Heat Treatment of Medical Device Fasteners

by Daniel H. Herring

Fasteners are used extensively throughout the medical device industry (e.g., dental & orthopedic implants, instruments), utilizing literally hundreds of different shapes and styles to keep the assemblies intact. Even though the components in the medical devices are small or even tiny, when a fastener fails, the device will almost always fail as well.

The correct fastener ensures that the device goes together and stays together for the intended life of the assembly, and that the device performs as desired. The right fastener can reduce the overall cost of a medical device and improve the quality of the entire assembly.

Medical devices fall into two broad categories, surgical/non-implant devices and implantable devices.

Figure 1. Surgical Staples

Surgical & Non-Implant Medical Devices

Examples of non-implant medical devices would be surgical and dental instruments, surgical staples **(Fig. 1)**, dental impression trays, guide pins, hollowware, hypodermic needles, steam sterilizers, storage cabinets and work surfaces, and thoracic retractors to name a few. The desired characteristics for these products are good corrosion resistance and moderate strength with applications often using a variety of stainless steels that can be easily formed into complex shapes.

Implantable Medical Devices

Surgical implants are also manufactured from specific grades of stainless steel, both austenitic and high-nitrogen austenitic types. Examples include aneurysm clips, bone plates and screws, femoral fixation devices, intramedullary nails and pins.

The vast majority of orthopedic implants **(Fig. 2)** are manufactured from titanium (e.g., Ti-6Al-4V alloy) or cobalt-based alloys (e.g., ASTM F75 or cobalt-chromium-molybdenum alloys). They are manufactured from castings, forgings, or bar stock.

Medical application examples include joints for ankles, elbows, fingers, knees, hips, shoulders and wrists as well as pins, bone plates, bone reamers **(Fig. 3)**, screws, bars, rods, wires, dental posts **(Fig. 4)**, expandable rib cages, spinal fusion cages, finger and toe replacements, hip and knee replacements and maxio-facial prosthetics.

Figure 2. Load of Knee Implants after Heat Treatment (Photograph Courtesy of Solar Atmospheres, Inc.)

The benefits titanium offers are high strength & strength-to-weight ratio, corrosion resistant, non-toxic & biocompatible, excellent fatigue and fracture resistance, non-magnetic characteristics, life, cost, and flexibility and elasticity that rival that of human bone.

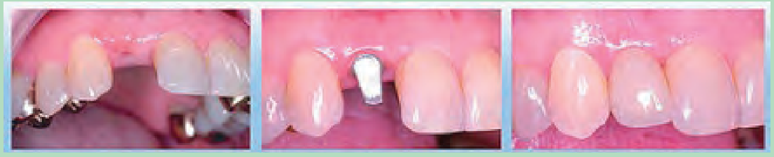
Types of Titanium Alloys

Titanium alloys are classified in four (4) main groups based on the types and amounts of alloying elements they contain:

- **Alpha (α) alloys** – cannot be strengthened by heat treatment; low-to-medium strength, good notch toughness, and good creep resistance (superior to beta alloys) at somewhat elevated temperatures. They are formable and weldable.
- **Near alpha phase alloys** – medium strength and good creep resistance.
- **Alpha-beta (α–β) alloys** – strengthened by heat treatment; medium to high strength, high formability, good creep resistance (but less than most alpha alloys), alloys with beta content less than 20% are weldable. The most familiar alloy in this category is Ti-6Al-4V.
- **Beta (β) alloys** –strengthened by heat treatment; high strength, and fair creep resistance.

Some alloying elements (e.g., Al, Ga, Ge, C, O, N) raise the alpha-to-beta transition temperature (alpha stabilizers) while others (e.g.,

Figure 4. Dental Implant Posts (Photo Credit: Dentist in Goa via Flickr)



Implant body under gum *Abutment or core* *Crown on Implant*

Mo, V, Ta, Nb, Mn, Fe, Cr, Co, Ni, Cu, Si) lower the beta transition temperature (beta stabilizers).

Other Uses for Titanium Alloys

In addition to medical devices, titanium and its alloys have experienced rapid growth in the industrial, commercial aerospace and military aerospace segments. Non-medical applications include:

- Manned and unmanned aircraft (e.g., commercial & military aircraft, rotorcraft)
- Artillery (e.g., howitzers)
- Military Vehicles (e.g., tanks, hovercraft)
- Naval and marine applications (e.g., surface vessels, submarines)
- Turbines (e.g., power generation)
- Chemical processing plants (e.g., petrochemical, oil platforms)
- Architecture (e.g., sculptures)
- Automotive (e.g., motorcycles, performance automobiles)
- Pulp and paper industry (e.g., washing & bleaching systems)
- Consumer electronics (e.g., batteries, watches)
- Sports equipment (e.g., bicycle frames, golf clubs)

Types of Heat Treatment

Due to the complexity of titanium heat-treating it is important to understand the properties required for the end-use application including strength, ductility and microstructure.

While pure titanium is soft and relatively weak, heat-treating can significantly enhance its properties. Titanium and titanium alloys are heat treated in order to:

Reduce residual stresses developed during fabrication (stress relieving);

- Produce an optimum combination of ductility, machinability, and dimensional and structural stability (annealing);
- Increase strength (solution treating and aging);
- Optimize specific properties such as fracture toughness, fatigue strength, and high-temperature creep strength or create specific conditions in the material.

