

MASTER THESIS

Development of a 3D stress foot plate meeting the medical device regulation and affordability

Product development without a business case

Daniëlle van Elst
s1855352

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Faculty of Engineering Technologies
Department of Biomechanical Engineering
Biomedical Device Design & Production

Examination Committee

Prof. dr. ir. G. J. M. Tuijthof (Gabriëlle)
Dr. ing. M. Asseln (Malte)
Dr. V. Kalpathy Venkiteswaran (Venkat)
Prof. dr. M. Poeze (Martijn)

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Summary

Ankle laxity and hindfoot instability are diagnosed through a physical examination by a clinician. During the examination, the clinician will manually check for signs of instability or abnormal range of motion in the ankle and hindfoot. These manual stress tests have the disadvantage of not being able to distinguish between talocrural instability, subtalar instability, or combinations thereof. A previously developed 3D CT stress test using a 3D stress foot plate to mimic manual stress tests in the CT scanner allows for quantitative one-stage measurement of subtalar and talocrural joint range of motion. This facilitates diagnosis and follow up of complex clinical cases.

A prototype of the 3D stress foot plate allows a clinician to manually load the foot in multiple directions relative to the lower leg. However, the device was designed more than a decade ago. Therefore, it does not meet the requirements of the Medical Device Regulation (MDR) legislation and cannot be used on patients. Also, since the 3D CT stress test is useful only for complex clinical cases in the hindfoot or perform medical research, it is highly unlikely that a business case can be developed.

This project was aimed at redesigning the 3D stress foot plate device such that it is easy to produce, with offering open source drawings, production techniques, off-the-shelf components and assembly manual; and offering all documentation and tests in order to comply with the MDR legislation.

First, a redesign was performed by using laser cutting and 3D printing as production techniques, and an IKEA-style assembly using glue as primary fixator. Second, documentation according to the MDR legislation was setup by performing a risk analysis, completing design requirements and accompanying tests. Based on completed documents for the MDR, an optimized end design was developed.

The results of this project provide an open source method to produce the 3D stress foot plate in an affordable manner, while being a safe medical device. In line with the open-source starting point, the imaging processing of the acquired CT scans can also be processed with open-source software. This was shown for a complex case of determining the range of motion of after ankle prosthesis replacement.

In conclusion, this thesis describes an open-source method to fabricate the 3D stress foot plate while complying with the MDR. The device is easy to manufacture using open-source drawings, easy-to-order manufacturing techniques, and easy-to-purchase components. This work can therefore be a showcase of how Class I medical devices could be offered, for which no business case can be made, but which still comply with the MDR and in this way can be made affordable.

Samenvatting

Laxiteit van de enkel en instabiliteit van de achtervoet worden gediagnosticeerd door middel van lichamelijk onderzoek door een clinicus. Tijdens het onderzoek zal de clinicus handmatig controleren op tekenen van instabiliteit of abnormaal bewegingsbereik in de enkel en achtervoet. Deze handmatige stresstesten hebben als nadeel dat ze geen onderscheid kunnen maken tussen talocrurale instabiliteit, subtalaire instabiliteit of combinaties daarvan. Een eerder ontwikkelde 3D CT-stresstest waarbij gebruik wordt gemaakt van een 3D-stressvoetplaat om handmatige stresstests in de CT-scanner na te bootsen, maakt een kwantitatieve een-staps-meting van het subtalaire en talocrurale gewrichtsbereik mogelijk. Dit vergemakkelijkt de diagnose en opvolging van complexe klinische gevallen.

Met een prototype van de 3D-stress voetplaat kan een clinicus de voet handmatig in meerdere richtingen ten opzichte van het onderbeen beladen. Het apparaat is echter meer dan tien jaar geleden ontworpen. Daarom voldoet het niet aan de eisen van de Medical Device Regulation (MDR)-wetgeving en kan het niet bij patiënten worden gebruikt. Aangezien de 3D CT-stresstest alleen nuttig is voor complexe klinische casussen in de achtervoet of voor het uitvoeren van medisch onderzoek, is het hoogst onwaarschijnlijk dat er een businesscase kan worden ontwikkeld.

Dit project was gericht op het herontwerpen van het 3D-stress voetplaat apparaat zodat het gemakkelijk te produceren is, met het aanbieden van open source-tekeningen, productietechnieken, kant-en-klare componenten en montagehandleiding; en het aanbieden van alle documentatie en tests om te voldoen aan de MDR-wetgeving.

Eerst werd een herontwerp uitgevoerd met behulp van lasersnijden en 3D-printen als productietechnieken, en een montage in IKEA-stijl met lijm als primair fixeermiddel. Ten tweede is de documentatie volgens de MDR-wetgeving opgezet door het uitvoeren van een risicoanalyse, het invullen van ontwerpeisen en bijbehorende testen. Op basis van ingevulde documenten voor de MDR werd een geoptimaliseerd eindontwerp ontwikkeld.

De resultaten van dit project bieden een open source-methode om de 3D-stress voetplaat op een betaalbare manier te produceren en tegelijkertijd een veilig medisch hulpmiddel te zijn. In lijn met het open-source uitgangspunt kan ook de beeldverwerking van de verworven CT-scans met open-source software worden verwerkt. Dit werd aangetoond voor een complexe casus van het bepalen van de bewegingsuitslag na het vervangen van een enkelprothese.

Concluderend beschrijft dit proefschrift een open-source methode om de 3D-stress voetplaat te fabriceren terwijl deze voldoet aan de MDR. Het apparaat is eenvoudig te vervaardigen met behulp van open-sourceteekeningen, gemakkelijk te bestellen productietechnieken en gemakkelijk te kopen componenten. Dit werk kan dan ook een showcase zijn van hoe klasse I medische hulpmiddelen aangeboden zouden kunnen worden, waarvoor geen business case gemaakt kan worden, maar die toch voldoen aan de MDR en op deze manier betaalbaar gemaakt kunnen worden.

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1. Introduction

1.1 Problem definition

The ankle (Figure 1) is surrounded by several ligaments that connect the bones to other bones, increasing stability and limiting the range of motion of the joint [1]. The ankle consists of two joints [2,3]; the talocrural joint between the tibia, fibula, and talus, and the subtalar joint between the talus and the calcaneus. The range of motion in the talocrural joint is limited to pulling up and pushing down the foot (dorsi- and plantar flexion). The subtalar joint allows us to move the foot laterally (inversion and eversion) [1,2].

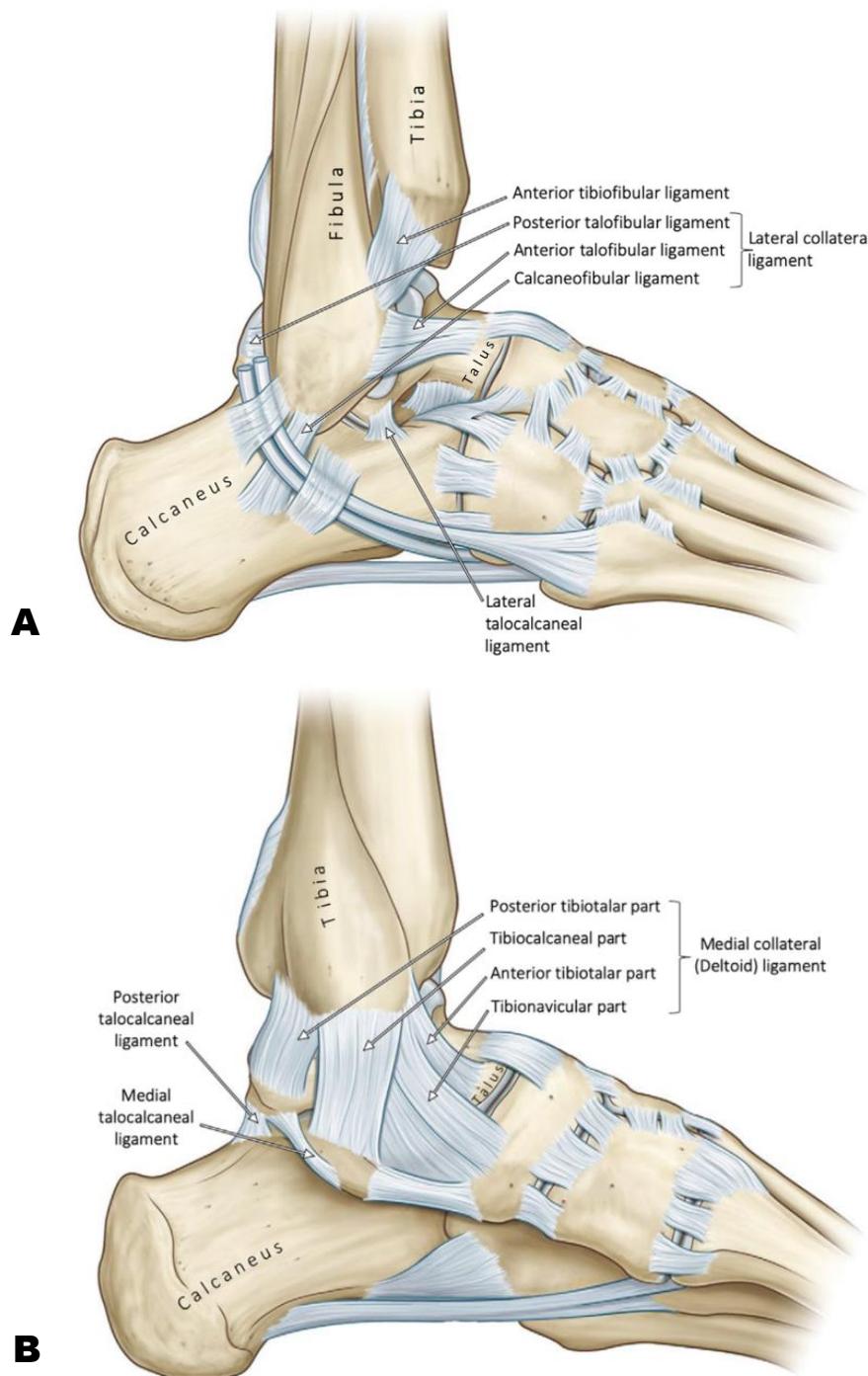


Figure 1. The most important ligaments in the talocrural and subtalar joint, acquired from Angin et al. [3].
A) Lateral ligaments of the ankle, B) medial ligaments of the ankle.

The lateral ligaments of the ankle consist of the anterior and posterior talofibular ligaments, and the calcaneofibular ligaments (Figure 1A) [3]. The anterior and posterior talofibular ligaments directly support the talocrural joint, while the calcaneofibular ligament supports both the talocrural and subtalar joint. The lateral collateral ligaments limit the excessive inversion motion of the ankle. The medial collateral ligament (Figure 1B) reinforces the medial side of the talocrural joint [3]. The orientation and location of these ligaments limit the extreme motion of eversion throughout the talocrural and subtalar joint. Additionally, it prevents lateral tilting of the talus.

Ankle laxity and hindfoot instability, and/or abnormal range of motion, are diagnosed through a physical examination by a clinician [4]. During the examination, the clinician will manually check for signs of instability in the ankle and hindfoot, by checking the relative motion of the foot to the lower leg [5]. Clinicians often use manual stress tests to establish a diagnosis, due to their quick and easy execution [6]. Stress tests are based on the concept that if one or more ligaments in the ankle rupture, the range of motion of the related joint(s) will be altered. This implies that abnormal range of motion could be detected with these stress tests. The most common stress test is the anterior drawer test [5,7,8]. In this test, the anterior translation of the talus is measured in relation to the tibia [7], which generally estimates the laxity of the ankle [10]. However, this manual test can be criticized for its subjective nature and inability to produce reproducible and quantitative results [5]. This manual stress test also has the disadvantage of not being able to distinguish between talocrural instability, subtalar instability, or combinations thereof [11].

For special complex cases, additional quantitative information on the range of motion of the ankle is necessary. Two examples are the assessment of the subtalar versus talocrural instability, as described in the article of Zengerink et al. [11], and determining the range of motion before and after an ankle prosthesis placement. To assess talocrural laxity and subtalar joints, a high-precision diagnostic tool is needed to measure the *in vivo* range of motion of the ankle and subtalar joints under weight-bearing conditions with three-dimensional computed tomographic images. The range of motion in the ankle prosthesis is needed to provide insight into the extent to which the range of motion has quantitatively improved compared to before the placement of the prosthesis. Additionally, evaluation of possible malrotation or loosening of the prosthesis can be examined. Therefore, in previous work [12], a 3D CT stress test has been developed. This 3D CT stress test enables quantitative one-stage measurement of the range of motion of the subtalar and talocrural joint simultaneously by CT scanning of the bones in various loaded conditions [11]. The 3D CT stress-test has great potential and relevance in the clinical case of suspected subtalar instability.

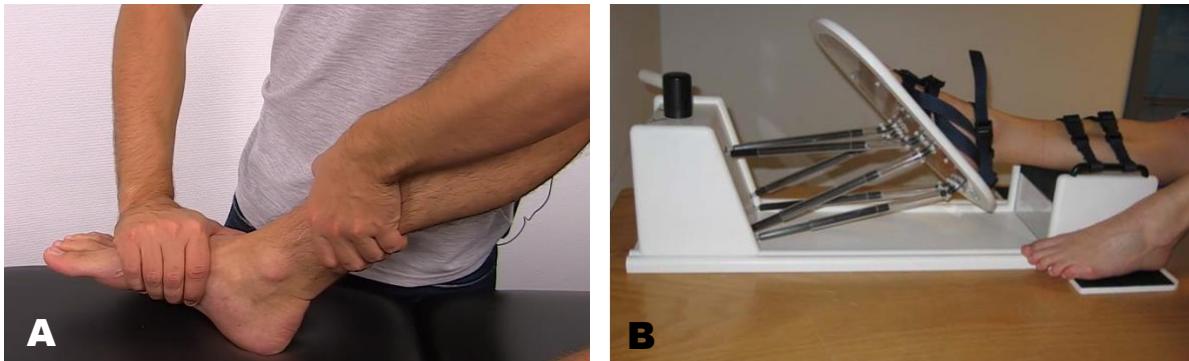


Figure 2. The foot in maximum plantar flexion. A) the examiner forces the foot manually into extreme plantar flexion, acquired from Physio tutors [14], B) The foot placed in extreme plantar flexion by using the 3D stress foot plate manually, acquired from Van der Zwaag [15].

Tuijthof et al. [13] developed a new 3D stress foot plate prototype (Figure 2B) that can assist in the 3D clinical diagnosis of hindfoot range of motion for objective and quantitative analysis of ankle range of motion. Manual stress tests performed for the ankle joint (Figure 2A) can be mimicked with the 3D stress foot plate [13]. This prototype device allows a clinician to manually load the foot in multiple directions relative to the lower leg. Therefore, the clinician is in control of which movements are made; the patient can say stop at all times when the movement made starts to hurt. Since the device can be fixed manually, a CT scan can be made with the determined extreme position of the foot, making the manual stress test quantitative. The 3D stress foot plate prototype has been demonstrated to have the potential for clinical application and was well-received by radiology technicians [13].

The 3D stress foot plate prototype was designed to diagnose all complex hindfoot laxities or ligament ruptures [13] in the clinical case. However, the device was designed more than a decade ago; therefore, it does not meet the requirements of the Medical Device Regulation (MDR) legislation [16,17]. As a result, the device cannot be used on patients at this time. The MDR is a European regulation that harmonizes the rules for medical devices in Europe. The regulation aims to improve patient safety. An additional complexity to this prototype is that the device probably will only be used in complex clinical cases or in clinical research setting where quantitative information is required. So, it will not be offered on a large scale, making it a commercially nonviable product. Therefore, we aimed to deal with this challenge in a novel way, to allow clinicians that do want to use such a device to be able to afford it. It is important that the device is offered in such a way that it is easy to produce, so that anyone can make the device.

1.2. Objectives

The aim is to develop an open-source method for fabricating the 3D stress foot plate, while meeting the MDR. The main focus was at redesigning the 3D stress foot plate device such that it is easy to produce, with offering open-source drawings, production techniques, off-the-shelf components and assembly manual; and offering all documentation and tests in order to comply with the MDR legislation. In addition, an initial start will be made in CT image processing, to quantitatively determine the kinematic performance of ankle prosthesis using an image processing workflow.

1.3. Approach and organization of the thesis

First, the 3D stress foot plate prototype of Tuijthof et al. [13] will be examined, after which a step will be taken to make the device easy and affordable to fabricate. To this end, three steps are taken: the design for manufacturing is applied (Step 1), the compliance with the MDR is applied (Step 2), and the application to a clinical case (Step 3).

Step 1: The design of the 3D stress foot plate prototype will be optimized to be easy to manufacture with easy off-the-shelf components and easy-to-order production techniques. The principle of Design for Manufacturing and Assembly (DFMA) has been used for this [18,19]. DFMA is a methodology that aims to ease the assembly and overall manufacturability of a product. It has the potential to reduce manufacturing and other product life-cycle costs. Easy off-the-shelf components and easy-to-order production techniques are needed, because the device has no business case. As a result, the starting point is that the device is easy to make and assemble for anyone.

Step 2: The design of medical devices requires special attention to ensure that these products can be used safely by healthcare professionals on patients. To be allowed to use the 3D stress foot plate device on patients, it will have to comply with MDR legislation [16,17]. The MDR is a European Union legislation that is enforced at national level. It applies to medical devices that are defined and categorized into classes. Depending on the class, stricter rules apply. The implementation of MDR will be done through ISO standards and forms that weigh the benefits and risks. Furthermore, the MDR requires that a risk management process that is consistent with ISO 14971 be implemented to ensure the quality and safety of the device on patients [20].

Step 3: A start will be made with the processing of possible CT images that can be obtained while using the device. This will focus on the case where the ankle prosthesis was placed in the ankle. The starting point is that this is done in an open-source program, and that a clear workflow is created.

2. The 3D CT stress test, a 3D stress foot plate medical device

The existing 3D stress foot plate prototype was developed by Van der Zwaag [15] and Tuijthof et al. [13]. This existing device will be referred to as 'device'.

First, the working mechanism of the device will be described and shown. Hereafter, the design considerations and demands behind the development of this device will be explained. Lastly, shortcomings considering the design of the device are formulated.

2.1. Working mechanism

To understand the working mechanism of the device, it is important to know how the functional units of the device are called. Those functional units are indicated in Figure 3. A step-by-step instruction will be given on how the device works.

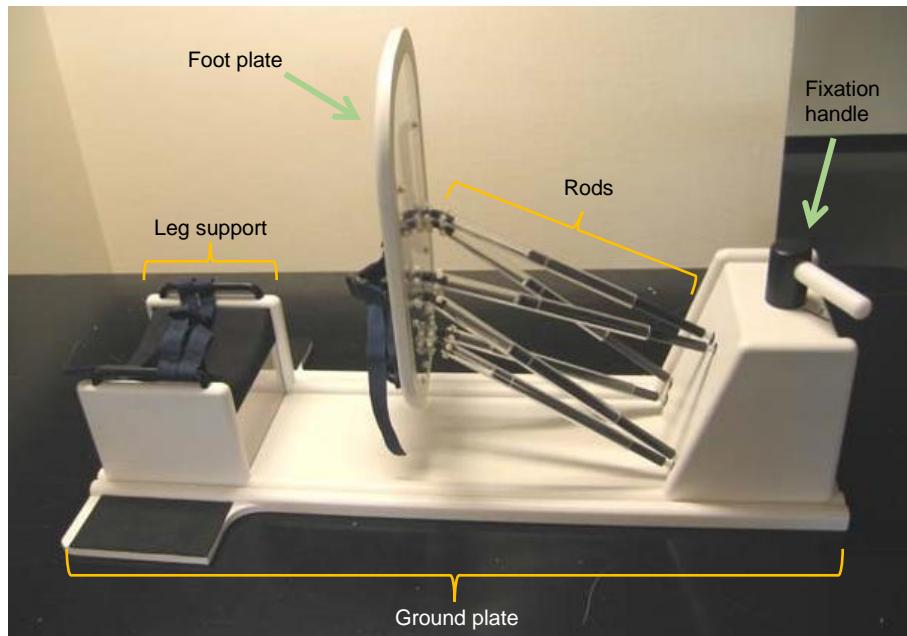


Figure 3. Complete device in fixated state, acquired from Tuijthof et al. [13]. Indicated how the functional units in the device are named.

Step 1: The patient lies on the CT bench, and the non-treated foot of the patient is placed on the ground plate at the level of the leg support (Figure 4). The foot plate is placed against the sole of the treated foot and secured by the clinician, and the lower leg is placed on the leg support and secured by the clinician.



Figure 4. Positioning the foot and lower leg on the device, figure acquired from Tuijthof et al. [13].

Step 2: The clinician manually rotates and translates the foot plate, thereby rotating the patient's ankle towards an extreme position relative to the lower leg (Figure 5).

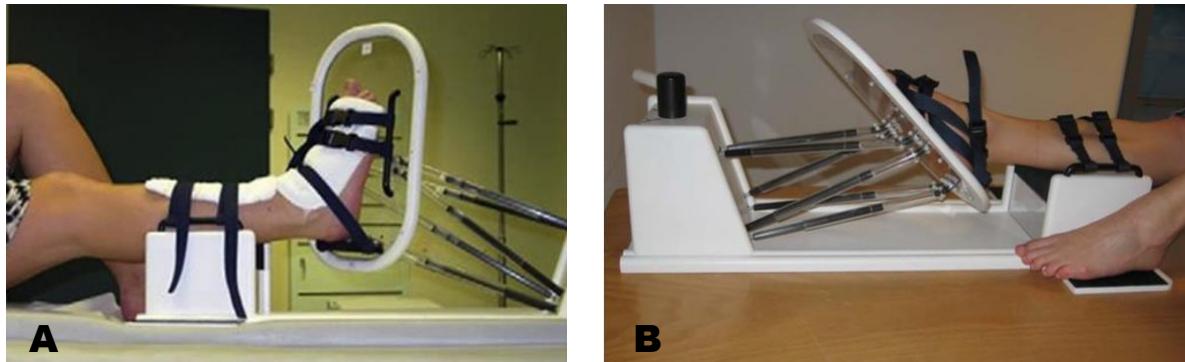


Figure 5. The device is positioned in different positions. A) foot fixated in extreme inversion, acquired from Tuijthof et al. [13], B) foot fixated in plantar flexion, acquired from Van der Zwaag [15].

Step 3: Once the targeted position of the foot relative to the lower leg is obtained, it is fixated by the clinician through turning the handle (Figure 6). The clinician should hold the position obtained with one hand, and at the same time turn the handle a quarter turn with the other hand.

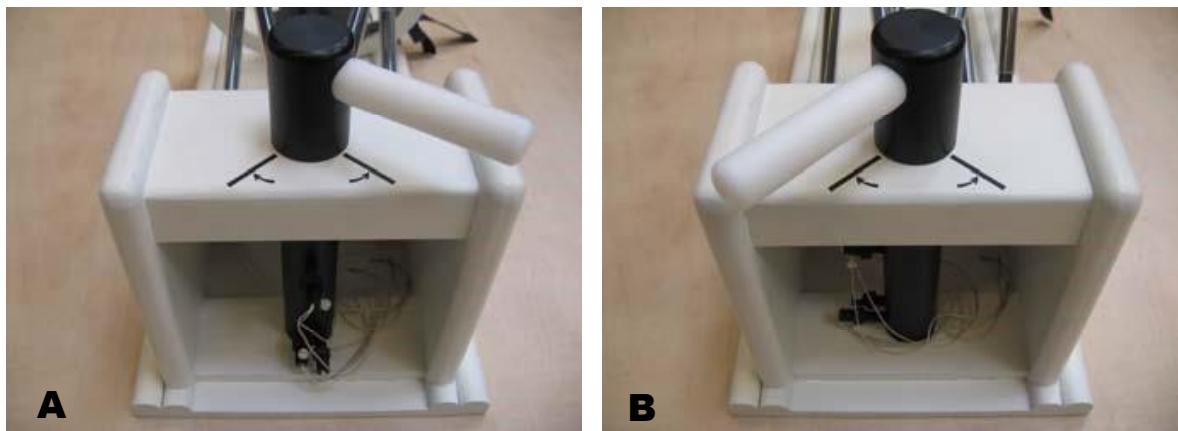


Figure 6. Close up of the fixation handle, figures acquired from Van der Zwaag [15]. A) fixation handle in loose state, the foot plate can be smoothly rotated, B) fixation handle in fixated state, the position of the foot plate is fixated.

The device is designed to meet the requirements, which were set out in the article by Tuijthof et al. [13]. Manual loading is used because this way of loading imitates the manual stress test the closest, the sense of control is optimal for the clinician due to direct force feedback, and in addition, the direct contact between the clinician and the patient increases the patients' feel of safety [13]. In this way, the patient can easily indicate when his foot starts to hurt. Requirements have been drawn up for the design of the device:

- The device should be able to manually position the foot in extreme positions relative to the lower leg
- The device should be able to manually fixate and unlock the foot in extreme positions relative to the lower leg
- The device should be compatible with different imaging systems (radiography, MRI- and CT scanners)
 - The device should be fabricated with materials that can be used in different imaging systems
 - The device should be dimensioned such that it fitted into different imaging systems
- Fixating the foot should not create additional damage to the ligaments
- The foot should be positioned in an extreme position mimicking a clinical stress test
- The operator should have a sense of control when using the device
- The device should require a separate manual fixation mechanism to preserve the desired extreme position of the foot
- The device should be dimensioned such that it can be used to diagnose 95% of an adult human population.
- Excursions of the upper extremities of the radiology technician should be kept within limits
- Different hand grips on the device should be allowed to apply manual loading
- The weight of the device should be a maximum of 12.7 kg to be portable
- The device should have a professional appearance and blend into the working environment
- The device should offer fast operation below 100 s
- The device should be operated by one person
- The device should be operated with minor physical and mental effort
- It should be clear (unambiguous) how to position the lower leg and the foot in the device
- The total acquisition time should not be increased by more than a maximum of 10-15% when using the device

2.2. Design considerations

The device is entirely handmade, which requires many steps. In Van der Zwaag's work [15], the dimensions and materials of the parts are documented. The ground plate is made entirely of 8 mm medium-density fiberboard (MDF) (Figure 3), which has been sanded manually to achieve smooth rounded edges and is subsequently painted to make the material water proof, so that it is easier to clean. The foot plate is made of 4 mm polyethylene terephthalate glycol (PETG), around which a rib of MDF has been placed. In addition, small pieces of Polymethyl methacrylate (PMMA) rods are glued to this foot plate so that the rubber hinges can be attached to the plate (Figure 7B). The bandages for the foot are attached to a polyvinyl chloride (PVC) tube that is attached to the foot plate itself. The PVC tube was cut to size, after which it was bent by means of heat, and then screwed to the foot plate. The lower leg bandages are attached to a PVC tube that is attached to the edge of the leg support. The PVC tube was also cut to size for this purpose, after which it was bent by means of heat, but in this case the tube was glued to the leg support. The lower leg rests on cell rubber, which offers comfort to the patient.

To allow the unrestricted motion of any type of foot around its own anatomic axes, a Stewart platform configuration is used [13]. On a Stewart platform, two surfaces can move in 6 degrees of freedom (DOF) relative to each other [21]. Usually, one surface is stationary and connected to the other surface by six rods (Figure 3). The connections of the rods to the surfaces are hinges with two DOF. The rods can change in length and are paired in a triangular configuration (Figure 3). The dimensions of the Stewart platform principle in the device have been adapted to fit within the working space of various CT scanners. Furthermore, in the device, all movements of the ankle can be simulated.

The Stewart platform is created on a slope relative to the ground plate. The other end of the rods is attached to the foot plate, being the second surface. Ball-and-socket joints allow the required two DOF of the rods at the slope (Figure 7A). Special compliant hinges made of rubber allow the required two DOF between the rods and the foot plate (Figure 7B). The ball-and-socket joint is clamped in the ground plate's ramp, using two plates that clamp around the joint so that the ball is rotatable but cannot be detached from the ground plate (Figure 7A).

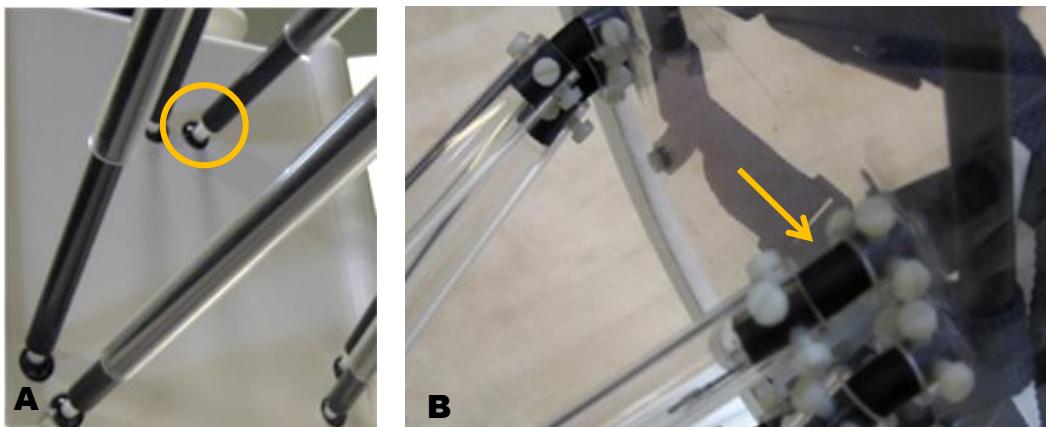


Figure 7. Close up of the mounting of the rods to the ground- and foot plate to obtain the Stewart platform, acquired from Tuijthof et al. [13]. A) detail of the ball-and-socket joints positioned at the ramp of the ground plate indicated in the yellow circle, B) detail of attachment between the foot plate and the rods by means of the rubber joint indicated with the yellow arrow.

The ball-and-socket joints are made of a plastic bead ($\varnothing 16 \text{ mm}$) and tube (length of 20 mm), which are glued together. A hole through this joint is needed to move a rope from the rod to the handle (will be explained in the next paragraph). The transparent rods are made of PMMA ($\varnothing 15 - 11 \times 220 \text{ mm}$), and the inner rods are made of carbon fiber ($\varnothing 9 - 7 \times 175 \text{ mm}$).

To keep the foot plate in a specific configuration, a fixation mechanism is designed, which can be activated by turning the fixation handle a quarter of a circle. The length of the rods is then fixed. These lengths can be locked with the use of the silicone tubing, placed inside the rods (Figure 8A). The silicone tubing is pressed together in order to create friction inside the inner rods, as the silicone tubing expands. The pressure on the silicone tubing is created by ropes, pulled through the silicone tubing (Figure 8B and C). By simultaneous tightening the ropes with one handle (Figure 8D), the rods could be fixated in any position by friction. However, the friction force turned out to be insufficient in some positions of the foot plate, in which the tensioning of the rope did not work sufficiently with the handle.

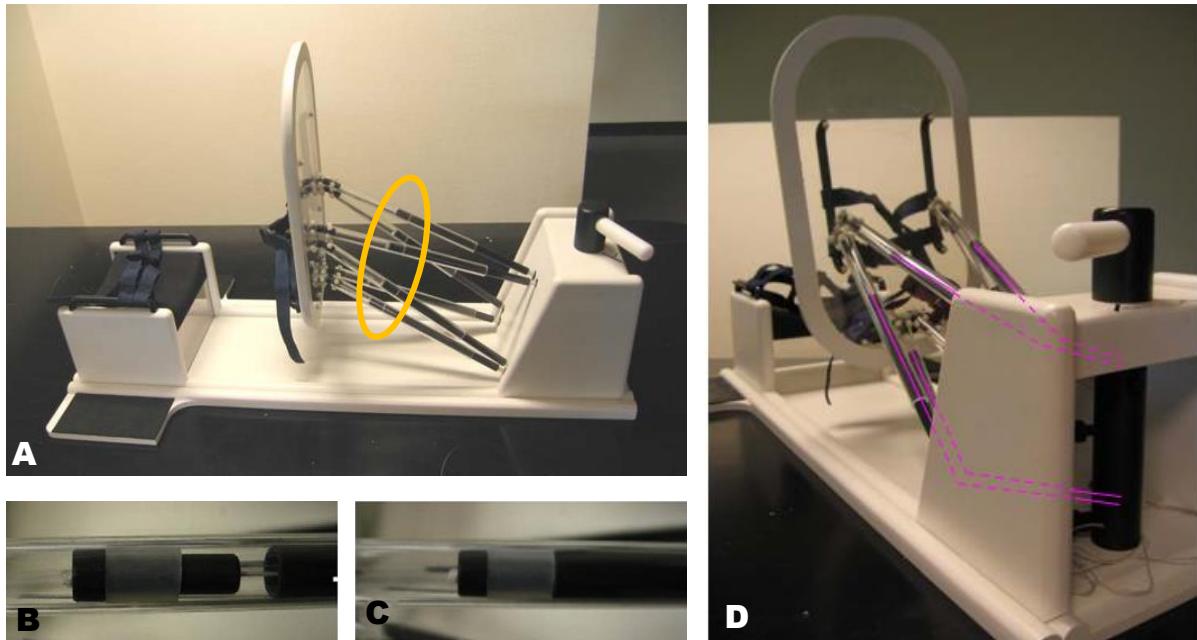


Figure 8. Fixation mechanism of the 3D stress foot plate, acquired from Tuijthof et al. [13] and Van der Zwaag [15]. A) complete prototype in fixated state, the position of the fixation plugs is indicated with the yellow circle, B) fixation plug in loose state, C) fixation plug in fixated state, D) The pink line indicates the ropes, which are used to pull the fixation plug. The ropes run through the fixation plug and the inner tube. The ropes enter the fixation house, running through the ball-and-socket joint. The ropes are tightened using a black cylinder.

In the works of Van der Zwaag [15] and Tuijthof et al. [13], the materials used differ to obtain friction for the fixation mechanism. The description above includes the materials used in the article by Tuijthof et al. [13]. Van der Zwaag [15] uses sponge rubber cylinders ($\varnothing 10 \times 28$ mm), which are also placed inside the outer rod, at the end of the inner rods (Figure 9A). The rubbers are pressed together to create friction inside the inner rods as the rubber expands. Pressure on the rubbers is created by ropes pulled through the rubber. The rope stays in place because of the stiff fixation part ($\varnothing 10 \times 5$ mm), so that the rope cannot go when there is tension on the rope. On the side between the rubber and the inner rod there is another unknown white piece, so the rubber does not get stuck in the rod. However, only the size is known about this piece ($\varnothing 10 \times 2$ mm), but not what it consists of.

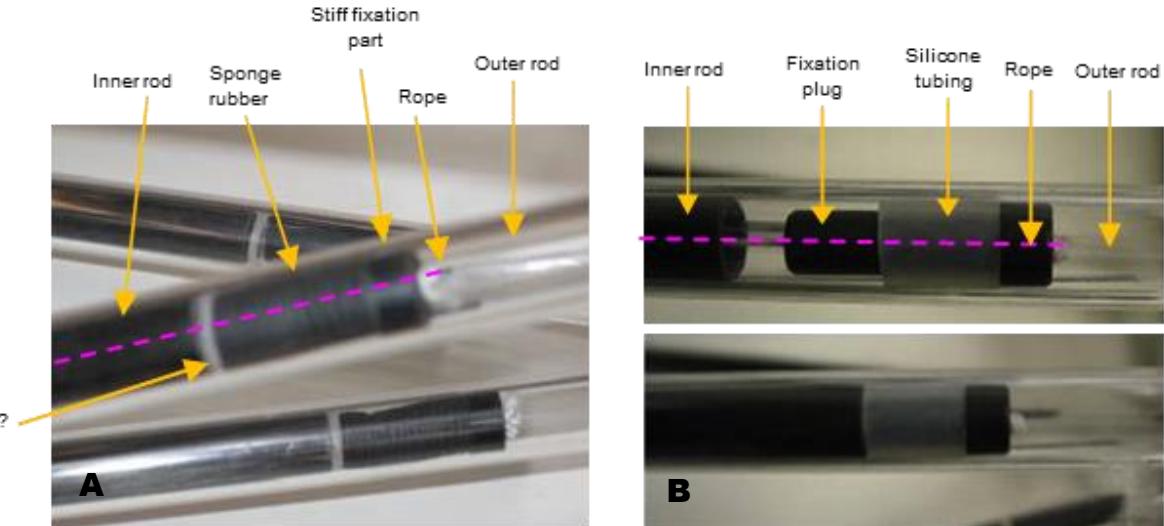


Figure 9. Different materials are used for obtaining friction between the rods. A) Rubber cylinders used from the work of Van der Zwaag [15], B) Silicone tubing used from the article of Tuijthof et al. [13].

Tuijthof et al. [13], uses a principle whereby fixation plugs ($\varnothing 11 \times 50$ mm) surrounded by silicone tubing were connected to the ropes (Figure 9B). The article does not describe the thickness of the silicone tubing, and therefore the thickness of the plug. In addition, it is not stated what the plug is made of.

Bandages with a side release buckle were used to fixate the foot and the lower leg to the device (Figure 5). On the foot plate, two buckle fasteners are used on the foot instep. One buckle fastener is used from the heel of the foot. Two buckle fasteners are used on the leg support to fix the lower leg.

3. Design for assembly - A functional model

With the description of the current prototype device in the previous chapter, the 3D stress foot plate can now be improved with the aim of optimizing the way of assembly and reducing the number of assembly steps. Also, the functional model presented in this chapter was used to perform a risk analysis with various stakeholders (as the old prototype was no longer available). Design requirements for the optimization of the assembly were set:

- Only use production methods that are easy to order online and require a minimum of engineering expertise
- Use as much as possible off-the-shelf components.

In this chapter, the improved production methods are discussed, how the functionality can be improved with off-the-shelf components, then the functional prototype will be presented.

3.1. Improved production methods

3.1.1. Laser cutting

Analyzing the original design, it was a straightforward option to fabricate the parts of the ground- and foot plate (Figure 3) using laser cutting, as all parts are flat surfaces with this technique only the parts are put together with glue. This eliminates the step of cutting parts to size yourself. 3D Computer-Aided Design (CAD) drawings of the individual parts of the ground plate and the foot plate (Figure 10) have been made in SolidWorks (Version 2022) to check the dimensions properly. Those 3D CAD drawings have been converted into 2D vector drawings for laser cutting.

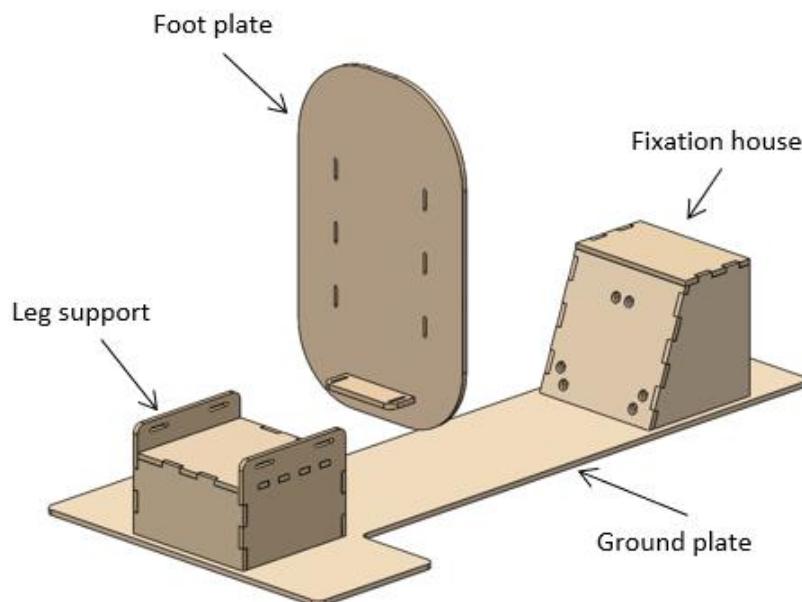


Figure 10. 3D CAD drawing of the 3D stress foot plate, consisting of the ground plate where the leg support and the fixation house are positioned, and the foot plate itself.

The length and width of the ground plate (Figure 3 and Figure 10), the height of the leg support, the slope of the fixation house, and the length between the leg support and the fixation house are taken from the work of Van der Zwaag [15]. This keeps the prototype compatible for different imaging systems and can be used in a large population [13]. Slots have been made in the sides of the leg support for the connection for fixing the leg to the leg support (Figure 10). The holes where the ball joints had to come into the fixation house have been placed in a triangular configuration. The maximum size has been chosen between the triangles in which the ball-and-socket joints are not hindered by the relevant support on which this plate is placed. For the ground plate, it was decided to create rounded corners.

The maximum length and width of the foot plate has also remained the same as in the article from Tuijthof et al. [13]. The shape of the foot plate is a flattened ellipse (Figure 10), which is similar to the article (Figure 3). In here, also slots are created on the same width as it was where the rails for the bandages were made in Van der Zwaag's work [15]. In addition, a support has been made where the heel of the foot must be placed. This has been placed on the foot plate in the same position as in the previous device, and the height and width of this support have remained the same.

The rods fixation parts are made on the back of the foot plate, where the rubber hinge can be clamped. The same thickness of the material is used, so that 2 pieces are placed on top of each other to achieve a comparable thickness as in the work of Van der Zwaag [15]. This part looks like a pretzel, where two rubber hinges can be clamped (Figure 11).

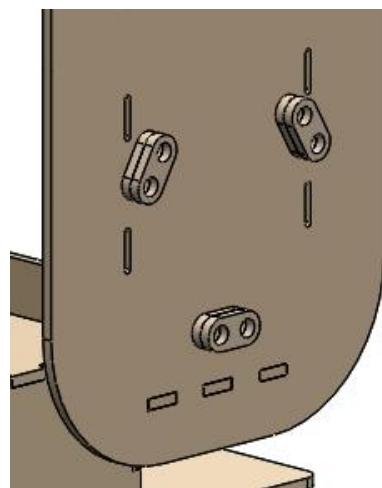


Figure 11. Back view of the foot plate. The pretzel shaped rods fixation parts can be seen here.

To verify the modifications and perform a risk analysis, a functional model was made of a 6 mm medium-density fiberboard. The laser cutting of all parts could be done on one medium-density fiberboard of 1200x600 mm.

3.1.2. 3D printing

With current technology, it is possible to have the ball-and-socket joint 3D printed (Figure 12A). This ensures that this joint is made in one piece, making this joint stronger. This joint must be printed on polymer materials to ensure that the prototype remains suitable for use in imaging devices. The 3D printing technique must be chosen so that the joint has a smooth finish, but is firm [22]. In addition, the joint should have a hole through which the rope can pass, and this hole should not be too large (Figure 12B). The 3D printing technique will have to be able to handle this.

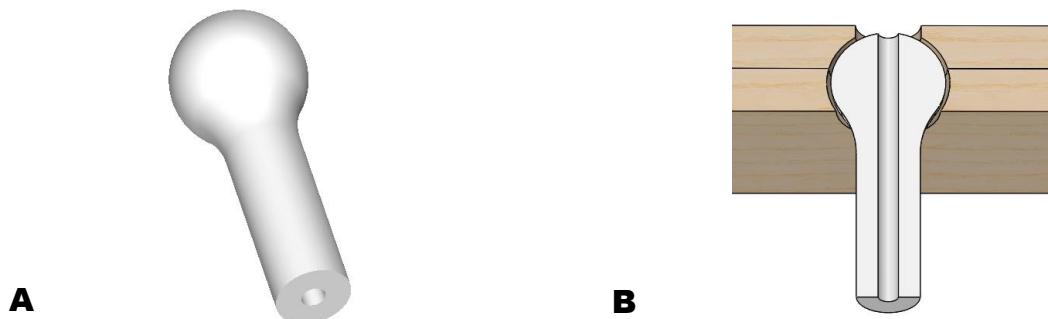


Figure 12. Ball-and-socket joint. A) CAD drawing of the ball-and-socket joint, B) cross-section of the ball-and-socket joint, taking into account the plates in which the joint must clamp.

The ball-and-socket joint will be printed with Selective Laser Sintering (SLS) [23,24]. SLS uses a laser to sinter powdered materials. The most commonly used material in SLS printing is nylon, which has a high tensile strength. SLS can make parts with a high degree of dimensional accuracy and surface finish. This is important, because there must be a hole through the joint, and the joint must be able to turn easily. To make the ball-and-socket joint, an STL file is needed, which can be easily converted from the CAD file. The CAD drawing was necessary to coordinate the overall design and dimensions. The ball-and-socket joint has a ball diameter of 14 mm, the length of the rod is 30 mm, and the hole made has a diameter of 2.5 mm.

3.2. Improved functionality

The current handle (Figure 6) which ensures fixation of the device, has been removed and is replaced by a mechanism that ensures that the ropes can be individually tightened. Different ways of clamping the rope have been looked at, so that tension can be applied to activate the friction plug. Many different types of rope clamps are used in sailing, making these clamps easy to recognize, understand and used with minimal mental effort. There exists a cam cleat that consists of a spring-loaded set of jaws with little rope-grabbing teeth that will grab and lock the ropes [25]. However, this spring load includes metals, making them unsuitable for an MRI/CT imaging modality. There are also clam cleats, which have a simple compact construction without any metals (Figure 13A).

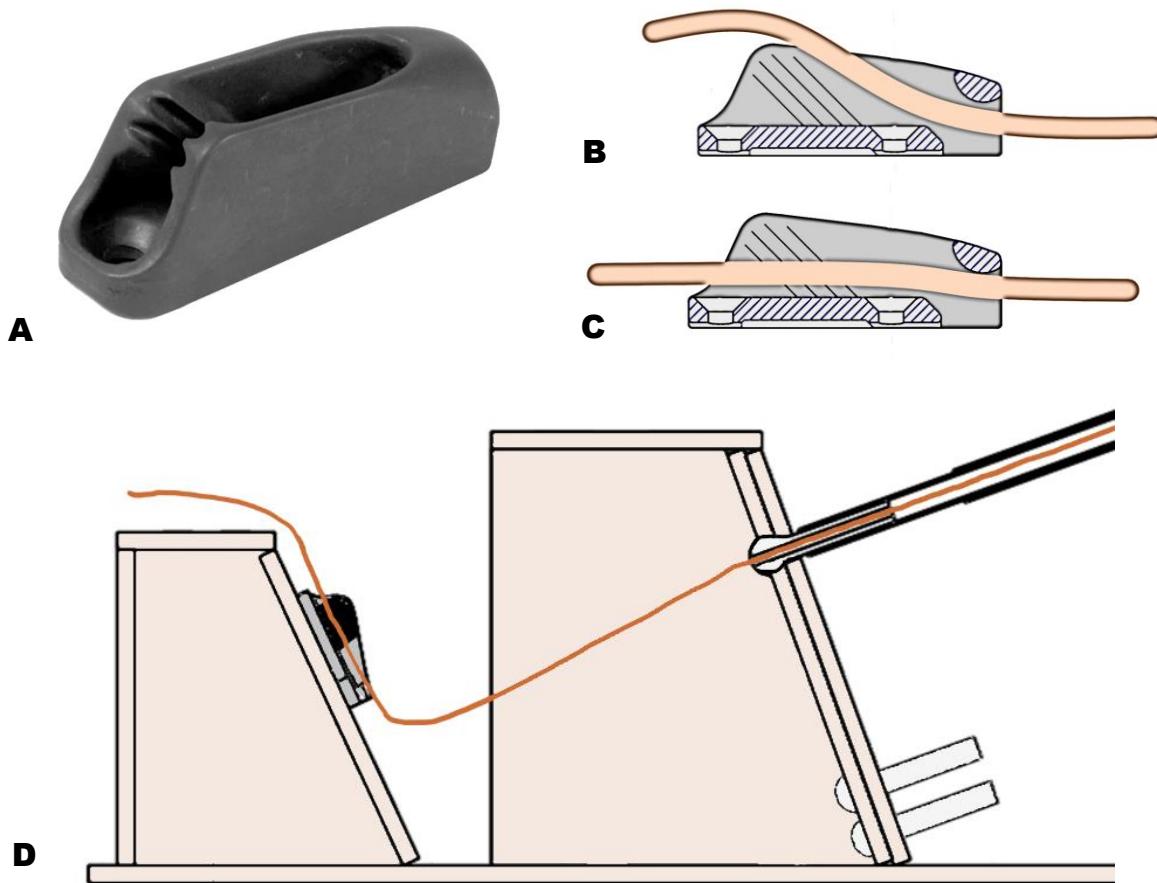


Figure 13. The clam cleat. A) Clamcleat CL263 nylon micros cleat, B) cross-section of the cleat in a loose state, C) cross-section of the cleat in the fixated state, load on the rope on the right side, D) schematic representation where the cleat is placed in the prototype, rope is also indicated.

By implementing the clam cleat rope cleat fixation from Clamcleat® [26], each individual rope can be fixated or adjusted (Figure 13A). The clam cleat works by securing the rope in the ribbed V shape (Figure 13B and C), with the load on the rope helping to hold it in place. In Figure 13D, it can be seen where the clam cleat is placed on the device. The ropes can be loosened by pulling the rope up (and away from the ribbed structures) and leading it through the holes. Important to note is that even though the ribbed structures provide a lot of grips, it is not sharp in the sense that it can cut the rope.

3.3. Prototyping for design for assembly

A functional prototype of the 3D stress foot plate was built (Figure 14). Clam cleats, which are placed on a slope (Figure 14B), ensure the fixation of the rods by means of friction in the rods (Figure 14E and F). The 3D printed ball-and-socket joints (Figure 14C) provided the similar required two rotational DOF of the rods, as described in the article by Tuijthof et al. [13]. Furthermore, the rod fixation parts (Figure 14D) ensure that the rubber hinge remains in place, as it ensures sufficient clamping.

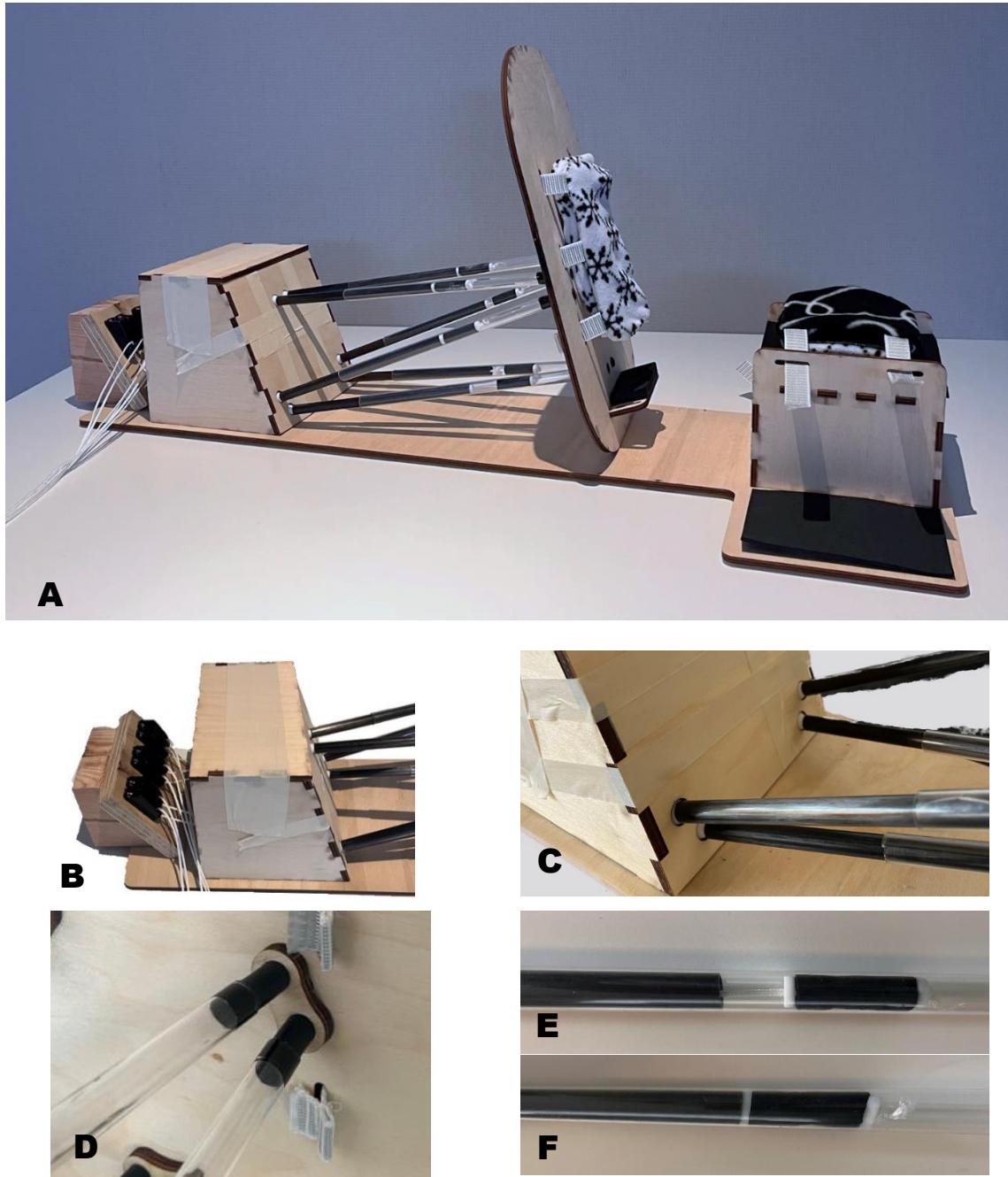


Figure 14. Functional model of the 3D stress foot plate. A) Complete prototype in loose state, B) close-up of the fixation house, C) close-up of the ball-and-socket joint, D) close-up of the hinge joint, E) rods in loose state, F) rods in fixation state.

The functional prototype can be positioned in several positions (Figure 15), after which it can also be fixated in that position. To secure the foot plate, each individual rope must be tensioned and secured in the rope clamp. The order in which this is done does not matter. The mechanism of the rope cleats seems to work well. Therefore, it can be used further. The added slope makes it easier to tension the ropes.

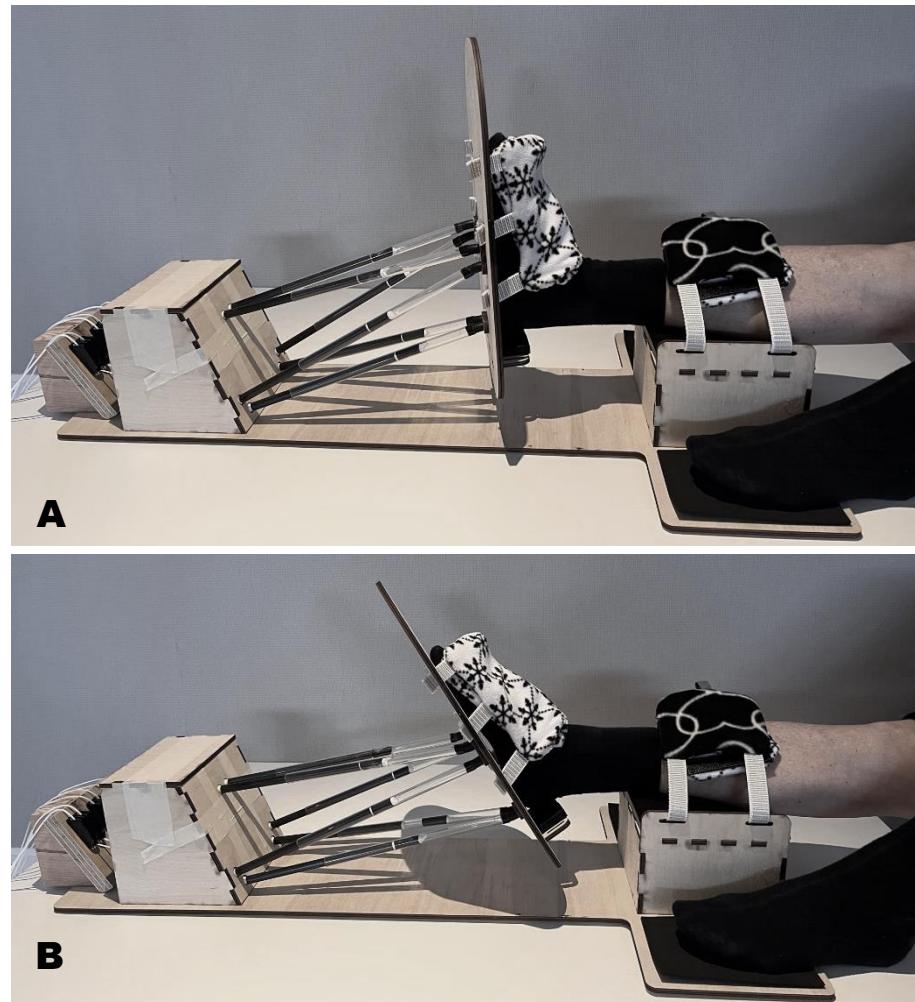


Figure 15. Functional prototype fixated in different positions. A) neutral position; in which the foot is at 90 degrees in relation to the lower leg., B) Plantar flexion of the foot

This functional prototype will be used to start the documentation that will have to be completed to comply with the MDR including the risk analysis. Although the functional prototype is only used in the risk analysis and is of no further importance, an evaluation has been carried out on the prototype. This evaluation can be found in Appendix A.

4. Compliance with Medical Device Regulation

The obtained functional device will be used for MDR compliance. Since safety is a crucial point in medical products, the quality and control processes of a medical device largely depend on a thorough risk analysis [27,28]. The guidelines and obligations for this risk analysis are available in ISO 14971: 2019 (Application of risk management to medical devices) [20]. First, the general product information will be discussed, in which the intended use and the classification of the product will be discussed. Then the hazards will be discussed with various stakeholders, with which a risk analysis will be performed. In addition to the requirements that have already been discussed in advance, requirements will also follow from the risk analysis. Finally, all requirements will be summarized and made measurable, so that it can be checked whether the device meets the requirements.

4.1. General product information

The classification of the device is determined by the intended use of the device [27]. The intended use of a medical device is the general purpose for which the device is intended to be used.

The intended use of the 3D stress foot plate is to move and fixate the foot in a certain extreme position relative to the lower leg for a short period of time.

The classification of medical devices used by EU medical device legislation is a risk-based system that takes into account the fragility of the human body and the potential risks associated with the devices [27]. This approach uses a series of criteria to determine classification. These criteria are set out in Annex VIII of the MDR [28], and are referred to as the 'classification rules'. The product is not an implantable product. In addition, the product is not an active product, as it may not contain any metal or magnetic products or fields because it must be used in a scan, so it is completely manual [27]. Therefore, the product is non-invasive and can be categorized as a Class I medical device. Class I devices are considered low-risk, so it will pose a low risk to the patients.

4.2. Risk analysis

With the aid of the intended use, characteristics related to the safety of the medical device prototype can be identified. In Annex A of NPR-CEN-ISO/TR 24971:2020 [29], 37 questions could be answered, which helps to identify all the characteristics of the medical device that could affect safety. For every question, it is indicated which factors should be considered in further detail, with the ultimate goal of identifying all hazards associated with the medical device. In Appendix B, the filled in questionnaire can be found.

Annex C of ISO 14971:2019 [20], provides a non-exhaustive list of possible hazards that can be associated with different medical devices. Using the above stated questions, the hazards that are important for the device risk analysis can be selected. There are six different hazard classes, which contain hazards that are relevant to the 3D stress foot plate device; energy hazards, biological or chemical hazards, examples of events and circumstances hazards, usability hazards, and functionality hazards. These relevant hazards are used to perform the risk analysis.

Tables are made for the six different hazard classes, clearly showing the hazards and the sequence of events that lead to hazardous situations which are relevant for the device. The risk analysis involves examining different sequences or combinations of events related to a single hazard that can lead to different hazardous situations. Each hazardous situation can lead to different types of harm.

The risk analysis was performed with the functional model fabricated in Chapter 3, and was performed with several stakeholders. Experts involved are members of the project itself (the project lead, a biomedical engineer, a mechanical engineer and a technician), and members of the expert / use team (a trauma surgeon, and an orthopedic (Foot and Ankle) surgeon). The participation list is listed in Appendix C.

4.2.1. Energy hazards

In Table 1, the risk analysis is presented for all energy hazards related to the device.

Table 1. Energy hazards

Risk analysis				Risk eval.
Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	
Falling objects	(a) The device is portable and will be taken in and out of the radiation rooms; (b) Tightening the rope	<ul style="list-style-type: none"> The device could fall and break The rope cleats could loosen and shoot away 	Product failure (damaged) Rope cleats will remain on the rope	Negligible
Moving parts	(a) The foot is attached with Velcro straps to the foot plate itself when positioning and fixating the foot in an extreme position for an X period of time.	<ul style="list-style-type: none"> Cramp/pain in patient's foot; A wound to the foot may be caused by friction of the Velcro straps 	Harm to the patient's foot	Negligible
Bending	(a) Moving the device, for example, to another room	<ul style="list-style-type: none"> When the device is lifted and bends too far 	Product failure (damaged)	Tolerable
Tension	(a) Securing/tightening the ropes (b) Foot attachment on the foot plate with Velcro straps	<ul style="list-style-type: none"> When the friction force is insufficient, the patient can move the foot himself; It is not clear when specific ropes are tightened. Attaching Velcro straps too tightly leads to entrapment and possibly a wound 	Harm to the patient	Negligible

The risk evaluation for the energy hazards shows that the bending hazard only poses a potential risk. The other hazards pose no risk to the patient and user.

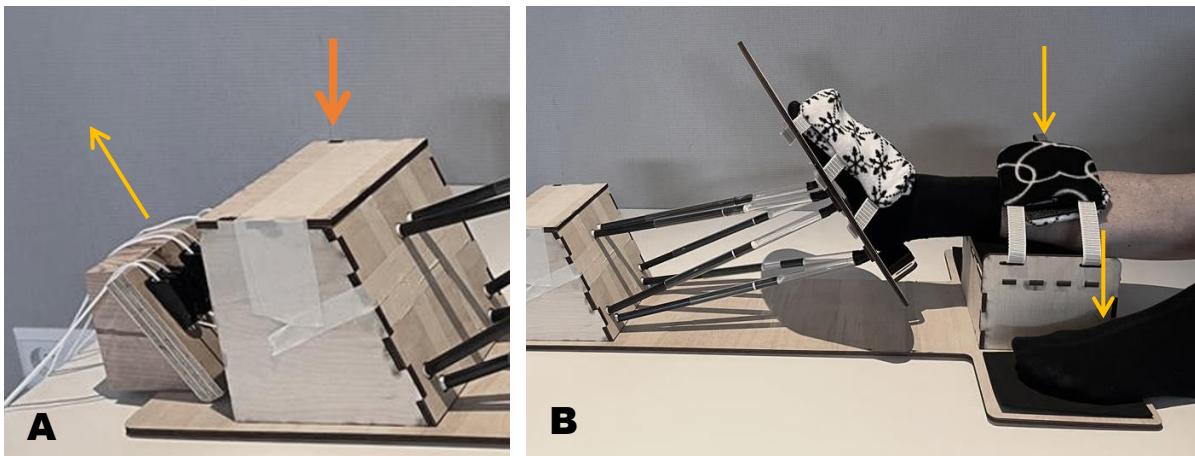


Figure 16. Important forces during use of the device. A) the yellow arrow indicates the force that must be exerted to pull the rope tight, for this a downward force must be exerted on the fixation house (orange arrow), B) the downward force generated by the patient, indicated by yellow arrows.

To tension the device, each of the six ropes will have to be tightened (Figure 16). However, when the ropes are secured and the clinician's hand is released, the ground plate bends upward. The bending stiffness of the ground plate is too low to keep it neatly flat on the table. Therefore, an additional requirement to the device must be added:

- The device should not exceed 5 mm of deflection when the foot is fixated

Referring to Table 1, all risks, except for bending, are negligible in the way that no improvements are needed to the device. However, it has been decided to take design measures to ensure patient safety. Therefore, an requirement has been set:

- The straps on the device where the foot is attached should be released in one movement

4.2.2. Biological or chemical hazards

The device will be used in an environment where sterile work is not required, but the device must be cleaned. Furthermore, the surface where the foot is placed (the foot plate) will come into contact with a part of the bare body. As a result, this part must be properly cleaned. There is a chance of bacterial infection in the patient when cleaning is not performed (Table 2).

Table 2. Biological or chemical hazards

Risk analysis				Risk eval.
Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	
Bacteria	(a) Repeatedly make use of the device without cleaning the device	• Re-use after previous use on another patient without cleaning	Bacterial infection to patient	Tolerable

To mitigate this risk, cleaning and disinfection instructions for the device will need to be provided to the user from a manufacturer's perspective. In addition, it is important that the material used is easy to clean and that the material used is biocompatible. Therefore, the following additional requirements were set.

- The materials that come into contact with the patient must be biocompatible
- The device must be easy to clean

4.2.3. Performance related hazards

Table 3. Performance related hazards

Risk analysis				Risk eval.
Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	
Image artifacts	(a) When the device is used with a patient and an imaging photo is taken	• The image photo is unusable due to artifacts, due to the material used.	-	Negligible

The 3D stress foot plate device will (mostly) be used in combination with an imaging system. This means that medical images are always taken when the device is used. This can cause image artifacts (Table 3). Therefore, the device will have to be made of compatible materials, so non-magnetic materials. A requirement has already been set for this in the article by Tuijthof et al. [13]. In addition, the hazard image artifacts have no harm to the patient and/or the user.

4.2.4. Hazards caused by a variety of events and circumstances

During device manufacturing and handling before actual use, hazards can occur (Table 4). For example, repeated incorrect use of the device can lead to damage, and the device can be wrongly made with incorrect or damaged materials.

Table 4. Hazards caused by a variety of events and circumstances

Risk analysis				Risk eval.
Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	
<i>Inadequate specification of: in-service requirements</i>	(a) Repeated use of the product, especially repeated use of the friction principle	<ul style="list-style-type: none"> • Wear on rope / rods • friction force not strong enough 	Product failure	Negligible
<i>Insufficient control of: manufacturing processes</i>	(a) Assembling the device	<ul style="list-style-type: none"> • No consistent manufacturing process; • wrong materials used, wrong dimensions 	Product failure	Negligible
<i>Insufficient control of: materials</i>	(a) Assembling the device	<ul style="list-style-type: none"> • Materials have different properties that may not meet the requirements set 	Product failure	Negligible
Inadequate packaging	(a) Individual parts on their way from supplier to place for assembly	<ul style="list-style-type: none"> • Damage during transport 	Product failure	Negligible
Inappropriate storage and environmental conditions	(a) Device stored while still in the fixated state. (b) Device stored under high temperature / high humidity.	<ul style="list-style-type: none"> • The device is fixated when stored. The device is under tension, making it more sensitive and fail under fatigue • When the device is stored at high temperature / high humidity, materials such as rubber and glue can deteriorate 	Product failure, financial deficit	Negligible
Inadequate performance of cleaning, disinfection or sterilization	(a) Device must be cleaned prior to a new patient	<ul style="list-style-type: none"> • Bacterial infection in the patient • Without proper cleaning, damage to the product can occur 	Harm to patient, Product failure	Negligible

The risks in Table 4 affect mainly the device itself, without direct impact on the patient, because they become apparent during the making and assembly of the device. Moreover, should the device spontaneously fall apart due to previous mistakes, the patient will not be inconvenienced because no parts of the device are placed on top of the patient.

However, these risks are important to us as a manufacturer. Since the device itself must be able to be assembled, built appropriately, and verified. In addition, the sturdiness of the device must be guaranteed. Therefore, the following requirements were established.

- The device should be easy to assemble by providing instructions through the generation of manuals and the material specifications
- The device should not break when accidentally falling during transport

4.2.5. Usability hazards

Usability hazards refer to the potential for medical devices to cause harm or injury due to difficulties in their use. These hazards can arise from a variety of factors, including poor design, inadequate labeling or instructions for use, and insufficient training for users. Table 5 shows the hazards that may occur with the 3D stress foot plate.

Table 5. Usability hazards

Risk analysis				Risk eval.
Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	
Confusing or missing instructions for use	(a) The foot can be placed incorrectly by the medical professional (b) It can be unclear how the ropes should be tightened and how the fixation principle works	<ul style="list-style-type: none"> Overextend the foot, causing damage to ligaments. The ropes are manually fixed, forcing the foot plate to move 	Harm to the patient	Negligible
Complex or confusing control system	(a) Not clear how to use the device, especially how to fixate the device	<ul style="list-style-type: none"> Abrupt movement of the foot, when this was not intended 	Harm to the patient	Negligible
Ambiguous or unclear state of the medical device	(a) Not clear whether the ropes are fixated or not	<ul style="list-style-type: none"> Moving the foot plate while it is in a fixed state 	Possible product failure	Negligible
Use by unskilled or untrained personnel	(a) A medical professional is required to mimic the clinical stress test	<ul style="list-style-type: none"> Damage to ligaments Compromised results 	Harm to the patient	Tolerable
Insufficient warning of side effects	(a) Straps may cause wounds to the foot. (b) Overextending of the foot	<ul style="list-style-type: none"> If the straps are pulled too tight, friction will occur and cause wounds Ligaments may damage 	Harm to patient	Negligible
Slips, lapses and mistakes	(a) Positioning the foot in an extreme position and thereby mimicking a clinical stress test is a critical performance measure to use this device	<ul style="list-style-type: none"> Not performing the clinical stress test properly 	Harm to patient	Tolerable

To reduce the risks that are tolerable from Table 5, the following requirement will have to be established to ensure patient safety.

- The device should only be used by someone with a medical background who has also received training in stress testing

In addition to that, the article by Tuijthof et al. [13], conducted a usability test with radiology technicians to evaluate ergonomics. This test focused on the self-explanatory capabilities of the device. It has been found that the 3D stress foot plate can be operated by one person with low mental effort, and that the foot can be positioned and fixed properly. As a result, it can be stated with certainty that the risks that are marked as negligible are actually negligible.

4.2.6. Functionality hazards

Functional hazards in medical devices refer to the potential for a device to cause harm because of its function. Over time, a component of the device may fail (Table 6).

Table 6. Functionality hazards

Risk analysis				Risk eval.
Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	
Failure of a component due to aging, wear, or fatigue	(a) Over time, the performance of mechanical components may decrease.	• Reliability of the device will gradually decrease	Product failure	Negligible

The device will have to be looked at periodically and will also have to be maintained. When defects in the device become apparent, such as when the rope or rope cleat shows signs of wear, the device will have to be repaired or, if this is not possible, replaced with a new device. A requirement has been drawn up that the device must meet in order to make maintenance sustainable.

- The device should at least be functional for 1 year without maintenance

4.3. Evaluation criteria

The risk analysis shows that there are still risks to the product that affect the patient. This can be remedied by changing the design of the product to a level that reduces the risk, which will be done in Chapter 5. It is important that the requirements for design and development, as well as for production and service, are presented in detail. Fulfilling the requirement to design and manufacture devices in accordance with the regulation means meeting the "Product Realization" requirements in Chapter 7 of ISO 13485:2016 (Quality management system for medical devices) [30].

All of this has led to one large requirement list that the product must meet. The requirements have been drawn from A) the article by Tuijthof et al. [13] (Table 7a), and B) the requirements from the risk analysis (Table 7b). In addition, the checklist general safety and performance requirements from Annex I of the MDR [28] are also looked at. This checklist contains the requirements that every manufacturer of medical devices selling their products in the European Union must comply with, regardless of the type and class of products. This resulted in one additional requirement that the device will have to meet.

- The device should not have sharp edges

Table 7 also indicates which requirements have already been met, and which do need to be tested using a combination of objective and subjective evaluation criteria.

Table 7a. Requirements to judge the functionality of the new 3D stress foot plate. The requirements in white are from the article by Tuijthof et al. [13], the other requirements are set out in this thesis. The requirements that are printed in italics could not be tested adequately with this setting. It is indicated which requirements have already been met, which do not need to be tested again.

Requirements	Objective verification	Subjective verification	Already compliant
1 The device should be able to manually position the foot in extreme positions relative to the lower leg	Range of motion of the foot plate that can be achieved		✓
2 The device should be dimensioned such that it can be used to diagnose 95% of an adult human population.	Anthropometric measurements		✓
3 The device should be compatible with different imaging systems (radiography, MRI- and CT scanners):			
a The device should be dimensioned such that it fitted into different imaging systems	Device dimensions within CT dimensions		✓
b The device should be fabricated with materials that can be used in different imaging systems	Properties of the used materials		
4 The weight of the device should be a maximum of 12.7 kg to be portable	Weighing the mass (3x)		
5 The device should require a separate manual fixation mechanism to preserve the desired extreme position of Friction force of rods > 50 N the foot			
6 Different hand grips on the device should be allowed to apply manual loading.	Testing with multiple people		
7 The device should offer fast operation below 100 s	Task time (sec.)		
8 The device should be able to manually fixate the foot in extreme positions relative to the lower leg	Range of motion of foot plate that can be maintained; Tightness of fastening the foot		
9 The operator should have a sense of control when using the device	Number of mistakes (n)		
10 Excursions of the upper extremities of the radiology technician should be kept within limits	Range of motion upper extremities during work cycle		
11 It should be clear (unambiguous) how to position the lower leg and the foot in the device	Number of mistakes (n)		
12 <i>The total acquisition time should not be increased by more than a maximum of 10-15 % when using the device</i>	Time		
13 Fixating the foot should not create additional damage to the ligaments		Question (True or False)	✓
14 The foot should be positioned in an extreme position mimicking a clinical stress test		Question (True or False)	✓
15 <i>The device should have a professional appearance and blend into the working environment</i>		Question (True or False)	
16 The device should be operated by one person		Question (True or False)	
17 The device should be operated with minor physical and mental effort		Mental and physical score (percentage)	

Table 7b. Requirements to judge the functionality of the new 3D stress foot plate. The requirements in white are from the article by Tuijthof et al. [13], the other requirements are set out in this thesis. The requirements that are printed in italics could not be tested adequately with this setting. It is indicated which requirements have already been met, which do not need to be tested again.

Requirements	Objective verification	Subjective verification	Already compliant
18 The materials that come into contact with the patient must be biocompatible	Properties of the used materials		
19 Use as much as possible off-the-shelf components	Number of off-the-shelf components compared to all components used		
20 The device should not exceed 5 mm of deflection when the foot is fixated.	Bending test, deflection $\leq 5\text{ mm}$		
21 The straps on the device where the foot is attached should be released in one movement	Time of detaching foot and lower leg		
22 <i>The device must be easy to clean</i>	<i>Time and effort of cleaning</i>		
23 <i>The device should be easy to assemble by providing instructions through the generation of manuals and the material specifications</i>	<i>Comparison properties of two assembled devices</i>		
24 <i>The device should at least be functional for 1 year without maintenance</i>	<i>Repeatedly using the device</i>		
25 <i>The device should not break when accidentally falling during transport</i>		Question (True or False)	
26 <i>The device should only be used by someone with a medical background who has also received training in stress testing</i>		Question (True or False)	
27 Only use production methods that are easy to order online and require a minimum of engineering expertise		Question (True or False)	
28 The device should not have sharp edges		Question (True or False)	

5. Final design

Now that the list of requirements has been completely drawn up, the final design can be created. The device will be presented, after which there will be an extensive description of what the device is made of and what the specifications are exactly.

5.1. Design for clinical application

The following changes have been implemented in response to the requirements arising from the risk analysis.

To make the device firmer, so that it no longer bends, an adjustment will have to be made. An extra rail will also be added to the long side of the ground plate to prevent bending, as can be seen in Figure 17.

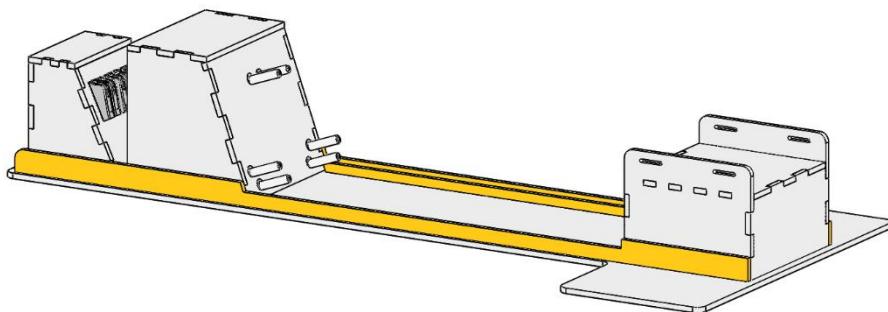


Figure 17. Added rail to the ground plate assembly, indicated in yellow.

To make the device easier to clean, the materials that come into contact with the patient will be made from polypropylene. Therefore, the ground- and foot plate will be made of polypropylene. Polypropylene is chosen because it is resistant to many cleaning agents and has high dimensional stability [31–33]. Therefore, this material is biocompatible. Due to its low-risk use, the device only needs to be cleaned by cleaning with an alcohol wipe. In addition, polypropylene can be laser cut, and does not need to be pre- or postprocessed when laser cut.

The detachment of the foot and the lower leg will be done by means of Velcro, so that the straps can be released in one movement. Sharp edges of the device can be remedied by sticking rubber on these edges. In addition, more self-explaining aspects will be added to the device; a foot symbol has been added that is placed on the foot plate, and color recognition is applied to the ropes. When red is shown, the rope is tensioned. If only white is visible, then there is no sufficient fixation. Furthermore, manuals will be made for assembling the device and using the device. The material specifications of the parts to be used will also be displayed.

5.2. Prototype

The final prototype of the 3D stress foot plate is shown in Figure 18. The specifications of the prototype will be discussed in the next section. Bandages with Velcro straps were connected to the foot plate and lower leg support for fixation of the foot and lower leg (Figure 18A). All rods could be fixated using plugs surrounded by silicone tubing that were placed in each of the six rods and were connected to the ropes (Figure 18C, and D, and E). The ropes can be tensioned by means of the clam cleats on the rope house (Figure 18B).

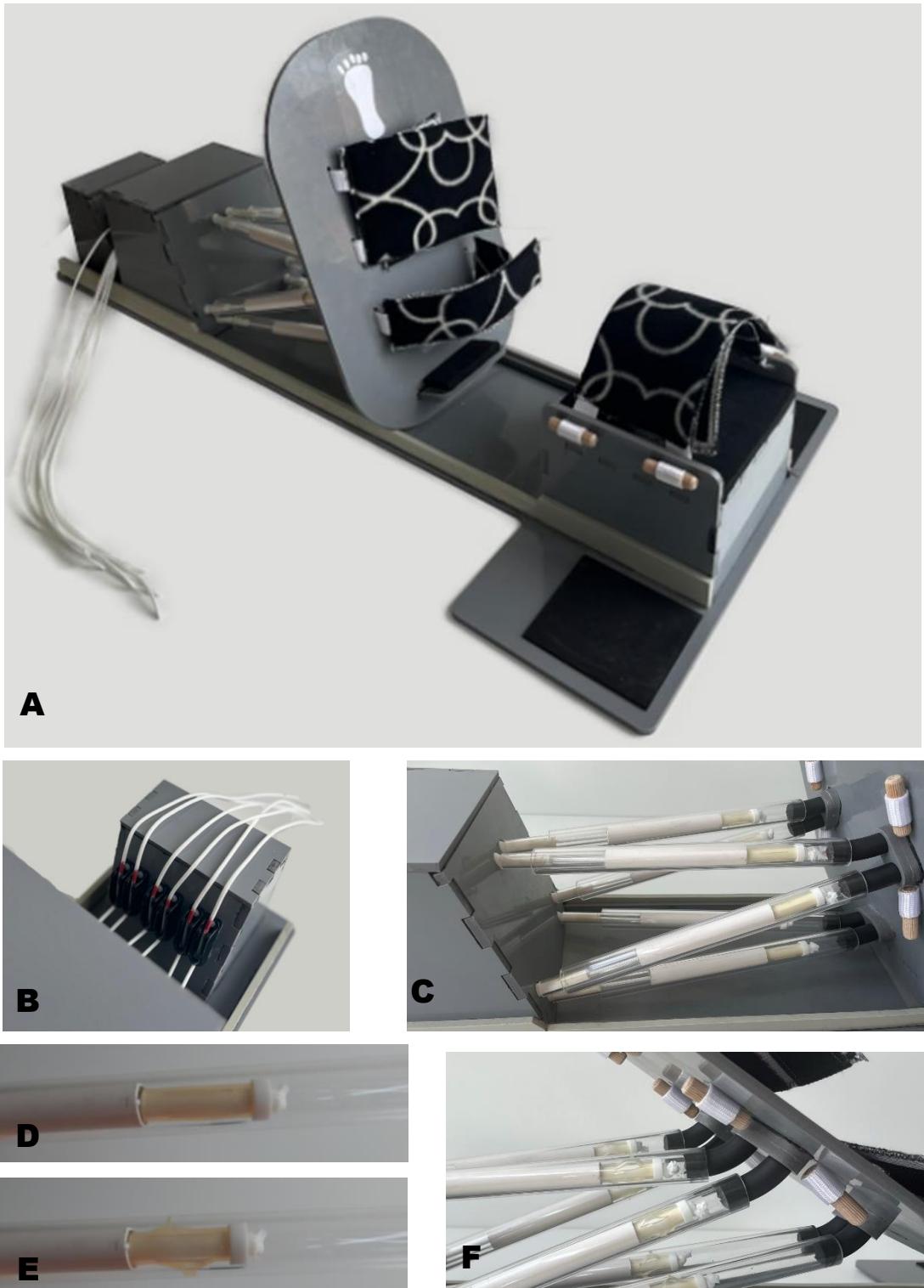


Figure 18. Final prototype of the 3D stress foot plate. A) Complete prototype in loose state, B) fixation via Clamcleat, in fixated state, C) detailed view of the rods in loose state, D) silicone in loose state, E) silicone in fixated state, F) detailed view of the compliant hinges, device in fixated state.

A list of materials has been drawn for the construction of the device. Of the easy off-the-shelf parts that have been purchased, Appendix D shows the dimensions and where it was purchased. The parts made with easy production techniques, the technical drawings are shown in Appendix E and F. In addition, the dimensions of fixation straps can be found in appendix G. An indication of price list is shown in Table 8.

Table 8. Bill of materials

Description	Amount	Make / Buy	Price (€)
Polypropylene parts	-	Make (Laser cut)	254.86 ²
Ball-and-socket	6	Make (SLS 3D printing)	22.65 ²
Fixation plug	6	Make (SLS 3D printing)	21.13 ²
Outer PMMA rod	6	Buy ¹	13.16
Inner PMMA rod	6	Buy ¹	5.03
Plastic rod	6	Buy ¹	4.95
Solid rubber	6	Buy ¹	5.93
Silicone tube	6	Buy ¹	<i>Unknown where to buy</i>
Rope	6	Buy ¹	2.16
Clamcleat	6	Buy	14.97
Nylon bolts	12	Buy	1.56
Nylon nuts	12	Buy	0.96
Glue	-	Buy	77.82
Other parts (for fixating the foot / lower leg)	-	Buy ³	39.46
Total price			€ 464.64

¹ Need to be cut to length.

² Indication of the price, when purchased online.

³ Needs to be put together (e.g., sewing, gluing).

There is a color difference in the last polypropylene rail added compared to the other polypropylene parts because this material was ordered at a different time. All propylene parts are glued together with a special plastic glue for polypropylene. The rubber hinge is also glued to the foot plate with this glue, as well as the rope cleats to the slope of the rope house. The rope cleats are also attached with plastic bolts and nuts for extra reinforcement.

To make sure that sharp edges are absent where the user or the patient is in contact with the device a layer of rubber is added, as can be seen in Figure 19.

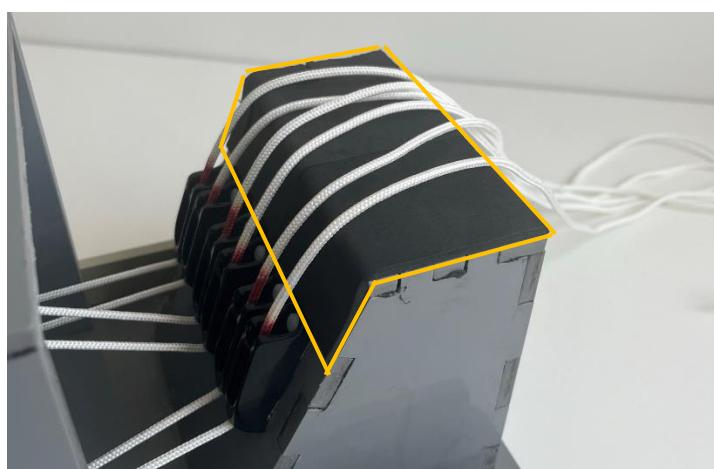


Figure 19. Black rubber placed on the rope house. Indicated with a yellow outline for clarity.

5.3. Specifications

5.3.1. Ground- and foot plate

Minor changes have been made to the dimensions of the ground plate (Figure 18A) compared to the functional prototype. The rope house has been given a permanent place on the ground plate behind the fixation house. The technical drawings, which are necessary for the laser cutting of the polypropylene parts, can be found in Appendix E.

5.3.2. Rods of the prototype

PMMA inner and outer rods are chosen with a thicker diameter. Since the rods can now be ordered from a single supplier, this provides an improvement point given the ease for manufacturing. The rods go from 1 mm thick to 2 or 3 mm thick, therefore the material will be able to withstand more pressure without deforming or breaking. The length of the rods remains the same. The inner rods with a thickness of $\varnothing 8 - 12 \text{ mm}$ and the outer rods with a thickness of $\varnothing 14 - 20 \text{ mm}$ have been chosen. Furthermore, an extra rod has been placed that fits exactly between the two rods ($\varnothing 12 - 14 \times 100 \text{ mm}$), as can be seen in Figure 20. This ensures that the rods move less easily in relation to each other.

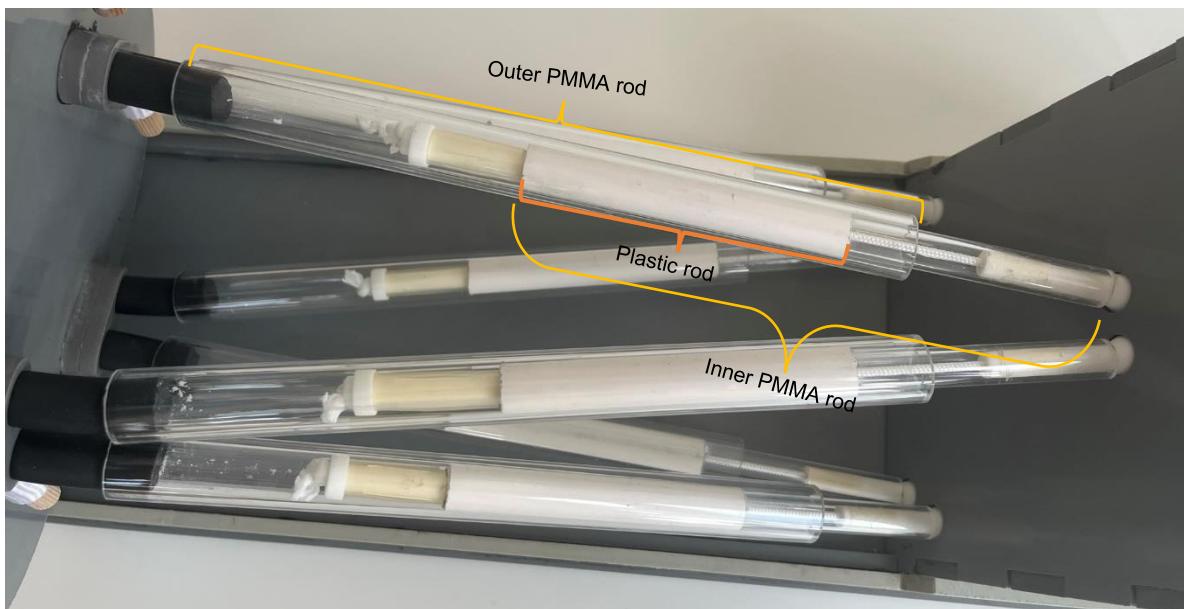


Figure 20. Close up of the rods, the PMMA rods and plastic part of one rod is indicated in the figure.

Since the rods have been thicker, the hinge rubber will also have to be adjusted ($\varnothing 14 \times 50 \text{ mm}$). This will have to be of the same thickness in order to obtain a connection to the outer rod, and the connection will also have to be adjusted on the foot plate.

For the fixation between the rods by means of friction, the materials selection of Tuijthof et al. [13] has been chosen in this design, since it is faster to assemble than the other way. A custom-made fixation plug has been made for this with SLS 3D printing. Because the rope also runs through this plug, a hole has been made in this plug. The plug has a length of 50 mm and a maximum diameter of 13 mm, the technical drawing is viewed in appendix F. A silicone umbrella tube ($\varnothing 8 - 10 \times 40 \text{ mm}$) was chosen that had a smaller diameter so that it did not touch the outer tube. In this tube, four notches have been made along the length of the tube. When the rope is tightened, the length of the tube will shorten and the silicone will expand (Figure 21). This silicone tube is less slippery and does provide fixation when the rope is tightened.

