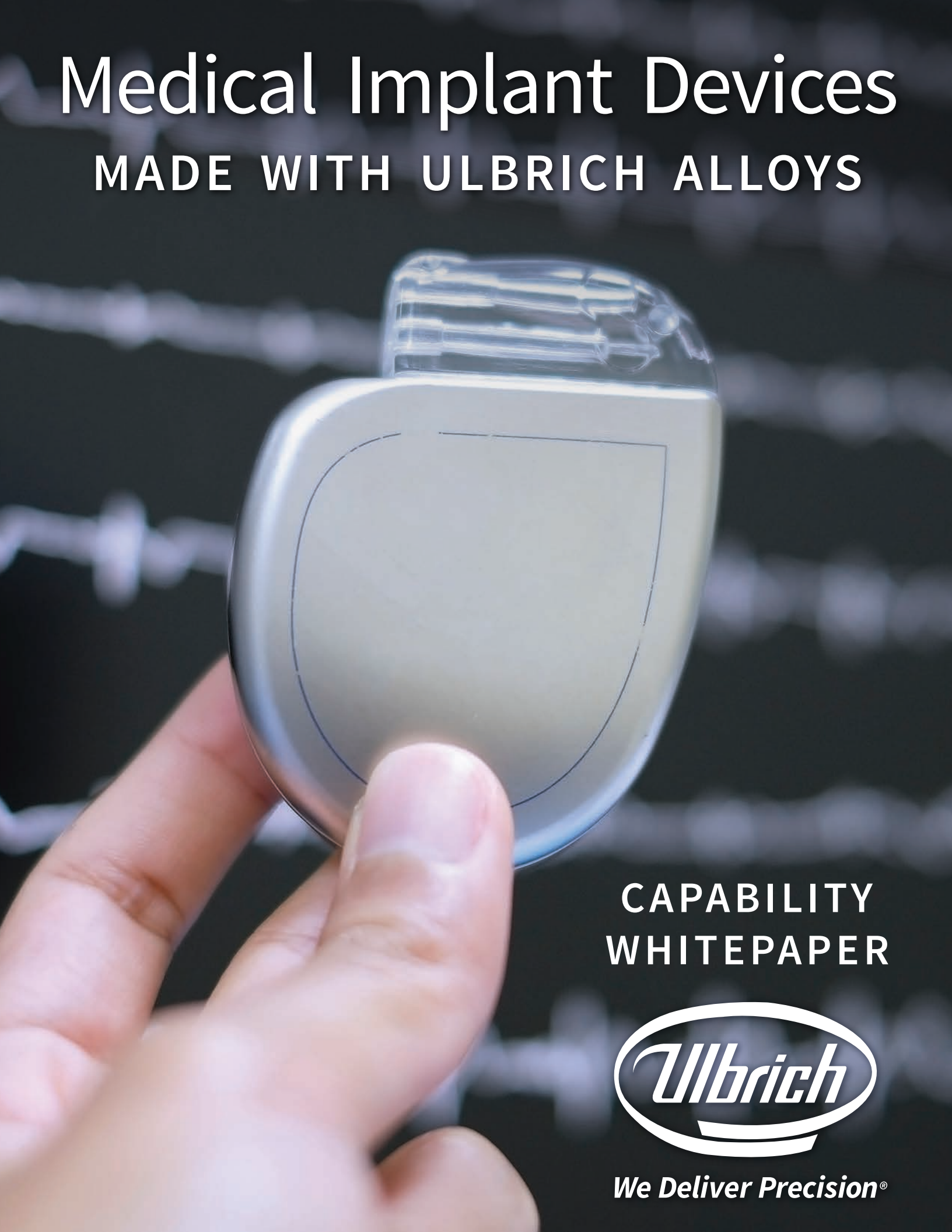
# Medical Implant Devices

## MADE WITH ULBRICH ALLOYS



## CAPABILITY WHITEPAPER

Ulbrich

*We Deliver Precision®*

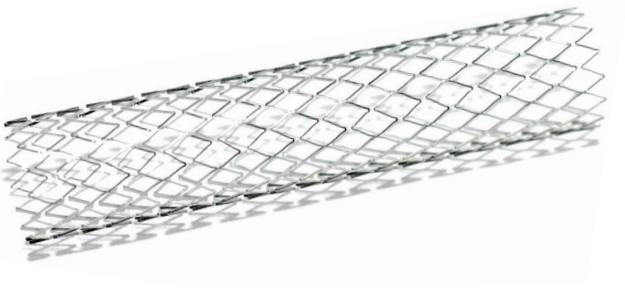
We Deliver Precision®

ULBRICH.COM

CAPABILITY SHEET

# Superior Alloys for Innovative Medical Implant Devices

**ULBRICH'S INNOVATIVE, PRECISION ROLLING AND SHAPING OF STAINLESS STEELS AND SPECIAL METALS PLAYS AN INTEGRAL ROLE IN CREATING LIFE-SAVING MEDICAL IMPLANT DEVICES**

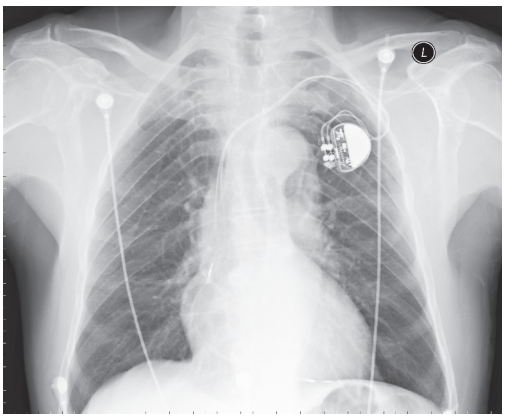


## ALLOYS

- 316LS SS
- 316LVM SS
- Ti Grade 9 (3-2.5)
- Ti Grades 1, 2 & 4
- Nickel 201
- Haynes 25 (L-605)
- Pure Niobium

## APPLICATIONS

- Pacemakers
- Defibrillators
- Hearing Aids
- Battery Components
- Neuro-Stimulation Devices
- Pain Management Devices
- Laser-Cut Stents



## ULBRICH DISTRIBUTES HIGH-QUALITY MATERIALS TO MEET YOUR MEDICAL IMPLANT NEEDS

With industry-leading dimensional control, real-time gauging, and Statistical Process Control (SPC), Ulbrich is able to produce stainless steels and special metals to the exact specifications necessary for medical implant devices. Our wide offering of medical alloys, combined with our world-class service, makes Ulbrich the go-to steel and metal supplier for medical device manufacturers in the world.

## COMBINING THE BEST MATERIALS WITH THE BEST PEOPLE AT ULBRICH

In addition to our large inventory of biocompatible titanium and titanium alloys, corrosion-resistant stainless steels, and pure nickel, the Ulbrich team is able to assist companies with ongoing developmental design efforts while providing technical proficiency, commercial expertise, and a consistent supply of steel and alloys.

