

2023 AF SYMPOSIUM (AFS)

AF MARKET INSIGHTS REPORT - SUMMARY



About the Author

AF Market Experts, LLC (“AFME”) was founded by industry veteran Ryan Bachman, who has a total of 16+ years of experience across Wall Street and the EP industry. For four years, Ryan covered the medical device industry as part of the equity research teams at Morgan Stanley and RBC Capital Markets. He then joined Biosense Webster, Inc., the recognized market leader in cardiac ablation, and he spent the next 12 years in various roles of increasing responsibility within Global Strategic Marketing. Across all roles at BWI, his core responsibilities included competitive intelligence and AF market insights.

AFME was founded to share the same level of AF market insights with clients by providing comprehensive coverage from all major AF industry congresses. We bring the AF podium to you.

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EXECUTIVE SUMMARY

The 28th annual AF Symposium (AFS) was held in Boston, MA from February 2-4, 2023, and attendance appeared comparable to events held before the COVID pandemic. Each year, AFS is one of the best venues for updates on the AF market due to the volume of presentations, the depth of content presented, and the quality of discussions among presenters, panelists, and the audience. The congress provides a breadth of information on technologies from both strategic competitors and start-up companies, with dedicated “Spotlight Sessions” highlighting new products in development from more than 15 start-ups.

Across the congress, the company with the largest podium presence was Biosense Webster, highlighted by four live/recorded case presentations and two late-breaking clinical trial (LBCT) presentations. Please see the summary of live and recorded cases on the next page for more details. Data from the “inspire” study in Europe with the VARIPULSE PFA catheter showed 70.9% freedom from atrial arrhythmias at 12 months in the pivotal phase of the trial (Wave 2). The U.S. IDE trial for VARIPULSE (“admIRE”) has also completed enrollment. Early preclinical work with a dual-energy, PF/RF application using the STSF catheter was presented and showed deeper lesions vs. PF or RF alone. Data from the U.S. IDE trial for BWI’s HELIOSTAR RF balloon were presented for the first time. Freedom from all arrhythmias at 12 months was just 67.7% and safety events in the trial caused much discussion – one death was reported from an atrial bronchial fistula and two permanent phrenic nerve injuries were also reported.

Boston Scientific had a similarly strong presence, and the FaraWave catheter captured the largest podium share of any individual product. To date, over 13,000 commercial cases have been performed in Europe, and the catheter was featured in two live cases. One case included presentation of a prototype software module to fully integrate FaraWave with the Rhythmia mapping system. Data from the U.S. IDE trial for FaraWave (“ADVENT”) will be presented later this year at either ESC or AHA. Safety with FaraWave, and PFA in general, was a frequent topic, and recent publications on coronary spasm were discussed the most. The perspectives remain mixed – some physicians were not concerned due to the ability to pre-treat with nitro and others continue to feel that more data are needed.

The two Medtronic Affera PFA catheters, Sphere9 and SpherePVI, were each featured in separate pre-recorded cases, and DiamondTemp was also the subject of multiple posters, although the impact of the posters was low. Although PulseSelect was not presented often during AFS, many physicians referenced the upcoming data presentation at ACC. On Monday March 6, results from the PULSED AF trial will be presented, and it will be the first data set from a U.S. IDE trial investigating PFA.

Also making news during the congress was Philips, which decided to shut down the EPD Solutions business according to local press articles. Philips originally acquired EPD in 2018 for total consideration up to \$300 million. The VeriSight Pro ICE catheter continues to be supported by Philips.

Among start up companies, a total of four catheters were presented publicly for the first time at AFS, and all use pulsed field energy. Field Medical introduced the “FieldForce” system during a Spotlight Session. Pulse Biosciences presented the “nsPFA” system in a poster. CardioFocus introduced a new PFA-enabled balloon based on its existing X3 platform. Finally, Arga Medtech reported FIM data from cases with its “multi-configurable catheter” capable of taking different shapes to facilitate different lesion sets. Galaxy Medical received CE Mark in August 2022, and it was disclosed that 300 commercial cases have been completed to date.

Outside of PFA catheters, the CardioNXT iMap mapping system was featured in four posters detailing successful integration with four different ablation catheters from both strategics and start-ups. Finally, a novel mapping system from Anumana-Neutrace was presented at the podium for the first time.

