

Ivoclar Vivadent, Inc.  
175 Pineview Drive  
Amherst, New York 14228

Tel: 800-533-6825  
Tel: 716-691-0010



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**URGENT MEDICAL DEVICE RECALL**

{US Dentist Letter}

April 14, 2014

Name  
Address 1  
Address 2

Dear Sir/Madam,

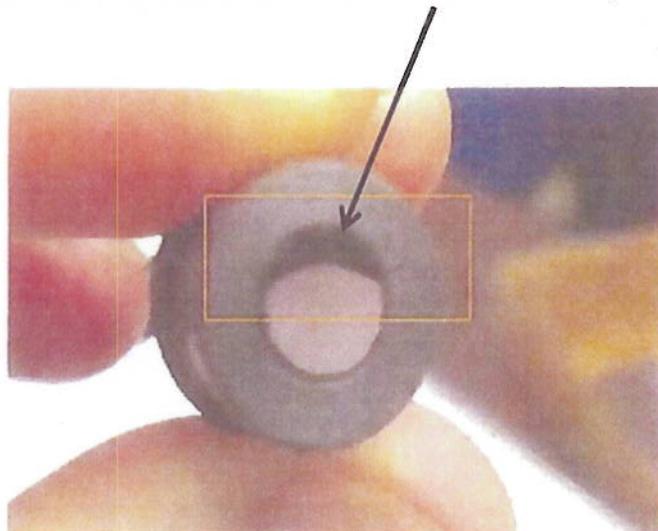
This letter is to inform you of a product recall involving:

**Bluephase Style Pin-Point Light Probe**

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

**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 a large number of these light probes showed broken glass fibers, which can be seen as dark area as in the picture below.

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



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### Device Labeling



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 and dentist in the US in February 2012.

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**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. In addition, there is a remote possibility of fracture of a Pin Point Light Probe due to the defect. In this unlikely occurrence, if the protective sleeve were not in use, the splinters are not sharp enough to cause injury.

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:**

- Complete, sign and return the attached acknowledgement form and return it to Ivoclar Vivadent via fax (716) 691-2294 or e-mail at [recall.us@ivoclarvivadent.com](mailto:recall.us@ivoclarvivadent.com)
- Check your operatory and segregate any Pin Point Probes with the material number 636 241. Please stop using the device immediately.
- Contact Ivoclar Vivadent Customer Service at 800-533-6825 as soon as possible between the hours of 9:00am and 7:00pm EST Monday through Friday and a representative will arrange to pick up your probes for return and credit.
- Both used and unused packages (no matter if dark areas as shown above can be identified) should be returned. Please mark the package "RECALL."

**Type of Action by the Company:**

Proper corrective measures are being undertaken and the Light Probe Pin Point Article no. 636 241 will again be available later in 2014 (presumably August). Since the date is not definite, and in order to minimize your inconvenience, Ivoclar Vivadent, Inc. is willing to provide the following in exchange for the return of your probe:

1. We will look to receive the completed acknowledgement form indicating you will be returning probe(s).
2. When the probe is received, a "free goods" coupon will be sent to the dental office with a value of US\$300. The coupon will provide instruction to allow you to order your choice of free goods from Ivoclar Vivadent, Inc.
3. When new pin-point probes become available in 2014, for those offices returning the device, a new probe will be delivered to your dental office.

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**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 at 800-533-6825 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, INC.

A handwritten signature in black ink, appearing to read "DMH", is written over a light blue horizontal line.

Donna Marie Hartnett  
Director QA/Regulatory Affairs

Enclosure

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**URGENT MEDICAL DEVICE RECALL  
MEDICAL DEVICE RECALL RETURN RESPONSE**

Dentist Acknowledgement and Receipt Form  
Response is Required

**Customer Information**

Account number \_\_\_\_\_  
Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Town, State, ZIP \_\_\_\_\_  
Phone number: \_\_\_\_\_

Dental Dealer/Branch \_\_\_\_\_

**Bluephase Style Pin-Point Light Probe Recall**

I have read and understand the recall instructions provided in the April 14, 2014 letter.

\_\_\_Yes \_\_\_No

{Check one}

\_\_\_\_\_ We do NOT have any stock of *Light probe Pin-Point 6>2 mm, Style:* \_\_\_\_\_

OR

\_\_\_\_\_ We are returning \_\_\_\_\_ {Quantity} units of *Light probe Pin-Point 6>2 mm, Style*

Any adverse events associated with the recalled product? \_\_\_Yes \_\_\_No

If yes, please explain:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Please return to:  
Attention: QA/Regulatory Affairs  
Ivoclar Vivadent, Inc.  
175 Pineview Drive  
Amherst, NY 14228  
Fax: 716-691-2294  
E-mail: [recall.us@ivoclarvivadent.com](mailto:recall.us@ivoclarvivadent.com)

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