AI SUMMIT

COLUMBUS, OH • OCTOBER 25–27, 2022

HOW AI CAN BE USED IN 3DP AND SMART MANUFACTUING:

FROM THE PERSPECTIVE OF INDUSTRY, HEALTH SYSTEMS, AND ACADEMIA

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

AFDO RAPS

AI SUMMIT
COLUMBUS, OH • OCTOBER 25–27, 2022

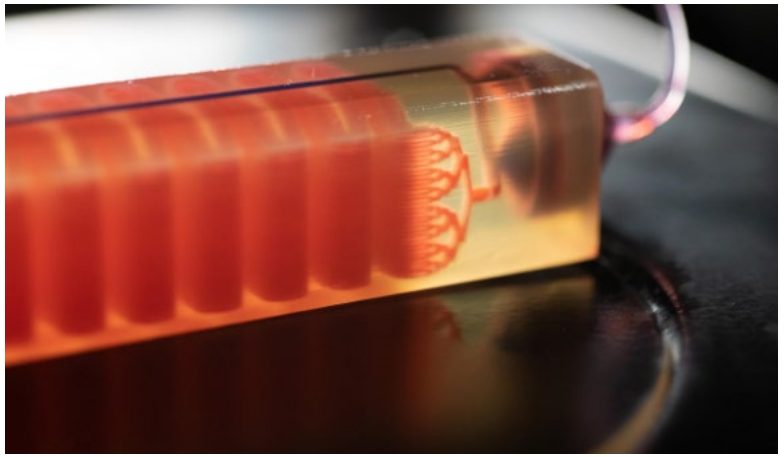
Lacey Harbour
Regulatory Manager,
Thermo Fisher

Todd Goldstein
PhD - Director, 3D
Design and
Innovation
Northwell Health

Federico Anzil
Advanced Technology &
Digital Manufacturing
Manger
LimaCorporate

The Future of Medicine is Precise, Personal, and POC

- With 3DP Applications in:
  - Bioprinting/ tissue engineering and implants
  - Oncological microfluidics (microprinting)
    - Diagnosis, modeling, and drug delivery
  - Pharmaceuticals
  - Orthopedic implants, surgical guides, and surgical models
  - Dental applications



AI SUMMIT
COLUMBUS, OH • OCTOBER 25–27, 2022

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.

For questions about this document regarding CDRH-regulated devices, contact the Division of Applied Mechanics at (301) 796-2501, the Division of Orthopedic Devices at (301) 796-5650, or Matthew Di Prima, Ph.D. at (301) 796-2507 or by email matthew.diprima@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

FDA U.S. FOOD & DRUG ADMINISTRATION

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

AFDO RAPS

Four Challenges with Dimensions of Risk

- Assuring devices 3D printed at the PoC are safe and effective
- Assuring appropriate control of devices 3D printed at the PoC
- Clarifying the responsible entity
- PoC training and capabilities

Definitions

- **Point of Care (PoC) 3D printing facility** – the physical location near or at the site of a patient (e.g., hospitals, ambulatory surgical facilities, outpatient treatment facilities, physicians' offices, or certain dental laboratories) that 3D prints medical devices.
- **3D printing medical device production system (MDPS)** – a collection of the raw materials, software and digital files, main production equipment and post-processing (if applicable) equipment intended to be used by a healthcare provider or healthcare facility, to produce a specific type of medical device at the point of care, for treating or diagnosing their patients, or preventing or mitigating disease, or to affect a structure or function of the body. An MDPS includes the medical device it is intended to produce.

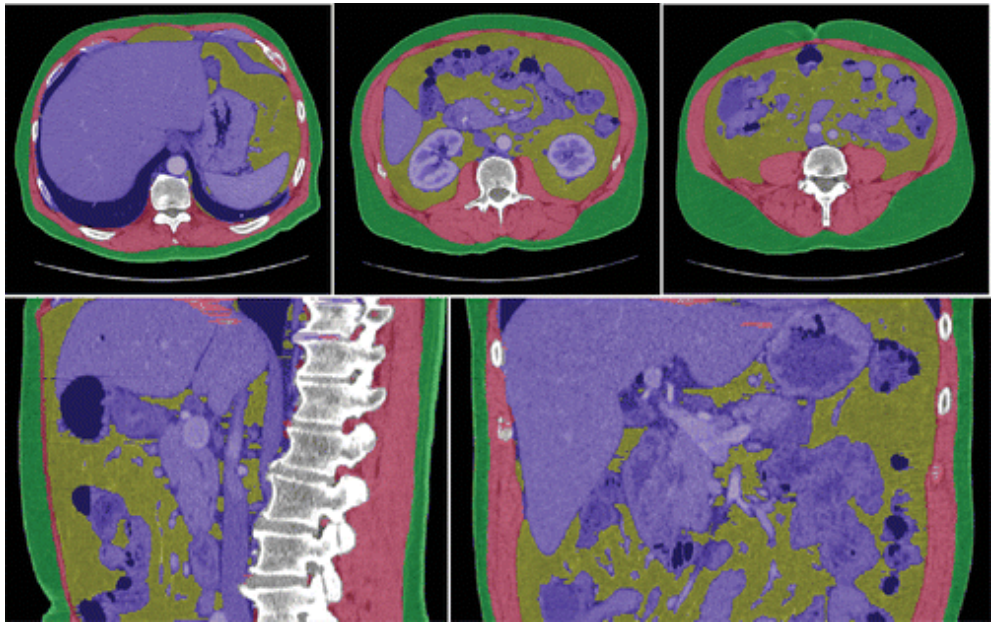
AI SUMMIT
COLUMBUS, OH • OCTOBER 25–27, 2022

For MDPS to be truly POC, AI is necessary.

