ARTHETA-0: An Innovative, Affordable, Approach to the Onsite, Rapid 3D Printing of Artery Stents, Parameterized to Fit Individual Patients' Needs

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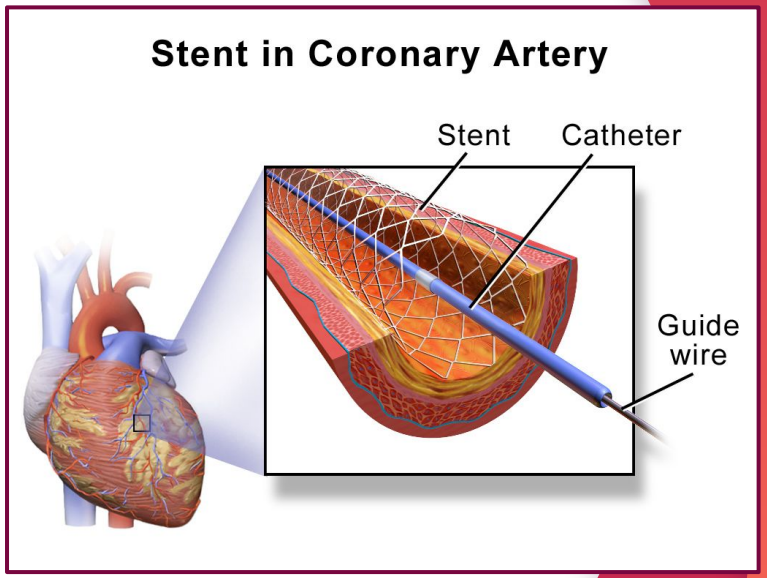
ARTHETA-0 Prototype

Research Background: About Stents

- A vascular stent is a tube inserted into the lumen of a blood vessel to keep the passageway open
- Over 2 million Americans undergo a stenting procedure every year, just for coronary arteries
- Post-stenting complications
  - The risk of re-narrowing of the artery is 10-20%
  - The risk of the artery clogging after stent placement is ≈5%



https://en.wikiversity.org/wiki/WikiJournal_of_Medicine/Medical_gallery_of_Blausen_Medical_2014

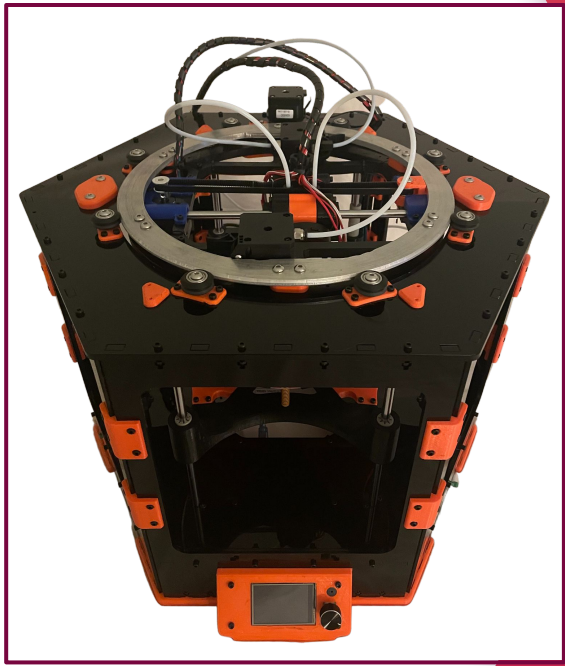
Research Problem: Shortcomings of Stent Manufacturing

- The most common methods include laser machining, die-casting, & micro-EDM
  - Cost >$100,000
  - One-size-fits-all approach
  - Must be completed off-site
- Industry Innovations in 3D Printing Stents
  - PBF (Powder Bed Fusion) 3D printers: far too expensive and cannot be available on-site (extensive infrastructure and capital)

https://www.additivemanufacturing.media/articles/3d-printed-nitinol-opens-new-possibilities-for-arterial-stents/template

