Class 2 Recall Zimmer Trabecular Metal" Total Ankle Tibial Base and Talar Components

See Related Information[21]

Date Posted	December 10, 2013
Recall Status[1]	Open
Recall Number	Z-0476-2014
Premarket Notification 510(K) Number	K120906[22]
Product Classification	Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer[23] - **Product Code** HSN[24]
Product	Zimmer Trabecular Metal Total Ankle Talar Component Right Sizes 1-6 Total ankle arthroplasty is intended to provide a patient with limited mobility by restoring alignment, reducing pain and preserving the flexion/extension movement within the ankle joint.The Zimmer Trabecular Metal Total Ankle is indicated as a total ankle replacement in primary or revision surgery for patients with: " Rheumatoid arthritis. " Post-traumatic arthritis. " Degenerative arthritis. This device is intended for cemented use only.
Code Information	Part Number Lot Number 00450002100 62163375 00450002100 62248804 00450002100 62248805 00450002100 62267632 00450002100 62279047 00450002500 62220671 00450002500 62220675 00450002500 62226571 00450002500 62279042 00450002500 62279049 00450002500 62285553 00450002500 62290846 00450002500 62290857 00450002500 62343556 00450002500 62357507 00450002500 62368386 00450002500 62375875 00450002500 62405317 00450002500 62409039 00450002500 62419539 00450002500 62428993 00450002500 62439679 00450002500 62442236 00450002600 11007905 00450002600 62163386 00450002600 62262903 00450002600 62264848 00450002600 62290827 00450002600 62297849 00450002100 62287975 00450002100 62331805 00450002100 62337206 00450002100 62337758 00450002100 62349863 00450002100 62357502 00450002100 62358897 00450002100 62397419 00450002100 62397420 00450002200 62163377 00450002200 62239777 00450002200 62239790 00450002200 62267633 00450002200 62267635 00450002200 62279048 00450002200 62279054 00450002200 62290840 00450002200 62290843 00450002200 62337207 00450002200 62343552 00450002200 62357504 00450002200 62375870 00450002200 62405311 00450002200 62416043 00450002200 62419536 00450002200 62453776 00450002200 62453777 00450002200 62459876 00450002300 11009092 00450002300 62163380 00450002300 62215391 00450002300 62215394 00450002300 62220673 00450002300 62267034 00450002300 62267636 00450002300 62279055 00450002300 62285552 00450002300 62305740 00450002300 62310753 00450002300 62323811 00450002300 62337208 00450002300 62337759 00450002300 62349864 00450002300 62357505 00450002300 62357506 00450002300 62372417 00450002300 62375873 00450002300 62378065 00450002300 62409035 00450002300 62409036 00450002300 62416044 00450002300 62419537 00450002300 62453778 00450002400 62163383 00450002400 62208155 00450002400 62239778 00450002400 62267035 00450002400 62267036 00450002400 62267637 00450002400 62267638 00450002400 62297851 00450002400 62305741 00450002400 62305742 00450002400 62310754 00450002400 62316171 00450002400 62343554 00450002400 62343555 00450002400 62349866 00450002400 62368385 00450002400 62372419 00450002400 62375874 00450002400 62378066 00450002400 62393806 00450002400 62397421 00450002400 62405314 00450002400 62405315 00450002400 62409037 00450002400 62409038 00450002400 62416045 00450002400 62416047 00450002400 62419538 00450002400 62453782 00450002400 62459863 00450002400 62459864 00450002400 62459866 00450002500 11008421 00450002500 11008423 00450002500 62163384 00450002500 62208156 00450002600 62297850 00450002600 62310755 00450002600 62331806 00450002600 62331812 00450002600 62337209 00450002600 62349867 00450002600 62357508 00450002600 62358902 00450002600 62368387 00450002600 62405319 00450002600 62419540 00830002100 62264853 00830002100 62316175 00830002100 62323787 00830002100 62337211 00830002100 62349871 00830002100 62459838 00830002200 11009324 00830002200 62204732 00830002200 62215397 00830002200 62323788 00830002200 62331820 00830002200 62343566 00830002200 62430807 00830002300 62204765 00830002300 62220678 00830002300 62297852 00830002300 62323789 00830002300 62323794 00830002300 62331822 00830002300 62349872 00830002300 62357512 00830002300 62419528 00830002400 62208151 00830002400 62264855 00830002400 62316178 00830002400 62323790 00830002400 62343567 00830002400 62349873 00830002400 62405298 00830002500 62204734 00830002500 62215398 00830002500 62316176 00830002500 62323792 00830002500 62331823 00830002500 62337217 00830002500 62357513 00830002600 62239781 00830002600 62305744 00830002600 62316179 00830002600 62323796 00830002600 62337220 00830002600 62349874 00830002600 62393802 00830002600 62428995
Recalling Firm/ Manufacturer	Zimmer, Inc. 345 E Main St Warsaw, Indiana 46580-2746

Manufacturer Reason for Recall	As part of routine manufacturing process monitoring by Zimmer, it was discovered that the Tibial Base and Talar Components from the Total Ankle system have the potential of containing elevated levels of manufacturing materials residue on the implants. The specific material was found to be mass media utilized during the manufacturing process to provide the uniform surface finish. This mass media
FDA Determined Cause [2]	PRODUCTION CONTROLS: Manufacturing Material Removal
Action	Zimmer sent an URGENT MEDICAL DEVICE RECALL notification letter dated November 12, 2013 to all consignees. The letter identified the product, the problem, and the action to be taken by the consignee. Consignees were instructed to locate and remove the affected product from their inventory and notify their Zimmer representataive. The Zimmer representative will remove the recalled product from their facility. For patients that previously had the affected product implanted, consignees were instructed to continue their operative follow up routine. Consignees with questions were instructed to call 1-877-946-2761. For questions regarding this recall call 800-613-6131.
Quantity in Commerce	265 units (US) 114 units (outside US)
Distribution	Worldwide Distribution - USA (nationwide) and Internationally to Australia, Canada, China, Finland, Germany, and Italy.
Total Product Life Cycle	TPLC Device Report[25]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[26]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database

- 510(K)s with Product Code = HSN and Original Applicant = ZIMMER, INC.[27]

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/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
11. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
12. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
13. /scripts/cdrh/cfdocs/cfStandards/search.cfm
14. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfClia/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
21. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=%3Ch3%3Erelated%20recalls%20for%20Zimmer%20Trabecular%20Metal%22%20Total%20Ankle%20Tibial%20Base%20and%20Talar%20Components%3C%2Fh3%3E&item1_url=www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=1&event_id=66717&item2_text=medical%20device%20recalls%20&item2_url=www.fda.gov/medicaldevices/safety/recallscorrectionsremovals/listofrecalls/default.htm&item3_text=fda%20enforcement%20report%20index&item3_url=www.fda.gov/safety/recalls/enforcementreports/default.htm
22. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K120906
23. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=HSN
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=HSN
25. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=HSN
26. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
27. ../cfPMN/pmn.cfm?start_search=1&productcode=HSN&applicant=ZIMMER%2C%20INC%2E

Page Last Updated: 12/21/2013

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

Class 2 Recall Zimmer Trabecular Metal" Total Ankle Tibial Base and Talar Components

See Related Information[21]

