

UCLA Technology Development Group

Bio-Zipper Tissue Closure Device

2021 UCLA Innovation Fund Pitch Day

Presented by:
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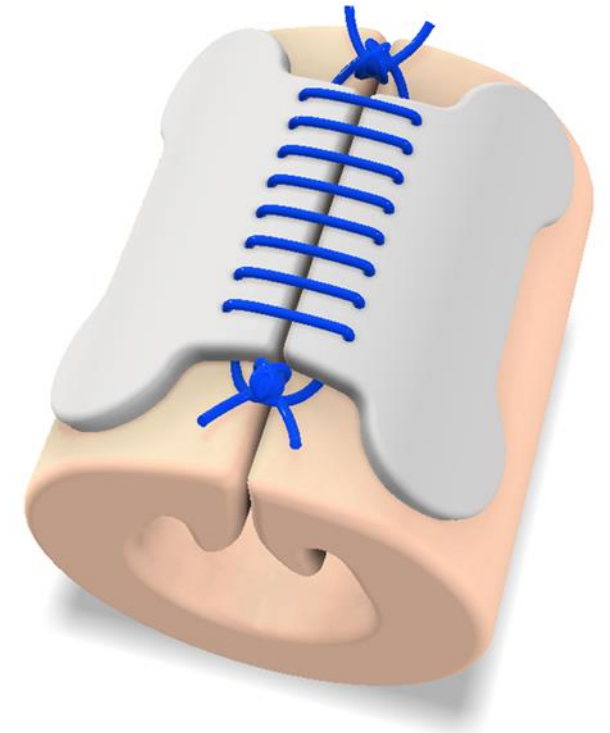
The Bio-Zipper: A Surgical Closure Device

Need: 680K annual urologic reconstructions in U.S.

Solution: Reinforces suture lines in complex surgical reconstruction

Predicted Impact: Decreases 30-day complications & readmissions ~**20% with savings of \$5,600 / procedure**¹

Development Stage: Working prototype in preclinical testing and ongoing material optimization



The Bio-Zipper Multidisciplinary Team

Bio-Zipper Founding Team



Renea Sturm, MD
Asst Prof, Urology
Surgeon-Scientist
UCLA



George E. Aninwene II, PhD
Project Scientist, Urology
BioE, Entrepreneurship
UCLA



Ali Khademhosseini, PhD
CEO, Professor
Materials Scientist
TIBI

Research Team

Hanjun Kim, PhD, DVM
Hossein Montazerian, BioE, UCLA
Peyton Tebon, BioE, UCLA
Kalpana Mandal, PhD, Physics, TIBI
Reihaneh Haghniaz, PhD, Biotechnology, TIBI
Marvin Mecwan, PhD BioE, TIBI
M. Ali Darabi, PhD, Materials TIBI

Advisory Team

Karim Chamie, MD Urologic Oncologist, UCLA
Gladys Ng, MD, Urologic Reconstruction, UCLA
Jennifer McCaney, PhD, UCLA Biodesign
Nirav Kamdar MD, UCLA Biodesign



Lower Urinary Tract Reconstruction



Limits of Suturing in High-Risk Urologic Surgery

Neobladder Stats:

~1-2 feet of bowel

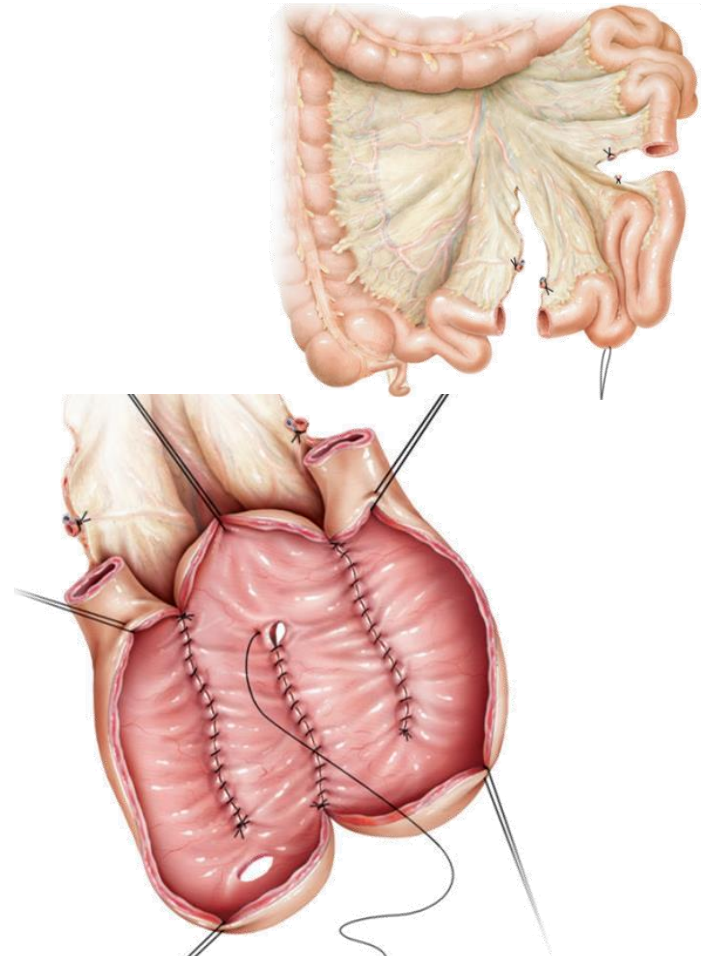
6 hour operative time

\$35K operative cost¹

Complications & Readmissions: 30-68%²

Cost: ~\$30K per Complication²

Neobladder Construction ⁽³⁾



1. Farber, Bladder Cancer. 2018

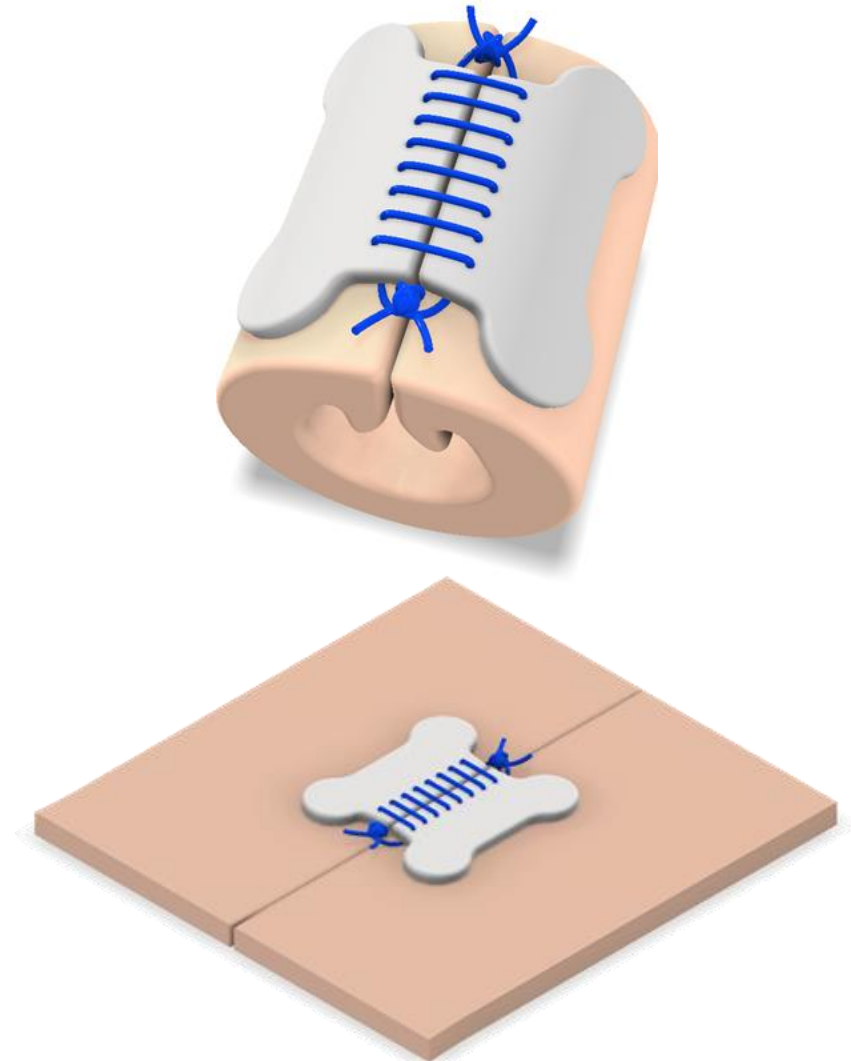
2. Barbieri, Curr Bladder Dysf Rep. 2016

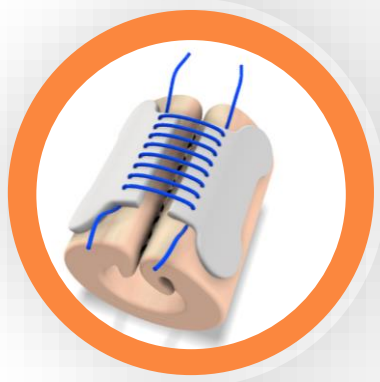
3. Hautmann, BJU Int. 2010

The Bio-Zipper provides Needed Tissue Support

A novel surgical device that:

- Leverages cutting-edge biomaterials
- Provides fast, consistent luminal closure
- Readily applied within standard procedure using open or robotic platforms



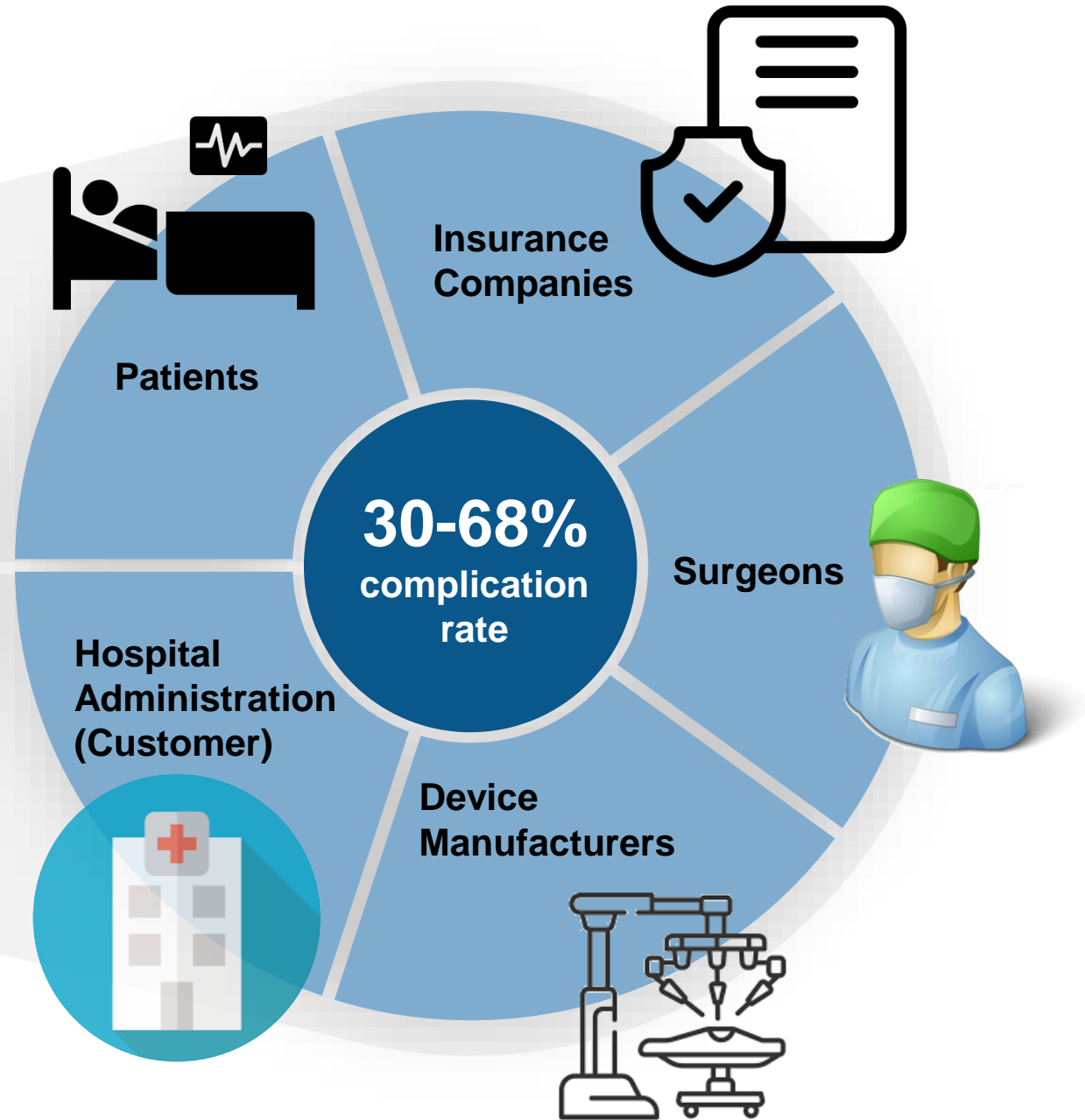


Customer Discovery

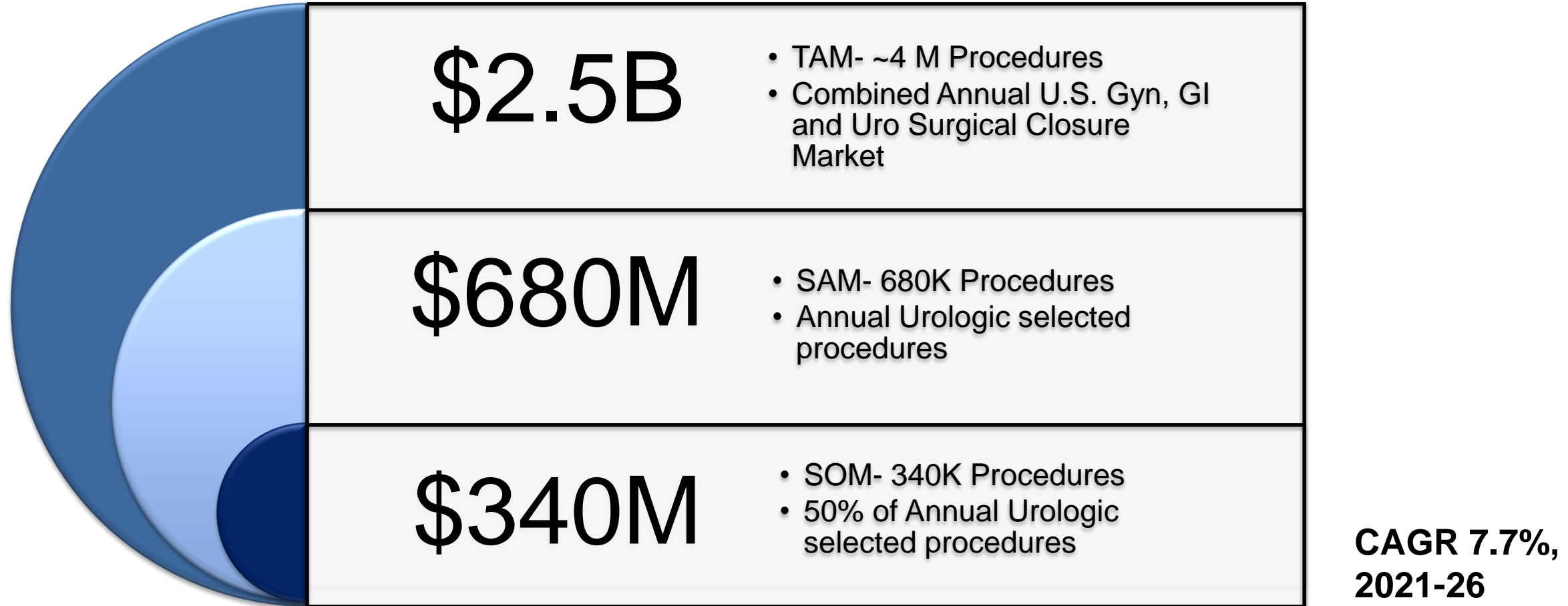
> 150 interviews

Conclusions

Decreased Complications +
Readmissions: The top priority



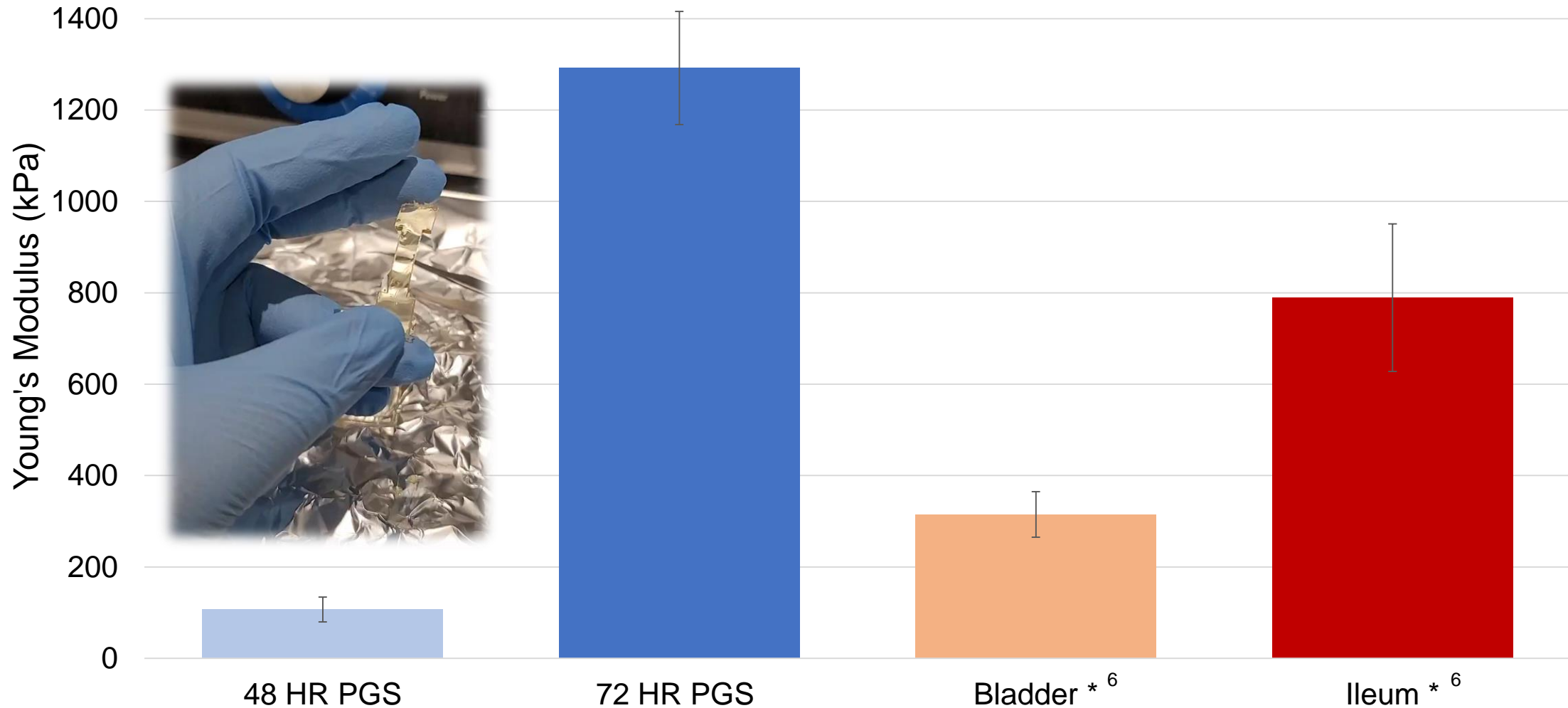
Surgical Closure Devices: A Growing Market



Based on procedural volumes (UCLA) extrapolated to the U.S.
Estimated \$500/device cost, 2 devices per LUTR, 1 for most other applications

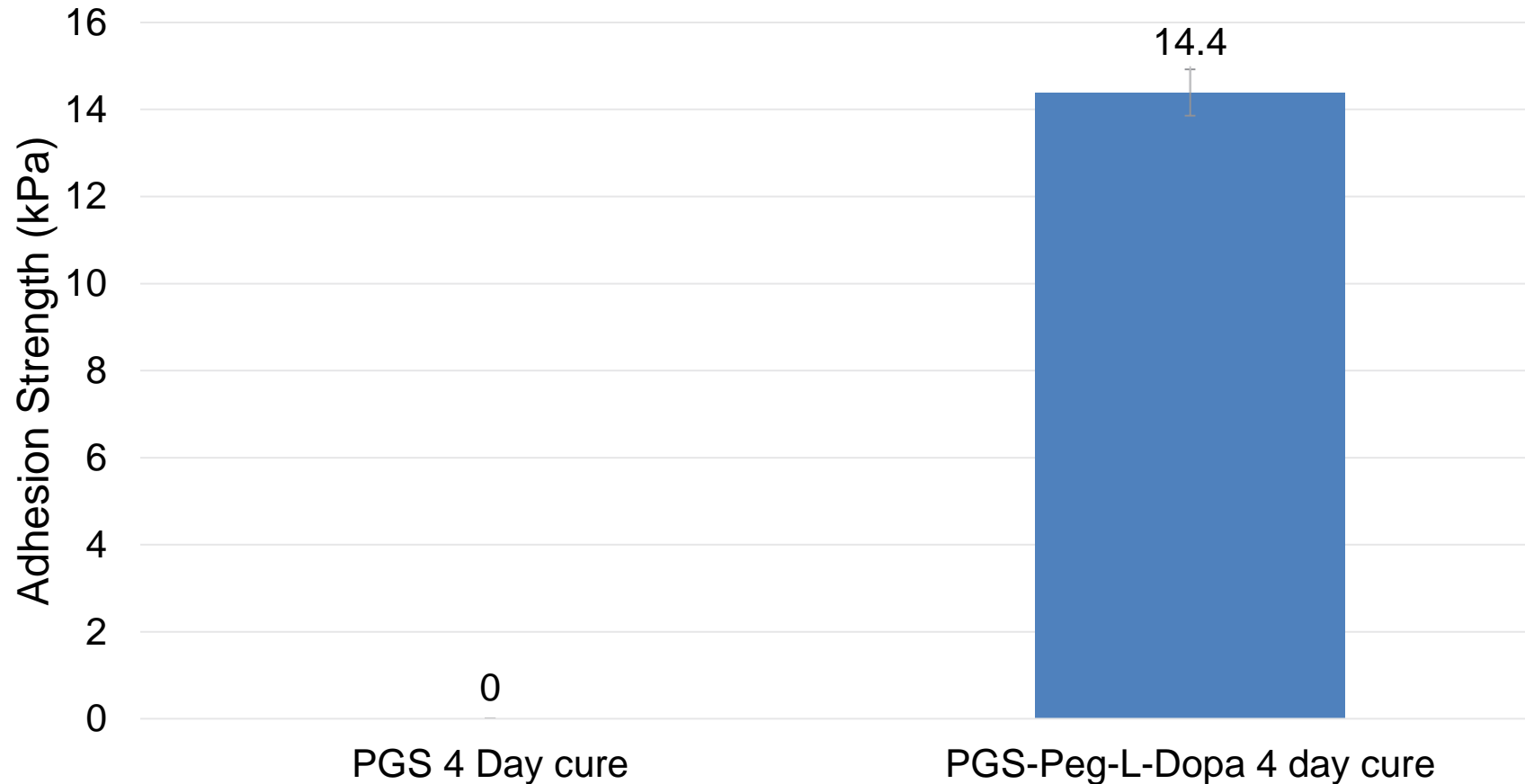
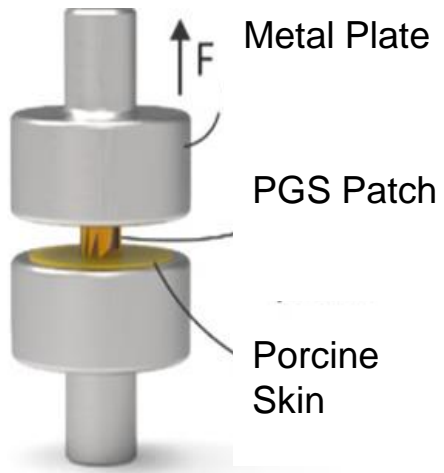


