Protocol for surgical instruments D 1.1.3

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Executive Summary

This document aims to establish a protocol on the steps of designing and additively manufacturing surgical instruments from image acquisition to use in clinics. This document was developed using a scaphoid drill guide as an example. The information in this document is only intended to describe a general process for designing and additively manufacturing a scaphoid drill guide and should not be used as a final guideline at this time. Furthermore, this document is subject to future updates on the design section, as this document is based on the initial design of the surgical guide 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 5.3.1-"Procedure to manufacture patient-specific 3D printed orthopaedic surgical guides".

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1. Introduction

In this document, a scaphoid drill guide is used as an example to set a protocol to design and manufacture such a surgical instrument. The scaphoid drill guide is a class IIa device according to Rule 6 of the Medical Device Regulation 2017/745 [1] (invasive device intended for transient use). The device is also considered as a custom-made device according to the definition set out in the Medical Device Regulation 2017/745. Therefore, all the requirements defined for custom-made class IIa devices apply to this given example (refer to Annex XIII of the MDR 2017/745). The workflow for producing a patient-specific scaphoid drill guide as well as the corresponding departments for monitoring and inspection of each step is illustrated in Figure 1, from image acquisition to its use in clinics. Details of each step should be recorded using the forms in Annex I of this document.

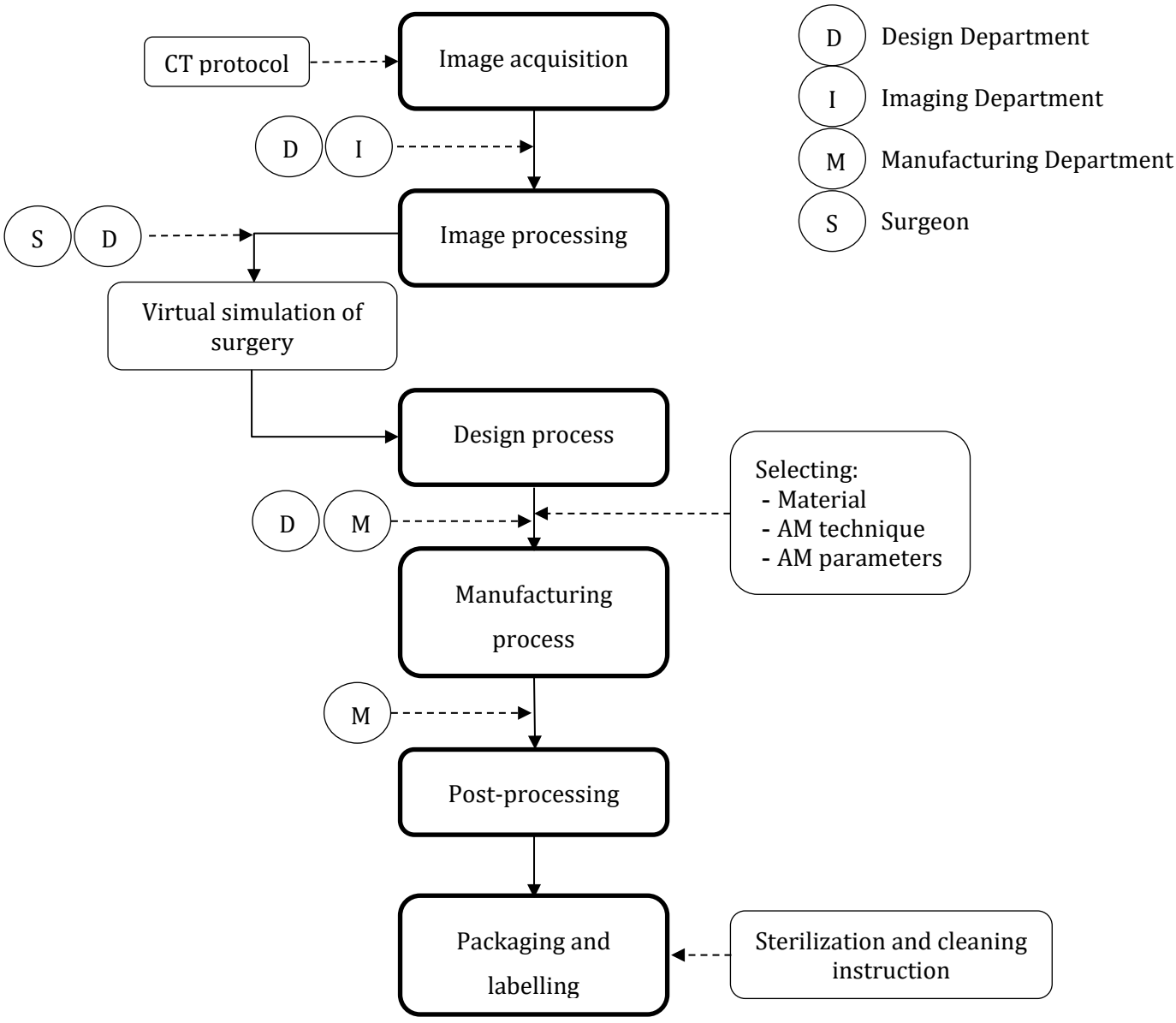

Figure 1: Workflow for producing a patient-specific scaphoid drill guide; the steps are specified with required actions and corresponding departments to monitor each stage.

2. Design specifications

A surgical drill guide will be patient-specific. The process of designing such a patient-specific medical device starts with medical imaging of the region of interest (*e.g.*, the scaphoid) and the images are processed using specific software to create a virtual 3D model. The device is then created from this 3D model. These steps are certainly needed to prepare an input file required for the manufacturing of the device using an additive manufacturing (AM) technique [2].

Patient-specific device design requirements are determined either directly by clinical staff, the device manufacturer or by a third party in response to clinical inputs and to the manufacturing method chosen. Person measures, clinical evaluations, patient imaging, or a combination of these sources may all be used to generate these inputs. Changes to the final device, as well as the techniques used to make the changes, can have a direct impact on the patient. Therefore, it is important to clearly identify the clinically relevant design parameters, the pre-determined range (min/max) for these parameters, and which of these parameters can be modified for patient-matching [2]. In the following sections, steps relevant to the design of a surgical drill guide are stated in details

2.1. Image acquisition and processing

Computed tomography (CT) and/or magnetic resonance imaging (MRI) scans can be used to design a patient-specific surgical instrument. In this document, an example imaging procedure has been provided to acquire medical images (*i.e.*, CT scan) needed for the accurate design and manufacturing of a patient-specific scaphoid drill guide.

Image quality and medical data post-processing would influence the end quality of a designed product to a certain degree. Therefore, a procedure should be followed to obtain acceptable medical images for subsequent procedures. The precise control of the size and shape of a patient-specific (either additively manufactured or not) medical device may be affected, among many others, by the following factors [2]:

- The minimum image feature quality and resolution (e.g., low-resolution may hamper the depiction of the structure of interest)
- Image post-processing algorithms (e.g., too much smoothing of a bone contour may have an adverse effect on bone shape/size determination)
- The rigidity of the anatomic structure of interest (e.g., the deformation of a soft tissue during respiration may cause difficulties)

2.1.1 Image acquisition

Image acquisition is the first point of data entry into the design process. For designing a scaphoid drill guide, CT scan is considered in this protocol.

Before image acquisition starts, the clinician should consider the following points:

- (If contrast-enhancement is needed) perform image acquisition on an empty stomach,

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- (scanning with possible iodine contrast medium administration) let patients with thyroid pathology to have their TSH blood level tested before scanning,
- (scanning with possible iodine contrast medium administration) let 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

Minimum criteria for obtaining medical images must be decided on a case-by-case basis.[1] They are mentioned below for scanning the scaphoid with a CT scan (adopted from Deliverable 5.3.1):

Maximum slice thickness*	<1 mm
Gantry tilt	0 degree
Area of interest and margin	hand, from wrist to mid-fingers
Position of patient during imaging	hand in a resting position
Maximum acceptable duration between surgery date and CT scan date**	unspecific as the condition does not evolve

**Lower slice thickness in cases that very small structures must be scanned (i.e., 0.5mm for the orbital floor)*
***In the trauma or any evolving condition (such as tumor), the maximum acceptable duration between surgery date and CT scan data would be reduced. Any change in the condition or in the anatomy would lead to mismatch or malfunction of a surgical guide.*

The recommendations for the above parameters, as well as other parameters that can affect the image quality, are specified in section 3 of Annex I- "Patient anatomy data".

The images should be inspected by a clinician. 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.

2.1.2 Image processing

The post-processing of medical images will be the next step following their acquisition. The post-processing stage can serve different purposes (*e.g.*, registration of images acquired using two or more imaging modalities) and steps involved in it depend on the application of interest. CE-marked software should be used to create a precise digital model of the anatomy include Synopsys Simpleware ScanIP and Mimics® Materialise. In this section, the focus will be placed on the scaphoid drill guide and the Synopsys Simpleware ScanIP software version R-2021.03 will be used for segmentation.

If the medical images received are deemed acceptable, the scaphoid will be segmented from them by following the steps indicated below:

- Open Synopsys Simpleware ScanIP software

[1] Refer to the deliverable D 3.5.2 "Tailored design for each group of products" for further information on medical imaging parameters (e.g., maximum slice thickness, gantry tilt, maximum acceptable duration between medical image acquisition date and surgery date).

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- Create a New Project under the name of the patient ID
- Import the DICOM images from the folder that consists of high contrast images (this would be important to better capture the anatomical structure of interest) and the highest number of images
- From the Image Processing menu, choose the Threshold tool and create a mask by choosing an appropriate range of Hounsfield units (HU) (Figure 2). The first mask gives a rough representation of the anatomy and a base to work from.
- Isolate the scaphoid from the other surrounding bones using a tool, such as Mask Flood Fill (Figure 3)

