REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
THE DIRECTOR GENERAL

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧/٢٥
رقم الصادر: ٣٨٣
بيروت، في: ١٣ تشرين الأول ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Femoral Hip, Free Lock Femoral Fixation System

الجهاز المعني بالمتابعة:

- Femoral Hip, Free Lock Femoral Fixation System
- Trade Mark: Zimmer Inc
- Local Representative: Intermedic

بناء على التقرير الصادر عن وكالة ال FDA
الذي يشير الى وجود خلل في عملية توضيب الصنف المذكور أعلاه مما قد يؤثر على فعالية التعقيم،
نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
قلم الدعوان
وزارة الصحة العامة

Class 2 Recall
Free Lock Femoral Fixation System

Date Posted
August 26, 2013

Recall Number
Z-2091-2013

Product
Free Lock Femoral Hip Fixation System Compression Tube/Plate, different length (59, 75, 91, 107, 123 mm), holes (2, 3, 4, 5, 6) and degree angles (130, 135, 140, 145 and 150). Item codes starting with 00-1181-130, 00-1181-135, 00-1181-140, 00-1181-145, 00-1181-150). ZIMMER Compression Hip Screw , orthopedic implant.

Code Information
60611049 60624520 60619105 60619109 60624518 60624519 60625544 60619107 60619879 60611045 60624521 60625511 60625536 60625542 60582204 60619887 60657047 60646266 60657046 60657070 60657071 60657072 60632725 60657051 60657073 60657083 60657075 60657078 60657088 60625545 60646267 60657049 60657052 60657077 60657079 60657087 60657084 60668304 60668305 60582089 60674430 60674431 60685115 60714886 60714872 60714893 60714875 60714897 60714851 60714890 60714892 60714850 60714877 60714896 60714891 60714894 60763218 60763232 60763219 60763220 60763221 60763226 60763230 60763234 60763223 60763227 60763229 60763222 60763224 60763225 60763231 60763233 60714895 60763228 60803587 60803589 60803591 60803592 60803593 60807853 60807854 60803588 60803590 60807855 60803586 60807868 60815019 60820809 60841203 60820796 60807857 60820798 60820801 60807858 60807859 60807861 60807856 60815017 60807865 60820810 60820807 60868474 60868478 60874089 60874093 60874097 60877491 60868477 60885177 60885178 60885180 60885182 60885175 60885179 60885185 60885184 60902841 60905697 60902842 60902843 60911345 60911346 60911348 60911350 60931165 60931166 60911349 60931164 60938423 60944574 60931167 60931168 60944606 60932394 60944525 60938427 60944551 60968742 60959978 60969382 60972805 60972806 60968739 60968744 60988403 60988405 60962160 60988402 60988407 60988408 60988404 60998291 60998292 61020344 61030741 61020343 61030740 61037492 61030742 61037493 61037494 61048120 61048117 61048116 61048119 61048115 61048121 61027553 61048118 61027552 61076085 61076086 61086854 61086857 61079836 61079834 61092273 61092280 61101553 61092247 61092249 61092258 61092281 61092283 61101552 61101554 61103203 61103208 61101551 61103202 61103204 61103206 61103207 61108242 61108243 61108244 61115872 61114143 61118976 61140178 61162614 61162616 61162617 61162615 61169420 61198462 61264756 61269944 61198455 61162618 61179754 61179757 61198458 61198460 61198461 61209574 61198456 61209572 61209573 61198457 61264754 61269949 61264753 61198459 61286925 61288126 61294831 61246085 61264748 61286923 61286928 61294832 61294833 61304496 61264749 61264750 61286930 61326116 61264752 61264751 61294834 61341158 61352935 61294835 61352934 61352936 61359996 61359995 61359994 61420344 61420343 61412173 61375175 61436467 61377328 61377330 61379892 61402004 61402005 61402007 61440257 61440688 61375177 61437988 61440689 61457772 61379890 61379891 61437989 61463554 61463555 61440690 61453112 61464380 61457773 61464381 61453111 61463557 61464379 61408293 61473803 61512406 61523582 61523859 61529230 61538716 61542608 61542610 61542611 61558660 61558661 61565485 61565484 61565488 61565486 61565487 61565489 61585377 61578712 61584969 61590989 61590993 61590994 61602063 61613172 61602064 61621833 61628735 61621843 61635176 61621834 61621838 61621842 61640885 61640886 61640887 61700444 61682532 61682545 61672121 61682542 61682544 61682546 61717286 61714071 61719312 61746531 61719308 61719314 61752596 61752594 61752599 61752602 61753041 61761524 61682547 61753042 61753043 61756193 61853082 61870425 61888704 61902191 61990140 62271890 62271887

Recalling Firm/ Manufacturer
Zimmer, Inc.
345 E Main St
Warsaw, Indiana 46580-2746

Consumer Instructions
Contact the recalling firm for information

For Additional Information Contact
Questions and Concerns Number
877-946-2761

Reason for Recall
Single packaging configuration used for the VERSA-FX-II Femoral Fixation System failed the leak test compromising the sterility of the product.

