Microscale Tissue Biopsy Dissociation Device
Product Design Specifications
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Function: To dissociate cells from small (1-2 mm^3) lung biopsy samples. The design must produce a measurable amount of viable cells for flow cytometry (approximately 10,000 white blood cells).

Client Requirements:

- Dissociate cells from lung biopsy samples retrieved from asthma patients during the duration of the asthma research study.
- Must be able to recover cells with minimal disruption to surface markers, so that the cells can be analyzed via flow cytometry.

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirements: The device should successfully dissociate tissue samples to obtain at least 10,000 cells, ideally 10,000 white blood cells. The device will be used daily by lab technicians using sterile techniques to load tissue and unload cells.

b. Safety: The device must be sterile and protect the lab tech from possible contamination due to the use of human tissue samples. The device should also be able to withstand spills and drops without shattering or breaking into sharp shards.

c. Accuracy and Reliability: The device must yield at least 10,000 cells from the sample of tissue. It should completely dissociate the tissue samples without disrupting cell markers and not resulting in cell lysis.

d. *Life in Service*: Life in service will depend on whether or not the device is reusable. If it is reusable it needs to last enough runs so that the cost per use is less than $10. If non-reusable, it would only need to last for a single tissue dissociation.

e. *Shelf Life:* While not in use the device should have a shelf-life of at least 5 years in case the client's study ends and starts up later.

f. *Operating Environment*: The device will be used in a laboratory setting. During use, the device will be exposed to various enzyme-containing solutions including collagenase G, sterilization agents, and possibly high temperatures and pressures present in an autoclave (if device is reusable, it should withstand temperatures of -20 to 130 °C).

g. *Ergonomics*: The device must be simple for lab technicians to control. This includes being able to easily load a sample into the microfluidic device and unload the output from it.

h. *Size*: The device should be capable of dissociating a tissue sample size of 1-2 mm^3. The device should be able to fit on a lab bench, but otherwise, the size of the device is not of huge concern as long as it is able to perform the task successfully.

i. Weight: The weight of the device is currently not applicable to the design criteria given by the client's wishes. The microfluidic device is small enough that weight will not be a factor in its utility.

j. *Materials*: The material for the device must be cheap enough to obtain the goal of the cost per run being less than $10. The materials used will depend on the final fabrication method chosen. The material will need to not induce any inflammatory reaction with the cells. The current material used is PLA and ABS.

k. *Aesthetics*, *Appearance, and Finish*: The device must be simple and not confusing to use. The specific aesthetics and appearance of the final product is not of large concern as long as the device functions properly.

2. Production Characteristics

a. *Quantity*: The client initially requested one device to be manufactured for use, but an additional device may be requested later on.

b. *Target Product Cost*: The budget for this project is $300 dollars. The cost of fabrication of the device will be determined at later time depending on the type of material, volume of material, and fabrication technique selected. The existing device is non-reusable and costs roughly $10 per cap with the tubes accompanying the device costing $6 per tube[1]. The target cost of the microfluidic device is $5-$10 per use.

3. Miscellaneous

a. *Standards and Specifications*: This is a custom device being used in a research setting; there are no international or national standards to abide by.

b. *Customer*: The client would prefer to have a removable lid on the device in order to remove potentially valuable tissue samples if the device does not run correctly.

c. *Patient-related concerns*: Patients will not be using this device; it will be used in a research setting. There is no storage of patient data incorporated in this device and the devices should be sterile with every use.

d. *Competition*: A current device for tissue dissociation is made by Miltenyi that includes a tube cap with an attached grinding component that is compatible with a machine, gentleMACS™, that initiates the grinding of the tissue. This device is currently used by the client, but since their tissue sample size is very small it is unable to be properly dissociated by the gentleMACS [3].

PDS References:

1. Miltenyibiotec.com. (2017). *gentleMACS™ M Tubes - Miltenyi Biotec*. [online] Available at: http://www.miltenyibiotec.com/en/products-and-services/macs-sample-preparation/tissue-dissociators-and-tubes/gentleMACS™-dissociators/gentleMACS™-m-tubes.aspx [Accessed 21 Sep. 2017].
2. Thermofisher.com. (2017). *Nunc™ 15mL & 50mL Conical Sterile Polypropylene Centrifuge Tubes*. [online] Available at: https://www.thermofisher.com/order/catalog/product/339650?SID=srch-srp-339650 [Accessed 21 Sep. 2017].
3. R.-P. D. Peters, E. D. Kabaha, W. Stöters, G. Winkelmayer, and F. G. Bucher, “Device for fragmenting tissue,” EP 2 540 394 B1, 2016.