CASE STUDY

SPECTRUM PLASTICS GROUP
A DuPont Business

Transforming reusable device to single-use improves patient safety and saves costs for global OEM

Challenge

A large medical device OEM planned to convert a reusable orthopedic instrument kit to single-use disposable. At the time, the product, which comprised several components, already met industry standards and was widely used in surgery centers. A single-use kit system would enable the OEM to reduce patient safety risks, streamline sales and inventory management processes, and save overall costs.

With a disposable version, the OEM could install a system in which physicians scan a code to get a kit dispensed. Rather than sales team members managing each component at point of use, the system would track each unit "sold" for inventory management and invoicing. A single-use kit also would eliminate the contamination risks associated with reprocessing reusable equipment. And it would make administration easier for all involved, i.e., the OEM, clinicians and healthcare systems.

To transform the kit, however, engineering and quality challenges needed to be overcome. From an engineering standpoint, the single-use kits would require tight tolerances and intricate dimensions for critical implants and instruments. In addition, as a disposable medical device, the kits must be sterilized and maintain that sterilization through handling, packaging and labeling to meet the product shelf life.

To realize its single-use program's promise, the orthopedic OEM needed a contract manufacturing partner with proven medical device design for manufacturability (DFM) expertise, vertically integrated capabilities and absolute quality. The contractor also had to be able to work within a tight budget and follow an aggressive timeline to meet a firm launch date. They OEM selected us.

Action

Our team of engineers, designers, machinists and toolmakers work together under one roof in the company's vertically integrated facility.

Using their deep knowledge and expertise developing thousands of orthopedic medical devices and components, our design engineers began working on transforming the reusable kit instruments to meet the needs of disposable ones. With processes designed to optimize product development and production for consistency and repeatability, the team began by evaluating and characterizing all manufacturing processes needed. A rigorous design for manufacturability (DFM) process helped prove out concepts for the challenging injection molded components, including the difficult snap-off parts. Through verification and validation, they used empirical data to understand and control variation sources that could affect the product quality of each component. They also proved out and provided documented evidence that each component met specifications.

In addition, from design through shipment, the team implemented and followed quality assurance processes using ISO-9001 and ISO-13485 certified systems. Our overall quality management systems, including the paperless and robust lot traceability, allowed for the management and control of multiple part numbers within the program.

Solution

Working closely with the OEM, our team met all of the end-to-end product development, manufacturing, assembly and packaging requirements. In addition, the program was completed within budget and ahead of the firm product launch date.

The global OEM reports satisfied customers in the field, and in-house. Next up, the OEM plans to re-engage with us to convert additional reusable product kits for single use.

Capabilities used

- Design for Manufacturability (DFM)
- In-house design and tooling
- Injection Molding
- Secondary operations
- Assembly, kitting and sterile packaging

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SPECTRUM
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Deliver your medical device promise

We make products that sustain – and save – lives.

We manufacture medical devices and components. That's all we do. And we do it with the utmost precision, consistency and rigor, because for you – and your customers – quality is essential. Reliability is a must. And delivering on what's promised is vital.

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