Product Design Specifications

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Title: Guidewire Organizer for Operation Room
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Function:

In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety and decrease the time it takes for surgeons to organize the wires.

Client requirements:

- The device must be easy to use and increase organization in the operating room
- The device must consist of a main storing unit (the crate) to house 4-5 guidewire wheels
- The final device must ultimately have biocompatible properties*
- The final device must be sterilizable by autoclave or other alternatives*

*Clients main goal is a successful prototype and proof of concept

Design requirements:

1. Physical and Operational Characteristics
    a. *Performance requirements*: The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The wheel must be able to hold guidewires with diameter sizes of 0.014 to 0.035 inches. Additionally, the guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the edge of the crate for the guidewire to sit on. It must be easy to load and remove the wire into the wheel while in the operating room [1]. The wheels must also be easily placed and removed from the crate.
    b. *Safety*: The device should be able to withstand heavy chemicals such as, glutaraldehyde, formaldehyde, ethylene oxide that are needed to sterilize medical tools in the operating room [2]. Additionally, there should be no risk for the user and all edges must be smooth to prevent the risk of cuts through medical gloves [1].
    c. *Accuracy and Reliability*: In order for the device to comply with the requirements made by the client, it must be able to fit 4-5 catheter guidewires, which ideally fit within the 11.8 inch diameter of each wheel, and each wheel must be able to hold a 0.035, 0.018, 0.014 inch guidewire [1]. In addition to the precision it will take to design the device, it also must be able to undergo surgeries and have the ability to keep the multiple guidewires used during surgery organized so the operating room

workers can navigate the guidewires easier than without the device.

d. *Life in Service*: This product is a prototype. The life of service should be long enough to confirm that it works and present to possible investors and to provide proof of concept. This could be up to a year, but the minimum time under little stress should be a month. If the product is eventually made to be sold, and made out of medical grade stainless steel, it should last for at least a lifetime, or 100 years [3].
e. *Shelf Life*: In order for our device to be practical for surgical use, and last at least 5 years, between uses the device will need to be autoclavable or some other form of sterilizable. With this in mind, the material used to design this device should be able to withstand sterilizable temperatures (121-132 °C) in order to maintain its shelf life after being used for the first time [4].
f. *Operating Environment*:
   This device will be used within an operating room and be fully functional within standard operating room conditions. These include a relative humidity of 20 to 60%, and a temperature between 68 and 75 °F [5]. It should be stored in a designated sterile storage room.
g. *Ergonomics*: The device should be easily gripped by the operator to ensure maximum control which includes minimizing excessive movement. Post operation, this device should be easily inserted into an autoclave for sterilization. When not in use, the device should be easily stored away in a storage room.
h. *Size*: The design consists of a circular wheel with a diameter of 11.8 inches. The crate for storing the wheels will be 12x7x6 in. The lip on the crate will be a semicircle with a diameter of .15 inches [1].
i. *Weight*: The prototype will be lightweight and under two pounds and easy to maneuver but able to withstand operating room size requirements and various table setting environments [6]. The final product will be heavier as it will be made of stainless steel.
j. *Materials*: The initial materials for the prototype will be plastic filament (PLA) from the Makerspace [6]. Beyond the prototyping phase the material should be medical grade stainless steel to make it possible to sterilize and reuse.
k. *Aesthetics*, *Appearance, and Finish:* The client addresses the device may be 3D printed [1]. The final device should be FDA medical grade steel and should have a smooth, clean finish [7]. The prototype should also have a smooth, clean finish. The color will be consistent throughout.

2. Production Characteristics
   a. *Quantity*: One prototype is needed, yet the prototype needs to be conceptually and physically sound and able to be utilized in real time. The main focus will be producing a single prototype to ensure proof of concept. In the future, this prototype will ideally be mass produced, so the ability to have steady organization of guidewires and catheters is available in all operating rooms, which leads to the

production of many devices.

b. *Target Product Cost*: Taking into consideration the materials and size, we estimate that the approximate cost of the 3D printed Guidewire Organizer prototype to be around 200 USD.

3. Miscellaneous
    a. *Standards and Specifications*:This product would likely be considered as a Class II medical device. There is no direct FDA regulation for this device, so it will be assumed to follow the same rules as a guide wire kit and guidewire torque device [8, 9]. Both of these are Class II and require premarket approval in the form of a 510k. There may be a way to prove that it does not require premarket approval, but the team would need further guidance to determine if it is possible [10].
    b. *Customer*: The target market for the guidewire organization device would ideally be cardiothoracic surgeons and medical facilities that perform routine surgeries. This would be the case due to the highly beneficial organization of the guidewires in endovascular catheter surgeries, as they are often misordered which leads to extended surgery time, making this prototype appeal to those who want to avoid the disorganization of guidewires during surgical procedures. The effect of disorganized guidewires can potentially lead to internal damage based on the insertion of the guidewire and where the wire leads to. Tips of a guidewire can break and the broken guidewire could harm the arterial wall that it is placed in [11].
    c. *Patient-related concerns*: Because this device will be used in endovascular procedures, it is important to take into account patient safety. The guidewire holder should ensure that the wire can be inserted in a safe way so the patient's health is not at risk.
    d. *Competition*: A guidewire organization device that currently exists is the Angio Assist™ Docking Station, by Teleflex which facilitates the introduction of guidewires into catheters and atherectomy burrs. This friction-fit guidewire holder is for the use of a single-operator and eliminates the need to touch or hold the stent during guidewire loading. There are two slots that facilitate the alignment of guidewires and catheters on this device. Another product is the Tierstein Edge Device Organizer, by Teleflex which has 6 friction fit slots for guidewires and catheters and is designed to minimize loss of motion control of eternal guidewire as well as increase security of excess wires during procedures [12].

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