions can spread into surrounding tissue indiscriminately

RADIOFREQUENCY ABLATION



CRYO ABLATION

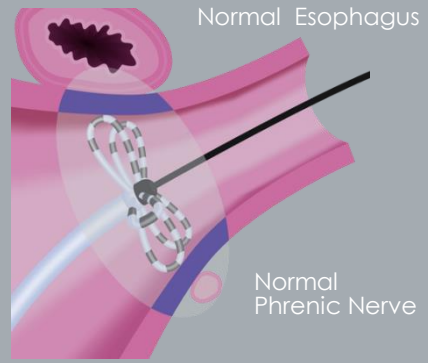


Potential Complications:

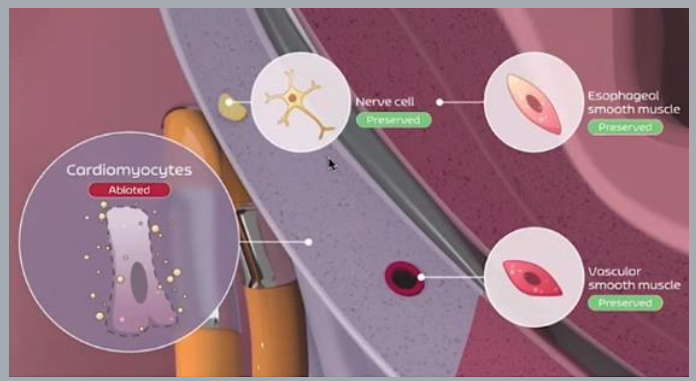
- PV Stenosis
- Phrenic Nerve Palsy
- AE Fistula

PFA can ablate myocardium while reducing collateral damage[1]

PULSED FIELD ABLATION



Cardiomyocytes have low thresholds to PFA



Other tissue/cell types are more resistant to PFA & remained uninjured despite exposure to the field

[1]Reddy VY et al. J Am Coll Cardiol. 2019;74(3): 315-26 LINK

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Pulse Field Ablation Mechanism of Action

Non-Thermal IRE

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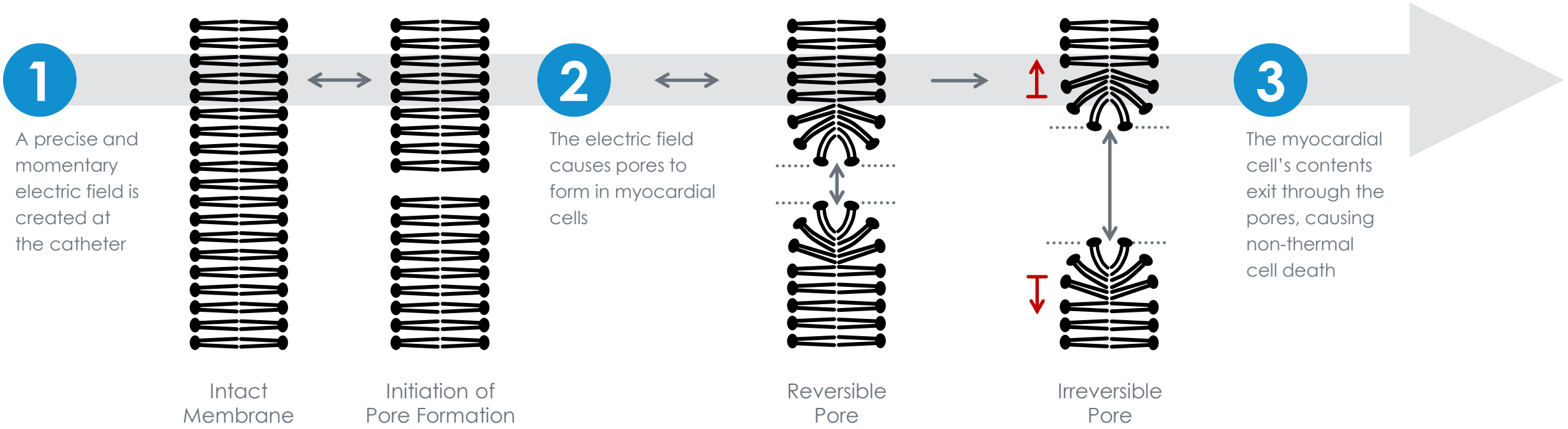
Irreversible Electroporation:
cell membrane pore formation & cell death occurs with sufficient electric field



T. Kotnik et al, *IEEE Electrical Insulation Magazine,* Vol. 28, No. 5 p. 14-23, 2012

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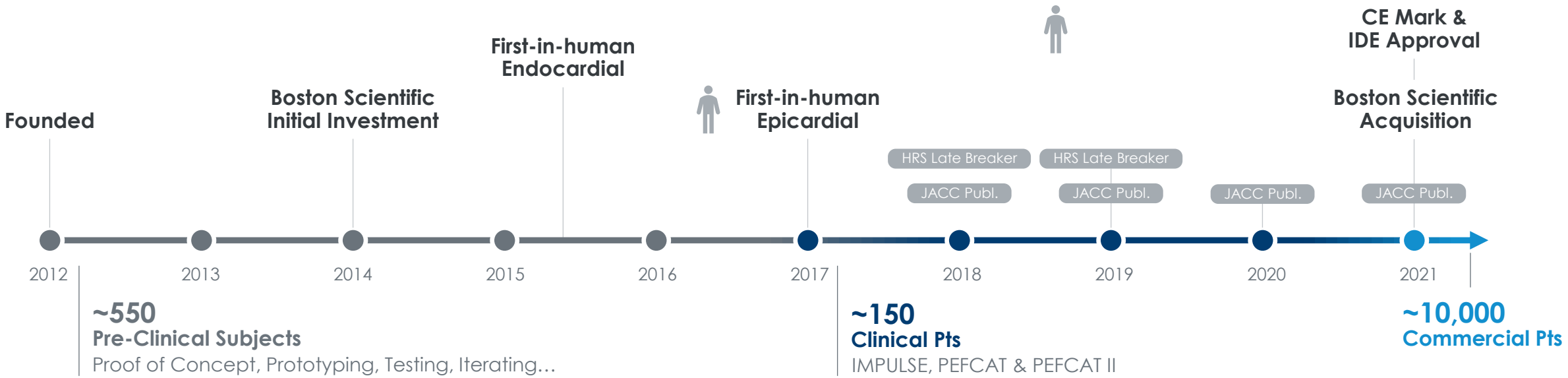
FARAPULSE Dedicated History

Pioneering PFA Technology

FARAPULSE has maintained a singular focus on cardiac PFA since 2012



Design Goals:

