Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

By Stratasys

ABSTRACT

The benefits of 3D printing within the medical industry include improved economics and better clinical outcomes for patients. The technology offers opportunities to hasten medical device prototyping and development and improve patient care through customized medical solutions and precise anatomical models for surgical preparation and training. Given the advantages of 3D printing, it's incumbent on

Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

the medical community to consider how this technology can improve the process, products and services it provides. However, each application poses different demands for materials that may include biocompatibility and sterilization. This white paper illustrates 3D printing applications in the medical industry using Stratasys® FDM® and PolyJet™ technology and provides specifications for appropriate material selection.

INTRODUCTION TO 3D PRINTING

3D printing, also known as additive manufacturing, is the creation of 3D objects from a digital model. A 3D printer uses software that "slices" the model into thin layers and uses that information to deposit material, layer by layer, where it's needed to create the object. Because it's an additive process, material use is minimized and complex shapes that would be difficult or impossible to make with conventional manufacturing methods are easily achievable.

Two popular Stratasys 3D Printing methods include FDM and PolyJet. While the concept of layered material deposition is the same for both, each technology is distinct in the materials it employs and the applications it serves best.

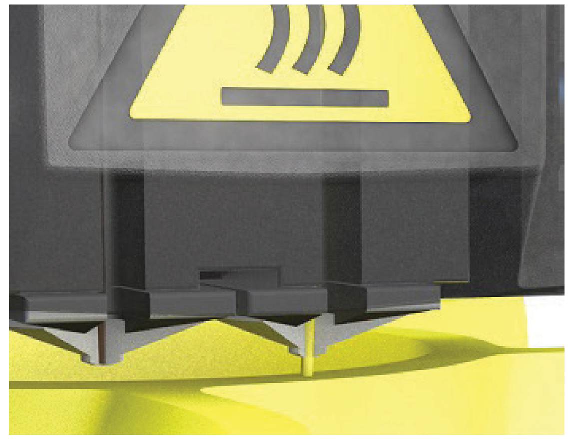

Figure 1 - The FDM extruded filament process.

The FDM Process

The FDM process uses two types of materials: one to make the part and one to support it during the build process. The two materials — thermoplastics fed into the 3D printer as solid filaments — are heated to a semi-liquid state, forced through an extrusion tip, and deposited in fine layers, alternating between part and support material as required by the design.

The print head moves in X-Y coordinates. Once a layer is complete, the modeling base is lowered down the Z axis to allow for the next layer. In this manner, the model and its support material are built from the bottom up.

The support material holds up overhanging structures while the model is being built, allowing for complex designs including nested structures and moving-part assemblies. When the print job is complete, an operator removes the support material, either by hand (breakaway support) or in a liquid solution (soluble support), and the model is ready for use or post-processing. Soluble support removal is automated, freeing up manpower. However, breakaway support removal is typically faster. The appropriate support choice depends on the object's geometry, the model material and the type of 3D printer used.

Figure 2 - A toy tractor model (white) with support material (brown) still attached.

The PolyJet Process

PolyJet technology differs from FDM in that it uses photopolymers instead of a thermoplastic filament. A photopolymer is a liquid plastic that solidifies when exposed to ultraviolet light. PolyJet 3D Printers deposit very fine droplets of photopolymer, also known as base resin, in successive layers of just 16 to 32 microns to build the part. As with FDM, the 3D printer's software determines the proper location to distribute the resin, using the CAD model as the source. As each layer is created, an ultraviolet light passes over the part, curing the material.

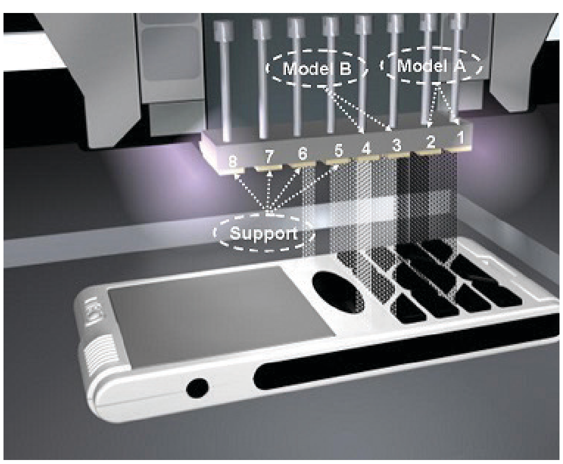

Figure 3 - The PolyJet process involves the deposition of combinations of photopolymers and support material.

PolyJet technology can produce a wide variety of material properties, achievable through carefully prescribed combinations of two or more base resins jetted simultaneously. This allows parts to be made with multiple characteristics, from rigid to flexible and clear to opaque, including multiple colors, all in the same build.

PolyJet technology can print in layers as fine as 16 microns. This means parts have a very smooth surface and can incorporate fine, delicate details. Like FDM, PolyJet uses support material in locations where it's needed to brace overhangs or create space between surfaces. Two types of support material are used: a gel-like substance that is removed using a water jet and a soluble support that's dissolved in an immersion bath.

3D PRINTING APPLICATIONS IN THE MEDICAL COMMUNITY

Additive manufacturing applications within the medical community are diverse. The technology enables quick, cost-effective development of new medical devices as well as customized end-use products that improve the delivery and results of a patient's care. These economic and outcome-based benefits span the medical community from device manufacturers to the patients.

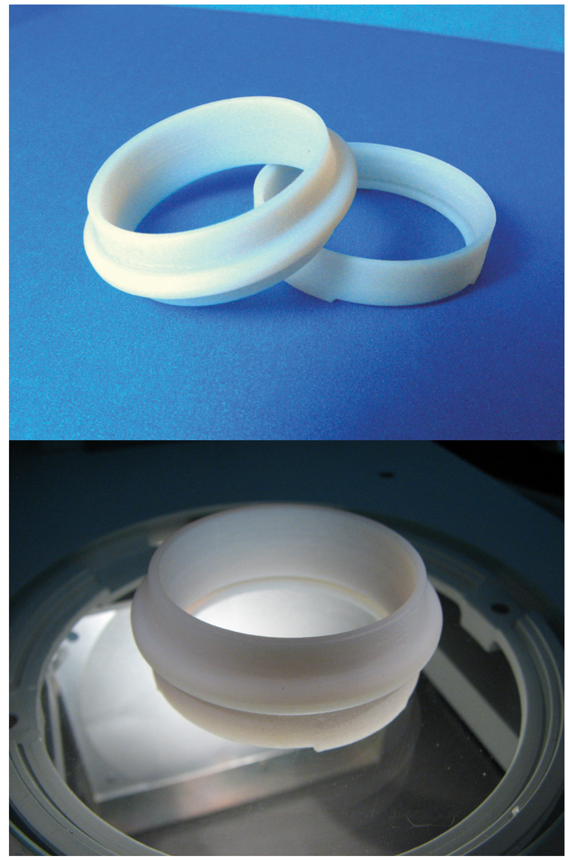

Figure 4 - Parts for a prototype silicone membrane Petri dish made with PolyJet technology.

