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Medical Device / Equipment ALERT

Date Issued : 9 April 2008

Ref:MDB/A/2008/001

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| IMMEDIATE ACTION | |
| ACTION | √ |
| UPDATE | |
| INFORMATION REQUEST | |

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| PRODUCT | Hospira butterfly winged needle infusion set – regular and intermittent. All batches manufactured prior to April 2008. |
| CLASS | Not Mentioned |
| USE | Hospira butterfly winged needle infusion set – regular and intermittent butterfly set. The regular set is terminated at the user end by a female Luer connector with cap; the intermittent set is terminated by a female Luer connector and reseal device. |
| SOURCE OF MEDICAL DEVICE RECALL / ALERT | MHRA website, date issued: 7 th April 2008 |
| RECALLING FIRM | Hospira UK Ltd Queensway Royal Leamington Spa Warwickshire C V31 3RW Tel: 01926 835 441 / 279 Fax: 01926 459 672 E-mail: tamsin.fay@hospira.com james.motley@hospira.com General product safety e-mail safetyemea@hospira.com |

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| <p>REASON</p> | <p>Leakage of fluid during IV administration e.g. radiopharmaceuticals during radionuclide imaging procedures.</p> <p>According to the MHRA website, they has received several reports of leakage from these devices including spillage of radiopharmaceuticals during nuclear medicine imaging. Leakage is occurring due to two manufacturing issues:</p> <ul style="list-style-type: none"> • Loose reseal device on intermittent set The reseal device may not have been attached securely enough in some circumstances and may leak, fall off, or already be detached on delivery. • Leakage at the joint between the tubing and the Luer connector In a number of the devices the bond between the tubing and the Luer connector is too weak. The risk of leakage may be further exacerbated by the use of small (2ml or 5ml) syringes, which exert greater pressure during use. <p>At the end of March 2008 the manufacturer introduced changes to improve the quality of its products, but is not intending to recall the existing batches affected by these problems.</p> |
| <p>SCENARIO IN MALAYSIA</p> | <p>No details available at this moment. Please check whether the device is available and contact the distributor.</p> |
| <p>ACTION</p> | <p>Use an alternative product if available. If none is available continue to use this device following the guidance stated below.</p> <ul style="list-style-type: none"> • Carefully check that the reseal device is securely attached to the luer connector before using the product (applies to the intermittent version). • Avoid wherever possible applying greater pressure than is required during fluid infusion through the device. |
| <p>RECOMMENDATION</p> | <p>Users of the abovementioned device should contact the distributors/supplier of this device (if available) and inform the Medical Devices Bureau, Ministry of Health providing the following information:-</p> <ol style="list-style-type: none"> a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available |

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| <p>CONTACT/ENQUIRIES IN MALAYSIA</p> | <p>Please refer to the supplier of the device(s) if available.</p> <p>LOCAL DISTRIBUTOR FOR HOSPIRA:</p> <p>Hospira Malaysia Sdn Bhd Suite 201 1st Floor, Wisma Glomac 3, Kompleks Kelana Centre Point, Jalan SS7/19, Petaling Jaya, 47301 Selangor. Tel :603 7804 7881 Fax: 603 7806 2881</p> |
| <p>REFERENCES</p> | <p>https://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON014526</p> |