BOAS BUDDY: Operating Room Table Frame for Dogs with Brachycephalic Obstructive Airway Syndrome

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BIM 110C: Biomedical Engineering Senior Design
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May 31, 2022

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To Dr Philipp Mayhew and the rest of the staff, we thank you for your support!

Executive Summary

Problem Statement

Brachycephalic dogs have shorter, more compressed cranial anatomies but maintain the same amount of tissue in their airways as non-brachycephalic dogs. Excess tissue often occludes the airways of brachycephalic dogs, leading to brachycephalic obstructive airway syndrome (BOAS) and requiring surgical remedy. Presently, there are some devices available on the market that assist surgeons during open mouth surgery, but none for canine BOAS treatment specifically. Therefore, to aid the surgeons' efforts and improve the quality of care, **there is a need for a novel device that improves the administration of intraoral surgery on dogs suffering from BOAS**. Our device will accomplish this by supporting the patient's head in a stable manner, holding the mouth open, depressing the tongue, accommodating endoscopic equipment use, and functioning with a large set of operating table sizes.

Design Objective

Our goal is to create a structural frame that can suspend a variety of brachycephalic dog head sizes in a stable manner, provide adjustable height support, depress the patients' tongues, and accommodate endoscopic equipment. The device should also maintain a relatively small profile to ensure ease of use when setting up the device and when transporting the device between operating tables. Such a device will help enhance surgical precision and warrant patient safety.

Design Solution

The goal of our objective is to improve the current gold standard, so our team has devised a device in order to accomplish our goals for improved head stability for BOAS treatment, feasible transportation, and an all-in-one design featuring an endoscopic arm and tongue depressor. The BOAS Buddy frame consists of a t-slot frame made of 6061 aluminum which makes the device lightweight and easy for transportation as well as easy frame modification by the t-slot component. The head support system is made by the cam cleat and rope system (figure i) which provides an adjustable and fortified method of stabilizing the patient's head during surgery. Furthermore, the additional attachment features of the endoscopic arm and tongue depressor provides semi-automatic support as the replacement from having additional veterinarian technicians from manually depressing the patient's tongue and precisely holding the endoscopic equipment used for BOAS surgery. The BOAS buddy is designed to decrease prep time, increase staff availability, improve on endoscopic equipment and tongue depression compliance, and overall improve the precision and efficiency of BOAS surgery.

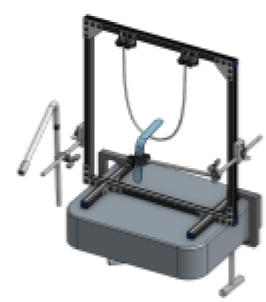


Figure i: CAD model of our latest Design

Design Assessment

Verification

Our team has aimed to deliver a device that is capable of providing a stable method for supporting the patients head, features head support height adjustability portability, and has integrated tongue depression and endoscopic camera support with the end goal of improving surgical precision, increasing staff availability in the veterinary clinic, and warranting patient safety.

Surgical precision is a tough metric to quantify, however, our team will make the assumption that surgical precision is tightly correlated with patient head stability, since the site of surgical operation is the patients oropharyngeal region (back of the throat) which is a part of the patients head. Therefore, we will quantify surgical precision with the performance of our head support during verification and validation testing.

Rope Displacement Verification Test Data				
Weight	Unit	Trial	Displacement of left CAM cleat	Displacement of right CAM cleat
32lbs	Inches	1, 2, 3	0, 0, 0	0, 0, 0

From the above analysis, it can be observed that there is no displacement of the rope in the CAM cleats for any of the tested weights. This test confirms that our CAM cleat - rope system functions as intended and will provide stable vertical support for the patients head.

Trials	Unit	Initial Distance	Final Distance	Final - Initial
1, 2, 3	Inches	$10\ ^{12.5}/_{16}$, $10\ ^{12.5}/_{16}$, $10\ ^{12.5}/_{16}$	$10\ ^{12.5}/_{16}$, $10\ ^{12.5}/_{16}$, $10\ ^{12.5}/_{16}$	0, 0, 0

Another end goal is to liberate a veterinary staff member from manually depressing the patient's tongue so that they may make an impact elsewhere within the clinic. This goal is a binary metric, as it depends solely on whether our tongue depressor and its mechanical arm function as intended. The mean change in the tongue holder's height relative to the floor is 0 inches. This indicates that our device will operate as intended during BOAS surgery as 0 inches is less than 0.2 inches.

Finally, our last overarching goal is to warrant patient safety throughout the surgical procedure. Our team has taken several precautions for potential failure modes, such as clamps to prevent the frame from tipping. The metric of 'patient safety' can be determined by the number of failure modes that do occur within a given period of time, thus determining the rate at which they occur.

Failure Mode of Occurence	Occurrence
Slide Carriage slid when unintended	1, after tongue depressor was being removed from patient

From our data, the rate at which failure modes occur is inconclusive given the small sample size. Future investigations would need to be conducted to determine the extent that failure mode will occur in the clinical setting.

Validation

Validation tests were conducted for both the setup and surgical use of the BOAS Buddy frame. These tests were conducted in order to ensure that our prototype meets the user needs of BOAS surgeons. Due to time constraints, our team was only able to run 1 validation trial for a successful setup and for the surgical procedure. Because only 1 trial was conducted, a statistical analysis cannot be conducted. Instead, other methods, such as percent difference, will be used along with displaying the raw data from the single trial.

The surgical setup procedure consisted of the surgeon carrying the BOAS Buddy frame from an arbitrary room to the OR room where surgery would be conducted. The surgeon then placed the frame onto the OR table, clamped the frame onto the table, and placed the malleable retractor into the tongue depressor attachment arm. The initial setup showed that the clamps were capable of successfully keeping the frame in a stable position. The setup time for the BOAS Buddy was 5 minutes and 15 seconds which only had a 4.878% difference from the reported 5 minute setup time of the gold standard. Because the percent difference between these two setup times are below the commonly used 5% threshold, these setup times are not significantly different.

The surgical procedure consisted of the surgeon conducting BOAS surgery on the brachycephalic patient. Our team recorded data regarding the stability of the patient's head, stability of the frame, the number of head detachments from the support rope, and the length of surgical time. These recorded values were compared to ideal target values. The stability of the patient's head, the stability of the frame, and the number of head detachments from the rope support were 0 inches, 0 inches, and 0 counts, respectively. The target values for these metrics were 0 inches, 0 inches, and 0 counts, respectively. This means that the results meet the target values for these metrics and ensure that our frame meets the user needs of being stable and reliable. The length of surgery was approximately 1.5 hours. This is the same surgery time as when the surgery is conducted using the gold standard (1.5 hours). Since our recorded value is the same as the target value, we have validated that our frame is competitive with the gold standard in terms of surgical time and does not increase the time of surgery.

Significance of Design

With no existing predicate device, the need for a dedicated device able to facilitate BOAS surgery is only increasing as the popularity of short-nosed dogs rises. Considering how the current "gold standard" is nothing more than a jerry-rigged rope strung across two IV stands, it is extremely prone to slippage and has been known to fall apart mid-procedure requiring physicians to halt surgery and reset their setup. This not only takes away time from the doctors at work but it can also compromise the safety of the patients. Moreover, the size of the current gold standard leaves physicians feeling encumbered, and is singular in use aiding in nothing aside from patient head support.

In contrast, our device was designed with the intention of minimizing the device's physical footprint while also ensuring multi-functionality, adjustability, and reliability. In the making of our device, we have not only tackled the previously mentioned flaws of the gold standard but we have also incorporated two separate arm attachments to aid in the surgery. One such arm will be used for patient tongue depression, while the other will be used to support endoscopic equipment. This allows our design to provide an immediate impact on BOAS surgery by removing the physician's need to maintain manual tongue depression and decluttering the operation room of additional endoscopic equipment. Our device will aid in patient safety and allow physicians to perform to the best of their ability.

Future Work and Improvements

With current time and resource constraints, our team was not able to implement all of the device improvements we would have wished to make but future design iterations have already been discussed within our team and with our client. In future designs we would like to see a simplification of design in order to minimize the part exposure, required cleaning and setup time. Moreover, we would like to implement excess rope management, longer tongue depressor rods, and a sterile tool holder to improve device versatility. Ideally, our future device would also see an improvement on storability, and support arm obstruction. Lastly, our team would like to explore designing a muzzle-like system that could better accommodate dogs that have small or no canines.

Final Bill of Materials

Sub-Category	Final Bill of Materials					
Frame	**Material**	**Catalog Number**	**Dimensions**	**Price per Unit**	**# of Components**	**Total Component Price**
	3-slot T-slot	47065T531	1" x 1" x 8'	$43.95	1	$43.95
	2-slot T-slot	47065T95	1" x 1" x 4'	$18.56	1	$18.56
	Flush 90º Angle Brackets	3136N157	1" x 3"	$15.08	2	$30.16
	90º Angle Brackets	47065T267	1" x 3"	$10.26	2	$20.52
	HARKEN Cam Cleat	B002NSY23S	7/8" x 1-7/8"	$29.03	2	$58.06
	Ravenox Solid Braid Nylon Rope	B07MTVJ7DC	1/4" x 50'	$15.40	1	$15.40
	Single T-Slot Fastener	47065T142	1" x 1"	Included with Brackets	20	$0.00
	T-slot Framing Fasteners	47065T147	-	$5.51	1	$5.51
	Stock Aluminum	8975K87	6"x3"x1/4"	$7.13	1	$7.13
	Screws for Cam Cleat	90086A685	#10-24 length (1.5")	$0.25	4	$1.00
	Corner Bracket	47065T239	2" x 2" x 7/8"	$7.07	4	$28.28
	Blue Plastic End Cap for T-Slots	3136N2	1" x 1"	$1.80	8	$14.40
	Clamps	50275A78	-	$19.37	2	$38.74
Tongue Depressor	**Details**	**Catalog Number**	**Diameter**	**Length**	**# of Components**	**Price**
	Aluminum Rod 1	8974K28	1/2"	1ft	1	$2.13

	Aluminum Rod 2	8974K28	1/2"	1ft	1	$2.13
	Universal C-Clamp	B018RLY6B2	X	X	1	$10.99
	Hex Nut	94575A350	3/8-16	-	1	$0.25
			Diameter A	Diameter B		
	Indicator Clamps Style 7	2067A53	1/2"	1/2"	1	$39.44
Endoscopic Arm	**Details**	**Catalog Number**	**Diameter**	**Length**	**1**	**Price**
	Aluminum Rod 1	8974K28	1/2"	1ft	1	$2.13
	Aluminum Rod 2	8974K48	5/8"	1/2'	1	$7.61
	Aluminum Rod 3	8974K13	1"	1/2'	1	$8.44
	On Stage 19 Microphone Gooseneck	B00080KNG8	5/8 - 27	19"	1	$12.95
	3 Prong Claw	3883N123	3/8" - 24	-	1	$25.55
			Diameter A	Diameter B		
	Indicator Clamps Style 7	2067A54	1/2"	5/8"	1	$40.84
Side Carriage	**Details**	**Catalog Number**	**Diameter**	**Length**	**# of Components**	**Price**
	Thumb Screw	90079A546	1/4"-20	1.25	2	$9.00
	Aluminum Extrusion	8975K626	-	6" x 1.75" x 1"	1	$12.87
	Quick-Release Pins	95255A268	1/4	1.25	2	9.44
	Screws for Side Carriage	90086A685	1/4 - 20	1.25	2	0.5
					Total Price	**$443.09**
Legend	Unavailable	Donated				

Manufacturing Instructions

The following is a complete list of the stock materials and tools required for manufacturing the custom components of the BOAS Buddy. For more detail, see the full bill of materials shown above, a tap drill size chart, and guidelines on appropriate machine speeds. Engineering drawings for each component are included in the appendix as well.

Stock material totals:

- Aluminum T-Slot Extrusions (LxWxH):
  - 3-slot (1” x 1” x 8’)
  - 2-slot (1” x 1” x 4’)
- Aluminum rods (∅xL):
  - (∅1/2” x 36”)
  - (∅5/8” x 16”)
  - (∅1” x 2”)
- Aluminum block extrusions (LxWxH):
  - (6” x 1.75” x 1”)
  - (6” x 3” x 1/4")

Required tools & equipment:

- Personal protective equipment (PPE)
- Measuring tape, ruler, calipers, micrometer
- Bandsaw (*or hacksaw)*
- Mill
  - Collet & collet block
- Lathe
- Belt grinder & sandpaper
- Tap and die
- Hand files & circular deburring tools

The following is a set of general instructions on how to manufacture the necessary parts using the aforementioned materials and tools.

1. Begin by cutting all stock materials to length on the bandsaw.
    a. Deburr all edges for safety and accurate measurements.
    b. *This completes the work for the t-slot extrusions.*

2. Test fit the ∅ 1/2” and ∅ 5/8” rods in swivel clamps.
    a. Rods should slide through clamps smoothly when loose but should remain fixed anywhere along their entire length once tightened.
    b. If too large, use a micrometer to measure and a lathe to turn down to a suitable diameter.
    c. Turn the rods down in small sections, working close to the chuck, using a live center to help stabilize the rods.

3. Add threads to rods.
    a. Refer to a tap and drill chart for appropriate sizing.
    b. Use cutting fluid and keep rods in lathe while cutting threads if possible.

4. Use a mill to precisely drill the two ∅ 1/4” holes in the side carriage rods (∅ 1/2” x 12”).
    a. Use a collet block to hold the rods securely for drilling.
    b. Deburr and sand any sharp edges.

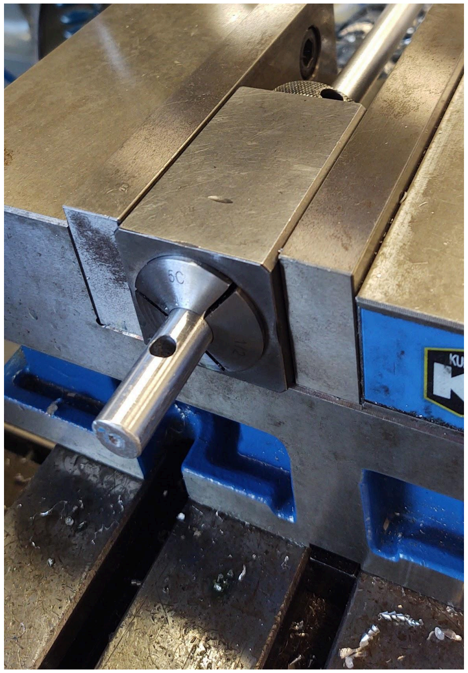
5. Use the mill to make the cam cleat adapter holes.
    a. Flatten faces and deburr edges for accurate measurements.
    b. Use #2 center drill bit for all holes
    c. See tap and drill guide

6. Use the mill to create the carriage blocks.
    a. Flatten faces and deburr for accurate measurements.
    b. Use a #2 center drill for the ∅ 1/4” holes and a #4 center drill bit for the ∅ 1/2” holes.
    c. Take care to ensure the pin and rod holes are centered with one another.

7. Round off all edges and corners of the cam cleat adapters and side carriage blocks on a belt grinder.
    a. Finish block corners with sandpaper.

8. Further deburr, sand, and clean all parts as needed.

9. Assemble parts in functional groups to ensure fit and function. (See following section for instructions)

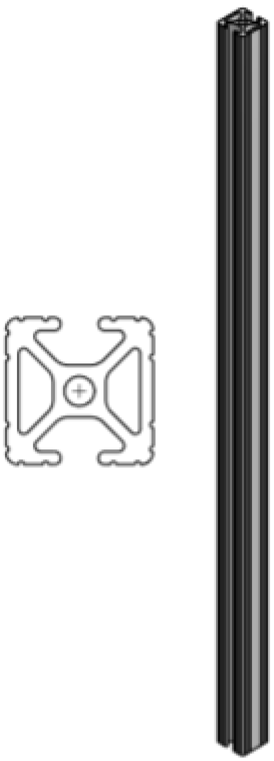


a. **b.** **c.**

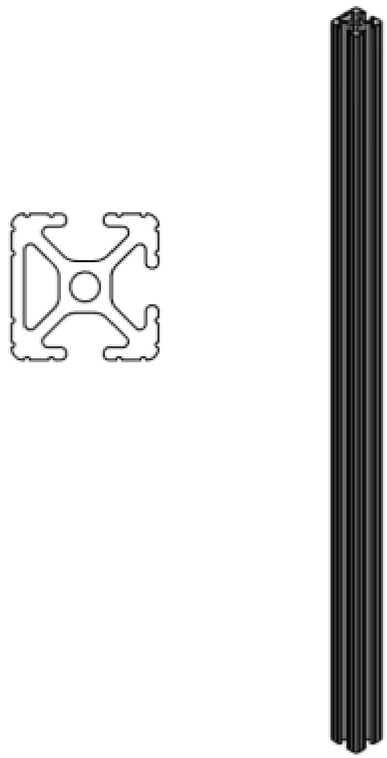
a. Using a collet block to drill into a ∅ 1/2” rod with a mill.
b. Tapping threads into a cam cleat adapter with a tap guide on a mill.
c. Before (top) and after (bottom) rounding off the corners of the cam cleat adapters with the belt grinder.

Assembly Parts:

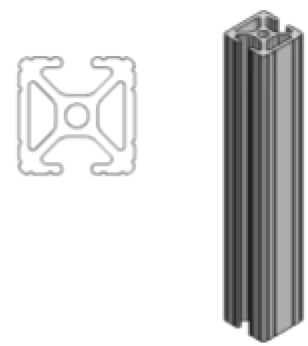
Base Frame & Winglets



#A1: x2 T-slot 2 rails (horizontal)

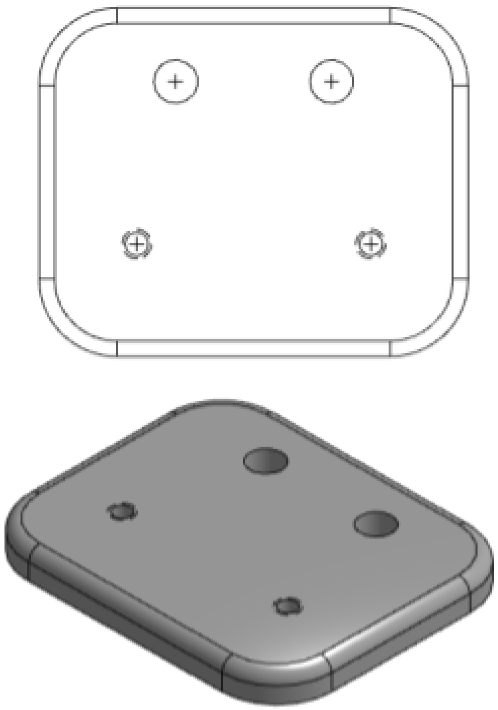


#A2: x2 T-slot 3 rails (vertical)



#A3: x4 T-slot Winglets (small)

Assembly Parts: Cam Cleats

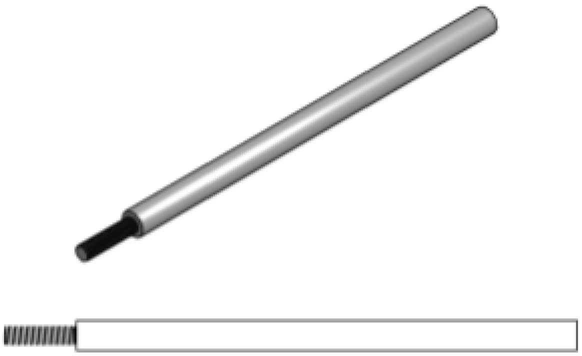


#B1: x2 Cam Cleat adapters

#B2: x2 Cam Cleats

#B3: x1 Nylon Rope
(head support)

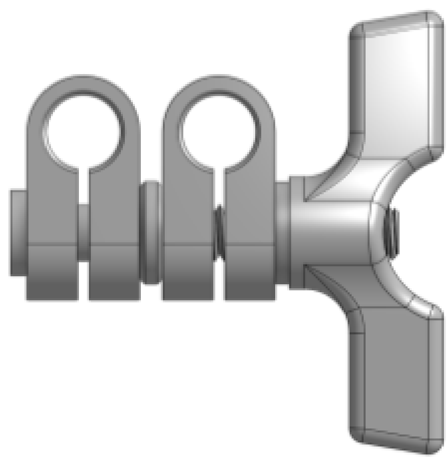
Assembly Parts: Tongue Depressor



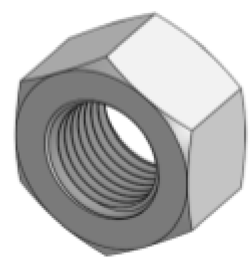
#C1: x1 ⅜"-16 rod
(outer dia (½"))

#C2: x1 ½" Dia Support Rod

#C3: x1 Tongue Depressor Clamp

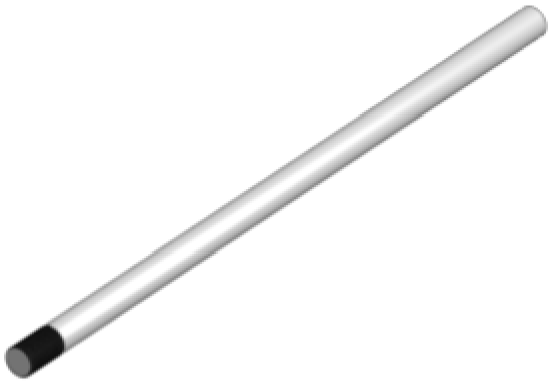


#C4: x1 Swivel Clamp ½ & ½



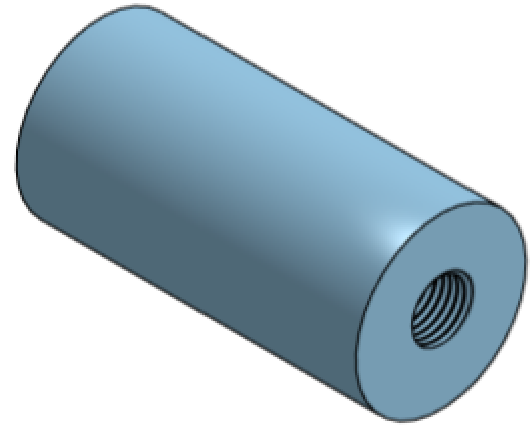
#C5: x1 ⅜-16 Hex nut

Assembly Parts: Endoscopic Support Arm



#C6:
x1 ⅝" rod partially threaded
(Connects to Buret claw)

#C2: x1 ½" Dia Support Rod



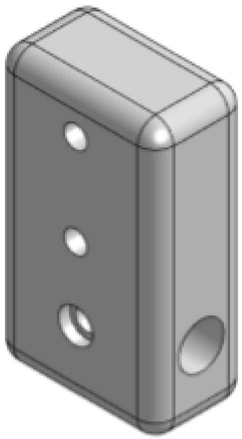
#C7: x1 Thread Adapter
(Gooseneck to Buret)

#C8: x1 Buret Claw

#C9: x1 Swivel Clamp ⅝" & ½"

#C10: x1 19" Gooseneck

#D1 Assembly Parts: Other Components



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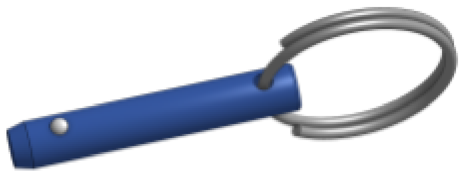
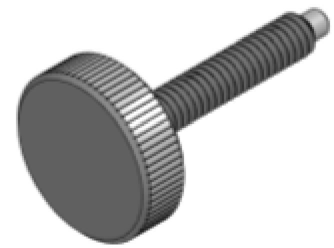


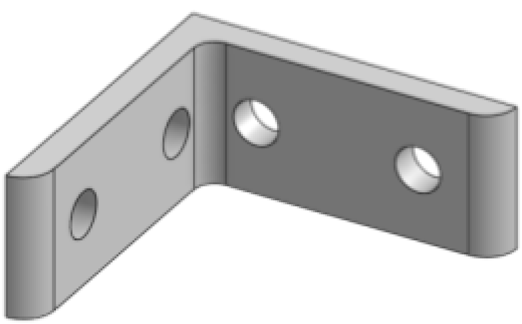


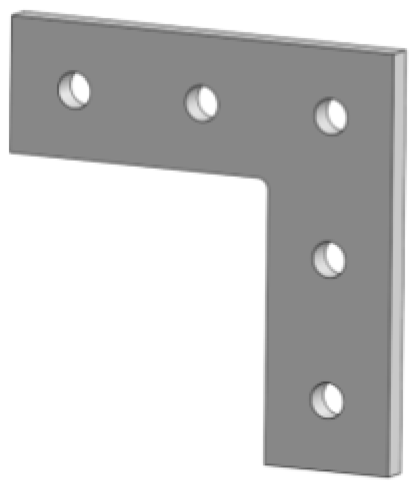
#D1: x2 Side Carriage

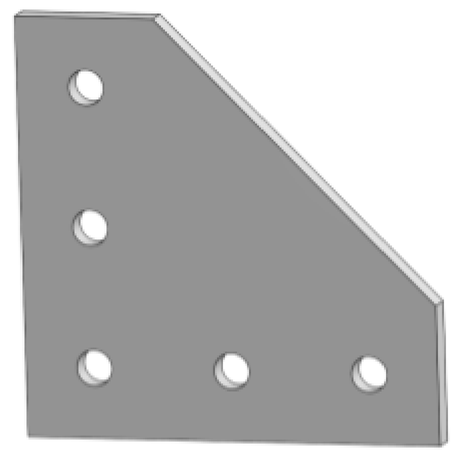
#D2: x2 Quick-Release Pins

#D3: x2 C-Clamps

#D4: x2 Knurled Set Screw





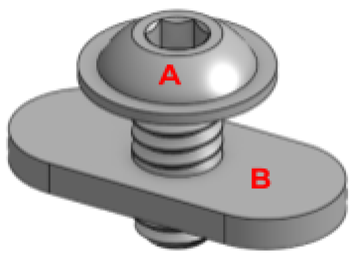


#D5: x4 Corner Bracket

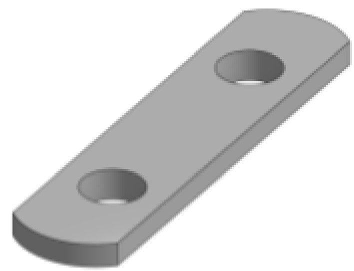
#D6:
x2 Angle Bracket (Lower)

#D7:
x2 Surface Corner Bracket (Upper)

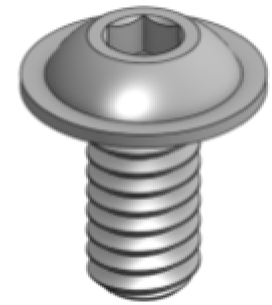
Assembly Parts: Screws and Fasteners



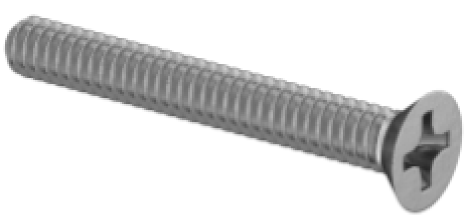
#1 a&b:
A x24 ¼-20 Flanged Button Head
B X36 Single Nut Fastener



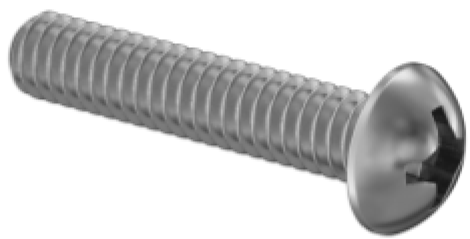
#2a:
x4 Double Nut Fastener



#2b:
x16 Flanged head No. 2
(Note: Head has smaller rim than #1a)



#3:
x4 #10-24 Phillips Screw
Length: 1.25” (Cam Cleat)



#4:
x2 ¼-20 (length 1.25”)
Round Phillips screw
(side carriage)

#5:
x8 Frame Endcaps

Assembly Instructions:

Cam cleats (For 2 sets)

Components:
- 4x #3: #10-24 Phillips Screws
- 2x #B1: Cam Cleat Adapter
- 2x #B2 Cam Cleat
- 4x #1a Flanged Button Head
- 2x #2a Double nut fastener

Steps:
1. Align Flanged button (**#1a**) and double nut **(#2a)** between the upper holes (larger holes) of the cam cleat adapter (**#B1**). Make sure there is enough space to slide into the t-slot rail. (figure __)

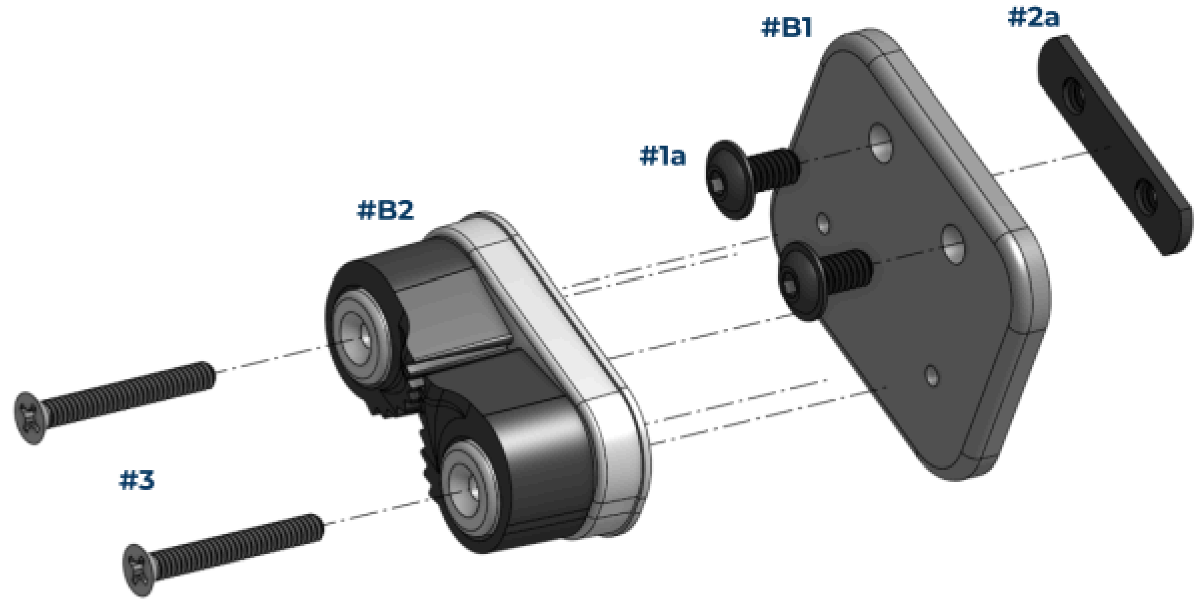


Fig __: Cam Cleat (#B2) to Cam Cleat (#B1) Adapter installation visual

Note: Make sure the flat piece of #2a is facing the back of #B1.

2. Screw Cam Cleats (**#B2**) onto #1a using the #10-24 Phillips screw (**#3**). It is heavily suggested to first lightly screw the screws until it reaches contact before tightening.

(warning: Do not overly tighten the screws or else it will damage the cam cleat adapters.)

3. Repeat steps for the second set of cam cleats

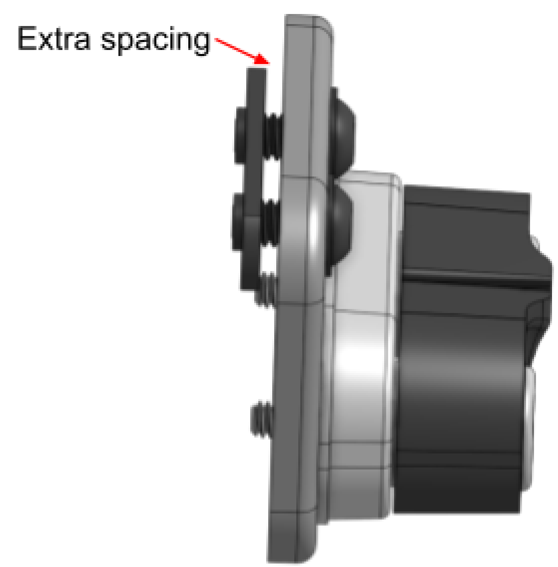


Fig__: *Step #1 Emphasis of spacing to slide into the frame for next step.*

Assembly Instructions: *Frame Part 1*

Components:

- 2x #A2 T-slot 3 Rails (vertical)
- 1x #A1 T-slot 2 rail (horizontal)
- 2 x Cam Cleats (already assembled)
- 10x #1b Single Nut Fastener

Instructions:

1. Slide in the cam cleats that were assembled prior on to the T-slot 2 rail (**#A1**). DO NOT tighten yet.
2. For one side of the frame (figure __), place three single nut fasteners (**#1b**) on the end of horizontal bar (**#A1**) and two on the vertical bar (**#A2**)
3. Repeat step 2 on the other side.
4. (optional) tighten cam cleats using an Allen wrench to the desired gap. You may do this at the end when the entire frame is assembled.

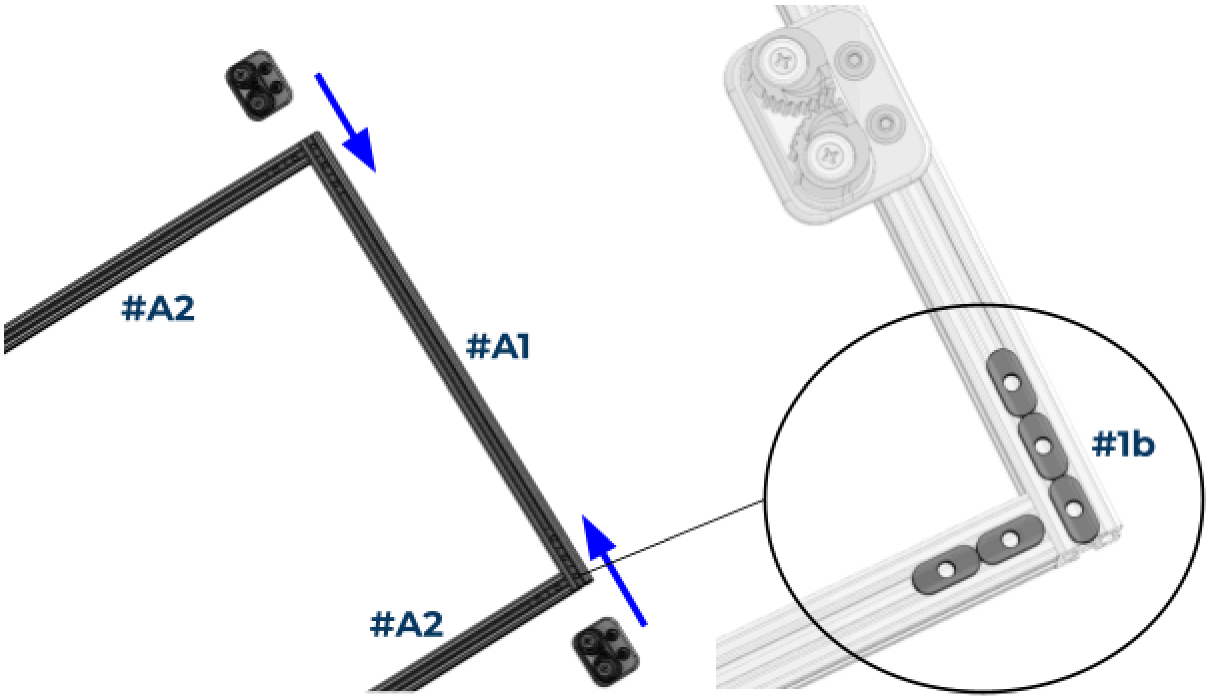


Fig__: Instructions for Frame Part 1

Assembly Instructions: *Frame Part 2*

Components:

- 10x #1a Flanged button head
- 10x #1b Single nut fastener (*already in slots*)
- 2x #D7 Surface Corner Bracket (upper)

Instructions:

1. Align #1a Flanged button heads, **#D7** Surface Corner Bracket, and **#1b** Single nut fasteners to create the 90 degree angle for the frame shown on Figure 1A.
2. Lightly tighten **#1a** screws from 1 to 5, shown on figure 1B. This will ensure the corner bracket is installed evenly. Tighten the screws afterwards (Not too tight).
3. Repeat steps for the other side of the frame.

