

October 25, 2017

To: Risk Managers

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: A.L.P.S. Locking Calcaneus Plate F.A.S.T. Guides

Item Number	Lot Number on the Label	Lot Etched on the Plate	UDI Number
816209003	989430	P0284	0 0887868 044670 989430



Figure 1: Correctly colored magenta F.A.S.T. Guide.



Figure 2: Incorrectly colored F.A.S.T. Guide

Zimmer Biomet is conducting a medical device recall for the A.L.P.S. Locking Calcaneus Plate F.A.S.T. Guides due to being manufactured with the incorrect F.A.S.T. guide color. The guides should be magenta, but are gold instead. **If the device is still in the packaging, lot 989430 will be on the product label, otherwise P0284 will be etched on the part itself.** Use of this product with the incorrect color may cause the drilling size and orientation to the locking plate difficult; however there is no risk of injury occurring as a result of this issue.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between 08/2017 and 09/2017.

Risk Manager Responsibilities:

1. Review this notification 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. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred



to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

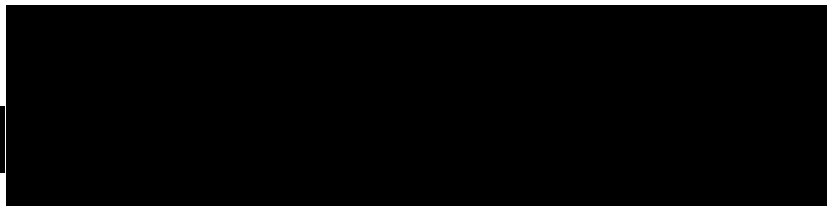
- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing product.experience@zimmerbiomet.com.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,





ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Calcaneal F.A.S.T. Guides **Field Action Reference:** ZFA2017-436

Please check one as applicable:

Hospital Facility

Do you have affected product in your facility?
(Hospital Facility Only: Please mark the appropriate response.)

Yes, we currently have one or more affected items in our facility.

No, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

Printed Name: _____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

City: _____ **State:** _____ **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 CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-372-4265.