



URGENT
FIELD SAFETY NOTICE

August X, 2016

Dear AMO Customer:

RE: Voluntary Recall of AMO Intraocular Lenses, Various Models

Abbott Medical Optics Inc. (AMO) is recalling 737 IOLs, of various models from 33 product lots.

AMO is initiating this action due to detection of an inspection equipment malfunction that resulted in a total of 737 distributed lenses not being fully checked prior to release. It has been identified that this malfunction may result in the release of mislabeled IOLs.

This action only affects the IOLs listed beginning on page 4. No other AMO IOLs are affected by this action. Use of a mislabeled IOL could lead to potential unexpected postoperative refractive error and may result in a secondary surgical intervention. IOLs with serial numbers included in this letter that have been implanted and resulted in an appropriate post-op refractive outcome are not affected by this action.

Our records show that you were shipped IOLs impacted by this action. We have pre-filled the attached Customer Reply Form with those specific IOL serial numbers on page 9.

Please undertake the following actions:

1. Compare your inventory against the attached list.
2. **STOP** using and remove from your inventory all **affected** IOLs listed in the attached Customer Reply Form.
3. Complete and return the attached Customer Reply Form **EVEN IF YOU HAVE NO INVENTORY** affected by this recall. AMO requires this information for reconciliation purposes with regulatory agencies.

The IOL serial number is displayed on the end of each individual unit carton (see page 3 for label example). The IOL serial number is also present on the IOL lens holder within the package.

This notice should be shared with anyone who needs to be aware within your organization or to any organization where the potentially affected products have been transferred.

If you have inventory of any of the IOLs with the serial number listed below beginning on page 4, please complete the Customer Reply Form, noting the serial numbers of the IOLs and return product to the address below:

[Insert return address]

The completed Customer Reply Form should be faxed to AMO Quality Assurance at **[Insert regional fax number]** or email to **[insert regional email address]** within **3 business days of receipt of this letter**.

If you have any questions related to the IOL return process, please contact an AMO Customer Service Representative at **[Insert regional contact number]**.

If you have product complaints or adverse events to report regarding the use of IOL, please inform AMO by calling **[Insert regional contact number]**. 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.

[National Competent Authorities have been notified of this action.]

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.

Sincerely,

[insert regional QA contact name and Title]

Abbott Medical Optics, Inc.



Abbott Medical Optics Inc.
1700 E. St. Andrew Place
Santa Ana, CA 92705

Product Unit Carton Label Example

Example:
Serial Number
location





Serial Numbers Affected By Recall per Model

Sensar 1 Piece IOL Model AAB00
Diopter 21.5
Serial No.
5050941602

Sensar Foldable IOL with OptiEdge Design Model AR40e
Diopter 9.0
Serial No.
2003061505

Sensar Foldable IOL with OptiEdge Design Model AR40e
Diopter 19.0
Serial No.
2004131506

Sensar Foldable IOL with OptiEdge Design Model AR40e
Diopter 20.5
Serial No.
2015871503

Sensar Foldable IOL with OptiEdge Design Model AR40e
Diopter 21.0
Serial No.
3848581509

Sensar Foldable IOL with OptiEdge Design Model AR40e		
Diopter 14.0		
Serial No.		
5626621507	5626911507	5627231507
5626641507	5626921507	5627241507
5626651507	5626931507	5627251507
5626661507	5626951507	5627261507
5626671507	5626971507	5627271507
5626681507	5627011507	5627281507
5626691507	5627021507	5627291507
5626701507	5627031507	5627301507
5626711507	5627041507	5627311507
5626721507	5627051507	5627321507
5626731507	5627061507	5627331507
5626741507	5627071507	5627341507
5626751507	5627081507	5627351507
5626761507	5627091507	5627361507
5626771507	5627101507	5627381507
5626791507	5627111507	5627391507
5626801507	5627121507	5627401507
5626811507	5627131507	5627411507
5626821507	5627141507	5627431507
5626831507	5627151507	5627441507
5626841507	5627161507	5627451507
5626851507	5627171507	5627461507
5626861507	5627181507	
5626871507	5627191507	
5626881507	5627201507	
5626891507	5627211507	
5626901507	5627221507	