Range of Elastomer Strengths (PGS) produced correspond with Target Tissue



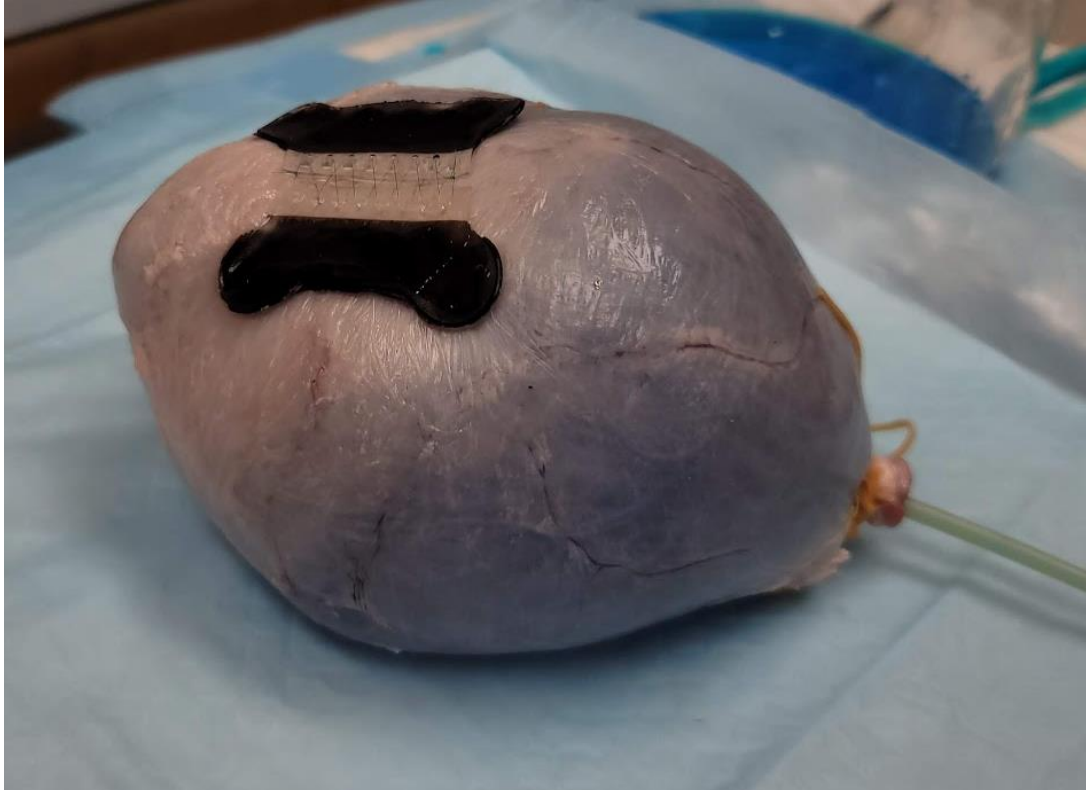
PGS (Poly(Glycerol Sebacate)) Tensile Data: PGS cured at 140°C for 48 or 72 hours (n=3) and Porcine Bladder or Ileum (Small Intestine) tissue (n=6); PGS: Bio-Zipper team data, *⁶Tissue Data Adapted from Davis, Urol. 2021

Modification of PGS Yields Adhesive Polymer

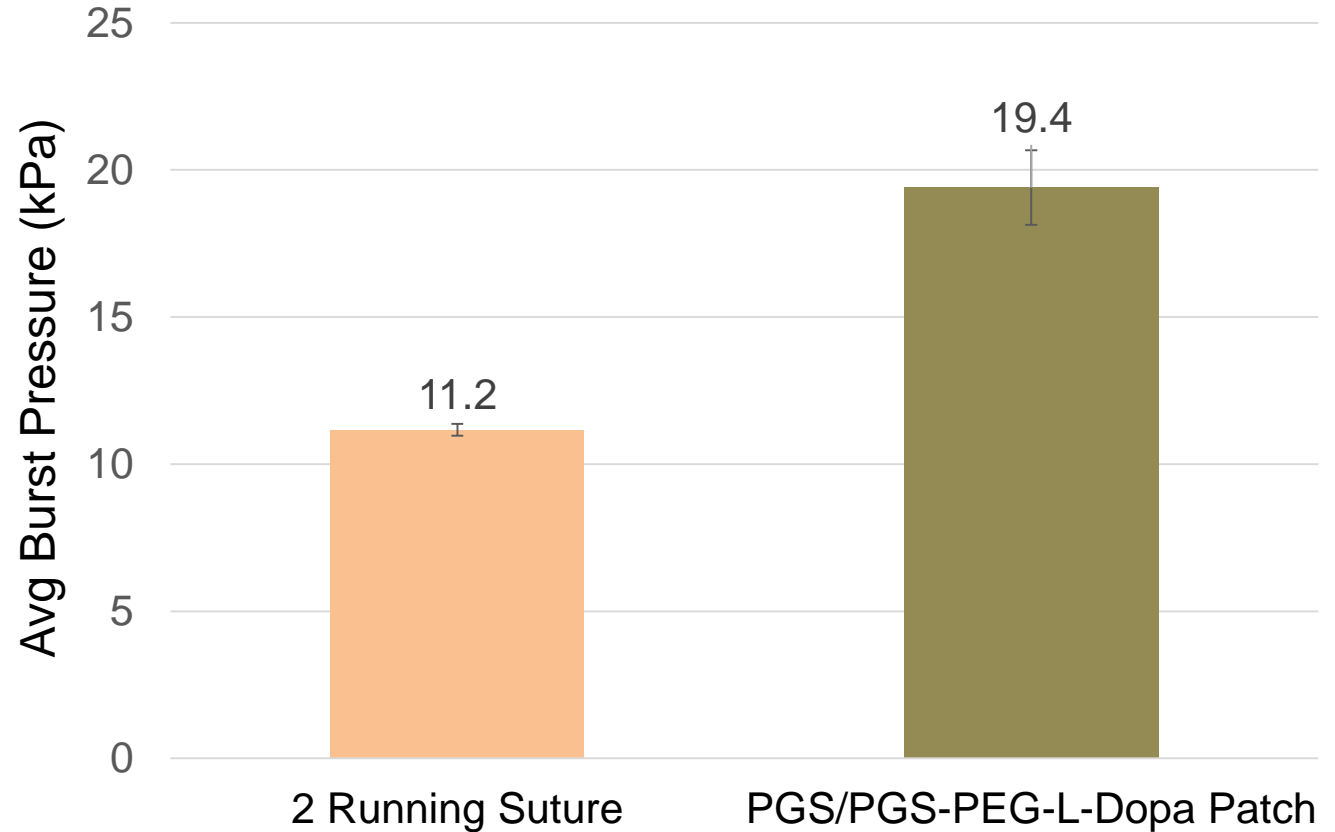


Adhesive Strength Analysis: PGS(Poly(Glycerol Sebacate)) vs L-Dopamine modified PGS (PGS-Peg-L-Dopa) adhesion data

Functionalized PGS increases the Pressure and Volume required for Bladder to Leak



Physiologic Bladder Pressure:
2.0 -> 7.8 kPa⁷



Porcine Bladder Burst Pressure Analysis: Incision was made on porcine bladder and closed with either two running sutures or two running sutures and adhesive patch. (n=3, p <0.05)

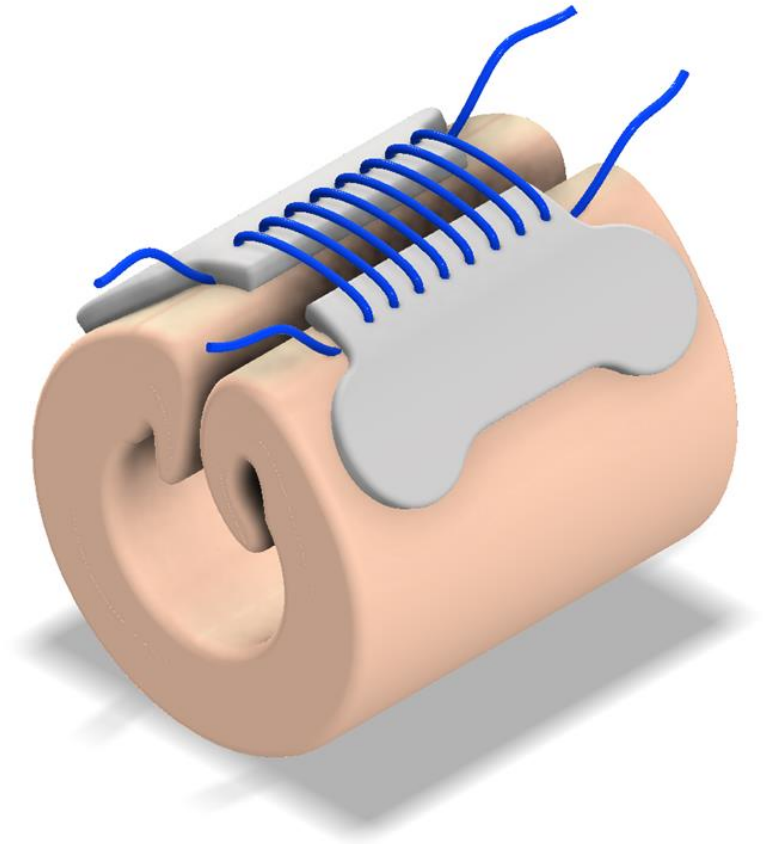
Intellectual Property protects Device Design

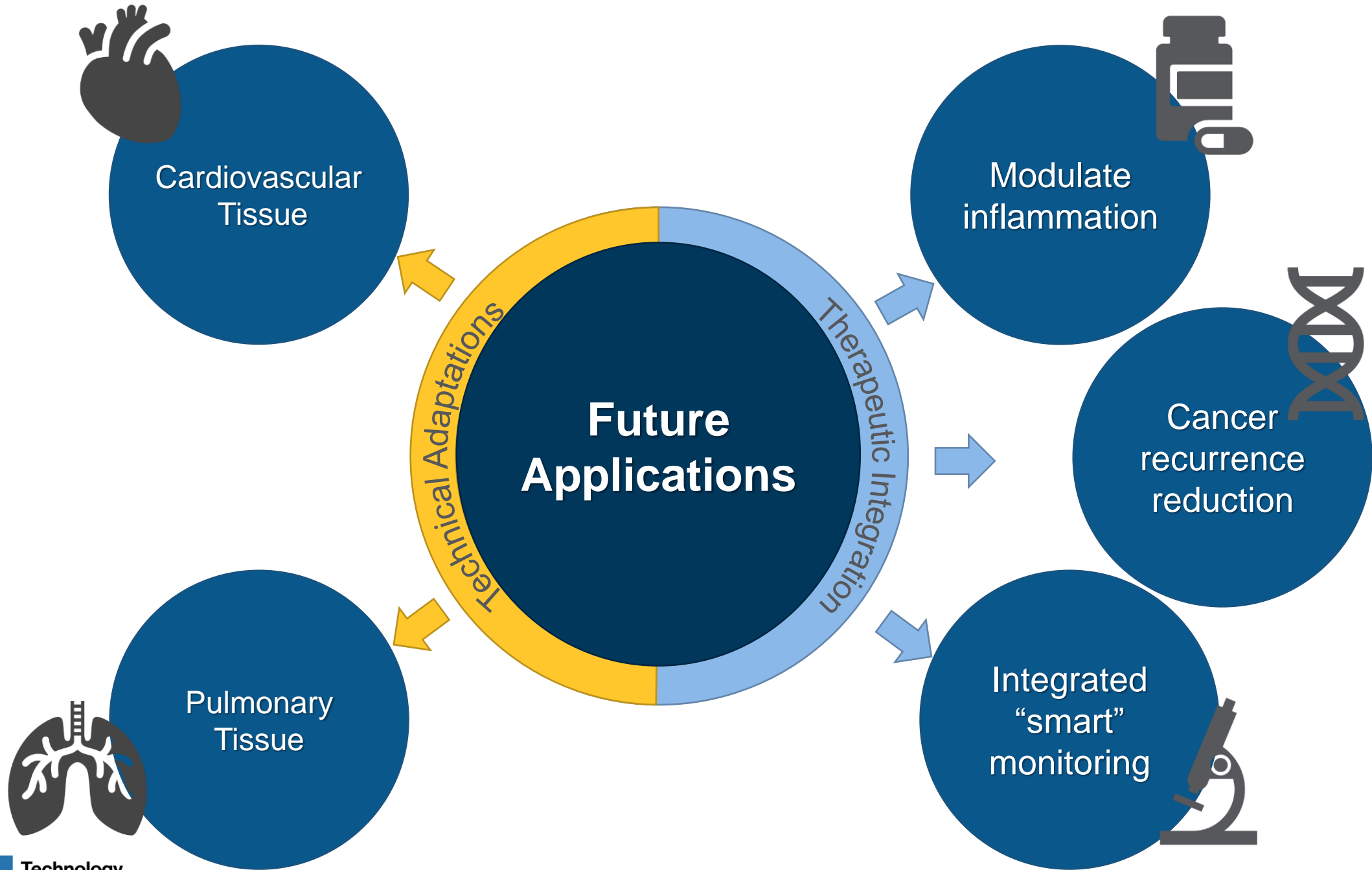
Patent Filed – Bio-Zipper Surgical Device

