Renal Team Design History File

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This file is meant to hold all necessary information for the selection, research, design, and risk analysis of our renal project.

Project Title: Early Detection and Reduced Peritonitis in Peritoneal Dialysis Patients

Contents (Click to Navigate to Section)

Clinical Challenges Identified Through Observations

Brief Description: Clinical challenges in the Renal Continuum of Care have been identified and grouped based upon specific points in the diagnosis and care timeline.

Early Detection/ Diagnosis (3)

	Clinical Challenge	Description
1	Kidney function assessment is lacking	Creatinine and BUN are only proxy biomarkers for kidney function and do not fully assess possible issues with the kidney.
2	GFR estimation is poor	GFR is a functional cornerstone of kidney function that remains difficult to measure. It often takes a special test wherein a patient must carefully follow a procedure to use inulin to measure the function
3	Many patients do not seek advanced kidney care until late stage Chronic kidney disease	Most kidney care is performed after a patient has reached stage 3 or 4CKD, resulting in a lot of already-lost kidney function that could have been prevented.

Preservation of Kidney Function (2)

	Clinical Challenge	Description
4	Acute kidney injury is not always prevented in the ICU even when it is a possibility	Patients, prior to having a procedure performed, could have a kidney ligation procedure to prevent "shocking" of kidney that may cause AKI and progress into ESRD
5	Patients with CKD/are on dialysis often have comorbidities that can conflict with kidney care recommendations	Many CKD patients are hypertensive, diabetic and have cardiovascular issues, where the treatments for those illnesses can be detrimental to remaining kidney function

Vascular Access (5)

	Clinical Challenge	Description
6	Vascular access function measurement is imprecise	Clinicians send patients to have their access (fistula) assessed by IR very frequently, not knowing if a stenosis is actually flow limiting. IR surgeons perform fistulagrams and feel compelled to perform angioplasties. Flow is measured qualitatively instead of quantitatively
7	Technique used in IR to get medication sterile in syringe is a hazard	The outside vial of medication is unsterile and is held by a HCP with bare sanitized hands as the doctor in gloves aims the syringe needle to puncture the vial: huge needle stick hazard.
8	Catheters are difficult to keep dry	Catheters that get wet lead to infection. Due to this constraint there is a rather large restriction on quality of life: no swimming and limited ways to

		shower. Keeping the area clean and dry in these risky scenarios is of utmost importance.
9	Visualizing and tracking a catheter through vessel networks is difficult	Visualization techniques in IR does not map 3D CT scan images to 2D fluoroscopy images leading to confusion to difficulty in placing the catheter in the correct vessel region
10	Patients can be in extreme pain during a catheter placement in IR	No or very little sedative is used during catheter placement in IR. A lot of physical force is needed to thread the catheter tubing through the subclavian vein. The operating stie was secured through a strong adhesive sheet

Renal Replacement Therapy (RRT) (In clinic) (11)

11	Dialysis is an insufficient therapy for those with ESRD Please Note: We do not think we have enough time to re-engineer dialysis or a different Renal Replacement Therapy (RRT). This simply points out the deficiencies of dialysis	- Dialysis only filters out smaller molecules; larger waste molecules are left in the body - Kidneys function continuously 24/7; dialysis is condensing all the filtration work into 12 hours - Kidneys produce important hormones such as erythropoietin, calcitriol, and renin that dialysis does not and often contribute to additional illness states such as anemia and mineral & bone disorder. - No pH control (electrolytes) - Limited in fluid balance (non-dynamic prescription)

	Clinical Challenge	Description
12	Diets are difficult to manage as a CKD patient	Patients with different deficiencies must consume/avoid certain foods - coming up with a plan that can provide the patient some flexibility/quality of life while also avoiding patient complications is challenging
13	Brady-arrhythmias are difficult to detect or predict in dialysis patients	Dialysis patient mortality often results from brady-arrhythmias
14	Access to dialysis is limited by the strict schedule requirements (often restricted by nurse staffing)	Since clinics can only host patients at specific times of the day depending upon open slots, patients are having to dialyze at times that conflict with their schedule. This results in worse compliance. If there was more flexibility, patients might be more compliant.
15	It is difficult to keep hemodialysis machines clean.	The machines have lots of nooks and crannies on them and blood pressure cuffs are used for all the patients that sit in that chair that day. Lots of sanitation is needed and the nooks increase risk of transferring illnesses through blood.
16	Patients often do not complete their	Patients can eat or drink large amounts of food or

	dialysis treatment	liquid before treatment that often makes them feel sick. They then request that they end the treatment early.
17	Hypotensive episodes during dialysis lead to the patient ending treatment early	Hypotensive episodes are difficult to predict in dialysis patients during dialysis. If ultrafiltration is too aggressive, it can cause a hypotensive episode.
18	Dialysis patient electrolytes can swing drastically or be shifted into dangerous regions due to dialysis treatment after “The long break”	Electrolyte concentrations drastically swinging or being left outside the normal range lead to bad outcomes. Labs are usually only taken once a month and do not sense electrolyte variability day to day.
19	Dosing is difficult for drugs which take days or weeks to take effect	Epogen and tacro are frequently guess work when it comes to giving a prescription. It is not uncommon to see levels overshoot because it is difficult to predict how a patient will react.
20	Patient electrolyte concentration is uncontrolled during the long break	Variability in a patient's day to day diet can lead to electrolytes being outside the normal range.
21	Patients do not complete their treatment because they arrive late to the dialysis clinic	Patients often come late to appointments due to logistical challenges. This often leads to patients not getting their full treatments.
22	Clotting can interrupt treatments	Heparin is currently given either through several doses or continuously; however each patient has different guidelines on when to administer the drug.

Transition to home dialysis (6)

	Clinical Challenge	Description
23	Home dialysis is under utilized. Explore: Sticking someone with a needle mental barrier to home hemodialysis	HHD is a relatively low utilized (less than 5%). There must be better persuasion or ease of transfer to home dialysis in order to hit the executive order target of 80% of new dialysis patients by 2025
24	Home dialysis patient caretakers get burned out	Caretakers can get burned out by how frequently dialysis is needed for the patient; it is ultimately constant can a lifelong commitment.
25	Home hemodialysis machine tubing easily becomes kinked	Kinks in tubing will set off and restart the dialysis machine
26	Home dialysis is under utilized. Explore: Good vision and dexterity are barriers to home dialysis	A caretaker or a patient who possesses good vision and dexterity is needed for home dialysis to manipulate the tubes and, in the case of home hemodialysis, “build” (setup) the dialysis machine
27	Infection is common with home peritoneal dialysis	There are 2 sterile connections patients themselves have to make with the Fresenius stay safe organizer. This exchange of connections has a high chance of infection if improperly performed.
28	It is difficult to remove the air bubbles from home hemodialysis tubing	Caretakers need to be aggressive with tubing to fill with saline and rid it of air bubbles.

Transplant

	Clinical Challenge	Description

Favorite Challenges and Rationale For Their Selection

(3) Many patients do not seek advanced kidney care until late stage Chronic kidney disease

This is a relatively unexplored part of kidney care. The techniques for evaluating kidney function are few and far between. We want to tackle this issue as a “public health issue” - kidney disease is not an illness that has much recognition. There are advantages to preventing further degradation of kidney health in order to avoid renal replacement therapy. There is a lot of room for creativity and out of the box engineering thinking here.

(6) Vascular access function measurement is imprecise

All measurements of vascular access (fistula) function are qualitative. Once patients are sent to Interventional Radiology to be examined, surgeons feel compelled to perform angioplasty because there is no way of confirming if a stenosis is flow-limiting. Having a baseline “before” measurement and comparing to an “after” measurement would be valuable in assessing the usefulness of procedures and nail down if a stenosis is the true reason for low flow in a fistula.

(18) Dialysis patient electrolytes can swing drastically or be shifted into dangerous regions due to dialysis treatment after “The long break”

Currently patient electrolyte levels are checked once a month through labs; these screens are expensive and time consuming, which is why they don’t happen every time the patient is dialyzed. Major changes in electrolyte concentrations or leaving electrolyte concentrations outside normal ranges, especially potassium, are presumed (but not scientifically confirmed) to lead to worse outcomes. If doctors had a way to measure concentrations on a per-treatment basis, they would change dialysate prescriptions accordingly.

(27) Infection is common with home peritoneal dialysis

There can be two parts to this problem and both are interesting. One is the two mechanical transfers of sterile connections that PD UVA patients must make with the existing peritoneal dialysis organizers. Patient error may cause this frequent infection. The other is early detection of infection by analyzing effluent fluid or some other detection mechanism.