TECNIS® 1-Piece IOL with TECNIS iTEC Preloaded Delivery System Model PCB00		
Diopter 12.5		
Serial No.		
7138301403	7138631403	7138991403
7138311403	7138641403	7139001403
7138321403	7138651403	7139011403
7138331403	7138661403	7139021403
7138341403	7138671403	7139031403
7138351403	7138681403	7139041403
7138361403	7138691403	7139051403
7138371403	7138701403	7139061403
7138381403	7138711403	7139071403
7138391403	7138721403	7139081403
7138401403	7138731403	7139091403
7138411403	7138741403	7139101403
7138431403	7138751403	7139111403
7138441403	7138761403	7139121403
7138451403	7138771403	7139131403
7138461403	7138781403	7139141403
7138471403	7138791403	
7138481403	7138801403	
7138491403	7138811403	
7138501403	7138821403	
7138511403	7138831403	
7138521403	7138851403	
7138531403	7138881403	
7138541403	7138891403	
7138551403	7138901403	
7138561403	7138911403	
7138571403	7138921403	
7138581403	7138941403	
7138591403	7138951403	
7138601403	7138961403	
7138611403	7138971403	
7138621403	7138981403	

TECNIS® 1-Piece IOL with TECNIS iTEC Preloaded Delivery System Model PCB00	
Diopter 16.5	
Serial No.	
2648751412	2649131412
2648761412	2649141412
2648771412	2649151412
2648781412	2649161412
2648791412	2649171412
2648801412	2649191412
2648811412	2649201412
2648821412	2649211412
2648841412	2649231412
2648851412	2649251412
2648861412	2649271412
2648871412	2649291412
2648881412	2649311412
2648891412	
2648901412	
2648911412	
2648921412	
2648931412	
2648941412	
2648951412	
2648961412	
2648981412	
2648991412	
2649001412	
2649021412	
2649031412	
2649041412	
2649061412	
2649081412	
2649091412	
2649111412	
2649121412	

TECNIS® 1-Piece IOL with TECNIS iTEC Preloaded Delivery System Model PCB00	
Diopter 22.0	
Serial No.	
2397761605	
2397981605	

TECNIS® 1-Piece IOL with TECNIS iTEC Preloaded Delivery System Model PCB00	
Diopter 24.0	
Serial No.	
3125171501	
3125181501	

TECNIS® 1-Piece IOL with TECNIS iTEC Preloaded Delivery System Model PCB00		
Diopter 23.0		
Serial No.		
7731731310	7732041310	7732391310
7731741310	7732051310	7732401310
7731751310	7732061310	7732411310
7731761310	7732071310	7732421310
7731771310	7732081310	7732431310
7731781310	7732091310	7732441310
7731791310	7732101310	7732451310
7731801310	7732121310	7732461310
7731811310	7732131310	7732471310
7731821310	7732141310	7732481310
7731831310	7732151310	7732491310
7731841310	7732161310	7732501310
7731851310	7732181310	7732511310
7731861310	7732191310	7732521310
7731871310	7732201310	
7731881310	7732211310	
7731891310	7732221310	
7731901310	7732231310	
7731911310	7732241310	
7731921310	7732251310	
7731931310	7732261310	
7731941310	7732271310	
7731951310	7732281310	
7731961310	7732291310	
7731971310	7732301310	
7731981310	7732311310	
7731991310	7732321310	
7732001310	7732331310	
7732011310	7732341310	
7732021310	7732361310	
7732031310	7732371310	

TECNIS® OptiBlue 1-Piece IOL with TECNIS iTEC Preloaded Delivery System Model PCB00V		
Diopter 26.0		
Serial No.		
5860621403	5860961403	5861551403
5860631403	5860971403	5861561403
5860641403	5860981403	5861581403
5860651403	5860991403	5861591403
5860661403	5861001403	5861601403
5860671403	5861011403	5861611403
5860681403	5861021403	5861621403
5860691403	5861031403	5861631403
5860701403	5861041403	
5860711403	5861051403	
5860721403	5861061403	
5860731403	5861081403	
5860741403	5861091403	
5860751403	5861101403	
5860771403	5861111403	
5860781403	5861391403	
5860791403	5861401403	
5860801403	5861411403	
5860811403	5861421403	
5860821403	5861431403	
5860831403	5861441403	
5860851403	5861451403	
5860871403	5861461403	
5860881403	5861471403	
5860891403	5861481403	
5860901403	5861491403	
5860911403	5861501403	
5860921403	5861511403	
5860931403	5861521403	
5860941403	5861531403	
5860951403	5861541403	

TECNIS® CL Foldable Silicone IOL with OptiEdge Design Model Z9002
Diopter 19.5
Serial No.
1075121602

TECNIS® 1-Piece IOL Model ZCB00
Diopter 18.0
Serial No.
2005271506

TECNIS® 1-Piece IOL Model ZCB00
Diopter 24.0
Serial No.
5914601206

TECNIS® 1-Piece IOL Model ZCB00
Diopter 24.5
Serial No.
4651021512

TECNIS® 1-Piece IOL Model ZCB00
Diopter 25.0
Serial No.
5807371506

TECNIS® 1-Piece IOL Model ZCB00	
Diopter 21.0	
Serial No.	
4427981206	4428271206
4427991206	4428281206
4428001206	4428291206
4428011206	4428311206
4428021206	4428321206
4428031206	4428331206
4428041206	4428341206
4428051206	4428351206
4428061206	4428361206
4428071206	4428371206
4428081206	4428381206

4428091206	
4428101206	
4428111206	
4428121206	
4428131206	
4428141206	
4428151206	
4428161206	
4428171206	
4428181206	
4428191206	
4428201206	
4428211206	
4428221206	
4428231206	
4428241206	
4428251206	
4428261206	

TECNIS® 1-Piece IOL Model ZCB00
Diopter 27.0
Serial No.
5152461501
5152471501
5152481501
5152491501
5152501501
5152531501
5152541501
5152551501
5152561501
5152571501
5152581501
5152591501
5152601501
5152611501
5152621501
5152631501
5152641501
5152651501
5152661501
5152671501

TECNIS® OptiBlue 1-Piece IOL Model ZCB00V
Diopter 16.5
Serial No.
2624401411
2624411411
2624421411
2624431411
2624441411
2624451411
2624461411
2624471411
2624481411
2624491411
2624501411
2624511411
2624521411
2624531411
2624541411
2624551411
2624561411
2624571411
2624581411
2624591411
2624601411
2624611411
2624621411
2624631411
2624641411
2624651411
2624661411
2624671411
2624681411
2624691411
2624701411
2624711411

TECNIS® OptiBlue 1-Piece IOL Model ZCB00V		
Diopter 22.0		
Serial No.		
5259101407	5259431407	5259761407
5259111407	5259441407	5259771407
5259121407	5259451407	5259781407
5259131407	5259461407	5259791407
5259141407	5259471407	5259801407
5259151407	5259481407	5259811407
5259161407	5259491407	5259821407
5259171407	5259501407	5259831407
5259181407	5259511407	5259841407
5259191407	5259521407	5259851407
5259201407	5259531407	5259861407
5259211407	5259541407	5259871407
5259221407	5259551407	5259881407
5259231407	5259561407	5259891407
5259241407	5259571407	5259901407
5259251407	5259581407	5259911407
5259261407	5259591407	5259921407
5259271407	5259601407	5259931407
5259281407	5259611407	5259941407
5259291407	5259621407	5259951407
5259301407	5259631407	5259961407
5259311407	5259641407	5259971407
5259321407	5259651407	5259981407
5259331407	5259661407	5259991407
5259341407	5259671407	5260001407
5259351407	5259681407	5260011407
5259361407	5259691407	5260021407
5259371407	5259701407	5260031407
5259381407	5259711407	5260041407
5259391407	5259721407	5260051407
5259401407	5259731407	5260061407
5259411407	5259741407	5260071407
5259421407	5259751407	5260081407

TECNIS® Multifocal 1-Piece IOL Model ZLB00
Diopter 15.5
Serial No.
8960421506
8960431506
8960441506
8960451506
8960461506
8960471506
8960481506
8960501506
8960511506
8960531506
8960541506
8960581506
8960591506
8960621506
8960631506
8960641506
8960651506
8960661506
8960671506
8960681506
8960691506
8960701506
8960711506
8960721506
8960731506
8960741506

TECNIS® Multifocal Foldable Acrylic IOL Model ZMA00
Diopter 19.5
Serial No.
8505901605
8505911605
8505961605

TECNIS® Symphony Extended Range of Vision IOL Model ZXR00
Diopter 22.5
Serial No.
8618391605
8618441605

TECNIS® Symphony Extended Range of Vision IOL Model ZXR00
Diopter 22.0
Serial No.
8231911605
8231921605
8231931605
8231961605

TECNIS® Symphony Extended Range of Vision IOL Model ZXR00
Diopter 24.0
Serial No.
8496921508
8496931508
8496941508
8496951508



AMO Product RECALL Letter Dated **August 26, 2016**

AMO IOL RECALL CUSTOMER REPLY FORM

Please complete and return immediately **EVEN IF YOU HAVE NO STOCK**
via Fax: **[fax number]** or email: **[Email address]**.

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

☐
☐
☐

We have no stock of IOLs involved in the recall.

All affected IOLs have been implanted or discarded.

We are returning affected IOLs

RGA # _____

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

AMO Account Number:	
Account Name:	
Address:	
City, State, Zip Code	
Country	
Telephone Number:	

Person completing this form acknowledges the receipt and understanding of the actions,
as stated in the Field Safety Notice:

Name: (print) _____

Title/Position _____

Signature: _____

Date: _____