

## **White Paper Title: Precision Additive Manufacturing of Medical Device**

### **Introduction**

The Overarching **goal** of this proposed effort is synthesis of precision additive manufacturing with national health care needs for patient specific medical implants. In view of the ageing population of USA, it is an urgent and technologically challenging problem. A team of experts in precision manufacturing, orthopedics surgeons, and material developer will work together to address this interdisciplinary problem as a team. The team will consist of POM Group Inc. ([www.pomgroup.com](http://www.pomgroup.com)), developer of precision manufacturing techniques, Dr. Perry W. Greene, Chief Adult Reconstruction and Director of Gehring Explant Retrieval Laboratory of Beaumont Hospital ([www.beaumont-hospitals.com](http://www.beaumont-hospitals.com)), University of Michigan at Ann Arbor ([www.umich.edu](http://www.umich.edu)), with expertise on patient specific bones and Stellite Inc. ([www.stellite.com](http://www.stellite.com)), a materials and special alloy developer. This team will have expertise and capability of solving the national need in this challenging area that is a marriage of Engineering with health Science.

### **Societal Challenge**

According to the Centers for Disease Control and Prevention (CDC), the proportion of the U.S. population over 65 years old is projected to increase from 12.4% in 2000 to 19.6% by 2030. Adding that factor to the increased prevalence of unhealthy lifestyle choices such as poor eating habits and sedentary daily routines, more and more Americans are going to require medical devices over time. On a global basis, the over-65 population is expected to grow from 6.9% to 12.0%. Because older people are more at risk for a variety of medical conditions (osteoporosis, heart disease, various cancers, gastrointestinal ailments, and others) the global medical technology market will continue to expand. This is of particular interest because 50% of all medical devices used worldwide are produced in the U.S.

The U.S. medical device manufacturing sector achieved a 9% growth rate in 2008 and by all indications, will remain a robust manufacturing industry throughout 2009 and beyond. In fact, over the past decade, medical device manufacturers in the U.S. have posted a constant growth rate of 8% at profit levels that surpass all other OEM sectors. In particular, the orthopedic and cardiovascular sectors have achieved double-digit growth over the past five years.

Global Industry Analysts Inc. projects that by 2015, the global market for orthopedic instrumentation will reach \$54.5 billion. With an increase in life expectancy rates, the number of joint replacement procedures has reported significant growth. Sports-related injuries in the younger generation, coupled with the growing popularity of minimal invasive surgery are fueling the demand for joint replacement surgeries. Medical device companies are now focusing on advanced materials and technologies in the field of orthopedic implants to address the emerging requirements of an aging population and active youth.

Consideration should also be given to the global dental market. According to a new technical market research report. The Dental Market Techniques, Equipment & Materials (HLC028C) from BCC Research, the global dental market is expected to reach \$7.9 billion in 2008. This

should increase to nearly \$10.0 billion by 2013, a compound annual growth rate of 4.7%. The dental equipment and supplies segment is expected to grow at a 5.8% compounded annual growth rate to reach \$4.2 billion in 2013.

One of the critical needs identified by Dr. Green of Beaumont Hospital is the tailored property needed for implant. Tailored properties required involve adherent ceramics coatings for wear resistant and desired toughness for joints such as Knee joint as well as toughness and flexibility for femur bone. Additive manufacturing techniques such as Direct Metal Deposition (DMD) has the potential to resolve both needs although it has to overcome some technical barriers.

One of the technical barriers for ceramics coatings of joints is the poor adhesion. Research in this project will explore the encapsulation of the ceramics in the prosthesis itself. However, relative difference of CTE (Coefficient of Thermal Expansion) and immiscibility of ceramics and metals poses a technical barrier, which needs to be alleviated to solve the problem.

Designer implants for bones such as femur with desired toughness and elasticity faces technical barriers such as their geometric shapes, materials selection, bio-compatibility and integration with adjoining muscles. Homogenization design theory can be used to overcome the geometric and elasticity needs. Bio-compatibility and related issues will require comprehensive study even if the starting point is FDA approved Titanium and Nickel alloys.

### **An Area of National Critical Need**

Today there is a high demand for high-precision products. The manufacturing processes are now highly sophisticated and derive from a specialized genre called precision engineering. But, the legitimate question is, what defines precision? A clear definition is needed to identify the best in class manufacturers in a highly competitive market. Since the market spans a very board range of industries, it is important not to limit the definition of precision, but instead expand it to three unique precision types, which are identified as micro precision, ultra precision, and nano precision. Using such definitions, precision can be identified in respect of the technology that a manufacturer might have and what can be expected in terms of quality and accuracy. Further, each precision type can also be used to define the technology and expectations within a machine tool, and can also be used to define the maximum part quality that can be expected from the machine without becoming over complicated. In additive manufacturing techniques such as laser aided Direct Metal Deposition (DMD), the demand for high precision is growing rapidly from not only commercial industries including medical devices but also other industries such as aerospace and defense. DMD together with laser ablation technique can overcome aforementioned obscurity of widely defined precision ranges, by precisely controlling laser input energy and materials, via highly advanced adaptable process control techniques. This is an area of national critical need for the advancement of US commercial industries.

### **A Transformational Result**

Production methods for surgical implants are today typically performed by making a near-net-shape part that is finished with specialized surface finishing or treatments for the desired surface,

mechanical and aesthetic effects. Today's tried and true techniques for production of these near-net-shape parts include traditional methods such as investment casting, forging or machining. Each of these methods requires some follow-up finishing by hand or machine to achieve the final desired properties. Additive manufacturing in metal represents a transformational option for production of orthopedic implants. Like today's accepted methods, the parts produced by additive processes will require final machining or hand finishing, but allow significant flexibility of manufacture for custom, short-run, complex or otherwise complicated to manufacture parts.

