

## **Project Design Specification**

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**Problem Statement:** A variety of biomaterials are currently being installed and embedded within biological system. The wear and tear of these biomaterials will cause changes to its intrinsic properties. Currently, a parameter and device with high specificity and selectivity in detecting failure within embedded biomaterials are unavailable. The goal of this project is to determine a specific property of biomaterial that changes as it reaches failure. We will determine a method to detect and quantify this change in property non-invasively. In the long term, we are hoping to design a device that will exploit these properties difference.

### **Client Requirements:**

1. Detect a specific property change on the biomaterial, regardless of the host response.
2. Determine a proper, non-invasive method to detect the differences in property determined in item one.
3. Method should be operable by a primary physician without consultation with expert, such as radiologist.

### **Design Requirements:**

#### **1. Physical and Operational Characteristics**

- a. Performance Requirements-* Used frequently as a part of routine check-up.
- b. Safety-* The method must be non-invasive. Method and product use may require FDA approval.
- c. Accuracy and Reliability-* Precisely determine the state of the biomaterial quantitatively and deliver qualitative output (answer) to the physician.
- d. Shelf Life-* N/A.
- e. Operating Environment-* The method must be compatible with hospital environment.
- d. Ergonomics-* N/A.
- e. Size and Shape-* N/A.
- f. Weight-* N/A.
- g. Materials (for testing procedure)-* Gelatin, biomaterials sample, apparatus depending on the method use.
- f. Aesthetics* N/A

## **2. Method Characteristics:**

- a. Quantity-* One working and well tested method by the end of the semester.
- b. Target production cost-* \$1500 for the initial testing of the method.
- c. Testing procedure-* Initial qualitative and quantitative testing should be done on phantom.
- d. Output-* Method should be able to quantitatively determined failure and convert the result to a qualitative answer for the primary physician.

## **3. Miscellaneous:**

- a. Standards and Specifications-* Obtain FDA approval.
- b. Customer-* The customer (primary physician) will use the product on daily basis.
- c. Patient-related concerns-* Maximum cost of \$500 per check-up.
- d. Competition-* MRI and X-ray scans.