ARTHETA-0: Addresses Every Industry Shortcoming

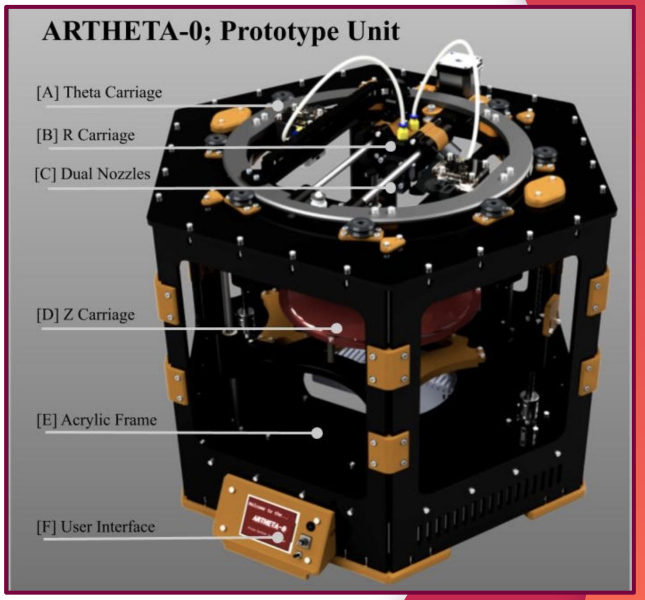
- **Innovative:** 3D printer with a novel motion system, specifically designed for printing the small and complex cylindrical structures of vascular stents
- **Affordable:** $471 per Production Unit & 10-15 cents materials cost per stent
- **On-site:** Simplistic Fused Deposition Modeling System (~3 cubic feet), allowing for on-site fabrication
- **Rapid:** Stent can be printed within 2 hours of parameter input
- **Customizability:** Can input patient-specific, custom dimensions in arGen software



ARTHETA-0 Prototype Unit

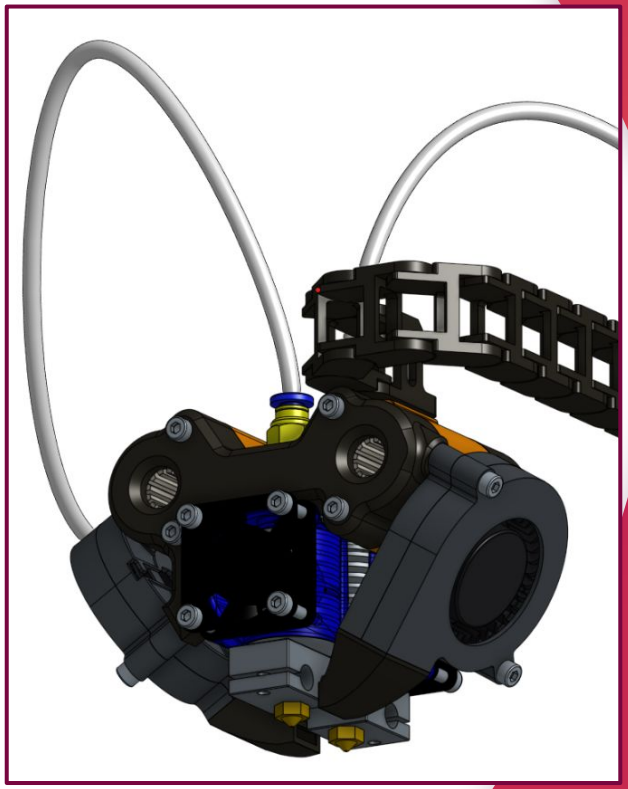
ARTHETA-0 Engineering Objectives

- Implement a polar motion system
  - Eliminate the need for axial synchronization
  - Reduce effects of mechanical slop
  - Allow for greater print quality
- Novel Application of Fused Deposition Modeling (FDM) Printing
  - First dual extrusion system on a polar motion system
  - First application of a horizontally static print bed on a polar printer
  - Increased axial rigidity, elimination of cantilevered axes
- Implementation of Novel arGen Software
  - Using stent parameters to directly generate G-code
  - Implement a streamlined user experience



Design: R-Carriage

- Mounted in Theta-Axis
  - Horizontal linear rods
- Comprised of 3d printed, PLA and PETG parts
- Dual E3DV6 hotends
- Bowden Configuration
  - Increased print speed and quality



R Carriage Render

Design: Theta-Carriage

- Supported by 8 v-groove bearings
  - 6 allow tensioning for carriage security
- Geared 476:20 from Nema17 output
- Houses extruder gearboxes for extrusion system and R-axis

