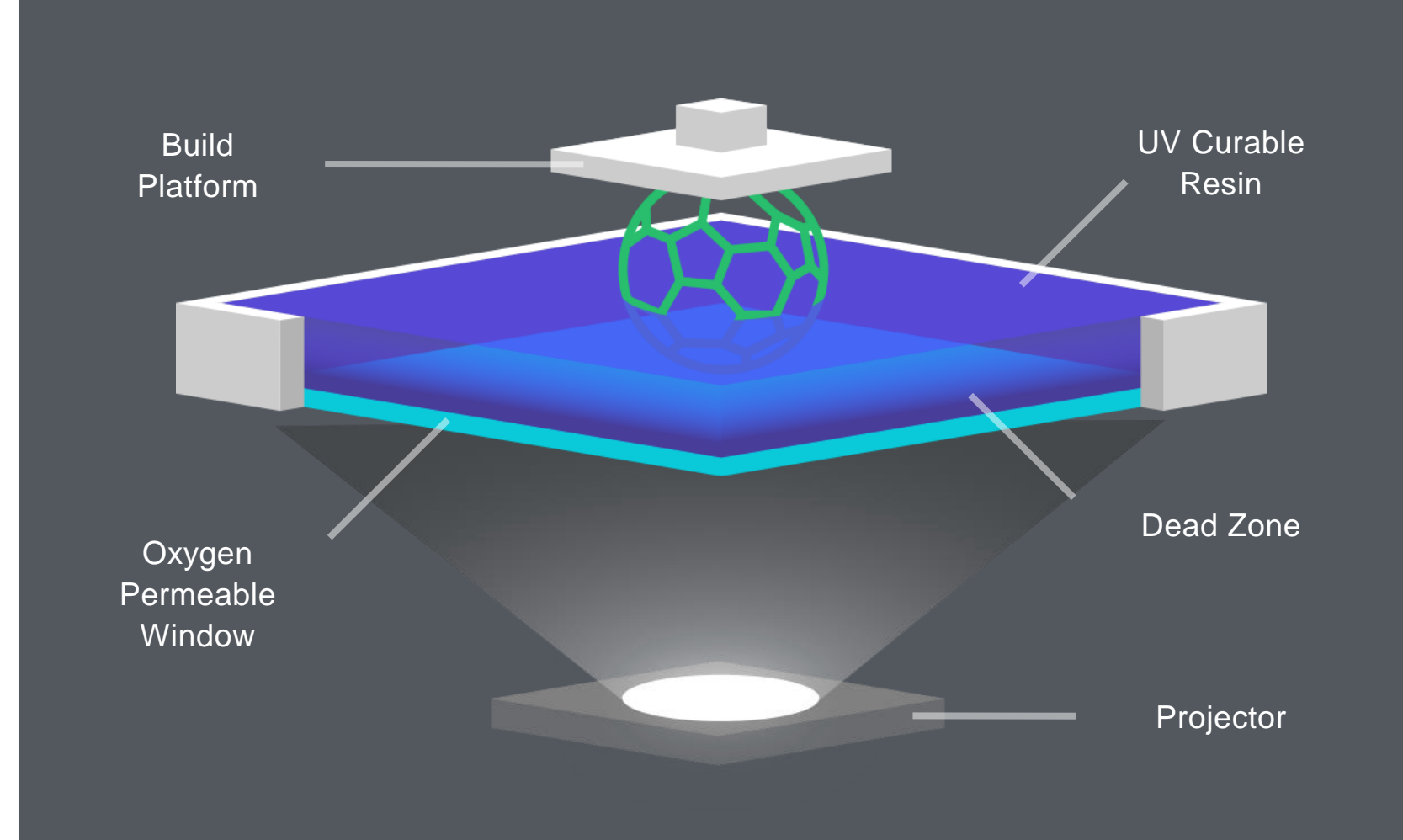


# CHANGING THE WORLD OF MEDICAL DEVICE MANUFACTURING AT SCALE THROUGH 3D PRINTING

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*Steve Pollack  
Sr. Staff Research Scientist  
Carbon  
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# TED

Ideas worth spreading

# THREE FUNDAMENTAL BREAKTHROUGHS: Our Technology



1

## Continuous Printing (CLIP): New 3D Printing Process

- Layerless
- Injection molded qualities
- Best-in-class printer uptime
- US Patent 9,498,920
- US Patent 9,360,757
- US Patent 9,211,678
- US Patent 9,205,601



2

## Dual-Cure Materials: New 3D Materials

- Wide range of proprietary materials
- Unmatched mechanical properties
- US Patent 9,676,963
- US Patent 9,598,606
- US Patent 9,453,142



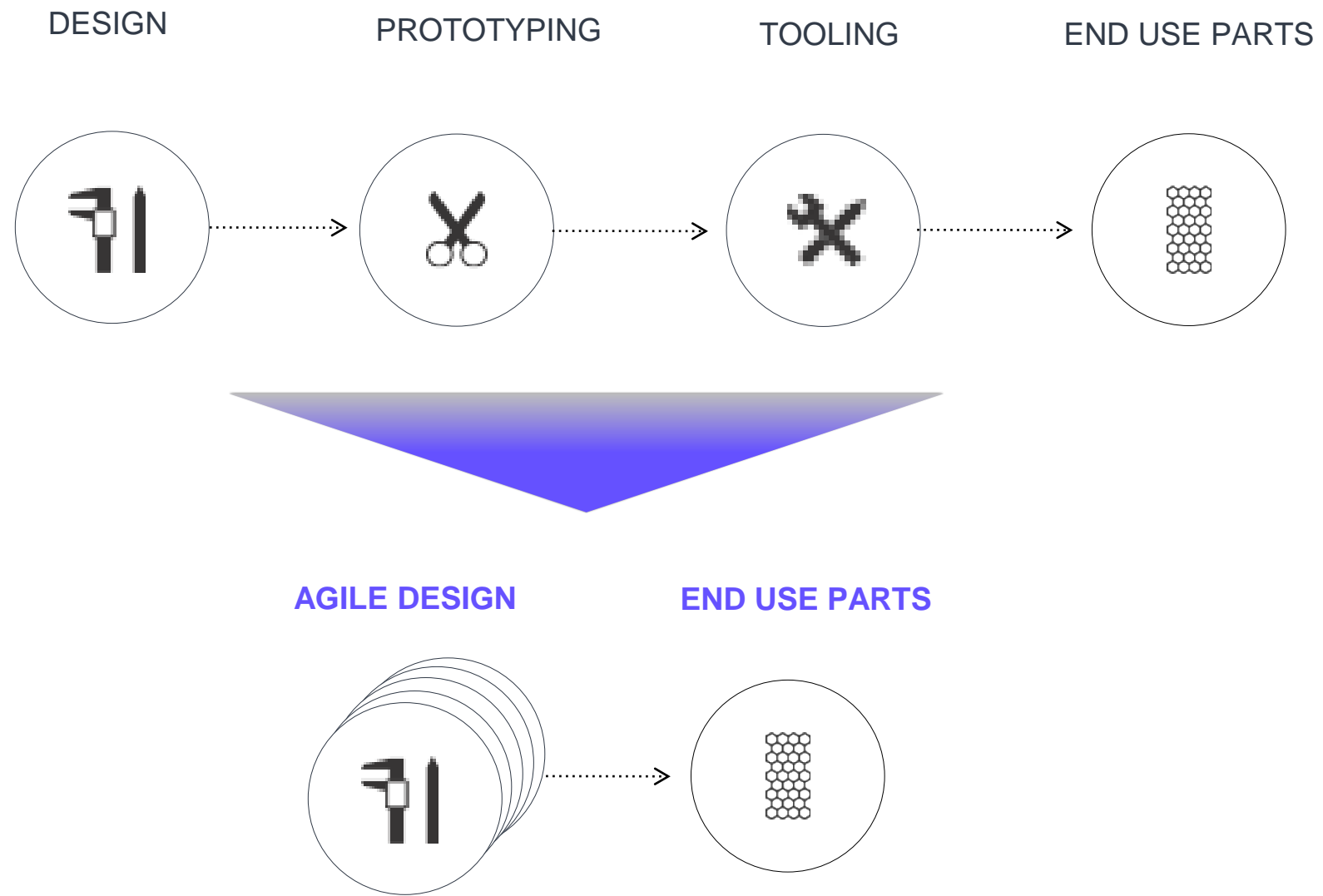
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## Modern Software: Securely Connected Architecture

