Due 3/15, 8:00pm.

* Using Ppt slides, restate your problem statement (again!)

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.

* List your top 5 Clinical Requirements (must have's)

Came up with a bunch, we can select the ones we like

**Safety**: Device shall enable enhanced prevention from infection

**Safety**: Device shall prevent the PD patient from touching the PD catheter tip during normal use.

**Sterilizable**: Device shall be able to be sterilized

**User**: Device shall be usable by a PD patient, right or left handed.

Use: Device shall be simple to use and able to be learned within 5 demonstrated uses by a clinical professional

**Environment**: Device shall be usable at home

Environment/Sterile: Device shall keep the catheter tip sterile even in a non-sterile environment.

**Use**: Device shall permit tactile manipulation of the catheter tip while keeping hands away from the tip

Safety: Tip must remain securely on the catheter when a transfer is not occuring

Use/Safety: Device shall be durable enough to survive a 3 foot fall.

Use: Device shall be watertight and create a channel for fluid to flow

Biocompatibility: Device shall be biocompatible with fluid flowing across it and into the PD patient, not leeching any toxic chemicals

Sterility: Device shall maintain sterility of the catheter tip.

Efficiency: Device shall permit fluid to flow quickly into and out of patient

Price: Device shall be cheap enough for single use, less than $5

Volume: Device shall 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 shall maintain sterility and remain undamaged during shipping

I found this document from the FDA 510(k) approval for the Fresenius Stay safe, has a lot of testing specifics in there:

<https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173651.pdf>

* Select a critical criteria that is testable “in the lab”

Ideas for testing criteria

1. Keeping hands away from tip -- during manipulation, patient must have fingers more than 1 inch away from the tip at all times
2. Keeping the tip clean - testing for bacteria after a use, ensure that no bacteria has grown
3. Testing catheter safety - how much pulling force to remove tip from catheter
4. Testing durability - drop device from varying heights (or about the height that the stay safe is on the IV pole) and ensure it still “works”

* State your related Engineering Specification including safety factor
* Cite relevant ASTM, FDA, ISSO, or other guidelines (if available)

**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>

* Create preliminary timeline for completing verification testing before 4/21.