
URGENT FIELD SAFETY NOTICE

RECALL AND FIELD CORRECTION TO FOCUS FORCE Intraocular Lens

Trade Mark: FOCUS FORCE

LOT number: 15071

Models: AS60125, AS60130, F260, UF60130, A100

January 12, 2017

Re: FOCUS FORCE Intraocular Lens

FSCA-identifier: 002/AS60130/17.00

Models: AS60125, AS60130, F260, UF60130, A100

Lot numbers of affected product shipped to you: 15071

Please Note: This recall is limited to LOT number 15071 only and does not affect other lots shipped to your facility.

Dear Customers,

A trade mark FOCUSFORCE intraocular lenses with a lot number of 15071, an issue has been encountered for dioptr deviation which comes from labelling process. The patient's vision can be adversely affected if the patient does not have proper lens dioptr. As a consequence of this situation, no patient has been reported to be seriously injured. However, this may require medical or surgical intervention in case that patient's vision function or structure is permanently damaged.

The product label is shown below to assist you in identifying the product within your facility.

XXXXX

This action represents a product recall and we have notified the appropriate authority of this recall.

The problem which comes from labelling process; fixed. To avoid this situation, do not use the intraocular lenses with 15071 lot number in your inventory. These lenses will be replaced with new lenses. These products will be collected in the recall process.

We kindly recommend you to read this notice carefully and complete the following activities.

1. Check your stocks immediately for the 15071 LOT number.
2. Hold all products in safety position and return the existing products to PLEASE CUSTOMIZE FOR YOUR COUNTRY
3. Send this field safety notice to all interested parties within the organization.
4. If the product with this lot number is implanted in the patient; please inform Anadolu Tıp Teknolojileri A.Ş. for any adverse event.
5. Please fill out the below customer response form and send to following e mail address. pkaymak@anadolutip.com.tr as well as to: PLEASE CUSTOMIZE FOR YOUR COUNTRY

Please use the contact information below for any problems and feedback.

We kindly ask you to respond within 7 calendar days of the receipt of this notification. We thank you for your interest and we apologize for the inconvenience.

With Best Regards.



Anadolu Tıp Teknolojileri A.Ş.
Organize Sanayi Bölgesi No:10 Merkez,
Sivas/Türkiye
P:+90 346 218 14 18
F: +90 346 218 14 20
pkaymak@anadolutip.com.tr

Recall and Field Correction Acknowledgement Form

Product Details

FOCUS FORCE Intraocular Lens

Models: AS60125, AS60130, F260, UF60130, A100

Lot numbers of affected product shipped to you: 15071

PRODUCT TRACEABILITY				
MODEL	LOT NO/SERIAL NO	RETURN UNIT QUANTITY	IMPLANTED UNIT QUANTITY	FOLLOW UP PATIENT QUANTITY

I have received a declaration from Anadolu Tıp Teknolojileri A.Ş. stating that they have started field activities for the above mentioned products / products and approve the following document.

Filled By:			
Hospital/Firm/Site		Telephone	
Address		Fax	
Date		E-mail	
Signature			