Action
The firm, Zimmer, sent an "URGENT MEDICAL DEVICE NOTIFICATION" letter dated July 11, 2013 to its customers. The letter describes the product, problem and actions to be taken. The customers were instructed to inspect the device according to the insert instructions; not use the device if damage to the corner of the inner tray is observed, and contact the firm for return and questions. Customers should also keep this notification in mind and inform Zimmer of product with this condition using zimmer.per@zimmer.com. If after reviewing this notification you have questions or concerns, please contact Zimmer at 1-877-946-2761.

Quantity in Commerce
85, 794 units in total

Distribution
Worldwide distribution: US Nationwide (including PR and USVI), and countries of: Israel, Argentina, Brazil, France, Mexico, Saudi Arabia, Beirut, China, Korea, San Salvador, Honduras, Canada, Australia, Switzerland, Germany, Arab Emirates, UK, Belgium, Egypt, Spain, France, Italy, Iran, Lebanon, Jordan, Iraq, Canary Islands.

New Search

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See Related Information 21

Class 2 Recall
Free Lock Femoral Fixation System

Date Posted	August 26, 2013
Recall Number	Z-2094-2013
Product	VERSA-FX II FEMORAL FIXATION SYSTEM COMPRESSION TUBE/PLATE, standard and short - low profile, different hole/length combinations (4/86, 5/102 and 6/118), different degree angles (130, 135, 140, 145 and 150). Item codes starting with 00-194-130, 00-1194-135, 00-1194-140, 00-1194-145, 00-1194-150)., orthopedic implant.
Code Information	60619089 60619099 60611043 60619098 60611039 60632532 60668205 60668241 60669598 60668240 60668247 60685095 60685102 60679344 60685066 60685104 60685096 60674425 60704366 60704367 60704370 60714913 60704368 60714914 60714915 60714916 60726325 60744850 60714917 60726326 60754395 60763214 60763215 60763216 60787010 60787191 60787194 60787198 60787190 60787192 60787193 60787196 60787199 60787197 60787189 60803585 60807846 60807848 60803584 60787195 60815493 60845778 60845777 60844062 60868471 60877490 60877489 60885169 60885171 60911343 60932392 60932393 60938417 60938419 60943339 60938421 60944523 60787188 60972802 60972803 60998290 61005007 60972801 61020337 61020339 61020335 61037487 61037488 61037489 61041090 61037490 61027502 61027507 61027516 61041091 61027510 61027523 61027511 60868468 61076083 61086851 61041093 61092223 61092239 61092241 61103196 61103197 61103198 61103201 61101549 61103199 61101547 61041089 61140177 61162619 61162620 61169415 61169416 61169417 61179752 61169418 61198454 61223003 61162621 61092237 61228339 61264745 61264742 61264746 61294830 61286877 61304472 61286880 61309349 61309350 61286879 61341982 61341983 61357166 61357172 61357171 61359993 61286878 61446407 61456386 61375171 61458224 61459335 61474332 61464382 61476801 61476802 61476803 61427113 61427114 61475572 61427115 61474333 61474334 61482163 61482164 61453113 61493898 61511595 61516366 61516367 61523581 61542781 61538715 61542606 61551564 61565482 61565483 61584968 61578708 61596986 61613171 61590988 61596985 61619259 61631410 61631417 61631426 61619260 61640888 61635177 61640895 61640889 61640890 61672132 61672134 61640891 61672127 61708338 61708350 61714083 61729213 61748334 61749017 61749009 61749012 61749027 61758148 61804344 61861311 62105419 62271938 62271936 62271934 62310747
Recalling Firm/ Manufacturer	Zimmer, Inc. 345 E Main St Warsaw, Indiana 46580-2746
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Questions and Concerns Number 877-946-2761
Reason for Recall	Single packaging configuration used for the VERSA-FX-II Femoral Fixation System failed the leak test compromising the sterility of the product.
Action	The firm, Zimmer, sent an "URGENT MEDICAL DEVICE NOTIFICATION" letter dated July 11, 2013 to its customers. The letter describes the product, problem and actions to be taken. The customers were instructed to inspect the device according to the insert instructions; not use the device if damage to the corner of the inner tray is observed, and contact the firm for return and questions. Customers should also keep this notification in mind and inform Zimmer of product with this condition using zimmer.per@zimmer.com. If after reviewing this notification you have questions or concerns, please contact Zimmer at 1-877-946-2761.
Quantity in Commerce	85, 794 units in total
Distribution	Worldwide distribution: US Nationwide (including PR and USVI), and countries of: Israel, Argentina, Brazil, France, Mexico, Saudi Arabia, Beirut, China, Korea, San Salvador, Honduras, Canada, Australia, Switzerland, Germany, Arab Emirates, UK, Belgium, Egypt, Spain, France, Italy, Iran, Lebanon, Jordan, Iraq, Canary Islands.

