An OEM's complete guide to sourcing coils for medical devices

20 YEARS | Custom Wire technologies, Inc

ISO 13485

Introduction

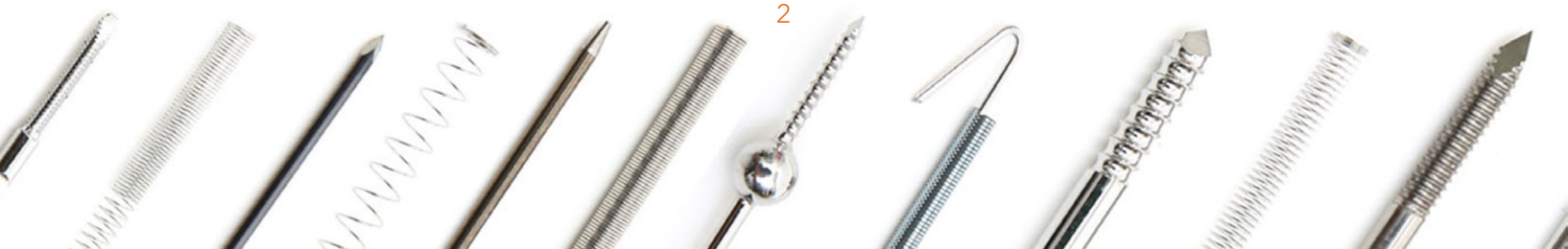
Compared with other industries, the medical device sector has been somewhat slower to take full advantage of the contract manufacturing model. Today, however, the production of complex parts and assemblies is often outsourced to specialist providers who can deliver custom designs.

While increased outsourcing has created a more complex supply chain for original equipment manufacturers (OEMs) to manage, it is generally seen as the quickest and easiest way to create a proof-of-concept for an innovative new device and often the most cost-effective option for supporting its commercial manufacturing.

Coils are important components in a wide range of medical device segments, including interventional cardiology, imaging, cardiac rhythm management and neurostimulation. Coils are central to the performance of many catheter and guidewire designs. In catheters, coil-reinforced tubing can improve the device's kink resistance and pressure holding. In guidewires, coils can provide similar reinforcement, and can be used on the tip for added flexibility and radiopacity.

As the medical industry trends towards increasingly smaller devices with the goal of minimising the discomfort and complications linked with invasive surgical procedures, manufacturers are looking to reduce coil diameters while maintaining the precision and performance of the component. Coil production is typically outsourced rather than handled in-house because manufacturing a coil with the precise dimensions and tolerances demanded by the medical device industry requires specialised equipment and a great deal of expertise.

This whitepaper is intended as a guide on sourcing coiled components. After an introduction to key concepts that determine a coil's geometry and properties, the paper will explore the strengths and limitations of two manufacturing techniques: point coiling and mandrel winding. In the second half, the whitepaper will discuss the market conditions affecting coiling demand and lead times, and it will share tips for choosing a coiling partner that enables OEMs to take full advantage of outsourcing benefits such as expertise, time savings and value-added services.



How are coils made?

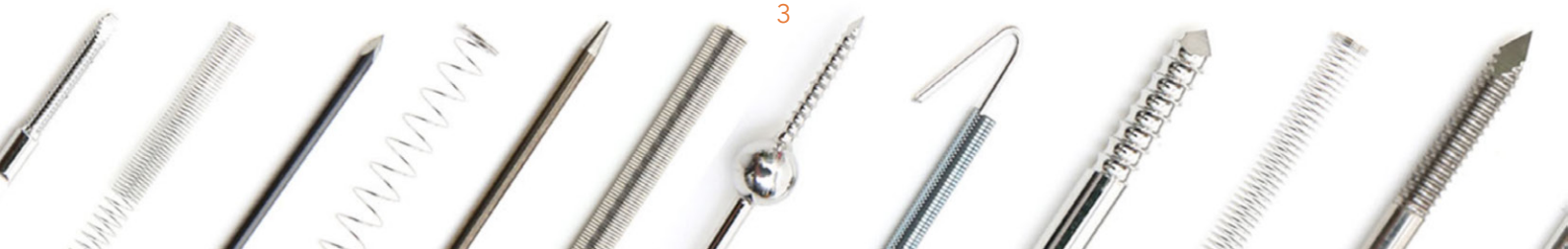
Determining the specifications for a coiled component requires strong understanding of how several key concepts can impact the coil's performance. The first is size. Medical coils typically have outer diameters of 0.008in to 0.032in, with various lengths according to the application. Micro coils for guidewires can have wire diameters as small as 0.001in, enabling surgeons to access particularly narrow areas of the vascular system. Maintaining precision while producing coils this small presents significant challenges that are most easily overcome with the help of a specialist.

