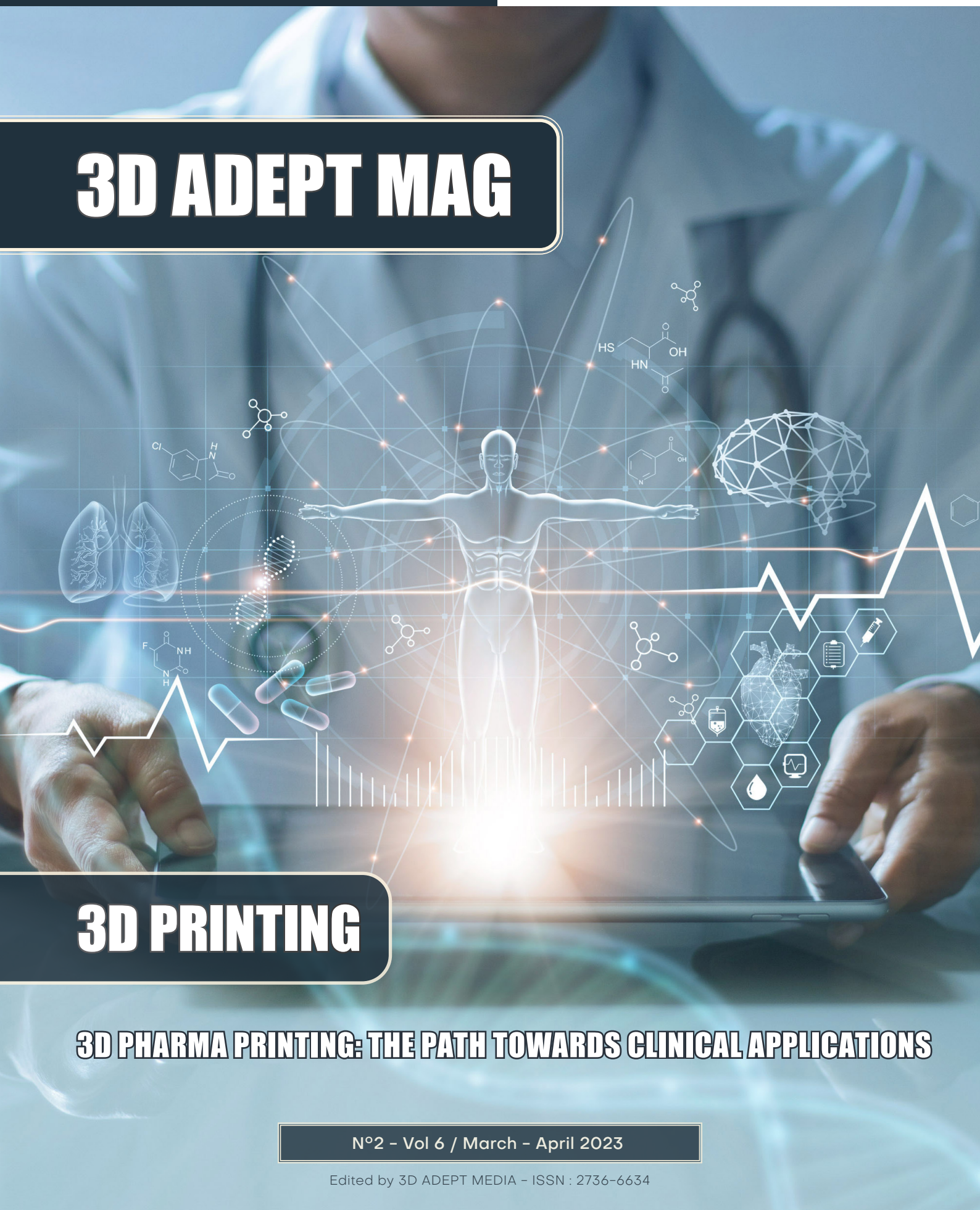
MANUFACTURING

additive



3D ADEPT MAG

3D PRINTING

3D PHARMA PRINTING: THE PATH TOWARDS CLINICAL APPLICATIONS

N°2 - Vol 6 / March - April 2023

Edited by 3D ADEPT MEDIA - ISSN : 2736-6634

3DADEPT.COM

Our online media covers a lot more information on a daily basis. Stay informed about the latest news on the Additive Manufacturing industry.Make sure you follow us on LinkedIn, Twitter and Facebook.

Do you have any current information related to 3D printing or a press release that needs to be published ?

Send an email to contact@3dadept.com

Additive Manufacturing / 3D Printing

AM NEWS · DOSSIERS · APPLICATIONS · PROMOTIONS · REPORTS

3D ADEPT MEDIA
All about Additive Manufacturing

www.3dadept.com
Tel : +32 (0)4 86 74 58 87
Email: contact@3dadept.com

Edited by 3D ADEPT Media

Graphic Designer
Charles Ernest K.

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

Proofreaders
Jeanne Geraldine N.N.

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

Periodicity & Accessibility:
3D ADEPT Mag is published on a bimonthly basis as either a free digital publication or a print subscription.

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

Table of Contents

Hello & Welcome

Staying in slowly but surely

I always have a heart full of various emotions when we write the «health» edition of 3D ADEPT Mag. Of all the vertical industries that are embracing additive manufacturing, the medical industry is always in my top 3. I have a specific admiration for companies that are all working towards a common goal: humankind's well-being. But this admiration is mixed with a sense of impatience because things never seem to move as fast as we'd like them to.

To date, about ten real applications have already been identified in the sector. This is a big step for humanity considering where we come from, but a small step for users when we see the work that still needs to be done in terms of process standardization, education for more thoughtful use, and manufacturing for more reliable processes.

It is an admiration mixed with some doubt when we see that the current processes are not clear. Fortunately for us, we can play a modest role at this level: that of confronting, of making explicit, to better enlighten the stakeholders.

In this issue of 3D ADEPT Mag, we look at the production of 3D-printed medicines, the digital manufacturing of 3D-printed medical devices, the development of implants or crowns with the appropriate materials, or the post-processing processes that evolve over time.

Things evolve slowly but surely.

Kety SINDZE
Managing Editor at 3D ADEPT Media
ketys@3dadept.com

Editorial

Significant Cost Savings on Additive Tool

Partnership between Thermwood and General Atomics

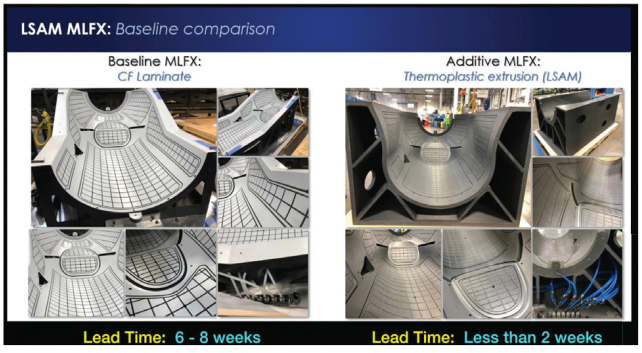
The Details

Using a Thermwood LSAM 1020, the tool was printed from ABS (20% Carbon Fiber Filled) in 16 hours. The final part weighing 1,190 lbs was machined in 32 hours.

Cost Savings of around $50,000 vs traditional methods

Total lead time for the part decreased from 6-8 weeks to less than 2 weeks by utilizing the powerful LSAM system.

GENERAL ATOMICS AERONAUTICAL

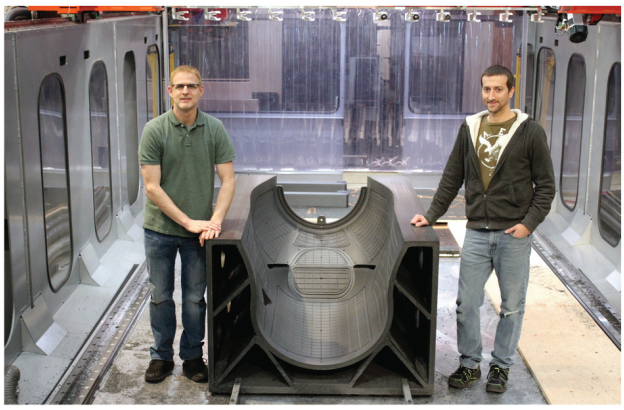


Scan QR code to view a video of the LSAM and General Atomics process.

THERMWOOD

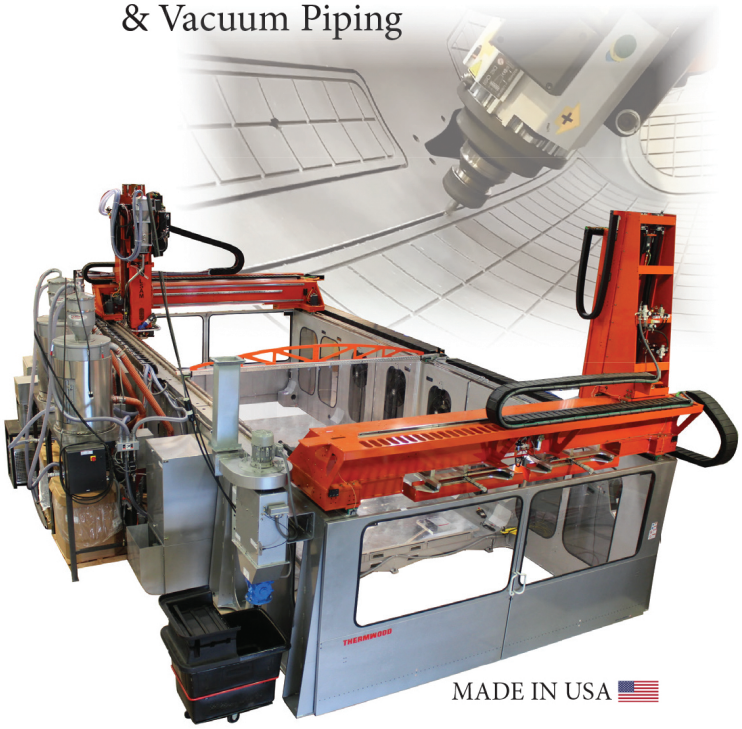
www.thermwood.com

800-533-6901



The Results

- Cost Reduction: 2-3 times
- Faster Development: 3-4 times
- Production Capable Tool
- Vacuum Integrity
- Suitable for Large, Deep 3D Geometries, Backup Structures & Vacuum Piping



MADE IN USA

3D Pharma Printing : The path towards clinical applications

One of the great complexities in projecting the prescription drug benefit costs for future benefit years lies in tracking new therapies in the pharmaceutical development pipeline and anticipating both their release date and the market dynamics (including price), and how they might affect the utilization and cost-per-unit factors. This complexity is amplified with the manufacturing of small batches of drugs with adjusted (and sometimes personalized formulation).

Indeed, when we look at the manufacturing process of drugs, conventional production processes rely on large-scale batch manufacturing, which is very efficient at churning out large volumes of drugs with uniform characteristics. However, these processes fail to meet time and cost requirements for small batches of drugs often needed for clinical trials. As you may know, Additive Manufacturing is uniquely positioned to meet these requirements since it enables the small-scale production of medications, in a relatively short time.

Here is the thing, as seen with applications across other industries, the use of AM for pharmaceuticals started in research laboratories. As the technology is carving out a substantial place within clinical and general hospitals, one needs to realize the pivotal role of legislation and certification in their adoption at scale and understand the different factors that may slow down the development of the 3D pharma printing market.

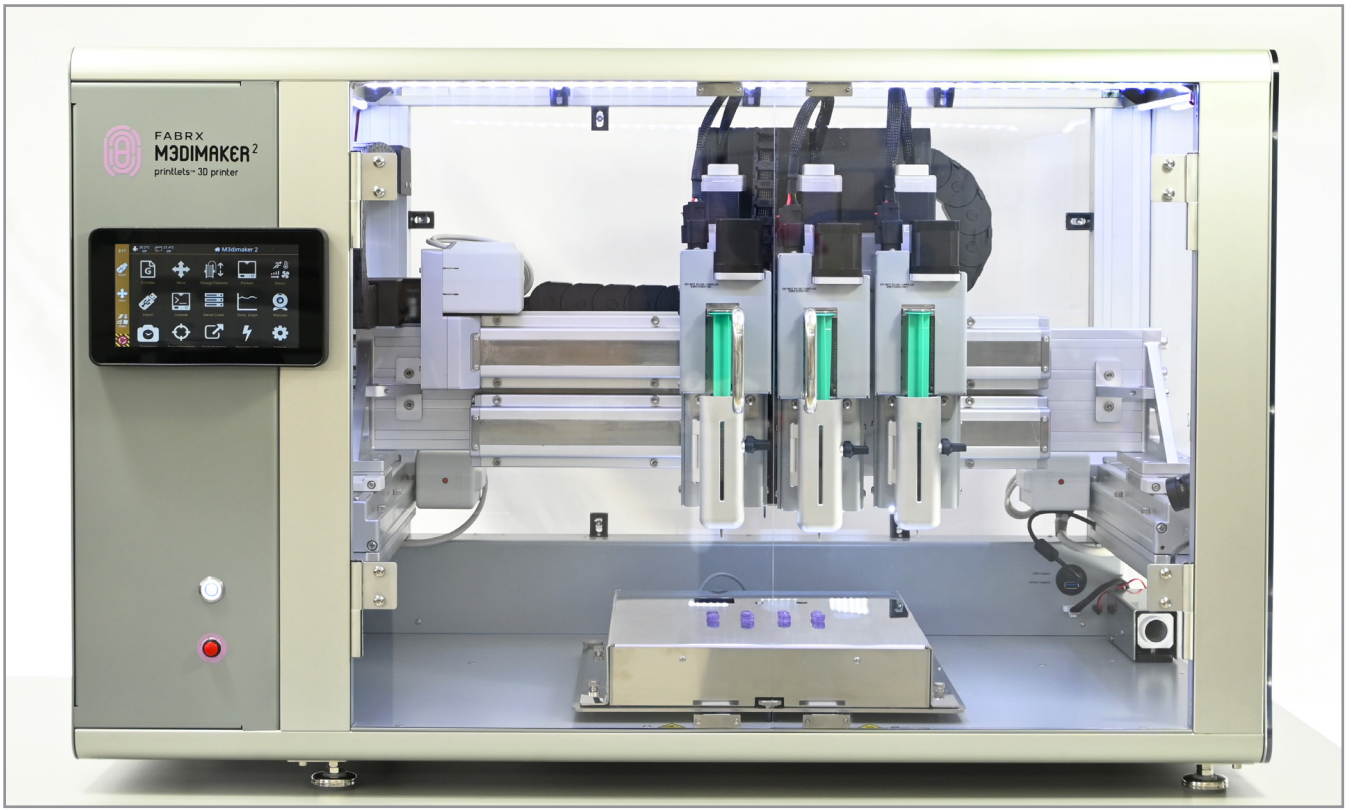
The dossier below ambitions to shed light on this go-to-market procedure as well as the key applications that 3D printing currently enables in this field of activity.

To discuss this topic, we invited Aprecia's CEO Owen Murray and Dr. Anna Worsley, Director of Innovation at FabRx to share their experience of 3D pharma printing.

Headquartered in the US, Aprecia Pharmaceuticals addresses unmet healthcare needs leveraging commercial scale 3D Printing for pharmaceutical manufacturing. Headquartered in the UK, FabRx is a biotech company that focuses on developing 3D printing technology for fabricating pharmaceuticals and medical devices.

Production and commercialization of 3D printed medicines

When one does not directly work in the field, the first thing that may come to mind when talking about launching a new drug, is advertising and promotion. Yet, in this field, a crucial understanding of the drug development process, clinical applications, FDA or EMA approval is necessary.



The drug development process is a set of steps that medical researchers and companies take to generate new medicines, treatments, or diagnostic tools to treat or prevent diseases. Interestingly, one could have thought that this process would be much more complicated for 3D printed drugs – given the "novelty" of the technology in a vital industry like this one. It turns out it is not:

"3D printed pharmaceutical products do not have a special path to approval in the United States. The same pathways apply for both traditional manufacturing and Additive Manufacturing. So, the process for an NDA or an ANDA is no different than product candidates manufactured by traditional technology. That said, careful construction of an acceptable clinical trial protocol with broad dosing range is needed to accommodate customized precision dosing based on individual patient need", **Owen Murray** states from the outset.

Although the same pathways apply for both traditional manufacturing and Additive Manufacturing, Dr. Anna Worsley believes that current legislation doesn't fit 3D printed drugs. Leading regulatory bodies such as the FDA, EMA and MHRA are working on new legislation for point-of-care manufacturing to help make 3D printing at the point of care for personalized medicine more accessible. In the meantime, pharmaceutical and other medical technology companies are working on the enhancement of new formulations for 3D printed drugs.

"At the moment, many drug dosages are already personalized via pharmaceutical compounding in specialist pharmacies around the world. Using this method, you can develop the new 3D printable formulation, carry out quality control assessments and then integrate it into your compounding workflows. To commercialize one of these formulations, or intermediate products, you would need to work with a 3D printer supplier such as FABRX and regulatory bodies for printing reliability and patient safety across different printing sites", **Dr. Anna Worsley** completes.

For pharmaceutical companies that are looking to explore AM, the most important challenges come at the level of production and the implementation of 3D printing. While drug dosages, drug combinations, release profiles and even flavors can be personalized with defined printing parameters, these advantages do not always answer the ***"mass customization"*** concern that may lead to strong profitability for pharmaceutical companies.

"Mass customization is possible", Worsley

Dr. Anna Worsley

notes. *"However, it will take much more field development and market growth for this to happen. Also, only drugs that need personalizing will be personalized. For example, drugs with a narrow therapeutic index will probably be the ones entering the market first and drugs like paracetamol will never be personalized. In the future, polypills combining your daily pills into 1 would also be very beneficial for many people on complex poly-pharmacy prescriptions."*

Beyond the economic concern, another important aspect to take into consideration is medication prescription and administration. Since 3D printing may enable the integration of several formulations into one single drug, does it change the "standard" prescription protocols? Are healthcare professionals able to reduce medication errors and harm by respecting the five rights: the right patient, the right drug, the **right dose, the right route, and the right time?**

According to Murray, *"once a product is approved for optimized dosing based on the individual needs of a patient suffering with a particular disease or disorder, the healthcare professional would not be required to change their current medication prescribing practice. Likewise, patients would not experience any change in the way they receive*

medications. Aprecia envisions a similar approach to how specialty medications are prescribed and dispensed. This often includes various hub services such as reimbursement support and clinical care guidance. The new piece would be the addition of a bespoke cGMP-compliant pharmaceutical manufacturing capability enabled by Aprecia's proprietary 3DP technologies".

"For medication that is already personalized via compounding, prescriptions can in theory stay the same. However, 3D printing increases the personalization options, meaning you can get an even more precise dosage, and personalize things like color and flavor. This would require additional prescription details but would benefit some patients massively. For drugs not already personalized, obviously the prescription would become more complex, but with the benefits that 3D printing offers, the treatment should be more effective overall", FabRx' Director of innovation highlights.

Lastly, **the cost**. In general, using AM for tailor-made applications has often proven to be more expensive than other mass-produced products using conventional manufacturing processes. We are tempted to think that the 3D pharma printing market is no exception to this theory, but our experts want to remain cautious:

"Like any pharmaceutical product, the cost to the patient will ultimately depend upon the unmet medical need being addressed, the clinical benefit of the product, and the level of payer reimbursement. This is largely driven by the pharmacoeconomic value proposition of the product. With respect to COGs, a comparison between technologies

Owen Murray

is not directly one-to-one. Aprecia's 3DP manufacturing technologies are often enabling and help pharmaceutical companies solve problems beyond the capabilities of traditional manufacturing technologies. 3D-printed products are often more complex and thus have different pricing components to be considered. Additive Manufacturing is competitive with other enabling manufacturing technologies for pharmaceuticals. However, the potential for supply chain efficiencies may result in significant cost savings", Aprecia's CEO shares.

"We foresee 3D printing to be cheaper than the current compounding methods used to personalize medicine, as it automates the process, freeing up staff time. It will be more expensive than mass manufacturing, although these higher expenses will be worth it down the line with more effective treatments, reduced hospitalizations and reduced waste", FabRx' expert adds.

Are the applications worth the final cost then?

A wide range of drugs can be

fabricated using 3D printing technologies. They include, for instance, drugs with a narrow therapeutic index, especially in high-risk patient groups such as pediatrics, or with high risks for side effects.

With respect to precision dosing, the production of drugs using 3D printing can provide significant advantages for patients suffering from rare and orphan diseases. Onerous dosing regimens are not uncommon when treating such diseases and the pill burden can be extremely challenging.

"One major advantage provided by Aprecia's 3DP technologies and our ZipDose formulation platform is drug delivery via tablets that disintegrate very rapidly with a small sip of liquid regardless of the weight. For example, Aprecia won FDA approval for a 1000 mg strength orodispersible tablet, which is much larger than any strength approved as an ODT product. This benefits patient populations that suffer from dysphagia, or difficulty swallowing. In addition to children, the elderly, and special needs patients, dysphagia is common in certain therapeutic areas such as neurology, psychiatry, oncology, and gastroenterology. Spritam®, Aprecia's FDA-approved 3DP product, is prescribed to treat epilepsy", **Murray** enthuses.

That said, it should be noted that Aprecia received FDA approval for a 3D printed drug in 2015 and has had the product available on the commercial market since 2016. The product Spritam is manufactured in Aprecia's ZipDose to provide an easy-to-swallow tablet for Epileptic patients. ZipDose is a specialized tablet created using Additive Manufacturing that rapidly disintegrates with a small sip of liquid. The rapid disintegration enables much larger dose sizes to be easily swallowed by patients.

In the meantime, the team at FabRx is currently involved in over 4 clinical studies and trials, with many more in the pipeline. So, hopefully, one might hear some good news from them in the upcoming months.

Moving forward, the company believes that if large pharmaceutical companies get involved and develop their own formulations of medicines using 3D printing, this might help propel the 3D pharma printing market forward.

Notes for the readers:

Aprecia *combines the layer-by-layer precision of 3DP and the unique needs of individual patients to deliver optimized dosing from the start of clinical trials through product commercialization. Digital precision enables the deposition of two separate powder blends and two different liquid blends enabling each layer of the 3D-printed tablet to be customized and adjusted as needed with respect to API, API and intermediates, API multiparticulates, and/or API dose. Aprecia's 3D-printed tablets are manufactured in primary packaging which enables tablet-level identification and traceability from first-in-human formulations to final dosage forms with minimal scale-up, the potential to scale out and commercial volume production capabilities. Aprecia believes its technology can be centralized or distributed and still maintain cGMP compliance.*

FabRx *believes in a world where medical treatment can be personalized to the individual needs of each patient (in terms of dosage, shape, size and dose combinations) for production on-site in pharmacies or clinical trial units. In this way, medicine taking is easier, more effective and associated with better patient outcomes. To achieve its goal, the company explores the use of several 3D printing technologies through their partnerships with healthcare institutes.*

AMSC 2023

The International Catalogue of AM Solutions

Although additive manufacturing is hundreds of years old, the last five years have been marked by the rise of a number of industrial revolutions and awareness on the technology potential by professionals.

The only thing is that, 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.

Please note that the International Catalogue of AM Solutions is distributed in all industry events where 3D ADEPT is a media partner and to our subscribers at home/in offices

Additive Manufacturing / 3D Printing

AM SYSTEMS **3D PRINTERS** **MATERIALS**

More info at « www./3dadept.com/contact-us/ » | contact@3dadept.com

New sustainable 3D printing materials

nearly 50 percent less CO_2

INFINAM®

Evonik is introducing new 3D printing grade of its INFINAM® PA12 powders with significantly reduced CO_2 emissions. The new sustainable materials are produced using renewable energy—based on biomethane—and certified by TÜV Rheinland attesting an improvement in the company's own carbon footprint of almost 50 percent.

EVONIK
Leading Beyond Chemistry

The reasons why Lithoz' Ceramic 3D printing is a great fit for restorative dentistry applications made with Lithium Disilicate

If you went to the dentist in the early 2000s, there is a great chance that you received a crown in metal or gold for your tooth that needed to be restored. Personally, seeing my dentist use a gold or metal material for a crown or a filling is not one of the best memories. A metal crown in the mouth made me feel I was one of these rappers who used to be featured in trending American music videos of the time. Thankfully today, it is possible to have a crown or a filling that perfectly matches the color of our teeth and it took a conversation with ***Daniel Bomze*** *for me to realize that the secret behind such a solution lies in the use of a glass-ceramic material called* ***Lithium Disilicate.***

Courtesy of Lithoz / Freisteller

If you're a regular reader of 3D ADEPT Media with a keen interest in healthcare 3D printing applications, then the name of Daniel Bomze may be familiar to you. The **Director of Medical Solutions** at ceramic 3D printing company Lithoz sat down with 3D ADEPT Media last year to discuss the factors to consider when exploring technical ceramics in medical Additive Manufacturing and why they are a good fit for dental applications. One of the key highlights of our conversation was that **Zirconia, ATZ** and **ZTA** – all part of Lithoz' materials portfolio – could be processed with the company's Lithography-based Ceramic Manufacturing (LCM) technology to achieve the mass production of certain dental applications.

Daniel Bomze - Director of Medical Solutions at Lithoz

Since our conversation, Lithoz has deepened its collaboration with Metoxit, a Swiss high-tech ceramics company that develops oxide ceramics. Together, they are exploring dental applications with ceramic AM. "*With Metoxit, we are currently exploring the use of ATZ (Alumina-Toughened Zirconia) to develop dental implants. Separately, we are also investigating the possibility of producing a wide range of devices such as burrs or milling tools. On the other hand, we are also working with a University on some applications surrounding this topic that we will hopefully release soon. The truth is, a lot of people now go for metal-free solutions when it comes to dental implantology. They pay a lot to have solutions with other materials such as Zirconia and ATZ but their use is often combined with some standard processes. When we realized that some manufacturers also provide some ceramic burrs, we decided to further explore the use of these materials for dental applications achieved with ceramic additive manufacturing – knowing that the advantages of the technology (freedom of design, and the ability to achieve various geometries) will play to our strengths to achieve applications with better results.*"

In the same vein, Lithium Disilicate, the glass-ceramic material acknowledged for its translucency (which means it can match the color of one's natural teeth), is widely used for dental restorations such as **crowns** and **veneers**.

3D-printed dental implants made of Alumina-Toughened Zirconia LithaCon ATZ 980. Images: Courtesy of Lithoz

The silicate anion (a tetrahedral structure of 4 oxygen atoms around a silicon atom) is the base material of most, if not all glass materials. Lithium is added in form of ions to achieve the desired properties of the dental glass-ceramic compared to standard window glass for example. The developer of the Lithography-based Ceramic Manufacturing (LCM) technology joined forces with **Ivoclar**, a manufacturer of integrated solutions for aesthetic, high-quality dental applications, to develop this new lithium disilicate material. Based on **IPS e.max lithium disilicate powder** (IPS e.max meaning it belongs to a family of dental restoration materials used via traditional shaping methods and used because of aesthetics and similar appearance to natural tooth), the material enables the fabrication of veneers as thin as 0.3 mm and crowns with high levels of detail especially at the occlusal surfaces.

Manufacturing process from Lithoz can fabricate the aforementioned applications using the newly developed Lithium Disilicate material. For those who are not familiar with this process, please note that during this fabrication process, ceramic particles are dispersed in a photosensitive resin and this dispersion is thereafter solidified by light layer-by-layer to form a part. Then the part undergoes a debinding and sintering process to deliver its ceramic properties and can be used for its final purpose.

The various manufacturing processes of Lithium Disilicate material

According to **Bomze**, there are currently three ways of creating restorative dentistry applications with this material –: the most traditional process is **heat-pressing**. The fabrication process starts with the model of the crown or veneer and relies on the use of a lost-wax technique, a process that is commonly used to cast dental alloys.

Another conventional process that can be used to process this material is **milling**. It uses diamond burs at high speed to achieve the final restoration shape. Lithium disilicate restorations are milled by hard machining prior to its full crystallization. Heat treatment is thereafter performed to achieve final mechanical and optical characteristics.

And there comes **3D printing**. In this specific case, the Lithography-based Ceramic

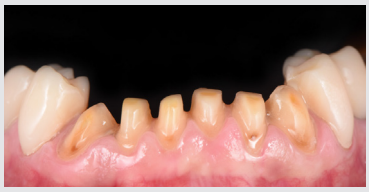
Courtesy of Josef Schweiger, M.Sc.

