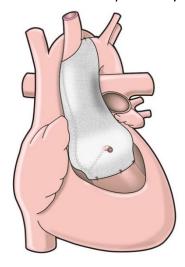


Medical Device Patient Information Leaflet

ExoVasc® Personalised External Aortic Root Support

The ExoVasc Personalised External Aortic Root Support is a custom-made implant manufactured to exactly match the shape of 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

The ExoVasc device is intended to support the first part of the aorta as it leaves the heart and to prevent any further dilatation or expansion of the aorta and minimise the risk of dissection or rupture of the vessel. The ExoVasc device is custom made for patients with connective tissue disorders and is fitted by the surgeon to effectively support the aorta to stop it enlarging further.

The ExoVasc device is manufactured using a polyester material that becomes part of the arterial wall. 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 conductive or magnetic and does not affect CT or MRI body scanners or 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://www.tga.gov.au)