# URGENT FIELD SAFETY NOTICE
# MEDICAL DEVICE RECALL

## Video Processor / Illuminator


**Recall Number: RA2021-2640074**
**March 19, 2021**

**Attn: Recall Coordinator**
**Account number:**
**Account name:**
**Account Address:**

## Response required

| Catalog number | UDI | Product description | Serial number(s) |
|---|---|---|---|
| PC9001 | 00858701006049 | Video Processor/Illuminator (VPI) | See Attachment A |

**Product description**

A video processor/illuminator (VPI), provides VIS/NIR (Visible/Near Infrared) illumination to the surgical laparoscope via a flexible light guide cable, as well as the image processing necessary to generate simultaneous, real-time HD (High Definition) video color and NIR (Near Infrared) fluorescence images.

**Intented Use**

Since the VPI is a component that is used with both the SPY-PHI and PINPOINT systems, the intended use for both imaging systems are being documented here:

*PINPOINT SYSTEM:*

PINPOINT Endoscopic Fluorescence Imaging System is intended to provide real-time endoscopic visible and near infrared fluorescence imaging. This imaging system enables surgeons to perform routine visible light endoscopic procedures as well as further visually assess circulation including blood flow in vessels and microvessels, tissue and organ perfusion, and lymphatics and perfusion associated with tumors and tumor margins with near infrared fluorescence imaging during minimally invasive surgery.

*SPY-PHI SYSTEM:*

The SPY Portable Handheld Imaging System (SPY-PHI System) is an active device used to visualize circulation, including lymphatics and blood vessels, as well as related tissue perfusion with near infrared fluorescence imaging during a variety of surgical procedures.

**Product issue**

It was discovered that a portion of the VPIs shipped between 10-Jan-2020 and 02-Feb-2021 are exhibiting flickering, loss of image or unintended VPI reboots.

**Potential risks and hazards**

When used with SPY-PHI, if loss of image or unintended VPI reboots occur during surgery, the potential harm is a delay of surgery. When used with PINPOINT, if loss of image or unintended VPI reboots occurs during surgery, the potential harm is conversion to open. The potential of harm is remote.

## Actions needed

1. Immediately check inventory to locate the product listed on Attachment A and **remove them from their point of use**.
2. Return the enclosed business reply form by email to xxxxxxxx@stryker.com to confirm receipt of this notification/document product segregation. RESPONSE IS REQUIRED.
    - **a.** If affected product is found, segregate the product and call Stryker customer service or email xxxxxxxxto arrange for product return and receive a replacement (upon availability) and complete Business Reply form, Attachment B on page 4.
    - **b.** If no product is found, complete Business Reply form, Attachment B on page 4 of this recall letter.
3. Maintain awareness of this communication internally until all required actions have been completed.
4. Inform Stryker if any of the subject devices have been distributed to other organizations.
    a. Please provide contact details so that Stryker can inform the recipients appropriately.
    b. If you are a Distributor, note that you are responsible for notifying your affected customers.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

6. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.

7. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
    a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request that you respond to this notice within XXX calendar days from the date of receipt.

The target date for completion of this action is XXX and your timely response will enable us to ensure that we meet this target/
This will enable us to update our records and negate the need to send unnecessary reminder letters.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,

# Attachment A

## Recalled Serial Numbers

**Device Description and Part Number:** PC9001 – Video Processor/Illuminator (VPI)
**Impacted Serial Numbers:**

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| PI20362910 | PI20082806 | PI20112868 | PI20322887 | PI20372920 | PI16180922 | PI20052735 | PI20362908 |
| PI20362911 | PI20092807 | PI20112869 | PI20322888 | PI20372921 | PI17381211 | PI20052740 | PI20362909 |
| PI20362913 | PI20102835 | PI20112870 | PI20322889 | PI20372922 | PI17381214 | PI20062759 | PI20463033 |
| PI20362912 | PI20102836 | PI20112871 | PI20322890 | PI20372923 | PI18041369 | PI20062766 | PI20463038 |
| PI20022723 | PI20102839 | PI20112872 | PI20322891 | PI20052734 | PI18041410 | PI20062768 | PI20463041 |
| PI20022724 | PI20102846 | PI20112873 | PI20362892 | PI20052736 | PI18181490 | PI20062771 | PI20463042 |
| PI20022725 | PI20102851 | PI20112874 | PI20362893 | PI20062747 | PI18241579 | PI20062772 | PI20463046 |
| PI20022726 | PI20112852 | PI20112875 | PI20362894 | PI20062754 | PI19182075 | PI20072773 | PI20463049 |
| PI20062749 | PI20112860 | PI20112876 | PI20362895 | PI20082802 | PI19182080 | PI20072780 | PI20463051 |
| PI20082795 | PI20112861 | PI20282879 | PI20362896 | PI20092808 | PI19242192 | PI20072781 | PI20463052 |
| PI20082797 | PI20112862 | PI20282880 | PI20372914 | PI20022701 | PI19342372 | PI20072784 | PI20463054 |
| PI20082798 | PI20112863 | PI20312881 | PI20372915 | PI20082788 | PI19372413 | PI20072787 | PI20463058 |
| PI20082799 | PI20112864 | PI20312882 | PI20372916 | PI20463062 | PI19432511 | PI20362904 | PI20463036 |
| PI20082801 | PI20112865 | PI20312883 | PI20372917 | PI14350291 | PI20052727 | PI20362905 | |
| PI20082804 | PI20112866 | PI20322885 | PI20372918 | PI15150533 | PI20052728 | PI20362906 | |
| PI20082805 | PI20112867 | PI20322886 | PI20372919 | PI15240575 | PI20052732 | PI20362907 | |

# Business Reply Form

**Account number:**
**Account name:**
**Account Address:**

## Attachment B – Business Reply Form

# Video Processor / Illuminator

**Recall Number: RA2021-2640074**
**March 19, 2021**

Please complete and sign this form. Email the completed form to **endorecall@stryker.com** by **01-June-2021.**
**Note:** Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

| Catalog number | Product | Serial number(s) | Quantity on hand |
|---|---|---|---|
| PC9001 | VIDEO PROCESSOR/ILLUMINATOR (VPI) | List here | |

**Form completed by:**

| | | | |
|---|---|---|---|
| **Printed Name** | | **Title** | |
| **Signature** | | **Phone** | |
| **Date** | | **Email** | |

☐ If you no longer have affected product on hand, please check here.
- Please state disposition of product no longer on hand: _____

If you have further distributed any affected product, please indicate to whom:

| | | | |
|---|---|---|---|
| **Product(s) Distributed** | | **Quantity** Distributed | |
| **Facility Name** | | **Contact Person** | |
| **Full Address** | | | |

**Return completed Business Reply Form to xxxxxxxxxxxxxxx**