

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

**Class 2 Device Recall Spirit Plus Bed**

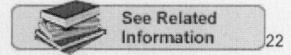


<sup>6</sup> 510(k)|<sup>7</sup> DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup>  
CFR Title 21<sup>16</sup>|Radiation-Emitting Products<sup>17</sup>|X-Ray Assembler<sup>18</sup>|Medsun Reports<sup>19</sup>|CLIA<sup>20</sup>|TPLC<sup>21</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Device Recall Spirit Plus Bed**



**Recall Date** August 03, 2016

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

**Recall Number** Z-2331-2016

**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 Plus Bed, A-C Powered Hospital Bed

**Code Information**

- 032260
- 032261
- 032262
- 032263
- 032264
- 032265
- 032266
- 032267
- 032268
- 032269
- 032270
- 032271
- 032272
- 032273
- 032274
- 032275
- 032276
- 032277
- 032278
- 032279
- 032280
- 032281
- 032282
- 032283
- 032284
- 032285
- 032286
- 032287
- 032288
- 032289
- 032290
- 032291
- 032292
- 032293
- 032294
- 032295
- 032296
- 032297
- 032298
- 032299
- 032300
- 032301

032302  
032303  
032304  
032305  
032306  
032307  
032308  
032309  
032310  
032311  
032312  
032313  
032314  
032315  
032316  
032317  
032318  
032319  
032320  
032321  
032322  
032323  
032324  
032325  
032326  
032327  
032328  
032329  
032330  
032331  
032332  
032333  
032334  
032335  
032336  
032337  
032338  
032339  
032340  
032341  
032342  
032343  
032344  
032357  
032358  
032359  
032360  
032361  
032362  
032363  
032364  
032365  
032366  
032367  
032368  
032369  
032370  
032371  
032372  
032373  
032374  
032375  
032376  
032377  
032378  
032379  
032380  
032381  
032382



032383  
 032384  
 032386  
 032387  
 032388  
 032389  
 032390  
 032391  
 032392  
 032393  
 032394  
 032395  
 032396  
 032397  
 032398  
 032399  
 032400  
 032401  
 032402  
 032403  
 032404  
 032405  
 032406  
 032407  
 032408  
 032409  
 032410  
 032411  
 032412  
 032413  
 032414  
 032415  
 032416  
 032417  
 032418  
 032419  
 032420  
 0

**Recalling Firm/  
 Manufacturer**

CHG Hospital Beds Inc  
 153 Towerline Place  
 London Canada

**For Additional  
 Information Contact**

Renata Sila  
 800-327-0770

**Manufacturer Reason  
 for Recall**

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.

**FDA Determined  
 Cause <sup>2</sup>**

Component design/selection

**Action**

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: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) " Regular Mail: use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://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).

<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>	<a href="#">TPLC Device Report</a> <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.

---

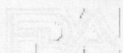
**Links on this page:**

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. [/scripts/cdrh/cfdocs/cfPCD\\_RH/classification.cfm](/scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm)
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfClaia/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm>
22. <http://www.fda.gov/safety/recalls/enforcementreports/default.htm>
23. [/scripts/cdrh/cfdocs/cfRES/res.cfm?start\\_search=1&event\\_id=74560](/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=74560)
24. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=FNL>
25. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=FNL>
26. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm?id=FNL>
27. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55>

Page Last Updated: 08/19/2016

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

[Accessibility](#) [Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA](#) [No FEAR Act](#) [Site Map](#) [Transparency](#) [Website Policies](#)



U.S. Food and Drug Administration  
10903 New Hampshire Avenue