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NOTICE**

# Non-sterile Assut Sutures AssuCryl and Silk Surgical Sutures

**IMB Safety Notice: SN2011(21)**  
**Circulation Date: 19 August 2011**

**MANUFACTURER:**

Assut Medical Sàrl

**TARGET GROUPS**

Hospital Managers / CEOs  
Risk Managers  
Clinical Directors  
Clinical Engineers  
Surgeons  
Theatre and Nursing Staff  
Purchasing Managers  
Nursing Managers  
Emergency Departments  
Hospital personnel  
Medical device distributors

**ISSUE**

Stolen non-sterile Assut Sutures AssuCryl and Silk surgical sutures are labelled as “Sterile”.

**BACKGROUND**

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 29<sup>th</sup> 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.

# SAFETY NOTICE

REF (reference)	Description	USP	Needle	Thread	LOT
4554	AssuCryl	3-0	TS-19	75 cm	107086
602	Silk	4-0	HR-13	75 cm	107083
602	Silk	4-0	HR-13	75 cm	107215
605	Silk	3-0	HR-17	75 cm	107119
654	Silk	2-0	TS-27	75 cm	107137
656	Silk	2-0	TS-30	75 cm	107117
653	Silk	3-0	TS-27	75 cm	107138
658	Silk	2-0	TS-38	75 cm	107118

Table 1

## ACTIONS OR RECOMMENDATIONS

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.

## ENQUIRIES

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](mailto:vigilance@imb.ie)  
Website: [www.imb.ie](http://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](mailto:cba@assutsutures.com)