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MEMS 411: The Pill Cutter

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SP21 MEMS 411 Mechanical Engineering Design Project

The Pill Splitter

The goal of this design project was to improve the current method of pill cutting for STL Hills Pharmacy. Pharmacists and other medical professionals cut hundreds of pills weekly. Their current methods can only cut one pill at a time with an error rate of 50%. Pills are often split without enough precision and need to be thrown out. Our project was designed to have a 10% maximum error rate, require 1/4 of the force, and split pills 4 times as fast.

To accomplish these goals, we designed a guillotine system controlled by a lever. In contrast with the current methods, our design cuts from a 90°angle. When paired with the increased force from the lever arm, this reduced the error rate to an acceptable range. The lever arm also significantly decreases the amount of force required by the user. To increase the speed of pill splitting, a removable tray with three holes for pills was added. This tray prevents the user from needing to place their hands under the blade, and decreases the chances of the pills moving. Finally, to increase the re-usability of the splitter, we utilized lead screws to secure the blade. After the blade dulls the machine can be closed, the screws can be removed, and the blade can be taken out and replaced.

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1 Introduction

The goal for this design is to make an ergonomic pill splitting device, which can precisely, and easily split pills of many sizes to halves, or quarters. This is common for veterinarian pill dosages, and more frequent, small size pills, expected for prescription-based medicine.

Upon interviewing a Pharmacist from the STL Hills Pharmacy who interfaces with an existing machine to split hundreds of pills daily, it was clear that the necessity for a robust mechanism is evident. It is not uncommon for the pharmacists to "crumble", or wreck 40% of the pills that they attempt to cut, due to predominantly pill slippage, and poor blade entry.

Typically, the existing pill splitters used by smaller pharmacies, like the one identified as our customer, are single cut splitters. This means that the mechanism is designed to cut, and split a singular pill at a time. This is due to the fact that prescription orders are filled out sequentially, as needed, to preserve pill expiration, which decays once the pill is 'opened' by the mechanism. Hence, it is not of utmost urgency to improve the pill splitter's maximal pill capacity per slice. Hence, it is more likely to improve upon some existing devices, which will be discussed in the following section.

2 Problem Understanding

2.1 Existing Devices

Several alternative pill cutting tools are currently sold. The following are three major competing designs from three different companies.

2.1.1 Existing Device #1: Apex Deluxe Pill Splitter

Figure 1: Apex Deluxe Pill Splitter (Source: Amazon)

Link: https://www.amazon.com/Apex-Deluxe-Pill-Splitter-splitter/dp/B000EGP5DC

Description: The Apex Deluxe Pill Splitter is the current pill cutter used by our customer. It is made of a transparent hard plastic material with a wedge to hold the pill and a tray to catch the cut pill. The cutter is manual and cuts via a lever arm. The blades are not replaceable, but can be cleaned when opened. The Apex pill cutter is designed to cut one pill at a time.

2.1.2 Existing Device #2: Equadose Pill Splitter

Figure 2: Equadose Pill Splitter (Source: Amazon)

Link: https://www.amazon.com/Equadose-Splitter-Cutter-Crafted-Doubles/dp/B00U84Q8OK/ref=sr_1_1_sspa?crid=29ZZH0LZKXMK5&dchild=1&keywords=equadose+pill+splitter&qid=1612376955&sprefix=equadose%2Chpc%2C173&sr=8-1-spons&psc=1&spLa=ZW5jcnlwdGVkUXVhbGlmaWVyPUExMDZQWk9JTl
Description: The Equadose Pill Splitter is a metal pill cutter with a plastic pivoting cover to retain cut pills. Blades on the Equadose Pill Cutter function via manual compression. These blades are not sharp to the touch but provide a safe cutting feature. A single pill can only be cut in half at a time but any shape works with this model.

2.1.3 Existing Device #3: The Pillcut Multiple Pill Splitter

Figure 3: Pillcut Multiple Pill Splitter (Source: Amazon)

Link: https://www.amazon.com/Multiple-Splitter-Alignment-Splitting-Quartering/\dp/B00JMHZ5BG/ref=sr_1_22?dchild=1&keywords=Swiss+large+pill+cutter&qid=1612377437&sr=8-22
Description: The Pillcut Multiple Pill Splitter is comprised of two stainless steel pieces. The bottom piece holds multiple pills (number limited by the size of the pill) while the top contains the separating blade. This blade is not replaceable. The bottom portion has two bars that pinch pills to secure them for cutting.

2.2 Patents

2.2.1 Dual-blade Pill Cutting Device (Patent #: US010772802)

This patent offers an alternate method with which to split the pills in half, with two sliding blades instead of the conventional single blade. The motion of both blades is suggested to reduce the amount of pill fracturing and subsequent waste by performing more of a cutting motion than a crushing motion. The blades also have a concave indent to cup the blade around the pill so as to cover as much surface area as possible with the blade and further reduce fracturing.

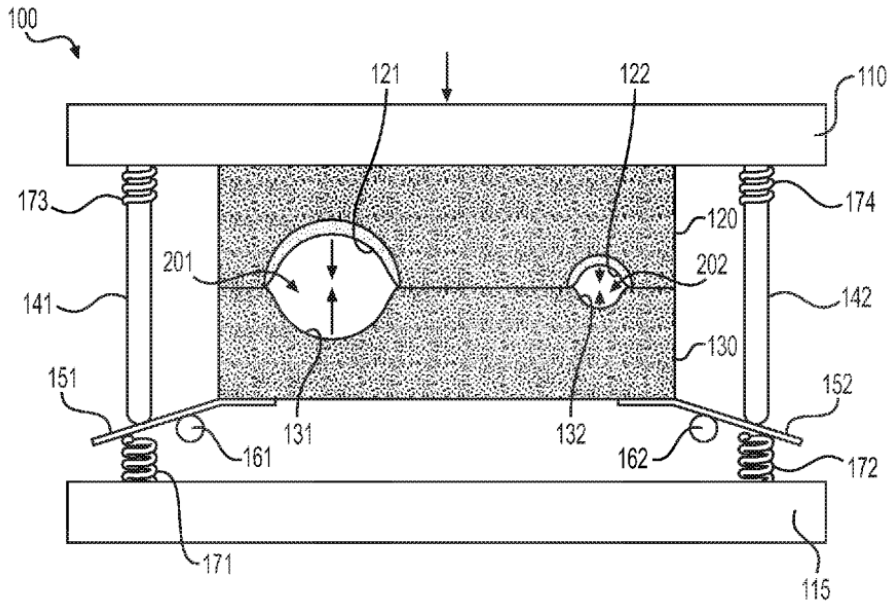


Figure 4: Patent Image for dual-blade pill cutter

2.2.2 Combination Pill Cutter and Crusher Pliers Patent #: US010864141

This mechanism proposes a handheld pliers-type device that allows both pill cutting and crushing. The user clamps both handles simultaneously to move the jaws with the blade to split the pill one at a time. The main advantage of this patent is that it is a very portable device, used with one hand and therefore not requiring any counter space.

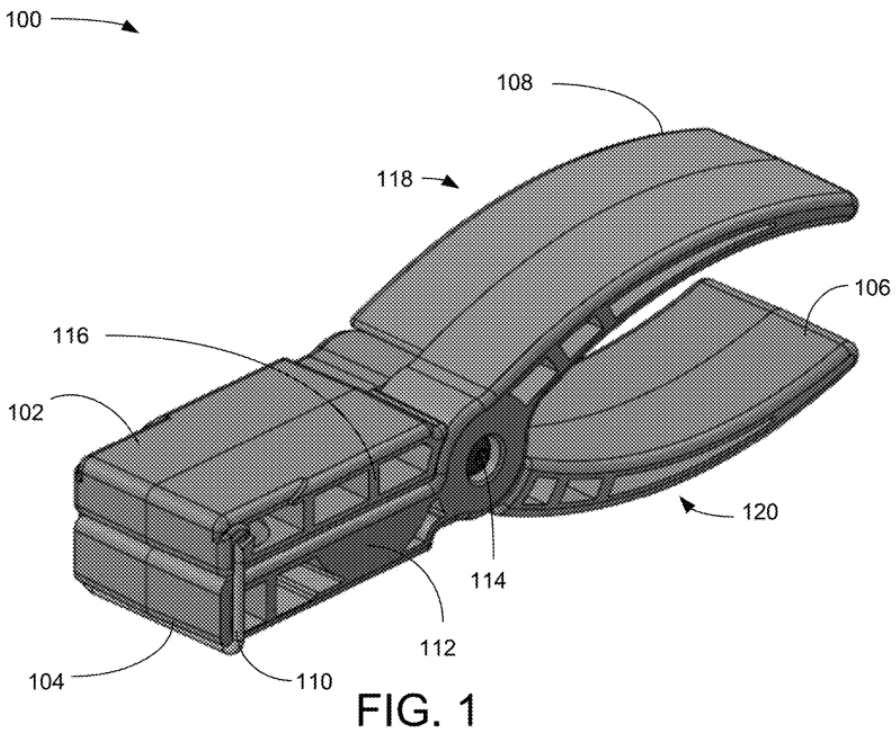


FIG. 1

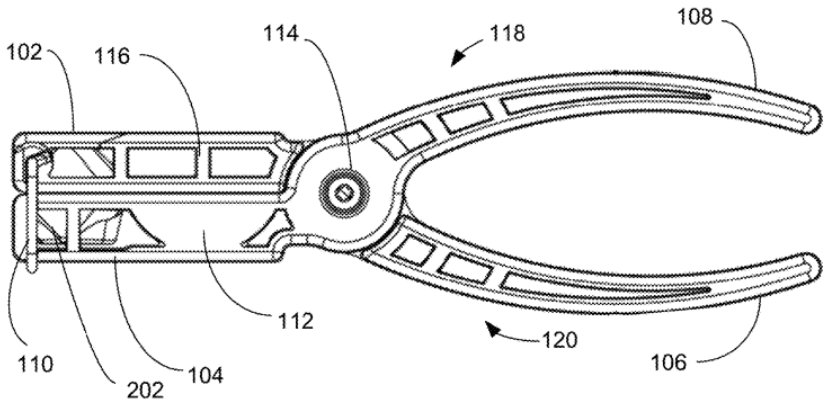
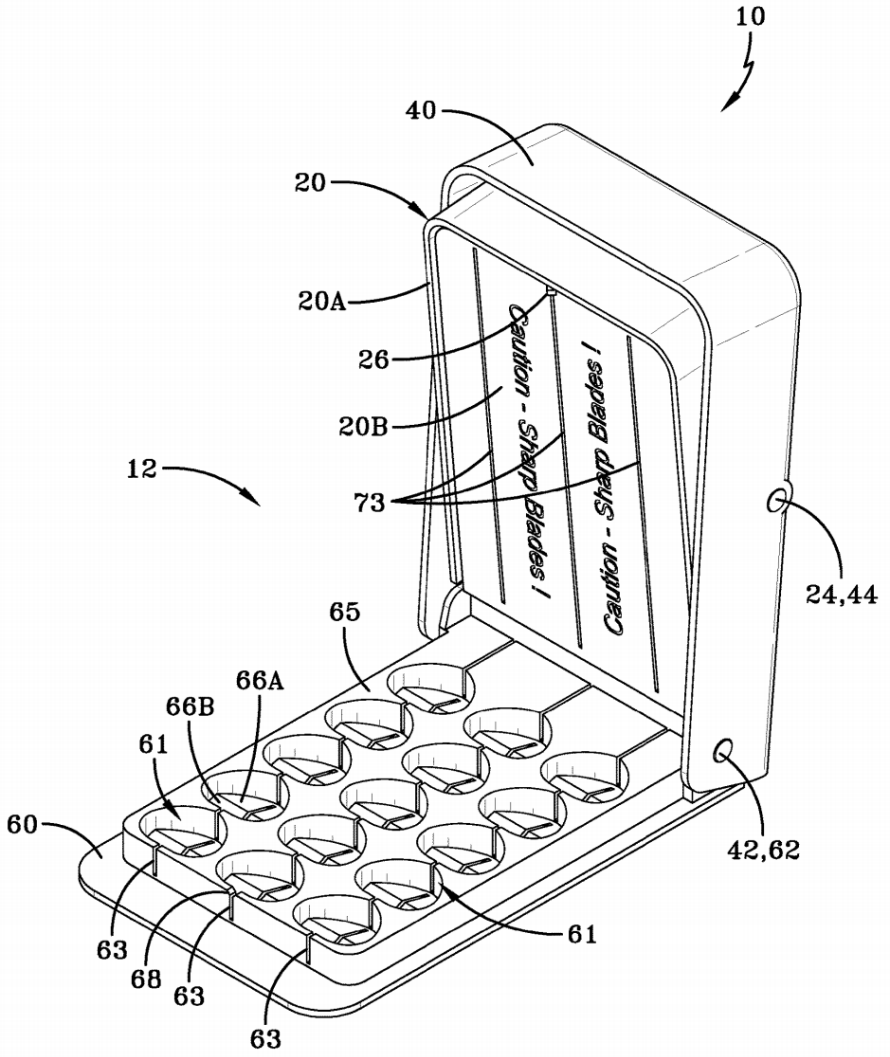


FIG. 2

Figure 5: Patent Image for pill cutter and crusher pliers

2.2.3 30 Day Pill Cutting Device Patent #: US010398628

This patent provides a means to cut a month-long supply of pills in one fell swoop. Pills are placed into the device individually in a grid, with each slot having a holder similar to the Apex Deluxe Pill Splitter. The lid of the container contains three long blades which cut the pills in their respective grid row as they are pressed down. The main advantage of such a device is the ability to quickly cut a large number of the same type of pill.



FIG−12

Figure 6: Patent Image for 30 day pill cutter

2.2.4 Multi-size Pill Splitter
Patent #: US010010484

This patent proposes a levered cutting mechanism similar to many current designs, but with a rotating wheel housing multiple slots for different pill sizes and shapes. Each slot has a recessed region in the shape of a given pill, with a slot cut out where the blade will come down to cut the pill. The advantage proposed here is that the pill will be held securely in its slot while being cut, and you have the ability to quickly and easily change over to a different pill type.

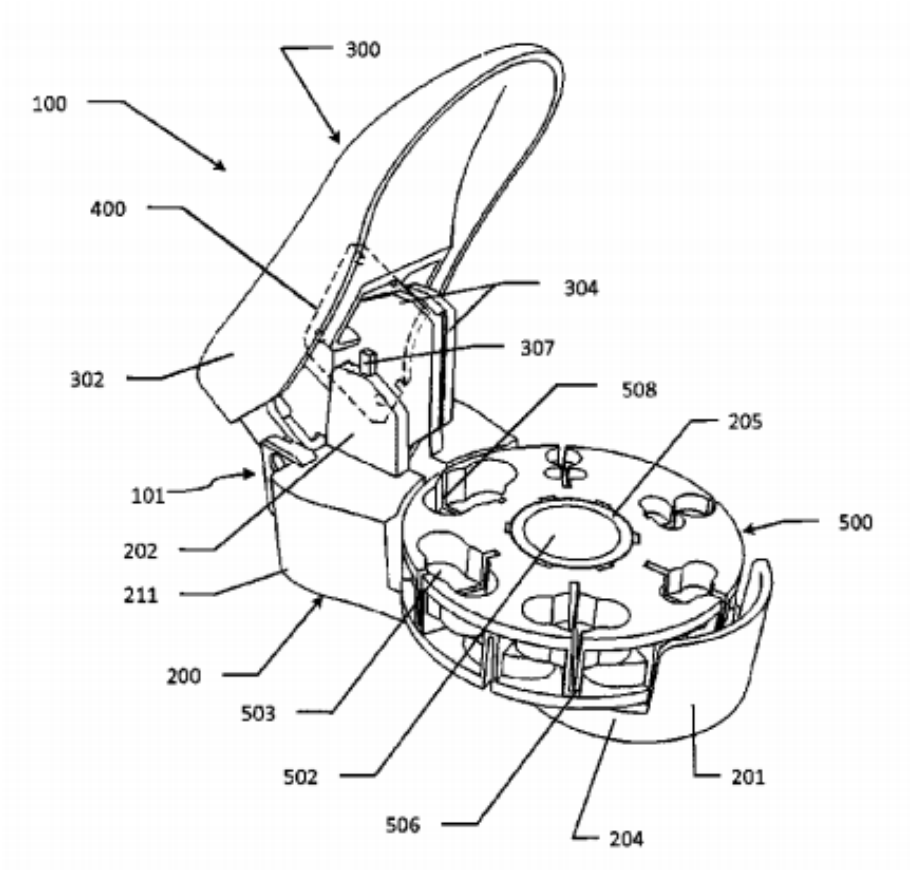


Figure 7: Patent Image for multi-size pill splitter

2.3 Codes & Standards

2.3.1 Standard Specification for Polyethylene Plastics for Medical Applications (ASTM F639-09)

This standard specifies which plastics can and cannot be used to construct a medical device.

2.3.2 Sampling and testing of in-process materials and drug products (CFR211.110)

Since pills will be cut using our device, this standard is to ensure that the amount of mass loss during the cutting will ensure viability.

2.3.3 Preparation of Food Contact Notifications for Food Contact Substances (FDA-2013-S-0610)

Since pills will be digested they need to be food safe. Using this standard will ensure that our pill-cutter will be food-safe.

2.3.4 NIOSH standard for classifying and listing Anti neoplastic and Other Hazardous Drugs (NIOSH-2016-161)

Pharmacies and hospitals deal with a wide variety of pills, some much more harmful than others. This standard is to ensure that the necessary precautions are taken for each type of pill that the user is intending to cut.

2.4 User Needs

This section describe the interview process, as well as how we determined the needs of the customer. From this section, we will develop basic ideas for our design.

2.4.1 Customer Interview

Interviewee: Dr. Tyler Taylor
Location: Interviewed over Zoom. Current employer: St. Louis Hills Pharmacy
Date: February 2^{nd}, 2021
Setting: During our Zoom interview, we asked a list of questions regarding the current tools used at St. Louis Hills to cut pills. We gathered information on pill sizes, shapes, quantities, and cut requirements. We also shared some ideas about what would be a better design for pill cutters. The meeting took about 30 minutes.

Interview Notes:
What is the overall pill-splitting process?

- Pills are place one at time into a pill cutter. The pill is then split in half or in quarters by pushing the top down. After being cut, the pills slide into a catch tray and separated.

What are the common pill sizes (maximum and minimum) and shapes?

- The pills are typically round tablets, though some are oblong. The smallest pill is amlodophine, which is cut into quarters.

Does each the pills have designated machines?

- The pills can be cut on the same machine but the machine must be cleaned to prevent cross-contamination.

Does the pill splitting machine need to be: light/robust?

- The pill machine is currently made out of a hard plastic and is disposed of after the blade becomes dull, about 1 per 2 months. The design does not have to be especially light or robust for St. Louis Hills Pharmacy, but in general pharmacies do not have much room. So, having a small easily stored machine would be generally beneficial.

Is safety a big concern?

- Safety is a concern, but as long as the blades are not overly exposed, the machine is acceptable. The machine will only be used by certified employees.

What is an acceptable error rate?

- On the current machine, 5 or 6 out of 10 pills are cut properly. So an acceptable error rate is about 50%.

How often would you want to change the blade?

- The blade currently dulls every month or two and then the entire machine is thrown out. Making the blade interchangeable would be great.

Would you then want the pills to be sorted?

- The pills do not need to be sorted after cut, but having a place to retrieve the cut pills is preferred.

How many different sizes do the pills need to be cut into?

- The pills need to be cut in half mostly, though some do require quartering.

How long does it take to split pills by hand?

- The actually cutting process is fast, but the current machine is imprecise. The total time is mostly spent trying to re-cut pills.

2.4.2 Interpreted User Needs

Upon interviewing the STL Hills Pharmacy, we were able to put together an interpreted user needs chart. The purpose of the chart is to clarify the necessity of each need from the customer perspective. By allocating the needs a relative importance weight, we hope to simplify the concept generation process, as the prioritization of the mechanism's functions will already be assorted accordingly. This table is displayed below.

Table 1: Interpreted Customer Needs

Need Number	Need	Importance
1	The mechanism doesn't crumble the pills when operated	5
2	The blade of the splitter is easy to change and clean	4
3	The pills, once cut, can be sorted and accessed easily	3
4	The splitter can be automated to perform it's task	2
5	The splitter can accept multiple pill sizes and shapes	5
6	The splitter is of minimal size	2
7	The splitter has high safety precautions	2
8	The mechanism's splitting assembly is food grade	5
9	The mechanism can slice multiple pills at once	2
10	The operation of the splitter is comfortable to use	4

Upon talking to the customer, it was established that the mechanism would be deployed within the pharmacy setting, and only being used by individuals who have training, and clearance to handle drugs. Thus, certain needs like safety precautions, and automation are minimal, as the operators are licensed and capable of cutting and sorting the pills. The STL Hills Pharmacy also indicated that the biggest problem in their case is being able to cut multiple sizes and shapes, without "crumbling" the pill, making it devoid for the customer. This meant that the priority is delegated to cutting multiple pills, with a minimal crumble rate.

As the pharmacy cuts the pills on a patient-by-patient basis, it was more important that the splitter can be cleaned, and have it's blade changed readily, as the pills are not cut in aggregate, but rather on an order-by-order basis. To this end, the pharmacy has additional space to cut the pills in as they do not cut many at once, so the size of the mechanism isn't paramount to the design.

2.5 Design Metrics

Below is our target specifications. The metrics are based directly off of the interpreted customer needs as well as several standards that apply to our design.

Table 2: Target Specifications

Metric Number	Associated Needs	Metric	Units	Acceptable	Ideal
1	1	Pill cutting and scoring must meet FDA guidelines. [1]	% mass	3	1
2	2	Cleaning must be easily completed regularly according to FDA guideline. [1]	binary	Pass	Pass
3	3	High sortability and accessibility for each pill that is cut	avg. score	$> 3/5$	$> 4/5$
4	1, 4, 5	Multiple pills and different shapes can be cut effectively	avg. score	$> 2/5$	$> 4/5$
5	7	Device will be made with non-toxic materials and will be up to Standard ASTM F639-09.	binary	pass	pass
6	7	Device will be able to be operated in a way that follows NIOSH and CDC guidelines for Hazardous Drugs [2].	binary	pass	pass
7	8	Food grade material according to FDA guideline. [1]	binary	Pass	Pass
8	9	Number of pills that are cut at once	integer	3	5
9	10	Rating "comfort" by class focus group	avg. score	$> 2/5$	$> 4/5$

[1] https://www.fda.gov/media/81626/download
[2] https://www.cdc.gov/niosh/docs/2010-167/pdfs/2010-167.pdf

2.6 Project Management

The Gantt chart in Figure 8 gives an overview of the project schedule.

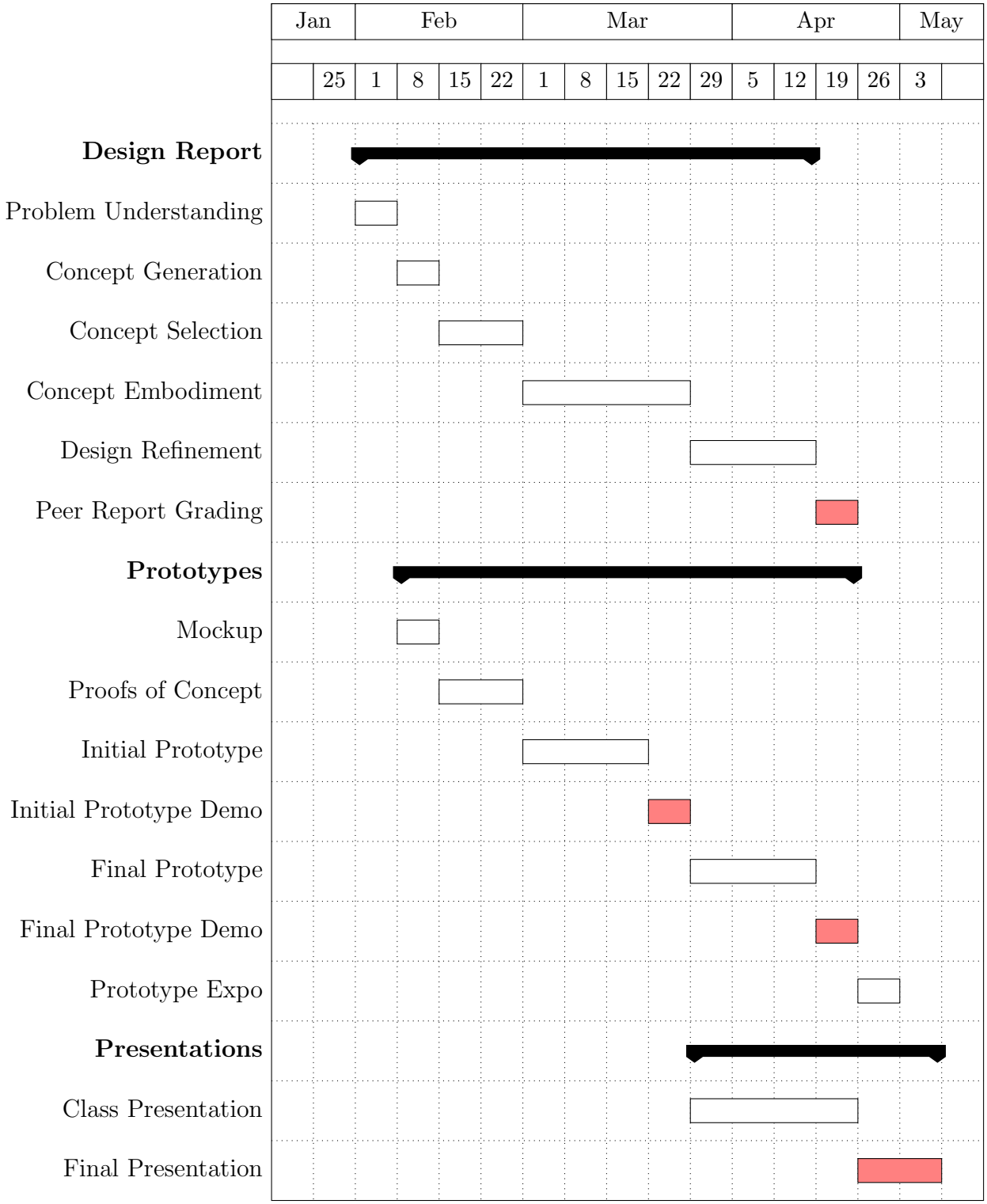


Figure 8: Gantt chart for design project

3 Concept Generation

3.1 Mockup Prototype

The prototype made was a simple can-crusher type of pill cutter. It stars a mounted blade on a top box assembly. The assembly is operated via hand lever, bringing the entire force of the assembly down to crush the pill, which is aligned on the slice deck. The slice deck itself has a pair of guide rails to ensure proper alignment, and pill stability when cut. An annotated version of this is shown in Fig. 9.

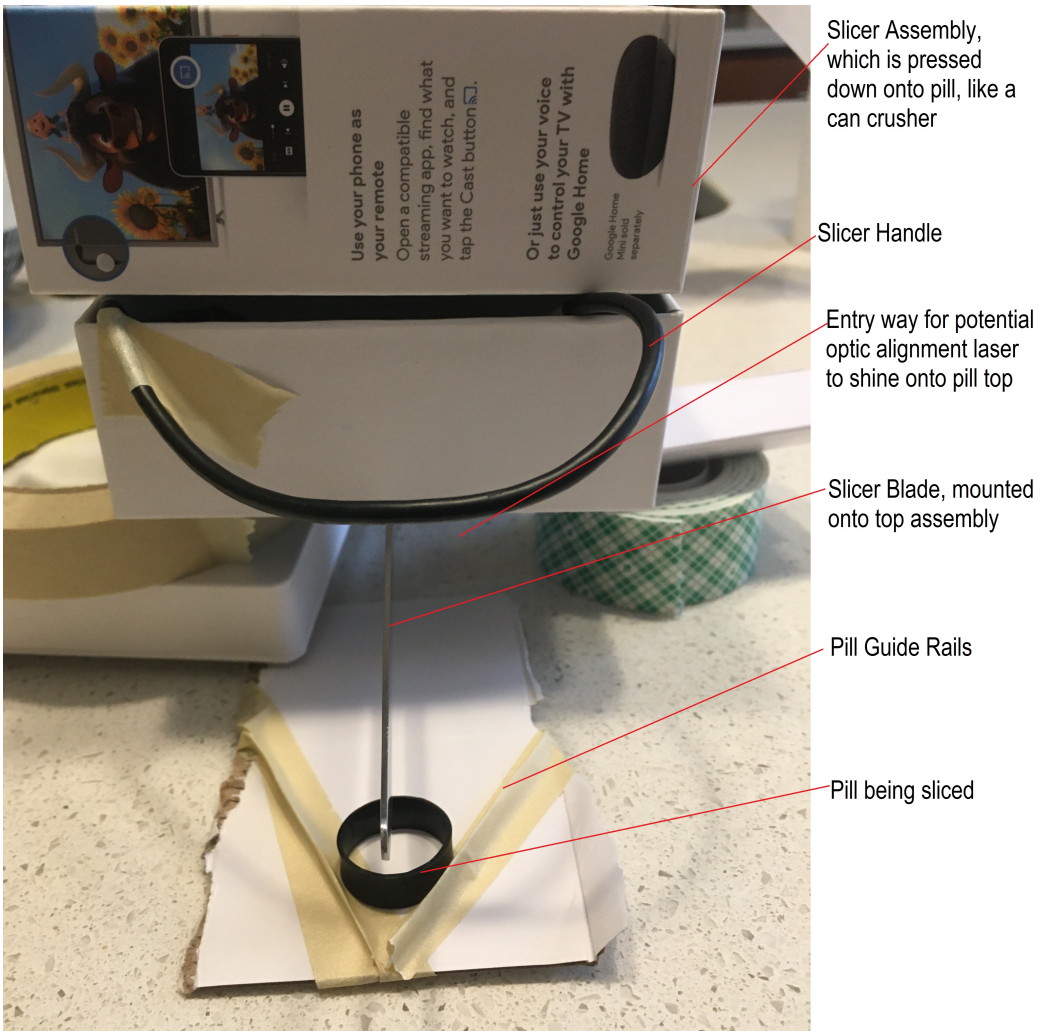
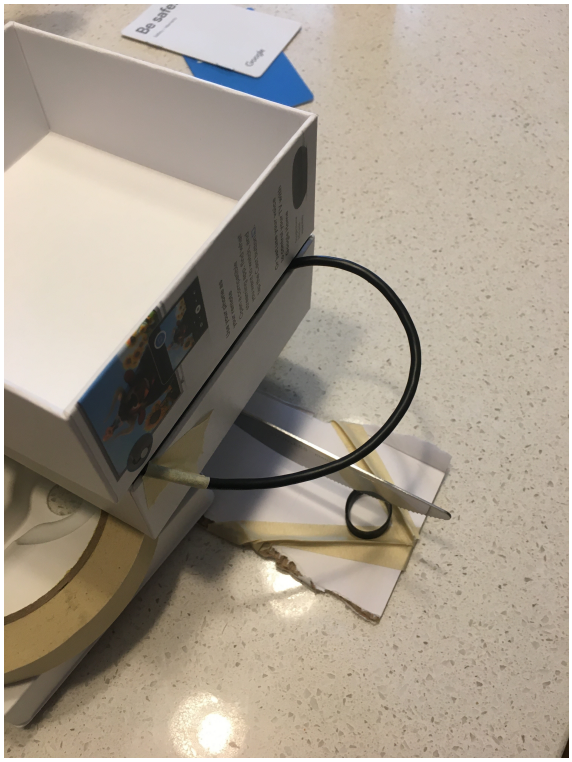
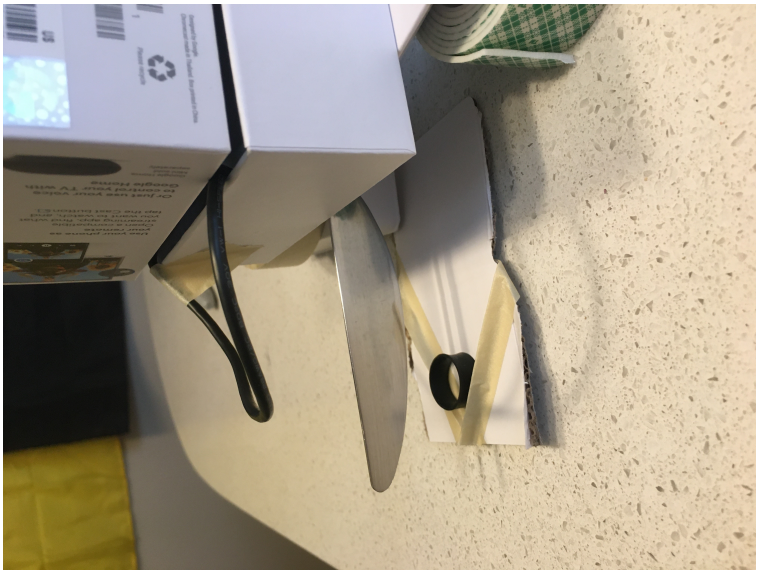


Figure 9: Labelled mock up pill slicer

A pair of auxiliary views of the slicer are shown on the next page in Fig. 10



(a) View 2



(b) View 3

Figure 10: Additional views of pill slicer mock up

3.2 Functional Tree

The function tree below sets up the evolution of the can crusher concept proposed later in the concept stage. Outlined on the left hand side of the chart are potential hazards, concerns, and issues that need to be addressed for the mechanism foremost in it's conception stage. Many of these needs and concerns are drawn directly from the customer interview. The chart is shown below in Fig. 11

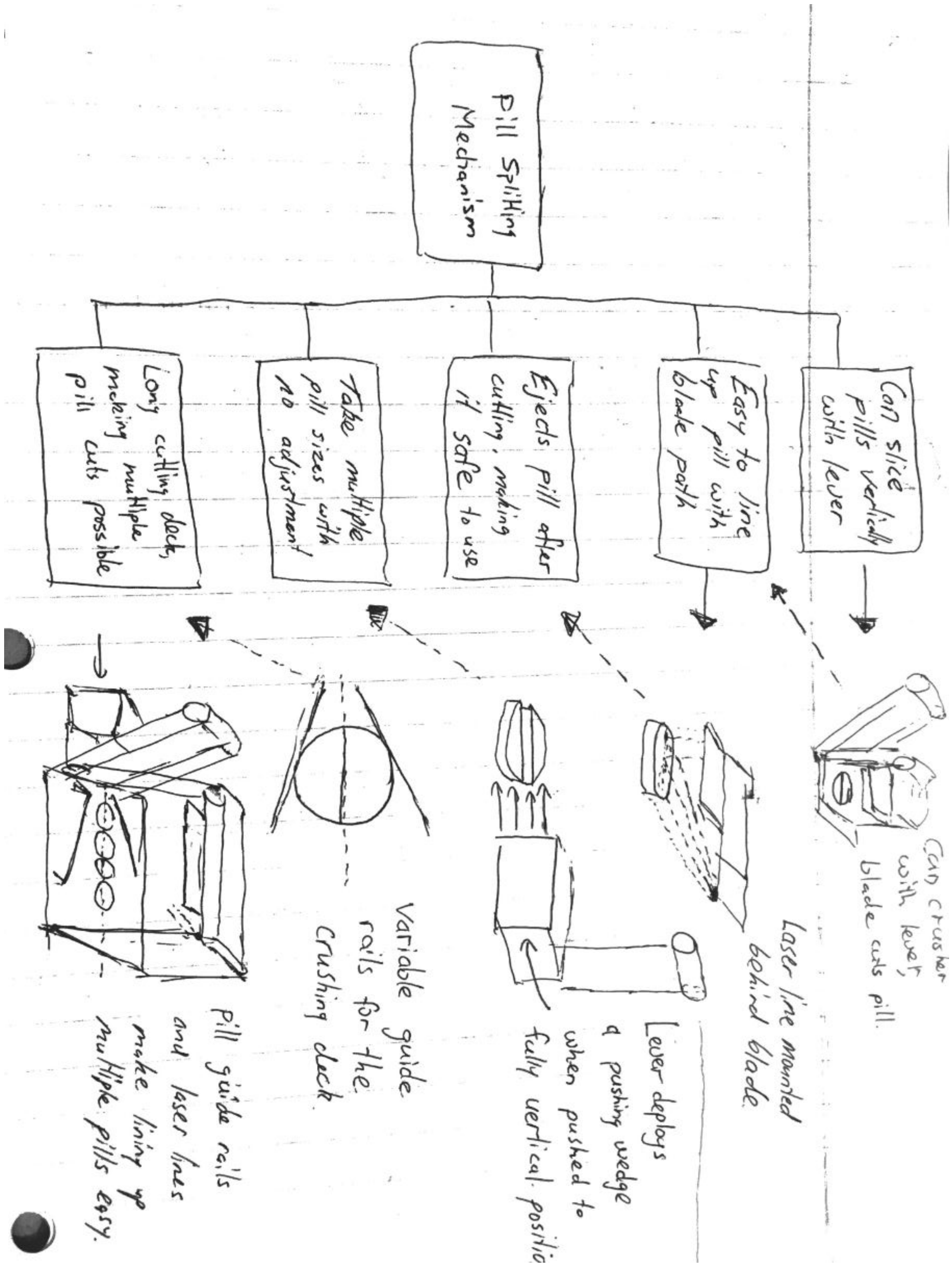


Figure 11: Function tree for can-crusher inspired pill slicer

3.3 Morphological Chart

Below is a morphological chart for the pill cutter. The chart contains the main issues that need to be solved and potential solutions for each.

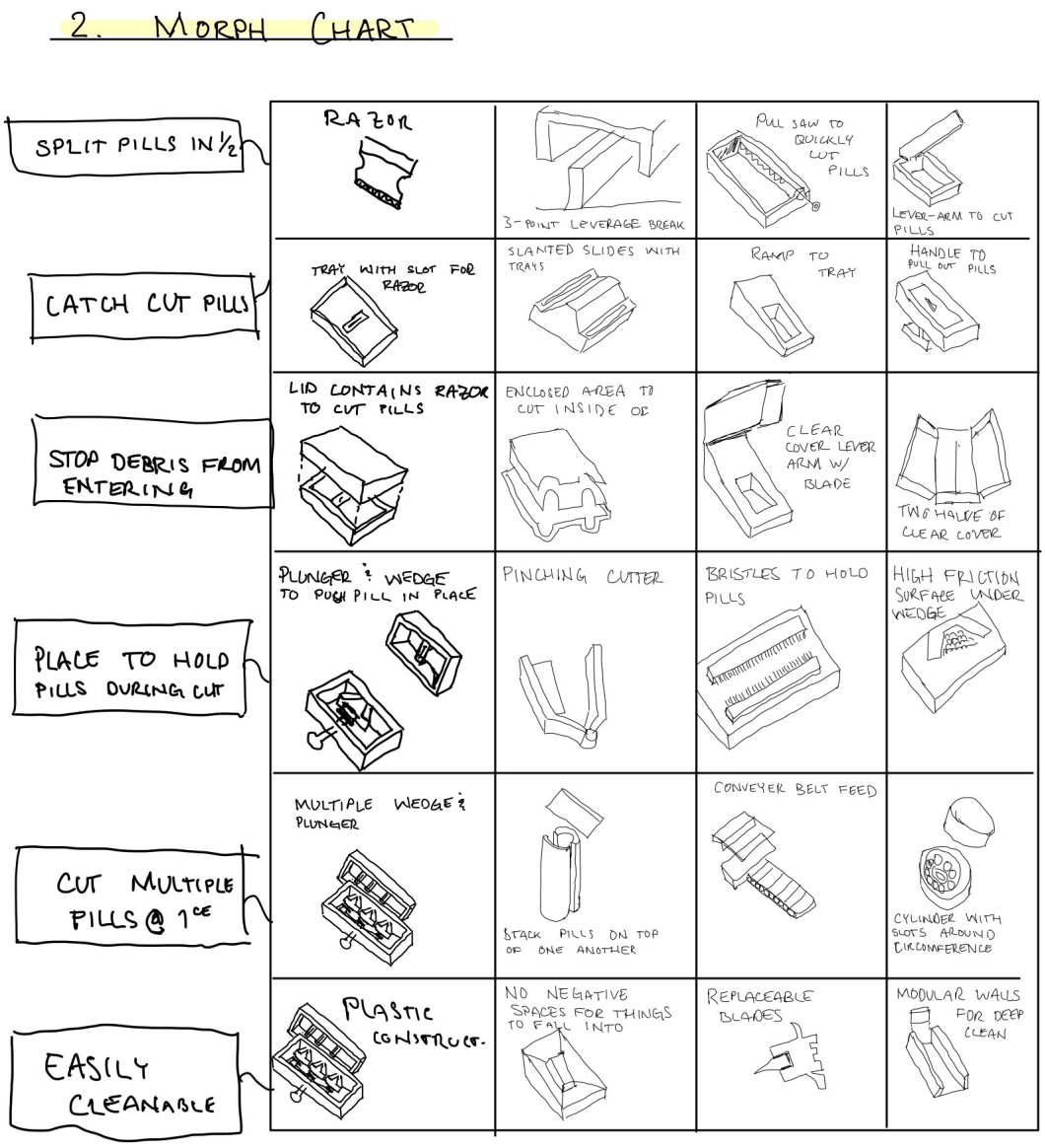


Figure 12: Morphological Chart for Pill Cutter

3.4 Design Concepts

3.4.1 Can Crusher Adaptation

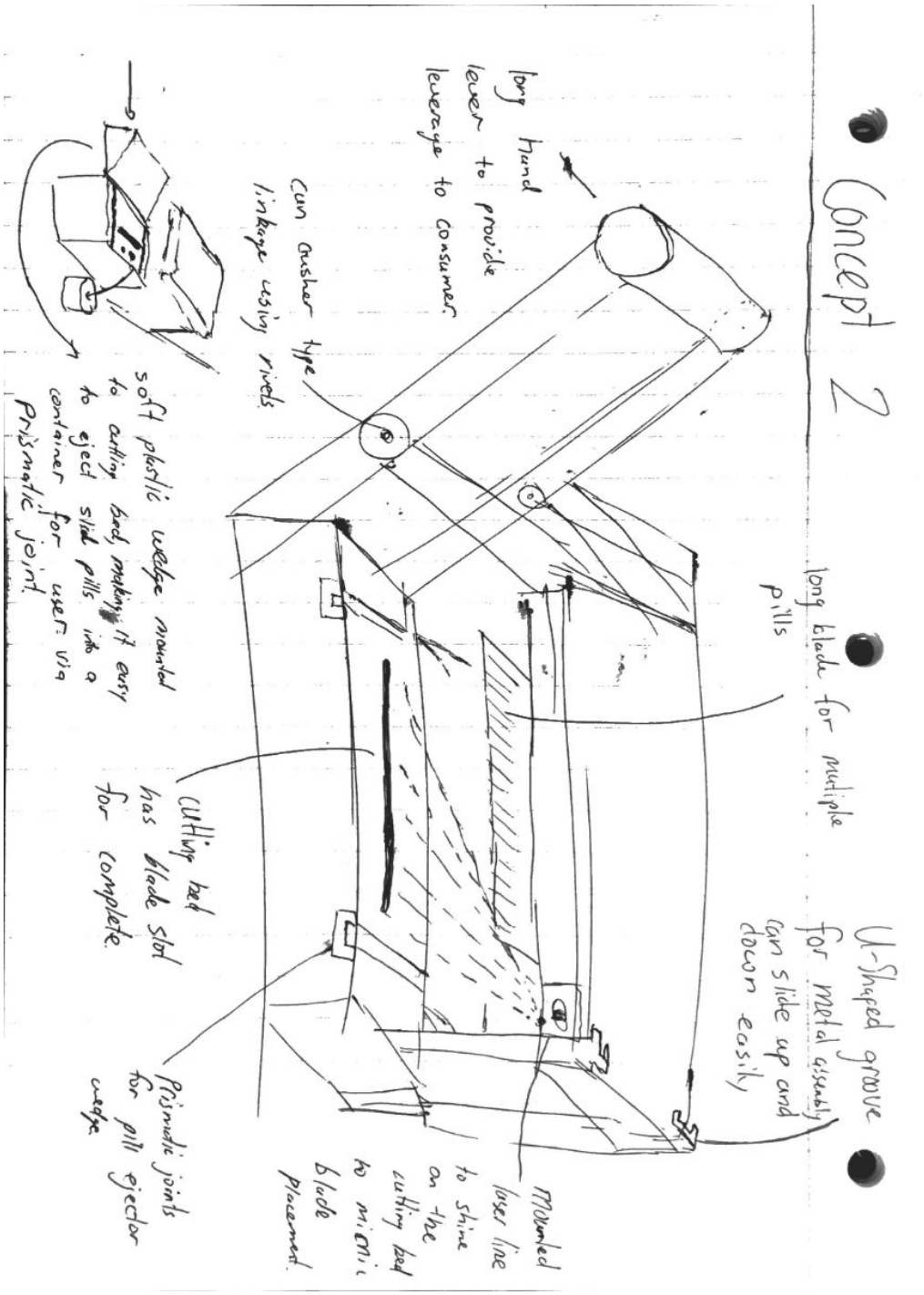


Figure 13: Preliminary sketches of Robotic Arm concept

Solutions from morph chart:

1. Mechanism can cut multiple pills on the slicing deck

2. Pills can be swept off the deck using prismatic wedge slider, making it safe
3. Lever provides maximal mechanical advantage, saving consumer energy
4. Horizontal blade allows for clean incisions, and minimal pill shifting
5. Exposed blade can be easily cleaned

Description: Using the can crusher type template, the user is afforded the luxury of immense mechanical advantage. This will mean clean, forceful breaks of the pill, reducing the crumbling rate of the pills. This design also allows some extra utility, in having a separated cutting bed from the cutting assembly. This includes the capability for a pill sweeping wedge, allowing the users to quickly clear the mechanism, along with a 3-point slicing structure, as the blade will impress through the slot in the cutting bed, increasing the mechanism's ability to achieve clean slices through the pill.

3.4.2 Gripping Plunger Pill Cutter

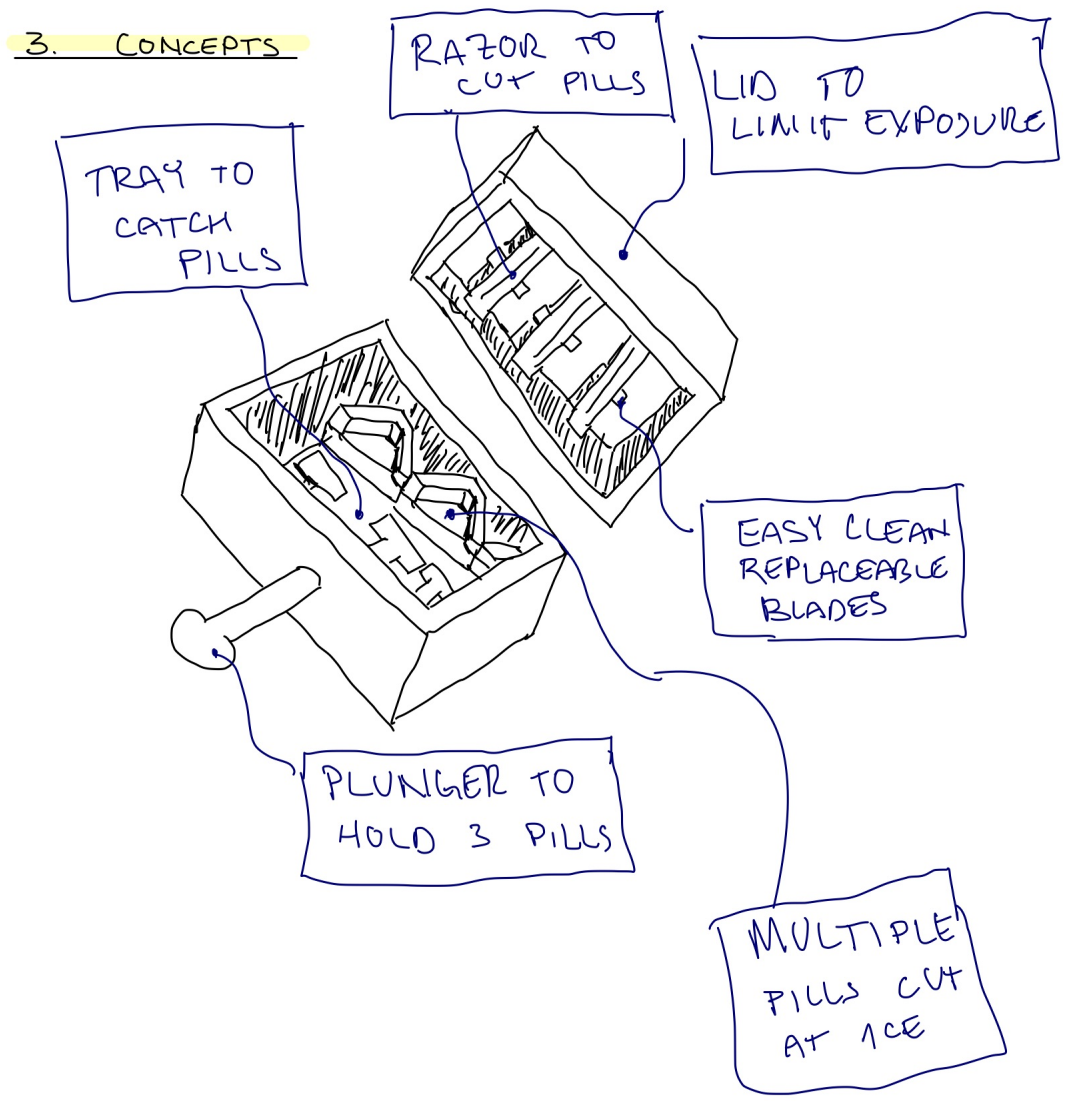


Figure 14: Sketch of both halves of plunger pill cutter.

Solutions from morph chart:

1. Tray to catch pills
2. Plunger grips pills during cuts

3. Razor used to cut pills
4. Razor is replaceable for easy cleaning
5. Top portion acts as lid to limit contamination
6. Three wedged area to hold multiple pills during one cut

Description: In this design, up to three pills are held by two wedges arms and a plunger arm. The wedged areas are slightly inclined to also prevent movement. Cut pills can be tipped forward in the bottom tray for storage. The cut is performed by three removable razor blades in the top portion of the pill cutter. This top portion functions as a lid and when pressure is applied, the pills are cut. The entire design will be modular for easy cleaning.

3.5 Alternative Design Concepts

3.5.1 Pill Storage

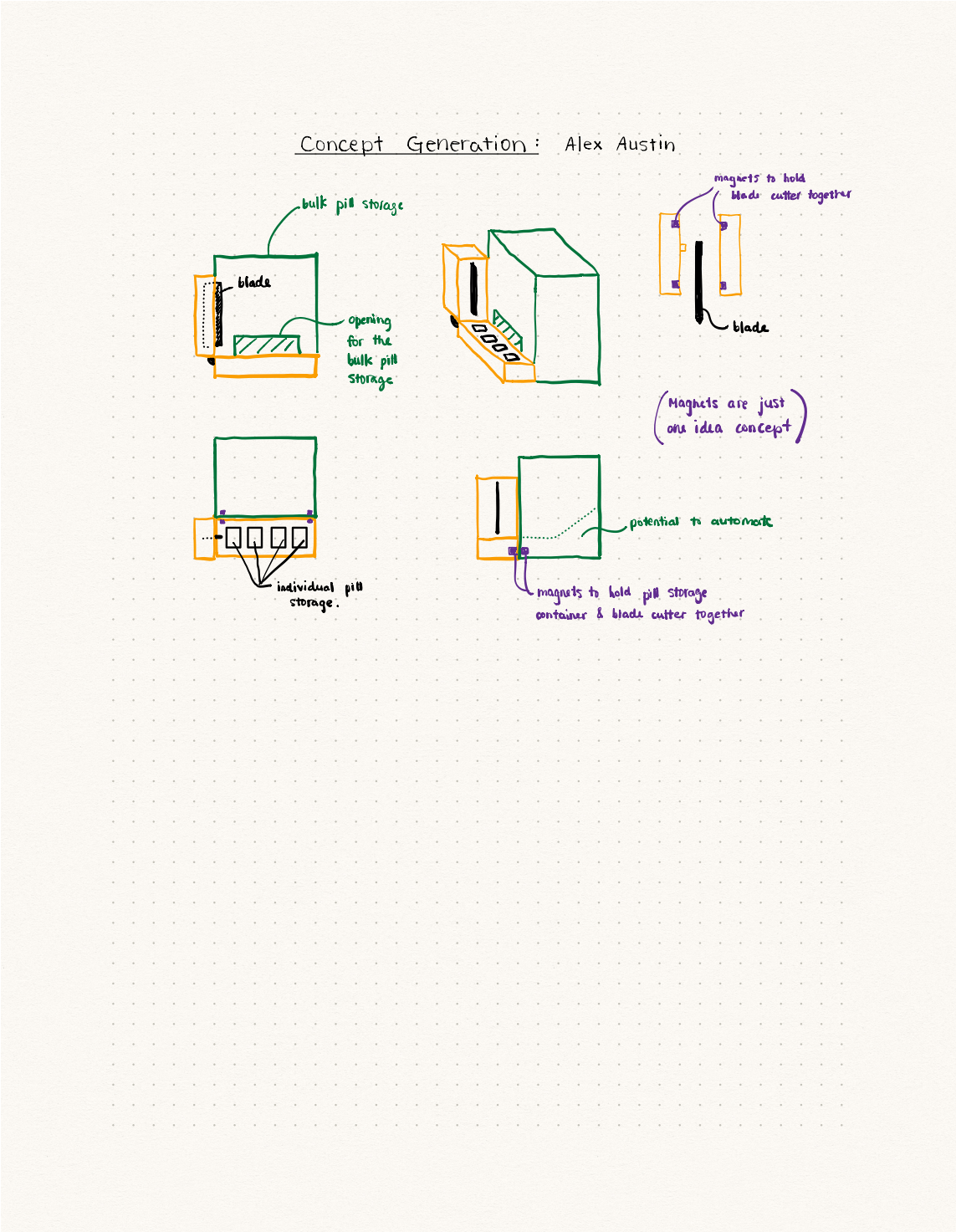


Figure 15: Preliminary sketches of Pill Storage concept

Solutions from morph chart:

1. Unit Stores a Multitude of Pills
2. Easily Replaceable Blade
3. Individual Pill Storage
4. Small footprint
5. Non-battery operated
6. Low cost

Description: The additional pill storage that is attached, but not permanently so, to the back of the pill cutter will be used when the user is needing to cut a bulk order of pills. It is lightweight, small in size, and non-battery operated which will reduce it's counter space footprint and overall cost of the pill-cutter. It also has the ability for quick, safe, and easy access to the blade so that it can be efficiently switched out.

3.5.2 Split and Flip Pill Cutter

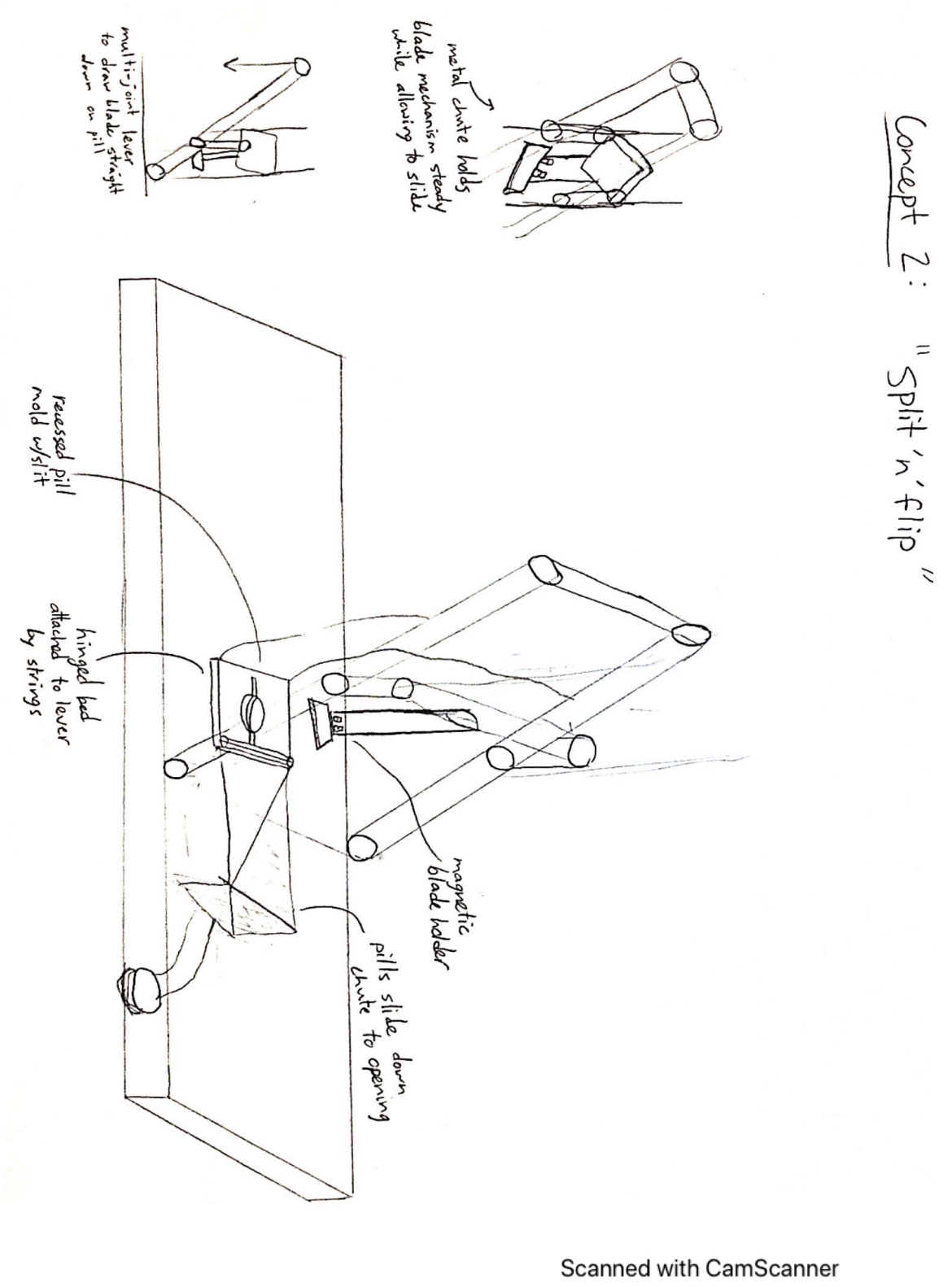


Figure 16: Preliminary sketches of Split and Flip Pill Cutter

Solutions from morph chart:

1. Single razor blade for a clean cut
2. Blade retracts when lever arm is raised
3. Recessed and slotted hole for pill to rest in
4. Easily swappable molds for different shapes and sizes
5. Hinged pill tray that lifts when raising lever to dispence pill halves
6. Magnetic blade housing for easy blade removal

Description: This design utilizes a multi-joint levered handle to translate the blade force vertically in order to negate any slipping or uneven cutting. The recessed slotted pill mold holds the pill firmly in place while allowing the blade to pass completely through the pill for a clean cut. The hinged pill mold acts raises with the handle so when the user goes to get another pill, the cut halves slide down the chute and into an opening for easy and safe access. The magnetic blade holder allows for easy cleaning and makes for a cost-effective design as the razor blades, which can be purchased cheaply, can be swapped out as needed.

4 Concept Selection

4.1 Selection Criteria

The selection criteria for our device are as followed: safety, portability, Reliability, easy to clean, and removable blade. Where, according to our client, ease to clean and removable blade are of the highest priority and safety and portability is of the lowest. This is reflected below in Fig. 17.

	Safety	Portability	Reliability	Easy to Clean	Removable Blade	Row Total	Weight Value	Weight (%)
Safety	1.00	0.20	0.14	0.11	0.11	1.57	0.02	2.32
Portability	5.00	1.00	0.20	0.14	0.14	6.49	0.10	9.62
Reliability	7.00	5.00	1.00	0.20	0.20	13.40	0.20	19.87
Easy to Clean	9.00	7.00	5.00	1.00	1.00	23.00	0.34	34.10
Removable Blade	9.00	7.00	5.00	1.00	1.00	23.00	0.34	34.10
					Column Total:	67.45	1.00	100.00

ONLY change the lower-left triangle of the matrix
The right 3 columns will be automatically calculated

Row criterion is _____ than/as column criterion

Numerical ratings:
9 -- Extremely more important
7 -- Very strongly more important
5 -- Strongly more important
3 -- Moderately more important
1 -- Equally important
1/3 -- Moderately less important
1/5 -- Strongly less important
1/7 -- Very strongly less important
1/9 -- Extremely less important

Figure 17: Analytic Hierarchy Process (AHP) to determine scoring matrix weights

4.2 Concept Evaluation

Based upon our AHP evaluations, we scored each design concept. The scores are reflected below in Fig. 18.

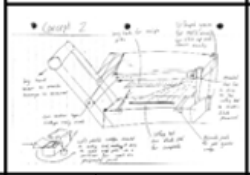
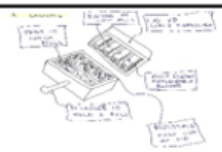
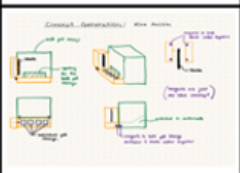
Alternative Deisgn Concepts		Dylan Stubs		Alex Posly		Alex Austin		Drew Marolf	
									
Selection Criterion	**Weight (%)**	**Rating**	**Weighted**	**Rating**	**Weighted**	**Rating**	**Weighted**	**Rating**	**Weighted**
Safety	2.32	5	0.12	5	0.12	2	0.05	5	0.12
Portability	9.62	5	0.48	5	0.48	5	0.48	5	0.48
Reliabilty	19.87	5	0.99	3	0.60	1	0.20	4	0.79
Easy to Clean	34.10	4	1.36	3	1.02	4	1.36	3	1.02
Removable Blade	34.10	3	1.02	5	1.71	5	1.71	4	1.36
	Total score	**3.978**		**3.921**		**3.795**		**3.779**	
	Rank	**1**		**2**		**3**		**4**	

Figure 18: Weighted Scoring Matrix (WSM) for choosing between alternative concepts

4.3 Evaluation Results

The results of the AHP and WSM are relatively conclusive, indicating the design by Dylan Stubbs was the most suitable for the task being performed. Knowing that the min criteria were the reliability, and the relative ease with which the consumer could clean, and service the mechanism, it makes sense that this design would prevail. Followed closely by the capsule design by Alex Posly, which features some highlights in the fields of portability and safety, however, with the rankings, determined by the customer interview, these needs were not as important, meaning it scored a lower overall evaluation. In totality, the AHP and the WSM were useful in quantitatively determining the utility of each design, in relation to weighted customer needs, making it a useful tool in the concept selection phase.

All of these concepts scoring approximately in the range of 3.8 - 4.0 is perhaps a relative inflation of the scores, as the original pill cutter served as the benchmark, having only a single blade, and very little maintenance, or safety precautions being needed. In reality, a little lower scores would perhaps be more indicative of the designs, however, in the scope of the customer needs, the scores are appropriate, and most importantly, it allows for a holistic analysis of each of the designs in comparison to one another, allowing for a complete, and fair selection process, to decide the best concept.

4.4 Engineering Models/Relationships

The first engineering model/relationship included in this report regards the stabilization of the cutting device. To reduce the force required to cut pills, a lever arm is utilized. The leaver arm creates a moment about the corner of the device. Preventing this is done via two different features: a suction cup or weighted bottom or by moving the lever arm attachment point. The final design will incorporate both of these solutions.

The first solution is the suction cup stabilization. By adding multiple suctions cups (or weights), the moment produced by the lever arm, equivalent to the pull force multiplied by the lever arm

length, is negated by the vacuum force in the suction cups. This solution works as long as the suction is equal to or greater than the moment.

The second solution is moving the attachment point backwards. When the attachment point is moved back on the base, the moment developed by the lever arm is less likely to tilt or flip the cutting device. This is because the moment is in line with the center of gravity of the device. Both of these designs are shown in Fig. 19 and in Fig. 20, and both solutions will be used in tandem. If both solutions are applied, the device will not require as strong of a suction through each cup (or overall bottom weight) to prevent it from falling.

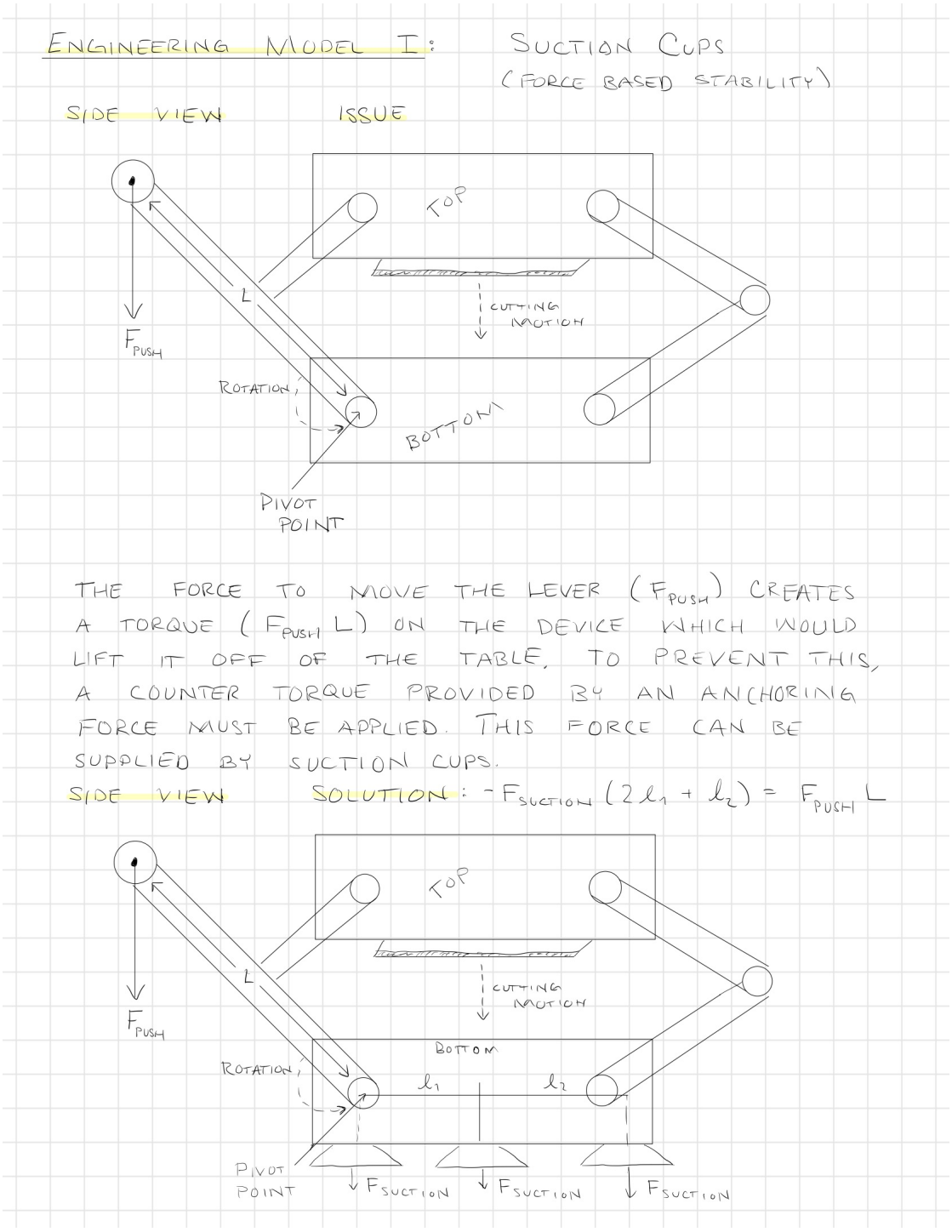


Figure 19: Model of moment and suction cup solution.

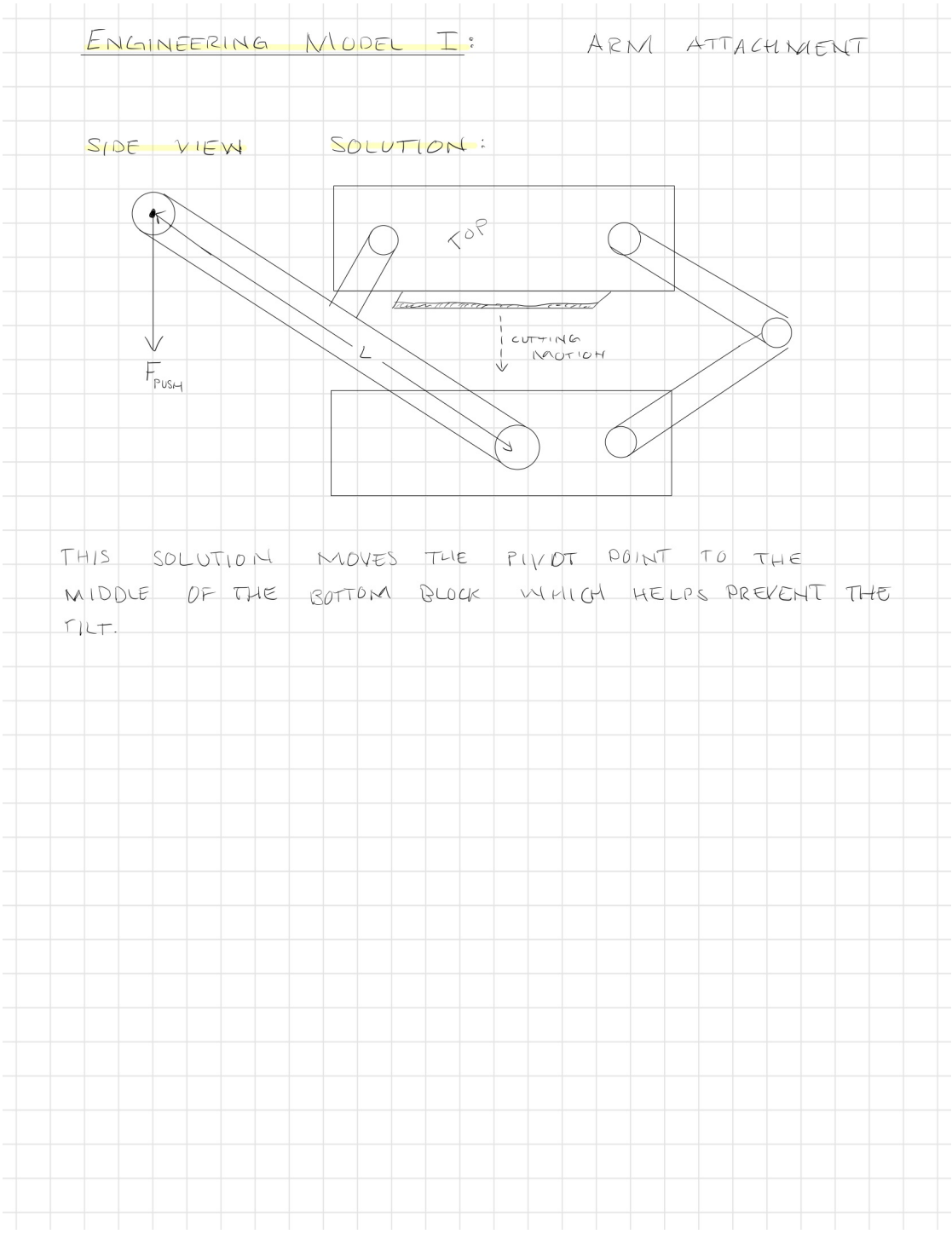


Figure 20: Model of attachment location moving solution.

The second engineering model involved the cutting interface between the razor blade and pill being cut. It is important to know the approximate amount of shear force that needs to be applied to the pill in order to split it in half. As such, some estimated properties of pharmaceutical tablets were determined such as cross-sectional area and height. An estimate of the razor blade width was also found. Using an estimated modulus of elasticity and Poisson's ratio, the shear modulus was determined. Then the blade thickness, pill height and cross-sectional area were used in order to determine the vertical force required to shear the pill in half. The results can be seen in Fig. 26

below.

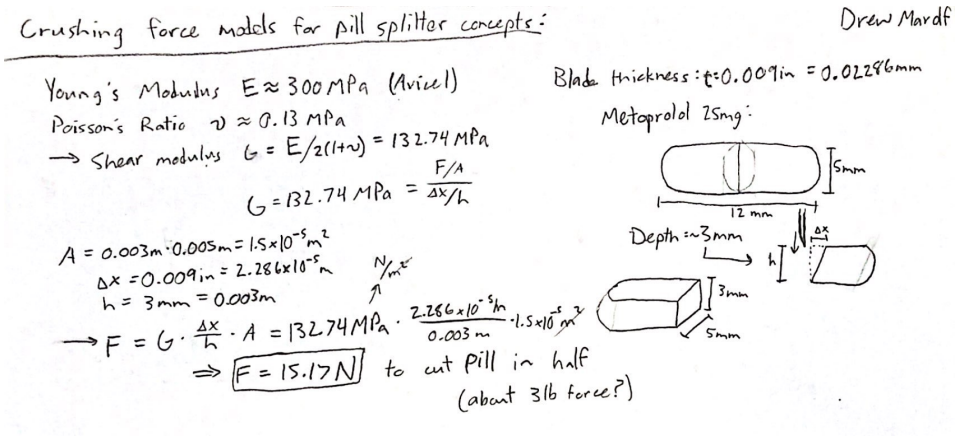


Figure 21: Model of crushing force required to split pill.

The third engineering model involved making a free-body diagram of the pill splitter's lever mechanism in order to determine the amount of force the user would need to apply in order to deliver the crushing force determined in the previous engineering model. This is an important metric as it will influence the size of the lever we need to make in order for the user to be able to comfortably split the pill with minimal effort, yet minimizing the size of the device. The results of this analysis are seen in Fig. 27 below.

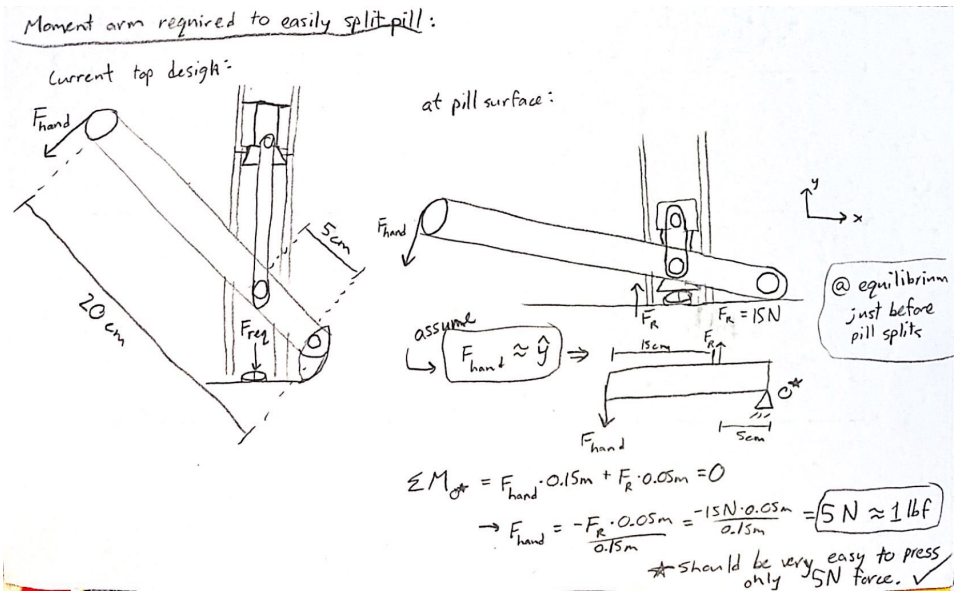


Figure 22: Model of moment arm required to split pill comfortably.

5 Concept Embodiment

5.1 Initial Embodiment

Below is the CAD drawings for the initial embodiment of the pill cutter. This prototype utilizes a Harbor Freight Can Crusher frame as a lever system. It also has three custom components: the top cutting bock, made from wood; the bottom cutting block, made from wood; the pill tray, 3D printed. The design contains other structural components including aluminum rods, screws, and washers.

