Medical Device Incident Investigations: Recommendations

Safety Alert: Oxygen regulator fires resulting from incorrect use of CGA 870 seals

The US Food and Drug Administration (FDA) and the National Institute for Occupational Safety and Health (NIOSH) have issued a Public Health Notification: "*Oxygen Regulator Fires Resulting from Incorrect Use of CGA 870 Seals - Updated: June 19, 2006*" concerning the incorrect re-use of single-use plastic seals between oxygen cylinders and regulators.

The FDA and NIOSH have notified healthcare professionals that twelve (12) incidents have been reported 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. The 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 recommended by many regulator manufacturers is a metal-bound elastomeric sealing washer that is designed for multiple use applications.

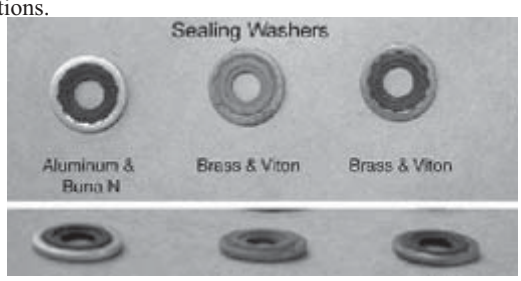

Figure 1. *Examples of some recommended sealing washers available for CGA 870 style medical post valves designed for multiple uses*

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.

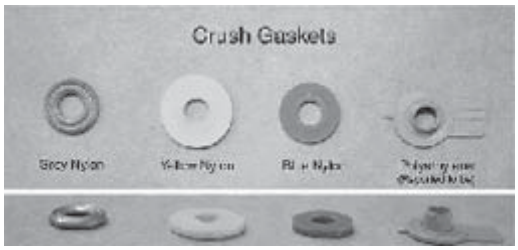

Figure 2. *Examples of crush gaskets available for CGA 870 type medical post valves which should NOT be re-used.*

When used more than once, 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 the 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

The 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 ensure that the regulator is equipped with only one clean, sealing-type washer (reusable metal-bound rubber seal) or a new crush-type gasket (single use, not reusable, typically Nylon®) that is in good condition.
- Always be certain the valve, regulator and gasket are free from oil or grease. Oil or grease contamination is widely known to contribute to ignition in oxygen systems.
- 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. If gas escapes at the juncture of the regulator and valve, quickly close the valve. Verify the regulator is properly attached and the gasket is properly placed and in good condition. If you have any questions or concerns contact your supplier.

Further information

Please contact your normal gas supplier for further information and supply of the recommended re-usable sealing washers for Oxygen cylinders. For further information about the FDA/NIOSH article, please contact Pamela Carter, IRIS Coordinator 02 6232 8713.

Safety Alert: Warm restart due to possible electromagnetic interference by data network cables on Drager Evita ventilators

The TGA has received several adverse event reports from one hospital site (concerning 4 different Evita XL ventilators) where the ventilators shut down while ventilating a patient. The initial episode resulted in blanking out of the screen. As the clinicians watched the screen come back on, they noticed that the ventilator was not ventilating the patient and replaced the ventilator.

Analysis of the Evita logbook indicated an error code that showed the software could not retrigger a watchdog and therefore carried out a warm restart. This warm restart is used to set all software tasks to zero and maintain the ventilation after an 8 second interruption period. The manufacturer's analysis detailed that the devices still continued the ventilation with the set parameter after this 8 second interruption and generated an MV low alarm.

Further investigation discovered that when the incidents occurred, all complaint ventilators were connected to the patient's monitors via copper cables. The manufacturer's root cause was that the hospital's data network caused electromagnetic interference (EMI) on the interface line to the Evita and caused the ventilator to restart. The manufacturer claimed that there have been similar incidents reported worldwide.

The manufacturer has developed an optical link interface and instructions for connecting Evita ventilators to a data network to fix this EMI-related problem. The manufacturer claimed that this optical cable had been installed in other hospitals with the same EMI-related problems and that the feedback was positive.

The TGA believes that this EMI problem may lead to serious adverse events if users of the device are not alerted to the problem. In response to the TGA's request, the manufacturer distributed a letter titled 'Device Alert' to its customers with information about the optical link interface.

Recommended actions

If you would like more information about having your Evita Anaesthetic machine connected to network systems via an optical cable, please contact Technical Support Specialist—Ventilation, at Draeger Medical Australia on 1800 800 327 or email med@draeger.com. The affected ventilator models are Evita 2 Dura, Evita 4 and Evita XL.

Safety Alert: Anaesthetic machine caught fire during cleaning procedure after use

The TGA received an incident report about an anaesthetic machine that caught fire during cleaning after use.

After this incident, the device was extensively examined by the manufacturer, an independent biomedical engineer and a forensic electrical fire investigator. A substantial amount of an unknown liquid had been found inside the interior of the machine. Further investigation discovered that the liquid ingress through the loose top lid had worked its way down on to the high voltage lead connection and was considered a strong possibility for ignition of machine components at room temperature. This unknown liquid was not water and was perhaps a solvent or anaesthetic agent.

Furthermore, the manufacturer revealed that the users were using a damp cloth soaked in Jaysol to clean these machines. The machine was also plugged in and connected at the time of the cleaning, which possibly

contributed to it catching fire. The manufacturer stated that the cleaning method used was contrary to the manufacturer's cleaning instruction '*no solvents should be used to clean the external or plastic surfaces of the machine, and the machine should be disconnected from the AC lines before being cleaned*'.

After this incident, the manufacturer drafted a service advisory bulletin note and intended to send it to all registered service organisations to advise them of the need for the correct installation and tightness of the top plate of the machine to eliminate the possibility of fluid ingress from spills on the top shelf. As a result of this incident and subsequent investigation, the manufacturer has decided to distribute a current copy of the cleaning instructions with a covering letter to all customers known to have this machine.

The TGA thinks that the looseness of the top lid that allowed the suspected solvent or anaesthetic agent ingress into the interior of the machine was a major contributor to the ignition of the fire, but failure to follow the manufacturer's cleaning instructions also directly contributed to the ignition of the fire.

Recommended actions

Please bring this Safety Alert to the attention of all anaesthetic technicians and operating theatre nurses.

Please refer to the manufacturer's cleaning instructions for your anaesthetic machine. Failure to follow these instructions may result in damage to the machine, electrocution, fire, and even threat to patient's and clinician's life.

Please refer to the Operator's Manual that is provided with each device for a complete list of all warnings and precautions associated with use of these devices.

MRI burns and other injuries—continuing to occur

Recently, a patient received a burn to the torso while being scanned in a Magnetic Resonance Imaging (MRI) machine. In this particular report, the patient received a burn when their side touched the side of the machine's magnetic bore.

Since MRI machines were introduced in the 1980s there have been numerous reports of patient injury from a wide variety of causes including:

- Injury from flying projectiles pulled toward the magnet bore.
- Metallic implants being moved by the magnetic fields.
- External devices affected by radiation from the MRI machine.
- Image artefacts caused by outside signals affecting diagnosis.
- Burns from looped leads; iron oxide heating in tattoos or tattooed eyeliner; ECG or pulse oximeter leads conducting currents; and patients contacting the bore of the magnet.

Burns are generally caused by patient contact with an electrically conductive cable, but sometimes they can occur when the tissue of the patient forms an electrically conductive loop, especially when there is a high-resistance point of contact that completes the loop. A concentrated electrical current or spark can cause tissue damage at the point of contact. The injury resembles burns from other causes. In addition, the use of very high settings on extremities has been known to cause ignition of special cuffs and sleeves.

In rare cases tattoos or tattooed eye liner containing iron oxide pigment has caused minor burns. Patients have also received burns when a limb or other part of the body touched the bore of the magnet. The risk of injury is especially high with unconscious or anaesthetised patients because they cannot report any discomfort.

Recommendation

Burns from MRI machines can be prevented by ensuring that no electrically conductive loops are formed by cables or by parts of the patient. Limbs should be separated from the body by insulated pillows or foam pads.

Ensure that the patient is not wearing any metal objects, wires that may either move or become hot through induction. Some medical devices are incompatible with MRI. This may not be immediately obvious. For example, the tips of some nasogastric tubes are weighted down by a metal insert. Therefore a thorough check of the patient's history is important.

Contaminated loan equipment

The TGA continues to receive reports about loan equipment being sent to hospitals which has not been properly cleaned and packaged for transport.

Several reports relate to instruments, particularly those with cannulas, that have bone, blood or tissue remaining from previous procedure(s). The hospitals reporting these incidents have followed the correct protocol of checking, cleaning and sterilising instruments sent to them either from other hospitals or the suppliers. The hospitals have found that some instruments have not been cleaned at all or only partially cleaned. Some instruments have not been able to be used due to this contamination, or have been damaged as a result of the lack of cleaning or the way the instrument has been packaged.

Reports have also been received about damaged instruments being sent to hospitals. The damage may have been caused during the previous procedure or during transportation. It appears from the evidence provided to the TGA that some instruments are placed back into trays in a haphazard manner. Some of the damaged instruments have been sent without the receiving hospital or the supplier knowing beforehand about the damage. This means that delays may result while other instruments are located.

Recommendation

- Ensure that all instruments in loan sets are properly cleaned and repackaged into their trays.
- Protect instruments during transport so that they cannot be damaged from being moved around.
- Notify the supplier and the receiving hospital if there are any damaged instruments so that replacements can be sourced quickly.

MEDICAL DEVICE INCIDENT REPORT INVESTIGATION SCHEME (IRIS) STATISTICS REPORT 01/01/2006 to 30/06/2006

Total Number Received: 373

Cause of Problem[1]	
Biocompatibility	10
Component Failure	59
Contamination	4
Design	23
Diagnostic Inaccuracy	7
Electrical	1
Inadequate Instructions	12
Labelling	7
Maintenance	14
Manufacture	21
Material/Formulation Deficiency	20
Mechanical	14
Not Applicable - ADR[2]	8
Not Device Related	59
Other	42
Packaging/Sterility	2
Quality Assurance	13
Unknown	88
Wear/Deterioration	12

Effect	
Death	22
Serious Injury	152
Temporary Injury	95
No Injury	67

Source Category	
Medical Administrator	17
Specialist	15
Coroner	9
Nurse	25
Blood Bank	12
Hospital Supply Service	25
Other	35
Sponsor	177
Overseas Advice	32
Biomed Engineer	13
Para Medical	2
Dentist	2

Result of Investigation	
Bulletin Article	6
Company Warned	9
Compliance Testing	10
No Further Action	85
Not Investigated[3]	134
Other	14
Problem Not Confirmed	45
Product Improvement	22
Recall/Hazard Alert	21
Refer to GMP	6
Safety Alert	16
User Education	31

Notes:

1. The problem causes are not mutually exclusive. For example, a material deficiency may have led to a mechanical malfunction or a biocompatibility problem.
2. ADR stands for Australian Device Regulatory [Action]. These devices are not on the Australian Register of Therapeutic Goods (ARTG) and companies are notified and/or warned that they must place the device on the ARTG prior to further supply.
3. Every report received by IRIS receives a risk analysis by the Scheme Coordinator and is discussed by a panel of technical and clinical professionals. In the case of reports that are "Not Investigated" the panel has made a decision that further investigation of the particular event is not necessary at that time. However, these reports are logged into the database for future reference and the trend of reports is monitored. In making their decision, the panel considers whether any similar reports have been received previously.