Patient Safety Alert

Veterans Health Administration Warning System
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AL09-16 March 5, 2009

Item: **Cylinder Valve Explodes from Oxygen Cylinder supplied with Rotarex/Ceodeux Post Type Cylinder Valve**

Specific Incident: A respiratory therapist was changing an oxygen E-cylinder that had a Ceodeux post type cylinder valve manufactured by Rotarex, Inc. After removing the plastic seal on the cylinder, the therapist slightly opened the valve on the cylinder. There was a loud bang and the valve stem was blown out of the top of the cylinder, hitting the ceiling. This incident could have resulted in severe injury or death if the therapist had been leaning directly over the top of the cylinder.

NOTE: This issue can potentially cause serious harm or death to both staff and patients, including patients on home oxygen. It can also cause damage to any objects that could be in the way of a valve ejection (e.g., medical devices, televisions, light fixtures).

General Information: Rotarex Inc. post type valves may be installed on various medical cylinders (oxygen, nitrogen, breathing air, nitrous oxide, carbon dioxide, helium and other gases) of different sizes. Rotarex Inc. issued an Important Product Correction Notification letter on March 9, 1999, and at that time issued retrofit instructions to correct the valve vulnerability (see Attachment 1). The vulnerability is in the design of the retaining collar on the valve stem, which if damaged, could weaken and fail, allowing the valve stem to eject very forcibly under cylinder pressure. The vulnerable valve is limited to Rotarex/Ceodeux post type valves manufactured prior to March 1998. Later valves were redesigned and manufactured to prevent this problem.

Actions: By close of business (COB) March 13, 2009:

1. The Facility Director (or designee) will inform all applicable VA staff, home oxygen patients, and home oxygen suppliers to make them aware of this safety

risk and instruct them to adhere to the following good practices when using high pressure cylinders.

a. Because cylinder valves are subject to mechanical damage from impact, the potential for valve ejection is always a possibility; therefore, users must point the cylinder in a safe direction - away from their body, other's bodies, or objects that could be damaged - when handling cylinders and/or opening the cylinder valve.
b. Because cylinders can become projectiles if knocked over, users must secure cylinders in an upright position in a carrier or to a fixed structure at all times.

2. The Respiratory Therapy Managers (or their designees) and all other service/department mangers (or their designees) that maintain a stock of medical gas cylinders shall inspect all cylinders in their inventories for Rotarex/Ceodeux valves, as shown in Figure 1 on Attachment 2. If any vulnerable valves are found, **do not open or vent these cylinders,** immediately remove them from service, place them in quarantine and label or tag them as "DEFECTIVE." Contact your gas supplier for cylinder return instructions.

3. All staff that receive medical gas cylinders delivered to their facility shall institute inspections of all cylinders for Rotarex/Ceodeux valves, as described in Attachment 2. If any vulnerable valves are found, **do not open or vent these cylinders,** immediately remove them from service, place them in quarantine and label or tag them as "DEFECTIVE." Contact your gas supplier for cylinder return instructions.

4. VISN Contracting Officers shall request their Home Oxygen supplier(s) to inspect their inventory and the inventory in patient's homes, and to replace any cylinders found with the vulnerable valve.

5. By close of business (COB) March 13, 2009, the Patient Safety Manager shall assure that this Alert has been addressed and the action status updated on the VA's Hazardous Recalls/Alerts website, http://vaww.nbc.med.va.gov/visn/recalls/index.cfm.

Addl. Information: This issue was the subject of Class II FDA Recall in May 1998 (see Attachment 3). It is recommended that cylinder valves that pass the inspection have a small white label affixed with the date of inspection.

Source: VA Medical Center

Attachments: (1) Rotarex Inc. North America Important Product Correction Notification Letter, March 9, 1999, to Rotarex/Ceodeux valve customers

(2) Inspection procedures for identifying vulnerable Rotarex/Ceodeux, Inc. medical gas cylinder valves

(3) Excerpt from FDA Enforcement Report, May 27, 1998: Recall of Ceodeux, Inc. Post Type Cylinder Valves for medical gas cylinders. Recall # D-134-8

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ATTACHMENT 1

Rotarex Inc. North America Important Product Correction Notification Letter, March 9, 1999, to Rotarex/Ceodeux valve customers

ROTAREX, INC.
NORTH AMERICA

IMPORTANT
PRODUCT CORRECTION NOTIFICATION LETTER

March 9, 1999

Dear Rotarex/Ceodeux Valve Customer:

As most of you are aware, Rotarex/Ceodeux has initiated a voluntary retrofit program to replace the upper spindle of our Post Type Cylinder Valve for Medical Gases with an improved design. This retrofit program was implemented following reports in a very small number of cases that the valve spindle ejected from the valve housing during a cylinder filling operations. Our investigation revealed that these instances occurred as a result of extraordinary impact or force on the spindle during transport or handling. As manufactured and tested, these valves still exceed the requirements of CGA V9 and CGA S1.1.

