

September 27, 2022

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Affected Product: G7® Shell and Liner, RingLoc®-X, Avantage® (see the affected scope in Appendix 1)

Biomet France, Biomet Orthopedics and Biomet UK Ltd. are conducting a lot specific medical device Field Safety Corrective Action (removal) for various products. The outer sterile cavity having the potential to be below the minimum wall thickness, and therefore it has been decided to remove the affected lots from the market.

The thin corner wall could potentially crack during transit, leading to the risks identified below. Signs of damage to the corner of the blister would be easily recognizable to the end user prior to its usage. The issue was discovered internally, and there have been no complaints received.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	A non-clinically significant extension of surgery to find another readily available product.	A clinically significant extension of surgery to find another non-readily available product.
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	Infection, leading to surgical intervention

Our records indicate that you may have received one or more of the affected products. The affected units were distributed in August 2022. 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 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. If the product has been further distributed, provide your customers with the Field Safety Notice for hospitals and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.gsc@zimmerbiomet.com.
5. This form shall be returned even if you do not have affected products at your facility.
6. Retain a copy of the **Certificate of Acknowledgement** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
7. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your Zimmer Biomet representative.

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Surgeon Responsibilities:

1. Review this Field Safety Notice 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.gsc@zimmerbiomet.com.
4. Retain a copy of the **Certificate of Acknowledgement** with your Field Safety Corrective 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.

Other Information

This 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 product or any other Zimmer Biomet product by emailing ProductComplaintGSC@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 Field Safety Notice has been delivered to the appropriate Regulatory Agencies.

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

Sincerely,



Francis Moloney, VP QA/RC EMEA



ATTACHMENT 1- Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: G7 Shell and Liner, Ringloc-X, Avantage
Field Safety Corrective Action Reference: ZFA2022-00192

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

Regarding the parts:

A thorough search has been performed for the affected products and the below are available for return.
Please provide a spreadsheet with the return of this form if the below table has not enough space to list all products.

Item Number	Lot Number	Quantity Returned

All products that are not available (for return) have been implanted or used: Yes No Unknown

All products that are not available (for return) will be considered as dispositioned on your location and therefore physical unavailable unless otherwise specified.

By signing below, I acknowledge that I have received, read, and understand the contents of this Field Safety Notice communication. All required activities are complete or are being completed.

Hospital Facility Surgeon *(Please check one as applicable)*

Printed Name: _____ Signature: _____

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

Facility Name: _____

Facility Address: _____

City: _____ Country: _____ 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 fielddaction.gsc@zimmerbiomet.com.

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APPENDIX 1

Item Number	Item Description	Lot Numbers		
010000661*	G7 Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 48 MM C	7248860	7301651	7301755
		7253248	7301652	7301756
		7289868	7301654	7301793
		7296571	7301658	7301798
		7296589	7301660	7304580
		7296607	7301750	7304664
		7301650	7301752	7304706
010000662*	G7 Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 50 MM D	7271065	7301759	7301807
		7271107	7301760	7301813
		7283661	7301763	7304582
		7286375	7301764	7304583
		7296592	7301801	7304667
		7296594	7301804	7304670
		7296595	7301805	7304711
010000663*	G7 Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 52 MM E	7289880	7296641	7301822
		7289908	7301685	7301824
		7289913	7301689	7304585
		7289918	7301690	7304586
		7289928	7301693	7304618
		7296578	7301739	7304645
		7296612	7301740	7304646
		7296616	7301745	7304673
		7296618	7301766	7304677
		7296636	7301771	7304679
		7296638	7301815	7304681
		7296639	7296641	7301822
010000664*	G7 Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 54 MM F	7253314	7301715	7301834
		7286499	7301773	7301841
		7289972	7301778	7301844
		7296656	7301780	7301845
		7296657	7301782	7301847
		7296663	7301783	7301851
		7296665	7301826	7301852
		7296670	7301827	7304588
		7301706	7301829	7304593
		7301707	7301833	7304683
7301711				

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010000665*	G7 Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 56 MM F	7286528	7301749	7304569
		7289888	7301785	7304570
		7290039	7301786	7304595
		7296683	7301789	7304598
		7301722	7301790	7304600
		7301727	7301857	7304603
		7301748	7301859	7304605
010000666*	G7 Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 58 MM G	7290047		
010000667*	G7 Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 60 MM G	7289844		
010000857*	G7 Acetabular Liner, Neutral, E1, 36 MM E	7315366		
010000936*	G7 Acetabular Liner, High Wall, E1, 36 MM F	7315350		
110010242*	G7 OsseoTi Acetabular Shell, 3 Hole, OsseoTi, Cementless, 48 MM C	7282628	7304424	7314444
		7286027	7304432	7314452
		7304407	7304445	7314457
		7304421	7304448	
110010243*	G7 OsseoTi Acetabular Shell, 3 Hole, OsseoTi, Cementless, 50 MM D	7300639	7300678	7304435
		7300652	7300682	7304436
		7300657	7304416	7312857
		7300677	7304429	
110010244*	G7 OsseoTi Acetabular Shell, 3 Hole, OsseoTi, Cementless, 52 MM E	7272285	7300683	7304414
		7300640	7304410	7312873
		7300669	7304411	7314477
		7300679		
110010245*	G7 OsseoTi Acetabular Shell, 4 Hole, OsseoTi, Cementless, 54 MM F	7242338	7300637	7300700
		7300636	7300685	
110010246*	G7 OsseoTi Acetabular Shell, 4 Hole, OsseoTi, Cementless, 56 MM F	7300638	7300643	7300686
110010265*	G7 OsseoTi Acetabular Shell, Multi-Hole, OsseoTi, Cementless, 54 MM F	7267773	7312836	
110010266*	G7 OsseoTi Acetabular Shell, Multi-Hole, OsseoTi, Cementless, 56 MM F	7304442		
110017099*	G7 Finned Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 44 MM A	7196611		
110017101*	G7 Finned Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 48 MM C	7281377		
110017102*	G7 Finned Acetabular Shell, 3 Hole, Porous Plasma, Cementless, 50 MM C	7247850	7281413	7296382
		7262651	7290389	7296390
		7262654		
110017104*	G7 Finned Acetabular Shell, 4 Hole, Porous Plasma, Cementless, 54 MM F	7296372		
110017105*	G7 Finned Acetabular Shell, 4 Hole, Porous Plasma, Cementless, 56 MM F	7258084	7274236	7274245
		7262650		
110017121*	G7 Finned Acetabular Shell, 3 Hole, Porous Plasma/Bone Master, Cementless, 48 MM C	7274262		

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110017222*	G7 Acetabular Liner, +5mm, E1, 36 MM H	7313987	
110017225*	G7 Acetabular Liner, +5mm, E1, 40 MM F	7319399	
EP-044060*	Ringloc-X, E1 Standard Liner, 60 mm D	7313956	
EP-053268*	Ringloc-X, E1 Hi-Wall Liner, 68 mm D	7324198	
P0463046**	Avantage Cemented, Cup A, Size 46X40	0001653419	
P0463048**	Avantage Cemented, Cup A, Size 48X42	0001645272	
P0463052**	Avantage Cemented, Cup A, Size 52X46	0001651022	

* Manufactured by Biomet UK Ltd.

** Manufactured by Biomet France