stryker

Stryker Europe, Middle East & Africa
Regus, Les Espaces de Sophia
80, Route des Lucioles, BP 037
Sophia Antipolis Cedex
06901
France

URGENT: FIELD SAFETY NOTICE

Our manufacturer has notified us of a Product Field Action concerning the Medical Devices referenced below. Our records indicate that you have been supplied with some of the subject devices. We would request therefore that you read this notice carefully and follow the instructions provided by the manufacturer.

We would like to reassure you that only the devices listed are affected by this action.

On behalf of Stryker we would like to thank you in advance for your cooperation and support in this matter.

Please note that in accordance with the Medical Device Directive and the Meddev Vigilance Guidance Document this Field Safety Corrective Action has been notified to the National Competent Authority of all countries where subject devices have been distributed.
This Field Safety Notice has been issued in accordance with the European Competent Authority detailed below.

Type of Action	Retrofit/ Upgrade
Date of report	2010-05-28
Stryker Internal Reference Number	RA2009-406
Name of Manufacturer	Stryker Communications
Website address	www.stryker.com
National Competent Authority	if appropriate - please delete if not
Regulatory Agency Reference No	if appropriate - please delete if not

Local Contact Information

Contact Person	
Contact tel number:	
Contact e-mail	

Product Information

Product Description	SwitchPoint Infinity 2 & SwitchPoint Element DOM Cards
Product Code/Catalogue No from:	0100224307 (SPI2 DOM Card), 0100224592 (SPE DOM Card)
Product Code/Catalogue No to:	0100224307 (SPI2 DOM Card), 0100224592 (SPE DOM Card)
Lot Numbers	All units distributed between 23 MAR 07 and 14 AUG 09
Software version (if applicable)	0
Quantities distributed to your facility	
Expiration date of product	Not Applicable
Expected shelf life/product life	Not Applicable

Issue

Description of problem

Complaints were received reporting that DOM cards were failing and causing the inability to re-route video in the operating room.

Population concerned

Patients where device is being used.

Potential Hazards associated with use of device

1 Inability to change video routes and hospital staff is unable acquire an alternate means to display video resulting in a possible delay to the start of patient treatment.

2 Inability to change video routes and hospital staff is unable acquire an alternate means to display video resulting in a possible delay to surgery of <30 minutes or less and possible additional exposure of the patient to additional anaesthesia.

3 Inability to change routes and hospital staff is unable to acquire an alternate means to display video resulting in a prolongation of patient treatment of 30 or more minutes.

4 Inability to change video routes and hospital staff is unable to acquire an alternate means to display video resulting in the conversion to an open procedure resulting in a possible prolongation of patient treatment of 30 or more minutes.

Mitigating circumstances/precautionary measures

The occurrence of this failure has been classified as remote. However, in the event that a drive on module failure is experienced by the user the following may be seen:

'Page Not Found' error message
Missing drop down options
A frozen touch panel

If this failure occurs whilst the unit is operational the existing video image will not be affected.

In the event that this does occur during a procedure the user can utilise the 'video backup'/'video safety pass-through' feature.

Specific advice for surgeons regarding patients with implanted devices

Not Applicable

Communications/Attachments

Customer response form	Indicate number of pages
IFU/User manual/Operative Technique	Indicate number of pages
Upgrade kit	indicate nature of kit
Distribution list	
Labels	
etc	

Immediate Actions

The devices may continue to be used providing that the following instructions are followed.

1 **Immediately locate all devices and ensure that users are made aware of this action.**

2 **Place a copy of the FSN in a prominent place where users of the device will be reminded of the action.**

3 **Maintain awareness of this of this notice internally until all required actions have been completed within your facility**

4 **Inform Stryker if any devices have been further distributed to other locations. Please provide contact information so that Stryker can contact the new users directly.**

5 **Inform Stryker if there have been any issues associated with use or attempted use of subject devices.**

6 **Comply with any local regulations on concerning notification of adverse events to National Competent Authorities.**

7 **Complete customer response form and return to Stryker.**
*** Please complete even if you no longer have any of the subject devices.**

8 **On receipt of the customer response form a Stryker representative will contact you to arrange for upgrade of units.**

Product Return Information

1 **Complete the attached customer response form**
(please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notices

2 **Return the completed form to:**

3 **A Stryker representative will then contact you to organise return of subject devices**

Name
Position
Signature

CUSTOMER RESP0NSE FORM

Please complete this form even if you do not have any product to return. This will preclude the need for future notices

Stryker RA Reference Number	**RA2009-406**			
Product Description	*SwitchPoint Infinity 2 & SwitchPoint Element DOM Cards*			
Product Code/Cat No	From:	0100224307 (SPI2 DOM Card), 0100224592 (SPE DOM Card)	To:	0100224307 (SPI2 DOM Card), 0100224592 (SPE DOM Card)
Lot/Serial Numbers	All units distributed between 23 MAR 07 and 14 AUG 09			

Please check your inventory for affected product and return completed form to our Quality Department as soon as possible. Please note only the product codes/catalogue numbers specified are affected by this action.

Product Disposition (Completed by Customer)

Product Code/Cat No.	Lot/ Serial No	Qty to be returned	Qty /Used Implanted	Qty Disposed /or destroyed	Qty not located	Upgraded

Customer Details

Response requirements (please complete/delete appropriate section)

I have checked inventory and can confirm that we do not have any affected product at this location.

I have checked inventory and completed the product disposition table.

Please have Stryker service contact our maintenance department to arrange upgrade of the above listed product

Please sign and return this form to acknowledge receipt of product notice.

Name of Hospital/ Organisation		**Address**	
Contact Name			
Contact Title			
Contact Signature			
Contact Phone No.		**Date**	

Completion Instructions

1. Complete and fax back this form to Stryker ……..
2. A Stryker Representative will call you to arrange collection of product/upgrade if necessary
3. Please ensure that the outer package is labelled with Stryker RA Reference number.
4. Ensure that forms are secured in a document wallet on the outer of the package
5. Please ensure that where appropriate a decontamination certificate is returned with product