MASTER THESIS

OPEN-SOURCE APPROACH FOR MEDICAL DEVICES WITHOUT BUSINESS CASE

OFFERING THE 3D FOOT PLATE OPEN-SOURCE AND EXPERT OPINION ON MDR COMPLIANCE FOR OPEN-SOURCE MEDICAL DEVICES

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ABSTRACT

Medical devices developed for small patient populations, or only used in complex clinical cases and research settings, can be commercially non-viable. To ensure that also small patient populations can benefit from medical devices, these medical devices could be offered as Open-Source Medical Device (OSMD). Like all medical devices in the EU, OSMDs must comply with the Medical Device Regulation (MDR) to ensure patient safety. This project aimed to explore possibilities of offering Class I medical devices, by making an inventory of suitable open-source platforms, working out a complete case including all relevant documentation in accordance with the MDR, and assessing expert opinions on this approach via interviews and focus groups. The results yield: (1) an advice on which open-source platform is the most suitable for offering OSMDs, (2) a medical device, called 3D Foot Plate, that can be manufactured with off-the-shelf components using common household tools and accessible manufacturing methods, while providing all documentation necessary to comply with the MDR and (3) an analysis of expert opinions on regulatory routes for offering OSMDs. This project could be considered a showcase of how to offer open-source medical devices that comply with the MDR.

SAMENVATTING

Medische hulpmiddelen ontwikkeld voor kleine patiëntenpopulaties, of alleen gebruikt in complexe klinische cassussen en onderzoekssettings, kunnen commercieel onhaalbaar zijn. Om ervoor te zorgen dat ook kleine patiëntenpopulaties baat kunnen hebben bij deze medische hulpmiddelen, kunnen ze aangeboden worden als Open-Source Medical Device (OSMD). Zoals alle medische hulpmiddelen in de EU, moeten OSMD ook voldoen aan de Medical Device Regulation (MDR) om patiëntveiligheid te garanderen. Het doel van dit project was het onderzoeken van mogelijkheden om medische hulpmiddelen aan te bieden. Dit is gedaan door middel van het maken van een inventarisatie van open-source platforms, het uitwerken van een complete casus waaronder alle relevante documentatie in overeenstemming met de MDR en het analyseren van de meningen van experts over deze aanpak door middel van interviews en focusgroepen. De resultaten brengen het volgende: (1) een advies voor welk open-source platform het meest geschikt is om OSMDs aan te bieden, (2) een medisch hulpmiddel, genaamd de 3D Foot Plate, die geproduceerd kan worden met kant-en-klare componenten, gebruikmakend van huishoudelijk gereedschap en toegankelijke productietechnieken, terwijl ook alle MDR documentatie wordt aangeboden en (3) een analyse van meningen van experts over regulatie-routes om OSMDs aan te bieden. Dit project kan worden gezien als een demonstratie voor hoe open-source medical devices die voldoen aan de MDR aangeboden kunnen worden.

TABLE OF CONTENTS

CHAPTER 1: INTRODUCTION

Open-Source Software (OSS) is defined as: “software with source code that anyone can inspect, modify, and enhance” [1]. Due to the increase of accessibility to 3D printers and electronic platforms [2], it has been possible to apply the open-source approach from exclusively software to hardware as well. OSHW (Open-Source Hardware) platforms [3] provide digital spaces where designers can either offer their designs to be fabricated by makers, or work collaboratively with other designers or end-users. It has also been possible to apply the open-source strategy for medical devices. A medical device offered as open-source is categorized as Open-Source Medical Device (OSMD). The definition of an OSMD according to De Maria et al. (2022) is the following [4]: “… a medical device whose design and product development information are made publicly available so that anyone can study, modify, distribute, make, and sell the medical devices, and their related software or hardware, based on the initial available design and information […]”. De Maria et al. also highlighted preconditions for sharing the OSMDs:

- Formats that enable validation, verification and modification;
- Usage of widely available materials and components;
- Design performed according to standards while guaranteeing patient safety;

Medical devices developed for small patient populations (less than 100 per year), or only used in complex clinical cases and research settings, can be commercially non-viable. The costs of development, certification and production then do not outweigh the profit, causing a halt on the development or market entrance of certain medical devices. To ensure that also these patients can benefit from such medical devices, medical devices could be offered as OSMDs [4]. Examples of already existing OSMDs [5] are the open-source CT scanner by Jansen [6] (Figure 1A) and the peristaltic pump by Fechko [7] (Figure 1B).

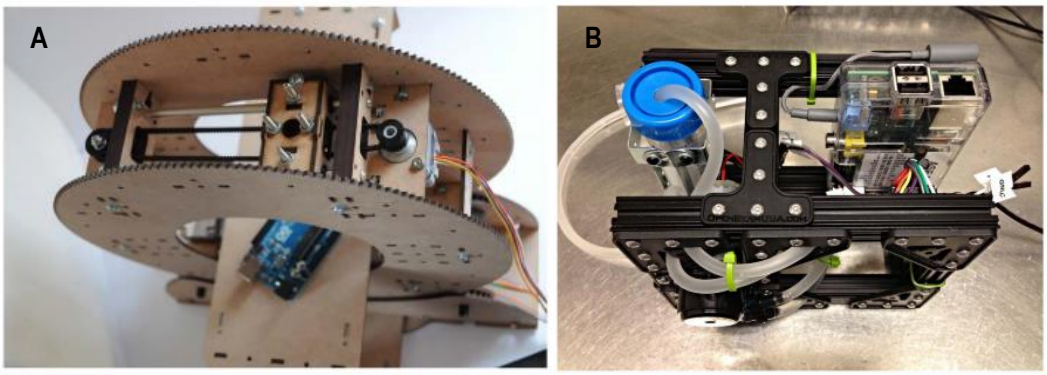


Figure 1: Two examples of existing open-source medical devices. 1A) Open-source CT scanner by Jansen [6]. 1B) Open-source peristaltic pump by Fechko [7].

Although open-source medical devices are already available on OSHW platforms, most do not comply with the Medical Device Regulation (MDR). The MDR is a set of rules that regulate the production and distribution of medical devices. Its main purpose is to ensure patient safety. Under the MDR, medical devices are classified as Class I, Class IIa, Class IIb or Class III based on risk. Class I medical devices are considered the lowest risk and are thus usually the most suitable as OSMD, since this classification does not require the involvement of a Notified Body. For OSMDs to be offered in the European Union, all OSMDs must conform with the Medical Device Regulation (MDR), but the regulatory routes for offering OSMDs are currently not clearly defined.

An example of a medical device without a business case is the 3D Foot Plate developed by Tuijthof et al. (2012) [8]. The 3D Foot Plate will only be used by referral centres such as academic hospitals in specific complex clinical cases, meaning the device is used for a small patient population (estimated 10 per year). This means that the 3D Foot Plate is not commercially viable, therefore we explore to offer it on an open-source platform. End-users can download relevant information including the Computer Aided Design (CAD) files and an assembly manual from the platform, after which it is possible to manufacture the device themselves. The master thesis of D. van Elst (2023) focused on the re-design of the 3D Foot Plate as an OSMD that complies with the MDR [9]. However, the design still needs improvements before it is possible to offer the medical device on an open-source platform.

This project aims to explore possibilities of offering class I Medical Devices as open-source medical device, by making an inventory of suitable platforms (CH 2), working out a complete case including all relevant documentation in accordance with the MDR (3D Foot Plate) (CH 3), and assessing expert opinions on this approach via interviews and focus groups (CH 4).

CHAPTER 2: OPEN-SOURCE PLATFORMS

The aim of making an inventory of open-source initiatives and platforms is to find out if there is a suitable platform on which novel medical device designs with no business case can be offered. This section describes the methods, results and discussion of a search to open-source platforms.

2.1 METHODS

The search was performed using Google (Scholar) for an Internet search and Scopus for a database search. Additionally, a Dutch professional association website for occupational therapists was used to find platforms used by occupational therapists to find assistive technology suitable for their patients. Lastly, a search was performed on the database of EU research results (cordis.europa.eu/). Within that database the search term "open-source" was used specifically in the *Science with and for Society program* category. For searches that resulted in more than 300 hits, only the first 200 hits were reviewed. Furthermore, the website traffic of the platforms found was investigated as part of the evaluation of suitability of a European platform.

The following search terms were used in Google:

String 1: ("medical device" or md or assistive) and (design or develop* or innovat* or fabricat*) and (open-source or "open source" or collabor* or co-design) and (hardware) and (initiative or platform or e-platform or commun*) and (eu or "european union" or europe*)

String 2: ("medical device" or healthcare or assistive) and (design*) and (open-source or "open source" or collabor* or co-design) and (hardware) and (initiative or platform or e-platform or commun* or repository) and (eu or "european union" or europe*)

The following search terms were used in Google scholar: Careables.org

In Scopus the following search terms were used:

String 3: TITLE-ABS-KEY (("medical device" OR assistive OR "daily living aid*" OR "disability aid*" OR mobility OR surgical OR osmd OR oshw OR osh OR healthcare) AND (design OR develop* OR innovat* OR fabricat* OR prototyp* OR tinker* OR build* OR "3d print*" OR "additive manufactur*") AND (open-source OR "open source" OR collabor* OR co-design* OR co-creat* OR distribut* OR open) AND (hardware OR equipment) AND (initiative OR platform OR e-platform OR communit* OR "online platform" OR repository) AND (eu OR "european union" OR europe*))

String 4: TITLE-ABS-KEY (("medical device" OR assistive OR "daily living aid*" OR "disability aid*" OR mobility OR surgical OR osmd OR oshw OR osh OR healthcare) AND (design OR develop* OR innovat* OR fabricat* OR prototyp* OR tinker* OR build* OR "3d print*" OR "additive manufactur*") AND (open-source OR "open source" OR collabor* OR co-design* OR co-creat* OR distribut* OR open) AND (hardware OR equipment) AND (initiative OR platform OR e-platform OR communit* OR "online platform" OR repository) AND (eu OR "european union" OR europe*) AND NOT software)

String 5: TITLE-ABS-KEY (("medical device" OR assistive OR disability OR mobility OR surgical OR osmd OR oshw OR osh OR healthcare) AND (design OR develop* OR innovat* OR fabricat* OR prototyp* OR tinker* OR build* OR "3d print*" OR "additive manufactur*") AND (open-source OR "open source" OR collabor* OR co-design* OR co-creat* OR distribut* OR open) AND (hardware OR equipment) AND (initiative OR platform OR e-platform OR communit* OR "online platform" OR repository) AND (eu OR "european union" OR europe*))

String 6: TITLE-ABS-KEY (("medical device" OR assistive OR disability OR mobility OR surgical OR osmd OR oshw OR osh OR healthcare) AND (design OR develop* OR innovat* OR fabricat* OR prototyp* OR tinker* OR build* OR "3d print*" OR "additive manufactur*") AND (open-source OR "open source" OR collabor* OR co-design* OR co-creat* OR distribut* OR open) AND (hardware OR equipment) AND (initiative OR platform OR e-platform OR communit* OR "online platform" OR repository))

To assess the suitability of the open-source platforms, criteria have been set. A distinction was made for platform-specific criteria and device-specific criteria. The platform-specific criteria (1-4) were based on a paper by Bonvoisin et al. (2020) [10]. The device-specific criteria (5-10) were based on the mandatory documentation needed to conform to the MDR and the Best Practices webpage [11] provided by the OSHWA (Open-Source Hardware Association). A platform conformed to these criteria if the platform gave the opportunity to the poster to add this information when posting a device on the platform.

1. Introduction
2. Access control
3. Guidelines provided by the platform
4. Presence of a moderator
5. Clinical need and intended use
6. Technical documentation, including at least:
    - Design and Development
    - Bill of Materials
    - General Safety and Performance Requirements checklist
    - Risk analysis
7. Design files (e.g. CAD files) and additional technical drawings
8. Instructions for use (IFU)
9. Assembly manual
10. Clinical evidence

2.2 RESULTS

In total 18 platforms were found. Eleven platforms were found from the Google search, three more were found from the Google Scholar search and two platforms were found from the Scopus database search (Table 1). One platform was found from the Dutch professional association website (Ergotherapie n=Nederland). Lastly, one additional platform was found from the EU research results search. An overview of the platforms is displayed in Table 2, including their characteristics. HackWithPeople and LivingHub appear to be focused on simulating patient cases in daily living activity situations. Since this is not within the research scope, these two platforms have been excluded from assessment.

Table 1: Search terms used in a Google (Scholar) Internet search and Scopus database search.

Database	**Search terms**	**# Results**	**Platforms**	**Ref**
Google	String 1	2520	(1) Careables (2) Makers Making Change (3) Patient Innovation	[3]
Google	String 2	6080	(4) UBORA	[12]
Google Scholar	Careables.org	39	(5) Thingiverse (6) Pinshape (7) Instructables (8) Hackaday (9) Hackster.io (10) Github (11) Open Assistive (12) HackWithPeople	(5)-(11) [13], (12)-(14) [14]

			(13) SS-AT (14) LivingHub	
Scopus	String 3	60	No relevant platforms found	
Scopus	String 4	40	No relevant platforms found	
Scopus	String 5	64	No relevant platforms found	
Scopus	String 6	64	(15) REHAB-LAB (16) Human Lab	[15]

Table 2: Characteristics of the open-source platforms found, including the host country, project name or ownership and which countries the visitors of the platforms are predominantly from (website traffic).

Platforms	**Host country**	**Project name/by**	**Website traffic**
Careables	Germany	Made4You project	Turkey, Netherlands
Makers Making Change	Canada	NA	Canada
Patient Innovation	Portugal	NA	Colombia, Turkey
UBORA	Unknown	UBORA project	Pakistan
Thingiverse	US	By MakerBot	US
Pinshape	Canada	NA	US
Instructables	US	By Autodesk	US
Hackaday	US	NA	US
Hackster	US	By Formlabs	US
Github	Unknown	NA	Unknown
Open Assistive	UK	NA	UK
SS-AT	Japan	NA	Unknown
REHAB-LAB	France	By CMRRF in Kerpape	France
Human Lab	France	By My Human Kit	France
Hulpmiddelentips	Netherlands	By EIZT and Hogeschool Zuyd	Netherlands
LOSH	EU	By OSHWA	EU

Since part of the criteria have been set using the MDR, platforms mostly used by non-EU countries have been excluded from further assessment. Table 3 displays to which extent the remaining six platforms conform to the criteria. Hulpmiddelentips.nl and losh/opennext.eu are both platforms that refer to other platforms.

Table 3: Open-Source platforms analysed with the set criteria. A ✓ indicates that the platform conforms to the criterion, a ~ indicates that the platform conforms to the criterion, but the information is not included for most devices and no symbol indicates tha

Platform	Intro	Clin. need	Technical doc.	Design files	IFU	Assem. manual	Clinical evidence	Access control	Guidelines provided	Moderator
Careables	✓	~		✓	~	✓		✓	✓	
Hulpmiddelentips.nl	✓	~		✓	~	✓			✓	✓
HumanLab	✓			✓	~	✓		✓	✓	
REHAB-LAB	✓			✓	~			✓		~
LOSH	✓			✓	~	✓				

Careables.org is a platform that has received funding from the EU Horizon 2020 program as a part of the Made4All project. When uploading a design, the designer is required to add a thumbnail, title, description and summary. Adding tags, a license, the goal of the project, specifications, roadmap, teams, references and images are optional. Only a limited number of projects provide IFU by images or using the description and summary function. Many projects for which assembly is necessary provide this with a manual or images. The clinical need can be put into the description, summary or goal of the project. Very few healthcare projects describe a clinical need. Design files can be added using the file function within the project page. Before uploading a design, Careables first requires the designer to make an account. Careables has a guide and explanation video for documenting a design on the host of the repository: welder.app.

From the platform options of the Dutch professional association website for occupational therapists), Hulpmiddelentips.nl was the only assistive device platform with a DIY category. The website provides guidelines for using the website by makers. The website does not offer possibilities to post designs on the platform, but instead offers designs from Thingiverse, MyMiniFactory and Pinshape. It must be noted that currently only four of the DIY designs refer to MyMiniFactory and Pinshape, while the rest refers to Thingiverse. Hulpmiddelentips.nl includes a description, application, tips, compensation resources, availability and price indication. In some cases, a very limited amount of text on the clinical need text is provided in the description. Since Hulpmiddelentips.nl usually refers to Thingiverse, the additional available information might vary per design.

REHAB-LAB.org is a French open-source platform by the Mutualist Center for Functional Rehabilitation and Rehabilitation (CMRRF) in Kerpape. Most designs are posted by the CMRRF or the Groupe Hospitalier du Havre (GHH) or another REHAB-LAB location. At this moment it is not possible for designers outside of the REHAB-LAB network to add their designs to the platform. It could therefore be argued that REHAB-LAB has a moderator. All projects include an introduction and design files. Only some projects have IFU included on their page.

HumanLab is a French platform by My Human Kit. New users are required to make an account and be verified by a FabLab manager. Also, when posting a design onto the platform, the designer must conform to a few rules set by the organization. For example, the project page must only contain information useful for reproducing the

prototype, being clear about the project's status and stating whether it has been verified or not. The designer can add a project description, specification, analysis of the current situation, materials, tools, cost, source files, step-by-step manufacturing steps and user feedback. However, not all project pages include this information.

The Library of Open Source Hardware (LOSH) by OPEN!NEXT refers users to other platforms such as Thingiverse, Github and Wikifactory. Designers can post their designs on those platforms and fill in a form on the LOSH website to ensure that their design will show up in the library. It is required to fill in a version and licensor, and it is optional to add a Technology Readiness Level and Documentation Readiness Level. Most designs the library refers to, within the medical devices category, include an introduction, design files and assembly manual. Only a few designs have IFU.

2.3 PLATFORM SELECTION

None of the platforms include technical documentation and clinical evidence. All platforms have an insufficient introduction. So far, only one project on the Careables platform has been observed having a clinical need and intended use in the introduction. Moreover, none of the platforms have included a proper IFU. Careables.org and Hulpmiddelentips.nl conform to the most criteria of all five platforms, making those the most suitable for implementation of medical devices with no business case. However, there is much room for improvement to conform to all criteria, especially regarding the technical documentation and clinical evidence.

CHAPTER 3: 3D FOOT PLATE OFFERED AS OSMD

To offer the 3D Foot Plate as OSMD, it is necessary to know the intended use and clinical need, as well as the specific requirements and points of interest. This section describes an introduction of the 3D Foot Plate, an analysis of the previous version of the device and design requirements. Based on the analysis, a redesign has been performed, which is extensively described in this section. Thereafter, an overview of the evaluation of the functionality and usability is provided.

3.1 INTRODUCTION TO THE 3D FOOT PLATE

The joints in the ankle consist of the talocrural, subtalar and tibiofibular joint [16]. The talocrural joint is the joint between the talus, tibia and fibula [17]. This joint allows dorsi flexion and plantar flexion motion of the ankle. The subtalar joint is the joint between the talus and calcaneus, and allows for the inversion and eversion of the ankle. The anterior talofibular and calcaneofibular ligaments are part of the lateral collateral ligament [18]. Injuries that involve these ligaments are one of the most common injuries that occur and in some cases patients that sustained this injury suffer from chronic instability in the hindfoot [19].

Currently, laxity and instability of the hindfoot is diagnosed through a manual stress test by a clinician [20] (Figure 2). A manual stress test consists of manual manipulation by a clinician on the patient's foot. According to Fujii et al. (2000), a clinician performs "inversion or anterior displacement until a firm endpoint is detected" [21]. Based on this, the clinician determines whether the joints show a normal or abnormal range of motion [8].

However, this test cannot distinguish between talocrural instability, subtalar instability or a combination of these. Moreover, in case of complex problems in the hindfoot, quantitative data is necessary. Therefore, the 3D CT-stress test has been developed [22], which uses a medical device called the 3D Foot Plate. This 3D CT-stress test mimics the manual stress test. Thereto, the 3D Foot Plate is used to position the foot relative to the lower leg and holds this position while performing 3D imaging to obtain quantitative data of the relative positions of the bones [8]. The 3D Foot Plate can be readjusted to a new position to acquire additional 3D images.

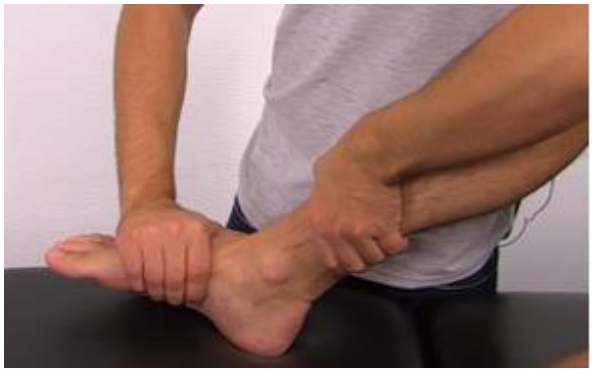


Figure 2: Demonstration of a manual stress test [23].

3.2 ANALYSIS REDESIGNED 3D FOOT PLATE FOR SUITABILITY TO OFFER AS OPEN-SOURCE

The 3D Foot Plate was redesigned by D. van Elst (2023) [9] to generate the needed documentation for MDR compliance and to offer it open-source [8]. Figure 3 and Figure 4 show this design, which is analysed for suitability to offer-as open source.

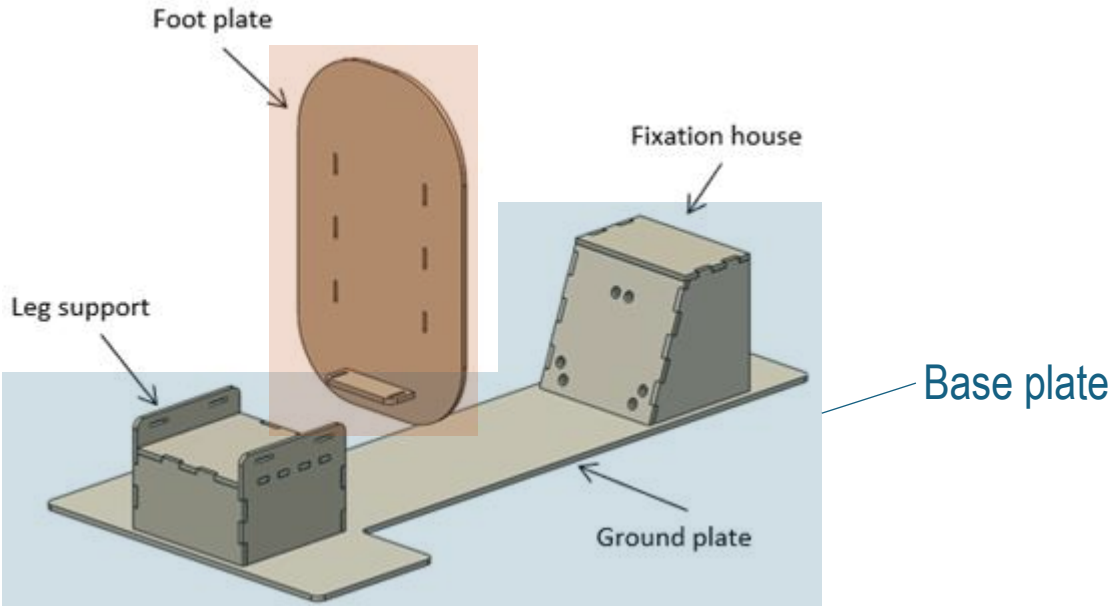


Figure 3: Schematic of polypropylene parts of the 3D Foot Plate, including an indication of the names of segments. Indicated in blue is the base plate, consisting of the ground plate, the leg support and the fixation house. Indicated in red is the foot plate.

Figure 4: Final prototype of the 3D Foot Plate by D. van Elst (2023) [9]. Colour correction was applied on the picture for clarity. Indicated with yellow is a zoom-in on the Stewart platform.

3.2.1 Results of analysis

In this section, the results of the analysis are presented by mentioning step-by-step which elements of the 2023 version have to be improved before it is possible to offer this medical device open source.

1. Glue connections

The base plate and foot plate (Figure 3, blue and red segments) of the device are made of laser cut polypropylene (PP). These parts are glued together using a polypropylene-specific glue, which drives up the manufacturing costs. Several other parts of the device are connected by superglue. An important issue that occurred over time is that the glue seems to deteriorate in less than a year, causing the prototype to lose its functionality.

2. Complexity of rope assembly

The rods of the Stewart platform can be fixated into the desired position through a rope fixation system. When the ropes are pulled, the silicon tubes inside the rods expand (see Figure 5A), causing friction which fixates the rods in that position. The ropes can then be placed into the clamp cleats (Figure 5B) to stay fixated. The rope assembly is too difficult to be operated by just one person, meaning that the requirement for this is not met.

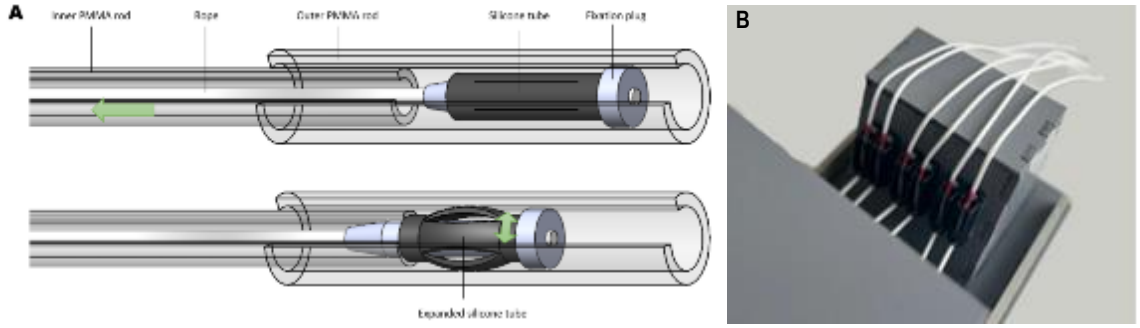


Figure 5:: Rope fixation system. (A) When the rope is pulled, the silicon tube expands. This causes friction between the silicon and the outer PMMA rod, fixating rods in that position. (B) The ropes can be placed in clam cleats to ensure that the ropes stay in the fixated position. [9]

3. Complexity of several manufacturing steps

The workflow of the manufacturing of the 3D Foot Plate of 2023 is shown in Figure 6. Step 1 includes the pre-processing steps necessary before the device can be assembled. This includes countersinking holes for attaching the ball-in-socket joints and cutting some components to size. Step 2 includes the assembling of three assemblies: (1) ground plate assembly, (2) foot plate assembly and (3) rods assembly, which are combined together in step 3. Too many steps require either special skills or special equipment thus not meeting the ease of offering it open-source, specifically the countersinking step (Figure 7) to attach the ball-joint to the back plate.

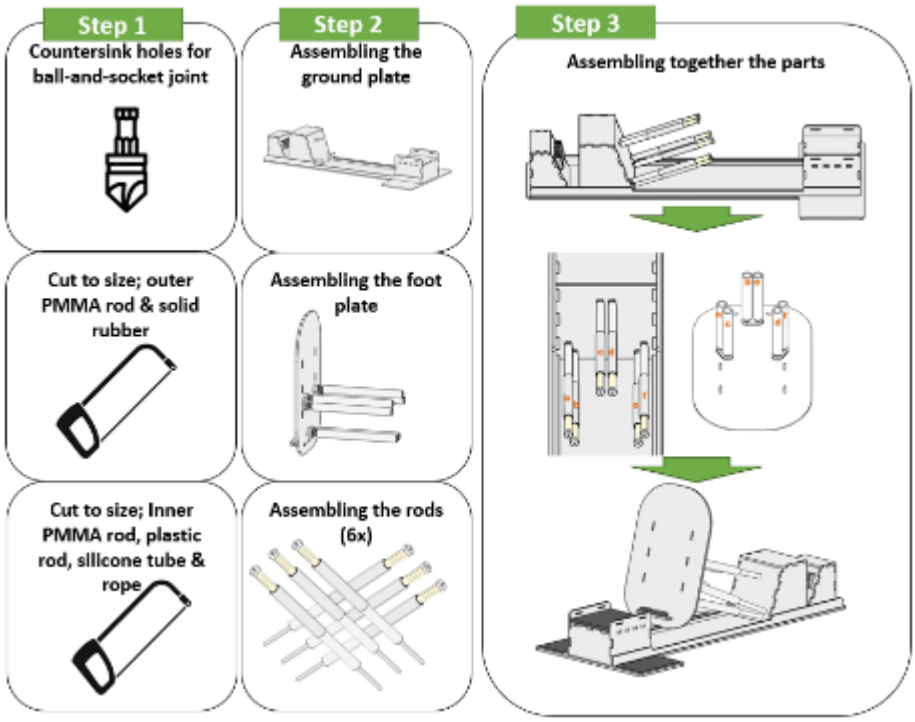


Figure 6: Workflow of the manufacturing of the 3D Foot Plate by D. van Elst (2023) [9].

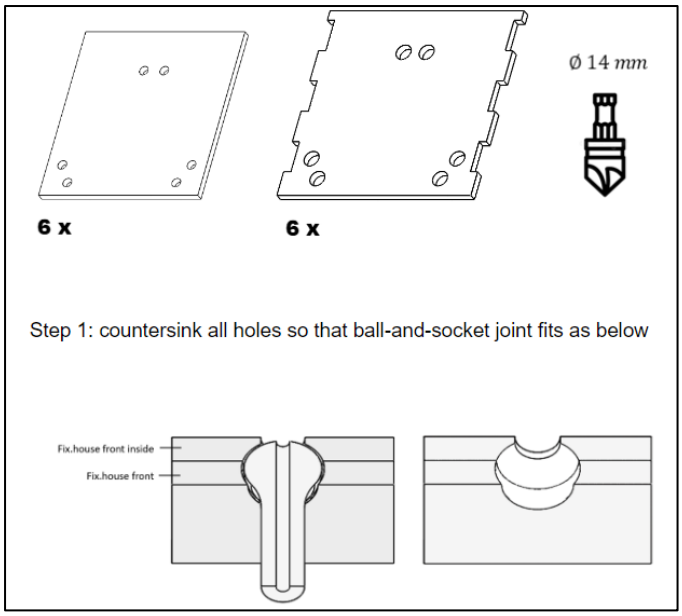


Figure 7: Excerpt of the assembly manual by D. van Elst (2023), containing the instructions for the countersinking step.

4. Sowing of fabric and Velcro straps

After the main part of the device is assembled, Velcro straps on fabric are added to create a piece of fabric that can be pulled to release the foot of the patient in one motion (Figure 8). This piece of fabric requires needle and thread to create a fabric consisting of the Velcro straps, water-repellent nylon and fleece. To attach it to the ground plate assembly, roller shutter belt loops were slid through the gaps of the PP laser cut parts on the leg support and foot plate. Wooden dowels are placed through the loops and fastened with glue. The need for needle and thread, causes the manufacturing of this part of the device to be tedious and time-consuming. Therefore, the ease of manufacturing is not up to par.

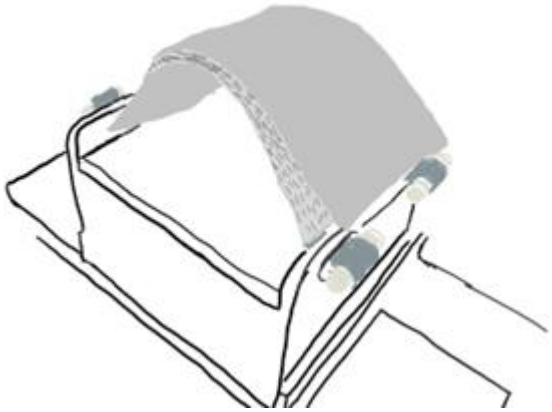


Figure 8: Schematic of the Velcro-fabric assembly of the 2023 version of the 3D Foot Plate for fixating the patient to the device [9].

5. Off-the-shelf availability

The compliant hinges (Figure 9) are made from rubber rods to create the 2 DOF motion required as connection between the foot plate and the PMMA rods. However, these rubber rods are not available as off-the-shelf component and require a pre-processing step of cutting to size. A replacement has to be found to meet the requirement of as many off-the-shelf components as possible. Another component that needed pre-processing in the 2023 version is the PMMA rod, as the supplier did not offer a service for pre-cutting the rods to a custom size. As of today, the supplier does provide this option. Therefore, the PMMA rods did not need to be replaced.

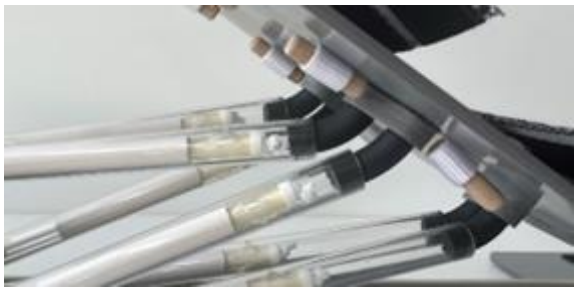


Figure 9: Compliant rubber hinges as 2 DOF joint on the 2023 version of the 3D Foot Plate [9].

3.3 DESIGN METHODOLOGY

The design approach that fits an open-source device is Design for Manufacturing and Assembly (DFMA). Important factors are to minimize complexity, and maximize the amount of digitally distributed components and off-the-shelf components to ensure [24]. Compared to traditional manufacture of medical devices, open-source offer leads to less control over who performs the manufacturing and how the manufacturing is performed. Because of the less strict control on the manufacturing through open-source offer and complying with the MDR is a must, it is vital that the manufacturing and assembly is designed to be fool proof. Moreover, the components should be available off-the-shelf to ensure that they can be easily obtained. With this design approach in mind, the redesign is performed leading to a design consisting of easily obtainable materials, accessible manufacturing methods and easy and fool proof manufacturing. This section describes a detailed explanation of the design process, including design requirements and design changes made.

3.3.1 Design requirements

The design requirements of this project mostly consist of requirements that have been set by the research of Tuijthof et al. (2012) and the thesis of D. van Elst (2023). In the thesis of D. van Elst (2023), a risk analysis was performed before their prototype was developed. From this risk analysis and looking at the General Safety and Performance Requirements checklist, several requirements have been set to meet the demands of the MDR (#18 - #28). These MDR-related requirements must still be met for a redesign.

From the functional requirements from Tuijthof et al. (2012), Requirement #3 has been changed and a new requirement has been added. Requirement #3 (#3a and #3b) has been adjusted from “different imaging systems” to solely CT scanners. This will allow for less material restrictions, since a small amount of metal is acceptable in CT scanners. Requirement #29 has been added, stating that the manufacturing of the 3D Foot Plate does not require glue. All requirements are displayed in Table 4.

Table 4: Requirements of the 3D Foot Plate

ID#	Requirements
	Requirements from article of Tuijthof et al. (2012)
1	The device should be able to manually position the foot in extreme positions relative to the lower leg
2	The device should be dimensioned such that it can be used to diagnose 95% of an adult human population.
3	The device should be compatible with CT scanners
3a	The device should be dimensioned such that it fits into CT scanners
3b	The device should be fabricated with materials that can be used in CT scanners
4	The weight of the device should be a maximum of 12.7 kg to be portable
5	The device should require a separate manual fixation mechanism to preserve the desired extreme position of the foot
6	Different hand grips on the device should be allowed to apply manual loading.
7	The device should offer fast operation below 100 s
8	The device should be able to manually fixate the foot in extreme positions relative to the lower leg
9	The operator should have a sense of control when using the device
10	Excursions of the upper extremities of the radiology technician should be kept within limits
11	It should be clear (unambiguous) how to position the lower leg and the foot in the device
12	The total acquisition time should not be increased by more than a maximum of 10-15 % when using the device
13	Fixating the foot should not create additional damage to the ligaments
14	The foot should be positioned in an extreme position mimicking a clinical stress test
15	The device should have a professional appearance and blend into the working environment
16	The device should be operated by one person
17	The device should be operated with minor physical and mental effort
	Requirements from thesis of van Elst (2023)
18	The materials that come into contact with the patient must be biocompatible
19	Use as much as possible off-the-shelf components
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

22	The device must be easy to clean
23	The device should be easy to assemble by providing instructions through the generation of manuals and the material specifications
24	The device should at least be functional for 1 year without maintenance
25	The device should not break when accidently falling during transport
26	The device should only be used by someone with a medical background who has also received training in stress testing
27	Only use production methods that are easy to order online and require a minimum of engineering expertise
28	The device should not have sharp edges
	Requirements from thesis of Masih (2024)
29	The manufacturing of the device does not require glue

3.3.2 Design

1. Base- and foot plate

For the base- and foot plate, it was chosen to keep the material, manufacturing method and its thickness, laser cut PP (d = 6mm), unchanged. To ensure a fool proof assembly, without glue and only one way of assembling, some changes were made (Figure 10). The back plate is attached to the side plates through a slide-in design, and the cross plate and leg support are attached to the side plates through a slanting locks system (Figure 11). This will hold the base plate assembly together without the use of glue.

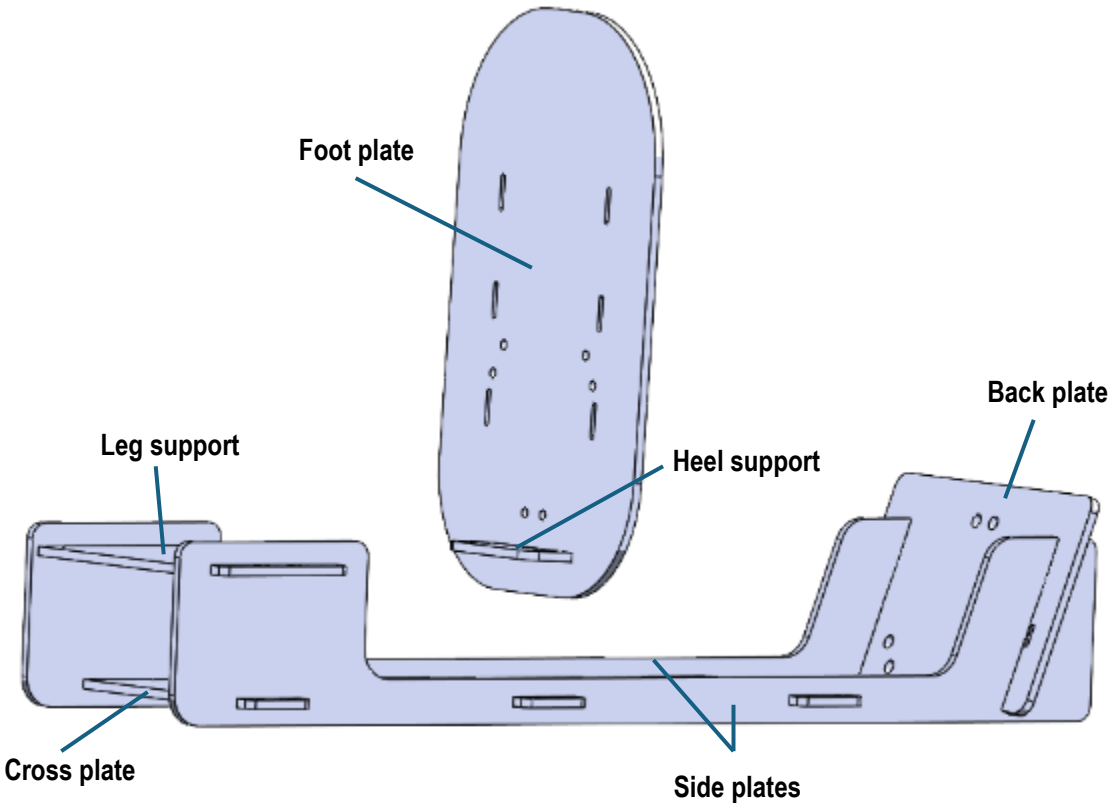


Figure 10: Assembly consisting of the polypropylene parts for the base- and foot plate.

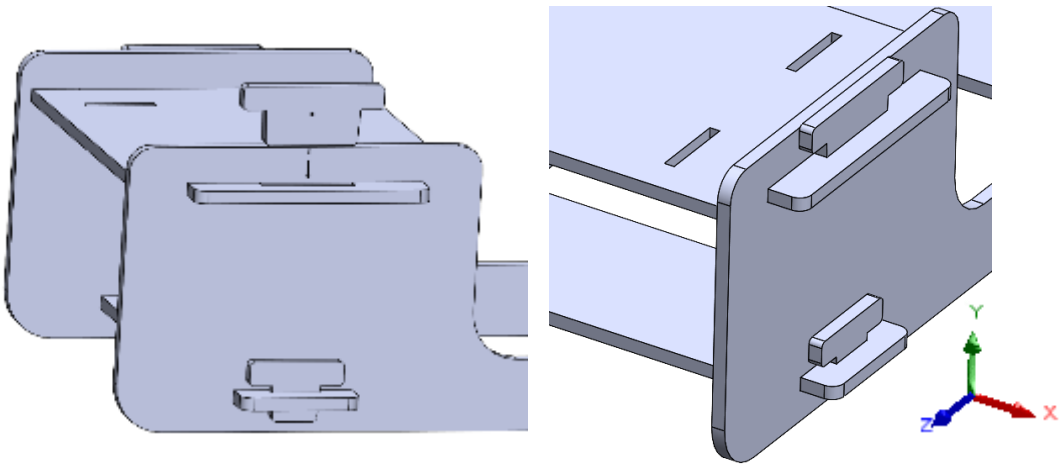


Figure 11: Initial slanting locks system.

Figure 11 shows the first version of the slanting locks. This component received an additional re-design to account for tolerances. There are two factors influencing whether there is a tight connection between the PP parts: (1) potentially varying thickness of the plates and (2) the tolerance of the laser cutter. Before the re-design, the slanting locks were accounting only for the tolerance of the laser cut gaps in one direction (Z-direction) and not for the varying thickness of the PP plates. However, the locking mechanism should ensure a tight fit in the X-direction and account for varying thickness of the PP plates. Therefore, the locks required a change in design (Figure 12). The locks have remained slanted, but in the X-direction to ensure a tight fit between the side plates and cross plates. A clip on the locks was added to ensure that the clip is pushed in when inserting the lock into the gaps, but expands to its initial state when passing the gap. This is done to prevent the locks from moving out of the gaps during transport and use of the 3D Foot Plate.

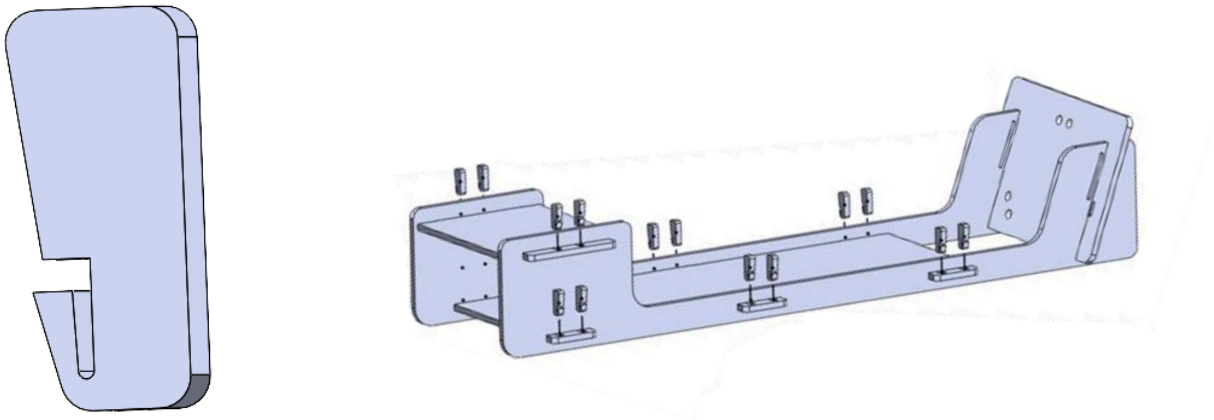


Figure 12: New design of the locks and how they fit into the gaps during assembly.

2. Stewart platform

The Stewart platform was found to be suitable to perform its function of positioning the foot in extreme positions. Therefore, it was chosen to keep the Stewart platform, along with the telescopic function of the off-the-shelf available PMMA rods. The telescopic rods were kept in the design, using of PMMA rods of the same supplier, which are now available in custom sizes. The ball-in-socket joint on the back plate is suitable for creating the necessary motion, which is why a ball-in-socket joint was kept in the design.

The fixation system, consisting of the ropes, was deemed too complicated to operate by one person. Therefore, a replacement for this system had to be found. Secondly, an off-the-shelf component needed to be selected to replace the unavailable rubber rods. Thirdly, a different solution is necessary for attaching the ball-joint to the back plate. For clarity, the connections in the Stewart platform are divided into segment, The segments are indicated as follows (Figure 13): The connection between the back plate and the thick tube (T1) is named C1. The connection between the rods is indicated by C2. The connection between the foot plate and the narrow rod (T2) is C3. C2 and C3 were the most difficult connections. For these connections, a morphological chart (Table 5) was created, showing the different options considered for the connections.

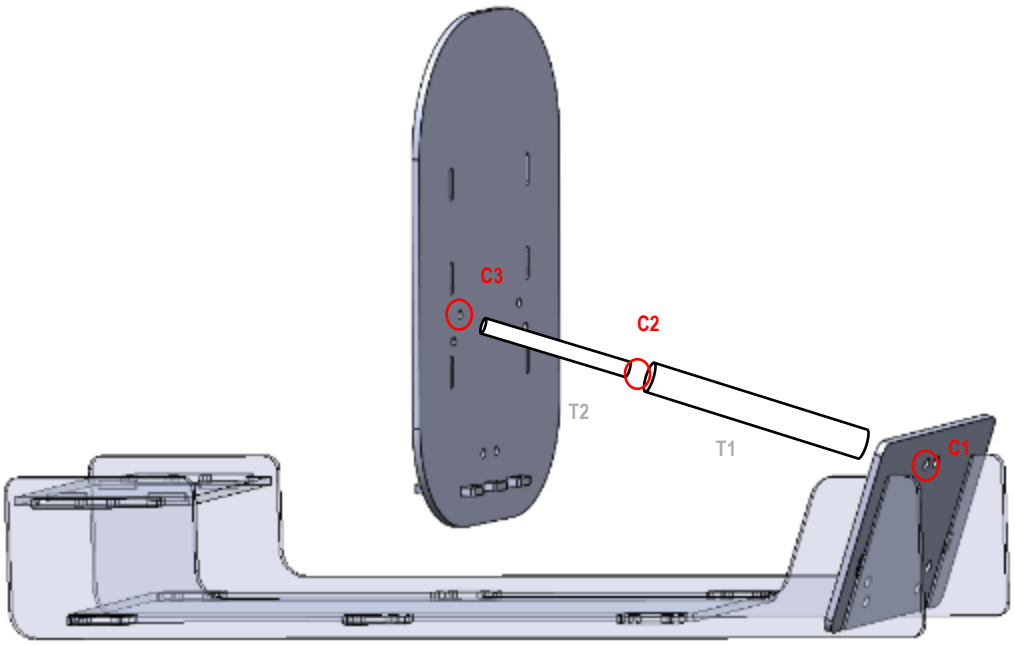
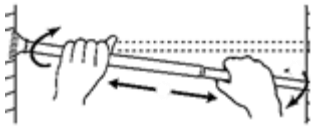
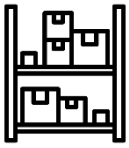
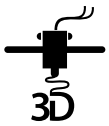
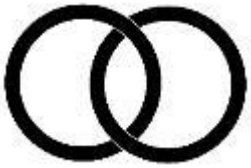


Figure 13: CAD model of the 3D Foot Plate indicating the connections (C1, C2 and C3) and tubes (T1 and T2).

Table 5: Morphological chart containing design solutions for C2 and C3.

C2	 Twist-and-lock curtain rods	 Telescopic fishing rods	 Telescopic tripod legs	 Off-the-shelf telescopic clamp	 3D-printed telescopic clamp
C3	 Rings	 Cardan			

C1 is required to be a ball-in-socket joint connection. To avoid the countersinking step, which created a socket in the back plate, an off-the-shelf component that comes with a socket was selected. **Error! Reference source not found.**A shows a picture of the component that can be ordered from the webshop of igus® [25]. There were multiple variations available of this component. The polymer variant has two options for the size of the ball, of which the larger (13 mm) option was chosen to ensure sturdiness. To attach the component to the back plate, only a screw or hex bolt is necessary, since the inside of the socket shaft is threaded. Another benefit of this component is that the extension of the other side is also threaded. To make a connection between the ball-in-socket joint and the tube, a threaded tube cap from the webshop of Verpas B.V. [26] was selected (**Error! Reference source not found.**B) This component can be easily inserted into a tube using a nylon hammer and is available for many different standard PMMA tube sizes.

A

B

For C2 multiple options were considered (Table 5). Twist-and-lock curtain rods are usually made of plastic and low-cost. However, at least three hands are needed to hold the foot plate (one hand) and to twist the rods (two hands). The telescopic fishing rods and tripod legs are easy to use with a clamping mechanism. However, these products are either made of metal, which is less suitable to be used in a CT scanner, or of carbon fibre, which increases the manufacturing costs substantially. Off-the-shelf telescopic clamps separate from rods are available, but in sizes too large. There are companies that specialize in telescopic clamps that offers smaller

sizes. However, these companies are located in the US, which makes it too expensive to have shipped to the EU. Considering these factors, it was decided to design a telescopic clamp that can be 3D printed.

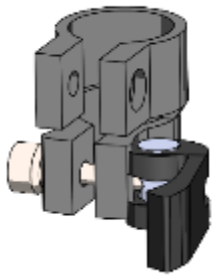
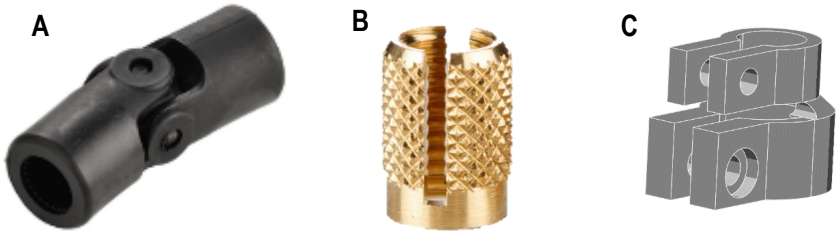


Figure 14: CAD design of telescopic clamp with lever on the bottom side and holes for permanent attachment on the upper side.

Figure 14 shows a CAD illustration of telescopic clamp. The clamp is a two-sided clamp, with one side being adjustable by a lever while the other is meant for permanent attachment after assembly. The lever can be flipped to fixate and loosen the telescopic clamps and the permanent attachment is achieved with a nylon bolt and nut. Since the clamp is 3D printed, separate rods need to be ordered. Flexinplex kunststoffen B.V. [27] offers PMMA tubes which can be cut into custom lengths by the company for a small additional cost. The diameters are chosen to ensure sturdiness, but also ensure that the rods can perform their telescopic function, meaning enough friction when the clamp is in the closed position and no friction when the clamp is in the open position. To ensure no friction in the open position, it was decided to have a ~1 mm discrepancy between the inner diameter of T2 and the outer diameter of T1. For T1 a diameter of Ø25 -21mm was selected and for T2 a diameter of Ø20-16mm was selected.

C3 requires a 2 DOF connection, which was previously achieved by rubber rods. As shown in Table 5, two options were considered. Since off-the-shelf rings were only available in metal, the cardan was chosen as a connector between the rods and foot plate.

Error! Reference source not found.A shows a picture of the connector for C3, which is a Nylon cardan that can be ordered through the webshop of Conrad [28]. The cardan is able to achieve the 2 DOF motion. To make a connection between the cardan and the PMMA rod, another clamp was chosen for consistency. This clamp is shown in **Error! Reference source not found.**C While the telescopic clamp had one adjustable side, this clamp relies on two permanent attachments to T2 and the cardan with nylon bolts and nuts. To attach the cardan to the foot plate, a brass insert was selected (**Error! Reference source not found.**B), which is available in the RS B.V. webshop [29]. The insert can be pushed into the cardan to provide threading on the inside. Then, a standard M6 plate screw can be used to attach the cardan to the foot plate.



3.4 PROTOTYPE

A prototype of all new component was made to assess the functionality (Figure 15). High quality VELCRO® straps are used to fixate the patient's foot and lower leg to the 3D Foot Plate. Additionally, the Instructions for Use (IFU) were elaborated to use a towel between the foot and lower leg and the Velcro straps for comfort. The levers of the telescopic clamps (Figure 15, Coloured green) were printed in a different vibrant colour to easily find them and to indicate to the user that only these have to be operated. This would prevent accidentally loosening of any of the nylon bolts.

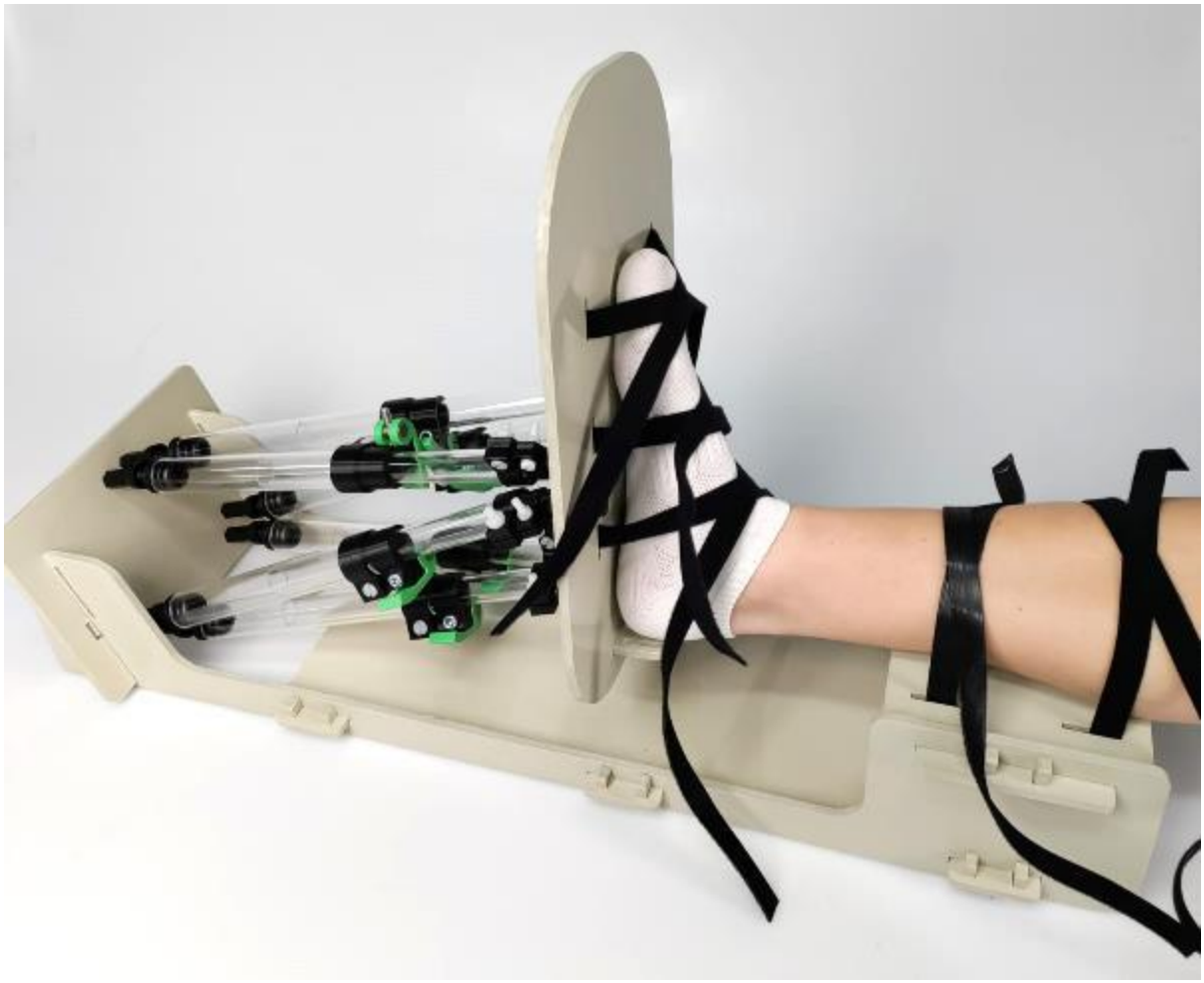


Figure 15: Final design of the 3D Foot Plate. Indicated in green are the telescopic clamp levers to signal the user that these are the only parts of the telescopic rods that need to be operated.

3.5 3D FOOT PLATE DOCUMENTATION

To offer the design of the 3D Foot Plate on an open-source platform, it is necessary to provide some documentation to guide the maker through the manufacturing process and to comply with the MDR. For the documentation related to the manufacturing and use (User Manual, Bill of Material, Assembly Manual) completely new documentation had to be created, due to the redesign. Additionally, an Investigational Medical Device Dossier (IMDD) has been created (Appendix B) and the related MDR documentation has been adjusted from the MDR documentation composed for the 2023 version. This section explains the set up and specifications of these documents.

3.5.1 User manual

It is important to provide the user with a user manual or Instructions for Use. The instructions must be clear to a clinician who is familiar with the manual stress test, and should be sufficient to provide the user with the necessary information for safe use with a patient. Since a training cannot be provided, it is important that the manual provides the reader with concrete steps and accompanying visualizations.

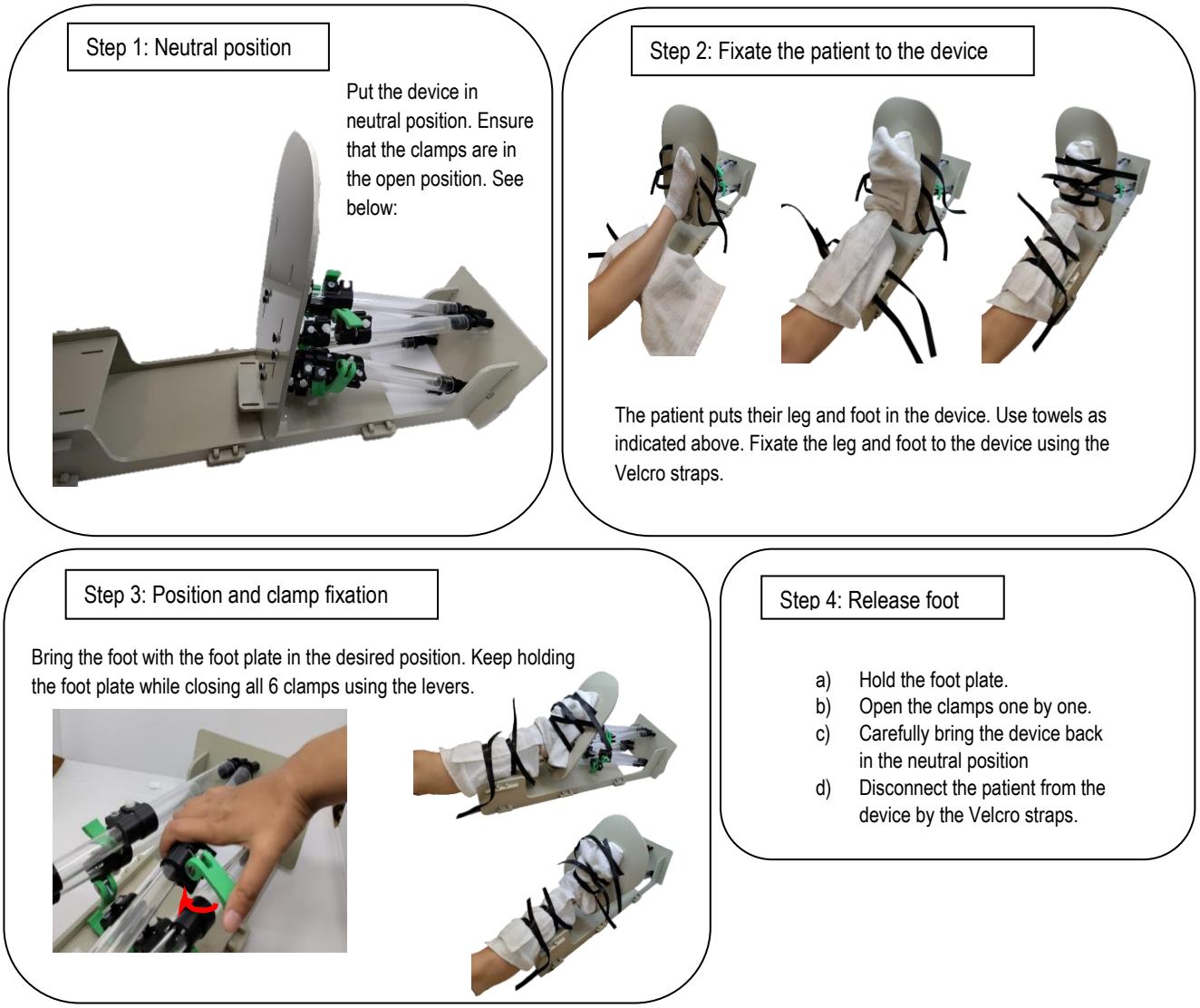


Figure 16: Overview of the Instructions for Use.

3.5.2 Bill of Materials

The Bill of Materials (BoM) contains a description of the components, necessary quantities and their costs. It also contains information about the supplier, manufacturer and a hyperlink of where to find and buy the components. It is important to provide the BoM for a maker to know where to find the components and how much of the component is needed. Table 6 and Table 7 contain parts of this information, excluding the supplier, manufacturer and hyperlink for conciseness. The extended BoM is shown in Appendix C.

Table 6: Bill of Materials for the custom-made laser cut parts

Component description	Quantity	Units
Base plate assembly		
Ground plate	1	pieces
Side plate	2	pieces
Leg support	1	pieces
Back plate	1	pieces
Locks	16	pieces
Foot plate assembly		
Foot plate	1	pieces
Heel support	1	pieces
Heel locks	3	pieces

Table 6 is specific to the laser cut PP components of the 3D Foot Plate. It is divided into the base plate assembly parts and the foot plate assembly parts.

Table 7: Bill of Materials for the off-the-shelf components

Component description	Quantity	Units	Cost	Total cost
Rods				
Thick PMMA rod - Ø25-21mm	6 * 175 mm	2 meter	€ 12,86	€ 12,86
Thin PMMA rod - Ø20-16mm	6 * 200 mm	2 meter	€ 11,91	€ 11,91
3D printed components				
Telescopic clamp	6	pieces	€ 0,93*	€ 0,93*
Telescopic lever	6	pieces	€ 2,90*	€ 2,90*
Connection clamp	6	pieces	€ 2,38*	€ 2,38*
Remaining components				
Ball-in-socket joint	6	pieces	€ 2,06	€ 12,36
Cardan	6	pieces	€ 6,19	€ 37,14
Tube insertion cap	6	pieces	€ 0,38	€ 1,88
Threaded insert	6	pieces	€ 0,49	€ 48,61**
RVS screw M6x12mm	6	pieces	€ 0,22	€ 1,32
Bolt with a cross nut	6	pieces	€ 0,70	€ 4,20
RVS screw M6x40mm	6	pieces	€ 0,13	€ 0,78
Nylon bolt M5	6	pieces	€ 1,66	€ 10,00
Nylon nut M5	6	pieces	€ 0,10	€ 0,60
Nylon bolt M6	12	pieces	€ 0,30	€ 3,60

Nylon nut M6	12	pieces	€ 0,10	€ 1,20
Nylon bolt M8x20mm	6	pieces	€ 0,55	€ 3,30
Rubber O-ring	6	pieces	€ 0,06	€ 3,79
Torx cap	6	pieces	€ 0,06	€ 0,72
Velcro	1	25 meter	€ 30,14	€ 30,14
Total				**€ 190,62**

* Based only on the material cost, excluding energy and maintenance costs
** Only available per 100 pieces

Table 7 is specific to the off-the-shelf and 3D-printed components. The table is divided into the rods, 3D-printed components and remaining components. The total price of the off-the-shelf components of the 3D Foot Plate comes to € 190,62. However it must be notes that the 3D-printed components are only calculated based on material price, obtained by the Ultimaker Cura software, and not on the energy and maintenance costs. Furthermore, the manufacturing costs are increased by the threaded insert only being available per 100 pieces. In conclusion, this Bill of Materials shows that the 3D Foot Plate is affordable to manufacture.

3.5.3 Assembly manual

To provide the maker of the device with instructions on the assembly of the 3D Foot Plate, an assembly manual has been created. The assembly manual is made as an IKEA-style manual to ensure errorless assembly through clear instructions and conspicuous warning signs. The assembly manual can be found in Appendix A.

3.5.4 MDR documentation

The MDR documentation for the 3D Foot Plate consists of the following files:

- Device Classification
- Design and Development file
- Bill of Materials
- GSPR checklist
- Hazard Traceability Matrix (risk analysis)
- Test report
- Instructions for Use (user manual)

The Device Classification file is used a support in the determination of the classification. This file has not been adjusted from the 2023 version, since there was no change in classification after the redesign. The Design and Development file is provided to declare all design changes made during the development of the medical device. This file has been used throughout the development process to track decisions and changes made. The Bill of Materials is also part of the MDR documentation. The extended Bill of Materials, as presented in the MDR documentation, can be found in Appendix C The GSPR checklist is a tool to document how a medical device meets the General Safety and Performance Requirements as prescribed by the MDR. This document was only slightly adjusted from the 2023 version by updating the references to files. The Hazard Traceability Matrix (risk analysis) file was adjusted as described in Appendix D The test report contains the information provided in section 3.6 of this thesis. The instructions for use are similar to the instructions provided in Figure 16.

3.6 EVALUATION OF FUNCTIONALITY AND USABILITY

Due to the design changes made after the redesign, a new prototype needed to be evaluated again. The functionality of the device was evaluated with three tests: friction test (requirement #8), release test (requirement #21) and usability test (requirement #1, #5 - #11, #14, #16 and #17). The ease of assembly (requirement #23) was evaluated with one test.

3.6.1 Performed tests

Test 1: Friction test

Goal: The aim of the friction test is to ensure that the new clamping mechanism consisting the telescopic clamp and the PMMA rods generates enough friction for the Stewart platform to stay in place when applying the maximum tensile force of at least 50N.
Methods: The clamp-rod assemblies (Figure 17) are pulled by an Unster with a resistance of at least 60 N, while the lever of the telescopic clamp is in a closed state. This is held for 2 minutes and repeated 10 times. All telescopic clamp-rod assemblies were tested.

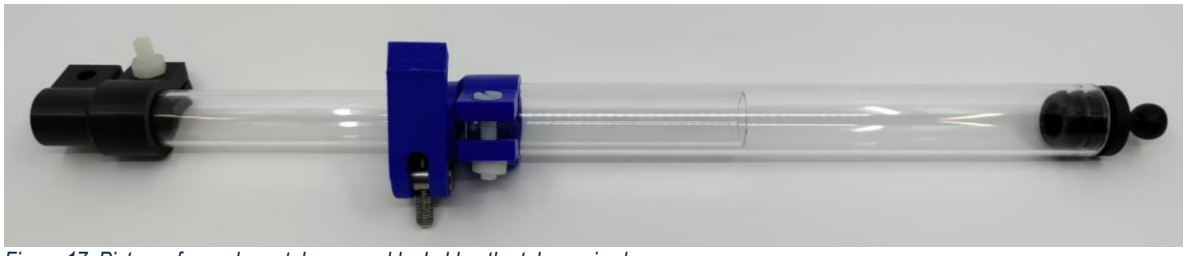


Figure 17: Picture of one clamp-tube assembly. In blue the telescopic clamp.

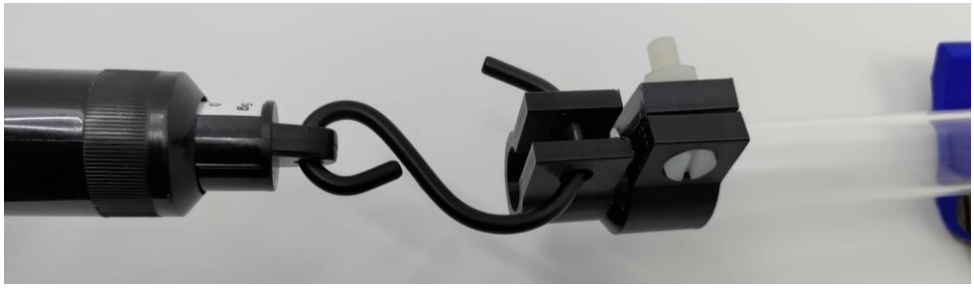


Figure 18: The hook of the Unster is pulled through the screw holes of the permanent clamp. Force is applied by pulling the Unster while the telescopic clamp is in closed-state.

Results:
The results are shown in Table 8. All attempts per clamp-rod assembly were successful.

Table 8: Overview containing the successfulness of the test per assembly and per test. "Yes" means that the test was successful and "No" means that the test was unsuccessful.

Assembly # /Attempt #	1	2	3	4	5	6	7	8	9	10
1	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Conclusion: All telescopic clamp assemblies can withstand 60N and the required force is 50N, meaning it can be concluded that the friction of the clamps is high enough to fixate the foot of a patient.

Test 2: Release test

Goal: The aim of the test is to validate/verify that the foot of the patient can be released from the device within a timespan of 7 seconds.

Methods: Two individuals were asked to participate in this test (Figure 19) by releasing a foot from the device three times. They were instructed to start releasing when the person in the device said "ow". Their times were recorded with a smartphone timer.

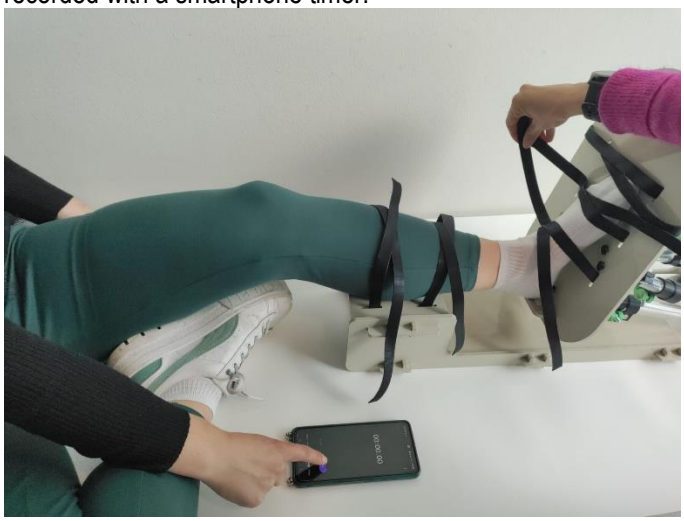


Figure 19: Release test, showing the foot in the 3D Foot Plate, an individual ready to release the foot and the smartphone timer used to record the time.

Results:

Person 1: 6.09 seconds, 5.46 seconds, 4.92 seconds.
Mean: 5.49 seconds

Person 2: 5.21 seconds, 5.04 seconds, 4.86 seconds.
Mean: 5.04 seconds

Conclusion: The foot was released within a timespan of 7 seconds for each attempt. As the results show, the amount of time decreased with each try.

Test 3: Usability test

Goal: The aim of the usability test is to again validate the usability of the 3D Foot Plate, because the fixation system has been changed.
Methods: The usability is tested through a demonstration by a clinician. The clinician was asked to position the foot in the neutral position, as well as plantar flexion and a position of their choice. The same clinician answered a short questionnaire.
The clinician testing the device answered the following questions:

1. On a scale of 1-5, to what extent can you perform the stress test as intended?
2. On a scale of 1-5, to what extent is it easy to operate the device by yourself?
3. On a scale of 1-5, how much effort does it take to operate the device? Both mentally and physically.
4. What is your opinion on the user manual?

Results:

Question	Answer
On a scale of 1-5, to what extent can you perform the stress test as intended?	4, the Velcro is too short to be properly operated.
On a scale of 1-5, to what extent is it easy to operate the device by yourself?	5, the clamps make it easy to operate the device with one person.
On a scale of 1-5, how much effort does it take to operate the device? Both mentally and physically.	Mentally 1. Physically 0.
What is your opinion on the user manual?	Overall good. The pictures need to include one with a foot in the device. There should be an instruction to use the device with a towel. The warning list includes two instances where materials fail. It should be more general: "If material fails, do not use the device."

Two additional remarks were made. (1) The clinician found the upper Velcro strap to not be useful, because it did not assist in the attachment of the foot. (2) The lower clamps are difficult to reach when the 3D Foot Plate is placed into a position close to the bottom of the device. The clinician was able to position the foot in the desired positions (Figure 20).

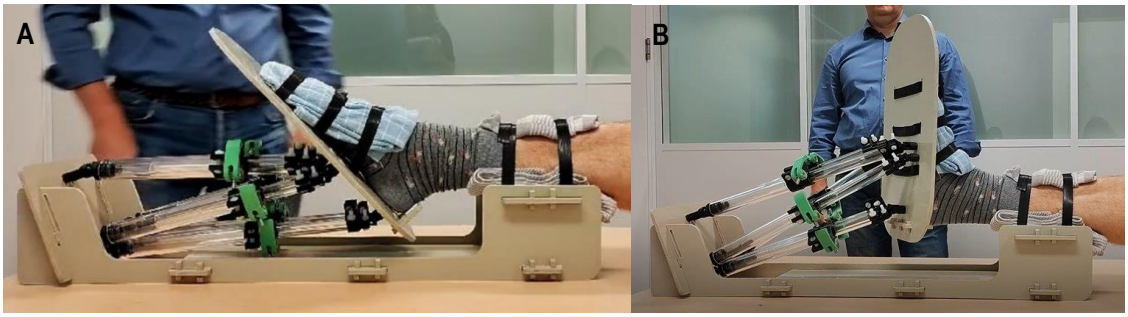


Figure 20: Usability test with a clinician. (A) The foot fixated in plantar flexion position. (B) The foot fixated in a position of the clinician's choice.

Conclusion: The Velcro straps need to be longer, which was immediately remedied by cutting new straps. It is difficult to reach the lower clamps. This has been compensated for by advising the user in the IFU to heighten the patient's foot in the device through an extra towel underneath the calf.

Test 4: Assembly test

Goal: The aim of the assembly test was to evaluate the ease of assembly of the 3D Foot Plate.
Methods: An individual was provided with the materials, assembly manual (Appendix A) and equipment for assembling the 3D Foot Plate. The equipment included: a set of screwdrivers, scissors, a nylon hammer and a bench vise. A recording was made to keep track of the assembly time and number of mistakes.

Results: The assembly took 50 minutes. Two mistakes were made: (1) an M5 bolt and nut were used for both sides of the small clamps, instead of an M5 for one side and an M6 for the other side and (2) the alignment of the cardan with the small clamp was incorrect.

Figure 21: Screenshot of the recorded assembly test. Shown are the assembly manual on the laptop, the materials and the equipment.

Figure 22: The picture displays the result of two errors made during the assembly test. In the white circle, the misalignment error can be viewed. The distance discrepancy is shown in red. The second error is indicated by the blue circle.

Conclusion: The mistakes made during the assembly test were not grave, but could be easily prevented by small changes in the assembly manual. Thereto, changes have been made in the assembly manual to emphasize the warning that is given for the alignment step.

3.6.2 Evaluation of requirements

In Table 9 an overview is provided on the compliance of the prototype per requirement. Some requirements have been evaluated through the testing, as mentioned in the previous section. Other requirements have been evaluated through the development process. The prototype meets most of the requirements. The design does not meet requirement #2 because the rods are 6mm too long. Requirement #23 is not fulfilled since there are three separate Velcro straps on the foot plate, which means that three movements are necessary to release the foot of the patient, the foot can be released within 7 seconds..

Requirement #12, #24 and #25 could not be tested.

Table 9: Requirements with indication (✓) whether the 3D Foot Plate meets them.

ID#	Requirements	Compliant
1	The device should be able to manually position the foot in extreme positions relative to the lower leg	✓
2	The device should be dimensioned such that it can be used to diagnose 95% of an adult human population.	
3	The device should be compatible with CT scanners	✓
3a	The device should be dimensioned such that it fitted into CT scanners	✓
3b	The device should be fabricated with materials that can be used in CT scanners	✓
4	The weight of the device should be a maximum of 12.7 kg to be portable	✓
5	The device should require a separate manual fixation mechanism to preserve the desired extreme position of the foot	✓
6	Different hand grips on the device should be allowed to apply manual loading.	✓
7	The device should offer fast operation below 100 s	✓
8	The device should be able to manually fixate the foot in extreme positions relative to the lower leg	✓
9	The operator should have a sense of control when using the device	✓
10	Excursions of the upper extremities of the radiology technician should be kept within limits	✓
11	It should be clear (unambiguous) how to position the lower leg and the foot in the device	✓
12	The total acquisition time should not be increased by more than a maximum of 10-15 % when using the device	
13	Fixating the foot should not create additional damage to the ligaments	✓
14	The foot should be positioned in an extreme position mimicking a clinical stress test	✓
15	The device should have a professional appearance and blend into the working environment	
16	The device should be operated by one person	✓
17	The device should be operated with minor physical and mental effort	✓
18	The materials that come into contact with the patient must be biocompatible	✓
19	Use as much as possible off-the-shelf components	✓
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	
22	The device must be easy to clean	✓
23	The device should be easy to assemble by providing instructions through the generation of manuals and the material specifications	✓
24	The device should at least be functional for 1 year without maintenance	
25	The device should not break when accidently falling during transport	
26	The device should only be used by someone with a medical background who has also received training in stress testing	✓
27	Only use production methods that are easy to order online and require a minimum of engineering expertise	✓
28	The device should not have sharp edges	✓
29	The manufacturing of the device does not require glue	✓

CHAPTER 4: MEDICAL DEVICES WITHOUT BUSINESS CASE

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Key words: Open-Source Medical Devices, OSMD, Medical Device Regulation, MDR, Open-Source Hardware, OSHW, OSH, Class I medical devices

ABSTRACT

Medical devices intended for a small patient population have difficulty entering the market, since the relatively high development costs do not outweigh the expected low sales numbers. With the introduction of the Medical Device Regulation, which is more strict, additional costs are required to provide more evidence regarding clinical benefit. Offering these medical devices open source is an interesting route to explore; as is shared in-house development. The aim of this research was to generate clarity on the position of the legal manufacturer and necessary documentation to offer medical devices via these routes. Two research questions have been answered: (1) “Who is the legal manufacturer and how do we deal with liability?”, (2) “Which (MDR) documentation is minimally required to offer medical devices open source while taking care of MDR compliance?”. This was performed via interviews and focus groups (10 persons with a medical technology background, who are familiar with the MDR) discussing three cases of medical devices Class I. For every case it was found that the experts’ opinions were divided. Case 1 is an accessory tool to be used in a CT scanner offered via an open-source platform. The leading opinion for this case (5 out of 10 experts) was to assign the legal manufacturer role to the recipient, via the in-house development route. 3 out 10 experts placed this role on the donator of the design and documentation. 2 out of 10 experts found the scenario unfeasible. Intended use and risk analysis documentation were mentioned most frequently as necessary for MDR compliance. Case 2 is an in-house developed surgical tool whose documentation is shared with another University Medical Centre to manufacture the surgical tool in house. 3 out of 10 experts indicate the legal manufacturer role onto the hospital that manufactures the surgical tool. 3 out of 10 experts found the scenario unfeasible. 2 out of 10 experts did not provide their opinion. 1 out of 10 experts suggested a shared role between both involves parties. 1 out of 10 experts placed the legal manufacturer role onto the donator. Intended use, risk analysis, assembly manual, Instructions for Use, General Safety and Performance Requirements, Bill of Materials, design and development file and CAD files were all mentioned as mandatory by 4 out of 10 experts. Case 3 is a hand-assistive device that is partly manufactured by a company and partly by occupational therapists or the patient. 3 out of 10 experts assigned the legal manufacturer role to the occupational therapist. 3 out of 10 experts found the scenario unfeasible. 2 our of 10 experts placed the legal manufacturer role onto the company. 1 out of 10 experts suggested a shared legal manufacturer role between the company and occupational therapist. 1 out 10 experts did not provide their opinion. The most frequently mentioned documentation for this case is an assembly manual. Results show that experts do not necessarily agree on how to deal with MDR-compliance for open-source medical devices. Suggestions are to work out individual cases in detail to gradually develop more clarity when and how it is suitable to offer a Class I device as open-source medical device.

4.1 INTRODUCTION

Medical devices developed for small patient populations, or only used in complex clinical cases and research settings, have difficulties entering the market. The reason is that the development costs do not offer return on investment with low sales volume. Thus, such medical devices are commercially non-viable. The stricter Medical Device Regulation (MDR) [30] contributes to this, since it requires to show clinical benefit and more documentation to adhere to the MDR, leading to even higher development costs [31–33]. To facilitate that such medical devices still end up with the patients or clinicians that need them, alternative routes are explored: open-source medical devices (OSMDs) and in-house manufacturing.

When following such alternative routes within the EU, still the medical devices need to comply with the MDR [5]. According to the best practices guidance of The European Association of Medical Devices Notified Bodies [34], the following technical documentation is minimally required for all medical device classifications: Device Description and Specifications, Declaration of Conformity, Labelling, Instructions for Use, Design and Manufacturing Information, General Safety and Performance Requirements, Benefit Risk Analysis and Risk Management, Product Verification and Validation, Clinical Evaluation, Post Market Surveillance.

According to De Maria et al. (2022) the definition of an OSMD is as follows [4]: "… a medical device whose design and product development information are made publicly available so that anyone can study, modify, distribute, make, and sell the medical devices, and their related software or hardware, based on the initial available design and information". De Maria et al. also highlighted preconditions for sharing the OSMDs:

- Formats that enable validation, verification and modification;
- Usage of widely available materials and components;
- Design performed according to international safety standards and processes aimed at guaranteeing patients' safety;

Open-source hardware (OSHW) has become increasingly available on open-source platforms [10], such as Careables.org [3] and Hulpmiddelentips.nl [35]Analysis of these platforms shows that medical devices are predominantly offered for assistive devices during rehabilitation, such as a spoon for eating adopted to grip of a single patient, while for example surgical tools are not present. Furthermore, the available documentation for OSMDs, do not comply with the MDR, as most are missing or incomplete [5,36].

Shared in-house manufacturing, defined as the transfer of the design and documentation of an in-house manufactured medical device from one health institution to another, is potentially another alternative route. Boyle et al. (2024) researched regulatory routes for in-house manufacturing [37], in which a comparison was made between in-house exemption, custom-made and full regulatory application. Article 5(5) in the MDR [30,38], applies to in-house manufacturing of medical devices by health institutions. In-house development has an exemption to the full regulatory application for health institutions, provided that the conditions described in Article 5(5) (a-h) have been met [30]. While most of the requirements of full regulatory application must be met, some requirements are less strict for the exemption. What this specifically entails is the following [37]: the Quality Management System (QMS) is less strict, in the sense that for full application ISO 13485 must be complied with, while for the in-house exemption an 'appropriate' QMS needs to be in place [39]. Instead a declaration of conformity and documentation of the design and performance has to be provided compared to exhaustive Technical Documentation for full regulatory application. Furthermore, there are no defined requirements for the person that is responsible for MDR compliance or for the clinical evaluation. However, this is usually a designated role in hospitals. Moreover, no Unique Device Identifier (UDI) nor Conformité Européenne (CE) mark is required. Importantly, the GSPR compliance is as strict as for full regulatory application and risk management is still required as part of the QMS [38]. Therefore, the Technical Documentation must still include a risk assessment. A downside to in-house medical devices is that in-house devices can then only be used within the

legal entity in which the medical device is developed. The University Medical Centres in the Netherlands usually have their own Research & Development (R&D) department for in-house development of unique medical devices. These departments are familiar with the MDR and accompanying documentation requirements. Two of these R&D departments are also ISO 13485 certified [40,41], which would make a transfer of documentation relatively efficient if a certified development site already prepared the necessary documentation. With the reduced workload, shared in-house development is a serious option to consider for medical devices that are to be used within the hospital environment.

This study aims to generate clarity on the feasibility and preconditions of offering medical devices in these two alternative ways by focusing on three cases and answering two main research questions: (1) Who is the legal manufacturer and how do we deal with liability?, (2) Which MDR documentation is minimally required to offer the device in the proposed route (either as OSMD or shared in-house)?.

4.2 METHODS

10 Dutch medical device experts were interviewed. All experts were approached via e-mail. The inclusion criteria of the experts were: a medical technology background and experience in using the MDR, for example as quality manager. The study focused on Medical Device Class I devices, and to ensure coverage of a variety of medical devices, three cases were analysed: 3D Foot Plate (Class I), Hedgehog Tool (Class Is) and T-GRIP (Class I).

The following information was provided to the experts per case in order of sequence:

1. Clinical need
2. Intended use
3. Manufacturing methods
4. Scenario to make the device publicly available

An overview of this information per case is provided below. The first paragraph consists of information on the clinical need, intended use and manufacturing methods. The second paragraph contains the information on the scenario to make the device publicly available.

Case 1: 3D Foot Plate

Currently, laxity and instability of the hindfoot is diagnosed through a manual stress test by a clinician [20]. However, this test cannot distinguish between talocrural instability, subtalar instability or a combination of these. Moreover, in case of complex problems in the hindfoot, quantitative data is necessary. Therefore, the 3D CT-stress test has been developed [22]. This test mimics the manual stress test. Thereto, the 3D Foot Plate positions the foot relative to the lower leg and holds this position while performing 3D imaging to obtain quantitative data of the relative positions of the bones [8]. The foot can be readjusted to a new position to acquire additional 3D images, e.g. CT scan. The 3D Foot Plate (Figure 23) is meant to be cleaned and disinfected, but does not have to be sterilised before and after use.

The 3D Foot Plate will only be used in specific complex clinical cases and therefore is useful for a small patient group, which means that no business case can be made. Therefore, the 3D Foot Plate is aimed to be offered on an open-source platform. These platforms offer designs of do-it-yourself (borderline) medical devices by designers. We aim to offer it on a platform for hospitals to access the CAD (Computer-Aided Design) files and assembly manual, with the intention to have the manufacturing be performed by the hospital themselves. The manufacturing method of the 3D Foot Plate is characterised as an IKEA style assembly method without needing specialized tools or manufacturing methods. Some components are laser cut or 3D-printed, which can be outsourced or manufactured by the hospital, while all other components are off-the-shelf and provided in a Bill of Materials.

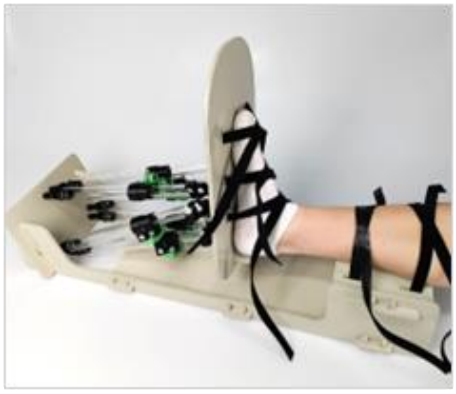

Figure 23: Picture of the redesigned 3D Foot Plate.

Case 2: The Hedgehog Tool

The Hedgehog Tool (Figure 2) is developed by IDEE, the R&D department of Maastricht University Medical Centre (MUMC), to aid the Hedgehog Autograft Technique [42]. This surgical technique can be used to reattach relatively large chondral fragments in paediatric patients' knees. The technique requires the surgeon to make incisions by hand in the sheared-off cartilage flake, which should promote healing when reattached. Challenges of this manual incision technique include time consumption, uneven incision distribution and possibility of cutting all the way through the chondral fragment [43]. A reusable surgical tool called the Hedgehog Tool [43] has been developed to overcome these problems Figure 24. This surgical tool acts similar to an egg-cutter to make parallel incisions in a sufficiently superficial and even way. The manufacturing of the Hedgehog Tool is performed by CNC machining in six parts from Stainless Steel 316L. Sterilization is performed by the Central Sterilization Department (CSD). During surgery, the assembly is performed in the Operation Room (OR) by the OR assistant, during which disposable surgical blades commonly available in the OR are inserted in the Hedgehog Tool.

Since the Hedgehog Tool can only be used in the specific situation of a pure shear-off in paediatric knees with therefore a small patient population (6.09 cases per 100,000 person-year), it is difficult to develop a business case. The Hedgehog Tool is being developed at IDEE, part of MUMC+, under the health institution exemption rule 5.5 of the MDR [39]. Therefore, the Hedgehog Tool can only be used within the MUMC+. To offer this medical device in an alternative way, the proposed route for the Hedgehog Tool is transferring the design and documentation with other UMCs, allowing the receiving UMC to manufacture the device themselves.

Figure 24: A picture of the Hedgehog Tool.

Case 3: The T-GRIP

Spinal cord injury (SCI) patients can experience impaired hand function and can lose the ability to pick up objects. The T-GRIP device [44] (Figure 25) has been developed as a robotic thumb exoskeleton to assist the hand in achieving lateral pinch grip. It is meant to be used for activities of daily living (ADL) in a home environment. The current design of the T-GRIP consists of three main parts: (1) 3D-printed hand parts, (2) a motor and (3) a control unit. The 3D-printed parts are required to be fitted to the patient's hand, which is done with metal rods in different sizes and curves. A motor is mounted to the hand parts and connected to the control unit. The patient can decide for themselves whether they prefer to operate the T-GRIP with a smartphone, smartwatch or the buttons on the control unit. Even though the T-GRIP is operated with a linear actuator, we consider it to be a Class I medical device, because the force it can generate is lower than the force generated by a healthy individual.

Similar to the other previously mentioned cases, the patient population for the T-GRIP is small I, which means that this product will likely be commercially non-viable. The initial patient population consists of 500 patients in the Netherlands, with an incidence of 20 patients each year [45] An additional challenge is the fitting procedure, which increases the effort to bring the T-GRIP to the market. Therefore, opportunities for alternative routes are explored. An alternative route is that the company or an external third-party sells the motor and control unit to the patient or occupational therapist and that the other (custom) parts are manufactured by the patient or occupational therapist themselves. Similarly, the fitting and calibration of the T-GRIP are outsourced to the patient or occupational therapist.

Figure 25: The T-GRIP by Hankamp Rehab.

Data collection, review and analysis

The researcher used a set of slides to introduce the topic and its aim, as well as to provide background information for each case. After each case was introduced, spoken data was collected by first asking what the experts in general thought of the case and followed by the two set research questions: (1) “Who is the legal manufacturer and how do we deal with liability?”, (2) “Which MDR documentation is minimally required to offer the device in the proposed route (either as OSMD or shared in-house)?”.

The data were obtained with a set of semi-structured interviews and two focus groups. 7 out of 9 sessions (including focus groups) were held online via Microsoft Teams. Permission was granted for all interviews to be recorded and transcribed, using the Microsoft Teams transcription software for the online interviews and the Microsoft Word transcription function for the on-site interviews. The transcripts were reviewed and edited where necessary, which included the removal of stammering and manual corrections on errors introduced by the transcription software.

The data were analysed using reflexive thematic analysis [46]. The following two domains were established: (1) Legal manufacturer positioning and liability (including related generic opinions), and (2) necessary MDR documentation. For the data of Domain 1, summaries were created per case. The data for Domain 2 was organized by tallying the number of documentation type mentioned per expert. The results are set out in per domain and per case within those domains including translated quotes. The original Dutch quotes are included in Appendix E.

4.3 RESULTS

Domain 1: Legal manufacturer and liability

For clarity, the roles within the alternatives routes have been defined as 'recipient': the receiver of the design and documentation, and 'donator': the person or organisation that offers the design and documentation. For none of the cases there was consensus between the experts on the position of the legal manufacturer. In Table 1 an overview is provided on the heterogeneity of the opinions of the experts regarding the three cases.

Case 1

There was no consensus between the experts about the position of the legal manufacturer for the 3D Foot Plate. The divided opinions were as follows:

5 out of 10 experts said that the legal manufacturer should be positioned with the recipient, in this case hospital that uses the device. Those experts also mentioned that the hospital can consider the device as an in-house medical device under the health institution exemption rule which is described in Article 5(5) of the MDR. Liability issues that were considered are: the reliability of the parts and ease of assembly of the device, that is potential errors or mistakes that can occur when assembling. A suggested precondition to ensure patient safety was to include a strict incoming goods inspection and validate the assembly process within the hospital that is assigned as legal manufacturer.

3 out of 10 experts would place the legal manufacturer position on the donator, in this case the person or organisation that offers the 3D Footplate design along with the documentation on an open-source platform. One expert said: *"Be aware that the moment you make a medical claim and you place something on the market, you are selling something. This also applies when you place something on the market for free. In that case, you are the legal manufacturer and a lot of obligations suddenly come your way. You have to be careful with that."* [Appendix E, Quote 1]

2 out of 10 experts expressed that the case was not feasible in their opinion due to the inability to conduct a post-market follow-up and recall procedure.

Case 2

Similarly to Case 1, there was no consensus between the experts for the Hedgehog Tool. A reflection of the divided opinions can be found below.

3 out of 10 experts found the recipient house were to be the legal manufacturer, in this case the health institution that receives the design and documentation. In order to comply with patient safety, it was mentioned that extensive sterility and reprocessing testing should be done by this health institution within their own cleaning and sterilisation workflows. Moreover, experts mentioned that the donator, in this case MUMC+, has the obligations to alert the receiving hospital about the transfer of responsibilities along with the transfer of the device design and documentation. Quotes that represent this opinion are shown below:

"In principle, it is possible for a hospital to share a development with another hospital, who can then produce it in-house. But how can they demonstrate sterility? Secondly, this is an instrument meant for reprocessing. Therefore, it is an instrument that will be repeatedly sterilised and reused. Has it been shown that the product can be sterilized a hundred times without losing its functionality? These are things that need to be done. I am all for in-house development in hospitals, including sharing their knowledge. Especially for commercially non-viable products. […] But I am placing this footnote with it: do it right." [Appendix E, Quote 2]

As a reaction to the question which UMC has full liability in case of issues after transfer: *"The hospital that manufactures the device is liable, because as soon as we are talking about in-house development, liability lies with that hospital. [The original developer] should not say: 'Here is a device and we guarantee that it works, everything has been done and if you use it this way everything will be fine.' They should not make that claim. [They should say]: 'We will share the device with you, but you yourselves are responsible for what you do with it.' That has to be very clear."* [Appendix E, Quote 3]

3 out of 10 experts expressed that the case was not feasible in their opinion due to the fact that by their gut-feeling the tool is a more complex medical device compared to the 3D Foot Plate since it is used in the OR and needs to be sterilised. Moreover, they thought that it would be too costly to perform tests, such as biocompatibility testing, in each hospital that the design of the device is transferred to. Therefore, in their opinion there would be no benefit to shared in-house development over regular in-house development.

2 out of 10 experts did not provide their opinion.

1 out of 10 experts suggested a shared legal manufacturer position with all participating UMC acting as one legal entity. In this case, the involvement of the other UMCs should happen before the device is put into service anywhere. The liability will be shared as established in agreement set by all legal departments of the participating UMCs.

1 out of 10 experts thought that the original developer of the device should act as the legal manufacturer.

Case 3

In line with the other cases, the opinions for Case 3 were divided as well.

3 out of 10 experts indicate that the set scenario the occupational therapist will become the legal manufacturers when they 3D print parts of the device and perform the fitting of the device to the patient. One of the experts with the opinion said the following: *"I believe that when you [the occupational therapist, red) transfer the medical device to the patient in this way, as a custom-made device, then you are responsible, and you are the legal manufacturer."* [Appendix E, Quote 4]

3 out of 10 experts found the case not feasible. Reasons for this opinion included the concerns regarding the legal burden on occupational therapists, the fear that the company would try to avoid responsibility and the fact that the T-GRIP is intended to stay on the patient's hand frequently and for a prolonged time. The following quote from an expert with this opinion: *"I would not suggest it as a DIY product, because they [the occupational therapist, red) might use a different 3D printer and a different printer means that the materials will act differently. Preferably, you would like to have the same grains, the same printer […] Then with a bit of luck, you can even use the tests of the material for the 3D printer plus that specific printer. Especially because [the device] is in contact with the [patient's, red) hands for an extended amount of time. I would stay away from placing the responsibility with hospitals, or occupational therapists, or something. Mostly because, if you look outside of hospitals, most people have no idea what the MDR is."* [Appendix E, Quote 7]

2 out of 10 experts thought that the company should take the legal manufacturer role due to the company's two-part responsibility: assuring the quality of their sold control unit, and ensuring that the fitting and calibration is performed well. The following quote reflects this opinion: *"The control unit is bought by the patient. And as it is purchased, therefore someone is bringing the product to the market. And if it has a medical purpose, then it is a medical device. Therefore, the responsibility lies with the entity that made the control unit to ensure that it is done appropriately. And someone else assembles the device. Then the company has to check: 'Do we have a manual? Do we have to train the occupational therapists?' Those sorts of issues. In this case, [the company]*

takes on a lot of responsibility, because they have to ensure it is done right and executed well in practice." [Appendix E, Quote 5]

1 out of 10 experts suggested a shared legal manufacturer role between the company and occupational therapists, in which the company would sell a license to the occupational therapist to fit the device to the patient. That would mean that the occupational therapist is responsible to execute the fitting according to the instruction provided by the company. In the expert's words: *"Maybe it is possible [for the company] to say: 'I sell some sort of license to the occupational therapist.' If the occupational therapist uses the device and fits the device completely according to the manual, then they [the occupational therapists] are relieved of their responsibility. Apart from their normal responsibilities as a healthcare professional, of course."* [Appendix E, Quote 6]

Multiple of these experts who found the case feasible set a precondition to increase patient safety by posing the necessity of offering a training for the fitting and calibration of the T-GRIP, arranged by the company.

1 out of 10 experts did not provide his/her opinion.

Table 10: An overview of the opinions expressed by experts per case on the position of the legal manufacturer.

Cases	# experts	Legal manufacturer
Case 1	5 out of 10	Recipient
	3 out of 10	Donator
	2 out of 10	Scenario not feasible
Case 2	3 out of 10	Recipient
	3 out of 10	Scenario not feasible
	2 out of 10	Opinion not provided
	1 out of 10	Shared position
	1 out of 10	Donator
Case 3	3 out of 10	Occupational therapist
	3 out of 10	Scenario not feasible
	2 out of 10	Company
	1 out of 10	Shared position
	1 out of 10	Opinion not provided

Domain 2: Necessary (MDR) documentation

On overview of the experts' opinions on which documentation is necessary to facilitate the scenario presented for each case is presented in Table 11.

Table 11: Inventory of the number of experts that thought specific documentation needed to be provided in order to facilitate the scenario for case 1. RSK = Risk Analysis, IFU = Instruction for Use, GSPRs = General Safety and Performance Requirements, BoM = Bill. The assembly manual, IFU, BoM and CAD files were already mentioned by the researcher and that these would be provided on an open-source platform. Therefore, these categories contain a '-'.

Documentation	Intended Use	RSK	Assembly Manual	IFU	GSPRs	BoM	DesDev	CAD files
# occurrence for 3D Foot Plate	6	7	-	-	2	-	3	-
# occurrence for Hedgehog Tool	4	4	4	4	4	4	4	4
# occurrence for T-Grip	0	3	4	3	1	1	0	0

4.4 DISCUSSION

Analysis of the different cases shows that Case 1 the 3D Foot Plate is found the most feasible case (8 out of 10 of the experts agree), which can be explained by the fact that by their gut feeling and expert assessment the risks of the 3D Foot Plate are lowest, because experts could imagine immediate measures taken to mitigate risks related to manufacturing and assembly when its intended user is trained professionals in a clinical setting. 5 out of 10 experts thought that Case 2 was a feasible case. As mentioned above, it could be explained by the contrast in application between the 3D Foot Plate and the Hedgehog Tool. The Hedgehog Tool is used in the OR, and requires validated sterilisation and reprocessing procedures, which could be associated with more risk. 6 out of 10 experts found Case 3 to be feasible. Experts did express that they were worried that suggesting the alternative route proposed for Case 3, might allow the company to walk away from their responsibilities and force those responsibilities on the occupational therapist. Therefore, the lower feasibility rate can be explained by the expert's concerns about liability issues for occupational therapists. de Jong et al. (2023) found that occupational therapists usually do not have enough knowledge about the MDR and its impact on the work of occupational therapists [47]. This study again highlights the importance of the suggestion by de Jong et al., namely to train individuals in working with the MDR and apply it to their work. For understanding an applying the MDR is vital for occupational therapist in the application of novel technologies and could very well be supported through collaborations with companies.

The results for the necessary documentation domain show a necessity for all documentation types for Case 1 and Case 2. For Case 3, less documentation types were mentioned. Many experts said that they found Case 3 to be more complex due to the presentation of different options regarding the involvement of multiple parties than the other cases. Based on this, it is possible that it was too difficult to provide an opinion instantly, which could explain the low amount of documentation types mentioned. For Case 1, it should be noted that the interviewer already suggested that the assembly manual, IFU, BoM and CAD files would be provided when presenting the case. As a result, it is be possible that less experts mentioned these documentation types. The results in Table 11 are also influenced by whether the expert thought the case was feasible. If the case was deemed unfeasible by an expert, the documentation requirements were not provided.

Analysing the cases together, the preconditions for considering alternative regulatory routes include, certainty that no business case can be made, that the number of devices needed is only a few per year and that the validation of processes is performed well to ensure patient safety. Notably, some experts were unsure about the classification of the Hedgehog Tool as Class Ir. During the interview, the researcher had to provide more information on this medical device to convince the expert of its classification. Furthermore, from observing hesitation in general shown by experts and how in three instances experts could not provide an opinion, it has become clear that the presentation of the cases might not have been detailed enough for the experts to assess them. A suggestion for future research is to provide the experts with all relevant information upfront for experts to gain a clear understanding of the risks, risk mitigation, and how patient safety is guaranteed.

The sample size (N = 10) is small and it would have been valuable to gain more opinions. However, as known in focus groups and interview saturation can occur, which means that no new information is gained after a while. The method of this study, regarding the sample size, is therefore in line with common practices. Multiple experts advised interviewing jurists with affinity to the MDR to gain their expertise. However, it was not possible to find a jurist with those specifications within the timespan of this research. It seems that the availability of specialised MDR jurists is not as established yet. A recommendation for future research is to perform this study with focus groups consisting of medical technology experts and MDR specialized jurists. Other institutes and organisations are useful to involve in this are IGJ, DEKRA and EMA.

Recently, other papers have been published on the topic of the MDR and how to navigate this relatively new legislation. Carl et al. (2024) explores which challenges the orthopaedic aids industry is faced with and their impact following the implementation of the MDR [48]. Ariza et al. (2022) identified issues and challenges, among which the MDR is named, in using open-source hardware for assistive devices [36]. the current study takes the next step by proposing a method that can eventually expert opinion for the previously identified challenges. Han et al. (2024) mapped various complexities of the MDR, of which its interpretation is one of the themes discussed [49]. Expanding on the findings of that research, the aim of this current study was to gain clarity on this specific topic by asking experts their interpretation of the MDR.

To conclude, this study aimed to gain generate clarity on the feasibility of offering medical devices in two alternative ways: open-source and shared in-house development. Experts do not necessarily provide consensus, not only whether they found the cases feasible but also where the legal manufacturer should be positioned and which (MDR) documentation is minimally necessary. Therefore, it has become clear that cases should be presented in greater detail and preferably in advance to medical technology expert and specialized MDR jurists, before it is possible to provide any clear guidelines. This study has taken a first step towards providing a method to assess the feasibility of a variety of Class I medical devices in cases where they can be offered as OSMDs or through shared in-house development when no business case can be made. With an improved methodology, this strategy has the potential to be useful in assisting the analysis of more cases and eventually providing policymakers with the tools to create guidelines for medical devices without business case.

CHAPTER 5: THESIS DISCUSSION AND CONCLUSION

The limitations of the analysis of expert opinions on regulatory routes for three cases have been discussed in Chapter 4. The limitations for the platform search and 3D Foot Plate redesign are discussed below.

A limitation of the platform search is that only English search terms were used, which could be the reason not many other European language platforms next to French were found. Another issue that arose during the Internet search is that Google was only showing the first 20 results, while still indicating that more results were found. It is advisable to perform the same search in other browsers or with different search engines for future research. Another limitation is that the criteria were not weighted. This might have resulted into one of the two most suitable platforms scoring higher than the other platform. As Careables is a platform available in English, it is selected as the more accessible platform compared to Hulpmiddelentips.nl.

Even though the prototype is functional, the laser cutting settings (Appendix F) used are not ideal in two ways: a post-processing was required and two rounds of laser cutting was necessary to cut through entirely. For the post-processing step, a putty knife was used to scratch off the jagged edges. These jagged edges were created due to slight 'melting' of the PP. However, since this manufacturing step will most likely be outsourced to a company specialised in laser cutting, this will not cause an issue. Another limitation of this version of the 3D Foot Plate, is that it is not suitable for imaging systems like an MRI scanner, since it contains metal in three parts of the Stewart platform.

Comparing other features of the prototype before and after the redesign, substantial improvements have been made in the following ways: more off-the-shelf components, less preprocessing steps, less time-consuming manufacturing steps, less specialised tools and skills necessary and no glue. Furthermore, the new prototype is proven by a clinician to have an increased usability, while still meeting the functional requirements. By meeting the requirements set up by D. van Elst (2023) related to the MDR and having adjusted the MDR documentation, complete MDR compliance is achieved.

It important to note that this research is intended to facilitate in offering medical devices without business case, while also complying with the MDR. This research is not intended as a workaround around the MDR and patient safety must be guaranteed as long as a device is classified as medical device and offered in the EU. As mentioned in Chapter 1, OSMDs are already being offered on open-source platforms, but do not comply with the MDR. Because patient safety is vital, this research has addressed ways to ensure MDR-compliance, while still all benefitting from the open-source approach. This has been shown in Chapter 3 through the redesign of the 3D Foot Plate, which is proven to be low-cost, easy to manufacture through a Bill of Materials and assembly manual, while still meeting the requirements set up for compliance with the MDR. Through expert opinion it has been identified that the in-house manufacturing route is suitable for offering the 3D Foot Plate through the Careables platform.

To conclude, this research has identified a suitable open-source platforms to offer a medical device, which has been redesigned to be offered as open-source medical device, and expert opinion has provided a regulatory route to ensure MDR compliance. The 3D Foot Plate design and documentation can be placed on the Carebles platform, and can be manufactured by a hospital through the in-house regulatory route.

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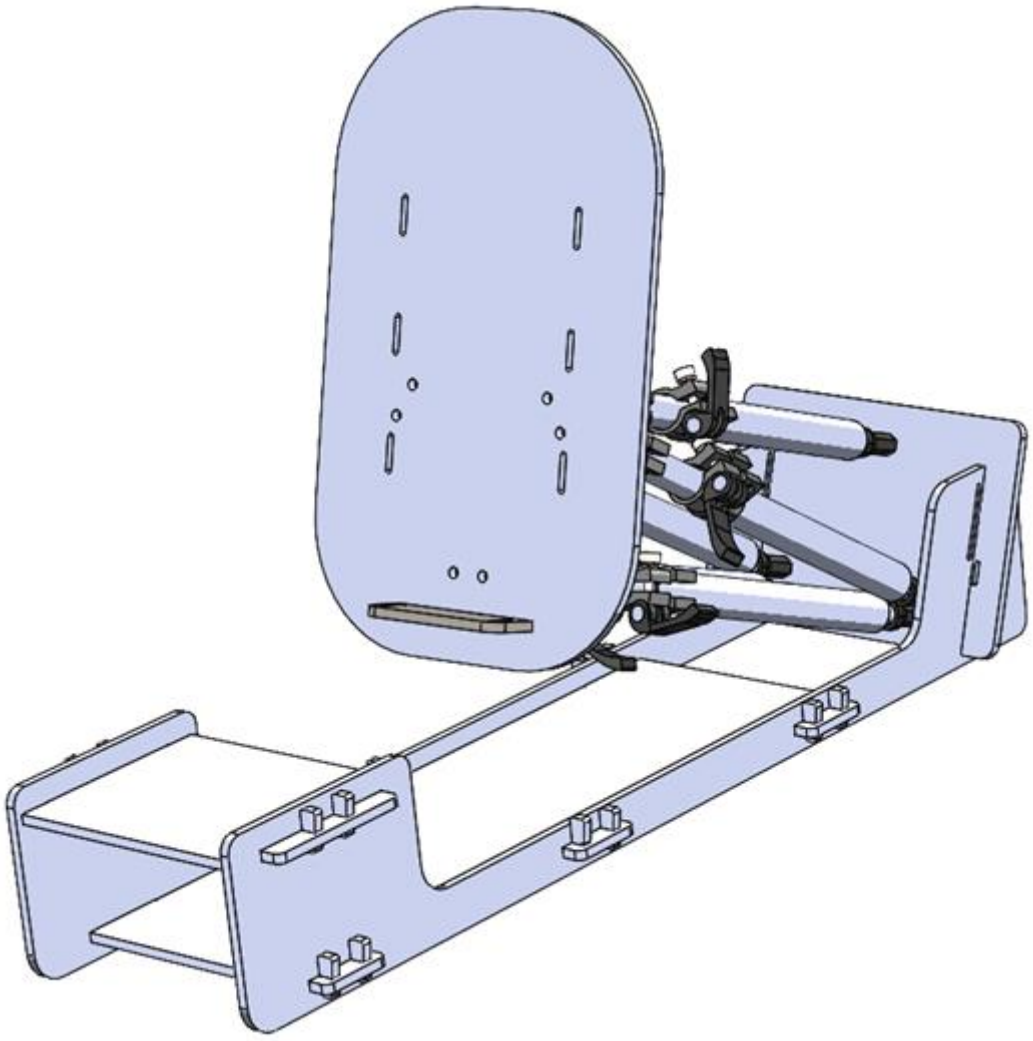
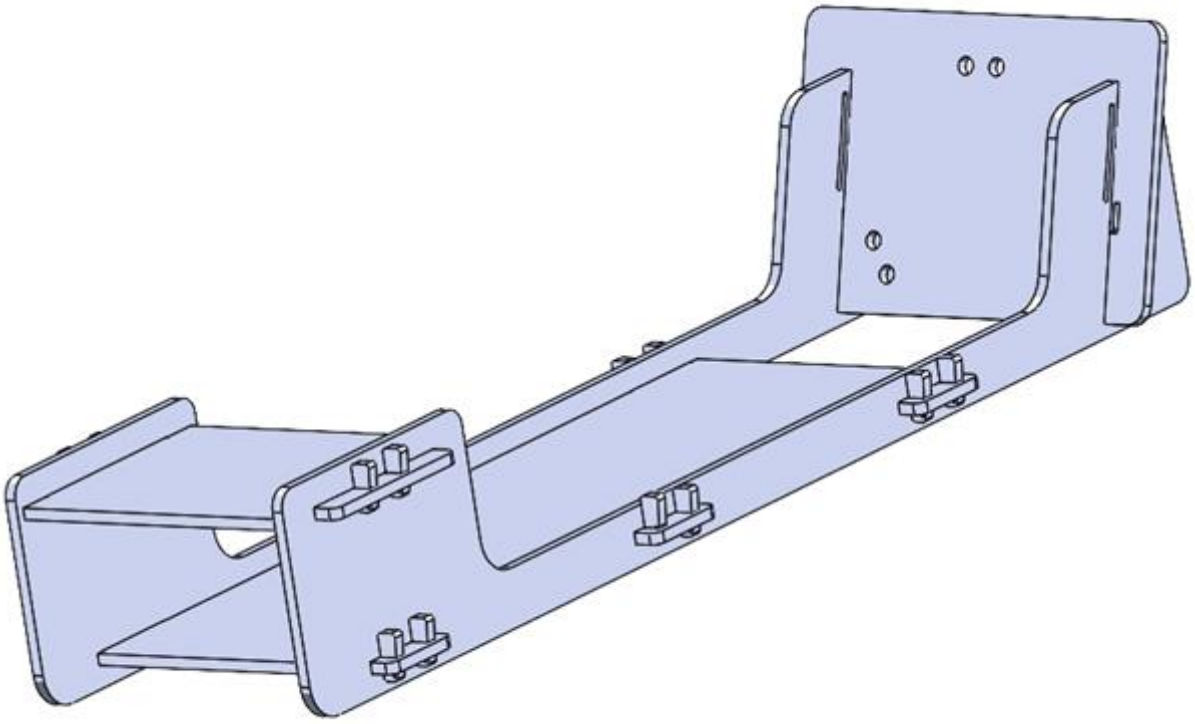
APPENDIX A: ASSEMBLY MANUAL

Manual for assembly of the 3D Foot Plate

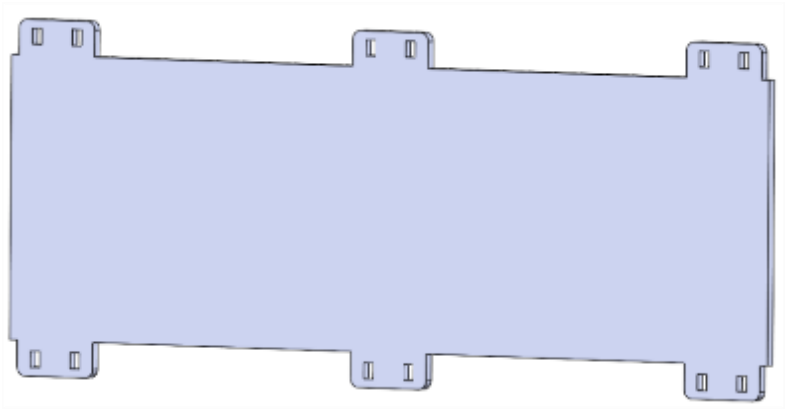


PART 1

Ground plate



Parts used



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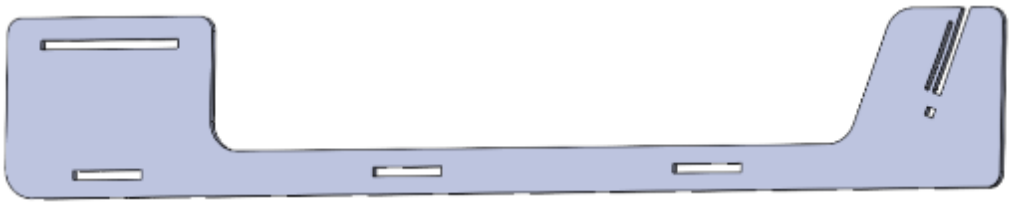

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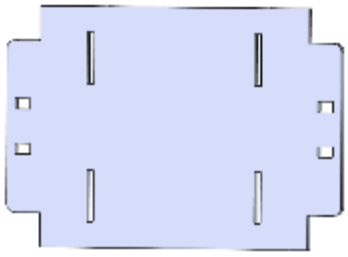

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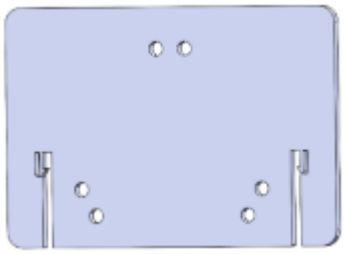

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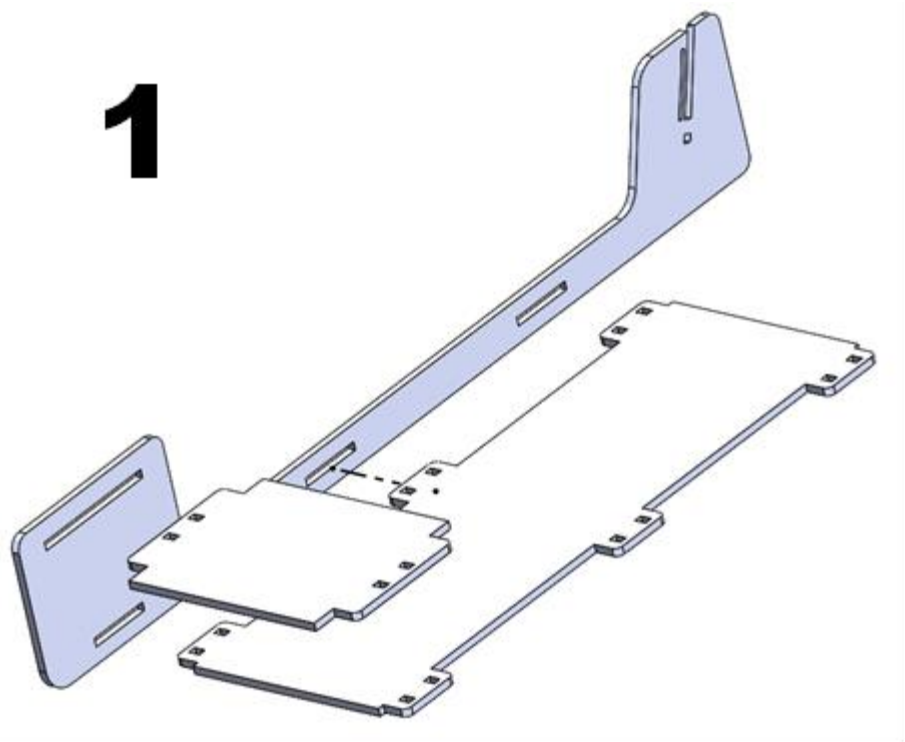
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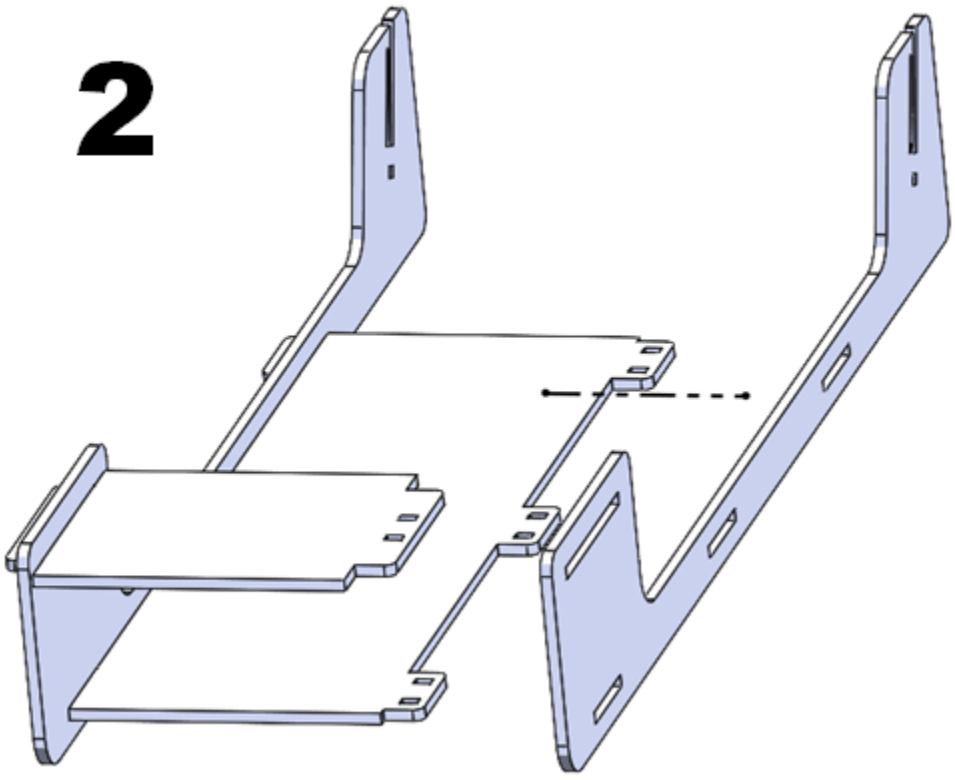
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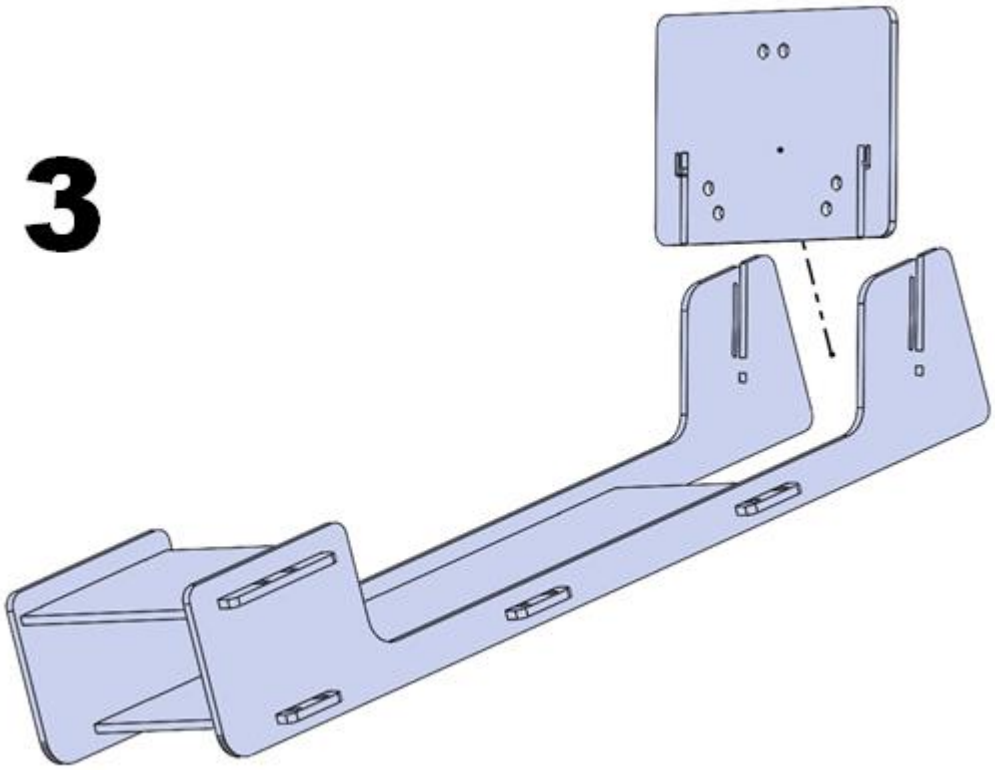

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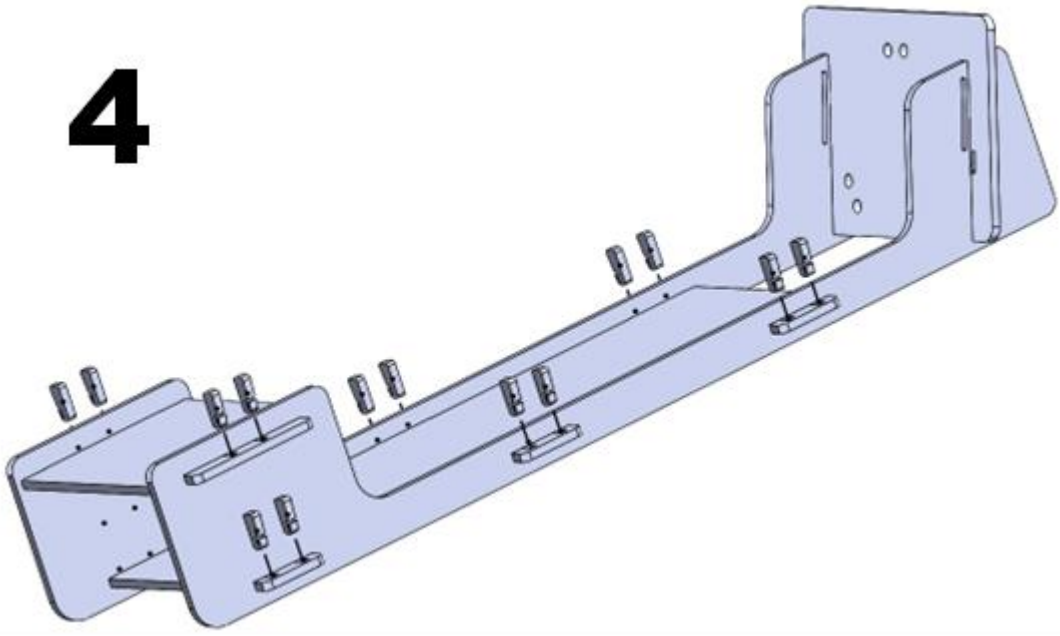
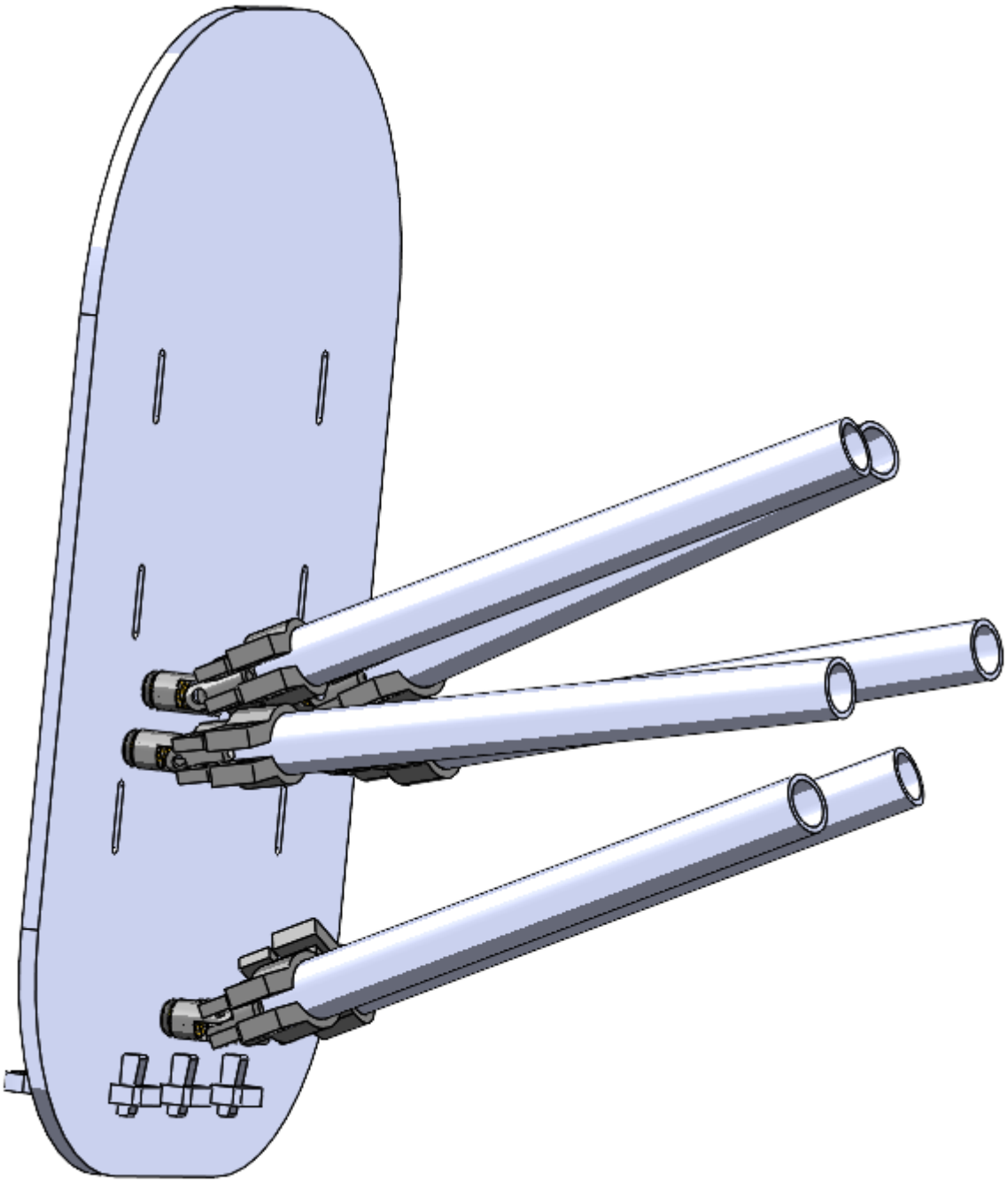


PART 2

Foot plate



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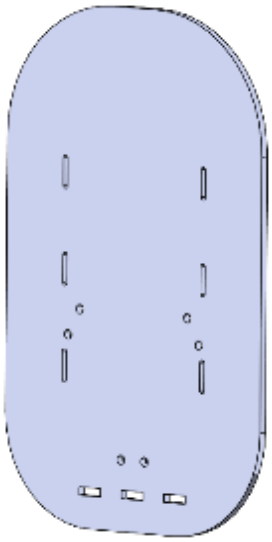

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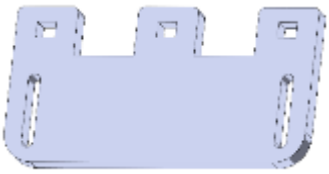

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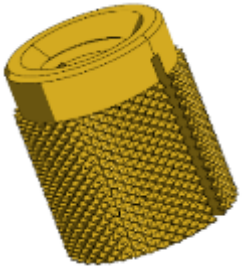
6X

6X



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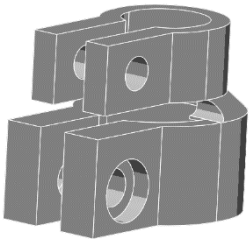

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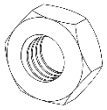
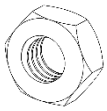


M6

6X



M5

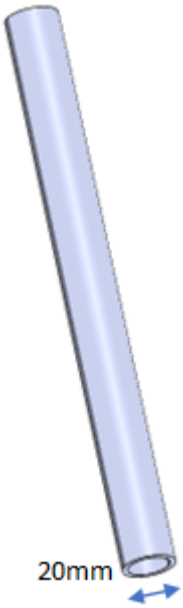
6X

M6

6X

M5

6X

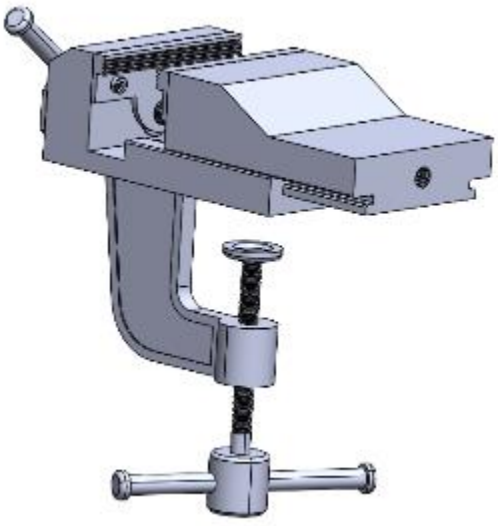


6X

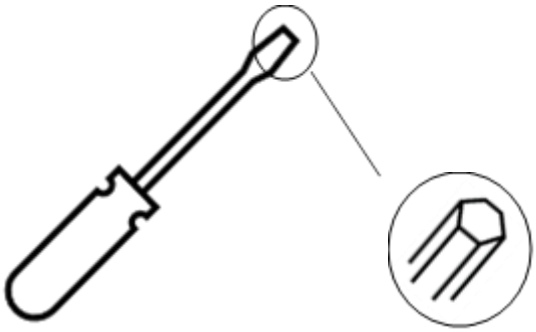
Thin rod

6X

Equipment used

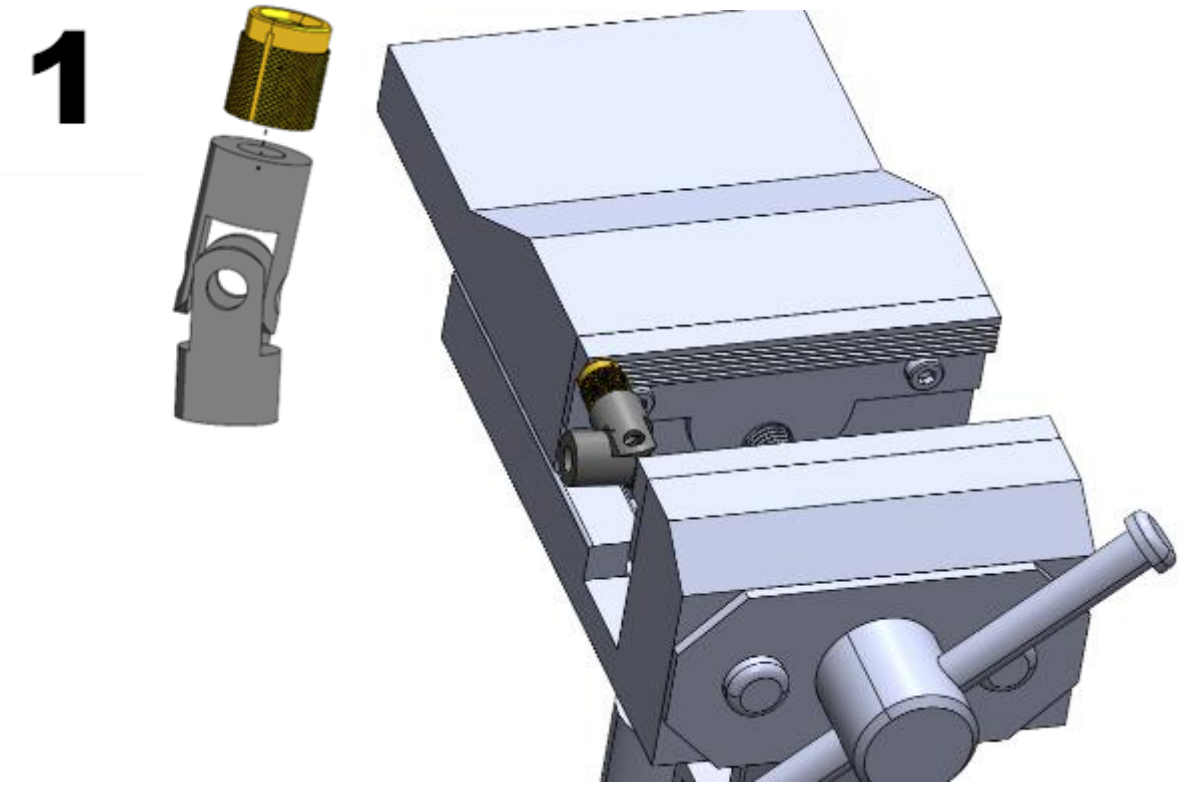


Bench vise



Hex screwdriver 4mm

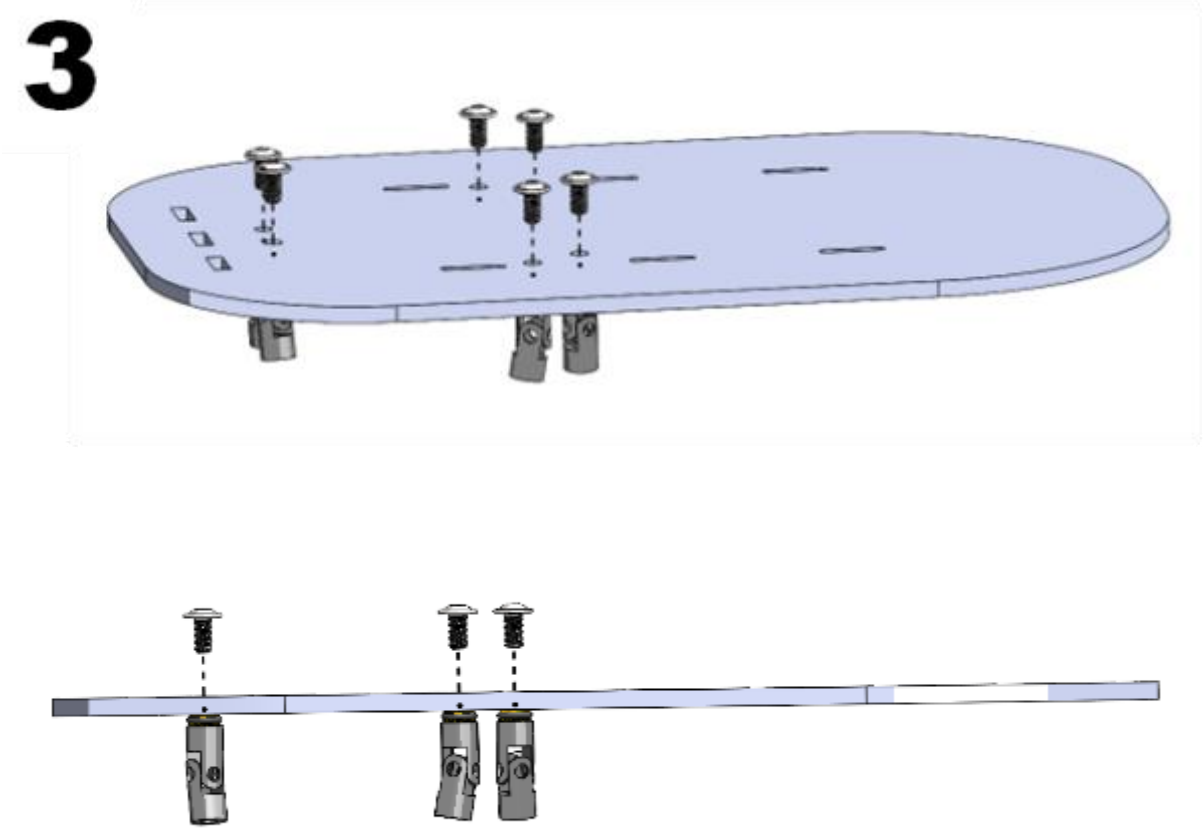
1



Use a bench vise to press the insert into the cardan as displayed in the figure above. Press until experiencing resistance.

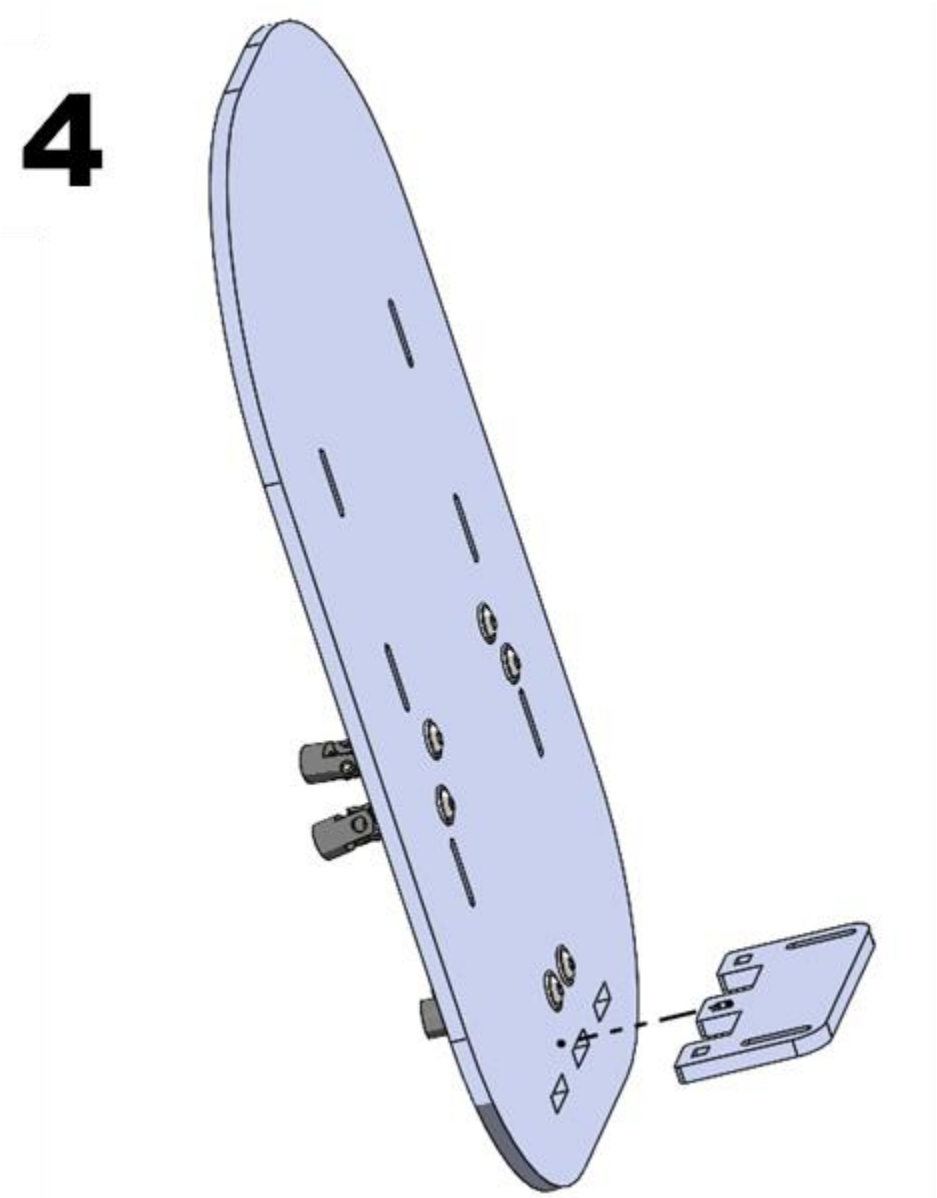
2

3



Note: When experiencing difficulty with screwing in, use a bench vice to hold the cardans.

