Lombard Medical

Lombard Medical Technologies PLC

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12th December 2006

Dear Doctor

Field Corrective Action of Generation II Aorfix™ (SG-HBB and SG-HPE only), temporary cessation of supply

We have recorded that a number of recent cases have experienced difficulty in accurately deploying the Aorfix™ in the aorta. Other than potentially increasing the duration of the procedure, we are not aware of any instance in which the health of patients either has or may have been affected by the difficult deployment.

As far as Lombard Medical is aware all affected products have been returned to the head office in the UK, however, if you find that you have product remaining with you, we advise that you do not use it and contact Lombard Medical for advice.

In a limited number of cases, the proximal end of the implant has skewed requiring additional manipulation, ballooning and the use of proximal cuffs to correct the position of the implant. In all these cases the device has landed more distally than was intended. This has, on occasion, given rise to an initial type 1 endoleak which has been corrected with a cuff. In some cases the ballooning of the proximal neck of the device or positioning of the cuff has been difficult due to the orientation of the proximal end of the stentgraft. We are not aware of any instance in which the implant has landed proximal to the intended landing site or where a renal, mesenteric or other significant artery has been compromised.

However, we are concerned that some Aorfix™ implants are more difficult than they should be and that there can be some difficulty in interpreting the orientation of the device when its deployment is skewed. With the rapid increase in use of the device, this is a concern for new users.

We are very confident that the integrity of the Aorfix™ implant (the stentgraft) is unaffected and that patients followed up in all trials, registries and reviews around the world continue to display outstanding results in terms of aneurysm regression, freedom from migration and freedom from stent fracture. There is no suggestion that patients already implanted with Aorfix™ stent grafts are exposed to any raised level of risk.

The cause of the deployment problem has been identified and arises from an additional manufacturing step introduced in the loading of the grafts. This step has been found to allow the stent graft occasionally to be presented to the loading mechanism slightly incorrectly, giving rise on some occasions to slightly incorrect deployment during use.

A revised procedure that prevents the problem occurring is being tested intensively. We plan to continue clinical use of the product from 22 January 2007, subject to successful evaluation of the modified loading procedure. All future Aorfix™ devices will be supplied with product assembled using this revised and approved procedure.

The Aorfix™ Aorto-uni-iliac (SG-T) and Aorfix™ first generation (SG-BB, SG-BL, SG-PE,

SG-DE, SG-DC) devices are not subject to this issue.

We apologise for this delay in the supply of product and we hope that as the delay falls over the Christmas period, the impact on your schedules and patients will be minimised.

Please be advised that this issue has not impacted on implanted stentgrafts and we do not recommend any change to your usual patient follow up procedures. If you have any thoughts or comments, please do not hesitate to contact Lombard Medical.

Yours faithfully,

[redacted]

[redacted]
Chief Executive
Lombard Medical Technologies PLC

Lombard Medical Technologies Plc

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Our Ref: LMT'A'/SMT

Thursday 14 December 2006

Dear Doctor

Field Corrective Action of Generation II Aorfix™ (SG-HBB and SG-HPE only), cease of supply.

Further to the detailed, attached company statement we would like to provide you reassurance regarding our confidence of the integrity of the Aorfix™ products you have implanted in recent months.

The temporary cessation only relates to Aorfix™ Generation II device (Code SG-HBB and SG-HPE). The issue potentially affected systems manufactured between June and December 2006. There is no effect on Generation I devices or the Aorfix™ Aorto-Uni-Iliac Device.

The field corrective action was implemented due to our awareness of a potential issue, which could cause increased complexity during the deployment process. An additional manufacturing step was introduced in the loading of the graft, allowing the graft to be presented to the loading mechanism slightly incorrectly.

We would like to reconfirm this is a potential delivery system problem which we have taken immediate steps to rectify and improve.

This issue has no effect on any graft which has already been deployed.

Therefore, there is no need to change your normal follow up process or recall patients in whom you have already implanted grafts. Please continue with your normal follow up processes you adopt for endovascular procedures.

If you have any questions please do not hesitate to contact Lombard Medical, your Regional Business Manager or Distributor.

Yours sincerely,

[redacted]
CEO Lombard Medical Technologies PLC