ZIMMER BIOMET

March 29th, 2017

To: Surgeons

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

Reference: ZFA2016-251

Affected Product: Certain lots of the following implants
Vanguard Rocc, Vanguard Alpina, Alpina APS, Alpina APR, Alpina Uni, Exception stem, Avantage cup

Brand name	Product names
Vanguard ROCC	VANGUARD RP FIN STEM TRAY COCR HA/PC 87MM VANGUARD ROCC POR FEMORAL S62.5 R VANGUARD ROCC TIBIAL TRAY COCR HA/PC SIZE 79MM VANGUARD ROCC POR FEMORAL S60 L
Vanguard Alpina	VANGUARD ALPINA POR FEMORAL S65 L
Alpina APS	ALPINA APS FEMORAL COMPONENT HAP.LEFT T13
Alpina APR	ALPINA APR FEMUR CEMENTLESS S7 RIGHT ALPINA APR FEMUR CEMENTLESS S9 RIGHT ALPINA APR TIBIA CEMENTLESS S.3 ALPINA APR TIBIA CEMENTLESS S.5
Alpina Uni	EMBASE ALP UNI HAP T3 IND/EXG
Exception stem	EXCEPTION STANDARD STEM LEFT SIZE 3 EXCEPTION STANDARD STEM LEFT SIZE 4 EXCEPTION STANDARD STEM LEFT SIZE 5 EXCEPTION STANDARD STEM LEFT SIZE 6 EXCEPTION STANDARD STEM RIGHT SZ 2 EXCEPTION STANDARD STEM RIGHT SZ 3 EXCEPTION STANDARD STEM RIGHT SZ 7 EXCEPTION STANDARD STEM RIGHT SZ 8 EXCEPTION VARISED STEM LEFT SIZE 2 EXCEPTION VARISED STEM LEFT SIZE 3 EXCEPTION VARISED STEM LEFT SIZE 5 EXCEPTION VARISED STEM LEFT SIZE 8 EXCEPTION VARISED STEM RIGHT SZ 4 EXCEPTION VARISED STEM RIGHT SZ 5 EXCEPTION VARISED STEM RIGHT SZ 9
Avantage cup	AVANTAGE ACETABULAR 3P SHELL 46MM AVANTAGE ACETABULAR 3P SHELL 48MM AVANTAGE ACETABULAR 3P SHELL 50MM AVANTAGE ACETABULAR 3P SHELL 50MM

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	AVANTAGE ACETABULAR 3P SHELL 56MM

Dear Sirs or Madams,

This notice is to inform you that Biomet France Sarl is conducting a voluntary medical device Field Safety Corrective Action of certain lots of above listed implants (for affected product references and lot numbers please see attachment 2).

Biomet France Sarl is made aware of a potential contamination of certain implants by a cooling agent during certain manufacturing steps conducted by one of its suppliers.

The potential risks associated with this issue are the following:

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	None	Acute toxic response.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	None	Pain Adverse body reaction Local loosening of the prosthesis. Revision surgery of the prosthesis due to loosening.

An assessment has been undertaken that concludes that no injuries are expected due to the potential contamination of implants. To date no complaints are reported for the listed product reference/lot number combinations which could be linked to the product issue.

As a precautionary measure Biomet France Sarl has decided to recall all potentially affected products. Our records indicate you may have received one or more of these products.

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Surgeon/ Clinic Responsibilities:

1. Review this notification and ensure affected personnel are aware of the content.
2. Assist your Zimmer Biomet sales representative quarantine all affected products available in your inventory.
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 to fr.complaints@zimmerbiomet.com or to your local Zimmer Biomet contact.
    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 contact your Zimmer Biomet sales representative.

Other Information

This voluntary medical Field Safety Corrective Action was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing fr.complaints@zimmerbiomet.com.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies as per MEDDEV 2.12-1 revision 8.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this Field Safety Notice.

Sincerely,

[redacted]

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ATTACHMENT 1
Certificate of Acknowledgement ZFA2016-251

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:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date:**____/____/____

Facility Name: _____

Facility Address: _____

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

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: fr.complaints@zimmerbiomet.com

Product reference	Lot	Number of products received	Number of product returned

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ATTACHMENT 2
Affected Product List

Reference	Device name	Lot
161416	VANGUARD RP FIN STEM TRAY COCR HA/PC 87MM	1081463
P0461046	AVANTAGE ACETABULAR 3P SHELL 46MM	1088633
P0461048	AVANTAGE ACETABULAR 3P SHELL 48MM	1077799
P0461050	AVANTAGE ACETABULAR 3P SHELL 50MM	1088105
P0461050	AVANTAGE ACETABULAR 3P SHELL 50MM	1089126
P0461056	AVANTAGE ACETABULAR 3P SHELL 56MM	1081459
P0461056	AVANTAGE ACETABULAR 3P SHELL 56MM	1088064
P097HG13	ALPINA APS FEMORAL COMPONENT HAP.LEFT T13	1094509
P098HD07	ALPINA APR FEMUR CEMENTLESS S7 RIGHT	1097601
P098HD09	ALPINA APR FEMUR CEMENTLESS S9 RIGHT	1087753
P09VMD04	VANGUARD ROCC POR FEMORAL S62.5 R	1069692
P1018H03	ALPINA APR TIBIA CEMENTLESS S.3	1089129
P1018H05	ALPINA APR TIBIA CEMENTLESS S.5	1076029
P1018H05	ALPINA APR TIBIA CEMENTLESS S.5	1085845
P1053D03	EMBASE ALP UNI HAP T3 IND/EXG	1086575
P1053D03	EMBASE ALP UNI HAP T3 IND/EXG	1086576
P10VH006	VANGUARD ROCC TIBIAL TRAY COCR HA/PC SIZE 79MM	1084202
P09VMG03	VANGUARD ROCC POR FEMORAL S60 L	1086603
P09HAG05	VANGUARD ALPINA POR FEMORAL S65 L	1089015
PS125Y03	EXCEPTION STANDARD STEM LEFT SIZE 3	1089087
PS125Y04	EXCEPTION STANDARD STEM LEFT SIZE 4	1084651
PS125Y05	EXCEPTION STANDARD STEM LEFT SIZE 5	1084749
PS125Y06	EXCEPTION STANDARD STEM LEFT SIZE 6	1084750
PS126Y02	EXCEPTION STANDARD STEM RIGHT SZ 2	1084752
PS126Y03	EXCEPTION STANDARD STEM RIGHT SZ 3	1089090
PS126Y03	EXCEPTION STANDARD STEM RIGHT SZ 3	1086526
PS126Y03	EXCEPTION STANDARD STEM RIGHT SZ 3	1086527
PS126Y03	EXCEPTION STANDARD STEM RIGHT SZ 3	1093532
PS126Y07	EXCEPTION STANDARD STEM RIGHT SZ 7	1085399
PS126Y08	EXCEPTION STANDARD STEM RIGHT SZ 8	1085406
PV125Y02	EXCEPTION VARISED STEM LEFT SIZE 2	1085419

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Reference	Device name	Lot
PV125Y03	EXCEPTION VARISED STEM LEFT SIZE 3	1085408
PV125Y05	EXCEPTION VARISED STEM LEFT SIZE 5	1085411
PV125Y08	EXCEPTION VARISED STEM LEFT SIZE 8	1085420
PV126Y04	EXCEPTION VARISED STEM RIGHT SZ 4	1085401
PV126Y05	EXCEPTION VARISED STEM RIGHT SZ 5	1085402
PV126Y09	EXCEPTION VARISED STEM RIGHT SZ 9	1085417