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«Title»
«Hospital»
«Address_1»
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URGENT: FIELD SAFETY NOTICE

24th September 2010

Stryker Reference:	RA 2010-079
Type of Action:	Retrofit / Upgrade
Affected Product:	Stryker ® Model 6100 M1 Ambulance Cot
Product/Model Ref:	6100-xxx-xxx
Serial Numbers:	001239066 - 091139098

Dear Customer,

Our manufacturer, Stryker Medical Kalamazoo, has notified us of a Product Field Action concerning the Medical Devices referenced above. 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.

Description of Problem

It has been found that the head end slide tube, bushings, and head end release rod can break during use, potentially resulting in the head end of the cot to collapse.

Population Concerned

Patients and caregivers (emergency medical personnel) using the affected ambulance cots.

Potential Hazards associated with use of device

1. Potential operator muscle strain from attempting to catch the collapsing head end of the cot.
2. Potential operator muscle strain from needing to carry a heavy patient on the removable litter over an increased distance due to the base no longer being functional.
3. Potential injuries to patient or operator due to instability of the cot.
4. Potential delay of treatment due to the need to call in a second ambulance and / or cot in order to transfer the patient to a functional cot for transport to the healthcare facility.
5. Potential worsening of a patient's condition due to a sudden collapse of the cot.

Mitigating Circumstances / Precautionary Measures

None.

Immediate Actions

1. Immediately locate all subject devices.
2. If the unit does not operate properly, remove the unit from service and contact your local Stryker Distributor as soon as possible.
3. Do not put the cot back into service until it is repaired by a Stryker Authorised Field Service Technician.
4. Circulate this list internally to all interested / affected parties.
5. Maintain awareness of this of this notice internally until all required actions have been completed within your facility.
6. 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.
7. Immediately inform Stryker of any adverse events concerning use of subject devices. Note- please ensure compliance with any local vigilance regulations.
8. Please indicate the serial numbers of any of the affected cots which have been scrapped or disposed of.

Product Upgrade Information

1. Return the enclosed customer response form to confirm receipt of this notification and compliance with the instructions provided by the manufacturer
2. Please complete this form even if you have not located any devices. This will preclude the need to Stryker to send any reminder notices.
3. Return the completed form either by post to the address provided above, fax on 01635 262464 or email to christopher.smejkal@stryker.com
4. A Stryker representative will then contact you to organise for subject devices to be upgraded. Please note that all affected cots will need to be upgraded even if they are currently functioning correctly.

Please see overleaf for details of the affected cots sent to your organisation. To assist you with identification we have also included a photo of the affected cot. PLEASE NOTE: The cot serial number is located in the centre of the bottom rail, at either the head or foot-end. An additional serial number is located behind the head-rest on the unit. We would like to advise to check both locations for affected serial numbers.

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

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.

On behalf of Stryker we would like to thank you in advance for your cooperation and support in this matter. Should you require any further information or have any queries on the matter please do not hesitate to contact the undersigned on 01635 262465.

Yours faithfully,

Christopher Smejkal
Regulatory Affairs Manager
CC: «cc»

Affected Cots

Customer: «Hospital»

Cot Model	Serial Number
«Model_1»	«Serial_1»
«Model_2»	«Serial_2»
«Model_3»	«Serial_3»
«Model_4»	«Serial_4»
«Model_5»	«Serial_5»
«Model_6»	«Serial_6»
«Model_7»	«Serial_7»
«Model_8»	«Serial_8»

CUSTOMER RESPONSE FORM

Stryker Reference:	RA 2010-079
Affected Product:	Stryker ® Model 6100 M1 Ambulance Cot
Product/Model Ref:	6100-xxx-xxx

PLEASE TICK APPROPRIATE SECTION

❑ WE HAVE PHYSICALLY CHECKED ALL AMBULANCE LOCATIONS, AND WE DO NOT HAVE THE AFFECTED COTS.

❑ WE HAVE DISTRIBUTED SOME/ALL OF THE COTS REFERENCED TO THE FOLLOWING ORGANISATION *(please provide details)*:

❑ WE HAVE LOCATED THE COTS REFERENCED IN THE ENCLOSED LETTER. PLEASE ARRANGE TO UPGRADE THE FOLLOWING COTS:

MODEL NO.	**SERIAL NO.**	**MODEL NO.**	**SERIAL NO.**

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	

Contact name regarding organisation of device upgrades (if different from above):	
Contact Phone No.	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO CHRISTOPHER.SMEJKAL@STRYKER.COM