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URGENT MEDICAL DEVICE RECALL NOTIFICATION
PRODUCT: NasoPore® Standard 8cm Nasal Dressings

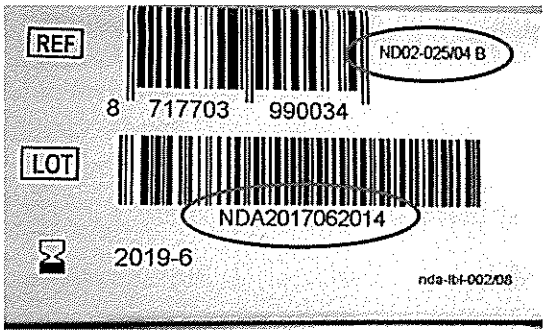
ATTN: Risk Manager, Operating Room Director, Materials Manager
cc: Chairman Medical Board and relevant Head of Departments

14-Nov-2017

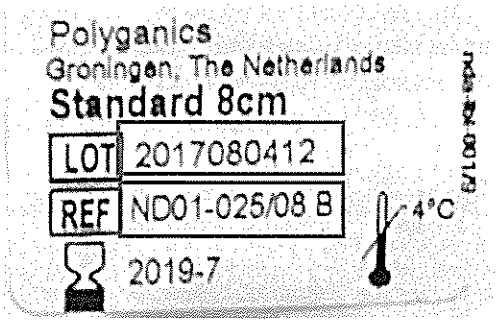
The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling one lot of NasoPore 8cm nasal dressings packaged in an 8/PK carton:

Product Number	Lot Number	Dates Distributed
Carton Label: ND02-025/04B, Individual product label: ND01-025/08B	Carton Label: NDA2017062014, Individual product label: NDA2017080412	September 18, 2017 to September 22, 2017

Carton label:



Individual product label:



Product Description:
NasoPore is a fragmentable nasal dressing and is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces; to help control minimal bleeding following surgery or nasal trauma by tamponade effect and blood absorption.

Reason for the Voluntary Recall:
A barcode label that was affixed to the product carton contained incorrect product identification and lot/expiry information.

Risk to Health:
There is no risk to health associated with the incorrect barcode label related to this recall.

Actions to be taken by the Customer/User:

1. Immediately review this Recall Notification.
2. Check all stock areas and/or operating room storage to determine how many NasoPore 8cm nasal dressings from the affected lot (listed above) are at your facility. Quarantine and discontinue use of the recalled NasoPore nasal dressings.

Stryker Instruments
4100 E Milham Road, Kalamazoo, MI 49001 USA | P 269 323 7700 | F 866 521 2762

3. Please complete and sign the enclosed Business Reply Form (BRF) to confirm receipt of this notification and identify how many, if any, affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand.

   Note: *Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification.*

4. If you have further distributed this product, please forward this letter and the attached BRF to all affected locations. Please indicate each location on the BRF.
5. Return the completed BRF to your Easmed representative or email to ASEAN.PMS@stryker.com.
6. If the BRF for your facility indicates that recalled product is currently on hand, an Easmed representative will contact you to return the products and discuss product replacement/credit.
7. Upon receipt of the recalled product, replacement product / credit will be provided.

Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to Easmed. Alternatively, healthcare professionals may report the adverse events to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online. Events that are reported to Easmed will be investigated and subsequently reported to HSA, as appropriate.

We apologize for any inconvenience this action may cause your facility. Please forward a copy of this letter to any other personnel within your facility that you deem appropriate.

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BUSINESS REPLY FORM

PRODUCT: NasoPore® Standard 8cm Nasal Dressings

Product Number	Lot Number	Quantity on Hand (Cartons)	Quantity on Hand (Individual Nasal Dressings)
Carton Label: ND02-025/04B, Individual product label: ND01-025/08B	Carton Label: NDA2017062014, Individual product label: NDA2017080412	63bx	0

1. Immediately review the Recall Notification.
2. Check all stock areas and/or operating room storage to determine how many NasoPore 8cm nasal dressings from the affected lot (listed above) are at your facility. Quarantine and discontinue use of the recalled NasoPore nasal dressings.
3. Complete this Business Reply Form (BRF) to confirm receipt of the notification and identify how many, if any, affected items are currently in your inventory. Please complete and return the BRF even if you don't have any affected product on hand.
   Note: *Your signature on the BRF indicates that you received and understand the Notification and have followed the instructions in the Notification.*
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5. Return the completed BRF to your Easmed representative or email to ASEAN.PMS@stryker.com.
6. If the BRF for your facility indicates that recalled product is currently on hand, an Easmed representative will contact you to return the products and discuss product replacement/credit.
7. Upon receipt of the recalled product, replacement product / credit will be provided.

[redacted]

If you have further distributed any affected devices, please indicate to whom below:

Contact Person _____ Facility Name _____

Address _____ Country _____

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