



Aug 01, 2019

**URGENT – Voluntary Medical Device Field Notification  
ADAPTIC™ Non-Adhering Dressing**

Dear Valued Customer:

KCI USA, Inc. (KCI) and Systagenix Wound Management (Systagenix) have become aware of potential sterile barrier breaches in some of the pouches of the ADAPTIC™ Non-Adhering Dressing, 7.6cm x 7.6cm (Product Code/SKU Number 2012), **Lot Number 1903V001**. If a sterile barrier breach has occurred, there is a remote potential to contaminate the wound application site.

It is important to note that no other products or lot numbers are impacted by this Voluntary Medical Device Field Notification. Neither KCI nor Systagenix have received any reports of patient injury or complications as a result of a sterile barrier breach for any ADAPTIC™ Non-Adhering Dressing.

KCI and Systagenix are in the process of identifying the root cause of these sterile barrier breaches and are committed to implementing the appropriate action(s) to prevent future occurrences of this issue.

Our records indicate that your facility may have received a quantity of ADAPTIC™ Non-Adhering Dressings, 7.6cm x 7.6cm (Product Code/ SKU Number 2012), **Lot Number 1903V001**, affected by this Voluntary Medical Device Field Notification and KCI requires you to take immediate action.

**Immediate Actions Required by Your Facility:**

- Locate and quarantine ADAPTIC™ Non-Adhering Dressing, 7.6cm x 7.6cm (Product Code/ SKU Number 2012), **Lot Number 1903V001** in your facility. Refer to Figure 1 below to locate the Lot Number on the dressing label.
- Destroy, by rendering the product unusable, the ADAPTIC™ Non-Adhering Dressing, 7.6cm x 7.6cm (Product Code/ SKU Number 2012), **Lot Number 1903V001**.
- Discard all impacted product per your facility disposal procedures.
- **Complete the ADAPTIC™ Non-Adhering Dressing Packaging Field Notification Acknowledgement**, See Attachment 1. NOTE: If you do not have any affected dressings, then write 0 in the Quantity field.



- Return the completed form via e-mail to [acelityregulatorycompliance@acelity.com](mailto:acelityregulatorycompliance@acelity.com) with “ADAPTIC™ Non-Adhering Dressing Field Notification” in the subject line.
- **If you have further distributed the products identified in this Voluntary Medical Device Field Notification, please forward a copy of this notification to those accounts.**



**Figure 1**  
ADAPTIC™ Non-Adhering  
Dressing Pouch Label

If you have any questions related to this Voluntary Medical Device Field Notification, please contact your local product representative.

This medical device field notification is made with the knowledge of the Regulatory Authorities where these products have been distributed.

KCI and Systagenix take the quality of our products seriously, and we always strive to meet or exceed our customers' expectations in quality and durability. We apologize for any inconvenience that this correction may cause.

Sincerely,

Steven Jackson  
Vice President, Global Quality  
Acelity



**Attachment 1: ADAPTIC™ Non-Adhering Dressing Packaging Field Notification Acknowledgement**

**URGENT – Voluntary Medical Device Field Notification  
ADAPTIC™ Non-Adhering Dressing**

**Customer Information**

Facility Name: \_\_\_\_\_

Facility Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

KCI/Systagenix Account Number: \_\_\_\_\_

Facility Contact: \_\_\_\_\_

Facility Contact Phone Number: \_\_\_\_\_

By return of this form, we are acknowledging that we have been made aware of the ADAPTIC™ Non-Adhering Dressing Packaging issue. We currently have the following ADAPTIC™ Non-Adhering Dressing, 7.6cm x 7.6cm inventory at our facility for Part Number SKU Number 2012, Lot 1903V001:

**Quantity:** \_\_\_\_\_

**By return of this completed form, we acknowledge that the above products have been destroyed, disposed of and/or will not be used.**

Please return the completed form by e-mail to [acelityregulatorycompliance@acelity.com](mailto:acelityregulatorycompliance@acelity.com) with “ADAPTIC™ Non-Adhering Dressing Field Notification” in the subject line. If you have any questions related to this Voluntary Medical Device Field Notification, and to find out how to receive replacement product, please contact your local product representative.

**Facility Contact**

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

