

Additive Manufacturing Standards: Thoughts on Orthopaedic Devices

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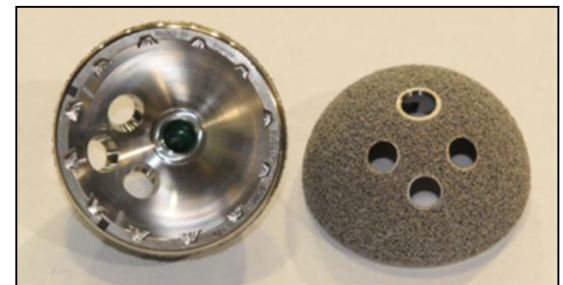
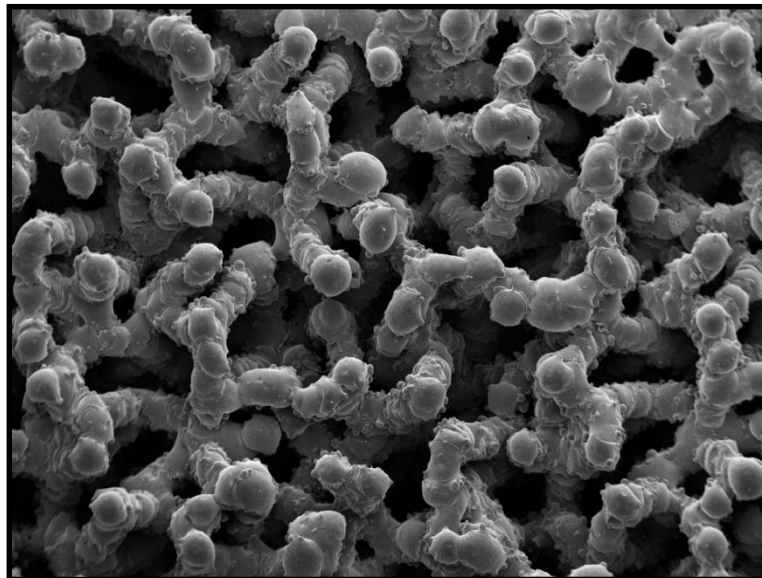
Stryker Orthopaedics

October 8, 2015

Penn State University, PA

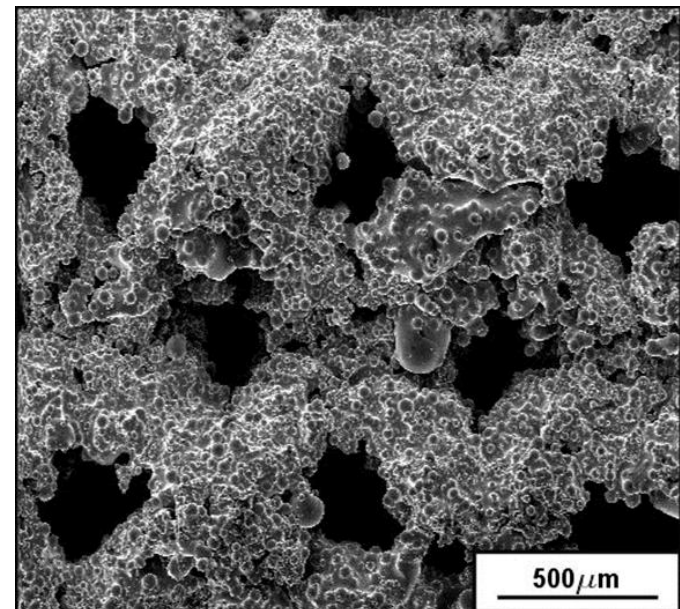
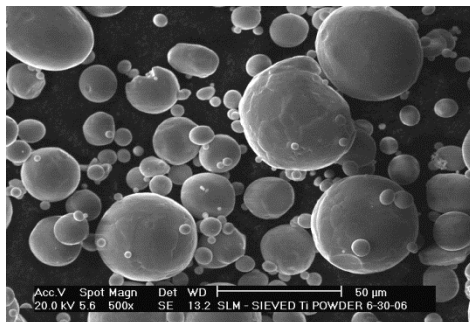
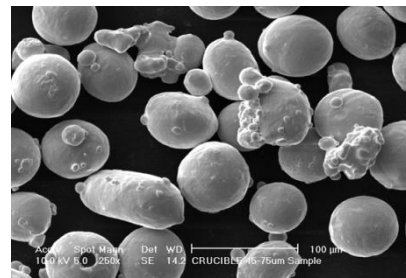
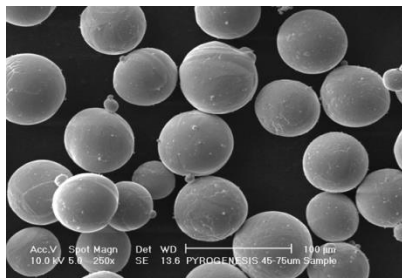
Implants

- Most implant standards address traditional processing means
- AM implants - unique designs, new surfaces, tissue in-growth structures
 - Material chemistries - what are the impurity maximums
 - Mechanical requirements - test coupons at worst case orientations
 - Crystal structures and phase distributions
 - Tissue in-growth structures - porosity, mechanical properties, surfaces
 - Organic and inorganic residual levels



Powders – Starting, recycling and residual

- Most powder standards address traditional application means (thermal spray and sintering)
- AM applications
 - Powder requirements - size, shapes, chemistry, biocompatibility
 - Recycling - requirements at the end of the life cycle
 - Residual powder levels in the implant - are there safe levels?



Looking Into the Future...

- Implant manufacturers – mass produced and customized implants
 - The technology and process are under tight control
- AM technology and equipment manufacturers are bound for the OR
 - The need for standards will be greatest when AM is in every OR



Today



In several years?