METALS

Microwire Use in Catheter-Based Medical Device Applications, Part 1

New materials and processes have led to advances in microwire products.

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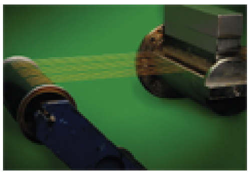


Insulating multiple wire paths with a polymer insulation applicator.

Wires can create conductive pathways that transport electrical energy down the length of invasive catheter devices. Because wire systems can provide microdiameter profiles while maintaining consistent high-quality metallic and insulation material properties and dimensions, they are leading the way in this field.

The nature of designing a product for use in a medical catheter emphasizes the relative microsizes and tight tolerances required by these products. Such conditions require conductor or wire elements with diameters between 0.001 and 0.003 in. (0.0254 and 0.0762 mm). The wires must be coated with insulation that is around 0.0005 in. (0.0127 mm) thick. At such microdimensions, the ability to produce at acceptable process tolerances becomes a limiting factor for most manufacturing systems.

Wire products for medical catheters can be constructed in various forms to deliver various mechanical and electrical properties. To make changes in conductive pathways, engineers can vary the metallic materials, insulating materials, bond materials, and design configurations to produce the optimal end result for a particular medical device design. Using a limited number of base components, engineers can produce a myriad of different finished products. By understanding these base component materials and construction options, engineers can better understand how to produce the desired effect in a catheter product that uses microwire components.

Wire Use in Innovative Medical Catheters

Electrophysiology applications, namely cardiac ablation products for treating forms of tachycardia and atrial fibrillation (AF) have been at the forefront of microwire product usage. In such designs, wire systems are used to transmit radio-frequency (RF) energy to the site of ablation and to sense tissue temperature during the treatment via thermocouple wire. Over time, these RF ablation–like catheter treatments have worked themselves into a much wider range of uses, such as tissue ablation for the treatment of arthroscopic, gastrological, gynecological, and oncological conditions. As with cardiac applications, electrical transmission wire, sensing thermocouple wire, or both are needed in the finished project.

Even outside the realm of ablation applications, microwire technology is finding uses in next-generation improvements to catheter designs as sensor-signal transmission pathways. Microwire designs, in conjunction with microsensors, are expanding the capability and value of catheter devices to the healthcare market. Sensors to measure and report metrics such as temperature, pressure, and flow rate, to name a few, are being deployed in catheter designs. It is plausible that future generations of invasive catheter designs will merge both diagnostic and therapeutic functions into a single platform in order to monitor a treatment or to determine the treatment's postprocedure level of success.

Microconductor Manufacturing Overview

Insulated microdiameter wire designs can be manufactured reliably down to sizes of around 0.001 in. (0.026 mm). Most applications currently use diameters within the range of 0.0025–0.0075 in. (0.064–0.192 mm) but, as with most catheter-based products, industry is pressured to reduce these sizes further. The production of medical wire products occurs through a series of different manufacturing steps or processes. Part 1 of this article describes this process and the materials used in the process as they relate to the manufacturing of wire products for use in medical catheter designs. In July, Part 2 will look at the design process to incorporate microwires into catheter uses, and how these electrical pathways open the way for a variety of sensors to be used within catheters and invasive medical devices.

Drawing. Microdiameter wire is manufactured in a process very similar to its much larger cousins. Although there are nuances within the manufacturing process of micro-diameter wire, the basic wire-drawing process is the same.

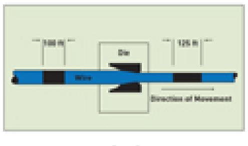


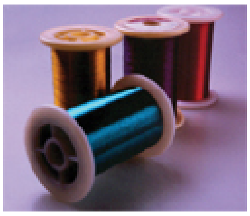
Figure 1. (click to

enlarge) Elongation effect of the wire-drawing process.

Wire with a diameter of x and length of y enters and is pulled through a drawing die with an opening diameter of less than x. The profile of the drawing die's tapered angle causes the metallic material to deform by means of compressive forces applied to it. Similar to first law of thermodynamics, mass of wire material is neither created nor destroyed, but changes forms. The die deforms the wire into a smaller diameter, and because the mass of the wire is conserved, the wire elongates to a length greater than y (see Figure 1).[1] This process is repeated until the required diameter is reached.

As smaller and smaller diameters are sought, such a drawing process becomes harder to control. Interestingly, especially in small sizes, the tension on the wire as it exits the die is greater than the maximum tensile strength of the wire. Breaking does not occur Phelps Dodge High Performance Conductors Spec Sheet, due to the compressive stresses created within the wire's metallic grain structure. The dies used are manufactured from monocrystalline diamond. Each diamond's crystalline structure is aligned in a specific way to give uniform drawing properties.[2] This ensures a consistently uniform diameter down the entire length of the wire.

Annealing. Once the wire is drawn or formed into the correct size, it is annealed. Annealing eliminates stress in the metal created during the drawing process. Stresses reside in the grain boundaries of the metal and negatively affect the metal's conductivity, strength, and mechanical toughness. The temperature needed to anneal the wire is about one-third the melt temperature of the metal material. The annealing temperature tends to be somewhat higher for alloy materials because of the adverse effects the alloying elements have on the material's conductivity.



Examples of silver-plated copper alloys insulated with biocompatible polymer coatings.

Insulating. Once wire is annealed, it can be insulated. Catheter designs always challenge their creators with cross-sectional area limitations. Designers need to understand the task that needs to be accomplished and how it can be done in the cross-sectional space provided. As the industry works toward more-invasive catheter procedures, we can expect this cross-sectional area to be reduced further. Because of the design-specific size constraints associated with catheter products, the insulation thickness must be very thin—0.0005 in. in some cases—and should be applied with a very tight tolerance (±0.0002 in.). In addition, the insulation must be capable of effective electrical isolation (dielectric strength) and must be mechanically robust for repeatable manufacturing in these microdimensions.

The most prevalent and familiar examples of electrically insulated wires are those coated with extruded thermoplastic materials. For catheter applications, different polymers and an entirely different insulating process technology are used. Thermoplastic extruded materials cannot meet the dimensional tolerances needed in the medical applications used as examples here. Moreover, such thermoplastic materials do not exhibit enough dielectric or mechanical strength at these microsizes. Therefore, wire that travels anywhere between the proximal and distal end within a catheter lumen should be insulated with materials that are applied as thin liquid polymers. The insulation is built by a layering process. A layer of liquid polymer is coated onto the wire, and this layer is solidified by a thermal curing process. The wire is then coated repeatedly, and each layer is solidified until the correct thickness is achieved.

Spooling. Spooling or winding is the process that essentially packages the wire material onto a spool, bobbin, or reel. This process is done in a way that allows the entire length of wire to be unwound when needed, while preserving the properties contained within it. The smaller the diameter of the wire, the more difficult it is to avoid spooling problems. The two most common problems arise close to the flanges of the spool: building up too much wire close to the flange, or leaving a gap between the layer of wire and the flange. Both conditions often lead to breakouts during unspooling of the material.

The first condition results from the build next to the flange collapsing, causing a tangle and subsequent breakout. The second breakout results when wire falls into the gap near the flange, causing the wire to pinch and break. Poor control of the functions of spooling wire causes such defects. Inconsistencies, such as a crooked spool, can also have the same effect. Wire tension during the spooling process is also critical. Excessive tension can cause permanent elongation, resulting in a reduction of the wire's cross-sectional diameter and an increase in its electrical resistance.

Quality Assurance and Inspection. Maintaining certain quality standards requires using a battery of tests during the setup process, and then performing the same tests plus some extras at the end of the run. The idea is that, if the front and tail are good, all in between is good as well. This is a good assumption provided that functions of the process do not change between the beginning and the end. Therefore, in-line monitoring and control of the process parameters are essential as well.

In-line testing is limited mostly to diameter gauges to monitor outside diameters (ODs) of the bare uninsulated wire and the insulated wire. By measuring ODs of both bare and insulated wire, wall thickness can be easily calculated and therefore estimated with a high degree of certainty. It is also common to see spark testers in-line, where the core metallic wire is grounded and the wire goes through some kind of medium (water bath, wet sponge, metal bead curtain, etc.) that is charged to a certain voltage. If the dielectric strength of the insulation is insufficient or if holes are present, the voltage is discharged and recorded. Occasionally, in-line testing can include surface quality testing that scans the surface for high or low points.

For OD testing that applies to both in-line and tabletop tests, it is important to maximize the number of axes that are tested. Maximizing the number of test axes enables the inspection of the diameter at different points around the diameter. The differences of various axis measurements indicate the concentricity, or the roundness, of the insulation that was applied to the bare wire.

Microconductor Materials

Only three basic raw material types are used in microwire constructions for medical devices. The metallic material used to transport an electrical signal and or provide physical strength; the insulating material used to isolate the metal from its neighboring environment, which could be within the catheter construction or in the bloodstream where the catheter is being used; and the bonding material. The bonding material is similar to the insulating material and is used to adhere individual wires into one solid group or to promote the thermal bonding of the wire construction within the body of the catheter.

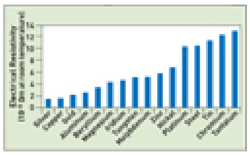


Figure 2. (click to enlarge) Electrical resistivity of common wire and wire alloying elemental materials (Source: Handbook of Chemistry & Physics).