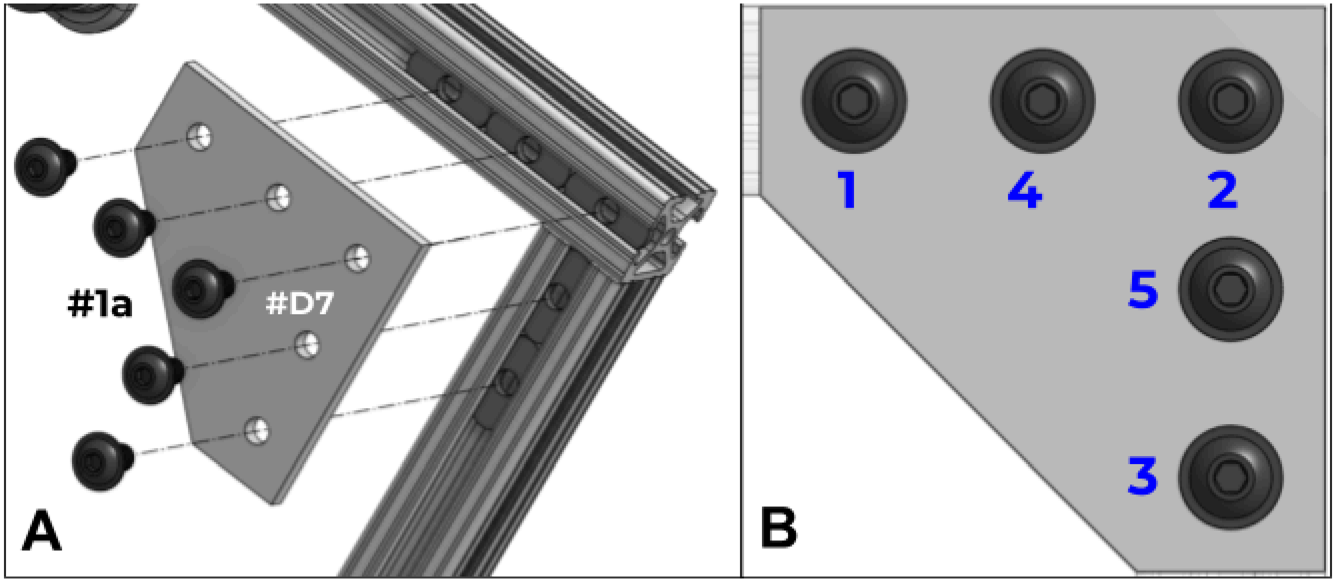


Figure 1: Frame Instructions Part 2
(**A**) Visual of one side
(**B**) Order of tightening screws 1 to 5

Assembly Instructions: *Base Frame & Winglets*

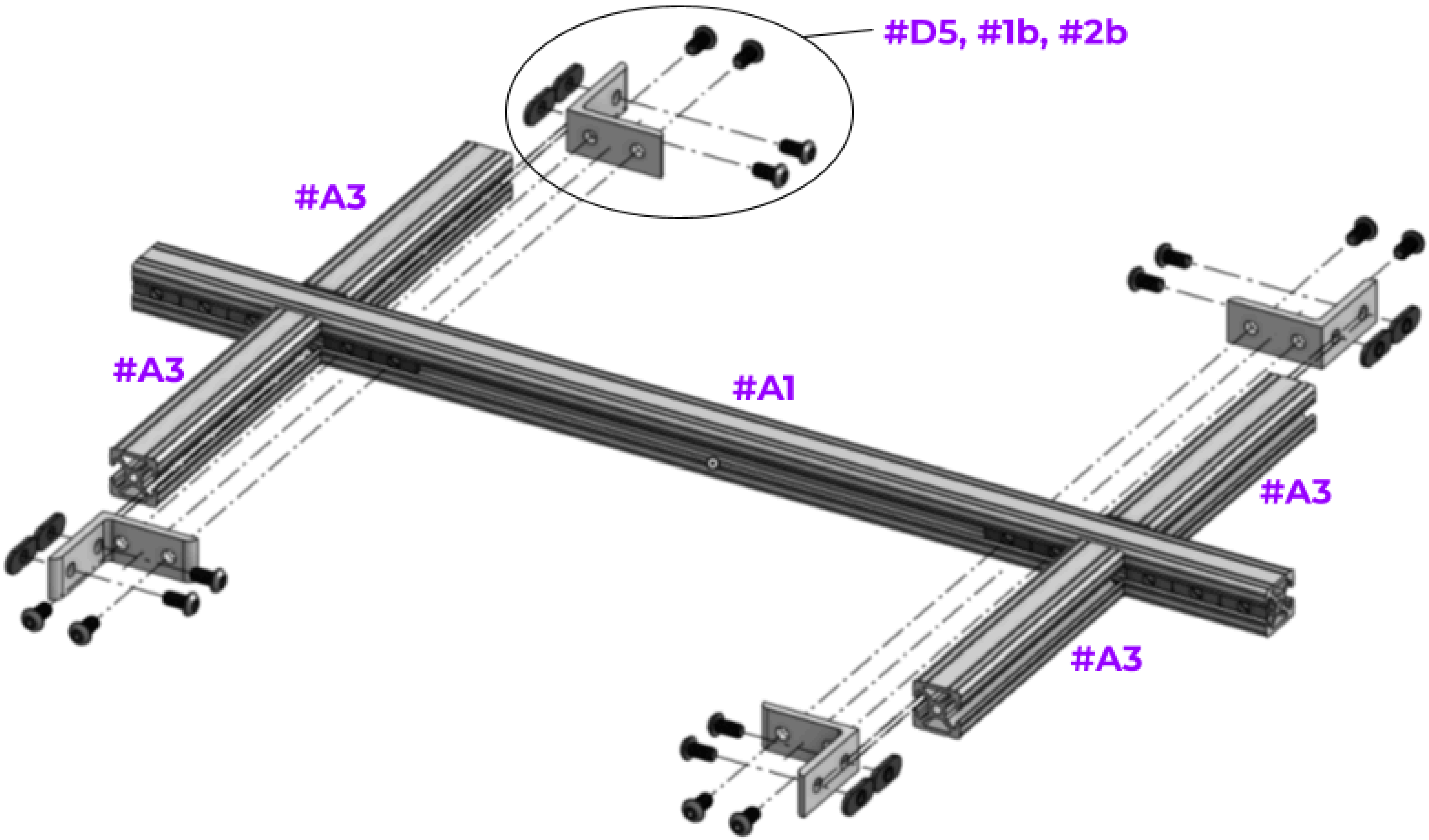


Figure 2: Overview for Winglet Assembly Instructions

Assembly Instructions: *Base Frame & Winglets*

Components:

- 1x #A1 T-slot 2 rail (unused)
- 4x #A3 T-slot Winglets
- 4x #D5 Corner Bracket
- 16x #2b Flanged head No. 2
- 22x #1b Single Nut Fastener

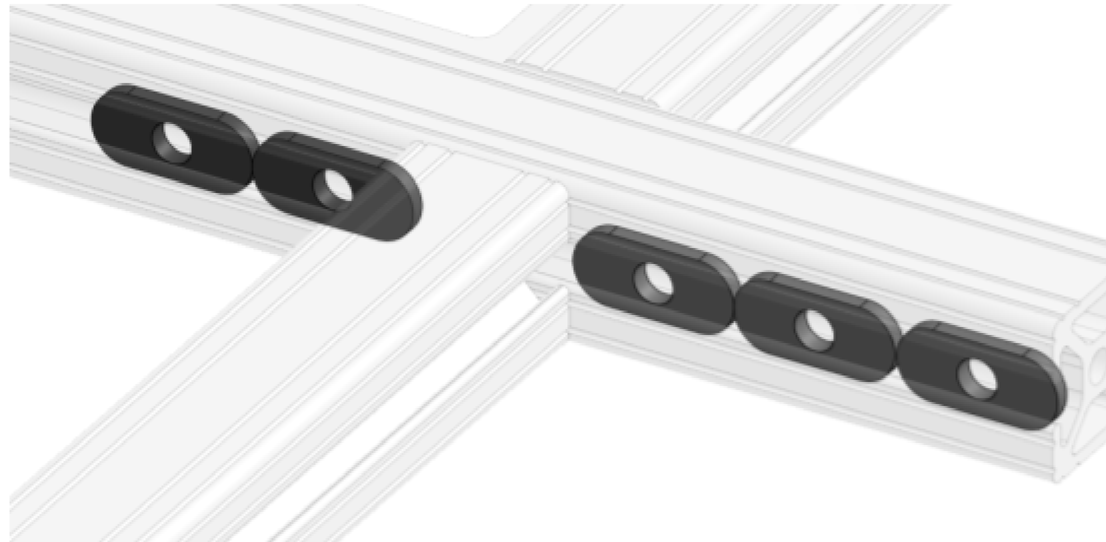


Figure 3: Step 1, Pattern of #1b Single nut Fasteners inside #A1 T-slot

Instructions:

1. To create the base frame, align the **#1b** Single Nut Fastener as shown on **figure 3** on to the **#A1** T-slot 2 rail that was not used from the prior step. Add a gap between two and three of the **#1b** fasteners for the **#A3** winglets. Do this pattern for only ONE side of the **#A1** rail.
2. For the backside of **#A3**, add the four **#1b** fasteners for the corner brackets.

(By now, you used 14 of the #1b Single Nut Fasteners)

3. Using the **#2b** Flanged heads, install the remaining **#1b** fasteners on each end of **#A3** T-slot winglets as shown on **figure 3**
4. Install the **#D5** corner brackets to the **#A1** rail by using the remaining **#2b** flanged head screws.
5. Your base frame should now look like **figure 2**. You can also customize the width of the winglets.

Assembly Instructions: *Frame Completion*

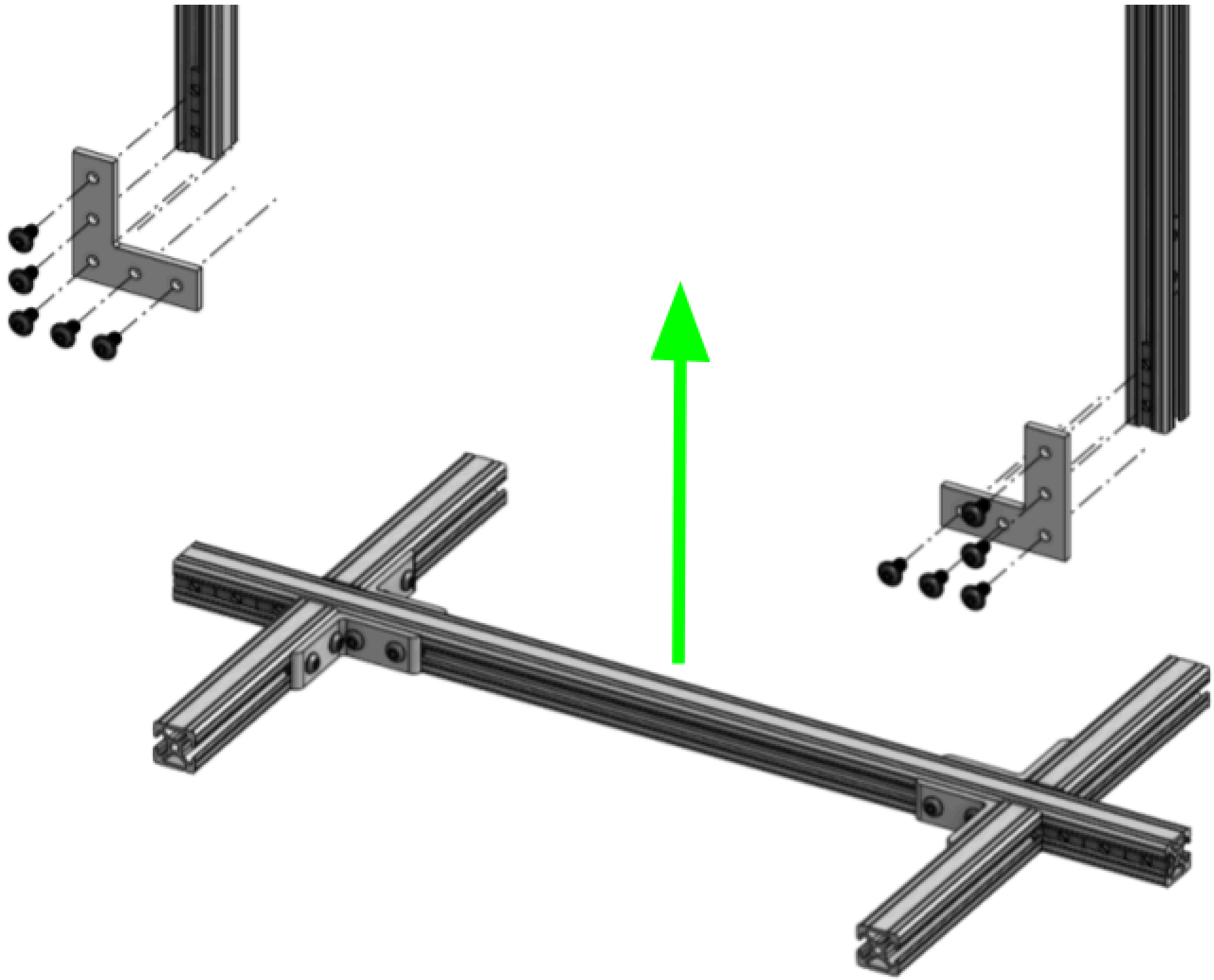


Figure 4: Base frame installed to complete frame.

Assembly Instructions: *Frame Completion*

Components:

- Complete base frame
- Complete upper half of the frame
- 2x #D6 Lower angle bracket
- 2x #2a Double nut fastener
- 4x #1b Single Nut Fastener
- 10x #1a ¼ - 20 Flanged Button Head

Instructions:

1. To complete the frame, insert two **#1b** single nut fasteners in the **FRONT** view t-slot and one **#2a** Double nut fastener on the **OUTER** t-slot (**figure 5**). #1b will be used for the L-bracket and the #2a will be used to install the #D1 side carriage.
2. **Stably** place the upper frame on to the base frame (**figure 4**). Keep it in position.
3. Using the **#1a** Flanged Button heads, install the **#D6** L-brackets on the **#1b** single nut fasteners. **Figure 6** shows the order of lightly tightening the screws before moderately tightening the bracket into the frame.

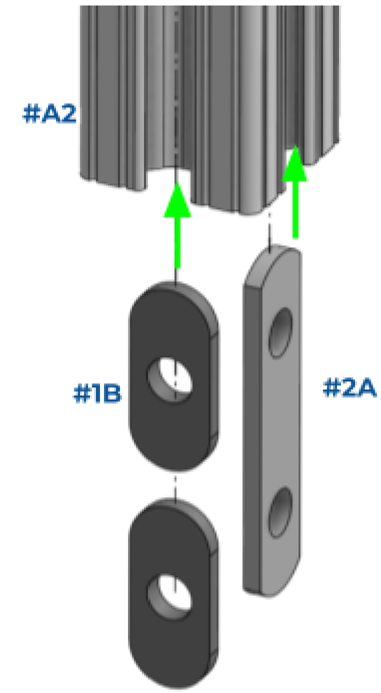


Figure 5: Step 1, Double fastener and two single fasteners installed

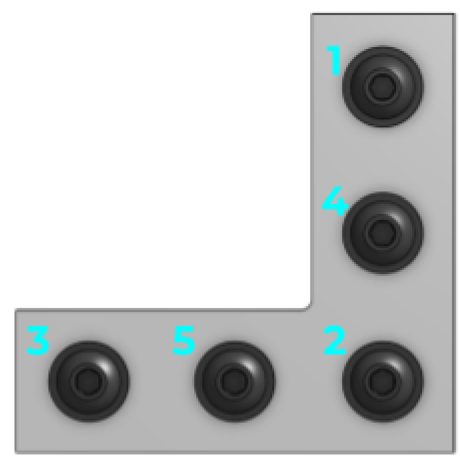


Figure 6: Order of tightening screws on L-Bracket

Assembly Instructions: *Side Carriage*

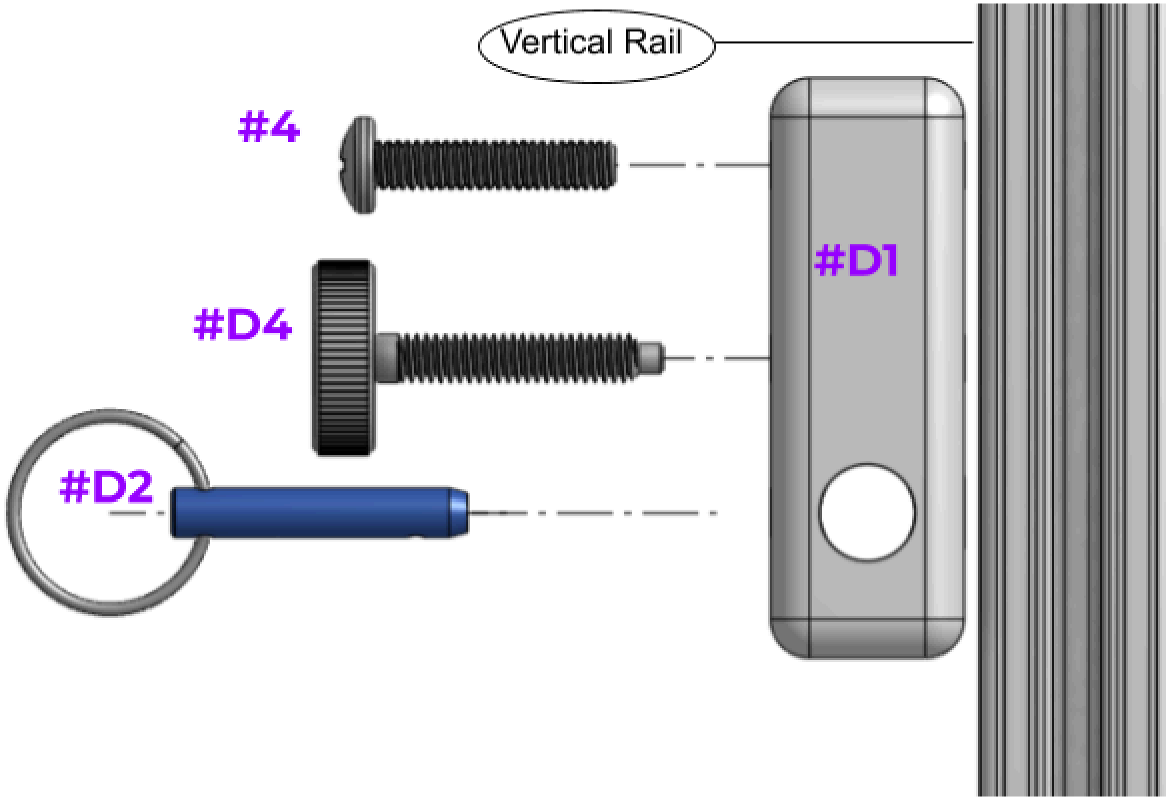


Figure 7: Overview installation of side carriage

Components:

- 2x D1 Side Carriage
- 2x #2a Double nut fastener (Already in t-slot)
- 2x #D4 Knurled Set Screw
- 2x #D2 Quick-Release Pins
- 2x #4 Round Philips Screw

Assembly Instructions: *Side Carriage*

Instructions:

1. Install the **#D4** Knurled Set Screw in the middle hole of the **#D1** side carriage shown on **figure 7**. It will connect into the **#2a** Double nut fastener that was already installed into the T-slot (**figure 8**).
2. Install the **#4** phillips screw into the **#D1's** upper hole (**figure 7**). It must be installed LOOSELY to keep the grip, but is still inside to support alignment. You can adjust by using your Phillips screwdriver.

Note: You will need to adjust the Philips screw until the side carriage can slide.

3. Insert the #D2 Quick-Release pins in the lower hole. This will set the support attachment arms for both endoscopic arm and tongue depressor.
4. Repeat steps for the other side of the frame.

Note: Make sure the side carriage is placed appropriately indicated on **Figure 9**. The backside is faced into the frame.

Figure 8: Reference of #2a inside T-slot

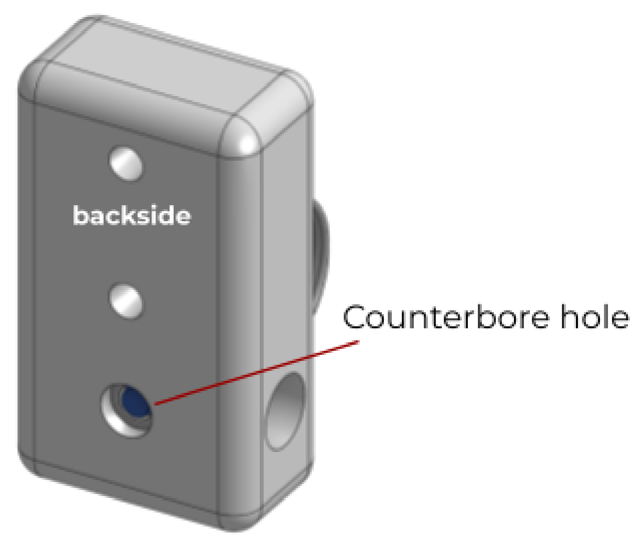


Figure 9: Back side of Carriage indicated by counterbore on lower hole of side carriage.

Assembly Instructions: *End Caps*

Components:

- X8 #5 Frame End Caps

Instructions:

1. Place frame end caps demonstrated in figure 10.
2. Insert pins to the middle hole of the T-slot frame to lock in place.

