**<Patient Letter Template – For Clinic and Physician Use Only>**

**Important Medical Device Information**

**For Medtronic Valiant Navion™ Thoracic Stent Graft System**

<Insert Date>

**Important Patient Advice**

Dear [INSERT NAME OF PATIENT]

We have recently been informed by the device company, Medtronic, about important information related to your Medtronic Valiant Navion™ Thoracic Stent Graft, used to repair your aorta during your operation on [INSERT DATE OF OPERATION].

A stent graft is a fabric tube supported by a metal mesh, called a stent, used to support a weak spot in the aorta (the large blood vessel in your chest). We are sending this letter to share this information with you.

What is the problem with the stent?

Based on longer term follow up of patients who have had this type of stent inserted*,* Medtronic has discovered a small potential for your stent graft device to develop a leak between your stent graft and your aorta, secondary to a tear in the fabric of the graft. This is called an “endoleak”.

It does not mean that your aorta itself is leaking or bleeding.

As a result, this particular device has been recalled worldwide, and will not be used until further notice for other patients.

What are we doing about your stent?

We are currently reviewing the CT scans of all patients who have had this graft inserted at the [INSERT NAME OF TRUST] and will be contacting you so that we can arrange appropriate follow-up and review.

Your consultant will be in touch with you soon, if s/he hasn’t already been in touch.

What happens next if there is a problem with my stent?

If there is a problem with your stent it is likely that we will monitor this with more regular CT scanning. However, it is possible, should you develop a tear in the fabric of the graft, that we would consider further surgical procedures, most likely with another type of stent graft. We will, of course, discuss this with you as part of your surveillance.

At the moment it looks like the chances of problems with your stent graft are relatively low (less than 1 in 10) so please do not be too alarmed. We are sorry this has happened but please be reassured that we will be keeping a close eye on your stent through regular scans and we will keep you updated with the results of each scan.

Your vascular consultant will either arrange to see you in clinic or book a telephone appointment to discuss this with you and answer any questions you may have.

Yours sincerely