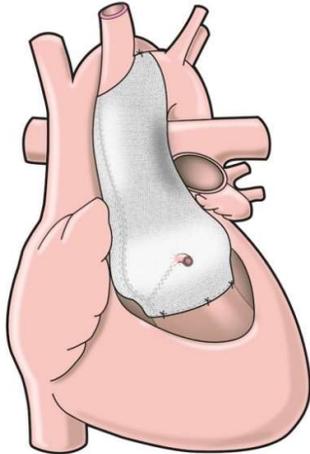


Medical Device Patient Information Leaflet

ExoVasc® Personalised External Aortic Root Support for use in the Ross Operation

The ExoVasc Personalised External Aortic Root Support is a custom-made implant manufactured to support the first part of the aorta – the main blood vessel leaving the heart that directs blood around the body. The device is manufactured to specifically fit an individual patient.



This illustration shows the ExoVasc implant fitted to the first part of the aorta

In the Ross operation, the patient's own pulmonary artery and valve – the first part of the vessel directing blood from the heart to the lungs – is transplanted to replace the first part of the aorta – the main vessel leaving the heart that directs blood around the body. The ExoVasc device is intended to support and to prevent expansion of the transplanted vessel and to help maintain the correct operation of the valve that prevents any backflow.

A replacement valve is placed in the pulmonary artery to allow blood to continue to flow from the heart to the lungs.

The ExoVasc device is manufactured using a polyester material that becomes incorporated into the outside wall of the pulmonary autograft and ascending aorta above it. It requires no maintenance and will last for the patient's lifetime. The polyester material used to manufacture the ExoVasc device is polyethylene terephthalate, which is biocompatible. It is not electrically conductive or magnetic and is compatible with CT, MRI body scanners and airport security scanners.

In the unlikely case of an adverse event being experienced, this should be reported to Exstent Limited, 12 Miller Court, Severn Drive, Tewkesbury, Gloucestershire GL20 8DN, United Kingdom (<https://www.exstent.com>) and to the Australian Therapeutic Goods Administration (<https://tga.gov.au>).