

March 5, 2018

**To:** Risk Managers

**Subject:** **URGENT MEDICAL DEVICE RECALL**

**Affected Product: Comprehensive Segmental Revision System (SRS)**

**See Attachment 1 – Affected Product List (LOT SPECIFIC)**

Zimmer Biomet is conducting a medical device recall for product from specific lots of the Comprehensive Segmental Revision System that may be in your inventory. Zimmer Biomet received reports that during assembly, an SRS Humeral Distal Body implant failed to engage correctly at the point of reduction with a Discovery Elbow System Humeral Condyle. A mismatch occurred between the screw holes in the Distal Humeral Body & the Discovery Elbow Condyle implant during vendor machine operation. The condition would be noticed during assembly and therefore, if the product has already been implanted, no further action is required. The mismatch does not always prevent engagement of the screw, based on complaints received it is estimated to prevent engagement of the screw in less than 1% of cases.



Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Surgical delay (< 30 minutes)	Screws are not implanted, leading to immediate loosening and pain
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	Revision

**Risk Manager Responsibilities:**

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 2 – Certificate of Acknowledgement** and send to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com). This form must be returned **even if you do not have affected products at your facility**.
4. Retain a copy of the acknowledgement form with your recall 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com).

**Other Information**

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [product.experience@zimmerbiomet.com](mailto:product.experience@zimmerbiomet.com).

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,



Kevin W. Escapule  
Post Market Surveillance and Regulatory Compliance Director



**ATTACHMENT 2**  
**Certificate of Acknowledgement**

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Affected Product: Comprehensive Segmental Revision System**

**Field Action Reference: ZFA 2018-00070**

**Please check one as applicable:**

Hospital Facility

**Do you have affected product in your facility?**  
(Hospital Facility Only: Please mark the appropriate response.)

**Yes**, we currently have one or more affected items in our facility.

**No**, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

**Printed Name:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

**Title:** \_\_\_\_\_ **Telephone:** (    ) \_\_\_\_\_ - \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Facility Name:** \_\_\_\_\_

**Facility Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **ZIP:** \_\_\_\_\_

**Note:** This form must 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 [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com) or fax to 574-372-4265.

**ATTACHMENT 1**  
**Affected Product List**

Item	Lot Number	Description
211250	095580	Compr Srs 50mm Dst Hml Bdy Lt
211250	119120	Compr Srs 50mm Dst Hml Bdy Lt
211250	130020	Compr Srs 50mm Dst Hml Bdy Lt
211250	142530	Compr Srs 50mm Dst Hml Bdy Lt
211250	155910	Compr Srs 50mm Dst Hml Bdy Lt
211250	162450	Compr Srs 50mm Dst Hml Bdy Lt
211250	162460	Compr Srs 50mm Dst Hml Bdy Lt
211250	241160	Compr Srs 50mm Dst Hml Bdy Lt
211250	257860	Compr Srs 50mm Dst Hml Bdy Lt
211250	304290	Compr Srs 50mm Dst Hml Bdy Lt
211250	305860	Compr Srs 50mm Dst Hml Bdy Lt
211250	309730	Compr Srs 50mm Dst Hml Bdy Lt
211250	337610	Compr Srs 50mm Dst Hml Bdy Lt
211250	389790	Compr Srs 50mm Dst Hml Bdy Lt
211250	400730	Compr Srs 50mm Dst Hml Bdy Lt
211250	419380	Compr Srs 50mm Dst Hml Bdy Lt
211250	430570	Compr Srs 50mm Dst Hml Bdy Lt
211250	443670	Compr Srs 50mm Dst Hml Bdy Lt
211250	545430	Compr Srs 50mm Dst Hml Bdy Lt
211250	546260	Compr Srs 50mm Dst Hml Bdy Lt
211250	548290	Compr Srs 50mm Dst Hml Bdy Lt
211250	550390	Compr Srs 50mm Dst Hml Bdy Lt
211250	586120	Compr Srs 50mm Dst Hml Bdy Lt
211250	606830	Compr Srs 50mm Dst Hml Bdy Lt
211250	611540	Compr Srs 50mm Dst Hml Bdy Lt
211250	636370	Compr Srs 50mm Dst Hml Bdy Lt
211250	636470	Compr Srs 50mm Dst Hml Bdy Lt
211250	688540	Compr Srs 50mm Dst Hml Bdy Lt
211250	704020	Compr Srs 50mm Dst Hml Bdy Lt
211250	714760	Compr Srs 50mm Dst Hml Bdy Lt
211250	793670	Compr Srs 50mm Dst Hml Bdy Lt
211250	806070	Compr Srs 50mm Dst Hml Bdy Lt
211250	829520	Compr Srs 50mm Dst Hml Bdy Lt
211250	829530	Compr Srs 50mm Dst Hml Bdy Lt
211250	881230	Compr Srs 50mm Dst Hml Bdy Lt
211250	950270	Compr Srs 50mm Dst Hml Bdy Lt
211250	970920	Compr Srs 50mm Dst Hml Bdy Lt

Item	Lot Number	Description
211251	019600	Compr Srs 60mm Dst Hml Bdy Lt
211251	110780	Compr Srs 60mm Dst Hml Bdy Lt
211251	130040	Compr Srs 60mm Dst Hml Bdy Lt
211251	157180	Compr Srs 60mm Dst Hml Bdy Lt
211251	185620	Compr Srs 60mm Dst Hml Bdy Lt
211251	203520	Compr Srs 60mm Dst Hml Bdy Lt
211251	241180	Compr Srs 60mm Dst Hml Bdy Lt
211251	278580	Compr Srs 60mm Dst Hml Bdy Lt
211251	330870	Compr Srs 60mm Dst Hml Bdy Lt
211251	364380	Compr Srs 60mm Dst Hml Bdy Lt
211251	424550	Compr Srs 60mm Dst Hml Bdy Lt
211251	430580	Compr Srs 60mm Dst Hml Bdy Lt
211251	457210	Compr Srs 60mm Dst Hml Bdy Lt
211251	544340	Compr Srs 60mm Dst Hml Bdy Lt
211251	583360	Compr Srs 60mm Dst Hml Bdy Lt
211251	636520	Compr Srs 60mm Dst Hml Bdy Lt
211251	706690	Compr Srs 60mm Dst Hml Bdy Lt
211251	714810	Compr Srs 60mm Dst Hml Bdy Lt
211251	810260	Compr Srs 60mm Dst Hml Bdy Lt
211251	853250	Compr Srs 60mm Dst Hml Bdy Lt
211251	881330	Compr Srs 60mm Dst Hml Bdy Lt
211251	883830	Compr Srs 60mm Dst Hml Bdy Lt
211251	891880	Compr Srs 60mm Dst Hml Bdy Lt
211251	923660	Compr Srs 60mm Dst Hml Bdy Lt
211251	923680	Compr Srs 60mm Dst Hml Bdy Lt
211251	991400	Compr Srs 60mm Dst Hml Bdy Lt
211252	033700	Compr Srs 70mm Dst Hml Bdy Lt
211252	053800	Compr Srs 70mm Dst Hml Bdy Lt
211252	062210	Compr Srs 70mm Dst Hml Bdy Lt
211252	110790	Compr Srs 70mm Dst Hml Bdy Lt
211252	160770	Compr Srs 70mm Dst Hml Bdy Lt
211252	185630	Compr Srs 70mm Dst Hml Bdy Lt
211252	241190	Compr Srs 70mm Dst Hml Bdy Lt
211252	247810	Compr Srs 70mm Dst Hml Bdy Lt
211252	257870	Compr Srs 70mm Dst Hml Bdy Lt
211252	347080	Compr Srs 70mm Dst Hml Bdy Lt

Item	Lot Number	Description
211252	583370	Compr Srs 70mm Dst Hml Bdy Lt
211252	611530	Compr Srs 70mm Dst Hml Bdy Lt
211252	636680	Compr Srs 70mm Dst Hml Bdy Lt
211252	638640	Compr Srs 70mm Dst Hml Bdy Lt
211252	674650	Compr Srs 70mm Dst Hml Bdy Lt
211252	688550	Compr Srs 70mm Dst Hml Bdy Lt
211252	775020	Compr Srs 70mm Dst Hml Bdy Lt
211252	829540	Compr Srs 70mm Dst Hml Bdy Lt
211252	848530	Compr Srs 70mm Dst Hml Bdy Lt
211252	889330	Compr Srs 70mm Dst Hml Bdy Lt
211252	950310	Compr Srs 70mm Dst Hml Bdy Lt
211252	976390	Compr Srs 70mm Dst Hml Bdy Lt
211252	988380	Compr Srs 70mm Dst Hml Bdy Lt
211252	991410	Compr Srs 70mm Dst Hml Bdy Lt
211253	028450	Compr Srs 50mm Dst Hml Bdy Rt
211253	028460	Compr Srs 50mm Dst Hml Bdy Rt
211253	053810	Compr Srs 50mm Dst Hml Bdy Rt
211253	062220	Compr Srs 50mm Dst Hml Bdy Rt
211253	098020	Compr Srs 50mm Dst Hml Bdy Rt
211253	155900	Compr Srs 50mm Dst Hml Bdy Rt
211253	160780	Compr Srs 50mm Dst Hml Bdy Rt
211253	231490	Compr Srs 50mm Dst Hml Bdy Rt
211253	241230	Compr Srs 50mm Dst Hml Bdy Rt
211253	251120	Compr Srs 50mm Dst Hml Bdy Rt
211253	251920	Compr Srs 50mm Dst Hml Bdy Rt
211253	257880	Compr Srs 50mm Dst Hml Bdy Rt
211253	281140	Compr Srs 50mm Dst Hml Bdy Rt
211253	330880	Compr Srs 50mm Dst Hml Bdy Rt
211253	347100	Compr Srs 50mm Dst Hml Bdy Rt
211253	367850	Compr Srs 50mm Dst Hml Bdy Rt
211253	400390	Compr Srs 50mm Dst Hml Bdy Rt
211253	450780	Compr Srs 50mm Dst Hml Bdy Rt
211253	493220	Compr Srs 50mm Dst Hml Bdy Rt
211253	494170	Compr Srs 50mm Dst Hml Bdy Rt
211253	527200	Compr Srs 50mm Dst Hml Bdy Rt
211253	546290	Compr Srs 50mm Dst Hml Bdy Rt
211253	548460	Compr Srs 50mm Dst Hml Bdy Rt
211253	548470	Compr Srs 50mm Dst Hml Bdy Rt

Item	Lot Number	Description
211253	548580	Compr Srs 50mm Dst Hml Bdy Rt
211253	586130	Compr Srs 50mm Dst Hml Bdy Rt
211253	611520	Compr Srs 50mm Dst Hml Bdy Rt
211253	636710	Compr Srs 50mm Dst Hml Bdy Rt
211253	665880	Compr Srs 50mm Dst Hml Bdy Rt
211253	704030	Compr Srs 50mm Dst Hml Bdy Rt
211253	761210	Compr Srs 50mm Dst Hml Bdy Rt
211253	829550	Compr Srs 50mm Dst Hml Bdy Rt
211253	853260	Compr Srs 50mm Dst Hml Bdy Rt
211253	889810	Compr Srs 50mm Dst Hml Bdy Rt
211253	914750	Compr Srs 50mm Dst Hml Bdy Rt
211253	923670	Compr Srs 50mm Dst Hml Bdy Rt
211253	923690	Compr Srs 50mm Dst Hml Bdy Rt
211253	925920	Compr Srs 50mm Dst Hml Bdy Rt
211253	927420	Compr Srs 50mm Dst Hml Bdy Rt
211253	937130	Compr Srs 50mm Dst Hml Bdy Rt
211253	991320	Compr Srs 50mm Dst Hml Bdy Rt
211254	062830	Compr Srs 60mm Dst Hml Bdy Rt
211254	119130	Compr Srs 60mm Dst Hml Bdy Rt
211254	130070	Compr Srs 60mm Dst Hml Bdy Rt
211254	185590	Compr Srs 60mm Dst Hml Bdy Rt
211254	196660	Compr Srs 60mm Dst Hml Bdy Rt
211254	201270	Compr Srs 60mm Dst Hml Bdy Rt
211254	241290	Compr Srs 60mm Dst Hml Bdy Rt
211254	247280	Compr Srs 60mm Dst Hml Bdy Rt
211254	247290	Compr Srs 60mm Dst Hml Bdy Rt
211254	257890	Compr Srs 60mm Dst Hml Bdy Rt
211254	338480	Compr Srs 60mm Dst Hml Bdy Rt
211254	347110	Compr Srs 60mm Dst Hml Bdy Rt
211254	350590	Compr Srs 60mm Dst Hml Bdy Rt
211254	366310	Compr Srs 60mm Dst Hml Bdy Rt
211254	554450	Compr Srs 60mm Dst Hml Bdy Rt
211254	636760	Compr Srs 60mm Dst Hml Bdy Rt
211254	648150	Compr Srs 60mm Dst Hml Bdy Rt
211254	704040	Compr Srs 60mm Dst Hml Bdy Rt
211254	714830	Compr Srs 60mm Dst Hml Bdy Rt
211254	750840	Compr Srs 60mm Dst Hml Bdy Rt
211254	767880	Compr Srs 60mm Dst Hml Bdy Rt

