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Welcome Letter From Viv Helwig

Welcome to the 2017 Medical edition of Titanium Today.

I am Viv Helwig, President of Vested Metals International, a Specialty Metals Distributor, ITA Member and I am pleased to be the current Chair of the ITA Medical Technology committee.

The Medical Technology committee is comprised of a variety of ITA Member organizations, all which have an interest in titanium used for medical applications. After being dormant for a few years, we relaunched a committee for the Medical market last Fall at the TITANIUM USA 2016 conference in Scottsdale, AZ. The committee is pleased to host the Ti in Medical Technology session at the TITANIUM USA 2017 conference this October 8-11th in Hollywood, Florida. Speakers include Don Urbanowicz, Principal at Urbanowicz Consulting, LLC; Dr. Prabhu Gubbi, Manager – Chemical, Microscopy & Materials Testing for ZimmerBiomet; Dean Hutchinson, Product Manager, Shoulder Arthroplasty Team for Arthrex; and Gene Kulesha Senior Director, Platform Technology Engineering; R&D (Additive Manufacturing) for Stryker

We were encouraged by the turnout and positive feedback we received from last year's Medical market session where we looked at the challenges and opportunities facing different sectors of the supply-chain ranging from the OEM level to the subcontract precision machine manufacturers to the raw material suppliers. Some of our goals as a committee have been to drive up-to-date market intelligence to you, our ITA members, as well as engage new ITA participants and members from the titanium Medical community, specifically, OEM's and finished component manufactures or subcontractors. Our theme at this year's panel will be two-fold in that we will look at current global and regulatory factors facing OEM's and how they affect the rest of the supply-chain. And secondly, we will focus on applications in the Medical market and what emerging technologies raw material suppliers will need to focus on to meet future demands.

As it relates to this Medical issue of Titanium Today, it's been two years now since our last medical issue and we are excited to bring you annual content again. We have put together some insightful topics in the pages ahead that we feel will help engage you more in the current happenings of this critical market to the titanium industry.

In the pages ahead, we'll give an overview and refresher on medical applications for titanium, new potential alloys and applications, explore Additive Manufacturing in this market further, as well as hear from some key experts as they give an overview on the global market.

A special thank you to the other committee members who have engaged in launching this initiative, Jennifer Simpson of the ITA, Stephen Smith of Edge International, Ric Snyder of Fort Wayne Metals, Bob Fletcher of Structure Medical, and Tom Zuccarini of Carpenter Technology for his input as well.

I will end by encouraging you to view the pages that detail the current and new members of the ITA and think about how your organizations can collaborate with each other to grow and move forward the mission of the ITA and ultimately the titanium industry.

I hope you will enjoy this edition and we hope to see you this October in Florida. Please contact the International Titanium Association with your thoughts and suggestions for future coverage.

Viv Helwig
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QuesTek's 'Materials by Design' Approach Creates Alloys Tailored For Medical Implants

By Michael C. Gabriele

QuesTek Innovations LLC, Evanston, IL, utilizing its trademarked "Materials by Design®" methodology, has developed a new generation of titanium alloys for Additive Manufacturing (AM) of medical implants. In casting trials and initial wire-based AM trials, QuesTek said these alloys demonstrated 20 percent higher strength at equivalent ductility compared with Ti-6-4, which currently is a titanium alloy of choice used in medical 3D printing. QuesTek is coordinating additional AM trials in powder bed, powder blown, Norsk wire and Sciaky wire builds this year and if all goes according to schedule, the company expects to roll out the first set of commercially available titanium alloys in 2018.

According to information on the company's website (www.questek.com), QuesTek underlines its expertise in the field of Integrated Computational Materials Engineering (ICME). QuesTek has employed this design method for various aerospace applications, and is now applying the technology to design alloys for medical components. QuesTek says ICME "has proven that high performance alloys and other materials can be developed much faster and at lower cost than via traditional (trial and error) methods."