# Alloys for Medical Manufacturing

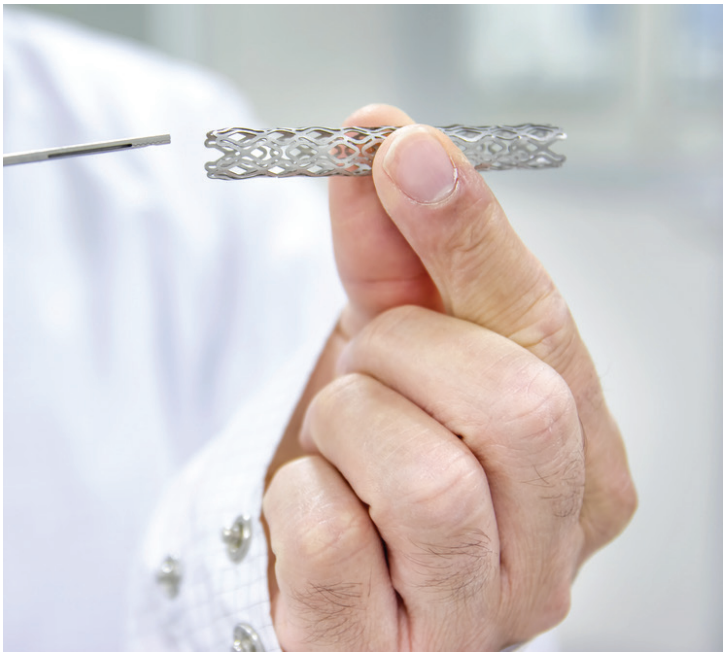
## THINGS TO CONSIDER WHEN EVALUATING WIRE ALLOYS FOR YOUR MEDICAL APPLICATION

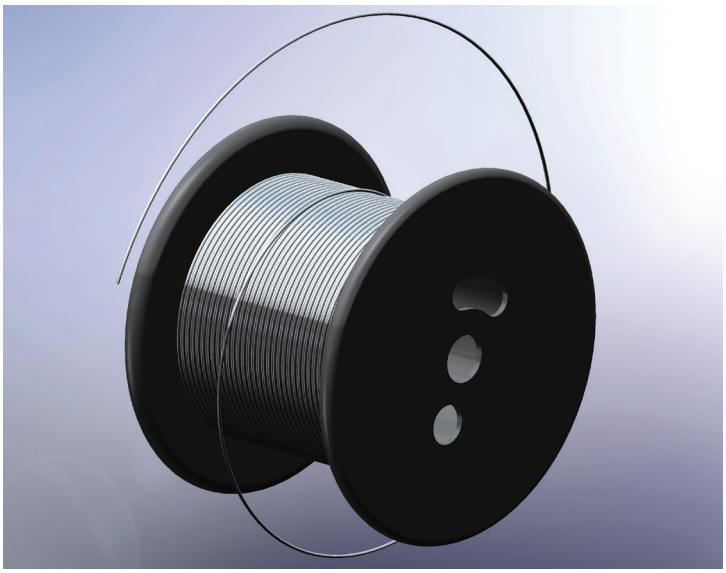
### WHAT ARE THE PROPERTIES TO CONSIDER?

Here is the short answer: any decision on chemical, mechanical and physical properties of metal alloys is highly dependent on what task the medical device will perform and the environment in which it will operate.

End-use applications dictate every single decision that goes into selecting an alloy, determining its shape and size and quantifying the amount of material needed. Other properties medical manufacturers and buyers should consider might be: atomic, electrical, environmental, magnetic, radiological, manufacturing properties such as castability or machinability, and even perhaps thermal properties of the material.

When specifying an alloy for your medical application, correct and uniform chemical properties should be decided upon early in the metal selection process. Taking careful steps to select the right chemical makeup of an alloy allows precision re-rollers or other metal suppliers to source accurate, high quality raw material—that has been smelted or manufactured long before arriving at our loading bays. At Ulbrich, Engineers, Product Managers and seasoned Sales professionals work together to communicate the best route to take in terms of material selection.



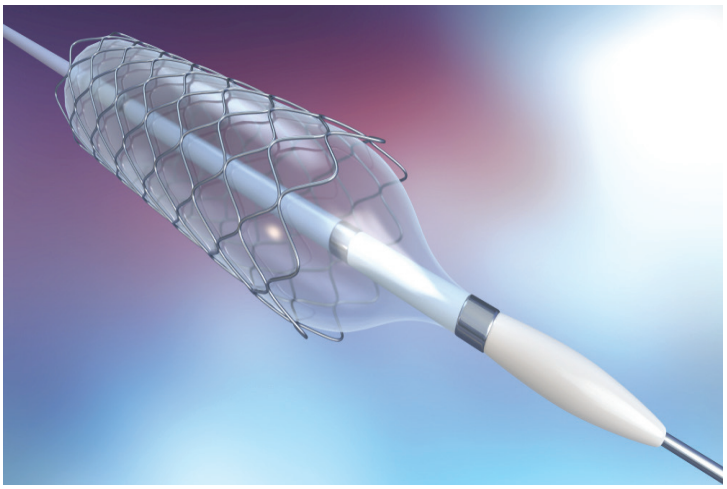


At Ulbrich Specialty Wire Products in Westminster, SC, where most of our medical device customers procure precision round and flat wire, we have medical manufacturing and metallurgical experts who help our customers select and procure the right material with the right properties based on their specific application demands. The most common mechanical properties are high strength and dimensional control for medical braid wire applications. Dimensional control, surface smoothness and elongation have also become of high importance for Mandrel applications.

