

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/25

Issued: 13th April 2006



HEALTH ESTATES

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For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section
<p>Medical Device/Equipment: Baxter Clearlink™ needle-free connector/valve for vascular access.</p>	▶ ①
<p>Problem: The instructions for use have undergone significant changes, in particular the maximum period of use of the device.</p>	▶ ②
<p>Action by: All medical and nursing staff responsible for patients with vascular devices. In particular, infection control teams and specialist IV nurses.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Ensure that relevant staff are aware of the revised instructions for use contained within the manufacturer's customer letter (see appendix). • Review local policies to ensure consistency with the revised instructions for use, incorporate changes and modify training. • The manufacturer is in the process of incorporating the revised instructions for use into the instructions supplied with the device. Following this action, previous editions of the instructions for use should be disregarded and destroyed. 	▶ ④
<p>Distributed by NIAIC to:</p> <p>Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> <p style="text-align: right;">Hospices</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and 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:

Baxter Clearlink™ needle-free connectors/valves for vascular access. This includes IV administration and extension sets with integral Clearlink™ connector/valve.

When the valve is activated by a device with a male luer fitting, such as a syringe (without a needle) or an administration set, the fluid pathway is opened to allow for the administration of fluids or aspiration of blood for sampling. Upon removal of the IV device, the fluid pathway is sealed.

2. PROBLEM:

The instructions for use have undergone significant changes, in particular the maximum period of use of the device.

3. ACTION BY:

All medical and nursing staff responsible for patients with vascular devices. In particular, infection control teams and specialist IV nurses.

4. ACTION:

Staff should ensure they possess and follow the revised instructions for use provided in the manufacturer's customer letter. The changes should be incorporated into local policies and training provided accordingly.

Staff should pay particular attention to the following aspects of the revised instructions:

- Clearlink™ valve can be used for up to 100 activations and over a period of 96 hours; replace when either limit is reached.
- Prior to swabbing, ensure that the top of the valve is flush with its housing (not recessed). Do not swab the valve if the downstream clamp is closed or the valve is not flush with its housing as ineffective swabbing may result. Replace the valve if it remains recessed.
- Clearlink™ valve is compatible with 70% isopropyl alcohol, 10% povidone iodine and 0.2% chlorhexidine antiseptic solution.
- To minimise reflux during flushing of the valve, if an in-line clamp or external clamp is present on the extension set or catheter, maintain positive pressure on the syringe while applying the clamp, then detach the syringe.

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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Directors of Anaesthetics
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Adult & Paediatric Intensive Care Units
- Adult & Paediatric Oncology units
- Anaesthetists
- Cystic fibrosis Specialist Nurses
- Nutritional nurse specialists
- Pharmacy Managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics, and Nursing Homes through RQIA
- Operating Theatre Staff
- Infection Control Staff
- Accident & Emergency Departments
- Coronary Care
- Resuscitation Officers
- Day Procedure Units
- Pharmacists
- Phlebotomists
- Radiographers
- Specialist IV nurses
- Maternity Wards
- Paediatric Units

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Derek Martin
Quality Systems Manager
Baxter Healthcare Ltd Ireland
Deansgrange Industrial Estate
Blackrock
Co Dublin

Tel: 00353 1 206 5599
Fax: 00353 1 206 5555
Email: derek.martin@baxter.com

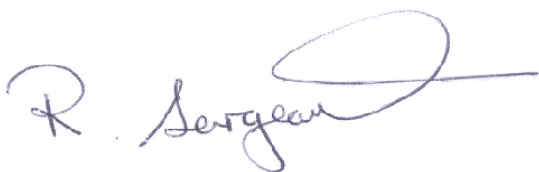
Enquires to NIAIC should quote reference number MDEA(NI)2006/25 and be addressed to:

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:

None required



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

Appendix to MDEA(NI)2006/025

**IMPORTANT
PRODUCT
INFORMATION**

Customer Name & Address

Date

Dear Customer

Clearlink System – Labeling revision

The purpose of this communication is to update you with important information relating to label copy revisions with Baxter's Clearlink needleless device. These stem from isolated reports of alleged increased infection rates from less than 1 % of customers using the Clearlink device, and our desire to provide more information with respect to swabbing and antiseptic choice.

Specific information related to reports of increased infection rates, including patient demographics, therapies, co-morbidities and other key clinical variables has not been provided to Baxter, and while causality has not been established, our preliminary assessment indicates that standard clinical practices, proper aseptic technique and product use instructions may not have been followed, which may have contributed to the reported observations. Through Baxter customer research, it has been noted that the increased use of luer activated devices (LADs) in recent years may be contributing to a relaxation of proper aseptic technique as part of standard clinical practice. As a result, we are revising our product labeling with additional statements that relate to product usage and reinforce standard clinical practices and proper aseptic technique. The revised labeling statements are as follows:

- Grasp finger grip to stabilize Luer activated valve.
- Ensure any downstream clamp (occlusion) is open prior to swabbing.
- **Swab carefully** Luer activated surface with preferred antiseptic prior to **first use and before every subsequent connection** and allow to dry.
- Access Luer activated valve by firmly pushing male Luer of connecting device directly against Luer activated surface and rotate until connection is secure. Engage Luer locking features, if applicable.

- To minimize reflux during **flushing** of Luer activated valve, maintain positive pressure on syringe while clamping. Detach syringe.
- Ensure valve is flush prior to swabbing. Do not swab Luer activated surface when downstream clamp is closed or valve is recessed (not flush with housing). Ineffective swabbing may result. Replace if valve remains recessed.
- **Do not access Luer activated valve with needles or cannula. Attempting such access will render the product damaged, replace immediately.**
- **Use of Luer lock connection is recommended. If Luer slip connection is used, insert into valve using a firm push and twist motion. Do not leave Luer slip unattended.**

- If 10 ml flush cannot be performed after blood infusion/sampling, replace valve immediately.
- Trace lines before connection. Do not connect any compressed gas device to intravenous injection sites.
- Flush Luer activated valve after injection to prevent inadvertent mixing of incompatible medications/fluids.
- Flush Luer activated valve with 10ml or more after blood infusion/sampling. If valve cannot be cleared of blood, replace immediately. Luer lock VACUTAINER holders, syringes and accessories are recommended for blood sampling.
- If blood or fluid residuals remain on valve surface after access, swab surface.
- Replace per institutional protocol. Luer activated valve can be used for up to 100 actuations and over a period of 96 hours; replace whichever comes first.
- Clearlink Luer activated valve is chemically and mechanically compatible with 70% Isopropyl Alcohol, 10% Povidone Iodine and 0.2% Chlorhexidine antiseptic solution.

In order to ensure effective use of the Clearlink needleless device, please communicate the above information to all relevant staff. As with all needleless devices, it is important to communicate that proper aseptic technique and all labeling instructions should be followed.

We want to assure you that Baxter is fully committed to training and supporting our customers in the use of the Clearlink needleless device. In addition to the forthcoming changes in the product labeling, we are developing a Tip-Sheet and Directions for Use Poster. Please contact me at the number below for additional information.

Yours sincerely,

Derek Martin
Quality Systems Manager
Baxter Healthcare Ltd Ireland
Telephone 00 353 1 206559