



Health Technology Review	
Technology Ref.:	HTA22009
Technology Name:	3D printing of anatomic models
Approvals by International Bodies:	FDA
Company name:	MAKERBOT INDUSTRIES LLC
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Short Description of the Technology:	<p>3D printing of anatomic models' implants is made by a process of additive manufacturing. Additive manufacturing uses a computer-aided process with a 3D printer to build devices one layer at a time. The most commonly used technologies in medical devices are powder bed fusion, stereolithography, fused filament fabrication, and liquid-based extrusion. Stereolithography systems use a vat of liquid that is cured by light. Fused filament fabrication melts a solid filament at the point of deposition, after which it solidifies, while liquid-based extrusion systems eject a liquid which then solidifies. Orthopaedic implants are frequently made with cobalt-chromium or titanium powder bed fusion, which uses an energy source such as laser or electron beam to melt or sinter a layer of metal powder onto the layer below.</p> <p>Additive manufacturing contrasts with the traditional methods of manufacturing, which include forging, casting, and machining. Advantages of additive manufacturing include the ability to manufacture complex structures that traditional manufacturing processes cannot, and to create devices or models individually matched to the patient's anatomy.</p>
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
<p>3D models can be used to improve patient care, enhance patient and provider education, and facilitate surgical planning for complex injuries. Surgeons are uniquely positioned to utilize 3D printing and heightened awareness of the methodology of this novel technology is advantageous. Complex malunion reconstructions are distinct and require a high degree of preparation when considering intraoperative approaches.</p> <p>With 3D printing, innovative techniques can be increasingly incorporated into clinical workflows to allow for individualized patient care. Patients and providers both benefit from increased understanding and communication when 3D models are integrated into the planning process.</p>	



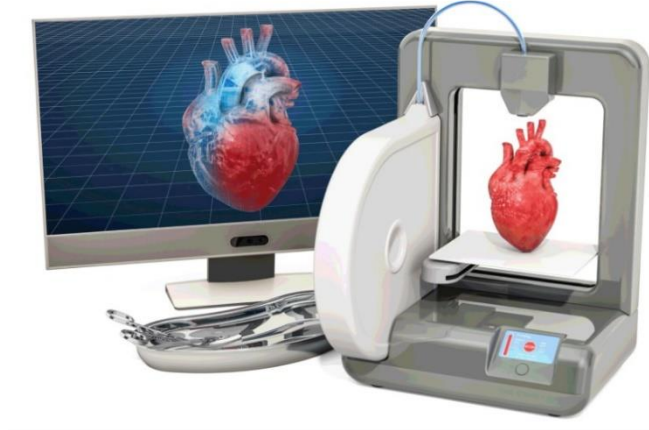
Advantages	Disadvantages
Safety is improved by the creation of highly accurate patient specific 3D anatomical models	many of printable materials cannot be recycled
Effective pre-surgical planning and improved predictability for patient outcomes and reduced theatre time	Raw materials are not exhaustive. This is due to the fact that not all metals or plastics can be temperature controlled enough to allow 3D printing.
Develop clinically relevant models and place real anatomy in the hands of healthcare professionals and research engineers	Another potential problem with 3D printing is directly related to the type of machine or process used, with some printers having lower tolerances, meaning that final parts may differ from the original design
Reduced the risk of complications within surgical planning, allowing professionals establish the optimal course of action by having a 3D model to help inform their decision-making process	Breathing in harmful materials: 3D printing can release particulates and other harmful chemicals into the air. Skin contact with harmful materials: Users can get hazardous materials, such as metal powders, solvents and other chemicals, on their skin
Show vascular locations in relation to internal tumors for radiotherapy assessment, Cardiology, trauma and dentistry	
Approved by FDA	

We recommend an **approve of using this technology** with the following conditions:

1. The healthcare providers must be trained and certified on operating the 3D printing of anatomic models beforehand.
2. The use of technology in hospitals and centers that are well-equipped with all needed medical equipment's and devices.
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and patients.
4. Provision of regular updates and reports outcome about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image



Population, setting and intended user for Technology “3D printing of anatomic models”

- **Population/ Intended User;**
 - Cardiology, trauma, dentistry and for educational purposes
- **To be performed by:**
 - Certified healthcare providers
- **Clinical Setting:**
 - Hospitals, specialized surgery centers
- **Condition of use:**
 - The healthcare providers must be trained and certified on operating 3D printing of anatomic models beforehand
- **Exclusion criteria:**
 - None