Expandable Sheath for Minimally Invasive Gallstone Removal

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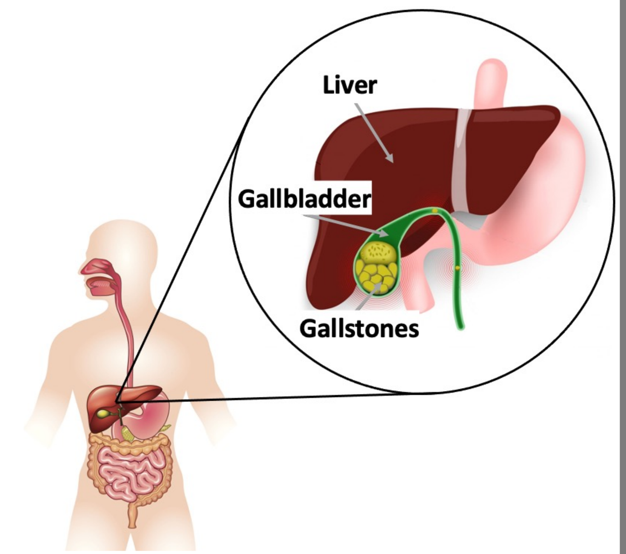
Background

- **Clinical Immersion**
  - Participated in clinical shadowing and identified unaddressed problems in the hospital
  - Sponsorship from National Institutes of Health (NIH) grant
- **Cholelithiasis (Gallstone Disease)**
  - Most common disorder affecting the biliary system (25 million people in the United States)
  - Characterized by stone formation, which can lead to painful symptoms and potential duct blockages
  - Subset of patient population has comorbidities, making them unable to undergo general anesthesia
- **Current Treatments/Options**
  - Cholecystectomy: surgical removal of the gallbladder (requires general anesthesia)
  - Percutaneous drainage: current solution to help relieve symptoms, but does not provide a long-term solution by fully removing gallstones from this patient population
    → disease continues and symptoms return quickly



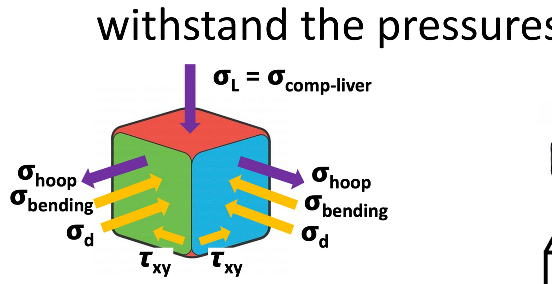
Problem Statement

1. Base Problem: A better solution to remove gallstones from non-operable patients suffering from gallstone disease is needed
2. Meetings with physicians and extensive research to determine:
   1) True root of the problem
   2) Available tools
   3) Physicians' needs and desires
3. Main problem identified to solve: The **lack of access** to the gallbladder that is limiting the use of current tools to remove gallstones in a minimally invasive manner

Goals and Preliminary Design

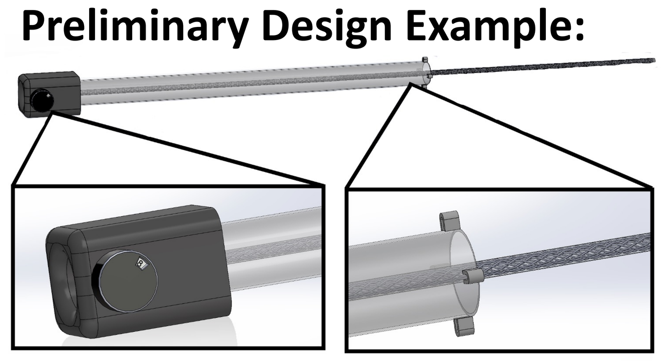
Overall Project Goals: Develop an easy to use and reliable device for physicians to increase access to the gallbladder, while keeping patients safe and providing maximum comfort

Initial Design Considerations:
- Wire mesh with similar function to finger trap toy mechanism
  - Force and safety factor (SF) calculations were done to discover that a stainless-steel mesh would be able to withstand the pressures of the body