Rapid Prototyping and Product Development

The ability to quickly create new products and speed the development cycle is a hallmark of the 3D printing process. It achieves this by replacing, where appropriate, time-consuming and costly traditional manufacturing methods. It gives designers and engineers the tools to quickly create and iterate designs, communicate more

Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

Figure 5 - A bio-model of lungs and associated blood vessels.

effectively using realistic prototypes and ultimately reduce time to market. Functional prototypes using high-performance materials allow the designer to test the design in verification and validation protocols, earlier in the design process. Gaining feedback early helps designers identify areas for improvement, resulting in medical devices that can better contribute to positive outcomes.

Biorep, a manufacturer of devices aimed at finding a cure for diabetes, used 3D printing for rapid prototyping and reduced product development time. Biorep traditionally used machine shops or service bureaus to quickly prototype small parts. However, an increase in manufacturing volume created the need to bring this capability in-house.

Part accuracy and surface finish were key design parameters that led Biorep to choose PolyJet technology. Their choice of a mid-sized model gave Biorep the capability for in-house prototyping in an easy-to-use 3D printer with a small footprint, compatible with their office environment. Quickly creating low-cost prototypes helped Biorep engineers gain management support for a novel pinch valve design, and to thoroughly test it. That helped identify problems early and avoid costly delays.

Rapid prototyping also lets designers quickly gather physician feedback on part design. Over the course of hours, the designer can digitally iterate the design based on physician input and then print the revised part for evaluation. The fast feedback loop accelerates design development.

Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

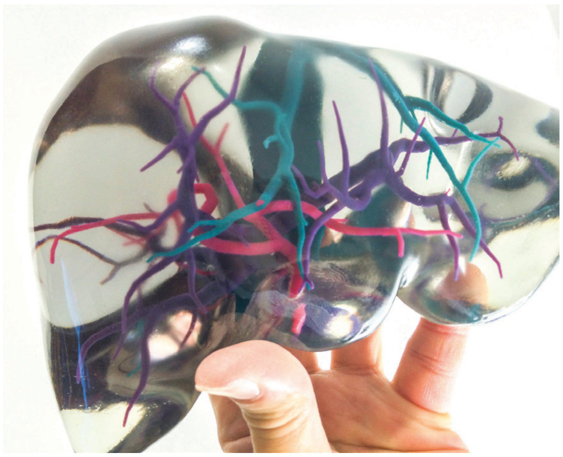

Figure 6 - This model of a human liver allows unobstructed views from any perspective that may not be achievable through scan data alone. Image courtesy of Fasotec.

Anatomical Models for Surgical Planning, Training and Device Testing

Historically, clinical training, education and device testing have relied on the use of animal models, human cadavers, and mannequins for hands-on experience in a clinical simulation. These options have several deficiencies including limited supply, expense of handling and storage, the lack of pathology within the models, inconsistencies with human anatomy, and the inability to accurately represent tissue characteristics of living humans. When it comes to individual patient care, pre-surgical analysis and planning using computed tomography (CT) and magnetic resonance imaging (MRI) scans are still limited to two-dimensional screen images.

The advent of 3D printing — especially the capacity to print in multiple materials, colors and textures — offers new possibilities in the training, device testing and execution of surgical procedures. 3D printed models made of different materials representing bone, organs and soft tissue are produced in a single print procedure. These

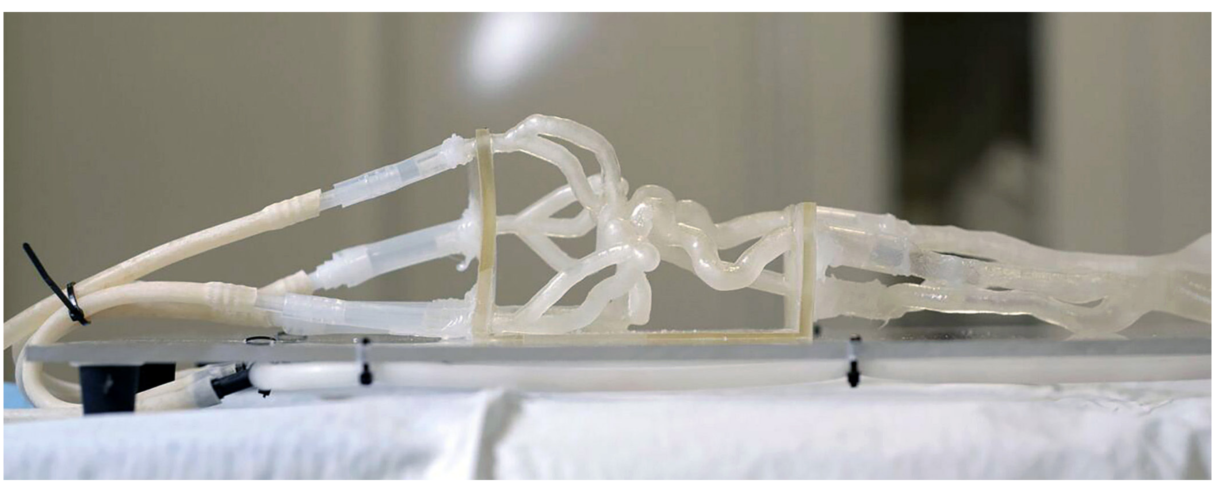

Figure 7 - Researchers at The Jacobs Institute use this vascular model to develop and test the next generation of neurovascular devices.

models can be designed based on actual patient anatomy to capture the complexity and realism of treating the human body.

The ability to model a patient's anatomy and pathology for surgical analysis and practice prior to an operation also offers clinical benefits, like the anticipation of complications and reduction of surgery time. This increases the likelihood of favorable results and faster patient recovery. These models can be stored digitally to allow for production as needed, and can be used in an office without special environmental controls.

Kobe University Graduate School of Medicine in Kobe, Japan, uses PolyJet multi-material technology to produce anatomical models for surgical preparation and medical training. While CT and MRI offer some visualization of a patient's status, they may not reveal conditions that could cause complications. The university's large, color 3D printer lets doctors create full-size models of a patient's organs.

According to Dr. Maki Sugimoto, associated professor at Kobe University, the multi-color and multi-material bio-models help surgeons uncover hidden tissues and blood vessels that may be blocked by larger organs in the 2D scans. Surgeons can examine the models from different perspectives and mark them as needed to plan surgical procedures, drastically reducing operating time. The models provide clearer perspectives and better visualization before the operation and more accurate treatments can be planned as a result.

A desire to use bio-models for training enhancements led the Centre for Biomedical and Technology Integration (CBMTI) at the University of Malaya to use 3D printing. CBMTI chose PolyJet technology because of its ability to print in multiple materials along with its speed and ease of use. This allows CBMTI technicians to make more and better models, scaling them down to save material when full size isn't necessary.

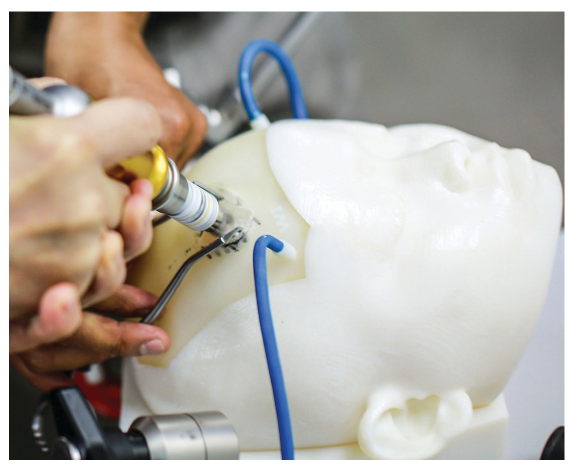

Figure 8 - This multi-material model allows physicians to train on neurosurgery procedures using the same devices and techniques used in live patient cases. Courtesy of the Centre for Biomedical Technology and Integration.

Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

As an example, CBMTI 3D printed a section of human skull that replicated bone and various tissues encountered during a brain tumor operation. The model is used to help teach training neurosurgeons how to perform the operation, which includes cutting the skin, opening the bone, cutting the brain lining and removing the tumor. This kind of 3D printing technology lets CBMTI provide researchers and medical instructors training models with accuracy, realism and tactile feedback consistent with human physiology.

The realism in texture and form of 3D printed anatomical models also make them effective tools for testing new medical devices. Researchers used a 3D printed model to validate the performance of the Covidien Solitaire Flow Restoration stent retriever. Using the bio-model, researchers compared the performance of conventional catheters and the Covidien device, ultimately demonstrating a higher success rate of neurovascular recanalization with the new device. The model's realism also let researchers note the specific anatomical location of blood clot loss during the tests.[1]

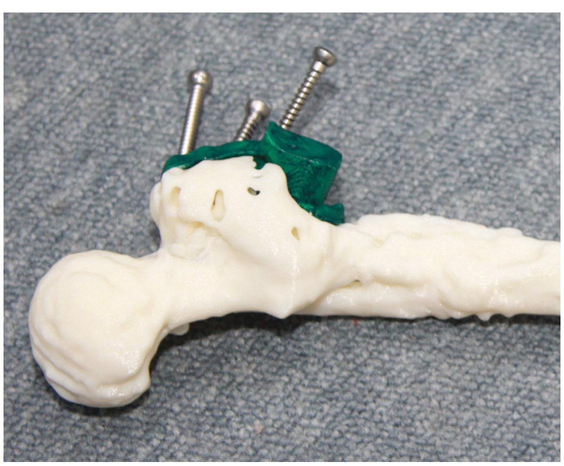

Figure 9 - A 3D printed bone model using a customized guide for pre-surgical planning.

Patient-Specific Surgical Guides

Scanning technology has made it possible for doctors to accurately visualize a patient's anatomy, helping them plan for surgical procedures. But when it comes to the precision needed during joint replacement or to repair bone deformities, this technology has limitations. Doctors must still rely on scan images and experience, as well as generic surgical guides, to accurately place hardware for bone repair.

The use of 3D printed surgical guides refines the traditional means of orthopedic care by allowing doctors to shape them to the patient's unique anatomy, accurately locating drills or other instruments used during surgery. This makes the placement of restorative treatments more precise, resulting in better post-operative results.

The Prince of Wales Hospital in Hong Kong uses FDM technology to make surgical guides and tools

[1] Original research – "Stent retriever thrombectomy with the Cover accessory device versus proximal protection with a balloon guide catheter: in vitro stroke model comparison" – Maxim Mokin, Swetadri Vasan Setlur Nageh, Ciprian N Ionita, J Mocco, Adnan H Siddiqui

along with bone models. The 3D printed models are used to plan and test the best locations for stabilizing screws or plates that conform to the patient's bone surface. The outcome of this preparation is a reduced risk of post-surgical complications like bleeding and infection.

According to professor Kwok-sui Leung of the Chinese University of Hong Kong, 3D printing allows in-depth assessment and pre-surgical rehearsal, resulting in implants that are more accurately fitted to the curvature of the patient's bone. On average, operation time was reduced by an hour when incorporating 3D printed parts in the pre-surgical process.

FDM technology also benefits this application with materials such as PC-ISO™, a biocompatible thermoplastic in its raw state that can be sterilized using ethylene oxide (EtO) or gamma radiation. Surgical guides, derived from patient scans to precisely match their anatomy and made from PC-ISO, are compatible with human tissue for short-term contact. This allows them to be placed against the patient's anatomy for a more precise cut or drill hole.

End-Use Parts for Clinical Trials

Reducing the time it takes to bring a medical device concept to the clinical trial stage has positive ramifications throughout the medical supply chain. Producers reduce cost and get more products to market faster, and patients benefit from new devices sooner. One barrier to success is the time and cost it takes to manufacture the product and revise it sufficiently to arrive at the right design. Lead times to create the tooling, whether in-house or outsourced, can be lengthy and expensive.

Additive manufacturing can drastically shortening the development process. Concepts can be produced overnight in the 3D printer, validated or quickly revised as needed, and be ready for clinical use without the need to implement the full design

Figure 10 - Ivivi Health Sciences 3D prints devices used in clinical trials.

and manufacturing process. Manufacturers can use these additively manufactured parts to support clinical trials or early commercialization while the final design is still in flux.

Ivivi Health Sciences in San Francisco, California, is a medical technology company that develops non-invasive, electrotherapy devices to accelerate patient recovery. The growth of opportunities for this technology meant that Ivivi needed a consistent production of devices in small quantities for clinical trials. However, the planning and product development necessary to prepare for them typically took months. Ivivi also outsourced their manufacture, and design adjustments were common prior to finalizing the design.

In a search to streamline the development cycle, Ivivi turned to 3D printing. The company chose a PolyJet system to satisfy the need for parts with a very smooth surface finish and sufficient durability. Using this technology, Ivivi was able to quickly create devices and deliver them to the clinical trial participants.

The adoption of 3D printing provided Ivivi with a return on investment in less than one year. It also enhanced their capacity to develop new prototypes and strengthen relationships with distribution partners, based on the ability to quickly modify devices and meet business and patient needs.

Personalized Prosthetics, Bionics and Orthotics

Additive manufacturing is well suited for individualized health care. It enables the creation of prosthetic and orthotic devices tailored to a patient's specific anatomy and needs, making those solutions more effective. In addition to the technical capabilities, the economics of 3D printing are ideal for low-volume and custom production, meaning cost often drops even while effectiveness increases.

Albert Manero is a Ph.D. student in mechanical engineering at the University of Central Florida

Figure 11 – Alex tries out his 3D printed bionic arm made with FDM technology.

Figure 12 - Emma's smaller, customized WREX, developed using FDM technology.

and Executive Director of Limbitless Solutions, an organization with the goal of developing bionic replacement limbs for a much lower cost than was previously typical.

One beneficiary of the team's efforts was 6-year-old Alex Pring, a boy born without a lower right arm. Limbitless Solutions designed and produced a low-cost bionic lower arm and hand for Alex. It uses electromyography sensors and a microcontroller in combination with Alex's bicep muscle to operate the hand.

His new arm was made with FDM technology, using ABSplus material to keep it strong but lightweight. The total cost was $350, compared with $40,000 for conventional medical solutions. As Alex grows, new arms can be made without the financial burden normally associated with this type of ongoing medical care.

FDM technology also played a role in helping Emma Lavelle begin living the life of a normal youngster. Emma was born with arthrogryposis multiplex congenital (AMC), a joint condition that limits her ability to move her arms.

Experts at the Nemours/Alfred I. DuPont Hospital for Children developed the Wilmington Robotic Exoskeleton (WREX), a device made from metal and resistance bands, that lets people with AMC move and control their limbs. WREX devices attached to a wheelchair had been made for children as young as 6, but Emma was only 2, with the capability to walk.

The solution developed by the Nemours team was a scaled-down, lighter version of WREX, made on an FDM 3D printer because the parts were too small and detailed to be produced on a CNC machine. The parts were customized for Emma's size and

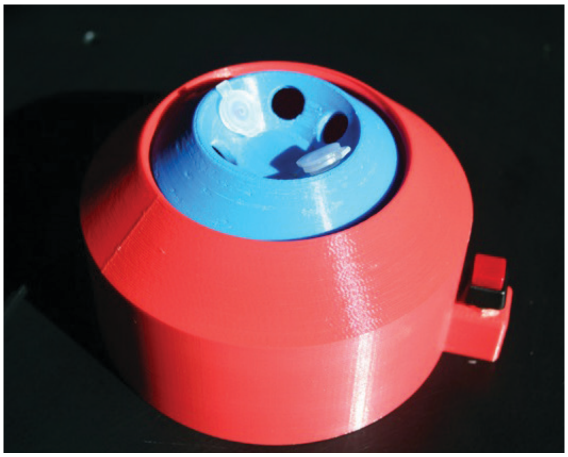

Figure 13 - A small, 3D printed centrifuge created for less than 10% of retail cost.

the ABS plastic was light yet durable enough for everyday use. Emma's customized WREX now lets her do things she couldn't do before and like Alex's bionic arm, a new WREX can easily be made to accommodate Emma as she grows.

Laboratory and Manufacturing Tools

A more conventional but equally significant application of 3D printing involves the creation of tooling, fixtures and other equipment that lets labs and medical device manufacturers work faster and reduce costs. Tools specific to a lab or process can be created quickly and revised as needed for little cost, simply by changing the tool's CAD file and reprinting it. They can also be stored in a digital file, eliminating the need for physical storage.

Hospitals and clinics can benefit by making custom surgical trays tailored to specific needs. And by using FDM materials such as ULTEM® 1010 resin, these trays can be sterilized using a steam autoclave process.

For Joseph DeRisi, head of the DeRisi Lab of the University of California San Francisco, a 3D printer is an indispensable part of the lab's workflow. The lab makes its own custom pipet racks, gel combs and other small parts. DeRisi Lab goes as far as making parts that are available from medical suppliers, noting the cost and speed advantages that 3D printing offers over those suppliers.

For example, rather than pay a supply house $350, the lab 3D printed its own small centrifuge using a $5 off-the-shelf motor. The total cost was $25 – less than 10 percent of the supplier's price. The ability to customize and specialize objects and tools in daily work lets DeRisi Lab work better and faster, for less cost.

Conclusion

Additive manufacturing offers new possibilities for the medical community with benefits for both medical device developers and health care providers. It does this by circumventing traditional manufacturing methods, replacing them with faster, less costly 3D printing technology, suitable for customization. It enables the creation of complex shapes, in multiple colors and textures, that can't be practically molded or machined.

Medical applications of 3D printing range from the prototyping and development of new medical devices to the creation of bio-models for surgical planning. The individualized nature of health care is a perfect fit for the customization that 3D printing offers, and is already benefiting individuals through personalized orthotics and bionics.

Stratasys FDM and PolyJet technologies give medical device developers the tools to reduce product development costs and time to market. They give physicians the capability to model a patient's anatomy using realistic materials for better planning that shortens surgical procedures.

This is not technology to come; it has already been adopted by producers and providers in the medical industry as an essential means of improving the economics and outcomes of health care.

