PFA Catheters: Industry Research & Design

BME: 178 Biomedical Product Realization

San José State University

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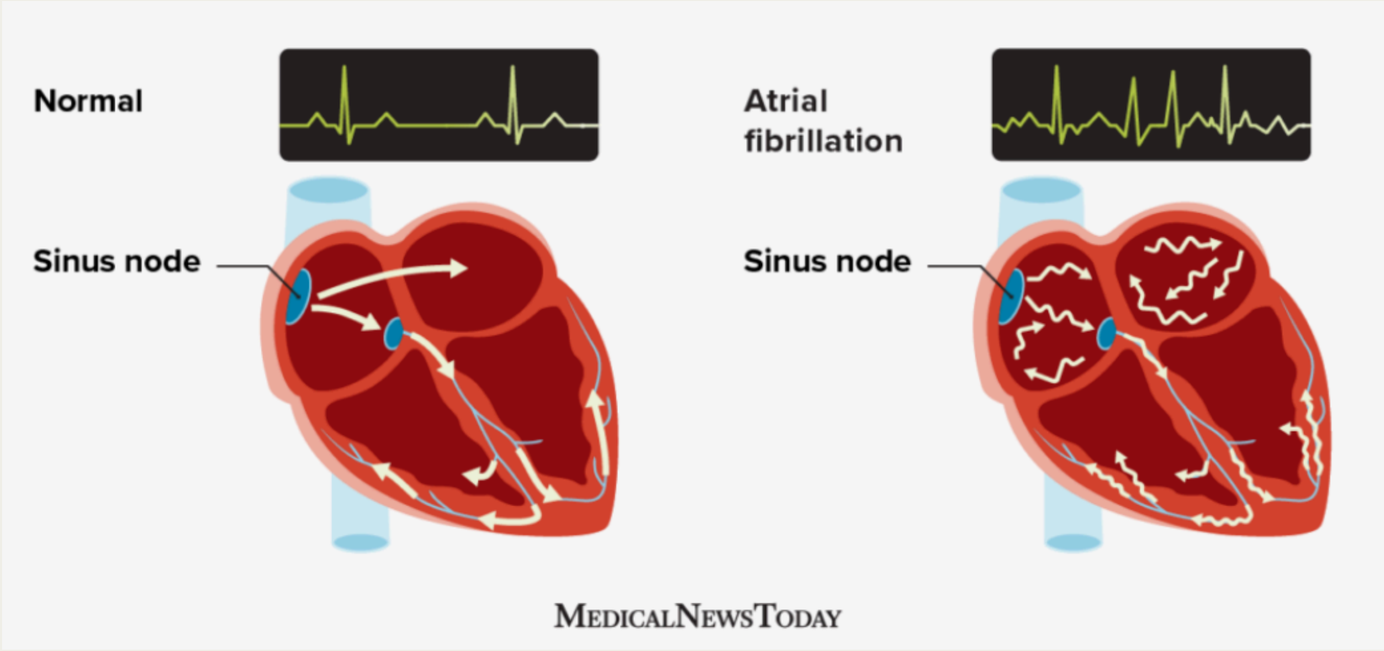
AGENDA

- What is PFA
- Interview #1: Dr. Rohit Seghal, MD - cardiologist at Washington Hospital
  - Q&A
- Interview #2: Brendan Koop. PhD Boston Scientific
  - Q&A
- Interview #3: Namratha Manthani
  - Q&A
- Current Market & Design Inspiration
- SSED & Requirement Specifications

WHAT IS ATRIAL FIBRILLATION

- Atrial fibrillation is an irregular heartbeat, or arrhythmia
  - Can lead to blood clots, stroke, heart failure and other cardiac events.
- Caused by dysfunctional myocytes
- Five million Americans are estimated to be living with AFib today.
  - More than 12 million people are projected to have it by 2030.



Normal Cardiac activity vs Atrial Fibrillation

According to the American Heart Association

What are PFA catheters?

- Medical device used to deliver pulsed electric fields to the heart to treat cardiac arrhythmias like atrial fibrillation
- Delivers short, controlled electric pulses that cause electroporation
- Creates precise lesions by disrupting abnormal heart cells (no heat involved)
- PFA is non-thermal and safer than Radiofrequency (RF) or Cryoablation
    - RF uses energy to generate heat and destroy abnormal tissue
    - Cryo uses extreme cold to destroy diseased tissue
- Allows faster patient recovery and fewer complications

Interview #1

Dr. Rohit Sehgal, MD

- Cardiologist at Washington hospital
- Professor of Cardiovascular medicine at Stanford, School of Medicine
- Been practicing interventional cardiology for over 20 years
- Dr. Sehgal specializes in the areas of Cardiovascular Disease, Internal Medicine & Interventional Cardiology.

Interview 1 Questions

1. From the standpoint of overall cardiac care, what do you see as the main clinical advantage pulse-field ablation (PFA) offers compared with traditional thermal ablation methods?
2. Which types of atrial-fibrillation patients in your practice would you consider the best early candidates for PFA, and why?
3. What features in a PFA catheter system would make it easier for non-electrophysiologists or smaller community hospitals to adopt the technique?
4. Looking five to ten years out, what single innovation — whether in catheter design, energy delivery, or imaging integration — would most improve patient outcomes and make PFA your first-line ablation choice?
5. What key metrics or symptoms do you track in the first six months after referring a patient for PFA, and how do these differ from patients who undergo thermal ablation?
6. How do you see AI being incorporated into PFA catheter technology
7. What's the single biggest risk or unknown that still makes you cautious about PFA?

Interview 1 Insights

- Selective, non-thermal energy — Targets heart tissue without heat, so nearby structures stay unharmed compared with RF/cryo.
- Early candidates: Patients with intermittent AF who don’t improve on meds.
- Single-shot, plug-and-play catheter — built-in mapping + contact force lets community labs adopt quickly.
- Next-gen game-changer: AI-guided basket — maps and ablates in one deployment; aims for sub-30-minute cases.
- First-6-month focus: rhythm freedom & zero collateral events — 14-day patch monitoring, symptom score, no esophageal/phrenic issues.
- AI adds value in planning & real-time control — image segmentation, pulse titration, early-recurrence prediction.
- Biggest unknown: long-term lesion durability & rare stroke risk — five-year multicenter data still pending.

Interview #2

Brendan Koop, PhD- Senior Fellow, R&D - Electrophysiology PFA Systems at Boston Scientific

- 20 + years in cardiac-rhythm management – pacemakers, ICDs, and catheter-based therapies.
- Leads PFA innovation – principal architect of the FARAPULSE™ system and FARAWAVE™ basket catheter.
- Patent & publication record – > 80 U.S. patents; multiple peer-reviewed papers on PFA and EP devices.
- Cross-functional R&D leadership – drives waveform design, catheter mechanics, and pre-clinical testing.
- Global impact – FARAPULSE platform now used in > 200,000 ablation procedures worldwide.

Interview 2 Questions

1. What core clinical problem drove the original geometry of the FARAWAVE basket?
2. How did you decide on the biphasic pulse parameters (voltage, width, spacing) for optimal tissue selectivity?
3. When moving from porcine to human atria, how do you recalibrate pulse amplitude and duration to maintain lesion depth without increasing collateral risk?
4. Which pre-clinical performance metric proved hardest to replicate once you reached first-in-human trials?
5. Over the next five years, which area will drive the biggest leap in PFA outcomes: smarter waveforms, robotic navigation, or disposable tip modules?
6. If you could add only one new on-catheter sensor in the next generation, would it be force, temperature, or impedance — and why?
7. How is Boston Scientific leveraging AI to improve lesion prediction or automate catheter positioning in upcoming versions?

Interview 2 Insights

- Five flexible splines expand 25 – 35 mm, letting the basket fit any vein size without twisting the wall.
- 1.9 kV × 2 µs, four pulses gave max myocyte kill yet spared nerves in bench tests, so those values stuck.
- Human atria are ~20 % thicker, so we added 10 % voltage and one extra pulse — depth preserved, risk unchanged.
- Impedance-drop predicted lesion depth in animals but not humans; blood-pool shunt forced us to rewrite that algorithm.
- Smarter adaptive waveforms; software can individualise energy faster than new hardware or robotics.
- Contact-force; real-time grams fixes both gaps and char better than temperature or impedance.
- Training models on past lesions to predict depth live and suggest micro-moves — first step toward semi-autonomous ablation.

Interview #3

No LinkedIn Profile Picture

Namratha Manthani, Associate Director for Regulatory Affairs at Abbott Vascular

- 20 years at Abbott Vascular and currently operating as Associate Director for Regulatory Affairs at Abbott Vascular.
- Great experience with cardiovascular device regulatory affairs in North America, Europe, APAC, and LATAM, with deep expertise in Class I-III devices.
- Specializing in global regulatory strategy, product approvals, and lifecycle management.

