NestléHealthScience

December 2, 2015

Dear Valued Distributor:

We are contacting you because Moog Medical Devices Group ("Moog"), the manufacturer of the EnteraLite® Infinity® Enteral Pumps and Administration Sets with Pre-attached ENFit™ Transitional Connectors, has notified Nestlé HealthCare Nutrition, Inc. ("Nestlé"), as Moog's exclusive distributor in North America, that they have received complaints regarding the ENFit™ Transitional Connectors. Some customers have reported formula leaking between the purple ENFit™ Connector and the white transitional stepped connector due to cracking or breaking of the purple connector.

A copy of Moog's notice to Nestlé is enclosed. Moog indicated that they have received 209 complaints involving leaking at the ENFit™ Transitional Connector since March 2015, when the administration sets entered the U.S. and Canadian markets. Nestlé's records indicate that during that period, more than 8 million of these sets have been delivered to customers in the U.S. and Canada.

Moog indicated that they are working on a permanent solution. In the interim, Moog will temporarily cease production of the Sets with the Pre-attached ENFit™ Transitional Connectors and resume production of the Sets with the previous Red-Stepped Connector.

Nestlé will offer the EnteraLite® Infinity® Administration Sets with the Pre-attached Red-Stepped Connectors until a suitable solution is found. Your customers will notice a change from a two piece white and purple connector to a single piece red connector, as shown below. The Red-Stepped Connector will require no change in clinical practice for the current, non-ENFit™ feeding tubes.

ENFit™ Transitional Connector (Current)

Red-Stepped Connector (Interim Replacement)

Nestlé will begin shipping the Sets with Red-Stepped Connectors as soon as our supply from Moog is adequate, based on normal ordering patterns. The chart below shows our expected first ship dates for the Sets with Red-Stepped Connectors. Effected contract pricing for your customers will be sent by the Memberships department within the next few days.

PRODUCT ON EXTENDED OUT OF STOCK			RED-STEPPED CONNECTORS (INTERIM / REPLACEMENT PRODUCT)			
Product Description	**Product Code**	**Case UPC (GTIN)**	**Expected First Ship Date**	**Product Description**	**Product Code**	**Case UPC (GTIN)**
EnteraLite® Infinity® 1200 mL Bag Pump Set with Pre-attached ENFit™ Transitional Connector	12250530	30814844000277	Late Dec 2015 / Early Jan 2016	EnteraLite® Infinity® Enteral Pump Delivery Set, 1200 mL	12223319	30814844000062
EnteraLite® Infinity® 500 mL Bag Pump Set with Pre-attached ENFit™ Transitional Connector	12250482	30814844000260	Late Dec 2015 / Early Jan 2016	EnteraLite® Infinity® Enteral Pump Delivery Set, 500 mL	12223317	30814844000055
EnteraLite® Infinity® Pump Set with SpikeRight® PLUS and Pre-attached ENFit™ Transitional Connector	12250531	30814844000253	Late Dec 2015 / Early Jan 2016	EnteraLite® Infinity® SpikeRight® PLUS Connector System	12223318	30814844000000

Nestlé HealthCare Nutrition, Inc
12500 Whitewater Drive
Minnetonka, MN 55343 (USA)

Nestlé requests that you inform all of your end-user customers that purchase EnteraLite® Infinity® Administration Sets with the Pre-attached ENFit™ Transitional Connectors about this situation.

We apologize for any inconvenience this situation creates. If you have questions or need more information, please refer to the following contact information:

For specific product availability information on the temporarily discontinued Sets, please contact your Nestlé Distributor Manager or our Customer Service Department at 1.877.463.7853.

For product quality related questions concerning the Sets, please contact Christopher Dodge, Manager, Moog Regulatory Affairs, at 801.264.1001, ext. 112, or via email at: cdodge@moog.com.

Sincerely,

Anna Mohl
Vice President of Medical Nutrition Sales, U.S.
Nestlé HealthCare Nutrition, Inc.

Nestlé HealthCare Nutrition, Inc.
12500 Whitewater Drive
Minnetonka, MN 55343 (USA)

URGENT Field Safety Notice

Moog Medical Devices Group
4314 Zevex Park Lane
Salt Lake City, Utah 84123

ph 801 264 1001
fx 801 264 1051
800 970 2337

www.moog.com/medical

EnteraLite® Infinity® Enteral Pump Delivery Set with ENFit Connector System and Transitional Stepped Connector

November 20, 2015

Leaking Between ENFit Connector and Transitional Stepped Connector

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Dear Valued Distributor,

Moog Medical Devices Group (MMDG) is issuing this notification to provide you important information regarding a voluntary Field Safety Notice for all EnteraLite® Infinity® Enteral Pump Delivery Sets with ENFit Connector System and Transitional Stepped Connector (INF0020-A, INF0500-A, INF1200-A).

Details on affected devices:

Brand Name: EnteraLite® Infinity® Enteral Pump Delivery Set with ENFit Connector System and Transitional Stepped Connector

There are three list numbers affected by this Field Safety Notice:

INF0020-A – EnteraLite® Infinity® Enteral Pump Delivery Set with ENFit Connector System and Transitional Stepped Connector (spike set)

INF0500-A – 500ml EnteraLite® Infinity® Enteral Pump Delivery Set with ENFit Connector System and Transitional Stepped Connector

INF1200-A – 1200ml EnteraLite® Infinity® Enteral Pump Delivery Set with ENFit Connector System and Transitional Stepped Connector

Description of the problem:

MMDG has become aware of an increase in the number of complaints for EnteraLite® Infinity® Enteral Pump Delivery Sets with ENFit Connector System and Transitional Stepped Connectors (administration sets) that are used with the EnteraLite® Infinity® Enteral Feeding Pump. Customers are reporting formula leaking between the purple ENFit connector and the white transitional stepped connector due to cracking or breaking of the purple connector. To date, 209 reports involving leaking at the ENFit connector have been reported since the administration sets entered the market in March, 2015. During that time there have been 5 reported adverse events.

If the problem occurs, the end user will notice a leak at some point after the enteral feeding initiates. The time from initiation of the feeding to the leaking varies as does the amount of leaking.

Risk to Health:

The following potential risks have been identified for patients:

- Set connections may leak or break causing under delivery of food or a delay in

therapy. Such a delay may result in a patient not receiving enteral nutrition, which could pose a potential for dehydration or a hypoglycemic episode.

- Set malfunctions may leak onto open wounds or surgical dressing leading to infection, requiring medical intervention.

There is a risk to those patients who are not routinely monitored, have a pre-existing condition, and are unable to detect or communicate/report the leaking formula. Certain patients such as those with Glycogen Storage Disease may be at a higher risk because they are required to receive a constant feeding to prevent hypoglycemia.

Necessary actions:

Nestlé must contact all known distributors of the EnteraLite® Infinity® Enteral Pump Delivery Sets with ENFit Connector System and Transitional Stepped Connectors and inform them that MMDG will cease production of all its enteral administration sets using ENFit connectors and transition back to the previous revision of the product codes that do not include the ENFit connector (INF0020, INF0500, and INF1200). Nestlé may also inform them that MMDG will produce the previous revision until a suitable solution to the ENFit connector material degradation problem is found.

Transmission of this Field Safety Notice:

This notice must be passed on to those who need to be aware within your organization.

Contact reference person:

For additional information or clarification, please contact Christopher Dodge, Manager, Regulatory Affairs at (801) 264-1001, ext. 112 or via e-mail at: cdodge@moog.com Monday through Friday, 8:00 AM to 5:00 PM, Mountain Time.

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (Form available to fax or mail), or
- Call FDA 1-800-FDA-1088

The undersigned confirms that this notice has been communicated to the appropriate Regulatory Agency.

Sincerely,

Christopher Dodge
Manager, Regulatory Affairs
Moog Medical Devices Group, Inc.