

Microscale Tissue Biopsy Device
Product Design Specifications
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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% 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 because the samples are from human tissue. The device should also have completely sealed electronics if they are necessary. 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. Accuracy and reliability will be later refined based on client needs.

d. Life in Service: The device will have an indefinite life in service and should not degrade after repeated sterilizations and multiple uses, but the 50 mL conical tube attached to the device will be discarded with the discretion of lab technicians.

e. Shelf Life: The device will be continuously used and should be functional for at least 10 years.

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. Must be able to withstand the torque from the motor turning it, and centripetal force from the device.

g. *Ergonomics*: The device must be simple for lab techs to fill with a sample. This includes being able to easily open and close the tube with minimal torque and low chance of spill.

h. *Size*: The client would like the grinding component of the device to be as small as possible to aid in the dissociation of the approximately 1-2 mm section of lung. The device should also be compatible with a 50 mm conical tube.

i. *Weight*: The weight of the device is currently not applicable to the design criteria given by the client. Ideally it could be similar to the existing larger dissociation cap made by Miltenyi so that it could function with the GentleMACS machine.

j. *Materials*: The material used for this project needs to be durable enough to withstand tissue grinding over a 10 year period with multiple uses per day. The material will need to be compatible with a 3-D printer and will need to not induce any inflammatory reaction with the cells.

k. *Aesthetics, Appearance, and Finish*: The tube needs to be transparent to allow viewing while the tissue is being gently dissociated. The device needs to be adorned with a color that compliments the GentleMacs dissociation machine.

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 we select. The existing device is non-reusable and costs roughly \$10 per cap with the tubes accompanying the device costing \$6 per tube¹. Our replacement 50 ml conical tubes would cost \$0.71 per tube².

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 if the device was compatible with the current dissociation device (gentleMACS) used in the lab.

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. [1] R.-P. D. Peters, E. D. Kabaha, W. Stöters, G. Winkelmayr, and F. G. Bucher, “Device for fragmenting tissue,” EP 2 540 394 B1, 2016.