



June 10, 2014

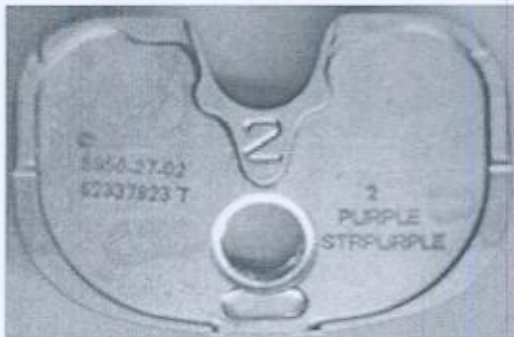
To: Risk Managers and Surgeons

Subject: URGENT MEDICAL DEVICE RECALL-LOT SPECIFIC

Affected Product: NexGen Complete Knee Solution MIS Total Knee Procedure Stemmed Tibial Component, Precoat, various sizes (see Attachment 1 for complete list)

Zimmer is initiating a voluntary recall of specific identified lots due to the potential that the threads may be out of specification. You are receiving this letter because our records indicate that you may have received or implanted the Affected Product. The Affected Product was distributed between February 26, 2010 and May 15, 2014.

Zimmer received twelve complaints over a period of two and a half years alleging difficulty threading an MIS Drop Down Stem Extension or a Drop Down Stem Plug into the MIS Stemmed Tibial Component. All lots manufactured at the Ponce, Puerto Rico manufacturing site previous to implementation of 100% inspection of the 7/16-20 Spirallock thread feature are being recalled.



Top View, MIS Stemmed Tibial Component



Close-up, view of threads

Risks

- The patient may be exposed to greater risk of infection if delay is incurred or if a secondary implant is not available for use and the surgeon elects to close the patient and return to surgery at a later date.
- Additional bone loss may occur if the MIS tibial is cemented in place when the issue is identified and the surgeon elects to remove and replace.
- Early revision may occur due to loosening (if the MIS Stemmed Tibial Component is implanted without a drop down stem extension), and/or infection.
- Disassociation of the implanted articular surface may occur if the stem extension does not fully seat, thus causing the articular surface to not properly lock.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. Locate and quarantine any affected product listed in Attachment 1 and notify your Zimmer sales representative.
3. Your Zimmer sales representative will remove the recalled product from your facility.
4. For patients that previously had this product implanted, it is recommended that you continue your normal post operative follow up routine.
5. If after reviewing this notification you have further questions or concerns please call the customer call center at 1-877-946-2761 between 8:00 am and 5:00pm EST.



zimmer

Vigilance Information

This voluntary notification will be reported to the U.S. Food and Drug Administration and to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 to the local health authority in your country.

Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product. Adverse events may be reported to Zimmer at zimmer.per@zimmer.com, or to your local Zimmer representative.

Kind regards

Doña M. Reust
Field Action Manager
Corporate Quality & Compliance

Manufacturer : Zimmer

Device Name: NexGen Complete Knee Solution MIS Total Knee Procedure
Stemmed Tibial Component, Precoat

Product Code :

1) Size 4:

Lot numbers: 370317 37214651 37218726 37219271 37220949 61417419 61417420
61442307 61442308 61442309 61442310 61442311 61450966 61451221 61451222
61459957 61459958 61475125 61475126 61475127 61475128 61488208 61488209
61488210 61488211 61518162 61518163 61518164 61526401 61538046 61543975
61543976 61558363 61567340 61567341 61567342 61567343 61592088 61592089
61627203 61627204 61627205 61627206 61643933 61643934 61658878 61658879
61658880 61658881 61658882 61678232 61678233 61682153 61682154 61682155
61692238 61692240 61721671 61721672 61721673 61774143 61774144 61774145
61774146 61774147 61774148 61827117 61827118 61827119 61863112 61863113
61863114 61863115 61863116 61912438 61914866 61914867 61914868 61914869
61934684 61934685 61934686 61934687 61958859 61958860 61958861 61979028
61979029 61979030 62016156 62016157 62016158 62022554 62022555 62029928
62029929 62029930 62041303 62041304 62060613 62060614 62064935 62064936
62077849 62077850 62077851 62143194 62143195 62143196 62143197 62143604
62143605 62143606 62143607 62168183 62168184 62193304 62193305 62193306
62200285 62200286 62214670 62214671 62214672 62227418 62227419 62261960
62261961 62261962 62261963 62261964 62261966 62315724 62319295 62319296
62319297 62326311 62326312 62332564 62332565 62345558 62345559 62358488
62358490 62363649 62377650 62383363 62383364 62390066 62390067 62390068
62454576 62454577 62454578 62465724 62465725 62465726 62473212 62473213
62473215 62528582 62528583 62586506 62586507 62586509 62586510 62586518
62610915 62610916 62640976 62640977 62640978 62640979 62646146 62646147
62649656 62649658

2) Size 3:

Lot numbers: 370316 37214039 61414610 61414611 61442294 61442295 61442296
61442297 61450963 61450964 61450965 61454951 61454952 61454953 61459941
61459942 61475123 61475124 61488064 61488065 61488066 61488067 61488068
61497512 61497513 61507223 61507224 61518151 61518153 61518154 61526398
61526399 61558358 61558359 61558360 61558361 61567336 61567337 61567338
61567339 61592084 61592085 61592086 61592087 61627191 61627192 61627193
61627194 61627195 61627196 61627197 61627198 61627199 61627201 61627202
61643928 61643929 61643930 61643931 61643932 61658872 61658873 61658874
61658875 61658876 61658877 61672561 61672562 61672563 61672564 61672565
61672566 61721668 61721669 61721670 61774134 61774135 61774136 61774137
61774140 61774141 61774142 61827112 61827113 61827114 61827115 61827116
61863088 61863090 61863091 61863093 61863094 61898777 61898778 61898779