Metal Materials. The metallic element of a conductor can be composed of a variety of materials. The most common materials are described below. Also described are materials that are used as alloying elements. The metallic material for a particular design is usually chosen based on the material’s resistivity (conductivity) and the mechanical properties of break strength and elongation (see Figure 2).

Conductivity of a metallic wire is based on the material’s natural resistivity and purity. The presence of tramp elements (or less-conductive materials) decreases the wire’s overall conductivity. Such is the case with many alloys. In general, alloys have a higher resistance with a much wider variance in electrical resistance than pure metal (see Figure 2).

The mechanical properties of break strength and elongation are dependent on the inherent properties, on the composition of the metal, and on the secondary processing. The secondary processes are primarily the manufacturing steps in which the metal is mechanically deformed and work hardened, or when the material is annealed. Differences in secondary processing are often mistaken for differences between different metal’s natural properties; therefore, the data in Figures 2 and 3 resulted from testing performed on fully annealed samples of different metals.

The annealing normalized the wire test samples from a secondary process perspective and thus allowed comparisons to natural material properties. Examining break strength and elongation is a good base for evaluating wire materials because from these two measurements, the catheter properties of pull strength, torque transmission, pushability, and stiffness or flexibility can be inferred. In addition, break strength and elongation tests are easy and quick to run.

As with conductivity, there is a certain amount of break strength and elongation that is inherent to the different elemental metallic materials (see Figure 3).[4] The more conductive an element is, the more natural softness or elongation it tends to have. Also, the purer the material, the more likely it is that its inherent properties will be maximized, as in the case of elongation. The presence of tramp elements, especially tramp elements in the grain boundaries, tends to be detrimental to the material’s elongation properties.

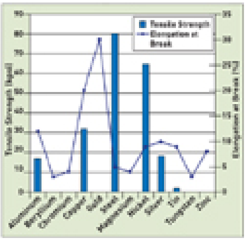


Figure 3. (click to enlarge) Tensile strength and elongation of various wire materials (Source: Phelps Dodge High Performance Conductors).[4]

The comparison of different materials’ properties and ways to choose the best available combination of properties will be discussed in more detail in Part 2 of this article.

Insulating Materials. Liquefied polymers comprise various thermoset and thermoplastic materials. These types of polymers are kept in a liquid form through the use of different organic solvent mixtures. The solvent portion of the liquefied polymers is anywhere from 65 to 85% of the liquid’s total volume and, therefore, solid polymer is only 15–35%. In a precisely controlled high-temperature environment, the solvents are removed or are flashed off in vapor form, at which time the polymer solidifies, forming an insulating film.

Prior to solidification, each solvent acts in a different way to keep the polymer in a liquid form. For thermoset material, the solvent acts to fill or tie up free-radical sites of the various molecules that constitute a polymer. Removal of the solvent allows bonding or cross-linking between molecules or atoms using primary bonds. For thermoset polymers, the plastic is actually polymerized on the wire’s surface. Similar solvents act differently when used with thermoplastic polymer materials.

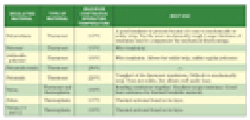


Table I. (click to enlarge) Usage guide for insulating materials. (Source: Tubing and Bare Insulation Materials, Phelps Dodge High Performance Conductors SpecSheet.pdf on CD, p. 14-22).

For thermoplastics, polymerization has already taken place. The solvent simply dilutes the polymer into a solution by coming between the different polymer chains and weakening the secondary bonding force between them. Thermoplastic insulation is generally a dispersion material, in which the polymer chains are dispersed among the solvent. Removal of the solvent reestablishes the secondary bonding mechanics resulting in solidification. See Table I for a list of insulating materials and their best uses.

Bonding Materials. Bonding materials, which are in most ways the same as insulating polymer materials, can be used to electrically insulate wire. Bonding materials are always composed of thermoplastic polymer materials that allow the wire coating to become tacky and to reflow when exposed to heat or a liquid solvent. This type of reaction allows the wire products to be bonded to each other or to be bonded within the body of the catheter during catheter assembly and manufacturing.

Copper-Based Alloys for Use in Medical Applications

Copper is one of the most conductive metallic materials. It is also one of the most economical, yet in microdiameter wire sizes, it fails to exhibit the needed strength characteristics. Currently, wire systems address this shortcoming by using various nickel alloys such as MP35N (or Constantan), or bimetallic materials such as copper-clad steel and silver clad with stainless steel (such as DFT). While all of these are good materials, they usually exhibit exceptionally high resistance, or they must be purchased at exceptionally high costs. A series of specialized copper alloys have been developed that address the strength limitations of pure copper without sacrificing much in terms of conductivity. These alloys are much less expensive than nickel alloys or bimetallic materials.

