



GULF MEDICAL CO. LTD
Adr 2
ALI BIN ABI TALEB STREET, SHARAFIAH
21455 JEDDAH
Saudi Arabia

Ettlingen, xx. September 2011

Urgent Field Safety Notice

AMO Sensor® Intraocular Lenses (IOLs),

Model	Description	Serial Numbers
AR40e	Sensor® Foldable IOL with OptiEdge	See page 4 of this letter

FSCA-identifier FSN2011-11

Type of action: Voluntary Recall

Dear AMO Customer

Abbott Medical Optics Inc. (AMO) is voluntarily recalling a limited number of Sensor IOLs. AMO is initiating this voluntary recall because of a possibility that two specific production orders of Sensor IOLs contain IOLs labeled with the incorrect diopter power. This recall affects one production order of 21.5 diopter IOLs (96 IOLs total) and one production order of 6.0 diopter IOLs (83 IOLs total). A mislabeled IOL could lead to potential unexpected postoperative refractive error and may result in an IOL explant.

This recall only affects the specific Sensor IOLs, Model AR40e, with the serial numbers listed on page 3. No other AMO IOLs are affected by this recall action. Sensor IOLs that have been successfully implanted are not affected by this recall.

Please undertake the following actions:

1. Review your inventory of Sensor IOLs to identify any **affected** serial numbers, using the list on Page 3 of this letter.
2. **STOP** using and remove from your inventory the **affected** Sensor IOLs.



3. Complete and return both pages of the included Facsimile Form as AMO requires this information for reconciliation purposes with regulatory agencies. Please indicate the status of each affected serial number on the form. Please complete and return the attached Facsimile Form **EVEN IF YOU HAVE NO INVENTORY** affected by this recall.

The IOL serial number is displayed on the end of each individual unit carton. The IOL serial number is also present on the IOL lens holder within the package.

If you have inventory of Sensor IOLs to return, please complete both pages of the Facsimile Form, listing the serial numbers of Sensor IOLs to be returned to AMO. The completed Facsimile Form should be faxed to AMO Quality Assurance at **+353 1675 4660** within the next **3 business days**.

The product should be returned to the address below:

**Abbott Medical Optics,
c/o Wincanton Mondia,
9 Rue de Chalon sue Saone,
67000 Strasbourg,
France**

If you have any questions related to the Sensor IOL return process, please contact an AMO Customer Service Representative at +353 1643 6272.

If you have product complaints or adverse events to report regarding the use of Sensor IOLs, please inform AMO by calling +353 1643 6272. If you do report a complaint, please provide the IOL serial number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.

This voluntary action reflects AMO's commitment to high quality standards and ensuring that our products fully meet your expectations. AMO 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.

Yours sincerely,

AMO Germany GmbH

i.V.

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AMO Sensar® Intraocular Lenses
Serial numbers affected by this recall:

AR40e IOLs, 6.0 Diopter	
5185681009	5186101009
5185691009	5186111009
5185701009	5186121009
5185711009	5186131009
5185721009	5186141009
5185731009	5186151009
5185741009	5186161009
5185751009	5186171009
5185761009	5186181009
5185771009	5186191009
5185781009	5186201009
5185791009	5186211009
5185801009	5186221009
5185811009	5186231009
5185821009	5186241009
5185831009	5186251009
5185841009	5186261009
5185851009	5186271009
5185861009	5186281009
5185871009	5186291009
5185881009	5186301009
5185891009	5186311009
5185901009	5186321009
5185911009	5186331009
5185921009	5186341009
5185931009	5186351009
5185941009	5186361009
5185951009	5186371009
5185961009	5186381009
5185971009	5186391009
5185981009	5186401009
5185991009	5186411009
5186001009	5186421009
5186011009	5186431009
5186021009	5186441009
5186031009	5186451009
5186041009	5186461009
5186051009	5186471009
5186061009	5186491009
5186071009	5186501009
5186081009	5186511009
5186091009	

AR40e IOLs, 21.5 Diopter		
5058981009	5059401009	5059831009
5058991009	5059411009	5059841009
5059001009	5059421009	5059851009
5059011009	5059431009	5059861009
5059021009	5059441009	5059871009
5059031009	5059451009	5059881009
5059041009	5059461009	5059891009
5059051009	5059471009	5059901009
5059061009	5059481009	5059911009
5059071009	5059491009	5059921009
5059081009	5059501009	5059931009
5059091009	5059511009	5059941009
5059101009	5059521009	
5059111009	5059531009	
5059121009	5059541009	
5059131009	5059551009	
5059141009	5059561009	
5059151009	5059571009	
5059161009	5059581009	
5059171009	5059591009	
5059181009	5059601009	
5059191009	5059611009	
5059201009	5059621009	
5059211009	5059631009	
5059221009	5059641009	
5059231009	5059651009	
5059241009	5059661009	
5059251009	5059671009	
5059261009	5059681009	
5059271009	5059691009	
5059281009	5059701009	
5059291009	5059711009	
5059301009	5059721009	
5059311009	5059731009	
5059321009	5059741009	
5059331009	5059761009	
5059341009	5059771009	
5059351009	5059781009	
5059361009	5059791009	
5059371009	5059801009	
5059381009	5059811009	
5059391009	5059821009	



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AMO SENSAR IOL RECALL FACSIMILE REPLY FORM

RETURN FAX TO: +353 1675 4660

Please complete and return immediately EVEN IF YOU HAVE NO STOCK

Please place an "X" in one of the boxes below.

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☐

We have **no stock** of AMO Sensor IOLs involved in the recall or all affected Sensor IOLs have been implanted or discarded.

We are returning affected
Sensor IOLs

RGA # _____

Serial Number	Status of IOLs (check one box for each serial number)		
	Implanted	Discarded	To be Returned
5186161009			

AMO Account Number:	
Account Name:	GULF MEDICAL CO. LTD
Address:	ALI BIN ABI TALEB STREET, SHARAFIAH 21455 JEDDAH
Country:	Saudi Arabia
Telephone Number:	

Person completing this form to provide name, signature and date below, acknowledging receipt and understanding of this letter:

Name:
(print)

Signature:

Date:

Please return this fax acknowledgement to AMO within 3 business days.