

February 18, 2020

To: Hospital and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE - REMOVAL**

Reference: ZFA2019-00433

Product: Innex Anchorage Stems

See **Attachment 2 – Potentially affected Product List**



Picture 1: Damaged Packaging of Innex Anchorage Stem

As a precautionary measure Zimmer GmbH is conducting a medical device Field Safety Corrective Action (Removal) for specific lots of Innex Anchorage Stems due to potential sterile packaging damage. Please refer to **Attachment 2** for the full list of potentially affected lots.

The issue is limited to the specific packaging configuration which is no longer used in production for Innex Anchorage Stems after the implementation of the packaging update in late 2017.

The damaged sterile packaging can be detected by user prior to implantation through the loss of vacuum state of the sterile pouch.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	A non-clinically significant extension of surgery to find another readily available product	A clinically significant extension of surgery to amend the surgical approach
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	Infection and potential further surgical intervention

Our records indicate that you may have received one or more of the potentially affected products. The units in question were distributed between 2012 January and 2020 January (Local deployment may differ).

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have potentially affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all potentially affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete Attachment 1 – Certificate of Acknowledgement and send to fieldaction.netherlands@zimmerbiomet.com. This form must be returned even if you do not have any potentially affected products at your facility.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility’s documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

Surgeon Responsibilities:

1. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow-up schedule.
2. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.netherlands@zimmerbiomet.com. This form must be returned even if you do not have any potentially affected products at your facility.
3. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility’s documentation.
4. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

Other Information



This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing nl.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies. We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field action.

Sincerely,

xxx

ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Potentially affected Product: Innex Anchorage Stem

Field Action Reference: ZFA2019-00433

Please return the **completed** form to your Zimmer Biomet contact person:

fieldaction.netherlands@zimmerbiomet.com

I received and understood the Field Safety Notice.

Regarding the products:

All inventories for the affected products have been checked and following products are to be returned:

Product Reference	Lot Reference	Number of products returned

OR

The potentially affected products which are unavailable for return have been: Implanted lost other: _____

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

Hospital Facility **Surgeon** *(Please check one as applicable)*

Printed Name: _____ **Signature:** _____ **Date:** ____/____/____

Title: _____ **Telephone:** () _____ - _____

Facility Name: _____ **Facility Address:** _____

City: _____ **ZIP:** _____ **Country:** _____

Note: This form will be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to fieldaction.netherlands@zimmerbiomet.com

ATTACHMENT 2

Potentially affected Product List

Item Number	Description	Lot Number				
01.02001.435	Innex [®] , anchorage stem, straight 0°, uncemented, ø 15-65	2696127	2725243	2774093	2794055	2800151
		2808397	2825635	2853327	2871916	
01.02001.436	Innex [®] , anchorage stem, straight 0°, uncemented, ø 17-65	2707225	2763852	2780769	2784081	2795551
		2800481	2804951	2816703	2826378	2910749
01.02001.437	Innex [®] , anchorage stem, straight 0°, uncemented, ø 19-65	2788140	2794057	2798007	2800483	2802709
		2805614	2813830	2861928	2911272	
01.02001.439	Innex [®] , anchorage stem, straight 0°, uncemented, ø 19-105	2635192	2693282	2710847	2733349	2764538
		2796424	2807365	2826380	2861221	2878394
		2890788	2911270			
01.02001.443	Innex [®] , anchorage stem, straight 0°, uncemented, ø 11-65	2677102	2687923	2693284	2736796	2746550
		2770453	2826250	2855750	2871272	2886235
01.02001.444	Innex [®] , anchorage stem, straight 0°, uncemented, ø 13-65	2639965	2683424	2693286	2710500	2749196
		2759576	2774988	2796426	2813639	2837668
		2854726	2880377	2902981		
01.02001.445	Innex [®] , anchorage stem, straight 0°, uncemented, ø 11-105	2688539	2696129	2746552	2768770	2774990
		2792609	2806767	2806791	2820400	2829095
		2842717	2862000	2901968		
01.02001.446	Innex [®] , anchorage stem, straight 0°, uncemented, ø 13-105	2921985	2922282	2925251	2638733	2664591
		2677104	2687925	2696064	2716710	2729513
		2745362	2757967	2763831	2782980	2795553
		2802501	2806773	2811396	2815531	2818780
		2839921	2842793	2855752	2875463	2879688
		2911268				
01.02001.447	Innex [®] , anchorage stem, straight 0°, uncemented, ø 15-105	2926049	2637027	2646376	2666171	2675713
		2684959	2694665	2699776	2726304	2738821
		2752079	2759578	2763825	2768090	2779314
		2786117	2796428	2804953	2811408	2814573
		2820402	2832066	2844673	2853329	2861223
		2878396	2887299	2905302		
01.02001.448	Innex [®] , anchorage stem, straight 0°, uncemented, ø 17-105	2926858	2638001	2647166	2658005	2677744
		2685752	2699779	2710849	2721287	2743015
		2752081	2759989	2764508	2772711	2785185
		2794059	2806414	2823134	2832076	2844680
		2855754	2869736	2894467	2905304	

Item Number	Description	Lot Number				
01.02001.450	Innex [®] , anchorage stem, straight 0°, uncemented, ø 11-135	2632710	2690338	2710851	2719993	2729515
		2749200	2766295	2804955	2874049	2907800
01.02001.451	Innex [®] , anchorage stem, straight 0°, uncemented, ø 13-135	2664593	2685754	2711904	2750956	2758522
		2768772	2773696	2794061	2808399	2826961
		2871274				
01.02001.452	Innex [®] , anchorage stem, straight 0°, uncemented, ø 15-135	2637025	2655206	2674580	2693288	2713468
		2757969	2766908	2780771	2794067	2804957
		2817405	2826963	2847778	2862002	2873568
01.02001.453	Innex [®] , anchorage stem, straight 0°, uncemented, ø 17-135	2646378	2664595	2693290	2722372	2746554
		2757971	2768774	2774992	2794069	2804959
		2806966	2815533	2844682	2862004	
01.02001.454	Innex [®] , anchorage stem, straight 0°, uncemented, ø 19-135	2641271	2681332	2693292	2714879	2741986
		2768776	2778399	2800485	2816705	2871276
		2882791	2911266			
01.02001.455	Innex [®] , anchorage stem, straight 0°, uncemented, ø 11-175	2921908	2660012	2674582	2675760	2703621
		2717563	2756915	2765200	2811398	2867433
01.02001.456	Innex [®] , anchorage stem, straight 0°, uncemented, ø 13-175	2690340	2696136	2749198	2755122	2782982
		2795560	2808401	2825263	2849565	
01.02001.457	Innex [®] , anchorage stem, straight 0°, uncemented, ø 15-175	2655204	2684961	2738009	2749202	2790959
		2798206	2805451	2813832	2831195	2851394
01.02001.458	Innex [®] , anchorage stem, straight 0°, uncemented, ø 17-175	2638003	2658946	2687915	2699782	2746556
		2755346	2797500	2804961	2808404	2818782
		2898228				
01.02001.459	Innex [®] , anchorage stem, straight 0°, uncemented, ø 19-175	2658948	2687917	2725241	2795562	2797502
		2803933	2806431	2811400	2825637	2910660
01.02001.460	Innex [®] , anchorage stem, 2° angle, uncemented, ø 11-135	2703623	2749214	2829738		
01.02001.461	Innex [®] , anchorage stem, 2° angle, uncemented, ø 13-135	2730319	2746558	2749221	2862008	2866665
		2874354				
01.02001.462	Innex [®] , anchorage stem, 2° angle, uncemented, ø 15-135	2724503	2726306	2823708		
01.02001.463	Innex [®] , anchorage stem, 2° angle, uncemented, ø 17-135	2730336	2726308	2749223	2862046	2886237
01.02001.464	Innex [®] , anchorage stem, 2° angle, uncemented, ø 19-135	2721289	2730338	2862050		
01.02001.465	Innex [®] , anchorage stem, 2° angle, uncemented, ø 11-175	2699784	2729519	2752083	2862058	

