



## Urgent Field Safety Notice

November XX, 2021

Dear Johnson & Johnson Vision Customer:

**RE: JJSV Field Safety Correction cybersecurity vulnerability/software patch of the iDESIGN® Refractive Studio & CATALYS™ Precision Laser Operating Systems**

**Table 1: iDesign Systems**

Trade Name(s)	Model Number(s)	Windows Version(s)
<i>[Insert regional trade name]</i>	<i>[Insert regional model number]</i>	<i>[Insert windows version]</i>

**Table 2: Catalys Systems**

Trade Name(s)	Model Number(s)	Windows Version(s)
<i>[Insert regional trade name]</i>	<i>[Insert regional model number]</i>	<i>[Insert windows version]</i>

Johnson & Johnson Surgical Vision, Inc. (JJSV, part of the Johnson & Johnson Vision group of companies) is voluntarily initiating a field safety corrective action of the iDESIGN® Refractive Studio & CATALYS™ Precision Laser System (this “**Action**”). JJSV is initiating this action to correct affected iDESIGN® Refractive Studios and CATALYS™ Precision Laser Systems with Windows versions listed in Table 1 and Table 2 (the “**Devices**”), as identified in this notice. The Windows version installed on each unit is not visible to the end user, however, one of the affected Windows versions listed in Table 1 or Table 2 is installed on each iDESIGN® Refractive Studio or CATALYS™ Precision Laser System, therefore, this field safety corrective action will apply to each unit model number listed in Table 1 and Table 2.

JJSV is issuing this Field Safety Notice due to a cybersecurity vulnerability for iDESIGN® Refractive Studios & CATALYS™ Precision Laser Systems utilizing Microsoft Windows operating systems and the Print Spooler functionality. The vulnerability is a remote code execution vulnerability that exists when the Windows Print Spooler service improperly performs privileged file operations. An attacker who exploits this vulnerability could potentially run arbitrary code with SYSTEM privileges. This would give them access to potentially install programs; view, change, or delete data; or create new accounts with full user rights.

This field safety corrective action affects iDESIGN® Refractive Studios and CATALYS™ Precision Laser Systems with windows versions listed in Table 1 and Table 2. **You are receiving this notice because our records indicate that you received a unit impacted by this Action.** An informative communication regarding this issue and including interim mitigation options was sent on August 27, 2021 to impacted users. A similar update was also posted to the Johnson & Johnson Product Security webpage on September 27, 2021.

The Devices require Windows OS patching to remediate the PrintNightmare vulnerability. While there have been no reports of related concerns regarding product quality or safety, Windows OS patching is needed to remove the risk from the Microsoft Print Spooler service. The identified issue is a remote, potential vulnerability and has not been confirmed to have been exploited on our systems. Both Devices also have multiple risk control measures in place to reasonably reduce the potential for patient harms relative to this vulnerability.

Potential Risks Identified in the event of the remote, potential Microsoft cybersecurity vulnerability are:

Catalys Systems:

- treatment would get interrupted
- interrupting an in-progress laser treatment
- theft of data and patient info
- negative impacts to the customer's network

iDesign Systems:

The treatment plans output from the iDesign system could produce results that are different than what would be required based on original manifest data. This could only occur if the user accepted the results of the iDesign output without doing the recommended checks and balances

- Output vs Manifest
- Verify graphical analysis displays (laser ablation graphs)
- Data Parameter matching

If it were exploited, this could result in significant under or over correction of a patient's eyesight compared to what would have been planned with the original manifest data

JJSV is in the process of finalizing a solution for patch deployment to all impacted units. Once the patch is applied, the security updates will be listed in the Windows Update history as successfully installed.

**REQUIRED SITE ACTION**

Since you have an impacted unit, please take the following actions:

1. Complete and return the attached Customer Reply Form (on page 4) to acknowledge receipt of this Field Safety Notice. Johnson and Johnson Vision requires this information for reconciliation purposes with regulatory agencies.
2. A Johnson & Johnson Vision Technical Service Representative will be contacting you to schedule the installation of the patch on the affected system. We are anticipating the correction of customer systems to occur in 2021 and throughout 2022.
3. To further mitigate the potential for exposure, please consider the following steps:
  - o Please review the Operating Manual and Instructions for Use for the Devices to familiarize yourself with available means to safeguard patients from potential harm and what to do in the event of a product malfunction.
    - For Catalys:

Operator's Manual Number	Revision(s)	Section Name(s)	Page(s)
<i>[Insert regional Operator's Manual Number]</i>	<i>[Revision #]</i>	<i>[Section #]</i>	<i>[Page #]</i>

- For iDesign:

Operator's Manual Number	Revision(s)	Section Name(s)	Page(s)
<i>[Insert regional Operator's Manual Number]</i>	<i>[Revision #]</i>	<i>[Section #]</i>	<i>[Page #]</i>

- o **For Catalys:** As specified in the operating manual,
- o **if the treatment is interrupted by a 'Critical Error', the system will go into a safe state and be disabled. Do not resume treatment afterwards. Revert to traditional cataract surgery.**
- o **For iDesign:**
  - o As specified in the operating manual, the physician should perform recommended checks between the plan sent and the plan designed based on manifest data including Output vs Manifest, Verify graphical analysis displays (laser ablation graphs) and Data Parameter matching.
  - As specified in the operating manual, confirm all iDesign Refractive Studio Measurements against the baseline pre-operative manifest refraction and do not proceed when outside of the



**recommended limits of difference, for sphere, cylinder and axis, as specified in the operator's manual and training material.**

- Maintain manual records of patient measurements in addition to measurements stored in iDESIGN® Refractive Studios.
- Ensure you comply with obligations under applicable privacy laws relating to putting in place security safeguards in connection with personal information about patients. Please keep this in mind as part of the steps you take to mitigate any risk of loss or theft, or unauthorized access, of personal information on the affected devices.

The completed Customer Reply Form should be emailed to **[insert regional email address]** within **3 business days of receipt of this letter.**

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 any questions related to the iDESIGN® Refractive Studio & CATALYS™ Precision Laser System service process, please contact a JJSV Technical Support at **[Insert regional contact number]**.

If you have product complaints or adverse events to report regarding the use of iDESIGN® Refractive Studio & CATALYS™ Precision Laser System, please inform JJSV by calling Technical Support at **[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.

If you believe that your iDESIGN® Refractive Studio & CATALYS™ Precision Laser System has been compromised, or, you have been the subject of a cyberattack and you own either of these Devices, please contact **[Insert regional contact number]**.

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

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

Sincerely,

**[insert regional QA contact name and title]**

Johnson & Johnson Surgical Vision, Inc.



**JJSV Product Field Safety Notice Dated November xx, 2021**

**2021 iDESIGN® Refractive Studio & CATALYST™ Precision Laser System FIELD SAFETY CORRECTION CUSTOMER REPLY FORM**

Please complete and return immediately via email: **[insert regional email address]**

System	List all systems' serial numbers
<b>iDESIGN® Refractive Studio</b>	
<b>CATALYST™ Precision Laser System</b>	

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: \_\_\_\_\_