

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.