Mechanical properties and oxide layers related to the specialty metal Nitinol, which is a shape-memory alloy, are known to be critical factors in the medical device industry these days.

Biocompatibility, or the capacity of the human body to adapt to contact with metal such as Titanium, is also a factor that medical manufacturers must often consider. For example, Titanium rods applied in oral surgeries bind to human flesh. The Titanium rods are permanently and effectively set in place making their biocompatibility extremely important to prevent rejection, corrosion, or infection. Titanium is highly biocompatible so it is often used in medical manufacturing such as dental implants, allowing patients to heal quickly and to use their jaw/teeth as if nothing happened.

Many medical manufacturers use a spring temper flat, round or custom shaped wire for their application. Different required characteristics that might be desirable based on manufacturing process or end use might warrant annealed, full-hard, half-hard, and quarter-hard wire which can be provided upon request from wire manufacturers.



The harder the temper, the more rigid the structure will be. This gives a good torque response to the device, which is also known as “torquability”. For example, in the production of catheters, special maneuverability is the key to success, making torquability of the material used in their production a very important requirement.

Catheters are medical devices that can be inserted in the body to treat diseases or perform surgical procedures. Mechanical properties play a huge role in the selection of metal for making catheters, since they are extruded over specialty metals like Nitinol to create catheters. Medical device customers must also decide whether to go with coiled-enforced or braid-enforced catheters for their application. In the production of catheters, many customers are now using Nitinol for coiled catheters used in especially sensitive surgeries where precision is paramount, like neural or cardiovascular surgeries.

## WHAT ARE THE DIFFERENT METHODS FOR ENSURING MATERIAL QUALITY FOR MEDICAL WIRE AND WHAT DO THEY ACCOMPLISH?

Methods for ensuring quality stainless steels and special metals for medical wire should be a big focus, not only for the quality assurance team at your organization, but it should be an expectation of yours that it is the utmost priority of your medical rolling mill.

Continuous dimensional data collection (SPC data) should be collected as the metal runs through the mill because it will improve consistency in the performance for your manufacturing process as well as the medical device. Working closely with metal manufacturers who have trained metallurgists on staff who have knowledge of how metal is shaped and sized at the miniscule, mathematical level is extraordinarily advantageous for medical device manufacturers. This type of quality control ensures that defects are less likely and therefore, time and energy savings are benefitting your medical device or component business and streamlining your production while reducing scrap, waste and failure. Most of all, dimensional data collection assures that materials are within your specifications and meet all regulatory and manufacturing requirements.

Surface cleanliness is another major factor that has an impact on improving or degrading material performance in demanding medical applications. The methods to ensure cleanliness can never be stringent enough, because people’s lives are literally on the line. Precision strip, flat wire and round wire must be as particulate-free as possible to ensure peak results, because anything else could be catastrophic.

Quality Control Coordinators, Machine Operators and Helpers at Ulbrich are continuously inspecting each work order with vigorous attention to detail. Team communication and collaboration are paramount to ensuring quality throughout the supply chain. When selecting a materials partner, you should work to understand if they have the same level of commitment to quality up and down the organizational chart as you would expect. Compliance with the latest ISO certifications are well and good, however, to meet the material needs of medical device customers, special precautions and utmost care should not only be standardized in the process, but engrained in the culture.

Personal Protective Equipment (PPE) is only step one to keeping material free and clear of contaminants. Custom barriers, guards, and other means of contaminant prevention should be installed on the machinery at every stage of material production to protect metal in progress (as well as the Machine Operators) from being compromised. This ensures that the material you receive is ready for, and has been manufactured to, the same level of cleanliness and attention to quality and performance that you set for yourself as a medical manufacturer.

A method on the front end of the manufacturing process starts with purchasing. Buying material from qualified sources and reputable vendors is essential. The chemistry makeup of the material must be carefully inspected while at the same time, inclusion rates should be as low as possible (non-existent in a perfect world).

In choosing a supplier and an alloy, medical device customers must seek those sources who sell materials with consistent and undeviating mechanical properties which are paramount to processing medical wire. Manufacturing sources as well as production methods are equally vital in the supply chain to attaining success in the world of high-tech medical devices.

Lastly, tedious spooling methods to avoid tangles during production are also of high importance. When medical device customers go to use bulk, Steeger or Wardwell bobbins, they do not want any breakages due to tangling wires. With round wire as thin as 0.00075" for nitinol and stainless steel alloys, tangling can cause massive strain on medical device production. Ulbrich cautiously wraps wire on spools with the next operation in mind, and we then ask for feedback on the performance of the spooling.

## WHAT ENVIRONMENTAL OR CONTEXTUAL FACTORS ARE DEVICES SUBJECTED TO THAT CAN AFFECT MATERIAL SELECTION?

Will the device be implanted in the body, or how long will the device be in there? Biocompatibility and response to blood is an essential factor here. MRI Compatibility may also be required depending on your application.

## HOW IMPORTANT ARE THE CORROSION RESISTANT PROPERTIES OF STAINLESS STEEL OR OTHER SPECIAL METAL WIRE FOR MEDICAL DEVICE MANUFACTURING?

Very Important. For example, 304V stainless steel wire has been vacuum arc remelted so that it has a more uniform chemistry with minimal voids and contaminants. 304V SS is a flexible, robust material that can easily be soldered or welded. 304V wire is used in many medical applications because of its low cost compared to other materials that meet the minimum standards for corrosion resistance.

## WHAT ARE COMMON MATERIALS WE SEE MEDICAL MANUFACTURERS TURNING TO?

Bi-metals are becoming more widely used and popularized. Special alloys and various metals like MP35N, a developmental project-based alloy, offer new, high performance capabilities for surgeons. Other bi-metals like Nitinol with a Platinum core (cladded) and a Nitinol with a Tantalum core have received greater exposure in the medical device marketplace as of late. Heavy metals like Platinum, Tantalum and Tungsten show up extremely well under a fluoroscope during cardiovascular surgery, for example, and allows surgeons to see where they are going within the human body.

Though these other special metal alloys have proven to be great alternatives for the medical industry, 304V stainless steel wire is still most often used in the majority of medical applications because the alloy meets the minimum standards for corrosion resistance while still being a safe and productive material.

## WHAT IS CRITICAL TO THE PRODUCTION AND PERFORMANCE OF SURGICAL INSTRUMENTS?

When it comes to surgical instruments, stainless steel alloys—like Austenitics, Martensitics, and PH Grades—that are shaped and designed to perform very specific tasks are critical and common. Alloys used to produce medical instruments should be manufactured to withstand the demands of daily use in healthcare environments, with rigorous attention to detail and quality. From cutting to pricking to stapling, the high-stakes demands of medical devices and surgical instruments require precision manufactured alloys with the exact specifications necessary to perform the job.

## ULBRICH IS DRIVING MEDICAL INSTRUMENT INNOVATION THROUGH PRECISION ALLOYS.

With the help of precision special metals, doctors and workers in the medical field can restore and preserve the health of ailing people. At Ulbrich, we take great pride in the fact that our work plays a part—however big or small—in the health of millions. And that's why we're always holding ourselves, our machines, and our processes to the highest of standards. Because with precision alloys, innovative surgical (increasingly robotic) instruments have the power to transform lives.

Different surgical instruments and incision tools require a diverse range of alloys and alloy characteristics. Choosing the best materials and having them produced to exacting mechanical, chemical, and physical specifications ensures that the resulting product, or component delivers more consistency, less waste, and lower failure rates. Ulbrich has a long history of providing alloys and bi-metals to the medical industry due to our strategic sourcing methods, our huge inventory of alloys, and immense rolling and annealing capabilities. It gives us a competitive advantage that we are able to pass on to our customers. So, whether your medical device requires an alloy to be heat-treated to a higher hardness (such as Precipitation Hardening Grades) or something non-magnetic and highly resistant to corrosion (like Austenitic alloys), we're able to make it happen.

## SURGICAL INSTRUMENTS MADE WITH PRECISION ALLOYS INCLUDE BUT ARE NOT LIMITED TO:

- Scissors
- Sheers
- Surgical Draws
- Catheters
- Needles
- Lances
- Surgical Grills and Grinders
- Surgical Staplers/Anvils
- Stapler Springs, Staples
- Cardiovascular Clamps
- Tissue Grabbers
- Strip Square
- Surgical Robotic Instruments
- and more...

