May 4, 2023

TAG Medical Products – Betta Link

Dear Valued Customer:

Zimmer Biomet is committed to the quality of our product offerings and patient safety. To serve you and your patients, it is our promise to always support you, including during unexpected events, such as a recall.

While the accompanying product field action is being initiated by our supplier, TAG Medical Products, your relationship is with Zimmer Biomet. We value your business and are committed to providing safe and effective treatment solutions for your patients. It is for that reason we ask for your immediate attention and response to the attached Tag Medical Products request.

To make this as seamless as possible for you, we ask that you follow the directions in the enclosed notice:

- Complete the Customer Response Form and return it to CorporateQuality.PostMarket@zimmerbiomet.com
- Immediately quarantine and return the impacted products to Zimmer Biomet at:

Zimmer Biomet
Product Service Department
ATTN: RECALLS
1777 West Center Street
Warsaw, IN 46580

- You may direct any questions regarding the recall to CorporateQuality.PostMarket@zimmerbiomet.com.

We are working very closely with TAG Medical Products to handle this event in a way that will minimize the impact to you. Thank you for your patience and cooperation in assisting us to properly complete the necessary process for this action.

Sincerely,

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Date: 23-APR-2023

Alert - Field Safety Notice

Reference: 8043971-04/23/23-001-R

Purpose

This Field Safety Notice (FSN) is to inform you about a recall due to potential for device integrity issue during the use of device.

Products affected by the issue

Product Name	Part No.	Lot No.	UDI
BETTA LINK SR KNOTLESS IMPLANT KIT	**110045154**	**See below**	**10818674025765**

Scope includes all quantities from the associated lots:

21R01, 21R02, 21R03, 22C02, 22C03, 22C06, 22C08, 22E01, 22E02, 22F01, 22F02, 22F03, 22J01, 22J02, 22J03, 22K01, 22K02, 22K03, 22K04, 22K05, 22K07, 22K08, 22K09, 22K10, 22K11, 22M01, 22M02, 22M03, 22M04, 22N01, 22P01, 22P02, 22P03, 22P04, 22P05, 22R01

Stock type: Consignment, Subsidiary and direct customer

Product Name	Part No.	Lot No.	UDI
BETTA LINK LG KNOTLESS IMPLANT KIT	**110045160**	**See below**	**10818674025772**

Scope includes all quantities from the associated lots:
21E28, 21R15, 21R16, 21R32, 21R35, 22C19, 22E29, 22F10, 22F35, 22J07, 22J08, 22J09, 22J18, 22J19, 22J27, 22J28, 22J33, 22K23, 22K24, 22K32, 22K33, 22K38, 22M03, 22M04, 22M24, 22P03, 22P09, 22P10, 22P11, 22P13, 22P14, 22P16

Stock type: Consignment, Subsidiary and direct customer

Product Name	Part No.	Lot No.	UDI
BETTA LINK SR REUSABLE PRONGED GUIDE	**110045150**	**See below**	10818674025802

Scope includes all quantities from the associated lots:
22A01, 22C01, 22C02, 22F01

Stock type: Consignment, Subsidiary and direct customer

Product Name	Part No.	Lot No.	UDI
BETTA LINK SR REUSABLE FISHMOUTH GUIDE	**110045151**	**See below**	**10818674025826**

Scope includes all quantities from the associated lots:
22A01, 22C01, 22C02

Stock type: Consignment, Subsidiary and direct customer

Product Name	Part No.	Lot No.	UDI
BETTA LINK LG REUSABLE PRONGED GUIDE	**110045156**	**See below**	**10818674025819**

Scope includes all quantities from the associated lots:
22A01, 22C01, 22F01

Stock type: Consignment, Subsidiary and direct customer

Product Name	Part No.	Lot No.	UDI
BETTA LINK LG REUSABLE FISHMOUTH GUIDE	**110045157**	**See below**	**10818674025833**

Scope includes all quantities from the associated lots:
22A01, 22C01, 22F01

Stock type: Consignment, Subsidiary and direct customer

Description of the issue

It was discovered by the product surveillance department that there is a trend in complaints for the device integrity of the drill guide, which was provided separately and as part of the instruments in the above implant kits.
The drill guides might bend when axial forces are applied by surgeon during procedure and result in potential metal shavings due to friction with the drill bit.
Risk to patients includes potential of injury.

Advise on action to be taken by the addressee of this notice

1. Immediately discontinue use, sale and distribution of the above products.
2. Please contact Zimmer Biomet at CorporateQuality.PostMarket@zimmerbiomet.com for questions and clarifications.
3. Our product surveillance specialists are available to answer questions regarding credit for affected devices in your possession.
4. The attached form must be used and sent back immediately.

Transmission of this Field Safety Notice

Please forward this Field Safety Notice (FSN) to all those who need to be aware of it within your organization or to any organization where the potentially affected devices have been transferred.

The relevant National Competent Authorities have been advised of this voluntary recall.

Contact information

Sincerely,

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MEDICAL PRODUCTS

Customer Response Form

Field safety notice / voluntary recall

Ref: 8043971-04/23/23-001-R

Return to	
At	**Zimmer Biomet** 1800 W Center St Warsaw, IN 46580
Email	CorporateQuality.PostMarket@zimmerbiomet.com
Tel	1-800-253-6190

From	
Name of the permanent establishment	
Address **City**	
Name	
Title	

Please fill out the form as follows and send it by e-mail to the above recipient:

☐ The products in question of the field safety notice are no longer in our stock, we will return the following products (please specify the quantity) to the above recipient:

☐

Article	Lot number	QTY

Place, Date Signature