

Undergraduate Technical Thesis

Designing a Novel Double-Barreled Syringe Device for Ultrasound-Guided Musculoskeletal Injections

Department of Biomedical Engineering


by

Michael Burns
Teodor Calin
Rohan Chandra
Evelyn Grace Park

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Technical Advisor:

Dr. Jeremy B. Kent, Department of Family Medicine

Approved 
Dr. Jeremy B. Kent, Department of Family Medicine

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Abstract

The Fourth-Year Capstone Design Project, involved designing a double-barreled syringe device for Dr. Jeremy Kent of UVA Family Medicine and Athletics Department to aid in ultrasound-guided musculoskeletal injections for athletic injuries. In order to design a double-barreled syringe device, the group needed to understand the current processes and user needs for an improved design. This process of ultrasound-guided injections involves drawing up and injecting two disparate solutions (a local anesthetic and a steroid), while also holding an ultrasound probe. Currently, Dr. Kent and other clinicians draw up each solution into two different syringes and inject the anesthetic into the patient after attaching a needle. Then, the needle remains inside the patient, while the anesthetic syringe is swapped out for the steroid syringe. This is very challenging for clinicians to perform, as they may only use one hand to operate the syringe while the other hand is occupied with the ultrasound probe. The current injection method causes significant discomfort for patients and procedural inefficiency for clinicians. With the help of Dr. Kent, design specifications were determined for ergonomic factors, leakage, and intermixing. The group developed a device to interface with existing syringes that allows solutions to be drawn up or injected from one syringe while blocking the other. This device uses a rotating rod design, which was three-dimensionally (3D) printed using a combination of flexible resins and hard plastic resins. Overall, the device was able to meet the ergonomic design specifications, perform with minimal leakage, and achieve no intermixing of solutions.

Introduction

Ultrasound-guided injections are commonly used to treat and diagnose patients with injuries to the hip, shoulder, or knee. These musculoskeletal injections often involve administration of multiple solutions (ex. local anesthetics and steroids) to targeted regions of the body. Many injection patients are athletes, thus coining the term sports ultrasound in 2015 for diagnosis and treatment in the field of sports

medicine (Daniels et al., 2018). Ultrasound technology allows physicians to accurately achieve injection location and depth, as opposed to previously used “blind” injections.

Despite the increased precision from imaging, the injections are still notably uncomfortable for the patient and difficult for physicians to administer. Currently, a single-barreled syringe is used to perform these injections, but limitations of this design result in discomfort and administration troubles. The positioning of the physician’s hands is shown in Figure 1.

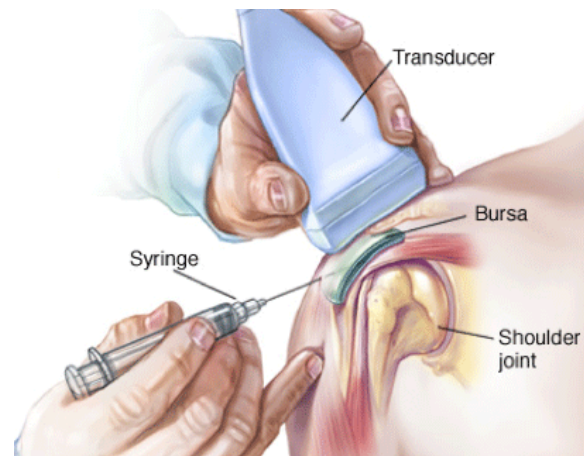


Figure 1: Depiction of current practice for ultrasound-guided musculoskeletal injections. The ultrasound device is shown being held in the left hand while the injection is guided by a standard syringe wielded in the right hand of the same individual (Powell, 2018).

Using a single-barreled syringe, a needle is inserted into the patient with the first solution in the syringe, after injecting the first fluid the needle remains in the patient while the syringe is swapped out for a new one containing the second solution to be injected. Since the current design can contain only one fluid, multiple syringes and needles are needed for injection of disparate fluids. This creates greater discomfort for the patient due to a high number of needle insertions and excess needle movement with syringe attachment. In an effort to reduce patient discomfort and increase physician efficiency, last year’s capstone group designed a double-barreled syringe to hold two solutions at once for independent injection. Their design experienced leakage near the tip and

path-switching mechanism of the syringe and was unable to maintain stagnant pressure in one barrel while the other syringe plunger was engaged. The goal of this year's work was to build off the work done by the 2020-2021 capstone team to modify or create a design that can functionally inject two fluids without leaking or mixing and adhere to clinical parameters set by medical professionals.

