Project: Injection Catheter for stem cells

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Problem Statement:

Different methods have been tried to deliver stem cells to damaged cardiac tissue caused by a heart attack or other disease. These methods include injecting cells into the general circulatory system, injecting directly into the coronary arteries or open heart surgery to inject cells directly into the heart muscle. These methods have been ineffective for delivering a large number of cells to the damaged tissue or are invasive. A minimally invasive method of delivering stem cells directly into and around the damaged tissue is needed.

Currently, injection catheters are inserted in the femoral artery and advanced to the left ventricle (LV). Once in the LV, the catheter can be steered to the desired locations on the LV walls and a needle can be extended out from the tip of the catheter to penetrate the heart muscle and inject stem cells. This is a very time consuming process to make the multiple injections of stem cells necessary to heal the damaged tissue. In addition, with current tip designs lack of anchoring the needle in the muscle wall during the injections leads to fewer cells injected into the muscle and it is also time consuming to calibrate the depth of needle penetrations as needle depth is altered by the curve the of the catheter as it is bent into the necessary positions to reach damaged tissue. Therefore, a new catheter which can speed up the process of stem cell injection will be of critical importance to successful delivery of stem cells to the heart. A method is needed to improve precision of needle penetration and lessen the time to complete the procedure. This could be done by having multiple injections into the heart without adjusting the catheter and employing a corkscrew needle or other designs to securely anchor the needle in the tissue and control the depth of penetration.

Client Requirements:

- **Multiple Injections:** The catheter must be able to create multiple, quick injections to decrease time of procedure.

- **Size:** Must be small enough to fit through the arteries and aorta
  - < 14 French diameter (4.66 mm)

- **Flexibility:** The catheter must be made out a flexible enough material to curve through aorta.

- **Consistency:** The needle must enter the muscle wall of the heart with a constant depth.

- **Accuracy:** The catheter must be positioned accurately in the heart to improve accuracy of injections

Design requirements:

Physical and Operational Requirements

a. *Performance Requirements* – The catheter must work throughout the whole procedure without any complications. The insertion procedure will always be the same but different injection locations are required so the catheter must be flexible enough to reach all areas of the left ventricle. Stem cells will also be injected using the same method for each procedure.

b. *Safety* – The unit cannot cause any additional harm the animal in any way by being too bulky to be inserted into the arteries. Tissue of the heart should not be damaged by the catheter or needle by being inserted too far.

c. *Accuracy and Reliability* – The unit should be able to do multiple injections when being used with the ability to know how far the needle is in the tissue of the heart.

d. *Life in Service* – The unit should be able to withstand frequent use in a controlled, clinical environment for a long duration.

e. *Shelf Life* – The unit should not degrade while in storage.

f. *Operating Environment* – The unit should be able to withstand contact with blood in the heart and arteries and not cause any harmful effects. It also must not affect the stem cells that are injected.

g. *Ergonomics* – The unit should not provide enough force to break arteries or damage tissue. The catheter should easily be rotated so injections can be in a 360^{o} fashion.

h. *Size* – The unit must be able to fit inside the femoral artery and up through the aorta into the left ventricle

i. *Weight* - The weight should be as minimal as possible.

j. *Materials* – The internal and external component will be made out of polyurethane which is what a majority of catheters are made of. The injection component will be made of an existing catheter.

k. *Aesthetics* – The catheter should be circular and smooth without any protrusions to prevent movement through the arteries.

Product Characteristics

a. *Quantity* – Only one catheter is required.

b. *Target Product Cost* – Budget will be adequate for the manufacturing of these units.

Miscellaneous

a. *Standards and Specifications* – The unit will fit within the client's current injection procedure, thus no further board approval is necessary.

b. *Customer* – Clinicians working with pigs to inject stem cells will use the unit in a clinical setting. A fool proof method of using the device is preferred

c. *Patient-related concerns* – The pigs should not be harmed during the insertion of the catheter and injection of stem cells.

d. *Competition* – Only a patent exists for a multiple injection catheter that has two needles that come out the tip.