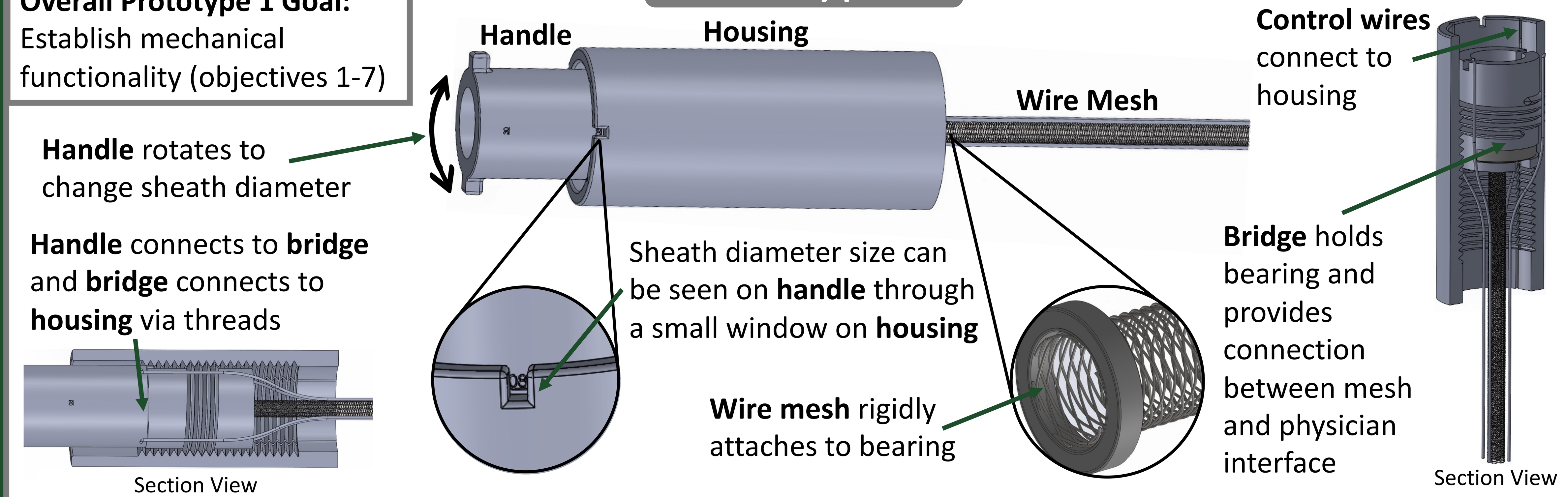
Maximum SF = **16.8**
Minimum SF = **11.2**

Preliminary Design Example:

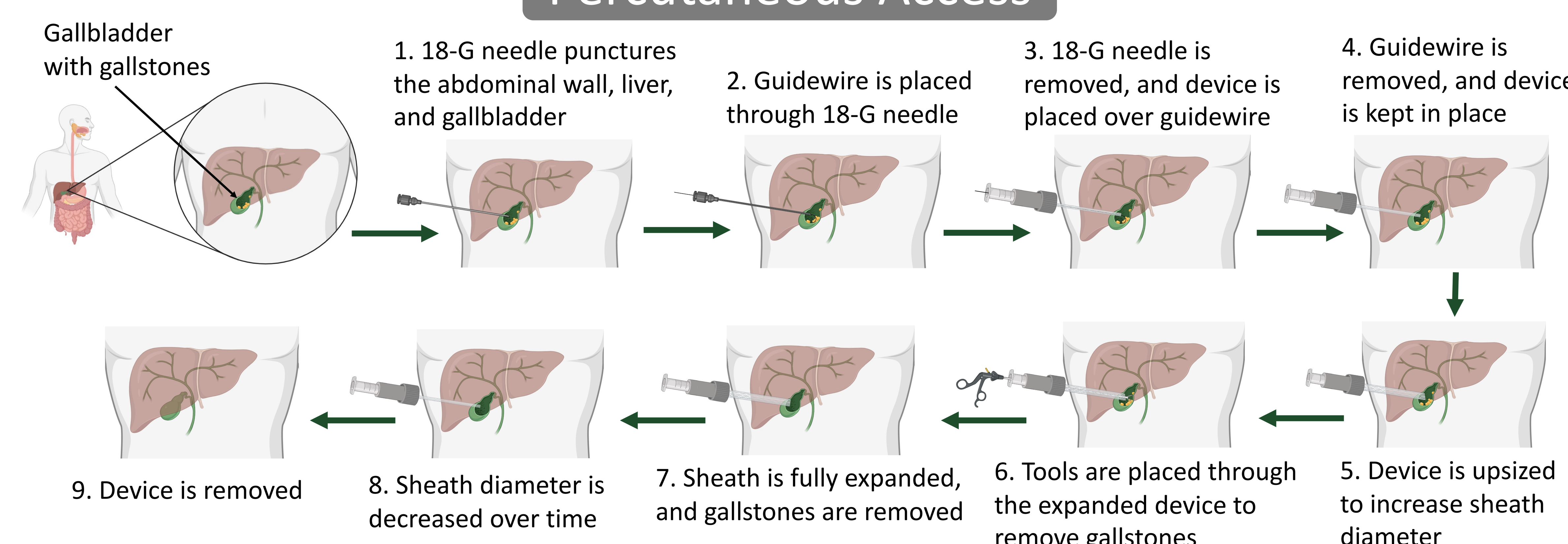


Prototype 1

Overall Prototype 1 Goal: Establish mechanical functionality (objectives 1-7)



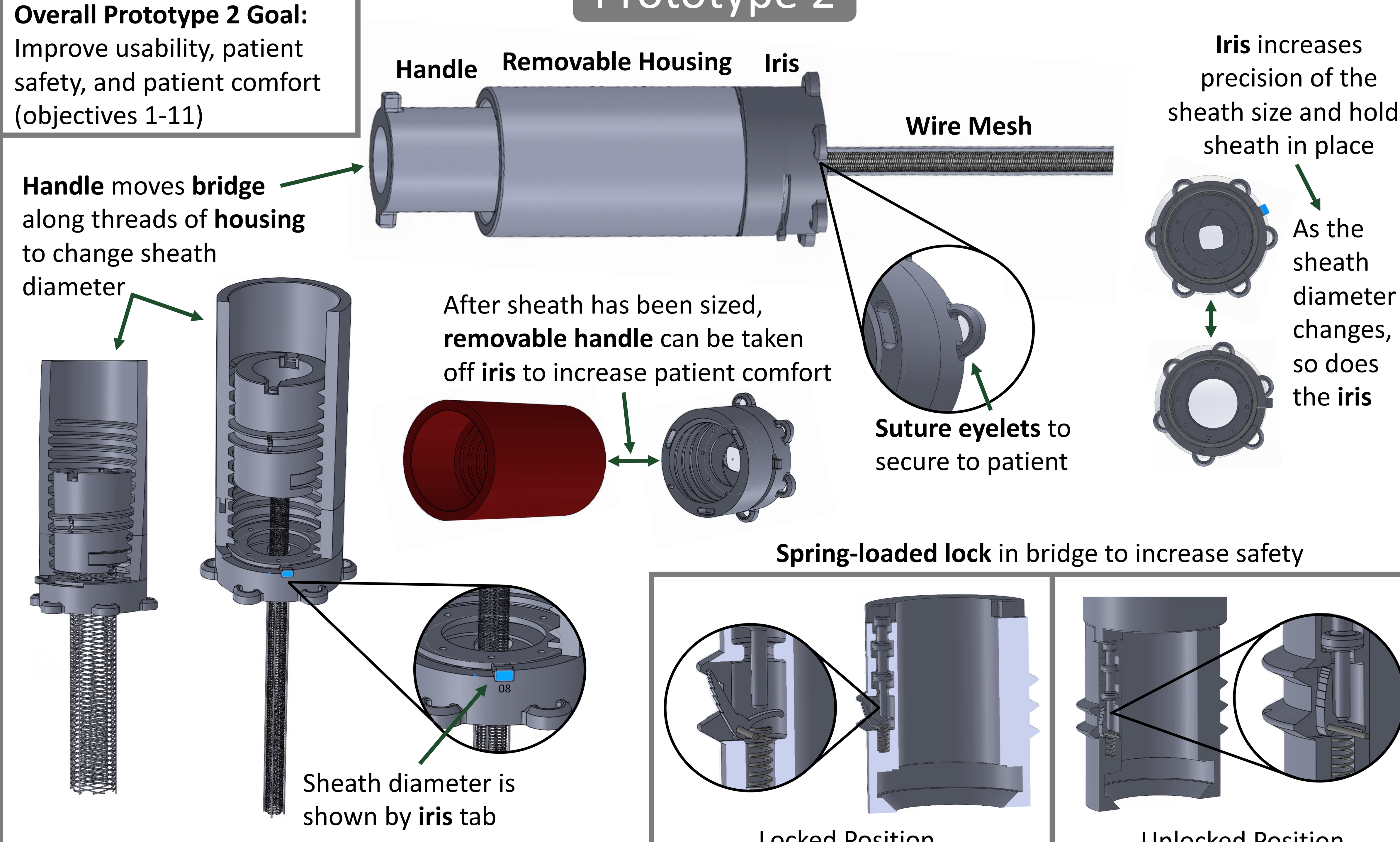
Percutaneous Access



Note: All placement done with pre-established imaging modalities

Prototype 2

Overall Prototype 2 Goal: Improve usability, patient safety, and patient comfort (objectives 1-11)



Objectives and Results

Design Objectives	Prototype 1	Prototype 2
1. Changing Diameter	Threaded physician interface	Threaded physician interface
2. Opposing Forces	Control wires	Control wires
3. Consistent Diameter	Control wire beads	Control wire beads
4. Known Diameter	Window and measurement	Iris and iris tab
5. Control Length Change	Locked control wires	Locked control wires
6. Minimize Movement	Bearing between bridge and mesh	Bearing between bridge and mesh
7. Easy to Use	Twist to desired size	Optimal thread angle; twist to desired size
8. Drain Attachment	NA	NA
9. Secure to Patient	NA	Suture eyelets
10. Locking Mechanism	NA	Spring-loaded lock
11. Patient Comfort	NA	Detachable housing

Impact and Conclusions

- **Current Impact**
  - Raises awareness of the lack of options for the target patients
- **Future Impact**
  - Provide patients with options and has potential to be used in other procedures – increasing patient care across many fields
  - Decrease follow-up procedures – decreasing waste and financial burden for both hospitals and patients
- **Conclusions and Accomplishments**
  - Determined the root problem to be lack of access
  - Proved mechanical feasibility of device
  - Filed provisional patent
  - Created a foundation for project continuation
  - Collaborated with individuals across professional fields
  - Maintained a positive team dynamic

Future Work

Immediate Plan: Compile tentative testing procedures, extra ideas, & current problems into a document for project pass off

3 – 6 Months	<1 Year	>1 Year
Determine suitable sheath coating and drainage plug	Develop to-scale, working prototype	Obtain patent and consistently producible product

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