Additive Manufacturing Industriale di protesi articolari personalizzate

@BiRex - 24/09/2020

Lincotek

Pierfrancesco Robotti
Technology and BD Manager @ Lincotek Medical

Core Business: Industrial Manufacturing Services

Multinational Organization - 100% Privately owned – **HQ in Parma, Italy**

Lincotek Group Divisions:

- 2 Vertical divisions
- 2 Horizontal divisions

Lincotek Surface Solutions

- Processing parts for commercial aircrafts and helicopters.
- Coatings for components in the hot gas section.

- Processing parts for Small to large Gas Turbine (4 to 567MW).
- Coatings for components in the hot gas section (Airfoils, turbine blades, parts in the combustion chamber).

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- Orthopedic devices design and development
- Orthopedic devices Manufacturing

Lincotek Equipment

- Equipment for Thermal Plasma Spray Coating and its ancillary processes
- Design & mfg of std and custom TPS equipment with high degree of automation.

Lincotek Additive

- Develop and Exploit the AM tech
- Focus: Orthopedic implants andInstruments, Components for IGT and Aerospace.

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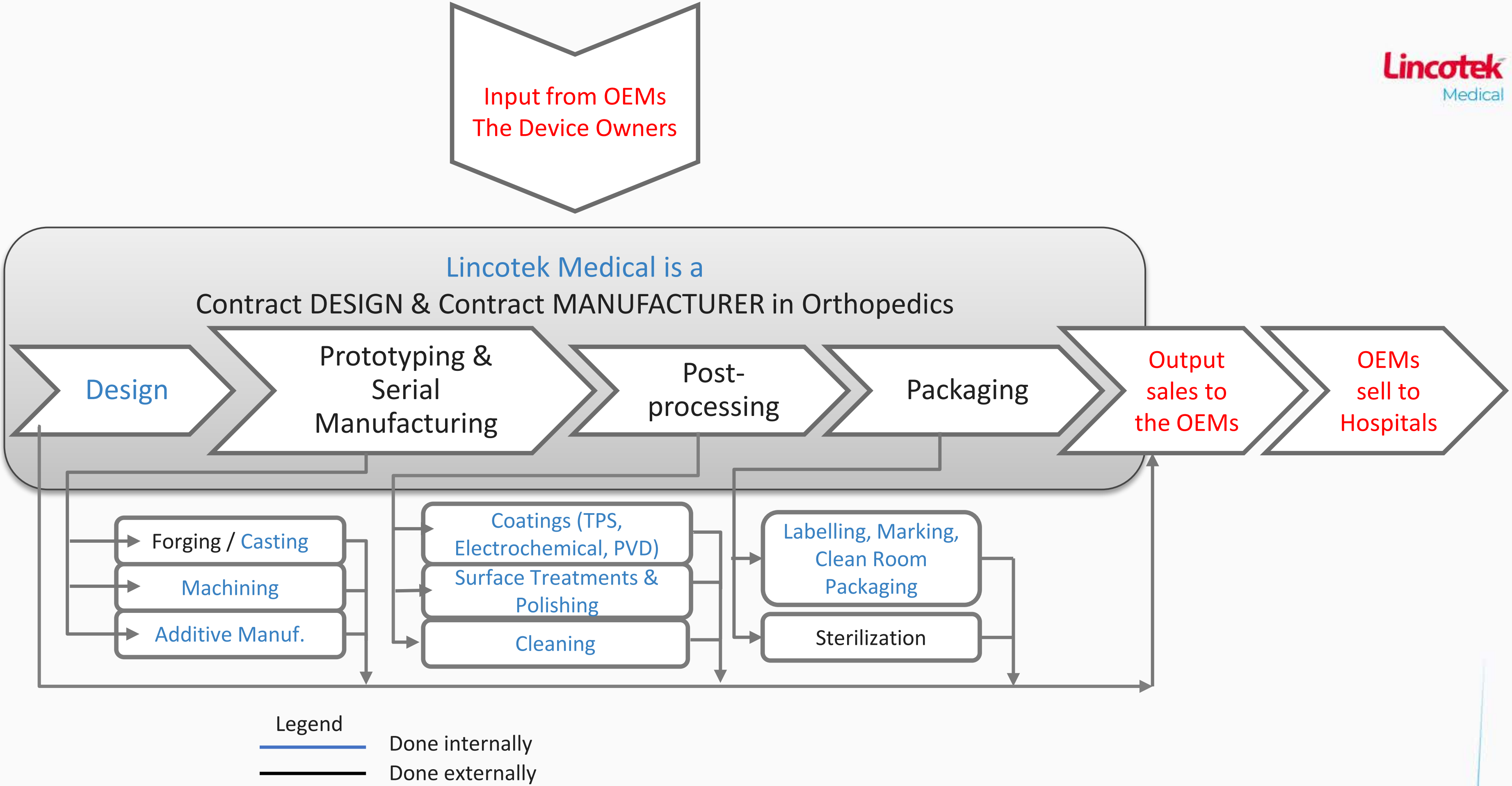
Medical


Input from OEMs
The Device Owners
Lincotek Medical is a
Contract DESIGN & Contract MANUFACTURER in Orthopedics
Design
Prototyping & Serial Manufacturing
Post-processing
Packaging
Output sales to the OEMs
OEMs sell to Hospitals
Forging / Casting
Machining
Additive Manuf.
Coatings (TPS, Electrochemical, PVD)
Surface Treatments & Polishing
Cleaning
Labelling, Marking, Clean Room Packaging
Sterilization
Legend
Done internally
Done externally

Comprehensive Development & Manufacturing Expertise

Lincotek Medical

- Over **130 Orthopedic OEM's served worldwide**: Europe, US, Asia
- Approximately **2.5 Million Orthopedic devices** produced **annually** (10K per day)
- **ISO 13485 QMS;** FDA, NMPA and JMHLW registered sites;

Spine Solutions

Reconstruction

Extremities

Sport Medicine & Trauma

Lincotek Medical Global Footprint

700+ employees worldwide

R&D / Product Development:
Logan, UT – U.S.A.
Bologna, Italy
Trento, Italy

Additive Manufacturing:
Trento, Italy
Memphis, TN –U.S.A.

Casting:
Portland, OR – U.S.A.

Precision Machining:
Bologna, Italy
Logan, UT – U.S.A.
Dayton, OH – U.S.A.
Portland, OR – U.S.A. (Femoral Grinding/Finishing)

Coating:
Trento, Italy
Salerno, Italy
Wuxi, China
Memphis, TN – U.S.A.
Cincinnati, OH – U.S.A.

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Additive

Lincotek Additive (Medical) at a glance

R&D
- Trento
- Additive machines dedicated to R&D
- PBF technology (EBM and Laser)

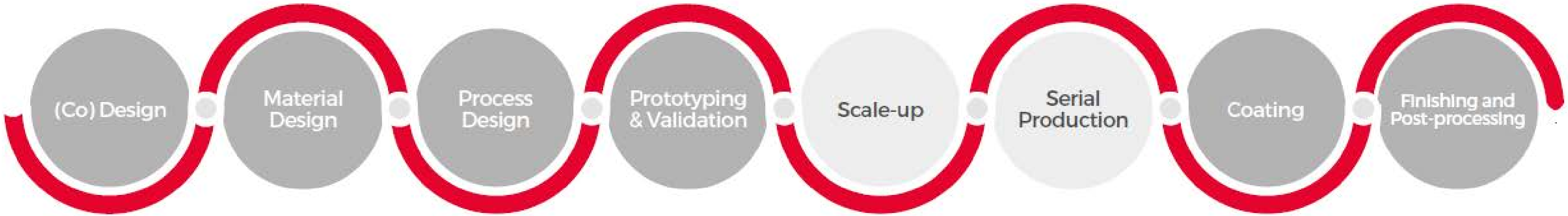
Medical Materials:
CpTi, Ti6Al4V, CoCrMo, 17-4 SS, Ceramics (R&D phase)

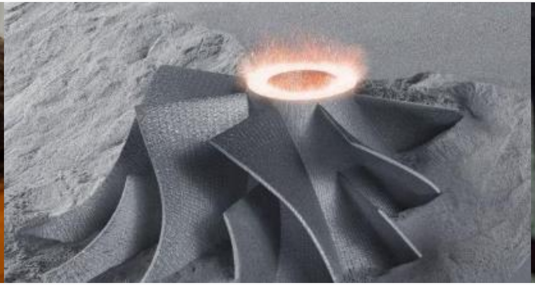
Validation and codesign:
- AM process validated for implantable medical device requirements (CE and FDA)

Serial Production
- production locations in Italy (Trento), USA (Memphis, TN), China (2021 – Wuxi, Jangsu)
- 22 machines in production with equipment and processes validated for implantable components
- more than 500,000 parts produced, operational since 2007
- +100K AM orthopedic implants manufactured in 2019.

From powder to ready-to-use part

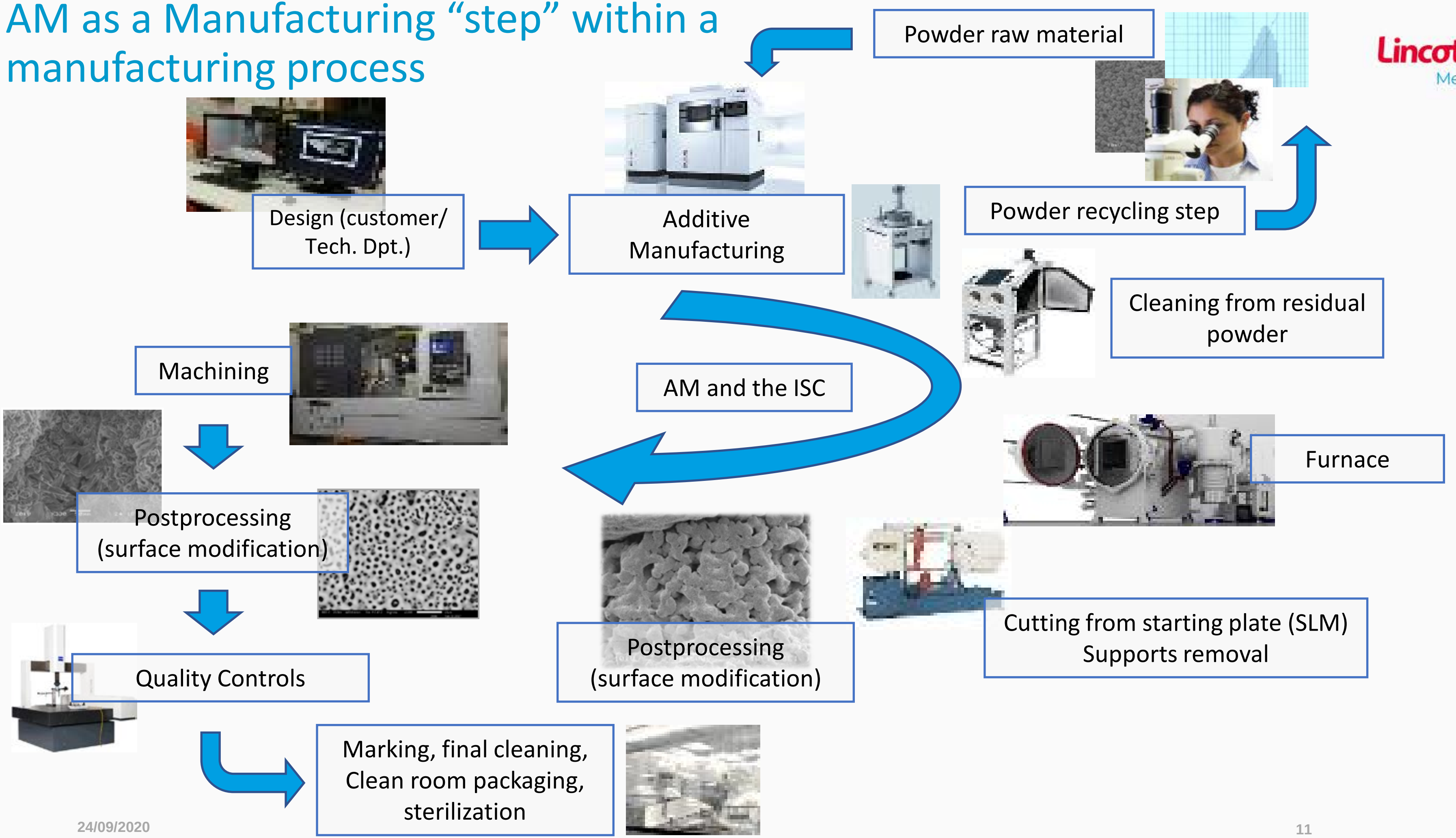
We take care of AM process, starting from co-design over process development to finished product, **in the scale up perspective**.
We believe in **AM for massive production**, either serial or customized.



One example: Integrated Supply Chain at work for AM Ti DMLS orthopedic devices

AM as a Manufacturing "step" within a manufacturing process



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AM OF CUSTOM MADE ORTHOPEDICS COMPONENTS

Patient Specific and Custom Made Implants

Tumoral recon, extreme revisions, rare diseases, large trauma not for urgent treatment, etc;

These are typical situations where the custom made implant is the preferred (if not unique) approach.

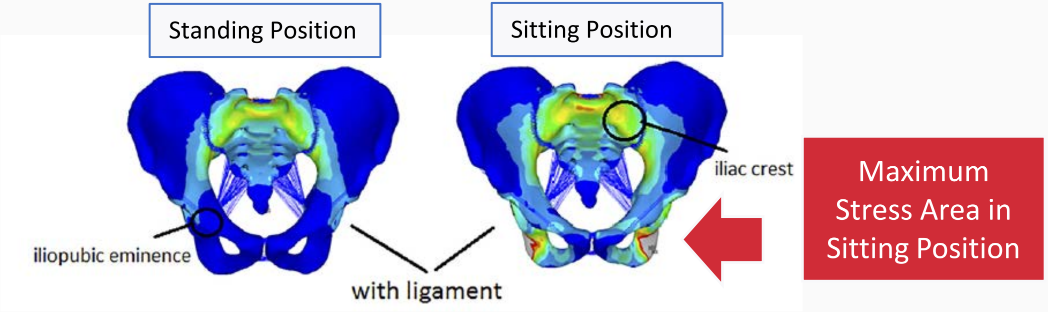
Main Characteristics and constraint: **Reactivity & Delivery Time** : (e.g. ~3 to 6 weeks)

Patient Specific and Custom Made Implants

AM play as enabling technology thanks to its flexibility in accommodate geometrical shapes along with topographic features.

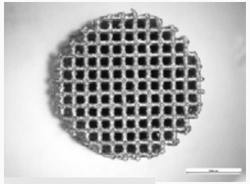
Patient Specific and Custom Made Implants

Execution demand a **fast, reactive and flexible** Integrated Supply Chain where AM is complemented by all the other essential manufacturing steps: from design to a ready to use part – at the OR.

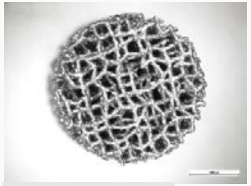


From the Article: "2019_Three-Dimensional Finite Element Analysis of the Effects of Ligaments on Human Sacroiliac Joint and Pelvis in two Different Positions. Jiajing Yang et Al.

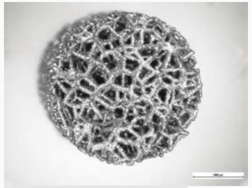
Design for Additive Manufacturing:



Regular



Irregular



Random

Engineering a porous structures for A.M.

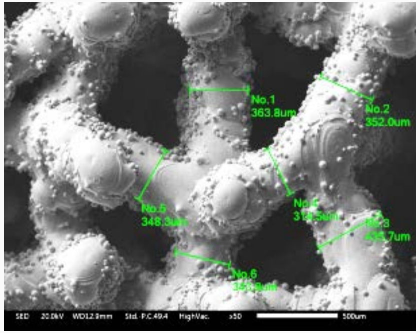
With Additive Manufacturing high theoretical design freedom however:

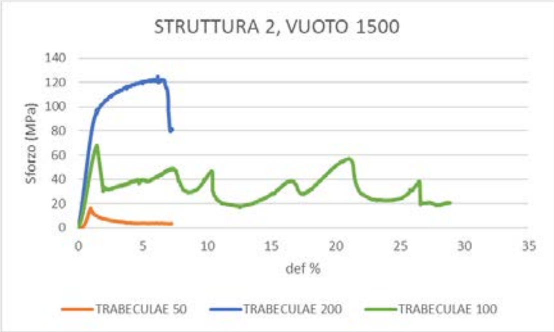
Constraints due to trade off mechanical & wear performances vs foams pores size and struts size – device vs osseointegration;

MORPHOLOGICAL

MECHANICAL

TRIBOLOGICAL





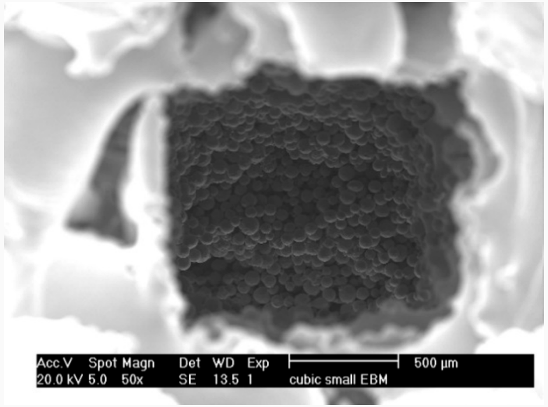
Design for Additive Manufacturing:

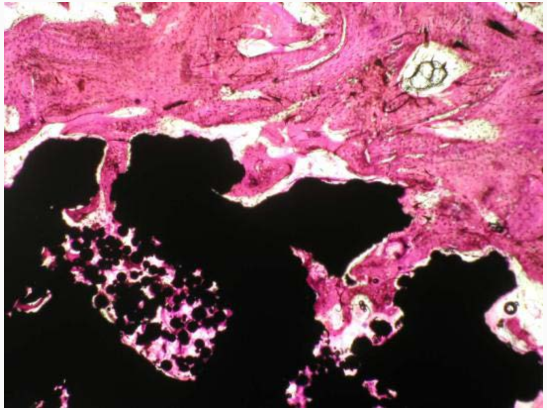
EXAMPLE OF A CRITICAL DESIGN STEP IN THE POST PROCESSING PERSPECTIVE

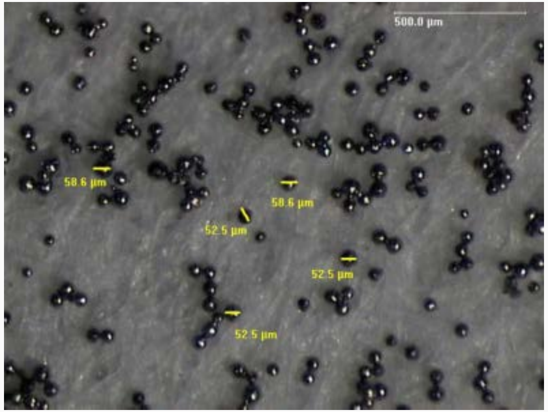
➢ Design for Cleaning:

It is mostly about printing parts compatible with the Cleaning Method(s) to be employed

Constraints due to actual possibility of cleaning the porous surfaces







CRITICAL DESIGN STEPS IN THE POST PROCESSING PERSPECTIVE

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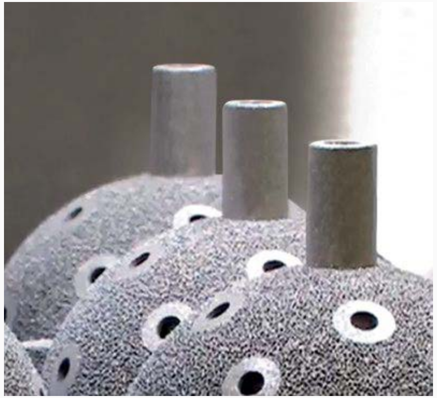
- Design for Additive Manufacturing:
- Design for Post Machining:
  - ✓ Deviation from near net shape only to favor post milling-turning: i.e. clamping areas, reference points for alignment, the amount of extra material to be machined out etc..
  - ✓ Trade off:

    Minimize extra material: only manufacture what is needed, limit the dimensions of the surface "uncoated".

    Increase the extra material to help reliability of output (i.e. minimize scrape rate).



Courtesy Smith&Nephew

MACHINING AM components

Main Challenges:

- Working parameters are definitively different from forged material.
- Working parameters are definitively different EBM from DMLS and the former is more difficult to machine in comparison with the latter.
- Surface roughness is mainly linked to advancing speed
- Tools wear is mainly linked to advancing speed
- Avoid or remove contaminants in the porous structure

Courtesy Ampower - https://additive-manufacturing-report.com/

Smoothing or Polishing, main challenges:

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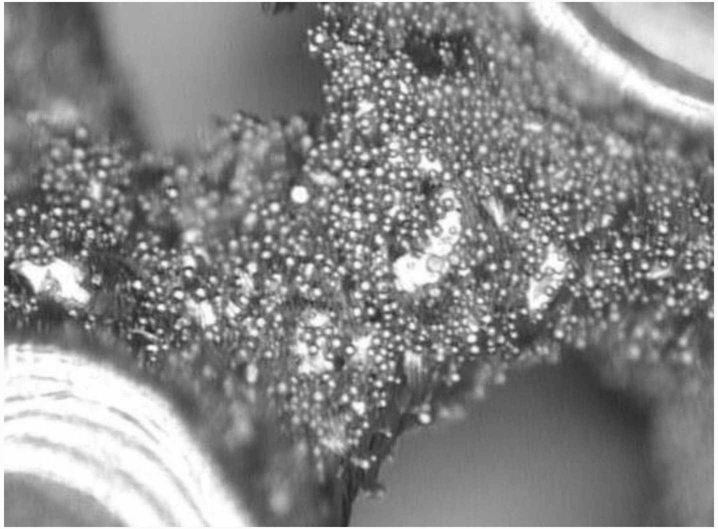
- Get different surfaces finishing on the same part, especially on contiguous areas
- Reduce roughness in the solid and preserve the roughness on the lattice structure
- Leave the part clean (residuals free)
- Use of processes suitable for mass production

LATTICE: CLEANING OF LUBRICANTS or PASTE RESIDUALS

Original state after machining: typical powder beads on the surface of lattice struts with grease residuals are visible

Specific post machining cleaning necessary to eliminate process residuals



Resuming and Conclusions

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Custom Made AM at Lincotek

- ✓ Advanced manufacturing process; there is no «magic» inside
- ✓ Same as for serial production, exploit as much as possible solutions already available to enable fast execution
- ✓ Need of accurate design at macro and micro level
- ✓ Understanding AM is just a part of a wider manufacturing flow

- ✓ Scientific approach
- ✓ Continuous R&D activities
- ✓ Continuous training of engineers and operators
- ✓ Continuous technology update to stay “on the edge”
- ✓ Equipment and process validation
- ✓ Raw material sourcing selection, qualification
- ✓ Machine dedicated to a single material
- ✓ Co-design of the geometry with the customer. Leverage on validated process for the rest
- ✓ Dedicated post processing
- ✓ Be oriented on Custom Made production

Q & A

francesco.robotti@lincotek.com

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Thank you

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