

URGENT MEDICAL DEVICE RECALL

April 22th, 2016

To: Health Care Professionals

Affected Product: All items listed in below Table 1.

Item	Description	Batches	Item	Description	Batches
REF 4341	Distal Plug 11 mm	0001058739, 0001063177 0001065224, 0001067375 0001070270, 0001074610 0001076399	REF 4343	Distal Plug 15 mm	0001061191, 0001068834 0001070272, 0001083001 0001085318
REF 4342	Distal Plug 13 mm	0001059243, 0001064055 0001067884, 0001070274 0001074642, 0001081272 0001085866	REF 4344	Distal Plug 17 mm	0001067882, 0001074645
			REF 4346	Distal Plug 21 mm	0001066208

Table 1



Dear Valued Customer:

This notification is to inform you that BIOMET France SARL has initiated a voluntary recall for the **Distal Plug*** batches listed above.

Our files indicate that you received at least one of the concerned batches.

This notice is to inform you that we have identified that some Distal Plug batches present a higher level of endotoxins than allowed according to predefined specifications.

Endotoxin is a lipopolysaccharide, with a high molecular weight, used in the composition of the outer cell wall of a Gram negative bacterium. These components are present in nature.

However, if released in sufficient quantities in the human body, the Endotoxin may cause :

- As immediate effects : fever, body aches, changes in the circulatory system, including increasing capillary permeability, or even shock and death. The response of the human body to endotoxin depends on the dose per kilogram body weight, the duration of exposure and the global health of the patient.

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- As long term effect different studies issued that the presence of endotoxins could be linked to osteolysis phenomenon. In this case, a revision surgery could occur.

To date, no incidents related to this matter were reported to Biomet France SARL.

Responsibilities:

1. Discontinue the use of any of the batches identified in this notice.
2. Locate any affected batches and remove them from your inventory as soon as possible. Please place the affected batches in a quarantine area pending return to Zimmer Biomet or to your local Zimmer Biomet distributor.
3. Send this information on to each person in your organization that uses or orders these products. Additionally, please ensure that a copy of this letter is provided to any other organization to which the affected batches may have been transferred.
4. Sign and return the enclosed "Fax-back form", and indicate the number of products that you expect to return. This confirms the fact that you have received, duly read, understand and will fully comply with this notice.

Other Information

This voluntary notification will be reported to the appropriate national health authorities. As the manufacturer, BIOMET France SARL is required to report any serious injury to the appropriate health authority if a product has contributed to or may have contributed to the reported event. Please inform BIOMET France SARL of any incident relating to this product. You may also notify your national Regulatory Authority if you experience any adverse reactions when using these products.

BIOMET France SARL prioritizes quality and patient safety, and we are committed to helping improve lives by developing and delivering high quality, safe and effective products. We apologize for any inconvenience which may have been caused and appreciate your continued business.

We thank you in advance for your attention to this matter.

If you have any questions regarding this communication, please contact your Zimmer Biomet local contact.

Yours sincerely,

Elisabeth Plane
Interim Quality and Regulatory Director
BIOMET France SARL
Plateau de Lautagne – 26000 Valence
France



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ATTACHMENT :

BUSINESS REPLY FORM / PACKING SLIP, Distal Plug

Instructions:

1. Complete the form below and fax to +33 4 75 75 91 01 or email a copy to fr.complaints@zimmerbiomet.com
2. If you have batches to return, contact your local Zimmer Biomet distributor the number below for an RMA number and return shipping label.
3. Return a copy of the Business Reply Form along with any affected product to the below to your local Zimmer Biomet distributor.

Please complete this Business Reply Form within five (5) business days.

Item	(Batch) Lot #	Quantity On-Hand	Quantity Returning

Name _____

Address _____ Phone Number: _____

Signature _____ Date _____

Please complete and fax or email to: **Fax** – +33 4 75 75 91 01 **Email** – fr.complaints@zimmerbiomet.com