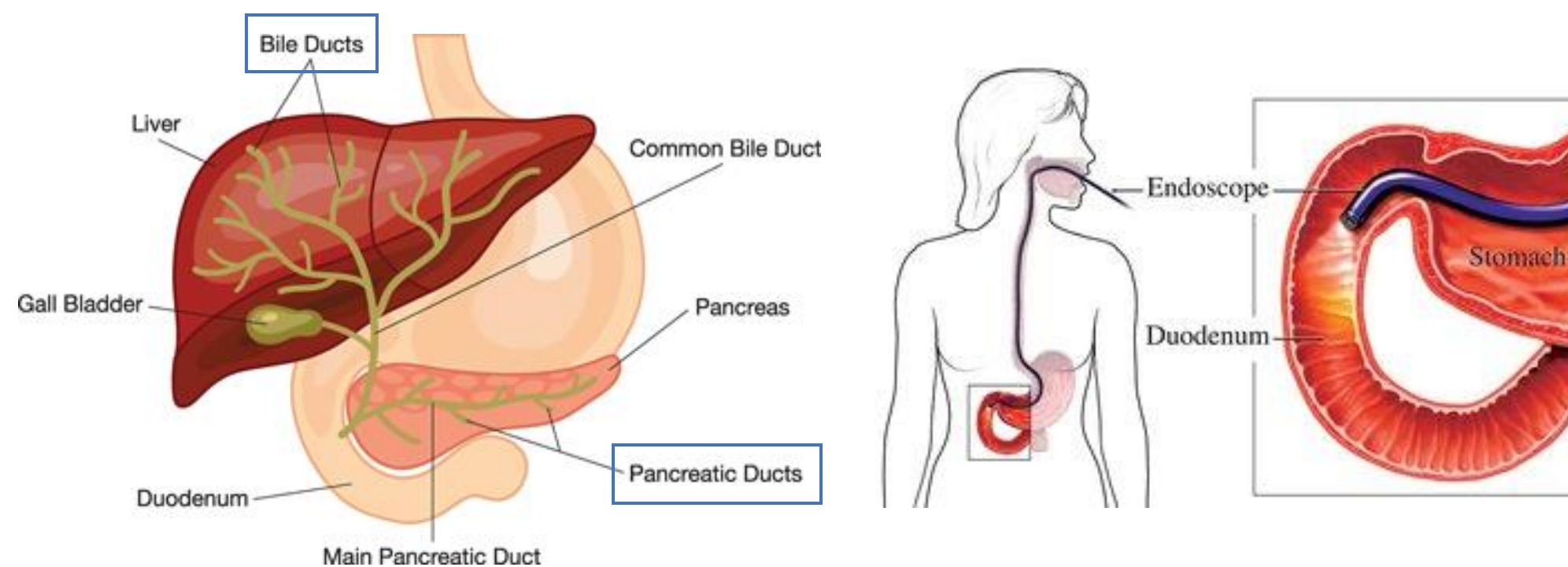


## Redesigning the handle-based fluidics system to provide expected duodenoscope performance and allow for ergonomic improvements.

### Endoscopic Retrograde Cholangiopancreatography (ERCP)

Endoscopes are long, thin flexible tubes with a light, tool insertion channel, and camera linked to an external, physician-facing screen. They also have a fluidics system with four states (neutral, insufflation, water, suction) to enable physicians to see throughout the procedure and perform necessary actions.

Duodenoscopes are specialized endoscopes for use in the upper gastrointestinal area and are primarily used for endoscopic retrograde cholangiopancreatography (ERCP). ERCP is a low-risk procedure done about 500,000 times a year in the United States which combines upper gastrointestinal endoscopy with X-rays to diagnose and treat bile and pancreatic duct problems. The procedure lasts around 30-90 minutes and involves having the duodenoscope inserted through the mouth and down the throat into the gastrointestinal tract.



### Duodenoscope Users

Unfortunately, ERCP has a high malpractice rate in comparison to other gastrointestinal procedures. This is largely due to the challenges of cleaning the intricate reusable scopes between patients. A 2020 review\* shows that 15.25% of reprocessed scopes were found to be contaminated, which has led to dozens of death since 2012.

In addition, the endoscope was designed over 50 years ago and hasn't been updated since then. Gastroenterologists train for years to use duodenoscopes to perform ERCP. They are highly reliant on muscle memory and need to consistently do procedures in order to maintain proficiency. The current design can lead to issues from repetitive strain and wasn't designed with smaller hand sizes in mind, making it inaccessible to some women and people with small hands sizes.



### Exalt Model D

Boston Scientific, a leader in the medical device industry, has introduced the Exalt Model D, a sterile, single-use duodenoscope developed to eliminate the need for reprocessing.

