



Electrophysiology Devices:

HOW A MULTI-COMPONENT SUPPLIER
HELPS STREAMLINE EP AND PFA
DEVICE DEVELOPMENT

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Introduction

The market for medical devices supporting electrophysiology (EP) is expanding rapidly due to the breadth of indications, including, but not limited to, atrial fibrillation (AFib), atrial flutter, and ventricular tachycardia. Each indication requires separate regulatory approval.

Pulsed field ablation (PFA) is the fastest growing subsegment in this field, often integrating cardiac ablation catheters with mapping and some diagnostic features. Catheters for such devices are highly complex to allow for multiple functionalities. This requires a wide range of highly precise components.

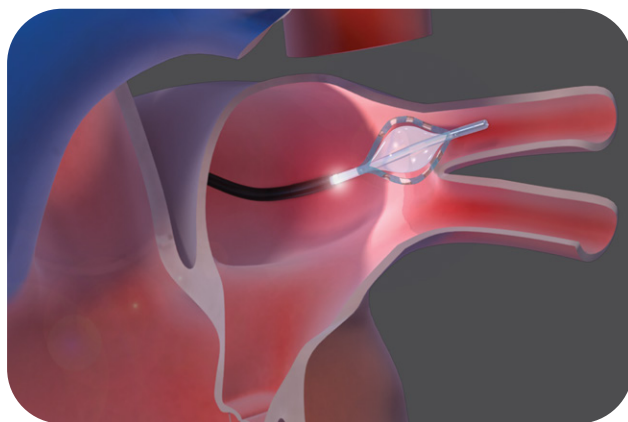
Selecting component suppliers capable of supplying precision components consistently is fundamental to market success. EP OEMs and CDMOs can simplify logistics and reduce cost by working with such suppliers that offer multiple components for a given device.



High Opportunity Demands Speed to Market

While once the standard of care in cardiac ablation, cryoablation and radio frequency ablation (RFA) are expected to be replaced by PFA for similar indications. However, these traditional therapies will likely continue in limited cardiac and specific non-cardiac indications, including oncology and denervation.

PFA is rapidly becoming the ablation therapy of choice for cardiac ablation. In November 2024, Johnson & Johnson joined Boston Scientific and Medtronic as the only OEMs with FDA-approved PFA devices for the treatment of AFib. In March 2025, Abbott joined the market when its device gained EU approval.



The growing competition has pushed PFA OEMs to innovate and to integrate different technologies to differentiate their devices. Examples include an active ablation catheter, which integrates diagnostic and imaging capabilities, and a next-generation catheter that features imaging capabilities and can harness two different types of energy, providing PFA or RFA within a single device.

Rapid innovation, speed to market, and consistent clinical performance are critical to success for any OEM. Component suppliers play a vital role throughout this process, including material selection, dimensional optimization, design for manufacturing, and cost management planning.


Since many components are used for each catheter (e.g. melt-extruded tubing, PTFE liners, PET heat shrink tubing, FEP heat shrink tubing, Polyimide, etc.) it is important to recognize the interplay between these components, including, but not limited to, stack-up tolerances. Suppliers who can provide multiple components within a PFA catheter are critical to the successful development and manufacturing of these devices.

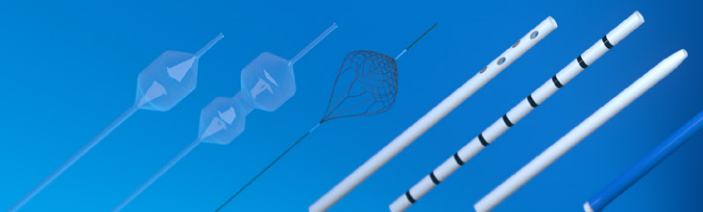
Isn't "Putting All Your Eggs in One Basket" Risky?

Reliance on fewer suppliers who offer multiple components can reduce operational complexity and by extension, customer risk. For example, if a product is composed of three different components sourced from three different suppliers, and one of those vendors suddenly is unable to meet customer demand for any reason, the OEM cannot build its product. Conversely, a multi-component supplier, providing parts for most or all of the assembly, will be more cognizant of the interplay between components and potential logistical challenges, putting mitigation strategies in place to safeguard their customers' investments.

Electrophysiology Capabilities


SINGLE-SOURCE PARTNER





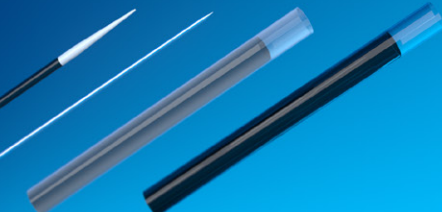
CATHETER TIPS

Balloon Extrusion
Complex Balloon Forming
Nitinol Elements
Hole Punching
Printing
Tipping
Tubes Shape Setting



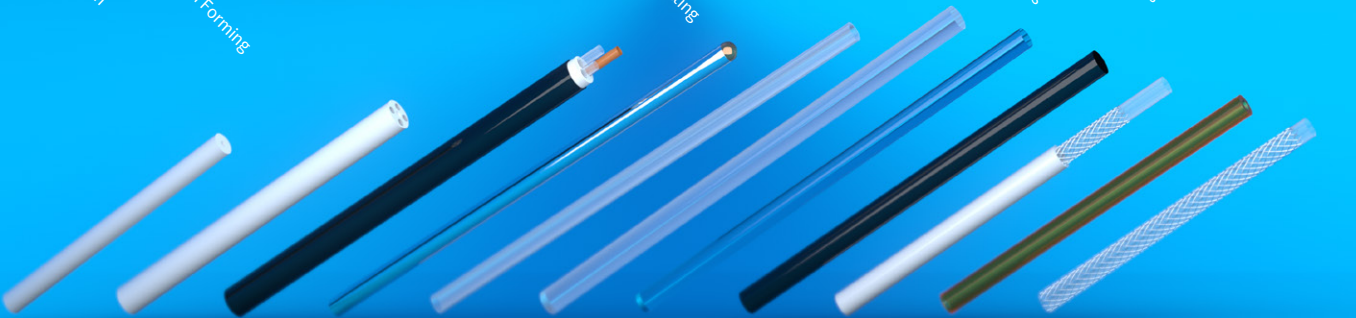
ACCESS

Introducers
Dilators



REFLOW AIDES

FEP Heat Shrinks
PET Heat Shrinks

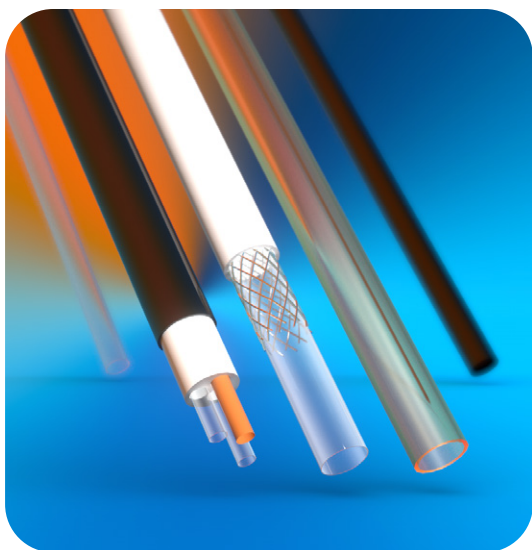


CATHETER & SHEATH COMPONENTS

Single Lumen Tubing
Multi-Lumen Tubing
Multi-Lumen with Liners (PTFE, Polyimide)
PTFE Liner, Film-Cast
PTFE Liner, Ram
FEP Heat Shrink
PET Heat Shrink
Single-Layer Tubing
Multi-Layer Tubing
Polyimide Tubing
Braid & Coil Reinforcement

Also, partnering with a primary supplier capable of designing and producing numerous components does not preclude OEMs from leveraging a secondary supplier to ensure redundancy for critical components — long considered a best practice. But usually, when a project begins, dual sourcing is not a consideration. That form of risk mitigation becomes more prevalent as a project advances to design for manufacturability or commercialization.

Project complexity is greatly reduced for OEM design engineers when collaborating with their primary supplier to provide or recommend components proven to work well with parts already integrated into the device design. In addition to component volume and diversity, multi-component suppliers have persevered through the common trials and tribulations associated with designing and manufacturing commercial components. They have proven acumen in efficient mass production and know how to identify and reduce quality issues without sacrificing efficiency.



A multi-component provider's depth of understanding in fitment and materials is also invaluable when assisting customers in developing requirements for their components. Device requirements are distinct from customer specifications: development starts with requirements from which specifications are derived. Multi-component suppliers often have the knowledge and experience to suggest specification adjustments that could improve component performance, quality, and cost early in development processes.

For example, a customer might request a tube with a very thin outer wall that the supplier knows will increase material and manufacturing costs of the component. In response, the supplier may suggest alternative strategies or designs that achieve the same intended result. Similarly, an OEM designing an EP device whose requirements include electrical insulation may benefit from supplier recommendations for alternative materials that provide enhanced electrical insulation at a lower cost per component.

Precision Engineering for Manufacturability

Simple-to-manufacture component designs, conducive to large-scale production, usually are part of an OEM's wish list, but design for functionality and design for manufacturability (DFM) can be easy for OEMs to overlook as they focus on meeting initial specifications. Manufacturability ultimately depends on the type of component, the manner of its interactions with other components, and its physical variables.

Some components are standard in design variables. For example, PET heat shrink tubing must meet customer specifications, including outer diameter, wall thickness, length, shrink ratio, and sometimes color. Being common and well-understood, such components are always manufactured at large scale.

Conversely, the design of more complex device components often requires refinement. But, the need to perform due diligence when developing new components should not unnecessarily extend project timelines. Any supplier an OEM engages with to provide proof of concept (PoC) for initial component design, or redesign, should be able to quickly produce prototypes, since having a component sample in-hand is the best way to expedite development. Moreover, such samples enable the OEM and the supplier to collaboratively determine shortcomings with the model — it could be too stiff, brightly colored, or large — and adjust them for the next iteration.

Add Volume and Device Features, Not Operational Complexity

Nordson MEDICAL uses an established process for carrying customer components through concept, prototype design, process validation, and commercialization. We are purpose-built to ensure that each new component in your system is designed for manufacturability at high volumes from start to finish.

Each Nordson MEDICAL product line — melt extrusions, balloons, PTFE, heat shrinks, polyimides, etc. — benefits from a dedicated Center of Excellence. When an OEM requires expertise in a specific area, they can be directed to that Center, where they have access to Subject Matter Experts (SMEs) and specialized working groups who can help each customer maximize their design's potential.





Additionally, Nordson MEDICAL has invested strategically in capacity, equipment, quality-focused programs, cellular manufacturing, and innovation around building components and systems that avoid “forever chemicals” like N-Methyl-2-Pyrrolidone (NMP) and Perfluoroalkyl Substances (PFAS).

In all partnerships — whether the contract covers large-scale production of one component or design and manufacture of several components spread across different product lines — the customer has a central contact within Nordson MEDICAL, while retaining access to all relevant experts when they want to delve into design specifics. That project manager facilitates conversations, coordinates activities, and promotes quick turnaround on decisions and actions.

Conclusion

Thus, when vetting EP device component suppliers, cost, speed, capability, quality and experience are paramount. Nordson MEDICAL is a proven partner in all five areas, able to assist in the design and manufacture of multiple assembly components. As a primary supplier, Nordson MEDICAL offers its clients simpler logistics, a more stable supply chain, and closer communication for more trouble-free development and production. Our unique combination of experience and expertise in serving medical device OEMs and CDMOs have made us a partner whose values, mission, and vision align well with these organizations. To learn more about the benefits of partnering with a multi-component primary components supplier, visit www.nordsonmedical.com, or reach out to your local account manager.



About Nordson MEDICAL

Nordson MEDICAL (Nasdaq: NDSN) is a global expert in the design, development, and manufacturing of complex medical device components. As a single-source partner, we enable our customers to save costs, speed time to market, and simplify supply chain management.

We work with companies at any point in the product life cycle, from concept to launch and beyond. With our flexible business model, we can provide a solution that meets the scope and scale of any project to bring innovative ideas to life.

Visit Nordson MEDICAL at nordsonmedical.com