A precise handheld injection device for cardiac interventions
Product Design Specification Report

Team Members
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Problem Statement
Our client, Dr. Amish Raval, of the University of Wisconsin School of Medicine and Public Health, researches the effect of stem cells on rebuilding muscle tissue. Currently, Dr. Raval uses a minimally invasive procedure in which he manually injects stem cells through a catheter to muscle tissue over a period of time. In order to eliminate the variable pressure from manual injection, an automated method is desired. Current syringe pumps are large, expensive, and only provide constant flow rates. The goal of this project is to create a low cost and handheld syringe pump that ensures cell viability by maintaining a constant injection pressure.

Client Requirements
- Small, handheld device
- Disposable after each use – must be able to be mass produced at a relatively low cost
- Must be non-motorized – no cords or plugs required; however, it can be battery operated
- Must inject at a constant infusion pressure
- Have a feedback system that will turn off if the pressure exceeds a certain threshold

Design Requirements

Physical and Operational Requirements
a) *Performance Requirements* – The device is designed to be disposable and thus is required to deliver the pressure at a constant rate for one injection. It should be small enough so that the operator is able to hold it in his hand while operating it independently. It needs to be able to handle up to a 3mL syringe.
b) *Safety* – The device should have an absence of sharp edges and abrasive surfaces. It must be light enough so that the operator is able to operate with one hand and is able to place it on the patient during surgery without any adverse consequences.
c) *Accuracy and Reliability* – This device is required to inject the stem cells at a continuous constant rate of delivery. There must be a pressure sensor with a feedback loop to maintain an accurate pressure input of the injection.
d) *Life in Service* – This is a disposable device and is needed only for a one-time use.
e) *Shelf Life* – It will need to be designed so it can be mass produced and be suitable for an enclosed shelf life for unlimited time before use.
f) *Operating Environment* – This device will be used in a sterile operating room. Each device needs to be sterilized and pre-packaged individually for use.

g) *Ergonomics* – This device needs to be operated by the user individually during a surgical procedure. It must not put any undue stress or strain on either the user or his environment during the operation.
h) *Size* – The model should be handheld and no larger than a 40 in^2 footprint
i) *Weight* – The model should weigh no more than 5lbs
j) *Materials* – All of the materials used in this device must be sterile, non-flammable non-radioactive, and non-corrosive
k) *Aesthetics* – The aesthetics of this design and not important. It just needs to be clean and sterile.

Product Characteristics

a) *Quantity* – One product that would be able to be mass produced in the future
b) *Target Product Cost* – The product must be able to be manufactured for under $50 per item.

Miscellaneous

a) *Standards and Specifications* – The syringe and catheter system is already approved and passes all regulations. Since our product will not come in contact with any component inside of this system it will not need any to undergo regulation approval
b) *Customer* – Our client wants a simple device that is easy to use and injects the stem cells at a constant pressure over a given time period with a feedback mechanism that prevents it from exceeding a certain threshold of pressure.
c) *Patient-related concerns* – The product needs to be sterile because it will be used during an injection operation in the operating room.
d) *Competition* – There are certain products on that market that contain a few components that will be incorporated into our final product; however there is no current design that accommodates all of our design specifications.