# Medical Device Alert

Ref: MDA/2012/072 Issued: 18 October 2012 at 15:00

## Device

AlboGraft polyester vascular graft.

Manufactured by LeMaitre.

All lots.

## Problem

In June 2012 the MHRA lifted the prohibition on the sale of AlboGraft polyester vascular grafts and withdrew MDA/2012/018.

However, the advice given in MDA/2012/010 – that these grafts should be leak tested prior to use – continues to apply until the end of December 2012.

## Action by

- Vascular surgeons.
- Cardiothoracic surgeons.
- Purchasing managers.

## Action

This notice updates MDA/2012/010.

- Test all affected grafts to assess them for blood leakage prior to implantation. A suitable method involves closing one end of the graft with a haemostat or other clamp and filling it with blood using a syringe with a Tibbs fitting. If any significant degree of blood leakage through the sidewalls of the graft is observed, it should be discarded and an alternative used.
- Ensure you have an appropriate back-up graft in theatre.
- Report any adverse incidents to the MHRA and to the manufacturer.

## CAS deadlines

Action underway: 01 November 2012

Action complete: 29 November 2012

## Contact

**Manufacturer**
Tobias Malcharczik
LeMaitre Vascular GmbH
Tel: 00 49 6196 659 2315
Fax: 00 49 6196 527 0702
Email: tmalcharczik@lemaitre.com

## Device

This device is intended to replace damaged or malfunctioning sections of the aorta or more peripheral arteries.

## Problem

In April 2012 the MHRA issued MDA/2012/018 informing users of the Prohibition Notice preventing the manufacturer from selling the AlboGraft in the UK. The MHRA has since carried out a detailed audit of the graft manufacturing facility. We were provided with evidence of a number of ongoing changes that the manufacturer was making to the processes to improve control of manufacturing. As a consequence the MHRA has now lifted the Prohibition Notice and permitted sales of the AlboGraft in the UK. Until the end of 2012, however, we are continuing to advise clinicians to undertake the leak test described in MDA/2012/010. This is to ensure that products manufactured before and during these improvements do not show any of the previous problems. The MHRA will issue more advice if further significant adverse incidents are reported.

## Distribution

This MDA has been sent to:
- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Vascular surgeons

### Independent distribution

### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

## Contacts

**Manufacturer**
Tobias Malcharczik
LeMaitre Vascular GmbH
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Germany
Tel: 00 49 6196 659 2315
Fax: 00 49 6196 527 0702
Email: tmalcharczik@lemaitre.com

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/072** or **2012/002/007/081/006**

**Technical aspects**
Clare Huntington or Alexander McLaren
Medicines & Healthcare products Regulatory Agency
Floor 4
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**Clinical aspects**
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## How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

## Wales

Enquiries in Wales should be addressed to:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk