

DFM with dual prototyping paths delivers repeatable micro-features for innovative cardiovascular device

Challenge

A global cardiovascular market leader needed help producing a game-changing medical device for the treatment of atrial fibrillation. As conceived, the device would overcome some of the then-current standard of care's limitations, making it easier and faster for physicians to perform the procedure. However, several critical micro-feature design challenges needed to be overcome before it could be manufactured repeatedly with consistency. The company turned to us, their longtime contract manufacturing partner, for design for manufacturability (DFM) engineering support.

Action

One of the most important elements in designing, developing and manufacturing a new product at scale, DFM comprises the collaborative process of proactively mitigating product design risks to optimize manufacturing functions and attain the best cost, quality, reliability, regulatory compliance, safety, time to market and product satisfaction.

The initial product design concept specified injection molding of a PEEK polymer to manufacture two critical micro-parts. However, based on the risks to meeting the product requirement objectives established

through DFM, our team recommended taking a dual path prototype approach to help keep the product launch timing and budget on track. Subsequently, prototypes were initiated with both injection molding and precision Swiss machining.

This enabled the engineers to test prototypes quickly and allowed them to finalize the designs for the production approach.

Through dual path testing, the collaborative engineering team realized the parts would be better achieved through precision machining. While injection molding can consistently transform thermoplastic and elastomeric polymers into molded components, in this case manipulating the PEEK with precision machining achieved the required precision and accuracy more readily. To refine the parts to exact specification, the team also designed and built sophisticated automation systems to deburr the machined parts. This eliminated operator variability and allowed for more consistent results and a higher level of meeting the specifications.

Another important part of the collaborative process was effectively communicating across

teams. As more became known about the DFM iterative results, our project management team worked closely with the global OEM's program managers to refine and adjust the product specifications, as well as the project scope and timeline to keep the product as close to schedule as possible.

Results

Through the DFM process with our engineering team, the global market leader landed on an ideally suited product design for the microparts that could be produced accurately, precisely and cost-effectively. Satisfied with the results, the global leader went on to launch its innovative medical device with confidence. As promised, the medical device is now helping physicians more easily and quickly provide life-saving treatment to patients around the world.

Capabilities used

- Design for Manufacturability (DFM)
- Injection Molding
- Precision Machining
- Prototyping
- Tool building



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