URGENT Field Safety Notice: RA2011-128

Dear Customer

Description: SERFAS Energy Probes Super 90S
Catalogue No: 279-351-300
Lot No: 11161AE2 to 11241AE2

Stryker® Endoscopy has initiated a Product Field Action for the devices identified above. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

Issue
Complaints have been received in which it was reported that the tip of the device broke intra-operatively.

Potential Hazards
The following potential hazards have been identified:

1. The tip may break intra-operatively and fall into the surgical site. This may result in:
    a. A delay in surgery time whilst the surgeon removes the tip.
    b. Additional patient exposure to anaesthesia.

2. The tip may break intra-operatively and remain implanted in the patient. This may result in:
    a. Patient adverse reaction
    b. The need for further surgery to remove the tip.

The actual occurrence rate in the field for the tip breaking condition for the lots referenced above is low (occurrence rate of 0.35%).

Type of Action
Immediate withdrawal of subject devices.

Patient follow up
There is no requirement for additional patient follow up. The failure would present itself during surgery.

Immediate actions
Our records indicate that you may have received one or more of the subject devices. It is Strykers responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication. We therefore request that you read this notice carefully and complete the following actions:

1. Immediately locate and quarantine all subject devices.
2. Ensure that this notice is forwarded internally to all appropriate personnel
3. Complete the customer response form attached indicating the number of units located.
4. Return the completed response form to your local Stryker distributor. Contact details indicated on the form.
    a. On receipt of the completed notice a Stryker representative will contact you to arrange for replacement of any non conforming devices.

    b. Please return this notice within five working days. This will enable us to order any replacement devices that you may need in a timely manner.
5. Please respond to this notice even if you do not currently have any subject devices. This will negate the need for us to send any reminder notices.
6. Inform Stryker of any adverse events associated with use of subject devices
    a. Please comply with any local regulations concerning the reporting of adverse events.

We sincerely regret any inconvenience that this action may cause you and on behalf of Stryker would like to thank you for your help and support in completing this action in a timely manner.

Should you have any queries on this matter please do not hesitate to contact the undersigned.

Yours faithfully …

RA2011-128: PFA ACKNOWLEDGMENT FORM

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I acknowledge receipt of the Field Safety Notice for RA2011-128 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*	

We have located the following devices:

Product description	Product Reference	Lot Number	Qty	Qty Quarantined

We have further distributed subject devices to the following organisations:

Facility Name		
Facility Address		

Form completed by:

Contact Name _____ **Contact Facility** _____

Contact address _____ **Contact Position** _____

_____ **Contact Tel No** _____

_____ **Contact Fax No** _____

_____ **Contact e-mail** _____

Please return the completed form to: