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MEMS 411: DialySqueeze

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DIALYSQUEEZE

Nurses across Canada and the world employ clips to section dialysis tubing. According to Sydney Livermore, a staff member at McMaster University, this clipping action by nurses contributes to thumb arthritis. Sydney Livermore is looking for a design to clamp the dialysis tube clip to prevent further damage to the nurses' hands. The device needs to be portable, ergonomic, safe, easy to clean, and multiply force on the tube clip.

To address the needs of Canadian nurses, the team developed various ideas for designs involving devices deriving inspiration from staplers, pliers, levers, and nutcrackers. After evaluating each concept, the team determined that a plier/lever-like device with a shaped cup to align a clip would serve the purpose of clamping the clip. The team used deflection and bending models to determine the size of the plier device.

The finalized design includes two 3D printed PLA lever arms held together by a rivet. A clip aligner is 3D printed separately and epoxied onto the lower lever arm. A torsion spring is employed around the rivet to create a "spring back" force which allows the device to be effective for clamping multiple clips in a row. This design met all three prototype performance goals. First, the device weighs 1.52 oz, well under the requirement of less than 4 oz. Second, the device multiplies the force by at least 4x, measured by pulling down on a force gage. Finally, the device can be used with both the left and the right hand and clamp 3 clips in under 5 seconds with either hand after it is pulled out of a pocket.

The clip models were analyzed by an external review board and will be sent to nurses in Canada to be tested for viability.

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1 Introduction

Sydney Livermore, a hospital nurse in Canada, is looking for solutions to clamp dialysis tubing as a part of her daily routine, along with many other nurses worldwide. The current universal clamp adds stress to the nurse's thumbs, which are responsible for engaging the clamp with the tubing. Nurses like Sydney are looking for an ergonomic solution to engage the clamp without constantly causing pain to their thumbs. This ergonomic device needs to be lightweight and portable, as nurses walk from room to room to clamp tubing, easily disinfected as it would be used in a hospital setting, and not have any sharp edges to avoid poking or injuring nurses. This project outlines the design process to address Sydney's needs and create a functional device for nurses in her workplace.

2 Problem Understanding

2.1 Existing Devices

2.1.1 Existing Device #1: Edward Tools Slip Joint Pliers

Figure 1: Slip Joint Pliers (Source: Edward Tools)

Link: https://www.amazon.com/Edward-Tools-Slip-Joint-Pliers/dp/B082DRQLFC
Description: The Edward Tools Slip Joint Pliers use a lever and fulcrum to multiply force from the hand to the target. They have a rubber and steel construction, which is durable and ergonomic. The slip joint allows the size of the jaws to be adjusted so that the pliers can apply force to a wide array of objects, such as different-sized clips.

2.1.2 Existing Device #2: Flinn Scientific Dialysis Tube Clamp

Figure 2: Dialysis Tube Clamp (Flinn Scientific)

Link: https://www.flinnsci.com/dialysis-tubing-clamp/ap4349/

The Dialysis Tube Clamp is used to temporarily restrict the flow of fluid through a rubber tube, specifically for dialysis equipment. The clamp is made from a single piece of plastic, which makes it lightweight and easy to clean. The clamp has ridges on the outside for an easier grip, and the jaw action of the clamp means the user can use their fingers and palm to close the clamp, which reduces the stress on the thumb joint.

2.1.3 Existing Device #3: McMaster Carr Squeeze Handle

Figure 3: Dialysis Tube Clamp (Flinn Scientific)

Link: https://www.mcmaster.com/products/flow-control-clamps/

The flow control clamp features a simple plastic and metal design. the user applies force at the end of the handles, which gives a mechanical advantage. The metal hinge also works as a spring to return the device to its original position. This action allows the user to clamp many tubes rapidly, as the tool is ready for use immediately after the user stops applying pressure.

2.2 Patents

2.2.1 Pipe clamp (US3330517A)

This patent features a product that connects to half shells to form a cylindrical shape. A snap closure connects and secures the half shells to each other through simultaneous elastic deformation. To re-open the clamp, the half shells are elastically deformed once again, thus diminishing the need for numerous bolts and nuts in the product.

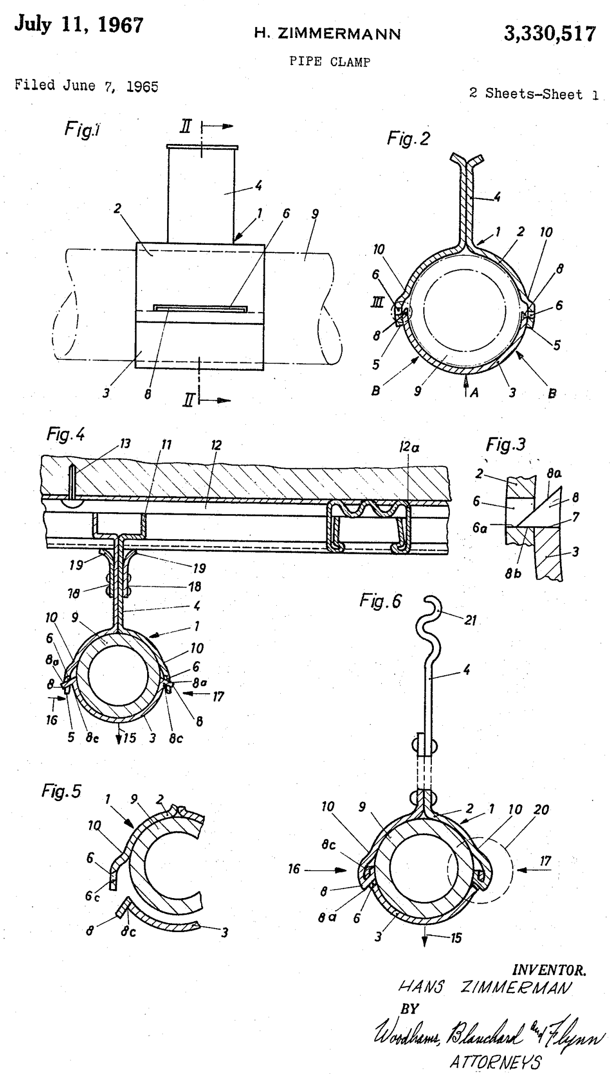


Figure 4: Patent Images for pipe clamp (sheet 1)

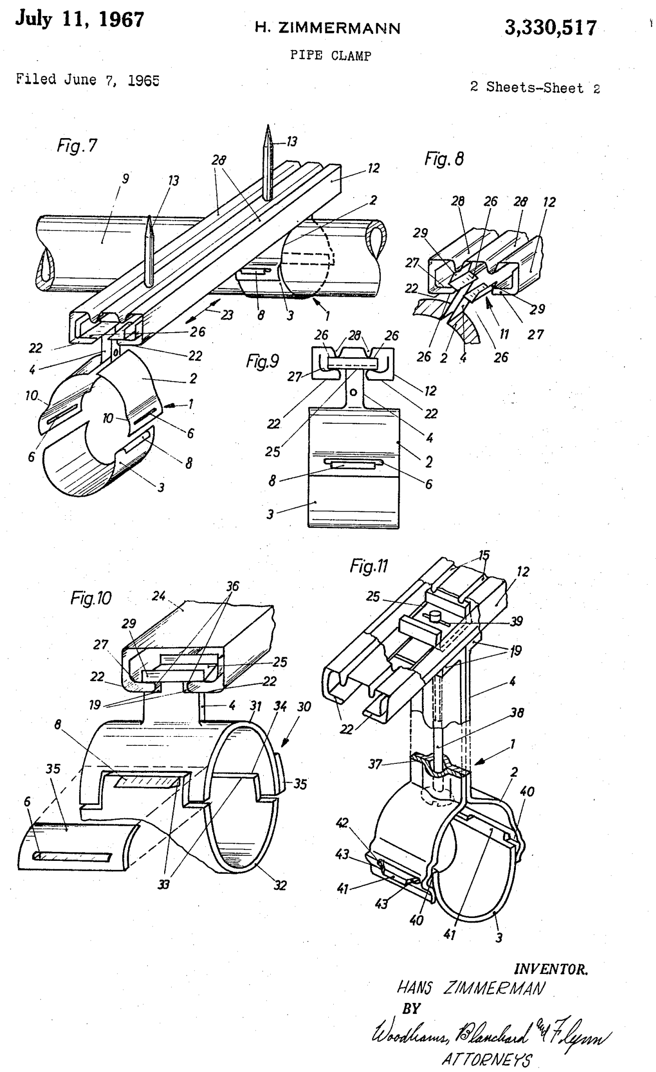


Figure 5: Patent Images for pipe clamp (sheet 2)

2.2.2 Tube clamp (US6708377B2)

This patent features a plastic clamp consisting of two semi-circular tangs. The tangs are connected together at one end by a hinge and connected at the other end by a screw and wing nut. A crossbar is used to prevent any angular displacement by the screw during use and also prevents against overtightening of the nut.

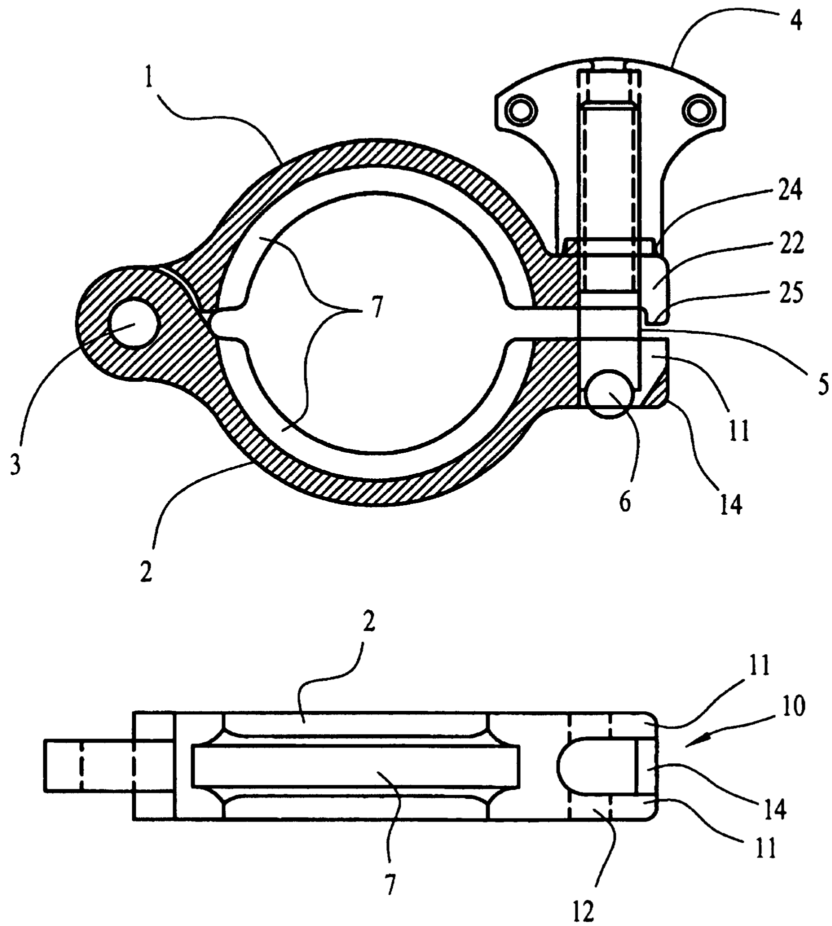


Figure 6: Patent Images for tube clamp

2.3 Codes & Standards

2.3.1 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process ISO 10993-1

This code covers the various tests that materials to be used in devices must undergo. These tests include blood compatibility, and making sure that the material is not toxic. We need to make sure that our device will not harm any patients or nurses in the hospital.

2.3.2 Additive Manufacturing - Design ASTM ISO/ASTM52910-18

This standard applies to designers planning to use additive manufacturing to create a product. Our team may design the device to be 3D printed, and this code will be useful in determining product requirements and identifying general issues. This code is relevant to our project because it can help give us direction in how we would like to manufacture our device and help us to identify any issues before we begin our manufacturing process.

2.4 User Needs

The group conducted an interview of the customer, Sydney Livermore, via Zoom on Friday, September 8. Sydney is a nurse at a hospital in Canada. Sydney suggested creating a device to add

2.4.1 Customer Interview

Interviewee: Sydney Livermore
Location: Zoom
Date: September 8^{th}, 2023
Setting: Zoom

Interview Notes:

Should we design our product for different sizes of clips?

- They are not sure at the moment, but are going to send us the clips that they are using at their hospital in Canada. They are going to try and get more information.

What current prototype are you working with?

- There are a couple of restrictions that we're working with. The fact that it needs to be used with both hands and has to be a one-handed device. Just so they can stabilize with their other hand while they're working, so this is yeah, really rough prototype, but hoping for something, whether it's a loop or handles that'll allow for that. One-handed use is really key. It put too much pressure everywhere. It's distributed too much. So some of the comments we had where it just has to be a little bit different, so that it creates the force. At sort of this end here and then that tip there also had to use like Sydney said in either hand, kind of getting in and around things. And also his comment was, It's unlikely for a nurse to maybe go and seek out a big bulky tool. So something that would be quite streamlined, so that it wasn't something that had to be. You know, this big extra thing that maybe something could just be on the lanyard, or something light and little, but those are some of the feedback he had is the right or left-hand able to get into awkward spaces, and then really accessible where a nurse wouldn't have to go and find a tool where they would just have it handy.

How does the device help you unclip?

- The main thing we're worried about is the actual clipping and the level arm being your thumb, which serves as a force multiplier, thus increasing the force at the CMC joint.

Is there a tool that a nurse currently does carry around with them that has a similar size to what you're looking for here?

- Yeah, I would even say, like pocket size, like something that could slip into their pocket. Cause a lot of the time like there'll be, or something that can even stay in the room. Is another great idea, but like even pocket size that they slide it in their pocket, and they can carry around or like Shona even said like cause there's not many things that they necessarily carry with them from room to room. It's all kind of set up for them. But even that kind of key chain idea, if it was able to be that size and do the job. Obviously, there's kind of the restrictions around. Could it do that force being such so small? But if it could fit in the pocket that they could kind of put away, carry around.

When you guys are talking about like clipping and unclipping? How often do these little clips like break do they ever break? Is that ever an issue? If we're applying more force? Do you think that could be an issue?

- They're fairly durable, but they are not reusing these clips.

Do they need to be easy to clean?

- Yeah, just in the hospital setting, or if some sort of like biohazardous material got on it, it just it's kind of a standard to sanitize it. So making sure that it can be pretty well disinfected.

Do you use one ridge clips, or multiple ridge clips?

- Just one ridge to get down.

Would we want something that could produce this type of force closing force on other things?

- Big for dialysis tubing, but could be used and pitched for economics' sake as a something that could help with general blood tubing clipping around the hospital.

What do you guys like about the current product?

- Truth be told, I wanna say it's just the standard of what's been given to the hospitals like these, this is your tubing. This is the clips. This is what you're using. Because I know we had mentioned, okay, how hard would it be to change the actual clip and make it more ergonomic? Or is the device for the clips better? So I think what's been seen is that those clips are just kind of the standard. This is what units and hospitals are using, and there hasn't been much question. So I think our thought process was what's the most effective way to make change and take those small steps? And it was to be creating a device that would allow for the clip to be pushed without using the thumb rather than trying to spark this big change of we need to change all these clips on all these tubing and all these brands, not to say it can't be done. I think it was the path of least resistance that let's try a device first, and see the benefits we can reap.

Are there any sort of common hand related work injuries that we should be mindful of so we don't accidentally make a device that has a different ergonomic problem even though it solves the thumb one?

- Yeah, I'd want to say your typical like, just kind of surface stuff. So definitely, we'll watch out for anything that could really irritate the skin like keeping it like more of a sleek design rather than something that's really gonna put pressure in places. We don't want it. The bigger the joints the better, so to say, it is a holding force. So if we can keep it off other fingers. So not just taking it from like removing the thumb force, but then saying, Okay, well, I'm gonna use like my other fingers for it, cause it's still gonna kind of present that same problem. But certainly your wrists and elbow, or those they are stronger joints. So they can handle a little more force, and usually won't present problems with the clip, because it's not enough force to hurt wrist, elbow. But certainly the thumb being a little more mobile and has a lot more movement and a lot of more things going on. It tends with the repetitiveness to kinda take a lot more impact. Rounded corners on this just because of the square design (referring to current prototype). This device should be a force multiplier.

Are you concerned with having the device be lightweight at all?

- It should be preferably lightweight, so it can fit in your pocket and be able to wipe it down easily. Lightweight, no sharp corners.

What are you willing to spend, and is this something that you would want every nurse to be carrying around?

- I think the goal would be something that's not gonna be this huge cost. As economically friendly as possible without worrying about the integrity of the actual device.

How complex can the device be? Should it be something that you can easily understand how to use it, or can there be a bit of a learning curve to it?

- A learning orientation could be good to not only teach people how to use it, but show them why they should use it.

Are there any other strains or possible damages that we should design for?

- As long as there is minimal force and strain being put on your hand or thumb, then there doesn't have to be much more consideration. Also, make the tool durable and able to be dropped a few times just in case.

Are you clipping consecutively, or is there ample time between clipping?

- They clip many clips when they are prepping a patient.

Should our device be just as easy and fast to use as simply clipping it with your thumb?

- It has to be just as fast or comparable as doing it with your thumb.

Which joint is the problem?

- The CMC joint because it is a 12x force multiplier.

2.4.2 Interpreted User Needs

From our interview, we determined that there are six main needs by nurses for the functionality of the tool that can be used to close the clamp. These needs are listed below, along with their specific levels of importance, in Table 1.

Table 1: Interpreted Customer Needs

Need Number	Need	Importance
1	The tool is portable	5
2	The tool multiplies force on the tube clip	4
3	The tool is safe and easy to clean	5
4	The tool has no sharp edges	3
5	The tool is ergonomic	5
6	The tool can be used for multiple sizes of clips	2

We have chosen the most prevalent needs and ranked their importance based upon their responses to our interview questions. The 2 most important needs were that it must be portable, and it must be safe and easy to clean. It must be portable because Sydney made it clear that the nurses will have to take this device from station to station to clip different sets of dialysis tubing. It must also be safe and easy to clean because the device will be used in a hospital, so it can't present a greater threat because that would defeat the purpose. The tool must multiply force on the tube clip was ranked as a 4 because, if we can find a way to reduce stress without multiplying force, then that would work.

But with given options, the tool should multiply the force to reduce risk of other stresses. This goes with another need that is extremely important which is that it must be ergonomic. As previously stated, the new device should not provide other stresses while compensating for the thumb. It must be easy to use and be comfortable for the user. The tool, additionally, should try and have no sharp edges. If they are necessary, they will probably be accepted, but we will try and avoid them to reduce the risk of cuts or other injuries. The final need we ranked a 2 because there were multiple questions asked if the device should be specifically designed for their clip or more general clip sizes. Sydney and Shona are our clients and should be prioritized so we will design it to definitely work with their clip, but if we can make it more general, we will.

2.5 Design Metrics

From our interview, we determined target specifications for the functionality of the tool that can be used to close the clamp. Our specifications are listed below, along with the acceptable and ideal quantities, in Table 2.

Table 2: Target Specifications

Metric Number	Associated Needs	Metric	Units	Acceptable	Ideal
1	1	Total weight	g	140	70
2	1	Longest dimension	*cm*	< 18	< 15
3	2,4,5	Rating of "comfort" by nurses	avg. score	$> 3/5$	$> 4/5$
4	1,5	Maximum time needed to engage the clamp with the tube	s	< 3	> 6
5	5	Number of compatible clips	integer	1	> 3
6	4, 5	Durable and efficient construction per ISO/ASTM 52910	binary	Pass	Pass
7	3	Suitable for a medical environment according to ISO 10993-1	binary	Pass	Pass

2.6 Project Management

The Gantt chart in Figure 7 gives an overview of the project schedule.

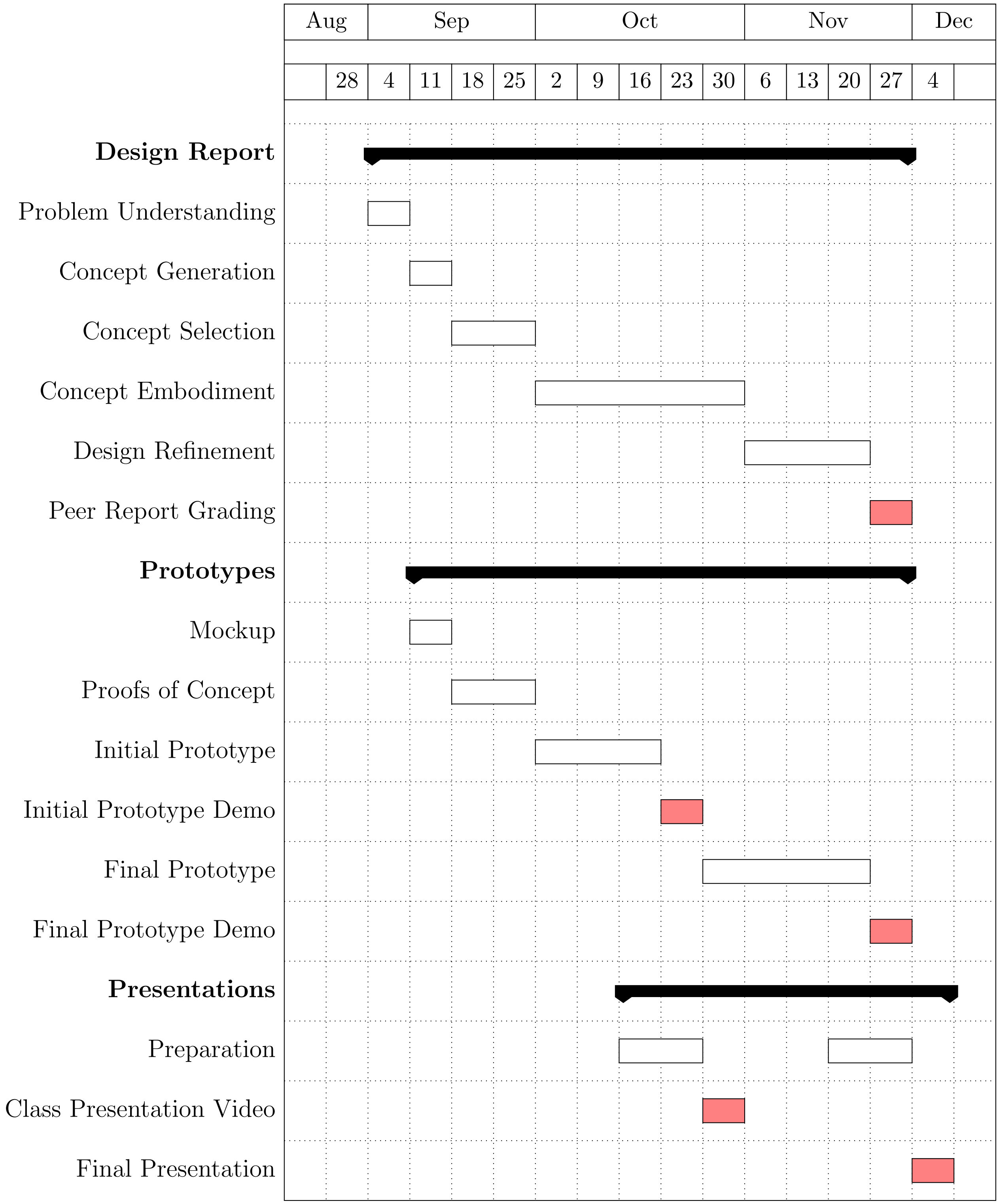


Figure 7: Gantt chart for design project

3 Concept Generation

3.1 Mockup Prototype

The mockup prototype features a clamping mechanism using the design of a pair of scissors and pliers to close the clamp. The figures shown below illustrate this prototype.

