3D-gedruckte personalisierte Implantate: Stand der Technik

27.05.2025, Swiss m4m Center

Nicolas Bouduban

We enable innovation and support MedTech and Dental companies to be successful with additive manufacturing

- 3D Printing
- Engineering
- Consulting
- Education

The Swiss m4m Center

Swiss m4m Center of Manufacturing Technologies for Medical Applications

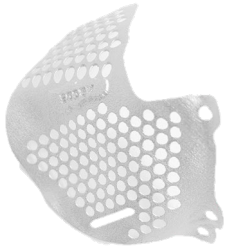
A best-in-class infrastructure

An integrated supply chain

ISO 13485:2016 certification

A dedicated partner ecosystem

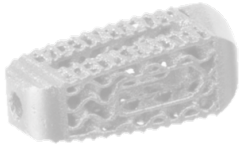
m4m Expertise



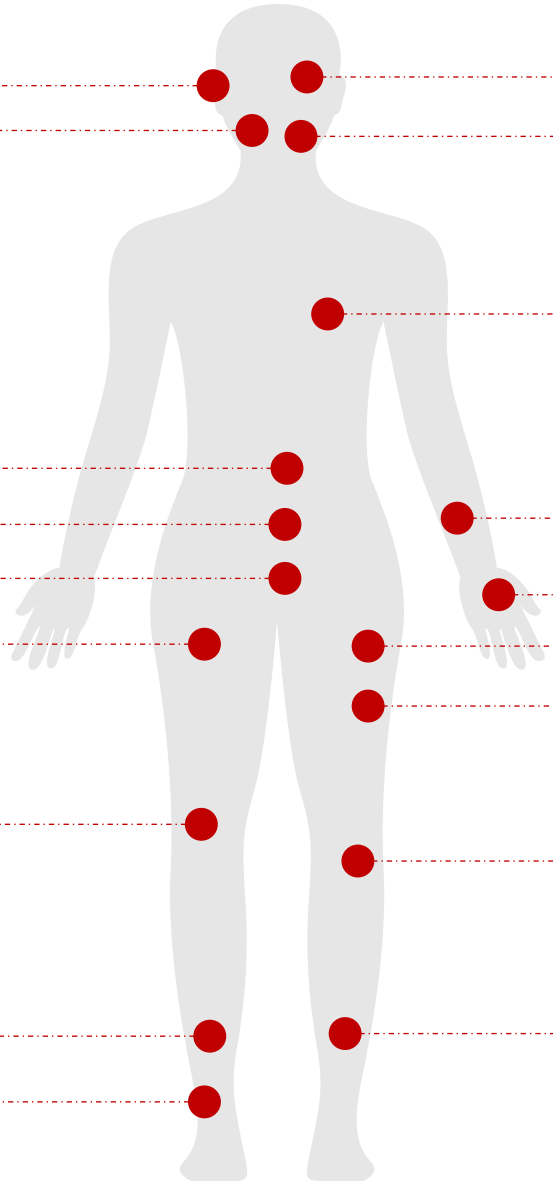
Otoplastics
Dental prosthetics
Orthodontic appliances
Custom abutments

Spine devices
Spacer, instrument
Laparoscopic instrument part
Hip blades & plates

Orthosis plug



Aiming guides
Arthrodesis nail



Orbital plates
Mandibula plates
Aiming guides

Cardiology device

Osteosynthesis instrument
Carpal implants
Hip cup
Femoral nail

Proximal Tibial plate

Trauma Templates

Various surgical instruments

The Rise of Medical 3D Printing

Value Drivers in Medical Device 3D printing

Design Freedom
Complex geometries enhance functionality

Customization
Tailored devices improve surgical outcome

Cost Efficiency
Reduced costs for specific designs

Time to Market
Accelerates production and delivery

Clinical Performance
Enhance patient outcomes

Supply Chain
Strengthens resilience through localized production

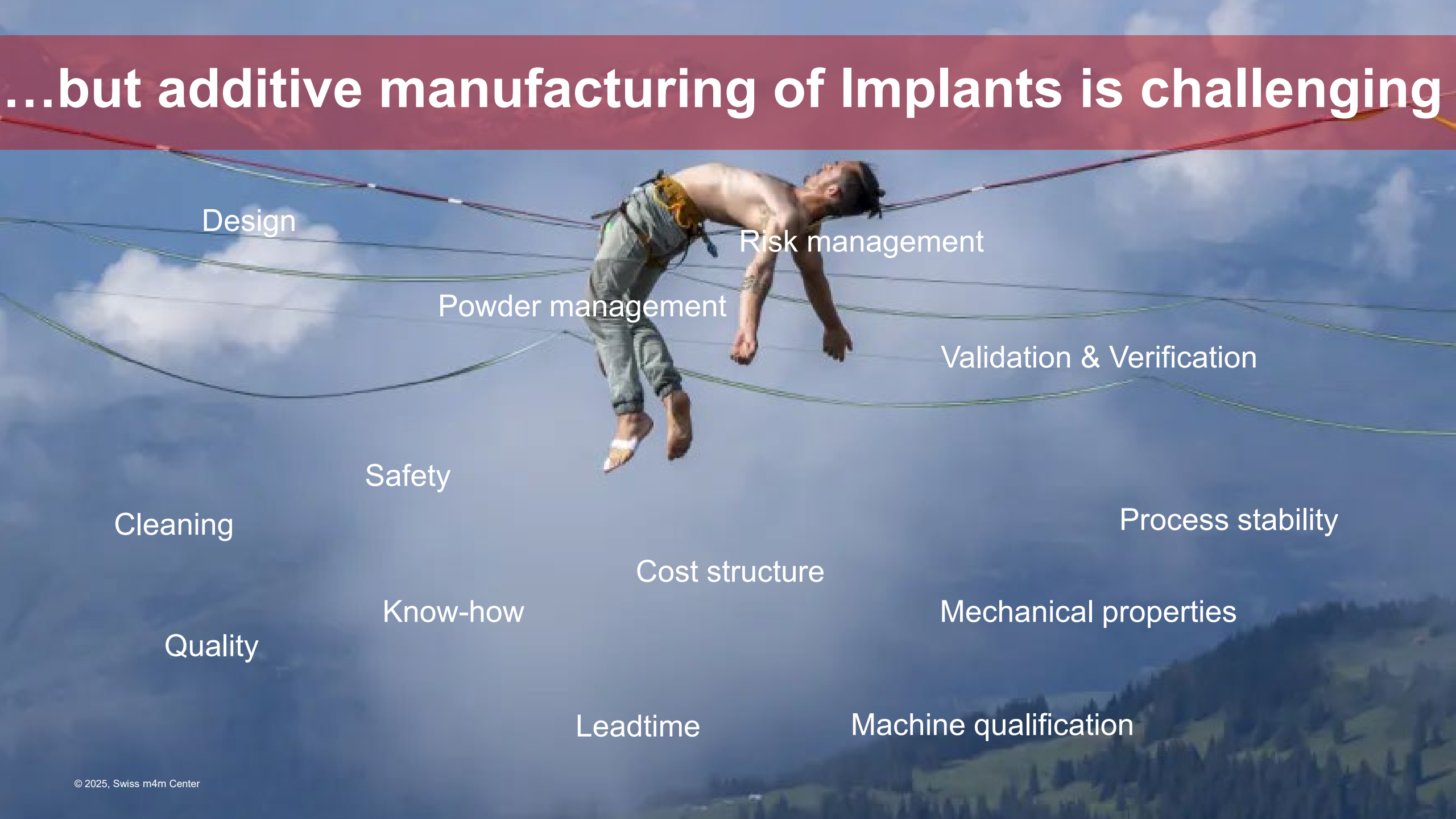
Market Access
Drives innovation and captures new market opportunities

Sustainability
Promotes energy efficiency and material reuse

The Rise of Personalization

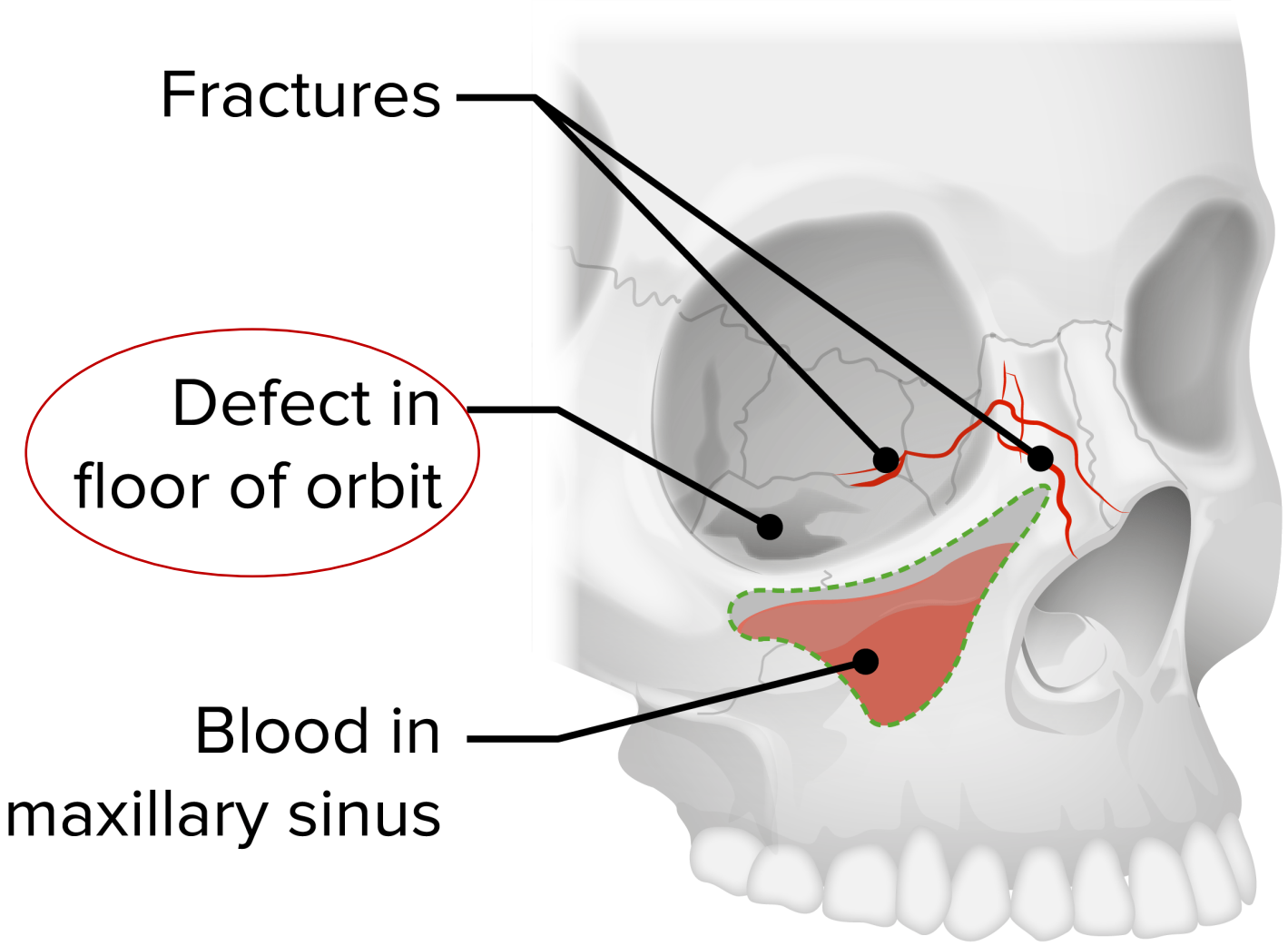
3D Printing of Custom Implants is fascinating…

…but additive manufacturing of Implants is challenging

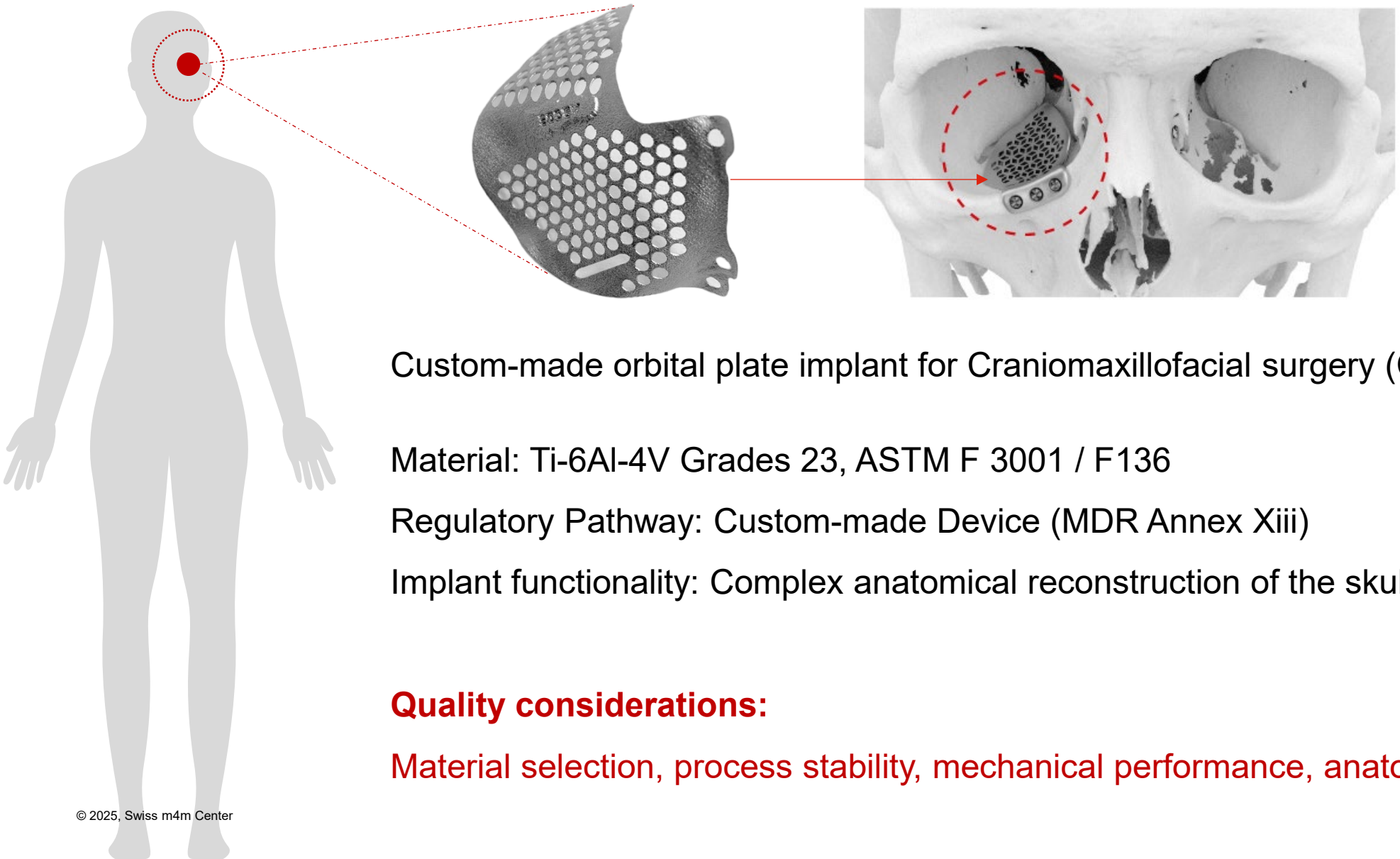


As a Starting Point…

As a Starting Point…



Craniomaxillofacial Orbital Plate Implant



Custom-made orbital plate implant for Craniomaxillofacial surgery (CMF)

Material: Ti-6Al-4V Grades 23, ASTM F 3001 / F136

Regulatory Pathway: Custom-made Device (MDR Annex Xiii)

Implant functionality: Complex anatomical reconstruction of the skull, low profile

Quality considerations:

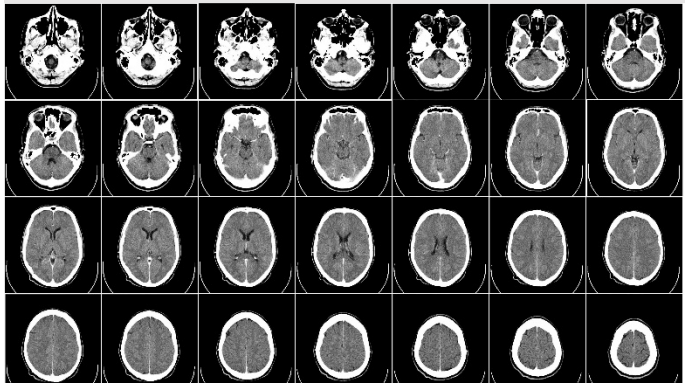
Material selection, process stability, mechanical performance, anatomical fit and cleanliness

