MIT Medical Device Design

Prof. Alexander H. Slocum

Walter M. May (1939) and A. Hazel May Chair in Emerging Technologies
Director, Precision Engineering Research Group

meddevdesign.mit.edu

MITMECHE MIT EECS HST imes

Designing better healthcare takes a team

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Professor
Mechanical Engineering
Precision Machine Design Guru

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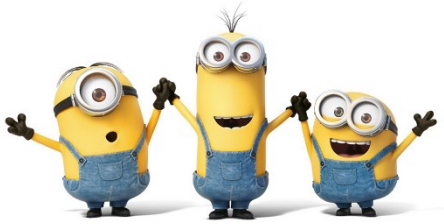
Gastroenterologist
Brigham & Women's

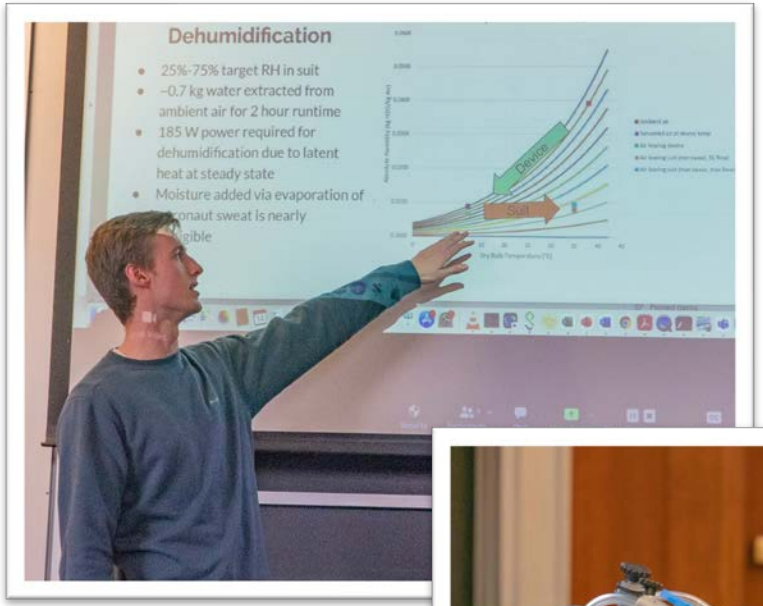
Ellen Roche, PhD
Professor
Institute for Medical Engineering & Science
Therapeutic Technology Design & Development

Nevan Hanumara, PhD
Research Scientist
Mechanical Engineering
Design, Human Factors, Entrepreneurship

Anthony Pennes
Instructor
Electrical Engineering
Electronics Wizard

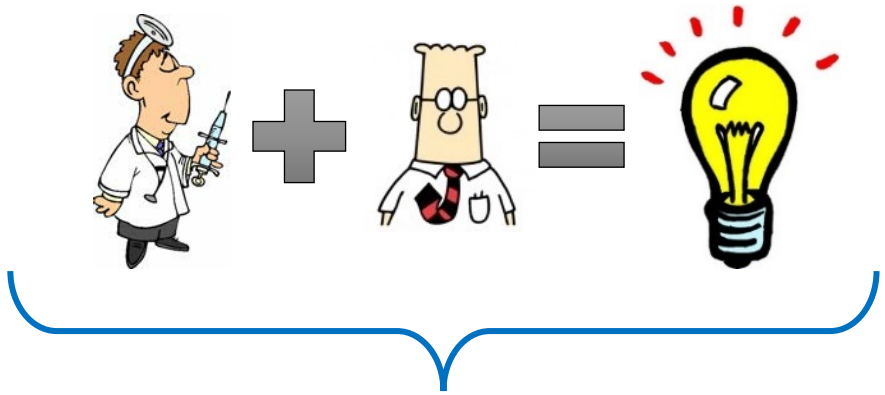


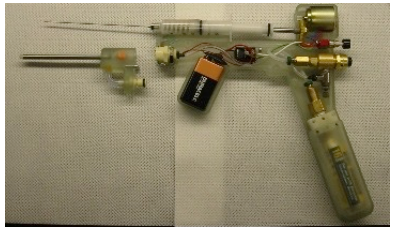
Our Mission: Prepare the next generation of healthcare innovators!



We bring together Clinicians, Companies, Engineers & Entrepreneurs

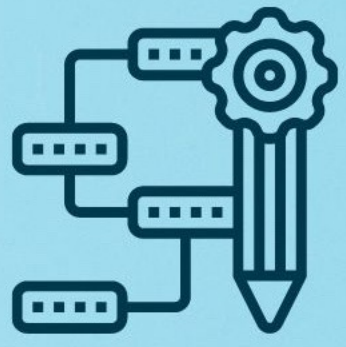
Experienced	Taught since 2003
Multidisciplinary	MechE, EECS, HST, SDM, others
Inclusive	Open to Grads & Undergrads
Clinically Driven	I need solution to …
Competitive	Students select the projects
Teamwork	8 teams of 4-6 students
Mentorship	Course staff support each team
Accelerated	12 weeks to proof-of-concepts
Efficient	$4k budget/team
Engagement	Industry participation essential





We follow an accelerated, industry-modeled design process: 12 Weeks – Three Phases

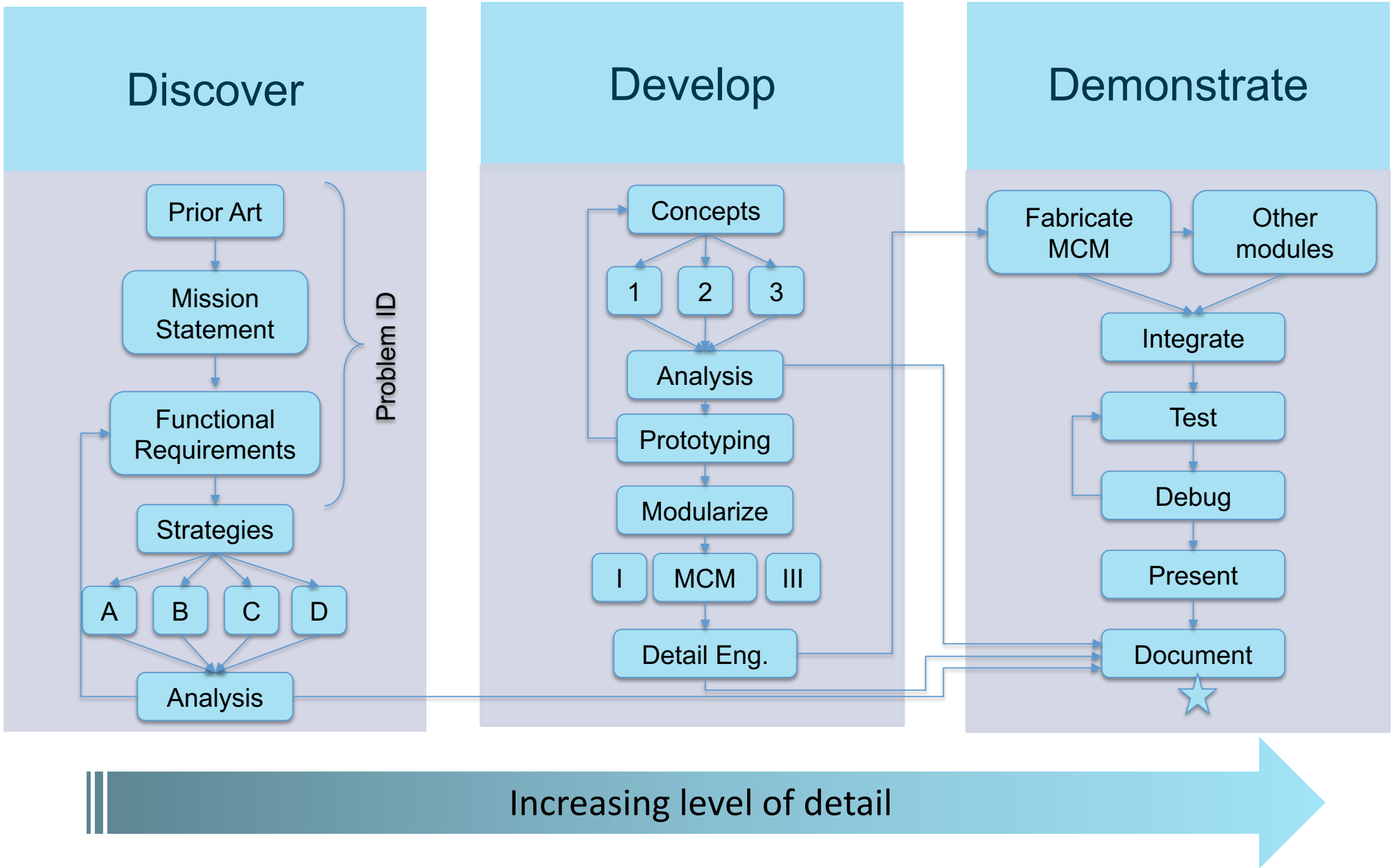
DISCOVER
Select a clinical challenge & dive deep



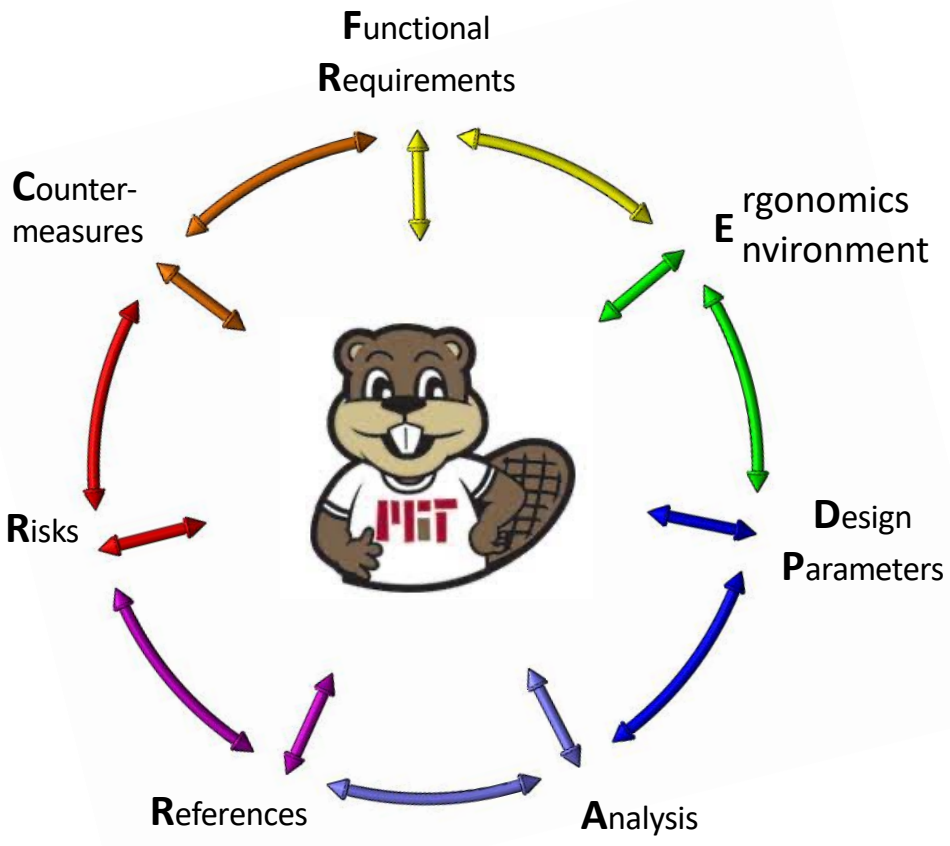
DEVELOP
Explore the options; build your prototype

DEMONSTRATE
Test your design and make it better

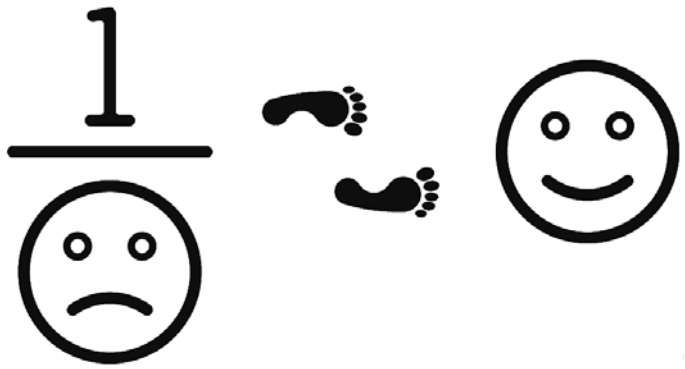
We learn and prototype together


Discover
Develop
Demonstrate
Prior Art
Mission Statement
Functional Requirements
Strategies
A
B
C
D
Analysis
Problem ID
Concepts
1
2
3
Analysis
Prototyping
Modularize
I
MCM
III
Detail Eng.
Fabricate MCM
Other modules
Integrate
Test
Debug
Present
Document
Increasing level of detail

We teach Deterministic Design & Teamwork



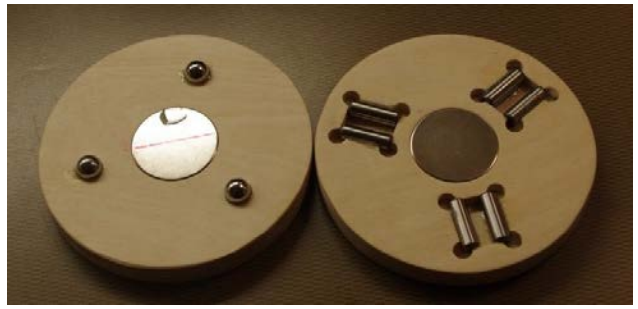
"FRED PARRC"

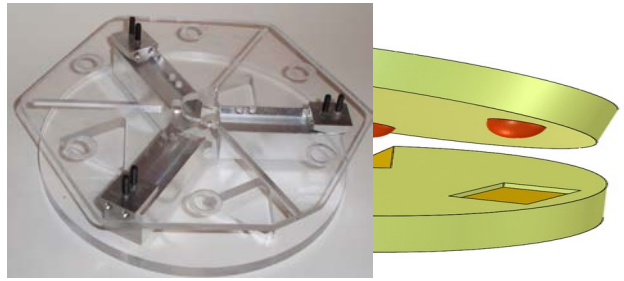


"OOSEH"

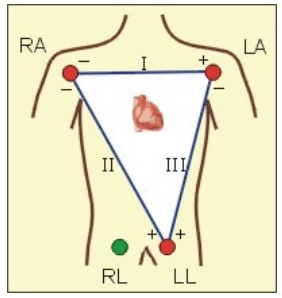
Labs reinforce the lectures

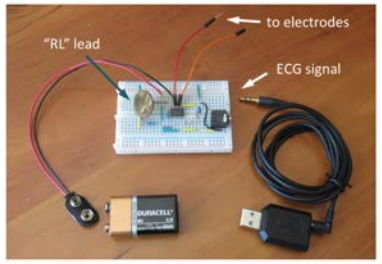
Precision Assembly
Kinematic Coupling

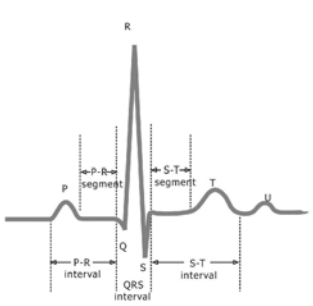


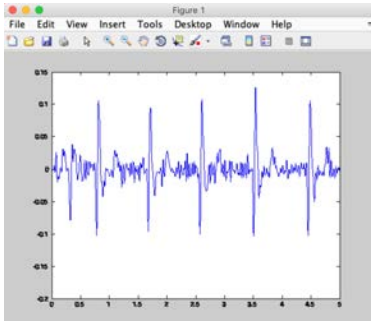


Biomedical Sensing
Electrocardiogram

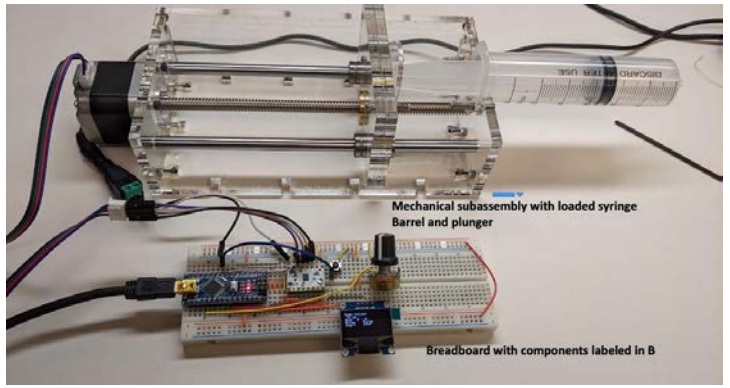






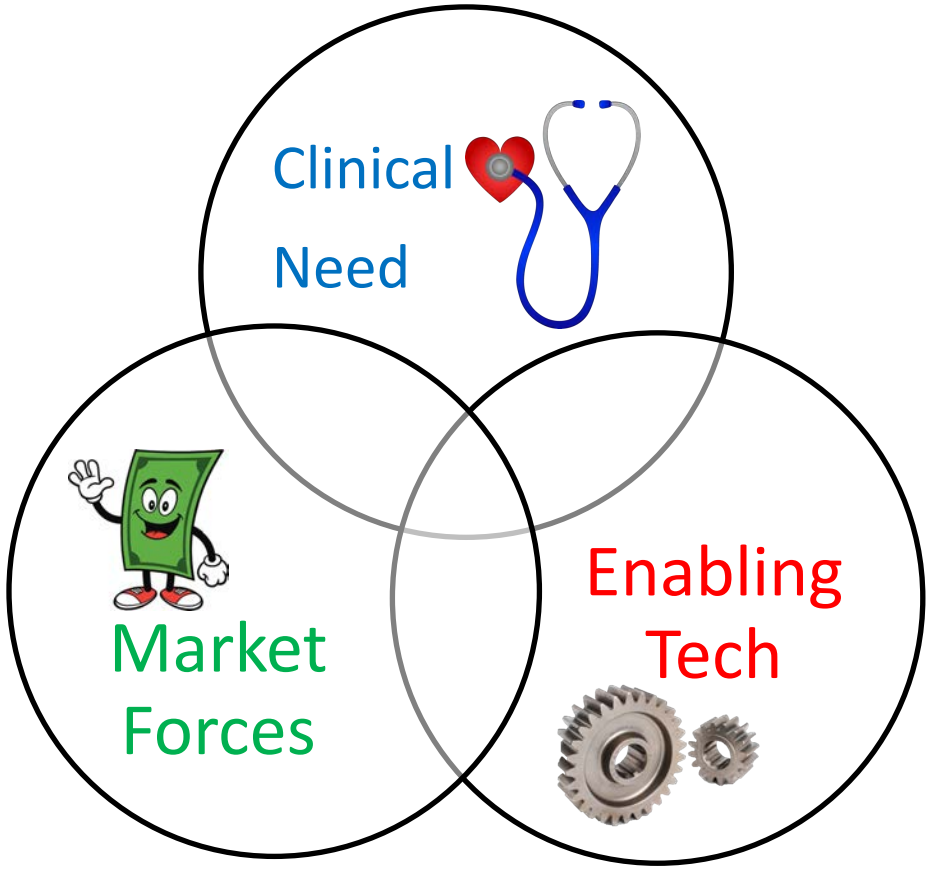


Mechatronics
Syringe Pump



A. Pennes, K. Mendez, N. Hanumara, E.T. Roche, G. Traverso, D. Custer, G. Hom, “A hands-on medical mechatronics exercise to pump up student learnings,” accepted for publication in J. Biomedical Engineering Education, Special Issue on Experiential Learning.

We teach best design practice in support of regulatory, IP reimbursment & business issues



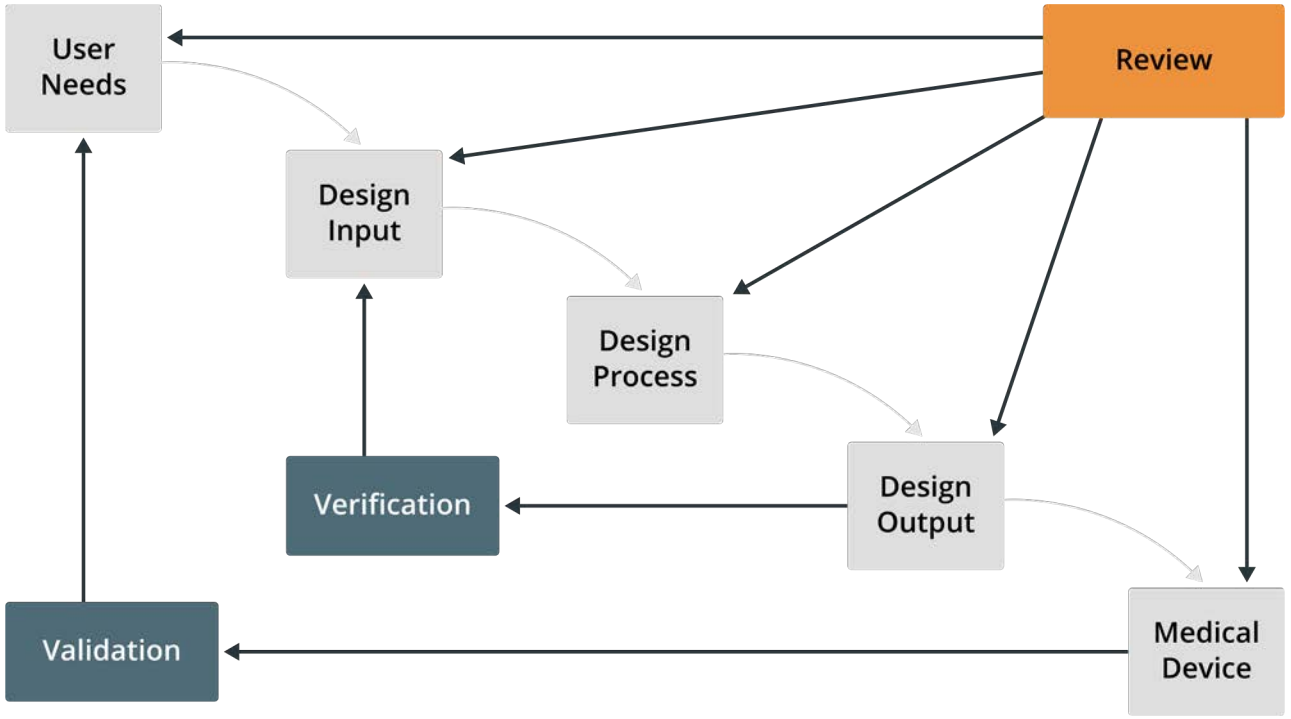
The Medical Device Tripod

- What is the unmet clinical need?
- Why is the current technology insufficient?
- What is the clinical burden of proof?

- What technologies already exist?
- How much better do you need to be?
- What is your biggest technological risk?
- What is your regulatory and IP path?

- Who pays? – Patient, Doctor, Hospital, Insurer?
- Will it make money? … Save money? … Cost more?
- Beachhead? Total Addressable Market (TAM)?
- Who is likely to acquire you? When?

It is never to early to start your DHF (Design History File)



User requirement specifications

System architecture

Software architecture

Component drawings

Risk analysis and risk assessments

System tests

Component tests

Validation activities

www.fda.gov/regulatory-information/search-fda-guidance-documents/design-control-guidance-medical-device-manufacturers

www.simplerqms.com/design-history-file

Example 2022 Projects

BRIGHAM AND WOMEN'S HOSPITAL

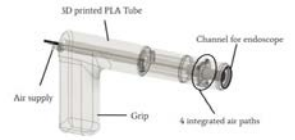
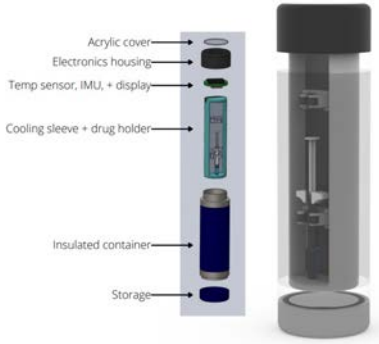


Figure 1: Computer-Aided Design (CAD) of 3D Printed Device Without Balloon

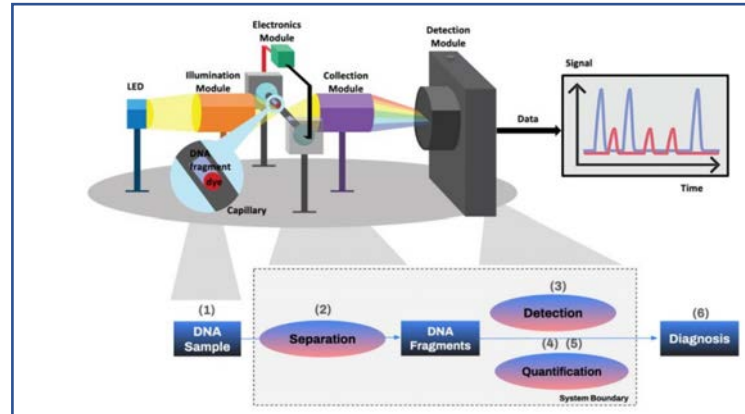
Figure 2: Final Device Prototype at a Deflated and Inflated State

Facilitating a screen and treat approach in cervical cancer



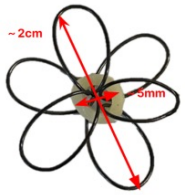
Drug storage & reminder device

Takeda



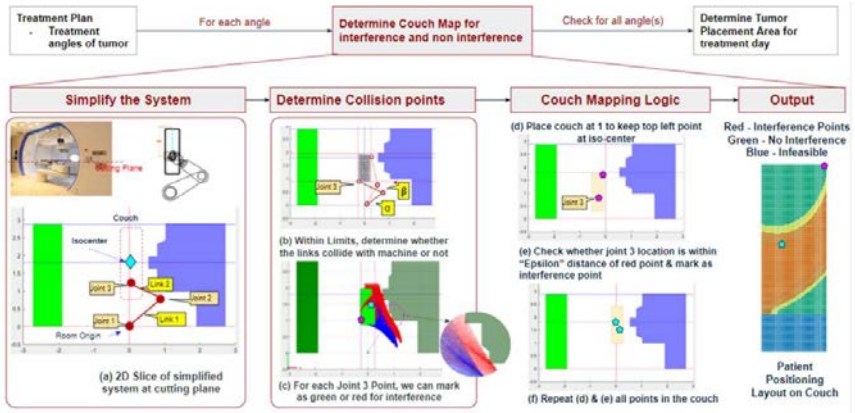
Low-cost capillary electrophoresis device for multiplexed DNA fragment analysis

DANA-FARBER CANCER INSTITUTE



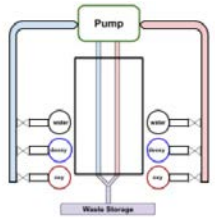
Improved Hydrocephalus ETV Procedure

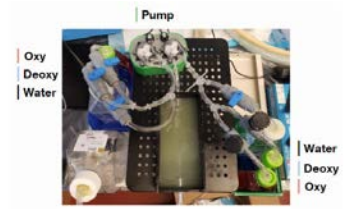
MGH 1811 GENERAL HOSPITAL



Proton therapy patient positioning

Sumitomo Heavy Industries, Ltd.





Building a Novel Monitor for Infants with Congenital Heart Disease

JOHNS HOPKINS MEDICINE

2.75 Outcomes: Papers, Patents

- Su Jin Kim, Alexander H. Slocum, Benjamin B. Scott,, “A miniature kinematic coupling device for mouse head fixation,” Journal of Neuroscience Methods, Volume 372, 2022, https://doi.org/10.1016/j.jneumeth.2022.109549.
- Butters, B., Fernández-Galiana, Á., Wollin, D., Traverso, G., Slocum, A., and Petrozza, J. (March 31, 2022). "A Retractable Six-Prong Laparoscopic Grasper for Laparoscopic Myomectomy." ASME. J. Med. Devices. September 2022; 16(3): 031003. https://doi.org/10.1115/1.4054013
- Oeding JF, Bockman S, Chiu H, Hua C, Connor J, Slocum A. “A Novel Approach to Open Reduction and Internal Fixation of Distal Radius Fractures Utilizing a Multi-Degree-of-Freedom Traction and Stabilization Device.” J Med Device. 2022 Jun 1;16(2):021006. doi: 10.1115/1.4052901. Epub 2022 Feb 3. PMID: 35284034; PMCID: PMC8905091.
- M. Das *et al.*, “A Low-Cost, Easily Deployable Vesicovaginal Fistula Occluding Device for Providing Interim Continence,” *Journal of Medical Devices*, vol. 16, no. 2, Mar. 2022, doi: 10.1115/1.4053603.
- J. Shen *et al.*, “Noninvasive Method and Metric for Monitoring Lung Condition,” in *2021 43rd Annual International Conference of the IEEE Engineering in Medicine & Biology Society (EMBC)*, Nov. 2021, pp. 6841–6844. doi: 10.1109/EMBC46164.2021.9630839.
- US10925655 Alexander Slocum, James Connor Jr., Jacob Mooney, NicholasWing-PingKwok , “Bone Reduction Forceps”, 02/23/2021

2.75 Outcomes: Papers, Patents

- Aggarwal, N. , Cavuto, M.L., Lia, M., Rodman, N.H., Slocum, A.H., Jee, K.W., Lub, H., “Design of a compact proton beam energy modulator for imaging”, Nuclear Instruments and Methods in Physics Research Section A: Accelerators, Spectrometers, Detectors and Associated Equipment, Vol. 955, 1 March 2020, 163269 https://doi.org/10.1016/j.nima.2019.163269
- M. Whalen *et al.*, “Device Prototype for Vaginal Delivery of Extremely Preterm Fetuses in the Breech Presentation,” *Journal of Medical Devices*, vol. 15, no. 021002, Dec. 2020, doi: 10.1115/1.4049086.
- S. Grown-Haeberli *et al.*, “Design and Applicability of a Mechanical Impedance Sensor for Vein Penetration Detection,” in *2020 42nd Annual International Conference of the IEEE Engineering in Medicine Biology Society (EMBC)*, Jul. 2020, pp. 4016–4019. doi: 10.1109/EMBC44109.2020.9175501.
- Cobi, A. C., Gray, L., Mittmann, E. R., Link, S. B., Hanumara, N. C., Lyatskaya, Y., Roche, E., Slocum, A. H., and Zygmanski, P. (October 9, 2019). "Design of a Reconfigurable Quality Assurance Phantom for Verifying the Spatial Accuracy of Radiosurgery Treatments for Multiple Brain Metastases." ASME. J. Med. Devices. December 2019; 13(4): 045003. https://doi.org/10.1115/1.4044402.
- R. Singh *et al.*, “Noninvasive Assessment of Jugular Venous Pressure via Force-Coupled Single Crystal Ultrasound,” *IEEE Transactions on Biomedical Engineering*, vol. 65, no. 8, pp. 1705–1710, Aug. 2018, doi: 10.1109/TBME.2017.2767828.