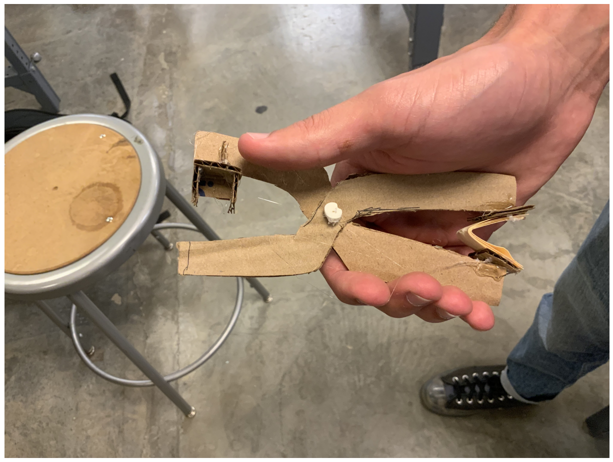


Figure 8: Prototype Opened

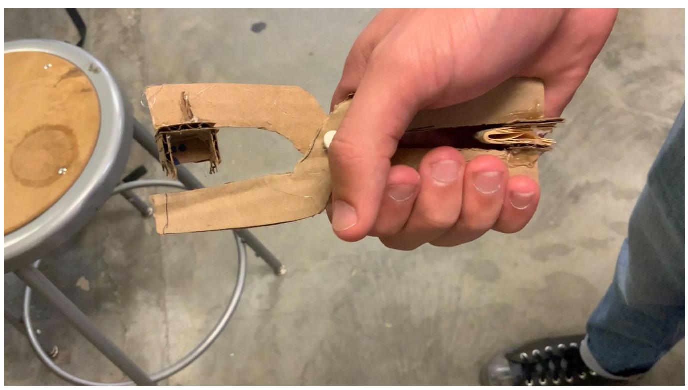


Figure 9: Prototype Closed

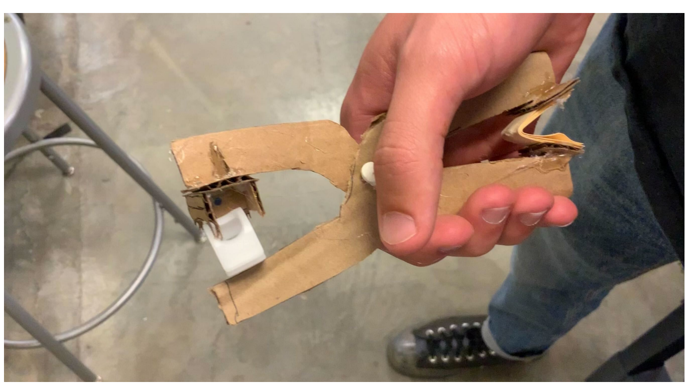


Figure 10: Prototype Closed with Clamp

This mockup was made primarily from cardboard and was modeled after a standard pair of pliers. The two arms are joined by a metal tack, with hot glue added to the other side to cover the sharp tip. Extra cardboard has been added to one of the plier tips. These pieces form a U-shaped structure that helps the user align the pliers with the clip. A spring was fashioned by cutting strips of manila folder and laminating them with hot glue. When the user closes the pliers, these strips bend, so when the user release the pliers, they push the arms back into the open position.

3.2 Functional Decomposition

A function tree for the clamp is shown below.

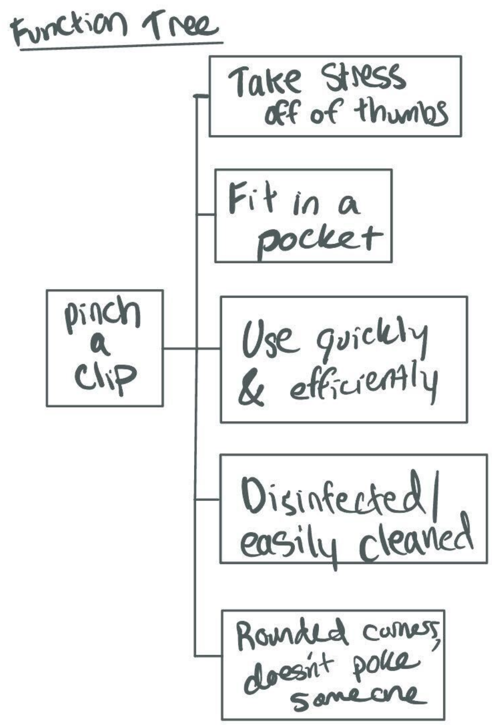


Figure 11: Function tree for clamp, hand-drawn and scanned

3.3 Morphological Chart

The morphological chart for the clamping mechanism is shown below as it relates back to the function tree.

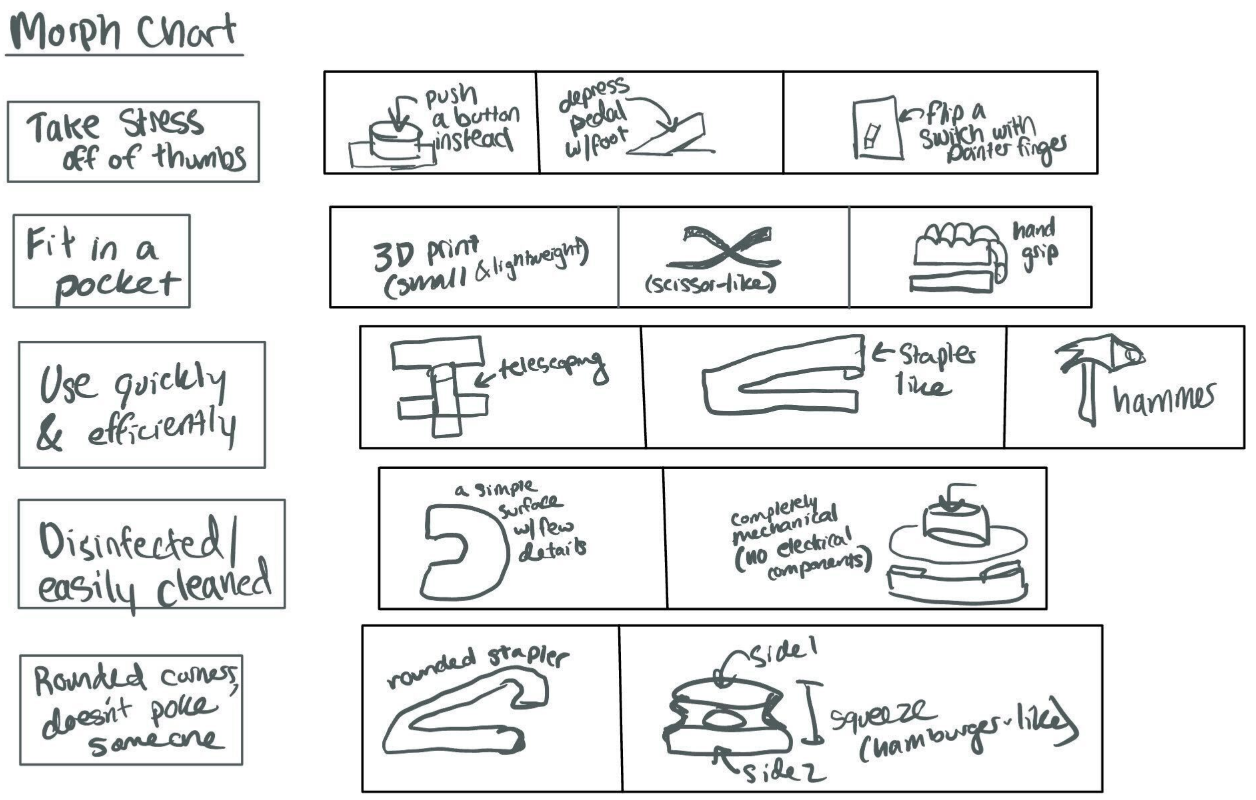


Figure 12: Morphological Chart for clamp

3.4 Alternative Design Concepts

3.4.1 Concept #1: Stapler

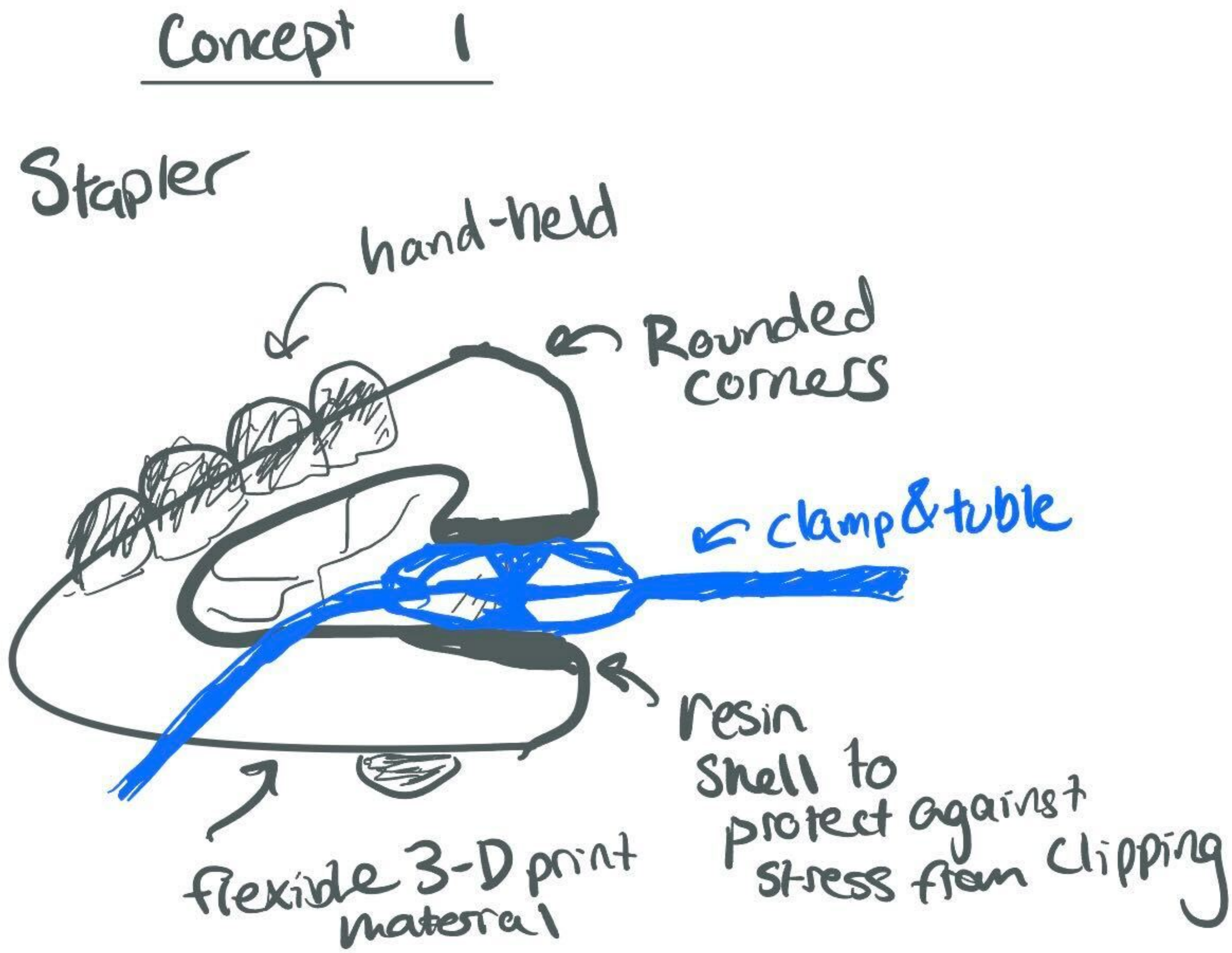


Figure 13: Sketches of Stapler concept

Description: A stapling device could help to use the entire hand to clamp the clip. The stapling device could have rounded corners to avoid poking nurses. The entire hand could be used to quickly operate the stapler to remove most of the stress on the thumb. Finally, flexible 3D printed material could be used to ensure that the stapler could be cleaned easily.

3.4.2 Concept #2: The Black Box

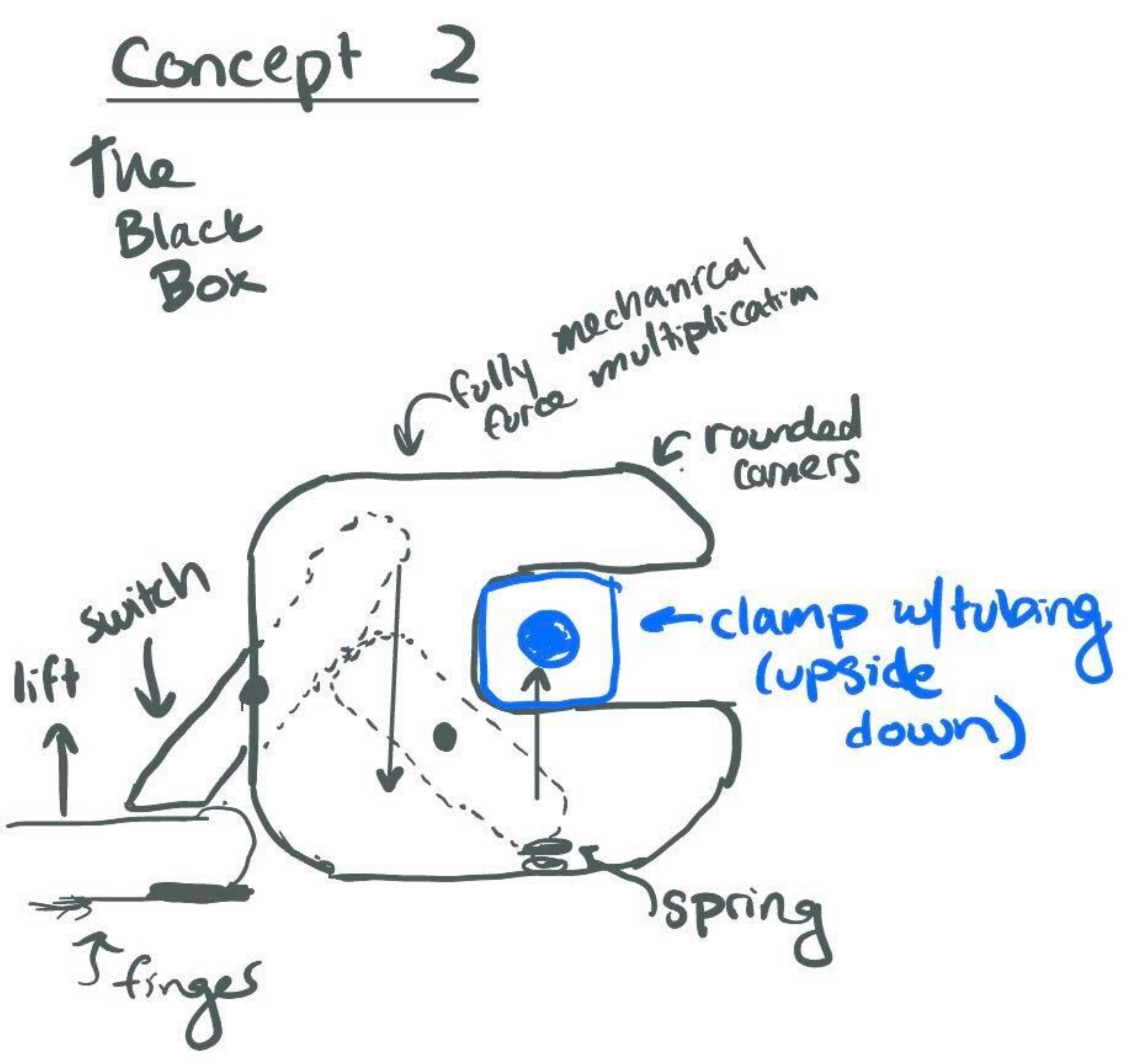


Figure 14: Sketches of The Black Box concept

Description: The Black Box design features a switch that can be lifted by a singular finger. A series of interior levers multiply force by activating a spring that causes the second lever to clamp the tubing. The box will have rounded corners and a slot to ensure the tubing fits perfectly.

3.4.3 Concept #3: Pliers

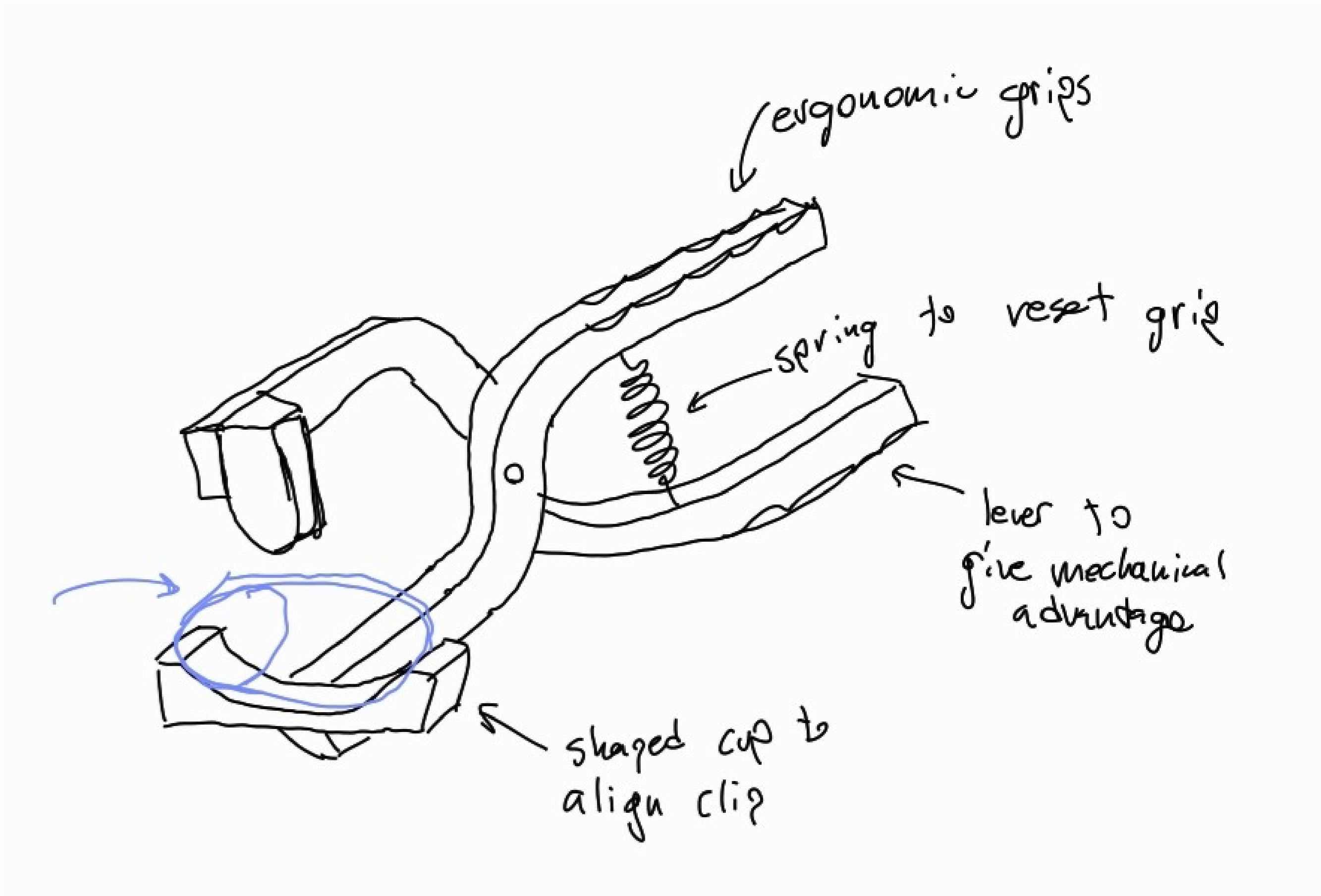


Figure 15: Sketches of Plier Concept

Description: The pliers concept works very similarly to a standard pair of pliers. By gripping the tool at the end, the user obtains a significant mechanical advantage. The tips of the pliers have been specially designed for this task. The bottom arm has a U-shaped surface to align the clip, while the top arm has a rounded nub to concentrate the grip force on closing the clip.

3.4.4 Concept #4: Yet Another Concept

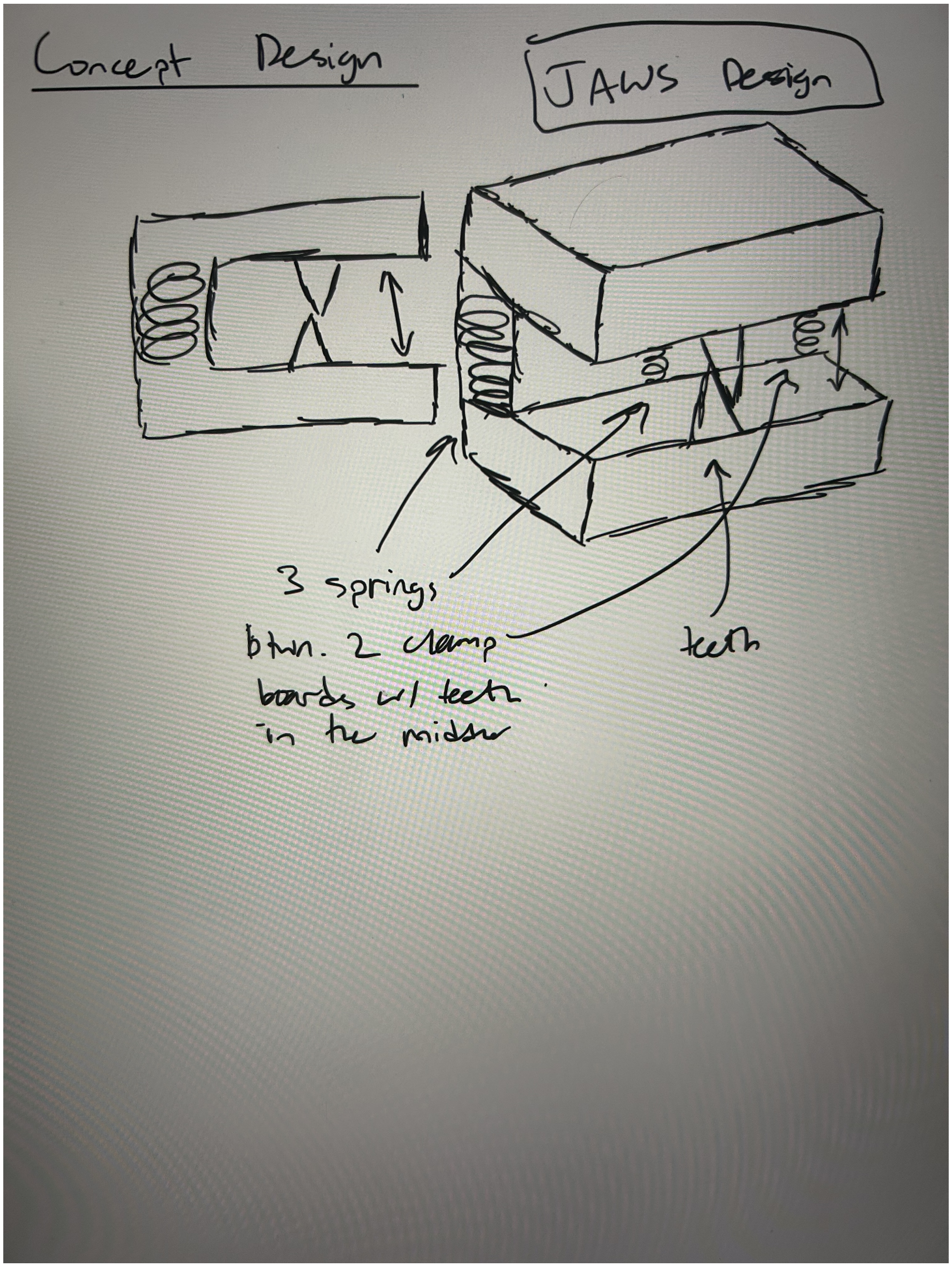


Figure 16: Clamp JAWS Design Concept

Description: The JAWS design is a very simple solution to redistributing the stress on the thumb to the entire hand. There are 2 rectangular platforms that will go around the clip. They are connected via 3 springs that line on end of the length side of the rectangle. The user will then squeeze it around the clip to apply a force between the teeth and that will clamp the clip.

4 Concept Selection

4.1 Selection Criteria

Figure 17 shows the group's selection criteria below via the analytical hierarchy process. User Speed describes the ability of the nurse to clip the clip quickly and safety describes the layout of the design so that it does not poke any nurses, meaning that the edges/corners are rounded.

	Portability	User Speed	Easy to Clean	Safety	Ergonomic Design	Row Total	Weight Value	Weight (%)
Portability	**1.00**	2.50	3.00	3.00	0.33	9.83	0.23	23.28
User Speed	0.40	**1.00**	1.00	0.20	0.33	2.93	0.07	6.94
Easy to Clean	0.33	1.00	**1.00**	0.33	0.14	2.81	0.07	6.65
Safety	0.33	5.00	3.00	**1.00**	0.33	9.67	0.23	22.88
Ergonomic Design	3.00	3.00	7.00	3.00	**1.00**	17.00	0.40	40.24
					Column Total:	**42.24**	**1.00**	**100.00**

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

4.2 Concept Evaluation

Figure 18 weighs the design concepts generated by team members.