Item Number	Description	Lot Number				
01.02001.466	Innex [®] , anchorage stem, 2° angle, uncemented, ø 13-175	2713470	2725239	2752983	2862056	2868762
		2886239				
01.02001.467	Innex [®] , anchorage stem, 2° angle, uncemented, ø 15-175	2703625	2730340	2917985		
01.02001.468	Innex [®] , anchorage stem, 2° angle, uncemented, ø 17-175	2729521	2764506			
01.02001.469	Innex [®] , anchorage stem, 2° angle, uncemented, ø 19-175	2714881	2749204	2838941		
01.02001.470	Innex [®] , anchorage stem, conical, uncemented, 50	2922036	2922037	2922038	2923746	2926859
		2929506	2632714	2635194	2635196	2637023
		2638737	2641273	2644006	2644008	2645032
		2646380	2646382	2647168	2653021	2653023
		2653025	2655202	2655827	2656688	2661480
		2660026	2660014	2663776	2664597	2667784
		2670525	2671473	2672377	2674576	2677761
		2679795	2681334	2682436	2684963	2684965
		2687919	2688566	2687921	2693294	2694663
		2699789	2701307	2699786	2703617	2703615
		2706354	2710496	2706356	2710492	2710494
		2711906	2715366	2716712	2721296	2719545
		2725235	2725237	2726310	2726312	2727798
		2729517	2732095	2734599	2736798	2738823
		2741988	2746565	2743984	2750958	2754331
		2756917	2757973	2763011	2766297	2768778
		2774095	2776747	2778401	2780777	2784083
		2789128	2790963	2794063	2796430	2798208
		2800487	2802503	2804963	2806433	2808411
		2811402	2817825	2821084	2826382	2828652
		2831197	2833876	2839923	2836683	2842715
		2844684	2848845	2847784	2852164	2850387
		2855761	2858557	2860770	2863177	2866277
		2868984	2872511	2874352	2873571	2877082
		2880950	2884726	2886589	2888661	2890493
		2892356	2894464	2897086	2899372	2901407
		2905316	2903927	2907802	2910761	2911264

Item Number	Description	Lot Number				
01.02001.471	Innex [®] , anchorage stem, conical, uncemented, 100	2926509	2632716	2634112	2638735	2645034
		2650943	2653027	2670527	2674578	2678785
		2685756	2693296	2699791	2710502	2718334
		2727198	2741023	2743991	2752085	2755124
		2759580	2767916	2774994	2782984	2790965
		2798215	2804965	2807368	2815535	2820404
		2829320	2833874	2842713	2850389	2857964
		2865202	2871918	2873573	2877746	2883633
		2891267	2897049	2907393	2915067	
01.02001.475	Innex [®] , anchorage stem, offset O3, uncemented, ø 11-105	2666173	2688089	2694661	2719547	2756921
		2768780	2780779	2793162	2798217	2807370
		2821086	2854728	2909219		
01.02001.476	Innex [®] , anchorage stem, offset O3, uncemented, ø 13-105	2915544	2648379	2655829	2671475	2684967
		2693207	2706482	2710508	2727200	2736805
		2746567	2763827	2774097	2785187	2795571
		2802505	2808413	2825639	2849567	2868665
		2879690	2903929			
01.02001.477	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 15-105	2632178	2639963	2650950	2670529	2673965
		2687927	2687929	2696066	2710510	2726314
		2741025	2755348	2766910	2777238	2800489
		2807372	2815537	2824223	2845497	2853331
		2863179	2871920	2892358	2911262	
01.02001.478	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 17-105	2638005	2648381	2653043	2681336	2696138
		2732097	2741990	2749206	2757975	2774099
		2790091	2807376	2824985	2842711	2853333
		2867032	2892360			
01.02001.480	Innex [®] , anchorage stem, offset O3, uncemented, ø 11-135	2639961	2685758	2706468	2754329	2766912
		2793164	2804967	2845499	2852160	2874350
01.02001.481	Innex [®] , anchorage stem, offset O3, uncemented, ø 13-135	2663778	2666175	2693298	2716714	2749208
		2763013	2780773	2796432	2800153	2807142
		2816061	2825210	2832996	2868029	2873764
01.02001.482	Innex [®] , anchorage stem, offset O3, uncemented, ø 15-135	2632718	2649441	2658950	2674574	2690342
		2733351	2743993	2768794	2780775	2799546
		2807381	2842795	2860772	2874348	2913635
01.02001.483	Innex [®] , anchorage stem, offset O3, uncemented, ø 17-135	2632643	2644010	2649443	2662390	2699794
		2743017	2763829	2795573	2807383	2826384
		2851308	2887693	2911260		

Item Number	Description	Lot Number				
01.02001.484	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 15-135	2638007	2646384	2653045	2688568	2696068
		2725232	2756919	2776749	2797504	2815539
		2826965	2851310	2871922	2898226	
01.02001.485	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 17-135	2632185	2662392	2662394	2688091	2694659
		2725230	2759582	2793167	2808420	2830905
		2866279	2878398	2913633		
01.02001.486	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 19-135	2644012	2653047	2690344	2696070	2719549
		2746569	2797521	2823129	2847788	2868066
		2879692	2915049			
01.02001.487	Innex [®] , anchorage stem, offset O6, uncemented, ø 19-135	2693300	2706617	2725245	2749210	2769443
		2815541	2834714	2851312	2886247	
01.02001.488	Innex [®] , anchorage stem, offset O3, uncemented, ø 15-105	2915595	2638009	2646386	2649445	2654318
		2660028	2674572	2684969	2699796	2710498
		2716716	2725247	2757977	2741027	2768782
		2774996	2789298	2797523	2807385	2820406
		2824987	2845501	2857985	2868987	2879694
		2907804				
01.02001.489	Innex [®] , anchorage stem, offset O3, uncemented, ø 17-105	2632645	2646388	2649447	2662401	2678781
		2688570	2703627	2716718	2726316	2741992
		2746571	2761490	2772713	2795580	2808422
		2826967	2839925	2854730	2871278	2905924
01.02001.490	Innex [®] , anchorage stem, offset O3, uncemented, ø 19-105	2641275	2658007	2699798	2755350	2774101
		2798219	2806440	2825641	2852153	2862006
		2892362	2915051			
01.02001.491	Innex [®] , anchorage stem, offset O3, uncemented, ø 19-135	2637021	2660030	2675762	2699800	2743019
		2769535	2789310	2803656	2820408	2833871
		2868989	2898224			
01.02001.492	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 11-105	2632647	2646390	2684971	2706470	2725249
		2745364	2757979	2770967	2794065	2812471
		2823711	2856853	2886241	2905914	
01.02001.493	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 13-105	2632187	2639959	2649449	2664599	2677106
		2696072	2710504	2721298	2735128	2757981
		2768784	2789312	2801389	2814575	2824225
		2851314	2867034	2872499	2886243	2911258
01.02001.494	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 19-105	2644014	2664601	2690351	2715368	2746573
		2774998	2790967	2804969	2823713	2835730
		2887691				

Item Number	Description	Lot Number				
01.02001.495	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 11-135	2703629	2757983	2772715	2801391	2804971
		2815543	2823716	2868741		
01.02001.496	Innex [®] , anchorage stem, offset O4.5, uncemented, ø 13-135	2641277	2649451	2690353	2706472	2745366
		2763015	2775000	2796434	2807387	2817403
		2852151	2886245	2911256		
01.02001.497	Innex [®] , anchorage stem, offset O6, uncemented, ø 11-135	2724297	2746575	2759584	2789130	2796870
		2804973	2814577	2824227	2829736	
01.02001.498	Innex [®] , anchorage stem, offset O6, uncemented, ø 13-135	2672379	2685760	2710506	2726318	2744000
		2799548	2811404	2833868	2878603	2892364
01.02001.499	Innex [®] , anchorage stem, offset O6, uncemented, ø 15-135	2641279	2699802	2749212	2777240	2807390
		2815545	2824229	2845503	2871924	
01.02001.500	Innex [®] , anchorage stem, offset O6, uncemented, ø 17-135	2716720	2766914	2801393	2818587	2829322
		2872497				