Special Metals Make Unparalleled

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From traditional metals such as titanium and copper to more modern alloys like Nitinol, the metals industry continues to meet the needs for advancing the medical device industry.

Around the world, people are living longer with more active lifestyles thanks to continuing advancements in medical technology. This evolution in technology stems from the development of sophisticated metals and alloys that are finding new uses in internal and external medical applications. From improvements in diagnostic guide wires to new alloys for permanent implants in the body, metals continue to find new uses.

Titanium has been a consistent performer for a number of years, tantalum is emerging, and copper is re-emerging, while advancements in technology are creating a worldwide demand for a variety of other metals along with new versions of long-established standards. Niobium and Nitinol are ideal for use in both internal and external medical applications. The metals industry has a long history of innovation, development, and processing metals and alloys, in step with medical devices development—from tiny screws for the smallest implants to complex surgical tools operated robotically. A large segment of the medical-metals market is the production of materials for hypodermic needles. Hypodermic-needle manufacturers use various production processes, but most needles are fabricated from flat strip or flat foil product, which are roll formed, welded into a tube, and redrawn to different needle diameters.

Wide variety of metals and uses

Titanium is the acknowledged workhorse metal used in medical applications, particularly in internal applications. It resists corrosion and connects to human bone when properly treated, with fewer negative reactions than other metals. Osseointegration is a unique phenomenon where the body's natural bone and tissue bond to the titanium implant, which firmly anchors the implant in place. Titanium is also a staple in the medical field for uses such as shields for implanted devices that control heart function; products that dispense medicine and perform various neuro-stimulation; and orthopedic rods, pins, and plates.

Pure titanium has low density, high strength, and high corrosion resistance. Titanium is a good candidate material when processing or forming into subassemblies or finished components. It is considered to be physiologically inert. Titanium alloys Ti-6Al-4V and Ti-6Al-4V ELI are especially nonreactive with fluids in the human body, and are commonly used in medical devices due to the low risk of rejection [1].

The human body accepts titanium much more readily than other metals, including stainless steel. Some of the most common uses for titanium are in orthopedic surgery (specifically back surgery), and as hip, knee, and shoulder- and elbow-joint replacements. Some forms of replacement heart valves use titanium housings or material support rings. Titanium pegs are used to attach prosthetic eyes and ears as a result of recent medical advances. For example the P-KTM Sleeved Peg System is used to couple the Bio-eye hydroxyapatite (HA) orbital implant (a registered trademark of Integrated Orbital Implants, San Diego, Calif.) to the artificial eye to create a fully integrated motility prosthesis. Titanium is a standard shield material in such implanted medical devices as pacemaker cases and centrifuges due to its resistance to attack by body fluids, high strength, and low modulus [2].

In addition to its use inside the body, titanium is an ideal choice for surgical instruments, such as drills, forceps, retractors, scissors, nee-

Nitinol strip before forming into wire.

Nitinol arch wires for dental braces.

Medical Devices Possible

dle holders, and Lasik eye-surgery equipment. The metal does not interfere with medical tests requiring MRIs or CT scans.

Niobium: There is growing interest in niobium and its alloys for use in medical devices. It is frequently found in devices such as pacemakers because the metal is physiologically inert. Niobium treated with sodium hydroxide forms a porous layer that aids osseointegration, which also makes it an attractive alternative for internal medical applications.

Tantalum is another increasingly popular metal that is highly corrosion resistant and has been used in medical devices as simple as diagnostic marker bands for more than 50 years. Tantalum is especially useful in shaped-wire applications, and its corrosion resistance makes it attractive for implants.

