



Urgent Field Safety Notice

Commercial name of the affected product: Tecnis™ 1-Piece Intraocular Lens (IOL)

Product Code: ZCB00

FSCA-identifier: Tecnis 1-Piece Field Safety Notice

Type of action: Field Safety Corrective Action/ Voluntary Limited Recall of AMO Tecnis™ 1-Piece Intraocular Lens with Certain Expiration Dates

9. November 2009

Dear AMO Customer

Abbott Medical Optics Inc. (AMO), formerly Advanced Medical Optics, Inc., is voluntarily recalling certain Tecnis™ 1-Piece Intraocular Lenses (IOLs). AMO is initiating this action to remove all affected Tecnis 1-Piece IOLs, as identified in Annex 1. Annex 1 also describes the expiration dates (also labeled as Use By dates) involved in this recall.

AMO has received reports that haptics of some Tecnis 1-Piece IOLs (model ZCB00) have adhered to the lens optic after insertion into the eye. This situation can lead to additional manipulation to separate the haptics from the optic during surgery which could lead to an injury.

Our root cause investigation concluded that this haptic phenomenon was a result of a recent minor change in a secondary production process specific to the Tecnis 1-Piece IOL. The original process has now been reinstated.

This recall only affects specific Tecnis 1-Piece IOLs (ZCB00) with expiration dates identified on Annex 1. No other AMO IOLs are affected by this recall action. Tecnis 1-piece IOLs that have been implanted are not affected by this recall. After the haptics deploy successfully, the lens functions correctly.



Please undertake the following actions:

1. **STOP** using and remove from your inventory **all affected** Tecnis 1-Piece IOLs listed in Annex 1.
2. Complete and return the included Facsimile Form (Annex 2) as AMO requires this information for reconciliation purposes with regulatory agencies. Please complete and return the attached Facsimile Form **EVEN IF YOU HAVE NO INVENTORY** affected by this recall.

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

If you have inventory of Tecnis 1-Piece IOLs to return, please complete the Facsimile Form, noting the expiration dates and quantity of Tecnis 1-Piece IOLs to be returned to AMO. The completed Facsimile Form should be faxed to AMO QA at [country specific fax number] within the next **3 business days**.

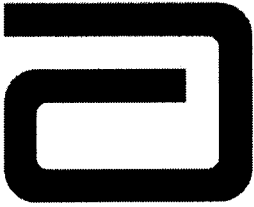
The product should be returned to the address below:

Full local DC address	or	local AMO market office address
Address		Address
Address		Address
Address		Address
Address		Address
Address		Address

If an AMO Representative has already assisted in the return of your affected Tecnis 1-Piece IOL inventory, please note on the Facsimile Form by checking the applicable box and faxing the completed form to AMO QA at [Country specific fax number].

If you have any questions related to the Tecnis 1-Piece IOL return process, please contact an AMO Customer Service Representative at [Country specific CS phone number]. **Press option 5 at anytime during the welcome message and you will be directed to a dedicated Tecnis hotline.** You may also e-mail your questions to ask.tecnis@amo.abbott.com.

If you have product complaints or adverse events to report regarding the use of Tecnis 1-Piece IOLs, please inform AMO by [Country specific CS phone number]. **Press option 5 at anytime during the welcome message and you will be directed to a dedicated Tecnis hotline.** 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.



AMO has resumed manufacturing Tecnis 1-Piece IOLs (ZCB00). During this temporary interruption in supply, AMO can also ship the following monofocal lenses immediately:

- Tecnis Acrylic 3-piece IOL (model ZA9003)
- Tecnis Silicone 3-piece IOL (model Z9002)
- Sensar Acrylic 3-piece IOL (model AR40e)

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.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please maintain awareness on this notice and resulting action to ensure effectiveness of the corrective action. The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Yours sincerely,

i.V.

AMO Germany GmbH
Quality and Compliance Manager
Europe/ Africa / Middle East
Rudolf-Plank-Str 31
76275 Ettlingen/ Germany
Phone: +49-7243-729-
Fax: +49 7243-58971-
e-mail: @amo.abbott.com



Annex 1: List of affected AMO Tecnis 1-Piece IOL Serial Numbers / Expiration dates Involved

Expiration / Use By date (YYYY-MM)	Remarks
2011-05*	Not all serial numbers with this expiration date are involved in the recall. However, return all IOLs with this expiration date.*
2011-06	All lenses with these expiration dates are involved. Return all lenses with these expiration dates.
2011-07	
2011-08	
2011-09	
2011-10*	Not all serial numbers with this expiration date are involved in the recall. However, return all IOLs with this expiration date in your inventory that you received prior to or on October 31, 2009.*

*Shipments received on or after November 1, 2009 of Tecnis 1-Piece IOLs may include lenses with an expiration date of 2011-05 or 2011-10 that are not affected by this recall.

Location of expiration date on end of IOL carton:





Annex 2: Acknowledgement of Receipt and Fax Back Form

Please fax back to:
[specific country fax number]
 or e-mail to ask.tecnis@amo.abbott.com

AMO TECNIS 1-PIECE IOL LIMITED RECALL FACSIMILE REPLY FORM
Please complete and return immediately EVEN IF YOU HAVE NO STOCK

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

<input type="checkbox"/>	We have no stock of AMO Tecnis 1-Piece IOLs involved in the recall.
<input type="checkbox"/>	AMO Representative has returned all affected IOL inventory on our behalf.
<input type="checkbox"/>	We are returning affected Tecnis 1-Piece IOLs (ZCB00) RG# <u> </u> ZCB <u> </u>

Expiration / Use By Date	Quantity of IOLs to be Returned
2011-05	
2011-06	
2011-07	
2011-08	
2011-09	
2011-10	

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

I confirm that I received and understood the attached Field Safety Notice about the Voluntary Recall of Tecnis 1-Piece.

Person completing this form to provide name, signature and date below:

Name: (print) _____

Signature: _____

Date: _____