MEDIMICRO™ WIRE

Manufacturing, Technology & Design in Catheter-based Medical Devices

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MWS® Wire Industries

Unique MediMicro™ Wire Solutions to Give You a Competitive Edge

Working with our customers on product development for new and innovative applications for improved performance of electronic components, MWS Wire Industries has the resources to give you a competitive edge.

With advances in technology and miniaturization in the 1990s, the landscape evolved in surgical procedures to less invasive ones. MWS's strengths in fabricating fine and ultra-fine single and multiple end wires in various combinations of conductor materials and film coatings resulted in an explosion of the range and volume of specialty wires produced.

Established in 1968, MWS has built its reputation on delivering wire sourcing solutions for its customers. With the largest, most varied inventory of magnet wire and specialty wire found anywhere, chances are good we already have exactly what you need.

Whether it's same day shipment from inventory or producing a wire to meet just-in-time schedules, our highly trained staff of wire professionals is committed to meeting the needs of wire users around the world on time, every time. Total customer satisfaction is the key to our long-term success and growth. Our primary objective is to exceed our customers' expectations of quality and service.

Manufacturing, Technology and Design in Catheter-based Medical Devices

Conductive pathways in the form of wires are being developed and used in various medical catheter applications to provide for the transport of electric signals and or electrical power down the length of an invasive device. Micro diameter wire systems lead the way in usage due to this technology's ability to provide smaller and smaller profiles, while maintaining consistent high quality metallic and insulation material properties and dimensions.

The nature of designing a product for use in a medical catheter emphasizes the relative micro-condition of the sizes and tolerances that are required by these products. Such conditions require conductor or wire elements with diameters between three and one one-thousandth of an inch (.001 inch – .003 inch or .0254mm-.0762mm) and coated with insulation with thickness' around five ten-thousandth of an inch (.0005 inch or .0127mm). As such dimensions are reduced, so is the need for a process that reduces tolerances within acceptable limits.

Wire products for medical catheters can be constructed in various forms and fashions to deliver differences in both mechanical and electrical properties. Changes in these conductive pathways are done by varying the different metallic materials, insulating materials, bond materials, and design configurations to produce the optimal end result for a particular medical device design. Using this limited number of base components, you can produce a myriad of different finished products. By understanding these base component materials and construction options, you can better understand how to produce the desired effect in your catheter product that uses these wire components.

Wire Use in Medical Catheter Innovations

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

Even outside the realm of ablation applications, micro wire technology is finding usage in next generation improvements to catheter designs as sensor signal transmission pathways. Micro wire designs in conjunction with micro sensors are expanding the capability and value of catheter devices to the healthcare market. Sensors to measure and report metrics such as temperature, pressure, rate of flow, to name a few, are being deployed in catheter designs. In fact, present invasive catheter designs merge both diagnostic and therapeutic functions into one platform in order to monitor the treatment or to determine the treatment's post-procedure level of success.

Micro Conductor 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. Part 2 looks 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.

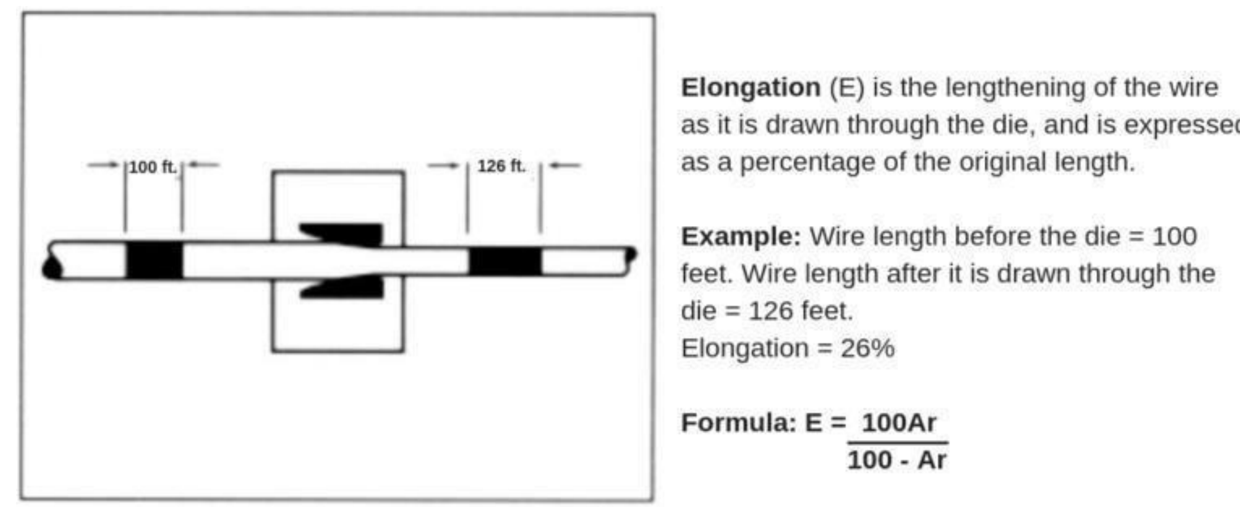
The annealing process eliminates stress in the metal created during the drawing process. Stresses reside in the grain boundaries of the metal and negatively affect the metal's conductivity, strength, and mechanical toughness.

MWS operates its own drawing equipment needed to successfully produce microwire for medical applications.

Drawing

Micro-diameter wire is manufactured in a process very similar to its much larger cousins. While the scale presents a set of challenges different for micro-diameter wire, the basic wire drawing process is the same.

Wire with a diameter of X enters and is pulled through a drawing die with an opening of less than X. The profile of the drawing die causes the metallic material to deform with compressive forces applied to it by the die profile. Similar to the thermodynamic principle, "Mass [of wire material] is neither created or destroyed, but changes forms". The die re-forms the wire into a smaller diameter, but because the mass of the wire is conserved, the wire elongates into a longer length. See elongation diagram below.



Elongation Effect of Wire Drawing Process [1]

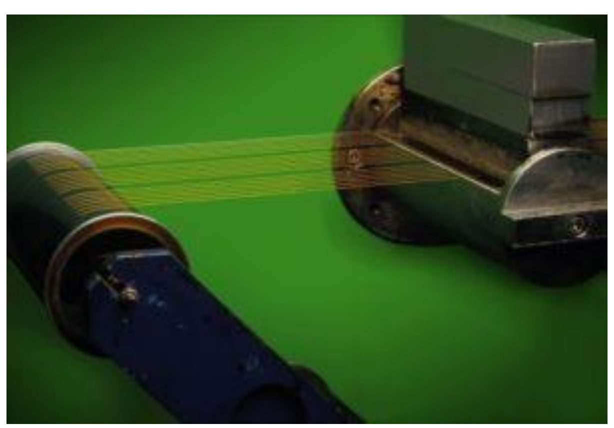
This process is repeated, again and again until the required diameter is reached. As smaller and smaller diameters are sought after, such drawing process becomes harder to control. Interestingly, especially in smaller sizes, the tension on the wire as it exits a die is greater than the maximum tensile strengths of the wire. Breaking does not occur due to the compressive stresses created within the wire's metallic grain structure because of the drawing process just described. Particularly in fine drawing processes, mono-crystalline diamond dies are used. Each diamond's crystalline structure is aligned in a specific way to give uniform drawing properties. This assures a consistent diameter throughout the entire length of the wire.

Annealing

The annealing process 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.

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

Insulating



Once the wire is annealed it can be insulated. Catheter designs always challenge their creators with cross-sectional area limitations. These challenges usually concern what task needs to be accomplished and how this can be done in the cross-sectional space provided. As the industry works toward less invasive catheter procedures, we can expect this cross-sectional area to reduce further. Due to these design specific size constraints associated with catheter products, the insulation thickness must be very thin, .0005 inch in some cases, and should be applied with very tight tolerances (±.0001 inch). In addition, the insulation must be capable of effective electrical isolation (dielectric strength) and must be mechanically robust

for repeatable manufacturing in these micro dimensions. The most prevalent and familiar examples of electrically insulated wires are those coated with extruded thermoplastic materials. However, for catheter applications an entirely different insulating process technology and polymers are used. Thermoplastic extruded materials are not capable of meeting the dimensional tolerances needed in most medical applications, nor do these thermoplastic materials exhibit enough dielectric or mechanical strength in these micro sizes. 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; each layer of liquid polymer is coated onto the wire and this layer is solidified by thermal curing process. Layers are coated and solidified until the correct thickness is achieved.

The spooling 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. MWS does all of its own spooling on premises.

Spooling

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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 for the entire length of the wire to be un-wound 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 most common problems arise close to the flanges of the spool. These are either building up to much wire close to the flange, or leaving a gap between the layer of wire and flange. Both conditions often lead to wire breaks during un-spooling of the material; the first from when the build next to the flange collapses, causing a tangle and subsequent wire break, and the second when a higher level of wire falls into the gap near the flange, causing the wire to pinch, and break. Poor control of the functions of spooling wire will cause these defects. Inconsistencies in the spool itself, such as spool straightness, can cause the same defects. Wire tension and pitch during this spooling process are also critical. Excessive tension can cause permanent loss of elongation, resulting in the reduction of the wire's cross-sectional diameter and an increase in electrical resistance. Improper winding pitch can cause difficulty in paying wire off a spool including tangling or even wire breaking.

MWS operates its own in-house wiring testing laboratory to conduct dimensional analysis, mechanical properties, electrical properties, thermal properties and materials analysis.

Quality Assurance and Inspection

Quality testing begins with samples in the set-up process and again upon completion of the run. Provided all functions of the process do not change between the beginning and end, this testing can be a very reliable method. However, advances in technology offer additional quality assurances using "inline" monitoring and control of the process parameters.

In-line testing generally consists of optically measuring diameters of bare and insulated wire. By measuring both insulated and bare wire, wall thickness can be easily calculated with a good 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, metal brush, metal bead curtain, etc.) that is charged to a certain voltage. If the dielectric strength of the insulation is not sufficient or holes are present, the voltage is discharged and recorded. In-line testing can include optical measurements that scan the surface for high or low points as a means of identifying surface defects.

In addition to testing the overall dimensions (OD), different axis points can be measured for concentricity – or how evenly the insulation was applied to the wire. Increasing the number of axis points tested around the diameter provides measure of the concentricity. Another test method is a resin encapsulated cross section of the wire that can be readily measured and give a visual representation of concentricity.

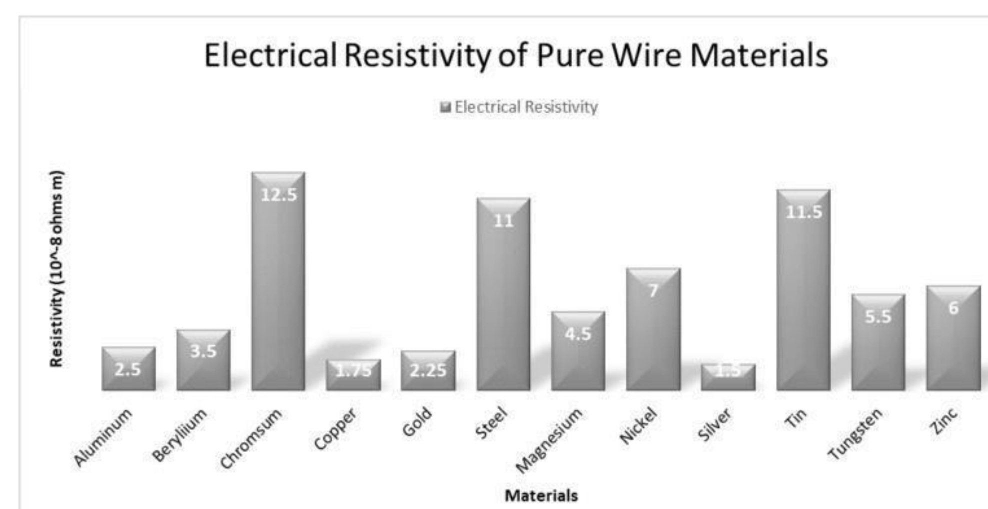
Micro Conductor Materials

Only three basic raw material types are used in micro-wire 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 the blood stream where the catheter is being used; and finally, the bonding material, which is similar to the insulating material and is used to adhere individual wires into one solid group or promote thermal bonding of the wire construction within the body of the catheter's construction.

1. Metal Materials

The metallic element of a conductor can be comprised from a variety of materials. The most common of these materials are given in the graphs below, as well as elemental materials used as alloying elements. The metallic material for a particular design is usually chosen in accordance to the material's resistivity (conductivity) and the mechanical properties of break strength and elongation. Therefore, the primary test platforms are narrowed to only two apparatuses, a resistance bridge and a tensile tester that plots stress and strain.

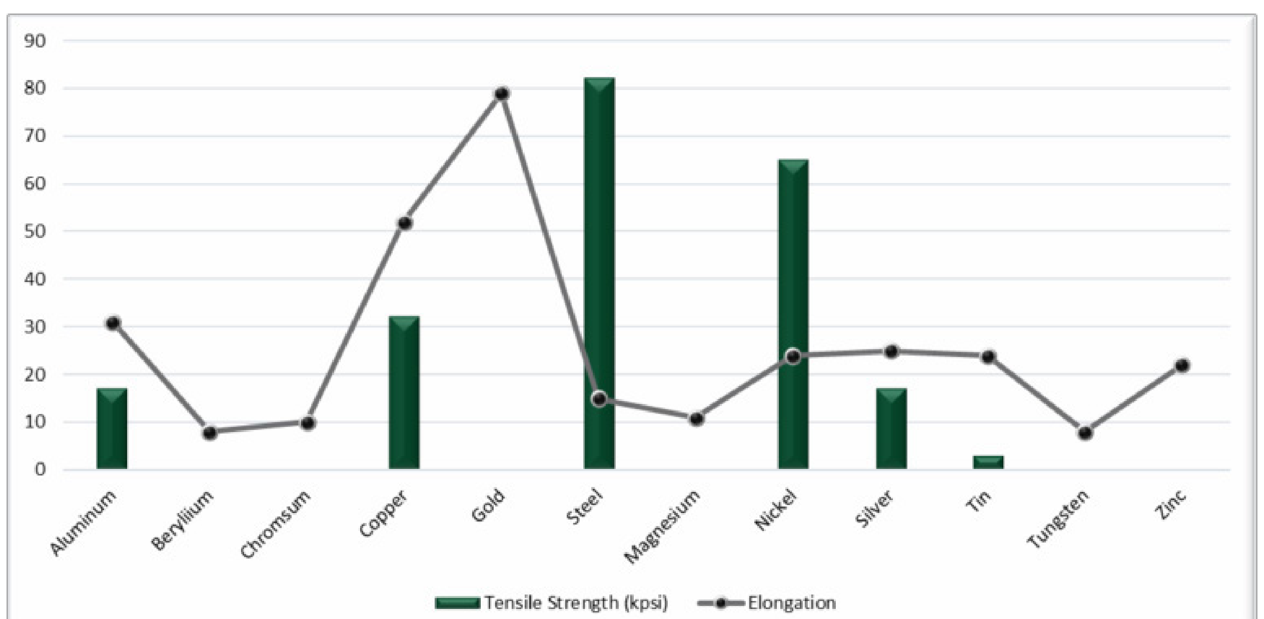
Conductivity of a metallic wire is based on the material's natural resistivity and the purity of this metallic material. Presence of "tramp" elements or less conductive materials (as in the case of many alloys) lessens the overall wire's conductivity. In general, alloys will have a higher resistance with a much wider variance in electrical resistance than a purer material.



The mechanical properties of break strength and elongation are also dependent on the inherent properties of the metal and the composition of the metal, as well as secondary processing of the metal. These secondary processes are mainly those manufacturing steps where 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 graphs given in this section result from testing performed on fully annealed test samples of different metals. The annealing normalizes the wire test samples from a secondary process perspective and allows for natural material property comparison.

Break strength and elongation are good base evaluations for different wire materials because from these two measurements you can infer the catheter properties of pull strength, torque transmission, push-ability, and stiffness/flexibility. Break strength and elongation are simple and quick tests to perform.

As with conductivity, there is a certain amount of break strength and elongation that is inherent to the different elemental metallic materials. The more conductive an element is the more natural softness or elongation it tends to have. Also, the purer these materials are the more inherent properties are maximized, as in the case of elongation. Presence of tramp elements, especially tramp elements in the grain boundaries, is detrimental to elongation.



In the “Design Process” section of this paper more will be discussed on the comparison of different material’s properties and ways to choose the best available combination of properties.

2. Insulating Materials

Liquefied polymers are comprised of various thermoset as well as thermoplastic materials. These types of polymers are kept in a liquid form by using different organic solvent mixtures. The solvent portion of these liquefied polymers is anywhere from 65 to 85% of the liquids total volume, while solid polymer comprises the minority of 15 to 35%. Within a precisely controlled high temperature environment, these solvents are removed, at which time the polymer solidifies forming an insulating film.

Prior to solidification, the solvents act in different ways to keep the polymer in liquid form. For thermoset materials, the solvent acts to fill or tie-up free radical sites of the various molecules that constitute a polymer. Removal of this solvent allows bonding or cross linking between molecules or atoms using primary bonds. In the case of thermoset polymers, the plastic is actually polymerized on the wire’s surface. Similar solvents act in a different way with thermoplastic polymer materials. 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, where the polymer chains are dispersed among the solvent. Removal of this solvent results in the re-establishment of secondary bonding mechanics, resulting in solidification.

Insulating Material	Type of Material	Max. Continuous Operating Temp	Best Use for Medical Microwire Applications
Polyurethane (P155)	Thermoset	155°C	A good insulator to process because it's easy to mechanically or solder strip. Not the most mechanically tough. Larger thickness of insulation used to compensate for mechanical shortcomings.
Polyester (PT)	Thermoset	180°C	Wire insulation with excellent chemical resistance.
Solderable Polyester (SPT)	Thermoset	180°C	Wire insulation. Allows for solder strip, unlike regular polyester.
Polyamide-imide (PT200)	Thermoset	200°C	Wire insulation with superior abrasion resistance.
Polyimide (ML)	Thermoset	220°C	Toughest of the thermoset insulations. Difficult to mechanically strip. Does not solder, but often is laser ablated.
Nylon (N)	Thermoset & Thermoplastic	130°C	Bonding conductors together. Excellent scrape resistance. Good heat resistance for thermal bond-able material.

3. Bonding Materials

Bonding materials are in most ways the same as insulating polymer materials and can be used to electrically insulate, except that bonding materials are almost always comprised of thermoplastic polymer materials. These materials begin to become tacky and re-flow when exposed to heat or a liquid solvent.

Copper-based Metallic Materials for use in Medical Applications


Catheters is just one of many applications for MWS precision wire in medical equipment.

Copper is one of the most conductive metallic materials, plus it is also one of the most economical. yet mechanically, in micro diameter wire sizes it does not exhibit the needed strength characteristics. Currently, wire systems address this shortcoming by using various nickel alloys (such as Constantan), or bimetallic materials such as copper clad steel, or composite metals or alloys that combine the desired physical and mechanical properties into a single wire. While all of these are good materials, they usually exhibit exceptionally high resistance and can add considerably to cost. 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 high-tension copper alloys can also be produced at relatively better prices.

Biocompatibility

The use of metals for internal medical applications necessitates understanding material biocompatibility. The truth is most metal materials are toxic if they can build up in the blood stream in significant amounts.[1] Specifically copper and its alloys are not meant for implantation, but use of these materials within temporary invasive medical devices poses little to no risk of toxic biological effects.

For copper or alloying elements within copper alloys to reach toxic levels in the blood stream, these metals must gain access to blood flow and be allowed to ionize, therefore becoming soluble within the blood. Such access into the blood stream is usually the result of an oxidized metal surface. This oxide easily ionizes within the bloodstream through a chemical process known as Oxidation-Reduction or a “Redox” reaction.[2] Initial accessibility can be prevented by isolation of the wire component within the body of the catheter and further isolation provided with certain surface treatments of the material. In the case of copper alloys such as beryllium copper (CDA 17200), the alloying element’s beryllium is used in very small amounts and locked within a metallic copper matrix. Therefore, the probability of direct contact is minimal. For added biocompatibility protection and a little added conductivity, not to mention improved brazing during termination, it is common to use these alloys with silver plating over them. This biocompatibility protection is further improved by then insulating these metallic conductors with a biocompatible polymer like the ones already discussed. Both of the silver plating and 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.


MWS offers a variety of Copper and Copper Alloy Wire solutions including **Certified OFHC (CDA 10100) OFHC Copper (CDA 10200)** and **ETP Copper (CDA 11000).**

Further precaution is added by sealing these conductors within the internal body of the catheter away from any blood contact. For instance, cytoxicity testing has shown no toxic effects of polymer insulated silver plated beryllium copper alloy for 24, 48, and 72 hours of exposure. In this testing, the silver plated insulated copper alloy wire was chopped into small pieces and soaked within the testing reagent for the three time periods described; after which, the reagent was introduced to mice cells to determine any toxic effect. The significance of this fact is that this method of biocompatibility testing resulted in direct exposure of the copper alloy to the testing reagent.

There are five such copper alloys ideally suited for usage in catheter design due their strength, conductivity, and affordability. These conductor materials are briefly described below with copper for comparison:

Alloy Name	Description	Break Strength (PSI)	Elongation (%)	Resistivity (u ohm cir mil ft)
ETP Copper	CDA 11000 (99.90%)	34,000 - 55,000*	6 - 36*	10.3
Beryllium Copper	CDA 17200	68,000 - 152,000*	1 - 42*	46.2
Phosphor Bronze	CDA 51000	51,000 - 110,000*	5 - 49*	69.1
XHTW	Extra High Tension Wire	50,000 - 62,000*	10 - 25*	11.8
EHTW	Extreme High Tension Wire	56,000 - 68,000*	10 - 30*	12.9

*Range based on temper and size

Science of Copper Alloys

The copper alloys discussed are strengthened from the use of small amounts of alloying elements that are added to the base copper material. These 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. In precipitation hardened alloys, the alloying elements are added in the copper's molten phase and are essentially mixed in. Rapid cooling places these alloying elements within the lattice of the metal's crystalline structure, which is then termed a "solid solution". Long heat-treating processes (2 to 4 hours) can drive these alloying elements from the copper crystal, causing them to nucleate in the grain boundaries of the now pure copper crystal. This nucleation reaction provides improved conductivity due to the alloys move out of the copper's crystalline structure, while also strengthening the copper matrix, which also tends to result in an increase in stiffness and higher yield strength.

Often precipitation hardened alloys are used in an un-precipitated state, meaning the long heat-treating process is not applied and the alloying elements remain in solid solution with the copper's crystalline matrix. This happens because the alloy still exhibits high strength characteristics. But what some fail to understand is that an un-precipitated alloy also has a high resistance.

Design Process

When incorporating wire-based constructions within your catheter design, consideration needs to be given not only to functionality, but also to the ability to repeatedly manufacture the product. When deciding on a wire product's design for your catheter/device, use the following elements to help guide you in this determination:

- Dimension
- Dielectric Strength
- Break & Yield Strength / Elongation (Stress-Strain Diagram)
- Conductivity (Resistance, ohms per length)
- Flexibility (Bend Resistance)

Dimension

The dimension in any conductor or wire design should first be thought of as the pathway that the conductor will need to follow from proximal to distal locations within the body of the finished catheter or medical device design, and the maximum allowable space within this pathway. By envisioning the pathway first, it is easier to obtain an understanding of dimensionally how much room is there for the conductor(s) to take up. Generally speaking, the more dimensional "real estate" there is for a conductor, the less problematic the conductor will be, both from a working design perspective, as well as in regard to manufacturability. Reduction of this available space should be more a part of design refinement and necessity than a beginning target on the onset of design development.

