ACCELERATING TIME TO MARKET FOR PULSED FIELD ABLATION (PFA) THERAPY

THE PROMISE OF PFA

Pulsed Field Ablation (PFA) is a cutting-edge technology in cardiac electrophysiology, aimed at treating atrial fibrillation (AFib) and other complex arrhythmias. Unlike traditional thermal ablation methods, PFA utilizes high-voltage, short-duration electrical pulses to induce cell death through a non-thermal process called electroporation. This process selectively targets cardiac tissue without heating or damaging surrounding structures, reducing the risk of complications that can arise from thermal-based ablation methods.

PFA ablation is currently experiencing rapid adoption having demonstrated considerable promise in terms of safety, efficacy, and reduced procedure times. As PFA technologies continue to advance, accelerating paths to market will be critical to meet the demand for safer, more precise arrhythmia treatment options.

AN INDUSTRY CHALLENGE

For companies developing PFA catheters, the primary challenge is balancing rapid technological development with rigorous research, regulatory compliance, and readiness for commercialization. The competitive landscape is also intensifying, with major players vying to establish differentiated technical advantage in this burgeoning market.

The technical demands of developing next-generation innovative PFA devices, from research and development through to clinical validation and large-scale manufacturing, require a partner with proven capabilities in innovation, manufacturing and regulatory strategy.

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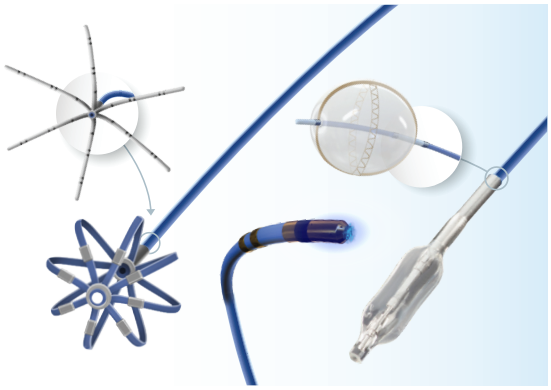
LEVERAGING EXPERTISE IN R&D, PROTOTYPING, AND MANUFACTURING

Freudenberg Medical has invested considerably in the technology, expertise, and resources necessary to fast-track PFA devices from concept to clinical trial readiness. Freudenberg Medical leveraged its expertise in medical device innovation and rapid manufacturing scaling for two leading OEMs.

1. **Gen-1 ablation catheter prototyping to undertake First-In-Human (FIH) study.**
   This involved advanced materials and precision engineering to create a PFA catheter that met stringent quality and safety standards. By rapidly delivering these prototypes, Freudenberg Medical enabled its OEM client to begin crucial early-phase clinical evaluations more quickly, gaining valuable feedback to refine their technology.
2. **R&D, Design for Manufacturability (DFM) and scale up of a PFA catheter sub-assembly to achieve a major industry 1st regulatory milestone.**
   Freudenberg Medical provided R&D and DFM expertise, ensuring the catheter sub-assembly design was optimized for performance and manufacturing efficiency. DFM input from Freudenberg Medical helped streamline the catheter's production process, minimizing material costs and enhancing production timelines. Additionally, Freudenberg Medical's capacity for commercial-scale manufacturing facilitated a seamless transition from prototype development to high-volume production, positioning its OEM client to meet accelerated market demand swiftly upon regulatory clearance.



ADVANCING PFA THERAPY: KEY RESULTS AND INDUSTRY FIRSTS

With Freudenberg Medical's support, its OEM partners achieved several key milestones toward advancing PFA therapy, including:

- Successful prototyping and initial testing for FIH studies, enabling valuable clinical data collection.
- Significant progress toward achieving a major regulatory milestone, marking one of the first industry advancements in the PFA arena.
- Capturing market share and first-mover advantage in the PFA market, with the manufacturing support to launch a commercial-grade product, at scale, immediately upon regulatory approval.

Freudenberg Medical has helped position its clients to be at the forefront of PFA therapy for AFib and to swiftly transition to a commercial offering once approval is obtained.

CONCLUSION

PFA is transforming EP & arrhythmia treatment by offering a safer, faster, and more precise therapy compared to traditional thermal ablation methods. The widespread & rapid adoption of PFA therapy is set to revolutionize cardiac care by reducing procedure-related complications, improving patient outcomes and enlarging patient throughput.

Freudenberg Medical's commitment to making a profound impact in Electrophysiology enabled its OEM partners to achieve critical milestones and accelerate time-to-market for this transformative technology. Through these collaborations, Freudenberg Medical has demonstrated its ability to advance pioneering medical technologies and drive meaningful change in patient care, reinforcing its position as a trusted partner in Electrophysiology.

"Our work in advancing medical innovations, such as Pulsed Field Ablation technology to treat AFib, highlights the transformative potential of our industry partnerships in revolutionizing cardiac care." said Paul Weafer, Director of Engineering at Freudenberg Medical.

Written by Paul Weafer, Director of Engineering at Freudenberg Medical.

For more information, visit www.freudenbergmedical.com

Freudenberg Medical is a leading partner for Minimally Invasive catheter design, development and manufacturing, facilitating access, delivery and visualization in the most complex clinical applications. Working in collaboration with its customers, Freudenberg Medical has enabled countless innovations in cardiovascular, electrophysiology, structural heart, peripheral vascular and neurovascular therapies.

Contact us today to explore how we can support your next EP catheter program.

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