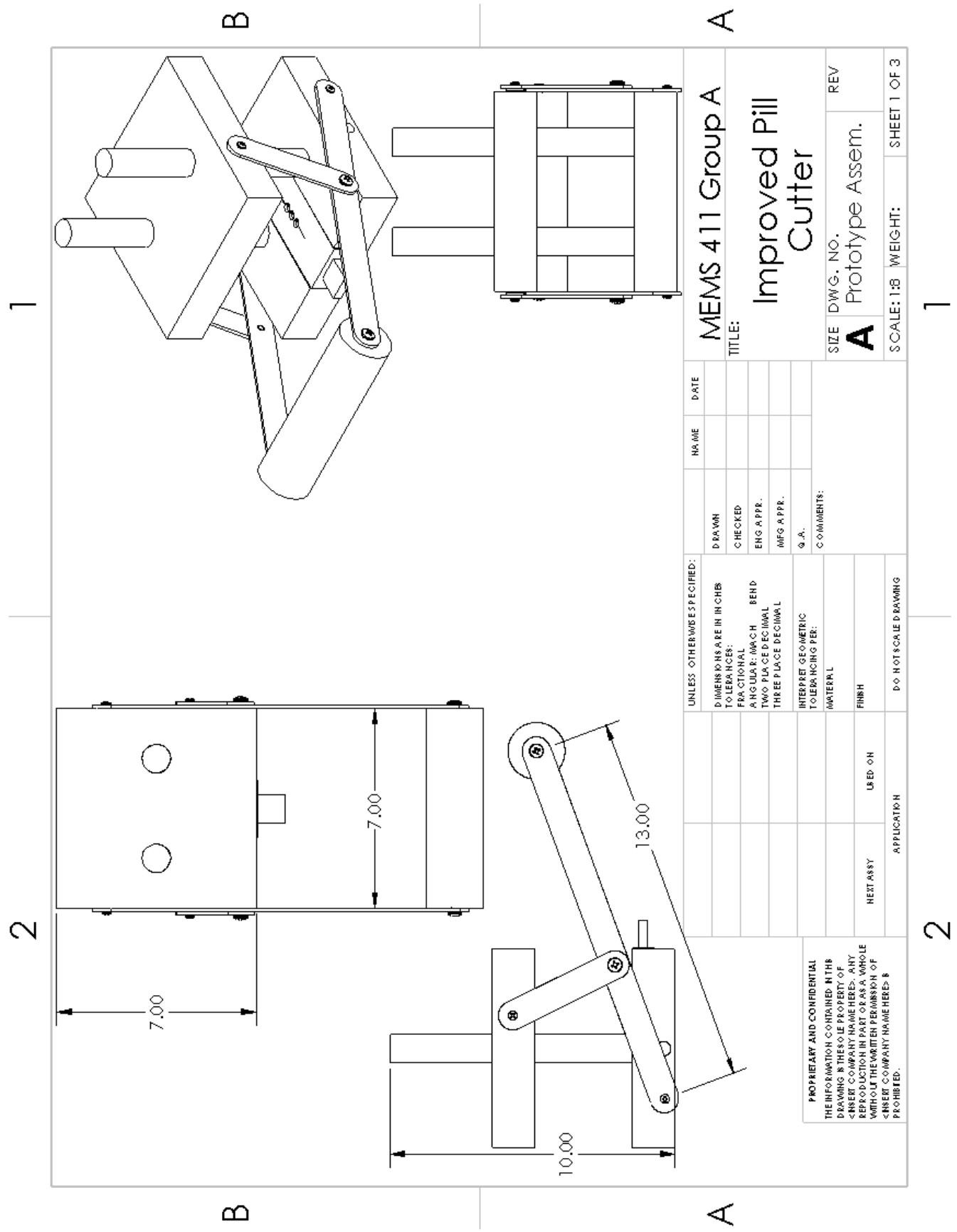


Figure 23: Assembled projected views with overall dimensions

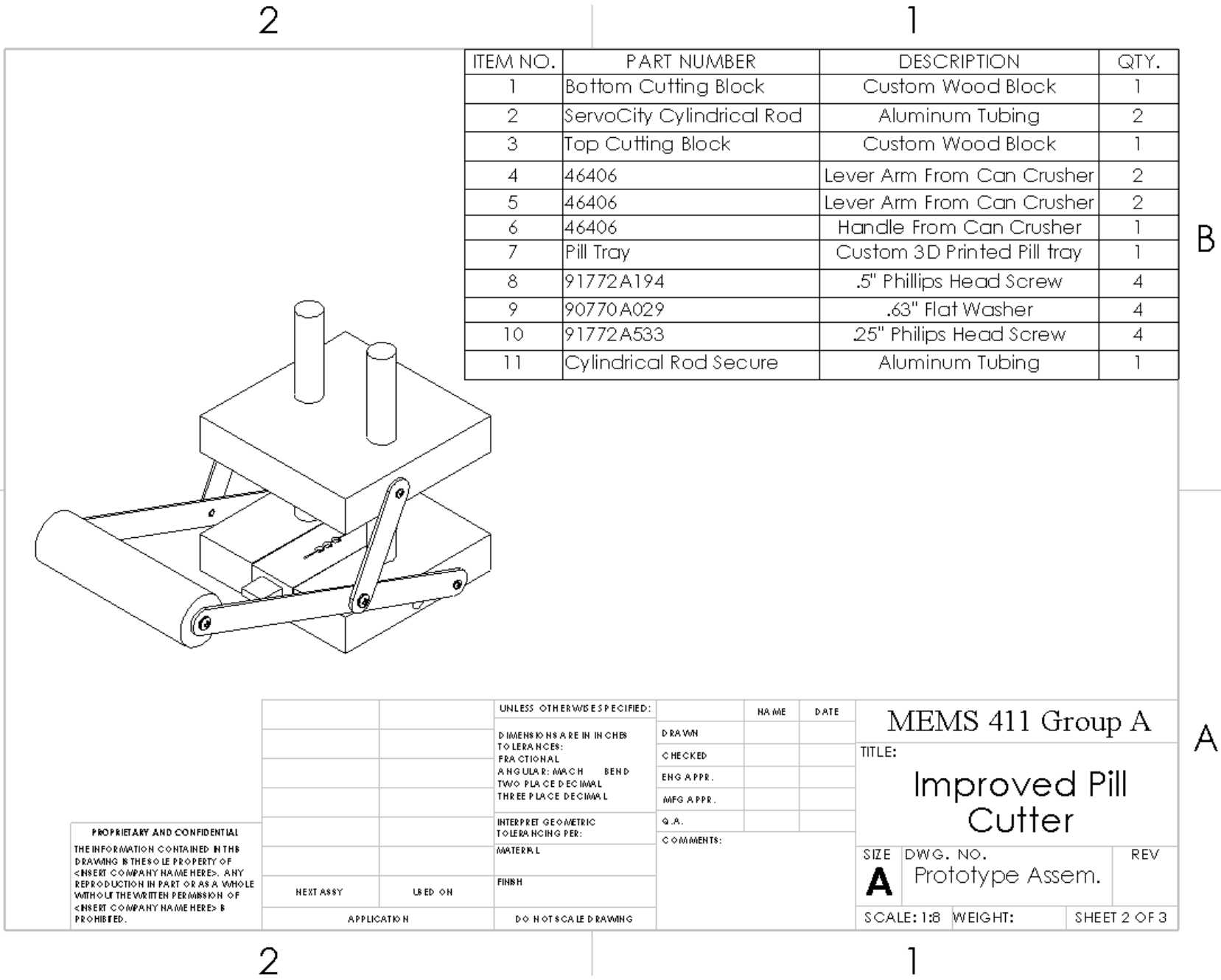


Figure 24: Assembled isometric view with bill of materials (BOM)

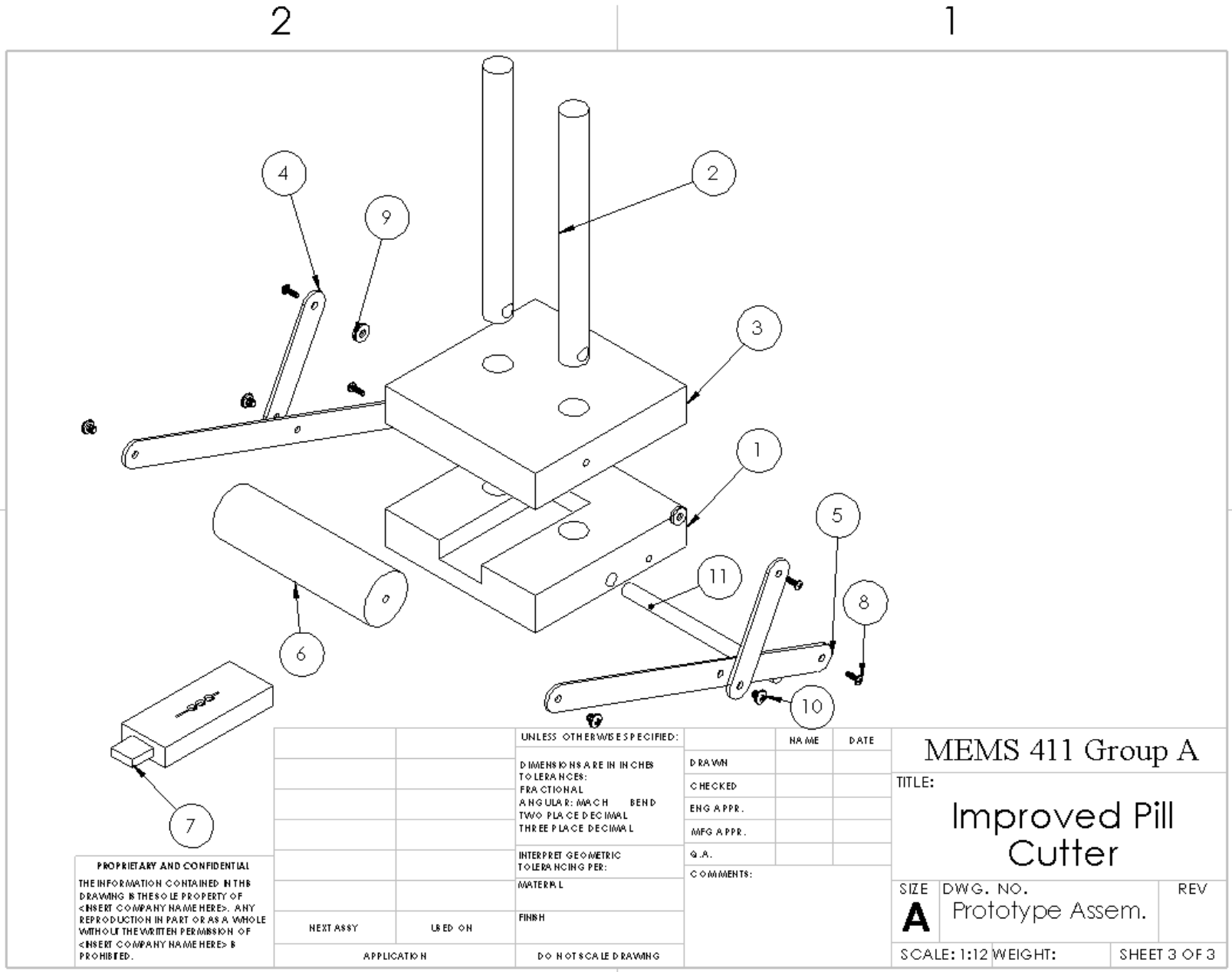


Figure 25: Exploded view with callout to BOM

Prototype Performance Goals

1. Device makes acceptable cuts at least 9 times out of 10 cuts.
2. Mechanical work needed for each pill cut is at least a quarter of the current method.
3. Device cuts pills at least 4 times faster than the current method.

5.2 Proofs-of-Concept

The proof of concept testing, which included testing for cut force, cut angle, and blade type, influenced our design by determining whether or not our lever system was effective. First, the cut force test determined the amount of force required to cut each pill. From this, the lever action force was determined to be large enough based on previous engineering models. Second, the cut angle test showed that a perpendicular blade, as opposed to the angled blade in the current methods, cut pills more accurately. From this, the perpendicular cut design was verified and proved more effective. Third, the blade type test showed that the sharpest blades out of a pocket knife, butter knife, and razor blade were the most effective. From this last test, the razor blade was chosen as the most effective blade for the prototype.

There are several changes from the concept selected. The first is that the lever arms of the prototype are no longer two separate joints. The arms, which were taken from a can crusher, are on combined piece connected to each other at one point and to each of the top and bottom blocks. The second is that the concept selected was to have a back plate that the top and bottom blocks would slide on during the cutting motion. This plate was scrapped in favor of two cylindrical rods on which the top block slides. Finally, the third change for the initial prototype was that the pill tray no longer has a gear and clamp mechanism to hold pills. In keeping with the customer needs, we have determined that the limited variation in pill size allows for a 3D printed pill tray for specific pills. This tray is simpler and easier to construct than the original idea of a gear and clamp mechanism.

6 Design Refinement

6.1 Model Based Design Decisions

The first model based design decision was based on the force requirement for pill cutting. The model, shown below, showed that the force needed to split the pill was at least 15N or 3lbf. This influenced our design by requiring a certain moment to be created. The moment arm would help reduce the amount of force required from the user to cut the pill.

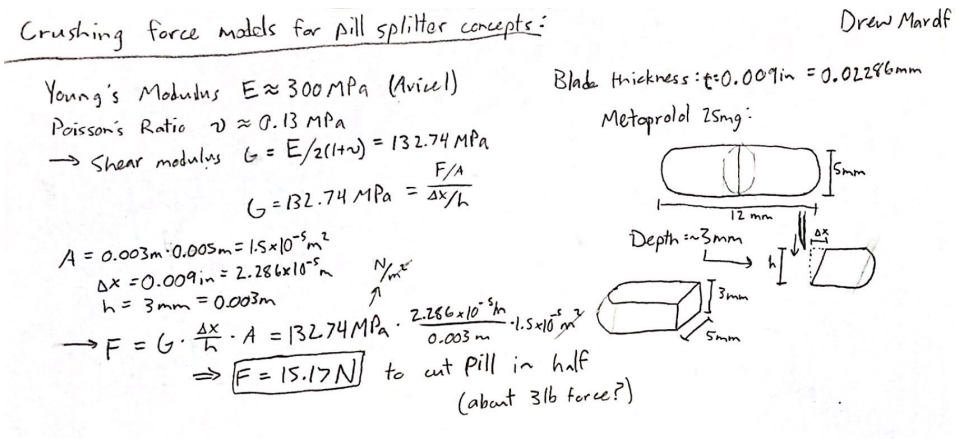


Figure 26: Model of crushing force required to split pill.

Note that that the primary equation that governed this model was:

$$F = \frac{GA\Delta x}{h} \tag{1}$$

Where F is the required force in N, G is the shear modulus in Pa, A is the area in m^2, Δx is the blade thickness in m, and h is the pill height in m.

The second design decision was directly correlated to the first because it was the calculation of the moment arm length and verification of its effectiveness. The model, shown below, illustrates a moment arm length of at least 20 cm or 7.87 in would require less than 15N. It would simultaneously convert the force provided by the user to a force more than 15 N to actually split the pill.

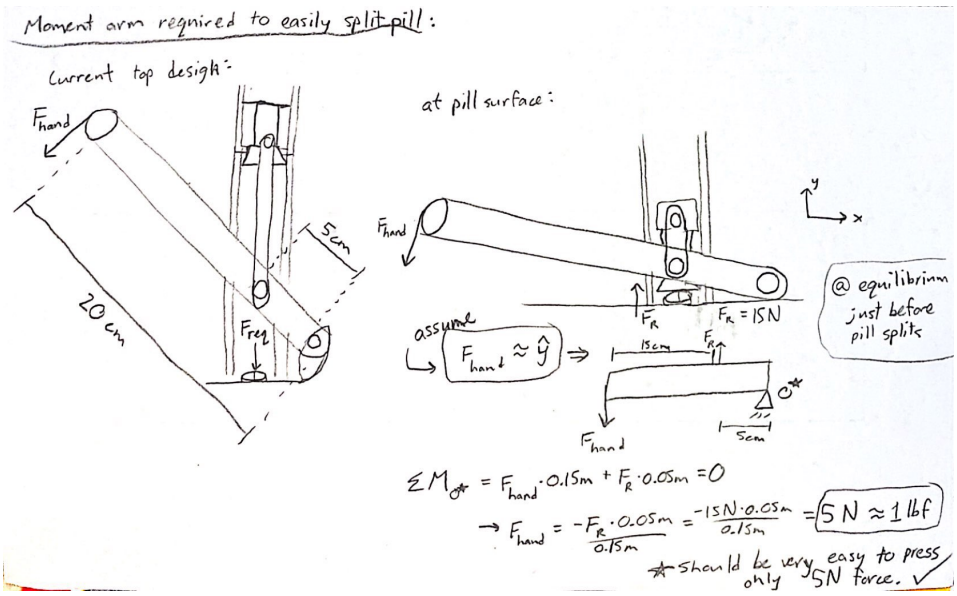


Figure 27: Model of moment arm required to split pill comfortably.

Again, note that the governing equation for this model was:

$$\sum M = 0 \tag{2}$$

Where M is a moment in Nm. The moments were summed to calculate the resulting force and check the arm length. For both of these models, we assumed that all force was only the vertical direction. This is valid because the forces that would be translated in other directions would be inconsequential to the pill splitting. Also we based these calculations off of one pill size assuming that the variation in size would not greatly effect the force required to split. This is valid because the majority of pills have similar consistency and shape which allows for an easy generalization of the material properties.

The final model has not been implemented on the prototype yet. The model is a calculation for how much force is required to stabilize the machine. When the operator pushes down on the lever, the resulting moment lifts the back of the machine. As of now, this is prevented manually. In future iterations, the calculation will be finalized and a stabilizing device will be attached. Originally, the device was theorized to be multiple suction cups. These would essentially divide the resulting moment among themselves and require a fraction of the force necessary to hold the machine in place.

6.2 Design for Safety

6.2.1 Risk 1: Over Leveraged Arm

Description: The leverage arm is forced too low which can pull the entire machine off of the surface or damage parts. The entire machine could fall from a table height.
Severity: Critical
Probability: Seldom
Mitigation: The force holding the device to the work surface will be over designed to ensure that unusual amounts of force will be required to separate it from the surface. Also, users generally being aware of the required force will help prevent this risk.