- R. Singh *et al.*, “Noninvasive Assessment of Jugular Venous Pressure via Force-Coupled Single Crystal Ultrasound,” *IEEE Transactions on Biomedical Engineering*, vol. 65, no. 8, pp. 1705–1710, Aug. 2018, doi: 10.1109/TBME.2017.2767828.

2.75 Outcomes: Papers, Patents

- Wortman, Tyler D., Jay D. Carlson, Edward Perez, and Alexander H. Slocum. “LesionAir: An Automated, Low-Cost Vision-Based Skin Cancer Diagnostic Tool.” Journal of Medical Devices 12, no. 2 (March 5, 2018): 021001.
- Slocum, Jr., A.H., A.H. Slocum, J. Spiegel, “Design and In-vitro Testing of a Pressure Sensing Syringe for use in Endotracheal Intubation”, Survey of Anesthesiology: February 2013 - Volume 57 - Issue 1 - p 48–49doi: 10.1097/01.SA.0000425543.94325.fa .
- Slocum Jr., A.H., S.C. Duffley, J.M. Gamazo, A.Watral, J.Spiegel, A.H.Slocum, “Design, Manufacture, and Testing of the Easycuff™ Pressure measuring Syringe”, ASME Jou. Med. Devices, September 2012, Vol. 6.
- Cervantes, T.M., E.K. Summers, R. Batzera, C. Simpson, R. Lewis, N.N. Dhanani, A.H. Slocum, “Evaluation of a Minimally Invasive Renal Cooling Device Using Heat Transfer Analysis and an *in vivo* Porcine Model,” Medical Engineering & Physics, Vol. 35(6), June 2013; dx.doi.org/10.1016/j.medengphy.2012.08.001; pp. 736-742.
- Hanumara, N.C.., N.D. Begg, C.J. Walsh, D. Custer, R. Gupta, L.R. Osborn, A.H. Slocum, “Classroom to Clinic: Merging Education and Research to Efficiently Prototype Medical Devices,” IEEE Journal of Translational Engineering in Health and Medicine, August 15, 2013. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4847477/
- *Begg, N.D., Slocum, A.H., “Audible Frequency Vibration of Puncture-Access Medical Devices,” Medical Engineering & Physics, 36 (2014) 371-377.

2.75 Outcomes: Papers, Patents

- Hanumara, N.C., A.H. Slocum, T. Mitamura, “Design of a Spherically Actuated Human Interaction Robot Head”, ASME Jou. Mech. Des., May 2012, Vol. 134
- Hoehl, M.M., P. J. Lu, P. A. Sims, A. H. Slocum, “Rapid and robust detection methods for poison and microbial contamination”, J Agric Food Chem. 2012 Jun 27;60(25):6349-58. Epub 2012 Jun 15.
- Vasilyev, N.V., M. Kawata, C. M. DiBiasio, K.V. Durand, J. Hopkins, Z. Traina, A.H. Slocum, P. J. del Nido, “A novel cardioport for beating-heart, image-guided intracardiac surgery“, J Thorac Cardiovasc Surg. 2011 Dec;142(6):1545-51, https://www.ncbi.nlm.nih.gov/pubmed/21855093#
- Petrzelka, J.E., M.C. Menon, C.J. Stefanov-Wagner, S.K. Agarwal, D. Chatzigeorgiou, M. Lustrino, A. H. Slocum, “An Articulating Tool for Endoscopic Screw Delivery”, Journal of Medical Devices 5.1 (2011): 011004.
- DiBiasio, C.M., K. V. Durand, J. Hopkins, Z. Traina, A. H. Slocum, N. V. Vasilyev, P. J. del Nido, 2011, “Design of a Surgical Port for Minimally Invasive Beating- Intracardial Procedures”, Journal of Medical Devices, 5(4): pp. 045001.
- Mitha, A.P., M. S. Ahmad, S. J. Cohen, J. S. Lieberman, M.R. Udengaard, A.H. Slocum, J.-V. C. E. Coumans, “A Modified Footplate for the Kerrison Rongeur”, Jou. Med. Dev., March 2010, Vol. 4 / 1-1.

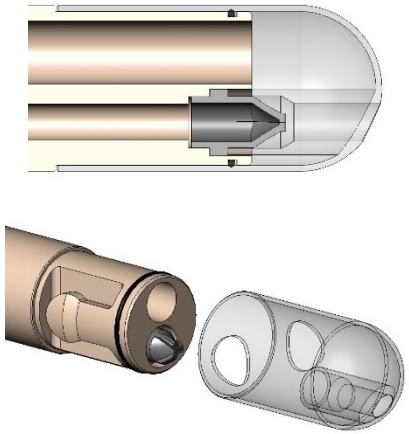
2.75 Products: CardioPort (2005)

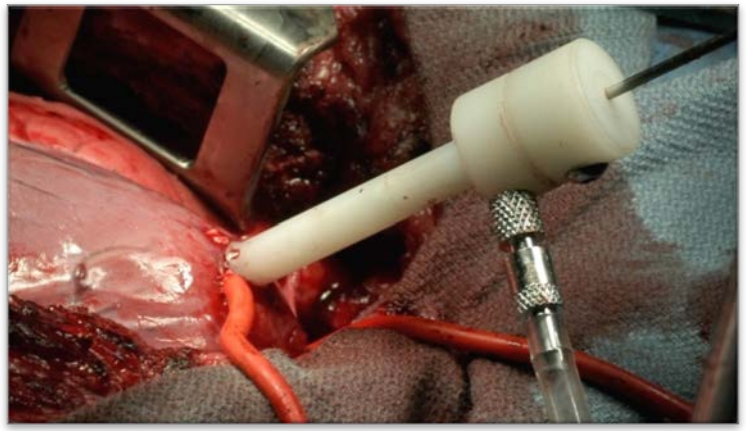
Nido Surgical

I need a device to enable minimally invasive access to a beating heart that:

- Allows an exchange of tools
- Maintains an airtight seal
- Causes no bleeding or damage

- Dr. Pedro Del Nido, Boston Children's





Early proto
Testing in an animal model

Gen 2 device designed

2017 – $1.3 million SBIR + $1.4 million from Broadview Ventures

Patent Issued 2013 - US20090275893A1

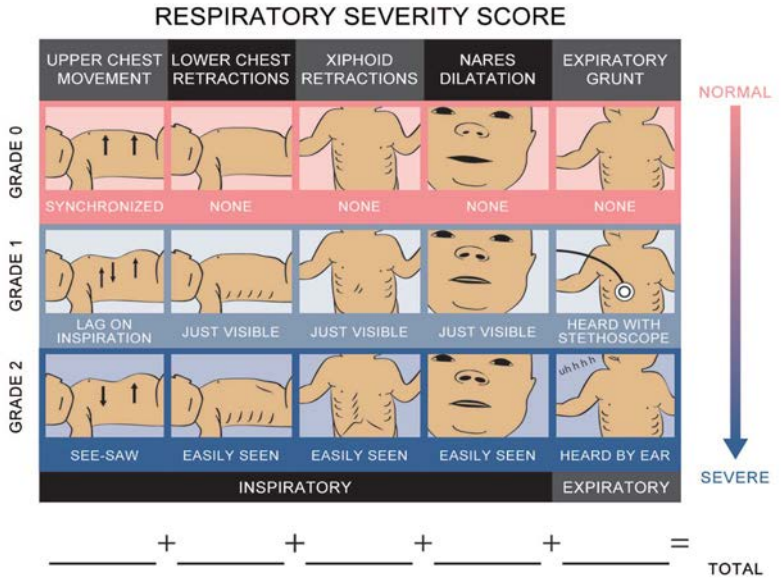
2022 – SEPIA (Solution for Epicardial Ablation) Acquired by an undisclosed medical device company

2.75 Products: InSync (2005)

"Assessing the work of breathing in a child in respiratory distress is more art than science.

We can objectively measure the respiratory rate, but the depth of a child's effort is all in the eyes of the beholder."

- Dr. Ryan Carroll, MGH Pediatrics



McAdams 2015

Current state of the art relies on manual "scoring" infants.

I need a way to measure the work of breathing in neonates that:

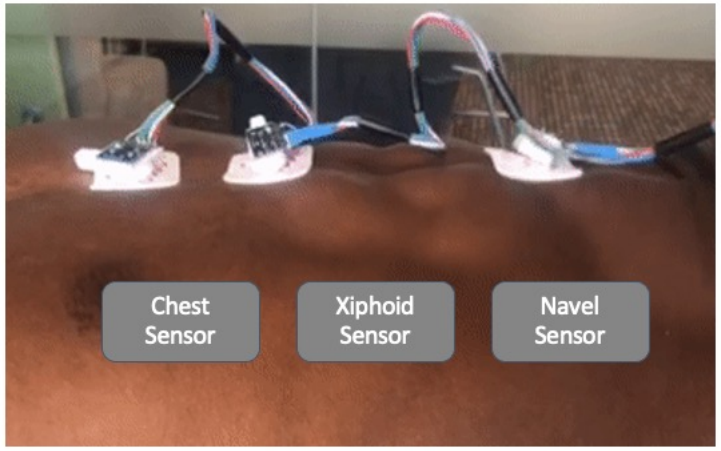
- Provides real-time information
- Is non-invasive & continuous
- Alerts at the onset of decline

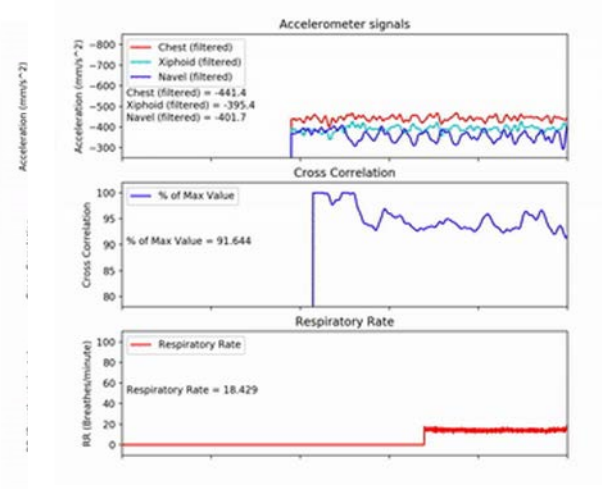
Taking the **guesswork** out of respiratory care.

DISATI

Identified the key physiological signature: See-saw chest motion

Developed novel 3 sensor package and monitoring algorithm

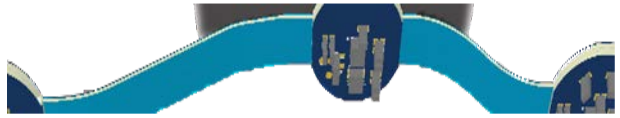




InSync has the potential to reduce the need for invasive ventilatory support, leading to shorter stays, up to 41%, and cost savings of $18K/patinet.

Patent Pending
US20220288333A1

Clinical trials ongoing at MGH



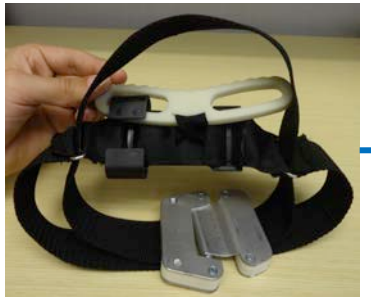
2.75 Products: Thor Torniquet (2013)
Traumatic Hemorrhage One-hand Response

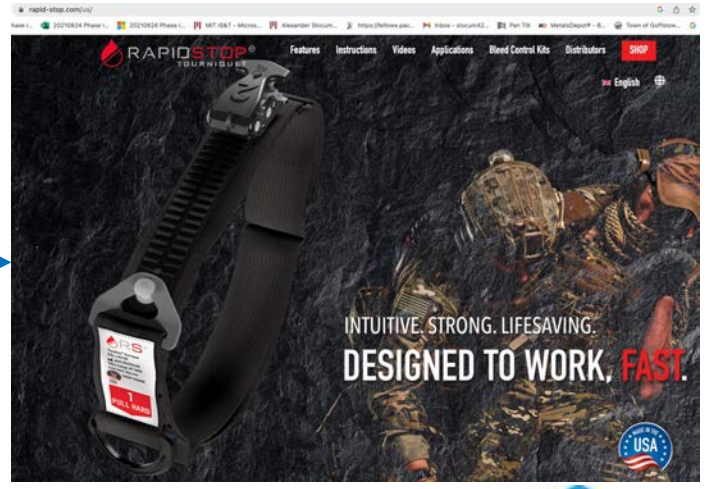
The Boston bombings highlighted the need for an easier to operate, faster to apply more reliable tourniquet.

- Dr. Jay Connor, Mt. Auburn Surgery

2.75 team created a unique one hand operable *Click, Pull & Tighten* design, suitable for use on trapped limbs, and nearly silent during operation.

Patent Issued 2019 - US10278708B2

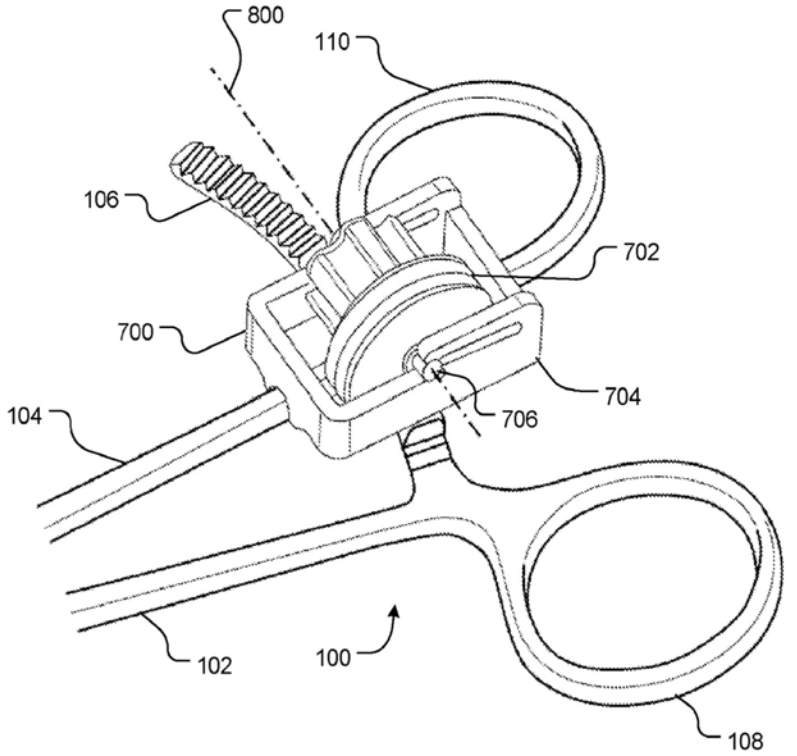




2022 – Available from https://rapid-stop.com/us/

2.75 Products: RollForce Clamp

- Bone reduction forceps with continuously adjustable for
  - Product in development for release 2024
  - NewCo being started by doctors and Prof. Slocum to bring 2.75 concept to hands of surgeons



(12) **United States Patent**
Slocum et al.

(10) **Patent No.: US 10,925,655 B2**
(45) **Date of Patent: Feb. 23, 2021**

(54) **BONE REDUCTION FORCEPS**

(71) Applicant: **Massachusetts Institute of Technology**, Cambridge, MA (US)

(72) Inventors: **Alexander Henry Slocum**, Bow, NH (US); **James Francis Connor, Jr.**, Cambridge, MA (US); **Jacob Alexander Mooney**, Westford, MA (US); **Nicholas Wing-Ping Kwok**, Novato, CA (US)

(73) Assignee: **Massachusetts Institute of Technology**, Cambridge, MA (US)

(52) **U.S. Cl.**
CPC ***A61B 17/8866*** (2013.01); ***A61B 17/2812*** (2013.01); *A61B 2017/00407* (2013.01); *A61B 2017/2837* (2013.01)

(58) **Field of Classification Search**
USPC 606/324–328, 151, 157, 51–52, 205–211
See application file for complete search history.

(56) **References Cited**

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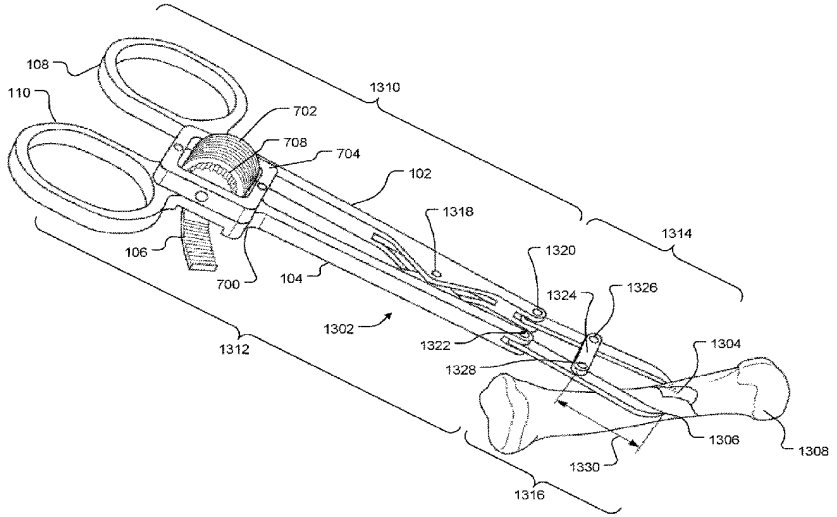
(Continued)



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The Teaching Team's Research - Examples

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Mechanical Engineering
Precision Machine Design Guru

Gio Traverso, MD
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Gastroenterologist
Brigham & Women's

Ellen Roche, PhD
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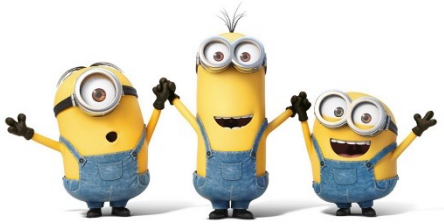

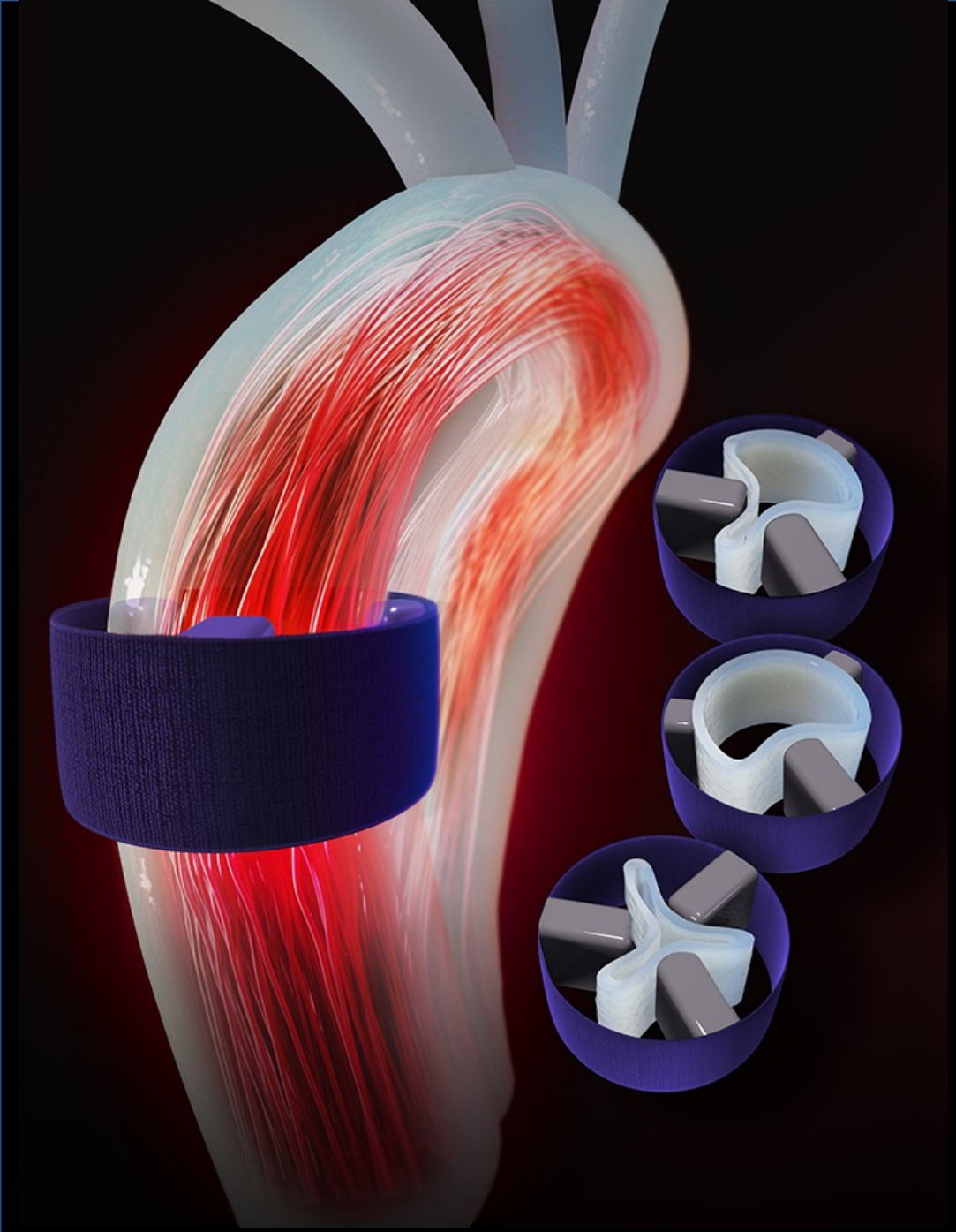

Superimposing soft active materials with dynamic organs and biological systems

Ellen Roche

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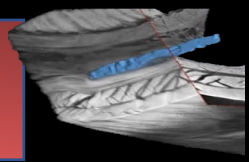
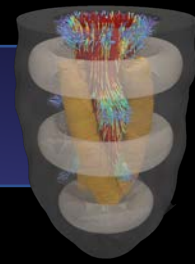
Therapeutic Technology Design and Development lab
ttdd.mit.edu

1. Mechanical augmentation of organ/system function

2. Structural/biological repair of tissue



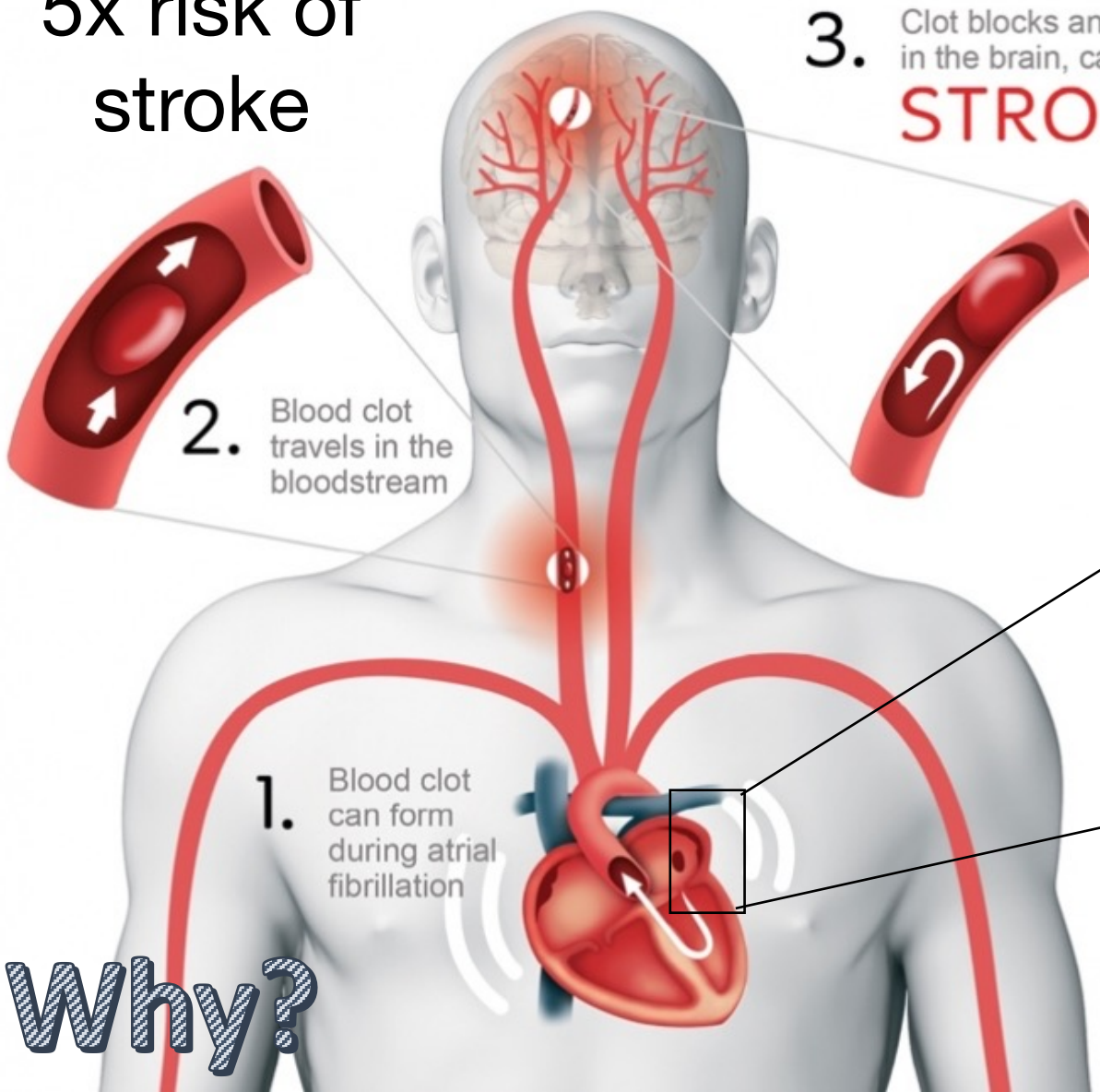
3. Multimodal simulations of biomechanics



An implantable ventilator that assists the diaphragm and mimics breathing mechanics

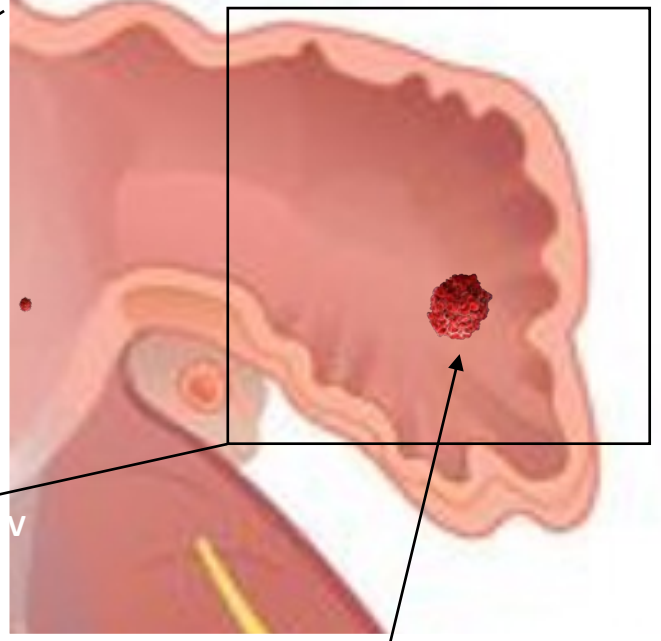
The clinical problem

5x risk of stroke



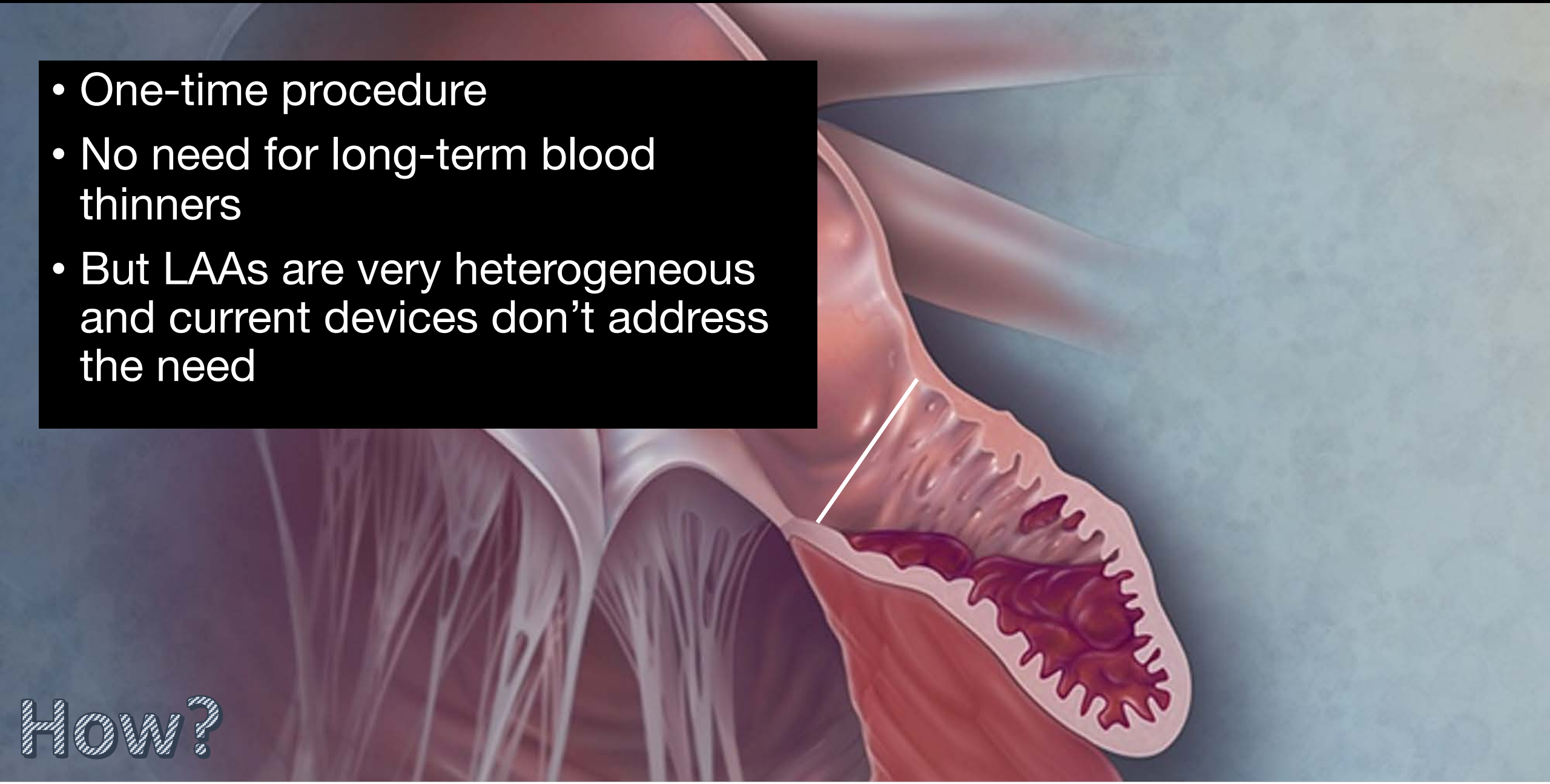
Why?

Left Atrial Appendage



90% of stroke-causing clots originate here

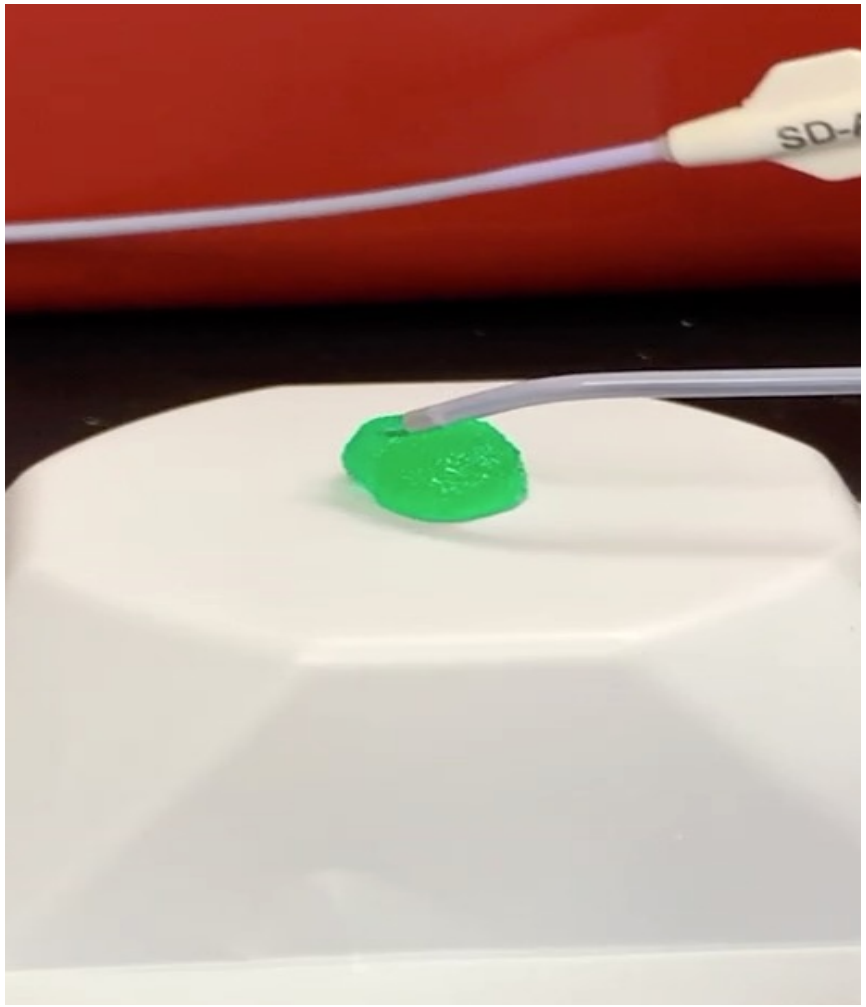
Block the LAA from the bloodflow

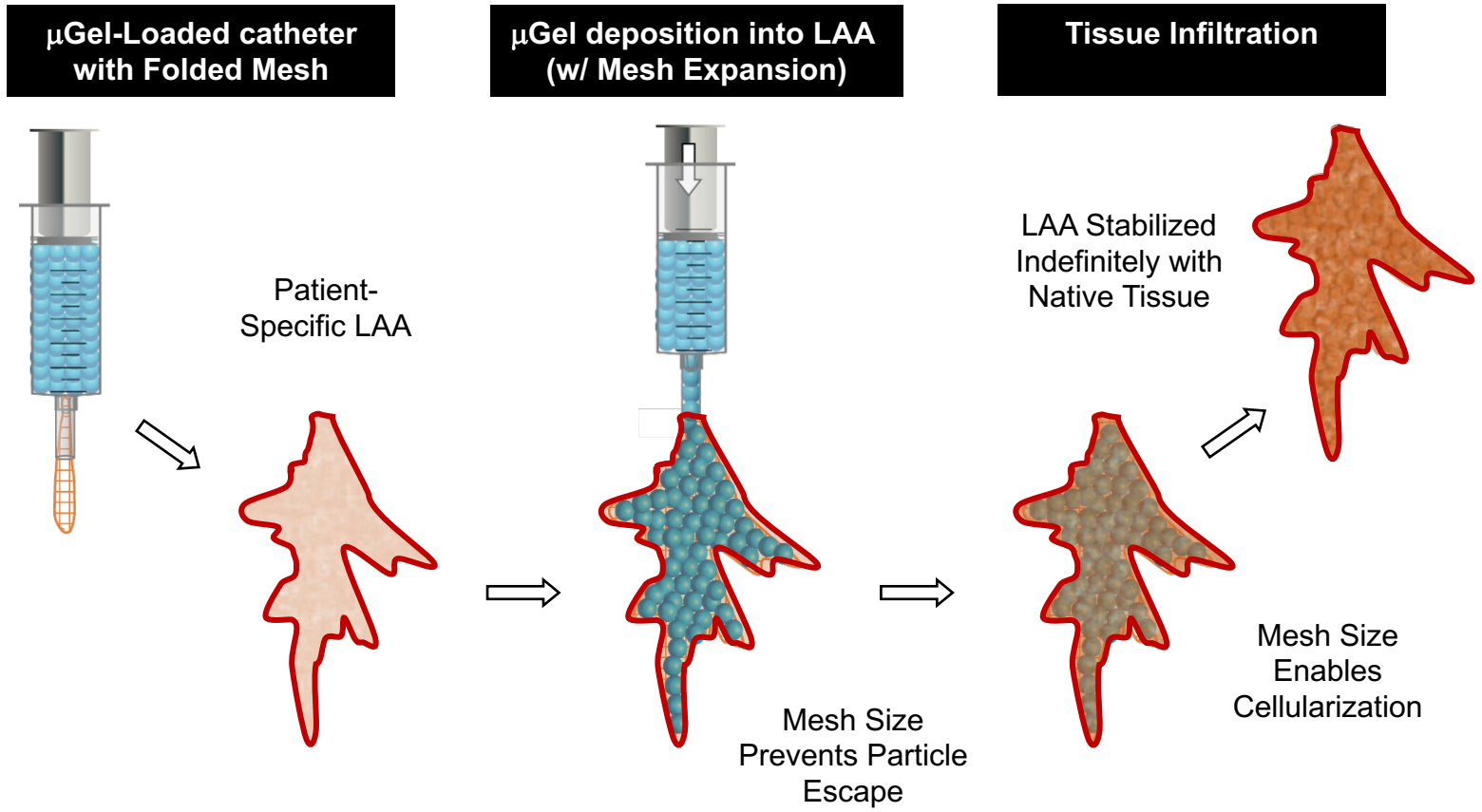


- One-time procedure
- No need for long-term blood thinners
- But LAAs are very heterogeneous and current devices don’t address the need

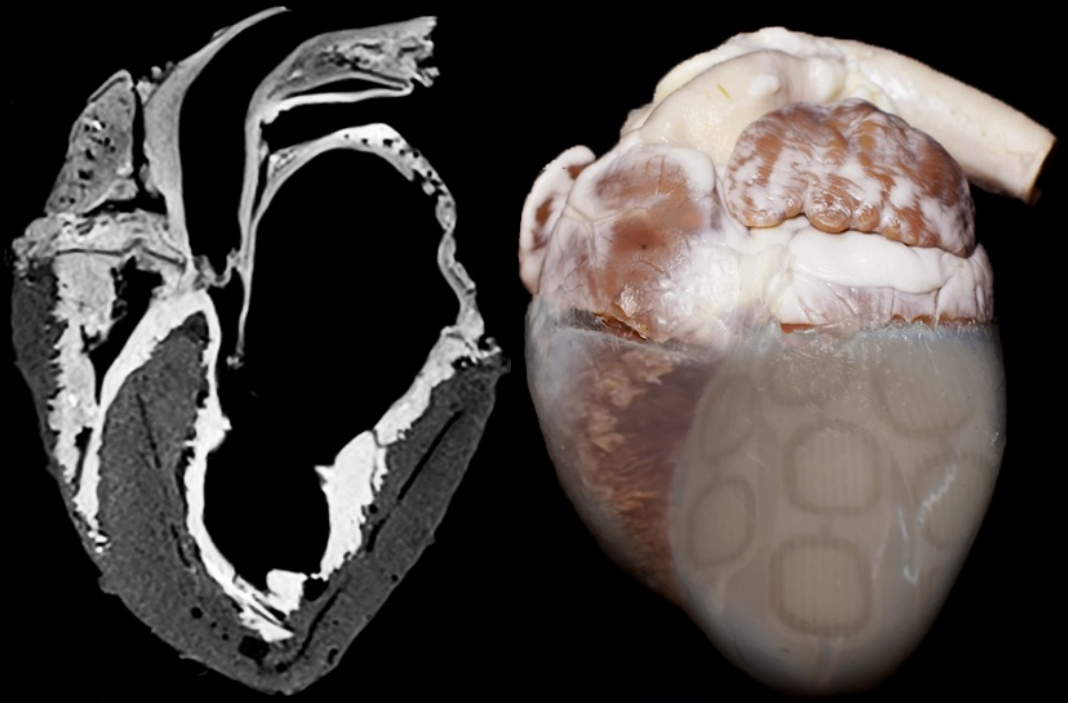
How?

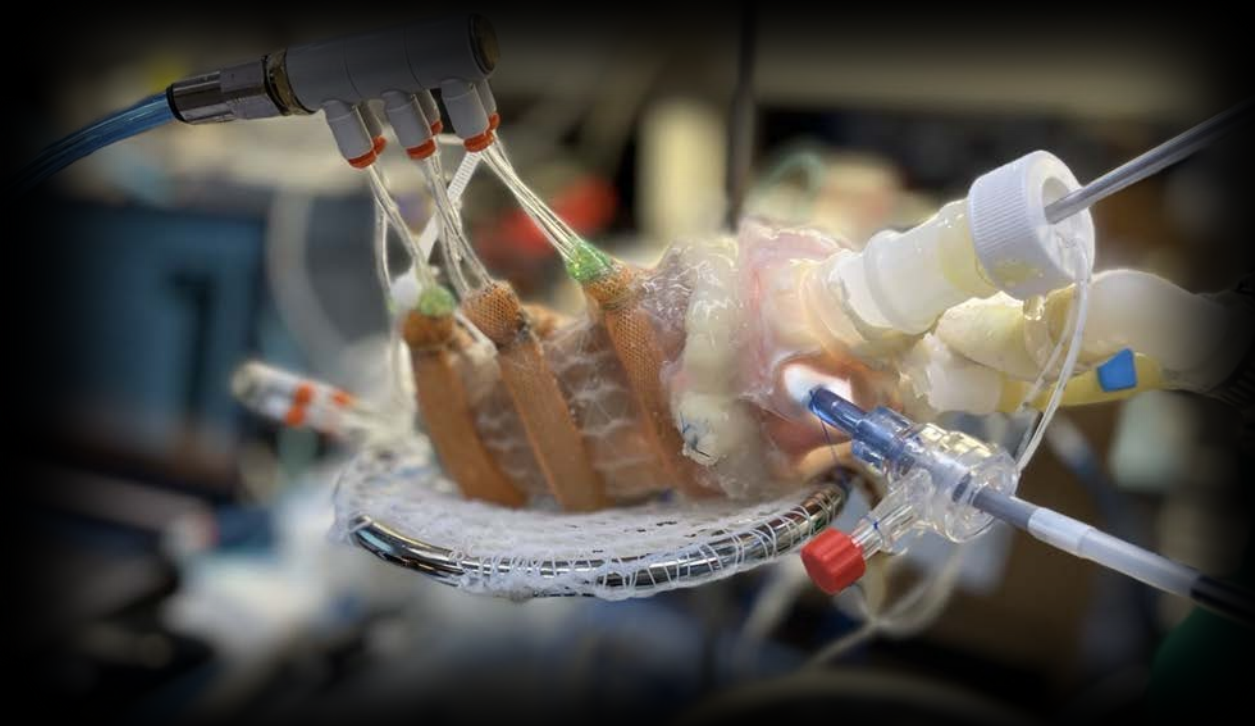
Jamming microgels for space filling and stabilization



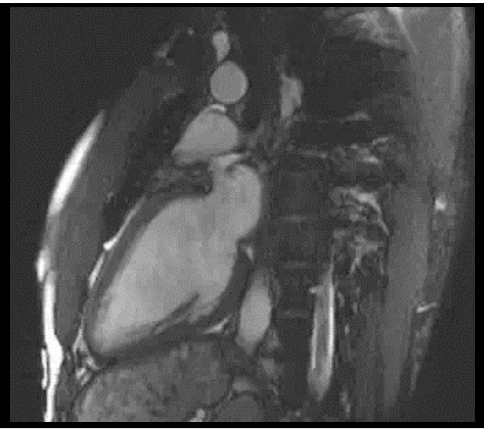


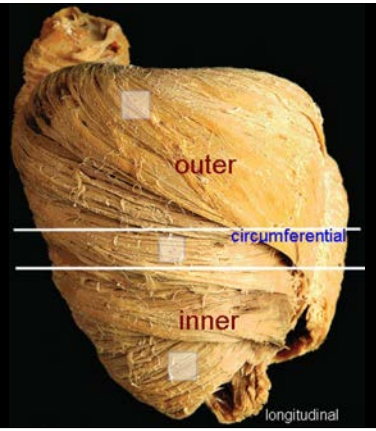
Development of a high fidelity cardiovascular *in vitro* simulator





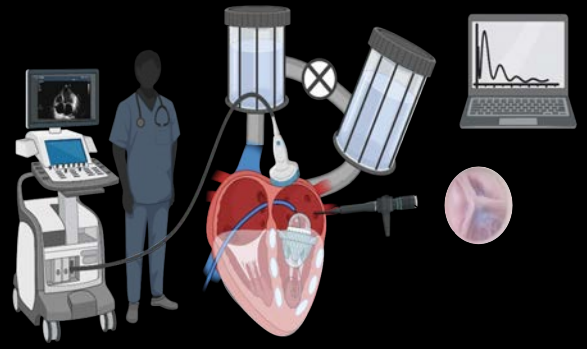
Problem

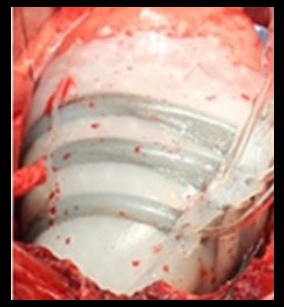




Difficult to replicate biomechanics and anatomy of the heart for a benchtop testing model

Need





Heart models are either not recapitulating biomechanics or not representing anatomy

Can we use our soft robotic approaches to enable better benchtop simulators?

Biohybrid approach to replicating the heart

Chemically preserved whole porcine heart

Remove muscle tissue

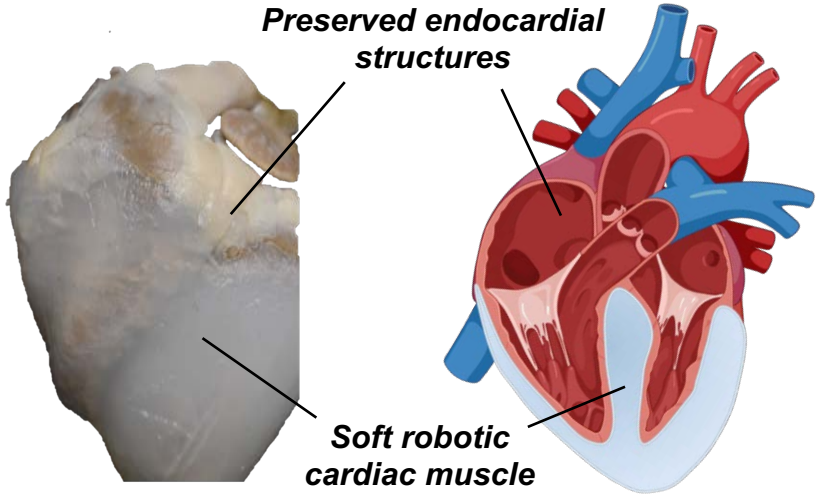
Endocardial scaffold

Soft robotic programming

Soft robotic cardiac muscle

Reanimate heart

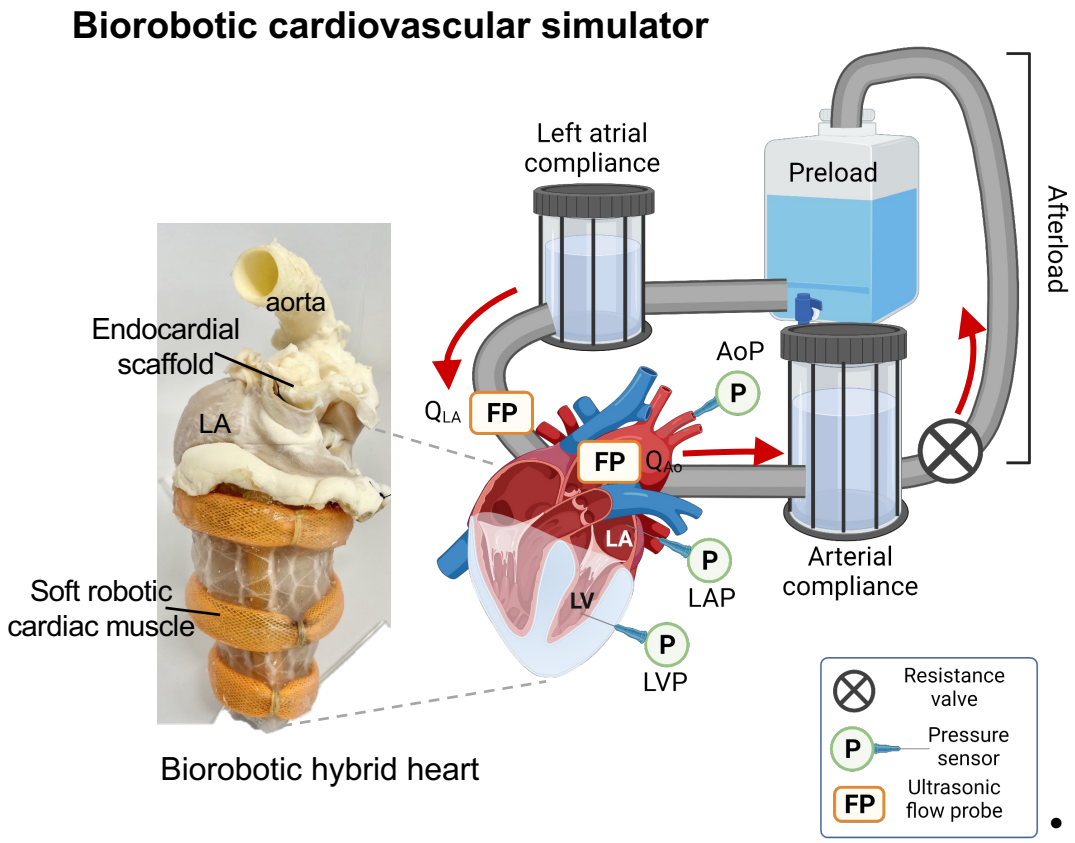
Biorobotic hybrid heart

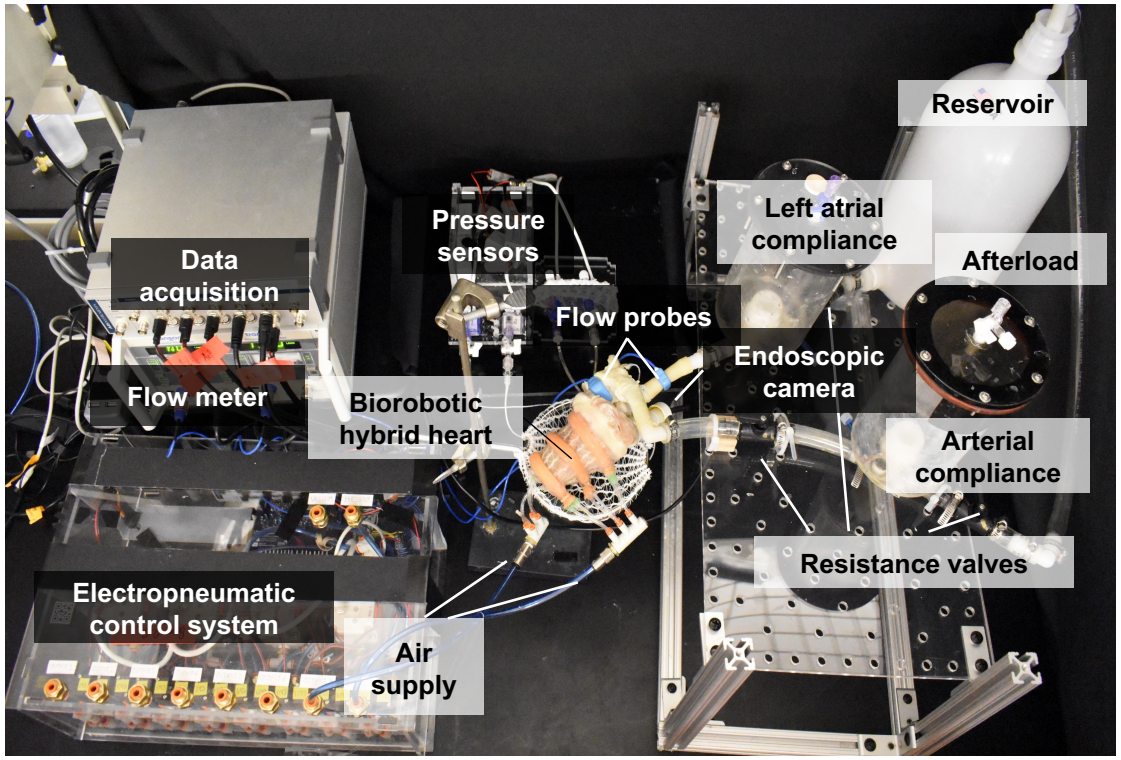


- Long-lasting components
- Accurate anatomical details
- Physiological cardiac motion
- Tunable motion via electropneumatic control

Biorobotic cardiovascular *in vitro* simulator

Biorobotic hybrid heart can be assembled with a left heart mock circulatory loop to drive flow

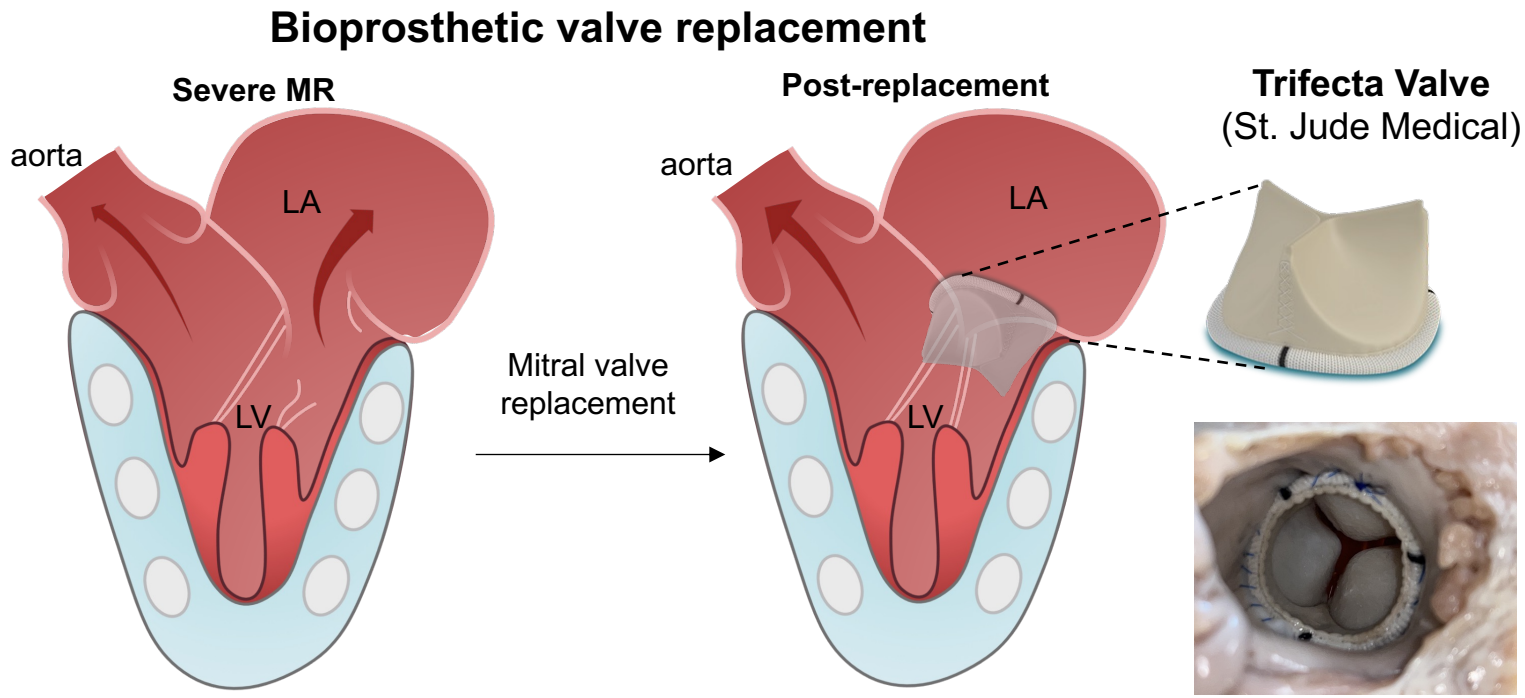




- Obtain real-time hemodynamics
- Directly observe intracardiac motion and device interaction
- Compatible with clinical imaging such as echocardiography

Demonstration of surgical valve replacement

The biorobotic cardiovascular simulator can be used to demonstrate surgical interventions



Featuring Prof. / Dr. Gio Traverso

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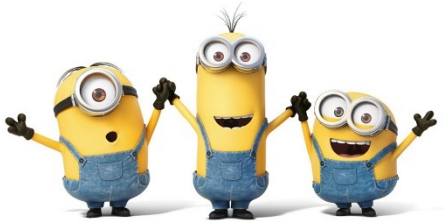

Device Engineering for Clinical Impact through the GI Tract

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Assistant Professor

Department of Mechanical Engineering, Massachusetts Institute of Technology

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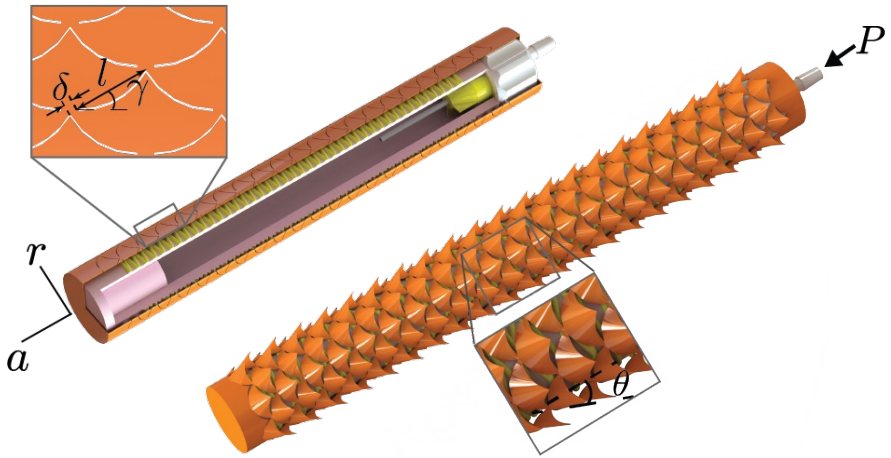
Massachusetts Institute of Technology