While we have received no reports of personal injury or damage during normal use, to avoid the potential for an accident, all customers and users of these valves are instructed to initiate a program to locate these valves and replace the bonnet/spindle assembly. If you are a distributor who has resold these units to other customers or end users, we request that you send a copy of this letter to your customers instructing them to locate and replace the bonnet/spindle assembly of these valves

This retrofit is easily performed. Upon locating the valve, the old valve stem should be unscrewed and the replacement valve stem should be screwed into the valve body (See the attached retrofit instructions for specific directions regarding the identification of valves and replacement procedures.) In order to obtain a supply of improved valve stems for retrofitting please call Rotarex at 1-800-325-5721. Rotarex will send you replacement valve stems within 48 hours of your call.

Rotarex/Ceodeux believes that this voluntary program will assure the industry of our commitment to public safety as well as to providing products of unmatched quality.

Sincerely,

Bert Pistor
Vice President
Rotarex Inc. North America

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ROTAREX Group
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Customer Service Westmoreland Technology Park ☎: *724-696-3345
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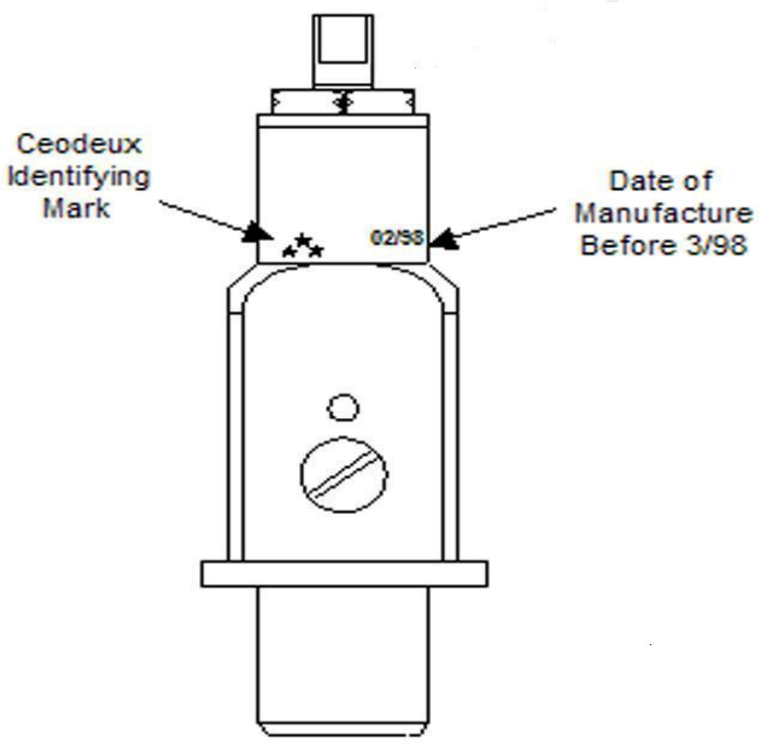
ATTACHMENT 2

Inspection procedures for identifying vulnerable Rotarex/Ceodeux,, Inc. medical gas cylinder valves

The vulnerable valve is limited to **Rotarex/Ceodeux, Inc. post type cylinder valves manufactured prior to March of 1998**, and thus does not apply to newer style valves or other valve manufacturers. Vulnerable valves are those that have the name Ceodeux (or three stars) and are date-stamped prior to **March 1998.** Please refer to Figure 1:

Figure 1



Ceodeux Post Valves
Made before March 1998

ATTACHMENT 3

Excerpt from FDA Enforcement Report, May 27, 1998: Recall of Rotarex/Ceodeux, Inc. Post Type Cylinder Valves for medical gas cylinders. Recall # D-134-8

The FDA Enforcement Report is published weekly by the Food and Drug Administration, U.S. Public Health Service, Department of Health and Human Services. It contains information on actions taken in connection with agency regulatory activities.

May 27, 1998 98-21

RECALLS AND FIELD CORRECTIONS: DRUGS -- CLASS II =========

PRODUCT	Post Type Cylinder Valves, for medical gas cylinders. Recall #D-134-8.
CODE	All lot codes.
MANUFACTURER	Ceodeux, Inc., Ultrapure Equipment Technology S.A., Lintgen/Luxembourg.
RECALLED BY	Rotarex, Inc., North America, Mt. Pleasant, Pennsylvania, by letter dated March 25, 1998. Firm-initiated field correction ongoing.
DISTRIBUTION	Massachusetts, Georgia, California, Pennsylvania, Maryland, North Carolina, Kansas, Canada.
QUANTITY	Approximately 125,000 units were manufactured and of that approximately 43,750 remained on market at time of recall initiation.
REASON	High velocity valve stem ejection.

Source: http://www.fda.gov/bbs/topics/ENFORCE/ENF00539.html