

## URGENT MEDICAL DEVICE RECALL

Biomet France SARL  
Plateau de Lautagne –26000 Valence  
Téléphone: (33) 04 75 75 91 00  
Fax: (33)04 75 75 91 01

January \*\*, 2016

To: Dentists and Health Care Professionals

### Affected Product:

Item	Description
ROX05	Endobon®-Xenograft Granules 0.5 ml
ROX10	Endobon®-Xenograft Granules 1 ml
ROX20	Endobon®-Xenograft Granules 2 ml
ROXLG20	Endobon®-Xenograft Granules 2 ml
ROXLG50	Endobon®-Xenograft Granules 5 ml
ROXLG80	Endobon®-Xenograft Granules 8 ml

Table 1

All products listed above with a shelf-life between January 2016 and September 2018 are affected.



Example photo

Dear Valued Customer:

This notification is to inform you that BIOMET France SARL has initiated a voluntary recall for the above listed **Endobon®** products.

As a precautionary measure, BIOMET France SARL has initiated this action based on limited (in vitro/bench) cytotoxicity testing that demonstrated failing results at 36 months (real-time) aging.

## URGENT: DEVICE RECALL NOTICE

### Risks:

- If the clinician places a ROX\* Endobon product which indicates an elapsed shelf-life of 19-36 months, the patient may experience soft tissue irritation, up to and including infection.
- If the Endobon product was placed within 18 months of shelf life, there is no increased risk.

All products listed in Table 1 that have an indicated shelf-life between January 2016 and September 2018 are affected and subject to recall.

### Responsibilities:

1. Please review this notice.
2. Identify, remove from service and segregate all affected **ROX\*** product in your inventory.
3. Complete the attached Business Reply Form (Attachment 1) and:
  - a. Fax it to \*\*\* or email it to Biomet\*\*\*@stericycle.com.
4. If you have product to return, contact BIOMET **3i** at the number on the Business Reply Form for an RMA number and return shipping label
  - a. Return a copy of the Business Reply Form along with any affected product to the address on the Business Reply Form.

Replacement product will immediately ship based upon availability.

Please maintain a copy of this notice and a signed copy of **Attachment 1** for your records to assist in any future regulatory agencies audits of this field action.

### Other Information

This voluntary notification will be reported to the U.S. Food and Drug Administration.

Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep BIOMET informed of any adverse events associated with this device or any other BIOMET product. Adverse events may be reported to BIOMET at [domesticcomplaints@biomet.com](mailto:domesticcomplaints@biomet.com) or [3ipbg-intcomplaint@biomet.com](mailto:3ipbg-intcomplaint@biomet.com).

MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm). Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

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 this may have caused and appreciate your continued business.

For assistance or other questions that you may have relative to this notice, please contact BIOMET **3i** at **1-800-342-5454** or 1-561-776-6700. Team members are available to assist you 8:00am to 6:00pm (Eastern), Monday through Friday.

Yours sincerely,

Christophe Mironneau  
Quality and Regulatory Director  
BIOMET France SARL  
Plateau de Lautagne – 26000 Valence  
France

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## ATTACHMENT 1 BUSINESS REPLY FORM / PACKING SLIP

### Instructions:

1. Complete the form below and fax to \*\*\* or email a copy to Biomet\*\*\*@stericycle.com
2. If you have product to return, contact BIOMET **3i** at 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.

Replacement product will be ordered by BIOMET **3i** customer service upon receipt of returned affected product. The replacement product will immediately ship upon availability.

### **Please Return Affected Product to:**

BIOMET **3i**  
Attention: Post Market Returns  
4555 Riverside Drive  
Palm Beach Gardens, FL 33410  
United States of America  
1-800-342-5454

*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 – \*\*\* Email – Biomet\*\*\*@stericycle.com**