Prior Art

Previous designs of double-barreled syringes have been made for use in dental surgery and care. Kozem and colleagues filed a patent for a "successive delivery multiple barrel syringe". This design uses two syringes with the intent to dispense each barrel successively through the use of one hypodermic needle. This design uses two independent mechanisms to control the flow of liquid from each barrel to the exit point at the needle. A screw mechanism is utilized on the side of each syringe snout to block fluid flow. The novel double-barreled syringe design utilizes a central rod mechanism that rotates within a central chamber to block flow at the point at which the two syringe pathways converge. By using a single central control mechanism to block flow, the source of any potential leakage is localized and can be remedied in a more efficient manner (Kozam et al., 1978). A major shortcoming of this design is that the switching mechanism requires multiple hands to operate. Another previous instance of a "dual syringe" was patented by Pizzino in which a slide or rotary valve is used to change which barrel is in communication with the needle. Although this design has many similarities to the novel design (multiple barrel delivery system with minimal mixing and leakage), it requires that the liquids be dispensed in a predetermined order. Due to the nature of the valve starting at one end of the barrels' snouts, one has to dispense the liquid in the nearest barrel before moving the valve inward to allow for the next barrel to be dispensed. The novel double-barrelled syringe design's central rod mechanism for switching between the two barrels can be done in any order, eliminating the need to predetermine barrel position and composition (Pizzino, 1986). Another patent

design from Pizzino entitled "dual syringe for either simultaneous or sequential injection of liquids" is another design involving multiple-barrel successive delivery. The key feature in this design is a rotary valve controlling flow that is capable of three positions instead of the two positions seen in many previous designs. The third position allows for both syringe flows to occur and results in simultaneous discharge of both syringes. This position is not needed for the novel double-barreled syringe design which is intended for sequential musculoskeletal injection. A three-position mechanism would be superfluous if included in the final double-barreled syringe design (Pizzino simultaneous). The previous designs are specialized for different functions and are insufficient to meet the aims and specifications set out by the project.

Hypotheses and Aims

The goal of this year's work is to build off the work done by the 2020-2021 Capstone team to modify or create a design that can functionally inject two fluids without leaking or mixing and adhere to clinical parameters set out by medical professionals.

The primary aim is to design and use a 3D printer to create a functional prototype that adheres to appropriate clinical specifications. After discussing with Dr. Kent, the following clinical specifications have been identified: The device must be able to draw and dispense solution from one barrel without contaminating the second, able to be used comfortably with one hand, be compatible with the standard luer lock needle attachment, be compatible with different syringe volumes, and be disposable after one use. Additional requirements and needs may be determined throughout the iterative design process and communication with medical professionals and/or patients. It is hypothesized that after two semesters of work, a functional prototype would be able to be created that meets the five requirements stated above.

The first step in validating the hypothesis will be to identify and design a set of test parameters that will accurately determine the success of

each design specification in relation to the overall functionality of the device. Testing the device for leakage and pressure will be among the parameters set to determine the success of the syringe.

Secondly, prototypes will be adjusted as needed with an iterative engineering process to optimize design specifications and reduce material waste. After testing the prototype, the design will need to be modified using Fusion 360 to meet all of the clinical requirements, along with patient and physician needs. Modifications will be informed through continuous communication with current patients and physicians that are participating in the ultrasound-guided injections and researching clinical standards. This process will continue until a functional prototype of the device is produced.

The second aim relies on the success of the first aim. The plan is to identify and assess stakeholder interest and marketability within relevant populations within UVA Health communities. The final design will be shown to medical professionals within the UVA Health System to gauge interest in the device. Additional communication with medical device companies could follow to determine whether the device could be licensed to a larger company with infrastructure for manufacturing. It is hypothesized that there will be provisional interest within the UVA Health System for the double-barreled syringe device.

It is the hope that by developing a double-barreled syringe, ultrasound-guided musculoskeletal injections will be more easily performed by physicians. By improving physician efficiency, it is expected that patients will experience less pain from the injections.