### STAINLESS STEEL:

- 304 Stainless Steel
- 304V Stainless Steel
- 304LV Stainless Steel
- 304LVM Stainless Steel
- 316 Stainless Steel
- 316L Stainless Steel
- 17-4PH Stainless Steel
- 17-7PH Stainless Steel
- 305 Stainless Steel
- 410 Stainless Steel
- 420 Stainless Steel
- 420 High and Low Carbon
- 440A Stainless Steel

### SPECIAL METALS:

- Nitinol
- Titanium
- MP35N
- Copper
- Aluminum
- Tungsten
- Beryllium Copper
- Molybdenum
- Phosphor Bronze
- L605
- and many other "bi-metals"

(combinations of cladded wire that may include Silver or Platinum)

# 316LS and 316LVM Stainless Steel UNS S31673

We Deliver Precision®

**STRIP, COIL, FOIL & WIRE, ASTM F138, ASTM F139, ISO 5832**

## 316LS AND 316LVM ALLOY DESCRIPTIONS

316LS and 316LVM are Stainless Steel grades that are vacuum arc remelted in order to maximize corrosion resistance and provide a ferrite free micro structure. The remelt allows the metal to reach very high levels of purity and cleanliness, making it a great selection for surgical implants. These versions of 316 Stainless Steel contain higher nickel, lower carbon, lower molybdenum and lower chromium content than standard 316L. They are dual certified and often referred to as on another. Both alloys have excellent resistance to pitting, crevice corrosion and physiological environments. All of these characteristics make the alloys a great candidate for both medical applications and high precision electronics.

## APPLICATIONS

- Medical Implants
- Surgical Instruments
- Electronic parts

ULBRICH.COM

# Titanium Grade 9 (Ti 3-2.5) UNS R56320

**STRIP, FOIL, COIL, WIRE, ASTM B265 GR9, MIL-T-9046 AB-5**

## TITANIUM GRADE 9 DESCRIPTION

Titanium Grade 9 (3-2.5 or Half 6-4) is a medium strength alloy with good weldability and fabricability for mildly reducing to mildly oxidizing media. It is a compromise between the facility of welding and manufacturing of the pure grades and the high strength of Grade 5. Containing 3% Aluminum and 2.5% Vanadium, it has great corrosion resistance and can be used extensively in medical, aerospace, chemical processing, marine, and automotive.

## MEDICAL APPLICATIONS

- Implantable battery cases/shields for CRM and Neurostimulation devices

# Titanium Grade 1 (CP TI35A) UNS R50250

**STRIP, COIL, FOIL, WIRE, ASTM F67, ASTM B265 GR1**

## TITANIUM GRADE 1 DESCRIPTION

Commercially Pure Titanium Grade 1 is one of the softest and most ductile titanium grades exhibiting the greatest formability. This unalloyed titanium has excellent corrosion resistance property and excellent weldability.

# Titanium Grade 2 (CP TI40A) UNS R50400

**STRIP, COIL, FOIL, WIRE, ASTM B265 GR2, AMS 4902, ASTM F67, MIL-T-9046CP3**

## TITANIUM GRADE 2 DESCRIPTION

Gr 2 is slightly stronger than Gr 1 but equally corrosion resistant against most applications. This unalloyed titanium has the best strength to weight ratio of any corrosion resistant material. This is one of the most common Ti Grades and can be used for parts requiring strength up to 400° F and oxidation resistance to 600° F.

## COMMERCIALLY PURE TITANIUM GRADE 1 & TITANIUM GRADE 2 MEDICAL APPLICATIONS

- Implantable battery cases/shields for CRM and Neurostimulation devices
- Implantable battery cathodes/connectors
- Stamped or etched fabrications

# Titanium Grade 4 (CP TI75A) UNS R50700

**STRIP, COIL, FOIL, WIRE, ASTM B265 GR4, AMS 4901, ASTM F67, MIL-T-9046CP1**

## COMMERCIALLY PURE TITANIUM GRADE 4 DESCRIPTION

Ti Grade 4 is the highest strength pure unalloyed Titanium with high oxygen and extra high strength. It combines excellent corrosion resistance with good formability and weldability. It can be used for parts requiring strength up to 400° F and oxidation resistance to 600° F.