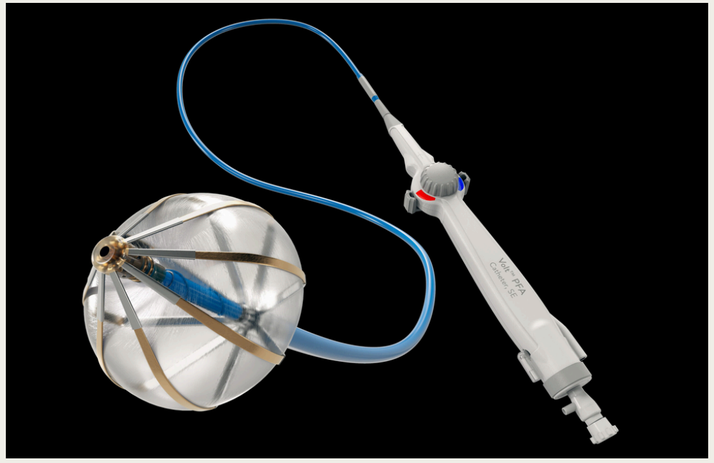
Interview 3 Questions

1. What are some of the key regulatory challenges when it comes to getting PFA technologies approved?
2. From your perspective, what factors influence how quickly new technologies like PFA are adopted in the field?
3. What kinds of factors seem to shape how and when clinicians begin to adopt newer technologies like PFA?
4. How do hospital purchasing decisions and equipment standardization influence the adoption of new platforms like PFA?
5. Do you think the pace of regulatory or clinical adoption is keeping up with the rate of innovation in ablation technology?

Interview 3 Insights

- Since PFA uses non-thermal energy (electroporation), it doesn't fit neatly into existing regulatory frameworks designed around RF or cryoablation
- Regulatory bodies often request more preclinical safety data due to the mechanism of action and limited long-term outcomes data.
- Clinicians tend to be cautious, prioritizing familiarity and long-term outcome data.
- Peer adoption, ease of use, and existing infrastructure also influence their decision-making.
- Hospitals may hesitate to invest in new systems that don’t align with existing workflows or staff training.
- Frequent changes in device interfaces discourage long-term commitment from physicians and procurement teams.
- Innovation often outpaces regulatory and clinical adoption due to safety, training, and system integration concerns.

CURRENT MARKET & DESIGN INSPIRATION



Abbott Volt PFA System

- Developer: Abbott (acquired from Affera)
- Overview: A PFA system designed for safe, non-thermal myocardial ablation.
- Key Feature: Integrated mapping and ablation catheter with real-time feedback.
- Status: Undergoing trials for atrial fibrillation and other arrhythmias.

Farapulse™ Pulsed Field Ablation System

- Developer: Boston Scientific
- Overview: One of first PFA systems with significant clinical use in Europe.
- Key Feature: Lattice-like catheter design with over-the-wire deployment, optimized for pulmonary vein isolation.
- Status: Approved in the EU; U.S. FDA approval anticipated following ADVENT trial results.

PulseSelect™ PFA System

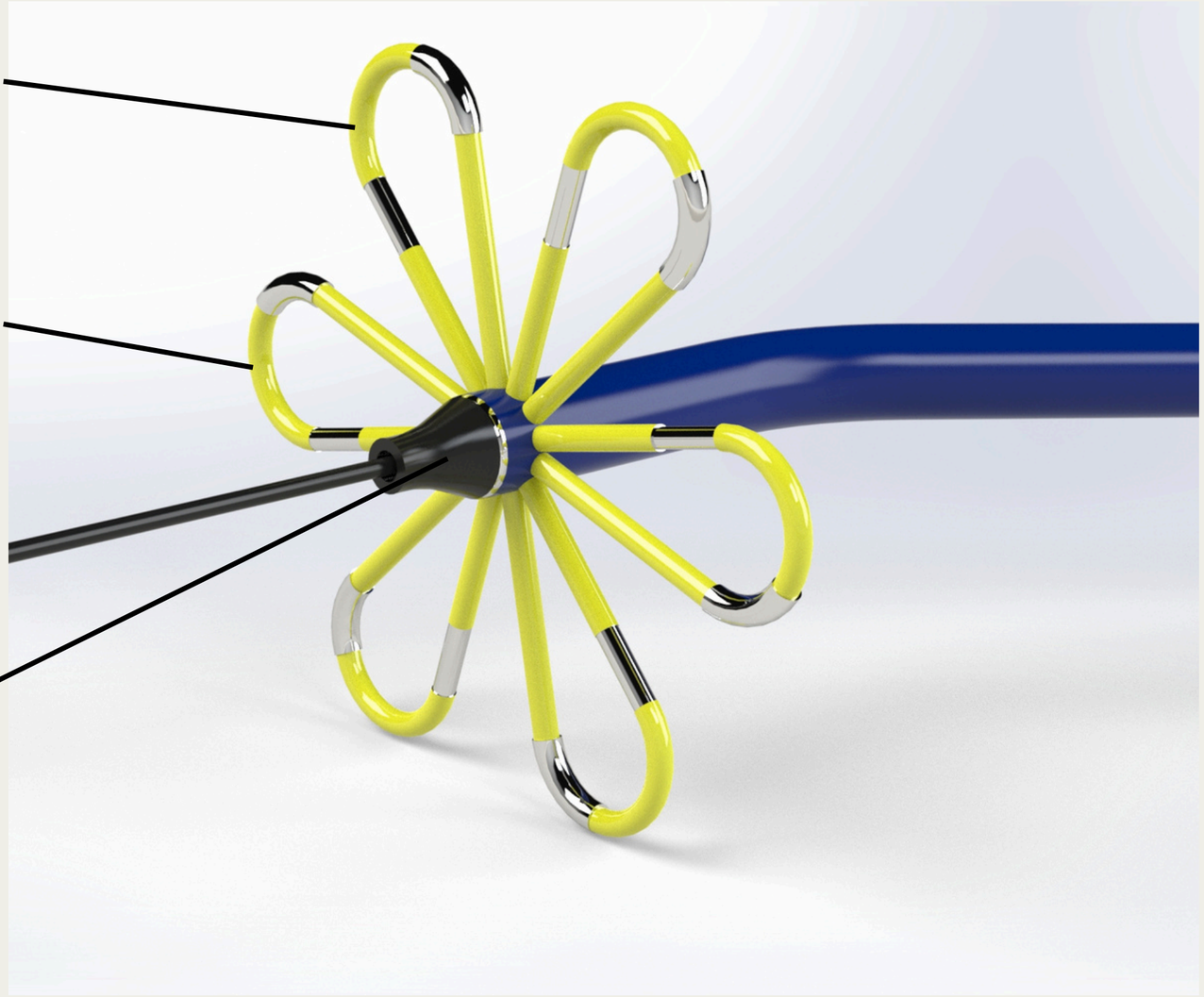
- Developer: Medtronic
- Overview: Developed to deliver precise, tissue-selective electroporation.
- Key Feature: Multi-electrode catheter that enables rapid, consistent ablation with customizable energy settings.
- Status: FDA approved (Dec 2023) — first FDA-cleared PFA system in the U.S.

Novel Design

STATE 1 25 mm inner loop, 6 electrodes

Contact-force sensors embedded in outer loop

Retractable outer loop



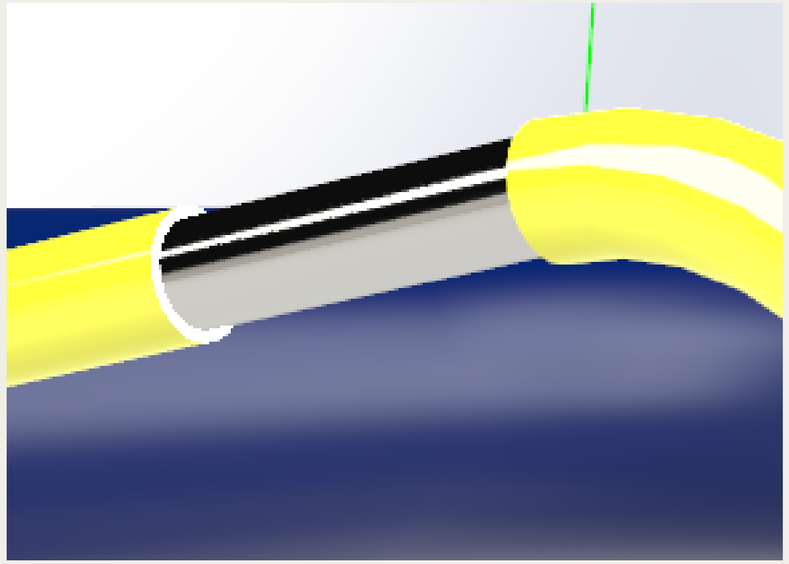
Inpsiration

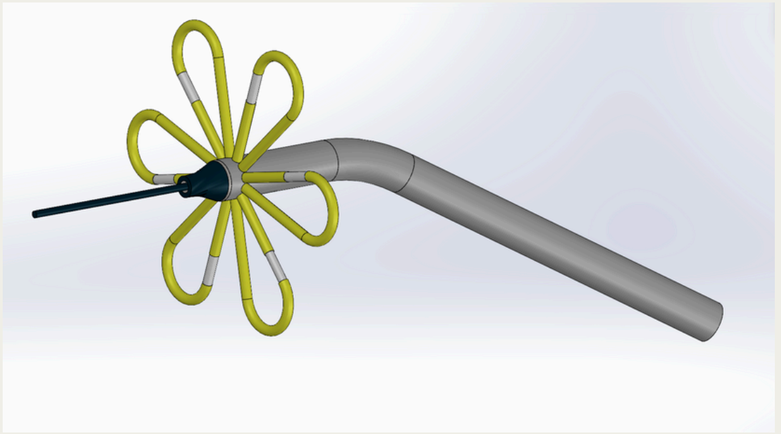
- An over-the-wire catheter in a flower configuration
- 6 electrodes that can transform into a basket configuration

