

Left Atrial Appendage Printing Procedure

A Senior Project

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By

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Executive Summary

The left atrial appendage senior design team aims to assist in closing off the left atrial appendage that is susceptible to coagulation due to non-valvular atrial fibrillation. Coagulation in the left atrial appendage (LAA) can be life threatening as it can lead to a stroke. Dr. Chris Porterfield performs a procedure that uses the Boston Scientific Watchman to close the appendage. He finds that sizing the Watchman properly is difficult with limited visuals from live CT scans. He proposed converting the CT scans into a 3D printed model of the left atrial appendage and left atrium so he can visually measure the opening and predict the trajectory angle of the Watchman device into the left atrial appendage. He currently has a base algorithm and procedure to convert and modify the CT scan into a .stl file, which can then be printed with standard PLA material using a 3D printer on Cal Poly's campus. The project is limited to the printers and their material capabilities on Cal Poly's campus. There are currently many programs that convert CT scans to printable files and this project aims to evaluate each to conclude which produces the most accurate 3D model. The procedure to create the model must also be quick to perform, repeatable and reproducible as well as easy to follow.

After researching the various programs, we concluded that 3D Slicer allows us to print anatomically accurate models of the left atrium and LAA. Using this software, the user uploads CT scans obtained from the radiologist as a DICOM file. Once uploaded, the user will proceed to setting the threshold parameter to the designated values. The user will then scroll through the CT scan to identify the left atrium and LAA in one of the views. After locating the anatomies, the user will use the scissors tool to extrude out any unnecessary anatomy. Once isolated, the model will need to be hollowed out and set to the defined parameters. After a final cut is made to open the model for internal viewing, it is saved as a .stl file and sent to a 3D printing software such as Cura. From this point on, the user will refer to the printer's manual for the printing procedure while using the parameters we listed as a guide. After the print is concluded, the user will be able to measure the opening of the LAA and determine which entry angle is most optimal.

The key customer requirements we aimed to achieve were ease of use, time, production cost, shape/accuracy, repeatability and reproducibility. For ease of use, we had users go through our MPI, Training Guide and Operations Manual and had them rate between 1-10 on how clear and concise our directions were. We scaled the range so that 1 meant that our procedure was clear and concise enough to replicate while 10 meant it was near impossible to follow. We aimed to achieve an average score of less than 3. For time, we were given a timeframe of 24 hour to fully slice and print the model. Since this procedure is not officially ICD-9 billable yet, the cost of production must remain below \$50 per print. Based on the sizing chart provided by Boston Scientific for the various sizes of the Watchman device, we decided that the shape/accuracy must be less than 10% variation from the CT scan, while the repeatability and reproducibility must have no statistical difference in variation from the ANOVA.

After running ANOVA on the data obtained from measuring the 9 testing prints, the results showed that our slicing/printing procedure and the measurements taken for testing were adequate enough to prove the functionality of all our protocols. The results of ANOVA showed that there were no significant differences in our data except for depth reproducibility which means that our customer requirements of reproducibility and repeatability were almost met. For the ease of use requirement, Dr. Porterfield and his clinical specialist, Sarah Griess, went through our Manufacturing Process Instructions,

Training Guide, and Operations Manual and performed the feedback survey we provided. Based on those results, we concluded that our protocols are functional and easy to follow which is essential to producing an accurate model. To prove model accuracy, we had Dr. Porterfield size the Watchman device as he currently does and confirmed that our printed models were accurate.

Statement of Work

Introduction:

Only 100 doctors across the country are trained to perform the Watchman left atrial appendage closure procedure. This preventative, catheter based surgery plugs off the left atrial appendage, preventing debris from traveling upstream and causing strokes. Strokes are the number one cause of disability in the United States and people with atrial fibrillation are more likely to have one due to irregular heartbeat. While the procedure is standardized and doesn't produce a lot of complications, doctors find picking the right size of Watchman to implant difficult. The left atrial appendage project aims to create a 3D printed model of the left atrial appendage and left atrium for cardiac physiologists to use to aid in sizing and placing the Watchman device during left atrial appendage closure procedures. Dr. Chris Porterfield in San Luis Obispo along with doctors across the nation could use this procedure and model to visualize what size Watchman to select and what angle the catheter must take for placement. The goal of this project is to create an easy to follow procedure to convert a CT scan of the left atrial appendage and left atrium into a 3D printed model. The model should accurately model patient anatomy and provide a quality resolution for physicians to evaluate the system. The Statement of Work outlines the background on this procedure, the design specifications the team aims to follow and a table of steps and timeline for the project.

Background:

The Watchman procedure is a one time procedure that places a permanent closure in the left atrial appendage in order to prevent pooling of blood in the left atrial appendage, later forming a clot. The Watchman comes in five sizes: 21, 24, 27, 30, and 33 mm to better accommodate varying appendage sizes and shapes. Dr. Porterfield has faced challenges while implanting the Watchman in the left atrial appendage due to limited pre-operative planning opportunities; currently he is limited to the 2D display of computed tomography (CT) scans. The minimally invasive nature of this procedure heavily relies on these scans because during the procedure therefore the user still does not receive a clear view of the anatomical structure. The 2D CT scan does not embody each individual's left atrial appendage's spatial geometry and relationship with the left atrium's anatomical structures. This restricts the user's ability to determine the angle required to puncture the atrial septum to adequately place the Watchman in the appendage.

Current Tools

The following table displays the existing open source segmentation software that aid in segmenting targeted anatomical features and converting CT scan files to 3D printable files.

Table 1: Current Software

Name	Features
SegD	<ul style="list-style-type: none">- Manual segmentation- Automated segmentation- Set parameters with python
ImageJ-Fiji	<ul style="list-style-type: none">- Download contains all the ImageJ plugins needed for CT scan segmentation- Free
3D Slicer	<ul style="list-style-type: none">- Made specifically for medical imaging- Plug-in capabilities for adding algorithms- Works with all organs- Bidirectional interface for devices
ITK-Snap	<ul style="list-style-type: none">- Manual segmentation in 3 orthogonal planes at once- Files supported: NIFTI and DICOM- Supports time variant images
InVesalius	<ul style="list-style-type: none">- Can export to STL, OBJ, and PLY files- Contains volume and surface area measurement- Manual segmentation- Semi-automatic segmentation

Patents

After reviewing current segmentation software, we researched patents and their claims that our group needs to avoid infringing while designing our process. The following table displays a summary of 5 patents that pertain to the algorithms and methods used in segmentation and file conversion for anatomical feature printing.

Table 2: CT/MRI scan to 3D printing patents

	Patent Number	Date	Patent Holder
1	10,409,235	May 12, 2016	Siemens Healthcare GmbH
2	10,417,804	July 8, 2019	TeraRecon, Inc.
3	10,438,357	June 16, 2016	Samsung Electronics Co., Ltd.
4	10,417,768	Jan 31, 2019	Shenzhen United Imaging Healthcare CO., LTD
5	10,438,351	June 20, 2019	International Business Machines Corporation

Patent 1 describes an automated method to segment and print 3D models from medical imaging. It uses a predetermined mesh that has a corresponding 3D printer ready model. Transforming the 3D mesh

alters the 3D model. A possible claim to infringe is Claim 12, our team can use a 3D printer that has two extruders, one with a water-soluble material such as PVA to act as a base material to be able to print the model in the anatomical orientation of the patient. Patent 2 contains a method to manipulate 2D medical images to produce 3D images in augmented reality. A possible claim of this patent to infringe is Claim 15, our team can keep the medical image data in DICOM format through the first rendered medical image, won't convert the file to STL or any other file not compatible with DICOM until all segmentation and meshing is completed. Patent 3's claim three describes image segmentation processes that include determining the boundaries of the medical image by manually adding boundaries. Our group can instead determine anatomical model boundaries through pixel density in the image. In a peer reviewed article we mention in our Statement of Work, we read that heart muscle and surrounding tissue will have different pixel density, so this can be our group's approach of distinguishing between our target anatomical body and the noise surrounding it. Patent 4's 8th claim bases segmentation about the sagittal plane, our team can avoid infringing this claim by segmenting about the transverse or coronal plane. Patent 5's owners use an electronic processor to determine the amount of anatomical structures represented in a medical image. The electronic processor then accesses a knowledge base to depict the photograph of each structure. In order to not infringe on this patent, we will be avoiding this process as well.

Research

The following provides relative information about the segmenting and 3D printing of CT and MRI scans. These journal articles aid in our understanding of the process and development of ideas.

3D printing is being applied to medical imaging for many different reasons. Models are being created for medical education, training, simulation and pre-operative planning. 3D printing in the medical imaging franchise has strong potential that can catalyze innovation in anatomical modeling. There are many opportunities to explore the relationship between medical imaging data and creating 3D models. These opportunities include: establishing an efficient method for image processing workflows to create accurate image segmentations, the usage of 3D printed models as phantoms for medical radiation and imaging studies, and education on what 3D models can do for interpretation of medical imaging. The intended use of the anatomical model will conclude the appropriate requirements for the model such as realism and touch, and these requirements will determine what material should be used for the printed model. Material capabilities in the current market include transparency, printing in different colors, tissue-like characteristics, and dissolvable support material. [1]

3D printing in congenital heart disease (CHD) procedures has been assessed with a sample pool of 28 studies. CT scans require the reader to have interpretive mental skills to visualize the depth and relationship between each medical image to imagine the heart structure, creating a learning curve for physicians. User data shows that 90% of users strongly agree or agree that a 3D printed model helps understanding of the CHD, reinforcing the need for better visualization for pre-operative purposes. Currently, time and cost are barriers to the everyday application of 3D printing in the medical industry. In addition to these barriers, the image segmentation process is challenging and time consuming. Segmentation is difficult due to the lack of contrast between heart muscle and surrounding tissue, demanding an experienced clinician who knows cardiac imaging and the software well. Even with the experienced clinician, executing the segmentation is a 3.5 hour process before the 3D printing can begin. [2]

3D printing is already being done with anatomical bodies aiding in prosthetics, dental implants, and custom implants. Current software that convert CT scans to 3D models are: OsiriX Imaging Software, 3D Slicer, Mimics, Magics, 3D doctor, and InVesalius. The authors in this journal article explore different additive manufacturing methods for an orthopedic application. They list different methods of additive manufacturing that includes:

- Stereolithography (SLA)
- Selective laser sintering (SLS)
- Fused deposition modelling (FDM)
- Direct metal laser sintering (DMLS)
- Polyjet 3D printing (PJP)
- Inkjet 3D printing (IJP)
- Laminated Object Manufacturing (LOM)
- Colour-Jet-Printing (CJP)
- Multi-Jet-Printing (MJP)
- Electron Beam Melting (EBM)

Each of these methods can be researched further for the application in our left atrial appendage model. Each method has its own limitations and advantages, this information can aid our teams investigation of material. [3]

The process of converting CT scan images to 3D printable models includes segmentation, mesh refinement, and 3D printing. Image segmentation is used to identify the organ of interest. An image is partitioned into labeled regions that locate the target and its boundaries. Heart muscle can be distinguished from surrounding tissue due to each tissue type having a characteristic range of pixel intensities. Mesh refinement is then used for touch ups before printing the part. These touch ups can be used to repair errors and discontinuities, smoothing the surface that has staircase-like surfaces due to the pixels, and appending, which converts the model into a usable form, removing unnecessary parts from the overall segmentation. There are three 3D printing technologies: extrusion printing, photopolymerisation and powder-based printing. Extrusion printing most commonly is applied through Fused Deposition Modelling (FDM), where the model is printed by layer through a nozzle. Photopolymerisation examples include Stereolithography and Digital Light Processing, where plastic is cured in a bath. Power-based printing is performed by binding particles together with heat or by using a liquid binding agent. The authors found that although FMD is a common 3D printing method, it isn't the most suitable for the creation of anatomical models due to how rigid its' compatible plastics are. An alternative to FMD would be Material Jetting, a photopolymerisation technique, where multiple polymers can be used within the same model, creating a gradient of flexibility. [4]

Quality assurance programs exist in medical imaging to ensure optimal performance and results. These quality assurance systems are being adjusted and implemented in the 3D printing of medical images. This is done by measurement methods which include measurement with calipers, photogrammetry, optical and contact-based surface scanning, and x-ray/CT scanning of a part. Verifying the 3D printed model is challenging due to the limited information on the patient's internal anatomy. The authors in this paper conducted their verification tests on their segmentation algorithm and 3D printer by utilizing cadaveric hearts. They placed the hearts in plastic containers filled with saline and iodinated

contrast to simulate the imaging of a heart in a patient. They followed by imaging, segmenting, and printing the cadaveric heart. They compared distinguishable features that could be recorded in length through photogrammetry in ImageJ. Results showed a standard deviation range of $\pm 0.8\text{mm}$ to $\pm 4.4\text{ mm}$ for linear measurements. The lighting in images of both the model and cadaveric heart proved to have a substantial impact on the accuracy of the measurements due to the blending of edges in certain lighting conditions. The anatomical accuracy verification methods used in this journal article can be useful in our team's printing accuracy verification. [5]

3D printing medical devices/processes regulations

The FDA has a guidance named "Technical Considerations for Additive Manufactured Medical Devices" to set forward their expectations on design and manufacturing and device testing. These expectations guide the fulfillment of the Quality System requirements. [6]

Objective:

The left atrial appendage project aims to create a 3D model of the left atrial appendage and left atrium from CT scans in order to provide accurate sizing and positioning for left atrial appendage closure procedures.

The problem includes using existing Cal Poly 3D programs and printers to 3D print the left atrium complex and making the printing procedure repeatable and reproducible for any complex. The print does not have to be a clinically relevant material and can be printed with basic polymers.

Our customers, Dr. Portfield and his patients, need this procedure and print to be easy to create, reproducible, repeatable and accurate shape. A full list of customer specifications can be seen in the Customer Requirements section. The print must be able to accurately model and represent a CT scan in order for Dr. Porterfield to make sizing and positioning decisions that benefit the patient.

Table 4 depicts the engineering specification tables where specifications are assigned quantitative numbers. Descriptions of how to measure all specifications can be found in Specification Development.

The only high risk specification is the design accuracy and confirming the print has a quality resolution. The purpose of this project is to create a 3D model in order to aid in Watchman sizing and placement which is based entirely on the shape and size of the left atrial appendage. Without proper sizing, the Watchman size might be incorrectly matched, causing serious complications during the procedure. Dr. Porterfield also wants to visualize what trajectory to take during the procedure, which can only be done if the model reflects actual patient anatomy. Accurate size and shape is of utmost importance to the success of the project and safety of patients.

Project Management:

We will begin our design process by altering the algorithm that Dr. Portfield has started. We want to ensure that our algorithm is essentially universal with converting CT scan data into STL files that will allow the printing of three-dimensional models. We will determine at that time if we need to incorporate more code into our algorithm to account for things such as various printer types, computer types, and software incorporation. We will run multiple iterations while making necessary adjustments. While we are

running our iterations, we will be developing a standard procedure that Dr. Porterfield and qualified cardiac surgeons will follow while performing this process. After we develop the procedure, we will use it as a guide to create our first prototype model. This prototype will be shown to Dr. Porterfield for analysis and feedback. The results of this print will allow us to determine what changes need to be made to the algorithm and the procedure before proceeding forward. Once all the corrections are made, we will begin working on our functional prototype that we will use for the first presentation demo and perform our testing methods on. The data we receive from testing and feedback will be used in our final adjustments. We will then proceed to create a more finalized functional prototype that we have Dr. Porterfield use in one of his procedures to determine the accuracy of the model. If this prototype is successful, we will make minor adjustments based on feedback before we prepare our final product for the final presentations and reports.

Dr. Chris Porterfield previously experimented with this process of developing a 3-D representation of CT scans of the left atrial appendage. We will be gathering his previous algorithm, results, and software to use as a starting point for our project. We will initially print on the same 3-D printer that Dr. Porterfield uses at Cal Poly but will alter the algorithm to meet our project specifications. There are no previous testing methods that we will be inheriting for the project.

Appendix 1 contains a table of key deliverables and the project timeline. The dates listed on this table are non-tentative and must be completed in entirety by the due dates.

The immediate next step in this process is to obtain all the previous information that Dr. Porterfield has available from his attempts to develop this process. We will use that information to first alter the established algorithm to meet our defined specifications. We will run through a series of tests to ensure that our algorithm will run smoothly, convert all files to an STL file, and print models with ease. At that time, we will determine if our algorithm is limited to the software we are using, or if we will be able to mimic that code to work with multiple sources.

The overall process will begin by completing the technical documents necessary for planning out our project process. These documents include our budget plan, statement of work, indication for use, conjoint analysis and the house of quality. These documents will allow us to define our project guidelines and ensure we are meeting all applicable criteria. We will then proceed to analyzing CT scans and previous work that Dr. Chris Porterfield has collected for us. After our analysis, we will be researching printers and software to determine how we need to alter our algorithm to make it more compatible with various devices. We will end this phase by creating our initial printing protocol. We will meet with Dr. Porterfield to have him examine our protocol and receive feedback on what direction we need to go next. As we start to redefine our protocol, we will begin our 3 iteration phases while starting to develop the standard procedure for the project. After completing the 3rd iteration, we will begin working on our critical design review which is to be completed with a report and presentation on November 29th. This milestone marks the beginning of our process to develop a functional prototype. We will begin working on our initial prototype over winter break as well as the video and test plan report. We will finalize these assignments when we return for winter quarter and prepare our functional prototype and video which is to be completed by January 27, 2020. Due on that same day is the test plan report and presentation. After submitting all these documents and receiving feedback from our presentations, we will start out user validation testing which will allow us to conduct tests in the beginning of February and give us data to analyze. After analyzing our data and altering our procedures and protocols, we will be able to verify and submit our proof of replication on February 28, 2020. We will then proceed to conduct our final test of

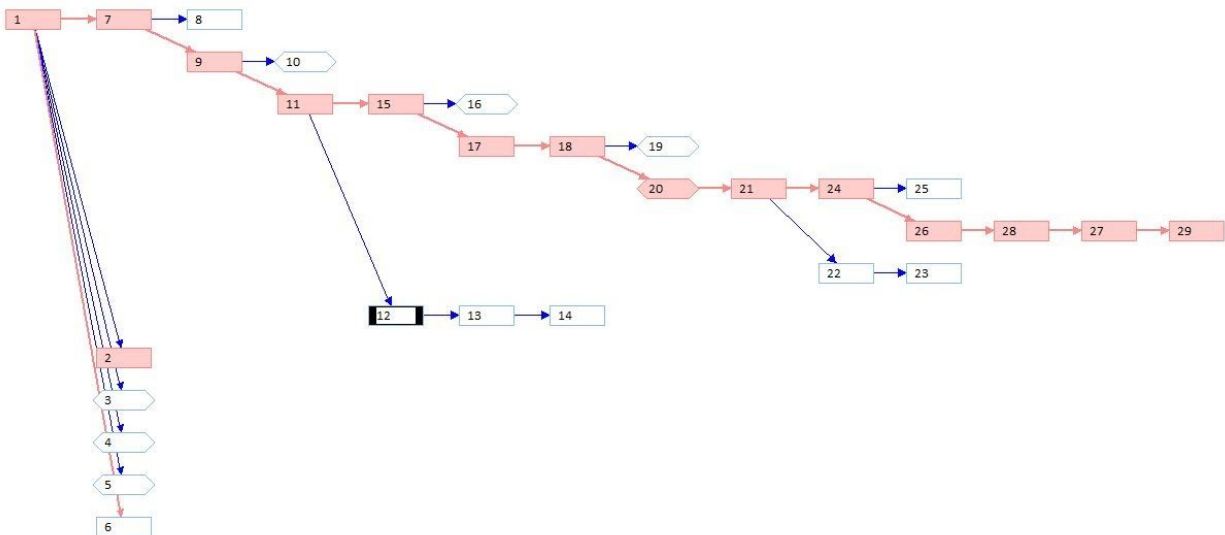
our functional prototype to ensure it meets all defined specifications. We will analyze those results and make any necessary adjustments before the demo and design review on March 9, 2020. During this time we will be working on our poster for the final poster presentation on March 16, 2020.

Conclusion:

The left atrial appendage team aims to create an accurate and easy to manufacture 3D printed left atrial appendage and left atrium. The 3D printed model will be used to size and preview a left atrial appendage closure procedure. Dr. Chris Porterfield performs this procedure with Boston Scientific's Watchman product, but he sometimes struggles to choose the right size and procedure pathway since CT scans don't offer great visuals of patient anatomy. This project allows physicians to visualize the procedure and properly select which Watchman size best fits the patient. The model and procedure to make the model must be easy for operators to use, reproducible, repeatable, be done in less than a day and accurately model the CT scan. In order to complete this project by the winter quarter deadline, we must achieve certain deliverables on defined dates. We plan to have completed research for the project by Oct. 15th, have completed our algorithm and performed the first print by 11/4 and completed our edits by 1/27. The final written procedure should be done by 1/27 as well so all of February can be used to validate the procedure and run an ANOVA test to verify our project is repeatable and reproducible. Our final poster presentation will be prepared for 3/16 and Dr. Porterfield may ask us to present this project at a cardiovascular physician conference in May.

Network Diagram

Provided below is our team's network diagram which illustrates the timeline of this project and the critical path of this project. The critical path is imperative to the project's timeline. A key is also provided to illustrate what each step entails.



1	Paperwork	11	Refine Printing Protocol	21	User Verification Testing
2	Budget Plan	12	Iteration 1	22	Conduct Test
3	IFU	13	Iteration 2	23	Analyze Results
4	Network Diagram	14	Iteration 3	24	Proof of Replication
5	House of Quality	15	Work on Critical Design Review	25	Conduct Test
6	Conjoint Analysis	16	Critical Design Review Report & Presentation	26	Analyze Results
7	Analyze CT Scans	17	Develop Procedure	27	Post Creation
8	Write Print Protocol	18	Work on Prototype Video, Test Plan Report	28	Demo and Design Review
9	Conceptual Model	19	Functional Prototype and Video	29	Poster Presentation
10	Concept Design Report	20	Test Plan Report & Presentation		

Figure 1: Left atrial Appendage Network Diagram and key

Indications for Use

The left atrial appendage closure device (Watchman) is indicated in patients who have a diagnosis of atrial fibrillation and cannot tolerate anticoagulation for stroke prevention. The left atrial appendage closure device process creates a three-dimensional model indicated for use by cardiac surgeons trained for this procedure to accurately size the device prior to implantation and allow for a projected entry angle from the right atrium for ease of implantation.

Budget

The budget was updated on March 6th, the budget modifications are reflected below.

Table 3: Left Atrial Appendage Budget

Item Description	Product Number	Purpose	Associated Task	Unit	Quantity	Cost/Unit	Total Cost
Printing filament	614	3D printing	Modeling Atrium and appendage	2 lbs	2	\$49.95	\$99.90
Printing filament	9732	3D printing	Support Material	2 lbs	2	\$47.95	\$95.90
Tax & Shipping					2	\$21.04	\$42.08
						Total	\$237.88

Customer Requirements

Our customer requirements came from multiple interviews with Dr. Porterfield. We used the Quality Function Deployment method of coming up with these requirements. We first identified our customers, Dr. Porterfield and any other doctor/operator that might want to print a model. Through interviews we collected the requirements he desired and used a conjoint analysis along with more questions to figure out which were most important. The requirements we came up with along with Dr. Porterfield were; ease of use, time, production cost, shape/accuracy, repeatability and reproducibility. We conducted a patent search to determine what already exists for this procedure to determine which areas could be targeted for our growth as well.

Specification Development

After coming up with requirements we put numeric values to our qualitative specifications. With Dr. Porterfield, we brainstormed what max/min values would be acceptable for the 3D model. These values guided the design of the engineering specifications. With numeric values, we then designed experiments of how to test for these values and confirm our model is within our specifications. The specifications and experiments are listed below. Further information is seen in Table 4.

- **Ease of use:** Ease of use will be evaluated with physician feedback. 3 physicians will rank the procedure of how to convert the CT scan into an stl file, upload it to the printer and print the complex. They will rank the procedure on a scale of 1-10, with one being very easy to use and 10 being difficult to navigate.
- **Time:** The entire print must be able to be completed in less than 1 day in order, which will be timed to confirm.
- **Production Cost:** Each print must cost less than \$50. Material cost and labor per unit will be recorded.
- **Shape:** The print itself will be compared to the CT scan in order to confirm accuracy. 3 critical measurements (depth, volume and appendage opening diameter) of the complex will be measured and the percent difference from the CT scan will be calculated. The percent difference must be less than 10% on each measurement in order to confirm accuracy.
- **Repeatability and Reproducibility:** An ANOVA study will be performed on the procedure itself. 3 operators will perform the print and 3 critical measurements will be taken of the printed model. Variation for both reproducibility and repeatability must not be statistically different from each other to confirm the procedure is well written and performed.

Table 4: Engineering Specifications

Specification	Parameter Description	Requirement/Target	Tolerance	Risk	Compliance
1	User Ease	Physician evaluation must rank <3 (1 easy - 10 hard)	Max	L	T
2	Reproducible Procedure	No statistical difference in ANOVA	Max	M	T, A, S
3	Repeatable Procedure	No statistical difference in ANOVA	Max	M	T, A, S
4	Time	1 day	Max	L	A
5	Production cost	\$50	Max	L	A
6	Shape	<10% difference from CT scan	± 5%	H	T, A, I

In order to relate the customer requirements to the engineering specifications listed above in Table 4, a house of quality was created. The house of quality also contains an analysis of how competitors satisfy the customers. The house of quality allowed us to better understand which engineering specifications to focus heavily on.

Left Atrial Appendage Closure Process		Who		Engineering Requirements						Program Options	
Customer Requirements (What's)		Operator	Dr. Porterfield	User Ease (10 easy -1 hard)	<10% Repeatability variance in gage R&R	<10% Repeatability variance in gage R&R	Time (mean 1day)	<10% difference in measurements for CT scan	Production Cost (mean \$50)	Estimating size from CT scan	Current printing capability
Customer Requirements	Easy to Use	30	20	●			○			2	1
	Reproducible	15	10	Δ	●					1	3
	Repeatable	5	10	Δ		●				1	3
	Quick To Do	15	15	○			●		○	5	2
	Accurate Shape	30	40					●		2	4
	Relevant Material	5	5					Δ	Δ	1	4
Specification Importance		Operator	Porterfield	335	135	45	225	275	50		
% Importance		Operator	Porterfield	31.5	12.7	4.2	21.1	25.8	4.7		
				22.9	8.8	8.8	19.0	35.6	4.9		
●=9	Strong Correlation										
○=3	Medium Correlation										
Δ=1	Small Correlation										
Blank	No Correlation										

Figure 2: House of Quality

Total Available Market

Since there are no direct competitors to the process we are creating, we explored the market potential for the left atrial appendage device process. Since the public release of the Watchman in February 2016, there have been over 100,000 Watchman implantation procedures completed worldwide. In the United States alone, there are approximately 540 implantation locations that house trained cardiac surgeons. This means there is a huge profit potential just here in the United States. According to a study done in 2013, there are approximately 33.3 million people that have signs or a diagnosis of atrial fibrillation who serve as potential candidates for the Watchman. Considering that the Watchman only applies to people that have non-valvular AFib and cannot tolerate anticoagulation, this number will decrease. However, there is still a potential for millions of patients to have this procedure done. The financial benefits for using this process is that there are Current Procedural Terminology (CPT) codes that allow reimbursement for three-dimensional model creations. These codes include 055T, 0560T, 0561T,

0562T. We estimated \$75 per code, based on 0561T in conjunction with 0562T, there is a \$13,500,00 billing potential.

Competitive Advantage

Our design can focus on many aspects that our competitors don't possess. While there are many companies that 3D print organs from CT scans, such as Embodi3D and 3D Systems, none specifically focus on individual left atrial appendages. We will aim to make our 3D print faster, cheaper and use software to make it as accurate. Making this procedure repeatable and reproducible will help make it more competitive as well. There aren't specific companies we are competing with for this project since it's specific to one anatomy and one procedure. Our competition is existing procedures and standards for sizing the Watchman. Currently doctors estimate the size based on CT scans, which can be inaccurate. This procedure can make sizing, consistent and accurate, preventing any second attempts of the procedure with the Watchman. Below in Table 5 is a competitor matrix, comparing our goal procedure with existing standards.

Table 5: Competitor Matrix

Specification	Sizing based on CT scan	3D printing at home	Outsourcing to 3D printing company	Left Atrial Appendage Team Design
Accurate Size	Poor	Ok	Great	Good
Price	None	Low	High	Low
Reproducibility	Poor	Poor	Great	Good
Repeatable	Poor	Poor	Great	Good
Manufacturing Time	None	Medium	Long	Short

Intellectual Property Assessment

Identifying current patents and patent applications is important to our design process. In order to not infringe on these patents, we must understand what claims of the patent/patent application we may potentially infringe on. Patents were found by using the key words: medical imaging, 3D print anatomical models, and print CT/MRI scans. These patents can be viewed in Table 6.

Table 6: Current and Relevant Patents and Patent Applications

	Patent Number	Claim	Addressing Claim
Patent 1	10,409,235	Method of printing model in a base & orientation that's not the anatomical orientation	Use a 3D printer that has two extruders, one with a water-soluble material such as PVA to act as a base material to be able to print the model in the anatomical orientation of the patient.
Patent 2	10,417,804	Converting the medical image data from DICOM compatible data to another image data format when producing the first rendered medical image.	Keep the medical image data in DICOM format through the first rendered medical image, won't convert the file to STL or any other file not compatible with DICOM until all segmentation and meshing is completed.
Patent 3	10,438,357	Claim three describes image segmentation processes that include determining the boundaries of the medical image by manually adding boundaries.	Determine anatomical model boundaries through pixel density in the image.
Patent Application 1	62634935	Intracardiac echocardiology as the two-dimensional imaging format that is to be converted into three-dimensional.	For our project, we would want the method to include CT scans as a form of two-dimensional images.
Patent Application 2	14/833165	Printing with a three-dimensional printer an implant-related device based on the model of the anatomic structure of the patient.	To combat this we cannot refer to our design as "implant related". Instead we will describe it as for instructional use and preoperative planning rather than aiding the implant itself.
Patent Application 3	16/349238	"A method for estimating the volume of an <i>atrium</i> (left (LA) or right (RA)) based on a plurality of emission tomography images, such as positron emission tomography images or single-photon emission computed tomography images, said method comprising the steps of.."	This patent intend to use all of these steps in an attempt to get a three-dimensional estimation of what the atriums should look like in vivo. For our project, we would use all these points and coordinates to create an algorithm where we can plot all these into an STL file which could be 3D printed for analysis.

Conjoint Analysis

A conjoint analysis is a market research statistical tool that aids in identification of product characteristics that are important to the customer. In this conjoint analysis, four factors or attributes were assessed by fourth year biomedical engineering students instead of actual intended users. Each factor had three levels. Below we have Tables 7, 8 and 9 which display our factors and levels, the conjoint table and the description of the 9 choice cards. Because this conjoint analysis was completed with fourth year biomedical engineering students rather than actual intended users, the results of this conjoint analysis will not steer our decision making and the factors and levels were instead discussed with our sponsor, the intended user.

Table 7: Factors and Levels.

Factor	Level 1	Level 2	Level 3
Software	ImageJ-Fiji	3D Slicer	SegD
Material	Flexible PLA	TPU	ABS
Time	<1 day	1-3 days	3-7 days
Printer	Ultimaker	Makerbot Replicator+	LulzBot Mini2

Table 8: Conjoint table on X and Y values.

Y	x1-Software (ImageJ)	x2-Software (3D Slicer)	x1-Material (PLA)	x1-Time (<1day)	x2-Material (TPU)	x2-Time (1-3 days)	x1-Printer (UltraMaker)	x2-Printer (makerBot)
1	1	0	1	1	0	0	1	0
2	1	0	0	0	1	1	0	1
3	1	0	1	1	0	0	1	0
4	0	1	1	0	0	1	0	0
5	0	1	0	0	1	0	1	0
6	0	1	0	1	0	0	1	0
7	0	0	1	0	0	0	0	1
8	0	1	0	1	0	0	1	0
9	0	0	0	0	0	1	0	0

Table 9: Description of Choice Cards.

