

MEDICAL DEVICE ALERT

Issued: **22 March 2006** at 11:00

Ref: **MDA/2006/022**

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

Device: Baxter MiniCap peritoneal dialysis disconnect cap with povidone-iodine.	
Problem: The povidone-iodine contained in the disconnect caps of these peritoneal dialysis sets has the potential to be a contributing factor to thyroid changes such as hypothyroidism. Patients more likely to be affected are infants and children with smaller peritoneal fill volumes, where higher dialysate concentrations of iodine can result.	
Action by: All nursing, medical and technical staff using these devices.	
Action: The thyroid function should be monitored in patients with small peritoneal dialysate fill volumes, typically infants and children. In order to minimise iodine exposure, the contents of the peritoneal cavity should be drained to the drain receptacle prior to the initiation of the next fill cycle whenever clinically possible. Users should be aware of the advice in Baxter's Safety Alert (see appendix).	
Distributed to: NHS trusts in England Healthcare Commission (CHAI) Primary care trusts in England – Chief Executives* – Headquarters – Chief Executives* * via CE Bulletin	► Page 2
Contacts: Details of manufacturer contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for Healthcare Commission.	► Page 2
Appendix: Baxter Safety Alert.	► Pages 4-6

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway) : 29 March 2006

Deadline (action complete): 03 May 2006

This notice is also on our website: <http://www.mhra.gov.uk>

Distribution:

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

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Adult & paediatric intensive care units
- Clinical governance leads
- Consultant biochemists
- Directors of pathology
- Health & safety officers
- Intensive care units
- Medical directors
- Neonatal intensive care units
- Nursing executive directors
- Paediatricians
- Peritoneal dialysis units
- Renal nurses
- Renal physicians
- Renal units and satellites
- Risk managers
- Special care baby units
- Supplies departments

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to all relevant staff including:

- Hospitals in the independent sector

Primary care trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Prison healthcare managers

Contacts:

Enquiries to the manufacturer should be addressed to:

Surecall-Baxter Medical Information
Baxter Healthcare Ltd
Wallingford Road
Compton, Newbury
Berkshire RG20 7QW

Tel: 01635 206 345

Fax: 01635 206 071

E-mail: surecall@baxter.com

Enquiries to the MHRA should quote reference number **2005/003/010/401/002** and be addressed to:

Technical aspects:

Mr J Lefever or Dr C McNie
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3262 / 3219

Fax: 020 7084 3209

E-mail: jim.lefever@mhra.gsi.gov.uk
catriona.mcnie@mhra.gsi.gov.uk

Clinical aspects:

Mr J Plumb
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3128

Fax: 020 7084 3111

E-mail: jonathan.plumb@mhra.gsi.gov.uk

Change of address or removal from address list for Healthcare Commission:

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre

Medicines and Healthcare products Regulatory Agency

Market Towers, 1 Nine Elms Lane, London SW8 5NQ

Telephone 020 7084 3080 or Fax 020 7084 3109

or e-mail: aic@mhra.gsi.gov.uk

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

Further information about **SABS** can be found at www.info.doh.gov.uk/sar/cmopatie.nsf

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12 December, 2005

**SAFETY
ALERT**

Dear Dialysis Center Medical Director,

Dear Peritoneal Dialysis Clinical Lead,

**Potential Changes to ESRD Patient Thyroid Function
Product codes: SPC4466, SPC4212, SPC4486**

Baxter Healthcare Corporation is sending you this safety alert letter to raise your awareness of the potential for changes in thyroid function of your ESRD patients on both haemodialysis and peritoneal dialysis (See references 1, 2, and 3 which can be accessed at www.pubmed.gov).

Based on research into these thyroid changes, Baxter has discovered the potential for the povidone-iodine contained in peritoneal dialysis disconnect caps to be a contributing factor in these changes. Patients potentially impacted are primarily limited to infants and children with smaller peritoneal dialysate fill volumes where higher dialysate concentrations of iodine can result.

Two related cases of hypothyroidism during PD treatment were reported in literature (See reference 4 which can be accessed at www.pubmed.gov), and Baxter has received two additional reports of potentially related cases. All four patients in these cases were children under the age of three with fill volumes below one liter.

As a result of this potential thyroid impact, Baxter recommends thyroid function be monitored in patients with small peritoneal dialysate fill volumes. In order to minimize iodine exposure, drain the contents of the peritoneal cavity to the drain receptacle prior to initiation of the next fill cycle whenever clinically possible. To underscore our commitment to ensuring patient safety, Baxter is adding the following precaution to the applicable directions for use

“It is recommended that thyroid function be monitored in patients with small peritoneal dialysate fill volumes, typically infants and children. In order to minimize iodine exposure, drain the contents of the peritoneal cavity to the drain receptacle prior to initiation of the next fill cycle whenever clinically possible.”

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Please ensure your staff carefully reviews your center's policies and procedures for regularly monitoring thyroid function in ESRD patients. *In addition, please complete the attached reply form confirming your receipt of the letter and fax it back to Baxter at the number provided on the form.*

If you have any questions regarding this letter, please contact Surecall - Baxter Medical Information on 01635 206345.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been advised of this communication.

Yours sincerely,

Paul East
CAPD and Renal Programs Manager
Renal Division
Baxter Healthcare Ltd

References:

1. Lim VS, Thyroid function in patients with chronic renal failure. *Am J Kidney Dis.* 2001 Oct;38(4 Suppl 1):S80-4. Review. PMID: 11576928 [PubMed - indexed for MEDLINE]
2. Kaptein EM, Thyroid hormone metabolism and thyroid diseases in chronic renal failure. *Endocr Rev.* 1996 Feb;17(1):45-63. PMID: 8641223 [PubMed - indexed for MEDLINE]
3. Castellano M et al, Thyroid function and serum thyroid binding proteins in prepubertal and pubertal children with chronic renal insufficiency receiving conservative treatment, undergoing hemodialysis, or receiving care after renal transplantation. *J Pediatr.* 1996 Jun;128(6):784-90. PMID: 8648537 [PubMed - indexed for MEDLINE]
4. Vulsma T et al, Iodine-induced hypothyroidism in infants treated with continuous cyclic peritoneal dialysis. *Lancet.* 1990 Sep 29;336(8718):812. No abstract available. PMID: 1976170 [PubMed - indexed for MEDLINE]

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Potential Changes to ESRD Patient Thyroid Function

Customer Reply Form

(Safety Alert letter dated December 2005)

<p>Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.</p> <p>Fax Number: 01604 704688</p>
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Facility Name and Address:	
Reply Confirmation Completed By: <i>(Please print name)</i>	
Title: <i>(Please print)</i>	
Telephone Number (including Area Code):	

We have received the above mentioned letter, performed the actions as outlined in the letter as needed, and have disseminated this information to our staff and to other services or facilities, as applicable.

Signature/Date:
REQUIRED FIELD _____

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