

**Design, testing and calibration of a small syringe for use with a power injector (Power Injector Syringe)**  
**Project Design Specifications**

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**Client:** Dr. Charles Strother

**Function:**

Angiography is a technique to produce x-rays of the inside of blood vessels, and over 1.6 million procedures are conducted yearly on humans alone. A small amount of contrast medium is injected through a syringe at the point of interest, which allows the image to show up clearly. Power injector syringes are the preferred delivery method, because they allow accurate amounts of medium to be dispensed at a constant rate. Currently, no small volume (0.2- 3 cc) syringes are available for small animal studies. Our goal is to design, construct, test, and calibrate a small syringe compatible with commercially available power injector.

**Client Requirements:**

- Design should deliver appropriate amount of contrast medium (0.2-3 cc) into the small animal
- Syringe must meet all medical device standards
- The device should be latex-free, clear material designed with a calibration system to prevent over-injection
- Syringe should be easy to load with contrast medium

**1. Physical and Operational Characteristics**

- Performance Requirements:** The device must be compatible with current power injectors. It must successfully deliver 0.2-3 cc of contrast medium. It must be easy to use and robust enough to ensure performance during loading or while the power injector is operating. The syringe must be able to load contrast medium easily as well.
- Safety:** The syringe must be properly calibrated and volumes must be properly labeled. The syringe must be clear enough for identification of bubbles present in the contrast medium or any that develop during contrast loading. Prevention of air bubble development must be included in the design. The device must not break

during operation in the power injector. There can be no latex in the design due to allergy concern. The syringe must be able to be cleaned and sterilized. A safety lock to prevent overdriving the piston should be incorporated into the design as well.

- c. **Accuracy and Reliability:** The syringe must deliver volumes consistently for each injection sequence. The accuracy of volume delivered should be  $\pm 2-3\%$ .
- d. **Life in Service:** The syringes should be disposable and used only one time.
- e. **Shelf Life:** The devices will likely be stored in a cabinet or similar space in or near the room the procedure (i.e. angiography) takes place. Components should not degrade easily over time. Typically, this is not a problem for rubbers, plastics, or glass.
- f. **Operating Environment:** Environment will typically be at room temperature. The syringe will be subjected to high pressure from the power injector. Other power injector syringes are rated to 1200 psi, so the syringe must be developed to withstand high pressures as well. The device will be filled with contrast medium used for angiographies, so it should not interact chemically with such substances.
- g. **Ergonomics:** The syringe will have to be easy to install and replace from the mechanism hardware. Ease-of-use is also important in the syringe design, so over-injection of contrast medium is impossible.
- h. **Size:** The design must fit the current machine, which holds 200 cc syringes. No alteration to this device can be done. The actual syringe must be capable of dispensing 0.2-3 cc measurements of contrast medium into the connector tubing to the catheter.
- i. **Weight:** The device has no true restrictions on weight.
- j. **Materials:** The syringe must be made of clear, latex-free material to ensure that no air bubbles are developing.
- k. **Aesthetics, Appearance, and Finish:** The syringe must appear professional and clean. Additionally, the device must have clear measurement markings to facilitate its use.

## 2. Product Characteristics

- a. **Quantity:** We will produce one working 0.2-3 cc syringe compatible with 200 cc power injecting equipment.
- b. **Target Product Cost:** Typical power injector syringes used in angiography procedures cost around \$10-\$20 per syringe, so this design will be similar to those values.

## 3. Miscellaneous

- a. **Standards and Specifications:** The final product must meet medical device standards.
- b. **Customer:** The intended user of this device will be researchers who are conducting angiographies of small animals and doctors working with patients who need angiographies done with small amounts of contrast medium.
- c. **Patient Related Concerns:** The designed syringe must not over-inject the rats with contrast medium, and must prevent air bubbles from developing in the syringe from loading. The device must be ergonomic, so inexperienced administrators may be able to correctly use the syringe.
- d. **Competition:** Many companies sell large syringes, but very few have developed small capacity syringes like the one being devised in this project. Therefore, there would be very little competition to this design.