Figure 10: Endcap placements

Assembly Instructions: *Tongue Depressor*

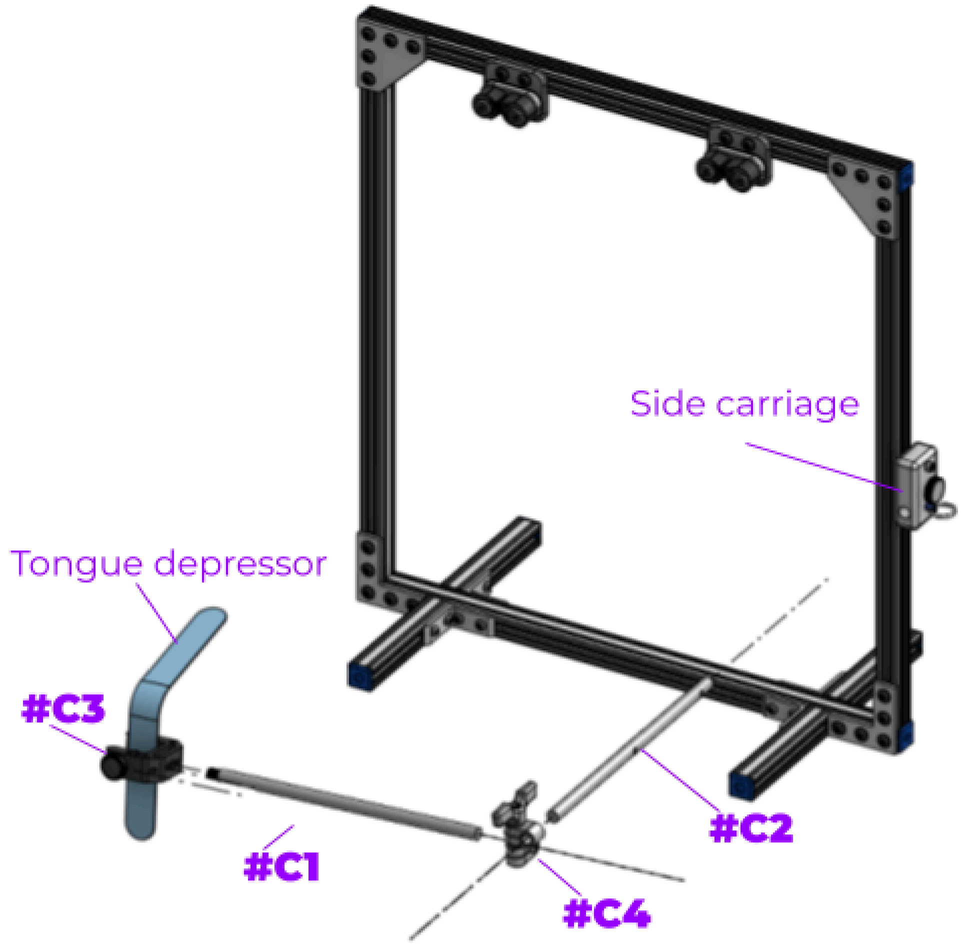


Figure 11: Overall setup on endoscopic arm setup.

Assembly Instructions: *Tongue Depressor*

Components:
- 1x #C1 ⅜"-16 rod
- 1x #C2 ½" Diameter support Rod
- 1x #C3 Tongue Depressor Clamp
- 1x #C4 Swivel Clamp ½" & ½"
- #C5 ⅜-16 Hex nut
- #D1 Side carriage (already assembled)

Instructions:
1. Insert **#C2** ½" diameter support rod into side carriage and align the hole on **#C2** with the lower hole inside **#D1** side carriage. This should be the same hole that the quick-release pin will align perpendicular as **figure 12** shows. There is also an alternative pin hole that can increase extension.
2. Thread in **#C1** ⅜" -16 rod into the tongue depressor to **#C3** Tongue depressor as shown on **Figure 11**.
3. Add the **#C5** ⅜-16 Hex nut in the clamps (**figure 13**) to stop the clamp from rotating.
4. Insert both **#C2** and **#C3** into the **#C4** Swivel clamp to either hole. Use the knob to tighten or loosen for adjustments and repositioning.

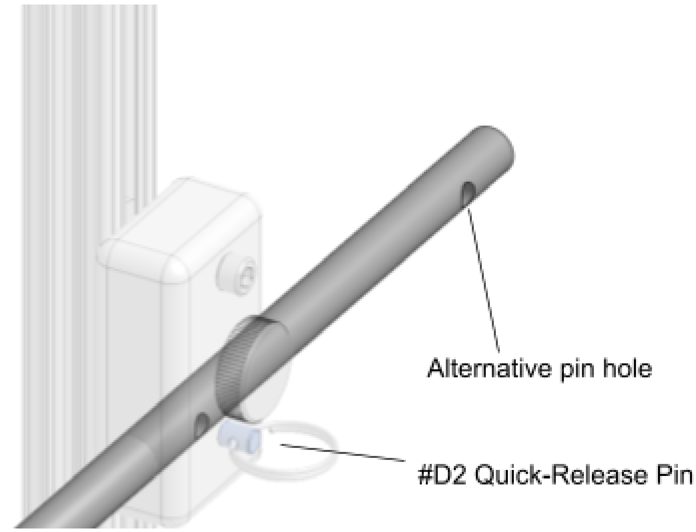


Figure 12: Visual of #D2 quick-release pin inside hole

Figure 13: Visual of step 3 with #C5 hex nut inside the clamp to prevent the clamp from rotating.

Assembly Instructions: *Endoscopic Arm*

Figure 14: Overview of Endoscopic Arm Installation

Assembly Instructions: *Endoscopic Arm*

Components:

- 1x #C2 ½" Dia Support Rod (unused)
- 1x #C6

Instructions:

1. **Repeat step one from the Tongue depressor instructions** (**figure 12**). The pin will be placed in adjacent holes to keep #C2 support rod in place.
2. Repeat step 3 by connecting #C2 and #C6 rods in their appropriate holes. Make sure that #C2 fits in the ½" hole (smaller) and #C6 rod fits in the ⅝" hole (bigger).
3. Thread in the **#C6** rod with the **#C10** gooseneck (female connector) to keep in place (**figure 14**)
4. Thread in **#C7** Thread Adapter to the **#C10** gooseneck. Make sure it connects with the ⅝" diameter hole.
5. Thread in the **#C8** Buret Claw into the **#C7** thread adapter on the ⅜" diameter sized connectors (**figure 14**).
6. (Alternative option): You can remove the gooseneck from and flip the ends of **#C6** rod. The other side has a female connector for the buret claw (**figure 15**). You also do not need the thread adapter.

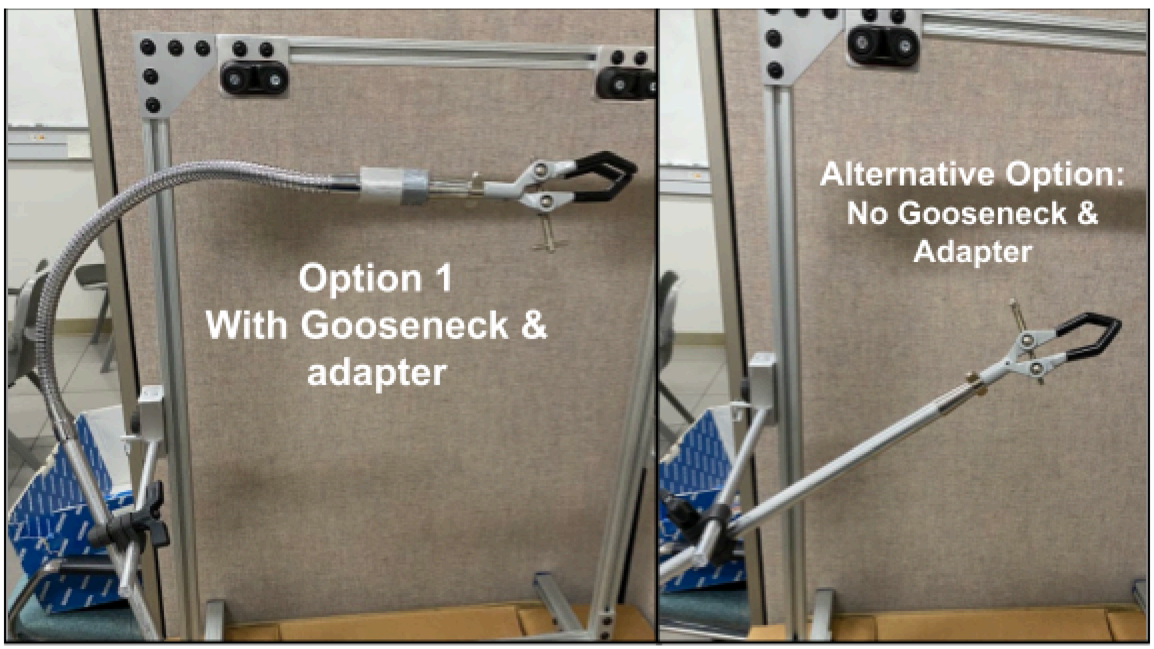


Figure 15: Original and alternative options of Endoscopic Arm Assembly

Assembly Instructions: Rope Placement to Cam Cleat

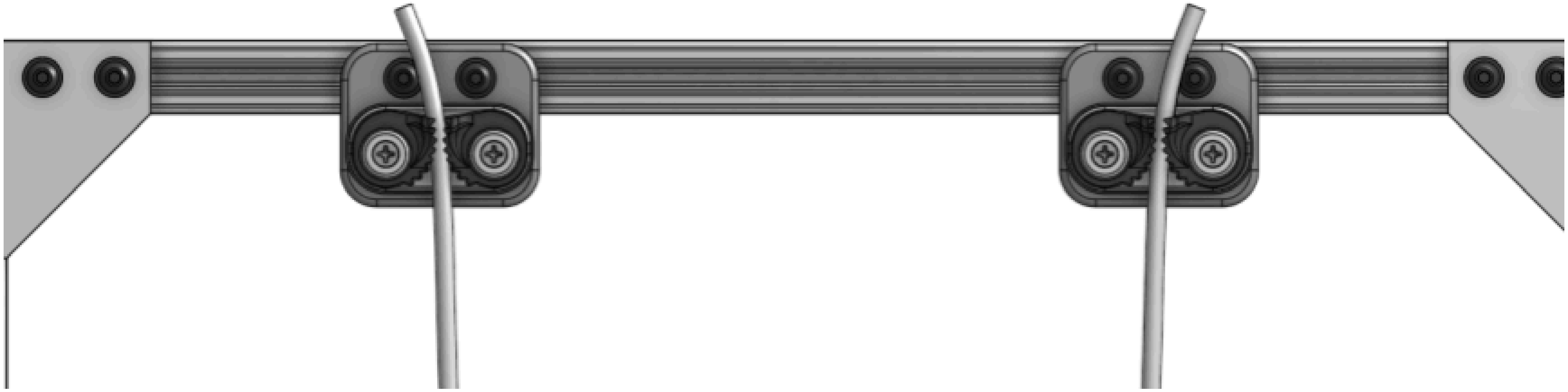


Figure 16: Rope attached to Cam Cleats

Components:
- 1x Attached Cam Cleats to COMPLETE frame
- 1x **#B3** Nylon rope

Instructions:
1. **Confirm cam cleats** are **tightened** to frame.
2. Connect each ends of the **#B3** nylon rope as shown on **figure 16**.
3. You may yank the rope downwards to confirm its strength.
4. You may also shorten or lengthen rope to customize the size for the patient.
5. Optional. If you want the rope to have plastic tubing in the middle, use a heat gun on an enlarged plastic tubing to shrink into size.
6. If the cam cleats need to be widened or shortened between one another, use an allen wrench to customize size.

Assembly Instructions: *Clamps*

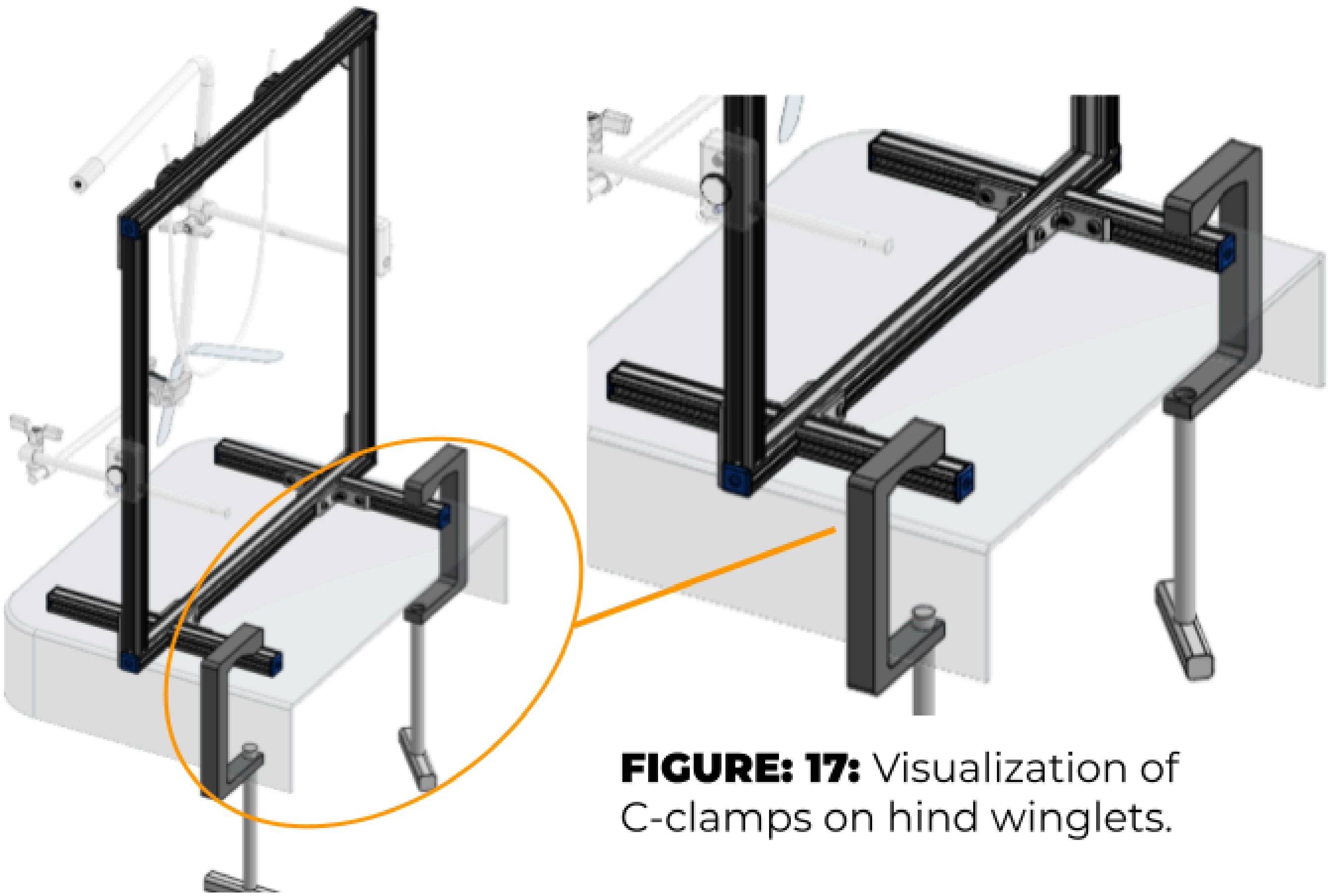


FIGURE: 17: Visualization of C-clamps on hind winglets.

Components:

- Complete BOAS frame
- 2x #D3 C-Clamps

Assembly Instructions: *Clamps*

Instructions:

1. Use both **#D3** C-clamps on each end of the winglets as desired to anchor the frame (**figure 17**).
2. You may position the clamps which are best fit depending on your needs. This is demonstrated on **figure 18**.

(Note: It is highly recommended to clamp the back legs of the design to prevent interference during surgery. Shown on **figure 19**, the BOAS surgeons will either crouch or sit down, which could be uncomfortable for the surgeons if the clamps are in the way.)

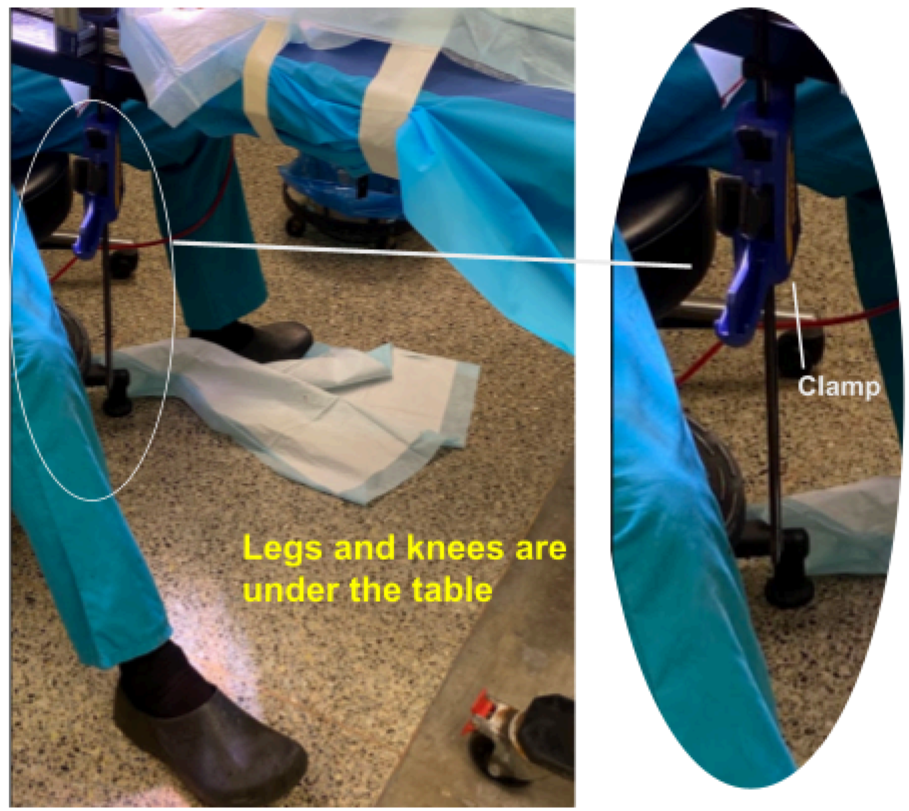


Figure 19: Our client positioning their legs for BOAS surgery and emphasizing the importance of mitigating interference by the clamps

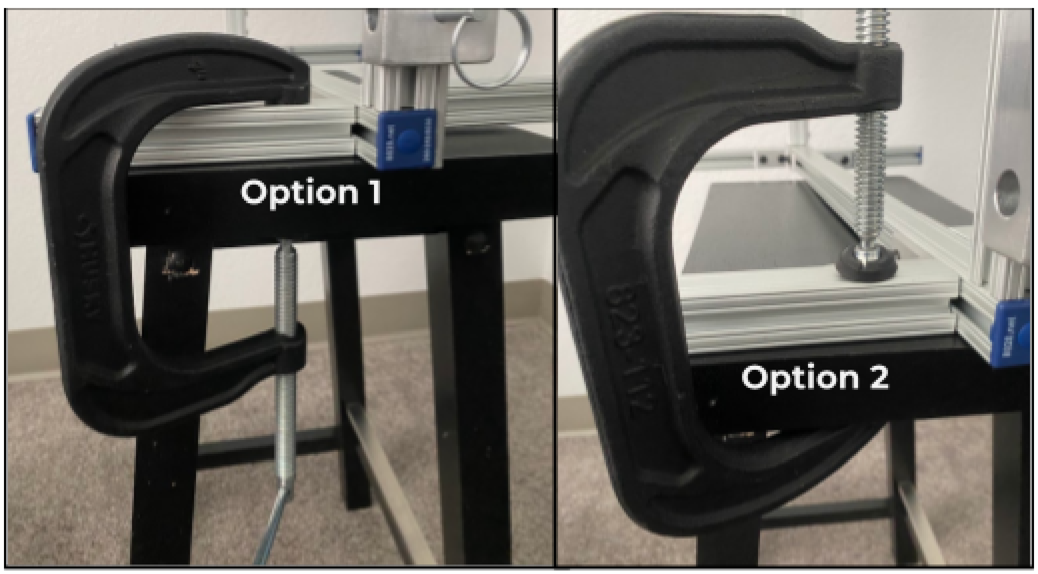


Figure 18: C-clamps set in different ways

How to Use:

Side Carriage:

The #D1 side carriages can be adjusted for height purposes as it can provide more range of motion for the patient (**Figure 21**). As shown on **figure 20**, the knurled set screw (#D4) will lock in place of the position by pinching the fastener into the T-slot. Meanwhile the Phillips screw prevents the side carriage from misaligning with the T-slot rail.

