FL-9494 Schaan
E-mail: alexander.schwaszta@ivoclarvivadent.com

URGENT MEDICAL DEVICE RECALL

{Dealer Letter}

March 03, 2014

Name
Address 1
Address 2

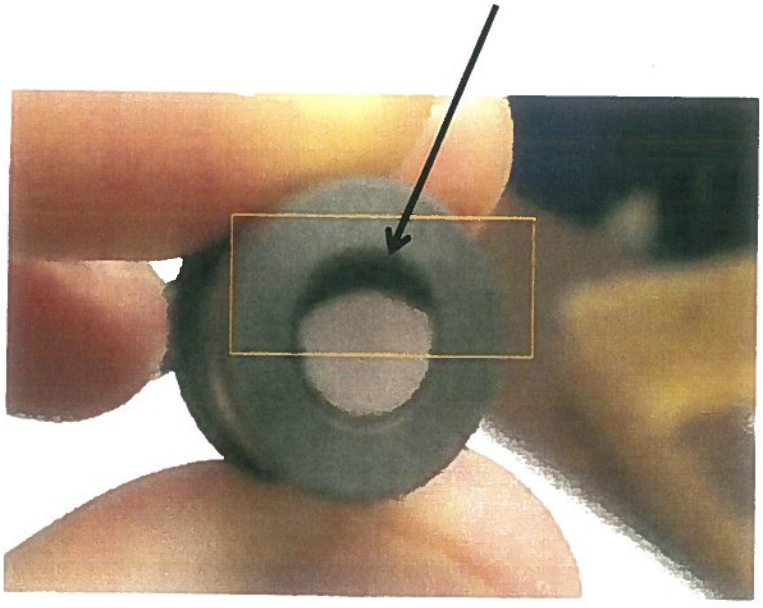
Dear Sir/Madam,

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

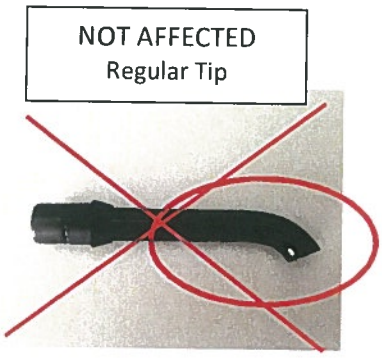
How to recognize your device is defect: There are dark areas in the glass rod as indicated below.



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 shows a 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 February 2012.

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 on stock it appeared that a large number of these light probes showed broken glass fibers, which can be seen as dark area in the above showed picture.

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 stock and segregate any Pin Point Probes with the material number 636 241. Please stop using the device.

Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
Fürstentum Liechtenstein

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

Bankverbindung:
Credit Suisse, Zürich
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

ivoclar vivadent
passion vision innovation

- 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

- 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.

Customer Notification - *Please indicate on the enclosed Dealer Acknowledgement and Receipt Form the manner in which you will agree to notify your dentist customers of this recall.*

This recall is intended to reach the end user of the device. If the product has been distributed by you, please check your records and identify your customers, notify them of the recall immediately, instruct them to stop using the product and to return all used and unused units as soon as possible. When you receive the product from your customers, please return it to Ivoclar Vivadent for credit.

Enclosed you will find a letter for use in notifying your customers regarding this issue. You may send the letter directly to your dentist customers or, **as a convenience to our dealer customers**, you may elect to provide us with a list of names and addresses of your dentist customers who may have received this product and we will undertake the necessary steps. Please forward an Excel spreadsheet with your customer names and addresses to alexander.schwaszta@ivoclarvivadent.com

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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.

Sincerely,

IVOCLAR VIVADENT AG

Patrik Oehri
Director – Corporate Quality Management

Enclosure

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