

Urgent Safety Information

Stop of use:

i-Visc ® 1.0 Sodium Hyaluronate

i-Visc ® 1.4 Sodium Hyaluronate

i-Visc ® 1.6 Sodium Hyaluronate

i-Visc ® 2.0 Hydroxypropyl Methylcellulose

8th May 2014

Sender:

i-Medical Ophthalmic International Heidelberg GmbH
Markircher Str. 7
68229 Mannheim

Addressee:

Practice
Street + No.
Postcode
Town

Dear Customer,

As a result of knowledge acquired from observing the market, we have decided to stop the use of the following medical productions in coordination with the supervisory authorities:

Identification of affected medical products:

i-Visc ® 1.0 sodium hyaluronate viscoelastic solution for intraocular application

Batch no: 11F11, 11M68, 12E25, 12J57, 13A06, 13H88

i-Visc ® 1.4 sodium hyaluronate viscoelastic solution for intraocular application

Batch no: 11M69, 12E24, 12M91, 13D41, 13K06

i-Visc ® 1.6 sodium hyaluronate viscoelastic solution for intraocular application

Batch no: 11M67, 12D10, 12F33, 12L82, 13D39, 13G75

i-Visc® 2.0 hydroxypropyl methylcellulose viscoelastic solution for intraocular application

Batch no: 11G33, 11M66, 12C04, 12G46, 12L72, 13B21, 13D37, 13H87, 13L23

Description of the problem including determined cause:

As the manufacturer of the afore-mentioned product, i-Medical Ophthalmic International Heidelberg GmbH arranged extensive testing and established that in retained samples the endotoxin limit was exceeded in some of the already recalled batches and batches in the i-Visc® product range not affected by this action. As a result, we have been able to establish the probable cause for incident reports on these batches. In addition, one batch (BATCH: 13M37 i-Visc® 1.6 sodium hyaluronate) had positive findings in the sterility test and there was evidence of the growth of aerobic and anaerobic bacteria. Despite normal endotoxin tests and sterility tests with retained samples from the afore-mentioned batches, at the current time it cannot be completely ruled out that individual products from these batches in the i-Visc product range are affected by problems, which is why we have decided to stop the use of these batches as a precautionary measure.

If the specific product exceeds the limit there is a risk of irritation, intraocular inflammatory reactions and/or the discharge of fibrin when using this product in the eye. In individual cases, it may also result in iris hyperaemia, hypopyon and/or corneal oedema.

What measures must be taken by the addressee?

We ask you to immediately block access to any stock of the afore-mentioned products and stop using the afore-mentioned products with immediate effect to avoid any risk to patients. Please separate the affected medical products from your stock.

As a user of our product we recommend that if the affected products i-Visc® 1.0, 1.4, 1.6 sodium hyaluronate or i-Visc® 2.0 hydroxypropyl methylcellulose were being used recently by patients you check the patient's eyes for any inflammation and immediately treat with a topical or systematic therapy, if necessary administering local or oral steroids or antibiotics.

Forwarding the information provided here

Please ensure within your organisation that all users of the afore-mentioned products and any other people that have to be informed receive notice of this **urgent safety information**. If you have passed the products on

to third parties, please forward them a copy of this information or inform the contact person below.

Please keep this information somewhere safe at least until the action has been concluded.

The Federal Institute for Drugs and Medical Products has received a copy of this "Urgent Safety Information".

Contact person:

i-Medical Ophthalmic International Heidelberg GmbH
Markircher Str. 7
68229 Mannheim
Tel.: +49 (621) 48 44 90-0 ; Fax +49 (621) 48 44 90-20
Email: info@imedical.de

We sincerely regret this incident and thank you for your understanding and cooperation in this matter.
We have arranged additional quality assurance measures and will be able to supply the product again soon.

Yours sincerely,

i-Medical Ophthalmic
International Heidelberg GmbH