BUILD
the ideal PFA system from the ground-up

OPTIMIZE
through pre-clinical & clinical safety, efficacy & lesion durability

VALIDATE
system in randomized trials & commercial use

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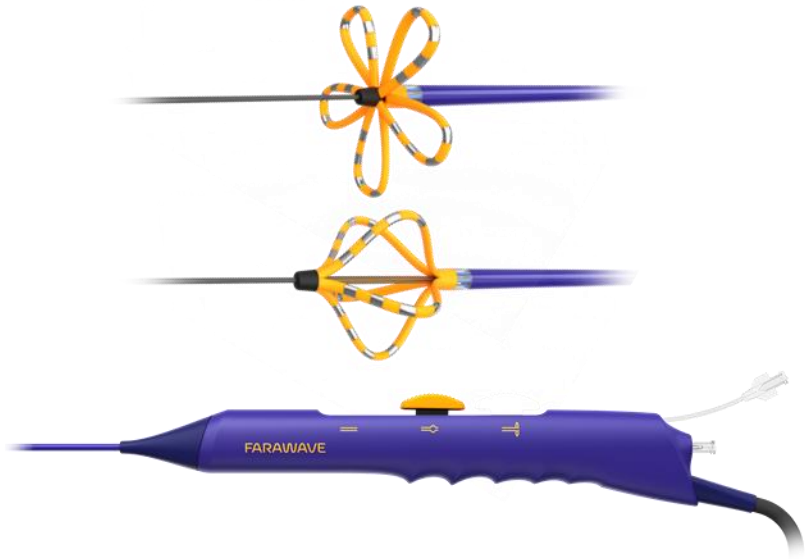
The FARAPULSE™ PFA System

Design Goals

FARADRIVE™*
Steerable Sheath

Steerable sheath designed to navigate the FARAWAVE catheter to targeted cardiac anatomy

FARAWAVE™*
Pulsed Field Ablation Catheter



Over-the-wire PFA catheter with distal end variable morphology **designed to treat a range of PV anatomies**

FARASTAR™*
Pulsed Field Ablation Generator

Bipolar & biphasic waveform generator designed to deliver proprietary PFA therapy through the FARAWAVE catheter

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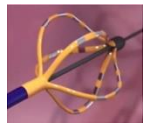
Clinical Data – Lesion Durability at Remap

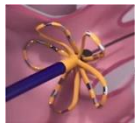
Acute Isolation Does Not Equal Durable Lesions

110 patients returned for prospective remaps at 93 ± 30 days

Cohort	N	Acute PVI (% PVs)	~3 Month Remap Durable PVI (% PVs)	~3 Month Remap Durable PVI (% pts)
Monophasic General anesthesia & paralytics	11	100%	45%	18%
Biphasic (Early/Other) Waveform eliminated need for GA	55	100%	84%	58%
Optimized Biphasic 4 paired applications (8 total) per PV at 1.8 – 2.0kV	44	100%	96%	84%



2 pairs in 'Basket'



2 pairs in 'Flower'

FARAPULSE Optimized Biphasic 96% PVs Durable Isolation at ~3 months[1]

[1]Reddy et al. *JACC: Clinical Electrophysiology* 7.5 (2021): 614-627 LINK

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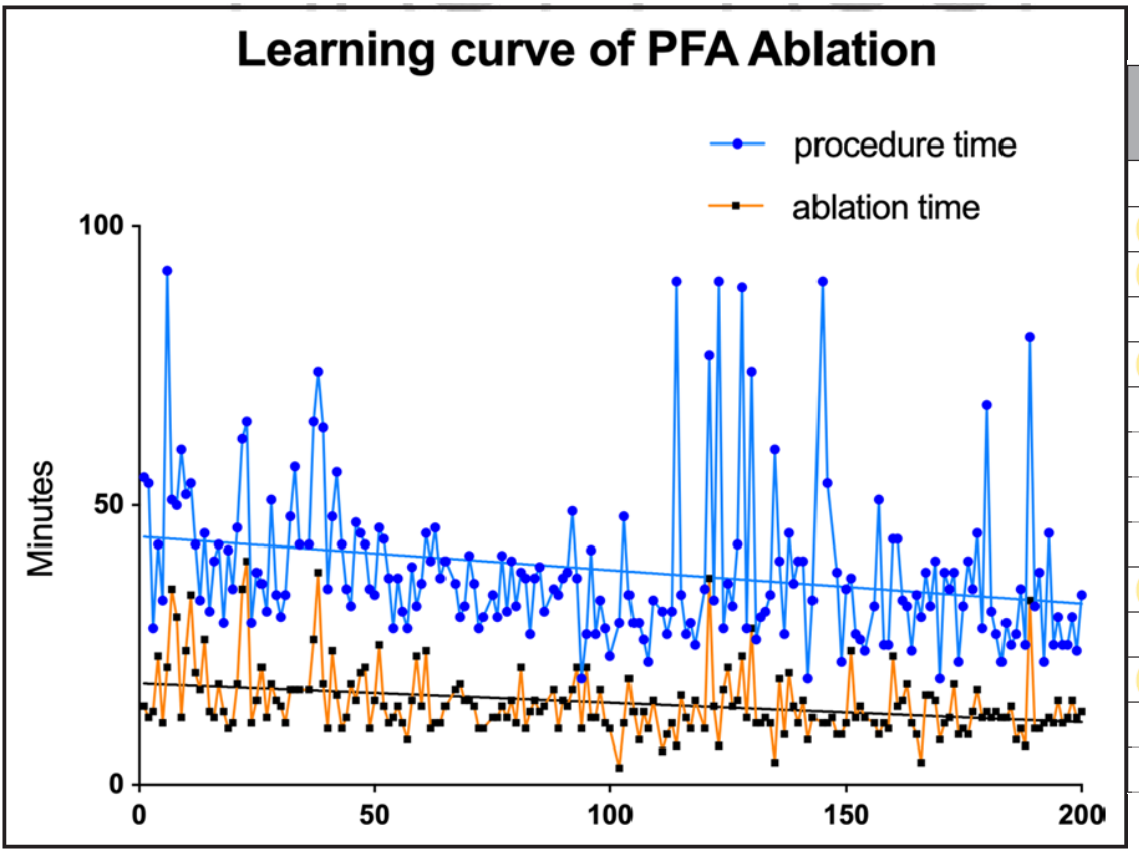
Real-World EU Single Center Experience

Experienced Short Learning Curve & Efficient Procedure



Procedural characteristics, n	Phase 1 25 Pts, 98 PV	Phase 2 166 Pts, 650 PVs	*P* value	Overall 191 Pts, 748 PVs
Duration of overall procedure, mins				
Mean±SD, n	46±14	38±14	0.004*	39±14
Median (min–max)	43 (28–92)	35 (19–90)		36 (19–92)
Overall fluoroscopy time, mins				
Mean±SD, n	11±5	8±4	0.001*	9±4
Median (min–max)	9.9 (5.1–22.9)	7.5 (3.9–27.9)		7.7 (3.9–27.9)
Number of catheters used				
1, n (%)	24 (96%)	166 (100%)		190 (99.5%)
2, n (%)	1 (4%)	0 (0%)		1 (0.5%)
Catheter size (31/35 mm), n (%)	14/11 (56%/44%)	82/84 (49%/51%)		96/95 (50%/50%)
Number of veins attempted, n	98	650	…	748
Number of applications, per vein	8±1	8±0		8±1
Single-shot isolation,† n (%)	95 (97%)	649 (100%)	0.007‡	744 (99.5%)
Patients with all PVs single-shot isolation, n (%)	22 (88%)	165 (99%)	0.006‡	187 (98%)

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Committed to Advancing PFA

Near term clinical studies and form factors

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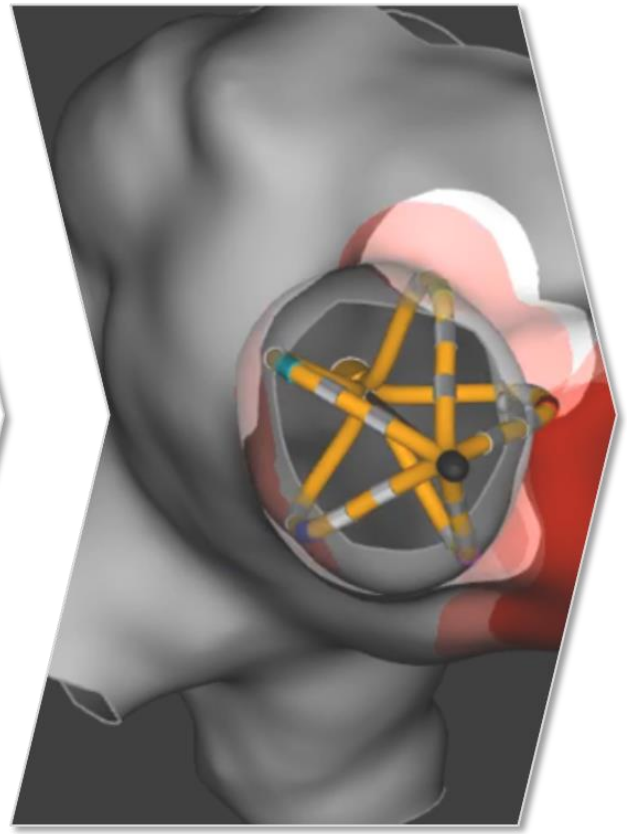
Paroxysmal Indication

ADVENT

FARAWAVE

FARAVIEW
Integrated Mapping



Persistent Indication &
Linear PFA Catheter

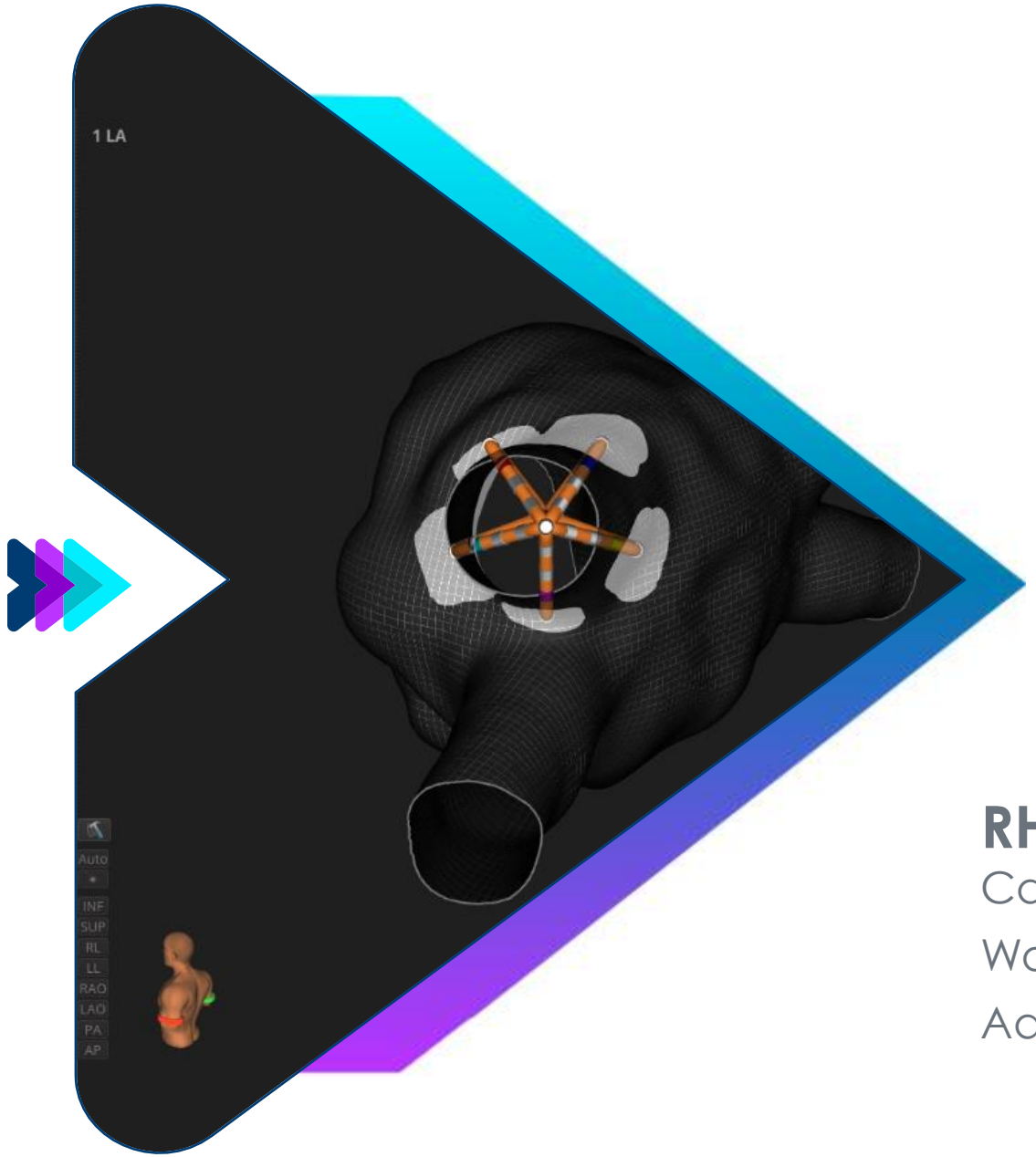
ADVANTAGE

+

FARAPOINT

Front-Line Persistent

AVANT GUARD



Harnessing the power of RHYTHMIA + FARAWAVE

RHYTHMIA HDx Integration Design Goals**

Catheter visualization with reduced fluoroscopy

Workflow support

Advanced versatility beyond PVI

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An Integrated Experienced

FARAWAVE™ with FARAVIEW™ Mapping Module**

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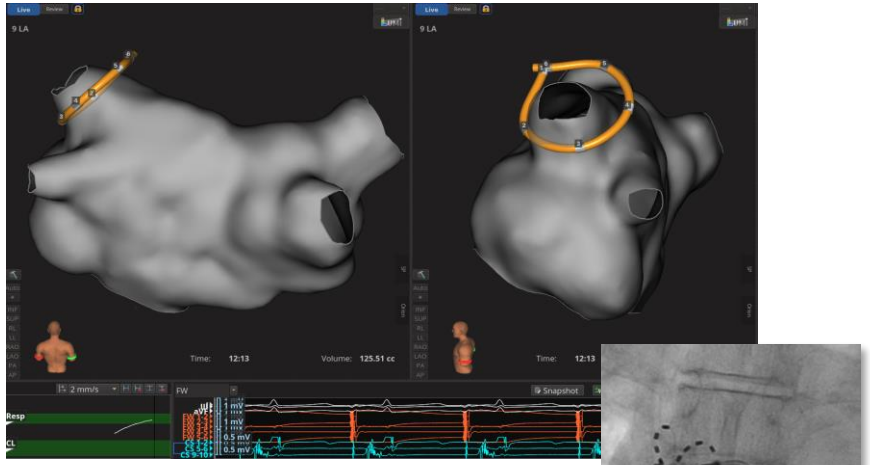
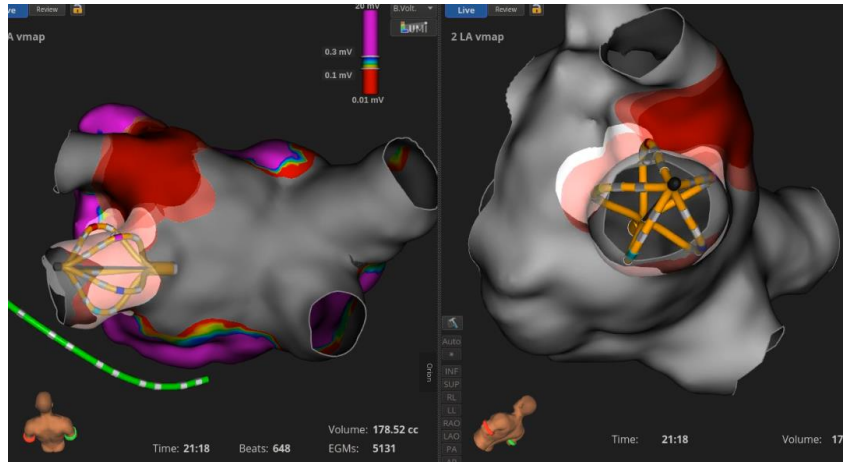
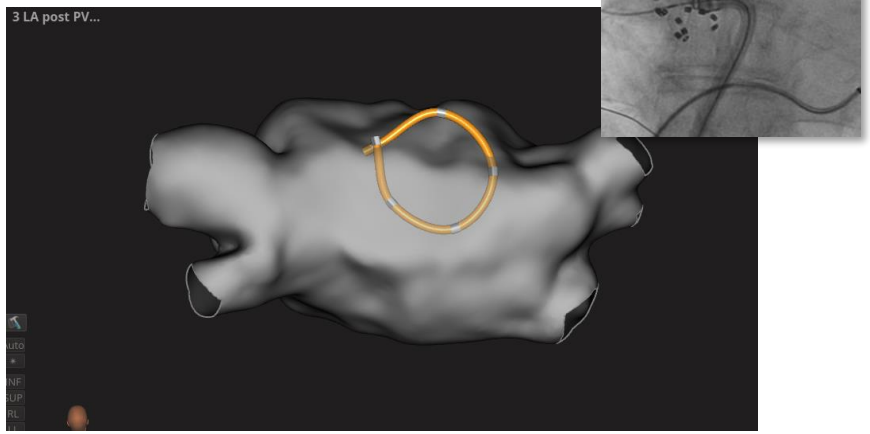
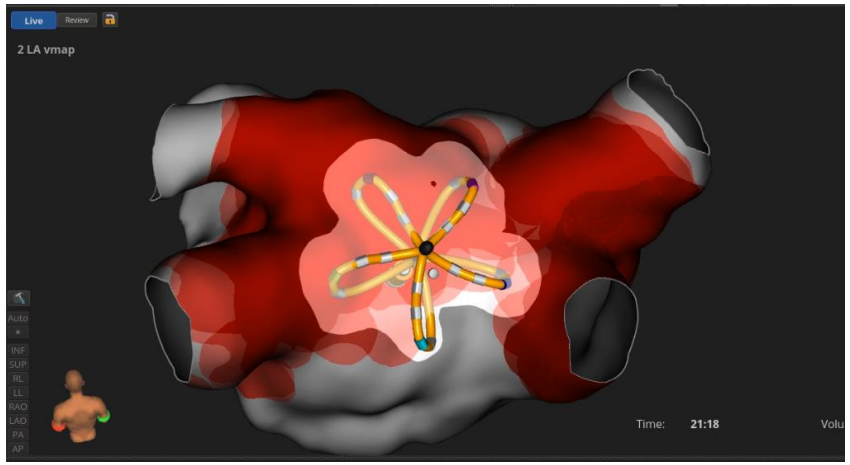
	Fluoro-Based / Impedance Tracked	FARAVIEW™ Mapping Module
Pulmonary Vein Isolation		
Posterior Wall Isolation		

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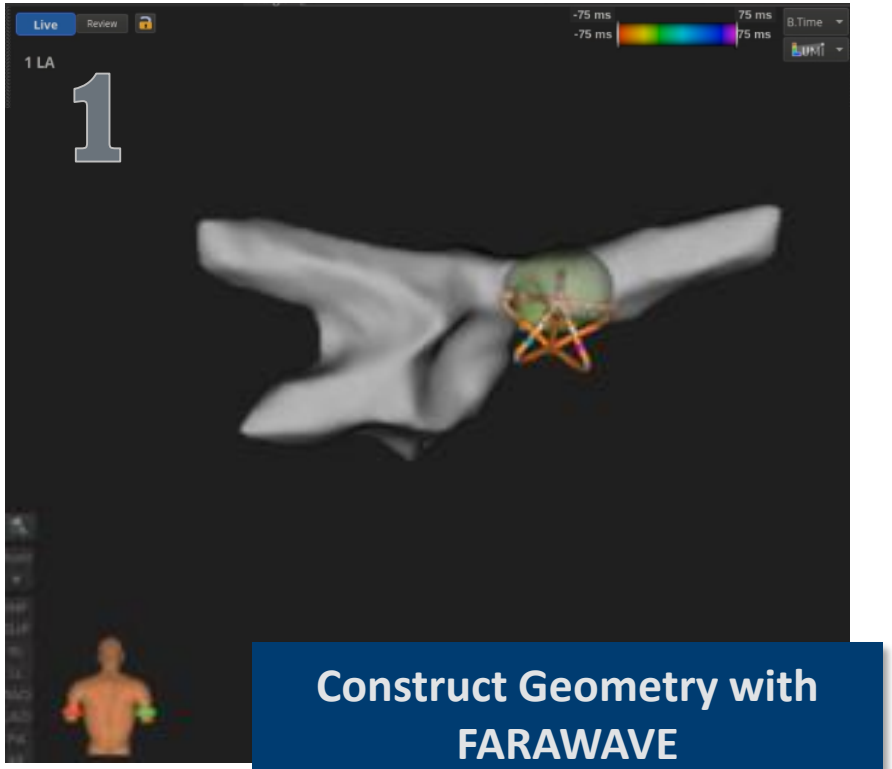
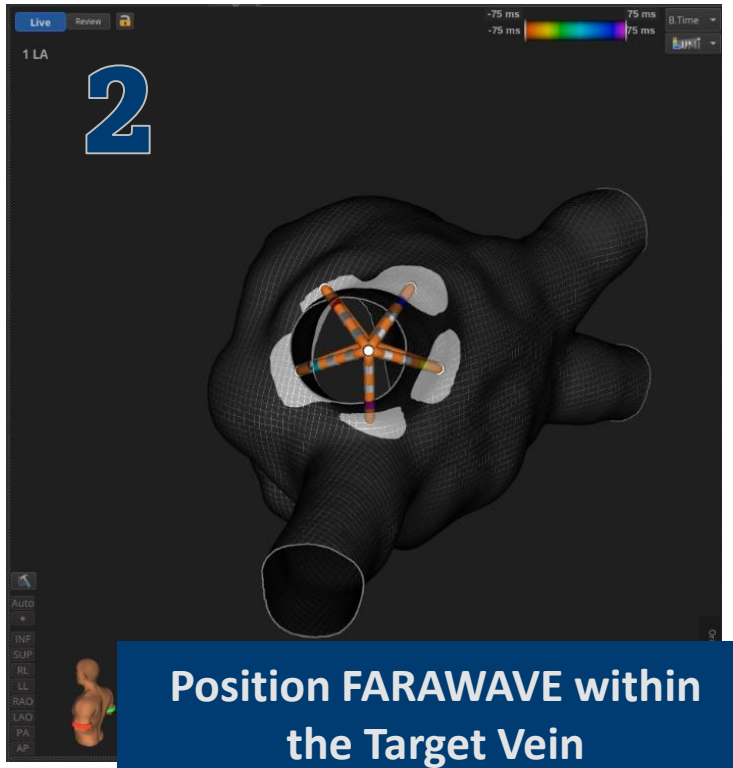
Maintain Workflow Simplicity

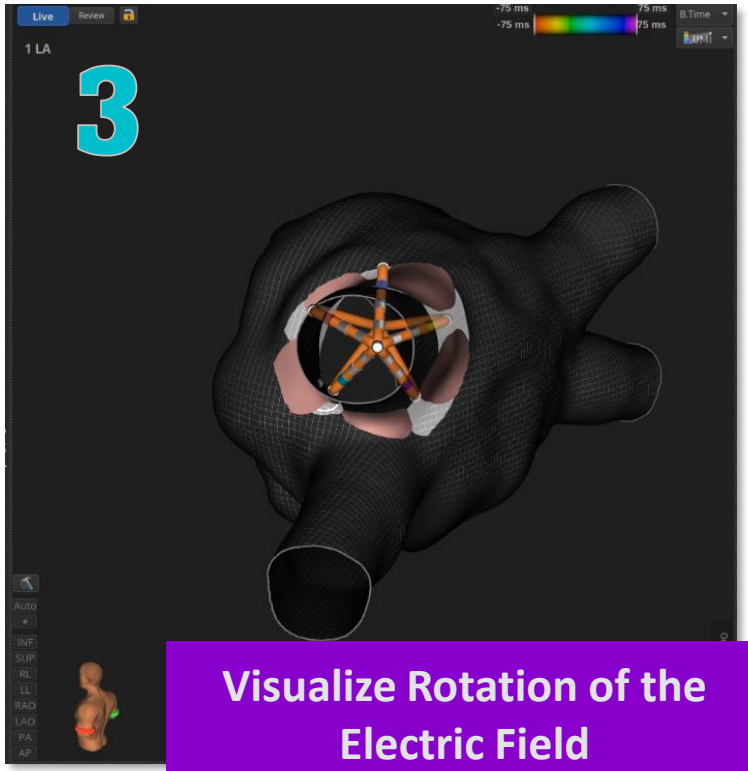
FARAWAVE™ with FARAVIEW™ Mapping Module**



Construct Geometry with FARAWAVE



Position FARAWAVE within the Target Vein



Visualize Rotation of the Electric Field

Tag shape for illustration / workflow guidance only

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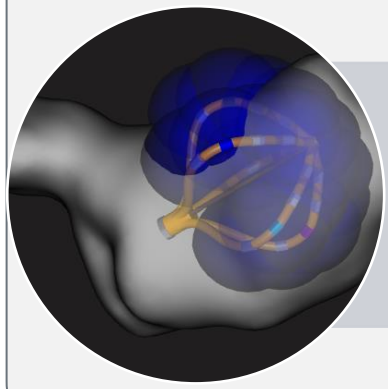
Visualize the Electric Field**

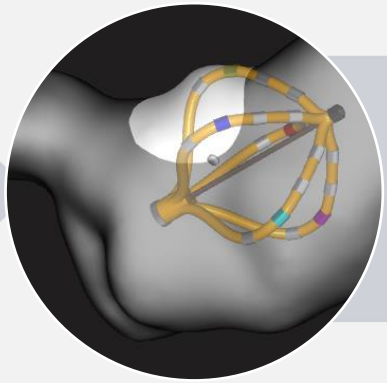
Field Tags Overview

Field Tags are a new tagging methodology designed specifically for PFA

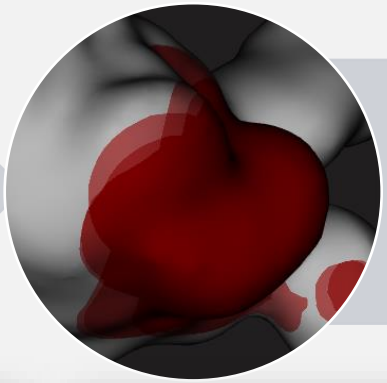
Approach:



Estimate the Field Volume

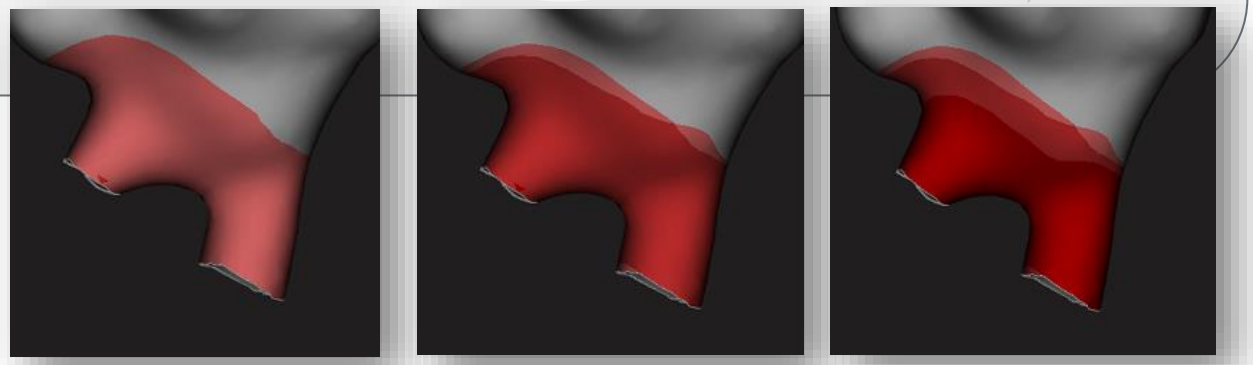


Visualize where the field intersects with the anatomy



Automatically tag highlighted area when PFA is detected

Saturation of Field Tag color increases with overlapping ablations



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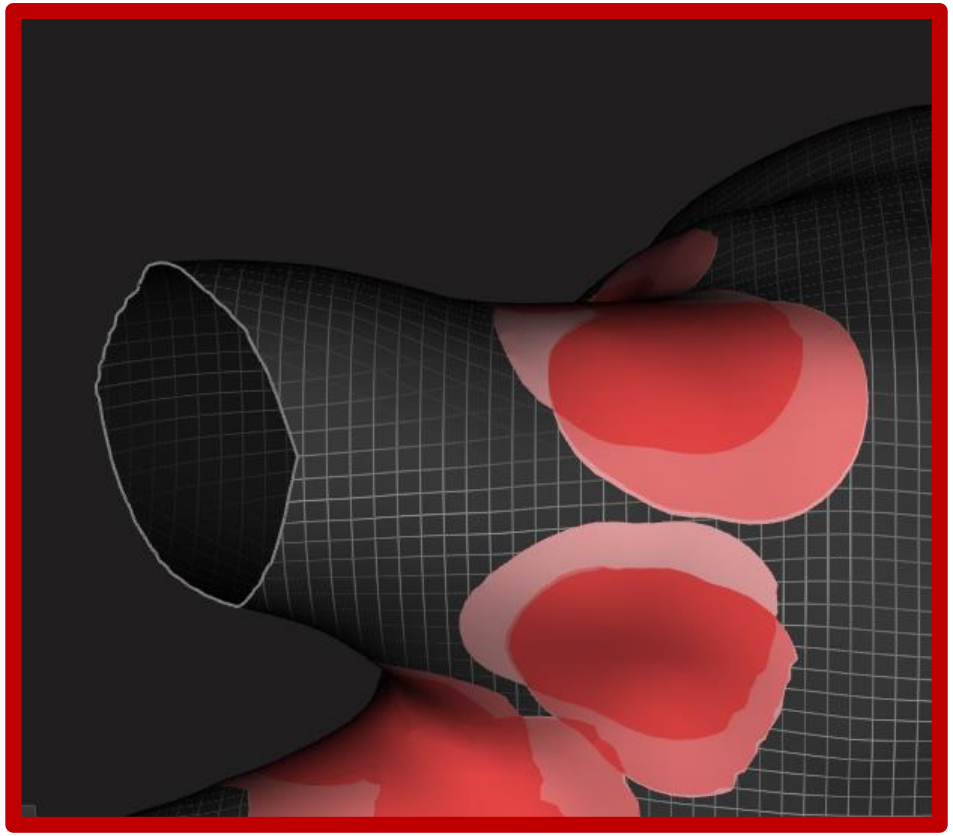
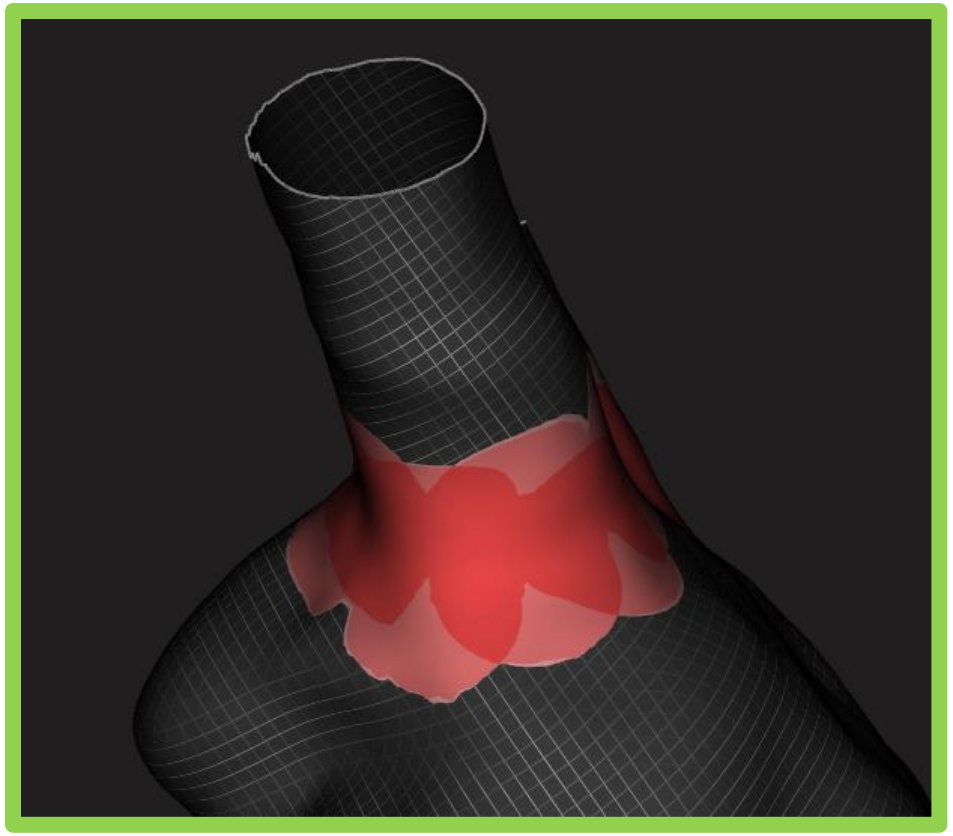
RHYTHMIA HDx™ Integration

FARAWAVE™ Workflow Guidance**

LA mold on Bench





Workflow guidance through tagging (and tag overlap) to assess uniformity of the ablation set.

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Appendix – Registry Data

MANIFEST-PF & EU-PORIA

VersaCross Connect

MANIFEST-PF (Safety and Effectiveness of Pulsed Field Ablation to Treat Atrial Fibrillation: One-Year Outcomes from the MANIFEST-PF Registry)

DOI: 10.1161/CIRCULATIONAHA.123.064959

Turagam, Mohit K., et al. "Safety and Effectiveness of Pulsed Field Ablation to Treat Atrial Fibrillation: One-Year Outcomes from the MANIFEST-PF Registry." *Circulation* (2023).

Objective

Retrospective analysis of safety, procedural endpoints, and long-term outcomes of all consecutive FARAPULSE™ cases, inclusive of learning curve.