Biocompatibility. For some people, any mention of copper's use in the body produces instant biocompatibility concerns or fears of toxic effects. The truth is that most metal materials are toxic if they build up in the bloodstream in significant amounts.[5] Copper and its alloys are not meant for implantation, but use of these materials in temporary invasive medical devices poses little risk of toxic biological effects.

For copper or elements within copper alloys to reach toxic levels in the bloodstream, they must gain access to blood flow and be allowed to ionize, making them soluble within the blood. Such access into the bloodstream is usually caused by an oxidized metal surface. The oxide ionizes within the bloodstream through a chemical process known as oxidation-reduction, or a redox reaction.[5] Initial accessibility can be prevented by isolating the wire component within the body of the catheter. Further isolation is provided with certain surface treatments.

In the case of copper alloys such as T-Flex and CS-95, the alloying element's cadmium and beryllium are used in trace amounts. They are locked within a metallic copper matrix, and, therefore, the probability of direct contact is minimal. It is common to use silver plating to add biocompatibility protection, to add some conductivity, and to improve brazing during termination. Adding a biocompatible polymer as an insulator over the metallic conductors also imparts protection.

Both the silver plating and the polymer coating act to isolate the copper or copper alloy conductor material away from the body, as well as to prevent oxidation of the copper and alloying elements. Further precaution is added by sealing conductors within the internal body of the catheter away from any blood contact. For instance, cytotoxicity testing has shown no toxic effects of polymer- insulated silver-plated beryllium copper alloy after 24-, 48-, and 72-hour exposures. In those tests, the silver-plated insulated copper alloy wire was chopped into small pieces and soaked within the testing reagent for each exposure time, after which the testing reagent was introduced to mice cells to determine any toxicity. It is significant that this biocompatibility testing method resulted in direct exposure of the copper alloy to the testing reagent, yet no toxic effect resulted.

Table II. (click to enlarge) A comparison of copper and copper alloys.[4]

Four such copper alloys have just recently begun to find their way into catheter usage due to their strength, conductivity, and affordability. These four conductor materials are briefly described in Table II; pure copper is included in the table for comparison.[4]

The Science of Copper Alloys

The copper alloys discussed are strengthened by the use of small amounts of alloying elements that are added to the base copper material. These alloying elements work to improve the mechanical properties of the copper by residing either in the grain boundaries of the copper or within the lattice of the copper's crystalline structure. The alloys listed in Table II as precipitation hardened are processed in a specific way to provide their high-strength characteristics with good electrical conductivity.


The wire spooling process.

In precipitation-hardened alloys, the alloying elements are added to the copper while it is in a molten phase and then are essentially mixed in. Rapid cooling of the molten metal mixture produces a solid solution of alloying elements and pure copper metal. This solid solution is exposed to a long heat-treating process of 2–6 hours. This process drives these alloying elements from the copper solid solution, causing them to nucleate in the grain boundaries of the now pure copper crystal. This nucleation reaction provides improved conductivity because the alloy elements move out of the copper’s crystalline structure. It also strengthens the metal because of the presence of the alloying elements at the grain binderies. This increase in the metal’s strength results in increased stiffness and yield strength of the alloyed metal.

Often precipitation-hardened alloys are used in an unprecipitated state, meaning the long heat-treating process is not applied and the alloying elements remain in solid solution within the copper’s crystalline matrix. In this state, the alloys can still exhibit high strength characteristics and can have better elongation properties than those exposed to the precipitation process. The major drawback of an unprecipitated alloy is its less-than-optimized electrical resistance.

The Design Process

When incorporating wire-based constructions within a catheter design, consideration needs to be given not only to functionality, but also to manufacturing repeatability. Part 2 of this article will focus on the following properties of wire components, among other considerations.

- Dimension.
- Dielectric strength.
- Break and yield strength and elongation (stress-strain diagram).
- Conductivity (resistance, in ohms per length).
- Flexibility (bend resistance).

Conclusion

Microwire is an often-underutilized component in the design of medical products. When considering the number of inputs, this may seem particularly true. There are a limited number of manufacturing process steps and minimal raw materials, and therefore microwire products seem much simpler than they really are. However, an examination of the details of microwire products shows that they do not fit standard assumptions in terms of the manufacturing process and raw materials used, which can be highly technical in nature.

This low-tech perception stems from both the common usage of wire in manufactured products and the fact that wire has been around for such a long time. Wire is often considered a standard item that does not offer much in terms of design options. Unfortunately, such perceptions limit design options. Medical device designers overlook the different design features and leave this component out of the design process altogether. When a medical catheter design needs a wire component, it is critical that designers consider the many microwire options in order to optimize their catheter designs.

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