A METALCUTTING WHITE PAPER

METAL TUBING IN THE 21ST CENTURY: WHO NEEDS IT?

THE FUTURE OF INNOVATION IN MEDICAL DEVICES

METALCUTTING
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With diverse properties, precise tolerances, and ease of fabrication, metal tubing continues to play a vital role in medical device design and production.

Metal tubing has been the foundation of much of the medical device industry for many years. For the last century or so, the tubing has largely been stainless steel. Early on, it was used mostly for transportation — for example, for drawing blood, dispensing medicines, and performing simple surgical procedures such as a lithotomy (used to remove calaculi, or stones formed in organs such as the kidneys, bladder, or gallbladder). However, as medicine advanced, metal tubing began to be used for more sophisticated procedures, such as in biopsies or for stents inserted during angioplasties.

The "death" of metal tubing has often been predicted, yet it is still used extensively. In fact, human ingenuity has continually found new applications for metal tubing and refined previous uses. With the demand for "better" tubing and the technological ability to produce it, the characteristic parameters of tubing have been pushed further in all directions. For example, it is now possible to make stainless steel tubing that has an inside diameter (ID) of 25 microns (µm); for comparison, the diameter of human hair varies from about 40 µm to 120 µm. In another example of progress, the finish on the ID of tubing can now reach an Ra of 0.0003". New materials, such as NiFreeT™[1], are being created, as are new uses for existing materials, such as substituting NP35N®[2] for stainless steel in high-pressure environments.

But while metal tubing has made great strides, tubing made of plastic has also taken on a larger role. For instance, for catheters utilized in a wide range of cardiovascular, urological, gastrointestinal, neurovascular, and ophthalmic applications, thin plastic tubes available in varying levels of stiffness (depending on the application) are commonly used for drainage, administration of fluids or gases, access by surgical instruments, and other tasks. Plastics are especially practical for a single-use applications such as intermittent catheterization — the insertion and removal of a catheter several times a day to empty the bladder — versus a silver or stainless steel catheter that is designed to be cleaned and reused multiple times. Easily coated or pre-lubricated and designed to be used once and then thrown away, these single-use catheters may be made from polyvinyl chloride (PVC), which is relatively stiff yet still pliable enough to pass through bends; or for a softer, more flexible catheter, silicone may be used.

Of course, whether metal or plastic is used, tubing cannot be made from just ANY material. Medical-grade tubing must meet industry requirements and, often, standards related to the specific application, be it fluid management, anesthesiology or respiratory equipment, intravenous (IV) therapy, peristaltic pumps, or laboratory equipment.

Metal vs. Plastic: Why select one over the other?

Choosing the most appropriate tubing material is a fundamental aspect of medical device design and production. In addition to looking at attributes such as material compliance, composition, and characteristics, inertness, biocompatibility, dimensional repeatability, flexibility, and cost, it is important to select a tubing material that can be prototyped cost effectively and then scale into long-term sourcing and production.

Rules and Regulations First

Medical device tubing is unique compared with other types of tubing, in that it must generally be designated specifically for medical applications. That means various industry standards and certifications often affect the choice of material and the specification requirements for medical tubing, to ensure the safety and reliability of devices for patient care, diagnostic testing, drug manufacturing, and other uses. In addition, there are production and testing practices in place — and in the U.S. and many other countries, required by law — to help ensure product quality. So, for example, tubing that meets all the production specifications may not be approved for medical applications if it was not produced according to Good Manufacturing Practice (GMP) guidelines.

Depending on the specific application, the requirements may include:

- International Standards Organization (ISO) 10993 standards for evaluating the biocompatibility of medical devices prior to a clinical trial or study
- U.S. Pharmacopeial Convention (USP) Class VI certification of material suitability for medical grade devices, based on standards including tests for toxicity, biochemical compatibility, leaching, and inertness
- Additional Food and Drug Administration (FDA) standards for certain types of medical tubing

Choice of Material Determines Performance

The type of material used to make medical tubing determines important performance properties, such as abrasion resistance, chemical resistance, hardness, flexibility, and durability. Material selection is also crucial for medical applications because incompatible materials can cause a number of problems. For example, incompatible tube materials can chemically alter medications and test samples or cause them to bind to the tube wall, resulting in failed delivery. Use of a material such as latex may pose a risk of allergic reaction in some patients. In addition, tubes that are radiopaque (x-ray absorbing) can interfere with the process of x-ray scanning, resulting in unacceptable image quality.

Medical device tubing is commonly rated based on a number of performance specifications provided by a product manufacturer. These include:

- The minimum or maximum pressure (in pounds per square inch, or psi) that the tube is designed to withstand
- The maximum vacuum pressure (usually in inches or millimeters of mercury) that can be created in the tube
- The minimum bend radius (typically, in inches or millimeters), or the acceptable amount of deformation the tubing cross-section can undergo (Note, the smaller the minimum bend radius, the higher the tube flexibility.)
- The full range of ambient temperatures within which the tubing is designed to operate

Having a drawn ID surface finish that is as smooth as possible — for instance, with an Ra value of 6-8 — can make the tubing easier to clean and help to reduce the chances of carryover in reusable tubing. In addition, the ID will determine how smoothly fluids flow through the tubing. Imperfections in the ID surface finish can result in swirling, eddying, or buffeting of the liquid as it moves out of the tube, creating problems in applications where it is critical that liquid is dispensed smoothly. A smooth surface finish on the OD of the tubing is also important if a testing process requires aspirating, in which the entire tube is inserted to draw a vacuum; however, OD surface finish is much less of a factor in dispensing processes. In other cases, such as in an operating room environment, smooth tubing may be problematic due to the issues caused by lights reflecting off the surface of instruments.

Different applications can also require different tubing fabrication methods. For example, in ultra high-performance liquid chromatography (UHPLC) and other high-pressure applications, seamless tubing is highly preferred to tubing that is welded and redrawn, with seamlessness eliminating the risk of leaks, cracks, or ruptures of weld lines when pressure is applied. However, seamless tubing is higher cost and there are limitations in available sizes, wider tolerances, and longer delivery times.

Medical tubing may also require different features depending on the specific application. One example is the opacity of the tubing wall; semi-transparent or clear tubing is often important in fluid delivery, to visually track fluid movement or monitor for air bubbles in a system. Other factors may include the ease with which a material can be sterilized, the need to coil the tubing for storage or transport, and spark or static resistance.

In addition, wherever the devices are reusable, the medical tubing material must be able to maintain its desired rigidity, strength, compatibility, biological or chemical resistance, and other characteristics with repeated exposure to disinfectants, sterilization, and routine cleaning processes. For example, while plastics can be sterilized for initial use, many are not designed for repeated use and can melt when exposed to some re-sterilization methods.

Physical Properties of Plastic and Metal for Medical Tubing

Required in a variety of shapes, sizes, and colors, medical device tubing is commonly made from such materials as thermoplastics and silicone polymers, and manufactured using extrusion techniques. Lightweight and versatile, plastic tubing is commonly used as flow lines for fluids and gases in medical applications. In addition, there is a wide range of plastic material to choose from, with different physical properties that lend themselves to varied uses. For instance:

- PVC has a broad range of physical properties including good chemical and corrosion resistance, excellent abrasion and wear resistance, excellent flexibility, and outstanding flow characteristics.
- Polyurethane (PU), which combines the best properties of plastic and rubber, has excellent flexibility and good chemical and abrasion resistance, and can also withstand higher pressures than PVC.
- Polyethylene (PE) is a lightweight plastic used in laboratory and chemical processing applications due to its high degree of inertness and low cost compared with other plastics.
- Polypropylene (PP), the lightest weight thermoplastic, has excellent dimensional stability and electrical properties, has good surface hardness and chemical resistance, and is a low-cost alternative to fluoropolymer tubing.
- Ethyl vinyl acetate (EVA), which exhibits high impact strength, excellent low temperature properties, and good resistance to grease and oil, is a frequent substitute for vinyl tubing in surgical and pharmaceutical applications.
- Fluoropolymers have excellent temperature resistance (-200°F to 500°F) and are inert to almost all industrial chemicals and solvents.
- Nylon (polyamide) has good temperature and chemical resistance, excellent elastic memory, high impact resistance down to subfreezing temperatures, and low moisture absorption.

Generally lighter than metal, plastic tubing used in medical devices can reduce user fatigue and make devices easier to control. In addition, plastic can be biocompatible and non-toxic, and does not have particulate issues that can be associated with some metals. Plastic tubing can be flexible or rigid, depending on the physical properties of the plastic and the intended purpose of the tubing. Silicone is a frequent choice because it is inert and does not react to bodily fluids and a range of other medical fluids with which it might come into contact. However, silicone is weak mechanically and may be prone to fracturing; therefore, it may not be the best choice for applications where pressure or repeated impact is applied.