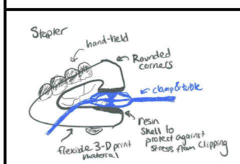
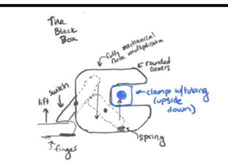
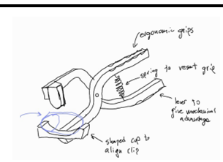
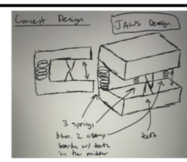
Alternative Design Concepts		**Concept #1**		**Concept #2**		**Concept #3**		**Concept #4**	
									
Selection Criterion	**Weight (%)**	**Rating**	**Weighted**	**Rating**	**Weighted**	**Rating**	**Weighted**	**Rating**	**Weighted**
Portability	18.52	3	0.56	2	0.37	4	0.74	2	0.37
User Speed	13.34	3	0.40	1	0.13	4	0.53	3	0.40
Easy to Clean	22.15	2	0.44	2	0.44	3	0.66	2	0.44
Safety	18.41	3	0.55	3	0.55	3	0.55	1	0.18
Ergonomic Design	27.59	3	0.83	3	0.83	4	1.10	4	1.10
	Total score	**2.779**		**2.327**		**3.594**		**2.501**	
	Rank	**2**		**4**		**1**		**3**	

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

4.3 Evaluation Results

The design that received the highest score was the Pliers Design. Its portability was rated a 4 from using outside knowledge. Pliers are often easily carried from room to room and can be passed around easily. User speed was given a 4 as well because the spring that is between the bottom arms of the pliers will quickly open the pliers back up after use. This will allow for quick repeatability. Ease of cleaning was rated a 3 which was tied for the highest rank with the other concepts. It is important to be easy to clean as this tool will be used in hospital rooms with potentially vulnerable clients. It is not ranked higher because we assume that the spring could be somewhat difficult to clean thoroughly. The safety of the chosen tool was also rated a 3 as there is potential for clamping your finger or dropping it on your foot. It is tied for the highest ergonomic design, which is the most important selection criterion. Pliers have been used for a long time as a force multiplier, and after testing with the mock-up it decreases overall stress on the thumb and hand significantly. With these values being weighted, it outscored the next best concept by almost a full point.

4.4 Engineering Models/Relationships

Figure 19 displays the deflection engineering model for the pliers. It can be used to help determine the necessary material thickness of the plier handle to prevent buckling. First, the spring force (or critical load) can be found using the spring equation. The spring force will be used to approximate the grip force, or critical load. Next, the length and material of the pliers will be used to find L_e and E, respectively. The buckling equation can be used to solve for I, the moment of inertia. The moment of inertia equation can be used to find the necessary thickness of each plier handle.

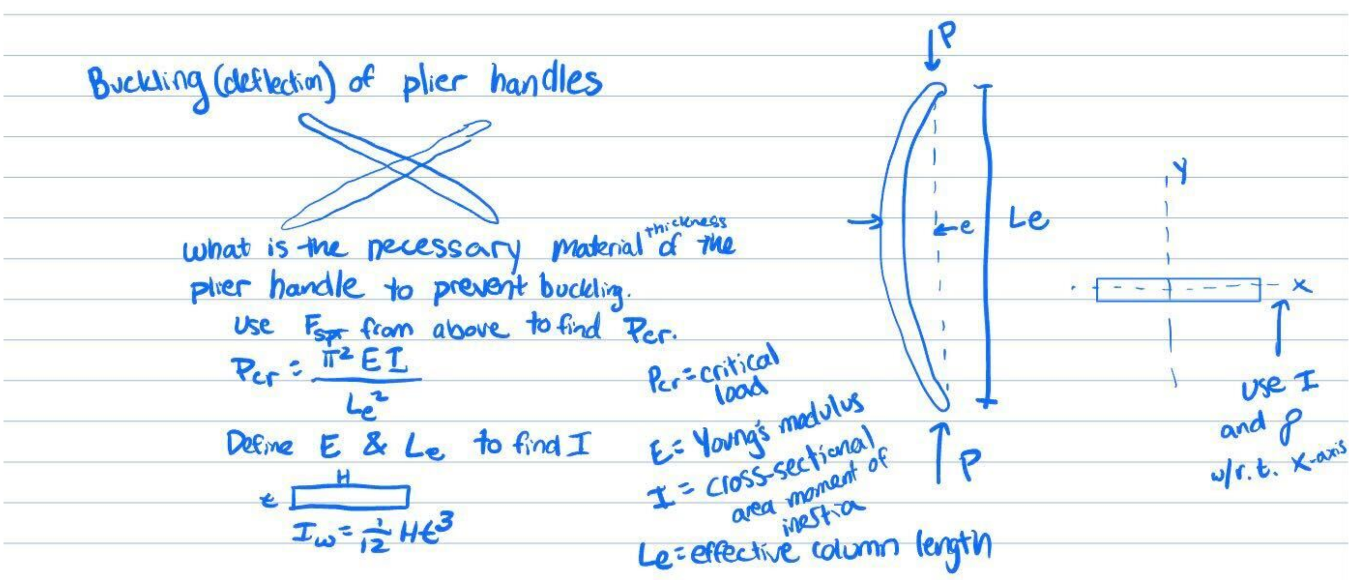


Figure 19: Deflection model for handles of pliers.

Figure 20 shows how the pliers may be simplified into a lever arm problem. Given the portability requirement of the pliers, there will likely be an overall length requirement L_0. We also know the acceptable grip force F_G based on the ergonomics requirement, and the force needed to close the clip F_C through empirical testing. We then have two equations:

$$L_C + L_H = L0 \tag{1}$$

$$L_C F_C = L_G F_G \tag{2}$$

And two unknowns, allowing us to solve for the location of the pivot.

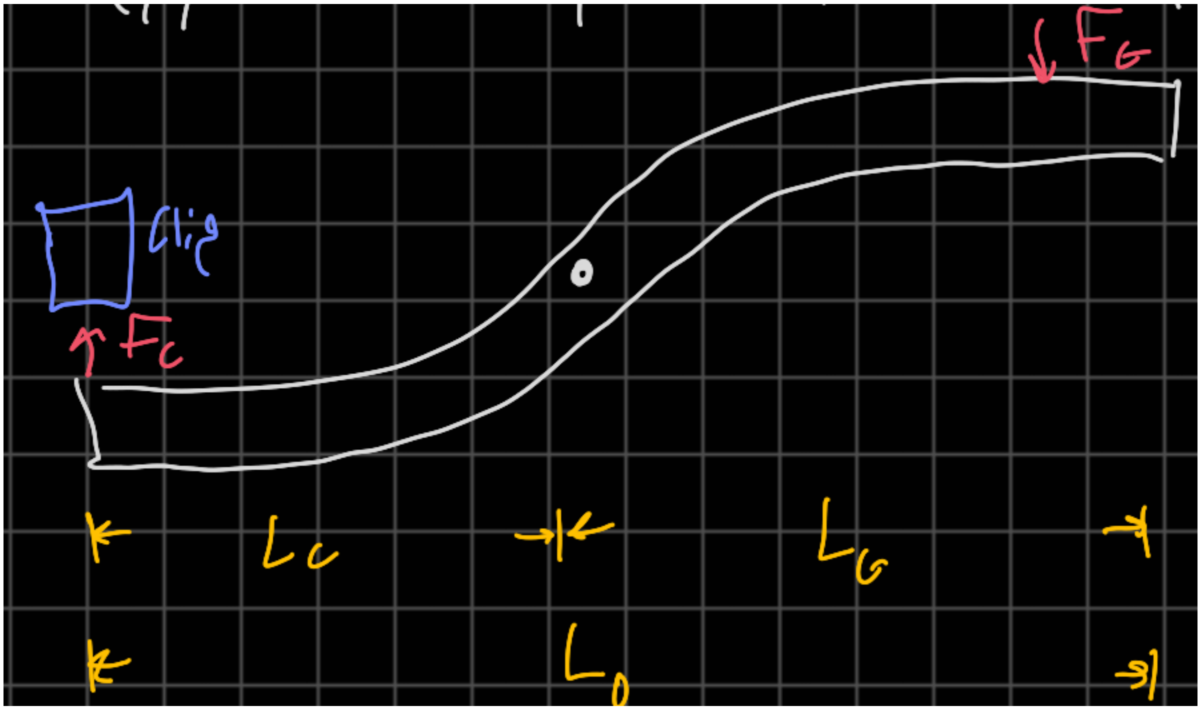


Figure 20: Moment balance for the tool

As force is applied, the tool will remain in static equilibrium until enough force is applied to close the clip. Figure 21 shows how the handle of the tool can be modeled as a beam with a fixed end. The equation for stress is:

$$\sigma_{max} = \frac{Mh}{2I} \tag{3}$$

Where h is the height of the beam and I is its moment of inertia. With M determined by the lever arm model, we can vary the geometry of the handle (h and I) to ensure $\sigma_{max} < \sigma_y$ of the material.

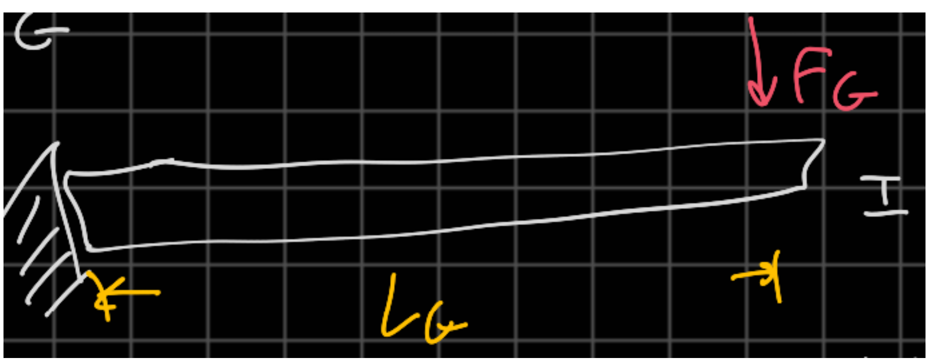


Figure 21: Bending beam model for the tool

5 Concept Embodiment

5.1 Initial Embodiment

The CAD drawings below display the initial prototype and a bill of materials.

