ivoclar vivadent
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URGENT MEDICAL DEVICE RECALL

{Dentist Letter}

March 03, 2014

Name
Address 1
Address 2

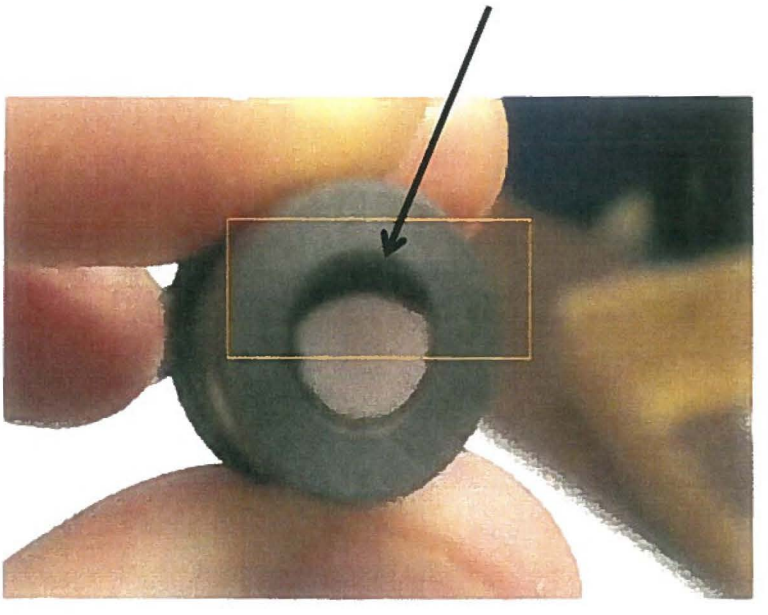
Dear Sir/Madam,

this letter is to inform you of a product recall involving:

Bluephase Style Pin-Point Light Probe

Article No.	Description	Batch No.
636 241	Light probe Pin-Point 6>2 mm, Style	all units

How to recognize your device is defect: There are dark areas in the glass rod as indicated below.



Ivoclar Vivadent AG
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Fürstentum Liechtenstein

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Telefax: +423 235 33 60
www.ivoclarvivadent.com

Bankverbindung:
Credit Suisse, Zürich
Konto: CHF 324526-71/BLZ 4835
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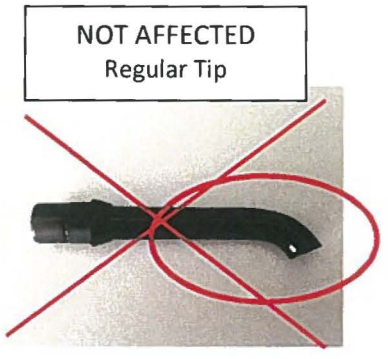
SWIFT: CRESCHZZXXX

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

Reason for the Voluntary Recall: Subject of this recall is an accessory to a dental curing light called Bluephase Style. The accessory is a pin point light probe which showed failure between the connector and the fiber bundle. After checking the units in stock it appeared that some of these light probes showed broken glass fibers, which can be seen as dark area in the above showed picture.

Only the Pin Point Probes are affected by this recall. The probe which came with your Bluephase Curing Light is not affected.



We began shipping this product to dental dealers in the US in February 2012.

Risk to Health:

The product is not affected by a defect that will affect the safety for the patient, user or third parties. The performance of the dental curing light is influenced by the light probe - in the Pin Point Probe, a reduction in light intensity output is possible.

Pin-Point light probes are suitable for the polymerization of confined areas, such as the attachment of veneers ("tacking") prior to excess removal. In the case of the affected Pin Point Probe, tacking may not be optimal. For thorough curing, it is necessary to change the light probe.

Actions to be taken:

- Please inform us by Email about the quantity you can remove from stock:

  Contact person: Mr. Alexander Schwaszta (alexander.schwaszta@ivoclarvivadent.com)

- Check your operatory and segregate any Pin Point Probes with the material number 636 241. Please stop using the device.

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- Please send all units with material number 636241 Light probe Pin-point 6>2mm black(Style) back to:

  Ivoclar Vivadent AG
  Mr. Alexander Schwaszta
  Benderer Str. 2
  FL-9494 Schaan
  Liechtenstein

Type of Action by the Company:

Until proper corrective measures are available, the Light Probe Pin Point Article no. 636 241 will no longer be available for sale. When returning the light probe please indicate if you prefer a replacement (when available; presumably August 2014) or provide us with your invoice number for a credit against other Ivoclar Vivadent products.

Other information:

This voluntary recall is the responsibility of the manufacturer Ivoclar Vivadent AG in Liechtenstein and we confirm it has been reported to the relevant authorities. Please communicate locally with Ivoclar Vivadent Customer Services for any questions.

Thank you in advance for your cooperation! We appreciate your understanding and would like to apologize for any inconvenience caused by this issue.

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Sincerely,

IVOCLAR VIVADENT AG

Patrik Oehri
Director – Corporate Quality Management

Enclosure

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