3-Defining Patient-Matched Implants

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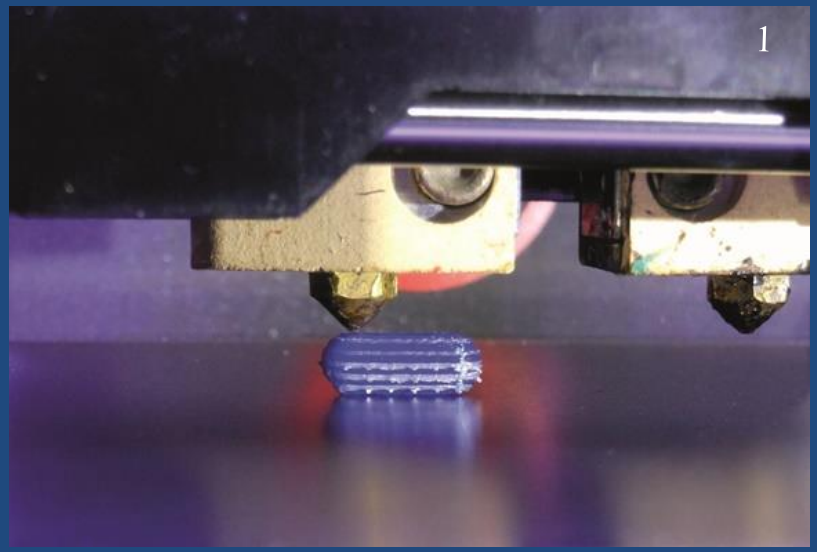
Regulatory Science Priority Area

4. Ensure FDA Readiness to Evaluate Innovative Emerging Technologies
    3. Assure safe and effective medical innovation
        c. Help stimulate the development, standardization, and validation of new techniques to assess safety and effectiveness

Additive Manufacturing



Current Applications in Medical Industry:

- Orthopaedic and Cranial Implants
- Dental Restorations and Crowns
- Surgical Instruments
- Pharmaceuticals

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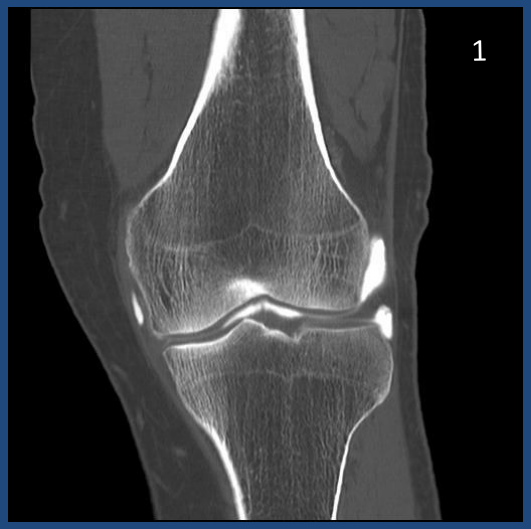
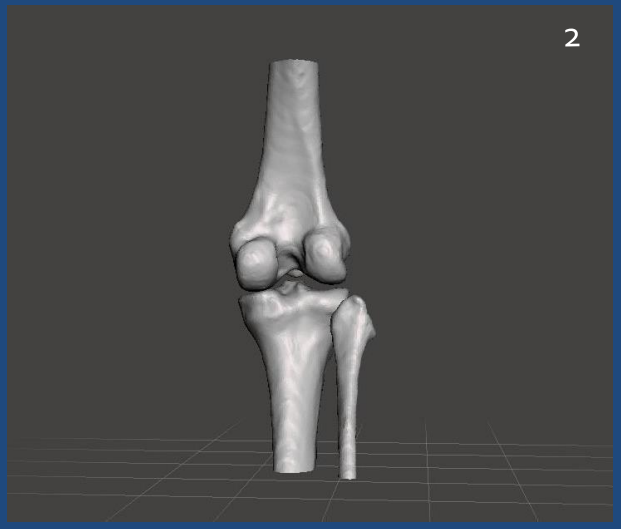
1. Pharmaceutical Journal 2015
2. BBC News 2012

Patient-Matched Implants





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1. UW Radiology
2. CGTrader
3. Conformis

FDA Draft Guidance

FDA May 2016:
"Technical Considerations for Additive Manufactured Devices"

Industry Response:

- *Ambiguity* – which regulations relate to patient-matched devices vs. AM?
- Call for *separate guidance document* for patient-matched devices

Johnson & Johnson

stryker®

zimmer
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Test Coupons

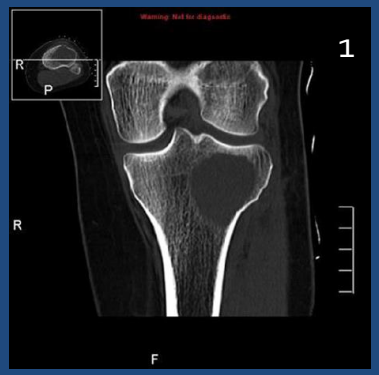
- Sample component created during the final print of the product for the purpose of destructive testing
  - Process validation or worst-case scenario build conditions
  - Simple geometry coupons are validated to be representative of the final device for standard sizes

The Problem…

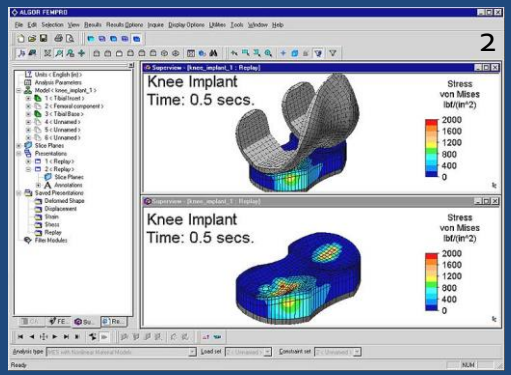
- Patient-matched implants introduce unique geometry in every implant due to variable anatomy
  - Simple geometry is not validated to be representative of this unique system
  - This new geometry may have different failure points than the test coupons, which can lead to safety concerns

Our Proposal: I-MATE

I : *Image*
M : *Model*
A : *Assign*
T : *Test*
E : *Evaluate*



1. Obtain patient geometry



2. Perform FEA to determine weakest part of implant

3. Duplicate weak component on build volume

4. Perform destructive testing of weak component

5. Evaluate and document results

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1. Beth Israel Deaconess Medical Center, 2017
2. Algor Inc. 2017
3. Stryker 2017
4. EndoLab 2017

Deliverables

- I-MATE: Streamlined quality process recommendation specific to Patient-Matched Implants
- Helps to ensure safety and effectiveness of each individual implant
- Clarifies ambiguity of current FDA Draft Guidance

Questions?

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