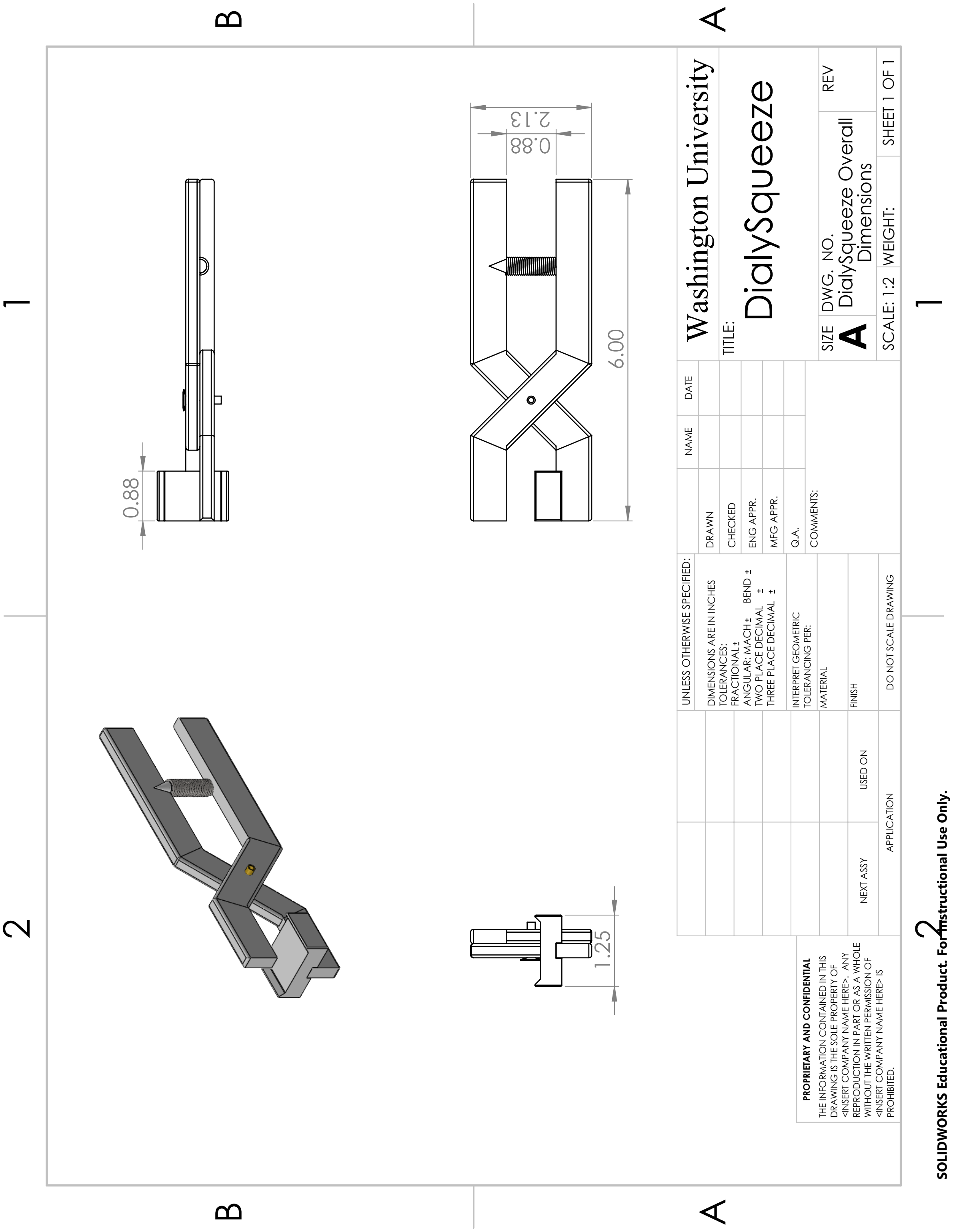
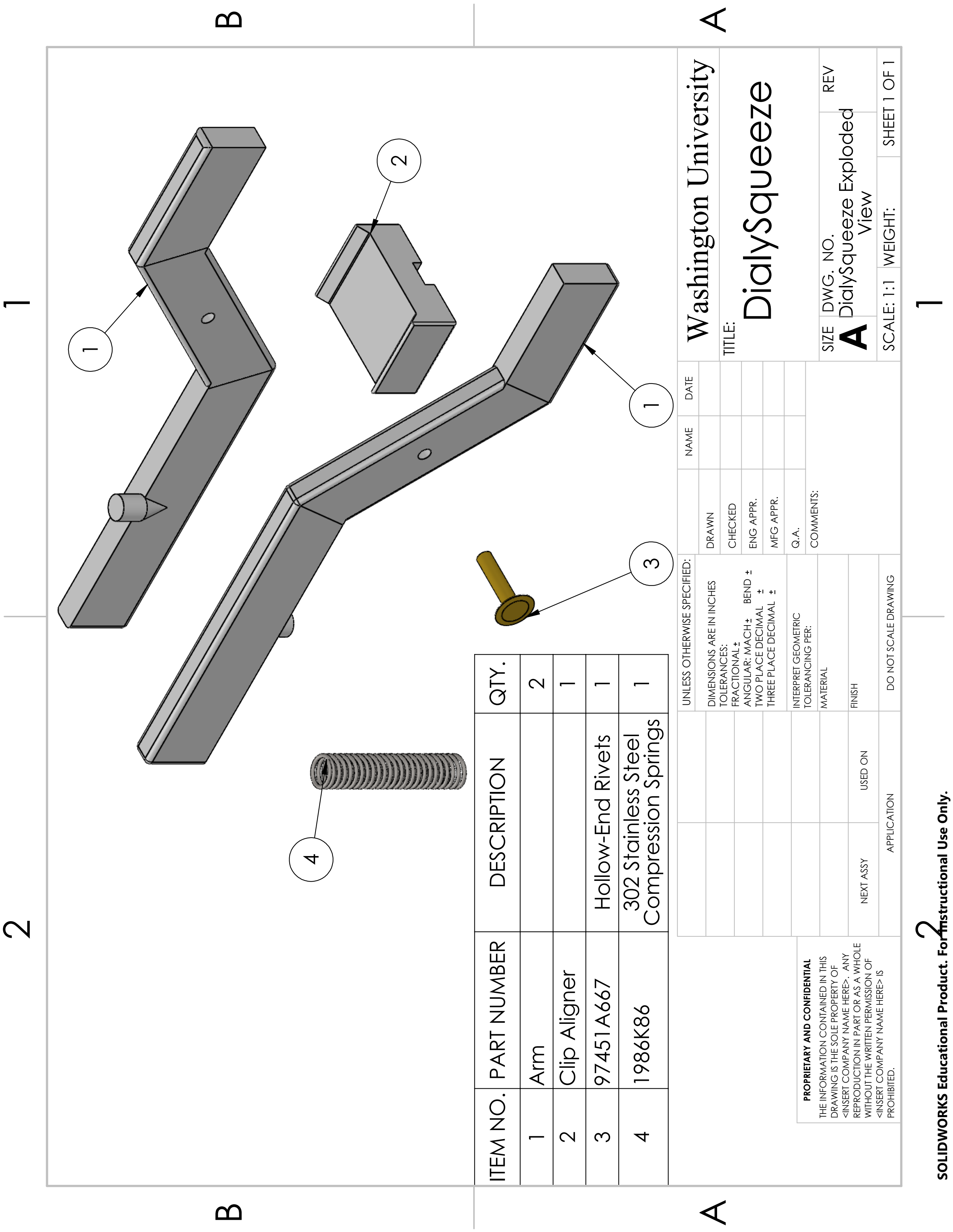


Figure 22: Assembled projected views with overall dimensions

Figure 23: Assembled isometric view



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Arm		2
2	Clip Aligner		1
3	97451A667	Hollow-End Rivets	1
4	1986K86	302 Stainless Steel Compression Springs	1

Figure 24: Exploded view with callout to BOM

Our prototype performance goals are as follows:

1. In < 5 seconds, using only one hand (e.g., the other hand behind one's back), the device can be removed from a pocket and used to engage 3 separate clamps on the larger (harder) size of tubing. This should be performed with both the user's dominant and non-dominant hand.
2. To engage a clamp, the device requires a maximum applied force that is < 1/4 of the maximum force needed without the device.
3. The device weighs < 4 oz.

The prototype shown above meets all of the prototype performance goals.

5.2 Proof-of-Concept

The device shown in Fig 25 is a proof-of-concept model made out of wood. A large spring found in the basement of Jolley is attached by drilling small holes into the wood and hot gluing the ends of the spring in the holes. Hot glue was used to glue the clamp holder to the wooden pliers. Additionally, a screw and nut was used to attach each side of the holder together. Working on this design allowed the group to make significant improvements for the initial prototype. The initial prototype will be 3D printed. The arms and clip aligner are very simple to print and can be made out of PLA (a common plastic used in 3D printing), which makes the pliers easy to clean, lightweight, and prevents the user from splinters (from wood). A rivet will be used for the pliers to prevent a screw from sticking out of the pliers (which could be dangerous) and simplify the assembly.

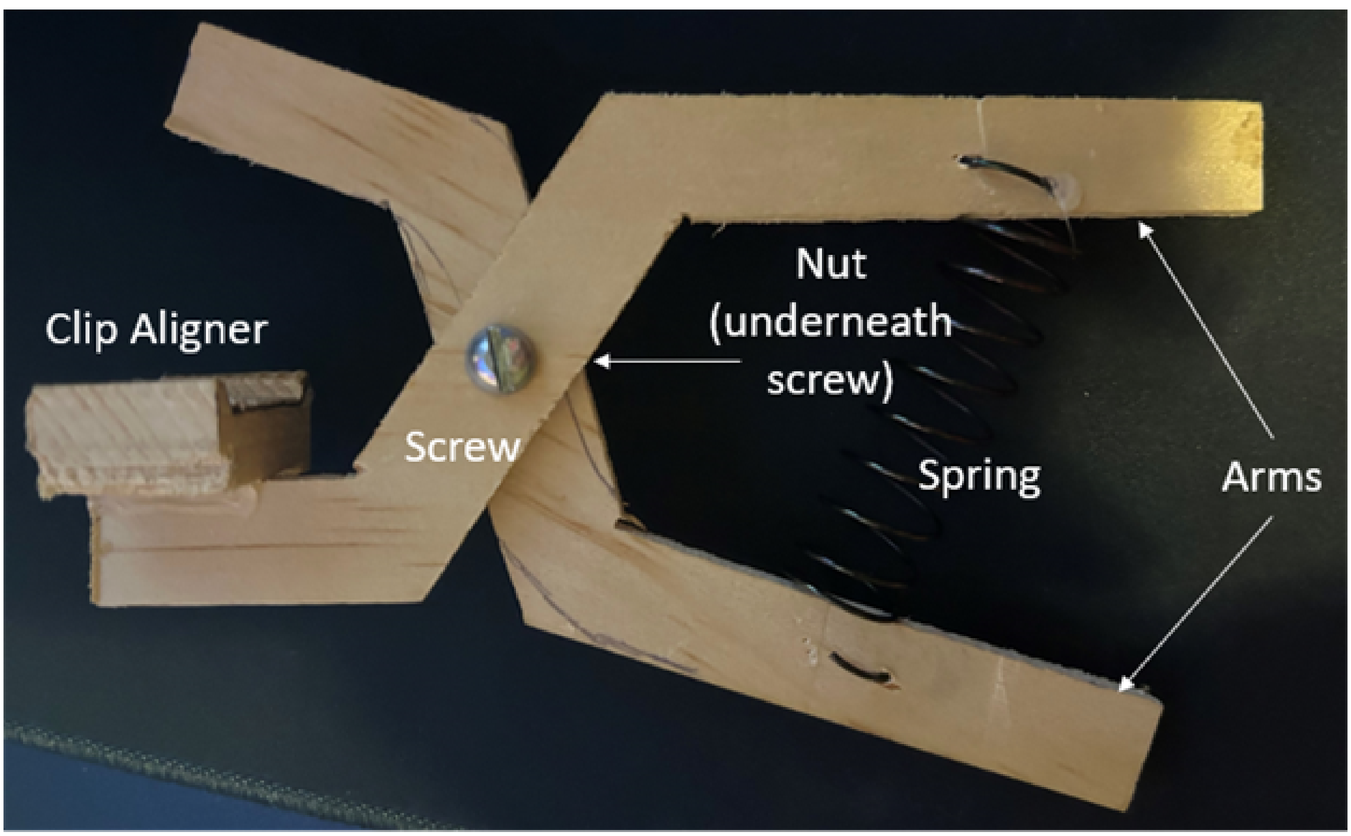


Figure 25: Proof-of-Concept Model

5.3 Design Changes

The group's chosen concept is Concept #3, the Pliers. The group's initial prototype resembles the pliers very closely. The initial prototype still has two 3D-printed arms that are connected closer on the clamping end. On the hand-grip end, both the chosen concept arms are connected by a spring to reset after one clamp. The shaped cup appears in both the initial prototype and the chosen concept, which holds the dialysis clip. On the prototype, there is no upper "hammer" to concentrate the clamping force on a single area (which was described on the selected concept). This part was not included to simplify the manufacturing process, but to also allow the device to be clamped at a variety of angles. Finally, ergonomic grips do not appear on the initial prototype, as they are shown in the selected concept, but will be added for the final prototype. Figure 26 shows a side-by-side comparison of the selected pliers concept and the initial prototype.

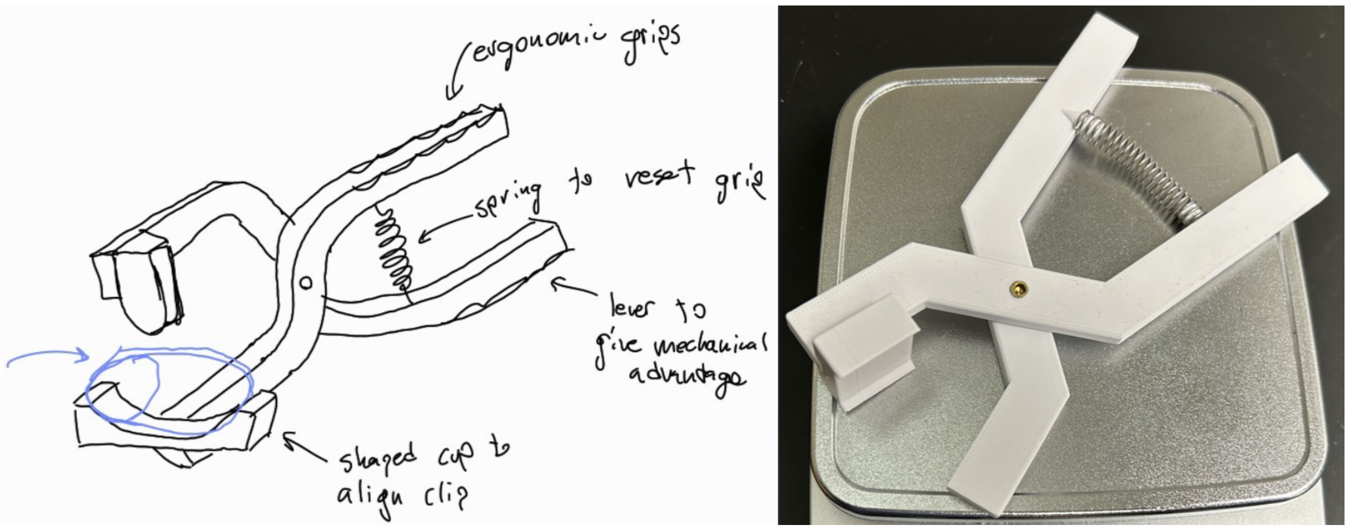


Figure 26: Left: Selected Concept & Right: Initial Prototype

6 Design Refinement

6.1 Model-Based Design Decisions

From Eq. 2, we showed that $L_C F_C = L_G F_G$. The design requirements stated the device must reduce the force required by a factor of four, thus yielding $F_C = 4F_G$. Plugging this into Eq. 2 shows that $L_G = 4L_C$. This model assumes that the clip and the user's hand apply point forces, which is not accurate. To account for this the point forces will be assumed to act at the average location of the clip and the user's hand, which reduces the effective length of the tool to five inches. There are now two equations:

$$L_G = 4L_C \tag{4}$$

$$L_G + L_G = 5 \tag{5}$$

Solving this system results shows that $L_G = 4\text{in}$ and $L_C = 1\text{in}$

Equation 3 shows that the stress is dependent on the lever geometry and the force applied. Empirical testing showed the force at the end of the handle was 12 lbf. Using $M = F \times r$, and

