



**Medical Devices Bureau, Ministry of Health Malaysia**  
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## Medical Device / Equipment **ALERT**

**Date Issued : 23<sup>rd</sup> July 2008**

**Ref:MDB/A/2008/009**

<b>IMMEDIATE ACTION</b>	
<b>ACTION</b>	√
<b>UPDATE</b>	
<b>INFORMATION REQUEST</b>	

<b>PRODUCT</b>	Procedure packs from various manufacturers which contain BD Medical Surgical Systems 2ml, 5ml and 10ml Plastipak Luer slip syringes.
<b>CLASS</b>	Not Available
<b>USE</b>	Procedure Pack
<b>SOURCE OF MEDICAL DEVICE RECALL / ALERT</b>	<b>Medicines and Healthcare products Regulatory Agency, MHRA United Kingdom's website,</b> Date issued: 1 <sup>st</sup> July 2008
<b>ALERTING / RECALLING FIRM</b>	<b>BD Medical Surgical System United Kingdom</b>
<b>REASON</b>	<p>Potential for the BD Luer slip syringes supplied in procedure packs to spontaneously disconnect or fail to maintain a secure connection to Luer fittings of other devices.</p> <p>In the United Kingdom, BD Medical Surgical Systems has identified that several batches of non sterile 2ml, 5ml and 10ml Plastipak syringes may spontaneously disconnect or fail to maintain a secure connection to Luer fittings</p> <p>BD has not supplied these non sterile syringes directly to users; the syringes have been provided in a procedure packs via third party companies.</p>

	<p><i>These syringes have the BD logo on them but do not carry a batch number or product code to enable them to be identified.</i></p> <p>The code associated with the procedure packs is not related to any syringe codes.</p> <p>According to the MHRA website, in the United Kingdom market the following manufacturers have identified from their records that syringes from the affected batches have been included in their procedure packs:-</p> <p>Alcon Laboratories (UK) Ltd  BD Ophthalmic Systems Ltd  Molnlycke Healthcare Group  Rociale  Smiths Medical  Sunlight Service Group  Unisurge</p> <p>It is advisable for the distributors or sales representative of the abovementioned companies in Malaysia to respond to this alert notice.</p>
<p><b>SCENARIO IN MALAYSIA</b></p>	<p><b>No details available at this moment.</b> For users, please check whether the device is available and contact the distributor.</p>
<p><b>ACTION</b></p>	<p>Ensure all systems are in place so that where a procedure pack contains BD Luer slip syringes and when the use of the syringes is unavoidable:</p> <ul style="list-style-type: none"> <li>• the syringes are used with caution and their use is avoided in situations where disconnection would pose a high risk to patients or users</li> <li>• the syringe is firmly attached to all Luer connections</li> <li>• syringes are not left unattended while connected to Luer fittings.</li> </ul> <p><b><i>Recommendations For Healthcare Professionals</i></b></p> <ul style="list-style-type: none"> <li>• Ensure that all relevant staff in your institution are informed of this safety alert/warning</li> <li>• Determine if you have the affected products</li> <li>• Locate and monitor the usage of the affected</li> </ul>

	<p>products</p> <ul style="list-style-type: none"> <li>• Determine how much of this product has been used</li> <li>• Follow the distributor / manufacturers recommendations for quarantine and disposal of product</li> <li>• Follow up patients as required.</li> </ul>
<b>RECOMMENDATION</b>	<p>Users of the abovementioned device should contact the distributors/supplier of this device (if available) and <b>inform the Medical Devices Bureau, Ministry of Health</b> providing the following information:-</p> <p>a. Name of healthcare centre/hospital/clinic  b. Contact person and contact number  c. Numbers of units available</p>
<b>CONTACT/ENQUIRIES IN MALAYSIA</b>	<p><b>Becton Dickinson Sdn. Bhd. (165273-H)</b>  1301 Bangunan TH Uptown 3  3 Jalan SS 21/39  47400 Petaling Jaya,  Selangor Darul Ehsan, Malaysia</p> <p>Phone: 603.7725.5517/5516  Fax: 603.7725.4990  Email: <a href="mailto:bd_malaysia@bd.com">bd_malaysia@bd.com</a></p>
<b>REFERENCES</b>	<p><a href="http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON020535">http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON020535</a></p>