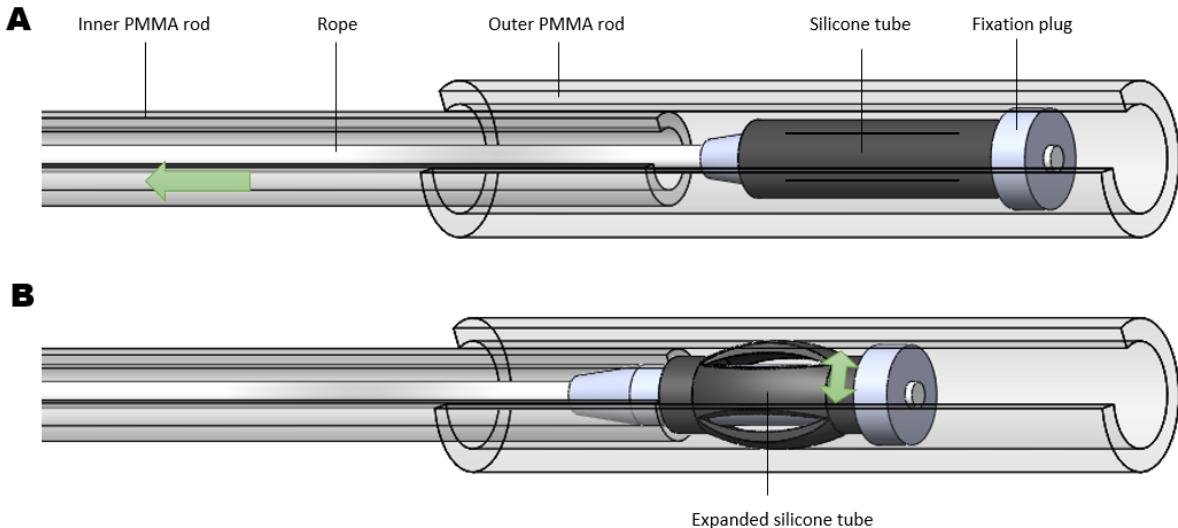


Figure 21. Silicone umbrella tube principle. A) Silicone in a loose state, rope must be clamped in the rope cleat to obtain expansion of the silicone tube, B) silicone tube expanded after fixating the rope in the rope cleat.

5.3.3. Joints of the prototype

The ball-and-socket joint has a longer tube compared to the design in the functional prototype, the tube now has a length of 45 mm, compared to the 30 mm it was before. Since the tube is longer, it will be less likely to detach from the inner tube. The PMMA inner rod clamps around the tube of the ball-and-socket joint, due to the additionally added tape around the tube (indicated in Figure 22). The technical drawing of the ball-and-socket joint can be seen in appendix F.



Figure 22. Close up of the ball-and-socket joint. Since the PMMA inner tube was loosely wrapped around the joint, some tape was placed around the stick of the joint, which can be seen with the yellow arrow.

5.3.4. Fixation of the foot and lower leg

Water-repellent nylon is used for the attachment of the foot / lower leg. This is a polyamide coated on the back with a PVC layer (polyvinyl chloride), making the material stretch-resistant. To this material, Velcro and a 19 mm wide strap, which is used as a loop for the dowels to pass through and remain attached, are attached with the sewing machine. It was decided to fixate the foot with two fasteners instead of one, to get the foot tighter attached to the foot plate. One attachment is around the forefoot and the other attachment is at the level of the instep of the foot.

A piece of wood will be slid into the loop of the strap, on the other side of the foot plate and leg support. This piece of wood is glued to the strap so that it cannot come loose, as can be seen in Figure 18A and Figure 23. The precise dimensions of the fabric and the materials used for this are shown in Appendix G.

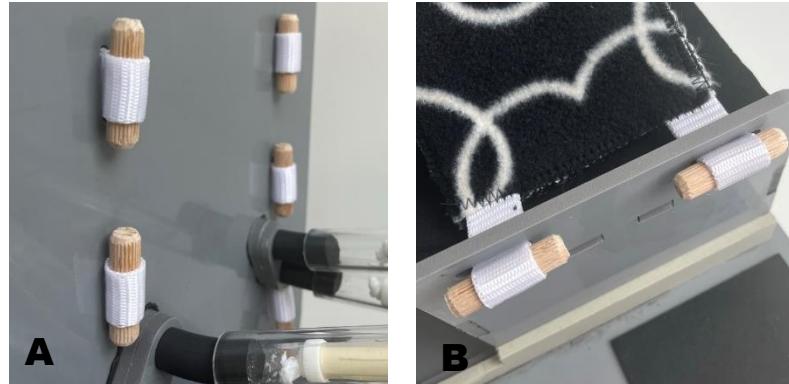


Figure 23. Attachment of the strap to the device, by means of a dowel. A) attachment to the back of the foot plate, B) attachment to the leg support.

5.4. Manuals

Before assembling the device, all needed easy off-the-shelf materials need to be obtained, what is needed can be found in Appendices D and G. In addition, for the polypropylene parts which have to be laser cut, technical drawings will have to be provided to the supplier, as well as for the parts that need to be 3D printed. The technical drawings can be found in Appendices E and F.

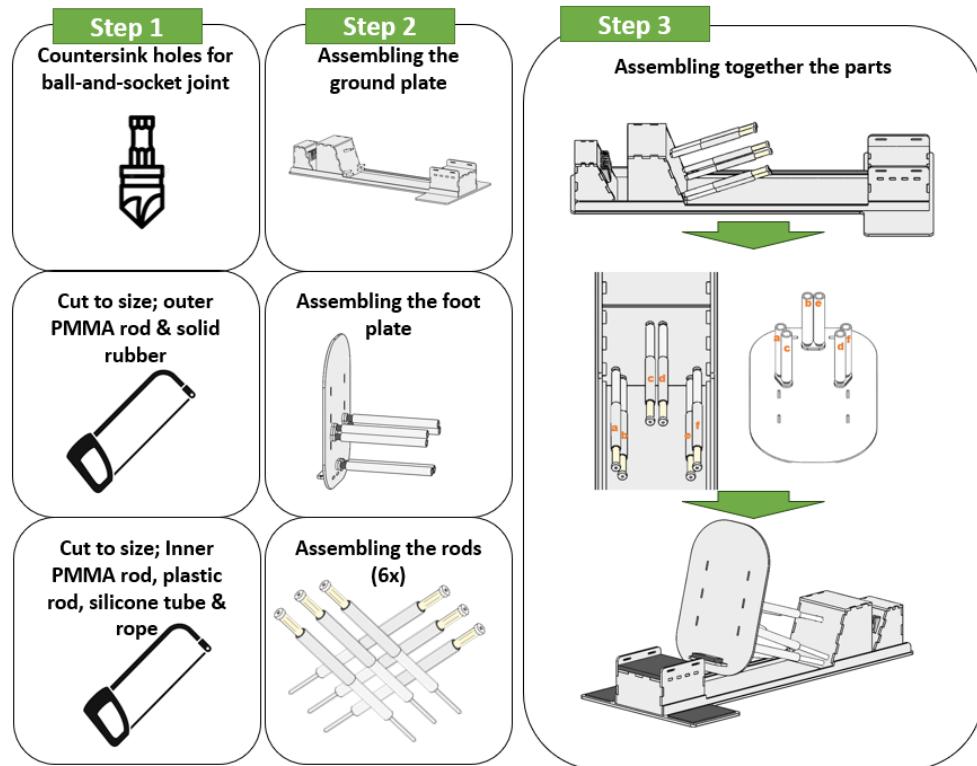


Figure 24. Workflow for assembling the 3D stress foot plate.

A workflow and a manual have been created for the assembly of the device. As can be seen in Figure 24, there are preprocessing steps before assembling the device. The polypropylene

part of the fixation house where the ball-and-socket joint is to be placed will still have to be milled so that the ball-and-socket joint moves smoothly between the two plates. In addition, the rods will have to be cut to size, this also applies to the solid rubber and the rope. In addition, the silicone tube must also be cut to size, and the notches will also have to be cut here. During assembly, three different parts of the device will first be assembled, after which the entire device can be assembled. An extensive manual, which looks like an IKEA manual, has been created for assembling the device. This manual can be found in Appendix H.

When the device is assembled, it is ready for use. An instruction flyer has been provided for the use of the device (Figure 25). This manual is suitable for the user of the device and shows how to use the device using simple figures. This manual is written in Dutch as the device will be tested in the Netherlands.



Figure 25. Instruction flyer for using the device. The flyer can be seen in its actual size in appendix I.

6. Evaluation

With the final design presented in the previous chapter, the requirements were evaluated (listed in Table 7 on page 24). The fulfilled requirements are given in parentheses. Finally, the list of requirements was created, showing which requirements were met.

6.1. Properties of the device

The properties of the device have been checked; the weight, the materials used and how these materials can be obtained. The device is made of non-magnetic materials, which can be seen in the bill of materials, which makes it suitable for various imaging systems (complied to requirement #3b). The device has a total weight of 3.6 kg, which makes it portable (complied to requirement #4). In addition, the foot plate, where the body actually comes into contact with the device, is made of polypropylene, which is a biocompatible material (complied to requirement #18).

The device consists of commercially available components in combination with parts from two different production techniques. In addition, straps are not manufactured with off-the-shelf components. Easy-to-order products were used for this, but many manual operations are performed with the sewing machine to assemble these straps. The materials supplied as standard, with the exception of the PMMA rods, only have to be cut to the right size. These materials cannot be cut by the supplier himself. Of the components used, most still require a manual step, requirement #19 cannot be met.

The manufacturing techniques of laser cutting and SLS 3D printing were used for the self-made components, so that these components are already delivered in the correct dimensions and are also easy to assemble. Two parts that are laser cut still need a pre-processing step; They need to be drilled with a countersink to allow the ball-and-socket-joint to fit between these pieces. This step needs to be done with precision and requires some experience with countersinking. Therefore requirement #27 cannot be fulfilled.

6.1.1. Force test

A simulated deformation test has been carried out in SolidWorks (Version 2022) to see what the maximum bending of the ground plate is when it is loaded by pulling the ropes, as can be seen in Figure 26.

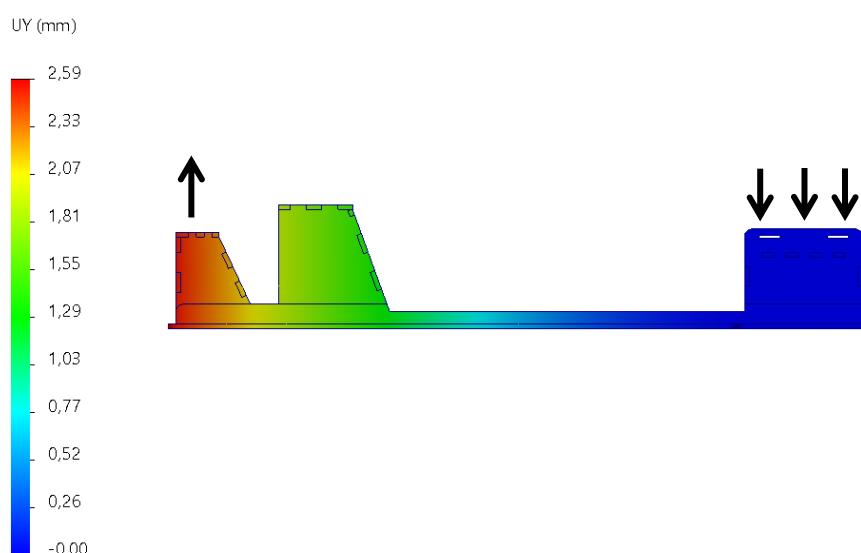


Figure 26. Deformation stress test acquired on SolidWorks (Version 2022). The leg support (positioned on the right) is the fixed component, whereas the pressure is applied on the top of the rope house.

In this case an unrealistic pressure of 100 N/m^2 has been applied to the top of the rope house. This pressure is applied in the upward direction. The maximum deflection, directed upwards (y direction), is 2.59 mm at the height of the rope house. This means that requirement #20 is fulfilled.

A test was set up to measure the maximum frictional force created by the expansion of the silicone tubing when the rope is pulled (Figure 27). For this test, the ground plate was used in combination with the parts of the rods through which the rope travels. A loose outer PMMA rod is attached to a dynamometer. All individual rods with silicone tubes are tested. In each position, the outer PMMA rod is slid around the inner rod with a silicone tube. This is held in position with one hand, after which the rope is tightened in the rope cleat. The dynamometer (Salter Super Samson 25kg / 100 g) measures the pull or pressure force applied to the outer tube.



Figure 27. Test set-up for measuring the tensile force.

Each silicone plug was compressed against the outer tube of each rod was able to withstand around 45 N ($\pm 4 \text{ N}$).

It is important to check whether these forces can also be achieved when the device is fully manufactured, i.e. with the correct position of the foot plate. An arrangement was attempted to allow the dynamometer to pull on the bottom of the device, as shown in Figure 28. The rope is wrapped around the foot plate and tied; An attempt is then made to apply a force perpendicular to the corner of the foot plate. To do this, the ground plate must be firmly attached to the table using adhesive clamps. The rope was used because a rigid piece of wood could not be attached to the back of the foot plate that could fit tight against the foot plate because of the foot fixation strap getting in the way.

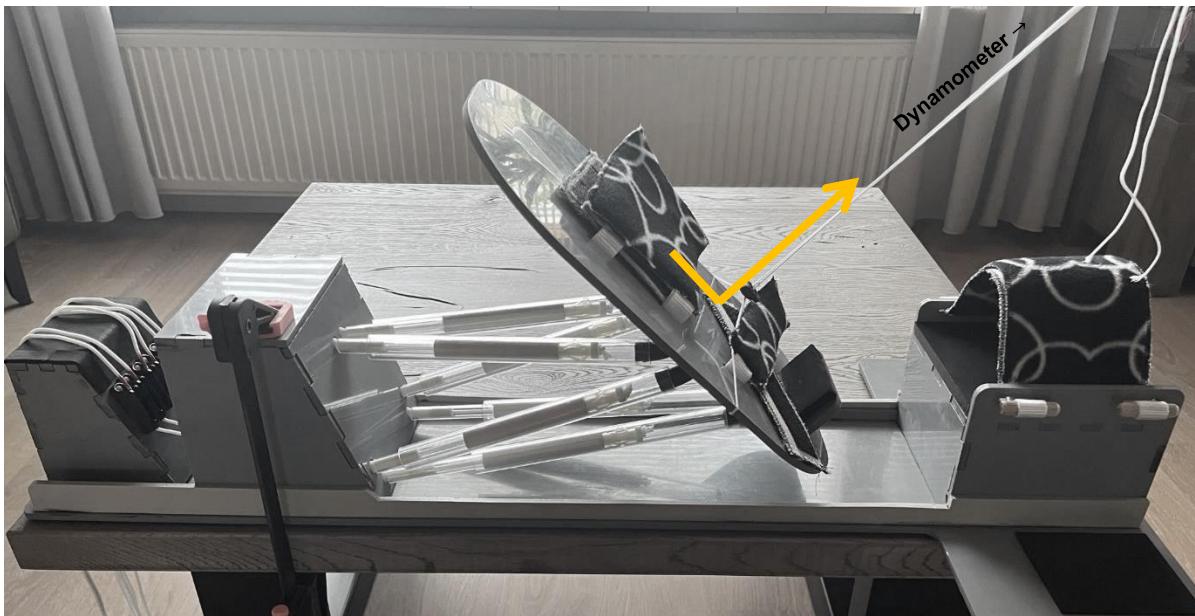


Figure 28. Set-up for measuring tensile force of the foot plate, the device is fixated in a slightly plantarflexion position. It is indicated, that an attempt was made to get the force perpendicular to the foot plate.

However, it turned out to be difficult to use the dynamometer correctly. The dynamometer gives a resistance of about 68 N ($\pm 6\text{ N}$) after five repeated measurements at one position, and this applied to three different positions. However, if the rope is pulled by hand, more force can be applied to the device. It can now be stated that the device meets the requirement to withstand a load of at least 60 N (complied to requirement #5). However, to know for sure what forces can handle it, another study needs to be done.

6.2. Usability tests

To determine if the device meets the other requirements, usability tests were performed to evaluate those requirements. Together with other students, we checked how quickly the straps can be undone and whether the device can be operated by anyone. A stress test was simulated with a clinician from Maastricht University Hospital to see if the device works well in a clinical setting.

6.2.1. Releasing foot and lower leg straps

It has been examined how quickly and in what way the fastening strap around the foot and lower leg can best be released (Figure 29). For this, four different students cooperated, each loosened the foot and lower leg three times on the left and three times on the right. Every student indicated that it is best to first loosen the strap from the lower leg, which makes it much easier to loosen the straps around the foot because you can then slide closer to the device (the leg can then be bent more easily).

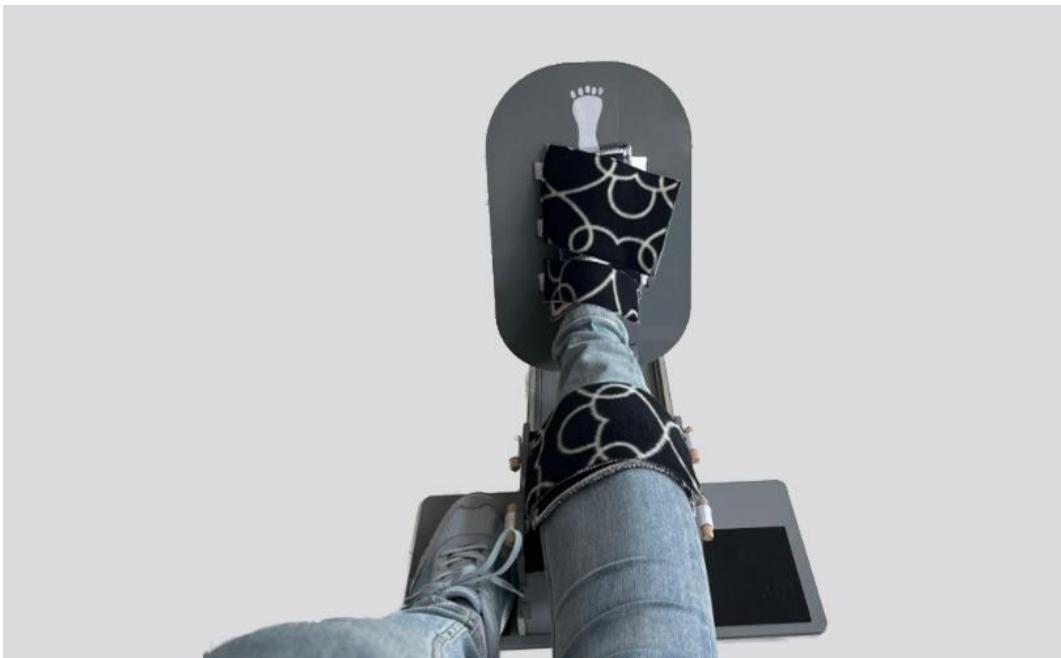


Figure 29. Foot and lower leg fixated in the 3D stress foot plate device. There are three attachment straps; one at the lower leg, and two at the foot.

The participating students had an average detachment speed of $4.92\text{ s} (\pm 0.32\text{ s})$. There was minimal difference in whether the left or right leg was attached to the device (average left 4.95 s , average right 4.89 s). This is the case when the leg strap is loosened first and then the foot is loosened. Measurements in which the foot was loosened first and then the leg strap was loosened were not performed. Taking into account that in real situations the patient actually experiences pain, it may be that loosening the straps is not as easy as outlined in this situation.

Returning to requirement #21, the straps can be pulled individually in one, so therefore the requirement is fulfilled. However, there are three fasteners that must be loosened to get the foot out of the device. This can be achieved in a very short time, so it can be concluded that these types of straps are good enough to use.

In addition, it was checked with these students, two of whom are right-handed, whether the device can be operated by these different students. Students were able to position and fixate the foot plate (without patient) in different positions. It can be concluded that the different hand grips can be used to fix the device (complied to requirement #6). Finally, the students were asked whether they experience any form of sharpness of the device during use. They were all of the opinion that this was not the case, so requirement #29 has been met.

6.2.2. 3D stress test

To evaluate the device itself, together with a clinician from Maastricht University Medical Center, the extent to which the device functions properly has been examined. For this purpose, a stress test was performed on one person. The amount of effort/effort with which the clinician performs the actions was examined. The clinician was recorded how long it took the clinician to position and fix a person. Because it was the first time the clinician used the device, it is possible that the speed can be improved. However, it must be taken into account that it remains difficult for the user, because this is always a different person.

Firmly securing the foot and lower leg takes about 28 seconds (Figure 30). It should be mentioned that the lower leg had to be fastened twice because it was not fastened sufficiently in the first case. It is important to ask for feedback from the patient whether he/she can still move easily or not.

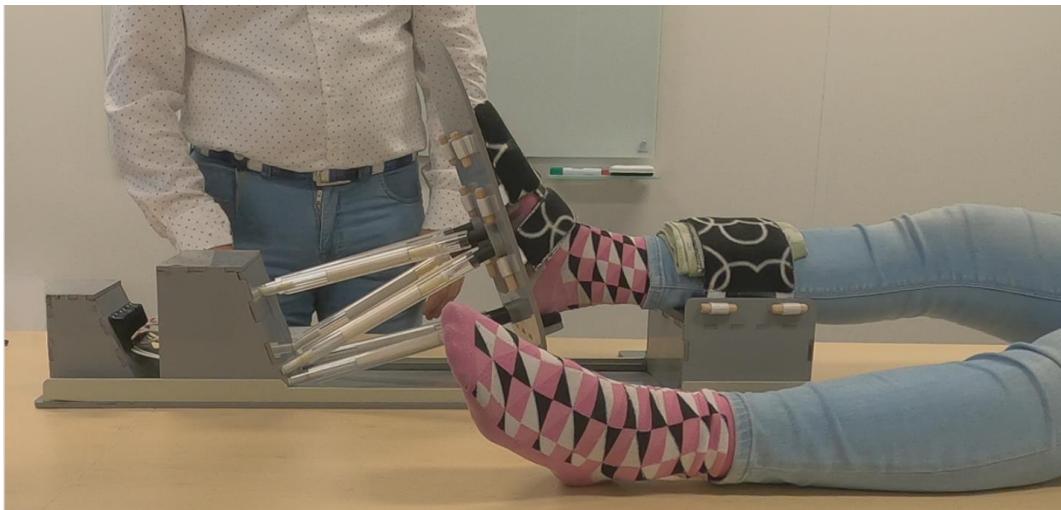


Figure 30. Securing the right foot and the right lower leg to the device. The device is in loose state, as the ropes are not placed in the rope cleats. A towel was used to secure the lower leg to the device.

Subsequently, the positioning and fixation of the foot was examined (Figure 31). It takes about 38 seconds for the user to complete this. It is important that the patient has positioned the other foot on the device, in the designated area. If this does not happen, the user will have more difficulty tightening the rope. The device can then be lifted too easily by pulling on the rope.

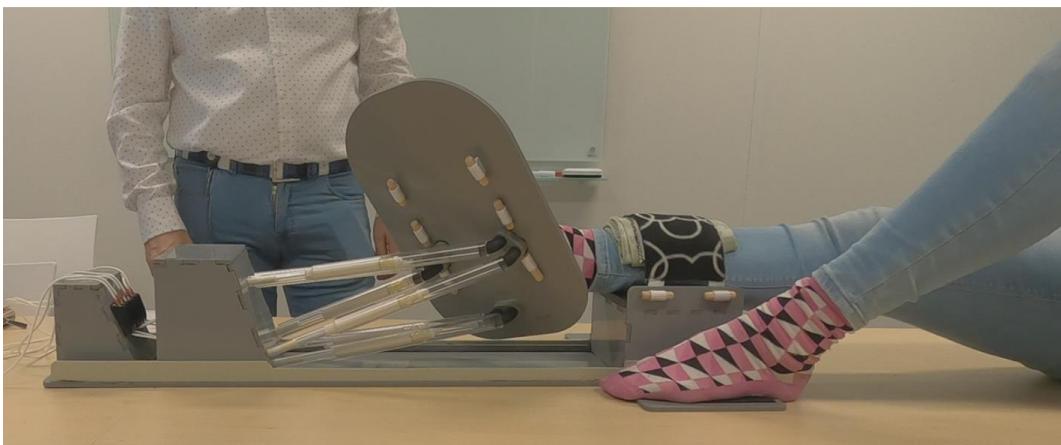


Figure 31. The foot was fixated in plantar supination.

Therefore, it takes 66 seconds to attach the patient's foot to the foot plate and then fixate it in an extreme position. This is less than the target 100 seconds that has been established as a requirement (complied to requirement #7).

When the device is fixated, it can still move slightly, but it is not the case that the foot can be moved out of position. The clinician thought that he could perform the clinical stress test well and that the device was easy to operate. He found that it was easy to operate the device alone (complied to requirement #16) and that he needed little or no effort to properly position and fix the device, therefore the physical and mental effort remains low (complied to requirements #17). However, the user manual could be a bit more precise in order to prevent errors. The fixation principle seems clear, but to undo and keep the fixation is not clear enough.

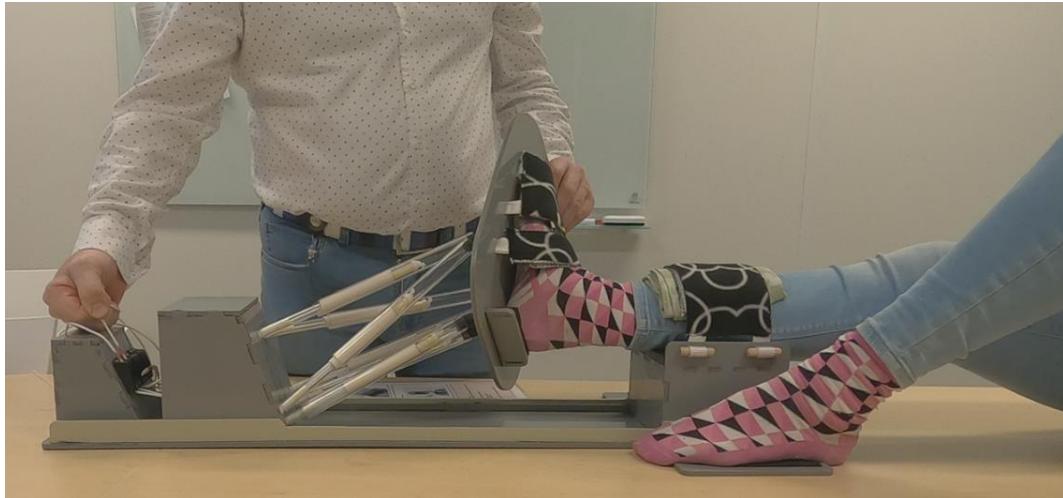


Figure 32. Fixation of the right foot in dorsiflexion and eversion. It can be seen how the clinician holds his hands while holding the foot in position and fixing the position with the other hand.

The clinician has placed the foot in two extreme positions relative to the lower leg (Figure 31 and Figure 32), so it can be said that requirement #8 is sufficient. The clinician found the principle of fixing the foot in the extreme position easy to understand, and had a real sense of control (complied to requirement #9). Moreover, he found the device easy to operate alone, but it is really important that the patient places the foot that is not fixed in the device on the platform next to the leg support. This will make it easier for the clinician to properly secure the rope.

The movement of the upper extremities during the positioning and fixation of the foot was examined (Figure 32). While holding the foot in place with one hand, the clinician can use the other hand to tighten the ropes. For this, the arms are not held in unusual positions. It must be said that it is not very easy to maintain the extreme position with one hand while maintaining it with the other hand. When the patient helps to maintain this position, it is easier for the clinician to tighten the rope without moving the foot (complied to requirement #10).

Partly due to the use of the user manual flyer and the foot symbol on the foot plate, positioning the foot in the device was easy to do (complied to requirement #11). However, the clinician had seen the functional device before, so he already knew how the device worked. This requirement will also have to be tested again with people who have never seen the device.

6.3. Summary of results

Due to the experimental set-up seven evaluation criteria could not be tested adequately (Table 7 printed in italics). For Requirements #12 and #22, a clinical test must be performed with the CT scan, in which the device must be cleaned prior to use, which has not been done in this evaluation. The prototype device was not designed with the intention of appearing professional, therefore Requirement #15 has not been tested. Requirement #23 could not be tested because the device was created only once, and the manuals were created based on that. It is therefore not yet possible to say whether the device is actually easy to assemble using the manuals. Because the device has not been used often, it is not possible to say whether the device can last one year without performing maintenance, which is why no statement can be made about Requirement #24. Requirement #25 has not been tested, because the device is still doesn't seem sturdy enough to actually drop it on the floor. Lastly, Requirement #26 is a requirement that must be met in order to use the device. It has not been tested whether this is actually necessary, because no risks are wanted for patients.

In summary, the design requirements that have been tested in the evaluation described in this chapter are shown in Table 9. This indicates which requirements have been complied through the evaluation and which requirements still need to be complied in a different way.

Table 9. Results of the design requirements tested in this evaluation section.

Requirements	Compliant	Remarks
3 The device should be compatible with different imaging systems (radiography, MRI- and CT scanners):	✓	
b The device should be fabricated with materials that can be used in different imaging systems	✓	
4 The weight of the device should be a maximum of 12.7 kg to be portable	✓	Weight of 3.6 kg
5 The device should require a separate manual fixation mechanism to preserve the desired extreme position of the foot	✓	Unknown maximum acceptable force
6 Different hand grips on the device should be allowed to apply manual loading.	✓	Tested with $n = 4$
7 The device should offer fast operation below 100 s	✓	Time = 66 seconds
8 The device should be able to manually fixate the foot in extreme positions relative to the lower leg	✓	Tested in two different extreme positions
9 The operator should have a sense of control when using the device	✓	Tested with $n = 1$
10 Excursions of the upper extremities of the radiology technician should be kept within limits	✓	Tested with $n = 1$
11 It should be clear (unambiguous) how to position the lower leg and the foot in the device	✓	Will have to be tested with people who know nothing about the device
16 The device should be operated by one person	✓	Tested with $n = 1$
17 The device should be operated with minor physical and mental effort	✓	Tested with $n = 1$
18 The materials that come into contact with the patient must be biocompatible	✓	
19 Use as much as possible off-the-shelf components	✗	Several components still need to be cut to size
20 The device should not exceed 5 mm of deflection when the foot is fixated.	✓	
21 The straps on the device where the foot is attached should be released in one movement	✓	Detachment speed < 5 seconds
27 Only use production methods that are easy to order online and require a minimum of engineering expertise	✗	Two parts need a pre-processing step after laser cutting (countersink drill)
28 The device should not have sharp edges	✓	Tested with $n = 4$

7. Image processing workflow

The first academic question that will be addressed with the 3D stress foot plate is the mobility of the ankle after prosthesis placement. The mobility of the prosthesis can be measured by using the device to make CT scans of different extreme positions of the foot.

In this thesis a start has been made in processing the CT scans in order to measure the mobility of the prosthesis. In line with the open-source availability of the 3D stress foot plate, the image processing is also done open source. It should be added that this can only be used in a research setting, because it is not approved legally for clinical use.

The academic question will be applied in collaboration with the Maastricht University Medical Center. It is important to know what kind of prosthesis is used in this hospital. In addition, an anonymized CT scan from the hospital will be used for the image processing workflow, as the device has not yet been used in patients with an ankle prosthesis. Protocols and workflows will be developed for the image processing for the prosthesis.

7.1. The INFINITY prosthesis

In the Maastricht University Medical Center, the INFINITY ankle prosthesis is used. The INFINITY ankle prosthesis [34] is a total ankle replacement system that consist of a talar dome, a tibial platform, and an ultra-high molecular weight polyethylene (UHMWPE) component (Figure 33). The implant replaces both tibia and talus articular surfaces. Components are available in a variety of sizes intended for both primary and revision applications. This prosthesis is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis [35]. Moreover, this ankle prosthesis is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

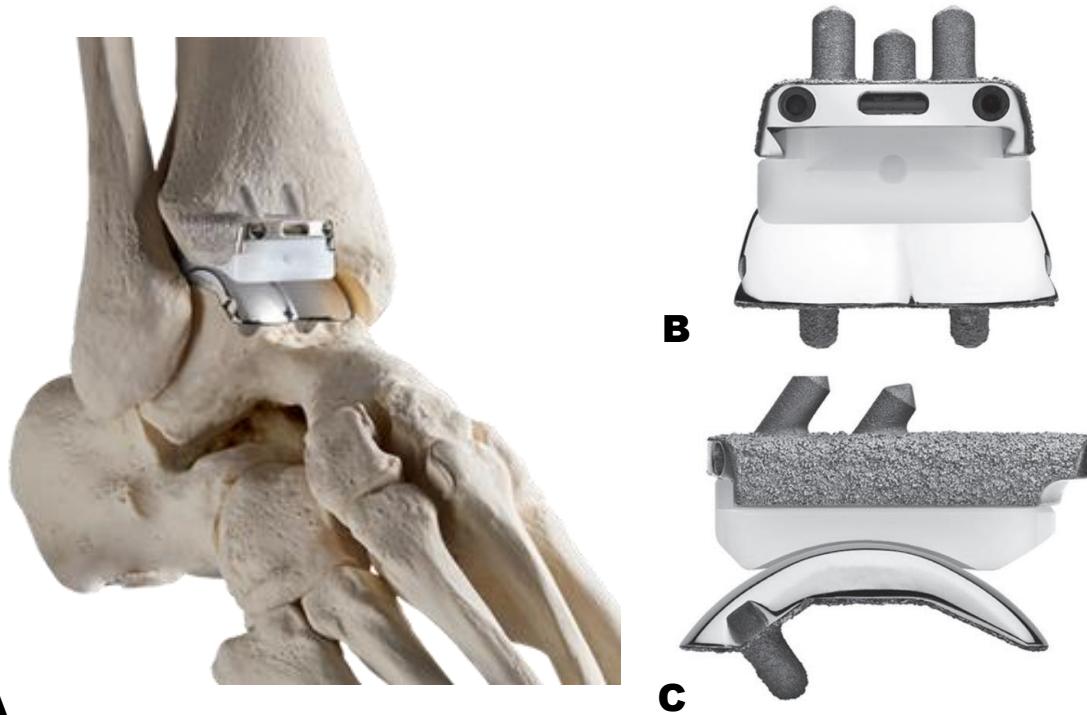


Figure 33. The INFINITY® prosthesis. A) The ankle prosthesis shown in a skeleton model, B) anterior view, C) sagittal view; left the front of the prosthesis, right the back.

7.2. Image segmentation with 3D Slicer

The processing of the CT scans will be done in the open-source program 3D Slicer (version 5.0.3.) [36]. 3D Slicer is a free open-source software platform for prototyping, development and evaluation of image analysis tools. 3D Slicer incorporates a DICOM converter, which allows to work directly with this format which is compatible with most 3D imaging systems.

With the acquired CT images, areas in the image will be delineated, usually corresponding to the anatomical structures. This is also known as image segmentation [37]. In this case, the individual parts of the ankle prosthesis will be delineated as a first step to obtain the movement of the prosthesis. To see what the movement of the ankle joint is, the movement of the talus component in relation to the tibial component must be considered. This examines the extent to which the ankle translates and rotates to an extreme position. Therefore, the next step is to look at the difference in extreme position and normal position, this is done with the registration tool in 3D Slicer. Prior to this registration, the segmented prosthetic parts are first shifted to the origin of the coordinate system to obtain clear transformation matrices.

For the protocols below, an anonymized CT scan of the ankle of a patient with an INFINITY prosthesis was used. This was obtained from the clinician from Maastricht University Medical Center.

7.2.1. Segmentation

3D Slicer can read DICOM data, which is a widely used and sophisticated set of standards for digital radiology [38]. The CT scan of the ankle with an INFINITY prosthesis will be loaded into 3D Slicer. In the program, the range of interest of the obtained images is cropped. After that, segmentation will be done using the threshold, growing from seeds, painting, erasing and smoothing. The workflow is presented in Figure 34. A precise step-by-step plan is shown in Appendix J.

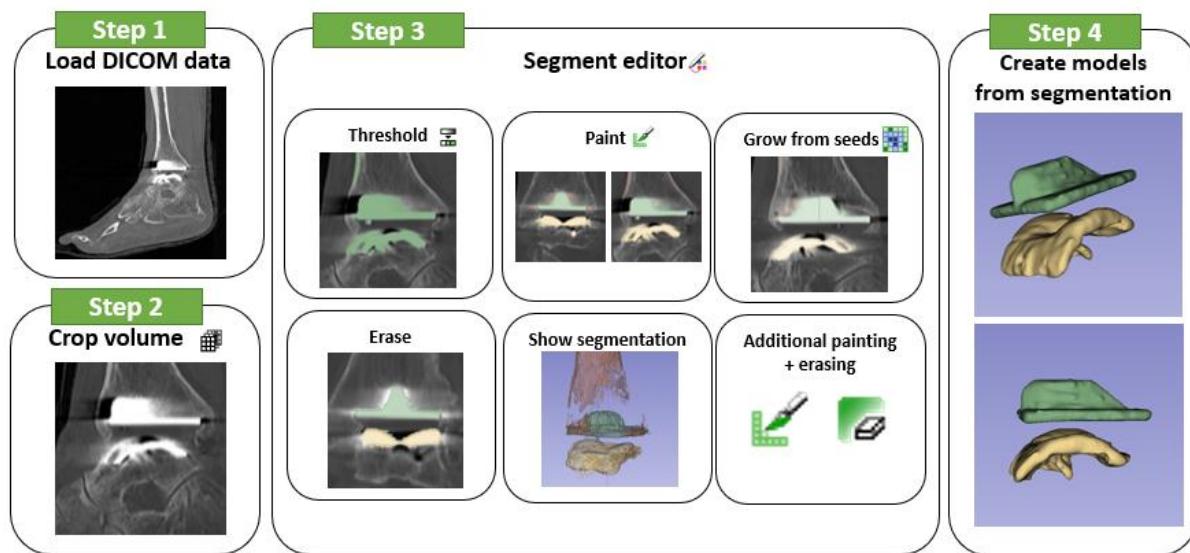


Figure 34. Workflow of the segmentation of the infinity prosthesis in 3D Slicer.

7.2.2. Local coordinate system

The movement of the talar component relative to the tibia component is of interest. For that it is important to change the coordinate system so that the prosthesis is in the origin and the movement is therefore only seen from the prosthesis. The origin of the coordinate system has been chosen to be in the tibial component, the x-axis is pointing forward (towards the toes), the y-axis is pointing left, and the z-axis is pointing upward, as is indicated in Figure 35.

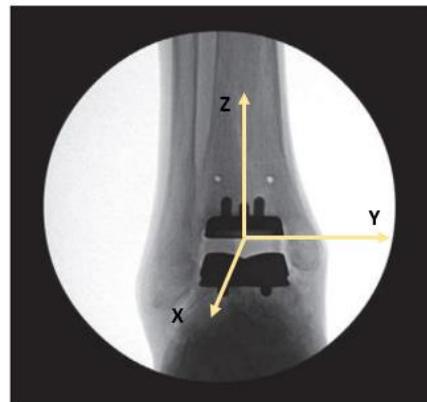


Figure 35. Placement of the local coordinate system on the tibial component of the INFINITY ankle prosthesis.

A protocol has been made in 3D slicer, in which the tibial component is shifted to the origin. The tibial component model is imported into 3D Slicer, after which the centroid of the bottom of the component is determined. Thereafter the direction of two planes is determined. The workflow is presented in Figure 36. A precise step-by-step plan is shown in appendix K.

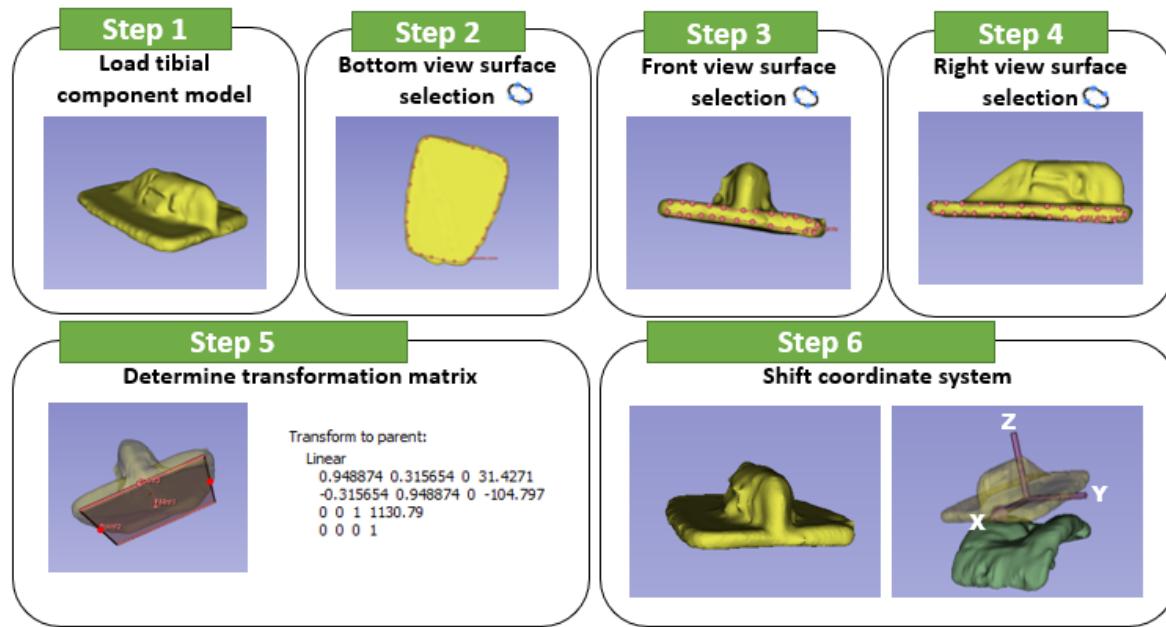


Figure 36. Workflow for determining the local coordinate system of the Tibial component in 3D Slicer.

7.2.3. Registration

To look at the movement of the talus component in relation to the tibial component, several CT scans in different positions will have to be made prior to this analysis. It is important that a zero position is determined, which means the position to which you have the other positions registered. The goal of the registration is to align the position and orientation of the models. This will be achieved with the *SlicerCMF* extension of 3D Slicer [39].

The models of the segmented prosthesis components in different positions will be loaded in the 3D Slicer. Hereafter, those models will be shifted through the transformation matrix obtained for the local coordinate system. The registration will then be performed for the tibial component first and hereafter for the talar component. As a result, you will have the transformation matrix of the movement of the talar component relative to the tibial component. Finally, for the decomposition of the transformation matrix, MATLAB (R2022b, MathWorks, NA) will be used. The workflow is presented in Figure 37. A precise step-by-step plan is shown in appendix L.

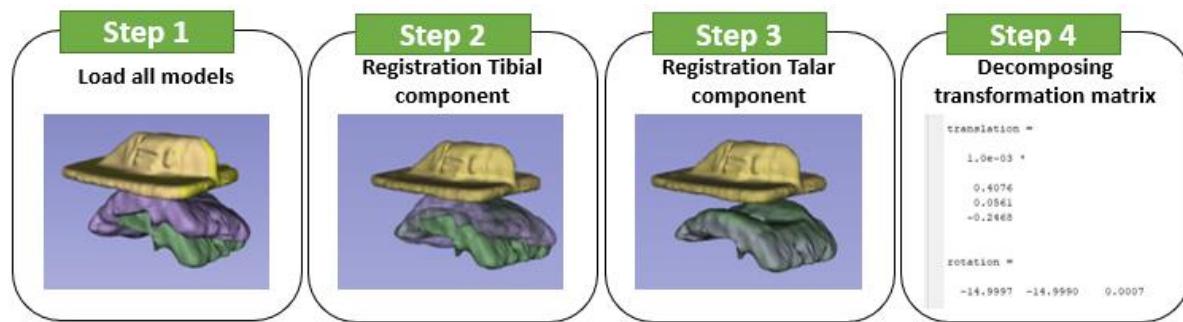


Figure 37. Workflow for the registration of the different bone positions in 3D Slicer.

8. Discussion and recommendations

This section will discuss the objectives that were stated in the introduction to be able to see to what extent the 3D stress foot plate is optimized and if it needs any improvements.

First, a functional model was created in which the optimization of the assembly techniques was examined. Only then was it considered which requirements the product must meet in order to comply with the MDR. Had the force exerted on the rods been studied prior to fabricating the functional device, the thickness of the rods required could already have been taken into account. As a result, the functional device could have been given more final dimensions, making the step to the end product easier to make. Should an optimization of a design be performed again, it will be necessary to address the requirements that the device must meet in order to comply with the MDR, leaving more time for other optimizations.

On the other hand, since device creation sometimes involves a lot of waiting time, it was helpful to have already worked on the image processing side. Much thought has already been given to what to do with the imaging images that can be taken of the ankle with the device. The obtained open-source image processing workflows with associated protocols can make an important contribution to the next steps of this research.

8.1. Design for fabrication and manufacturing

A prototype of a device was produced, the manufacturing process of which was optimized by the production methods laser cutting and 3D printing in such a way that it is easy to manufacture. Using easy-to-order components such as rods and rubbers, the device can be assembled using the supplied manuals and a few pre-processing steps. In addition, the device meets almost all requirements that could be tested with the corresponding setup, the requirements that have yet to be tested must be tested in the clinical environment. The way of cleaning and the total acquisition time can be taken into account. Also in the long term it will be necessary to check whether the device can be used repeatedly without requiring maintenance and whether the device is stable enough if it is dropped once.

Two requirements are not met with the current set-up, as can be seen in Table 9. Looking at requirement #19, use as many off-the-shelf components as possible, there are still components, particularly for the parts of the rods, that need to be cut to size yourself as this cannot be done by the respective supplier. It doesn't take much time and experience to cut this yourself. However, different fabrics, straps and Velcro fasteners have to be sewn together for the straps that are needed around the foot and lower leg. This takes some expertise to assemble this together. It is possible to glue the different parts of the straps together instead of sewing them, but then there is a high risk of fraying the fabric. As a result, wear occurs more quickly and new straps have to be made earlier. The exclusive use of a Velcro fastener without an intermediate fabric does not contribute to the comfort of the patient. This means that the mounting method for the straps cannot be improved. Thus, it can be said that requirement #19 is satisfied.

To meet requirement #27, no pre-processing step will need to be done on the laser cut parts. Two parts of the ground plate currently need to be milled after they come out of the laser cutter will have to be optimized so that this milling step can be eliminated. This can be solved by also having these two-parts 3D printed in the correct shape, so that the ball-and-socket joint can be clamped between these two plates without any processing.

Assembling the device is possible in university hospitals where there is a workshop. All easy-off-the-shelf products must be ordered in advance, and the vector drawings, and STL files must be submitted for the production methods, laser cutting and SLS 3D printing. This workshop is necessary to tailor the parts that still need to be custom made. In addition, the parts that need

to be pre-processed will be pre-processed in this workshop. After which the assembly is glued together as described in the manual. Finally, the straps of the foot and lower leg will also have to be sewn here, after which they will be assembled on the device.

If the device is going to be used more widely, i.e. in hospitals where the workplace is not so extensive, it is important that no pre-processing steps need to be done on parts of the device. Cutting the easy-to-order parts to length is no problem. However, attention will have to be paid to how the foot and lower leg are attached to the device, as these attachments are sewn entirely by hand. For this purpose, a completely different method of fastening will have to be devised, which can preferably be ordered ready-made and can be used.

Looking at the parts that are now incorporated in the device, there are some improvement points to make the device totally perfect. Time will tell if the white plastic rod, now placed for more strength, really matters. This requires doing some testing to see if the device degrades to such an extent without these rods. If this rod is no longer placed, the assembly process will be accelerated, since this rod itself has to be cut and then glued to the PMMA rod. In addition, the method of tightening the rope, which ensures fixation, meets the requirements. With this method, all six ropes must be tensioned individually. To make it even easier for the user, a lever principle can be considered, in which the ropes are pulled with a lever and placed in the clamp cleats at the same time. Since the rope is the same length for each attachment, this should be possible. It just needs careful thought on how this leverage principle allows the ropes to get in and out of the cam cleats.

Polypropylene, which is used as the main material, is widely used in medical devices. However, it was disappointing that the material is difficult to glue. A special adhesive with a primer is required for this, which enables bonding. In addition, the adhesive surface of the parts to be bonded was not large, which can make the device weaker. Since no tests on the robustness of the device have yet been carried out, it cannot yet be conclusively said whether these adhesive surfaces should be enlarged or not. Due to the fact that the glue used is a special glue and primer for polypropylene, its cost is very high in relation to the cost of the device itself. If there are objections to this, a follow-up study must be carried out to determine whether another material that is easier to glue can be used, for example with normal all-purpose glue. This material must then be biocompatible and suitable for laser cutting.

The expansion of the silicone (the silicone umbrella) ensures that enough force can be exerted on the foot plate without it moving. However, the material was obtained through the supervisor. To date, it has not been possible to obtain the same type of material that provides sufficient grip in the PMMA rod. Most silicone tubes are too slippery so there is no grip when it expands. In addition, silicone tubes that have a larger diameter have already been looked at, but the silicone was too stiff, so it did not expand. More research will have to be done into the properties of the different silicone tubes on the market in order to make the right choice in which tube to use for the fixation mechanism.

8.2. Medical device regulation

The MDR legislation has been dealt with, for this almost all files have been filled in to demonstrate that the device complies with the MDR. A few requirements still need to be demonstrated to meet the established requirement through a clinical evaluation. Furthermore, all documents required for the legislation of a class 1 medical device have been treated. Partly due to the clinical tests already demonstrated in the article by Tuijthof et al. [13], it will hopefully not take much time to get approval for this legislation.

However, because we ourselves as a manufacturer have carried out the conformity assessment, it cannot guarantee that the documents drawn up, and in particular the risk

analysis, are sufficient to comply with the MDR legislation. It may be that more tests need to be performed to ensure that the product is actually safe for the patient and user.

8.3. Image processing

For the processing of possible CT scans, an open-source program for processing these images was considered. An open-source program has been used in line with the open-source provision of the device. This open-source program is suitable for segmenting the prosthesis and showing the mobility of the prosthesis from different positions.

There are also some points of improvements here, segmenting the prosthesis takes a lot of time. Through an automatic process, the contours of the prosthesis can be made visible, but corrections then have to be made per slide by coloring what the prosthesis is and what is not. In addition, the dimensional accuracy of segmentations, like the accuracy of prosthesis segmentation, depends on how manual segmentation is performed. This means that the accuracy of the segments obtained can differ depending on the segmentation. As a result, the segmented part of the prosthesis does not correspond 1 to 1 to the actual prosthesis.

Since the prosthesis used has a standard size, it will be stated in the patient file. Those specific dimensions can be looked up. If these dimensions can be linked to CAD models of the prosthesis, it will be possible to search for contours of the specific CAD model in the relevant CT scan. Here, a registration will be made, as it were, of the CAD models on the CT scans. These models then have a certain position that can then be used to determine the mobility of the prosthesis. However, whether this is applicable in this open-source method is unknown, nor is it known whether the CAD models of the prosthesis can be obtained easily.

However, when the processing of the CT images is important in the hospital itself, other clinically approved programs can be used for the processing of these CT images. These programs are more precise and faster in automatic segmentation, making processing these images easier.

9. Conclusions

In conclusion, this thesis describes an open-source method to fabricate the 3D stress foot plate while complying with the MDR. The device is easy to manufacture as it offers open-source drawings and easy-to-order production techniques, such as laser cutting and 3D printing. All other used components can be easily purchased online. To make assembling the unit as easy as possible, instructions for assembling the device are included, which look like IKEA instructions.

The work contributed to compliance with the MDR by offering all documentation and tests in order to comply with it. Moreover, contributions to the image processing workflow have been made by providing open source workflows for CT image processing to quantify the kinematic workflow. This work can therefore be a showcase of how Class I medical devices could be offered, for which no business case can be made, but which still comply with the MDR and in this way can be made affordable.

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Appendix A – Evaluation of functional prototype

Looking at the making of the device, it can still be noted that the way of fixating with the sponge rubber is not optimal. The assembly of this construction takes a long time because the rope has to be pulled through the rubber manually. In addition, the rope that has been pulled through the rubber already causes a slight expansion, so the sponge rubber cannot move properly through the tube in an unfixed state (Figure 14E and F).

The rods, rubber and rope only had to be cut to the correct length for assembly. This does not take much time, but because the PMMA tube is thin, it quickly breaks. Moreover, due to this manual step, the lengths are not accurate enough and will slightly differ.

The model has been tested by positioning several feet in the prototype. This test showed that the model can be used to fixate the foot in all required positions. The used dimensions have been declared suitable for this purpose. The thickness used for the ground plate and foot plate in this model is strong enough. In addition, the size of the ball-and-socket joint is sufficient, and all rotations can be achieved. However, since this joint clamps against the carbon rod, the length of the ball-and-socket joint rod can be longer to provide more strength.

When the device is fixed, the tensioned rope still shows a lot of stretch, which means that the rope is not stiff enough. A thicker rope, which is more braided, will provide more stiffness. In addition, it is now not easy to see when the rope is tensioned and when it is not. This really requires a look at whether the rubber is pressed tightly against the inner rod.

Due to the fact that the ground plate is large, it can bend too easily when lifting the device. The ground plate also bends when the rope is tightened, thereby applying force to the device. As a result, the device is not stable enough.

The foot and lower leg were secured with fleece on which Velcro was attached. However, the fleece turned out to be able to move too much when the Velcro was attached to the foot and lower leg.

Appendix B – Identification of hazards and characteristics related to safety

The questions in Annex A of NPR-CEN-ISO/TR 24971:2020 [29] cover many aspects of medical devices and can assist in identifying the characteristics related to safety. This questionnaire has been completed and hazards have emerged from this (Table B1).

Table B1. Questions related to the identification of hazards and characteristics related to safety, took over from annex A of NPR-CEN-ISO/TR 24971:2020 [29].

No	Question	Applicable (Y/N)	Comment	Identified Hazard
1	What is the intended use and how is the medical device to be used?	Yes	The intended use is to move and fixate the foot in a certain extreme position relative to the lower leg for a short period of time.	
2	Is the medical device intended to be implanted?	No		
3	Is the medical device intended to be in contact with the patient or other persons?	Yes	The foot and lower leg of the patient are in contact with the 3D stress foot plate	Bacteria
4	What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Yes	Used materials are materials that are compatible with different clinical imaging systems, such as wood, rubber and different kinds of plastics.	Inadequate performance of cleaning, disinfection or sterilization
5	Is energy delivered to or extracted from the patient?	Yes	Load and displacement are offered to the patient's foot via the 3D stress foot plate by the user	Bending
6	Are substances delivered to or extracted from the patient?	No		
7	Are biological materials processed by the medical device for subsequent re-use, transfusion or transplantation?	No		
8	Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	No		
9	Is the medical device intended to be routinely cleaned and disinfected by the user?	Yes	The foot plate should be cleaned after each use	Inadequate performance of cleaning, disinfection or sterilization
10	Does the medical device modify the patient environment?	No		
11	Are measurements taken?	No		
12	Is the medical device interpretative?	No		
13	Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	Yes	The device was made compatible with different imaging systems (radiography, MRI- and CT-scanners).	image artefacts

14	Are there unwanted outputs of energy or substances?	No		
15	Is the medical device susceptible to environmental influences?	Yes	Rubber and glue can disintegrate quicker when exposed to UV (sunlight)	Failure of a component due to ageing, wear or fatigue
16	Does the medical device influence the environment?	No		
17	Does the medical device require consumables or accessories?	No		
18	Is maintenance or calibration necessary?	Yes	To achieve the correct friction force, the device will have to be monitored and maintenance will have to be carried out when necessary.	in-service requirements (e.g. maintenance, reprocessing)
19	Does the medical device contain software?	No		
20	Does the medical device allow access to information?	No		
21	Does the medical device store data critical to patient care?	No		
22	Does the medical device have a restricted shelf-life?	Yes	The fixation mechanism could deteriorate over time	Failure of a component due to ageing, wear or fatigue
23	Are there any delayed or long-term use effects?	No		
24	To what mechanical forces will the medical device be subjected?	Yes	Friction force to keep the rods fixated, force of the foot of patient to keep in the same position.	tension
25	What determines the lifetime of the medical device?	Yes	Deterioration of materials, in particular, the fixation rod mechanism	Failure of a component due to ageing, wear or fatigue
26	Is the medical device intended for single use?	No		
27	Is safe decommissioning or disposal of the medical device necessary?	No		
28	Does installation or use of the medical device require special training or special skills?	Yes	The amount of load to position the foot in an extreme position should be the same as when applied in a clinical stress test. The performance of clinical stress tests requires medical training	Use by unskilled or untrained personnel
29	How will information for safety be provided?	Yes	Safety instructions in the accompanying manual before using	Confusing or missing instructions for use
30	Are new manufacturing processes established or introduced?	No		
31	Is successful application of the medical device dependent on the usability of the user interface?	Yes	Positioning the foot in an extreme position and thereby mimicking a clinical stress test is a critical performance measure to make use of this device	Use by unskilled or untrained personnel

31,1	Can the user interface design features contribute to use error?	Yes	Device may be incomprehensible how to position the leg/foot	Complex or confusing control system Ambiguous or unclear state of the medical device
31,2	Is the medical device used in an environment where distractions can cause use error?	No		
31,3	Does the medical device have connecting parts or accessories?	No		
31,4	Does the medical device have a control interface?	No		
31,5	Does the medical device display information?	No		
31,6	Is the medical device controlled by a menu?	No		
31,7	Is the successful use of the medical device dependent on a user's knowledge, skills and abilities?	Yes	Positioning the foot in an extreme position and thereby mimicking a clinical stress test is a critical performance measure to make use of this device	Use by unskilled or untrained personnel
31,8	Will the medical device be used by persons with special needs?	No		
31,9	Can the user interface be used to initiate unauthorized actions?	No		
32	Does the medical device include an alarm system?	No		
33	In what way(s) might the medical device be deliberately misused?	Yes	Deliberately placing the foot in a wrong position of using other body parts such as the wrist in the same device	Confusing or missing instructions for use
34	Is the medical device intended to be mobile or portable?	Yes	The device can be taken in and out of the imaging rooms	Falling objects
35	Does the use of the medical device depend on essential performance?	Yes	Positioning the foot in an extreme position and thereby mimicking a clinical stress test is a critical performance measure to make use of this device	Slips, lapses and mistakes
36	Does the medical device have a degree of autonomy?	No		
37	Does the medical device produce an output that is used as an input in determining clinical action?	No		

Appendix C – Risk analysis participation list

Team	Date	Session purpose	
Project team	28-11-2022	Risk analysis	
Name	Title	Affiliation	Expertise
G.J.M. Tuijthof	Prof. Dr. Ir	University of Twente	Project lead
D. van Elst	Bsc.	University of Twente	Biomedical engineer
B. Oosterbroek	Bsc.	University of Twente	Mechanical engineer

Team	Date	Session purpose	
Expert team / use team + Project team	17-03-2022	Expert review	
Name	Title	Affiliation	Expertise
G.J.M. Tuijthof	Prof. Dr. Ir	University of Twente	Project lead
D. van Elst	Bsc.	University of Twente	Biomedical engineer
M. Poeze	Prof. Dr.	Maastricht University Medical Center +	Trauma surgeon
J.P.S. Hermus	Drs.	Maastricht University Medical Center +	Orthopedic (Foot and Ankle) surgeon

Appendix D – Material list

The materials purchased for the device are shown in the table below (Table D1). The specifications of the materials (dimensions, amounts) of the materials are shown here. It is also indicated where this part can be purchased.

Table D1. Specifications of the bought components.

Component ID	Part (specifications)	Amount	Dimensions	Supplier	Where to buy
2.1.1	Outer PMMA rod ¹	6	Ø 14-20 × 220 mm	Flexinplex Kunststoffen B.V.	https://www.flexinplex.nl/plexiglas-xt-buis-glashelder-%C3%98-20x3mm-l-2000mm
2.1.2	Inner PMMA rod ¹	6	Ø 8-12 × 175 mm	Flexinplex Kunststoffen B.V.	https://www.flexinplex.nl/plexiglas-xt-buis-glashelder-%C3%98-12x2mm-l-2000mm
2.1.3	Plastic rod	6	Ø 12-14 × 100 mm	Modelbouwshopnederland.nl	https://www.modelbouwshopnederland.nl/a-43504330/buis-1-meter/buis-12-0-x-14-0mm-419-68-1-meter/
2.2.1	Solid rubber (Hardness 60+/-5 Shore A)	6	Ø 15 × 50 mm	Rubberwebshop.nl	https://www.rubberwebshop.nl/rubber-rond-snoer/rubber-rond-snoer-15mm
2.2.2	Silicone tube	6	Ø 8-10 × 40 mm	-	<i>Unknown where to buy</i>
2.4.1	Rope (blind cord PA)	6	Ø 2.6 mm × 1000 mm	Schottert	https://www.schottert.com/bouw-industrie/bevestigingsmateriaal/touw/jaloeziekoord/jaloeziekoord-pa-2-6mm-wit-per-meter.html
2.4.2	Clamcleat (Micro Nylon CL263)	6	-	NauticPro	https://www.nauticpro.nl/cleats/clamcleat-micro-nylon-cl263-1-4mm-set-van-2-zwart
2.4.3	Nylon bolts	12	M3 × 10	Bits & Parts	https://www.bitsandparts.nl/Bout-M3x10-Nylon-p107467
2.4.4	Nylon nuts	12	M3	Bits & Parts	https://www.bitsandparts.nl/Moer-M3-polyamide-2-4mm-p107474

¹ These parts can be cut to length by the supplier

Appendix E – Technical drawings for Laser cutting

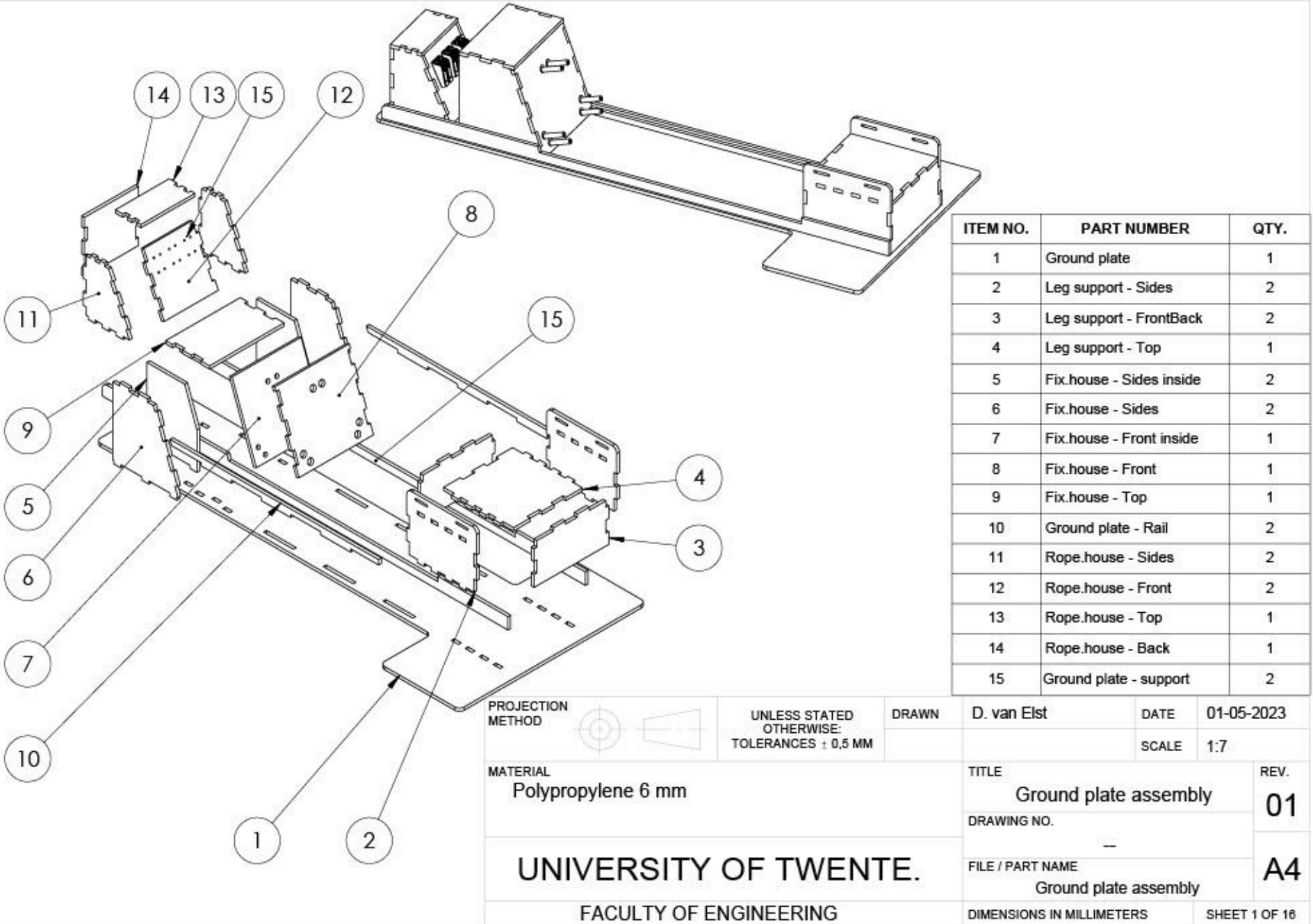
Technical drawings are provided for the parts of the ground plate and foot plate that are laser cutted. An overview of the parts needed is viewed in Table E1. The technical drawings are viewed on the next pages.

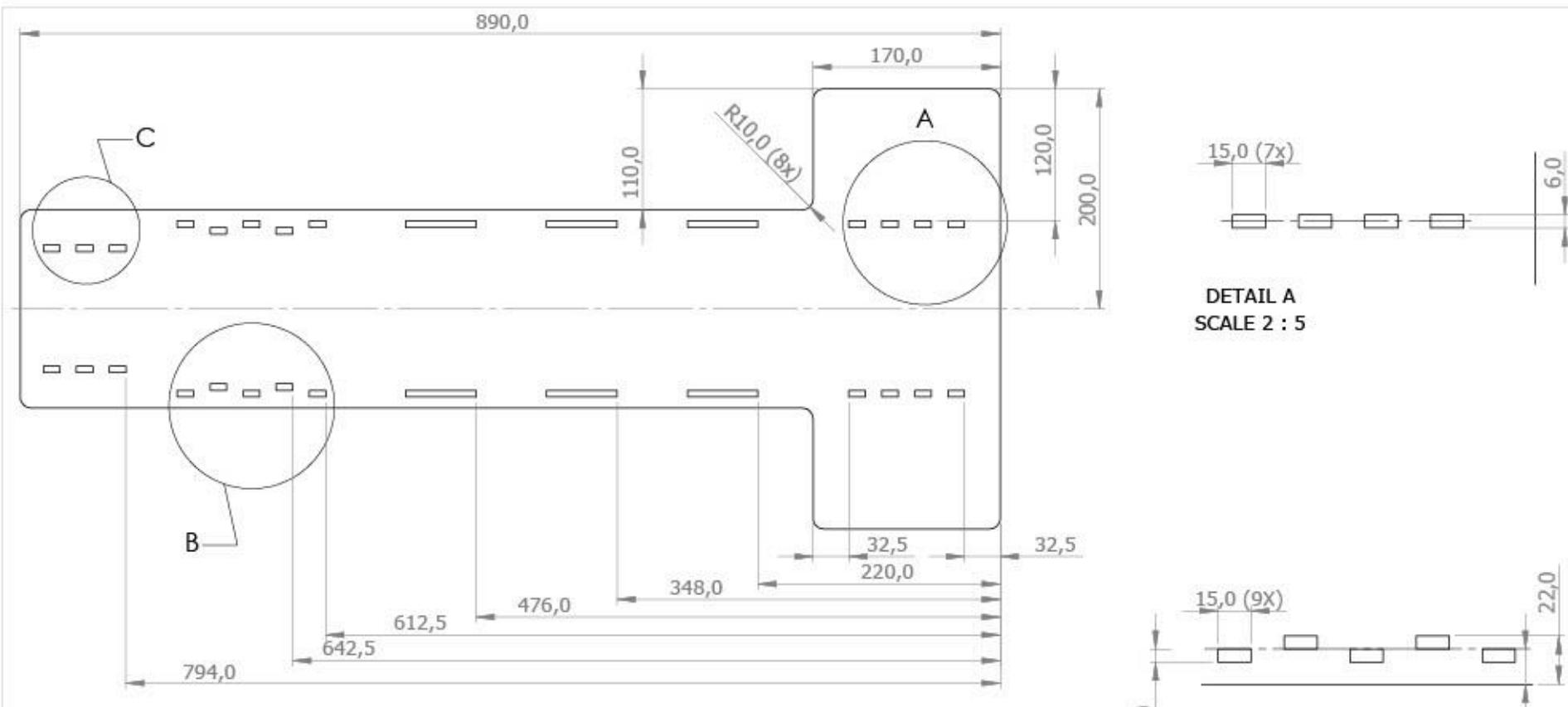
Table E1. Parts that must be laser cut.

Component ID	Component / Part name	Amount
1.1.0	Ground plate assembly	
1.1.1	Ground plate	1
1.1.2	Rib	2
1.1.3	Support	2
1.2.0	Fixation house assembly	
1.2.1	Front inside	1
1.2.2	Front	1
1.2.3	Sides	2
1.2.4	Sides inside	2
1.2.5	Top	1
1.3.0	Leg support assembly	
1.3.1	FrontBack	2
1.3.2	Sides	2
1.3.3	Top	2
1.4.0	Rope house assembly	
1.4.1	Back	1
1.4.2	Front	1
1.4.3	Sides	2
1.4.4	Top	1
1.5.0	Foot plate assembly	
1.5.1	Foot plate	1
1.5.2	Heel support	1
1.5.3	Rods fixation	6

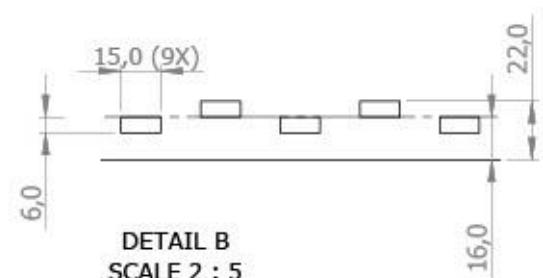
If a laser cutter is available, such as the Trotec Speedy 400, these parts can be cut from a polypropylene sheet. It will have to be taken into account that the laser cutter can handle the largest size of the parts, that is part Ground plate. The polypropylene sheet can then be purchased from Flexinplexplastics. Below is a link with where it can be ordered.

<https://www.flexinplex.nl/polypropeen-plaat-grijs-7032-2000x1000x6mm>

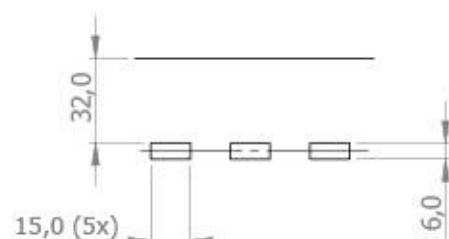




DETAIL A
SCALE 2 : 5



DETAIL B
SCALE 2 : 5



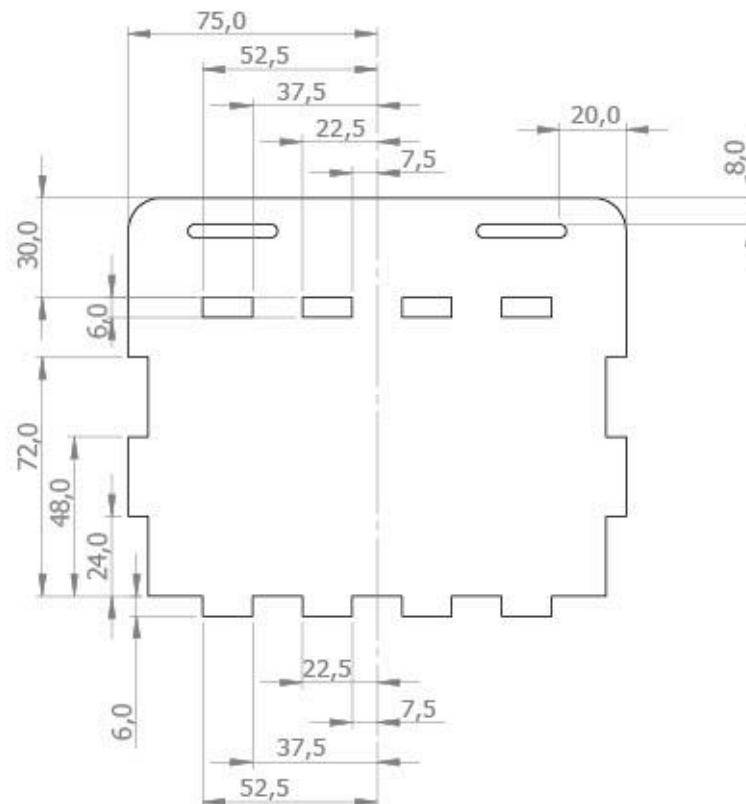
DETAIL C
SCALE 2 : 5

PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:5
			TITLE	Ground plate item no. 1		
			COMPONENT ID	1.1.1		
			FILE / PART NAME	Ground plate assembly		
			DIMENSIONS IN MILLIMETERS	SHEET 2 OF 16		

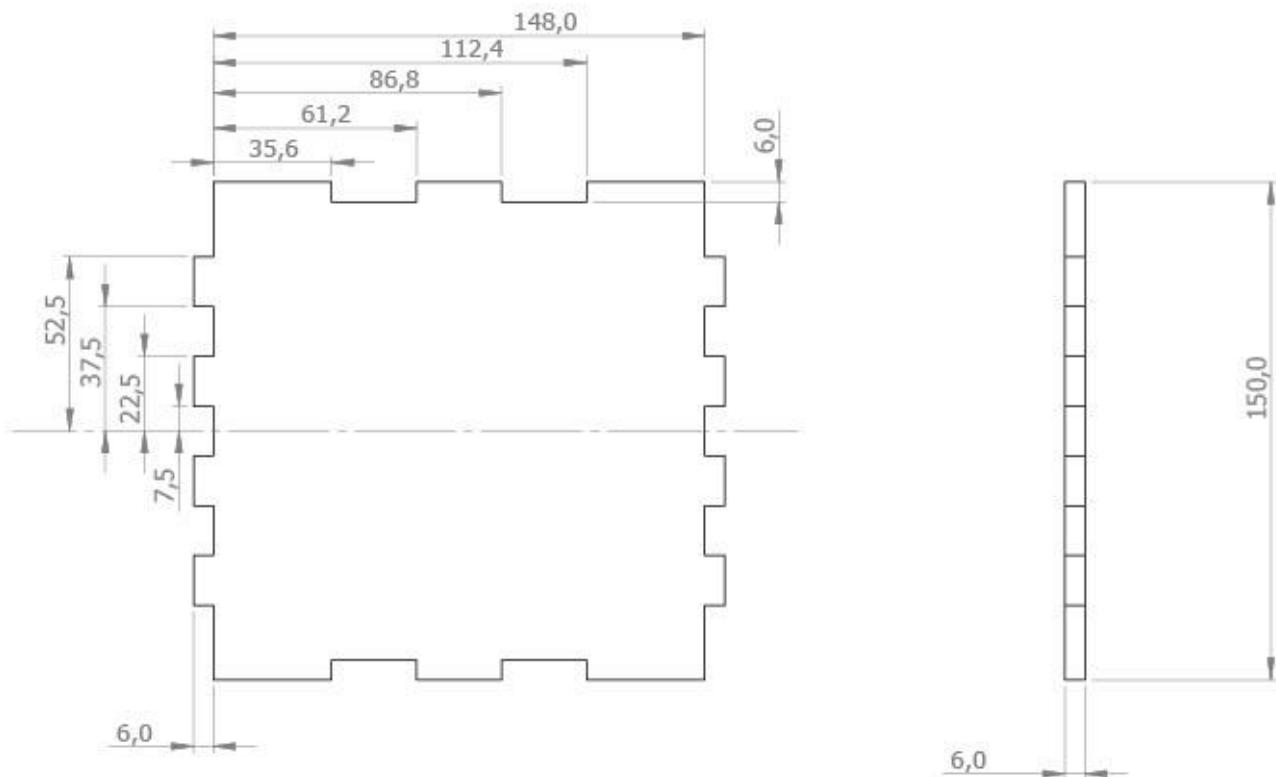
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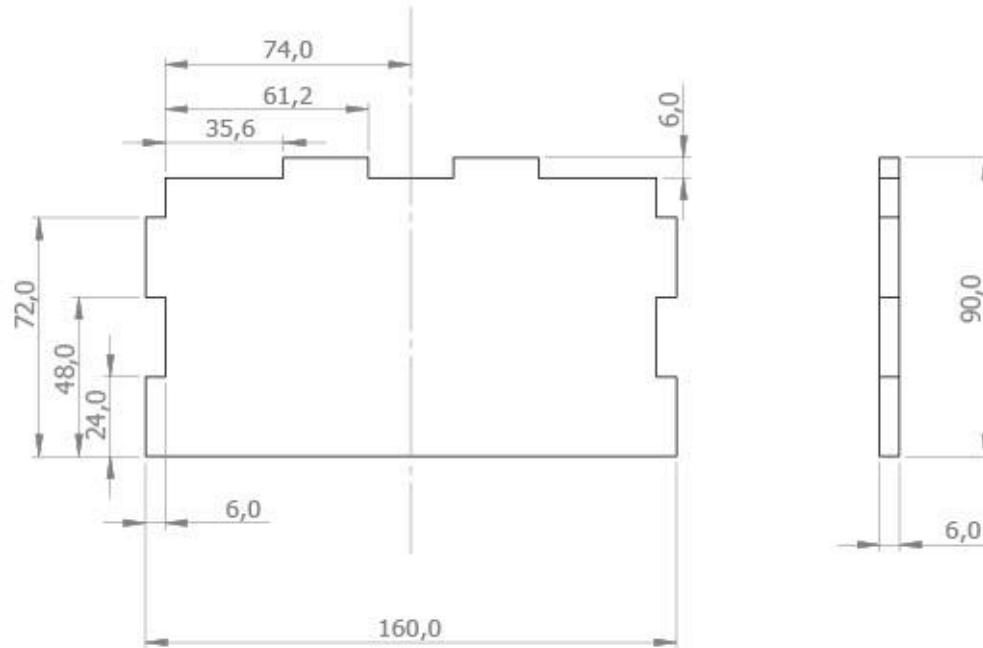
A4



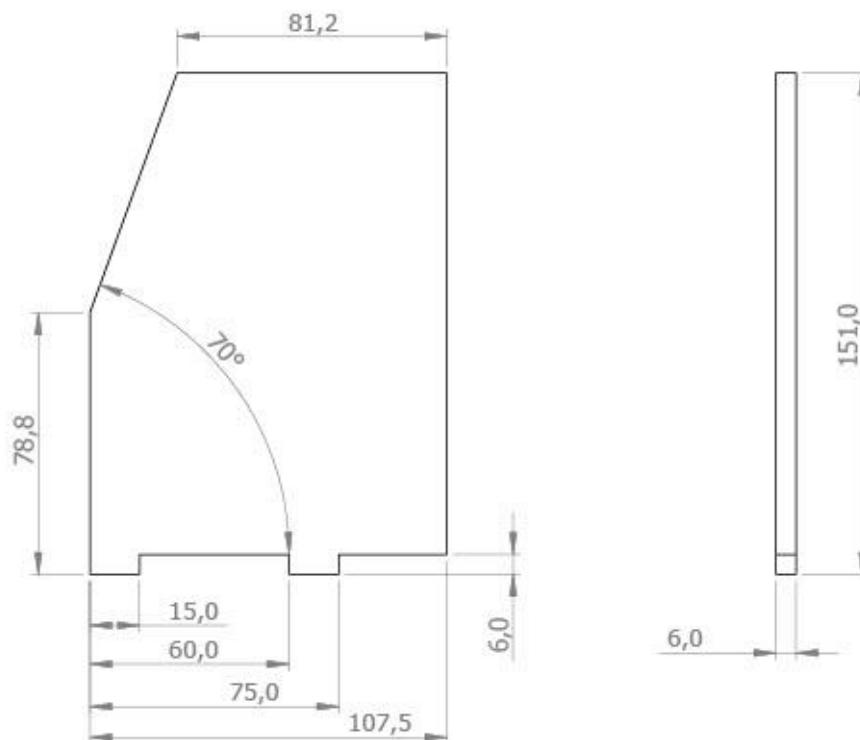
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:2
			TITLE	Leg support - sides item no.2	REV.	
			COMPONENT ID	1.3.2	01	
			FILE / PART NAME	Ground plate assembly	A4	
			DIMENSIONS IN MILLIMETERS	SHEET 3 OF 16		



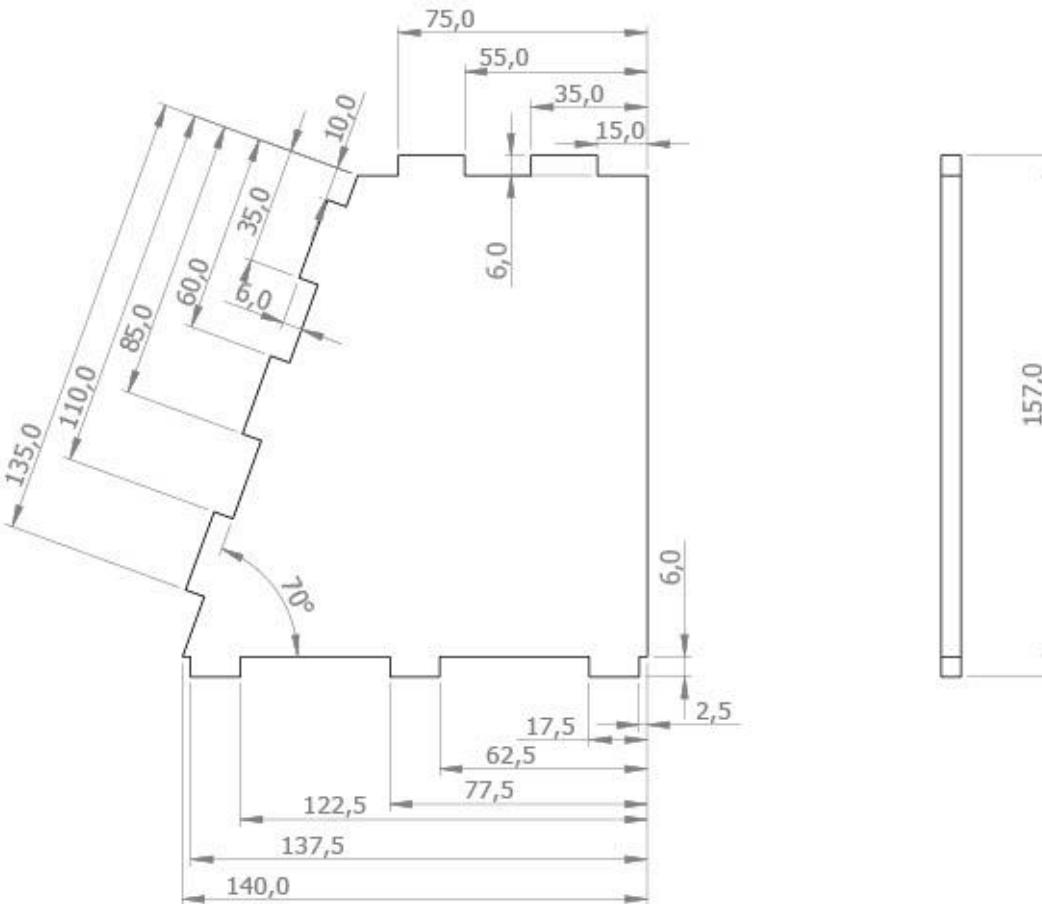
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL					SCALE	1:2
Polypropylene 6 mm					TITLE	Leg support - top item no.3
					COMPONENT ID	1.3.3
					FILE / PART NAME	Ground plate assembly
					DIMENSIONS IN MILLIMETERS	SHEET 4 OF 16
						A4



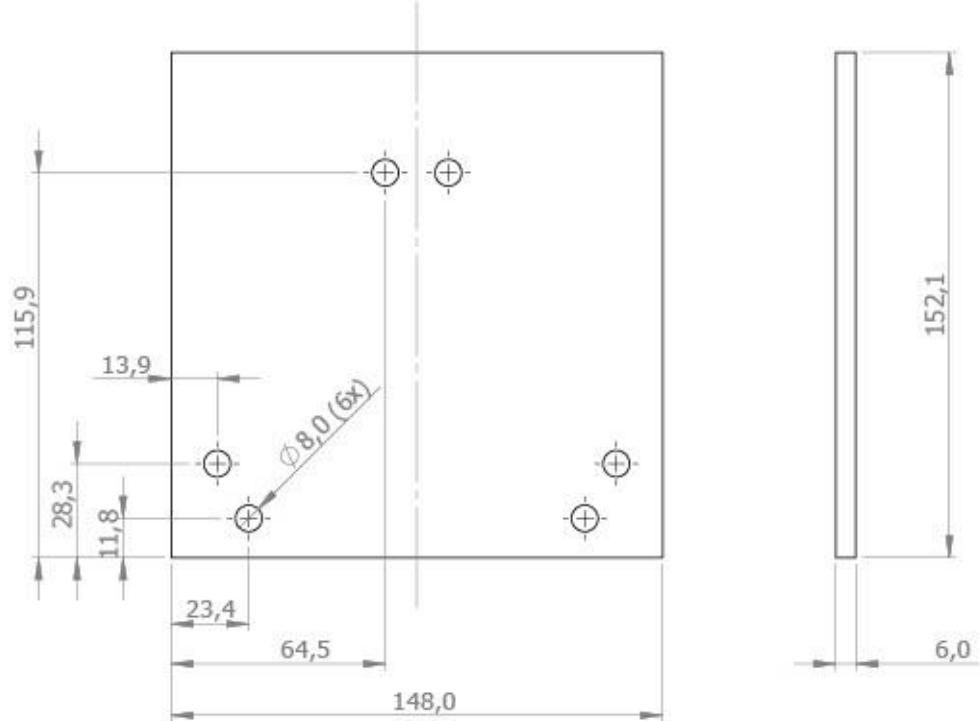
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL					SCALE	1:2
Polypropylene 6 mm					REV.	
					01	
			TITLE			
			Leg support - frontback item no.4			
			COMPONENT ID			
			1.3.1			
			FILE / PART NAME			
			Ground plate assembly			
			FACULTY OF ENGINEERING	DIMENSIONS IN MILLIMETERS	SHEET 5 OF 16	A4



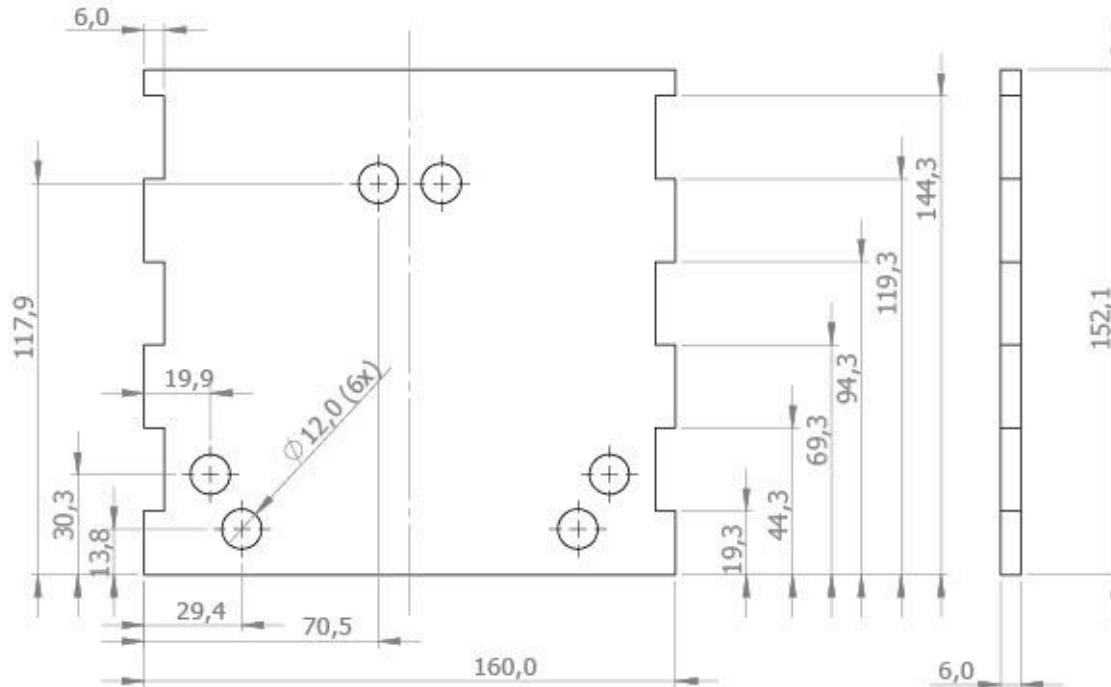
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:2
			TITLE		REV.	
			Fix. house - side inside item no.5		01	
			COMPONENT ID			
			1.2.4			
			FILE / PART NAME			
			Ground plate assembly			
			DIMENSIONS IN MILLIMETERS		SHEET 8 OF 16	



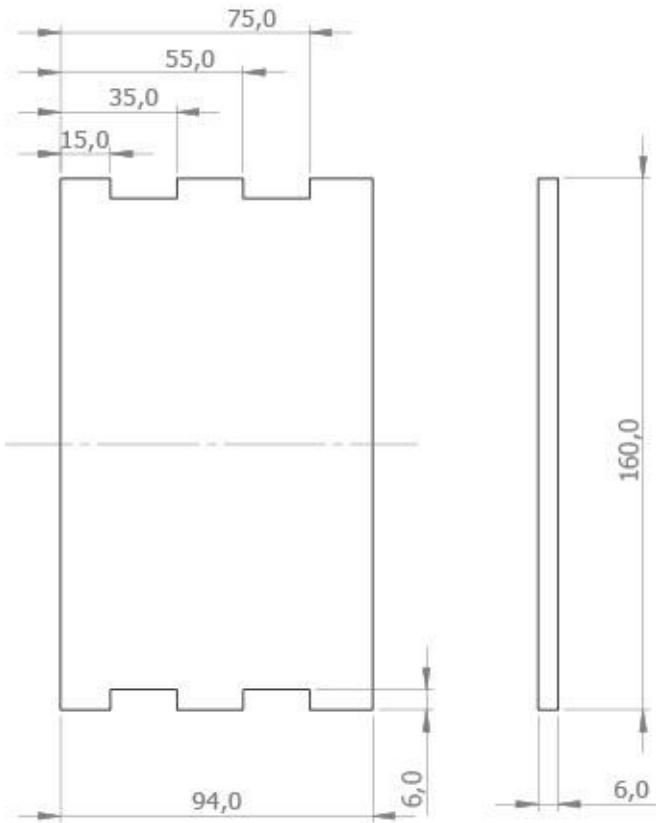
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:2
			TITLE	Fix. house - side item no.6	REV.	01
			COMPONENT ID	1.2.3		
			FILE / PART NAME	Ground plate assembly	A4	
			DIMENSIONS IN MILLIMETERS	SHEET 7 OF 16		



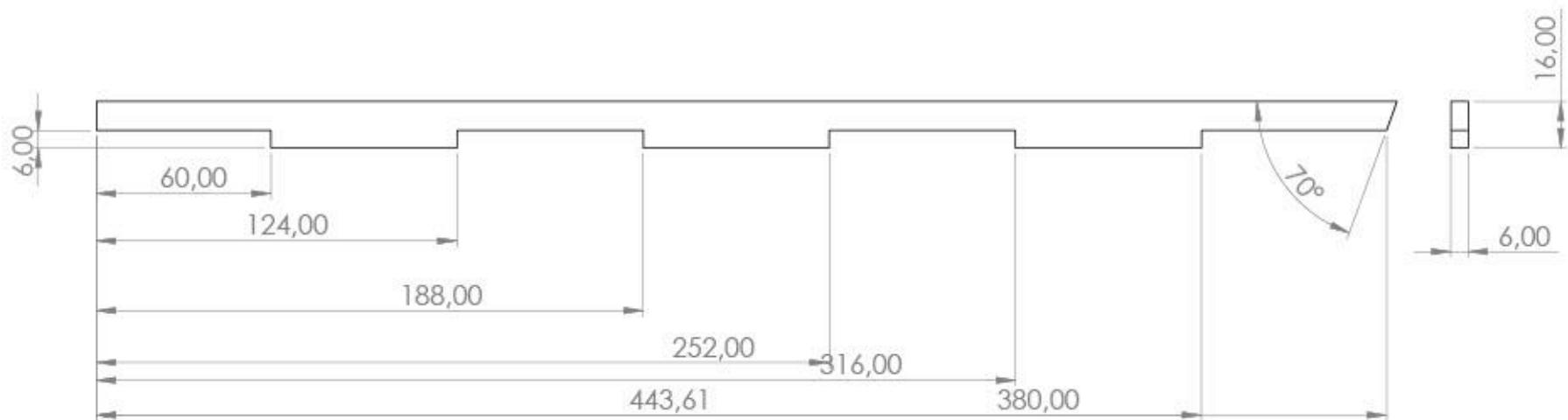
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL					SCALE	1:2
Polypropylene 6 mm					TITLE	
					Fix. house - front inside item no.7	REV.
					COMPONENT ID	01
					1.2.1	
					FILE / PART NAME	A4
					Ground plate assembly	
					DIMENSIONS IN MILLIMETERS	SHEET 8 OF 16
FACULTY OF ENGINEERING						



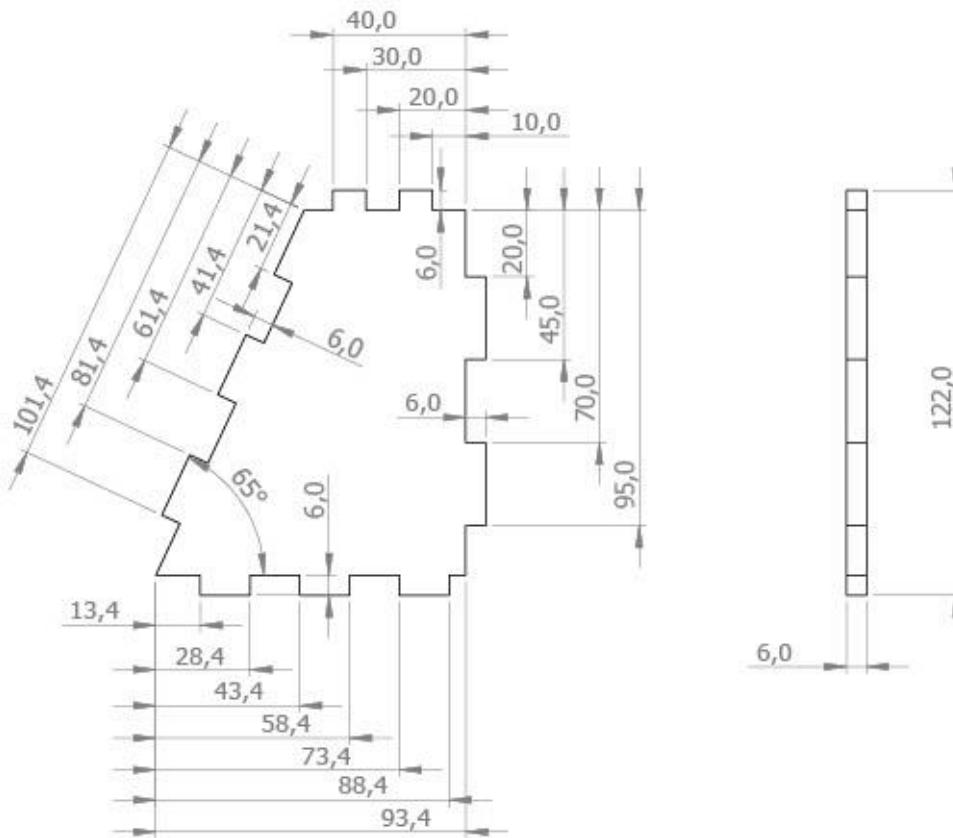
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL					SCALE	1:2
Polypropylene 6 mm					TITLE	Fix. house - front item no.8
					COMPONENT ID	1.2.2
					FILE / PART NAME	Ground plate assembly
					DIMENSIONS IN MILLIMETERS	SHEET 9 OF 16
						A4



PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:2
			TITLE	Fix. house - top item no.9	REV.	01
			COMPONENT ID	1.2.5		
			FILE / PART NAME	Ground plate assembly	A4	
			DIMENSIONS IN MILLIMETERS	SHEET 10 OF 16		



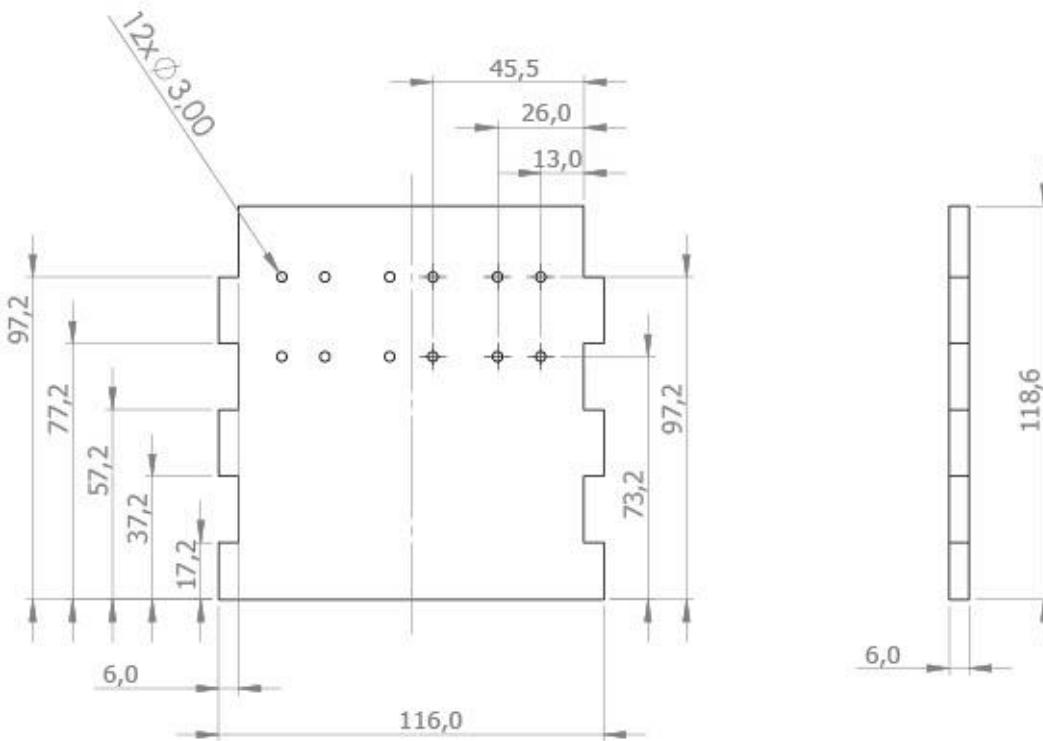
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:2
			TITLE	Groundplate - Rib item no.10	REV.	
			COMPONENT ID	1.1.2		01
			FILE / PART NAME	Ground plate assembly	A4	
			DIMENSIONS IN MILLIMETERS		SHEET 11 OF 16	



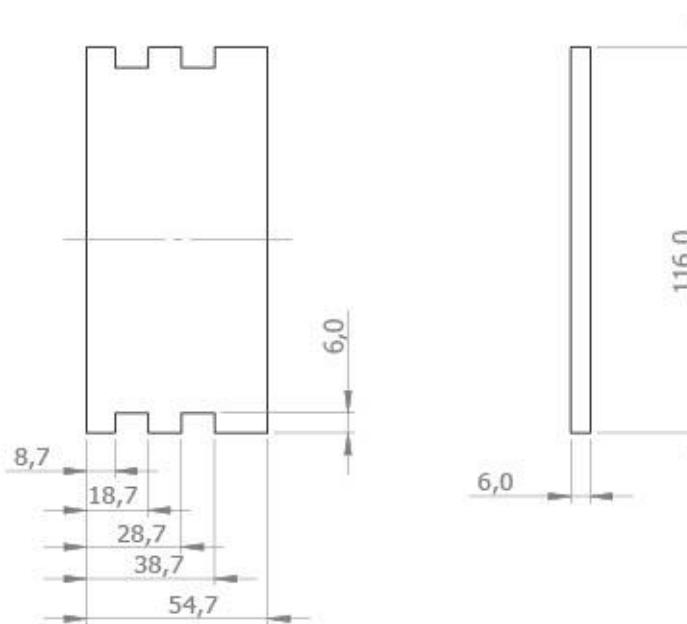
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:2
			TITLE	Rope house - sides item no.11	REV.	
			COMPONENT ID	1.4.3		01
			FILE / PART NAME	Ground plate assembly	A4	
			DIMENSIONS IN MILLIMETERS	SHEET 12 OF 16		

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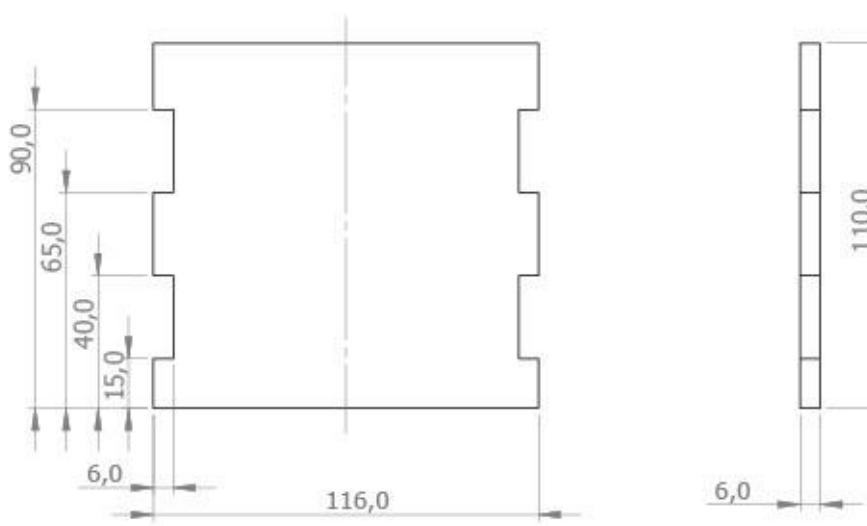
FACULTY OF ENGINEERING



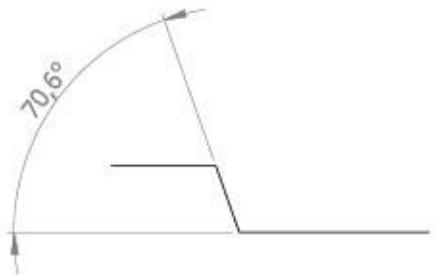
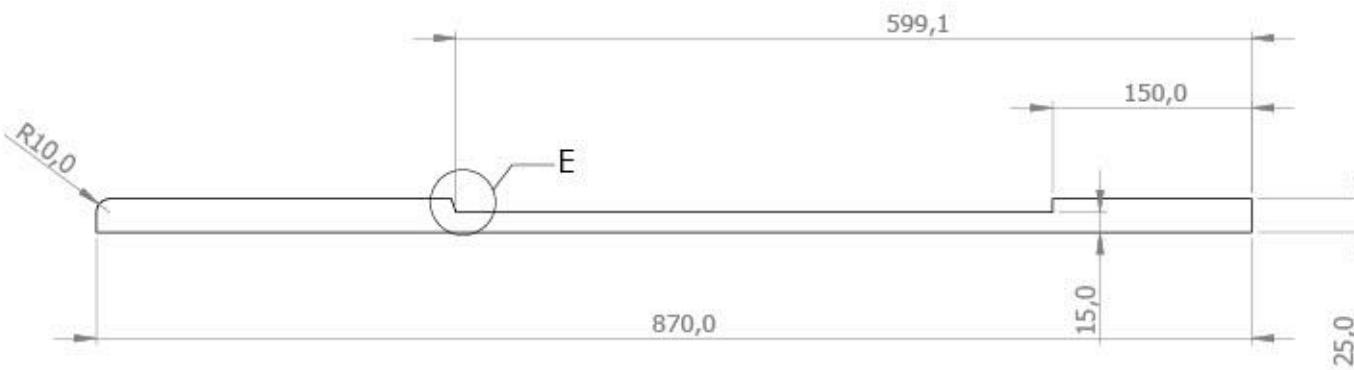
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL					SCALE	1:2
Polypropylene 6 mm					REV.	
					01	
			TITLE	Rope house - front item no.12		
			COMPONENT ID	1.4.2		
			FILE / PART NAME	Ground plate assembly		
			DIMENSIONS IN MILLIMETERS		SHEET 13 OF 16	A4
FACULTY OF ENGINEERING						



PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:2
			TITLE	Rope house - top item no.13	REV.	
			COMPONENT ID	1.4.4		01
			FILE / PART NAME	Ground plate assembly	A4	
			DIMENSIONS IN MILLIMETERS	SHEET 14 OF 16		



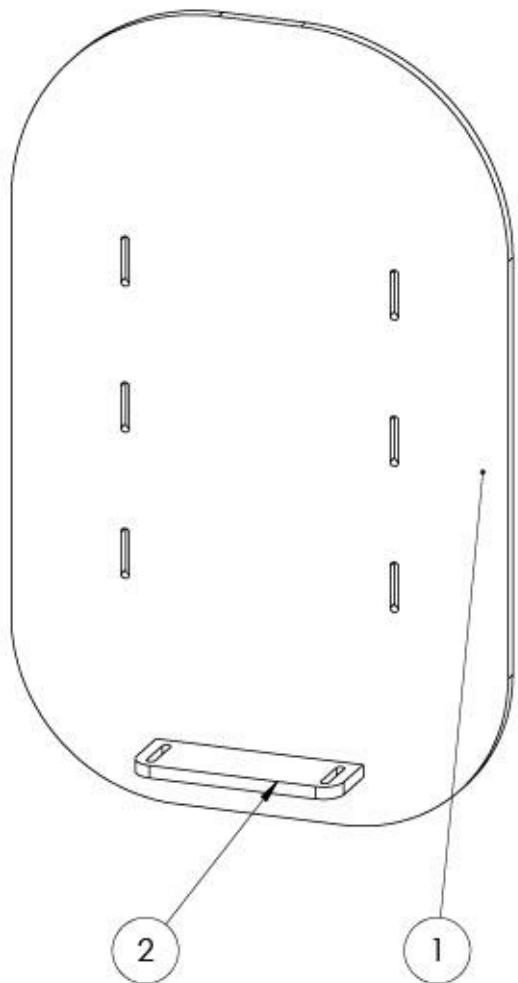
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:2
			TITLE	Rope house - back item no.14	REV.	
			COMPONENT ID	1.4.1		01
			FILE / PART NAME	Ground plate assembly	A4	
			DIMENSIONS IN MILLIMETERS		SHEET 15 OF 16	



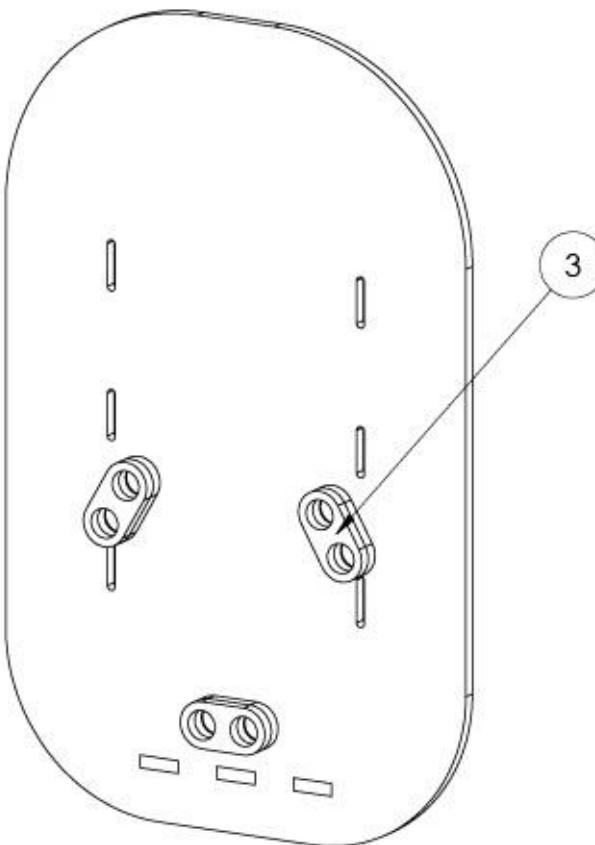
DETAIL E
SCALE 1:1

PROJECTION METHOD	 	UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm		TITLE	Ground plate - Support item no.15		REV.
			COMPONENT ID	1.1.3		01
UNIVERSITY OF TWENTE.			FILE / PART NAME	Ground plate assembly		A4
FACULTY OF ENGINEERING	DIMENSIONS IN MILLIMETERS			SHEET 16 OF 16		

FRONT

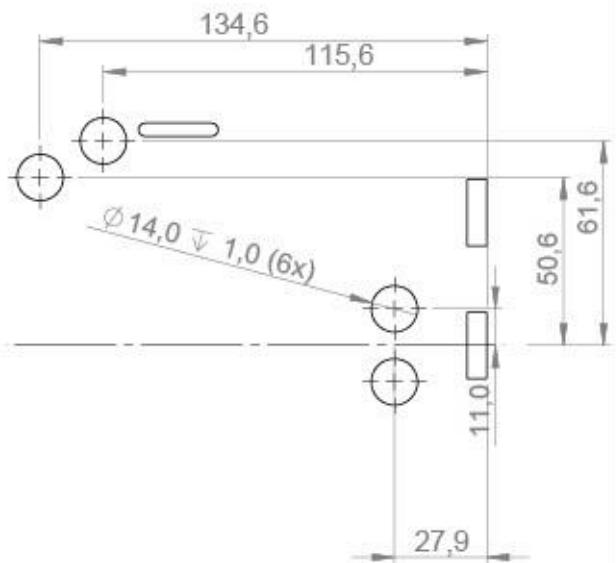
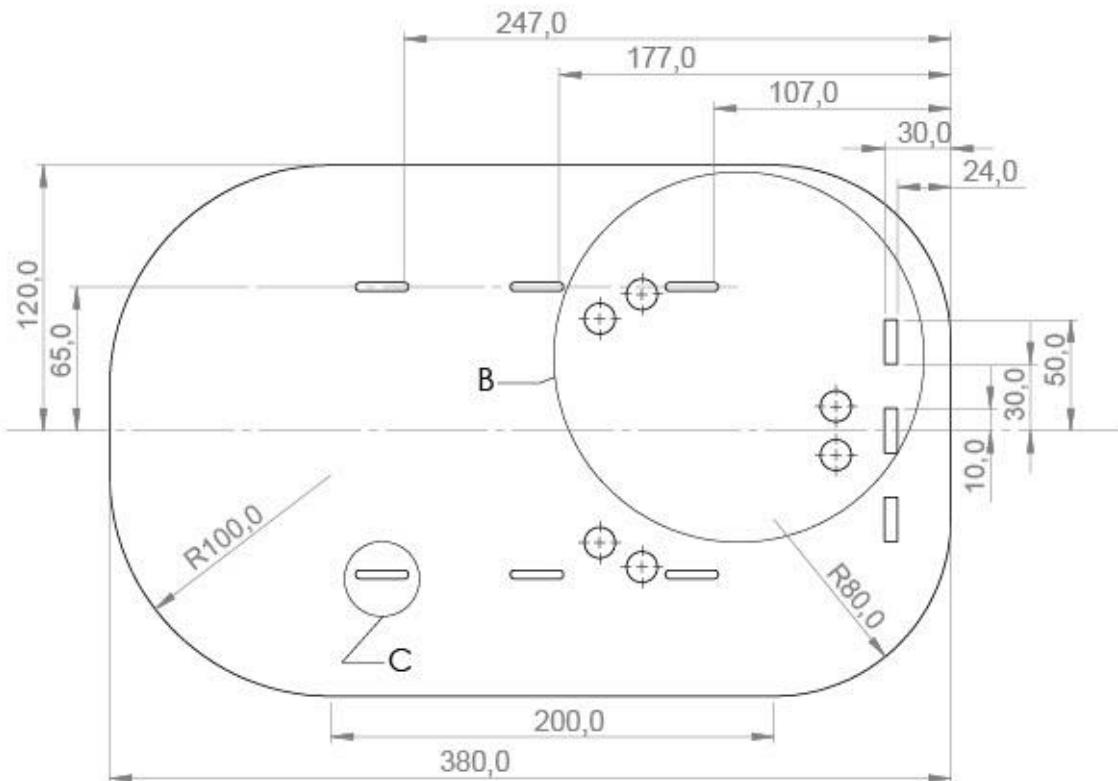


REAR

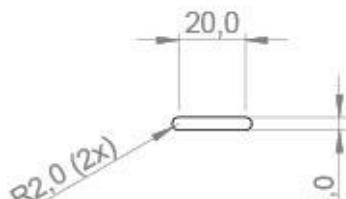


ITEM NO.	PART NUMBER	QTY.
1	Footplate	1
2	Heel Support	1
3	Rods Fixation	6

PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES ± 0.5 MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL				CHECKED	SCALE	1:3
Polypropylene 6 mm				TITLE		
				Footplate Assembly		
				FILE / PART NAME		
				Foot plate assembly		
UNIVERSITY OF TWENTE. FACULTY OF ENGINEERING				DIMENSIONS IN MILLIMETERS		SHEET 1 OF 4

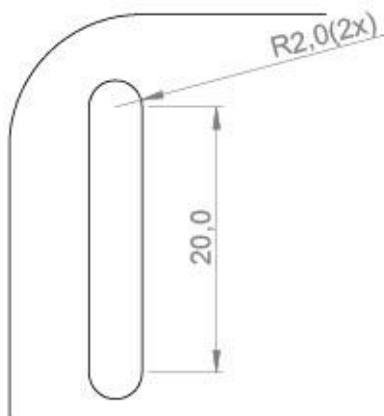
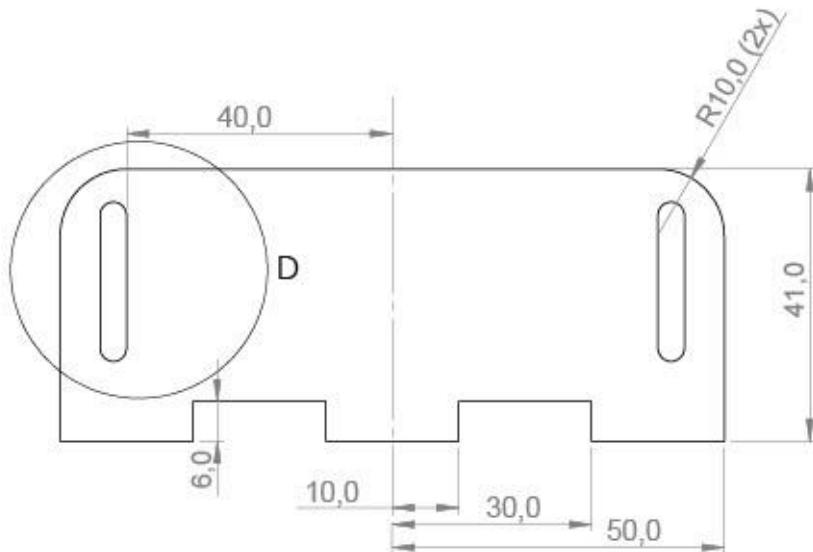


DETAIL B
SCALE 1:2



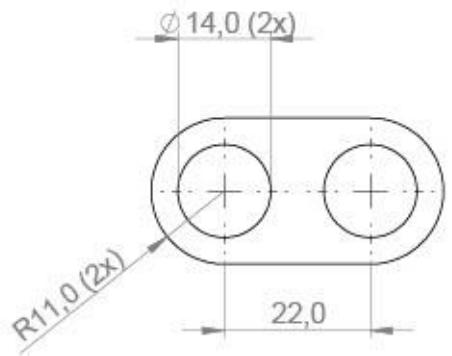
DETAIL C
SCALE 1 : 2

PROJECTION METHOD	 	UNLESS STATED OTHERWISE: TOLERANCES ± 0.5 MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm			TITLE	Footplate Item no.1	REV.
				COMPONENT ID	1.5.1	01
				FILE / PART NAME	Foot plate assembly	A4
FACULTY OF ENGINEERING				DIMENSIONS IN MILLIMETERS		SHEET 2 OF 4



DETAIL D
SCALE 2 : 1

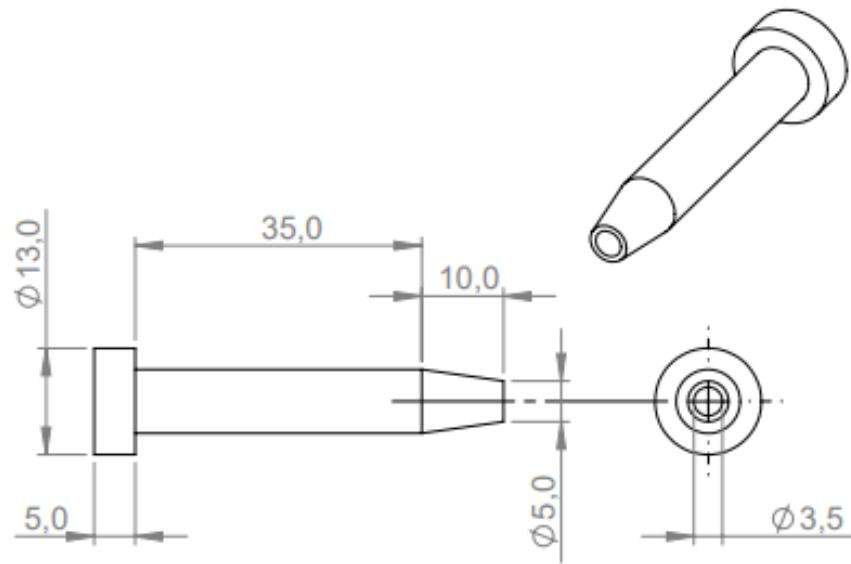
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES $\pm 0,5$ MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL					SCALE	1:1
Polypropylene 6 mm					REV.	
					01	
			TITLE	Heel support Item no.2		
			COMPONENT ID	1.5.2		
			FILE / PART NAME	Foot plate assembly		
			FACULTY OF ENGINEERING		DIMENSIONS IN MILLIMETERS	SHEET 3 OF 4



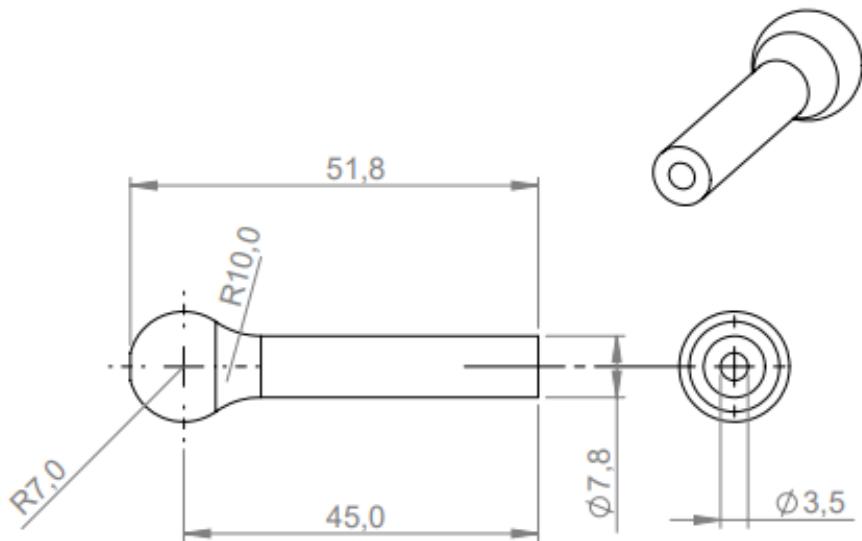
PROJECTION METHOD		UNLESS STATED OTHERWISE: TOLERANCES ± 0,5 MM	DRAWN	D. van Elst	DATE	01-05-2023
MATERIAL	Polypropylene 6 mm				SCALE	1:1
			TITLE	Rods fixation Item no.3	REV.	
			COMPONENT ID	1.5.3		01
			FILE / PART NAME	Foot plate assembly	A4	
			DIMENSIONS IN MILLIMETERS		SHEET 4 OF 4	

Appendix F – SLS 3D printing

Dimensions of the fixation plug and the ball-and-socket joint are viewed in Figure F1.



A



B

Figure F1. Dimensions of the parts to make with 3D SLS printing, all dimensions are in millimeters. Tolerances of ± 0.3 mm. A) dimensions of the fixation plug, B) dimensions of the ball-and-socket joint.

Appendix G – Foot and lower leg fixation straps

Technical drawings are provided for the fabric used for fixating the foot and lower leg. First, a bill of materials will be displayed with which products have been used for this. First, a bill of materials will be displayed with which products have been used for this (Table G1). After that, a technical drawing will be displayed for each part.

Table G1. Bill of materials for the foot and lower leg fixation.

Component	Where to buy
Water-repellent nylon fabric	https://takoy.nl/waterafstotend-nylon-zwart-ns-1178
Fleece	https://takoy.nl/2e-keus-micropolar-fleece-leo-grijs-nt-2271
Roller shutter belt 19 mm	https://www.gamma.nl/assortiment/rolluikband-19-mm-5-meter/p/B839761
Velcro straps 20 mm	https://klittenbandwinkel.nl/product/dubbelzijdig-klittenband-20-mm/
Dowel Ø10 mm	https://www.praxis.nl/gereedschap-installatiemateriaal/handgereedschap/deuvels/wolfcraft-houten-deuvel-gegroefd-40x10mm-30-stuks/1755342
All-purpose glue	https://www.praxis.nl/bouwmaterialen/bouwbenodigheden/tape-lijm/kit-lijmen/loctite-secondelijm-precision-super-glue-3-5gr/1270674

The water-repellent nylon fabric is used as a base, because it is not stretchable. Fleece is sewn on one side and Velcro straps on the other side. A loop of the roller shutter belt will first be placed on the water-repellent nylon fabric.

For the fixation of the lower leg, two same patterns are used to create the fabric. Figure G1 shows a schematic representation of how the substance is placed on the device. Figure G2 shows the technical drawing / pattern of the fabric to be made.

Note; the length of the belt must be long enough for the loop you want to create, this loop is then attached to the water-repellent nylon fabric.

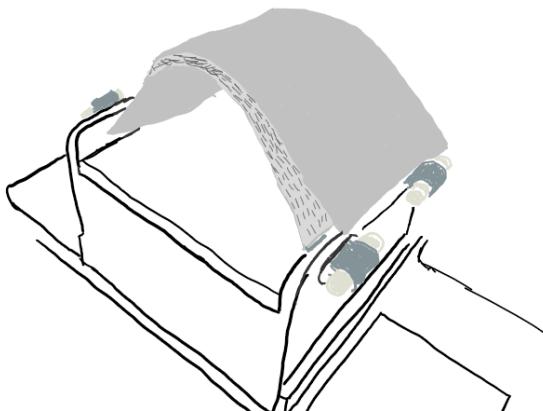


Figure G1. Schematic drawing of the placement of the fixation strap for the lower leg.

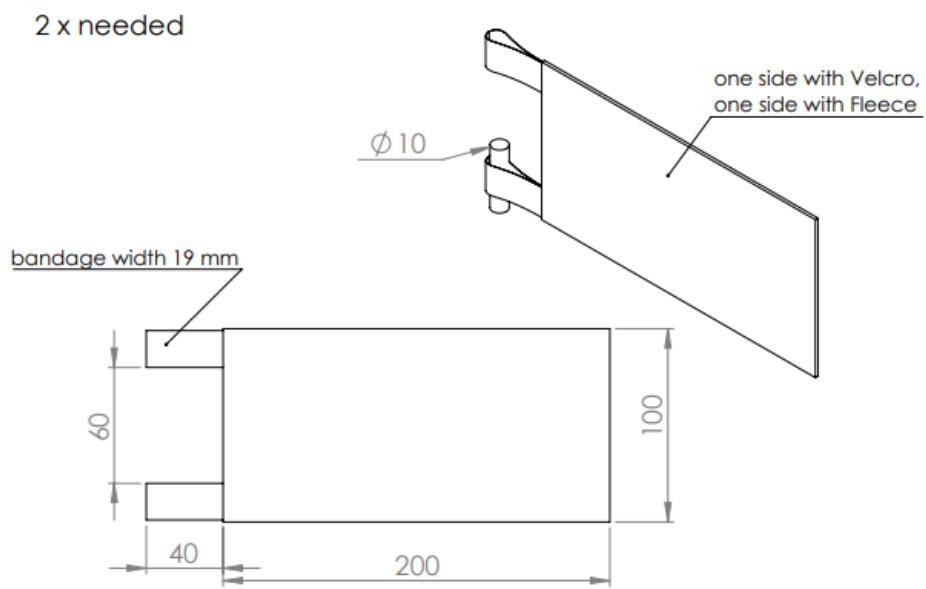


Figure G2. Technical drawing of the fabric used for the fixation band for the lower leg. Dimensions in millimeters. Several patterns are required for the fixation of the foot to the foot plate. Figure G3 shows the schematic drawing of the fabrics to be placed on the foot plate, in which it is indicated with numbers that there are 3 different patterns. Figure G4 shows the technical drawings / patterns of the fabrics to be made.

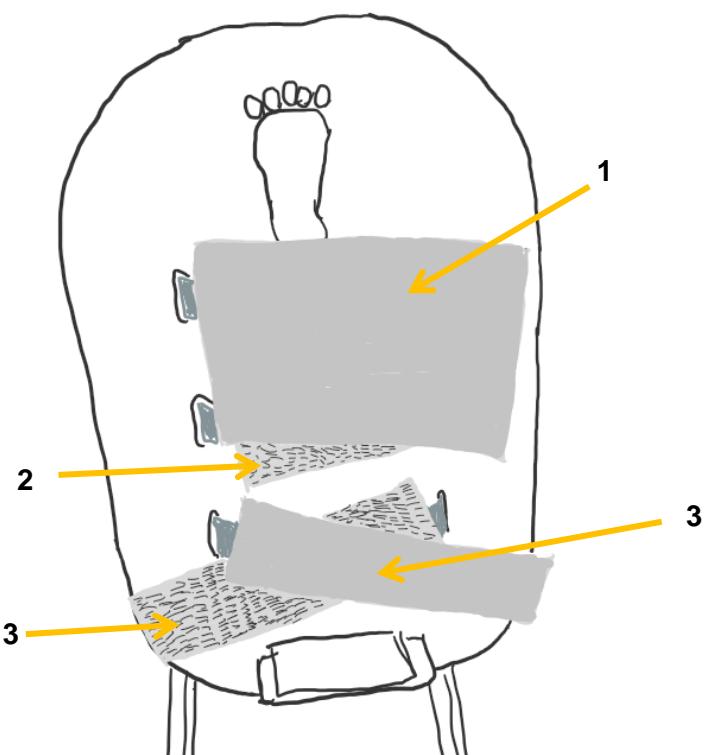


Figure G3. Schematic drawing of the placement of the fixation bands for the foot on the foot plate.

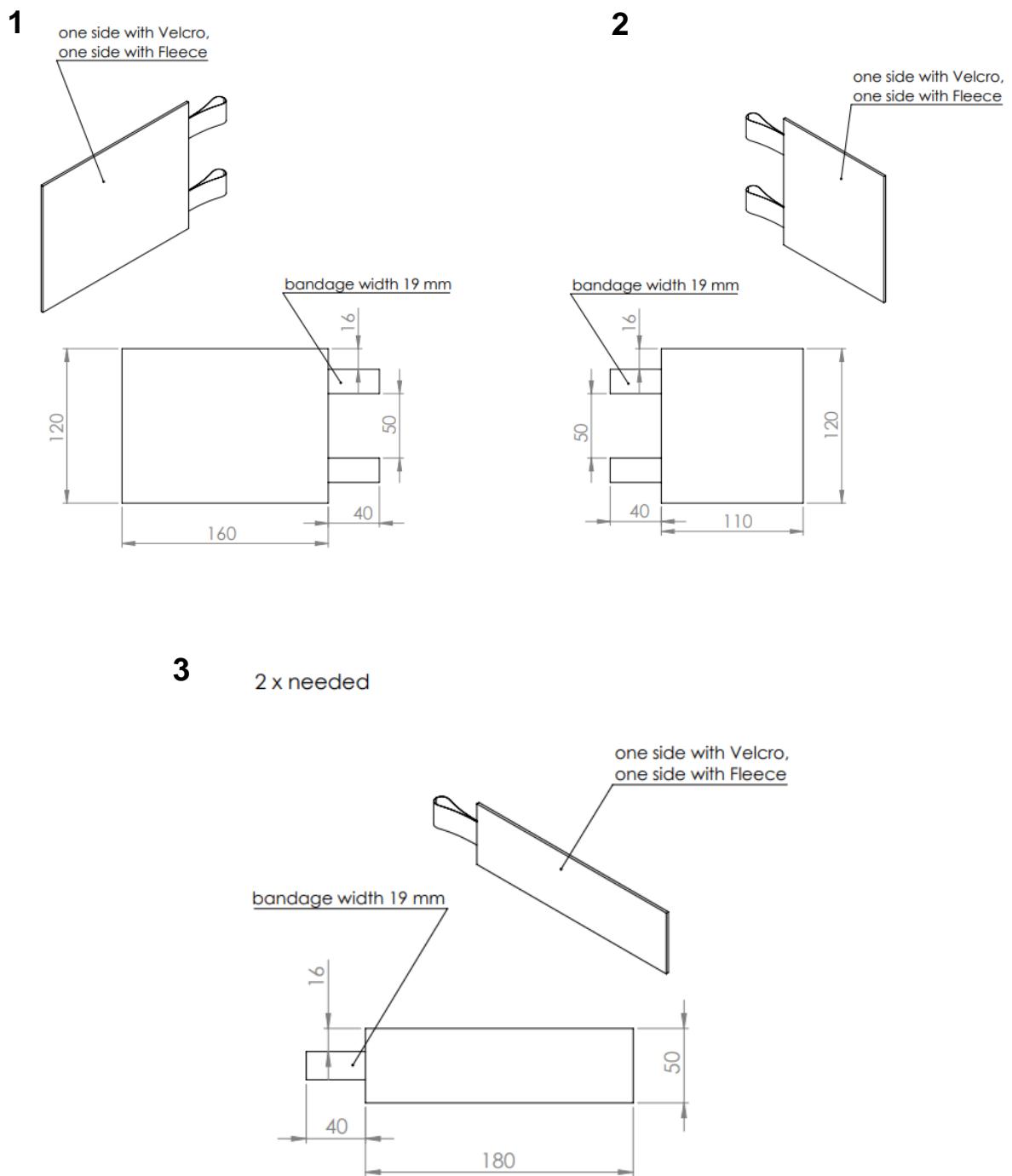


Figure G4. Technical drawings of the parts for fixation the foot to the foot plate.

Appendix H – Manual for assembly

Glue is required for certain steps to assemble the device. The bill of materials for the adhesive is shown in Table H1. It should be borne in mind that gluing polypropylene should be done with a primer. This primer is included in the package with the Loctite glue and a separate primer is required for the other glue.

Table H1. Bill of materials for the adhesives used for assembling.

Component ID	name	Where to buy
2.5.1	Loctite super glue-3 all plastics	https://www.praxis.nl/bouwmaterialen/bouwbenodigden/tape-lijm/kit-lijmen/loctite-secondelijm-super-glue-3-all-plastics-2gr-4ml/3565003
2.5.2	Saba primer 4518	https://www.vandijkenpro.nl/saba-primer-4518.html
2.5.3	Sabatack 780	https://www.vandijkenpro.nl/sabatack-780.html
2.5.4	All-purpose glue	https://www.praxis.nl/bouwmaterialen/bouwbenodigden/tape-lijm/kit-lijmen/loctite-secondelijm-precision-super-glue-3-5gr/1270674

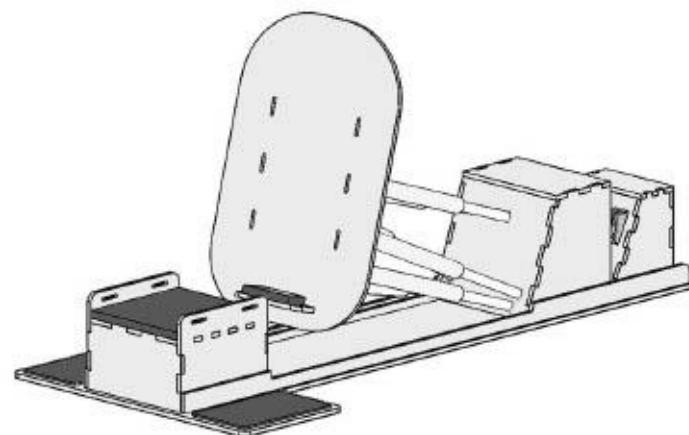
Moreover, this manual does not take into account the placement of the rubbers for the comfort of the patient and user. These are described below, and a bill of materials (Table H2) has also been added.

Table H2. Bill of materials for the rubbers used in the assembly.

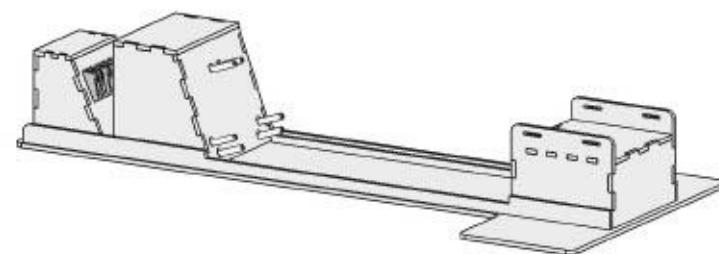
Rubber used for	name	Where to buy
Heel support + Leg support	Soft rubber 10 mm thick	unknown
Placing the other foot on the device at the level of leg support	Deltafix - Anti-sliprubber zwart 90x100 mm	https://www.kluswijs.nl/nl/1546934/anti-sliprubber-zwart-90x100/
against sharp edges (on the rope house) and against slipping of the device (bottom of the ground plate)	HANDSON - anti slip rubber 50x100 mm zwart 3 stuks	https://www.karwei.nl/assortiment/hanson-anti-slip-rubber-50x100-mm-zwart-3-stuks/p/B107820

The assembly of the device, including the materials used, are listed on the following pages.

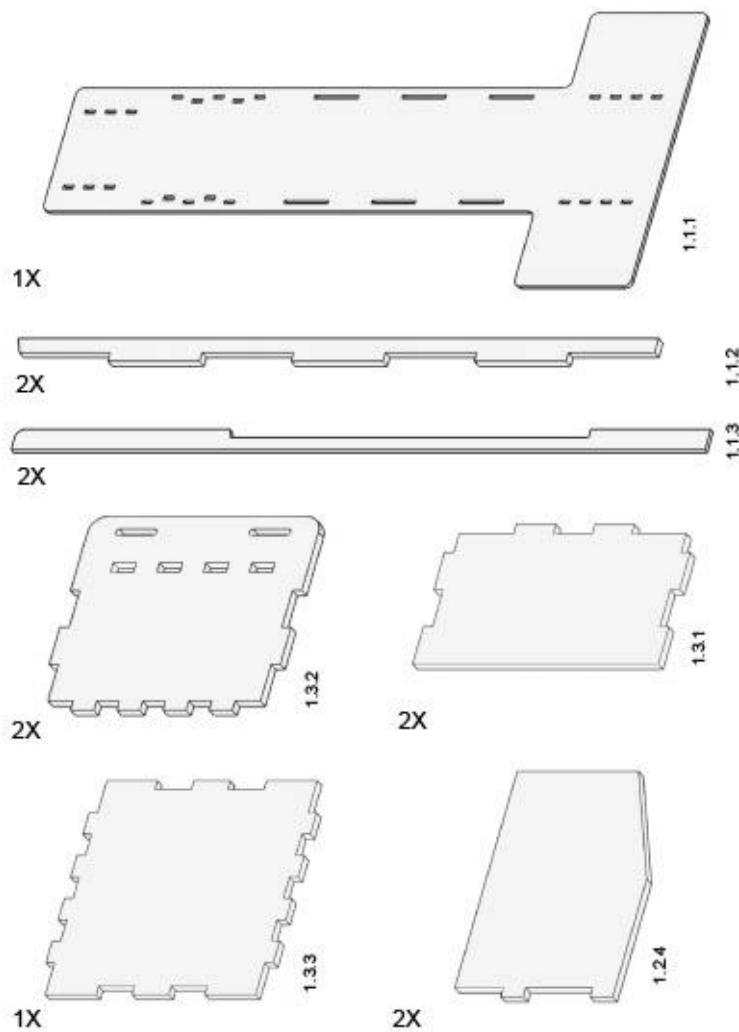
Manual for assembly of the 3D Foot plate

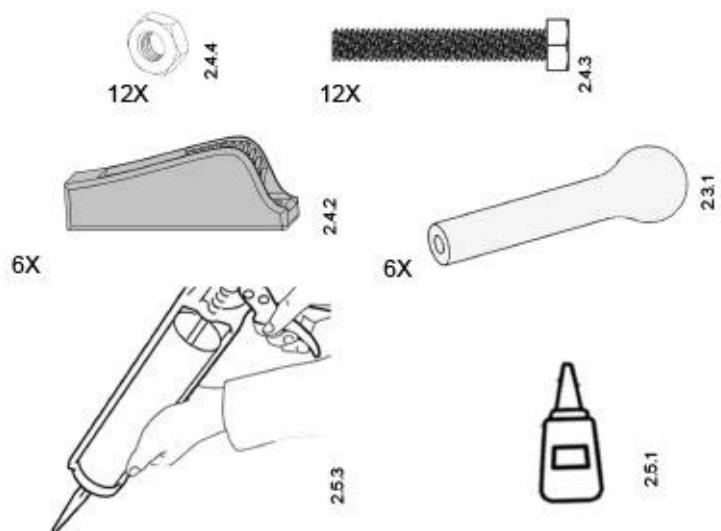


PART 1 Ground plate



Parts used

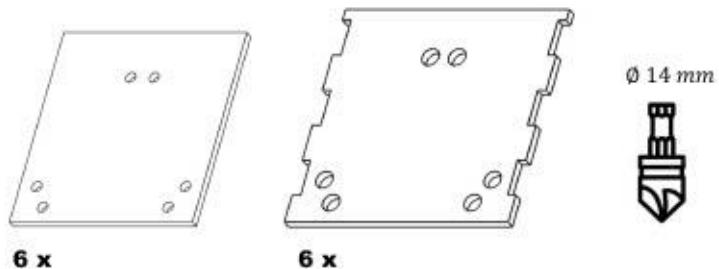




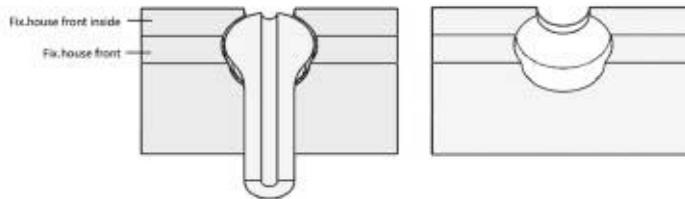
When this glue is used, primer (2.5.2) must first be used

Preprocessing step

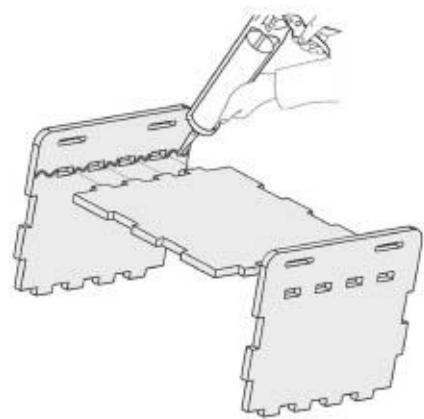
needed



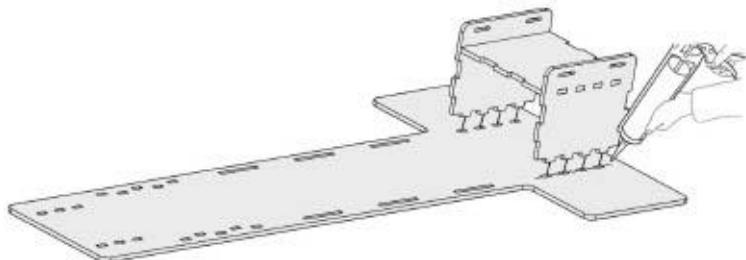
Step 1: countersink all holes so that ball-and-socket joint fits as below



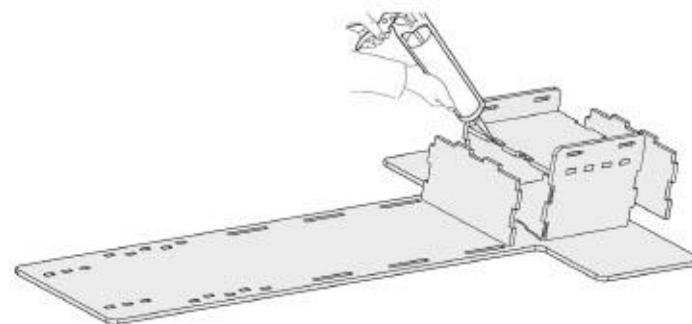
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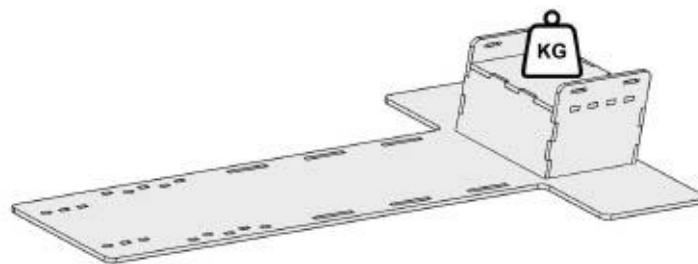
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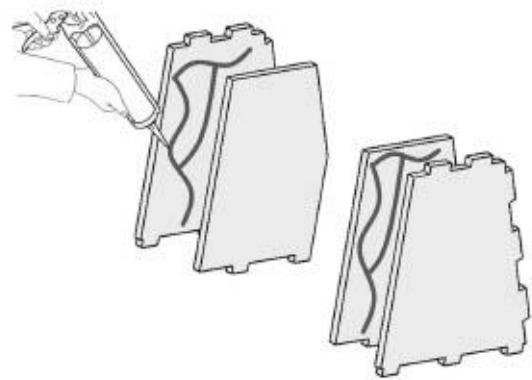
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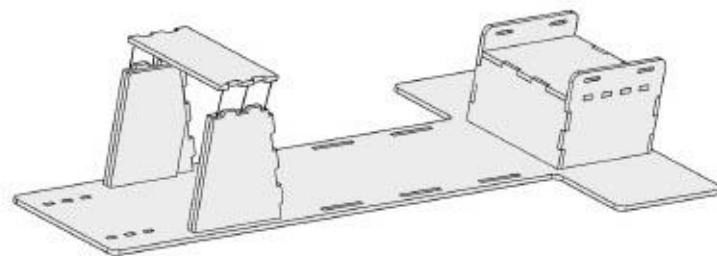
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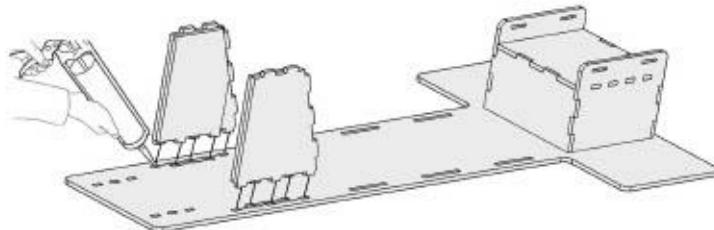
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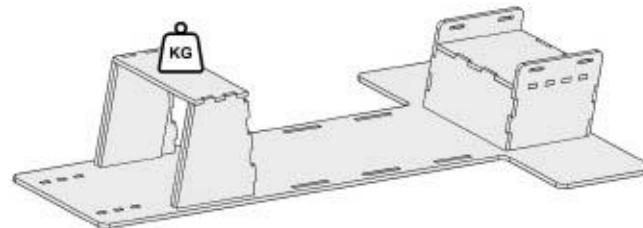
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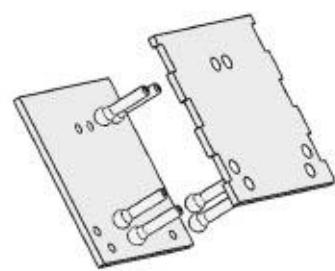
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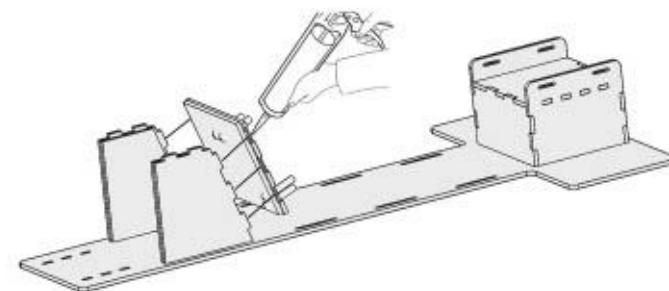
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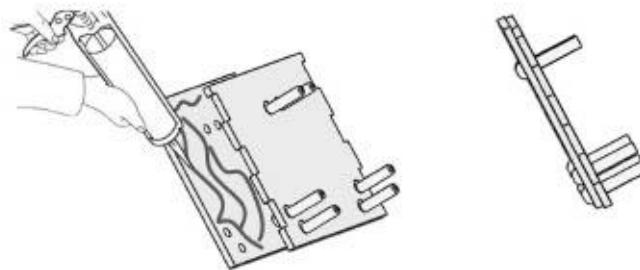
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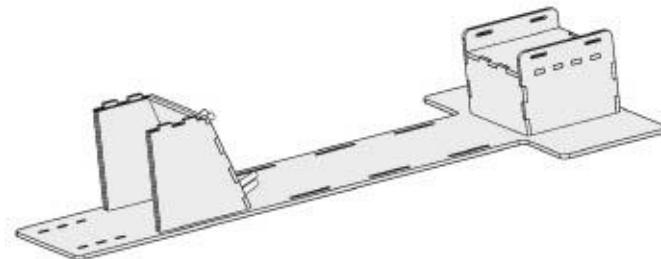
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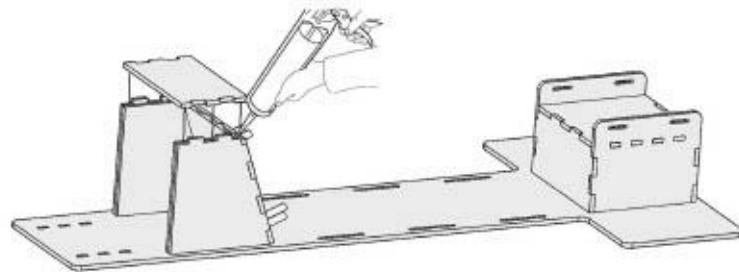
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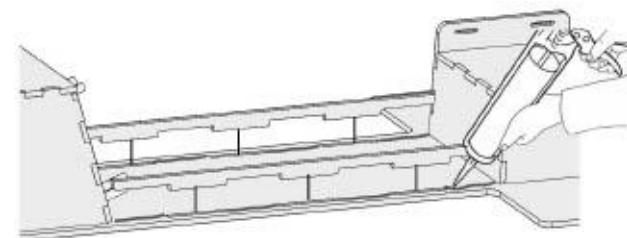
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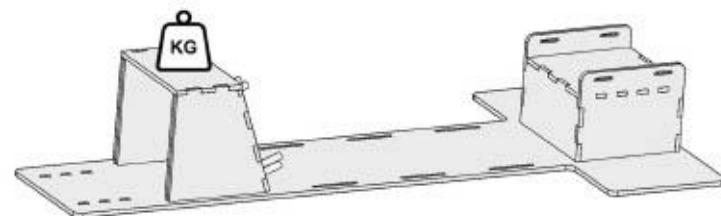
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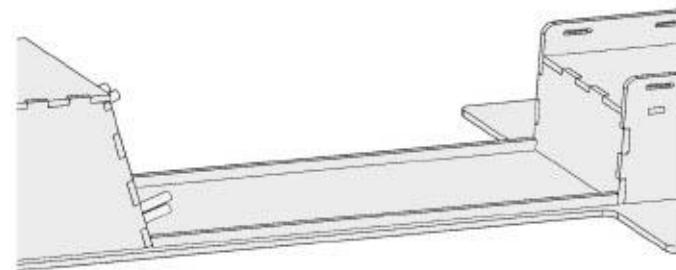
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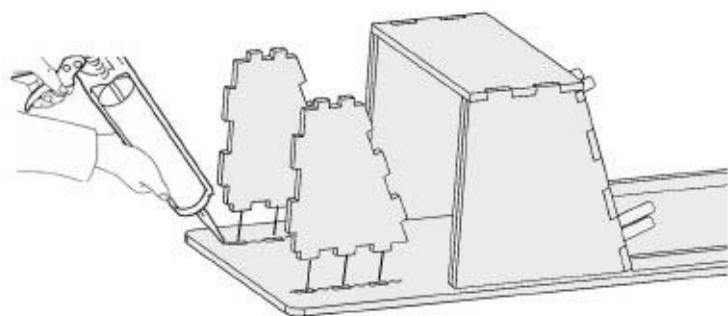
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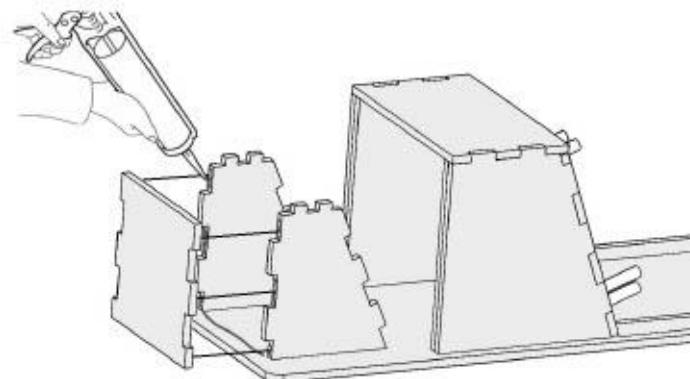
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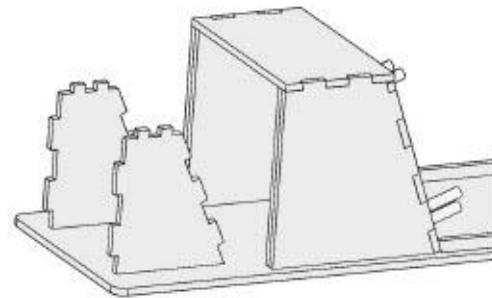
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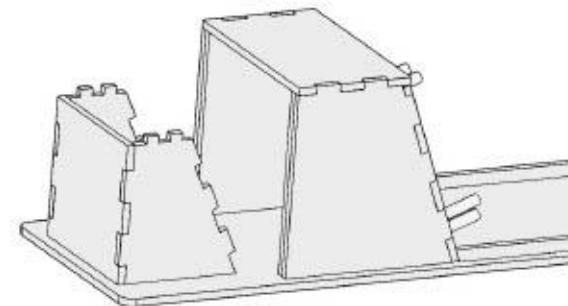
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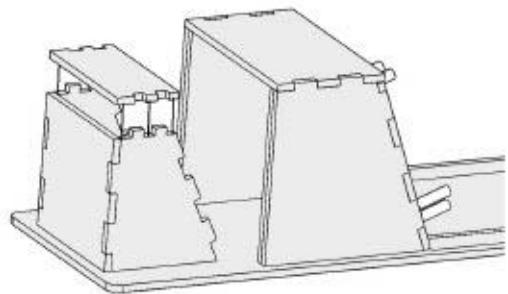
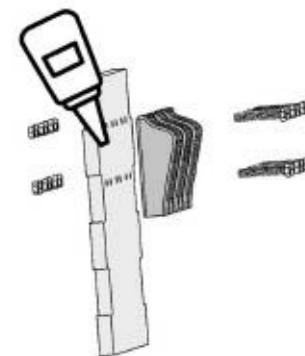


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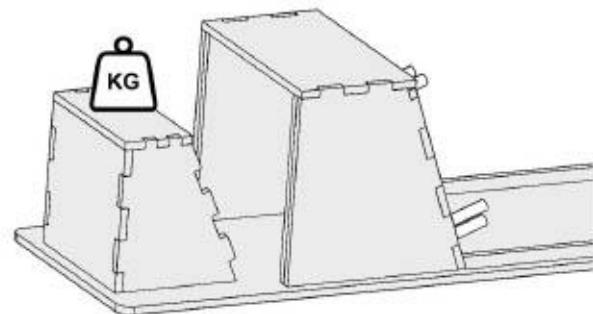
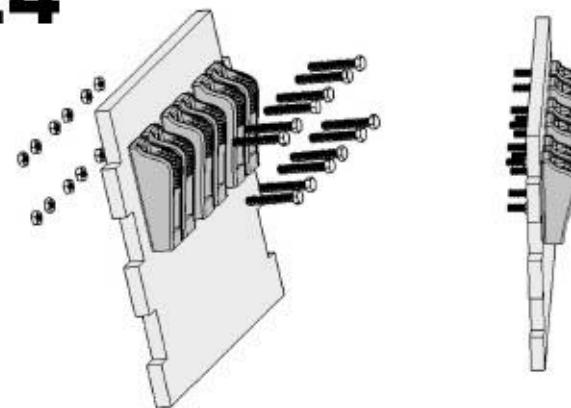


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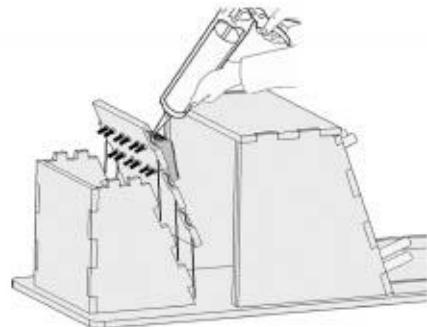


21**23**

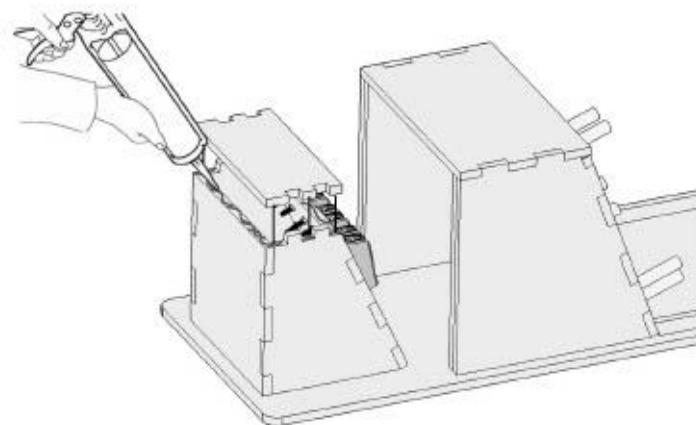
Glue added between rope cleats and rope house - front

22**24**

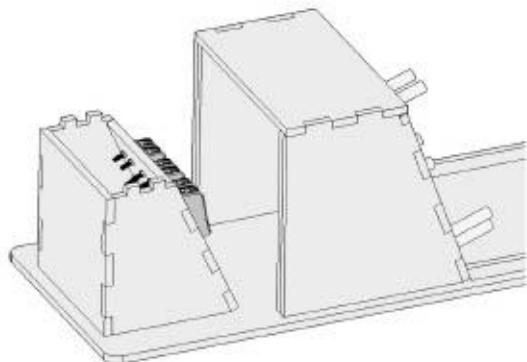
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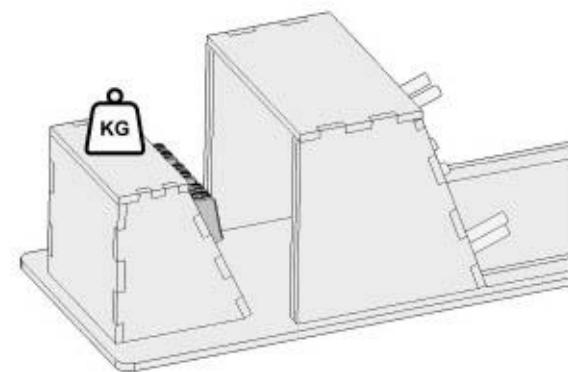
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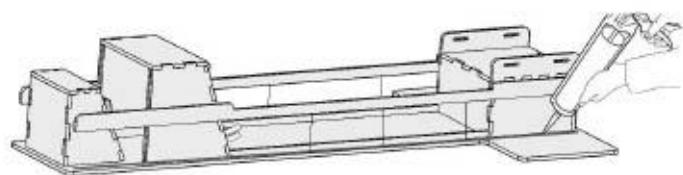
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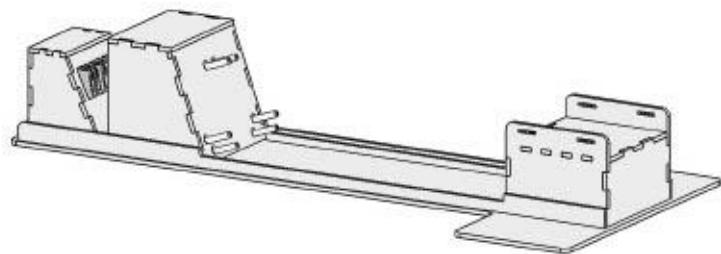
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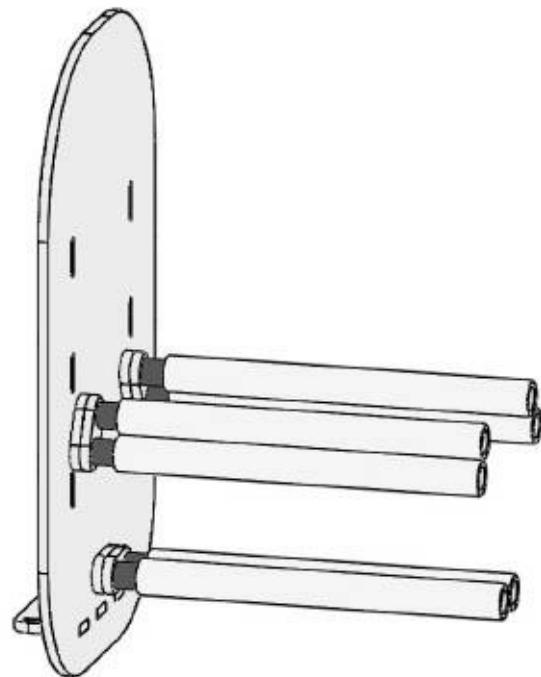


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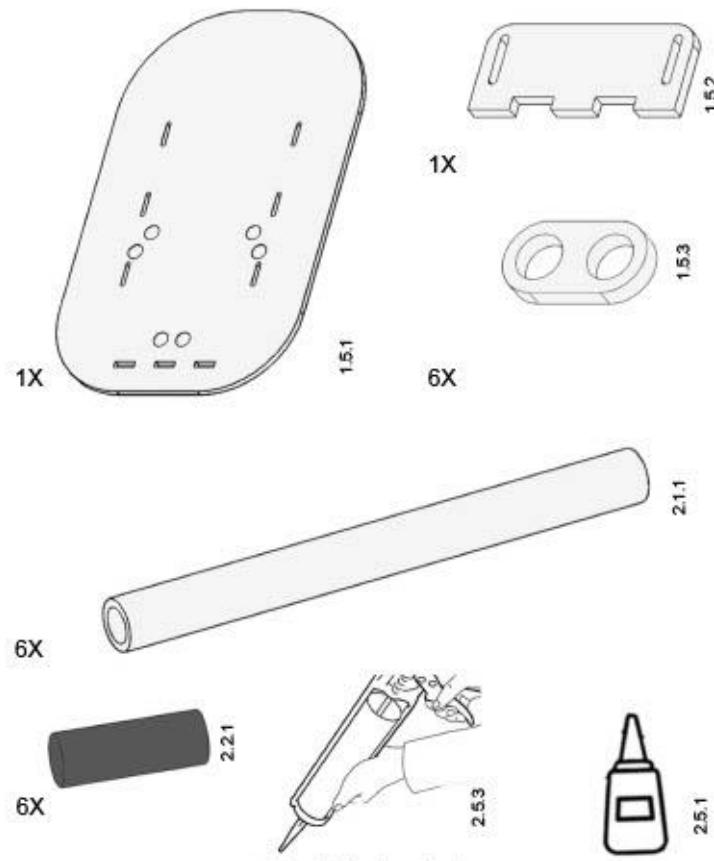


PART 2

Foot plate



Parts used

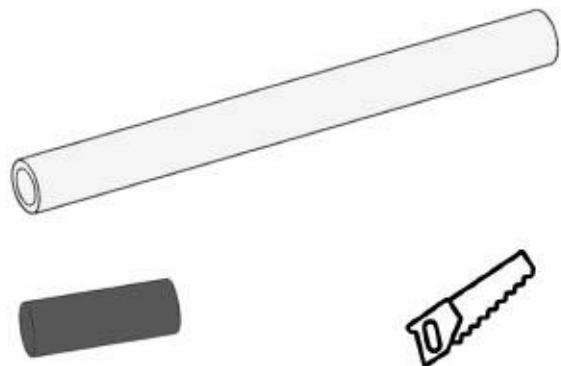


When this glue is used, primer
(2.5.2) must first be used

Preprocessing step

Only if not custom supplied by manufacturer

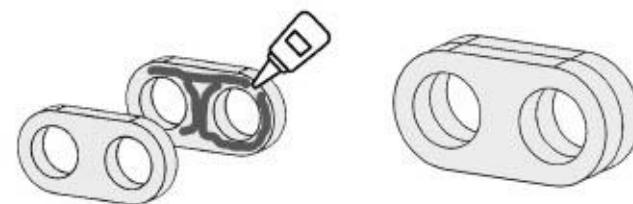
Needed



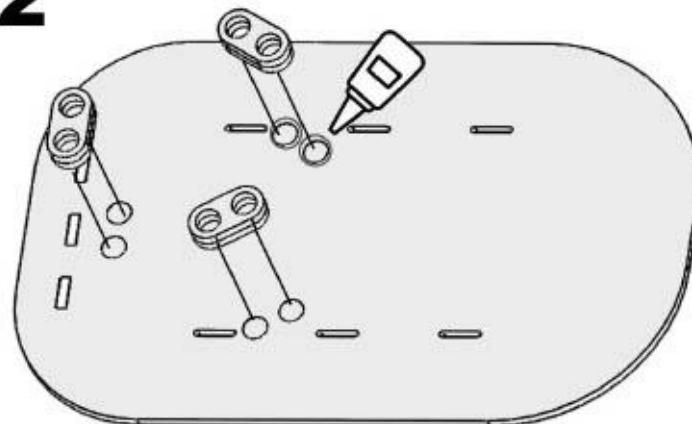
Step 1: Cutting the PMMA rod to size → $6 \times 220\text{ mm}$

Step 2: Cutting the Solid rubber to size → $6 \times 40\text{ mm}$

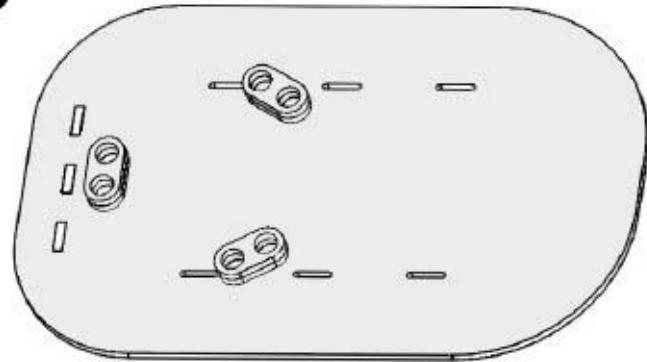
1



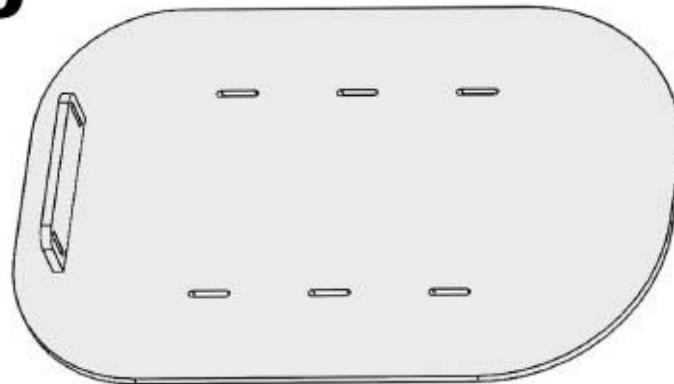
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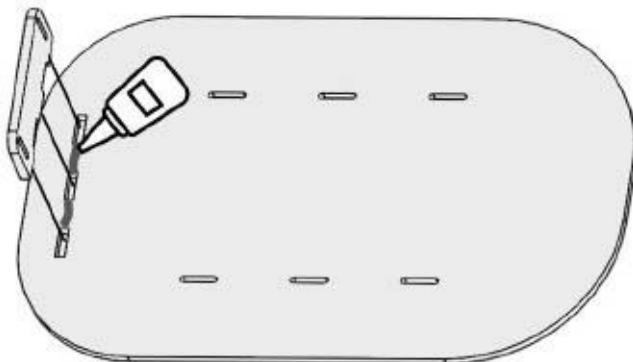
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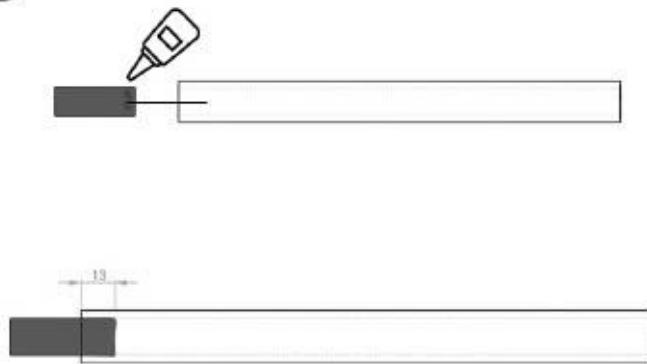
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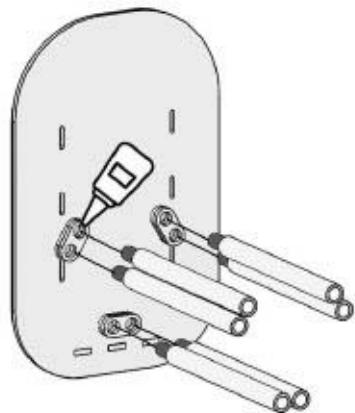
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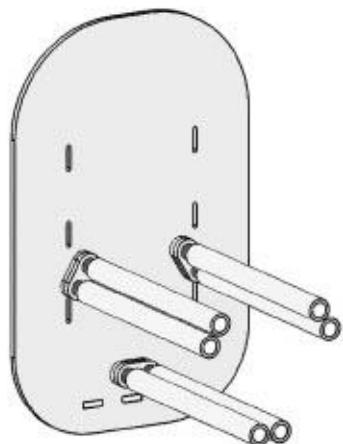
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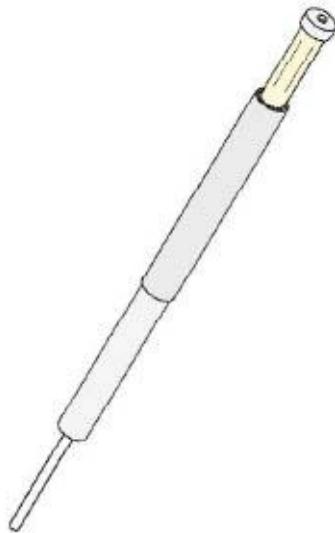


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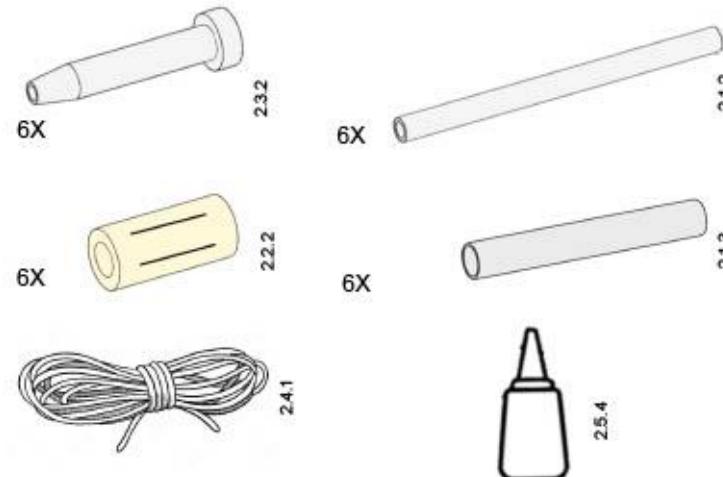


PART 3

Expanding rods

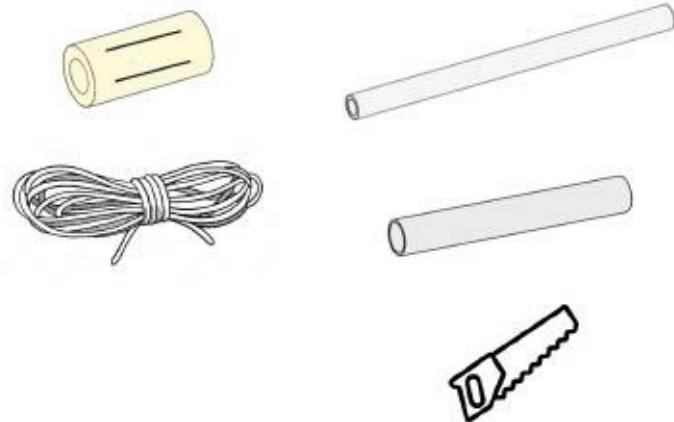


Parts used



Preprocessing step

Needed



Step 1: Cutting the PMMA inner rod to size → $6 \times 175 \text{ mm}$

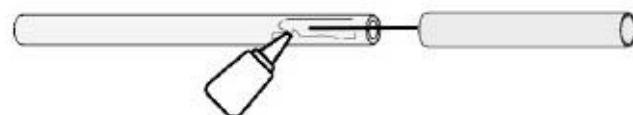
Step 2: Cutting the plastic rod to size → $6 \times 100 \text{ mm}$

Step 3: Cutting the ropes to size → $6 \times 1000 \text{ mm}$

Step 4: Cutting the silicone tube to size → $6 \times 40 \text{ mm}$

Step 4a: Cutting the silicone rods in 4 places, with the same distance between each other, and a length of 30 mm.

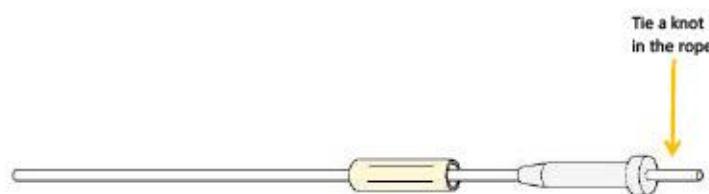
1



2



3



5



4

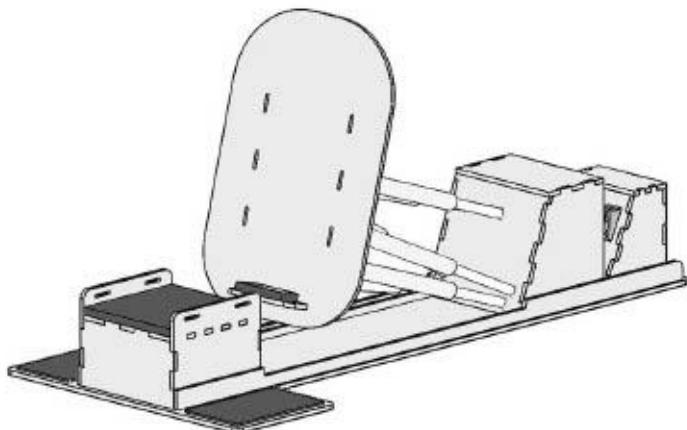


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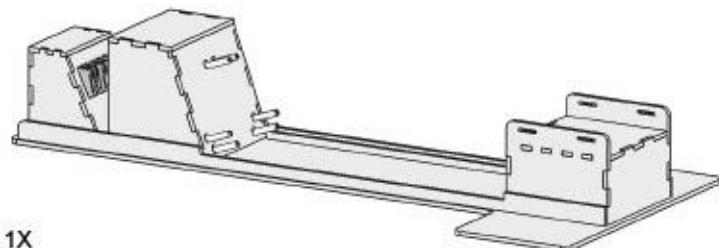


Part 4

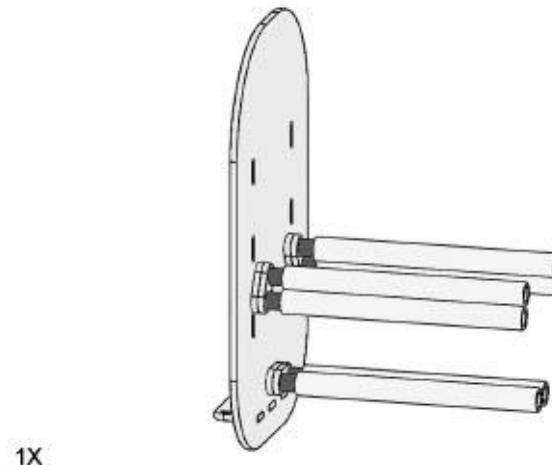
Assembling together



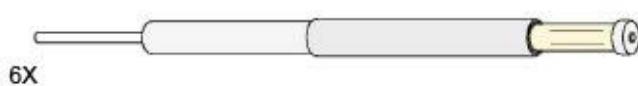
Assemblies used



1X



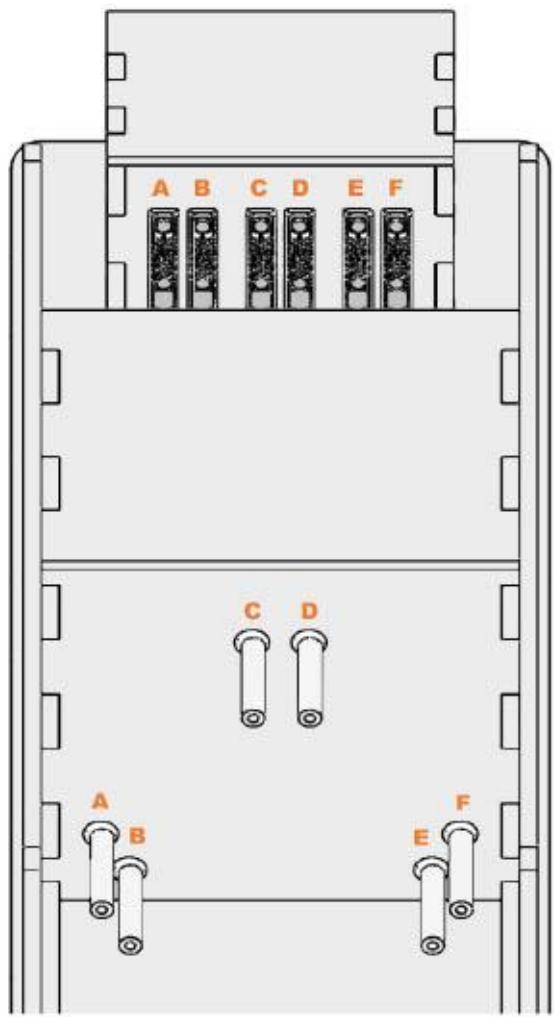
1X



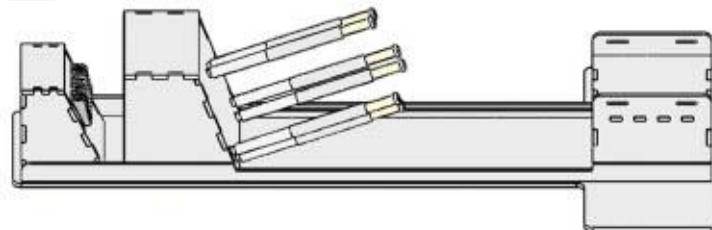
6X

The rope of the rods will have to be pulled through the ball-and-socket joint and then clamped to the clam cleats. It is indicated from which ball-and-socket joint to which clam cleat the rope should be pulled.

1



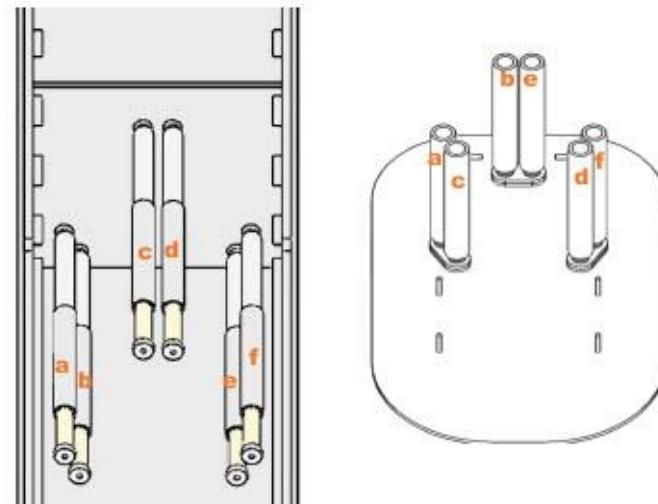
2



3

Step 1: Now the rods must be removed from the ball-and-socket joint again, but the rope must still remain in place through the ball-and-socket joint and the clam cleat.

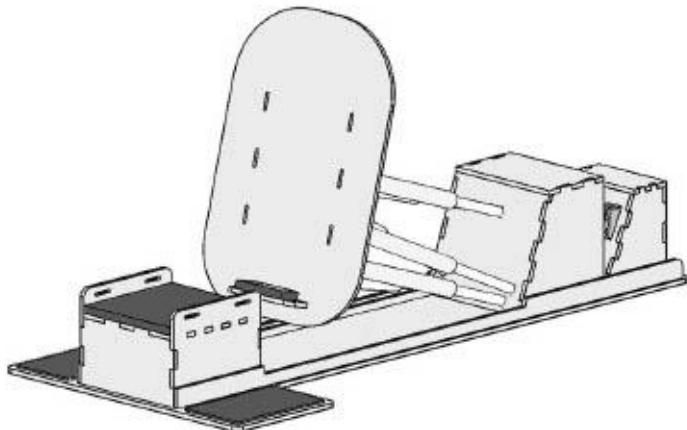
Step 2: The rods assembly will be placed in the outer rods of the foot plate. On the next page it is indicated which rods assembly should be placed with which outer rod.



4

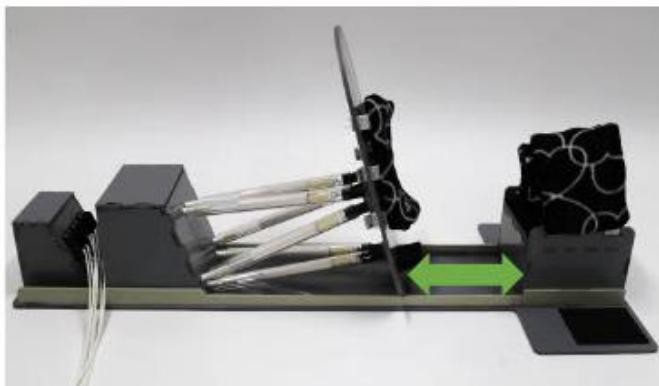
Step 1: When the rods are together, the end of the inner rods can be slid over the ball-and-socket joint.

Step 2: The rubbers can now be placed on the leg support, heel of the foot plate, and place on the ground plate where the foot should stand.

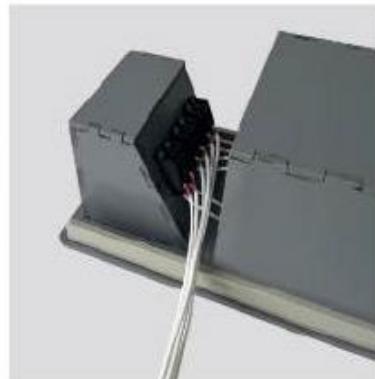


Appendix I – Manual for use

STAP 1 – Device in begin positie plaatsen



- Buizen volledig ingeschoven
- Touwen los van Cleats



STAP 2 – Voet van de patiënt bevestigen aan voetplaat



- Patiënt legt zelf been/ voet op positie.
- Eerst voet vastmaken aan de voetplaat, d.m.v. klittenband (nr. 1 daarna nr. 2)
- Daarna been vastmaken aan de steun, d.m.v. klittenband (nr. 3)

**⚠ De band moet strak om de patiënt heen zitten.
Indien niet strak genoeg; theedoek om voet/been binden en daarna opnieuw vastmaken d.m.v. klittenband**

STAP 3 – Positioneren van de voet

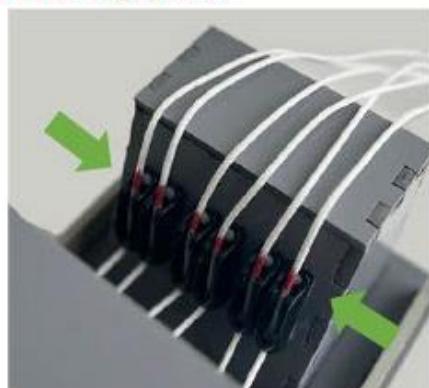
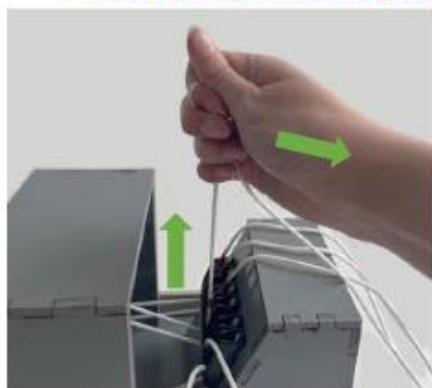
- De voetplaat bewegen naar een extreme positie

Z.O.Z.

STAP 4 – Fixeren van de voet

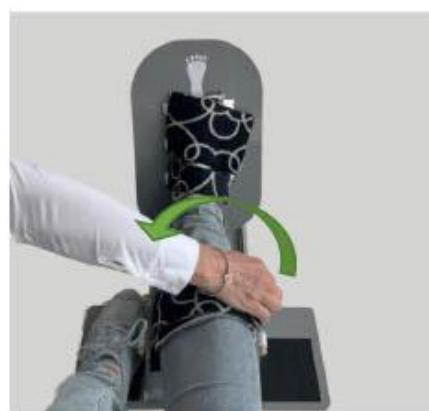
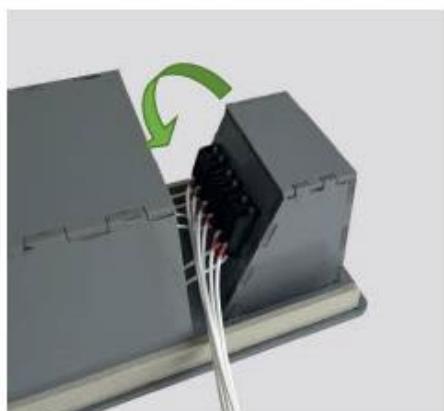
- Touw één voor één aantrekken tot je rode streep boven de zwarte Clamcleat ziet.

 **Houd hierbij ook de voetplaat vast in huidige positie**



STAP 5 – Losmaken fixatie + voet

- Eerst touwen losmaken, vervolgens klittenband losmaken



PROBLEMEN

- ❖ Rode streep van touw kan niet worden bereikt →
 - Fixatie plug in buis klemt tegen binnenste buis. Een paar keer tegen die buis aan tikken dan kan je het wel aantrekken
- ❖ Grijze polypropyleen plaat laat los → met Duct tape vastmaken
- ❖ ZWARTE rubber schiet los → Device niet meer gebruiken
 - Dienen weer opnieuw vast te worden gelijmd
- ❖ Bij andere problemen, die niet omschreven staan, het device niet meer gebruiken

Appendix J – Segmentation protocol 3D Slicer

In this protocol the segmentation of the ankle prosthesis is viewed. This segmentation is done using 3D Slicer. A step-by-step plan is presented.

Table of contents

- 1) Installing 3D Slicer
- 2) Load data
- 3) Rename data of the study
- 4) Crop the volume
- 5) Segmentation
- 6) Saving the data

For this protocol, the anonymized dataset with Study Date 20190115 and the series description “foot/ankle 1.0 Br64 2” was used.

1) Installing 3D Slicer

To download Slicer, use the following URL: <https://download.slicer.org/>
Use the “Stable Release” to avoid errors in the release. In this protocol, the 3D slicer Version 5.0.3. has been used.

2) Load data

Open 3D Slicer and use the Welcome panel, (shown left in **Figure J1**) to load your own data or download sample data to explore.

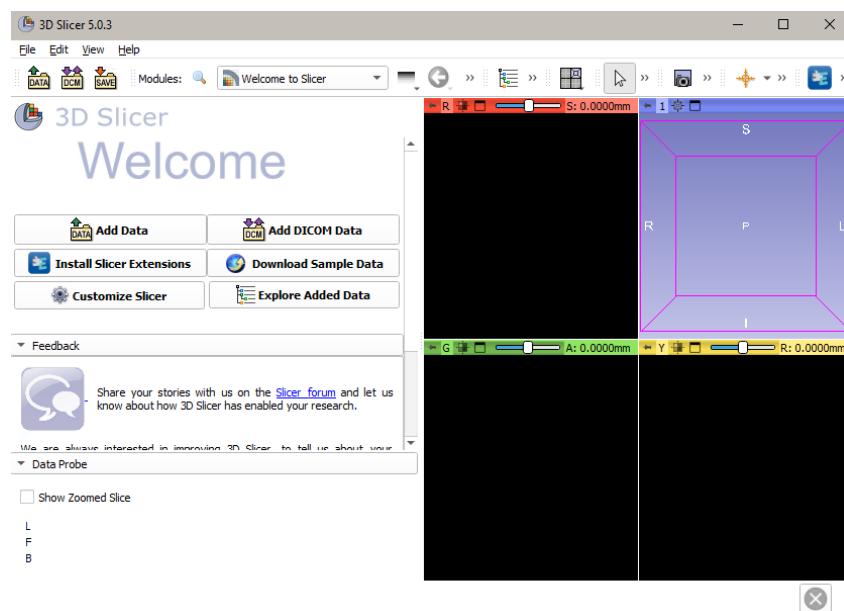


Figure J1. Welcome screen of 3D Slicer.

Step 1: Click on **DICOM Add DICOM Data**, thereafter click on **DICOM Import DICOM files**. Here, you select the DICOM data you want to import from a specified directory.

Now the DICOM data is placed in the DICOM database.

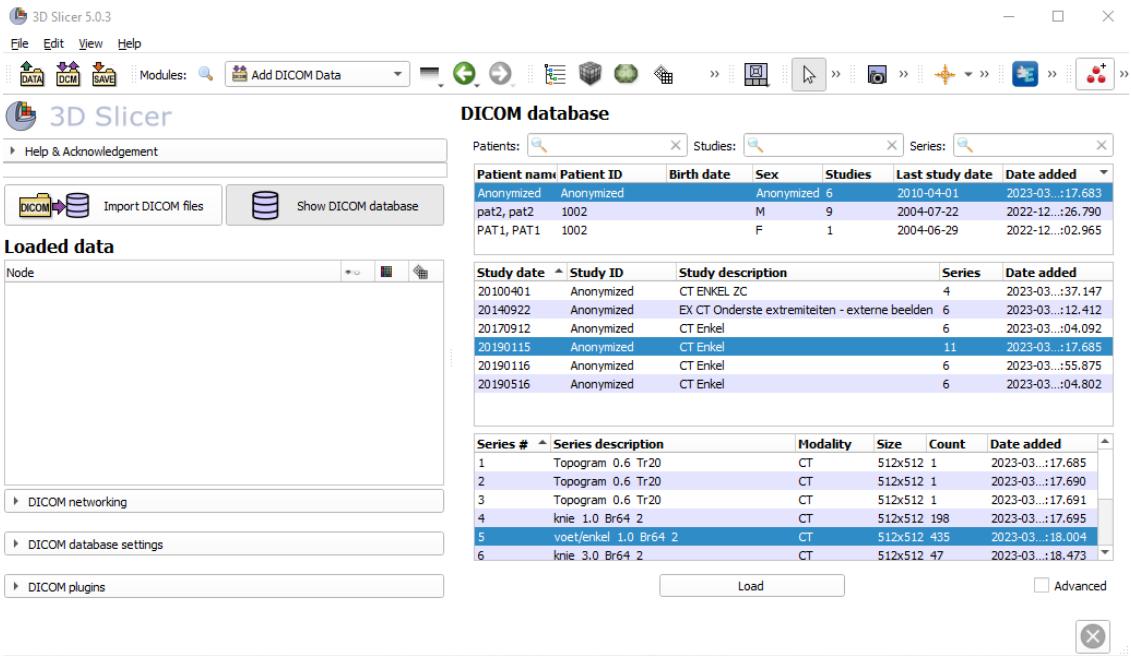


Figure J2. DICOM data added to the database of the 3D slicer application.

Step 2: In the module “Add DICOM Data” (as shown in Figure J2), click in the right panel on the patient. Thereafter, you select the *Study ID* you want to import in 3D Slicer and you select the right series. Subsequently click the ‘load’ button.

Note: When several CT scans have been made in succession, there are several Study IDs, otherwise only 1 study ID is shown. Moreover, there are not always several series in a file.

When clicked on load, another layout appears, as can be seen in Figure J3.

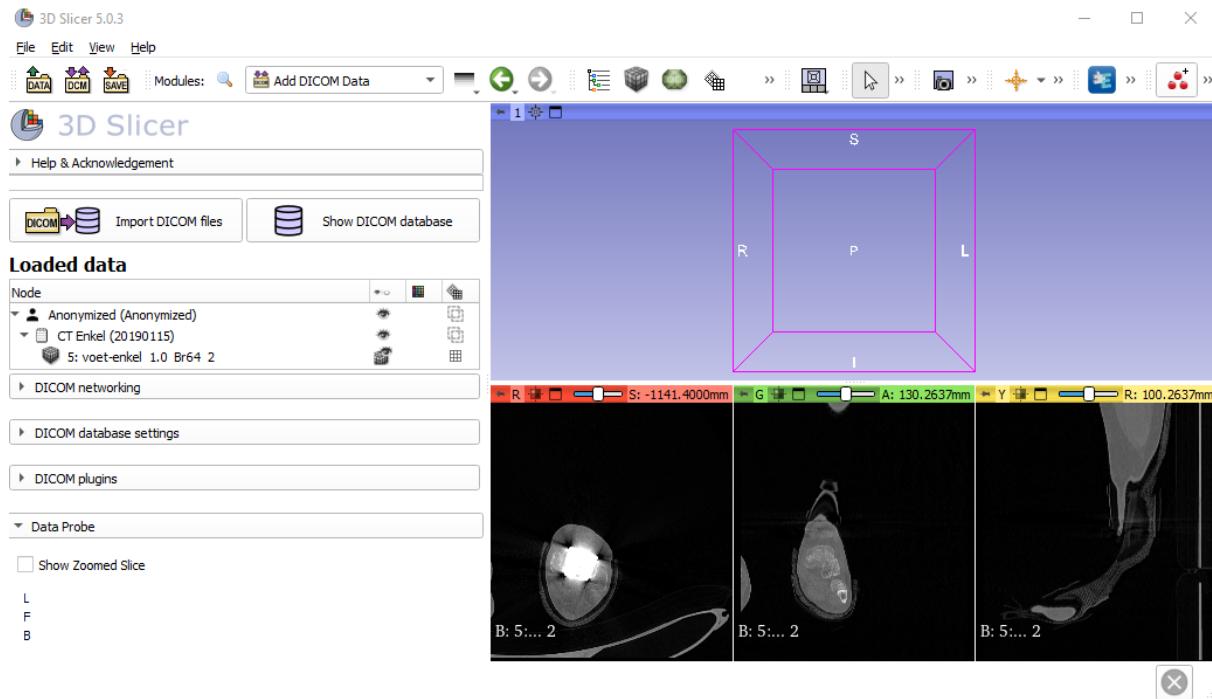


Figure J3. Screenshot of the Add DICOM data module after loading the DICOM data.

3) Rename data of the study

Rename the name of the study/data to get a structured data hierarchy.

Step 1: In the toolbar, at modules, click on the down-oriented arrow

Click on the module  Data (Figure J4)

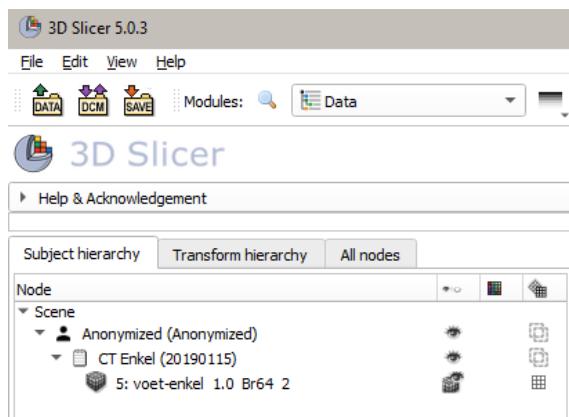


Figure J4. The left panel shows the Data module. Illogical names are stated in the subject hierarchy.

Step 2: In the left panel, under the tab *Subject hierarchy* (as seen in Figure J4) the nodes of the loaded study are stated. Right-click at a certain node to rename the node into a clear description. The “CT Enkel (20190115)” will be renamed to “CT normal position”.

4) Crop the volume

When unwanted regions are visible on the CT scan, the region of interest can be adjusted using the Crop Volume module. In addition, when the region of interest becomes smaller, this promotes the speed of creating the segments in the next step. Since only the prosthesis is of interest, the image can be cropped so that it is clearly visible and there is not much bone around it.

Step 1: In the toolbar, at modules, click on the magnifier and search for “Crop Volume”.

Switch to that module.

Step 2: In the left panel, scroll down and click on “Fix” next to **select or create a new ROI input** (as shown in Figure J5)

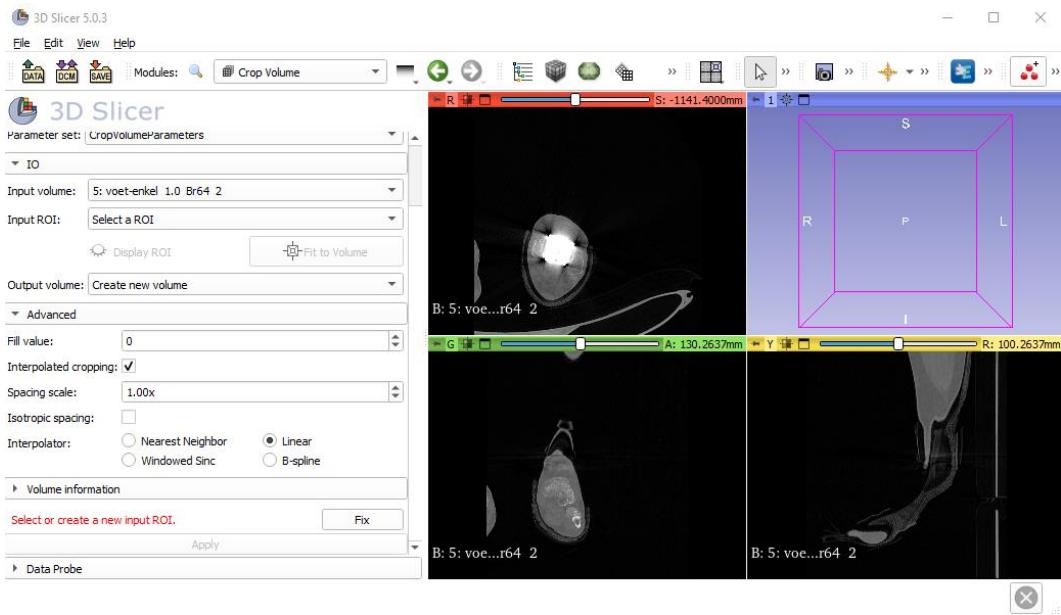


Figure J5. The module Crop Volume is shown. In the left panel, there is already been scrolled down.

Now planes have been placed on the different views of the CT scans.

Step 3: The planes can be made smaller by clicking on the colored dots and moving this area (Figure J6).

Note: To see whether you now have the correct range of interest, when you hover over the CT images with the mouse, you can scroll to see whether all images are in this defined ROI.

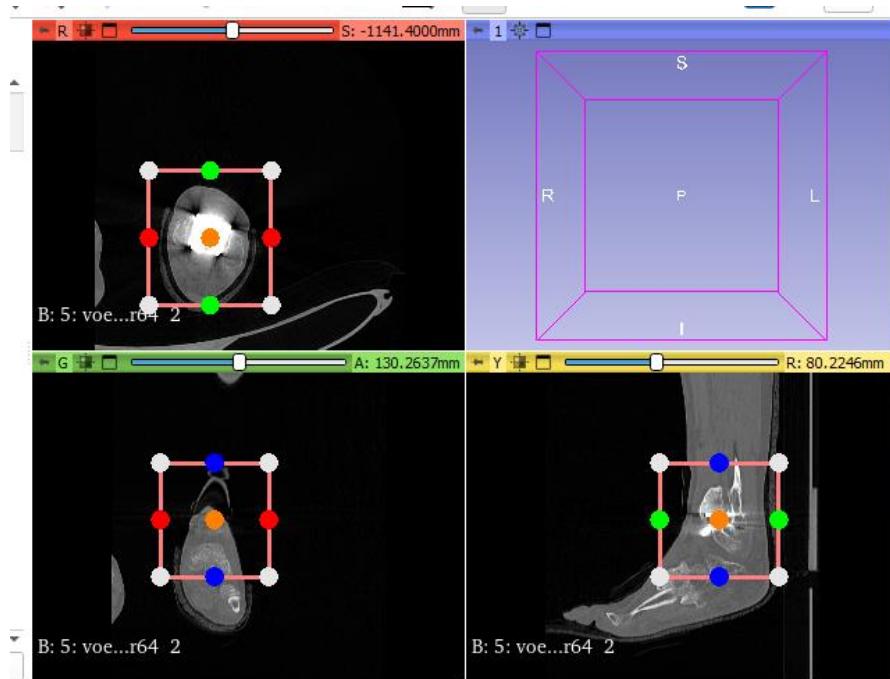


Figure J6. The range of interest corners should be placed just like this.

Step 4: When you are satisfied with the ROI, you can click on "apply" in the left panel. After that it is only important to have the ROI box no longer visible, this is done by clicking on the eye at "display ROI" in the left panel. The cropped images will now appear in the image.

5) Segmentation

Segmentation of images is a procedure for presenting regions in the image, typically corresponding to anatomical structures. In this case the bones of the foot. The Segment Editor module in 3D Slicer offers a wide range of segmentation methods.

Step 1: In the toolbar, at modules, click on the magnifier and search for “Segment Editor”.
Switch to that module.

Step 2: In the left panel click on  four times. Since we want to have four different segments in the foot bones.

Step 3: Rename the segments by double-clicking on the “Segment_x” name. Rename them to: *Tibial Component*, *Talar Component*, and *Other* (Figure J7).

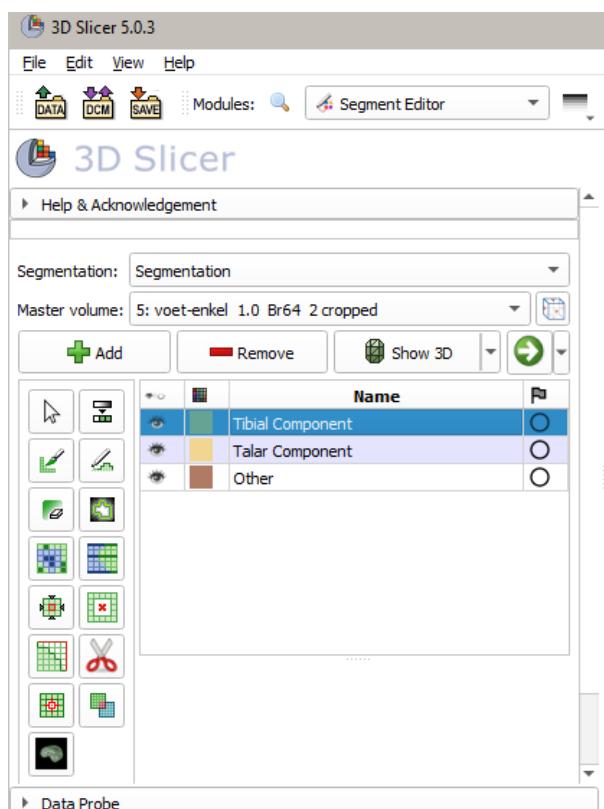


Figure J7. The left panel of the Segment editor module.

Step 4: Click on the threshold icon , which is placed in the left panel.

The threshold easily ensures that almost only the prosthesis itself can be tinted. In this case only with the color green. This threshold is then used to differentiate between the different components of the prosthesis in this range of color. The other color is needed to get rid of what is still colored of the bone, what you don't want to see, from your segmentation.

Step 5: Scroll down in the left panel to fill in the threshold range.

- The minimum needs to be around 1350.00, and the maximum is the overall maximum.

Step 6: Thereafter click on “use for masking”

After this, you have arrived at the screen where you will color the prosthesis. For this, you color at least 2 different CT images, and then you must have colored 2 different views.

Step 7: Click on the segment in the left panel, then color in the CT view the selected segments. Color at least 2 different views. (just as in Figure J8)

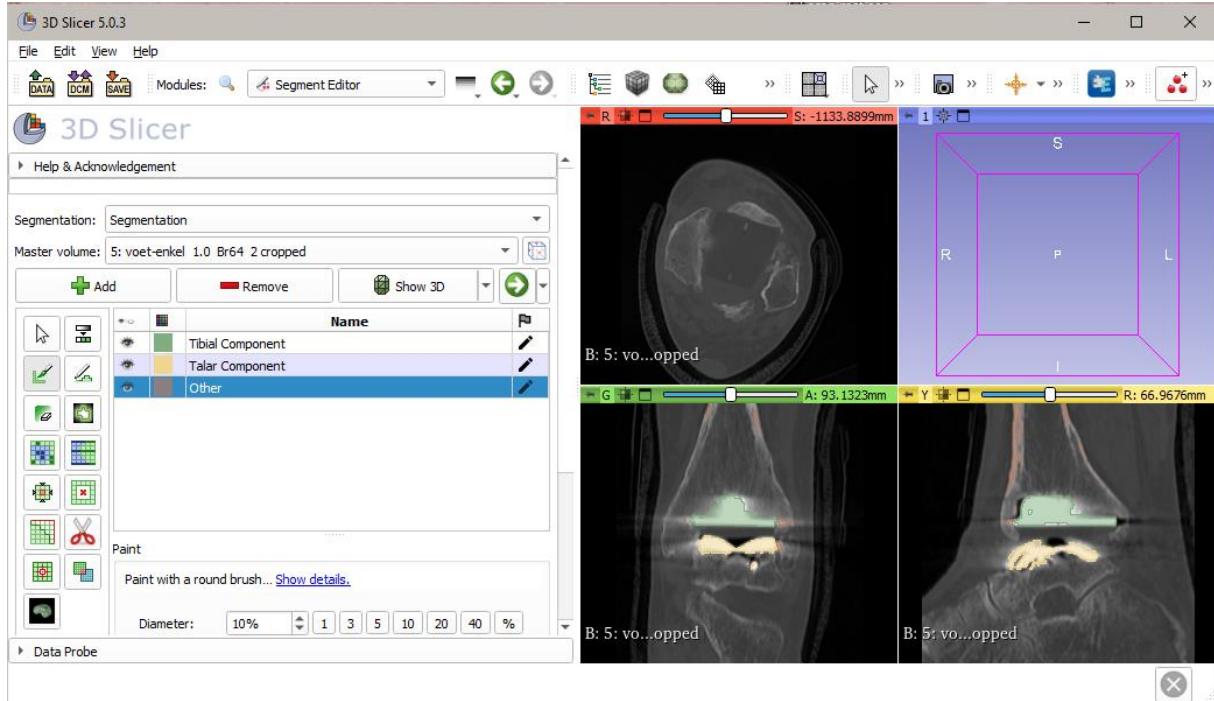


Figure J8. The coloring of two views on the CT scans.

Note: The brush can be adjusted in size to make the painting more easy.

Step 8: Thereafter click on the icon “Grow from seeds” .

Step 9: In this left panel, below the segments, click on Initialize.

Note: It can take a long time to finish loading, so be patient.

Step 10: Click on show 3D, and thereafter on the purple screen right corner above click on center view . Now you can see the segmented bones.

In the purple screen you can see to what extent the segmentation has been successful (Figure J9).

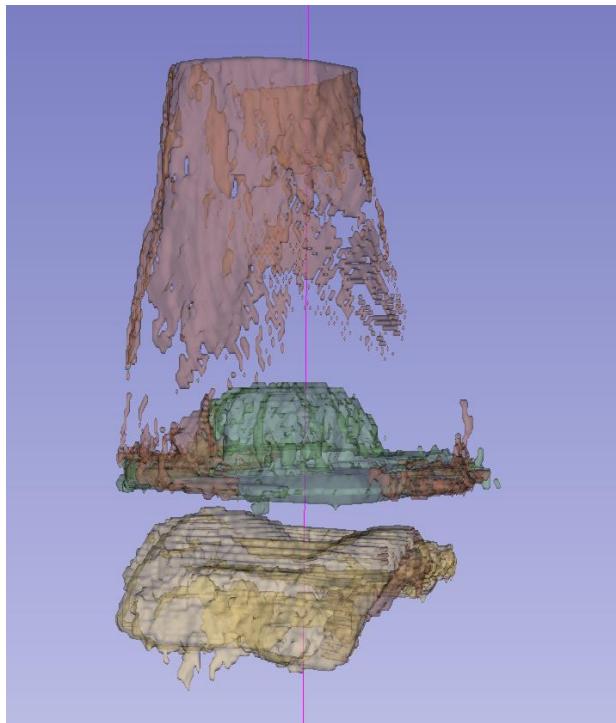


Figure J9. Segmentation result obtained with the Grow from seeds algorithm.

Note: The orientation of the 3D image can be determined with click and drag, and you can also zoom in or out with scrolling.

Note: In the grow from seeds screen, the display option allows the bar to be moved in order to achieve a sharper image in the 3D image.

Now we have to adjust the temporary segmentation by going through all of the slices and painting the bone to the right segmentation.

Step 11: When some aspects are not properly segmented (if the wrong color is on a certain piece of bone), this can be adjusted with the brush under the “Paint” icon  in the CT scan on the correct image. When you color something, 3D Slicer will have to load in order to optimize the grow from seeds algorithm.

Warning: If you accidentally color in with the wrong color, you will ruin the algorithm. This is not easy to do. The easiest way is to delete all segments and start segmenting again.

Step 12: If you are satisfied with the segmentation, you can click on "Apply" under grow from seeds, then the segments are definitively saved.

In the data module, you can now see the segments under the subject hierarchy (Figure J10).

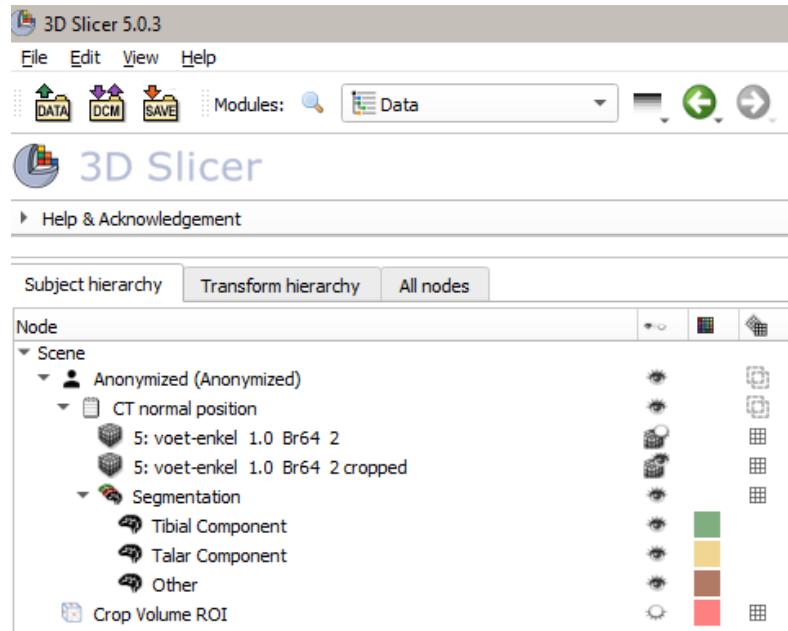


Figure J10. Segmentation is viewed in the data module.

Now to fill in the contours of the bones, the segmentation has to be adjusted by manually going through all of the slices and adding or removing bone from the sacrum or ilium with paint and erase.

Step 13: In the Segment Editor module, unselect the editable intensity range (Figure J11).

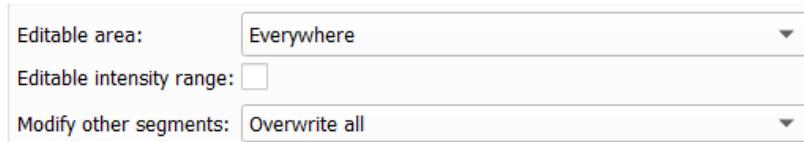


Figure J11. Uncheck the editable intensity range.

Step 14: Select the brush or erase button to manually add and remove the prosthesis of the Tibial and Talar Component , .

Note: It takes a long time to go through all the slices.

If you are satisfied with the segmentations, you might get a result as can be seen in Figure J12.

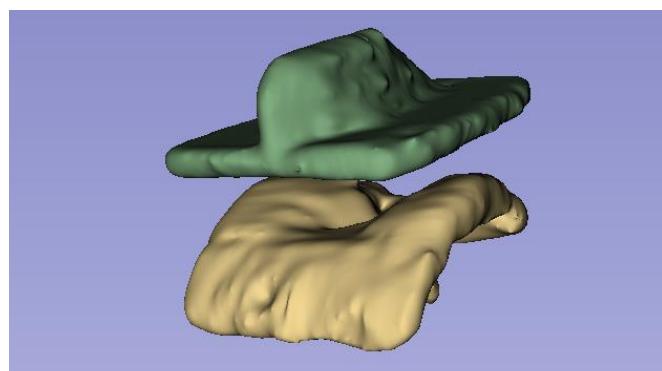


Figure J12. Final segmentation, only the 3D view is showed here.

6) Saving the data

You can choose to save the entire data set. To continue with the local coordinate system or to register, only segmentation is sufficient to save.

To save the entire dataset

Step 1: Save the data by clicking on the Save data widget  . Click thereafter on the gift box and rename the file name. put it under a logical directory and save the data.

To save only the segmented bones

Step 1: Save the data by right-clicking on segmentation in the data module, then clicking on export to file...

Ideally, save the segmented bones as models.

Step 1: Save the data by right-clicking on segmentation in the data module, then clicking on Export visible segments to models. Thereafter right click on the “segmentation-models” and click on export to file...

Appendix K – Local coordinate system protocol 3D Slicer

In this protocol, the local coordinate system will be placed in the tibial component of the infinity prosthesis. A step-by-step plan is presented

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- 1) Import data
- 2) Surface selection from three views
 - 2.1) Surface selection bottom
 - 2.2) Surface selection front
 - 2.3) Surface selection right
- 3) Determine the transformation matrix
- 4) Z-transform
- 5) Save the transformation

1) Import data

Make sure the models of the segmentations of the positions are stored in the ‘Segmentation-models’ folder. In this protocol only the model of the Tibial component of the null-position is needed.

Step 1: Open the Slicer 5.0.3. application.

Step 2: Click on  **Add Data** in the main toolbar under ‘File’. An pop-up screen named “Add data into the scene” appears.
Step 3: In the pop-up screen, Click on ‘Choose file(s) to Add’. In the, again, pop-up screen choose the STL file of the Tibial Component of the null-position, and open this file. Thereafter choose under ‘Description’ the option ‘Model’. Click ‘Ok’. (Figure K1)

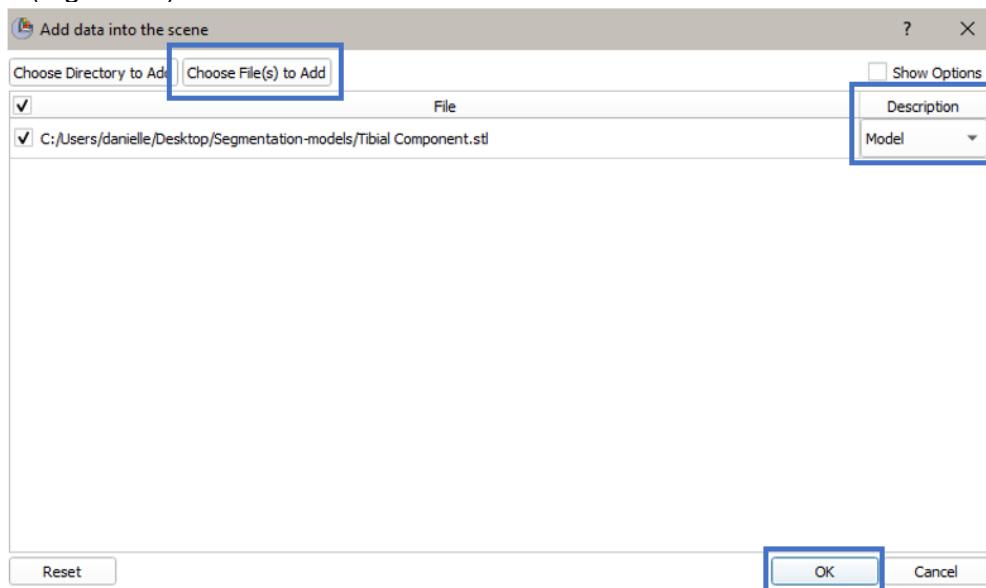


Figure K1. Load in the STL file of the model of the null position.

The model of the Tibial Component is now loaded.

Step 4: Go to  Welcome to Slicer, click on the small down-sided arrow to open the menu and click on 'Data'. In the 'Subject hierarchy' window, the model should be seen (Figure K2).

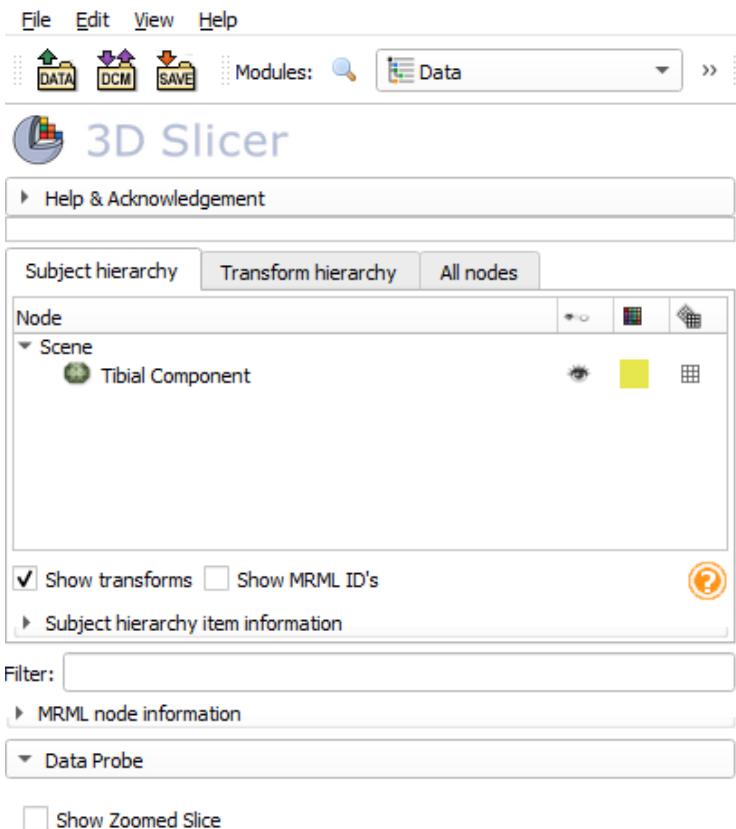


Figure K2. Model of the tibial component is viewed.

Step 5: The model is already present in the 3D view, only probably it is not visible yet. We are only interested in the 3D view only. To change this, go to the main toolbar.

Select 'view', under view select 'Layout', in here click on  3D only.

Step 6: In the 3D view, click on  to center the view of the model.

Note: The orientation of the model can be changed by clicking and dragging using the left and middle button of the mouse. Only when your mouse is in the blue screen.

2) Surface selection from three views

2.1) Surface selection bottom

Surface selection of the downside of the Tibial Component

- Step 1. Go to  Welcome to Slicer . Click on the small arrow to open up the menu and select 'Markups'.
- Step 2. Rotate the orientation of the Tibial component so that you can view the downside of the model. Select  Closed Curve under 'Create Markups'. Place points at the edges of the Tibial component in the 3D view by clicking on the left button of the mouse. End the selection by clicking on the right button of the mouse. (just like as in Figure K3)

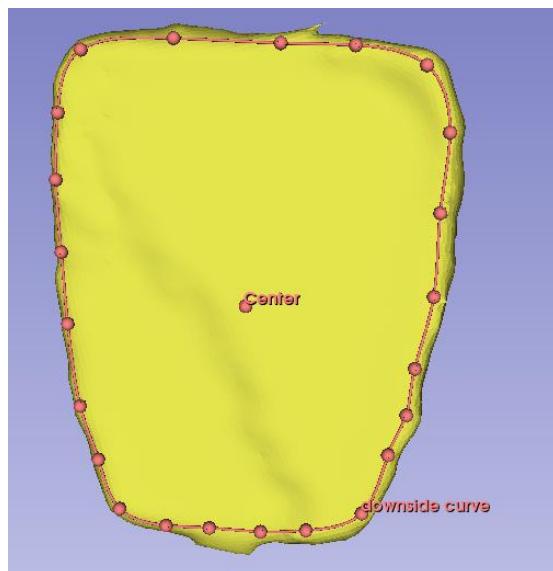


Figure K3. Select the bottom surface of the tibial component. Also the center is viewed which is composed in step 6.

- Step 3. Right-click on the curve  and select 'Rename'. Rename the curve to '**downside curve**'. Select 'Ok'.

Note: It is important that the curve has exactly this name for the next steps.

- Step 4. Click on the **python interactor**  , that can be found in the main toolbar (or as shortcut "Crtl + 3"). Now the python interactor can be seen under the 3D view (Figure K4).

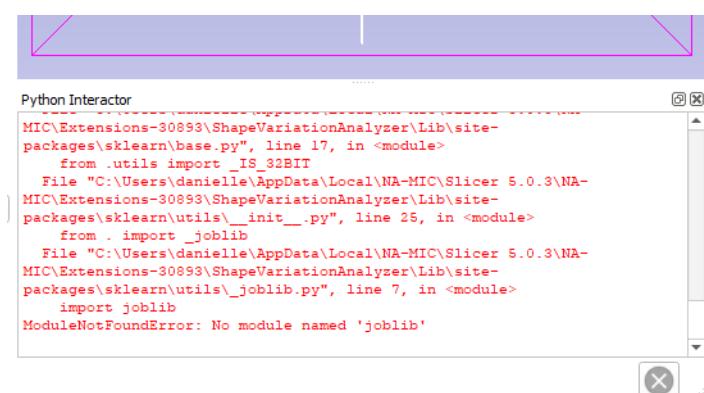


Figure K4. Python interactor, it does not necessarily have to give all errors as shown above.

Step 5. Click on the text inside the python interactor, thereafter “Crtl + A” . then right click on the selected text and click on delete.

Step 6. Copy the text below in the frame as a whole, and paste it into the python interactor. Thereafter click the enter key on your keyboard

```
# Script for creating markups point center

import numpy as np

A = np.average(array('downside curve'), axis=0)

# Place a markups point on the middle point of the downside curve.
pointListNode =
slicer.mrmlScene.AddNewNodeByClass('vtkMRMLMarkupsFiducialNode')
pointListNode.CreateDefaultDisplayNodes()
pointListNode.AddFiducialFromArray((A[0], A[1], A[2]), 'Center')
```

If all goes well, an extra markup has now been placed in the middle of this downside curve.

Step 7. Go to the **Data** section, by clicking on the downside arrow next to markups. A new markups node has now been placed here, it is called “MarkupsFiducial”. It should be renamed to “Center”.

Step 8. The downside curve doesn't have to be visible anymore, by clicking on the eye next to the “downside curve” node.

2.2) Surface selection front

Surface selection of the downside of the Tibial Component

Step 1. Go to the **Markups** section, by clicking on the downside arrow next to Data.

Step 2. Rotate the orientation of the Tibial component so that you can view the front of the

model. Select  under ‘Create Markups’. Place points at the edges of the Tibial component in the 3D view by clicking on the left button of the mouse (Figure K5). End the selection by clicking on the right button of the mouse.

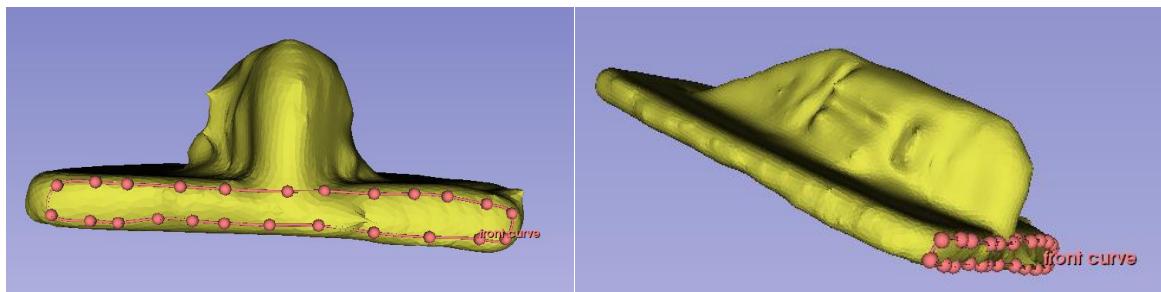


Figure K5. Select the front part of the tibial component.

Step 3. Right-click on the curve  and select ‘Rename’. Rename the curve to ‘front curve’. Select ‘Ok’.

Step 4. Click on the text inside the **python interactor**, thereafter “Crtl + A” . then right click on the selected text and click on delete.

Step 5. Copy the text below in the frame as a whole, and paste it into the python interactor. Thereafter click the enter key on your keyboard

```

# Script for creating markups point front

import numpy as np

B = np.average(array('front curve'), axis=0)

# Place a markups point on the middle point of the downside curve.
pointListNode =
slicer.mrmlScene.AddNewNodeByClass('vtkMRMLMarkupsFiducialNode')
pointListNode.CreateDefaultDisplayNodes()
# use the Z coordinate of the center to get the right axes
pointListNode.AddFiducialFromArray((B[0], B[1], A[2]), 'Front')

```

If all goes well, an extra markup has now been placed in the middle down of this front curve.

Step 6. Go to the Data section, by clicking on the downside arrow next to markups. A new markups node has now been placed here, it is called “MarkupsFiducial”. It should be renamed to “Front”.

Step 7. The front curve doesn't have to be visible anymore, by clicking on the eye next to the “front curve” node.

2.3) Surface selection right

Surface selection of the downside of the Tibial Component

Step 1. Go to the **Markups** section, by clicking on the downside arrow next to Data.

Step 2. Rotate the orientation of the Tibial component so that you can view the right side

of the model. Select  under ‘Create Markups’. Place points at the edges of the Tibial component in the 3D view by clicking on the left button of the mouse (Figure K6). End the selection by clicking on the right button of the mouse.

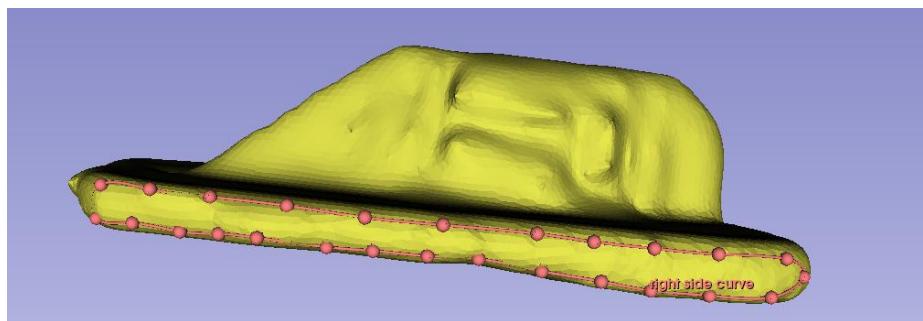


Figure K6. Select the right side of the tibial component.

Step 3. Right-click on the curve  and select ‘Rename’. Rename the curve to ‘right side curve’. Select ‘Ok’.

Step 4. Click on the text inside the **python interactor**, thereafter “Crtl + A” . then right click on the selected text and click on delete.

Step 5. Copy the text below in the frame as a whole, and paste it into the python interactor. Thereafter click the enter key on your keyboard

```

# Script for creating markups point right

import numpy as np

C = np.average(array('right side curve'), axis=0)

# Place a markups point on the middle point of the downside curve.
pointListNode =
slicer.mrmlScene.AddNewNodeByClass('vtkMRMLMarkupsFiducialNode')
pointListNode.CreateDefaultDisplayNodes()
# use the Z coordinate of the center to get the right axes
pointListNode.AddFiducialFromArray((C[0], C[1], A[2]), 'Right')

```

If all goes well, an extra markup has now been placed in the middle down of this right side curve.

Step 6. Go to the **Data** section, by clicking on the downside arrow next to markups. A new markups node has now been placed here, it is called “MarkupsFiducial”. It should be renamed to “Right”.

Step 7. The right side curve doesn’t have to be visible anymore, by clicking on the eye next to the “right side curve” node.

3) Determine the transformation matrix for the new coordinate system

Determine the transformation matrix to transform the sacrum to the new coordinate system with the created MarkupsFiducials using the script in the frame below.

Step 1. Click on the text inside the **python interactor**, thereafter “Ctrl + A” . then right click on the selected text and click on delete.

Step 2. Copy the text below in the frame as a whole, and paste it into the python interactor. Thereafter click the enter key on your keyboard

Note: Assign the same names to the MarkupsFiducials (Center, Front and Right) stated above otherwise the script will not run. If you want to use different names for the MarkupsFiducials you can change the names of the MarkupsFiducials in the script.

```
#### This script determines the transformation matrix of the new defined
coordinate system.####

#Get the nodes of the three input points (positive x-axis is from point1 to
point2, positive z-axis is from point1 to point3)
pointListNode1 = getNode("Center") # Fill in the markups name of the Center
pointListNode2 = getNode("Right") # Fill in the markups name of the Xdirection
pointListNode3 = getNode("Front") # Fill in the markups name of the Ydirection

#Get the arrays of the nodes
Point1 = slicer.util.arrayFromMarkupsControlPoints(pointListNode1)
Point2= slicer.util.arrayFromMarkupsControlPoints(pointListNode2)
Point3 = slicer.util.arrayFromMarkupsControlPoints(pointListNode3)

#Save the points in a list
pointListNode = slicer.mrmlScene.AddNewNodeByClass('vtkMRMLMarkupsFiducialNode')
pointListNode.CreateDefaultDisplayNodes()
pointListNode.AddFiducialFromArray((Point1[0,0], Point1[0,1], Point1[0,2]),
'Point1')
pointListNode.AddFiducialFromArray((Point2[0,0], Point2[0,1], Point2[0,2]),
'Point2')
pointListNode.AddFiducialFromArray((Point3[0,0], Point3[0,1], Point3[0,2]),
'Point3')

#Make a plane from the fiducial point list
def makePlaneMarkupFromFiducial(FNode, planeName):
    """Create MarkupsPlane using first three control points of the input fiducial
node.
    """
    if FNode.GetNumberOfControlPoints()<3:
        logging.warning('Not enough control points to create plane markup!')
        return
    planeNode = slicer.mrmlScene.AddNewNodeByClass('vtkMRMLMarkupsPlaneNode',
planeName)
    planeNode.SetPlaneType(planeNode.PlaneType3Points)
    for cpIdx in range(3):
        pos = vtk.vtkVector3d()
        FNode.GetNthControlPointPositionWorld(cpIdx, pos)
        planeNode.AddControlPointWorld(pos)
    return planeNode

planeNodeForBlock1 = makePlaneMarkupFromFiducial(pointListNode, 'F11')

#Change plane to coordinatesystem
planeToWorld = vtk.vtkMatrix4x4()
getNode('F11').GetObjectToWorldMatrix(planeToWorld)
print(planeToWorld)
```

Step 3. If the code has run properly one markups pops up under 'Subject hierarchy' and a transformation matrix is visualized in the python interactor (Figure K7).

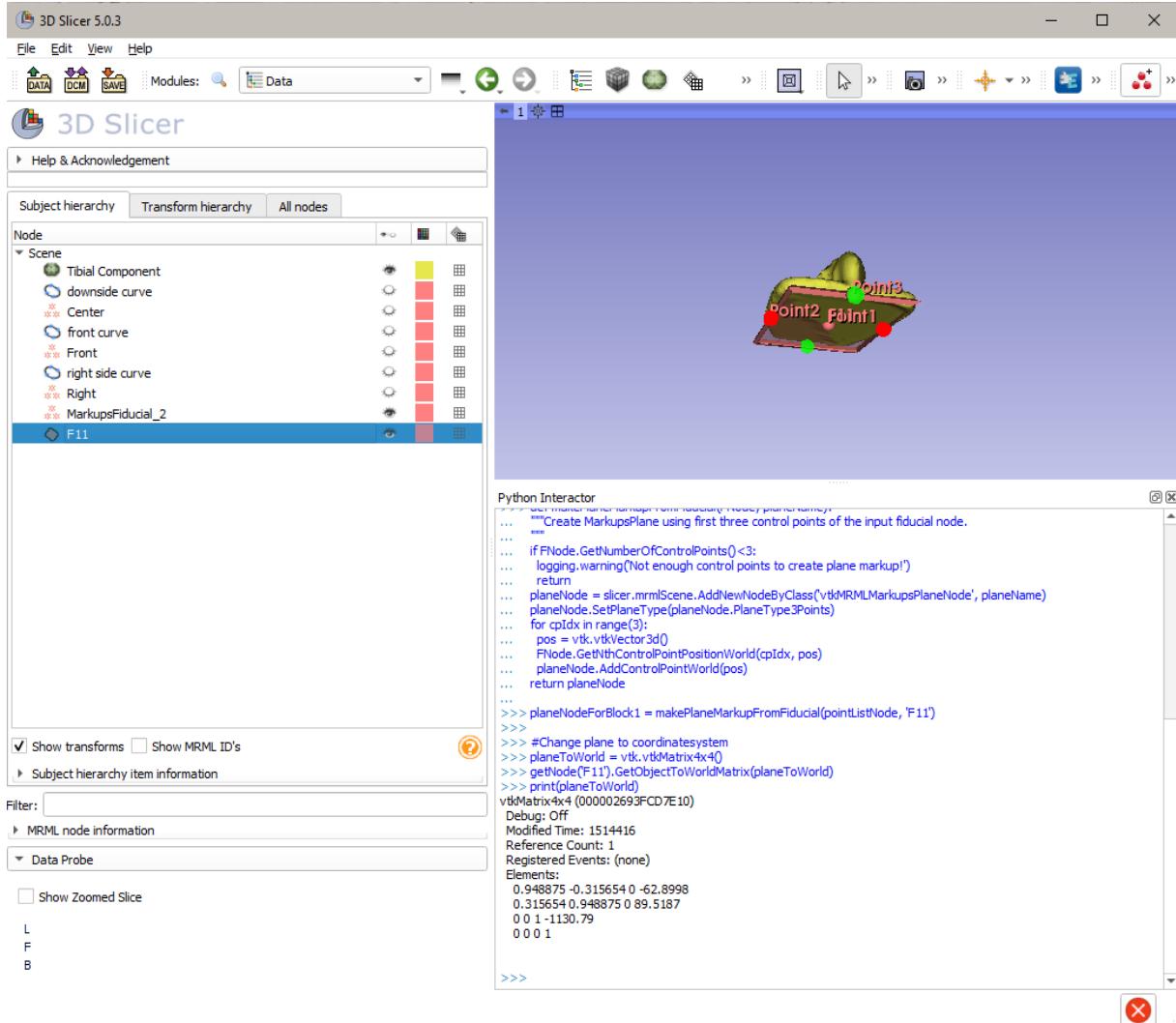


Figure K7. Run the script to get the transform of the new coordinate system.

Step 4. Copy the resulting transformation matrix from the python interactor.

Step 5. Go to the **Transforms** section, by clicking on the downside arrow next to Data.

Step 6. Select under 'Active transform': 'Create new LinearTransform as...'. Name the transform as 'New coordinatesystem1'

Step 7. Paste the copied transformation matrix from the python interactor in the 'Transform matrix'. Select the left corner and press **Ctrl + v**

Step 8. Scroll down a bit in the 'Transform matrix' window. Select the 'Invert' button

Invert

, a minus will appear behind the name of the transformation matrix (Figure K8)

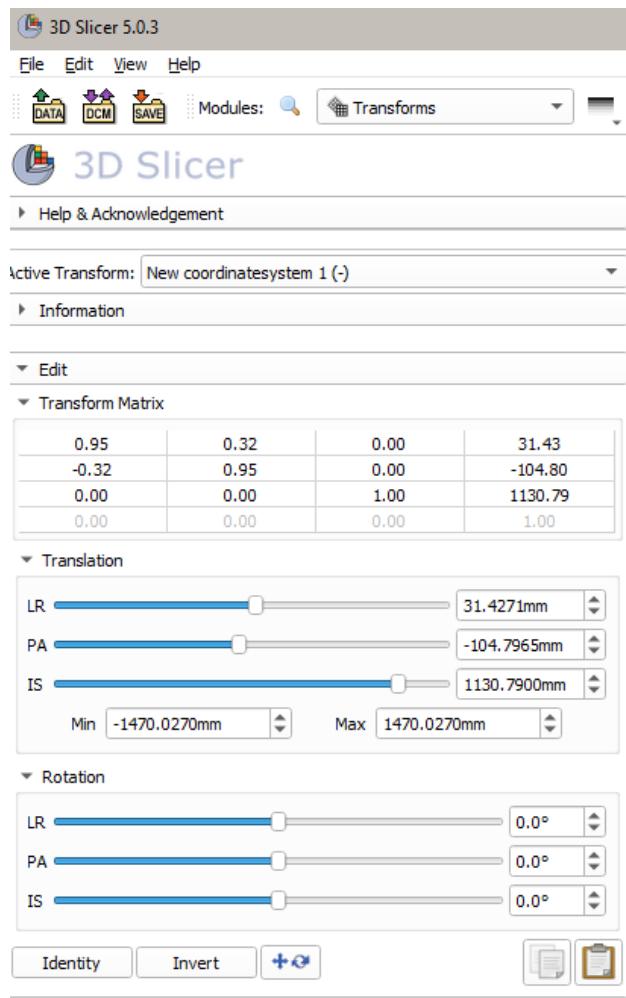


Figure K8. The inverted transformation matrix. Inverted since the added (-).

4) Z-transform

To set the axes correctly, another transformation around the z-axis has to be done. A rotation of -90 degrees must be done.

- Step 1. Create a new linear transform as “Z-transform”
- Step 2. The rotation matrix must be filled in like below, as can also be seen in Figure K9.

$$\begin{matrix} 0 & 1 & 0 & 0 \\ -1 & 0 & 0 & 0 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{matrix}$$

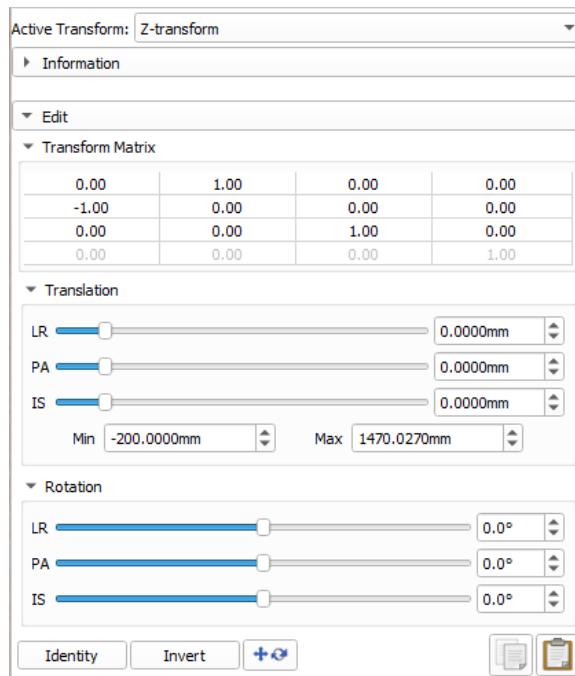


Figure K9. The Z-transform.

- Step 1. Go to the **data** section, by clicking on the downside arrow next to Transforms.
- Step 2. Right click on the “New coordinatesystem 1”, click on “**clone**”.
- Step 3. Rename the cloned coordinate system to “Final coordinate system”.
- Step 4. Apply the Z-transform on the Final coordinate system, by right clicking on the on the line of the final coordinate system, thereafter click on “Z-transform”. The transform is applied when the grid is rotated .
- Step 5. Right click on the rotated grid, click on ‘**Harden transform**’.

Now the transformation is done, it only has to be saved.

5) Save the transformation

Save the file as a whole

- Step 1. Select ‘File’ in the main toolbar and select ‘Save data’.
- Step 2. Select ‘Change directory for selected files’ to choose the folder in which the file is saved and select ‘Save’.

Save the transform “Final coordinate system”

- Step 1. Right click on the node “Final coordinate system”, click on Export to file...
- Step 2. Save the file in a specified folder.

Appendix L – Registration protocol 3D Slicer

In this protocol the registration of the talar component with respect to the tibial component is discussed.

Since in my case I only have one dataset with the ankle prosthesis, I performed a transformation on the prosthesis myself beforehand. This step will also be discussed, but will not be necessary if there are actually 2 data sets available from the same patient.

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- 1) Preparatory step; Transformation of the components
- 2) Preparatory step; Save the transformed models
- 3) Download the extension
- 4) Load data
- 5) Registration of the tibial component
- 6) Registration of the talar component
- 7) Save file
- 8) Decomposing the transformation matrix to rotation and translation

1) Preparatory step; Transformation of the components

Step 1. Load the models of the *Tibial component* and the *Talar component*. Also load the transformation matrix *Final coordinate system*.

Step 2. Go to the **Transforms** section.

A translation of +1 in the x axis, and +1 in the y axis, will be done in both models. In addition, a rotation of 15 degrees around the x axis and 15 degrees around the y axis is also done at the talar component.

Step 3. Create a new linear transform as “trans_tibial”. In this transform paste below, as can also be seen in Figure L1.

1	0	0	1
0	1	0	1
0	0	1	0
0	0	0	1

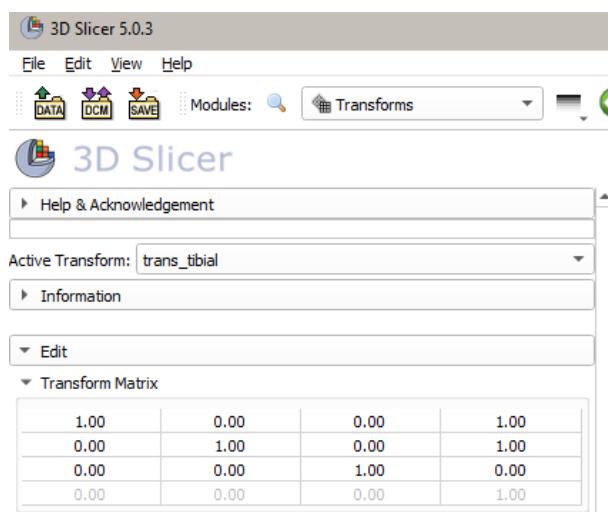


Figure L1. Transformation matrix for Tibial component 1.

Step 4. Create a new linear transform as “trans_rot_talar”. In this transform paste below, as can also be seen in Figure L2.

```
0.965926 0.0669873 0.25 1
0 0.965926 -0.258819 1
-0.258819 0.25 0.933013 0
0 0 0 1
```

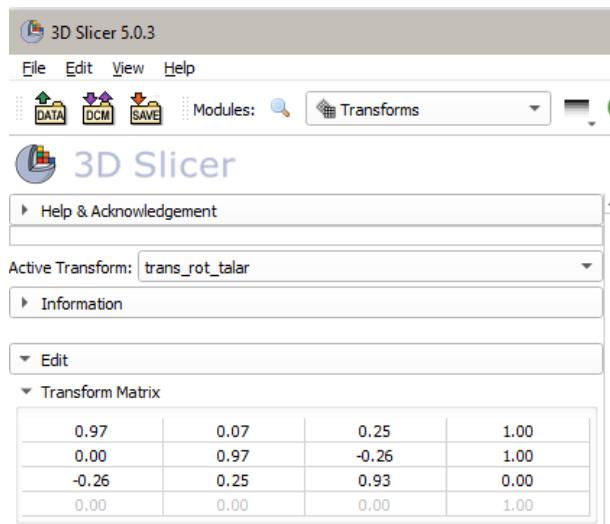


Figure L2. Transformation matrix for the Talar component 1.

- Step 5. Go to the **Data** section, by clicking on the downside arrow next to **Transforms**.
- Step 6. Right click on the grid next to the Tibial component , click on “Final coordinate system”. The transform is applied when the grid is rotated.
- Step 7. Right click on the rotated grid, click on ‘**Harden transform**’.

This step must also be performed with the Talar component .

- Step 8. Right click on the grid next to the Tibial component , click on “Final coordinate system”. The transform is applied when the grid is rotated.
- Step 9. Right click on the rotated grid, click on ‘**Harden transform**’.

Save the original data which is now properly shifted to the origin by means of the appropriate transformation.

- Step 10. Right click on the node “Tibial component ”, click on Export to file... save the model.
- Step 11. Right click on the node “Talar component ”, click on Export to file... save the model.

Rename the models to “Tibial component 1”, and “Talar component 1”

- Step 12. Right click on the node “Tibial component ”, rename the model to “Tibial component 1”.
- Step 13. Right click on the node “Talar component ”, rename the model to “Talar component 1”.

Now the specific transformations that have just been created still need to be applied.

Step 14. Right click on the grid next to the Tibial component 1, click on “**trans_tibial**”. The transform is applied when the grid is rotated.

Step 15. Right click on the rotated grid, click on ‘**Harden transform**’.

Step 16. Right click on the grid next to the Talar component 1, click on “**trans_rot_talar**” The transform is applied when the grid is rotated.

Step 17. Right click on the rotated grid, click on ‘**Harden transform**’.

2) Preparatory step; save the transformed models

Step 1. Right click on the node “Tibial component 1”, click on Export to file... save the model as .STL .

Step 2. Right click on the node “Talar component 1”, click on Export to file... save the model as .STL .

Step 3. Close the program.

3) Download the extension

Step 1. Open 3DSlicer

Step 2. Go to the ‘Extension manager’ under ‘View’ in the main toolbar. Select the ‘Install extensions’ tab. Type ‘SlicerCMF’ in the search bar. Select ‘Install’ (Figure L3).

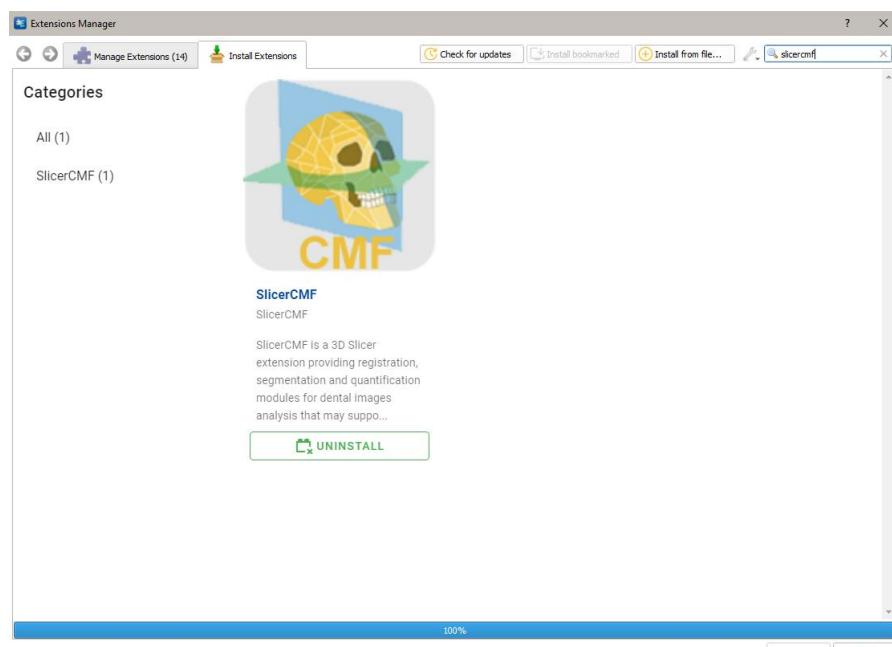


Figure L3. Downloading SlicerCMF in extension manager.

4) Load data

Step 1. Select **Add Data** in the main toolbar under ‘File’. Select ‘Choose file(s) to Add’ in the pop up. Select the STL files of the Tibial component and Talar component in both positions. For each of these files, choose under ‘Description’ the option ‘Model’. Click ‘Ok’ (Figure L4).

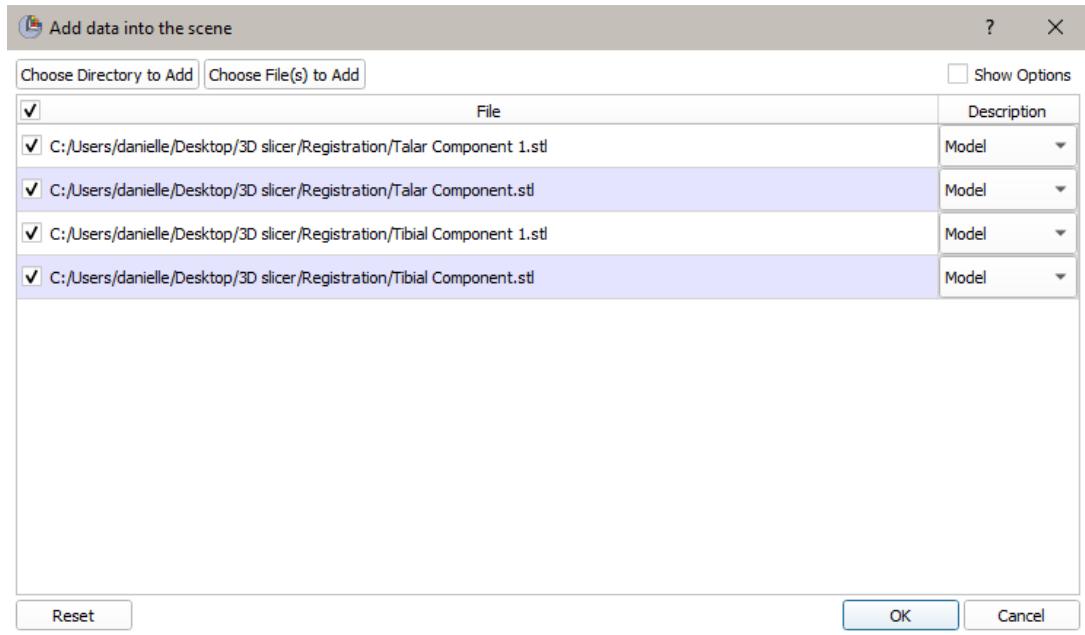


Figure L4. Importing the models as STL.

- Step 2. Go to . Click on the small arrow to open up the menu and select 'Data'.
 Step 3. Double click on the colored squares of each of the models of the bones to change the colors of the models to different colors, as shown in Figure L5.

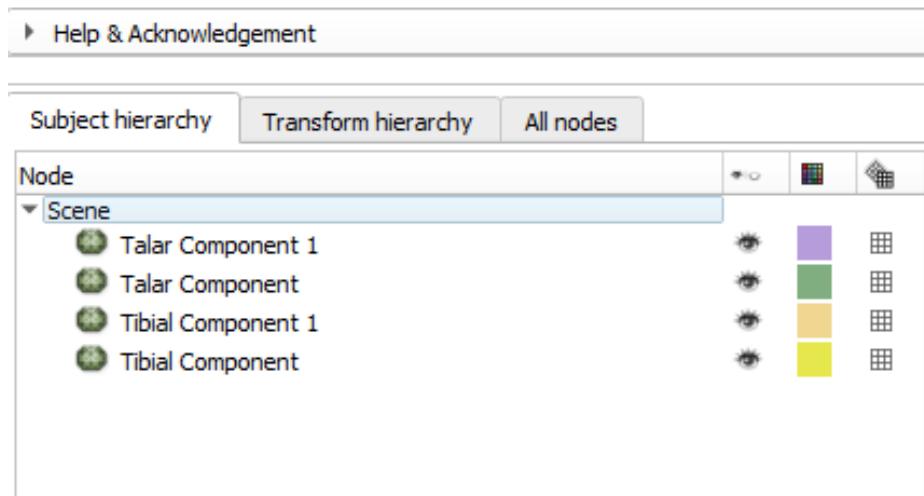


Figure L5. Change the color of the models.

Note: The bones may be not visible yet in the 3D view. First zoom out by scrolling. The orientation of the bones can be changed by clicking and dragging using the left and middle button of the mouse

- Step 4. View the models on maximize 3D view (Figure L6).

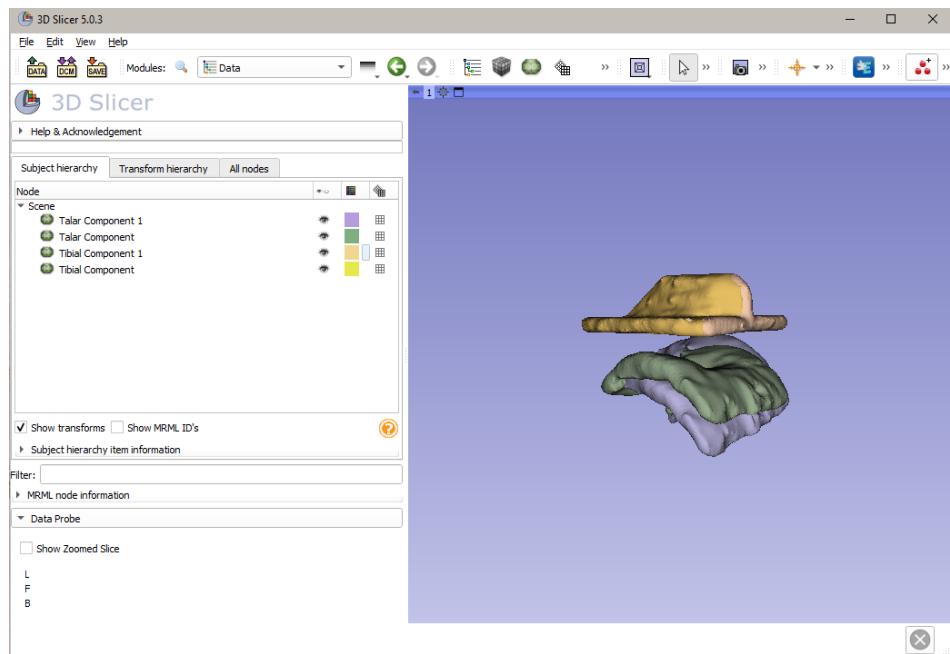


Figure L6. Maximize the 3D view to view the models of the prosthesis.

5) Registration of the tibial component

The process of registration of the tibial component means that the Distraction 1 position is aligned with the tibial component of the Null position. This same transformation is subsequently applied to the talar component to align the Distraction 1 position and the Null position with the tibial component as a center.

Step 1. Go to the and select 'Registration', 'CMF registration' and then 'Surface registration' (Figure L7).

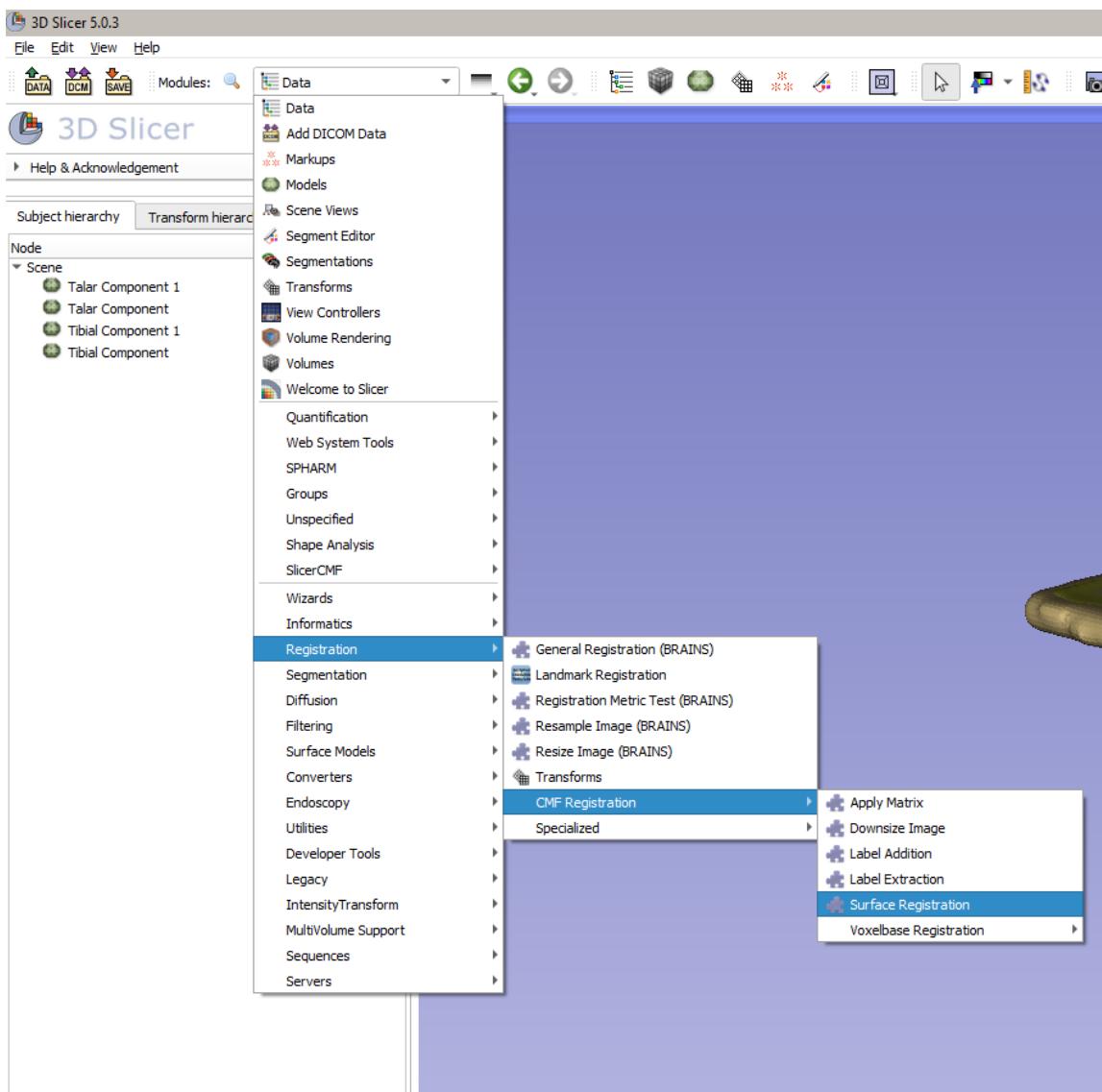


Figure L7. Go to the surface registration module.

Step 2. Select under type of registration ‘surface registration’

Step 3. Select under ‘inputs’ for ‘fixed model’ → Tibial component, and for ‘moving model’ → Tibial component 1. Select under ‘Outputs’ for ‘Output Transform’ the option ‘Create new LinearTransform as..’. Rename the transform to ‘Transform Tibia’. Select ‘Compute’ (Figure L8)

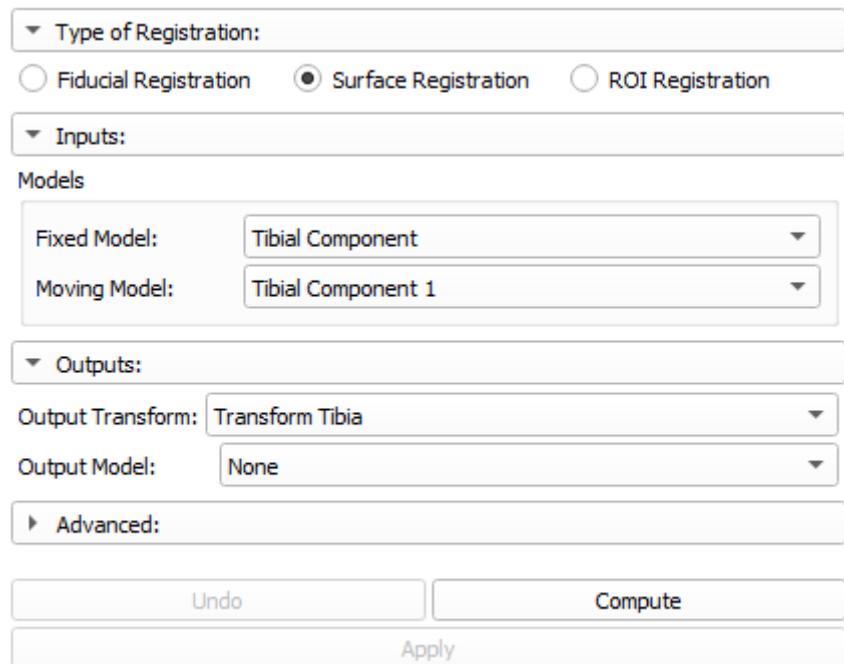


Figure L8. Inputs in the surface registration for the registration of the tibia.

- Step 4. Go to **Surface Registration**. Click on the small arrow to open up the menu and select 'Transforms'.
- Step 5. Select under 'active transform' the transform of the tibial component '*Transform Tibia*'.
- Step 6. In the left column scroll down to "apply transforms"
- Step 7. Select the model of the 'Talar component 1'. Select the arrow directing to the right; now the 'Talar component will shift to the Transformed section (Figure L9).

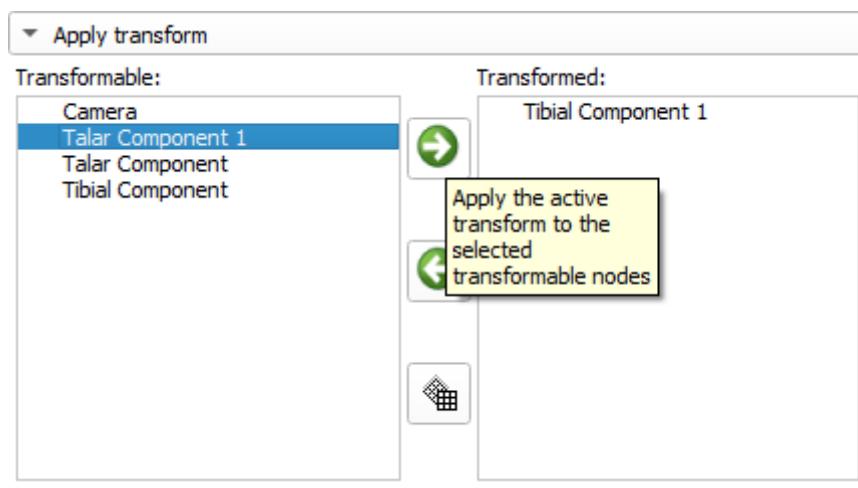


Figure L9. Move the segmentation to the transformed side.

- Step 8. Go to the **Data** section
- Step 9. Select again the models of the tibial and talar component 1 in the transformed section using ctrl. Select the grid 'Harden transform' . The models will shift back to the transformable section.

6) Registration of the Talar component

Again the registration will be done, only now with the Talar component.

- Step 1. Go to the  Data and select 'Registration', 'CMF registration' and then 'Surface registration' (Figure L7).
- Step 2. Select under type of registration 'surface registration'
- Step 3. Select under 'inputs' for 'fixed model' → Talar component, and for 'moving model' → Talar component 1. Select under 'Outputs' for 'Output Transform' the option 'Create new LinearTransform as..'. Rename the transform to 'Transform Talus'. Select 'Compute' (Figure L10).

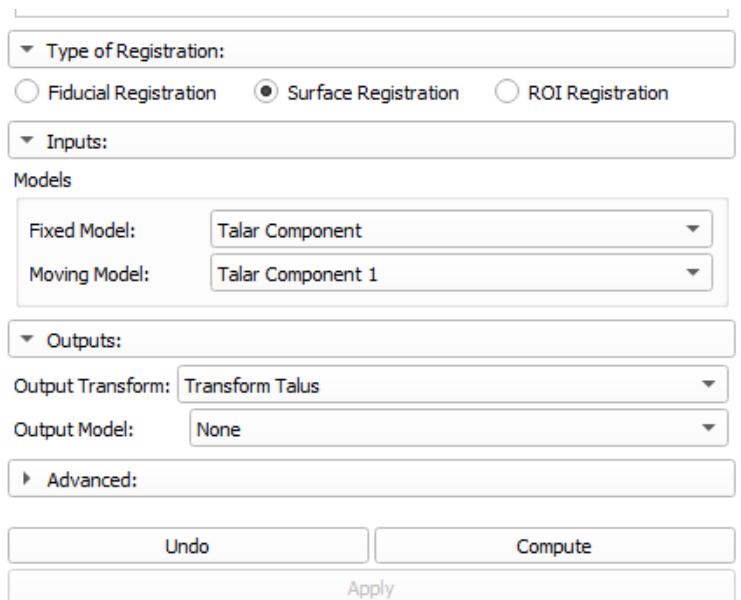


Figure L10. Inputs in the surface registration for the registration of the talus.

7) Save file

Save the file and the transformations.

- Step 1. Select 'Save data' under 'File' in the main toolbar.
- Step 2. Select 'Change directory for selected files' to change the directory in which the file is saved to the Registration folder, select 'Save'.

8) Decomposing the transformation matrix to rotation and translation

The transformation matrix of the talus can be decomposed to express movement in rotation and translation of the distraction 1 position compared to the null position.

- Step 1. Go to the **Transforms** section.
- Step 2. Select under 'Active transforms' the transform of the talus 'Transform talus'
- Step 3. Unfold the information tab  **Information**. This tab shows the transformation matrix, copy the transformation matrix (Figure L11).

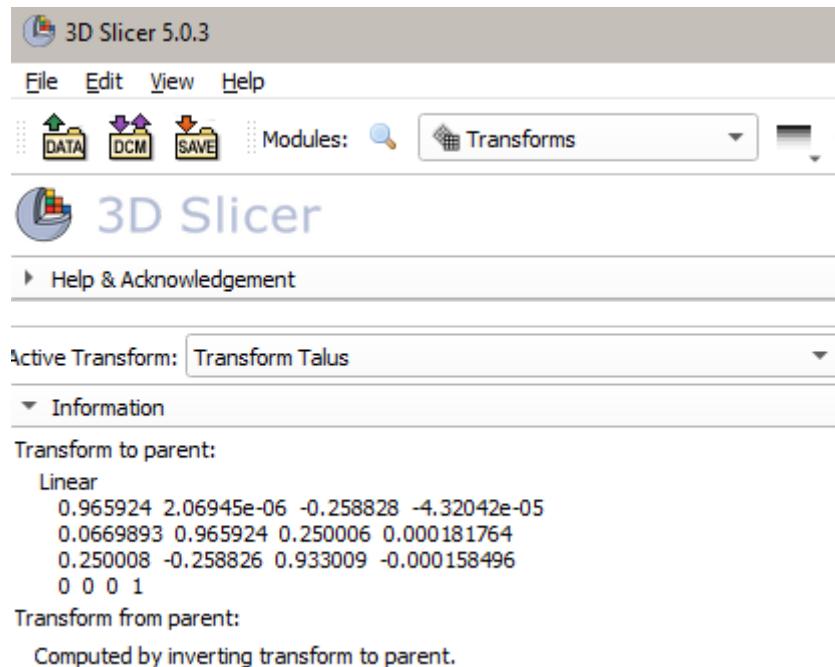


Figure L11. Copy the transformation matrix under the information tab.

- Step 4. Go to MATLAB, and insert the lines below in an empty script.

```
% Script for decomposing the rotation and translation of the
% transformation matrix
% by D. van Elst

%% input the transformation matrix
% paste after [ the transformation matrix
R = [
];

%% function needed for decomposing rotation
ang(1) = atan2d(-R(2,3),R(3,3));
ang(2) = asind(R(1,3));
ang(3) = atan2d(-R(1,2),R(1,1));

%% Viewing the translation and rotation
translation=R(1:3,end)
%rotation in degrees
rotation=[ang]
```

- Step 5. Paste the transformation matrix in the code in line 7 after the `R = [`, make sure that the lines of the matrix align such as in Figure L12.

```

1 % Script for decomposing the rotation and translation of the
2 % transformationmatrix
3 % by D. van Elst
4
5 %% input the transformationmatrix
6 % paste after [ the transformation matrix
7 R = [ 0.965924 2.06945e-06 -0.258828 -4.32042e-05
8 0.0669893 0.965924 0.250006 0.000181764
9 0.250008 -0.258826 0.933009 -0.000158496
10 0 0 0 1 ];

```

Figure L12. Paste the transformation matrix in line 7 of the MATLAB code.



Step 6. Select the run button in MATLAB . A pop-up will open, in which you have to save the file. The file can be saved under the name “rotation_matrix”. Thereafter the results of the translation and rotation of the Talar component are showed in the command window (Figure L13). The rotation is viewed in degrees.

Command Window

```

>> rotation_matrix

translation =
    1.0e-03 *
    -0.0432
    0.1818
    -0.1585

rotation =
    -15.0004   -15.0005   -0.0001

```

fx >>

Figure L13. Results of the translation and rotation of the Talar component.