Customer Needs

Team 314: Abbott Reusable RF Probes

1. What is causing the probes to be limited to only 50 uses?
    - Sponsor's Response: Main limiting factor: materials used for the construction. The materials selected cannot withstand the continued and repeated stresses.
    - Interpreted Need: The product needs to be made with biocompatible materials that withstand at least 100 uses.

2. What is the operating frequency of the RF generator?
    - Sponsor's Response: For RF ablation, the frequency used is 460kHz. To confirm the probe's location concerning motor and sensory nerves, frequencies between 2Hz and 100Hz are used.
    - Interpreted Need: The device can propagate RF signals ranging from 2 Hz-465 kHz.

3. What are the variables that the [probe] electrode is capable of measuring?
    - Sponsor's Response: Measures temperature at the tip of the probe. The current method is by using a thermocouple.
    - Interpreted Need: The electrode is capable of measuring the temperature at the tip of the probe where the tissue is to be treated.

4. What is the leading property for reusability?
    - Sponsor's Response: Ability to withstand repeated heat stress.
    - Interpreted Need: The device needs to withstand repeated sterilization and stress of the procedure.

5. What is the current unit cost of the device? If we increase the probe's reusability to 100 or more, is it acceptable to increase the production cost?
    - Sponsor's Response: Current price target is $200 or less for a production cost per probe. The production cost can increase but depends on the scale of the cost.
    - Interpreted Need: The final product has a production cost of $200 or less.

6. What would the FDA approval process look like for this product?
    - Sponsor's Response: Typically, it would go through their approvals department for a device like this. The current reusable RF electrode is submitted as a class 3 through the FDA. However, depending on the modifications made to the device, it may qualify for 510k exemptions. However, we should plan for a premarket approval process. More details on this process will be provided as the sponsor presents them.
    - Interpreted Need: The device is classified as a "life-sustaining device." Therefore, plan for a full approval process for the entire device. The approval process is dependent on the scope of the change to the device.