Renal Care Spring 2020 Project Update

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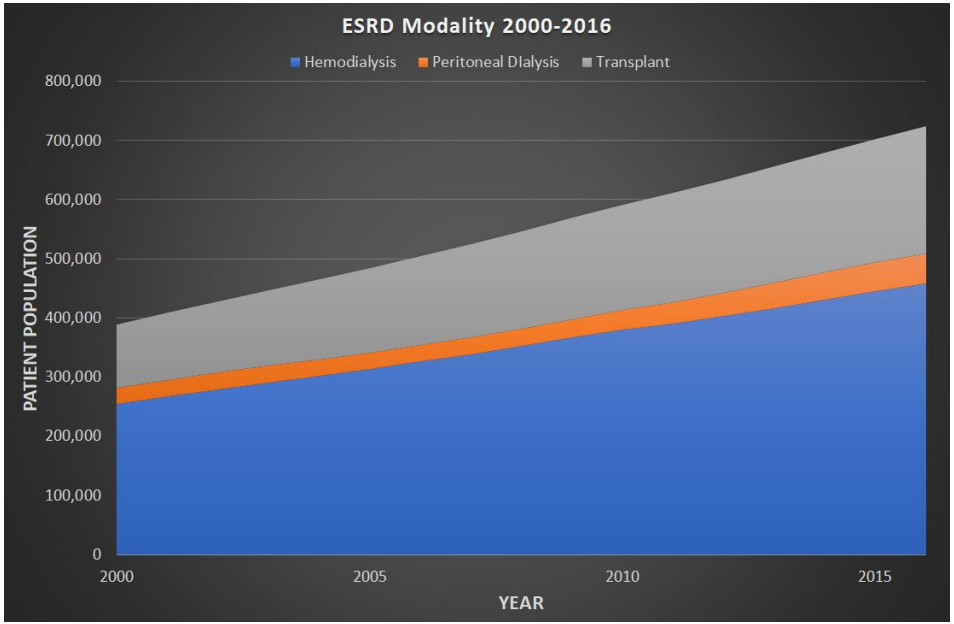
Background

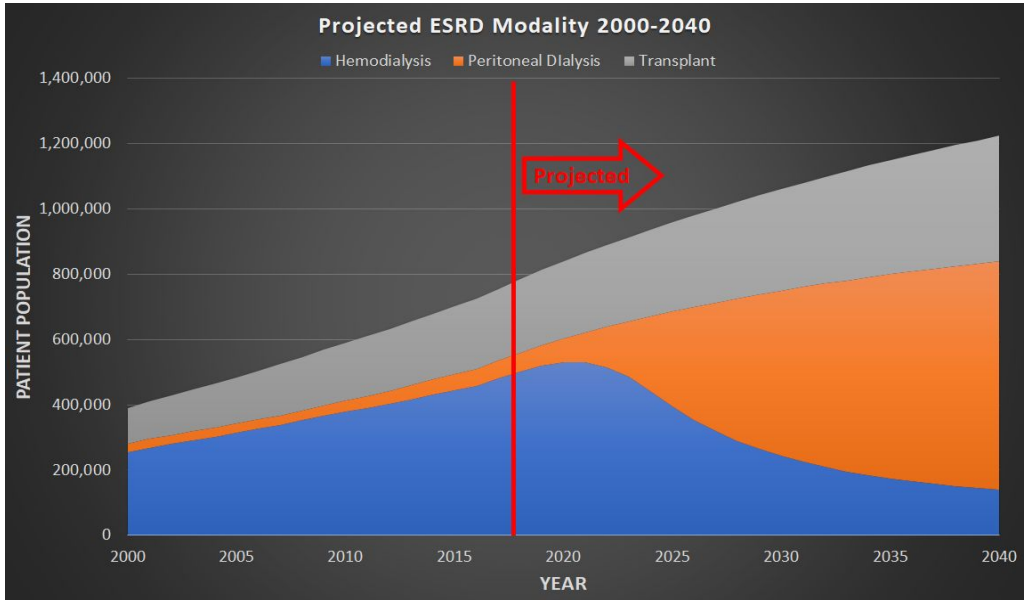
- 750,000 People have been diagnosed with End Stage Renal Disease in the US
  - Population grows by 20,000 every year
- Renal Replacement Therapy is paid for by Medicare
  - 7% of the Medicare budget, less than 1% of the Medicare Population
  - Home dialysis accounts for ~10% of the Dialysis patient population
- Average wait time for a kidney transplant is 4-5 years



Data from USRDS 2018 Annual Report

Background

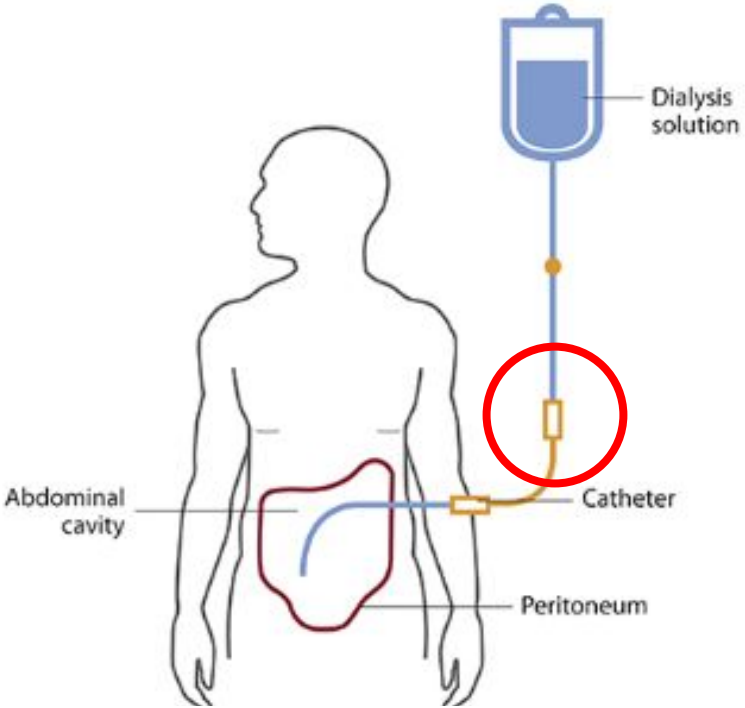
- Executive Order: Advancing American Kidney Health
  - In-Clinic Dialysis ➔ **Home Dialysis**
  - Public-Private Partnerships



"The kidney has a very special place in the heart" -- Pres. Donald Trump (7/10/19)

