



رقم المحفوظات: ٨١٢٥  
رقم الصادر: ٢٤٠١٤  
بيروت، في: ٢٤/١٤/٢٠١٣

### جانب نقيب المستشفيات الخاصة في لبنان

#### الموضوع: إشعار بمتابعة جهاز طبي

Implants, non active, intraocular lens, Hoya-AF-1 iMICS1, AF-1 toric, iSERT and iSERT toric

#### الجهاز المعنى بالمتابعة:

- Implants, non active, intraocular lens, Hoya-AF-1 iMICS1, AF-1 toric, iSERT and iSERT toric
- Trade Mark: Hoya Corporation
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة، والتي تشير الى وجود مضاعفات جراء استعمال الصنف

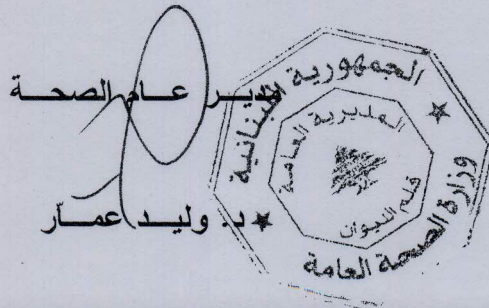
الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

#### مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة

#### يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



## **URGENT – FIELD SAFETY NOTICE**

22nd February 2013

Certain HOYA One-Piece Intraocular Lenses

| <b>Model</b> | <b>Description</b> | <b>Serial Numbers</b>         |
|--------------|--------------------|-------------------------------|
| NY-60        | HOYA AF-1 iMICS1   | see attachment of this notice |
| 311          | HOYA AF-1 Toric    | see attachment of this notice |
| 250 and 251  | HOYA iSert®        | see attachment of this notice |
| 351          | HOYA iSert® Toric  | see attachment of this notice |

**FSCA – Ident No. FSN13-02-2013**

**Type of Action: Voluntary Recall**

Dear

Last month, HOYA Surgical Optics announced a voluntary suspension of shipment of five of our products while we investigated reports of higher than expected rates of inflammation and/or endophthalmitis from doctors using NY-60, iSert® 250 and iSert® 251 IOLS in a few countries. The patient data shared with us showed sterile, resolved reports without any permanent injury following appropriate treatment in all but very few cases.

An extensive review of our manufacturing process revealed that some products had trace residual foreign particulates on them. We have been unable to definitely determine if they were linked to the adverse events but the potential may exist. Therefore, as a precaution, effective immediately, we are initiating a voluntary recall of NY-60, iSert® 250 and iSert® 251, Toric 311, and iSert® Toric 351. Although no adverse events have been reported with the toric lenses, we included them because they follow a similar manufacturing process and we want to ensure that you receive only the highest quality IOLs. No other HOYA IOLs, in particular no Three-Piece IOLs, are affected by this voluntary recall initiated by HOYA.

We are notifying the appropriate regulatory agencies of this action and working closely with various ophthalmic professional associations. We are also implementing manufacturing improvements to prevent a similar issue in the future. Once regulatory approval is received, we plan to resume this manufacturing of all five products as soon as possible. We apologise for any inconvenience this may create and sincerely appreciate your co-operation and support as we work through this issue.

**What you should do:**

- Please **STOP** usage of the attached list of IOLS and **RETRIEVE** all of them from your stock.
- This notice needs to be passed on to all those who need to be aware within your organisation or any other organisation where the devices have been transferred.

- Please complete the attached list accordingly and make a cross according to your action per each listed serial number and send the completed list via Fax to 01625 619959.
- Please return the completed attachment within the **next 5 working days** due to requirements of the national competent authorities, **even if you have none of the affected IOLs** in your inventory.
- Please maintain awareness of this notice and resulting action for an appropriate period to assure effectiveness of the corrective action.
- We are urgently requesting from Hoya details of its recommendations in relation to any patient already implanted with one of the lenses included in this recall. We will let you know just as soon as we have this information. In the meantime, we can confirm that, in the UK, we are aware of no reports of any cases of inflammation and or endophthalmitis associated with the IOLs we have distributed. Hoya has also stated that outside the UK, there is no evidence, and they have received no reports, of any new cases of inflammation and or endophthalmitis associated with the IOLs that have been implanted for six (6) months or longer.

Please return the affected IOLs back to:

Spectrum  
Unit H5  
Redwood Court  
Springwood Way  
Macclesfield  
Cheshire  
SK10 2XH

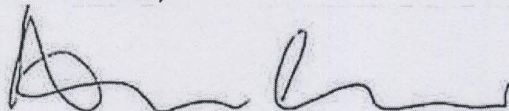
In case of questions with regard to product return, please contact Spectrum Customer Services on 01625 618816.

In case of complaints or adverse events in connection with the recalled IOLs, please contact Spectrum Customer Services on 01625 618816.

We are aware of the inconvenience this voluntary recall creates and gratefully acknowledge your support and efforts in sending back the completed form and IOLs listed in the attached table at your earliest convenience.

HOYA Surgical Optics strives to always provide exceptional customer care. This voluntary recall is an expression of our commitment to the highest quality standards and our desire to fully meet your needs at all times. If you have any questions or if there is anything we can do to assist you, please contact us.

Yours sincerely



Andrew Geddes  
Director