

Bringing high standards of precision and excellence in AM to the medical industry

3D Medlab partners with Linde to strengthen its innovative lead in additive manufacturing (AM)



Customer

As the name suggests, 3D Medlab specializes in 3D printing – also known as additive manufacturing (AM) – for the medical sector, focusing in particular on the engineering, design and production of orthopedic and cardiovascular devices. Based in Marignane, near Marseille in southern France, 3D Medlab has over 15 years of expertise in this field. The company is devoted to helping healthcare professionals master the challenges involved in additive manufacturing so they can deliver the benefits of this rapidly evolving technology to patients.

In addition to supporting hospitals looking to integrate AM into their development capabilities, and medical device manufacturers interested in extending their portfolio to include additively manufactured parts, 3D Medlab runs an extensive R&D department. This department is constantly studying new materials and exploring emerging 3D manufacturing processes to develop innovative and futuristic medical devices for its customers, always working in strict compliance with all regulatory standards. R&D work also focuses on the role of gases in both AM powder storage and the build process, as well as their impact on the quality and reproducibility of the final device.



ADDvance® powder cabinet installed at 3D Medlab.



Interbody fusion cage made from Ti-6Al-4V.

Challenge, solution and benefits

Challenge

Given the impact of medical devices and implants on patient safety, this is a highly regulated area – with strict requirements governing process documentation, validation and traceability. Consequently, 3D Medlab keeps a close eye on evolving FDA and EU recommendations. Based on industry guidance issued by the FDA in 2017, all AM manufacturers who fabricate devices for the medical industry are advised to document a storage plan for the materials or powders used in the process.

To remain in full compliance with all FDA recommendations, 3D Medlab thus needed a controlled storage solution to overcome the unpredictability challenges that typically arise when powder is not stored in a precisely controlled environment. Oxygen in ambient air and humidity in particular can affect AM powders and their chemical and physical properties, causing them to age.

Solution

The company turned to Linde, its trusted supplier of 3D printing gases such as nitrogen (N₂), helium (He) and argon (Ar) as well as innovative Ar/He mixtures for R&D. Linde suggested that its custom-designed ADDvance® powder cabinet was the best way to maintain quality standards and comply with regulatory requirements.

Designed for maximum efficiency, the ADDvance powder cabinet uses a selective purge gas stream to maintain a non-critical moisture and oxygen value in the storage cabinet. It works by continuously measuring humidity levels. Whenever the cabinet doors are opened and these levels rise, the system triggers a high-volume purge gas flow as soon as the doors close again. This rapidly removes moisture and oxygen from the air. It then applies a lower-volume stream of gas to maintain this low level until the doors are opened again to remove more powder. It thus protects sensitive substances from ambient air and humidity, making them more resistant to contamination while also improving safety for operators. 3D Medlab thus installed the ADDvance powder cabinet in the spring of 2019 and has been working successfully with it ever since.

Benefits

The cabinet gives 3D Medlab the precision it needs to comply with FDA and other regulatory recommendations governing quality, traceability and documentation. “Our experience with the ADDvance powder cabinet shows that Linde is committed to the same high standards of precision and excellence in AM fabrication as we are,” says Gaël Volpi, 3D Medlab President/CEO. “Full regulatory compliance is an important building block in our engineering and design process – our customers trust us to ensure all the proper measures and controls are in place.”

