CUSTOMER SITUATION

This startup company had begun developing a 5 mm single-procedure laparoscopic energy delivery device for general surgery applications. The small team had faced many reliability and performance issues associated with developing a first-generation product with a novel core technology that was significantly different from competitive solutions.

The customer’s objectives were to solve the technical challenges and accelerate product development for commercialization. Team members also faced time pressure due to strategic milestones that they had to achieve to raise funding to bring the product to market.

The customer was impressed with Nordson MEDICAL’s detailed technical knowledge of laparoscopic instruments, energy delivery devices, design for high-volume manufacturing, and the product development process for low-cost, single-procedure instruments.

NORDSON SOLUTION

The Nordson MEDICAL team began with a 3i Project Booster Session, a stand-alone, affordable, brainstorming event. During this event, the team took an in-depth look at the current design, its shortcomings, and the target performance requirements. Nordson MEDICAL proposed a development path to first address performance and reliability issues, then achieve cost reduction by applying design for manufacturability and assembly (DFMA) principles.

The customer engaged Nordson MEDICAL to implement the plans that resulted from the 3i event. The Nordson MEDICAL team worked in concert with the customer, functioning as an extension of its product development team. Designed to be a versatile instrument for use across different procedures, the device combined the strengths of different energy modalities. The key engineering challenges involved meeting stringent mechanical, electrical, and thermal performance requirements.

The Nordson MEDICAL team designed and built several rounds of functional prototypes that demonstrated significantly improved performance, culminating in a concept freeze. Guided by DFMA principles, the project then transitioned to a detailed design phase, including final materials selection, scalable manufacturing processes, and reduced assembly time.

Leveraging component expertise, Nordson MEDICAL supplied polyimide tubing due to its thin profile and superior thermal properties, as well as printed PET heat shrink tubing for its electrical insulation properties. Nordson MEDICAL also contributed supply chain expertise by identifying and working with suppliers of critical components to meet high-volume manufacturing cost targets that were an important part of the customer’s business strategy.

Prototypes tested in a large preclinical animal model demonstrated performance superior to any of the previous device designs, as well as time-saving advantages over currently available products.

OUTCOME

The Nordson MEDICAL team completed its phase of work (detailed design development) on time and within budget. The customer completed the Verification & Validation phase in house, obtained its 510(k) clearance, and went into its first-in-human study. The startup was then acquired by a minimally invasive surgical company, which is now gearing up to commercialize the device.

Partnering with Nordson MEDICAL brought the necessary expertise and expanded capacity that allowed the customer to take its device to the next level, significantly increasing the quality of its product and speed of product development.