



**URGENT
FIELD SAFETY NOTICE**

January 17, 2014

Dear AMO Customer:

**RE: Voluntary Recall of AMO TECNIS iTec Preloaded Delivery System, Model PCB00
FSN2014-01**

Product Code	Description	Serial Numbers Affected
PCB00	TECNIS iTec Preloaded Delivery System, Model PCB00	See Page 3 of this letter

Abbott Medical Optics Inc. (AMO) is voluntarily recalling a limited number of TECNIS iTec Preloaded Delivery System Lens, Model PCB00. AMO is initiating this action due to a potential manufacturing process non-conformance. There are 113 lenses potentially impacted by the non-conformance.

AMO has not received any reports of adverse events associated with the affected lenses. The non-conformance that occurred during the manufacture of these lenses does not indicate that there is a significant patient safety risk; however as a precautionary measure, AMO is retrieving any of the lenses that have not been implanted.

This recall only affects the specific TECNIS iTec Preloaded Delivery System Lenses with the serial numbers listed on page 3. No other AMO IOLs are affected by this recall action. TECNIS iTec Preloaded Delivery System lenses that have been implanted should not be recalled. Surgeons that have already implanted affected lenses are encouraged to track these patients, bring them back for a follow-up visit (if they have not done so) to review the patient's outcome. It is recommended that patients be observed for any signs of increased intraocular inflammation in the three months following IOL implantation.

Our records show that you were shipped **XX** of the recalled IOLs. We have pre-filled the attached Facsimile Form with those specific IOL serial numbers.

Please take the following actions related to your inventory:

1. STOP using and remove from your inventory all affected TECNIS iTec Preloaded Delivery System lenses listed on Page 3.
2. Complete and return the included Facsimile Form (see Page 4) as AMO requires this information for reconciliation purposes with regulatory agencies. The completed Facsimile Form should be faxed to AMO at **[country fax number]** within the next 3 business days.
3. Please contact Customer Support at **[insert regional contact number]** to arrange pick up of lenses to be returned.



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 product complaints or adverse events to report regarding the use of TECNIS iTec Preloaded Delivery System Lens, please inform AMO by calling [insert regional contact number]. If you do report a complaint, please provide the 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 correction of this product.

Yours sincerely,

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Serial numbers affected by this recall:

5527371306	5528421306	5528401306	5527651306
5527481306	5528241306	5528131306	5527811306
5527611306	5528231306	5528071306	5527821306
5528301306	5527621306	5527981306	5528031306
5527721306	5527421306	5528051306	5528041306
5527511306	5527531306	5528441306	5527571306
5527351306	5527941306	5527691306	5527681306
5527441306	5528091306	5528251306	5527831306
5527541306	5528261306	5528371306	5528101306
5527551306	5528201306	5527671306	5528211306
5527741306	5528411306	5528291306	5528381306
5527841306	5528331306	5528061306	5528431306
5527931306	5528081306	5527591306	5528461306
5527991306	5527581306	5527871306	5527361306
5528181306	5527801306	5527341306	5527431306
5528481306	5528021306	5528191306	5527451306
5527971306	5528311306	5527471306	5527521306
5527761306	5527771306	5527951306	5527391306
5527791306	5528111306	5528351306	5527701306
5527861306	5527631306	5527601306	5527881306
5527731306	5527661306	5527751306	5528161306
5527491306	5527901306	5527851306	5528271306
5527711306	5527961306	5527921306	5528141306
5527781306	5528011306	5528171306	
5527891306	5528121306	5528281306	
5528321306	5528471306	5528221306	
5528151306	5527561306	5527461306	
5528341306	5527911306	5527411306	
5528451306	5528391306	5527501306	
5528361306	5528001306	5527641306	



Recall, AMO TECNIS iTec Preloaded Delivery System Lens
January 17, 2014

TO: AMO
Attention: [insert regional fax number]

**AMO TECNIS iTec Preloaded Delivery System LIMITED RECALL FACSIMILE REPLY
FORM**

Serial Number	Status of IOLs (check one box for each serial number)	
	Implanted	To be Returned
[Pre-fill S/Ns]		

AMO Account Number:	
Account Name:	
Address:	
Country:	
Telephone Number:	

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

Name: (print) _____

Signature: _____

Date: _____