Urgent Field Safety Notice

MEDICAL DEVICE RECALL

NX3 Try-In Gel Recall
Due to a Production Error

SEPTEMBER 2013

Dear Valued Customer:

Details on affected devices:
KerrHawe is voluntarily recalling one (1) lot of **NX3 Try-In Gel**, some of which may have been shipped to your facility from June 2012 through September 2012.

Product Description	Part Number	Syringe Lot Number	Autobag Lot Number
NX3 Try-In Gel Syringe Refills, Bleach	33660	4580333	4584609

Description of the problem:
It has recently come to our attention that some of the NX3 Try-In Gel syringes in the affected lot contain a different product material. The material in the affected syringe does not match the shade of the cement as it is labeled. There is a risk that use of the affected material to evaluate shade prior to cementation may result in an unanticipated final restoration color requiring the need to remove and repeat the restoration.

Advise on action to be taken by the user:
If you have any of the affected product listed in the tables above, please stop using the product and return it to KerrHawe. Contact **KerrHawe Customer Care at 00800 41 05 05 00 to receive an RMA number.** The RMA will allow for a quick return and replacement or credit.

KERRHAWE KINDLY REQUESTS YOUR COOPERATION IN COMPLETING AND FAXING BACK THE ENCLOSED RECALL REPLY FORM IN ORDER TO CONFIRM YOUR RECEIPT OF THIS RECALL NOTIFICATION REGARDLESS OF WHETHER YOU HAVE ANY PRODUCT IN YOUR INVENTORY.

As you are an authorized KerrHawe distributor, we request that you identify those customers that may have been shipped the affected product and contact those customers within forty-eight (48) hours of receipt of this recall notification to inform them of the issue and retrieve their affected product.

Transmission of this Recall Communication:

Kindly pass this notice on to all those within your organization who need to be aware of this Recall Communication. Additionally, please pass this notice to any organization where the affected NX3 Try-In Gel product may have been shipped.

This recall is being conducted in cooperation with EU competent authorities for KerrHawe's authorized representative and in the countries where this FSCA is has been reported.

We sincerely apologize for the inconvenience this causes you and your patients.

Your cooperation in this matter is greatly appreciated.

Thank you for your patience and support.

Sincerely,

Wendy Garman
Director, Regulatory Affairs

RECALL RETURN FORM

Product Description

NX3 Try-In Gel

Product Description	Part Number	Syringe Lot Number	Autobag Lot Number
NX3 Try-In Gel Syringe Refills, Bleach	33660	4580333	4584609

☐ ***We acknowledge receipt of the NX3 Try-In Gel Recall Notification. We have checked our inventory and were able to locate one or more units of the above-mentioned product. We will be returning the following quantity to KerrHawe.***

Authorized Kerr Distributors: *Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to recover their affected product.*

Quantity Returned

☐ ***We acknowledge receipt of the NX3 Try-In Gel Recall Notification. We have checked our inventory and were <u>unable</u> to locate any of the above-mentioned product.***

Authorized Kerr Distributors: *Additionally, we acknowledge that we will identify those customers that may have been shipped the affected product lot and contact these customers within forty-eight (48) hours of receipt of this notification in order to recover their affected product.*

_____ _____

Contact Person (Please Print) Facility

_____ _____

Signature Date

PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO THE FOLLOWING NUMBER REGARDLESS OF WHETHER YOU HAVE ANY PRODUCT TO RETURN.

00800 41 05 05 14