URGENT
FIELD SAFETY NOTICE

Product: Catalys® Precision Laser System

Type of Action: Voluntary and Limited Field Removal

May 14, 2018

Dear CATALYS® System Customer:

AMO Manufacturing USA, LLC (a Johnson & Johnson Vision company) is voluntarily initiating a field action for the software version 5.00.33 installed on Catalys® Precision Laser System (this "**Action**"). Johnson & Johnson Vision is initiating this Action, as identified in this notice.

A failure has been identified related to the Daily Alignment Verification which involves the co-registration of the pulse pattern in the overlay. As you are aware, the purpose of the Daily Alignment Verification is to assure proper placement of intended laser energy. While there have been no reports of patient harm from this issue, potential injury to the eye could occur and may include damage to the iris, possibly resulting in additional intraoperative and postoperative complications.

Please note that this action is limited to Catalys® Precision Laser Systems with software version 5.00.33 installed.

You are receiving this notice because our records indicate that you have received a Catalys® Precision Laser System impacted by this Action.

No harm has been reported for any patients treated with this software version 5.00.33. If your patient has already undergone successful surgery, there is unlikely to be an impact from this issue.

Since software version 5.00.33 has been installed on your Catalys® Precision Laser System, as previously discussed, please immediately take the following actions:

1. **STOP** using the affected system.
2. A Johnson & Johnson Vision Technical Service Representative will be contacting you, if not already, to schedule the removal of the affected software, and will advise of actions to be taken with your Catalys® Precision Laser System to provide you with software version 3.9.
3. Complete and return the attached Customer Acknowledgement Form.

The completed Customer Reply Form should be faxed to Johnson & Johnson Vision Quality Assurance at [**Insert regional fax number**], emailed to [**insert regional email address],** or provided to your Johnson & Johnson Vision Representative within **3 business days of receipt of this letter.**

This notice should be shared with anyone who needs to be aware within your organization.

If you have any questions related to the Catalys® Precision Laser System service process, please contact a Johnson & Johnson Vision Technical Service Representative at *[Insert regional contact number]*.

If you have product complaints or adverse events to report regarding the use of Catalys® Precision Laser System, please inform Johnson & Johnson Vision by calling *[Insert regional contact number]*. If you do report a complaint, please provide the System 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 Johnson & Johnson Vision's commitment to high quality standards and ensuring that our products fully meet your expectations. Johnson & Johnson Vision 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 removal (and replacement) of the affected software.

Sincerely,

[insert regional QA contact name and Title]

CATALYS® System Notification Acknowledgement by Customer

2018 Catalys cOS 5.00.33 Field Removal

Site Information – REQUIRED

Catalys System Serial Number: _____

Account Name: _____

Customer Address: _____

_____

_____

I acknowledge the receipt and understanding of the actions, as stated in the Catalys Precision Laser System Voluntary and Limited Field Removal Letter.

Medical Director Name: **PRINT**		Nurse/Mgr. Name: **PRINT**	
Signature:		Signature:	
Date Signed:		Date Signed:	

Please return this completed acknowledgement form to Johnson & Johnson Vision within THREE business days.

Return this Customer Acknowledgement Form via:

Fax:*[fax number]*, **email:** *[Email address]*, **or provide a copy to your Johnson & Johnson Vision Representative.**