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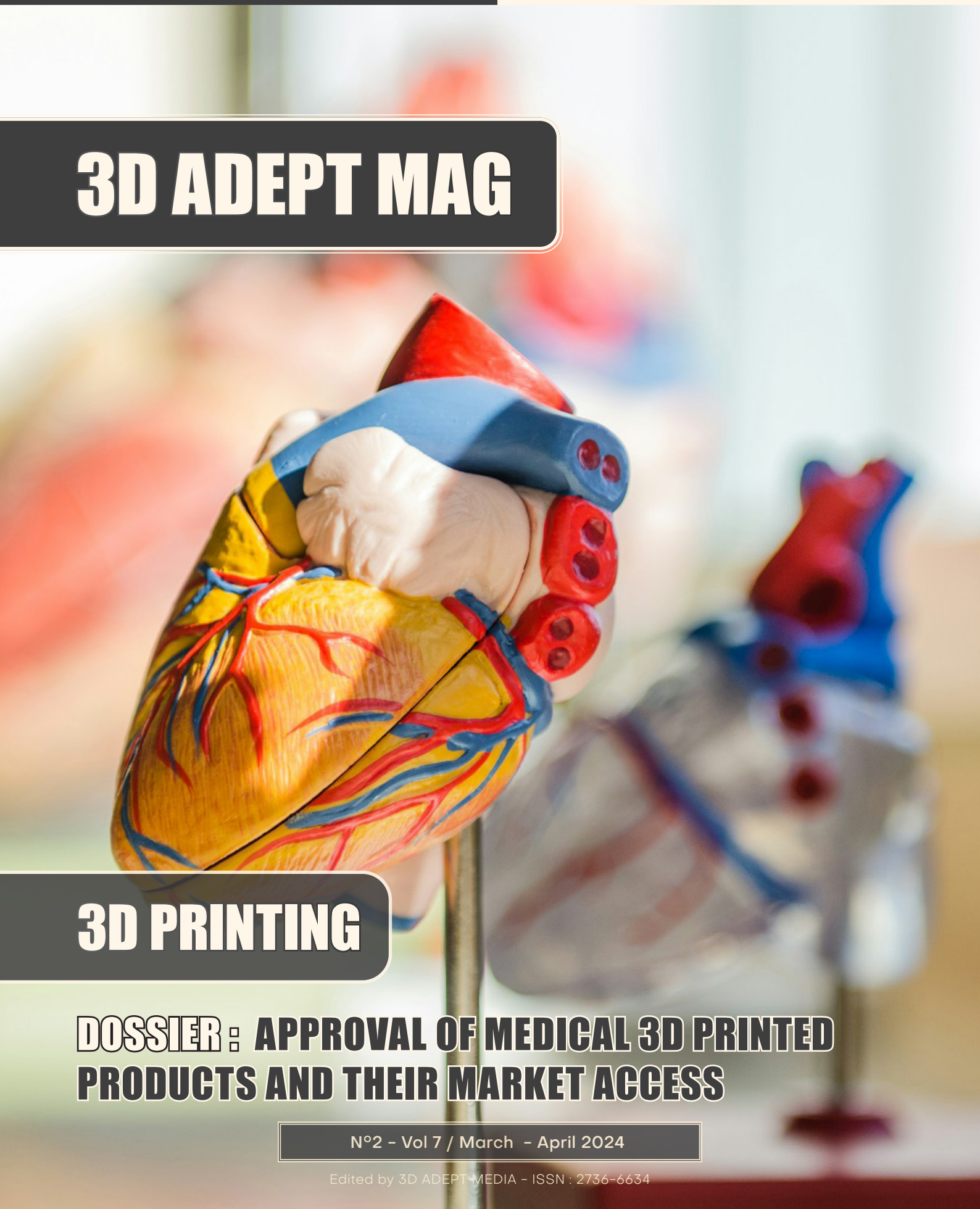
3D ADEPT MAG



3D PRINTING

DOSSIER : APPROVAL OF MEDICAL 3D PRINTED PRODUCTS AND THEIR MARKET ACCESS

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Graphic Designer
Martial Y.

Editorial team
Kety S., Yosra K., Martial Y.

Proofreaders
Jeanne Geraldine N.N.

Advertising
Laura Depret – Laura.d@3dadept.com

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Questions and feedback:
3D ADEPT SPRL (3DA)
VAT: BE0681.599.796
Belgium –Rue Borrens 51 – 1050 Brussels
Phone: +32 (0)4 86 74 58 87
Email: contact@3dadept.com
Online: www.3dadept.com

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Hello & Welcome

Increasingly tangible...

Of all the industries adopting Additive Manufacturing, the healthcare industry is probably the one for which it's hard to explain this technology's impact. Yet, as I always say, it's the industry that remains in my top 3 of the sectors I personally love to cover.

The problem here is that everything requires careful handling. When you know that an application or solution can change someone's life, every explanation can be real puzzle to demystify. Yet, this time it's different, and that's probably because we've been out in the field. We talked with users, and a few times, we met patients who were benefiting from 3D-printed solutions.

It's similar to having the opportunity to test a device before buying it. You're more aware of what you're buying, how you're going to use that device, and what you're going to get out of it.

In this issue of 3D ADEPT Mag, it's this feedback from the field that we wanted to convey. We wanted to share these benefits: through industrial machine tests, the use of specific materials or AM solutions, feedback from doctors and medical experts, and even key information on the approval of 3D printed medical products and their access to the market.

For once, the words to explain all these things easily came to us.

Kety SINDZE
Managing Editor at 3D ADEPT Media
KETYS@3DADEPT.COM

Editorial

Edited by 3D ADEPT MEDIA

DOSSIER

Approval of medical 3D printed products and their market access

"Just because you can print it doesn't mean you can use it."

While the healthcare and medical industries are the first sectors to propel the growth of Additive Manufacturing (AM), this sentence from 3D-Side resonated even louder during the Covid-19 pandemic as the more people (companies and individuals) used 3D printing to fabricate medical equipment, the more their use revealed a lack of knowledge regarding market access of medical 3D printed products. Most importantly, for medical professionals in the field, it is sometimes unclear when a 3D printed device is considered a medical device and it's hard to understand what a point of care (POC) 3D printing solution is. Beyond that, it is still confusing if relying on one or the other solution requires to meet a specific legal framework. The article below ambitions to address these concerns.

As AM continues to grow as a serious manufacturing process within the healthcare field, it's crucial to demystify the complexity surrounding market access to medical 3D-printed devices. The wide range of medical applications covered by AM from surgical instruments, prosthetics to bone applications raises a number of questions that should be taken into consideration to follow specific guidance from the legislator:

- What is a medical device?
- Is it different from point of care solutions?
- The importance of a Quality Management System (QMS)
- Who holds the responsibility for medical 3D printed devices?

The concept of medical devices

Simply put, a medical device (MD) is a product or a device with an intended medical purpose. It *"can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used alone or in combination for a medical purpose."*

In other words, they help diagnose, treat or monitor individuals with potential disease states. Regulating MDs is therefore crucial as they must fulfill the purpose for which they were designed, be robust and avoid harm to the patient and operator. That's why, depending on their safety risks, some MDs might be subject to tighter regulations than others.

"As a manufacturer, you are required to know about the legal regulations for your devices, depending on their risk class and on where you are marketing them. Regulations in the EU differ from those in the USA and the regulatory pathway to get a device to market is different. The production technology does not influence your regulatory pathway, so 3D printed devices follow the same pathway as e.g. milled devices," **Erik Boelen**, Consultant Medical 3D Printing & ISO 13485 Quality Management explains.

That being said, as far as the EU market is concerned, **Alberto Bardají de Quixano** from TÜV SÜD Product Service GmbH outlines that *"Medical Devices marketed in the European Union are subject to the Medical Device Regulation 2017/745 (MDR) – this includes devices manufactured using additive manufacturing techniques. Medical Devices are classified based on their intended purpose, duration of use and nature of the contact with the body within other aspects. The Regulation defines different possible assessment routes for Medical Devices based on the classification of the device. Another consideration that may impact the requirements outlined in the Regulation is whether the device is custom-made for a specific patient or mass-produced and available off-the-shelf."*

In case you do not know, **custom-made devices** are intended for a case where an individual's specific needs cannot be met, or when an alternative device available on the market cannot

meet the appropriate level of performance desired for a given application. In that case, one creates a custom-made device for a unique patient especially, following the written prescription from a surgeon or medical doctor and following specific design indications.

Patient-matched devices are matched to the patient's anatomy within a specific design envelope using techniques such as scaling or contouring using CT imaging of the patient. This may potentially also be done in consultation or prescription from a medical doctor, but the design responsibility lies on the manufacturer who offers a range of validated parameters for the product design.

According to **Boelen**, *"the MDR only speaks about custom-made medical devices, but it would be better to speak about* ***personalized medical devices****, as in the guidance document IMDRF WG/N58. According to the definitions in IMDRF WG/N49;* ***custom-made devices*** *are devices that are uniquely made for the specific anatomy/pathology of one patient as prescribed by his/her surgeon, when there's no suitable device available on the market.*

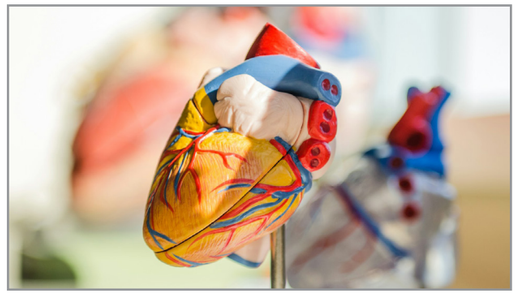
Patient-matched devices *are devices that are also uniquely made for a particular patient, but their design is pre-determined (within a design envelope) and matched to each patient and they are typically produced in a batch process that can be validated and reproduced.*

In the TGA document "Personalized medical devices, v5.0", it is shown nicely that ***most devices that were previously considered 'custom-made' are now considered 'patient-matched'."***

The main differences with point-of-care solutions

The term **Point-of-Care (PoC)** may be misleading. As a trade press that covers the AM industry, we quickly learned that POC means "at the healthcare facility". Reality is, the term is normally used as "at the patient's bedside".

To avoid further confusion, we recommend keeping in mind that POC solutions are those devices manufactured and used within healthcare institutions.



"These devices are subject to Article 5.5 in the Regulation and must comply with the General Safety and Performance Requirements outlined in Annex I. They must also be manufactured 'under an appropriate Quality Management System'. So, it is an obligation that these devices are produced under an implemented QMS. The best way to ensure adequacy of the QMS is compliance with ISO 13485. At TÜV SÜD we offer auditing of the QMS to ISO 13485 with a specific focus on 3D printing processes according to ISO/ASTM 52900. This specific expertise in AM may benefit any 3D printed device manufacturer and also point of care producers which may want to ensure the effectiveness of their QMS and ultimately the safety of their products" TÜV SÜD Product Service GmbH expert points out.

Important note for US-based professionals:

In a risk-based framework developed by FDA's Center for Devices and Radiological Health, one can identify different scenarios in which AM can be used for POC manufacturing of MDs.

Scenario	Description
1. Minimal risk of 3D printing	Devices in this scenario would pose minimal risk of harm to patients. AM can therefore be used to produce models for patient education and counseling
2. Device designed by OEM using a validated process: turnkey system	Here, manufacturers would sell a ready-to-use package or system to a point-of-care facility. This might include software, hardware and process parameters. The manufacturer would need to receive clearance or approval from FDA for its product to be used at the POC, which would require a demonstration that product specifications can be met when 3D printed by the end-user. In this case, the healthcare facility would be responsible for printing the product within the manufacturer's cleared or approved specifications, and for using the product for its cleared or approved intended use.
3. Device designed by the manufacturer using validated process: additional health care professional capability requirements.	The main difference with scenario n° 2 is that the POC might undergo more complex manufacturing or post-printing processes. The cleared or approved device would likely have labeling that included additional instructions for the end user and the clearance process may also include requirements for on-site testing and training from the manufacturer to facilitate appropriate 3D printing by the healthcare facility. Needless to say trained staff and appropriate equipment are indispensable.
4. Manufacturer is co-located at the POC	This means a device manufacturer is located at the same POC facility or as close as possible. The manufacturer would be responsible for most or all aspects of 3D printing, including using its own personnel and equipment.
5. Healthcare facility becomes a manufacturer	This scenario is meant for a POC facility that would like to print devices outside of the minimal-risk classification but wants control over its own operations. By becoming a 3D printing device manufacturer, it becomes responsible for all regulatory requirements, and for device development, design and testing.