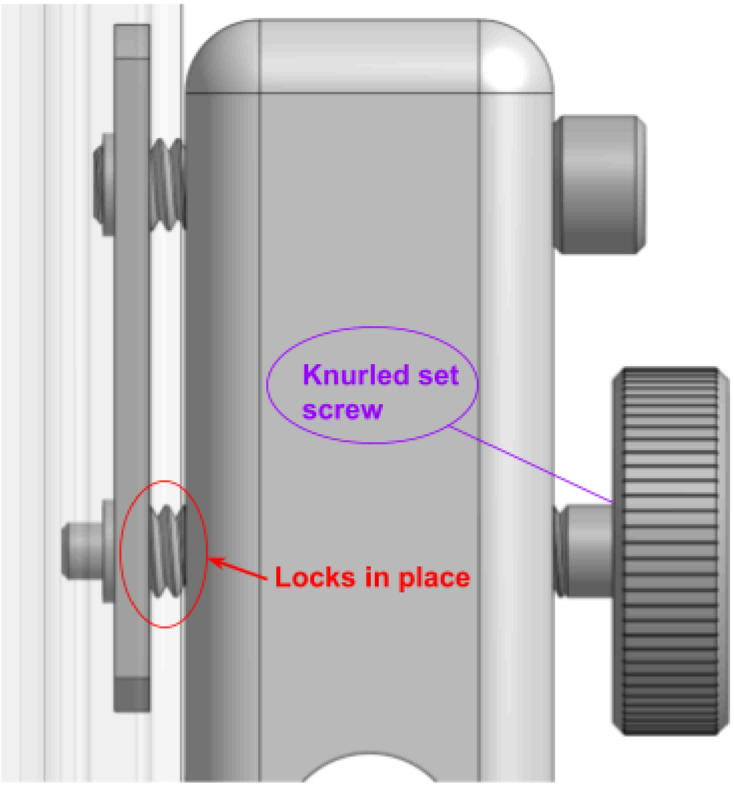


Figure 20: Demonstration of how the Knurled set screw works

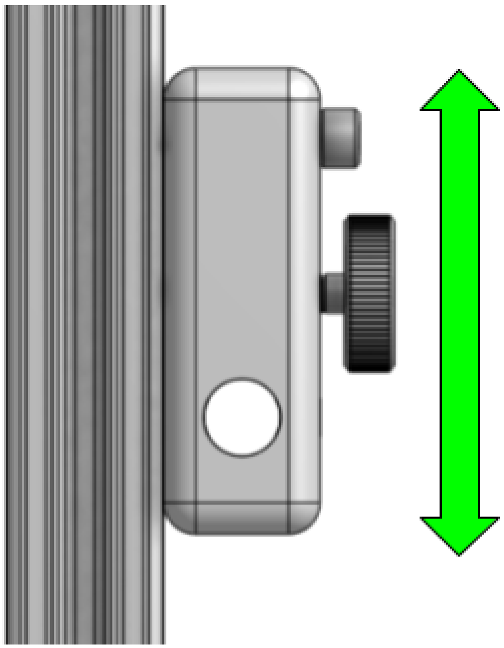


Figure 21: The rod can go up and down as shown indicated by the arrow.

Buret Claw (Endoscopic Arm):
The buret claw is positioned the same way as the screwdriver (**figure 22**) is positioned. The endoscopic arm they used has a long scope as it is designed to look inside the patient's throat in great detail (**figure 23**).

Figure 22: The screwdriver is a placeholder of how the camera will position on Buret Claw.

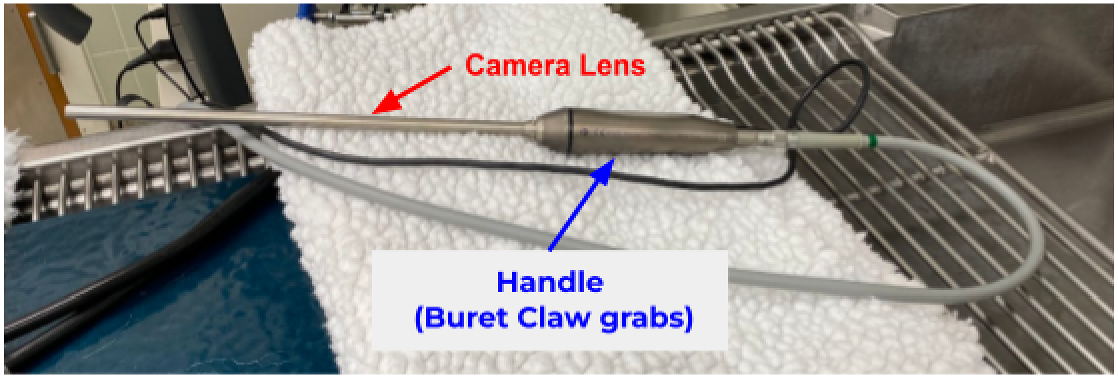


Figure 23: This is the endoscopic equipment they use for BOAS surgery. The Buret claw will grab the handle indicated on the image.

How to Use:

Tongue Depressor:

The mechanism of the tongue depressor arm is very simplistic as it can hold any type of tongue depressor and can be used in multiple ways depending on how the user will use the arm. The best way to use the tongue depressor is by using it to hold a large malleable retractor or a long stick that can maintain the patient's tongue.

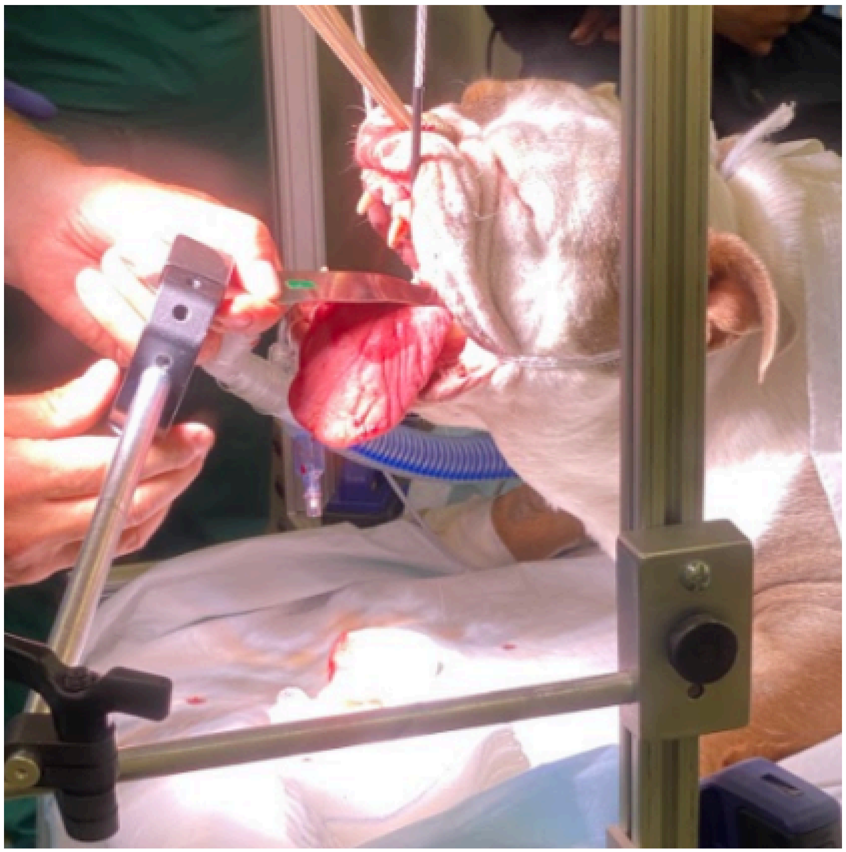


Figure 24: Client is positioning the tongue depressor using a large malleable retractor towards a live patient

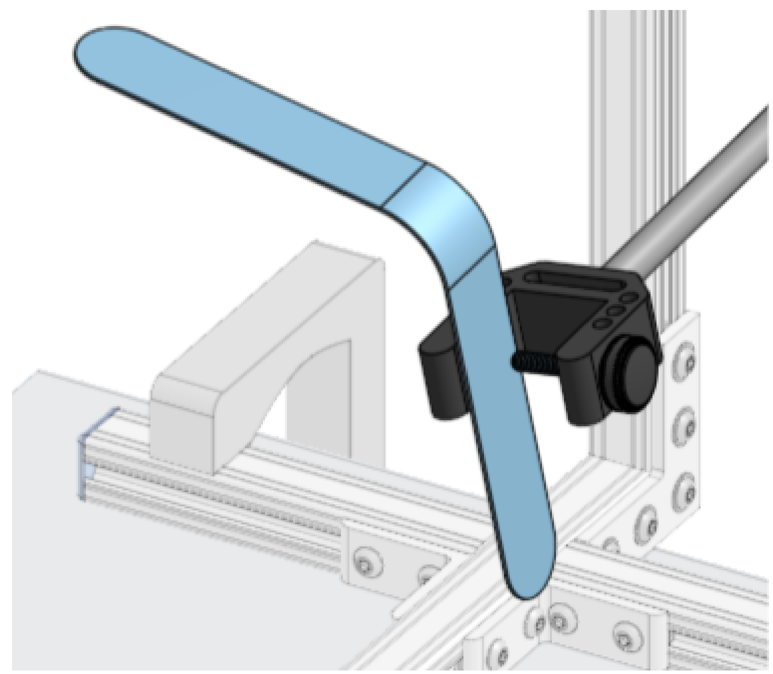


Figure 25: The malleable retractor can be locked in place by using a C-Clamp mechanism.

How to Use:

Swivel Clamps:
The Swivel Clamps Mechanism allows a large range of motion for the support arms. This can allow the user to position their equipment as desired as well as decrease surgery interference if possible. The swivel clamps can rotate 360 degrees and can be locked in place by tightening the knob. The swivel clamp can also grip at any part of the rod to lengthen or shorten the position of the support arm.

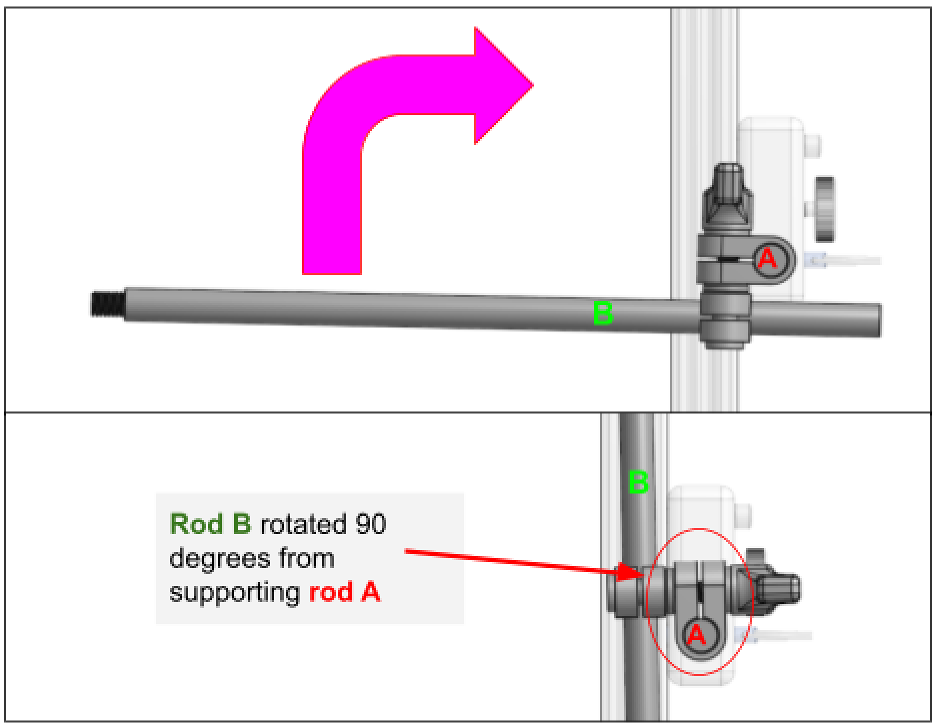


Figure 26: The Swivel clamp moves support arm 90 degrees upward to demonstrate part of its range of motion.

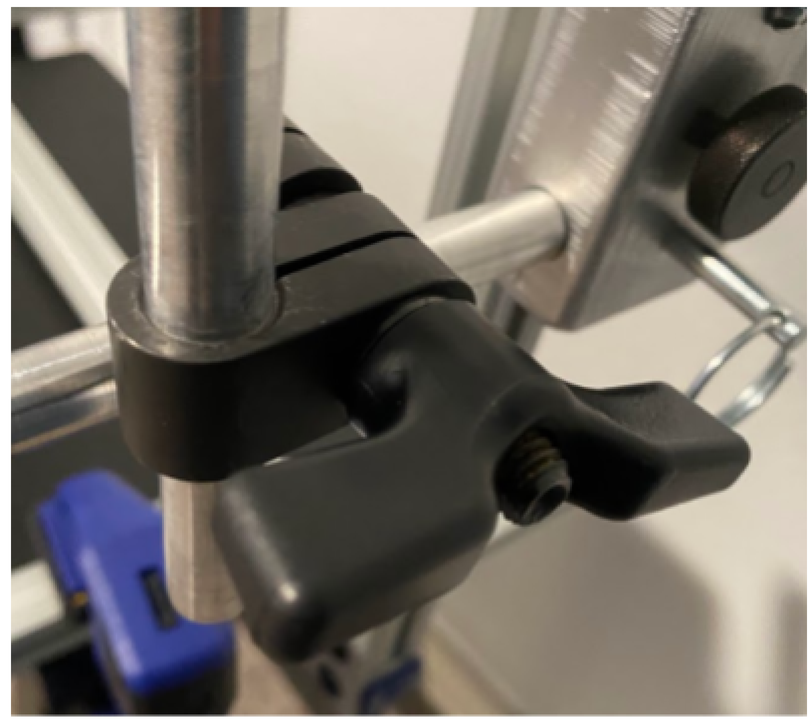


Figure 27: Tightened knob to show the stability in place after positioning the swivel clamp.

Safety Precautions

1. *Use caution, and two hands, when adjusting support arms:* Erratically adjusting the support arms into a new position by loosening the bar joints could result in the rods completely detaching from the assembly. This could result in damage of any equipment that is being held by the support arms. There is potential injury to the patient in the event that the equipment falls and strikes the patient due to carelessness when adjusting the support arms.
2. *Ensure the frame is securely clamped to the OR table before use:* Use of this device without clamps could jeopardize the stability of the frame and lead to patient injury.
3. *Ensure that only the head of brachycephalic breeds are supported by the rope:* Loading the cam cleat - rope system with dog heads that weigh more than typical brachycephalic dog heads could result in the rope becoming disengaged from the cam cleat system and could potentially result in patient injury.
4. *Wipe down mouth guard and frame after each surgery:* Improper sanitization practices could lead to unsanitary conditions and result in patient infection.
5. *Do not load more than 2.5 lbs onto the support arms:* Loading more than 2.5 lbs onto a support arm could result in failure of the support arm, damage to any instrument that the arm is holding, and possible injury to the patient.
6. *Do not use bleach to clean the device:* Bleach is a corrosive agent and may cause metal components to rust thereby reducing the longevity of the device.
7. *Ensure rope ends are pushed completely into the cam cleat system:* Not doing so will lower the security of the head support system and could result in potential injury to the patient.

Individual Component Verification

To ensure that our final product is fully functional and adequate for servicing all of our clients needs, our team will conduct a multitude of verification processes. We will isolate individual components on our device to ensure that they function correctly whilst independent of other components. Such verification will reduce any confounding variables that may be present if we were to only test components in systems. Our team will verify that each component satisfies our EDS as well as functions as intended.

Rope Tensile Strength (Rope Elasticity)

Purpose: We need to verify that the rope can withstand applied loads without breaking

Standard: ASTM D3822/D3822M-14(2020) [7]

Protocol:

1. Fix rope at each CAM cleat where the distance between the frame's base beam and the rope 12 inches
2. Mark the rope at both apexes of the CAM cleats. This will determine the initial starting positions
3. Remove the rope and measure the distance between the two markings. This serves as the initial distance between the two markings, before any permanent strengthening (or lengthening) of the rope
4. Fix rope at each CAM cleat, matching the markings to the apex of each CAM cleat
5. Suspend 7, 25, and 32 lbs for 3 trials each (total of 9 trials) from the middle of the rope
6. Allow 12 hours to elapse
7. Remove the rope from the CAM cleats and measure the distance between the two markings
8. Calculate the percent difference of the new length of the rope to the initial length of the rope. This will dictate how much the rope has deformed, or strength (or lengthened)

Rope Tensile Strength Verification Test Data				
Weight	Trial	Initial Distance between Markings	Final Distance between Markings	Difference between initial and final marks (amount of stretch; distortion)
7lbs	1	$40^1/_{16}$in	$40^1/_{16}$in	0in
	2	$40^1/_{16}$in	$40^1/_{16}$in	0in
	3	$40^1/_{16}$in	$40^1/_{16}$in	0in
25lbs	1	3ft + 4in = 40in	3ft + 4in = 40in	40 - 40 = 0in

	2	3ft + 4in = 40in	3ft + 4in = 40in	40 - 40 = 0in
	3	3ft + 4in = 40in	3ft + $4^3/_{16}$in = $40^3/_{16}$ in	40 - $40^3/_{16}$ = $^3/_{16}$
32lbs	1	40in	$40^1/_{16}$in	$^1/_{16}$in
	2	$40^1/_{16}$in	$40^1/_{16}$in	0in
	3	$40^1/_{16}$in	$40^1/_{16}$in	0in

Perform a one-way Anova test
Null Hyp: $\mu_1 = \mu_2 = \mu_3$
Alt Hyp: $\mu_1 \neq \mu_2 \neq \mu_3$
If P-value < 0.05, we reject the null hypothesis

Verdict:
The one-way Anova test yields a P-value of 0.533
Since 0.533 > 0.05, we fail to reject the null hypothesis that the mean length distortion of rope is the same.

Rule of Thumb for a one-way Anova test
*If the p-value is greater than the significance level, **you do not have enough evidence to reject the null hypothesis that the population means are all equal**. Verify that your test has enough power to detect a difference that is practically significant.

Component Dimensions

Purpose: For each individual part, it is imperative that our team verifies that their dimensions are within the tolerance specified from our vendor. This is to ensure compliance and functionality of the systems that will be composed of these individual parts.
Standard: N/A
Protocol:
1. Measure each component delivered with caliper, tape measure, etc.
2. Compare measurement of component to advertised dimensions
3. Determine if the delivered components are within the advertised tolerance

Frame	Material	Dimensions	Measured Dimensions	

	3-slot T-slot	1" x 1" x 8'		1" x 1" x 8'	
	2-slot T-slot	1" x 1" x 4'		1" x 1" x 4'	
	Flush 90º Angle Brackets	1" x 3"		1" x 3"	
	90º Angle Brackets	1" x 3"		1" x 3"	
	HARKEN Cam Cleat	7/8" x 1-7/8"		7/8" x 1-7/8"	
	Ravenox Solid Braid Nylon Rope	1/4" x 50'		1/4" x 50'	
	Stock Aluminum	6"x3"x1/4"		6"x3"x1/4"	
	T-slot Framing Fasteners	-		-	
	Screws for Cam Cleat	1/4" - 20		1/4" - 20	
	Corner Bracket	2" x 2" x 7/8"		2" x 2" x 7/8"	
	Blue Plastic End Cap for T-Slots	1" x 1"		1" x 1"	
	Clamps	-			
Tongue Depressor	**Details**	**Diameter**	**Length**		
	Aluminum Rod 1	1/2"	1ft	0.509	
	Aluminum Rod 2	1/2"	1ft	0.512	
	Universal C-Clamp	X	X	X	
		Diameter	Diamete		

		A	r B		
	Indicator Clamps Style 7	1/2"	1/2"	0.498”	0.498”
Endoscopic Arm	Details	Diameter	Length		
	Aluminum Rod 1	1/2"	1ft	0.506”	
	Aluminum Rod 2	5/8"	1/2'	0.629”	
	Aluminum Rod 3	1"	1/2'	1.02”	
	On Stage 19 Microphone Gooseneck	5/8 - 27	19"	5/8 - 27	19"
	3 Prong Claw	3/8" - 24	-	3/8" - 24	
		Diameter A	Diameter B		
	Indicator Clamps Style 7	1/2"	5/8"	0.498”	0.626”
Side Carriage	**Details**	**Diameter**	**Length**		
	Thumb Screw	1/4"-20	1.25	1/4"-20	1.25
	Aluminum Extrusion	-	6" x 1.75" x 1"	-	6" x 1.75" x 1"
	Clevis Pins	1/4	1	1/4	1
	Screws for Side Carriage	1/4 - 20	1.25	1/4 - 20	1.25

Any dimensions that were not compliant with other components were modified (cut down) to enable compliance.

System Verification

The design of our device features unique interactions between different components to yield a function. It is important for our team to evaluate the viability of these functions by assessing these interactions.

Tongue Depressor Resistance

Purpose: The tongue depressor arm will be subjected to an upward normal force exerted by the downward depression of the tongue depressor. Our team needs to verify that the indicator swivel clamp will be able to resist this force and maintain its position.
Standard: ASTM F3023-18 [9]
Protocol:

1. Lock tongue depressor support arm into a position as if it were to depress a tongue
2. Secure a tongue depressor into the tongue depressor holder
3. Measure distance from the floor to the top of the tongue depressor holder. Record this value
4. Suspend a 1lb weight from a pulley, where the other end is supporting the tongue depressor. This will apply an upward force of 1lb onto the tongue depressor, mimicking the action of depressing a patient's tongue, which would exert an upward force.
5. Allow 12 hours to elapse
6. Measure the distance from the floor to the top of the tongue depressor holder. Record this value
7. Take the difference of the two recorded values (final - initial) to determine if the tongue depressor holder moved
8. Perform 3 trials
9. The tongue depressor arm fails if it moves by more than 0.2 inches

Trials	Initial Distance from Floor to Tongue Depressor Holder	Final Distance from Floor to Tongue Depressor Holder	Difference between final and initial distances - How much did the tongue depressor holder move?
1	10 $^{12.5}/_{16}$ inches	10 $^{12.5}/_{16}$ inches	0 in
2	10 $^{12.5}/_{16}$ inches	10 $^{12.5}/_{16}$ inches	0 in
3	10 $^{12.5}/_{16}$ inches	10 $^{12.5}/_{16}$ inches	0 in

The mean change in the tongue holder's height relative to the floor is 0 inches. This indicates that our device will operate as intended during BOAS surgery as 0 inches is less than 0.2 inches.

Endoscopic Arm Strength

Purpose: The tongue depressor arm will be subjected to an upward normal force exerted by the downward depression of the tongue depressor. Our team needs to verify that the indicator swivel clamp will be able to resist this force and maintain its position.

Standard: ASTM F3023-18 [9]

Protocol:

1. Lock endoscopic support arm into a position as if it were to hold a camera in view of the surgical site
2. Measure the distance between the floor and the endoscopic claw
3. Apply a weight of 1 and 2 lbs for 3 trials each
4. Allow 4 hours to elapse (due to time constraints)
5. Measure the distance between the floor and the endoscopic claw
6. Determine the displacement of the endoscopic claw for each weight applied
7. Use a 2-way t-test to determine the functionality of the endoscopic arm. The endoscopic arm is fully functional if $p >> 0.05$. H_0: $\mu = 0$, H_a: $\mu \neq 0$

Weight	**Trial**	**Initial Height**	**Final Height**	**Displacement**
1 lb	**1**	**12 in**	**12 in**	**0**
	2	**12 in**	**12 in**	**0**
	3	**12 in**	**12 in**	**0**
2 lbs	**1**	$8^{6.5}/_{16}$	$8^{6.5}/_{16}$	**0**
	2	$8^{6.5}/_{16}$	$8^{6.5}/_{16}$	**0**
	3	$8^{6.5}/_{16}$	$8^{6.5}/_{16}$	**0**

The mean displacement that occurs for both 1lb and 2lbs is 0 inches. This is a strong indicator that our device should function as intended. It should be noted that the endoscopic equipment was estimated to weigh about 2 lbs by Dr. Mayhew.

Rope Displacement

Purpose: Our team needs to verify that the rope will not experience substantial displacement (from the CAM cleats) when a load is applied to ensure stability of the patient's head during surgery.

Standard: ASTM E2309/E2309M-20 [10]

Protocol:

1. Place rope into CAM cleat where the distance between the frame's base beam and the rope is 12 inches
2. Mark the rope at the apex of each CAM cleat as its initial position

3. Apply a load of 7lb, 25, and 32 lbs for 3 trials each (9 trials in total)
4. Allow 12 hours to elapse
5. Mark part of rope at apex of CAM cleats
6. Extract rope from CAM cleats
7. Measure the distance between the two markers on the rope
8. Assess the significance of the rope's displacement using a one sided t-test with a 95% confidence interval in order to compare the measured displacement to the desired displacement (which is zero). The null hypothesis that there is no displacement of the rope.

Rope Displacement Verification Test Data			
Weight	Trial	Distance between initial and final marking of left CAM cleat	Distance between initial and final marking of right CAM cleat
7lbs	1	0in	0in
	2	0in	0in
	3	0in	0in
25lbs	1	0in	0in
	2	0in	0in
	3	0in	0in
32lbs	1	0in	0in
	2	0in	0in
	3	0in	0in

*Note that the front face of the frame is so that the CAM cleats are visible. This is important as it determines the left and right side of the frame

From the above analysis, it can be observed that there is no displacement of the rope in the CAM cleats for any of the tested weights. This test confirms that our CAM cleat - rope system functions as intended and will provide stable vertical support for the patients head.

Full Assembly Verification

Full assembly verification incorporates all of the individual components and accounts for their dependent interactions. The tests performed here are to ensure that our device functions as expected and adheres to our EDS.

Cost

Purpose: Our cost is expected to be below the budget of $500.

Standard: N/A

Protocol:

1. Sum up all prices of final materials and components ordered.

	Material	Price per Unit	# of Components	Total Component Price
Frame	3-slot T-slot	$43.95	1	$43.95
	2-slot T-slot	$18.56	1	$18.56
	Flush 90º Angle Brackets	$15.08	2	$30.16
	90º Angle Brackets	$10.26	2	$20.52
	HARKEN Cam Cleat	$29.03	2	$58.06
	Ravenox Solid Braid Nylon Rope	$15.40	1	$15.40
	Stock Aluminum	$7.13	1	$7.13
	T-slot Framing Fasteners	$5.51	1	$5.51
	Screws for Cam Cleat	$0.60	2	$1.20
	Corner Bracket	$7.07	4	$28.28
	Blue Plastic End Cap for T-Slots	$1.80	8	$14.40
	Clamps	$19.37	2	$38.74
Tongue Depressor	Aluminum Rod 1	$2.13	1	$2.13
	Aluminum Rod 2	$2.13	1	$2.13
	Universal	$10.99	1	$10.99

	C-Clamp			
	Indicator Clamps Style 7	$39.44	1	$39.44
Endoscopic Arm	Details	Price	1	Price
	Aluminum Rod 1	$2.13	1	$2.13
	Aluminum Rod 2	$7.61	1	$7.61
	Aluminum Rod 3	$8.44	1	$8.44
	On Stage 19 Microphone Gooseneck	$12.95	1	$12.95
	3 Prong Claw	$25.55	1	$25.55
	Indicator Clamps Style 7	$40.84	1	$40.84
Side Carriage	Thumb Screw	$9.00	2	$9.00
	Aluminum Extrusion	$12.87	1	$12.87
	Clevis Pins	$8.38	2	$8.38
	Screws for Side Carriage	$1.2	2	$1.2
			Total Price	**$443.04**
Legend	Unavailable	Donated		

From summing up the cost of all of our ordered components, our total cost was $443.04. It should be noted that this is below the budget of $500.

Weight

Purpose: Our device is expected to be relatively lightweight as it is designed to be handheld.
Standard: ASTM F2918-11(2015) [14]
Protocol:

1. Weight our full assembly on a scale with precision up to 0.01lbs

	Weight	EDS Weight
Full Assembly	8lbs	<22 lbs

Overall Size (Length, Width, and Height)

Purpose: Our full assembly is expected to sit on top of an operating table, therefore, its length and width should be of appropriate size. The height also has a desired size determined by Dr. Mayhews input. The measurement tool used to obtain these measurements will be a tape measure with a precision of 1/32 of an inch

Standard: ASTM D6536/D6536M-18 [15]

Protocol:

1. Measure Width of full assembly with measuring tape
2. Measure Length of full assembly with measuring tape
3. Measure Height of full assembly with measuring tape
4. Measure maximum distance that arm extend from frame

	Width	Depth	Height	Max Distance of Arm Extension from Center
Full Assembly	2ft = 24in	1ft = 12in	2ft + 8 in =32in	1ft = 12in

Frame Stability (Center of Mass)

Purpose: Our team will need to determine the locations and magnitudes of applied loads that will induce sway and tipping. This is critical as it is unfavorable for sway or tipping to be present during use as it may result in injury and environmental damage.

Standard: ASTM F3052-14(2020)e1[12]

Protocol:

1. With no external loads or clamps applied to the full assembly, extend equipment support arms out completely.
2. Observe the extent of sway or tipping while recording the process with a slow motion camera. On camera, determine the angle the frame's base is displaced off of the table.

The above image shows the frame 3.51° above the surface after an applied load of about 15 lbs on the frame's apex beam.

The above image shows the frame 6.22° above the surface after an applied load of about 15 lbs on the frame's apex beam.

Edge and Corner Sharpness

Purpose: We need to verify that any interactions between a living organism and the edge and corners of our device will not result in injury.
Standard: 16 CFR § 1500.49 [16]
Protocol:

1. Wrap one layer of polytetrafluoroethylene (TFE) tape around the full circumference of the mandrel in an unstretched state. The ends of the tape shall be either butted or overlapped not more than 0.10 inch (2.5 millimeters).
2. Apply the mandrel, at the approximate center of the tape, to the edge of the test sample with a force of 1.35 pounds (6.00 Newtons) measured in a direction at right angles to the mandrel axis. The mandrel shall be placed so that its axis is at 90 degrees ±5 degrees to the line of a straight test edge or 90 degrees ±5 degrees to a tangent at the point of contact with a curved test edge. The point of contact between the test edge and the mandrel shall be in the approximate center of the width of the tape. The axis of the mandrel may be positioned anywhere in a plane which is at right angles to either the line of a straight test edge or to a tangent at the point of contact with a curved test edge. The operator should seek the orientation most likely to cause the edge to cut the tape.
3. Maintain the force against the edge and rotate the mandrel through one complete revolution while preventing any linear motion of the mandrel along the edge.
4. Release the mandrel from the edge and remove the tape without enlarging any cut or causing any score to become a cut. A cut in the tape with a length of not less than 1/2 inch (13 millimeters) identifies an edge as sharp. (The test instruments used by the Commission in its test for compliance with the regulation will be calibrated to ensure that the force with which the mandrel is applied to a test edge does not exceed 1.35 pounds.)

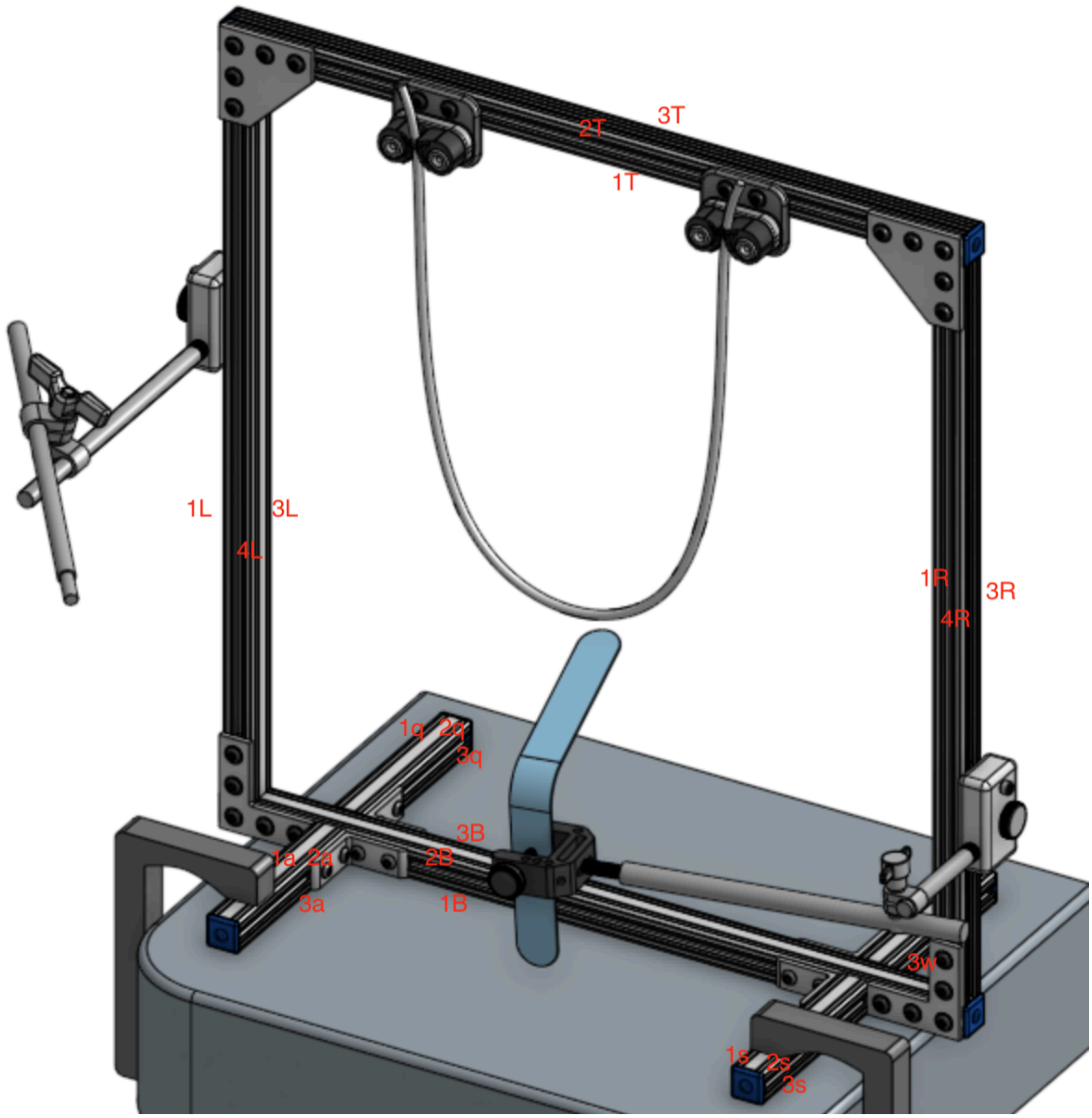
Improvised protocol:

1. Wrap TFE tape around a cylindrical object
2. Place cylindrical object on edge of interest
3. Place a 1 lb weight on top of the pencil
4. Hold the 1 lb weight in place while the cylindrical object is rotated 360º
5. Remove weight and cylindrical object, and measure length of cut present in tape
6. If the cut is < ½ inches, the edge is not not sharp. If the cut is ≥ 1/2 inches, the edge is sharp
7. Execute protocol for every edge present on device

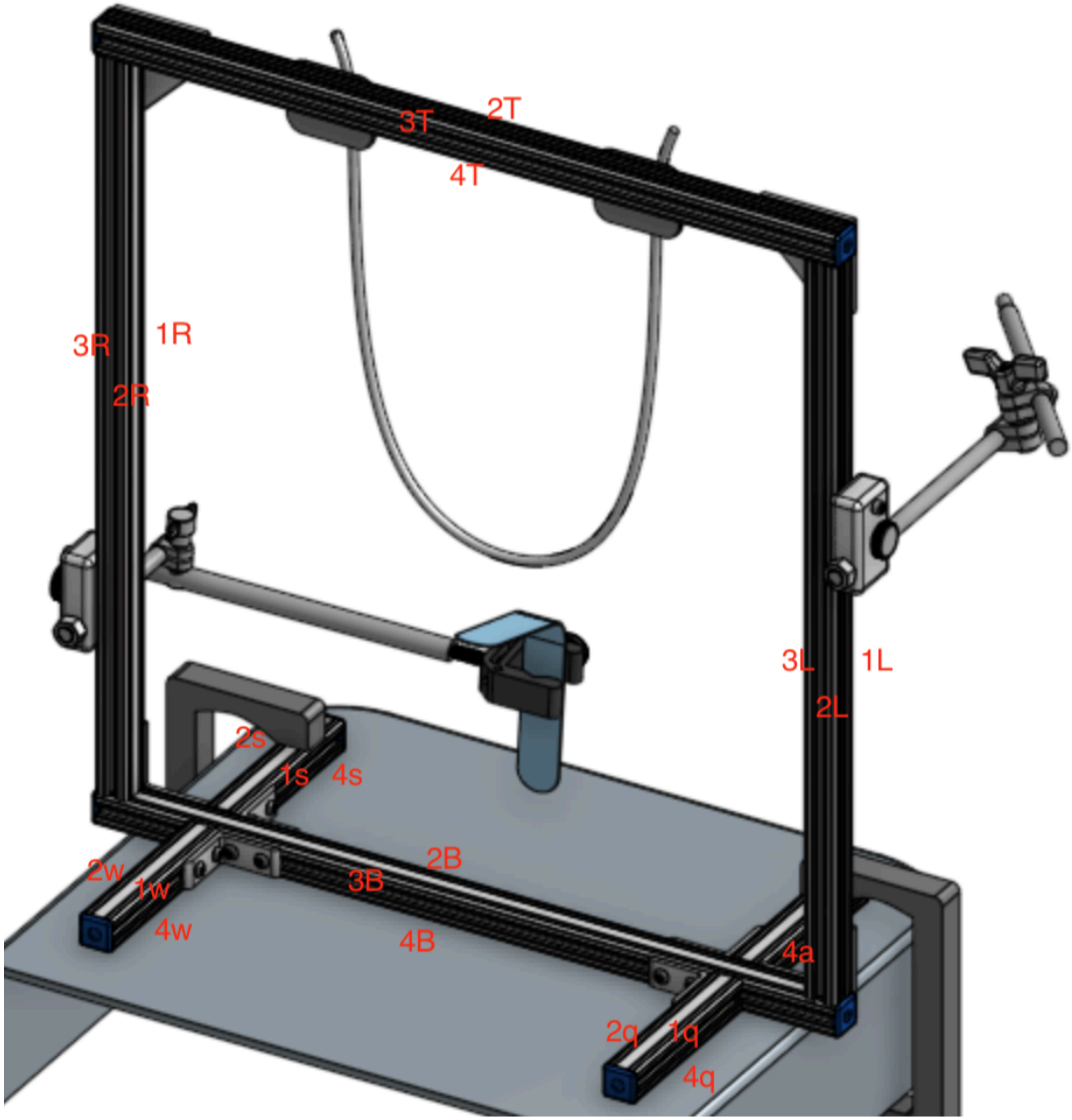
Edge Number	Length of Cut
1L	0 in
2L	⅛ in
3L	¼ in
4L	0 in
1R	0 in
2R	0 in

3R	0 in
4R	0 in
1B	0 in
2B	0 in
3B	0 in
4B	0 in
1T	0 in
2T	0 in
3T	0 in
4T	¼ in
1a	0 in
2a	0 in
3a	0 in
4a	0 in
1q	0 in
2q	0 in
3q	0 in
4q	0 in
1s	0 in
2s	1/32 in
3s	0 in
4s	0 in
1w	0 in
2w	⅛ in
3w	0 in
4w	0 in

According to all of the collected data, all of the edges that will interact with the patient and surgeon are less than ½ in. This indicates that all of our edges are not too sharp. The mean length of cut for all edges is 0.0244 inches, which is significantly less than 0.5 inches. The mean length does not validate each edge (only the specific data determines viability), but it is an interesting metric.