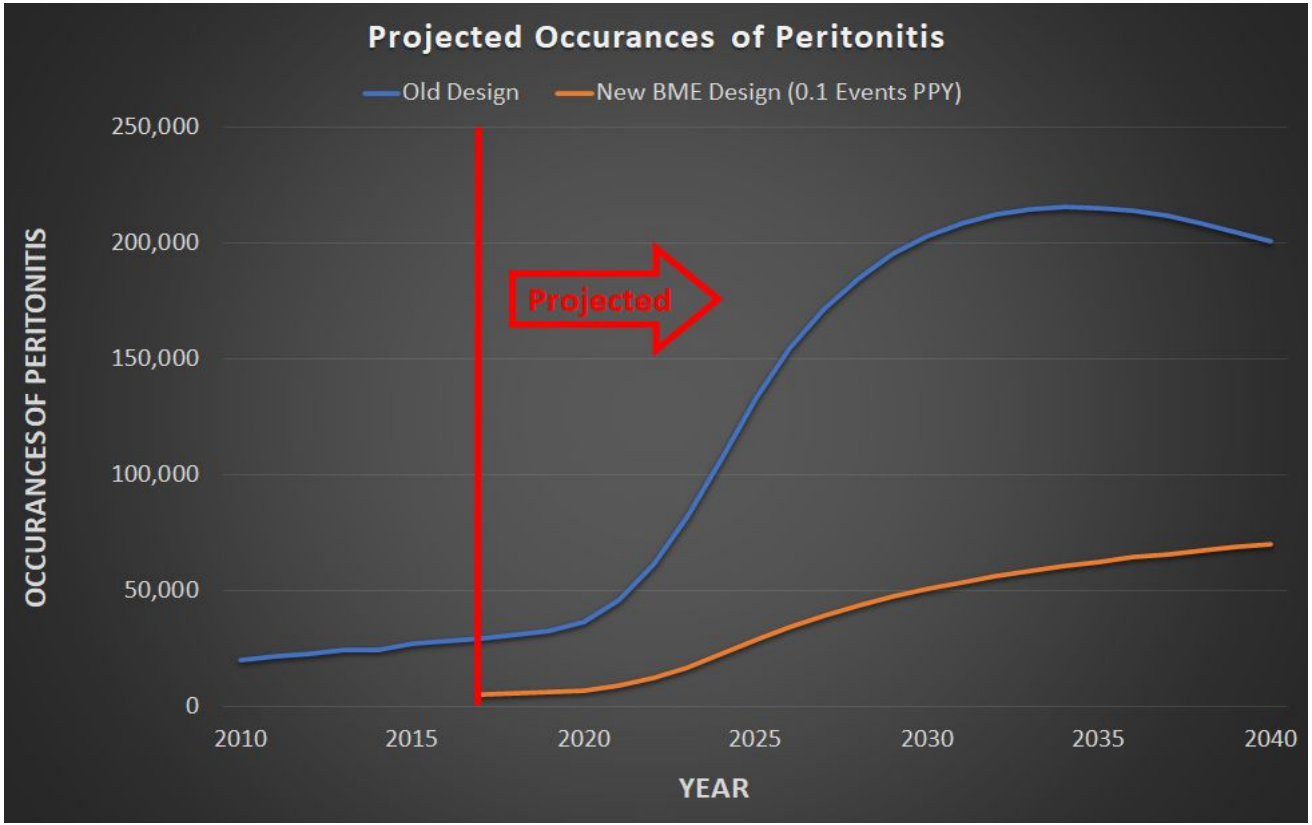
Background: Peritoneal Dialysis

- A dialysis modality that does not involve pumping blood through an external filter
- Uses the peritoneum as the “filter”
- Dialysis solution fills the peritoneal cavity, solutes exchange through osmosis, and effluent is drained hours later
- Major Complication: Peritonitis
  - 0.67 Events Per Patient Year in the US
- **Peritonitis can affect the viability of the peritoneum for continuing dialysis**



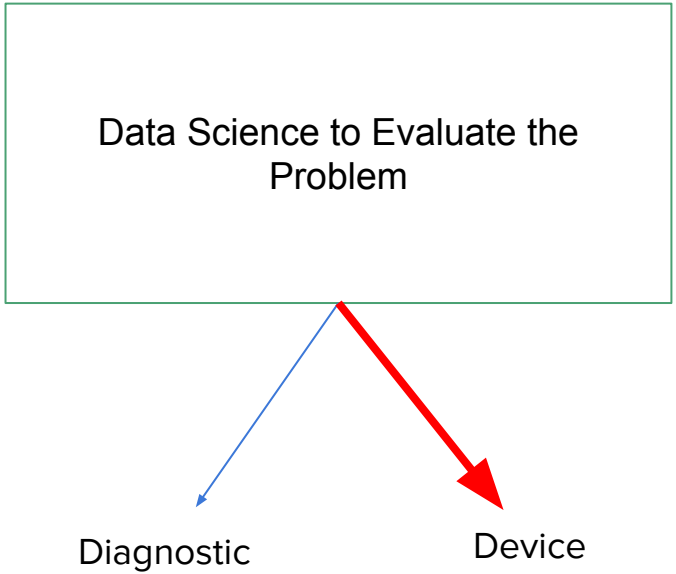
Picture Source: https://www.niddk.nih.gov/

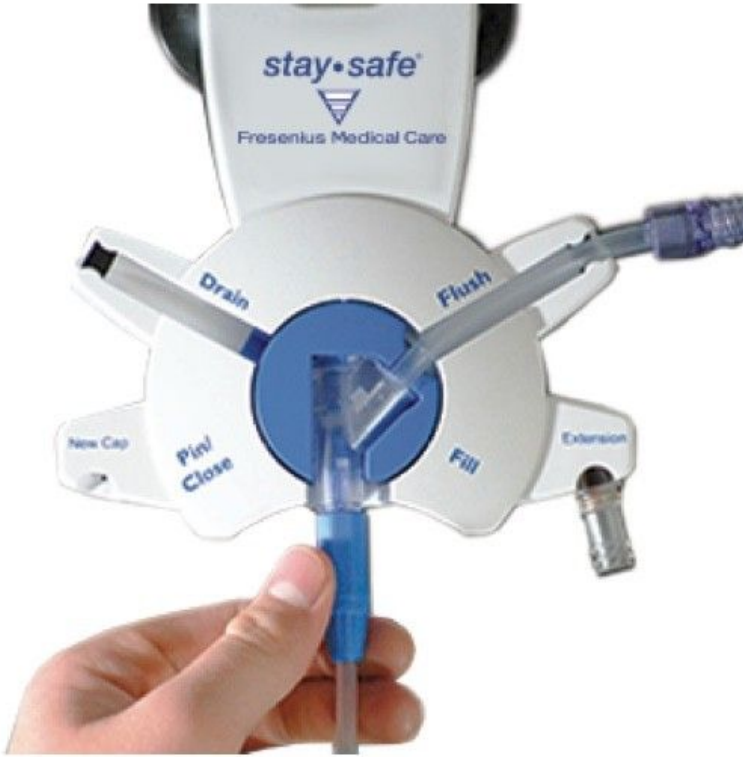
Background: Peritoneal Dialysis



Problem Statement

The purpose of this project is to decrease the incidence of peritonitis for current and future peritoneal dialysis (PD) patients by identifying infection in its early stages and refining/replacing the mechanics of existing PD devices.





Current Technology

- To dialyze, patients must make two sterile connections at home
  a. Expose catheter ➜ Dialyzer
  b. Dialyzer ➜ New Cap
- Simultaneous twist motion

Clinical Requirements

During observations we saw many different clinical requirements surrounding PD care.

We want to focus on the requirements that protects people from infection in a non-sterile environment to facilitate the inventive parts of our device

- Procedure is frequent
- Prone to error

1. Device **must** enable enhanced prevention from infection.
2. Device **must** maintain catheter tip sterility even in a non-sterile environment.
3. Device **should** decrease the time it takes to complete the PD procedure.

Clinical Requirement: Must Enable Enhanced Prevention From Infection

Corresponding Device Requirements

Shall prevent the PD patient from touching the PD catheter tip during normal use	**Should** decrease amount of time catheter tip is exposed to non-sterile environment.	**May** be able to connect faster than with current screwing mechanism.

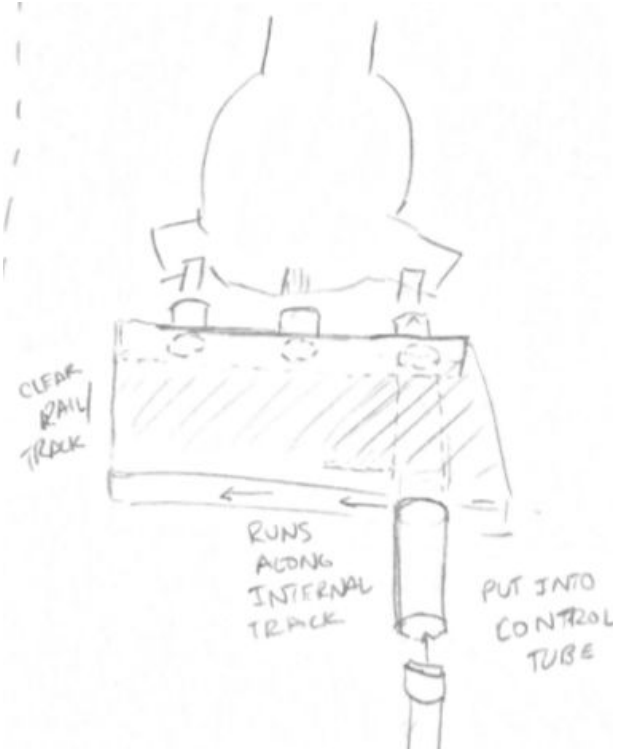
Device Specifications

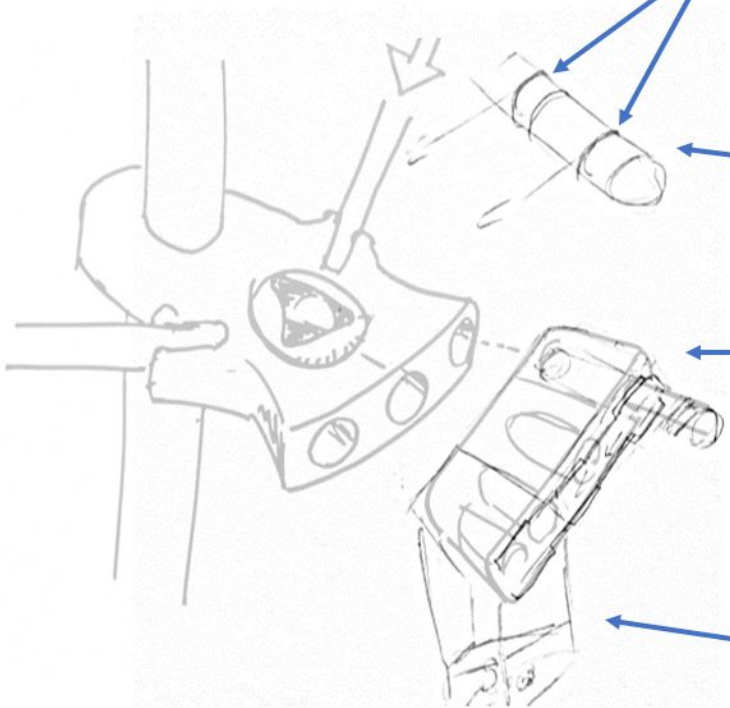
Device Requirements		Device Specifications
Device **shall** prevent the PD patient from touching the PD catheter tip during normal use	→	Device shall keep patient fingers or foreign bodies at least ___ inches away from the sterile tip.
Device **should** decrease amount of time catheter tip is exposed to non-sterile environment	→	Cap should only open in provided sterile environment. ____ force must be applied to expose sterile catheter tip.
Device **may** be able to connect faster than with current screwing mechanism	→	Device connection may have magnetic/automatic properties.

Verification Strategy

Device Specifications	Verification Strategy
Device shall keep patient fingers or foreign bodies at least ___ inches away from the sterile tip.	Proximity to body surfaces when performing connections (“Manipulation distance from fingers”).
Cap should only open in provided sterile environment. ____ force must be applied to expose sterile catheter tip.	Sterile catheter tip to cap connection strength - Pull Force Test Plan - Load Force Test Plan
Device connection may have faster magnetic/automatic properties.	Measure time catheter is exposed to air during connection performance

Design Iterations: Sketches





Has rails to track inside the transfer rail case

Catheter holder,
Firmly holds catheter to allow for twisting
Is inserted into transfer rail case

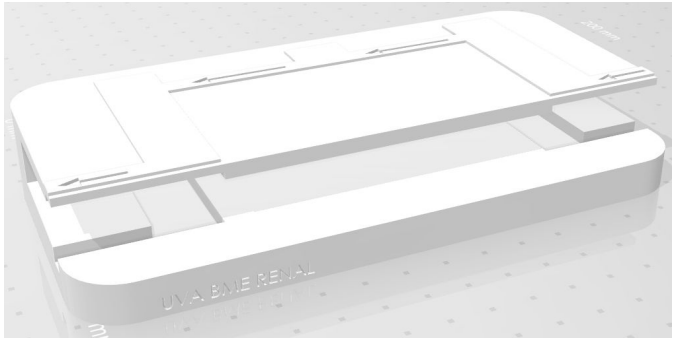
Transfer Rail Case

Magazine for extra tips

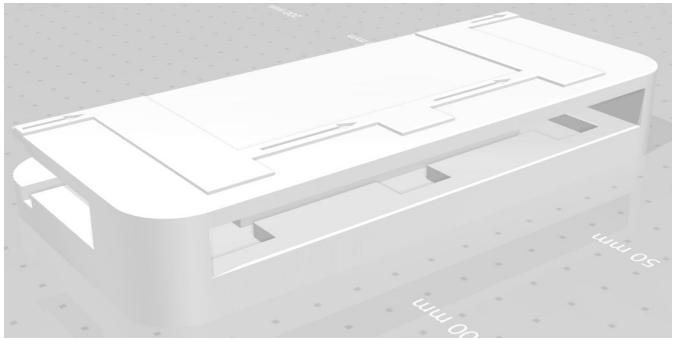
Design Iterations

Version 1

Front (patient-facing)

