




# MEDISAVER: Verification and Validation

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# Outline

- Verification Plans
  - Validation Plans
  - Proof of Concept Testing
  - Project Updates
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# Verification

- ▶ Physical Measurements
  - ▶ Weight, Width, Portability
- ▶ Experimental Testing
  - ▶ Temperature Dependence, Prep & Deliver Time, Ease Of Use, Invasiveness
- ▶ Biological Testing
  - ▶ Onset of Absorption, Dose Accuracy, etc.
- ▶ Product Testing
  - ▶ Durability, Activation Force
- ▶ Miscellaneous Testing
  - ▶ Safety, Cost, Longevity

# Verification Tests

Specification	Test
Weight	Scale
Width	Ruler
Portability (Volume)	Water Displacement
Temperature Dependence	Heat & Cool device -> then use
Invasiveness	Measure Injection Depth
Application Site Side Effects	Measure Size of Damaged Gel
Ease Of Use	Qualitative Measurement with 3 <sup>rd</sup> Party Users
Onset Of Absorption	Measure in vivo concentrations after certain time points
Plasma Concentration over time	Measure in vivo concentrations after certain time points
Dose Accuracy/Variability	Inject and measure non-injected volume
Durability (Fall)	Drop from 1 meter and inject
Durability (Compression)	Load using axial loading machine (400N) and inject
Longevity	Qualitative (Could only do over long period of time)



# Biological Testing

- ▶ Cannot Actually Perform Biological Tests on patients within the time frame
- ▶ Would require approval from FDA and probably years of paperwork
- ▶ Use other metrics, like injection depth, injection time, to estimate
  - ▶ Would use same medicant



# Product Testing

- ▶ Durability will be assessed by measuring injection depth, injection time and volume delivered after certain tests
- ▶ Two types of Durability are being tested:
  - ▶ Fall Durability
    - ▶ 1m fall, then test
  - ▶ Compression Durability
    - ▶ Axial Load 400N, then test



# Validation

- ▶ Series of Injections with Ballistic Gel
- ▶ We will have a friend who carries an EpiPen be our 3<sup>rd</sup> party tester
- ▶ Simulate the process of anaphylactic shock from start to finish
  - ▶ Pocket to injection time
  - ▶ Injection time, Distance, Volume
- ▶ Working on gel recipes to mimic fat tissue
  - ▶ Will also use cloth to mimic clothing



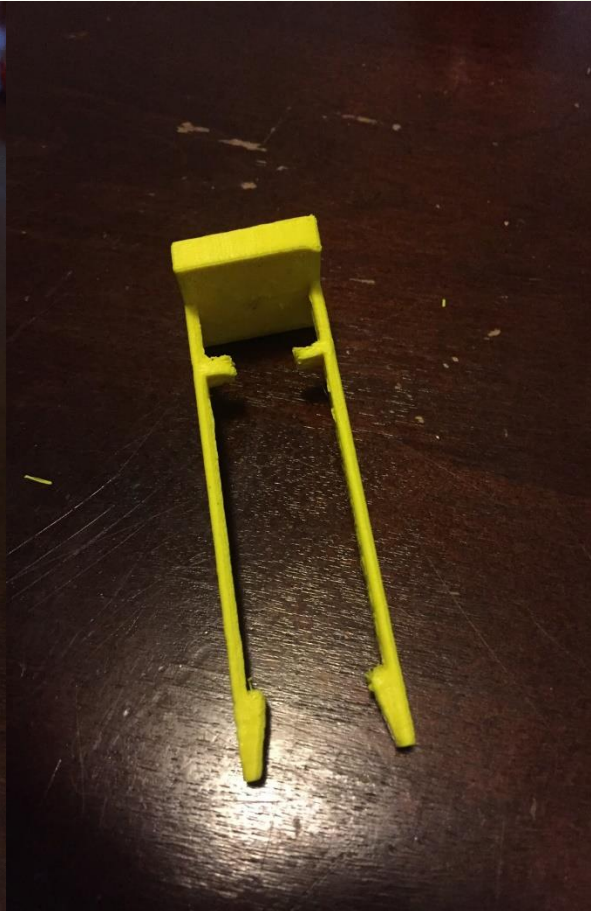
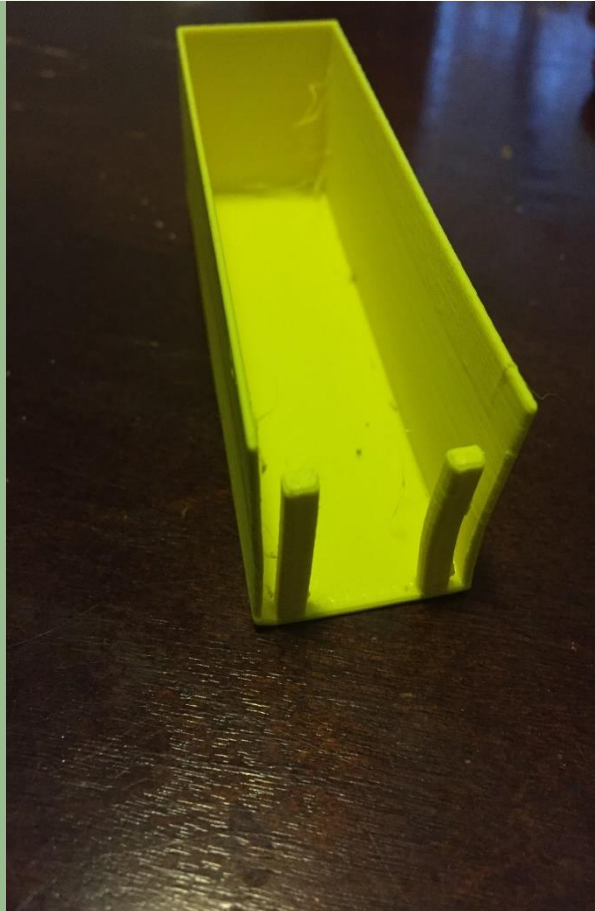
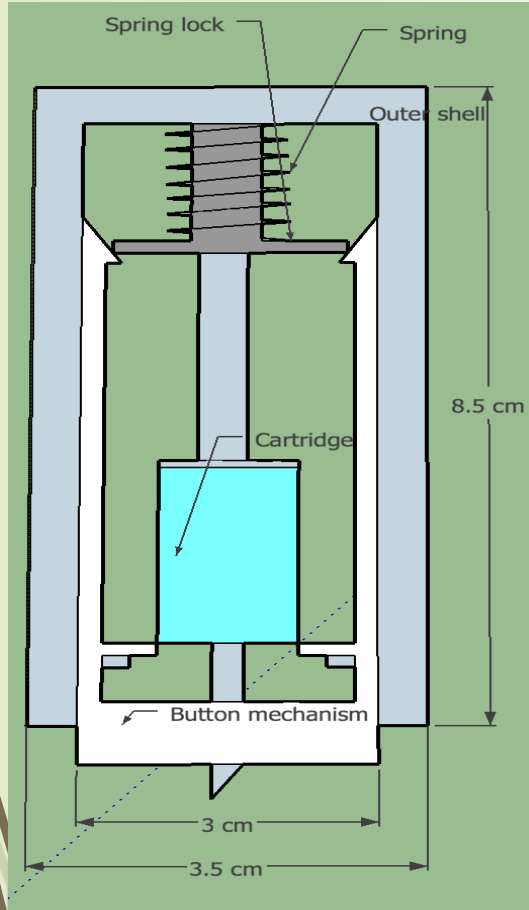
# Proof Of Concept Testing



- ▶ Feasibility of Using a Small Needle (6mm) to achieve a reasonable injection depth
- ▶ Problems with 3D printed parts
  - ▶ Measurements
  - ▶ Thickness (Spring force too high)
- ▶ Used Spring and Plunger in Series to Test with Ballistic Gelatin (6mm needle)
  - ▶ Average Injection Lengths of 21 mm
  - ▶ Other injectors ~ 28-29 mm
- ▶ Next Step: Investigate different spring constants, needle sizes, plungers



# Project Updates





# Thanks for Listening

➤ Any Questions?