Specifications

- 25 MM inner loops
- 6F loop diameter
  - Consistent with predicate designs
- Irrigation ports in shaft
  - Stroke / embolus mitigation
- Contact-Force Sensors
  - Live force read-out
- Retractable outer loop
  - +35 mm

NOVEL DESIGN CONT.





Component	Material	Function
Outer Shaft / Sheath	Pebax (polyether block amide)	Provides flexibility and pushability; protects internal components
Inner Shaft / Lumen	PTFE (Teflon) or Pebax	Houses the guidewire; reduces friction during advancement
Electrodes	Platinum-Iridium or Stainless Steel	Delivers pulsed electric field energy to target tissue
Insulation Layer	Polyimide	Electrically isolates electrodes and prevents leakage or cross-talk
Conductive Wires	MP35N or Silver-coated copper	Transmits high-voltage PFA pulses from generator to electrodes
Pull Wires / Steering	Stainless Steel	Enables catheter deflection and maneuverability through mechanical control
Marker Bands	Platinum or Gold	Radiopaque markers for visualization under fluoroscopy
Tip Electrode / Array	Platinum-Iridium, with polymer base	Ablates tissue; shaped for optimal pulmonary vein contact

SSED and Specification

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

I. GENERAL INFORMATION

Device Generic Name: Pulsed Field Ablation System

Device Trade Name: FLOWRAVE™ Pulsed Field Ablation (PFA) System

Included Components:

- FLOWRAVE™ Pulsed Field Ablation Catheter
- FLOWCONNECT™ Catheter Connection Cable
- FLOWGUIDE™ Steerable Introducer Sheath
- FLOWGEN™ Pulsed Field Ablation Generator
- FLOWREC™ Recording Interface Module (optional)

Device Classification: Class III / QZI — Percutaneous Cardiac Ablation Catheter for the Treatment of Atrial Fibrillation with Irreversible Electroporation

Applicant Name and Address: [To be filled in — your company name and address]

PMA Number: [To be assigned]

Date of FDA Notice of Approval: [To be assigned]

Date(s) of Panel Recommendation: None

II. INDICATIONS FOR USE

The FLOWRAVE™ Pulsed Field Ablation (PFA) System is intended for the isolation of the pulmonary veins in the treatment of atrial fibrillation by rendering targeted cardiac tissue electrically non-conductive to prevent the initiation or maintenance of arrhythmia.

The FLOWRAVE™ PFA Catheter is indicated for the isolation of pulmonary veins in the treatment of drug-refractory, recurrent, symptomatic **Paroxysmal Atrial Fibrillation (PAF)**.

The FLOWGUIDE™ Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left atrium through a transseptal approach.

The FLOWCONNECT™ Connection Cable is intended to be used with the FLOWRAVE™ Catheter during an electrophysiology procedure for cardiac tissue ablation.

The FLOWGEN™ Generator, when used in conjunction with the FLOWRAVE™ Catheter, is indicated for the isolation of pulmonary veins in the treatment of drug-refractory, recurrent, symptomatic PAF.

The FLOWREC™ Recording Interface Module is indicated for use in an electrophysiology lab environment as a filtering/protection unit to be connected between the patient and attached ECG and recording systems, and as an interface for synchronous stimulation output.

III. CONTRAINDICATIONS

The FLOWRAVE™ PFA System is contraindicated for use in the following situations:

- In patients with active systemic infection
- In patients with a mechanical prosthetic heart valve through which the catheter must pass
- In patients with conditions where catheter insertion or manipulation in the cardiac chambers is unsafe (e.g., presence of intracardiac thrombus or myxoma, recent cardiac surgery involving atriotomy)

LINKS:

- Dr. Rohit Sehgal: https://www.mywtmf.com/find-a-doctor/rohit-sehgal-md/
- Brendan Koop, PhD.: https://www.linkedin.com/in/brendankoop/
- Namratha Manthani: https://www.linkedin.com/in/namratha-manthani-8505122/

Thank you!