Our conversation with Bomze enabled us to understand the various pros- and cons- that each manufacturing process brings to the table:

	Pros-	Cons-
Heat-pressing	There is a chameleon effect that enables to have better optimal properties than zirconia. Process that relies on the use of a lost-wax technique. Low investment costs for equipment. Known to most dental technicians. Low material costs as ingots are comparably low-priced and several restorations can be made from one ingot.	The fact that parts of the process can be performed manually increases the duration of the fabrication process (Wax-up (generation of the wax modell), vesting and devesting are manual. The heat presses are available as automatic and manual ones). Limited in terms of accuracy and finishing.
Milling	There is a chameleon effect that enables to have better optimal properties than zirconia. The process delivers an improved surface quality to the part. A final flexural strength of approximately 500 MPa. Can be suitable for indirect Class II MOD restorations in various cavity preparation designs.	According to a research, there is a reduction of about 33% in the characteristic strength of lithium disilicate specimens after milling. Potential cracks or defects may occur due to stress accumulation or the changing diameter of the burrs. Requires a lot of material during the fabrication process (80% of the material could be wasted here.) Production of one veneer at the time. High material costs of a single restoration. It can take up to five days to get the final restoration.
Lithography-based Ceramic Manufacturing process	There is a chameleon effect that enables to have better optimal properties than zirconia. The finishing with AM will be identical to the patient's teeth. **A lot of material savings. If the milling process wastes up to 80% of "x" amount of material for a given application, ceramic AM loses only less than 10% of material for the same application.** **Stability of the operation.** **Better scalability and mass customization: one can produce up to 100 tailor-made veneers at the same time using this material and a CeraFab System S65 Medical 3D printer.** **Possible to perform a minimum invasive treatment in certain applications. A wide range of applications can be achieved with AM.**	Can take up to two or three days to get the final restoration.

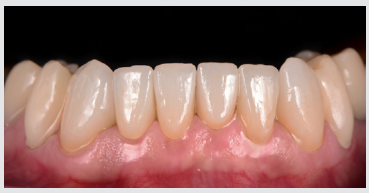
It is well-known that the nature of ceramic materials suffers from a few problems, such as brittleness, low tensile, bending, and impact strength, which restrict their applications in dental restorations. However, one needs to recognize that 3D printed veneers may deliver the **same mechanical properties as pressed and milled lithium disilicate** (with a strength that is in the range of 470–530 MPa).

On another note, while most patients aspire to have their dentistry restoration achieved during the same rendez-vous at their dentist' clinic, this timing is hard to achieve no matter what manufacturing process is leveraged. At present, AM ensures the best performance in terms of timing for veneers and fillings and the best part is, *"no maintenance is required. Once the restoration is 3D printed, the success of the treatment depends on the expertise of a dentist,"* Bomze outlines.



Preparation of the severely abraded front teeth with 0.5 shoulder on the mesial and approximal sides. The lingual side remained untouched.

Additively manufactured veneers after individualization on the additively produced cast, based on the intraoral scan.



Additively manufactured veneers after adhesive fixation in situ.

Additively manufactured veneers after adhesive fixation in situ.

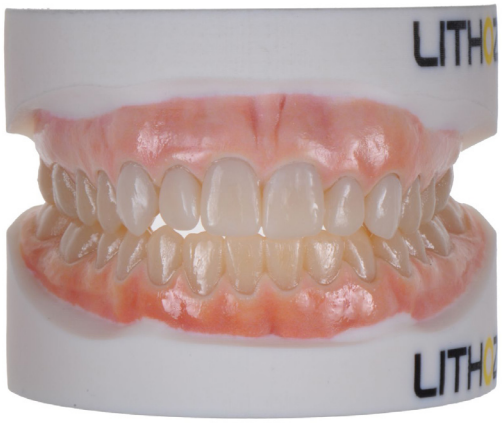
Legend: *The picture above shows 4 different «stages» of one application. First: Preparation of the teeth – Second: the produced veneers on the dies that the dental technician uses to check for fit. Third and Fourth stages are the restorations in-situ (in the patients mouth)*

In addition to the technical advantages that may result from the use of ceramic AM with Lithium Disilicate, I have been impressed with the different cases or scenarios where this technology can add value:

"For people that have ***diastema*** *for instance [a gap or space between the teeth], a minimum invasive treatment can be performed to address the issue. In this case, no-prep veneers are a great application candidate for ceramic AM,"* Bomze explains. Moreover, depending on the patient's specific requirements, 3D printed veneers can be performed in-situ, after adhesive fixation or based on the intraoral scan, after individualization on the additively produced cast.

Moving forward...

While the USA will be the first market where lithium disilicate products will be made available to customers, research activities continue at Lithoz to advance the use of this material and its applications within the ceramic 3D printing landscape. The company is currently exploring the combination of two shapes of lithium disilicate to achieve a 3D printed multi-material part. *"If the results of this project are conclusive, this application will be a game-changer in the digital dentistry field,"* Bomze concludes. And given Lithoz's installed base and big market share, I have no doubt the company is poised to capitalize on this relatively underdeveloped market opportunity.



Courtesy of Josef Schweiger, M.Sc.

This content has been written in collaboration with Lithoz.

A few words on Lithoz & Daniel Bomze

Lithoz is the world and technology leader for high-performance ceramic materials and 3D printers. Founded in 2011, Lithoz is committed to breaking the boundaries of ceramic production and supporting customers in expanding the manufacturing opportunities for the ceramic industry. As an innovative specialist for the high-precision ceramic 3D printing of complex dental and bioresorbable medical applications, Lithoz was also the first system provider worldwide to successfully develop high-end dental ceramics for 3D printing. The company has an export share of almost 100%, 150 employees and 4 different sites worldwide. Since 2016, Lithoz has also been ISO 9001-2015 certified.

Dr. Daniel Bomze is a polymer chemist by training and received his Ph.D. from TU Wien. In his Ph.D. thesis, which was conducted at the Institute of Applied Synthetic Chemistry, Dr. Bomze developed alternative irradiation-based curing methods for epoxy resins. He started his professional career as a freelance web application engineer as well as a project assistant at the TU Wien. Dr. Bomze acquired broad experience in materials research in different areas and is the author of numerous publications and patents. Starting from November 2016, he was employed as a medical business developer at Lithoz. In 2019, he became head of the medical business unit, which also includes dental applications. Starting from 2022, Dr. Bomze is Director of the Medical Solutions division at Lithoz.

How do we use resin 3D printing materials in the healthcare industry ? - Beyond dental applications

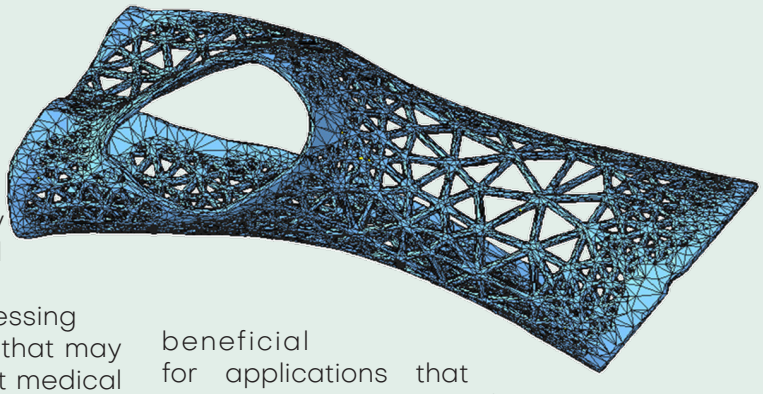
Among the wide range of 3D printing materials that can be used for medical devices, resins have often been harnessed and considered the materials of choice for dental applications. This was already considered a win for technology providers when we know that due to the expensive cost of the technology, the latter was only available to the largest, best-resourced medical centers and device manufacturers. Here is the thing, the affordability and accessibility of 3D printers came along with a demand for a variety of specifically engineered biocompatible materials with varying intended uses.

As a reminder, biocompatibility is an umbrella term for materials specifically engineered to interact with living tissues without causing an immunological response.

The challenge here lies in the ability to highlight these various intended uses, their biocompatibility certifications, post-processing technique or potential challenges that may arise during their utilization so that medical professionals can make an informed and safe decision regarding material selection. This is what this article ambitions to understand.

The majority of 3D printing resins were specifically designed for dental applications. This can be explained by the fact that when you are designing a new medical 3D printing material, there is always an application linked to this. With dental materials, there are roughly 20 applications that are quite well documented. So when you design a new material it is clear what to develop. All this information is needed when registering new material. If you develop a material for the medical sector, you can't just design one material that is suitable for every application as it is impossible to register and get FDA or CE approval. Same as in dentistry, you would need to develop a specific material per application. But there are many more applications, that would require a high investment to develop. Additionally, all parts used for dentistry fits easily within the build volume of most resin 3D-printers, which makes resin 3D-printing perfect for digital dentistry.

Ultimately, those dental materials – or their formulation - are being explored for other medical uses or specific medical applications. Resin 3D printing can be



beneficial for applications that require patient specific customization. Among the other medical applications that are being explored right now, one notes **orthopedic exoprostheses, surgical guides, hearing aids, contact lenses, intraocular lenses,** specialized **surgical instruments, medical models or even implants.**

The question is, can resin 3D printing be used to produce end-use parts for these applications? Well, almost all of these applications may require materials for end-use parts. In some cases, like hearing aid applications, it's possible to have end-use parts using photopolymer materials and VAT photopolymerization technology. ACS Custom for instance a manufacturer of custom hearing protection, in-ear monitors and other communication devices quadrupled the production of custom hearing protection three years ago using resin 3D printing technologies and a specific photopolymer material.

On another note, it's crucial to keep in mind that the selection of a material for medical applications is directly linked to the selection of the 3D printer and the requirements to meet in a given application. It turns out that depending on their final purpose, medical applications may require **flexible materials, rigid materials** or **multiple materials**.

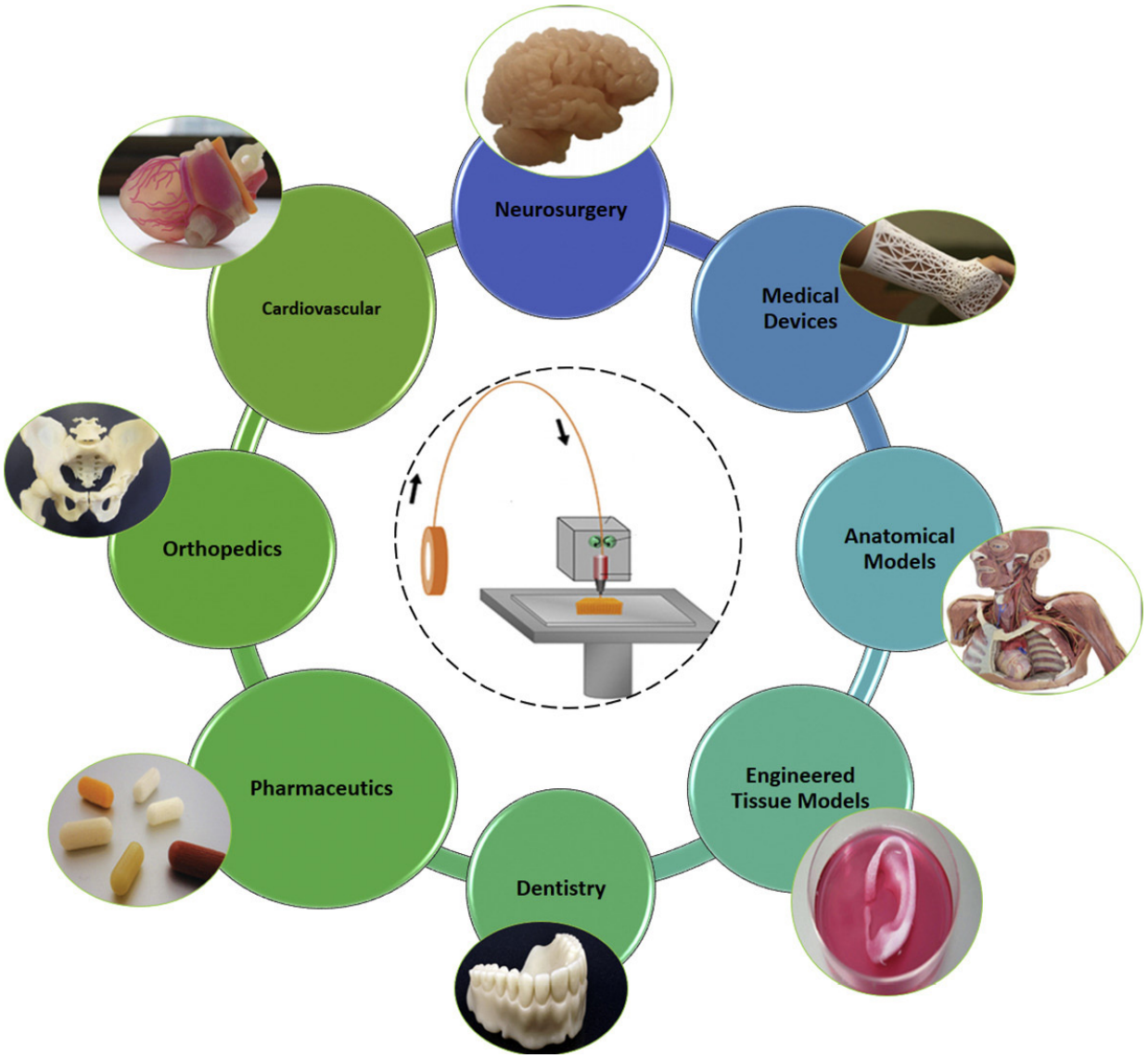
Which type of materials for which applications?

As the majority of the materials are rigid, 3D printing turns out to be the ideal production candidate for human bones. According to research, the most common option remains acrylonitrile butadiene styrene (ABS) processed by FDM 3D printing but powders of plaster and hydroquinone were also used by Binder Jetting, as well as a mix of polyamide with glass beads by SLS. Rigid materials may also be adequate in the context of preprocedural planning, to help surgeons better prepare for the theatre room.

As far as flexible materials are concerned, one learns that the combination of SLA 3D printing with resin materials might enable the production of flexible hearts made in urethane, suitable for cutting and suturing practices without postprocessing. Whether one uses SLA 3D printing or Polyjet (with a rubber-like material mixable with a rigid photopolymer to control the flexibility of a given structure), the ultimate goal is often to create a part as realistic as possible, in order to evaluate a surgical device.

As for multiple materials, they can be combined to create a proper phantom. For some researchers, multimaterial composites should be a key area of interest in medical 3D printing applications since none of the currently available materials can mimic elastic and biological tissues.

No matter what materials are used, biocompatibility remains a primary concern for medical device manufacturers.