Theta Carriage Render

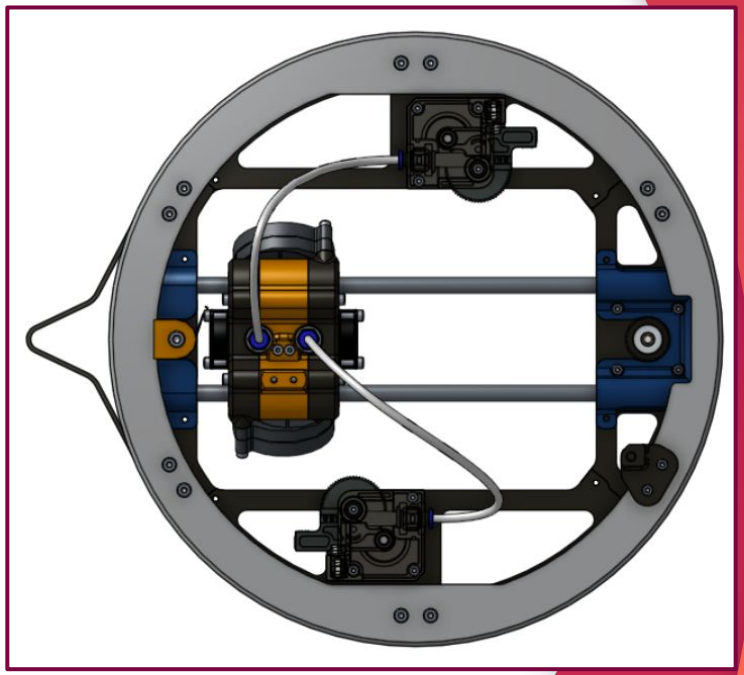
Design: Z-Carriage

- Body comprises of 6 interlocking 3d printer plates
- Heated Print bed attached to carriage on adjustable, spring-loaded mount
- Driven by 2 lead screws (each powered by Nema17 stepper)
- Horizontally static print bed
  - Increased part quality
  - Reduced mechanical slop