Date Posted	December 10, 2013
Recall Status[1]	Open
Recall Number	Z-0477-2014
Premarket Notification 510(K) Number	K120906[22]
Product Classification	Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer[23] - **Product Code** HSN[24]
Product	Zimmer Trabecular Metal Total Ankle Tibial Base Component Sizes 1-6 Total ankle arthroplasty is intended to provide a patient with limited mobility by restoring alignment, reducing pain and preserving the flexion/extension movement within the ankle joint.The Zimmer Trabecular Metal Total Ankle is indicated as a total ankle replacement in primary or revision surgery for patients with: " Rheumatoid arthritis. " Post-traumatic arthritis. " Degenerative arthritis. This device is intended for cemented use only.
Code Information	Part Number Lot Number 00450004100 62143211 00450004100 62215399 00450004100 62226572 00450004100 62239797 00450004100 62248808 00450004100 62285639 00450004100 62290853 00450004200 62143212 00450004200 62208157 00450004200 62208158 00450004200 62215401 00450004200 62220683 00450004200 62226573 00450004200 62248809 00450004200 62267650 00450004200 62285554 00450004200 62299545 00450004200 62393808 00450004200 62416048 00450004200 62419541 00450004300 62143213 00450004300 62160229 00450004300 62208159 00450004300 62215402 00450004300 62220681 00450004300 62220684 00450004300 62267645 00450004300 62279057 00450004300 62285555 00450004300 62285556 00450004300 62305745 00450004300 62305746 00450004300 62310757 00450004300 62349877 00450004300 62357515 00450004300 62368389 00450004300 62378070 00450004300 62397422 00450004300 62409042 00450004300 62416049 00450004300 62419542 00450004300 62442239 00450004300 62453785 00450004400 62168364 00450004400 62208160 00450004400 62215403 00450004400 62220686 00450004400 62232378 00450004400 62267647 00450004400 62297853 00450004400 62299546 00450004400 62299547 00450004400 62299548 00450004400 62343569 00450004400 62349879 00450004400 62372420 00450004400 62393809 00450004400 62397423 00450004400 62405323 00450004400 62409043 00450004500 62143215 00450004500 62215404 00450004500 62220688 00450004500 62232379 00450004500 62248810 00450004500 62254967 00450004500 62279058 00450004500 62299549 00450004500 62368390 00450004500 62378071 00450004600 62143216 00450004600 62239795 00450004600 62239796 00450004600 62248811 00450004600 62254968 00450004600 62285640 00450004600 62290855 00450004600 62405325 00830004100 62208152 00830004100 62316180 00830004100 62363978 00830004200 62204737 00830004200 62226574 00830004200 62239798 00830004200 62316181 00830004200 62337230 00830004200 62375878 00830004300 62204736 00830004300 62226575 00830004300 62232380 00830004300 62297854 00830004300 62323804 00830004300 62343570 00830004300 62372421 00830004300 62439685 00830004400 62204738 00830004400 62226576 00830004400 62232381 00830004400 62267658 00830004400 62323802 00830004400 62337231 00830004400 62375879 00830004500 62204739 00830004500 62232382 00830004500 62310759 00830004500 62331825 00830004500 62363980 00830004600 62239782 00830004600 62331826 00830004600 62357516
Recalling Firm/ Manufacturer	Zimmer, Inc. 345 E Main St Warsaw, Indiana 46580-2746
Manufacturer Reason for Recall	As part of routine manufacturing process monitoring by Zimmer, it was discovered that the Tibial Base and Talar Components from the Total Ankle system have the potential of containing elevated levels of manufacturing materials residue on the implants. The specific material was found to be mass media utilized during the manufacturing process to provide the uniform surface finish. This mass media
FDA Determined Cause [2]	PRODUCTION CONTROLS: Manufacturing Material Removal
Action	Zimmer sent an URGENT MEDICAL DEVICE RECALL notification letter dated November 12, 2013 to all consignees. The letter identified the product, the problem, and the action to be taken by the consignee. Consignees were instructed to locate and remove the affected product from their inventory and notify their Zimmer representataive. The Zimmer representative will remove the recalled product from their facility. For patients that previously had the affected product implanted, consignees were instructed to continue their operative follow up routine. Consignees with questions were instructed to call 1-877-946-2761. For questions regarding this recall call 800-613-6131.

Class 2 Recall Zimmer Trabecular Metal" Total Ankle Tibial Base and Talar Components

See Related Information[21]

