## To be printed on site letter headed paper

<<Date>>
<< Physician Name>>
<< Address 1>>
<< Address 2>>
<< City, Post Code>>

## <u>Title:</u> Multi-centre, Observational, Post-Market, Real World Registry to Assess Outcomes of Patients Treated with

the Altura™ Endograft System for Endovascular Abdominal Aortic Aneurysm Repair: ALTITUDE

Dear Colleague,

Your patient, << Patient Name>>, is participating in a clinical registry as identified above. The registry is sponsored by Lombard Medical Technologies LTD.

#### Study Objective:

This is a post-market registry to assess the clinical outcomes of the Altura<sup>™</sup> system in an all-comers real world patient population with subjects receiving endovascular treatment for their abdominal aortic or aorto-iliac aneurysm (AAA).

### **Primary Study Evaluations:**

- 1. Immediate procedural technical success
- 2. Freedom from endoleak of any type, apart from type 2, through to 5-years post-procedure
- 3. Assessment of peri-operative safety parameters (up to 30-days post-procedure)
  - a. Procedural blood loss > 1000mL
  - b. Mortality (all case)
  - c. Bowel ischaemia
  - d. Paraplegia
  - e. Renal failure
  - f. Myocardial infarction
  - g. Respiratory failure
  - h. Stroke

The Altura System was designed to simplify EVAR procedures. The endografts are constructed from braided Nitinol which is covered by ribbed polyester graft fabric. There are a pair of aortic components that have a 'D'-shaped cross section that sit with their flat faces adjacent to each other in the centre of the aorta. This arrangement creates a circular cross section with a mid-line septum, and each part connects with its own modularly-attached limb. There is no need for cannulation, while the braided construction allows each graft component to be expanded or collapsed at will, allowing the placement in the aorta to be repositioned and adjusted.

Participants will be followed-up until 5-years post procedure. For any medical concerns outside this trial, your patient will be directed back to you.

# ALTITUDE REGISTRY GP Letter

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If you would like to discuss the inclusion / exclusion criteria, receive additional information on the trial, and / or if you know of any reason why your patient should not continue in the study, I would be grateful if you could let me know as soon as possible.

Yours faithfully