URGENT FIELD SAFETY NOTICE

February X, 2016

FSCA-identifier

Limited Voluntary Recall of Two Lots of AcuFocus KAMRA™ ACI 7000 Corneal Inlay

Details on Affected Devices:

Product Name: AcuFocus KAMRA ACI 7000 Corneal Inlay

Product Numbers	Lot Number
76195-01, 76195-10	A534-1014
76195-01	A535-1014

Dear Customer:

AcuFocus, Inc. is voluntarily recalling two (2) lots of KAMRA ACI 7000 Corneal Inlays due to concerns with the labeled shelf life. Only the two (2) lots identified in the table above (A534-1014 and A535-1014) are impacted.

Due to a secondary processing which occurred during the manufacture of these units, an incorrect shelf life was assigned to the product. The incorrect labeled expiry date does not pose a patient safety risk based on data available; however, in an abundance of caution, AcuFocus is retrieving the two (2) lots of KAMRA inlays from the market. No other lots of KAMRA inlays manufactured and distributed by AcuFocus are affected by this recall action.

This recall only affects the two (2) specific KAMRA inlay lots identified above. The lot number is displayed on the printed label of each unit carton. The lot number also appears on the tray label of each individual device and patient labels.

Advice on action to be taken by the user:
If you have implanted an inlay from one of these lots in a patient, no specific action is to be taken; however, AcuFocus, Inc. is providing the following guidance:

- Report any abnormal appearance of the implanted KAMRA inlay to AcuFocus, Inc.

Please undertake the following actions related to your inventory:

1. **STOP** using and remove from your inventory **all affected** KAMRA inlays identified from the above referenced lot numbers.
2. Complete and return the attached **Customer Recall Response Form** as AcuFocus, Inc. requires this information for reconciliation purposes with regulatory agencies. Please complete and return the attached Recall Response Form within the next 3 business days **EVEN IF YOU HAVE NO INVENTORY** affected by this recall.
3. Return the product to the AcuFocus address communicated by the AcuFocus Customer Service Representative, including a reference to the RMA number.

Transmission of this Field Safety Notice:

This notice shall be communicated to any customer or organization where the affected devices have potentially been transferred or further distributed.

If you have product complaint events to report regarding the KAMRA™ inlays involved in this recall event, please inform AcuFocus, Inc. by calling +1 (949) 585-9511 ext 608. If you have any questions related to the return process, please contact an AcuFocus Customer Service Representative at +1 (949) 585-9511 ext 608.

This voluntary action reflects AcuFocus, Inc.'s commitment to high quality standards and ensuring that our products fully meet your expectations. AcuFocus, Inc. remains fully committed to serving you and your patients with safe and effective products. We recognize the inconvenience this causes you and appreciate your assistance in expediting the return of this product.

Sandra Selvaggi
Senior Director, Quality and Manufacturing Systems
AcuFocus, Inc.

AcuFocus™

CUSTOMER RECALL RESPONSE FORM

To: Customer

Re: AcuFocus KAMRA™ ACI 7000 Corneal Inlay

Product Numbers	Lot Numbers
76195-01, 76195-10	A534-1014
76195-01	A535-1014

Please check ALL appropriate boxes EVEN IF YOU HAVE NO STOCK.

☒ I have read and understood the recall instructions provided in the Feb X, 2016 letter.

☒ I have checked my stock and have quarantined inventory totaling 0 units.

☒ I will be returning 0 units.

Indicate the disposition of recalled product:

Product Code	Description	Lot Number	Quantity Shipped to you	Quantity to be Returned
76195-01	KAMRA Inlay	A534-1014	0	0
76195-10	KAMRA Inlay	A534-1014	0	0
76195-01	KAMRA Inlay	A535-1014	0	0

Account Name: [redacted]

Address: [redacted]

Contact Name:

Telephone Number: [redacted]

Signature: [redacted] [redacted]

Name *Date*

PLEASE RETURN **COMPLETED** RESPONSE FORM TO ACUFOCUS:
E-mail: customerservice@acufocus.com
Fax: +1 (949) 585-9545 Attn: Recall Coordinator
Mail: AcuFocus Inc., Attn: Recall Coordinator, 32 Discovery, Suite 200, Irvine, CA 92618, USA

AcuFocus, Inc. will issue an RMA # and reply to you with the number and shipping instructions.