December 20, 2016

To: Risk Managers

Subject: **URGENT MEDICAL DEVICE RECALL-LOT SPECIFIC**

Affected Product: Comprehensive Reverse Shoulder Tray

Refer to Attachment 2 – Affected Product List for the affected items/lot combinations.

Zimmer Biomet is conducting a lot specific medical device field action for Comprehensive Reverse Shoulder Trays manufactured prior to September 2011 due to a higher than anticipated rate of fracturing. Devices manufactured after this date have design enhancements that increased the strength of the device.

Our records indicate you may have received one or more of the affected products. The affected units were distributed between October 2008 and September 2015.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Highest Severity*
	None	*None*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Highest Severity*
	Revision procedure due to device fracture.	*Revision procedure due to device fracture.*

Risk Manager Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected product.
3. Your Zimmer Biomet sales representative will remove the affected product from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy within three (3) days to corporatequality.postmarket@zimmerbiomet.com.
    b. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your facilities documentation.
5. If after reviewing this notice you have further questions or concerns please call 411 Technical Services at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of the call center operating hours will receive a prompt to record a voicemail or be transferred to an on-call representative in the case of an emergency. Alternatively, your questions may be sent by email to corporatequality.postmarket@zimmerbiomet.com.

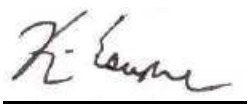
Other Information
This voluntary medical device recall was reported to the U.S. Food and Drug Administration, and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: 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 even. 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.

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 recall.

Sincerely,



Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

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

[ ] **Hospital Facility**

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 can be considered closed for your account. It is important that you complete this form and email a copy to: corporatequality.postmarket@zimmerbiometcom.

ATTACHMENT 2
Affected Product List

Item Number: 115340				Description: Reverse Shoulder Humeral Tray					
Lot numbers									
041870	153410	310590	415090	557440	607420	660040	697130	767370	848210
041880	153420	310600	420630	557620	607430	668550	697150	771810	848220
041890	153430	310610	424640	557840	609780	668560	697160	788670	848230
052860	159650	310620	424650	558840	613990	668570	697170	788680	848240
060500	159660	329390	424660	558880	630660	668580	697180	788690	848250
070330	161960	349140	424670	558890	633600	668590	697190	791260	848260
079900	172670	349150	424680	558900	634660	668600	697200	791270	848270
085130	215990	351030	424690	558910	634860	668610	704050	791280	848280
118250	216000	351040	424700	558920	635190	668620	704810	818790	848290
118260	216010	367300	424710	561910	637190	668630	706840	839150	848300
118270	256990	367310	424720	562430	637240	668970	712090	846190	848310
118280	257000	367320	424730	563440	641220	674320	715990	846200	848320
118290	257010	367330	424740	568870	641350	677090	716200	846210	854210
118300	257020	367340	436760	569050	641390	677100	723830	846230	854220
118340	278300	367350	436770	569060	641680	677110	723850	846240	854240
118350	278310	367360	440500	569070	648790	677140	723870	846280	854250
118360	278320	367370	457900	569080	648800	677150	723880	846290	854260
118370	278330	367380	492370	569090	648810	677160	725550	846300	854290
118380	278550	372290	492380	569100	648820	677170	725560	846310	854300
118390	278560	372310	492390	569120	648830	677180	725760	846320	854310
132020	278580	372320	492400	569130	648860	677190	726590	846330	854320
132030	278590	385090	492410	569140	659950	677200	726710	848110	863330
153330	300090	402880	492420	569150	659960	680720	734810	848120	889690
153340	300100	411980	492430	569690	659970	680730	745350	848130	908010
153350	300110	413530	492440	578920	659980	680740	762930	848140	950390
153360	300120	415040	492450	595090	659990	680750	764700	848150	950400
153370	300130	415050	501830	597740	660000	680760	765560	848160	963700
153380	300140	415060	551660	607390	660010	697100	765830	848170	974990
153390	300150	415070	556800	607400	660020	697110	765870	848190	981260
153400	310580	415080	556820	607410	660030	697120	767360	848200	981270