- Cloud-based
- Regular upgrades until production
- Traceability of digital process
- New design tools (lattices, textures)

# DESIGNING ON THE MEANS OF PRODUCTION

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# CARBON'S EXPANDING FAMILY OF RESINS



**UMA** Urethane Methacrylate

Rigid, fast prints



**CE** Cyanate Ester

High temperature resistance, strength, stiffness



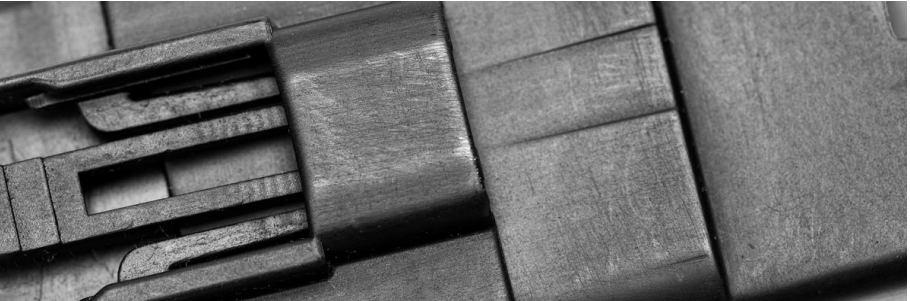
**SIL** Silicone-Urethane

Soft touch, biocompatible, and tear resistant



**RPU** Rigid Polyurethane

Tough + abrasion resistant, stiff



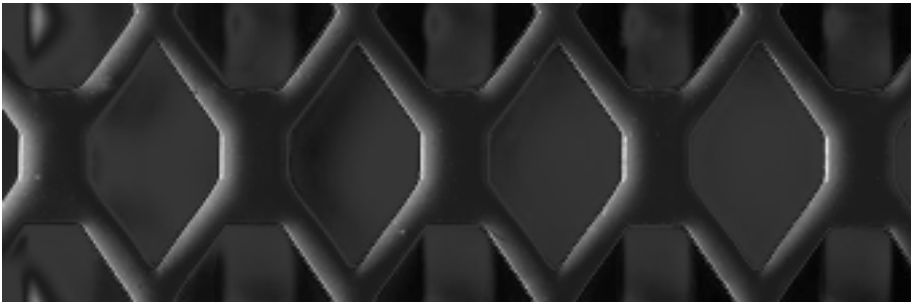
**EPX** Epoxy

Temperature resistant, strong, accurate



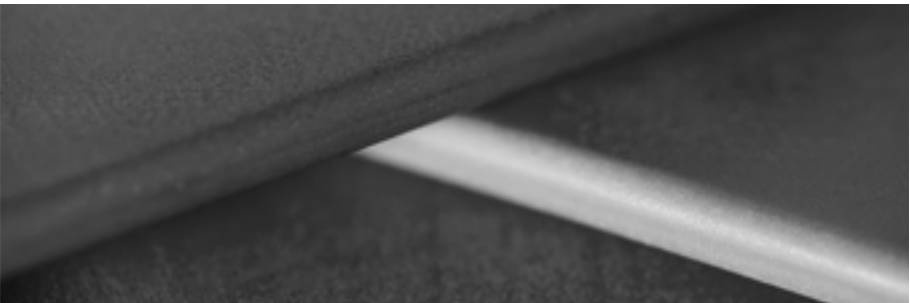
**Dental Production**

Prints fast and accurately



**EPU** Elastomeric Polyurethane

Highly elastic, resilient



**FPU** Flexible Polyurethane




Tough, impact + abrasion resistant, moderate stiffness



**Third-party Materials**





Clear, biocompatible, and print fast and accurately

# CARBON RESINS PASS INITIAL BIOCOMPATIBILITY TESTING

METHOD	STATUS
Cytotoxicity	All resins pass 
Irritation	UMA, RPU, EPU, CE, EPX, SIL pass; other resins not yet tested 
Sensitization	UMA, RPU, EPU, CE, EPX, SIL pass; other resins not yet tested 

Note: Tests conducted in Q4 2016 by NAMSA  
Passed ISO 10993-5 and -10 for skin and mucosal contact

# COMPATIBLE WITH MULTIPLE STERILIZATION METHODS

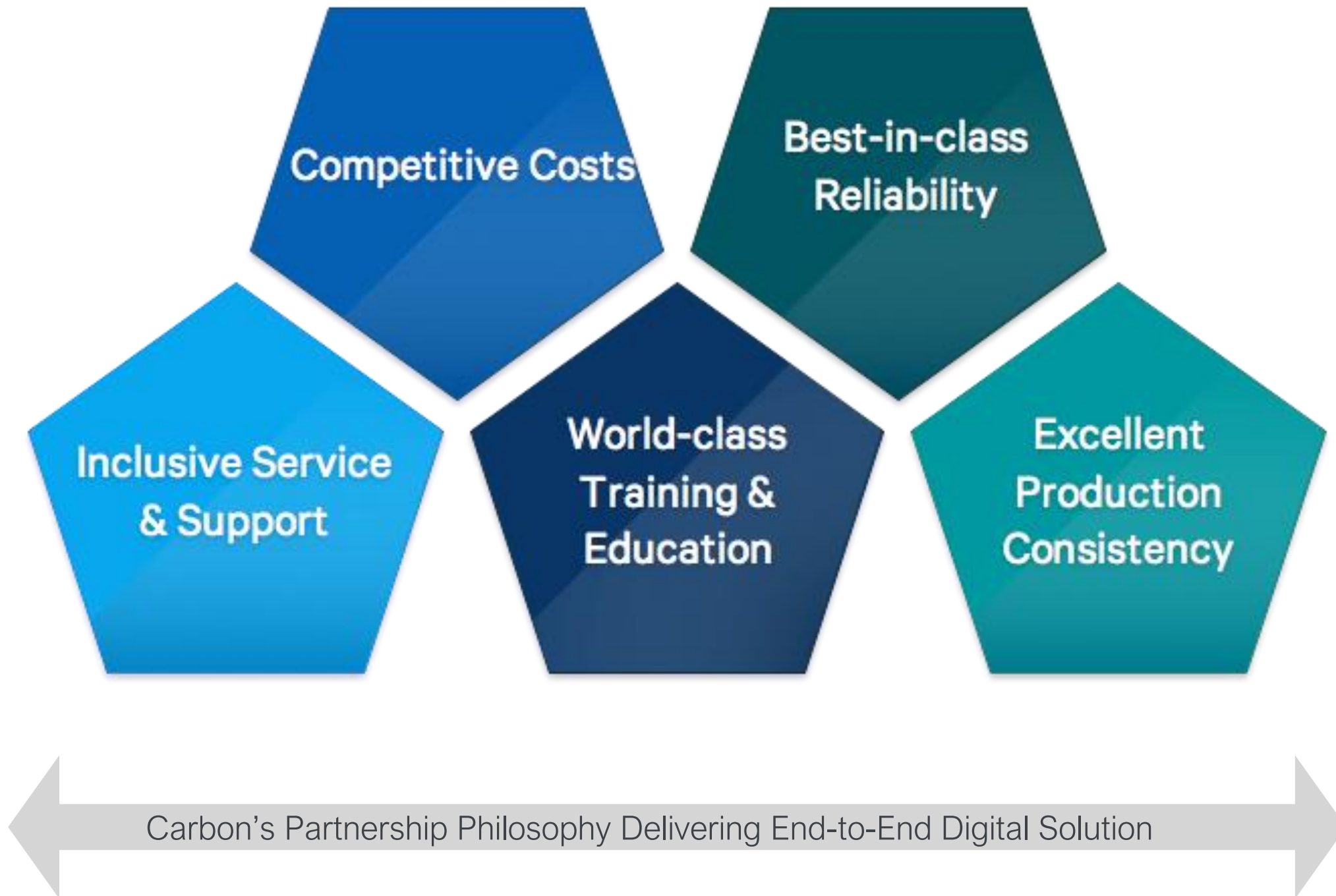
METHOD		STATUS
HIGH TEMP	Steam Sterilization	EPX, RPU* CE (limited cycles) 
COLD STERILIZATION	Ethylene Oxide Exposure	CE, EPX, RPU, FPU, EPU, Silicone; all pass 
	Electron Beam Irradiation	CE, EPX pass RPU, FPU, EPU, Silicone* 
	Gamma Ray Irradiation	CE, EPX pass RPU, FPU, EPU, Silicone* 

\* Some changes in mechanical properties

# DENTAL



# Carbon + Dental Industry



Dental models, gingiva mask, surgical guide, and impression tray

+

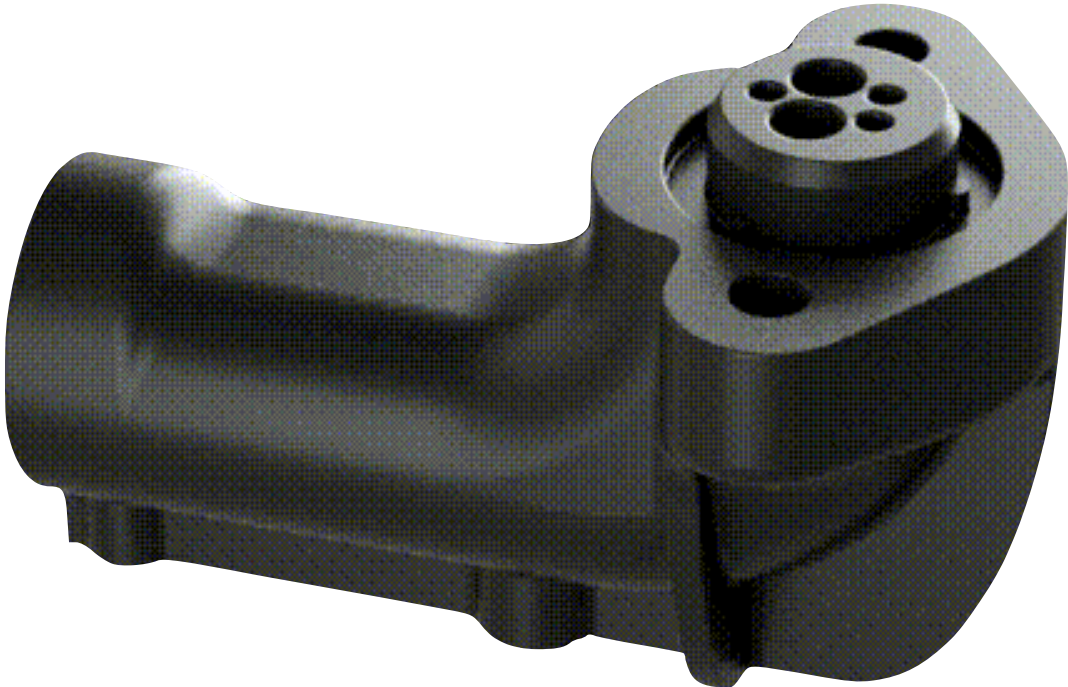
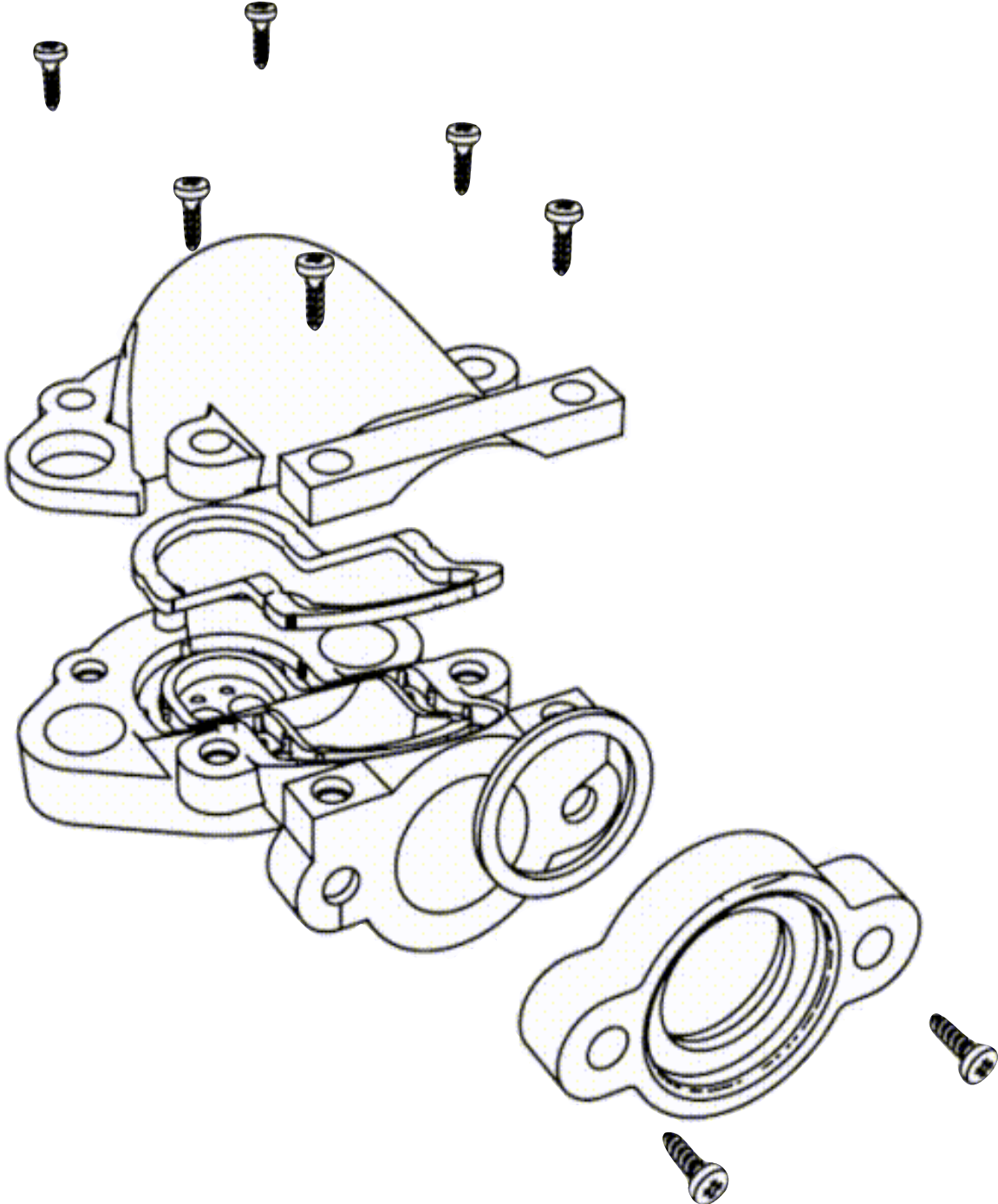


