

Design Through Manufacturing Transfer of a Sensor Integrated Diagnostic Catheter

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The Challenge

An industry leader in the design and manufacture of interventional and diagnostic technology was looking to branch into a new clinical application with a disposable, sensor integrated, diagnostic catheter. They engaged Freudenberg Medical as a development and manufacturing partner.

The product posed some challenges as the technology was new for this application, the product was outside the customer's area of expertise, and a key sensor component was being developed by another vendor.

Perhaps most challenging, the customer's initial sales projection was significantly expanded late in the implementation of the manufacturing plans from 30 to 500 units per day. This required a rethinking of the processes, equipment needs, and training necessary to meet the new production targets.

The Solution

Freudenberg Medical's ability to take a napkin sketch idea all the way through commercial manufacturing was a perfect fit for this customer. Design engineers, process engineers, quality engineers, and program managers were all engaged on the project. From the beginning, our team developed and built the first handful of units with an eye toward efficient manufacturing and commercialization. We were also able to work closely with the customer's existing vendor to help them deliver the sensor component in a way that best integrated with our production processes.

Leveraging lean principles, a 3P (Production Preparation Process) Kaizen event was held to address the substantial increase in production output the customer required. Many ideas were generated after a three-day brainstorming session including engineers, technicians, and production workers. Each alternative was tested and ranked to find the best result by creating full-scale mock line layouts. This included bringing actual components in and



moving them through the line to make sure everything worked as designed. From this 3P event, an action plan was created to systematically reduce bottlenecks on the actual line.

The Result

Working closely with the customer and their sensor technology development vendor, Freudenberg Medical was able to develop a sophisticated product with an integrated new sensor technology and optimize it for commercialization. When the projected demand for this product dramatically increased, Freudenberg Medical applied proprietary lean principles to efficiently ramp up production with no new capital equipment expenditures. A cost avoidance/savings of \$1.5 million was realized before the first unit was put in production.

Freudenberg Medical operators increased daily output from the originally specified 30 parts per day to nearly 500 parts per day by implementing 'Standard Work' for each process, leveraging and refining best practices, techniques and methods, and then standardizing this for all operators. Examples of our Standard Work success:

- Yield was increased from 76% to 93% in one year
- Scrap for the top failure mode was cut in half in 45 days
- Product handling efficiencies improved quality with decreased part variability and reduced wait time at work stations, with one station's improved cycle time decreasing from 249 to 160 seconds



- Hourly output was increased by over 50% by reducing bottlenecks through line balancing and layout change

The success of this first project with a new customer has become a strong eight-year long term manufacturing partnership, highlighted by Freudenberg Medical being named their Supplier of the Year two years in a row.