

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/78

Issued: 19 December 2006



HEALTH ESTATES

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For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	✓

	Section
<p>Medical Device/Equipment: Radial artery introducer sets: William Cook Europe Flexor[®] Check-Flo[®] Micropuncture[®] Radial Artery Access Introducer Sets with AQ[®] Hydrophilic Coating. See appendix for part numbers.</p>	▶ ①
<p>Problem: The manufacturer has received reports of inflammatory responses at the access site of a number of patients following use of this device. The cause of these events has not been identified.</p>	▶ ②
<p>Action by: All clinicians involved in arterial catheterisation.</p>	▶ ③
<p>Action: Ensure all users are aware of the action detailed in Section 4, page 2</p>	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of NIAIC contacts for technical aspects</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Radial artery introducer sets: William Cook Europe Flexor® Check-Flo® Micropuncture® Radial Artery Access Introducer Sets with AQ® Hydrophilic Coating. See appendix for part numbers.

2. PROBLEM:

An inflammatory response has been observed at the access site in a number of patients following use of this device. Reports indicate that the observed response is not due to infection, and generally appears from several days to several weeks after use. Despite extensive investigation by Cook, the cause of these events has not been conclusively identified.

The manufacturer has issued an information letter to all customers and also updated the Instructions for Use to warn users of this potential risk. At this time, no reports of similar responses have been received from other William Cook Europe products having the same hydrophilic coating.

This MDEA has been issued to ensure users are aware of this potential risk.

3. ACTION BY:

All clinicians involved in arterial catheterisation.

4. ACTION:

Ensure all users are:

- aware of the potential risks associated with the use of this device, as outlined in the attached customer letter
- following the guidance in the attached letter which includes:
 - using a small incision in the skin to facilitate sheath insertion
 - firmly wiping the length of the sheath with sterile saline wetted gauze prior to insertion
- adhering to local infection control policy particularly when using the wetted gauze.
- Ensure procedures are in place to report any inflammatory response associated with the use of this device to the manufacturer William Cook and the NIAIC.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- Anaesthetists
- Cardiac catheterisation laboratories
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Clinical governance leads
- Coronary care departments
- Coronary care nurses
- Health and safety managers
- Interventional radiologists
- IV nurse specialists
- Medical directors
- Radiology departments
- Radiology nurses
- Risk manager
- Supplies departments
- Theatre managers

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Peter Maglehøj Hansen
William Cook Europe ApS
Sandet 6, 4632 Bjaevershov
Denmark

Tel: +45 56 86 86 86

Fax: +45 56 86 86 96

E-mail: p.m.hansen@cook-wce.com

Enquires to NIAIC should quote reference number MDEA(NI)2006/78 and be addressed to:

Northern Ireland Adverse Incident Centre
(NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

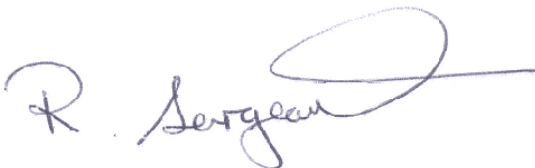
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

Report any adverse reactions to this product to the NIAIC.



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety



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December 15, 2006

To Whom it May Concern:

Our records indicate that you have purchased the Cook Flexor® Check-Flo® Micropuncture® Radial Artery Access Introducer Set with AQ® Hydrophilic Coating within the last three years. A list of the part numbers for this product is provided at the end of this letter.

It has come to our attention that a sterile inflammatory response has been observed at the access site in a small number of patients after use of the Cook Flexor® Check-Flo® Micropuncture® Radial Artery Access Introducer Set with AQ® Hydrophilic Coating. Reports indicate that the observed response is not infectious, and generally presents from several days to several weeks after use. Two articles providing additional details, along with potential treatment options (see Kozak, *et al.*), are referenced below.^{1,2}

Despite extensive investigation by Cook, the cause of these events has not been conclusively identified. Data published by Kozak, *et al.* suggest possible contributions to the risk of inflammatory response from the use of latex gloves and the use of powdered gloves; however, there may be other factors involved as these reactions have also been observed in cases where no source of protein allergens has been identified. At this time, no reports of similar responses have been received for any other Cook Incorporated product having the same hydrophilic coating, and investigation continues. For your information, a list of part numbers is enclosed on the following page. Furthermore, the suggested Instructions for Use have been updated to reflect this potential risk.

Although supportive data are not available, experienced physician users suggest that the use of a small skin nick to facilitate sheath insertion (as specified in the Instructions for Use), may help reduce the likelihood of an access site reaction. An additional suggestion has been to firmly wipe the length of the sheath with saline wetted 4x4 gauze as part of (or following) coating activation.³

¹ Kozak M, Adams DR, Ioffreda MD, et al. Sterile inflammation associated with transradial catheterization and hydrophilic sheaths. *Catheterization and Cardiovascular Interventions*. 2003; 59:207-213.

² Subramanian R, White CJ, Sternbergh WC, et al. Nonhealing wound resulting from a foreign-body reaction to a radial arterial sheath. *Catheterization and Cardiovascular Interventions*. 2003; 59:205-206.

³ Garratt K. Prevention, identification, and treatment of complications in transradial access. *Advances in Cardiac and Endovascular Therapies*. New York, NY; October 10, 2006.

The risks of use of radial sheaths with hydrophilic coating must be weighed against the potential benefits, which may include reduced vessel spasm and reduced pain on sheath withdrawal. An article describing these characteristics is also referenced below.⁴

We continue to investigate this situation and will provide additional information as it becomes available.

Yours sincerely,

Theodore Heise, PhD, RAC
Director Regulatory Scientific Affairs
Cook Incorporated

Peter Maglehøj Hansen
Quality Assurance Manager
William Cook Europe ApS

**Part numbers of the Cook Flexor® Check-Flo® Micropuncture®
Radial Artery Access Introducer Set with AQ® Hydrophilic Coating
(as of October 13, 2006)**

KCFN-6.0-18-7-RA2.5L-HC	KCFN-6.0-18-13-RA2.5L-HC
KCFN-6.0-18-23-RA2.5-HC	KCFN-5.0-18-13-RA2.5-HC
KCFN-6.0-18-13-RA2.5-HC	KCFN-7.0-18-23-RA2.5-HC
KCFN-5.0-18-13-RA2.5L-HC	KCFN-7.0-18-23-RA2.5L-HC
KCFN-7.0-18-13-RA2.5-HC	KCFN-5.0-18-13-RA2.5S-HC
KCFN-6.0-18-13-MCO-HC	KCFN-6.0-18-23-RA2.5L-HC
KCFN-5.5-18-23-RA2.5L-HC	KCFN-5.0-18-23-RA2.5L-HC
KCFN-6.0-18-7-RA2.5-HC	KCFN-6.0-18-23-MCO-HC
KCFN-7.0-18-13-RA2.5L-HC	KCFN-5.0-18-23-RA2.5-HC
KCFN-5.5-18-23-RA2.5-HC	KCFN-6.0-18-13-RA2.5S-HC

⁴ Kiemeneij F, Fraser D, Slagboom T, et al. Hydrophilic coating aids radial sheath withdrawal and reduces patient discomfort following transradial coronary intervention: a randomized double-blind comparison of coated and uncoated sheaths. *Catheterization and Cardiovascular Interventions*. 2003; 59:161-164.