Product Design Specifications

Date of Last Revision: Feb 9, 2022

Title: Guidewire Organizer for Operation Room
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Section Number: BME 301

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 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 wheel while wheel is stored on the stand
- The final market device must ultimately have biocompatible properties**
- The final market device must be sterilizable by autoclave or other alternatives**

*Client provided the basic concept of the wheel design, requires testing and alteration of dimensions

**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 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 3 wheels at once. The stand should allow easy access to the guidewire at any point during a procedure.
    b. *Safety*: The final market 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 3 catheter guidewires, which ideally fit within the 188 mm diameter of each wheel, and each wheel must be able to hold a 0.035, 0.018, 0.014 inch guidewire 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 so the operating room workers can 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*: This product is a prototype. The life of service for the prototype should be long enough to confirm that it works and present to possible investors and to provide proof of concept. A large amount of prototype testing will be conducted over the next six months, so the prototype must be able to withstand multiple loading/unloading tests during this time to show it operates properly and efficiently.
e. *Shelf Life*: In order for the final market device to be practical for surgical use, and last at least 5 years, between uses the final market 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 [3].
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 [4]. It should be stored in a designated sterile storage room.
g. *Ergonomics*: The should be easily gripped by the operator to ensure maximum control which includes minimizing excessive movement. Ensure that the circular and storage devices 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 188 mm, and an inner diameter cutout of 45 mm. The circular wheel will have a thickness of 45 mm. The stand will have dimensions of 210 mm outer diameter, with a 35 mm inner diameter pole. The stand will have a 90 mm tall wall and a 5 mm thick wall around half of the device.
i. *Weight*: The prototype will be lightweight, under two pounds, and easy to maneuver but able to withstand operating room size requirements and various table setting environments [5]. The stand must be heavy enough to not tip over while using the wheels. This is approximately 5 pounds.
j. *Materials*: The initial materials for the prototype will be plastic filament (PLA) from the Makerspace [5]. The stand may require weights in the base. After the prototyping

phase, the final market device material should be medical grade stainless steel to make it possible to sterilize and reuse.

k. *Aesthetics*, *Appearance, and Finish:* The client requests that the prototype be 3D printed to allow for easy replication of the device that remains cost efficient [1]. The final market device should be FDA medical grade steel and should have a smooth, clean finish [6]. 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. In the initial prototyping phase, many wheels will be produced and modified to allow for ample testing until the final prototype is produced. The final prototype will consist of 3 wheels and a stand, which will house the wheels.
    b. *Target Product Cost*: Taking into consideration the materials and size, we estimate that the approximate cost of the 3D printed stand and wheels prototype to be around 200 USD, but the client's budget is flexible.
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 [7, 8]. 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 [9].
    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 [10].
    c. *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.
    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 [11].

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