61898780 61898781 61912437 61914863 61914864 61914865 61934678 61934679
61934680 61934681 61934682 61958855 61958856 61958857 61958858 61979024
61979025 61979026 61979027 61993771 61993773 61993774 61993775 61993776
62022557 62029925 62029926 62029927 62037892 62041300 62041301 62041302
62060611 62060612 62064931 62064932 62064933 62069538 62077846 62077847
62077848 62080358 62080359 62080360 62143198 62143199 62143201 62143601
62143602 62143603 62168181 62168182 62193299 62193301 62193302 62193303
62200277 62200278 62200279 62214665 62214666 62214667 62214668 62214669
62227415 62227416 62227417 62271422 62271423 62271424 62271425 62271426
62284606 62284607 62284608 62298568 62298569 62319299 62326502 62326503
62332546 62332547 62335852 62335864 62345560 62352633 62352634 62357204
62357205 62377654 62377655 62383356 62383357 62389590 62389591 62389592
62423838 62423839 62423840 62454586 62454587 62460233 62460234 62462894
62462895 62465729 62465730 62465731 62473291 62473292 62473294 62525438
62525439 62525440 62528591 62528592 62528593 62528594 62528595 62610905
62610906 62610907 62610908 62610909 62640971 62640972 62640973 62640974
62640975 62646143 62646144 62646145 62649650 62649652 62649653 62649655

3) Size 2:

Lot numbers: 37214650 61417415 61417416 61442278 61459938 61459939 61459940
61488069 61497510 61497511 61518148 61518149 61538023 61543972 61543973
61543974 61567335 61592049 61592050 61627189 61627190 61672554 61672555
61672556 61672557 61672558 61682128 61682129 61721665 61721666 61721667
61774118 61774119 61774120 61827109 61827110 61827111 61863080 61863081
61863083 61863084 61863085 61912434 61915370 61915371 61979021 61979022
61979023 62016175 62020276 62041296 62060610 62069533 62091728 62141255
62141256 62141257 62155305 62155306 62155307 62177111 62214660 62214661
62214662 62214663 62214664 62251565 62251566 62271420 62298567 62315723
62319301 62326315 62337922 62337923 62345561 62345562 62377649 62383365
62411732 62411733 62411735 62411736 62411737 62586465 62586467 62610913
62610914 62640980 62646141 62646142

4) Size 5:

Lot numbers: 370318 37214652 61424997 61442318 61442319 61442320 61451223
61454955 61454956 61459968 61459969 61459970 61475130 61475131 61475132
61488234 61518182 61518183 61518184 61526402 61543977 61567344 61567345
61592091 61592092 61627258 61627260 61643935 61643936 61658884 61658885
61658886 61774178 61774179 61774180 61774181 61774182 61774183 61863148
61863149 61863150 61863151 61863152 61912439 61934688 61934689 61935101
61935102 61979031 61979032 61979033 62016160 62016162 62022559 62037894
62037895 62051524 62051525 62069546 62089014 62089015 62143608 62168185
62177112 62193308 62200281 62200282 62200283 62214674 62214675 62227420
62261968 62261972 62261973 62261975 62298570 62332566 62352641 62358491
62358492 62377651 62423843 62455679 62460240 62460242 62460243 62525441
62525442 62586581 62586582 62610910 62610911 62610912 62640982 62646149
62646150

5) Size 6:

Lot Numbers: 370319 37213647 37218135 37218727 37219556 37220950 61414605
61414606 61442322 61451224 61451225 61451226 61479488 61479489 61479490
61518197 61518198 61518199 61538053 61543978 61592093 61592094 61627261
61643938 61672569 61682157 61685470 61721675 61721676 61774189 61774190
61774191 61774195 61863158 61863159 61863160 61863161 61863162 61979034
61979035 62016163 62022560 62037896 62041306 62041308 62069549 62077856
62141261 62143609 62168186 62177113 62227421 62227422 62251569 62251570
62261977 62261978 62326316 62330687 62341281 62369796 62369797 62377652
62473295 62473296 62602804 62602805 62602806 62602807 62602808

6) Size 7:

Lot Numbers: 370320 37214653 61424998 61442326 61459971 61459972 61488229
61518205 61543979 61658887 61658888 61827120 61827121 61827122 61979040
61979041 62051526 62091729 62200288 62227423 62251572 62330688 62383359
62383362 62401016 62401017 62602812 62602813 62640983

7) Size 8:

Lot numbers: 370321 37213648 37216196 61424999 61543980 62029931 62390069

8) Size 4+:

Lot numbers: 61424996 61459959 61475129 61538052 61563971 61573791 61573792
61592090 61627207 61685463 61721674 61774165 61863139 61870152 61934692
61935096 61979044 61979045 62020278 62064940 62091727 62214673 62251567
62251568 62319307 62337924 62369795 62401020 62423841 62436412 62471736
62602816 62646169

9) Size 1:

Lot numbers: 37217848 61424993 61507222 61543969 61774117 62141262 62193298
62251564 62261955 62383353 62602809 62602810 62602811