First Quality
in Ophthalmology

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Adress

17. Februar 2017

Field Safety Notice

Voluntary field Safety Corrective Action:

Pseudophagic intraocular lens A4SW00 Acrylic IOL, AddOn, Spherical, hydrophilic, clear; -10,0 D to +10,0 D

Dear Sir or Madam,

With this letter we inform you about the voluntary recall of spherical AddOn intraocular lenses (IOL), article number: A4SW00.

1stQ has identified involved articles in your organization as listed in attachment.

Description of the problem and the identified cause:

1stQ conducts this recall, after few single cases of fibrin reactions after the implantation of spherical AddOn lenses have been reported.

These single cases, correlated to the entire amount of spherical AddOn IOL implanted, do not necessarily indicate that the AddOn IOL is the cause of the fibrin reaction.
Due to the symptoms described, TASS (toxic anterior segment syndrome) is likely to be the reason for the fibrin reaction. TASS is described as an inflammatory reaction restricted to the anterior eye chamber, which is caused by noninfectious foreign particles within the eye [1,2]. The cases described in literature identify different products for cataract-surgery as reasons for TASS. Therefore it is currently difficult to specify the definite cause.

In order to exclude any risk for patients, all spherical AddOn IOLs listed in table 1 are recalled. The recall applies only to spherical AddOn IOLs, which have been produced from a particular lot of hydrophilic acrylate.

Toric and progressive AddOn intraocular lenses are not affected by the recall.

Required Measures

Block all lenses with the mentioned serial numbers. In case one of those lenses has been implanted already, it is recommended, to observe the patient one month post-operatively. If no symptoms are observed, no further measures have to be taken.

If any TASS cases occur, please report this to either us or the responsible health authority.

Please return all acrylic IOLs, AddOn, spherical, hydrophilic, clear, A4SW00, possessing a serial number listed in attachment and the completed response form to the following address:

Contact data:

1stQ GmbH
Dr. M. Kirchenbauer
Harrlachweg 1
68163 Mannheim
Germany

You can return the completed response form via Fax: 0049 (0)621 71763-33 or Email: kirchenbauer@1stq.de.

Replacement or credit will take place after consultation.

1stQ GmbH apologizes for any inconveniences, occuring in relation to this measure. 1stQ GmbH has emphasize on high quality standards, so that this measure will be conducted with utmost care.

Distribution of relevant information:

Please ensure, that all users and relevant persons in your organization are informed about this field safety notice. In case you distributed this product to a third party, forward a copy of this FSN or inform the contact person indicated below.

Notification to authorities

1stQ GmbH has informed the responsible national authority.

Kind regards

Dr. M. Kirchenbauer

[1] Lucien A. M. van Philips; Toxic Anterior Segment Syndrome after Foldable Artiflex Iris-Fixated Phakic Intraocular Lens Implantation; Journal of Ophthalmology; Volume 2011, Article ID 982410, 5 pages

[2] Kremer I et al; Toxic anterior segment syndrome following iris-supported phakic IOL implantation with viscoelastic Multivisc BD.; Eur J Ophthalmol. 2010 Mar-Apr;20(2):451-3.

Please complete the response form with listed items in the attachment.

Name and titel of the person completing the form:

Organisation:

Please return the completed form via Fax: 0049 (0)621 71763-33 or Email: kirchenbauer@1stq.de