FDA cleared denture base + teeth

# MEDICAL DEVICES + DIAGNOSTICS

# DESIGN SIMPLIFICATION

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## Intraosseous Infusion Device

### DESCRIPTION

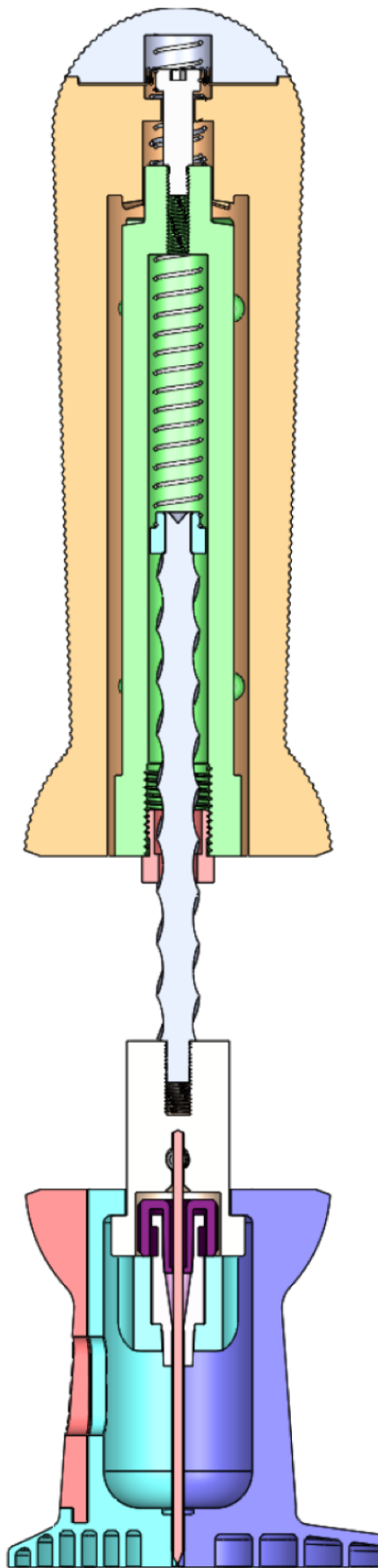
- Affordable intraosseous (into bone) infusion device
- Pre-assembled and pre-sterilized
- Designed for the developing world
- Based on “Persian” or “Yankee” drill

### UNMET DEVELOPMENT NEEDS

- Quick turn-around time for production quality parts
- Better material properties for design iterations
- Reduction of part count and design freedom

### SOLUTION

- User-friendly single-use bone drill that inserts a cannula into the femur within 10 s to rehydrate patients



## TB Diagnostic Cassette

### DESCRIPTION

- Easy-to-use, affordable tuberculosis dx device
- Uses urine to detect a biomarker for TB

### UNMET DEVELOPMENT NEEDS

- Lengthy, costly product development cycle
- Traditional mold costs \$25,000/mold

### SOLUTION

- Rapid, economical product development
- 10 iterations in 2.5 months (2–3x faster)
- Successfully field tested >1,000 devices

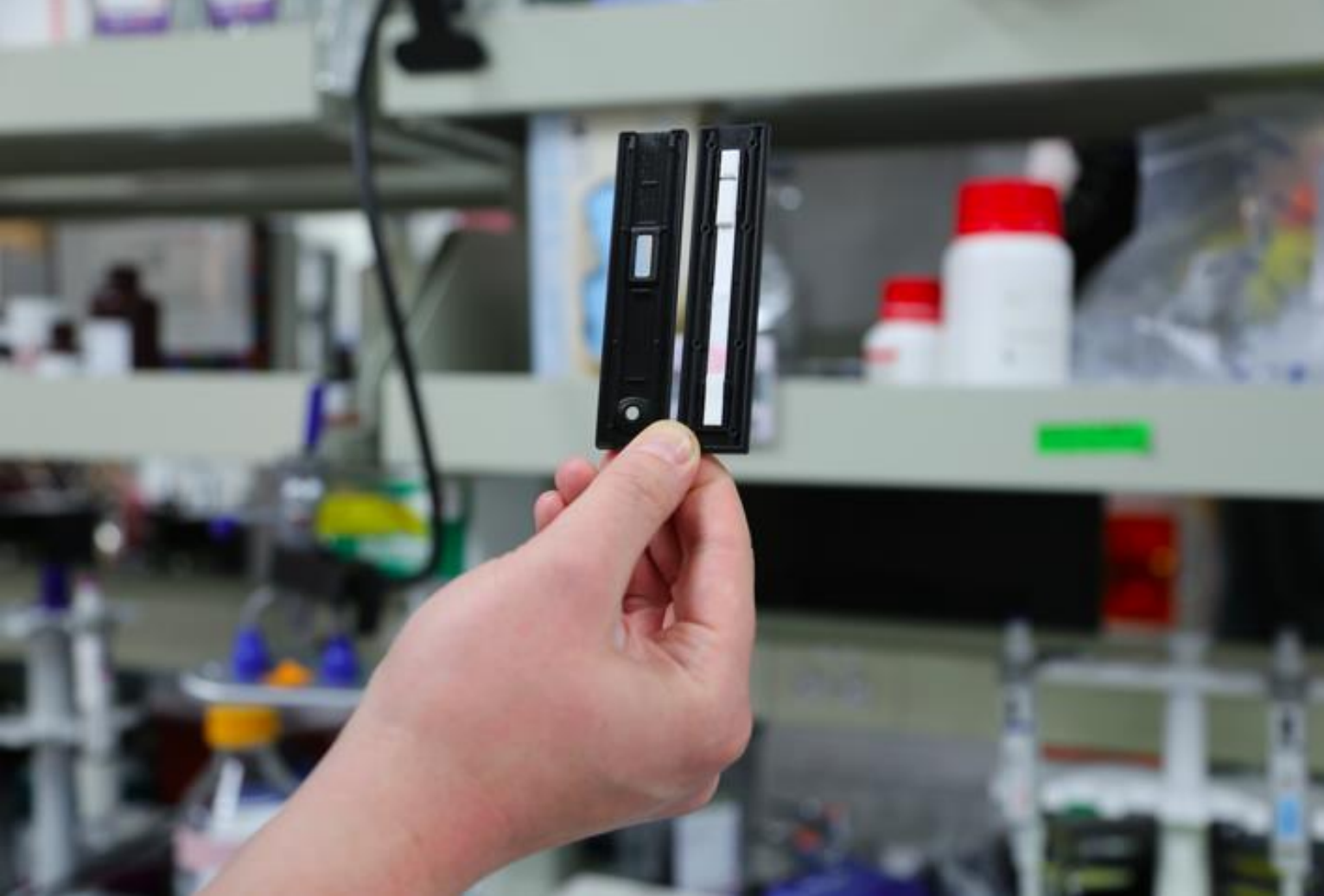


Figure 1: Tuberculosis diagnostic cassette, 3D manufactured using Carbon technology



## Pediatric Tracheal Stents

### DESCRIPTION

- Percutaneous, removable airway stent for pediatric patients (0–2 years of age)

### UNMET DEVELOPMENT NEEDS

- Conventional layer-by-layer approaches result in parts with ridges that cause stents to clog
- Alternative approaches couldn't print 2-mm wall thickness – “the parts crumble”

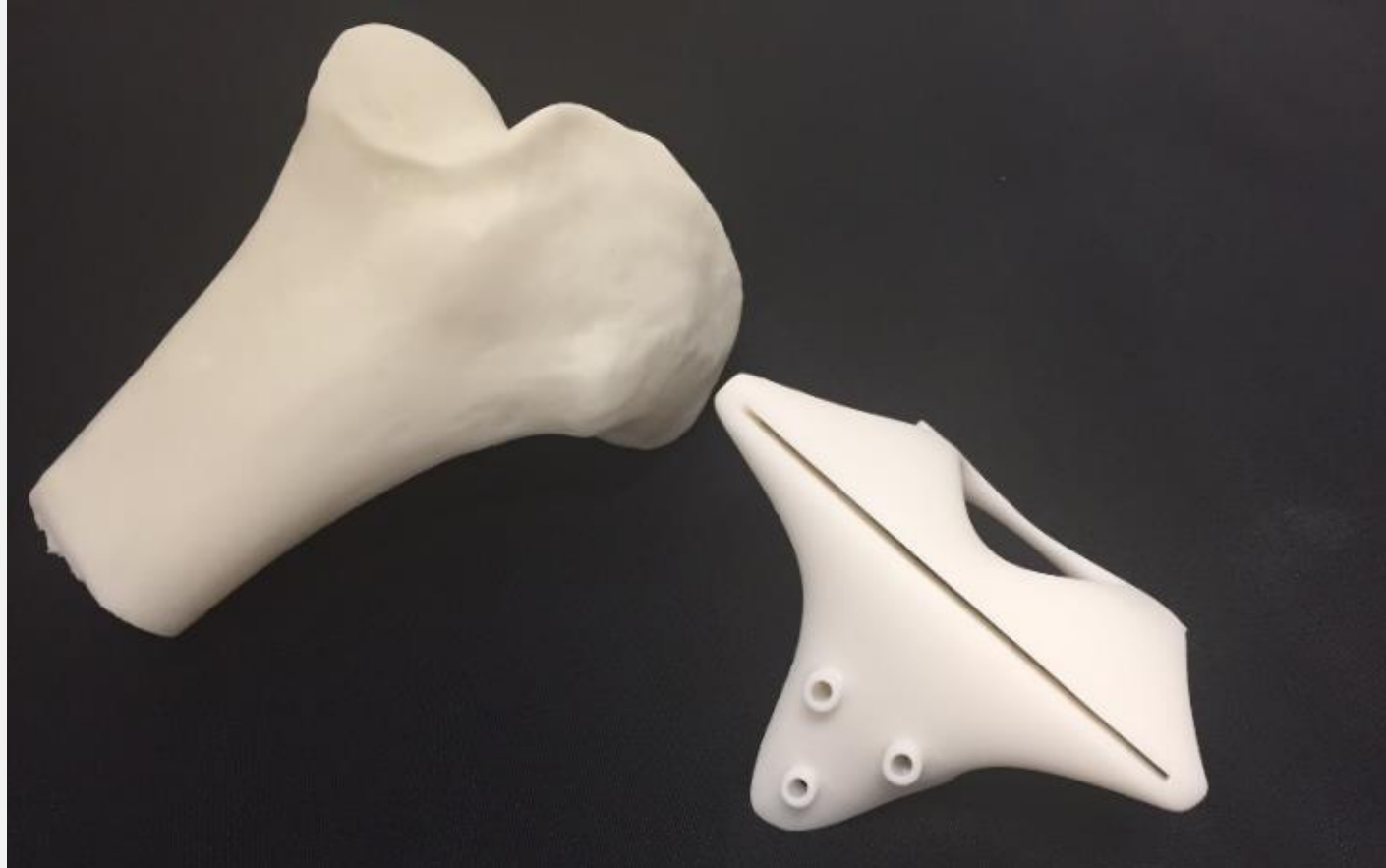
### SOLUTION

- *“Carbon’s silicone material offers smooth finish with the durability to withstand dynamic action of the airway.”*
- - Dr. Robroy MacIver, Congenital Heart Surgeon



Figure 1: Different sizes of 3D printed airway stents, produced using Carbon printers and SIL 30





## Arthroplasty Femoral Cutting Guide

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### DESCRIPTION

- Surgical cutting guide for the femoral head
- Used in knee replacement surgery to ensure proper fit / alignment

### UNMET DEVELOPMENT NEEDS

- Current guides limited to several sizes
- Not tailored for individual patients' anatomy

### SOLUTION

- Personalized cutting guide designed using a patient's CT scan
- Produced in biocompatible RPU material

## Hearing Aid Fixtures

### DESCRIPTION

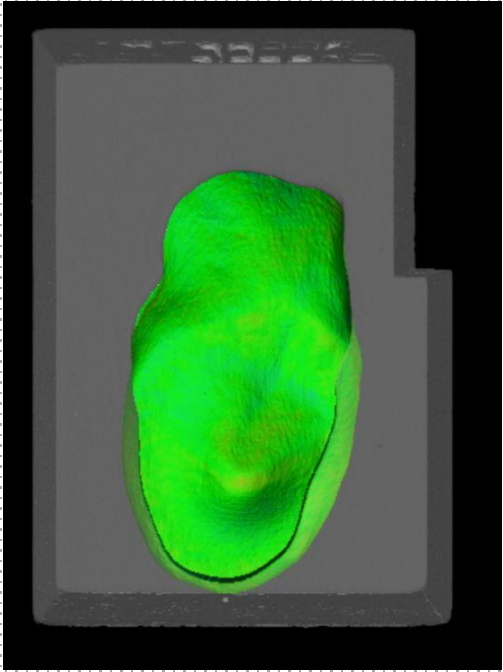
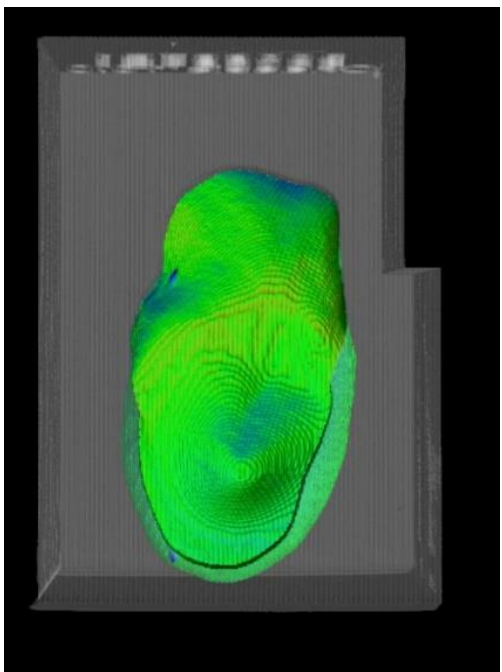
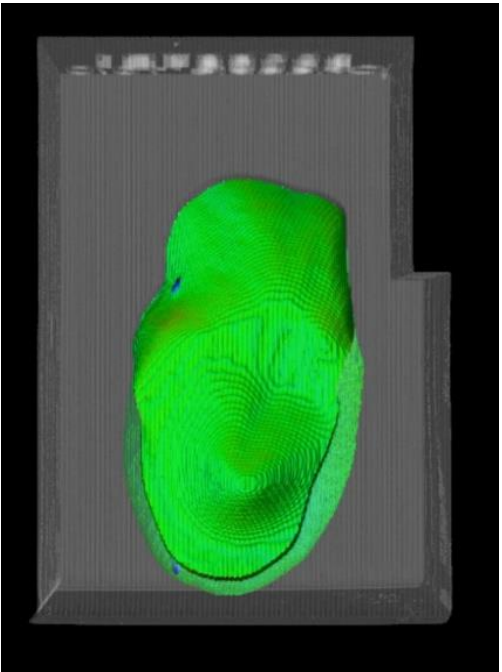
- Manufacturing tools for patient-matched hearing aid components

### UNMET DEVELOPMENT NEEDS

- Conventional SLA takes 3 hours
- Produces anatomical fit of only 32–37  $\mu\text{m}$