Choice Cards	Description
1	ImageJ-Fiji, Flexible PLA, <1Day, Ultimaker
2	ImageJ-Fiji, FTPU, 1-3 days, Makerbot Replicator+
3	ImageJ-Fiji, ABS, 3-7 Days, LulzBot Mini2
4	3D Slicer Flexible PLA, 1-3 Days, LulzBot Mini2
5	3D Slicer, TPU, 3-7 Days, Ultimaker
6	3D Slicer, ABS <1Day, Ultimaker
7	SegD, Flexible PLA, 3-7 Days, Makerbot REplicator+
8	SegD, TPU, <1 Day, LulzBot Mini2
9	SegD, ABS, 1-2 Days, Ultimaker

Statistical Summary:

SUMMARY OUTPUT								
Regression Statistics								
Multiple R	0.29168928							
R Square	0.08508264							
Adjusted R Square	0.06116323							
Standard Error	2.50576229							
Observations	315							
ANOVA								
	df	SS	MS	F	Significance F			
Regression	8	178.673541	22.3341927	3.55705452	0.00058531			
Residual	306	1921.32646	6.27884464					
Total	314	2100						
	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	5.4270949	0.42319732	12.8240296	2.0155E-30	4.59434976	6.25984003	4.59434976	6.25984003
x1-Software (ImageJ-Fiji)	-1.3501718	0.42319732	-3.1904073	0.00156815	-2.182917	-0.5174267	-2.182917	-0.5174267
x2-Software (3D Slicer)	-0.2415207	0.49702455	-0.4859332	0.62736228	-1.2195392	0.73649768	-1.2195392	0.73649768
x1-Material (PLA)	-0.9908025	0.35047206	-2.8270512	0.00500737	-1.6804427	-0.3011622	-1.6804427	-0.3011622
x1-Time (<1day)	0.25865408	0.47305224	0.54677698	0.58493045	-0.6721929	1.18950108	-0.6721929	1.18950108
x2-Material (TPU)	-0.4130217	0.44125922	-0.936007	0.3500077	-1.2813081	0.45526469	-1.2813081	0.45526469
x2-Time (1-3 days)	0.36078389	0.42319732	0.85251933	0.39459267	-0.4719612	1.19352903	-0.4719612	1.19352903
x1-Printer (Ultimaker)	0.58855866	0.61051632	0.96403429	0.33578995	-0.6127828	1.78990015	-0.6127828	1.78990015
x2-Printer (MakerBot)	0.50656473	0.46132188	1.0980722	0.27303623	-0.4011999	1.41432935	-0.4011999	1.41432935

Figure 3: Conjoint Analysis results

Interpretation of Results:

If p-values are less than .05, the specifications are significant. The ones that are significant are Software and Material. Since the coefficients of both are negative on the X1 variable for material and software, the customer wants the specification on the higher level. This indicates that the customer prefers 3D Slicer

software with TPU material but doesn't think the time to produce the model or the printer used are important.

Morphology

Our morphology chart is shown in Appendix 2. It describes all the features that our design might use based on different key functions. The figure below shows different concepts we generated from the morphology. Each concept takes prominent features and combines them in logical pathways. Our concepts are not sketches of models, but rather the possible procedures to follow to result in the 3D printed model.

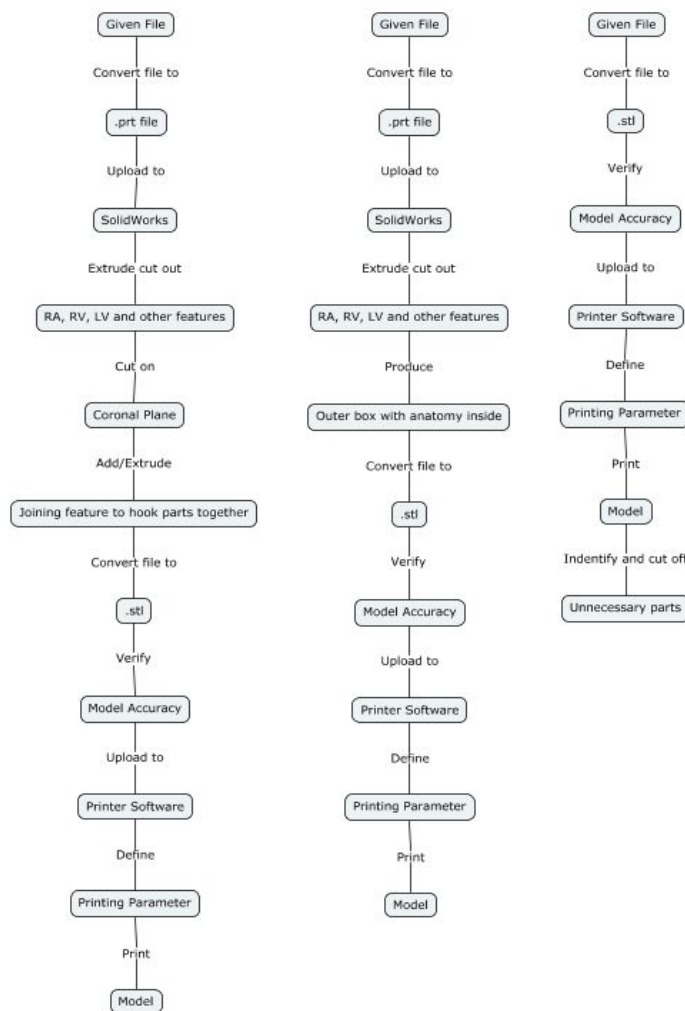


Figure 4: Concepts 1 (left), 2 (middle), 3 (dark).

Concept descriptions are as such:

Concept 1 (left): This concept utilizes extra steps between the given file and the stl file, the process includes converting the given file into a prt file to upload to solidwork to modify the model *before* printing. This added step in the process extrude cuts unnecessary heart features to reduce printing time and wasted material. An additional step in this procedure requires the body to be cut about the coronal plane to improve visual after print, and adding joining features to line up the model when needed.

Concept 2 (middle): This concept also includes converting the file to a prt file and importing it to solidworks and cutting out unnecessary heart features to ultimately end up with an outer box with the necessary anatomy on the inside.

Concept 3 (right): Concept 3 does not require an extra conversion of file between the given file and the stl file. The given file will be converted to an stl file and then uploaded to the printer software without any model modifications before print. 3It can be modified after the print by cutting off unnecessary parts.

Concept Evaluation (Pugh Chart)

To evaluate our concepts, we used a Pugh Chart. The Pugh Chart compared the concepts to each other based on our customer specifications and our QFD. Pugh's Method provides a complex pro-con analysis and is applied to multiple concepts simultaneously. Each member of the team performed each chart on their own, each chart had each alternative as the baseline. When scoring on the Pugh Chart, the other two concepts were scored in relation to the concept that was used as a baseline. At the end of each chart, each concept's score was tallied and compared. The results were then viewed by the team, all Pugh charts done by the 3 team members are shown in Appendix 3.

After evaluating the options with the Pugh Charts, Concept 2 shows the most promising results. While there were differing opinions between our team of how much design varied, most ranked Concept 2 highest. It has above the normal accuracy and it is easier to use than Concept 1 which requires more SolidWorks input. Concept three lacks the same reproducibility as the Concept 1 and 2. Concept 2 consists of converting the given file to a .prt file and uploading to SolidWorks. We then would extrude cut off all unnecessary portions of the CT can shorten print time. The bottom of the 3D model would be open to allow visuals going in. It doesn't require much extra work in SolidWorks and no after print modifications.

Conceptual Model

Description:

The left atrial appendage procedure outlines the procedure of taking a CT scan, uploading it to SolidWorks for editing and then 3D printing the part. The 3D printed part will be used to size the

Watchman, a device used to close the left atrial appendage. Local physician, Dr Chris Porterfield struggles to select which Watchman size to select based solely off CT scans and would like a physical model to place the Watchman into.

The CT scan will be given to use as an .stl file and converted into a .prt file to edit the CT scan within SolidWorks to only possess needed anatomy. This will lower the print time since less material will be used. It will also make it easier to see the targeted anatomy. A hole will be cut at the mitral valve so the Watchman can be placed inside the appendage. The part will be checked for proper cuts and sizing within SolidWorks before proceeding. The file is then converted to an .stl and uploaded to the printer. Printer settings are predefined and outlined in the procedure. The printed model will be checked at critical measurements to ensure the .prt file in SolidWorks to ensure sizing was correct. The percent difference between the model and SolidWorks will be analyzed to see how well the model matches the scan.

Since we do not currently have the appropriate program or initial file for the 3D printing procedure, we created a procedure of what we think will occur with an arbitrary SolidWorks part we created. We will be starting with the image as a .stl or .dxf file and uploading it to SolidWorks to be altered. Dr. Porterfield will later provide a different kind of file that will add steps before converting to a .prt file.

Procedure:

1. Convert .stl file rendered from CT scan into a .dxf file using MeshLab
 - i. Open .stl file in MeshLab
 - ii. Drop down “File” menu
 - iii. Click on “Export Mesh As”
 - iv. Drop down “Files of Type” menu and select .dxf
 - v. Save file with the same name as .stl file in the same folder for organization purposes
 2. Upload .dxf file into SolidWorks
 - a. Drag .dxf file into SolidWorks
 - b. The DXF/DWG Import tool will appear:
 - i. Select “Create new Solidworks drawing”, “Convert to SolidWorks entities,” “Import to a new part as:” and “3D curves or model”
 - ii. Select “Finish” and wait for SolidWorks to process the file
** this will take up about an hour **
- Note: The mesh has been converted to multiple surfaces
3. Identify which sections of the heart to keep by referring to anatomical models
 - a. Correctly identify the left atrium and left atrial appendage
 4. Extrude cut out unnecessary sections of the heart
 5. Extrude cut out mitral valve so visual opening into atrium is present

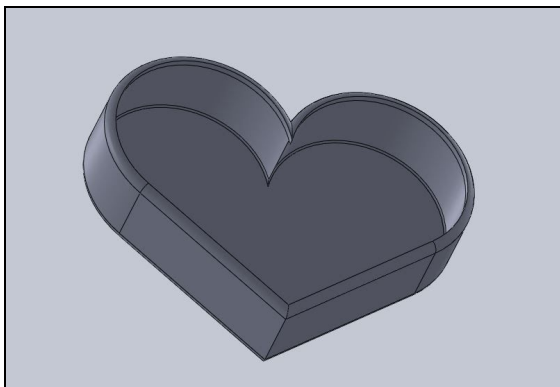


Figure 5: Solidworks anatomy trimmed

6. Check part to ensure left atrium and left atrial appendage have not been removed
7. Convert file to .stl
 - a. Select “File”-”Save As” and changed file type to .stl
8. Upload file to 3D printer software: Ultimaker Cura
 - a. Define as seen in Figure 2 below:
 - i. Infill
 - ii. Quality
 - iii. Shell
 - iv. Material
 - v. Speed
 - vi. Cooling
 - vii. Support material
 - viii. Build Plate Adhesion

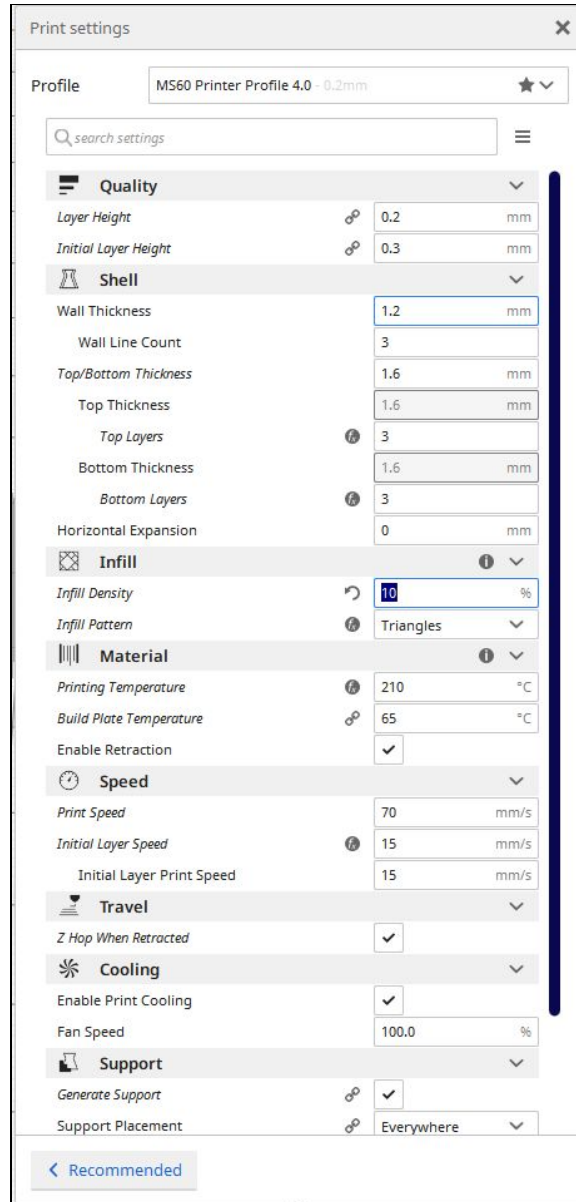


Figure 6: Ultimaker Cura setting

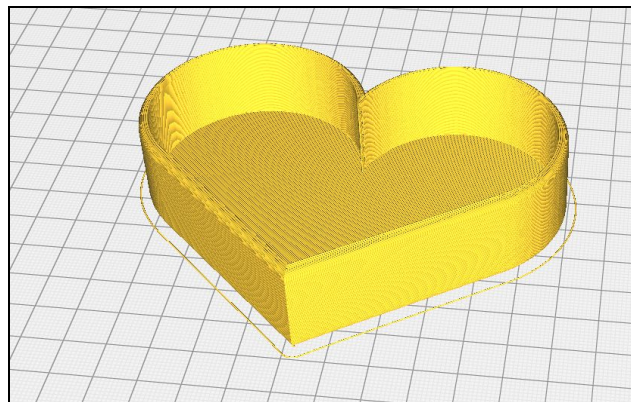


Figure 7: Sliced part in Cura software

9. Upload and modify printer settings
 - a. Load filament into machine
 - b. Press “Bed”-”Heat” to heat up system
 - i. Check temperature of nozzle and plate by pressing “Bed/Extrude” on the printer panel
 - ii. Press “Print”- find file (file will have settings listed first then file name)
 - iii. Confirm “Yes”
 - iv. Wait for plate to finish heating up and clear any extra plastic from platform
 - c. Wait for first layer of print to be printed before leaving print alone
Note: This is important to ensure the print will print appropriately because most failures occur in the first layer if they were to occur
10. Allow the printer 1.5x the estimated time of the print



Figure 8: Final example print

11. Remove any support brims
12. Check length and volume measurements from SolidWorks
13. Collect length and volume measurements from model
14. Compare percent difference
 - a. Must be below 10% difference

Analysis:

To ensure our procedure matches the dimensions of the printed model, we measured the difference between key dimensions of the printed part and the SolidWorks model. When using the actual part file, we will later use the CT scan as the reference material for the measurements. Volume, wall thickness, height and widest part were measured and compared to the measurements taken in SolidWorks. Results are shown in Table 10.

Table 10: Measurements and percent error

Measurement	SolidWorks	Printed	% error from SolidWorks model
Volume	117.47mL	121mL	3%
Wall thickness	2mm	2.6mm	30%
Height	24mm	23.8mm	.8%
Widest part	105.34mm	104.9mm	.417%

All measurements except the wall thickness were within our 10% error specification. Wall thickness difference could be due to improper printer settings. We tried a standard setting for wall thickness to allow for a more stable structure.

For the procedure, many more steps need to be added to account for the procedure difficulties with file conversion. We began our procedure with a .prt instead of an .stl, which made steps much easier than we expect to do.

What We Learned:

We learned that there are many more steps involved in converting the file to a .prt than we originally thought. Issues arose when large .prt or .stl files couldn't be uploaded into SolidWorks. After research we realized that SolidWorks only accepts files that have less than 20,000 facets. This may become an issue later on if CT scan files are too large. We might have to backtrack and have files that Dr. Portfield provides for us more edited and processed to be the correct anatomy. The mesh created from the CT scans is also too refined for SolidWorks capabilities so we had to bypass Solidworks' built in file conversion from .stl to .prt. We may have to use another software and file type between the CT scan data and importing into SolidWorks, MeshLab, which is an open source software needed to convert the stl file into a dxf file before importing to SolidWorks.

During the printing procedure we learned how specific the settings need to be in order to get the proper result with wall thickness being a main focus of our next print.

Future Development:

We plan to research and proceed with another 3D modeling software that has larger file capabilities than SolidWorks. If this does not work, we will have to leave behind this process and continue with a modification of one of our other two processes. Continuing with a different process will mean that we will have longer printing times than we hoped for due to the inability to modify the model to eliminate unnecessary features that may be driving printing time up.

As far as the model itself, we will need to begin printing actual heart models to determine what print settings need to be changed. The heart has many different geometries within it that may prove difficult during printing. Since the thinner parts of the printer model were not fully complete, we will have

to adjust settings. Based on the data from the CT scans and provided three-dimensional renderings, we will have to determine if we need to extrude any common pieces of the heart that are not essential to the goal of this project.

Since there were conversion difficulties with files we initially assumed would not be an issue, we will need to make sure that we clearly define the file conversion aspect of our final process. We will need to make a decision on what files can be used for our process to make sure that the operator can save the renderings in the appropriate file type. At this point, accurate file conversions is our main issue that we will coordinate with Dr. Porterfield's assistant Sarah to ensure an efficient solution.

Conclusion:

Our model development brought awareness to challenges that our team did not foresee. These challenges occurred in our extrusion of unnecessary features which we believed would be rather simple. Our team will go ahead and refine this process still including the extrusion of unnecessary material. If we do not find methods to do so, we will go ahead and proceed with one of our other processes that does not include this feature.

Detailed Design

The process we will proceed with for the final design will consist of using 3D Slicer to segment CT scans in an attempt to virtually isolate the right atrium, left atrium, and left atrial appendage which will be printed using a 3D printer. The model will allow physicians to accurately size the appendage and accurately estimate the entry trajectory angle. Originally we were to extrude unnecessary tissue and anatomy from the virtual model using Solidworks from .dcm files. However, we have decided that we will be taking raw CT scans and segment them using 3D slicer to our specified requirements. After following the procedure described in the Prototype Manufacturing Plans section, the virtual model that will be printed will look similar to that in Figure 9 below.

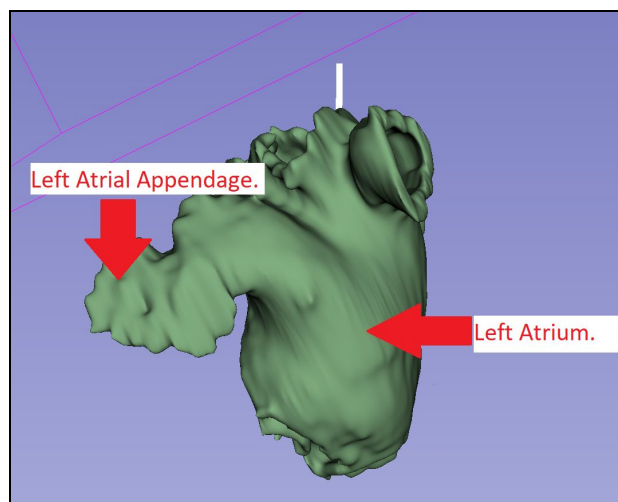


Figure 9: Virtual model of the left atrium and left atrial appendage.

Since we are using printing resources provided by Cal Poly, the cost estimation only consists of the filament used by the 3D printers. The prints we are currently processing are done on the Ultimaker printer in the BMED Lab which require PLA and PVA filament that will cost \$118.94 after tax and shipping. Since this process creates a model that is used for sizing, the dimensions of the model must be identical to the anatomical measurements of that patient. We will use the Ultimaker printer to determine the potential of accuracy that 3D printing these models can be with a higher end printer. Since most offices including those in French Hospital will not allocate a large amount of money for 3D printers, we will use cheaper printers for future prints because we want to ensure we update our printing settings to compensate for lack of quality of the cheaper printers. This will decrease the cost estimate of future prints. The diagram below explains the overall process from CT scan to print. The main ideas behind each of these steps will remain the same, though the smaller details may change as we continue to update our procedure.

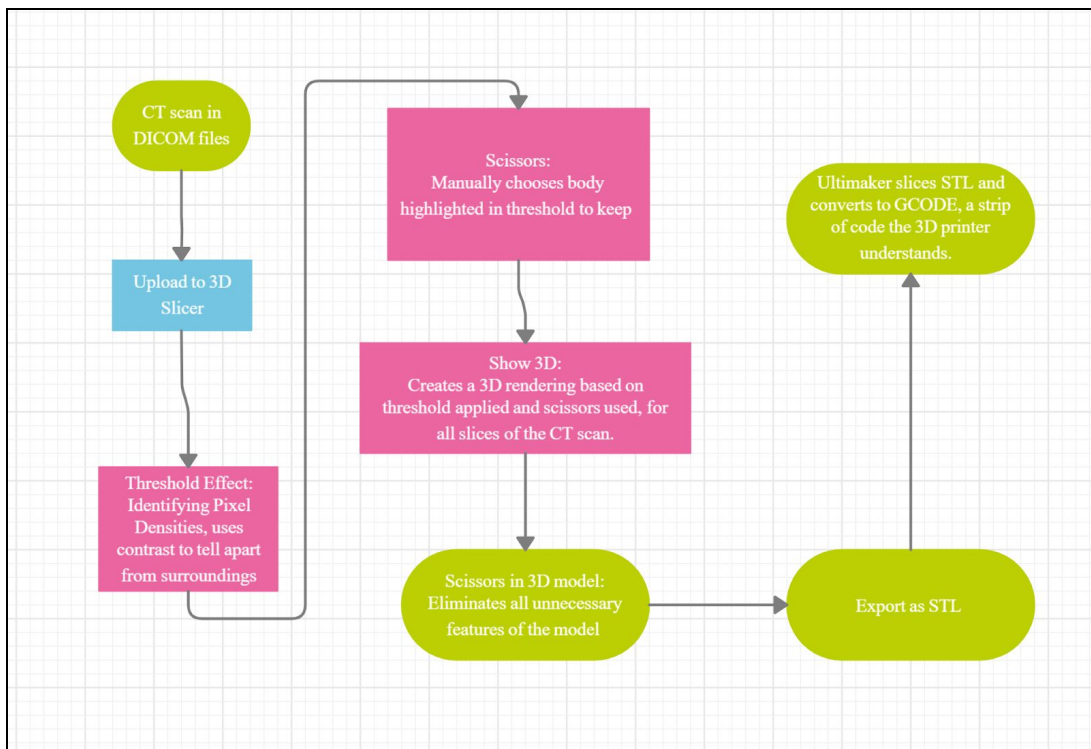


Figure 10: Manufacturing Process flowchart

Prototype Manufacturing Plans

CT scans would have been taken and saved as stackable DICOM files prior to this method.

1. Upload DICOM File into 3D Slicer
 - a. Select “Load DICOM Data”.

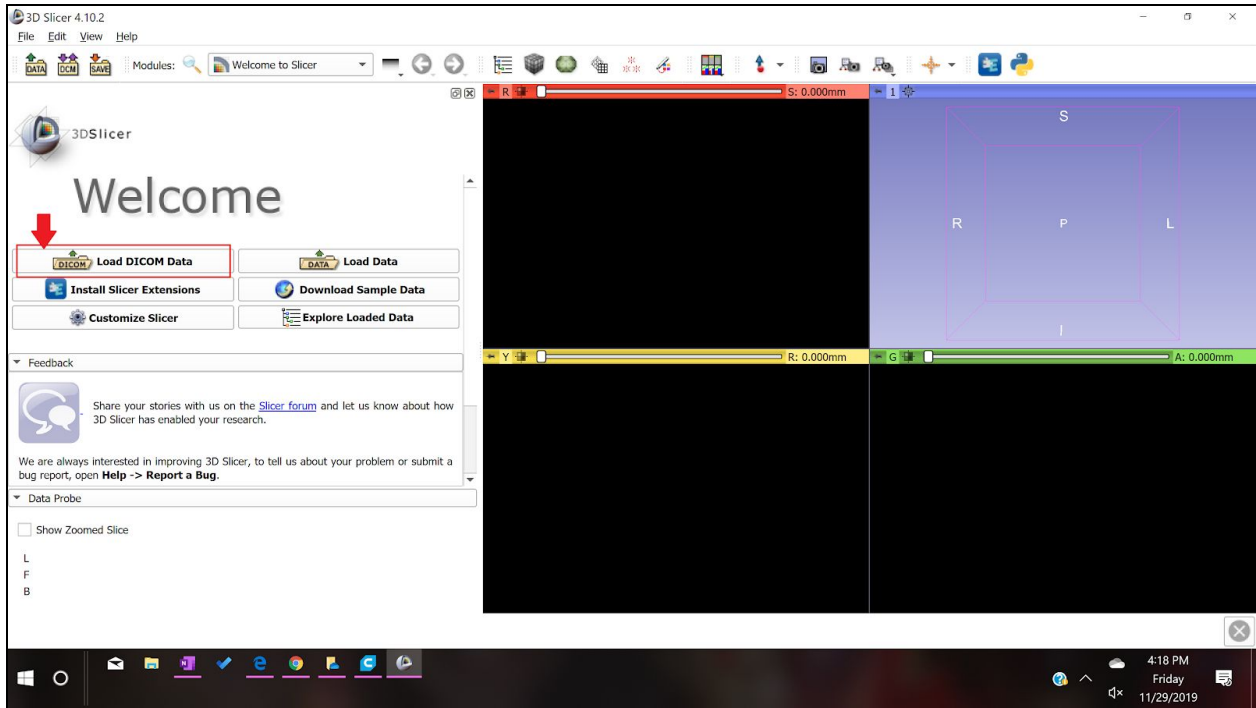


Figure 11: Loading DICOM

b. Select "Import".

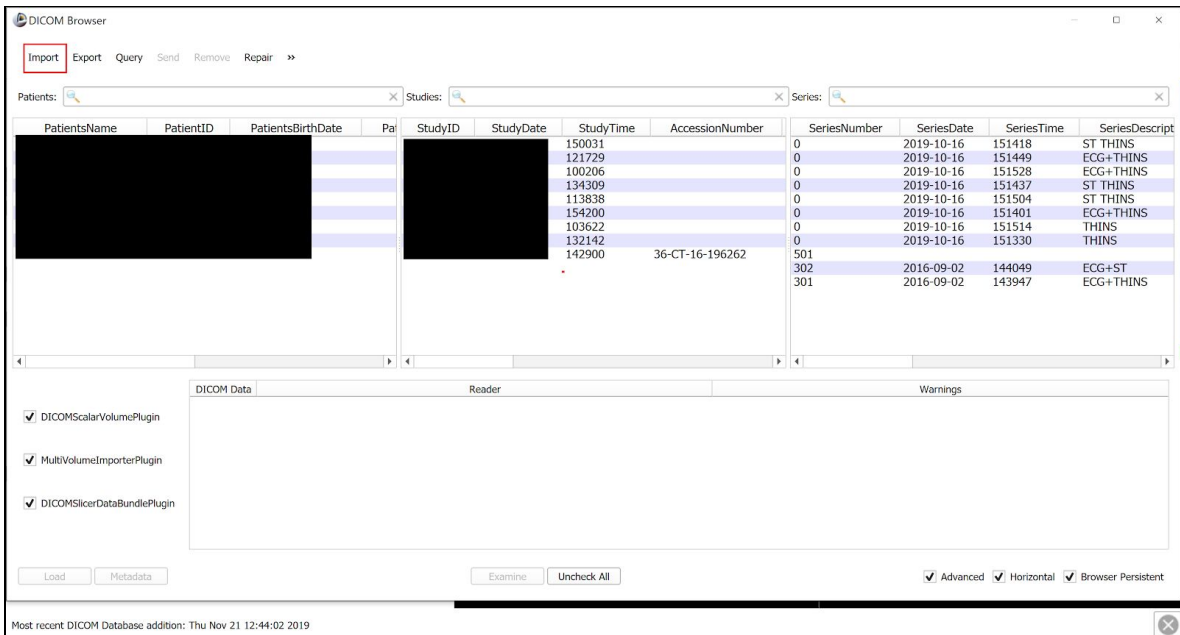


Figure 12: Importing data

c. This menu brings you to the files on the computer, navigate your files and select the folder that contains all the DICOM files for the patient.

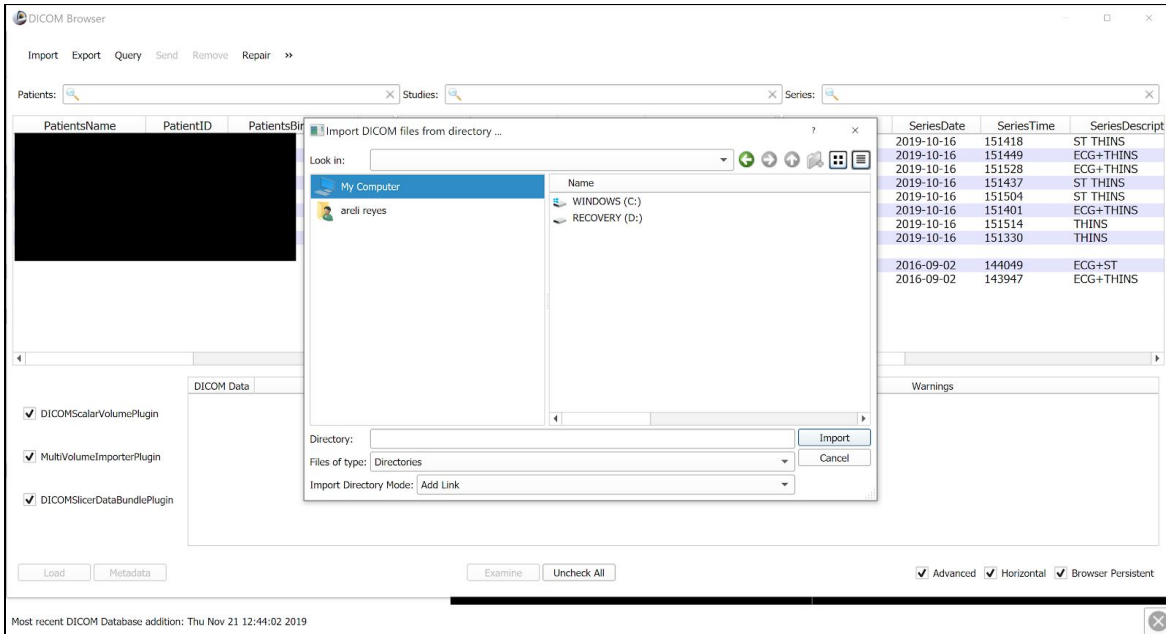


Figure 13: Select patient file

- d. Your patient will populate the first row of the list, select that row until your patient is highlighted blue. Select “Load” to finish importing the file.

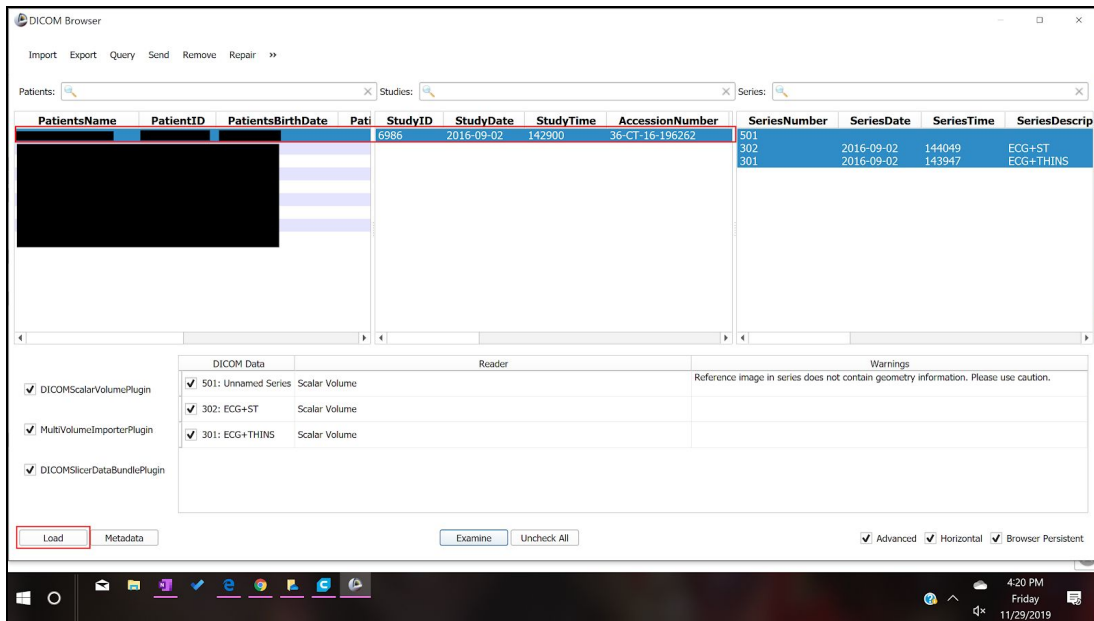


Figure 14: Loading data

- e. A warning will come up, go ahead and ignore it and select “Ok”.

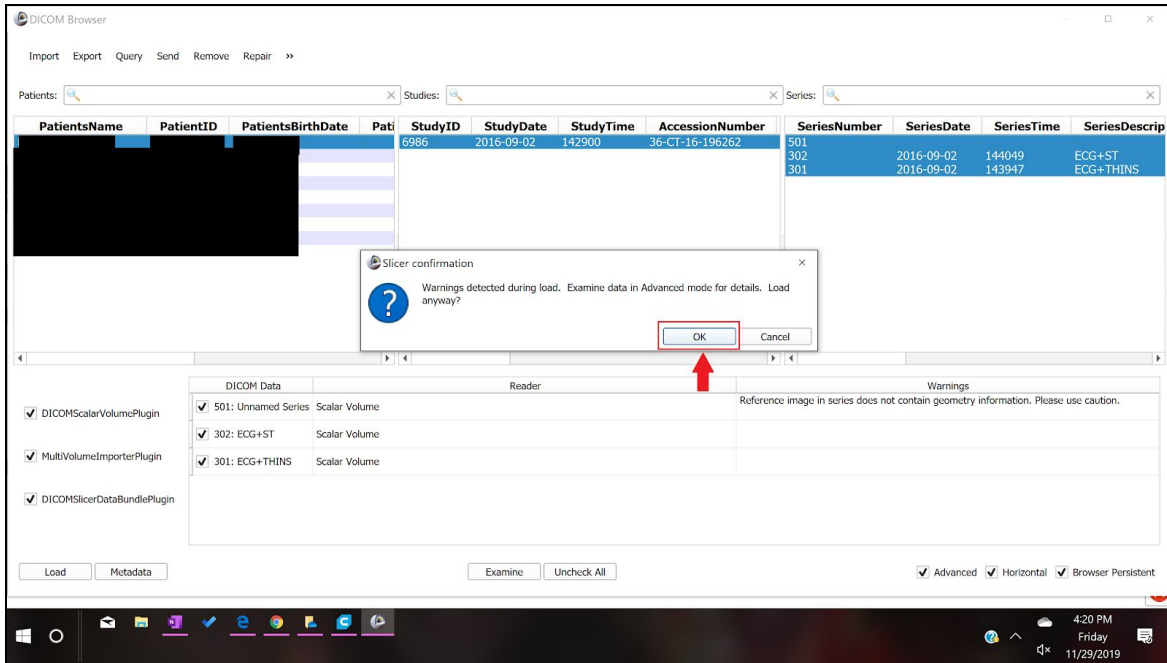


Figure 15: Select OK

f. The DICOM files of the patient will now populate the screen.

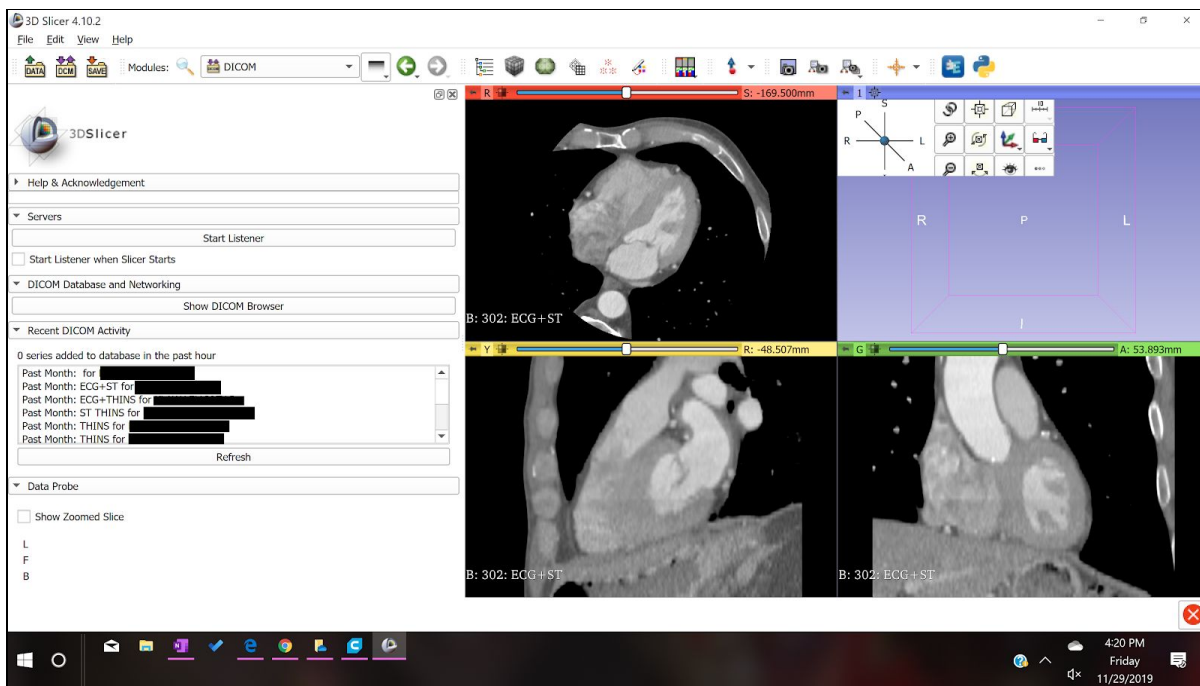


Figure 16: Screen display

2. Below is a labeled view of the four screens that we will be focusing on for the rest of the tutorial.

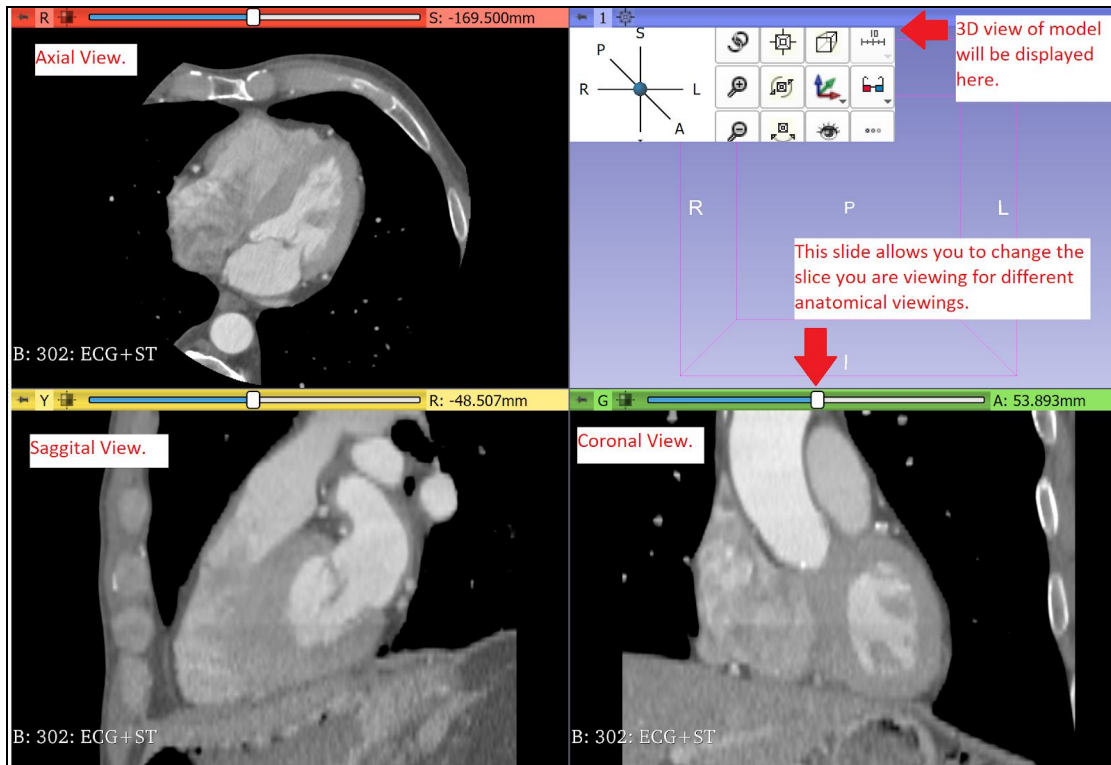


Figure 17: Labeled views

3. In order to make a 3D model from the numerous slices contained in the DICOM files, the segment editor will be used for editing and cropping to only select the left atrium and the left atrial appendage. The tools in the segment editor that will be used are “Threshold”, “Scissors” and “Hollow”.
 - a. In the Segment Editor, select “Threshold” from the “Effects” menu.

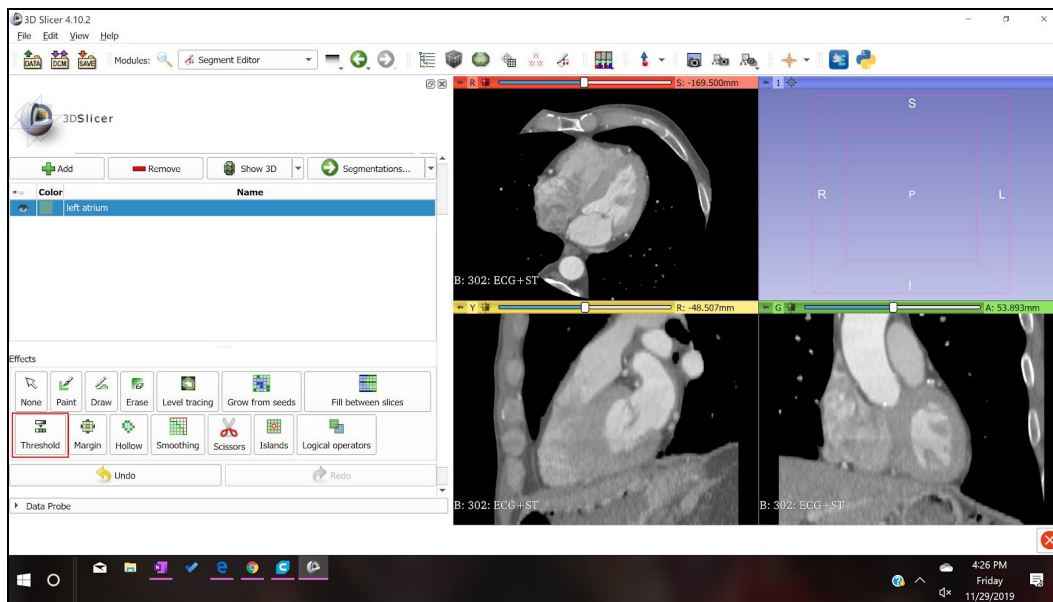


Figure 18: Add segment

- b. After selecting “Threshold” the menu for “Threshold” appears as seen below, adjust your settings to similar ones to this tutorial. Select “Apply” when this range is selected.

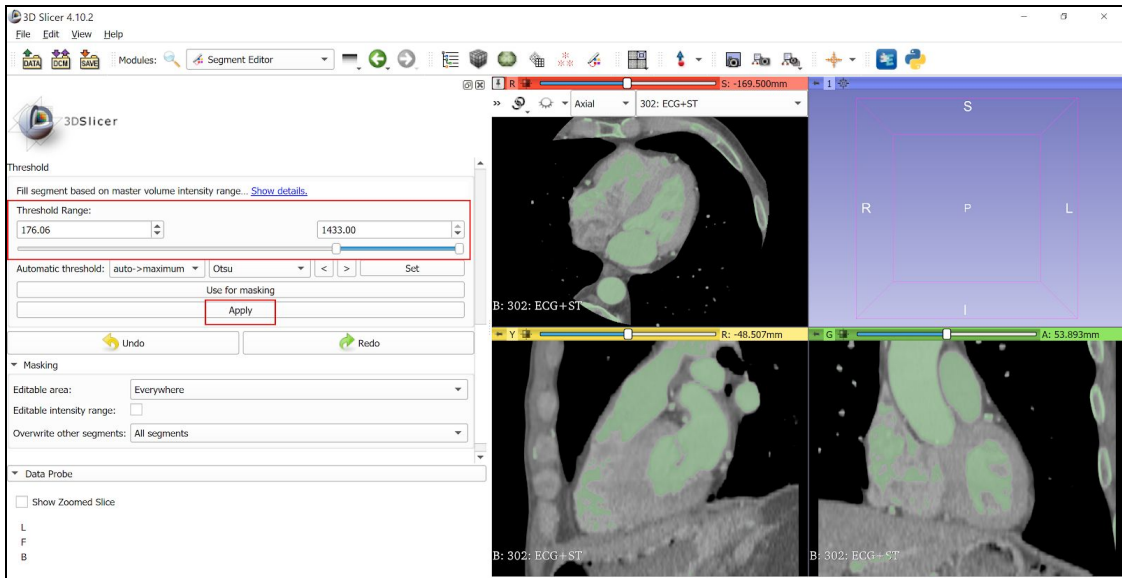


Figure 19: Select threshold parameters

- c. Before proceeding with the edits in the segmenting tool, change the slice in the “Axial” view so that the left atrium and the left atrial appendage can be clearly seen, use the slider at the top of the Axial view to change the slice.

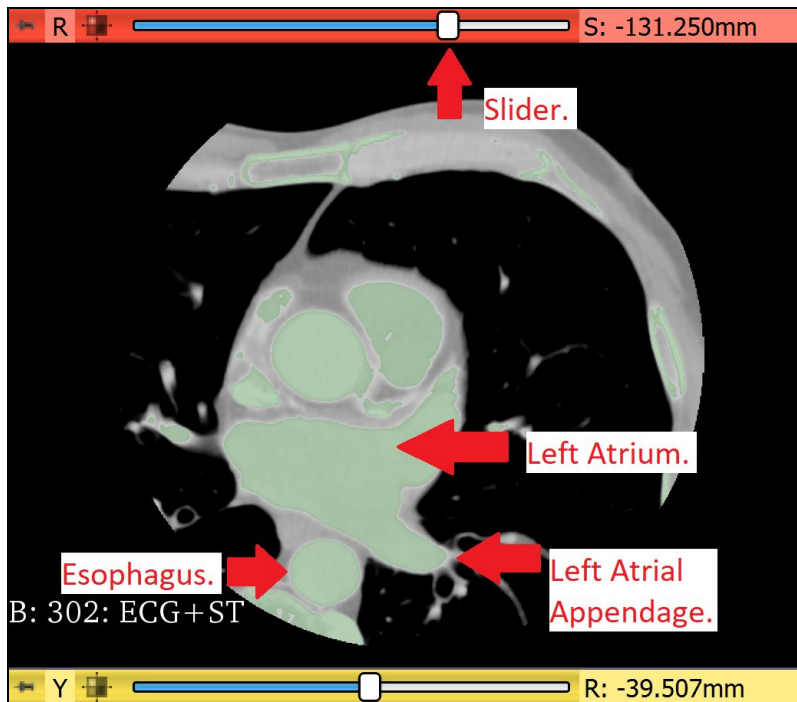


Figure 20: Labeled CT scan

- d. Select “Scissors” and crop around the left atrium, left atrial appendage, and esophagus. The esophagus will be used for reference later on. The scissors will appear on your screen and the left atrium can be cropped as shown in the yellow outline below.

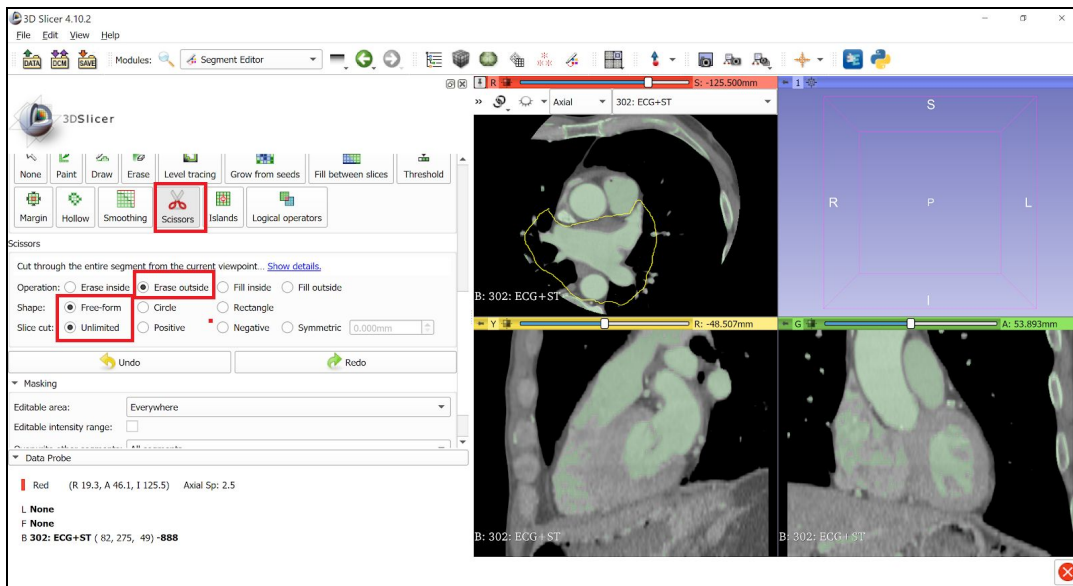


Figure 21: Select scissor feature

- e. After the scissors are applied, then a 3D model can be rendered from the cropped slices. Select “Show 3D”.

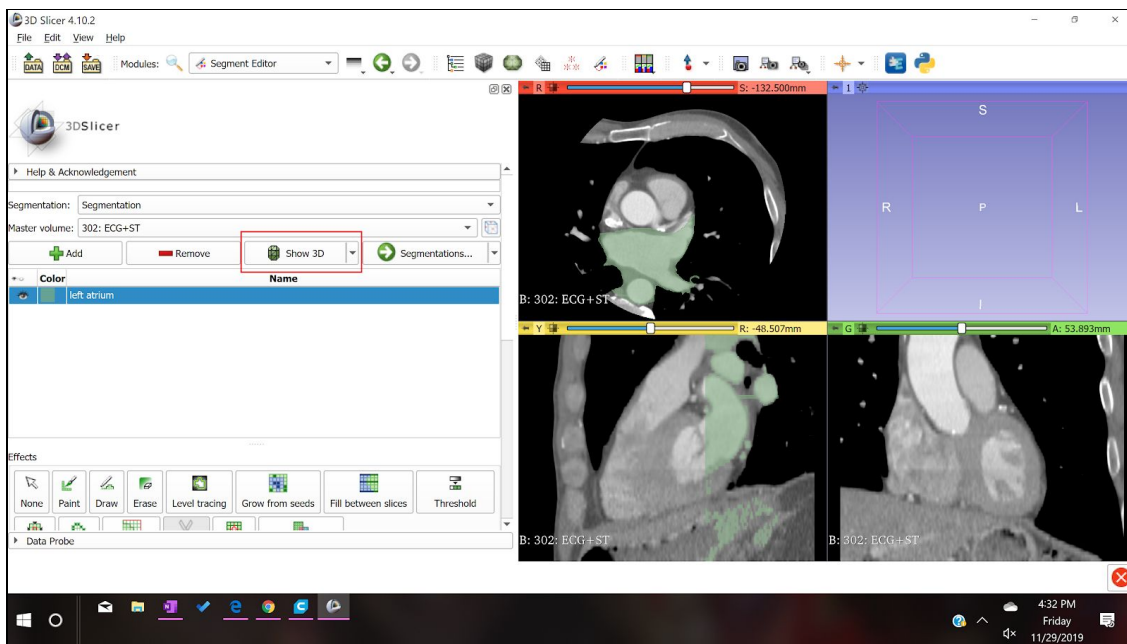


Figure 22: Select Show 3D feature

- f. The 3D model shows up in the upper right quadrant. Select the drop down menu highlighted below and select “3D only” to only view the 3D image.

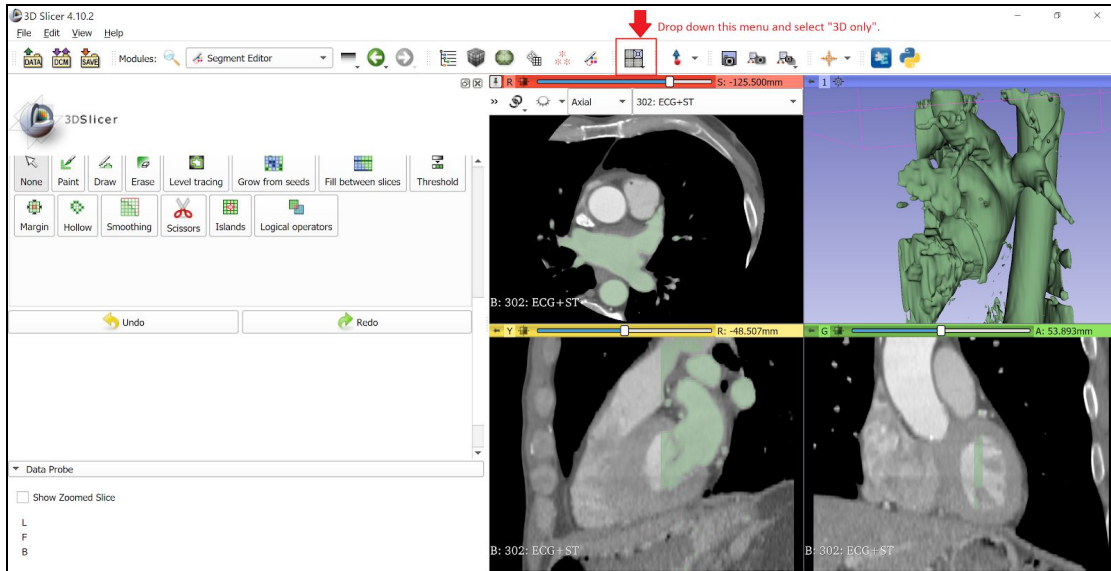


Figure 23: Change views

4. The 3D image populates the entire screen for further cropping in the 3D view.

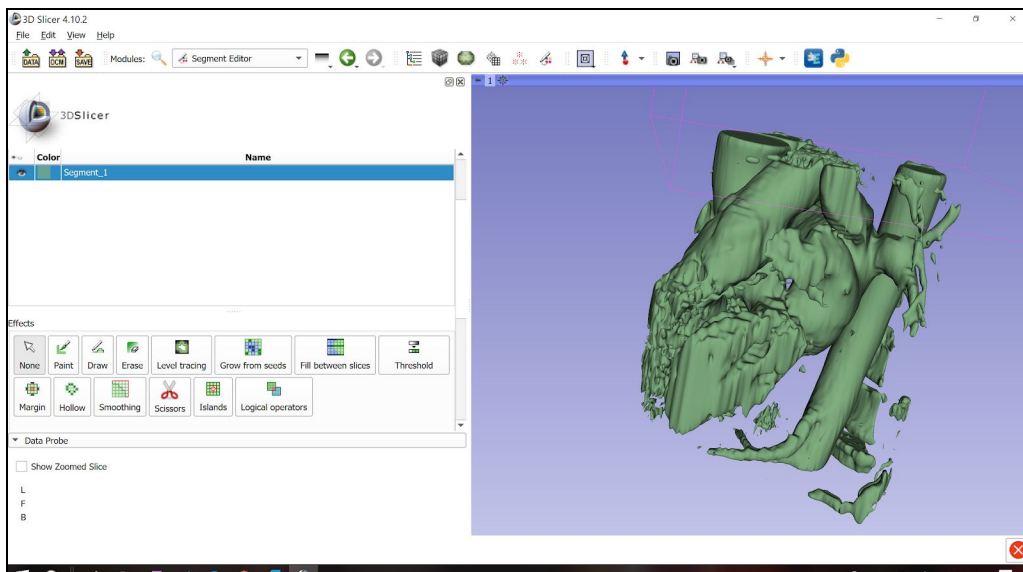


Figure 24: Uncropped 3D model

- a. Before cropping, make the empty spaces hollow to be able to see cavities. Use the same hollow settings as marked below and select “Apply”.

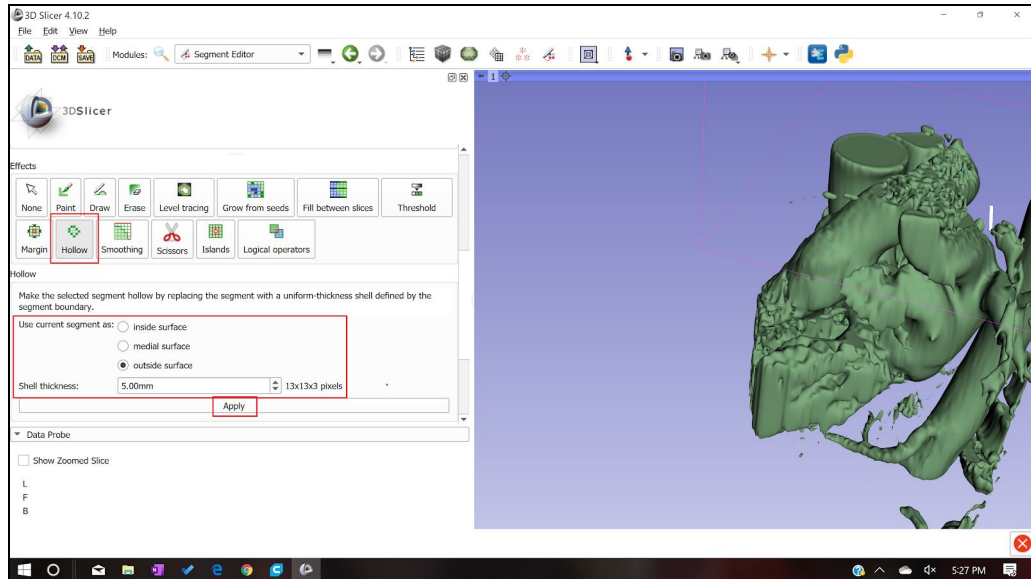


Figure 25: Select Hollow feature

b. Now select “Scissors” and crop out unnecessary anatomy.

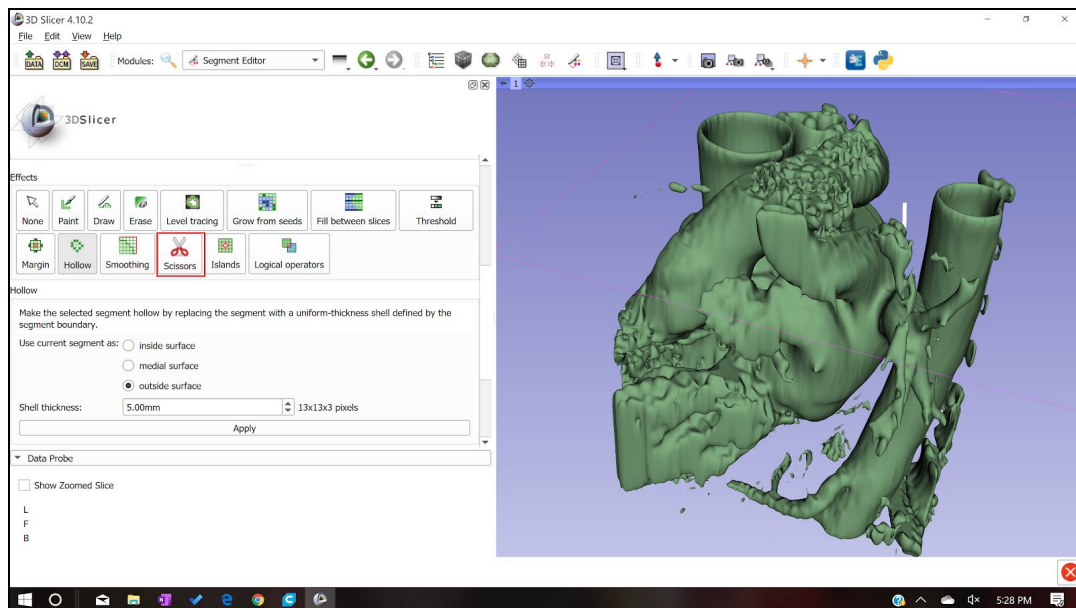


Figure 26: Select scissor feature

c. The left atrium can be identified to the left of the esophagus when looking from the posterior view, behind the esophagus. Once the left atrium and left atrial appendage are identified based on this identification factor, the esophagus can be cropped out with the scissors set to crop “inside”. The image below shows the heart at a midpoint of cropping.

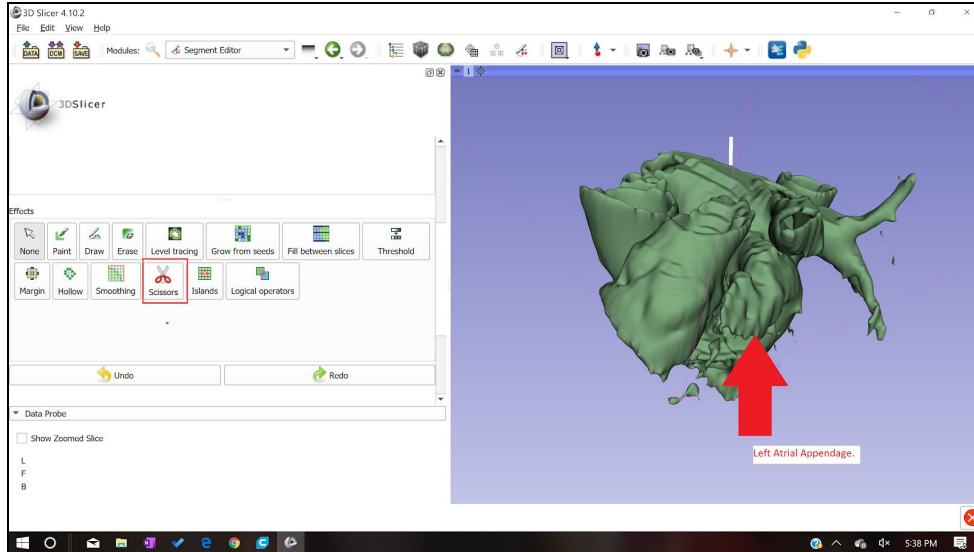


Figure 27:Labeled left atrial appendage

- d. Crop until you have a simple geometry left that still shows the left atrial appendage and the left atrium. When cropping, consider cropping a top portion of the left atrium to have for viewing the left atrial appendage from the inside.

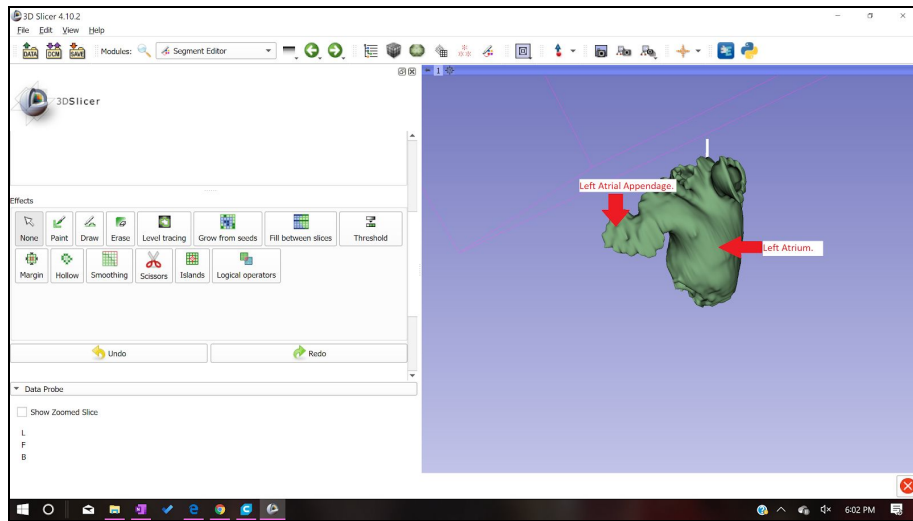


Figure 28: Cropped 3D model

- e. Save the model, click on “Segmentations”, here the drop down menu will come up. In that drop down menu select “Export to Files...”

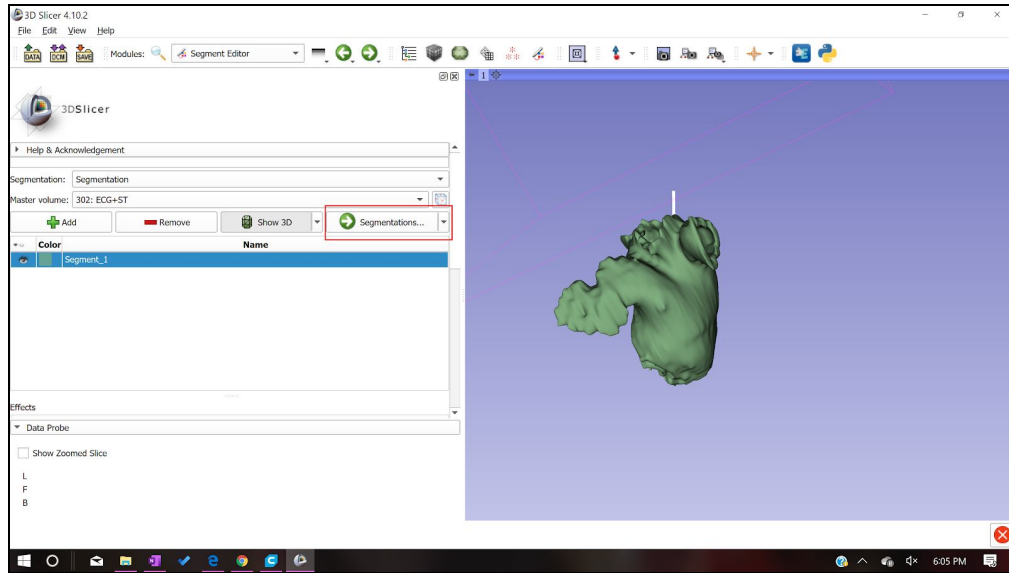


Figure 29: Export 3D model as an .stl

- f. After selecting “Export to Files...” select a Destination Folder. We advise you to select a folder that contains this particular patient’s files. Before selecting export, make sure that the file format chosen is “STL”. Select export.

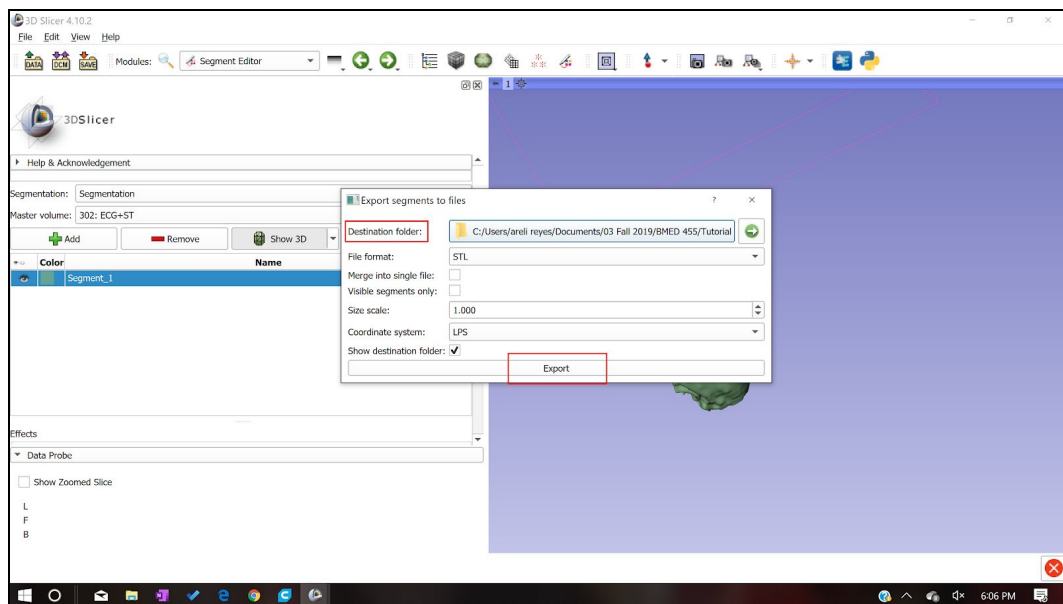


Figure 30: Exporting setting

5. Upload the STL file to the Ultimaker Cura program.

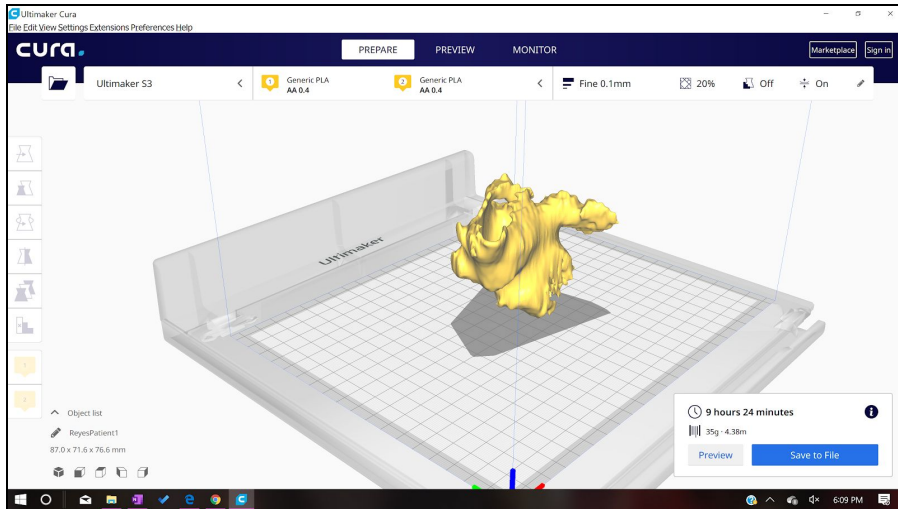


Figure 31: 3D model in Ultimaker Cura software

- a. Define as seen in Figure 10 below:
 - i. Infill
 - ii. Quality
 - iii. Shell
 - iv. Material
 - v. Speed
 - vi. Cooling
 - vii. Support material
 - viii. Build Plate Adhesion

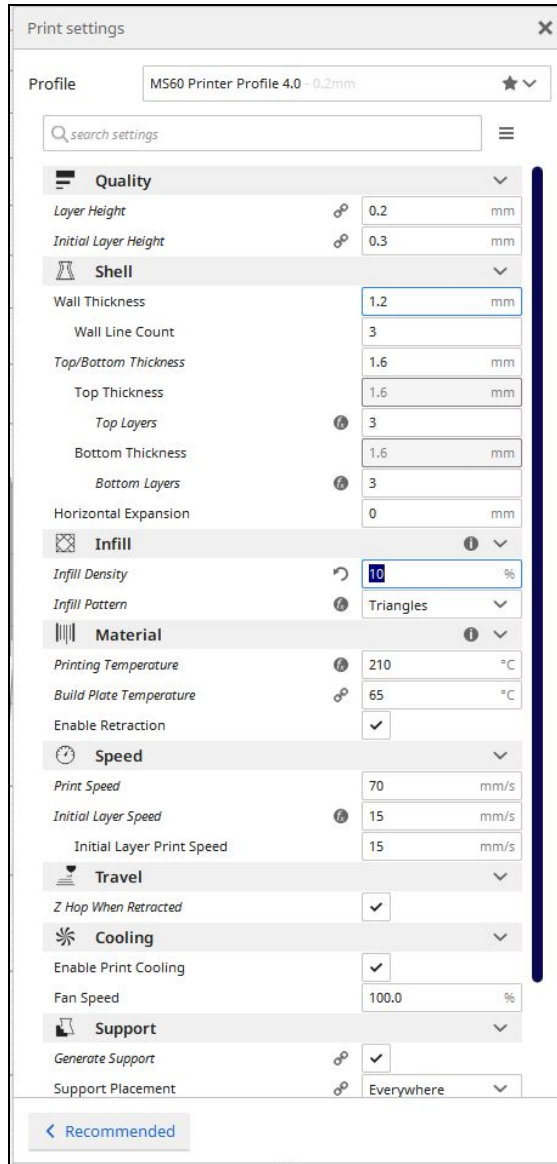


Figure 32: Ultimaker Cura Setting

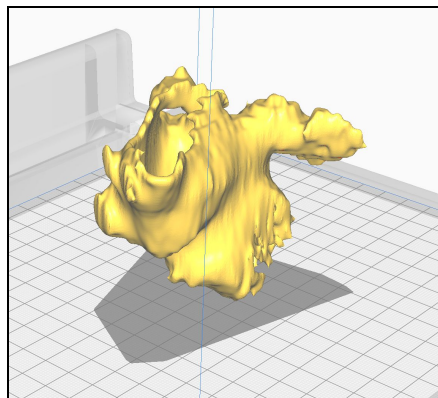


Figure 33: Sliced part in Ultimaker Cura Software

- b. Upload and modify printer settings

- i. Load filament into machine
- ii. Press “Bed”-”Heat” to heat up system
 - 1. Check temperature of nozzle and plate by pressing “Bed/Extrude” on the printer panel
 - 2. Press “Print”- find file (file will have settings listed first then file name)
 - 3. Confirm “Yes”
 - 4. Wait for plate to finish heating up and clear any extra plastic from platform
- c. Wait for first layer of print to be printed before leaving print alone
 - Note: This is important to ensure the print will print appropriately because most failures occur in the first layer if they were to occur
- 2. Allow the printer 1.5x the estimated time of the print.
- 3. Remove any support brims
- 4. Check length and volume measurements from SolidWorks
- 5. Collect length and volume measurements from model
- 6. Compare percent difference
 - a. Must be below 10% difference

Bill of Materials

Table 11: Bill of Materials

Bill of Materials					
Product: Left Atrial Appendage Model				Date: 12/1/2019	
Assembly: 3-D Print					
Item #	Part #	Qty	Name	Material	Source
1	1614	2	Printing filament	PLA	Amazon
2	9732	2	Printing filament	PVA	Amazon
3	4.10 and above	1	3D Slicer	Software	slicer.org
Team member: Brandon Mukai			Prepared by: Brandon Mukai		
Team member: Areli Reyes			Checked by: Areli Reyes		
Team member: Mia von Knorring			Approved By: Mia von Knorring		

Final Manufacturing Process Instructions

After completing our prototype, we recreated our MPI to be easier to read and follow. The final MPI is shown in Appendix 4. It is broken down into 3 parts: segmenting in 3D slicer, printing and post processing.

Operation Manual

Our Operation Manual, shown in Appendix 5 expands on features of the MPI. It describes what commands do and how to properly use them. It should be used as a supplement to the MPI to further understand the slicing procedure.

Training Guide

Before operators are authorized to perform the MPI for sizing the Watchman device, they must prove their ability to follow the procedure correctly. We have created a Training Guide, which can be found in Appendix 6 that must be followed to be checked off. The Training Guide is the same document as the MPI, but instead of printing the entire left atrium and left atrial appendage, the user will be printing $\frac{1}{3}$ of the left atrium with the left atrial appendage. One patient CT scan is referenced in the training guide, here the user will perform measurements on the left atrial appendage they print and then determine the sizing of Watchman for that patient. They will only pass the training if they determine the appropriate size watchman for that patient, which will already be sized beforehand.

In addition to the Training Guide, there is the Training Completion Form, Appendix 7, which will be used to document which users are authorized to use the MPI for sizing the Watchman device.

Test Protocols

Testing Overview:

There are 3 parts to the Left Atrial Appendage Testing:

1. **User Feedback-** Dr. Porterfield and Sarah will follow procedure and take a survey of different features to obtain feedback on user experience (n=2 operators on n=1 trials). They must rank each feature 1-10 (1 easy, 10 hard). All features must obtain < 3.
2. **Model Accuracy-** We will segment and print 3 models, each with a different CT scan (n=3). We will then select which Watchman size based on our model. This selection will be based on appendage diameter and depth. Dr. Porterfield will then look at the CT scan and choose the Watchman size (current sizing method).
3. **ANOVA-**We will be conducting an ANOVA of our procedure to analyze repeatability and reproducibility. The test will be done by each of our team members (n=3 operators) throughout Winter Quarter 2020. As part of the ANOVA, each operator (Mia, Areli and Brandon) will segment the same CT scan using 3D Slicer then upload and print the appendage according to the procedure. The operator will then measure 3 critical points on the 3D printed model and repeat the procedure 2 more times (n=3 trials). The data will be analyzed in Minitab to see the variability between operators and runs of the procedure. We expect no statistical difference in the ANOVA to validate the procedure is viable.

Protocols:

1. User Feedback

1. Dr. Porterfield and Sarah (operators) both train to Training Protocol
2. Operators follow MPI and Operational Manual
 - a. Operators segment the CT scan in 3D slicer and convert into an .stl file
 - b. Operators upload .stl file to Ultimaker Cura Software and input correct settings
 - c. Operators print the appendage on any 3D printer compatible with the Ultimaker software
3. Operators take the following survey.

1 is the best ranking and 10 is the worst.

Question	Ranking	Comments
Was the MPI formatted in an easy-to-follow design?	1 2 3 4 5 6 7 8 9 10	
Does the training adequately access operator proficiency?	1 2 3 4 5 6 7 8 9 10	
Were directions clear?	1 2 3 4 5 6 7 8 9 10	
Was our method of isolating the left atrium and left atrial appendage efficient?	1 2 3 4 5 6 7 8 9 10	
Could you easily locate the left atrial appendage from MPI instructions?	1 2 3 4 5 6 7 8 9 10	
Did the Operation Manual explain each tool's purpose clearly?	1 2 3 4 5 6 7 8 9 10	
Was the printing process easy to understand from the training guide and MPI?	1 2 3 4 5 6 7 8 9 10	

2. Model Accuracy

1. Operators follow the Left Atrial Appendage Manufacturing Process Instructions with 3 patient files
 - a. Operators segment the CT scan in 3D slicer and convert into an .stl file
 - b. Operators upload .stl file to Ultimaker Cura Software and input correct settings
 - c. Operators print the model on the BMED 3D printer
2. Operators size the Watchman based on the following chart:

Table 1. Compression as recommended by the manufacturer and new proposed oversizing range.					
Device Size [mm]	Guidelines for 8%-20% Compression		Scheme With 10%-30% Compression as Practiced in St. Georg		LAA Diameter in the Registry
	Maximum LAA Diameter [mm]	Minimum LAA Diameter [mm]	Maximum LAA Diameter [mm]	Minimum LAA Diameter [mm]	Mean LAA Diameter [mm]
21	19	17	18	15	17.3 ± 0.9
24	22	19	20	17	19.7 ± 0.45
27	25	22	23	19	21.5 ± 0.6
30	28	24	26	21	23.4 ± 1.1
33	30	26	28	23	26.5 ± 1.0

Data provided in mm ± standard error of the mean.

Figure 34: Boston Scientific Watchman sizing chart

3. Dr. Porterfield will choose the Watchman size based on examining the CT scans (current industry standard method).
4. Selection of the Left Atrial Appendage Team must match 100% that of Dr. Portfield.

3. ANOVA

1. Train operators on 3D slicer according to Training Protocol
2. 3 operators follow the Left Atrial Appendage Manufacturing Instructions with one patient file
 - a. Operators segment the CT scan in 3D slicer and convert into an .stl file
 - b. Operators upload .stl file to Ultimaker Cura Software and input correct settings
 - c. Operators print the appendage on any 3D printer compatible with the Ultimaker software
3. Operators take 3 critical measurements on the printed model
 - a. Volume
 - i. Operators use a 10mL graduated cylinder to slowly fill the appendage with water. Operators fill the appendage up to the ostium. Operator records how many mL it took to fill the appendage.
 - b. Depth
 - i. Operators use calipers to measure the depth of the appendage up to the ostium
 - c. Widest diameter
 - i. Operators will use calipers to measure the widest diameter in the opening of the appendage

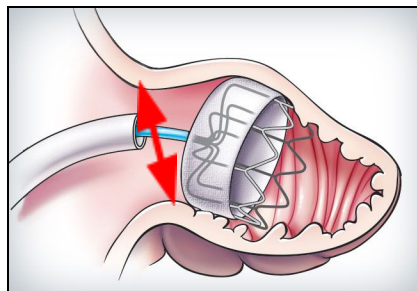


Figure 35: Ostium measurement

4. Operators repeat the procedure 2 more times.
Note: Each segmenting and printing repetition should be done on a different day
5. Run a ANOVA study in MiniTab with the 9 models for each of the critical measurements

- a. No statistical difference between operators and trials for repeatability and reproducibility with a p value of 0.05 concludes that the procedure is valid

Testing Details:

Facilities

All operators have 3D slicer on their computers. The .stl will be uploaded to the Ultimaker software. Both are open source software that can be downloaded to any computer. The appendage models will be printed in the BMED 3D printing lab using PVA and PLA filament or in the Mustang '60 Machine Shop using just PLA. Measurements will be taken in the BMED 455 Lab classroom using calipers and 10mL graduated cylinders. The appendages will be cut with a saw if necessary in the Mustang '60 Machine Shop.

Equipment:

We will be using the 3D Slicer software to segment and the Ultimaker Cura software to upload to the printer. Any printer compatible with Ultimaker Cura software can be used for the procedure, but we will be using the BMED printer in Engineering IV with PVA and PLA filament. Calipers and a 10mL graduated cylinder will be used to make measurements.

Bill of Materials:

Will be using PLA filament and PVA filler filament to produce our models.

Training:

All operators must be trained how to use 3D Slicer and the Ultimaker software. All operators will follow the Training Guide to print a standardized appendage. The printed appendage must match the dimensions of the standardized model. A manager will sign the Training Completion Form if the printed appendage is <10% different from the standardized model.

Testing Data and Analysis

User Feedback Survey:

Dr. Porterfield and Sarah Griess both took the User Feedback Survey and results are displayed below:

Dr. Porterfield's Survey

Question	Ranking	Comments
Was the MPI formatted in an easy-to-follow design?	1 2 3 4 5 6 7 8 9 10	N/A
Does the training adequately access operator proficiency?	1 2 3 4 5 6 7 8 9 10	N/A
Were directions clear?	1 2 3 4 5 6 7 8 9 10	N/A
Was our method of isolating the left atrium and left atrial appendage efficient?	1 2 3 4 5 6 7 8 9 10	N/A
Could you easily locate the left atrial appendage from MPI instructions?	1 2 3 4 5 6 7 8 9 10	N/A
Did the Operation Manual explain each tool's purpose clearly?	1 2 3 4 5 6 7 8 9 10	N/A
Was the printing process easy to understand from the training guide and MPI?	1 2 3 4 5 6 7 8 9 10	N/A

Sarah's Survey

Question	Ranking	Comments
Was the MPI formatted in an easy-to-follow design?	1 2 3 4 5 6 7 8 9 10	Great!
Does the training adequately access operator proficiency?	1 2 3 4 5 6 7 8 9 10	N/A
Were directions clear?	1 2 3 4 5 6 7 8 9 10	N/A
Was our method of isolating the left atrium and left atrial appendage efficient?	1 2 3 4 5 6 7 8 9 10	Might have been more efficient with a tighter threshold in certain CTs. Would be helpful to know how to segment/reassign the LAA off of the LA and turn "on" and "off" for editing purposes.
Could you easily locate the left atrial appendage from MPI instructions?	1 2 3 4 5 6 7 8 9 10	Good use of different views
Did the Operation Manual explain each tool's purpose clearly?	1 2 3 4 5 6 7 8 9 10	Very helpful.
Was the printing process easy to understand from the training guide and MPI?	1 2 3 4 5 6 7 8 9 10	Only giving this a 3 because I had to figure out the settings on my own. Could have been a different version?

ANOVA Results:

We used calipers and a 10mL beaker to measure the ostium diameter, depth and volume of the appendage. The set up for volume is shown Figure 36 and Figure 37, depth is shown in Figure 38 and diameter is shown in Figure 39.

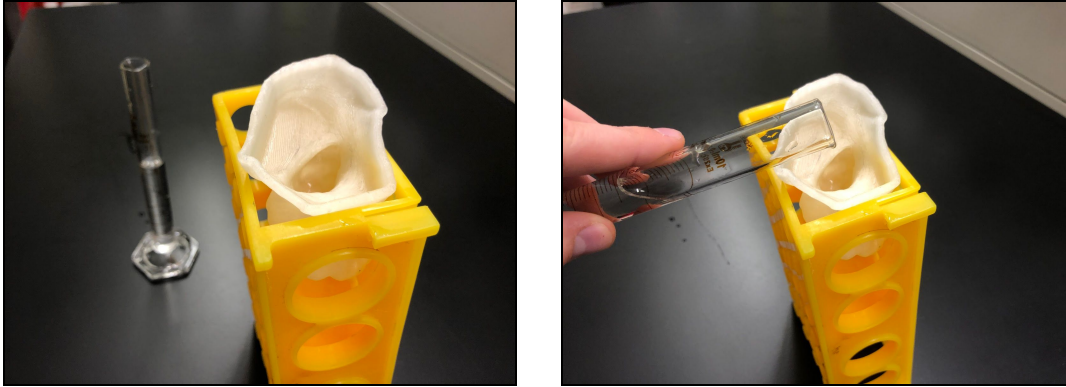


Figure 36 and 37: Volume measurement set-up



Figure 38 and 39: Depth (left) and diameter (right)

Table 12: Appendage Measurement Testing Results

Operator	Model Number	Depth (mm)	Diameter (mm)	Volume (mL)
Operator 1 (Mia)	1	35.1	22.8	9.8
	2	36.1	22.5	12.2
	3	35.4	22.5	9.8
Operator 2 (Areli)	1	34.8	23.7	9.7
	2	34.4	21.1	9.6
	3	33.5	24.2	9.5
Operator 3 (Brandon)	1	35.4	23.4	9.7
	2	36.1	24.3	9.6
	3	35.5	24.0	9.3

We ran an ANOVA study in Minitab with our 9 models to find the repeatability with the same operator and reproducibility between operators for all 3 measurements. Minitab results are shown below:

Table 13: ANOVA Results

Operator	Test	P- Value	Statistical Difference	Conclusion
Volume	Reproducible	.290	No	Passed
	Repeatable	.401	No	Passed
Diameter	Reproducible	.404	No	Passed
	Repeatable	.592	No	Passed
Depth	Reproducible	.036	Yes	Failed
	Repeatable	.271	No	Passed

Model Accuracy:

Figure 40 displays the measurements taken directly off the CT scan on 3D slicer. Table 14 displays the model accuracy results.

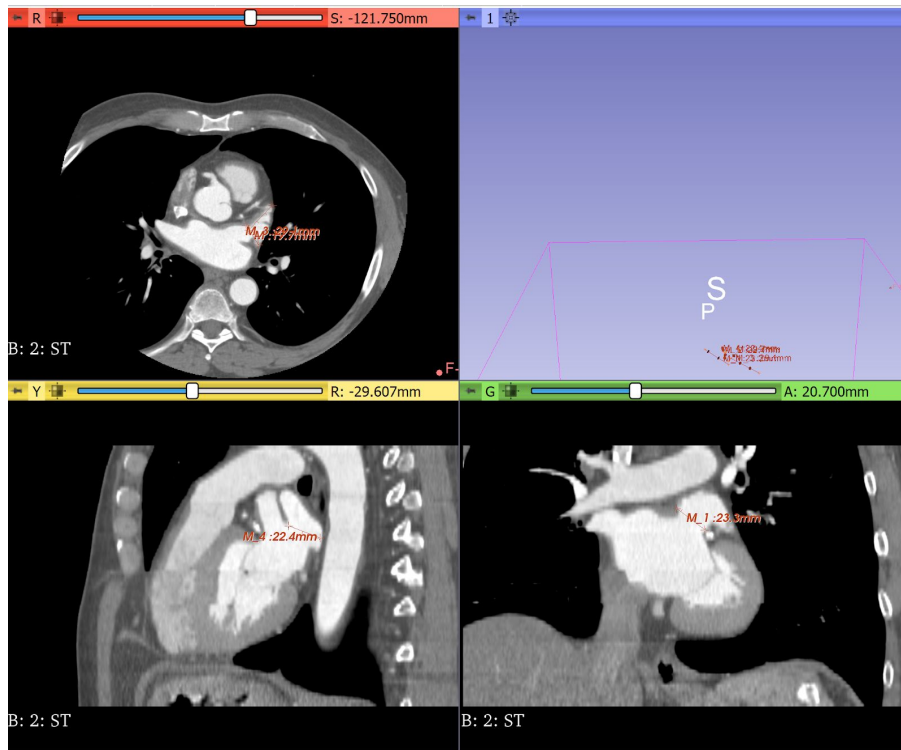


Figure 40: Diameter and volume measurements taken from CT scan.

Table 14: Model Accuracy results

Measurement	3D Model Result			CT Scan Results
	Model 1	Model 2	Model 3	
Diameter average (mm)	22.6	23	23.9	21.8
Depth average (mm)	35.53	34.23	35.66	29.1
Volume average (mL)	10.6	9.6	9.53	10.5
Watchman Sizing	27	27	27	27
Diameter % different from CT Scan	3.6%	5.37%	9.2%	N/A
Depth % different from CT Scan	19.87%	16.2%	20.25%	N/A
Volume % different from CT Scan	.94%	8.95%	9.68%	N/A

Conclusion

Results demonstrated that the Left Atrial Appendage printing procedure accurately models the left atrial appendage ostium and produces repeatable and reproducible results. The User Feedback Survey also demonstrated the procedure is easy to follow and understand. We met our customer specifications for all User Feedback and Model Accuracy testing categories. For User Feedback, Dr. Porterfield and Sarah Griess both scored all of the questions of the User Feedback Survey < 3, which was our engineering specification. Sarah provided some feedback for the MPI to improve clarify and design which we added to the MPI and noted in the Discussion. ANOVA testing demonstrated that measurements of diameter and volume were all consistent between operators and trials. All comparisons had a p-value<.05, confirming repeatability and reproducibility of these features. Depth measurements however resulted in a p-value of .036 between operators. This discrepancy could be due to the challenging angle measurement. Since the anatomical models are curved and irregularly shaped, it was difficult to measure the depth consistently between models. Lack of consistency PVA removal could also cause this design specification failure. On some models, PVA still remained in small cavities after post processing was completed even though we tried to remove as much as possible. Even though inconsistency between operators exists in the depth measurement, depth is not a critical measurement to Watchman sizing. Boston Scientific's chart chooses Watchman sized based on ostium diameter. Model accuracy was verified with Dr. Porterfield to see if all

3 measurements had a <10% difference to the CT scan. The 3D printed model had a <10% difference in volume and diameter, but had a 18.8% difference in depth. After discussing this result with Dr. Porterfield, we concluded that this measurement is subjective and hard to keep consistent. The depth is not critical to the Watchman sizing and with the diameter and volume having very low percent differences, our model can still be verified as accurate.

Discussion

Overall, this procedure accurately modeled the left atrial appendage in order to properly size the Watchman. Many improvements could be done to this procedure to produce even more accurate and consistent results including modifying the “threshold” feature range per patient. In 3D slicer, we chose a range of pixel density that encompassed most of the left atrium and left atrial appendage, but this could vary based on different CT scan parameters. Perhaps not all CT scans were obtained with the same machine or transferring the .DICOM files changes pixel quality. To improve this, we would add in a broader threshold range and have the operator modify it based on visually noting where the boundaries of the left atrium and appendage lie. This requires more operator training to be able to identify the proper anatomy and adds another factor of variability to the model. Our project was also limited by the software available and chose to use 3D Slicer instead due to its ease of use and free access. However 3D Slicer is not proven or validated for clinical use. When opening up the application the message “This software is not intended for clinical use” appears. To further improve and validate the procedure, the procedure can be done using the Abbott, EnSite Precision. EnSite Precision is currently used in operating rooms performing electrophysiology procedures. Using filament with tissue-like properties could also help with sizing the Watchman. More flexible material is clinically relevant and could allow doctors to see the compression the Watchman could cause on the appendage to ensure that the device is correctly sized.

Many sections of the procedure create variability that could change procedure outcomes. While our ANOVA demonstrated overall consistency between operators and trials, there could be variability in printer operator. We had the same lab assistant print all of our models, but he created certain parameters and printer features for all his prints that could possibly change between operators. To mitigate this risk, we recorded all notable parameters in our procedure. Variability could also arise when anatomy is being cropped. Operators could remove too much necessary anatomy or include more anatomy to create a larger model. In some patients, the pulmonary arteries are in close proximity to the left atrial appendage. When cropping, one operator selected this feature as part of the left atrial appendage, creating an outlier in the data. We discussed this with Sarah Griess, Dr. Porterfield’s clinical specialist, and she stated her position is specifically trained to look out for this anatomical phenomenon. We added a note in the MPI for operators to recognize the two features and ensure they are not grouped together.

The slicing and printing procedure could be used in many other applications. Within cardiology, sizing of heart valves could be done based on 3D printed models. The risk of incorrectly sizing would decrease and anatomical anomalies would be identified pre-procedure, allowing the doctor to plan ahead for difficult procedures. This could also be applied to other device sizing for organs that use CT scans as well.

Appendix:

Appendix 1: Table of Deliverables

Deliverable	Date
Team Contract	9/24/2019
Intellectual Property ID	10/8/2019
Conjoint Analysis Report	10/10/2019
House of Quality	10/10/2019
Network Diagram	10/10/2019
Statement of Work/IFU	10/10/2019
Budget	10/10/2019
Project Requirements Document	10/15/2019
Project Plan Meeting	10/15/2019
Project Plan Meeting	10/17/2019
Pugh Chart	10/22/2019
Conceptual Model	10/29/2019
Status Update Memo	10/29/2019
Hazard and Risk Assessment	10/30/2019
Conceptual Design Prototype	11/04/2019-11/07/2019
Status Update Memo	11/12/2019
Peer Evaluations/Team Health Assessment	11/12/2019
Yellow Tag Test Complete	11/14/2019
Status Update Memo	11/18/2019
Critical Design Review Presentation	12/02/2019-12/05/2019
Design Notebook Progress Check	12/9/2019
Updated Project Plan	1/9/2020
Team Health Assessment	1/9/2020
Ethics Reflection	1/16/2020

Status Update Memo	1/21/2020
Functional Prototype Demo	01/27/2020-01/30/2020
Test Plan Presentation	1/27/2020
Test Plan Report	1/27/2020
Functional Prototype Video	1/27/2020
Status Update Memo	2/3/2020
Peer Evaluations/Team Health Assessment	2/3/2020
Status Update Memo	2/10/2020
Status Update Memo	02/18/2020
Status Update Memo	02/24/2020
Status Update Memo	03/02/2020
Demo Day/Design Review Presentations	03/09/2020-03/12/2020
Senior Project Design Report	03/09/2020
Design Notebook Due	03/16/2020
BMED Expo Poster Presentations	03/16/2020

Appendix 2: Morphology

Morphology				
Product: Left Atrial Appendage Printing Process		Organization Name : Left Atrial Appendage Team		
Function	Concept 1	Concept 2	Concept 3	Concept 4
Determining face to print	Use biological markers to find face to slice	Use coordinate system to find face to slice	Use judgement	
Converting to PR file	Straight from CT file			
Extrude unnecessary features	Solidworks	Fusion		
Converting to STL file	Mimics	From given software	Solidworks	Fusion
Printing anatomical body	3D print whole heart	Trim image then 3D print only necessary parts		
Visibility	Transparent material/whole body	Split in half about the coronal plane	Split in half about the sagittal plane	1 whole body, mitral valve & tricuspid valves opened
Team member: Mia von Knorring		Team member: Brandon Mukai		Prepared by: Areli Reyes
Team member: Areli Reyes		Team member: Brandon Mukai		Checked by: Mia von Knorring
<i>The Mechanical Design Process</i> Designed by Professor David G. Ullman Copyright 2008, McGraw Hill Form # 15.0				

Appendix 3: Pugh Charts

Mia

Mia				
Issue: Choose a design/procedure to 3D print the left atrial appendage		Concept 1	Concept 2	Concept 3
Accuracy	40		0	-1
Easy of Use	20		1	1
Time	10		-1	1
Reproducibility	15		0	-1
Repeatability	15	Datum	0	-1
Total			0	-1
Weighted Total			10	-40
Issue: Choose a design/procedure to 3D print the left atrial appendage		Concept 2	Concept 1	Concept 3
Accuracy	40		0	-1
Easy of Use	20		1	1
Time	10		-1	1
Reproducibility	15		0	-1
Repeatability	15	Datum	0	-1
Total			0	-1
Weighted Total			10	-40
Issue: Choose a design/procedure to 3D print the left atrial appendage		Concept 3	Concept 2	Concept 1
Accuracy	40		1	1
Easy of Use	20		-1	-1
Time	10	Datum	-1	-1

Reproducibility	15		1	1
Repeatability	15		1	1
	Total		1	1
	Weighted Total		40	40

Areli

Areli				
Issue: Choose a design/procedure to 3D print the left atrial appendage		Concept 1	Concept 2	Concept 3
Accuracy	40		1	-1
Easy of Use	20		-1	1
Time	10		1	1
Reproducibility	15		1	1
Repeatability	15	Datum	1	1
	Total		3	3
	Weighted Total		60	20
Issue: Choose a design/procedure to 3D print the left atrial appendage		Concept 2	Concept 1	Concept 3
Accuracy	40		-1	-1
Easy of Use	20		-1	1
Time	10		-1	1
Reproducibility	15		-1	1
Repeatability	15	Datum	-1	1
	Total		-5	3
	Weighted Total		-100	20
		Concept 3	Concept 2	Concept 1

Issue: Choose a design/procedure to 3D print the left atrial appendage				
Accuracy	40	Datum	1	-1
Easy of Use	20		-1	-1
Time	10		1	-1
Reproducibility	15		1	-1
Repeatability	15		1	-1
Total			3	-5
Weighted Total			60	-100

Brandon

Brandon				
Issue: Choose a design/procedure to 3D print the left atrial appendage		Concept 1	Concept 2	Concept 3
Accuracy	40	Datum	1	-1
Easy of Use	20		1	-1
Time	10		1	1
Reproducibility	15		1	-1
Repeatability	15		1	0
Total			5	-2
Weighted Total			100	-65
Issue: Choose a design/procedure to 3D print the left atrial appendage		Concept 2	Concept 1	Concept 3
Accuracy	40	Datum	-1	-1
Easy of Use	20		-1	-1
Time	10		-1	-1

Reproducibility	15		-1	1
Repeatability	15		-1	1
	Total		-5	-1
	Weighted Total		-100	-40
Issue: Choose a design/procedure to 3D print the left atrial appendage		Concept 3	Concept 2	Concept 1
Accuracy	40		1	1
Easy of Use	20		1	0
Time	10		1	0
Reproducibility	15		1	-1
Repeatability	15	Datum	1	-1
	Total		5	-1
	Weighted Total		100	10

Appendix 4: Manufacturing Process Instructions (MPI)

Slicing Procedure

1: Upload DICOM File into 3D Slicer

1.1: Select “Load DICOM Data” shown in Figure 1.

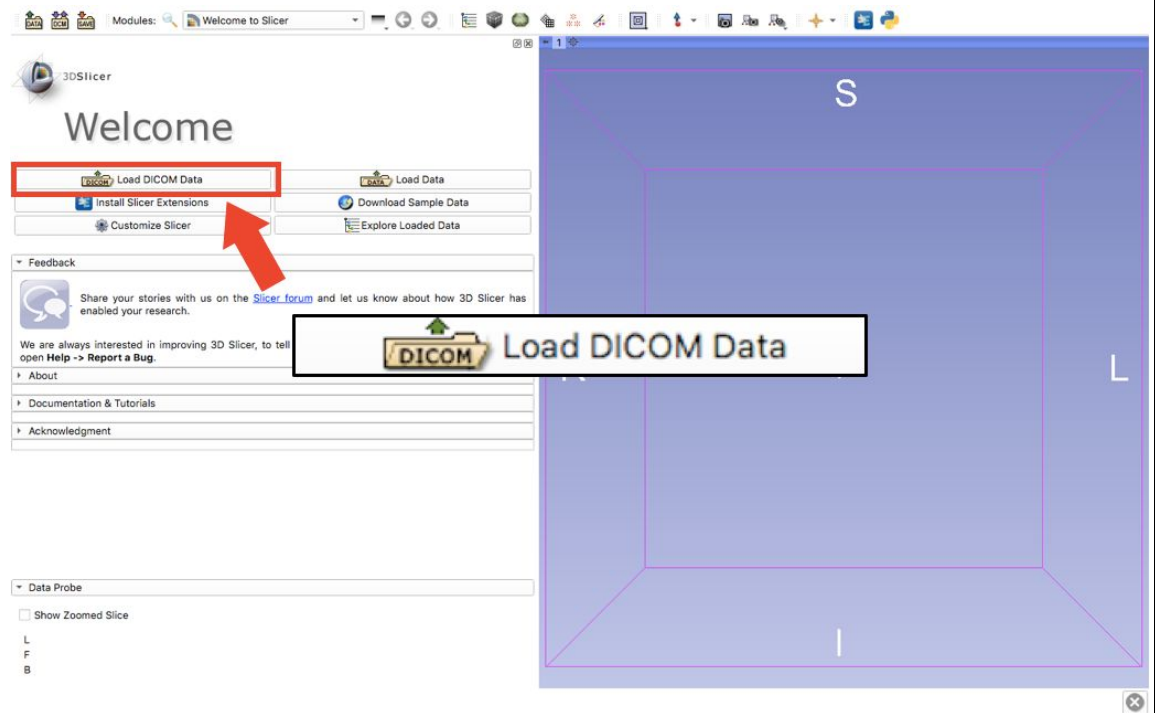


Figure 1

1.2: Select “Import” shown in Figure 2

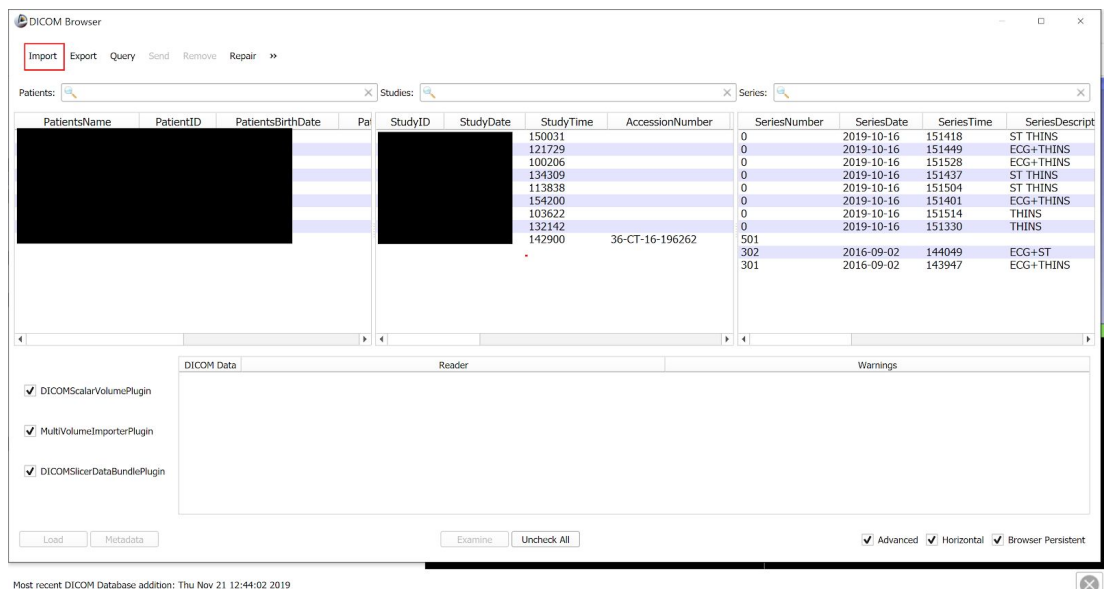


Figure 2

1.3: This menu brings you to the files on the computer, navigate your files and select the folder that contains all the DICOM files for the patient as shown in Figure 3.

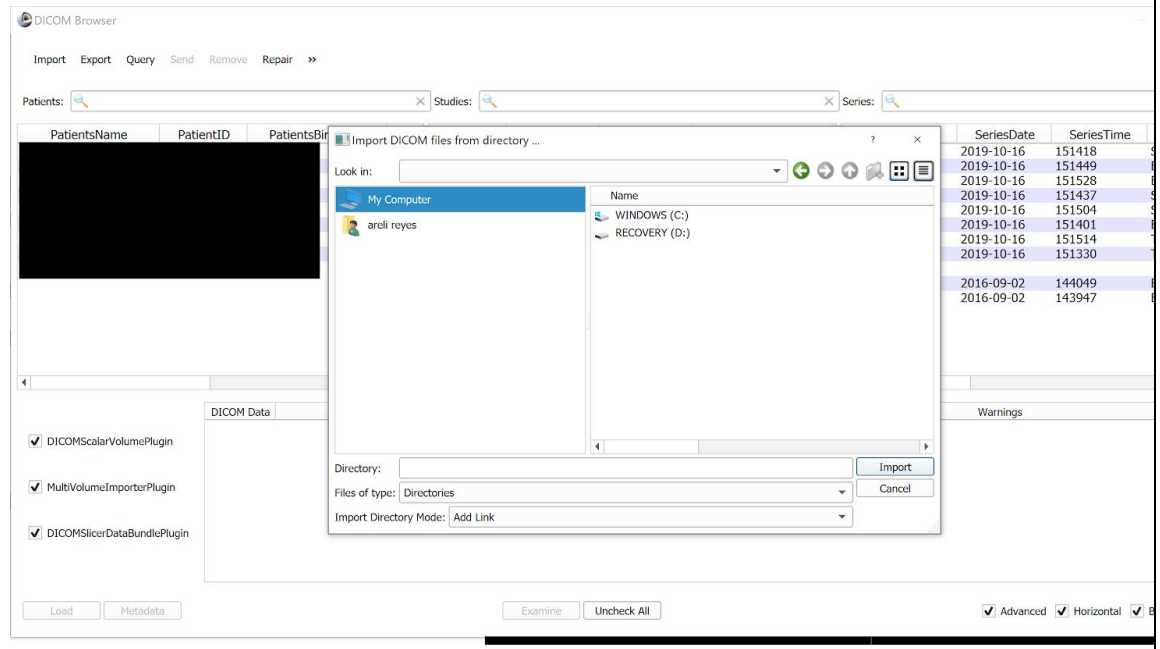


Figure 3

1.4: Your patient will populate the first row of the list, select that row until your patient is highlighted blue. Select “Load” to finish importing the file as shown in Figure 4.

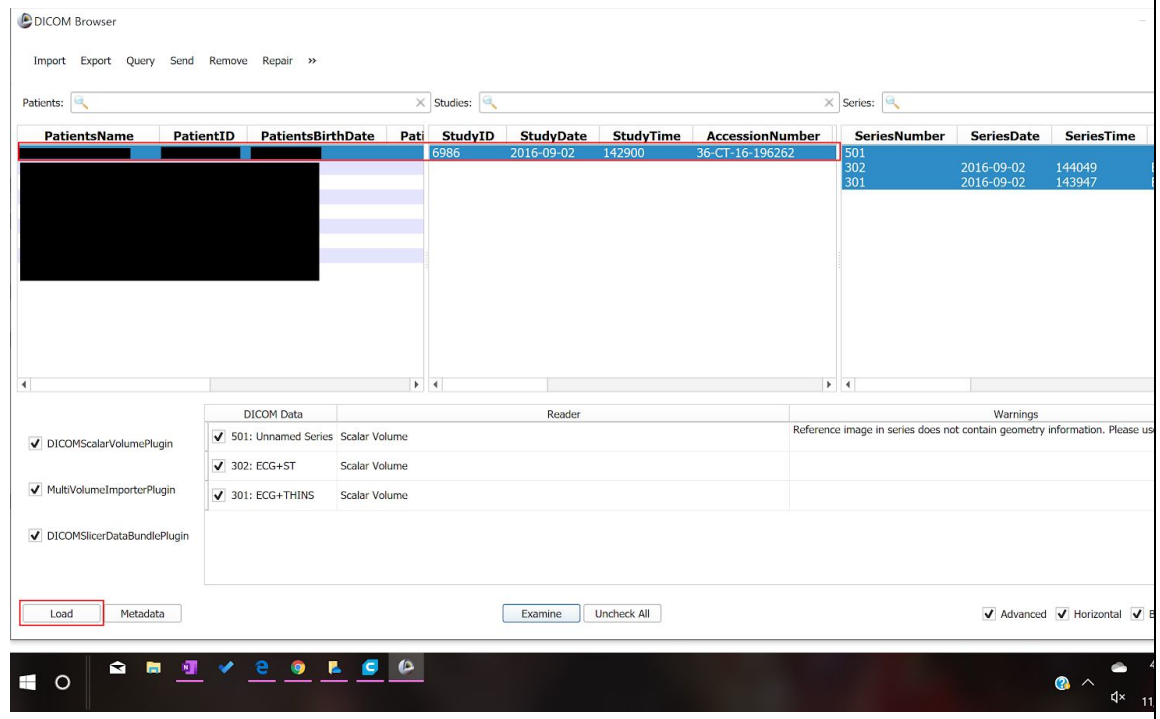


Figure 4

1.5: A warning will come up, go ahead and ignore it and select “OK” shown in Figure 5.

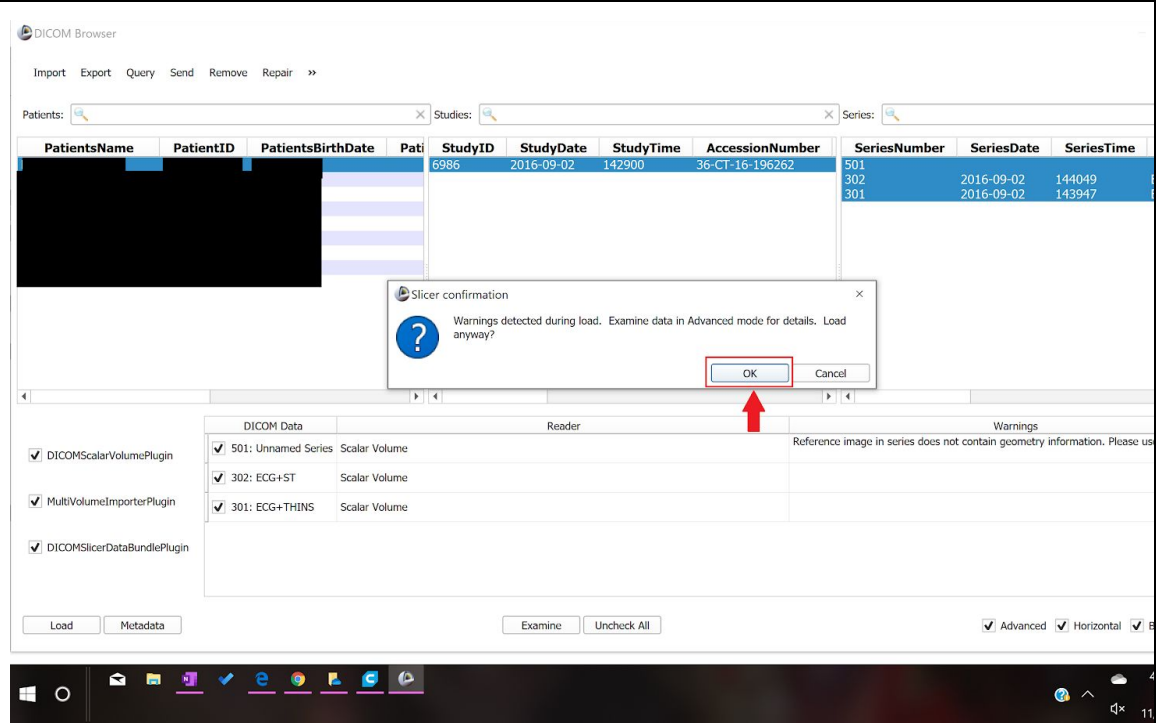


Figure 5

1.6: The DICOM files of the patient will now populate the screen as shown in Figure 6. Figure 7 displays a labeled view of the four screens that we will be focusing on for the rest of the tutorial.

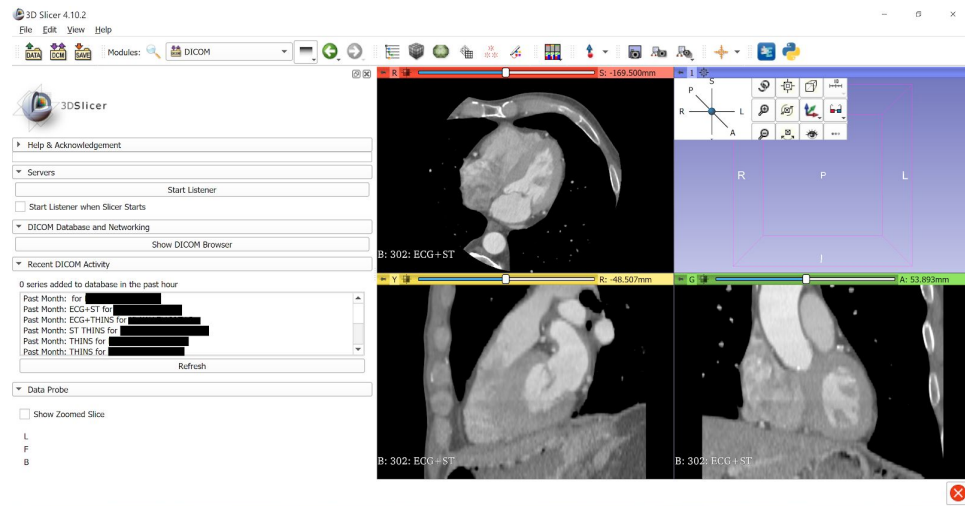


Figure 6

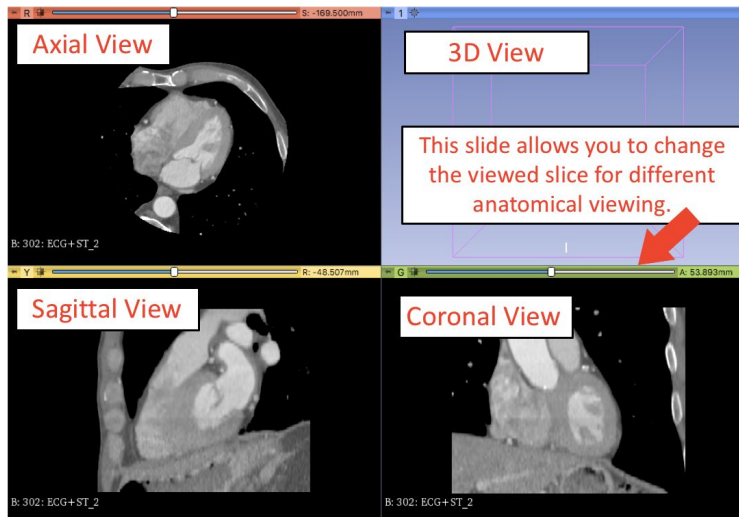


Figure 7

2: Select the drop down error shown below, select “All Modules,” shown in Figure 8 and select “Segment Editor” shown in Figure 9.

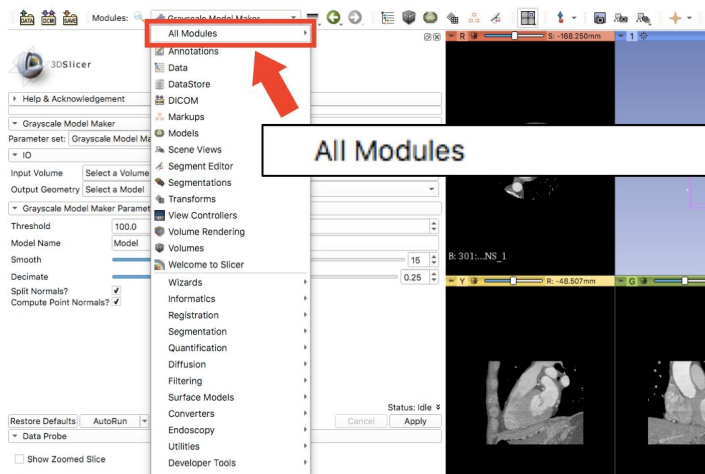


Figure 8

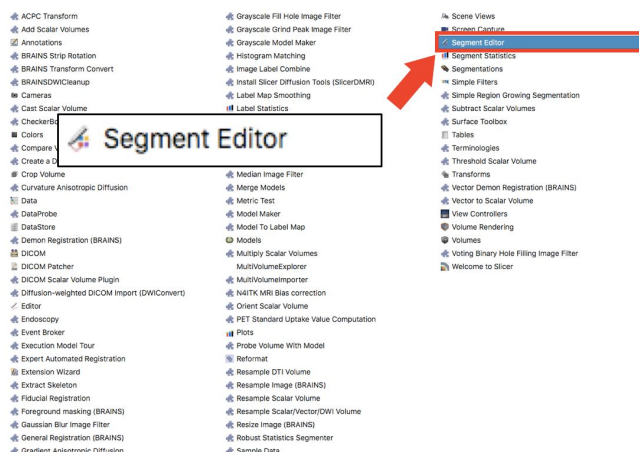


Figure 9

3: Change Image Threshold.

In order to make a 3D model from the numerous slices contained in the DICOM files, the segment editor will be used for editing and cropping to only select the left atrium and the left atrial appendage. The tools in the segment editor that will be used are “Threshold”, “Scissors” and “Hollow”.

3.1: Select “Add” as shown in Figure 10.

3.1.1: Select “Threshold” from the “Effects” menu shown in Figure 11.

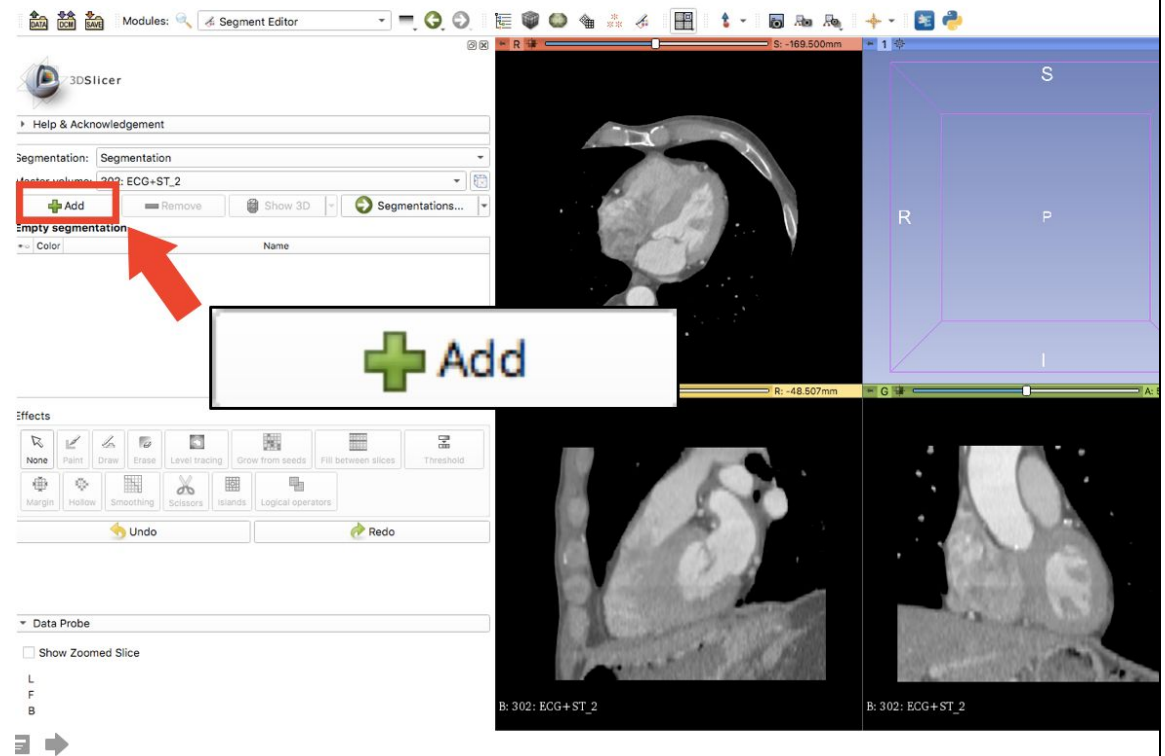


Figure 10

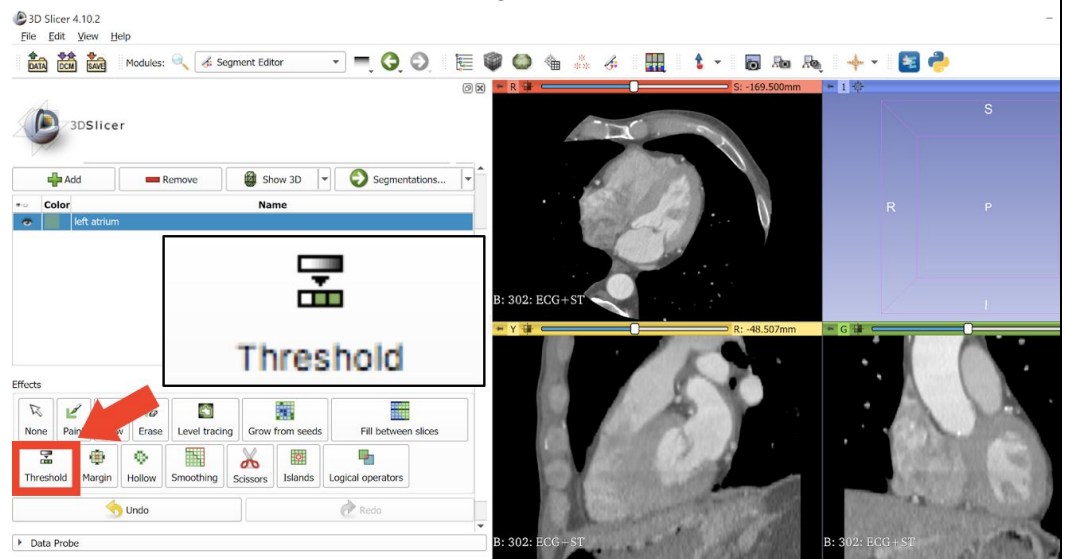


Figure 11

3.2: The menu for “Threshold” appears as seen below. Adjust your settings to match those shown in Figure 12. Select “Apply” when this range is selected.

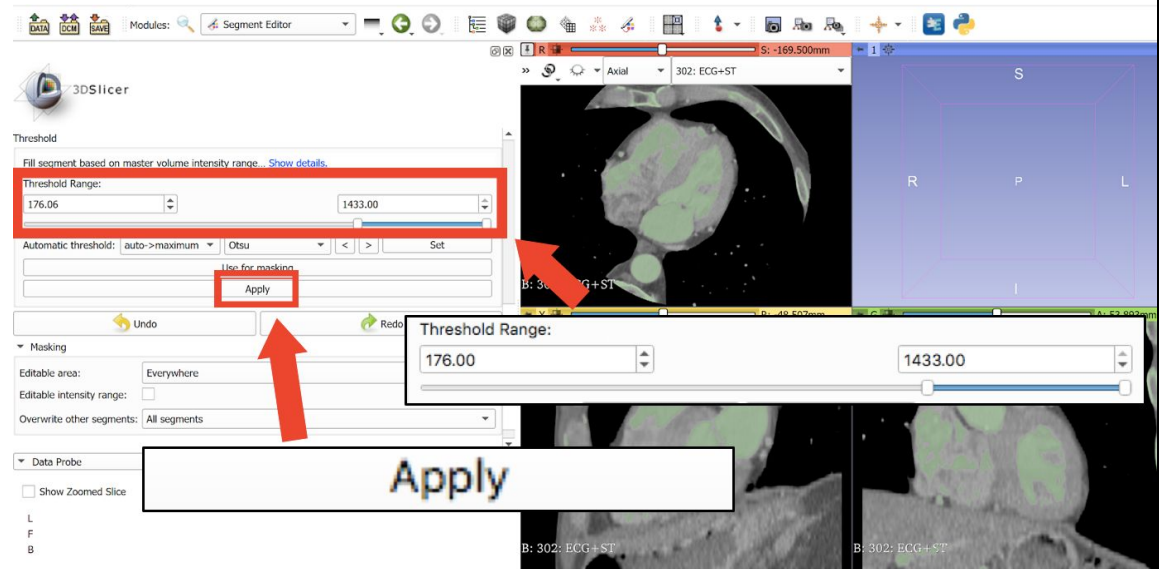


Figure 12

3.3: Change the slice in the “Axial” view so that the left atrium and the left atrial appendage can be clearly seen as shown in Figure 13. Use the slider at the top of the Axial view to change the slice.

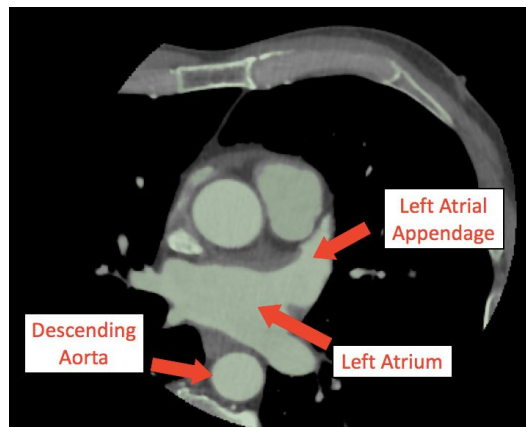


Figure 13

4. Crop out unnecessary anatomy from 2D view.

4.1: Select “Scissors” and change “Scissor” parameters to match the ones shown in this tutorial. Crop around the left atrium, left atrial appendage, and descending aorta by dragging the mouse around the needed anatomy. The descending aorta will be used for reference later on. The necessary anatomy can be cropped as shown in the yellow outline in Figure 14.

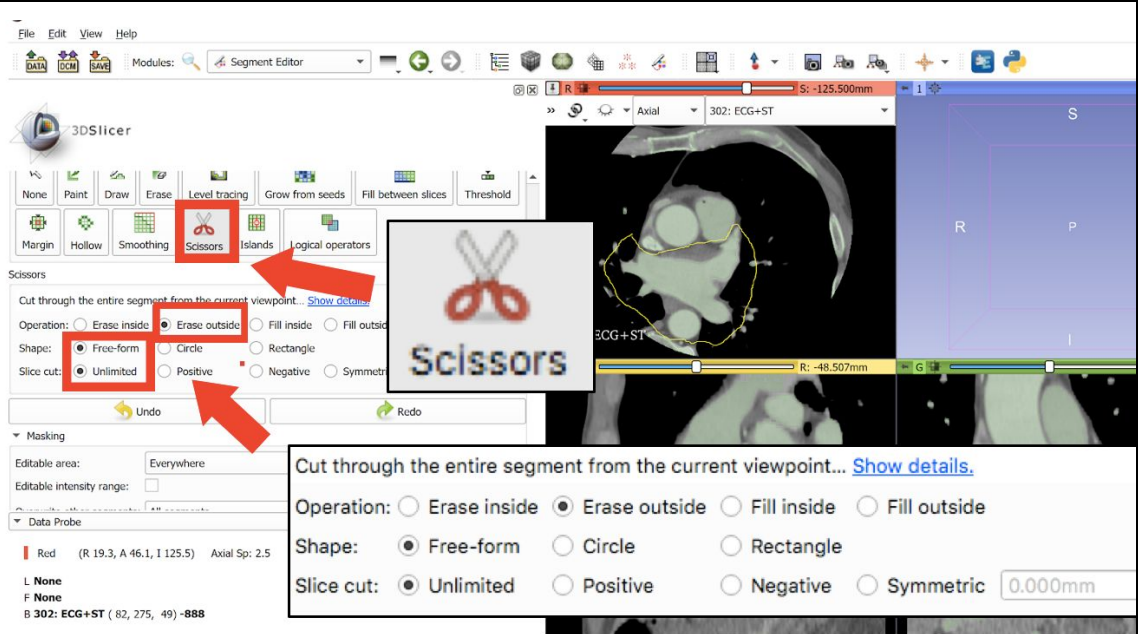


Figure 14

4.2: Select “Show 3D” shown in Figure 15.

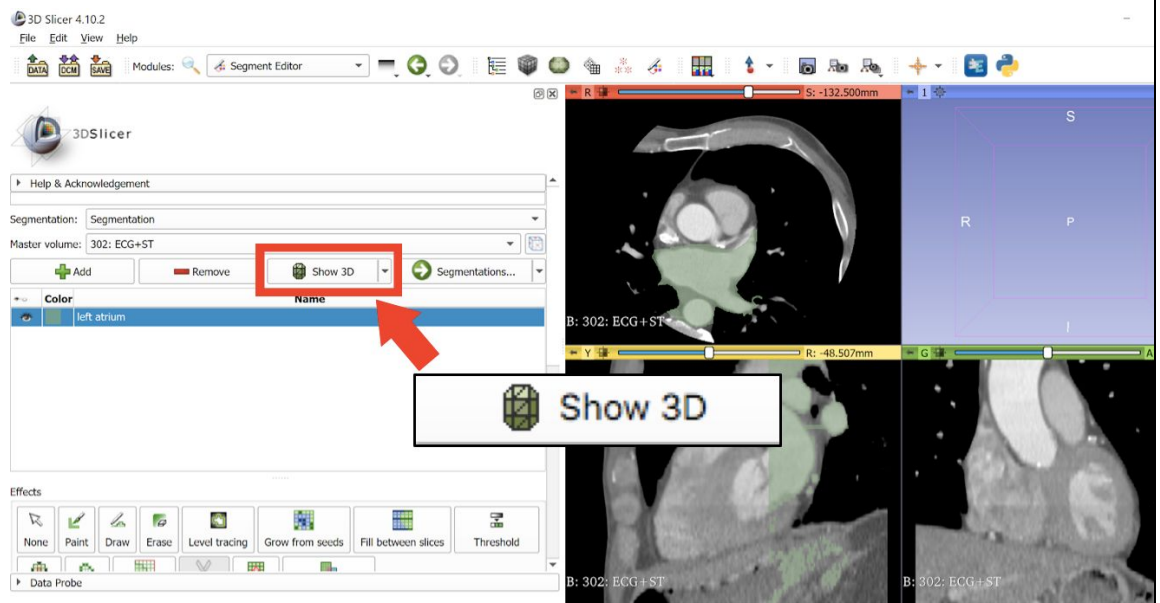


Figure 15

4.3: The 3D model shows up in the upper right quadrant. Select the “Viewer” drop down menu highlighted in Figure 16 and select “3D only” to only view the 3D image. The 3D image populates the entire screen as shown in Figure 17 for further cropping in the 3D view.

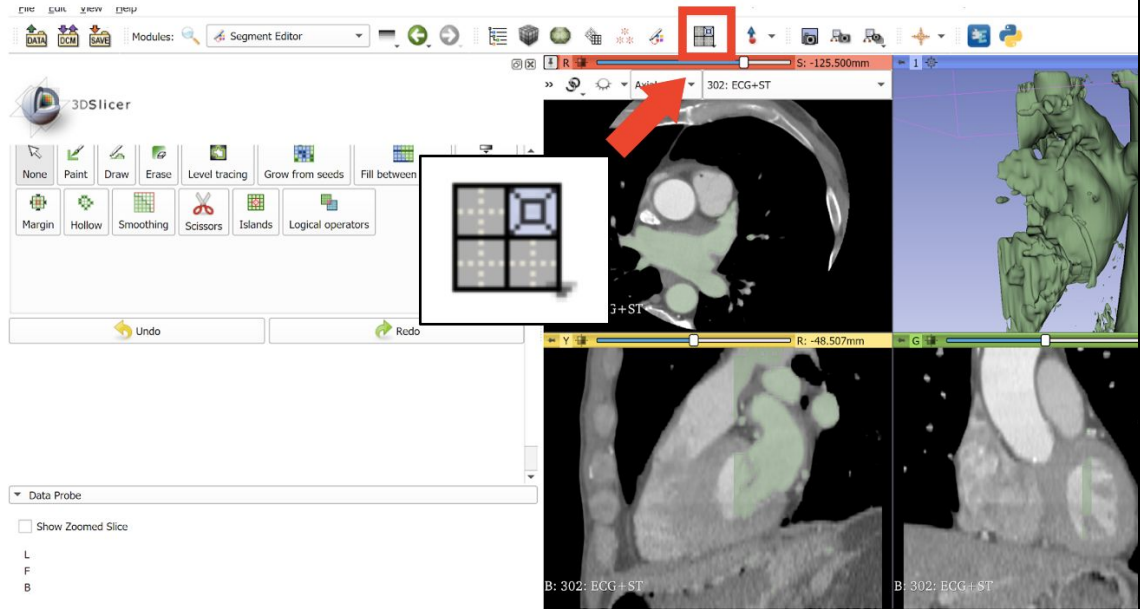


Figure 16

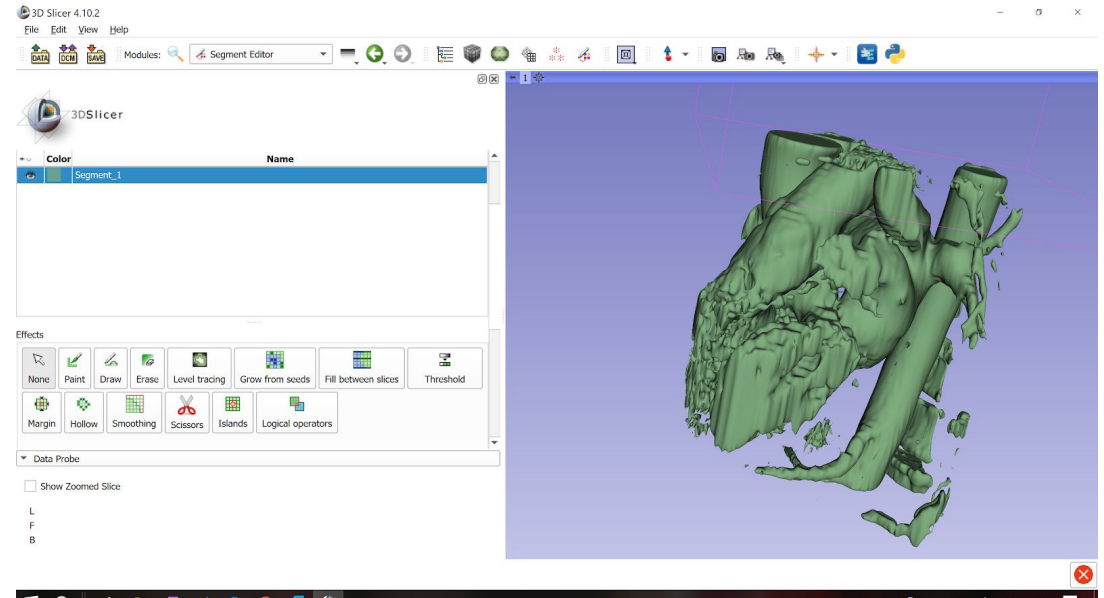


Figure 17

5: Crop unnecessary anatomy from 3D model.

5.1: Select “Scissors” and crop out unnecessary anatomy. Set scissors to crop “inside” shown in Figure 18.

Note: If pulmonary artery is touching the left atrial appendage, be sure to crop out.

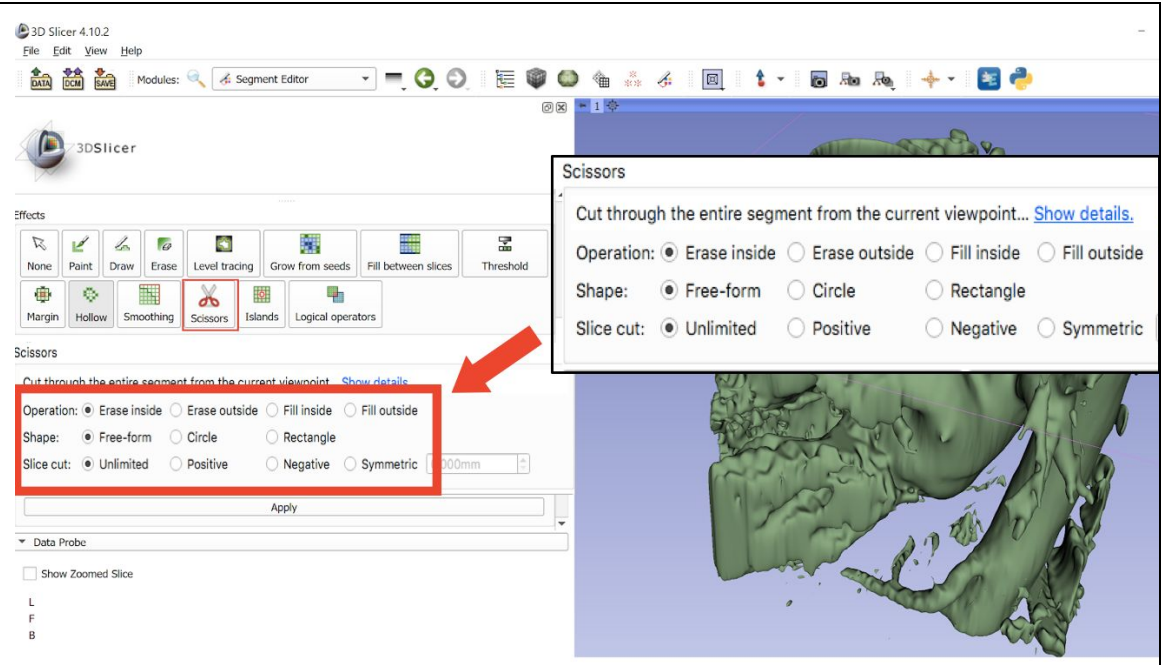


Figure 18

5.2: Identify anatomy. The left atrium can be identified to the left of the descending aorta when looking from the posterior view, behind the esophagus.

5.3: Use “Scissors” to crop the descending aorta out. Cropping is done by dragging the mouse around unnecessary anatomy.

Note: All anatomy inside the “Scissor” will be cropped. Use the “Normal” effect to rotate the image to crop proper anatomy.

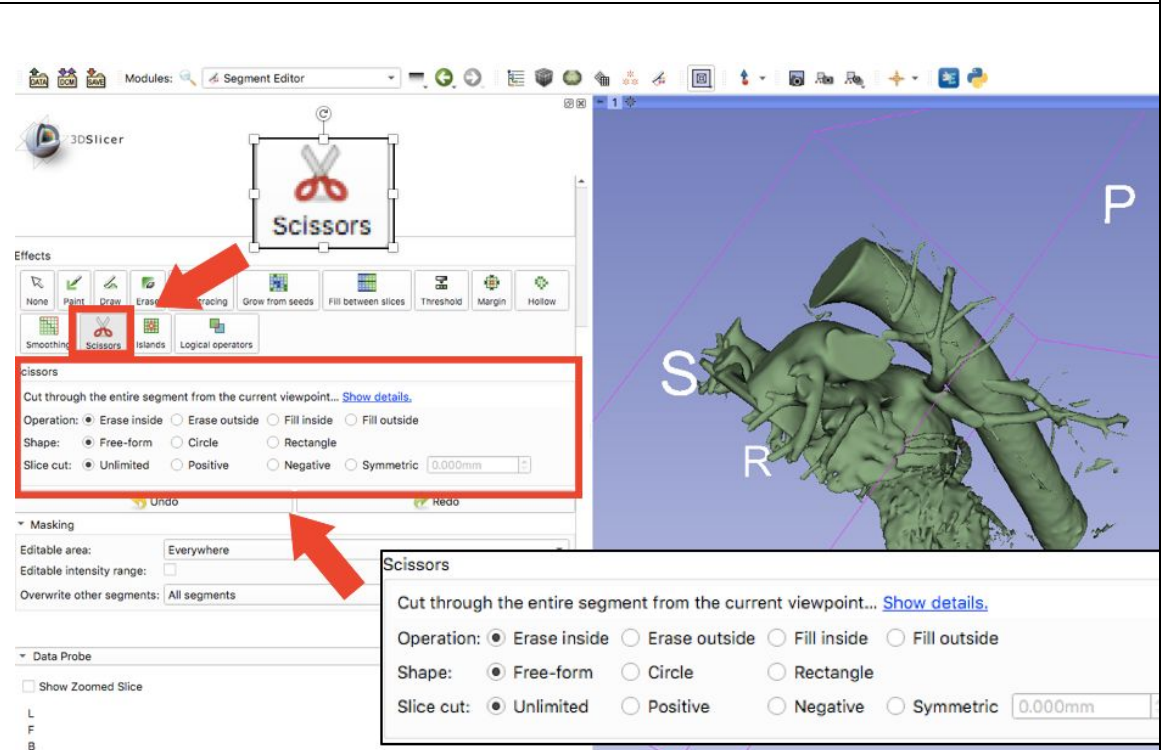


Figure 19

5.4: Continue to crop until you have a simple geometry left that still shows the left atrial appendage and the left atrium. Figure 20 displays this anatomy. Note: When cropping, consider cropping a top portion of the left atrium to have for viewing the left atrial appendage from the inside.

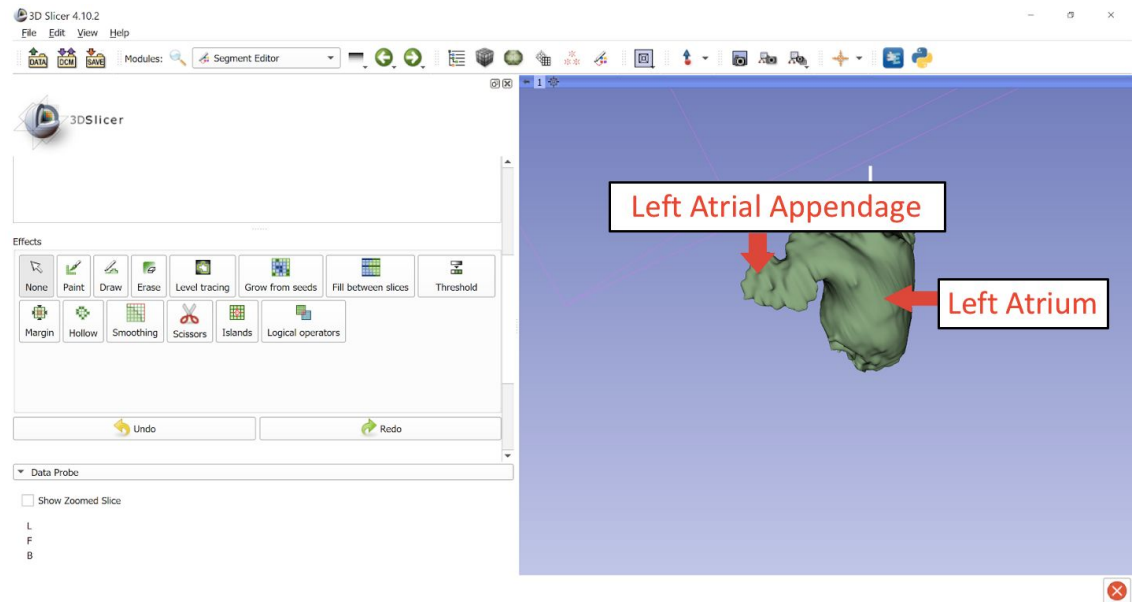


Figure 20

6: Hollow the body.

6.1: Select “Hollow” to be able to see cavities. Select “Hollow” parameters to match the ones shown in Figure 21 and select “Apply”.

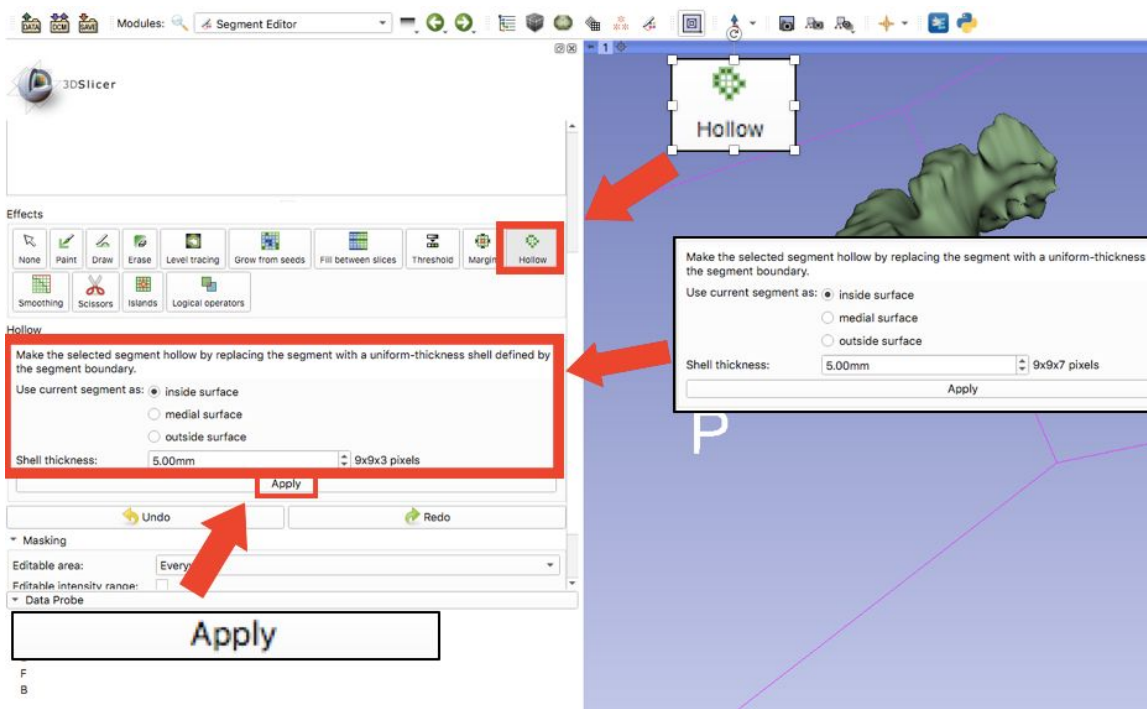


Figure 21

7. Save the model.

7.1: Click on “Segmentations”

shown in Figure 22. A drop down menu will appear. In that drop down menu select “Export to Files...”

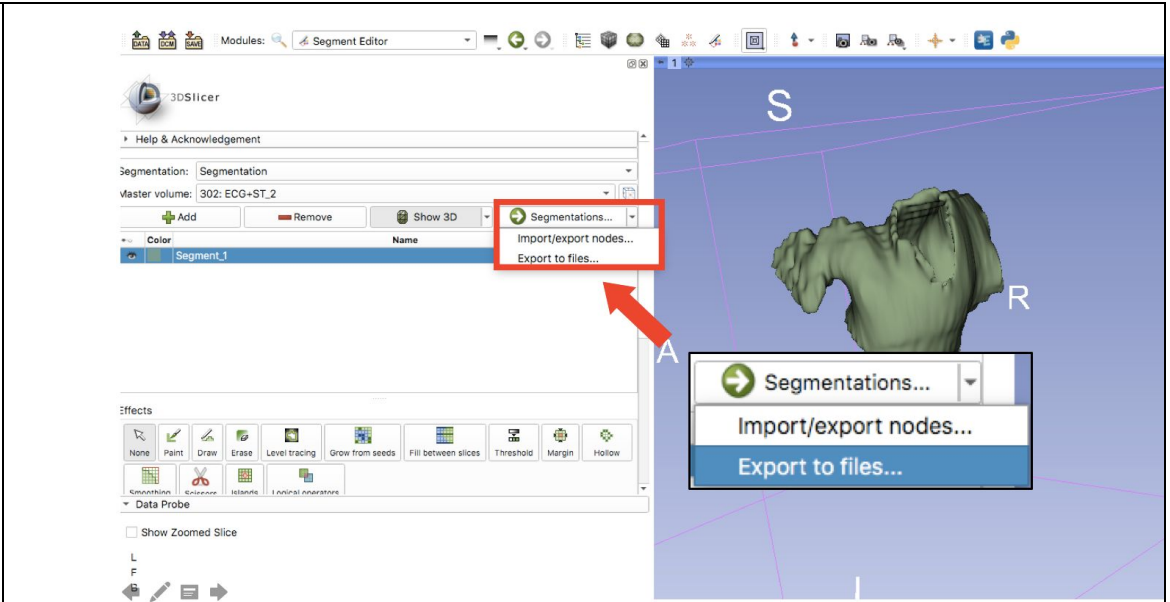


Figure 22

7.2: After selecting “Export to Files...” select a Destination Folder shown in Figure 23. Chose file format “STL”. Select export.

Note: We advise you to select a folder that contains this particular patient’s files.

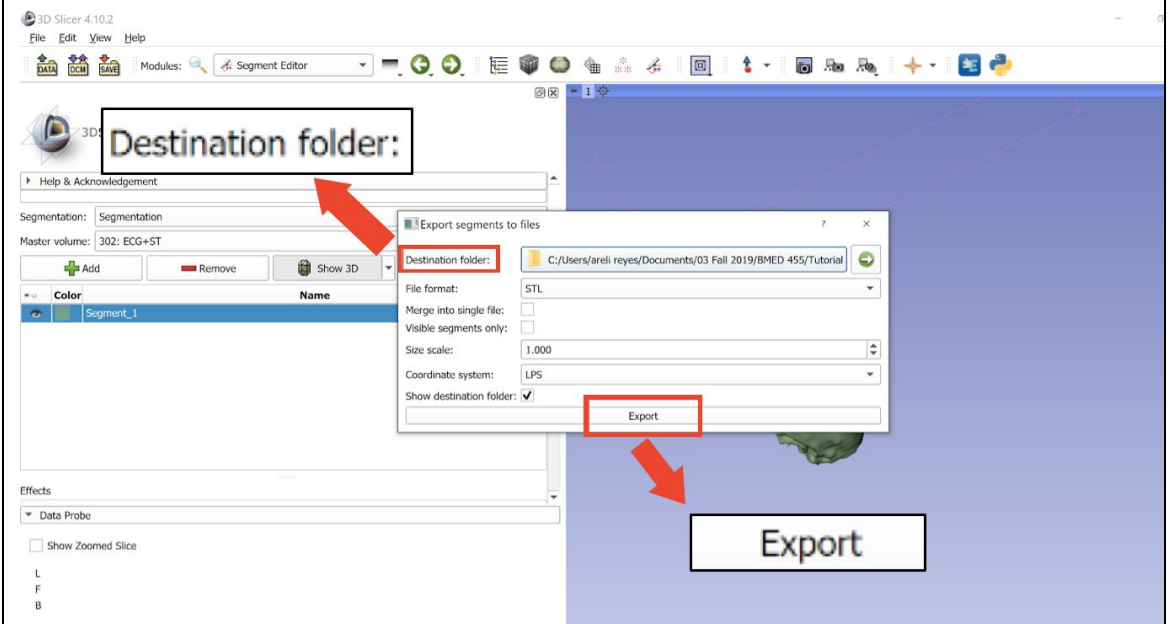


Figure 23

Printing Procedure

8: Upload the STL file to the Ultimaker Cura program shown in Figure 24.

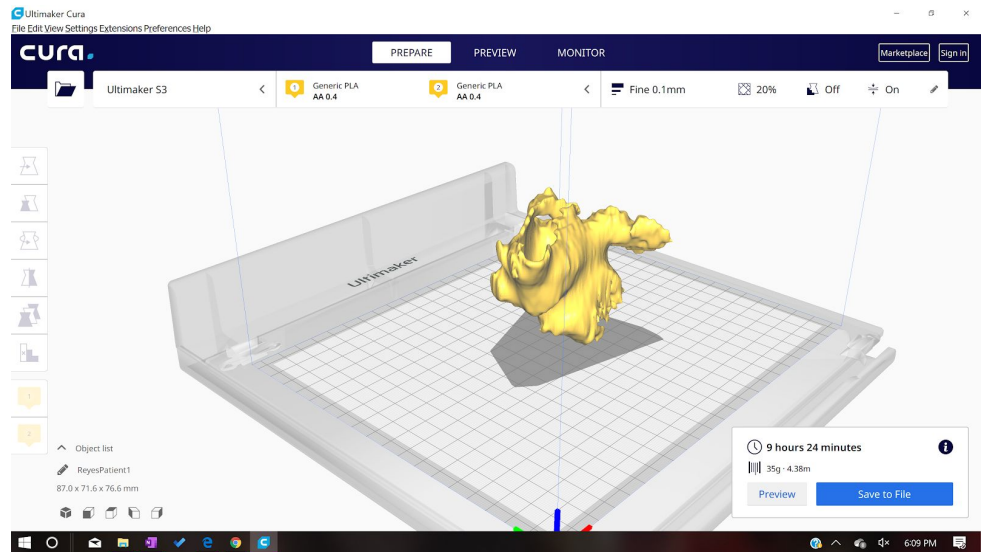


Figure 24

8.1: Define all parameters as shown in Figure 25.

- Infill
- Quality
- Shell
- Material
- Speed
- Cooling
- Support material
- Build Plate Adhesion

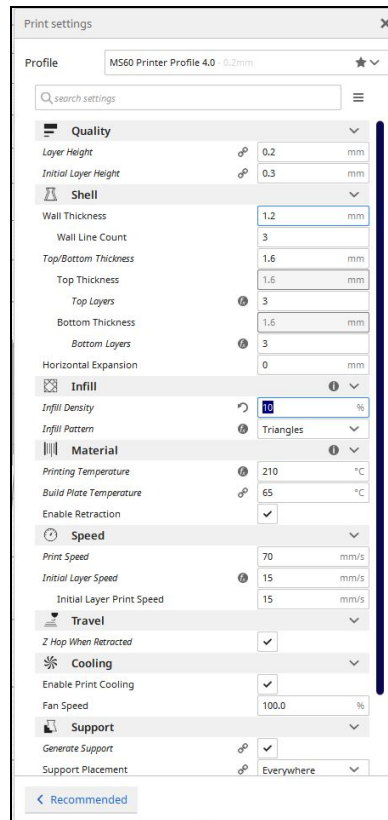


Figure 25

9: Upload file to printer and modify settings.

9.1: Load filament into machine.

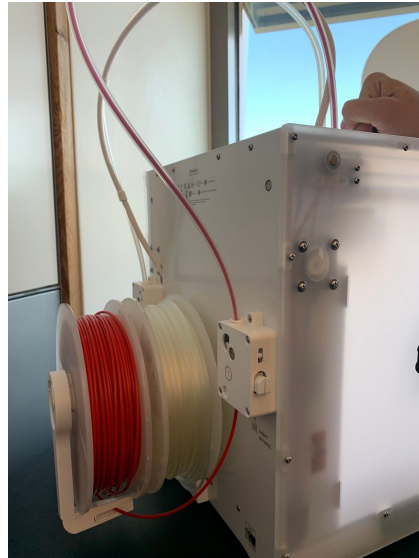


Figure 26

9.2: Press “Bed”-”Heat” to heat up the system.

9.2.1: Check temperature of nozzle and plate by pressing “Bed/Extrude” on the printer panel.

9.2.2: Press “Print”- find file (file will have settings listed first then file name).

9.2.3: Confirm “Yes”.

9.2.4: Wait for plate to finish heating up and clear any extra plastic from platform

10: Wait for the first layer of print to be printed before leaving print alone. Allow printer 1.5x estimated time to print
Note: This is important to ensure the print will print appropriately because most failures occur in the first layer if they were to occur.

11: Remove print from platform and remove any support brims.
Note: Clean printing platform properly after print is removed.

Post Processing Procedure

12: After you have removed the print off the printing bed, there will be excess PVA to remove before you can use the model for sizing.



Figure 27

13: Fill a sink or tub with hot water to submerge the print.



Figure 28

14: Ensure that there are no air bubbles in the model before you leave it.



Figure 29

14.1: Position the model so that the opening of the model is on the bottom surface of the sink. (This is so all the PVA that dissolves rests into the sink rather than the cavity of the model.)

*May need to weigh it down as seen in the photo.



Figure 30

14.2: After allowing the model to bathe for 30 min, rinse model, prepare a new bath, and re submerge for 20 minutes. (This is to ensure all the PVA is being removed.)



Figure 31



Figure 32

14.3: After allowing the model to bathe for 30 min, rinse model, prepare a new bath, and re submerge for 20 minutes. (This is to ensure all the PVA is being removed.)



Figure 33



Figure 34



Figure 35

15: Return in 30 minutes and remove the rest of the PVA off model with fingers or brush, ensure you are emptying the cavity.



Figure 36

Appendix 5: Operation Manual

This guide is intended to show the user what is occurring as they are going through this process. 3D slicer is a free software used to analyze CT scans and create 3D models from stacked 2D images.

After inserting the patient's CT scan, four windows will be populated. You as the user can change the view. But by default, the top left window shows the axial view, the bottom left window shows the sagittal view, the right bottom window shows the coronal view, and the top right window will later show your 3D model after you segment your CT scan images.

The first tool you will be using to begin segmenting and isolating your left atrium and left atrial appendage is the *threshold tool*. The threshold tool distinguishes anatomical features from each other through each anatomical body's pixel density. The threshold range recommended has been found to contrast each cavity from surrounding tissue the best.

The second tool used is the *scissors tool*. The tool is used to continue isolating the left atrium and left atrial appendage before generating the 3D model decrease necessary editing in the 3D view. The scissors tool allows you to erase outside or inside of the enclosed area. The scissors can be used in all three views, which is advised so you can make sure you are not cutting out parts of your target geometry. Note: The clearest view of the left atrium and appendage can be found in the axial view so always use this view as your datum.

The third tool needed is *show geometry*. Show geometry will generate a 3D model of the heart you have isolated by using the threshold and scissors tools in the 2D views. This tool stacks all the CT slices in all three axis and meshes them together to create a model.

The scissors tool is then used again in the 3D view to remove the anatomical features outside of the left atrium. Like before, the scissors tool can be used to erase outside or inside of the enclosed area. It's important that you change the orientation of the model to make sure a necessary anatomy isn't sitting behind the anatomy you are removing because it will be removed as well.

The *hollow tool* creates a uniform thickness shell around the cavity you want to enclose. The body you currently have is the hollow space inside of the left atrium and left atrial appendage, what you can get with the hollow tool is the negative of this space to now have a shell around the cavity. This shell encloses the cavity as the myocardium but does not play as an accurate representation of the myocardium surrounding the cavity as it is uniform and not the thickness of the tissue\

Appendix 6: Training Guide

Slicing Procedure

1: Upload DICOM File into 3D Slicer.

1.1: Select “Load DICOM Data” shown in Figure 1.

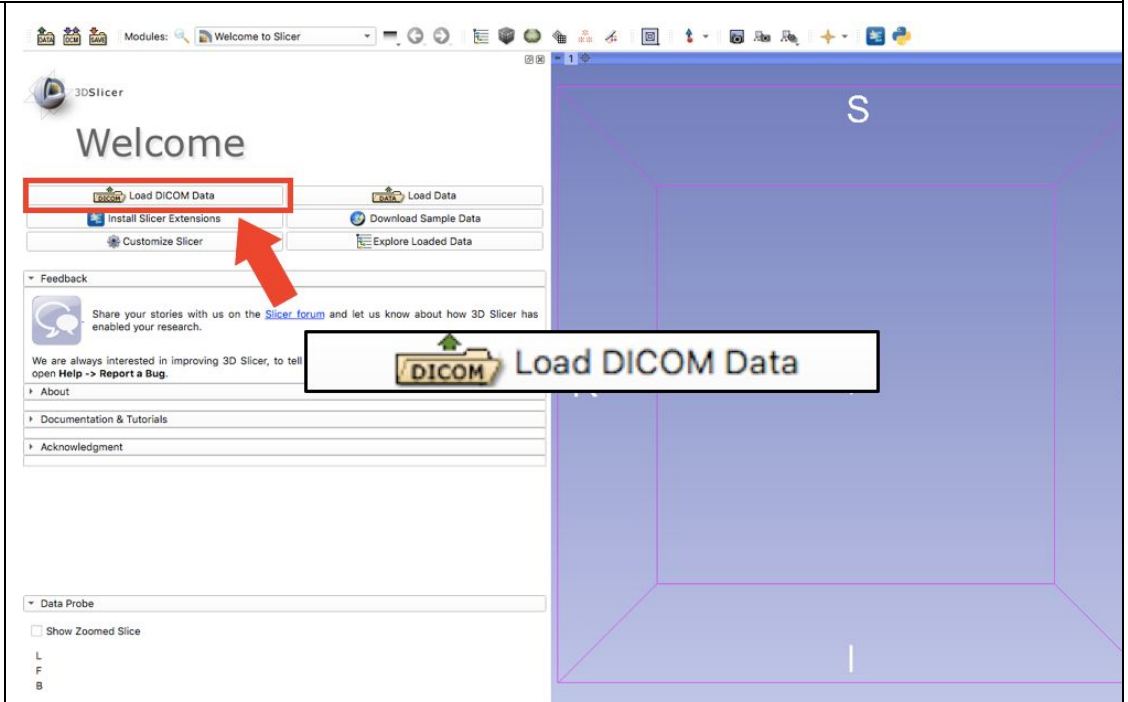


Figure 1

1.2: Select “Import” shown in Figure 2.

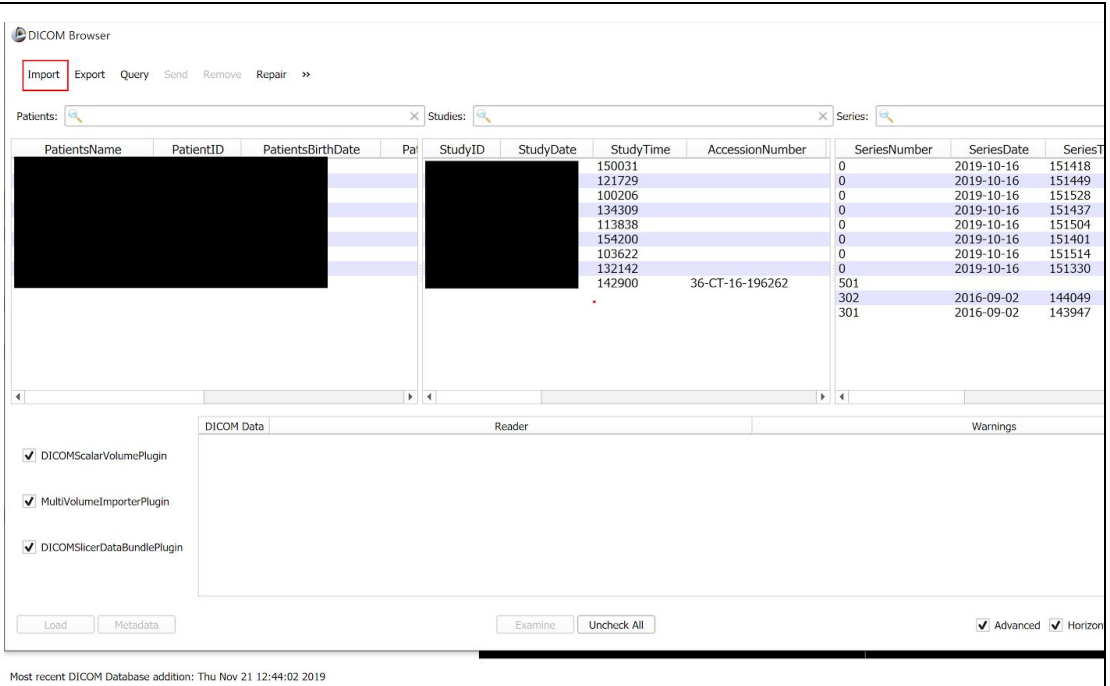


Figure 2

2.1: This menu brings you to the files on the computer, navigate your files and select the folder that contains all the DICOM files for the patient as shown in Figure 3.

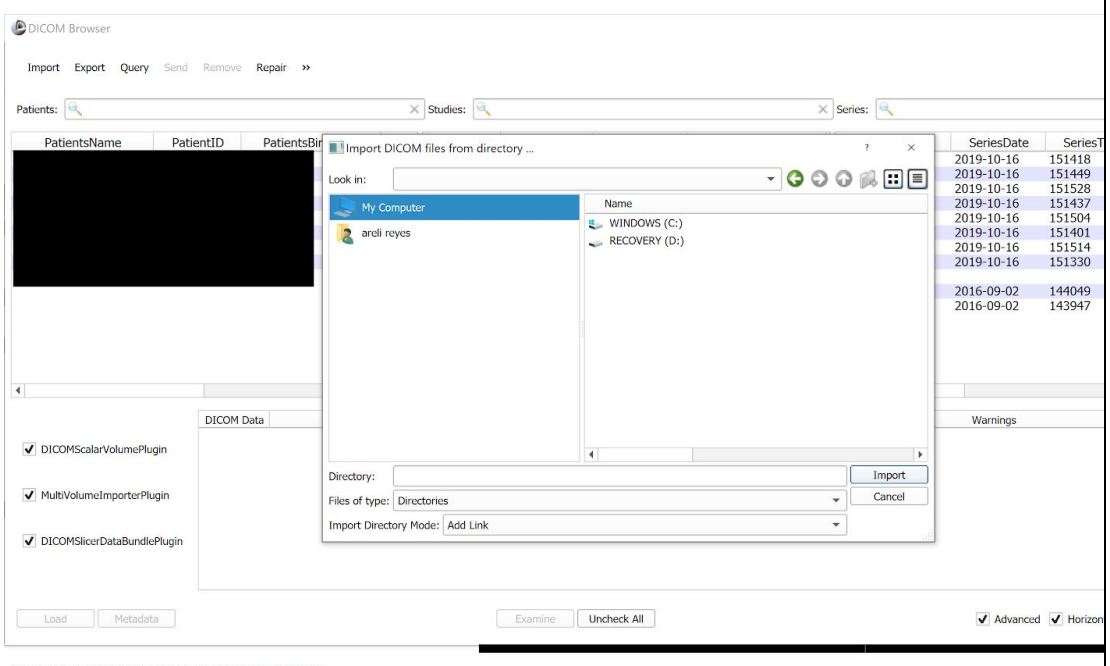


Figure 3

2.2: Your patient will populate the first row of the list, select that row until your patient is highlighted blue. Select “Load” to finish importing the file as shown in Figure 4.

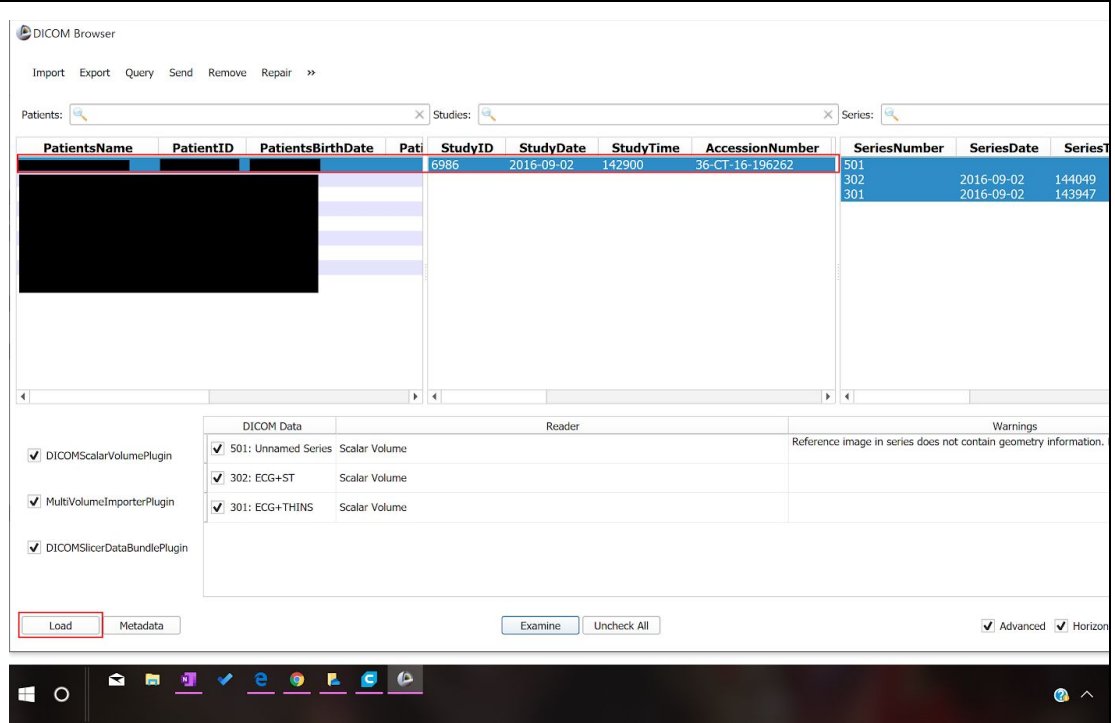


Figure 4

2.3: A warning will come up, go ahead and ignore it and select “OK” shown in Figure 5.

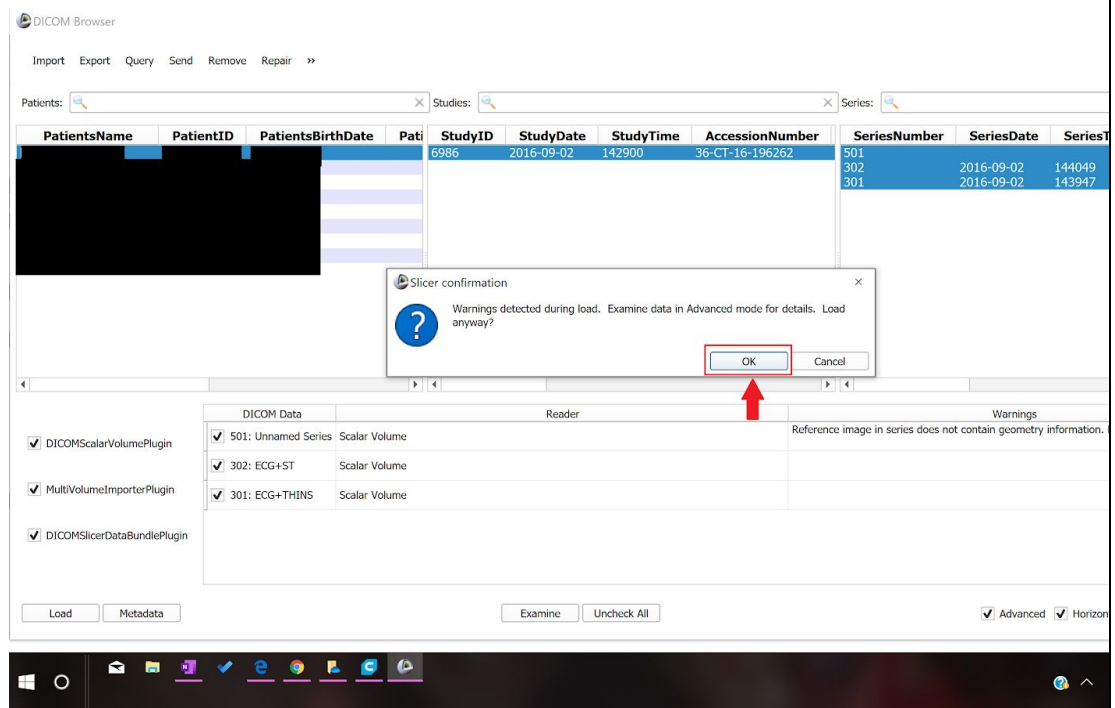


Figure 5

2.4: The DICOM files of the patient will now populate the screen as shown in Figure 6. Figure 7 displays a labeled view of the four screens that we will be focusing on for the rest of the tutorial.

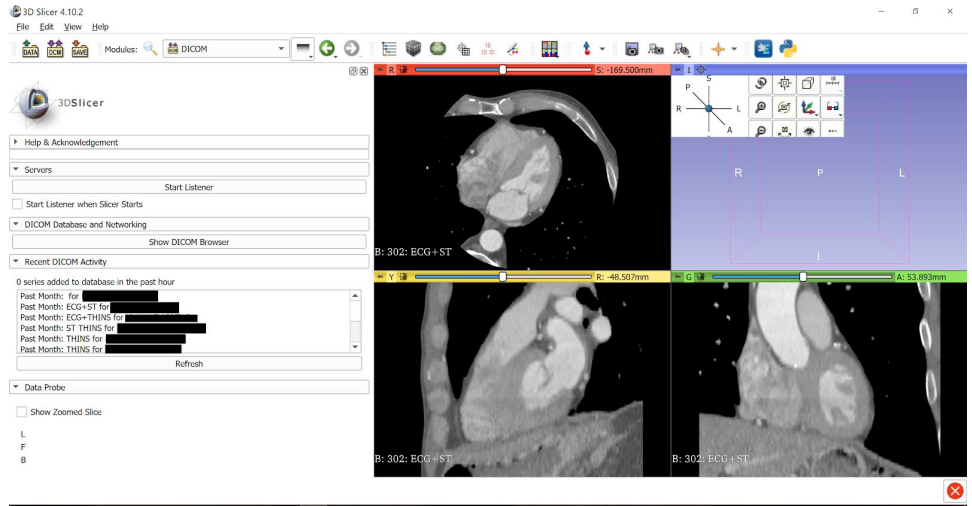


Figure 6

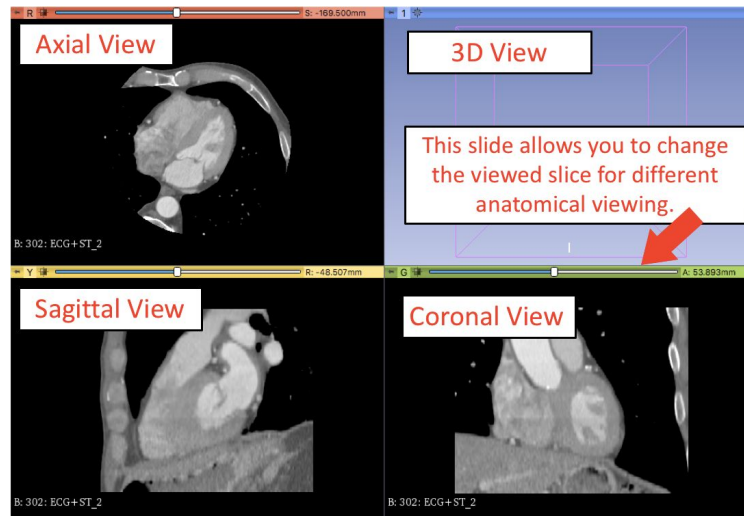


Figure 7

3: Select the drop down error shown below, select “All Modules,” shown in Figure 8 and select “Segment Editor” shown in Figure 9.

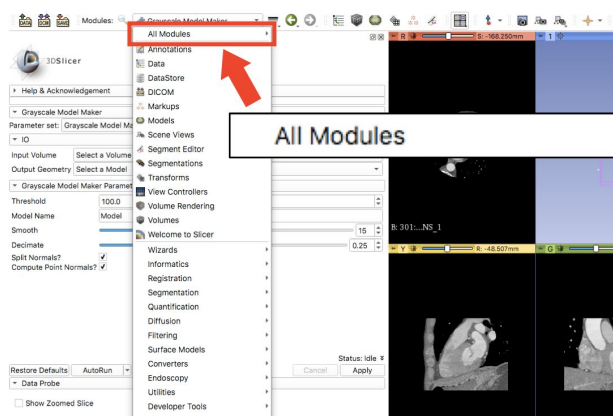


Figure 8

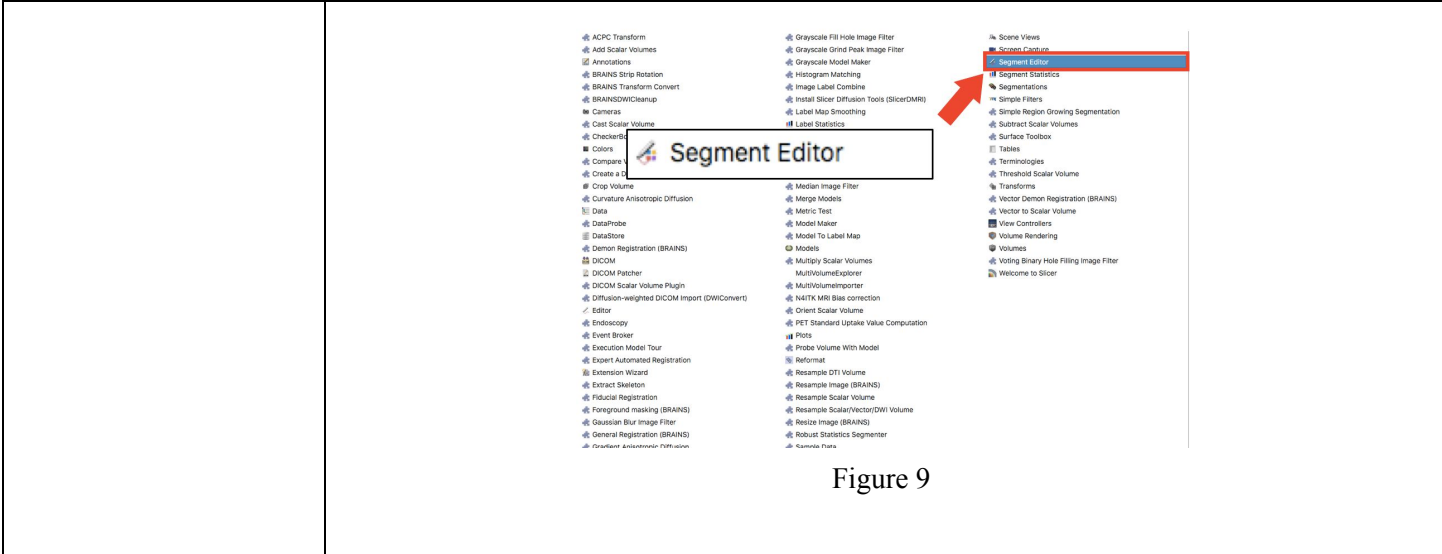


Figure 9

4: Change Image Threshold.

In order to make a 3D model from the numerous slices contained in the DICOM files, the segment editor will be used for editing and cropping to only select the left atrium and the left atrial appendage. The tools in the segment editor that will be used are “Threshold”, “Scissors” and “Hollow”.

4.1: Select “Add” as shown in Figure 10.

4.2: Select “Threshold” from the “Effects” menu shown in Figure 11.

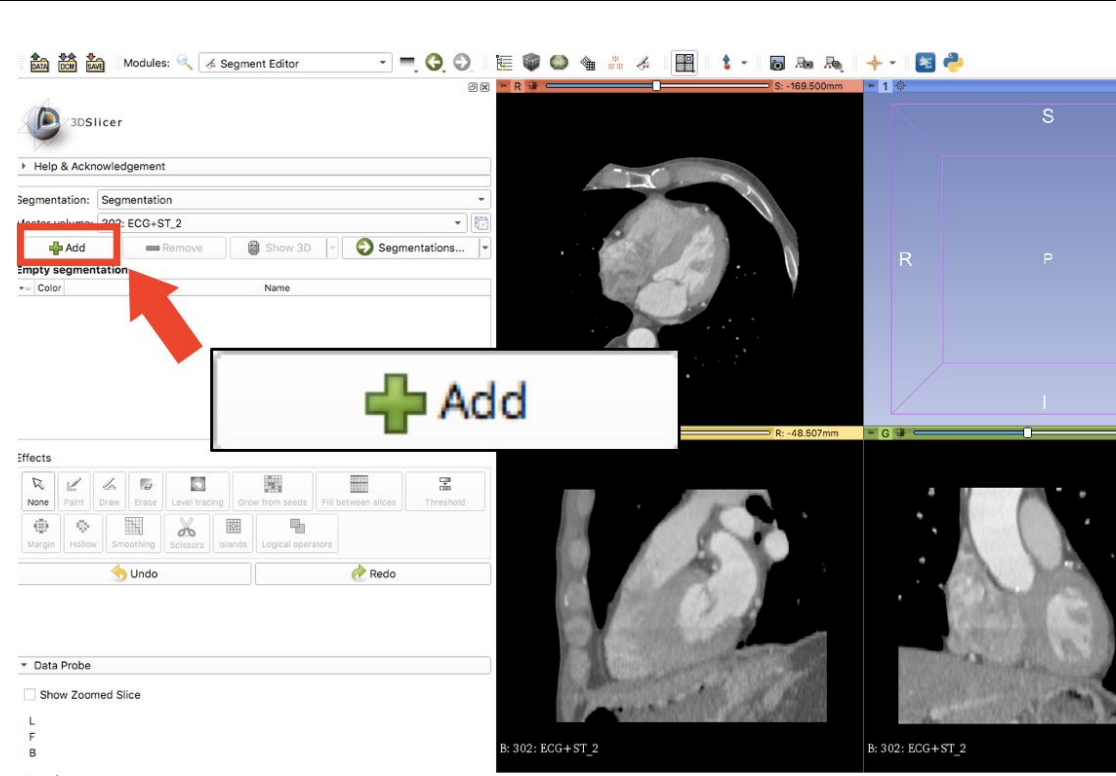


Figure 10

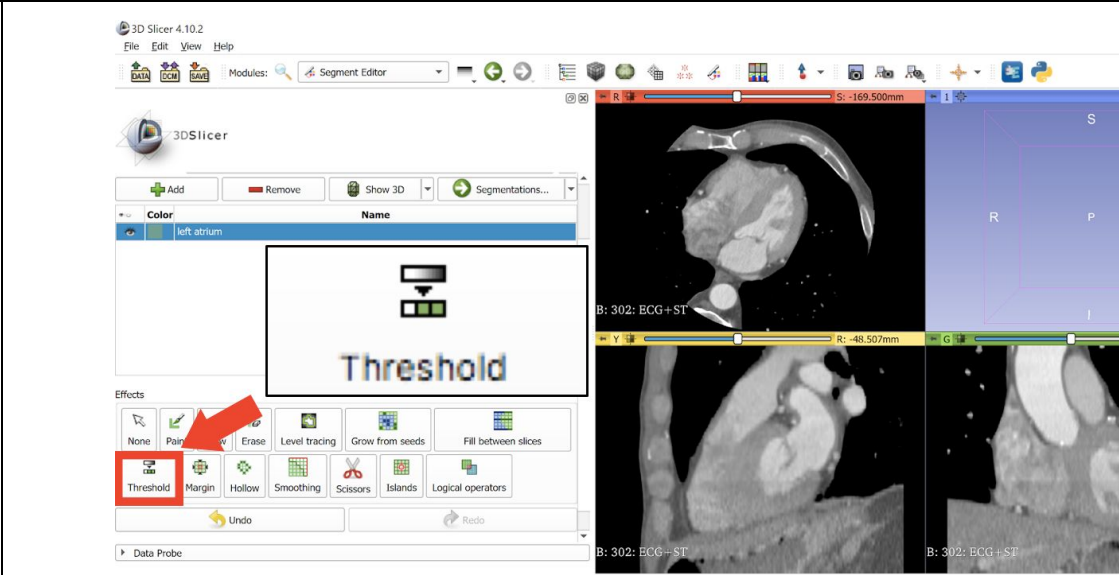


Figure 11

4.3: The menu for “Threshold” appears as seen below. Adjust your settings to match those shown in Figure 12. Select “Apply” when this range is selected.

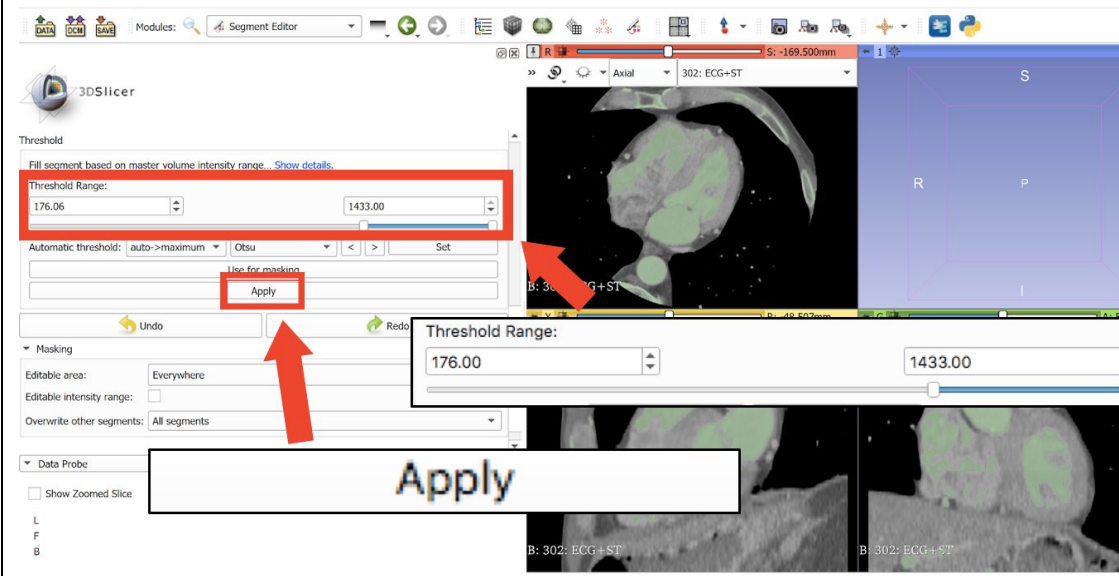


Figure 12

4.4: Change the slice in the “Axial” view so that the left atrium and the left atrial appendage can be clearly seen as shown in Figure 13. Use the slider at the top of the Axial view to change the slice.



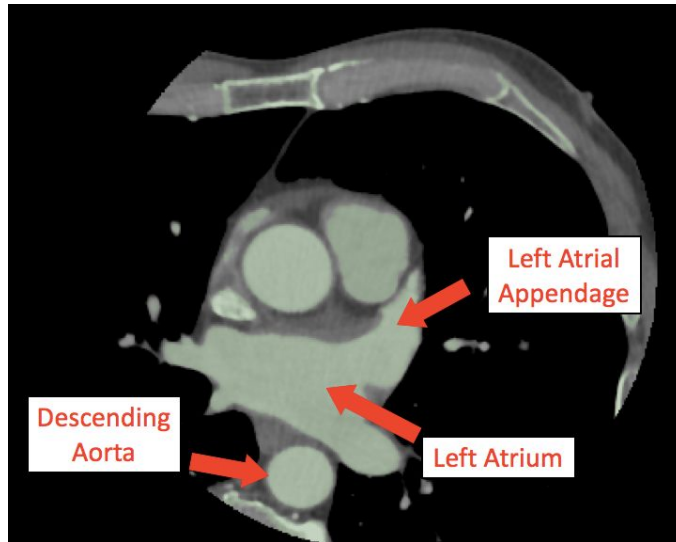


Figure 13

5: Crop out unnecessary anatomy from 2D view.

5.1: Select “Scissors” and change “Scissor” parameters to match the ones shown in this tutorial. When cropping the appendage, make sure to leave enough room so you do not cut into the opening. After you print, the opening of your model will be measured and compared to the training model for accuracy. Figure 14-2 shows a second cut you should make to eliminate unnecessary anatomy.

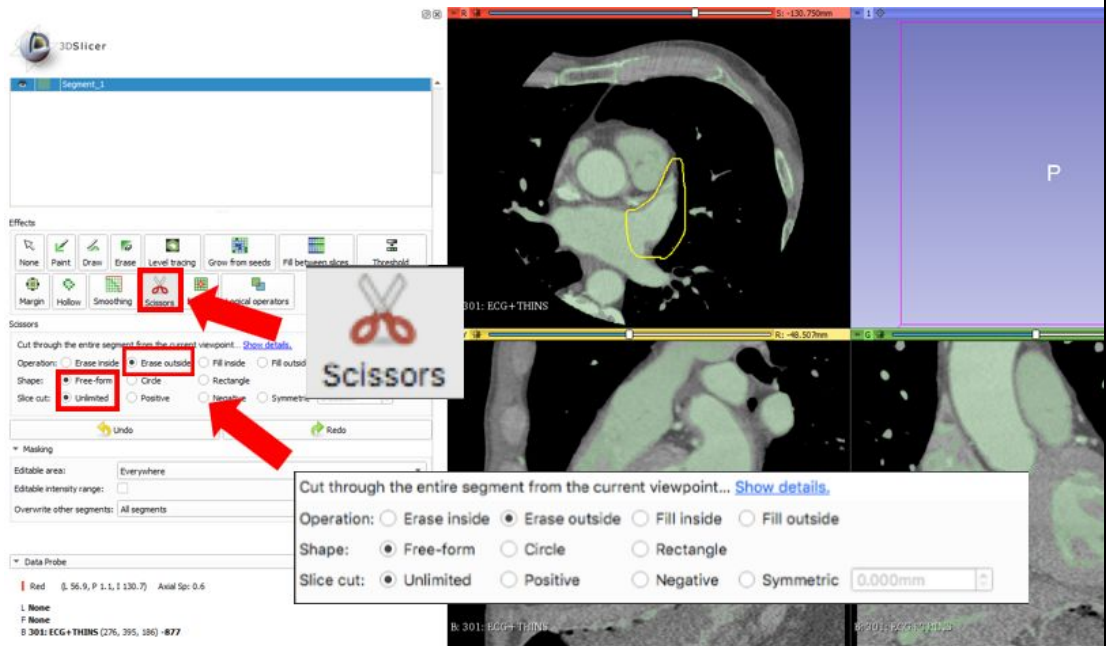


Figure 14

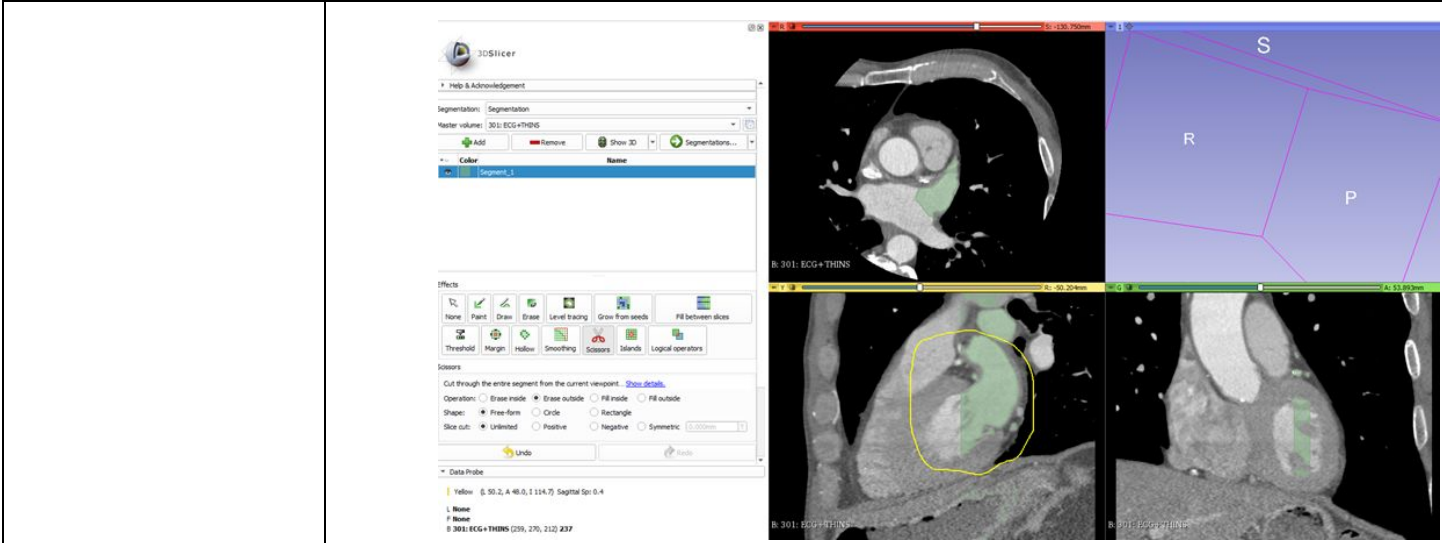


Figure 14-2

5.2: Select “Show 3D” shown in Figure 15.

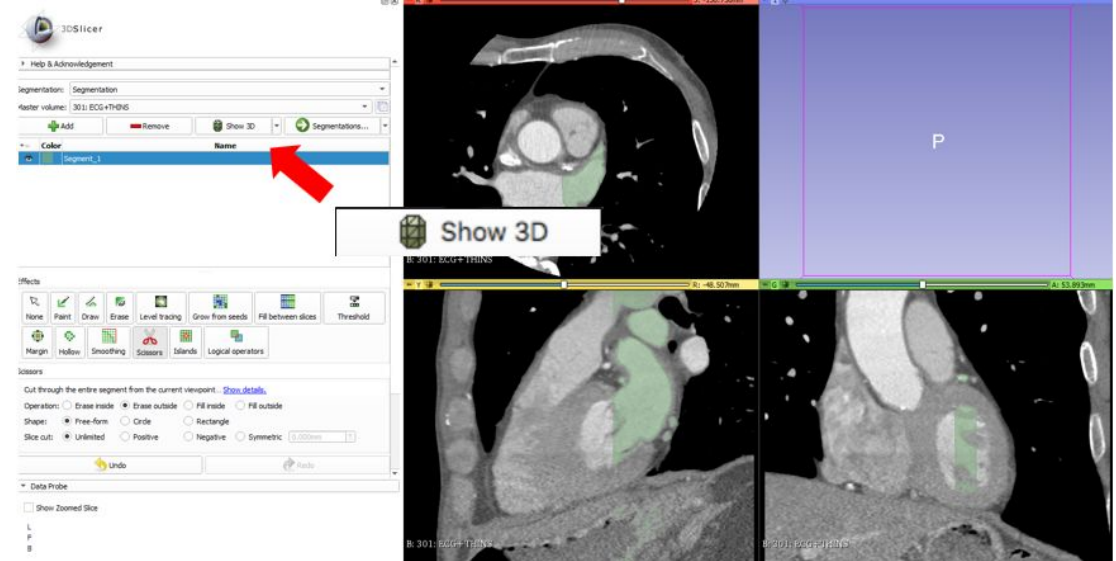


Figure 15

5.3: The 3D model shows up in the upper right quadrant. Select the “Viewer” drop down menu highlighted in Figure 16 and select “3D only” to only view the 3D image. The 3D image populates the entire screen as shown in Figure 17 for further cropping in the 3D view.

