

Urgent Field Safety Notice

Commercial name of the affected product: ala®octa
FSCA-identifier: 13.11.2015
Type of action: Recall

Date: November 13th 2015

Sender: alamedics GmbH & Co.KG, Hauffstrasse 21, D-89160 Dornstadt

Attention: distributor and user of ala®octa

Details and Identification of affected devices:

ala®octa	PFO 200612	PN: 101001, PN 101003
ala®octa	PFO 040712	PN: 101004
ala®octa	PFO 060912	PN: 101001, PN 101003
ala®octa	PFO 241012	PN: 101002
ala®octa	PFO 261112	PN: 101001, PN 101003
ala®octa	PFO 171212	PN: 101002, PN 101004
ala®octa	PFO 110213	PN: 101001, PN 101003
ala®octa	PFO 030713	PN: 101002, PN 101004
ala®octa	PFO 170713	PN: 101001, PN 101003
ala®octa	PFO 060813	PN: 101002, PN 101004
ala®octa	PFO 041213	PN: 101004
ala®octa	PFO 200114	PN: 101002, PN 101004
ala®octa	PFO 180214	PN: 101001, PN 101003
ala®octa	PFO 150414	PN: 101004
ala®octa	PFO 050514	PN: 101002, PN 101004
ala®octa	PFO 070714	PN: 101002, PN 101004
ala®octa	PFO 080714	PN: 101003
ala®octa	PFO 061014	PN: 101002, PN 101004
ala®octa	PFO 171214	PN: 101002, PN 101004
ala®octa	PFO 060515	PN: 101002

Description of the problem:

Since the cause of the toxic and unclear behavior of individual batches of ala@octa cannot be explained by in vitro cytotoxicity assays, alamedics stops distribution of the product and recalls all still existing products in market.

After the partial recall of ala octa from 07.13.2015, which has been completed now, as well as the complete recall from 11.13.2015, for following batches following information is available:

Following batches were tested as non-cytotoxic:

PFO 060813 Syringe
PFO 200114 Syringe
PFO 180214 Vial
PFO 180214 Syringe
PFO 150414 Syringe
PFO 050514 vial
PFO 050514 Syringe
PFO 070714 vial
PFO 070714 Syringe
PFO 080714 vial
PFO 080714 Syringe

Following batches which were tested according to DIN EN ISO 10993-5 with an incubation time of 24 h were evaluated as „no clear cytotoxic potential“:

PFO 061014 Syringe
PFO 171214 Syringe
PFO 060515 Vial

Following batches which were tested in an in vitro cytotoxicity assay according to DIN EN ISO 10993-5 with a long-term incubation (68-72 h) showed a cytotoxic effect:

PFO 110213 Syringe	(current available information from 2015-11-16)
PFO 061014 vial	(already recalled)
PFO 061014 Syringe	(already recalled)
PFO 171214 vial	(already recalled)
PFO 171214 Syringe	(already recalled)
PFO 210115 Syringe	(was not delivered)
PFO 060515 Vial	(already recalled)

Risks and their evaluation

Based on the previous observations it cannot be excluded that usage of ala@octa as intraoperative tamponade leads to postoperative decrease in visual acuity or to complete visual loss.

Therefore, it is required immediately to stop application of the product on patients.

Advise on action to be taken by the user:

- Immediate identification of ala@octa devices on site of the customer
- Immediate quarantining of all ala@octa devices on site of the customer (no further usage)
- Immediate return of all ala@octa via the local distributor to alamedics GmbH & Co. KG
- Immediate filling of the 'Confirmation from tob e sent back to the manufacturer'

Transmission of this Field safety Notice:

This notice needs tob e passed onto all those who need tob e aware within your organisation or to any organisation (customers) where the potentially affected devices have been transferred.

Provided that you delivered the products to a third party, please forward a copy of this information or inform the contact person stated below.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice an resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

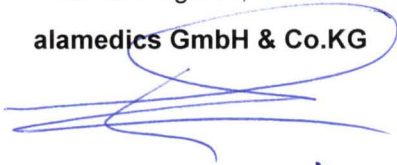
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The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

With kind regards,

alamedics GmbH & Co.KG



Dr. Christian Lingenfelder, Geschäftsführer