FORWARD AM
Innovating Additive Manufacturing

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Navigating Additive Manufacturing for the Healthcare Industry

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EXECUTIVE SUMMARY

The healthcare industry has become increasingly captivated by Additive Manufacturing (AM), also called 3D printing, because of its freedom of design and the transformative benefits for numerous medical applications, like external wearables, point-of-care (POC) tools, medical devices, and implants.

The inherent character of AM is a perfect fit for the field of healthcare because it enables production that is fast, customizable, and lends itself to intricate and complex designs. With traditional manufacturing, highly personalized devices require expensive special tooling, while a 3D printer only requires a digital file, making it possible to customize a design more easily and economically. This flexibility is essential for creating made-to-measure articles like prostheses, orthoses, and insoles that need to be precisely adapted to the anatomy of the patients and the issues they are facing.

Also, the wide range of AM technologies and materials provides a versatile platform suited for quickly converting prototypes into commercial products. This capability facilitates trends like decentralization at POC, which can alleviate disruptions in supply chains like those evidenced during the COVID-19 pandemic.

Another advantage of AM is the ease of integration into existing manufacturing workflows. The orthopedic footwear use case from the 3D printing service provider PROTIQ and Forward AM is a compelling example of AM fitting seamlessly into an established production process. In this case, the last (a three-dimensional mechanical form shaped like a human foot—typically created out of materials like wood or metal) was reimagined using 3D printing and a high-performing SLS TPU. This digitally designed bespoke last integrates smoothly into the shoemaker's process and offers numerous benefits over conventionally produced lasts, including significantly reduced production times and high fitting accuracy.

With the increasing demand for environmental sustainability and new directives and regulations in review for products like medical devices, the healthcare industry needs to find innovative ways to respond. Luckily sustainability benefits are widespread with AM, helping to create less waste, use less energy, and employ fewer raw materials. For example, 3D printing is an additive process that precisely builds an item layer by layer. Meaning the amount of waste produced during the manufacturing of medical applications is dramatically reduced compared to traditional manufacturing methods.

Unlocking the full potential of AM for healthcare, however, is not without challenges. This innovative technology provides a wealth of freedom, but this freedom comes with the need for expert guidance, specialized tools, and high-performing materials.

At Forward AM, we provide our healthcare industry customers with a one-stop solution, including a broad product portfolio along with deep material expertise, an end-to-end virtual workflow, and industry-leading AM process expertise.

In this whitepaper, we will explore the following critical considerations for AM in Healthcare applications:

- Certifications and Regulatory Considerations for Healthcare Applications
- AM Workflow of Design for the Healthcare Industry
- Material Selection for AM Healthcare Projects

Special Consideration:

Forward AM is the producer of materials that are not associated with a specific printer. Meaning, we do not need to fulfill CGMP requirements nor issue Certifications of Biocompatibility. We do, however, provide Product Information with the following disclaimer: "It remains the responsibility of the device manufacturers and end-users to determine the suitability of all printed parts for their respective application." Additionally, we do not offer medically certified materials, but we have invested in extensive testing and analysis to assess the biocompatibility of a selection of our products.

CERTIFICATIONS AND REGULATORY CONSIDERATIONS FOR HEALTHCARE APPLICATIONS

Even though regulatory agencies certify the safety and efficacy of finished medical devices rather than their component materials, material selection remains a critical consideration for medical manufacturers. It's necessary to establish a stringent process for selecting the raw materials used in their products to consistently meet the applicable requirements and specifications for the regions where they market their devices. Underlining the importance of standardized processes and requirements for medical applications, TÜV Süd recently summarized essential steps how to consistently 3D print safety-compliant medical parts[1].

Partnering with Forward AM can help facilitate device approval because we offer a range of materials compliant with FDA, EU MDR, USP VI, and ISO 10993 specifications.

Regulatory requirements for medical devices and healthcare applications are understandably stringent, and several compliance classifications need to be carefully observed. Adding to the complexity are the differences between these classifications in the US and Europe. Medical devices marketed in the US are subject to the regulatory controls of the Food and Drug Administration (FDA) following the quality system known as current good manufacturing practices (CGMP's).

The European Medical Device Regulation EU/2017/745 (EU MDR) as of 5 April 2017 ensures high quality and safety standards for medical devices produced in or supplied into Europe. It is necessary to obtain or apply for a CE marking verifying that a medical device complies with all applicable EU regulations. In May 2021, the EU MDR came into force and replaced the EU's current Medical Device Directive (93/42/EEC) and Directive on Active Implantable Medical Devices (90/385/EEC). The analyses conducted are compliant with this recent regulatory update.

Medical devices are categorized into classes across both the EU and US regulatory agencies (FDA has classes I, II, or III and MDR has classes I, IIa, IIb, or III), based on the degree of the potential risk to the patient. Class I devices present the lowest risk and are subject to the least regulatory control, and class III devices are subject to the most stringent regulatory supervision.

The table below summarizes the classes of devices for the US and EU regulatory controls with example applications, requirements, and offerings from Forward AM:

US (FDA)[2] AND EU (MDR)[3] RISK CLASSIFICATIONS FOR MEDICAL APPLICATION

	Definition	Example Applications	Requirements	FORWARD AM Offer
Class I **FDA & MDR**	**Low to moderate risk:** • Limited exposure – less than 24 hours of contact with internal human body fluids or tissue.	Manual stethoscopes	**FDA** • Most Class I devices are exempt from review if they are notably low-risk or similar to existing devices. **MDR** • Manufacturer is responsible for ensuring that the product complies with all relevant Essential Requirements of the Directive.	Applications identified as Class I.
Class II **FDA** **Class IIa & IIb** **MDR**	**Moderate to high risk:** • Prolonged exposure – up to 29 days of contact with internal human body fluids or tissue.	Powered wheelchairs	**FDA** • Most **Class II** devices require a 510(k) review to determine whether the new device is "substantially equivalent" to an existing device. **MDR** • **Class IIa -** The manufacturer is responsible for ensuring that the product complies with all relevant Essential Requirements of the Directive. A notified body must back the declaration with a conformity assessment. • **Class IIb –** same as IIa with the additional requirement of an audit by a notified body.	Applications identified as Class II (including IIa and IIb).
Class III **FDA & MDR**	High risk: • Permanent Contact - Greater than 29 days of contact with internal human body fluids or tissue.	Implants	**FDA** • Most Class III devices require Premarket Approval with a thorough classification process and clinical trials. **MDR** • Class III controls are like those for Class IIb devices but also require the manufacturer to submit the design dossier to the notified body for approval under Annex II.	Applications identified as Class III are out of scope at this point in time.

Biocompatibility

Biocompatibility encompasses all aspects of a completed device, including the individual components, assembly processes, and overall design. However, thoughtful material selection makes a significant impact on the overall biocompatibility of the final device.

Biocompatible materials are determined to be safe for contact and interaction with the human body and may be used in applications like 3D printed eyeglass frames, medical devices, or prostheses parts.

It can be helpful to select a material that has undergone a biocompatibility assessment like ISO (International Organization for Standardization) 10993 and USP (United States Pharmacopeia) Class VI. These tests define the ability of a material to perform the required function without causing adverse effects on the human body by confirming that the material is non-toxic and safe for use with living tissue. Specifically, the ISO 10993 set offers a series of standards for evaluating the biocompatibility of medical devices to manage biological risk. For example, ISO 10993-5 test methods assess the in vitro cytotoxicity of medical devices, and ISO 10993-10 test methods assess the potential of a material to produce irritation and skin sensitization[4].

USP Plastic Class VI uses 3 test methods, systemic injection, intracutaneous, and implantation, to assess there are no harmful reactions or long-term bodily effects.

In addition to the specific biological evaluations done to assess the safety of a material, declarations of conformity for food-contact applications can also be good indicators to rule out the suitability of materials for medical applications. Forward AM's Ultrasint® PA11 is an example of a material that has a declarations of conformity for food-contact applications.

The table below shows a range of Forward AM materials and the ISO 10993 and USP Class VI testing requirements for biocompatibility that they have passed.

BIOCOMPATIBILITY ASSESSMENTS FOR MATERIAL SELECTION

		Class I			Class II
	FORWARD AM Materials	**ISO 10993-5** *Cytotoxicity*	**ISO 10993-10** *Skin irritation*	**ISO 10993-10** *Skin sensitization*	**USP Class VI** *No harmful reactions or long-term issues are caused to the body*
Photopolymers	**Ultracur3D® ST45** — Multi-purpose resin with optimum toughness and processing speed	✓	✓	✓	
	Ultracur3D® ST 80 — Multi-purpose resin targeting the lowest cost per part	✓	✓	✓	
	Ultracur3D® RG 35 — Rigid resin with optimum combination of strength, stiffness and temperature resistance	✓	✓	✓	
	Ultracur3D® EL 60 — Flexible resin with quick elastic response and low hardness	✓	✓	✓	

Powders	**Ultrasint® TPU01** — Thermoplastic Polyurethane Powder for HP Jet Fusion Printers	✓	✓* ISO 10993 -10 test under development, already passed OECD Guideline No. 439.	✓	
	Ultrasint® TPU 88A — Thermoplastic Polyurethane Powder for Durable Parts with Excellent Flexibility	✓	✓* ISO 10993 -10 test under development, already passed OECD Guideline No. 439.	✓	
	Ultrasint® PA11 — Bio-Derived Powder for Durable Parts with Exceptionally High Toughness	✓	✓	✓	✓
	Ultrasint® PP nat 01 — Advanced Polypropylene Powder for a Wide Range of Innovative Applications	✓	✓	✓	
	HP 3D High Reusability PP enabled by BASF — Fully functional polypropylene for use on HP JF5200 series printers	✓	✓	✓	
Filaments	**Biocompatibility Evaluations for Filaments**: Ultrafuse® PP, Ultrafuse® PRO1, Ultrafuse® ABS Fusion+, Ultrafuse® PET CF15, Ultrafuse® PLA, and Ultrafuse® TPU64D are currently used in Class 1 applications by our customers. These customers determined the applicability of these materials based on their own internal risk assessments and knowledge of the attributes of the raw materials. Forward AM is currently completing tests for biocompatibility on Ultrafuse® PP, Ultrafuse® PRO1, Ultrafuse® TPS90A, and Ultrafuse® TPU95A.				

The test indicated above are performed on parts manufactured from our materials on our printing equipment with a controlled process and post-treatment of the printed parts. The results obtained by the customer may vary as they depend greatly on the combination of printer, process and cleaning of the printed parts. Of course, we assist our customers in selecting the right material and manufacturing process to obtain compliant items for their intended application.

Sterilization and Cleaning

Forward AM understands that choosing a sterilization method is a critical step in designing a medical device. To reduce the prevalence of HAIs (Healthcare-associated Infections), it is imperative for hospitals to use sterilization techniques like autoclaving, Ethylene oxide (EtO), and E-Beam (a method using high-energy electrons to inactivate microorganisms). Repeated exposure to these methods can cause critical property failure in plastic medical devices.

It is essential to select a material that offers excellent resistance to cleansers and harsh sterilization techniques in these cases. Forward AM has conducted extensive performance testing and research on selected AM materials like photopolymers and even filaments. For example, Ultrafuse® PPSU (polyphenylsulfone) for Fused Filament Fabrication (FFF) is sterilizable, although not approved for skin contact. Specific sterilization test results, including EtO, steam, and E-beam, are available on request for Forward AM materials

ADDITIVE MANUFACTURING WORKFLOW OF DESIGN FOR HEALTHCARE APPLICATIONS

Additive Manufacturing unleashes a spectrum of medical application opportunities. However, various designs and other factors need to be recognized and understood to gain all the expected benefits and optimize time and resources – from the first design idea to the finished product. That's why it's essential to begin with a well-defined AM design workflow. Forward AM has the specialized services and solutions to define and support the entire AM design workflow for healthcare applications. This unit specializes in optimizing part designs, simulating part and process properties, consulting on the best-matching 3D printing process, testing part behavior under load, plus post-processing, including coating.

Ultrasim®, the Virtual Engineering suite by BASF, is a powerful digital workflow that enables a smart search for the optimal geometry to fulfill an application's unique mechanical performance requirements. This makes it possible to create lattice structures that offer varying levels of stiffness across different zones and even simulate absorption and rebound behavior to optimize the comfort and performance of medical applications like insoles.

Find more information here on how Ultrasim®'s Virtual Engineering Offer can accelerate the design process and shorten the concept-to-component time, achieving significant cost savings.

The following example features an overview of the steps involved in creating a tailor-fit brace for an injured limb, in this case, a wrist.

Special Consideration:

The following example is fictitious - Forward AM does not have deep knowledge about the mechanical requirements a medical brace requires. Based on customer information, Forward AM is able to create a mechanical load case and a corresponding simulation.

Design Workflow: Orthotic Wrist Brace

From Scan to Printable File

The first step is to scan the affected limb with an optical scanner to create a digital representation of the wrist that is output as a point cloud (a set of data points in space representing a 3D shape). It is then converted into a 3D model mesh like e.g a stereolithography file (.stl file). Next, the .stl file is imported into a special CAD software. Using the CAD software, the model is optimized, e.g., the model can be cropped to reveal the pertinent section; the model mesh can also be sculpted to address any irregularities of the scanned appendage so that the brace structure will encourage the injured limb to heal properly (Image 1).

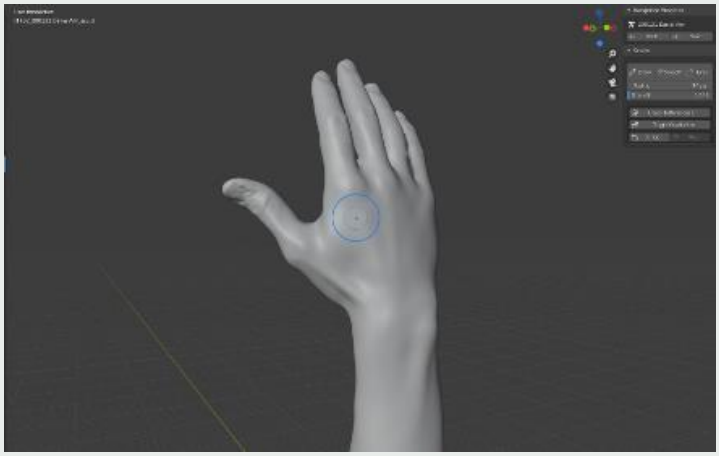


Image 1: Optimized and sculpted mesh model (Source: Forward AM).

