



Case Study

Get Straight To The Point: KMM Solves Guidewire Production Challenge

Background

A Salt Lake City-based biotechnology firm that designs and develops guidewires and microcatheters for neurovascular stroke surgeries, peripheral vascular disease, and interventional oncology approached us in 2019. We met their team for the first time at a tradeshow in California. We learned that they developed patented micromachining and microfabrication technologies to produce most of its access devices and therapies in-house. However, this medtech firm had a previous partnership with our competitor to help them manufacture specialty neurovascular guidewires, a critical component for devices designed for two stroke intervention procedures: thrombectomy and endovascular coiling.

Fast-forward a year later to February 2020, when we met again at the same show. This time, the medtech firm was interested in learning more about our precision medical device manufacturing capabilities. The following month, they revealed that their current vendor was struggling to provide good parts amid growing demand for its neurovascular guidewires. As its order volumes grew, the firm was forced to reject an alarming number of defective guidewires, returning them to the manufacturer and delaying component production. Worried that its supply chain would dry up and threaten its gaining market acceptance, this medtech team needed immediate help.

Having already been introduced to our medical device component manufacturing capabilities a year earlier, we hit the ground running. Their lead engineer flew to our Philadelphia-area manufacturing facility with great urgency after recently rejecting a large shipment of defective parts for an order they needed to produce quickly. We spent a couple of days with our client developing a production strategy and preparing for a whirlwind validation process that we completed in a record two months. Finally, we were ready to help our new client get their production back on track.



CHALLENGE

When manufacturing a guidewire test run, we encountered the same challenge our competitor faced: the wire bent during high-volume production runs. It arced so sharply that it prevented our client's proprietary device from completing its mission of reaching blood clots faster and deeper than any other access device or therapy on the market. With an understanding of the high stakes, our challenge was determining how to manufacture the specialty vascular guidewires in mass production quantities without allowing them to bend.



SOLUTION

Working swiftly, our engineering and technical development teams dove deep to uncover the manufacturing solution that would prevent the guidewires from bending. Our process included a high-touch communication strategy involving weekly calls with our client's management team. These meetings allowed us to share our progress and uncover valuable insights for greater clarity.

We determined a multi-faceted solution, drawing on our extensive experience working with all types of materials and in-depth understanding of the grinding process. We spent several days modifying aspects of workholding, tooling, the grinding wheel, and the grinding machine to reduce the stresses in the process to achieve sustainable production of bend-free corewires.

Thanks to our team's ingenuity and an in-depth understanding of precision medical device manufacturing and the intricacies of this project, our equipment modifications allowed us to produce bend-free specialty guidewires successfully. Starting with an initial production run of 2,000 parts to rejuvenate our client's production capabilities, we gradually increased the order quantities, manufacturing about 25,000 parts over the next several months.

Critical Dimensions

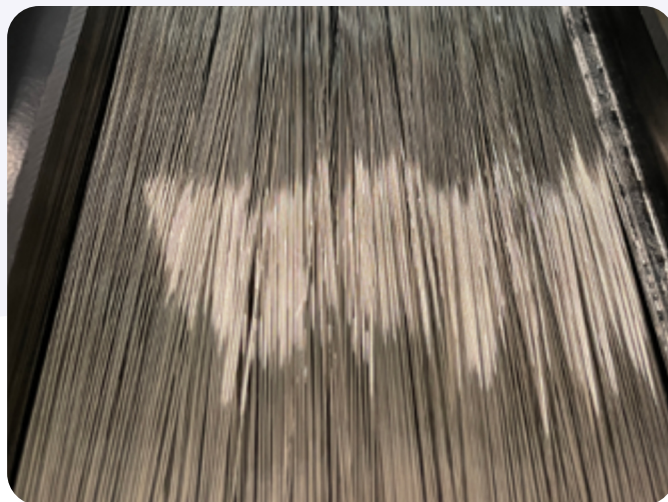
Material: 304 stainless steel

Grind length: 20-24"

Diameter: Multiple diameter sizes, down to .002"

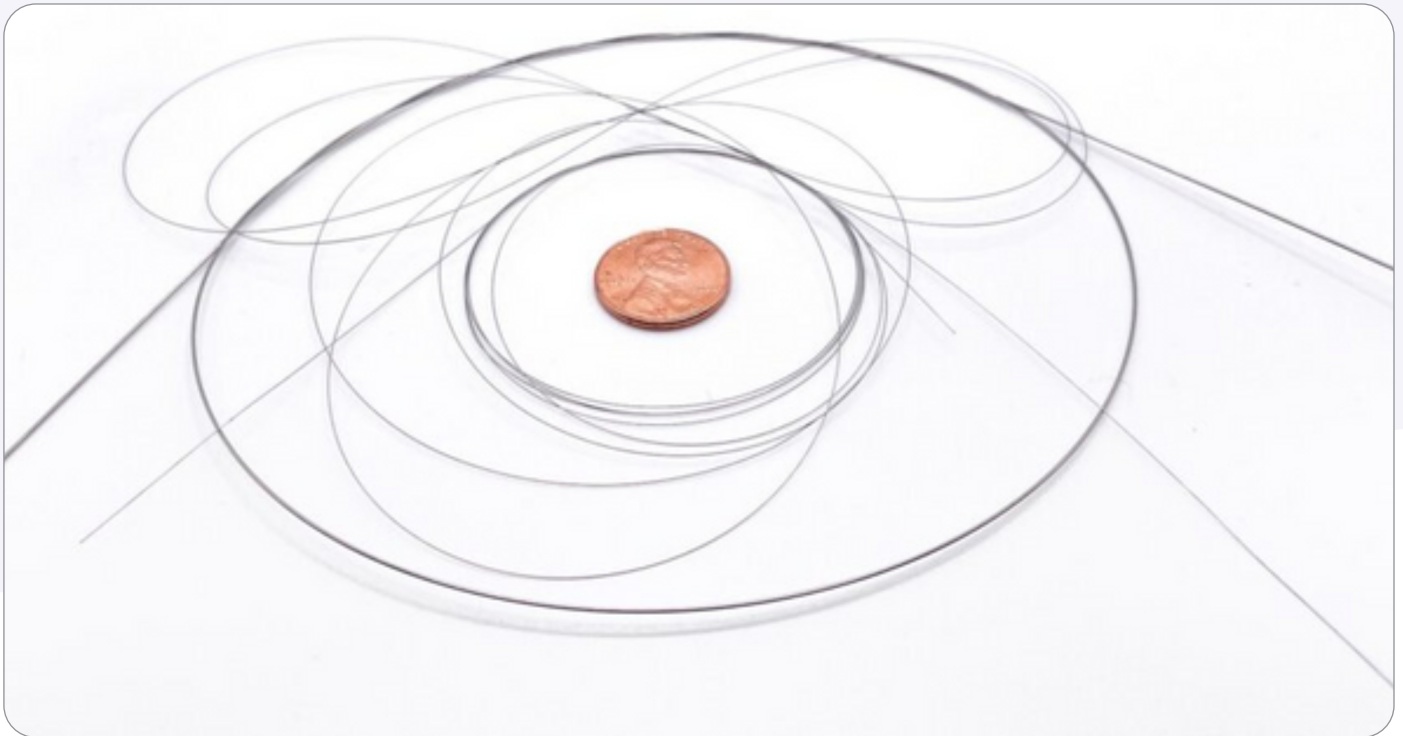
Tolerance: +/- .0002"

Surface finish: 8 Ra max



RESULTS

After producing several lots of specialty neurovascular guidewires, our client was ecstatic. It was the first time the company had a stable supply chain in over a year. Before, they had to approach sales cautiously because the team lacked confidence in receiving good inventory. As a result, the firm couldn't target as many hospitals as they wanted, knowing that 100% of the surgeons who tried their guidewires switched to using them. Now with a reliable supply chain, our medtech client was finally ready to scale their business. Today, this firm is expanding, securing funding, and hiring an internal sales force to help them grow with confidence.





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