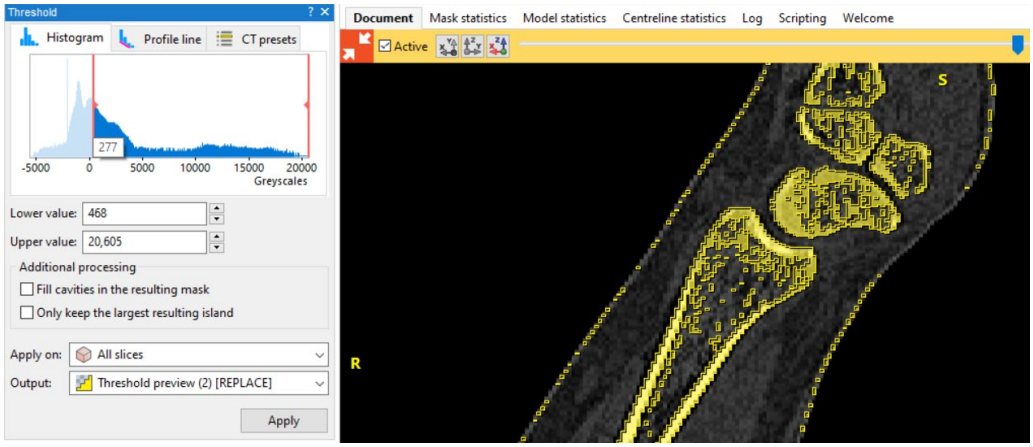

Figure 2: Choosing an appropriate HU range to create a mask

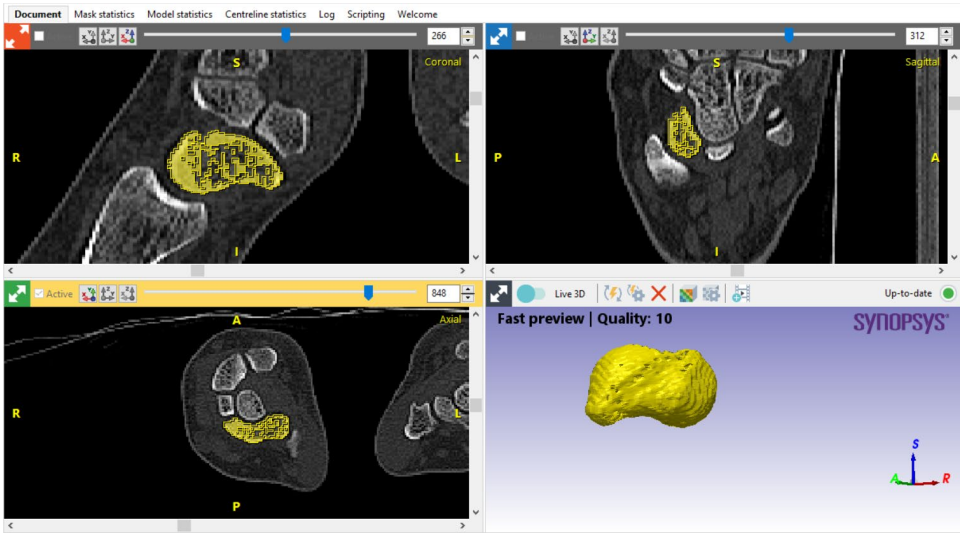

Figure 3: Select and isolate the scaphoid

- Use tools such as “Fill cavities in the resulting mask” and “Only keep the largest resulting island” to fill in the gaps within the mask depicting the scaphoid (Figure 4)

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- Smooth the scaphoid mask by using a tool/filter, such as Recursive gaussian or Mean filter. The smoothing factor to be used should be fine-tuned if the smoothing is too “aggressive”. Always check back the mask in the slices after smoothing operation.
- Check the correctness of the contours of the scaphoid and manually adjust the mask, if it is necessary. (It is critical that the segmentation is accurate as the fit of a patient-specific drill guide will depend on it. The final segmentation should be checked by another qualified person, by reviewing the final mask overlay on the scan slices in all three anatomical planes.)
- 3D reconstruct the scaphoid based on the scaphoid mask using “Model Preview”
- Export the 3D reconstructed scaphoid as an STL file format and save the project
- Fill the form given in section 4 Annex I

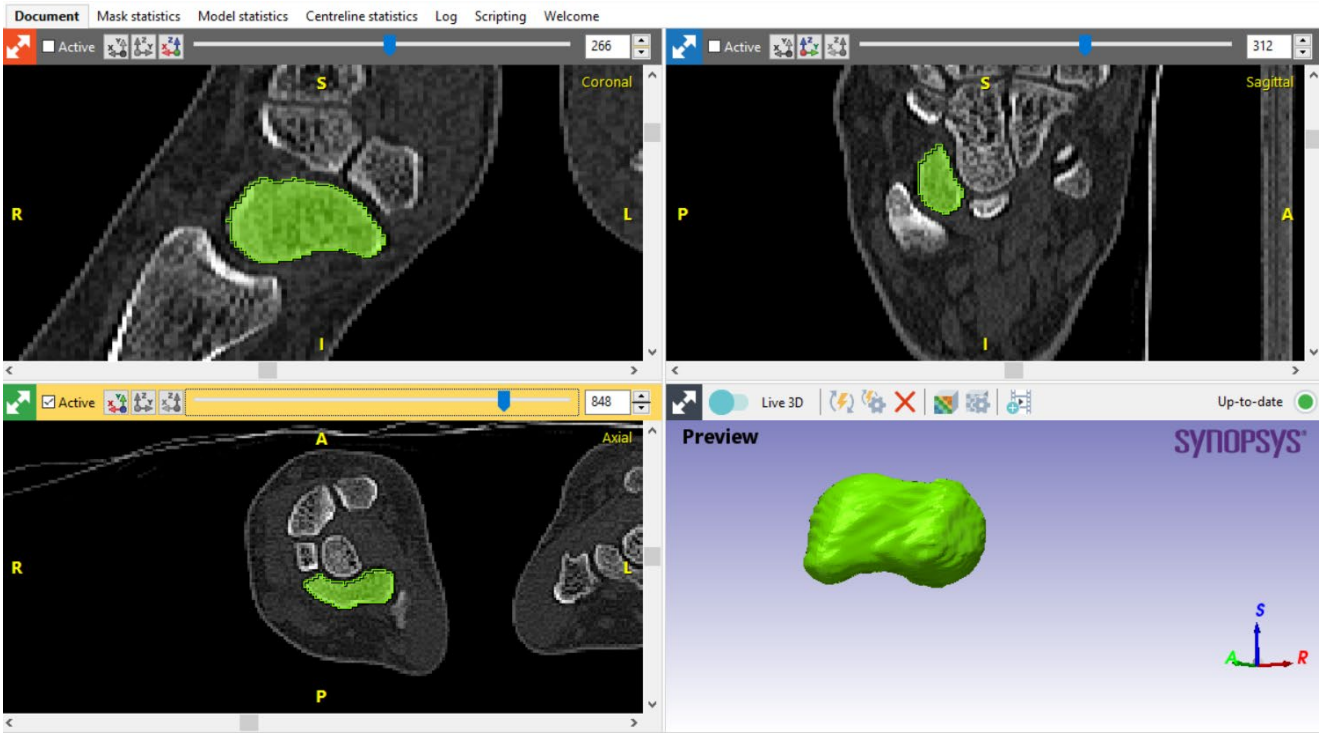

Figure 4: Modifying the 3D model of scaphoid

2.2 Patient-specific design

The patient-specific design must be based on the anatomy of the patient and validated segmentation that has been reviewed and approved by the surgeon or practitioner who has prescribed the guide. Free-form 3D model design software will be the most appropriate to design the patient-specific device.

The design entity should ensure that the design characteristics given by the practitioner are reasonable. This should be evaluated at the beginning of the project, based on the 3D printing process selected. Typically, a minimum surface thickness in contact with the bone must be determined. Ideally, design boundaries would be specified.

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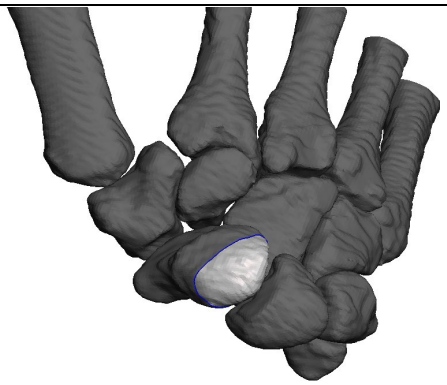
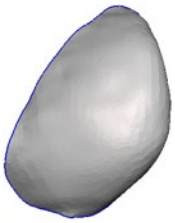
The design of the device must be performed by a designer understanding the surgery, keeping in mind some crucial information such as:

- Aim of the surgery
- Surgical approach used
- Other instruments used during the surgery (particularly screws and drill bits)
- Anatomical obstacles
- Accessible anatomical landmarks during surgery

For more information about what criteria should be understood by the designer, please refer to “Virtual simulation of surgery” in section 4 of Deliverable 5.3.1.

According to D 5.3.1, a patient-specific scaphoid drill guide can be designed by following the steps below with Meshmixer software version 3.5.474:

- Define the acceptable design tolerance by the clinician/surgeon provided the prescription for the guide	
- Review the validated segmentation and virtual simulation of the surgery	
- Mark the region of interest using a tool, such as select tool in Meshmixer software	
- Separate the region of interest using the separate tool from the edit menu	
- Smooth and re-mesh the extracted surface if necessary, by selecting the smooth tool in the deform menu	

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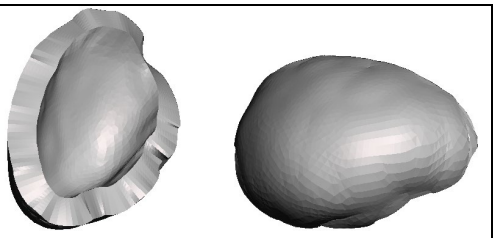
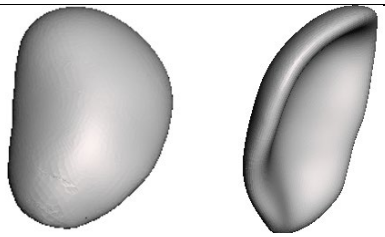
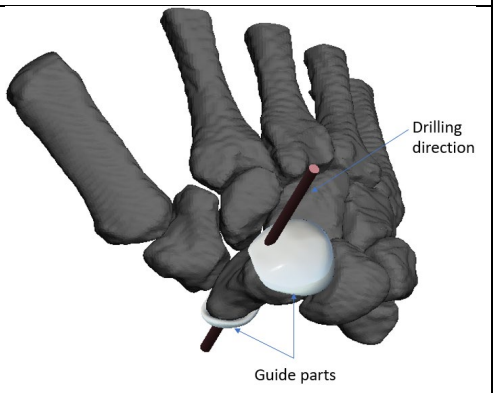
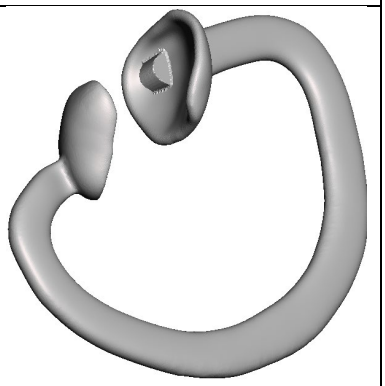
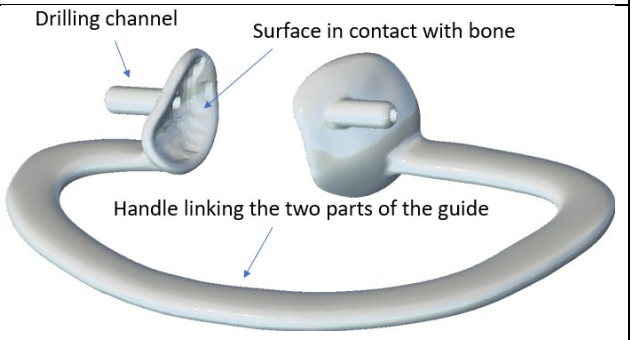
- Extrude the fine surface outward of 2 mm to create a part. *The thickness would vary depending on the type of guide and on the manufacturing process chosen.	
- Smooth the created part	
- Position a cylinder that represents the drilling direction	
- Link the guides by a handle and create a single part	
- Create the drilling channels which are aligned to the previously positioned cylinder. These are combined with the other parts of the guide to create a single shell. - Boolean subtracting between the device designed and the anatomy of the patient	

- Label the device to associate it to the right patient and with necessary indications such as laterality or symbolic advice	
- Check that the design output matches the design requirements, and that the design is suitable for the manufacturing method chosen (referred to as "design transfer" in ISO 13485:2016). Validate the final design before being printed by the clinician/surgeon provided the prescription. - Fill the form in section 5 of Annex I.	

3. Material and manufacturing specifications

3.1 3D printing

Following the completion of the design, additional preparatory processes are needed before the product can be additively manufactured. This procedure can be carried out by the means of build preparation software which is typically divided into four steps, i.e., build volume placement, addition of support material, slicing, and creating build paths. Each AM technology and machine model has its own set of parameters and configurations, and the optimal settings and parameters for a single machine model will differ significantly when printing different devices or components. Furthermore, even when printing the same devices or components, optimal settings and parameters will differ between machines of the same type [2]. Therefore, documenting machine parameters for each specific design is highly recommended according to section 6 of Annex I.

Before selecting a 3D printing process for the manufacturing of the surgical guide, it is advisable to consider the material that the surgical guide would be produced by. The criteria that should be taken into account to select the material and the process used to manufacture a surgical drill guide are as follows:

- Biocompatibility
- Transparency of the material
- Mechanical properties of the material
- Accuracy of the 3D printing process needed (depending on the intended use of the guide)
- Costs
- Timeliness (duration of printing + post processing)

Table 1 shows the recommended 3D printing technique based on the chosen material for the surgical guide instrument.

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Table 1: The most commonly used materials for the manufacturing of surgical guides and their 3D printing techniques (adopted from D.5.3.1)

Material	**3D printing process**
Nylon 12 (Polyamide)	Selective Laser Sintering
Titanium Ti6Al4V	Selective Laser Melting
Ultem 1010	Fused Deposition Modelling
MED610	Polyjet
MED620	Polyjet
Surgical guide resin (Formlabs)	Stereolithography

Due to the high cost of material and 3D printing process, Titanium Ti6Al4V, ULTEM 1010 or Med610/620 are not the best options for surgical guides unless the 3D printed designs are expected to withstand high amounts of stress or force.

Table 2 compares the previously mentioned criteria, such as biocompatibility and transparency of the material, for PA-12 and surgical guide resin. Taking these criteria into consideration, the 3DMed project suggests manufacturing scaphoid guides with PA-12 and the SLS printing method. The form in section 6 of Annex I should be completed by the manufacturing department and the material properties and printing parameters should be well documented.

Table 2: Comparing material and manufacturing criteria between PA-12 and Surgical guide resin for the scaphoid drill guide

Material	PA-12	Surgical guide resin
Biocompatibility	Meet the requirement	Meet the requirement
Transparency of the material	Meet the requirement	Meet the requirement
Mechanical Properties	Meet the requirement	Meet the requirement
Printing Technique	SLS	SLA
Cost of printing machine for in-house manufacturing	£100-500k	£4-20k
Cost of equipment maintenance and materials	Low	High

Accuracy	+/-100 micron	+/-25 micron
Support structure	No or minimum	Yes
Timeliness (printing + post-processing)	Fast	Slow
Post-processing	De-powdering the build plate Recycling unused powder	Remove excess resin Final heat treatment

4. Post-treatment

4.1 Post-processing

Post-processing is a very effective way to overcome or remove the undesired properties that have been built-in the final product during additive manufacturing processing. Furthermore, post-processing can be used to add specific functionalities to the final product.

Post-processing activities depend on the type of 3D printing process used. For the case of the scaphoid drill guide which is produced by PA-12 and the SLS technique, support removal is not necessary as SLS uses the unsintered powder as a support structure.

The printed materials should be blasted with PA12 unsintered powder (instead of glass beads) to ensure that no material contamination occurs and that the biocompatibility results remain unaffected.

Furthermore, no other post-processing procedures, such as tumbling, polishing, colouring, or coating, are recommended for medical devices intended for invasive use, as the effect of these processes on the material's biocompatibility is unknown.

All post-processing steps shall be documented following section 7 of Annex I.

4.2 Cleaning

Patient-specific surgical guides are invasive devices which need to be sterilised before their use during surgery. The sterilization instructions will be provided to the hospital along with the device, and shall be validated to ensure that the device will be sterile when instructions are followed.

In order to perform an effective sterilization, the device must reach a certain level of cleanliness, determined by the manufacturer. For SLS printed PA-12, the automated cleaning and disinfection procedure in washer-disinfection is presented in Table 3 according to ISO 15883-1.

Table 3: Cleaning procedure according to ISO 15883-1:2009 (reproduced from D 5.3.1)

Method	**Time (min:sec)**	**Temperature (°C)**	**Water**	**Neodisher MediClean forte® dosage**	**Neodisher MediKlar® dosage**

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				(%)/(°C)	(%)/(°C)
Cleaning 1	05:00	45	½ DW or RO – ½ WW or only DW or RO	0,5/40	
Cleaning 2	05:00	55	½ DW or RO – ½ WW or only DW or RO		
Rinsing 1	02:00		CW or WW or RO or DW		
Thermal disinfection	05:00	90	RO or DI		0,07/60
Drying	15:00	110			

CW=Cold Water; WW=Warm Water; RO=Reversed Osmose Water; DW=Demi Water

In addition, adequate controlled environment or protection shall be implemented between final cleaning and packaging to prevent contamination of instruments after final cleaning of the devices.

4.3 Sterility

According to the MDR, the scaphoid drill guides are considered as custom-made devices, therefore, the manufacturer can choose to either provide a custom-made product sterile or consider that the device intended to be cleaned and sterilized by the hospital (*i.e.*, the person who made the prescription), following commonly used sterilization cycles in healthcare settings. However, the manufacturer should provide a cleaning and sterilization validation in order to show compliance with EN-ISO 17664- 'Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices'.

For instance, according to Table 4, if the surgical guide is made of PA12, it should be sterilized using a steam sterilizer that meets the criteria defined in EN 285 standards (ISO 17665-1:2016).

Table 4: Sterilization method based on the material used in the surgical device (adopted from D.5.3.1)

Material	**Sterilization Method**
Nylon (PA 12) (Polyamide)	Steam sterilization
Titanium Ti4Al6V	Steam sterilization
Ultem 1010	Steam sterilization
MED610	Steam sterilization Gamma sterilization
MED620	Steam sterilization Gamma sterilization

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Surgical guide resin (Formlabs)	Steam sterilization

The manufacturer is expected to provide the detailed and validated instructions under ISO 17665 including the cycle, temperature, time of exposure, cool time, and drying time for the use of steam sterilization, as presented in Table 5, as well as a validation report.

Table 5: Steam sterilization procedure according to ISO 17665-1:2016 (reproduced from D.5.3.1)

Method	Moist heat sterilization according to EN ISO 17665-1:2016
Cycle	Pre-Vacuum (Pre-Vac)
Temperature	134 °C
Exposure Time	3 minutes
Cool Time	30 minutes (minimum, in chamber)
Drying Time	60 minutes (minimum, at room temperature)

4.4 Biocompatibility Evaluation

According to ISO 19227:2018, cleaning validation is interconnected with the biological evaluation and implant sterilization validation. The surgical guide is delivered by the manufacturer non-sterile, however, the biocompatibility shall be evaluated after cleaning.

The ISO 10993 standards concerns biocompatibility and determines which tests shall be performed, depending on “Nature of body contact” and “Contact duration” (see Table A.1 in Annex II from the Use of International Standard ISO 10993-1 [3]).

Taking into account the intended use of the scaphoid drill guide, it would be classified as:

- Nature of body contact:
  - Category: Implant Device
  - Contact: Tissue/Bone
- Contact Duration:
  - Category: A (limited contact duration; ≤ 24 hours)

Based on this classification, the proposed endpoints and their corresponding standards for the device made of PA-12 (PA2200), are given in Table . In fact, the material supplier, in this case EOS GmbH (https://www.eos.info/en), should provide an annual report with the most recent test results for the material. In Table 6, the evaluation results which have been assessed are given.

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Table 6: The evaluation of biocompatibility endpoints for PA-12(PA2200)

Endpoints	Standard	Evaluation
Cytotoxicity	ISO 10993-5	Pass
Sensitization	ISO 10993-10	Pass
Irritation	ISO 10993-10	Pass
Acute systemic toxicity	ISO 10993-11	Negligible Due to very short duration of use (less than 1 hour) and the fact that the devices are cleaned and sterilized (ready for use) and distributed for single use
Material mediated pyrogenicity		
pyrogenicity from chemicals Source: non-sintered powder	ISO 10993-1	Negligible Non-sintered powder could be removed from the device by cleaning and sterilization process prior to use
Pyrogens from bacterial endotoxins Source: water used for steam sterilization	ISO 10993-1	Negligible Can be controlled by using a validated sterilization protocol and good filtration

Section 8 of Annex I (Biological evaluation) should be completed by referring to comparable existing devices (those with good biocompatibility and known and documented endpoints), and it does not need to evaluate the biocompatibility of the device if the new device has the same:

- Material formulation
- Manufacturing process
- Geometry and physicochemical properties
- Contact area
- Sterilization process/method/dose

In order to determine whether actual testing needs to be performed, the biological evaluation flowchart (Figure 5 and Figure 6) should be followed. The flowchart is applied to all components that have been selected for biological evaluation.

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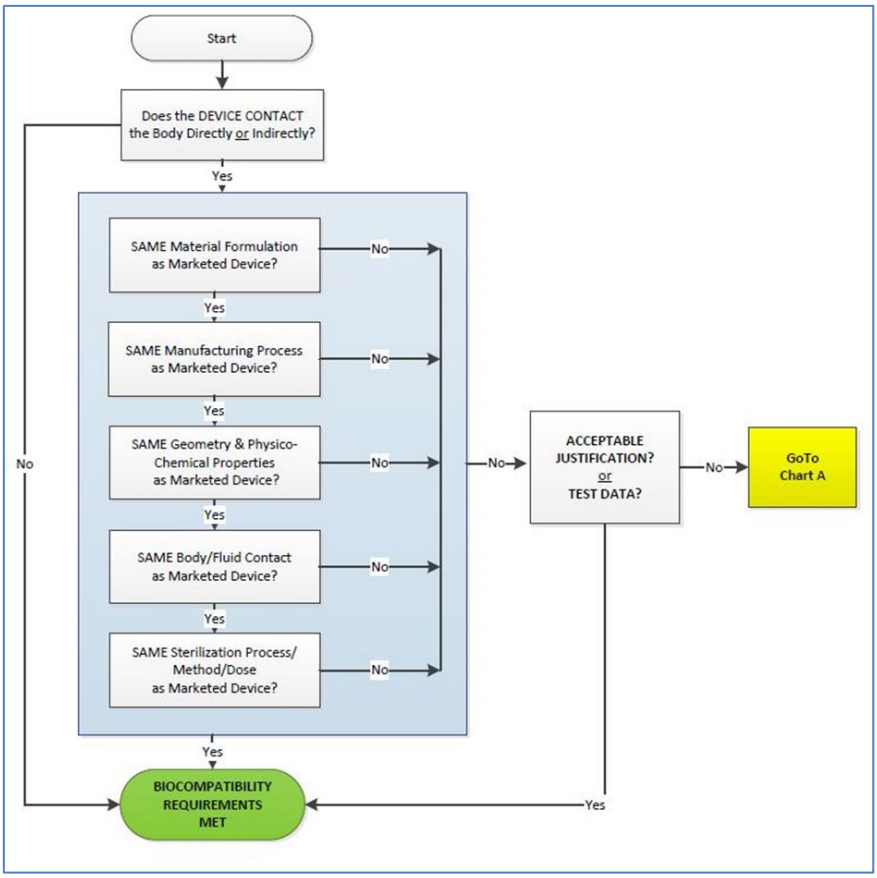

Figure 5: Biological evaluation flowchart [3]

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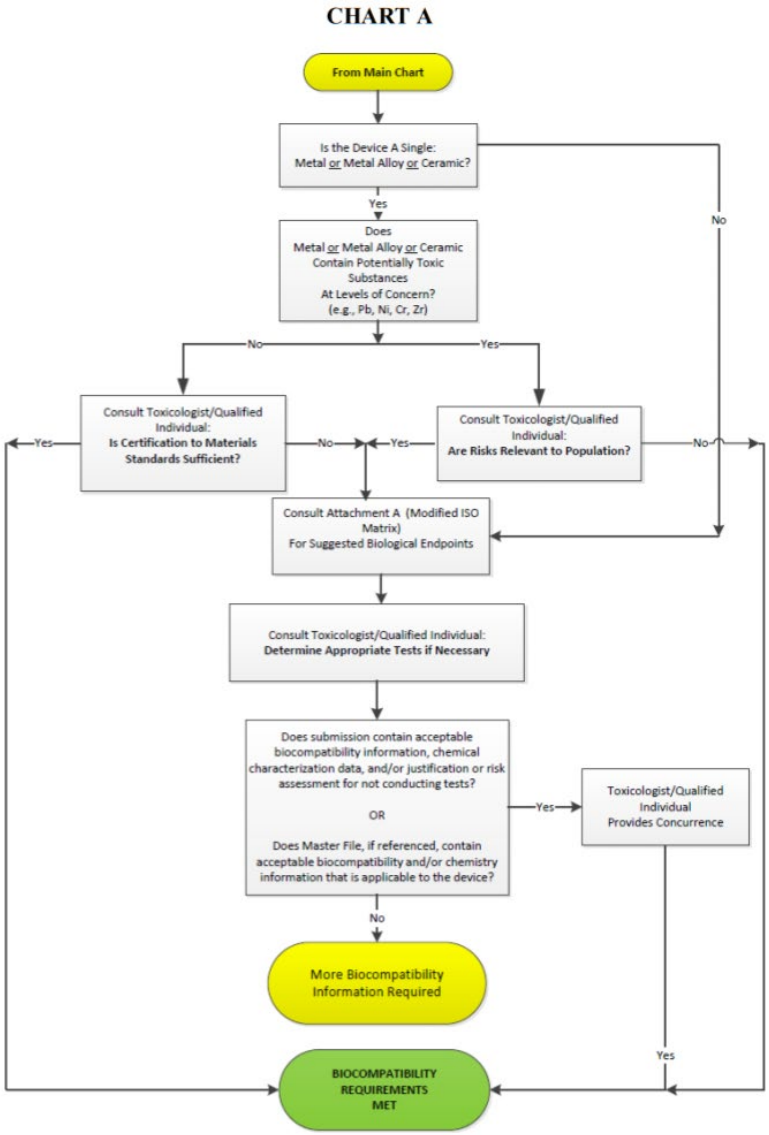


Figure 6: (Continued)[3]

5. Packaging and labelling

5.1 Packaging

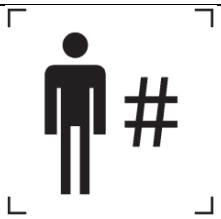
For each medical device, except the ones that pertain to Class I or IIa, an instruction for its use should be included in its packaging according to MDR 2017/745. As a surgical drill guide is in Class IIa, there is no need for the inclusion of such a document in its package. The following points shall be considered for the packaging system of a non-sterile surgical drill guide. The packaging system shall:

- maintain the integrity and cleanliness of the product
- minimize the risk of microbial contamination
- be suitable taking account of the method of sterilisation indicated by the manufacturer

5.2 Labelling

Table 4 can be used as a reference to label the surgical guide instruments. Considering the requirements for labelling that are specified in "General Safety and Performance Requirements, Chapter III, paragraph 23 of the Medical Device Regulation 2017/745" and internationally recognized symbols in the "ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied", labels provided in Table 4 shall be used where appropriate and documented in the form given in section 9 of Annex I.

Table 4: General Safety and Performance Requirements and statement from (MDR) 2017/745 and their related symbols from ISO 15223-1:2016

Text from the MDR 2017/745	**Symbols and their title**
-The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device; -If the device is custom-made, the words 'custom-made device'	*Trade name of the device* Custom-made device
-The name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;	 Manufacture
-Patient's ID	 Patient number
-Where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;	 Date of manufacture
-An unambiguous indication of the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;	 Use-by date

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-If the device is supplied sterile, an indication of its sterile state and the sterilization method;	 Non-sterile
-If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the European Union;	 Do not re-use
-Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users	 Do not use if package is damaged  Fragile, handle with care
The following information is recommended to be stated	
the name of the ordering physician	

An example of some labels used for patient-specific devices are provided in Figure 7, where the parts in italic should be replaced by the specific information for each device.

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Figure 7: Examples of labels used in patient-matched devices according to ISO 15223-1:2016

6. References

[1] European Parliament and the Council, Regulation (EU) 2017/745, Official Journal of the European Union, 2017.

[2] FDA FaDA. Technical Considerations for Additive Manufactured Medical Devices. Guidance for Industry and Food and Drug Administration Staff 2017.

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

Annex I: Requirements regarding design, manufacturing, and post-processing of the patient-specific scaphoid drill guide

During design, manufacturing, and post-processing of the patient-specific scaphoid drill guide, 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.

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1. General Information

Patient name	Click or tap here to enter text.
Patient number	Click or tap here to enter text.
Date of receiving order (DD/MM/YYYY)	Click or tap to enter a date.
Date of planned surgery (DD/MM/YYYY)	Click or tap to enter a date.
Date of delivery (DD/MM/YYYY)	Click or tap to enter a date.

Aim of the surgery:

Surgical approach:

Click or tap here to enter text.	Click or tap here to enter text.
Surgeon	Hospital
Click or tap here to enter text.	Click or tap here to enter text.
Phone	E-mail
Click or tap here to enter text.	
Secondary contact information (name, e-mail, phone)	
Click or tap here to enter text.	Click or tap here to enter text.
Shipping address (country, city, postal code)	
Click or tap here to enter text.	Click or tap here to enter text.
Signature of the Person Submitting this Form	Date (DD/MM/YYYY)
Click or tap here to enter text.	
Name of the Person Submitting this Form	

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2. Accessories Summary

Screw name & code:

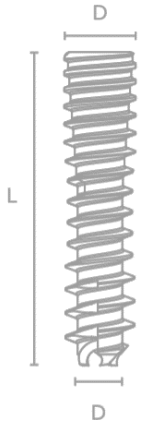
Screw details:

Tip diameter (mm):

Tail diameter (mm):

Length (mm):

Drill diameter (mm):



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3. Patient Anatomy Data

Notes: Use scanning protocol in the section 2.1.1 of the Deliverable 1.1.3 as a guideline

Does the patient have anatomical obstacles related to the surgery? (Specify below)

Image Acquisition

Date of Image acquisition — Click or tap to enter a date.

☐The scan is taken less than two (2) months before the surgery.

Scan Provided by: — Click or tap here to enter text.

File format — ☐DICOM

Image Acquisition Technique — ☐CT Scan

Region of Interest: — ☐Right-hand

☐Left-hand

☐ The scan covers the region of interest (ROI).

☐Image does not contain major artifacts such as metal and motion artifacts.

Scanning Parameters

Click or tap here to enter text.	Click or tap here to enter text.
Scanner Model	Matrix (512×512 pixels is recommended)
Click or tap here to enter text.	Click or tap here to enter text.
kVp	mAs
Click or tap here to enter text.	Click or tap here to enter text.
Image reconstruction Algorithm (Bone/Details is recommended)	Field of View (FOV)
Click or tap here to enter text.	Click or tap here to enter text.
Slice increment (contiguous is recommended)	Slice thickness (<1mm is recommended)

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Click or tap here to enter text.	Click or tap here to enter text.
Gantry Tilt (0˚ is recommended)	Pitch (<1 is recommended)
Click or tap here to enter text.	Click or tap to enter a date.
Imaging department approval	Date (DD/MM/YYYY)

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4. Segmentation

Software	☐Simpleware ScanIP ™
Segmentation method	☐Single level thresholding
HU range: (Min & Max)	Click or tap here to enter text.

☐Isolate the scaphoid using Mask Flood Fill.

☐Fill in the gaps using:	☐Fill cavities in the resulting mask
	☐Only keep the largest resulting island
☐Smoothing/filtering using:	☐Recursive Gaussian
	☐Mean filter

☐The correctness of the contour is checked and approved.

☐3D reconstruct the scaphoid using “Model Preview”.

Brief description of segmentation procedure (in case manual work has been employed):

Exported file	☐STL
Click or tap here to enter text.	Click or tap to enter a date.
Operated by	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)

Protocol for surgical instruments

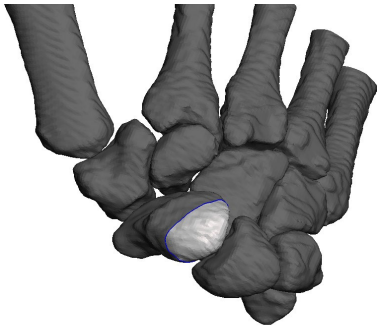
5. Patient-Specific Design

Notes: Use scanning protocol in the section 2.2 of the Deliverable 1.1.3 as a guideline.

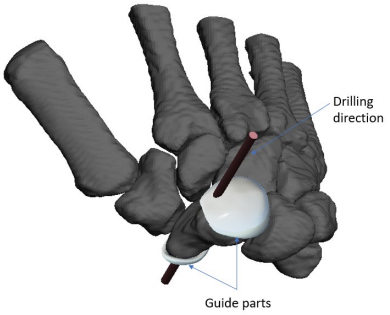
Click or tap to enter a date. Date of Receiving validated segmentation (DD/MM/YYYY)	Software

☐ The design department discussed the surgery with the surgeon in order to correctly perform the simulated surgical simulation.

Region of interest (Insert the image of the selected region here)



Drilling direction & position



Click or tap here to enter text.	Click or tap here to enter text.
Minimum thickness of guide surface	Diameter of the handel linking (mm)
Click or tap here to enter text.	Click or tap here to enter text.
Drilling channel diameter (mm)	Drilling channel length(mm)

Texts and Labels to be printed on device

☐Name_____

☐Laterality_____

☐Directions_____

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

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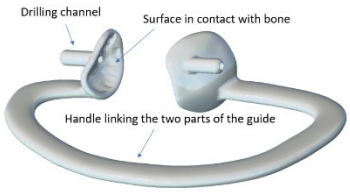
Insert finalized design here:



Click or tap here to enter text.	Click or tap to enter a date.
Designed by	Date (DD/MM/YYYY)
Click or tap here to enter text.	Click or tap to enter a date.
Surgeon 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)

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6. Material and Manufacturing

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

Material Specifications

Material details:

☐PA12 ☐ Fresh ☐ Re-used

Click or tap here to enter text.	Click or tap here to enter text.
Material provider	Identification/ Catalogue No.
Click or tap here to enter text.	Click or tap here to enter text.
Storage conditions	Expiration date (MM/YYYY)

Manufacturing Specifications

Printing technique: ☐Selective Laser Sintering (SLS)

☐The design do not need support for printing.

Click or tap here to enter text.	Click or tap here to enter text.
Max. part dimension	Estimated manufacturing time

Printing parameters

Click or tap here to enter text.	Click or tap here to enter text.
Print Orientation	Layer thickness
Click or tap here to enter text.	Click or tap here to enter text.
Wall thickness	Laser power

Click or tap here to enter text.
Other relevant parameters

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.
Manufacturing department approval	Date (DD/MM/YYYY)

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7. Post-processing

Click or tap to enter a date.
Received printed part on (DD/MM/YYYY)

Note: Post-processing procedures, such as tumbling, polishing, colouring, or coating, are NOT recommended for medical devices intended for invasive use.

☐ Cleaning Method: ☐ blasting with PA12 unsintered powder

Explain:

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8. Biological evaluation and sterilization Method/dose

☐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.

Note: Suggestions made in this section should be provided in the package to the hospital.

Sterilization method:	☐Steam Sterilization
Click or tap here to enter text.	Click or tap here to enter text.
Method (i.e., moist heat sterilization)	Cycle
Click or tap here to enter text.	Click or tap here to enter text.
Temperature	Exposure time
Click or tap here to enter text.	Click or tap here to enter text.
Cool time	Drying time
Click or tap here to enter text.	Click or tap to enter a date.
Technician	Date (DD/MM/YYYY)

Protocol for surgical instruments

9. Packaging & Labelling

Click or tap to enter a date. Date of packaging (MM/DD/YYYY)	Click or tap to enter a date. Expiration Date (MM/DD/YYYY)
Click or tap here to enter text. Catalog number of the product	Click or tap here to enter text. Batch number or serial number (if applicable)

Labelling checklist

☐ Manufacturer & address details

☐ Name of ordering surgeon

☐ Number of products in the package

☐ Barcode

☐ Warnings and precautions

☐ Logo

☐ Sterilization status

☐ Package includes instruction for Sterilization

☐ Can be used once

☐ Storage and handling instructions

☐ Indication of how to open the packaging

☐ Specific information

☐ Special instructions for use

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

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Annex II: Biocompatibility evaluation endpoints

Table A.1: Biocompatibility Evaluation Endpoints [3]

Medical device categorization by			Biological effect												
Nature of Body Contact		Contact Duration	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@
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – permanent (> 30 d)													
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				

Medical device categorization by			Biological effect												
Nature of Body Contact		Contact Duration	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@
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – permanent (> 30 d)													
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.