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MOOG MEDICAL DEVICES GROUP ANNOUNCES VOLUNTARY RECALL OF SELECT CURLIN ADMINISTRATION SETS DUE TO POSSIBLE HEALTH RISK

Salt Lake City, UT-Moog Medical Devices Group (MMDG) is issuing a voluntary recall for certain lots of Curlin Intravenous Administration Sets. Use of the affected sets may cause desanguination (blood loss), an under-delivery of prescribed medication/fluid, or a potential delay in therapy. Continued use of the affected administration sets may cause a potential risk of serious injury or death.

The following REF (catalog) and lot numbers, which were sold and distributed in the U.S. between December 2011 and May 2012, are included in the recall:

REF Code (REF Codes are found in the top right hand corner of the administration set packaging):

340-4114	340-4115	340-4126	340-4128	340-4128-V	340-4130	340-4130-V	340-4133	
340-4137	340-4144	340-4165	340-4166	340-4173	340-4176			

Lot Numbers (Lot numbers are found in the lower right hand corner of the administration set packaging):

					
CF1127990	CF1134390	CF1200492	CF1202592	CF1205492	CF1208091
CF1127991	CF1134391	CF1200493	CF1204092	CF1206890	CF1208092
CF1127992	CF1133490	CF1200293	CF1204093	CF1206891	
CF1129990	CF1134392	CF1200494	CF1203391	CF1205493	
CF1130190	CF1134990	CF1200294	CF1204091	CF1206090	
CF1130690	CF1134393	CF1201893	CF1203392	CF1206091	
CF1130691	CF1135490	CF1201890	CF1203390	CF1206092	
CF1130693	CF1135491	CF1201190	CF1204090	CF1208090	
CF1131190	CF1135492	CF1201192	CF1204690	CF1206893	
CF1131191	CF1200290	CF1202591	CF1204691	CF1207592	
CF1130692	CF1200291	CF1202590	CF1205491	CF1207590	
CF1132290	CF1200292	CF1201891	CF1204692	CF1207591	
CF1132291	CF1200490	CF1201191	CF1205490	CF1207593	
CF1133491	CF1200491	CF1201892	CF1205990	CF1209091	

Patient safety and product quality are MMDG's first priorities. The recall was initiated as a result of the discovery of a reverse pump segment by customers and reported to Moog. To date, Customer complaints have identified (3) three out of 544,900 suspect sets manufactured for the United States. Despite the potential for reverse flow when using an affected set, MMDG has not received any reports injury or death as a result of this issue. MMDG has identified and corrected the root cause by immediately initiating a supplier corrective action request (SCAR) and implementing additional preventative measures.

MMDG has notified the U.S. Food and Drug Administration and is working with them to coordinate recall activities. Direct customers and distributors will be notified of the process for obtaining replacement administration sets. Patients in a home environment, please contact your home healthcare provider or clinician for proper handling and the replacement process of your affected set(s). For additional questions, contact Moog Customer Advocacy at (800) 970-2337.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Online: http://www.fda.gov/medwatch/report.htm

Regular Mail: use postage-paid FDA form 3500 available at:

http://www.fda.gov/MedWatch/getforms.htm. Mail to MedWatch 5600 Fishers Lane,

Rockville, MD 20852-9787 **Fax:** 1-800-FDA-0178

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