IRISH MEDICINES BOARD
SAFETY NOTICE

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Intracranial Stent SILK

IMB Safety Notice: SN2010(06)
Circulation Date: 14 June 2010

MANUFACTURER/SUPPLIER
Balt Extrusion

TARGET GROUPS
Neuroradiologists

ISSUE
Potential for patient death if the device is used to treat intracranial aneurysms without using embolisation coils.

BACKGROUND
The manufacturer (Balt Extrusion, France) issued an urgent field safety notice on 09 March 2010 advising the customers of reports of patient deaths associated with the use of the SILK device (please see the attached field safety notice). These fatalities occurred between 5 and 150 days after implantation. The causes of these deaths have not been conclusively determined. However, each of these patients had been treated for an existing giant intracranial aneurysm (18 to 31mm) and without the use of additional embolisation coils.

The manufacturer advised that it does not currently have the clinical data to support the use of the SILK device without the use of embolisation coils. The manufacturer now intends to amend the instructions for use (IFU) to reflect this advice. It is also planning a post-market clinical trial to investigate the use of the SILK device without coils in aneurysms with a diameter less than 15mm.

The manufacturer has notified the Irish Medicines Board (IMB) that they recommend the following actions are taken for the follow up of the patients:

- Identify patients who have been implanted with the SILK device without embolisation coils.
- Assess the status of the aneurysm at approximately 3 months post implant by a non-invasive technique, e.g. Computed Tomography Angiography (CTA), Magnetic Resonance Angiography (MRA).
- Assess the status of the aneurysm at approximately 6 months post implant by an invasive technique, e.g. angiography.
- Insert a further stent if the aneurysm status is unsatisfactory at these times.

The users can contact Dr Kulcsar (tel. 00.41.44.63.53800), neuroradiologist in Zurich, who collects and analyses the post implantation complications with the Silk device.

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IMB RECOMMENDATIONS

- Ensure the appropriate personnel are made aware of this notice.
- Ensure that the patient follow up recommended by the manufacturer is followed (please see above).

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
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E-mail: vigilance@imb.ie
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Enquiries should be addressed to:

Manufacturer:

Balt Extrusion
10 rue de la Croix Vigneron
95160 Montmorency
France

Telephone: +33 139 34 61 84
Fax: +33 134 17 03 46
Email: quality.manager@balt.fr

Contact person: Eric Largen / Aude Chapuis-Hardy