6.2.2 Risk 2: Blade Exposure

Description: While in the open position, the blade could potentially be exposed. The razor is sharp and could cause cuts or other physical harm to the user.
Severity: Catastrophic
Probability: Unlikely
Mitigation: The connection with the blade and the device is such that the use will not need to remove the blade by touching the sharp edge. The device will also be designed to prevent an opening large enough for fingers to slide under. Also, the pills will be inserted in a tray that slide into the device, thus completely removing all need for a user to make contact with a sharp blade.

6.2.3 Risk 3: Pinch Risk

Description: While closing the pill cutter, the top and bottom blocks could make contact and create an area for the user to be pinched. This could cause physical harm to the user.
Severity: Critical
Probability: Unlikely
Mitigation: The top and bottom blocks will be designed such that in the closed position, no contact will be made. This will be done by using the blade size to create a gap between the blocks. When the machine is closed, the blade will make contact with the bottom before the top block so as to stop any potential source of pinch.

6.2.4 Risk 4: Pill Contamination

Description: When the pills are cut, small amounts of debris are left behind in the pill tray. This can cause contamination and forced disposal of cut pills because of health hazards.
Severity: Marginal
Probability: Likely
Mitigation: The pill cutter is designed with a vertical cutting motion which was shown to be more effective at reducing debris production. The trays will also be made with FDA compliant materials that can be cleaned easily between cutting sessions to prevent cross contamination.

6.2.5 Risk 5: Over Opened Device

Description: The lever arm is opened beyond the intended top range of motion resulting in a force bypass of bolts and an inverted handle. This would cause damage to the structure of the machine and potential prevent further use.
Severity: Critical
Probability: Occasional
Mitigation: The device will be designed to help limit the range of motion with protruding bolts. The lever arms will also be constructed such that little slop exists in the lateral axis. This should prevent a user from being able to over open the device.

6.2.6 Risk Assessment Heat Map

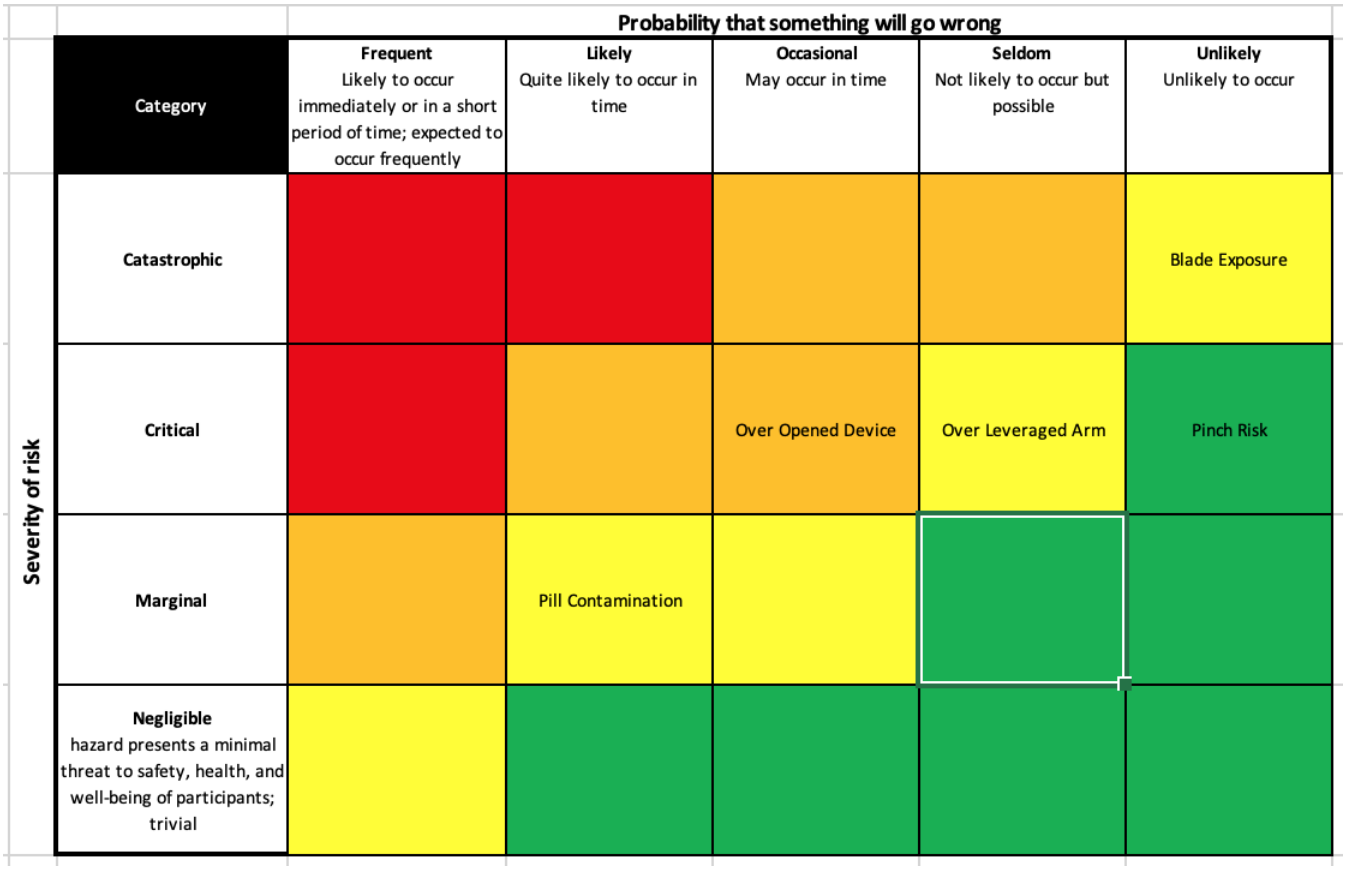


Figure 28: Heat map of the five safety risks.

6.2.7 Safety Priorities

According to the above heat map, the highest priority is the risk that the lever arm can be over opened. The second highest is between the three yellow risks: pill contamination, over leveraged arm, and blade exposure. Based on the probability and the customer needs, the pill contamination is second highest. The next, based on the risk to the user, is the risk of blade exposure. The fourth is the risk of over leveraging the arm which is moderate in both probability and severity. The last risk with the least priority in the design process is the pinch risk. It has very low probability and mild severity.

6.3 Design for Manufacturing

Number of Parts: 13
Number of Threaded Fasteners: 10
Theoretically Necessary Components (TNCs)

1. 2x 13" Long lever arms - Made from 6061 Aluminum
2. 2x 4" Short lever arms - Also made from 6061 Aluminum
3. Soft sponge Handle - necessary to connect long leverage arms; cannot be combined with other TNCs because this is a custom component built to limit slop
4. Top block made from Douglas fir softwood
5. Bottom block, made from identical material as top block
6. 2x Aluminum tubing pipes - necessary to align top and bottom block, allow for vertical translation; used as separate TNCs to control lateral and rotational motion.
7. Blade - necessary to cut pills; cannot be combined with other TNCs because it is sold separately
8. Custom Pill Tray - necessary to house pills during cut; cannot be combined with other TNCs because a removable tray is integral to the ease of use design

Our design is already quite close to a minimum number of TNCs. Some of the objects we may be able to combine are the long and short lever arms. These are able to be manufactured as two pieces instead of four if the short and long arms are connected. This same logic is extended for the top and bottom block, which need to be dimensionally symmetrical, and hence it is advantageous to manufacture them from the same material. Over all, the prototype has influenced us to change most of the components to reduce the TNCs. One major change was to utilize the custom handle system so that only one bottom and one top block were necessary. In the prototype, multiple blocks were required to close the gap caused by a restrictive range of motion, due to the use of a pre-existing lever system, coming from a can-crusher. An image of the multiple blocks used in the prototype with the pre-made handle is shown below.

Figure 29: Initial prototype with multiple wooden blocks used to close gap between top and bottom blocks caused by the pre-made handle.

Another component that was removed after building the prototype was the use of a threaded rod spine through the bottom block to stabilize the two aluminum tubes, acting as slide bars, and allowing for the long lever bar to anchor onto. Instead, the aluminum tubes are going to be set in place using an adhesive, while a $\frac{1}{4}$" aluminum rod will be place in either side to attach the lever arm to, which will now be held in place using a washer and shaft collar.

This will increase the TNC count by 2 units, but will greatly simplify the construction of the mechanism, as the threaded rod placement took many hours in the prototype design, having to thread through 4 holes, with minimum tolerance, while reaching through an 8 inch block. This alternative is very easy to make, and hence is worth the additional number of construction components.

6.4 Design for Usability

Vision: To make our device more accessible to people who are red/green color blind, we can utilize different colored materials. These colors would contrast the colors of the pills like bright yellow or dark brown. These contrasting colors could help a color blind user differentiate the blade from the rest of the device and the pills from the rest of the device.
Hearing: Operating this device should not be effected by those with hearing impairments because operational ques are primarily visual. A user looks to see if a pill is cut and can feel the vibration during the movement/cutting process. Thus a hearing impaired user should be capable of operating this device by sight and feel.
Physical: A major design focus was making this pill cutter easier to operate than current models by using leverage. This leverage requires less force from the user to actually cut the pill. To accompany this reduction of force, a soft handle will be implemented which will help to increase

re-usability and decrease fatigue.
Control: Because of the intent for this device, it should not be operated while in a fatigued or intoxicated state. The materials being handle can be toxic to the user and to patients if miss handled. To prevent injury from fatigued users, the opening for the pills to be placed will not be large enough for an operator's fingers. Also, the blade removal process has been designed to eliminate the need to touch the sharp end of the blade. Because this device is intended for non-commercial and medical use, users should be qualified and careful. Uneducated operators can be injured.

7 Final Prototype

7.1 Overview

Our final prototype succeeded in two of its three goals. First, it was successful in achieving a cutting rate of at least 4 times that of the current method. Second, it was successful at decreasing the force required to cut pills by 3/4. Finally, it was unsuccessful at a successful cut rate of 9/10 pills. This failure was due to an error in the 3D printed pill tray. The tray dimensions were incorrect which lead to play in the pill placement. Over all, we believe that, using the below final prototype with a more accurate pill tray, the final prototype would have been 100% successful.

7.2 Documentation

Below are figures illustrating the final prototype and its key design features.

Figure 30: Front view of final prototype

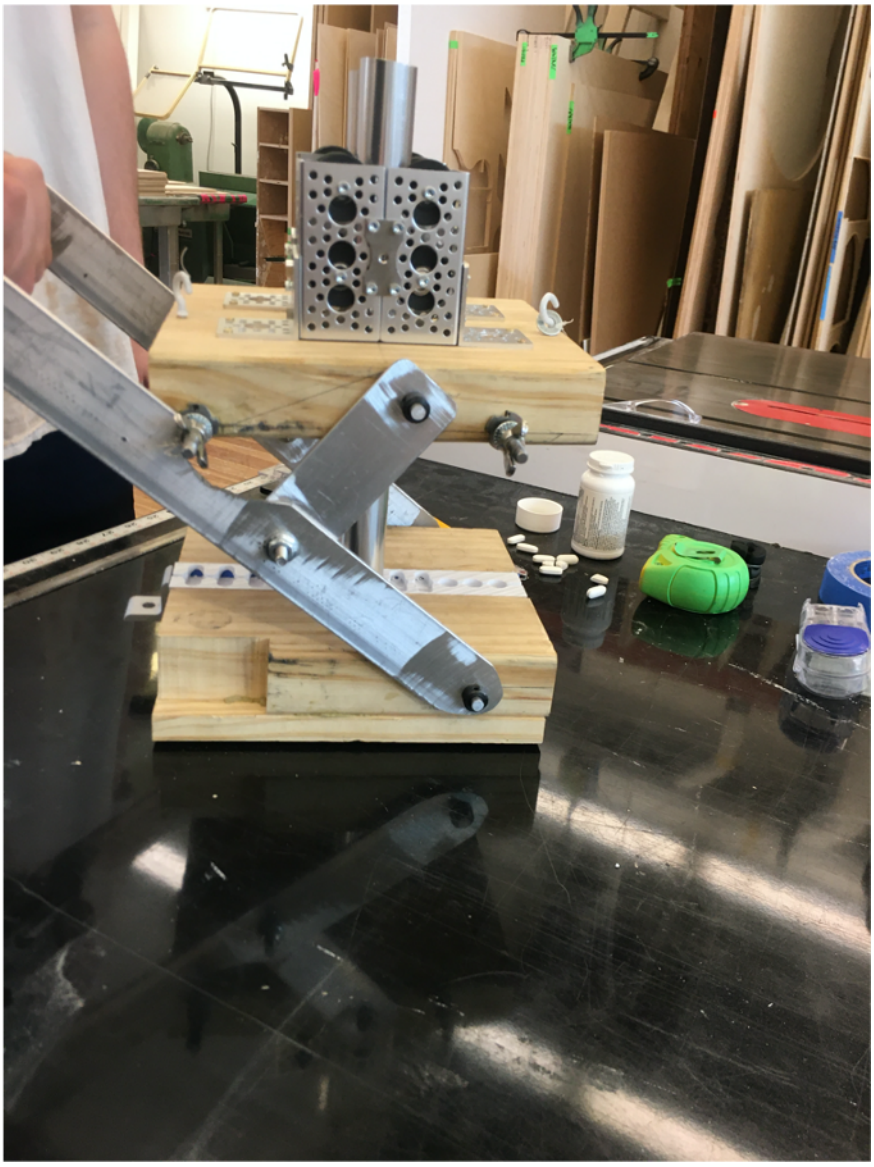


Figure 31: Side view of final prototype

Figure 32: Bottom view of final prototype showing the suction cups

Figure 33: View of final prototype pill tray