## MEDICAL APPLICATIONS

- Implantable battery cathodes/connectors
- Stamped or etched fabrications

# Nickel 201 UNS N02201

**STRIP, COIL, FOIL, WIRE, ASTM B162**

## NICKEL 201 DESCRIPTION

Alloy 201 ia a wrought commercially pure Nickel with a maximum carbon level of 0.02%. This alloy provides highly ductile mechanical properties across a wide temperature range. It provides corrosion resistance in neutral to moderately reducing environments. It is used primarily for parts requiring excellent corrosion and strong magnetic properties. Nickel 201 is ferromagnetic. It provides high thermal and electrical conductivity in comparison to nickel-base alloys, stainless and low alloy steels. Because of its low carbon content (.02% max.) Nickel 201 may be considered for service above 600°F (316°C), where alloy 200 with higher carbon content is not recommended.

## MEDICAL APPLICATIONS

- implantable battery anode/connector tabs for CRM and Neurostimulation devices
- stamped or etched fabrications

---

# Haynes® 25 (L-605) UNS R30605

**STRIP, COIL, FOIL, WIRE, AMS 5537**

## HAYNES® 25 (L-605) DESCRIPTION

This cobalt based alloy combines good forming and excellent high temperature properties. The alloy is resistant to oxidation and carburization to 1900°F. Alloy 25 can only be hardened significantly by cold working. Cold working will increase creep strength up to 1800°F and stress rupture strength up to 1500°F. Strain aging at 700-1100°F improve creep and stress rupture strengths below 1300°F.

## MEDICAL APPLICATIONS

- implantable laser-welded balloon stents for Vascular
- stamped/wire EDM, or etched fabrications

---

# Niobium Type 1 Reactor Grade Unalloyed UNS R03400 and Type 2 Commercial Grade Unalloyed UNS R04210

**STRIP, COIL, FOIL, WIRE, ASTM B393**

## PURE NIOBIUM DESCRIPTION

Pure Niobium is a very soft refractory metal with an extremely high melting point and corrosive resistant properties. High thermal/electric conductivity, easily fabricated and bio-compatible.

## MEDICAL APPLICATIONS

- implantable battery inter-connect-ribbons (ICR's) for CRM and Neurostimulation devices

We Deliver Precision®

ULBRICH.COM

## STRIP COIL CAPABILITIES

# Metals for Medical

### STRIP APPLICATIONS:

- Implantable Housings:
  Pacemakers, Hearing Aids, Defibrillators
- Surgical Instruments
- Hypodermic Needles and Shields
- Staple Guns
- Endoscopic Products

### SLITTING CAPABILITIES:

| | |
|---|---|
| **GAUGES** | .0004 — .125 inch (0.010 — 3.175mm) |
| **RIBBON WOUND WIDTH** | .020 in — 48 inch (0.508 — 1220mm) |
| **OSC WOUND WIDTH** | .125 in — 1.5 inch (3.175 — 38.1mm) |

*The full range of widths can be produced on all thicknesses.*

### PACKAGING:

- Oscillate Wound
- Ribbon Wound
- Cut to Length

**#1 ROUND EDGE**

**#3 SLIT EDGE**

**#5 SQUARE EDGE**

### MEDICAL GRADE ALLOYS:

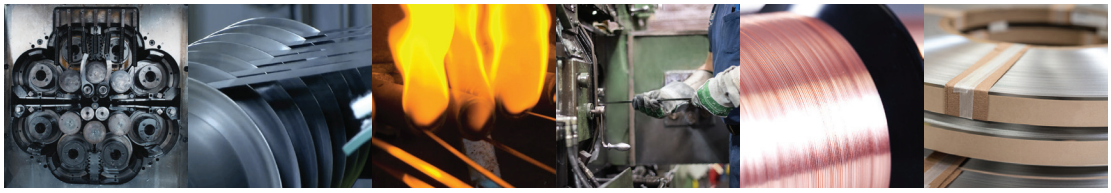
| | |
|---|---|
| **STAINLESS STEELS** | • 301 • 304 • 305 • 316 • 410 • 420 • 440A • 17-7PH • 17-4PH |
| **SPECIALTY METALS** | • Niobium Type 1 • Nickel 201 • Inconel® 625 • Haynes® 25 L-605 |
| **TITANIUM** | • Ti Gr 1 • Ti Gr 2 • Ti Gr 3 • Ti Gr 4 • Ti Gr 9 (3-2.5) • Ti 15-3-3-3 |

