

Customer Name/Address

Urgent Field Safety Notice

MEDICAL DEVICE RECALL

**Maxcem Elite Recall
Due to Polymerization Issue**

[DATE]

Dear Valued Customer:

Details on affected devices:

KerrHawe is voluntarily recalling several lots of **Maxcem Elite**, some of which may have been shipped to your facility from October 2012 to February 2013.

The Maxcem Elite part and lot numbers are listed in the enclosed Lot Number Tables. Please review the tables and determine if you have any of the affected product in your inventory.

Description of the problem:

It has recently come to our attention that an issue with the raw material used to produce the affected lots of Maxcem Elite causes the material to prematurely polymerize in the syringe. The product could be difficult to extrude or demonstrate a shorter work-time as the material may prematurely set prior to placing restorations on the tooth or core build-up. As a result, the restoration may not adhere properly.

Advise on action to be taken by the user:

Please review the enclosed lot number tables to determine if you have any of the affected product in your inventory. If you have any of the affected product listed in the lot number tables, please 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 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 these customers to inform them of the issue within forty-eight (48) hours of receipt of this field correction notification.

Transmission of this Recall Communication:

Kindly pass this notice on to all those within your organization who need to be aware of this Field Correction Communication. Additionally, please pass this notice to any organization where the affected Maxcem Elite product may have been shipped.

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,

A handwritten signature in black ink, appearing to read "Wendy Garman". The signature is fluid and cursive, with the first name "Wendy" and last name "Garman" clearly distinguishable.

Wendy Garman
Director, Regulatory Affairs

Customer Name/Address

RECALL RETURN FORM

Product Description

Maxcem Elite

Please refer to the enclosed Lot Number Tables to determine if you have any of the affected product in your inventory.

- We acknowledge receipt of the Maxcem Elite 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 Kerr Corporation. 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.***

Part Number(s)	Lot Number(s)	Syringe Lot Number(s)	Quantity Returned

- We acknowledge receipt of the Maxcem Elite Recall Notification. We have checked our inventory and were unable to locate any of the above-mentioned product. 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

MAXCEM ELITE LOT NUMBER TABLE 1

The table below lists the affected *Maxcem Elite Kit Lot Numbers*

PART NO.	DESCRIPTION	LOT NUMBERS
34055	MAXCEM ELITE STANDARD KIT	4620128
		4656894
		4680372
		4709328
		4728932
		4732387
		4733719
		4735545
		4748933
		4759314
34056	MAXCEM ELITE VALUE KIT	4719214
		4759315
34057	MAXCEM ELITE MINI KIT	4698814
		4709329
		4714775
		4728934
		4732388
		4756503
34058	MAXCEM ELITE REFILL CLEAR	4628189
		4728840
		4728844
		4728935
		4730842
		4732144
		4735257
		4735546
		4748934
4756504		
34059	MAXCEM ELITE REFILL WHITE	4705713
		4728936
		4745082
		4756505
34060	MAXCEM ELITE REFILL WHITE OPAQUE	4719215
		4735547
		4768408
34061	MAXCEM ELITE REFILL YELLOW	4700948
		4705714
		4728937
		4756506
		4768409
34062	MAXCEM ELITE REFILL BROWN	4709330
		4738886
		4749728

MAXCEM ELITE LOT NUMBER TABLE 2

The table below lists the affected *Maxcem Elite Syringe Lot Numbers* that are included in the kits listed above.

DESCRIPTION	LOT NUMBERS
MAXCEM ELITE CLEAR FILLED SYRINGE	4681816
	4681817
	4694026
	4694028
	4694030
	4721155
	4733694
	4741330
	4756672
	4756673
	4766817
MAXCEM ELITE WHITE OPAQUE FILLED SYRINGE	4684879
	4733678
MAXCEM ELITE YELLOW FILLED SYRINGE	4689433
	4693134
	4717719
	4743042
	4770898
MAXCEM ELITE BROWN FILLED SYRINGE	4708392
MAXCEM ELITE WHITE FILLED SYRINGE	4685882
	4708393
	4717716