In addition, high-performance polymers can provide metal-comparable levels of strength and rigidity at ambient temperatures, along with ergonomic improvements such as a range-of-grip options. Polymers can also be colored, enabling (for example) the production of devices in a variety of sizes that can be color-coded for quick and easy identification.

In applications where the tubing needs to be translucent or completely see-through so that liquid flow can be monitored, plastic can provide this characteristic.

However, compared with other types of tubing, metal is stronger and more robust, making it well suited for applications requiring a high degree of structure, high tensile modulus (stiffness), or high-pressure fluid flow. Therefore, despite the widespread use of plastics, certain medical device applications may require tubing made from metal, including various types of stainless steel. Such tubing can be used to fabricate a wide range of devices, from stents and fixtures to surgical cutting instruments and bone screws.

Metal tubing offers flexibility in the way it can be constructed, including welded, welded and drawn, or seamless, which is typically achieved through extrusion. Because metal tubes are rigid, they hold to a specific shape. Rigid but bendable tubing can be achieved by taking small diameter metal tubing and coiling it into a spring shape, enabling the spring to be stretched and retracted while still allowing liquid to flow through it. Most metal tubes designed for fluid flow have circular cross sections, but other shapes — such as circular, oval, rectangular, square, or customized — are available for different applications. Circular tubes are the most common because they provide even strength distribution in all directions through the tube; metal tubing can also be constructed in multiple concentric layers.

Since having a clean, burr-free ID is critically important to both cleaning the tubing and the way material flows though it, metal tubing also offers advantages in that there are a number of methods for fine-tuning its ID surface finish. Some options include:

- Micropolishing and/or passivation
- Bore enhancement via use of a “bright draw” process
- Coatings such as silicone, PTFE, or PSX
- Abrasive flow machining or extrude honing

Specialty coatings can be applied to enhance the functionality of devices using metal tubing, such as to increase lubricity, reduce the risk of infection, or add other desired characteristics. For example, coatings of heparin or other drugs that combat restenosis are often applied to stents to increase their therapeutic value. How a metal will react to coatings, as well as any possible issues associated with a finishing method, must be taken into account when selecting a tubing material and weighed against the overall goals. For instance, while coating metal tubing can help to resolve carryover problems, parts of the coating could be exposed — and in that way,material lessening its effectiveness — when the tubing is cut to meet the requirements of a particular system and application. (Incidentally, Metal Cutting Corporation is successful in cutting coated tubing without adversely affecting the coating, with results validated in testing for specific applications.)

The Expense Factor

With cost savings being a major driver in healthcare and the medical industry, there has been a concurrent move to replace metal with plastic, and designers are often tasked with decreasing costs by converting metal devices to devices made with plastics. For example, in one case study an OEM was able to switch from a $300 titanium part to a $20 injection molded device for use in an orthopedic targeting guide.[3] In another study, surgical retractors made of Ixef® polyarylamide (PARA) and AvaSpire® polyaryletherketone (PAEK)[4] showed advantages of high-performance polymers over metals, delivering cost reductions and opening a new market in single-use instrumentation for the manufacturer.[5]

In general, plastics offer the ability to make devices that are disposable and therefore, easier and cheaper to manage than metal devices that need to be re-sterilized after use. Utilizing disposable devices can also help to cut down on the spread of infection, a critical and often costly issue for hospitals, surgical centers, and other healthcare facilities. On the other hand, the amount of plastic waste generated by medical facilities poses ongoing environmental concerns. The incineration of plastics adds pollutants to the air; even when plastics are properly disposed of, they remain in the environment for a very long time because they are specifically made *not* to degrade.

Plastics can be cheaper to process than metals, allowing designs to incorporate long, thin geometries that can be produced via injection molding. Plastics are also commonly used in the manufacture of catheters, ventilator tubes, and other medical devices in which flexibility is a must. However, the need to mold plastic parts and the cost involved in making the mold generally makes it uneconomical to mold a small number of parts. While the parts may be cheap once the mold is made, the cost to make a mold can (depending on the type of mold) be thousands or even tens of thousands of dollars in initial outlay. As an aside, this has left an opening for 3D printing of prototypes used to validate design, which once validated can be made from plastic. Nevertheless, and despite cost, metal continues to be the material of choice in many devices requiring precise tolerance, resistance to certain solvents or fluids, or other functional characteristics.

Where is metal tubing used in medical devices?

In addition to allowing for the extraction of samples and delivery of fluids and gases, metal tubing has played an important role in the development of devices that allow for less invasive diagnostic and therapeutic procedures, as well as *in vitro diagnostics* (IVD) and other medical systems. Today's uses for metal tubing range from syringe needles and implantable device components, to IVD probes and marker bands for catheters and guidewires, as well as more sophisticated uses such as heat-exchanger tubes for controlling blood temperature and surgical microtools. Below is a closer look at several medical applications for metal tubing.

Biopsies

One advantage of metal tubing is that it generally holds its shape — and this is particularly important when the tube is the working end of a biopsy device. In taking a biopsy, matter is removed from inside the body for a more thorough examination. Some types of biopsies involve aspirating (i.e., removal from the body by use of an aspirator or by syringe suction), while other so-called core biopsies involve taking a core of material from bone or tissue. In either case, it is unlikely that one would want plastic as the material from which to make the biopsy needle, which has to go through the bone or tissue to secure a sample and bring the sample out. Even with the use of stainless steel, it is not that unusual for a biopsy needle to deform during use, because of the density of bone.

Generally, the precision of the needle is not a concern for biopsies, at least with respect to the needle's biopsy function. The amount of material taken, whether by aspirating or core biopsy, is not so exact that a tube that is plus or minus 0.001 will affect the outcome. This is not to say there may not be a need for precision. For example, many breast biopsies are taken using a biopsy gun, where a very thin needle shoots out, takes the sample, and is retracted. In such a device, there may be a need for extreme precision because all the parts need to work and fit together.

Automated Liquid Dispensing Systems

These systems — widely used in pharmaceutical development, medical research, and IVD — dole out tiny, precise amounts of liquid at high throughput, performing a task that would be tedious, time consuming, expensive, and subject to human error if performed by hand. The characteristics of very small metal tubing, with an ID as small as 50 or 100 microns, play a vital role in helping to ensure that these systems are accurate and their results, valid.

For example, the well plates in today's testing systems have upwards of 1,500 very small openings for depositing samples. This requires the tubing in liquid dispensing systems to be straight, cleanly sheared, and properly finished at its end — for instance, flat, angled, or rounded, depending on what is being tested — so that the tubes align precisely with the tiny wells in the test plate. With metal, not only can the tubing be cut to the correct length and drawn to the desired OD and ID, but it can also be easily shaped (that is, flat, angled, or rounded) at the end for dispensing accuracy. In addition, the proper end cut can help to eliminate wicking and the last drop problem, reducing the risk of carryover.

As mentioned earlier, having metal tubing with a clean, burr-free ID also makes cleaning more effective, reduces surface roughness that can trap contaminants, and helps to ensure that liquid flows out of the tube with minimum swirling, eddying, or buffeting.

Surgical Instruments

High-quality metal tubing, in materials such as stainless steel and titanium alloys, is used in a wide range of surgical and dental instruments, including endoscopy equipment, cannulas, and spinal cages. Here, metal tubing excels in meeting required strength-to-weight ratios, as well as microbiological corrosion resistance and fatigue life. Available as precise thick wall or thin wall tubing in seamless, welded, and redrawn forms, metal tubing also offers the ID and OD surface finishes, tolerances, and shapes needed for unique microtools.

Stents

Metal tubing is used in vascular stents, which for almost 30 years have been revolutionizing the way physicians treat patients for coronary artery disease and heart attacks. A small, metal mesh tube that expands inside a coronary artery, a stent is placed in a previously narrowed or blocked blood vessel during or immediately after an angioplasty to help prevent the artery from closing up again. As mentioned earlier, stents are often also coated with medicine to further lower the chance of the artery reclosing in the future.

In the case of heart attacks, rapid placement of a stent can reduce the severity of heart muscle damage and improve survival; in coronary artery disease, stents help to reduce symptoms of chest pain or shortness of breath and improve quality of life for patients.[6]

The first stents used in cardiac arteries were bare metal, often stainless steel; today, many stents use cobalt chromium alloys and nickel titanium (also called nitinol). In addition, the use of platinum chromium alloy and platinum group metals (PGMs) in stents may grow due to the metals' compatibility with the human body and resistance to high temperatures and corrosion. While plastic stents have been promised for years — including a "bioresorbable vascular scaffold" made of corn-based, biodegradable plastic that is designed to be implanted and then reabsorbed by the body when it is no longer needed[7] — they have yet to become a reality.

What are the criteria when choosing a metal tubing material?

While plastic might seem to be a good, cost-effective option for medical tubing, it is important to remember that plastic cannot be cut as exactly as metal can be — an important consideration wherever the accuracy of a tube is vital, and especially in the business of medical devices, where lives may very likely depend on that accuracy.

