Version 1.0
12 November 2024

To be printed on site letter headed paper

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

Study Title: **Post-market European & Asian Registry with Low-profile Minos™**
Study ID: **PEARL REGISTRY**

Re: Patient participation in the post-market registry study PEARL

Dear Colleague,

Your patient, <<Patient Name>>, is participating in a post-market clinical registry as identified above. The registry study is sponsored by Shanghai MicroPort Endovascular MedTech (Group) Co., Ltd (Endovastec™) and managed by Lombard Medical Ltd.

Study Objective:
This is a post-market registry to assess the clinical outcomes of the Minos™ system in an all-comers real world patient population with subjects receiving endovascular treatment for their abdominal aortic aneurysm (AAA).

Study Evaluations:

Primary Outcome:
- Technical success rate at 12 months

Secondary Outcomes:
- Incidence of major adverse events at 30 days
- Immediate technical success rate
- Incidence of successful aneurysm treatment at 2-5 years
- All-cause mortality up to 5 years post-procedure
- Aortic aneurysm related mortality up to 5 years post-procedure
- Secondary intervention rates up to 5 years post-procedure.
- Aneurysm diameter and variation in aneurysm diameter from 30 days to 5 years post-procedure
- Incidence of type I, III endoleaks from 30 days to 5 years post-procedure
- The incidence rate of stent migration, fracture, stenosis, occlusion and distortion from 30 days to 5 years post-procedure

The Minos™ Abdominal Aortic Stent Graft and Delivery System is indicated for the endovascular treatment of abdominal aortic aneurysms with proximal aneurysm neck length ≥15 mm. It is a new generation of abdominal aorta stent graft system developed by MicroPort® Endovastec™. Its delivery sheath outer diameter is only 14F, which significantly reduces the requirements for vascular access during surgery. The stent structure adopts a tri-modular design, which can be flexibly assembled in the body to meet different anatomical needs and cover the common iliac artery lesion area to the greatest extent.

There is currently a paucity of data on its use and outcomes in the European population. Larger series have so far only been published on its use in Asian populations.

Participants will be followed-up procedurally, to hospital discharge, 30 days, 6 months and thereafter annually up to 5 years (total follow-up commitment) as per institutional standard of care. For any medical concerns outside this study, your patient will be directed back to you.

If you would like to discuss the inclusion / exclusion criteria, receive additional information on the study, 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

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Name of the investigator
Hospital:
Address:
Contact details: