

Medical Device Alert

Immediate action

Ref: MDA/2009/055 Issued: 17 August 2009 at 14:00

Device

Intro-Flex introducers manufactured by Edwards Lifesciences Ltd for the insertion of Swan-Ganz catheters.

Specific batches of specific models.



Problem

The blue connector on the introducer may break during use, which may result in significant blood loss. The manufacturer is recalling all affected devices.

Action

- Check stock for affected devices.
- Quarantine devices from affected batches.
- Contact the manufacturer to arrange for their return.

Action by

All staff responsible for the storage and use of these devices, in particular supplies departments and intensive care units.

Contact

Manufacturer

Miss Andleeb Arshad
Edwards Lifesciences Ltd

Tel: 0870 606 2040

Fax: 0870 606 2050

E-mail: Andleeb_arshad@edwards.com

CAS deadlines

Action underway: 24 August 2009

Action complete: 01 September 2009

[Link to full Medical Device Alert](http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON054539)

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON054539>