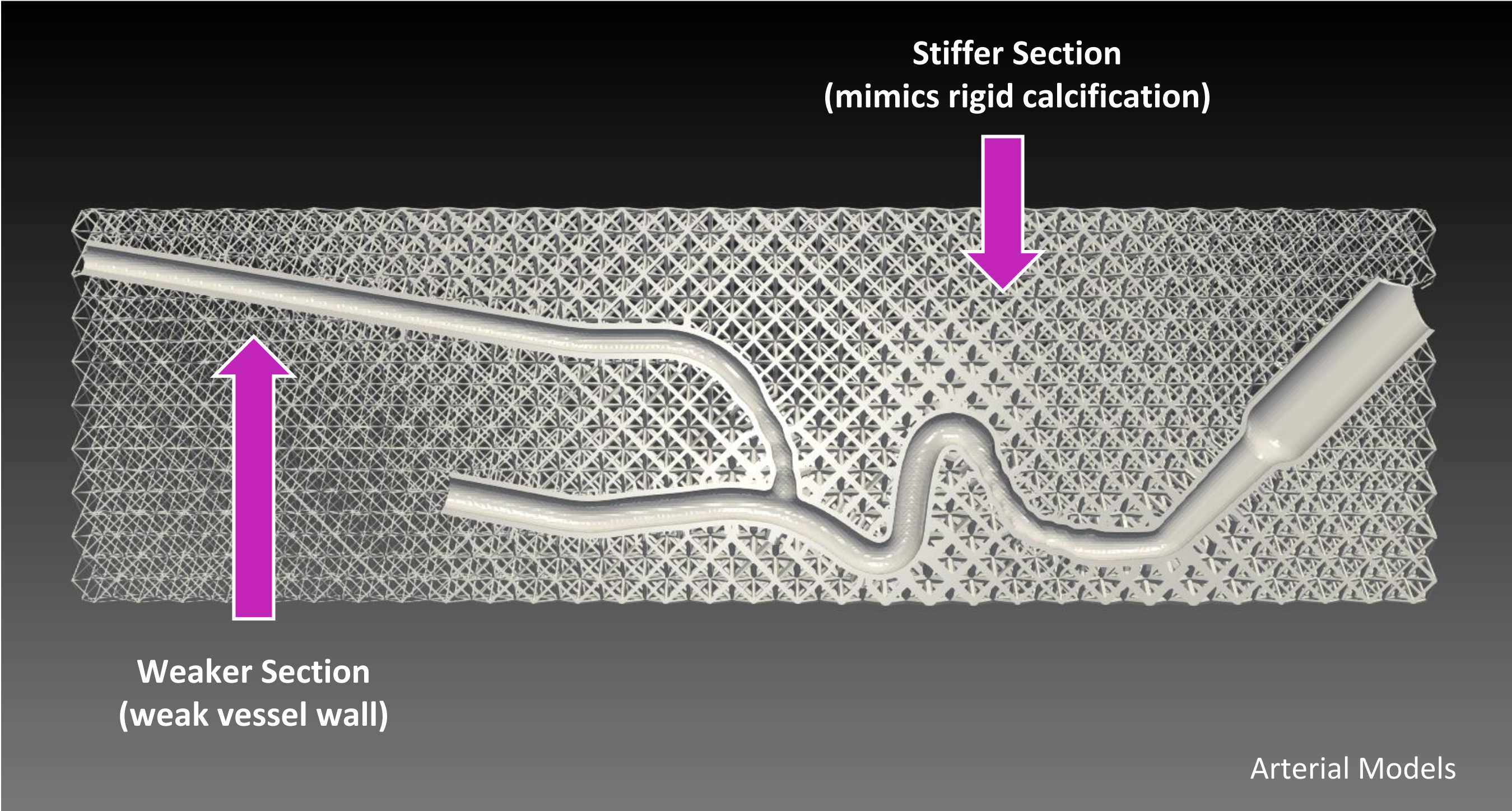
### SOLUTION

- Printed in “PR Black” resin, 45 minutes
- Software-driven optimization of accuracy
- Achieved desired accuracy of 28–30  $\mu\text{m}$

“Conventional” SLA Parts	Carbon Initial Print	Carbon After SW Update
90% within 32 $\mu\text{m}$	90% within 45 $\mu\text{m}$	90% within 30 $\mu\text{m}$
		



# VARYING LATTICE DENSITY TO MIMIC RADIAL COMPLIANCE OF THE VESSEL





# MEDICAL DEVICE LABELING

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Printing extremely fine **part labels / instructions** and **unique device identifiers** eliminates a secondary processing step

- Product tracking and traceability
- Compliance with regulations
- Product recall and withdrawals
- Logistics and quality management
- Support of patient safety