Z Carriage Render

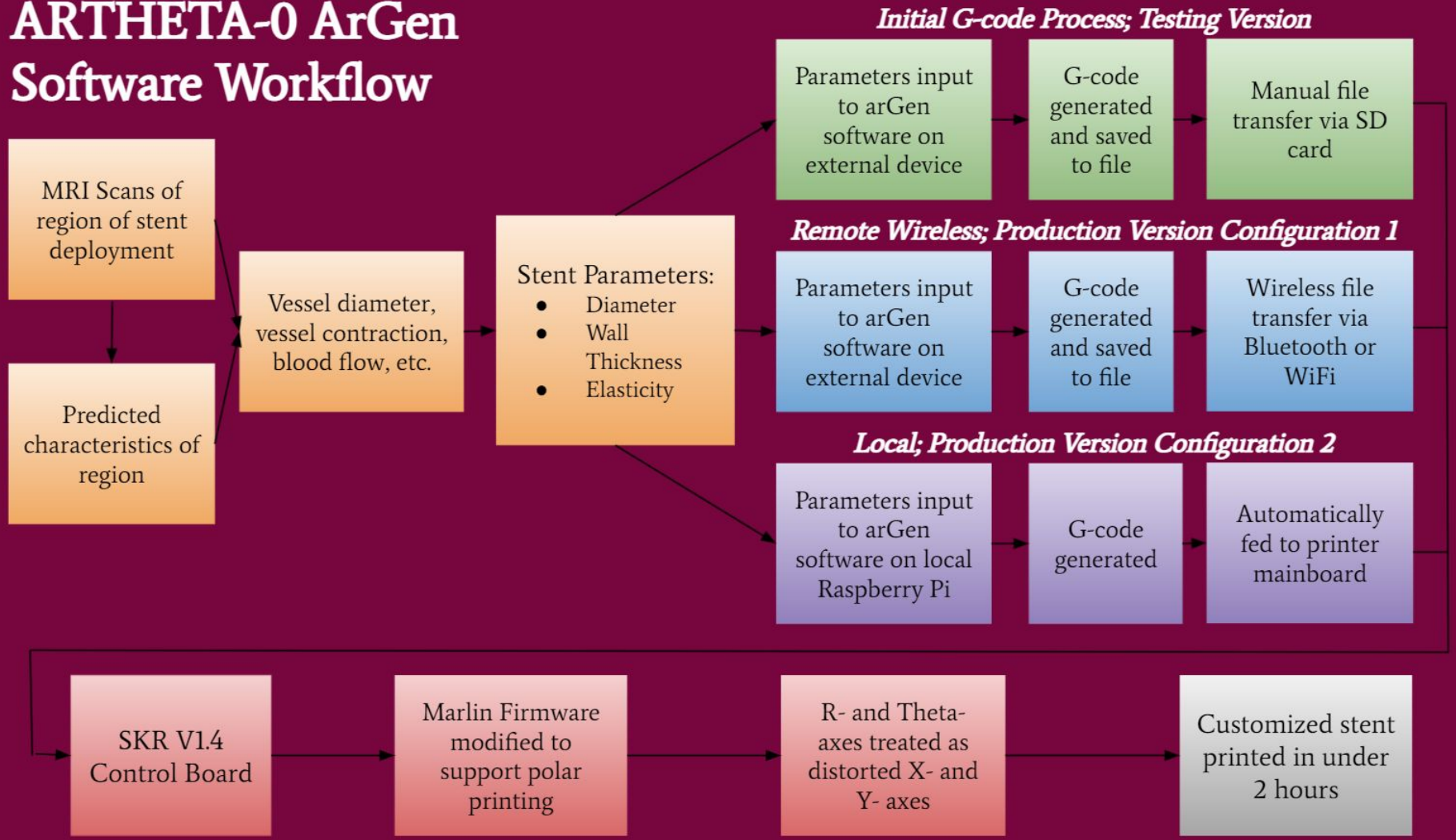
Design: Dual Extrusion

- Prints with two materials simultaneously separate hotends - allows different heat settings
- 2 polymers
  - TPU (Thermoplastic Polyurethane)
  - PVA (Polyvinyl Alcohol)
- Allows for more complex stent mesh geometries
- Complex designs and drug-eluting stents