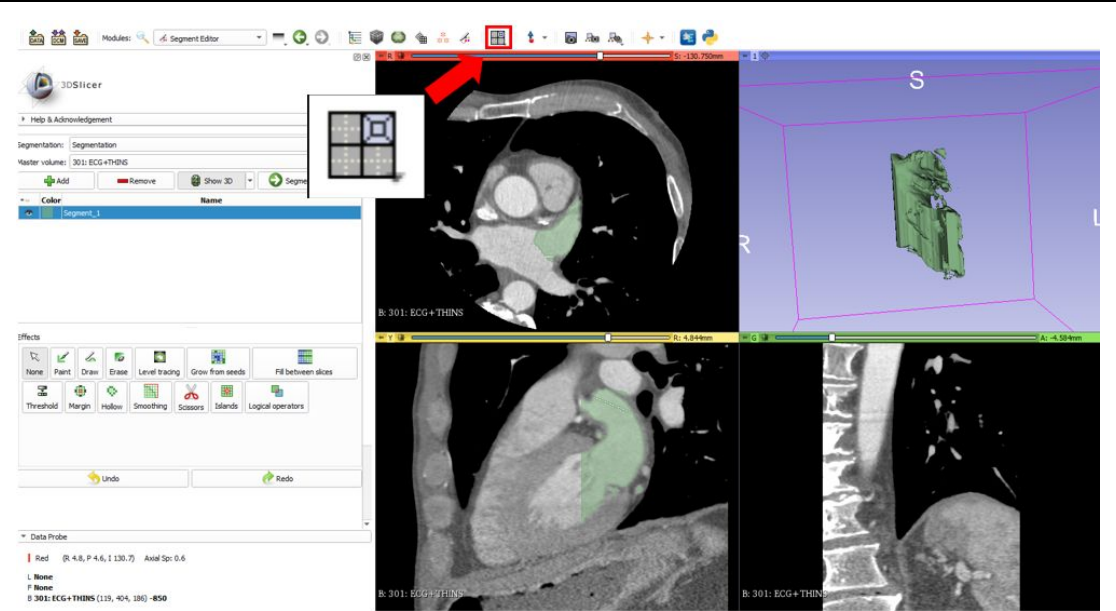


Figure 16

5.4: Use the button shown in Figure 17, center the model in the middle of the 3D screen.

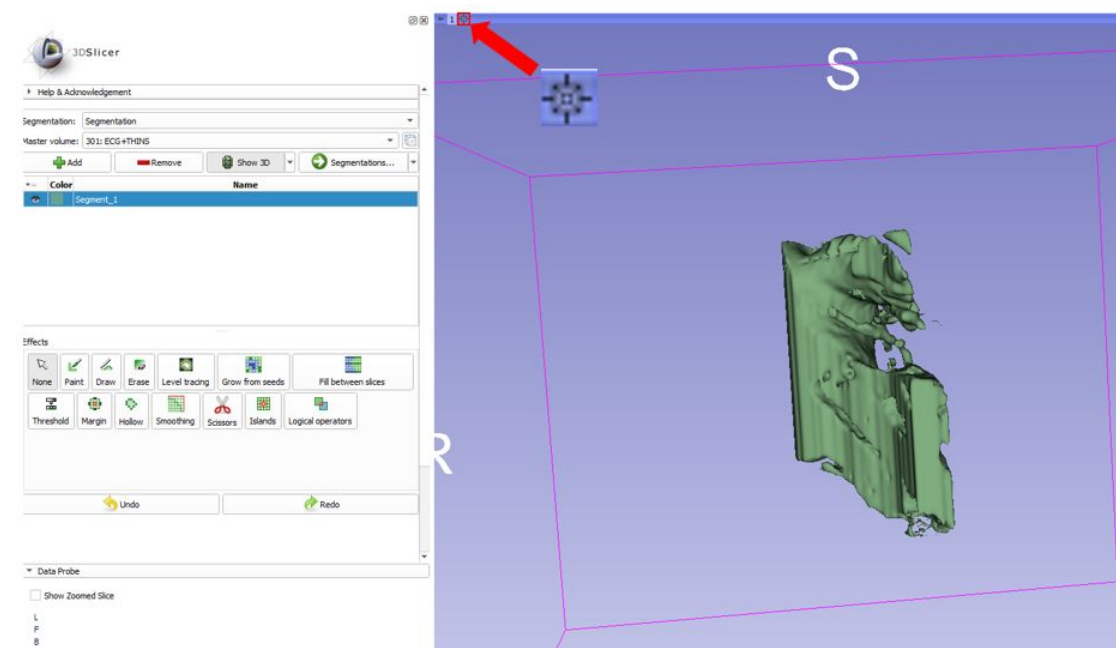


Figure 17

6: Crop unnecessary anatomy from 3D model.

6.1: Select “Scissors” and crop out unnecessary anatomy. Set scissors to crop “inside” shown in Figure 18. Cropping is done by dragging the mouse around unnecessary anatomy.

Note: All anatomy inside the “Scissor” will be cropped. Use the “None” button to rotate the image to crop proper anatomy

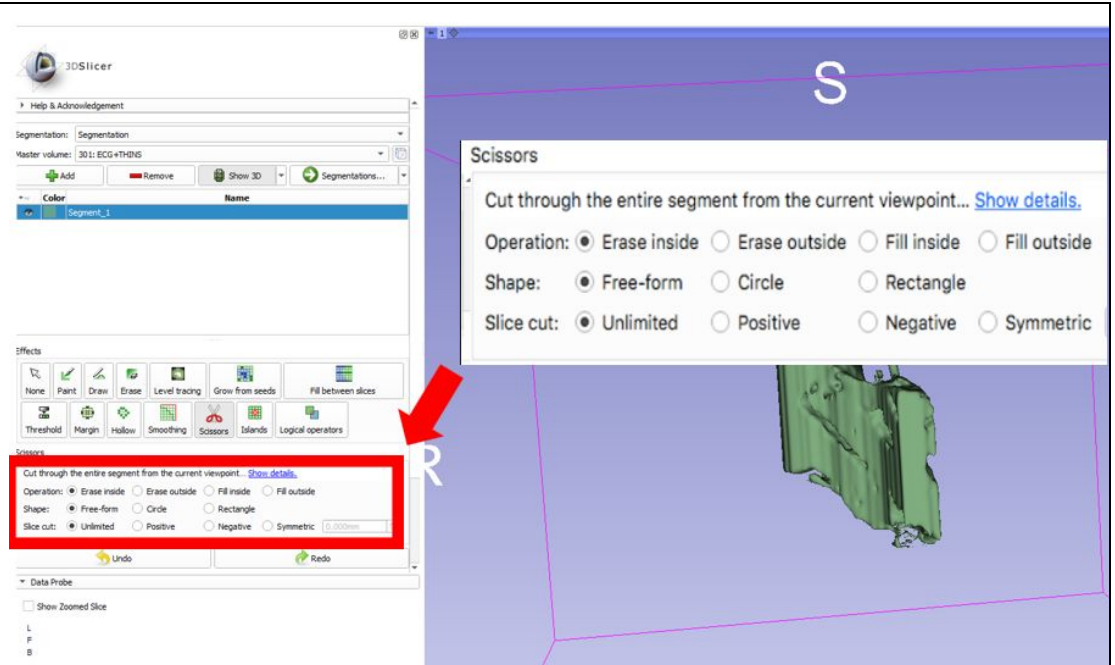


Figure 18

6.2: Continue to crop until you have a simple geometry left that shows the left atrial appendage and a small portion of the left atrium. Figure 19 displays this anatomy.

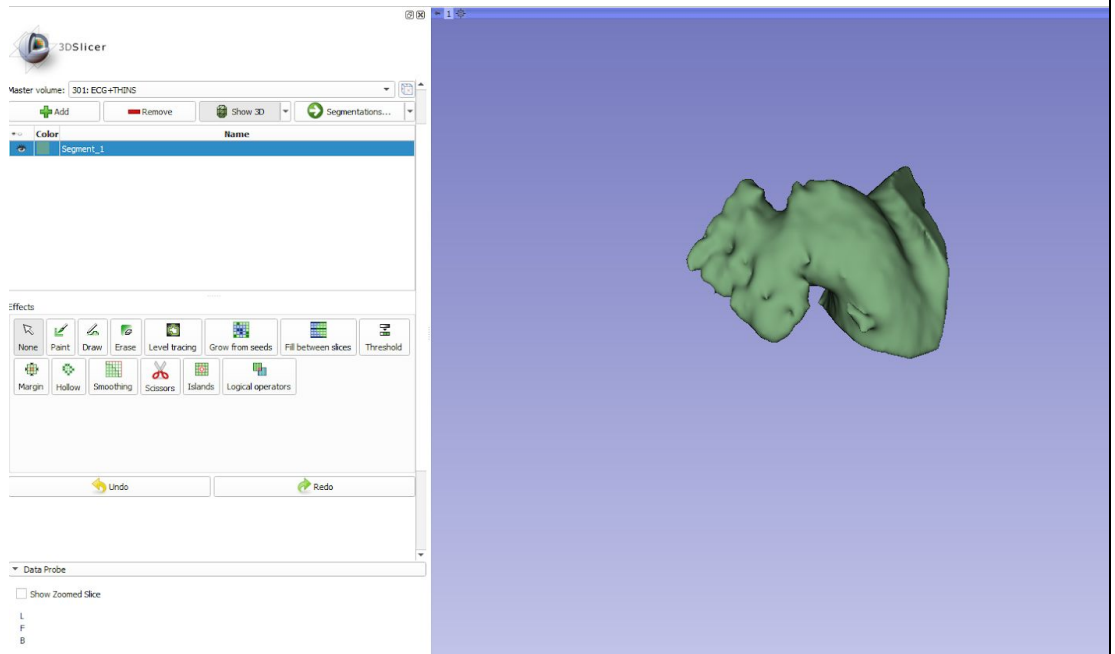


Figure 19

6.3: Hollow the body.

6.4: Select “Hollow” to be able to see cavities. Select “Hollow” parameters to match the ones shown in Figure 20 and select “Apply””.

6.5: After hollowing the model, if there is not a visible cavity that shows the opening of the appendage, cut a slice of the farthest segment of the model as shown in Figure 21. After cutting out a slice, the model should look similar to that in Figure 22.

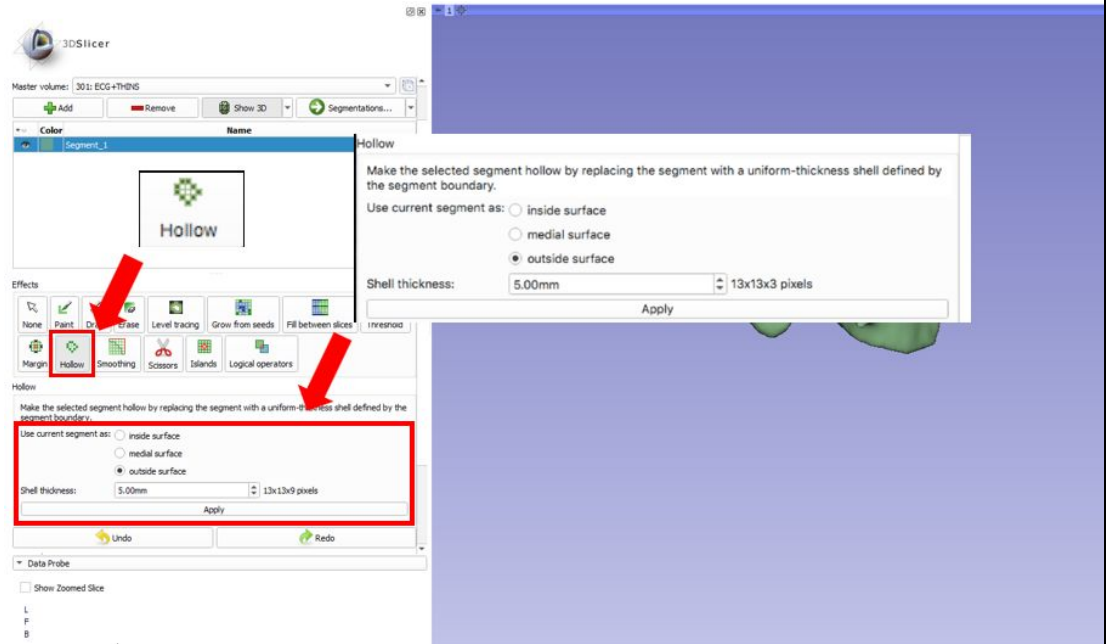


Figure 20

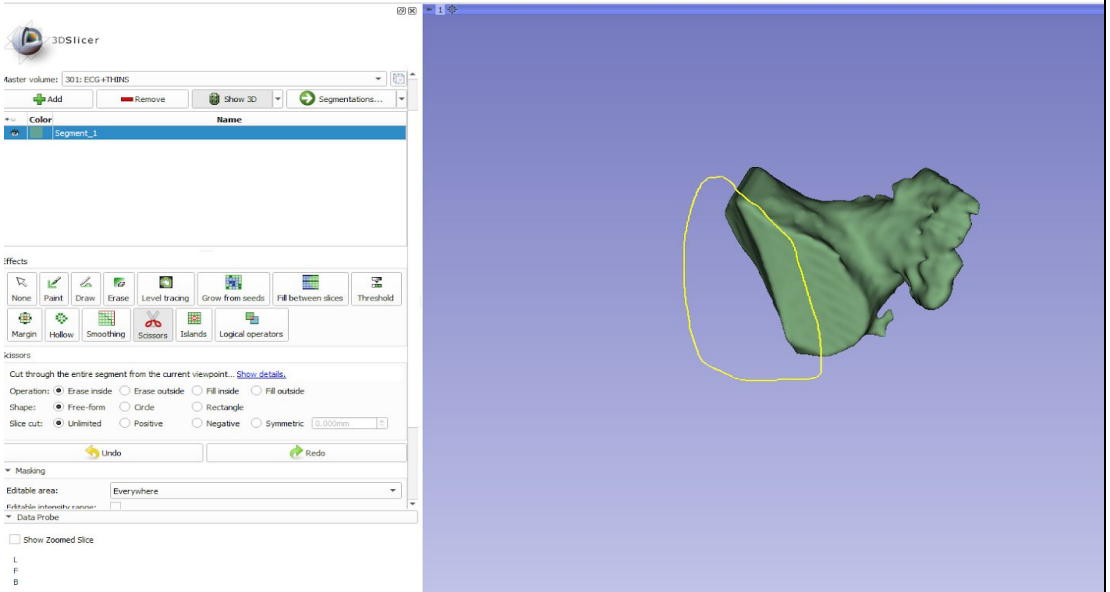


Figure 21

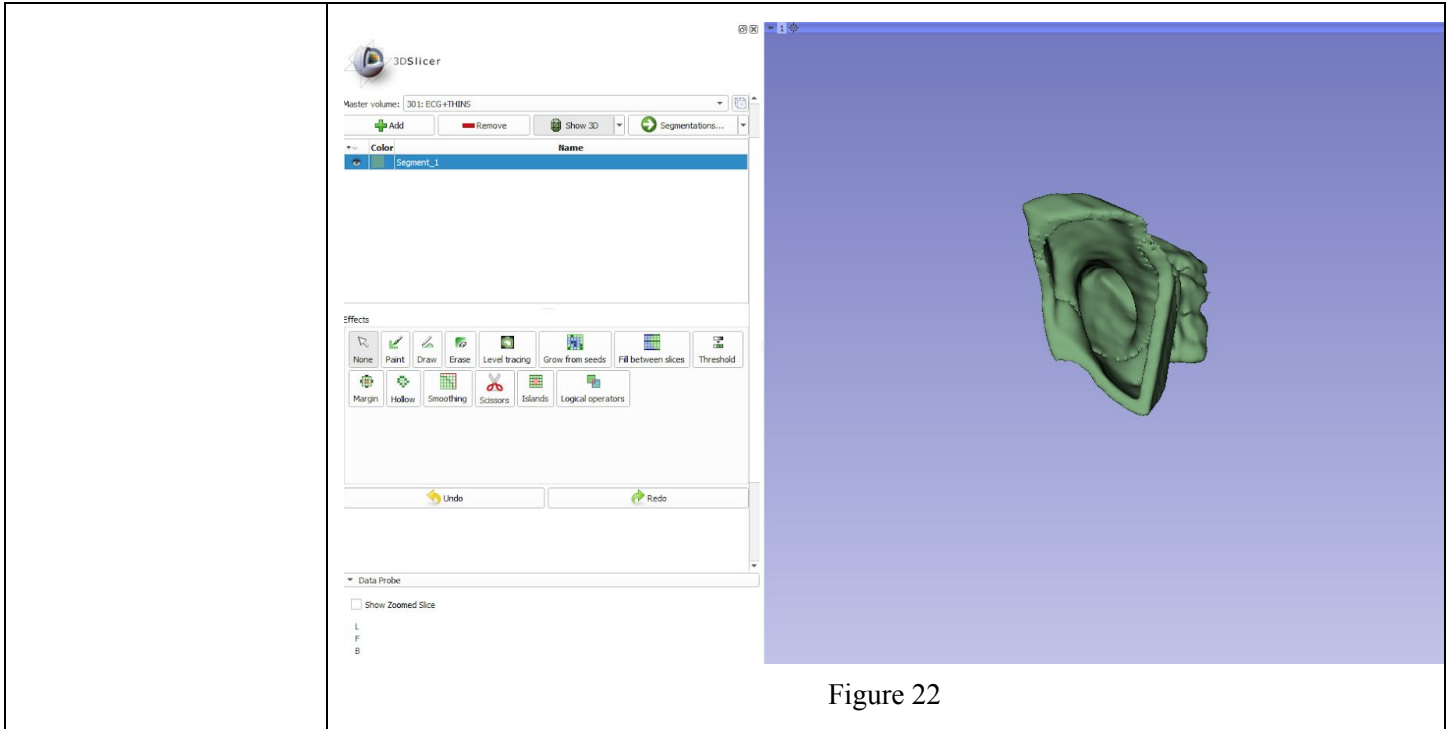


Figure 22

7: Save the model.

7.1: Click on “Segmentations” shown in Figure 23. A drop down menu will appear. In that drop down menu select “Export to Files...”

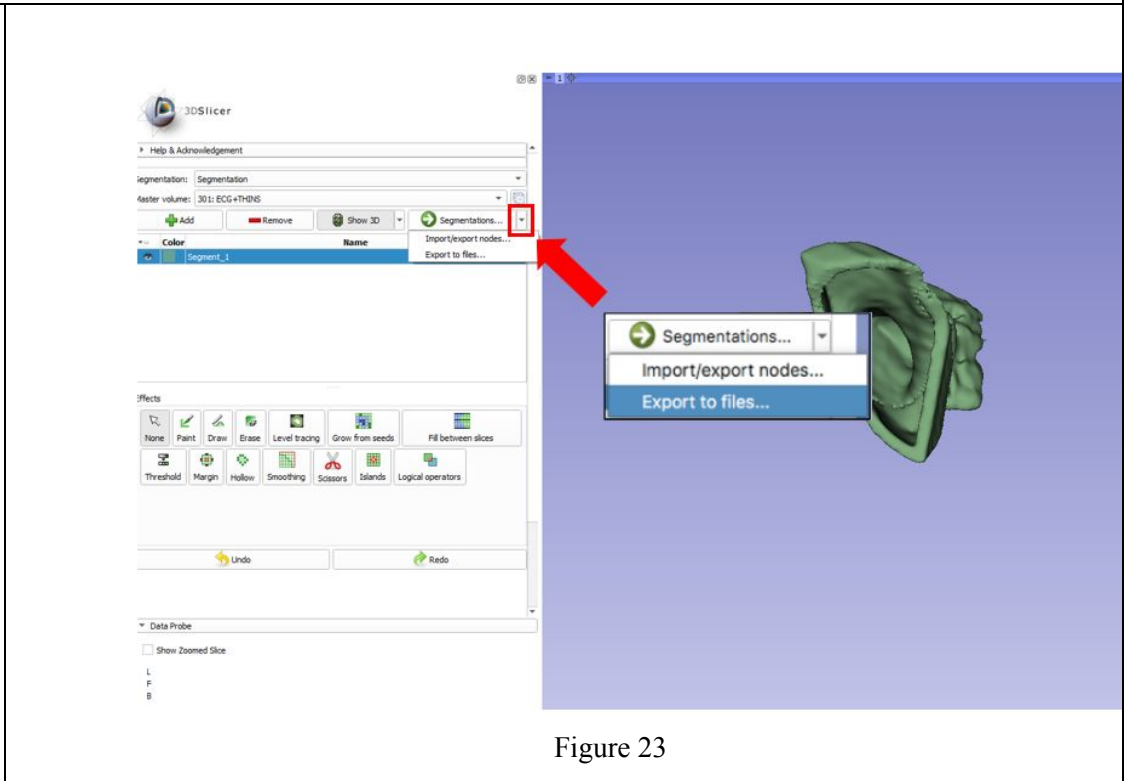


Figure 23

7.2: After selecting “Export to Files...” select a Destination Folder shown in Figure 24. Chose file format “STL”. Select export. Note: We advise to select a folder that contains this particular patient’s files.

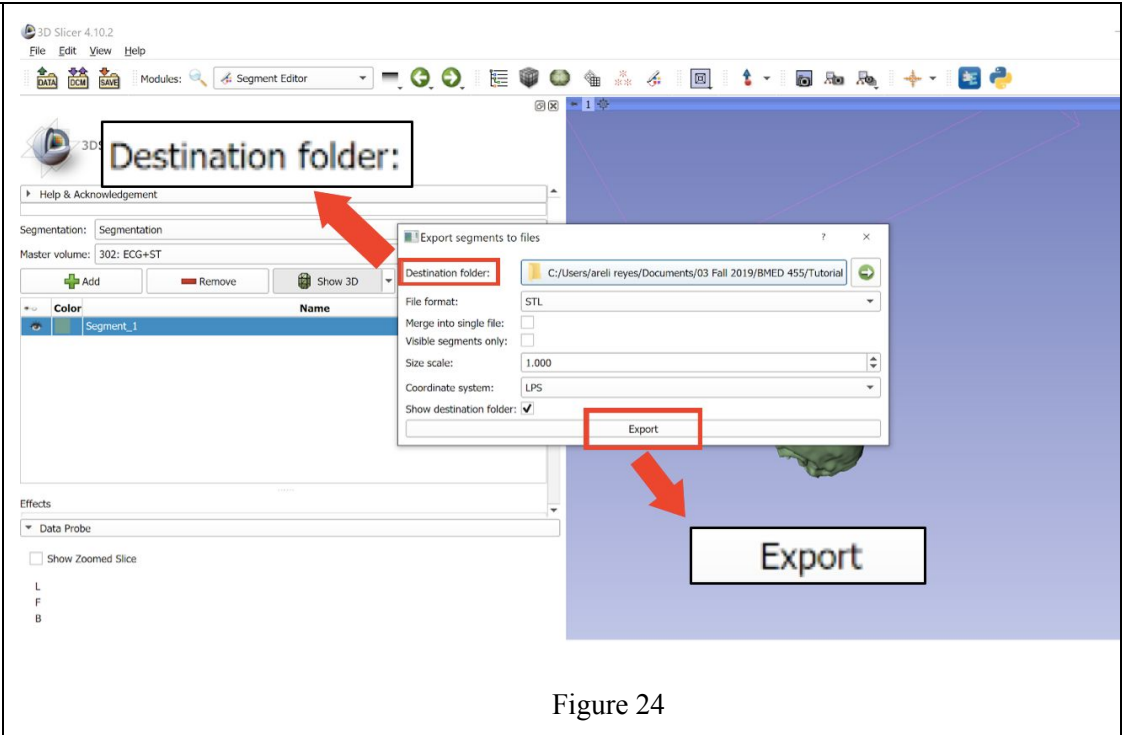


Figure 24

Printing Procedure

8: Upload the STL file to the Ultimaker Cura program shown in Figure 25.

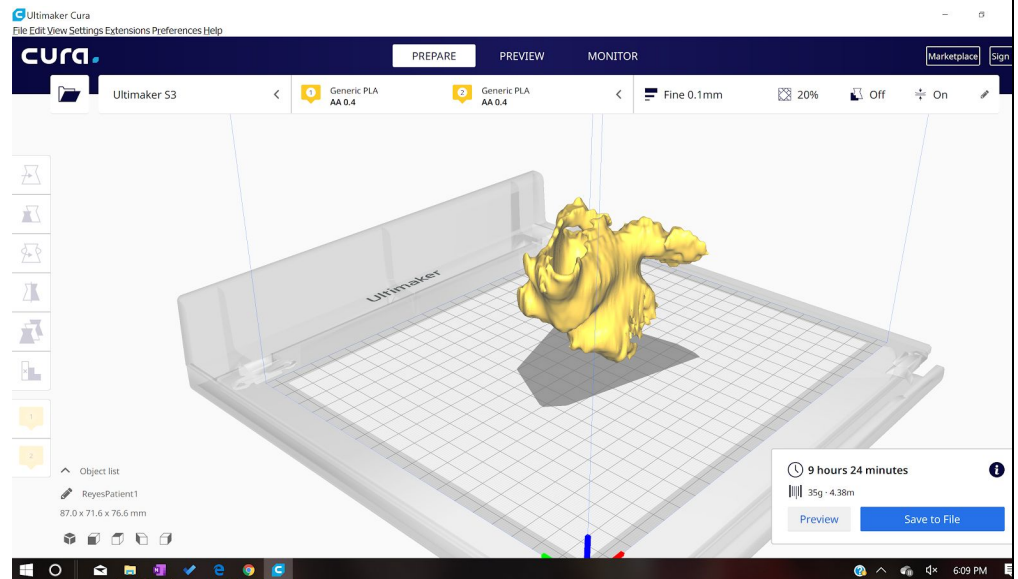


Figure 25

8.1: Define all parameters as shown in Figure 26.

- Infill
- Quality
- Shell
- Material
- Speed
- Cooling
- Support material
- Build Plate Adhesion

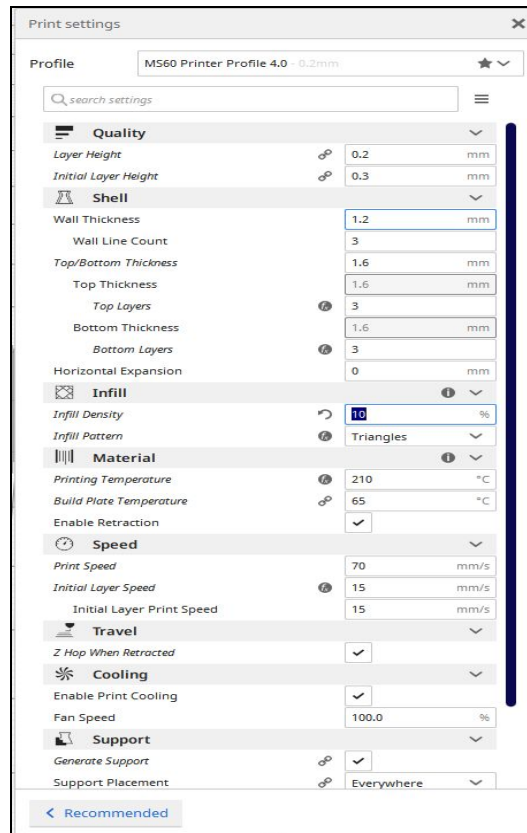


Figure 26

9: Upload file to printer and modify settings.

10.1: Load filament into machine

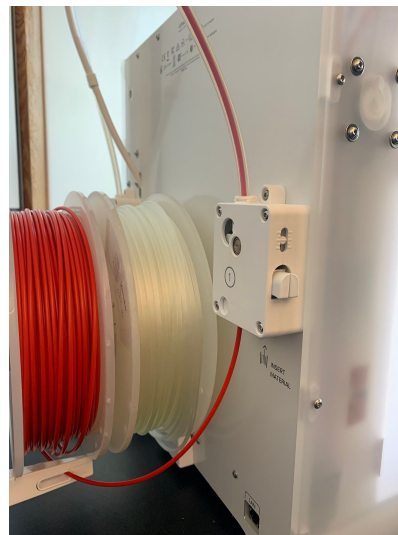


Figure 27

10.2: Press “Bed”-”Heat” to heat up the system.

10.2.1: Check temperature of nozzle and plate by pressing “Bed/Extrude” on the printer panel

10.2.2: Press “Print”- find file (file will have settings listed first then file name)

10.2.3: Confirm “Yes”

10.2.4: Wait for plate to finish heating up and clear any extra plastic from platform

11: Wait for the first layer of print to be printed before leaving print alone. Allow printer 1.5x estimated time to print
Note: This is important to ensure the print will print appropriately because most failures occur in the first layer if they were to occur.

12: Remove print from platform and remove any support brims

Note: Clean printing platform properly after print is removed

Post Processing Procedure

13: After you have removed the print off the printing bed, there will be excess PVA to remove before you can use the model for sizing.

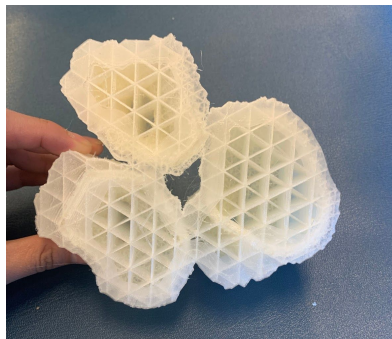


Figure 28



Figure 29

14: Fill a sink with hot water to submerge the print.



Figure 30

15: Ensure that there are no air bubbles in the model before you leave it.



Figure 31

15.1: Position the model so that the opening of the model is on the bottom surface of the sink. (This is so all the PVA that dissolves rests into the sink rather than the cavity of the model.)



Figure 32

16: After allowing the model to bathe for 30 min, rinse model, prepare a new bath, and re submerge for 20 minutes. (This is to ensure all the PVA is being removed.)



Figure 33

17: Return in 30 minutes and remove the rest of the PVA off model with fingers, ensure you are emptying the cavity.



Figure 34

Appendix 7: Training Completion Form

Left Atrial Appendage Closure Process Training Completion Form

I, _____, acknowledge that I:
(Print Name)

_____ Read and understand each step of the Manufacturing Process Instructions
(Initial)

_____ Read the Operational Manual
(Initial)

_____ Have completed the Training Guide
(Initial)

_____ Have verified with my training administrator that my print is accurate based on the provided
(Initial) model

My signature below indicates that I have completed the required tasks above and certify that I ready to use this process in a clinical setting:

(User Signature)

(Date)

Official Use Only

I hereby declare that the user mentioned above has completed the training required to use the Left Atrial Appendage Closure process in a clinical setting:

(Training Administrator Signature)

(Date)

Reference:

- [1] Squelch, Andrew. “3D Printing and Medical Imaging.” *Journal of Medical Radiation Sciences*, vol. 65, no. 3, Sept. 2018, pp. 171–172., doi:10.1002/jmrs.300.
- [2] Lau, Ivan, and Zhonghua Sun. “Three-Dimensional Printing in Congenital Heart Disease: A Systematic Review.” *Journal of Medical Radiation Sciences*, vol. 65, no. 3, 2018, pp. 226–236., doi:10.1002/jmrs.268.
- [3] Haleem, Abid, and Mohd Javaid. “Role of CT and MRI in the Design and Development of Orthopaedic Model Using Additive Manufacturing.” *Journal of Clinical Orthopaedics and Trauma*, vol. 9, no. 3, 2018, pp. 213–217., doi:10.1016/j.jcot.2018.07.002.
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