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Medical Technology

PFA coming to US faster than expected

Industry Overview

PFA timelines moving up in last few weeks

We update our PFA timing thoughts here as it's becoming more apparent PFA is coming to the US faster than expected. MDT's PulseSelect received approval in mid-Dec roughly 7 months post filing. BSX now expects Farapulse approval in Q124 (vs prior 2H24) which is about 5-6 months post FDA filing. It now seems likely three of the four major EP franchises will have PFA devices in the US by end of 2024. We think US launches will go faster than Europe and note BSX's view is PFA could be 40-60% of the market by 2026.

BSX's Farapulse next up in Q124

Last week BSX said it anticipates approval for Farapulse in Q124. We think even with the earlier approval BSX will work hard to ensure supply is ready for the launch. BSX's second Minnesota manufacturing site was validated late July 2023 and supply began hitting Europe early Q423. This supply was expected to ramp even more into the second half of Q423 and into Q124. As a reminder, the Europe Farapulse launch has been limited by console supply (not catheter) which has limited account openings.

JNJ's Varipulse potentially mid-2024 to 2H24

As of April 2023 the US pivotal study for Varipulse (admIRE) completed enrollment. JNJ has said it expected the last patient to complete 12 month follow up in November 2023. We expect a early 2024 filing and approval potentially in mid-2024 to 2H24.

MDT Affera data spring 2024; approval could be 2H24

MDT completed enrollment of Affera persistent trial in Dec 2022 and 1-year follow up was expected to complete in Dec 2023. MDT is targeting a data presentation in Spring 2024 which we think means Affera FDA approval could potentially be later in 2024.

Kardium FDA approval likely late 2025

Kardium's US IDE study began in March 2023 and enrollment in the paroxysmal cohort is expected to complete Jan 2024. The follow up is 12 months so final data for the paroxysmal cohort will be available in January 2025. Kardium can then submit to the FDA early 2025 which could put approval by end of 2025. Kardium is first enrolling the paroxysmal cohort and once paroxysmal enrollment is complete persistent enrollment will begin. This will allow for a faster FDA submission. Persistent approval is expected to lag paroxysmal by about 6 months. In Europe there is another trial of 69 patients ongoing and the full data set is expected to be presented at AF Symposium in Feb.

Quick review of PFA in Europe

BSX's Farapulse received CE Mark in 2021 and was more broadly introduced to the market in 2H22. MDT's Affera received CE Mark in April 2023 and PulseSelect in November 2023. Affera remains in limited market release as manufacturing remains a gating factor. PulseSelect does not have the same manufacturing constraint. JNJ expects Varipulse CE Mark in early 2024. JNJ already has CE Mark for the TRUPULSE generator which a must-have to launch the technology.

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PFA = pulse field ablation

MDT = Medtronic

EP = electrophysiology

BSX = Boston Scientific

JNJ = Johnson & Johnson

Refer to important disclosures on page 5 to 7.
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PFA devices, ongoing trials, and data landscapes

Exhibit 1: PFA device landscape
In the US, PulseSelect received FDA approval in December 2023 and Farapulse is expected in Q1'24. We estimate JNJ's Varipulse could follow in mid-2024.

Company	Device	FDA Approval	CE Mark	Energy	Type of Afib	Technique	Tissue Contact	Type of Energy	Waveform
BSX	Farapulse	Submitted to FDA as of Q3'23. Approval expected in Q1'24	CE Mark in 2021; full market release in 2H22	PFA	Paroxysmal; running trial for Persistent	Single shot	Independent	Bipolar	Biphasic or Monophasic
MDT (internal)	PulseSelect	Approved Dec 2023	Pivotal trial results at ACC in March 2023; CE Mark in Nov 23	PFA	Paroxysmal or Persistent	Single shot	Independent	Bipolar	Biphasic
MDT (Affera)	Sphere-9	Potentially 2H'24 (completed trial enrollment Dec '22, 12 mo follow up)	CE Mark in March 2023	PFA / RF	Paroxysmal or Persistent	Point-by-point	Dependent	Bipolar	Biphasic
JNJ	Varipulse	Likely 2024, admIRE trial last patient 12 mo follow up visit expected in Nov 2023	Presented inspIRE pivotal data at AF symposium in Feb 2023; CE Mark early 2024E	PFA	Paroxysmal	Single shot	-	Bipolar	Biphasic
JNJ	Thermocool SmartTouch	US smartfIRE initiating enrollment shortly as of Aug'23	First cases in Europe Feb '23 in smartfIRE trial, enrollment completed as of Aug'23	PFA / RF	Paroxysmal	Contact force–guided radiofrequency	Dependent	-	-
JNJ	Omnypulse	-	Enrolling in European trial	PFA	Paroxysmal	Large focal	-	-	-
ABT	Volt	First in human likely this yr, FDA approval 2025+	First in human likely in 2023, CE Mark approval 2025+	PFA	Paroxysmal or Persistent	Single shot	Dependent	Bipolar	Biphasic
Adagio	iCLAS	Plans to initiate a pivotal study	Plans to initiate a trial to support CE Mark	PFA / Cryo	Paroxysmal or Persistent	-	Dependent	-	-
Kardium	Globe PF System	Initiated IDE study in March '23, US data for paroxysmal cohort in Jan 2025, FDA approval in late 2025/early 2026	European data to be presented at AF Symposium Feb 2024	PFA	Paroxysmal or Persistent	Single shot	-	-	-
Galvanize	Centauri (PEF System)	First patient treated in IDE study in March 2023	CE Mark in Aug 2022	PFA	Paroxysmal or Persistent	Force sensing catheters	-	-	-
Galvanize	QuickShot (catheter)	-	Clinical study initiated in March 2023	PFA	Paroxysmal or Persistent	Point-by-point	Dependent	-	-

Source: Company materials, BofA Global Research

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Exhibit 2: PFA ongoing trials by company
BSX recently announced initiation of its AVANT GUARD trial to evaluate PFA with Farapulse system as front line therapy for persistent AF. JNJ's US trial for Varipulse (admIRE) completed 12 month follow up in November 2023 and we would expect to see data from this trial in 2024. Kardium expects data from its European trial to be presented at AF Symposium in Feb 2024.

Trial	Device	Patient #	Start Date	Est Completion Date	Trial Details	Next Update
BSX						
ADVENT	Farapulse	900	March 2021	June 2023	Pivotal study comparing Farapulse with force-sensing RF catheters and cryoballoon catheters for persistent afib	FDA approval expected in Q1'24
PersAFOne III	Farapulse	60	Feb 2022	Jul 2024	Feasability study for persistent afib	-

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Trial	Device	Patient #	Start Date	Est Completion Date	Trial Details	Next Update
RWS of the Farapulse	Farapulse	30	Jan 2023	Apr 2023	Real world study of Farapulse for treatment of Paroxysmal afib in a Chinese population	-
ADVANTAGE AF	Farapulse/Farapoint	755	Feb 2023	Feb 2025	Piviotal study for persistent afib. First phase evaluating Farapulse for treatment of persistent AF. Extension arm evaluating Farapoint, a point-by-point PFA focal catheter for CTI ablations, used to treat atrial flutter.	First cohort completed enrollment in Q3'23. Second phase with Farapoint, expect to complete enrollment in Q1'24.
AVANT GUARD	Farapulse	500	Dec 2023	-	PFA as front line therapy for persistent AF. Outcomes will show PFA vs AAD therapy	Trial initiated Dec 2023
MDT						
PULSED-AF	PulseSelect	418	Dec 2019	Nov 2022	Pilot phase followed sequentially by a pivotal consisting of 3 arms enrolling: Roll-in, Paroxysmal AF, Persistent AF	Results were presented at ACC on Mar 6, 2023
SPHERE Per-AF	Sphere-9	477	Dec 2021	Nov 2023	Study comparing Sphere-9 vs the THERMOCOOL SMARTTOUCH SF RF ablation on persistent afib	Complete 12 mo follow up in US 2023 year end, FDA submission to follow
SpherePVI	SpherePVI	50	July 2021	July 2023	Single-arm study to evaluate SpherePVI catheter for treating paroxysmal AF	-
JNJ						
inspIRE	Varipulse	550	Aug 2020	May 2023	EU pivtoal study on paroxysmal afib	CE Mark expected early 2024E
admIRE	Varipulse	362	Apr 2022	Jan 2024	US pivotal study on paroxysmal afib. First patient enrolled in May 2022. Company said enrollment completed in April 2023.Last patient 12 mo follow up visit in November '23. FDA submission to follow.	2024?
afIRE	Varipulse	135	Dec 2022	Dec 2024	PFA study in China	-
smartfIRE	Thermocool SmartTouch SF	135	Feb-23	Nov 2024	European clinical trial on paroxysmal afib	European trial completed enrollment as of Aug'23. US enrollment in 2H'23
Omny-IRE	Omnypulse	160	Sept-23	Apr-2025	Europeans tiral to demonstrate safety and effectiveness of Omnypulse in treatment of participants with paroxysmal afib	Currently enrolling as of Dec 2023
Private Companies						
Kardium (PULSAR)	Globe	435	Mar 2023	Jan 2025	Piviotal study on Globe PFA for treating patients with paroxysmal or persistent afib	12 mo follow up data by Jan 2025 then can submit to FDA.
Kardium (PULSE EU)	Globe	110	Aug-21	Dec-23	EU study on Globe PFA for treating AF	Data to be presented at AF Symposium Feb 2024
Adagio (PARALELL)	CryoPulse PFCA	78	Oct 2022	Mar 2024	First-in-human clinical study on Adagio PFA and PFCA Systems for persistent afib	-
Galvanize (ECLIPSE AF)	Centauri	200	Sept 2022	Apr 2023	Study on patients with paroxysmal or persistent afib	-
Galvanize (QuickShot PEF-AF)	QuickShot		March 2023		-	-

Source: Company materials, clinicaltrials.gov, BofA Global Research

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Exhibit 3: Summary of 1-year PFA data vs 1-year RF/cryo data
In 2023 key PFA data was presented for MDT's PulseSelect (PULSED AF trial) and BSX's Farapulse (ADVENT). PULSED AF met both its primary effectiveness endpoints, 66.2% for paroxysmal and 55.1% for persistent vs the predetermined performance goals at 12 months of >50% and >40%. In ADVENT the primary effectiveness endpoint was met with the success of PFA at 73% at 1 year vs thermal 71%. In 2024 we expect to see data from JNJ's US Varipulse study (admIRE), MDT's Affera/Sphere-9 US study, and Kardium's European study.

Company	Device	Energy	Clinical Trial / Study	Type of Afib	1-year Afib Freedom Efficacy
Pulsed Field Ablation					
BSX	Farapulse	PFA	MANIFEST-PF survey	Paroxysmal	81.6%
BSX	Farapulse	PFA	MANIFEST-PF survey	Persistent	71.5%

Exhibit 3: Summary of 1-year PFA data vs 1-year RF/cryo data

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Company	Device	Energy	Clinical Trial / Study	Type of Afib	1-year Afib Freedom Efficacy
BSX	Farapulse	PFA	IMPULSE, PEFCAT, and PEFCAT II for CE Mark	Paroxysmal	84.5%
BSX	Farapulse	PFA	ADVENT	Paroxysmal	73.3%
JNJ	Varipulse	PFA	inspIRE clinical trial	Paroxysmal	70.9%
MDT	PulseSelect	PFA	PULSED AF clinical trial	Paroxysmal	66.2%
MDT	PulseSelect	PFA	PULSED AF clinical trial	Persistent	55.1%
MDT	Sphere-9	PFA/RF	EU study to support CE Mark	Paroxysmal	78.3%
MDT	Sphere-9	PFA/RF	EU study to support CE Mark	Persistent	77.9%
Other RF / Cyro Trials					
BSX	Cryoablation Arm	Cryoablation	ADVENT	Paroxysmal	73.6%
BSX	RF ablation Arm	Radiofrequency	ADVENT	Paroxysmal	69.2%
BSX	POLARx	Cryoablation	FROZEN AF	Paroxysmal	79.9%
MDT	Arctic Front	Cryoablation	FIRE AND ICE clinical trial	Paroxysmal	65.4%
JNJ	NaviStar ThermoCool	Radiofrequency	FIRE AND ICE clinical trial	Paroxysmal	64.1%
MDT	Arctic Front	Cryoablation	STOP Persistent AF	Persistent	54.8%
JNJ	THERMOCOOL SMARTTOUCH	Contact force–guided radiofrequency	PRECEPT clinical trial	Persistent	61.7%
JNJ	THERMOCOOL SMARTTOUCH	Contact force–guided radiofrequency	SMART SF clinical trial	Paroxysmal	74.9%
JNJ	HELIOSTAR	Radiofrequency balloon	STELLAR IDE	Paroxysmal	67.7%
MDT	Arctic Front	Cryoablation	STOP AF First clinical trial	Paroxysmal	74.6%

Source: Clinical papers. Note: FIRE AND ICE primary outcome was recurrent atrial fibrillation which occurred in 34.6% of the cryoballoon ablation group versus 35.9% of the radiofrequency group. PRECEPT had a primary effectiveness success rate of 61.7% and a clinical success rate of 80.4% at 15 months. Note: STOP AF First on Artic Front is the only clinical that led to FDA approval for first line treatment of afib ablations with cryoballoon.

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