Rapid manufacturing (RM) for any application offers key benefits to select areas of production. Within the medical realm this is very true, with RM offering advantages in the key areas of: (1) demand-based manufacturing in small to medium size quantities, (2) customized implants for a specific patient, (3) ease of manufacturing complex, freeform shapes and (4) an upgrade in material properties when compared to traditional manufacturing via investment casting. These will all be briefly defined with regard to surgical implant applications.

#### Demand-Based Manufacturing

Efficiency and flexibility offer great benefits in manufacturing in terms of increasing simplicity and decreasing inventory expense. Rapid manufacturing of metallic implants can offer the implant manufacturer a way to avoid two costly areas: (1) excess inventory and (2) the ability to make only what is needed. When only 50 to 100 of a particular item are needed in a given year and the minimum order from a financial feasibility standpoint is 500, this creates a huge inefficiency. By offering the ability to make only the number that is needed a huge reduction in cost and inventory can be achieved.

#### Customized Implants

The ability to quickly and cost-effectively produce a customized implant has always been appealing from a marketing and manufacturing standpoint. Historical barriers to this becoming a reality have included the inability to properly design a net shape implant in a digital environment and the inability to manufacture the implant in a digital manner. With the advent of better design tools and more options for output in manufacturing materials providing truly customized implants is possible today.

#### Complex Shape Manufacturing

As with all additive fabrication processes (both prototype and manufacturing) the ability to make ultimately complex objects is possible. This important factor is one that can add much value to the entire business of RM, and this is no different in medical uses for the technology. Hard to manufacture designs are typically discarded in today's manufacturing world in exchange for simplicity, which most times equals reduced cost. With RM, one need not worry about complexity of design because of the additive nature of these new wave manufacturing processes. A great example of the benefits of additive technologies is seen in construction of porous lattice structures. Many are now researching applications for porous constructs that are brand-new ideas for products not thought to be possible to manufacture using traditional processes. Again, these areas are key to finding value and financial gain from the use of RM in medicine.

#### Material Property "Upgrade"

Certain additive metal processes can be shown to produce material properties superior to their traditional manufacturing counterparts. For example, products that are typically produced in titanium alloy by investment casting have inferior properties to those produced from wrought material. Casting has offered many benefits - one of which is directly parallel with its RM counterpart; the ability to produce very complex shapes easily. By discarding the investment cast method in favor of an additive method - in this case laser aided deposition - one can realize better mechanical properties without sacrificing the ability to make a complex, freeform shape.

As an example, deposited material by laser aided direct metal deposition (DMD) is fully dense and mechanical and physical properties of the DMD material are as good as or better than that of comparable wrought or cast materials. Tensile and hardness data of some typical DMD materials (bio-compatible) that include Ti-6Al4V alloy, and 17-4 stainless steel (Fe-alloy) are shown (Table 1) and compared with that of conventionally fabricated materials. Higher strength of DMD materials including Co-Cr-Mo base alloy, Ti-6Al4V alloys, and 17-4 stainless steel, offers an opportunity to reduce section thickness of implants and thereby, reduce the weight of the implant on the patient.

Table 1. Comparison of DMD material property with conventionally fabricated materials.

Material	Condition	Tensile strength (Mpa)	Yield strength (Mpa)	Elongation (%)	Hardness (HRC)
Ti-6Al-4V (DMD)	As deposited	1163	1071	6	20
Ti-6Al-4V (V) wrought (conventional)	Annealed	950	880	14	33
17-4 stainless steel (DMD)	As deposited	1016	568	9	20
17-4 stainless steel (conventional)	Wrought	993	869	20	33

### Precision Optical Manufacturing

The use of lasers for precision manufacturing has become increasingly important in the field of medical device manufacture due to their precision, flexibility and ability to work at small scales for the miniaturization of medical components. Lasers can be used for many processes, such as circuit fabrication, encapsulation, marking, welding and microhole drilling, etc.

### Benefits

For anyone looking for somewhere to invest, the medical device industry would be a safe bet. Emerging technologies, including stents and sensor-laden implantables, are receiving much attention from investors. Small-industry growth is expected in the neurostimulation and the orthopedic markets. The industry is growing and it could not be a more exciting time to be a part of it. David Turkaly, a senior medical technology analyst with WR Hambrecht & Co ([www.wrhambrecht.com](http://www.wrhambrecht.com)), stated that both large and small-cap medical device firms have outperformed the S&P 500 in the past three years. The statistics speak for themselves. AdvaMed ([www.advamed.org](http://www.advamed.org)) cites a 10% year over year annual growth for the United States medical

device market. By the end of 2006, U.S market size was approximately \$86 billion. Now, the medical device market has grown to a robust and profitable \$100 billion strong. The international market grew from \$220 billion in 2006 to over \$300 billion. According to the US Department of Labor's Bureau of Labor Statistics, in 2006 (the latest year for which data were available), 305,530 workers were employed in the medical equipment and supplies manufacturing industry. (By 2014, the number of workers is projected to reach 312,000.) These numbers represent one-third of all bioscience industry employment, according to Medical Product Outsourcing magazine ([www.mpo-mag.com](http://www.mpo-mag.com)). The average annual salary for all occupations within this industry was \$42,190—higher than the national average for salaried workers, which remains less than \$40,000 annually.

For medical implants, specific benefits are as following; patient specific custom implants provide more comfort and quicker recovery. Using DMD together with laser ablation, net shape product can be implemented and it means less machining and less cost. Since patient specific implant means reduction in surgical time, overall (life-cycle) costs adapting the technique will be greatly saved.