

Scanning Protocol for the ExoVasc[®] Personalised External Aortic Root Support to manage a dilated aorta.

This specification provides instructions on the image acquisition protocol required to produce the data set required by Exstent for modelling the ascending aorta in patients who are to receive the ExoVasc[®] Personalised External Aortic Root Support to manage a dilated aorta.

We recommend the use of a modern CT scanner that is able to provide high resolution images with minimal radiation exposure. While MR scanning can be used to image the ascending aorta, it is less able to visualise the coronary origins.

While the basic image acquisition protocol may vary in detail from scanner to scanner, the following considerations are important:

1. Good opacification

The entire ascending aorta from the left ventricular outflow tract to the top of the aortic arch should be appropriately opacified using a contrast agent and bolus tracking/time density curve to ensure that a high signal to noise ratio image is obtained.

2. Cardiac gating

Acquiring images between 60% to 80% of the R-R interval during ventricular diastole gives good image quality and the best dimensional data for the PEARS modelling process.

3. 3D reconstruction

Acquiring and saving the image data as a 3-dimensional data set in the natural resolution of the scanner in question gives good image quality with minimal interpolation error. Resolution of voxel size 0.5mm x 0.5mm x 0.5mm, 0.6mm x 0.6mm x 0.6mm or 0.75mm x 0.75mm x 0.75mm is ideal. It is essential that contiguous, thin slices are acquired and that the reconstructions should be the thinnest possible without overlap. For example, when using a Siemens CT Scanner, use the "smooth kernel" [B26F] with the "cardiac/angio" window setting.

4. Image area

The image must extend from 20mm below the lowest sinus in the Left Ventricular Outflow Tract, (thereby including the proximal origins of ALL the 3 sinuses), to about 20mm up the brachiocephalic artery at the top of the aortic arch, (thereby including the origins of the brachiocephalic and common carotid arteries).



5. Movement and imaging block artefact

It is important that all anatomical structures can be visualised in correct spatial relationship to each other; specifically, it is critical that the coronary arteries are clearly imaged without movement artefact obscuring or spoiling spatial relationships and that the image block is a single unit and not two or more image blocks with registration artefact lines across the anatomical structures being imaged.

6. File transfer

A full set of DICOM files should be provided. Since these will be used to create a personalized implant, it is vital that these are correctly labelled with unique information to identify the patient. The imaging files should be transferred to Exstent Limited directly using a specific link that will be provided to the company ShareFile secure server at https://exstent.sharefile.com