

**Notice Information: - Advisory
19 August 2011**

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:

Part 4. Background Information

a) Background Information:

Assut Medical Sàrl notified the Irish Medicines Board of a stolen shipment of two boxes containing multiple lots of the Assut Sutures AssuCryl and Silk surgical sutures. These devices are identified on their labelling as being sterile. However, the boxes were stolen before the lots were sterilised and are therefore non-sterile. Use of these non-sterile devices may lead to infection.

The stolen boxes included all devices from the specific lot numbers listed in table 1. The devices that were stolen were in bulk boxes and were not in the sales packaging used for the device, which contain either 1 or 3 dozen devices.

The boxes were stolen in Columbia the 29th July 2011 and it is not known if the products have left or will leave Columbia. As a precautionary measure, Assut Medical Sàrl will be informing its customers worldwide about the issue. Assut Medical have never sold these devices in Ireland.

Part 5. Action to be taken

a) Action to be taken:

The IMB advises that you:

- Check your inventory for the affected product.
- Monitor all incoming shipments for the affected product.
- If you have any of these identified devices in your current inventory or receive any future delivery of these batches of devices, do not use the devices and contact Assut Medical Sàrl.
- If healthcare professionals suspect or know that the stolen non-sterile devices have been used, it is recommended that they monitor and treat patients accordingly.

Part 6. Enquiries

- a) All enquiries should be made to:

If you have any enquiries relating to the above you may contact the Medical Devices Vigilance & Compliance section of the Human Products Monitoring Department of the Irish Medicines Board at the contact details listed below.

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

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Assut Medical Sàrl

Av. de Rochettaz 57

1009 Pully

Switzerland

Contact person: Catherine Baerfuss

Telephone: +41 21 728 64 35 Fax: +41 21 728 64 49 E-mail: cba@assutsutures.com

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