2T
3T
1T
1L
3L
4L
1R
3R
4R
1q
2q
3q
3B
1a
2a
2B
3a
1B
3w
1s
2s
3s



2T
3T
4T
3R
1R
2R
3L
1L
2L
2s
1s
4s
2B
2w
1w
3B
4w
4B
4a
2q
1q
4q

Validation

To ensure that our frame meets the needs of our end user, we will disseminate a validation survey to the BOAS surgeon responsible for the surgical setup and procedure. In this case, the surgeon who conducted the validation procedures was Dr. Mayhew. This validation survey will allow our team to gather qualitative data about the user experience and how the device compares to the gold standard under realistic surgical conditions. Additionally, we will perform validation testing by directing technicians and surgeons to perform a validation procedure.

Validation Procedure

There will be two separate validation procedures: one will be performed by the technician, surgeon, or team members which will test for the setup of the device to ensure that our frame is capable of affixing to many different operating tables in a timely manner, and the other will be performed by the veterinary surgeon and will test the safety and efficacy of the frame when used to conduct BOAS surgery. Data will be collected during both validation procedures so that a comparison to the gold standard can be performed.

Purpose of setup procedure:

The purpose of the setup procedure is to ensure that the BOAS frame can be transported and set up in any or most rooms and operating tables in a timely manner that is similar to or faster than the gold standard. We must ensure that the frame is capable of affixing to the operating tables since the sizes and styles of each operating table vary throughout the veterinary clinic.

Materials for setup procedure:

The fully assembled BOAS frame, two IV drip stands and medical tape to set up the gold standard surgical setup, and access to an unused operating room table within the UC Davis Veterinary Hospital.

Protocol for setup procedure:

The technician, surgeon, or a team member will begin the setup process by picking up the frame and transporting it to an adjacent room. The individual will proceed to place the frame onto the operating room table and clamp down the base of the frame to the table with the provided clamps. The tongue depressor will be inserted into the housing of the tongue depressor arm and positioned into a desirable position for the veterinary surgeon to conduct surgery. Multiple trials will be performed to ensure that the setup of this device is feasible and that this device can be set up in various different operating rooms with different operating tables. Data regarding the setup time for the gold standard will not be recorded due to time constraints, but this data will be collected via the Validation Survey. The data on the time taken to set up will be recorded and a statistical analysis will be performed using a 2-sample student's t-test using a p-value of 0.05 to compare the data.

Purpose of surgical procedure:

The purpose of the surgical procedure is to ensure that the BOAS frame is capable of providing a safe environment for the patient to receive BOAS surgery from the veterinary surgeon. This will allow our team to assess the stability of the frame itself, the stability of the patient's head while supported by the frame, and how secure the patient's head is supported by the rope. Our team can compare these metrics obtained using the BOAS frame and compare it to the gold standard.

Materials for surgical procedure:

The fully assembled BOAS frame, two IV drip stands and medical tape to set up the gold standard surgical setup, access to an unused operating room table within the UC Davis Veterinary Hospital, and a proxy brachycephalic dog that could act as the surgical subject so that an actual dog would not subjected to such preliminary testing.

Protocol for surgical procedure:

The veterinary surgeon will begin the surgical procedure by adjusting the tongue depressor support arm into an optimal position. The frame will have already been set up as would occur in any normal surgery. Actual BOAS surgery will be performed on a brachycephalic patient. Our team will analyze this procedure and record data over one trial. Only one trial was performed due to time constraints. The following data will be recorded: displacement of the top of the frame from its initial position, lateral displacement of the patient's head, the number of instances that the patient's head becomes detached from the support rope, and time taken to perform the surgery. A 1-sample student's t-test will be used to analyze this data with a p-value of 0.05. The sample data will be compared to the known population mean or our target values. Ideally, means would be used in the statistical analysis, but since 1 trial was performed, the mean is equal to the value of the data itself.

Qualitative Analysis

Our team will disseminate a validation survey to the veterinary surgeon to gather qualitative data on the safety and efficacy of the frame. It should be noted that we only received a response from Dr. Mayhew. This survey will allow our team to create quantitative data from the qualitative data with rating scales, and it will allow us to receive additional feedback or input from the end users based on their experience with the device. The validation survey is provided in the appendix.

The survey data will be analyzed depending on the style of question. The survey is currently designed to have five different question types: "yes or no", multiple choice, rating scale, short answer, and long answer.

The "yes or no" questions are designed to provide feedback on whether the device component is capable of performing its basic functions and will indicate if anything on the BOAS frame is nonfunctional. Our team will analyze this data by ensuring that either 95% of the responses are either "yes" or "no" to determine which option more clearly represents the functionality of the component.

Multiple choice questions will be analyzed using a weighted average. Since the multiple choice questions are asking the end user to rate their experience with a component from "very difficult to use" to "very easy to use" with five options, we will assign a value of 1 being very difficult and a value of 5 being very easy. The weighted average will provide our team with a number that will be representative of the difficulty level of use.

The rating scales will be analyzed in the exact same manner as the multiple choice questions. This question type was only asked differently since this style of presentation was more sensible for some of the questions.

The short answer questions are designed to gather information regarding the surgical setup times and surgical procedure times with both the gold standard and the BOAS frame. This provides our team with more information without our team members having to sit in on multiple surgeries that may last an hour or longer. This will provide our team with quantitative data on a larger scale so that we can analyze this data using a 2-sample student's t-test (if the sample size is less than 30) or a 2-sample z-test (if the sample size is greater than or equal to 30) with a p-value of 0.05. A 2-sample t-test or 2-sample z-test are being used so that the BOAS frame can be compared to the gold standard. Whether we perform a student's t-test or a z-test will depend on the number of people that take and submit our survey.

The long answer questions will not provide any quantitative information, but rather serve to provide the end users with feedback for our consideration. This will allow our team to make changes, if possible, to our current design and improve it.

Quantitative Analysis

The following metrics will be analyzed via the validation procedure in order to test the following metrics: setup time, surgical procedure time, frame stability, and patient head stability. The setup time and surgical procedure time will be measured via stopwatch, the frame stability will be measured by the displacement of the top beam, and the patient head stability will be measured by the displacement of the patient's head due to lateral movement.

Since the setup and surgical times mentioned in the quantitative analysis will be recorded by our team members in person, we will only have enough time to perform these measurements 1 time due to our own time constraints. Thus, the sample size will be one and a 2-sample student's t-test will be performed with a p-value of 0.05 to compare these times of the BOAS frame against the gold standard.

The frame and head displacements will be analyzed using a 1-sample student's t-test with a sample size of 1 and a p-value of 0.05. A 1-sample t-test is being used in this scenario since we want to compare the actual values to target values.

Validation Results

Only 1 validation trial was performed due to time constraints. Because only 1 trial was able to be performed, we cannot perform a statistical analysis. Instead, we will compare the values of the BOAS frame to target values.

Setup Time:

The recorded setup time for the BOAS frame was 5 minutes and 15 seconds. According to the Validation Survey, our clinician reported that the gold standard has a setup time of approximately 5 minutes. These times only differ by about 4.878% which is below the common 5% threshold. This means that the setup time between the BOAS frame and the gold standard do not differ significantly.

Time of Surgery:

The time of the surgical procedure that our team witnessed was approximately 1 hour and 30 minutes. According to a Validation Survey response, the time to perform the surgery with the Gold Standard is approximately 1 hour and 30 minutes as well. Even though the BOAS frame does not improve surgical times, it is competitive with the gold standard.

Interpretation of Results:

Displacement of Frame:

When recording this data, our team set up a camera to capture the side view of the frame while it was assisting in the surgical procedure. Going back through the footage showed no discernable displacement. We therefore assign the frame of having a displacement value of 0. Our target value for this displacement was 0, and because our recorded value meets our target value, we have validated that the displacement of the top of the frame is negligible and is therefore stable.

Lateral Head Displacement of Patient:

There was no discernable lateral head displacement of the patient while undergoing surgery. Thus, the head displacement is assigned a value of 0 and meets our target value of 0. This means that the patient's head is steady while undergoing surgery.

Head Detachment Count:

During the surgical procedure, the patient's head remained supported by the head support system for the entire duration of the surgery. Therefore, the patient's head detached 0 times which meets our target value of 0 for the head detachment count. This means that the head support system is capable of safely supporting a brachycephalic patient's head during the entire duration of a surgical procedure.

Validation Data Summary

Metric	Unit	Actual Value	Target Value
Displacement of Frame	Inches	0	0
Lateral Displacement of Head	Inches	0	0
Head Detachment Count	Occurrences	0	0
Length of Surgery	Hours	1.5	≤ 1.5
Do Clamps Fit	Boolean (Yes/No)	Yes	Yes
Setup Time	Minutes	5.25	5 ± 1

Validation Survey Results

The results of the validation survey will be included in the appendix. To summarize the results, our clinician found our device to be much more stable and much easier to use than the gold standard. It also provides a much greater field of view and working area for the surgeon to conduct surgery. A critique of our product would be to integrate the clamps into the design; however, this is a minor critique as the stability was excellent.

Large Scale Validation

According to Dr. Mayhew, neither IACUC nor IRB approval will need to be obtained in order to perform large-scale validation since the frame is only being used to facilitate surgery and is not an actual surgical technique. This means that this device can be used for BOAS surgeries after being constructed and large-scale validation can commence with many trials of BOAS surgery so that data can be collected and a statistical analysis can be performed to compare the safety and efficacy of this device to the currently employed gold standard. Large scale validation would occur if more time and resources were granted and would only take place after initial prototype validations were performed.

During our initial validation stage, our team did not have the endoscopic arm manufactured in time for validation testing. Therefore, large scale validation trials would incorporate "in-the-field" testing of the endoscopic arm to ensure that it meets the user needs of BOAS surgeons.

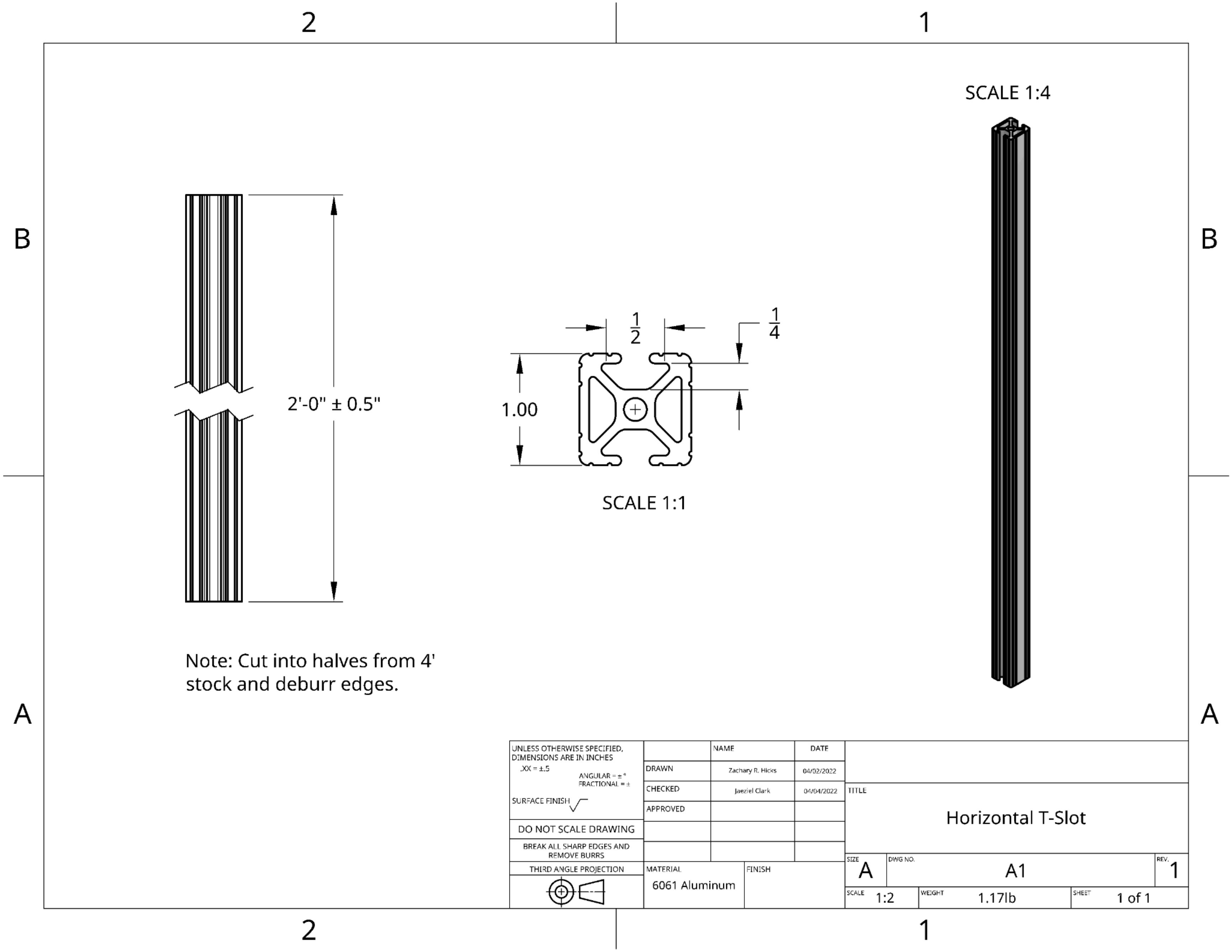
Procedure:

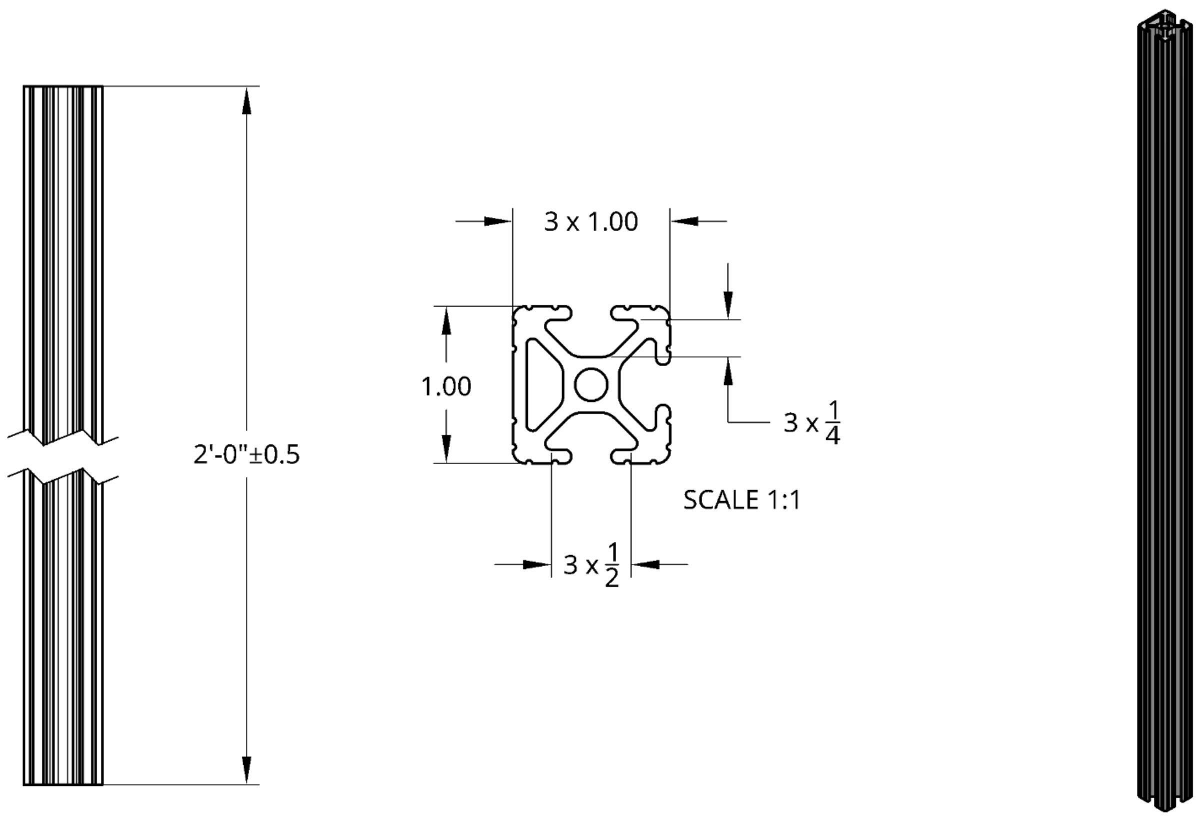
Large scale validation will be conducted on brachycephalic dogs suffering from BOAS who's condition requires surgical intervention. One group ($n = 30$) of patients will have their surgery conducted with the BOAS frame while another group ($n = 30$) will have their surgery conducted with the gold standard setup. These trials cannot be blinded from the veterinary surgeons perspective due to the nature of the surgery and the fact that the surgeon must interact with the surgical setup in order to successfully perform the surgery. Ideally, we would have many different surgeons conducting these surgeries with both the gold standard and our BOAS frame.

Because we are using sample sizes of 30 for each sample population, and we will compare the mean values for the following tests using a 2-sample Z-test ($p = 0.05$): setup and takedown time, surgical procedure time, displacement of frame, and displacement of patient's head. We also intend to analyze how many people are needed during setup, surgery, and take down of the device. This statistical test will allow us to conclude whether the BOAS frame performs equivalently or better than the gold standard. The null hypothesis is that each of these measured metrics are equivalent while the alternative hypothesis will state that the metrics for the BOAS frame are significantly less than, a lower value for both time and displacement is desirable, the golden standard.

Ideal large scale validation would continue on beyond the 2022 spring quarter to assess how well our device meets the users' needs over a longer period of time. On a larger scale, much of this data collection could be done by hospital staff and returned to us for analysis. This could be accomplished using a pre-made data collection form for users to fill out.