Dual Extrusion System

ARTHETA-0 ArGen Software Workflow



ARTHETA-0 ArGen Frontend

arGen 1.0.4

Parameters

Outer Diameter

Input

Wall Thickness

Input

Length

Input

Mesh Angle

Input

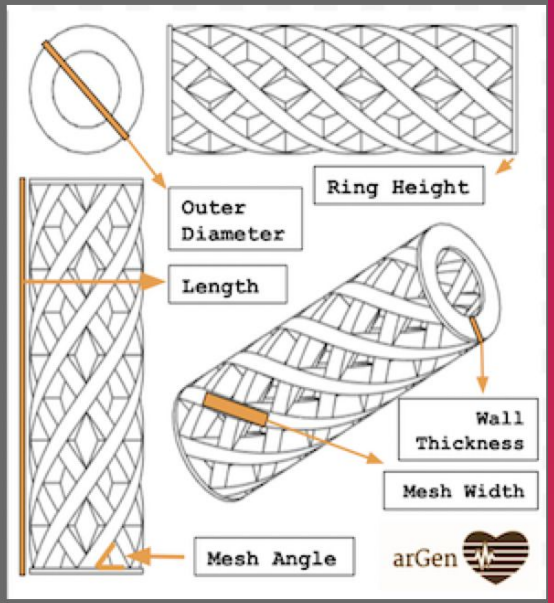
Mesh Width

Input

Ring Height

Input

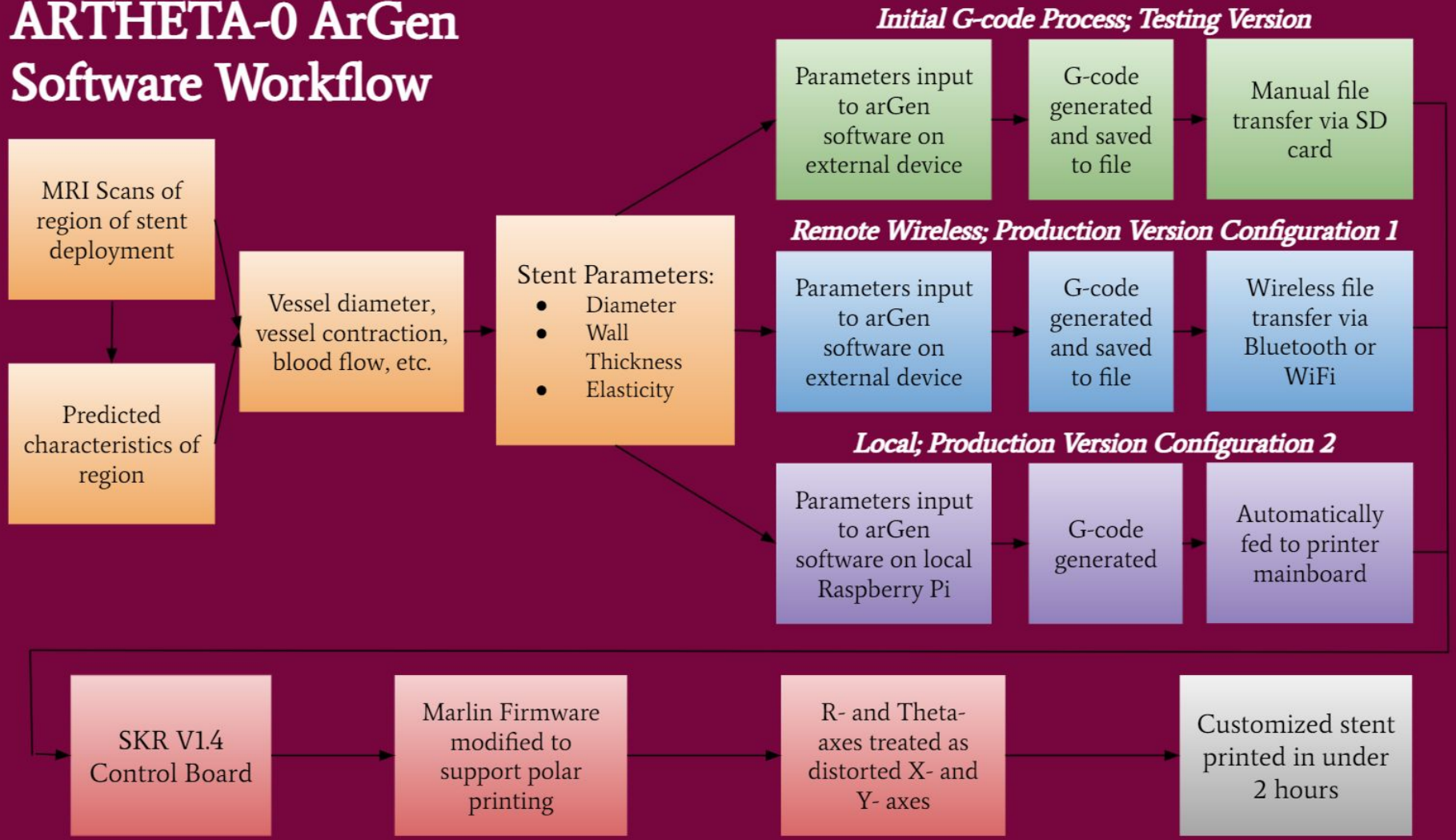
Render Stent



File Name

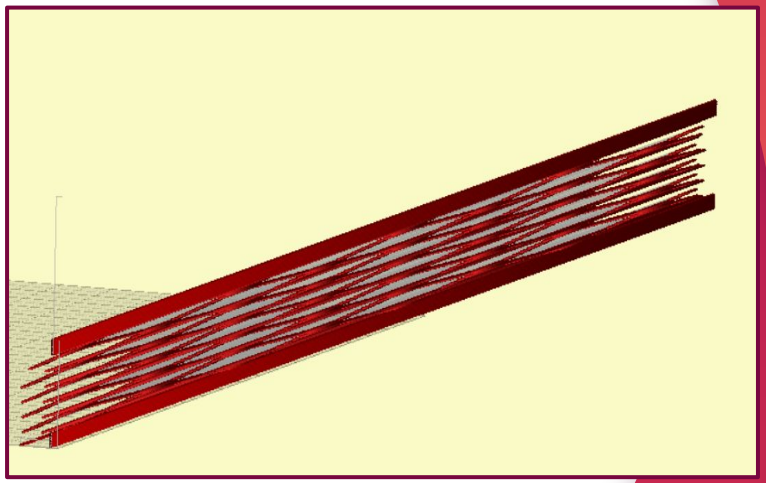
Save File

ARTHETA-0 ArGen Software Workflow



Printing Output

- Output: Stent Features and Specifications
- The ARTHETA-0 is capable of printing vascular stents with extreme accuracy and precision
  - Outer stent diameter of as low as 2 mm
  - Stents printed with 15 micron total precision (assuming reasonable slop)
- All stents are biodegradable/bioresorbable since they are made of flexible polymer, TPU
  - This reduces the probability of post-stenting complications such as restenosis
- Parameters of printed stents can be easily adjusted using arGen software



Stent g-code render in cartesian form

Testing & Results

- Mechanical and Quality Testing
  - All parts of the ARTHETA-0 have been tested and revised to optimize functionality