4



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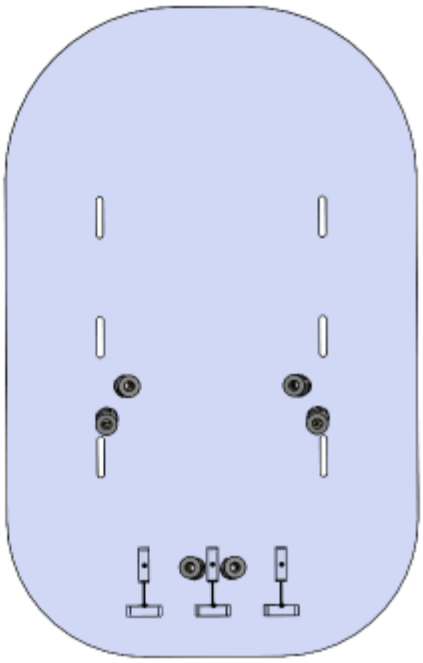

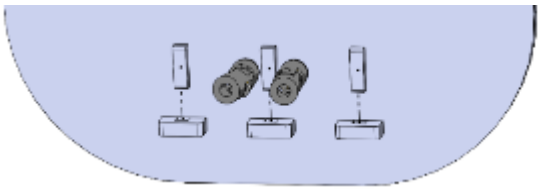

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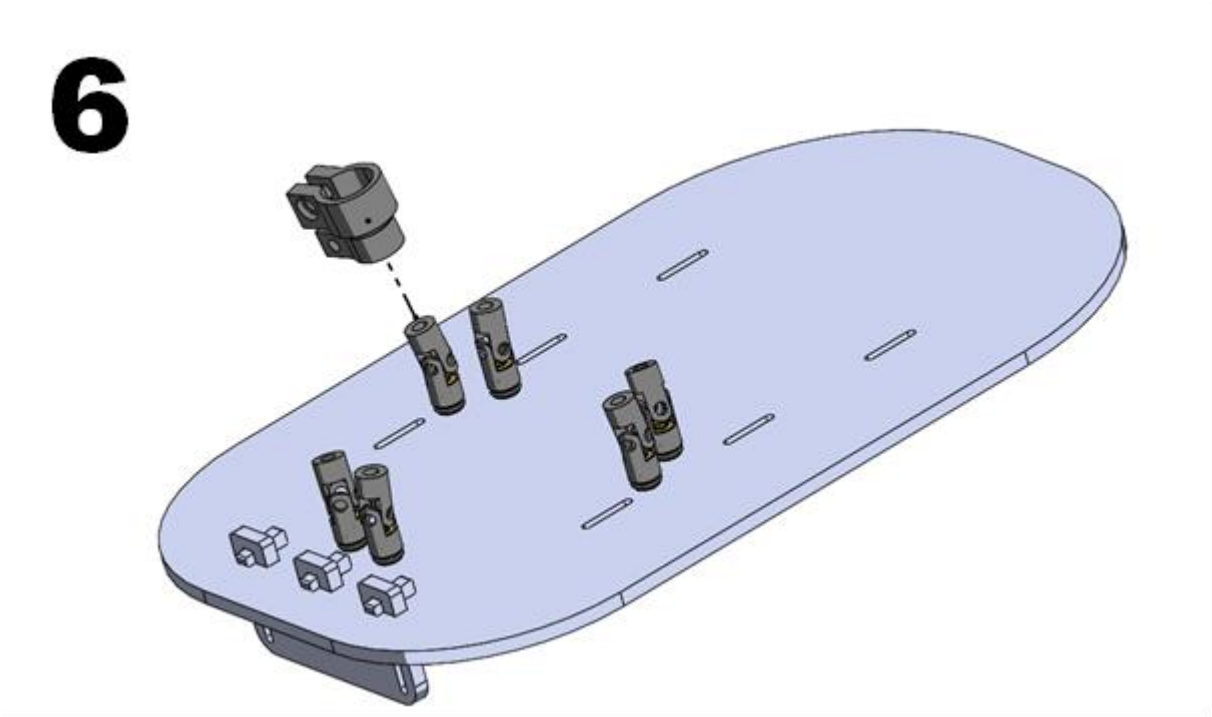
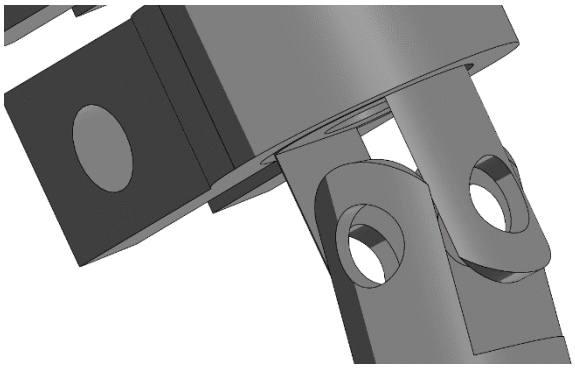


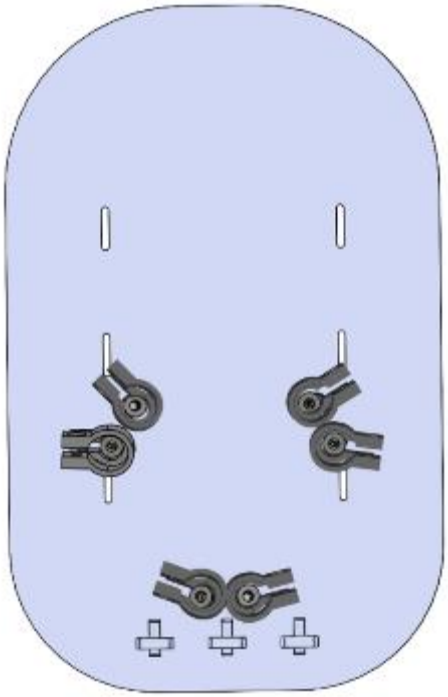
Slide the clamp over the cardan. Use M5 Nylon screws and nuts to tighten the side of the clamp closest to the plate.

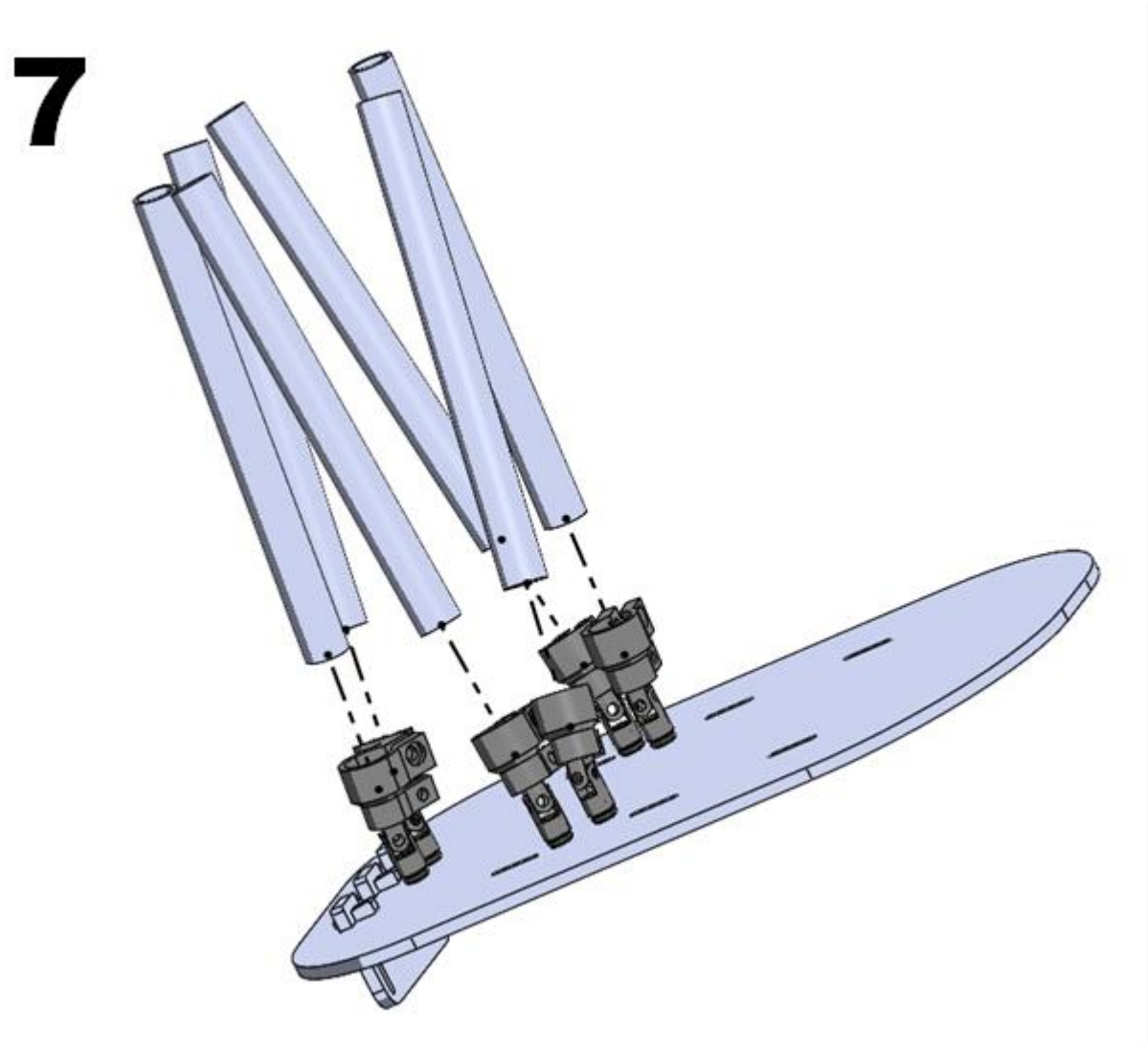
Warning!

Ensure that the edge of the clamp and edge of the cardan align in the following way:



Position the clamps before tightening, in the following way:

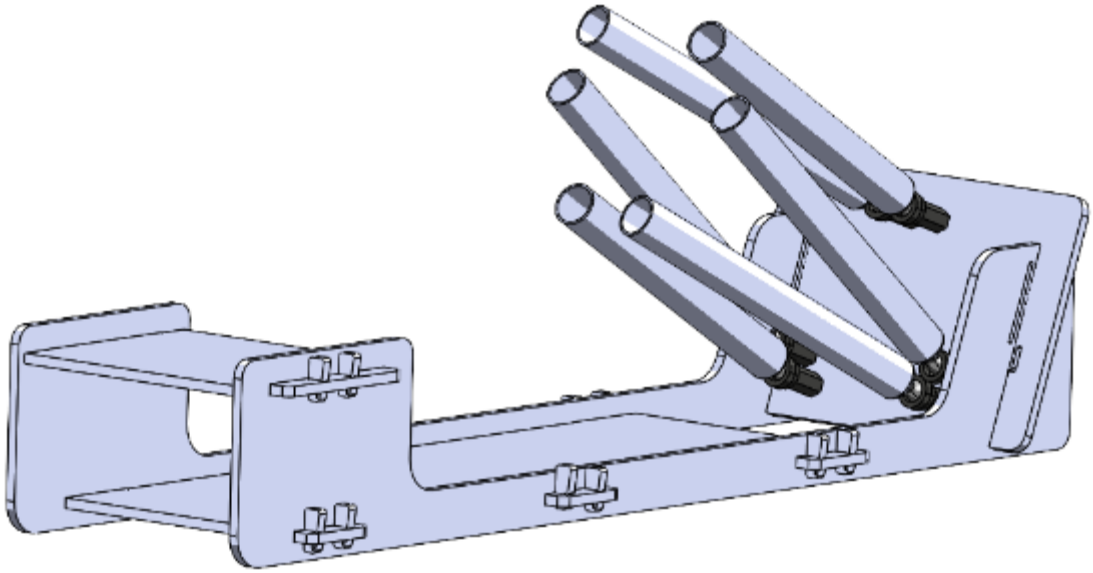




Use M6 Nylon screws and nuts to tighten the side of the clamp closest to the rod.

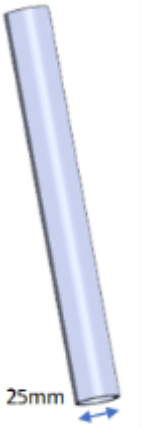
PART 3

Ball-in-socket joints



Parts used

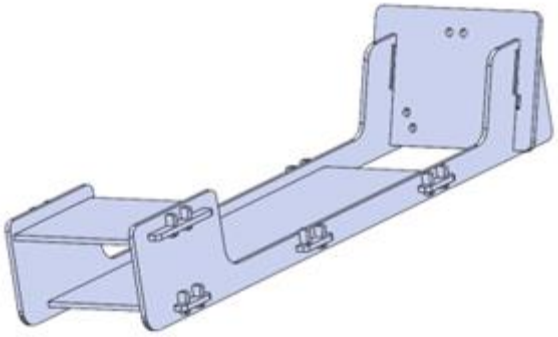
6X



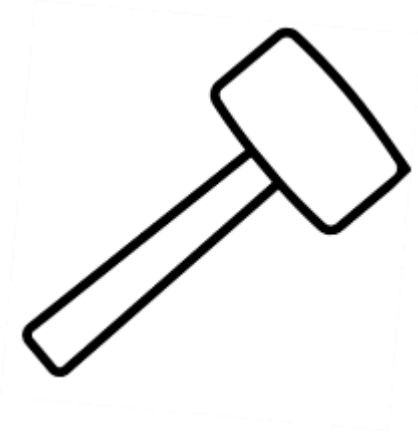
Thick rod 6X

M8 6X

6X



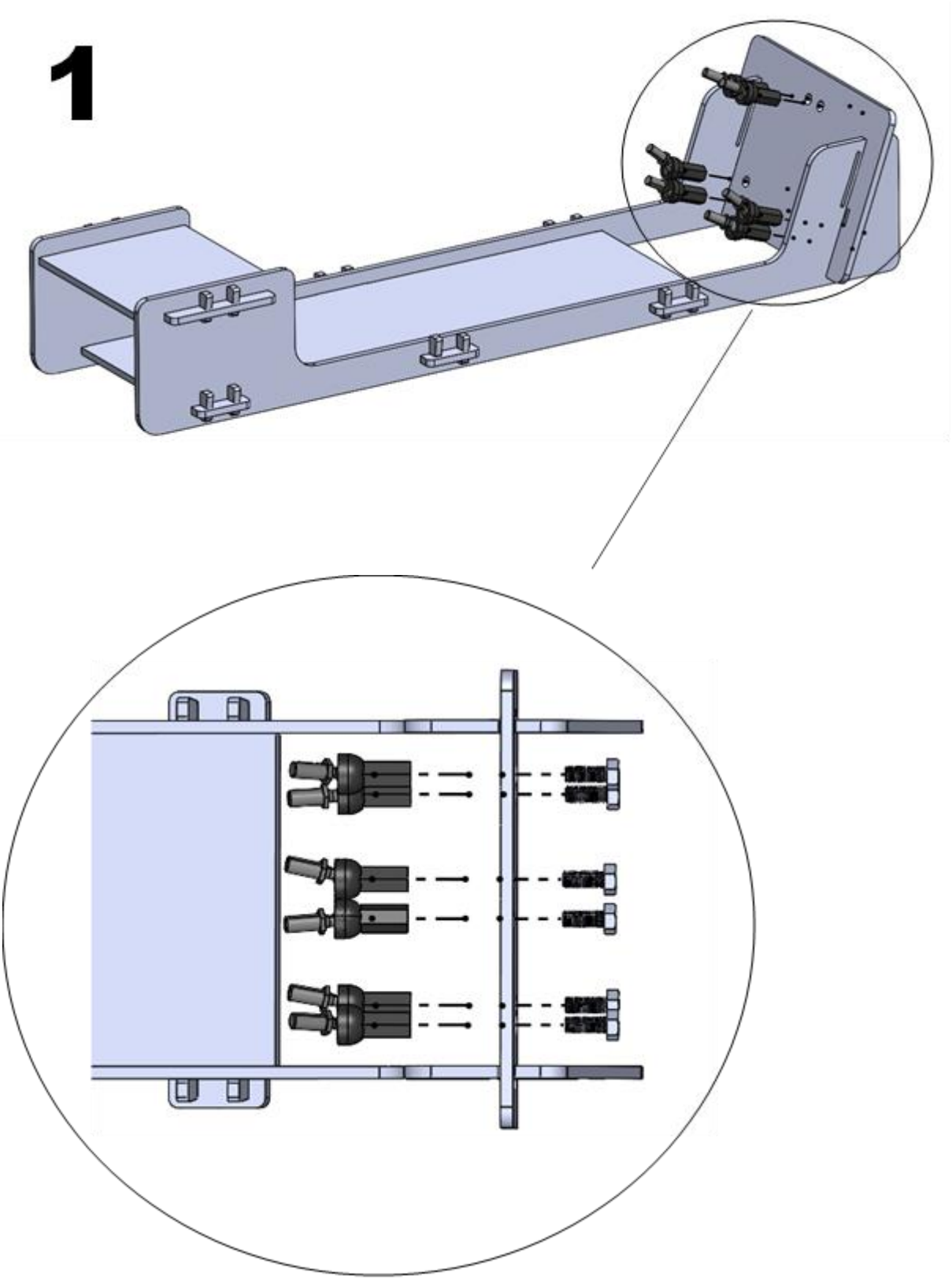
Equipment used



Nylon hammer

External hex screwdriver M8

1



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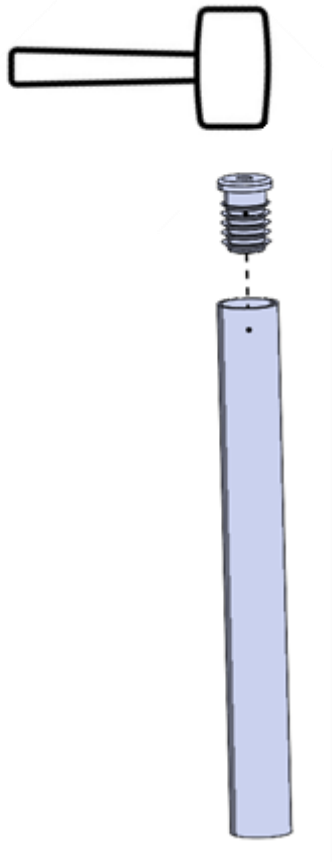

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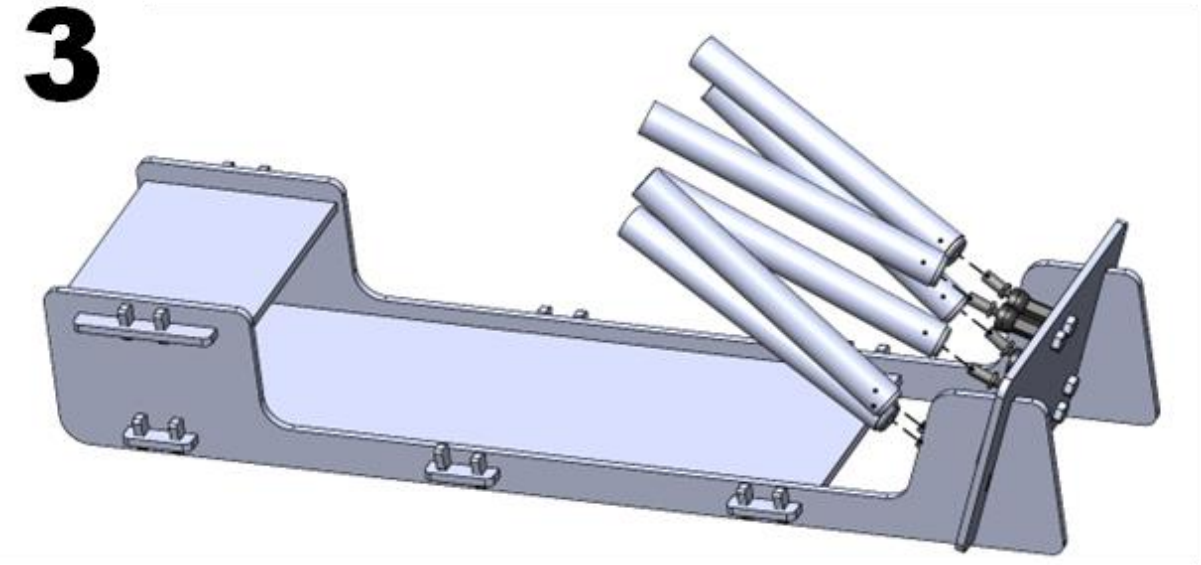
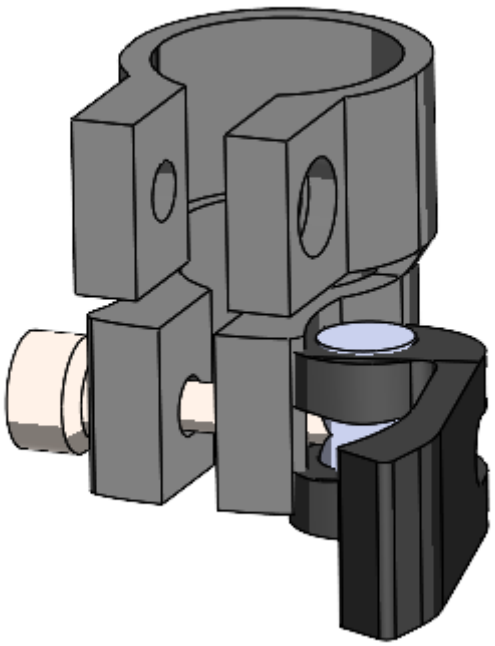
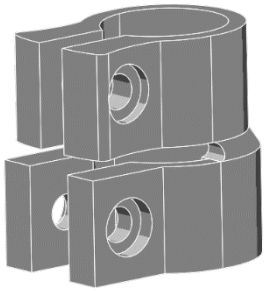


Part 4

Telescopic clamp



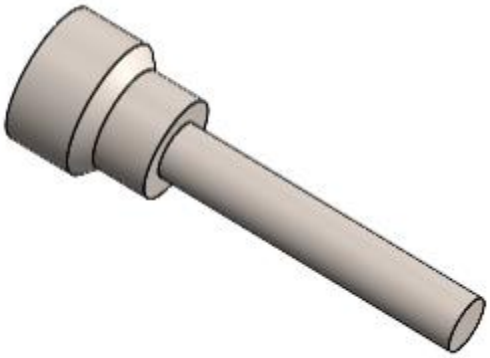
Parts used



6X

Large clamp

6X



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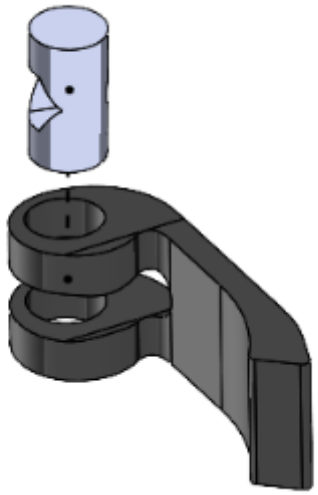
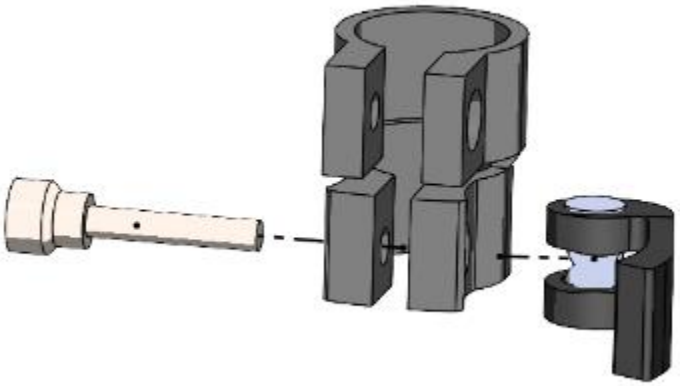
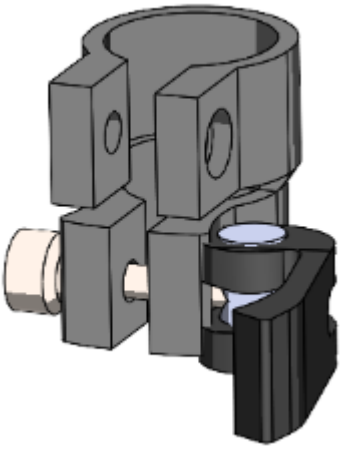
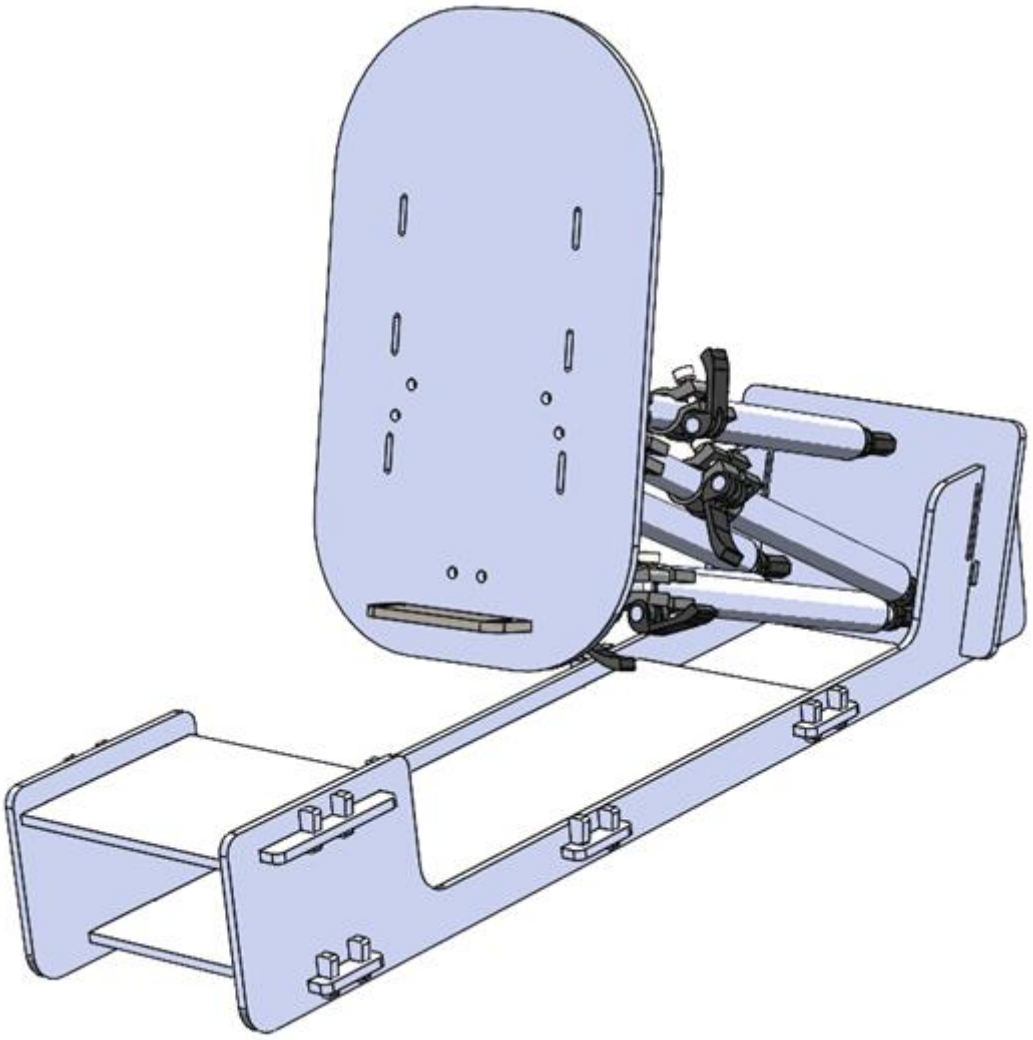




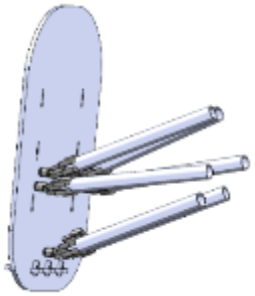


Part 4

Assemble together



Assemblies used



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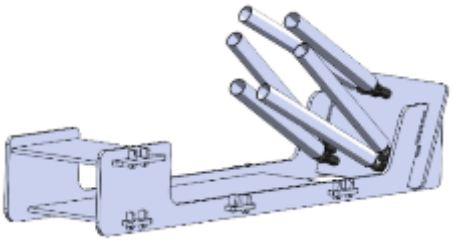

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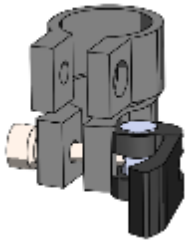

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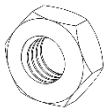
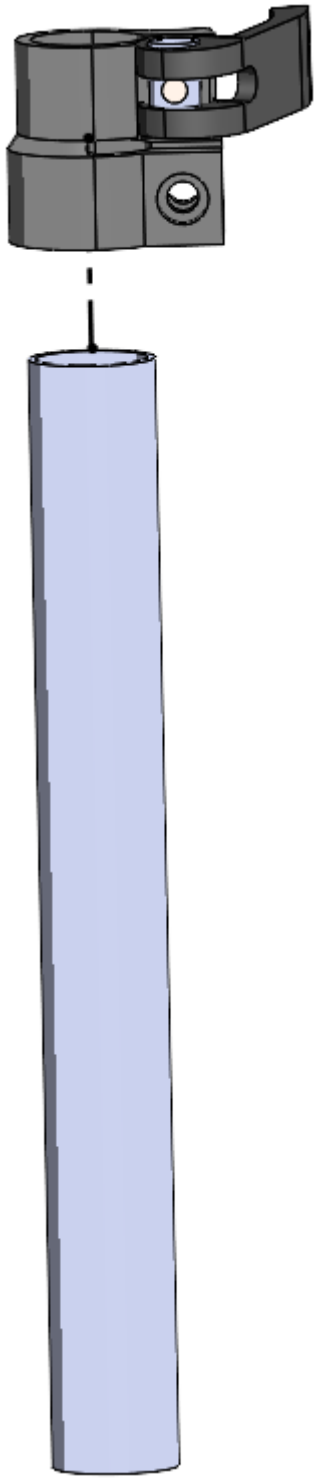


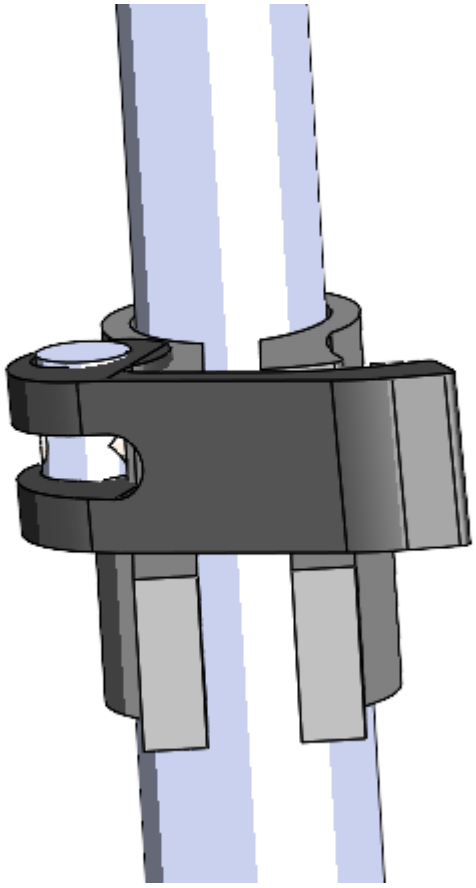
M6 6X

M6

6X



Place the clamp on the thick rod. Tighten the lower part of the clamp with an M6 Nylon bolt and nut. Repeat for the remaining thick rods.



CALIBRATION: Close the clamp with the lever as depicted above. Tighten the screw until it is not possible to move the inner rod anymore. Repeat for all other telescopic tube assemblies.

Part 5

Final steps

- Add anti-slip tape where the ground plate assembly touches the surface
- Add Velcro tape on the backside of the foot plate assembly and underneath where the calve rests on the device
- Add screw caps to the M6 bolts on the foot plate assembly
- Add anti-slip tape on the heel support
- Pass Velcro straps through the foot plate assembly and calve rest slits

APPENDIX B: IMDD 3D FOOT PLATE

Investigational Medical Device Dossier

3D foot plate, version 0.1.
24-07-2024

AUTHORS

Name	Position and organisation	Responsible for the following part(s) of IMDD
Eliane Masih	University of Twente	All

TABLE OF CONTENTS

Abbreviations

CE	Conformité Européenne
CMR	Carcinogenic, mutagenic of toxic to reproduction
EN	European standard
GSPR	General Safety and Performance Requirement
IMDD	Investigational Medical Device Dossier
ISO	International standard or the International Organization for Standardization
MDR	Medical Devices Regulation 2017/745
MREC	Medical Research Ethics Committee
NEN	Dutch standard
PMCF	Post-market clinical follow-up
QMS	Quality Management System
SSCP	Summary of Safety and Clinical Performance
STED	Summary TEchnical Documentation

Scope

The Investigational Medical Device Dossier (IMDD) specifies all items that must be covered (if relevant) for an application to a Medical Research Ethics Committee (MREC) in the Netherlands. This document is written for non-CE-marked medical devices within the scope of the Medical Devices Regulation 2017/745 (MDR) [1], which are intended for clinical investigation. If a non-CE-marked medical device, manufactured and used only within a single health institution (in-house manufactured medical device), is subject to a clinical investigation, all items specified in this IMDD are also considered applicable. A clear rationale and justification shall be provided for any deviation(s) from the IMDD. For CE-marked medical devices used outside the intended use, the format of the IMDD can also be used, see also the paragraph on information to be submitted. Good clinical practice and the design and conduct of the clinical investigation are outside the scope of the IMDD and shall be described in the clinical investigation plan. The requirements regarding personal data protection are also outside the scope of the IMDD.

IMDD format

The requirements for information to be submitted by a sponsor of a clinical investigation with a non CE-marked medical device are laid down in Annex XV of the MDR. However, the information to be submitted is mostly stated generally. Section 4.6 of Chapter II of Annex XV allows the competent authority to request additional information to be submitted. Annex II of the MDR contains detailed requirements for the technical documentation that a manufacturer has to compile to prove that the medical devices meet the requirements of the MDR. To facilitate uniform submission of documentation for medical devices for clinical investigation, it was decided to use the technical documentation requirements as specified in Annex II of the MDR as the basis for the documentation to be submitted. This IMDD guidance document provides additional guidance on the interpretation of some parts and provides information on the required documentation to be submitted, see paragraphs 1-6.

The first version of the IMDD was published in 2011 and was based on the Summary TEchnical Documentation (STED) drawn up by the Global Harmonization Task Force [2]. The required information in this updated version of the IMDD does not significantly differ from the information required in the first version of the IMDD. However, the structure and numbering of the items to be submitted are different.
The text of Annex II of the MDR is presented in normal type font. Reference to annexes in that part of the IMDD refer to Annexes of the MDR. For the IMDD, reference is made to appendices. Bold text is guidance to the required information in the MDR.
Where it is mentioned in Annex II of the MDR that a medical device is 'placed on the market', for the IMDD, this should be read and understood as 'used in the clinical investigation'. The term 'manufacturer' could in several instances be read and understood as 'sponsor of the clinical investigation'.

Information to be submitted
The sponsor of the clinical investigation, regardless whether it is a legal manufacturer or an investigator, shall use the IMDD format for submitting the required documentation to the MREC. The information in the IMDD and the information referred to in the IMDD can be submitted in English or in Dutch.
To obtain adequate and complete information in the IMDD, active involvement of the manufacturer of the investigational medical device is advisable, as they should have all technical information required for the IMDD available.

The information requested in the IMDD shall be compiled in a documentation set. The documentation set shall be presented in a clear, organised, readily searchable and unambiguous manner.
If an IMDD item is dealt with in another item or document supplied for the clinical investigation, for instance the investigator's brochure, as described in NEN-EN-ISO 14155 [3], or technical construction file, reference to that item or document is acceptable when a brief description of the information in that item or document is provided in the IMDD. Appendix I of the IMDD provides a table of contents for the documentation set. Using that table, cross references can be made between the items required by the IMDD and the documents submitted. If an item of the IMDD is not applicable for a medical device (e.g. 'electrical safety' or 'medicinal substances'), this shall be clearly indicated.
If separate documents are submitted, each document shall include a date/version number and identify author(s) that contributed significantly.
If the information to be submitted for one or more items (e.g. software validation for imaging devices) is very extensive, the level of detail of the documentation for such items shall be agreed upon with the MREC.

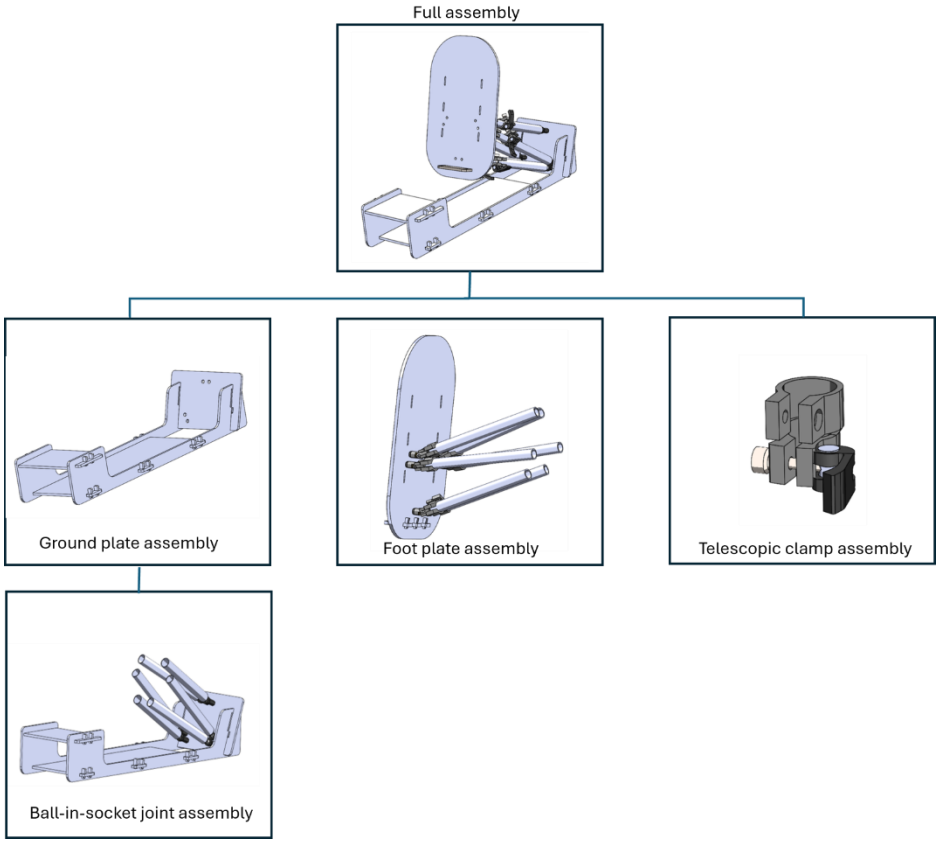
In case the sponsor intends to change (the intended purpose of) an already CE-marked medical device and needs clinical investigation data to support the change, no full IMDD of the original medical device needs to be submitted. The documentation submitted shall contain a clear description of the change(s) as compared to the CE-marked medical device and its intended use(s) and a rationale for the change to the medical device. The documentation shall contain a description which items of the IMDD are affected by the change and updated documentation on these items shall be submitted. The items medical device description (item 1), instructions for use (item 2), risk benefit analysis (see item 5) and General Safety and Performance Requirements (GSPRs, see item 4) will always have to be submitted. This will provide insight into the changes and how all GSPRs are addressed for the new design/intended use and how additional risk related to the change have been addressed.
If a Summary of Safety and Clinical Performance (SSCP) has been drawn up for a CE-marked medical device as described above, this SSCP shall also be supplied.
In the IMDD, the use of harmonized standards for fulfilling requirements of the MDR is preferred. Therefore, harmonized standards are referred to when applicable. Other solutions can be used, but a rationale shall be provided why this is considered similar to the approach in the harmonised standard.

Certain aspects, such as interoperability or usability, that are considered crucial by the MREC or investigators, might not be elaborated upon in the requirements in the MDR and therefore in the IMDD. Additional requirements can be discussed between the investigators, sponsor and MREC, as applicable.

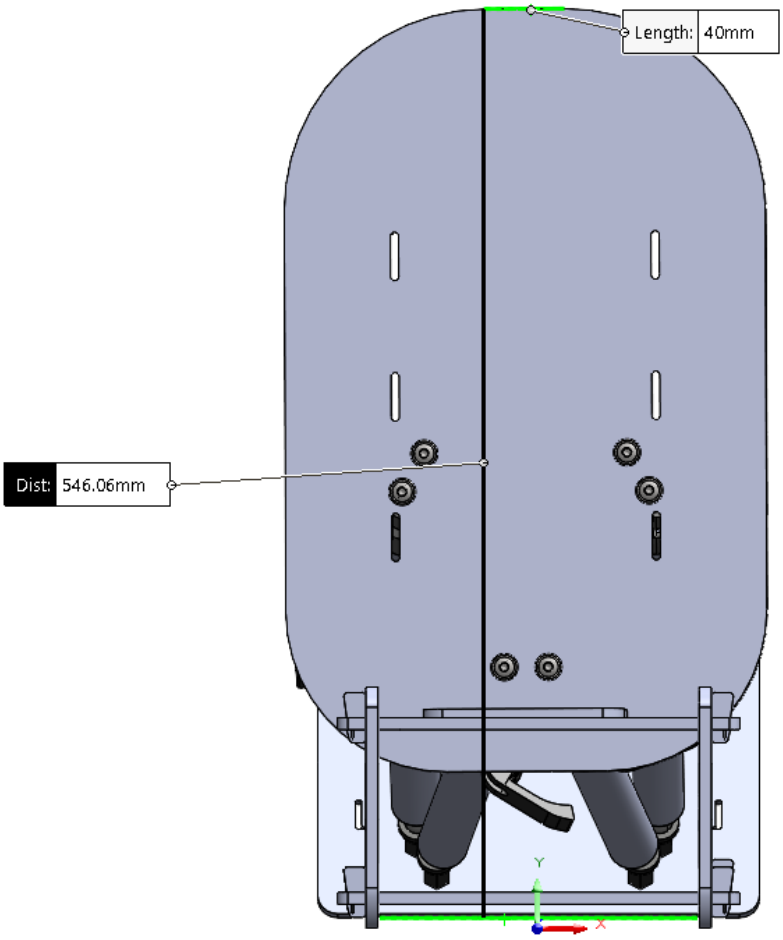
Device description and specification, including variants and accessories

1.1 Device description and specification

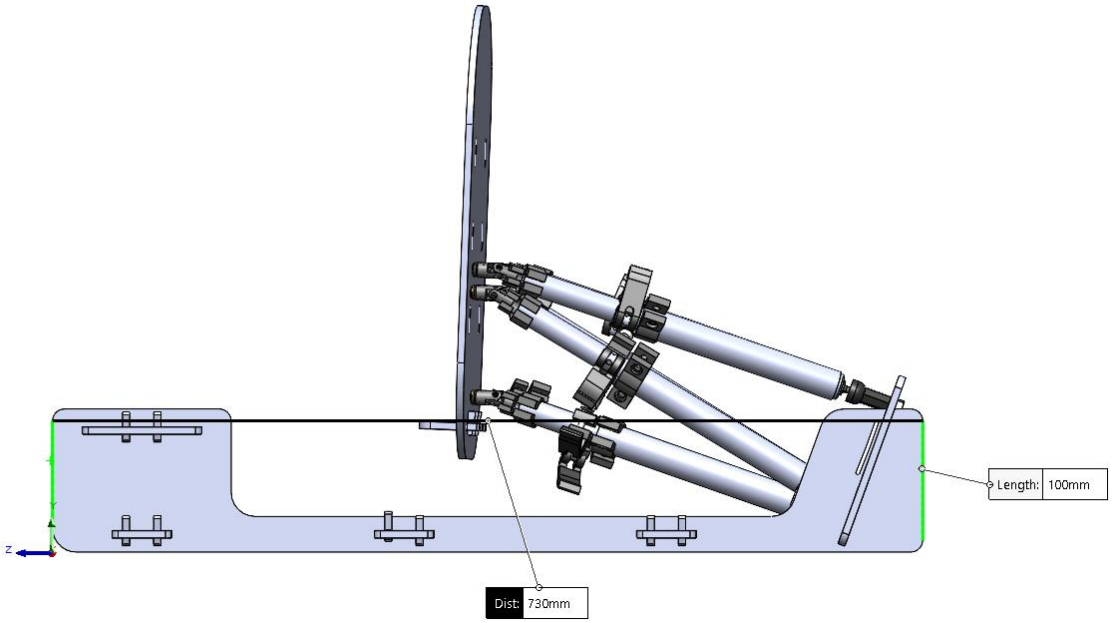
a. product or trade name and a general description of the device including its intended purpose and intended users; **This shall include the name and contact details (visiting address, telephone number and e-mail address) of the manufacturer and, if not the same as the manufacturer, the sponsor.**
The intended use of the 3D 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 device is to be operated by a clinician. Universiteit Twente Horst Complex (building no. 20), room W113 De Horst 2 7522 LW Enschede +31534899322 g.j.m.tuijthof@utwente.nl
b. the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability; **The method used to trace the medical device shall be included, either a UDI, which is only required for medical devices to be brought onto the market, or another unambiguous reference.**
NA
c. the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings; **This concerns the contra-indications and warnings known prior to the start of the clinical investigation.**
This device is meant to diagnose ankle laxity and instability of the hindfoot. The intended patient population are patients that show complex problems extending over multiple joints. Diagnosis is necessary because these patients have a chance of developing chronic ankle instability [1]. [1] Verhagen RAW, de Keizer G, van Dijk CN. Long-term follow-up of inversion trauma of the ankle. Archives of Orthopaedic and Trauma Surgery 1995;114:92–6. doi:10.1007/BF00422833.
d. principles of operation of the device and its mode of action, scientifically demonstrated if necessary;
The foot of the patient can be fixated through attachment of the foot to the plate of the device with straps, after which the plate can be positioned, and then fixated through six clamps. This information is supported by the following file: 1.02.3D foot plate - User manual v3.0
e. the rationale for the qualification of the product as a device; **Please note that device in the context of the MDR means every device that falls under the MDR, i.e. a medical device, an accessory or an Annex XVI device.**
The 3D foot plate is a medical device. It is used as a diagnostic accessory tool in the CT scanner. Without the device, it is not possible to obtain accurate and reliable quantitative data for a diagnosis. It can also be used as a research tool for obtaining research data on the ankle joint.
f. the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII;
Class I. Answer is supported by the following file: 1.01.3D foot plate Device Classification v1.0.xlsx
g. an explanation of any novel features; **Novel should be interpreted as novel to previous versions of the medical device or similar products on the market.**
A novel feature to previous version of the 3D foot plate is the replacement of the fixation system. The new version fixates the foot using a telescopic rods system with a lever clamp. This feature replaces a rope system that was present in both previous versions.

h. a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it;
The 3D foot plate is used within a CT scanner.
i. a description or complete list of the various configurations/variants of the device that are intended to be made available on the market; **This concerns the various configurations/variants of the medical device to be used in the clinical investigation. A rationale shall be included explaining why these configurations are used for the clinical investigation.**
NA
j. a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;
 The full assembly consists of the ground plate assembly, foot plate assembly and telescopic clamp assembly. Combining the foot plate assembly and ball-in-socket joint assembly, a telescopic rods system is created. The telescopic clamp is added to the assembly to achieve fixation when closed and can be opened to allow its telescopic function. The patient's calve rests on the ground plate assembly and has their foot on the heel support of the foot plate, while being attached to the foot plate with straps.
k. a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;
The device is mainly made from polypropylene plates (thickness: 6mm). Other elements touching the patient are Velcro straps, Polyethylene screw caps and possibly the stainless steel screws underneath the caps.
l. technical specifications, such as features, dimensions and performance attributes, of the device and any variants/configurations and accessories that would

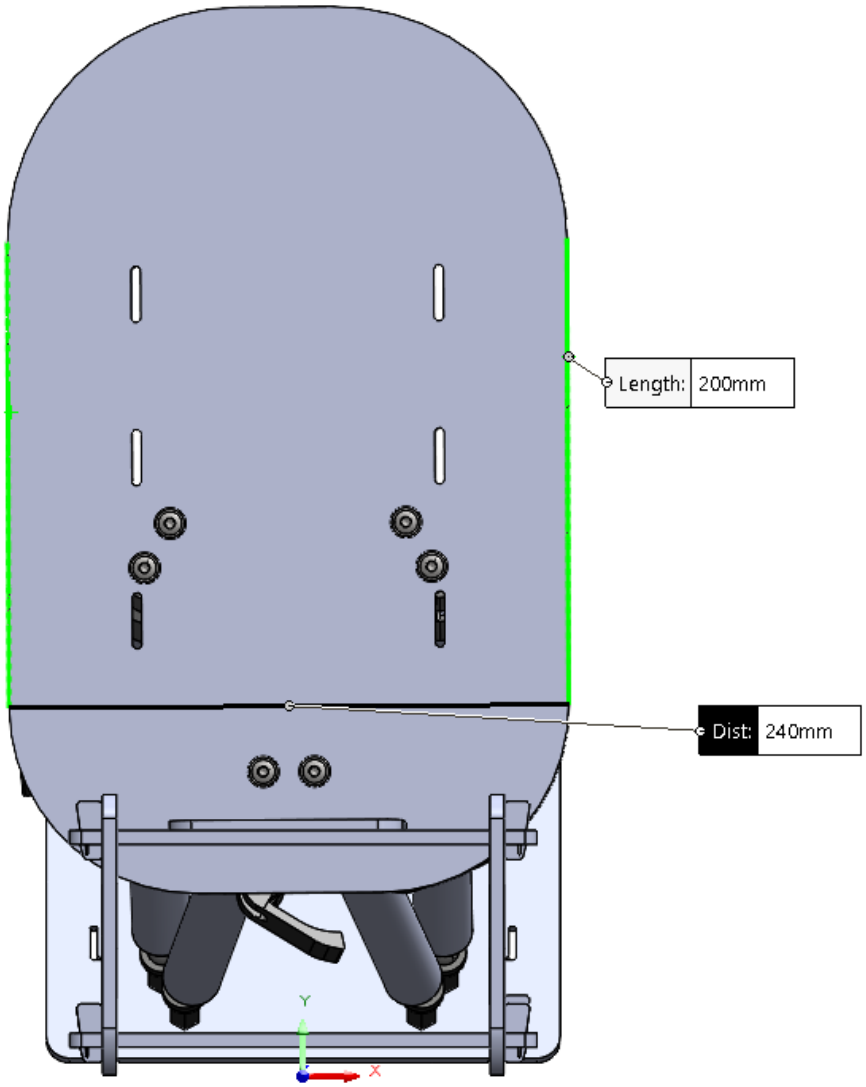
typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.
This concerns the variants/configurations and accessories to be used in the clinical investigation.



The height of the device is 546 mm.



The length of the device is 730 mm.



The widest part of the device is the foot plate, which is 240 mm in width.

1.2 Reference to previous and similar generations of the device

a. an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist; **A brief description of the key features of previous generations of the medical device is sufficient.**
3D foot plate by Tuijthof et al. (2012). The device has a fixation mechanism in which all rods are fixated at once using plugs surrounded by silicone tubing that were placed in each of the 6 rods and connected to ropes. By simultaneous tightening of the ropes with one handle, the rods could be fixated in any position by friction. 3D foot plate by van Elst (2023). For the fixation between the rods by means of friction, a custom-made fixation plug and a silicone umbrella tube are placed in each of the 6 rods. When the rope is tightened, the length of the tube will shorten and the silicone will expand. The ropes have to be tightened one by one and placed in clam cleats to maintain their tension.
b. an overview of identified similar devices available on the Union or international markets, where such devices exist. **A brief description of the key features of similar medical devices is sufficient.**
None.

1. Information to be supplied by the manufacturer

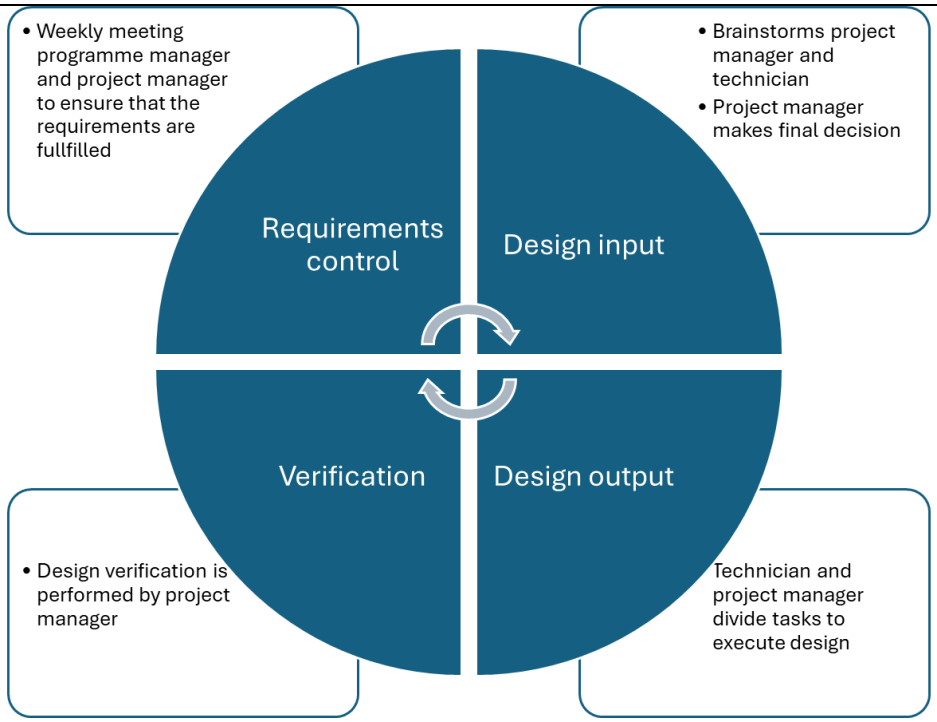
A complete set of:

a. the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; and
Since the device is an open-source medical device, the parts will be supplied by external suppliers directly to the user of the medical device. Labels and packaging depend on the external supplier's management.
b. the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold.
Instructions for use are available in English. The manual is contained by the following file: 1.02.3D foot plate - User manual v3.0

The labels(s) on the medical devices and the packaging and the instructions for use shall be the ones associated with the medical devices as used during the clinical investigation. The packaging does not have to be the final sales packaging. The label shall include the words "exclusively for clinical investigations" or "uitsluitend voor klinisch onderzoek", as required by the MDR, Annex I, clause 23.2(q) or clause 23.3(f).
For professional users, such as physicians, laboratory technicians and nurses, both English and Dutch are accepted languages for the instructions for use.
The instructions for use shall comply with the requirements from paragraph 23.4 from Annex I of the MDR. Important aspects to be included in the instructions for use are the required training and/or qualifications of the users or other persons and the warnings, precautions and contra-indications.
Other instructions, apart from the instructions for use, accompanying the medical device, e.g. for installation, maintenance or maintaining hygienic standards, do not have to be submitted as part of the IMDD.
Note 1: these documents should be included as part of the investigator's brochure.
Note 2: instructions for use have to be included for class IIb and class III medical devices. By way of exception, instructions for use are not required for class I and class IIa medical devices if such medical devices can be used safely without any such instructions. When showing compliance to the GSPRs (see paragraph 4), omitting the instructions for use will be elaborated upon.

2. Design and manufacturing information

a. information to allow the design stages applied to the device to be understood; **Information shall be provided to obtain a general understanding of the design process for the medical device under investigation. It is not intended to replace the more detailed information required for a quality management system (QMS) audit or other conformity assessment activity. A process flow chart showing an overview of the different steps in the design process, instead of extensive documentation, is considered acceptable.**



The design process is performed by 3 persons. The project manager is a master student, the programme manager is the supervisor of the student, and the technician is a technician employed at the university. The project manager has weekly meetings with the programme manager to ensure the requirements are being met. Dependent on the outcome, the project manager brainstorms with the technician. The project manager makes the final decision. If necessary, this decision is communicated with the programme manager via e-mail. The project manager divides the design execution tasks between the technician and themself. The design verification is performed by the project manager. Then, the project manager communicates the outcome with the programme manager. If the requirements are not met yet, a brainstorm session is planned again. And so, the process starts again. This information is supported by the following file: 3.01.01.3D Foot Plate - DesDev v1.0

b. complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation;
The documentation shall contain information to allow a reviewer to obtain a general understanding of the manufacturing processes. It is not intended to replace the more detailed information required for a QMS audit or other conformity assessment activity. A process flow chart showing an overview of production, assembly, any final product testing, and packaging of the finished medical device, instead of extensive documentation, is considered acceptable.

This information is found in the assembly manual. The manual is contained by the following files: Manual for assembling v1.1 and 030303.3D Foot Plate Bill of Materials v2.2

c. identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.
The documentation shall contain information about the QMS for design and manufacturing. QMS certificates are considered acceptable and a clear copy of the original certificates shall be provided.
Note: NEN-EN-ISO 13485 [4] is the standard used for QMS by nearly all manufacturers of medical devices.

If a company is not yet certified to NEN-EN-ISO 13485, the IMDD shall contain a statement, that procedures are available for the following (as applicable):
- Design control
- Supplier selection and control
- Production control for the clinical batches
- Clinical evaluation / clinical investigation

In this case, the manufacturer should also indicate the planning for obtaining the NEN-EN-ISO 13485 certification. **For medical devices, manufactured and used only within a single health institution, information to allow an understanding of the QMS applied should be provided. It is not intended to replace the more detailed information required for a QMS audit or other conformity assessment activity. A process flow chart showing an overview of the different aspects of the quality management process, instead of extensive documentation, is considered acceptable, together with a rationale why this QMS is considered appropriate for the design and manufacture of the medical device under investigation (e.g. comparing to NEN-EN-ISO 13485).**
The manufacturers and suppliers of each component are listed in the following file: 030303.3D Foot Plate Bill of Materials v2.2. An incoming goods and quality inspection is performed by the technical department of the clinical setting that the user works at. Tolerances have been considered during the design phase.

3. General safety and performance requirements

The documentation shall contain information for the demonstration of conformity with the general safety and performance requirements set out in Annex I that are applicable to the device taking into account its intended purpose, and shall include a justification, validation and verification of the solutions adopted to meet those requirements. The demonstration of conformity shall include:

a. the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;
The GSPR checklist is contained by the following file: 4.01.3D foot plate - GSPR checklist v1.0
b. the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;
See above.
c. the harmonised standards, common specification or other solutions applied; and
See above.
d. the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, common specification or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.
See above.

This information is usually reported in a checklist. Appendix II of the IMDD provides an example of such a checklist.
At the time of the submission of the IMDD to the MREC, all GSPRs need to be fully addressed, except for the GSPRs that require (additional) evidence intended to be obtained through the clinical investigation. GSPRs, where the clinical investigation will be providing (additional) evidence, shall be clearly identified, and it shall be explained how the data obtained in the investigation will contribute to fulfilling the specific GSPR. In the GSPR checklist, documents shall be referenced that demonstrate conformity to a specific GSPR. The documents referenced in the checklist do not need to be submitted, if not required in other items of the IMDD.

4. Benefit-risk analysis and risk management

The documentation shall contain information on:

a. the benefit-risk analysis referred to in Sections 1 and 8 of Annex I (of the MDR), and

The benefit-risk analysis and risk management is contained in the following file: 5.01.3D Foot Plate - Hazard Traceability Matrix Template v1.0
b. the solutions adopted and the results of the risk management referred to in Section 3 of Annex I.
See above.

The documentation shall contain the latest versions of the document(s) containing the risks identified, analysed and evaluated, and how these risks have been mitigated or controlled to an acceptable level, usually the risk analysis.
It should be identified which risks, related to the design and use of the device, are specifically investigated in the clinical investigation. A justification shall be provided why it is considered acceptable to start the clinical investigation in view of the uncertainties about these risks. Preferably, a multidisciplinary team has been involved in the risk analysis and the involvement of the team members that had a significant contribution to the risk analysis shall be mentioned in the risk analysis.
NEN-EN-ISO 14971 [5] is the standard used for the risk management system by nearly all manufacturers of medical devices. If the standard NEN-EN-ISO 14971 is not used, a rationale shall be provided why this standard is not used and why the approach taken is considered to be at least as appropriate as using NEN-EN-ISO 14971.
See Appendix III of the IMDD for more information on risk management.

5. Product verification and validation

The documentation shall contain the results and critical analyses of all verifications and validation tests and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements.

6.1 Pre-clinical and clinical data

a. results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications; **For the literature evaluation, a description of the search protocol, references to the publications included in the review, a summary of the review and conclusions shall be submitted.**
• Friction test to test if the telescopic clamp clamping force can withstand pulling of 50N. All clamps were able to withstand 60N for 2 minutes. • Strap release test to verify that the foot of the patient can be released from the device within 5 seconds. • Usability test with a clinician. The device works as intended. However, the Velcro straps were too short, the bottom clamps could not be reached easily, and anti-slip tape should be added to the bottom of the device.
b. detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular: **For all applicable testing mentioned in the following bullet items, at least a summary of the tests conducted, the methodology, standards applied, results and conclusions shall be submitted. Detailed information regarding test design (e.g. test protocols) and test results is not required.** **Also, a short rationale for the selection of the tests conducted shall be provided.**
This information can be found in the following file: Foot plate testing v1.0.pdf
• the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user; **At a minimum, tests shall be conducted on samples from the finished, sterilised (when supplied sterile) medical device. Data of previously tested medical devices/materials/products can be used to show biocompatibility.** **If biocompatibility testing has been undertaken on materials and/or previous versions of the medical device, this information can be used for the current device. A rationale shall be provided on the applicability of the available data and the testing still required for the current medical devices. This information should be available in the**

biological safety evaluation report (see the horizontal standard on biological safety testing, ISO 10993-1 [6]). **See 6.1.b for the level of detail required.**
Polypropylene [1], polyethylene [2] and stainless steel [3] are all biocompatible. They will only come into contact with the intact skin of the patient. [1] Sastri VR. Commodity Thermoplastics: Polyvinyl Chloride, Polyolefins, Cycloolefins and Polystyrene. Plastics in Medical Devices 2022:113–66. doi:10.1016/B978-0-323-85126-8.00002-3. [2] Klecandová L, Nakonieczny DS, Reli M, Simha Martynková G. Antibacterial and Biocompatible Polyethylene Composites with Hybrid Clay Nanofillers. Materials 2023, Vol 16, Page 5179 2023;16:5179. doi:10.3390/MA16145179. [3] Geantă V, Voiculescu I, Stefănoiu R, Rusu ER. Stainless steels with biocompatible properties for medical devices. Key Engineering Materials 2014;583:9–15. doi:10.4028/WWW.SCIENTIFIC.NET/KEM.583.9.
• physical, chemical and microbiological characterisation; **The applicable physical, chemical and microbiological specifications shall be provided, no further information on testing has to be submitted.**
NA
• electrical safety and electromagnetic compatibility; **See 6.1.b for the level of detail required.**
NA
• software verification and validation (describing the software design and development process and evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer); **For software, a number of standards are available. Three standards are elaborate upon underneath, but this list is not exhaustive and other standards can also be applicable.** **NEN-EN-IEC 62304:2006 Medical device software – Software life cycle processes [7], covers both software as a component of a medical device and standalone software (a medical device in its own right).** **NEN-EN-IEC 82304-1:2017 Health Software – Part 1: General requirements [8], provides requirements for the safety and security of health software products.** **NEN-EN-IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance [9], contains a section specifically on programmable electrical medical systems.** **For the choice of methods and standards used for software verification and validation, the manufacturer shall provide a rationale.** **See 6.1.b for the level of detail required.**
NA
• stability, including shelf life; and **The manufacturer shall indicate the shelf life for the medical devices used during the clinical investigation and on which information/testing the determination of the shelf life was based.**
No testing has been performed.
• performance and safety. **For a clinical investigation with a non-CE-marked device, other testing performed than mentioned above (e.g. on usability) prior to the commencement of the clinical investigation shall be submitted,**

which could include clinical data. **See 6.1.b for the level of detail required.**
Usability test

Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council shall be demonstrated.
Directive 2004/10/EC relates to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.
Where no new testing has been undertaken, the documentation shall incorporate a rationale for that decision. An example of such a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service.
See also the requirements on biocompatibility, 6.1.b), first bullet point.

c. the clinical evaluation report and its updates and the clinical evaluation plan referred to in Article 61(12) and Part A of Annex XIV; **For a non-CE-marked medical device, a final clinical evaluation report will not be available at the time of submitting an application for a clinical investigation with that device. However, the sponsor shall submit the clinical evaluation plan, in which the clinical investigation is included [1], either as Annex to the IMDD or as separate document referenced in the IMDD. The clinical evaluation plan shall also indicate how other testing, as presented in 6.1 of the IMDD, is included in the clinical evaluation of the medical device. A clinical evaluation plan is not required for in-house manufactured medical devices (see Article 82 of the MDR).** **For a CE-marked medical device, the latest version of the clinical evaluation report can provide useful information for the MREC.**
NA
d. the PMCF plan and PMCF evaluation report referred to in Part B of Annex XIV or a justification why a PMCF is not applicable. **For a non-CE-marked medical device, a post-market clinical follow-up (PMCF) plan is not yet necessary.**
NA

6.2 Additional information required in specific cases

a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as referred to in the first subparagraph of Article 1(8), a statement indicating this fact. In this case, the documentation shall identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device. **The documentation shall contain information on the medicinal substance and the specific risks related to the substance and the management of such risks, as well as evidence for the added value of incorporation of such constituent in relation to the clinical benefit and/or safety of the medical device.** **If a scientific opinion of the national competent authority or the European Medicines Agency is available, this is considered sufficient. The scientific opinion concerns the quality and safety of the registered medicinal product including the clinical benefit/risk profile of the incorporation of the substance into the medical device. No further information required in this case.**
NA
b. Where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, and is covered by this Regulation in accordance with points (f) and (g) of Article 1(6), and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by this Regulation in accordance with the first subparagraph of Article 1(10), a

	statement indicating this fact. In such a case, the documentation shall identify all materials of human or animal origin used and provide detailed information concerning the conformity with Sections 13.1. or 13.2., respectively, of Annex I. **The documentation shall contain information on the tissues, cells or their derivatives, and the specific risk management in relation to the tissues, cells or their derivatives, as well as evidence for the added value of incorporation of such constituents in relation to the clinical benefit and/or safety of the medical device.**
NA	
	c. In the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to: • absorption, distribution, metabolism and excretion; • possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions; • local tolerance; and • toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device. In the absence of such studies, a justification shall be provided. **See 6.1.b for the level of detail required.**
NA	
	d. In the case of devices containing CMR or endocrine-disrupting substances referred to in Section 10.4.1 of that Annex I, the justification referred to in Section 10.4.2 of that Annex.
NA	
	e. In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues. **Information shall be submitted to show that the efficacy of the sterilization process used is sufficient for this specific medical device. Such information is usually provided in a validation report. If other testing was performed or additional testing was not considered necessary, a rationale to substantiate that decision shall be provided. A summary of the results of other testing shall be submitted.** **Note 1: for ethylene oxide sterilization, specific guidance for sterilizing small batches, e.g. for products used during clinical studies, has been developed as an annex to standard NEN-EN-ISO 11135 [10].** **Note 2: for reusable medical devices, the validated method for reprocessing shall be included in the instructions for use. The validation report of the reprocessing method should be made available upon request.**
NA	
	f. In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications.
NA	
	g. If the device is to be connected to other device(s) in order to operate as intended, a description of this combination/configuration including proof that it conforms to the general safety and performance requirements when connected to any such device(s) having regard to the characteristics specified by the manufacturer. **The description of this combination/configuration used in the clinical**

investigation shall be submitted, including a rationale why this combination is considered safe and effective.
NA

References

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

[2] GHTF/SG1/N011:2008 Summary technical documentation for demonstrating conformity to the essential principles of safety and performance of medical devices (STED)

[3] NEN-EN-ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice

[4] NEN-EN-ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

[5] NEN-EN-ISO 14971:2019 Medical devices – Application of risk management to medical devices

[6] ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
Note: during the development of this version of the IMDD, ISO 10993-1 was recently published and the European version (EN ISO 10993-1) was not yet available.

[7] NEN-EN-IEC 62304:2006 Medical device software – Software life-cycle processes

[8] NEN-EN-IEC 82304-1:2017 Health software – Part 1: General requirements for product safety

[9] NEN-EN-IEC 60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

[10] NEN-EN-ISO 11135:2014 AMD 2018 Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

Appendix I Table of contents for the IMDD to be submitted

Paragraph IMDD	Description	Applicable (yes/no)	Reference to submitted documentation (document(s) number/annex number)
1.1	Device description and specification	yes	
1.2	Reference to previous and similar generations of the device	yes	
2.a	Label(s) on the device and on its packaging	no	
2.b	Instructions for use	yes	
3.a	Design information (flow chart)	yes	
3.b	Manufacturing information (flow chart)	yes	
3.c	QMS documentation	yes	
4	Checklist GSPRs	yes	
5	Benefit-risk analysis and risk management	yes	
6.1.a	Results of testing	yes	
6.1.b	Information of biocompatibility testing	yes	
6.1.b	Physical, chemical and microbiological characterization	no	

6.1.b	Electrical safety and electromagnetic compatibility	no	
6.1.b	Software verification and validation	no	
6.1.b	Stability, including shelf life	yes	
6.1.b	Performance and safety	yes	
6.1.c	Clinical evaluation report and clinical evaluation plan	no	
6.1.d	PMCF plan and PMCF evaluation report	no	
6.2.a	Medicinal substance	no	
6.2.b	Tissues/cells of human or animal origin	no	
6.2.c	Substances intended to be absorbed or locally dispersed in the human body	no	
6.2.d	CMR or endocrine-disrupting substances	no	
6.2.e	Product delivered sterile or in a defined microbiological condition	no	
6.2.f	Measuring function	no	
6.2.g	Connection to other devices	no	
Optional for CE-marked device	SSCP for implantable or class III CE-marked medical devices	no	

Appendix II Checklist GSPRs

Example layout Checklist GSPRs:

Note: this is just an example, tables with a different format, but containing all necessary information, can also be acceptable.

Location			
Dated			
Title or reference of documentary evidence			
Relevant applied standard(s) used for this product			
Description of fulfilment of requirement			
Applicable/ not applicable			
GSPRs	**Chapter I: General requirements**	1 Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.	Etc.

The GSPRs in Annex I of the MDR cover the following elements. Each element can consist of multiple separate items:

CHAPTER I:
General Requirements
GPSR 1-9: General requirements, mainly related to risk management and benefit-risk ratio
CHAPTER II:
Requirements regarding design and manufacture
GSPR 10: Chemical, physical and biological properties
GSPR 11: Infection and microbial contamination
GSPR 12: Devices incorporating a substance considered to be a medicinal product and devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body
GSPR 13: Devices incorporating materials of biological origin
GSPR 14: Construction of devices and interaction with their environment
GSPR 15: Devices with a diagnostic or measuring function
GSPR 16: Protection against radiation
GSPR 17: Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves
GSPR 18: Active devices and devices connected to them
GSPR 19: Particular requirements for active implantable devices
GSPR 20: Protection against mechanical and thermal risks
GSPR 21: Protection against the risks posed to the patient or user by devices supplying energy or substances
GSPR 22: Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons
CHAPTER III:
Requirements regarding the information supplied with the device
GSPR 23: Label and instructions for use

Appendix III Risk management

The following table is an example of a table that can be used for the risk analysis.

Example layout of a table with hazard identification, estimation and mitigation etc.
Note: this is just an example, tables with a different format, but containing all necessary information, can also be acceptable.

Residual risks, if applicable		
Comment		
Acceptable/not acceptable		
Residual risk estimated		
Mitigation measures		
Risks estimated		
Causes		
Hazard		

A risk analysis, which can consist of one document or be composed of several documents covering different types of risk, shall cover all possible hazards for the medical device concerned. In the table underneath, examples are given for several types of hazards that could be applicable (NEN-EN-ISO 14971:2019, Table C.1).

ENERGY HAZARDS	BIOLOGICAL AND CHEMICAL HAZARDS	FUNCTIONALITY AND INFORMATION HAZARDS
Acoustic energy • infrasound • sound pressure • ultrasonic **Electric energy** Electric fields Leakage current	**Biological agents** Bacteria Fungi Parasites Prions Toxins Viruses **Chemical agents**	**Data** • access • availability • confidentiality • data transfer • integrity **Delivery** • quantity

• earth leakage • enclosure leakage Magnetic fields Static discharge Voltage **Mechanical energy** Kinetic energy • falling objects • high pressure fluid injection • moving parts • vibrating parts **Potential (stored) energy** • bending • compression • cutting, shearing • gravitational pull • suspended mass • tension • torsion **Radiation energy** Ionizing radiation • accelerated particles (alpha particles, electrons, protons, neutrons) • gamma • x-ray Non-ionizing radiation • infrared • laser • microwave • ultraviolet **Thermal energy** Cryogenic effects Hyperthermic effects	Carcinogenic, mutagenic, reproductive Caustic, corrosive • acidic • alkaline • oxidants Flammable, combustible, explosive Fumes, vapours Osmotic Particles (including micro-and nano-particles) Pyrogenic Solvents Toxic • asbestos • heavy metals • inorganic toxicants • organic toxicants • silica **Immunological agents** Allergenic • antiseptic substances • latex Immunosuppressive Irritants • cleaning residues Sensitizing	• rate **Diagnostic information** • examination result • image artefacts • image orientation • image resolution • patient identity / information **Functionality** • alarm • critical performance • measurement

APPENDIX C: BILL OF MATERIALS

Component ID	Component description	Revision	Revision date	Quantity	Units	Cost	Total cost	Manufacturer	Supplier/Distributor
2.1.0	**Rods**								
2.1.1	Outer PMMA rod - Ø25-21mm	1.0	13-5-2024	6 * 175 mm	2 meter	€ 12,86	€ 12,86	Flexinplex Kunststoffen B.V.	Flexinplex Kunststoffen B.V.
2.1.2	Inner PMMA rod - Ø20-16mm	1.0	13-5-2024	6 * 200 mm	2 meter	€ 11,91	€ 11,91	Flexinplex Kunststoffen B.V.	Flexinplex Kunststoffen B.V.
2.2.0	**3D printed components**								
2.2.1	Telescopic clamp	1.0	16-5-2024	6	pieces	€ 0,93	€ 0,93	Vormz	vormz.nl
2.2.2	Telescopic lever	1.0	16-5-2024	6	pieces	€ 2,90	€ 2,90	Vormz	vormz.nl
2.2.3	Connection clamp	2.0	17-5-2024	6	pieces	€ 2,38	€ 2,38	Vormz	vormz.nl
2.3.0	**Remaining components**								
2.3.1	Ball-in-socket joint	1.0	1-5-2024	6	pieces	€ 2,06	€ 12,36	igus	igus
2.3.2	Cardan	1.0	24-4-2024	6	pieces	€ 6,19	€ 37,14	Reely	Conrad
2.3.3	Tube insertion cap	1.0	13-5-2024	6	pieces	€ 0,38	€ 1,88	Verpas B.V	Verpas B.V.
2.3.4	Threaded insert	1.0	28-6-2024	6	pieces	€ 0,49	€ 48,61	RS	RS
2.3.5	RVS screw M6x12mm	1.0	23-7-2024	6	pieces	€ 0,22	€ 1,32	Dresselhaus	Hornbach
2.3.6	Bolt with a cross nut	1.0	16-5-2024	6	pieces	€ 0,70	€ 4,20	BAUHAUS	BAUHAUS
2.3.7	RVS screw M6x40mm	1.0	18-8-2024	6	pieces	€ 0,13	€ 0,78	Dresselhaus	Hornbach
2.3.8	Nylon bolt M5	1.0	16-5-2024	6	pieces	€ 1,66	€ 10,00	Unknown	Bol.
2.3.9	Nylon nut M5	1.0	18-8-2024	6	pieces	€ 0,10	€ 0,60	Dresselhaus	Hornbach
2.3.10	Nylon bolt M6	1.0	16-5-2024	12	pieces	€ 0,30	€ 3,60	Dresselhaus	Hornbach
2.3.11	Nylon nut M6	1.0	16-5-2024	12	pieces	€ 0,10	€ 1,20	Dresselhaus	Hornbach
2.3.12	Nylon bolt M8x20mm	1.0	23-7-2024	6	pieces	€ 0,55	€ 3,30	Dresselhaus	Hornbach
2.3.13	Rubber O-ring	1.0	23-7-2024	6	pieces	€ 0,06	€ 3,79	RS	RS
2.3.14	Torx cap	1.0	18-8-2024	6	pieces	€ 0,06	€ 0,72	Dresselhaus	Hornbach
2.3.15	Velcro	1.0	13-5-2024	1	roll	€ 30,14	€ 30,14	VELCRO®	Bol.

APPENDIX D: HAZARD TRACEABILITY MATRIX

This appendix contains the adjusted Hazard Traceability Matrix.

	Risk analysis								Risk eval.
ID#	Hazard	Reasonably foreseeable sequence or combination of events	Hazardous situation	Harm	Notes	Occurrence	Severity	Detectability	Criticality Index
1	falling objects	(a) The device is portable and will be taken in and out the radiation rooms; (b) If the telescopic clamps are not closed and the holder tilts the device when transporting, the foot plate with thin rods can slide off and fall to the ground	The device could fall and break	Product failure	No patient harm	6	10	1	60
2	moving parts	(a) The foot is attached with Velcro straps to the footplate itself when positioning and fixating the foot in an extreme position for an X period of time	- Cramp/pain in patient's foot; - A wound on the foot may be caused by friction of the Velcro straps	Harm to the patient's foot		8	6	4	192
3	bending	(a) The patient pulls on the device when	-The polypropylene ground plate assembly can bend and the	The product cannot perform its		3	6	5	90

		the rods are fixated	patient can move their foot	intended use					
4	tension	(a) Telescopic clamp fixation	- When the friction force is insufficient, the patient can move the foot himself	Harm to the patient		6	3	6	108
5	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		8	6	8	384
6	image artefacts	(a) When the device is used with an patient and an imaging photo is taken	- Imaging photo is unusable due to artifacts, because of metal or movement artefacts	Additional radiation to the patient	Imaging photo must be redone	5	5	5	125
7	in-service requirements (e.g. maintenance, reprocessing)	(a) Repeatedly use the product, especially repeated use of the friction principle.	- Wear on clamps / rods - Friction force not strong enough	Product failure		3	7	6	126
8	manufacturing processes	(a) Assembling the device	- No consistent manufacturing process - Wrong materials used, wrong dimensions	Product failure		6	3	6	108
9	materials	(a) Assembling the device	- Materials have different properties that may not meet the	Product failure		6	3	6	108

			requirements set						
10	Inappropriate storage and environmental conditions	(a) Device stored while still in the fixated state (b) Device stored under high temperature / high humidity	- The device is fixated when stored. The device is under tension, making it more sensitive and fail under fatigue - When the device is stored under high temperature / high humidity, materials such as PLA might deform	Product failure and Financial deficit.		5	3	7	105
11	Inadequate performance of cleaning, disinfection or sterilization	(a) Device must be cleaned prior to a new patient	- Bacterial infection in patient - Without proper cleaning, damage to the product can occur	Harm to patient, product failure		5	3	7	105
12	Confusing or missing instructions for use	(a) There are two types of clamps	- The medical professional tries to use turn on the screw of the small clamps	Harm to the patient, product failure		5	8	6	240
13	Complex or confusing control system	(a) Not clear how to use the device, especially how to fixate the device	- Abrupt movement of the foot, when this was not intended.	Harm to the patient		6	2	3	36

14	Use by unskilled or untrained personnel	(a) A medical professional is required to mimic the clinical stress test	- Damage of ligaments - Compromised results	Harm to the patient		6	8	5	240
15	Insufficient warning of side effects	(a) Straps may cause wounds on the foot (b) Overextending of the foot	- if straps are pulled too tight, friction will occur and cause wounds - Ligaments may damage	Harm to the patient		3	4	3	36
16	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 make use of this device	- Not performing the clinical stress test properly	Harm to the patient		6	8	5	240
17	Failure of a component due to ageing, wear or fatigue	(a) Over time, the performance of mechanical components may lower	- Reliability of the device will gradually decrease.	Product failure (during use)		3	10	1	30

#3 has been mitigated from a yellow to a green risk through a risk control of inherent safety by design. #4 has been changed from a rope system to a telescopic clamp system. #6 has an increased criticality index. The metal in the device can cause metal artefacts. Inadequate packaging has been removed as a risk. #12 has an increased criticality index, but has also been mitigated through an indication to the user to only use the green parts of the clamps.

APPENDIX E: DUTCH QUOTES

This appendix includes the original Dutch quotes used in Chapter 4.

Quote 1: *"Blijf oppassen dat op het moment dat je een medische claim doet en je brengt iets op de markt, dat je iets verkoopt. Dat kan ook voor geen geld zijn. Ja dan ben je gewoon de legale fabrikant en dan komen er opeens heel veel eisen op je af, dus je moet daar gewoon voorzichtig mee omgaan."*

Quote 2: *"Ja, dat kan he. Dus in principe kan een ziekenhuis die ontwikkeling delen met een ander ziekenhuis en die kunnen het intern maken. [Maar, red.] hoe hebben ze aangetoond en dat het ook steriel wordt? Het tweede is [dat, red.) een instrument als dit gaat over re-processing. Dus het is een instrument wat keer naar keer gesteriliseerd wordt en herbruikt wordt. Hoe goed is getest dat een product ook 100 keer gesteriliseerd kan worden zonder functie te verliezen? Dat zijn wel dingen die gedaan moeten worden. Ik ben helemaal voor in-huis doen van dingen wat het ziekenhuis kan doen, ook helemaal voordat ze die kennis delen, zeker voor producten die commercieel niet haalbaar zijn. Zijn ze wel commercieel haalbaar, dan moeten ze het [niet via de in-huis route ontwikkelen, red.). Maak er dan een commercieel product van."*

Quote 3:

Interviewer: *"Welk ziekenhuis is verantwoordelijk bij problemen?"*

Expert: *"Het ziekenhuis wat het maakt, want op het moment dat je over in-house productie praat, ligt het in het ziekenhuis. Is het ziekenhuis aansprakelijk? Ja, want eigenlijk formeel gesproken, zegt universiteit hier: 'Je hebt je wat doe er maar mee wat je wil.' Het ziekenhuis moet niet gaan zeggen: 'Hier heb je een device en het werkt sowieso en hier alles is gedaan en als je het zo doet, dan is het wel goed'. Die claim moet je niet gaan maken."*

Interviewer: "*Dus zij moeten er ook voor zorgen dat het andere ziekenhuis dan bewust is van: 'Hé, jullie moeten ook jullie dingen op orde hebben.'?*

Expert: "*'Wij delen wat met je, maar je bent zelf verantwoordelijk voor wat je ermee gaat doen.' Dat moet wel heel duidelijk zijn."*

Quote 4: *"Volgens mij als jij het hulpmiddel overdraagt aan de patiënt op deze manier, als custom-made device, dan ben jij volgens mij verantwoordelijk en ben jij de fabrikant."*

Quote 5: *"Die control units, die wordt dan aangekocht door de patiënt. Maar die wordt wel gekocht, dus daarmee brengt iemand dat dan op de markt. En als dat dus een medisch doel heeft, dan is dat een medisch apparaat. Dus dan ligt de verantwoordelijkheid bij diegene die de control unit maakt, om ervoor te zorgen dat het op een goede manier gebeurt. En iemand anders die gaat iets in elkaar zitten. Dus die fabrikant, die moet dan wel gaan kijken van: 'Hebben wij een handleiding?' Dat het ook goed kan. 'Moeten we die behandelaars gaan trainen?'. Dat soort zaken bijvoorbeeld. In dit geval neemt [het bedrijf, red.) wel heel wat verantwoordelijkheid op zich, want die moeten ervoor zorgen dat dat op een goede manier ook gebeurt en dat het in praktijk op de goede manier wordt uitgevoerd."*

Quote 6: *"Misschien kan [het bedrijf, red.) ook wel zeggen van: 'Ik verkoop aan die ergotherapeut een soort licentie.' Als de ergotherapeut het dan gebruikt en aanmeet helemaal conform de handleiding, dan is die daarmee gevrijwaard. Al heeft hij natuurlijk wel zijn normale verantwoordelijkheid als zorgverlener, als ergotherapeut."*

Quote 7: *"Ik zou het niet in de DIY hoek stoppen, want dan gaan ze naar een andere 3D printer toe en een andere 3D printer betekent dat de materialen weer andere dingen gaan doen. Je wilt het liefst gewoon dezelfde korrels hebben dezelfde 3D [printer, red.). En één keer klaar. En dan kun je met een beetje geluk zelfs de testen van de 3D printer voor dat materiaal plus die printer gebruiken. Vooral omdat het zo lang in contact is met*

handen. Ik zou wegblijven bij dingen in ziekenhuizen neerleggen of bij ergotherapeuten of dat soort dingen. Voor een groot deel helemaal als je buiten ziekenhuizen gaat kijken, hebben mensen geen enkel idee wat het MDR is."

APPENDIX F: LASER CUTTING SETTINGS

This appendix contains information on the laser cutting settings used for performing the laser cutting of polypropylene (thickness = 6mm).

Laser cutter Trotec speedy 300

Lens: red 1.5inch

Polypropylene (PP) 6mm is a difficult material to laser cut, because the settings to cut all the way through cause the material to "melt". A 2-passes method versus 1-pass-twice method has been tested. The two-passes means that the material will be cut in the same place twice. The 1-pass-twice method means that the laser cutter will first cut the whole template, after which the job has to manually be restarted again, and then the template will be cut again a second time. The 1-pass-twice method is preferred because the material has had some time to cool down again. This will result in less "melting" of the material. Therefore, it has been experimentally determined that the material should be cut with the 1-pass-twice method. The settings for the first and second time are slightly different.

Settings first time

Power	90%
Speed	0.09
PPI/Hz	Auto
Auto	On
Passes	1
Air Assist	On
Z Offset	-
Direction	-
Advanced	-

Settings second time

Power	85%
Speed	0.09
PPI/Hz	Auto
Auto	On
Passes	1
Air Assist	On
Z Offset	-
irection	-
Advanced	-