

<<Customer Information>>

URGENT: FIELD SAFETY NOTICE

Date: 28th October 2013

**Commercial Name of
Affected Product:** Alcon AcrySof® CACHET® Phakic Lens

FSCA Identifier: 06.02.2012

Type of Action: Shipment Suspension and Action Plan

Dear Healthcare Professional,

This letter is being provided to update our healthcare professionals on the actions Alcon is taking concerning the Alcon AcrySof® CACHET® Phakic Lens. This is further update to the communications Alcon issued in February 2012, July 2012 and March 2013. The CACHET® Phakic Lens is a CE marked medical device marketed by Alcon since 2008 and is available in approximately 70 countries for the treatment of patients with moderate to severe myopia.

Description:

The AcrySof® CACHET® Phakic Lens clinical data showed high efficacy as defined by visual acuity, but a small subset of patients (approximately 1.6% of implanted lenses to date) showed a risk for accelerated corneal endothelial cell loss (ECL) that led to the need for explantation of the lens. Based upon the further analysis of the clinical data, the evaluation by Medical Advisory Boards, and the feedback from various Health Authorities, Alcon is now prepared to implement the below activities related to the AcrySof® CACHET® Phakic Lens to ensure physicians have the information they need to appropriately treat and monitor patients, and that patients can make an informed choice about their treatment.

As previously instructed, strict patient monitoring and follow-up will also be emphasized, per the DFU (one, three and six months following surgery, and every six months thereafter).

Advise on Actions to be taken by the User:

1. Physicians should become familiar with the updates to the AcrySof® CACHET® Phakic Lens Directions for Use (DFU)(Revision 5):

- Slight adjustment of the minimal endothelial cell density (ECD) requirements based on the completion of the 5 year clinical studies

Before		Revision	
Age	Minimum Cell Density (cells/mm ²)	Age	Minimum Cell Density (cells/mm ²)
21 - 25	3750	21 - 25	3700
26 - 30	3300	26 - 30	3250
31 - 35	2900	31 - 35	2850
36 - 40	2500	36 - 40	2500
41 - 45	2200	41 - 45	2150
≥ 46	2000	≥ 46	2000

- The Warnings and Precautions sections were updated with additional guidance.
 - Warning #1 was added to emphasize the importance of careful measurement of the anterior chamber for selection of the appropriate IOL size.
 - Warning #8 was added to indicate a higher trend of endothelial cell loss (ECL) in two sub-populations, based on clinical data.
 - Warning #6 was revised to provide additional guidance on when to conduct more frequent monitoring.
 - Precautions #1 and #5 were revised to contain language describing the new patient and physician information materials.
- A new section of data, Tables 20 to 23, was included on the long-term follow-up study to support the warning regarding the ECL trend in two sub-populations.
- A new section of data was included on the post-market experience with CACHET

2. Physicians should be aware of and utilize the Alcon developed patient and physician information materials, including a patient brochure and patient acknowledgement of risk form. This material will be made available to physicians by local Alcon representatives beginning in November 2013.

3. Physicians should be aware of the more formalized access program, which includes verification of surgeon training of the proper use of the product as well as confirmation of a patient's qualifications. Training and details on the ordering process will be made available to physicians by local Alcon representatives beginning in November 2013.

Alcon expects the voluntary shipment hold of its AcrySof® CACHET® Phakic lenses to be lifted by the end of the year, and at that time, product will be available for order under a revised process. We expect to make the lenses available to trained surgeons in countries with CE marking by the end of 2013.

Details on affected devices:

This notice relates to all models (L-series) of the Alcon AcrySof® CACHET® Phakic Lens.

This notice does not affect the AcrySof® family of intraocular lenses (including monofocal IOLs; Toric IOLs; ReSTOR® family of Multifocal and Multifocal Toric IOLs) that are indicated to treat cataracts and are intended as a replacement for the human crystalline lens and implanted in the capsular bag.

Transmission of this Field Safety Notice:

Please forward this information to all departments within your organization who may be using the Alcon CACHET® Phakic Lens. Additionally, please ensure that a copy of this notification is provided to any other organization to which the product may have been transferred.

Contact reference person:

Alcon appreciates your attention to this matter and hopes this notice reassures you of our commitment to providing you with the most up-to-date information about our products for you and your patients.

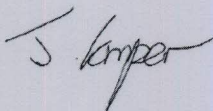
Please sign this Field Safety Notice for confirmation that you understand the issue and will follow the information provided. The signed letter should be returned to Alcon at:

James Comper,
Regulatory Officer UK & Ireland,
Alcon Eye Care UK Ltd,
Park View,
Watchmoor Park,
Camberley,
Surrey, GU15 3YL.
United Kingdom

Should you have any questions or concerns about this matter, please contact Alcon Medical Information at:

Telephone: +44 (0) 871 376 1402
E-mail: GB.ADR@alcon.com

Yours sincerely



James Comper

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