Preliminary Pugh Chart

Brief Description: First pugh chart ranking our top 4 clinical challenges .

	Patient Prevalence	Feasibility to complete in class	Likelihood or ease of Clinical use	Ease of integration into non-clinical settings	Financial Impact	Total
Many patients do not seek advanced kidney care until late stage Chronic kidney disease	5	3	5	5	3	21
Vascular access function measurement is imprecise	2	2	4	2	5	15
Dialysis patient electrolytes can swing drastically or be shifted into dangerous regions due to dialysis treatment after “The long break”	4	2	4	3	3	16
Infection is common with home peritoneal dialysis	2 or 3	5	3	5	3	19

Secondary Pugh Chart

Brief Description: Second pugh chart ranking our top 3 clinical challenges.

	Patient Prevalence	Feasibility to complete in class	Likelihood or ease of Clinical use	Ease of integration into non-clinical settings	Financial Impact	Total
Many patients do not seek advanced kidney care until late stage Chronic kidney disease	5	3	5	5	3	21
Dialysis patient electrolytes can swing drastically or be shifted into dangerous regions due to dialysis treatment after “The long break”	4	2	4	3	3	16
Infection is common with home peritoneal dialysis	2 or 3	5	3	5	3	19

Preliminary Clinical Requirements and Needs

Brief Description: Top three clinical requirements and their respective clinical needs.

Patients do not seek advanced kidney care until late stage CKD
Clinical Need: A better way to detect CKD at earlier stages

1. Must have high sensitivity (not many false negatives)
2. Must be capable of being deployed in a variety of locations
3. Could coordinate with/provide information to clinical providers

Out of range or drastic swings in electrolyte levels is dangerous dialysis patients
Clinical Need: A dialysis setting real-time reading of electrolyte level

1. Must inform clinicians if patient electrolytes are in dangerous zones
2. Must be real-time
3. Must allow clinicians to correct electrolyte levels
4. Must not impair the normal
5. Could automatically change electrolyte levels
6. Could link information with current technologies

Infection is common with home peritoneal dialysis
Clinical Need: A way of preventing infection during the “transfer of connections” for patients performing PD

1. Must aid in the prevention of infection
2. Must be simple enough for patients to perform/use/complete
3. Should be easy for patients with neuropathy/impaired sight to use
4. Should be easy for clinicians to train patients on the solution
5. Could provide information back to clinicians about the risk of infection or other vital statistics
6. Could be linked with currently used technologies (Tyto, smartphones)

Final Updated Pugh Chart

Brief Description: Final pugh chart allowed us to pick our clinical problem of choice.

	How will it fit in with public policy	How will it fit in with existing clinical practices?	How broad can the solution be?	Impact on Patient	Danger Prevalence	Total
Patients do not seek advanced kidney care until late stage CKD	4	2	5	4	4	19
Out of range or drastic swings in electrolyte levels is dangerous for dialysis patients	3	4	3	5	3	18
Infection is common with home peritoneal dialysis	5	5	4	5	5	24

Clinical Compact and Problem Statement

Brief Description: This begins our inquiry into the complications that patients undergoing Peritoneal Dialysis face. The peritonitis complication is multifaceted, where there is potential for solution-finding in both prevention and detection. The problem can be further investigated using data science.

Project Title: Early Detection and Reduced Peritonitis in Peritoneal Dialysis Patients

Clinical Challenge (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.

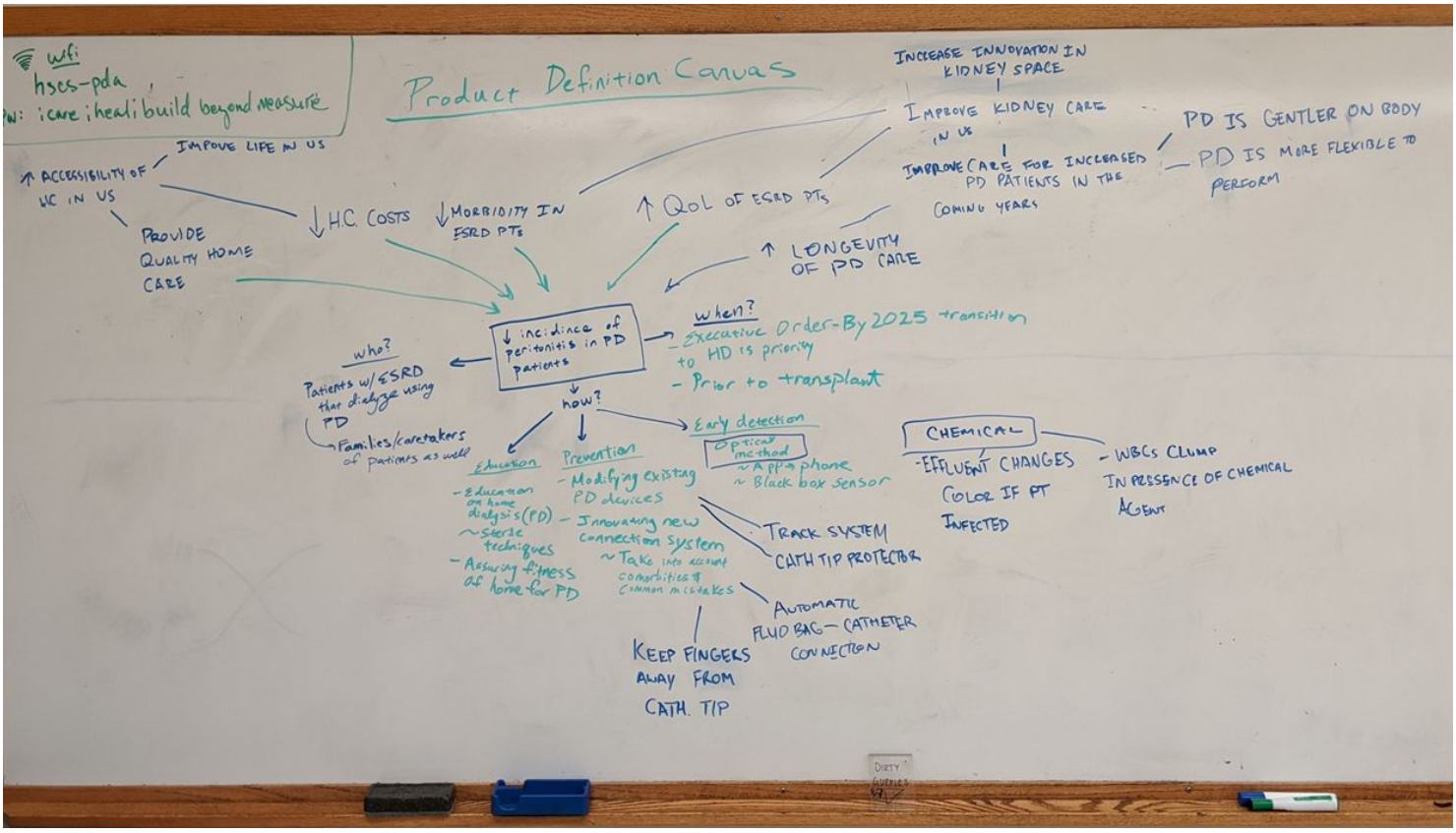
End stage renal disease healthcare is experiencing a shift from in-center hemodialysis to home dialysis due to the recent executive order on Advancing American Kidney Health (AAKH). Peritoneal dialysis is considered the simplest form home dialysis option and will likely be the form that most new dialysis patients will utilize. However, the major complication preventing consistent, long-lasting peritoneal dialysis viability is commonly occurring infection of the peritoneal cavity, or peritonitis. Peritonitis incidence rate is approximately 0.67 per patient per year in the United States.