Orbital Plate Digital Workflow

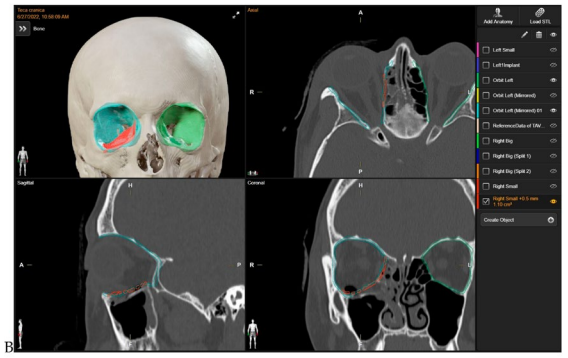
End to End Process in 5 days

Digital Medical Imaging

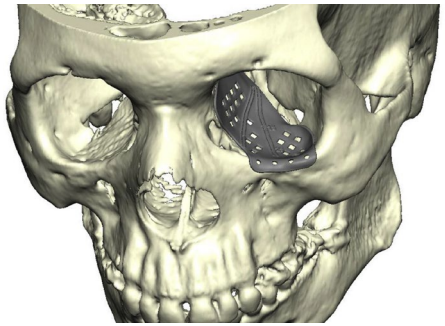
Medical Image Processing



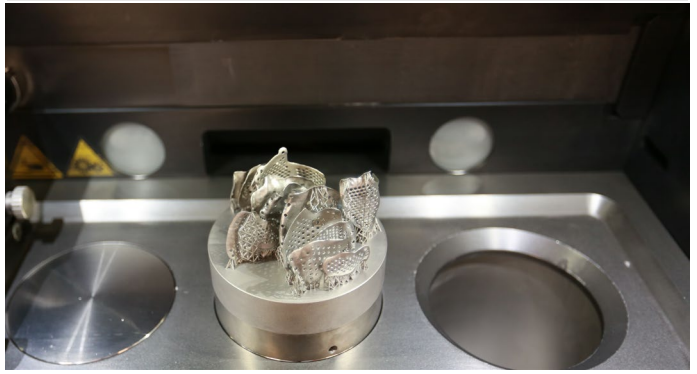
Surgery Planning



Design of Implants



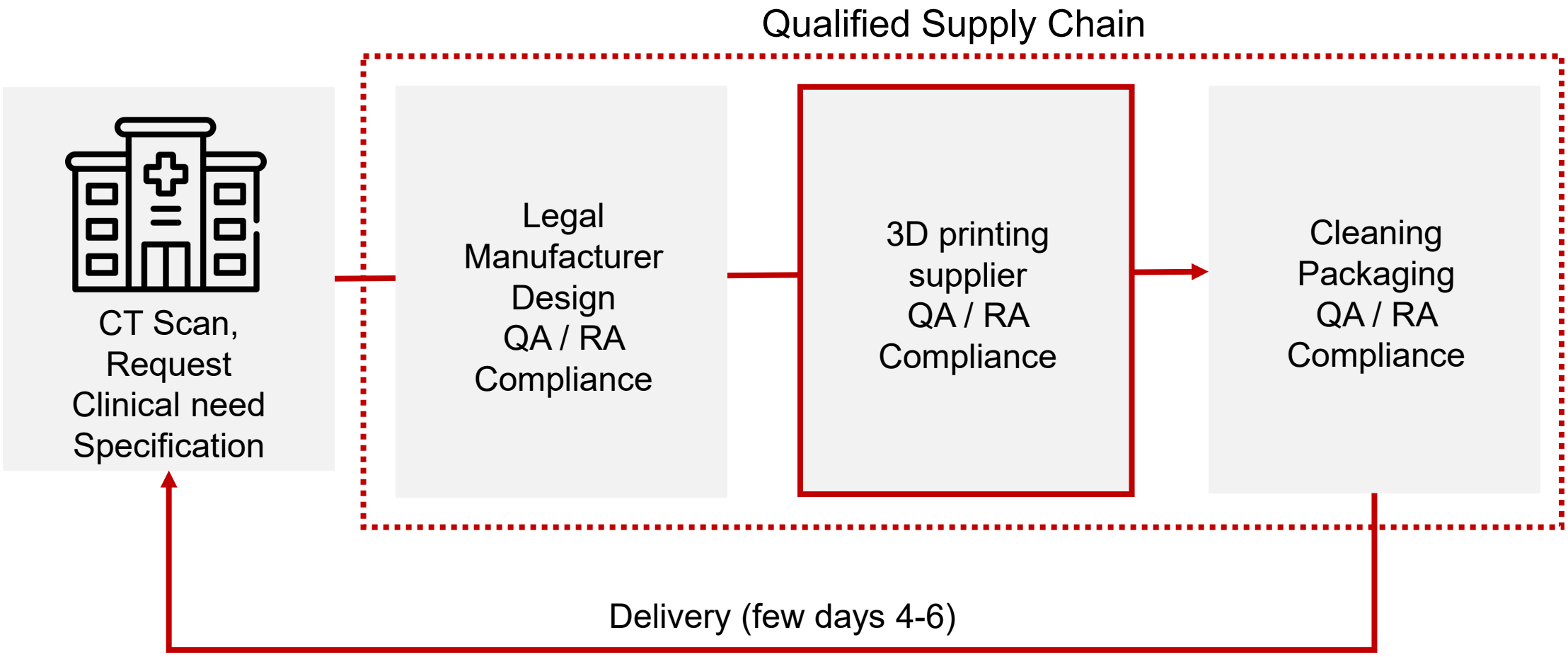
Implant manufacturing



Surgery and Implantation

Orbital Plate Supply Chain

End to End Process



Production under ISO 13485

Orbital Plate Implant

ISO 13485:2016

Pre Processing | In Processing | Post Processing

Request Verification

Data Preparation

Powder Management

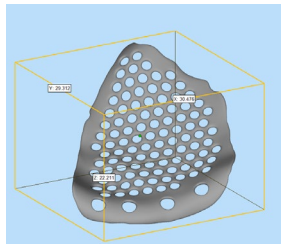
Additive Manufacturing

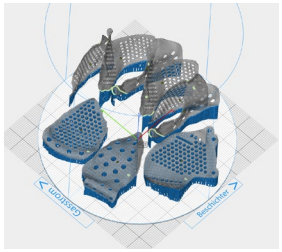
Heat Treatment

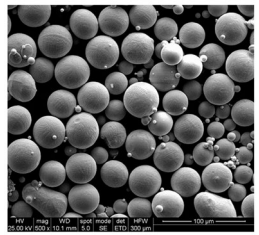
Surface Treatment

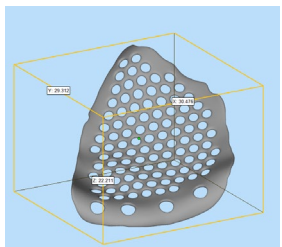
Control

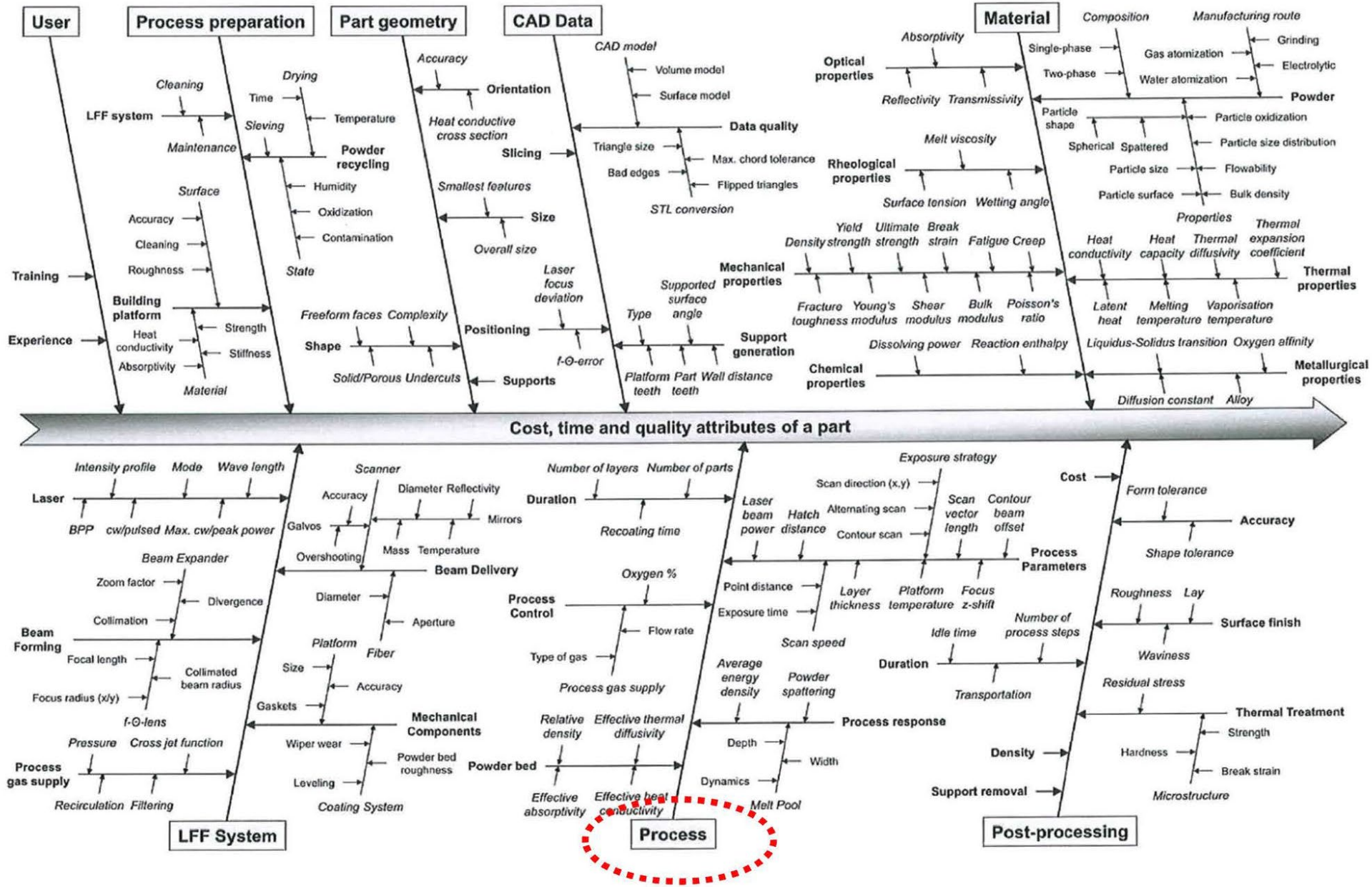
Cleaning

