

Recall

i-Visc 1.0; Batch: 13M27

Dear Customer,

i-Medical Ophthalmic International GmbH has supplied you with the following article:

i-Visc 1.0

Batch: 13M27

We have received a notification from the market that inflammations / Fibrin secretions have occurred in connection with the use of the above product from the above batch.

We have therefore decided to recall the affected batch to avert any risk to patients.

Please do not use any more products from the affected batch and block all stocks.

Please prepare existing stocks for collection and notify our Sales Department to arrange the collection.

Please complete the enclosed recall questionnaire to document the recall, and return it by e-mail / fax / post to:

I-Medical Ophthalmic International GmbH
Wieblinger Weg 100
D-69123 Heidelberg
Tel. +49 (0) 6221-75 00 30-0; Fax +49 (0) 6221-75 79 79 od. info@imedical.de

We regret this incident, and would like to thank you for your understanding and cooperation in this matter.

With kind regards
i-Medical Ophthalmic International GmbH

Field Safety Corrective Action – Questionnaire

Customer:

Customer no.:

Address:

The purpose of this questionnaire is to ensure as part of the corrective measures that no goods delivered to you by I-Medical Ophthalmic International GmbH, and recalled, are no longer in your possession, and that the goods were returned to the manufacturer in accordance with its instructions.

If you have passed on the recalled products to third parties, you are requested to notify them accordingly, using our recall letter, and to ensure that all such products supplied to third parties are also recalled and returned to us. The recall of products supplied by you to third parties must be documented.

The following products affected by the recall have been supplied to you:

Qty.	Delivery note no. Delivery date	REF	Article designation	Batch

The undersigned confirms

- that he is no longer in possession of any of the products listed above,
- that he has not supplied any products to third parties,
- that he has notified third parties of the recall, if they have received recalled products from him,
- that he will return to the manufacturer all above products supplied to him, which are still in his possession, or that of third parties, in accordance with the manufacturer's instructions.

Please enter the returned products, specifying the quantity and batch no., in the following table:

Qty.	Delivery note no. Delivery date	REF	Article designation	Batch

Please notify

I-Medical Ophthalmic International GmbH
Wieblinger Weg 100
D-69123 Heidelberg
Tel. +49 (0) 6221-75 00 30-0; Fax +49 (0) 6221-75 79 79

to arrange for the collection of the goods.

Date: _____

Signature: _____

Name (in block letters): _____

Stamp: