THE DESIGN, DEVELOPMENT, AND ANALYSIS OF AN EXTRACTION DEVICE FOR RETRACTED CATHETER NEEDLES FOR MULTIPLE REUSES ON SIMULATION MANIKINS

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of the Requirements for the Degree
Master of Science

by
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December 2014
Accepted by the faculty of the College of Science and Technology, Morehead State University, in partial fulfillment of the requirements for the Master of Science degree.

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Dr. Nilesh Joshi
Director of Thesis

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Dr. Ahmad Zargari, Chair

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Dr. Nilesh Joshi (Director)

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Dr. Ni Wang

December 03, 2014
THE DESIGN, DEVELOPMENT, AND ANALYSIS OF AN EXTRACTION DEVICE FOR RETRACTED CATHETER NEEDLES FOR MULTIPLE REUSES ON SIMULATION MANIKINS

Travis Fisher, M.S.
Morehead State University, 2014

Director of Thesis: _________________________
Dr. Nilesh Joshi

Healthcare students all over the world use IV catheter inserters to study and practice the different techniques of inserting intravenous (IV) catheters used for various intravenous purposes on simulation (practice) manikins. These IV inserters come with needle safeguard mechanisms that cause the inserter needle to retract into a safety barrel, which renders the catheter needle unusable and ready for disposal after only one use. While the use of catheter needles with needle safeguard mechanisms reduces the risk of accidental needle-stick injuries and blood exposure during IV insertions for actual patients, application of such techniques on practice manikins, however, does not present the contamination risks that are addressed by the needle safeguard mechanisms. Nevertheless, despite the potential for reuse of IV catheter inserters into the arm of a manikin rather than an actual patient, the current practice of disposing of each inserter after a single use is proving far too expensive for healthcare educational programs. Not only is the full cost of catheter inserter incurred for each single application of a catheter by a student on a practice manikin, the associated cost of properly disposing of the catheter needle is also incurred. Despite this widespread and unnecessary waste of functional catheter needles in educational environments, however, efforts to address this waste have been minimal. The proposed “Extraction Device for Retracted Catheter Needles” addresses this problem. The device
will be used to extract the retracted catheter needles and thus to reset the IV inserters for multiple uses. The device is specifically developed for the use by healthcare programs in the US and worldwide for providing cost effective IV insertion training to students. It will not only save thousands of dollars that are now being spent by these programs on new catheter needles but also will minimize waste.

Accepted by:

__________________________
Dr. Ahmad Zargari, Chair

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Dr. Ni Wang
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Finally, I dedicate this work to my loved ones, to whom I am indebted beyond repay. To my parents for their unwavering love, my grandmother for always believing in me, and Maria for all of her support and encouragement. Above all I thank God, for in him all things are possible.
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Chapter 1: Introduction

1.1 General area of concern

Healthcare students all around the world use practice manikins to develop and hone different techniques for inserting IV catheters for various intravenous purposes. The IV inserters being used are industry standard, with this comes industry standard safety regulations and procedures. These syringes are retractable and can be used only once before being disposed per safety regulations. The proposed “Extraction Device for Retracted Catheter Needles” is a stationary device that will be used for extracting the retracted catheter needles and thus resetting the IV inserters for multiple uses after the needle has been retracted. The device is specifically developed for use by medical schools, nursing programs, and other health related programs in the US and worldwide for providing cost effective IV insertion training to their students. Since during such training workshops IV inserters are only used on practice manikins, sterility is of no concern. The current practice of disposing of each injector after a single use on practice manikins puts a strain on departmental budget and on the student’s freedom to learn at their own individual pace. Thus, it would be more economical for such programs to be able to utilize their equipment to its maximum life cycle. The proposed apparatus will make this possible and has the potential to save thousands of dollars that are now being spent by these programs on new catheter needles.

The proposed design can safely extract the retracted catheter needles so they can be used many times. The cost savings due to the device will increase significantly depending on the how much it is utilized. Depending on the brand of retractable catheter needles a particular healthcare program uses to instruct their students with, an appropriately designed and dimensioned insert can be separately purchased for that specific catheter needle. All inserts will be compatible with the device, such that if an instructor decides to pursue the use of a different brand of catheter
needle, he/she can buy the insert that is designed for that brand instead of buying an entirely new extraction device.

1.2 Purpose of study

The problem under investigation has nothing to do with the functionality of the IV inserter but of its reuse, which is not recommended by the medical industry due to safety concerns. The problem is that once the needle is retracted into the safety barrel it must be disposed of due to the obvious concerns of contamination. However, under the training circumstances on practice manikins, the needle will not be exposed to any biological contaminants that will render it infeasible for reuse from an educational standpoint. In the industry it is essential to dispose of the catheter needle after a solitary use due to health and safety precautions, so the academic world is called to follow suit, even though the needles contact with blood borne pathogens is not a viable concern since the students will only use the needles on practice manikins.

Fisher (2012) designed a first generation extraction device to reset the IV inserters for multiple reuses during the training situations. The first generation device had several limitations that restricted its practical implementation. The purpose of this study is to evaluate the failures of the first generation extraction device designed in 2012 and develop a new device that addresses these shortcomings. After investigating and brainstorming multiple designs and their functionalities, using the concept screening and scoring matrices, the best device redesign will be carefully selected.

Several criterions will be thoroughly considered during the selection of the most appropriate redesign of the device. The devices will be graded according to their adherence to the following specific criteria:
• Ease of handling
• Ease of use
• Durability
• Ease of prototyping/manufacturing
• Portability
• Safety
• Repeatability
• Aesthetics
• Cost
• Serviceability

Refinement of the previous design and innovation are the primary objectives of this project. This means rethinking everything, from the overall look and feel of the product to the functionality and user experience. The goal is to create a sleeker, more elegant looking product that functions with more intuition and consistency than its predecessor while enhancing safety and simplicity. In addition to being a stationary device for extracting retracted IV catheter needles for multiple uses, the new design enables a very safe and cost effective method for the healthcare academia throughout the world to utilize the catheter equipment they purchase to its fullest extent.

Solidworks 3D modeling software is used to create a parametric model and test the integrity of the design, and a fused deposition modeling (FDM) rapid prototyping machine is used to fabricate a working prototype.
1.3 Objectives

- Use first generation extraction device design as a benchmark for the current model.
- Enhance safety and functionality by enabling the needle to extract back into the catheter sheath and cap.
- Design refinement:
  - Eliminate any possible moving parts in the first generation design.
  - Create more intuitive push button mechanisms and catheter orientation.
- Develop a fully functional prototype to undergo further testing.

1.4 General design methodology

The methodology adopted in this research is represented in the flow chart below in Figure 1.1. The methodology is divided in four phases. Problem identification and definition phase was relatively easy. There is an obvious need for a device that can safely and swiftly extract retracted IV inserter needles. The second phase, ideation and concept generation stages includes brainstorming techniques such as hand sketches and concept screening and scoring tables to generate the alternative product designs. A final design will be selected using the screening/scoring tables, and the analysis of the final design will begin in the third phase. A physical prototype will be made and further analysis can be gathered from its functionality in the phase four.
1.5 Potential limitations

The device is developed for use only by certified supervisors in healthcare educational programs in the US and worldwide for providing a safe and cost effective alternative for such programs to conduct intravenous training. During the development of the design and its future implementation, we have encountered a plethora of limiting obstacles similar to any other engineering design project. The following is the detailed list of barriers that we face:

- Insufficient existing research.

- Materials and equipment are too expensive to develop and test multiple prototypes on a tight budget.

- Legal and liability issues.

- Potential patent infringement with large catheter manufacturers.

- Healthcare industry is reluctant to adopt a new procedure or product due to the potential safety concerns.

- Potential for unauthorized use of the product leading to reuse of catheter needles in the hospital settings particularly in the third world countries.
1.6 Definition of terms

- **Catheter**: A hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway (Free Dictionary, 2013).

- **Intravenous (IV)**: Within or administered into a vein. A drug, nutrient solution, or other substance administered into a vein (Free Dictionary, 2013).

- **BD Insyte Autoguard**: Becton, Dickinson and Company (BD) defines BD Insyte Autoguard as the unique push-button shielding mechanism that releases the spring and allows the needle and flash chamber to quickly retract into the safety barrel. The clinician maintains control of the process by deciding when to active the push-button shielding mechanism (BD, 2013).

- **Needle-stick Injury**: A wound caused by accidental penetration of the skin by a needle. Needle-stick injuries can cause transmission of blood borne pathogens (ToolingU, 2012).