Source of the conceptual framework: Qserve.

No matter where we are based, following specific guidance for MDs or POCs require to take into account Quality Management Systems (QMS).

The importance of QMS

There is no difference in the meaning of QMS for MDs and its meaning in an industrial setting. It remains a collection of business processes and procedures that aims to ensure that the quality of products or services meets – or exceeds – customer expectations.

That's the reason why Boelen says QMS has an image of being boring and bureaucratic, but that mainly has to do with the *"rigidity"* of the system. *"A paper-based QMS makes document review, approval, and versioning very cumbersome, but in digital systems, this is quite straightforward. I also believe that if you have a separate, dedicated system for your QMS, most employees hardly ever need to use that (besides the Quality Manager), which increases the threshold to do so. That's why I advocate for the use of a company wiki that includes the QMS; since such a wiki is used regularly to build a knowledge base and record shared meeting notes, the QMS is much more accessible since it is embedded in daily work practices,"* he adds.

Furthermore, as per the words of **Bardají de Quixano**, it's important to keep in mind here that *"we are currently transitioning from the old European Directive to the MDR. The MDR ultimately aims to ensure safety and performance of the devices used in patients. This is positive even if ensuring and proving compliance may pose some challenges. As we transition to the new Regulation, we also find room for pragmatism and practicality in the application of its requirements."*

On a more practical note, Boelen adds that the type of tests required to qualify medical 3D printed products depends on the intended use of that device. For example, if the device is load-bearing, mechanical tests will be inevitable. Biocompatibility tests on the final device should be considered as the 3D printing process changes the material during printing and the resulting material may not be as biocompatible as the starting material.

Furthermore, Bardají de Quixano reminds that 3D-printed Medical Devices are subject to the same requirements as devices manufactured using traditional techniques. These requirements are defined in the General Safety and Performance Requirements in Annex I of the Regulation and include aspects like Biological Safety, Cleanliness, Fracture Resistance, Wear Resistance and Fatigue Resistance among others.

However, *"there is a series of ISO and ASTM standards specific to Medical Devices that define state-of-the-art test methods which are considered acceptable to prove compliance with these requirements. The acceptance criteria are the same for AM devices as for any other device as they are defined by the intended purpose and expected performance. Special attention must be paid in the case of 3D printed devices to aspects like variability in the test results and failure mode analysis due to the*

nature of the manufacturing process.

Validation and control of the 3D printing process and post-processing is pivotal to obtain repeatable test results. ISO/ASTM 52900 and the rest of ISO/ASTM 529xx series constitutes a useful tool to set-up, validate and control 3D printing processes. There are also other ASTM standards which are helpful for specific 3D printing techniques and associated material specifications and test methods. These standards are of general application but valid for Medical Devices. ASTM F3335:2020 provides guidance for assessing the removal of powder debris in SLS Medical Devices," he adds.

Who holds the responsibility for medical 3D-printed devices then?

Both experts agree with the fact that in general, the manufacturer is responsible for manufacturing MDs under an appropriate Quality Management System. Nevertheless, a small nuance should be made when it comes to custom-made devices as the surgeon holds responsibility here. For POC manufacturing, the hospital is considered the manufacturer and, therefore, holds the responsibility for medical 3D-printed devices. Overall, you should remain mindful. There can be tricky situations where, because a device fails for instance because of a wrong material, the manufacturer could be held responsible.

In a nutshell?

Regulatory frameworks can be complex to follow depending on where you're based and what you want to do. While we hope we have been able to share insights that could help you understand what to consider in the market access of medical 3D printed devices, it's important to keep in mind that there are always medical professional organizations that continuously release guidelines for utilizing 3D printing at the point of care. Those guidelines may include, for instance, recommendations on how to consistently and safely produce 3D-printed anatomical models generated from medical imaging, as well as criteria for the clinical appropriateness of using 3D-printed anatomical models for diagnostic use.

Editor's notes

I had the pleasure of hosting a panel discussion on this topic at **AM Medical DAYS 2023** in Berlin, a medical 3D printing event held in Berlin in December 2023 and organized by IPM AG. The panel gathered **Alberto Bardají de Quixano**, Orthopaedic Implants Product Specialist, TÜV SÜD Product Service GmbH; **Bernhard Pultar**, CEO & Co-Founder, POC APP AG; as well as **Dr. Erik Boelen**, Consultant Medical 3D Printing & ISO 13485 Quality Management, Qase3D. The panel received such positive feedback that we decided to share in this issue key insights medical device manufacturers should keep in mind while walking the road of medical 3D printed devices. Given the length requirements of this article, we only shared Alberto Bardají de Quixano and Erik Boelen' insights.

AM SHAPERS:
CURRENT POSSIBILITIES OF ADDITIVE MANUFACTURING IN THE CRANIO-MAXILLOFACIAL FIELD

A conversation with Prof. Florian Thieringer.

Among the wide range of specialists found in medicine, I have often called craniomaxillofacial surgeons gifted artists. Their ability to treat the soft tissue and skeletal structures of the face and skull or congenital facial malformations, as well as injuries caused by cancer, other diseases or traumatic events, is a true work of art: difficult to explain when one is not part of the field, yet beautiful and impressive. When I found out that this field of activity is the ***7th out of 13 to benefit from Additive Manufacturing in reconstruction surgeries****, I couldn't help to ask myself the basic questions: What AM processes? How? Why? Given the limited number of European hospitals that rely on AM technologies for reconstruction surgeries, I reached out to* ***Prof. Florian M. Thieringer*** *from the University Hospital Basel, with the hope that his rich experience could help other healthcare providers take the leap on AM – or at least see this technology as a new opportunity to improve their art.*

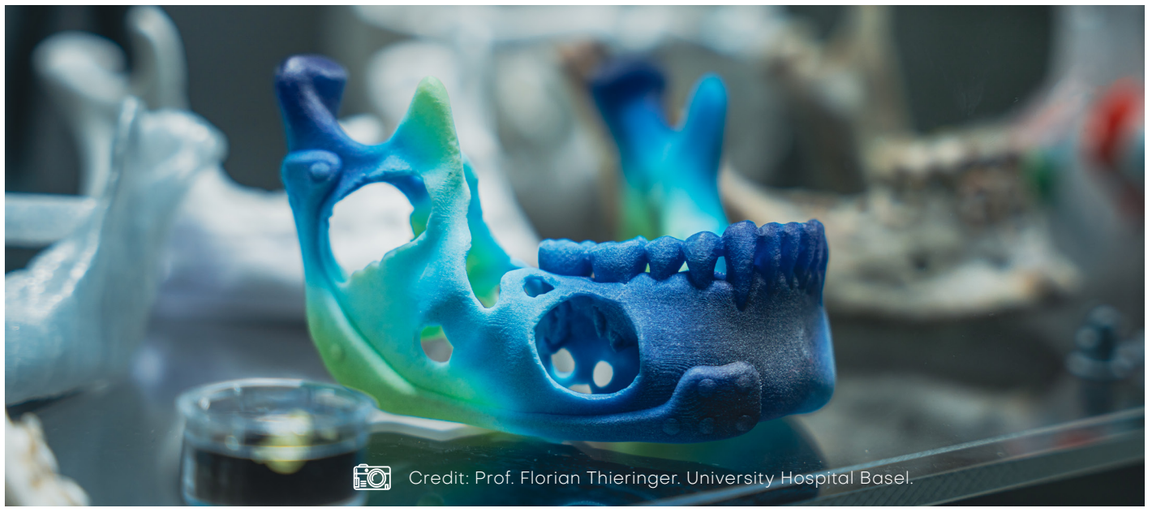
Prof. Thieringer is a man with multiple hats and outlining his various functions would probably take an entire page, so to make it simple, I would like to stick to this one: he is an Oral and Cranio-Maxillofacial surgeon and a medical 3D expert, who focuses on Tumor-, Trauma-, Reconstructive- and Orthognathic Surgery. Interestingly, the common thread across the multiple functions he holds seems to be Additive Manufacturing (AM).

To explain the various reasons that could explain this thread, he recalls: *"More than 20 years ago, when I was studying medicine, I joined the research group of my mentor* ***Professor Hans-Florian Zeilhofer*** *in Munich, Germany. He is one of the pioneers in medical 3D printing. Even at that time, he demonstrated that 3D printing could be very beneficial for treating our patients. With no other technology, it was possible to transfer the anatomy of a patient in a realistic, haptic, three-dimensional representation. We found it fascinating to hold the anatomy of the patients in our hands even before the operating room and accordingly and very precisely plan surgical procedures."*

Prof. Florian Thieringer

Even though nowadays, AM helps Pr. Thieringer and his team manufacture complex, anatomical models and patient-specific implants that fit very perfectly, it should be noted that they work with several other digital technologies along the treatment process from the very beginning until the end. *"3D printing remains one of the very valuable chains of this whole process in the medical field"* – alongside other digital solutions such as AR/VR or robotics.

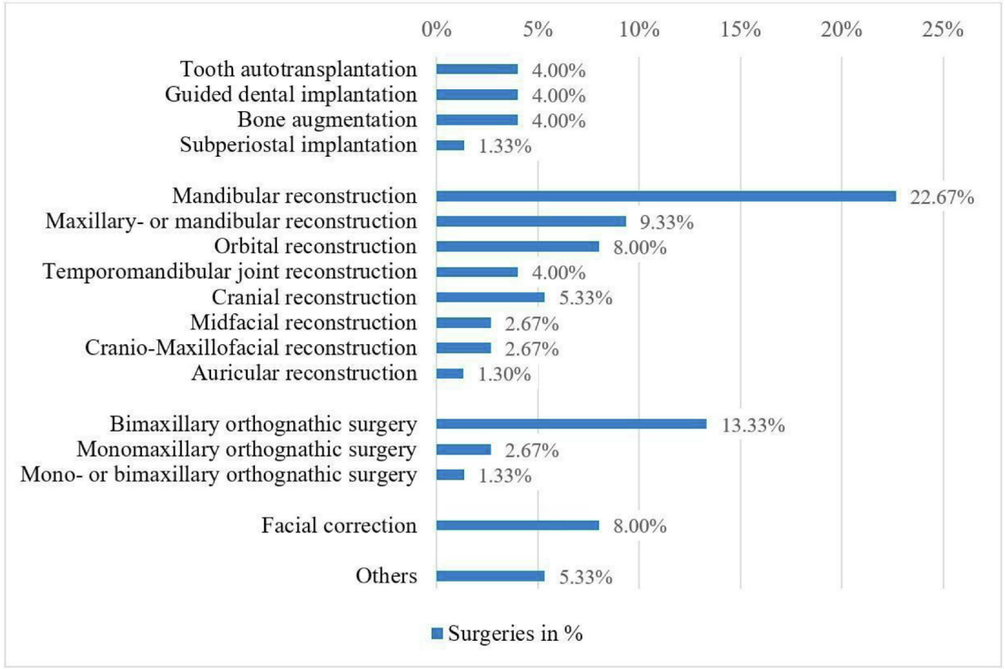
For the sake of this article, we'll keep the focus on its use in cranio-maxillofacial applications.



Credit: Prof. Florian Thieringer. University Hospital Basel.

AM in reconstructive surgeries

Research reveals that AM has already been used in mandibular and orbital reconstructions, temporomandibular joint reconstruction, cranial, midfacial, cranio-maxillofacial or even auricular reconstructions.



List of performed surgeries with the aid of 3D Printing. Source: Medical 3D printing with a focus on point-of-care in Cranio-Maxillofacial Surgery. A systematic review of literature.

As far as cranio-maxillofacial reconstructions are concerned, **high-precision models, implants, surgical guides, and fixation devices** – all of which can be manufactured using AM - have proven to be valuable tools for surgeons.

