Variable Stiffness Guidewire - PDS

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Function: A catheter guidewire of variable stiffness to be used in a cerebral catheterization procedure and in situations where the conventional guidewires fail. The wire must be flexible enough to reach the correct point in the vessel, but stiff enough to provide stability for the catheter to follow into the vessel.

Client Requirements:

- 10-20 cm of variable stiffness between flexible tip and stiff remaining wire.
- Wire diameter of 0.97 mm.
- Guide around turns angles of 100-140° in vessels.

Design requirements:

1. **Physical and Operational Characteristics**
   a. *Performance requirements*:
      - Single-use.
      - Change rigidity from flexible to stiff.
      - Conform to existing guidewire standards.

   b. *Safety*:
      - Non-hazardous biomaterials.
      - Cannot change the environment of its surroundings (e.g. temperature, size).

   c. *Accuracy and Reliability*:
      - Must maneuver through desired vessel turns effectively.
      - Withstand internal conditions of human body.

   d. *Life in Service*:
      - Withstand one catheterization.

   e. *Shelf Life*:
      - 1-year shelf life.

   f. *Operating Environment*:
      - Blood vessels of human body.

   g. *Ergonomics*:
      - 0.97 mm in diameter
      - Physician-friendly.

h. *Size*:
    - Total length of 150 cm.
    - Tip length of 3 cm.
    - 10-20 cm of variable stiffness.

i. *Weight*:
    - Cannot alter normal functions.

j. *Materials*:
    - Stainless steel or similar material for inner portion of wire.
    - Hypoallergenic, hydrophilic coating.

k. *Aesthetics, Appearance, and Finish*:
    - Similar to existing guidewires.

2. Production Characteristics

a. *Quantity*:
    - One.

b. *Target Product Cost*:
    - Projected cost of $40-50 at the most.

3. Miscellaneous

a. *Standards and Specifications*:
    - Must be FDA approved.

b. *Customer*:

c. *Patient-related concerns*:

d. *Competition*:
    - One such guidewire currently undergoing research at Cook, Inc.