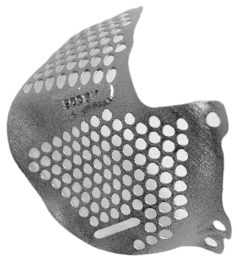




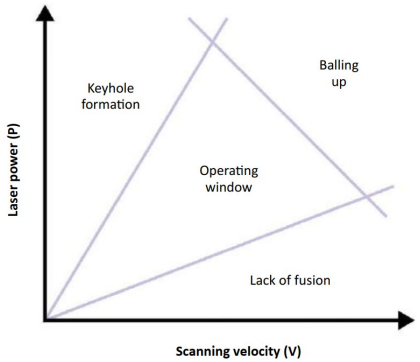




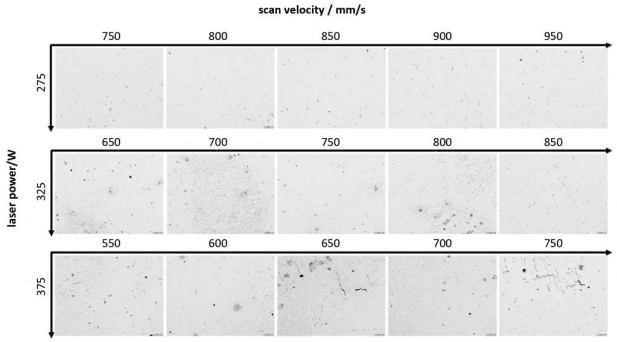




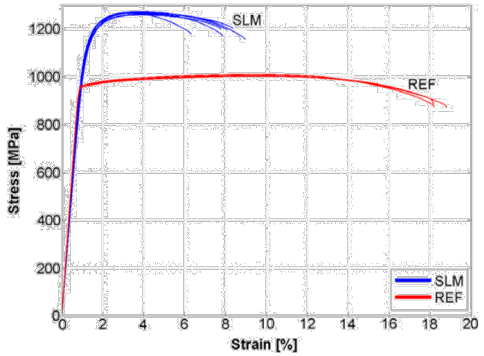
Some Process Considerations



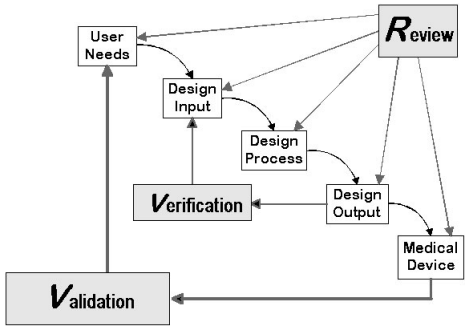
AM Parameters



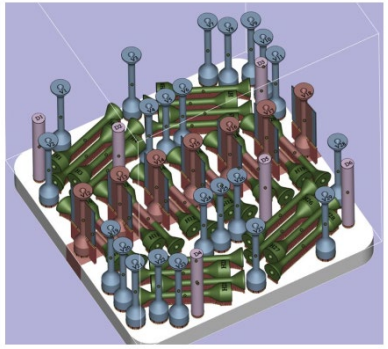
Density



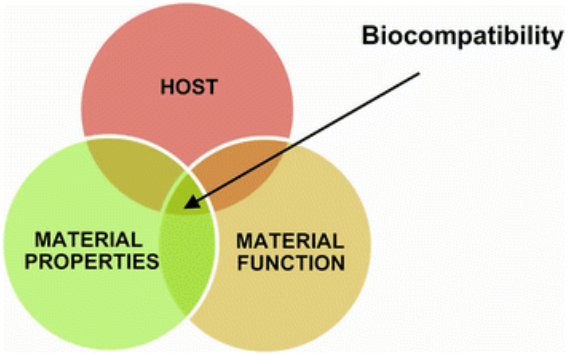
Mechanical performance



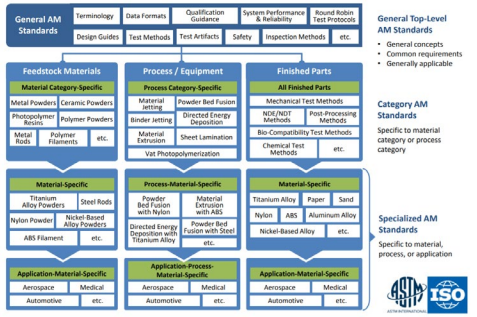
V&V



Reproducibility

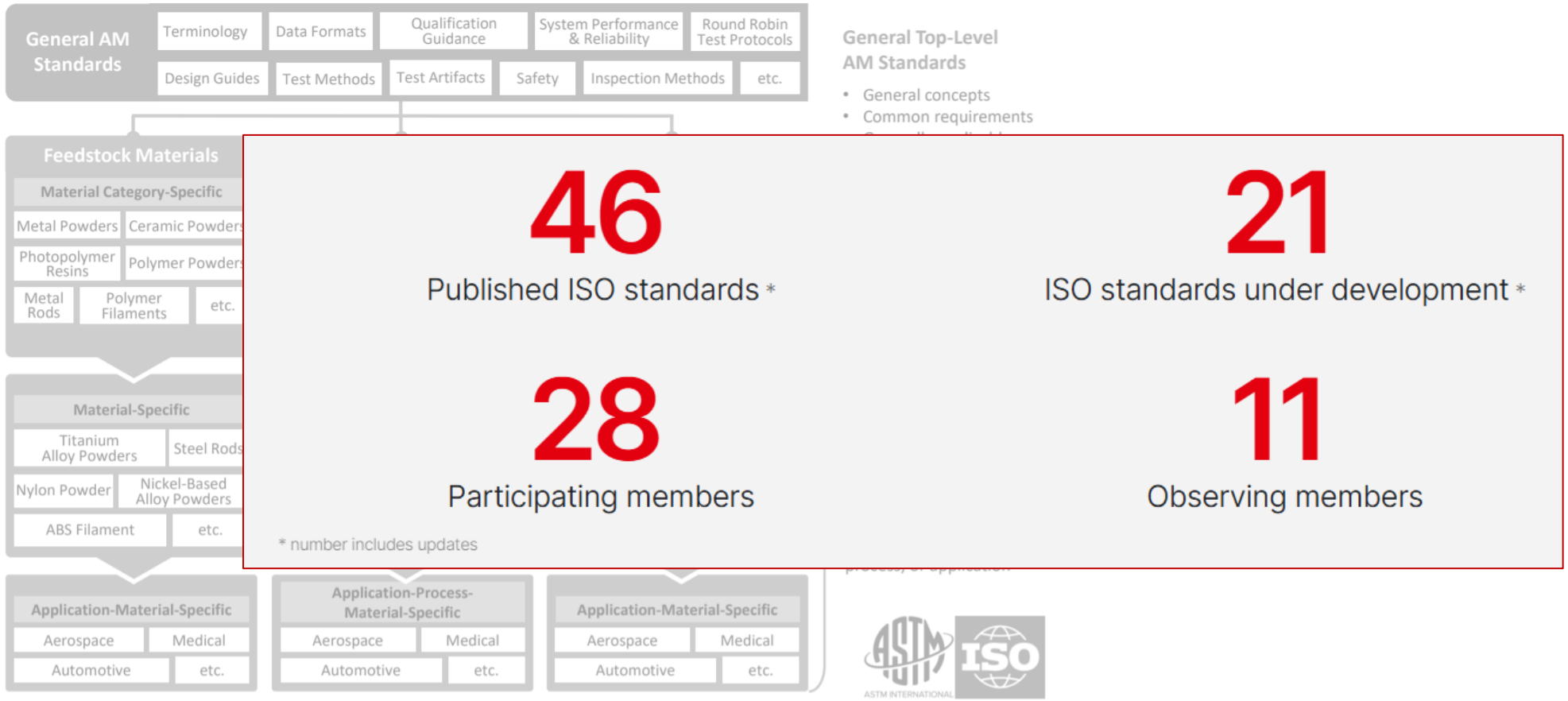


Biocompatibility



Norms

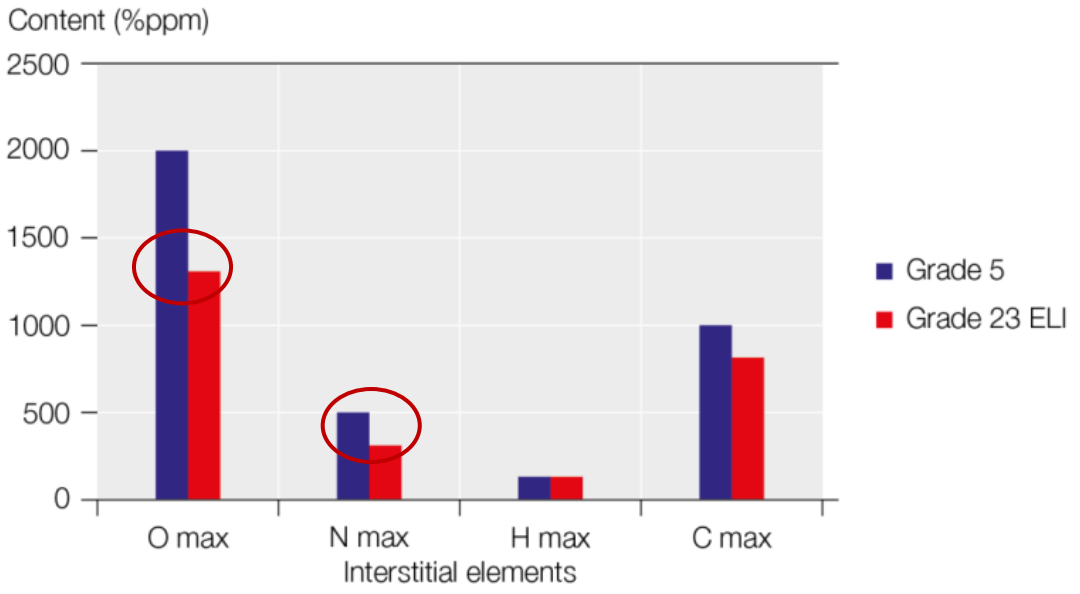
ASTM F42 / ISO TC 261

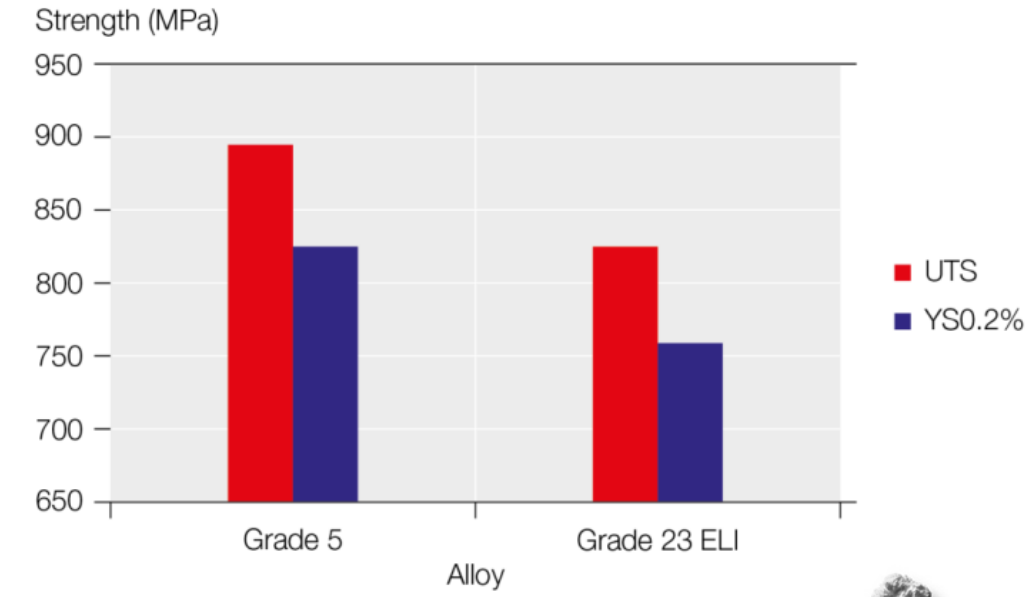


► Growing numbers of standards but still too few to support regulated 3D printing activities.

Material Selection: Ti-6Al-4V Grade 23

Standards: ASTM F 3001 / F136





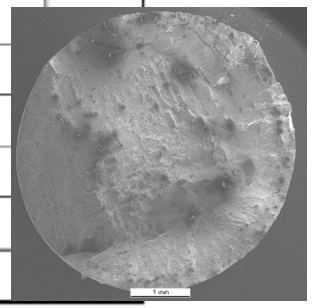
Mechanical properties	According to ISO and/or ASTM:	
	Strength UTS/Rm	≥ 900 MPa
	Yield strength $R_{0.2}$:	≥ 795 MPa
	Elongation A:	≥ 10%

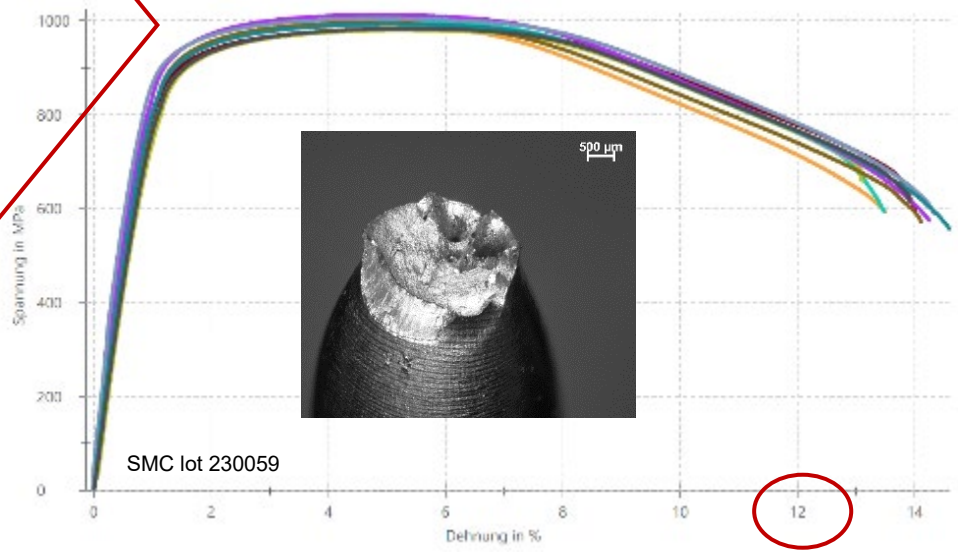
► Material of choice for long-term implants.

Process Qualification

SMC lot 200054 SFP (200062)

Mechanische Eigenschaften		
Charge 200062 / Ident. Nr. O20_0029_1_1		
Zugprüfung DIN EN ISO 6892-1:2017 (Verfahren A) / ASTM E8M – 16 (Methode B)		
Anzahl Zugprüfungen (n = 7)		
Implantatlegierung aus Ti-6Al-4V	*Messwerte*	*Vertrauensbereich P95%*
Dehngrenze $R_{p0.2}$ in MPa	1022	± 42.9
Zugfestigkeit R_m in MPa	1181	± 9.5
Bruchdehnung A in %	2	± 0.7
Brucheinschnürung Z in %	10	± 5.6
Bemerkung: Bei n ≥ 5 ist ± als Vertrauensbereich P95% wiedergegeben.		



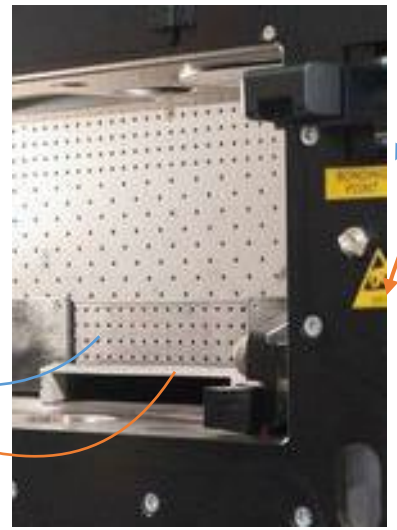


Process Qualification

►The machine indicating low Oxygen, does not necessarily mean there is no leakage...

►The machine indicating low Oxygen, does not necessarily mean there is low Nitrogen...