"AM is a tool for challenging cases in the cranio-maxillofacial field. It's an important part of the surgical armamentarium, therefore, the more complex the surgery will be, the more likely it is that we will use AM", the medical 3D expert told us. Speaking of specific applications where the technology adds value, he elaborates:

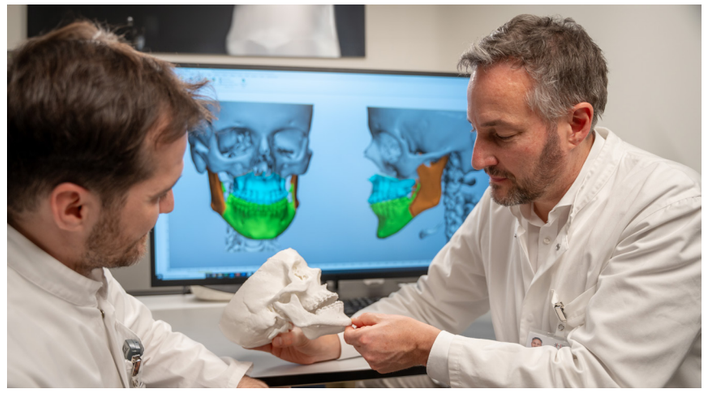
"3D printing has become a standard in our clinic in the area of ***complex trauma****. When we have patients with complex trauma injuries, we rely on 3D printing, especially when it comes to patients with orbital floor fractures and we'd like to adapt implants to our patients' anatomy. We also use AM as a standard* ***for our orthognathic patients*** *who need corrective jaw surgeries.*

Producing surgical guides in dental implantology or tumor surgery remains one of our key applications though. And I believe we remain one of the only international clinics that can produce patient-specific implants for direct use on the patient in the area of cranial reconstruction."

For the expert, perfectly fitting patient-specific implants could be designed in AR/VR and be produced by intra- and extracorporal 3D printing.

[In an extracorporal 3D printing approach, the most important work occurs before the operation. The team works on a digital workflow where the implant will be designed for the patient.

In an intracorporal approach, a robotic solution will go into the head/or the place to operate and print to regenerate the defect. Pr. Thieringer explains that they can also open the skin and the printer will directly 3D print the part. While there is still an ongoing bioprinting research on the topic, and given the stringent medical device regulations, the process still needs to be validated before any in-situ application.]



Credit: Prof. Florian Thieringer. University Hospital Basel.

A possible comparison with conventional operating approaches?

So far, and in general, AM has proven to be a safe tool for craniomaxillofacial surgeons, and can sometimes deliver better results. According to the research *"Medical 3D printing with a focus on Point-of-Care in Cranio- and Maxillofacial Surgery"*, no study reported worse results with the aid of 3D printing. 3.14% of the studies reported comparable results to conventional approaches and 96.86% of the studies that mentioned surgical results, reported a satisfying outcome or even a better outcome with 3DP compared to conventional approaches. 93.75% of the studies that mentioned the treatment time reported shorter operations because of 3D-printed objects.

If the measuring items here are not the same as the ones used to compare AM with conventional manufacturing processes in an industrial setting, **Pr. Thieringer** draws attention to the fact that despite its advancement, AM remains a new approach in medicine.

"For example, to stabilize the bone, an implant will be adapted during surgery. This will take a lot of time and will never be 100% accurate and perfect. So, with the so-called virtual surgical planning, and 3D printing, we benefit from the transfer of the planning time in a pre-operative setting. And with the manufacturing of perfectly fitting patient-specific implants, we can treat our patients in a totally different way."

Needless to say, what works for one case, does not necessarily work for another.

However, from a logistic perspective, one measuring item that is found in both industrial and healthcare units is **the "stock"**. *"By using 3D printing for every patient, you do not have to hold on to a lot of stock – in this case, traditionally manufactured implants; because each implant is produced when it is needed."*

On a more practical note, over the years, Pr. Thieringer and his team have achieved applications made from a wide range of technologies: **FDM, SLA, SLM, SLS** and **PolyJet**. As a university hospital, they probably have one of the largest fleets of 3D printers in the market.

"Every technology has its niche in the medical field. So, it highly depends on the application. We have more than 30 3D printers working for different applications. Actually, at some point, I stopped counting them. FDM for instance is being used for cost-effective anatomical models. If you just need an anatomical model in a short time or very basic models, FDM is the ideal production candidate. We also use FDM for our PEEK implants in cranial reconstruction. If you want to add additional features to your model like color or even biomechanical properties of hard- or soft tissues, or if you need transparent models, Polyjet will certainly be the ideal choice. We rely on SLM for high-performance implants made in titanium, which at the moment are still manufactured by our partners at the University of Applied Sciences. SLS is ideal for robust models or biocompatible surgical guides while SLA and DLP make sense for dental solutions", the surgeon points out.

The adoption curve with AM

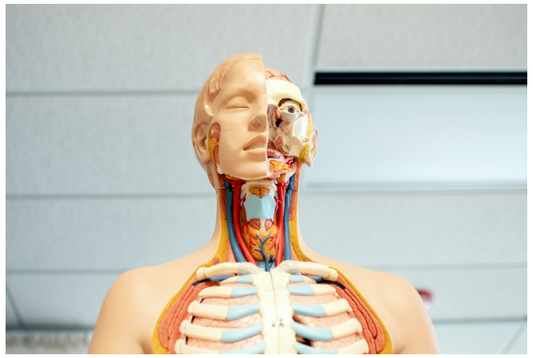
In the midst of all these healthcare fields adopting AM, **digital dentistry** remains the one leading the way for our guest.

The truth is the learning curve remains a tough path because of the huge need for interdisciplinary expertise. *"You cannot start as a surgeon, you need engineers and technicians but not only, the traditional workflow and mindset also need to change. Adding to that the cost and regulatory aspects, one obtains a mix of items that may slow down adoption within hospitals"*, the expert says.

While I am not surprised to hear these arguments, I would like to draw the attention of healthcare professionals to these cost considerations: they highly depend on several factors that are often inherent to each hospital. These factors might include personnel, budget, or even the healthcare system within their country.

What's important to keep in mind is that you should have *"a clear understanding of the clinical needs and how AM can solve them. It's crucial as AM is not the solution to everything. Furthermore, it remains valuable to invest money in training and interdisciplinary collaboration when thinking about integrating AM in your hospital. Lastly, it's important to navigate the regulatory side. It's pivotal to have a risk-management system and to ensure that the processes are compliant,"* Pr. Thieringer states.

In conclusion, medical 3D printing in the cranio-maxillofacial field, as showcased by Prof. Florian Thieringer's experiences, is not just an innovative approach but a transformative force in surgical procedures. Its capacity to produce patient-specific implants and surgical guides with remarkable accuracy underscores a future where 3D printing is seamlessly integrated into clinical processes. As technology evolves and regulatory frameworks adapt, medical 3D printing will undoubtedly play an increasingly crucial role in enhancing patient outcomes and operational efficiency in healthcare. The journey of additive manufacturing from a novel concept to a standard in clinical practice is emblematic of the broader shift towards personalized medicine and digital transformation in healthcare. For Pr. Thieringer and his team *«3D printing in medicine isn't just an innovation; it's the future of personalized patient care.»*



SOFTWARE:
THE DIGITAL MANUFACTURING STAGES OF 3D PRINTED PATIENT-SPECIFIC DEVICES

From patient data to an end-use prosthetic device at Quorum Prosthetics

At 12, Joe Johnson lost his leg in a motorcycle accident. He faced initial challenges with a basic prosthetic until he discovered how AM could help produce a tailor-made and more comfortable 3D-printed prosthetic. Johnson's story could have ended after he got his first prosthetic, but he didn't see anyone willing to take the risks to help amputees. His journey therefore led him to found Quorum Prosthetics, a prosthetics company that makes prosthetic arms and legs, custom bracing, and the Quatro adjustable 3D printed sockets. Over time, the company has been continuously exploring the use of digital manufacturing technologies to give amputees the right fit. If we are talking about it today, that's because Johnson's experience allowed us to understand the digital manufacturing stages of 3D-printed patient-specific devices.

Quorum Prosthetics itself is a journey of resilience. We share its story today because *"Additive Manufacturing is a vehicle to [its] ideas"* – in the words of Johnson. However, in 1998, when the company was founded, it wasn't. It took Johnson a lot of investment, energy and trust in engineering expertise to bring his company to where it is today – yes, because Johnson is not an engineer by training.

"I had this recipe 8 years ago of what I wanted Quorum to achieve. We wanted to standardize a good design for prosthetics

as it was difficult to carefully replicate existing ones. [From conventional manufacturing techniques such as lamination resin and plaster, we took the leap to AM in 2019. Today, with a distributed manufacturing model, we can help amputees beyond our frontiers]", the founder adds.

On a more practical note, it's important to understand that regaining mobility hinges on having a prosthetic device that is both functional and properly fitted. A conventional manufacturing process would require the use of a plaster cast customized for the patient and lamination using carbon and resin. "The problem is, even though the final socket is comfortable, the manufacturing process is inaccurate for replication", Johnson told 3D ADEPT Media. Not to mention that the shape and volume could change over time, causing a sort of pressure or discomfort on the wearer.

The **Quatro socket** from Quorum Prosthetics is based on a patented design that enables wearers to adapt the volume and compression using adjustable reels and interchangeable comfort cells. The truth is the process to get there demands a meticulous and comprehensive digital workflow. Commenting on the development of such patient-specific devices in the realm of prosthetics and orthotics, Johnson explains that each step of the digital workflow is *"imperative to ensure the creation of prosthetic sockets, such as the Quatro socket, that seamlessly integrate with the patient's anatomy, optimize comfort, and enhance functionality."*

What are these steps?

On a very technical level, the digital manufacturing stages can be gathered in 3 main steps:

- 3D scanning & digital model creation
- Print & process
- Patient fitting

At Quorum Prosthetics, the entire manufacturing process from patient assessment to outcome evaluation takes **10 steps.** These steps include:

- Patient assessment: Any healthcare provider would agree with the fact that this step is obvious as it offers a better understanding of the patient's specific needs and requirements, and helps to gather relevant medical data such as residual limb measurements, skin condition, and functional capabilities.

- 3D scanning: With this step one can capture the shape and contours of the residual limb accurately. In general, Computerized Tomography (CT) scans, Magnetic Resonance Imaging (MRI) scans, X-rays, and handheld 3D scanners can be utilized to capture the details of the patient's anatomy. This digital representation becomes the foundation for the subsequent steps in the AM process.

Quorum uses an **Artec 3D scanner** to perform this task.

- Digital model creation: Thereafter, the designer uses a specific software solution to convert the 3D scan data into a digital model. Certain adjustments based on the patient's anatomy can also be made at this stage.

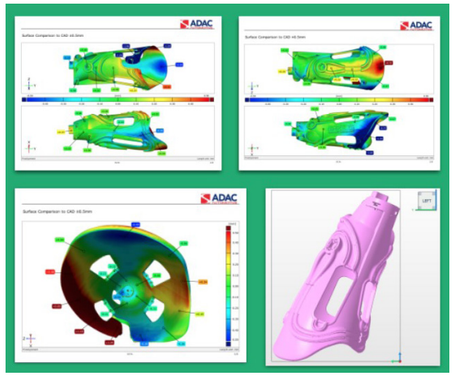
- Socket design: The level of sophistication in the design software is crucial here, as it dictates whether the process remains a manual craft or progresses toward partial or full automation. This digital modeling phase permits unparalleled precision, guaranteeing that the eventual prosthetic seamlessly conforms to the individual anatomy and requirements of the patient.

With the help of Geomagic Freeform, they can design the socket and integrate features such as pressure-relief areas, suspension mechanisms, and reinforcement. Johnson explained that they held a **patent for the Quatro socket**, which had precise design requirements, and Freeform was an ideal solution for meeting those requirements. Essentially, Freeform enables them to create custom-fitted sockets for individual patients, resulting in unique shapes for each. However, the standardized layout of adjustment lines and the entire Quatro system in Freeform streamline the design process, making it efficient and straightforward. Most importantly, through conventional methods, developing a socket design of this nature could require as much as 12 hours. Yet, the Quorum team can finalize a design in a fraction of the time, typically within four to six hours.

- Manufacturing preparation requires for instance to confirm that all digital models are within the boundaries of the print bed.

- Fabrication: Quorum relies on HP Multi-Jet Fusion to manufacture its sockets. Any other AM process could be assessed to ensure that the end part is biocompatible and that it delivers the ideal strength and weight. That being said, there are important differences at the geometry level when one compares a socket that is traditionally made and one that is fabricated with MJF. Other differences include connection points and thickness (Carbon fiber to have 6mm uniform thickness leveraging 4 layers of fiber weave and 2 bases of resin.)

Legend: Adjustments can be made with pinpoint accuracy. Credit: Quorum Prosthetics



Legend: The Quatro is strength-tested using ADAC's metrology lab, ensuring a safe socket experience each time. Credit: Quorum Prosthetics

- Quality control: Beyond meeting quality standards and specifications, it's about ensuring accuracy and comfort for the user. It should be noted that no official testing protocol exists to test socket performance. That's why healthcare providers often rely on various testing methodologies. ISO 10328:2016 for instance specifies procedures for static and cyclic

strength tests on lower limb prostheses which typically produce compound loadings by the application of a single test force. The compound loads in the test sample relate to the

peak values of the components of loading which normally occur at different instants during the stance phase of walking.

- Assembly & customization: Aesthetics and functional requirements should be met at this level.

- Fitting and adjustment: After fitting the socket onto the patient's residual limb, a couple of adjustments can still be made. When required, Quorum for instance adds comfort cells into the perforations of the flexible inner socket to provide the patient with more cushion.

- Outcome evaluation: throughout this process, the Quorum team follows up with the patient to assess the performance of the device in real-world

scenarios.

Concluding thoughts?

While healthcare providers might face labor shortages and size capacity when relying on AM, the advantages of using the technology for 3D printed prosthetics are those you might already be familiar with, if you know the technology: customization, improved comfort, reduced production time and cost-efficiency.

As a matter of fact, as regards the cost factor, Quorum's adjustable sockets can now be covered by insurance companies under prosthetic volume adjustment.

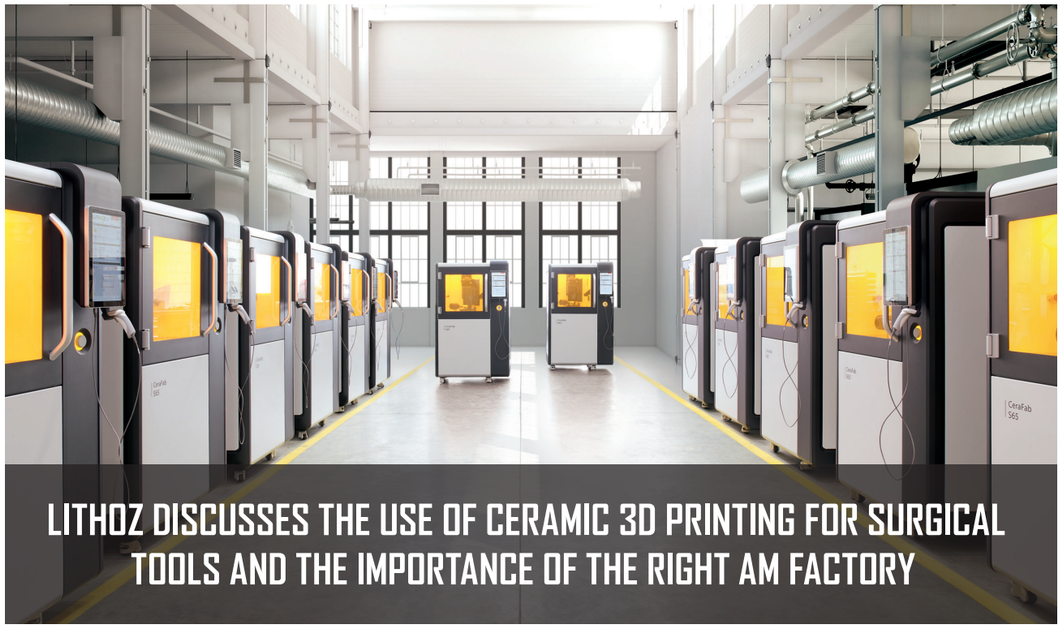
As AM continues to evolve, it will continue to reshape the prosthetics landscape, offering newfound accessibility and improving the overall welfare of individuals in need. With more than 57.7 million people living with limb amputation due to traumatic causes worldwide, I hope to see more "Quorum Prosthetics" emerge across the world.

STAY TUNED FOR KEY INSIGHTS INTO MEDICAL 3D PRINTING

Get ready to learn about significant insights in the field of medical 3D printing. Experts in this field differentiate between medical care and healthcare. While medical care is a service, healthcare is a broader industry or system, of which medical care is just a part. In this section, both terms are often used interchangeably to discuss the influence of Additive Manufacturing technologies in these fields

While questions remain about how commonplace AM will become in health care, reimbursement policies regarding medical 3D printed devices or regulations, we can't remain silent about the growing number of applications achieved in the field. In the end, the more applications there are, the more likely it is to reach a consensus on a regulated use of the technology.

Discover the latest 3D printing technologies designed for this field as well as key applications that foster the growth of AM in healthcare and medical.



LITHOZ DISCUSSES THE USE OF CERAMIC 3D PRINTING FOR SURGICAL TOOLS AND THE IMPORTANCE OF THE RIGHT AM FACTORY

During the past 7+ years, I have had the pleasure to see ceramic 3D printing being applied in an increasingly diverse range of fields: healthcare & medical, aerospace, energy, architecture and even art. Of all these fields, I remain fascinated by the applications of this technology in the healthcare and medical fields. If you have a slight interest in ceramic 3D printing, you probably already know that the landscape of ceramic 3D printing technologies that can enable such applications is very broad. But to be honest with you, I probably owe my fascination to Lithoz's technologies – and I will tell you why.

If you're a regular reader of 3D ADEPT Media, the name Lithoz should probably already ring a bell to you. With more than a decade of activities in the AM field, an acquisition, and three proprietary technologies (LCM, LIS, LSD Print), Lithoz's work has been validated across three main vertical industries: medical, aerospace & space, and semiconductor. Of all these fields, the company has demonstrated that its market-leading LCM technology has become a promising production candidate in the healthcare & medical industries.

If you're not familiar yet with LCM which stands for **lithography-based ceramic manufacturing**, note that it is a process where ceramic particles are dispersed in a photosensitive resin. This dispersion is thereafter solidified by light layer-by-layer to form a part. Then the part undergoes a sintering process to develop its ceramic properties and can be used for its final purpose.

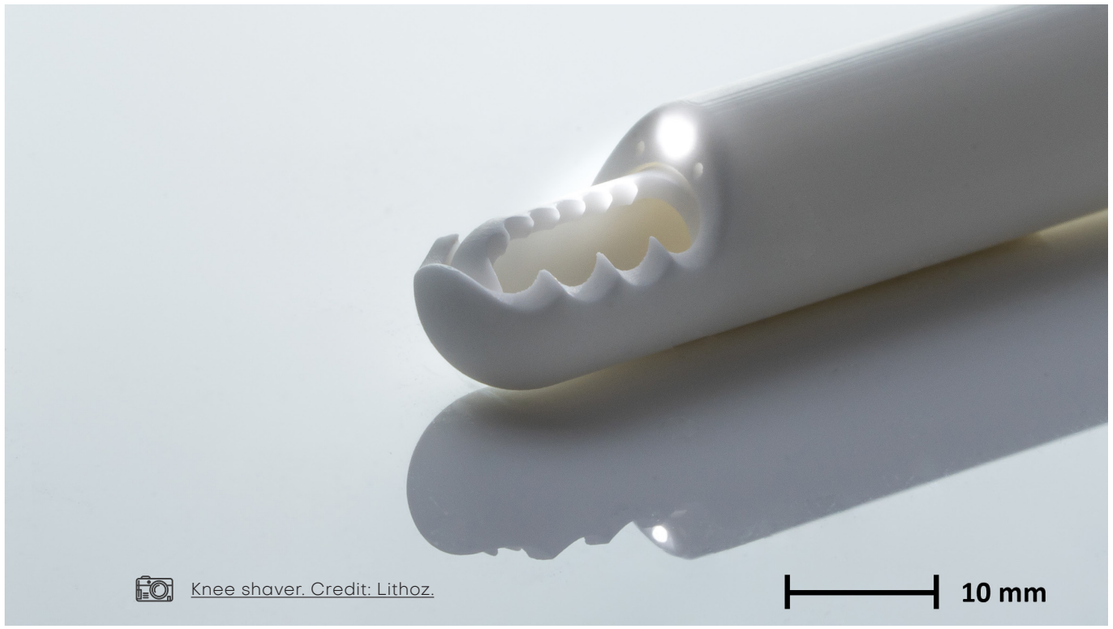
Over the years, the Austrian company has expanded the scope of this technology with the release of new materials, opening up new applications in dentistry. In what has become our traditional one-on-one, **Daniel Bomze**, Director of Medical Solutions, told me what has been happening behind the scenes ever since they unveiled their Lithium Disilicate material.

"It all comes down to three main points:

First of all, 3D printing applications for highly aesthetic dental restorations with our lithium disilicate material are gaining traction in the dental field. We continue to receive tremendous interest in these applications across the world. Our latest appearance at the LMT Lab Day in Chicago reflects that interest. This market will continue to see huge traction moving forward, as it highlights a new way of manufacturing after decades in the field.

We have also been involved in several interesting projects where we could push the boundaries of what's possible with ***our multi-material ceramic 3D printing.***"

Credit: Lithoz



Knee shaver. Credit: Lithoz.

10 mm

As a reminder, in 2020 Lithoz launched the CeraFab Multi 2M30 3D printer, a 3D printer that could process materials with opposing material properties like conductivity and insulation in one print run, creating the next generation of 3D printed multi-functional parts which was previously unachievable with a level of complexity.

"As far as the healthcare field is concerned, we focused especially on multi-material bone replacement solutions", Bomze explains. "One example that is worth mentioning here is the ***mandibular augmentation after bone atrophy*** *which so far has always consisted of one material. Normally, you have a bone replacement material and on top of it, you always need a kind of membrane to prevent premature ingrowth of soft tissues. Indeed, if a soft tissue like gingiva grows into the scaffold, there will be no residual space for the bone itself. This is possible because bone will just grow much slower than the soft tissue. That's why as part of a research project, we combined a comparably fast resorbing material like tricalcium phosphate with another very good bioactive material of hydroxyapatite on the outside shell in order to obtain a ceramic membrane. This ceramic membrane then should prevent the ingrowth of the soft tissue during the healing phase. We are very happy with the results so far; we will hopefully share more details on this project soon.*

And the third topic that has been receiving a lot of attention lately is ***surgical tools like burs and shavers*** *as well as similar applications. We found that we actually hit the nerve of the industry here because it is often quite challenging to achieve high quality in traditional manufacturing and being able to achieve high productivity with a lot of design freedom with ceramic 3D printing is something we are very proud of,"* he adds.

Ceramic 3D printing & healthcare applications: focus on surgical tools

Over the years, we came to realize that applications of ceramic 3D printing in the healthcare industry could be explored from four main angles: applications in extracorporeal assisted medical care, such as medical models and rehabilitation aids, medical devices, applications related to biologically active and biodegradable materials, such as long-term implantable tissue engineering scaffolds or bioactive materials for tissue regeneration and repair as well as bioprinting.

Interestingly, the very first set of applications is currently used in clinical settings across the world and plays **a crucial role in surgical planning, improving surgical efficiency, and enhancing cure rates.**

One thing I specifically like about Lithoz's approach is that not only does their medical engineering team go the extra mile to improve the manufacturing process, taking into account the limitations of conventional manufacturing processes, they also take into account existing limitations of

Implant Multimaterial Mandibular Ridge Augmentation – Credit: Lithoz.

their proprietary technology. In the end, do we not say: *"Compare yourself to who you were yesterday"*?

Bomze outlines here that *"surgical tools have gotten significant interest from medical professionals because one could now drastically improve the mechanical properties of 3D-printed high-performance ceramics. This is something that's not easy to achieve in conventional manufacturing given the lack of desired properties often delivered by the materials."*

Speaking of their LCM technology and how they have been able to push its capabilities, he adds: *"we could also broaden the processing window of some of our materials. This means that with the same material, we could produce very delicate parts with tiny features as well as bulky parts which are really sturdy and for load-bearing applications (an artificial hip joint for example). A year ago, we would have told medical professionals that this "wall thickness" is not possible to achieve with our LCM technology. With the advancement in material today, we can develop custom or patient-specific artificial hip joints."*

To give an example of a surgical tool where ceramic 3D printing offers a better way to manufacture compared to a conventional manufacturing approach, the Lithoz medical director made me envision a real-life scenario.

