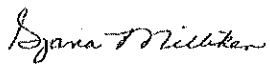




FAX COVER

<p><i>National Distribution & Contracting, Inc.</i> <i>Djana Milliken – Compliance</i> ***URGENT*** <i>***This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.***</i></p>	
<p>To: <i>Purchasing or Regulations Department</i></p>	<p>Date: 11/9/2016</p>
<p>Pages: <u>7</u> (Including cover page)</p>	
<p>Regarding: <i>Nestle - Compat Replacement Balloon Gastrostomy Tubes, 16 FR Item # 08741600</i></p>	
<p>Comments: <i>Dear Distributor, Nestle recently discovered error on certain packaging labels for Compat Replacement Gastrostomy Tubes item # 08741600. Nestle distributed affected recalled product from January 29, 2016 through October 13, 2016. Our records indicate that you purchased this product from us. Please read attached letter and follow instructions given. <u>If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.</u> Additionally, if you have distributed these products to your customers, please advise them of the letter. Thanks,  Djana Milliken</i></p>	

CUSTOMER BULLETIN

November 4, 2016

Risk Manager
Natl Distribution & Contracting Inc
407 Sanford Rd
La Vergne, TN 37086-4184

Delivered via UPS Overnight

Re: Packaging Label Error on the Compat® Replacement Gastrostomy Tube
(16FR Tube with 15 cc Balloon)

Dear Valued Customer:

We would like to bring to your attention to a recently discovered error on certain packaging labels for the Compat® Replacement Gastrostomy Tubes (16 French diameter with 15 cc balloon size only) that are manufactured for Nestlé HealthCare Nutrition, Inc.

One section of the packaging label for these products inaccurately indicates the tube diameter as "14 FR" (should state "16 FR") and a balloon size of "5cc" (should state "15cc") as highlighted in the product label image on page 4 of this bulletin. **All other portions of the packaging label, including the instructions for use and the product itself, correctly indicate a tube diameter as 16 French and a balloon size of 15 cc for these products.**

The affected product package involves only the one Nestle product code (reference number 08741600) and the lot-codes indicated below shipped from Nestlé distribution centers between January 29, 2016 and October 13, 2016:

Product Description	Nestlé Product Code (Reference No.)	Case UPC (GTIN)	Affected Lot Codes
COMPAT® Replacement Balloon Gastrostomy Tubes, 16 FR	08741600	10043900874163	930701, 936301, 940402, 943301, 947105, 936101

Please refer to the sections "Product Label Error" and "Packaging and Contents – Location of Product Reference No. and Lot Code" below for additional details on the location of the labeling error and the impacted product lot codes.

We have conducted an assessment of this packaging label error and have concluded that there is no patient safety risk associated with this labeling error. In accordance with our strict quality standards, we are providing this bulletin to customers to notify and clarify this error on the packaging label. Nestlé is not asking customers to return the product. **THE PRODUCT IS NOT AFFECTED AND MAY CONTINUE TO BE USED AS DESCRIBED IN THE INSTRUCTIONS FOR USE.**

We have also initiated an internal company corrective action pursuant to which all existing inventory with the packaging label error have been purged and shipments of product with the correct packaging label are anticipated to start in mid-December 2016.

We apologize for any inconvenience this may have caused. **If you are a distributor of this product**, we request that you immediately notify your customers of this packaging label error.

If you have questions or need more information, please refer to the following contact information:

For product quality related questions, please contact Nestlé Consumer Response at 800.422.2752.

For product availability questions, please contact Nestlé Customer Service at 877.463.7853.

Sincerely,



Anna Mohl

Regional Business Head, North America - Medical Nutrition Business
Nestlé HealthCare Nutrition, Inc.

Frequently Asked Questions

Q: What is the issue with the COMPAT® Replacement Balloon Gastrostomy Tubes size 16 French package label?

A: There is an error in one section of the packaging label affecting certain lot codes. For details on the location of this error on the affected packaging labels, refer to image on page 4 below under the section “Packaging and Contents – Label Error”.

Q: Does affected product need to be returned?

A: No. Our assessment has clearly shown that that there is no increased patient risk resulting from this mislabeling.

Q: Are any other COMPAT® Replacement Balloon Gastrostomy Tubes affected?

A: No

Q: Is there a quality issue with the device itself?

A: No. The device fully meets Nestlé quality standards. The only issue is the packaging labeling error.

Q: Is there any safety risk to the patient?

A: Our assessment has clearly shown that that there is no increased safety risk to the patient resulting from the packaging label error.

Q: When will Nestlé restart shipments of the COMPAT® Replacement Balloon Gastrostomy Tubes size 16 French?

A: Shipments will restart as soon as correctly labeled inventory is available, which is anticipated to be mid-December 2016.

