Medical Applications of Additive Manufacturing/3D Printing

	General	Anatomical Modeling	Surgical Planning	Personalized/Precision Prosthetics	Permanent Implants	Active & Wearable Devices	Pharmaceuticals*	Bioprinting/Tissue Fabrication
Brief Description	Non-personalized, instruments or prototypes	Patient-matched anatomical models from medical imaging studies (CT/MRI)	Templates, guides, and models after preparing a patient-specific surgical plan in a software environment (The 3D printed items are brought into operating room.)	Patient-matched prosthetics or orthotics	"Off-the-shelf" (Ability to create fine details easily, such as porous structures/surfaces) and patient-matched implants	Devices that include electronics or other active element	Printed for quick dissolving structure and other factors; potential to match a patient's unique requirements	3D printing of living cells or structures that regenerate living cells

Examples of What is 3D Printed	• Simple instruments: plastic or metal
	
	• Specialized metal/other instruments for hospital/surgical use (e.g. plate bending)
	
	• Testing pieces built with new materials
	
	• Prototypes for iterative design process
		• Models for surgical preparation, training, and simulation (e.g. pediatric cardio, conjoined twins)
		• Models for teaching or training purposes ("off-the-shelf" models)
		• Models for communicating with patient, parents, and colleagues (e.g. scoliosis model)
		• Simulation/Demo models to test fit and fixation of a device (e.g. stent deployment, implant sizing)
			• Guides that mark without cutting or injection; Examples:
			  a. Surgical marking guide
			  b. Implant placement guides (i.e. guiding placement of "off-the-shelf" total joint replacement components for total hip, knee and shoulder surgery)
			  c. Radiation shields
			  d. Imaging frames
			• Cutting/Drilling guides for surgical injection/instrumentation; Examples:
			  a. Guiding osteotomies in the bone
			  b. Surgical saw guide
			  c. Surgical drill guide
				• Patient-Matched Prosthetics/Orthotics
				  d. Direct Contact with Non-Mucosal Surface (e.g. glasses, body braces, hearing aids, casts, prosthetic limbs and attachments, etc.)
				  e. Direct Contact with Mucosal Surface (i.e. dental and orthodontic applications)
				• Assistive device
					• Serialized Implants
					  a. Metallic Implants (e.g. titanium, titanium alloys, cobalt chrome alloy)
					  b. PEEK/PEKK Implants
					  c. Temporary or Permanent Implants
					• Patient-Matched Reconstructive Implants
					  a. Small Quantity Cases (e.g. limb salvage, oncology cases)
					  b. "Everyday" types of implants (e.g. knee replacements)
					  c. Temporary/Removable Implants (i.e. nasal stents)
					  d. Permanent Implants: Non-Dissolvable (e.g. knee/bone implants) or Dissolvable Implants (e.g. tracheal splint)
						• Wearable sensors
						• Lab on a chip
						• Microfluidics
						• Electronics for active devices
							• First FDA cleared drug: Spritam from Aprecia Pharmaceuticals, a quick dissolving epilepsy medication	• Tissues or scaffolds used for regenerative engineering, drug delivery, drug discovery, toxicology, tissue engineering, etc.
								• Tissue/organ on a chip
								• Tissue and bone scaffolds

Technology	- 3D Printing - Materials	- 3D Printing/Additive Manufacturing - Image Processing Software - Materials	- 3D Printing - Biocompatibility - Design Software - Materials - Surgical Planning Software - Templating	- 3D Printing - Design Software - Digitizing Anatomy - Manufacturing Workflows - Materials - Scanning	- Additive Manufacturing (DMLS, EBM, SLS) - Materials -	- 3D Printing - Materials - Telemetrics	-	- 3D Printing - Materials - Bioreactors
Issues of Importance	- Material Properties - Repetitive Use - Aging - Cleaning and sterilization - Re-use - Foreseeable Misuse(e.g. device which was designed as a holding aid is bent or stuck with a mallet during use, or)	- Imaging protocols - Automation of Software - Biocompatibility - Cleaning and Sterilization - Model Accuracy - Multi-Materials - Color - Point-of-Care - Proving it Matters (Reimbursement)	- Imaging protocols - Biocompatibility (including the debris from drilling/cutting) - Sterilization - Efficiency - Foreseeable Misuse - Point-of-Care - Proving it Matters (Reimbursement)	- Automation of Design - Biocompatibility - Sterilization - Build Orientation - Foreseeable Misuse - Model Accuracy - Part Strength - Secondary Post Processing - Shelf Life - Workflows and Efficiency	- Biocompatibility - Build Orientation - Cleaning and Sterilization - Part Strength - Porous structure evaluation - Process Control - Secondary Post-Processing - Shelf Life - Speed and Relation to Cost - Validations - Verification and Inspection	- Biocompatibility - Cleaning and Sterilization Process Control - Secondary Post-Processing - Shelf Life - Speed and Relation to Cost - Validations - Verification and Inspection	- Drug purity - Cleaning and Sterilization - Process Control - Secondary Post-Processing - Shelf Life - Speed and Relation to Cost - Validations - Verification and Inspection	- Biocompatibility - Cell Survival - Materials - Point-of-Care - Sterility
Reimbursement model	- Generally, not reimbursable	- Covered by insurance in Japan (2016) - Elsewhere, not directly reimbursable - Cost generally covered as an overall savings to OR, hospital time	- Not directly reimbursable - Included by device manufacturers as a value-add - Cost generally covered as an overall savings to OR, hospital time	- Reimbursement same as existing similar, existing implants.	- Reimbursement same as existing similar, existing implants. New types implants possible through AM/3DP, follow same path as all new devices.	- Reimbursement same as existing similar, existing devices. New types implants possible through AM/3DP, follow same path as all new devices.	- Reimbursement same as existing drugs. New drugs follow same path as all new drugs.	-
Scale	-	-	-	-	-	-	-	-

*While 3D-printed drugs are growing, it is not a primary focus of the SME Medical AM/3Dp Workgroup.