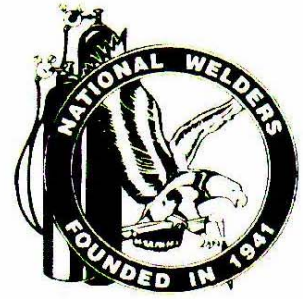




P.O. Box 31007
Charlotte, NC 28231-6098
Phone 704/333-5475
Fax 704/393-5412



TO: Medical Oxygen B, C, D, E, CGA 870 cylinder users

**RE: FDA AND NIOSH PUBLIC HEALTH NOTIFICATION: OXYGEN
REGULATOR FIRES RESULTING FROM INCORRECT USE OF CGA 870
SEALS**

GREETINGS:

We have had a number of inquiries from our health care customers concerning subject and anticipate that others may have similar concerns or questions. The disposable single-use nylon washers on all of our B, C, D, AND E, Medical Oxygen cylinders are provided strictly as a convenience item and are safe when used as intended. However, if a washer is not needed (because the regulator is equipped with a reusable sealing washer in good condition) then it should be discarded. So, we recommend that medical providers should be instructed and trained to:

1. Only use the provided nylon washer if needed.
2. **Never** use a nylon crush washer more than once.
3. **Never** use a sealing washer in conjunction with another washer, whether single-use type or reusable (i.e., **never** "double washer" your regulator).

Background: Why do we provide the nylon crush washers at all?

This program got started a number of years ago when regulator manufacturers did not provide sealing washers in the CGA 870 yoke at all. Now, it is standard practice that all U.S. manufacturers of the B, C, D, and E, CGA 870 yoke type regulators are including either a reusable or disposable washer on the CGA 870 yoke. Since some regulator suppliers still do not include the reusable washer with the regulator and, in other cases, the reusable seal may be damaged and a replacement is not immediately available, we will continue to provide a nylon washer to ensure proper sealing and safe use of the Medical Oxygen. Because we can't know in every case what type regulator is being used or its condition, the nylon, single-use washer is provided for our customers' safety and convenience. It remains the customer's responsibility to determine the need for the washer at the point of use.

This notification and action is in response to the FDA/NIOSH PUBLIC HEALTH NOTIFICATION, Dated 24, 2006 regarding the fire safety issue, in which fires have occurred when two (2) washers were installed on an oxygen cylinder with a CGA 870 Yoke. We strongly recommend that you follow the safety precautions and recommendations listed in the following attachments.

Unfortunately, this is NOT A NEW PROBLEM, Please note attached MDSR, of November, 1990,

If you have any questions, or if you need a supply of the Re-Usable seals, your National Welders sales representative will be happy to assist you.

NOTE: The introduction and use of the integrated regulator/valve/flow-gauge (Walk O2 Bout) E Oxygen cylinders should minimize the impact of this bulletin, as the CGA 870 seals are not used. Contact your National Welders sales representative for more information about the Walk O2 Bout.

ATTACHMENTS:

(A) **FDA AND NIOSH Public Health Notification: Oxygen Regulator Fires Resulting from Incorrect Use of CGA 870 Seals**(B) **Oxygen Regulator Fire Caused by Use of Two Yoke Washers**

(B) Hazard [Health Devices Nov 1990;19(11):426-7]



FDA AND NIOSH Public Health Notification: Oxygen Regulator Fires Resulting from Incorrect Use of CGA 870 Seals

(You are encouraged to copy and distribute this information)

Issued: April 24, 2006

Dear Colleagues:

This is to alert you to the danger of fires at the interface of oxygen regulators and cylinder valves because of incorrect use of CGA 870 seals, and to point out an important precaution you can take to avoid such fires.

Background

FDA has received 12 reports in which regulators used with oxygen cylinders have burned or exploded, in some cases injuring personnel. Some of the incidents occurred during emergency medical use or during routine equipment checks. FDA and NIOSH believe that improper use of gaskets/washers in these regulators was a major factor in both the ignition and severity of the fires, although there are likely other contributing factors.

