3D Printing Medical Devices at Point of Care

CDRH Additive Manufacturing Working Group

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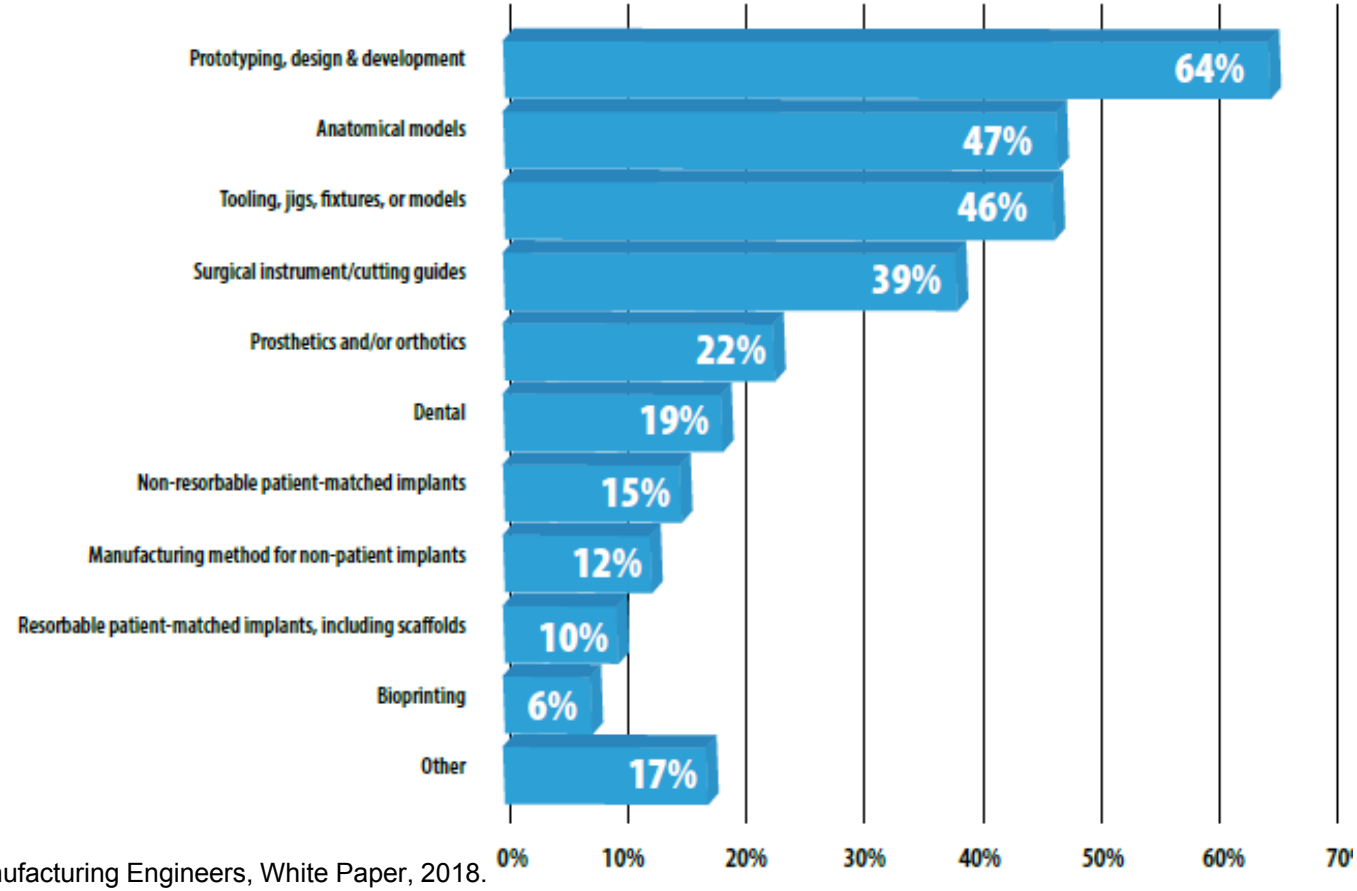
How it is being used at PoC



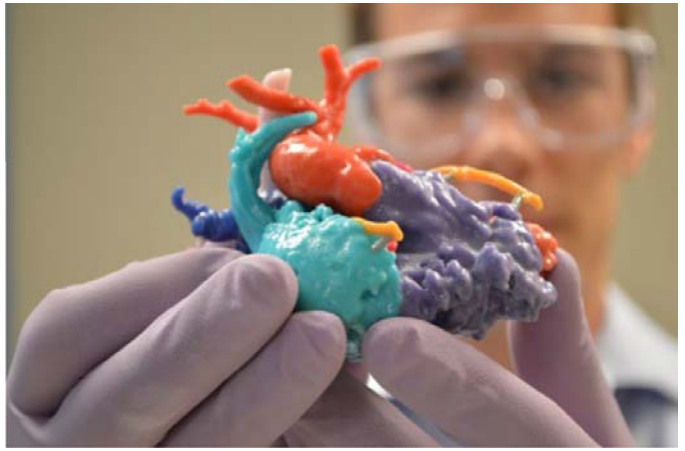
Society of Manufacturing Engineers, White Paper, 2018.
https://www.sme.org/smemedia/white-papers-and-reports/medical-additive-manufacturing-3d-printing-annual-report-2018/

3DP at PoC Conceptual Framework

- Availability of innovative products
- Safety and effectiveness regardless of how the product is manufactured
- Proper quality control so that product specifications are met and patient risk is minimized
- 3DP PoC personnel and organizations have necessary knowledge and expertise
- Clearly identified responsible party for activities during the medical device total product life cycle

Guiding Principles for Discussion

- Employ a risk-based approach
- Device specification are identified regardless of location of manufacture
- Capabilities available at a PoC can help mitigate production risks
- Entities should have clarity as to their responsibilities
- Leverage existing controls



Society of Manufacturing Engineers, White Paper, 2017. http://www.sme.org/POC/

Potential 3DP Scenarios

Scenario	Description
A	Minimal Risk 3DP by HCFP
B	Device designed by manufacturer using validated process • Turn-key system
C	Device designed by manufacturer using validated process • Additional HCFP capability requirements
D	Manufacturer co-located at PoC
E	HCF becomes a manufacturer
F	Others?

Scenario A - Concepts

Risk Level	Who Uses Printers
Minimal	HCFP

Minimal risk in terms of patient safety and ability to print

Society of Manufacturing Engineers, White Paper, 2017 http://www.sme.org/POC/

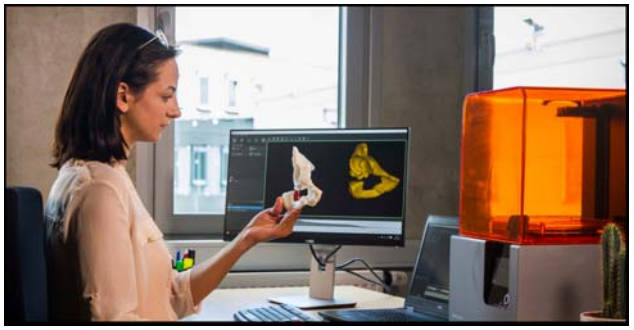
Scenario A – Concepts for Minimal Risk 3DP by HCFP at PoC

- Minimal risk of harm to patients
- Employ monitoring and risk mitigations strategies
- Leverage existing standards, certifications
- **Not intended for** implants, life-supporting / life-sustaining devices or devices that present a serious health risk to patients

Scenarios B and C – Concepts

- Device designed by Mfr to be printed by HCFP
- Cleared or approved based on validated 3DP process
- Workflow demonstrating that product specifications can be met when 3DP by end user

Scenario	Who Uses Printers
B – Automatic or self-contained post-processing steps (turn-key system)	HCFP
C – Additional HCFP capability requirements	HCFP



https://www.materialise.com/en/medical/software/materialise-mimics-inprint

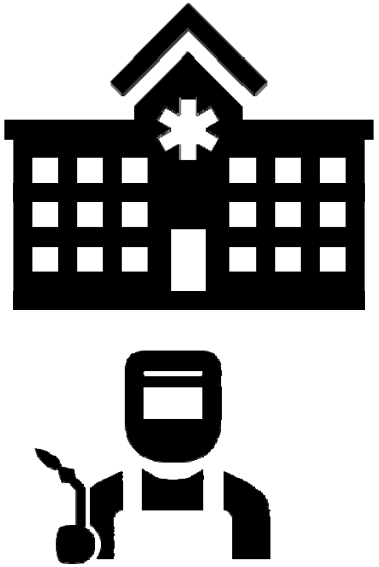
Scenario B – Concepts for Turn-Key 3DP Systems

- Device designed by manufacturer to be printed by the healthcare facility
- Uses a validated process that has been evaluated by FDA
- Post-processing steps are automatic or self-contained
- HCFP uses device consistent with cleared indications and manufacturer instructions for use

Scenario C – Concepts for 3DP Systems with Additional Processing

- More complex manufacturing and post-printing processes (e.g., machining, precision drilling, certain sterilization procedures, heat treatment)
- HCFP would have to have appropriately trained personnel and proper equipment
- Labeling, training, instructions for calibration, testing on-site, facilitate appropriate 3DP by HCFP

Scenarios D and E - Concepts



Scenario	Who Uses Printers
D – Mfr or contract manufacturer co-located at PoC	Mfr and/or Contract
E – HCFP chooses to become a Mfr (develop, test, print)	HCFP

Scenario D – Concepts for Manufacturer Co-located at PoC

- HCFP doesn't intend to setup and manage their own 3DP facility or devices are not minimal risk

- 3DP performed by traditional manufacturer, contract manufacturer, or other 3rd party using their equipment and personnel

Scenario E – Concepts for HCFP as a Traditional Manufacturer

- HCFP desires to design and control own 3DP operations and device is not minimal risk
- HCFP responsible for development/design, testing, and printing
- HCFP responsible for all regulatory requirements

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We would like to hear your **comments and questions** about these ideas. Please send them to the email address above

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- www.fda.gov/3DPrinting


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