



Titanium Powder and its Alloys for Medical Applications

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Introduction

Reading Alloys Inc. (RAI) has been manufacturing master alloys for over 50 years, and is well known in both the Titanium and Aerospace industries. Master alloys are typically supplied in the size range of 6.3mm (¼ inch) to 212µm (70 mesh) and are used, for example in the production of Titanium alloys by providing Aluminum, Vanadium, Tin, Molybdenum, Chromium, and Iron alloying elements. These Titanium alloys exhibit high strength and low density, which make them ideally suited for aerospace applications.

Titanium and its alloys also exhibit other important key characteristics, such as high corrosion resistance and very good biocompatibility, and are also used extensively in implantable medical applications [1]. As the technology of implantable devices continues to improve, the working life of these components continues to get longer, and patients are electing to consider replacement surgery at an earlier age than before. This makes implantable medical devices an interesting business growth area.

Ti and its alloys are used to make both the implants as well as modifications to the implant surface. This article will focus on the key powder characteristics needed for modification of the implant surface. [2] These surface modifications are designed to increase surface roughness and enhance adhesion and bone growth onto the implant. The key powder characteristics that will be discussed are powder morphology, chemistry and particle size distribution and their impact on the finished medical device.

Discussion

Over the past five years RAI has been developing and expanding its product range to include metal and alloy powders in the range of 300µm (50 mesh) to 45µm (325 mesh). The focus of this work has been on manufacturing pure Titanium and Titanium - 6wt% Aluminum - 4wt% Vanadium, (Ti-6-4) and other associated alloy powders. The RAI manufacturing process is based on the Hydride-Dehydride (HDH) route, which relies upon the brittle nature of some metal hydrides that can be milled and screened to produce fine powders. After the powder has been sized the interstitial Hydrogen is then removed using high vacuum and heat to produce the finished metallic powders. Medical powders are then magnetically screened and acid washed to remove any

free Iron, in order to avoid any contamination issues. A schematic drawing of the process route is given in Figure 1.

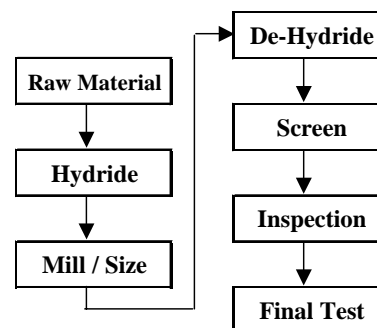


Figure 1. Process Flow for HDH Route.

The morphology of finished medical powder is strongly influenced by the structure of the starting raw material. If wrought type raw materials are used then the finished morphology is very angular, but if sponge type raw materials are used then the finished morphology is more rounded and the powder particles remain porous as shown in SEM images in Figure 2.

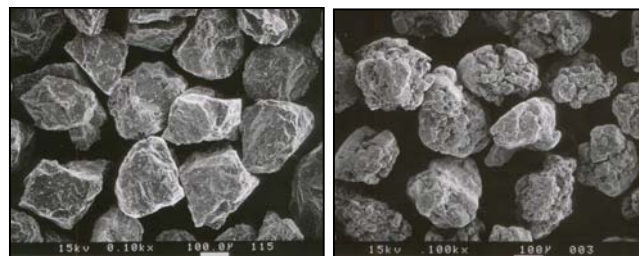


Figure 2. Morphology of Fine Titanium Powder.

For medical applications the finished chemistry of the fine powder is very important. RAI uses its Nadcap certified laboratory to determine and certify chemistry against customer and industry standard specifications such as;

- ISO 5832-2, Implants for Surgery - Metallic Materials, Part 2 Unalloyed Titanium, Chemical Composition,
- ASTM F 1580-1, Titanium and Ti-6Al-4V Alloy Powders for Coatings of Surgical Implants, as shown in Figure 3.

For medical Titanium applications Oxygen is a critical impurity as is directly impacts strength and ductility.

Titanium has a very strong affinity for Oxygen forming a very stable surface oxide layer. Control of the entire manufacturing process is critical to produce low Oxygen powder. The stable surface Oxide layer also impacts very fine powders with high surface area to volume ratio, which can significantly increase the final powder Oxygen content.

Elements	Unalloyed Ti Powder		Ti-6Al-4V Powder	
	Weight Percent		Weight Percent	
	Min	Max	Min	Max
Aluminum			5.50	6.75
Vanadium			3.50	4.50
Oxygen		0.40		0.20
Iron		0.50		0.30
Carbon		0.10		0.08
Hydrogen		0.05		0.015
Nitrogen		0.05		0.05
Copper				0.10
Tin				0.10
Silicon		0.04		
Chlorine		0.20		
Sodium		0.19		
Titanium	balance		balance	

Figure 3. ASTM F 1580-1 Chemistry Limits.

Different coating process equipment and process routes require unique powder particle size distributions (PSD) in order that the powder correctly bonds with the underlying implant surface. As a rule of thumb the applied powder coating needs to be as rough as possible and must stay bonded to the implant. The implantable device will also be exposed to high cycle fatigue, so if the powder coating-bonding process creates localized stress concentration defects, this will significantly reduce the functionality of the implantable device. [3] Medical coating users take great care in specifying the morphology and PSD requirements for their process, and in many cases will have as many as five or more PSD specifications depending on the medical device being treated.

Control of the finished particle size distribution is another critical powder parameter. Many medical coating users specify sieving screen analysis using US screen sizes (mesh or microns) for powders. For some finer powder grades, laser PSD measurement is preferred which significantly increases the PSD resolution below 75um (200 mesh). RAI offers either Microtrac or Malvern laser PSD certification. Laser PSD values are reported in microns and as a percentile value of the total particle size distribution, i.e. D_{10} , D_{50} and D_{90} value. Also specified against each percentile value will be a +/- tolerance value. A representative Microtrac powder distribution is shown in Figure 4.

Reading Alloys Inc. offers a full range of medical grade Ti and Ti-6Al-4V powders to meet customer specific or standard commercial specifications. RAI continues to develop its powder products in order to meet specific demands, and work with new and existing customers on new alloy powder developments for Medical, Powder Metallurgy and Injection Molding applications.

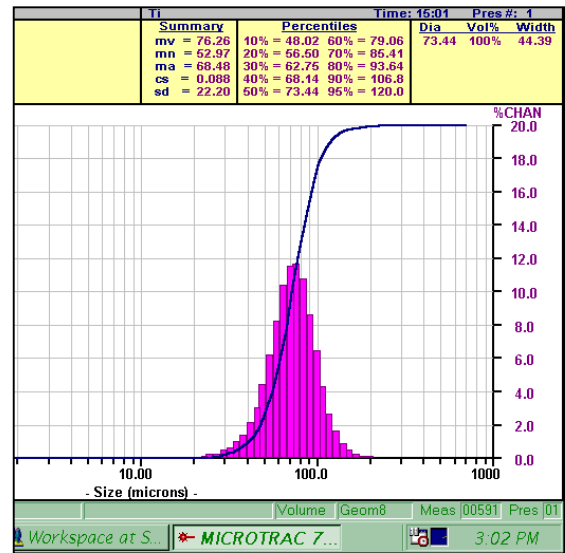


Figure 4. Microtrac Particle Size Distribution for a Typical Medical Titanium powder.

Conclusions

Titanium and its alloys are used extensively for coating the surface of implantable medical devices to accelerate bone growth and the healing process. Along with its very high biocompatibility, RAI's medical grade Ti powders meet the highest standards in composition and chemical purity. The coating of implantable devices requires control of other key powder characteristics such as morphology and particle size distribution, which are engineered to meet each customer's specific requirements.

References

1. K. Merritt and S.A. Brown, *Metal Sensitivity Reactions to Orthopedic Implants*, Int. J. Dermatol., Vol20 March 1981 p 89-94.
2. H. Hahn, P.J. Lare, R.H. Rowe, Jr., A.C. Fraker, and F. Ordway, *Mechanical properties and structure of Ti-6Al-4V with graded porosity coatings applied by Plasma-Spraying for use in Orthopedic Implants*, American Society for testing and Materials, 1985, p 179-191.
3. T. Smith, *The effect of Plasma-Sprayed Coatings on the Fatigue of Titanium Alloy Implants*. JOM, Feb 1994, p54-56.