Advanced Medical Models

Currently, there is a great need for improved medical models for education and training, and pre-clinical device testing. The importance of these models cannot be underestimated as they help prepare emerging surgeons for procedures, update current surgeons on unique pathologies, and enable medical device developers to test their innovations in clinically relevant pathology.

Animal, cadaver and mannequin medical models have many limitations. Animal models can only approximate human anatomy, may not represent targeted pathology, are expensive, have ethical concerns and must be examined in a controlled environment. Cadaver models have a number of limitations as well. They are highly processed, don't retain live-tissue feel, may not contain the targeted pathology, are difficult to obtain and must be examined in a controlled environment. Mannequins do not approximate real human tissue and provide limited haptic feedback.

Advanced Medical Models offer anatomically accurate, biomechanically realistic, highly functional models created from human anatomy

scans. These models are available in a range of tissue properties from bone to soft tissue and an integration of anatomical microstructure.

Complex, multi-texture models, such as a spine with vertebras, discs, nerve roots and hearts with valves, annulus and calcification are possible. These highly accurate, realistic and functional models enable simulation of clinical procedures, such as drilling and reaming, cutting and suturing, and device placement.

Examples Of Validated Models	
Spine models	healthy spine, degenerative spine, scoliosis spine, less invasive spine
Bone models	femur, radius
Heart models	healthy heart, hole in heart
Other	individual vertebrae, custom segments of vertebrae and discs

Companion And Reference Materials	
Technical application Guide	Document
Advanced Medical Models Brochure	Document
Sell Sheets (heart and spine)	Document
Videos	• The SickKids Hospital • The Jacobs Institute • Montage
Additional documents	• Case studies (3) • Best Practices (1)

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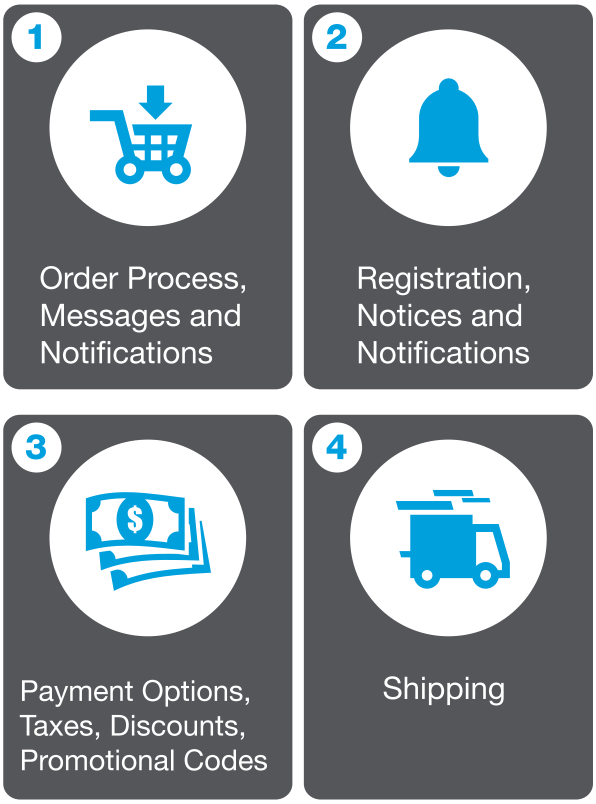
1.0 Process Overview

Advanced medical models is a medical models solution, providing the user with anatomically accurate, repeatable, pathology-specific models. These models replicate true haptic feel and enable the user to train, practice and repeat both routine and highly specific procedures with convenience and cost savings, over animal and cadaver labs.

Beginning in 2018, advanced medical models will offer a library of available parts through Stratasys Direct Manufacturing (SDM).

For more information: www.stratasys.com/medical/contact-advanced-medical-models-expert



2.0 Biomimics™ Building Blocks

2.1 Hearts

The advanced medical models heart solution introduces a new material, TissueMatrix, developed to imitate soft, compliant human tissue, and when incorporated into heart models, replicates the behavior of human heart tissue during typical surgical and interventional procedures. Cutting, suturing, compliance and introduction of various devices including artificial valves, VSD patches and ventricular assist devices are enabled with this material. Different microstructures and digital materials can be assigned to structures of the heart, such as leaflets, annulus, chordae, tedninae and calcium deposits with varying mechanical properties.

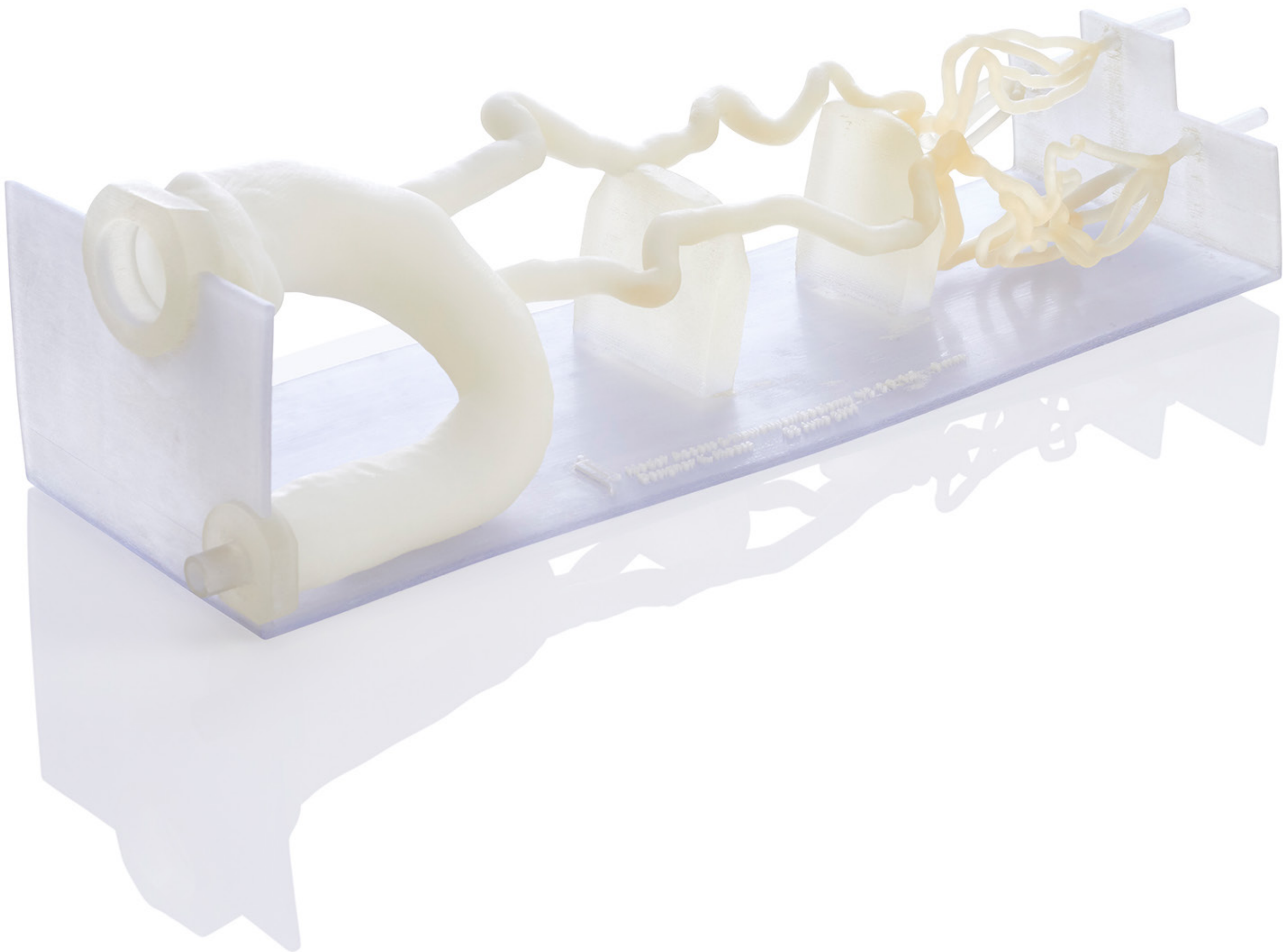
- The Hospital for Sick Children (SickKids) in Toronto, has approximately 500 new congenital heart defect cases each year. Their surgical training incorporates 25 different heart models, ranging from an atrial septal defect to transposition of the great arteries. Over the course of the eight cardiac surgeon training courses the Hospital has offered, 100% of students say the training models are helpful in developing their surgical skills.

2.2 Blood Vessels

The advanced medical models blood vessel models employ a unique method of support removal in order to enable more complex vascular models than ever before. Using a unique support removal process developed by advanced medical models, blood vessels with internal diameter as small as 2mm can be printed, while keeping the inner channel open and allowing liquid flow. Certain variance in compliance of the vessel can be achieved by modifying the thickness of the wall. Calcifications can be printed from a radiopaque rigid material.

Advanced medical models are available with calcifications visible under fluoroscopy as well as varying wall thicknesses of blood vessels to mimic different compliance values. Functionality includes guide wire and catheter insertion and functionality under fluoroscopy. These models have been validated to work under a closed liquid loop, and enable the user to experience flow and contrast visualization with the same tools used in the OR. Connectors are present to allow watertight connection of liquid flow system.

- The Jacobs Institute, in Buffalo, New York, a collaborative partnership of clinicians, researchers, engineers and entrepreneurs, are working to develop next generation technologies in vascular medicine. Their testing of complex 3D printed neurovascular models for treatment of cerebrovascular diseases such as strokes and aneurysms have gone beyond visual representations of complex vasculature to actual use cases involving training a physician to retrieve a blood clot from a blood vessel deep within the brain. The JI has found advanced medical models offer superior results for the resolution for complex shapes, intricate details and smooth surfaces that can stand up to repeated flexing and bending. These qualities enable effective surgical planning, training and education, and medical device testing.



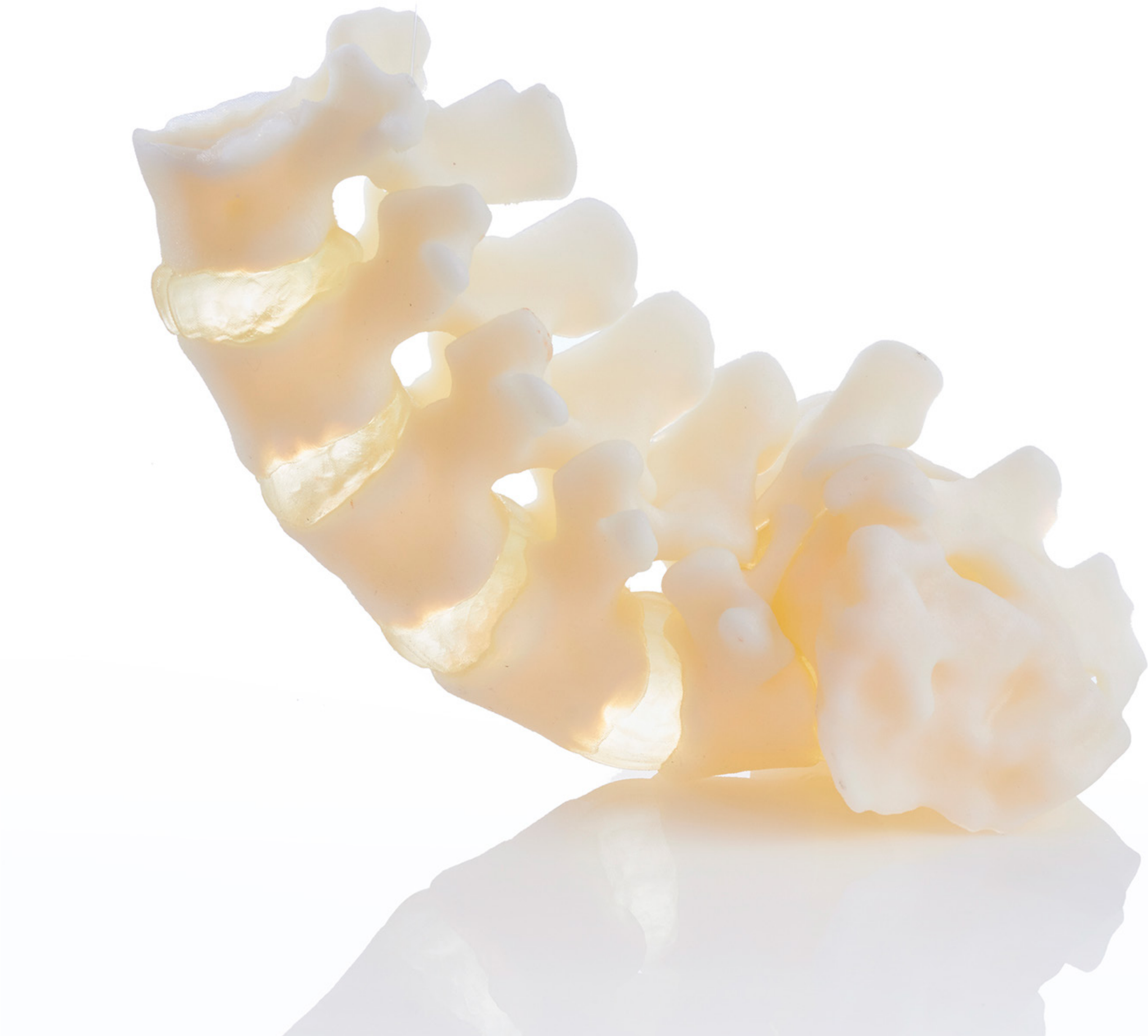
2.3 Bones

Advanced medical models uses a specially developed software to replicate the internal structure of human bones. It can replicate the cortical, cancellous and marrow regions of the bone. It can even imitate pathologies such as osteoporosis to assist with the choice of the right equipment. Several materials are composed in order to provide unique properties to each region of the bone and replicate the desired mechanical behavior.

Advanced medical models bone models are available in various bone densities, such as healthy and osteoporotic, mimicking the internal structure of the bone to replicate cortical bone, cancellous (trabecular) bone and bone marrow. The ability to design models with complex internal structures, versus a monolithic model, enables features such as strain relief regions for pedicle screw insertion, and even complex models which include both bones and soft tissues, such as ligaments and roots.

Spinal discs that respond the same way to discectomy as human discs can be incorporated, and allow for complex interactions while keeping design freedom. Models provide the same resistance to manipulation to replicate the straightening of a scoliotic spine.

- The DePuy Synthes Spine Institute, part of the J&J family of companies, in Raynham, Massachusetts, offers a laboratory training setting to pre-fellows through experienced spinal specialists for hands-on training. The advanced medical models spinal models solution offers a range of tissue properties, from complex anatomy, such as a scoliotic spine with vertebras, discs and nerve roots, to a healthy spine, enabling training and education, as well as pre-surgical planning.



3.0 Range Of Anatomy Modifications And Properties

3.1 Hearts

- Advanced medical models heart tissue material is a composite material which has two elements: a soft core which closely approximates the properties of the heart, and a variable Agilus30™ coating which allows the user to choose the rigidity of the tissue.
- By using Stratasys Digital materials, different elements can be more rigid than others; for example, the Annulus can be set to a Shore A 40 hardness level, which allows it to have shape memory and allows the user to deploy a valve.
- Two distinct hardness levels were created: DM400 and DM600.
- When using a thicker coating, the heart tissue would be slightly more rigid and also more durable for suturing, cutting and potential tearing.
- Based and pedestals can be designed to allow easy placement and interaction.
- Text, graphics and emblems can be incorporated to highlight anatomical regions or steps in design introduction.
- Any other element would be a digital material composed of Agilus30 and Vero PureWhite™, allowing Shore values from 30 to 90.

