Class 2 Device Recall Spirit Plus Bed

Class 2 Device Recall Spirit Plus Bed

See Related Information[22]

Recall Date	August 03, 2016
Recall Status[1]	Open
Recall Number	Z-2331-2016
Recall Event ID	74560[23]
Product Classification	Bed, ac-powered adjustable hospital[24] - **Product Code** FNL[25]
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 [2]	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 " 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).
Quantity in Commerce	4,308 units total
Distribution	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
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] 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=fdamain
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
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /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/tplc.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.

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