Material Data

The following tables provide key specifications of Stratasys FDM and PolyJet materials, including biocompatibility, sterilizability and 3D printer compatibility. Biocompatibility and sterilization specifications are for raw materials. Part design, manufacturing and post-processing can affect material characteristics, so these data may not hold for printed parts. They are presented here to provide information on which specific Stratasys materials have been tested for these capabilities. Note that the U.S. Food and Drug Administration (FDA) approves the biocompatibility of the finished medical device, not the specific materials used in the manufacture of those devices[2].

It is the user's responsibility to determine the appropriate criteria and means necessary to determine biocompatibility and/or sterilization for parts and assemblies made with these materials. Additional information and complete material specification sheets can be found at Stratasys.com.

[2] FDA Draft Guidance for Industry and FDA Staff – Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"

Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

FDM MATERIALS

ULTEM 1010

ULTEM 1010 is a high-performance FDM thermoplastic and has the highest tensile strength and chemical and heat resistance of any FDM thermoplastic. It has NSF 51 food contact certification and is biocompatible per ISO 10993 and USP Class VI certification. It can be sterilized using autoclave and other methods, making it appropriate for medical tools such as surgical guides. It has the lowest coefficient of thermal expansion of any FDM material, making it suitable for many industrial tooling applications and other parts that require the unique combination of strength and thermal stability. ULTEM 1010 is used on Fortus Production Systems.

Material

PROPERTIES	ULTEM 1010	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Stratasys tests: • Acute systemic injection test – USP Class VI • Intracutaneous irritation test – USP Class VI • USP Intramuscular implantation test – USP Class VII Manufacturer tests: • Systemic toxicity – ISO 10993 • Intracutaneous toxicity - ISO 10993 • Implantation test - ISO 10993 • Cytotoxicity - ISO 10993 • Hemolysis test - ISO 10993 • Pyrogenicity test - ISO 10993 • Sensitization test - ISO 10993 • Physico-chemical test - ISO 10993	
Sterilization Methods	Autoclave (steam), flash autoclave, EtO, hydrogen peroxide gas plasma, gamma radiation	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	11,700 psi	81 MPa
Tensile Modulus (XZ Axis)	402,000 psi	2,770 MPa
HDT @ 264 psi (1.82 MPa)	415 °F	213 °C
Elongation at Break (XZ Axis)	3.3%	
Hardness (Rockwell)	109	
Printer Applicability	Fortus 400mc/450mc/900mc	
Colors	Tan	
Support Material	Breakaway	

ABS-M30i™

ABS-M30i blends strength with biocompatibility and sterilization capability. It complies with ISO 10993 and USP Class VI for biocompatible testing and can be sterilized using gamma radiation, hydrogen peroxide gas plasma or EtO methods. Parts made with ABS-M30i have excellent mechanical properties and are well-suited for conceptual modeling, functional prototyping, manufacturing tools, and end-user parts.

Material		
PROPERTIES	ABS-M30i	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Stratasys tests: • Cytotoxicity – ISO 10993-5 • Irritation and delayed-type hypersensitivity – ISO 10993-10 • Systemic toxicity – ISO 10993-11	
Sterilization Methods	EtO, hydrogen peroxide gas plasma, gamma radiation	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	4,650 psi	32 MPa
Tensile Modulus (XZ Axis)	320,000 psi	2,230 MPa
HDT @ 264 psi (1.82 MPa)	180 °F	82 °C
Elongation at Break (XZ Axis)	7%	
Hardness (Rockwell)	109.5	
Printer Applicability	Fortus 380mc/400mc/450mc/900mc	
Colors	Ivory	
Support Material	Soluble	

Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

PC-ISO

PC-ISO is an FDM polycarbonate with biocompatibility per ISO 10993 and USP Class VI. The material can be sterilized using EtO and gamma radiation. PC-ISO has high tensile and flexural strength and a high heat deflection temperature. In these categories its values are 33 percent to 59 percent higher than those of ABS-M30i. Applications include medical devices and food and drug packaging.

Material

PROPERTIES	PC-ISO	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Stratasys tests: • Cytotoxicity – ISO 10993-5 • Irritation and delayed-type hypersensitivity – ISO 10993-10 • Systemic toxicity – ISO 10993-11	
Sterilization Methods	EtO, gamma radiation	
	ENGLISH	METRIC
Tensile Strength	8,300 psi	57 MPa
Tensile Modulus	289,800 psi	2,000 MPa
HDT @ 264 psi (1.82 MPa)	260 °F	127 °C
Elongation at Break (XZ Axis)	4%	
Hardness (Rockwell)	---------------	
Printer Applicability	Fortus 380mc/400mc/450mc/900mc	
Colors	White, Translucent Natural	
Support Material	Breakaway	

ABS*plus*™

ABS*plus* is an affordable, all-purpose FDM thermoplastic suitable for creating models and parts with durability and long-term stability. These characteristics make it an appropriate material when multiple design iterations and/or prototypes are anticipated. This material is compatible with both soluble support material and breakaway support (BST 1200es only).

Material		
PROPERTIES	ABS*plus*	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	Not tested – verification required	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	4700 psi	33 MPa
Tensile Modulus (XZ Axis)	320,000 psi	2,200 MPa
HDT @ 264 psi (1.82 MPa)	180 °F	82 °C
Elongation at Break (XZ Axis)	6%	
Hardness (Rockwell)	109.5	
Printer Applicability	uPrint SE, uPrint SE Plus, Dimension Elite, Dimension SST 1200es, Dimension BST 1200es, Fortus 250mc	
Colors	Ivory, White, Black, Dark Gray, Red, Blue, Olive Green, Nectarine, Fluorescent Yellow	
Support Material	Breakaway and soluble	

ABSi™

ABSi is a production-grade thermoplastic characterized by its translucency and superior strength compared with standard ABS plastic. It is suitable for applications requiring visibility through the material, such as fluid containers, syringes and similar uses. ABSi is compatible with soluble support material.