A unique feature of the AF Symposium each year is the inclusion of “Spotlight Sessions” in the agenda. These presentations are only 5 minutes in duration, and they feature an emerging company and its technology under development. Below is a table comparing the companies featured in both the 2023 and the 2022 AF Symposium, along with the physician presenter.

AF Symposium "Spotlight Sessions"				
2023		2022		
Featured Company	Presenter	Featured Company	Presenter	
Acutus Medical	Dr. Robert Bernat	Ablacon	Dr. David Haines	
ADAS 3D Medical SL	Dr. Diego Penela	Aqua Heart	Dr. Srijoy Mahapatra	
Anumana-NeuTrace	Dr. Kalyanam Shivkumar	BioSig Technologies	Dr. DJ Lakkireddy	
AtriAN Medical	Dr. Vivek Reddy	CardioNXT	Dr. Thomas Kurian	
CardioFocus	Dr. David Haines	Cardiva Medical	Dr. Walid Saliba	
CardioNXT	Dr. Usman Siddiqui	CathVision	Dr. Mintu Turakhia	
CathVision	Dr. Suneet Mittal	Circle Cardiovascular Imaging	Dr. Saman Nazarian	
EP Frontiers	Dr. Jonathan Piccini	ElectroPhysiology Frontiers	Dr. Jonathan Piccini	
Field Medical	Dr. Usman Siddiqui	Kardium	Dr. Atul Verma	
LuxMed Systems	Dr. Jacob Koruth	NeuTrace	Dr. Andrea Natale	
MedLumics	Dr. Atul Verma	Philips EPD Solutions	Dr. Lucas Boersma	
Volta Medical	Dr. John Hummel	Volta Medical	Dr. Seth Goldberg	

Note: Only companies within cardiac ablation are included. Companies included in both 2023 and 2022 have been highlighted in the same color.

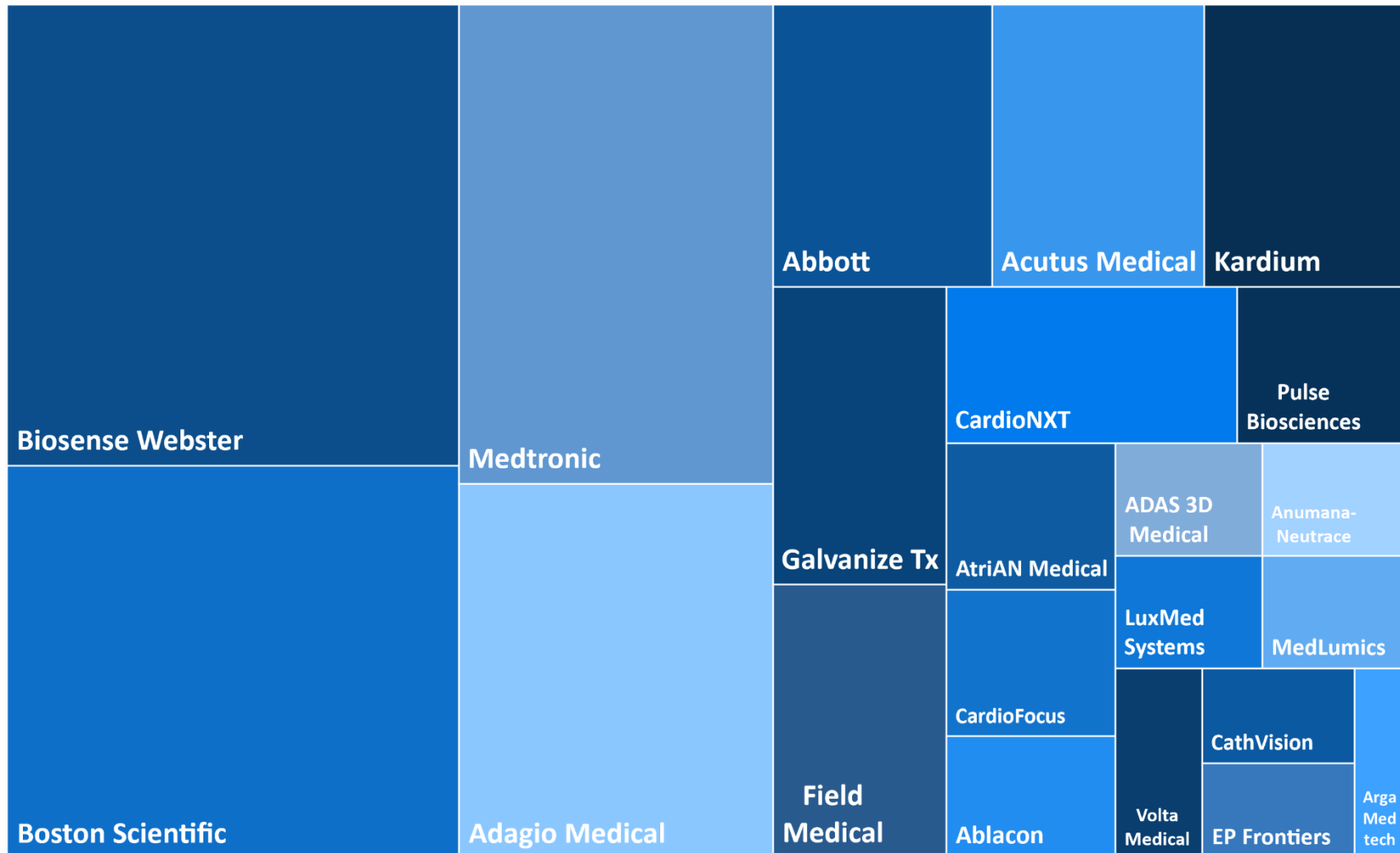
In addition to the Spotlight Sessions, the AF Symposium always includes a strong lineup of live and pre-recorded cases featuring new technology. The table below summarizes the cases featured at the event this year, along with supporting details.

2023 AF Symposium: Live & Pre-Recorded Cases				
Event Type	Physician Operators/Presenters	Site of Case	Technologies Featured	Manufacturer
Live	Dr. Daniel Steven	University Hospital Cologne Cologne, Germany	TactiFlex EnSite X Version 2	Abbott EP
Live	Dr. Jean Baptiste Chierchia	Heart Rhythm Management Center Brussels, Belgium	HELIOSTAR	Biosense Webster
Live	Dr. Srinivas Dukkupati	Mount Sinai Medical Center New York, NY	QDOT OctaRay	Biosense Webster
Live	Dr. Mattias Duytschaever	St. Jan Hospital Brugge-Oostende, Belgium	FaraWave	Boston Scientific
Live	Dr. Gabor Szeplaki	Mater Private Hospital Dublin, Ireland	FaraWave Rhythmia	Boston Scientific
Pre-Recorded	Dr. Charles Athill	Sharp Memorial Hospital San Diego, CA	VARIPULSE	Biosense Webster
Pre-Recorded	Dr. Moussa Mansour	Massachusetts General Hospital Boston, MA	VARIPULSE	Biosense Webster
Pre-Recorded	Dr. Kevin Makati	St. Joseph's Hospital Tampa, FL	POLARx FIT	Boston Scientific
Pre-Recorded	Dr. Andreas Rillig	University Heart and Vascular Center Hamburg, Germany	CENTAURI Generator	Galvanize Therapeutics
Pre-Recorded	Dr. Petr Neuzil Dr. Vivek Reddy	Homolka Hospital Prague, Czech Republic	The Globe PF System	Kardium
Pre-Recorded	Dr. Moussa Mansour	Massachusetts General Hospital Boston, MA	Sphere9	Medtronic Affera
Pre-Recorded	Dr. Petr Neuzil Dr. Vivek Reddy	Homolka Hospital Prague, Czech Republic	SpherePVI	Medtronic Affera

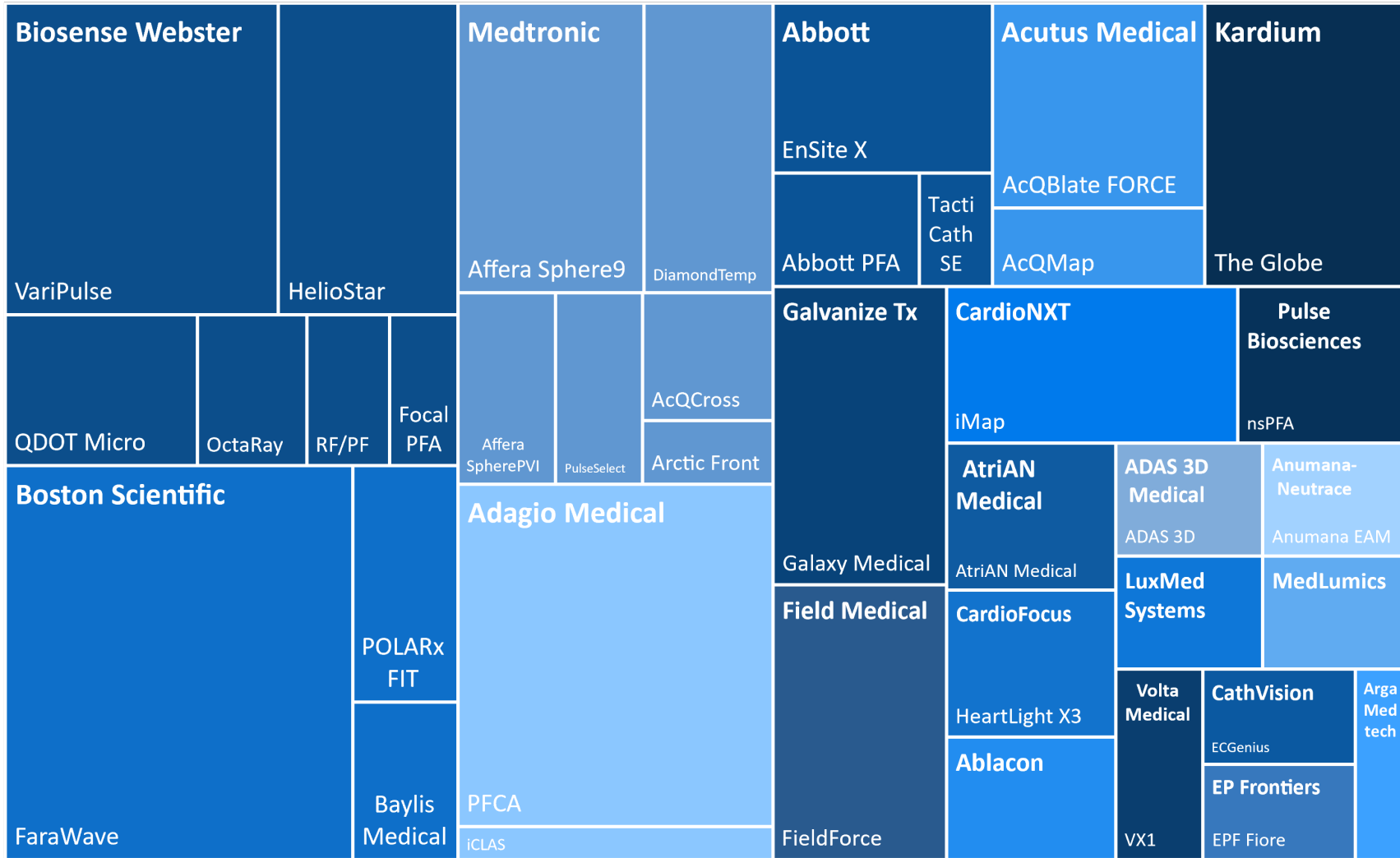
PODIUMSHARE ANALYSIS

The PodiumShare infographics below represent the relative podium presence each Company and individual Product captured during AF Symposium. The size of each area represents the podium share captured: a larger area = stronger podium presence. For the 2023 AF Symposium, Biosense Webster captured the largest podium share as a company (see graph on this page), but Boston Scientific's FaraWave catheter captured the largest podium share of any individual product (next page). Details on the methodology can be found below the graphics.

PODIUMSHARE BY COMPANY



PODIUM SHARE BY PRODUCT



Methodology: AF Podium Connection incorporates a proprietary methodology to score all events that are included in this report. Types of events included in the report are presentations, live cases, and posters, among others. Each type of event receives a score, and we also include a score for the impact of content presented during the event. Finally, each event is tagged for individual products discussed and the respective manufacturer. Scores are then totaled by Company and by Product, enabling the “PodiumShare” calculations across each group.

SUMMARY NOTES BY COMPANY

Abbott Electrophysiology

[Abbott Electrophysiology Website](#)

The most important update on Abbott came from Dr. Vivek Reddy, who presented the internally-developed PFA system for the first time. A live case featured the new TactiFlex ablation catheter and EnSite X v2. TactiFlex was mentioned in passing at the podium on several occasions, with several physicians referencing the recent commercial launches in Europe and Japan.

Ablacon

[Ablacon Website](#)

Ablacon's "electrographic flow" (EGF) mapping technology was featured in a late-breaking clinical trial presented by Dr. Vivek Reddy. In the FLOW AF trial with PsAF patients, freedom from AF at 12 months was 70% when ablating additional targets identified by EGF, in addition to PVI. However, freedom from all arrhythmias (AF/AT/AFL) at 12 months was approximately 50%. The number of patients enrolled was small, with only 46 being randomized to PVI-only (N=24) vs. PVI + EGF (N=22).

Acutus Medical

[Acutus Medical Website](#)

The Acutus contact force ablation catheter (AcQBlate FORCE) was featured in both a Spotlight Session and a late breaking clinical trial. However, the trial results reported on treatment of flutter patients - the trial for AF has not yet started. The AcQMap system was presented in two posters, with one comparing the Acutus maps directly to those created with HD Grid + EnSite. No updates were provided on progress with the Acutus PFA technology.

Adagio Medical

[Adagio Medical Website](#)

Adagio Medical sponsored a lunchtime product theater with a total of seven presentations, most of which focused on the PFCA technology that uses both PFA and cryo. In addition to the product theater, PFCA was presented several times during the main sessions. Collectively, there were many discussions, as shown in the PodiumShare results, but no new trial data were presented.

ADAS 3D Medical

[ADAS 3D Medical Website](#)

ADAS was featured in just one podium presentation during the Spotlight Sessions, but the topic of pre-procedural imaging was mentioned frequently at the podium.

Anumana-Neutrace

[Anumana Website](#)

The Anumana technology was presented at the podium for the first time during AF Symposium, and the company appears to have developed a novel mapping system. However, Dr. Shivkumar did not provide full details on the system during the Spotlight Session. According to a recent press release, Anumana has acquired NeuTrace, a company featured last year at a Spotlight Session during AFS.

Arga Medtech

[Arga Medtech Website](#)

Clinical data from FIM experience with the Arga PFA system were presented for the first time during AFS. In addition, details on the company's catheter were also provided publicly for the first time. Arga has developed a "multi-configurable catheter" that is capable of taking multiple shapes to complete multiple lesion sets, beyond just PVI. The system delivers a proprietary type of PFA called "coherent sine burst" (CSE). Early acute data with the first uses of the system showed durable PVI of 84% (16/19 veins).

AtriAN Medical

[AtriAN Medical Website](#)

AtriAN was featured in a Spotlight Session presented by Dr. Vivek Reddy, who presented both an overview of the technology and an update on clinical progress. Currently, AtriAN requires a surgical approach to ablate GPs on the epicardial surface using PFA. Studies to date have included patients undergoing concomitant CABG procedures, and 12-month follow up is ongoing for the first series of 12 patients treated with the technology. Dr. Reddy said next steps include transition to a sub-xiphoid approach to access the epicardial surface.

Biosense Webster

[Biosense Webster U.S. Website](#)

BWI had a strong presence at AFS, as seen by the company reaching the top of our PodiumShare analysis. Technologies from BWI were featured in 2 late-breaking clinical trials and 4 live/recorded cases. Data on the VARIPULSE PFA system were presented for the first time and showed 12-month freedom from atrial arrhythmias of 70.9% in the pivotal phase of the trial (Wave 2). Clinical success, defined as freedom from symptomatic arrhythmias, was 78.9% in Wave 2. Early work with a combined PF/RF approach using STSF to deliver both energies was also presented. Beyond PFA, data from the global IDE with BWI's HELIOSTAR RF balloon were presented. Results showed efficacy of just 67.7%, below what is currently seen with other technologies. In addition, one death and two permanent PNPs were reported in this trial. Finally, the QDOT Micro focal RF catheter was featured in a live case using vHPSD (90W for 4 seconds).