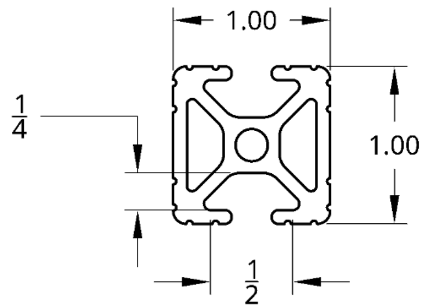
Engineering Drawings





SCALE 1:2

UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES .XX = ±.01 ANGULAR = ± ° FRACTIONAL = ± SURFACE FINISH		NAME	DATE		
	DRAWN	Zachary R. Hicks	04/02/2022	TITLE	Vertical T-Slot
	CHECKED	Jaeziel Clark	04/02/2022		
	APPROVED				
DO NOT SCALE DRAWING					
BREAK ALL SHARP EDGES AND REMOVE BURRS				SIZE A	DWG NO. A2 / REV. 1
THIRD ANGLE PROJECTION	MATERIAL 6061 Aluminum	FINISH		SCALE 1:4	WEIGHT 1.17 lbs to 1.46 lbs / SHEET 1 of 1



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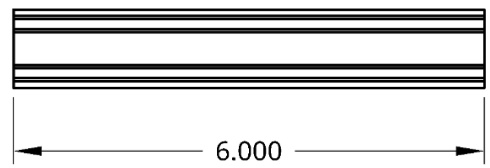
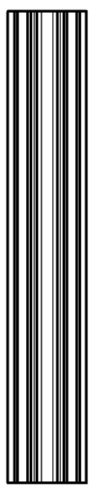
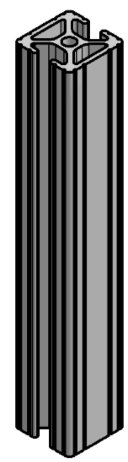
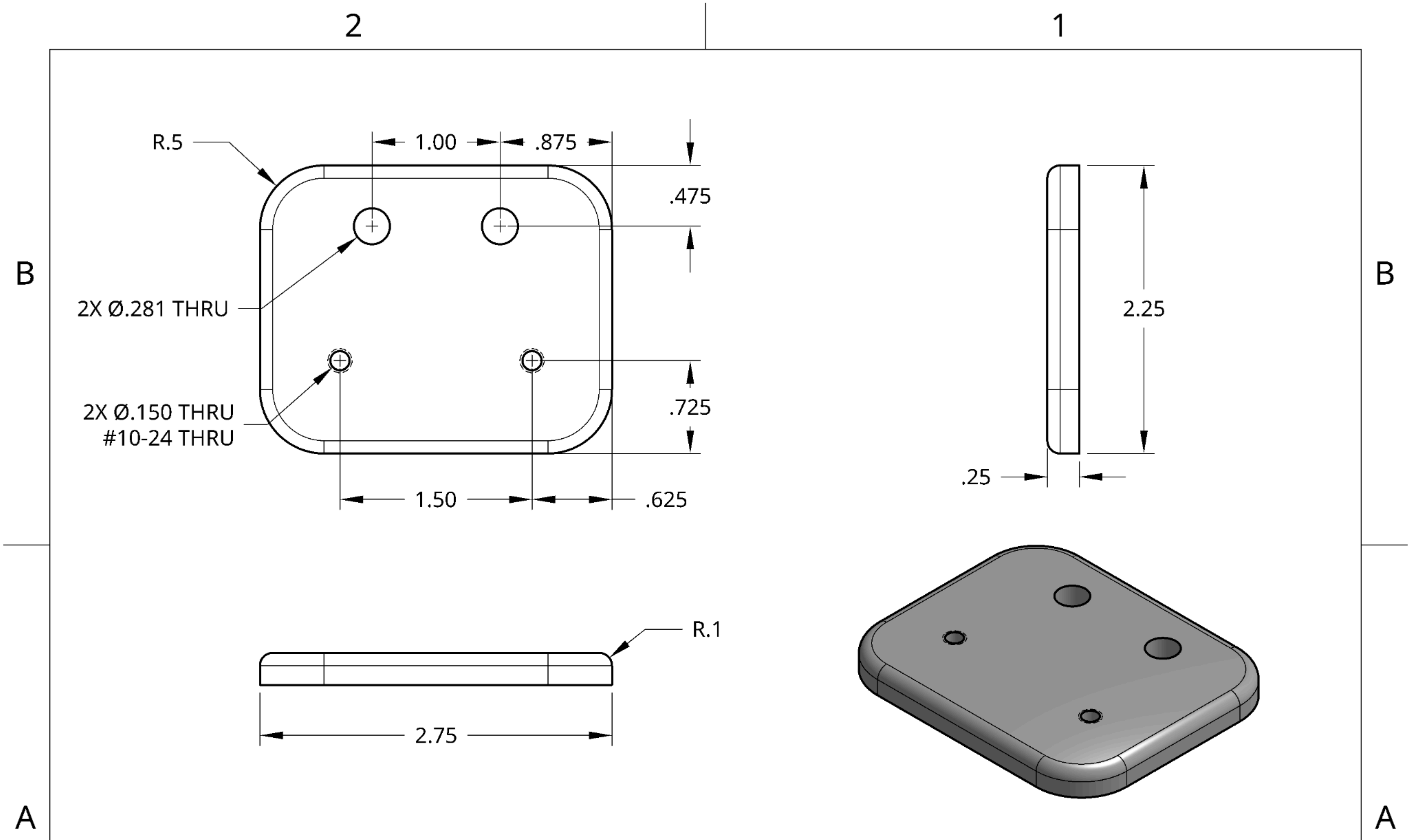






UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES .XX = ±.0- .XXX = ±.00- .XXXX = ±.000- ANGULAR = ± ° FRACTIONAL = ± SURFACE FINISH		NAME	DATE
	DRAWN	Zachary R. Hicks	04/05/2022
	CHECKED	Andrew Heying	04/05/2022
	APPROVED		
DO NOT SCALE DRAWING			
BREAK ALL SHARP EDGES AND REMOVE BURRS			
THIRD ANGLE PROJECTION	MATERIAL 6061 Aluminum	FINISH	

TITLE	Winglet T-Slot		
SIZE A	DWG NO. A3		REV. 1
SCALE 1:2	WEIGHT	SHEET 1 of 1	



UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES
.XX = ±.0-
.XXX = ±.00-
.XXXX = ±.000-
ANGULAR = ± °
FRACTIONAL = ±
SURFACE FINISH

DO NOT SCALE DRAWING

BREAK ALL SHARP EDGES AND REMOVE BURRS

THIRD ANGLE PROJECTION

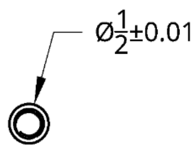
	NAME	DATE
DRAWN	Zachary R. Hicks	04/02/2022
CHECKED	Jaeziel Clark	04/04/2022
APPROVED		

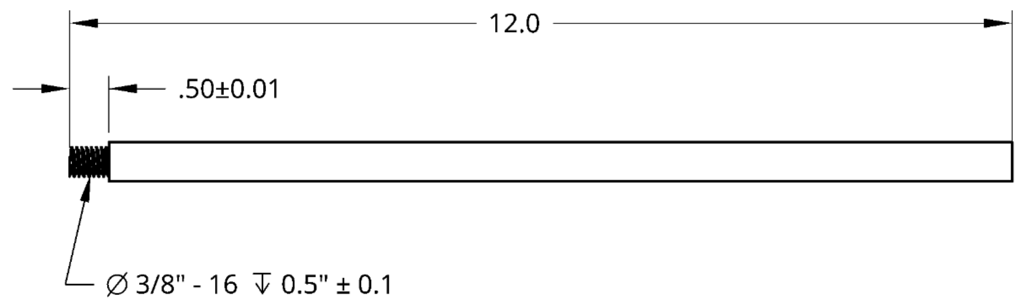
MATERIAL: 6061 Aluminum
FINISH:

TITLE: Cam Cleat Adapter

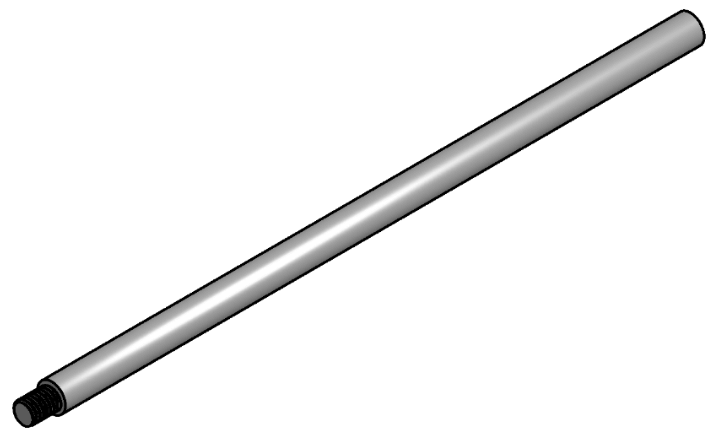
SIZE: A | DWG NO.: B1 | REV.: 2

SCALE: 1:1 | WEIGHT: 0.02 lbs | SHEET: 1 of 1

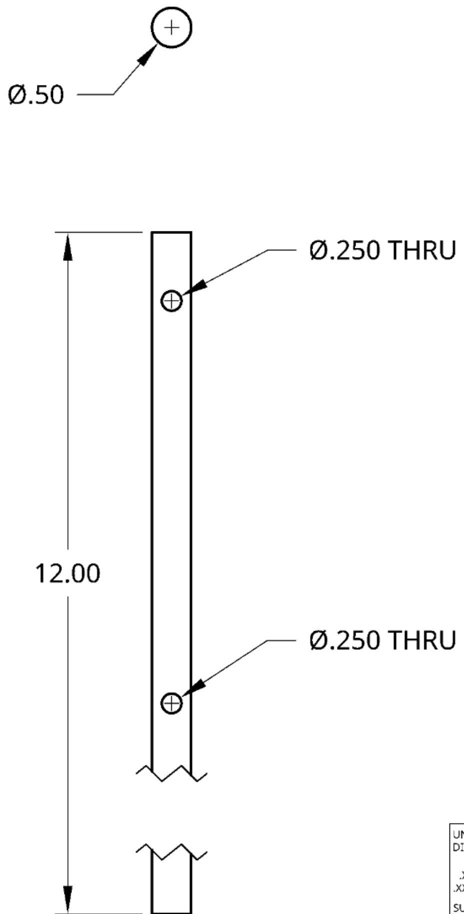


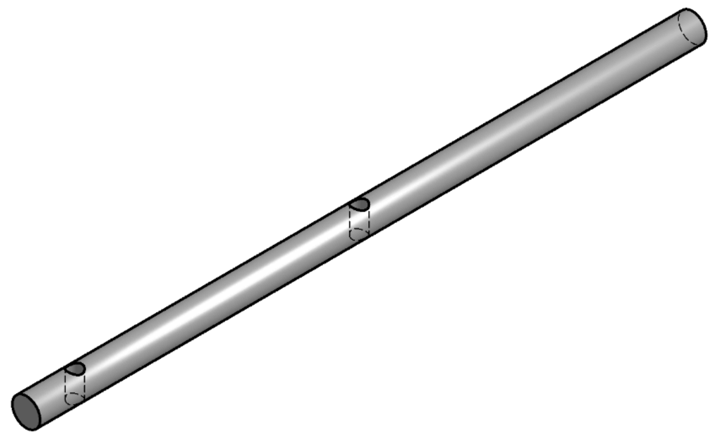


Note: Rods come too large to fit on diameter sized swivel clamp holes. Needs to be shaved down to a tighter tolerance of 0.001 or until fits



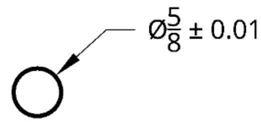
UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES .XXX = ±.001 SURFACE FINISH √		NAME	DATE	
	DRAWN	JAEZIEL CLARK	04/04/2022	
	CHECKED	Zachary R. Hicks	04/04/2022	TITLE Tongue Depressor Rod C-Clamp to Swivel Clamp
	APPROVED			
DO NOT SCALE DRAWING				
BREAK ALL SHARP EDGES AND REMOVE BURRS				SIZE A · DWG NO. C1 · REV. 1
THIRD ANGLE PROJECTION	MATERIAL 6061 Aluminum	FINISH		SCALE 1:2 · WEIGHT · SHEET 1 of 1

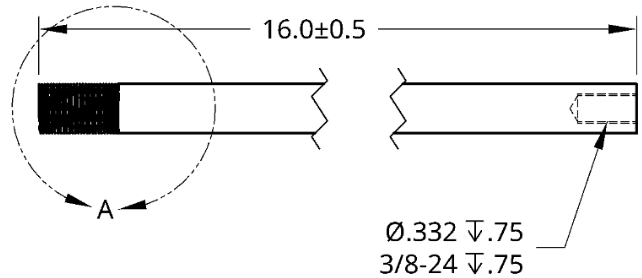


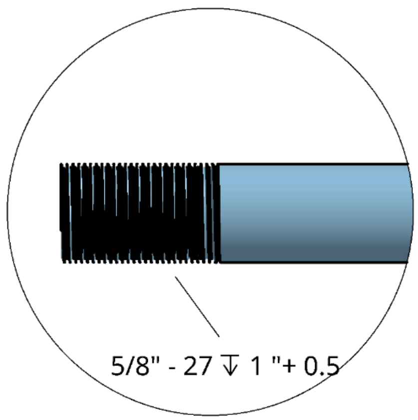


UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES .XX = ±.0- .XXX = ±.00- .XXXX = ±.000- ANGULAR = ± ° FRACTIONAL = ± SURFACE FINISH		NAME	DATE
	DRAWN	Zachary R. Hicks	05/30/2022
	CHECKED	Jaeziel Clark	05/31/2022
	APPROVED		
DO NOT SCALE DRAWING			
BREAK ALL SHARP EDGES AND REMOVE BURRS			
THIRD ANGLE PROJECTION	MATERIAL 6061 Aluminum	FINISH	

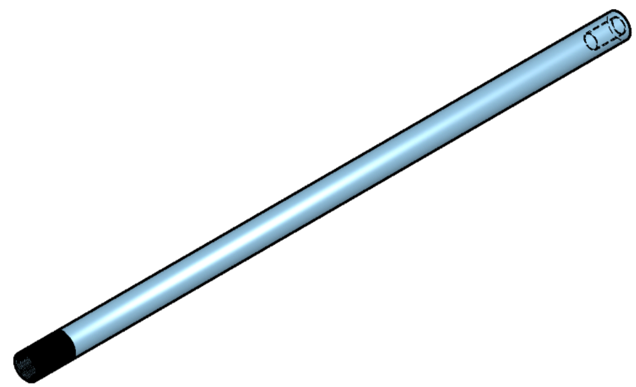
TITLE Attachment Arm Side Carriage Rod		
SIZE A	DWG NO. C2	REV. 2
SCALE 1:2	WEIGHT	SHEET 1 of 1







DETAIL A
SCALE 1:1

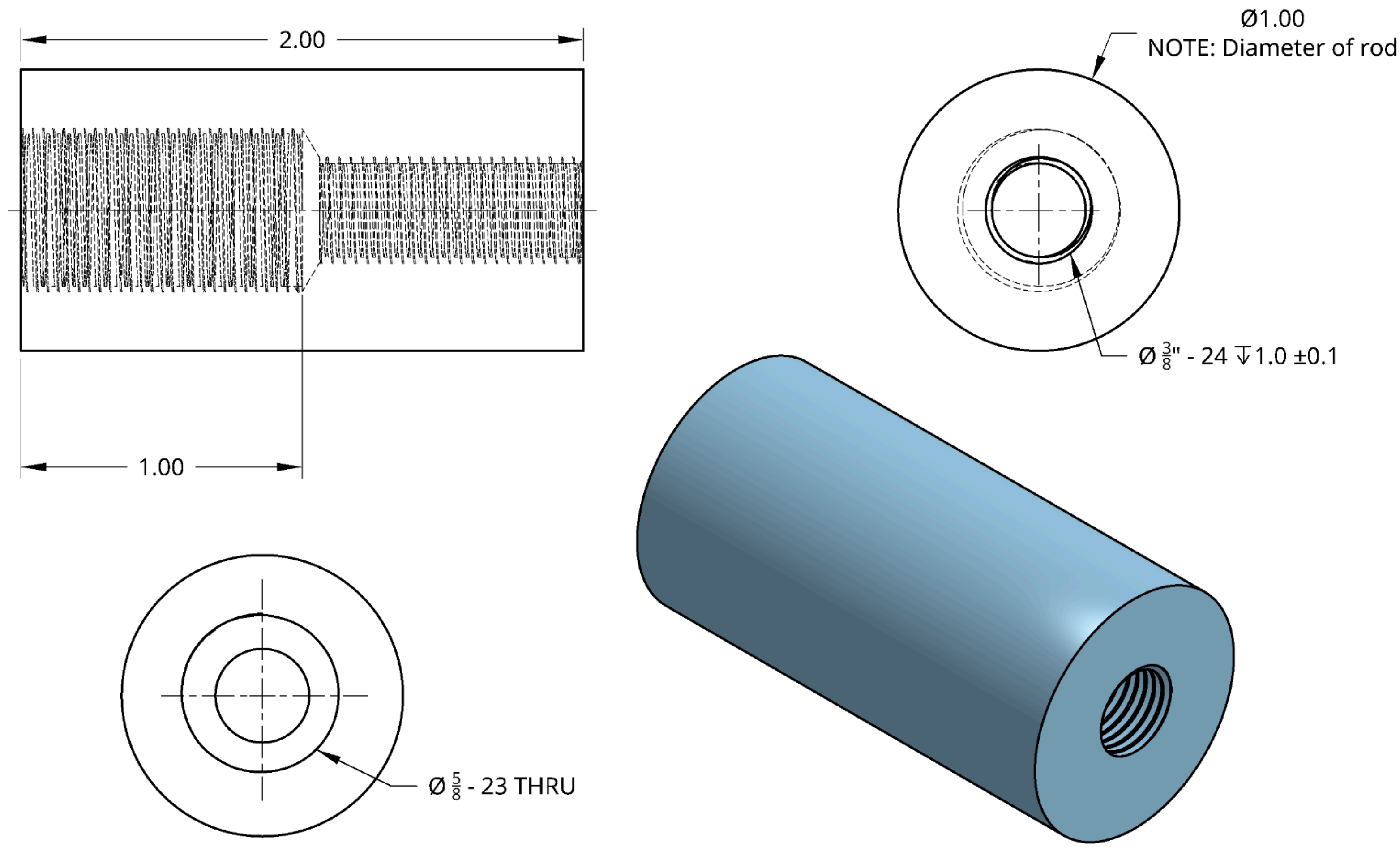


SCALE 1:3

Note: This will connect to Gooseneck from Swivel Clamp arm

UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES .XXX = ±.001 ANGULAR = ± ° FRACTIONAL = ± SURFACE FINISH		NAME	DATE
	DRAWN	Zachary R. Hicks	05/30/2022
	CHECKED	Jaeziel Clark	05/31/2022
	APPROVED		
DO NOT SCALE DRAWING			
BREAK ALL SHARP EDGES AND REMOVE BURRS			
THIRD ANGLE PROJECTION	MATERIAL 6061 Aluminum	FINISH	

TITLE	Endoscopic Arm Partial Thread		
SIZE A	DWG NO. C6		REV. 2
SCALE 1:2	WEIGHT	SHEET 1 of 1	



Note: Using Ø1" stock aluminum rod

UNLESS OTHERWISE SPECIFIED, DIMENSIONS ARE IN INCHES .XX = ±.01 ANGULAR = ± ° FRACTIONAL = ± SURFACE FINISH		NAME	DATE
	DRAWN	JAEZIEL CLARK	04/02/2022
	CHECKED	Zachary R. Hicks	05/18/2022
	APPROVED		
DO NOT SCALE DRAWING			
BREAK ALL SHARP EDGES AND REMOVE BURRS			
THIRD ANGLE PROJECTION	MATERIAL 6061 Aluminum	FINISH	

TITLE
Double Female Thread Adapter
Buret Claw Adapter

SIZE	DWG NO.	REV.
A	C7	2

SCALE	WEIGHT	SHEET
2:1	0.12 lb	1 of 1