Registry Design

- 24 European Centers
- 77 Operators
- 1568 Patients
  65% PAF
- All FARAPULSE™ PFA
  Cases from 3/21-5/22

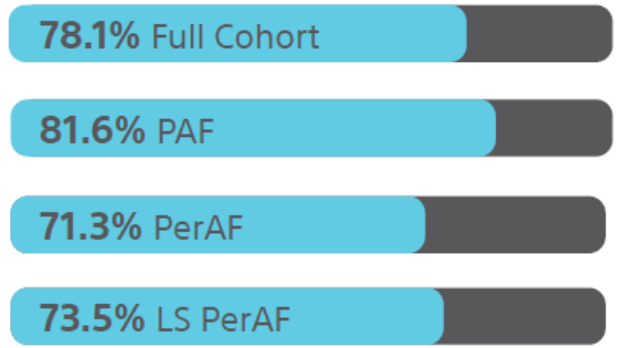
Results

- 61 min Median Procedure Time
- 1.9% Major Complication Rate
  4.0% Minor Complication Rate
- **81.6%**
  PAF One-Year Freedom from AF/AFL/AT

Conclusions

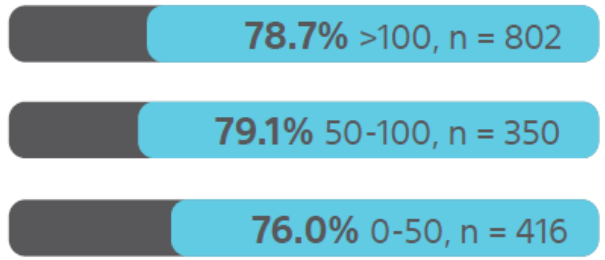
- In an all-comer AF patient population of the first patients undergoing ablation with FARAPULSE
  - The acute PV isolation rate was 99.2% with ~1 hour procedure times
  - The one-year freedom from AF/AFL/AT was 81.6% for paroxysmal AF patients
  - The adverse event rate was low with no reported esophageal damage or PV stenosis

Full Cohort and AF Sub-Type



By Center FARAPULSE™ Procedural Volume

(PFA procedure number)



EU-PORIA (European Real-World Outcomes with Pulsed Field Ablation in Patients with Symptomatic Atrial Fibrillation)

DOI: 10.1093/europace/euad185
B. Schmidt, et al. "EUropean Real World Outcomes with Pulsed Field AblatiOn in Patients with Symptomatic AtRIAl Fibrillation - Lessons from the multicenter EU-PORIA Registry." *Europace* (2023).

Objective

To describe real-world adoption, workflow, acute and long-term outcomes after pulsed field ablation (PFA) in an all-comer atrial fibrillation (AF) patient population in high-volume European centers, inclusive of learning curve.

Registry Design

- 7 High Volume Centers (400-1400 ablations/yr)
- 42 Operators
- 1233 Patients 60% PAF
- All FARAPULSE™ PFA Cases from 3/21-5/22

Results

- 58 min Median Procedure Time
- 1.7% Major Complication Rate
  1.9% Minor Complication Rate
- **80%** PAF One-Year Freedom from AF/AT

Table 1 :
Freedom from AF/AT* and Vein Reconnection rate

One-Year Freedom from AF/AT	74% [95% CI, 71%-76%], full cohort 80% [95% CI, 77%-83%], paroxysmal AF 66% [95% CI, 61%-71%], persistent AF 67% [95% CI, 48%-82%], LS persistent AF
One-Year Freedom from AF/AT by Operator AF Ablation Experience	65%, [95% CI, 31%-88%] <2 years 72%, [95% CI, 66%-77%] 2-5 years 76%, [95% CI, 73%-79%] >5 years
Freedom from AF/AT Recurrence by Previous Primary Ablation Modality	75%, [95% CI, 70%-80%] Radiofrequency (RF) 72%, [95% CI, 65%-78%] Cryoablation (cryo) 75%, [95% CI, 72%-79%] Both RF and cryo
Vein Reconnection Rate during Repeat Ablation	149/1233 repeat ablations at 226 [157-290] days Of the 584 veins that were remapped, 72% (418/584) were durably isolated

Table 1. *Kaplan-Meier estimate with a median follow-up of 365 [323-386]

Conclusions

- Procedure times were short (58 min) despite a large number of operators with varied experience and workflow.
- There was a low rate of safety events (3.6%) and promising one-year efficacy rate (74%) in a large spectrum of AF patients.
- Similar one-year AF/AT recurrence rates among users with varying AF ablation experience demonstrated rapid adoption of the technology.
- Patients returning for a repeat ablation revealed a high rate of PVI with 72% of PVs durably isolated.

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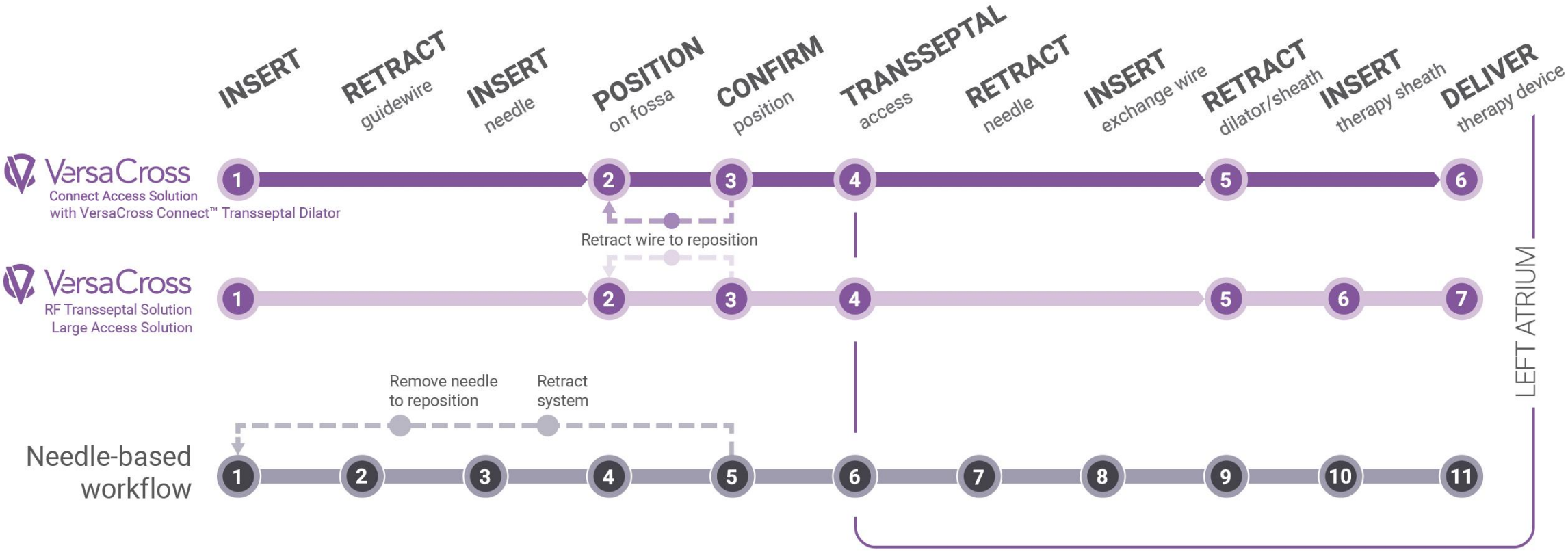
Integration with VersaCross will further simplify workflow

