

URGENT MEDICAL DEVICE RECALL -- July 21, 2010 INOMAX® DS Drug-Delivery System

Dear Healthcare Professional:

We have identified a risk associated with the potential failure of the pressure switch in the INOMAX® DS drug-delivery system which may have an impact on the administration of INOMAX® (nitric oxide) for inhalation to patients.

What is the issue?

Specifically, a component within the pressure switch, which monitors for loss of drug supply, may tear, causing INOMAX to leak from the rear of the system. As a result, the INOMAX cylinder empties more quickly than normal. An interruption or delay in the administration of INOMAX therapy may cause:

- worsening of systemic oxygenation indices (i.e., hypoxemia, especially manifested as decreased arterial oxygenation saturation);
- hypotension; and/or
- increase in pulmonary arterial pressure.

What should I look for?

If a pressure switch tears, you may hear a hissing sound, **however, the flow of INOMAX to the patient is not immediately interrupted**. The system alarm for Low NO/N₂ pressure remains functional and will alert the clinician should the cylinder pressure reach a critically low level, indicating the need to replace the cylinder. As long as the pressure remains above 23 psi, the INOMAX DS should operate normally, although the INOMAX cylinder will deplete more rapidly.

What should I do?

If a leak is suspected, follow these immediate actions:

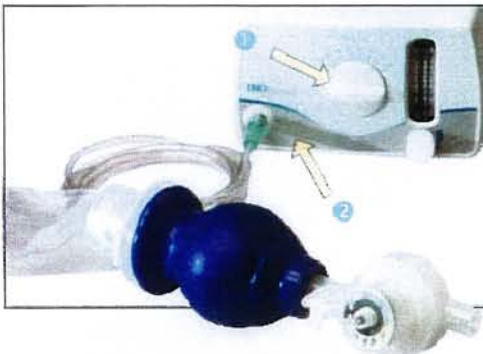
1. **Do not interrupt the delivery of INOMAX**
2. Verify an adequate amount of INOMAX remains in the cylinder
3. Switch to the manual back-up system using the INOblender® by connecting the INOMAX Inlet Hose of the INOblender directly to the INOMAX regulator, and follow the standard procedure for use of the INOblender as the primary back-up method for manual ventilation. See Figure 1

Figure 1: Page 13, Item 2, INOblender Operation Manual



Note: Check the INOblender and connection hoses for signs of wear or damage, replace as needed. Ensure white plastic tip is in place on the regulator connector and not chipped or cracked. Remove and replace as necessary. (See page 23)

1. Connect the INOmax regulator to the cylinder.
2. Connect the INOmax regulator hose to the INOblender inlet hose using the quick connect fittings.
3. Connect the oxygen supply to the O₂ inlet fitting. Note: 50 psig (nominal)



1. Make sure the INOmax dose setting dial is turned to zero.
2. Attach a manual resuscitation bag to the INOblender outlet fitting.

4. Contact Ikaria Customer Care at 1-877-KNOW-INO (1-877-566-9466) for assistance.

Additionally, Ikaria recommends the following:

- Maintain a full back-up cylinder on each INOMAX DS cart. If your institution does not have adequate back-up cylinders, additional cylinders will be provided to you.
- Depressurize the INOMAX regulator when not in use, per the INOMAX DS Operation Manual (page 21).
- Ensure all operators of the INOMAX DS drug-delivery system are aware of this situation.

Ikaria plans to replace all INOMAX DS drug-delivery systems with remediated INOMAX DS systems, and will leave notification with your institution that the impacted system(s) has/have been replaced. This recall is being conducted with the knowledge of the U.S. Food & Drug Administration (FDA). This issue does not apply to the INOvent® drug-delivery system.

