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Design and Analysis of an Extraction Device for Retracted Catheter Needles for Multiple Reuses on Simulation Manikins

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ABSTRACT

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.

Key words: catheter, simulation manikins, extraction, needle, concept screening, concept scoring, CAD

INTRODUCTION

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) [1]. 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. WulfingLuer 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 [2]. 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. 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 InsyteAutoguard* IV Catheter with push button retracting needle [3]. 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 [1]. Fisher designed a first generation extraction device to reset the IV inserters for multiple reuses during the training situations [4]. 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. There is a computer-based method of teaching that allows the students to practice their techniques on a virtual simulator. Engum, Jeffries, and Fisher [5] conducted a comparative study of computer based vs. traditional intravenous catheter training systems. There are advantages to utilizing virtual simulators such as students being able to practice with no consequences, and risks associated with the traditional methods are reduced [5]. Also if manikins are cheap (not lifelike) there could be very little variability and the students' growth may be hindered. 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 was built upon the premise that educational institution uses traditional methods (simulation manikin) to teach their students.

METHODS & MODELING

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.

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. 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 and use, durability, ease of prototyping/manufacturing, portability, safety, repeatability, aesthetics, cost and 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 [6].

The specific objectives can be listed as follows.

- 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.

General design methodology

The methodology adopted in this research is represented in the flow chart in Figure 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.

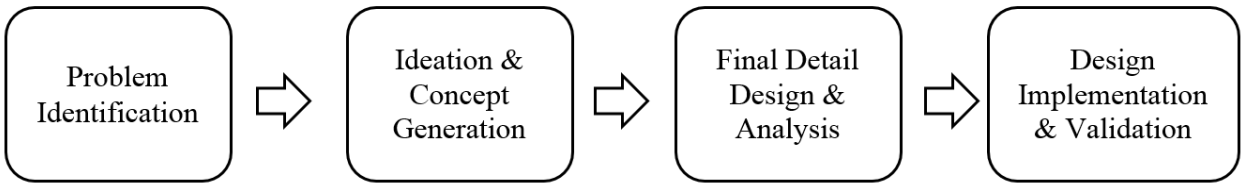


Fig. 1 Flow-chart of the Design Methodology

Potential limitations

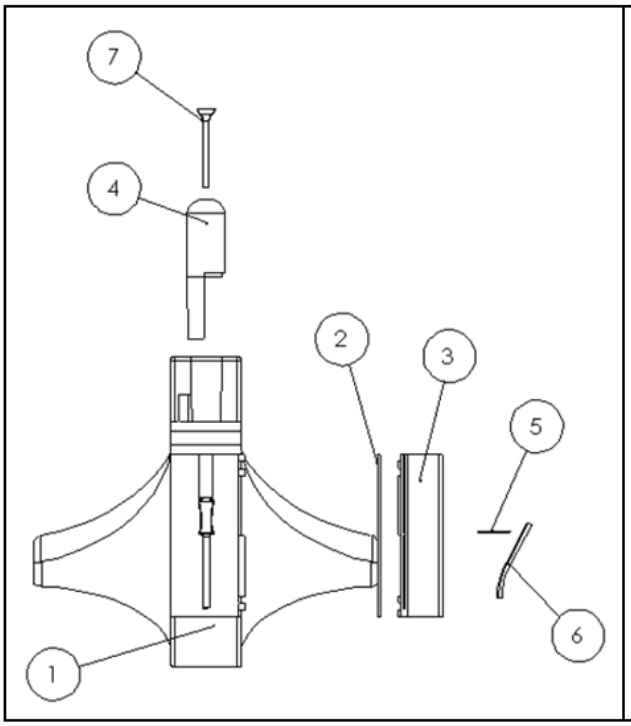
The device is developed for use only by certified supervisors in healthcare educational programs in the US and worldwide for providing a safe and cost effective alternative for such programs to conduct intravenous training. During the development of the design and its future implementation, we have encountered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

- 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 developing nations.

A randomized, pre-test-post-test experiment design was employed to 163 participants [3]. 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 pre-test scores, in the post-test 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 conclusion 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.

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*, *Safetydoor*, *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. Figures 2, 3 and 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, 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.



ITEM NO.	PART NAME	QTY.
1	Split Body Catheter Enclosure	1
2	Hinge	1
3	Safety Door	1
4	Push Button Cap	1
5	Spring Steel Button Pin	1
6	Spring Steel Button	1
7	Push Button Pin	1

Fig. 2 Assembly Drawing with the Bill of Materials

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 Fisher model, the realized areas for improvement have been implemented into the current redesign.

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 Kentucky (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 Fisher 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.

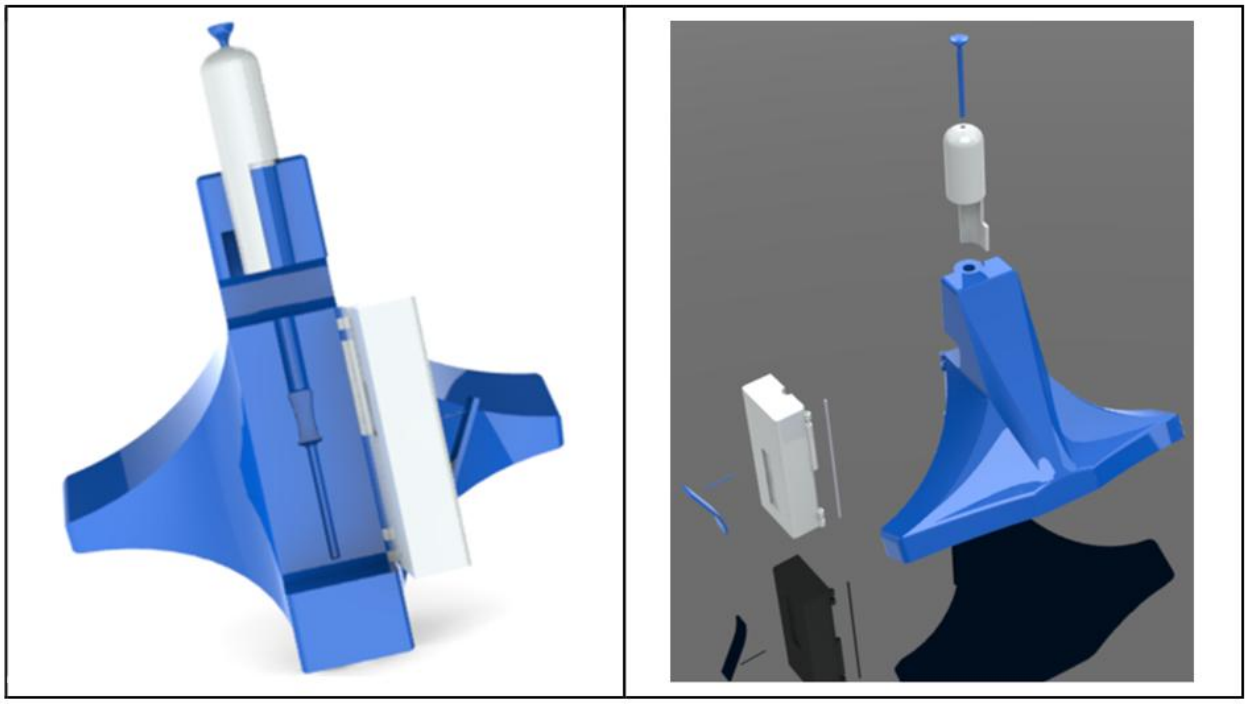


Fig. 3 3D Virtual Model of the First Generation Extraction Device

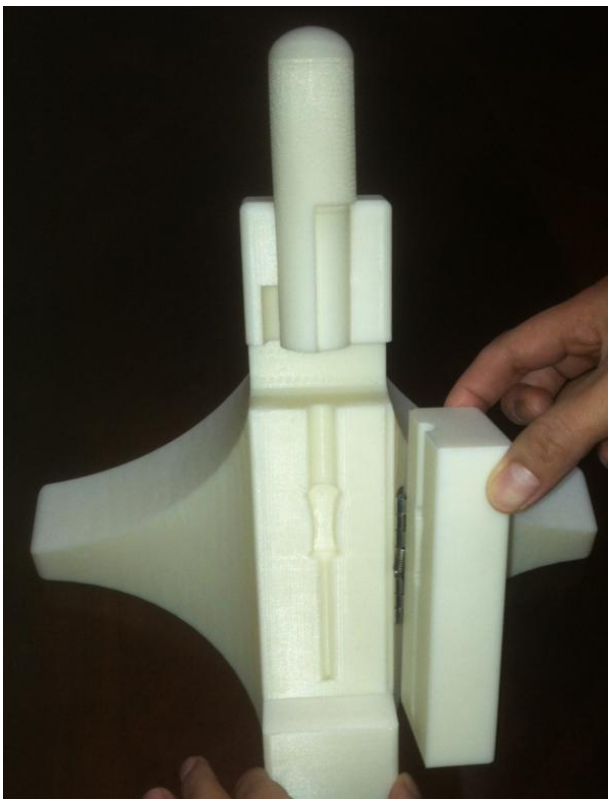


Fig. 4 Physical Prototype of the Fisher Model Made Using a Rapid Prototyping Machine

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 [7]. 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 are sold every year in America [8]. 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 [9]. Within the US, there are 141 accredited medical schools; approximately 400 major teaching hospitals and health systems, including 51 department of veterans affairs - medical centres'; and nearly 90 academic and scientific societies [10]. According to National League for Nursing, there are a total of 4503 Nursing Programs in US [9]. Additionally, there are 28 veterinary schools in US and every year approximately 2,700 veterinary students graduate from those programs [11]. The pie chart in figure 4 shows the Size of the US Academic market for the proposed extraction device.

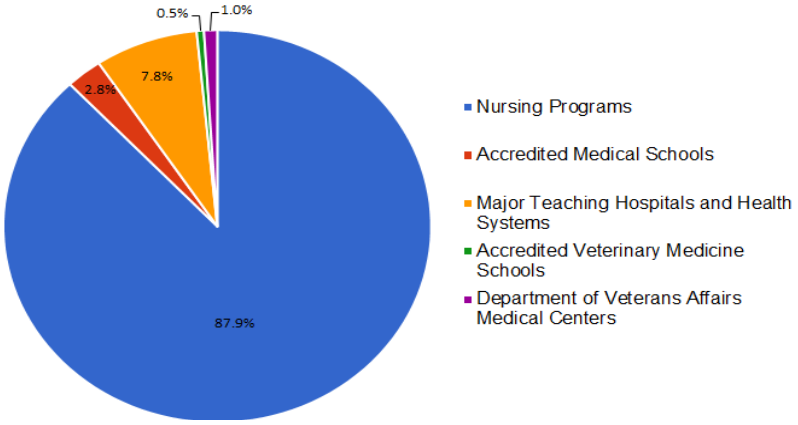


Fig. 5 Pie Chart Showing the Size of the US Educational Market [12]

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 [13]. Makary et al., conducted a survey among surgeons in training at 17 medical centres and found that 83% had some kind of needle-stick injury during training [14]. 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 (Morehead State University)'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.

Conceptualization and Ideation: 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 formative 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. 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 [15-16]. This interview included the use of a camera to record pictures and videos of the needles being used first hand.

Conceptualization and Ideation: Concept generation (brainstorming)
Figure 6 shows a BD InsyteAutoguard Catheter Inserter [17]. This was the reference inserter initially used to design the extraction device. In figure 6, on the left side, you will see *before activation* and on the right side, *after activation*.

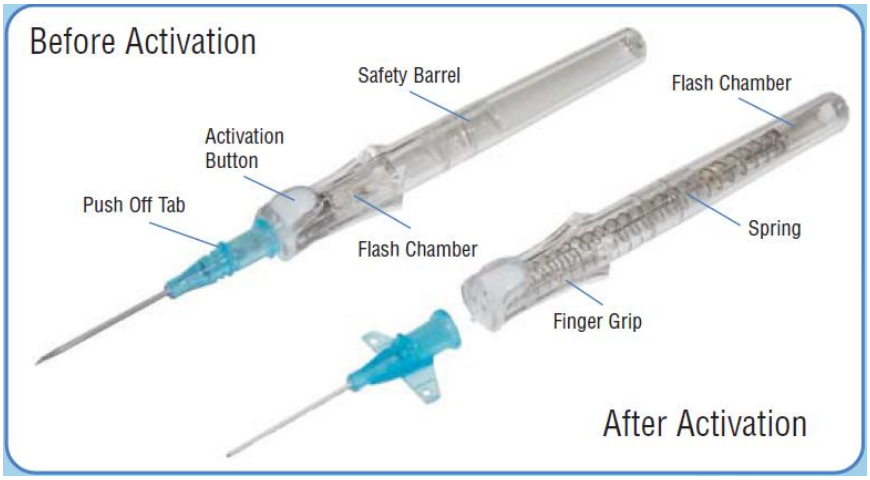


Fig. 6 BD InsyteAutoguard Catheter Inserter [17]

BD InsyteAutoguard Catheter Inserter's dimensions were measured using dial callipers.

Conceptualization and Ideation: Concept generation phase
The following three concept designs were generated and compared; First generation extraction device; Portable hand-held extraction device, and the Extraction device with customized inserts for different brands of IV inserters

Figure 7 show a concept sketch of the portable hand-held extraction device. These sketches are shown to make realise the serious brainstorming and ideation exercises that were performed prior to the actual design using a computer-aided design software.

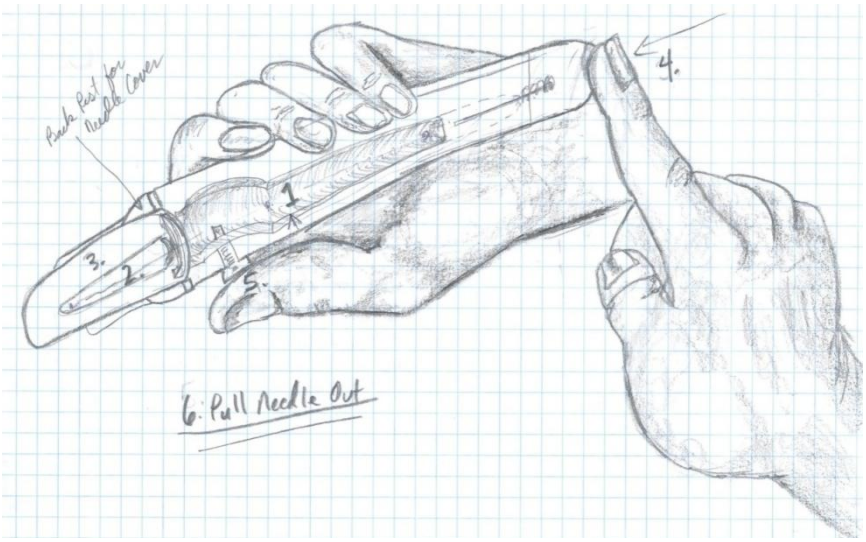


Fig. 7 Sketch showing the two-hand operation of the portable hand-held extraction device

ReCatheter concept generation
We call the third concept design (Extraction device with customized inserts for different brands of IV inserters) 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 inserters 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 8, 9 and 10 show the concept sketches of the "ReCatheter" design.

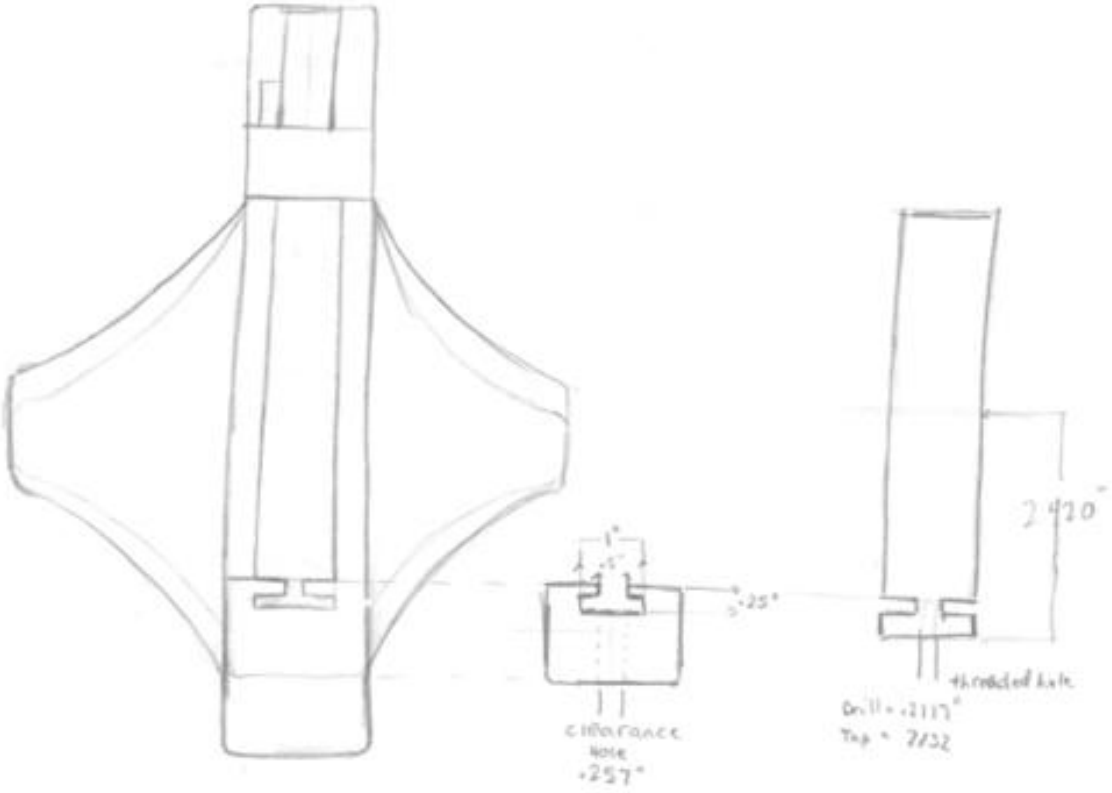


Fig. 8 Concept sketch of the "ReCatheter" design with the specialized insert

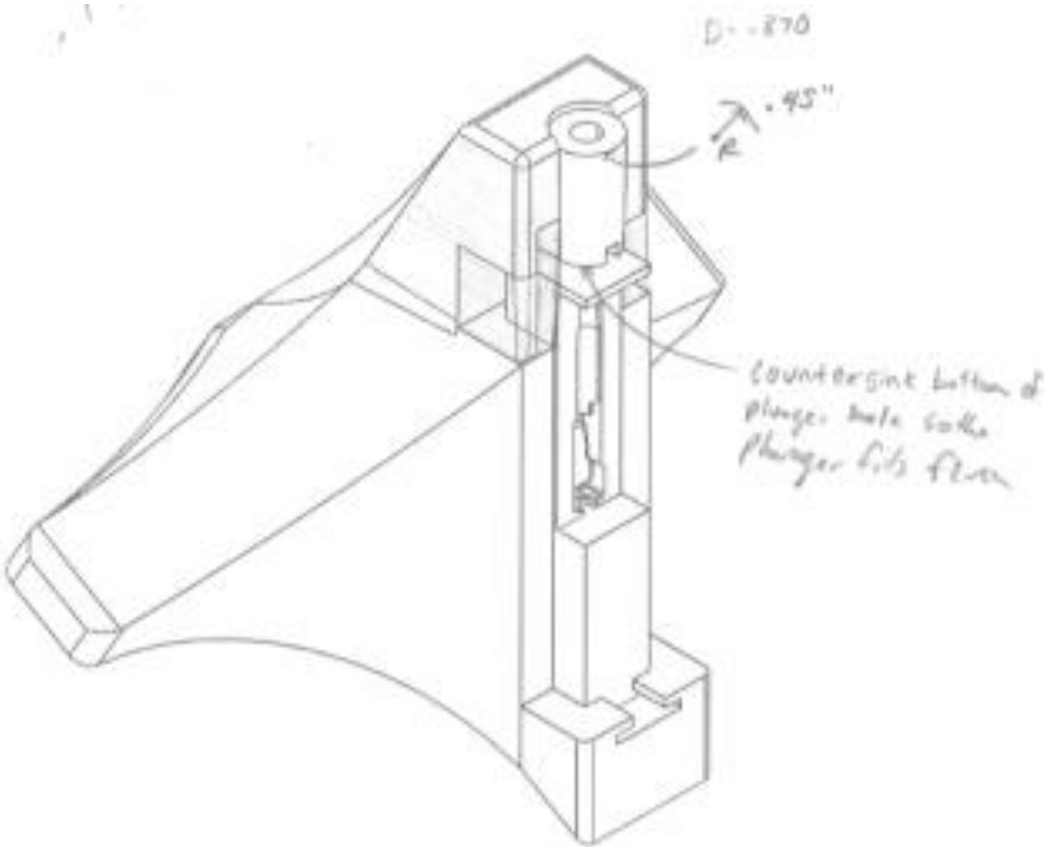


Fig. 9 Sketch showing the complete assembly of ready-to-use extraction device with insert

Fig. 10 CAD renderings of (a) first generation extraction device, (b) portable hand-held extraction device, and (3) "ReCatheter" design

Figure 10 shows side-by-side CAD renderings of the three concept designs described in the previous section for easy comparison.

RESULTS AND DISCUSSION

Concept Comparison and Scoring

Table 1 documents the concept screening scores for the three concept designs shown in Figure 10. 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 -1 Concept screening table [18]

Concept Scoring							
		First generation extraction device		**Portable hand-held extraction device**		**ReCatheter design**	
Selection Criteria	Weight	Rating (0 = lowest; 5 = highest)	Weighted Score	Rating	Weighted Score	Rating	Weighted Score
Ease of handling	8%	2	0.16	3	0.24	4	0.32
Ease of use	10%	2	0.2	3	0.3	4	0.4
Durability	6%	1	0.06	4	0.24	4	0.24
Ease of Prototyping	8%	2	0.16	5	0.4	2	0.16
Portability	5%	3	0.15	5	0.25	3	0.15
Safety	20%	2	0.04	3	0.06	4	0.08
Repeatability	10%	1	0.1	2	0.2	4	0.4
Ergonomics	8%	2	0.16	3	0.24	4	0.32
Aesthetics	8%	3	0.24	2	0.16	4	0.32
Cost	10%	2	0.2	4	0.4	3	0.3
Serviceability	7%	1	0.07	3	0.21	3	0.21
	Total Score	1.54		2.7		2.9	
	Rank	3		2		1	
	Continue?	No		No		**Develop**	

Figure 11 shows the bar chart of raw scores, each of the concept design received on various selection criteria. Again, it can be observed that the "ReCatheter" design turned out to be the best alternative. Thus, this particular concept was chosen for further design. The ReCatheter design has a high score especially when it comes to ease of use, ease of handling, aesthetics, ergonomics and to a decent extent, serviceability. The challenge faced by the ReCatheter design is in portability as expected when compared to the portable device. This is not much of an issue especially when most practice mannikins experiments are conducted on an experimental site. The issue of

safety seems to be almost the same across the three designs. The extraction apparatus seems to fare the worst among the three designs.

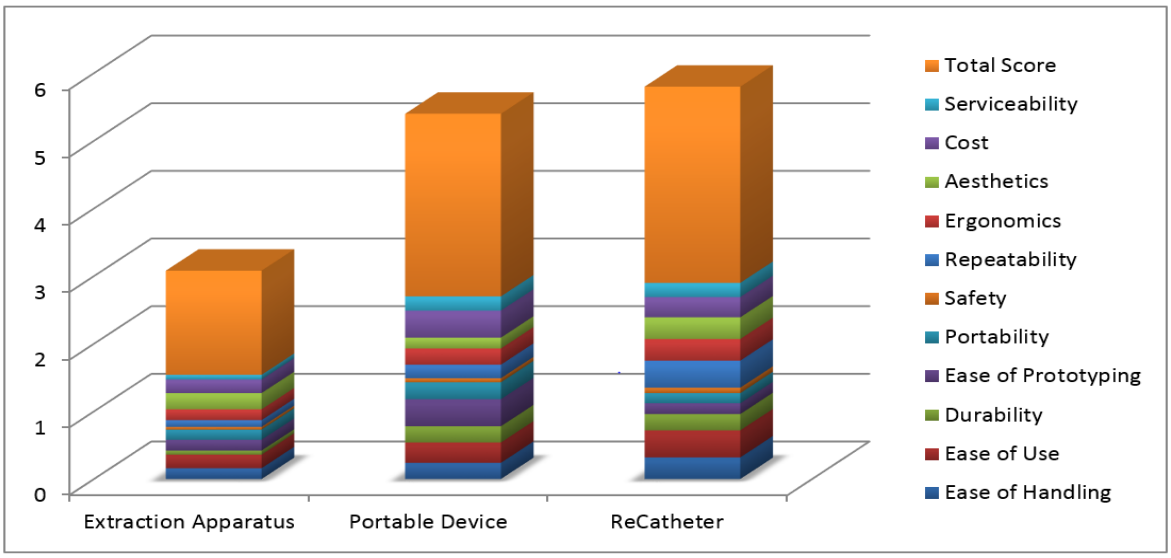


Fig. 11 Bar chart of the raw scores of the three concept designs on various selection criteria

Cost Savings Analysis

A detailed cost savings analysis for MSU's Nursing School after the deployment of the extraction device for retracted catheter needles was performed. Based on the numbers given by MSU's Nursing School, it is determined that there will be a savings of 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%)

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.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 an outside business services consultant. This analysis will focus on value to the end-user, value to the university, and how the design can defend its position in the market place.

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