ExoVasc® Personalised External Aortic Root Support

DIRECTIONS FOR USE

Read these instructions carefully before using this product

CUSTOM-MADE DEVICE

Manufactured in England by Exstent Limited

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CAUTION: THE EXOVASC® PERSONALISED EXTERNAL AORTIC ROOT SUPPORT IS A CUSTOM-MADE DEVICE AND SHOULD BE USED ONLY ON THE PATIENT FOR WHOM IT WAS MANUFACTURED. PLEASE READ THE PRODUCT LABEL ON THE PACKAGED DEVICE FOR DETAILS OF THE IDENTITY OF THE PATIENT.

USE ONLY IF PACKAGE AND DEVICE ARE INTACT AND UNDAMAGED

ExoVasc® Personalised External Aortic Root Support

1 DEVICE DESCRIPTION

The ExoVasc® personalised external aortic root support is manufactured from knitted polyethylene terephthalate (polyester) textile sutured using a polyester yarn and tailored to fit the external surface of the ascending aorta in a specific patient.

The devices are manufactured as custom-made devices with a size and shape to match the external surface of the ascending aorta of a specific named patient following imaging of the patient's ascending aorta. The surgeon is provided with copies of both the images and the models used to prepare the implant, and approves the models as the prescription for that individual patient prior to the manufacture of the devices.

Devices are supplied sterile in sealed double paper and transparent foil packaging, and are ready to use.

2 INTENDED USE

The ExoVasc® personalised external aortic root support is intended to be applied to the external surface of the ascending aorta in patients with genetically determined aortic root dilatation, to strengthen the ascending aorta and minimise the risk of further dilatation and dissection. The device is custom-made to fit the shape of the ascending aorta for an individual patient, and should only be used for the patient for whom it was designed.

3 CONTRAINDICATIONS

This device is not intended for any use other than the intended use as stated above. The device is custom-made to fit the shape of the ascending aorta for an individual patient, and should only be used for the patient for whom it was designed.

4 PRECAUTIONS

- The ExoVasc® device is supplied sterile in sealed double paper and transparent foil packaging, and should be opened following aseptic technique. The device should not be used if the package is open or visibly damaged.
- Placement of the device must be carried out by a qualified cardiac surgeon and requires appropriate surgical procedure and care to avoid damage to the aorta, right ventricular outflow tract and the coronary arteries during placement.

- Care must be taken when dissecting around the coronary ostia. Dissecting beneath the left main coronary artery is more difficult than the right because it is usually directly posterior to the aorta. There is often a small fat pad which serves to alert the surgeon to the proximity of the left main stem. In the case of a very short left main stem (LMS) or even a double orifice left coronary artery, extra care has to be taken and it may take as much as one hour to complete this part of the dissection. It is a prerequisite for a successful procedure to have an accurate picture of both coronary ostia from the CT scan. Thus, the presence of a short LMS should not come as a surprise.

- In order to prevent any chance of impingement the edge of the fabric on either coronary artery, the opening in the mesh sleeve should be cut into the shape of an asterisk or star [*]. The final test of the integrity of the coronary artery lumen is to examine the colour trans-oesophageal echocardiography Doppler signal to ensure, at a mean arterial pressure of at least 70mmHg, that there is laminar flow.

- Trans-oesophageal echocardiography with colour Doppler should be used to confirm a normal flow in the coronary arteries during and immediately after the procedure and especially during dissection of the coronary arteries and implantation of the ExoVasc® device.

5 INSTRUCTIONS FOR USE

- Check that the ExoVasc® device is labelled with the name, date of birth, and hospital identification number of the patient scheduled for surgery, and that both the package and the device are intact. The labelling can be found on both the outer package and around the base of the plastic former. Where two devices are provided of different diameter (usually scaled 95% and 100%) note the labelling and select the device to be used to give the best anatomical fit or desired degree of reduction in diameter, retaining the second device as a reserve.

- The patient is prepared for midline sternotomy in the manner usually followed for cardiac surgery. The lungs should be partially deflated and the pericardium opened. Trans-oesophageal echocardiography with colour Doppler should be used to confirm a normal flow in the coronary arteries during the procedure and especially during dissection proximal to the coronary ostia and during implantation of the ExoVasc® device. The area around the ascending aorta is prepared for implantation by carefully dissecting down to the left ventricular outflow tract. It is recommended that arterial blood pressure is held at about 60 mmHg (or for short periods as low as 45 mmHg) during dissection of the coronary artery. Note that cardio-pulmonary bypass is not routinely used in this procedure, but may be employed if required to safely dissect down to the aorto-ventricular junction.

- Aseptically remove the ExoVasc® device from its package, and leaving the device on its plastic former, make a visual comparison between the device and the patient's ascending aorta to ensure that the shape, size and orientation of the device appears to be correct. If more than one size of implant has been prepared, select the device that appears to give the most appropriate anatomical fit or desired degree of reduction in diameter.

- The position of the two coronary arteries is marked on the support by holes in the plastic former. Using a marker, place a mark on the support over the position of the hole in the former to mark the position of the coronary ostia.

- Make three incisions angled to each other to form an asterisk pattern [*] centred on the position of the coronary ostium. These incisions should match the diameter of the coronary artery which is to be accommodated.

- Pull the distal end of the chain stitch on the implant's axial hem. This suture thread will come away as a single piece leaving the support open. Put the plastic former aside – the former does help to indicate the precise position of the coronary ostia, but it is not required once the ExoVasc® support has been removed.

- Taking care to retain the correct orientation, check that the support locates correctly around the aorta, and check that the position of the coronary arteries match those marked on the support.

- Make 2 circumferential incisions from the axial hemline to each of the coronary origins. This produces 2 fabric "tabs" which will need to be placed proximal to their respective coronary arteries. It is helpful to moisten these "tabs" with liquid paraffin or an equivalent sterile lubricant to avoid snagging when the material is pulled through.

- Dissect around the aortic root to provide access to the aorto-ventricular junction. Note that the plastic former on which the ExoVasc implant is supplied can be used for orientation in identifying the position of the left main stem and the depth of the aorto-ventricular junction beneath the coronary ostia.

- Position the two tabs created in the support around the aorto-ventricular junction.

- Suture the support into the aorto-ventricular junction using six interrupted sutures of braided material evenly spaced. It is convenient to place these in line with each commissure and the three intermediate points. Ensure that the base of the implant is sutured proximal to the sinuses into ventricular tissue. Stitch the two cut edges of the support from the axial seam to the edge of each of the openings left to accommodate the coronary arteries, taking care that the coronary arteries are not constrained or deformed by the support. Check for normal flow in the coronary arteries using trans-oesophageal ultrasound.

- Using braided suture material and locking stitches at 5mm intervals, stitch the axial seam of the support to re-close it snugly around the ascending aorta.

- Place the top of the support loosely around the brachiocephalic artery, cutting the support if necessary, to allow placement around the brachiocephalic vessel. Suture the support in the area above the brachiocephalic artery taking care that the suture is placed away from the smaller vessel so that there is no risk of friction between the suture and this artery.

- Check that the fit around the ascending aorta is smooth and that following a return to normal blood pressure there is no laxity in the support material.

- Using trans-oesophageal echocardiography, check for each of the following:
  - normal flow in both coronary arteries,
  - the correct operation of the aortic valve

- the absence of regional wall abnormality of the heart
- the comparative size of the aortic root.

- Close the pericardium and the patient's chest following conventional thoracic surgery procedure.

- Note that the ExoVasc® device is MRI and CT compatible, but contains no materials to enhance its appearance by any imaging technique.

- Complete the Case Report Form provided with the implant and return this to Exstent Limited.

- Any adverse events occurring within 10 years of implantation of the ExoVasc should be reported to Exstent Limited

For further information on the operative procedure, including video please refer to: **Pepper J, Petrou M, Rega P, Rosendahl U, Golesworthy T, Treasure T.** 2013, *Implantation of an individually computer-designed and manufactured external support for the Marfan aortic root.* Multimedia Manual of Cardio-Thoracic Surgery. http://mmcts.org/tutorial/29