3.2 Blood Vessels

- Advanced medical models blood vessels can be originated in one of two methods: a vascular model (which has a predefined wall thickness) or a blood pool (in this case, a Stratasys AE will create a constant or variable wall around the pool); in order to remove the support, the vessel has to have at least two openings; in the case of a blood pool these have to be defined by the user.
- The thickness of the wall can be defined by the compliance (change of volume as a function of pressure) of the model. Typically, a jig or frame is built to hold the model in place. A user may supply this jig or a Stratasys AE can design it.
- Calcifications and aneurysms can be defined by the user and will have different composition of material to imitate either the mechanical or radiographic characteristic of it.
- A user may define thinner/thicker regions in a blood vessel (for example, to simulate an aneurysm) by coloring (texture mapping) the blood pool to correspond with the effected regions.

3.3 Bones

i. Long bones

- Long bones (femur, fibula, tibia, radius, humerus, ulna, metacarpals and metatarsals) can be created from a simple STL mesh describing the external geometry of the bone. There is no need to describe internal regions of the bone.
- Stratasys' advanced medical models software can generate the internal structure of the bone without having to design it by CAD or undergo complicated segmentation.
- The user defines the orientation of the bone, the desired pathology (healthy or osteoporotic) and any special conditions (open end, fracture); additionally, the bone can be encapsulated inside soft tissue and include connective tissue as defined by the user.

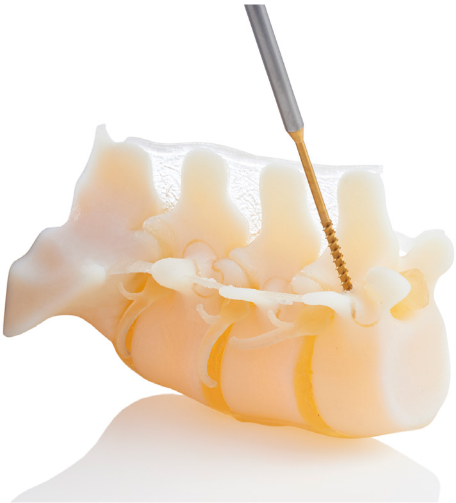
ii. Spine

- Spinal simulators can be created using a simple segmentation of the vertebras and/or soft tissue (discs, ligaments, tendons, muscles); the internal structure of the vertebrae was tested to replicate the tactile and mechanical elements of pedicle screw insertion.
- Special elements are designed to allow the use of commercially available pedicle screw systems, with the same workflow used on living patients and cadavers.

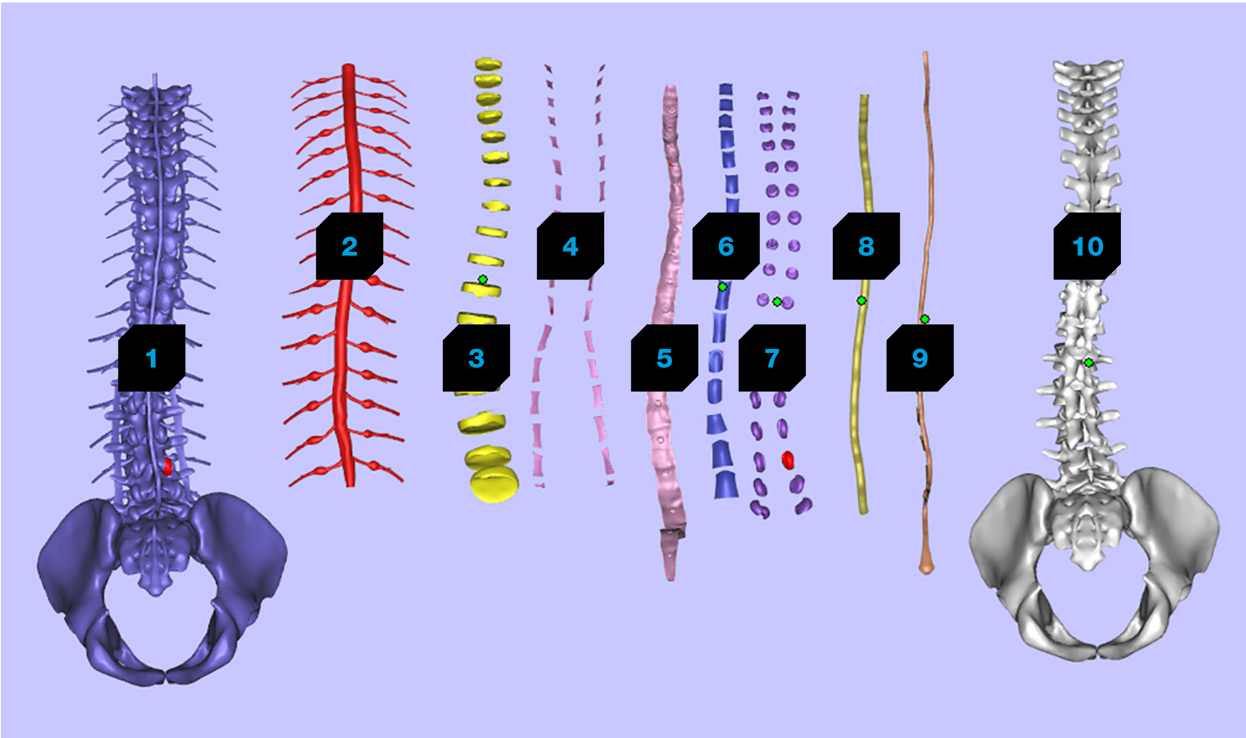
- The internal disc structure can imitate healthy or degenerated disc and Discectomy as well as spinal deformity such as scoliosis.
- Soft tissue can be included to simulate obstruction of view, unique surgical approaches and minimally invasive procedures.

iii. Irregular bones

- Advanced medical models software can enable the generation of very fine internal structures in bones, without the need to design them in CAD or undergo lengthy manual segmentation.
- Once a bony structure (mandible, for example) was defined, it can be easily applied to similar anatomies without the need to redesign, enabling the user to create various conditions and simulations with relative ease.



Advanced medical models allows model designers to create complex anatomies that replicate a wide range of different tissue properties. A single model can include many different structures, each with different biomechanical or design features. For example, the spine model below is built from 10 different structures, each one assigned a different advanced medical models Building Block structure or material.



1 | Full assembly

2 | Nerves and spinal cord

3 | Intervertebral discs

4 | Intertransverse ligaments

5 | Posterior longitudinal ligament (P.L.L)

6 | Ligamentum Flavum

7 | Facet Capsulary ligament

8 | Anterior longitudinal ligament (A.L.L)

9 | Interspinous ligament

10 | Sacrum and vertebrae

4.0 Dicom To Print And Stl Requirements

4.1 Basic Requirements

- For models available through the SDM library, no print files are necessary. The models are pre-segmented and designed by Stratasys AEs.
- For custom parts, segmentation of the anatomy is required.
  1. For heart files, a segmentation of the myocardium is required. Additional structures (such as valves, calcifications and holders) can be provided as an STL assembly.
  2. For blood vessels, either a blood pool of a vascular wall is acceptable as an input. Additional structures (such as calcifications, plaque, frames) can be provided as an STL assembly.
  3. For long bones, only an external mesh of the bone is required.
  4. For spine models, a segmentation of the vertebras and discs is required. Muscles, ligaments and other structures are optional.
- For all anatomies, the basic requirements for a healthy STL are similar.

For assemblies or complex anatomies, the user has to export multiple meshes using the same coordinate system.

4.2 Assemblies or Complex Assemblies

- The process starts with identifying both the anatomy that needs to be replicated and the procedural steps and devices that need to interact with the model.
- Once the anatomy is represented by one (or more) mesh files (in STL/VRML formats) it can be processed to reproduce the desired tissue characteristics.
- The model can be designed and enhanced to optimize the user experience for specific devices or procedures. For example, tumors and lesions can be designed to be removable in order to simulate a procedure.

3D printing requires exporting one or more (if using a multi-material platform) closed surfaces as an STL assembly. This is done by marking the relevant data and discarding the surrounding data. In (Figure 1) both the skin and bone are shown in the 3D view, and only the bone is shown in (Figure 2).

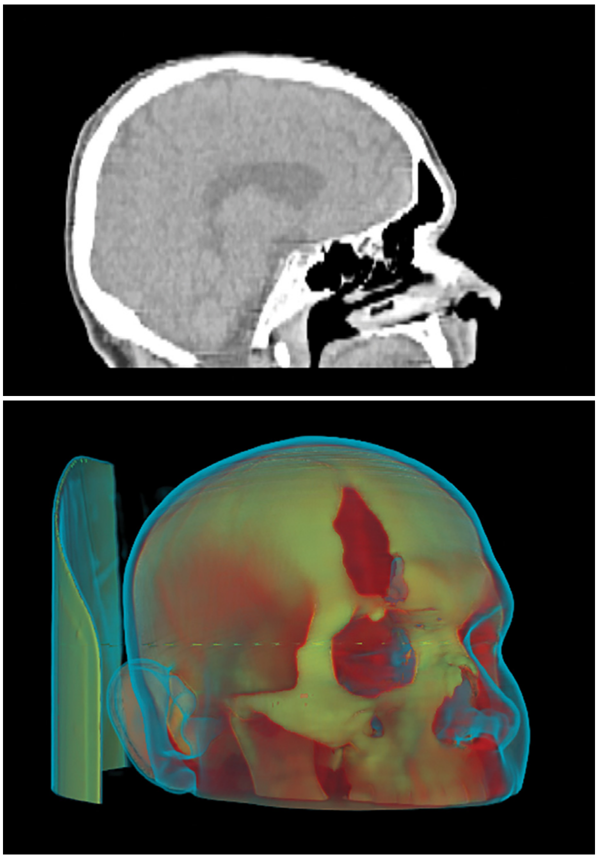


Fig 1: A scan of a human head showing tissue and bone.

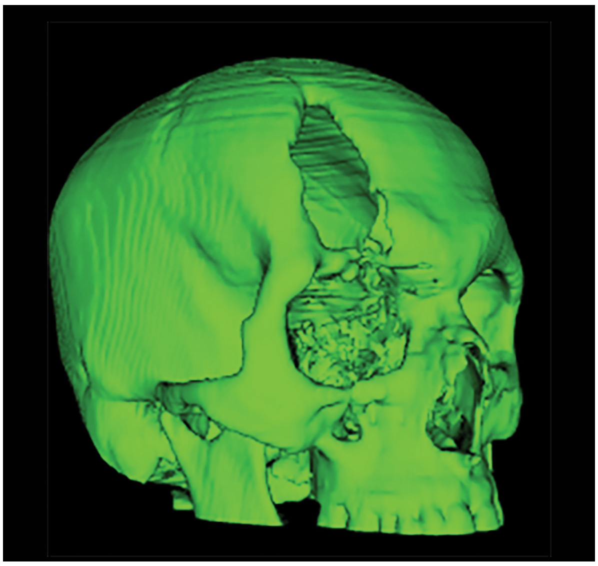


Fig 2: Isolated bone is the objective of this segmentation exercise.

5. Fulfillment

5.1 Stratasys Direct Manufacturing (SDM)

- In its Alpha Phase, the Medical eStore will serve existing SDM and/or Stratasys customers, beginning in 2018.
- The Medical eStore will serve the U.S. only, currency USD.

ii. Library of validated models

a. Pediatric hearts

b. Spine: vertebrae

c. Long bone: femur, radius

d. Vascular, coming soon, TAVR, neurovascular

Custom models

a. Based on existing CAD/STL design

b. Source MR/CT imaging study and segment

c. Customize with validated advanced medical models enhancements

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