



# Medical Device Alert

MDA/2018/020

Issued: 20 June 2018 at 14:00

Valid until: June 2019

**Smiths Medical CADD® Non Flow-Stop Medication Cassette Reservoirs – recall of specific lots due to risk of under delivery of medication**

## Summary

Smiths Medical CADD® Non Flow-Stop Medication Cassette Reservoirs may have been manufactured with an incorrect pressure plate which could cause partial or total occlusion of the tubing with no alarm.

## Action

- Refer to the manufacturer's [Field Safety Notice](#) (FSN) for a list of affected product codes and the attached spreadsheet for a list of affected lots
- Identify, stop using and quarantine these devices
- Contact Stericycle to return the devices as directed in the manufacturer's [FSN](#)

### Action by

All healthcare professionals who are responsible for, or who use these devices

### Deadlines for actions

Actions underway: 04 July 2018

Actions complete: 18 July 2018

**Medical Device Safety Officers** (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help ensure FSNs are acted upon fully within your organisation and the manufacturer informed appropriately.

**Remember:** if your organisation receives an [FSN](#) from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

## Device details

CADD® Medication Cassette Reservoirs are intended for ambulatory volumetric infusion of small doses (up to 50ml, 100ml, or 250ml), and are designed to be used with a variety of CADD ambulatory infusion pumps (except CADD-Micro™, CADD-MS® 3 and CADD-TPN® pumps).

In addition to the [Field Safety Notice](#) which details affected products, please refer to the spreadsheet which accompanies this MDA for additional unique device identification information, and models and lot numbers.

## Manufacturer contacts

Smiths Medical  
Tel: 01233 722 227  
Email: [fieldactions@smiths-medical.com](mailto:fieldactions@smiths-medical.com)

Stericycle  
Email: [smithscadd101@stericycle.com](mailto:smithscadd101@stericycle.com)

## Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

### Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All wards
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiology departments
- Cardiology nurses
- Cardiothoracic departments
- Chief pharmacists
- Clinical perfusionists
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- District nurses
- Endocrinology units
- ENT departments
- Equipment stores
- Equipment libraries and stores
- Gastroenterology departments
- General surgery

- General surgical units, directors of
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Health and safety managers
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- In-house maintenance staff
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical libraries
- Medical oncologists
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Nutrition nurses
- Obstetrics and gynaecology departments
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- Operating department practitioners
- Orthopaedic surgeons
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Peritoneal dialysis units
- Purchasing managers
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urology departments

## ***Independent distribution***

### **Establishments registered with the Care Quality Commission (CQC) (England only)**

- Care homes providing nursing care (adults)
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: [safetyalerts@mhra.gov.uk](mailto:safetyalerts@mhra.gov.uk) and requesting this facility.

## **Enquiries**

### **England**

Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/020** or 2017/010/012/701/035.

### **Technical aspects**

Ruth Lloyd-Williams, Jenifer Hannon, MHRA

Tel: 020 3080 6972 / 7153

Email: [ruth.lloyd-williams@mhra.gov.uk](mailto:ruth.lloyd-williams@mhra.gov.uk), [Jenifer.Hannon@mhra.gov.uk](mailto:Jenifer.Hannon@mhra.gov.uk)

### **Clinical aspects**

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto:dct@mhra.gov.uk)

### **Reporting adverse incidents in England**

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

### **Northern Ireland**

Alerts in Northern Ireland are distributed via the [NICAS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,  
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: [niaic@health-ni.gov.uk](mailto:niaic@health-ni.gov.uk)  
<https://www.health-ni.gov.uk/niaic>

### **Reporting adverse incidents in Northern Ireland**

Please report directly to NIAIC using the [forms on our website](#).

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

### Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to [Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to [Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

## Wales

Enquiries in Wales should be addressed to:

Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

### Reporting adverse incidents in Wales

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.

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