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TITANIUM IN MEDICINE PANEL PRESENTATIONS (PART I)

Titanium applications in the medical sector will be on display at TITANIUM 2010, the 26th annual conference and exhibition, which will be held Oct. 3-6 at the Gaylord Palms Hotel and Convention Center, Kissimmee, FL. Prof. Lyle Zardiackas, professor emeritus, University of Mississippi Medical Center, Jackson, MS, will serve as the moderator for the first of two speaker panels addressing titanium's advances in the field of healthcare. Allegheny Technologies Incorporated will sponsor the session.

Prior to becoming professor emeritus two years ago, Zardiackas served as the chair of the Department of Biomedical Materials Science, and Professor, Department of Orthopaedic Surgery, School of Medicine, at the University of Mississippi Medical Center. Zardiackas and his University of Mississippi Medical Center associates--Michael D. Roach, doctoral student in biomedical materials science and Randall "Scott" Williamson, graduate studies in biomedical materials science--will begin the discussion by presenting a paper on "Recent Advancements in Laboratory Instrumentation and Analysis Techniques to Characterize Fatigue Mechanisms in Metallic Alloys."

As stated in an abstract preview, recent advancements in laboratory instrumentation and advanced evaluation techniques available for materials characterization are greatly advancing the knowledge base on fatigue mechanisms in a variety of materials including titanium and stainless steel alloys. The combination of electron backscattered diffraction (EBSD) and atomic force microscopy (AFM) analysis at selected intervals throughout the fatigue life of a sample provides valuable information on the slip and crack initiation mechanisms taking place. Once a fatigue crack has been initiated in the analysis area, additional information on the crack propagation mechanisms may also be collected at later intervals. Representative samples of Ti-6Al-4V ELI and 316L stainless steel will be discussed to demonstrate the capabilities of these characterization techniques.

"The U.S. Food and Drug Administration (FDA) and International Governmental Agencies Role in Materials for Medical and Surgical Devices" will be presented by Donald E. Marlowe. Marlowe is recently retired from the FDA, Silver Spring, MD, where he served as the agency standards coordinator. Product approval, particularly medical device approval, as performed by the FDA, should be viewed as from the perspective of risk management--the assessment of the risks and benefits to patients and users of the device, according to Marlowe. He will review the current regulatory picture on both sides of the Atlantic and the importance of standards in medical product risk management.

The majority of medical devices the United States and Europe are regulated as Class 2 products--reviewed against existing voluntary consensus standard when such are available. FDA generally approves medical devices for market, not the materials of manufacture. While there are a few exceptions to this rule, the materials of which the device is manufactured only get reviewed in the

context of their application, such as biological safety, electromagnetic compatibility or corrosion resistance.

Typically, review of the material only consists of review of the voluntary consensus standard which describes the material. For orthopedic implants, these are the standards developed by the relevant committees of ASTM International and the ISO. The committees (ASTM F04 on Medical and Surgical Devices and Materials and ISO TC 150 Surgical Implants) have almost a 50 year history in the development and management of materials standards such as those for titanium.

Prof. Jack E. Lemons, Ph.D., University of Alabama at Birmingham, will discuss the "Current state of Titanium and Titanium Alloys for Biomedical Applications." Titanium has evolved from multiple sources and properties to standardized biomaterials that are selected by composition and properties for multiple types of surgical implants. Specialized physical, mechanical, chemical and electrical properties of titanium biomaterials, especially the surface oxide and biocompatibility profiles, have expanded applications and success ratios for many types of implants in medicine and dentistry.

Current clinical applications exceed 1 million devices per year within several surgical specialties. Importantly, clinical outcome assessments of longevity for treatments utilizing titanium often exceed decades, with some devices remaining in clinical function for the lifetimes of patients treated. According to Lemons, national and international reviews indicate that biomedical applications of synthetic-origin biomaterials, including titanium, will expand in the coming years as populations age and demand an enhanced quality of life.

Another presentation by University of Mississippi Medical Center representatives will explore "Stress Corrosion Cracking (SCC) Characterization of Elevated and Nominal Oxygen Weight Percent α+β Ti-15 Molybdenum." SCC research was conducted on both an experimental elevated oxygen weight percent (0.74%) heat and a nominal oxygen weight percent (0.13%) heat of α+β Ti-15 molybdenum. SCC testing was conducted using the slow-extension rate methodology outlined in ASTM G129 in both smooth and notched sample configurations. Both smooth and notched samples were tested in distilled de-ionized water and in Ringer's solution at physiological temperature (37°C). Percentage of elongation ratios (PER) and reduction of area ratios (ROAR) were calculated and scanning electron microscopy (SEM) was used to examine the fracture surfaces. According to the findings, the PER and ROAR for both heats showed no indications that SCC mechanisms were present in either the smooth or notched conditions.

The International Titanium Association (ITA) is the host and sponsor of TITANIUM 2010, which is designed to suit the needs of titanium producers, suppliers, customers and stakeholders. Jennifer Simpson is the executive director of the ITA (Web site www.titanium.org). Call (303) 404-2221 for more information.

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