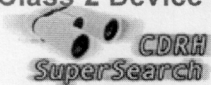


FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

### Class 2 Device Recall Spirit Select Bed

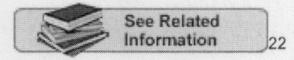


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### Class 2 Device Recall Spirit Select Bed



**Recall Date** August 03, 2016

**Recall Status<sup>1</sup>** Open

**Recall Number** Z-2332-2016

**Recall Event ID** 74560<sup>23</sup>

**Product Classification** Bed, ac-powered adjustable hospital<sup>24</sup> - **Product Code FNL**<sup>25</sup>

**Product** Spirit Select Bed, A-C Powered Hospital Bed

**Code Information**

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<b>Recalling Firm/ Manufacturer</b>	CHG Hospital Beds Inc 153 Towerline Place London Canada
<b>For Additional Information Contact</b>	Renata Sila 800-327-0770
<b>Manufacturer Reason for Recall</b>	Stryker Medical is initiating a voluntary recall of the Spirit Select and Spirit Plus A-C powered hospital beds due to reports of hi-lo actuators broken at the mount ends, which could cause the bed to unexpectedly lower resulting in patient injury.
<b>FDA Determined Cause <sup>2</sup></b>	Component design/selection
<b>Action</b>	The firm, Stryker Medical, issued an "URGENT MEDICAL DEVICE RECALL" letter dated 7/8/2016 by FedEx to its customers and included a revised preventive maintenance checklist. The letter described the product, problem and actions to be taken. The customers were instructed to: locate the units listed on the attached business reply form; remove these units from service, if not possible to remove units from service, place units in the height position according to instructions; file the revised preventative maintenance checklist; return the Business Reply Form to confirm receipt of the notification by fax (269)488-8691 or email productfieldaction@stryker.com. If customers have loaned or sold any of the beds listed in this letter, please forward a copy of the recall notice to the new users and advise us of their new location in the space provided on the business reply form. Your Stryker Field service Representative will contact your facility to add support brackets to your beds. 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: <a href="http://www.fda.gov/medwatch/report.htm">www.fda.gov/medwatch/report.htm</a> " Regular Mail: use postage-paid FDA form 3500 available at: <a href="http://www.fda.gov/MedWatch/getforms.htm">www.fda.gov/MedWatch/getforms.htm</a> . 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).
<b>Quantity in Commerce</b>	4,308 units total
<b>Distribution</b>	Worldwide Distribution: US (nationwide) including states of: AK , AL, AR, AZ, CA, CO, CT, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, TN, TX, VA, WA, and WI; and country of: Canada
<b>Total Product Life Cycle</b>	<u>TPLC Device Report</u> <sup>26</sup>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)<sup>27</sup>

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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