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September 30, 2013

To: **Surgeons**

Subject: **URGENT MEDICAL DEVICE RECALL (Product Removal)**

Ref: **2648920-08/28/2013-003-R**

**Affected Product: Versys® Hip System Cemented Revision/Calcar Femoral Stem  
Versys Heritage® Hip Prosthesis Femoral Revision Stem**

Zimmer recently conducted a review of historic packaging validations completed. Based on this review, it was determined that a subset of product packaged at a single Zimmer facility required testing to ensure that previously packaged product from this facility met the established requirements for sterile barrier integrity. The acceptance criteria established for this testing was 90% confidence and 99% reliability to provide a high degree of statistical confidence. After searching the available Zimmer inventory, there was one Hip tray configuration that did not have adequate sample quantities available to meet the established acceptance criteria. Specifically, the available inventory underwent the testing; however, the limited sample size capped the statistical results to a 90% confidence and 98.4% reliability (0.6% below acceptance level). This tray configuration is used for the Versys® Hip System Cemented Revision/Calcar Femoral Stem and Versys Heritage® Hip Prosthesis Femoral Revision Stem. As a result, Zimmer is initiating a lot specific recall due to insufficient sample availability for testing necessary to ensure sterile barrier integrity with the established statistical confidence. The affected part and lot numbers can be found in Attachment 1, which includes lots packaged at the single Zimmer facility referenced previously.

#### **Risks**

- If an issue with the seal integrity is detected during surgery, this will result in a slight delay to obtain another implant.
- If there is an issue with seal integrity that goes undetected and also has resulted in a loss of sterility, a periprosthetic infection may occur. The risk associated with a periprosthetic infection is a revision or potential multi-stage revision to treat the infection.

Please note that Zimmer has **not** received any complaints from clinicians regarding the integrity of the packaging seal for the Versys® Hip System Cemented Revision/Calcar Femoral Stem or Versys Heritage® Hip Prosthesis Femoral Revision Stem. This voluntary product removal is due to unavailability of adequate sample quantities.

#### **Your Responsibilities**

1. Review the notification and ensure affected personnel are aware of the contents.
2. If you find any product from the list in Attachment 1, quarantine the product and notify your Zimmer sales representative.
3. Your Zimmer sales representative will support you in the removal of the recalled product from your facility. The chart in the attachment 2 should be used.
4. For patients that previously had this product implanted, it is recommended that you continue your normal post operative follow up routine. However, should the patient present with potential signs of infection please take this notification into account when considering your diagnosis and treatment path for the patient.
5. **If after reviewing this notification you have further questions or concerns please contact your Zimmer Representative Person.**

#### **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.



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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](mailto:zimmer.per@zimmer.com), or to your local Zimmer representative.

Kind regards



Post Market Surveillance & Regulatory Compliance Associate Director



**ATTACHMENT 1**

Item Number	Part Description	Lots
00-7857-035-22	VERSYS HERITAGE FEM STEM 15X220MM REV	See List Below
00-7857-037-18	VERSYS HERITAGE FEM STEM 17X180MM REV	
00-7871-013-60	VERSYS CEM/REV/CALCAR 13X170MM	
00-7871-013-61	VERSYS CEM/REV/CALCAR 13X210MM	
00-7871-013-62	VERSYS CEM/REV/CALCAR 13X250MM	
00-7871-013-63	VERSYS CEM/REV/CALCAR 13X300MM	
00-7871-015-60	VERSYS CEM/REV/CALCAR 15X180MM	
00-7871-015-61	VERSYS CEM/REV/CALCAR 15X220MM	
00-7871-015-62	VERSYS CEM/REV/CALCAR 15X250MM	
00-7871-015-63	VERSYS CEM/REV/CALCAR 15X300MM	
00-7871-017-60	VERSYS CEM/REV/CALCAR 17X190MM	
00-7871-017-61	VERSYS CEM/REV/CALCAR 17X230MM	
00-7871-019-60	VERSYS CEM/REV/CALCAR 19X200MM	

Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
00785703522	00369898	00787101361	60821293	00787101560	61286063
00785703522	60979638	00787101361	60829412	00787101560	61286064
00785703522	61266268	00787101361	60864603	00787101560	61290066
00785703522	61294352	00787101361	60864604	00787101560	61290067
00785703522	61565732	00787101361	60864605	00787101560	61304636
00785703718	00369673	00787101361	60864621	00787101560	61328297
00785703718	60486158	00787101361	60889536	00787101560	61332279
00785703718	61156128	00787101361	60889537	00787101560	61336899
00785703718	61293625	00787101361	60940777	00787101560	61336901
00787101360	00369984	00787101361	60940778	00787101560	61340239
00787101360	00370161	00787101361	60940779	00787101560	61340240
00787101360	00370406	00787101361	60940786	00787101560	61361723
00787101360	60495799	00787101361	60940787	00787101560	61361724
00787101360	60545572	00787101361	60973574	00787101560	61380343
00787101360	60565682	00787101361	60989972	00787101560	61380344
00787101360	60589392	00787101361	60989973	00787101560	61425523
00787101360	60609870	00787101361	60996702	00787101560	61425525
00787101360	60644570	00787101361	61028276	00787101560	61425527
00787101360	60661955	00787101361	61028277	00787101560	61468736
00787101360	60661956	00787101361	61028278	00787101560	61484545
00787101360	60661957	00787101361	61028279	00787101560	61484546
00787101360	60676452	00787101361	61028280	00787101560	61501405
00787101360	60712462	00787101361	61098175	00787101560	61505383
00787101360	60712463	00787101361	61098176	00787101560	61522959
00787101360	60712464	00787101361	61098177	00787101560	61532218
00787101360	60712465	00787101361	61098178	00787101560	61541555
00787101360	60726764	00787101361	61098179	00787101560	61541556
00787101360	60745879	00787101361	61098189	00787101560	61546109
00787101360	60745880	00787101361	61098190	00787101560	61567506



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Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
00787101360	60768909	00787101361	61098191	00787101560	61588983
00787101360	60768910	00787101361	61185519	00787101560	61588984
00787101360	60768911	00787101361	61190026	00787101560	61619976
00787101360	60768912	00787101361	61197652	00787101560	61619978
00787101360	60768913	00787101361	61199976	00787101560	61631076
00787101360	60770498	00787101361	61243385	00787101560	61634125
00787101360	60770499	00787101361	61250055	00787101560	61637668
00787101360	60770501	00787101361	61264041	00787101560	61637669
00787101360	60770502	00787101361	61273002	00787101560	61647168
00787101360	60793095	00787101361	61282897	00787101560	61694913
00787101360	60793096	00787101361	61282898	00787101560	61696343
00787101360	60793097	00787101361	61304637	00787101560	61708135
00787101360	60793098	00787101361	61318398	00787101560	61727046
00787101360	60793099	00787101361	61332282	00787101560	61736281
00787101360	60821283	00787101361	61361718	00787101560	61750609
00787101360	60821284	00787101361	61361719	00787101560	61750610
00787101360	60821285	00787101361	61380336	00787101560	61779319
00787101360	60821287	00787101361	61380337	00787101560	61779320
00787101360	60821288	00787101361	61380338	00787101560	61803834
00787101360	60821289	00787101361	61380339	00787101560	61827388
00787101360	60821290	00787101361	61386432	00787101560	61830021
00787101360	60829409	00787101361	61386433	00787101560	61841625
00787101360	60829410	00787101361	61425514	00787101560	61851859
00787101360	60864596	00787101361	61425515	00787101560	61860459
00787101360	60864597	00787101361	61425516	00787101560	61886915
00787101360	60864598	00787101361	61453522	00787101560	61905764
00787101360	60864599	00787101361	61468742	00787101560	61936130
00787101360	60864601	00787101361	61505384	00787101560	61947692
00787101360	60864602	00787101361	61505385	00787101560	61955602
00787101360	60864619	00787101361	61522960	00787101560	61957366
00787101360	60864620	00787101361	61528626	00787101560	61975892
00787101360	60873796	00787101361	61541558	00787101560	61988894
00787101360	60889533	00787101361	61541559	00787101560	61999751
00787101360	60889534	00787101361	61548465	00787101561	00369989
00787101360	60889535	00787101361	61567507	00787101561	00370163
00787101360	60893301	00787101361	61588981	00787101561	00370301
00787101360	60893302	00787101361	61588982	00787101561	00370377
00787101360	60940773	00787101361	61613234	00787101561	00370405
00787101360	60940774	00787101361	61619975	00787101561	60644588
00787101360	60940775	00787101361	61634127	00787101561	60661968
00787101360	60940776	00787101361	61637663	00787101561	60676459
00787101360	60980309	00787101361	61637664	00787101561	60768928
00787101360	60980310	00787101361	61658288	00787101561	60768929
00787101360	60980311	00787101361	61658289	00787101561	60793161



