operation (expansion and contraction) will be performed in SolidWorks and using established analytical solutions to bellows behavior to maximize mechanical performance[illegible].

A simple method was devised to fabricate the convoluted bellows geometry using a lost-wax like technique[illegible]. Polyethylene glycol (PEG) replicas will be produced by replica casting in silicone rubber molds. Parylene will be deposited over PEG replicas, and then the PEG will be dissolved by immersion in warm water to release the Parylene bellows structure. We will use a modified process that enables rapid production of reliable bellows from precision machined molds (Fig. 11). Bellows mechanical performance will be verified in load deflection experiments in a custom test fixture that allows computer controlled pressure regulation of a compressed nitrogen source. Vertical deflections will be recorded with a compound microscope having 1 µm resolution. Bellows will be subject to batch-to-batch testing to verify repeatability of the manufacturing process.

Figure 11: Side view of prototype polymer bellows (left) at rest (right) expanded.

Actuators: Actuators will be assembled by filling the bellows with electrolyte (double deionized water) and bonding to the electrode base with biocompatible adhesive[illegible]. Constant current will be applied to the actuators using a computer controlled current source. A custom test fixture that incorporates a drug reservoir and catheter will be used to confirm desired pumping performance. Pumping at different currents will be performed confirm a wide dynamic range of flow rate capability to satisfy user needs. Precise timing of activation will be controlled through the software user-interface. Flow rate is calculated from measurements of pumped volume; a 2 µL air bubble is introduced into the tubing and tracked with a stereomicroscope and micrometer. The influence of catheter diameter (3.2-5 Fr) and length (1, 2, 4, 8 cm) will be determined. Operation under backpressure (11 mmHg is the venous pressure of the mouse) will be evaluated (over 5-20 mmHg). To determine the effect of temperature, experiments will be conducted with the test fixture submerged in a temperature-controlled water bath (between 22-40 °C). Flow rates of solutions have different viscosities will be determined (0.5-5 cP) using standard sugar solutions[illegible]. Viscosity will be verified using a Cannon-Fenske capillary tube viscometer at 37 °C. Bolus (intermittent power) and continuous (continuous power) delivery will be demonstrated. At the conclusion of these studies, precise and repeatable dosing will be demonstrated.

Refill port: The refill port is formed from a silicone rubber septum housed in medical grade polymer pump housing. This design is based on our previous ports suitable for >20 uses with non-coring 30G needles[illegible]. The refill port will be accessed repeatedly with non-coring 30G needles and tested for leakage as described previously[illegible]. Pressurized and non-pressurized conditions will be tested. The following standards will be applied to production of the refill septum: ASTM F2038 - 00(2005) Standard Guide for Silicone Elastomers, Gels and Foams Used in Medical Applications Part I - Formulations and Uncured Materials, and ASTM F2042 - 00(2005) Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II - Crosslinking and Fabrication.

3.2 Objective 1B: Pump component integration

Check valve: A commercially available check valve will be packaged in-line using heat-shrinkable flexible tubing, a technique developed during previous research efforts[illegible]. Check valve operation under forward and reverse pressure will be verified. Cracking pressure under forward flow conditions will be assessed. Reverse pressure of 5-20 mmHg will also be applied. We have built an apparatus that enables the controlled application of forward and reverse pressure to a packaged valve.

Micropump housing: To date, the pump housing has been fabricated through rapid prototyping utilizing a 3D stereolithographic (SLA) process. The housing materials were coated in a thin protective Parylene C