Alcon

<<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):