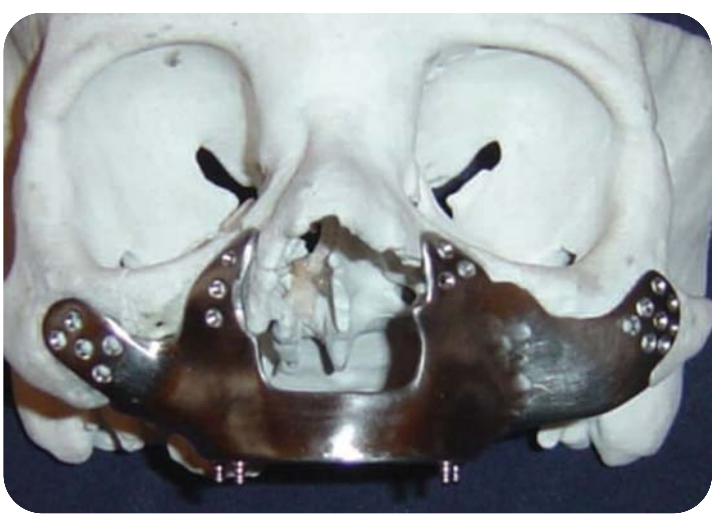
Pure tantalum is ideal for use in permanent bone implants and other uses including vascular clips, flexible stents to prevent arterial collapse, and in repairing bone fractures. It is not ferromagnetic, and therefore, is MRI compatible.

Nitinol is a nickel-titanium (about 51% Ni) shape memory alloy with superelastic properties—a reversible response to an applied stress. Shape memory refers to Nitinol's ability to undergo deformation at one temperature, and then recover its original shape upon heating above its transformation temperature. Nitinol's extraordinary ability to accommodate large strains, coupled with its physiological and chemical compatibility with the human body have made it an often sought after material in medical device engineering and design.

Nitinol devices, such as stents, can be fabricated at one temperature, deformed or folded smaller at another temperature, then inserted into an artery where the body heats the material above its transformation temperature where it returns to its original size. Thus, a stent can be inserted when small, and expand after insertion, opening up the vein or artery where it was placed. Its superelastic effect allows use of Nitinol devices that have been bent or shaped to allow introduction or use inside the body. Tools such as small grasping and biopsy devices can extend from a tube and expand to a much larger area than devices made from standard alloys.

Nitinol's light weight and unique properties make it especially attractive for use in biomedical applications including heart valve tools, stents, staples, bone anchors, sophisticated septal defect devices, and a variety of implants. Its medical uses include devices for reconnecting intestines after surgery, implantable stents, diagnostic guide wires and repositionable wire markers to locate

Pacemaker-related components made of a titanium alloy.



Titanium surgical face plate.

Rolling tantalum strip.

breast tumors for less invasive lumpectomy procedures in treating breast cancer.

Copper: Recently, the medical industry became interested in copper, which previously was off limits for most medical purposes, particularly any internal device. At the heart of this interest is the fact that properly shielded copper can be effectively used to carry signals to small implants and diagnostic tools. Leading manufacturers and processors of copper for medical devices typically produce the shielded metal wire or strips on their own dedicated equipment to maintain 100% quality control and avoid outside contamination.

Copper is ductile with very high thermal and electrical conductivity. Pure copper is relatively soft and malleable. It is easily worked, and the ease with which it can be drawn into wire in addition to its excellent electrical properties makes it useful for medical electrical devices when properly shielded. Due to its high conductivity, it is possible to embed smaller copper wires into devices to send or receive signals or carry electrical charges to accomplish tasks inside the body.

Copper ions are soluble in water, where they function at low concentration as bacteriostatic substances, fungicides, and wood preservatives. For this reason, copper can be used as an antigerm surface that can add to the antibacterial and antimicrobial features of buildings such as hospitals. Uses in hospital clothing, linens, and other products are being explored as a means of reducing infection rates.

Conclusion

Successful applications of the above metals result from manufacturers working closely with end users, starting with the desired design and materials specifications, through to completion of a device. The creators of medical devices typically engage early and maintain a dialogue with metals manufacturers from the design through production stages. ❍

References

1. Gratton, B. Buford, T. Goswami, D. Gaddykurten, and L. Suva, Research paper: Fatigue Behavior of Biomedical Implants, www.atu.edu/ces/drgoswami/biomat.pdf.
2. U.S. Patent 5169597: Biocompatible low modulus titanium alloy for medical implants, J. Davidson, P. Kovacs, www.freepatentsonline.com/5169597.html.

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