Apr 30, 2020

To: Hospital

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

Reference: **ZFA2020-00103**

Affected Product: **Various Polyethylene Implants**

Biomet Orthopedics LLC is conducting a lot specific medical device Field Safety Corrective Action (removal) for various polyethylene implants (see **Attachment 2 – Potentially Affected Product List**). The potentially affected products are being removed due to the potential presence of elevated endotoxin levels that exceed the specification limit. The issue was discovered during routine bacterial endotoxin testing (BET). There have been no complaints received related to the potentially affected lots in scope.

Endotoxins (pyrogens) are substances found in certain bacteria. The FDA-adopted standard for endotoxin levels is 20 EU/device. There were three polyethylene implant samples during an approximate 6 week period that were found to exceed this level. As a result, the polyethylene implants manufactured between December 2016 and January 2017 are being removed. Potentially affected products that have the potential to exceed process limits for endotoxins could present the potential risks described below:

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
	None	Adverse Local Tissue Reaction, pain or ache (critical), reaction to allergen or toxin (severe systemic)

Our records indicate that you may have received one or more of the potentially affected products (see **Attachment 2 – Potentially Affected Product List**). The potentially affected products were distributed between December 2016 and February 2020 (local deployment may differ).

Hospital Responsibilities:

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. If you have any potentially affected products at your facility, assist your Zimmer Biomet sales representative and quarantine all potentially affected products. Your Zimmer Biomet sales representative will remove the potentially affected products 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 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 Field Safety Notice, please contact your Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Corrective Action that are recommended beyond your existing follow-up schedule.
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 potentially affected implants at your facility.
4. Retain a copy of the acknowledgement form with your Field Safety Corrective Action (removal) records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this Field Safety 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 units or any other Zimmer Biomet product by emailing per.nl@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 Safety Corrective Action.

Sincerely,

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ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Potentially Affected Product: Various Polyethylene Implants

Field Safety Corrective Action Reference: ZFA 2020-00103

Please return the completed form to your Zimmer Biomet contact person or by e-mail
fieldaction.netherlands@zimmerbiomet.com

☐ I received and understood the Field Safety Notice.

Regarding the parts:

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

Item Reference	Lot Number	Number of parts returned

OR

☐ The potentially affected products which are unavailable for return have been used

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:**_____

ATTACHMENT 2

Potentially Affected Product List

Item Number	Lot Number	Item Description
Extremities Products		
113954	597000	Hybrid Glenoid Glenoid Base, 4 MM
XL-115364	744880	Comprehensive Reverse Humeral Bearing, ArComXL, 44 MM X 36 MM, +3MM
XL-115366	502510	Comprehensive Reverse Humeral Bearing, ArComXL, 44 MM X 41 MM, Standard
Hip Products		
110010462	752470	RingLoc Hip System, Acetabular Bi-Polar Cup, 28 MM X 51 MM
110010462	854070	RingLoc Hip System, Acetabular Bi-Polar Cup, 28 MM X 51 MM
11-165218	094360	RingLoc Bi-Polar Hip System, Acetabular Cup, 28 MM X 47 MM
XL-105916	588500	RingLoc Hip System, Acetabular Liner, 36 MM, Size 26
Knee Products		
141356	561760	Regenerex Series-A Patella 3 Peg, 31 MM
141358	091090	Regenerex Series-A Patella 3 Peg, 37 MM
150414	292720	Orthopedic Salvage System (OSS) Tibial Bearing, 20 MM Standard
154335	666130	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Left, Cemented, D3
154336	570480	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Left, Cemented, D4
154339	589030	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Left, Cemented, D7
154355	602820	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Right, Cemented, B3
154361	570490	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Right, Cemented, C4
154366	447920	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Right, Cemented, D4
154370	328350	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Right, Cemented, E3
154375	560530	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Right, Cemented, F3
154375	827910	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Right, Cemented, F3
154376	570510	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Right, Cemented, F4
154376	786780	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Right, Cemented, F4
154377	602860	Oxford Partial Knee System, Fixed Lateral Tibial Construct, Right, Cemented, F5
155308	570460	AGC Knee System PS Molded Tibial Component, 10 MM X 65 MM
155326	515880	AGC Knee System PS Molded Tibial Component, 10 MM X 70 MM
155326	578470	AGC Knee System PS Molded Tibial Component, 10 MM X 70 MM
155328	447820	AGC Knee System PS Molded Tibial Component, 12 MM X 70 MM
155330	602810	AGC Knee System PS Molded Tibial Component, 14 MM X 70 MM
155344	494090	AGC Knee System PS Molded Tibial Component, 10 MM X 75 MM
155346	505320	AGC Knee System PS Molded Tibial Component, 12 MM X 75 MM
155388	494030	AGC Knee System PS Molded Tibial component, 18 MM X 85 MM
159575	374340	Oxford Partial Knee System Anatomic Meniscal Bearing, Right Medial, Medium, 3 MM
183620	458440	Vanguard Knee System PS Tibial Bearing, 10 MM X 63/67 MM
183622	443160	Vanguard Knee System PS Tibial Bearing, 12 MM X 63/67 MM
183742	294130	Vanguard Knee System, PS+ Tibial Bearing, 12 MM, 71/75 MM
183742	294130R	Vanguard Knee System, PS+ Tibial Bearing, 12 MM, 71/75 MM
183744	175980	Vanguard Knee System, PS+ Tibial Bearing, 14 MM, 71/75 MM
184762	508390	Vanguard Knee System, Series-A Standard Patella, 28 MM
184764	309810	Vanguard Knee System, Series-A Standard Patella, 31 MM
189048	376090	Vanguard Knee System, AS Tibial Bearing, 18 MM X 67 MM
189082	678080	Vanguard Knee System, AS Tibial Bearing, 12 MM X 75 MM
189260	630770	Vanguard Knee System, CR-L Mono Lock Tibial Bearing, 10 MM X 71 MM
189260	646170	Vanguard Knee System, CR-L Mono Lock Tibial Bearing, 10 MM X 71 MM
189320	570570	Vanguard Knee System, CR-L Mono Lock Tibial Bearing, 10 MM X 83 MM
189420	530900	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 63 MM
189420	727060	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 63 MM
189420	772740	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 63 MM
189420	796110	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 63 MM
189420	796120	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 63 MM
189422	548950	Vanguard Knee System, PS Mono Lock Tibial Bearing, 12 MM X 63 MM
189422	602870	Vanguard Knee System, PS Mono Lock Tibial Bearing, 12 MM X 63 MM

Item Number	Lot Number	Item Description
189426	505430	Vanguard Knee System, PS Mono Lock Tibial Bearing, 16 MM X 63 MM
189440	570620	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 67 MM
189440	581950	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 67 MM
189440	608380	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 67 MM
189440	644080	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 67 MM
189440	708620	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 67 MM
189440	884680	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 67 MM
189440	884710	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 67 MM
189442	530930	Vanguard Knee System, PS Mono Lock Tibial Bearing, 12 MM X 67 MM
189442	588890	Vanguard Knee System, PS Mono Lock Tibial Bearing, 12 MM X 67 MM
189442	602930	Vanguard Knee System, PS Mono Lock Tibial Bearing, 12 MM X 67 MM
189442	697510	Vanguard Knee System, PS Mono Lock Tibial Bearing, 12 MM X 67 MM
189442	700830	Vanguard Knee System, PS Mono Lock Tibial Bearing, 12 MM X 67 MM
189460	530940	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189460	758560	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189460	758570	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189460	758580	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189460	796150	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189460	828010	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189460	828040	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189460	830730	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189460	855380	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189460	855390	Vanguard Knee System, PS Mono Lock Tibial Bearing, 10 MM X 71 MM
189700	477430	Vanguard Knee System, CR Mono Lock Tibial Bearing, 10 MM X 79 MM
189704	505490	Vanguard Knee System, CR Mono Lock Tibial Bearing, 14 MM X 79 MM
189720	530980	Vanguard Knee System, CR Mono Lock Tibial Bearing, 10 MM X 83 MM
EP-183420	596810	Vanguard Knee System, CR Tibial Bearing, E1 Infused, 10 MM X 63/67 MM
EP-183608	509970	Vanguard Knee System, PS Tibial Bearing, E1 Infused, 18 MM X 59 MM
EP-183608	509970R	Vanguard Knee System, PS Tibial Bearing, E1 Infused, 18 MM X 59 MM
EP-183608	509990	Vanguard Knee System, PS Tibial Bearing, E1 Infused, 18 MM X 59 MM
EP-183608	509990R	Vanguard Knee System, PS Tibial Bearing, E1 Infused, 18 MM X 59 MM
US154705	630710	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, B6
US154707	570430	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, B7
US154709	570440	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, B8
US154711	455810	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, C4
US154711	463400	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, C4
US154713	690010	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, C5
US154719	560370	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, C8
US154720	630720	Vanguard M Partial Knee System MonoBlock Tibial Tray, Left Medial/Right Lateral, D4
US154721	548690	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, D4
US154722	548700	Vanguard M Partial Knee System MonoBlock Tibial Tray, Left Medial/Right Lateral, D5
US154723	560390	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, D5
US154725	560400	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, D6
US154725	570450	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, D6
US154727	548720	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, D7
US154727	560410	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, D7
US154730	697340	Vanguard M Partial Knee System MonoBlock Tibial Tray, Left Medial/Right Lateral, E4
US154731	697350	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, E4
US154734	630700	Vanguard M Partial Knee System MonoBlock Tibial Tray, Left Medial/Right Lateral, E6
US154735	615650	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, E6
US154745	560420	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, A6
US154745	630740	Vanguard M Partial Knee System MonoBlock Tibial Tray, Right Medial/Left Lateral, A6
US154746	570420	Vanguard M Partial Knee System MonoBlock Tibial Tray, Left Medial/Right Lateral, A7