

PRODUCT NOTIFICATIONS AND RECALLS

FORD F-SERIES 6.7 LITER DIESEL AMBULANCE PACKAGE RECALL

Ford announced on 11/1/13 that it is recalling about 3,100 F-Series ambulances because the engines can stop unexpectedly. The F-350, F-450 and F-550 "Super Duty" ambulances have 6.7-Liter diesel engines. They're from the 2011 and 2012 model years. Ford says a faulty exhaust gas temperature sensor can cause the engines to stop and not be restarted for at least an hour. The company says it has no reports of the problem affecting patient care. Most of the ambulances were sold in the U.S., with some in Canada and other countries. Dealers will replace the sensor. Ford says the problem could occur on non-ambulance versions of the same trucks, but the company isn't recalling them. Drivers will get a warning and enough time to safely pull off the road before the engine shuts down.

HEARTSINE SAMARITAN 300/300P PUBLIC ACCESS DEFIBRILLATORS



Certain Samaritan 300/300P PAD devices manufactured from August 2004 to December 2010 have been found to intermittently turn on and off, which may eventually deplete the battery. In addition and separately, certain Samaritan 300/300P PAD devices containing early versions of the battery management software may misinterpret a temporary drop in battery voltage as signaling a low battery and subsequently turn the device off. In certain instances, a device experiencing either condition could be unable to deliver therapy during a cardiac event.

Samaritan 300/300P PAD devices with the following serial numbers inclusive are affected by one or both of these issues: 0400000501 to 0700032917, 08A00035000 to 10A00070753 and 10C00200000 to 10C00210106

Because a device experiencing the on/off issue will function appropriately if it has an adequate power source, HeartSine is sending affected customers a new 1,500 mAh PAD-PAK to be held in reserve and an accompanying hang tag with instructions for when and how to insert the reserve PAD-PAK so that the customer always has the ability to deliver therapy in a rescue attempt. In addition, HeartSine is providing a software upgrade with a CD, data cable and associated User Manual to bring all users up to a more recent version of the software that the company's data shows is no longer susceptible to the secondary issue.

For additional information go to <http://www.heartsine.com/en/recall/>

DUODOTE® AUTO-INJECTORS



Meridian Medical Technologies, a Pfizer Inc. company, has issued a notice that based on a review of product lots at its manufacturing site, Meridian personnel determined that a small number of DuoDote® Auto-Injectors are out of specification. This could potentially prevent some of the units from activating or cause the patient to receive less of the drug than is intended. Delivery of clinically inadequate drug doses is infrequent and occurs in approximately 7 units out of a thousand DuoDote® Auto-Injectors. Auto-injectors are not being recalled but the company notice indicates Meridian and government agencies are working together to ensure that customers receive replacement product as quickly as possible, and based on priority of need. DuoDote® (atropine and pralidoxime chloride injection) Auto-Injector is indicated for the treatment of poisoning by organophosphorous nerve agents as well as organophosphorous insecticides.

According to news reports, Pfizer is being questioned about a 5 month lag in notifying civilian customers about the problem. Civilian-emergency personnel and wholesale suppliers around the United States were sent a notice about problematic DuoDote syringes on 8/27/13, six days after a widely publicized sarin-gas strike in Syria's civil war. The Pentagon, though, had already been notified five months earlier about defects in similar syringes that it bought from the company to treat troops exposed to sarin.

Additional information is online at <http://www.cwfaohio.com/DOC036.pdf>

EMERGENCY CRICOTHYROTOMY KIT BY H&H MEDICAL CORPORATION

H&H Medical Corporation initiated a nationwide recall of 6,619 units of the H&H Emergency Cricothyrotomy Kit. The product has been found to have the potential for a defective cuff balloon on the provided endotracheal airway. The cuff balloon may be defective due to a very particular set of circumstances (a reduction in package density, a higher than average dose of gamma sterilization, and the occasional slippage of a protective silicon sleeve during shipping used to shield the cuff balloon at the end of the endotracheal airway). To date, no injuries or deaths have been reported to H&H or to the FDA.

The product lot number can be identified by a lot number and manufacture label applied at the top opening of the kit. The recalled version of the H&H Emergency Cricothyrotomy Kit was produced between 8/16/12 and 7/29/13. See firm press release for complete list of lot numbers.

EMS agencies who have product should stop using the product and return them to their original place of purchase for immediate credit. Distributors are instructed to return all recalled items meeting the lot numbers listed for return credit or for immediate replacement. Users should quarantine this product from inventory and return it to the original source of sale for credit or to request immediate replacement. Consumers with questions may contact H&H Medical Corporation via telephone at 800-326-5708 between the hours of 8 a.m. and 4:30 p.m. (Eastern Time Zone) or contact the company via e-mail at mmorgan@gohandh.com.

Read the MedWatch Safety Alert, including links to the H&H press release at:
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm370781.htm>

MICHELIN TIRE RECALL

Michelin is recalling one version of a specific size of the Michelin LTX M/S tire. These tires are typically found on such vehicles as commercial light trucks, full-sized heavy duty vans, small RVs, some large pickup trucks and ambulances and 1st responder vehicles. Michelin is issuing the recall because a small number of the tires being recalled experienced tread loss and/or rapid air loss. The tires were produced between January 2010 and June 2012 and were fitted as original equipment on some new vehicles and were also sold as new replacement tires.

The tire version and size are:

Michelin LTX M/S LT 225/75R16 115/112R LRE

DOT Sequence B3JHAKEX

DOT Production Periods 0210 - 2512

Michelin recommends removal of these tires as soon as possible. Owners of the affected tires should visit an authorized Michelin retail location as soon as possible to have the tires replaced at no charge. For addition information contact Michelin Consumer Care at (800) 231-5893.