

Address

Berneck, 4 July 2019

Batch recall of titanium tips

Name of the product concerned: TITANIUM TIP EASYTIP 2.2MM 30°

Article no.: VV800735A

Type of measure: Batch recall

Dear client

We herewith inform you that we have detected a malfunction in the TITANIUM EASYTIP 2.2MM 30°. The measure concerns solely titanium tips with article number VV800735A and it includes the following batches:

19.01000.01
19.01333.01
19.01772.01
19.02238.01
19.02878.01
19.03816.01
19.05388.01
19.05389.01

No other Oertli phaco tips are affected by this measure.

Problem description: Due to a manufacturing error, a tip breakage may occur when using the titanium tip. Usually, the tip breakage occurs during performance of the phaco test outside the eye, in rare cases, however, also during surgery. As a tip breakage can result in patient damage in very rare cases, we have decided to recall the affected batches.

As you may have received some affected products, please immediately proceed as follows:

1. Compare your inventory with the item name and number listed above and the batch numbers listed in the chart.

Article number, article designation and batch number (LOT) are shown on the label as follows:



2. Immediately **stop using** the affected products listed in this letter and remove them from your inventory. Note: Any other batches that are not affected by this recall can still be used.
3. Please fill in the enclosed answer form and send it back to us, even if you have no stock affected by this recall action. Oertli requires your information for coordination purposes with the supervisory authority.

Share this message with all persons within your institution who need to be informed of it and with any institutions that may have received the products concerned.

We regret any inconvenience that may arise and thank you for your cooperation in dealing with this recall. If you have any further information related to this batch recall, please get in touch with your Oertli contact person.

The authorities concerned have been notified of this batch recall.

Yours sincerely

Norbert Brill
QMB
Oertli Instrumente AG

Answer Form

Please fill in the form and return it to us no later than **19.07.2019** by fax or email to the address below:

Oertli Instrumente AG
Quality Management
Hafnerwissenstrasse 9
9442 Berneck
Switzerland

Email: quality@oertli-instruments.com

Fax: +41 (0)71 7474290

Batch recall of titanium tips

Please fill in the following chart:

Number	Batch no.	Used / disposed of / returned (please state)

We have no stock of titanium tips that is affected by this recall action.

Clinic / company _____

Postal code _____

Country _____

I confirm receipt of the batch recall. The information it contains has been forwarded to all users.

Name _____

Signature _____

Date _____