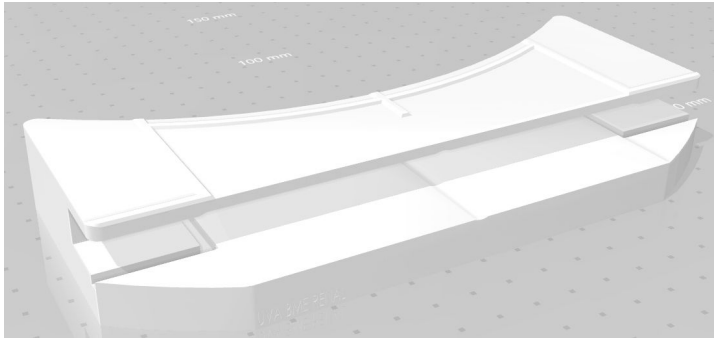


Back (Fluid port facing)

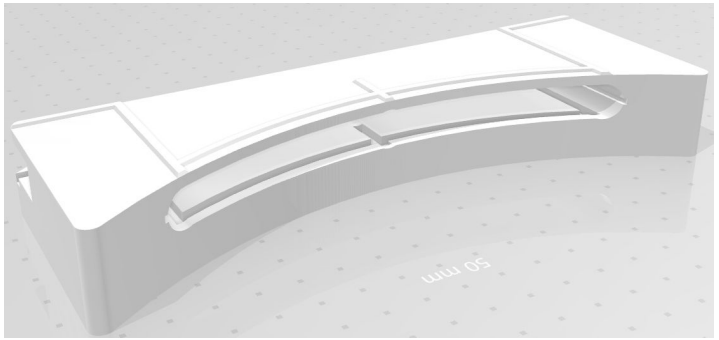


Version 2

Front

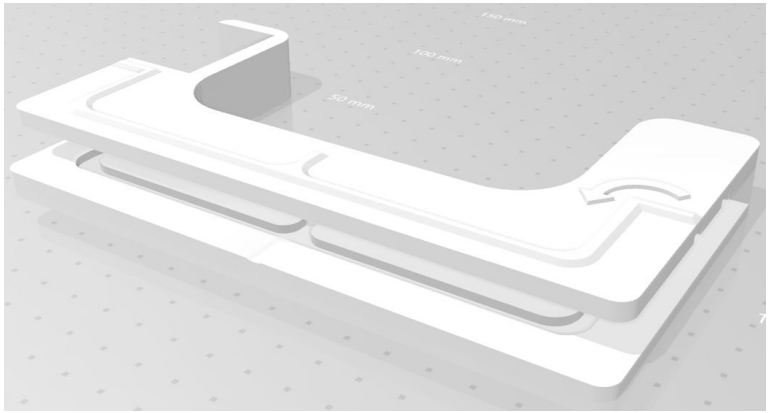


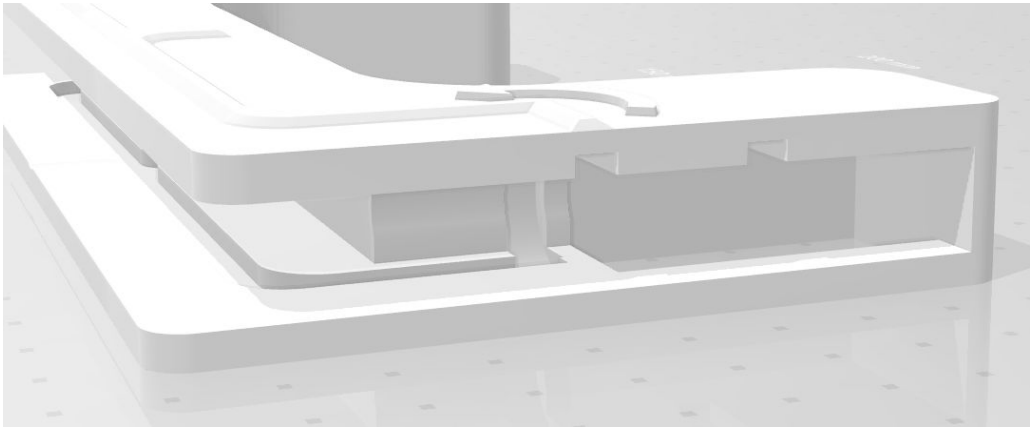
Back



Risk of Infection Mitigated Through Design

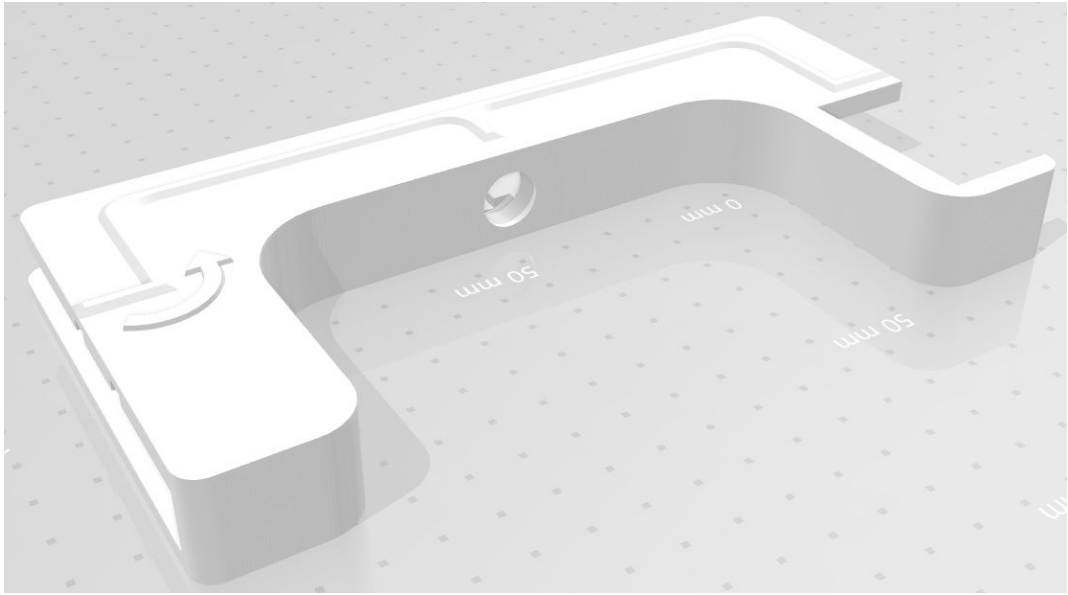
How does it fail? Catheter becomes disengaged from the channel while the sterile tip is exposed
Mitigation Measure: Closed channel design that requires twisting of the catheter body before entering or exiting the channel





