HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

MAHURKAR Acute Triple Lumen Catheter; MAHURKAR Acute Dual Lumen Catheter; Argyle Acute Single Lumen Catheter

Priority 2 – Warning

HPRA Safety Notice: SN2019(15) **Issue Date: 21 May 2019**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Covidien/Medtronic	V39863

ISSUE
Medtronic has issued a field safety notice (FSN) to clarify that the priming volume values printed on the MAHURKAR and Argyle acute catheters and Instructions for Use (IFU) are higher than the volumes required to fill each lumen. Depending on the catheter size and configuration, an overfill of between 0.1 mL – 0.5 mL per lumen could occur which may lead a clinician to administer more heparin than intended. Please refer to the accompanying FSN for further details.

ACTION OR RECOMMENDATIONS
The HPRA advises that healthcare professionals 1. Refer to the accompanying FSN and follow the instructions provided. 2. Acknowledge receipt of the FSN if you have not already done so. 3. 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. 4. Report any concerns regarding these devices and this issue to the manufacturer and the HPRA.

TARGET GROUPS

Accident & Emergency Departments	Hospital Managers / CEOs
Clinical / Medical Directors	Public and Private Hospitals
Clinical Nurse Managers	Purchasing Managers
Consultant Nephrologists	Radiology departments
Dialysis Nurses	Risk Managers
Dialysis Wards	Supplies Managers

BACKGROUND

MAHURKAR and Argyle acute catheters are used in haemodialysis, apheresis, infusion, renal replacement therapy, high pressure contrast injection and central venous pressure monitoring.

Medtronic has indicated that the priming volumes were initially established using a maximum calculated volume plus an additional volume to ensure the catheter was fully locked. This has resulted in the printed priming volumes on current MAHURKAR and Argyle acute catheters exceeding the actual locking volume needed to fully fill the lumen.

The instructions for use for these devices will be updated to provide clarity on the currently printed priming volumes. In due course, upon re-evaluation of the priming volume for all configurations and sizes of the MAHURKAR and Argyle acute catheters, the product and the product labelling will be subsequently updated.

While the instructions for use are being updated Medtronic recommends the use of a non-heparinized lock solution to mitigate the potential risk associated with unintended administration of additional concentrated heparin. Please refer to the accompanying FSN for further details.

The HPRA is issuing this safety notice to raise awareness of this issue.

MANUFACTURER CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Medtronic Customer service
on behalf of
Covidien LLC
15 Hampshire Street
Mansfield
MA 02048
USA

Telephone: +353-1-5111400
E-mail: vigilance.eu@medtronic.com

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