



March 04, 2022

To: Distributors

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

Affected Product: Upper Trauma, Lower Trauma, Foot & Ankle and Sports Medicine

See Attachment 2 – Affected Product List

Biomet Orthopedic LLC is conducting a lot specific medical device Field Safety Corrective Action (removal) for various implants used in Upper Trauma, Lower Trauma, Foot & Ankle and Sports Medicine surgical procedures. Internal testing indicated that the packaging seal may not have sufficient adhesion on all sides of the pouch, which could potentially lead to a compromised sterile barrier and the risks identified below. The issue has been identified internally and so far, Zimmer Biomet did not receive complaints related to the issue.

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	A non-clinically significant extension of surgery to find another part readily available
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 between June 2021 and January 2022.

Your Responsibilities

1. Review this Field Safety Notice and ensure that affected team members are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Immediately return all affected product from your distributorship and from affected hospitals within your territory.
 - a. Complete **Attachment 1 – Inventory Return Certification Form** and send to fieldaction.gscq@zimmerbiomet.com. This form must be returned even if you do not have affected products available to return in your country.
 - b. Include a hardcopy of **Attachment 1** in each carton of your return shipment for immediate processing.
 - c. Mark “RECALL” on the outside of the returned cartons.
4. Retain a copy of your **Inventory Return Certification** and product return forms for your records in the event of a compliance audit of your facility.
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 product or any other Zimmer Biomet product by emailing GSCC.Supplier.Quality@zimmerbiomet.com or 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 and regret any inconveniences caused by this Field Safety Corrective Action.

Sincerely,

xxx



ATTACHMENT 1 - Inventory Return Certification Form
IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: Upper Trauma, Lower Trauma, Foot & Ankle and Sports Medicine
Field Safety Corrective Action Reference: ZFA 2021-00263

Country: _____ **Account Number:** _____

Account Name: _____

Account Address: _____

Please return the affected product to the appropriate address below with a spreadsheet containing item number, lot number, and quantity:

Zimmer GmbH
Biomet Global Supply Chain Center B.V.
Hazeldonk 6530, Dock 20
Breda 4836 LD, Netherlands

This is the final return for the entire territory. An exhaustive search has been performed for the affected products.	Check one of the following:	
	Yes <input type="checkbox"/>	No <input type="checkbox"/>

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

Credit My Account

Send a Replacement

Item Number	Lot Number	UDI Number	Quantity Returned

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to fielddaction.gscc@zimmerbiomet.com with this form.

Certificate of Acknowledgement

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

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** (____) _____ **Ext.:** _____ **Date:** _____

Note: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to fielddaction.gscc@zimmerbiomet.com.

Please do not return affected product with other returns.

ATTACHMENT 2 - Affected Product List

Item Number	Lot Number	Description	UDI Number	
110010371	549910	JuggerLoc Slotted Reamer, 6 MM	(01)00887868465758(17)310603(10)549910	
110010371	061400		(01)00887868465758(17)310630(10)061400	
110010371	061410		(01)00887868465758(17)310723(10)061410	
110010371	089370		(01)00887868465758(17)310726(10)089370	
110010372	886220	JuggerLoc Slotted Reamer, 7 MM	(01)00880304857285(17)310726(10)886220	
110010372	886210		(01)00880304857285(17)310727(10)886210	
110010372	886240		(01)00880304857285(17)310805(10)886240	
110010372	886120		(01)00880304857285(17)310805(10)886120	
110010372	886200		(01)00880304857285(17)310805(10)886200	
110010372	886230		(01)00880304857285(17)310813(10)886230	
110010372	886270		(01)00880304857285(17)310922(10)886270	
110010372	886290		(01)00880304857285(17)310917(10)886290	
110010372	886260		(01)00880304857285(17)310922(10)886260	
110010372	954760		(01)00880304857285(17)310922(10)954760	
110010372	954740		(01)00880304857285(17)310922(10)954740	
110010372	503610		(01)00880304857285(17)310924(10)503610	
110010372	503410		(01)00880304857285(17)311011(10)503410	
110010372	503430		(01)00880304857285(17)311011(10)503430	
110010372	503460		(01)00880304857285(17)311011(10)503460	
110010372	637200		(01)00880304857285(17)311027(10)637200	
110010372	539370		(01)00880304857285(17)311105(10)539370	
110010372	796600		(01)00880304857285(17)311105(10)796600	
110010373	577860		JuggerLoc Slotted Reamer, 8 MM	(01)00880304857292(17)310917(10)577860
110010373	577830			(01)00880304857292(17)310917(10)577830
110010373	577840	(01)00880304857292(17)310922(10)577840		
110018275	260770	JuggerLoc Slotted Reamer, 5 MM	(01)00880304857261(17)310917(10)260770	
110018275	503420		(01)00880304857261(17)310924(10)503420	
110018275	503450		(01)00880304857261(17)310924(10)503450	
110018275	796610		(01)00880304857261(17)311027(10)796610	
131812126	101220	DVR Crosslock Extra Long Plate, Right, 24 MM X 125 MM	(01)00887868446191(17)310623(10)101220	
131812126	101560		(01)00887868446191(17)310624(10)101560	
131812176	101340	DVR Crosslock Extra Extra Long Plate, Right, 24 MM X 174 MM	(01)00887868446207(17)310625(10)101340	
131822126	101450	DVR Crosslock Extra Long Plate, Left, 24 MM X 125 MM	(01)00887868446313(17)310630(10)101450	
131822126	119180		(01)00887868446313(17)310630(10)119180	
131822126	154060		(01)00887868446313(17)310630(10)154060	
212000022	119750	DVR Drill Bit, 2.2 MM	(01)00887868446054(17)310624(10)119750	
212000022	119760		(01)00887868446054(17)310624(10)119760	
212000022	120800		(01)00887868446054(17)310630(10)120800	
212000022	120810		(01)00887868446054(17)310713(10)120810	
212000022	331590		(01)00887868446054(17)310723(10)331590	



Item Number	Lot Number	Description	UDI Number
212000022	331600	DVR Drill Bit, 2.2 MM	(01)00887868446054(17)310726(10)331600
212000022	391450		(01)00887868446054(17)310816(10)391450
212000022	416500		(01)00887868446054(17)310817(10)416500
212000022	416510		(01)00887868446054(17)310817(10)416510
212000022	416520		(01)00887868446054(17)310819(10)416520
212000022	416640		(01)00887868446054(17)310823(10)416640
212000022	331580		(01)00887868446054(17)310803(10)331580
214227160	834950		ALPS Calibrated Drill, 2.7 MM X 160 MM
214227160	896640	(01)00887868446733(17)311101(10)896640	
214227160	896660	(01)00887868446733(17)311027(10)896660	
824150170	534680	ALPS Cortical Tap, 3.5 MM X 140 MM	(01)00887868446948(17)310713(10)534680
824150170	534690		(01)00887868446948(17)310713(10)534690
824150170	836360		(01)00887868446948(17)310119(10)836360
824150170	534700		(01)00887868446948(17)310812(10)534700
824150170	610840		(01)00887868446948(17)310915(10)610840
824273100	386440	ALPS Drill, 4.5 MM X 150 MM	(01)00887868447105(17)310809(10)386440
829029170	820340	ALPS Drill, 2.5 MM X 140 MM	(01)00887868447006(17)310618(10)820340
829029170	084850		(01)00887868447006(17)310621(10)084850
829029170	084870		(01)00887868447006(17)310623(10)084870
829029170	084860		(01)00887868447006(17)310623(10)084860
829029170	084880		(01)00887868447006(17)310624(10)084880
829029170	102920		(01)00887868447006(17)310630(10)102920
829029170	205750		(01)00887868447006(17)310714(10)205750
829029170	204700		(01)00887868447006(17)310714(10)204700
829029170	102930		(01)00887868447006(17)310716(10)102930
829029170	492660		(01)00887868447006(17)310722(10)492660
829029170	102960		(01)00887868447006(17)310728(10)102960
829029170	103120		(01)00887868447006(17)310728(10)103120
829029170	102940		(01)00887868447006(17)310729(10)102940
829029170	102950		(01)00887868447006(17)310729(10)102950
829032170	014490		ALPS Drill, 3.5 MM X 140 MM
829516150	939270	ALPS Bayonet Tip Guide Pin, 1.6 MM X 150 MM	(01)00887868447068(17)310601(10)939270
829516150	964360		(01)00887868447068(17)310603(10)964360
829516150	014500		(01)00887868447068(17)310608(10)014500
829516150	014520		(01)00887868447068(17)310610(10)014520
829516150	391660		(01)00887868447068(17)310811(10)391660
829516150	391470		(01)00887868447068(17)310811(10)391470
829516151	806490		ALPS Threaded Tip Guide Pin, 1.6 MM X 150 MM
829516151	391670	(01)00887868447075(17)310811(10)391670	
856204008	913430	ALPS Fibula Composite Locking Plate, 8 Hole	(01)00887868445897(17)310616(10)913430