Table 1: Design Specifications

Design Constraint	Unit of Measure	Marginal (Acceptable)	Ideal Value	Final Value
Does Not Leak	mL	0	0	0
Degree of Solution Separation	% (mL/mL)	0-5	0	0
Clinical Operability	Clinician Approval Scale (1-5)	4-5	5	
Width	mm	35-50	45	45
Height	mm	110-130	120	99.50
Thickness	mm	23-27	25	17
Mass/Weight	g	20-35	20	20.599
Stable Luer Lock Interface	mm of interfacing device movement	0-0.5	0	0
Fluid Volume	% (mL/mL)	0	0	0

Design Specification Generation

The design specifications for the project are presented in Table 1. Discussion with Dr. Kent highlighted the issue the 2020-2021 group had with leakage in the mechanics of the design. Understanding this to be the primary setback of the project, a self-contained vessel with functionality while avoiding leakage became the primary objective. The design specifications pertaining to the degree of solution separation is imperative to the autonomous functions of both syringes, with the acceptable values being approved by Dr. Kent. Single-handed device operability was explicitly requested by Dr. Kent. This request was measured by the design specifications of width, height, length, and weight dimensions, which was developed based off of the 2020-2021 design. Clinician approval rating was measured to indicate efficacy and receptivity within the clinic, and assess the ergonomic features of the device. A stable luer lock interface is crucial to the overall function of

the design and leakage prevention, so by referencing clinical standards of care it was determined to be imperative. Having accurate volume measurement for patient injection is essential to ensure safe, effective distribution of numbing medication and steroid solutions. These design specifications were developed in collaboration with Dr. Kent, with acceptable and optimal values for each displayed in Table 1.

Materials and Methods

In order to develop the double-barreled syringe device, the design process began with conducting literature reviews and investigating similar technology. The aim was to assess previous art with two syringes next to each other leading to a needle with a novel switching mechanism to understand possible approaches for the project. Advisors were consulted in the Biomedical Engineering (BME), Mechanical Engineering (ME), and Architecture departments to brainstorm possible solutions. Suggestions included a stopcock-like design from Dr. Guilford of UVA's BME Department, and then a simple design meant for dual injections by Professor Dart in the ME department. Using this input, designs were developed in an iterative process throughout the year.

The design process consisted of weekly design sprints. This included brainstorming ideas, applying these ideas to designs, developing prototypes of the design, and testing based on the design specifications. The team met each week with Dr. Kent to discuss the successes and pivot points of the sprint for the week and used his feedback to guide us through the next sprint and make design decisions. The largest design decisions are highlighted in the Decision Tree in Figure 2.

Design Methodology

The first decision the group faced was to continue with the 2020-2021 capstone group's design or develop a new design from scratch. The 2020-2021 capstone group described that the device was unable to properly draw and inject without leaking, which was confirmed by testing the device in the Fall. Small iterations

were performed that may improve the functionality of the previous device, however after considering the design specifications as determined with Dr. Kent, a decision was made to explore other options with less components, thus reducing the opportunity for leakage.

Several broad design concepts were brainstormed, which diverged into two paths: using existing syringes or 3D printing the syringe bodies and plungers. After looking into the design of standard syringes and the complications resulting from the 3D-printed syringe bodies from the 2020-2021 group's design, it was decided to pursue a design that uses existing 5mL syringes. This decision also introduced the need for stable male and female Luer locks to secure the syringes and the needle, along with a syringe holder to stabilize the syringes during the injections.

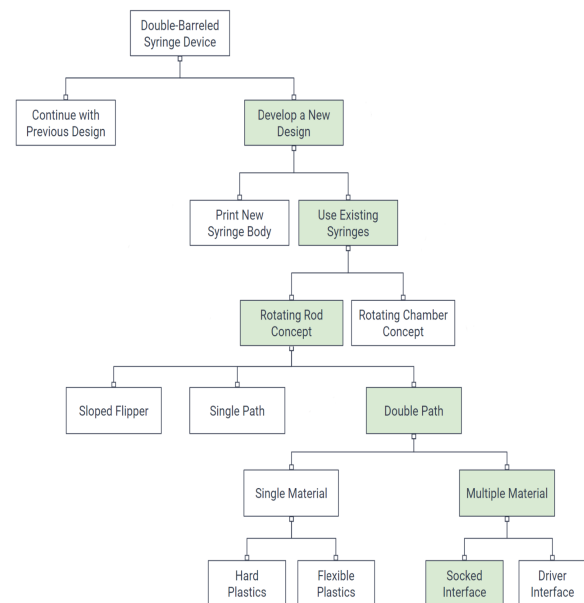


Figure 2: Decision tree for the iterative design process. The branches chosen to reach the final design are highlighted in green.

Once the decision was made to use a syringe holder for existing syringes, two main design concepts were discussed (Figure 3). The first design was a rotating chamber design. This design has a syringe holding device, luer locks, a snout containing two channels for fluid flow, and a rotating chamber that restricts fluid flow in one channel while allowing fluid flow in the other. The rotating chamber design resembles the concept from the 2020-2021 design, however it attempts to solve the leakage problem faced last year with the addition of silicone O-rings to work as better sealing elements when rotation occurs. The rotating rod design consists of a syringe holder attached to a tip that contains a cavity for a center rod. The center rod is inserted in the slot in the barrel holder and rotates in order to block one syringe's fluid path while the other is open (for drawing up or injection). Both designs were developed on AutoCAD Fusion and 3D printed in FormLabs Clear V2 Resin. After iterating upon both designs for approximately two months, the rotating rod design was selected as it utilized less components and proved to hold a tighter seal, thus limiting leakage.

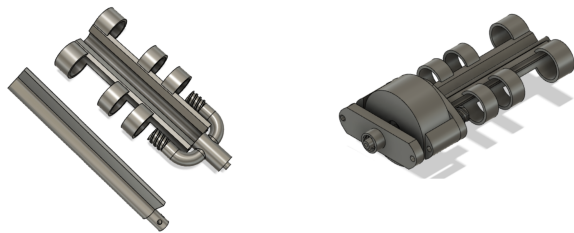


Figure 3: Rotating Rod vs. Rotating Chamber

The tip of the center rod was then iterated upon to find the most optimal design. Sloped tip, single path tip, and double path tip designs were developed and 3D printed in both hard (FormLabs Clear V2 Resin) and flexible (FormLabs Flexible 80A) resins (Figure 4). In both materials, the double path design held the tightest seal, evident by its lack of leakage and air bubbles. In assessing the best material to use, the flexible resin held the tightest seal, however, when the rod was rotated it would deform under the force. Three main designs were created to

test different materials and their applications: a.) Single Piece Hard Plastic Rod + Tip, b.) Single Piece Flexible Plastic Rod + Tip, c.) Hard Plastic Rod + Flexible Tip (“Combination Driver Design”), and d.) Hard Plastic Rod + Flexible Sock (“Combination Sock Design”). As shown before, design A was not successful because an all-hard plastic rod had too much friction to easily rotate back and forth, and it also introduced leakage. Design B deformed when rotated, so this design was also proven unsuccessful. It was determined based on these tests that a combination of both hard and flexible plastics were needed in order for the rod to function properly. Design C utilized a concept similar to a Phillips Head Screwdriver in which a hard plastic rod was attached to a flexible tip using a cross design. This design also allowed for too much deformity during rotation. Design D used a thin flexible “sock” surrounding the hard plastic rod, and this design was ultimately chosen as it reduced leakage and deformity upon rotation.

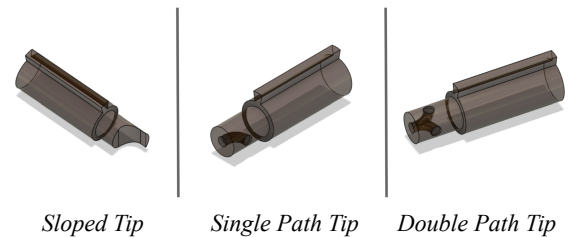


Figure 4: Center rod tip design

Results

After iterative cycles spanning the course of design and in pursuit of a successful mechanism, a final design was reached. A picture of the final printed prototype, with syringes attached, is shown in Figure 5 along with a Computer-aided design (CAD) rendering of the assembled device. The engineering drawings from each of the three pieces in CAD are shown in appendices 1A, 1B, and 1C.

