Microscale Tissue Biopsy Dissociation Device
Preliminary Product Design Specifications
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Function:

Extract Eosinophils from a small (1-2mm^3), human lung sample to study the correlation between the presence of eosinophils in lung tissue and asthma. The device should extract approximately 10,000 cells for examination with flow cytometry.

Client Requirements:

The device must have minimal disruption to the eosinophils to allow proper flow cytometry to be performed while still producing a sufficient sample of eosinophil separated from the remainder of cells in the tissue sample. The eosinophils must also be able to be properly identified using flow cytometry. The eosinophils are of primary concern and the other cell types can remain intact in the tissue as long as all the eosinophils are dissociated.

Design Requirements:

1. Physical and Operational Characteristics:

A. *Performance Requirements:* 50% (+/- 10%) of the total cellular mass must be recovered in a single cell suspension in order to be analyzed by flow cytometry. This will require that the cells are not lysed during the dissociation procedure. The device needs to be able to extract roughly 10,000 eosinophils through tissue dissociation of the lung sample. The device will need to be operational daily and subject to common sterilization techniques.

B. *Safety:* The device must cause no inherent dangers to the user while also keeping the user safe from human contamination.

C. *Accuracy and Reliability:* The device needs to extract enough cells for flow cytometry while also not altering cell surface markers or causing cell lysis. At least 10,000 eosinophils but be obtained after the used of the device.

D. *Life in Service:* Non reusable option only need to last for one tissue dissociation. A reusable tissue dissociator will need to be reusable for approximately three years.

E. *Shelf Life:* The device should have a shelf life of approximately 5 years to allow for starting and stopping of the clients study.

F. *Operating Environment:* The device will be used in a common lab benchtop setting and will be subjected to various enzymes and sterilization products. The product may also be subject to a variety of temperature depending on whether it is reusable or not.

G. *Ergonomics:* Simplicity is the main goal of the ergonomic aspect of the device.

H. *Size:* The device must be able to fit on a lab bench and be able to dissociate a tissue sample of an approximate size of 1-2 mm^3.

I. *Weight:* The device is of a small enough size where weight can be considered negligible.

J. *Materials:* The materials used in the tissue dissociator must be biocompatible as not to interact with the tissue sample. A large component of the materials is that they must be cost effective as a disposable devices must be less than $10 per unit if they are to be considered disposable.

K. *Aesthetics, Appearance, Finish:* Aesthetics and appearance are not a large factor in the making of this device. The device should generally be simple to cause as little confusion as possible as the functionality of the device is the main goal.

2. Production Characteristics

A. *Quantity:* In initial testing only one prototype is required for testing. One device should be used per patient if it is not reusable. If the device is reusable, a fewer quantity will be needed. If chemical dissociation is used, each container should be used once.

B. *Target Product Cost:* A budget for the full project is not defined. The target price of production for a disposable device is around $10. The target price of production for a reusable device would be higher as the client can get more uses out of it. The exact number isn't established as it would depend on how many times the client would be able to reuse it.

3. Miscellaneous

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

B. *Customer:* The client desires a way to recover any valuable human tissue should the device not be able to completely disassociate it as it is extremely difficult to procure these samples.

C. *Patient-Related Concerns:* This device will be used in a research setting and the patient will not have contact with the device. No patient information will be retained in the device. The device will be sterilized after each use if reusable, or if device is one time use it will be disposed.

D. *Competition:* As of now, there exists other devices that allow for tissue dissociation. However, these devices often require a large amount of tissue to be passed through them in order for the

process to occur. The current Miltenyi tissue dissociator costs $6.40 per sample tube [1]. Currently there are no devices on the market that are capable of taking in such a limited quantity of tissue and being able to completely disassociate it.

References:

1. Miltenyibiotec.com. (2018). gentleMACS™ M Tubes - Miltenyi Biotec. [online] Available at: https://www.miltenyibiotec.com/US-en/products/macs-sample-preparation/tissue-dissociators-and-tubes/c-tubes/gentlemacs-c-tubes.html [Accessed 20 Sep. 2018].