Material		
PROPERTIES	ABSi	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	EtO, hydrogen peroxide gas plasma, gamma radiation	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	5,400 psi	37 MPa
Tensile Modulus (XZ Axis)	277,700 psi	1,920 MPa
HDT @ 264 psi (1.82 MPa)	163 °F	73 °C
Elongation at Break (XZ Axis)	4.4%	
Hardness (Rockwell)	108	
Printer Applicability	Fortus 400mc/900mc	
Colors	Translucent Natural, Translucent Amber, Translucent Red	
Support Material	Soluble	

ABS-M30™

ABS-M30 is specifically engineered for use with Fortus 3D Production Systems. It is 25% to 75% stronger, with greater tensile, impact and flexural strength than standard ABS plastic. ABS-M30 is available with the Xtend 500™ Fortus Plus material option, which provides over 400 hours of unattended build time with compatible systems.

Material		
PROPERTIES	ABS-M30	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Not tested - verification required	
Sterilization Methods	EtO, hydrogen peroxide gas plasma, gamma radiation	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	4,650 psi	32 MPa
Tensile Modulus (XZ Axis)	320,000 psi	2,230 MPa
HDT @ 264 psi (1.82 MPa)	163 °F	82 °C
Elongation at Break (XZ Axis)	7%	
Hardness (Rockwell)	109.5	
Printer Applicability	Fortus 360mc/380mc/400mc/450mc/900mc	
Colors	Ivory, White, Black, Dark Gray, Red, Blue	
Support Material	Soluble	

Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

ABS-ESD7™

ABS-ESD7 is an FDM thermoplastic with electrostatic dissipative qualities, typically used where protection from static discharge is required. It is also well suited for dusty applications and in the presence of powders where airborne particulate might be attracted to plastic components due to static electricity. ABS-ESD7 avoids attracting atomized liquid, so it's beneficial for medicine inhalers that must deliver the entire drug dose to the patient and not leave mist adhering to the inhaler's internal surfaces.

Material		
PROPERTIES	ABS-ESD7	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	EtO, hydrogen peroxide gas plasma, gamma radiation	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	5,200 psi	36 MPa
Tensile Modulus (XZ Axis)	350,000 psi	2,400 MPa
HDT @ 264 psi (1.82 MPa)	180 °F	82 °C
Elongation at Break (XZ Axis)	3%	
Hardness (Rockwell)	109.5	
Printer Applicability	Fortus 380mc/400mc/450mc/900mc	
Colors	Black	
Support Material	Soluble	

Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

ASA

ASA is an all-purpose FDM thermoplastic with UV stability to resist fading, usable on Fortus 3D Printers. It is suitable in applications that require color-fastness in the presence of sunlight or other ultra-violet lighting conditions.

Material		
PROPERTIES	ASA	
Physical Characteristics	UV-stable, production-grade thermoplastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	Not tested – verification required	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	4,750 psi	33 MPa
Tensile Modulus (XZ Axis)	290,000 psi	2,010 MPa
HDT @ 264 psi (1.82 MPa)	196 °F	91 °C
Elongation at Break (XZ Axis)	9%	
Hardness (Rockwell)	82	
Printer Applicability	Fortus 360mc/380mc/400mc/450mc/900mc	
Colors	Black, Dark Blue, Dark Gray, Green, Light Gray, Yellow, White, Orange, Ivory, Red	
Support Material	Soluble	

Advancing Health Care With 3D Printing

APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

FDM Nylon 12

This material is the same nylon 12 widely used in manufacturing, adapted for use with FDM 3D Printers. It is a tough material with the highest impact strength of all FDM thermoplastics. It also has superior fatigue resistance relative to other FDM materials making it highly appropriate for repetitive snap fits and closures. Nylon 12 parts exhibit 100% to 300% better elongation at break and superior fatigue resistance over any other additive manufacturing technology.

Material

PROPERTIES	Nylon 12*	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	Not tested – verification required	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	6,650 psi	46 MPa
Tensile Modulus (XZ Axis)	186,000 psi	1,282 MPa
HDT @ 264 psi (1.82 MPa)	180 °F (annealed)**	82 °C (annealed)**
Elongation at Break (XZ Axis)	30%	
Hardness (Rockwell)	-----------	
Printer Applicability	Fortus 360mc/380mc/400mc/450mc/900mc	
Colors	Black	
Support Material	Soluble	

* Specifications are for conditioned material – 20 °C and 50% RH for 72 hours
** Annealed 2 hours at 140 °C

PC (Polycarbonate)

Polycarbonate offers excellent strength, durability and heat-resistant characteristics with mechanical properties superior to ABS plastic. PC has high tensile and flexural strength, sufficient for demanding applications such as tooling and fixtures as well as patterns for metal and composite forming.

Material		
PROPERTIES	PC (Polycarbonate)	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	EtO, hydrogen peroxide gas plasma, gamma radiation	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	8,300 psi	57 MPa
Tensile Modulus (XZ Axis)	282,000 psi	1,944 MPa
HDT @ 264 psi (1.82 MPa)	261 °F	127 °C
Elongation at Break (XZ Axis)	4.8%	
Hardness (Rockwell)	115	
Printer Applicability	Fortus 360mc/380mc/400mc/450mc/900mc	
Colors	White	
Support Material	Breakaway and soluble	

PC-ABS

PC-ABS combines the strength and heat resistance of PC (polycarbonate) with the flexibility of ABS plastic. It is used with Fortus 3D Production Systems. It has one of the highest impact strength ratings of all the FDM materials along with the good flexural strength, feature definition, and surface appeal of ABS.

Material		
PROPERTIES	PC-ABS	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	EtO, hydrogen peroxide gas plasma, gamma radiation	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	5,000 psi	34 MPa
Tensile Modulus (XZ Axis)	260,000 psi	1,810 MPa
HDT @ 264 psi (1.82 MPa)	205 °F	96 °C
Elongation at Break (XZ Axis)	5%	
Hardness (Rockwell)	110	
Printer Applicability	Fortus 360mc/380mc/400mc/450mc/900mc	
Colors	Black	
Support Material	Soluble	

PPSF/PPSU

PPSF/PPSU (polyphenylsulfone) is a very strong thermoplastic with high heat tolerance and excellent chemical resistance. It can be sterilized using steam autoclave, EtO, plasma, chemical and radiation procedures. These qualities make it appropriate for demanding applications in the medical, aerospace and automotive industries.

Material		
PROPERTIES	PPSF/PPSU	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	EtO, hydrogen peroxide gas plasma, gamma radiation, autoclave (steam), plasma	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	8,000 psi	55 MPa
Tensile Modulus (XZ Axis)	300,000 psi	2,100 MPa
HDT @ 264 psi (1.82 MPa)	372 °F	189 °C
Elongation at Break (XZ Axis)	3%	
Hardness (Rockwell)	86 (scale M)	
Printer Applicability	Fortus 400mc/900mc	
Colors	Tan	
Support Material	Breakaway	

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APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

ULTEM 9085

ULTEM 9085 resin is a high-performance FDM thermoplastic with a high strength-to-weight ratio, heat resistance and flame, smoke and toxicity (FST) rating. Its strength allows for autoclave sterilization, among other methods. The strength, durability, and resistance to heat and chemicals make ULTEM 9085 a good choice for fully functional prototypes or production parts. It is available on Fortus Production Systems.

Material

PROPERTIES	ULTEM 9085	
Physical Characteristics	Production-grade thermoplastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	Autoclave (steam), flash autoclave, EtO, hydrogen peroxide gas plasma, gamma radiation	
	ENGLISH	METRIC
Tensile Strength (XZ Axis)	9,950 psi	69 MPa
Tensile Modulus (XZ Axis)	312,000 psi	2,150 MPa
HDT @ 264 psi (1.82 MPa)	307 °F	153 °C
Elongation at Break (XZ Axis)	5.8	
Hardness (Rockwell)	---------------	
Printer Applicability	Fortus 400mc/450mc/900mc	
Colors	Black, Tan	
Support Material	Breakaway	

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APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

POLYJET MATERIALS

MED610

MED610 is a rigid, clear, biocompatible photopolymer with strong mechanical properties and good dimensional stability. Biocompatibility approval includes testing for cytotoxicity, genotoxicity, sensitivity, irritation and USP Class VI. These characteristics make it a good choice for orthodontic and orthopedic surgical guides, hearing aids, and other applications that involve prolonged skin contact and short-term mucosal membrane contact. MED610 is compatible across a broad range of PolyJet 3D Printers ranging from small, desktop 3D printers to large, triple-jetting systems. The material is used with SUP705 support material.

Material

PROPERTIES	MED610	
Physical Characteristics	Rigid, transparent photopolymer	
Biocompatibility	Tissue contact and duration approvals: • Skin contact >30 days • Short-term mucosal membrane contact up to 24 hours Stratasys tests: • Genotoxicity ISO 10993-3 • Cytotoxicity ISO 10993-5 • Irritation and delayed-type hypersensitivity – ISO 10993-10 • Chemical characterization – ISO 10993-18 • Acute systemic injection test – USP Class VI • Intracutaneous irritation test – USP Class VI • Intramuscular implantation test – USP Class VI	
Sterilization Methods	Not tested - verification required	
	ENGLISH	METRIC
Tensile Strength	7,300-9,400 psi	50-65 MPa
Tensile Modulus	290,000-435,000 psi	2,000-3,000 MPa
HDT @ 264 psi (1.82 MPa)	113-122 °F	45-50 °C
Elongation at Break	10-25%	
Hardness (Shore - D)	83-86	
Printer Applicability	Objet30 Prime, Objet Eden250/350/260V/260VS/350V/500V, Objet260/350/500 Connex, Objet260/350/500 Connex1/2/3	
Support Material	Gel-like (WaterJet removable)	

Consult the MED610 Terms of Use and Maintenance for more specific information on 3D printing biocompatible parts with MED610.

PolyJet Materials Simulating Engineering Plastics

This group of PolyJet materials includes DigitalABS and High Temperature material. DigitalABS has qualities similar to ABS plastic and is a composite material created by combining PolyJet base resins.

Material		
PROPERTIES	PolyJet Digital ABS and High Temperature	
Physical Characteristics	Rigid, opaque, thermoset plastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	Not tested – verification required	
	ENGLISH	METRIC
Tensile Strength	8,000-11,500 psi	55-80 MPa
Tensile Modulus	375,000-510,000 psi	2,600-3,500 MPa
HDT @ 264 psi (1.82 MPa)	124-135 °F	51-57 °C
Elongation at Break	10-40%	
Hardness (Shore)	85-88 (scale D)	
Hardness (Rockwell)	67-73 (scale M)	
Printer Applicability	Refer to the PolyJet Systems and Materials matrix at Stratasys.com	
Support Material	Gel-like (WaterJet removable), soluble (depending on printer system used)	

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APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

PolyJet Materials Simulating Standard Plastics

The following tables represent groups of PolyJet materials simulating a range of standard industrial plastics, both transparent and opaque, including simulated polypropylene. Suitable applications for transparent materials include the simulation of clear thermoplastics such as PMMA (acrylic), used for fluid containers, syringes, lenses and glassware. Simulated polypropylene is suitable for applications requiring repetitive flexibility such as closures and snap fits. Both opaque and transparent materials are capable of a smooth surface finish and fine detail.

Material		
PROPERTIES	PolyJet Transparent (RGD720 & VeroClear)	
Physical Characteristics	Rigid, transparent photopolymer	
Biocompatibility	Not tested – verification required	
Sterilization Methods	Not tested - verification required	
	ENGLISH	METRIC
Tensile Strength	7,250-9,450 psi	50-65 MPa
Tensile Modulus	290,000-435,000psi	2,000-3,000 MPa
HDT @ 264 psi (1.82 MPa)	113-122 °F	45-50 °C
Elongation at Break	10-25%	
Hardness (Shore)	83-86 (scale D)	
Hardness (Rockwell)	73-76 (scale M)	
Printer Applicability	Refer to the PolyJet Systems and Materials matrix at Stratasys.com	
Support Material	Gel-like (WaterJet removable), soluble (depending on printer system used)	

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APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

Material

PROPERTIES	PolyJet Opaque (Vero Family)	
Physical Characteristics	Rigid, opaque, thermoset plastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	Not tested - verification required	
	ENGLISH	METRIC
Tensile Strength	7,250-9,450 psi	50-65 MPa
Tensile Modulus	290,000-435,000 psi	2,000-3,000 MPa
HDT @ 264 psi (1.82 MPa)	113-122 °F	45-50 °C
Elongation at Break	10-25%	
Hardness (Shore)	83-86 (scale D)	
Hardness (Rockwell)	73-76 (scale M)	
Support Material	Gel-like (WaterJet removable), soluble (depending on printer system used)	

Material

PROPERTIES	PolyJet Simulated Polypropylene (DurusWhite and Rigur)	
Physical Characteristics	Rigid, opaque, thermoset plastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	Not tested - verification required	
	ENGLISH	METRIC
Tensile Strength	2,900-6,500 psi	20-45 MPa
Tensile Modulus	145,000-345,000 psi	1,000-2,100 MPa
HDT @ 264 psi (1.82 MPa)	90-122 °F	32-50 °C
Elongation at Break	20-50%	
Hardness (Shore)	74-84 (scale D)	
Hardness (Rockwell)	58-62 (scale M - Rigur RGD450 only)	
Printer Applicability	Refer to the PolyJet Systems and Materials matrix at Stratasys.com	
Support Material	Gel-like (WaterJet removable), soluble (depending on printer system used)	

PolyJet Materials Simulating Rubber

This group of PolyJet materials represents flexible, rubber-like polymers with a range of hardness, elongation and tear resistance values. Flexible materials are available with both opaque and translucent properties.

Material		
PROPERTIES	PolyJet Simulated Rubber (Tango Family)	
Physical Characteristics	Flexible (rubber-like), thermoset plastic	
Biocompatibility	Not tested – verification required	
Sterilization Methods	Not tested - verification required	
	ENGLISH	METRIC
Tensile Strength	115-725 psi	0.8-5 MPa
Elongation at Break	45-220%	45-220%
Tensile Tear Resistance	18-60 Lb/in	2-12 Kg/cm
Compressive Set	0.5-5%	
Hardness (Shore)	26-77 (scale A)	
Printer Applicability	Refer to the PolyJet Systems and Materials matrix at Stratasys.com	
Support Material	Gel-like (WaterJet removable), soluble (depending on printer system used)	

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APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

Material Matrix

The following tables present the biocompatibility, sterilizability and support material compatibility across FDM and PolyJet materials.

FDM Material

	FDM						
	ABSplus	ABSi	ABS-M30	ABS-M30i	ABS-ESD7	ASA	Nylon12
BIOCOMPATIBILITY	Not Tested[1]	Not Tested[1]	Not Tested[1]	Yes	Not Tested[1]	Not Tested[1]	Not Tested[1]
ISO 10993-3: Genotoxicity							
ISO 10993-4: Hemocompatibility							
ISO 10993-5: Cytotoxicity				✔			
ISO 10993-6: Implantation Effects							
ISO 10993-10: Irritation & Sensitization				✔			
ISO 10993-11: Systemic Toxicity				✔			
USP Class VI: Systemic Injection Test							
USP Class VI: Intracutaneous Test							
USP Class VI: Implantation Test							
STERLIZABILITY	Note[2]	Yes	Note[2]	Yes	Yes	Note[2]	Note[2]
EtO		✔		✔	✔		
Hydrogen Peroxide Gas Plasma		✔		✔	✔		
Gamma Radiation		✔		✔	✔		
Autoclave (steam)							
Flash Autoclave							
SUPPORT							
Soluble Support	✔	✔	✔	✔	✔	✔	✔
Breakaway Support	✔						

Notes:
1 – Material has not been tested for biocompatibility. Refer to ISO 10993 for appropriate test requirements for the intended application.
2 – Material has not been tested for sterilizability.
3 – Biocompatibility tests conducted by raw material manufacturer.

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APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

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FDM Material

	FDM					
	PC	PC-ABS	PC-ISO	PPSF/PPSU	ULTEM 9085	ULTEM 1010
BIOCOMPATIBILITY	Not Tested[1]	Not Tested[1]	Yes	Not Tested[1]	Not Tested[1]	Yes
ISO 10993-3: Genotoxicity						
ISO 10993-4: Hemocompatibility						✔[3]
ISO 10993-5: Cytotoxicity			✔			✔[3]
ISO 10993-6: Implantation Effects						✔[3]
ISO 10993-10: Irritation & Sensitization			✔			✔[3]
ISO 10993-11: Systemic Toxicity			✔			✔[3]
USP Class VI: Systemic Injection Test						✔
USP Class VI: Intracutaneous Test						✔
USP Class VI: Implantation Test						✔
STERLIZABILITY	Yes	Yes	Yes	Yes	Yes	Yes
EtO	✔	✔	✔	✔	✔	✔
Hydrogen Peroxide Gas Plasma	✔	✔		✔	✔	✔
Gamma Radiation	✔	✔	✔	✔	✔	✔
Autoclave (steam)				✔	✔	✔
Flash Autoclave					✔	✔
SUPPORT						
Soluble Support	✔	✔				
Breakaway Support	✔		✔	✔	✔	✔

Notes: 1 – Material has not been tested for biocompatibility. Refer to ISO 10993 for appropriate test requirements for the intended application.
2 – Material has not been tested for sterilizability.
3 – Biocompatibility tests conducted by raw material manufacturer.

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APPLICATIONS AND GUIDANCE ON MATERIAL SELECTION

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PolyJet Material

	POLYJET					
	Clear, Rigid Biocompatible	Simulated Engineering Plastics	Simulated Standard Plastics			
	MED610	Rigid Opaque	Rigid Transparent	Rigid Opaque	Simulated Polypropylene	Flexible
BIOCOMPATIBILITY	Yes	Not Tested[1]	Not Tested[1]	Not Tested[1]	Not Tested[1]	Not Tested[1]
ISO 10993-3: Genotoxicity	✔					
ISO 10993-4: Hemocompatibility						
ISO 10993-5: Cytotoxicity	✔					
ISO 10993-6: Implantation Effects						
ISO 10993-10: Irritation & Sensitization	✔					
ISO 10993-11: Systemic Toxicity						
USP Class VI: Systemic Injection Test	✔					
USP Class VI: Intracutaneous Test	✔					
USP Class VI: Implantation Test	✔					
STERLIZABILITY	Note[2]	Note[2]	Note[2]	Note[2]	Note[2]	Note[2]
EtO						
Hydrogen Peroxide Gas Plasma						
Gamma Radiation						
Autoclave (steam)						
Flash Autoclave						
SUPPORT						
Gel Support (WaterJet removable)	✔	✔	✔	✔	✔	✔
Soluble Support		✔[3]	✔[3]	✔[3]	✔[3]	✔[3]

Notes: 1 – Material has not been tested for biocompatibility. Refer to ISO 10993 for appropriate test requirements for the intended application.
2 – Material has not been tested for sterilizability.
3 – Soluble support compatibility dependent on printer system used.

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