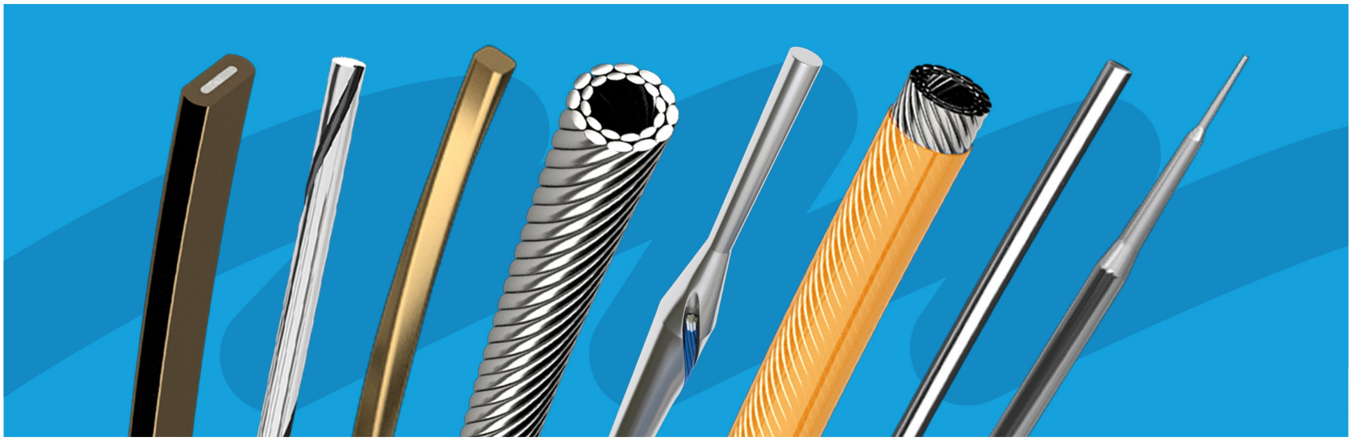


Material, Wire, and Construction Selections that Shape Precision Interventional Device Performance

An interventional device must do contradictory things simultaneously. It must push hard enough to advance through resistance, follow tortuous curves without kinking, transmit torque from the operator's hand to the distal tip, hold internal pressure without bursting, and shrink its outer profile to reach anatomy a previous-generation device could not. No single material property satisfies that list. When our customers design their products, they are challenged to find a workable combination across properties that pull against each other.

This challenge can be simplified into three interconnected engineering considerations. First, designers establish the mechanical requirements for the wire, including tensile strength, elongation, modulus, and yield strength. Next comes material selection, balancing physical, mechanical, chemical, and cost factors. Finally, designers choose the reinforcement architecture, whether braid, coil, hollow tubular construction, or a hybrid approach. While each decision can be evaluated independently, they are closely linked. Mechanical requirements narrow material options, material properties influence device capabilities, and reinforcement design ultimately determines how those capabilities are translated into device performance.

Mechanical properties that shape device performance

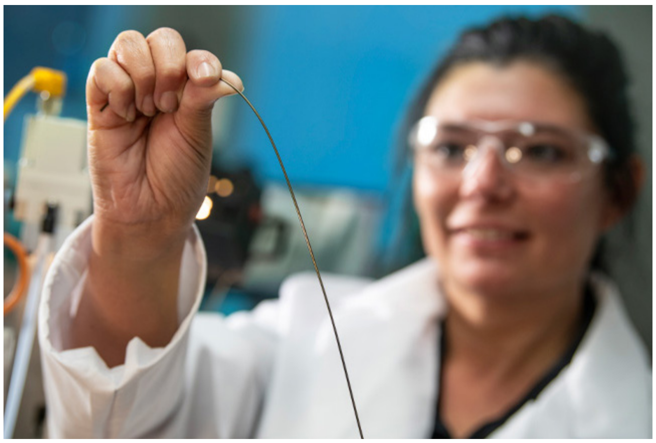
For catheters and guidewires, four properties drive most of the material selection conversation: tensile strength, elongation, modulus of elasticity, and, in some cases, yield strength.

Tensile strength is the load a wire can carry to fracture at a given diameter. It sets the wire breakage and pull-failure ceilings for the device built from that wire.

Yield strength is the load at which permanent deformation begins. Designers specify yield rather than tensile when the device must not yield under maximum service load, even if it would not fail outright. The two values are not interchangeable, and the decision about which one to call out depends on whether the failure mode that matters is fracture or permanent set.