- Provisional PCT/US20/55766
- PCT application pending (published Apr-2021)

Novel Features

- Flexible bioabsorbable backbone
- Bio-adhesive Mechanism
- Methods to pull together device across closure line





Surgical Closure Landscape

Device	Reinforces Suture Lines	Bio-absorbable	Designed for Urology	Reduces Complications in UTR
Bio-Zipper	✓	✓	✓	✓
Sutures	—	✓	✓	—
Medical Adhesives	✓	✓		
Staplers	✓			

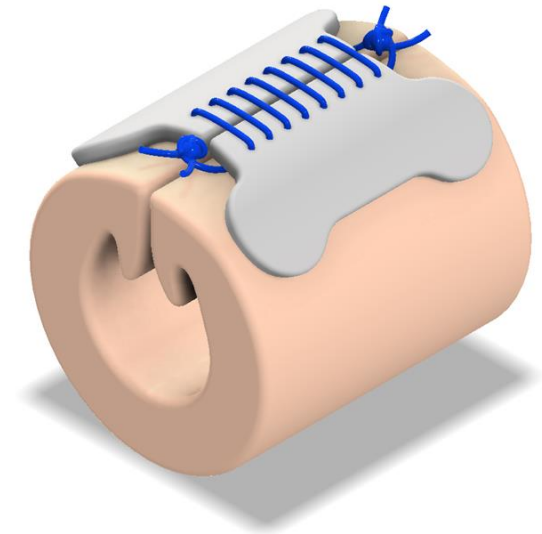
Path to Market

Early Partnerships With Larger Surgical Device Companies

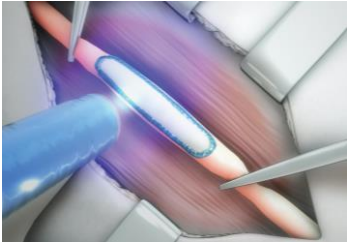
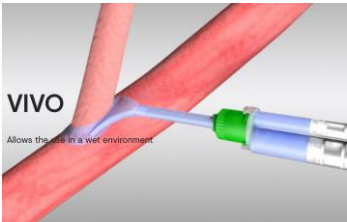
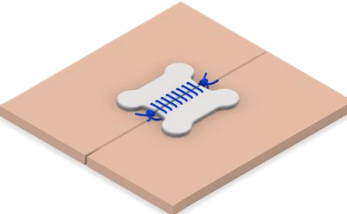
- Optimize device production
- Expedite Initial Clinical Trials
- Leverage Their Market Penetration

Initial Sales To Academic Hospitals

- Through Industry Partners



Active M&A and VCs in Surgical Biopolymers

Product	Technical Specs	Clinical Application	Exit
Tissium 	Biomorphic, applied viscous polymer, blue light activated	<ul style="list-style-type: none"> - Cardiovascular, CE Mark product adjuncts to sutures - GI, ear, nose, throat, nerve reconstruction - Suture line reinforcement 	<u>8/31/2021</u> Series C VC: \$70.2M Valuation: \$259.65M
Adhesys Medical 	Polyurethane prepolymer, amino-based curing agent	<ul style="list-style-type: none"> - Vascular reconstructions - Suture line reinforcement in cardiovascular 	<u>4/7/2017</u> Acquired by Grunenthal, terms undisclosed
Bio-Zipper 	PGS - prefabricated polymer and bio-adhesive	<ul style="list-style-type: none"> - Urologic procedures - Future gynecologic and GI applications - Suture line reinforcement 	<u>With the Innovation Fund's help!</u>

