

## MEDICAL DEVICE RECALL

June 2016

Dear Sir, dear Madam,

we hereby inform you, that as a precautionary measure, Ivoclar Vivadent AG is recalling the product listed below.

The affected polisher may suffer increased wear during use. In this case there is no increased health risk to patients, users or the environment. Further measures, e.g. for patients who have already been treated, are not necessary.

### We ask you to carry out the following measures:

- Please check your stock and secure the affected products and batch.
- Contact the author of this letter by email and inform them of the amount of stock secured in your warehouse.
- Please return all items of concern in your possession to:

Ivoclar Vivadent AG  
Ms Sandra Schwarzenberger  
Bendererstrasse 2  
FL-9494 Schaan

You will receive a credit note immediately.

Below you can find information about the amount of affected product which was delivered to you:

| Art. no.: | Description                             | Batch no. | Delivered quantity | Delivery date |
|-----------|---|-----------|--------------------|---------------|
| 634458    | OptraPol Small Flame                    | VL0704    |                    |               |
| 634462    | OptraPol PromoPack                      | VL0715    |                    |               |
| 634463    | OptraPol TestPack                       | UL0838    |                    |               |
| 634464    | OptraPol Assortment                     | VL0705    |                    |               |
| 634459    | OptraPol Cup Refill                     | VL0733    |                    |               |
| 634459    | OptraPol Cup Refill                     | UL0843    |                    |               |
| 680184AN  | Tetric N-Ceram System Kit A2/N Univ. 6g | V17591    |                    |               |
| 680184AN  | Tetric N-Ceram System Kit A2/N Univ. 6g | V19571    |                    |               |
| 680184AN  | Tetric N-Ceram System Kit A2/N Univ. 6g | V19572    |                    |               |
| 680184AN  | Tetric N-Ceram System Kit A2/N Univ. 6g | V19573    |                    |               |
| 680184AN  | Tetric N-Ceram System Kit A2/N Univ. 6g | V20677    |                    |               |

|          |   |        |  |  |
|----------|---|--------|--|--|
| 628244AN | Telio CS C&B Starter Kit A2             | V19582 |  |  |
| 664756   | Direct Restoratives Workshop Kit        | V19868 |  |  |
| 664703   | Composite Workshop Kit (Emp. Bulk Fill) | V20567 |  |  |

The batch no. (Lot) is on the product packaging:

Article no. 634458, 634462, 634464, 634459



Article no. 6344663



Article no. 680184AN



Article no. 664756



Article no. 664703



Article no. 628244AN



**Measures undertaken by the company:**

Additional quality controls were introduced to prevent a recurrence of this error.

**Further information:**

This voluntary recall is the responsibility of the manufacturer Ivoclar Vivadent AG, Liechtenstein. We confirm that this matter has been reported to the appropriate authorities.

We would like to thank you in advance for your cooperation and for your understanding. We apologize for any inconvenience caused to you by this matter.

Best regards

IVOCLAR VIVADENT AG

[Redacted]  
Patrik Oenn  
Director – Corporate Quality Management  
Safety Officer