The Exalt Model D, modeled after current on-the-market reusable scopes, provides familiar device performance to physicians. In addition, the disposable nature of the scope creates opportunities for future customization and ergonomic improvements.

The system uses another existing BSC product, single-use Orca valves, which act as push buttons for fluidics control.

### Opportunities

As the Exalt Model D fluidics system was not designed for disposability, it is not performing as expected. Additionally, the current Orca valve footprint limits a modifications to introduce a smaller handle design.

**Boston Scientific tasked this SCOPE team with redesigning the fluidics system to meet these size and performance needs.**

### Design Requirements

Can the design achieve all 4 states? *Neutral, Water flow, Air flow (Insufflation), and Suction*  
Can it accommodate the specified flow rates?  
Can suction and water be activated simultaneously?

#### Safety and Functionality

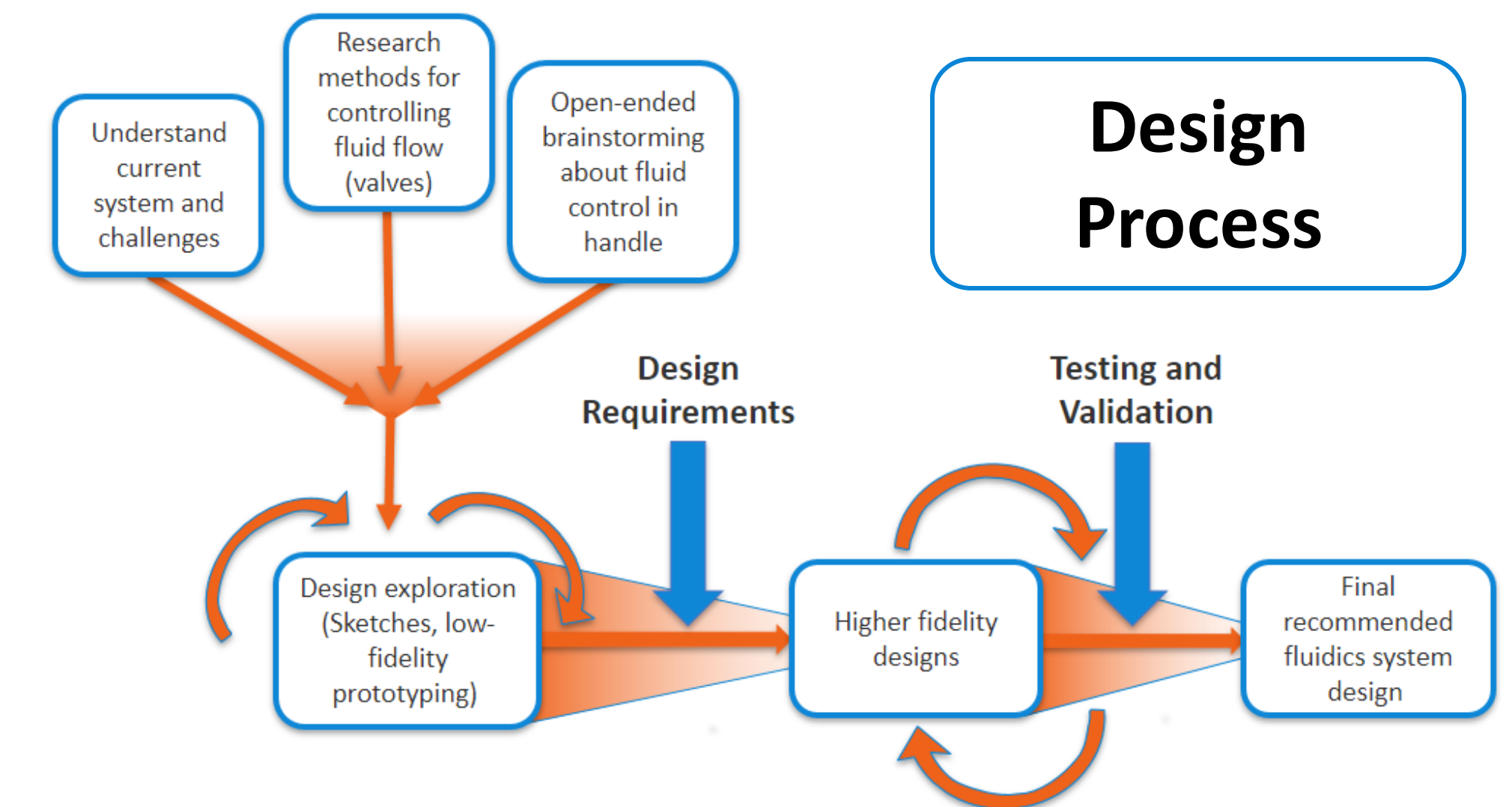
- No risk of suction re-entering the patient
- Allowance for post-manufacturing ETO sterilization
- Ability to be scaled down without disrupting fluid flow.

#### User-Friendliness

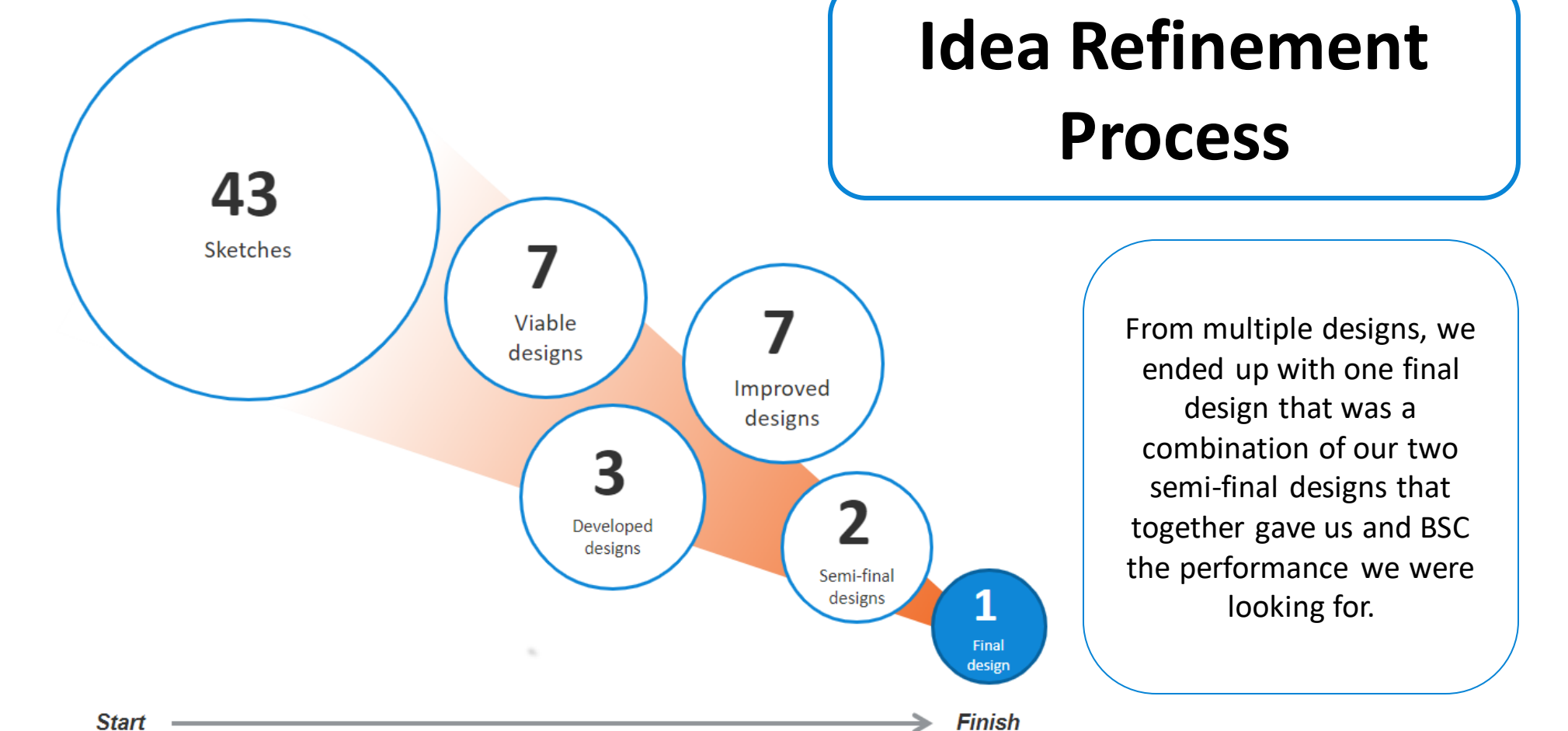
- Actuation that is similar to the existing version
- Actuation requiring two or less fingers
- Ease of physician / technician assembly to reduce user error
- Reduced required force to trigger

#### Manufacturing Feasibility

- Mechanistic simplicity
- Ease of manufacturing parts
- Ease of assembly
- Ability to be built out of biocompatible materials
- Overall design affordability
- Ease of disposal



### Idea Refinement Process



### Final Deliverable

In collaboration with the Exploratory, Marketing, and Human Factors teams at Boston Scientific, we were able to create a novel fluidics handling system that allows for ergonomic improvements and provide plans for system integration for BSC to move forward.

BSC is planning to file a patent and uniquely excited about real system integration.

Sources: NIH, GI Alliance, SAGES, FDA, Larsen et al 2020, New York Times, Cappell 2019, Drugwatch, Larsen 2020

