

Nordson MEDICAL Takes Innovative Balloon Catheter from Concept to Commercialization



CUSTOMER SITUATION

A small start-up company had an idea for a catheter-based device that would offer the first interventional approach to treating mitral valve regurgitation, a condition currently only treated with open surgery. The device would cut through cardiac tissue with minimal force using RF energy.

The balloon had to:

- Lock into the valve anatomy
- Maintain shape throughout inflation
- Hyperextend leaflet without overdistension of the annulus
- Rapidly inflate/deflate

As a small company mostly comprising business and medical experts, the customer needed to outsource most technical and engineering needs. The customer chose to work with Nordson MEDICAL as a single-source partner for its expertise in balloon design and fabrication, its vertically integrated components, and its ability to provide the full range of services needed to bring the product to market, from concept through manufacturing.



NORDSON SOLUTION

Nordson MEDICAL's in-house design team explored various concepts and materials to design the "dog bone" balloon geometry the customer had envisioned, with Design for Manufacturability (DFM) in mind. Leveraging Nordson MEDICAL's balloon-blowing capabilities, the team first fabricated a PET balloon. However, preclinical studies showed that the PET balloons

were susceptible to premature burst when inflated in valves with calcification. The team repeated the study with nylon balloons, which showed better resistance to premature burst when inflated in calcified valves.

Working closely with the customer, Nordson MEDICAL managed the processes of verification and validation, clinical and pilot manufacturing, and commercial manufacturing.



OUTCOME

A year after the product launched into the global marketplace, the customer signed a distribution agreement with a large, multinational medical company. Nordson

MEDICAL is currently working with the customer on its next-generation technology.