We Deliver Precision®

ULBRICH.COM

# Our Industry Leading Capabilities

## DESIGNED WITH YOUR SUCCESS IN MIND



### OVERVIEW OF MANUFACTURING

Our state-of-the-art equipment, technology, and staff make us the go-to stainless steel and special metals producer for numerous manufacturing markets, including the medical, aerospace and automotive industries.

### ROLLING TOLERANCES

Our largest H-mill can handle incoming strip material up to .125” thick, while our smallest Z-mill can roll foil as light as .00039″: an order of magnitude thinner than a human hair.

### SLITTING & EDGING

From Round to Square edge, our slitters have the ability to separate a wide strip into “mults” or narrower strips to achieve your desired width with as much minimized burr as possible.

### ANNEALING

Utilizing hydrogen, nitrogen, and argon controlled atmospheres, we properly anneal all the alloys we offer to satisfy the most demanding specifications of the aerospace, medical, and nuclear industries.

### MATERIAL PROPERTIES

From Bright to Dull or Quarter Hard to Extra Full Hard, Ulbrich has the ability to control your desired surface finish and mechanical properties of your Precision Strip & Wire products.

### COATING & PLATING

Based on your exact requirements, we expertly apply protective coatings with various thicknesses, adhesion properties, colors, and opacity to ensure your product is successfully brought to completion. Additionally, our multiple plating lines, first-rate production capabilities, and expert metallurgists can handle any plating needs you have.

### PACKAGING

With production and shipping capabilities spanning the entire globe, we are able to accommodate steel and metal product packaging and transit to almost any international destination.

# Precision Products & Alloys for Medical

## WE'RE ALWAYS LOOKING FOR WAYS TO INNOVATE AND IMPROVE UPON MEDICAL DEVICES

In addition to our state-of-the-art capabilities in rolling, slitting, and annealing, Ulbrich is continuously testing, researching, and analyzing alloys and their chemical and mechanical properties to maximize performance potential. What does this mean for you? It means when you partner with Ulbrich, you not only get the best of the best in personnel, process, and product—you also get a promise of a team that truly cares about making your medical device as consistently successful and effective as possible.

## GLOBAL REPRESENTATION WITH SERVICE & DISTRIBUTION CENTERS LOCATED WORLDWIDE

Ulbrich Stainless Steels & Special Metals, Inc., is a family owned company in its fourth generation of leadership. Established in 1924, Ulbrich has become a critical supplier of stainless steels and special metals to the Medical Device Industry. During this time, we have participated in the development and manufacturing of hundreds of innovative medical applications. With industry leading Dimensional Control, real time gauging and Statistical Process Control (SPC), a large variety of medical alloys, and the best customer service available, we strive to produce and distribute the highest quality materials to you. Ulbrich is comprised of a series of manufacturing divisions that supply specialty strip and foil, as well as precision flat, fine, round, and shaped wire, all with local management and all designed to provide custom metals products to satisfy the needs of the medical devices original equipment manufacturers.

## YOU HAVE IDEAS. WE HAVE RESOURCES. PARTNER WITH LEADING EXPERTS.

With Ulbrich's world-class Development Innovation Team, you can gain access to product specialists and quality metallurgists, each with expertise that is best-suited for your unique raw material needs. Our team can deliver custom material solutions to maximize the performance of your application. Talk to a specialist today to learn about what finishes, edge capabilities, mechanical properties, packaging and lengths we can offer for your application! Learn more about our Development Partnership online at **www.ulbrich.com/company/development-partnership**

Contact Ulbrich For Your Medical Needs!

**info@ulbrich.com** | **800-243-1676**



Ulbrich

*We Deliver Precision®*

**ULBRICH.COM**