Item	Lot Number	Description
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211254	829560	Compr Srs 60mm Dst Hml Bdy Rt
211254	878430	Compr Srs 60mm Dst Hml Bdy Rt
211254	927430	Compr Srs 60mm Dst Hml Bdy Rt
211254	948090	Compr Srs 60mm Dst Hml Bdy Rt
211254	952960	Compr Srs 60mm Dst Hml Bdy Rt
211254	970930	Compr Srs 60mm Dst Hml Bdy Rt
211254	976410	Compr Srs 60mm Dst Hml Bdy Rt
211255	040470	Compr Srs 70mm Dst Hml Bdy Rt
211255	192770	Compr Srs 70mm Dst Hml Bdy Rt
211255	241300	Compr Srs 70mm Dst Hml Bdy Rt
211255	258540	Compr Srs 70mm Dst Hml Bdy Rt
211255	288580	Compr Srs 70mm Dst Hml Bdy Rt
211255	293740	Compr Srs 70mm Dst Hml Bdy Rt
211255	320100	Compr Srs 70mm Dst Hml Bdy Rt
211255	340150	Compr Srs 70mm Dst Hml Bdy Rt
211255	347700	Compr Srs 70mm Dst Hml Bdy Rt
211255	364660	Compr Srs 70mm Dst Hml Bdy Rt

Item	Lot Number	Description
211255	419900	Compr Srs 70mm Dst Hml Bdy Rt
211255	442840	Compr Srs 70mm Dst Hml Bdy Rt
211255	462480	Compr Srs 70mm Dst Hml Bdy Rt
211255	462490	Compr Srs 70mm Dst Hml Bdy Rt
211255	569770	Compr Srs 70mm Dst Hml Bdy Rt
211255	611040	Compr Srs 70mm Dst Hml Bdy Rt
211255	611930	Compr Srs 70mm Dst Hml Bdy Rt
211255	688560	Compr Srs 70mm Dst Hml Bdy Rt
211255	770690	Compr Srs 70mm Dst Hml Bdy Rt
211255	780490	Compr Srs 70mm Dst Hml Bdy Rt
211255	815100	Compr Srs 70mm Dst Hml Bdy Rt
211255	818160	Compr Srs 70mm Dst Hml Bdy Rt
211255	829690	Compr Srs 70mm Dst Hml Bdy Rt
211255	867530	Compr Srs 70mm Dst Hml Bdy Rt
211255	891270	Compr Srs 70mm Dst Hml Bdy Rt
211255	923980	Compr Srs 70mm Dst Hml Bdy Rt
211255	924160	Compr Srs 70mm Dst Hml Bdy Rt
211255	927440	Compr Srs 70mm Dst Hml Bdy Rt