February 01, 2017

To: Risk Managers and Surgeons

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

Affected Product: Comprehensive Reverse Shoulder Tray
Item 115340

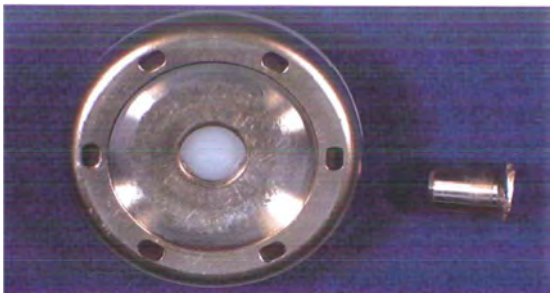
Refer to Attachment 3 – Additional list of affected items/lots combinations.

This is a follow up to the medical device field action notification you received dated December 20, 2016. Zimmer Biomet has since identified additional product lots that have been added to the affected product list, as well as included patient monitoring guidance for surgeons. Please review Attachment 3 additional list of affected items/lots combination.

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 May 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	*Most Probable*	*Highest Severity*

consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Revision procedure due to device fracture.*	*Revision procedure due to device fracture.*

Risk Manager Responsibilities:

1. Review this updated 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 with new signature and date.
    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.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing surgical follow up protocol.
3. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy 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 documentation.

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,

[redacted]

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** **[ ] Surgeon** (Please check one as applicable)

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@zimmerbiomet.com.

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
085130	172670	349150	424680	558900	634660	668600	697200	791270	848270
118250	215990	351030	424690	558910	634860	668610	704050	791280	848280
118260	216000	351040	424700	558920	635190	668620	704810	818790	848290
118270	216010	367300	424710	561910	637190	668630	706840	839150	848300
118280	256990	367310	424720	562430	637240	668970	712090	846190	848310
118290	257000	367320	424730	563440	641220	674320	715990	846200	848320
118300	257010	367330	424740	568870	641350	677090	716200	846210	854210
118340	257020	367340	436760	569050	641390	677100	723830	846230	854220
118350	278300	367350	436770	569070	641680	677110	723850	846240	854240
118360	278310	367360	440500	569080	648790	677140	723870	846280	854250
118370	278320	367370	457900	569090	648800	677150	723880	846290	854260
118380	278330	367380	492370	569100	648810	677160	725550	846300	854290
118390	278550	372290	492380	569120	648820	677170	725560	846310	854300
132020	278560	372310	492390	569130	648830	677180	725760	846320	854310
132030	278580	372320	492400	569140	648860	677190	726590	846330	854320
153330	278590	385090	492410	569150	659950	677200	726710	848110	863330
153340	300090	402880	492420	569690	659960	680720	734810	848120	889690
153350	300100	411980	492430	578920	659970	680730	745350	848130	908010
153360	300110	413530	492440	595090	659980	680740	762930	848140	950390
153370	300120	415040	492450	597740	659990	680750	764700	848150	950400
153380	300130	415050	501830	607390	660000	680760	765560	848160	963700
153390	300140	415060	551660	607400	660010	697100	765830	848170	974990
153400	300150	415070	556800	607410	660020	697110	765870	848190	981260
310580	415080	556820	660030	697120	767360	848200	981270	561950	

ATTACHMENT 3
Additional Affected Product List

Item Number: 115340				Description: Reverse Shoulder Humeral Tray					
Lot numbers									
334260	473090	695900	208290	212200	479370	634870	556460	561530	917830
334370	482000	695920	541900	016140	479380	558040	723860	558000	934930
049710	482010	075330	228630	840600	679060	561890	633570	557790	600320
049740	361860	433020	228640	840610	557830	556000	630690	557760	433590
696270	361870	433030	228650	767270	556360	359640	635820	876790	384350
696280	361880	433040	228660	767260	561560	359660	557390	762700	767250
696290	361890	433050	228670	725800	637250	359630	997320	307790	026690
696300	361900	391660	927760	525920	561790	359680	997330	905340	597970
696310	212230	320150	541880	525910	359610	634670	359650	905280	683040
696320	212240	208280	541890	479360	679070	555280	557520	870120	704440
906550	918800								

December 20, 2016

To: Risk Managers

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

Affected Product: Comprehensive Reverse Shoulder Tray

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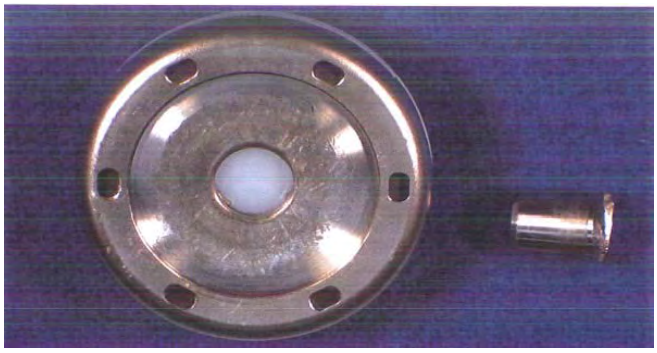

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Highest Severity*
	None	*None*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.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

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