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Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
00787101360	60980312	00787101361	61668389	00787101561	60821301
00787101360	60996691	00787101361	61685080	00787101561	60821302
00787101360	60996692	00787101361	61688417	00787101561	60821303
00787101360	60996693	00787101361	61694910	00787101561	60864624
00787101360	60996694	00787101361	61708137	00787101561	60873799
00787101360	60996695	00787101361	61718331	00787101561	60889516
00787101360	60996696	00787101361	61731613	00787101561	60889540
00787101360	60996697	00787101361	61731614	00787101561	60952988
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00787101360	60996701	00787101361	61750605	00787101561	60989976
00787101360	61045838	00787101361	61750607	00787101561	61028289
00787101360	61045839	00787101361	61774061	00787101561	61028290
00787101360	61045840	00787101361	61776728	00787101561	61028291
00787101360	61045842	00787101361	61786997	00787101561	61028292
00787101360	61045843	00787101361	61798088	00787101561	61050856
00787101360	61045845	00787101361	61827387	00787101561	61098185
00787101360	61125868	00787101361	61841620	00787101561	61138051
00787101360	61125869	00787101361	61843322	00787101561	61138052
00787101360	61125870	00787101361	61856105	00787101561	61185517
00787101360	61125871	00787101361	61864096	00787101561	61197653
00787101360	61125872	00787101361	61868571	00787101561	61243381
00787101360	61127819	00787101361	61886912	00787101561	61286066
00787101360	61127821	00787101361	61936125	00787101561	61304639
00787101360	61127822	00787101361	61943372	00787101561	61332278
00787101360	61127823	00787101361	61955601	00787101561	61336902
00787101360	61127824	00787101361	61957368	00787101561	61336903
00787101360	61152612	00787101361	61975891	00787101561	61401525
00787101360	61156098	00787101361	61977878	00787101561	61401526
00787101360	61156099	00787101361	61988893	00787101561	61468741
00787101360	61156101	00787101361	61999750	00787101561	61506284
00787101360	61156102	00787101361	62005386	00787101561	61528627
00787101360	61158975	00787101362	00370371	00787101561	61607574
00787101360	61163194	00787101362	60661960	00787101561	61619972
00787101360	61175608	00787101362	60676455	00787101561	61634124
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00787101360	61214470	00787101362	60821294	00787101561	61706078
00787101360	61222210	00787101362	60829413	00787101561	61718327
00787101360	61231906	00787101362	60829414	00787101561	61750616
00787101360	61243383	00787101362	60829415	00787101561	61779322



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Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
00787101360	61243384	00787101362	60829418	00787101561	61783643
00787101360	61250054	00787101362	60864606	00787101561	61907701
00787101360	61255823	00787101362	60864607	00787101561	61957370
00787101360	61264039	00787101362	60864622	00787101561	61999752
00787101360	61264040	00787101362	60864628	00787101562	00369996
00787101360	61273004	00787101362	60940780	00787101562	00370082
00787101360	61282902	00787101362	60940782	00787101562	00370165
00787101360	61282903	00787101362	60940788	00787101562	00370245
00787101360	61286062	00787101362	60940789	00787101562	00370382
00787101360	61290062	00787101362	61024978	00787101562	60658265
00787101360	61290063	00787101362	61024979	00787101562	60676460
00787101360	61290064	00787101362	61024980	00787101562	60737992
00787101360	61293823	00787101362	61024981	00787101562	60737996
00787101360	61304635	00787101362	61024982	00787101562	60768930
00787101360	61312305	00787101362	61028281	00787101562	60793162
00787101360	61318395	00787101362	61028282	00787101562	60821304
00787101360	61318396	00787101362	61028283	00787101562	60864611
00787101360	61332281	00787101362	61045846	00787101562	60889541
00787101360	61336882	00787101362	61185522	00787101562	60940792
00787101360	61336883	00787101362	61197656	00787101562	60952989
00787101360	61340236	00787101362	61214472	00787101562	61028301
00787101360	61340237	00787101362	61250083	00787101562	61028302
00787101360	61340238	00787101362	61264044	00787101562	61028303
00787101360	61361715	00787101362	61282904	00787101562	61050857
00787101360	61361716	00787101362	61290065	00787101562	61050858
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00787101360	61380329	00787101362	61336895	00787101562	61179458
00787101360	61380330	00787101362	61336896	00787101562	61185518
00787101360	61380331	00787101362	61380340	00787101562	61264042
00787101360	61380332	00787101362	61380341	00787101562	61282905
00787101360	61380333	00787101362	61490071	00787101562	61293824
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00787101360	61386434	00787101362	61541557	00787101562	61495874
00787101360	61401521	00787101362	61565696	00787101562	61541560
00787101360	61401522	00787101362	61607569	00787101562	61658291
00787101360	61401523	00787101362	61619971	00787101562	61668390
00787101360	61453520	00787101362	61634126	00787101562	61683766
00787101360	61453521	00787101362	61637665	00787101562	61696342
00787101360	61468737	00787101362	61679037	00787101562	61718328
00787101360	61468738	00787101362	61685082	00787101562	61774064
00787101360	61468739	00787101362	61688419	00787101562	61776729
00787101360	61479388	00787101362	61708142	00787101562	61925003
00787101360	61483129	00787101362	61718329	00787101562	61943371



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Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
00787101360	61483130	00787101362	61736280	00787101563	00369995
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00787101360	61490070	00787101362	61750608	00787101563	00370285
00787101360	61495872	00787101362	61774062	00787101563	00370378
00787101360	61495873	00787101362	61783642	00787101563	00370428
00787101360	61505378	00787101362	61803831	00787101563	00370621
00787101360	61505379	00787101362	61817980	00787101563	60658266
00787101360	61505380	00787101362	61820802	00787101563	60676462
00787101360	61505382	00787101362	61841622	00787101563	60745898
00787101360	61506282	00787101362	61859933	00787101563	60768931
00787101360	61509854	00787101362	61936131	00787101563	60770519
00787101360	61522961	00787101362	61957369	00787101563	60821305
00787101360	61522962	00787101362	61977879	00787101563	60829425
00787101360	61522963	00787101362	61997517	00787101563	60864625
00787101360	61528629	00787101362	62024613	00787101563	60889542
00787101360	61541561	00787101362	62038338	00787101563	60889543
00787101360	61541562	00787101363	00370162	00787101563	60940793
00787101360	61541563	00787101363	00370244	00787101563	61028304
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00787101360	61546111	00787101363	60661962	00787101563	61098187
00787101360	61548467	00787101363	60676456	00787101563	61222211
00787101360	61567508	00787101363	60768919	00787101563	61282901
00787101360	61589001	00787101363	60768921	00787101563	61336906
00787101360	61589003	00787101363	60821295	00787101563	61433838
00787101360	61589004	00787101363	60821296	00787101563	61433840
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00787101360	61616202	00787101363	60889538	00787101563	61907536
00787101360	61619973	00787101363	60952986	00787101563	61964719
00787101360	61619974	00787101363	60996686	00787101563	62005385
00787101360	61631077	00787101363	60996687	00787101760	00370166
00787101360	61631078	00787101363	60996688	00787101760	00370246
00787101360	61637660	00787101363	60996689	00787101760	00370379
00787101360	61637661	00787101363	61045847	00787101760	00370417
00787101360	61637662	00787101363	61045848	00787101760	00370620
00787101360	61649685	00787101363	61098180	00787101760	60644589
00787101360	61664244	00787101363	61098181	00787101760	60661971
00787101360	61664245	00787101363	61237797	00787101760	60676463
00787101360	61685084	00787101363	61264043	00787101760	60768932
00787101360	61691775	00787101363	61282899	00787101760	60768933
00787101360	61694911	00787101363	61293825	00787101760	60821306
00787101360	61694912	00787101363	61318397	00787101760	60889544



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Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
00787101360	61696344	00787101363	61336898	00787101760	60940784
00787101360	61708139	00787101363	61361722	00787101760	60940794
00787101360	61708140	00787101363	61380342	00787101760	60973576
00787101360	61708141	00787101363	61483131	00787101760	60989977
00787101360	61727048	00787101363	61506283	00787101760	61028307
00787101360	61727049	00787101363	61532219	00787101760	61028308
00787101360	61731615	00787101363	61556919	00787101760	61045850
00787101360	61736282	00787101363	61616203	00787101760	61147352
00787101360	61744430	00787101363	61637667	00787101760	61179530
00787101360	61747537	00787101363	61649684	00787101760	61185515
00787101360	61748924	00787101363	61673737	00787101760	61214471
00787101360	61750612	00787101363	61688416	00787101760	61273006
00787101360	61750613	00787101363	61711956	00787101760	61286065
00787101360	61750614	00787101363	61727047	00787101760	61290068
00787101360	61750615	00787101363	61748923	00787101760	61425536
00787101360	61774060	00787101363	61774063	00787101760	61425539
00787101360	61776727	00787101363	61803832	00787101760	61453519
00787101360	61783640	00787101363	61817981	00787101760	61509855
00787101360	61783641	00787101363	61820803	00787101760	61541566
00787101360	61798089	00787101363	61856104	00787101760	61637670
00787101360	61803833	00787101363	61873631	00787101760	61694914
00787101360	61820799	00787101363	61925004	00787101760	61708136
00787101360	61820801	00787101363	61964718	00787101760	61718330
00787101360	61827386	00787101363	61997518	00787101760	61744431
00787101360	61830020	00787101363	62019777	00787101760	61798090
00787101360	61841619	00787101560	00369988	00787101760	61846922
00787101360	61843321	00787101560	00370300	00787101760	61945122
00787101360	61846920	00787101560	00370374	00787101760	61977880
00787101360	61846921	00787101560	00370409	00787101760	62100680
00787101360	61851860	00787101560	60545574	00787101761	00369997
00787101360	61859932	00787101560	60589394	00787101761	00370240
00787101360	61860458	00787101560	60661964	00787101761	00370411
00787101360	61868570	00787101560	60661965	00787101761	00370475
00787101360	61882602	00787101560	60661966	00787101761	60644590
00787101360	61886910	00787101560	60676457	00787101761	60661974
00787101360	61905763	00787101560	60712468	00787101761	60676464
00787101360	61907698	00787101560	60712469	00787101761	60768934
00787101360	61907699	00787101560	60745893	00787101761	60821307
00787101360	61924997	00787101560	60768925	00787101761	60873801
00787101360	61924998	00787101560	60768926	00787101761	60889545
00787101360	61936127	00787101560	60768927	00787101761	60952990
00787101360	61936128	00787101560	60770513	00787101761	60973577
00787101360	61936129	00787101560	60770514	00787101761	61028309
00787101360	61947693	00787101560	60793106	00787101761	61028310





**zimmer**

Part Number	Lot Number	Part Number	Lot Number	Part Number	Lot Number
00787101360	61952540	00787101560	60793107	00787101761	61045852
00787101360	61952541	00787101560	60821297	00787101761	61185523
00787101360	61952542	00787101560	60821298	00787101761	61199980
00787101360	61957367	00787101560	60821299	00787101761	61222209
00787101360	61968008	00787101560	60864609	00787101761	61304640
00787101360	61975889	00787101560	60864610	00787101761	61318394
00787101360	61975890	00787101560	60864623	00787101761	61386435
00787101360	61977877	00787101560	60873797	00787101761	61453523
00787101360	61997514	00787101560	60889539	00787101761	61468743
00787101360	61997515	00787101560	60893303	00787101761	61658292
00787101360	61997516	00787101560	60940783	00787101761	61776730
00787101360	62005389	00787101560	60940790	00787101761	61790439
00787101360	62038337	00787101560	60940791	00787101761	61983701
00787101360	62042578	00787101560	60952987	00787101761	61988895
00787101360	62055954	00787101560	60973575	00787101960	00369998
00787101360	62199401	00787101560	61028284	00787101960	00370103
00787101361	00369985	00787101560	61028285	00787101960	00370242
00787101361	00370074	00787101560	61028286	00787101960	00370471
00787101361	00370299	00787101560	61028287	00787101960	00370906
00787101361	00370407	00787101560	61028288	00787101960	60495801
00787101361	60545573	00787101560	61028336	00787101960	60565683
00787101361	60589393	00787101560	61028337	00787101960	60676467
00787101361	60609871	00787101560	61045849	00787101960	60821308
00787101361	60661958	00787101560	61052375	00787101960	60864612
00787101361	60661959	00787101560	61098182	00787101960	60940785
00787101361	60676454	00787101560	61098183	00787101960	60974182
00787101361	60745885	00787101560	61098184	00787101960	61028311
00787101361	60745886	00787101560	61152610	00787101960	61028312
00787101361	60768914	00787101560	61158981	00787101960	61179529
00787101361	60768915	00787101560	61163195	00787101960	61231907
00787101361	60768916	00787101560	61185516	00787101960	61250053
00787101361	60770505	00787101560	61190025	00787101960	61320350
00787101361	60793101	00787101560	61197654	00787101960	61332280
00787101361	60793102	00787101560	61199977	00787101960	61747539
00787101361	60793103	00787101560	61231908	00787101960	61779318
00787101361	60821291	00787101560	61243382	00787101960	62012577
00787101361	60821292	00787101560	61264038	00787101960	62075163



## Attachment 2

Versys® Hip System Cemented Revision/Calcar Femoral Stem  
Versys Heritage® Hip Prosthesis Femoral Revision Stem

**REMOVAL**  
**RESPONSE FORM**

Send completed form via email or Fax to

Your local Zimmer Representative.

Fax-Number: \_\_\_\_\_ Email: \_\_\_\_\_

Use the table below to record quantities of affected product(s):

Part Number	Lot Number	Quantity to be returned

Clinic Name and Address: \_\_\_\_\_

\_\_\_\_\_

Signature of person completing this form \_\_\_\_\_

Printed name \_\_\_\_\_

Title \_\_\_\_\_ Telephone (    ) \_\_\_\_\_ - \_\_\_\_\_

Date: \_\_\_\_\_