We ask that you report any adverse events, or direct any questions you may have about this letter, to Ikaria Customer Care at 1-877-KNOW-INO (1-877-566-9466) 24 hours a day, 7 days a week. Adverse events also should be reported to the FDA's MedWatch Program at www.fda.gov/medwatch, by telephone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, or by mail at MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

Sincerely,

Geoffrey Nichol, M.B., Ch.B.
Chief Medical Officer
Ikaria



IKARIA® RECALLS INOMAX® DS DRUG-DELIVERY SYSTEM

Clinton, NJ, August 9, 2010 – Ikaria, Inc. announced today that its INOMAX® DS drug-delivery systems in the United States are being voluntarily recalled due to the potential failure of a pressure switch which may have an impact on the administration of INOMAX® (nitric oxide) for inhalation to patients. This potential failure was identified by Ikaria as part of its ongoing quality monitoring and review processes. This class I recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA). All INOMAX DS systems in Canada also are being voluntarily recalled.

Specifically, a component within the pressure switch, which monitors for when the drug supply should be replaced, may tear. In the event of a tear, the flow of INOMAX to the patient is not immediately interrupted. While the patient is not immediately impacted by the pressure leak, subsequent risks to the patient may include interruption of drug flow due to an empty cylinder, and/or the time taken to switch to a replacement system. An interruption or delay in the administration of INOMAX therapy may cause:

- worsening of systemic oxygenation indices (i.e., hypoxemia, especially manifested as decreased arterial oxygenation saturation);
- hypotension; and/or
- increase in pulmonary arterial pressure.

If a leak is suspected, clinicians should: 1) not interrupt the delivery of INOMAX; 2) verify an adequate amount of INOMAX remains in the cylinder; 3) switch to the manual back-up system using the INOblender® by connecting the INOMAX Inlet Hose of the INOblender directly to the INOMAX regulator, and follow the standard procedure for use of the INOblender as the primary back-up method for manual ventilation, and; 4) contact Ikaria Customer Care at 1-877-KNOW-INO (1-877-566-9466) for assistance. Although the risk of INOMAX exposure to pregnant women is unknown, it is advised that healthcare professionals who may be pregnant avoid the immediate area in which a leak is suspected.

Ikaria has already begun the replacement process of all INOMAX DS drug-delivery systems with remediated INOMAX DS systems. This recall does not apply to the INOvent® drug-delivery system.

Ikaria sent recall notices to healthcare professionals on July 21, 2010 informing them of this action and identifying steps that are intended to reduce the potential risks associated with a system failure. These notices contain more detailed information about the device usage and are available at www.inomax.com or www.ikaria.com. Customers with questions regarding this notice may contact Ikaria Customer Care at 1-877-KNOW-INO (1-877-566-9466) for assistance. Adverse reactions associated with the use of these products may also be reported to the FDA's MedWatch Program by fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

"Ikaria is committed to ensuring the safe and effective delivery of INOMAX to NICUs and patients who require the drug," said Daniel Tassé, Chairman and CEO of Ikaria, "and we are working very closely with our customers to complete a timely and orderly replacement of the affected INOMAX DS systems."

About Ikaria, Inc.

Ikaria, Inc. is a biotherapeutics company focused on developing and commercializing innovative therapeutics and interventions designed to address the significant unmet needs of critically ill patients. The company's lead product is INOtherapy®, an all-inclusive offering of drug product, services and technologies. INOMAX® (nitric oxide) for inhalation, the drug included in the INOtherapy offering, is the only FDA-approved drug for the treatment of hypoxic respiratory failure associated with pulmonary hypertension in term and near-term infants. INOtherapy also is marketed in Puerto Rico, Canada, Australia, Mexico and Japan. Ikaria acquired the North American and Australian rights to LUCASSIN® (terlipressin), a potential treatment for hepatorenal syndrome Type 1, as well as the exclusive worldwide license to IK-5001, a potential treatment for preventing cardiac remodeling and subsequent congestive heart failure following acute myocardial infarction. The company also has a number of investigational compounds in development. Ikaria is headquartered in Clinton, NJ, with research facilities in Seattle, WA and Madison, WI, and a manufacturing facility in Port Allen, LA. Please visit www.ikaria.com.

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