There are a number of factors to consider when deciding which particular metal tubing material can and should be used. For example, as mentioned earlier, the material must be biologically and chemically compatible with any bodily materials, samples, and systems with which it will have contact. Some biological samples will "stick" to the surface of stainless steel tubing, causing issues such as loss of sample, low yield, and carryover. So, in this case a commonly used tubing material, such as a molybdenum-alloyed stainless steel, might be replaced by titanium or any number of other metals that won't have this problematic "sticking" issue. Alternatively, a portion of the device may be made from plastic and disposed of after each use, while the main body of the device is made from metal.

The Need for Precision

It is critical that the chosen tubing material offers precise levels of dimensional control and consistency, so that it can be cut, drawn, extruded, and finished to achieve the correct length, burr-free ID and OD, proper wall thickness, and clean end cut.

Precise sizing of medical device tubing is vital to ensuring that the tubes fit into any necessary connections and equipment; in addition, the dimensions of the tubing influence important performance properties, such as flow rate. Where tubing requires a diameter almost as small as a hair, special care must be taken to attain a clean, burr-free end cut and not collapse the tube during the cutting process. In addition, metal properties such as tensile strength, formability, and biocompatibility must be matched to the desired environment and function.

Each tubing material has pros and cons that need to be assessed for the intended device application and production goals. For example, surgical instruments involving the brain require a specialized material, such as a stainless-steel alloy that can be machined to precise tolerances yet remain free of minute metallic particles. Hypodermic needles might be made from a grade of stainless steel that can withstand burr-free machining methods that will significantly speed production. The alloy used for a stent might be chosen based on the material's shape-memory characteristics and biocompatibility — or, it might be selected for its ability to be coated more effectively than other metals. And as with all materials used in medical manufacturing, metal tube fabrication requires monitoring and tight control of material characteristics.

When evaluating a tubing material for medical devices, consider these questions:

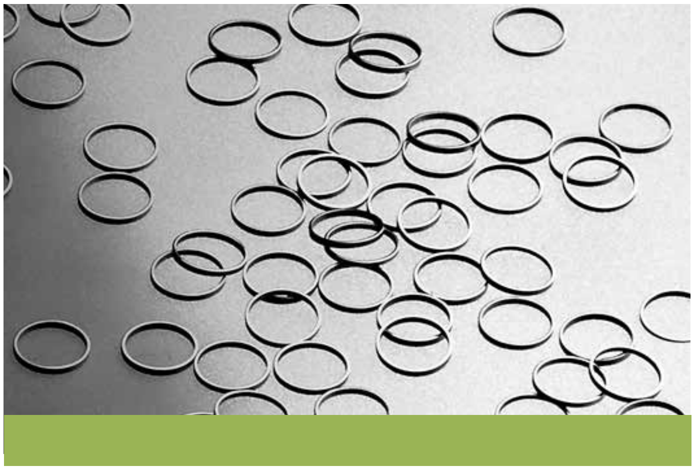
- Does the material need to meet any test and/or certification requirements for a particular medical use?
- Will the material interact biologically or chemically with any biological tissue involved in the procedure?
- Will the material interact biologically or chemically with other device parts?
- Will the tubing be under high pressure — for example, will it be used in a process such as UHPLC or a pump-driven liquid dispensing system?
- Can the tubing withstand the operating conditions — both pressure and temperature?
- How short must the tubing be cut?
- Can the material be drawn to the size needed?
- Just how small do the tube ID and OD need to be?
- How smooth can the ID surface finish be made?
- What finishing method would need to be used on the ID?
- How hard is it to cut the tubing without collapsing, chipping, or other deformations?
- Is the end of the tubing burr-free?
- Is the tubing's ID centered?
- How will the material interact with or be enhanced by any coatings that may be applied?
- What, if any, additional machining and/or finishing methods will be needed?

The Need for Cleanliness

With any medical or lab procedure, maintaining a clean environment is crucial. In hospitals and labs where a large number of procedures and tests are performed, reducing the risk of contamination while also maintaining productivity and cost effectiveness can be challenging. Naturally, the ability to clean the tubing in a medical device is a critical consideration in the material selection process. For example, in liquid dispensing systems, proper cleaning helps to not only reduce carryover and contamination, but also reduce the total cost of testing through more efficient use of reagents — which are very expensive — and improve the accuracy of results through more precise dispensing of test samples.

How expensive are reagents? The HiSeq X Ten Sequencer launched by Illumina in January 2014 was touted as the first to deliver the first personal genome sequencing for $1,000 — and of that, the reagent cost was $797.

Some metals may require the use of specific cleaning solutions. In addition, depending on the material characteristics, metal tubing can be re-sterilized using a number of methods, including autoclaving, dry heat, gamma irradiation, and chemical disinfectant. The overall effectiveness of the cleansing process — including, with reusable products, whether all residue from previous procedures can be removed — will vary from one application to another, since cleaning is a function of many factors, including the time allowed for cleaning, the particular solution and amount used, the number of cleaning and/or rinse cycles, and the amount of pressure applied in the process.



The Characteristics of the Metal

Metal tubing for medical devices can be made of titanium, precious metal such as gold or platinum, tungsten, and a range of specialized and/or proprietary materials, as well as a variety of stainless steel alloys. In addition to considering cost, it is critical to consider the individual characteristics of each material and look at properties such as strength, chemical and corrosion resistance, thermal stability, and rigidity to determine which is the best choice for a particular metal tubing application.

Manufacturers of metal tubing can achieve distinct characteristics through careful selection of materials and processes. For example, tubing made from cobalt alloys can be used in the production of rigid or stiff endoscopes for use in certain diagnostic procedures; however, nitinol or another more elastic material can be used to produce an endoscope with a high degree of flexibility and kink resistance. Another example is in UHPLC, where as the application has moved to higher bars of pressure (from 6,000 to 9,000 psi), it has led to changes in the tubing material; for instance, the use of a nickel-cobalt alloy can allow for UHPLC tubing that withstands higher pressure than, but with the same wall thickness as, stainless steel.

Stainless steel is frequently used in medical tubing applications ranging from stethoscopes to cannulas, as well as in medical devices for which the material characteristics — such as the ability to be precisely formed and machined — are critical. The term *stainless steel* does not refer to a single metal, but rather to a range of relatively strong alloys of steel with generally excellent chemical and corrosion resistance. In use for more than a century, stainless steel comes in a wide variety of grades and, depending on the application, other alloys can be included to give stainless steel varying properties and resistance.

When choosing stainless steel for an application, it is important to understand the end use and then choose the appropriate grade of material. Some common examples of stainless steel include the following:

- The most common grade of stainless steel is type 304 (also known as A2). It often contains 18% chromium, a hard and brittle metal that does not tarnish when exposed to air, and 8% nickel, which is known for its corrosion resistance (even at high temperatures), ductility, and strength. Versatile and widely used, 304 stainless steel is also known for its forming and welding properties, and excellent toughness and ease of cleaning. Additionally, due to its low carbon composition, it is perfect for high-temperature applications and when seeking to minimize carbide precipitation.
- The second most common grade of stainless steel is type 316 — a popular chromium, nickel, molybdenum-bearing stainless steel that has better overall corrosion resistant properties than 304. Although 316 is often referred to as marine grade stainless steel, it is not resistant to seawater; however, 316 is known for its resistance to pitting and crevice corrosion in chloride environments. Therefore, it is found in a wide variety of applications, including lab equipment, pharmaceutical processing equipment, chemical containers, and surgical implants.
- Grade 316LVM, the low carbon vacuum melt version of 316, is immune from sensitization (grain boundary carbide precipitation); therefore, it used is extensively in heavy gauge welded components (over about 6 mm). For example, seamless 316LVM stainless steel tubing has been used

to produce devices used during brain surgery, as well as coronary stents — applications where the material must be formed and machined with high precision, and the finished part must be particle free.

- Type 420 is a martensitic, high-carbon stainless steel that is highly polishable and has high strength at room temperature or slightly higher. Its uses include surgical instruments and scissors.

Bright annealed stainless steel is generally specified for medical applications. For additional cleanliness, the bright annealed tubing can be thermocouple cleaned; for the highest degree of cleanliness and smoothness, electropolishing following cleaning imparts a chromium-enriched interior surface that is advantageous.

Other materials often selected for use in medical devices using metal tubing include the following:

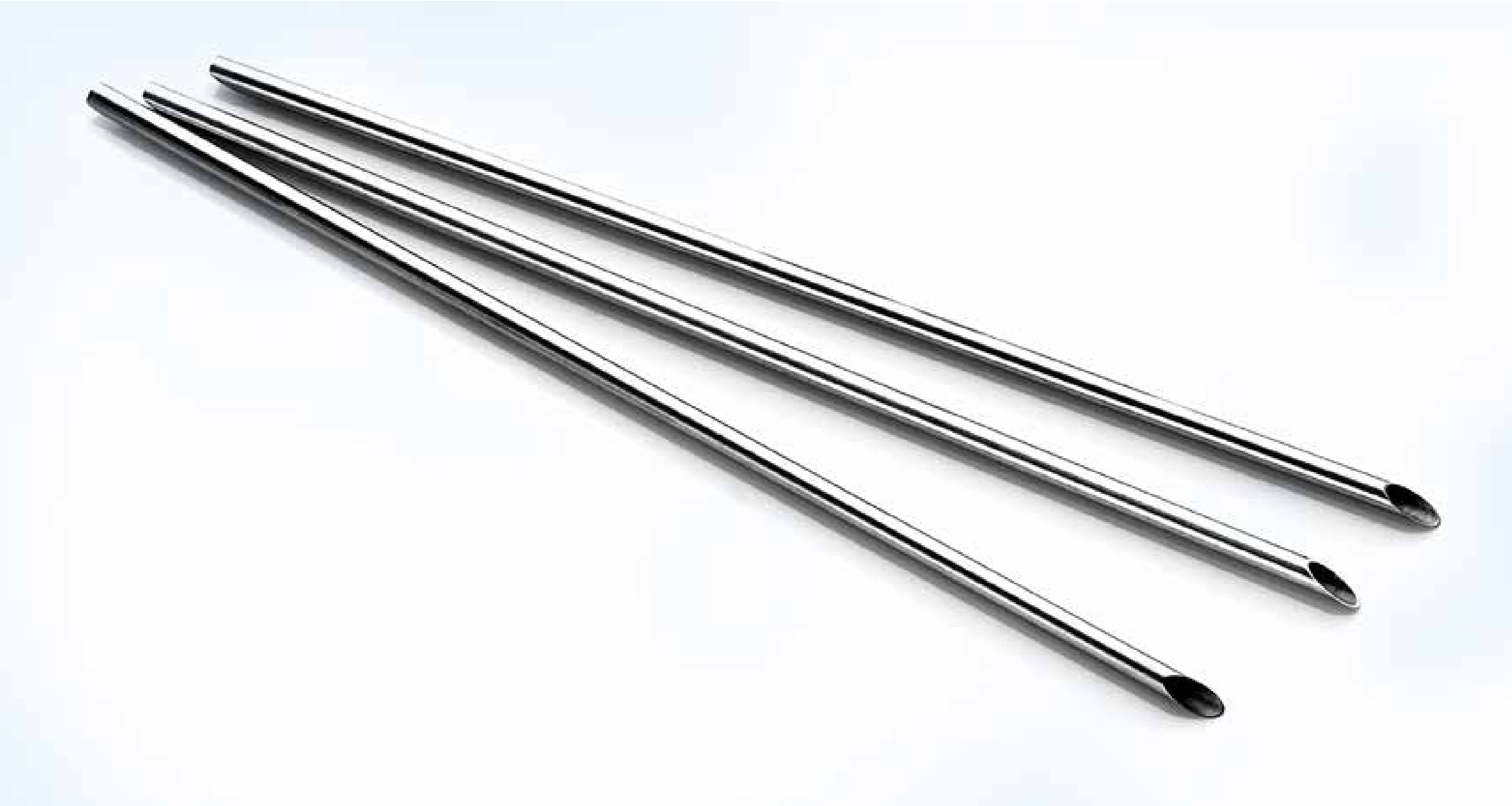
- Nitinol is a "springy" material that is used to advantage in applications such as catheter guidewires, stents, and super-elastic needles for microsurgery. When properly treated, the material has excellent corrosion resistance and offers a high level of biocompatibility. For some applications, nitinol is selected because of its kink resistance, which allows manufacturers to tightly coil long metal tubes for efficient packaging.
- Titanium is a high-strength, low-weight material with high corrosion resistance. Titanium alloy tubing is more expensive than stainless steel but provides a high strength-to-weight ratio, making it an excellent choice for a diverse range of applications.
- Gold, platinum, and other precious metals, in a variety of alloy compositions, can be fabricated as thin-walled metal tubing for medical device products. Characterized by their high melting points, radiopacity, resistance to corrosion, electrical conductivity, and biocompatibility, these alloys are commonly used for marker bands, guidewires, electrode tips, electrode rings, tip coils, pacemakers, and defibrillators.
- Tungsten tubing in the form of precision wire is often part of medical devices used to perform minimally invasive laparoscopic and endoscopic surgical procedures. Tungsten's hardness, high melting point, and thermal shock resistance enable it to withstand rapid temperature changes and repeated on and off cycles. Almost as dense as gold, but less expensive, tungsten tubing can be substituted for gold where radiopacity is required; with a density greater than that of lead, tungsten can also be used as radiation shielding material in medical devices.

As technological capabilities grow, medical devices get smaller, and procedures become more sophisticated, new and innovative applications for metal tubing — made from these and other alloys, as well as a range of specialized and proprietary materials — will continue to emerge.

Conclusion

Evolving alongside medical technology and growing out of more than a century's use of stainless steel, metal tubing continues to play a key role in medical device design and production and, ultimately, in patient care. Even as plastics and their uses continue to grow, the properties of metals — including their tensile strength and the ability to cut, form, and finish them to tight tolerances for length, ID, OD, and end cut — make metal tubing invaluable in the fabrication of a wide range of devices, from syringe needles, IVD probes, and liquid dispensing systems to stents, cannulas, and spinal cages, to heat-exchanger tubes and surgical microtools.

Tubing material and its characteristics, as well as the precision of the fabrication method, surface finishing, and other production attributes, have an impact on the safety, reliability, and performance of the medical devices and systems in which the tubing is used. That means choosing the most appropriate



tubing material is a fundamental aspect of medical device design and production.

Medical tubing is commonly rated based on a number of performance specifications, including pressure resistance, maximum vacuum pressure, minimum bend radius, and operational temperatures range. In addition to looking at attributes such as material compliance, composition, and characteristics, inertness, biocompatibility, dimensional repeatability, flexibility, and cost, it is important to select a tubing material that can be prototyped cost effectively and then scale into long-term sourcing and production.

Compared with other types of material, metal tubing is stronger and more robust, making it well suited for applications requiring a high degree of structure, high tensile modulus (stiffness), high-pressure fluid flow, precise tolerance, resistance to certain solvents or fluids, and other functional characteristics. Specialty coatings can also be applied to enhance the functionality of devices using metal tubing, such as to increase lubricity, reduce the risk of infection, or add other desired characteristics. While plastic might sometimes be a cost-effective alternative to metal tubing, it is important to remember plastic cannot be cut as exactly as metal can be. This can be an important consideration where lives may literally depend on the accuracy of the tubing in medical devices.

Each tubing material has pros and cons that need to be assessed for the intended medical device application and production goals. With the innumerable material options available today — both metal and plastic — deciding on a tubing material can be a daunting task. However, a knowledgeable materials supplier and its engineering team can assist in selecting the best option based for the specific application, budget, and end goals.

Footnotes:

1 NiFreeT™ is a trademark of Nippon Piston Ring.
2 NP35N® is a registered trademark of SPS Technologies.
3 Source: http://www.plasticsnews.com/article/20120703/NEWS/307039975/metal-to-plastic-medical-device-conversions-promise-lsquo-endless-possibilities-rsquo
4 Ixef® and AvaSpire® are registered trademarks of Solvay Specialty Polymers.
5 Source: http://www.medde8 MP35N™ is a trademark of Carpenter Technology Corporation.viceonline.com/doc/medical-device-metal-to-plastic-conversion-in-steps-0001
6 Source: http://www.wcvb.com/bethisrael/stents-little-tubes-that-changed-the-world/31737822
7 Source: http://www.thedailybeast.com/cheats/2010/07/29/can-plastic-save-your-life.html

METAL CUTTING
CORPORATION

Excellence in precision metal cut off

As an expert in the manufacture of burr-free, tight tolerance metal parts, Metal Cutting Corporation cuts millions of tubes every year, in all different types, shapes, and sizes. That is because we provide the precision required in the medical device industry, as well as in the automotive, electronics, biotechnology, semiconductor, aerospace, fiber-optic, electrical, and many other diverse industries.

At Metal Cutting, we are specialists with over 45 years of experience in providing precision components to medical device manufacturers. In addition to providing tubing and other components, we cut, grind, lap, polish, and machine metal parts to the tightest tolerances. Our expertise, inventory, and capabilities provide the skills and capacity to meet the needs of medical device manufacturers. Specialty metals, micron tolerances, low or high volumes, complex metrology — all these and more are the requirements we achieve every day for products shipped worldwide.

Questions? Call Metal Cutting today.

We hope you have found this guide to metal tubing in medical devices to be helpful. We invite you to consult with us for *your* metal tubing and other product needs, including tungsten wire, rod, and other forms of tungsten and molybdenum. We think you'll agree that hearing what we have to say will be one of the best decisions you make.

Call Metal Cutting today at 973-239-1100 or email sales@ metalcutting.com.