Dielectric Strength

Dielectric strength defines the average voltage where the insulation breaks down and energy "shorts" through the insulation. By defining the maximum voltage applied to the conductor material, this helps you define the minimum thickness of insulation material needed around a conductor. You can recognize from the given data the importance of insulating the wire materials with this type polymer. As previously noted, extruded polymers are unable to match dielectric strength of the materials below from .001 inch of insulation wall thickness.

	Dielectric Strength (Volts per .001" of insulation) Dry-DCTest
Thermoset Grade	
Polyimide	6,300
Polyimide (w/fiber or particle composite)	3,000
Polyamide-imide	5,000
Thermoset/Thermoplastic Mix	
Polyester	2,700
Polyurethane	2,900
High Temp Polyamide	3,100

Testing involves twisting two wires together and applying a DC voltage potential to each leg until a "short" occurs. The dielectric strength is usually listed in units of volts per mil (.001 inch) of insulation thickness and is calculated from the breakdown voltage divided by twice the insulation's wall thickness. If you are using alternating current (AC), reduce the given dielectric strengths to half the given value. Keep in mind this value is tested in a dry condition. Introduction of moisture of any kind, especially ion loaded moisture such as saline, results in 30 to 50% less dielectric strength. If a conductor's insulation is exposed to any moisture or humidity for an extended length of time, you should consider using a fluoropolymer like FEP or PTFE due to their extremely strong hydrophobic properties. Except for fluoropolymers, many of these insulations are very hydroscopic due to the nature of their molecular bonding, and therefore will absorb water when exposed to moisture over approximately one hour.

Within high temperature applications or manufacturing processes the dielectric strength begins to exponentially diminish about 5 to 10 degrees beyond the maximum operating temperature. Even with this being the case, these polymers are extremely thermally stable in comparison to other plastics.

Break & Yield Strength / Elongation (Stress-Strain Diagram)

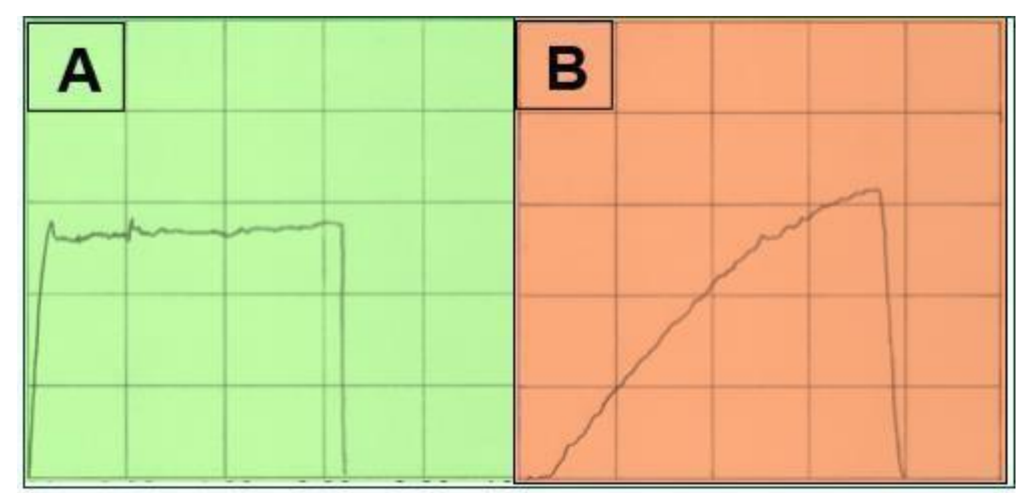
When evaluating a wire design, you should always perform a number of tensile and elongation tests with the purpose of establishing a stress-strain diagram that represents the entire construction. This goes for multi-conductor designs as well as single wires. The stress-strain diagram goes a long way in understanding a design and how it will react during use. Such diagrams can help identify potential problems before the product gets into use.

The most crucial elements of a stress-strain diagram for catheter design are the elastic limit and slope of the line up to the elastic limit value.

The elastic limit is the stress or force at which the conductor transitions from elastic elongation to plastic elongation (permanently deforms) [1]. This provides a maximum force limit that can be applied to the assembly process of the catheter, as well as the catheter's use during its application. A wire conductor that experiences a force beyond the Elastic Limit results in permanent property changes that negatively change the metal's conductivity and break strength characteristics.

As for the "Slope of the Line Up to the Elastic Limit Value", this is the Young's Modulus or Elastic Modulus calculation, which is an excellent indicator of the wire construction's flexibility. The Elastic Modulus calculation is the slope of the linear portion of the stress-strain diagram. The modulus is a ratio of change of stress over change of strain, or in other words, the amount of stress produced by one unit of strain. The smaller this number is, the better the flexibility.

The two graphs below are examples of stress-strain curves. The X-axis represents the tensile force or tensile stress applied to the wire construction. The Y-axis represents the change in the length of the test sample as this tensile force is applied. This Y-axis is also referred to as the "Strain" component of the plotted curve.



Stress-Strain Diagram allows the designer to make many predictions and observations.

As already stated, the Stress-Strain Diagram allows the designer to make many predictions and observations concerning the wire component to be used in their catheter design. Below are examples of these observations associated with the presented Stress-Strain Diagrams A & B.

Diagram A – This is a good high tensile conductor that does not start plastically elongating until it reaches its maximum tensile strength. It's good tensile strength is well balanced with a significant amount of elongation. This is not a brittle wire design. It is strong as well as tough and will resist damage during assembly. The slope of the elastic line is very steep, meaning it has a high value indicating a high degree of stiffness. While the wire will add resistance to bending, it will also help in transmitting torque (if needed).

