

Endovascular Devices For Cath Lab And Operating Room Procedures

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An endovascular procedure is a minimally invasive technique used to diagnose and treat vascular diseases. The growing endovascular device market is currently \$2.05B USD and is expected to gain market growth from 2022 to 2028 at a compound annual growth rate (CAGR) of 4.1%, surpassing \$2.61B USD by 2028 (Endovascular Treatment, 2023). As chronic diseases increase and the geriatric population grows, the need for minimally invasive procedures becomes more apparent. This growing market indicates a need for innovative technologies to ensure well-done and efficient procedures. With today's medical advances, catheter-based intervention is replacing traditional surgery and is reaching a wider range of patients, as it can be applied to patient groups where open surgery is not possible. These procedures rely on guidewires (GW) and catheters to travel the vascular system and access the desired position. The use of GWs spans a variety of different surgical sectors including: angioplasty, stenting, and pacemaker insertion (Sharei et al., 2018). Endovascular surgeries are becoming increasingly common with cardiovascular disease as the leading cause of death in the US in 2021 (CDC, 2023). Additionally, it was estimated that there are more than 1 million cardiac catheterization procedures performed annually in the US (Yugandhar et al., 2021).

During endovascular procedures, surgeons use multiple GWs that are often removed and reinserted multiple times. The exact number of GWs depends on both the physician and procedure; for example, in coronary total occlusion procedures, an average of 4.32 GWs are used (Karabulut et al., 2020). Since each minute in an operating room (OR) costs an average of \$60 (Gül, 2008), GWs management becomes a critical concern. Currently, most doctors store used GWs under a wet towel. However, these towels shed fibers onto the wire and those fibers have the potential to be displaced into the body, putting the patient at risk for lint contamination complications (Truscott, 2021). Additionally, the excessive length of GWs also poses an issue. There is no form of dispensing mechanism for the GW, thus as it is inserted into the body, the remainder of the GW is fully exposed and poses the risk of entanglement. In a study about endovascular procedure complications, it was found that 13.3% of procedure errors were due to device failure, which could be attributed to GW knotting or tangling (Antonacci et al., 2008). As for commercial devices, there is the Cath Clip (Cath Clip, 2017). GWs are stored *together* in a single bowl of saline. The Cath Clip does not optimize GW storage because GWs do not stay separated and there is no dispensing mechanism so the full length of the guidewire is released all at once. The lack of a true storage and dispensing option for GWs causes entanglement and sterilization concerns, requiring a new GW to be used, raising procedure costs and time spent in the OR.

To address the market needs, the team developed the GWDisc: a *single-use* system that stores GWs *separately* and *dispenses* GWs. The device consists of two components: (1) a wheel to hold a single GW and (2) a stand to hold up to three wheels. To use the device, a GW is wound into a circle by the user, then placed in the cavity of the wheel. The GW can be dispensed from the wheel while on the stand or with the wheel in hand by pulling at the exposed GW tip. GWDisc aims to increase procedure efficiency by having an organized system that alleviates the potential risks current storage techniques pose. Based on preliminary testing of the device, it was found that the device did not greatly increase the amount of time it takes to store a GW (2.9s) compared to the current storage methods, proving it does not add complexity to GW storage. Residents were also surveyed to obtain their experiences from competing designs. When asked about the organization of the wet towel method, 75% said the method causes disorganization issues about half the time in the OR. 75% also claimed they would prefer a new storage method that is more efficient and creates fewer problems in the OR. The wheel and stand are a safe and efficient storage and dispensing solution for the fast-paced environment of endovascular procedures, and commercialization of the device will advance the way healthcare professionals operate in endovascular procedures.