The Arcam EBM® process: A walkthrough
Overview

• Arcam & EBM® Process
• Design for EBM®
• EBM® - Core Benefits
• Validating EBM®
Arcam

- Swedish innovation from the beginning of the 1990’s
- Arcam AB incorporated 1997
- First EBM system delivered in 2003
- Turnover 16 M€ (2012)
- About 100 systems installed worldwide
- 50 people, in Sweden, the U.S., Italy and China
- Listed on NASDAQ OMX Stockholm Small Cap
Products & Services

• Machines and Equipment for Electron Beam Melting

• Service, Application Support and training

• Powder Metals and other Consumables

• Contract manufacturing of Orthopedic Implants through partner DiSanto

NEW!!
EBM® - Electron Beam Melting

- The electron beam gun generates a high energy beam (up to 3,000 W)
- The beam melts each layer of powder metal to the desired geometry
- Extremely fast beam translation with no moving parts
- **High beam power** -> high build rate (up to 80 cm³/h) and **productivity**
- **Vacuum process** -> eliminates impurities and yields **excellent material properties**
- **High process temperature** (700 °C for titanium) -> **low residual stress** and **no need for heat treatment**
What is Additive Manufacturing (AM)?
Overview

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Build orientation

- Insufficient heat transfer leads to **curling & poor part quality**
- Adequate heat transfer is more difficult to achieve in **down-facing surfaces**
Build orientation

- Build orientation determines how heat will be transferred through the parts
- Parts should be orientated to minimize the amount of down-facing surfaces
Wafer supports

• Wafer supports **increase heat transfer and mechanical stability**
• Wafer support placement must insure easy removal, minimal invasion on part surface and minimal overstock material
• Knowledge about **post-processing** is helpful when deciding build orientation and wafer support settings
Process Themes

- Solid parts, trabecular structures and wafer supports require different melt strategies

- Dedicated process themes control the desired energy input

- Process themes are designed to handle a wide range of geometries

- Parts outside of the geometrical coverage may need extra optimization

- Process theme settings affect part quality, material properties and throughput
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Customer benefit, Cost

EBM technology is used to replace present technology, for example casting, producing the same products as previously produced:

• No tooling cost
• Shorter lead time
• Less material use, more efficient

Our customers will make their production more efficient, thus reducing their costs
Production Benefits

- Single-step production of solid and porous sections
- High process temperature gives low residual stress and eliminates need for heat treatment after the build
EBM Productivity: Stacking of Parts

- Acetabular cups have excellent geometry for stacking
- Production example 108 cups:
  - Non-stacked: 140h
  - Stacked: 82h
- Build time reduction: ~35%
Customer benefit, Optimization

EBM technology is used to produce products with new unique properties

- **Weight reduction** (aerospace)
- **Advanced cooling** (aerospace)
- **Improved mechanical properties** (aerospace)
- **Improved bone ingrowth** (orthopedics)

*Our customers will optimize the properties of their product, thus making their product more valuable*
Trabecular Structures™ with EBM
Why Trabecular Structures™?

Implants

• Trabecular Structures™ for optimized osseointegration:
  ▪ Pore geometry
  ▪ Pore size
  ▪ Relative density
  ▪ Roughness

• Apply your trademark structure to your implant design
• Add value to your products by integrating new functions in conventional implant designs
• Tailor stiffness and strength to mimic the mechanical behavior of bone
## Tailoring porosity and pore size with EBM

**Layer thickness:**
50 µm

**Desired porosity:**
60-80 %

**Desired pore size:**
100-500 µm

Garret et al, Otsuki et al:
100-400 µm

Mullen et al, Stamp et al:
100-700 µm

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Creating Trabecular Structures™

- Trabecular Structures™ are repeated sequences of interconnected unit cells combined into a 3-dimensional shape.

- Trabecular Structures™ can be generated with STL-based polyhedron unit cells in CAD software.

- Pseudorandom Trabecular Structures™ can be created during part slicing.

EBM Lattice Generator
Fixa Ti-Por™ Acetabular Cup

- Material: Ti6Al4V
- Trabecular structure: Ti-Por™
- CE-certified since 2007
- Build time: 16 cups in 12 h

Courtesy of Adler Ortho S.p.a.
Delta TT™ Revision Cup

- Material: Ti Grade 2
- Trabecular structure: Trabecular Titanium™
- CE-certified since 2007
- Build time: 4 cups in 16 h

*Courtesy of Lima-Lto S.p.a.*
FUSE™ Lumbar PLIF Cage

- Material: Ti Grade 2
- Dimensions: 8 x 9 x 24 mm
- CE-certified since 2009

Courtesy of Advanced Medical Technologies AG
Customized Trabecular CMF Implant

- Material: Ti6Al4V
- All-porous implant
- More than 50 EBM-produced customized trabecular CMF implants have been implanted at the Walter Reed Army Medical Center in Washington D.C.

Courtesy of Dr. Stephen Rouse
EBM® - Core Benefits

- Freedom in Design
  - Design for function
  - Integrated trabecular structures for improved osseointegration
  - Enables mass customization

- Excellent Material Properties
  - Controlled microstructure
  - Better than cast
  - Compliant with applicable industry standards

- Cost-Efficient Production
  - High productivity
  - Material recycling
Overview

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CE-certified & FDA-cleared Implants

- **CE-certified** acetabular cups with integrated Trabecular Structures™ since 2007
- Implants with **FDA clearance since 2010**
- > 30,000 cups implanted
- 2% of the global production of acetabular cups is now manufactured with EBM®

Adler Ortho, IT
2007

Lima-Lto, IT
2007

Exactech, US
2010
Implant Categories

- Acetabular cups
- Revision cups
- Augments
- Femoral stems
- CMF
- Spine
- Shoulders
- Triflanges
- Tibial trays
- Femoral knees

In production with EBM
Additive vs. Conventional Manufacturing

Conventional Manufacturing

Additive Manufacturing
Key Differences

• Structural continuity between solid and porous sections

• Process is controlled and monitored on a micron level

• With Additive Manufacturing economy of scale is no longer a key driver

• The recommended starting point is volume production of standard implants, as it is easier to validate

• Production of patient-specific implants is possible, but is often more of a challenge to validate
The Need to Adapt

- Additive Manufacturing (AM) relies upon a stable process for *each* layer.

- The process parameters become geometry-dependent, so that steady-state is maintained.

- Changing the geometry, or the number of parts in a build, *may* affect the build.

- However, these are *controlled* and *calculated* variations.
Adapting Validation Approaches

- Validating 93/42/ECC, FDA 21 CFR or ISO 13485 for *additively manufactured standard implants*:
  - Installation Qualification (IQ) ensures the machine is operating correctly
  - Operational Qualification (OQ) establishes the process window for normal operation and challenges worst-case scenarios
  - Performance Qualification (PQ) measures stability and repeatability between batches in volume production
- OQ must be adapted for Additive Manufacturing, whilst IQ and PQ require no modification
Adapting Validation Approaches

**EBM® Operational Qualification - Process level**
- Ensure that the process is capable of delivering the required material properties, pore sizes etc
- Generic test pieces

**EBM® Operational Qualification - Part level**
- Input and iterate general design, part geometry, integrated structures etc
- Prototyping
- Initial performance testing

**EBM® Operational Qualification - Production level**
- Duplicate parts, optimise geometry and build parameters
- Verify that part performance is not altered
Process Themes

• To maintain a stable process for each layer, the energy input and output must be balanced

• “Conventional” process parameters such as beam speed and power are continuously adjusted

• This calculation is done by the EBM® Control software using a set of process themes

• Process themes determine how this is performed

• Process themes should be validated in Additive Manufacturing, not process parameters

• Process themes reduce the number of variables to be validated
Controlled and Repeatable

Fixed geometry + Fixed version of EBM® Control + Fixed process themes

Controlled and Repeatable Process
Beam speeds and currents will vary for each layer in a build, but they will vary in exactly the same way as for the previous build.
Change Control

- Change monitoring is vital in each step

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<tr>
<td>Process design</td>
<td>EBM® Control software and process theme versions</td>
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<tr>
<td>Production design</td>
<td>Geometry (number of parts) in each build cycle</td>
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- Change logs must be rigorous

- Minimise operator influence by creating build projects containing:
  - Build file
  - Process themes
Keeping Track

EBM Control Build Report

Verification Result

Events

Process Step Change Log

Build Summary

Validation Result

R1083_2012-03-29_12.24
EBM® Production Cycle

Process design & operational validation

EBM® process

Powder removal & recovery

Sifting & recycling of powder

Parts

Post-processing, inspection

Powder metal
Supply Chain

• Powder recycling is a new dimension to those not familiar with Additive Manufacturing processes

• While general guidance is provided, the specific solution is decided by the implant producer

• Regardless of which solution that is implemented, the integrity of the validation must be maintained

• Routines needed to measure, re-certify and archive!

Designation: F2924 – 12

Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion\(^1\)

- Powder blends are allowed
- Used powder allowed
- Chemical composition must be regularly measured
- Used powder must be sieved
Validation Template - Summary

• The Arcam EBM® process is today widely used for production of implants. The validation template is a tool helping to implement vital AM procedures

• Most implant companies have limited experience from validating an Additive Manufacturing process

• Arcam has gained experience from validations performed by its implant-manufacturing customers

• A template document with Arcam’s view on each aspect of FDA validation guidelines and linked documents such as checklists, procedures etc

• The purpose is an easier and faster validation
Validation Template

**Purpose of this Document**

The validation template is created by Arcam to help and guide Arcam's medical implant customers to validate their *serial produced* medical implants in the Arcam EBM Machine to meet standards set by ISO 13485:2003, FDA, and CE (93/42/EEC).

**Introduction**

The validation template is a help and guide for the serial production customer of medical implants to find information about the Arcam EBM Machine and Process which is valuable for the validation process which the customer has to do to standardize and certify their medical implant. Here, the customers can search for Arcam documentation and read Arcam's thoughts about different processes of the Arcam EBM Machine which the customer can use in their validation process.

*This is information which Arcam finds important, based on experience, for the Medical implant production validation process. However, the customer is solely responsible for their validation of their medical implants.*
The Road to Customisation

- Patient-specific implants introduce an additional level of complexity and variation

- An already validated process is easier than starting from scratch

- A combination of risk assessment and process trials is required to establish the process-geometry operating window

- Maintaining process themes fixed is an advantage
Conclusion

- EBM® is a controlled and repeatable process used for volume production of orthopaedic implants

- EBM® opens new avenues but pitfalls do exist

- Defined validation templates and methods help shorten the time from concept to manufacturing
Contact

Thank you for your attention!

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Arcam – CAD to Metal®