$r = 4\text{in}$, $M = 48\text{in} - \text{lbs}$. The modulus of PLA is 859 ksi, so we can then solve for the beam geometry in Eq. 3:

$$I/h = \frac{M}{2\sigma} I/h = \frac{48}{2 * 859 * 10^3} I/h = 2.79 * 10^{-5} \text{ in}^3 \tag{6}$$

For a square beam, $I = \frac{bh^3}{12}$, so $I/h = \frac{bh^2}{12}$. For our design, $h = 0.63\text{in}$ and $b = 0.25\text{in}$, so we can verify our design:

$$I/h = \frac{bh^2}{12} I/h = \frac{0.25 * 0.63^2}{12} I/h = 8.27 * 10^{-3} \text{ in}^3 \tag{7}$$

We assumed that the beam is in static equilibrium when doing these calculations. This assumption holds since the clip does not engage until the maximum force is applied. Therefore, solving for the stress in the static case will also ensure the arm is strong enough while the clip is engaging. Our I/h value is much larger than the theoretical requirement, so our design will be strong enough.

6.2 Design for Safety

Five risks have been identified from the Initial Prototype Design.

6.2.1 Risk #1: Cut from spring

Description: The spring could pop out of the upper and/or lower holders and cut a nurse or patient during use (while relaxing the clamp) with its pointy edges.

Severity: Critical - exposure to blood in a hospital workplace could spread illnesses and wound a person who is already sick.

Probability: Seldom - The spring has never popped out of the holders during testing, but it is possible for a cut to occur since the spring is not clamped in place.

Mitigating Steps: Develop a method to clamp the spring in place or use a torsion spring that is clamped interior to the device (not exposed).

6.2.2 Risk #2: Fingers could be caught in the clamp

Description: When the clamp closes, someone could accidentally close the clamp on their finger.

Severity: Marginal - If fingers are caught in the clamp, the damage will be marginal if anything because the clamp edges are rounded and are not intended to pinch a finger.

Probability: Seldom - The area in which to hold the clamp is very obvious to spot since it will be difficult for fingers to grasp onto the end that holds the clip.

Mitigating Steps: Ensure that the device is held with the clamp area facing away from the body and that a handle is easily identified perhaps with a rubber grip.

6.2.3 Risk #3: Clamping could cause fatigue to hand and wrist

Description: Repetitive habitual clamping could damage aspects of the musculoskeletal system in the hand and wrist.

Severity: Critical - Damages to the musculoskeletal system in the hand and wrist could be permanent and prevent a nurse from completing their job.

Probability: Seldom - The clamp has been tested multiple times in a row and does not appear to cause aching in the user's hand and wrist. Additionally, the clamp has been proven to act as a force multiplier.

Mitigating Steps: Ensure that clamp does not wear out hand/fingers over time by stretching out hand before and after use. Additionally, ensure that clamp accurately functions as a force multiplier.

6.2.4 Risk #4: Clamp device could be dropped on someone's foot/toes

Description: Dropping the clamp on the foot could damage the nurse's toes and feel painful, which could interfere with the normal work routine.

Severity: Marginal - the clamp weighs under 4 oz and is created from lightweight materials. Nurses must wear close-toed shoes, so dropping the clamp would not create any noticeable damage to the foot and will most likely just bounce off of a shoe.

Probability: Occasional - the clamp will be stored in a pocket and could likely slip out if a nurse is rummaging for something else in their pocket.

Mitigating Steps: Ensure that clamp is lightweight and is actively held closed so that heavy objects do not damage nurse's toes. Additionally, ensure nurse is wearing close-toed shoes.

6.2.5 Risk #5: Rivet connecting clamp arms rusts.

Description: Interaction with water or cleaning supplies might damage the rivet and cause the clamp to not rotate around the rivet easily.

Severity: Negligible - The water damage would not cause harm to people and the harm to property would be negligible since the rivet is currently made from brass.

Probability: Unlikely - the rivet is made from brass so it is unlikely that it will experience any corrosion.

Mitigating Steps: Ensure that clamp is kept dry and does not interact with a moist environment often. Swap out rivet for a pin so it is replaceable.

6.2.6 Heat Map

Figure 27 displays the heat map for the initial prototype. The cut from the spring is the highest priority. The group plans to address this concern for the final prototype by employing a torsion spring to use internally. Next, the priorities are to keep the device lightweight and to prevent fatigue in the hand and wrist. The group can address the clamp device drop issue by ensuring it appears in a different color compared to lab coats and other common hospital items. Additionally, more testing can be determined to see if the clamping mechanism causes fatigue/aching in the hand and wrist. Finally, the fingers catching in the clamp could be addressed with varying the color of the clamp. The lowest priority is the pin because it is unlikely to rust.

Severity of risk		Probability that something will go wrong				
	Category	**Frequent** Likely to occur immediately or in a short period of time; expected to occur	**Likely** Quite likely to occur in time	**Occasional** May occur in time	**Seldom** Not likely to occur but possible	**Unlikely** Unlikely to occur
	Catastrophic					
	Critical			Cut from spring	Clamping could cause fatigue to hand and wrist	
	Marginal			Clamp device could be dropped on someone's foot/toes	Fingers could be caught in the clamp	
	Negligible hazard presents a minimal threat to safety, health, and well-being of participants; trivial					Pin connecting clamp arms rusts

Figure 27: Heat Map

6.3 Design for Manufacturing

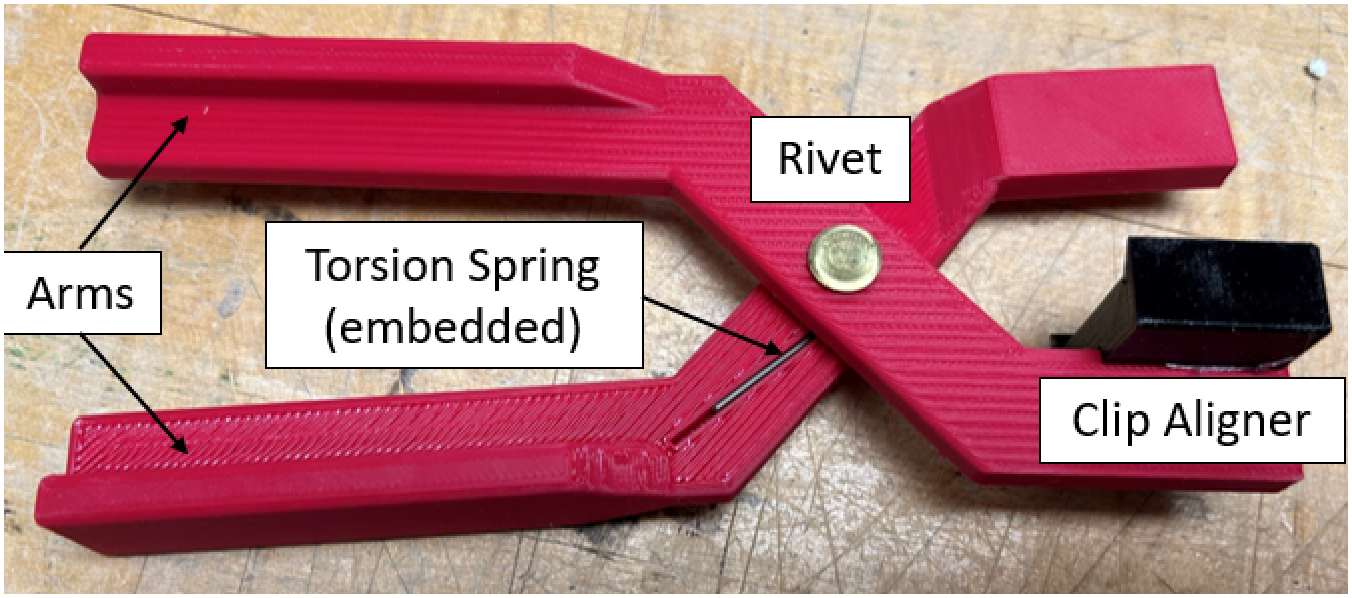


Figure 28: Labeled Schematic of tool

In the current design there are 5 total parts: 2 arms, 1 clip aligner, 1 rivet, and 1 torsion spring as shown in Fig. 28. There is only one theoretically necessary component. In order to close the clip, there only needs to be the 2 arms that move relative to each other. The jaws must close to provide enough force to clamp the clip. Theoretically, one of the arms could remain stationary, while the other is forced towards the other arm around its central pivot point.

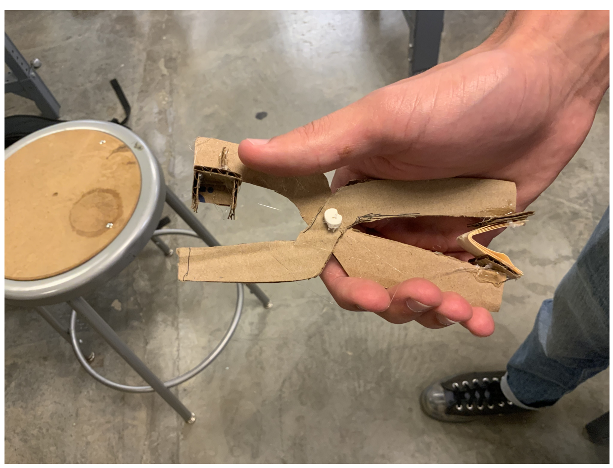


Figure 29: Example with torsion spring replacement

Hypothetically, the design could be changed to only contain the 2 arms. To do this, we would print a peg at the central pivot point on one arm, and a hole at the corresponding central pivot point in the other arm. The peg would then snap into the hole, but be able to free run, so that the arms can still rotate about the pivot point. To replace the torsion spring, we could some extra material towards the bottom of one of the arms that would extend across and attach to the other arm as shown in Fig. 29. However, instead of being a separate part as shown in the figure, it would be added to the print of one of the arms. This would serve to keep the arms from getting too wide, while also keeping them open when not in use to provide ease of repeatability.

6.4 Design for Usability

Vision, hearing, physical, and control impairments could impact the use of the clamping device.

A vision impairment might make it possible for someone to not be able to distinguish the device easily. For example, if the device is white, it might be difficult to distinguish from other white countertops/surfaces commonly found in a hospital. Additionally, if the device is all one color, it might be difficult to distinguish which area of the device should be held.

A hearing impairment impacts the usability of the device because it might be difficult to hear when the tubing is officially clipped, since the actual process of clamping the tubing is not a direct action by the nurse. The nurse needs to have some confirmation that the tube was clamped correctly. Those who cannot hear the clipping will need to be able to easily visually inspect the device.

A physical impairment significantly impacts the use of the device. The entire nurse's hand is required for operating the tubing clamp. A muscle weakness would prevent the nurse from completing their daily tasks. This applies to our project, but nurses wouldn't be able to clamp tubing at all with physical impairments. It would be interesting to make the design more ergonomic so that those with arthritis and muscle weakness could use the clamp.

A control impairment from distraction and excessive fatigue could impact the use of the device. Nurses have a lot to manage as part of their daily routine and work long hours with repetitive work. Distraction or fatigue could cause the nurse to drop the clamp, use it on the wrong side, or accidentally clamp a finger. Measures should be taken to clearly identify which side of the clamp should be held. A rubber grip is important to ensure it is not dropped.

6.5 Design Considerations

Table 3: Factors considered for design solution

Design Factor	Applicable	Not Applicable
Public Health	X	
Safety	X	
Welfare	X	
Global		X
Cultural		X
Societal		X
Environmental		X
Economic	X	

Table 4: Contexts considered for ethical judgments

Situation	Applicable	Not Applicable
Global context		X
Economic context	X	
Environmental context		X
Societal context		X

7 Final Prototype

7.1 Overview

The final prototype has ended up not being too different from our original mock-up idea. We have tried new things as discussed in previous sections but have ultimately settled on the design shown below in Fig. 30.

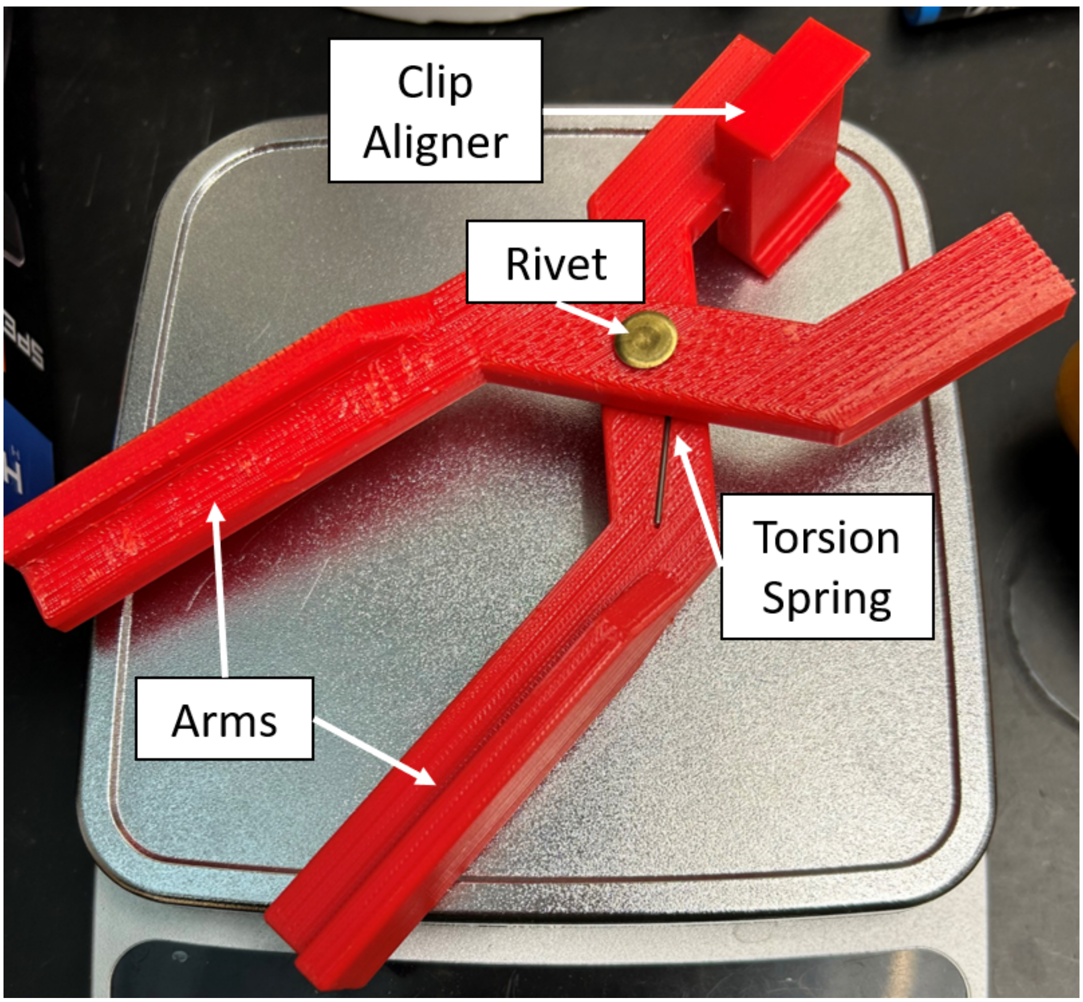


Figure 30: Labeled Image of Final Prototype

It has 2 arms and one clip aligner. The 2 arms are connected with a rivet and are held in place by an embedded torsion spring. Wide, flat surfaces have also been added to the arms to provide a more ergonomic grip. Figures 31 and 32 show the 3-view and exploded views of the final prototype, showing the dimensions of the new grips and the integration of the torsion spring.

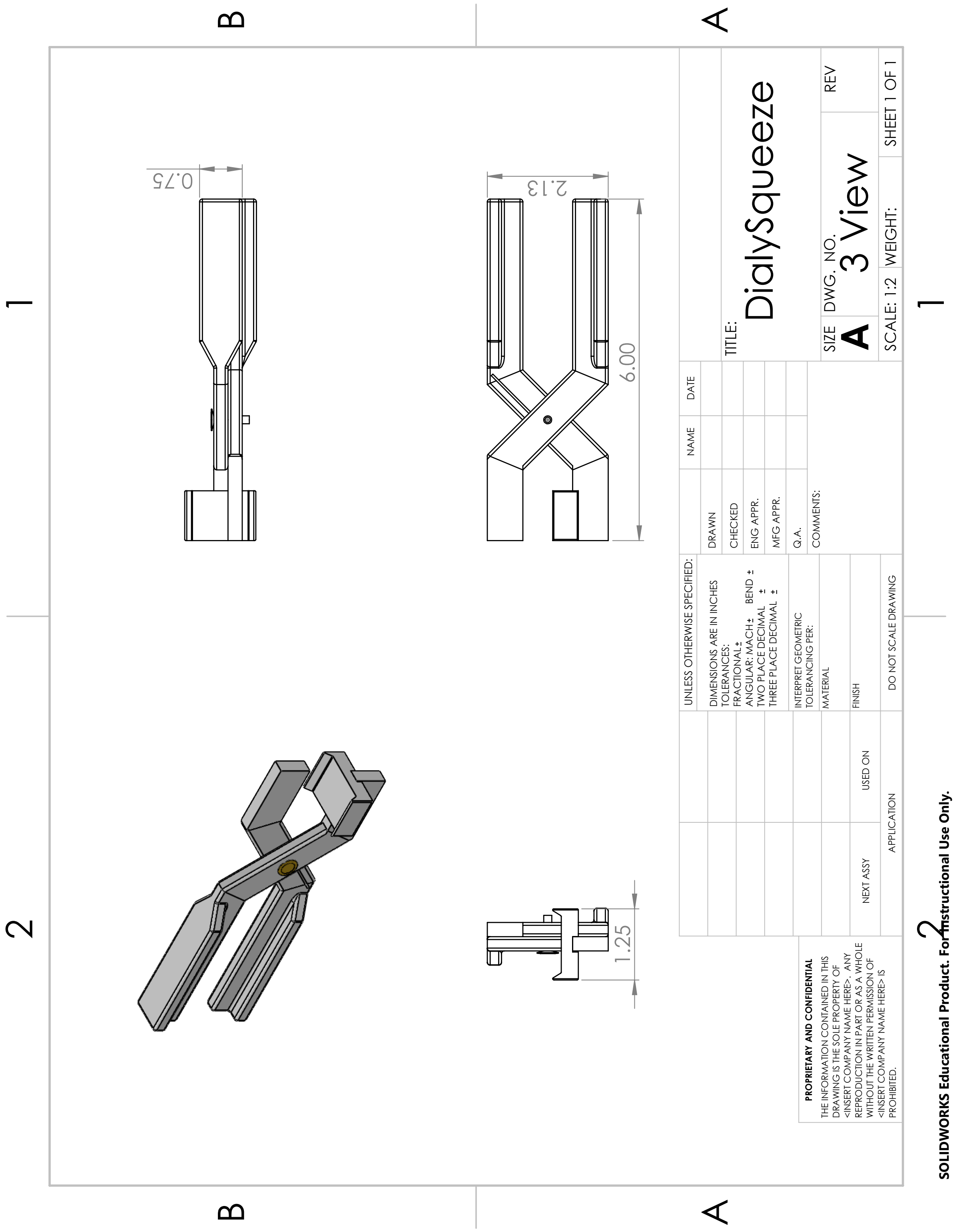


Figure 31: Final Exploded view

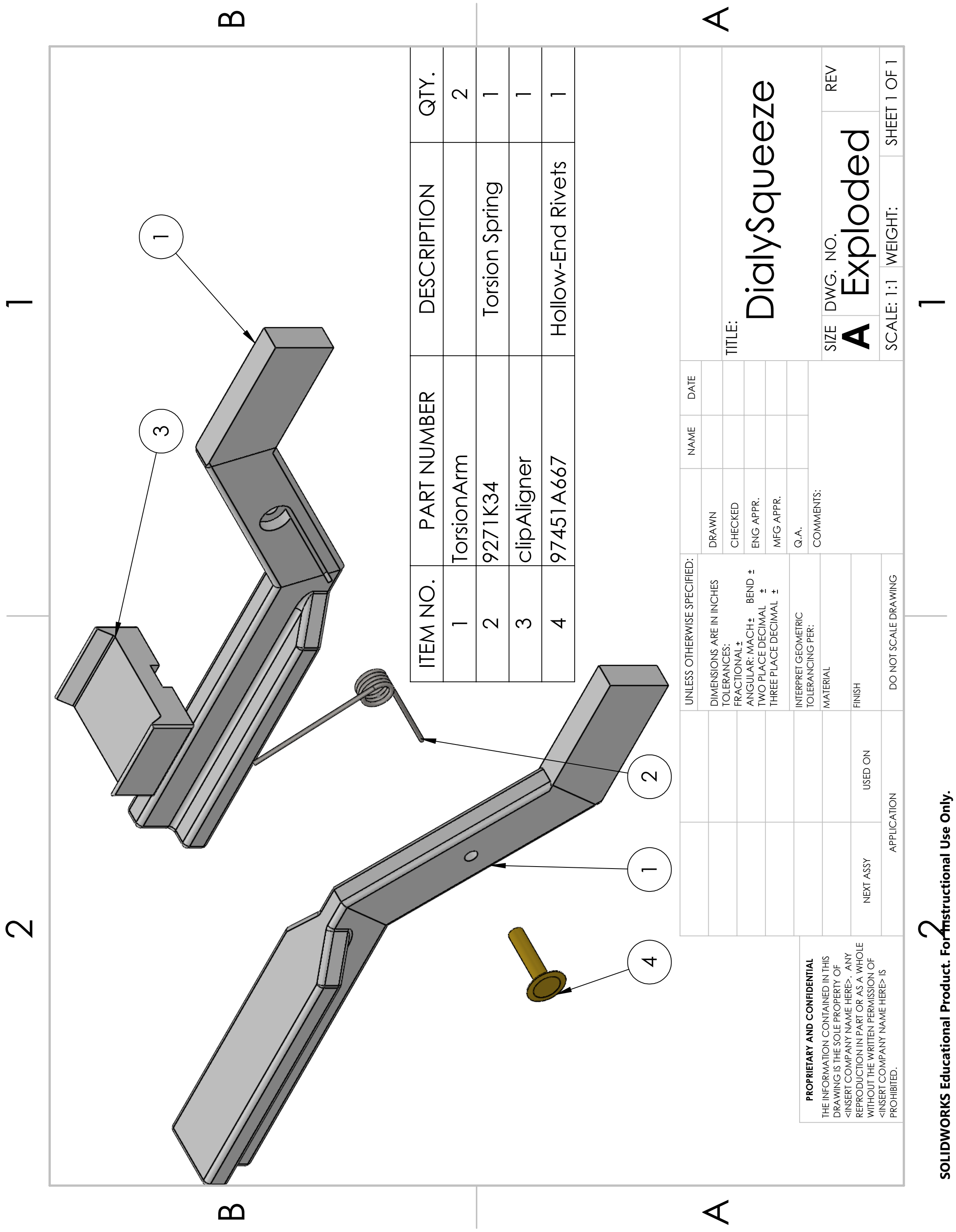


Figure 32: Final 3-View

Replacing the linear spring with the torsion spring makes cleaning the device much easier since there are fewer exposed parts. It is also safer since the metal spring is not a cutting risk. There is also no additional manufacturing steps needed since the spring is held in place by the same rivet as the arms. The grips increase the comfort of the user, allowing the clamping force to be spread across their palm.

This design was able to satisfy all 3 performance goals described earlier. It weighs 1.52 oz. which meets the maximum weight requirement of 4 oz. It allows the user to input 1/4 the force required to close the clip when compared to closing the clip without using the tool. The tool allows the user to apply 3 lbs. of force to exert 12 lbs. of force to close the clip. The design also was able to successfully satisfy the time trial requirement. The requirement was to be able to clip 3 clips in under 5 seconds with either hand. Maeve was able to clip 3 clamps in less than 4 seconds with both hands.