Risk of Infection Mitigated Through Design

How does it fail? Catheter tip becomes exposed from the back of the case (side of the case facing the fluid port)
Mitigation Measure: Back of the case has been closed except for the hole to interface with the fluid port



Regulatory Strategy

- Popular predicate device: Fresenius Stay Safe, especially relevant to UVA
- Routinely reviewed on 510k basis
  - §876.5630: Peritoneal dialysis system and accessories.
  - We can meet predicate device characteristics to get device to pass in 510k basis
    - Class II (Special Controls)
    - PMA Exempt
  - We would include similarities in intended use, principle of operation, sterilization method, biocompatibility and design characteristics.

Problem 2: Diagnostics

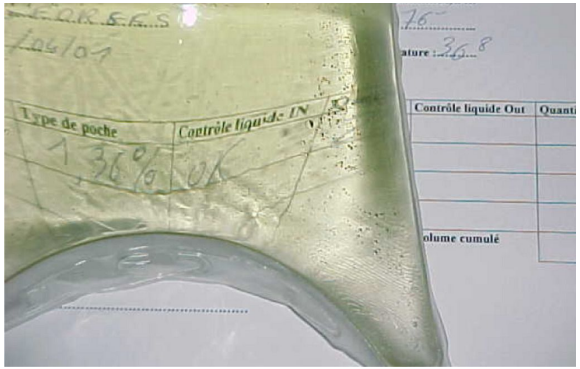
There will still be cases of peritonitis

Addressing peritonitis at an early stage is paramount

- Reduce Hospital Admissions
- Ensure viability of the peritoneum

Gold Standard: Reading through the effluent bag

High potential for innovation with an automatic test



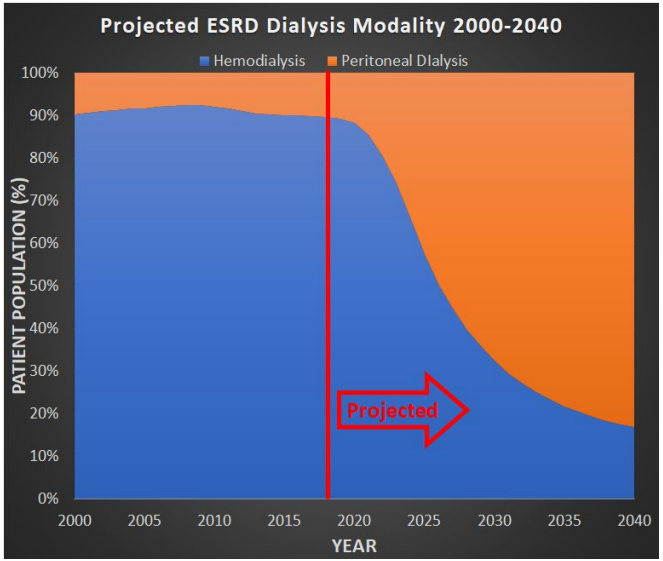
PD and Data Science

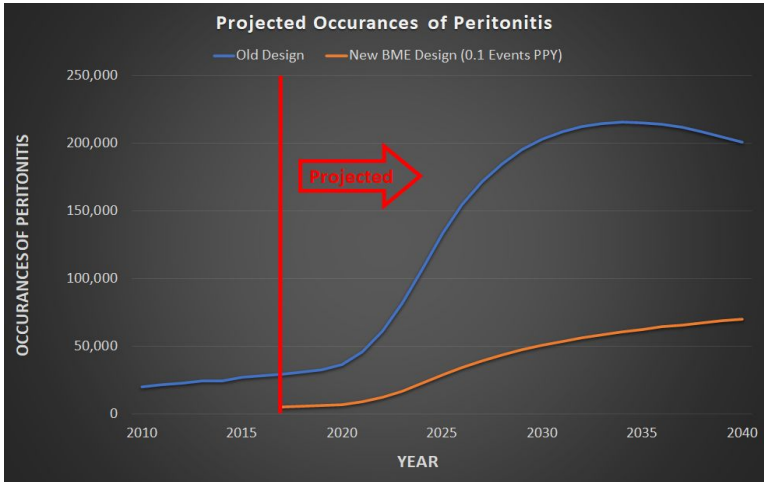
Executive Order on Advancing American Kidney Health will have large effects on the industry and the 15% of US citizens that have Chronic Kidney Disease

Phase 1: Projection of PD patients and peritonitis

Phase 2: Validation of Phase 1 projections based on the UVA Population

Phase 3: Evaluation of how our device would mitigate Peritonitis





A Special Thanks To:

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David Chen
Ty Hagler and Andrew Dimeo
Kim Fitzhugh-Higgins
BME-ME Class of 2020

Backup

Product Description:
The Peritoneal Dialysis (PD) transfer case and catheter cap system is a single use, sterile accessory that provides enhanced procedural measures for the ensurement of the sterile field. The device uses a rail and automatic catheter uncapping, sterile lumen engagement, and catheter recapping system. It consists of a clear plastic rail case and a loaded sterile catheter tip. It is to be operated by a patient that is undergoing Continuous Ambulatory Peritoneal Dialysis at home when prescribed by a physician.

Intended Use:
For use with End Stage Renal Disease Patients that are undergoing Continuous Ambulatory Peritoneal Dialysis.
For use with CAPD tubing sets including PD catheter, dialysate bag tubing, and drainage bag tubing.
For use in a home environment.

Indications for Use:
This device is indicated for use in increasing sterility when performing the transfer between sterile PD connections, including between a sterile cap and sterile dialysate bag tubing and the reverse.
This device is indicated for use in keeping the hands and fingers from contact with the sterile PD lumen while the PD catheter does not have a protected sterile terminal.

