Whitepaper

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EOS M 300-4 Machine Capability Study

Machine Performance Evaluation for Mechanical & Physical Properties

This Whitepaper gives answers to:

- Examines machine performance of EOS Operational Qualification Layout built with the EOS M 300-4 with Ti64 ELI
- Compares lattice specimens built on 3 different batches Ti64 ELI
- Discuss results from an Additive Manufacturing (AM) OEM's perspective as well as Medical Device Producer's perspective

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Introduction

Additive manufacturing (AM), commonly known as 3D printing, has become a transformative force across industries. The medical device manufacturing sector is not an exception, but a pioneer in the implementation of AM. This whitepaper was developed in cooperation with Lincotek and explores the profound impact of additive manufacturing on medical device production, highlighting key benefits and innovations. Additionally, it delves into the required process validation in the medical device industry, emphasizing its importance and implications for product quality and efficiency. Lastly it provides insights into the current performance level of the EOS M 300-4 system when manufacturing solid and lattice test samples.

Lincotek is the ideal partner for this study, thanks to its pioneering role in the medical field and its extensive experience in additive manufacturing (AM). Lincotek produces close to one hundred thousand medical devices per year using AM technology. Furthermore, Lincotek has expanded its laboratory capabilities with a range of instruments that are crucial for understanding and mastering the quality and production of AM parts.

AM in Medical Device Manufacturing

In the dynamic field of medical device manufacturing, AM is a game-changer, revolutionizing the industry with its ability to create intricate, personalized devices. AM is well-suited to craft complex structures, such as lattice structures, cost-effectively to enhance implant fixation and osseointegration. The customization based on patient specific data is a standout feature, significantly impacting patient life quality.

AM's efficiency extends to rapid prototyping during research and development studies, accelerating design improvements, and ensuring optimal functionality and fit. Distinguishing itself from traditional manufacturing, AM minimizes material waste, aligning with sustainability and cost-effectiveness.

During serial production, AM's production on-demand capabilities prove essential for optimizing inventory and reducing lead times. AM's adaptability to a variety of biocompatible materials is crucial for versatile medical applications, enabling the production of devices suitable for implantation or direct contact with biological tissues.

In conclusion, AM significantly enhances medical device manufacturing, enabling the production of highly customized, efficient devices. It contributes to advancements in patient care, design flexibility, and sustainability, marking a transformative journey from intricate geometries to personalized solutions. AM's prevalent influence shapes the exciting future of medical devices.

Process Validation in the Medical Device Industry

Process validation is a critical term in the medical device industry, signifying that a process has undergone rigorous scrutiny to ensure that pre-defined requirements have been met. This is particularly crucial when the predetermined requirements of a product can only be assured through destructive testing.

While regulatory requirements mandate process validation, manufacturers may opt for it to improve overall quality, reduce costs, eliminate scrap, enhance customer satisfaction, among others. When combined with well-controlled design and development activities, a validated process can result in reduced time to market.

The validation of a process involves several phases, in which we will be addressing the three main qualification phases and steps:

1. **Installation Qualification (IQ):** Qualification of equipment and provision of necessary services.
2. **Operational Qualification (OQ):** Demonstration that the process produces acceptable results and establishment of process parameter limits.
3. **Performance Qualification (PQ):** Establishment of long-term process stability.

There are many methods and quality tools that can be used in process validation. Control charts, capability studies, designed experiments, tolerance analysis, robust design methods, failure modes and effects analyses, sampling plans, are some examples.

