

1. List two to four Desired Needs of your project that led to your final design objectives.

- Device must accurately sort out unhealthy organoids
- Device must be cost effective/accessible
- Device must keep organoids safe and undamaged / ensure biocompatibility and sterility
- Device must be compatible with standard lab workflows

2. List the major Constraints on your design/project

a) Safety/Regulatory Affairs

- Biocompatibility and Sterility
- Reducing pressure buildup to reduce change of device rupture

b) Risks

- Organoid viability: Design must be gentle on organoids and reduce shear stress

c) Global Impact

- Improve organoid pool homogeneity for more accurate research and developments

d) Manufacturability

- Using inexpensive and accessible materials

e) Quality Control/Marketability

- Device should be able to be “set” for different laboratory needs and specifications

3. List the major Engineering Standards on your design/project

- ISO 22916 (Microfluidic devices - interoperability requirements for dimensions, connections and initial device classification)
- ISO 10993-1 (Biological evaluation of medical devices: Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process)
- ISO 14971 (Medical devices - Application of risk management to medical devices)
- ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes).

4. Explain Ethical, Environmental, or Societal concerns for practical applications of your project.

- Societal concerns: Current solutions include large, bulky, and extremely expensive (>\$10,000), our device aimed to be accessible to every lab at low costs.

5. Describe Active Teamwork and Leadership in your design group

- Collaboration and team brainstorming for diverse pool of knowledge
- Combining ideas and giving collective, constructive feedback to find design solutions
- Dividing work into subgroups to ensure efficiency and that we reach our goal by the deadline
- Meeting with PI regularly to discuss progress and receive feedback and guidance
- Being motivated to complete our individual tasks to support the project progress

6. What were the most significant motivating factors that led you to

After learning about our goal through mentorship and motivation from our PI, the freedom and opportunity to design and create something that would improve current research motivated us to work hard to find design solutions. Our PI also made sure to educate us to make sure we were informed in making our decisions.

7. What are your most innovative and/or entrepreneurial ideas for this project

Our most entrepreneurial idea was to make this device portable, inexpensive and accessible. Using low cost materials and an easily reproducible manufacturing workflow also allows for fabrication by other labs.