The final design's injection procedure is as follows:

1. Insert syringes into the double-barreled holder and twist to lock with Luer locks.

2. Attach a needle to the tip of the device.
3. Flip the rod to the direction of the steroid syringe.
4. Draw up steroid solution into the steroid syringe.
5. Flip the rod to the direction of the anesthetic syringe.
6. Draw up fluid into the anesthetic syringe.
7. Inject the patient with the anesthetic solution.
8. Flip the rod in the direction of the steroid syringe.
9. Inject the patient with the steroid.

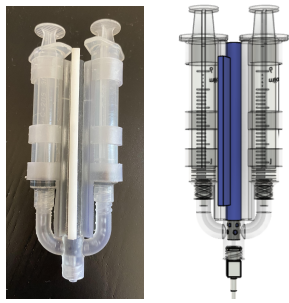


Figure 5: Final Design. The left shows the 3-D printed and assembled prototype. The right shows the final CAD assembly.

A series of tests were performed with the final iteration of the device to validate success. Tests were designed to generate metrics comparable to set design specifications. The tests performed, along with the results are outlined below.

Leakage

The problem of leakage mitigation was the primary focus for much of the design process and motivated much of the iteration in pursuit of a leakage free mechanism. Leakage was initially measured by visual inspection with each design. At each iteration a qualitative location and amount (vast vs. miniscule), along with a quantitative number of locations was noted. For the final design the level of leakage was assessed by simulating a musculoskeletal injection in an open system with water. The volume of leakage was used to determine whether the leakage parameter has been met or not. When the device was injected quickly, there was a small amount (less than 1 mL) of leakage.

There was no leakage, when the device was injected slowly.

The “leakage” parameter expanded into not only fluid leakage, but also aspiration of air bubbles leaking into the syringe. The pressure within the syringe was determined by observing air bubbles and physical resistance when simulating the injection. If the syringe is a complete vacuum, this means the fluid channel is not aligned properly and the draw for injection will fail. If there are air bubbles when the fluid is drawn up, this means the seal within the syringe device is not secure and the injection will fail. In order to be successful, the syringes must be able to draw fluid with no air bubbles and minimal resistance. The final design displayed minimal air bubbles when the solution was drawn up slowly, along with minimal resistance.

All other design specifications were tested under the assumption no leakage was present, as these issues which were attributed to production methods, and not design issues, would be mitigated by improved production mechanisms (ie. injection molding).

Degree of Solution Separation

The test used for evaluation of solution mixing included food coloring dyed water being drawn into one chamber and undyed water being drawn into the other. The device was shaken for 10 seconds and the flipper position was changed. Then, with the flipper in the proper orientation, the clear water was expelled from the device out of the channel. By a visual analysis there was no mixing as this expelled water had no characteristic green color. Using this as a determination, it is concluded there is 0 mL solution mixing in the final design. Alternative methods of testing include pH testing or solutions with different viscosities to get more accurate values.

Clinical Operability and Approval

To gain clinical operability and approval metrics of the final design, a survey was created in Google Forms to capture the opinions of clinicians (doctors, nurses, therapists, etc.). The survey included the questions and accompanying

answer choices observed in Table 2. All data collected was not used to generate the final operability metric, but was also used to assess device marketability or desire.

Table 2: Questions, answer choices, and final values for clinical operability and approval survey. The survey was conducted on 10 individuals from across the University of Virginia community. Individuals of a multitude of backgrounds were included for attainment of a holistic rating. Scales range from 1(worst) to 5(best).		
Question	Answer Choices	Results
(1) “Please denote your profession below”	Nurse Physician Other	Nurse (66.7%) Physician (11.1%) Other (22.2%) (Clinical Student, Medical Student)
(2) “How comfortable are you holding the device?”	Scale: 1 (not comfortable) - 5 (very comfortable)	Average: 4.8
(3) “How easy is it for you to use the flipper to switch between syringe settings?”	Scale: 1 (difficult) - 5 (very easy)	Average: 5
(4) “How easy is it for you to draw liquid through the device?”	Scale: 1 (difficult) - 5 (very easy)	Average: 4.4
(5) “How easy is it for you to dispense liquid through the device?”	Scale: 1 (difficult) - 5 (very easy)	Average: 4.7
(6) “Would you prefer using this device more than using two syringes separately?”	Yes No	Yes (100%) No (0%)

The survey was administered to any individual who had clinical knowledge and experience with syringes and were comfortable using one. All participants were given the final prototype and a short explanation of what it does. They were

then asked to use, feel, and play with the prototype and any questions asked were answered by the surveyors. After being given time the participant was prompted with the survey and asked for feedback.

The first question was included to understand the study population, which will be important for future steps. Questions 2-5 were included to obtain a final value on clinical operability by a single hand (the intended clinical application). The final clinical operability value was determined by averaging the survey output of these four questions, yielding a single value of 4.725. The sixth question is aimed at determining whether the clinicians approved of the overall design and concept, providing a basis of demand for the product. This demand was established as shown by the 100% preference over current solutions.

Dimensions

The prototype dimensions were assessed by measurement with no needle attached to the end, but the two 5 mL syringes were included in their slots. It is important to note the syringes were fastened into the luer locks and the plungers were included, but pushed all the way down (as when no liquid is being held). As provided in Table 1, the width is 45 mm, height is 99.50 mm, and mass is 20.599 g.

Mass/Weight

Similar to the dimensions, the mass was obtained with and without two 5 mL syringes attached, but no needle in either measurement. The mass of the device itself is 20.599 g, which meets the desired design specifications. With the syringes and plungers, this mass increases to 121.787 g, making the device about ¼ lb. for the clinician to hold.

Luer Lock Interface Stability

Male and female luer locks were used in the design for attaching syringes and the needle respectively. The luer lock interfaces for this design were generated in the Fusion 360 CAD models using the “Luer Fitting Generator” from Ortus Lab, available online. To assess the

stability of these interfaces the device was fastened such that only the attached piece (syringe or needle) was able to move. The final value for this specification was 0 mm.

Fluid Volume

The fluid volume remained the same before and after injection, meaning that all of the fluid drawn up was injected. The amount of fluid remaining in the device was negligible, as it was less than 1 mL and could not be measured.

Discussion

After extensive iteration and testing, the final prototype was able to meet many of the design specifications outlined in the initial aims of the project. The design reached acceptable levels of degree of solution separation (0%), one handed operability, dimensional constraints, and appropriate fluid volume retention. There were a few discrepancies with several design specifications. Most notably, the final prototype struggled with sporadic leakage issues when fluid was drawn or dispensed at a very fast rate. However, when used at a slow and controlled pace, the prototype did not leak. Additionally, the stability of the luer lock interface could be improved which may also provide an avenue for fixing the leakage issues.

Limitations

Over the course of the design iteration process with Form Labs Form 2 Printers, a lack of precision and repeatability was discovered with the current manufacturing process. It was found that performing identical prints of the prototype resulted in different results when undergoing experimental testing against optimal design specifications. The scale of layer length at which the printers were operating was not small enough to guarantee the level of precision required to create a functional prototype that needed to form a water-tight seal. Therefore, it is recommended to upgrade the manufacturing means for continuation of the project in order to improve accuracy and precision. This could be done ideally with injection molding or a higher quality precision 3D printer.

Ethical Considerations

There are numerous ethical considerations to explore as updated manufacturing processes are explored. For example, the potential for large amounts of plastic waste that could contribute to the already large amount of waste occurring within the medical device field. Another consideration is the misuse of the device in the context of injecting drug users. The misuse of this technology in the hands of those who would reuse this device to inject substances is potentially dangerous to individuals. However, syringe exchange programs and proper syringe disposal methods can mitigate the perils of this misuse as has been shown in areas prone to disease spread through drug apparatus (Springer et al. 1999).

Future Directions

While the design met the design requirements, in order to become a marketable product, there are several steps that could be taken by future engineers. To increase the uniformity of the design, a different manufacturing process, such as injection molding, would need to be utilized. This process would help hold a tight seal among all devices, and would reduce manufacturing costs if more than 100 devices were to be produced. Injection molding is a process that syringe manufacturers, such as Becton Dickinson, Cardinal Health, and Novo Nordisk, are already using. For future work, students could look into licensing the double-barreled syringe device to one of these medical device manufacturers. Based on the licensing agreement, additional steps could be taken in terms of FDA Approval and intellectual property. It was determined through research that patenting this device would not violate claims made in the patents of devices used as prior art. The option of submitting a 510(k) Premarket Notification Application was explored with a standard syringe as the predicate device. In order to prove substantial equivalence, future students may complete testing for ISO 7886-1 (sterile hypodermic syringes for single use), ISO 80369-7 (Luer connections), USP 36-NF 31<85> Bacteria Endotoxin Limit, Biocompatibility, ISO 19033

(Cytotoxicity, Skin Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Pyrogen Test, Hemolysis Test, Particulate Test), and Labeling via 21 CFR 801.

Moving toward the critique of the functional prototype, the current researchers acknowledge that improvements can be made to improve the design. There exists some unwanted motion in the rod that controls the flipping mechanism of the design. Some possible remedies include adding a protruding ridge and a corresponding channel in which to lock it into place. This will help the rod lock into an axially stable position so that pressures from the device during liquid drawing and dispensing will not dislodge the rod from its position at the interface of the two syringe paths. In addition to building upon the logistics of commercializing the double-barreled syringe device, future students may make design enhancements to improve the ergonomics of the device. The device currently has some sharp edges and thick plastic components, which were not noted by clinicians when assessing the device, however they may pose a potential hazard. This reduction in thickness can help a user have more freedom with needle angle upon insertion of the ultrasound-guided injection. There could also be improved tolerance values to allow the syringes to slide more easily into the double-barreled device. The device design could also be adjusted to limit the amount of plastic being used, which would reduce medical waste caused by using this single-use device. Because the device does not directly interface with human tissue, it may be possible to sterilize and reuse this device. The lifecycle of this device could be reassessed in future works after further research of sterilization strategies and FDA requirements.

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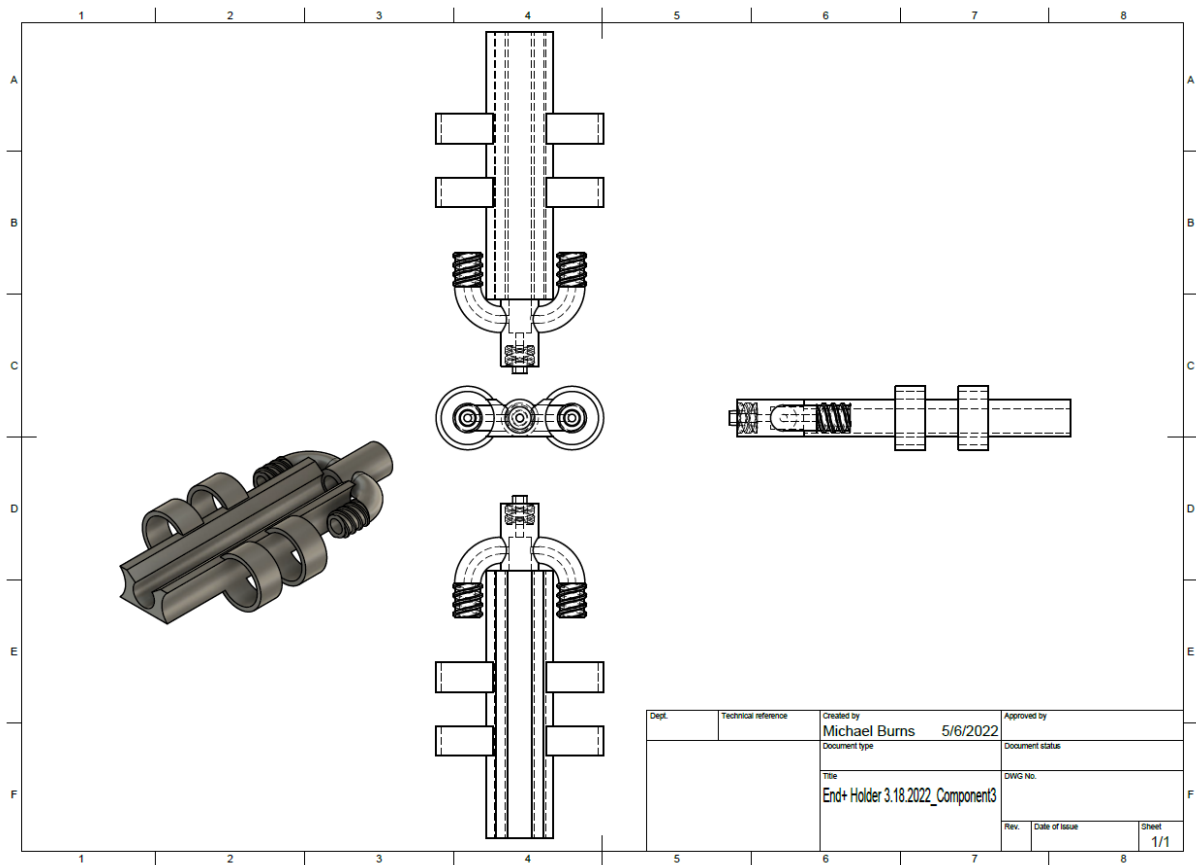
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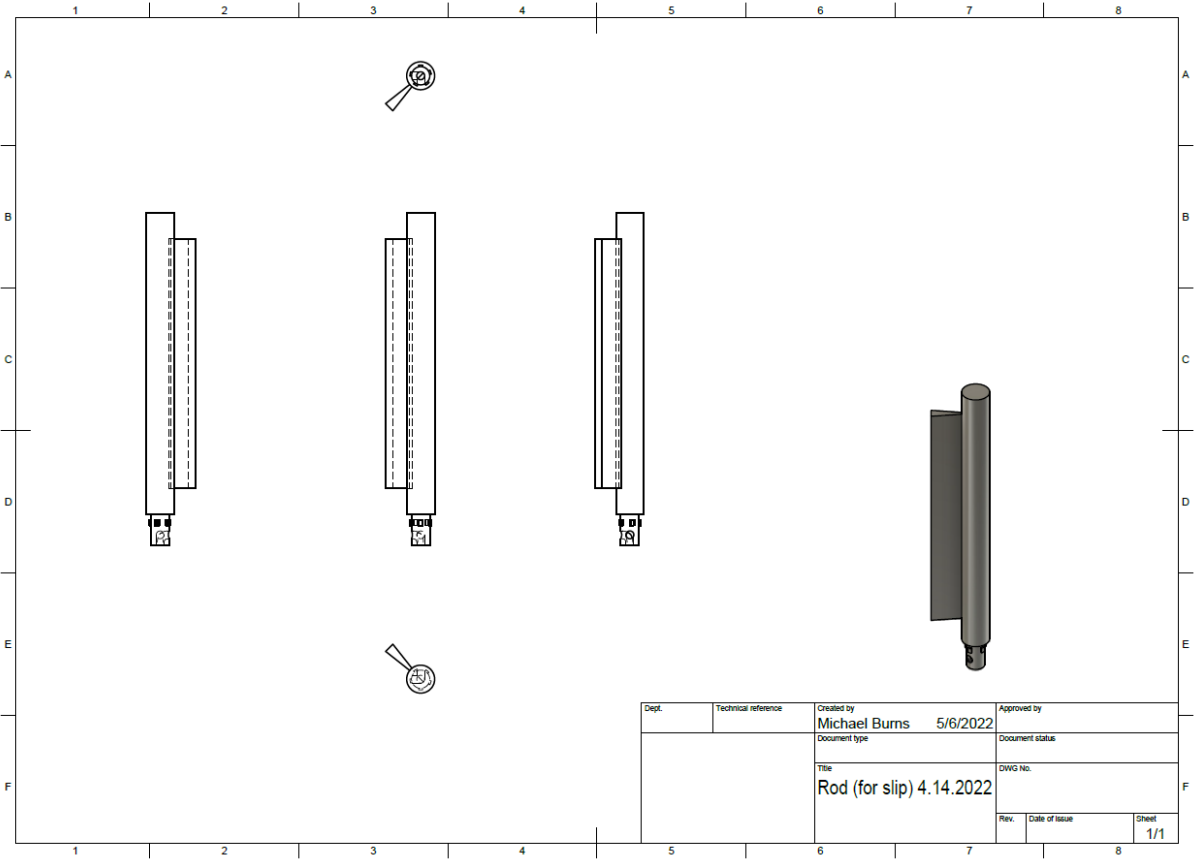
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Appendices
Appendix 1A:



Appendix 1B:



Appendix 1C:

