

Safety Notice

Medical Devices

CADD[®] Medication Cassette Reservoirs (Non Flow-Stop), 50ml and 100ml



Priority 2 – Warning

HPRA Safety Notice: SN2018(07)

Issue Date: 05 February 2018

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Smiths Medical	V33553

ISSUE

The Health Products Regulatory Authority (HPRA) published [Safety Notice SN2017\(38\)](#) in November 2017 in relation to a Smiths Medical recall of specific lots of Non Flow-Stop CADD[®] Medication Cassette Reservoirs.

In January 2018, Smiths Medical extended this recall to include additional lot numbers of Non Flow-Stop CADD[®] Medication Cassette Reservoirs, part numbers 21-7001-24, 21-7002-24 and 21-7100-24. The additional affected products were shipped between October 2012 and November 2017 and have an expiration date prior to July 2022.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1. Refer to the accompanying field safety notice (FSN) and follow the instructions provided by the manufacturer.

2. Report any concerns regarding these devices to the manufacturer and the HPRA as soon as possible.
3. Contact your healthcare professional with any concerns.

The HPRA advises that healthcare professionals:

1. Refer to the accompanying FSN and follow the instructions provided by the manufacturer.
2. Forward a copy of this safety notice and the FSN to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.
3. Quarantine all affected product identified at your facility as soon as possible.
4. Acknowledge receipt of the FSN if you have not already done so.
5. Report any concerns/adverse incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Hospital Managers / CEOs	Outpatient Clinics
Risk Managers	Pharmacists
Clinical Directors	Nursing Homes
Purchasing Managers	Community Care Managers
Supplies Managers	Community Nurses
Clinical Engineers	General Practitioners
Nursing Managers	Hospices
Nursing Staff	Carers
All Wards	

BACKGROUND

Smiths Medical has extended the recall to include the following lot numbers:

17X195	17X275	17X320	17X357	17X398	17X433
17X216	17X276	17X321	17X358	17X399	17X434
17X217	17X277	17X322	17X359	17X400	17X435
17X237	17X278	17X340	17X376	17X411	17X448
17X240	17X279	17X341	17X379	17X412	17X449
17X241	17X280	17X342	17X380	17X413	17X450
17X242	17X300	17X343	17X381	17X422	17X451
17X243	17X301	17X344	17X382	17X423	17X458
17X244	17X318	17X345	17X397	17X424	17X459
17X259	17X319	17X346			

The potential risks associated with the use of recalled medication cassette reservoirs are highlighted in the accompanying FSN.

The manufacturer has advised that all products with an expiration date prior to July 2022 are now included in this recall.

The HPRA is issuing this safety notice to raise awareness of the expansion of this product recall.

AUTHORISED REPRESENTATIVE CONTACT INFORMATION

Enquiries to the **European authorised representative** should be addressed to:

Smith Medical International Limited 1500 Eureka Park Lower Pemberton Ashford Kent TN25 4BF United Kingdom	E-mail: smithscadd101@stericycle.com
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HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2	Telephone: +353-1-6764971 Fax: +353-1-6344033 E-mail: devicesafety@hpra.ie Website: www.hpra.ie
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