

19 October 2023

To: Hospitals

Subject: URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Affected Product: Compress® Device Segmental Anchor Plug and Compress® Device Short Anchor Plug (see Attachment 2 – Affected Product List)

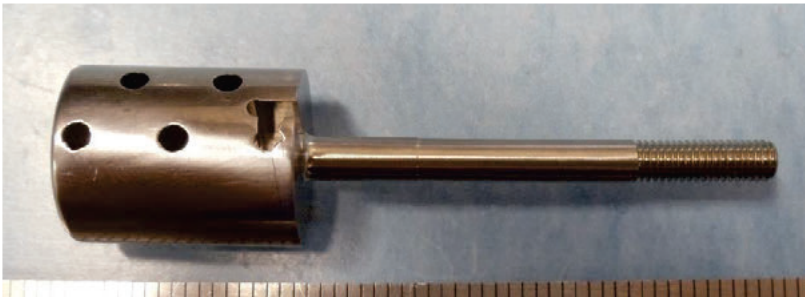


Figure 1: Compress Device Segmental Anchor Plug

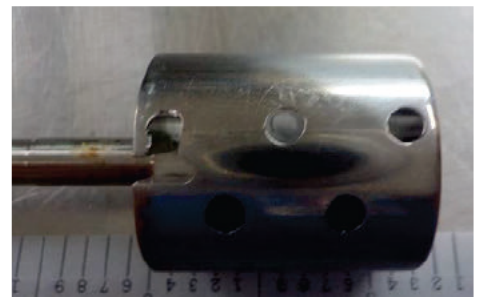


Figure 2: Compress Device Short Anchor Plug

Biomet Orthopedics LLC is conducting a batch/lot specific medical device Field Safety Corrective Action for the Compress Device Segmental Anchor Plug and the Compress Device Short Anchor Plug products listed in **Attachment 2 – Affected Product List**. The impacted anchor plugs potentially have metal burrs in the transverse holes of the device, preventing the drill or pins from passing through. The issue was determined to be caused by a manufacturing process update impacting select batches/lots manufactured prior to 2019. To date, there have been five complaints received for the issue.

The potential interference issue would be recognizable at the point of use. **Any products previously implanted from the affected batch/lot numbers are not impacted by this Field Safety Corrective Action.**

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Clinically insignificant extension of surgery to find another readily available replacement.	Clinically significant extension of surgery to find a non-readily available replacement.
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.	None.

Our records indicate that you may have received one or more of the affected products. The affected products were distributed between February 2017 and September 2023. Local distribution may differ.

Hospital Responsibilities

1. Review this Field Safety Notice and ensure that affected team members are aware of the contents.
2. If you have affected products at your facility, assist your Zimmer Biomet sales representative and quarantine all affected products. 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 this Field Safety Notice and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement Form** and send to fieldaction.gsc@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
5. Retain a copy of the **Attachment 1 – Certificate of Acknowledgement Form** with your records in the event of a compliance audit of your facility.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Other Information

This Field Safety Corrective Action was reported to all relevant Competent Authorities and Notified Bodies as required under the applicable regulations for Medical Devices 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 ProductComplaintGSCC@zimmerbiomet.com.

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,

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ATTACHMENT 1 - Certificate of Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

**Affected Product: Compress® Device Segmental Anchor Plug and Compress® Device Short Anchor Plug
Field Safety Corrective Action Reference Number: ZFA2023-00161**

<p>Do you have affected products in your facility? (Please mark the appropriate response.)</p> <p><input type="checkbox"/> Yes, we currently have one or more affected products in our facility.</p> <p><input type="checkbox"/> No, we currently have no affected products in our facility.</p>

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

Note: Any product not returned or found in your facility is considered dispositioned at your location and unavailable for use.

Complete the table below for all affected products returned. If additional space is needed, please provide a spreadsheet and return it to fieldaction.gsc@zimmerbiomet.com with this form. **Do not return products with other returns.**

Material/Item Number	Batch/Lot Number	Returning Quantity

Certificate of Acknowledgement

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.

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** _____ **Date:** _____

Hospital Name: _____

Hospital Address: _____

City: _____ **Country:** _____ **ZIP/Post Code:** _____

ATTACHMENT 2 - Affected Product List

Material/Item Number	Material/Item Description	Batch/Lot Number	UDI Number
178400	Compress Device Segmental Anchor Plug, 10 MM	541470	(01)00880304259690(17)270629(10)541470
		608490	(01)00880304259690(17)280302(10)608490
		608580	(01)00880304259690(17)271030(10)608580
		609140	(01)00880304259690(17)271112(10)609140
		671410	(01)00880304259690(17)271030(10)671410
		671650	(01)00880304259690(17)271030(10)671650
		856920	(01)00880304259690(17)271030(10)856920
178402	Compress Device Segmental Anchor Plug, 12 MM	240750	(01)00880304259713(17)270112(10)240750
		671330	(01)00880304259713(17)271114(10)671330
		671420	(01)00880304259713(17)270831(10)671420
		671660	(01)00880304259713(17)270901(10)671660
		752730	(01)00880304259713(17)270802(10)752730
		752760	(01)00880304259713(17)270816(10)752760
		798010	(01)00880304259713(17)270120(10)798010
		921660	(01)00880304259713(17)270724(10)921660
		930670	(01)00880304259713(17)270727(10)930670
		930680	(01)00880304259713(17)270802(10)930680
178404	Compress Device Segmental Anchor Plug, 14 MM	017900	(01)00880304002890(17)270912(10)017900
		017900R	(01)00880304002890(17)270912(10)017900R
		240760	(01)00880304002890(17)270120(10)240760
		332020	(01)00880304002890(17)270725(10)332020
		332040	(01)00880304002890(17)270629(10)332040
		608500	(01)00880304002890(17)270830(10)608500
		608590	(01)00880304002890(17)271030(10)608590
		609150	(01)00880304002890(17)270830(10)609150
		671670	(01)00880304002890(17)271030(10)671670
		712220	(01)00880304002890(17)270114(10)712220
		752770	(01)00880304002890(17)270814(10)752770
178406	Compress Device Segmental Anchor Plug, 16 MM	798020	(01)00880304002890(17)270120(10)798020
		965310	(01)00880304002890(17)271112(10)965310
		018050	(01)00880304259744(17)270807(10)018050
		018050R	(01)00880304259744(17)270807(10)018050R
		056160	(01)00880304259744(17)270108(10)056160
		332030	(01)00880304259744(17)270702(10)332030
		332050	(01)00880304259744(17)270710(10)332050
		608510	(01)00880304259744(17)270924(10)608510
		608600	(01)00880304259744(17)271026(10)608600
178408	Compress Device Segmental Anchor Plug, 18 MM	671730	(01)00880304259744(17)270831(10)671730
		752780	(01)00880304259744(17)270817(10)752780
		017910	(01)00880304259768(17)270807(10)017910
		017910R	(01)00880304259768(17)270807(10)017910R
		018060	(01)00880304259768(17)270817(10)018060
		332060	(01)00880304259768(17)270817(10)332060
		608610	(01)00880304259768(17)271204(10)608610
		671740	(01)00880304259768(17)271117(10)671740
		671740R	(01)00880304259768(17)271117(10)671740R
		752790	(01)00880304259768(17)270816(10)752790
178408	Compress Device Segmental Anchor Plug, 18 MM	752790R	(01)00880304259768(17)270816(10)752790R
		965290	(01)00880304259768(17)271030(10)965290

Material/Item Number	Material/Item Description	Batch/Lot Number	UDI Number
178410	Compress Device Segmental Anchor Plug, 20 MM	332070	(01)00880304259782(17)270812(10)332070
		608620	(01)00880304259782(17)271113(10)608620
		671750	(01)00880304259782(17)271115(10)671750
		752800	(01)00880304259782(17)270816(10)752800
		856930	(01)00880304259782(17)271030(10)856930
		856930R	(01)00880304259782(17)271030(10)856930R
		930690	(01)00880304259782(17)270630(10)930690
178412	Compress Device Segmental Anchor Plug, 22 MM	332080	(01)00880304259805(17)270706(10)332080
		671760	(01)00880304259805(17)271026(10)671760
		752810	(01)00880304259805(17)270725(10)752810
		856940	(01)00880304259805(17)271030(10)856940
		930700	(01)00880304259805(17)270816(10)930700
178414	Compress Device Segmental Anchor Plug, 24 MM	017930	(01)00880304259829(17)270702(10)017930
		018070	(01)00880304259829(17)270629(10)018070
		608560	(01)00880304259829(17)271030(10)608560
		752820	(01)00880304259829(17)280222(10)752820
		752830	(01)00880304259829(17)270817(10)752830
178552	Compress Device Short Anchor Plug, 10 MM	331640	(01)00880304461659(17)270726(10)331640
		331660	(01)00880304461659(17)270629(10)331660
		331670	(01)00880304461659(17)270726(10)331670
		477980	(01)00880304461659(17)280112(10)477980
		577330	(01)00880304461659(17)270725(10)577330
		577640	(01)00880304461659(17)270816(10)577640
		608520	(01)00880304461659(17)271030(10)608520
		608530	(01)00880304461659(17)280112(10)608530
		608630	(01)00880304461659(17)271204(10)608630
		671430	(01)00880304461659(17)271204(10)671430
		671810	(01)00880304461659(17)271117(10)671810
		735610	(01)00880304461659(17)271209(10)735610
		735960	(01)00880304461659(17)271202(10)735960
		795170	(01)00880304461659(17)290305(10)795170
		856960	(01)00880304461659(17)271115(10)856960
		930720	(01)00880304461659(17)270703(10)930720
		975150	(01)00880304461659(17)270731(10)975150
982350	(01)00880304461659(17)270723(10)982350		
178554	Compress Device Short Anchor Plug, 12 MM	331680	(01)00880304461703(17)270726(10)331680
		331690	(01)00880304461703(17)270806(10)331690
		331700	(01)00880304461703(17)270726(10)331700
		331700R	(01)00880304461703(17)270726(10)331700R
		541430	(01)00880304461703(17)271119(10)541430
		577340	(01)00880304461703(17)280112(10)577340
		577340R	(01)00880304461703(17)280112(10)577340R
		577660	(01)00880304461703(17)270630(10)577660
		608640	(01)00880304461703(17)271030(10)608640
		671450	(01)00880304461703(17)271030(10)671450
		671820	(01)00880304461703(17)270830(10)671820
		712430	(01)00880304461703(17)271111(10)712430
		735640	(01)00880304461703(17)271031(10)735640
		735660	(01)00880304461703(17)280416(10)735660
		856970	(01)00880304461703(17)280212(10)856970
		930730	(01)00880304461703(17)271030(10)930730

Material/Item Number	Material/Item Description	Batch/Lot Number	UDI Number
178556	Compress Device Short Anchor Plug, 14 MM	331710	(01)00880304461635(17)270702(10)331710
		331720	(01)00880304461635(17)270723(10)331720
		331730	(01)00880304461635(17)270629(10)331730
		331740	(01)00880304461635(17)270726(10)331740
		477990	(01)00880304461635(17)270820(10)477990
		541450	(01)00880304461635(17)270725(10)541450
		577360	(01)00880304461635(17)270801(10)577360
		577690	(01)00880304461635(17)270814(10)577690
		577700	(01)00880304461635(17)270725(10)577700
		608540	(01)00880304461635(17)270902(10)608540
		608650	(01)00880304461635(17)271030(10)608650
		608670	(01)00880304461635(17)271030(10)608670
		671830	(01)00880304461635(17)270901(10)671830
		829350	(01)00880304461635(17)270823(10)829350
178558	Compress Device Short Anchor Plug, 16 MM	331750	(01)00880304461673(17)270726(10)331750
		331760	(01)00880304461673(17)270725(10)331760
		331770	(01)00880304461673(17)270901(10)331770
		577380	(01)00880304461673(17)270725(10)577380
		608690	(01)00880304461673(17)271030(10)608690
		671340	(01)00880304461673(17)271026(10)671340
		671350	(01)00880304461673(17)271127(10)671350
		671460	(01)00880304461673(17)271030(10)671460
		671840	(01)00880304461673(17)271117(10)671840
		735690	(01)00880304461673(17)271030(10)735690
		735720	(01)00880304461673(17)271109(10)735720
		735720R	(01)00880304461673(17)271109(10)735720R
		930750	(01)00880304461673(17)270726(10)930750
		178560	Compress Device Short Anchor Plug, 18 MM
331790	(01)00880304461680(17)270726(10)331790		
331810	(01)00880304461680(17)270703(10)331810		
507020	(01)00880304461680(17)270724(10)507020		
507020R	(01)00880304461680(17)270724(10)507020R		
608550	(01)00880304461680(17)271103(10)608550		
608700	(01)00880304461680(17)271030(10)608700		
671490	(01)00880304461680(17)271117(10)671490		
671850	(01)00880304461680(17)271102(10)671850		
857020	(01)00880304461680(17)271117(10)857020		
178562	Compress Device Short Anchor Plug, 20 MM	331820	(01)00880304461666(17)270710(10)331820
		478000	(01)00880304461666(17)270629(10)478000
		535420	(01)00880304461666(17)270826(10)535420
		608710	(01)00880304461666(17)271114(10)608710
		608740	(01)00880304461666(17)271113(10)608740
		671500	(01)00880304461666(17)271030(10)671500
		671510	(01)00880304461666(17)280121(10)671510
		857040	(01)00880304461666(17)271112(10)857040

Material/Item Number	Material/Item Description	Batch/Lot Number	UDI Number
178564	Compress Device Short Anchor Plug, 22 MM	441020	(01)00880304461628(17)270915(10)441020
		535430	(01)00880304461628(17)270701(10)535430
		577560	(01)00880304461628(17)270725(10)577560
		577740	(01)00880304461628(17)271114(10)577740
		608760	(01)00880304461628(17)271112(10)608760
		671870	(01)00880304461628(17)280131(10)671870
		975160	(01)00880304461628(17)270806(10)975160
178565	Compress Device Short Anchor Plug, 23 MM	930790	(01)00880304528697(17)270709(10)930790
178566	Compress Device Short Anchor Plug, 24 MM	535440	(01)00880304461642(17)270803(10)535440
		577570	(01)00880304461642(17)270726(10)577570
		577590	(01)00880304461642(17)270802(10)577590
		608770	(01)00880304461642(17)280201(10)608770
		671520	(01)00880304461642(17)280131(10)671520
		671530	(01)00880304461642(17)271026(10)671530
		671880	(01)00880304461642(17)271114(10)671880
		671880R	(01)00880304461642(17)271114(10)671880R
		735750	(01)00880304461642(17)271102(10)735750
		735750R	(01)00880304461642(17)271102(10)735750R
		965240	(01)00880304461642(17)280113(10)965240
178568	Compress Device Short Anchor Plug, 26 MM	535450	(01)00880304461611(17)270727(10)535450
		577600	(01)00880304461611(17)270630(10)577600
		577610	(01)00880304461611(17)270702(10)577610
		577760	(01)00880304461611(17)270629(10)577760
		671540	(01)00880304461611(17)271124(10)671540
		671890	(01)00880304461611(17)271114(10)671890
		671890R	(01)00880304461611(17)271114(10)671890R
		857060	(01)00880304461611(17)280324(10)857060
		930770	(01)00880304461611(17)270725(10)930770
178570	Compress Device Short Anchor Plug, 28 MM	535460	(01)00880304461697(17)270811(10)535460
		535460R	(01)00880304461697(17)270811(10)535460R
		671550	(01)00880304461697(17)271124(10)671550