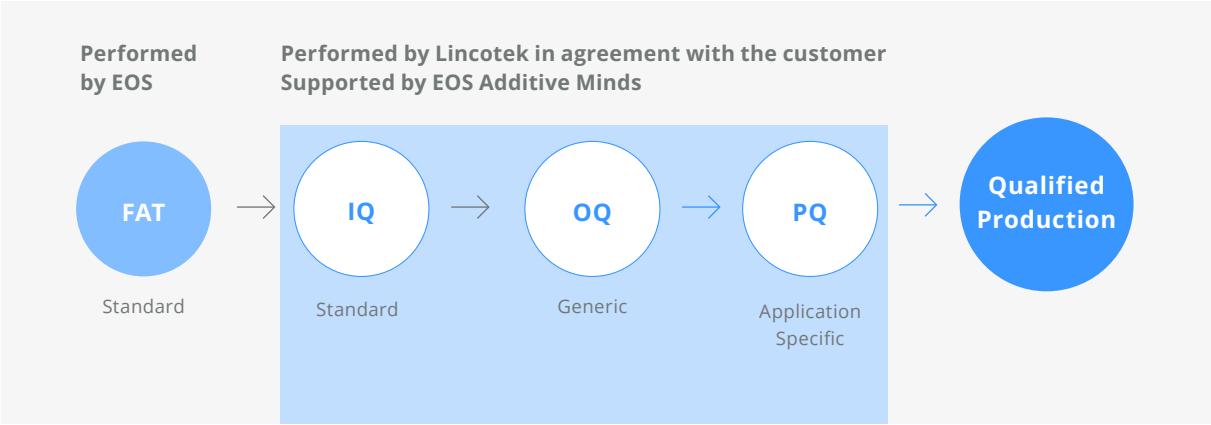

Figure 1: Established Qualification Roadmap for medical device production

Capability studies are performed to evaluate the ability of a process to consistently meet a specification. This is accomplished by calculating capability indices, that give us insight in to the process spread (Pp) and location between the tolerances (Ppk). If acceptable values are obtained, the process consistently produces product that meets the specification limits. Capability studies are frequently used towards the end of the validation to demonstrate that the outputs consistently meet the specifications. However, they can also be used to study the behavior of the inputs in order to perform a tolerance analysis.

In conclusion, a capability study for an AM machine can be crucial to assess and understand its performance and reliability. By setting and achieving specific targets and objectives in this study, manufacturers gain insights into their AM machines, leading to improved process control, enhanced product quality, and increased overall efficiency. This comprehensive approach ensures reliable and high-quality medical devices for end-users.

Targets and Objectives of this Study

As we delve into the operational qualification (OQ) phase of medical device process validation, a critical spotlight shines on the additive manufacturing capability study. This study, the outcome of a successful collaboration between Lincotek and EOS, offers a first insight on the solid and lattice properties of components produced using the EOS M 300-4 and assesses the reliability of the Ti64 ELI Direct Metal Laser Solidification (DMLS) process parameters.

In this exploration, we meticulously evaluate the static mechanical properties measured from additive manufactured test coupons, scrutinizing them against predetermined and standardized acceptance criteria. Our focus extends to understanding the distribution and capability of the data within these manufactured parts.

We assess the relative density and compressive yield strength of the lattice test coupons, providing first insight on process spread and location when using parameters historically developed for the EOS M290 system.

In conclusion, this capability study utilizing additive manufactured test coupons within the OQ phase of medical device process validation seeks to demonstrate the additive manufacturing process's reliability and consistency. Reviewing and optimizing this process related to solid and lattice properties contributes to overall product quality, performance, and regulatory compliance. Findings from this study can guide decisions and enhancements in the manufacturing process, ensuring the production of superior quality medical devices.

Results and Discussions

An EOS M 300-4 machine was used to build the specimens with DMLS technology. The machine is equipped with 4 × 400W Yb-fiber lasers each of which can expose the entire build platform with dimensions of 300 mm × 300 mm × 400 mm.

Figure 2: EOS M 300-4 with IPM M Setup Station configuration (Source: EOS)

Two different layouts were taken from 9 build jobs produced with 3 different powder batches of EOS Ti64 ELI material.

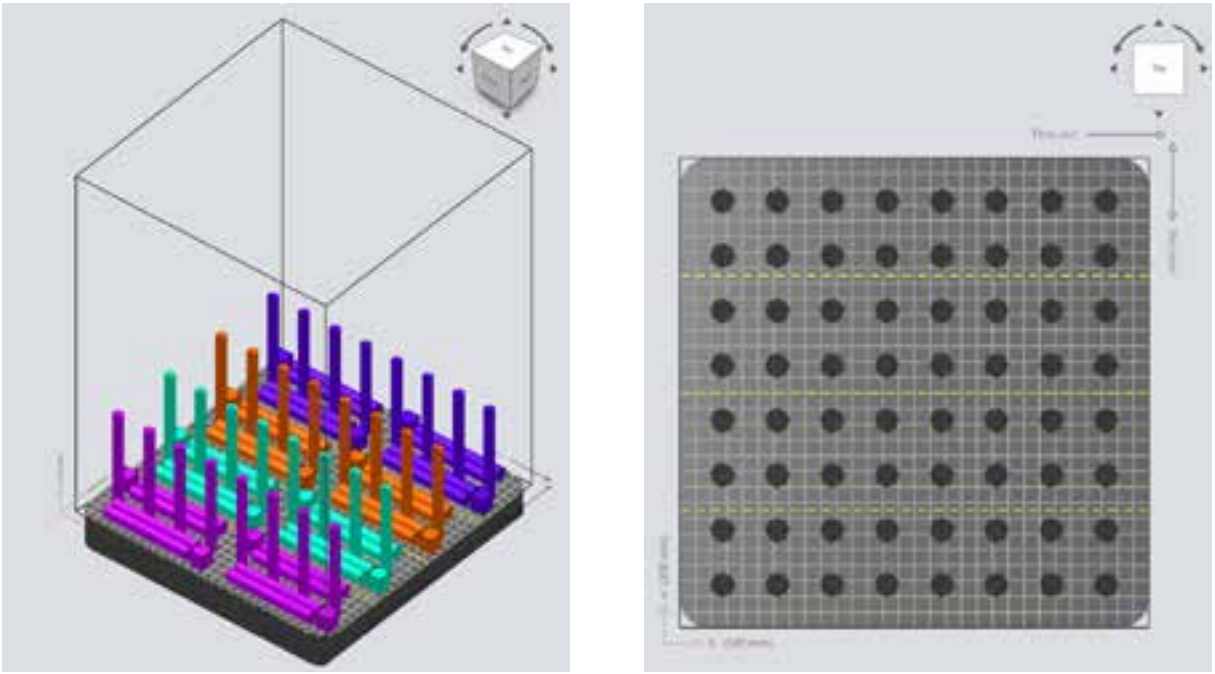

Figure 3: The Qualification layout that consist of density cubes, horizontal and vertical tensile bars (left). The lattice job layout that consists of 16 cylindrical specimens per laser.

Bulk Density

The average density value obtained from density measurements of cubes following ISO3369 is 4.305 g/cm³, with a standard deviation of less than 0.001 g/cm³, derived from a sample size of 144 density cubes. Analysis of mean measurement values was conducted with respect to batch, job, and position. No correlation with position was noted. The findings indicate a minimal dependency on powder batch, attributed to variations in chemical composition across batches. Metallographic examination of samples with the lowest and highest density values revealed no discernible relation-ship between density and porosity, with maximum observed porosity at 0.011%. These outcomes affirm that density differences fall within the margin of measurement uncertainty. The nominal values of measurements fall below the theoretical reference density of Ti64 ELI, which is 4.43 g/cm³. This is believed to be due to the limitation of the test method and some other factors like surface condition of the samples or the operator.

