Additive Manufacturing of Medical Devices

FDA Small Business Regulatory Education for Industry (REdI)

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Learning Objectives

- Describe the 7 types of additive manufacturing technologies and their applications for medical devices
- List the types of medical devices made using additive manufacturing
- Describe the contents of the FDA Guidance “Technical Considerations of Additively Manufactured Medical Devices”

Additive Manufacturing Technologies

Terminology

- **3D Printing or Additive Manufacturing (AM) is:**

"a process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies" - ISO/ASTM 52900

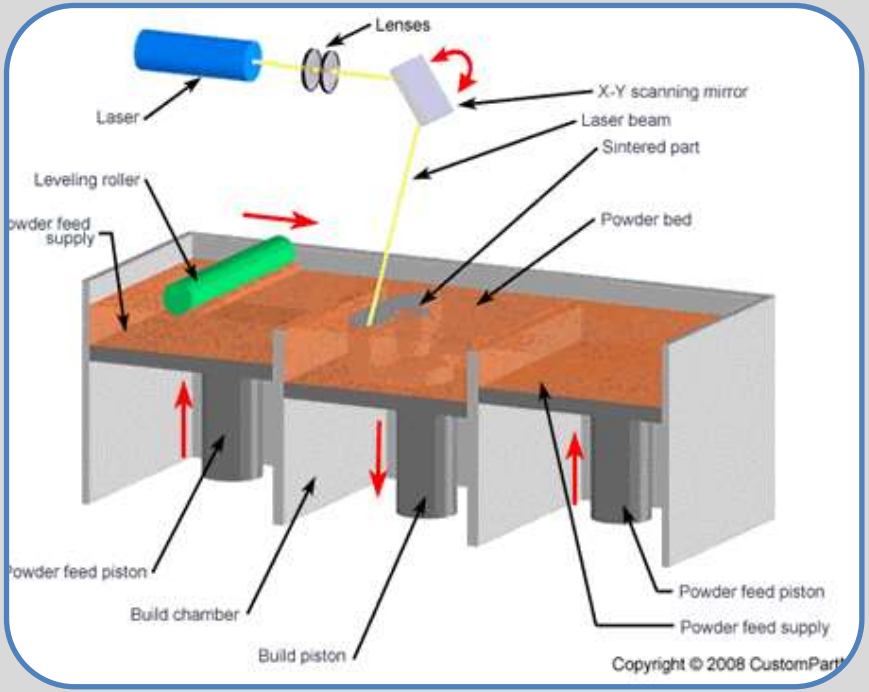
- **Other terms include:**
  - Rapid Prototyping, Direct Metal Fabrication, Additive Layer Manufacturing, Additive Fabrication, Reverse Engineering, Direct Digital Manufacturing, Solid Freeform Fabrication

1. Powder Bed Fusion

Powder Bed Fusion:

Process in which thermal energy selectively fuses regions of a powder bed

- Implants and cutting guides

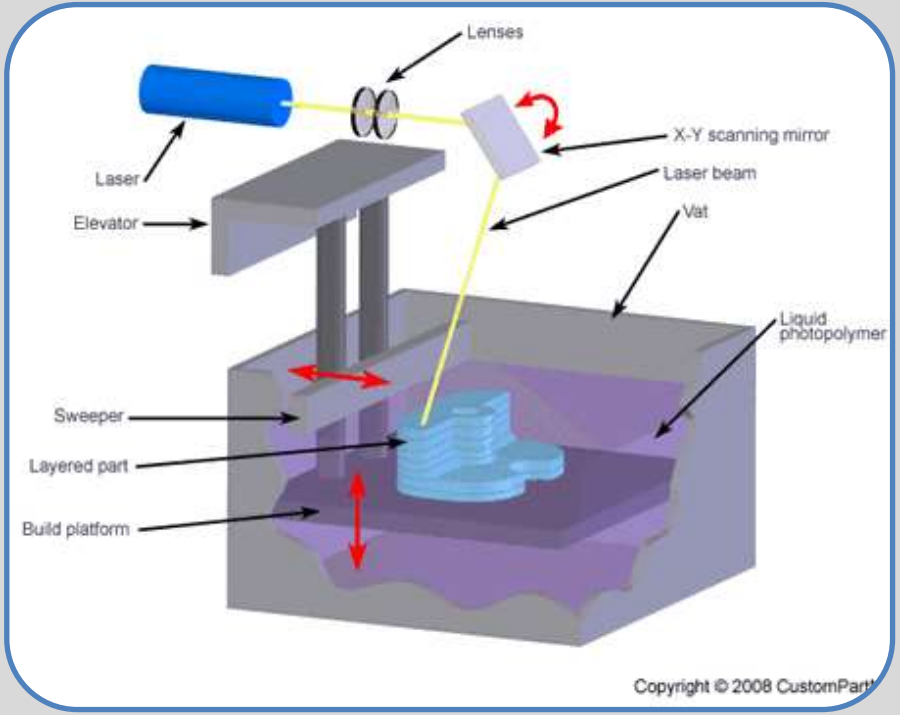


2. Vat Photopolymerization

Vat Photopolymerization:

Process in which liquid photopolymer in a vat is selectively cured by light-activated polymerization

- Dental products
- Drug printing

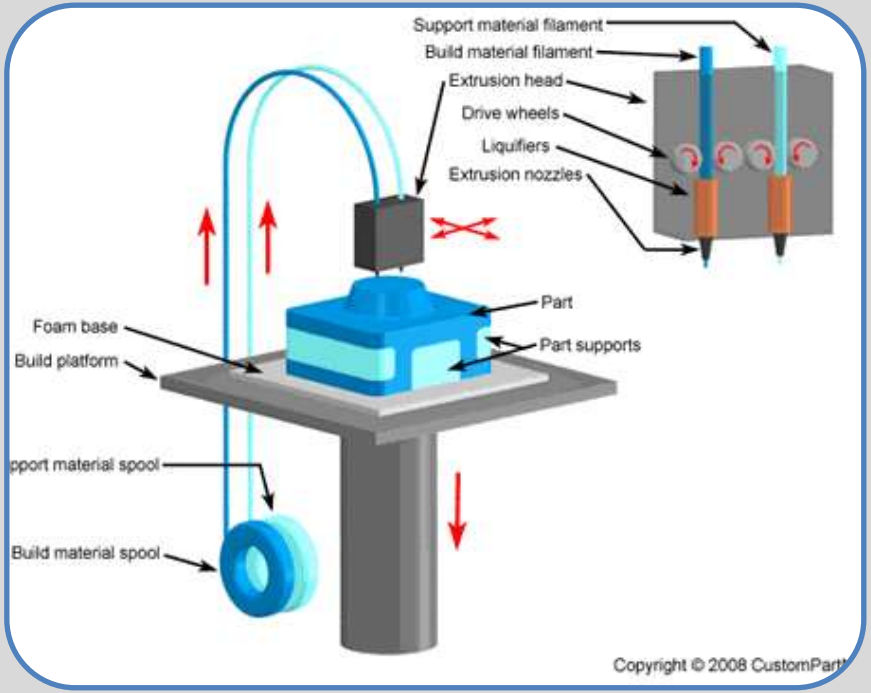


3. Material Extrusion

Material Extrusion:

Process in which material is selectively dispensed through a nozzle

- Bio printing
- Pill printing
- Prosthetics/anatomical models

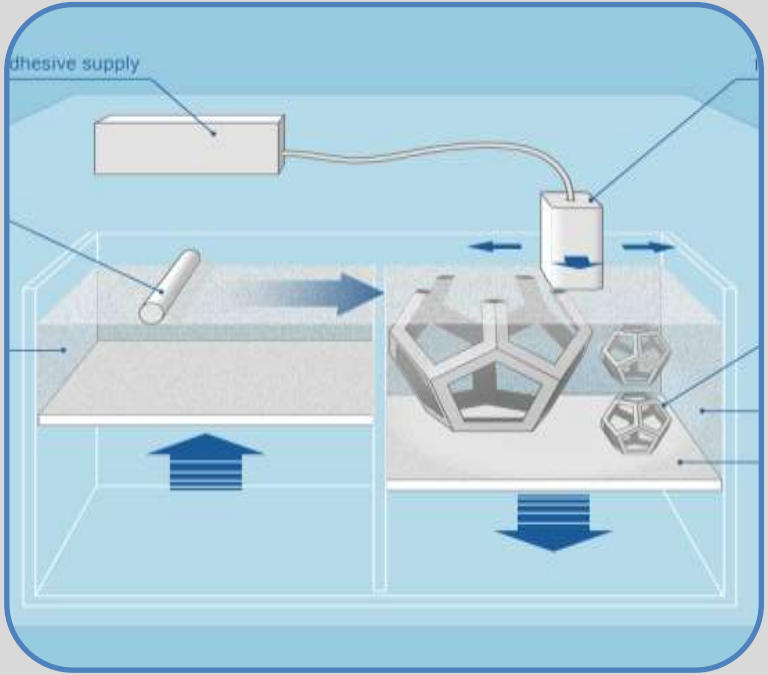


4. Binder Jetting

Binder Jetting:

Process in which a liquid bonding agent is selectively deposited to join powders

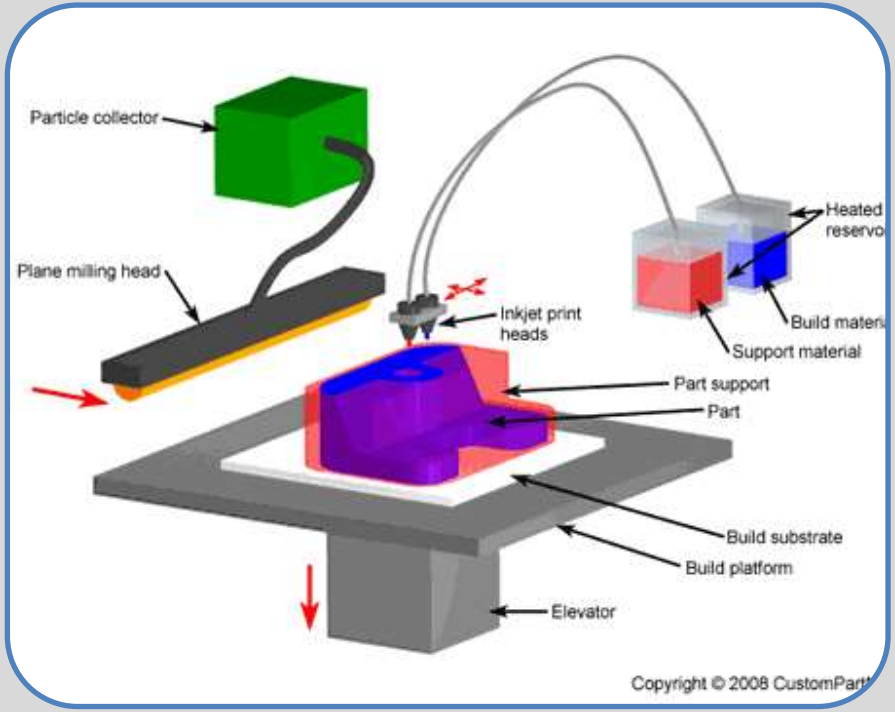
- Anatomical models
- Pill/drug printing



5. Material Jetting

Material Jetting: Process in which droplets of build material are selectively deposited

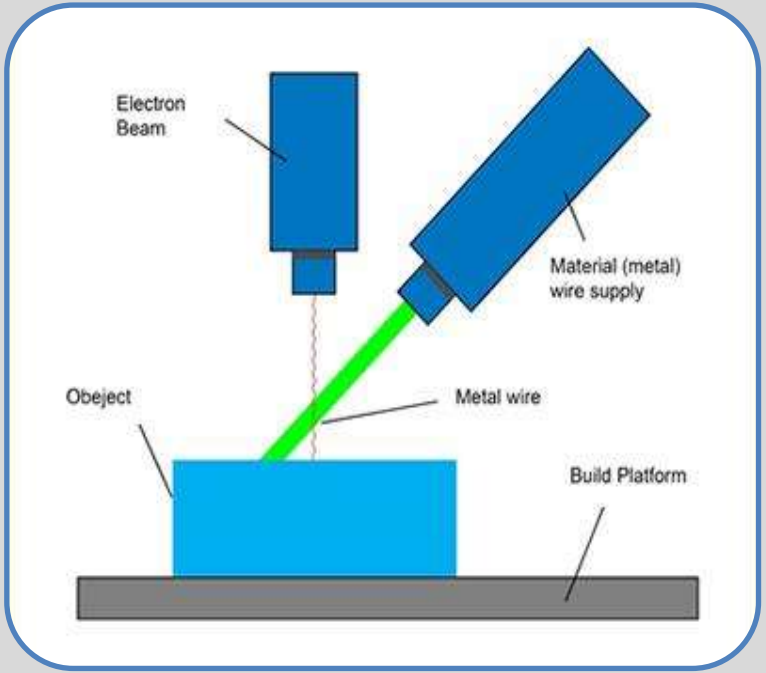
- Bioprinting
- Anatomical models



6. Direct Energy Deposition

Direct Energy Deposition: Process in which focused thermal energy is used to fuse materials by melting as they are being deposited

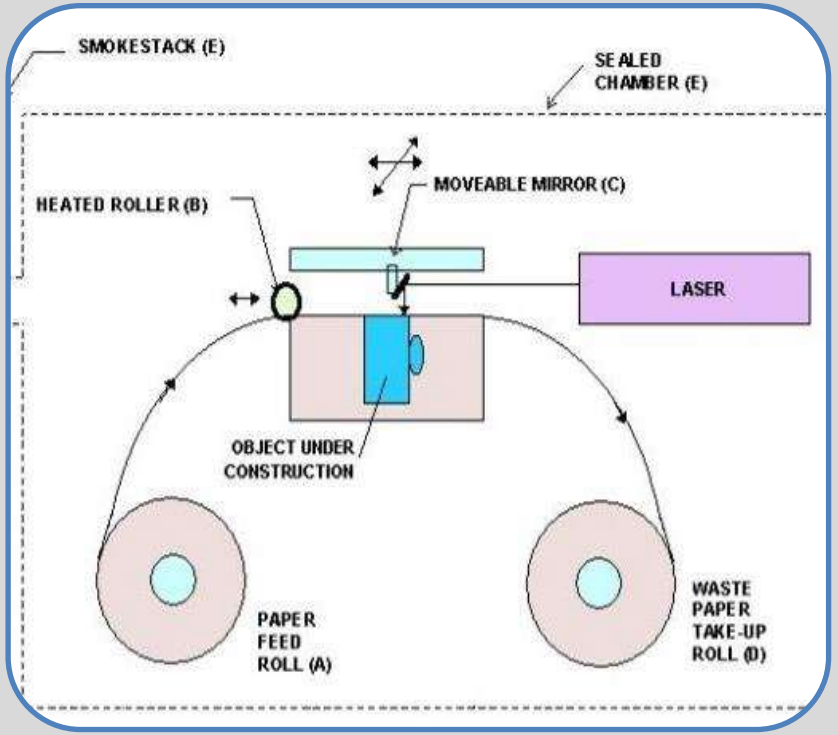
- Limited use in orthopedic devices



7. Sheet Lamination

Sheet Lamination: process in which sheets of material are bonded to form a part

- Not currently used in medical applications
- There is a bioprinting technology that uses this concept

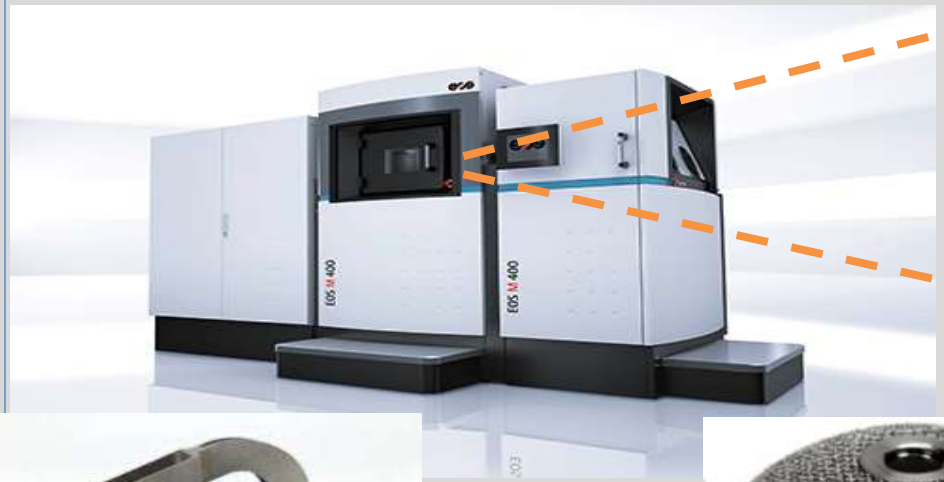


Knowledge Check 1

Which AM Technology has not been used to manufacture medical devices to date:

1. Powder Bed Fusion
2. Sheet Lamination
3. Vat Photopolymerization
4. Material Jetting

3D Printing in Medicine



Instruments/Guides

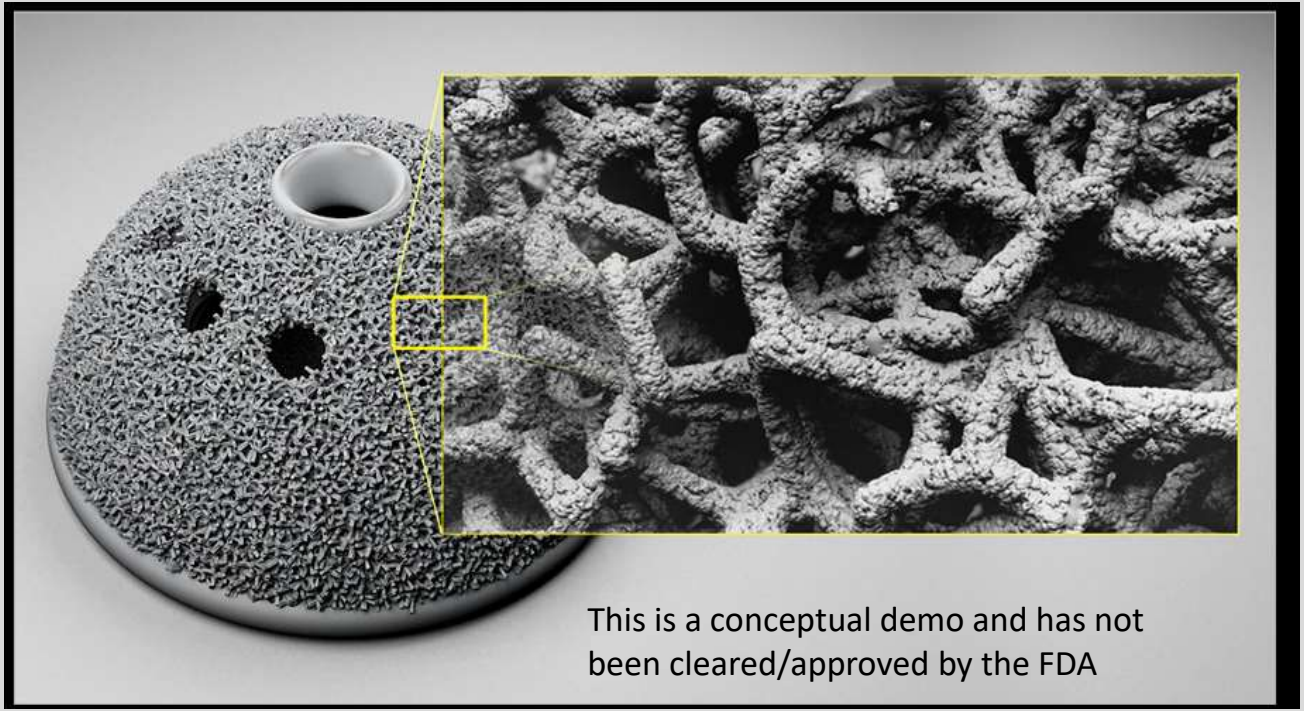
Medical Implants

Personalized Medicine

Complex Structures

- Within resolution, residual material removal, and support structure limitations, additive manufacturing is generally not affected by part complexity
- This allows for complex architecture to be engineered, complex structures to be seamlessly integrated to solid components, and more organic designs
- 68% of cleared AM implants utilized a complex or porous structure

Engineered Structures



www.withinlab.com/case-studies/index13.php

Personalized Medicine

- Pairing 3D imaging (CT, MRI, optical scanning) with 3D printing allows for personalized medical devices

- Incorporating virtual surgical software allows for personalized cutting guide and tools

Patient Matched Devices

K133809:

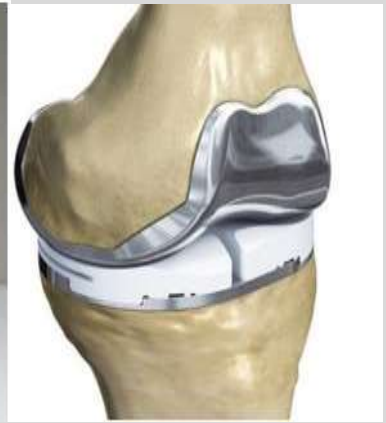
www.oxfordpm.com/news/article/2014-08-19_oxford_performance_materials_receives_fda_clearance_for_3d_printed_osteofab_patient-specific_facial_device.php

www.accessdata.fda.gov/cdrh_docs/pdf13/K133809.pdf

K121818:

www.oxfordpm.com/news/article/2013-02-18_osteofab_patient_specific_cranial_device_receives_510k_approval_-_osteofab_implants_ready_for_us_market_and_beyond.php

www.accessdata.fda.gov/cdrh_docs/pdf12/K121818.pdf



K122870:

www.conformis.com/customized-knee-implants/products/itotal/

www.accessdata.fda.gov/cdrh_docs/pdf12/K122870.pdf

Cleared AM Devices (2010 – 2016)

SCIENCE TRANSLATIONAL MEDICINE | PERSPECTIVE

REGULATORY SCIENCE

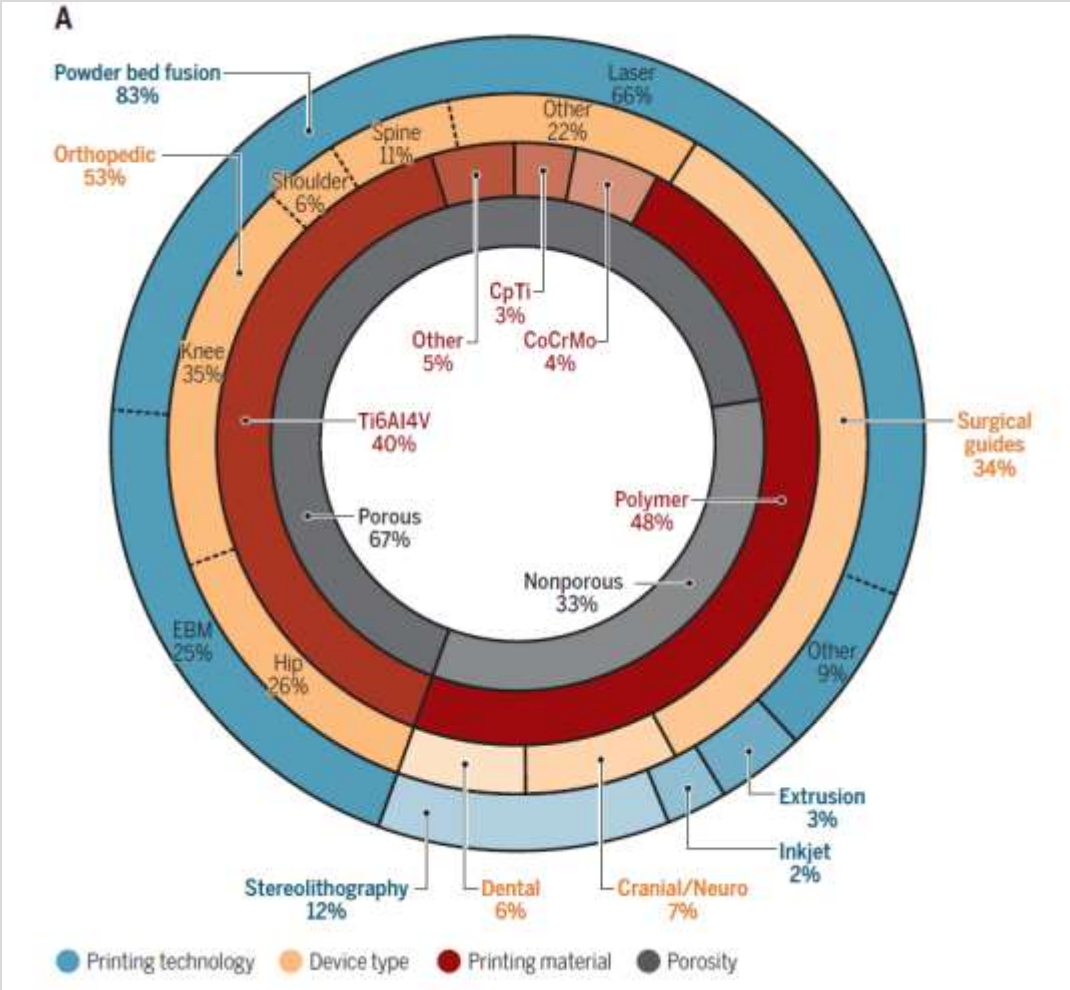
Regulating 3D-printed medical products

Laura M. Ricles[1,2], James C. Coburn[3], Matthew Di Prima[3], Steven S. Oh[1]*

Additive manufacturing [also known as three-dimensional (3D) printing] is the layer-wise deposition of material to produce a 3D object. This rapidly emerging technology has the potential to produce new medical products with unprecedented structural and functional designs. Here, we describe the U.S. regulatory landscape of additive manufactured (3D-printed) medical devices and biologics and highlight key challenges and considerations.

Review Methodology

- **Searched FDA database from 2010 – 2016 for the terms:**
  - Additive manufacturing
  - 3D Printing
  - Rapid manufacturing
  - Additive fabrication
  - Electron beam melting
  - Selective laser sintering
- **Manually verified and filtered**
- **Data de-identified and aggregated**



Analysis of 510(k)-cleared AM devices, from 2010 - 2016

Knowledge Check 2

Between 2010 – 2016, what statement about FDA 510(k) cleared AM device is false?

1. Powder Bed Fusion was the most commonly used technology
2. Knees were the most cleared AM product
3. Relatively few AM products made from polymers
4. Two thirds of implants had a porous structure

Technical Considerations for Additive Manufactured Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 5, 2017.

The draft of this document was issued on May 10, 2016.

Guidance Covers

- **Design and Manufacturing Considerations**
  - Provides technical considerations that should be addressed as part of QS requirements
  - QS requirements determined by existing regulatory classification/regulations
- **Device Testing Considerations**
  - Describes what AM specific information should be included in a premarket submission
  - Type of premarket submission is determined by regulatory classification

Guidance Sections

- **Design and Manufacturing Considerations (Post-market)**
  - Device Design
  - Software Workflow
  - Material Controls
  - Post Processing
  - Process Validation and Acceptance

- **Device Testing Considerations (Pre-Market)**
  - Performance Testing
  - Material Characterization
  - Removing Manufacturing Material Residue and Sterilization
  - Biocompatibility
  - Additional Labeling Considerations

Device Design

- **Motivation**
  - AM technologies have different design considerations
  - Patient matching is easier, accomplished through many methods
- **Technical Consideration**
  - Device description includes
    - Description of AM technology
    - Process flowchart
  - For patient matching
    - Describe patient-matched features
    - Provide design envelope

Material Controls

- **Motivation**
  - Final material is produced in the AM system
  - Quality and consistency of starting materials are very important
  - Each technology, process, and even intended use may have different material requirements
  - Material reuse can affect the final part

- **Technical Consideration**
  - Ensure starting material and re-use protocol (if applicable) will yield the appropriate physical and chemical properties

Performance Testing

- **Motivation**
  - Technology-specific concerns affecting performance of final finished device including
    - Orientation
    - Build location
    - Other parameters

- **Technical Consideration**
  - Part orientation and location should factor into worst case consideration for testing
  - Can leverage validation testing of system using representative coupons
  - **Looking to demonstrate that worst case device is being assessed**

Patient matching considerations

- Not custom devices
  - See §V.E of Custom Device Exemption Guidance
- Treated as a specified design envelope
  - Requires validation
  - Show Substantial Equivalence of worst case(s)
- Addresses patient matching in conjunction with AM
  - Does not address ***all*** concerns with patient matched devices

Knowledge Check 3

What does the 2017 AM Technical Guidance not cover?

1. Pre-market considerations for AM devices
2. Post-market considerations for AM devices
3. Policy on using AM to manufacturing devices at hospitals or other points of care

Summary

- We reviewed the 7 types of additive manufacturing technologies and their applications for medical devices
- Several types of medical devices use additive manufacturing, and notably with orthopaedic products
- FDA has published a guidance that outlines design, manufacturing, and device testing considerations for additive manufactured devices

Thank You and Questions!

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