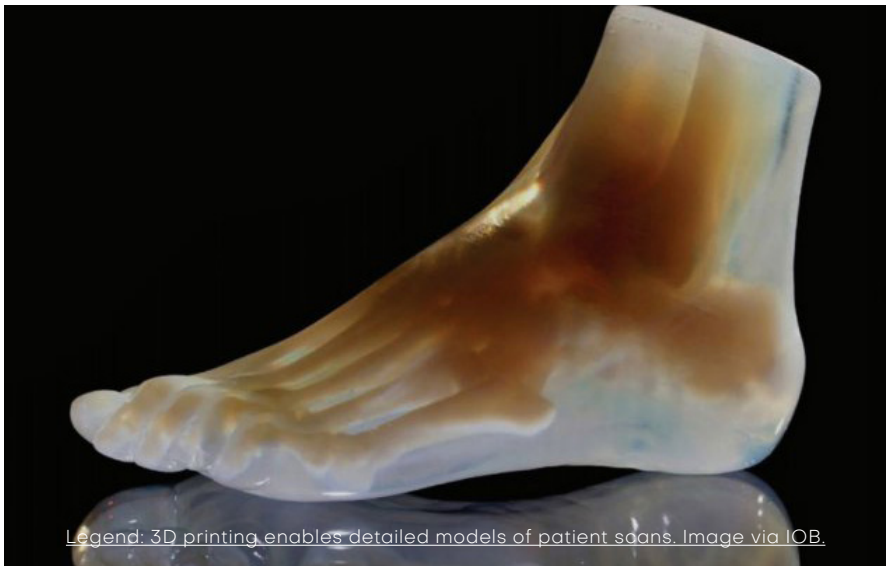
Assessing biocompatibility and sterilization requirements in resin 3D printing applications

If a material is intended to be used in contact with skin for 24 h for example, that material must be certified to remain chemically stable and not cause an immunological response for that duration. This seems obvious in theory.

The thing is, in practice, there are different requirements regarding biocompatibility or sterilization depending on the intended use. Biocompatibility is measured on parts with a specific manufacturing process (3D-printer, washing and post-curing). This means that biocompatible materials must be tested and certified with reference to the properties marketed by the manufacturer. When scaling-up it is important that the manufacturers' process is exactly followed to produce biocompatible end-parts.

Nevertheless, medical professionals should be aware of the fact that sometimes, resins are broadly marketed by manufacturers as biocompatible but are supplied with either little or no detail of the specific intended uses or related certifications. Therefore, to achieve biocompatibility, they have to ensure best practice is used throughout the process by implementing a system of validation and control.

At the manufacturing level, specific process instructions from the manufacturer should be strictly followed to get the material to comply with the requirements for each application. There should be specific hardware validated, in combination with its post-processing instructions for medical resins, for example.



Legend: 3D printing enables detailed models of patient scans. Image via IOB.

As another example, implantable devices are very difficult to develop and certify for that use as they are in continuous contact with the human body and blood. This is different compared to a surgical guide which is used on the short term in a wound (still in contact with blood) to make an accurate bone cut. Easier are the parts that are in contact with the skin or medical models that are only used for inspection or practice. On the side of material specifications, there are still steps to be made to mimic medical thermoplastic polymers like PEEK and PA. These thermoplastics have a long track record in medical applications. When resin with these types of properties can be printed and validated in clinical studies for long-term applications, they could open up a new era for medical 3D printing.

The reality is, for a lot of applications there aren't any 3D-printing resins available yet. Alternatively, there might be 3D-printed metals (titanium) or SLS/FDM thermoplastics available for some applications. If an alternative 'digital' material is already available for such an application, the registration process is much shorter. For other applications, the resin developers and medical professionals should work closely together on each application to investigate the feasibility to digitize these processes and use resin 3D-printed parts.

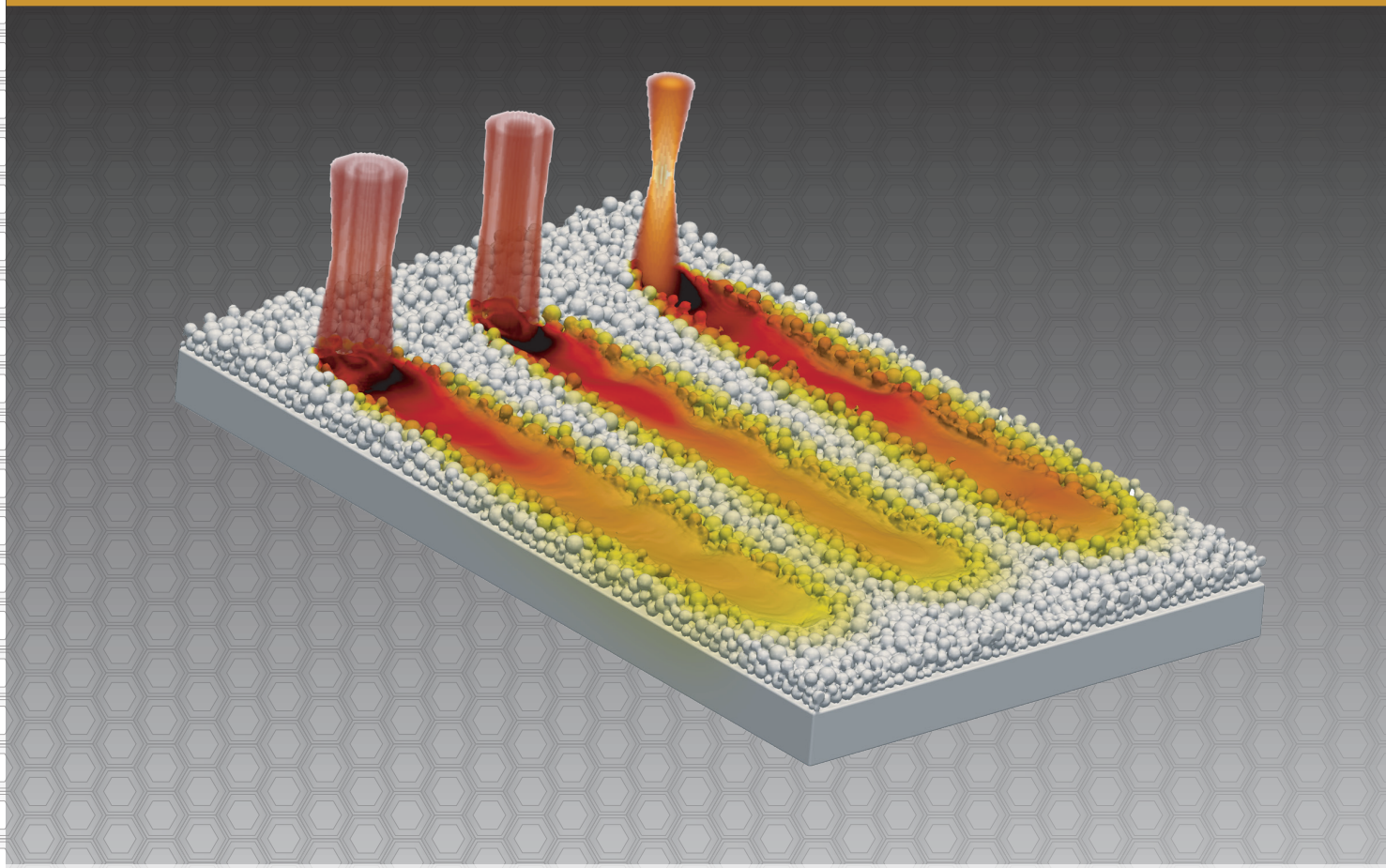
Authors and contributors

This article has been co-written with Liqcreate, a company that develops photopolymers for SLA and DLP technologies. Their high-end polymers are suitable for a wide range of industries including prototyping, industrial, entertainment, consumer goods, healthcare and automotive. In a previous article, 3D ADEPT Media worked with Liqcreate to shed light on the different forms of toxicity and solutions explored to reduce it in resin 3D Printing.

Other contributions include a study on "Biocompatible 3D printing resins for medical applications" and another one on "3D printing materials and their use in medical education."

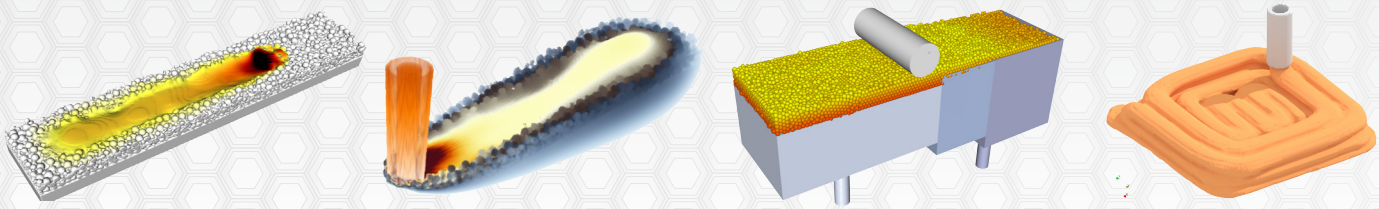
FLOW-3D® AM

CFD Simulations for Additive Manufacturing



FLOW3D.COM/AM

LASER POWDER BED FUSION - DIRECTED ENERGY DEPOSITION - FUSED DEPOSITION MODELLING - MATERIAL EXTRUSION



Contact us at info@flow3d.com or +1 (505) 982-0088 to learn how ***FLOW-3D AM***'s multiphysics capabilities can improve your Additive Manufacturing process.

FLOW Science®

Evonik on the role of polymer materials in improving the next generation of 3D printed implants ?

Anywhere, anytime: someone may get ill or get seriously injured, thus requiring a medical implant. According to a jointly report published by the American Joint Replacement Registry (AJRR) and the American Academy of Orthopedic Surgeons (AAOS), when one looks at hip and knee replacement procedures, for instance, over 1.7 million hip and knee replacement procedures are performed worldwide on 1.2 million patients per year. Here is the thing, many don't realize that such implants may eventually fail in 5% to 10% of patients. While no one can be 100% sure that a hip or knee replacement will be the last operation needed on a specific joint, the ultimate goal for medical device manufacturers and healthcare professionals remains to explore all possible solutions that can increase the chances of a long-term successful surgery. One of these solutions lies in the choice of the right ***materials.***

As you may guess, off-the-shelf implants have made it easier for medical professionals to treat the most common patient needs quickly. As technology advances, one realizes that Additive Manufacturing is not just an alternative method for manufacturing hip cups and spine cages at scale; the technology helps to reshape what implants can do, and how patients can be treated. The problem is, very often the use of AM in medical applications is highlighted through the use of metals. Yet, they are not necessarily the ideal materials for every application.

The article below ambitions to highlight the role of polymer AM materials in creating and improving the next generation of 3D printed implants. To do so, we will discuss:

- The use of polymer materials in AM vs the use of polymer materials in conventional manufacturing

- The metals vs polymers choice

Before we dive into this topic, it's crucial to make the difference between **biopolymers and biomaterials**.

"Per definition, all materials used for long-term implant applications are biomaterials since they are in contact with body tissue, liquids and/or bone. One crucial requirement for biomaterials should be their excellent biocompatibility.

"Biopolymers" on the other hand are defined as a polymer of biological origin, e.g. microbial. It is not a general requirement for a polymer biomaterial to be a biopolymer", **Marc Kebel**, Head of Medical Systems at **Evonik** lays emphasis on this.

This means that biopolymers can be biocompatible and biodegradable, and can be used in applications that go beyond the healthcare industry; applications such as edible films, emulsions, and packaging materials in the food industry for example.

Specialty chemicals company Evonik specifically provides biomaterials of biological as well as non-biological origins. The **RESOMER® material** is a degradable biopolymer and **VESTAKEEP®** is a biostable polymer. Both materials can be processed by 3D printing, RESOMER® via SLS, FFF and Freeform printing and VESTAKEEP® via FFF or Freeform printing.

Marc Knebel, Head of Medical Systems at Evonik

The use of polymer materials in AM vs the use of polymer materials in conventional manufacturing

From a manufacturing standpoint, traditional subtractive manufacturing makes sense for manufacturers who want to produce ready-made solutions that can treat the most common patient needs. However, given the complexity of anatomical structures, such technology rapidly becomes limited in the geometries it can produce, as well as the number of pieces of equipment required to make an implant. Not to mention that the time required for machining can be significant, especially when working with harder metals.

First and foremost, *"3D printing of polymer-based implants is not restricted to a particular type of implants. All current implants for which polymers are being used are possible. With the new possibilities of additive technologies, potentially even wider range of applications is achievable. One example shows the company BellaSeno [a developer of 3D printed absorbable scaffolds] uses 3D printed resorbable implants in applications that use silicone (breast implants). The most important is that 3D printed implants fulfill the biocompatibility and mechanical requirements for an implant.*

More generally – 3D printing has substantial advantages in two main fields: (1) Patient-specific implants that has an n=1, that is unique to the patient and that conventionally would result in a large amount of material loss, e.g. from machining, easier logistics and less working capital. (2) New designs and functionalities, not achievable with

conventional technologies. This includes hollow or porous structures of particular surface properties," **Knebel** explains.

As far as materials are concerned, it should be noted that whether they are processed via conventional manufacturing processes (such as injection molding or machining) or via AM, they should deliver the same mechanical properties. That being said, whether we talk about extrusion, resin, and powder 3D printing processes, polymer 3D printing can provide versatility for materials selection and support designs with diverse architectures, responses, and layouts. This is something that the **Head of Medical Systems** outlines:

"The same quality and documentation for the material are required as it is for any long-term body contact (implant) application. Same as for other processing technologies, all processing steps have to be validated and qualified (IQ/OQ/PQ) and it must be assured that a safe medical device is produced.

The difference, e.g. to injection molding, is that 3D printing offers substantially more variables to adjust in the process and all these parameters have to be checked and validated."

Needless to say that decisions across the material, the ideal 3D printing process, and design strategies are made in a nonlinear way that requires careful consideration and knowledge of their relation to a given application. Choosing a polymer material, therefore, requires considering a wide range of measurable properties that we cannot assess here. However, for the manufacturing of 3D printed implants, **Evonik** recommends focusing on **"Smart Biomaterials"**, a type of material that can combine multiple features.

"One example of this is the VESTAKEEP® Fusion Filament for FFF printing. In this product, we have integrated a bioactive additive that combines the excellent biocompatibility and mechanical properties of PEEK with bioactive properties for faster bone healing and therefore a faster patient recovery", Knebel explains.

Moreover, from a treatment standpoint, a primary concern all healthcare professionals have is the acceptance of the implant by the patient's body. AM addresses this concern as it allows for the inclusion of porous structures within the implant, a pivotal attribute that enables the biomedical fusion of the implant.

The metals vs polymers choice

Polymers only make up about 10% of the global implants market; a percentage that seems unfair when one knows the arguments that play to the strengths of these materials in applications related to 3D printed implants.

The high stiffness of metal implants for example can lead to mechanical issues such as stress shielding forces that are transferred from the metal implant on the remaining bone. (Understand here that stress shielding is the reduction in bone density (osteopenia) as a result of removal of typical stress from the bone by a metal implant.) When it comes to safety equipment, polymer-printed lattices achieve efficient energy absorption with a rapid fabrication process that bypasses the supply chain limitations of bulk manufacturing.

To these arguments, Knebel adds the natural flexibility of polymer materials such as PEEK which is close to the natural bone –leading to less stress shielding and eventually to implant loosening. He also mentions the fact there are no image artifacts under the x-ray of MRT. This is even more important for new development in robotic surgery that does not allow image artifacts during the surgery for high precision.

"As a metal-free solution, polymers can be the material of choice for allergy patients.

With respect to the 3D printing of metal implants, the SLS technology is well established. The major obstacle here is the powder handling and subsequent powder removal from the final implant. This very work and time-consuming powder handling and removal limit the use of this technology to a low number of centralized facilities.

The FFF-technology for processing of polymers offers the advantage of decentralized point-of-care implant production, e.g. directly in the hospital. Machines are smaller, filament handling is safe and easy, and post-treatment much easier. Implant production can be directly integrated into the fully digital workflow in the hospital for a faster patient treatment," He continues.

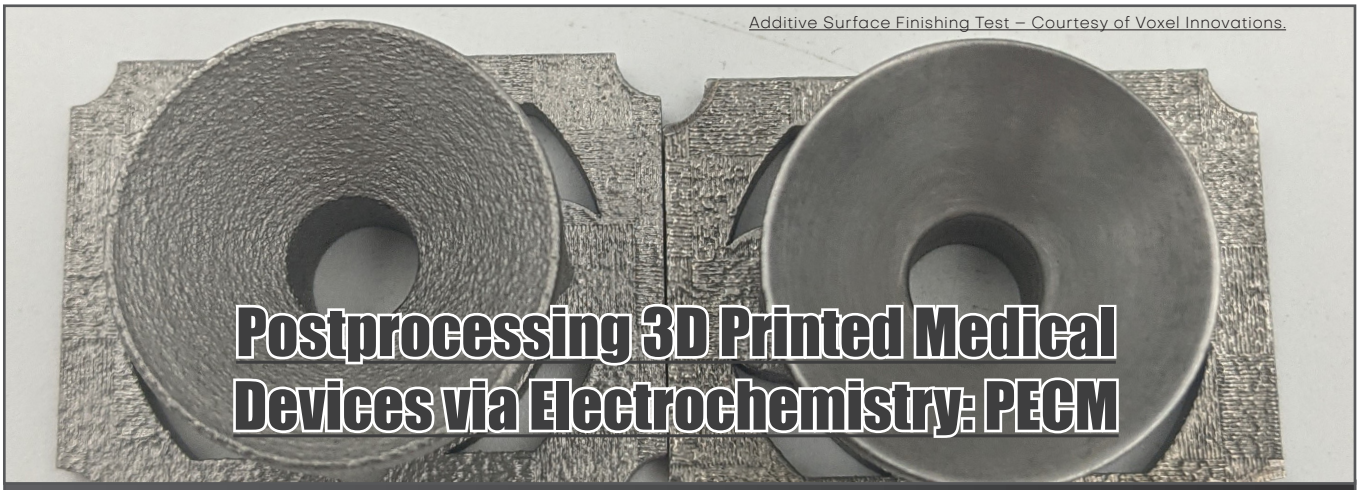
From a healing standpoint, *"healing is generally also well understood and positive for metal materials. However, allergies occur more frequently vs. no allergic reaction is reported for PEEK.*

Healing of the implant can be further increased by 3D printing with structure and surface design, e.g., the roughness of porous structures. Also, fast healing materials such as VESTAKEEP Fusion for faster bone growth accelerate the patient recovery".

Conclusion

Due to their high risks for the end-user and their potential failure, implants are classified into the class III of products subject to general controls by the FDA. Using AM comes with a number of variables that mitigate these risks while providing reasonable assurance of safety and effectiveness. Currently, more than 80% of implants would last longer than 25 years. A research reveals that this number could increase with additively manufactured implants. To continue on this path, a couple of success factors include: a continuous collaboration between material producers and 3D printer manufacturers, "a close connection to key opinion leaders (e.g., surgeons) and OEMs to understand unmet needs; trust in the market and reliable producer of safe materials, as well as a material expertise and backward integration to understand polymer well and having the capabilities and know-how to modify polymer design as needed.".

This content has been created in collaboration with Evonik.



Additive Surface Finishing Test – Courtesy of Voxel Innovations.

Postprocessing 3D Printed Medical Devices via Electrochemistry: PECM

In recent years, the orthopedic device manufacturing industry has leveraged rapid prototyping technology to produce patient-specific implants. Most notably, additive manufacturing methods have been increasingly utilized to produce custom metal or PEEK implants for hip arthroplasty and spinal surgery. Metal additive technology has been advantageous by allowing quicker design iterations, minimizing weight via topology optimization, and allowing customizable implants to contour to a patient's anatomy—with improved osseointegration as the primary objective.

Osseointegration, a key term in this article, is defined as the ability of an artificial implant to fuse with bone on a molecular level, improving functionality, strength, patient mobility, and safety.

A few design considerations that affect osseointegration may include, but are not limited to:

· Materials that limit or eliminate the possibility of cytotoxic molecules to be discharged from the implant (for example, cobalt ions discharged from a Cobalt-Chrome hip implant)

· Rough, porous osseointegrative surface quality where the part touches bone, allowing higher contact ratio and improved 'bone anchorage'

· Part geometry (and material) that creates uniform load distribution, avoiding isolated load on a particular area of the part and/or bone over time that can cause part failure

However, osseointegrative surfaces and unique part designs are increasingly difficult to implement as demand for metal-AM grows and the limitations of the technology become increasingly apparent. As Metal-AM transitions into volume production for orthopedic implants, costs-per-part become critical, and manufacturers must seek to reduce these costs in creative ways—sometimes at the detriment of surface quality and part resolution. For example, manufacturers may reduce costs via larger powders, faster laser scan strategies, thicker layer lines, or more aggressive re-coater methods. These issues are exacerbated by the strict tolerance requirements and superfinished surface quality needed for implants to have sufficient fatigue strength, biocompatibility, and osseointegration.

Fortunately, there may be a technology capable of alleviating some of these manufacturing challenges for high-volume AM parts. ***Pulsed electrochemical machining***, improves part resolution and surface quality for metal orthopedic implants in higher part volumes.

How PECM Works

PECM is a non-contact, non-thermal material removal process that utilizes electrochemistry, as opposed to friction and/or heat, to remove the workpiece material. PECM flushes a charged electrolytic fluid within a microscopic gap between the tool (cathode) and workpiece (anode), and the proximity of the tool and workpiece is correlated with the removal rate of the workpiece. To do so, the cathode is shaped as the inverse of the desired geometry on the workpiece.

This electrolytic fluid simultaneously performs two crucial functions. First, it acts as the conductor for the electrochemical reaction to take place. Secondly, the fluid acts as a flushing agent that removes the waste products leftover from the reaction, and eliminates any residual heat that may otherwise affect the local conductivity of the electrolyte.

The unique nature of this process affords

it unique advantages. For example, the process is capable of both machining and finishing simultaneously, as the lack of heat or contact removes the possibility of any surface irregularities associated with other processes, such as recast layers or burrs.

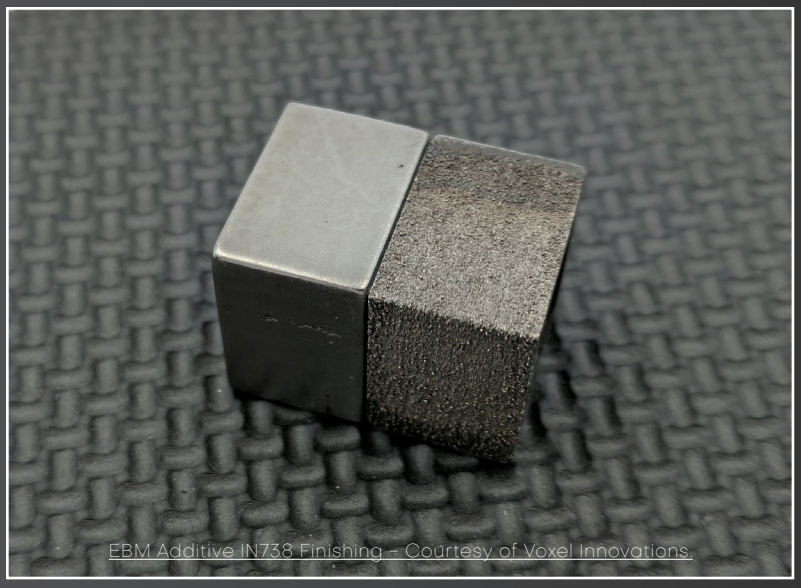
The lack of heat or contact also allows the process to largely eliminate tool wear. PECM is therefore ideal for machining high-volume parts and identical features in tandem, with a single, custom cathode.

PECM is primarily used as a machining process for complex metal components for the energy, aerospace, and medical device industries, and generally machines a workpiece that begins as bar stock or a near-net shape. However, the process can also be used as a secondary machining or postprocessing operation on additive components, and its unique capabilities can be especially advantageous for additive medical implants.

AM and Osseointegration for Spinal Cages

AM's ability to develop customized parts specific to each patient can vastly improve safety, patient mobility and comfort. Let's review a quick example with spinal cages, a type of orthopedic implant that can replace one or more vertebra.

One of the most important design considerations for spinal cages used in, for instance, lumbar spinal surgery, is to avoid implant subsidence, a sort of fatigue wear over time. Implant subsidence in an uneven or conventionally machined



EBM Additive IN738 Finishing - Courtesy of Voxel Innovations.

spinal cage can cause the cage to partially penetrate the vertebral endplate, which can impact the structural integrity of the implant, reduce patient mobility, and cause significant pain.

However, with modern additive technology, engineers and surgeons can produce a part that simultaneously maximizes the contact area between the implant and the vertebral endplate (uniformly distributing the load), while avoiding too large of an implant that would impair patient mobility. A Canadian study from 2022 provided evidence of this point, evaluating the respective load distribution of custom AM and conventionally-machined spinal cages--ultimately finding that the custom-manufactured cages that match the anatomical features of the patient had better functionality, durability, and osseointegration.

Despite these benefits, however, AM has inherent limitations which may disrupt both the economics of manufacturing these parts, as well as their functionality—and many of these limitations are centered around surface quality.

Surface Quality and Implants

Surface quality is crucial for the functionality and safety of orthopedic implants (as well as most other medical devices). For one, high surface quality is essential for the safety and durability of orthopedic implants involving friction, such as the "ball-and-socket» feature on the acetabular cup on a hip arthroplasty device. Not only does high surface quality reduce friction which may cause patient discomfort or limit the lifespan of the components, but materials with potentially cytotoxic ions (which we discussed earlier) are less likely to release these particles if the surface quality is smoother.

Good surface quality is also safer for the patient from an anti-bacterial perspective. Staphylococcus aureus (Staph infection), is the most common cause of periprosthetic infections by adhering itself to the implant in a 'biofilm'. A primary way to avoid this

biofilm adhesion is with superfinished surfaces across the implant (osseointegrative surfaces are, expectedly, more susceptible to biofilm; surgeons may put an antibacterial adhesive on the osseointegrative surface of the implant to ensure the bone adheres itself to the surface first).

AM's Surface Quality Limitations

Unfortunately, modern additive technology has important limitations; it cannot produce super-finished surface qualities on most medical device components without a secondary machining process. Some causes of surface irregularities may include the layer lines themselves, re-melted material, support structure remnants, or powder particles. Furthermore, most AM processes cannot achieve adequate resolution on some features, such as downskin surfaces.

These limitations are further exacerbated when metal additive manufacturers utilize larger powders, faster laser scan strategies, thicker layer lines, or more aggressive re-coater methods to reduce costs for high-volume part production.

Limitations can also be specific to the part, such as with the spinal cages used in lumbar interbody fusion surgery mentioned earlier. While certain aspects of the cage must have a porous, osseointegrative surface, other aspects must have smoother surface quality, and these combined features may be difficult for AM processes to produce in higher part volumes.

PECM's Fix

Fortunately, PECM may be capable of alleviating many of these limitations, acting as both a secondary machining and finishing operation for high-volume metal-AM implants, such as spinal fusion cages, hip arthroplasty devices, and others.

First, PECM can act as a secondary machining operation that can allow additive parts to achieve improved resolution—most notably on difficult features, such as thin walls and downskin surfaces. As most metal additive processes can only achieve a minimum wall thickness of around 0.3 – 0.5 mm (0.012 – 0.020 inch), a custom PECM tool can easily reduce the wall thickness to <100 µm (0.004 inch).

Furthermore, according to data from Voxel Innovations, PECM can improve the surface quality of metal 3D printed parts from 5 – 10 µm (196 – 393 µin) Ra to less than 0.5 µm (19.6 µin), even to 0.1 µm (3.9 µin) Ra. PECM is also generally quicker than conventional processes, and can replicate these thin-walled, higher-resolution features potentially tens of thousands of times without incurring tool wear.

As the process prioritizes electrical conductivity of a given material over its hardness, PECM is capable of machining complex features in tough materials commonly used in metal additive implants, such as Cobalt-Chrome alloys and titanium alloys, including Ti64.

PECM can achieve these high-resolution, high-surface quality features because there are no burrs, recast layers or surface irregularities involved in the process, and it is capable of both machining and finishing simultaneously, saving manufacturers time.

PECM could also utilize a custom cathode to selectively finish certain aspects of an additively manufactured medical part. While PECM could not replicate porous, osseointegrative surfaces on the vertebral-facing areas of a spinal cage, for instance, it could both selectively finish the side features and improve part resolution on downskin surfaces in higher part volumes.

Despite the exponential growth and popularity of metal additive processes, and its increased presence in the medical device market, manufacturers should be wary of its limitations. Therefore, they should consider an alternative postprocessing technology that can complement the strengths of AM and diminish its disadvantages. Pulsed electrochemical machining (PECM) may be capable tool by improving part resolution and creating superfinished surfaces in high part volumes.

About the author

Kirk Gino Abolafia is the technical marketing manager of Voxel Innovations in Raleigh, North Carolina, United States. For additional content on electrochemical machining, see Voxel's education portal.

2023

RECEIVE THE MAG AT HOME !

We have a range of free print and digital subscription options globally, all of which deliver a unique understanding of the industry with integrity.

SUBSCRIBE AND RECEIVE THE LATEST AM INSIGHTS AND THE NEXT ISSUE OF THE MAG

WWW.3DADEPT.COM/SUBSCRIPTION/

Inside of a depowdering system. Courtesy of Solukon.

The medical 3D printing market keeps growing. How do the latest advancements in depowdering fit into this evolution?

A couple of years ago, I took part in a MedTech conference in Eindhoven (The Netherlands) where I accidentally stumbled upon a book that read: «modern medicine was no accident, except when it was. The history of medical innovation, which spans centuries, is filled with killer diseases, scientific inquiry, accidental discoveries, and brilliant machines.» It was true, sad, and kind of heroic. Don't ask me why, that's what I thought. So yes, during the past decades, medical technology advances have changed the practice of medicine. Whether we talk about mind-reading exoskeletons, 3D-printed drugs or implants, those innovations are coming to healthcare almost every day and it turns out – they ultimately want to address a challenge that stands the test of time: the ***need for more personalized care***.

Needless to say that the timeline of milestones achieved in medical technology will vary from one expert to another, and most importantly, will depend on everyone's field of expertise and/or area of interest. When we look at AM/3D printing for instance, one realizes that the technology was first used for medical purposes as dental implants and custom prosthetics in the 1990s but we had to wait until the 2000s when patents related to the technologies, started expiring to see a growing exploration of the technologies across medical applications and other fields of activity.

«In the 90s, 3D printed anatomical models gave the first opportunity to better plan surgeries. As an example, conventionally manufactured jaw plates for tumor treatments were adapted to the anatomy using 3D-printed plastic models. This resulted in more efficient surgery for the patient», **Nicolas Bouduban**, CEO of medical technology company Swiss m4m Center, comments.

Fast forward to today: the

Nicolas Bouduban, CEO of medical technology company Swiss m4m Center

healthcare segment is shaping up with advances in digital healthcare technologies, such as artificial intelligence, VR/AR, 3D printing, robotics or nanotechnology, and among these technologies, the strides made in AM often outshine the limitations that still needed to be addressed by medical device manufacturers.

This article aims to highlight what enables AM to stand out from the crowd on a market cluttered with various digital healthcare technologies. With a key focus **on depowdering equipment**, it will discuss how these «brilliant machines» fit into this evolution, as well as the limitations that are still raising concerns among medical device manufacturers.

It's about the small steps

We don't often realize how far we have evolved until a milestone is celebrated. Remember, six years ago, when we first discussed with automated powder removal expert **Solukon**, they made us realize that post-processing was considered a modest priority by manufacturers, yet it was the stage that often increased the final cost of the 3D-printed part. Over the years that followed, we dedicated time to understanding the ins and outs of this process; we shed light on the reasons why we believed post-processing in additive manufacturing of medical parts is a matter of liability, but we eventually failed to understand why this awareness process took a little longer in the medical field.

For **Andreas Hartmann, CEO/CTO of Solukon**, the reason is first and foremost a **question of size and complexity**. While he recognized that medical device manufacturers are increasingly aware of the importance of automated powder removal, *«the fact that this learning process took a little longer than in other industries (e.g., aviation) is because, at a first glimpse, medical devices seem not that challenging to depowder compared to complex, heavy and huge heat exchangers or rocket propulsion components.»*


Andreas Hartmann, CEO/CTO of Solukon

For our expert, three main reasons have truly fostered the need for automated depowdering solutions:

1. The numbers of additively manufactured parts and the cost pressure in the medical industry that require an automated instead of a manual depowdering solution are steadily rising.

2. In the medical industry, production needs to be on demand and fast. Automated depowdering ensures leaner and faster postprocessing which contributes to a faster overall manufacturing process.

3. MedTech is a strictly regulated industry. This results in high requirements for transparency and traceability of the entire manufacturing process, including the depowdering process. Not to mention that manual powder removal procedures are not at all sufficient here.

If you wondered what automated powder removal solution was trending at the time, let me tell you now, it was the **SFM-AT200** – an affordable system developed by Solukon. Like any technology developer, Solukon has upgraded and diversified its portfolio. Today, a machine called **SFM-AT350** is also suitable for medical 3D printed parts.

«The SFM-AT200 is still an ideal candidate for the medical industry. The system has a very small footprint and therefore also a small process chamber that is filled up with inert gas in under two minutes. It can depowder parts with dimensions up to 300 x 300 x 230 mm and is equipped with one automated rotation axis and manually adjustable frequency excitation. The SFM-AT200 is the right system to depowder rather small, medium-complex parts and a very cost-effective automated depowdering solution.

In comparison, the SFM-AT350 offers enhanced freedom of motion with a two-axis rotation (endless on the rotation plate, 250 degrees on the horizontal axis), a bigger process chamber (for parts up to 350 x 350 x 420 mm) and -even more importantly- all features for process monitoring (Digital-Factory-Tool) and automation integration (OPC UA)», Hartmann outlines.

By highlighting the digital factory tool and automation integration as key features of the SFM-AT350, Solukon's CEO refocuses the debate on a key item that enables AM to stand out from the crowd in a market already full of various digital healthcare technologies.

For the sake of humanity

Orthopedics, traumatology, cardiology, ophthalmology are a few examples of sectors of activity that have already benefited from Additive Manufacturing. According to Bouduban, when we look at serial production, prosthetic parts with lattice structures for hip, knee or shoulder endoprosthetics are examples of parts that may require the use of AM in fabrication. Individualized parts for craniomaxillofacial surgery (orbita or jaw plates), semi-finished dental products such as metal frameworks or bridges and orthodontic products are other examples worth mentioning.

Interestingly, one common thread that surrounds the use of AM across these sectors is **digitalization** – a "catch all" term that the Gartner Glossary defines as "the use of digital technologies to change a business model and provide new revenue and value-producing opportunities." A term that is often used interchangeably with digitization which refers to the process of converting information into a digital (i.e. computer-readable) format.

In the medical field, "***data acquisition*** is the starting point for being able to perform fully digitized «workflows»", Bouduban points out. As medical technology aims to be more and more personalized, this should be reflected in the design and production decisions that medical device manufacturers make.

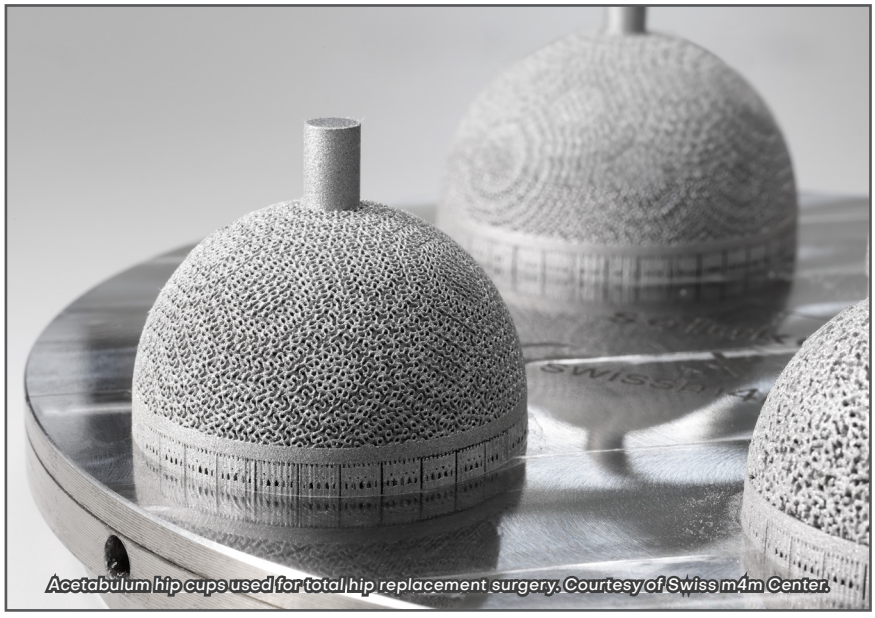
SFM AT200 SFM AT350

At every step of the manufacturing value chain (design, fabrication process, post-processing), collecting and maintaining complete data about how a medical device is fabricated and inspected is of paramount importance. In their production facility – and depending on the volumes of production to achieve, a medical device manufacturer will use a wide range of equipment to track the progress of projects, for production scheduling and for quality control.

The information gathered about the whole process then becomes very fragmented, hence the use of a manufacturing execution system (MES) that will digitize and centralize AM production data from beginning to end. This is just one example that reflects the need to acquire data across the entire value chain, data that can be traceable.

This need for transparency and traceability is also pivotal at the depowdering stage. As a matter of fact, these are features that make *"the SFM-AT350 the machine of choice for medical AM manufacturers that need full process transparency (even to get a certified production environment)"*, Hartmann recalls.

The truth is, *"MedTech, together with aerospace and space, is the industry with the highest demand for process traceability and repeatability. This is where our Digital-Factory-Tool comes into play. The [latter is] a sensor and interface kit that records all relevant depowdering process data and summarizes the values in a protocol file. Critical limits can be set for relevant data so that deviations can be directly displayed and assessed.*


Acetabulum hip cups used for total hip replacement surgery. Courtesy of Swiss m4m Center.

The DFT monitors data in the parts, such as residual oxygen, humidity, chamber pressure, temperature and frequencies. Information on the selected cleaning program is also available. The user can add specific information manually such as the type, batch, customer job and material used so that, in the end, a PDF-format protocol file is created", he adds.

To date, Solukon's collaboration with AM users has enabled the team to identify other pain points to address – which will lead to an upgraded version of the Digital-Factory-Tool. Hartmann shares for instance, that thanks to these collaborations, they know, users "*need some more numbers from the depowdering process with respect to part quality and energy consumption during depowdering.*" "*In the medical field, more than in other industries, one comprising digital job ticket of the whole build and post-process must be the goal. We do everything to make the depowdering process transparent and are also contributing to work on a digital protocol for the whole process*", he completes.

Moving forward…

While digitalization has been mentioned as the common thread that surrounds the use of AM across the aforementioned medical sectors, the increasing adoption of these technologies comes with a growing number of pain points that require the attention of both technology providers like Solukon and technology users like Swiss m4m Center. Those pain points seem even more crucial when discussed in a vital industry like the medical one.

To those mentioned earlier – and with regards to depowdering, Solukon added the need for developing a sort of catalog that spells out the complex and resulting limitations of the depowdering process. This would mean actively matching part complexities (e.g. section of openings, length of channels, spread of openings on the part, structure depth) with their depowdering process.

"*With a depowdering guide that aligns with relevant norms such as ASTM F3335, we will optimize the postprocessing process of our medical customers even further*", Hartmann concludes.

This content has been produced in collaboration with [Solukon Maschinenbau GmbH](#).

Software

Q&A with Matthew Shomper on (Computational) DfAM & 3D Printed Medical Devices.

Matthew Shomper is an innovative engineering leader with extensive expertise in the computational design of biologically advantageous medical implants. With many cleared medical devices released into the field now residing in several patients across the world, we couldn't find a better subject matter expert to get advice on how designers can improve or get started on their computational DfAM journey and how nature might inspire some of the complex structures that once – 3D printed –, help hundreds of thousands of people on the road to recovery.

Shomper works today as Director of Engineering at Tangible Solutions, a company that specializes in the manufacture of **3D printed titanium orthopedic implants**. In this role, he drives the design and development of medical devices from concept development to market launch, and thus helps customers to understand their pain points, timeline, and budget constraints.

3DA: We are used to hearing the term DfAM. Is it something different when it is preceded by computational?

Matt Shomper (MS): It is mostly the same and also a little different. DfAM is a set of principles that govern good design practices and ultimately lead to better manufacturing efficiency. These principles are based both upon the final product (consumer, aerospace, medical, etc.) and specific manufacturing technology (i.e., LPBF, SLA, Binder Jetting, etc.. The preceding term "computational" slightly skews the difficulty. Very rarely (in my experience) do structures become easier to produce the more complex they are. Therefore, this places the additional responsibility on the designer when considering CDfAM.

3DA: Would you say such a framework works best for complex geometries? Or is it a great alternative for those who are not really experts in design?

MS: Computational design is a great enabler of complex structures. Virtually all creative endeavors have limitations. Although boundless creativity exists inside the human brain, a substantial constraint of humans is the inability to parse and process large datasets. Computational design removes this limitation, giving designers the ability to morph this data into functional products, solutions, and actions.

Computational design is not for the faint of heart. The tools are rather inaccessible (with large learning curves) and it usually requires a dual knowledge of designing for requirements and aesthetics at the same time. Good design sense is a must regardless of what's being created, and I don't believe computational design is a 'shortcut' to get around solid engineering principles.

3D printed hip cups. Courtesy of Matthew Shomper

3DA: Despite Tangible' extensive expertise in 3D Printed Titanium Medical Devices, we believe each application is unique. What are some of the complex design challenges you've faced over the years? And how did you overcome them?

MS: A lot of designs in orthopedic implants revolve around specific porosity targets. This has been well-studied and usually means the outside of the device must maintain a target pore size and volume fraction. On top of this, there are also surface area targets as well as device stiffness targets. Prior to computational design, engineers had to use parametric tools to design structures to meet all these targets. Many times this led to disconnected areas of the devices that each met their specific design target but did not create an elegant combined whole. Computational design allows for this combination to happen much more seamlessly. Each specific structure can be represented as a field, and those fields combined, added, subtracted, averaged, etc. as the designer sees fit according to the specifications. There have been several instances where the customer was surprised that such a rigorous set of variables could be solved with computational design, since typically some items have to be deprioritized. These solutions would not have been possible several years ago.

3DA: The latest Healthcare edition of 3D ADEPT Mag revealed that designers and engineers are increasingly inspired by nature. (How) does it apply to some of the medical devices designs you create?

MS: I've always been fascinated by nature and the types of structures that are present when we take a close look at them. Chief among my interests are structures that are both flexible but strong. I'll use my favorite animal – the peacock mantis shrimp – as an example. The tensor armor in its clubs is capable of some of the strongest impacts known in nature. When reducing such a structure to its base form, a springlike web of disconnected

Complex design. Courtesy of Matthew Shomper

coils can be computationally modeled. I have used such structures to design flexible but strong medical device concepts – such as spinal cages. What's interesting to note is that not all biomimetic structures are easy to engineer. Or even relevant for product design for that matter. There is as much inefficiency as beauty in nature, so designers must first research the nature of the structures and ensure they are applicable for the problem at hand.

3DA: Simulation is a big part of the DfAM process. With the current advances in software solutions, would you say it is the absolute route to go for any engineering requirements?

MS: I'm a huge believer in simulation as part of a robust feedback loop for computational design. This can be helpful in two ways:

Rapid iterations: Although 3D printing can produce certain products quicker than some traditional manufacturing methods, the best iterations require no monetary spend on products at all. Designs are best assessed using simulation in an "apples to apples" approach. This allows for different structures to be weeded out quickly. The advances in simulation (particle-based physics, homogenization, implicit simulation) also mean that increasingly complex structures can be represented

and solved quicker than ever before.

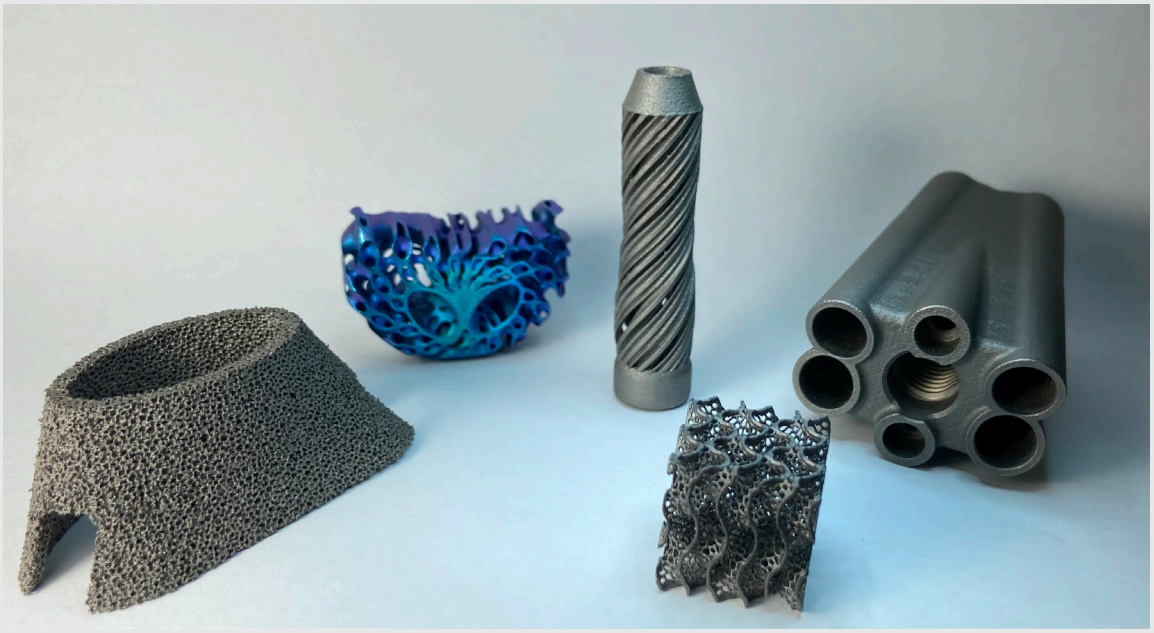
Use of simulation data to augment computational design: This newer advance (brought upon by softwares like nTopology) allows for simulation data (stresses, strains, displacements, etc.) to be drivers in a structure's fundamental design. The data can be processed, interpolated, then applied to grade the structure in response to the particular load it is undergoing. Simulation combined with computational tools and scripting also allows for an iterative loop where custom solutions can be converged.

3DA: We are on a mission to help more professionals understand the DfAM process and how they can better leverage it. What would you say to healthcare professionals in this regard?

MS: The additive manufacturing landscape is ever changing, with rapid advancements being made continually. To understand ***any*** *design for manufacturing principles, the designer must understand which technologies they are designing for. Because additive processes can vary greatly, the first step is to become a fundamental* ***user*** *of the specific tech. Then one must develop a mastery of the tools used (i.e., software). As mentioned previously, these tools can be difficult to pick up, but they augment traditional design for additive manufacturing and tend to make things easier once mastery has been achieved.*

3DA: Any last words to add?

MS: Historically, designers and engineers have taken parallel pathways. While both consider design an important aspect of what they do, designers fundamentally conceptualize and engineers actualize. Designers are often concerned with the aesthetic and usability and engineers with form and function. Computational design for medical products is a fascinating intersection of art and function. Engineers using computational design to create medical products (in particular) may find that form creates function, especially when considering bio-inspired design. The engineer may find themselves doing far more "design" than they ever thought they would. But this is the beauty of computational design – the creation of elegant yet functional objects!

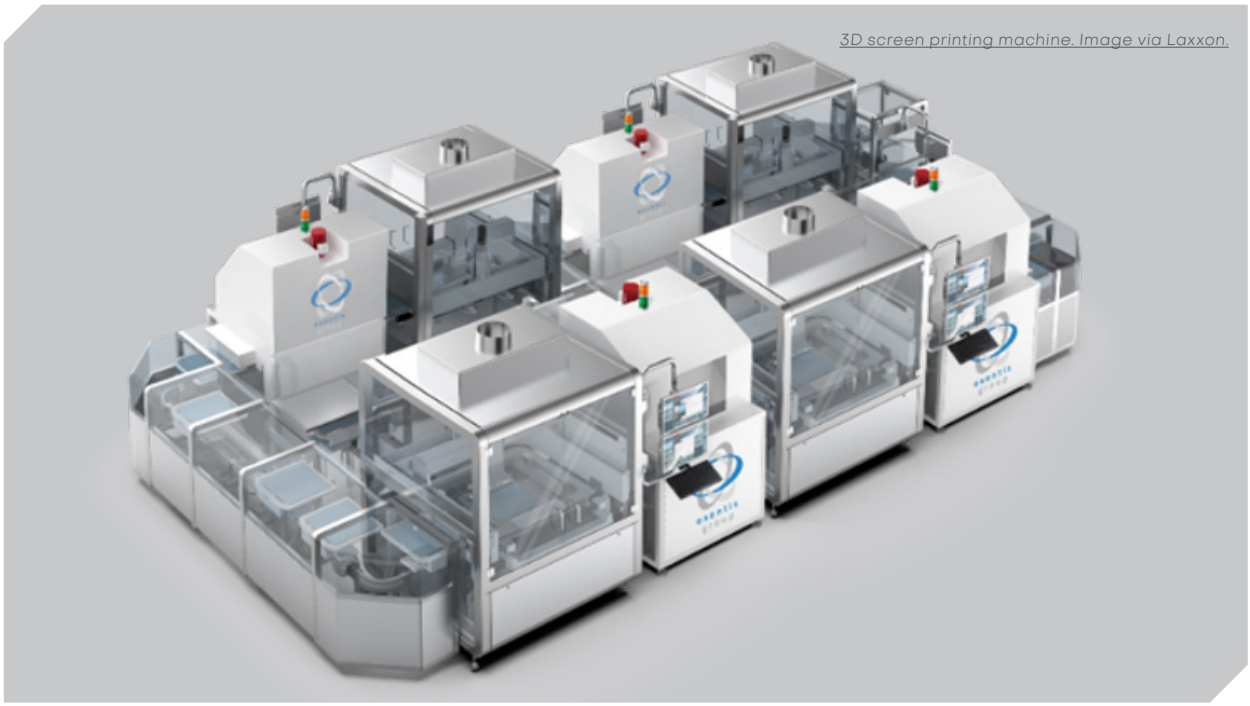


A variety of designs produced by Matthew Shomper

2023 EVENTS

STAY UP-TO-DATE WITH THE LATEST ADDITIVE MANUFACTURING INDUSTRY EVENTS, CONFERENCES, EXHIBITIONS AND SEMINARS.

GERMANY	USA	UK
AM MEDICAL DAYS DATES TBC	7TH ANNUAL MILITARY ADDITIVE MANUFACTURING SUMMIT 1-2 FEBRUARY, 2023	AM FOR AEROSPACE & SPACE 21-23 FEBRUARY, 2023
EBAM CONFERENCE 22-24 MARCH, 2023	ADDITIVE MANUFACTURING STRATEGIES 2023, 7-9 FEBRUARY, 2023	TCT 3SIXTY 7-8 JUNE, 2023
HANNOVER MESSE 17-21 APRIL, 2023	AMUG CONFERENCE MARCH 19 – 23, 2023, HILTON CHICAGO	THE ADVANCED MATERIALS SHOW 28-29 JUNE, 2023
RAPID.TECH 3D 9-11 MAY, 2023	RAPID + TCT 2-4 MAY, 2023	VEHICLE ELECTRIFICATION EXPO 28-29 JUNE, 2023
	SPAIN	**THE NETHERLANDS**
AM FORUM BERLIN 4-5 JULY, 2023	ADDIT3D 6-8 JUNE, 2023	3D DELTA WEEK 27-31 MARCH, 2023
EMO HANNOVER 18-23 SEPTEMBER, 2023	METAL MADRID 15-16 NOVEMBER, 2023	
AMTC, DATES TBC	**PORTUGAL**	**FRANCE**
FORMNEXT 2023 7-10 NOVEMBER 2023	EURO PM2023 1- 4 OCTOBER, 2023	GLOBAL INDUSTRIE 7-10 MARCH, 2023
MEDTECLIVE 2023 23-25 MAY, 2023	AM SUMMIT 2023 COPENHAGEN	PARIS AIR SHOW 19-25 JUNE, 2023
MORE EVENTS WILL BE ADDED LATER !		



3D screen printing machine. Image via Laxxon.

Start-up Area

Understanding SPID®, Laxxon's Screen Printed Innovative Drug Technology and its business model

On March 8th, 2022, **Laxxon (short for Laxxon Medical)**, a pharma-technology company appeared on our radar when **Evonik Venture Capital**, the venture capital business of specialty chemicals company Evonik, announced an investment that expanded their activities on the healthcare 3D printing market. Laxxon was founded in 2017 by **Helmut Kerschbaumer**, **Dr. Achim Schneeberger** and **Klaus Kühne**, who bring to the table over 20 years in the pharmaceutical industry.

The company's activities lie in the development of a 3D screen printing technology that seems to drastically change the manufacture of drugs in the pharmaceutical industry. The truth is, other companies have been, and are exploring the use of 3D printing for the manufacture of drugs but Laxxon's process is intriguing as it requires **paste** as starting material. Furthermore, there are very few companies that develop and commercialize 3D printing technologies for the pharmaceutical industry, but their applications are yet to be commercialized. Laxxon brings a fresh air to this market, as it can already demonstrate how it is effectively improving some treatments in the healthcare industry.

So, what is this 3D screen printing technology?

"We were excited by 3D screen printing once we learned the breadth of its pharmaceutical applications. In particular, the almost unlimited possibilities with influencing the release profiles in a drug delivery system. This is what motivated us to start Laxxon", Klaus Kühne, COO, told 3D ADEPT Media.

Laxxon's 3D screen-printing process is based on SPID® (Screen Printed Innovative Drug) Technology, a hybrid process between traditional 3D printing and screen printing.

"Unlike 3D printing, our technology does not rely on lasers nor a heated nozzle to administer printed products. This is important because when working with active pharmaceutical ingredients (APIs), the application of heat drastically limits the ingredients which can be used. With our technology – similarly to a traditional screen printing process used in the aerospace industry/electronic industry etc. – we apply a thin layer (as fine as 10 microns) of our printing paste onto a printing tray, which then oscillates between the printing station and the drying station until the

batch of tablets is complete. Through varying screens and the composition of the printing pastes, tablets – or any drug delivery system produced with our technology – we can print complex geometric structures layer by layer, allowing for the heterogeneous distribution of APIs and controlled release once administered to a patient. Compared to traditional tablet manufacturing, which consists of pressing a homogeneous API solution, our technology is playing a game of chess while traditional approaches are playing checkers.

What is also unique and advantageous about SPID®-Technology is its ability to handle small batch sizes for pre-clinical/clinical trials in addition to industrial-scale mass production. Currently, our technology can produce up to 560 million units per year.

In terms of materials, our printers can process almost all APIs with no limitations. Our team of chemists at our R&D site in Jena, Germany works to develop our pastes per product in our pipeline", Kühne explains.

The 3D screen-printing technology draws attention in a context where 3D printing technologies are increasingly used in drug delivery systems due to its potential advantages over customizing drugs in individually adjusted doses. On another note, the technology also raises concerns regarding its ability to manufacture more complex oral dosage forms in the setting of mass production with high reproducibility.

"Laxxon's technology works to reduce the daily intake of a tablet, thus allowing for multiple dosages within one pill. This differs from the polypill concept – personalized medication based on a patient's genetics and prescriptions.

Laxxon does deal with multiple APIs in a single tablet, but only APIs which are classically paired, such as Levodopa and Carbidopa, or an active API and a buffer", Kühne adds without emphasizing whether they can achieve mass production with high reproducibility.

To provide a tangible example of how they play their part in the pharmaceutical industry, the company recently explained how their technology presents opportunities to improve ***Levadopa***, a treatment used against Parkinson:

"One severe effect of Parkinson is the 'freezing of gait' effect where patients are not able to move in the morning until they have their standard Levodopa dose. If patients are not able to move, they need a nurse or relative to administer the intake of Levodopa.

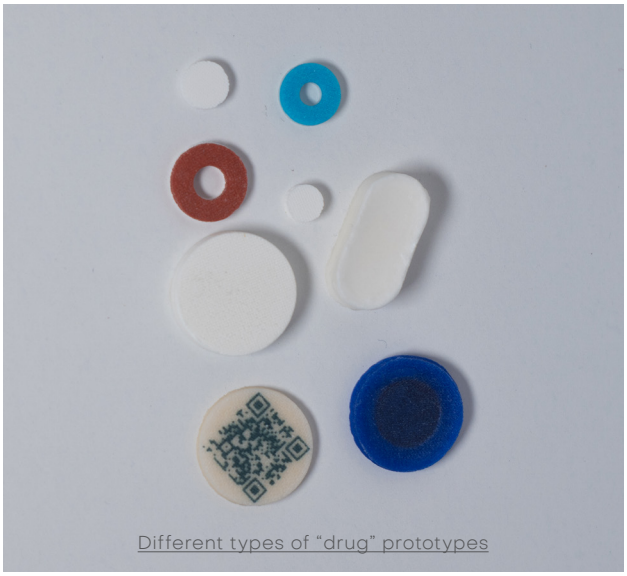
Laxxon has been developing a 'new product generation' of Levodopa with a delayed release program of 8-9 hours. This means the patient can, for example, take our Levodopa tablet in the evening and it will be released automatically after 8 to 9 hours to prevent the freezing of gait effect. This will be a dramatic improvement for the Parkinson's patients suffering from freezing of gait".

The business model behind Laxxon' SPID® and what's next in the pipeline

Laxxon's business model is twofold. The company outlicenses their technology to pharmaceutical companies looking to develop new drugs or optimize their current drugs. They also offer these pharma companies R&D, their technology, and a final product that can then be manufactured. This does not take into account the fact that they have their own in-house product development pipeline for generic drugs.

Lastly, ever since Evonik invested in Laxxon, both teams have been working on multiple product development projects. A **delayed release profile DDS concept** is currently one of their key areas of interest.

"This delayed release profile allows for multiple dosages of medication to exist within one tablet. For some patients and medications, this would lessen the number of pills and the number of times a day required of a patient. For others – such as Levodopa/Carbidopa, the leading Parkinson's Disease medication – our delayed release profile means autonomy for patients who no longer would require a caretaker to administer medication due to the medicine's short half-life", **Kühne** concludes.



Different types of "drug" prototypes

AM Event : RAPID + TCT returns to Chicago for its 32nd edition

Remember when we told you that "being early is the same as being wrong"? Well, this happens to be true for a lot of companies in the Additive Manufacturing industry – be it technology providers or technology users. The truth is, AM is one of these technologies that has been a victim of its own success, thus resulting in several overly early predictions concerning what it could/would do. That was in the mid-2010s.

Fast forward to 2023: the world is facing some of the most pressing challenges of its time: supply chain issues, energy transition, on-site and local manufacturing, etc. The list is non-exhaustive. And today, the advancements in AM and all auxiliary equipment have never been so timely to address them.

The only thing is, once you've decided that you want to follow the AM route or reach another level in your AM journey, there are hundreds of questions that still need to be answered: What technology? Why? For which type of applications? How?

The one question we can legitimately answer right now is where you should start and that is at the upcoming **RAPID + TCT event**, set to take place from May 2nd to 4th in Chicago.

Produced by technology event leaders SME and Rapid News Publications, and touted worldwide as North America's largest and most influential AM event, the 32nd edition of this AM trade show will host over 350 exhibitors from around the world.

But **RAPID + TCT** is more than just its exhibition floor. The trade show is packed with industry keynotes and thought leaders, a variety of conference sessions and networking events, as well as SME Additive Manufacturing Community Awards.

This year, for example, the RAPID + TCT Conference features eight tracks specific to additive manufacturing hand-selected by industry-leading experts – with industry insiders from Divergent Technologies, Lockheed Martin Space to GE Research, to name a few. Topics will range from tips on getting started with large-format AM in consumer goods applications to the use of micro-AM in prototyping and designs in healthcare.

Furthermore, the SME Additive Manufacturing Community Awards, made up of the AM Industry Achievement Award, Aubin AM Case Study Award, AM Start-Up Technology Award and Digital Manufacturing Challenge Award, will all be presented in the SME ZONE. This year especially, three new awards will be granted, for achievements that have been implemented or deployed in a commercial/industrial environment, outstanding use cases of AM adoption and implementation, and technology and an application that solves an existing problem or unique approach.

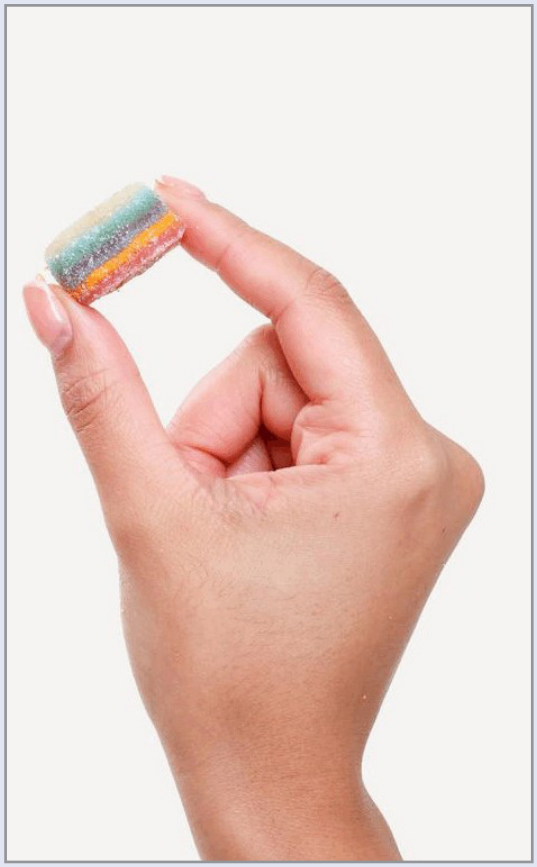
The spring 3D printing/AM trade show season has officially started – and among the events that should make your list, make sure you count **RAPID + TCT** in. For a free Expo Pass courtesy of 3D Adept, use promo code RP23BP when registering.

NEWS ROUND UP

What are the latest 3D printing applications that have recently been developed in the healthcare industry?

In an industry where new products are being announced every week, seeing tangible applications is the sign that AM is not an abstract technology. It's the sign that medical companies are walking the talk. This news roundup shares a few examples of applications recently completed in the healthcare industry.

Neutrogena and Nourished launch personalized, 3D-printed skin supplements



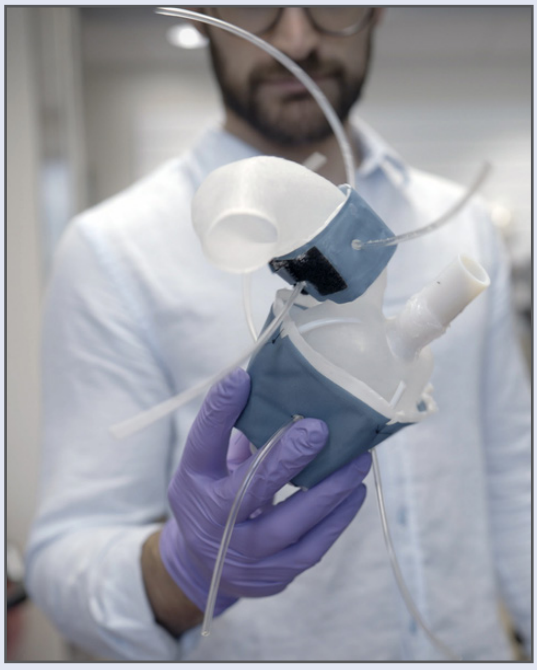
Neutrogena, a leading cosmetics brand, and Nourished, an **avid proponent of supplements created using 3D printing** turn to inner beauty. While the news is not really surprising for Neutrogena that has developed a 3D printed sheet mask, this is a giant step into the Direct-to-consumer market for Nourished that is diversifying its range of products with **Skin Stacks**, a new line of personalized gummy supplements.

The skincare brand is leveraging Neutrogena's existing **Skin360 mobile app** to utilise artificial intelligence and the latest in 3D printing technology to create on-demand dietary supplements carefully crafted with skin-loving ingredients designed to help consumers meet their personal skincare goals.

Once combined with Nourished's proprietary 3D printing, Neutrogena's digital skin assessment uses over 100,000 skin pixels to analyse over 2,000 facial attributes and consumers' skin needs and goals.

This data is then used to identify and recommend a daily vegan, sugar-free, skin-nutrient gummy with seven layers of vitamins and nutrients to achieve their specific skin health goal, such as ageless, clear, hydrate, glow or resilient.

MIT Researchers 3D print custom heart replicas that pump like real ones



MIT engineers are hoping to help doctors tailor treatments to patients' specific heart form and function, with a custom robotic heart. The team has developed a procedure to 3D print a soft and flexible replica of a patient's heart. They can then control the replica's action to mimic that patient's blood-pumping ability.

The procedure involves first converting medical images of a patient's heart into a three-dimensional computer model, which the researchers can then 3D print using a polymer-based ink. The result is a soft, flexible shell in the exact shape of the patient's own heart. The team can also use this approach to print a patient's aorta — the major artery that carries blood out of the heart to the rest of the body.

To mimic the heart's pumping action, the team has fabricated sleeves similar to blood pressure

cuffs that wrap around a printed heart and aorta. The underside of each sleeve resembles precisely patterned bubble wrap. When the sleeve is connected to a pneumatic system, researchers can tune the outflowing air to rhythmically inflate the sleeve's bubbles and contract the heart, mimicking its pumping action.

The researchers can also inflate a **separate sleeve** surrounding a printed aorta to constrict the vessel. This constriction, they say, can be tuned to mimic aortic stenosis — a condition in which the aortic valve narrows, causing the heart to work harder to force blood through the body.

Doctors commonly treat **aortic stenosis** by surgically implanting a synthetic valve designed to widen the aorta's natural valve. In the future, the team says that doctors could potentially use their new procedure to first print a patient's heart and aorta, then implant a variety of valves into the printed model to see which design results in the best function and fit for that particular patient. The heart replicas could also be used by research labs and the medical device industry as realistic platforms for testing therapies for various types of heart disease.

A 3D printed implant helps man regenerate jaw

When **John Manwaring** lost half of his jaw to cancer, he started having trouble breathing, speaking and eating. The man of 58 had his jaw reconstructed using a part of a bone in his leg – the most commonly adopted method. But the bone disintegrated following further cancer treatment.

Many years ago, Australian surgeon **Michael Wagels** had come up with a solution to just this type of predicament: a special 3D implant is printed and a little shaving of the lining of the bone is wrapped around the implant. He decided to duplicate this procedure for Manwaring and it turned out to be a success.

Manwaring's body will regenerate bone tissue inside the scaffolding of the implant, which – over the next two years – will slowly be absorbed into the body. The result is the perfect trifecta of 3D printing, accurate surgical technique and the human body's incredible ability to regenerate.

"We replace something that's lost with something that is not permanent, it's going to disappear, and it's essentially going to turn into the patient's own tissues, which is really exciting to me. Not having to perform a second surgery to harvest bone to be used as an implant reduces the overall risk to the patient. There's a belief in surgery in general – but reconstructive surgery in particular – which is, all implants fail eventually. If the implant disappears, then we hope we can show that the risk profile is much more favourable," Dr Wagels said.

"Because of the way we 3D printed the implant, it has the propensity to enable tissue and vessels to grow into it, not just around it, but through the entire volume of the scaffold," Osteopore's **Dr Jing Lim** said. *"That is really down to the porous structure that we incorporated during the printing process, and the understanding of what sorts of materials would be best suited to facilitate this regeneration. It will take about two years for the implant to harmlessly dissolve in the body"*, he says.

Manwaring is proud to be part of this one of a kind surgery, which he hopes will make a difference for other people facing similar reconstructions.

A custom 3D printed medical-grade cushion for wheelchair users

Wheelchair users sometimes have to contend with health issues such as pressure injuries like pressure ulcers, also known as decubitus ulcers or bedsores. These occur as a result of long-term pressure on localized areas of skin causing chronic inflammation, which is difficult to manage and can be painful and costly to treat.

To address this issue, CSEM – public-private, non-profit Swiss technology innovation center – joined forces with the Swiss Paraplegic Foundation (SPS) to develop a custom 3D-printed medical-grade cushion for wheelchairs.

So, how can a simple object like cushion address the aforementioned issues?

Compared to traditional air-filled orthopedic cushion, this cushion is breathable, washable, and digitally customizable. And, crucially it could help enhance the quality of life of wheelchair users by helping to prevent pressure injuries, the experts from CSEM explain.

This solution is the result of a joint project between CSEM and SPS that aims to explore the potential of **"open-cell" 3D printing.**

"Our printers give us the ability to produce objects with an open-cell structure. The open-cell characteristics mean that the resulting printed structures are, amongst other things, exceptionally good at distributing and thereby relieving pressure, and they are very flexible", **Christoph Joder**, who works at CSEM, explains.

While the first prototype was quite heavy and took hours to 3D print, selective adjustments to the structure can enable to print a custom made product and address these issues.

CSEM originally developed this technique for a project with the Paul Scherrer Institute (PSI) . *"However, we were at a lunch presentation, expounding the benefits of the open-cell structure to an audience of SPS employees, when one of the participants spoke up," recalls Joder. "This particular individual happened to be a research associate with the SPS and also a person who uses a wheelchair. They saw the potential in the 3D print technology immediately. They asked CSEM's team whether it would be possible to use the 3D printer to make open-cell seat cushions."*

Custom-made support cushions and seat cushions play an important role in preventing pressure injuries, and related health issues in individuals who require them. However, until now the manufacturing process has been extremely laborious and expensive, with cushions being made individually by hand. Additionally, cleaning them can be challenging, which makes them less sanitary.

Not only are 3D printed cushions are easy to wash, but the traceability of changes is hugely valuable from a regulatory point of view.

The next step for CSEM is now to look-out for a transfer partner to commercialize and further customize this product.

MAKE SURE YOU SUBSCRIBE TO OUR NEWSLETTER

TO RECEIVE THE LATEST INDUSTRY NEWS AND ADVANCES IN ADDITIVE MANUFACTURING.

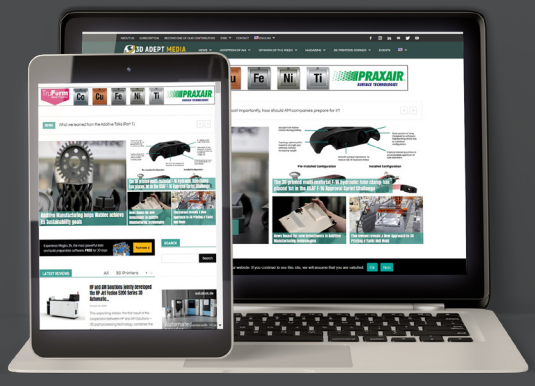
3D Adept is a Communication Company dedicated to the 3D printing industry. Our Media provide the latest trends and analysis in the 3D printing industry in English & French. 3D Adept Media includes an online media and a bimonthly magazine, 3D Adept Mag. All issues of 3D Adept Mag are available to download free of charge. Our mission is to help any company develop its services and activities in the 3D printing industry.

3D ADEPT MAG

All about Additive Manufacturing

Get it !

6 issues per year



WWW.3DADEPT.COM

Contact us !!!

Email: contact@3dadept.com
Tel: +32(0) 486 74 58 87
www.3dadept.com / www.additive-talks.com

Together with Medtec SUMMIT

SHAPE THE **FUTURE** OF MEDICAL TECHNOLOGY PRODUCTION

23–25.5.2023

Nürnberg, Germany 2023

MedtecLIVE

Connecting the medical technology supply chain

with T4M

PARTNER COUNTRY IRELAND

THE TRADE FAIR FOR DOERS AND DECISION-MAKERS

MedtecLIVE with T4M is the key trade fair for medical technology in Europe – and is also much more. This is where your industry becomes a special experience, knowledge comes to life, trends are addressed, and innovations become real.
The exhibition focuses on the complete manufacturing process in medical technology, from the initial idea to production. Together with the MedtecSUMMIT, you will enjoy a comprehensive programme with top speakers and key players in the industry.

SEE FOR YOURSELF!

secure your ticket now
medteclive.com/en/visit

Honorary sponsors

MedTech Pharma · VDMA Working Group Medical Technology · SWISS MEDTECH

NÜRNBERG MESSE