When it comes to material, there are a range of possibilities. Stainless steel has been a material of choice for medical devices for many years, and nitinol is witnessing growing use by the industry due to its unique benefits. Titanium and cobalt chrome have their place in certain applications, as do precious metals such as gold, silver, platinum and platinum alloys. All materials offer their own application-specific advantages and challenges. Gold, tungsten and tantalum are considered to be radiopaque, meaning they absorb X-rays and are visible under fluoroscopy.

Coils can be unifilar (one wire) or multifilar (two or more wires), depending on the number of wires they are wound with. Multifilar coils can provide a magnetic field, making them suitable for sensor applications such as wearable medical devices and implants such as hearing aids and pacemakers. For a standard coil used to support catheter and guidewire designs, a unifilar coil is typically sufficient.

Pitch and stiffness are key specifications required to place a coil order. Pitch refers to the distance between the active coils of a winding, while stiffness denotes the amount of flexibility in a coil. In a catheter design, achieving the right level of flex while still providing enough support to the tube is a critical balance.

Another coiling consideration is left-hand or right-hand – the terminology used to describe wind direction. Different directions can have an impact on certain applications, so this is worth keeping in mind.



Manufacturing methods

There are two methods to manufacture a coil: point coiling and mandrel winding. Both processes can be used to produce parts of the same specification, although each process has adjustable parameters that can affect the performance of the coil.

Point coiling

In point coiling, the material is pushed into tooling to deflect it into the desired shape and size. Point coiling is generally a fast operation and can cut the parts to length on the machine.

"Higher-volume applications are most efficient if run in a point-coiling operation," says Jim Boldig, director of sales and engineering at Custom Wire Technologies, an experienced contract manufacturer of custom medical wire components. "However, the major limitation of point coiling is the wind direction of the coil.

Machines are generally set up for left-hand or right-hand wind directions. It is not possible to make a left-hand coil in a right-hand machine. This plays a major role in deciding which machine to use if a customer has a specific wind direction needed." There are also size limitations to consider when point coiling. Industry refers to this as the spring index, which is calculated by dividing the mean coil diameter by the wire diameter. To be successful at point coiling, this number needs to be greater than or equal to 3.0.

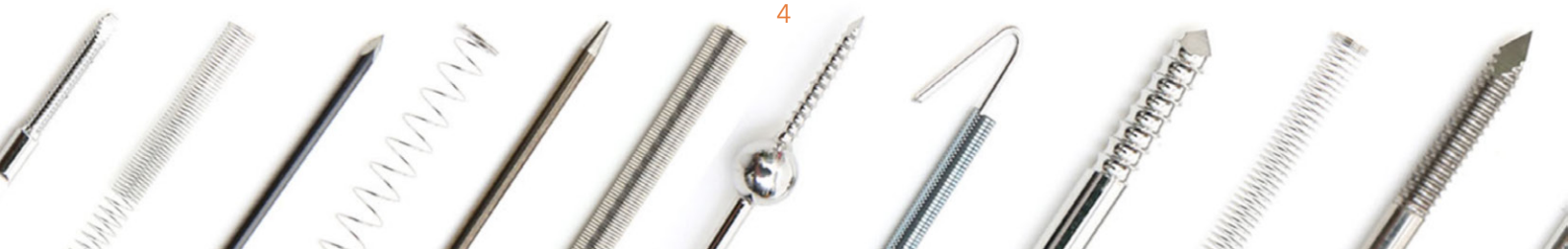
Mandrel winding

In mandrel winding, the material is wrapped around another wire of a specific diameter to achieve the end specification. Mandrel-winding machines can be set up to produce parts quickly and efficiently.

"Nearly all our rapid prototyping is done in a mandrel wind setting to be most efficient for our customers," says Boldig. "Another benefit of mandrel winding is the scale of the part to be manufactured. We have been successful in producing parts with inner diameters of 0.003in and 0.004in. Point coiling these small inner diameters has limitations due to tooling needs."

Two specific limitations of mandrel winding can have an impact on efficiency. Coils with more complex geometries such as tapers require a custom-made mandrel, whereas point coiling does not. In addition, unlike point coiling, every coil that is wound needs to be cut or trimmed to length after being removed from the mandrel.

"These two limitations have some impact on pricing and lead time," says Boldig.



Market trends and challenges

The rising number of vascular procedures has boosted demand for catheters and guidewires. By 2030, GlobalData predicts the number of interventional cardiology procedures performed in the US will reach 10.64 million, doubling from the number performed in 2015. Meanwhile, US peripheral vascular procedures are expected to total 14.028 million by 2030.

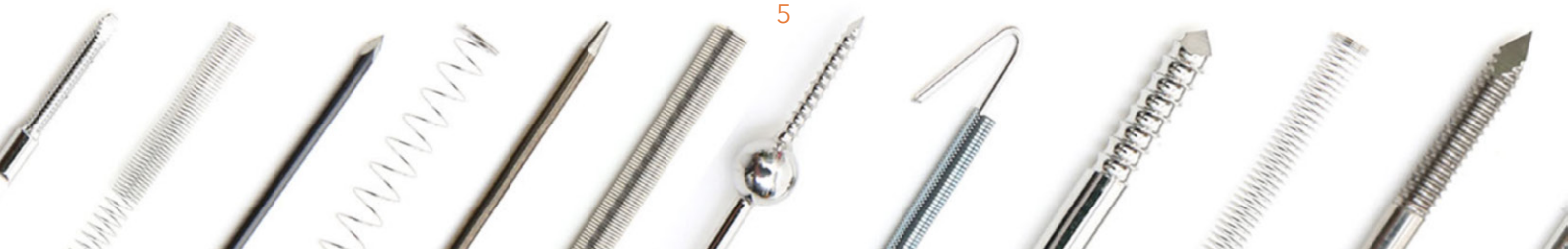
Demand for coils has naturally followed, witnessed first-hand by US-based Custom Wire Technologies (CWT). The company was founded on the idea of manufacturing catheter reinforcement coils for medical device OEMs after its founder, Bob Boldig, was approached to support a growing segment of one firm's business 20 years ago.

"Bob seized the opportunity and we have been manufacturing coils for them ever since," says Jim Boldig, director of sales and engineering at CWT. "The first two machines we purchased from our vendor were their first built for the medical field. Those two machines still operate at CWT today, but they've undergone retrofitting to bring them up to today's technological advances."

With the vision of becoming a one-stop shop for medical wire, CWT has since expanded into wire grinding and wire forming while also offering a range of value-added services such as cleanroom assembly. Yet coiling is still the backbone of the business and the department has seen significant investment to support its growth.

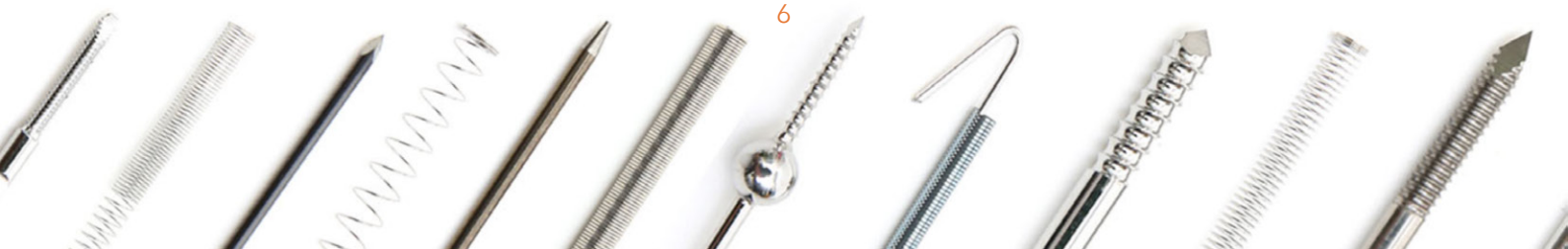
Boldig explains: "The increase in demand at CWT over the last 20 years has led to more machine acquisitions, personnel expansion and separate coiling departments. We currently have three departments that support our coiling capabilities. These departments operate across three shifts and with a current employee base of around 20. A diversification-of-product offering has led to our increase. We have further developed manufacturing techniques for radiopaque marker coils and nitinol catheter coils. Increased demand in these product categories have required us to expand. Currently, there are a total of 15 machines that support our coil-manufacturing lines."

In recent years, CWT has witnessed growing demand for one type of coil in particular – those made from a super-elastic alloy of nickel and titanium, known as nitinol. With the ability to take up to 8% strain before plastic deformation – a considerably higher amount than stainless steel – nitinol has become a great candidate for catheter reinforcement applications where kink resistance is a key concern.



With demand rising for all types of coils, lead times have become extended. Material shortages during the Covid-19 pandemic had a heavy impact on supply chains, which have still not returned to normal. When placing a large-volume order, it has become imperative to plan six months to a year ahead of production. During the iterative design process, however, this is unfeasible. Not only do R&D teams lack sufficient foresight to plan far ahead, unaware of what design challenges they will face, they also require much smaller volumes for prototyping.

To provide a solution for engineers working in the R&D stage, CWT launched its QwikCoil™ programme mid-pandemic. It delivers coiling orders within a speedy turnaround window of just one week and is powered by the company's mandrel winding capabilities and vertical integration, with CWT grinding all of its own mandrels in-house. To submit an order, the company requests details for the coil's outside diameter, inside diameter, wire outside diameter, coil length, coil gap/spacing and pitch.



How to choose a coiling partner

This guide has covered coiling basics, manufacturing processes, and the demand-based challenges affecting both OEMs and their contract manufacturers today. In this final section, we discuss tips for finding a coiling partner who is dedicated to your success and set up to deliver.

Engineering know-how

The manufacturer's level of experience should be one of your first considerations as the knowledge to set up and run the equipment is key to success. Any issues there can lead to delays and potentially lower-quality products than you might receive from a provider who has been producing coils for decades.

"We train our operators to perform simple setup techniques to keep operations running smoothly. Our experience with a diverse collection of designs helps CWT overcome some of the manufacturing challenges present in today's industry," says Jim Boldig.

Efficient customer service

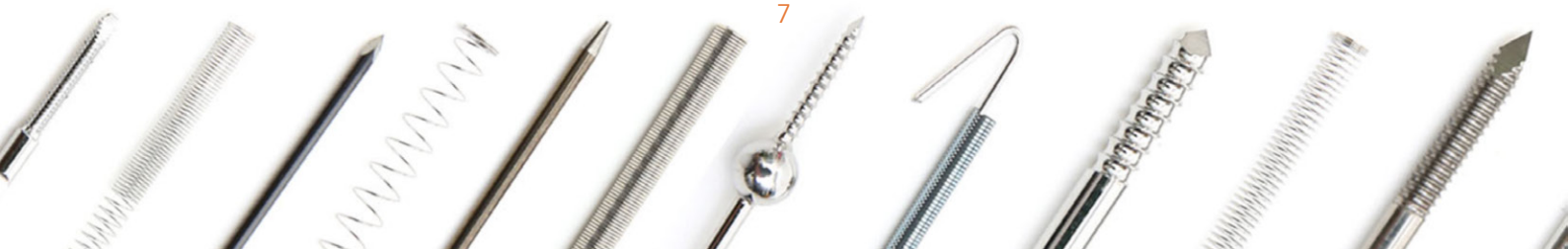
Speed and responsiveness are also critical attributes to look for in a contract manufacturer. New innovations need to move fast. A supplier who is slow to provide order status updates or cannot keep pace with their customer's need for rapid prototyping or on-the-fly design changes could be a stumbling block during product development, and a potential source of delay during manufacturing. This is often the case with larger companies.

"CWT is committed to providing a superior level of customer service, even as we continue to grow," says Boldig. "We have people in different positions across the organisation that can get the answers fast. We understand how important these projects are, and helping our customer base quickly is essential to our continued success."

Value-added services

As OEMs seek to simplify their supply chains to mitigate risk, and save time and work, many are placing more value on the complementary services that a specialist provider can offer. CWT has built a 2,000ft² Class 7 hard-walled cleanroom where it takes care of assembling coils to other components using laser and plasma welding techniques.

"This allows customers to reach one vendor to provide an end-to-end solution," explains Boldig. "We can also laser mark, ink print, passivate and polytetrafluoroethylene (PTFE) coat coils for various applications. CWT continues to expand our value-added services to eliminate the need for complex supply chains with multiple vendors and logistical inefficiencies."



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