Stryker Europe, Middle East & Africa
Les Espaces Antipolis
300 Route des Crêtes
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06902 Sophia-Antipolis
France

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	2010-07-23
Stryker Internal Reference Number	RA2010-126
Name of Manufacturer	Stryker Endoscopy San Jose
Website address	0
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	Crossfire Consoles
Product Code/Catalogue No from:	475-000-000
Product Code/Catalogue No to:	N/A
Lot Numbers	All
Software version (if applicable)	N/A
Quantities distributed to your facility	
Expiration date of product	N/A
Expected shelf life/product life	N/A

Issue

Description of problem

The issue occurs when the iSwitch Footswitch is used with the Crossfire Console. When the footpedal is released, the shaver continues to run at a low speed and/or the RF probe stays activated (both situations for 1 - 5 seconds).

[redacted]

Please note:
You may have been informed of Field Safety Corrective Action Ref RA2009-449 which was initiated to increase the timing of the Crossfire Consoles "disconnect" message from 800ms to 1.6 seconds thereby addressing a disconnectivity issue between both the Crossfire Console and the iSwitch Receiver.

The dongle provided to upgrade the software for this action also incorporates the changes affected by RA2009-449. Therefore if the requested upgrade was not completed on all subject devices for your facility there is only a requirement to complete the software upgrade loaded onto the dongle for upgrade ref RA2010-126.

On this basis RA2009-449 is considered closed and superseded by RA2010-126

Population concerned

Limited to patients being treated with subject devices

Potential Hazards associated with use of device

1 Surgeon removes foot from the pedal and the shaver/RF continues to activate within the surgical site. Potentially this could lead to:
1. Conversion from minimally invasive to open surgery
2. Additional tissue or cartilage being removed or damaged
3. Extension in surgery time
4. Longer post operative recovery period for the patient

Based on investigation results and sales to complaints analysis the probability of occurence has been classed as remote. Also not every customer with a Crossfire system will see this issue.
It is common for customers to have a wired footswitch available in their facility even if they use iSwitch to communicate wirelessly. Stryker order data was reviewed and found that 94% of customers that ordered the iSwitch and Crossfire Console also ordered a Crossfire Footswitch.

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

1 **Immediately locate and quarantine all subject devices**

2 **Install the software using the donige and instructions provided by the manufacturer**
Please note:
*** one dongle may be used for multiple upgrades**
*** Stryker will complete the upgrade for any users not wishing to undertake this work themselves.**

3 **Circulate this list internally to all interested/affected parties**

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

5 **Inform Stryker if any of the subject devices have been distributed to other organisations. Please provide contact details so that Stryker can inform the recipients appropriately.**

6 **Immediately inform Stryker of any adverse events concerning use/attempted use of subject devices.**

7 **Comply with any national regulations concerning notification of adverse events to National Regulatory Bodies.**

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

[redacted]

Signature

CUSTOMER RESPONSE 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	RA2010-126			
Product Description	*Crossfire Consoles*			
Product Code/Cat No	From:	475-000-000	To:	N/A
Lot/Serial Numbers	All			

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 arrange for collection of product

I have completed the upgrade/maintenance of all the product listed above in accordance with the Product Field Action

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