



Llywodraeth Cymru
Welsh Government

Medical Device Alert

2nd July 2018

Parc Cathays
Caerdydd CF10 3NQ

Cathays Park
Cardiff CF10 3NQ

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

- 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](#)

Sent to:

NHS Wales Shared Services Partnership
Directors of Public Health,
Chief Executives, NHS Trusts
Chief Executives, LHBs
Medical Directors, NHS Trusts
Nurse Directors, LHBs
Executive Nurses, NHS Trusts
NHS Direct
CSSIW
Social Services
HIW

A list of people who need to have early sight of this information is given in the Notice.
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

Points of particular importance in Wales:

Healthcare Quality Division
Welsh Government
Cathays Park
Cardiff CF10 3NQ



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

Stericycle
Email: 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 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, Jenifer.Hannon@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: 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
<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

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

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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Addressees may take copies for distribution within their own organisations

Catalogue number (Manufacturer product code) :21-7001-24		Device Identifier: 30610586022115	
12X384	14X112	15X178	16X519
12X389	14X122	15X206	16X522
12X397	14X135	15X226	16X541
12X410	14X144	15X266	16X542
12X421	14X157	15X276	16X671
12X432	14X172	15X309	16X683
12X443	14X184	15X317	16X684
12X458	14X212	15X318	16X706
12X480	14X236	15X335	16X740
12X494	14X242	15X349	16X774
12X513	14X290	15X378	16X775
12X543	14X297	15X379	16X780
12X573	14X323	15X409	16X793
13X010	14X338	15X410	16X794
13X022	14X372	15X454	16X817
13X037	14X388	15X466	16X841
13X058	14X413	15X477	16X851
13X077	14X427	15X483	16X867
13X104	14X447	15X515	16X884
13X118	14X472	15X516	16X915
13X125	14X485	15X529	16X928
13X156	14X499	15X547	17X013
13X184	14X513	15X667	17X039
13X197	14X523	15X675	17X055
13X204	14X524	16X003	17X070
13X215	14X554	16X004	17X094
13X233	14X566	16X099	17X113
13X257	14X583	16X108	17X127
13X271	14X599	16X118	17X128
13X288	14X602	16X171	17X142
13X291	14X617	16X210	17X151
13X322	14X628	16X244	17X178
13X343	14X648	16X269	17X215
13X353	14X655	16X286	17X237
13X356	14X679	16X287	17X238
13X369	14X682	16X288	
13X387	14X701	16X306	
13X408	14X720	16X330	
13X409	14X722	16X359	
13X438	15X004	16X396	
13X459	15X009	16X404	
13X475	15X019	16X411	
13X503	15X040	16X412	
13X517	15X065	16X429	
13X558	15X118	16X431	
13X559	15X118	16X438	
14X023	15X135	16X455	
14X052	15X146	16X476	
14X071	15X160	16X479	
14X085	15X177	16X503	

Catalogue number (Manufacturer product code): 21-7002-24		Device Identifier: 30610586022122	
12X393	13X029	13X239	13X434
12X394	13X031	13X240	13X440
12X399	13X040	13X243	13X443
12X402	13X044	13X244	13X444
12X403	13X041	13X249	13X449
12X412	13X049	13X251	13X451
12X424	13X052	13X252	13X454
12X427	13X054	13X254	13X456
12X429	13X055	13X259	13X463
12X433	13X062	13X261	13X465
12X437	13X066	13X262	13X477
12X450	13X074	13X268	13X483
12X452	13X078	13X273	13X500
12X460	13X085	13X282	13X505
12X463	13X087	13X295	13X508
12X468	13X088	13X296	13X511
12X472	13X091	13X305	13X512
12X475	13X098	13X306	13X523
12X478	13X100	13X309	13X536
12X483	13X101	13X310	13X538
12X485	13X111	13X330	13X548
12X487	13X114	13X331	13X551
12X488	13X123	13X332	13X556
12X489	13X127	13X338	13X572
12X501	13X129	13X346	13X573
12X511	13X138	13X357	13X589
12X517	13X143	13X360	13X591
12X519	13X150	13X363	13X592
12X523	13X153	13X365	14X001
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12X539	13X163	13X375	14X004
12X546	13X164	13X382	14X005
12X555	13X170	13X383	14X007
12X562	13X178	13X384	14X009
12X566	13X179	13X398	14X010
12X567	13X185	13X400	14X011
12X576	13X186	13X401	14X012
12X578	13X187	13X406	14X022
13X001	13X191	13X412	14X024
13X002	13X193	13X414	14X041
13X003	13X198	13X421	14X043
13X014	13X199	13X424	14X046
13X017	13X214	13X426	14X063
13X019	13X219	13X427	14X074
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