

Integration Speeds Ablation Catheter from Concept to Clinical



CUSTOMER SITUATION

A startup company aimed to develop a next-generation ablation catheter to treat a chronic condition. Its goal was to develop superior technology and re-establish ablation as an effective therapy for this condition, as it had fallen out of favor due to shortcomings with previous ablation systems. The customer set aggressive milestones to develop the device.

Device requirements included:

- *5 Fr catheter to allow radial access, rather than traditional femoral access via an 8 Fr or 10 Fr catheter*
- *Ability to deliver low-power RF energy that would result in effective therapy while maximizing patient safety and comfort*

The customer had confidence in Nordson MEDICAL's expertise in catheter product development, ablation/energy delivery, critical components, and decades of experience manufacturing and assembling complex devices. In addition, the customer appreciated Nordson MEDICAL's integration as a means of compressing the product development timeline.



NORDSON SOLUTION

As an integrated, single-source supplier, Nordson MEDICAL was able to provide the critical components and services needed for this project in-house, accelerating the timeline. Team members at various facilities designed, developed, and manufactured the device under one quality system, saving significant time compared with working with a network of outside suppliers.

The team rapidly generated concepts and prototypes to demonstrate design feasibility in 6 weeks, providing proof-of-concept evidence for a key investor milestone.

One of the primary challenges was designing a 5 Fr catheter that could accommodate the complex array of electrodes and sensors required for multipoint ablation and

real-time monitoring, while meeting all standards for electrical safety testing.

The team saved valuable time by leveraging Nordson MEDICAL's expertise in:

■ Engineered shafts:

- An inner, film-cast, braid-engineered polyimide shaft for strength and flexibility
- A middle extruded layer with a complex geometric profile to provide connectivity to the electrodes and sensors
- An outer laminated, multidurometer thermoplastic shaft to provide structure and kink resistance

■ PET heat shrink tubing: This tubing was ideal to add strength at stress points and provide ultrathin insulation at electrical junctions

■ Balloons: Drawing on its expertise in balloons, Nordson MEDICAL devised an innovative means of increasing the efficiency of the RF energy delivered for treatment, while protecting the patient from excess RF energy

■ Molded components: The catheter handle required ergonomic design and human factor engineering to make it comfortable to hold and easy to operate while viewing the device under fluoroscopy

Nordson MEDICAL strategically deployed team expertise for each stage of the project, engaging various technical leaders within the organization while maintaining continuity by focusing on key priorities and deliverables at each phase.

Throughout the project, the team operated within Nordson MEDICAL's Quality Management System and followed Nordson MEDICAL's stage-gate process: Concept & Feasibility, Design & Development, Verification & Validation, and Manufacturing Transfer & Clinical Manufacturing.



OUTCOME

The ability to draw on a broad range of expertise within one company was a major factor in the team's success in delivering this unique ablation catheter within the deadline and within budget.

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The device achieved all the customer's technical requirements and offered many advantages over existing ablation technology.

Nordson MEDICAL was closely involved in preclinical testing, in which the therapy showed statistically significant improvement in the primary therapy metric. The customer received CE Mark late last year, and clinical trials are currently underway.

Nordson MEDICAL is continuing to work with this customer and is in the early stages of a new program for a similar, first-generation ablation therapy system for another chronic condition.