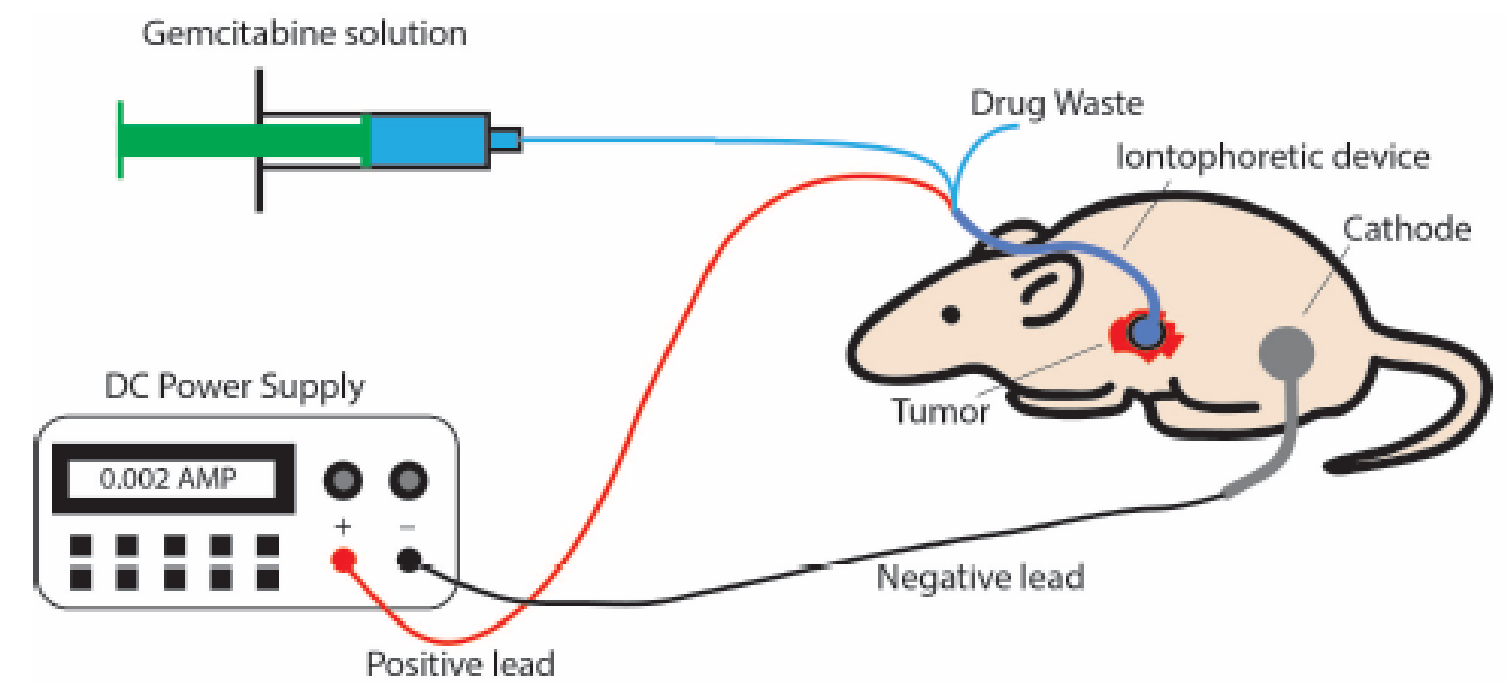
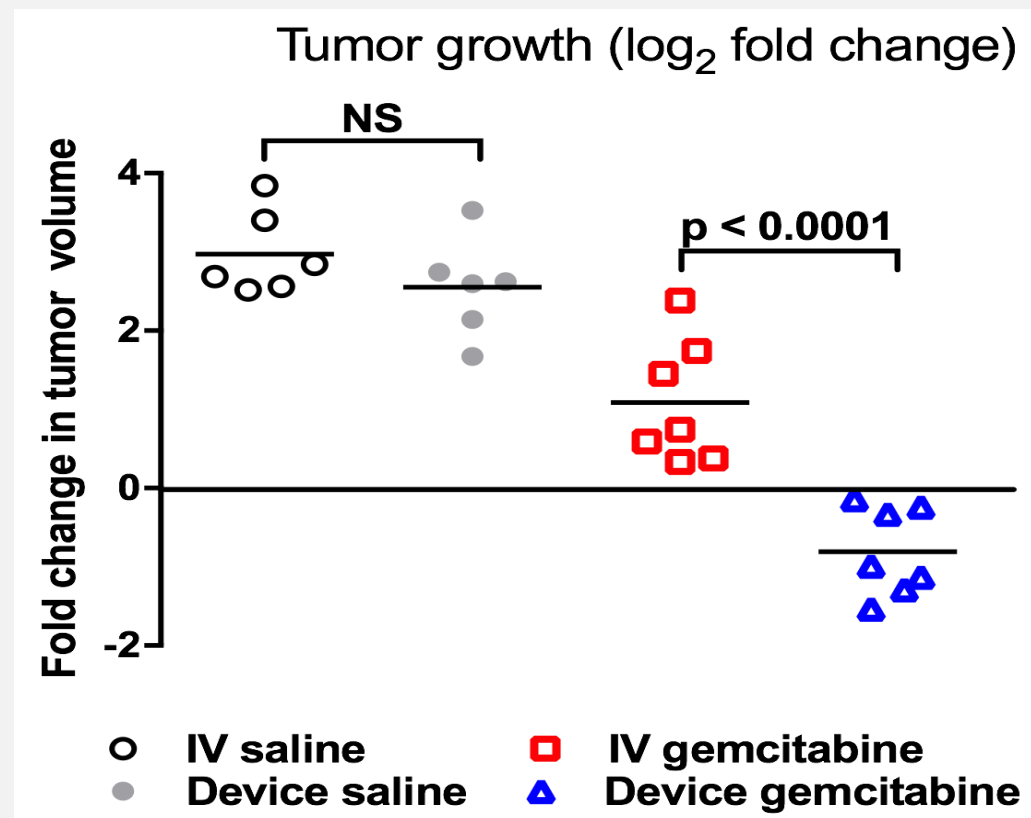
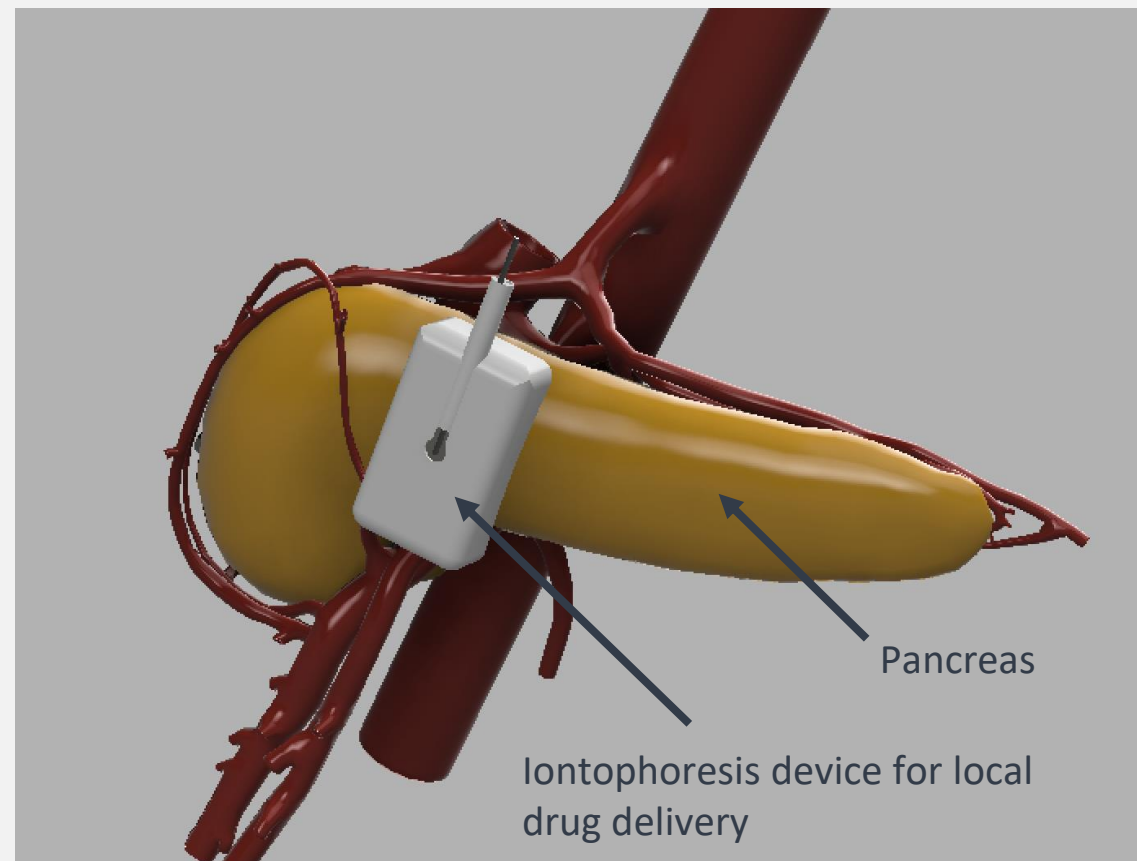


Serial number or ID number automatically generated and included in STL file tracks build number and part location on the build platform.

# DRUG + BIOLOGICS DELIVERY

## Local Drug Delivery: Pancreatic Cancer

- 53K new pancreatic cancer cases each year
- 5-year survival rate < 7%
- Only 15% of patients eligible for surgery
- Iontophoresis drug delivery shrinks tumors by 40%



<sup>2</sup>“Local iontophoretic administration of cytotoxic therapies to solid tumors”, Byrne JD et al. *Sci Transl Med.* 2015 Feb 4;7(273).



## IVR for Infertility Treatment

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### DESCRIPTION

- Intravaginal ring for sustained release of progesterone

### UNMET DEVELOPMENT NEEDS

- 1.7 million women treated annually for infertility in the US
- Current treatments: daily gels, inserts, or IM injections
- Total market \$1.5B

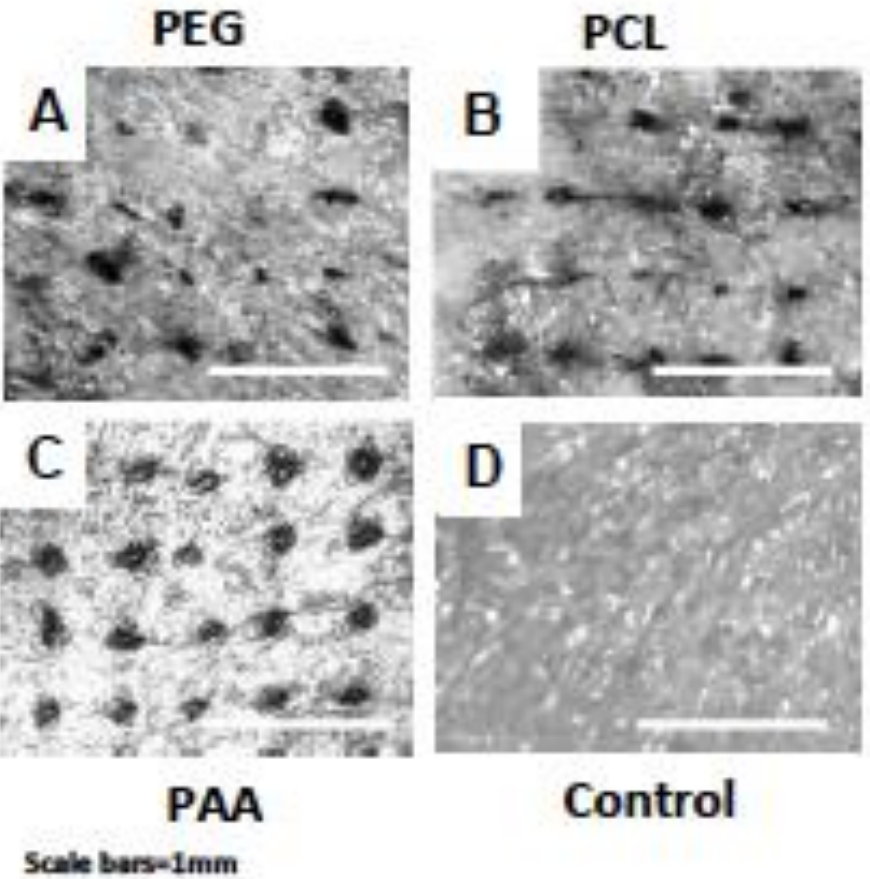
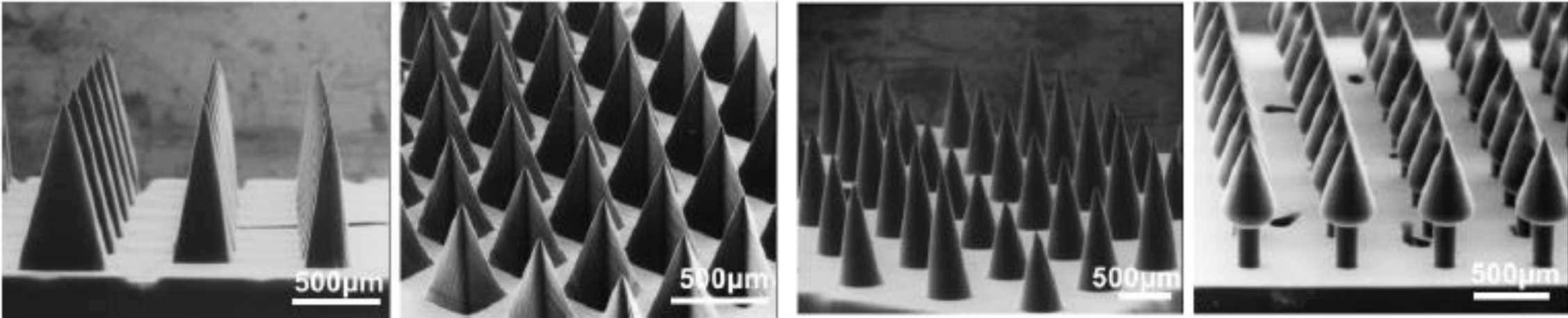
### SOLUTION

- Design controls mechanical properties, release kinetics
- Sustained release of progesterone for 30–90 days
- 100% release vs. 15–20% release with conventional IVRs
- *In vivo* local and systemic safety data in rodents



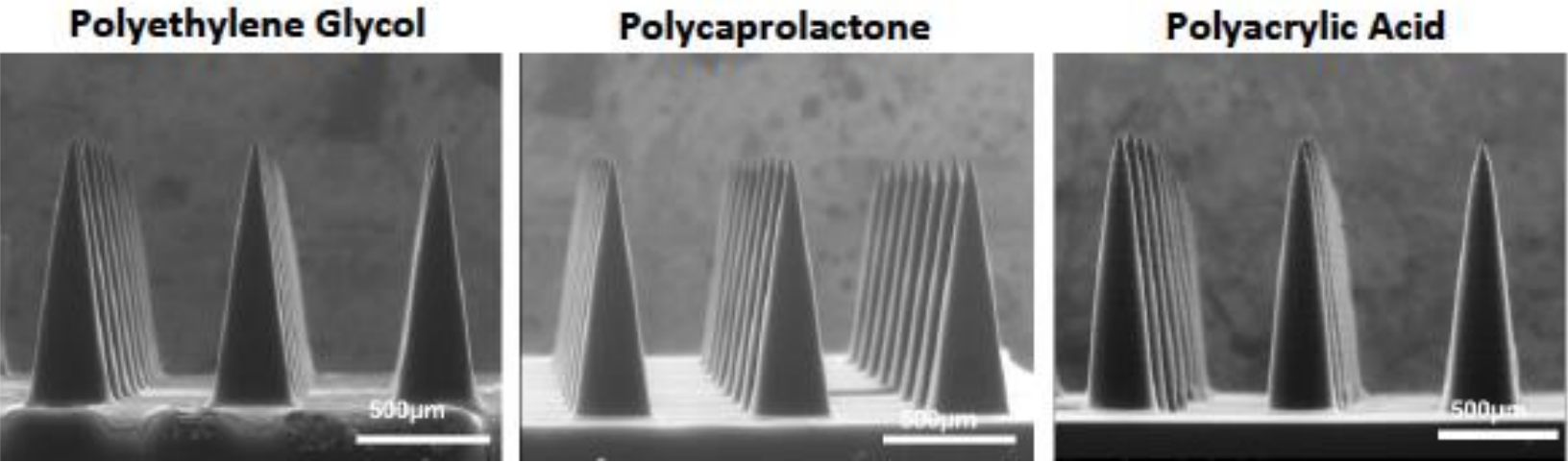
AnelleO PRO: Anello is a UNC-CH startup founded by Rahima Benhabbour.

# TRANSDERMAL DRUG DELIVERY VIA MICRO-NEEDLES

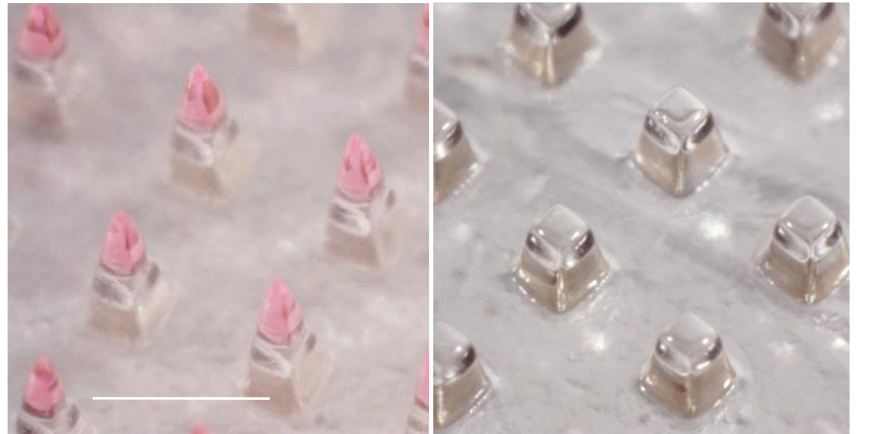
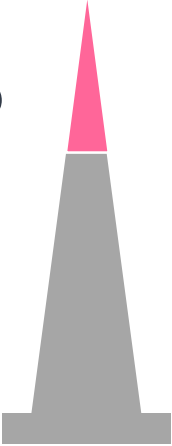


Tumbleston et. al (2015), *Science* ; Johnson et. al (2016), *PLOS One*.

17



Dissolvable Tip  
Non-dissolvable base



**Carbon**

# A future fabricated with light