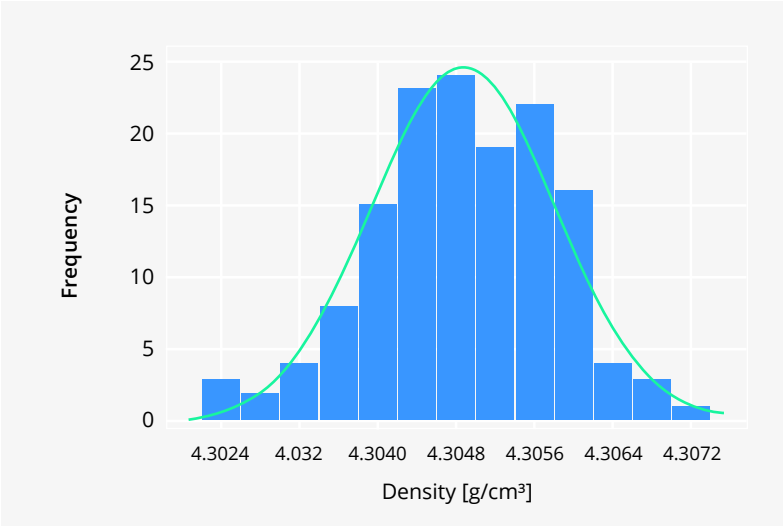

Figure 4: Histogram of Archimedes density measurements

Figure 5: Cross-cut porosity analysis the sample with the lowest Archimedes density of 4.3022 g/cm³ and 0.003 porosity based on metallographic analysis

A total of 12 density cubes, which have the minimum and maximum density levels were selected for metallographic porosity analysis to test the above-mentioned hypothesis. The maximum measured porosity level of 0.011% was found with an automated internal EOS test methodology.

Tensile Testing

Tensile testing was performed following the guidelines outlined in ISO 6892 and ASTM E8M. Specimens were machined to according to ASTM E8M – Specimen Type 3 which has 6 mm diameter with an initial length of 90 mm. While ASTM F3001 specifies the minimum requirements for AM-Ti6Al4V ELI and ASTM F136 delineates those for Wrought Surgical Implants, no upper limit is defined for these properties. To address this, a novel approach was devised, employing the principle that "the higher the strength, the lower the ductility," and vice versa, to define upper limits for each property. (Yağmur et al, Machine Capability Study, EOS M 290 & EOS Titanium Ti64ELI, 2020) Maximum values for tensile strength and yield strength were computed based on a model derived from data on both as-built and heat-treated specimens. Correlations between tensile/yield strength and ductility were explored using regression models, and maximum values for these mechanical properties were determined accordingly. The analysis was conducted on 288 heat-treated and 288 as-built tensile bars. However, this whitepaper focuses solely on heat-treated properties, omitting discussion of as-built mechanical properties.

The sample size for this whitepaper was taken from 9 build jobs composed of 64 tensile bars each, with a total of 576 heat treated bars. Tests were done at the Lincotek internal laboratory. Notably, the tensile properties exhibited remarkable repeatability, with individual results demonstrating a very narrow distribution range. For instance, the standard deviation of tensile strength was 18.42 MPa, significantly lower than the industry-accepted range of 100 MPa for metallic materials.

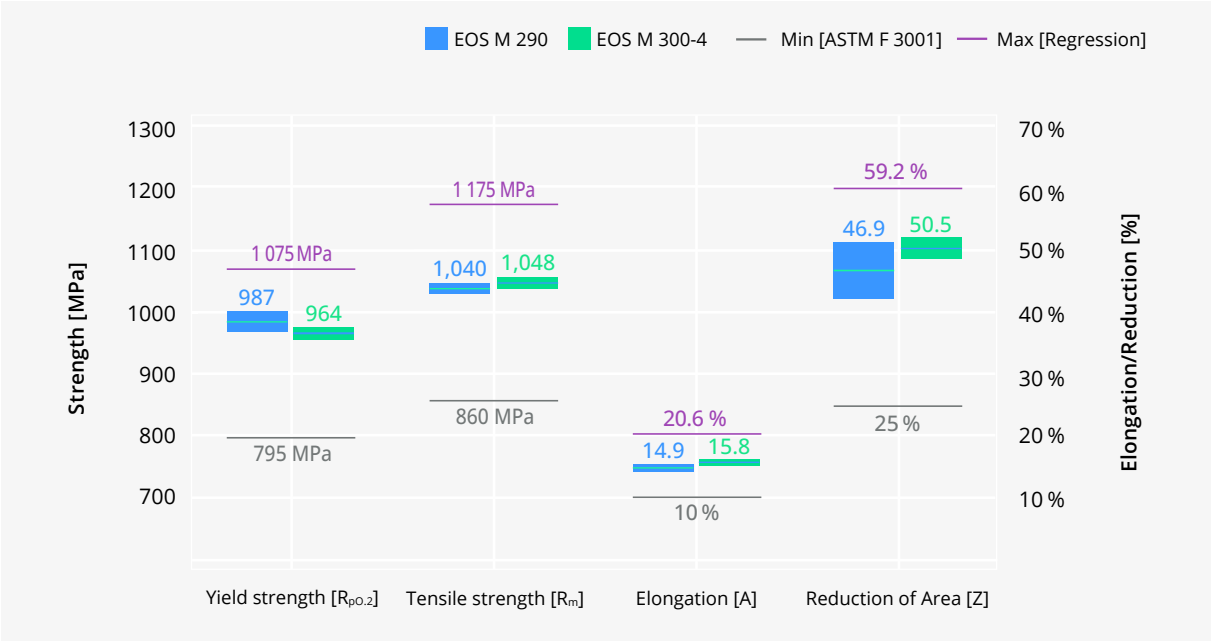

Figure 6: Comparison of tensile properties EOS M 290 and EOS M 300-4

	Yield Strength [MPa]	Tensile Strength [MPa]	Elongation [%]	Reduction of Area [%]
P_p	2.39	2.85	1.63	1.65
P_{pk}	1.90	2.30	1.48	0.84

Figure 7: Statistical capability values of tensile properties for EOS M 300-4

The values from the EOS M 300-4 machine are equivalent to the EOS M 290 study. Since the upper process limits were modeled solely from EOS M 290 data, the index values for EOS M 300-4 are lower, nonetheless this method gives the reader the chance to make one-to-one comparison.

Roughness

The roughness measurements were performed with contact profilometer to ISO 4287 and the results were analyzed via two different methods: Ra (average) and Rz (max. difference). The sample size for the roughness testing was taken from the same 9 build jobs and comprises of 144 as-built density cubes with 720 measurements for Ra and Rz.

Both features are capable and within specification limits. The overall mean and standard deviation is 10 ± 1.3 µm and 62 ± 8.3 µm for Ra and Rz, respectively. Tests were done at the Lincotek internal laboratory. According to the EOS Titanium Ti64ELI material data sheet, micro blasting can lower the roughness Ra to 5-9 µm and Rz to 20-50 µm.

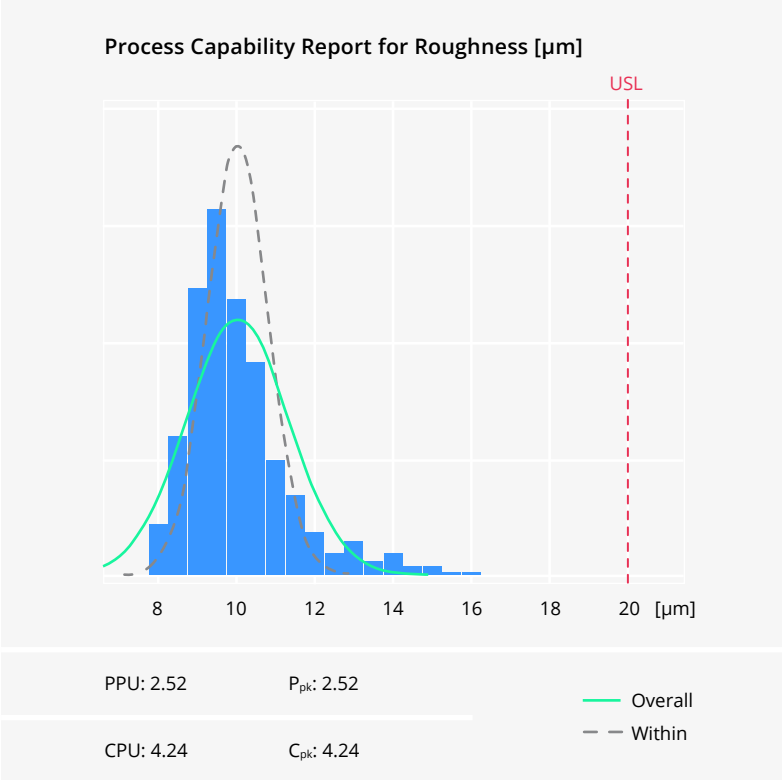

Figure 8 – Process capability histogram for Roughness Ra of as-built density cubes [%]

Lattice Density & Compression Test

One batch of EOS Titanium Ti64ELI powder was utilized to fabricate a specific test job design. Lattice samples featuring stochastic pore distribution were crafted with a cylindrical geometry, measuring 15 mm in diameter and 22.5 mm in height. The build plate was subdivided into an 8 × 8 matrix, resulting in a total of 64 samples per job (refer to Figure 8).

The machine underwent maintenance in accordance with EOS standard protocols, and a laser power measurement was conducted prior to job commencement. Due to the strut thickness within the lattice structure, conventional parameters couldn't be used, as the melt pool's penetration depth would surpass the strut diameter. Therefore, parameters were fine-tuned to suit the unique 3D network of the lattice structures, which feature a high surface-to-volume ratio. The applied energy density was set at 12.5 J/mm³ within EOSPRINT while utilizing a hard recoating system.

Subsequent evaluation of specimens took place at the Lincotek internal laboratory, focusing on two key properties:

1 **Relative Density,** which is defined as:

$$\text{Relative Density [\%]} = \frac{\text{Volume}_{\text{Lattice}}}{\text{Volume}_{\text{Equivalent Cylinder}}} \times 100$$

2 **Compressive yield strength,** which is measured acc. ISO 13314 and defined as:

$$\text{Compressive Yield Stress [MPa]} = \frac{\text{Force}_{\text{maximum}}}{\text{Cross Sectional Area}_{\text{Cylinder}}} \times 100$$

Prior to testing, the specimens were cleaned with compressed air.

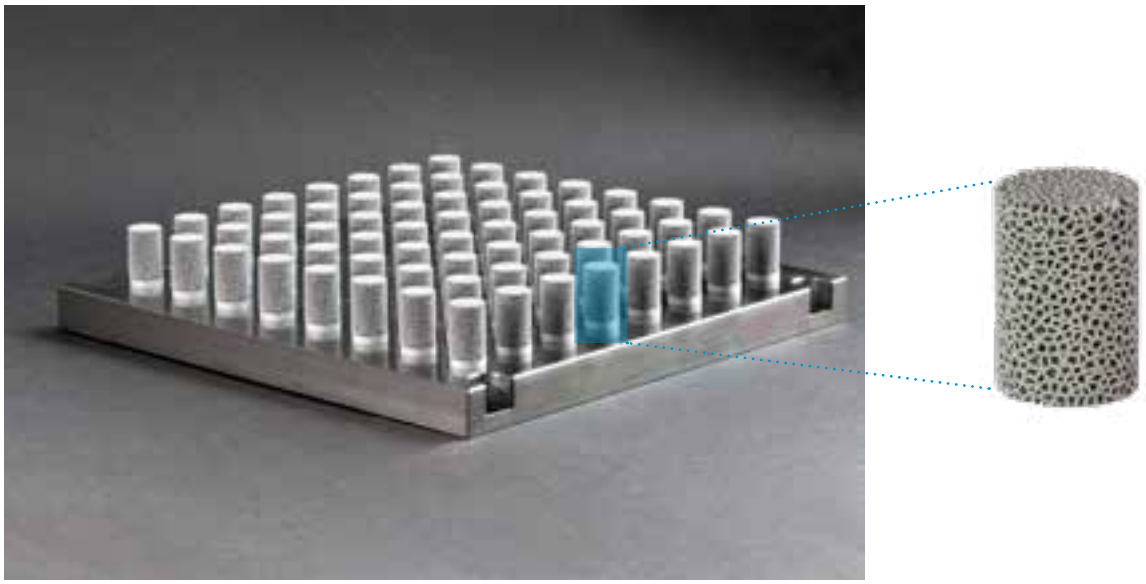

Figure 9: Lattice Sample and Test Job Layout

The relative density of the lattice coupons was measured to be 31.90% as average with a standard deviation of 1.157%. These values correspond to Ppk value of 1.44 when the process limits of Average ±5% are applied. The coupons were built with the same geometry and exposure parameters from M290 study without any modification. Better capability values can be achieved with optimization of the process parameters for M300-4.

The aim of a successful manufacturing process is to attain consistent characteristics in the products within defined parameters. This involves guaranteeing the precision and steadiness of these characteristics' distribution, even amidst typical fluctuations. Since there isn't currently an accepted standard in AM for the mechanical traits of lattice structures, conversations took place with engineers from top producers of lattice components made through AM to set evaluation boundaries.

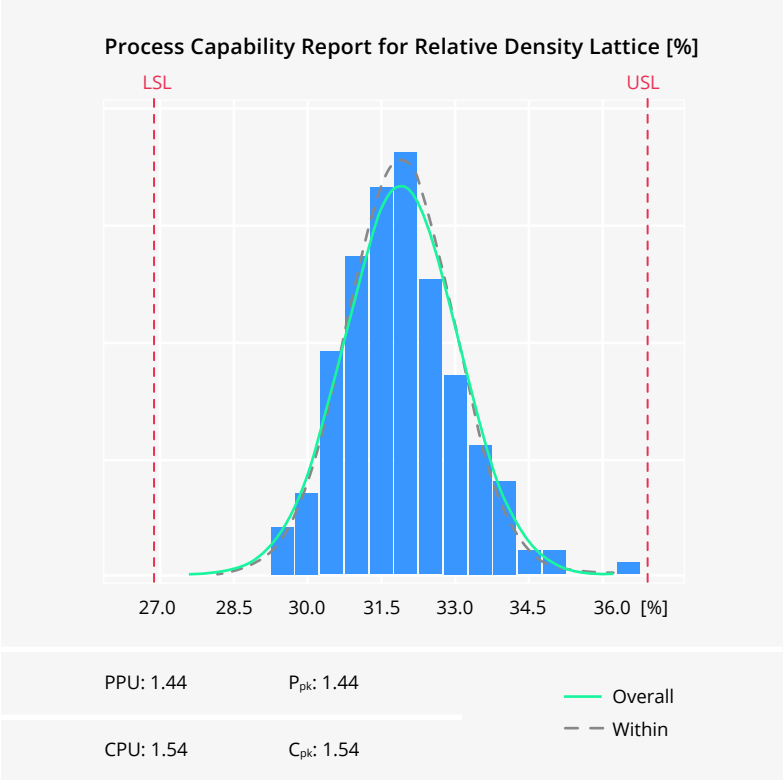

Figure 10: Histogram and capability values of Relative Density [%] of cylindrical lattice coupons

The mean compression strength value of the lattice coupons was noted as 55.35 MPa, which corresponds to a P_{pk} value of 1.35 with tolerance values of ±25MPa.

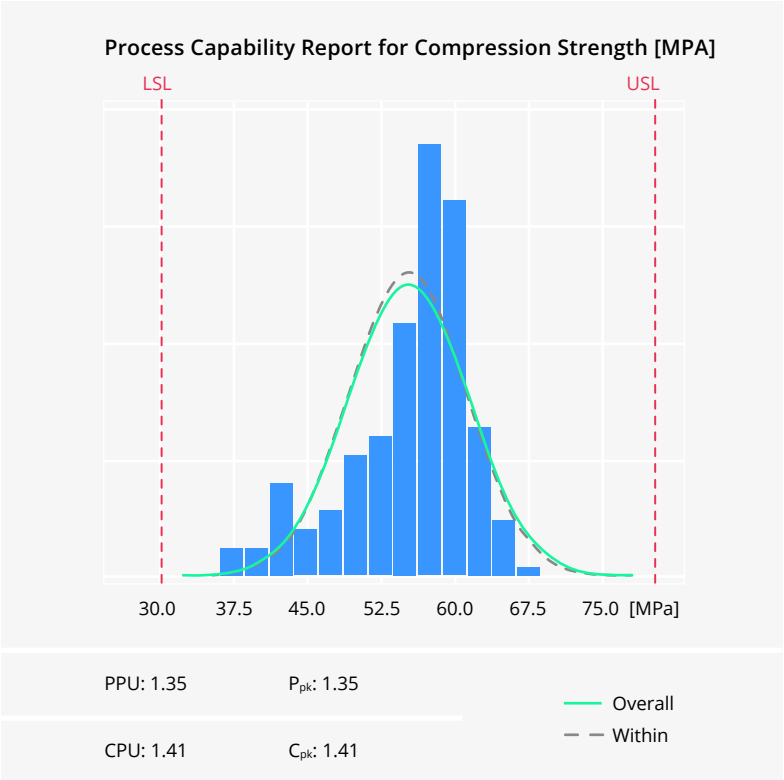

Figure 11: Histogram and capability values of Compression Strength [MPa] of cylindrical lattice coupons

Conclusions and Outlook

OEM Perspective

With the results from comprehensive set of methods and sample size, the Ti64-ELI DMLS process on the EOS M 300-4 was proven to have highest degree of capability and reliability to produce medical devices.

Lattice mechanical properties were proven to be reliable and repeatable. The properties can be further adjusted based on the specific requirements by optimizing the process parameters.

EOS M 300-4 was proven to continue the legacy of the EOS M 290 with improved productivity without compromising the quality and reliability of the properties.

Medical Device Manufacturer Perspective

The EOS M 300-4 system is proven to meet the stringent requirements of the medical device industry, such as precision, repeatability, quality, and traceability. It enables the production of complex and customized geometries, such as solid and lattice structures, that can enhance the functionality and performance of medical devices. It also allows for various degrees of automation and flexibility, making it adaptable to different production scenarios and future upgrades. The four high-power lasers that cover the entire build area ensure a high productivity and cost competition.

The EOS M 300-4 system is a proven and mature solution that has been successfully implemented at the Lincotek Additive production site to produce high-quality components for various orthopedic applications. The system has demonstrated consistent results in terms of dimensional accuracy, surface quality, chemical and mechanical properties.

This study, in collaboration with Lincotek Additive, demonstrates that the EOS M 300-4 system is a valuable asset to leverage the potential of additive manufacturing to create competitive products that can improve the quality of life of patients. The system offers a high level of reliability, scalability, and digital connectivity, making it a future-proof solution for the medical device industry.

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Aydın's passion is exploring the mechanisms of lasermaterial interaction, inspired during his studies in B.Sc. (Metallurgical Eng. at METU, Ankara.) and M.Sc. (Materials Science, at Uni-Stuttgart).

After an early career of 6 years specializing in conventional manufacturing processes and materials, he joined the Additive Minds team in September 2017, to support customers in different subjects such as evaluating machine capability of EOS metal machines and implementing Smart Fusion technology.

He executes customer specific projects, utilizing his expertise in understanding effect of the DMLS process parameters on the part properties, to develop the optimum solution with required quality and cost for industrial AM.

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Massimiliano has a background as a Materials Engineer, with a focus on Biomaterials, from the University of Trento, Italy.

As part of the Lincotek Medical Research and Development team, he manages several R&D projects and supports customer related projects on Additive Manufacturing technologies, defining from a technical point of view the process flow for new products and technically supporting the production.

Massimiliano has extensive experience in 3D printing, especially with powder bed fusion technologies, in the cleaning and metal powder removal from 3D printed components and in the development of processes for the production of implantable medical devices.

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