Boston Scientific

FAST TRACK to your therapy delivery in a SINGLE SOLUTION



VersaCross Brief Summary

VersaCrossTM RF Wire
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
INDICATIONS FOR USE: The VersaCrossTM RF Wire is indicated for creation of an atrial septal defect in the heart.
CONTRAINDICATIONS: The VersaCrossTM RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other Baylis RF Generator or any other device.
WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during RF puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The VersaCrossTM RF Wire and Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse either devices. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The VersaCrossTM RF Wire must be used with the Connector Cable provided. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Do not use the VersaCrossTM RF Wire with electrocautery or electrosurgery generators, connector cables or accessories as attempted use can result in patient and/or operator injury. • The Connector Cable must only be used with the RFP-100A Baylis RF Generator and the included VersaCrossTM RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • The VersaCrossTM RF Wire must be used with 0.035" compatible transseptal sheath and/or dilator devices. Use of incompatible accessory devices may damage the integrity of the VersaCrossTM RF Wire or accessory devices and may cause patient injury. • The VersaCrossTM RF Wire has only been validated for transseptal puncture use through VersaCrossTM dilators which have been demonstrated to provide the required support for optimal function. • The VersaCrossTM RF Wire is not intended for use with neonatal patients (i.e. less than one month of age). Do not attempt to treat neonatal patients with the VersaCrossTM RF Wire.
PRECAUTIONS: • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • Careful manipulation of the VersaCrossTM RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the VersaCrossTM RF Wire or ancillary sheath and/or dilator assembly. Excessive force may lead to bending or kinking of the device limiting advancement and retraction of sheath and/or dilator device. • The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the VersaCrossTM RF Wire and/or DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • If using electroanatomical mapping guidance, it is recommended to use it along with alternative imaging modality in the event there is loss of visibility of the device.
ADVERSE EVENTS: Adverse events that may occur while creating an atrial septal defect include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Arteriovenous fistula • Pericardial effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/entanglement • Foreign body/wire fracture
EP-1504711-AA

VersaCross ConnectTM Transseptal Dilator
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
INDICATIONS FOR USE: The VersaCross ConnectTM Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired. **CONTRAINDICATIONS:** There are no known contraindications for this device.
WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended. • The VersaCross ConnectTM Transseptal Dilator and accompanying guidewire are intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross ConnectTM Transseptal Dilator or accompanying guidewire. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may results in patient complications. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Dilator advancement should be performed under imaging guidance. Fluoroscopic or echocardiographic imaging is recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury.
PRECAUTIONS: • The VersaCross ConnectTM Transseptal Dilator is compatible with introducer sheaths 12.5F or larger. • The VersaCross ConnectTM Transseptal Dilator is for use with specified models of 12F ID WATCHMANTM Access Sheath that are 75cm in length. • The VersaCross ConnectTM Transseptal Dilator is compatible with 0.035" transseptal devices and guidewires or smaller. • The VersaCross ConnectTM Transseptal Dilator is NOT compatible with transseptal needles such as the "NRGTM Transseptal Needle".
ADVERSE EVENTS: Adverse events that may occur while using the VersaCross ConnectTM Transseptal Dilator and accompanying guidewire include: • Infection • Air embolus • Local nerve damage • Vessel trauma • Vessel spasm • Pseudoaneurysm • AV fistula formation • Atrial septal defect • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Valve damage • Pericardial/pleural effusion
EP-1506005-AA

VersaCrossTM Large Access Transseptal Dilator
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
INDICATIONS FOR USE: The VersaCrossTM Large Access Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired. **CONTRAINDICATIONS:** There are no known contraindications for this device.
WARNINGS: Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended. • The VersaCrossTM Large Access Transseptal Dilator and accompanying guidewire are intended for single patient use only. Do not attempt to sterilize and reuse the VersaCrossTM Large Access Transseptal Dilator or accompanying guidewire. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may results in patient complications. • Care should be taken to ensure that all air is removed from the dilator before infusing through the proximal hub. • Do not attempt direct percutaneous insertion of the dilator without a guidewire as this may cause vessel injury.
PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Dilator and guidewire advancement should be performed under imaging guidance, such as fluoroscopy or echocardiography. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • The VersaCrossTM Large Access Transseptal Dilator is compatible with introducer sheaths 12.5Fr or larger. • The VersaCrossTM Large Access Transseptal Dilator is compatible with .035" transseptal devices and guidewires • The VersaCrossTM Large Access Transseptal Dilator is NOT compatible with transseptal needles such as the "NRGTM Transseptal Needle". • Do not reshape distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury.
ADVERSE EVENTS: Adverse events that may occur while using the VersaCrossTM Large Access Transseptal Dilator and accompanying guidewire include: • Infection • Air embolus • Local nerve damage • Vessel trauma • Vessel spasm • Pseudoaneurysm • AV fistula formation • Atrial septal defect • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Valve damage • Pericardial/pleural effusion
EP-1506604-AA

VersaCrossTM Steerable Sheath
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
INDICATIONS FOR USE: The VersaCrossTM Steerable Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum. **CONTRAINDICATIONS:** There are no known contraindications for this device.
WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended. • The VersaCrossTM Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCrossTM Steerable Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel. • DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury.
PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur. • The VersaCrossTM Steerable Sheath kit is not compatible with transseptal needles such as the "NRGTM Transseptal Needle".
ADVERSE EVENTS: Adverse events that may occur while using the VersaCrossTM Sheath include: • Infection • Air embolus • Local nerve damage • Vasovagal reaction • Dissection • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Aortic puncture • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Stroke • Valve damage • Myocardial infarction • Pericardial/pleural effusion • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pacemaker/defibrillator lead displacement
EP-1506705-AA

VersaCrossTM Transseptal Sheath
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
INDICATIONS FOR USE: The VersaCrossTM Transseptal Sheath kit is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation/puncture. **CONTRAINDICATIONS:** There are no known contraindications for this device.
WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended. • The VersaCrossTM Transseptal Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCrossTM Transseptal Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended.
PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • The VersaCrossTM Transseptal Sheath is compatible with introducer sheaths 11Fr or larger. • The VersaCrossTM Transseptal Sheath and Dilator are compatible with transseptal devices and guidewires .035" or smaller. • The VersaCrossTM Transseptal Sheath kit is NOT compatible with transseptal needles such as the "NRGTM Transseptal Needle".
ADVERSE EVENTS: Adverse events that may occur while using the VersaCrossTM Transseptal Sheath kit include: • Infection • Air embolus • Local nerve damage • Hemorrhage • Embolic events • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Valve damage • Catheter entrapment
EP-1506605-AA

VersaCrossTM Transseptal Dilator
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.
INDICATIONS FOR USE: The VersaCrossTM Transseptal Dilator is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum. **CONTRAINDICATIONS:** There are no known contraindications for this device.
WARNINGS: • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The VersaCrossTM Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCrossTM Steerable Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to follow this instruction may result in patient complications • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel.
PRECAUTIONS: • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.
ADVERSE EVENTS: Adverse events that may occur while using the VersaCrossTM Sheath include: • Infection • Air embolus • Local nerve damage • Vasovagal reaction • Dissection • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Aortic puncture • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Thromboembolic events • Stroke • Valve damage • Myocardial infarction • Pacemaker/defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pericardial/pleural effusion
EP-1506213-AA