HARVARD MEDICAL SCHOOL

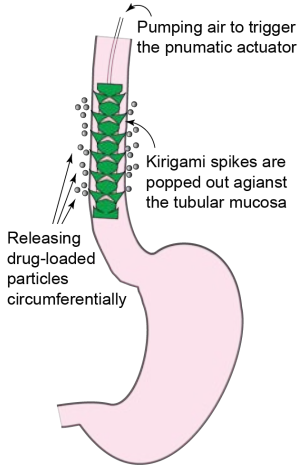
BRIGHAM AND WOMEN'S HOSPITAL

MITMECHE

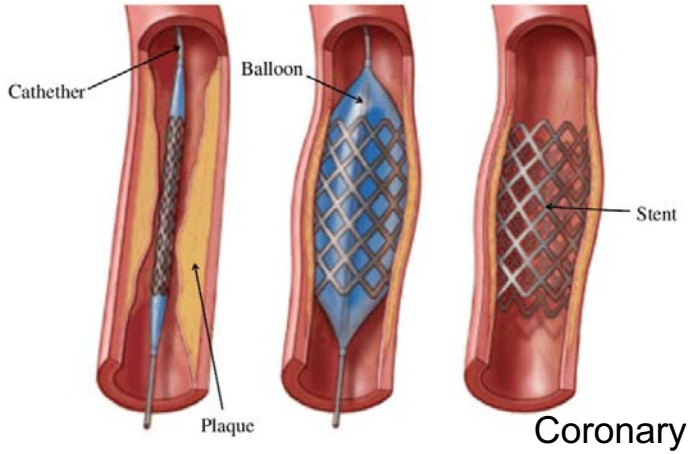
Overview: Kirigami-based stents



Kirigami surface

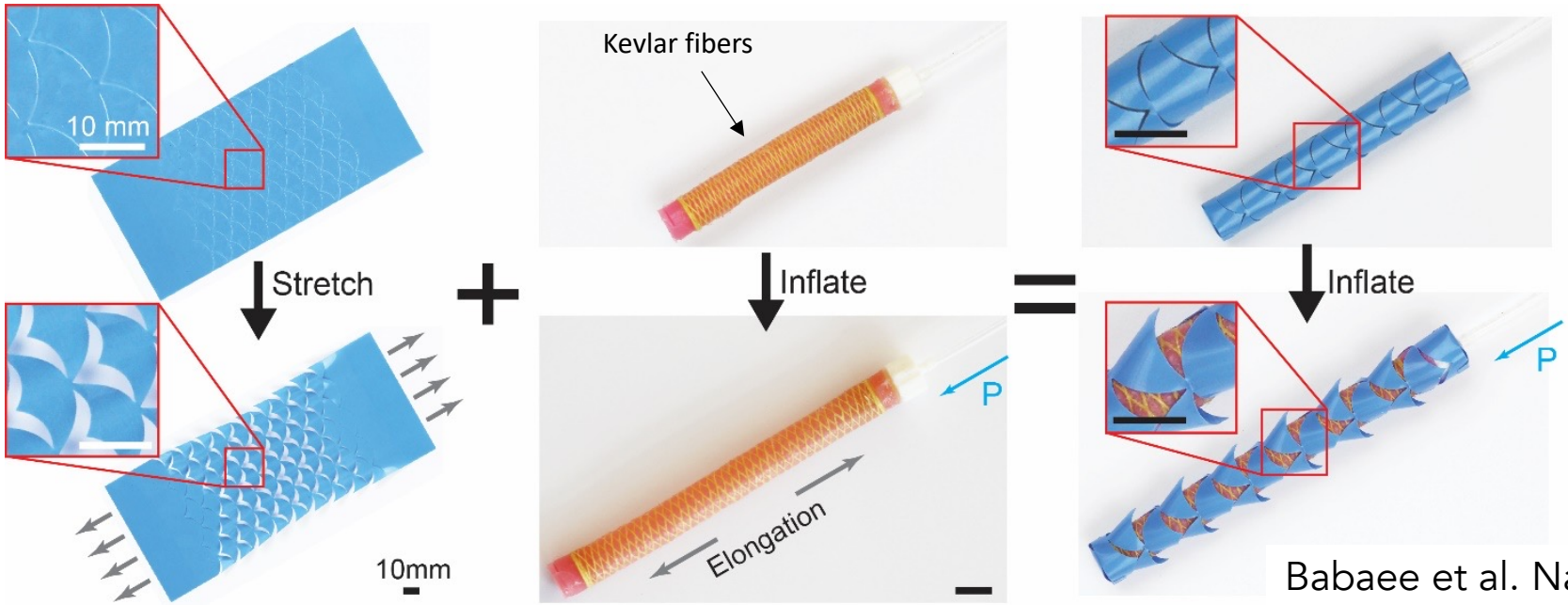


Soft linear actuator



Coronary stent

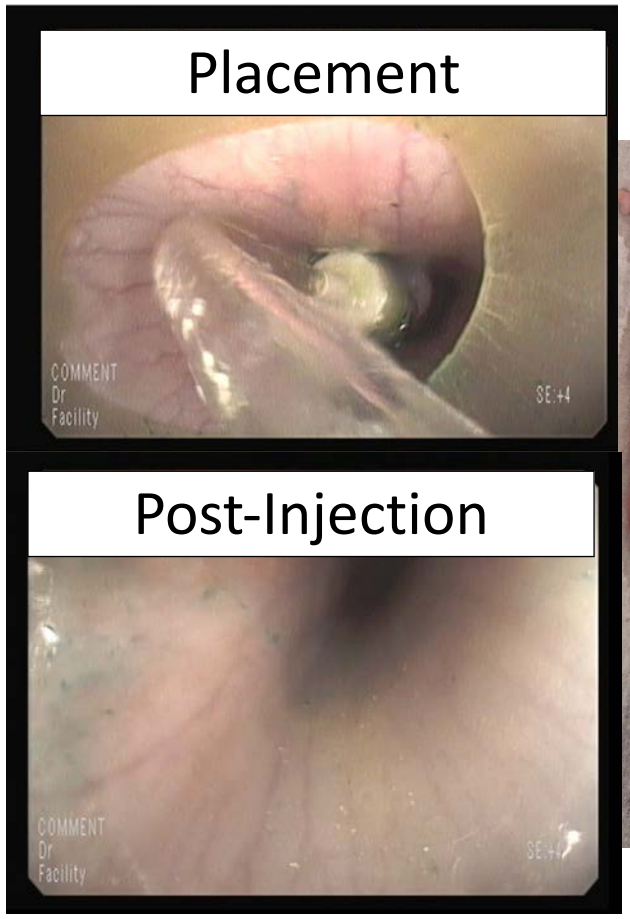
Kirigami stent

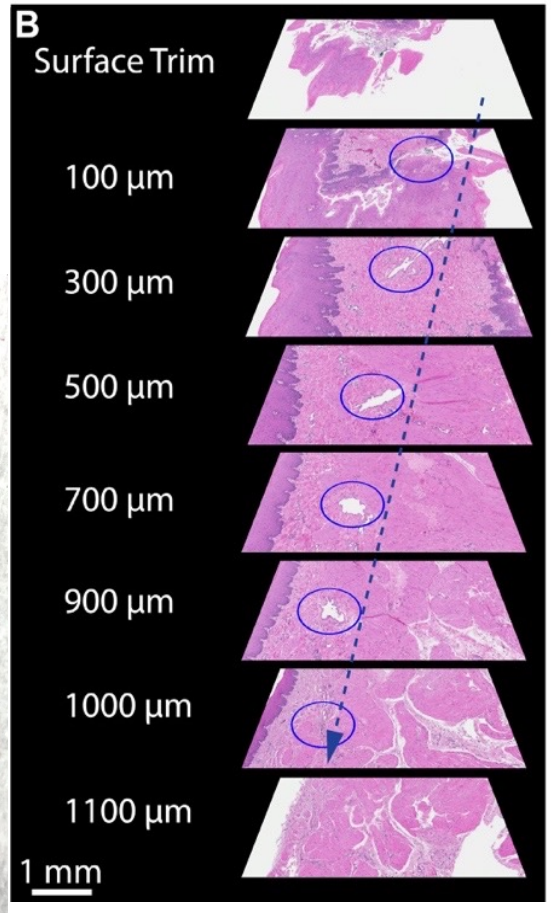


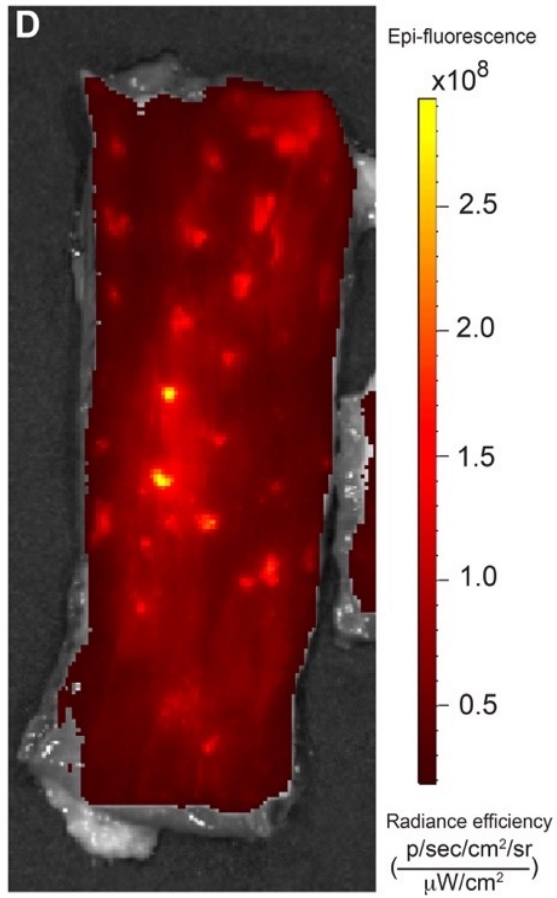
Babaee et al. Nature Materials 2021

In vivo esophageal delivery

Tissue Marking Dye



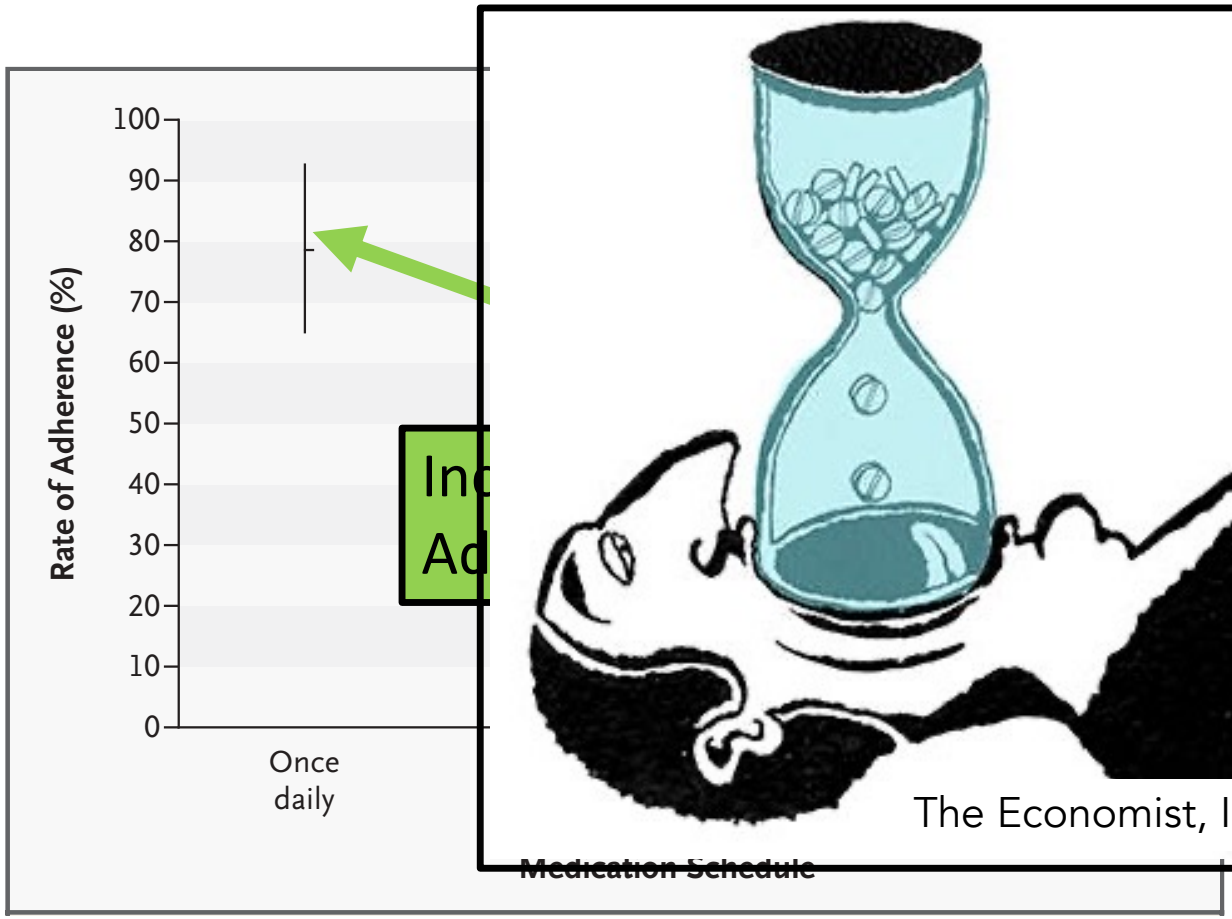




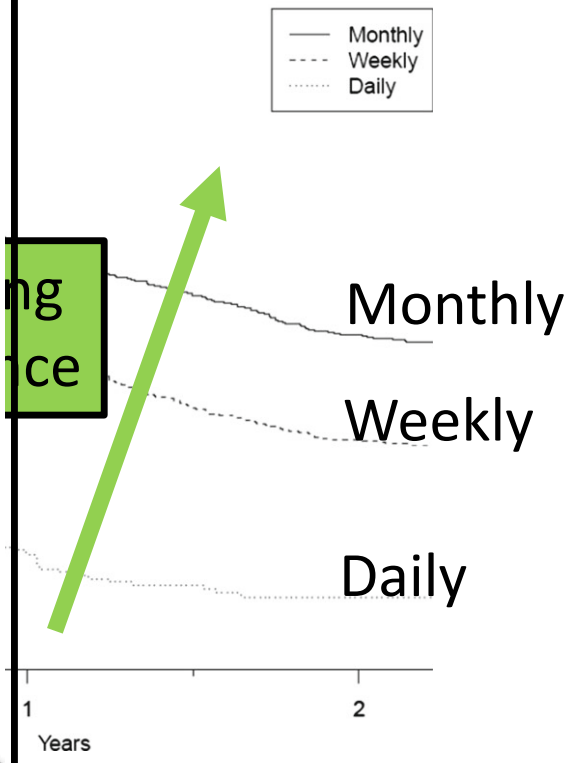
Fluorescent magnetic microparticles
(1.0% w/v, 4.0-4.9 µm)

Babaee et al. Nature Materials 2021

Compliance increases with more infrequent dosing regimens



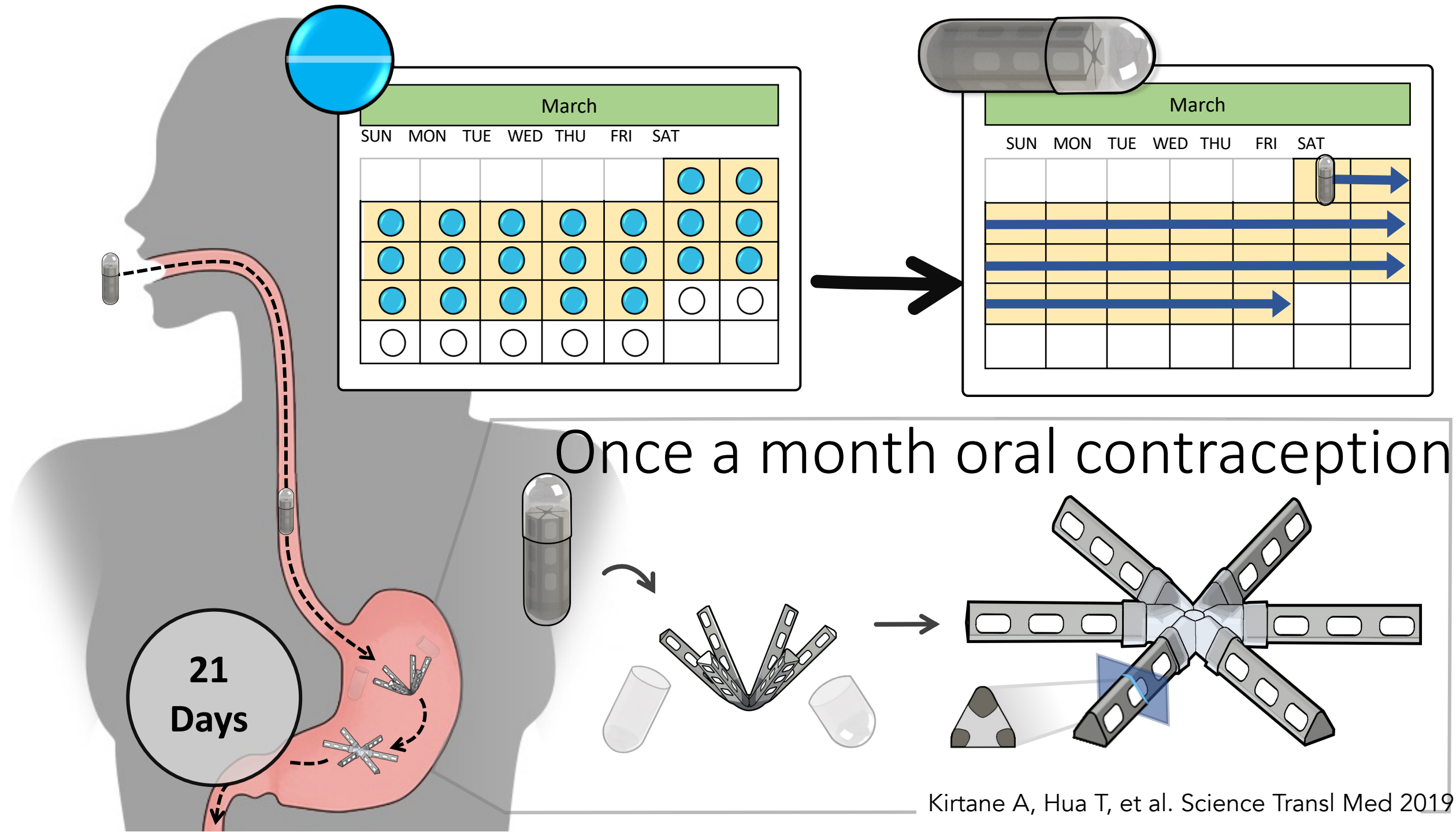
The Economist, In for the long haul, Sept 5, 2015



Monthly	4,538	2,837	1,730	720	397
Weekly	4,392	2,404	1,345	714	270
Daily	396	116	45	26	18

Claxton et al Clin Ther 2001; Osterberg et al NEJM 2005

Kishimoto et al Arch Osteop 2015

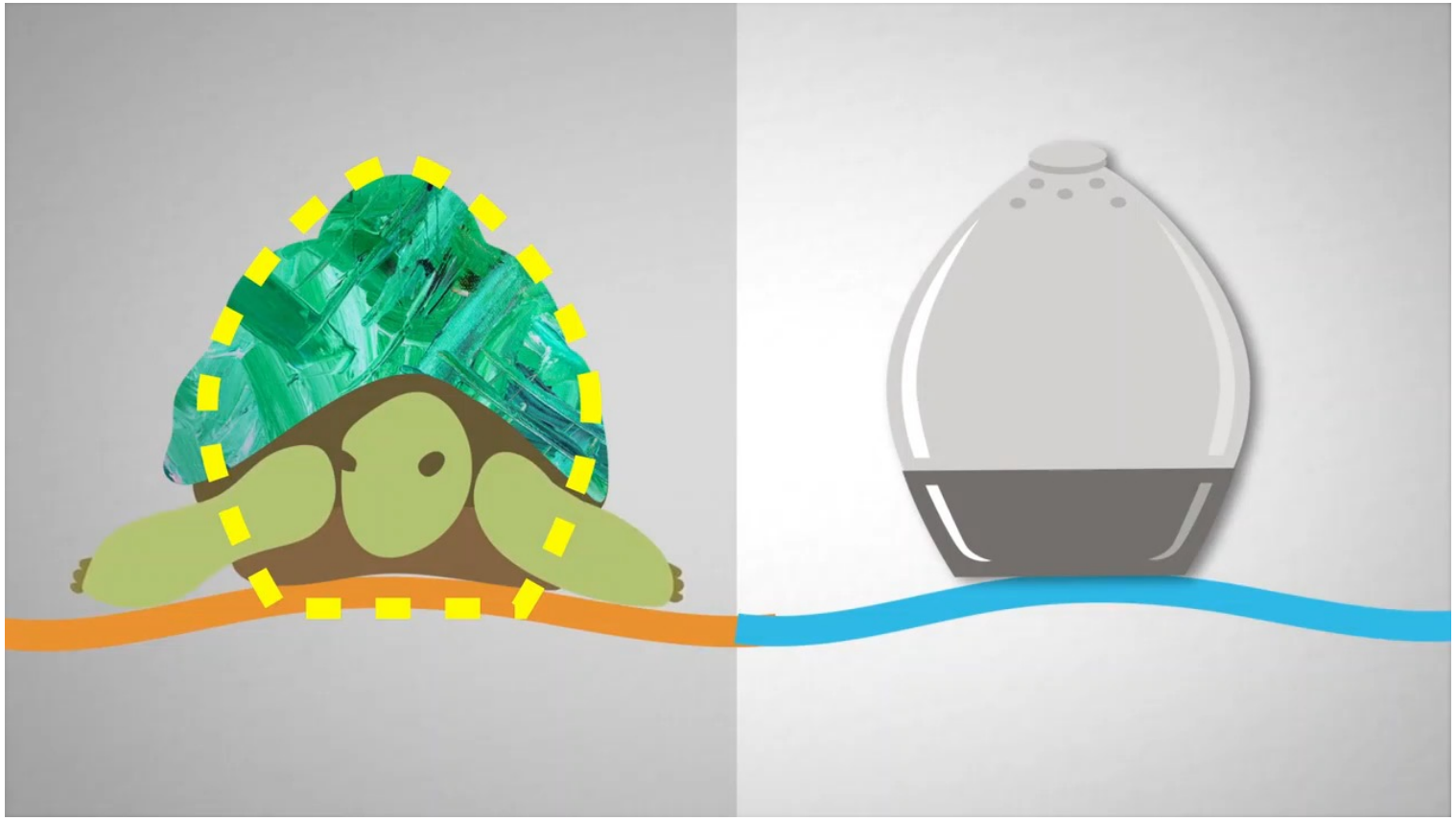


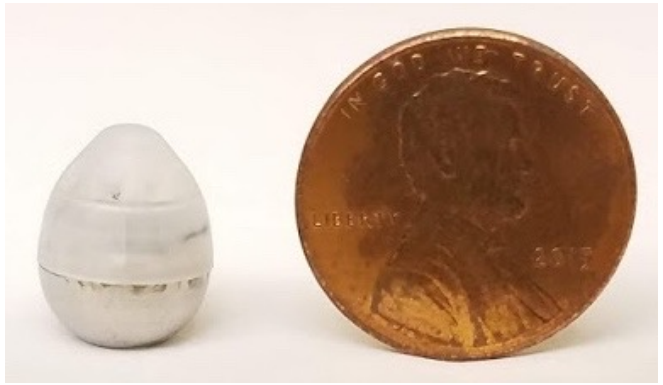
Once a month oral contraception

Kirtane A, Hua T, et al. Science Transl Med 2019

Self-Orienting Millimeter-Scale Injector

Inspired by a tortoise, the Self-Orienting Millimeter-Scale Actuator (SOMA) passively orients an injector towards the stomach wall after ingestion

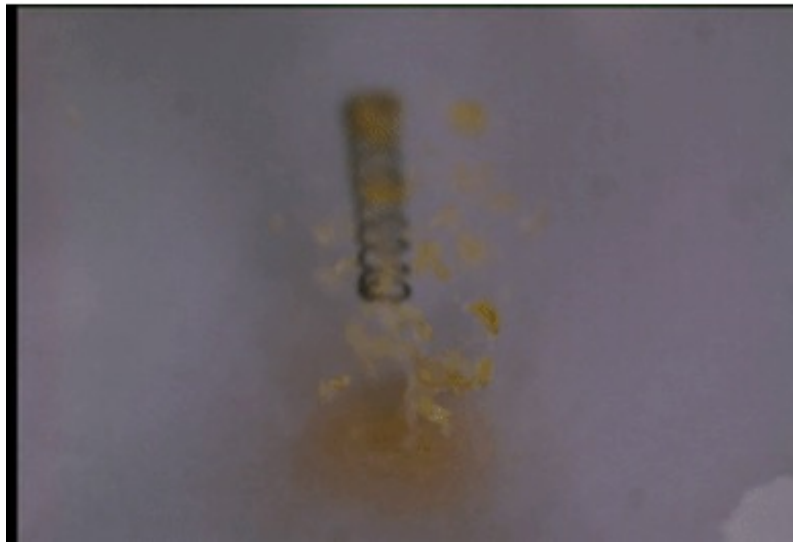


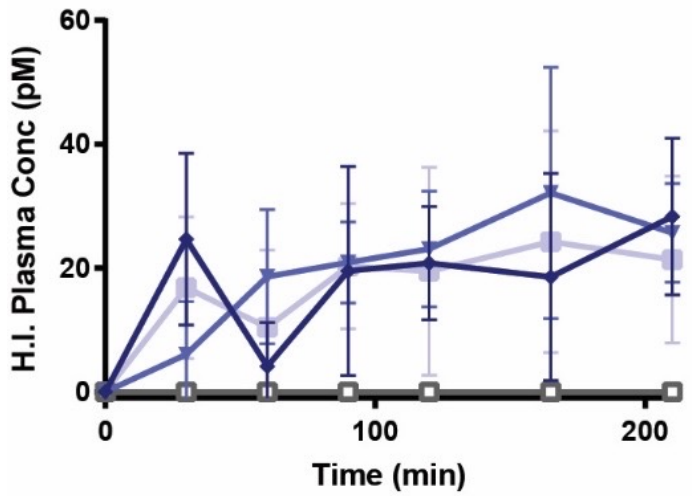


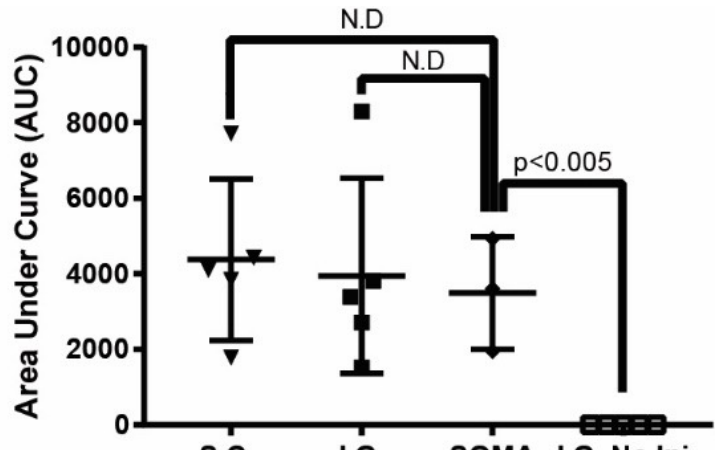
Abramson et al, *Science (2019)*

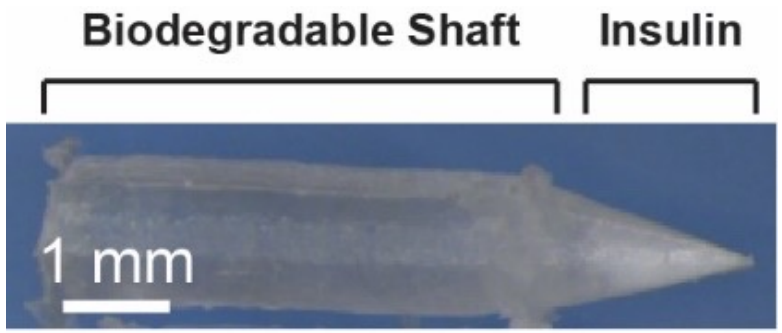
Actuation and Delivery

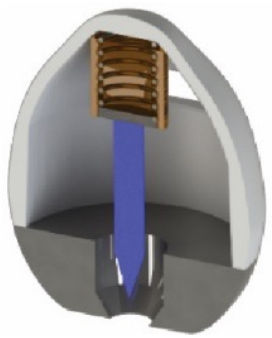
A compressed spring encapsulated in sugar drives a needle into tissue once released

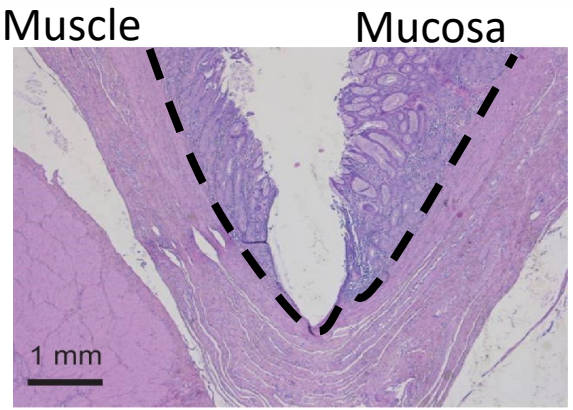












Because sugar is brittle, it releases the spring in 1 ms

Abramson et al, *Science (2019)*

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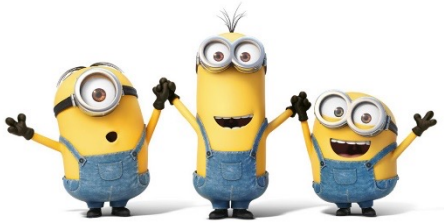
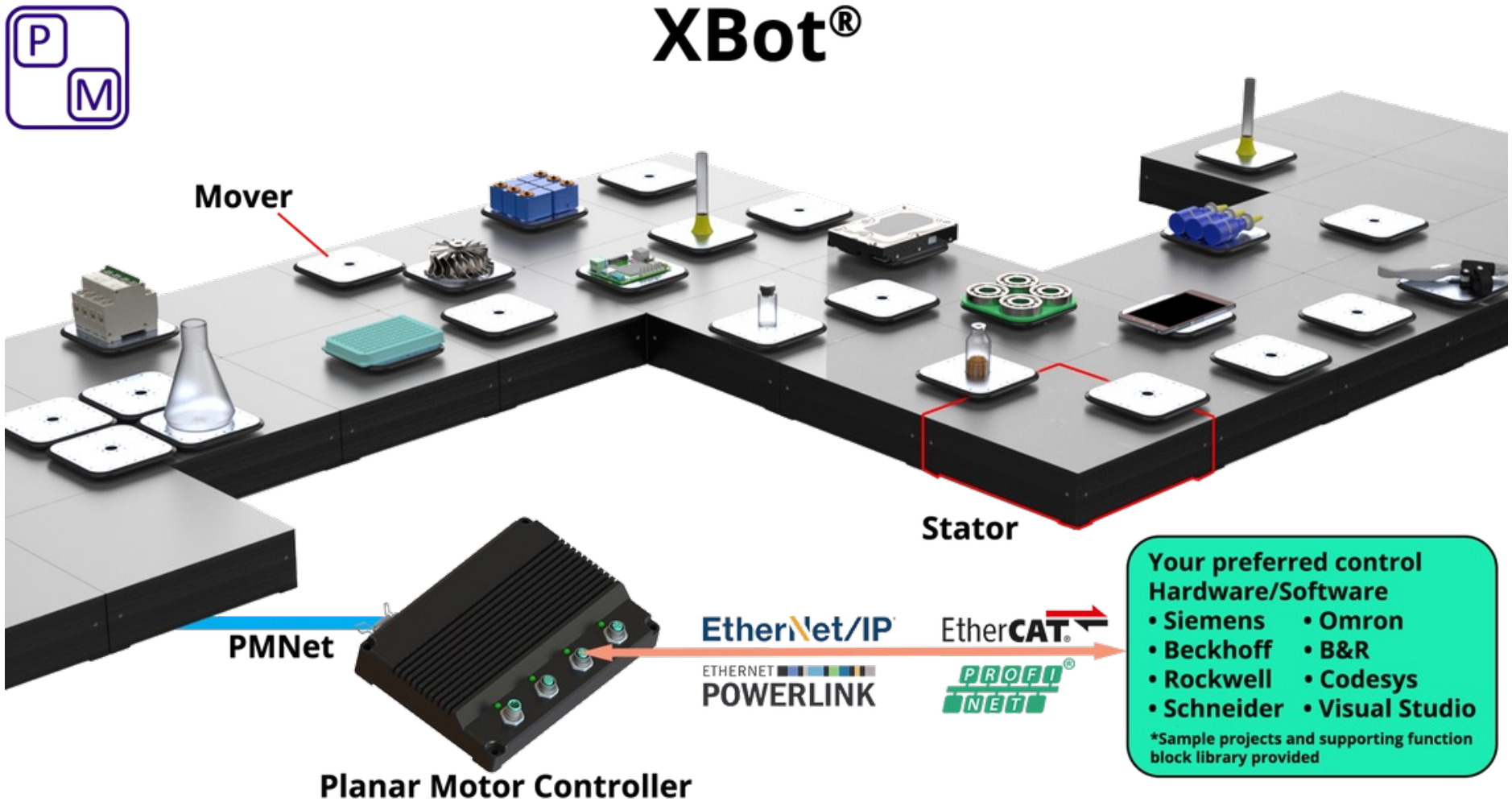


Example: Student research spun off to form enabling technology company

www.planarmotor.com

XBot® enables smart manufacturing, with unprecedented flexibility, reliability, agility, and efficiency to enable ultra clean (non-contact motion) fast flexible manufacturing, e.g., pharma manufacturing



Example: “LeHit” Ortho medical tool Development

(will be announced mid 2023, sorry cannot say more now)

meddevdesign.mit.edu

2.75-admin@mit.edu