Clinical Requirements: Prevention

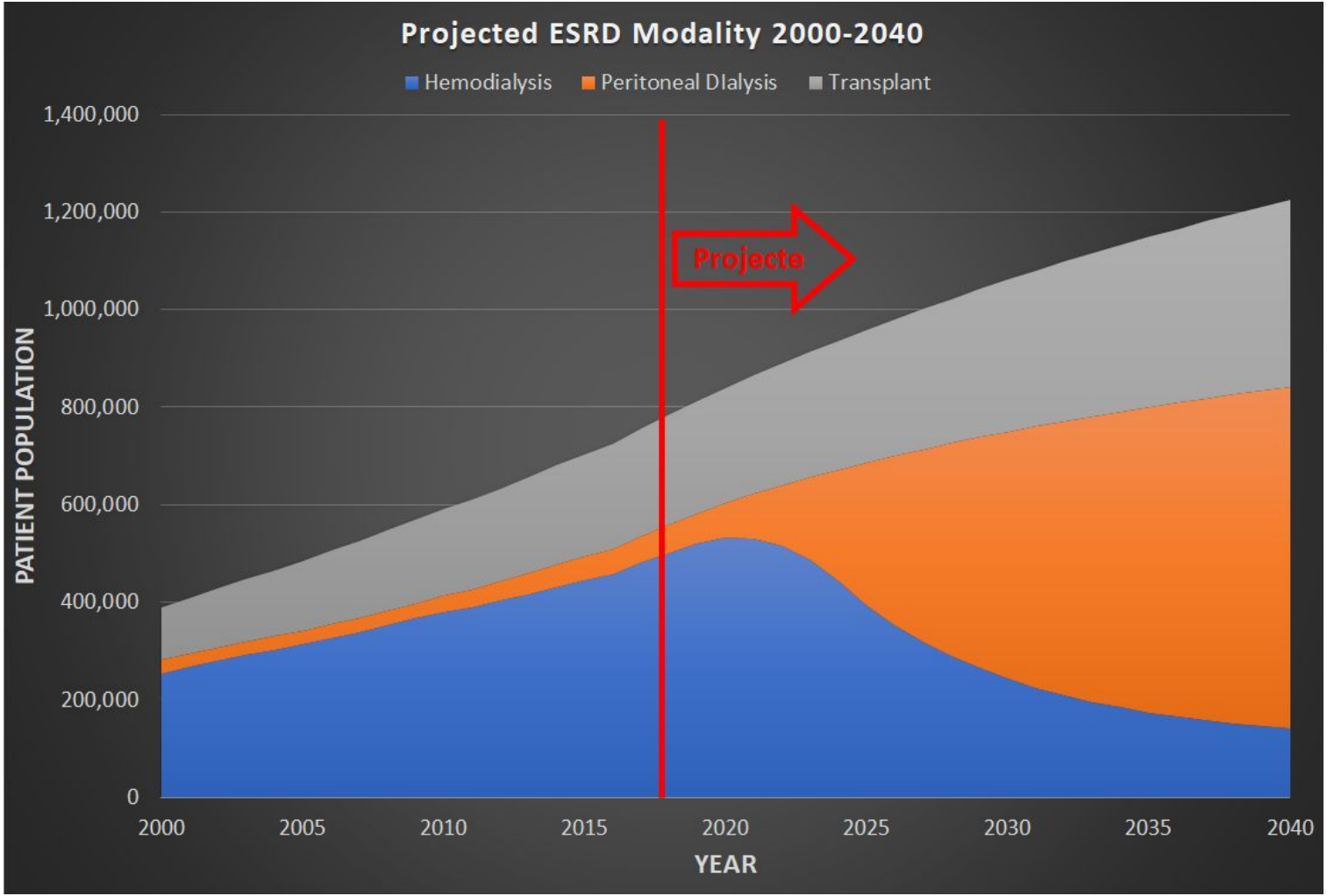
Efficacy	Device **must** enable enhanced prevention from infection
Use	Device **should** decrease the time it takes to connect to the dialyzer.
	Device **should** decrease amount of time catheter tip is exposed to non-sterile environment
Sterilizable	Device **must** be able to be sterilized
User	Device **must** be usable by a PD patient that is right or left handed.
User	Device **should** be usable by a PD patient including those with comorbidities
Environment	Device **must** be usable at home
Environment/Sterile	Device **shall** keep the catheter tip sterile even in a non-sterile environment.
Use	Device **shall** permit ease of grip of the catheter tip while keeping hands away
Use	Device **should** permit tactile manipulation of the catheter tip while keeping hands away
Safety	Tip **must** remain securely on the catheter when a transfer is not occuring
Use/Safety	Device **should** be durable enough to survive a 3 foot fall.
Use	Device **can** be watertight and create a channel for fluid to flow
Biocompatibility	Device **must** be biocompatible with fluid flowing across it and into the PD patient, not leeching any toxic chemicals
Sterility	Device **must** maintain sterility of the catheter tip.
Efficiency	Device **should** permit fluid to flow quickly into and out of patient
Price	Device **must** be economically viable within existing reimbursement codes
Use	Device **should** be single use
Volume (manufacturing)	Device **should** have a tip component that is disposable and manufactured at high volume Current Market: 50k Pts * 4 times/day * 365 days/year = 73 million Future Market (2030): 500K Pts * 4 times/day * 365 days/year = 730 million
Packaging	Device **must** maintain sterility and remain undamaged during shipping

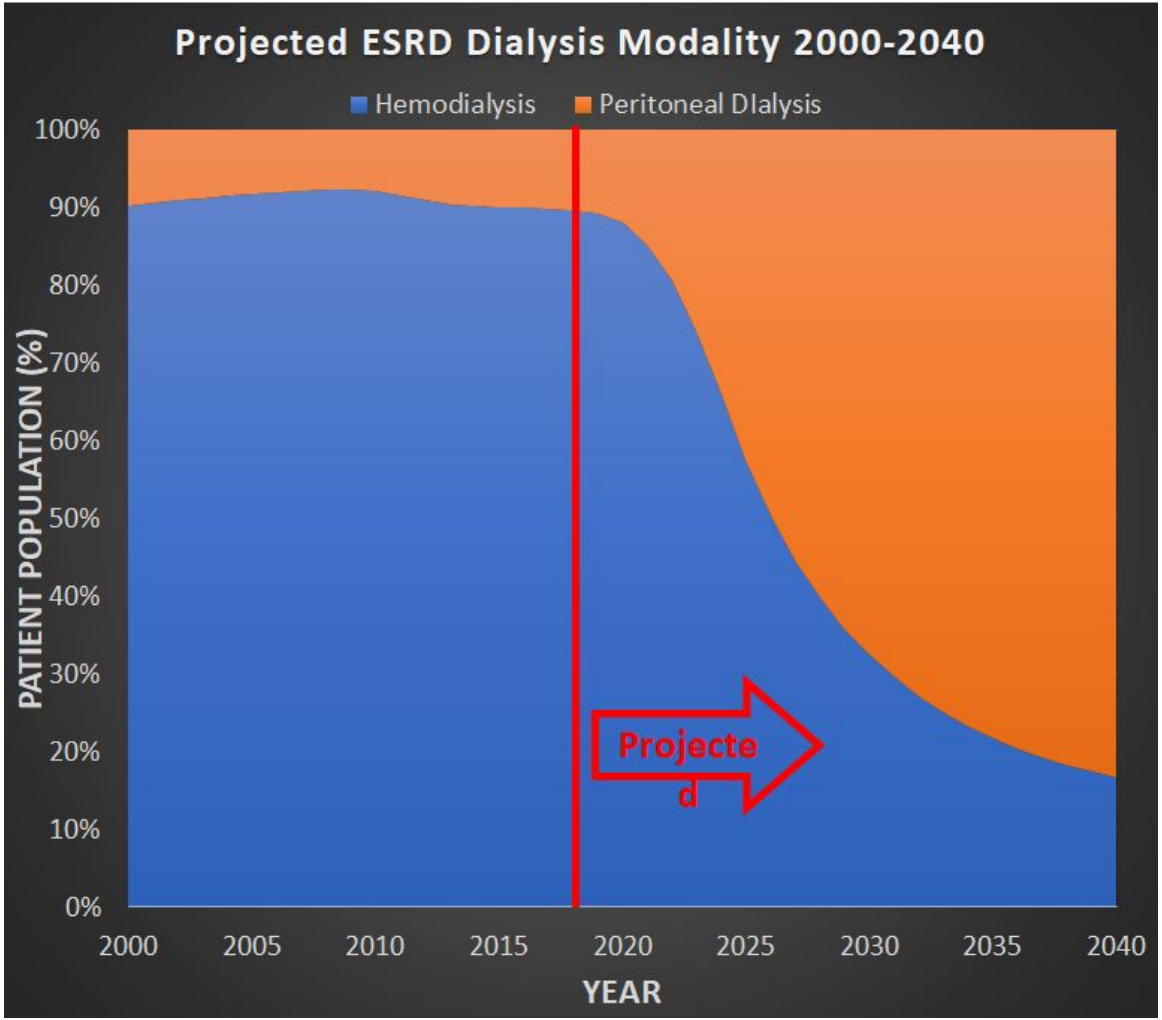
Clinical Requirements: Diagnostics

Efficacy	Device **must** enable early diagnostic detection of peritonitis
Efficacy	Device **must** return result faster that current detection methods
User	Device **should** be usable by PD patient with comorbidities
Efficacy	Device **must** provide clear and accurate results
Efficacy	Device **must** be able to detect infection no matter what strain
Environment	Device **should** be usable at home
Safety	Device **must** be biocompatible and safe
Use	Diagnostic **should** be run very frequently
Use	Device **must** not indicate/change when not in use
Shelf Life	**Shall** be storable for up to 1 year
Price	Device **can** be cheap enough for single use
Packaging	Packaging **must** permit shipping without damage

O = Occurrence 1 (occurs very infrequently)
---- 10 (occurs very frequently)
S = Severity 1 (least severe, no effect)
---- 10 (most severe, causes death, ~5 = directly cause infection)
D = Detection 1 (easiest to detect)
---- 10 (most difficult to detect)

Function	Failure Mode	Cause	O	Effect	S	Detection Method	D	RPN
Slide Catheter along case channel	Catheter becomes disengaged	Bad fit between catheter tip and case channel (knobs too small for channel)	4	Possible **exposure of the sterile lumen to non-sterile surfaces**	5	Trial run of channel-cap connection after manufacturing - fit test design verification	2	40
		Channel not properly manufactured	4	Difficult for patient to direct catheter correctly, **possible exposure of sterile lumen**	5	Scan of channel profile after manufacturing - design verification	4	80
		Patient uses too much force	4	**Possible exposure of the sterile lumen to non-sterile surfaces**	5	Force testing of channel-cap connection	4	80
Cap remains securely on the Catheter when transfer is not occurring	Catheter cap comes off when transfer is not occurring	Thread mechanism fails	3	**Possible exposure of the sterile lumen to non-sterile surfaces**	5	Fit test - design verification	2	30
		Cap was never screwed on fully, leaving only the clicking mechanism to hold the cap	5	**Threat of exposure of the sterile lumen to non-sterile surfaces**	4	Inspection	1	20
		Cap is too big for the catheter body	3	**Threat of exposure of the sterile lumen to non-sterile surfaces**	4	Fit test - design verification	2	24


Projected ESRD Modality 2000-2040
Hemodialysis
Peritoneal DIalysis
Transplant
1,400,000
1,200,000
1,000,000
800,000
600,000
400,000
200,000
0
PATIENT POPULATION
Projecte
2000
2005
2010
2015
2020
2025
2030
2035
2040
YEAR


Projected ESRD Dialysis Modality 2000-2040
Hemodialysis
Peritoneal DIalysis
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
PATIENT POPULATION (%)
2000
2005
2010
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2035
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YEAR
Projecte
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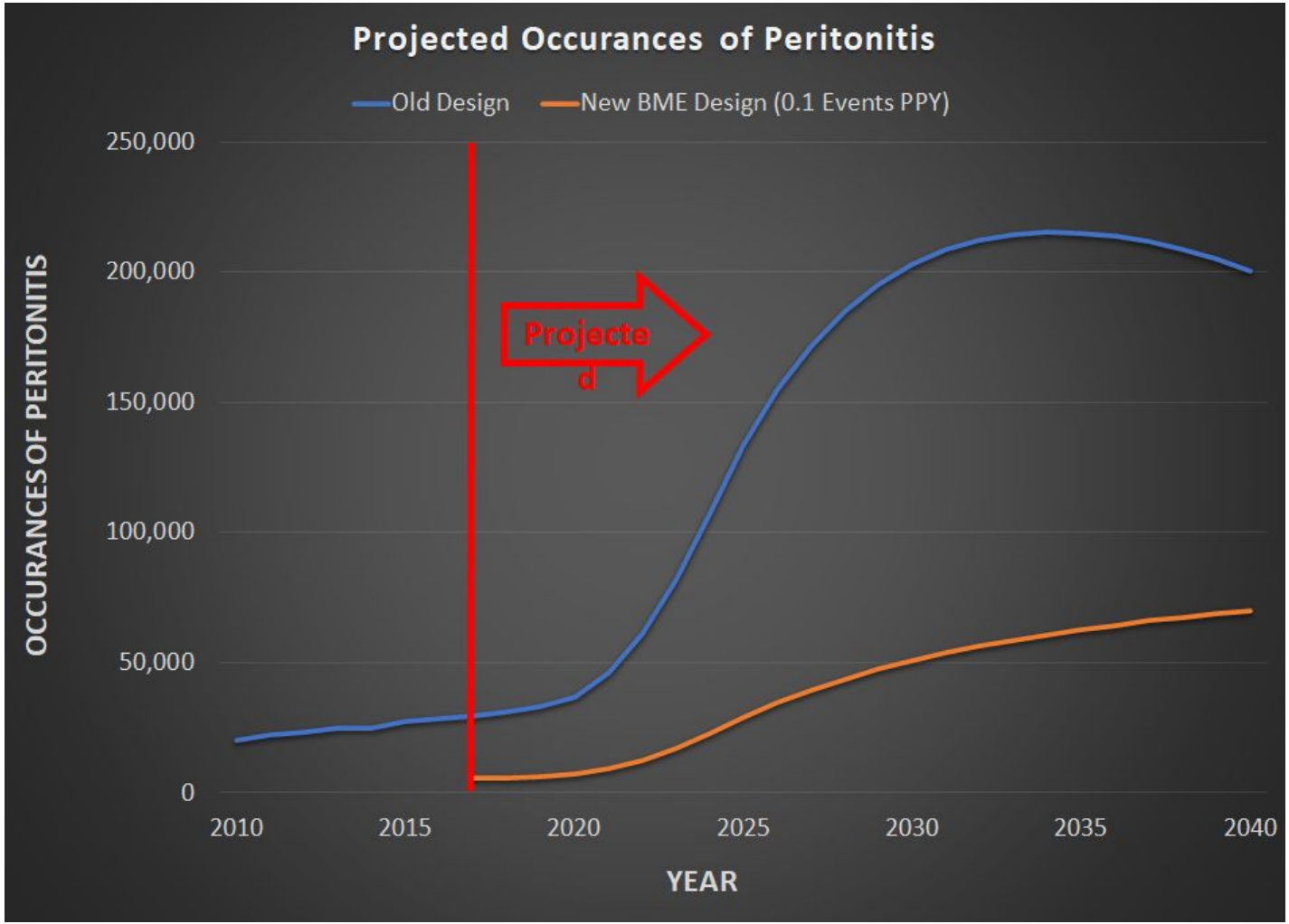
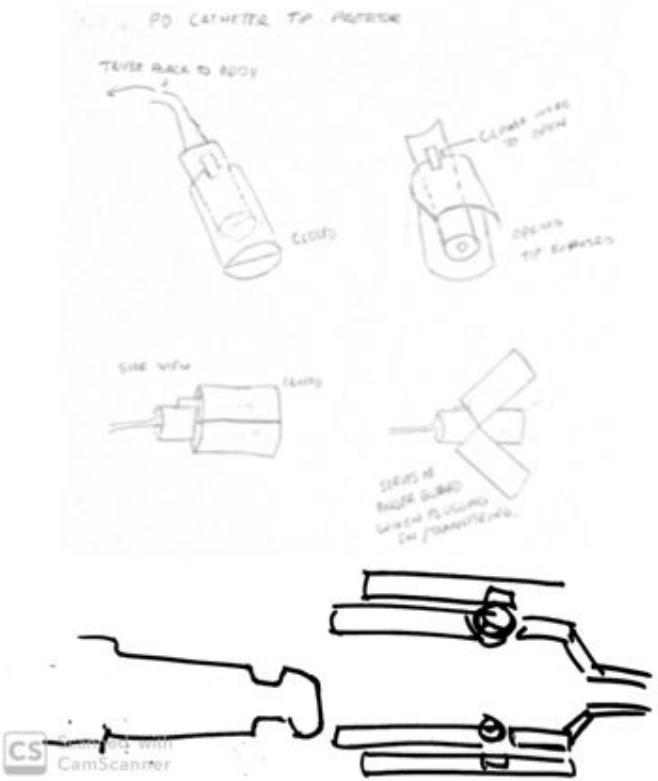
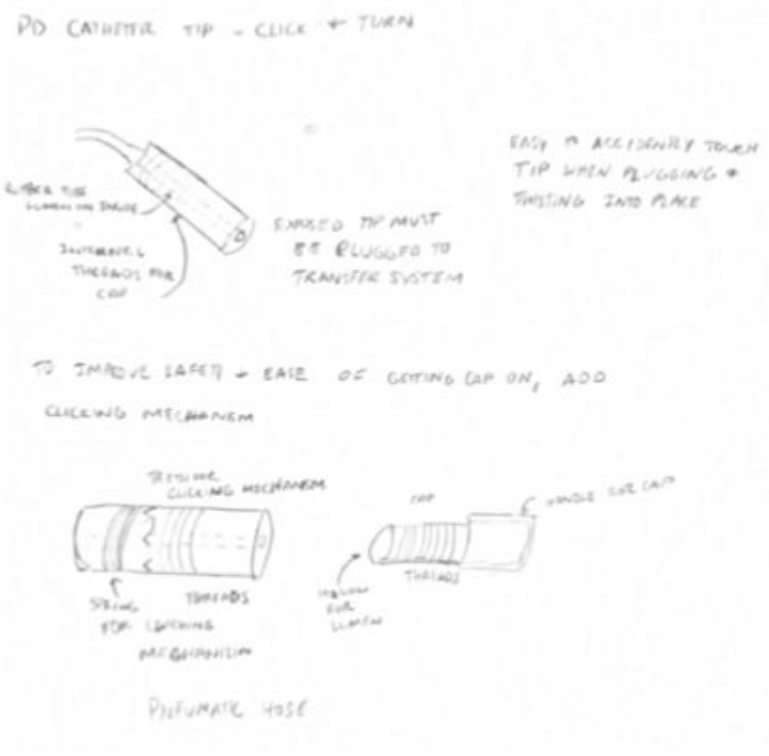

Projected Occurances of Peritonitis
Old Design
New BME Design (0.1 Events PPY)
250,000
200,000
150,000
100,000
50,000
0
OCCURANCES OF PERITONITIS
Projecte
d
2010
2015
2020
2025
2030
2035
2040
YEAR

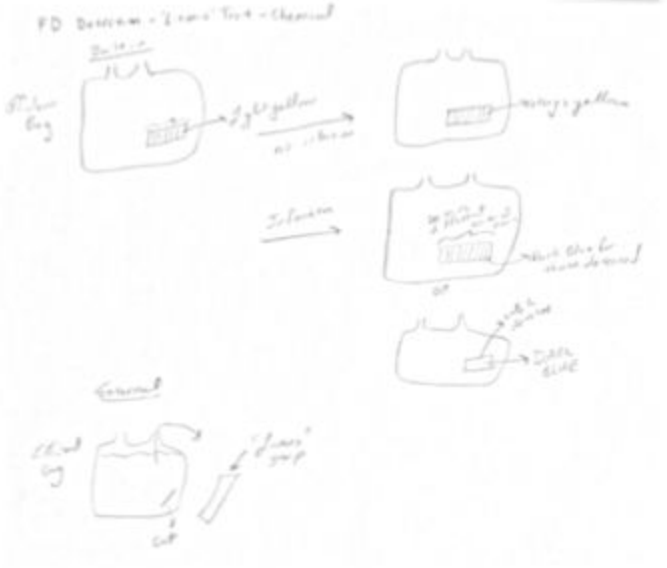
Other Design Sketches – Catheter Tip



Magnetic ball bearing connection



Other Design Sketches - Detection



Other Design Sketches - Detection