

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

Description of the problem:

On July 13th 2015 three LOT of ala@octa were recalled. The analysis of the cause of reported incidents which were linked to the ala@octa is still ongoing. Despite of comprehensive analysis of a variety of all produced ala@octa lots, which so far confirm high purity and conform biocompatibility (no in vitro cytotoxicity), alamedics recalls all ala@octa from all markets until the investigations are completed to protect all 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 form to be sent back to the manufacturer'

Transmission of this Field Safety Notice:

This notice needs to be passed onto all those who need to be 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 and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Dr. Christian Lingenfelder
General Manager
alamedics GmbH & Co.KG
Hauffstr. 21
D-89160 Dornstadt

Fon: +49 (0) 7348 4 07 70 11 Fax: +49 (0) 7348 4 07 70 20 Christian.Lingenfelder@alamedics.de

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

alamedics GmbH & Co. KG – Hauffstrasse 21 – 89160 Dornstadt, Germany

With kind regards,

alamedics GmbH & Co.KG



Dr. Christian Lingenfelder, CEO