Looking ahead



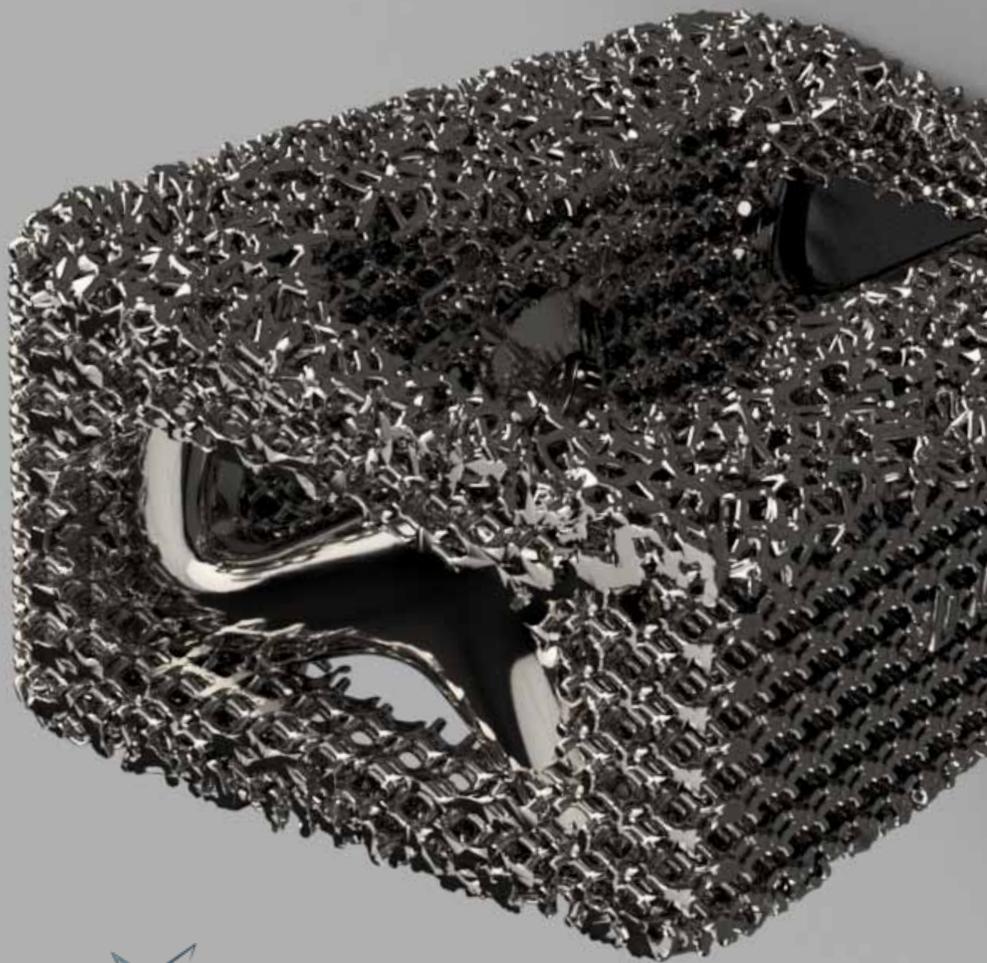
The ADDvance® O₂ precision solution working alongside 3D Medlab's printer.

Following the successful installation of the powder cabinet, 3D Medlab decided to extend its partnership with Linde. It was particularly interested in Linde's ongoing research into innovative AM gas mixtures and their ability to influence the quality and reproducibility of final products based on oxygen-sensitive materials such as Ti-6Al-4V. The companies thus signed a joint development agreement and Linde subsequently installed its ADDvance® O₂ precision solution at 3D Medlab.

ADDvance O₂ precision is a first-of-its-kind measuring and analyzing unit that guarantees the perfect mix of gases within the printer

chamber, giving 3D Medlab precise, granular control over the oxygen concentration and humidity level in its printer chamber. Both companies are now exploring various printing gas mixtures, in particular the ability of He/Ar mixtures to create interesting lattice structures with very fine details and a smoother finish.

The initial research work is focused on Ti-6Al-4V lattice structures, and future efforts will look at the potential of nickel titanium, also known as nitinol, in view of its shape memory effect and superelasticity. This makes this alloy an ideal candidate for next-generation stents.



"Our joint development agreement with Linde is a perfect match between two companies positioned at the forefront of current AM technologies and actively advancing cutting-edge research and innovation in this fast-evolving field to the benefit of healthcare patients worldwide. We are very excited about our collaboration with Linde."

Gaël Volpi, 3D Medlab President/CEO

Getting ahead through innovation

With its innovative concepts, Linde is playing a pioneering role in the global market. As a technology leader, it is our task to constantly raise the bar. Traditionally driven by entrepreneurship, we are working steadily on new high-quality products and innovative processes.

Linde offers more. We create added value, clearly discernible competitive advantages, and greater profitability. Each concept is tailored specifically to meet our customers' requirements – offering standardized as well as customized solutions. This applies to all industries and all companies regardless of their size.

If you want to keep pace with tomorrow's competition, you need a partner by your side for whom top quality, process optimization, and enhanced productivity are part of daily business. However, we define partnership not merely as being there for you but being with you. After all, joint activities form the core of commercial success.

Linde – ideas become solutions.

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