

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/25

Issued: 16th March 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION	



HEALTH ESTATES

creating healing environments

This alert replaces the guidance issued on 21 December 2006 in MDEA(NI)2006/80.

	Section
<p>Medical Device/Equipment: All QUATTROcare spray cans, manufactured prior to 05 March 2007, for use in KaVo QUATTROcare dental handpiece maintenance systems.</p>	▶ ①
<p>Problem: KaVo Dental Ltd have recalled all their QUATTROcare spray cans due to a risk of fire/explosion. QUATTROcare spray cans may leak flammable gases when attached to the QUATTROcare maintenance system.</p>	▶ ②
<p>Action by: All those involved in cleaning and maintaining dental hand pieces.</p>	▶ ③
<p>Action: 1. Remove the QUATTROcare spray can from the maintenance system immediately. (see page two for further actions)</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 For onward distribution see Section 5</p> <p style="text-align: right;">General Dental Practitioners</p>	▶ ⑤
<p>Contacts Details of supplier contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

All QUATTROcare spray cans manufactured and distributed prior to 05 March 2007 for use in the QUATTROcare dental handpiece maintenance system.

The spray cans are manufactured by Kaltenbach & Voigt GmbH (also known as KaVo) and have been distributed by several companies in the UK

2. PROBLEM:

This alert replaces the guidance issued on 21 December 2006 in MDEA(NI)2006/80. At that time KaVo recalled their QUATTROcare spray cans manufactured prior to 18 November 2006 due to the possibility that when attached to the maintenance system some of the spray cans may leak.

The manufacturer has now extended that recall to include all QUATTROcare spray cans currently on the market (up to and including 05 March 2007). The manufacturer states that there is a residual risk of gas escaping from the can when it is attached to the maintenance system. The gas is a highly flammable mixture of propane, butane and pentane and any local build up of this gas may lead to an explosion if it comes into contact with a source of ignition. So far no reports of explosions have been received but KaVo Dental Ltd is recalling the product as a precautionary measure.

It is important to note that KaVo state that the QUATTROcare spray cans will not leak prior to connection and when disconnected from the maintenance system.

3. ACTION BY:

All those involved in cleaning and maintaining dental hand pieces.

4. ACTION:

Do not leave any QUATTROcare spray cans within the QUATTROcare maintenance system and discontinue use of the system until KaVo manufacture and distribute updated QUATTROcare spray cans.

Partially empty cans may still contain propellant and are therefore classified as dangerous goods. Contrary to the advice in the manufacturer's recall letter, they should not be disposed of as normal waste but sent back to the supplier in the packaging that will be provided with the replacement cans. Empty cans can be disposed of as normal waste.

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:

- Clinical governance leads
- Dental departments
- Dental hospitals
- Dental nurses
- Dentists
- Equipment stores
- Fire safety officers
- Health and safety managers
- Maintenance staff
- Risk managers
- Sterile services departments
- Supplies managers
- Theatre managers
- Community dental practices
- Community hospitals
- Dental managers
- Dental nurses
- Dental practices
- Dental practitioners
- Community dental practices
- Community hospitals
- Dental managers
- Dental nurses
- Dental practices
- Dental practitioners
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

6. CONTACTS:

Enquiries to the supplier should be addressed to:

Kevin Sayer
T & QM Manager
KaVo Dental Limited
Raans Road
Amersham
Buckinghamshire HP6 6JL

Tel: 01494 733 012/0790 0282 629

Fax: 01494 431 168

E-mail: kevin.sayer@kavo.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/25 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

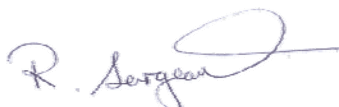
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 21st March 2006
Deadline (action underway)	: 21st March 2006
Deadline (action complete)	: 28th March 2006



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

16 March 2007

URGENT: EXTENDED PRODUCT RECALL for a medical device
Warning: Technical problem with QUATTROcare Spray cans

Dear Sir,

In November 2006, KaVo initiated a recall for all QUATTROcare Spray cans produced prior to 18 November 2006. Unfortunately, we have discovered that the newly-delivered spray cans do not meet the high quality standards set by KaVo. As a residual risk cannot be absolutely excluded, KaVo is extending the recall to include all QUATTROcare Spray cans currently on the market. The QUATTROcare devices themselves are not affected by the recall. As safety and quality are of the utmost importance for KaVo, the delivery of the QUATTROcare spray is being suspended for the time being.

We would, therefore, urgently request you as a user of the KaVo QUATTROcare not to use this device until further notice as there could be a possible residual risk of gas and oil escaping.

KaVo is placing the utmost importance on the development of a safe solution for the QUATTROcare Spray cans. We will inform you as soon as this product improvement is available.

As this development will take some time, for the interim period KaVo is offering 2 cans of KaVo Spray 2112A for manual cleaning as a substitute. These 2 spray cans and reusable spray heads may be requested free of charge through your normal sales outlet.

Please only return any full unused QUATTROcare Spray cans so that we may issue a credit note. Please pack the QUATTROcare Spray cans safely and ensure that the return transport to our address complies with legal provisions.

All empty or partially-empty cans must not be returned; instead these must be disposed of through your normal hazardous waste collector.

Should you have any queries, please contact our Order Processing Department on 01494-733002 or alternatively contact me on the number below.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'KEVIN SAYER', with a long, sweeping horizontal stroke extending to the right.

Kevin Sayer

IT & QM Manager
KaVo Dental Limited

Tel. 01494-733012

Email Kevin.sayer@kavo.com