Boston Scientific Electrophysiology

[Boston Scientific Electrophysiology Website](#)

Boston Scientific had a strong presence throughout AFS, and the focus was predominantly FaraWave, the top individual product in our PodiumShare analysis. FaraWave has been used in over 13,000 commercial cases in Europe since receiving CE Mark two years ago. At AFS, it was featured in two live cases, one of which showed a prototype version of integration with BSX's Rhythmia mapping system. Discussion of the software under development revealed that it will display full catheter visualization, including spline deformation. The Rhythmia system will also display the predicted energy field prior to delivery. Data from the U.S. IDE trial (ADVENT) is expected later this year at either ESC or AHA, according to Dr. Calkins. Finally, safety remains a key topic, and many discussions at AFS focused on coronary spasm. Most comments seemed to indicate physicians are comfortable with the ability to prevent it by pre-treating with nitroglycerin. However, they also acknowledge experience is still early with PFA. Outside of PFA, the next-generation POLARx "FIT" expandable cryoballoon (from 28mm to 31mm) was featured in one live case.

CardioFocus

[CardioFocus Website](#)

CardioFocus recently shifted its focus to PFA and announced completion of certain preclinical milestones with a prototype PFA balloon based on its current X3 platform. At AFS, Dr. David Haines showed an image of this “PFA balloon” for the first time. Although it was not completely clear, it appears that CardioFocus has placed flexible electrodes on the exterior surface of the balloon in order to deliver PFA. Dr. Haines did not provide any expected timelines for FIM or clinical trials.

CardioNXT

[CardioNXT Website](#)

The iMap system from CardioNXT was featured in a Spotlight Session that also included presentation of a new HD basket mapping catheter, “iON.” This catheter has 2 EM sensors, 38 high fidelity flat electrodes across six splines, and a diameter of just 1cm. iMap is an open mapping system and four posters at AFS showed successful integration of ablation catheters from both strategics (MDT DiamondTemp) and start-ups (Acutus AcQBlate FORCE, Field Medical, and Pulse Biosciences). CardioNXT has previously reported on successful integration with BSX FaraWave ([here](#)).

CathVision

[CathVision Website](#)

CathVision was featured in a Spotlight Session for the second consecutive year, and Dr. Suneet Mittal presented the technology this year. The “ECGenius System” is a recording system and has been approved by FDA. Four modules are in development and two have been submitted to FDA for approval. Additional modules are also being developed for disease states outside of AF, including VT and SVT.

Electrophysiology Frontiers

[EP Frontiers Website](#)

EP Frontiers was presented publicly for the first time at the 2022 AF Symposium, and Dr. Piccini presented the technology again this year. The EPF catheter has been named “Fiore” and the design remains consistent with last year. FIM is now expected later this year, and the EU pivotal trial is expected to run from 2024 to 2026. Expectations for a U.S. IDE trial were not presented.

Field Medical

[Field Medical Website](#)

Field Medical was founded by Dr. Steven Mickelson in 2022 and the technology was presented at the podium for the first time during AFS. Dr. Mickelson was a co-founder of Farapulse, Inc. (formerly The Iowa Approach, Inc.), and he was most recently the Chief Translational Science Officer at Acutus Medical. The “FieldForce” system includes a focal catheter with a proprietary PFA generator, and combined, the technology enables “field bending” to reduce far field stimulation. The catheter also provides contact force data. No expected clinical timelines were provided.

Galvanize Therapeutics (Galaxy Medical)

[Galvanize Tx Website – CENTAURI System](#)

The iMap system from CardioNXT was featured in a Spotlight Session that also included presentation of a new HD basket mapping catheter, “iON.” This catheter has 2 EM sensors, 38 high fidelity flat electrodes across six splines, and a diameter of just 1cm. iMap is an open mapping system and four posters at AFS showed successful integration of ablation catheters from both strategics (MDT DiamondTemp) and start-ups (Acutus AcQBlate FORCE, Field Medical, and Pulse Biosciences). CardioNXT has previously reported on successful integration with BSX FaraWave ([here](#)).

Kardium

[Kardium Website](#)

Data from Kardium were featured in a late-breaking clinical trial presented by Dr. Vivek Reddy, and the data showed strong durable PVI (99%) with multiple PF applications from The Globe catheter. Dr. Reddy also co-led a pre-recorded case with Kardium along with Dr. Petr Neuzil. In his comprehensive update, Dr. Moussa Mansour said a total of 69 patients have been treated to date with The Globe (PFA application), and a global IDE trial across the Europe, Canada, and the U.S. is expected to start this year.