Now that the scanned model of the limb is optimized designing the brace structure is the next step. This starts with sketching the brace structure/topology onto the 3D model, taking the following considerations into account (Image 2):

- Stable design
- Fixation of the hand/limb in a defined position
- Optional flexibility in a specified direction if required
- Ease of attachment to the hand/limb
- Optional space for additional strapping belts/lace fastening
- Any other features/restrictions as defined by the doctor

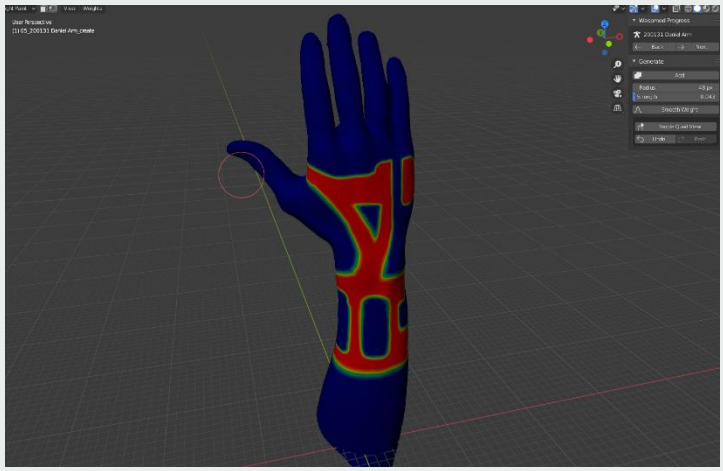


Image 2: Sketching of the brace structure onto the 3D model (Source: Forward AM).

The thickness of the wrist brace structure is adjusted and turned into a solid model (Image 3). The wrist brace is then extracted from the scanned model of the limb so that additional details can be defined and features/attachments for belts/lances can be added. Once the design of the orthotic wrist brace model has been fully optimized, it is exported as a printable .stl file (Image 4).

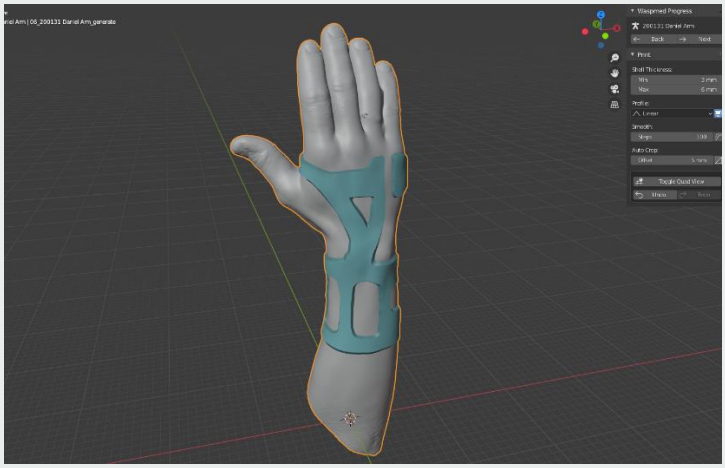


Image 3: Brace structure output (Source: Forward AM).

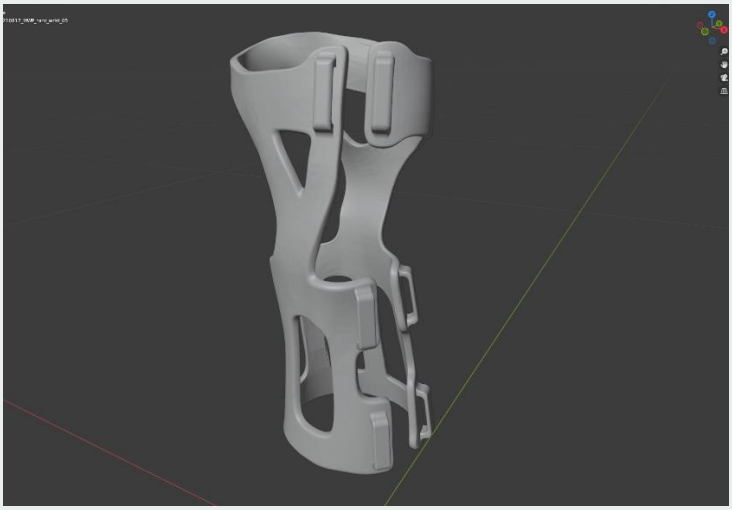


Image 4: Structure with fasteners (Source: Forward AM).

Structural analysis using Finite Element (FE) simulations

Starting off, the .stl file is converted into a three-dimensional FE model that simulates stress distribution and deformation in the overall range of movement (Image 5). This helps to determine how well the design of the brace will support the injured appendage. The simulation applies our proprietary Ultrasim® material model which accounts for all relevant mechanical properties of the printed material to predict correctly the real-life behavior of the brace.

Image 5: Wrist brace .stl imported into FE software (Source: Forward AM).

For this example, a lateral bend and a downward bend simulate two different static load cases (Image 6).

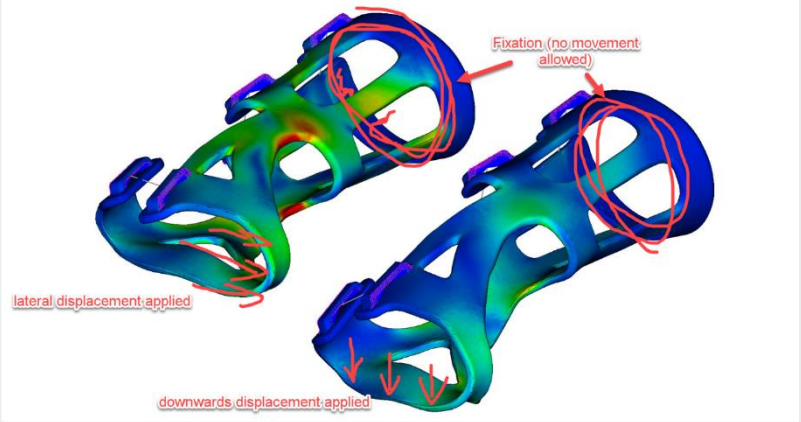


Image 6: Lateral bend and downward bend static load cases (Source: Forward AM).

Please note: *In a real-life scenario, the customer would provide the Simulation Engineering team with the actual mechanical loading and resistance requirements, and a custom simulation would be designed accordingly.*

With the selected simulation cases, it is possible to observe if the wrist brace is deforming as planned, if the deformation is in an allowable range, and if the general shape is maintained during the bending. Stress distribution can also be determined to identify if the stresses are in an acceptable range or if local stress peaks occur, which may lead to failure/breakage. Resulting forces vs. displacement curves indicate the stiffness of the brace - the higher the force at a certain displacement, the stiffer the brace.

In our example, the two force-displacement curves show that the brace is more rigid in lateral bending than downward bending. In some cases, this might be beneficial for an injury where the hand is allowed to bend downwards, but the lateral movement needs to be restrained (Image 7).

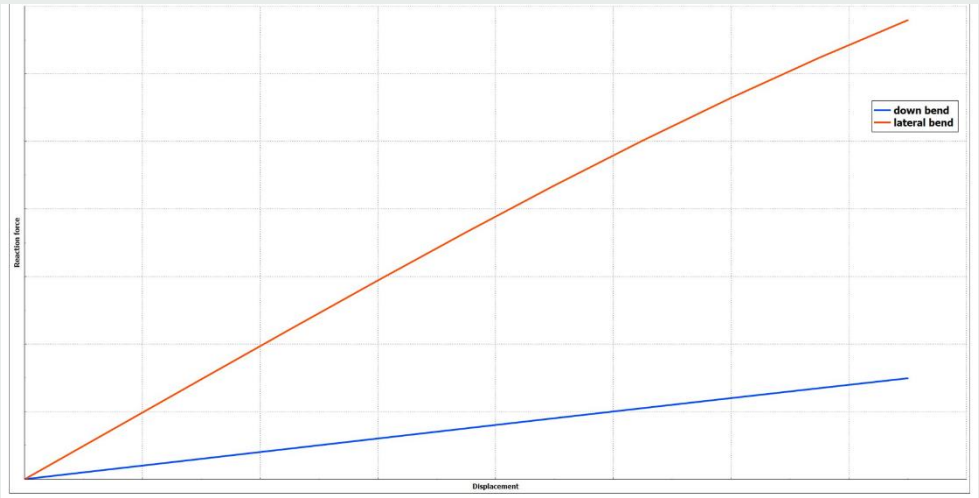


Image 7: Resulting forces vs. displacement curves (Source: Forward AM).

Now that the design of the brace has been analyzed and confirmed using FE, it is time to proceed to the printing of the brace using the .stl file produced in the previous steps.

Here's a look at the printed wrist brace before post-processing (Image 8).

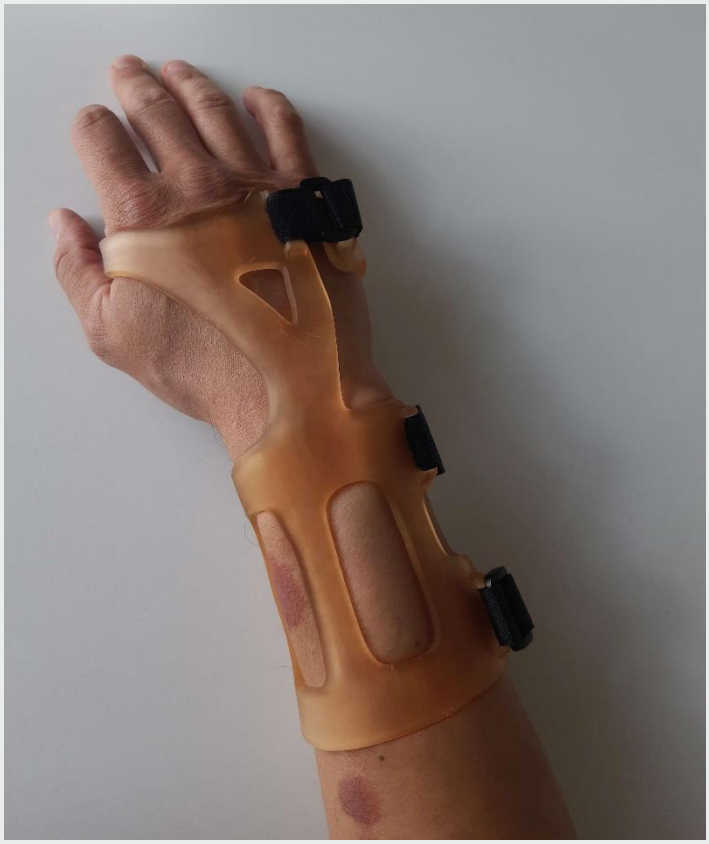


Image 8: Printed brace (Source: Forward AM).

Post-processing for a 3D printed brace can include coating, adding padding, mechanical grinding, and adding components like Velcro straps.

Another application highly relevant for the medical industry is insoles, one of the most commonly used orthopedic products. Placed within the shoe, they are used to correct the foot's orientation – to support, correct, and balance the foot. As feet are highly individual, 3D printing is the ideal manufacturing process – with its great freedom of design and the capability to create lattice structures.

Image 9: Insoles with lattice structures printed with Ultrasint® TPU01, final part hardness 30-70 A depending on used lattice (Source: Forward AM).

Lattices offer tremendous benefits for a variety of applications and industries (read more in our use case here). However, identifying and creating the right lattice structure for an application fulfilling impact requirements meant time- and cost-intensive "design-print-test-redesign" iterations. Ultrasim®, the Virtual Engineering suite by BASF, overcomes this challenge and establishes itself as the industry 3D Virtual Engineering service of choice. A powerful digital optimization workflow, Ultrasim® enables the smart search for the optimal lattice geometry to fulfill each application's unique mechanical performance requirements. By accelerating design and test iterations, Ultrasim® cuts concept-to-component time, unlocking significant cost and material savings.

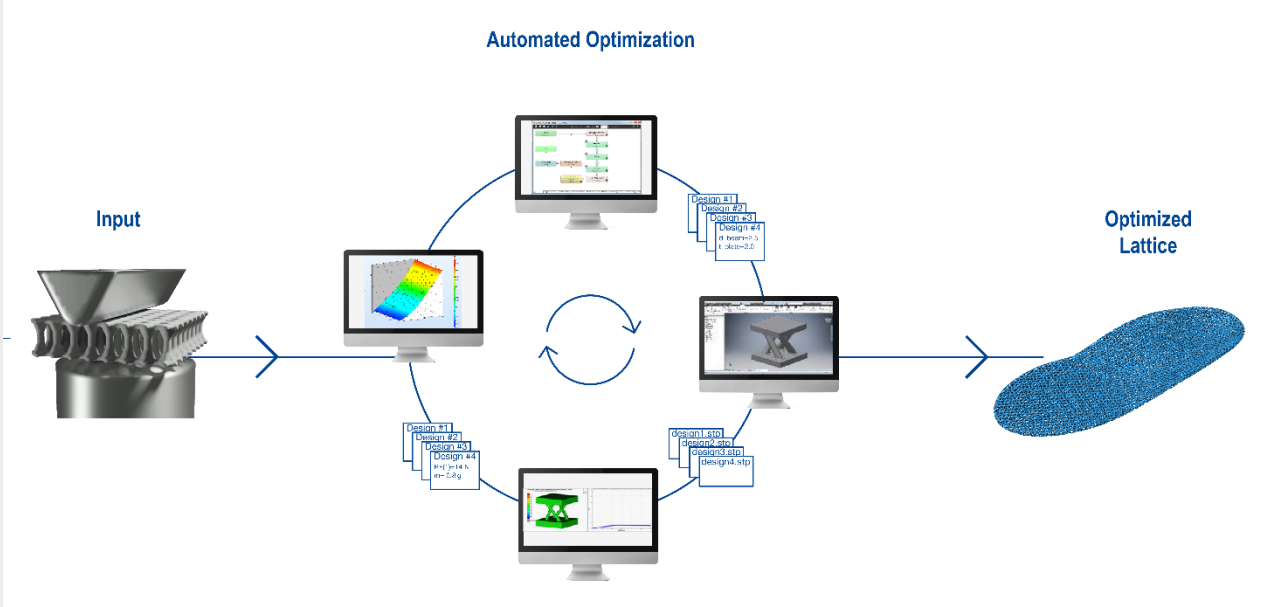


Image 10: How to create optimized lattices via Forward AM's automated optimization process (Source: Forward AM).

Leveraging the flexible and shock-absorbing properties of the polymer powders Ultrasint® TPU01 and 88A, Forward AM developed insoles with varying levels of hardness. The combination of effective material properties with the transformational capabilities of Ultrasim®, individualized lattice structures can be designed to optimally fulfill each insole's purpose. In accordance with ISO 10993-10 and ISO 10993-5, both thermoplastic polyurethane powders successfully passed skin sensitization and cytotoxicity tests. Meaning they can be used in applications that come in contact with the human body without any concerns or reservations.

MATERIAL SELECTION FOR AM HEALTHCARE PROJECTS

All AM projects require close attention to detail, but the needs of medical applications can pose additional, sometimes unique, concerns when it comes to material selection.

The performance of medical applications is inextricably linked to the properties of the material employed. Material properties like strength, impact resistance, biocompatibility, temperature, and chemical resistance help ensuring patient safety.

Forward AM's comprehensive portfolio of polymer powders, photopolymers, and advanced filaments, provides an unbeatable set of materials for 3D printing new-generation medical applications. This broad catalog of products also means that Forward AM takes a technology-agnostic approach when consulting with customers because this gives us the liberty to recommend the product and process best suited for the application.

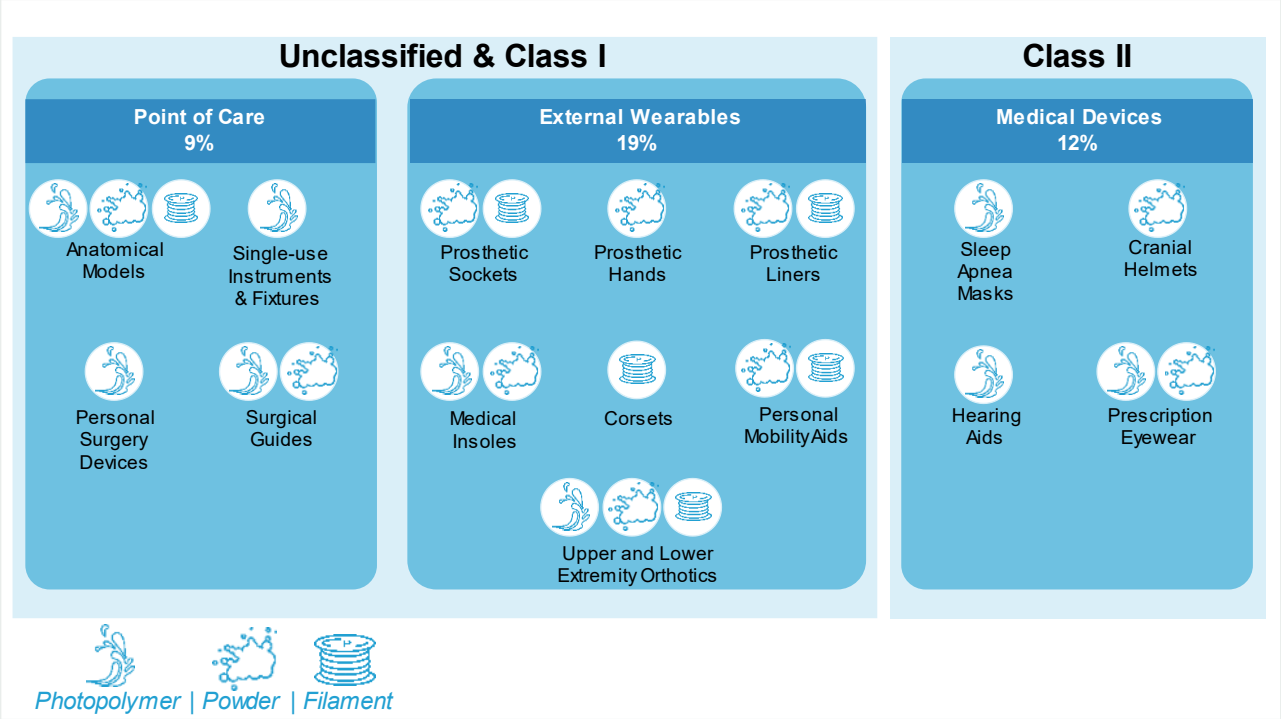
As we've already seen in some of the earlier sections of this paper, determining the most suitable material for medical applications will have consequences throughout the entire product lifecycle—from design through testing and the regulatory approval process as well as production and finally disposal.

Another consideration for material selection is determining the impact of post-processing and options for adding coatings to improve skin contact safety and enhance aesthetics like colors and surface quality.

AM technologies for medical applications

The infographic below gives an overview of recommended AM materials used for key applications in the medical industry, including their percentage of the total market. Please note that the remaining 60% fall under implants in the Class III category.

AM MATERIALS AT SCALE FOR KEY MEDICAL APPLICATIONS



Material Selection for AM Healthcare Projects

The following table breaks down the specific Forward AM materials, their indicated technology, and the benefits of those materials for the medical industry:

	FORWARD AM MATERIAL	MATERIAL BENEFITS
PHOTOPOLYMERS	**Ultracur3D® ST 45** — Multi-purpose resin with optimum toughness and processing speed → Find out more about Ultracur3D® ST 45 in our use case for a dental application here.	• Excellent combination of high strength, toughness, and impact resistance, as well as temperature stability • Suited for applications that benefit from incredible printing speed and biocompatibility
	Ultracur3D® EL 60 — Flexible resin with quick elastic response and low hardness	• Very versatile and easy to print, combining good torsional strength and elongation at break with low water uptake. • High softness (Shore 71A)

	Ultracur3D® ST 80 — Multi-purpose resin targeting the lowest cost per part	• High toughness, impact resistance, and long-term UV stability of 3D printed parts at an economical price
	Ultracur3D® RG 35 — Rigid resin with optimum combination of strength, stiffness and temperature resistance	• Extremely high stiffness and high-temperature resistance with high accuracy and low water shrinkage • Low water uptake
POWDERS	**Ultrasint® PA11** — Bio-Derived Powder for Durable Parts with Exceptionally High Toughness	• Easy processing on any Powder Bed Fusion (PBF) equipment with exceptionally high toughness • Suitable for skin contact and especially safe in medical applications
	Ultrasint® PP nat 01 — Advanced Polypropylene Powder for a Wide Range of Innovative Applications **HP 3D High Reusability PP enabled by BASF —** Fully functional polypropylene for use on HP JF5200 series printers	• High ductility with exceptionally high rigidity provides an economical alternative to PA12 • Excellent chemical resistance • High elongation at break (approx. 30%) • Recycling rate up to 60 % • Refundable through insurance
	Ultrasint® TPU01 — Thermoplastic Polyurethane Powder for HP Jet Fusion 5200 series printers **Ultrasint® TPU 88A** — Thermoplastic Polyurethane Powder for Durable Parts with Excellent Flexibility → Find out more about Ultrafuse® TPU in our use case for a prosthetic socket here.	• High elasticity, rebound, and resistance to fatigue with excellent surface quality and level of detail • High process stability and easy-to-print on any PBF equipment • Easy finishing incl. smoothing, dying, and Ultracur3D Coat F • High recycling rate of 80%
FILAMENTS	**Ultrafuse® PP** — Polypropylene-based Filament → Find out more about the Ultrafuse® filaments in our use case for orthoses here.	• High-performance thermoplastic with low density, high elasticity, and high resistance to fatigue • The mechanical properties make it an ideal material for 3D-printing applications that must endure high stress or strain. The filament has high chemical resistance and a high isolation value
	Ultrafuse® TPU64D — Thermoplastic Polyurethane Flexible Filament	• Extremely flexible yet still tough • Good chemical resistance • Abrasion-resistance
	Ultrafuse® TPU 85A —Thermoplastic Polyurethane Flexible Filament Developed with Elastollan®	• Good flexibility at low temperature, good wear performance, and good damping behavior
	Ultrafuse® PET CF15 — Amorphous Polyethylene Terephthalate Based Filament	• High strength with outstanding printing results and good layer adhesion • A large operating window for printing (temperature vs. speed), enables printing on every 3D-printer

	Ultrafuse® PLA PRO1 — Polylactic acid Blend Based Filament	• Extremely versatile and tough filament that reduces printing time by 30% – 80% (subject to printer and object limitations) with strength that exceeds overall mechanical properties of printed ABS parts

Post-processing to enhance healthcare applications

Depending on the application, the AM technology, and the material, post-processing may be a required step, or it may be utilized to offer a wealth of possibilities to enhance the appeal, durability, and overall quality for demanding 3D printed medical components.

In addition to providing all these benefits for 3D printed medical components, post-processing solutions are safe for skin contact.

Post-processing considerations for healthcare applications include the following:

Flexible Coatings like Ultracur3D® Coat F significantly improve properties like abrasion resistance, UV protection, chemical resistance, dirt repellence, surface haptics, and even breathability as well as giving applications a colorful touch.

Chemical Smoothing using an automated solution like PostPro® by AMT delivers an injection molded surface quality, improved airtightness, and bacteria protection on parts printed using Laser Sintering, HP Multi Jet Fusion, High-Speed Sintering, or Fused Deposition Modelling technology. For more details, refer to our whitepaper with AMT here.

CONCLUSION

Multiple sectors across the healthcare industry are already benefiting from Additive Manufacturing. The technology is offering compelling new ways to provide personalized care and create better-performing medical devices.

For those looking to take advantage of this opportunity, Forward AM is the place to start. With our engineering-grade AM materials, vast experience in Virtual Engineering, and rigorous in-house testing facilities, we'll help ensure that medical applications perform to specification, fit perfectly, feel comfortable, and are more affordable and faster to produce.

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[1] "Validating additive manufacturing processes to meet medical regulations. Ensure safe and reproducible manufacturing results." (PDF). TÜV Süd. tuvsud.com/en/-/media/global/pdf-files/whitepaper-report-e-books/tuvsud-additive-manufacturing-medical.pdf Retrieved 07 October 2021.

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[3] "REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC" *(PDF). medical-device-regulation.eu. Medical Device Regulation. Retrieved 04 October 2021.*

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