



RECALL

CUSTOMER PRODUCT REMEDIATION NOTICE

FRETTING CORROSION ISSUE

NO CUSTOMER ACTION NECESSARY – REMEDIATION COMPLETED

INOMAX® DS (Delivery System)
Nitric Oxide Administrative Apparatus
Nitric Oxide Administrative Apparatus, Back-up System
Nitric Oxide Analyzer
Nitrogen Dioxide Analyzer

Model Number: 10003

December 22, 2011

Dear Valued Customer:

This letter is to inform you of a recall action that has been completed for the INOMAX® DS drug-delivery system regarding a fretting corrosion issue. There is no action necessary as the remediation has been completed. This correspondence is an effort to keep our customers informed regarding this issue.

In an investigation conducted by Ikaria in April 2010, it was determined that fretting corrosion (micro-movement at the electrical contact interface of non-noble metals, such as tin) was the root cause for erratic nitric oxide (“NO”) monitoring reported when the INOMAX DS was used for NO delivery to patients. Following the investigation, Ikaria implemented a service process change involving the application of DeoxIT®, an anti-corrosion lubricant specifically formulated to prevent fretting corrosion, to the flex cable/connector of the monitoring circuit board of the INOMAX DS. This application was determined to be effective in mitigating the observed erratic NO monitoring. Replacement of the 20-conductor ribbon cable, with application of DeoxIT to the new cable, was added to the Preventive Maintenance plan for the devices and was performed when the INOMAX DS devices rotated through the INO Therapeutics/Ikaria Regional Service Centers for any service activity.

There is a reasonable likelihood of serious adverse health consequences or death associated with such failures. The associated health risks may include hypoxia, hypotension, bradycardia, cardiac arrest, organ damage, ARDS, and neurological deficits.

This remediation notice is being issued at the direction of the U.S. Food and Drug Administration.

Your continued support is appreciated. Please direct any questions you may have about this letter to Ikaria Customer Care at 1-877-KNOW-INO (1-877-566-9466).

Sincerely yours,

Aparna Mohan, M.D., Ph.D.

Vice President

Head of Drug and Device Safety and Pharmacovigilance