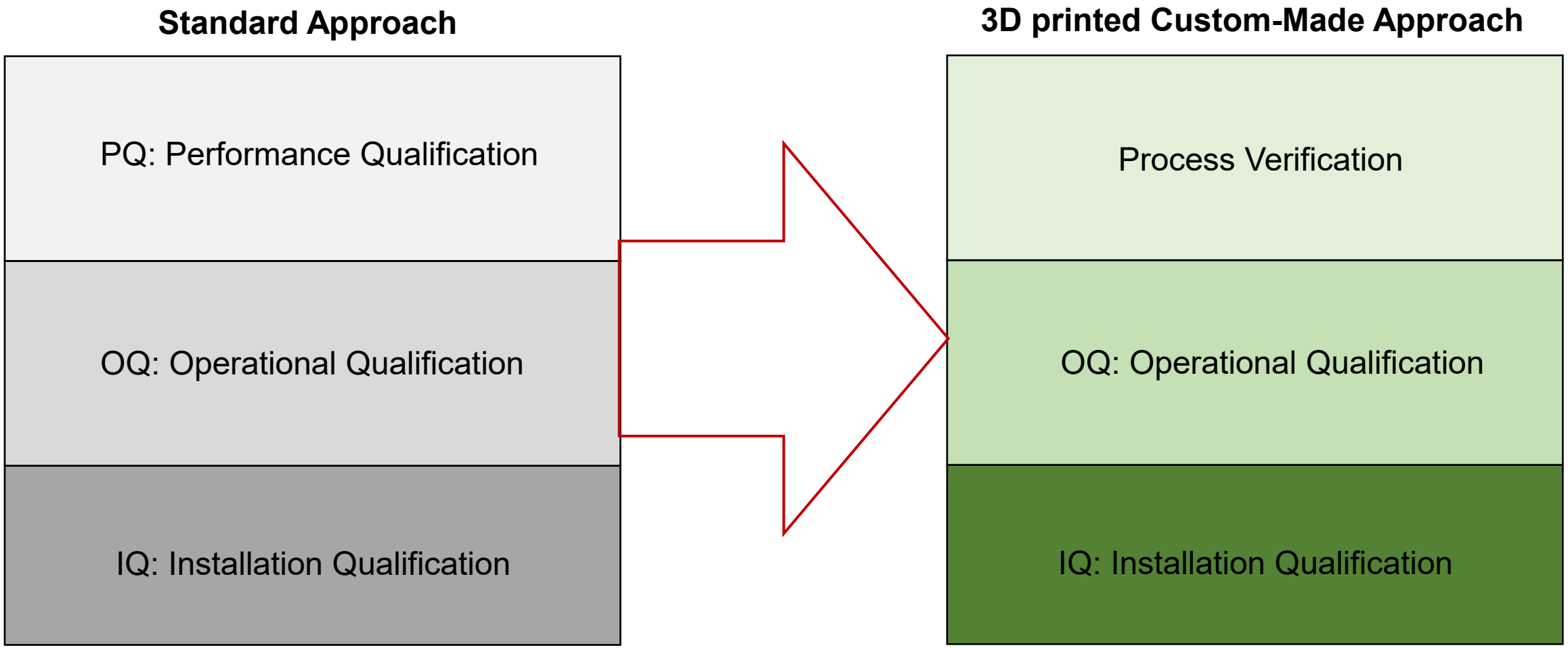
►Permanent Argon addition helps to minimize O2 and N2 intake and improve mechanical properties.



O2

N2

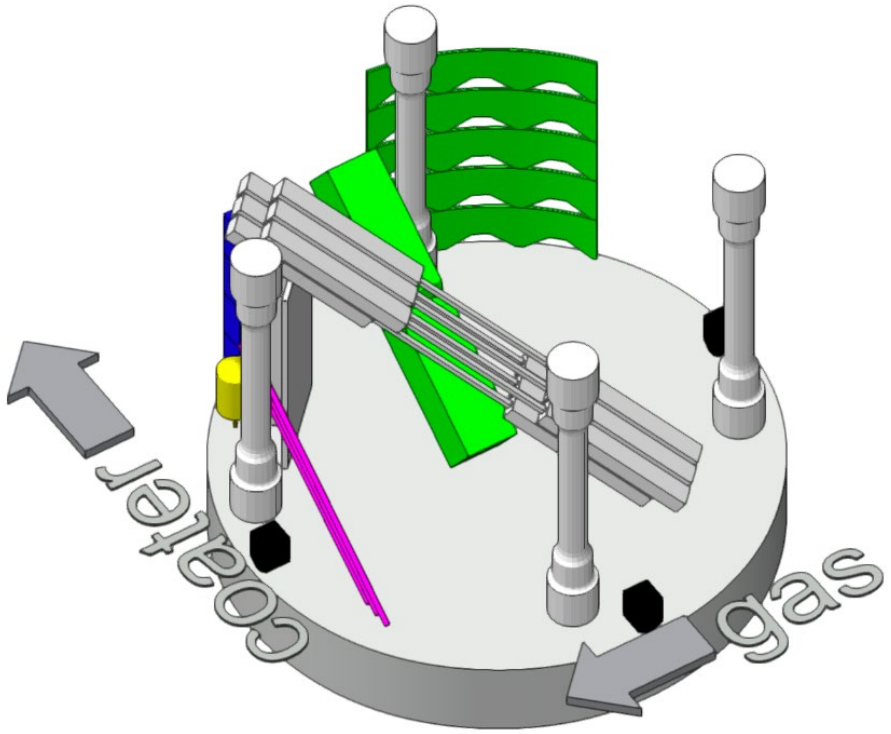
Process Stability: Equipment Qualification



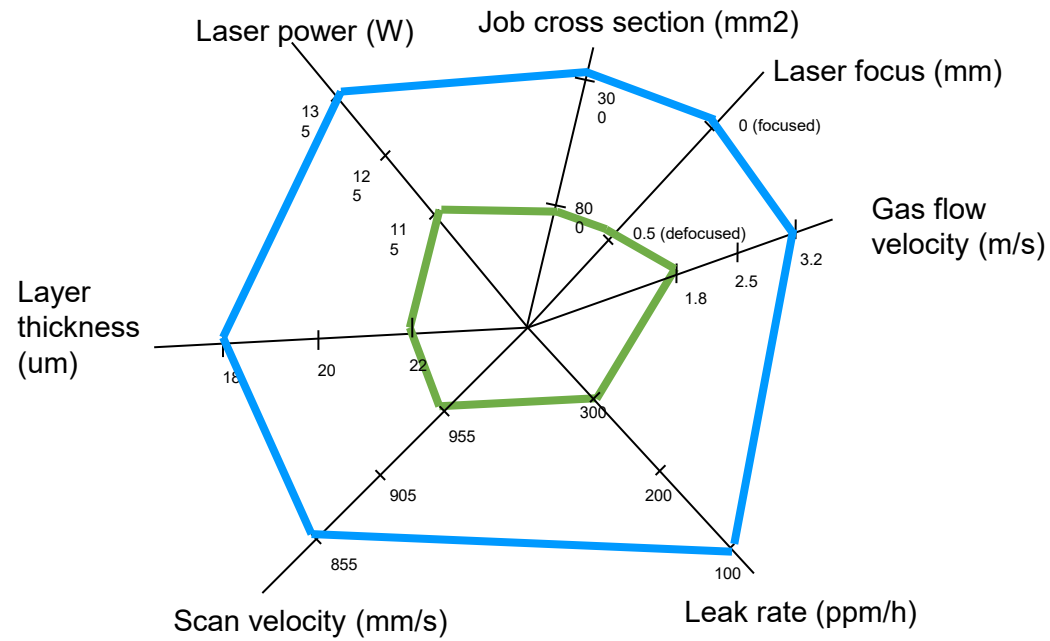
► This allows to consider more variability of use cases

Process Stability: OQ Runs (Min / Max)

Build Job Definition



Operating Window



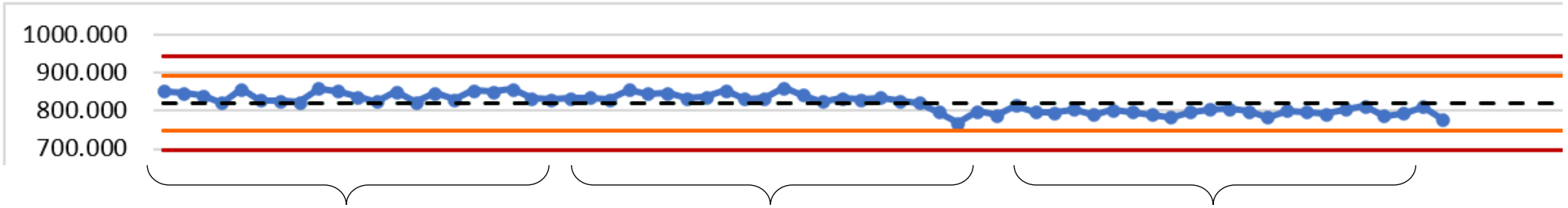
Minimum energy density

Maximum energy density

Process Stability: OQ Runs (Min / Max)

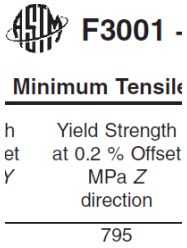
Std Deviation (s)	23.895
Mean (m)	821.349
Upper Control Limit (UCL)	893.035
Lower Control Limit (LCL)	749.663

Sample Size	**67**
Short Term Capability (Cp)	**1.72**
Short Term Centered Capability (Cpk)	**1.71**



m4m lots: 220016 – 220020 (OQ max) 220042 – 220046 (OQmax) 220047 – 220049 (OQmin)

Yield strength 5mm diam
N/mm2
Raw surface

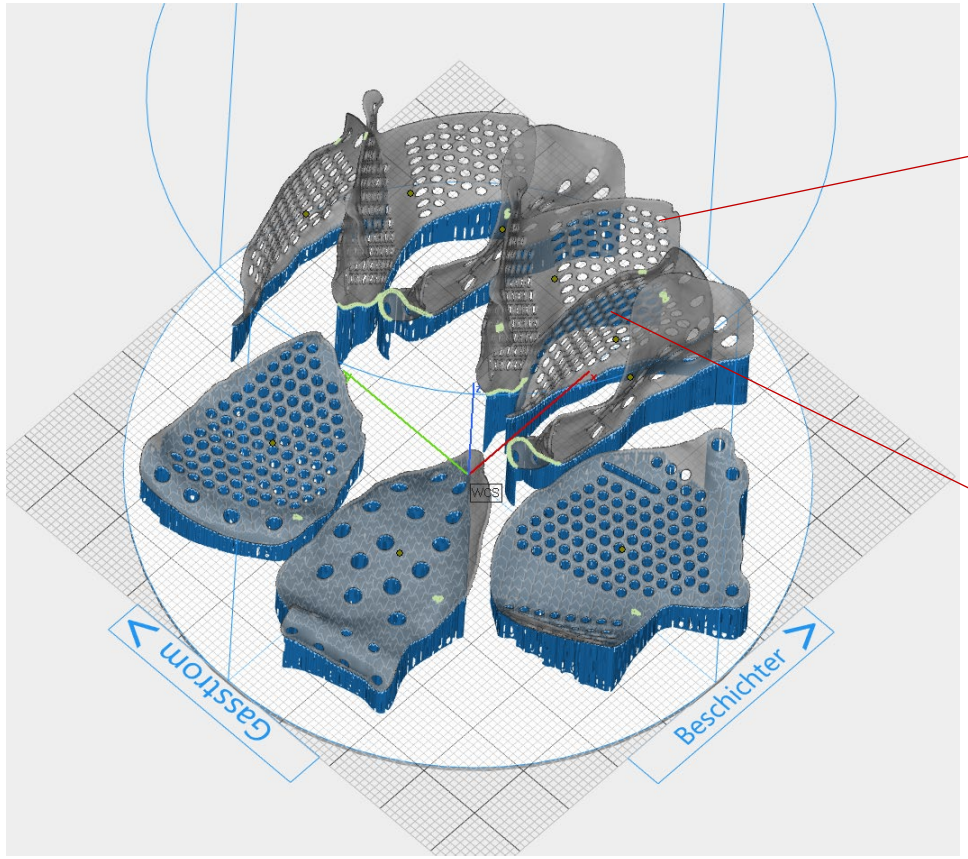

F3001 -

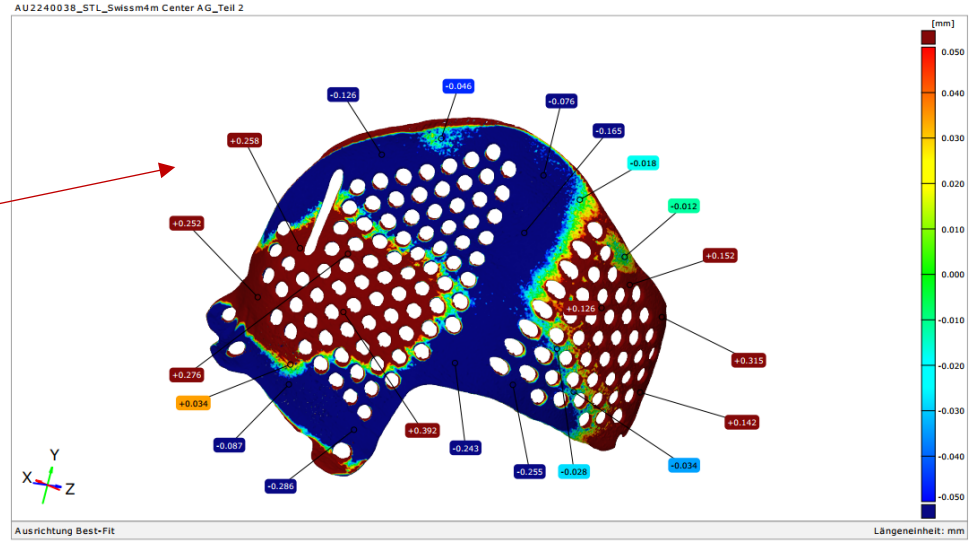
Minimum Tensile

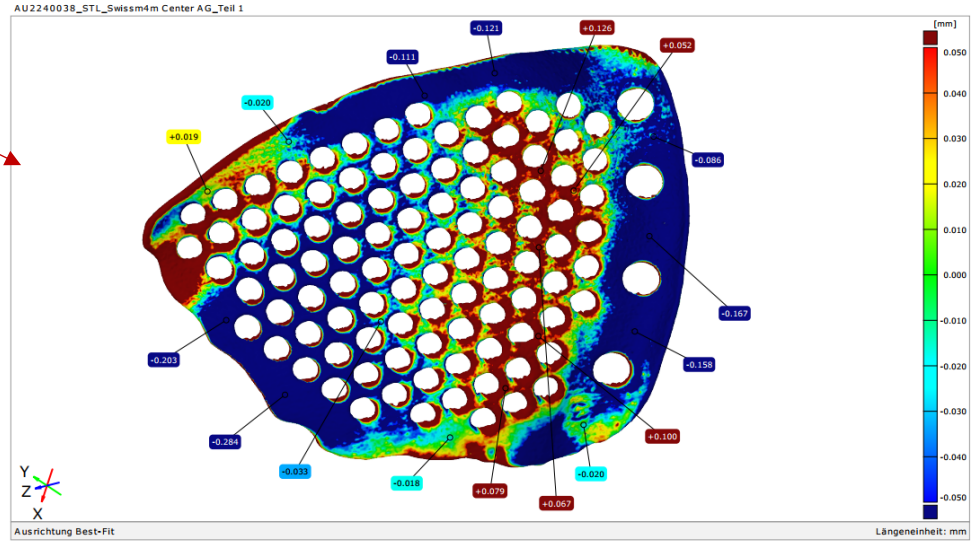
h et Y	Yield Strength at 0.2 % Offset MPa Z direction
	795

► Constant process meeting the expectations for as-build parts

CAM Parameter Analysis (build orientation)



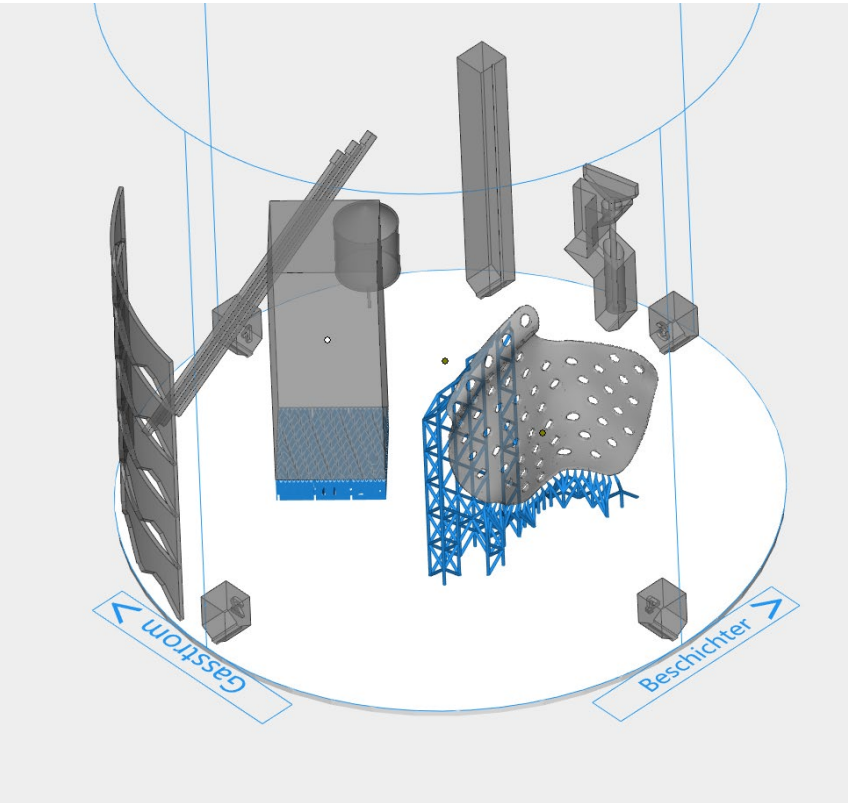




►Best fit in standing position: ± 0,3mm

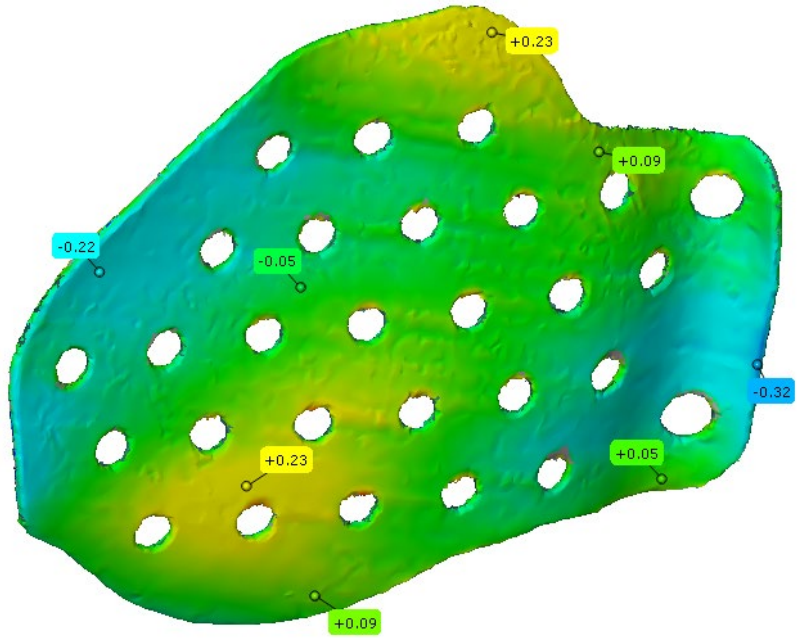
Process Verification

Print job verification with specific test coupons



1) Geometry
2) Shape accuracy
3) Bending behavior
4) Density
5) Down-Skin

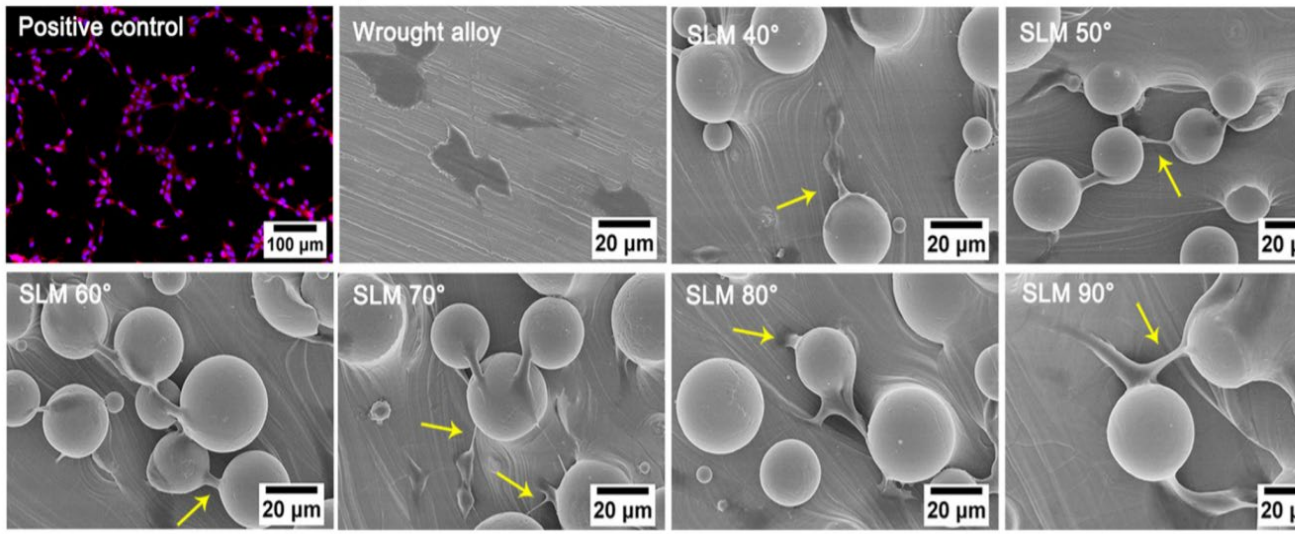
Optical 3D Scan for variance comparison

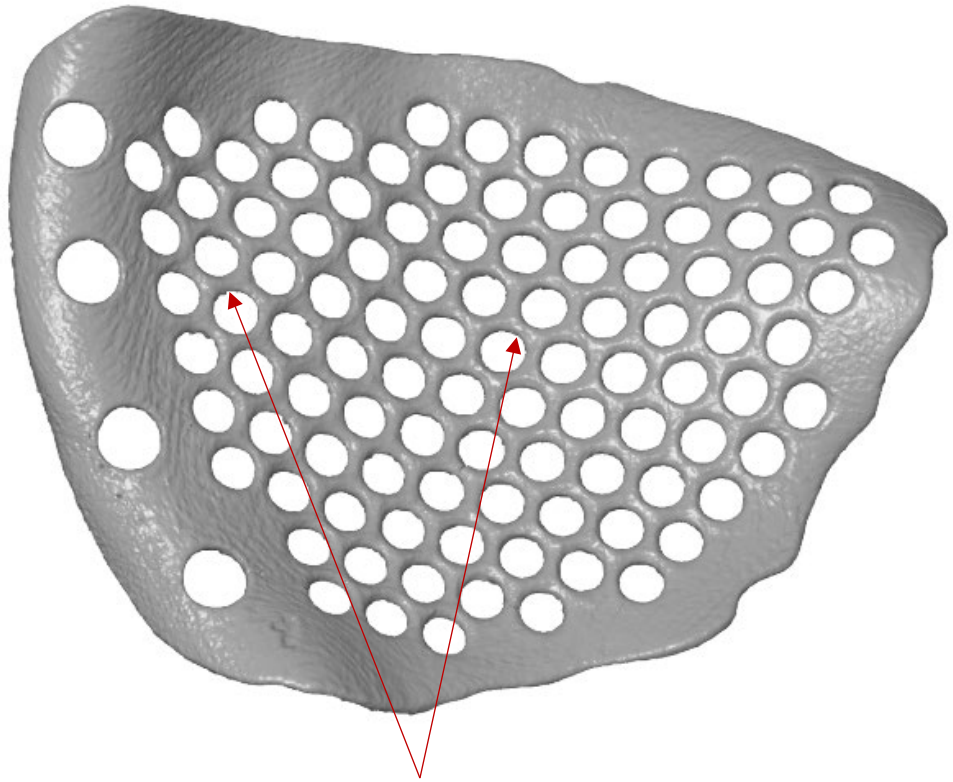


Acceptance criteria due to customer specification

Implant Cleanliness

Powder Adhesion





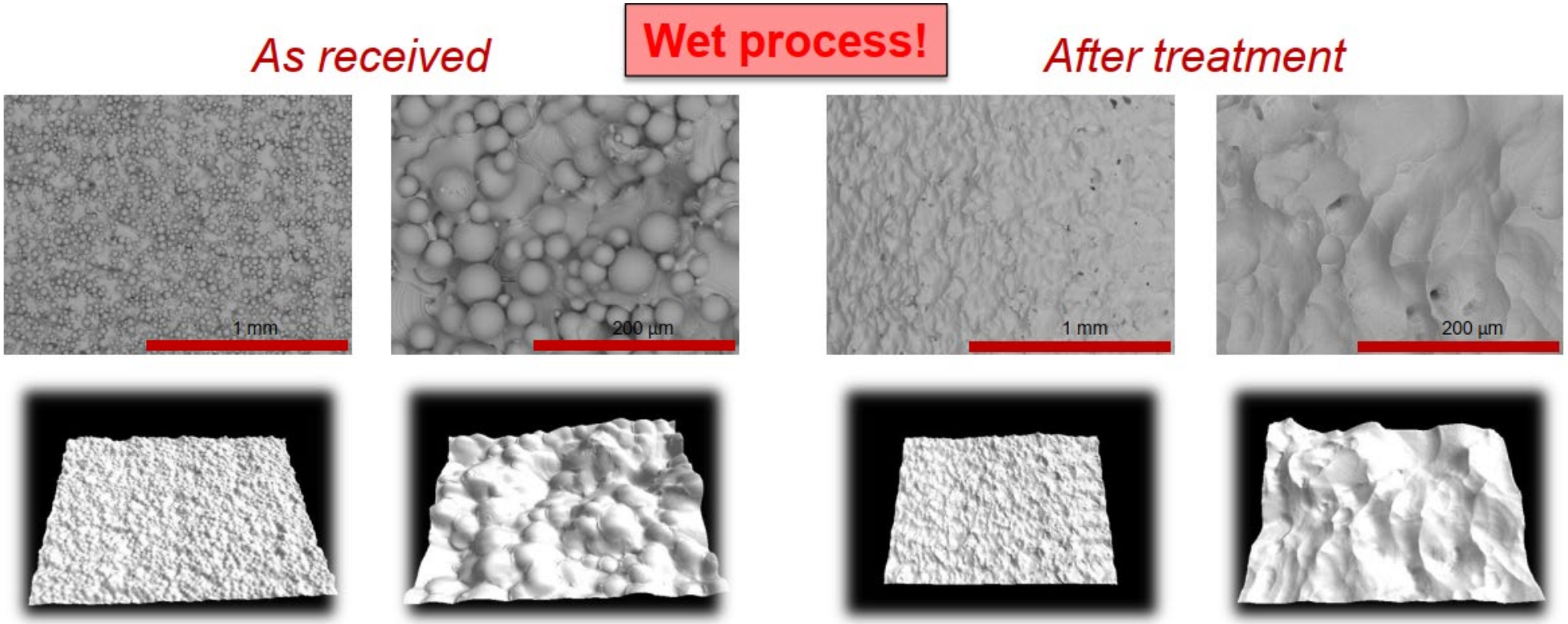
Fused powder in the holes

► This risk needs to be assessed, mitigation according customer specifications

Ref: Cen Chen et al: 3D printed porous Ti6Al4V cage: Effects of additive angle on surface properties and biocompatibility; bone ingrowth in Beagle tibia model, Materials & Design, Volume 175, 5 August 2019

Implant Cleanliness

Powder Adhesion



► Powder Adhesion may be minimized by the use of specific post-processing steps such as pickling.

Quality Management is Key to Master Implant AM

It’s not about ideas.
It’s about making ideas happen… Scott Belsky

Thank You

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Virtual Tour