Standard heat treatments are typically done in vacuum style furnaces or in inert (argon) atmosphere furnaces and include:

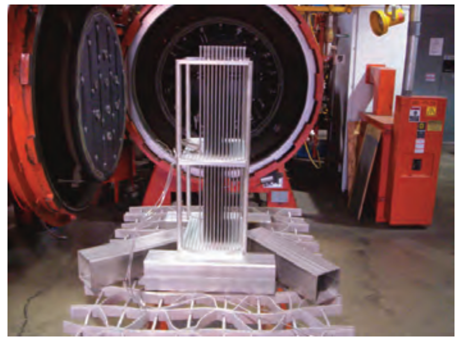


Figure 3. Load of Bone Reamers After Heat Treatment (Photograph Courtesy of Solar Atmospheres, Inc.)

- **Annealing** –increases fracture toughness and ductility (at room temperature) as well as dimensional stability and improved creep resistance. Annealing may be necessary following severe cold work and to enhance fabrication and machining.
- **Homogenizing** – for improved chemical homogeneity in castings.
- **Solution Treating and Age Hardening (Aging)** –a process of heating into the beta or high into the alpha-beta region, quenching, and then reheating again to the alpha-beta region. A wide range of strength levels is possible; fatigue strength increases while ductility, fracture toughness, and creep resistance is enhanced.
- **Stress Relief** –used to reduce residual stresses during fabrication or following severe forming or welding to avoid cracking or distortion and to improve fatigue resistance. Strength and ductility will not be adversely affected and cooling rate is not critical.
- **Tempering** – When titanium is quenched from an elevated temperature, reheated to a temperature below the beta transus, held for a length of time and again quenched, it is said to have been tempered. Three variables exist in tempering: the phases present, the time held, and the tempering temperature.

Custom heat treatments include:

- **Beta Vacuum Annealing & Vacuum Aging** – improves fatigue and yield strength as well as elongation in alloys such as Ti-5553 (Ti-5Al-5V-5Mo-3Cr).
- **Brazing** – induction, resistance and furnace brazing in an argon atmosphere or in vacuum; torch brazing is not applicable. Cleanliness is important to avoid contamination.
- **Creep Forming** – takes advantage of the fact that titanium moves and takes a set at temperature.
- **Degassing** – involves removing of entrapped gases such as hydrogen (to under ← 50 ppm) to avoid embrittlement.
- **Diffusion bonding** – primarily in powder metallurgy where individual particles fuse together from intimate contact of their surfaces.
- **Hydriding/Dehydriding** – the deliberate addition of hydrogen to embrittle the material followed by the removal of the hydrogen after crushing the material into powder. These are the basic steps in the production of titanium powders.
- **Isothermal Transformation** – involves quenching an alloy from the all beta region into the alpha-beta field, holding and then continuing to quench to room temperature. Treatment in this way causes precipitation of the alpha phase from the beta.
- **Sintering** – typically involving hot isostatic pressing and laser sintering of powder particles to form near net shape components.
- **Carburizing** – to enhance the wear and strength properties, especially for repair devices **(Fig. 5)**.

Practical Considerations – What's Important

The heat treatment of titanium and titanium alloys is commonly done in a vacuum furnace **(Fig. 6)**. Since many titanium parts are often limited by volume rather than weight, heat treat furnace capacity is an important consideration. Load support is a critical issue in many applications to prevent creep or other dimensional changes, especially on intricate or complex part geometries typical in a medical device.

Temperature measurement and control must be exact, usually ± 5.5°C (±10 °F) or better throughout the entire working zone of the furnace. Work thermocouples are needed; part temperature not just the furnace temperature must be known. Caution: when heating parts over 945°C (1730°F) titanium cannot be in contact with a nickel alloy or stainless steels since eutectic melting will occur. The use of hydrogen is also strictly prohibited.

Figure 6. Typical Vacuum Furnace (Photograph Courtesy of Solar Atmospheres, Inc.)

Figure 5. Hip Repair Screw After Heat Treatment (Photograph Courtesy of Midwest Thermal-Vac)

Vacuum pumping systems must be capable of reaching high vacuum levels, 1 x 10-5 Torr or lower before starting to heat. This vacuum level must be maintained while heating (requiring very slow ramp rates) as well as when at temperature. Diffusion pumping systems must be properly maintained for maximum efficiency and to avoid backstreaming.

Since titanium is a strong getter material, vacuum furnace interiors must be pristine; ideally, all metal hot zones and dedicated furnaces are desired, but graphite lined furnaces also used for other processes are typical throughout the industry as a practical necessity. Thus, fixtures and furnaces must be "baked out" (cleaned) before use typically at 1150°C - 1315°C (2100°F - 2400°F).

In Conclusion

Fasteners are at the heart of the medical device industry and heat treatment plays a critical role in the manufacturing process. Whether using titanium, cobalt-based super alloys, stainless steels or tungsten carbide, proper heat treatment to maximize mechanical and metallurgical properties is essential for both implantable and non-implantable applications.

References

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