Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 16, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Symbios Medical Products Recall

SUGGESTED ACTION: **Unclassified Recall; All GoPump Rapid Recovery System kits and GOBlock Kits manufactured with flow control components assembled prior to July 2012. These products have been found to potentially cause excessively high flow rates; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products were distributed in the State of Indiana. This recall affects only the fifty (50) United States plus the District of Columbia. Distributors and clinical provider sites using these Symbios Medical Products have been notified of the affected product codes and lot numbers. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

****

Symbios Medical Products Issues Nationwide Recall of GOPump and GOBlock kits

FOR IMMEDIATE RELEASE:

Symbios Medical Products
7301 Georgetown Road Suite 150
Indianapolis, Indiana 46268 317-225-4447 Ext 25
www.symbiosmedical.com On May 10, 2013, Symbios Medical Products initiated a voluntary recall of all GoPump Rapid Recovery System kits and GOBlock Kits manufactured with flow control components assembled prior to July 2012. These products have been found to potentially cause excessively high flow rates, which presents a risk of patient toxicity and serious injury (e.g., seizure, dysrhythmia, death) due to the rapid influx of medication particularly in patients with low body mass or advanced age. To date, there have been 5 complaints received, 2 of which involved serious consequences. There have been no patient deaths reported. The root cause is understood and processes have been put in place to address the issue.

This recall affects only the fifty (50) United States plus the District of Columbia. Distributors and clinical provider sites using these Symbios Medical Products have been notified of the affected product codes and lot numbers. Symbios is working to secure all affected product and have it returned. Products subject to this recall were distributed between April 1st, 2011 and April 30th, 2013. Recall action was begun immediately upon the knowledge of the product related issues.

GOPUMP / GOBLOCK KITS SUBJECT TO RECALL Range of Affected Kit Lot #'s			
Kit PN	**From Kit Lot #**	**To Kit Lot #**	**Kit description**
510042	11-100251	13-100128	GoPump kit 150mL, 2 mL/hr Epidural Catheter
510042-BP	12-101300	12-101300	GoPump kit 150mL, 2 mL/hr, Epidural Catheter & BIOPATCH
510080-BP	11-100215	12-100508	GoPump kit 300mL, 2 mL/hr/side, 5" Fenestrated Catheter and Biopatch
510110	11-100664	11-100664	GoPump kit 150mL, 2 mL/hr 2.5" Fenestrated Catheter
510110-BP	11-100838	12-101560	GoPump kit 150mL, 2 mL/hr 2.5" Fenestrated Catheter and Biopatch
510112-BP	11-100839	13-100225	GoPump kit 300mL, 2 mL/hr/side, 2.5" Fenestrated Catheter & BIOPATCH
510141-BP	12-100460	12-100673	GoPump kit 300mL, 2 mL/hr/side, 10" Fenestrated Catheter & BIOPATCH
510201-BP	12-100108	12-101538	GoPump kit 300mL, 2 ml/hr, 5" Fenestrated Catheter & BIOPATCH