



## **Project Design Specification: Engineering Equipment for a Simplified Central Venous Catheterization**

October 5, 2007

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*Purpose: The Project Design Specification (PDS) establishes the requirements that must be met in order to produce a functional device. This document includes requirements for the client, functionality, safety, and economic considerations.*

### **Product Function:**

In order to decrease the occurrence of medical error complications, we are designing a device that minimizes the complexity of the CVC placement procedure. The redesigned CVC placement device will contain a pressure sensor which will measure the pressure generated by blood in the punctured vessel. The sensor will display the measured pressure along with a light indicator. The light will signal green if the pressure measured is venous (below 20mmHg) and will indicate red if it is arterial (above 30mmHg). The device will have a newly designed handle to provide a more ergonomic grip for the clinician. The handle will be clear and contain a small hole to provide visual feedback that the clinician has entered a blood vessel. A three way connector will attach the needle, handle, and pressure sensor. The connector will allow visualization of blood flow and will have a one way valve that prevents blood flow out of the connector. Finally the guide wire must be able to slide through valve in the connector and through the needle into the patient to allow the continuation of the procedure. The design should be included as a part of a cost efficient CVC placement kit.

### **Client Requirements:**

- All materials within the kit must be sterile
- The kit must contain all parts required for CVC placement which includes:
  - Two introducer needles, 5mm and 7mm, with catheters
  - Scalpel
  - Newly designed handle
  - 45cm long guide wire with depth markings
  - Dilator (variable diameter based on catheter diameter)
  - Catheter (either triple or double lumen with variable lengths, lumen diameters, and catheter diameters)
  - Three way connector piece
  - Pressure sensor
- The device should be easy to learn to use within one training session
- The device and kit can only be used once and must be disposable
- The device must meet all safety regulations currently in place for syringes
- The kit must include safety warnings to prevent puncture of the heart or catheterization of the artery

- The kit may be kept at room temperature

### **Design Requirements:**

#### 1) Physical and Operational Characteristics:

##### a. Performance Requirements:

The appropriate 5mm or 7mm syringe should be inserted into the internal jugular vein. The pressure sensor will display a reading and light up when a change in pressure is detected in order to indicate arterial (above 30mmHg and red) or venous (below 30mmHg and green). The pressure sensor will be activated immediately after blood enters the device thereby indicating venous or arterial puncture in less than one second following insertion. During a successful insertion, the sensor will only be used once. However, if the carotid artery is punctured, the syringe must be removed from the patient and reinserted once the carotid artery has been stabilized. Therefore the sensor will have the capability of working more than once. To ensure reliability even after several unsuccessful insertions, the sensor must be capable of correctly detecting pressure twenty times.

Following confirmation that the needle is in the vein, the handle can be removed from the three way connector. Blood flow should be stopped by the one way valve. The pressure sensor should continue to measure the pressure and provide feedback to the clinician ensuring that the needle remains in the vein. Once the handle is removed the guide wire may be inserted into the three way connector, pushing the valve slightly open in order to be inserted into the vein to the correct depth of approximately 16cm. Once the guide wire is in place, the needle and connector can be removed. The device can only be used once and therefore must then be disposed of and the rest of the CVC placement procedure can be completed. The catheter must be able to withstand a flow rate within 3.0–9.9 mL/sec[1] without catheter injury.

##### b. Safety:

All needles should be sheathed prior to use and immediately disposed of following use to prevent accidental sticks or exposure to patient's blood. The packaging must be completely untampered with. All materials must be sterilized in order to prevent infection. As with any CVC placement, appropriate protective clothing should be worn: surgical gown, hair cap, face mask, and surgical gloves. The device should only be used by properly trained medical personnel.

##### c. Testing:

Human model blood vessel simulation will be the main testing method for the final product. The syringe will be tested to ensure that the indicator light is correctly activated for the appropriate blood pressure. The syringe must be able to detect a correct insertion by recognizing a venous blood pressure below 30mmHg and an arterial blood pressure above 30mmHg. Qualitative quality

evaluations by clinicians will also be used to compare the new product with the conventional CVC kit. The time to successful CVC insertion with the new device will be compared to the time for insertion with the current procedure in order to provide quantitative data on the success of the device.

d. Accuracy and Reliability:

The pressure sensor should read and recognize venous and arterial pressures within +/- 4mmHg. The device should give adequate visual feedback to the clinician. The valve should allow no more than 0.1mL of blood exit the connector following removal of the handle.

e. Life in Service:

The device is a one-time use piece of equipment and must therefore only last through the maximum duration of the procedure: approximately 5 minutes.

f. Shelf Life:

The kit should be able to be used for up to two years following production. A shelf life longer than two years will not ensure sterility of the contents of the kit.

g. Operating Environment:

The device would be used at room temperature, approximately 25°C, in a surgical hospital facility. The kits may be stored at room temperature. The manufacturing, packaging and storage must ensure sterility through the use of the device. The materials must be able to withstand contact with bodily fluids. The device should be able to withstand up to 50% humidity. It will be used in a clean environment. The device will be handled by a clinician placing the CVC as well as the technicians and nurses assisting them.

h. Ergonomics:

The kit should be easily handled and understood. Proper warning labels should be clearly visible. The handle will be designed for the most ergonomic handling of the needle. The clinician should be comfortable holding and inserting the needle, removing the handle, guiding the guide wire into the vein, and removing the needle and connector while performing the CVC placement standing behind the patient's head and right shoulder. The orientation of the syringe is important to ensure that the sensor light is visible to the clinician. All components should be easily accessible to the user following the opening of the packaging.

i. Size:

The entire packaged kit should be no larger than 1x1 ft. The handle will be approximately 10cm long and 2cm in diameter. The connector will be approximately 2.5cm long, 1cm in outer diameter, and 0.5cm in inner diameter. The needle will be an 18 Gauge needle of variable length.

j. Materials:

The handle and connector will be made with autoclavable materials such as strong plastic and stainless steel. The materials must be sterilized and must last for a two year shelf life.

- k. **Cleaning:**  
The device will be sterile when taken out of the packaging and used. It can only be used once and will therefore require no additional cleaning.
  - l. **Disposal:**  
All parts in the kit should be properly sealed in biohazard disposal containers before disposing to avoid contamination to the environment. All parts with sharp ends or blades must be disposed in special containers which prevent accidental needle sticks. Syringes can never be reused after the CVC procedure.
- 2) **Product Characteristics:**
- a. **Quantity:**  
One prototype will be constructed. In order to test the design, the prototype will need to be reusable. Parts from other CVC kits may be reused to enable testing of the syringe prototype.
  - b. **Target Product Cost:**  
The CVC kits will be sold in bulk to hospitals and clinics. A bulk package of 10 kits will be in the range of \$500. The individual kits should be no greater than \$5 over the cost of current CVC kits.
- 3) **Miscellaneous:**
- a. **Standards and Specifications:**  
FDA guidance documents classify similar devices as Class II. The device must meet all FDA regulations for this classification and must meet clinician approval before being used for human patients.
  - b. **Legal:**  
The product should not be available to the general public for sale to avoid abuse or misuse. Mechanical testing on the final product should be done to ensure no parts would dissociate during normal usage to ensure the engineered structures are reliable. Mechanical and chemical testing will be done on the materials before fabrication to ensure that no breakage of the materials should occur during usage and that no toxic materials are incorporated in the design.
  - c. **User Training:**  
Technical representatives should be sent out to demonstrate the new protocol while advertising. The training will include proper handling technique as well as other relevant aspects of a CVC operation. Additional training for the use of this device is not required, as its use is nearly identical to the current CVC placement

technique. The only constraint applying to this device is that the indicator light must be visible at all times.

d. Competition:

The competition includes all manufacturers of CVC kits. The device must have a quicker and more convenient protocol when compared to the current CVC kits. The kit must be cost effective to ensure a competitive advantage. The major market will be all medical institutions in the United States, with the need of performing central venous catheterizations.

e. Customers:

The primary consumers of the redesigned CVC kit will be patients, clinicians, risk management investors, and hospital purchasing managers. The device should lessen patient anxiety due to the shortened operation time. Clinicians will have a less complex procedure leading to decreased error. Decreased error will appease the risk management personnel. Purchasing managers will be interested in a cost effective kit and lowered amounts of CVC related medical incidents.

f. Resources:

- Dr. Joseph Samosky, Ph.D, Director of Research and Development at the Peter M. Winter Institute for Simulation, Education and Research
- The Peter M. Winter Institute for Simulation, Education and Research (WISER)
- Dr. Bill McIvor, anesthesiologist and associate director of medical student programs
- Christine Barton, WISER coordinator of simulation services
- University of Pittsburgh Medical Center (UPMC) staff, clinicians, and researchers

g. References:

1. <http://www.ajronline.org/cgi/content/abstract/183/6/1829>