Diagram B – This design is very elastic. The line of the diagram almost stays linear or elastic up to two-thirds of its maximum tensile strength. The slope calculation of the linear portion of the diagram line produces a relatively smaller number, therefore indicating good flexibility. Care must be taken in manufacturing not to expose the wire conductor to tensile forces over the elastic limit. The type of material indicated by this curve suggests the wire component's conductivity should be checked after assembly and after usage to verify no changes to the material's resistance.

Conductivity

Conductivity and resistance are products of the metal's inherit conductive properties and the cross sectional area of the metallic portion of the conductor. The catheter's application and use usually determine the required resistance of the conductive pathway. Understanding the maximum resistance for your electrical wire pathways is one of the first steps in determining a wire's material type and size. Since maximum resistance is application hardware dependent, it is important to consider this value early in the design phase. If you are faced with a situation where your conductor has excessive conductivity you may consider using a material with less conductivity but greater tensile strength, knowing that assembly will be less susceptible to conductor damage during manufacturing. In all cases where conductivity is plentiful you are always better off exchanging this conductivity for stronger material properties and or small cross-sectional dimension.

Conductivity of a wire is also dependent on the cross-sectional area of that conductor. Note the equation for Resistance, where p is the material resistivity, l is the length of the wire, and A is the cross-sectional area of the wire. $R = pl/A$. For that reason, a given length of wire is only as conductive as its smallest cross-sectional area so that wire diameter control becomes very important during the wire drawing process. Also, manufacturing steps that could potentially damage or reduce the wire's cross-section at one particular location need to be considered.

Conductive wires are susceptible to work hardening and depending on the degree, this can increase the resistance of a wire. Work hardening is a product of physical force in some way being applied to the metal wire material. Bending, crushing, elongating and twisting are some of the ways in which wire can become work hardened. Work hardening causes disorder and stress at the grain boundaries; this is what causes the increased resistance or the reduction of conductivity.

Flexibility

Flexibility or a wire's resistance to bending greatly affects the catheter's maneuverability and torque transmission. Stronger materials with greater tensile strength and steeper slopes in the elastic range of the stress-strain curve result in a stiffer and less flexible material. Conductors with less strength and greater elongation generally translate into more flexibility.

The greatest control over flexibility a catheter designer has in dealing with wire conductor systems is how the conductor is deployed within the catheter shaft. More flexible designs are achieved by deploying the conductor in a lumen that has at least 30% more cross-sectional area than is required to fit all the individual insulated wire cross-sections. In addition to extra room in the passage lumen, the wires ideally should be twisted or coiled into a helical geometry. Finally, utilizing a top coating material that has a low coefficient of friction on the outer surface of the insulated wire will enhance maneuverability. All these construction elements serve to reduce a wire construction's resistance to bending.

All this results in creating a design that allows for free movement of individual wire members within the body of the catheter construction. An individual wire should not be bonded or secured to other individual wire members or to the body of the catheter. This allows the wire material to adjust to the compression and elongation associated with mechanical bending.

Keep in mind the wire elements do not need to be coiled around anything; simply twisting multiple wire elements together achieves the same coiling effect that will benefit the catheter shaft's flexibility.

Termination of Wire Product in Finished Assembly

The insulation materials used in micro-diameter wire constructions are strong, often thermoset polymers that provide a high level of mechanical strength in relatively small dimensions. While the mechanical strength of these insulations is usually considered a positive attribute, when it comes stripping away the insulation to expose the metal, such strength can pose problems.

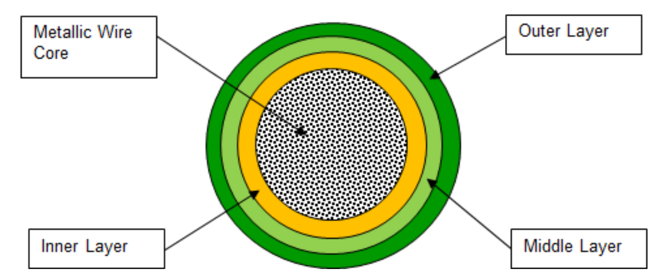
Various techniques may be employed to remove these insulation materials to access the metallic conductor as part of the catheter's assembly. Some techniques are very simple, others more complex. The simplest of these is mechanically scraping the insulation away. Sandpaper, razor blades, anything with a hard, sharp edge is often used in conjunction with a microscope to systematically remove insulation from a specific location along the length of an insulated conductor. These methods are very time consuming and may create poor quality results or can be difficult to repeat consistently in a manufacturing environment. As already stated, medical devices have become dimensionally smaller, therefore reducing the cross-sectional size of the wire used. This move toward smaller conductor sizes has compounded the problem of stripping away insulation materials. Many means of mechanically stripping small diameter wires can result in damage to the metallic conductor as well as removing the insulation. This damage can produce stress concentration points that can cause tensile failures in the catheter during or after assembly. This damage can also create variations in the wire's conductivity/resistance, due to removal of some of the metal along with the insulating material.

Over time with the use of insulated micro-conductors, mechanical stripping has shown some improvements. One such improvement is the "Bead Blasting" or "Particle Abrasion" method. This method is very similar to sandblasting, but on a micro scale. Specialized equipment is used to blow particulate material, everything from micro plastic pellets to baking soda. Chemicals can also be employed to chemically breakdown the polymer insulation, but this method is not popular due to the safety issues of the chemicals in use and the possibility of this chemical remaining with the wire as a residue.

Advances in electrophysiology require packing more wires into smaller packages. Polyimide type insulations offer the greatest density of interconnects due to the thin tough polymer coating. But these coatings are difficult to strip, especially at the tiny scale of wires used in catheter designs. Laser energy can effectively ablate away the insulation material without causing damage to the metallic conductor. The energy is in the form of light waves that are absorbed by the polymer, causing the atoms to be ripped from the wire surface. At the same time light is reflected from the metallic conductor generating very little heat and a "cold" vaporization of the insulation. While carbon dioxide laser technology is commonly used in larger wire stripping applications to vaporize or melt away plastic insulation material, this is not a suitable solution in micro-wire stripping. UV laser technology uses short wavelength ultra-violet light coupled with nanosecond duration pulses, enabling instant vaporization of polyimide and leaving a clean metallic surface for terminating. The process is gentle enough to leave thin plating layers like gold or silver without damaging or removing them.

Advances in the development of interconnects in the medical device market have resulted in novel miniature ribbon cable assemblies. The precise nature of laser ablating can now be done selectively into small windows, speeding up and simplifying the process of making connections of the cable.

Multi-Layer Constructions



One aspect of insulated wire designs most often not considered in the development process is the use of insulating materials for characteristics other than just dielectric strength. This liquid dip coating technology lends itself to using different insulations at different layers to enhance functionality of the overall conductor design.

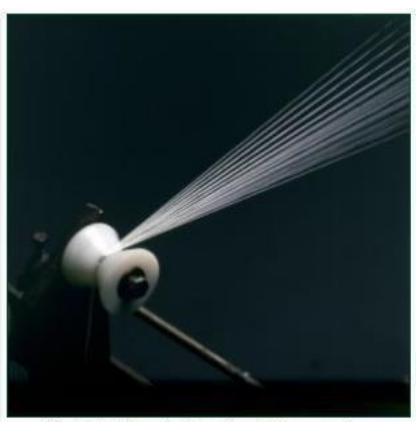
It is best to think of the insulated wire from the perspective of its cross-section. From this, you can see the insulation as different layers and then consider how these layers can be comprised of different materials to produce different functionality in the finished design.

Since the liquid dip coating process can produce wall thicknesses as thin as .00025 inch, a wire with a .00075-inch total wall thickness can potentially contain 3 different materials.

While three different materials are possible, most often hybrid insulation designs utilize only two different materials. The inner layer material generally provides dielectric strength, but the outer layer can be used to benefit the outer surface's interaction with the outside environment. The key to utilizing this design aspect is to understand the properties of available insulating materials that can be dip coated and incorporated into this insulating process.

Inner Layer	Middle Layer	Outer Layer	Outcome Of Design
Pure Polymer	Polymer Loaded with Radiopaque Material	PTFE Loaded Polymer	An electrically insulated wire with an improved fluoroscope image and good sliding friction on the OD for assembly or during usage.
Polyimide	Polyimide	Low Friction Top Coat of PTFE Loaded Polyimide	An electrically insulated wire for a high voltage application with good friction properties to make assembly.
Polyurethane	Polyurethane	Thermoplastic Pebax	An electrically insulated wire conductor that is easy to strip by hand and bonds well to Pebax outer member of the catheter.

Multi-End Constructions


Multiple Wires fed into Single Construction

Often medical device designs require more than one wire. When multiple wires are used for a design, they can be assembled into a single group by either physically bonding the neighboring wires together via an adhesive process or by twisting together the individual wires.

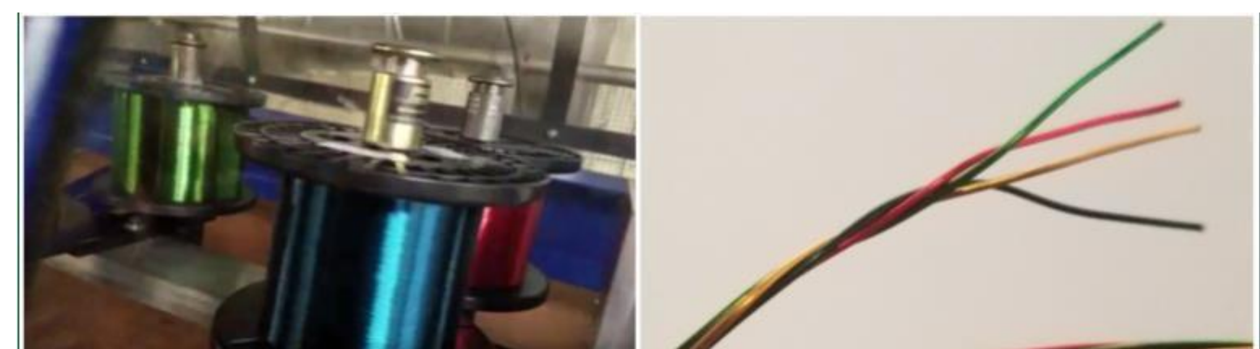
Multi-end wire constructions take two basic forms: Twist and Parallel. Within these two design forms the individual single ends can be insulated, uninsulated or a mix of both. Insulated elements are used for electrical conduction in some manner, where uninsulated elements are structural reinforcements, such as stainless steel. Also, single-end conductive wires are usually insulated with different colors to aid in proximal and distal termination. In the case of structural wires or filaments, they do not need to be conductive or metallic at all. Polymeric filament materials like Kevlar®, Vectran®, and Kynar® have been used successfully in such applications. When using polymeric filament materials among conductive wires in a single group, it is generally best to use filaments with diameters that are the same or close to the diameter of the conductive wires being used.

Twist Multi-End Constructions

Twisted designs utilize mechanical twisting to secure the single individual elements together in one continuous grouping. The individual conductors or filaments are not bonded together but remain separate, forming multiple loose helical coils.

The advantages of Twist design:

- Good flexibility. This property improves as the twist concentration increases, or increase in the number of twists per linear length of the construction.
- Good torque transmission, also improved by increases to twist concentration.
- Bending stress is not focused on specific point along length of material during repeated bend cycles.
- Good break strength. The break strength is greater than the sum of all individual wire or filament break strengths.


MWS is the exclusive producer of Twistite Magnet Wire ® that provides superior performance and tighter control over twisted wire construction. For more information go to Twistite Magnet Wire.

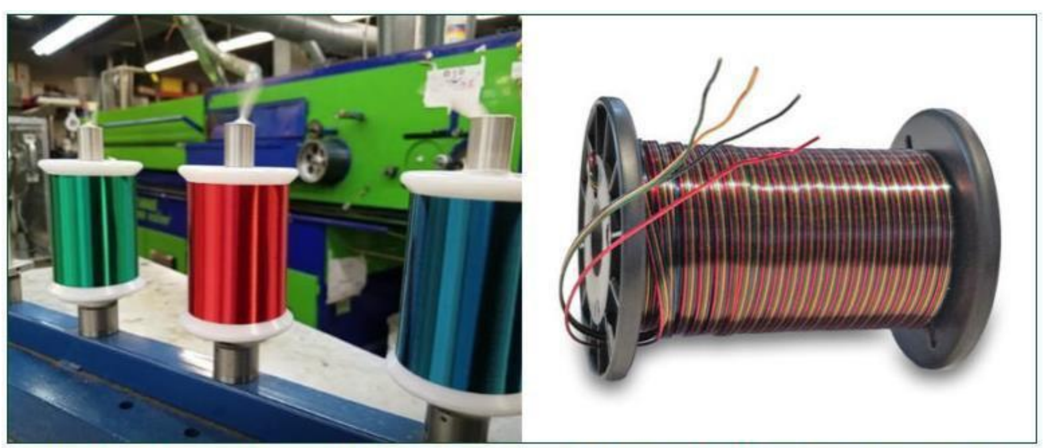
The disadvantages of Twist design:

- Added electrical resistance due to added length from wires following coiled pathways.
- Twist Constructions of multiple wires tend to require more space to accommodate them within a catheter construction

Parallel Multi End Construction

Parallel constructions utilize a bonding material to join the single conductors side by side. As with the twisted designs these individual ends can be comprised of different metallic or non-metallic materials insulated or uninstalled.

Unlike the Twist designs, every individual element in a Parallel design is generally coated with a bonding material. This bonding material is separate and distinct from the insulation applied to the single-end to produce dielectric isolation. Plus, it is always located at the top of the overall multi-end construction. Parallel Multi-end designs create a ribbon cable that can be comprised of two to ten or more individual wires. The benefits of this Multi-end design option are different conductor materials, and colors can be combined into the cable design.



MWS is the exclusive manufacturer of Multifilar® Magnet Wire Parallel bonded magnet wire for more consistent capacitance and impedance characteristics.

Flat Wire/ Non-round Shapes

Wires may be produced in cross-sections other than round in order to reduce catheter profile or maximize conductivity within the limited area in a lumen. Shaped wires can theoretically come in infinite configurations. But from a practical and economic standpoint, they are generally made as flat wire, also referred to as ribbon wire. Care must be taken as wires shaped with sharp corners may cause damage to other catheter components. Insulating them is also difficult with limitation in ability to achieve uniform coating around the periphery, leading to insufficient dielectric properties.

Manufacturing Technique

Ribbon wire is usually made by rolling round wire into radius edge flat wire. This is a reasonably inexpensive process that yields smooth bright bare wire with excellent dimensional tolerances and can be made into width to thickness ratios up to ten to one in most alloys. Tensile strength is determined by the manufacturing technique and can range from annealed to spring temper. The flattening process also lends itself to pre-insulated wire ensuring a consistent thickness of insulation around the conductor, as all edges are rounded. By changing the degree of flattening, wire can be produced with cross-sections that vary from high aspect ratio to rectangle to nearly square. Rolling flat wire is a cold work process that adds tensile strength (additional temper) and a slight increase in resistance to the conductor. Bare wires are rolled to a target temper or tensile range and can be easily reannealed. Pre-insulated wires that are rolled flat but need to be annealed in their final form require high temperature insulations such as polyimide that are robust enough to survive the re-softening process.

Summary

Micro diameter wire constructions provide an effective and efficient means of creating pathways for electrical impulses that can create a certain reaction or can be the result of a reaction that can be read and interpreted. Once these pathways are in place, a broad range of applications open up to the catheter designer. Many uses of these electrical impulses go far beyond the more current applications already discussed.

- RF energy for ablative electrodes- often delivered via insulated nickel or nickel alloy
- Intra-vascular ultrasound (IVUS)- a miniature wiring harness for sending signals that allow imaging to evaluate the coronary artery for suitability for balloon delivery or arterial stents
- Fractional Flow Reserve (FFR)- used to measure blood flow to diagnose arterial blockage

- Thermocouple wire- for monitoring tip temperature to ensure tissue damage is controlled
- Sensor catheters- typically connected to control and analysis equipment to generate images from raw imaging data and display physiological parameters
- Micro pumps- deliver impulse to drive or open valves in pumps at the distal end for use in drug delivery systems
- Real time heart information- feedback from sensors deployed in the heart or vascular system to diagnose a condition or evaluate the outcome of a procedure
- Neurostimulation electrodes- mainly used in pain management systems
- Telemetry devices- ultra-fine copper sensing coils to assist the physician in catheter location during surgery

Conclusion

Use of invasive catheters, for the most part, are very manual procedures that are based on feel, touch and experience. While the abilities of an experienced physician can never be substituted, use of micro-wire conductors as electrical pathways for various sensor technologies allows the ability to revolutionize catheter designs in these respects. Micro- insulated wires can potentially open the way for the use of sensor technologies within invasive catheter platforms.

Use of these sensor technologies can and will allow for objective feedback during catheter placement, catheter treatment and evaluation of post-treatment success. During catheter placement sensors can provide feedback into computer systems that will monitor out-puts and assure such out-puts stay within an optimal range. Then if such range is exceeded, alarms can notify the physician prior to permanent damage being done. For example, damage to a blood vessel wall is preventable by monitoring the pressure at the catheter tip during placement. Another example is in the area of post-treatment evaluation of a catheter procedure. Flow-rate downstream of a stent or angioplasty site can integrate sensing to determine the success level of the treatment and then determine if more treatment is needed. The ideas are limited only by the number sensor applications.

While wire as a concept has been in existence for hundreds of years, new materials and newly refined processes have allowed this very simple concept to evolve into a very sophisticated product that has usage in some of the most technological applications of our time.

[1] Dartmouth Toxic Metals Research Program © 2001, Center for Environmental Health Sciences at Dartmouth, Retrieved April 8, 2005, from www.dartmouth.edu/~toxmetal/HM.shtml

[2] George E. Dieter, Mechanical Metallurgy, Third Edition, New York, McGraw-Hill, 1986.

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