ivoclar vivadent
passion vision innovation

Field Safety Notice

Recall of medical device

An: Hr.
Händlername
Strasse
PLZ / ORT
Land

Recall No. 12-2013-002-R
Compoglass F
A1

..... January 2014

Dear Sir or Madam

We wish to inform you that Ivoclar Vivadent AG are recalling specific batches of Compoglass F.

Reason for voluntary recall:
We have determined that the batches of material listed in the table below, due to a production error, do not meet the specified curing depth. The requirements of the product specific Standard EN ISO 4049:2009 Dentistry – Polymer-based restorative materials (ISO 4049:2009) have however been fulfilled.

Health risk:
As the affected batches meet the requirements of the product specific Standard, no risks are present for patients. Further actions, for example regarding patients who have already been treated, must not be undertaken.

The recall covers the following batches:

Article No.	Description	Batch No.	Expiry Date
546980AN	Compoglass F Refill 20x0.25g 110/A1	S09397	25.08.2015
574992AN	Compoglass F Intro Pack 40x0.25g/AdheSE	S12098 Kit containing: A1 Batch S09397	04.02.2015
574992AN	Compoglass F Intro Pack 40x0.25g/AdheSE	S51722 Kit containing: A1 Batch S09397	01.07.2015
574992AN	Compoglass F Intro Pack 40x0.25g/AdheSE	S52483 Kit containing: A1 Batch S09397	01.07.2015

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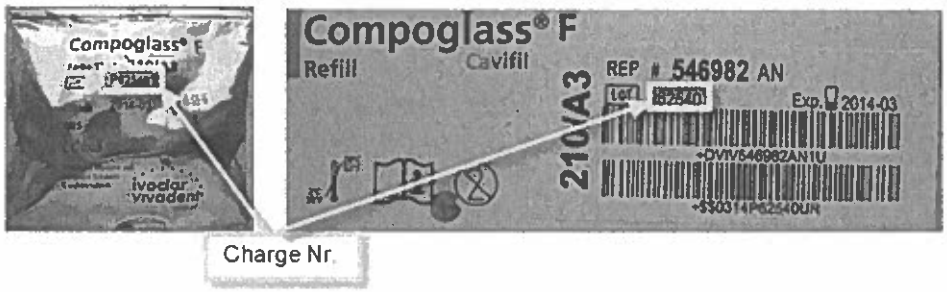
Konto CHF 324526-71/BLZ 4835
IBAN: CH10 0483 5032 4526 7100 0
SWIFT: CRESCHZZXXX

Rechtsform: Aktiengesellschaft
Sitz der Gesellschaft: 9494 Schaan
ÖR-Nr.: FL-0001.001.595-7
MWST-Nr. 50639

To check if a product is affected, refer to the Batch No (Charge Nr.).

This is printed on the labelling



Necessary action:

- According to our documentation the material was first supplied by Ivoclar Vivadent AG to customers on 19.02.2013.
  Please check your stock and block all stock with the Batch Numbers listed above.
- Please inform us by Email about the quantity of packages you can remove from stock, per batch, unless this information has already been provided. Contact person: Mr Alexander Schwaszta (alexander.schwaszta@ivoclarvivadent.com).
- Please send the attached Field Safety Notice direct to customers who have purchased the affected batches. Or send us a list of these customers with contact information so that we can undertake this for you.

Action undertaken by Ivoclar Vivadent AG
Additional quality control measures have been introduced to ensure this problem cannot occur again.

Further information:
This voluntary recall is the responsibility of the legal manufacturer Ivoclar Vivadent AG, Liechtenstein. We confirm that it has been reported to the relevant Authorities.

We express our thanks in advance for your co-operation and understanding. We apologise in advance for any inconvenience that is caused through this issue.

Yours faithfully
IVOCLAR VIVADENT AG

Patrik Oehri
Director R&D Services

Attachment