Product Design Specifications

Microscale Tissue Biopsy Device
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2017/12/13

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Function: To dissociate cells from small lung biopsy sample. The design must produce a measurable amount of viable cells for flow cytometry.

Client Requirements:

- Dissociate cells from small tissue samples from asthma patients for the duration of the asthma research study
- Must be able to recover cells with minimal disruption so that the cells can be run through a flow cytometer.

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirement: The device should successfully dissociate tissue samples with 50% ± 10% cell recovery. 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 50% (+/- 10%) cell recovery from each sample of tissue. It needs to reliably dissociate the tissue sample to completion.

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 about $5-$10.

e. *Shelf Life:* Shelf life will also depend on whether the device is reusable or not. If the device is not reusable then the device will be used once and then thrown away. If it is reusable, it should be able to be used as many times as possible to make the cost come to $5-$10 per use.

f. *Operating Environment*: The device will be used in a laboratory setting. During use, the device will be filled with various enzyme-containing solutions including collagenase, sterilization agents, and possible high temperatures and pressures present in an autoclave.

g. *Ergonomics*: The device must be simple for lab techs 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 1-2mm. The overall size of the device is not of huge concern as long as it is able to perform successfully.

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

j. *Materials*: The material for the device must be cheap enough to obtain the goal of the cost per run being $5-$10. The material should be able to be 3D printed and 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, although an additional device may be requested later on.

b. *Target Product Cost*: The initial budget for this project is $300 dollars per device. The cost to manufacture the device on the 3D printer will be determined at later time depending on the type and volume of material 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 customer 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 although since their tissue sample size is very small it is unable to be properly dissociated by the larger device [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.