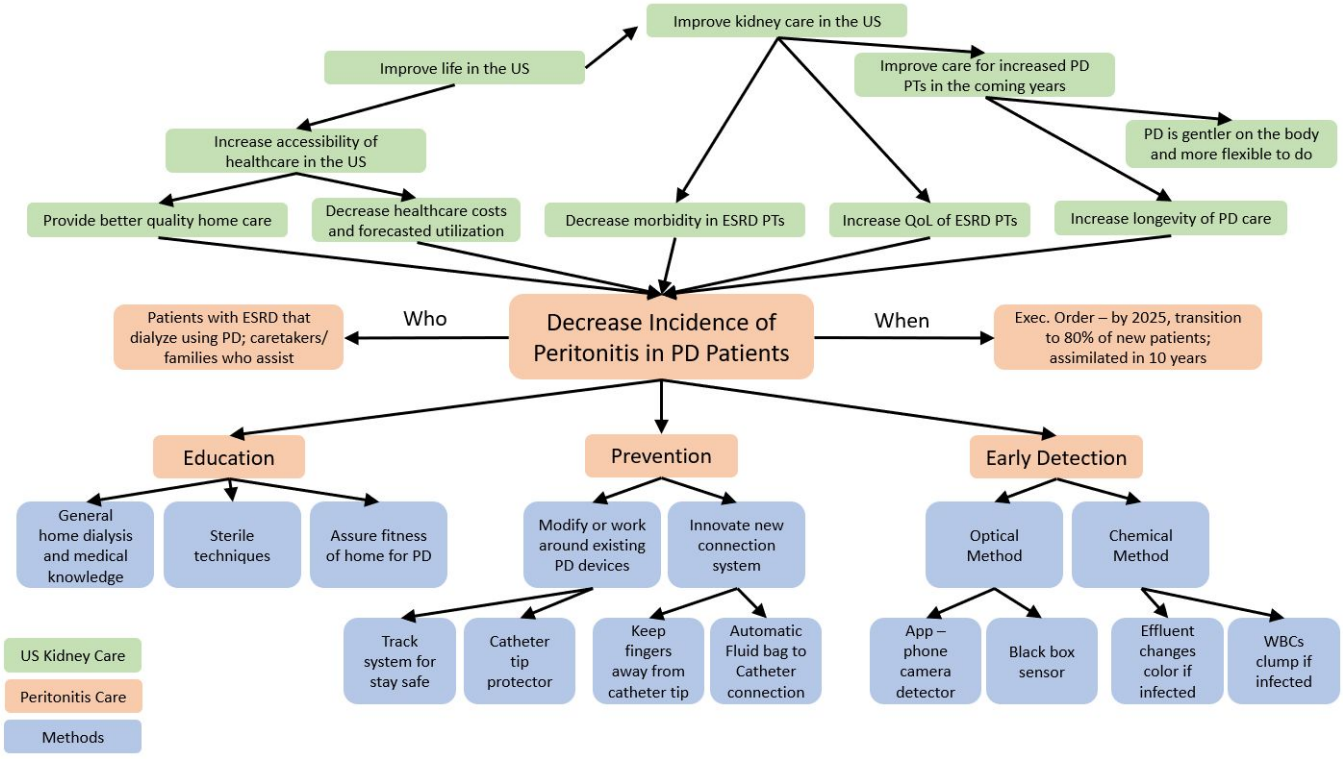
Potential Contribution to Patient Care: The AAKH order set a goal of putting 80% of new dialysis patients on home dialysis by 2025. Attenuating the major downside of peritoneal dialysis -infection- is likely to make a big impact in the next five years and in a ESRD population that is mostly undergoing PD. Less infection of the peritoneal cavity will result in 3 major health contributions:

1) Less distress and better quality of life for the patient
2) Fewer patients seeking emergency care for infection
3) Longer-lasting viability of the peritoneal cavity, and thus a longer time to utilize peritoneal dialysis as a therapy

Product Development Canvas

Brief Description: Expansion on problem statement in scope.





Relevant Standards

Brief Description: ISO guidelines, FDA Regulations, and FDA Guidelines that are relevant for Peritoneal Dialysis Accessories and for the application of human factors.

ISO

ISO guidelines 13485:2016
https://www.iso.org/iso-13485-medical-devices.html
ISO 6385:2016(en): Ergonomics principles in the design of work systems
https://www.iso.org/obp/ui/#iso:std:iso:6385:en
ISO 11737-2:2019(en): Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
https://www.iso.org/obp/ui/#iso:std:iso:11737:-2:ed-3:v1:en

FDA Regulations

FDA guidelines Code of federal regulations, Chapter I, Subchapter H: medical devices
Part 820: Quality System Regulation
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820
Part 860: Medical Device Classification Procedures
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=860
Online resource for FDA guidelines Code of federal regulations, Chapter I, Subchapter H: medical devices
https://www.ecfr.gov/cgi-bin/text-idx?SID=97a37b9f359c91a0a19d1f916b8db994&mc=true&tpl=/ecfrbrowse/Title21/21cfrv8_02.tpl#0
Online resource for FDA guidelines directly related to PD devices
https://www.ecfr.gov/cgi-bin/text-idx?SID=9d32ffeeefcef5feb46879a57b365739&mc=true&node=se21.8.876_15630&rgn=div8

FDA Guidelines

Applying Human Factors and Usability Engineering to Medical Devices:Guidance for Industry and Food and Drug Administration Staff
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices

Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" :Guidance for Industry and Food and Drug Administration Staff
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and

Recognized Consensus Standards for JTO -- Diagnostic

- 7-197 CLSI M35-A2 (Replaces M35-A)
  Abbreviated Identification of Bacteria and Yeast; Approved Guideline - Second Edition.

This document provides procedures for performing testing and providing accurate, reliable, and useful results to laboratories with differing levels of expertise in anaerobe bacteriology.

CMS (Centers for Medicare and Medicaid Services) -- ESRD and dialysis specific
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-22-ESRD.pdf

Risk Management Plan

Brief Description: The risk management plan for the development of our PD device including development of device requirements, analysis of risk, and mitigation of risk. This plan is meant to span the entire design process, as the likely severity of a risk is high, possibly causing infection and having the opposite intended effect.

Product Description: indicate the scope of the device itself

- Defining the product included.
- Describing the intended use and indications for use of the device.
- Stating the clinical requirements of the device
- Stating the technical requirements of the device
- Defining engineering specifications to fit the technical requirements

Risk Analysis: methods of testing the device's requirements and specifications

- Verification testing plan of the device
- FMEA Matrix

Risk Evaluation and Acceptability:

- Describe severity, occurrence, and detection matrix criteria
- Determine limits of acceptability

Risk Mitigation

- Indicate how the design will take into account the major risks through
    - Safety by design
    - Protective measures in the device or manufacturing process
    - Provide information for safety or instructions for use

Regulatory Specifications

Brief Description: FDA Codes, product description, intended and indications for use for both peritonitis preventative and diagnostic products.

For Prevention:
(Example From Fresenius Stay-Safe Organizer
https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173651.pdf)

Product Code: KDJ
Set, Administration, For Peritoneal Dialysis, Disposable
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KDJ

Title 21: Food and Drugs
PART 876—GASTROENTEROLOGY-UROLOGY DEVICES
Subpart F—Therapeutic Devices
§876.5630 Peritoneal dialysis system and accessories.
(https://www.ecfr.gov/cgi-bin/text-idx?SID=9d32ffeeefcef5feb46879a57b365739&mc=true&node=se21.8.876_15630&rgn=div8)
Class II (Special Controls)
PMA Exempt -- From 876.5630: A catheter finger grip that is non-patient contacting and intended for single use with a peritoneal catheter

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.
(optional) This device is compatible with Fresenius stay•safe for Peritoneal Dialysis (PD)

For Diagnostic:
Product Code: **JTO**
Device: Discs, Strips and Reagents, Microorganism Differentiation
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JTO

TITLE 21 -- FOOD AND DRUGS
PART 866 -- IMMUNOLOGY AND MICROBIOLOGY DEVICES
Subpart C -- Microbiology Devices
§866.2050 Staphylococcal typing bacteriophage.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=866.2050

"Gram-positive cocci such as Staphylococcus epidermidis, other coagulase negative staphylococcoci, and Staphylococcus aureus (S. aureus) are the most frequent aetiological agents of PD-associated peritonitis worldwide. Empiric antibiotic therapy must cover both gram-positive and **gram-negative** organisms."

Class I (general controls). The device is exempt from the premarket notification procedure in subpart E part 807 of this chapter subject to the limitations in 866.9 (limitation of exemptions form section 510(k) of the FDA.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=866.9

- We definitely fall under these limitations
    - Sec. 866.9 a) & b) For optical approach
    - Sec. 866.9 c8) c9) For chemical approach
- MUST submit Premarket notification to FDA before introducing or introduction into interstate commerce for commercial distribution.

§876.5630 Peritoneal dialysis system and accessories
Class II (Special Controls)
Pre-Market Approval needed -- Is NOT one of the items listed as PMA Exempt from 876.560

Intended Use:
The intended use for this device is to detect early stages of peritonitis in PD patients.

Indications for Use:

- This device is indicated for use in measuring optical density of PD effluent each time a patient dialyzes.
- This device is indicated for use in chemical reactions with PD effluent causing vibrant change of color when pathogens are detected.
- This device is indicated for use in addition to PD effluent to clump WBCs each time a patient dialyzes.

Clinical Requirements

Brief Description: Clinical requirements for preventative and diagnostic products.

Must, shall – this is a requirement
Should – this is a recommendation
May – this is optional and permissible
Will – this is a consequence
Can - this indicates that something is possible

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

Detection/Diagnostic

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 **must** be economically viable within existing reimbursement codes
Packaging	Packaging **must** permit shipping without damage

Technical Specifications

Brief Description: Converting the above mentioned clinical requirements into device requirements and specifications, which will be later used as metrics in testing.

Prevention

Clinical Requirement	Device Requirement	Device Specification
Device shall enable enhanced prevention from infection	Device shall prevent the PD patient from touching the PD catheter tip during normal use	Device shall keep patient fingers or body at least ____ inches away from the sterile tip
Device shall keep the catheter tip sterile even in a non-sterile environment.	Device shall have a cap that has double protection, cap to remain in closed position	To click open the cap, you must apply at least X force
	Cap doesn't fall off/fail before the rubber tubing of the PD catheter	
	Device closure must keep pathogens and other particulates out	Device cap must have X amount of inherent forces keeping it closed
	Device should decrease the amount of time the catheter tip is exposed to non-sterile environment.	
Device must allow fluid flow	Device must be watertight and allow for efficient fluid flow in and out of patient	Lumen of catheter tip measures _____
Device must be usable at home	Devices must be fit in typical household measurements and conditions.	House dimensions like, door and room length. SDH like air quality, pets or small children, electricity, even internet, cleanliness, need to be taken into account
Device must be biocompatible	Material must be biocompatible and non-corrosive	Device may be made with _____
Device shall be durable enough to survive a 3 foot fall.	Device must withstand ____amount of blunt force	Device may be made with _____

Detection/Diagnostic

Clinical Requirement	Device Requirement	Device Specification
Device shall enable early diagnostic detection of peritonitis	Must interact with pathogen or pathogen quality in some way	Device shall use an optical sensor/ chemical detection - Must be able to detect it at this level (dilution, parts per
Device shall return result	Must detect infection before	

faster that current detection methods	naked eye does	million). - What's the resolution of the eye?
Diagnostic must be run very frequently Must be able to run diagnostics every time patient dialyzes.	Device must be made out of easily disposable and abundant material OR reusable	Device shall be made with _____
Device shall return result faster that current detection methods	Device must detect result before cloudiness of effluent is visible naked eye without culturing	Device must provide a result in less than ____
Biocompatibility	Material must be biocompatible and non-corrosive Device shall be biocompatible with fluid flowing across it and into the PD patient, not leeching any toxic chemicals	Device must be made with _____
Device must be able to detect infection not matter which strain	Detection methods must some sensitivity to different biomarkers, size characteristics of bacteria, and effect on WBC counts	Device shall use an optical sensor/ chemical detection
Device shall not indicate/change when not in use	Active ingredient/ material must be inert/kept away from reactive materials	Device will be made of _____
PD patient must be able to use device, with or without comorbidity	Device must be simple to use and teach	Device shall be simple to use and able to be learned within 5 demonstrated uses by a clinical professional
Device must be usable at home	Device must be fit in typical household measurements and conditions.	House dimensions like, door and room length. SDH like air quality, pets or small children, electricity, even internet, cleanliness, need to be taken into account

Design Verification

Brief Description: Outline of the testing that will verify the design of the product based upon the requirements.

Board Scope Design specifications to be tested

- Dimensions
- Durability
    - Pull Force Test Plan
        - Pull # devices along active axis to failure
        - Measure force
        - Analyze statistics: mean, standard deviation
- Physical performance
    - Allows less time for catheter tip to be exposed
        - Timing Use Test Plan
            - Use # devices through whole connection in PD
                - Keep fluid exchange time the same and measure timing of physical manipulation of the catheter.
                - Analyze statistics
    - Sterile catheter tip to cap connection strength
        - Pull Force Test Plan
            - Pull # devices at connection to failure
            - Analyze statistics
        - Load Force Test Plan
            - Crush # devices at connection to failure
            - Analyze statistics
- Biocompatibility
    - Biocompatible Test Matrix
        - Surface device
- Sterility
    - Sterility of inside of device through process
        - Sterilization
        - Packaging integrity
        - Aging studies
        - Ship Testing
        - Timing

Each specification must trace to a test

Design of experiments

Factors that impact tip to cap connection strength

- Type of connection (screw, magnet, spring)

Factor that impact sterility

- Time exposed to air
- Proximity to body surfaces
- Barrier coverage and tightness

Repeat each experiment X times

Which engineering specifications are we most interested in testing that we could do ourselves. What is under our control.

- Time for procedure
- Manipulation distance from fingers
- Sterility is important but it is non trivial

Confirm that the design output meets the design input:

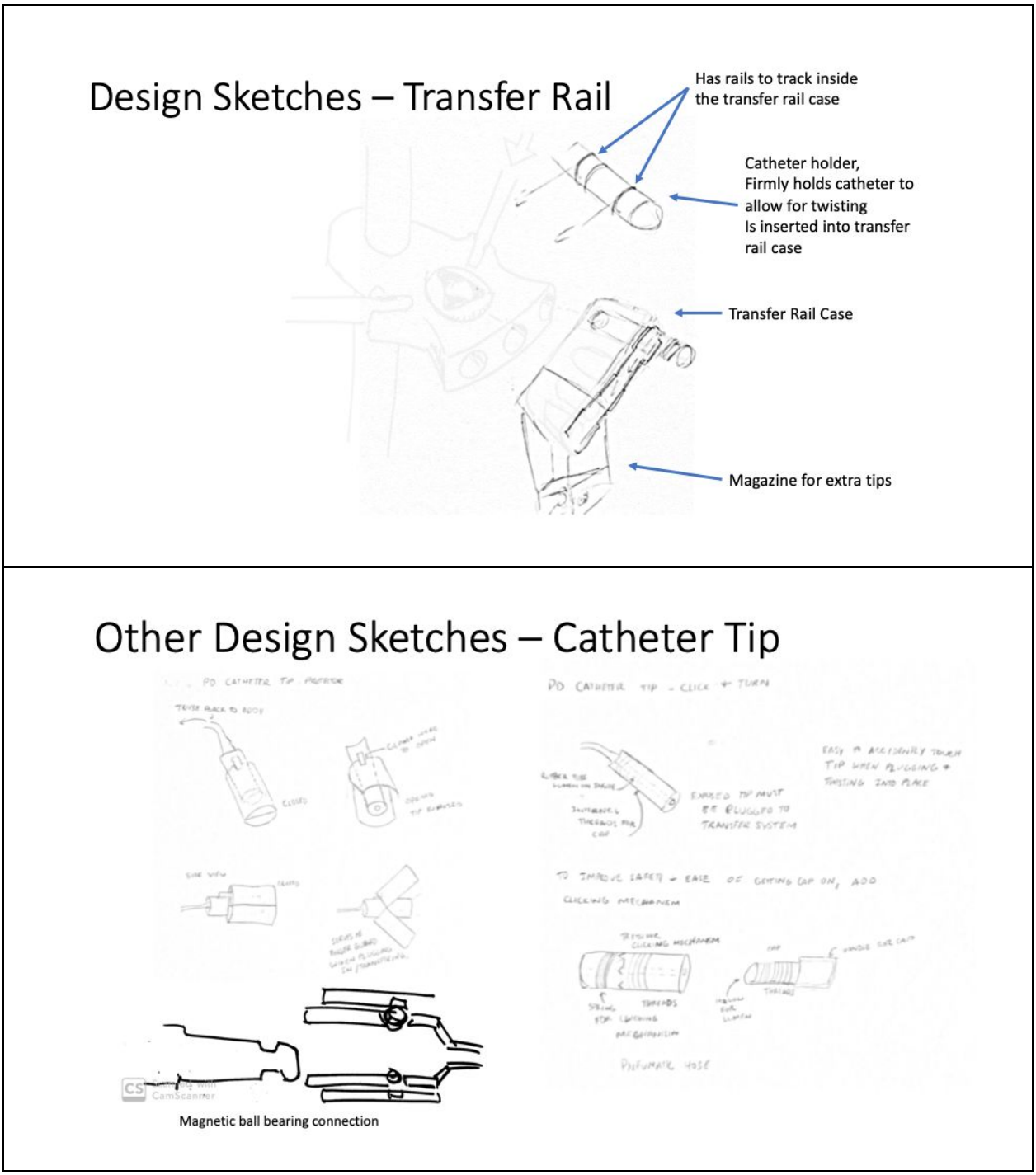
- Identification of the design

Preliminary Design Verification Matrix

Req ID	Requirement Description	Business Justification /Need	Test Strategy	Tester	Status	Date	Comments
1	Device **must** be usable by a PD patient that is right or left handed	Device should be able to be used with wide range of people	30 patients test both left and right hand. Measure time.	Lisa			
2	Tip **must** remain securely on the catheter when a transfer is not occuring Device **must** keep the catheter tip sterile even in a non-sterile environment.	Device should not easily introduce outside particulates to exposed catheter	Pull testing to be done. Load testing to be done.	James			
3	Devices **should** be durable enough to survive a 3 foot fall.	Device should not break in use or accidental mistake	Pull testing to be done. Load testing to be done.	Lisa			
4	Device **must** enable enhanced prevention from infection	Device should be effective in its designed use	Measure Time of Catheter Exposure	Lisa and James			

Preliminary Drawings

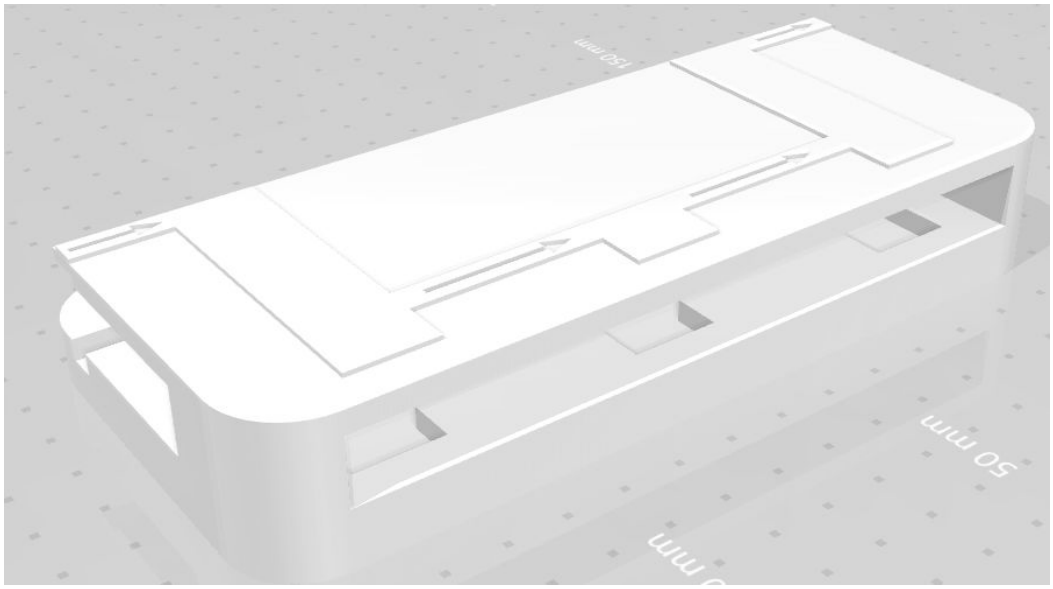
Brief Description: A compilation of design sketches that shows the early stages in the development of the device for prevention.



Preliminary Designs

Brief Description: CAD designs that show 3D drawings of both the PD catheter case and PD catheter cap as well as some design features.

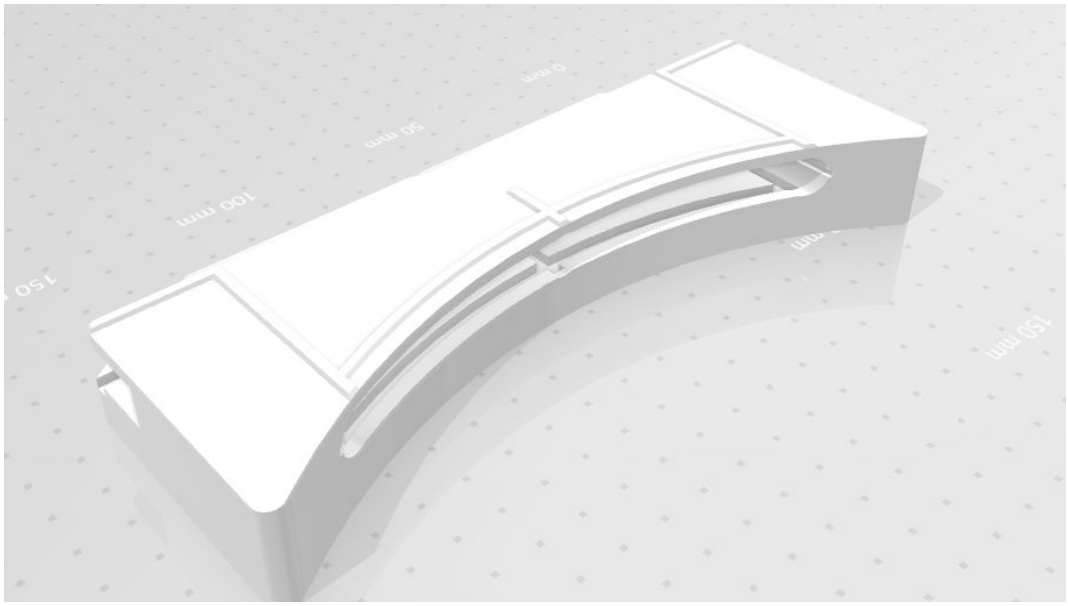
Transfer Case v1



Design Features

- Channel design for integration with cap notch
- Triple port slots for interfacing with Fresenius Stay-Safe
- Offset channel guide on top of case for easier procedure progression
- Not pictured: top of case will be clear plastic to permit viewing of progression of procedure when guiding through channel path

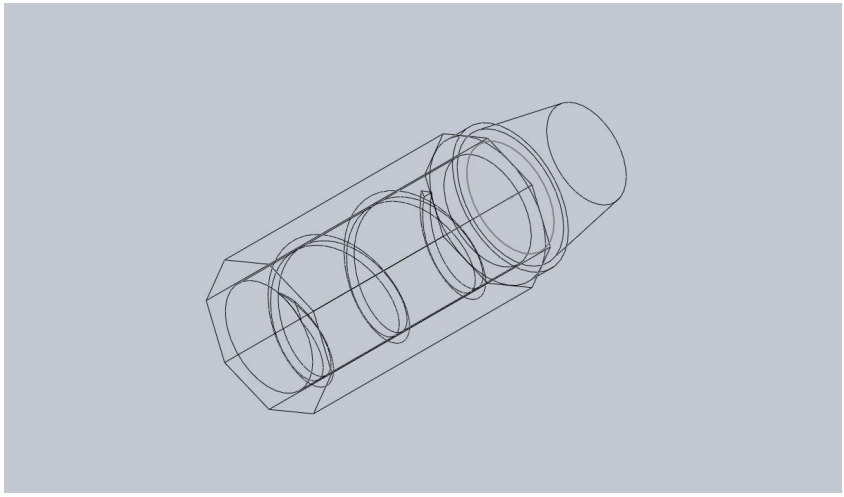
Transfer Case v2



Design Features

- Notches in internal sides of case for ensured correct alignment of cap with Stay-Safe ports
- Smaller channel notches so that catheter offsets can be smaller for greater patient comfort
- Curved design to fit around Stay-Safe

Basic Catheter Tip



Risk Analysis

Brief Description: Risk Analysis using FMEA for tabulating the most harmful effects if the device were to fail.

FMEA Matrix

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
Disengage cap from catheter tip	Catheter cap does not properly disengage from catheter body	Spring mechanism fails	2	Cap is left on the catheter, PD procedure interrupted	2	Inspection	1	4
		Cap too tight on catheter body	1	Cap is unable to be removed from body of catheter, procedure is interrupted	2	Fit test - design verification	2	4
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	5	**Threat of**	4	Inspection	1	20

		screwed on fully, leaving only the clicking mechanism to hold the cap		**exposure of the sterile lumen to non-sterile surfaces**				
		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
Used cap is left behind after disengagement	Used cap is not placed/dropped in its proper disposal receptacle	Interfacing of case to cap is incorrect	1	Leaving of biohazardous materials in places that they shouldn't be, possible interruption of future PD procedures	2	Inspection	1	2
		Case was not setup properly	2	Continued interruption of PD procedure	2	Inspection	1	4
Engage new cap onto catheter tip	Catheter cap does not click onto catheter body	Screw mechanism fails	3	Must manually put on new tip (**possible exposure to infection**) or get new tip and slot into case	4	Inspection	2	24
	Catheter cap does not line up with catheter body	Case and new cap are not interfacing correctly	5	Must manually put on new tip (**possible exposure to infection**) or get new tip and slot into case	4	Design verification	2	40
	Catheter cap does not fit on catheter body	New cap is too big for catheter body	1	Must load new cap	3	Fit test - design verification	2	6
		New cap is too small for catheter body	1	Must load new cap	3	Fit test - design verification	2	6
Automatically engage catheter lumen with fluid channel	Lumen does not line up with fluid channel	Case channel does not line up with fluid channel - positioned incorrectly	5	Must reposition case mid-procedure (**possible exposure to infection**)	4	Inspection	1	20
		Case channel does	5	Must set up new	4	Inspection	1	20

		not line up with fluid channel - case manufactured incorrectly		case mid-procedure (**possible exposure to infection**)				
	Lumen does not form a water-tight seal with the fluid channel	Catheter body does not interface correctly with fluid channel	1	Leaking fluid makes a mess	2	Inspection	1	2
Provide clear procedure for patient	Procedure of tracing catheter through channel pathways is not clear	Pathway is not clearly indicated	1	Procedure takes longer than anticipated or cannot be completed safely	1	Human factors testing	4	4
		Plastic top is not clear enough to see through	1	Procedure takes longer than expected	1	Human factors testing	4	4

Risk Evaluation Criteria And Acceptability

The risk related to occurrence of harm has not been tested, but is the projected occurrence. Severity contributes to risk the most because any effect that results in peritonitis is a moderate to severe risk. Since the primary purpose of the design is to mitigate the chance of infection, these risks will have the greatest impact on the final product.
Detection of the harm is primarily visual inspection. More difficult detection requires human factors testing and design verification.

Risk Mitigation Measures

Brief Description: Tabulating the most harmful failure modes and how that risk may be mitigated

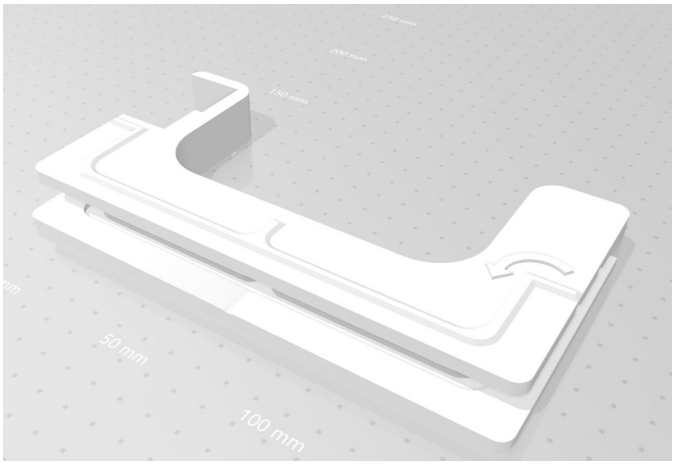
Function	Failure Mode	Cause	RPN	Mit. Req?	Mitigation Measures
Slide Catheter along case channel	Catheter becomes disengaged	Bad fit between catheter tip and case channel (knobs too small for channel)	40	Y	permit less compliance in cap to case channel interface
		Channel not properly manufactured	80	Y	Manufacture device with precise plastic extrusion, permit less compliance in cap to case channel interface
		Patient uses too much force	80	Y	Select materials that can hold up through high force interactions, make knob on cap large enough to keep catheter in case
Disengage cap from catheter tip	Catheter cap does not properly disengage from catheter body	Spring mechanism fails	4		
		Cap too tight on catheter body	4		
Cap remains securely on the Catheter when transfer is not occurring	Catheter cap comes off when transfer is not occurring	Thread mechanism fails	30	Y	Proper labeling for second-option procedure to place a new cap safely
		Cap was never screwed on fully, leaving only the clicking mechanism to hold the cap	20	Y	Integrate into case design a necessity to screw cap before removing the cap from the case, proper labeling for second-option procedure
		Cap is too big for the catheter body	24	Y	
Used cap is left behind after disengagement	Used cap is not placed/dropped in its proper disposal receptacle	Interfacing of case to cap is incorrect	2		
		Case was not setup properly	4		

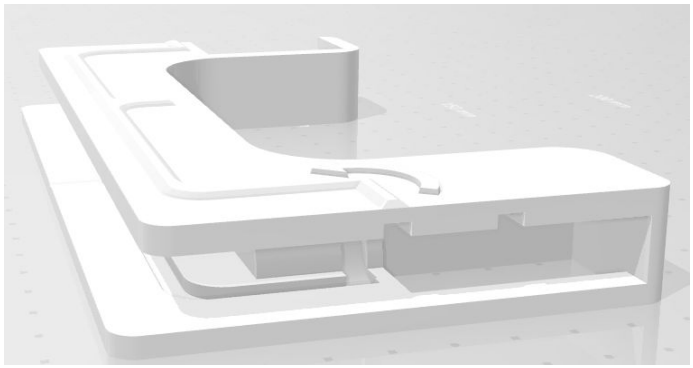
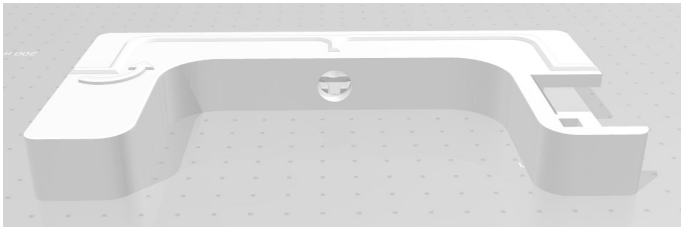
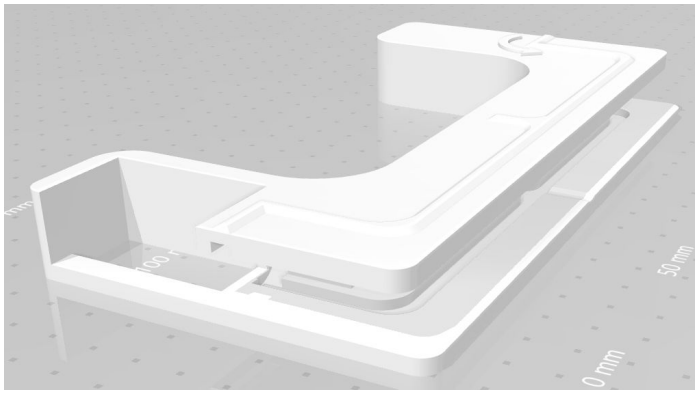
Engage new cap onto catheter tip	Catheter cap does not click onto catheter body	Screw mechanism fails	24	Y	Proper labeling for second-option procedure to place a new cap safely
	Catheter cap does not line up with catheter body	Case and new cap are not interfacing correctly	40	Y	Permit less compliance in cap to case channel interface, proper labeling for second-option procedure
	Catheter cap does not fit on catheter body	New cap is too big for catheter body	6		
		New cap is too small for catheter body	6		
Automatically engage catheter lumen with fluid channel	Lumen does not line up with fluid channel	Case channel does not line up with fluid channel - positioned incorrectly	20	Y	Design measures to ensure channel lines up with catheter correctly
		Case channel does not line up with fluid channel - case manufactured incorrectly	20	Y	Design measures to ensure catheter lines up with fluid channel properly
	Lumen does not form a water-tight seal with the fluid channel	Catheter body does not interface correctly with fluid channel	2		
Provide clear procedure for patient	Procedure of tracing catheter through channel pathways is not clear	Pathway is not clearly indicated	4		
		Plastic top is not clear enough to see through	4		

Risk Mitigation Measures: Implemented

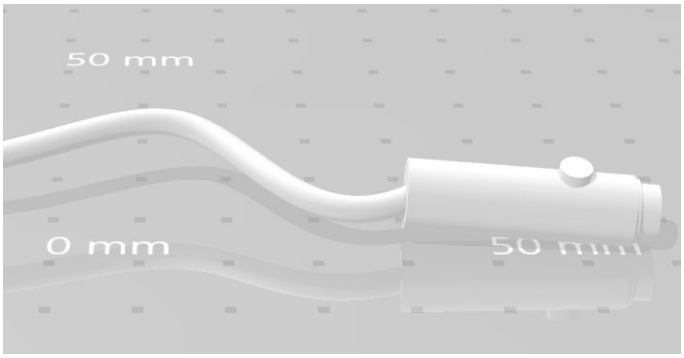
Brief Description: The third iteration of the design of the PD transfer case for the purpose of mitigated risk. Features have been included in the CAD explanation. RPNs have been adjusted based on the features in the new design.

Version 3 Iteration of PD Transfer case

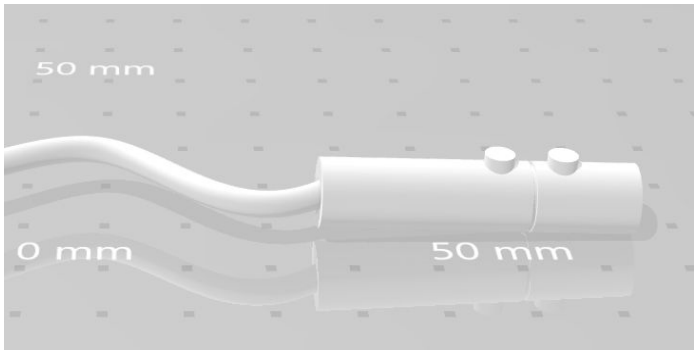
<table>
<tr>
<td> 

Isometric patient-facing top view
Closed the cap rail so that twisting of the PD catheter is ensured before removing the catheter from the case.</td>
<td> 
Right-side (relative to patient) view
Double notches for the cap and catheter knobs ensure the catheter is inserted into the case correctly and engages with the catheter channel/rail.</td>
</tr>
<tr>
<td> 
Back view.
Back of case closed so that it is no longer open to the air. Just the hole for the catheter at the fluid port remains.</td>
<td> 

Left-side (relative to patient) view
Added screw channel that ensures twisting of the catheter to secure the cap before removing from the case. Cartridge opening shown above permits multiple caps to be loaded; if a cap is not compliant and does not correctly interface with the catheter, a new cap cartridge can be loaded without major disruption to the procedure.</td>
</tr>
</table>



PD Catheter: cap off
Knobs on the PD catheter interface with the PD case channel.



PD Catheter: cap on

Other Features

- Notches and screw mechanism permit disengagement and engagement of cap with the case, independent of the Stay-Safe
- Cartridge system permits cap “magazine” and backup plan in case a cap has been manufactured incorrectly
- Back of case is closed to reduce exposure of the sterile lumen
- Channel now does not require backtracking of catheter because that part of the procedure has been integrated into cap disengagement and engagement.

Risk Mitigation via Design

Occurrence, Severity, Detection (O,S,D) column has old and new updated values

Function	Failure Mode	Cause	Old RPN	Mitigation Measures From PD Case Design V3	O,S,D Old vs New	New RPN
Slide Catheter along case channel	Catheter becomes disengaged	Bad fit between catheter tip and case channel (knobs too small for channel)	40	Case now has closed channels that require a twisting motion to engage and disengage. Catheter can no longer disengage from the channel by sliding out.	(4,5,2) -- (1,5,2)	10
		Channel not properly manufactured	80	Channel design has been simplified so that it is not as complicated to manufacture	(4,5,4) -- (2,5,2)	20
		Patient uses too much force	80	Closed channel design is more secure than the open channel. The channel guide makes it easier for the patient to understand the flow of the procedure and not use excessive force to advance the catheter in the wrong direction. The channel path is more	(4,5,4) -- (2,5,2)	20

				simplified for a simpler procedure		
Cap remains securely on the Catheter when transfer is not occurring	Catheter cap comes off when transfer is not occurring	Thread mechanism fails	30	Thread mechanism can be simplified because there is only 180 degrees of revolution needed to secure the cap	(3,5,2) -- (1,5,1)	5
		Cap was never screwed on fully, leaving only the clicking mechanism to hold the cap	22	Case requires the cap be fully screwed on before removal because of the channel guide.	(5,4,1) -- (2,4,1)	8
		Cap is too big for the catheter body	24	Cartridge system allows for repeat tries of engaging a new cap (backup plan)	(5,4,1) -- (2,3,1)	6
Engage new cap onto catheter tip	Catheter cap does not click onto catheter body	Screw mechanism fails	24	Thread mechanism can be simplified because there is only 180 degrees of revolution needed to secure the cap	(3,4,2) -- (1,4,1)	4
	Catheter cap does not line up with catheter body	Case and new cap are not interfacing correctly	40	Notches on either side of case when engaging and disengaging ensures proper alignment between the catheter, cap, and case	(5,4,2) -- (2,4,2)	16
Automatically engage catheter lumen with fluid channel	Lumen does not line up with fluid channel	Case channel does not line up with fluid channel - positioned incorrectly	20	Closed back and fluid channel hole ensure that the catheter lines up with the fluid channel properly	(5,4,1) -- (2,4,1)	10
		Case channel does not line up with fluid channel - case manufactured incorrectly	20	Closed back and fluid channel hole ensure that the catheter lines up with the fluid channel properly. Channel design has been simplified for easier manufacturing.	(5,4,1) -- (2,4,1)	10

Intellectual Property/Prior Art

Brief Description: List of patented devices and inventions that constitute prior art for both our device and our diagnostic.

Prevention: Cap, Transfer, and Connection

Method for continuous ambulatory peritoneal dialysis
https://patents.google.com/patent/US4239041A/en?q=Continuous+Ambulatory+Peritoneal+Dialysis&oq=Continuous+Ambulatory+Peritoneal+Dialysis+

Transfer Sets for therapy optimization
https://patents.google.com/patent/EP2391404B1/en?q=Continuous+Ambulatory+Peritoneal+Dialysis+transfer&oq=Continuous+Ambulatory+Peritoneal+Dialysis+transfer

Prefilled sterilant fluid releasable coupling connector apparatus for catheter applications
**https://patents.google.com/patent/US5190534A/en?q=peritoneal+dialysis+transfer+set+prevent+infection&scholar&oq=peritoneal+dialysis+transfer+set+prevent+infection

Peritoneal dialysis patient connection system
https://patents.google.com/patent/US20120209168A1/en?q=peritoneal+dialysis+transfer+set+prevent+infection&scholar&oq=peritoneal+dialysis+transfer+set+prevent+infection&page=1

Antiseptic Cap
https://patents.google.com/patent/US9707349B2/en?q=peritoneal+dialysis+transfer+set+prevent+infection&scholar&oq=peritoneal+dialysis+transfer+set+prevent+infection&page=2

Sterile Connector
https://patents.google.com/patent/US6485479B1/en

Sterility-maintaining connection system for medical system and use thereof
https://patents.google.com/patent/US7070589B2/en?oq=7070589

Dialysis catheters with optimized user friendly connectors
https://patents.google.com/patent/WO2004016301A2/en?q=peritoneal+dialysis+transfer+set+prevent+infection&scholar&oq=peritoneal+dialysis+transfer+set+prevent+infection&page=3

Interesting add on to transfer sets for CAPD:
Antimicrobial ultraviolet irradiation of connector for continuous ambulatory peritoneal dialysis
https://patents.google.com/patent/EP0080485B1/en?q=Continuous+Ambulatory+Peritoneal+Dialysis+transfer&oq=Continuous+Ambulatory+Peritoneal+Dialysis+transfer

Resource:
Great article on history of connectors
https://patents.google.com/scholar/11337639302591175106?q=peritoneal+dialysis+transfer+set+prevent+infection&scholar&oq=peritoneal+dialysis+transfer+set+prevent+infection&page=2

Diagnostic: Early Detection of Infection

“Peritoneal dialysis systems and related methods”
https://patents.google.com/patent/WO2019173001A1/en?q=detection+peritonitis+peritoneal+dialysis&oq=detection+of+peritonitis+in+peritoneal+dialysis

“Diagnostic test with lateral flow strips” **take a closer look
https://patents.google.com/patent/CN108290156A/en?q=detection+peritonitis+peritoneal+dialysis&oq=detection+of+peritonitis+in+peritoneal+dialysis

Early stage peritonitis detection apparatus and methods may be infringing? And very well thought out.
https://patents.google.com/patent/CA2594634C/en?q=detection+peritonitis&oq=detection+of+peritonitis

Apparatus and method for early peritonitis detection including a self-cleaning effluent chamber
https://patents.google.com/patent/JP2011510324A/en?q=detection+peritonitis&oq=detection+of+peritonitis

Intelligent peritoneal dialysis device
https://patents.google.com/patent/CN110234371A/en?q=detection+peritonitis&oq=detection+of+peritonitis

Apparatus and method for early detection of peritonitis and biological examination of body fluids
https://patents.google.com/patent/JP2011512881A/en?q=detection+peritonitis&oq=detection+of+peritonitis

Apparatus and methods for early stage peritonitis detection and for in vivo testing of bodily fluid
https://patents.google.com/patent/US20080183126A1/en?q=detection+peritonitis&oq=detection+of+peritonitis

Peritoneal dialysis system with sensors and configured to diagnose peritonitis
https://patents.google.com/patent/WO2020023754A1/en?q=detection+peritonitis&oq=detection+of+peritonitis

Regulatory and Commercial Strategy

Brief Description: This section contains the patentability, and key inventive aspects of our respective inventions. It also contains a brief description on the regulatory and commercialization strategy we would most likely take with our device.

For Our Invention(s):

Prevention

Description:

The present invention relates to peritoneal dialysis patient connection system under sterile condition, and more particularly to sterile docking having a rail element mainted in slidable guide mechanism in sterile environment

Abstract/Summary:

Claim:

“A peritoneal dialysis connector set assistor comprising:

A guide rail including:

One port for receiving catheter at the distal end

A mechanism to automatically remove sterile cap

A lock mechanism starting at distal end running through organizer other ports

A mechanism to engage the distal end of an exposed catheter with a corresponding PD port

A mechanism to automatically place cap

A connector including:

Snap to hook on to organizer

Whereby said connector set assistor prevents contact with non-sterile surfaces from time of insertion to new cap placement."

Key Inventive Aspects

- New assistive function
- Higher sterility → better performance
- Completely new structure

Patentability

- New combination of parts and structure
- Useful because it will help PD patients health
- Possibility of automatic sterile connection

Commercialization Strategies

- Baxter
- Fresenius

Diagnostic

Description:

Optical

The present invention provides medical methods and apparatus that test PD effluent (with a APD or CAPD setup) to detect the onset of peritonitis, based on the optical characteristics of the effluent resolved at cellular scales of distance. (Taken almost directly from a prior art patent, only difference is fluid flow vs not).

Chemical

The present invention provides a diagnostic test for peritonitis with lateral flow test / "Litmus" strip test based on a few characteristics/biomarkers of pathogens. (Also almost taken directly from patent).

The present invention provides a diagnostic test for peritonitis with an induced chemical reaction that induces a physical change such as clumping in effluent to indicate infections.

Abstract/Summary:

Claim:

"Apparatus for testing PD effluent comprising A. an illumination source that illuminates peritoneal effluent, B. a detector that includes a lens that resolves at a cellular scale of resolution illuminant reflected and/or scattered by the effluent, such that separate cellular-sized components of a same type are distinguishable from one another within the illuminant resolved by the lens, where those components are white blood cells, red blood cells, fibrin, bubbles, and/or other cellular-sized components of the effluent, and C. the detector detects and counts, in said illuminant resolved by the lens, illuminant reflected and/or scattered from separate cellular-sized components in the effluent, and D. the detector signals an onset of peritonitis if

said counts change over time and or/vary from baseline.” Taken straight from patent because it’s all relevant. Our claims could perhaps be broader in that it doesn't need to resolve what kind of cells are present but just the overall optical density with a phone camera and app. Can make the argument of less elements.

Key Inventive Aspects

- Does not require PD effluent in a flow path
- Outcome is different (just the optical density vs. cell counts).

Patentability

- Useful for preserving the peritoneum
- New in that it is simpler

Commercialization Strategies

- Baxter
- Fresenius

Fresenius Commercialization Strategy

- Popular predicate device of the Fresenius Stay safe is especially relevant to UVA.
- Iterations on it by Fresenius are routinely reviewed on a 510k basis, under FDA Title 21 §876.5630.
- This section includes peritoneal dialysis systems and accessories which our device would fall neatly under.
- Our strategy would be to show that our device meets predicate device chractersitcs to get it passed under a 510k basis
    - Subjected to Class II (Special Controls)
    - PMA Exempt
- We would include similarities to predicate device of
    - Intended use
    - Principle of operation
    - Sterilization method
    - Biocompatibility
    - Design characteristics
    - Technological characteristics
- We would include
    - Key performance characteristics:
        - Less time of catheter exposure
        - Distance from user fingers
        - Less error while performing
        - Overall increased protection against infection

    To show we have still made significant advancements as a new device.

Reimbursement Analysis

Since peritoneal dialysis is not a typical “procedure” in the sense that it is not performed by a clinician in a clinical setting, the reimbursement is more complicated.

ICD 10 codes are necessary for the diagnosis of ESRD and PD Catheter placement. These codes are listed under the ICD 10 Z49* code tree and include procedures such as adequacy testing for dialysis and placement of catheters.

In conjunction with ICD codes for diagnosis of renal failure, there is a corollary system called the Healthcare Common Procedures Coding System (HCPCS). This code system is used to report supplies, equipment, and devices and is administered by the Centers for Medicare and Medicaid Services. Under HCPCS there exist two levels.
Level I is the Current Procedural Terminology (CPT) and is not applicable for this device
Level II is the coding system normal referred to as the HCPCS codes and does include take-home dialysis supplies under the codes “A4653-A4932: Dialysis Equipment and Supplies.”

On the following updated 2019 Guidance for Dialysis billing from CMS:
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf
the 70.* and 80.* Sections detail payment for Peritoneal dialysis. There are two methods for the distribution of supplies to the patient.

In Method I, a dialysis facility provides all necessary supplies and services. Payments for supplies under this method are included in the composite rate payment, which is the same payment that the facility would receive for an in-facility patient.

In Method II, a dialysis facility provides services but supplies are furnished by a Durable Medical Equipment Regional Carrier (DMERCs). These supplies are paid through claims made to CMS using the CMS-1500 form.

The new executive order emphasizes quality-based payment, where if patients live for longer, keep their labs normal, reduce negative events such as infection or hospital admissions, and are generally provided better care, the patient facility will receive a higher payment. Our device, with its potential to lower the incidence of infection, could have a large impact on dialysis facilities’ bottom line through both the Method I and Method II payment system. If patients’ quality of care is higher, that will be reflected in the quality metrics that reimbursement is based upon.

Future Plan for Reimbursement

There likely needs to be data that proves our PD device helps mitigate incidence of infection in order for CMS to accept it as a reimbursed item. Therefore, in partnering with a major medical provider such as UVA, we can collect such data with a randomized controlled trial, present the gathered data to CMS, and receive a decision on whether CMS will reimburse for it. We need to prove that this device performs better than the gold standard. As Diage points out from her article from NAMSA, it is a difficult balance to strike when trying to prove to the FDA that the device is similar to a predicate device, but also prove to CMS that it solves a problem in a novel way. However, I am confident that we will be able to prove this, since the gold standard is manipulation of a catheter with a sterile tip with the hands.

Other References:
Methods I and II payment: https://oig.hhs.gov/oei/reports/oei-07-01-00570.pdf

Article from major contract Research Organization NAMSA about reimbursement of devices
https://www.namsa.com/wp-content/uploads/2015/10/NAMSA-Planning-for-Successful-Medical-Device-Reimbursement.pdf

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICD9-10CM-ICD10PCS-CPT-HCPCS-Code-Sets-Educational-Tool-ICN900943.pdf

Difference between ICD codes, CPT, and HCPCS:
http://www.rxeconsult.com/healthcare-articles/Similarities-And-Differences-Between-ICD-10-CPT-And-HCPCS-Medical-Codes-1267/

Future Work

Brief Description: This section lays out several goals in our future work.

1. Continued work on Diagnostic section
    a. Risk Analysis and Mitigation
    b. Refine commercialization and commercialization strategy
    c. Begin designing if possible
2. Data Science
    a. Exploring UVA's data on rates of infection in peritoneal dialysis patients
3. More iterations on device design (sketches or CAD)
    a. Cap
        i. 3D print if possible!
    b. Rail
        i. 3D print if possible!
4. More refined design verification testing
    a. Final design verification matrix paralleled with most important design specifications
    b. Implementation of verification testing