



Recall -- Firm Press Release

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Atrium Initiates Voluntary Recall Action Regarding HYDRAGLIDE™ Brand Heparin-Coated Thoracic Drainage Catheters used for Autotransfusion during Cardiopulmonary Bypass Surgery

Contact:

Atrium
1-800-5-ATRIUM

FOR IMMEDIATE RELEASE -- HUDSON, New Hampshire – May 12, 2008 – Atrium Medical Corporation today announced that it is initiating a voluntary and precautionary recall of selected lots of HYDRAGLIDE™ Brand Heparin-Coated Thoracic Drainage Catheters. Limited lots of Atrium heparin-coated Hydraglide Thoracic Catheters were manufactured with heparin found to have been contaminated with oversulfated chondroitin sulfate (OSCS). The patient risk associated with the presence of OSCS in heparin-coated medical devices is not known at this time. The U.S. Food and Drug Administration has received reports of serious injury and death in patients who have been administered injectable heparin products containing high levels of OSCS. While Atrium's HYDRAGLIDE Catheters do not contain high levels of heparin, there still exists a potential exposure of OSCS to the patient.

Customers with affected lots are advised to immediately discontinue use of these devices and obtain replacement catheters from Atrium. Atrium will be working with our customers to replace the affected product as soon as possible. If a non-elective procedure requires use of this catheter, we recommend that you do not use the catheter with either a cell saver autotransfusion system or direct autotransfusion chest drainage collection system for cardiopulmonary bypass surgery.

Atrium has not received reports of any OSCS-related adverse events arising from any use of their Hydraglide Thoracic Catheters. This voluntary recall is being initiated as a precaution to minimize any future potential risk.

The above Customer Notification actions are being taken with the knowledge of the U.S. Food and Drug Administration. Physicians and hospital personnel with product related questions should call the

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company at 1-800-5-ATRIUM, Monday –Friday, 8:00 AM to 5:00 PM EST.

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