Product Label Error

ENTERAL FEEDING TUBE



**Compat Replacement Balloon
Gastrostomy Tube with Universal
"Y" Adapter and Stretch-Lok Strap**

NOT MADE WITH NATURAL RUBBER LATEX

**16
French**

Correct size

Should state 16 FR



• 14 FR. Replacement Balloon Gastrostomy Tube with Sliding Retention Disc

- Clear Medical Grade Silicone

- Open Flow-Thru Tip

Should state 15cc



• 5cc Balloon

- External Centimeter Graduations

- Radiopaque Marker

• Medium Universal "Y" Adapter with Stretch-Lok® Strap

• Directions for Use

• Nursing Manual

Important Information:

1. Inspect contents of kit. If damaged, do not use.

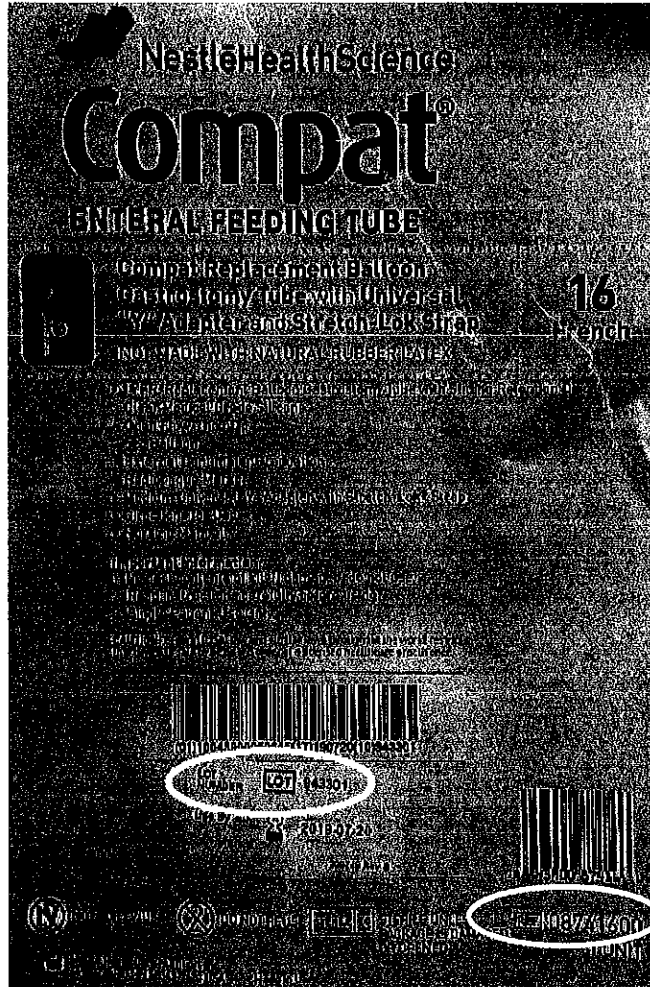
2. Read instructions carefully before using.

3. Single Patient Use Only.

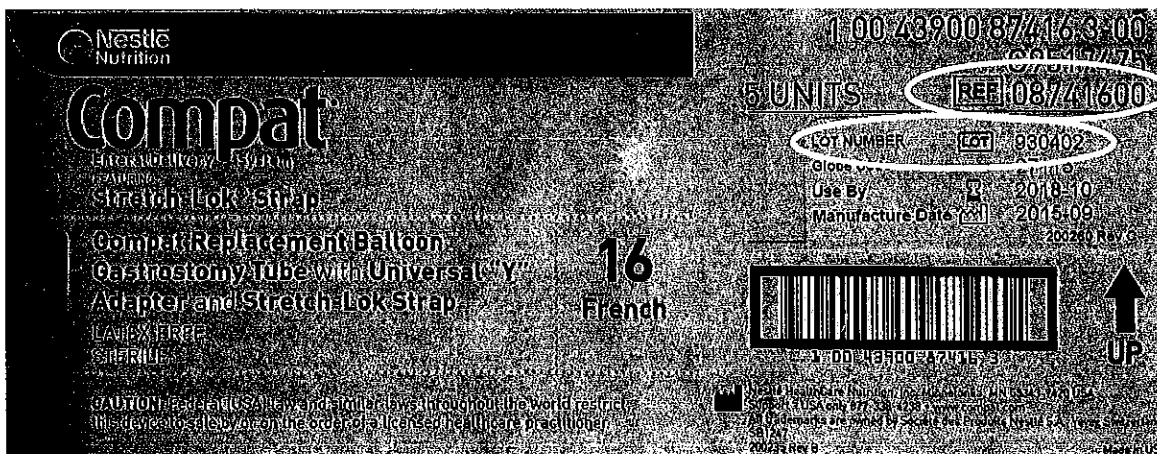
CAUTION: Federal (USA) law and similar laws throughout the world restrict this device to sale by or on the order of a licensed healthcare practitioner.

Packaging and Contents – Location of Product Code (REF) and Lot Code

On Device Label



On Device Shipping Carton Label





11/8/2016

Nestle- COMPAT Replacement Balloon Gastrostomy Tubes, 16 FR

Please fill out and fax/email this distributor form within 10 business days, even if you do not have the recalled product.

Please complete and fax to: 615-229-6801 Or email to: Compliance@ndc-inc.com

Acknowledgment of Receipt

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item number
NVT 08741600

- I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.
- We have inspected our inventory and have no product related to this recall

Completed by: (Print Name /Signature/Date)

Returned Completed form to:
Fax #: Djana Milliken
615.229-6801
Email: compliance@ndc-inc.com

*Delivering Efficiency to Healthcare**

402 BNA Drive, Suite 500 / Nashville, TN 37217
www.ndc-inc.com / 615.366.3230