Examples from academia and industry

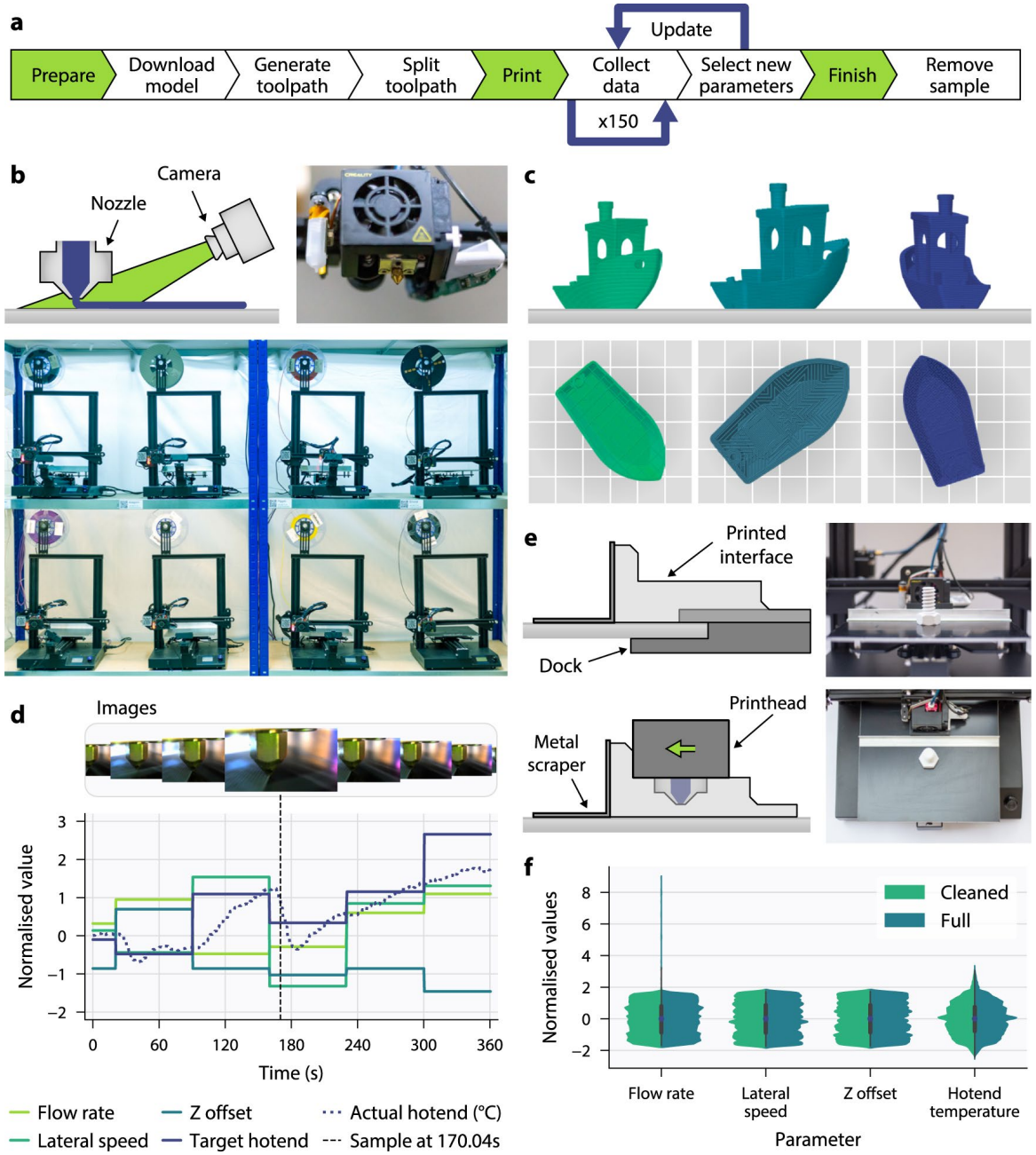
Segmentation with DL

Automated Abdominal Segmentation of CT Scans for Body Composition Analysis Using Deep Learning, Erickson et. al., 2019



Continuous Process Monitoring and Error Prevention

Generalisable 3D printing error detection and correction via multi-head neural networks Pattinson, S.W., Brion, D.A.J., 2022

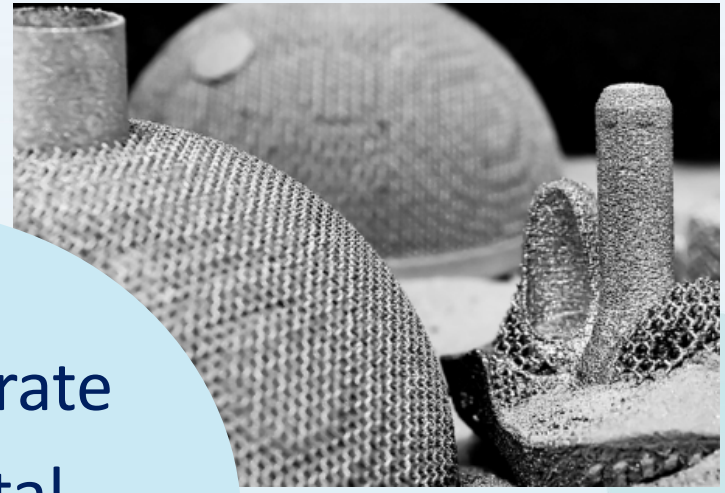


AI SUMMIT
COLUMBUS, OH • OCTOBER 25–27, 2022

Two Use Cases

Northwell Health

(In-Hospital Engineering/ Acedemia)



LimaCorporate

(In-Hospital Medical Device Manufacturer)

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

AFDO RAPS

AI SUMMIT

COLUMBUS, OH • OCTOBER 25–27, 2022

In-House Design and 3D Printing

Todd Goldstein PhD

Director 3D Design and Innovation

AVP Joint Venture Operations

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

Northwell Health®

- We're a network of collaborators, research pioneers, entrepreneurs and educators that is 80,000 strong. As the largest health system in New York, we are privileged to treat more New Yorkers—over two million each year—than anyone else.* Caring for so many of our own is how we’re helping to create a brighter tomorrow

A mission to serve

Northwell Health®

At Northwell, we strive to improve the health of the communities we serve and are committed to providing the highest quality clinical care; educating the current and future generations of healthcare professionals; searching for new advances in medicine through the conduct of biomedical research; promoting health education; and caring for the entire community regardless of the ability to pay.

80,000+
Employees

Work at Northwell

850+
Hospitals and care centers

Explore locations

4,200
Physicians

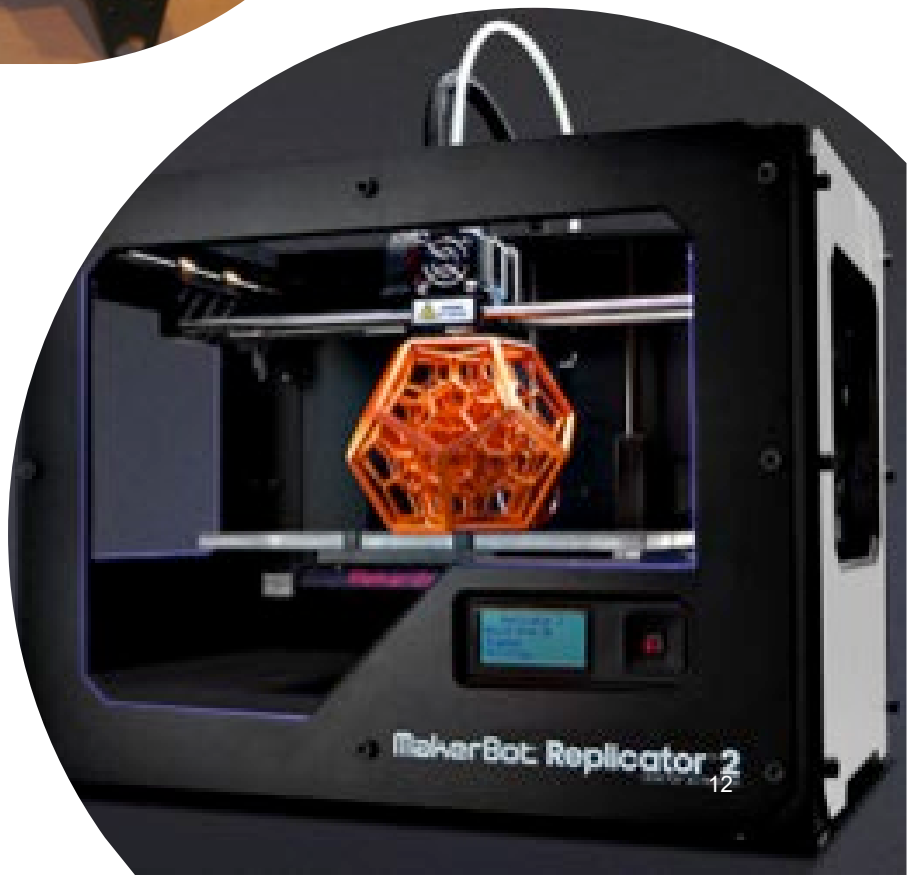
Find a doctor

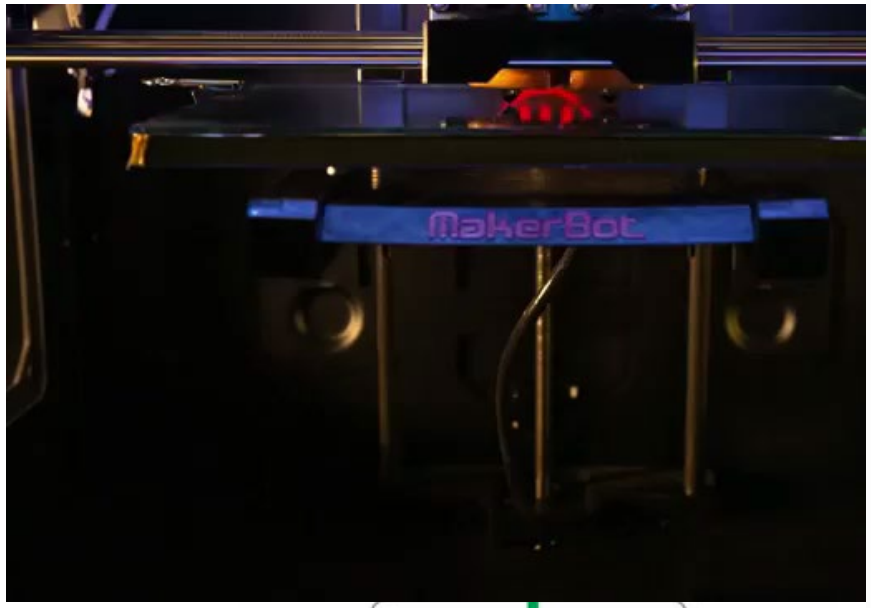
$1.44b
Contributed

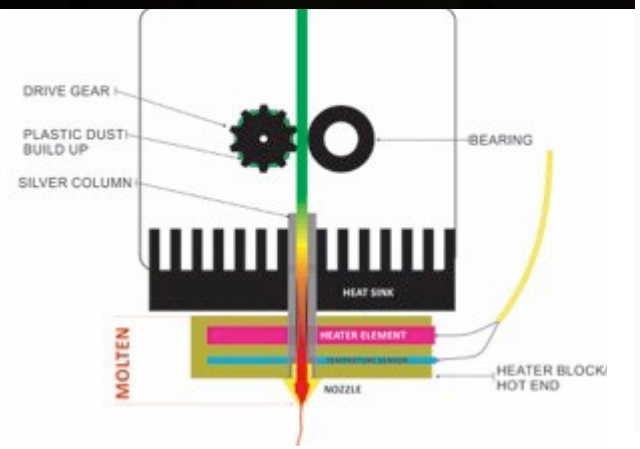
Community initiatives

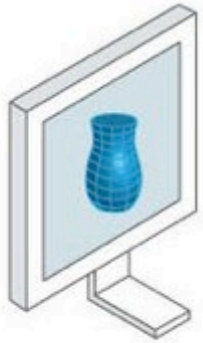
3D Printing

- Process for making a physical object from a three-dimensional digital model, typically by laying down many successive thin layers of a material, however many other printing processes exist.



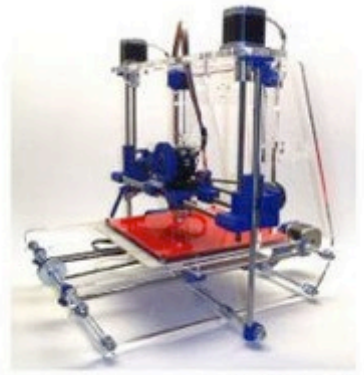




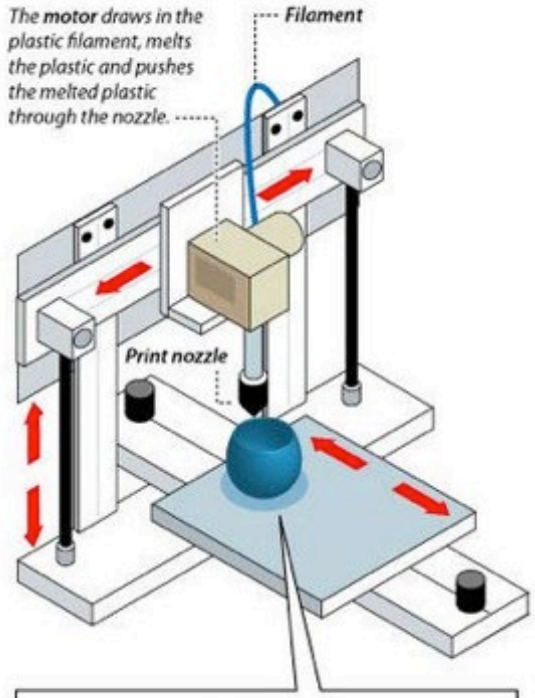


1 A 3D image is created using a computer-aided design software.

2 The CAD file is sent to the printer.



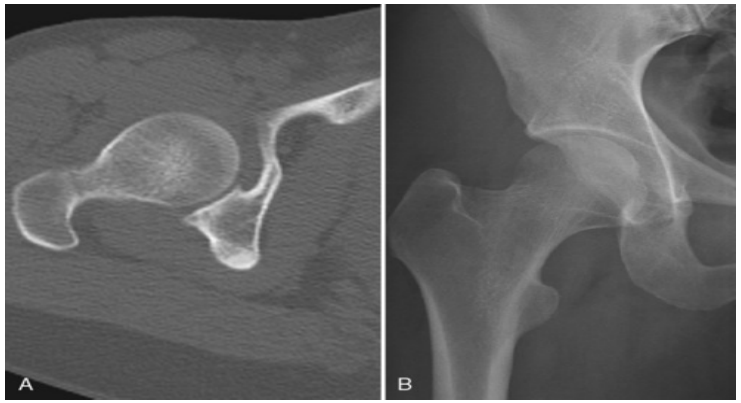
Credit: airwolf3d.com

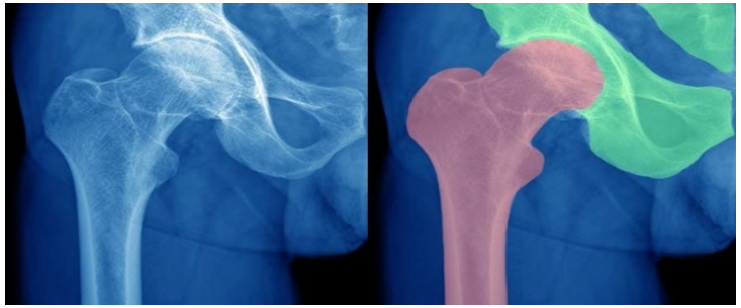


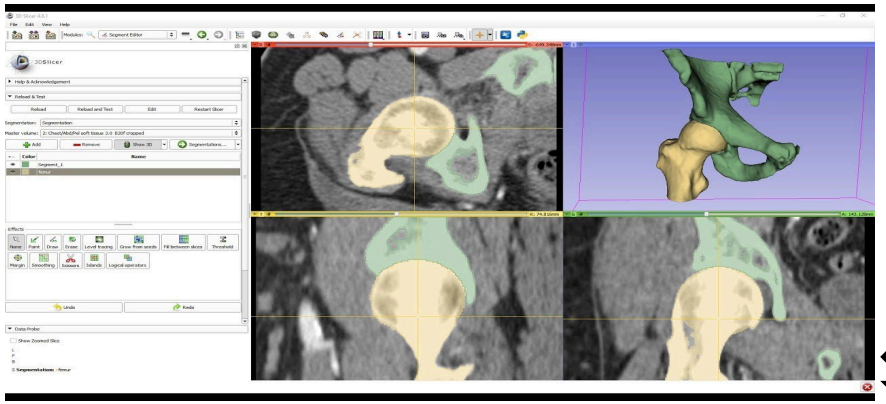
3 The printer lays down successive layers of liquid, powder, paper or metal material and builds the model from a series of cross sections.

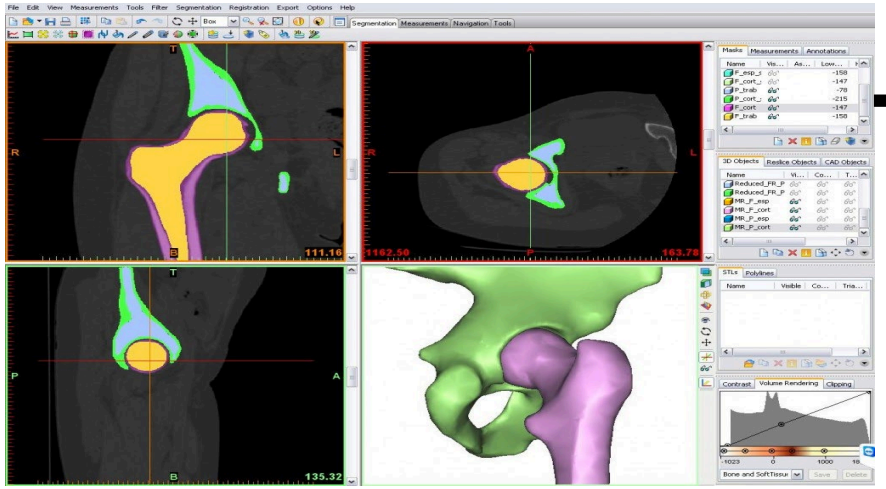
- Take your pick of brand / model

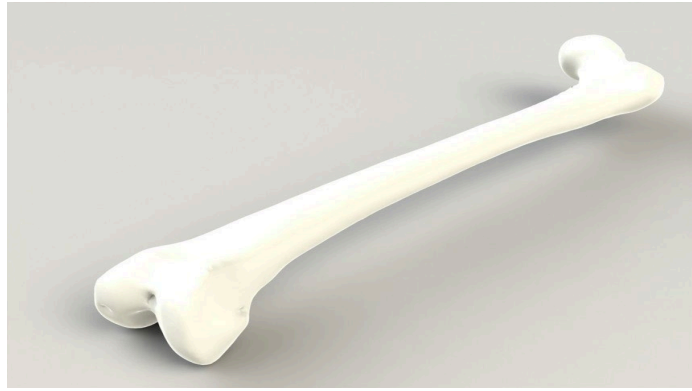
Segmentation

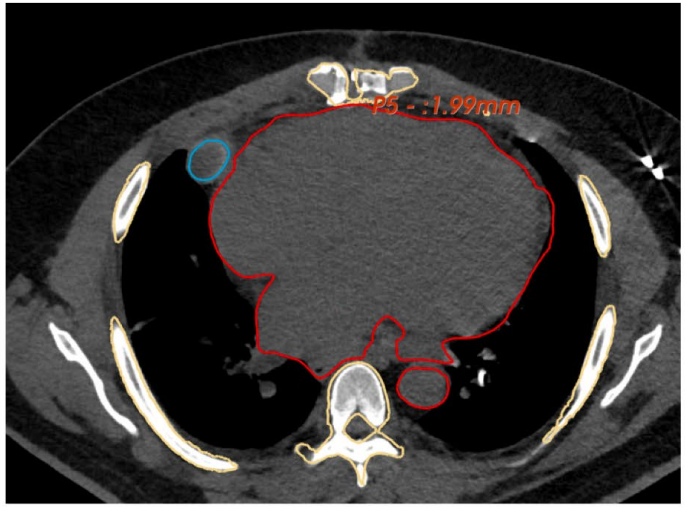
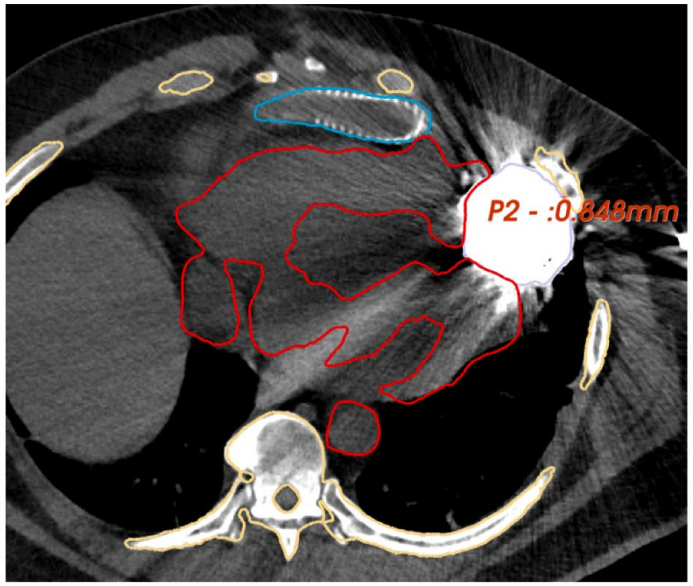






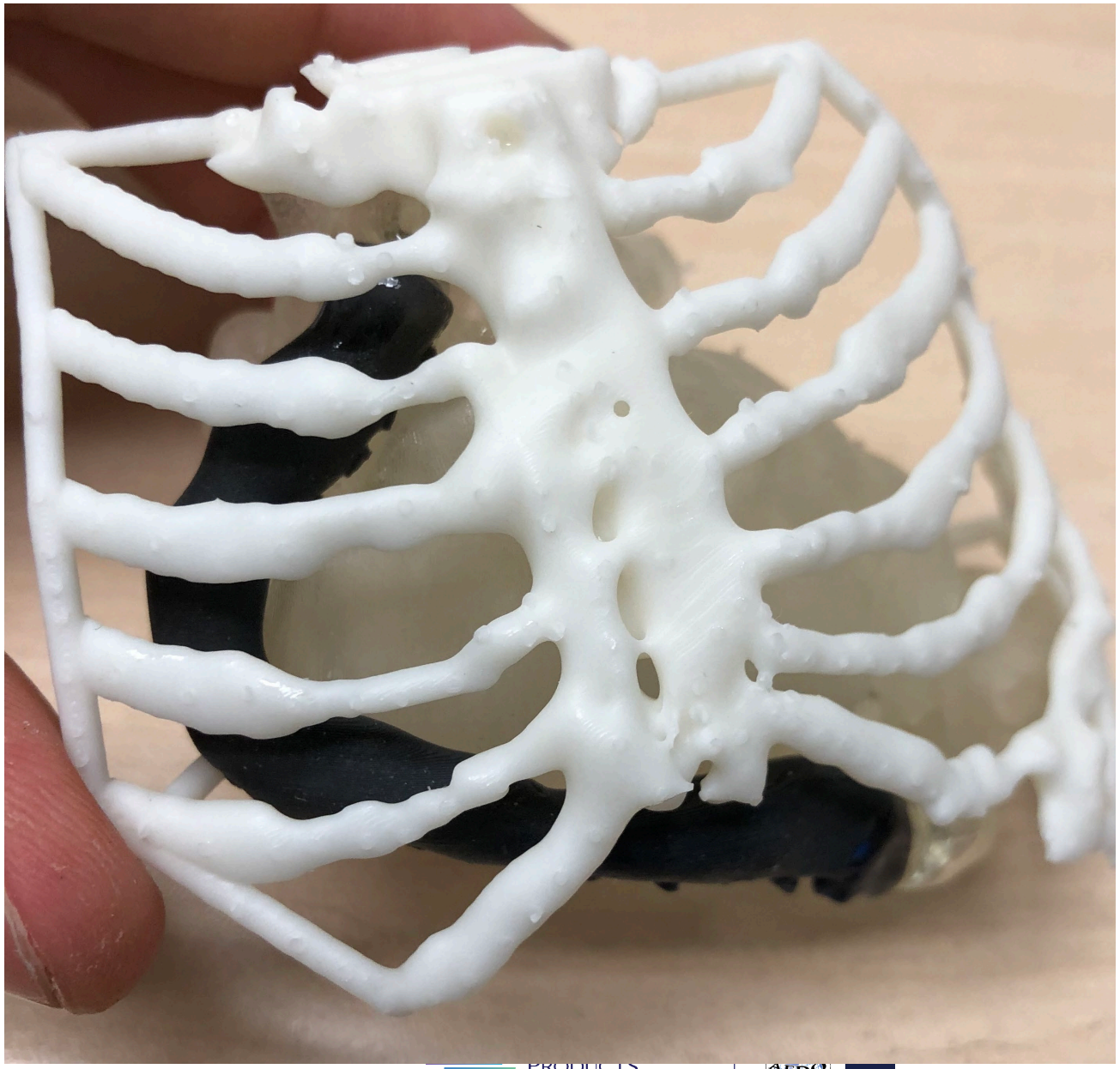




P5	1.991 mm	Distance from mediastinal structures to the posterior sternum	
P2	0.848 mm	Distance from Pump to Rib	

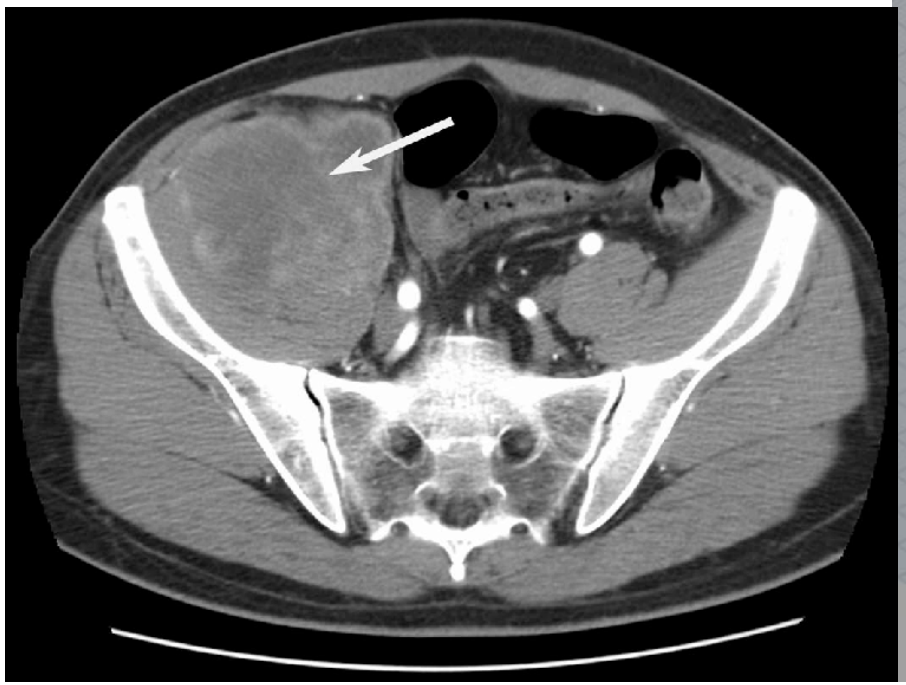
AI SUMMIT
COLUMBUS, OH • OCTOBER 25–27, 2022

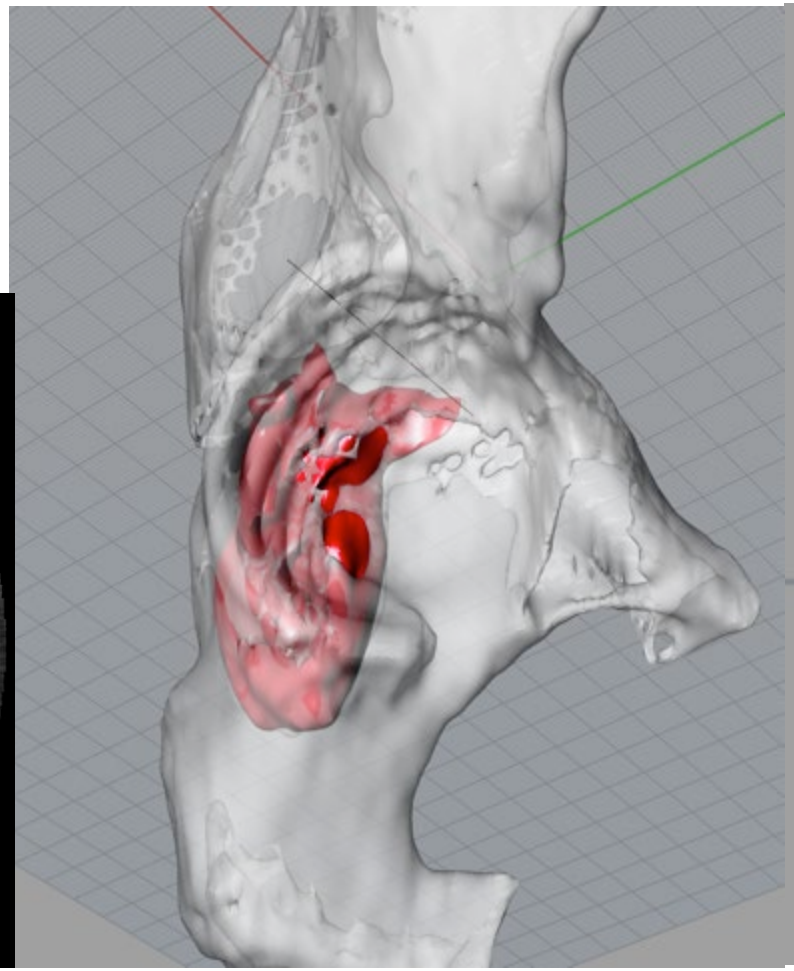
LVAD Surgical Planning Model

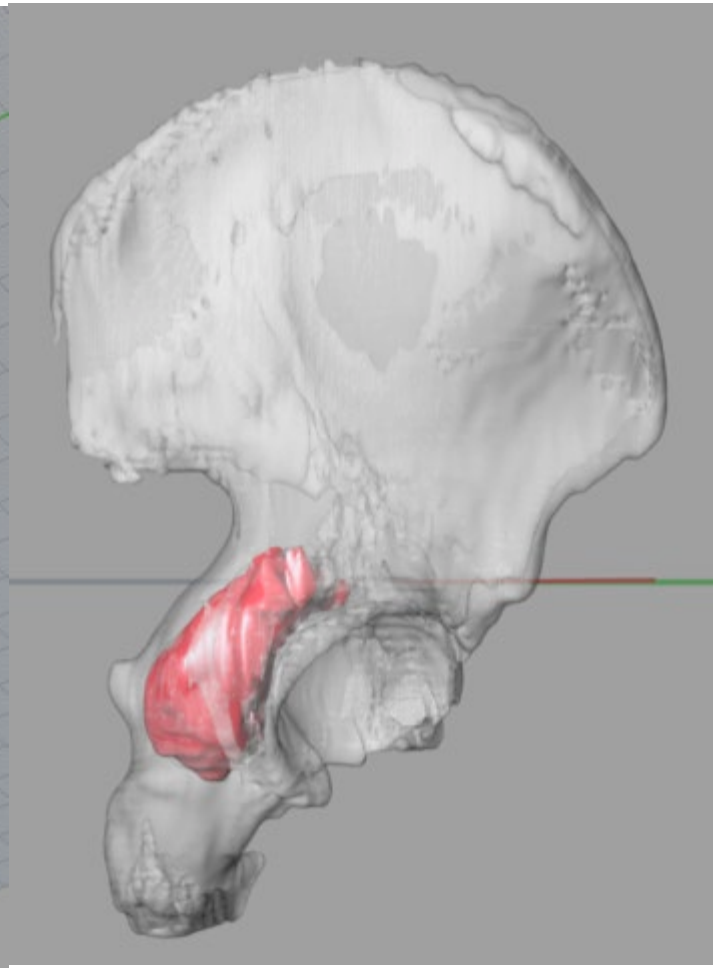


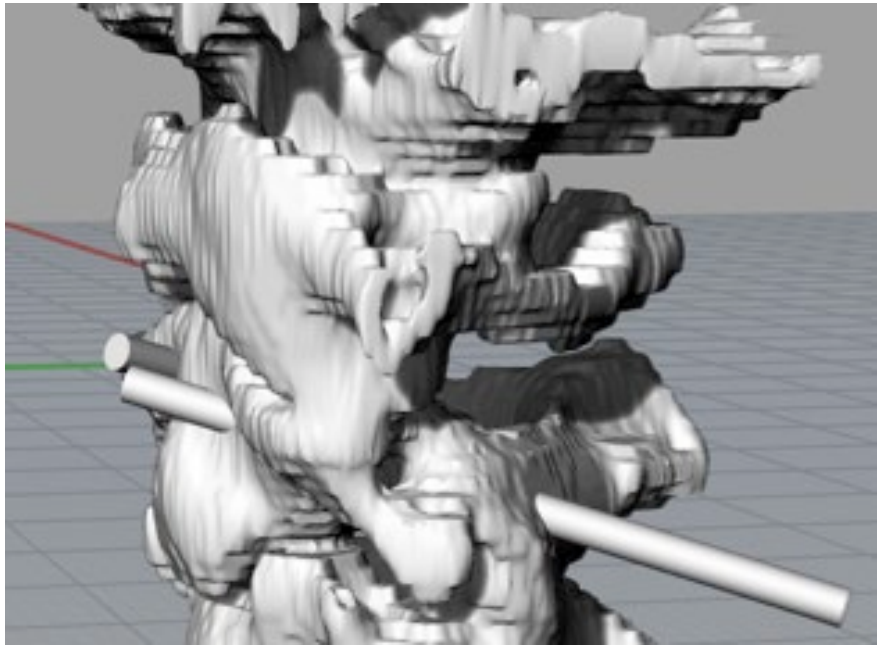
RAPS PRODUCTS COLLABORATIVE | AFDO RAPS

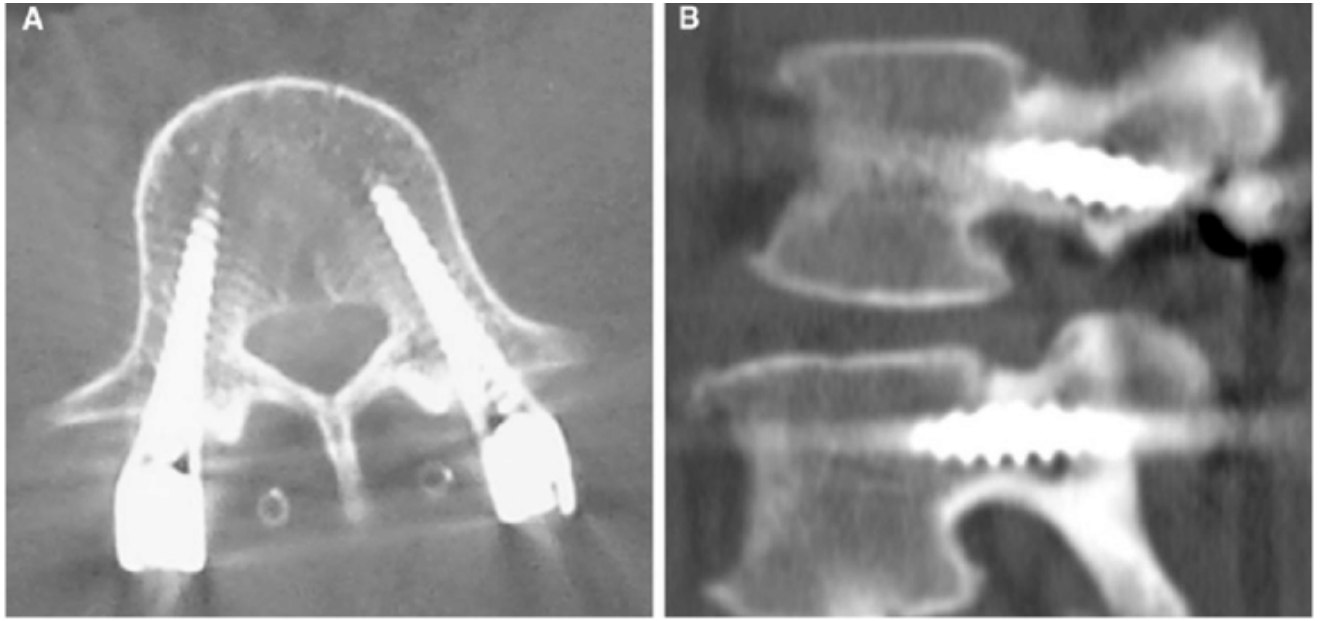
Tumor Resection

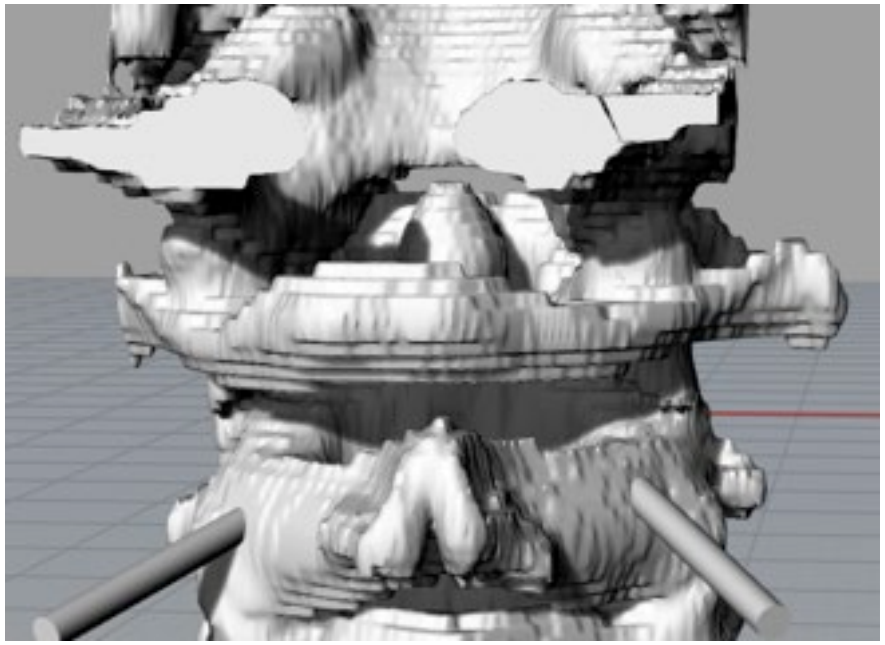




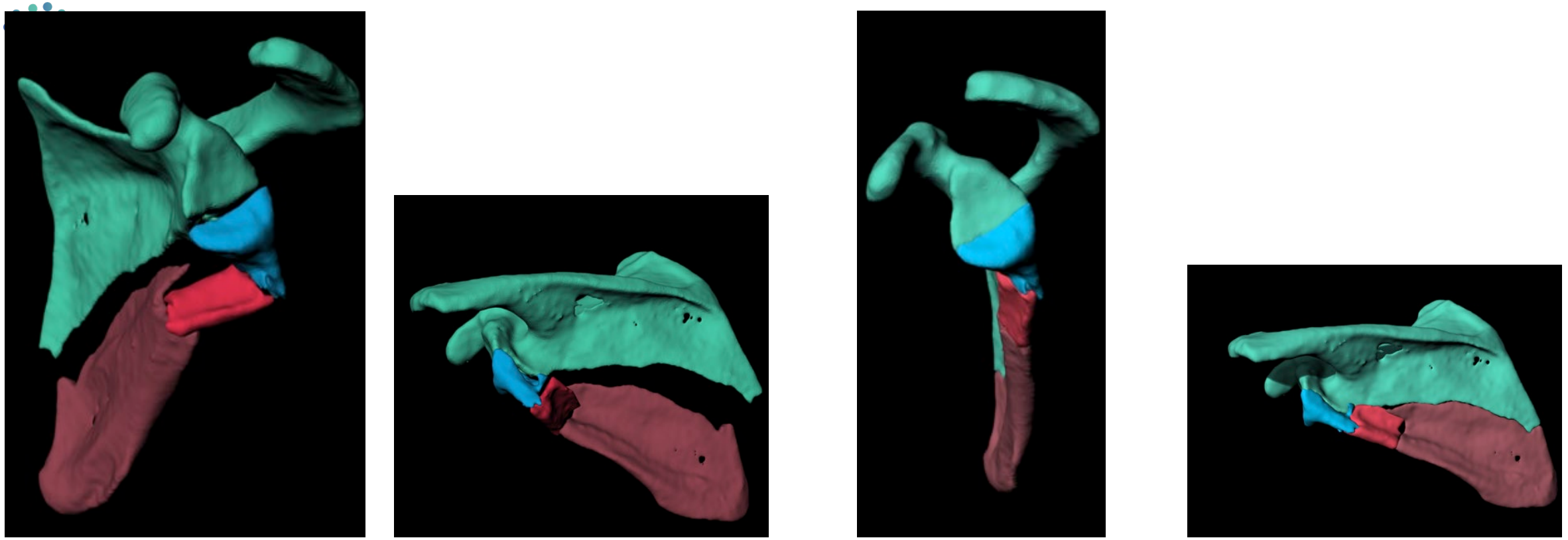








Trajectory Guides



Shoulder Fracture & Reduction

PubMed.gov

artificial intelligence segmentation

Search

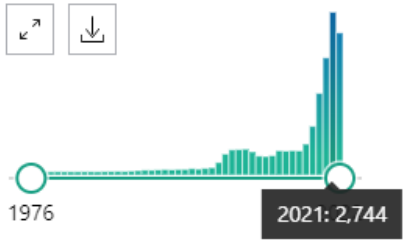
Advanced Create alert Create RSS User Guide

Save Email Send to Sorted by: Best match Display options

MY NCBI FILTERS

12,834 results Page 1 of 1,284

RESULTS BY YEAR



TEXT AVAILABILITY

- Abstract
- Free full text
- Full text

ARTICLE ATTRIBUTE

- Associated data

ARTICLE TYPE

- Books and Documents

1 Cite Share

Artificial Intelligence and Cellular **Segmentation** in Tissue Microscopy Images.

Durkee MS, Abraham R, Clark MR, Giger ML.

Am J Pathol. 2021 Oct;191(10):1693-1701. doi: 10.1016/j.ajpath.2021.05.022. Epub 2021 Jun 12.

PMID: 34129842 Free PMC article. Review.

With applications in object detection, image feature extraction, image classification, and image **segmentation**, **artificial intelligence** is facilitating high-throughput analysis of image data in a variety of biomedical imaging disciplines, ranging from radiolog ...

2 Cite Share

Toward High-Throughput **Artificial Intelligence**-Based **Segmentation** in Oncological PET Imaging.

Yousefirizi F, Jha AK, Brosch-Lenz J, Saboury B, Rahmim A.

PET Clin. 2021 Oct;16(4):577-596. doi: 10.1016/j.cpet.2021.06.001.

PMID: 34537131 Review.

Artificial intelligence (AI) techniques for image-based **segmentation** have garnered much attention in recent years. ...This work reviews existing AI techniques for **segmentation** tasks and the evaluation criteria for translational AI-based **segmentation** ...

3 Cite

Artificial intelligence in ultrasound.

Shen YT, Chen L, Yue WW, Xu HX.

Eur J Radiol. 2021 Jun;139:109717. doi: 10.1016/j.ejrad.2021.109717. Epub 2021 Apr 12.

The Future?

AI SUMMIT
COLUMBUS, OH • OCTOBER 25–27, 2022

AI in 3DP

The Lima Corporate Use Case

Please request slides