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 by decreasing the time it takes for surgeons to organize the guidewires.

Client requirements:

- The project consists of two pieces: a guidewire wheel and wheel stand.
- The team will determine and finalize the dimensions (diameter, wall thickness and hand slot) of the current guidewire wheel design.
- The wheel will sucessfully load guidewires of varying stiffnesses.
- The wheel stand will stack three guidewire wheels.
- Guidewires must be able to be removed from the wheel while the wheel is stored on the stand.
- Single use device (SUD).
- The final market device must be able to be mass produced and released into the market in an FDA approved material at a low cost.

Design requirements:

1. Physical and Operational Characteristics
    a. *Performance requirements*: The device will consist of two pieces: (1) a stand to store 3 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 and varying stiffnesses. Additionally, the guidewire must stay organized and unknotted when removed from the wheel while on the stand. It must be easy to load and remove the wire into the wheel while in the operating room [1]. The wheels must be easily placed and removed from the stand. The stand must hold the 3 wheels at once. The stand should allow easy access to the guidewire at any point during a procedure.
    b. *Safety*: 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, the device must be able to fit 3 catheter guidewires, which ideally fit within the finalized optimized diameter of each wheel, and each wheel must be able to hold various guidewire sizes separately [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. This will allow the operating room workers to navigate the guidewires easier than without the device. The stand should not interfere with the performance of the wheel. The stand should keep the wheel firm in place to allow for efficient loading and unloading.
d. *Life in Service*: The final product will be a SUD. It must be able to withstand the loading and unloading of a guidewire 3-5 times during a single procedure.
e. *Shelf Life*: Although the final market device will be discarded after each use, the product must last at least two years on the shelf. To ensure the material of the device will not degrade, the device will be stored in an environment where the humidity and temperature are regulated to the material's specifications.
f. *Operating Environment*: The final market 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°F and 75°F [2].
g. *Ergonomics*: The wheel should be easily gripped by the operator to ensure maximum control which includes minimizing excessive movement. A surgeon's hand should be able to easily slide into the wheel to load the guidewire. The average male surgeon's hand circumference is 21.35 cm and female is 18.95 cm. The hand opening should take these dimensions into consideration. The circular wheel and storage devices should have a minimum learning curve to hasten the use. The stand device should not slip on surfaces.
h. *Size*: The design consists of a circular wheel with a diameter of 15-25cm and an inner diameter cutout of 10-25 cm for maximum control by the operator [3]. The circular wheel will have a thickness of 3-8 mm. The stand will have dimensions that will be determined based on the wheel dimensions
i. *Weight*: The final wheel design will be lightweight and easy to maneuver by the operator. The stand must fit within operating room size requirements and various table setting environments [4]. The stand must be heavier than the wheel design so it does not tip over while holding the wheels.
j. *Materials*: The initial materials for the prototype will be plastic filament (PLA) from the Makerspace [4]. The stand may require weights in the base. The final product will be made out of an FDA approved polymer that can be mass manufactured while fulfilling weight, size, and shelf life requirements.
k. *Aesthetics*, *Appearance, and Finish:* The final market device should be an FDA

approved plastic and should have a smooth, clean finish [5]. 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 final design will consist of 3 wheels and a stand, which will house the wheels. However, the final manufactured design will be mass produced.
    b. *Target Product Cost*: Taking into consideration the materials and size, the estimated cost of the final product will be approximately $2 per wheel and $5 per stand [1].
3. Miscellaneous
    a. *Standards and Specifications*: This product would likely be considered as a Class I medical device. There is no direct FDA regulation for this device; both the stand and wheel are assumed to be a Class I device and may require premarket approval in the form of a 510(k) [6].
    b. *Customer*: The target market for the guidewire organization device would ideally be cardiothoracic surgeons and medical facilities that perform routine endovascular 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 [7].
    c. *Packaging*: The client wants the product to be packaged with guidewires and distributed in conjunction with guidewires [1]. It will be assembled and packaged in a clean room environment. The stand will be purchased separately.
    d. *Patient-related concerns*: Because this device will be used in endovascular procedures, it is important to take into account patient safety. The guidewire wheel and stand should ensure that the wire can be inserted in a safe way so the patient's health is not at risk.
    e. *Competition*: A main competing guidewire organization device is the Cath Clip. To use the Cath Clip, an operating technician winds the guidewire into a neat circle and clips it together using the device. Cath Clip is a single-use and lint-free device device. The Cath Clip can lead to disorganization as the guidewires do not stay separated when placed on the table. Since there is no additional storage unit included for the device, after it is placed on the table it can fall onto the floor if bumped or not secured [8]. Another guidewire organization device produced by Medline Industries is the Guidewire Bowl. This device comes in various sizes ranging from 8.5 inches to 11 inches in diameter. These bowls have 5 interior tabs that overhang to hold various guidewires within the bowl while submerged in saline. This device is also

plastic and single use [9]. 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 [10].

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