

Berneck, 13. December 2013

**Urgent Safety Note  
Product recall / field safety corrective action**

Article number: VV690311 / VV690211  
Article description: Silicone application set, sterile for Opsia syringe  
Product description: Application set for the injection of silicone oil  
by applying an Opsia syringe with Oertli OS3 or  
Oertli faros device family during retina surgery  
Oertli reference: CAPA 13.012

Dear Sir or Madam,

Oertli Instrumente AG has noticed that there is a considerable risk when injecting silicone oil by using the above-mentioned silicone application set if the intended Opsia syringes - as defined in the instructions for use - are not applied. We have learnt from the market that in most cases third party syringes with different dimensions rather than the intended Opsia syringe are used. There is no guarantee that the syringe can be safely connected to the connecting part if a third party product is used. The syringe can become undone from the connection or it can burst during application.

For safety reasons, we will therefore immediately withdraw the product from the market and cease trading it.

We ask you to bar any existing products for further use and to dispose of them. Please inform us of the number of units concerned by using the fax form. We will refund them in full.

The authorities concerned have been informed of this safety note.

The process stipulated by the supervisory authorities requires you to confirm **by 31.12.2013** that we have informed you of this recall. Please use the attached fax form when sending your confirmation to us.

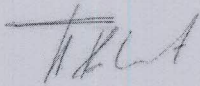
We ask you to forward this note within your company/establishment to all the persons who need to be informed as well as to all other persons who have received the product concerned.

If you are a distributor, please forward the information to your clients immediately and ask them to confirm reception of our information with the fax form attached **by 31.12.2013**.

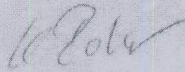
We sincerely apologise for the inconvenience caused and thank you for your cooperation in this matter.

Yours faithfully,

**Oertli Instrumente AG**



T. Bosshard  
Head of Marketing & Sales  
Member of the Executive Board



K. Rohr  
Head of Quality Management &  
Regulatory Affairs  
Member of the Executive Board