Product Design Specification for BME 301 Group 27: Intracoronary Guidewire
(As of March 11, 2009)

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Problem Statement:

Currently it is difficult to maneuver around tortuous vessels and largely occlusive clots during percutaneous transluminal coronary angioplasty (PTCA). Presently guidewires can be reshaped while outside the body but must be removed each time. The client requests a device to improve Guidewire steerability by allowing for conformational changes in the guidewire's tip *in vivo*.

Client Requirements:

- Biocompatable (medically safe to use in patient)
- Percutaneous
- Steerable, trackable, and torqueable

1. Design Requirements

The device must meet all of the client requirements

a. *Performance requirements:* Design must be able to be easily manipulated through tortuous vasculature.
b. *Safety:* Reduce risk of puncturing vessel wall *in vivo.* Will not elicit immune response.
c. *Accuracy and Reliability*: Durable enough to not break *in vivo*.
d. *Life in Service*: The device will only be used once in actual operation, thus the maximum usage time will be a few hours.
e. *Shelf Life*: Similar devices typically have a shelf life around one year. As of this time, we do not have provided standard.
f. *Operating Environment*: Tortuous vessels in the human body, specifically in the heart.
g. *Ergonomics*: Easy manipulated by a surgeon and mechanism for bending must be self-explanatory.
h. *Size*: Maximum outer radius of 250- 450 μm. Length can range from 140 to 300cm.
i. *Weight*: Not Applicable.
j. *Materials*: Nitinol, stainless steel, and insulating material (exact material not yet determined).
k. *Aesthetics*, *Appearance, and Finish*: Not applicable.

2. Product Characteristics

a. *Quantity*: Only one working prototype, could be mass produced based on demand and performance

b. *Target Product Cost*: Unknown at this time. Similar products tend to cost around $100.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval needed before actual implementation.
b. *Customer*: The client and potentially other physicians involved in coronary angioplasty.
c. *Patient Related Concerns*: Must not cause interference when inserted into the vessels
d. *Competition*: Currently, our only competition is non-steerable wires that are bent into place by a scalpel or a surgeon's fingers.