Two types of washers, referred to as CGA 870 seals, are commonly used to create the seal at the cylinder valve / regulator interface: The type required by many regulator manufacturers is a metal-bound elastomeric **sealing washer** that is designed for multiple use applications. The other common type, often supplied free-of-charge with refilled oxygen cylinders, is a plastic (usually Nylon ®) **crush gasket** suitable for single use applications.

The nylon crush gaskets require higher torque than the elastomeric sealing washers in order to seal the cylinder valve / regulator interface, and if they are used again, they require more torque with each successive use. The cylinder valve / regulator connection is designed to be hand-tightened. If the crush gaskets are re-used, the need for increased torque may require using a wrench or other hand tool, which can deform the crush gasket and damage the cylinder valve and regulator. This can result in leakage of oxygen past the cylinder valve seat and across the nylon crush gasket. According to a forensic analysis supported by FDA and NIOSH, “flow friction” caused by this leakage of compressed oxygen across the surface of the crush gasket may produce enough thermal energy to spontaneously ignite the nylon gasket material.

Recommendations

FDA and NIOSH recommend that plastic crush gaskets never be reused, as they may require additional torque to obtain the necessary seal with each subsequent use. This can deform the gasket, increasing the likelihood that oxygen will leak around the seal and ignite.

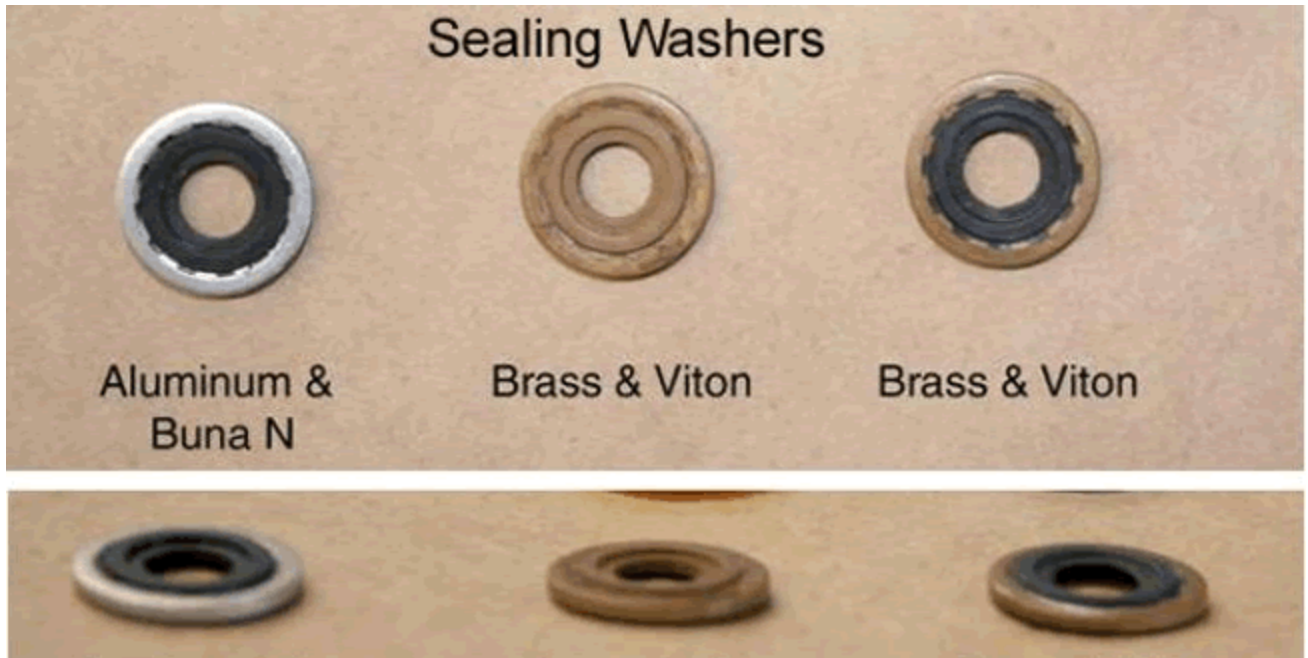
The following general safety precautions should also be taken to avoid explosions, tank ruptures and fires from oxygen regulators.

