

IMPORTANT MEDICAL DEVICE NOTIFICATION

**RE: Stryker Performance-LOAD Cot Fasteners
MODEL: 6392**

ATTENTION: Fleet Manager/Recall Coordinator

Date November 8, 2016

Product Affected	Manufacturer Model Numbers	Product Description	Serial Number(s)
	6392-000-001 6392-000-002, 6392-000-003, 6392-000-004	Stryker Performance-LOAD (manufactured between March 20, 2016 – October 28, 2016)	See Attachment

Product Description Performance-LOAD is a manual cot fastener designed to secure compatible ambulance cots into a ground-based transport vehicle for patient transportation purposes.

Product Issue It was discovered through complaints and service reports that some cots compatible with the Performance-LOAD cot fastening system may not have been securely fastened or had an inability to fasten into the Performance-LOAD (bounced back during loading).

The fastening issues between the cot and the fastener are associated with the Foot End Fastener (Figure 1) on the cot and the Foot End Interface (Figure 2) of the Performance-LOAD.

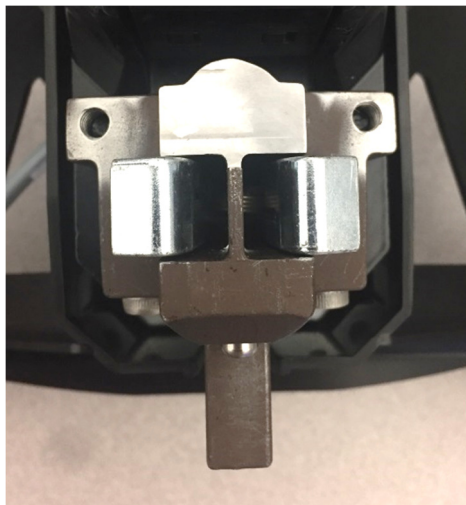


Figure 1: Foot End Fastener
(Cot Side)



Figure 2: Foot End Interface
(Performance-LOAD Side)

Potential Hazard

A Health Hazard Evaluation was completed which determined that there is a high probability of temporary or reversible harm, specifically mild soft tissue contusion or muscle strain not requiring medical intervention. There have been no reports of injury associated with this issue.

Actions Needed

1. Locate the units listed on the attached business reply form and identify the address where they can be serviced.
2. Return the enclosed business reply form to confirm receipt of this notification by fax (269)488-8691 or email productfieldaction@stryker.com
3. Upon receipt of the completed business reply form, Stryker will contact you to arrange for the modification/repair of your Performance-LOAD unit to ensure that the unit securely fastens the cot within the ambulance.
4. In the interim, until the service can be performed, there are additional actions that users can and should take to ensure that the cot is securely fastened into the Performance-LOAD system.
 - a. Per the Performance-LOAD Operations Manual (P/N 6392-009-001, pages 26-27; excerpt attached) complete steps 1-5 as described to load a cot into the Performance-LOAD system.
 - b. **Depress and hold the Performance-LOAD release button** while completing step 6 as described in the Operations Manual, which states: Push the cot into the vehicle patient compartment until the cot locks in the cot fastener. **Do not release the button until the cot is in the transport position.** (See Figure 3)



Figure 3: Performance-LOAD Release Button

- c. Proceed with Step 7, to ensure that the cot is fully locked into the fastener.
 - i. If cot is not securely fastened, repeat steps a. and b.
 - d. If you desire additional training associated with this interim step, please contact our Technical Support team.
5. 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.

6. If you have disposed of any of the Performance-LOAD 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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm.
Mail to MedWatch , P.O. Box 3002, Rockville, MD 20847-3002
- Fax: 1-800-FDA-0178

If you have any questions or concerns, please contact Stryker Customer Service (1-800-327-0770). Our normal business hours are Monday-Friday 8 a.m-6 p.m. (EST).

We apologize for any disruption that this notification may cause. We strive to make products that meet our customers' expectations for quality and durability.

Sincerely,

Renata Sila

Renata Sila
Chief Regulatory Affairs Specialist
Stryker Medical

Once again, please fax (269-488-8691) or e-mail (ProductFieldAction@stryker.com) the enclosed acknowledgement of this notification.

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Loading a compatible cot into Performance-LOAD

WARNING

- Always load or unload an occupied cot into a vehicle with a minimum of two trained operators.
- Always allow occupants to enter the vehicle patient compartment after the compatible cot has been loaded into the vehicle patient compartment.
- Always check for sheets, restraints, or debris that may catch in the cot transport or load wheels.

CAUTION

Do not push the cot into the vehicle patient compartment until you fully retract the cot base.

1. Lift the vehicle bumper to the raised position, if equipped.
2. Fully extend and lock the cot retractable head section before you load the cot into the powered cot fastener.
3. Place the cot in a loading position (any position where the loading wheels meet the vehicle patient compartment floor height).
4. Roll the cot to the open vehicle patient compartment.
5. Push the cot forward until the loading wheels are on the vehicle patient compartment floor and the safety bar passes the safety hook.

Note: For maximum clearance to lift the base, pull the cot out until the safety bar is connected to the safety hook.

For model 6500, model 6506, model 6516 with **Performance-LOAD**:

- Grasp the cot frame at the foot end.
- Lift the foot end of the cot and press and hold the retract (-) button on the cot control switch to fully retract the cot undercarriage.

Note: The cot undercarriage will retract in less than three seconds.

For model 6086 with **Performance-LOAD**:

- Operator 1 (foot end): Grasp the cot frame at the foot end. Squeeze and hold the cot manual release.
- Operator 2 (side): Grasp the outer rail to stabilize the cot. Then, grasp the base frame. After the foot end operator has lifted the cot and squeezed the cot manual release, retract the undercarriage with one hand and hold it in place.
- Operator 1 (foot end): Release the cot manual release to lock the undercarriage in the retracted position.

6. Push the cot into the vehicle patient compartment until the cot locks into the cot fastener.
7. Make sure that the cot is locked into the cot fastener by firmly pulling in and out and side to side on the foot end of the cot.