  - Every subsystem has been proved to be mechanically viable through mechanical motion testing
  - Stents printed on ARTHETA-0 using g-code developed by arGen

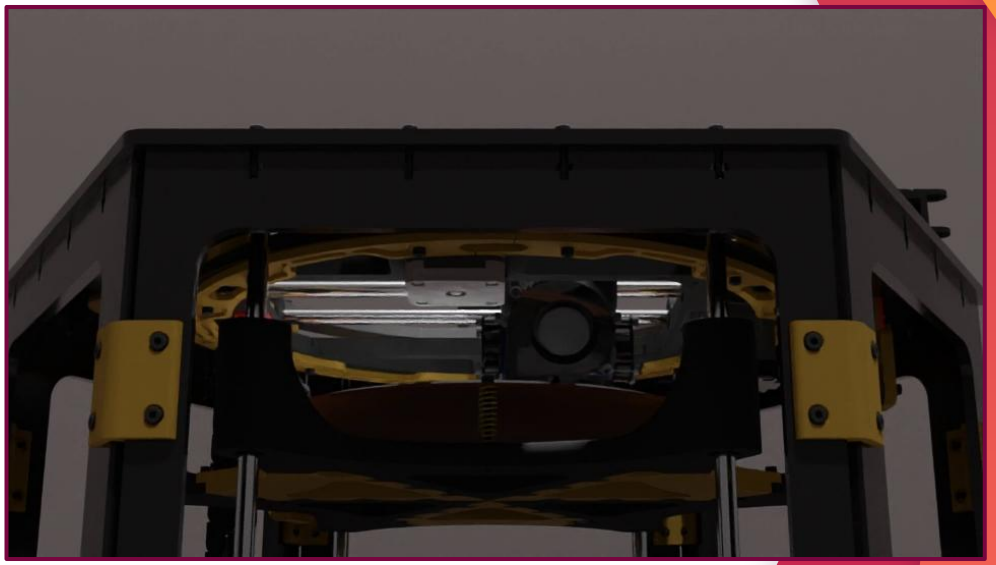
Pre-slop Precision Based off Tech Specifications & Mechanical Design (ARTHETA-0 vs Traditional Cartesian)		
R-axis vs X-axis	Theta-axis vs Y-axis	Z-axis vs Z-axis
125µm* vs 125µm	2µm vs 125µm	25µm** vs 25µm

**The effect of R-axis precision error in the ARTHETA-0 is negligible (unlike x-axis) because structure restrains R-error*
***Due to reinforcements, Z-axis slop is much less than traditional printers*

Technical Specifications	
Motor Sprocket Tooth Count	20
Theta Sprocket Tooth Count	472
Nema 17 Precision	1.8°
Motor Sprocket Pitch Diameter	11 mm
Assumed Outer Stent Diameter	3 mm

Future Directions: Engineering

- Implement dual-extrusion software support
- Further optimize
- ARTHETA-0 production unit
  - Substitute sheet metal for the acrylic frame
  - Optimize efficiency of theta-axis to reduce costs and manufacturing times
  - Implement arGen locally on the ARTHETA-0

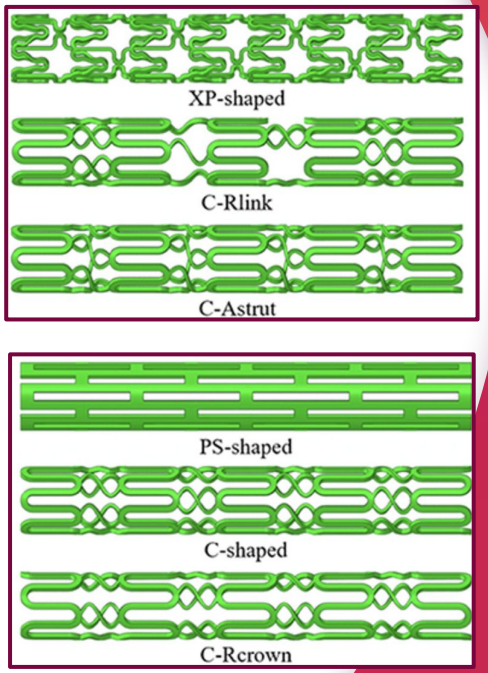


ARTHETA-0 Render Animation

Future Directions: Medical

- Assess biocompatibility of stent materials with lab tests
  - Model Fibroblast Cell Line
  - Human epithelial cell lines
  - Testing will be done in static and dynamic conditions
- Utilize existing Dual Extrusion for more complex stent designs
  - Drug-eluting stents
- Extend Print Materials to PCL and PLA to introduce customizability in stent rigidity, flexibility, and degree of biocompatibility

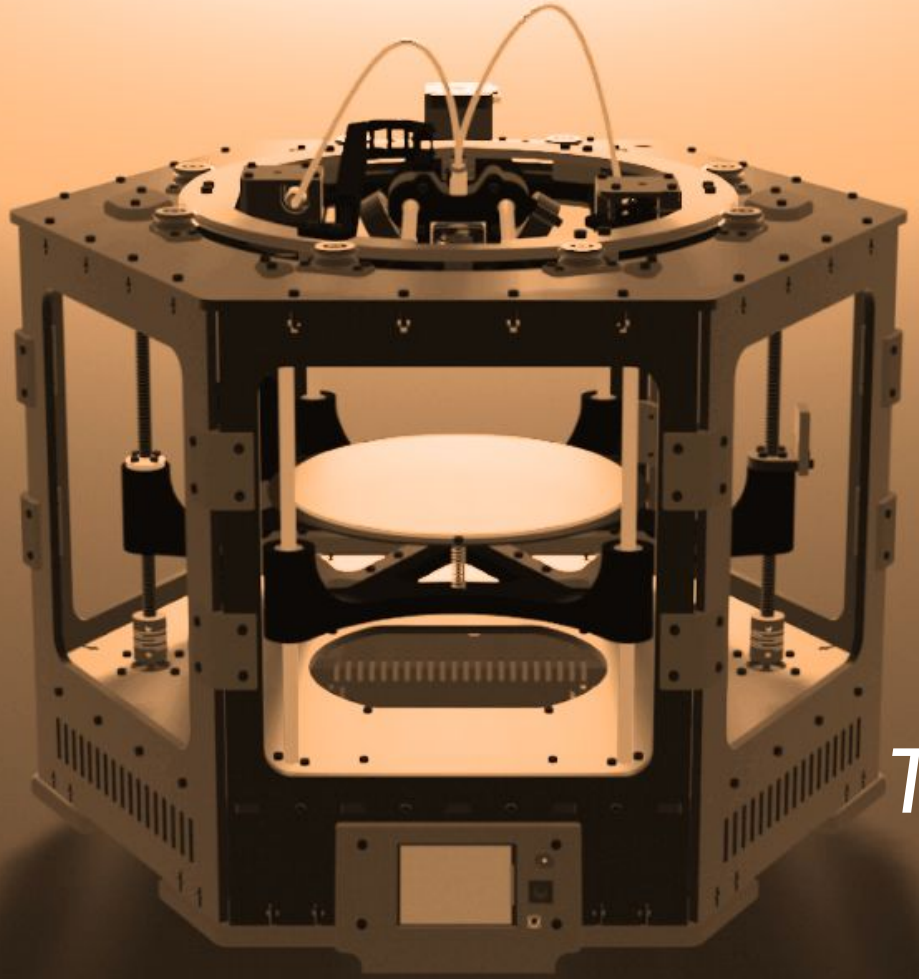
Complex Stent Geometries



https://www.frontiersin.org/files/Articles/492755/fbioe-07-00366-HTML/image_m/fbioe-07-00366-g001.jpg

In Conclusion,

The Innovation of the ARTHETA-0 allows us to envision a future where doctors can use current medical scanning techniques to image a patient's arteries and receive a custom-fabricated stent available for use within 2 hours of parameter inputs. All under $500.