Elongation expresses ductility as a percentage of original length. It tells the designer how far the wire can stretch before breaking. In most wire materials, increasing tensile strength comes at the expense of elongation. High-tensile cold-worked wire generally has low elongation. Annealed wire has high elongation but yields under very small loads. Because these properties trade off against one another, designers must balance strength and ductility based on the demands of the application.

Modulus of elasticity is the slope of the elastic portion of the stress-strain curve. It is set largely by alloy selection rather than processing, and it determines how stiff the wire feels at a given diameter. A higher modulus translates to better pushability and torque transmission because the wire transfers load from one end to the other with less deflection. The trade-off is reduced flexibility and greater resistance to bending under load.



The combined effects of tensile strength and modulus are ultimately reflected in device performance. Materials with higher strength and stiffness typically provide greater pushability and torque control, while materials with lower strength and stiffness generally offer improved flexibility and trackability. As flexibility increases, designers must ensure that performance attributes such as pushability, torque response, crush resistance, and wire breakage resistance remain appropriate for the application. Stainless steel covers a wide range of these property combinations, while Nitinol (nickel-titanium) is often selected for applications that require shape memory or superelastic behavior.

The current upper end of cold-worked stainless capability is the ultra-strength condition in 304V, which reaches approximately 3.3 GPa [480 ksi] in fine wire. In small-diameter wires below 0.0508 mm [0.002 in], 304-family stainless can exceed 3.5 GPa [about 500 ksi], and tungsten-based and molybdenum-based high-density wires can exceed 5.5 GPa [about 800 ksi] — strength levels that have not previously been available to interventional device designers.

Beyond mechanical properties: Other factors in material selection

Mechanical properties are often the starting point for material selection, but they are not the only consideration. Physical properties, chemical behavior, and cost can all influence whether a material is suitable for a specific interventional device application.

Many **physical properties** are determined by alloy composition and change very little during processing. One of the most important for interventional devices is density. Higher-density materials are generally more radiopaque, improving visibility under fluoroscopy. Electrical conductivity, thermal conductivity, and magnetic behavior are also largely determined by composition rather than processing.

Magnetic properties become particularly important when MRI compatibility is a requirement. Material selection must account for how the device will interact with the imaging environments it may encounter. Depending on the application, engineers may choose alloys that minimize magnetic response while still meeting performance requirements.

Chemical properties influence corrosion and oxidation resistance, both of which are important for biocompatibility and long-term device reliability. Materials that resist chemical degradation are better suited for exposure to physiological environments and demanding service conditions.

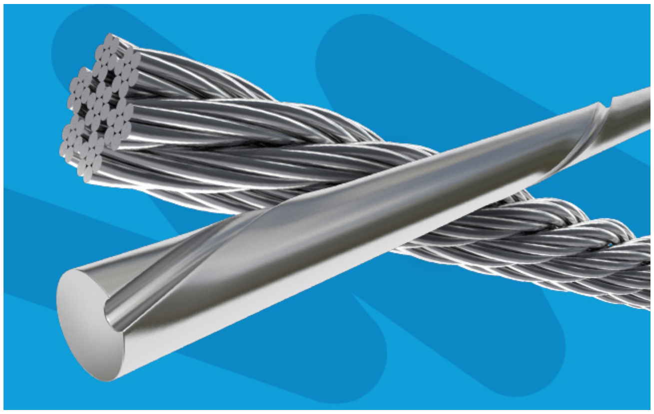
Cost is rarely the primary driver of material selection, but it is always a consideration. Total material cost reflects both the selected alloy and the processing required to achieve the final specification.

- Raw material cost reflects the alloy's elemental composition and the supply economics of those elements.
- Processing cost includes the operations required to produce the wire to specification, along with secondary processes such as coatings and surface treatments. Depending on the application, these secondary processes can contribute more to total cost than the alloy selection itself.

The challenge is balancing these competing requirements. In most applications, one or two properties drive the material selection process, while the remaining requirements are addressed through device design. Engineers may adjust wire diameter, wall thickness, reinforcement architecture, or other design features to compensate for properties that are less than ideal. For example, a device that prioritizes radiopacity may favor a higher-density material, even if that choice increases cost or reduces ductility. Device geometry can then be optimized to achieve the desired performance balance.

Advanced material options for interventional devices

Three Fort Wayne Metals developments are worth tracking because each shifts the design envelope in a different direction.



Grooved wire integrates electrical functionality directly into a structural wire. Helical grooves formed in the wire profile can accommodate electrical conductors, creating a continuous pathway for signal transmission or localized stimulation while maintaining a compact design. This capability can be applied across a range of medical devices, including tooling guides, braid wire, and needles.

Typical grooved wire diameters range from 0.25 mm to 0.762 mm [0.0098 in to 0.03 in], and groove geometry can be tailored to application requirements. Multiple grooves can be incorporated around the circumference, and their smooth radiused profile helps minimize stress concentrations. Grooved wire is typically supplied in straight lengths rather than spooled.

For applications that push beyond the limits of conventional high-strength materials, **ultra-strength wire** offers additional design flexibility. Standard 304-family stainless steel can exceed 3.5 GPa [about 500 ksi] in fine diameters, while tungsten- and molybdenum-based wires can exceed 5.5 GPa [about 800 ksi].

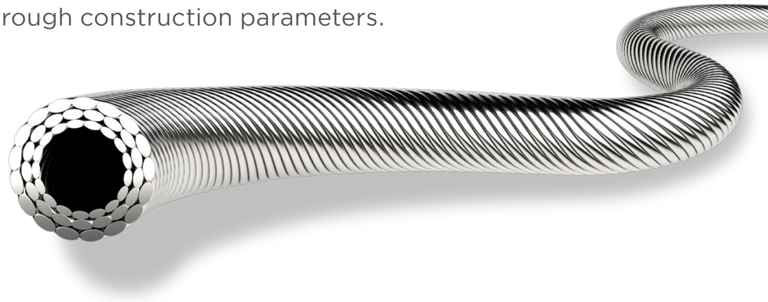
The design benefit is straightforward: increased strength creates opportunities to reduce wall thickness and gain lumen space, or to maintain the same dimensions while increasing pull strength, torque capacity, and resistance to wire breakage.

Shape memory alloys are expanding the range of options available to device designers. A nickel-titanium-niobium alloy offers greater stiffness and strength than conventional Nitinol while retaining shape memory behavior, making it attractive for applications that require both pushability and shape recovery. Nickel-free beta titanium alloys provide an alternative for applications where nickel-containing materials are not preferred.

HHS® tube: Balancing torque and flexibility

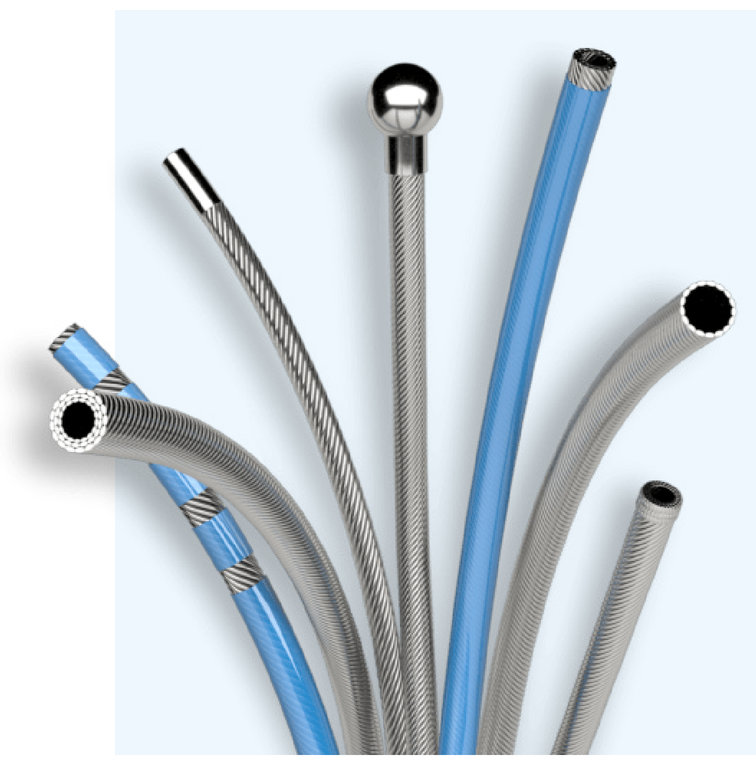
Braids and coils have long been the primary wire constructions used in interventional devices, each with well-known trade-offs. Braids are often selected for torque transmission and durability, while coils are valued for flexibility and crush resistance. HHS® tube offers a different combination of properties, bringing together torque transmission and flexibility in a single design.

HHS® tube is a hollow torque strand with an open working channel. The construction is helical rather than woven, with one or more layers of round or flat wire wound around the lumen axis. The target functional properties are flexibility, torque transmission, elongation resistance, and compression resistance. The designer dials in the proportions through construction parameters.



Two product forms are offered. Round wire is available in single, dual, or triple-layer constructions. Flat wire is available in dual- or triple-layer constructions and produces a thinner wall for the same number of layers. Within each form, four design parameters are adjustable: alloy, wire count per layer, wire size, and lay direction. The result is a construction that can be tuned across a wide performance space from a single base architecture.

Lay direction is the parameter least familiar to designers coming from braid or coil work. Lay refers to the rotational orientation of the wire as it wraps the lumen. For a device whose primary intended rotation is clockwise as viewed proximal to distal, the appropriate lay on the outer layer is left-hand. For counterclockwise rotation, it is right-hand. The convention is that the outer layer carries the primary direction and the layers beneath alternate. The reasoning is mechanical: the outer layer takes most of the torsional load in the intended rotation direction, and alternating directions in the inner layers balance bending and elongation behavior.



Inside diameter capability runs from approximately 0.076 mm to 2.21 mm [0.003 in to 0.087 in], covering many common interventional catheter and microcatheter sizes. The form factor and open working channel mean that components needed at the site of intervention pass through the device, and the construction's flexibility creates a pathway through vascular curvature without compromising lumen integrity.

The structural choice within HHS® tube depends on which properties dominate. Flat wire constructions produce thin walls and favor direct torque transmission. Triple-layer round wire constructions favor flexibility while delivering strong bidirectional rotational control. Between those endpoints, intermediate combinations of layer count, wire size, and lay direction populate a continuous design space.

Secondary operations extend the form further. Swaging tapers the outer profile for transitions between catheter sections. Coatings, including fluoropolymer, polyamide, and PTFE chemistries, provide insulation, lubricity, or adhesion control depending on the specification. Shape setting, cutting, welding, and assembly into subassemblies are also available, which allows HHS® tube to ship as a customized part rather than as raw stock that the designer has to finish.

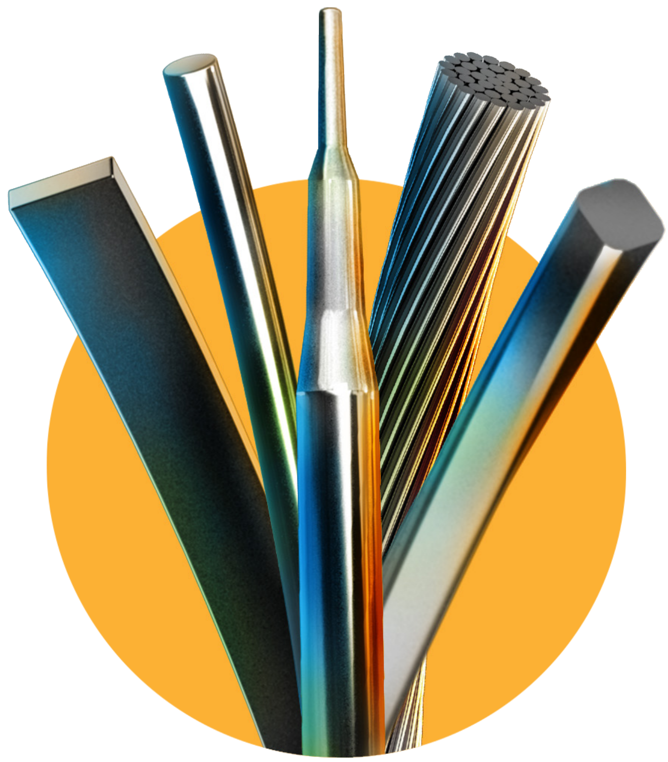
A practical question that comes up often is whether HHS® tube replaces braid and coil. The honest answer is that it can but does not have to. HHS® tube can serve as the sole reinforcement, or it can carry a coil over or under it or sit inside a braid. Polymers can be bonded over the outer surface of the HHS® tube as part of a catheter shaft assembly. A polymer liner inside the lumen is also compatible with HHS® tube, although that operation is typically performed downstream by the catheter manufacturer rather than by the wire supplier.

Starting with device requirements

While materials and wire properties define what is possible, device requirements typically drive the design process. Considerations such as outer profile, lumen size, working length, torqueability, fluoroscopic visibility, MRI compatibility, and regulatory requirements establish the performance targets. Designers then evaluate construction methods, materials, and wire properties to achieve the desired balance of performance characteristics.

Device development requires balancing multiple interrelated decisions. Material selection, wire properties, and construction methods influence one another, and changes in one area often create opportunities or constraints in another. The best solutions come from evaluating these trade-offs together rather than treating each decision independently.

Technologies such as ultra-strength wire, refractory metal wire, grooved wire, advanced shape memory alloys, and HHS® tube do not eliminate engineering trade-offs. They simply provide more options for addressing them. By expanding the range of available material, wire, and construction choices, these technologies give designers greater flexibility in how they achieve device performance requirements.



Fort Wayne Metals works with interventional device designers to evaluate material, wire, and construction options for new and existing programs. Our engineering team can help identify solutions that align with device performance requirements and design objectives.

To learn more, visit fwmetals.com