- Always “crack” cylinder valves (open the valve just enough to allow gas to escape for a very short time) before attaching regulators in order to expel foreign matter from the outlet port of the valve.
- Always follow the regulator manufacturer’s instructions for attaching the regulator to an oxygen cylinder.
- Always use the sealing gasket specified by the regulator manufacturer.

- Always inspect the regulator and CGA 870 seal before attaching it to the valve to insure that the regulator and seal are in good condition and the regulator is equipped with only one integral metal and rubber seal that is in good condition. Avoid plastic seals.
- Tighten the T-handle firmly by hand, but do not use wrenches or other hand tools that may over-torque the handle.
- Open the post valve slowly, while maintaining a grip on the valve wrench so that it can be closed quickly if gas escapes at the juncture of the regulator and valve.



Figure 1 : Examples of crush gaskets available for CGA 870 type medical post valves



.Figure 2: Examples of some sealing washers available for CGA 870 Style medical post valves.

Reporting to FDA

To report your experience regarding the devices in this Notification, please use MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at <http://www.fda.gov/medwatch/report.htm>.

Getting More Information

If you have questions about this notification, please contact the April Stubbs-Smith, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, by Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voicemail message at 301-594-0650 and we will return your call as soon as possible.

FDA medical device Public Health Notifications are available on the Internet at <http://www.fda.gov/cdrh/safety.html>. You can also be notified through email on the day the safety notification is released by subscribing to our list server. To subscribe, visit: <http://list.nih.gov/archives/dev-alert.html>.

Sincerely yours,

Daniel Schultz, MD

Director
Center for Devices and Radiological
Health
Food and Drug Administration

Nancy Stout, Ed. D

Director, Division of Safety Research
CDC, NIOSH

Updated April 25, 2006

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Center for Devices and Radiological Health / CDRH

Oxygen Regulator Fire Caused by Use of Two Yoke Washers

Hazard [Health Devices Nov 1990;19(11):426-7]

Problem

An ECRI investigation of a fire that occurred between an oxygen regulator and an E-cylinder valve revealed that the fire resulted from the use of two washers between the regulator body and the E-cylinder yoke. In this incident, a specific model oxygen regulator, which had a durable washer, had been placed on a new E-cylinder without first removing the cylinder's disposable washer. The use of two washers allowed an oxygen leak on the high-pressure side of the regulator, which, in the presence of minor hydrocarbon contamination, resulted in a flash fire between the regulator and the cylinder valve.

Discussion

Most new oxygen regulators are supplied with a plastic or nylon yoke washer that may develop leaks with repeated use. Hospitals tend to remove these washers and use the disposable yoke washer that is commonly supplied with a new oxygen cylinder. However, this model regulator is supplied with a replaceable, durable, partially metallic yoke washer that is less susceptible to developing leaks. Users familiar with nylon washers may not be aware that this regulator has a more durable washer, especially since this regulator is most commonly used in the prehospital environment. In addition, the manufacturer's operating instructions and labeling do not inform users of the washer's new design and use in its regulator. At least one other regulator manufacturer, of those known to ECRI, also markets regulators with durable yoke washers.

Action

With the new design, it is *essential* that any washer present on an oxygen cylinder yoke be removed before installing the oxygen regulator. **Only one washer of any type should be used at any time.** We encourage all manufacturers of oxygen cylinder regulators equipped with durable yoke washers to label their regulators with instructions to remove the yoke washer on the cylinder before installing the regulator. In the interim, we urge users to follow the recommendations below.

Recommendations

1. Determine whether your oxygen regulators are equipped with a durable yoke washer. If so, affix a label or tag stating: **This regulator is equipped with a durable yoke washer. Remove any washers from the oxygen tank cylinder before installing the regulator.**
2. Ensure that all respiratory therapy, nursing (including nurses aides), emergency medicine, and anesthesia personnel are made aware of this report.
3. If you are uncertain whether your oxygen regulators are equipped with a durable washer, contact the regulator supplier.

UMDNS Terms

- Regulators, High-Pressure Gas [13-323]
- Medical Gas Cylinders [16-501]

Cause of Device-Related Incident

Device factor: Design/labeling error

User error: Device misassembly

External factor: Medical gas and vacuum supplies

Mechanism of Injury or Death

Fire