<<Customer Information>>

<<Date>>

FIELD SAFETY NOTICE

Commercial Name of Affected Product:	**Alcon AcrySof® CACHET® Phakic Lens**
FSCA Identifier:	**06.02.2012**
Type of Action:	**Product Discontinuation**

Dear Healthcare Professional,

This letter is 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 has previously issued in February 2012, July 2012, March 2013 and October 2013, where we described updates to the directions for use (DFU) and advised healthcare professionals of an acute adverse event for endothelial cell loss (ECL). 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.

National Competent Authorities have been advised of this notice.

Description:

Alcon is committed to the safety of our patients and our products. As part of this commitment, we are voluntarily discontinuing the CACHET® Phakic Lens based on data analysis from an ongoing 10-year study to evaluate the safety of the CACHET® Phakic Lens in patients with myopia (near-sightedness) from -6.0 to -16.5 D vision correction.

The clinical data analysis indicates an increase in the number of cases of endothelial cell loss (ECL). In the clinical study, patients' endothelial cell density (ECD) levels are monitored at 6 month intervals, as recommended by the current CACHET® Phakic Lens directions for use (DFU). To date, only 2.7% of the 1,323 CACHET® Phakic Lenses implanted in the clinical study were explanted due to ECL. None of these explanted patients experienced permanent vision loss.

Patients with the CACHET® Phakic Lens should continue with the ongoing monitoring and evaluation outlined in the current DFU. In cases where an explant is warranted in

accordance with the criteria set out in the DFU, Alcon will work with the treating ophthalmologist to ensure that the affected patients receive an explant without incurring out-of-pocket costs.

Details on affected devices:

This notice relates to all models (L-series) of the 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 intended as a replacement for the human crystalline lens and implanted in the capsular bag.

Advice on action to be taken by the user

Alcon is voluntarily discontinuing the CACHET® Phakic Lens and it will no longer be available.

The CACHET® Phakic Lens is typically ordered on an as-needed basis and is not a normal inventory item for a healthcare professional. If a healthcare professional does have inventory of the CACHET® Phakic Lens, these lenses can be returned to Alcon for reimbursement. Please contact your Alcon representative for details.

For patients with the CACHET® Phakic Lenses already implanted, Alcon recommends adherence to the monitoring requirements described in the current DFU. Adherence to these requirements by patients will help to timely identify significant ECL and determine the appropriate treatment plan. In cases where an explant is warranted in accordance with the criteria set out in the DFU, Alcon will work with treating ophthalmologist to ensure that the affected patients receive an explant without incurring out-of-pocket costs.

Transmission of this Field Safety Notice:

Please forward this information to all departments within your organization who may be using the 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,
Senior 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) 345 266 9363
E-mail: gb.medicaldepartment@alcon.com

Yours sincerely

James Comper

Senior Regulatory Officer
Alcon Laboratories (UK) Ltd.
Direct Tel: +44 (0)1276 673374
E-mail: james.comper@alcon.com

FIELD SAFETY NOTICE

Commercial Name of Product	**Alcon AcrySof® CACHET® Phakic Lens**
Identifier/Date	**06.02.2012**
Type of Action	**Product Discontinuation**

Alcon is requesting that customers sign and return a copy of the last page of this communication in order to acknowledge the receipt and understanding of the information. Please send to Alcon at:

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

Fax: +44 (0)1276 673971
E-mail: gb.medicaldepartment@alcon.com

I have read this notice and understand that Alcon is discontinuing the CACHET® Phakic Lens and that patients with the CACHET® Phakic Lens should continue with the ongoing monitoring and evaluation requirements as outlined in the current DFU.

_____

Customer's Signature

_____

Customer's Name (Please Print): Date