

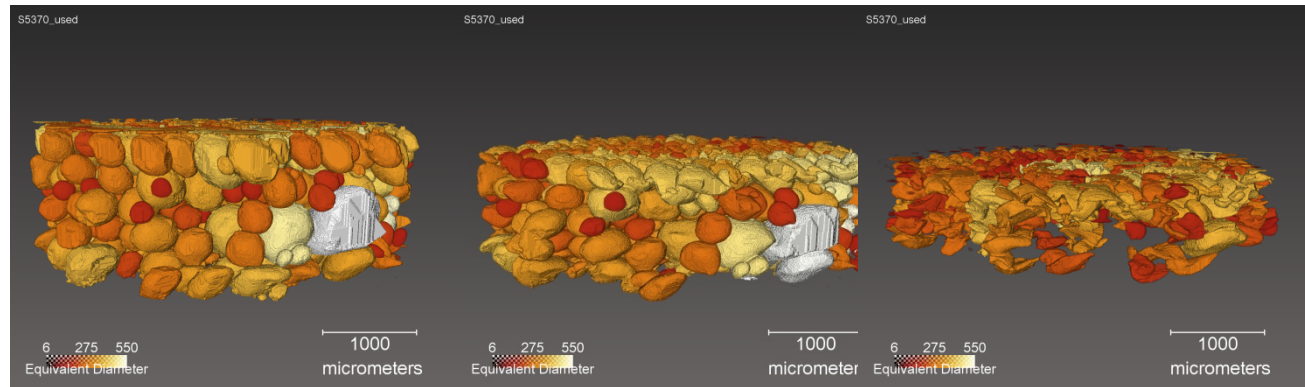
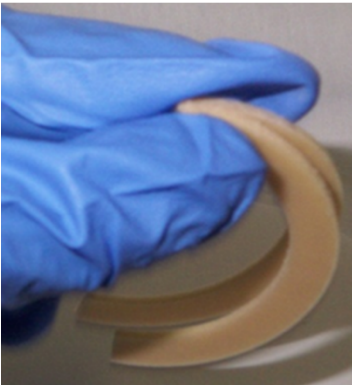
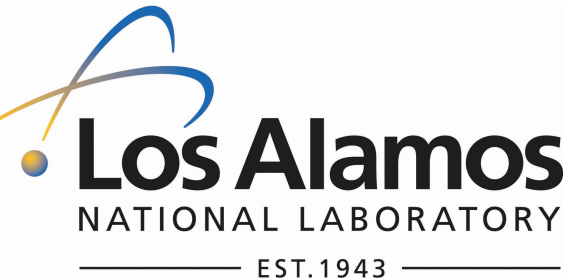


# Materials, Medicine & Manufacturing: *Materials Awareness and Selection*

**Dr. Crystal G. Morrison**  
Principal Investigator and Senior Materials Scientist

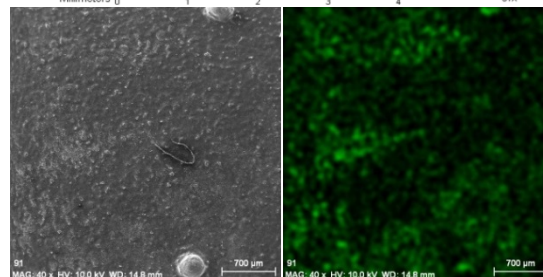
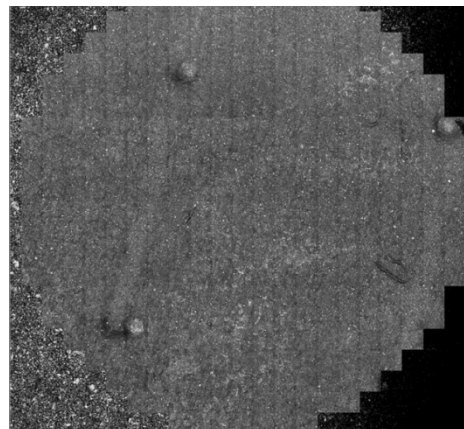
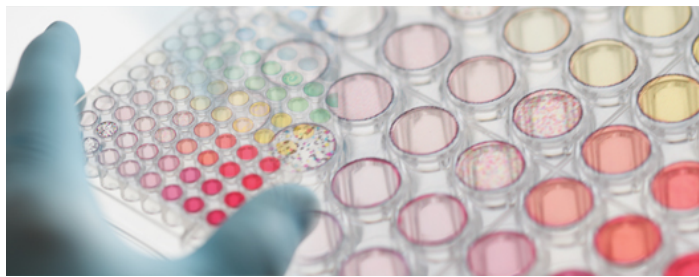
# Dr. Crystal G. Morrison

- Ph.D. – University of Michigan
- Postdoc – Agnew National Security Fellow at Los Alamos National Laboratory (LANL)
- Lead Polymer SME for LANL Nuclear Weapons Program



# Dr. Crystal G. Morrison

– Technical Lead for Polymeric Materials



# Additive, Military and Medicine?

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- Additive Manufacturing Direction

- Rapid prototyping ...
- Novel designs...

BUT,

- Increasing interest and focus on using AM for high value, high performance, critical parts and assemblies





# Materials Emphasis

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- AM Trend:
  - High Value and Performance
- AM Focus:
  - Materials → Processes → Product V&V
- Materials understanding across the lifecycle of the product

*Awareness of Considerations Unique to  
the AM Community*



# Possibilities and Questions

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I've made a zillion rapid prototypes with this material.  
I can move forward with production, right?

ABS, ABS “like”, medical grade, food grade... it's all the same. Or is it?

I have years of data on this device design made with X plastic using injection molding. I'm going to use X plastic with an AM method. Do I really need testing?

I buy my powdered raw materials from X, who gets them from Y, who is a distributor for Z. I think it's good stuff. Right?



# Response

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Don't assume or underestimate!

**Q:** Where do I start when selecting polymeric materials for an AM-produced device?

**A:** Use systematic materials assessment with focus on Requirements, Materials Screening, and Manufacturability



# Moving forward...

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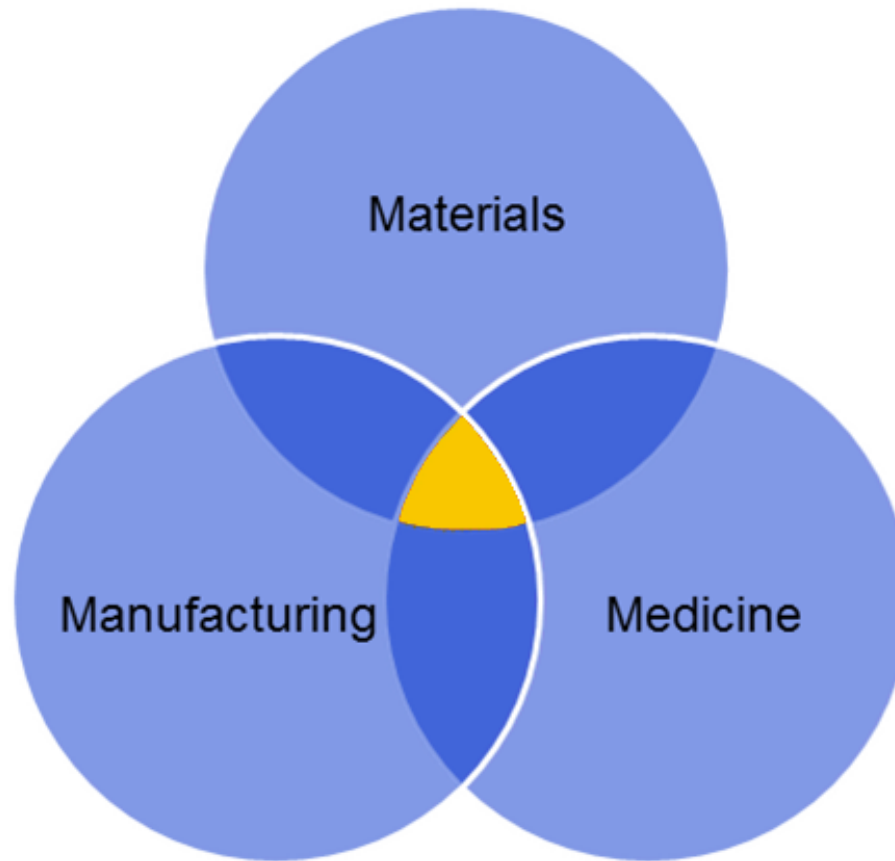
- Polymers and Plastics in Medical Devices
  - Emerging Considerations
- Selection Process Overview
- Considerations for Additive Manufacturing
  - Requirements
  - Material Screening
  - Manufacturability
  - Ranking
- Summary





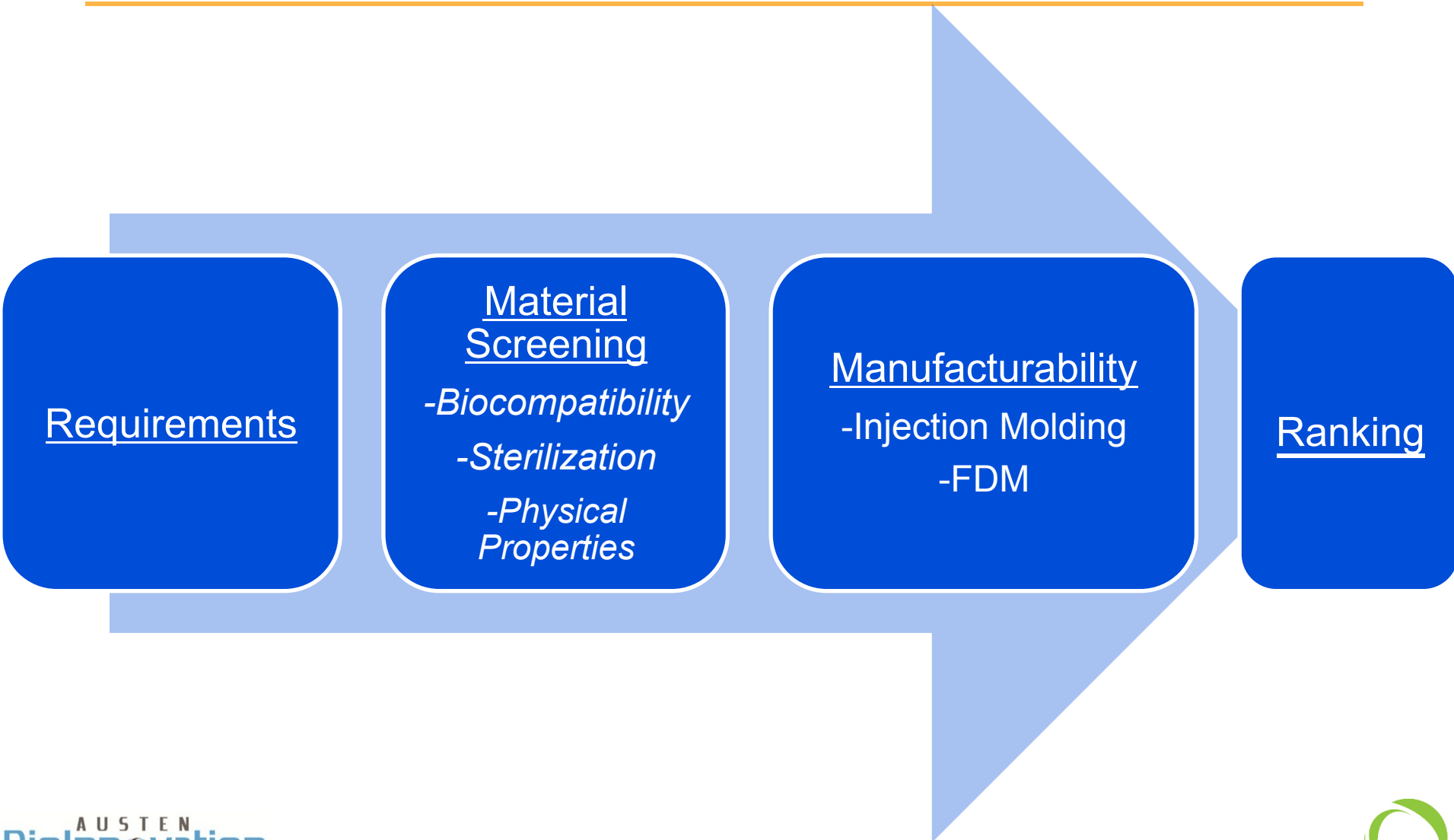
# Emerging Considerations

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# Selection Process Overview

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Requirements

Material  
Screening

- Biocompatibility*
- Sterilization*
- Physical Properties*

Manufacturability

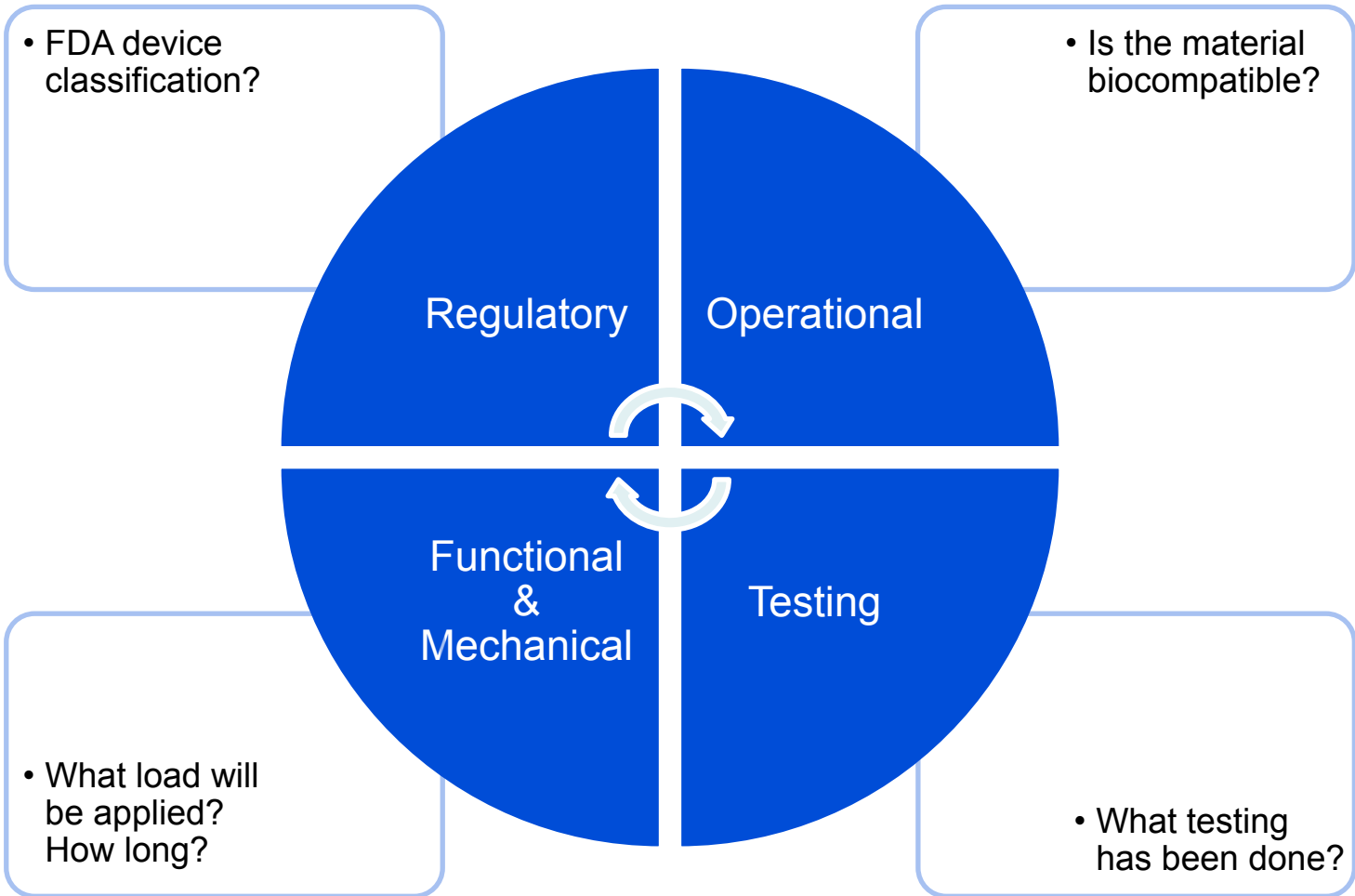
- Injection Molding
- FDM

Ranking



# Requirements

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Requirements

Material  
Screening

*-Biocompatibility*  
*-Sterilization*  
*-Physical  
Properties*

Manufacturability

*-Injection Molding*  
*-FDM*

Ranking



# Materials Screening

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- Biocompatibility
  - USP Class VI
  - ISO 10993
    - Nature of physical contact vs biological risks
    - Cytotoxicity, Sensitization, Irritation



Limited selection of  
materials for AM now...  
but not for long.



# Materials Screening

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- Select VisiJet® clear materials
- Accura® ClearVue and Y-C 9300R
- Dreve Fototec hearing aid material
- DuraForm® PA and PRO



- Somos® materials
  - Watershed XC11122
  - ProtoGen 18420
  - BioClear



- Select e-Shell materials



- PA 2200



Fortus®

- PC-ISO
- ABS-M30i

Objet

- MED610



- OXPEKK®

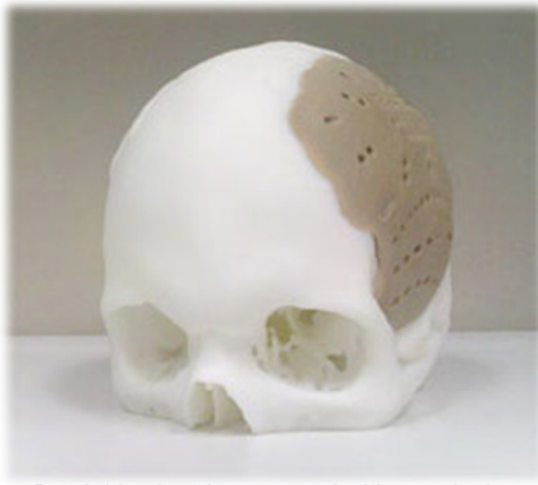
List compiled by Sam Anson for Medical Plastics News.



# Materials Screening

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- The first FDA approval for an additively manufactured polymer implant was Oxford Performance Material's OsteoFab® cranial device made from PEKK
- FDA 510(k) clearance for its 3D printed OsteoFab® Patient-Specific Facial Device (OPSFD).



Images used with  
permission by OPM





# Materials Screening

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- Sterilization

- Radiation (gamma/e-beam)
- Chemical (EtO)
- Autoclave (steam)



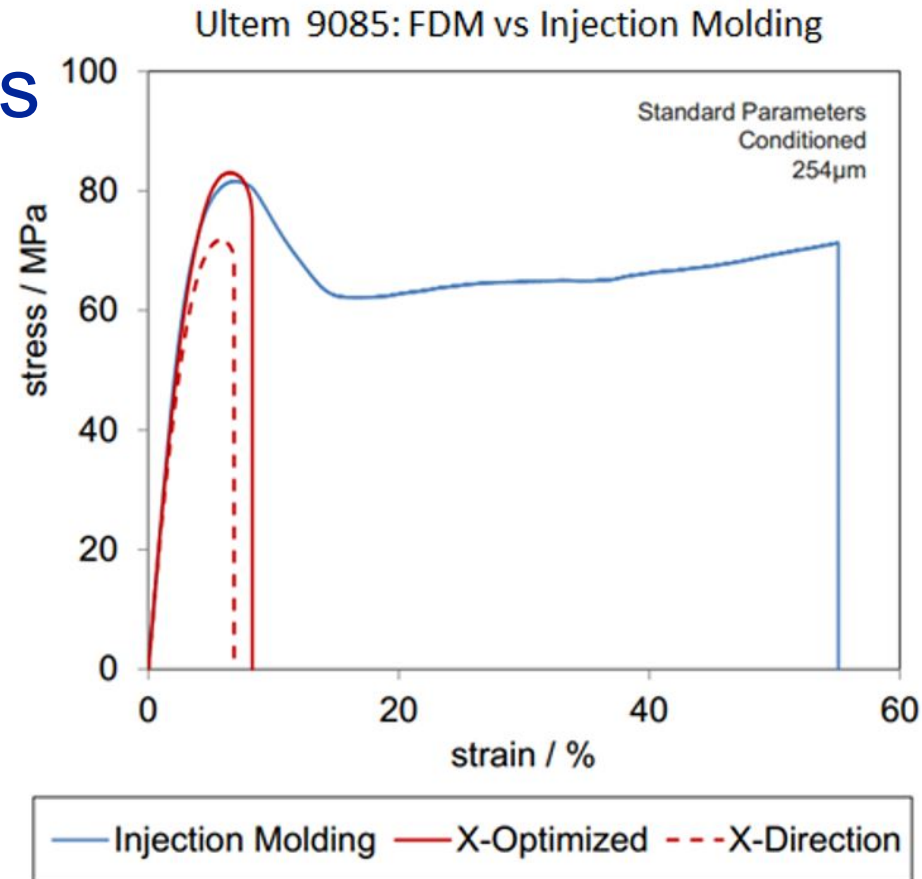
- Chemical Resistance

- Isopropyl Alcohol
- Bleach
- Peroxides

# Materials Screening

- Mechanical Properties

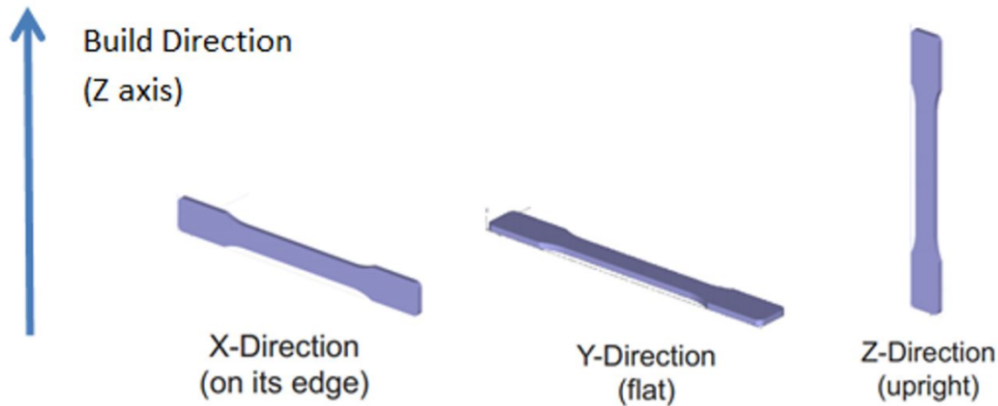
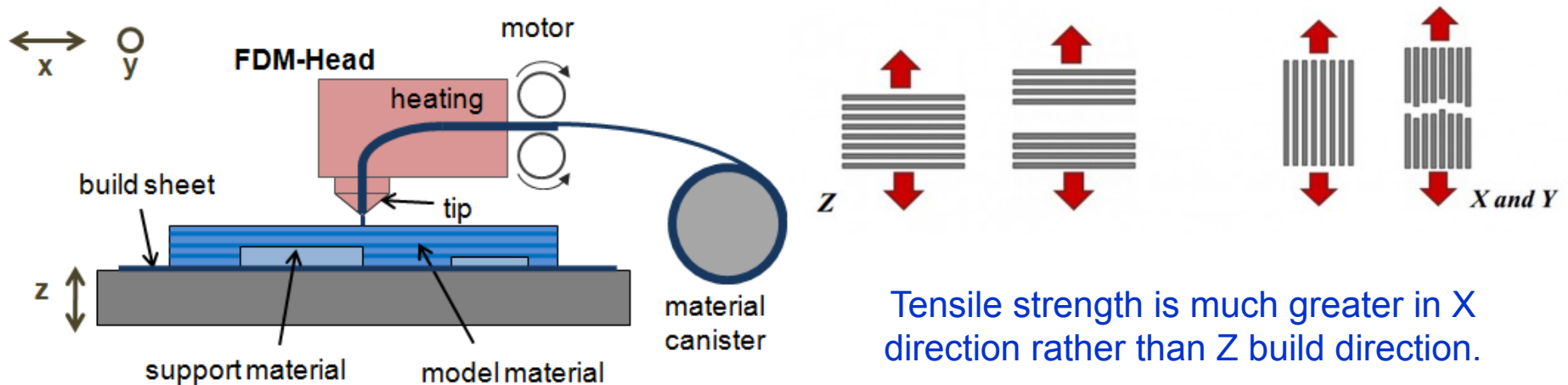
- Conventional vs. Additive
- Ultem® amorphous thermoplastic polyetherimide (PEI) resin family from SABIC



*Research from Fischer and Josupeit at  
Direct Manufacturing Research Center  
(DMRC) in Paderborn Germany*



# Materials Screening



Research from Fischer and Josupeit at Direct Manufacturing Research Center (DMRC) in Paderborn Germany

# Materials Screening

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- Wear Resistance
  - Mechanical properties can be different
  - Surface properties and wear debris
  - Other factors
    - Pairs (combination of materials in contact)
    - Conditions (wet or dry)
    - Configurations (rotating, sliding, oscillating)

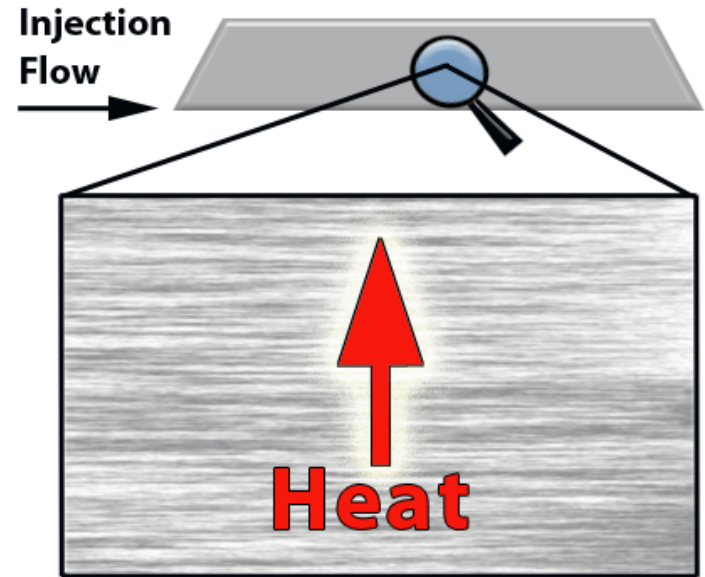




# Materials Screening

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- Thermal Properties
  - Filler
  - Orientation
  - Crystallinity
  - Conventional vs. Additive



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Requirements

Material  
Screening

*-Biocompatibility*  
*-Sterilization*  
*-Physical  
Properties*

Manufacturability

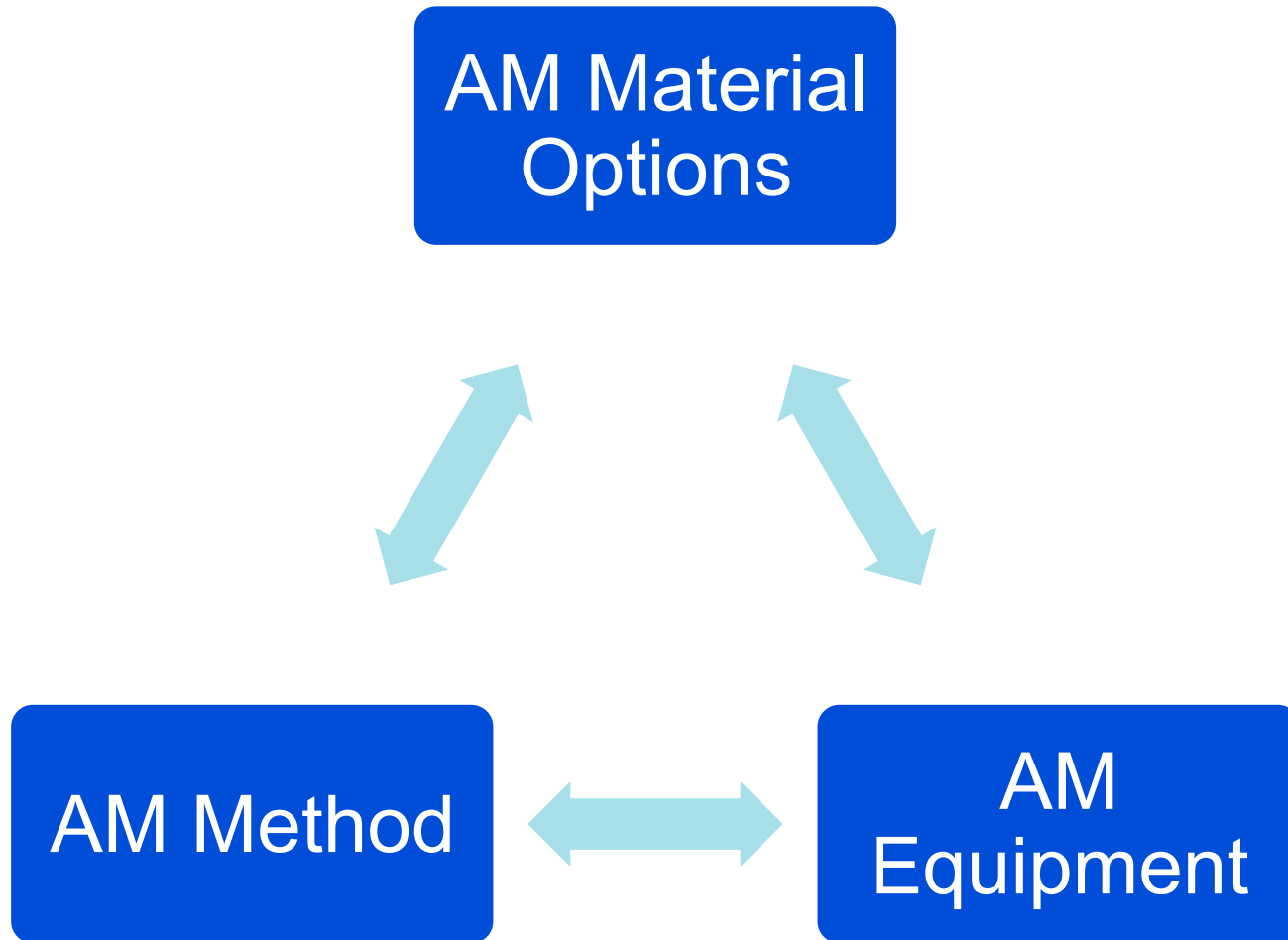
*-Injection Molding*  
*-FDM*

Ranking



# Manufacturability

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# Impact

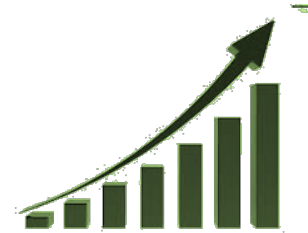
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**Schedule**



**Testing**



**Success**



**Design**



**Process  
Improvement**



**Troubleshooting**



# Impact – Manufacturer Liability

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- Biomaterials Access Assurance Act (BAAA) of 1998
- Responsibility and liability for the device performance
- High quality materials and testing



# Summary/Conclusion

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- Landscape is exciting... and overwhelming
- Awareness of materials considerations
- Systematic assessment
- Requirements, Materials Screening, Manufacturability
  - Simultaneous, Evolving Dialogue
- Impact



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# Questions?





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“Creating Vision Across the Polymer Lifecycle” published  
September 11<sup>th</sup>, 2013



# Materials Screening