Potential Challenges

Challenge

De-risking Method

Technical

Adhesive stability on backbone



Surface modification of bulk material

Non-toxic degradation



Conduct in vivo experiments

Ease of application



Simulation trials with surgeons

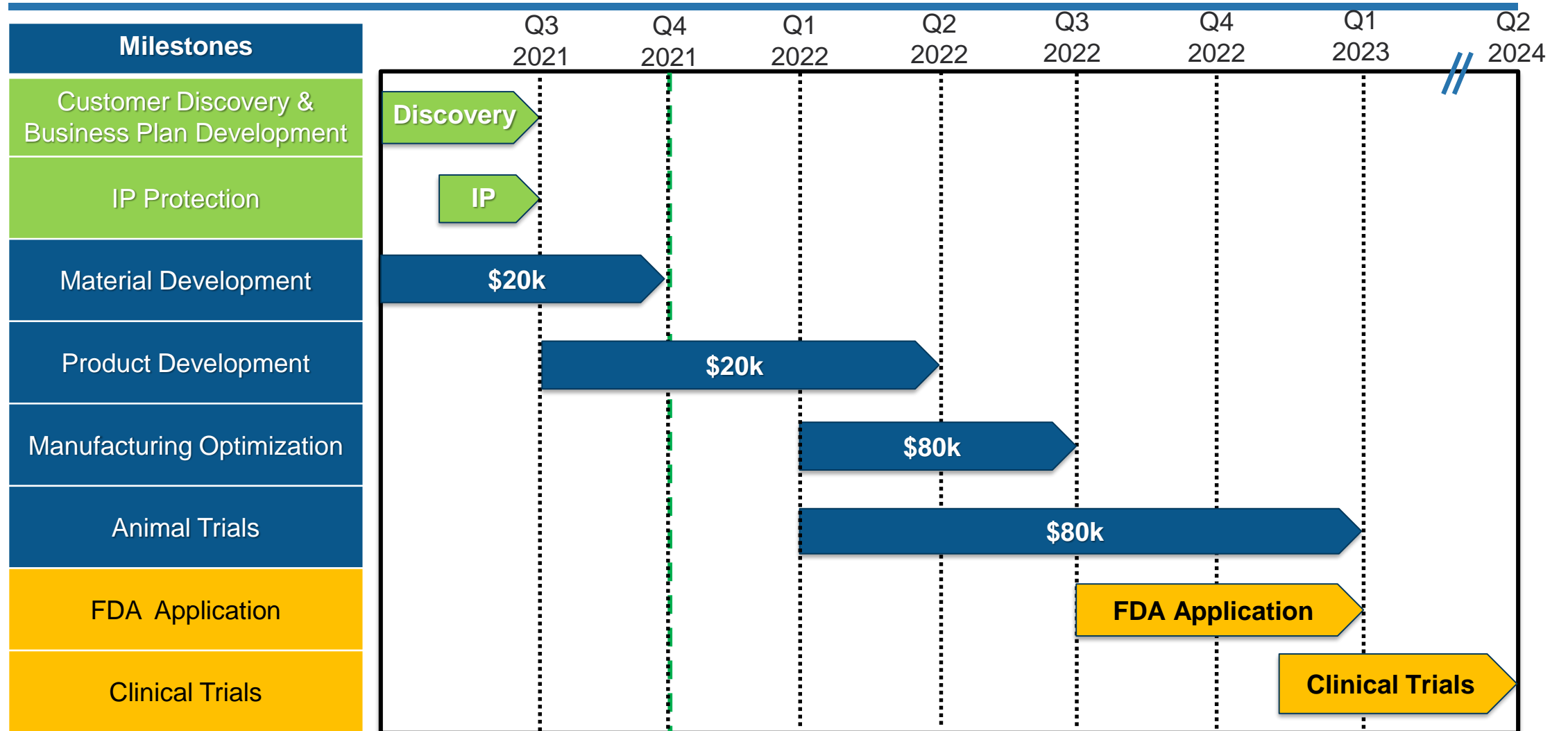
Potential Challenges

Challenge	De-risking Method	
Technical		
Adhesive stability on backbone	➔	Surface modification of bulk material
Non-toxic degradation	➔	Conduct in vivo experiments
Ease of application	➔	Simulation trials with surgeons
Market		
Multiple players in surgical closures	➔	Urologic focused need, patent submission

Potential Challenges

Challenge		De-risking Method
Technical		
Adhesive stability on backbone	→	Surface modification of bulk material
Non-toxic degradation	→	Conduct in vivo experiments
Ease of application	→	Simulation trials with surgeons
Market		
Multiple players in surgical closures	→	Urologic focused need, patent submission
Regulatory		
Planned <i>de novo</i> device submission	→	Show predicate devices & safe use of component materials in FDA approved devices; 510K if required

Development Timeline



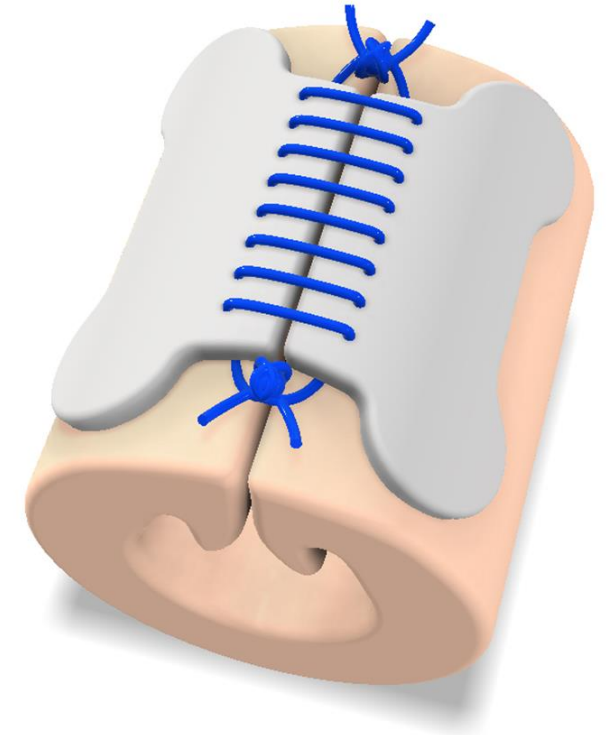
Bio-Zipper: An Impactful, Novel Solution

Novelty: Materials, Bio-Adhesive, Urologic Application (Open & Robotic)

Predicted Impact: Decreases 30-day complications & readmissions ~**20%** with savings of **\$5,600 / procedure**¹

Future Applications:

CV, Pulm, GI, Drug Delivery, Smart Sensing



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THANK YOU FOR YOUR
SUPPORT