XX February 2019

URGENT Field Safety Notice: RA2018- 1976124

FSCA identification: Product recall RA2018- 1976124

Action type: Field Safety Corrective Action

Affected items: See attached list

Product description: LIFEPAK 15 Monitor/Defibrillator

Dear Customer,

Stryker is conducting a Field Action for specific LIFEPAK 15 Monitor/Defibrillator devices that may lock-up after a defibrillation shock is delivered. This communication is intended to provide you with critical safety information regarding the readiness of your device. Please forward this notice to all of your sites, trainers and users.

The issue is limited to LIFEPAK 15 Monitor/Defibrillator devices with certain System Printed Circuit Board Assemblies. The attached impacted device list provides serial numbers that our records show are in your possession.

Description of issue

Stryker has become aware that certain LIFEPAK 15 Monitor/Defibrillators were reported to experience a lock-up condition after a defibrillation shock was delivered. This condition is defined as a blank monitor display with LED lights on, indicating power to the device, but no response in the keypad and device functions. A device in this condition has the potential to delay delivery of therapy, and this delay in therapy has the potential to result in serious injury or death.

Since the initial commercialization of LIFEPAK 15 in 2009, Stryker has become aware of 58 complaints reported globally for this issue, including 6 events in which the patient died following a delay in therapy. In all six of these cases, at least one shock was delivered prior to the device experiencing the lock-up condition. There are 13,003 devices potentially affected by this issue and within scope of this field action.

Stryker's planned actions

The Company is contacting customers with impacted devices to schedule the correction of their device(s), which will include an update to the firmware for the affected component on the System PCBA. Stryker anticipates that all devices subject to this field action will be serviced by December 31, 2019.

Required customer actions

We request that you read this notice carefully and complete the following actions:

1. **Continue to use your LIFEPAK 15 Monitor/Defibrillator according to the Operating Instructions until the correction can be completed.**

Stryker UK
Stryker House, Hambridge Road, Newbury, Berks. RG14 5AW | P +44 1635 262400 | F +44 1635 580300| stryker.com

Device Automatic Self-Tests do not identify this fault, as it occurs during defibrillation. Customers should continue to perform the daily check as described in the Operator's Checklist, specifically, the QUIK-COMBO therapy cable check as described in the General Maintenance and Testing Section (pages 10-4 and the LIFEPAK 15 Monitor/Defibrillator Operator's Checklist, number 7).

If a device exhibits the lockup condition during patient use, the steps from the General Troubleshooting Section (page 10-18) of the LIFEPAK 15 Monitor/Defibrillator Operating Instructions should be followed:

Press and hold **ON** until the LED turns off (~5 seconds). Then press **ON** to turn the device back on.
If the device does not turn off, remove both batteries and disconnect the device from the power adapter, if applicable. Then reinsert batteries and/or, reconnect the power adapter, and press **ON** to turn the device back on.

2. Circulate this Field Safety Notice internally to all interested/affected parties.

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

4. Inform Stryker if any of the subject devices have been distributed to other organisations.
    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.

6. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

7. 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.

8. 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 organise any applicable ongoing actions.

We request that you respond to this notice within 07 calendar days from the date of receipt. The target date for completion of this action is XX-XX-XX and your timely response will enable us to ensure that we meet this target.

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: XXXXX
Position: XXXXX

Telephone: XXXXX
E-mail: XXXXX

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.

Yours faithfully,

Acknowledgment of Field Safety Notice: RA2018- 1976124

FSCA identification: Product recall RA2018- 1976124

Action type: Field Safety Corrective Action

Affected items: See attached list

Product description: LIFEPAK 15 Monitor/Defibrillator

I acknowledge receipt of the Field Safety Notice for RA2018-1976124 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	Serial Number
We have further distributed subject devices to the following organisations:		
Facility Name		
Facility Address		

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO XXXXXX
OR EMAIL TO XXXXX