- **Blood borne Pathogens**: A microorganism present in human blood and other bodily fluids that can cause disease. Blood borne pathogens include the hepatitis B virus, hepatitis C virus, and human immunodeficiency syndrome (ToolingU, 2012).

1.7 Significance of study

This project was initiated when the Nursing Department at Morehead State University (MSU) initially approached the Applied Engineering and Technology (AET) Department with a request to develop a mechanism that can extract the retracted catheter needles and reset the IV inserters for multiple uses on practice manikins. An investigation was then conducted to discover any currently existing products to fulfill this need. A patent lawyer was hired by the MSU Intellectual Property Department (IP) to assist with the process. Our extensive investigation for
potential commercial solutions that address this issue led to the conclusion that currently there are no such devices available in the market.

This research is built upon the premise that the educational institution uses traditional methods (simulation manikin) to teach their students. However, there is a computer-based method of teaching that allows the students to practice their techniques on a virtual simulator. Engum, Jeffries, and Fisher (2003) conducted a comparative study of computer based vs. traditional intravenous catheter training systems. There are advantages to utilizing virtual simulators such as (Jeffries, Fisher, & Engum, 2003):

- Students can practice with no consequences.
- Reduces the risks associated with the traditional methods.
- If manikins are cheap (not lifelike) there could be very little variability and the students’ growth may be rendered.

A randomized, pretest-posttest experiment design was employed to 163 participants. Of those participants 70 were baccalaureate nursing students and 93 were third-year medical students beginning their fundamental skills training. The ages of students ranged from 20 to 55 years (25 average), 58% female and 42% male where 68% claimed being moderately literate with computers and 25% claimed excellence.

Two educational methods of intravenous catheter insertion underwent comparison. The traditional method of instruction involved a 10-minute informative videotape, instructor demonstration, and hands-on-experience using a plastic manikin arm. The second method involved the students using a virtual reality catheter simulator program. Although these two methods had similar results for the pretest scores, in the posttest the students showed a
significant improvement in “cognitive gains, student satisfaction, and documentation of the procedure with the traditional laboratory group compared with the computer catheter simulator group.” The conclusions was that “Technology alone is not a solution for stand-alone IV catheter placement education. A traditional learning method was preferred by students.” The authors also suggested that perhaps by combining these two educational methods the students’ satisfaction and skill acquisition level would be enhanced.
Chapter 2: Background and Market Review

2.1 Historical review of intravenous injection and Becton, Dickinson and Company

Intravenous injection and infusion began in 1670. In 1853, Dr. Charles Gabriel Pravaz of France and Dr. Alexander Wood of Scotland first developed a syringe with a fine needle to pierce the skin. The first hypodermic syringe had a hollow pointed needle made of steel with a hard rubber “slide” hub. Since then, needle development focused on improvements in fashioning the hollow metal cannula, research into more suitable materials, and refinements in needle point and hub design.

In 1897 Maxwell W. Becton and Fairleigh S. Dickinson founded Becton, Dickinson and Company (BD). It is believed that the company’s first sale was a Luer-all-glass syringe imported from France, at a price of $2.50. BD acquired all the patent rights to the all glass syringe developed by H. Wulfing Luer of Paris, France for $40. Prior to 1924 improvements in the all-glass luer syringe include finger and thumb rests to provide a firmer grip and enable one-handed injection and aspiration, stronger and better flanges to prevent rolling and give a better hold, reinforcements to prevent breakage, and a holder to keep the plunger from falling out.

In 1954, BD produced the first completely disposable syringe, made of glass, for use in a large-scale field test of the polio vaccine developed by Dr. Jonas Salk. During the late 1950’s, BD researchers also launched an all-out effort to find a more suitable material for the manufacture of disposable products. Polypropylene was the answer. BD was the first to introduce polypropylene syringes and pioneered the use of this material for medical products. The new material was inert, nonreactive and did not deteriorate. It was translucent enough that a scale could be put on the barrel to show the amount of fluid within.
In 1962, the company decided to go public to fund the mass production of disposable medical devices, becoming the first syringe and needle manufacturer to make the huge transition from tool and die mechanical engineering to expertise in the new fields of plastics, sterile packaging, industrial applications of microbiology, process engineering on a large scale, and quality assurance. This commitment by BD led to dramatic reductions in blood borne infections in hospitals that were associated with improper re-sterilization of reusable devices.

In 1988, BD introduced the first syringe with a built-in feature to protect healthcare workers from needle-stick injuries. The 3cc BD Safety-Lok syringe was designed with a protective shield that moves forward and locks in place, eliminating the need for contaminated needle recapping.

In 1995, BD introduced the *BD Insyte Autoguard* IV Catheter with push button retracting needle. This product became the leading IV catheter used in the U.S., and the leading safety catheter in the world.

Since 2004, BD has been developing new technologies that include new “microneedle” devices that incorporate ultra-tiny needles roughly the diameter of a human hair. In addition to the potential of minimizing the pain of injection, these devices have the potential of enhancing the therapeutic effectiveness of vaccines and other injectables (BD, 2004).

2.2 Technical assessment of the first generation extraction device

As stated in Chapter 1, this project was initiated in February 2012 when MSU’s Nursing Department requested the Applied Engineering and Technology (AET) Department to develop a tool that will enable safe extraction of the retracted catheter needles in order to allow for multiple reuses of used catheter inserters on simulation manikin. An extensive investigation was conducted in search of potential commercial solutions that address this issue and it was
concluded that currently there are no such devices available in the market. Moreover, currently there are no IV catheter inserters being produced and marketed specifically for training situations in which the associated contamination risk addressed by needle safeguard mechanisms is not relevant. Thus, we developed our own extraction device for extracting retracted catheter needles. This device is developed for use only by certified supervisors in healthcare educational programs in the US and worldwide for providing a safe and cost effective alternative for such programs to conduct intravenous training. The proposed device has five major parts: Split body catheter enclosure, Safety door, Push button mechanism, Spring steel button, and Hinge.

An initial prototype of the device was developed in 2012. The total cost of the product is based primarily on the cost analysis conducted for this earlier model, which estimated that the manufacturing cost of the device would be in the range of $30 -35. The following figures 2.1, 2.2, 2.3 and 2.4 show the progress of the design from the concept, to the 3D virtual model, to the initial working prototype stage.

The device is easy to operate. First, the retracted IV inserter is placed upside down in the catheter inserter slot shown in the device (see Figures 2.2, 2.3, and 2.4), and then the safety door is closed to prevent exposure of the needle during the extraction process. Next, the push button on the top of the device is pressed to extract the needle, and once the push button is in the fully depressed state, the spring steel button located on the door should be pressed to reset the catheter latch. Finally, the safety door is opened and the reset catheter can be removed from the device and is ready for the reuse.
Figure 2.1: Concept Design of the First Generation Extraction Device for Catheter Needles
Figure 2.2: Assembly Drawing with the Bill of Materials

<table>
<thead>
<tr>
<th>ITEM NO.</th>
<th>PART NAME</th>
<th>QTY.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Split Body Catheter Enclosure</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Hinge</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Safety Door</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Push Button Cap</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Spring Steel Button Pin</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Spring Steel Button</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>Push Button Pin</td>
<td>1</td>
</tr>
</tbody>
</table>

Figure 2.3: 3D Virtual Model of the First Generation Extraction Device
Figure 2.4: Physical Prototype of the 2012 Model made on the Rapid Prototyping Machine

The preliminary tests were conducted on the prototype and the shortcomings in the initial prototype were noted. Based on the results of the post development testing performed on the 2012 model, the realized areas for improvement have been implemented into the current redesign.

2.3 Product liability issues

The potential product liability issues are given a thorough consideration during the design process. The following specific actions are taken to address any such issues:

1. The purpose and design of the device was discussed with the KY State Industrial Hygienist, whom confirmed that there are no sterility or biological hazard issues with the device since the reset IV inserters will only be used on practice manikin. Moreover, the
device is intended to be used only by certified supervisors in healthcare educational and training institutions to avoid any misuse. To this effect, a detailed instruction sheet for the safe use and warning labels will accompany each device sold.

2. Originally in the 2012 model when operating the device, the catheter needle would always be submerged inside of the safety tube inside the safety-door, thus eliminating the chances of needle-stick injuries only while the needle was inside the device. However, upon extraction, the user would have to manually place the sheath and cap back onto the catheter needle to enable for reuse. The new design completely eliminates this manual step in the first generation device, thus further enhancing the safety.

2.4 Market Assessment

A recent report published on intravenous access devices market by Transparency Market Research values the global IV access devices market at USD 27.2 billion and this market is expected to grow at 7.8% during the 2013-2019 period (Transparency Market Research, 2014). The University of Michigan spin-off, Tangent Medical Technologies states that the US IV catheters market is worth $1.3 billion. Approximately 275 million to 350 million devices sold every year in America (AnnArbor.com, 2014).

The proposed device has a strong potential to succeed in the US as well as in the international markets. There are an estimated 2420 medical schools in the world. Every year an estimated 389,000 doctors and 541,000 nurses graduate in the world (Frenk et al., 2010). Within the US, there are 141 accredited medical schools; approximately 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies (AAMC.org, 2014). According to National League for Nursing, there are a total of 4503 Nursing Programs in US (Dataview, 2014). Additionally, there are 28
veterinary schools in US and every year approximately 2,700 veterinary students graduate from those programs (National Academies, 2013).

The pie chart below shows the Size of the US Academic market for the proposed extraction device:

![Pie Chart Showing the Size of the US Educational Market](image)

**Figure 2.5: Pie Chart Showing the Size of the US Educational Market**

### 2.5 Commercial assessment

Currently, healthcare educational and training programs around the world all practice the same procedure of simulating IV insertion on practice manikin and dispose the IV inserter once the needle is retracted after a single use. These retracted catheter needles can be extracted manually by jamming something like a paper clip into the safety barrel, but this method is not safe because it leaves the needle exposed for potential injury and would not be allowed under the Needle-stick Safety and Prevention Act of 2001 (Murphy, 2001). Makary et al. (2007) conducted a survey among surgeons in training at 17 medical centers and found that 83% had some kind of
needle-stick injury during training. Thus, there is a need for a device that would not just extract the retracted needle in the IV inserters, but it would do so in a safe manner.

After meeting with the simulations specialist in MSU’s nursing department in 2012, it was understood that this problem was not only a drain on the department’s yearly budget, but it also constrained the students from acquiring the necessary hands-on experience due to financial limitations on the number of IV catheter inserters the department could procure. It was evident that this problem is faced by the most schools across the world. The proposed device provides a mechanism that allows for IV catheter inserters and inserter needles to be safely utilized multiple times for educational and training purposes on practice manikins throughout their life cycle, thereby significantly decreasing equipment usage and disposal costs that would otherwise be incurred by educational and training institutions from single-use disposal of the IV catheter inserters. The device can be utilized to allow for students and trainees to reuse IV catheter inserters and inserter needles for practicing their application on simulation manikins as much as desired, without having to limit the actual hands-on portion due to budgetary reasons, thereby assuring that students are given ample opportunities to acquire one of the most important skills in their profession.
Chapter 3: Conceptualization and Ideation

3.1 Research design (benchmarking)

This project is designed according to an exploratory approach as it relies heavily on qualitative research such as an end-user interview. This type of formulative research is necessary when the purpose of a study is to gain familiarity with a particular phenomenon. There is a need for flexibility in approaching such problems and for allowing the proposed product/process being integrated to solve the said problem to flow and filter naturally through a continuous process of operation of analysis and improvement, hence the redesign.

3.2 Survey instrument used

The instrument used here to gather information in this study was an in-depth interview with the Morehead State University Nursing Departments Simulation Specialist, Mrs. Ruth Huffman. This interview included the use of a camera to record pictures and videos of the needles being used first hand. Mrs. Huffman’s healthcare background is extensive and she has the necessary experience with the tools that nurses use to see areas where they could be improved. She approached the AET Department at MSU in 2012 with a problem she was beginning to realize. The problem was the finite lifecycle of the catheter needles her students were using (Huffman, 2012). Upon delving deeper into the matter it was clear that there truly was an excellent opportunity for a new specialized product development opportunity.
3.3 Concept generation (brainstorming)

3.3.1 Measurement phase

Figure 3.1 shows a BD Insyte Autoguard Catheter Inserter. This was the reference inserter initially used to design the extraction device. In Figure 3.1, on the left side, you will see before activation and on the right side, after activation.

![Image of BD Insyte Autoguard Catheter Inserter](Source: BD, 2013)

Figure 3.1: BD Insyte Autoguard Catheter Inserter

BD Insyte Autoguard Catheter Inserter’s dimensions were measured using dial calipers. Figure 3.2 documents the measured dimensions on the next page.
3.3.2 Concept generation phase

The following three concept designs were generated and compared:

- First generation extraction device
- Portable hand-held extraction device
- Extraction device with customized inserts for different brands of IV inserters
First generation extraction device:

Figures 2.1, 3.3 and 3.4 show concept sketches of the first generation extraction device. Specifically, Figure 3.3 shows upright extraction device design and Figure 3.4 shows the push button mechanism design.

Figure 3.3: Concept sketch showing upright extraction device design
Figure 3.4: Concept sketch of push button mechanism design
Portable hand-held extraction device concept generation:

Figures 3.5, 3.6, 3.7, 3.8 and 3.9 show concept sketches of the portable hand-held extraction device.

Figure 3.5: Initial basic concept of the portable hand-held extraction device
Figure 3.6: Sketch showing a more developed portable device design
Figure 3.7: Sketch describing the function of the portable hand-held extraction device

Figure 3.8: Sketch showing the preliminary dimensions of the portable hand-held extraction device
ReCatheter concept generation:

We call the third concept design as the “ReCatheter” design. In this design, we tried to overcome the limitations of the first generation extraction device, mainly focusing on the flexibility of use of the device for different brands of IV inserter by using specialized inserts. Another important change in the “ReCatheter” design is the addition of a mechanism that enables the needle to extract back into the catheter sheath and cap. This further enhanced the safety and functionality of the device. Figures 3.10, 3.11, 3.12, 3.13, and 3.14 show the concept sketches of the “ReCatheter” design.
Figure 3.10: Concept sketch of the “ReCatheter” design with the specialized insert

Figure 3.11: Sketch showing the functionality of the specialized inserts
Figure 3.12: Sketch showing the extraction device with the insert installed

Figure 3.13: Sketch showing installation of insert using a countersunk screw through the bottom
Figure 3.14: Sketch showing the complete assembly of ready-to-use extraction device with insert

3.4 Concept comparison and scoring

Figure 3.15 below shows side-by-side CAD renderings of the three concept designs described in the previous section for easy comparison.

Figure 3.15: CAD renderings of (a) first generation extraction device, (b) portable handheld extraction device, and (3) “ReCatheter” design
Table 3.1 documents the concepts screening scores for the three concept designs shown in Figure 3.15. As shown in the table, 11 selection criteria were used with varying weights of importance. Each of the three designs were rated on each of the 11 selection criteria on a 0-5 scale, where “0” and “5” stand for the lowest and the highest rating respectively. As can be seen from the table, “ReCatheter” design received the highest total weighted score of 2.9, closely followed by the portable hand-held extraction device design.

Table 3.1 Concept screening table

<table>
<thead>
<tr>
<th>Selection Criteria</th>
<th>Weight</th>
<th>Rating (0 = lowest; 5 = highest)</th>
<th>Weighted Score</th>
<th>Rating</th>
<th>Weighted Score</th>
<th>Rating</th>
<th>Weighted Score</th>
<th>Weighted Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of handling</td>
<td>8%</td>
<td>2</td>
<td>0.16</td>
<td>3</td>
<td>0.24</td>
<td>4</td>
<td>0.32</td>
<td></td>
</tr>
<tr>
<td>Ease of use</td>
<td>10%</td>
<td>2</td>
<td>0.2</td>
<td>3</td>
<td>0.3</td>
<td>4</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Durability</td>
<td>6%</td>
<td>1</td>
<td>0.06</td>
<td>4</td>
<td>0.24</td>
<td>4</td>
<td>0.24</td>
<td></td>
</tr>
<tr>
<td>Ease of Prototyping</td>
<td>8%</td>
<td>2</td>
<td>0.16</td>
<td>5</td>
<td>0.4</td>
<td>2</td>
<td>0.16</td>
<td></td>
</tr>
<tr>
<td>Portability</td>
<td>5%</td>
<td>3</td>
<td>0.15</td>
<td>5</td>
<td>0.25</td>
<td>3</td>
<td>0.15</td>
<td></td>
</tr>
<tr>
<td>Safety</td>
<td>20%</td>
<td>2</td>
<td>0.04</td>
<td>3</td>
<td>0.06</td>
<td>4</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>Repeatability</td>
<td>10%</td>
<td>1</td>
<td>0.1</td>
<td>2</td>
<td>0.2</td>
<td>4</td>
<td>0.4</td>
<td></td>
</tr>
<tr>
<td>Ergonomics</td>
<td>8%</td>
<td>2</td>
<td>0.16</td>
<td>3</td>
<td>0.24</td>
<td>4</td>
<td>0.32</td>
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<tr>
<td>Aesthetics</td>
<td>8%</td>
<td>3</td>
<td>0.24</td>
<td>2</td>
<td>0.16</td>
<td>4</td>
<td>0.32</td>
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<tr>
<td>Cost</td>
<td>10%</td>
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<td>0.2</td>
<td>4</td>
<td>0.4</td>
<td>3</td>
<td>0.3</td>
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<tr>
<td>Serviceability</td>
<td>7%</td>
<td>1</td>
<td>0.07</td>
<td>3</td>
<td>0.21</td>
<td>3</td>
<td>0.21</td>
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</tr>
</tbody>
</table>

| Total Score        | 1.54   | 2.7                             | 2.9            |        |                |        |                |                |
| Rank               | 3      | 2                               | 1              |        |                |        |                |                |
| Continue?          | No     | No                             | Develop        |        |                |        |                |                |

Table 3.1 Concept screening table
Figure 3.16 shows the bar chart of raw scores each of the concept design received on various selection criteria. Again, we can notice that the “ReCatheter” design turned out to be the best alternative. Thus, this particular concept was chosen for further design.

**Figure 3.16: Bar chart of the raw scores of the three concept designs on various selection criteria**
Chapter 4: Detailed Design and Prototype Fabrication

Chapter 4 discusses the detailed parts design, and prototype fabrication of the “ReCatheter” design of the extraction device for retracted catheter needles. The detailed operating instructions for the device are provided in Appendix A.1. The recommended manufacturing process for large scale deployment of the prototype is also discussed in this chapter.

4.1 Detailed Design

The detailed design of the “ReCatheter” concept was developed using SolidWorks 3D Modeling software. On the next page figure 4.1 shows assembly drawing with the bill of material table.
The final design consists of five parts as shown in the Figure 4.1: ReCatheter body, button cap, insert button, push button, insert, and a countersunk screw. The selected material for each part is shown in the bill of material table. As can be seen from Figure 4.1, three different materials are used. These materials were chosen based on the rather moderate frequency of use of the device and small stress loads that will be applied to the device during its operation.
Figure 4.2 below shows the CAD renderings of the final assembly and the exploded assembly of the “ReCatheter” design.

Figure 4.2: CAD renderings of the final assembly and the exploded assembly of the “ReCatheter” design
Figure 4.3: CAD renderings of the final “ReCatheter” design from various angles
Figure 4.3 and 4.4 show the CAD renderings of the final “ReCatheter” design from various angles. Detailed part drawings of the ReCatheter body, button cap, and the customized insert for the BD Insyte Autoguard IV catheter can be found in Appendix A.2.
4.2 Prototype fabrication

After completion of the detailed parts design of the extraction device for retracted catheter needles, three of the five parts (ReCatheter body, button cap, and the customized insert for the BD Insyte Autoguard IV catheter) were fabricated on a Fused Deposition Modeler (Rapid Prototyper). Fused deposition modeling is an additive manufacturing process where the product is formed from the ground up, layer by layer, by heating and extruding thermoplastics (FDM Technology, 2013). Figure 4.5 shows the pictures of the physical prototype made on the rapid prototyping machine. Although this process is great for making prototypes, it is not so ideal when trying to mass produce products. The recommended manufacturing process for this product for mass scale deployment is injection molding.
Figure 4.5: Physical prototype made on the rapid prototyping machine
Chapter 5: Discussion, Future Work and Conclusions

The proposed design of extraction device for retracted catheter needles for multiple reuses on simulation manikins has created an outstanding cost saving opportunity for the healthcare programs all around the world on an annual basis by reducing the amount of IV Inserter / Catheter Needles being unnecessarily disposed of. For every single time a needle can be reused on the practice manikin nearly three dollars could be saved.

Understanding proper intravenous techniques is a crucial skill in the healthcare industry. Such fundamental training should be learned thoroughly through much repetition. It is vital that students get all the practice time inserting catheters into manikin arms that they require. With a device that could provide a way to reuse these catheter needles the healthcare industry would not only save time and money but also improve training provided to students in a cost-effective manner. More importantly, the proposed device will also help reduce the hazardous waste produced by IV insertion training programs all over the world and reduce their carbon footprint.

Section 5.1 provides detailed cost savings analysis for MSU’s Nursing School after the deployment of the extraction device for retracted catheter needles. Section 5.2 discusses future commercialization plan and Section 5.3 lists the equipment and facilities available to carry forward future work on this project.

5.1 Cost savings analysis

Based on the numbers given by MSU’s Nursing School, we determined that they will save 95% of the costs associated with purchase and subsequent safe disposal of IV inserters using the proposed extraction device. The detailed calculations are outlined below:
Costs associated with disposing the IV inserter after a single use:

Individual catheter cost, $2.40 (Approximately 2400 needles/yr.)

Cost of Biohazard Sharps container to dispose, $50.00 (Each box can contain 100 needles)

Total cost = 2.4 * 2400 + 50 * 24 = $6960

Cost savings due to the proposed extraction device:

With approximately 20 reuses, total needles needed per year, 2400/20 = 120

Total cost = 2.4 * 120 + 50 * 2 = $340

Total annual savings = $6960 - $340 = $6620 (95%)

5.2 Future commercialization plan

The primary goal of this research was to complete the design of the extraction device for retracted catheter needles. Now that the main objective is accomplished, it is time to outline the future steps. The following is the commercialization and development plan for the product:

1. **On-field testing**: During the preliminary tests, the proof of concept mostly worked as per the expectations. More rigorous on-field tests will be conducted on the final working prototype in MSU’s Nursing Department to ensure accuracy and precision of various prototype functions.

2. **Intellectual Property (IP) protection**: A “Confidential Disclosure and Record Invention” form has been filled with the Morehead State University’s Office of Research and Sponsored Programs. The Office of Research and Sponsored Programs at MSU has already filed a provisional application to the USPTO for obtaining the utility patent for the proposed design.
3. **Commercialization and product promotion:**

In near future, we plan to seek funding from State and/or Federal Government programs such as Kentucky Science and Engineering Foundation, SBIR/STTR for the commercialization of the product. Depending on the future availability of funding, following activities can be undertaken.

- A strong technical team and a commercialization team can be built with the help from an outside business services consultant.
- In-depth market place analysis can be conducted with the help from the outside business services consultant. This analysis will focus on value to the end-user, value to the university, and how the university can defend its position in the market place.
- Decision on university spin-off vs. licensing the technology can be made in due course of time based on factors such as overall cost to start the new venture, product profitability, etc.
- A detailed commercialization plan can be prepared.

5.3 **Equipment and facilities available for future work**

The project can utilize equipment and facilities available in the AET Department as well as in the Nursing Department of MSU for future work. AET Department’s Siemens sponsored SDMS (Systems Design, Modeling, and Simulation) lab can be used for implementing further changes to the design, and building final working prototypes. This lab has multiple high configuration computers with Product Lifecycle Management applications installed on them. The lab also has a rapid prototyping machine that can be utilized to build the parts of the prototype in future.
MSU’s newly constructed Center for Health Education and Research (CHER) can be used for on-field testing and validation of multiple prototypes. This facility offers state-of-the-art, high definition manikins for testing purposes.

MSU’s Innovation & Commercialization Center can provide all the assistance with commercialization of the technology and product promotion.
Appendix A.1: Detailed Operating Instructions for the Extraction Device for Retracted Catheter Needles

Operating instructions:

1. Place used catheter in the desired slot with the safety button facing to the right.

2. Place the catheter tip inside of the catheter cap then insert the cap into its desired location until it locks in place.

3. Push down until the top button is fully depressed. At this point the needle should be fully extracted.
4. While holding down on the top button push in on the side button with your free hand. This will reset the catheter latch.

5. At this point the catheter is reset and ready for reuse. Open the door and carefully remove the catheter.
Appendix A.2: Technical Drawings

Figure A.2.1: Detailed part drawing of the “ReCatheter Body”
Figure A.2.2: Detailed part drawing of the customized insert for the BD Insyte Autoguard IV catheter
Figure A2.3: Detailed part drawing of the button cap
References


BD Medical. (2004). BD Insyte Autoguard Shielded IV Catheters. Sandy, Utah, US.


"Medical Schools - About the AAMC - AAMC." Web. 07 Apr. 2014. 
<https://www.aamc.org/about/medicalschools/>.