LuxMed Systems

[LuxMed Systems Website](#)

Technology from LuxMed has been presented at industry congresses as far back as 2015, according to the company website. At 2023 AFS, Dr. Jacob Koruth presented updates during a Spotlight Session that included images of two catheters that we believe have not been presented at the podium previously – “OptoSpider” and “HexaClaw”. Dr. Koruth said each catheter will include the core LuxMed technology to assess tissue viability in real time, which could potentially enable lesion assessment immediately following energy delivery. No regulatory timelines were discussed during the presentation, however.

MedLumics

[MedLumics Website](#)

The “PulseView” system was presented during a Spotlight Session and preclinical data showed that the proprietary “PS-OCR” technology can also assess tissue birefringence following PFA. Dr. Atul Verma said that the system (catheter + generator) is now progressing to FIM studies, but he did not provide an expected timeline.

Medtronic Cardiac Ablation Solutions

[Medtronic Cardiac Ablation Solutions – U.S. Website](#)

The Medtronic Affera catheters were presented multiple times and referenced throughout the symposium. Pre-recorded cases were presented with both the large tip “Sphere9” catheter and the single-shot “SpherePVI” catheter. Both catheters are fully integrated with the Affera mapping system. Several physicians referenced the upcoming PulseSelect data presentation at ACC, which will results from the first completed IDE trial with PFA. Dr. Mansour also said the internally-developed PulseSelect would “soon” be integrated with the recently-acquired Affera mapping system. DiamondTemp was featured in three posters, but the impact was low – one reported results in flutter patients and one focused on legacy benchtop data.

Pulse Biosciences

[Pulse Biosciences Website](#)

PFA technology from Pulse Biosciences was presented publicly for the first time at AFS. Pulse is a small publicly traded company (PLSE) that has developed proprietary nano-pulse IRE technologies originally targeted for applications in dermatology. In November 2022, the company announced a shift in corporate strategy to focus on cardiac ablation (press release [here](#)). During AFS, Dr. Vivek Reddy presented the “nsPFA” system, which includes a new catheter design. A poster also showed that successful integration of this catheter with the CardionXT iMap system has already been achieved. Preclinical work has been completed but no timelines were provided for FIM.

Volta Medical

[Volta Medical Website](#)

Dr. John Hummel presented a comprehensive review of the Volta Medical technology that included discussion of a new module in development, “AF-Xplorer”. This module will include auto-tagging when used with EnSite X and it will also include integration with BWI’s OctaRay catheter. Regulatory timelines were not presented. In a separate press release, Volta announced completed enrollment for the TAILORED-AF trial, a multi-center RCT that included 370 patients. The company is planning two additional trials – RESTART for redo procedures and a clinical registry. Across these three trials, over 960 patients will be enrolled.

ABBREVIATIONS & ACRONYMS

ABT	Abbott	MI	mitral isthmus
ACE	asymptomatic cerebral emboli	mins	minutes
AEF	atrial esophageal fistula	mos	months
AF	atrial fibrillation	NTG	nitroglycerin
BSX	Boston Scientific	OTW	over the wire
BWI	Biosense Webster	PAF	paroxysmal atrial fibrillation
CABG	coronary artery bypass graft surgery	PFA	pulsed field ablation
CE Mark	Conformite Europeenne	PFCA	pulsed field cryoablation
CF	contact force	PI	primary investigator
CMC	circular mapping catheter	PN	phrenic nerve
CTI	cavotricuspid isthmus	PNP	phrenic nerve palsy
EAM	electroanatomic mapping	PsAF	persistent atrial fibrillation
EDEL	endoscopically detected esophageal lesion	pts	patients
FDA	Food and Drug Administration	PVI	pulmonary vein isolation
FEM	finite element modeling	PWI	posterior wall isolation
FIH	first in human	RA	right atrium
FIM	first in man	RV	right ventricle
Fr	French	SAE	serious adverse events
GA	general anesthesia	SCE	silent cerebral emboli
GUI	graphical user interface	SCL	silent cerebral lesion
HPSD	high power short duration	SDD	same day discharge
ICE	intracardiac echo	SVT	supraventricular tachycardia
KM	Kaplan Meier	TBD	to be determined
LA	left atrium	TSP	transseptal puncture
LV	left ventricle	TTI	time to isolation
MDT	Medtronic	ULTC	ultra low temperature cryoablation
MDT CAS	Medtronic Cardiac Ablation Solutions	vHPSD	very high power short duration
		VT	ventricular tachycardia



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