

# URGENT FIELD SAFETY NOTICE: RA2018-1748498

**Product: M-1® Cot Fastener**

**Model: 6376, 6381**

ATTN: Risk Management/ Fleet Manager



March, 2018

**FSCA identification: RA2018-1748498**

**Action type: Medical device correction**

Model numbers	Product description	Serial number(s)
6376-000-000 6381-000-000	M-1® Cot Fasteners shipped between 8/2/2017 and 12/15/2017	See Attachment

The purpose of this letter is to advise you that Stryker Medical is voluntarily correcting specific serial numbers of **M-1 Cot Fastener, Model: 6376, 6381**

### Product Description:

The Stryker Model 6376 and 6381 ambulance cot fasteners hold a compatible ambulance cot in an emergency vehicle for patient transport purposes. The Model 6376 and 6381 ambulance cot fasteners perform this function after the user manually loads the compatible cot into the emergency vehicle and guides it into the fastener.

### Reason for the Voluntary Correction:

During a review of Operations Manual and the Maintenance Manual, it was discovered that the various warnings and cautions were missing in the sections titled "Operating the Cot Fastener" and "Cleaning Sections" and had incorrect information that did not pertain to the 6376 and 6381 Cot Fasteners.

### Risk to Health:

A Health Hazard Evaluation was completed which identified the highest potential hazard for the user of temporary or reversible harm not requiring medical intervention due to missing warnings and user instructions. The highest potential hazard for the patient is discomfort.

### Actions to be taken by the Customer/User:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

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

1. Locate the operations manual shipped with each unit listed on the attached business reply form and replace it with the corrected manual included with this letter. Please dispose of the incorrect manual.  
**Note:** All product operations and maintenance manuals are available online at <https://techweb.stryker.com>.
2. Return the enclosed business reply form to confirm receipt of this notification to  
(*Insert desired return information here*)
3. If you have loaned or sold any of the products listed in this letter, please forward a copy of this notice to the new users and advise us of their new location in the space provided on the business reply form.
4. If you have disposed of any of these units and they are no longer in use, please, advise us of their obsolescence by providing us with their serial number in the space provided on the business reply form

We request that you respond to this notice within **XXX** calendar days from the date of receipt.

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:** \_\_\_\_\_ **Position:** \_\_\_\_\_ **email:** \_\_\_\_\_

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 Sincerely,

**XXXXXX**

Business reply

## Product: Cot Fastener

Model:

6376 M1® Cot Fastener

6381 M1® Cot Fastener

Account number:

Account name:

Below, please find the list of affected serial numbers that have been shipped to your location.


Please complete and return this form to Stryker's Regulatory Department by fax **269 488 8691** or email **productfieldaction@stryker.com**

**Note:** Your signature indicates that you have received and understand the enclosed notification.

\_\_\_\_\_  
Printed name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Contact phone number

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Email address

\_\_\_\_\_  
Fax number

If you have loaned or sold any of the units listed, please, forward a copy of this notice to the new users and advise us of their new location. If you have disposed of any of the units and they are no longer in use, please, advise us of their obsolescence by providing us with their serial numbers.

\_\_\_\_\_  
\_\_\_\_\_  
Regulatory Affairs  
Phone: 269 389 8306  
Fax: 269 488 8691  
Email: productfieldaction@stryker.com

Note: Please keep a copy of this completed, executed form for your records.