

Medical Device Alert

Immediate action

Ref: MDA/2010/072 Issued: 16 September 2010 at 15:00

Device

Vascular catheters:
 K-Flow Access Catheters.
 Kimal High Flow (HF) Haemodialysis Catheters.
 Kimal Right Atrial (KRA) Catheters.

Manufactured by Kimal.

Devices with specific product codes and expiry dates are affected.

Problem	Action
<p>The CE marking of these specific catheters is invalid.</p> <p>The safety and performance of these devices has not been submitted for independent assessment.</p>	<ul style="list-style-type: none"> Identify the affected stock and return it to the manufacturer. For patients with catheters in situ, the MHRA currently considers that the benefits of continuing to use the device outweigh the risks of removal and replacement.
Action by	
<p>All staff responsible for ordering and using these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 30 September 2010</p> <p>Action complete: 28 October 2010</p>	<p>Manufacturer Kimal PLC Tel: 01527 572 323 Fax: 01527 572 331 Email: amanda_makemson@kimal.co.uk</p>

Device

To identify affected devices you will need to check the expiry date as well as the product code. The expiry dates are visible on the packaging and will be in the format YYYY-MM e.g. 2014-04 for April 2014.

The affected catheters are:

K-Flow Access Catheters with expiry dates from 2013-10 to 2015 -06 inclusive.

Kimal High Flow (KHF) Haemodialysis Catheters with expiry dates from 2011-09 to 2015 -06 inclusive.

Kimal Right Atrial (KRA) Catheters with expiry dates from 2012-09 to 2014 -01 inclusive.

	Product Name	Product Codes	French size (Fr)	Expiry Dates (inclusive)	NHS Supply Codes
Short Term	K-Flow Access 360 Temporary	KF360T/1512/1J	15.5	2013-10 to 2015 -06	-
		KF360T/1515/1J	15.5		-
		KF360T/1520/1J	15.5		-
		KF360T/1515/S	15.5		-
		KF360T/1520/S	15.5		-
		KF360T/1524/S	15.5		-
		KF360T/1528/S	15.5		-
Short Term	K-Flow Access Temporary	KFT1213C	12	2013-10 to 2015 -06	-
		KFT1213S	12		-
		KFT1215C	12		-
		KFT1215S	12		-
		KFT1220C	12		-
		KFT1220S	12		-
		KFT1224C	12		-
		KFT1224S	12		-
		KFTT1215C	12		FSQ915
		KFTT1215S	12		FSQ909
		KFTT1220C	12		FSQ916
KFTT1220S	12	FSQ911			
KFTT1224S	12	FSQ913			
Short Term	K-Flow Access PICC-CT	KFPCT5S	5	2013-10 to 2015 -06	-
		KFPCT6D	6		-
Short Term	K-Flow Access PICC	KFMP5	5	2013-10 to 2015 -06	-
		KFP3S	3		-
		KFP4D	4		FSU337
		KFP4S	4		FSU335
		KFP5D	5		FSU338
		KFP5S	5		FSU336
		KFP6D	6		FSU339

	Product Name	Product Codes	French size (Fr)	Expiry Dates (Inclusive)	NHS Supply Codes
Long	K-Flow Access	KFH1424C	14.5		-
Term	Haemo	KFH1424S	14.5		-
		KFH1428C	14.5		-
		KFH1428S	14.5	2013-10 to 2015 -06	-
		KFH1432C	14.5		-
		KFH1432S	14.5		-
		KFH1436S	14.5		-
Long	K-Flow Access	KFS1524	15.5		-
Term	Split	KFS1528	15.5	2013-10 to 2015 -06	-
		KFS1532	15.5		-
		KFS1540	15.5		-
Long	K-Flow Access	KFSL1428	14		-
Term	Stepped Silicone	KFSL1432	14	2013-10 to 2015 -06	-
Long	K-Flow Access	KFRA125T	12.5		-
Term	Right Atrial	KFRA95D	9.5	2013-10 to 2015 -06	-
		KFRA7S	7		-
		KFRA95S	9.5		-
Long	Kimal	KHF24	14.5		-
Term	High Flow (aka KHF)	KHF24/k	14.5		-
		KHF24/K/LGH	14.5		-
		KHF28	14.5		-
		KHF28/K	14.5	2011-09 to 2015 -06	-
		KHF28/K/LGH	14.5		-
		KHF32	14.5		-
		KHF32/K	14.5		-
		KHF36	14.5		-
		KHF36/K	14.5		-
Long	Kimal	KRA95D/KGY	9.5		-
Term	Right Atrial (aka KRA)	KRA95S/K	9.5	2012-09 to 2014 -01	-

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

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

Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Anaesthetists
- Cardiac laboratory technicians
- Clinical governance leads
- Coronary care departments
- Equipment stores
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Intensive care units

- Intensive care, directors of
- IV nurse specialists
- Medical directors
- Nurse executive directors
- Oncologists
- Oncology nurse specialists
- Paediatric oncologists
- Radiologists
- Renal medicine departments
- Renal medicine, directors of
- Risk managers
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector

Contacts

Manufacturer

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Worcestershire

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/072** or **2010/008/013/081/013**.

Technical aspects

Roopa Prabhakar or Nicole Small

Medicines & Healthcare products Regulatory Agency

Market Towers

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Clinical aspects

Jonathan Plumb

Medicines & Healthcare products Regulatory Agency

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Fax: 020 7084 3111

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How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

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

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

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

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.irc@nhs.net

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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