The company's Materials by Design methodology involves a systems-based approach to materials design that utilizes CALPHAD (CALculation of PHAse Diagrams)-based tools in combination with proprietary databases, property models, and software to design materials tailored to meet specific performance targets defined by an end user or for specific manufacturing processes such as AM.

ICME and Accelerated Insertion of Materials (AIM) are the design tools that allowed QuesTek to create the company's "QuesTalloy SMA," a nanodispersion-strengthened, high-performance, shape-memory alloy that the company is marketing as an improved material for use in stents and catheter wires.

In layman's terms, the molecular structure of a shape-memory alloy is designed to have an inherent temperature "trigger," which causes the metal component to change shape, allowing devices made of these alloys to expand or contract when exposed to certain temperatures. Once inserted into an artery at body temperature, such a trigger would cause a shape-memory alloy stent to open up, providing improved blood flow.

Jeff Grabowski, QuesTek's manager of business development, explained that ICME provides an efficient way to produce an alloy with the properties needed for a given design, while AIM greatly minimizes the risk, time and costs associated with the materials qualification process.

Many existing alloy powders and materials used in additive manufacturing typically are not optimized for the 3D additive manufacturing process, according to QuesTek. "The range of alloys to which additive manufacturing can be applied is limited and often accompanied by significant property sacrifices relative to the baseline (wrought or cast) alloys," Grabowski said. "We have been funded on 18 different projects to resolve materials issues observed in AM, across titanium, aluminum, nickel, iron and tungsten systems. This demands the design of material compositions and microstructures specifically tailored for the additive manufacturing processes." He added that QuesTek also is developing concepts to make its high-performance SMA and other shape-memory alloys printable.

Dana Frankel, a materials design engineer at QuesTek, speaking at the Steel Research Group conference held earlier this year, said the company's approach to develop alloys with improved fatigue life involves improved inclusion control along with an increase in yield strength achieved by precipitate strengthening from a nanoscale Heusler phase. Low-nickel and nickel-free Heusler-strengthened shape-memory alloys have been designed using ICME-based models for precipitation, transformation temperature, and yield strength, Frankel said. "Process scale-up of patent-pending alloy designs will investigate both conventional melting/drawing methods and rapid solidification/surface modification techniques to refine inclusion structure."

Rather than relying on a trial-and-error process for alloy development, ICME uses physics-based computational models that draw upon density functional theory, material thermodynamics, and mechanistic property models to develop process-structure-property relationships. The process begins with databases of thermodynamic and kinetic properties of the elements, and crunches the information with predictive models and their respective software platforms to quickly go through thousands of iterations of chemistries and thousands of subsequent virtual heat treatments to optimally target a set of defined performance requirements.

Once the results are in, QuesTek selects two or three "targeted chemistries," which are melted in coin-sized samples in its laboratory and tested to determine the alloy's microstructure and physical/functional properties.

The AIM methodology uses ICME models and predictive tools to forecast minimum material properties based on the possible variations in chemistry and processing parameters that can occur within the full production pathway. Further, these models are calibrated to a minimal set of data points, allowing for both risk and cost mitigation through providing a high degree of confidence with only a few production runs of material.

QuesTek has shown the efficacy of this approach through the development of two aerospace steels, accurately predicting the minimum properties of ten full-scale heats with data from only the first three heats. Incorporating these models early in the development process will allow for any necessary modifications to be made to the material or processing specifications prior to investing in the full alloy development.

Frankel said QuesTek focuses on the near-equiatomic nickel/titanium system, commercially known as Nitinol. "Our low-nickel compositions use palladium (Pd) as a substitute for nickel to help improve biocompatibility. A little bit of aluminum is added to help form the strengthening precipitates. We are focusing on single alloy compositions of our low-nickel and nickel-free alloy designs for optimization and scale-up, but these alloys could be expanded into alloy families with varying chemistries to target specific transformation properties depending on the application."

As for a commercial rollout, QuesTek will make its shape-memory alloy and additive alloys available as cast bar, wires and powders and will likely be licensed to one or more alloy producers, original equipment manufacturers and end-users. The company is exploring most of the major AM processes: powder bed, powder blown and wire. ICME methods can be tweaked to tailor the alloys depending on the AM processing specifics. In addition to shape-memory alloy stents and catheter wires, QuesTek is considering possible opportunities for its alloys in cast titanium orthopedic implants or fixture devices.

Regarding the company's aim to engage with the titanium industry and become part of the medical industry's supply chain, Grabowski pointed out that QuesTek has had major success in using ICME to design a family of Ferrium steels that are commercially available from Philadelphia-based Carpenter Technology Corp. (a producer and distributor of specialty alloys) and are being used and qualified in demanding applications such as U.S. Air Force and Navy landing gear, flight critical components on SpaceX Falcon and Dragon programs, and next generation helicopter transmissions. ICME tools also can be used across various alloy systems as evident with its new line of shape-memory and cast titanium alloys. QuesTek has demonstrated success in improving upon legacy Nitinol and Ti-6-4, which is relevant to titanium alloy producers, end-users and the medical industry.

A privately held, limited liability company, QuesTek was established in 1996 by individuals affiliated with Northwestern University (of Evanston, IL) to commercialize the academic work of Professor Gregory B. Olson in the field of computational materials design. QuesTek contributed to the AIM program spearheaded by the U.S. Defense Advanced Research Projects Agency and the Office of Naval Research.

Utilizing additive manufacturing technology, company markets novel titanium hearing aids

By Michael C. Gabriele

Sonova, Stäfa, Switzerland, a provider of innovative hearing care solutions, earlier this year introduced its Phonak Virto B-Titanium hearing aid, a medical device produced via 3D additive manufacturing.

According recent news reports and information posted on the company's website (http://www.sonova.com/en), the process to design the titanium hearing aid begins with an impression of a patient's ear canal, which is made by hand using silicone. This mold is 3D scanned and then turned into a digital model using software from Materialise, a software solutions company, headquartered in Belgium. Fried Vancraen, the chief executive officer of Materialise, said the company's product development mission is bolstered by an "in-depth knowledge" of additive manufacturing software.

The Phonak Virto B-Titanium hearing aid is produced through a powder-bed fusion method of metal 3D printing, which makes the hearing aid casing that is 15 times stronger than the shell of an average acrylic device and highly resistant to moisture and wear. Sonova officials describe the titanium hearing aid as "no bigger than a fingertip." Scott Witt, director of product management at Phonak, quoted in the trade press, said the Virto B-Titanium is "the most discrete hearing aid ever produced" by the company.

Company officials say titanium "allows for a shell that's half as thin as traditional custom shells, resulting in a deep, comfortable fit that sets new standards for discretion. The overall size is reduced significantly, thus increasing invisible-in-the-canal fit rate by 64 percent." Virto B-Titanium runs on the AutoSense OS™ system that analyzes sounds every 400 milliseconds.

An online innovation feature posted by the Sonova news room reported that the 3D process enables the company to design products tailored for the wearer's individual ear canal and degree of hearing loss. Prior to the use of 3D printing, production of hearing aids had been "the sole preserve of modelers who finished each unique piece by hand in a time-consuming and costly process," according to the company. As such, the use of 3D technology represents a technological breakthrough as well as a competitive advantage in the international medical market.

Sonova's subsidiary brand Phonak produces and markets thousands of custom-made hearing aids for patients around the globe. The company estimates that 1 billion people throughout the world have hearing problems, which significantly affects a person's overall quality of life.

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The TITANIUM series is hosted by International Titanium Association (ITA). A non-profit trade group established in 1984, the ITA's mission is to connect the public with Member organizations who may provide technical and sales assistance. Over 200 international organizations with more than 1,600 individuals worldwide comprise the membership of the Association.

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