



IMPORTANT SAFETY NOTICE REGARDING MEDICAL OXYGEN CYLINDERS

January 26, 2007

Dear Customer:

One of our home health agency customers has reported oxygen content loss with Catalina aluminum cylinders equipped with a certain single o-ring valve manufactured by Young-Do Industries Co., Ltd. Although the possible problem might be identified by testing and addressed in most circumstances without any implications for patient health, **there are rare situations in which content loss could pose a serious risk to patients.** For that reason, Catalina is notifying each of its customers that have purchased Catalina cylinders equipped with this particular valve, to urge you to:

- Identify patients who have kept cylinders for “back up” use;
- Test those cylinders for possible loss of contents; and
- Take appropriate corrective action, as outlined below.

As you may know, under FDA regulatory requirements, tests conducted during cylinder filling or refilling should ordinarily detect any leaks before cylinders are provided to patients. Because of these regulatory standards and the routine checks and maintenance performed throughout the industry, leaks – which are bound to occur in some number of cylinders and valves over time – are almost always prevented or detected before there is any risk to patients. It is possible, however, that cylinders kept by patients in their homes as “back up” to their primary oxygen supply might go an extended period of time without being used or checked, which means a leak might go undetected. In such a circumstance, it is possible that the cylinder would experience loss of content. Although we have received no reports of any patient injury, this could pose a risk to patients who turn to their “back up” supply and have no oxygen.

What products are at issue?

The products that are the subject of this notice are Catalina aluminum cylinders that were fitted with Young-Do CGA 870 post valves (single o-ring design). Catalina purchased and installed these valves between February 1999 and March 2003. As the attached diagram shows, the valves can be identified by the Young-Do logo and a lot number beginning with the numbers 99, 00, 01, or 02 (for year of manufacture). The Catalina cylinders are marked either “M4002 . . . CATALINA” or “CLIFFDIV,” each followed by a serial number, and have a warning label with the Catalina logo attached to the side of the cylinder.

In addition, other companies may have independently purchased and installed these same valves on Catalina cylinders, and medical gas manufacturers or fillers may have installed single o-ring Young-Do valves on Catalina cylinders during the course of periodic hydrostatic

SPECIALIST IN HIGH PRESSURE ALUMINUM GAS CYLINDERS

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testing, routine maintenance, and valve repair. Because those actions are independent of Catalina, we cannot know what lot numbers of those valves might be implicated.

What steps need to be taken?

- Home health agencies should ask each of their customers if they have any oxygen cylinders that have been kept for “back up” and not used for an extended period of time.
- If the customer has a “back up” cylinder, the home health agency should check to see whether it is a Catalina cylinder with a Young-Do CGA 870 post valve (single o-ring design).
- If it is, the home health agency should check the cylinder for loss of content.
- If there is loss of content, the home health agency or filler should investigate the possible causes. They may include a damaged or worn o-ring, improper torque of the valve in the cylinder, an issue with the operation of the valve, or damage to the cylinder gland (where the o-ring sits). In many instances, a simple repair or replacement of the o-ring will adequately address the problem. In some circumstances, however, it may be necessary to replace the valve. All maintenance should be conducted by qualified personnel to current industry standards. The single o-ring valve relies on one o-ring for seal integrity, and care should therefore be taken during o-ring replacement to avoid damage during installation.

Where is there additional information?

If you have questions, please contact Catalina’s Quality Department by phone at 714-890-0999, or by fax at 714-890-1744.

We have received no reports of patient injury. If anyone becomes aware of a serious adverse event associated with any oxygen cylinder, they should be encouraged to submit a report to FDA’s MedWatch Adverse Event Reporting program. Information on how to do this is available at www.fda.gov/medwatch or by calling 1-800-FDA-1088.

Sincerely,

Thomas R. Newell
Vice President and General Manager

Attachment

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This notice regards Young-Do CGA 870 straight threaded post valves single o-ring design. As shown in the diagram below, these valves have the Young-Do logo



engraved on the valve, along with the manufactured year of 99, 00, 01 or 02 as the first two digits of the lot number. The valves can be in the wrench, toggle or hand wheel configuration.

