

Advanced Micro-Catheter Design Improves Patient Experience

Recognizing an increasing concern of vascular injury, infection and misplacement, a global medical device company chose to partner with Flexan, LLC to design an advanced micro-catheter.

CHALLENGE

Over 5 million central venous catheters are inserted every year in the United States, accounting for 15 million central venous catheter days. However, these ubiquitous procedures could cause hazardous patient conditions and increased healthcare costs. These issues are especially concerning because government organizations, such as Medicare, no longer reimburse for various preventable complications related to central line placement. Yet, with new catheter design manufacturing technologies, standardization of insertion techniques and the use of ultrasound guidance, complication rates have reduced from 11.8% down to 4-7%.

GOAL

The customer was seeking a supplier who could employ catheter build techniques and material selection that would reduce reported incident complaints.

SOLUTION

Flexan facilitated design improvements and managed the over-molding production over thin-walled 5FR triple lumen, 4FR dual lumen and 3FR single lumen small diameter PICCs made of polyurethane-material technology (all extrusions provided by an external vendor).

PROCESS

The Flexan team was able to mold using a urethane material that enters the body rigid but softens in the body, which minimizes placement complications. Flexan's broad experience in tip forming using the latest in RF technology reduced insertion complications. Further, the Flexan team designed and manufactured a 4FR thin-walled catheter that has a 14% smaller diameter compared to standard 5FR catheters, but same sized lumen. The team also produced a catheter with equivalent kink resistance for a 4FR thin-walled catheter compared to a 5FR standard catheter with an equivalent lumen size.

RESULT

Collaborating with the customer to realize the design intent, Flexan successfully achieved the production of a new and improved micro-catheter design improving the functional performance of the PICC catheter. The team also developed a robust process control plan and inspection methods to ensure bond consistency for all vital components of the catheter device. This successful thin-walled catheter project paved the way to incorporate these design changes in future projects.



INCREASED DEMAND FOR PRECISION MANUFACTURING

- The global vascular access devices market is expected to register a CAGR of nearly 6.5% during the forecast period of 2018–2023.
- Among the regions, North America accounts for the largest regional share in the global vascular access device market in 2016.
- **Complication Statistics:**
 - Failure to place the catheter – 22%
 - Arterial puncture – 5%
 - Catheter malposition – 4%
 - Pneumothorax – 1%
 - Subcutaneous hematoma – 1%
 - Hemothorax – < 1%
 - Asystolic cardiac arrest – < 1%

FLEXAN: The vascular access device experts

Our experienced engineers and high-precision manufacturing provide an innovative combination for end-to-end development. This means that we, at all times, crawl, walk or run beside you at every step of the design, manufacturing, molding, extruding, assembly and packaging processes. This strategy enables us to maximize control and minimize complications at every touch point.

- Produced 130 million silicone and thermoplastic devices in 2017
- Has more than 1,700 active SKUs
- Holds cutting edge device design patents, including the Reduced Friction Catheter (US Patent: US20070123825)
- Has built over 500,000 cannula units across 25 SKUs

We offer contract manufacturing services for your end-to-end medical device outsourcing needs.

For more information, please contact us at salesinfo@flexan.com

Sources

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