DATA SHEET No 12
Titanium for Medical Applications

(1st August 2001)

The high strength, low weight, outstanding corrosion resistance possessed by titanium and titanium alloys have led to a wide and diversified range of successful applications which demand high levels of reliable performance in surgery and medicine as well as in aerospace, automotive, chemical plant, power generation, oil and gas extraction, sports, and other major industries.

More than 1000 tonnes (2.2 million pounds) of titanium devices of every description and function are implanted in patients worldwide every year. Requirements for joint replacement continue to grow as people live longer or damage themselves more in by hard sports play or jogging, or are seriously injured in road traffic and other accidents. Light, strong and totally bio-compatible, titanium is one of few materials that naturally match the requirements for implantation in the human body

Medical grade titanium alloys have a significantly higher strength to weight ratio than competing stainless steels. The range of available titanium alloys enables medical specialists designers to select materials and forms closely tailored to the needs of the application. The full range of alloys reaches from high ductility commercially pure titanium used where extreme formability is essential, to fully heat treatable alloys with strength above 1300 MPa, (190ksi). Shape–memory alloys based on titanium, further extend the range of useful properties and applications. A combination of forging or casting, machining and fabrication are the process routes used for medical products. Surface engineering frequently plays a significant role, extending the performance of titanium several times beyond its natural capability.

Titanium Performance in Medical Applications

'Fit and forget', is an essential requirement where equipment in critical applications, once installed, cannot readily be maintained or replaced. There is no more challenging use in this respect than implants in the human body. Here, the effectiveness and reliability of implants, and medical and surgical instruments and devices is an essential factor in saving lives and in the long term relief of suffering and pain. Implantation represents a potential assault on the chemical, physiological and mechanical structure of the human body. There is nothing comparable to a metallic implant in living tissue. Most metals in body fluids and tissue are found in stable organic complexes. Corrosion of implanted metal by body fluids, results in the release of unwanted metallic ions, with likely interference in the processes of life. Corrosion resistance is not sufficient of itself to suppress the body's reaction to cell toxic metals or allergenic elements such as nickel, and even in very small concentrations from a minimum level of corrosion, these may initiate rejection reactions. Titanium is judged to be completely inert and immune to corrosion by all body fluids and tissue, and is thus wholly bio-compatible.

The natural selection of titanium for implantation is determined by a combination of most favourable characteristics including immunity to corrosion, bio-compatibility, strength, low modulus and density and the capacity for joining with bone and other tissue - osseointegration. The mechanical and physical properties of titanium alloys combine to provide implants which are highly damage tolerant. The human anatomy naturally limits the shape and allowable volume of implants. The lower modulus of titanium alloys compared to steel is a positive factor in reducing bone resorbtion. Two further parameters define the usefulness of the implantable alloy, the notch sensitivity, - the ratio of tensile strength in the notched vs un-notched condition, and the resistance to crack propagation, or fracture toughness. Titanium scores well in both cases. Typical NS/TS ratios for titanium and its alloys are 1.4 - 1.7 (1.1 is a minimum for an acceptable implant material). Fracture toughness of all high strength implantable alloys is above 50MPa$m^{-1/2}$ with critical crack lengths well above the minimum for detection by standard methods of non-destructive testing.

Titanium Medical Specifications

Forms and material specifications are detailed in a number of international and domestic specifications, including ASTM and BS7252/ ISO 5832 examples overleaf:

ASTM	BS/ISO	Alloy(s) designation (s)
F67	Part 2	Unalloyed titanium – CP Grades 1 – 4 (ASTM F1341 specifies wire)
F136	Part 3	Ti-6Al-4V *ELI* wrought (ASTM F620 specifies ELI forgings)
F1472	Part 3	Ti-6Al-4V *standard grade (SG)* wrought F1108 specifies *SG* castings)
F1295	Part 11	Ti-6Al-7Nb wrought
-	Part 10	Ti-5Al-2.5Fe wrought
F1580	- -	CP and Ti6Al-4V *SG* powders for coating implants
F1713	- -	Ti-13Nb-13Zr Wrought
F1813	- -	Ti-12Mo-6Zr-2Fe Wrought

Bone and Joint Replacement

About one million patients worldwide are treated annually for total replacement of arthritic hips and knee joints. The prostheses come in many shapes and sizes. Hip joints normally have a metallic femoral stem and head which locates into an ultrahigh molecular weight low friction polyethylene socket, both secured in position with polymethyl methacrylate bone cement. Some designs, including cementless joints, use roughened bioactive surfaces (including hydroxyapatite) to stimulate osseointegration, limit resorption and thus increase the implant lifetime for younger recipients. Internal and external bone-fracture fixation provides a further major application for titanium as spinal fusion devices, pins, bone-plates, screws, intramedullary nails, and external fixators.

Dental Implants

A major change in restorative dental practice worldwide has been possible through the use of titanium implants. A titanium 'root' is introduced into the jaw bone with time subsequently allowed for osseointegration. The superstructure of the tooth is then built onto the implant to give an effective replacement.

Maxillo and Cranio/facial treatments

Surgery to repair facial damage using the patients own tissue cannot always obtain the desired results. Artificial parts may be required to restore the ability to speak or eat as well as for cosmetic appearance, to replace facial features lost through damage or disease. Osseointegrated titanium implants meeting all the requirements of bio-compatibility and strength have made possible unprecedented advances in surgery, for the successful treatment of patients with large defects and hitherto highly problematic conditions.

Cardiovascular devices

Titanium is regularly used for pacemaker cases and defibrillators, as the carrier structure for replacement heart valves, and for intra-vascular stents.

External Prostheses

Titanium is suitable for both temporary and long term external fixations and devices as well as for orthotic calipers and artificial limbs, both of which use titanium extensively for its light weight, toughness and corrosion resistance.

Surgical Instruments

A wide range of surgical instruments are made in titanium. The metal's lightness is a positive aid to reducing any fatigue of the surgeon. Instruments are frequently anodised to provide a non reflecting surface, essential in microsurgical operations, for example in eye surgery. Titanium instruments withstand repeat sterilisation without compromise to edge or surface quality, corrosion resistance or strength. Titanium is non magnetic, and there is therefore no threat of damage to small and sensitive implanted electronic devices.

FOR FURTHER INFORMATION CONTACT

TIG, tel. +44 (0) 1709 722 463
Fax. +44 (0) 1709 724 999, enquiries@titaniuminfogroup.co.uk
www.titaniuminfogroup.co.uk