"Imagine an athlete who injured their soft tissue at the level of the knee while jogging. If the meniscus tears, it can get incarcerated over time and this incarceration can eventually lead to pain and limit mobility. As far as it's possible, the surgeon will try to treat it conventionally but at some point, this conventional treatment will not be enough. The doctor will need to do a minimally invasive surgery where small incisions will be made in several parts of your knee and insert a different type of tools in order to remove those torn or injured meniscus. The tools used for this specific application are known as knee shavers.

Depending on the way the surgeon operates the device, it will go inside the tissue or remove a superficial amount of tissue, with all the tissue that has been removed being sucked away through the big central channel. There are also different channels on the upper side with different diameters in this specific tool, which used for rinsing the surgery site with a rinsing fluid while the central upper channel holds a glass fiber (light guide) to illuminate the surgery area. This should help the surgeon to have a better view and control, thus only removing what is torn and not healthy tissue. AM will help to produce such a complex tool while reducing the necessary assembly steps significantly."

Simply put, the idea of using AM at the manufacturing level, is to have less debris during the surgery – making it easier to avoid any accidental scars that could have occurred in a traditional surgery. Not to mention that AM provides maximum durability with a minimal production effort.

A conventional manufacturing route would have required the use of milling and HIP (hot isostatic pressing) to mill the specific device before a final usage.

3D-printed dental implants made of Alumina-Toughened Zirconia LithaCon ATZ 980

The manufacturing perspective

Bomze' example made me question the different manufacturing requirements in a medical environment. As a trade press that covers the use of AM across various industries, it's easy to talk about the importance of an AM factory in an industrial setting. In a medical/healthcare environment, I was curious to know what it looks like.

"First of all, surgeons get their 3D-printed parts from medical device manufacturers who remain Lithoz's key targets in this industry", Bomze clarifies. "That being said, there is a broad variety of companies that would be able to build up an AM factory for medical devices.

Key components of an AM factory may therefore include an industry-standard 3D printer and thermal post-processing materials that fulfill the requirements in terms of biocompatibility as a basis. Needless to say that it is possible to scale up this equipment depending on one's needs.

"What's important to keep in mind is that this AM factory – if made up of the right equipment - will allow you to achieve freedom of design while saving time and costs where necessary. It's not only about the 3D printer but also about having quality standards from A to Z that could help you deliver predictable and repeatable results in serial production.

What we learned during the past 13 years is that a predictable and repeatable result is important for most of our customers. It is even more important in medical device manufacturing as part manufacturers must achieve the same result every single time. In this vein, it's our duty as manufacturers of such AM factories to offer the possibility for automated documentation of the production process, and also smart designs of our devices and software to prevent human errors."

With its array of technologies and one of the biggest material portfolios in the industry, Lithoz can pride itself on developing a technology portfolio that could meet production requirements beyond the healthcare industry.

While cost and performance comparison between a Lithoz's AM factory and another factory (powered by conventional manufacturing processes or other AM technologies) are too broad and complex to be discussed in this article, I strongly believe the applications discussed today and the partnerships the company continuously signs in the healthcare industry testify to the potential of their solutions.

In the end, whether we talk about dental restorations, surgical tools or implants, Lithoz's journey shows that advancements are being made in the research and application of ceramic 3D printing technology in healthcare. Being able to witness its development one step at a time makes me confident that its best days are yet to come.

Cleaning station. Credit: Lithoz

Post-processing

THE EFFECT OF PIEZOELECTRIC EXCITATION IN AN AUTOMATED DEPOWDERING PROCESS: THE CASE OF MEDICAL 3D PRINTED PARTS.

Key insights into a depowdering test with a build plate of medical 3D printed parts

Once you've decided that an automated depowdering machine is the right device for your (medical) 3D printed parts, the next step can be quite stressful: making the right decision when it comes to purchasing a machine that will ensure your products and personnel safety, reduce the risk of product failures and most importantly comply with industry standards. That's the reason why, in another article, we discussed the must-have technical features in an automated powder removal system. The thing is, the more the market advances, the more new features are being developed and the more customers' requirements become complex and stringent. At this point, a holistic experience that comes from a depowdering test might help tilt the balance in favor of one machine or another and confirm certification for use in a given industry or for a given application. To understand how such a test is being performed, we asked ***Solukon Maschinenbau GmbH*** *something unusual: share insights into a depowdering test performed for one of their customers active in the medical and healthcare industries.*

Solukon's core expertise remains automated depowdering for AM. For this article, the depowdering test was performed on the company's latest system – the **SFM-AT350-E** for medium-sized parts up to 60 kg– in collaboration with the Swiss m4m Center, a technology transfer center that leverages AM for the medical and dental industries. As an advocate for AM technologies, we have been following Swiss m4m's journey with AM since its beginning.

Solukon - SFM-AT350-E

Insights into the brand-new SFM-AT350-E & applications at the heart of the test

Designed for metal 3D printed parts, the SFM-AT350-E is a special version of the automated depowdering machine SFM-AT350. Unveiled last year at Formnext 2023, the new machine comes with three key upgrades: full compatibility with intelligent **SPR-Pathfinder® depowdering software, enhanced functions of the Digital Factory Tool** as well as **piezoelectric excitation**.

If the SPR-Pathfinder® depowdering software and the Digital Factory Tool are now well-known features of Solukon's depowdering systems and also available for the standard SFM-AT350 machine, the piezoelectric excitation tool remains intriguing for most users as a unique and special solution in the field.

During the launch, Solukon explained that excitation originates directly at the rotary table of the automated depowdering system which enables the part to be shifted to the optimal vibration range with high precision. The high frequencies of the electronic excitation are considerably higher than the harmful natural frequency of the part. As the frequency constantly controls and regulates itself, the risk of exciting the resonance frequency and damaging sensitive structures is avoided.

The test was performed with several medical 3D printed parts provided by Swiss m4m: **hip cups, spinal cages** and **medical instruments**.

"Hip cups are a very typical application. The characteristic lattice structures allow tissue ingrowth. Also, the spinal cages for stiffening the spine in cases of instability (e.g. herniated disc). The medical instruments are used as prototypes for wet room testing. Their complex support structures with lots of long tight channels are the most difficult to depowder," **Marco Flury**, Project Manager at Swiss m4M explains. As you will see below, Swiss m4m provided Solukon with different data on these parts.

Overall, the test enabled to identify specific considerations that should be taken into account for these applications as well as key specifications related to the piezoelectric excitation tool.

The depowdering test: 6 key steps

According to **Hemank Raj**, Process Development Engineer at Solukon, the depowdering test requires to assess **machine data, component data, visual control prior to cleaning**, perform **the cleaning procedure**, assess the cleaning results and ensure a **visual control after the cleaning step**.

1. As far as machine data are concerned, it's important to note that the alloy used during the test is not classified as reactive. The process was carried out in a non-inert atmosphere.

2. As for the component data, Swiss m4m shared information related to the measurements of the parts (W x L x H), buildplate, buildplate thickness, weight (including buildplate), hole pattern, and material. Figures translate into this:

Component measurements	- Ø60mm hip cups with lattice structures (0.3-0.9mm pore size) - 23 x10 x10 mm spinal cages (0.3-0.9mm pore size) - The tallest parts are medical instruments approx. 70mm in Z-height with support structures of intricate structure (smallest diameter <1 mm)
Buildplate measurements	Round buildplate. Diameter 204 mm.
Buildplate thickness	23 mm
Weight incl. buildplate	Approx. 13 kg
Hole pattern of the buildplate	TRUMPF TruPrint 2000 buildplate. No through holes.
Material	Stainless Steel 17-4 PH

3. The visual control revealed there was no visual damage, and no powder lumps on the build plate which means the material can withstand moisture absorption. However, the structures of the parts seemed to be entirely filled with powder.

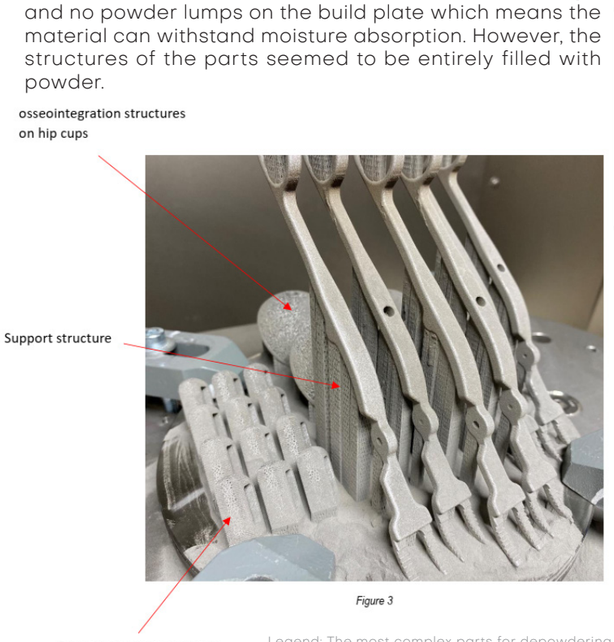


Figure 3

Legend: The most complex parts for depowdering are the areas indicated on the picture above.

4. During the cleaning phase, the build plate was mounted on the rotating plate using four clamps.

Each part of this process was well timed and lasts approx. **17,5 minutes** – from part loading, cleaning in automatic mode, cleaning part using air gun, checking cleaning results to part unloading.

For those who are familiar with a depowdering process based on pneumatic excitation, it's important to note that the cleaning steps are similar with those conducted in a depowdering process based on ultrasonic.

Raj drew our attention to one key advantage though: *"You do not have to set any excitation parameters because the depowdering system automatically sets the best excitation (= self-regulating frequency). In addition, the process was conducted in a volume maximum of 53.6 dB (for reference: a normal conversation = 60 dB) which is very silent. The process in ultrasonic excitation comes with a minimum compressed air consumption."*

(That being said, in terms of technology features, a depowdering process based on pneumatic excitation comes with a programmable high-frequency knocker to dissolve powder clumps and the SPR-technology integrates a combination of rotation and vibration).

As explained above, the test confirmed that the piezoelectric excitation tool excites the 3D-printed part at an ultrahigh frequency. According to Raj, this acceleration is enormous while the amplitude is minimal. Due to the acceleration at this frequency, the powder loses its adhesion (literally the "ground under its feet") and slides off the surface.

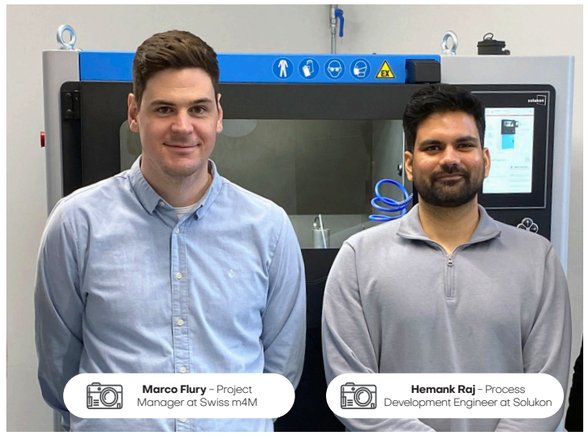
The team realized that the SFM-AT350-E has proven to be the ideal depowdering candidate for delicate and fragile structures. Not to mention that with the *"Digital-Factory-Tool we have access to all relevant depowdering data (e.g. temperature in the machine chamber, humidity and all customer specified presets) – crucial for data-sensitive industries like MedTech"*, Raj adds.

5. After the cleaning phase, the team checked the cleaning results by visual control and by blowing into the opening of the parts with compressed air.

Not only did they not find any powder residues in the complex structures, but the powder covering the component's surface was removed by blowing. However, to avoid any potential minor powder residues that may have been left inside the complex structures, they recommend conducting a final cleaning (ultrasonic cleaning) before using the 3D-printed part or before the next step of the manufacturing process.

In total, Flury from Swiss m4m **recollected 977 grams of powder** from this testing.

6. Lastly, with the visual inspection, no damages and no powder resting were found. All parts were still well attached to the substrate plate.



Concluding thoughts

First and foremost, it's crucial to keep in mind that the time and figures outlined in this article are only meant for the depowdering process of medical 3D printed parts performed as part of this test. This means that operators should be mindful of the component data and specifications of each 3D-printed part they will have to depowder. In the end, although the SFM-AT350-E and its piezoelectric excitation tool have proven advantages compared to conventional depowdering with pneumatic excitation, a few nuances can be observed for 3D-printed parts produced in other industries or for other medical applications.

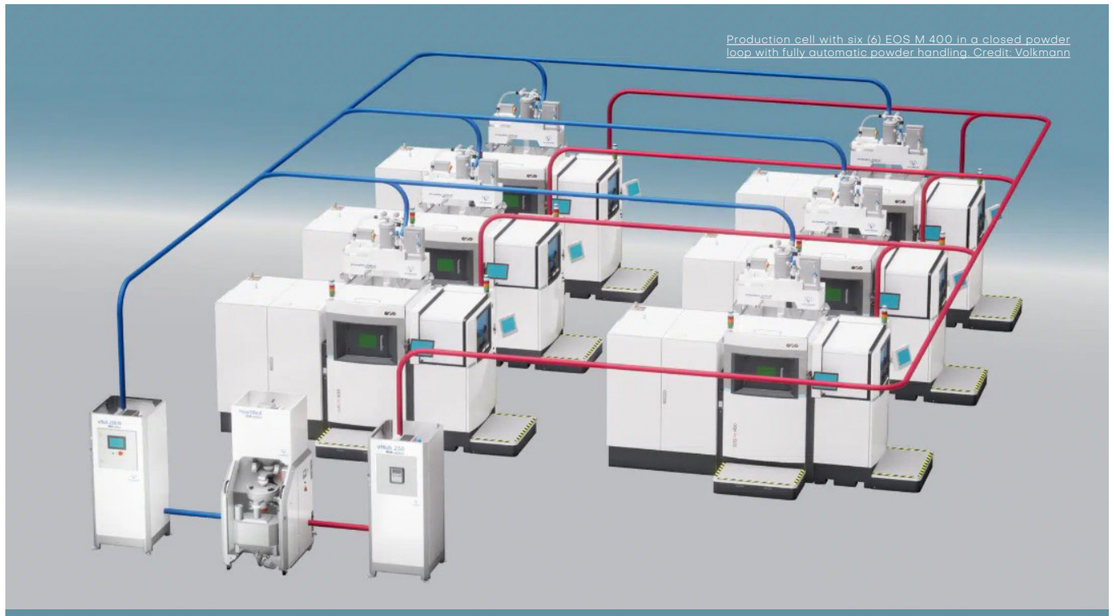
As Raj notes for instance, "*compared to pneumatic excitation with a turbine or knocker, the acceleration and frequency are many times higher and the amplitude much lower. (This is why you do not see any vibration/movement of the component during excitation). The excitation frequency is between 30 kHz and 38 kHz. This means that we are far beyond the natural frequencies of the components. This prevents oscillation and damage at the resonance frequency.*"

Between its ability to ensure a low-noise depowdering process, its self-regulating excitation mode and minimized compressed air consumption, this test reveals advantages that play to the strengths of this automated depowdering machine when it comes to its certification for a medical production environment. Not to mention that, even though the Digital-Factory-Tool and the SPR-Pathfinder® Software are optional tools, they remain interesting to make the most out of this machine. "*With specially developed technology, we were able to set up endless rotation of the turntable in the SFM-AT350-E and thus enabled the unlimited use of the SPR-Pathfinder software*", says **Andreas Hartmann, CEO/CTO at Solukon**.

Overall, "*the results suggest that the process works similarly well with titanium alloys. The excitation form of the SFM-AT350-E is ideal for this type of sensitive components. The cleaning process is very short and you can achieve a very high cycle rate since one single cleaning is completed in under 7.5 minutes. If we assume that loading and unloading together take 10 minutes, then you could aim for four cleaning jobs per hour with one depowdering system (given that no inert atmosphere is required where inerting time and door holding time need to be considered)*", Raj concludes.

Visual control after cleaning.

All images: Courtesy of Solukon.



Production cell with six (6) EOS M 400 in a closed powder loop with fully automatic powder handling. Credit: Volkmann

VOLKMANN GMBH ON THE CONCEPT OF CLOSED CIRCUIT IN POWDER HANDLING FOR 3D-PRINTED PARTS

As you may already know, once they pop out of the 3D printer, 3D printed parts must undergo some sort of post-processing (such as removing supports, tumbling, sandblasting, CNC milling, chemical dips or even powder handling). In the range of these tasks, powder handling requires special attention due to the overall production time and costs, but also due to the safety concerns metal powders raise for operators. As we continuously explore the capabilities of the different solutions available on the market, we came to realize that ***Volkmann GmbH*** *is one of those companies that advocate for the complete automation of this process.*

Volkmann popped up on our radar when it signed a partnership with 3D printer manufacturer EOS. Headquartered in Germany (Soest, Westphalia), OEM is one of those companies that has built up extensive expertise in a previous field before entering the AM market. In this specific case, it brings about 5 decades of expertise in the development and commercialization of vacuum conveying systems for powder transport. This expertise enabled the team to expand their scope of expertise to powder handling in the AM industry. Over time, the company has created standards for powder transport, sieving and preparation of the powder, fully automatic depowdering, mixing and drying of powders. To understand the specifications of their powder handling solution for the AM industry, we asked the team 4 key questions.

As a regular reader of 3D ADEPT Media, you may already be familiar with powder handling, that step of the manufacturing process meant to convey and sieve materials that were not processed in the build job during the manufacturing process.

Volkmann refers to the process that goes from filling the AM machine to closing the loop as a closed circuit of powder handling. After the filling phase, this circuit involves unpacking and depowdering, cleaning, mixing of reclaimed powder as well as buffering of the powder.

"The powder loop begins with the extraction of the powder when the build job is unpacked in the 3D printer or an unpacking station. The next process step is the preparation of the powder by sieving to separate out foreign bodies and agglomerates, e.g. with a ***Volkmann PowTReX system****. The powder loop ends with the 3D printer being refilled with the prepared powder, e.g. by a Volkmann vLoader 250,"* the company says.

"The current practice is a powder cycle using containers such as metal bottles or containers. These are docked at one station, filled, undocked and transported to the next station. During each docking and undocking process, there is a risk of metal powder and dust being released into the environment; or that contaminants from the environment enter the container and contaminate the metal powder. In addition, operator errors and the mixing up of containers can lead to an incorrect batch or cross-contamination. From an economic point of view, these manual processes are time-consuming and expensive.

In a closed powder circuit, the powder is transported or conveyed between the stations through pipes. A vacuum is used for this purpose. This largely eliminates the risks for the product, personnel and the environment. A powder circuit can also connect several 3D printers to a central powder preparation station, but this requires the use of one type of metal powder for all printers.

Conveying with an inert gas such as argon or nitrogen is possible, but most users do not do this for cost reasons. Many users have also been unable to identify any significant differences in the quality of the components. When conveying with air, however, the powder must be flushed with an inert gas before the printer is filled.

In a powder circuit, a buffer container such as the Volkmann vHub 250 can help to increase performance. On the one hand, large quantities of powder can be transferred from the printer, for example, even if the downstream powder processing unit has no free capacity. On the other hand, a powder container can also be used to store powder for supplying the connected printers. Especially in production cells with several 3D printers in a closed powder loop, such buffer containers are indispensable.

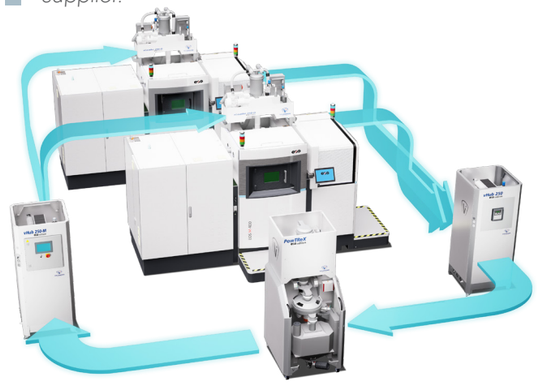
With some 3D printers (e.g. EOS M 400), the removable frame can be removed from the machine with the build job in the powder bed. Volkmann has developed the DPS Metal 1 system for fully automatic unpacking and powder removal. The extracted metal powder is transferred by pipeline to a Volkmann PowTReX system for subsequent processing", they explain.

As far as materials are concerned, the company's solutions can process all types of AM powders, from polymer to metal and ceramic powders.

"Even bulk densities of 10 kg/l, such as those occurring with tungsten carbide powders, pose no problem. The systems are designed differently depending on the material. In the case of relatively light polymer powders, for example, the main focus is on throughput. With metal powders (especially toxic and respirable particles), the focus is on making the systems particularly leak-proof and, due to the large masses of the materials, on a particularly stable design," the team outlines.

As this edition of 3D ADEPT Mag focuses on medical 3D printing, we couldn't help but ask what they find the most challenging in the powder handling of medical 3D printed parts. To this question, the company replies:

"When handling powders for the medical sector, special attention must be paid to avoiding cross-contamination, GMP-compliant production and batch traceability and the materials used. Volkmann has known the pharmaceutical industry and its customers in this sector for decades. We then incorporate the knowledge gained into powder handling for our customers in the medical 3D sector. As the requirements of the customers and the powders used can vary greatly, these special projects must be coordinated in great detail between the user/customer and the machine supplier."



Closed powder loop. Credit: Volkmann

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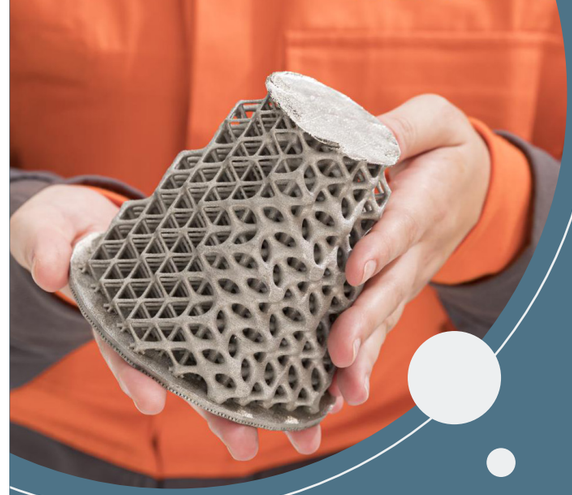

DISCOVER KEY AM APPLICATIONS

Additive Manufacturing (AM) is increasingly adopted across various industries for the most demanding applications and the less complex ones.

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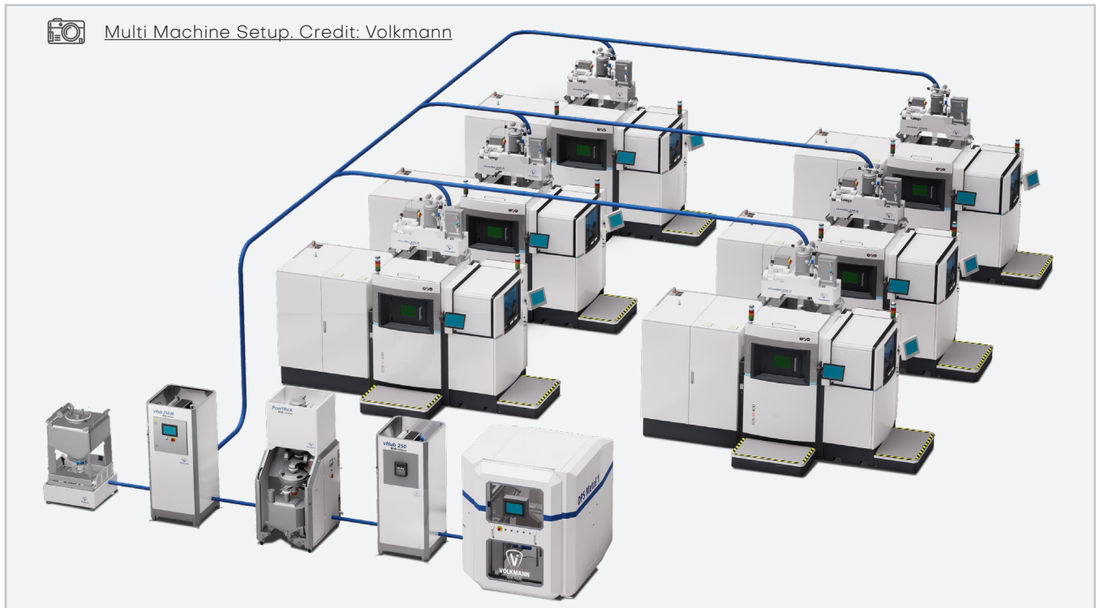
How is automation being handled during that process?

"The great advantage of 3D printing in the medical sector is the individual production of parts for patients. The systems for pre-and post-processing are just as individual as the prostheses, orthoses and dentures from the printer. Powder handling can be purchased for specific printers. As most manufacturing companies still work with a small number of printers and very small quantities of powder, fully automated systems for post-processing are not yet in use. Initial approaches have been developed for automotive parts as part of the IDAM project. Due to the high requirements concerning the qualification and quality of the parts, these work steps are still largely carried out manually. Major growth is expected over the next few years, particularly in medical 3D printing. It can therefore be assumed that fully automated systems will also be used in larger companies in the medium term," the company concludes.



Multi Machine Setup. Credit: Volkmann

Season four of Additive Talks has begun.

Additive Talks

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Materials & Software

The potential of metamaterials for (medical) Additive Manufacturing

Remember when we said that the true success of an application usually depends on an underappreciated component: material? Well, the more AM advances, the more we realize that the array of opportunities materials offer are yet to be discovered. In this specific case, I am thinking of opportunities that necessarily intertwine ***innovative design methods*** *and* ***AM*** *to ensure that optimum functionality and target behaviors are built into a new range of specialized materials. While a lot is being done at the research level, a Swiss startup gives hope for future commercialization of* ***metamaterials.***

To be honest, the first time I heard about metamaterials also known as lattice materials, I thought they were too good to be true. While there is still a bit of controversy on their exact definition, one thing scientists seem to agree with is that they are architected cellular materials that can be inspired by nature or human engineering intuition and that undergo modification in order to possess properties they don't naturally possess.

If the concept of metamaterials was first introduced in 1967 by Victor Vesalago, it should be noted that their ability to become mainstream could largely depend on the growing adoption of AM across industries and the cost considerations of the technology that will enable them.

As AM is more mature today than it was 10 years ago, it's about time to draw the industry's attention to what could be the next material driving the development of new applications.

At the intersection of software design and material development

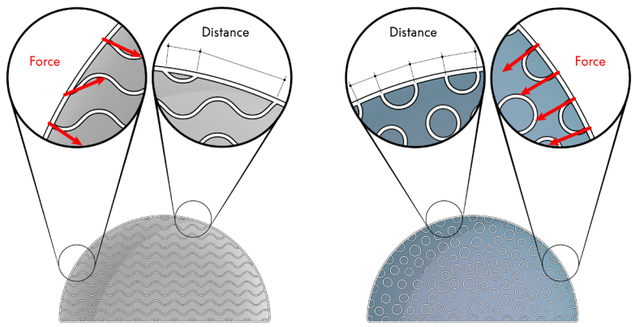
The development of metamaterials would logically call for so many cross-disciplinary competencies that it might be hard to define the people behind their creation as exclusive material producers. After a conversation with **Daniel Bachmann**, Chief Innovation Officer of Swiss startup **Spherene Ltd.**, I am tempted to define the developers of metamaterials as organizations/companies at **the intersection of software design and material development.**

Bachmann explains that in 2018, by working on a paper model, the team at Spherene explored the development of a new class of minimal surface which led them to the creation of a specific algorithm. Based on a cloud-based API, this algorithm can fill a design volume with an **Adaptive Density Minimal Surface** (ADMS), that follows inverted spherical surfaces to create a strong yet open framework within a given object. Simply put, they develop lattices using an algorithm based on a minimal surface which allows for the creation of accurate shapes with optimal geometry.

One of the strengths of Spherene probably lies in the distribution of forces in the desired area. According to Bachmann, while a sphere can distribute forces around an empty volume, a spherene allows for the distribution of forces across the interior in an ideal manner.

"Our technology enables us to apply forces in any direction of the sphere. These isotropic and surface conformal capabilities help for instance to make a piece of steel as light as aluminum and to save a lot of energy to produce the end material", Bachmann outlines.

Spherene's solution makes it possible to develop metamaterials based on **plastics** (filaments), **metals**, or even **resins**. Despite these varieties of materials, the Chief Innovation Officer confirms the solution is most advanced to produce **parts in powder-based materials**. *"It does not matter if it is plastic or metal. Resin comes in 2nd position while FDM might take a longer time to print new materials developed with our technology"*, he adds.



Credit: Spherene™ | Comparison: Gyroid vs spherene™

To date, Spherene licenses its software solution so that organizations can create the form they need for each material. They also provide the service to do that if the customer does not want to.

If Spherene's solution is **already ready to reach a wider audience**, another approach that is worth mentioning is the AI-based design method developed by **Rayne Zheng**, associate professor of materials science and engineering at Berkeley Engineering and his team of engineers.

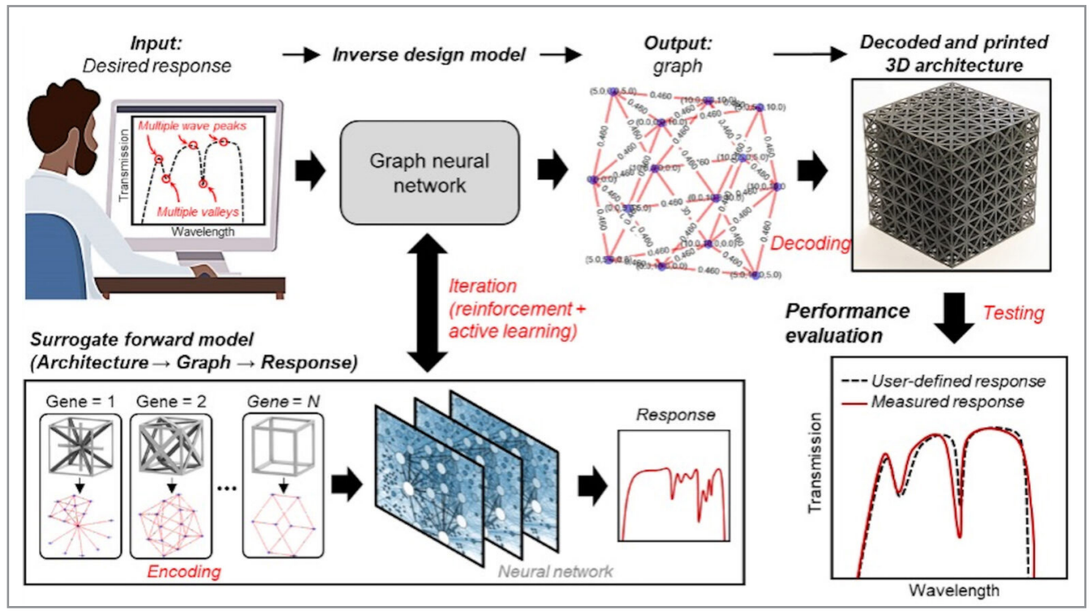
Zheng and his team used machine learning to inversely design complex mechanical behaviors of a material and engineering product that can be printed by a desktop 3D printer.

"With our method, a user can input the desired mechanical behavior described by a curve, and this data is then fed into the machine learning code to generate a design — a process that takes only a few seconds. And once that design is 3D printed, it will replicate the desired mechanical behavior," said **Zheng**. *"While still in its early stages, our machine learning-based design method can produce almost any type of material behavior with nearly 90% accuracy."*

To create their AI-based design approach, the researchers first had to develop and implement an integrated machine learning framework, which consists of an inverse prediction module and a forward validation module.

"The inverse module uses the desired mechanical behaviors to design the micro-structure of the material, and the designed material is passed to the forward module for the evaluation of its mechanical behaviors," said **Chansoo Ha**, co-lead author of this study and formerly a postdoctoral researcher at Virginia Tech in Zheng's lab. *"This helps ensure that the desired properties are accurately reflected in the finished product."*

Next, they developed a family of cubic symmetric, strut-based cells to train the machine learning model. The cells' lattice structure makes it possible to achieve almost any mechanical behavior and the corresponding stress-strain curve. The researchers then 3D printed the cells and tested them to generate training datasets.



The AI-based design method for metamaterials enables the rapid creation of material with prescribed user-defined performance and target properties. (Image courtesy of Rayne Zheng)

What considerations should one take into account to develop metamaterials?

As with any new technology, the use of the Spherene API will require a learning curve. First and foremost, since *"our technology is relatively new in the market. It's crucial for the engineer to operate a shift from traditional engineering to modern engineering"*, the Chief Innovation Officer says. The same argument was uttered multiple times when AM was not mature enough. Exploring the development of metamaterials requires a shift in mindset.

Secondly, it's important to consider one's existing workflow. Using the Spherene API makes it easy to adapt one's workflow and to insert all the variables to test it on a 3D printer.

Thirdly, cost is a factor that could tip the balance. While they anticipate organizations might find the cost of the license quite substantial (which makes sense given the novelty of the solution), Bachmann would like to urge industrials to keep in mind the advantages they can benefit from:

- Material & time savings: newly created designs filled with the exact structures lead to materials that are rapidly processed by 3D printers which leads to time savings. Taking the example of a satellite application, Bachmann explains how in 5 minutes, they have been able to save 20 hours of engineering time;

- A self-supporting method which means one can print without supports;

- Lightweighting: the spherene metamaterial can remove bulk material regardless of its density, thereby reducing the component weight;

- Customization at the design level: the spherene geometry can be positioned alongside solid sections to seal specific areas, incorporate screw holes, or form inner voids. Gradients can also be utilized to decrease material usage, adjust the center of gravity, or manage elasticity.

spherene_titanium implant

Shoe sample.

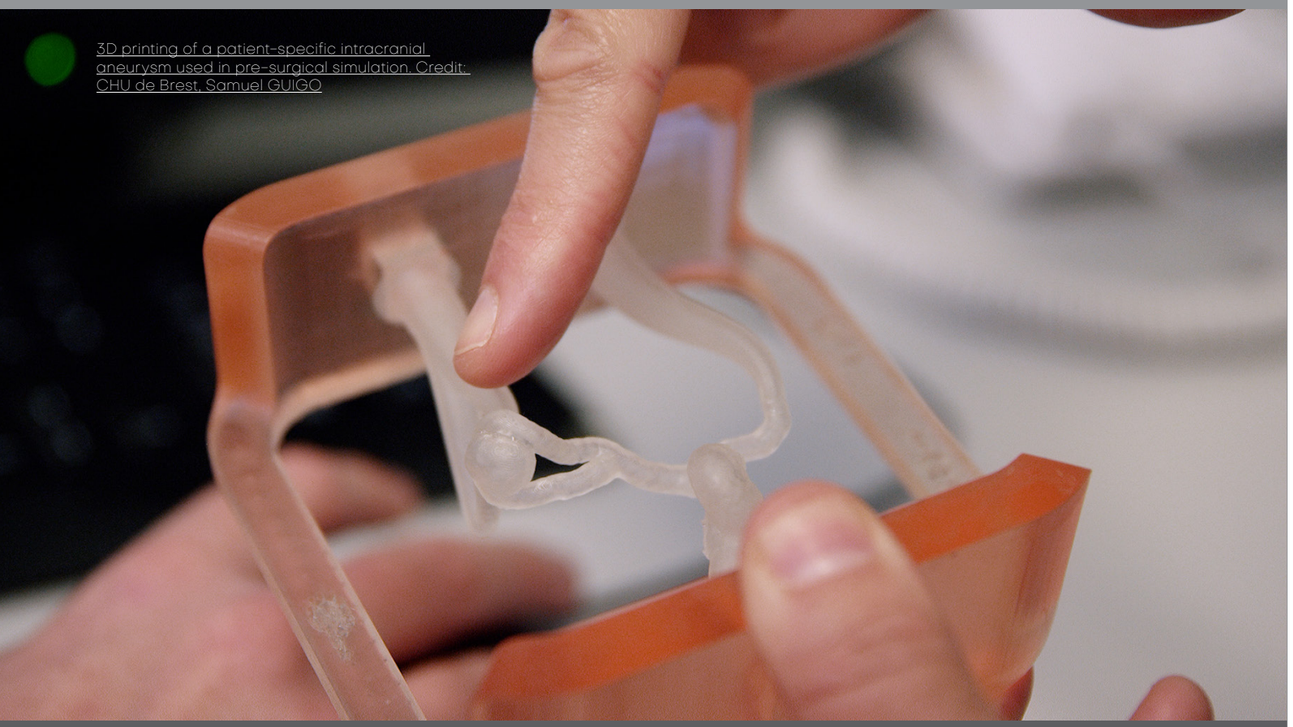
Ceramic implant.

Applications of metamaterials

Researchers have explored the potential of metamaterials in electronics, communications, and defense applications. Among the wide range of applications that could help validate the capabilities of their technology, **Spherene Ltd**. counts an ESA satellite bracket, a waveguide for a communication satellite, and a bioceramic implant tested for bone ingrowth. They are currently working on testing the capabilities of their technology on **shoes for diabetics**.

Further information about the implant can be found here.

The spherene metamaterial is set to become commercially available soon (around May), and will be available through the company's network of resellers.



3D printing of a patient-specific intracranial aneurysm used in pre-surgical simulation. Credit: CHU de Brest, Samuel GUIGO

GOING BEYOND HEALTHCARE NEEDS WITH 3D PRINTING

Elements healthcare providers should consider when getting into 3D printing and talking to 3D printing professionals

As pointed out in our conversation with Prof. Florian Thieringer (PP XX of this issue), the learning curve of Additive Manufacturing (AM) is a tough path to follow because of several considerations that range from the required interdisciplinary expertise to cost considerations. Cost considerations highly depend on several factors that are often inherent to each hospital. These factors might include personnel, budget, or even the healthcare system within their country.

To optimize these costs and the use of their 3D printing equipment, some healthcare providers may rely on creative ideas that enable professionals outside of the healthcare field to benefit from the advantages of Additive Manufacturing.

The example of the France-based hospital CHU de Brest is one that's worth mentioning here. The hospital's use of AM as well as the coordinator's profile clearly demonstrate that the use of 3D printing in a hospital is not limited to direct healthcare requirements.

Samuel GUIGO is the coordinator of W.PRINT, CHU de Brest' 3D printing laboratory that integrates 7 FDM 3D printers, a resin 3D printer and a Polyjet machine. The laboratory is located just a few meters from the hospital, allowing users to directly come on-site, if need be.

Guigo was previously a radiographer at the hospital. He seized the opportunity offered by AM to expand his scope of expertise to support other needs of the hospital. By brilliantly handling every task in the 3D printing lab (CAD, manufacturing, QA, communication, contract and more), he demonstrates that non-medically trained healthcare professionals can explore other career paths, thus creating a new path in their profession.

After the laboratory's first 3D printing project in 2019 on an aneurysm case, the teams realized that 3D printing could be used on a broader scale for various applications such as the manufacturing of custom-made parts, anatomical models and much more.

"Our very first case led to the creation of a production unit in the hospital in order to provide custom-made services. I realized that a wide range of applications could help us make this service viable. These applications did not necessarily need to focus on surgery cases but can simply be a support that enhances the quality of life at work. The repair of non-critical biomedical parts, for instance, helps the hospital to save money when and where required.

That being said, healthcare applications remain the core of our expertise – whether we provide 3D printing services to other hospitals or for internal needs. We use AM the most to manufacture 3D-printed surgical guides that are used prior to the theatre room, 3D-printed models that serve an education purpose as doctors cannot train on patients, or even ultrasound models to teach young doctors how to cut an artery," Guido told 3D ADEPT Media.

This conversation with Guigo also highlights the lack of information surrounding the first steps healthcare providers can take to get into 3D printing.

What are these steps?

For those who are looking to integrate AM in the hospital, the 3D printing expert from CHU de Brest recommends *"defining the different and specific needs in the hospital, gathering a small team and exploring both medical and biomedical applications in order to optimize costs."*

"Starting with simple cases studies is also a good way to get hands-on experience, or using open-source software to design models can be useful when you will be working with other first-time users. Most importantly, do not be afraid to reach out to other hospitals that are already quite advanced in their learning curve.

I also believe it is very important to have a guarantee of quality, i.e. an ISO-certified platform (for instance ISO13485). This is the next step in our development at W.PRINT as it is crucial to earn some legitimacy at both scientific and specialist levels," he adds.

If investing right away in in-house equipment is not for you, then adjust your expectations, find, and talk to 3D printing service bureaus.

During your first conversation with a 3D printing service bureau, you should be ready to answer a couple of questions. We've identified **5 of the most important questions** to keep in mind below :

What's the intended purpose of the model you want to produce?

The part's function and how it's going to be used are pivotal to think through the design, materials and other manufacturing requirements. As you may guess, a medical device that will be in contact with skin or bodily fluids will have stricter requirements that a non-medical part.

For which volume production?

The answer to this question will help determine the AM process that will be used, the cost and eventually help to explore other manufacturing options. In the end, depending on the volume, maybe 3D printing will not be the ideal production candidate for your case.

Are there any environmental considerations?

Answering this question will help in the selection of materials and other manufacturing requirements. Think of the different exposures the part may be subject to or may have to withstand: chemicals, liquids, temperatures, loads, etc.

Are there any regulatory requirements?

As explained in the article "Approval of medical 3D printed products and their market access" (PP XX of this issue), just because you can print it doesn't mean you can use it. Therefore, be informed about the market access of your medical 3D printed products.

Is there a desired price threshold?

Money is the sinews of war – even in the healthcare industry.

*Note: ***The conversation with Samuel Guigo has been edited for brevity and clarity.***

Images: CHU de Brest, Shared by Samuel Guigo

REFLECTING ON TWO DECADES OF RAPID.TECH 3D - ADDITIVE MANUFACTURING HUB

Two years ago, when Rapid.Tech 3D | Additive Manufacturing Hub got back on track, after a year of digital events due to the Covid-19 pandemic, the first thing that came to my mind was: *"almost two decades of an industry event that has shaped the way companies have grown their knowledge and use of AM technologies."*

I would have loved to say that time flies when you're having fun, but the truth is, in 2004, AM only raised the interest of a few insiders. Nothing would have predicted that the global Additive Manufacturing market size would be estimated at USD 15 billion in 2022 and is anticipated to surpass around USD 95.62 billion by 2032.

And here we are today, in 2024, reflecting on the opportunities that Messe Erfurt GmbH, the organizer of Rapid.Tech 3D, has been creating for the AM community over time. One thing Mr. Michael Kynast, Managing Director of Messe Erfurt GmbH would like to keep in mind is their focus on users:

"Rapid.Tech 3D has its origins in a strongly user-oriented congress. It is still the heart of the event and has been supplemented over the course of two decades by a trade exhibition and attractive networking opportunities. It is precisely this evolved triad that makes the event a unique meeting place for the entire AM industry. This is made possible in particular by the exceptionally high level of commitment of our advisory board and our motivated partners and regular exhibitors. We have also recognized that visitors use a wide range of options to prepare for their visit. That is why we have transformed our website into a 365-day platform that now offers exciting content and matchmaking opportunities for both exhibitors and visitors all year round."

Mr. Michael Kynast, Managing Director of Messe Erfurt GmbH

Copyright: Christopher Schmid. Shared by Rapid.Tech 3D

From a rapid prototyping event to a "glocal" AM community

What started as a local event in Erfurt, a city once lauded as the City of Towers, has become a hub that attracts several other organizations with the same vision: shaping the engineering landscape of Germany. This can be seen through the numerous partnerships signed over the years to make the event more and more attractive and educational for industrials.

Credit: Christian Seeling. Shared by Rapid.Tech 3D

"[Those partnerships] demonstrate the unbroken appeal of the pioneering AM event as a trailblazer for the industrialization of 3D printing. As of this year, the Additive Manufacturing Working Group of the German Engineering Federation VDMA is the conceptual sponsor of the trade congress. It is organizing the new AM4industry forum in Erfurt. The growing importance of AM for the chemical industry was demonstrated last year at the Chemical and Process Engineering Forum, which was held for the first time. Due to the great interest, the forum will be continued – with the new cooperation partner DECHEMA, the German Society for Chemical Engineering and Biotechnology. With Springer Nature Progress in AM and the RTe Journal, the AM Science Forum has gained further renowned publication partners. The new international publication channels have once again significantly increased the attractiveness of the forum, as evidenced by the further significant increase in the number of papers submitted compared to previous events. The diversity of topics at Rapid.Tech 3D is also evident in the other specialist forums that have been on the agenda for years. These include the Aerospace, Mobility, Software/KI/Design, Innovations in AM and AM Science by Fraunhofer forums," **Mr. Kynast** said.

Furthermore, today, as the AM industry keeps evolving into a "glocal" community (a community that is both global and local), Messe Erfurt GmbH has expanded the reach of the event with international cooperations.

"Since 2023, Rapid.Tech 3D has been cooperating with AMTech Expo, India's largest business networking platform and trade fair for AM. Mutual visits and presentations help to get to know the potential of the respective markets and open doors for possible cooperation between Indian and German companies. The joint platform for knowledge and technology exchange is to be further expanded with a joint Indian stand at the 20th Rapid.Tech 3D", the Managing Director explains.

Credit: Christian Seeling. Shared by Rapid.Tech 3D

The 2024 edition of Rapid.Tech 3D

We would recommend three specific angles to plan your visit at Rapid.Tech 3D 2024: by choosing the sub-event that raises your interest the most, the topic you would like to learn more about in the programme or by discovering what's happening in the exhibition floor.

Commenting on the key supporting programmes, **Mr. Kynast** said:

"The keynote speeches at the specialist congress are a highlight. This year, experts from the microelectronics, chemical and automotive industries will speak about the importance of AM for the various sectors. Another highlight is the exhibition and award ceremony for the finalists of the international design competition 3D Pioneers Challenge. Of course, participants at this year's event can also look forward to the gala evening to celebrate the 20th anniversary."

Credit: Christian Seeling. Shared by Rapid.Tech 3D

Each event is sometimes a combination of experiences that leave a lasting and unique impression. And for that to happen, you just must experience it yourself. That's in any case what we plan to do from **May 14 to 16, 2024** in the beautiful backdrop of the city of Erfurt.

Editor's notes

We may be talking about Rapid.Tech 3D as the event will be held in just a couple of weeks, from ***May 14 to 16, 2024*** *but it's important to keep in mind that, today, Rapid.Tech is more than just 3 days of interactions. Throughout the year, it's still possible to discover the innovations, expertise, offers, and events from leading suppliers of the industry.*

Industry events 2024

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HANNOVER MESSE 22-26 APRIL 2024 HANNOVER www.hannover messe.de	**SPACE TECH EXPO US** 14-15 MAY, 2024 LONG BEACH, CA www.spacetechexpo.com
RAPID.TECH 3D MAY 14, 2024 TO MAY 16, 2024 ERFURT TRADE FAIR, ERFURT, GERMANY www.rapidtech-3d.com	**SWEDEN**
SPACE TECH EXPO EUROPE 14 – 16 NOVEMBER, BREMEN www.spacetechexpo-europe.com	**EURO PM2024 CONGRESS & EXHIBITION** SEPTEMBER 29, 2024 TO OCTOBER 2, 2024 MalmöMässan Exhibition & Congress Center, Malmö europm2024.com
SPAIN	**CANADA**
ADDIT3D 2024 4-7 JUNE, 2024	**FABTECH CANADA 2024** JUNE 11, 2024 TO JUNE 13, 2024 The Toronto Congress Centre (South Building), Toronto, United States canada.fabtechexpo.com
METAL MADRID 2024 20-21 NOVEMBER, 2024	**MORE EVENTS WILL BE ADDED LATER !**
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TCT 3Sixty JUNE 5, 2024 TO JUNE 6, 2024 NEC, NATIONAL EXHIBITION CENTRE, BIRMINGHAM www.tct3sixty.com	

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AMSC 2024

The International Catalogue of AM Solutions

Once you've decided that Additive Manufacturing/3D Printing is right for your project/business, the next step might be quite intimidating. In their quest for the right technology, be it by email or during 3D printing-dedicated events, professionals ask us for advice or technical specifications regarding different types of 3D printing technologies & post-processing solutions that raise their interest. Quite frequently, these technologies are not provided by the same manufacturer.

The International Catalogue of Additive Manufacturing Solutions comes to respond to this specific need: be the portal that will provide them with key insights into valuable AM & post-processing solutions found on the market.

More importantly, an important focus is to enable potential users to leverage the latest developments in Additive Manufacturing. Companies can now feature the strengths of their AM Machine / Material offerings.

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