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6. /scripts/cdrh/devicesatfda/index.cfm

Class 2 Recall
Free Lock Femoral Fixation System

Date Posted	August 26, 2013
Recall Number	Z-2092-2013
Product	VERSA-FX FEMORAL FIXATION SYSTEM COMPRESSION LAG SCREW, several length (55 mm to 155 mm), diameters (12.7 mm and 15.8 mm) and short thread, standard thread and large thread. Item codes starting with 00-1193-005, 00-1193-010 and 00-1193-015. orthopedic implant.
Code Information	60550146 60585234 60585240 60621358 60612822 60585235 60612824 60585239 60629949 60629951 60573157 60612823 60612832 60629948 60629756 60629755 60629950 60560744 60621346 60621347 60621348 60621350 60612826 60621349 60621351 60621353 60585244 60612820 60612830 60621354 60621356 60621357 60612825 60612829 60612831 60653083 60653092 60653075 60653078 60653085 60653088 60653100 60653111 60539408 60539409 60653095 60653098 60653107 60653110 60653114 60653116 60653115 60653121 60671979 60671980 60653146 60671982 60561143 60653108 60653109 60653119 60653123 60653124 60653125 60653130 60653134 60653135 60653136 60653139 60653143 60653104 60653118 60653127 60682963 60671976 60653117 60653129 60653132 60661882 60671959 60671977 60671962 60671967 60653142 60621355 60653141 60671965 60671963 60671964 60523364 60612818 60653131 60671961 60615110 60653133 60653140 60536820 60671970 60671978 60671969 60671971 60671972 60671975 60671981 60690731 60653122 60671960 60680440 60653145 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62116937 62116938 62137453 62142285 62157179 62137454 62137457 62137456 62146203
62160329 62171305 62171306 62146188 62146192 62146190 62142288 62137451 62124275
62213267 62227193 62317533 62317536 62322864 62322881 62158917

Recalling Firm/ Manufacturer	Zimmer, Inc. 345 E Main St Warsaw, Indiana 46580-2746
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Questions and Concerns Number 877-946-2761
Reason for Recall	Single packaging configuration used for the VERSA-FX-II Femoral Fixation System failed the leak test compromising the sterility of the product.
Action	The firm, Zimmer, sent an "URGENT MEDICAL DEVICE NOTIFICATION" letter dated July 11, 2013 to its customers. The letter describes the product, problem and actions to be taken. The customers were instructed to inspect the device according to the insert instructions; not use the device if damage to the corner of the inner tray is observed, and contact the firm for return and questions. Customers should also keep this notification in mind and inform Zimmer of product with this condition using zimmer.per@zimmer.com. If after reviewing this notification you have questions or concerns, please contact Zimmer at 1-877-946-2761.
Quantity in Commerce	85, 794 units in total
Distribution	Worldwide distribution: US Nationwide (including PR and USVI), and countries of: Israel, Argentina, Brazil, France, Mexico, Saudi Arabia, Beirut, China, Korea, San Salvador, Honduras, Canada, Australia, Switzerland, Germany, Arab Emirates, UK, Belgium, Egypt, Spain, France, Italy, Iran, Lebanon, Jordan, Iraq, Canary Islands.

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Reason for Recall	Single packaging configuration used for the VERSA-FX-II Femoral Fixation System failed the leak test compromising the sterility of the product.
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Distribution	Worldwide distribution: US Nationwide (including PR and USVI), and countries of: Israel, Argentina, Brazil, France, Mexico, Saudi Arabia, Beirut, China, Korea, San Salvador, Honduras, Canada, Australia, Switzerland, Germany, Arab Emirates, UK, Belgium, Egypt, Spain, France, Italy, Iran, Lebanon, Jordan, Iraq, Canary Islands.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA