	COOK MEDICAL MANAGEMENT SYSTEM (CMMS) DOCUMENT			
	Form			
	Document Number: D00257385	Revision: 002	QMS Owner: Cook Medical Holdings LLC	Page: 1 of 4
	Title: Device Planning and Request Worksheet (EVPS_RPR_F02)			

DEVICE PLANNING AND REQUEST WORKSHEET

ALL information must be completed.

See instructions on page 4.

Date:

NOTE: This form requires a pdf viewer that enables javascript.

- DO use [Adobe Reader](#) or Acrobat on Windows or Mac desktop/laptop computers.
- DO use the free [PDF Expert](#) app if using Apple mobile devices.
- DO NOT use a web browser or Android mobile devices.

Patient ID:	Secondary ID: <small>(DoB, Hospital number, etc..)</small>
Hospital:	Physician name:
Cook representative:	Physician phone:
	Physician e-mail:


First customization

Will imaging be provided?: <input type="checkbox"/> Yes <input type="checkbox"/> No	Proximal diameter:	Distal diameter:
Primary disease treated:	Intermediate diameter (if required):	Overall length (must not exceed 250 mm):
Type of device required:		
Fixation:	Is there an existing graft in situ?: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Proposed proximal landing zone:		
Proposed distal landing zone:		

Number of features

Graft Plan:

Distal bifurcated component:	
<input type="checkbox"/> ZFEN-D- - -	<input type="checkbox"/> Custom distal body length =
	<input type="checkbox"/> None
<input type="checkbox"/> UNIBODY- -	
Leg extension options:	ZSLE ZISL

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Second customization (optional)

Will imaging be provided?: ☐ Yes ☐ No

Primary disease treated:

Type of device required:

Fixation:

Proposed proximal landing zone:

Proposed distal landing zone:

Proximal diameter:

Intermediate diameter (if required):

Distal diameter:

Overall length (must not exceed 250 mm):

Is there an existing graft in situ?: ☐ Yes ☐ No

Third customization (optional)

Will imaging be provided?: ☐ Yes ☐ No

Primary disease treated:

Type of device required:

Fixation:

Proposed proximal landing zone:

Proposed distal landing zone:

Proximal diameter:

Intermediate diameter (if required):

Distal diameter:


Overall length (must not exceed 250 mm):

Is there an existing graft in situ?: ☐ Yes ☐ No

Additional information:

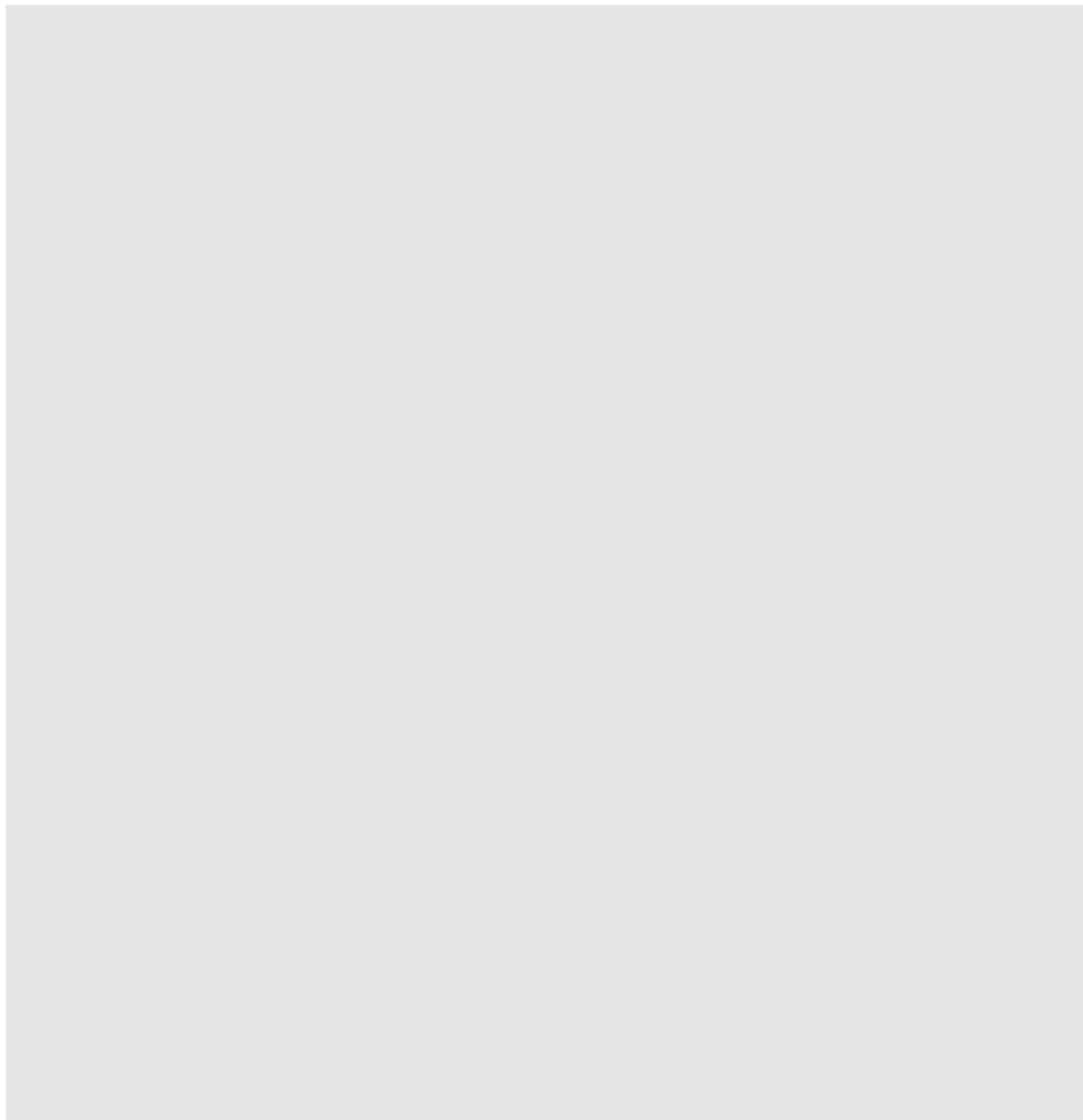
(E.g., relevant clinical history, additional surgery/workarounds (conduit), other device preferences, existing endografts, etc.)

Additional comments:


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USER INSTRUCTIONS

Drawing/diagram



Form submission

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USER INSTRUCTIONS

ALL information must be completed before the request can be processed.

In order to provide the services requested by you for your patient, Cook requires certain minimum personal data of the physician and the patient be made available to it. By submitting this form, you acknowledge that, as data controller of your patient's personal data, you have provided the appropriate notices to your patient and have an appropriate lawful basis for sharing this information with Cook. For further information on how Cook collects and processes personal data of HCPs/Customers and/or patients, please contact your Cook representative or DataProtectionEurope@Cookmedical.com.

Section 1 - Patient/Physician details

Indicate the date of this request. The Patient ID is requested as an identifier for the device and in accordance with regulatory requirements, it must be uniquely traceable to an individual patient and also match with any imaging provided. A secondary ID can also be provided if you consider it necessary. The hospital, physician name and contact details must be that of the intended signee and are required so we can contact the correct person. If you are unsure of your Cook representative, mark this box as N/A.

Section 2 - Device concept

Select if imaging will be provided with the request. If imaging is provided, this may reveal health information about your patient which the planning team will review for the purposes of providing feedback on your plan. If imaging is not provided, the planning team will provide a graft plan to your exact specification only.

Specify the main disease type to be treated with this device from the drop down menu. The disease type is required so we can provide the most appropriate device based on your patient's specific medical needs. If the disease type is not listed, select Other and add an additional comment. Using the drop down menus, select the type of device required, preference for fixation and indicate the sealing zones. Using the free text boxes, provide the diameters and ideal length of the custom component, ensuring suitable oversizing.

Section 3 - Graft features

Indicate the number of features required. Using the drop down menus, select the type of features required.

Distance/depth : For scallops and double-width scallops, indicate the required depth. For fenestrations, nominate the distance from the proximal edge of the graft to the centre of the fenestration. For branches, nominate the distance from the proximal edge of the graft to the distal opening of the branch (manufacturing restrictions apply).

Clock: Nominate the desired clock position for each feature (manufacturing restrictions may apply). 15 minutes of separation = 7.5° of angulation.

IVD: Measure the inner vessel diameter at the level of the feature.

Diameter: Nominate the diameter required for each feature. Branches are only available in 8mm or 6mm. The diameter is not required for scallops or double-width scallops.

Section 4 - Additional components and information

If a distal bifurcated component is required, please indicated the specification using the drop down menus. If a custom made bifurcated component is required, please indicate the desired length to the bifurcation. Custom made distal bifurcated components will be manufactured using an inverted contralateral limb (contact your local Cook representative for additional information).

Use the additional information text box to provide any supporting information about the case that you consider necessary, such as existing endografts, previous arterial surgery or overcoming potential challenges. Please only provide information that is relevant for the purposes of planning the custom made device.

Use the additional comments text box to list any further device preferences or additional components required.