Protocol for external prosthetic and orthotic devices

D 1.1.2

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Protocol for external prosthetic and orthotic devices

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Executive Summary

This document aims to establish a protocol on the steps of designing and additively manufacturing external prosthetic and orthotic devices from image acquisition to use in clinics. This document was developed using a transtibial socket as an example. The information in this document is only intended to describe a general process for designing and additively manufacturing a transtibial socket and should not be used as a final guideline at this time. Furthermore, this document may subject to future updates on the design section and the design is still under development. As a result, the 3DMed project accepts no liability or responsibility for the clinical use of the first version of this document. This document is directly linked with Deliverable 1.2.3 “Report on shape optimization”, Deliverable 1.3.1- “Report on the effect of topology optimisation on the design of medical devices”, Deliverable 4.1.1 “Topology optimization strategies for prosthetic and orthotic devices”, Deliverable 4.2.1 "Material database for AM orthotic and prosthetic devices", deliverable 4.2.3 “Medical grade post-processing”, deliverable 4.3.1 “Design procedures for patient-specific AM orthotics with complex functionality”, and deliverable 4.4.1 “Set of FEM models for limb prostheses”.

1 Introduction

This document specifies the required steps for the design and additive manufacturing of a transtibial socket as an example of external prosthetic devices. The responsible technician and/or biomechanical engineer should adhere to the specifications outlined in this document in order to meet the needs of the patient and document the procedure in accordance with Annex I of this document. Figure 1 depicts the workflow for designing and manufacturing a patient-specific transtibial socket as well as the divisions responsible for monitoring and inspecting each phase of the process from image acquisition to patient use.

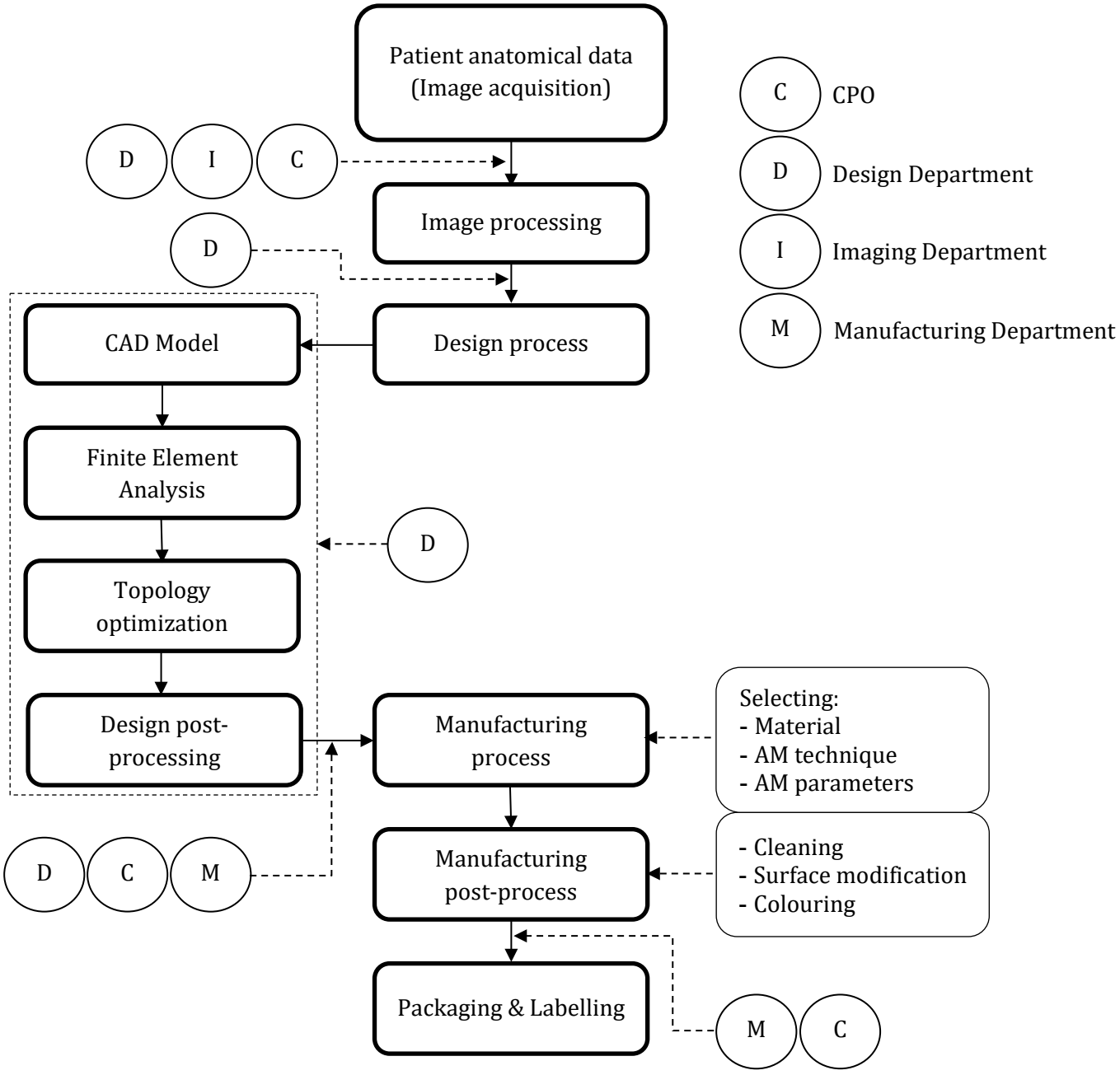


Figure 1 Workflow for producing a patient-specific transtibial socket; the steps are specified with required actions and the corresponding departments to monitor each step.

Before placing a medical device on the European market, compliance with European Commission Regulation (EU) No. 2017/745 [1], commonly known as the Medical Device Regulation (MDR), is

necessary. The common requirements applicable to medical devices are delineated in Annex I General Safety and Performance Requirements (GSPRs) of the MDR. In addition to compliance with the GSPRs, for all devices, a technical file is required. The requirements for the technical file will depend upon the Conformity Assessment Procedure selected. The MDR [1] provides in Annexes II and III detailed instructions on what is the minimum content of technical documentation, also defining a specific structure for it. The technical file should also provide evidence to show that the device satisfies the GSPRs detailed in Annex I of the MDR [1].

Annexes IX, X and XI of the MDR [1] should be used to define the conformity assessment procedure. Device classification partially determines the type of conformity assessment. External prosthetic and orthotic devices are in most cases classified as Class I devices. Class I manufacturers can self-declare the conformity of their products by issuing the EU declaration of conformity mentioned in Article 19 of the EU MDR [1] (once the appropriate technical and quality documentation has been gathered). Self-declaration means neither the Notified Body certification is required nor any other kind of approvals from any certification bodies.

2 Design specifications

The prosthetic socket is a patient-specific design since each patient has a unique anatomical stump that requires its own socket. The prosthesis's aim is to support the patient's weight and restore function to the amputated limb. To accomplish this goal, the socket design should meet the following design requirements:

- The socket should have a perfect fit with a correct stress distribution over pressure-tolerant and pressure-relief areas to prevent discomforts.
- The socket should have adequate strength, to be able to bear the patient’s weight.
- The socket should generate good stability since the prosthesis needs to support the body as stable as an ordinary leg when standing.
- The socket should be adapted to the needs of the patient relative to its activity.
- The socket should be low-weight.
- The design should be cost-effective.

To design a patient-specific optimized transtibial socket, the steps in Figure 2 should be followed to have a realistic finite element (FE) model. In the following sections, the steps for designing a transtibial socket are stated in detail.

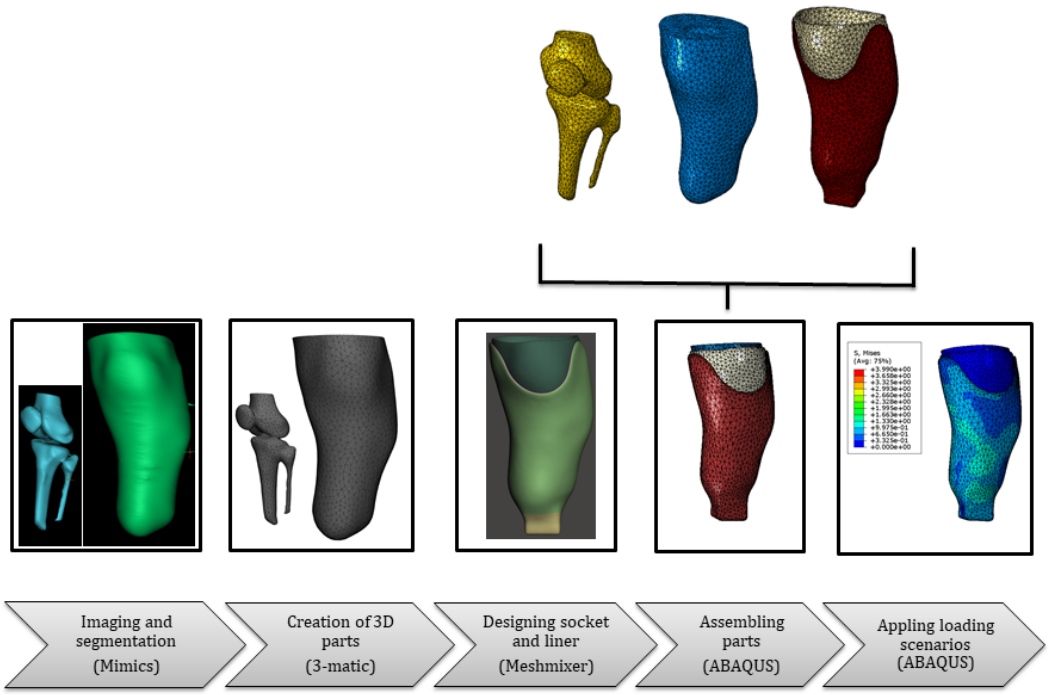


Figure 2 Different steps in designing a patient-specific optimized transtibial socket as well as the associated software (reproduced from D 4.1.1).

2.1 Image Acquisition

The first step of designing a patient-specific optimized transtibial socket is obtaining the geometry of the socket, liner and residual limb consisting of bone and tissue body. In order to make a computer-aided design of the socket, the patients' data and characteristics of the stump should be digitalized. Different image acquisition techniques are used to obtain data for creating a digitally positive model of the residual stump. To provide an accurate model for the external and internal shape of residuum, computed tomography (CT) and optical contact and non-contact scan can be used in the 3DMed project.

The following points and measurements should be considered and specified during the image acquisition:

- Specify the type of the liner to be used
- Measurements and images should be taken over the liner
- Take measurements when the stump is suspended, to avoid any changes in the form of the stump
- Take all measurements while the patient's shoe is removed
- Specify the orientation of the socket and the connection of the adaptor
- Measure the following items:
    - Length from patella to heel
    - Length from patella to the end of the residuum
    - Length from patella to tibial end
    - Length from popliteal depression to the end of the residuum (in flexion posture)
    - Length from tibial end to the end of the residuum
    - Distal circumference with liner
    - Position of patella, lateral condyle, and medial condyle

The aforementioned items as well as the details about the imaging technique used, should be documented according to the Section 2 of Annex I "Patient anatomy data".

2.1.1 Optical scan

Optical scanners differ in the way they provide three dimensional (3D) models of scanned surfaces and the software they use to process the data. The scanner used in the 3DMed project is a Structure Sensor scanner attached to an iPad, using Captevia software[i] with an accuracy of +/- 4 mm at a distance of approximately 40 cm[ii].

To be able to use the scanners in clinical practice, they should have a good reliability and usability. The reliability of the scanners is satisfactory, but the repeatability coefficients of all scanners are pretty large due to outliers. The reliability of the Structure Sensor scanner is also found clinically acceptable, if control measures are taken.

When using an optical scanner, it is hard to accurately determine the areas digitally. One option to overcome this problem is to let the prosthetist first mark the areas on the residual limb and afterwards scan the limbs. Another option is to add landmarks and zones on the real-time obtained 3D model.

The use of optical scanners

The process of image acquisition using the Structure Sensor scanner attached to an iPad, using Captevia software includes the following steps:

1) On your home screen, you can either create a new patient or select an existing one.
   It is necessary to fill in at least his/her first name, last name and gender.
2) Once the patient has been created or chosen from the list, you will be able to select different body parts. When selecting certain body parts, there may be different scanning methods. The name of the body part and the selected scanning method appear at the top left of the screen.
3) Choose "BK", this method allows taking trans-tibial stump scans.
4) Click START to begin, the TT stump contours will appear along with a target with the default settings. This target will tell you whether to close in or go back.
5) The size of the contours can be adjusted using the "Size" slider at the bottom right of the screen. Once the contours have been properly adjusted and positioned, the target turns green and the scan box appears.
6) You can also get more settings with the arrow on the left side of the screen. Here you will find explanations on how to proceed with scanning. Again, you will find the slider to adjust the size of the contours. You can also rotate the contours using the "Default rotation" slider.
7) The placement of the scan box may be modified. You can choose between "Fixed", "Gravity" and "Automatic".
   a. If the chosen placement is "Gravity", new instructions will appear. In this mode, contours will no longer exist.
   b. Similarly, if the placement is "Fixed", new instructions will appear. In this mode the outlines would have also disappeared.
8) Once the settings have been chosen, scanning may begin by clicking on START. When scanning, your distance from the scan box is indicated. In addition, these changes only apply to the current scan.

[i] https://www.rodin4d.com/en/captevia-app-scan-3d
[ii] https://www.rodin4d.com/en/structure-sensor

9) As soon as the scan is complete, the result will appear on your screen. If you are satisfied, click on DONE.
10) You can then export your file by selecting the button: your file will be exported in CPX format to your iPad files (locally), in the CapteviaPlus folder. A dedicated Captevia tool can be used to convert the CPX file to an STL file.

2.1.2 CT scan

CT scanning is another image acquisition technique that allows for fast 3D reconstruction. The following steps should be taken during the image acquisition process to ensure an accurate and eligible CT scan.

1. Preparing and aligning the patient
    - (scanning with possible iodine contrast medium administration) let the patients with thyroid pathology to have their TSH (thyroid stimulating hormone) blood level tested before scanning.
    - (scanning with possible iodine contrast medium administration) let the patients with kidney failure to have their creatinine blood level tested before scanning.
    - remove any non-fixed metal prosthesis or jewellery within the Field of View (FOV).
    - Notify the patient not to move during the CT scan. Every movement, such as tilting and/or rotating the head, can add motion artifacts and compromise the reconstructed images, however, natural breathing is permitted. In the case of movement, rescanning of the patient is necessary.
    - Position the patient as follows: supine, feet first (SFF), patellae pointing forward, and the knees in maximal extension. (If possible), in a way both limbs are as close to the same position as feasible.
    - Always place a marker on the contralateral knee (for the indication of left or right). Use a marker that doesn't hinder the quality of the CT scan.
    - If an implant is present in the contralateral knee, elevate the contralateral knee to prevent artifacts appearing in the joint line of interest.
    - Adjust the table height so that the scan area is centered in the scan region. DO NOT raise or lower the CT table between slices. DO NOT alter the X or Y centering between scans. Center points must be identical.
2. Scanning (the following or the closest approximation possible parameters should be used)
    - Region of interest: knee to the end of stump.
    - No gantry tilt
    - kVp : 100
    - Spiral Pitch Factor : 0.65
    - Matrix : 512×512
    - Slice thickness : 0.5 mm
    - Slice increment : 0.0 mm (HELICAL_CT)
    - Feed per rotation : 6.5 mm
    - Algorithm : FC81

The images should be inspected by the image department, design department and certified prosthetist/orthotist (CPO). In case the scan quality is acceptable, the images should be saved in an uncompressed DICOM format to further proceed with the image post-processing process.

It should be noted that all information requested in the Section 2 of Annex I “Patient Anatomy Data” should be documented by the imaging department.

2.2 CAD model

In order to implement the particular model for computational biomechanics, the geometries of the residual limb, the bony structure, tissue, liner and transtibial socket are needed (Figure 3). Therefore, a 3D scan of the stump with liner is needed to generate the CAD model of the required sections. If liner geometry needs to be captured, a 3D scan of the stump without the liner is required, and a CT scan of the leg is required if bony structure needs to be captured. After receiving the image, a CPO should digitally ‘correct' the 3D scan of the stump with liner in order to improve patient fit. The trimline of the TT (fit transtibial) socket should also be specified digitally by the CPO. Based on the corrected scan the CAD geometry of the socket could be designed.

The data from the image acquisition step can be converted to reconstructed CAD model by segmentation tools. The 3DMed project recommends Mimics® 21.0 (Materialise, Belgium) to reconstruct the 3D model. The design department should document all applicable parameters and procedures for modeling bone and tissue in detail on the form given in Annex I, Section 3 "CAD Model".

The first step in segmentation is importing the DICOM data from CT or optical scans. Then, making the contours around the anatomical region of interest, such as skin and bone in the raw images. Following that, such contours should be selected and segmented. After the creation of the 3D surface model, it is possible to check the accuracy of geometry.

The initial design of the transtibial socket is based on the residual limb's surface boundary. Using the residual limb's outer surface and patient anatomy details, the transtibial socket could be designed by Autodesk Meshmixer™ (version 3.5). Please see deliverable 4.4.1 “Set of FEM models for limb prostheses” for more details on the design process.

To prevent patient from suffering in flexion position, length from patella to the end of the residuum, length from popliteal depression to the end of the residuum in flexion posture, position of patella, lateral condyle, and medial condyle should be considered during the design. Remarks from CPO may be effective at this stage. The design department shall include all details requested in section 4 of Annex I "Patient-Specific Design". Based on the finite element analysis (FEA) software, the exported format should be suitable for further processing.

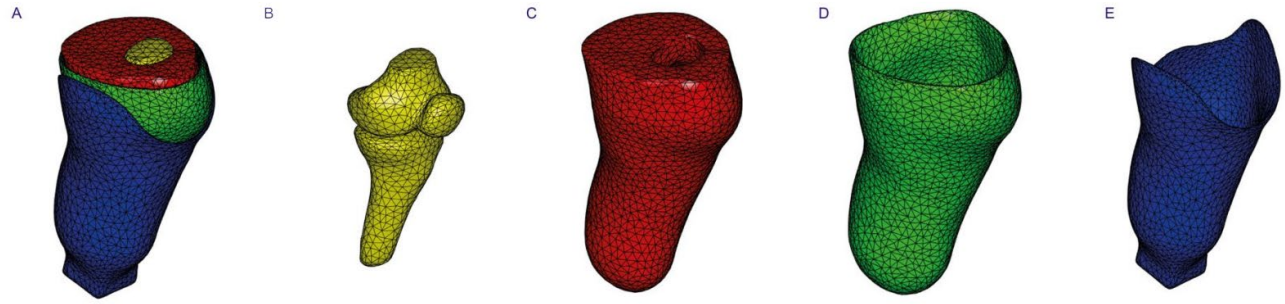


Figure 3 A) The whole model after segmentation, B) femur, patella and tibia, C) the body tissue, D) the liner, E) the transtibial socket with adaptor.

2.3 Finite element analysis

Abaqus FEA software version 2017 can be used for FEA and simulating the socket-stump interaction, the load distribution over the socket in rest and during activity, and assess the structural safety of the socket. FEA will result in pressure values of the socket which can be used to optimize the socket design. Elements that need to consider creating an FEA model for the socket-stump interactions are the mesh generation, material characterization, and boundary conditions. In FEA, the mechanical properties of residual limb, liner, and socket, as described below, are assigned to the imported model from the previous step.

2.3.1 Material properties for socket, liner, bone, and soft tissue

The material properties for each part should be used as Table 1 (derived from the literature review and mechanical test on PA12). The literature review on material properties is discussed in Deliverable 4.1.1.

Table 1 Mechanical properties used in the FE model.

Parts	Young's Modulus [MPa]	Poisson's ratio[-]
Bone	16000	0.3
Body tissue	0.3	0.45
Liner	20	0.45
Socket (made of PA12)	1750	0.4

2.3.2 Interactions

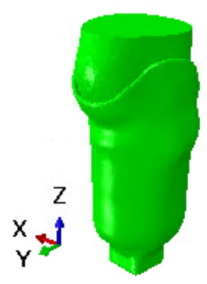
Interaction should be defined between the residual limb and liner as well as the liner and socket. The 3DMed project suggests assuming a tie constraint between these surfaces since there is no movement between the liner and tissue, and the vacuum suspension system prevents the movement between socket and liner.

2.3.3 Boundary condition and loading scenarios

Several activities for loading condition can be used to evaluate the performance of the designed socket. Walking at two velocities (2 and 5 $\frac{Km}{h}$), cycling, one leg stance, and jumping jack could be selected to simulate normal and intense (the worst-case scenario) activities. These activities are chosen based on regular routine activity: 3 normal activities and 2 intense activities. For the boundary condition, the top surface of tissue and bone should be fixed.

All of the forces and moments applied to the knee joint were collected from www.orthoload.com, and the forces and moments used in this particular design for a patient weighing 80 kg is shown in Table 2. Please find more information about force and moment calculations in Deliverable 4.4.1 "Set of FEM models for limb prostheses".

Table 2 Forces and moments for various activities for an 80 kg patient.

Activity	F_x[N]	F_y[N]	F_z[N]	M_x[N.mm]	M_y[N.mm]	M_z[N.mm]	
Walking (2 $\frac{Km}{h}$)	7.46	49.11	1811.04	23767.48	3584.62	6075.9	
Walking (5 $\frac{Km}{h}$)	2.15	171.78	2128.73	2351.64	34187.8	129	
Cycling (60 rpm)	60.9	30.64	821	3417.41	15440.3	1471.5	
One leg stance	-4.96	131.9	2400	8977.7	33429.38	4230.1	

Jumping jack	-13.69	412.45	2883.65	-35517.9	-2968.68	5037.4	

A reference point should be established in the center of the distal end of adaptor. Then all degrees of freedom of the nodes of the lower half part of the adaptor are coupled to this reference point to fully extend the load to all nodes. All forces and moments are applied to that reference point (see Figure 4).

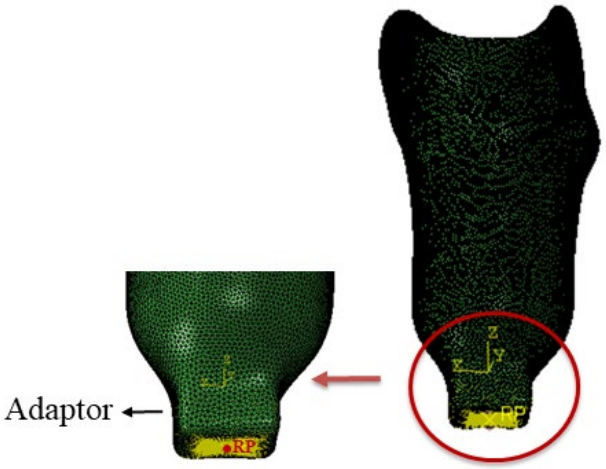


Figure 4 Reference point for applying loading conditions.

2.3.4 Topology optimization

Topology optimization provides the optimal usage of material for design space to meet the requirement on strain energy, stress and displacement, etc. Abaqus Tosca is the software that is used for structural optimization. Software such as Siemens Simcenter, MSC Marc and COMSOL are available as alternatives.

The goal of topology optimization is finding the optimal design which could satisfy the objective function. Therefore, the optimization task should be created, based on the strain energy and volume for design responses in the Abaqus topology optimization module (ATOM). The strain energy should be assigned as objective function and volume as a constraint. The relative strain energy density of the elements plays a crucial role in topology optimization, the elements with the large relative strain energy density are preserved and the element with the small relative strain energy is assumed to be void. In the end, the optimization specifies a new material density for the initial design.

Loading scenario should be chosen considering normal activity and intense activity; in this document jumping jack and walking [5km/h] are considered. The geometric restriction option should be used to freeze two parts of the transtibial socket (Figure 5). The upper part, and the bottom part of the socket which is the adaptor, should stay in the design since the upper part protect the knee area and the bottom part is important to be solid, which makes it attach to the pylon or real adaptor.

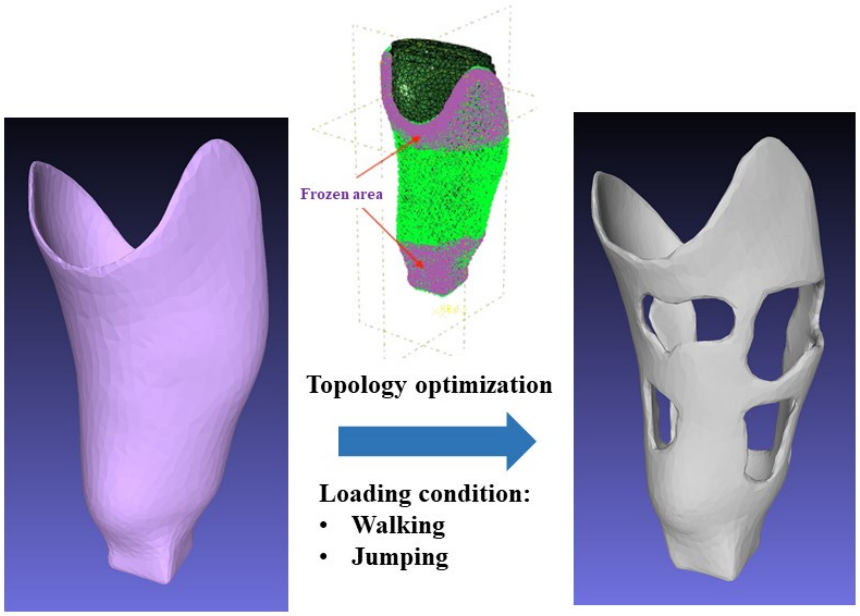


Figure 5 Topology optimization of the transtibial socket and frozen areas in the structural topology optimization (reproduced from D 1.3.1).

For more details on topology optimization of transtibial sockets, please see Deliverable 4.4.1 "Set of FEM models for limb prostheses," and for more detail on medical device topology optimization, please see Deliverable 1.3.1 "Report on the impact of topology optimization on the design of medical devices". Post-processing after topology optimization is needed to smooth sharp edges and the surface of the socket for manufacturing . To this aim, the optimized design of the socket should be extracted and it should be manually modified by either Autodesk Meshmixer™ or 3-matic® (Materialise, Leuven, Belgium) to smooth the roughness and non-smooth edges.

2.3.5 Shape optimization

According to Deliverable 1.2.3 "Report on shape optimization", shape optimization is not required in the case of the transtibial socket as there are no significant differences in stress distribution before and after shape optimization.

2.3.6 Design post-processing

Sharp edges and irregular surfaces are common in structures proposed by topology optimization, which enhance localized stress concentrations (Figure 6 (a)). To prepare the final design for further simulations and manufacturing, post-processing is needed after topology optimization. Software such as Materialise 3-Matic®, SolidWorks®, Autodesk meshmixer™ or Meshlab can be used for 3D CAD post-processing. The steps below shall be considered for design post-processing:

- From the optimized model's ODB file, export the socket's topology optimized design as an object file (*.obj, OBJ format).
- Delete duplicated faces and vertices (if any) by importing the object file into Meshlab (version 2020.12) (an open-source software framework for processing and editing meshes). To this aim, follow the menu bar → filter → cleaning and repairing → remove duplicated faces/remove duplicated vertices.
- Save the edited mesh as an STL/OBJ file to use in the Meshmixer™ (version 3.5) for more post-processing.

- Manually smooth borders and surfaces, removing spikes and isolated mesh segments. To avoid unwanted mass reduction, use local smoothing instead of smoothing the entire structure.
- Use the fill and erase tool to fill in small gaps by selecting the surrounding area of the hole.
- To allow for vacuum suspension, add an internal layer of 1.5 mm thickness to the socket; the socket should not have any holes (Figure 6 (b)).
- Check the optimized design for both regular (i.e., walking) and intensive (i.e., jumping) activities by running the final post-processed design.
- After validating the fully optimized design, add the cavities for the adaptor inserts and vacuum valve (Figure 7). This is done by the following steps:
    - Glue the vacuum valve at the side of the socket.
    - The adaptor inserts consist of 2 parts: (a) an upper part to be inserted into the TT socket and (b) a bottom pyramid shaped part to be placed at the bottom of the TT socket (this part should be connected to the pylon which connects the TT socket to the foot prosthesis). Four countersunk screw are used to attach the pyramid shaped bottom part to the upper part, with the 3D printed material in between.

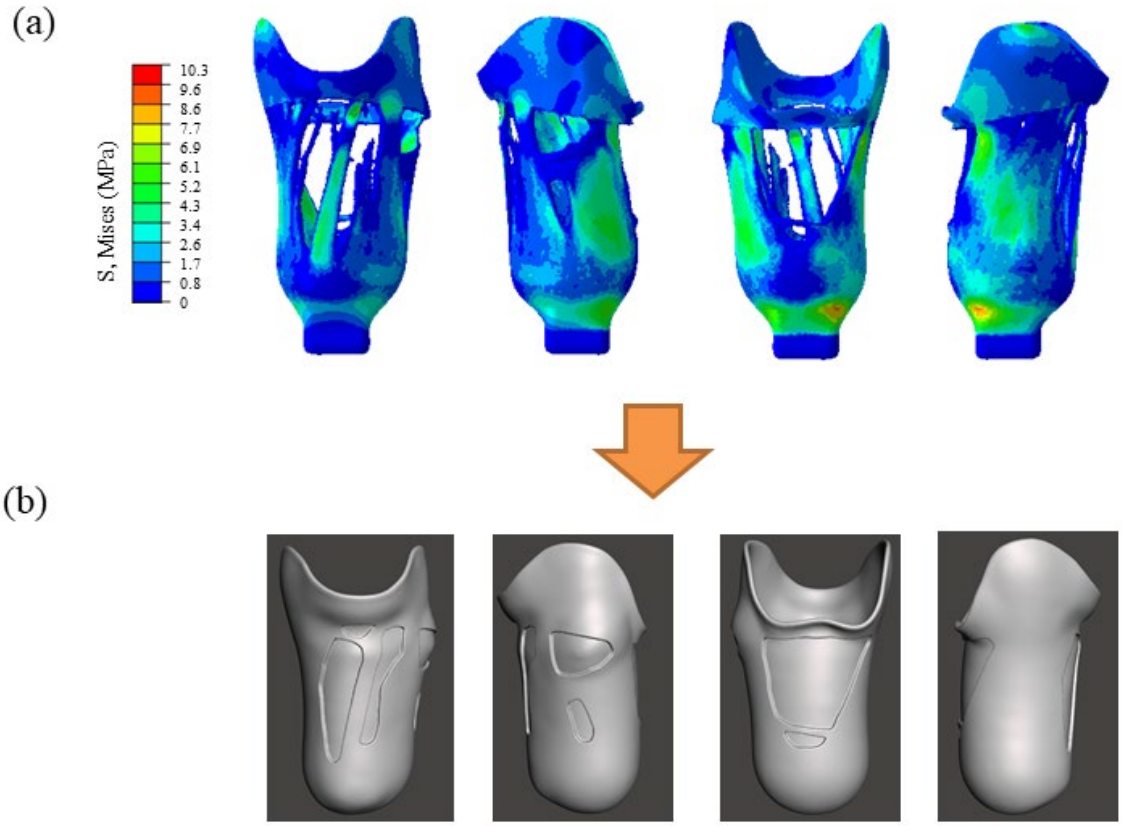


Figure 6 The procedure of post-processing after topology optimization (a) FE results of topology optimization (b) Post-processing after topology optimization (reproduced from D 1.2.3).

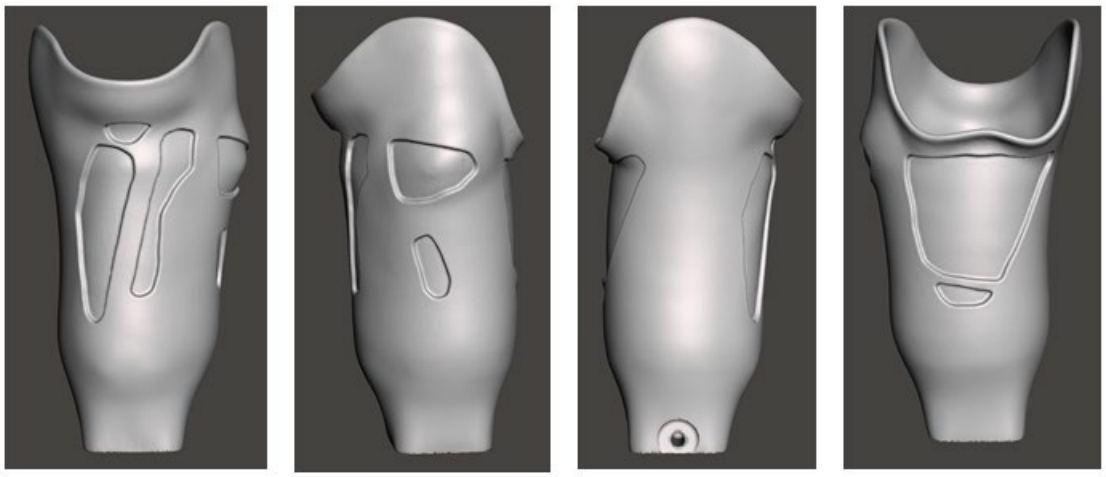


Figure 7 Integration of cavities for the adaptor inserts and vacuum valve (reproduced from D 1.2.3).

As defined in Annex I section 4 “Patient-specific design”, all phases of the FEA should be recorded, and the design should be reviewed and approved by the design department, manufacturing department, and CPO. The guidelines for the design of the transtibial socket as well as scoliosis brace, hand brace, and cast replacement have been given in detail in deliverable 4.3.1 “Design procedures for patient-specific AM orthotics with complex functionality”. For more detail on topology optimization strategies for 3D printed prosthetic and orthotic devices, such as transtibial socket, scoliosis brace, hand brace and cast replacement, please refer to Deliverable 4.1.1 “Topology optimization strategies for prosthetic and orthotic devices”.

3 Material specifications

External prosthetic and orthotic devices are designed to meet specific requirements for flexibility, strength, durability, porosity, and hardness. Materials used in medical applications must meet several requirements. When selecting a material for external prosthetic and orthotic systems, biocompatibility and strength are critical factors to consider. To prevent skin maceration and bacterial invasion, it should also have a high thermal conductivity. The material should be sweat-resistant and functional at body temperature (importance of high thermal conductivity, high thermal capacity, and low thermal degradation properties).

Durability and fatigue resistance are critical specifications for dynamically loaded applications (e.g., a transtibial socket or a hand brace). As a result, the material database should also contain dynamical mechanical properties. The dynamical mechanical properties, on the other hand, are largely unknown. To assess these properties for specific materials, a systemic analysis should be performed.

In the 3DMed project, Nylon 12 (PA12) was chosen as the material for the transtibial socket. This material has a strength and flexibility suitable for sockets. The biocompatibility, mechanical properties, and material characteristics of PA12 were given in Table 3 from Deliverable 4.2.1- "Material database for AM orthotic and prosthetic devices.". To select a material for processability, the refresh rate and melting temperature are also included in the external material database.

Table 3 Biocompatibility, mechanical properties and material characterization of PA12 (PA2200)(adopted from D 4.2.1).

General information

Material name	PA12
Commercial version	PA2200
Supplier	EOS Gmbh (https://www.eos.info/en)
Biocompatibility	
Biocompatible	Yes
Cytotoxicty (ISO 10993-5)	Passed
Irritation test (ISO 10993-10)	Passed
Sensitization (ISO 10993-10)	Passed
Refresh Rate (%old/%new)	50/50
Material properties	
Young's modulus XY (MPa)	1760
Young's modulus Z (MPa)	1750
Tensile strength at break XY (MPa)	50
Tensile strength at break Z (MPa)	50
Strain at break XY (%)	20
Strain at break Z (%)	10
Flexural modulus (MPa)	1500
Izod notched impact strength XY (kJ/m2)	4.4
Charpy notched impact strength XY (kJ/m2)	4.8
Shore hardness (D)	75
Melting temperature (°C)	176

All of the values mentioned in Table 3 and the external material database (D.4.2.1) are optimum values provided by the material supplier and the material database should be updated by the material supplier annually. Details of the material used in the socket should be documented by the manufacturing department in accordance with the Section 5 of Annex I.

4 Manufacturing specifications

The two most used AM techniques for manufacturing prosthetic sockets are selective laser sintering (SLS) and fused deposition modelling (FDM). The SLS technique is used to create the transtibial socket in the 3DMed project.

Following steps should be followed in order to build an additively manufactured transtibial socket. Section 5 of Annex I should be used to document all of the measures described in this section.

4.1 Pre-processing of the digitally design

The transtibial socket design should be exported to the 3D printer. To encode the surface geometry of a 3D object, a specific file format like STL is needed. Since every modelling software exports to STL in a different way, file checking is necessary to ensure that the file is printable and that the slicing software can process it. The 3DMed project recommends to check the file for errors and 'printability' through Autodesk Netfabb (edition 2021). File checking examines STL files for holes, degenerate triangles, duplicate triangles, non-manifold vertices, and other irregularities.

A typical repair workflow contains the following steps:

1) Auto-repair
2) Separating shells
3) Closing holes, bridging gaps
4) Resolving overlaps and intersections
5) Stitching open edges and remaining holes.
6) Manual repair by deleting and creating triangles.
7) Remeshing

After file checking, the mesh file is put into a slicer software. Autodesk Netfabb translates the mesh file to a layer-by-layer toolpath with specific machine settings and preferences. Each printing technique has its own settings to set up a new printing job.

4.2 3D printing

The manufacturing process is automatically performed by the 3D printer, however, printing parameters, such as infill ratio, printing temperature, and layer height, should be determined and documented by the manufacturing department according to section 5 of Annex I. It should be noted that each AM technology and machine model has its own set of parameters and configurations, and when printing various devices or parts, the optimum settings and parameters for a single machine model can vary significantly.

The 3DMed project suggests manufacturing transtibial sockets with PA-12 and the SLS printing method. In this project, the EOSINT P system machine was configured with a wall thickness of 4mm, a layer thickness of 0.1 mm, and the input volumetric energy of 0.3 J/mm^3.

Regardless the printing techniques, critical process parameters to consider are:

- Temperature and humidity of the environment
- Processing temperature
- Printing speed
- Layer thickness, layer adhesion
- Material temperature

- Specific machine parameters
    - For SLS: scaling factors, scanning speed, laser power, beam offset, scan spacing, scan strategy

A CPO should inspect the quality of the transtibial socket after it has been printed, and if the quality of the product is acceptable, the socket should go through the required post-processing.

4.3 Post-processing

Following the AM process, post-processing is often needed to make the product available for clinical use of additively manufactured transtibial sockets.

Post-processing operations are generally dependent on the type of 3D printing process used. For the case of the transtibial socket which is produced by PA12 and SLS technique, support removal is not necessary as SLS uses the unsintered powder as a support structure.

As the socket is fabricated by SLS technique, the socket related post- processing step can be achieved by polishing the internal surface. In addition, the outer surface of the socket should be cleaned. If the texture of the material is not smooth enough, the socket must be polished to achieve this aim.

For the case of the transtibial socket, the following post-processing operations were considered during the 3DMed project. More information on the methods for post-processing additively manufactured prosthetic and orthotic applications can be found in Deliverable 4.2.3 "Medical grade post-processing".

- Cleaning
    - Bead blasting
    - Ultrasonic cleaning
- Surface modification
    - Vibro polish: tumbling and/or polishing:
    - Chemical polishing: using Boundary Layer Automated Smoothing Technology (BLAST)
- Colouring
    - Dye process
- Assembly

All post-processing steps shall be documented according to the Section 6 of Annex I, and it should be checked that the biocompatibility of the printed material is not affected according to the Section 7 of Annex I. After post-processing and assembly of the final product, the final product should be checked and approved by the manufacturing department and CPO.

4.4 Packaging and labeling

According to Chapter III of EU MDR [1]- “Requirements regarding the information supplied with the device”, the label shall bear the following particulars:

- (Design) name of the device
- Date of manufacture
- Information strictly necessary for identifying the device (i.e., case number)
- Manufacturer name and address details
- Storage and handling conditions

- Specific warnings important for the end user (e.g., Body mass limit not to be exceeded more than 80 kg)

Before shipment, the final product should be packaged with bubble wrap and styrofoam protective packaging beads, and the Section 8 of Annex I "Packaging and labeling" should be completed.

5 Validation specifications

5.1 Biocompatibility validation

Biocompatibility testing is an essential requirement for regulatory approval of a medical device. The ISO 10993 standards concerns biocompatibility and determines which tests shall be performed, depending on “Nature of body contact” and “Contact duration” (see Table 4).

According to ISO 10993-1 [2], external prosthetic and orthotic devices can be considered as surface devices with intact skin contact and a contact duration > 30 days. Based on Table 4, this product category only requires assessment of cytotoxicity, skin sensitization and irritation of the final medical device. Choosing materials that have already been determined by the supplier to be biocompatible (according to ISO 10993-1) is a good starting point.

D 4.2.1, the external material database, contains information about the biocompatibility of PA12 (PA2200), and test certificates are available upon request. Indeed, the material supplier should have an annual report containing the most recent test results for the material. Table 3 shows the results of the biocompatibility tests for PA12 (PA2200). It is the responsibility of the end-manufacturer to prove the biocompatibility of the final medical device. Therefore, Section 7 of Annex I should be completed and approved by the CPO.

Medical device categorization by			**Biological effect**												
Nature of Body Contact		**Contact Duration**													
Category	**Contact**	**A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – permanent (> 30 d)**	**Cytotoxicity**	**Sensitization**	**Irritation or Intracutaneous Reactivity**	**Acute Systemic Toxicity**	**Material-Mediated Pyrogenicity**	**Subacute/Subchronic Toxicity**	**Genotoxicity**	**Implantation**	**Hemocompatibility**	**Chronic Toxicity**	**Carcinogenicity**	**Reproductive/Developmental Toxicity#**	**Degradation@**
Surface device	Intact skin	A	X	X	X										
		B	X	X	X										
		C	X	X	X										
	Mucosal membrane	A	X	X	X										
		B	X	X	X	O	O	O		O					
		C	X	X	X	O	O	X	X	O		O			
	Breached or compromised surface	A	X	X	X	O	O								
		B	X	X	X	O	O	O		O					
		C	X	X	X	O	O	X	X	O		O	O		
External communicating	Blood path, indirect	A	X	X	X	X	O				X				
		B	X	X	X	X	O	O			X				

Table 4: (continued)[2]

Medical device categorization by			Biological effect											
Nature of Body Contact		Contact Duration												
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – permanent (> 30 d)	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity	Material-Mediated Pyrogenicity	Subacute/Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental Toxicity#	Degradation@
device		C	X	X	O	X	O	X	X	O	X	O	O		
	Tissue+/bone/ dentin	A	X	X	X	O	O								
		B	X	X	X	X	O	X	X	X					
		C	X	X	X	X	O	X	X	X		O	O		
	Circulating blood	A	X	X	X	X	O		O^		X				
		B	X	X	X	X	O	X	X	X	X				
		C	X	X	X	X	O	X	X	X	X	O	O		
Implant device	Tissue+/bone	A	X	X	X	O	O								
		B	X	X	X	X	O	X	X	X					
		C	X	X	X	X	O	X	X	X		O	O		
	Blood	A	X	X	X	X	O		O	X	X				
		B	X	X	X	X	O	X	X	X	X				
		C	X	X	X	X	O	X	X	X	X	O	O		

X = ISO 10993-1:2009 recommended endpoints for consideration*
O = Additional FDA recommended endpoints for consideration*
Note * All X's and O's should be addressed in the biological safety evaluation, either through the use of existing data, additional endpoint-specific testing, or a rationale for why the endpoint does not require additional assessment.
Note + Tissue includes tissue fluids and subcutaneous spaces
Note ^ For all devices used in extracorporeal circuits
Note # Reproductive and developmental toxicity should be addressed for novel materials, materials with a known reproductive or developmental toxicity, devices with relevant target populations (e.g., pregnant women), and/or devices where there is the probability for local presence of device materials in the reproductive organs.
Note @ Degradation information should be provided for any devices, device components, or materials remaining in contact with tissue that are intended to degrade.

5.2 Physical and mechanical validation

To clinically verify the socket, two factors must be considered: quantitative evaluation and qualitative assessment. These include computational criteria for evaluating the fitting quality of prosthetic sockets as well as patient/CPO satisfaction with socket fitting. The outcomes of the fitting evaluation should be recorded in Annex I, Section 7.

The most significant factors affecting patient satisfaction with prostheses are gait normality and stump-socket interface stress distribution. During the patient-specific design, the FEA attempts to control these variables. However, these variables should also be assessed during the fitting process.

To prove the clinical safety and effectivity, the additive manufactured socket should be assessed for long-term durability and performance. The ISO 10328:2016 titled "Structural testing of lower-limb prostheses" contains static and cyclic strength test to test the components of the lower-limb prosthesis" [3].

Based on ISO 10328:2016 [3], the two test principles in general can be applied as follows:

- The statistic test procedure consists of a proof strength test and an ultimate strength test. This test procedure is carried out to determine the performance of the load-bearing structures under typical sever loading conditions that can occur during use by users as occasional single events.

- The cyclic test procedure consists of repeated applications of a prescribed load to a test sample with loading conditions typical of normal walking, followed by a final static test for which the loading and unloading procedures of the relevant static proof apply.

To meet the standard, damage is allowed to occur during ultimate strength testing, as long as there is no complete failure. The different loading levels and test loadings can be found in the standard.

During the 3DMed project, a compression test was performed to determine the compressive strength of a transtibial socket built and printed in polyamide 12 according to the protocol outlined in this document. The socket was tested using the LLOYD instrument (LR5K) machine equipped with a 5 kN load cell in a displacement-controlled compression test at a rate of 0.5 mm/min. Following ISO10328, the test was continued to a maximum compression force of 4500 N, and the test was repeated, with no component failure observed.

6 References

1. E.p.a. Council, Regulation (EU) 2017/745, Official Journal of the European Union, 2017.

2. Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", FDA Guidance.

3. ISO 10328. Prosthetics-structural testing of lower limb prostheses-Requirements and test methods, 2016.

Annex I: Requirements regarding design, manufacturing, and post-processing of the patient-specific Transtibial socket

During design, manufacturing, and post-processing of the patient-specific transtibial socket, the following information shall be documented by each related department. In this annex, the required information is provided in the order of the production process.

Protocol for external prosthetic and orthotic devices

1. General Information	
Date of receiving order(DD/MM/YYYY)	Click or tap to enter a date.
Scheduled patient fit date (DD/MM/YYYY)	Click or tap to enter a date.
Patient name	Click or tap here to enter text.
Patient number	Click or tap here to enter text.
Prosthetist name	Click or tap here to enter text.
E-mail	Click or tap here to enter text.
Phone	Click or tap here to enter text.
Shipping address (country, city, postal code)	Click or tap here to enter text.

Patient Information

Sex	☐Female	☐Male
Age	Click or tap here to enter text.	
Weight (kg)	Click or tap here to enter text.	
Height (cm)	Click or tap here to enter text.	
Specific skin allergy	Click or tap here to enter text.	
Amputation side	☐Left	
	☐Right	
	☐Bilateral	
Activity level	☐Low	
	☐Moderate	
	☐High	
	☐Very high	
Socket style	☐TSB-Total Surface Bearing	
Liner ☐ Silicon	☐Locking-with locking pin attachment	
☐Copolymer	☐ Locking with vacuum	
☐ Urethane	☐Anatomical locking (no pin or vacuum used)	
☐ Foam		

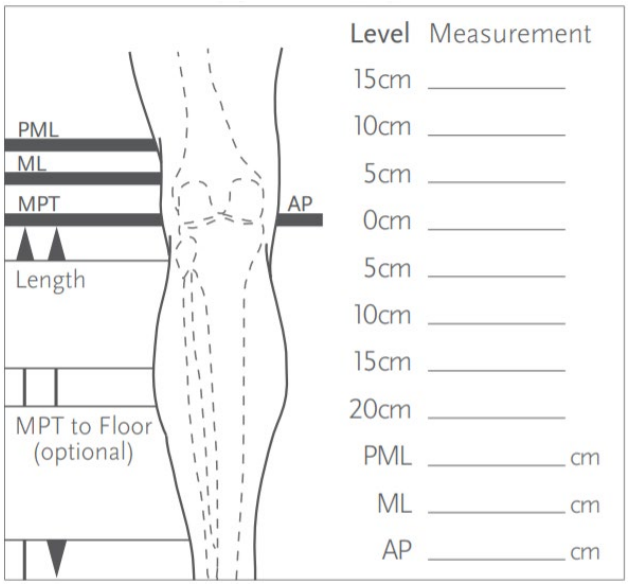
Click or tap here to enter text.	Click or tap to enter a date.
Initial & Signature of CPO	Date (DD/MM/YYYY)

2. Patient anatomy data

***Notes: Use scanning protocol in section 2.1 of Deliverable 1.1.2 as a guideline.

Measurements

☐Measurements have taken over liner.



Reference: https://www.ossur.com/

Length from patella to end of residuum (mm)	Click or tap here to enter text.
Length from patella to heel (mm)	Click or tap here to enter text.
Length from patella to distal tibia (mm)	Click or tap here to enter text.
length from distal tibia to end of stump (mm)	Click or tap here to enter text.
Length from popliteal depression to the end of the residuum (in flexion posture) (mm)	Click or tap here to enter text.
Distal Circumference with liner (mm)	Click or tap here to enter text.
Position of patella (mm)	Click or tap here to enter text.

Image Acquisition

Date of image acquisition	Click or tap to enter a date.	
Image acquisition technique	☐Optical scanning	☐CT-scan

☐The liner is worn during image acquisition.

☐Optical Scan

***Note: Do not press one side of the foot against the surface during the scanning.

Scan Provided by	Click or tap here to enter text.
☐The scanner is calibrated.	
File format	☐STL
Scan Technique	☐Non-contact scanning
Scanner Model	Click or tap here to enter text.
Type of sensor	Click or tap here to enter text.
Type of hardware	Click or tap here to enter text.
Type of software	Click or tap here to enter text.

Protocol for external prosthetic and orthotic devices

Accuracy (mm)	Click or tap here to enter text.
☐CT-Scan	
Scan Provided by	Click or tap here to enter text.
File format	☐DICOM
Region of interest	Click or tap here to enter text.
Scanner model	Click or tap here to enter text.
Matrix	Click or tap here to enter text.
Algorithm	Click or tap here to enter text.
Image slice interval	Click or tap here to enter text.
Image slice thickness	Click or tap here to enter text.
Gantry Tilt	Click or tap here to enter text.
Pitch	Click or tap here to enter text.
☐ The scan covers the region of interest (ROI).	
☐Image does not contain major artifacts such as metal and motion artifacts.	
☐The orientation of the socket and the connection of the adaptor are specified.	
Click or tap here to enter text.	Click or tap to enter a date.
Imaging department approval	Date (DD/MM/YYYY)
Click or tap here to enter text.	Click or tap to enter a date.
Design department approval	Date (DD/MM/YYYY)
Click or tap here to enter text.	Click or tap to enter a date.
CPO approval	Date (DD/MM/YYYY)

3. CAD Model	
Software	☐3-Matic® version: Click or tap here to enter text.
Bone structure	
Exported file	☐STL
HU range (Min & Max)	Click or tap here to enter text.
Segmentation method	Click or tap here to enter text.
Brief description of segmentation procedure (in case manual work has been employed):(i.e., extended region, filling holes,…)	
Click or tap here to enter text.	
Tissue	
Exported file	☐STL
HU range (Min & Max)	Click or tap here to enter text.
Segmentation method	Click or tap here to enter text.
Brief description of segmentation procedure (in case manual work has been employed):	
Click or tap here to enter text.	
Click or tap here to enter text.	Click or tap to enter a date.
Design department approval	Date (DD/MM/YYYY)

4. Patient-Specific Design

Date of Receiving validated CAD model (DD/MM/YYYY) Click or tap to enter a date.

Design Software: ☐Meshmixer™ version: Click or tap here to enter text.

Accessories Summary

☐ Pylon: ☐22mm ☐30mm ☐34mm

☐Steel ☐Titanium ☐Aluminium

☐ Pylon adaptor: Click or tap here to enter text.

☐ Foot: Click or tap here to enter text.

Acceptable manufacturing tolerance: Click or tap here to enter text.

Initial design

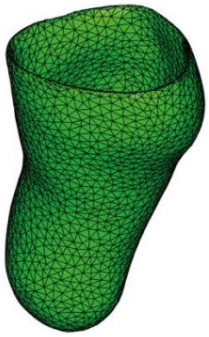
Liner

Software: ☐Meshmixer™ version: Click or tap here to enter text.

Exported file: ☐STL

Liner thickness (mm): Click or tap here to enter text.

Insert the liner here (see below for an example)

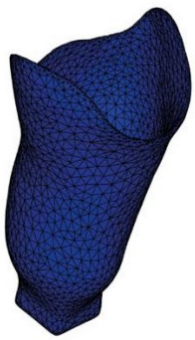


Socket thickness (mm): Click or tap here to enter text.

Brief description of designing procedure (specify where smoothing and thickening is used)

Click or tap here to enter text.

Insert initial design of the socket here (see below for an example)



Parts Assembling and Finite Element Analysis

Software:	☐Abaqus version: Click or tap here to enter text.

Parts Specifications

☐Bone	
Type of element	☐C3D4_ 4-node linear tetrahedron
Number of elements	Click or tap here to enter text.
☐Body tissue	
Type of element	☐C3D4_ 4-node linear tetrahedron
Number of elements	Click or tap here to enter text.
☐Liner	
Type of element	☐C3D4_ 4-node linear tetrahedron
Number of elements	Click or tap here to enter text.
☐Socket	
Type of element	☐C3D4_ 4-node linear tetrahedron
Number of elements	Click or tap here to enter text.

Material properties

☐Bone	
Young's modulus (MPa)	☐16000
Poisson ratio	☐0.3
☐Body tissue	
Young's modulus (MPa)	☐0.3
Poisson ratio	☐0.45
☐Liner	
Young's modulus (MPa)	☐20
Poisson ratio	☐0.45
☐Socket	
Young's modulus (MPa)	☐1750
Poisson ratio	☐0.4

Interactions

☐Bone & Tissue:	
Master	☐Bone
Slave	☐Tissue
Type	☐Tie constraint
☐Tissue & Liner:	
Master	☐Tissue
Slave	☐Liner

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Type ☐Tie constraint

☐Liner & Socket:

Master ☐Socket

Slave ☐Liner

Type ☐Tie constraint

Boundary conditions

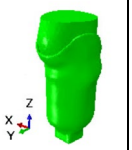
Explain assumed boundary conditions in detail

Click or tap here to enter text.

Loading conditions

Note: Loading scenarios only applicable to patients weighing 80 kg. For other weights, please refer to Section 2.3.3 of D.1.1.2.

Activity	F_x[N]	F_y[N]	F_z[N]	M_x[N.mm]	M_y[N.mm]	M_z[N.mm]
☐Walking (2 $\frac{Km}{h}$)	7.46	49.11	1811.04	23767.48	3584.62	6075.9
☐Walking (5 $\frac{Km}{h}$)	2.15	171.78	2128.73	2351.64	34187.8	129
☐Cycling (60 rpm)	60.9	30.64	821	3417.41	15440.3	1471.5
☐One leg stance	-4.96	131.9	2400	8977.7	33429.38	4230.1
☐Jumping jack	-13.69	412.45	2883.65	-35517.9	-2968.68	5037.4



Maximum stress (von Mises) Click or tap here to enter text.

Anatomical location on the residuum Click or tap here to enter text.

Stress concentration (location) Click or tap here to enter text.

☐ In comparison to the yield stress of the material, the maximum von Mises is acceptable.

Topology optimization

Software Abaqus Tosca version:Click or tap here to enter text.

Objective function ☐Strain energy

Constraint ☐Volume

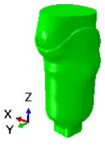
☐The number of cycles was initially set to 50.

Total cycle after TO Click or tap here to enter text.

Maximum stress Click or tap here to enter text.

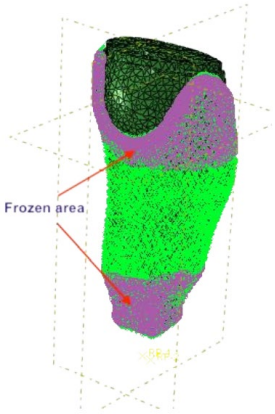
Loading condition for TO

Activity	F_x[N]	F_y[N]	F_z[N]	M_x[N.mm]	M_y[N.mm]	M_z[N.mm]
☐Walking (5 $\frac{Km}{h}$)	2.15	171.78	2128.73	2351.64	34187.8	129
☐Jumping jack	-13.69	412.45	2883.65	-35517.9	-2968.68	5037.4



Specify frozen area here (see below for an example)

Protocol for external prosthetic and orthotic devices



Topology optimization- Post Processing

Software Meshmixer™ version:Click or tap here to enter text.

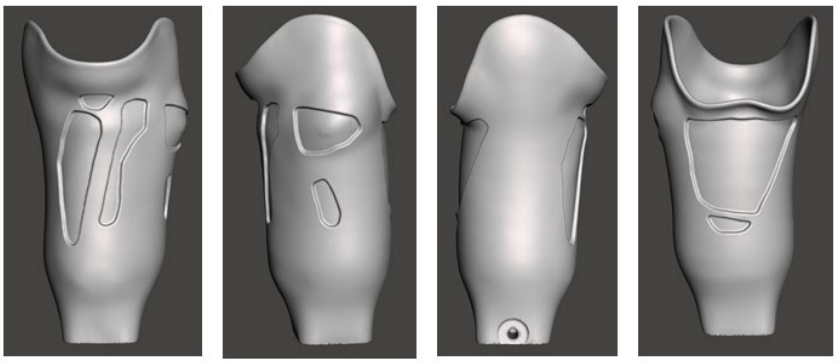
Explain what modifications have been made to the optimized model (i.e., smoothing sharp edge, remove islands,…)

Click or tap here to enter text.

Thickness of the added inner wall: Click or tap here to enter text.

Insert final topology optimized design here (see below for an example)

Insert design after adding inner wall, adaptor, and valve (see below for an example)



Click or tap here to enter text.	Click or tap to enter a date.
Design department approval	Date (DD/MM/YYYY)
Click or tap here to enter text.	Click or tap to enter a date.
CPO approval	Date (DD/MM/YYYY)
Click or tap here to enter text.	Click or tap to enter a date.
Manufacturing department approval	Date (DD/MM/YYYY)

5. Material and Manufacturing			
Received validated design on (DD/MM/YYYY)	Click or tap to enter a date.		
Material Specifications			
Material details:	☐PA12	☐Fresh	☐Re-used
Material supplier	Click or tap here to enter text.		
Identification/ Catalogue No.	Click or tap here to enter text.		
Particle size (µm)	Click or tap here to enter text.		
Particle shape	Click or tap here to enter text.		
Young's modulus XY (MPa)	Click or tap here to enter text.		
Young's modulus Z (MPa)	Click or tap here to enter text.		
Tensile strength at break XY (MPa)	Click or tap here to enter text.		
Tensile strength at break Z (MPa)	Click or tap here to enter text.		
Strain at break XY (%)	Click or tap here to enter text.		
Strain at break Z (%)	Click or tap here to enter text.		
Elongation[%]	Click or tap here to enter text.		
Hardness	Click or tap here to enter text.		
Storage conditions	Click or tap here to enter text.		
Expiration date (MM/YYYY)	Click or tap here to enter text.		
Manufacturing Specifications			
Printing technique	☐ Selective Laser Sintering (SLS)		
Machine model	Click or tap here to enter text.		
Max. part dimension	Click or tap here to enter text.		
Estimated manufacturing time (min)	Click or tap here to enter text.		
Slicing software	☐Autodesk Netfabb version:Click or tap here to enter text.		
☐ The STL file has been checked and found to be printable.			
Printing parameters			
Print orientation	Click or tap here to enter text.		
Layer thickness (µm)	Click or tap here to enter text.		
Wall thickness (mm)	Click or tap here to enter text.		
Total volumetric energy input (0.3-0.5 J/mm^3)	Click or tap here to enter text.		
Click or tap here to enter text.	Click or tap to enter a date.		
Manufacturing department approval	Date (DD/MM/YYYY)		

6. Post-processing	
Received printed part on (DD/MM/YYYY)	Click or tap to enter a date.
☐ Surface modification Explain:Click or tap here to enter text.	☐Vibro polish ☐Chemical polishing
☐ Cleaning Explain:Click or tap here to enter text.	☐Bead blasting ☐Ultrasonic cleaning
☐ Colouring Explain:Click or tap here to enter text.	☐Dye process
Click or tap here to enter text.	Click or tap to enter a date.
CPO approval	Date (DD/MM/YYYY)
Click or tap here to enter text.	Click or tap to enter a date.
Manufacturing department approval	Date (DD/MM/YYYY)

7. Biological, physical, and mechanical evaluation	
☐Sufficient justification/clinical data for risk assessment is documented.	
☐Sufficient data for all chemicals in the material is documented.	
☐Product was tested according to EN-ISO 10993-5 and was NOT found cytotoxic.	
☐Product was tested according to EN-ISO 10993-10 and was NOT found sensitizing.	
☐Product was tested according to EN-ISO 10993-10 and was NOT found irritating.	
☐Biocompatibility sufficiently demonstrated according to EN-ISO 10993-1.	
☐The biological risk is acceptable.	
☐The socket have a perfect fit.	
☐The socket have adequate strength, to be able to bear the patient's weight.	
☐The socket generate good stability and is as stable as an ordinary leg when standing.	
Click or tap here to enter text.	Click or tap to enter a date.
CPO approval	Date (DD/MM/YYYY)

8. Packaging & Labelling	
Date of packaging(MM/DD/YYYY)	Click or tap to enter a date.
Expiration Date(MM/DD/YYYY)	Click or tap to enter a date.

Labelling checklist

☐(Design) name of the device	☐ Storage and handling instructions
☐Date of manufacture	☐ Indication of how to open the packaging
☐ Manufacturer & address details	☐ Logo (if applicable)
☐Patient case number	☐ Warnings and precautions

☐ Specific information:Click or tap here to enter text.

☐ Special warning:Click or tap here to enter text.

☐Socket is packaged with bubble wrap and styrofoam protective packaging beads.

Click or tap to enter a date.	Click or tap here to enter text.
Date of shipping(MM/DD/YYYY)	Operated by