Date Posted	December 10, 2013
Recall Status[1]	Open
Recall Number	Z-0475-2014
Premarket Notification 510(K) Number	K120906[22]
Product Classification	Prosthesis, Ankle, Semi-Constrained, Cemented, Metal/Polymer[23] - **Product Code** HSN[24]
Product	Zimmer Trabecular Metal Total Ankle Talar Component Left Sizes 1-6 Total ankle arthroplasty is intended to provide a patient with limited mobility by restoring alignment, reducing pain and preserving the flexion/extension movement within the ankle joint.The Zimmer Trabecular Metal Total Ankle is indicated as a total ankle replacement in primary or revision surgery for patients with: " Rheumatoid arthritis. " Post-traumatic arthritis. " Degenerative arthritis. This device is intended for cemented use only.
Code Information	Part Number Lot Number 00450001100 62072174 00450001100 62248802 00450001100 62264833 00450001100 62267033 00450001100 62279041 00450001100 62279043 00450001100 62331803 00450001100 62331808 00450001100 62337755 00450001100 62343558 00450001100 62357496 00450001100 62357497 00450001100 62397412 00450001100 62397413 00450001100 62430803 00450001200 11007903 00450001200 11008443 00450001200 62168362 00450001200 62239775 00450001200 62239789 00450001200 62267626 00450001200 62267627 00450001200 62279044 00450001200 62279050 00450001600 62168363 00450001600 62239794 00450001600 62264836 00450001600 62264837 00450001600 62267631 00450001600 62290823 00450001600 62290824 00450001600 62297847 00450001600 62297848 00450001600 62310752 00450001600 62316170 00450001600 62323809 00450001600 62331810 00450001600 62337757 00450001600 62349862 00450001600 62357499 00450001600 62372416 00450001600 62405309 00450001600 62419534 00450001200 62285546 00450001200 62290833 00450001200 62290835 00450001200 62372414 00450001200 62375863 00450001200 62397414 00450001200 62405304 00450001200 62416035 00450001200 62419530 00450001200 62430804 00450001300 62160227 00450001300 62163379 00450001300 62215393 00450001300 62264834 00450001300 62267628 00450001300 62267629 00450001300 62279045 00450001300 62279051 00450001300 62285548 00450001300 62290836 00450001300 62299551 00450001300 62331811 00450001300 62337756 00450001300 62349856 00450001300 62349857 00450001300 62368383 00450001300 62375865 00450001300 62375868 00450001300 62378060 00450001300 62397415 00450001300 62397416 00450001300 62409032 00450001300 62409033 00450001300 62416036 00450001300 62419532 00450001300 62430805 00450001400 11007904 00450001400 11008529 00450001400 62163382 00450001400 62208153 00450001400 62239776 00450001400 62239786 00450001400 62264835 00450001400 62279052 00450001400 62290829 00450001400 62299552 00450001400 62305739 00450001400 62310750 00450001400 62316168 00450001400 62316169 00450001400 62343549 00450001400 62343550 00450001400 62343551 00450001400 62349858 00450001400 62368384 00450001400 62372415 00450001400 62378062 00450001400 62393803 00450001400 62393804 00450001400 62397417 00450001400 62405306 00450001400 62409034 00450001400 62416038 00450001400 62416039 00450001400 62416040 00450001400 62419533 00450001400 62459855 00450001500 62072172 00450001500 62208154 00450001500 62215392 00450001500 62220672 00450001500 62220674 00450001500 62226570 00450001500 62279046 00450001500 62279053 00450001500 62285550 00450001500 62290842 00450001500 62331809 00450001500 62349859 00450001500 62349861 00450001500 62357498 00450001500 62358906 00450001500 62378063 00450001500 62393805 00450001500 62397418 00450001500 62405308 00450001500 62416042 00450001500 62439673 00450001600 11007906 Part Number Lot Number 00830001100 62264850 00830001100 62316172 00830001100 62323776 00830001100 62337212 00830001100 62357509 00830001200 62204729 00830001200 62215395 00830001200 62316173 00830001200 62323778 00830001200 62331816 00830001200 62343559 00830001300 11008422 00830001300 62204730 00830001300 62220676 00830001300 62267038 00830001300 62267040 00830001300 62323781 00830001300 62331817 00830001300 62337216 00830001300 62349869 00830001300 62409040 00830001400 62208150 00830001400 62264851 00830001400 62310756 00830001400 62316177 00830001400 62323783 00830001400 62343560 00830001400 62343561 00830001400 62368388 00830001500 62204731 00830001500 62215396 00830001500 62305743 00830001500 62323784 00830001500 62343563 00830001500 62357510 00830001500 62428994 00830001600 62264852 00830001600 62299553 00830001600 62316174 00830001600 62323786 00830001600 62337210 00830001600 62343565 00830001600 62357511
Recalling Firm/ Manufacturer	Zimmer, Inc. 345 E Main St Warsaw, Indiana 46580-2746