Stabilizer Device for Intracardiac Echocardiography (ICE) Catheter

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Intracardiac echocardiography (ICE) is commonly used during catheter-based procedures to treat congenital, valvular, and myocardial diseases. There are different brands and types (3D or 4D) of ICE catheters, which all have unique shapes. Typically, an ICE catheter is introduced into the right atrium from a femoral vein for imaging, while a separate therapeutic catheter performs the intervention. Often, the ICE catheter drifts, losing the imaging perspective and requiring readjustment. Hence, a re-sterilizable device is needed to stabilize various ICE catheters, preventing migration during use.

The current method of using wet towels to stabilize ICE catheters is ineffective, as it fails to withstand breathing forces. While stabilizers exist for other catheters (e.g., MitraClip, Triclip, EVOQUE), none are designed specifically for ICE catheters to accommodate adjustability and various handle sizes. To fill this gap, the team developed a universal ICE catheter holder compatible with various models. It includes a removable sterile component that allows users to adjust the height and accommodate patients of different sizes.

The marketability of the device is significant, as it has many applications and features a disposable sterilized piece which is to be sold and shipped in sterile packaging. According to Siemens, their ICE catheter has been in use for 20 years with over 2 million procedures performed; this is just one brand of ICE catheter with many more out in the market. While the device was conceived and designed for ICE catheters during mitral valve procedures, the device has many other potential applications. Any procedure using a catheter with a cylindrical handle that is inserted into a femoral vein has potential compatibility with this product. Additionally, the steel base and middle parts of the device are reusable after cleaning as they do not need to be sterile under the sterile drape, but the top part is a sterile plastic piece that can be sold as individual units pre-sterilized. This allows for a more consistent revenue stream as these pieces must be reordered after every procedure. These top pieces also come in varying sizes, allowing for further adaptability and customization.

The final design features three main parts, referred to as the base part, middle part, and the top part. The base part consists of a flat metal plate upon which the patient's legs rest, with a vertical pole protruding in the middle featuring a pole clamp at the top. The middle part has a pole which slides into the pole of the base plate, and is secured at varying heights with the pole clamp. Atop the pole of the middle part is the dock for the top part, which contains an ‘X’ locking ridge and magnets. The top part, which magnetically attaches to the middle part across the sterile drape, features a complementary ‘X’ groove pattern on the bottom and a saddle shape on the top to hold the handle of a catheter. There are two knobs on either side of the saddle for holes on the rubber strap to secure onto, holding the catheter in place. The saddle also features a rubber lining to improve grip on the catheter handle, and comes in several heights to allow for further height adjustment after the height of the middle part is initially set under the sterile drape.

While other proprietary catheter stabilizers exist, no other stabilizer features the magnetic coupling mechanism that maintains the integrity of the sterile drape. This mechanism holds significant potential for intellectual property as other stabilizers employ the use of screws, knobs, sliding rails, or other mechanical mechanisms to adjust the position of the catheter. While this device also utilizes features such as these, the use of magnetic coupling to assemble the stabilizer through the sterile drape is a novel method that has the potential to be patented.

The device was validated by comparing the force needed to dislodge two types of ICE catheters against the current wet towel method. The device demonstrated significantly greater stability, requiring 4x more bending force and 7x more tensile force in worst-case scenarios—comparable to the difference between lifting air and lifting a basketball—highlighting its superior performance. Based on a survey, the client and his colleagues reported that they liked the device and would consider purchasing it in the future. Real-world testing also confirmed that the device did not interfere with any medical equipment during procedures.

The device was able to secure many different ICE catheters over the drape during mock operations. It can be adjusted in height both before and after the sterile drape is applied, and maintains the integrity of the sterile field. It requires two hands to secure an ICE catheter using a rubber strap locking mechanism.