Thank You

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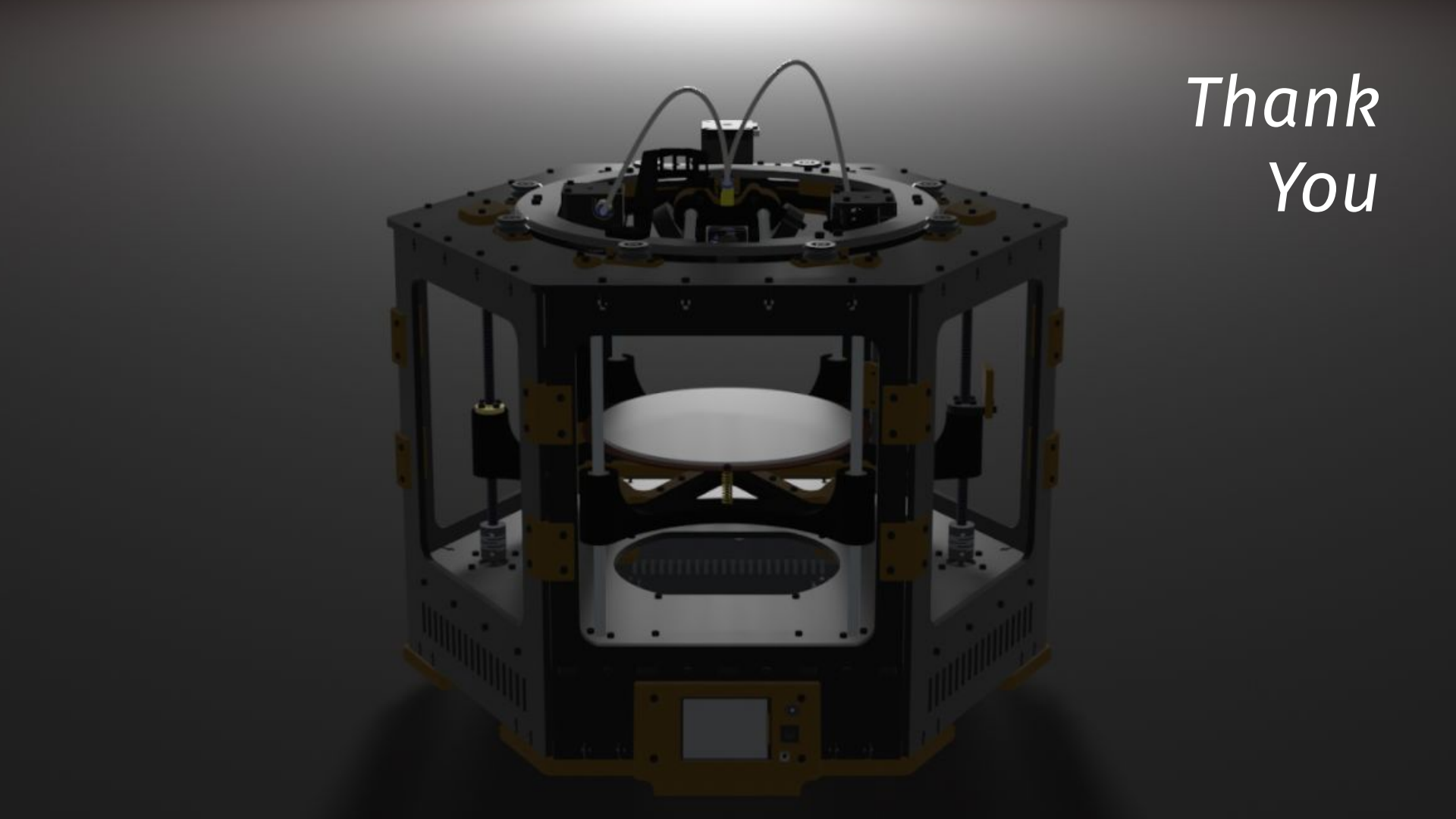
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