

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

February 1, 2016

To: Dentists and Health Care Professionals

Affected Product:

All items listed in Table 1.

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

Affected Batch #'s:

All batch #'s listed in Attachment 1.



Example photo of Endobon® product

Dear Valued Customer:

This notification is to inform you that BIOMET France SARL has initiated a voluntary recall for the **Endobon® Xenograft Granules** products listed in Attachment 1.

As a precautionary measure, BIOMET France SARL has initiated this action based on limited (in vitro/bench) results which indicated cytotoxicity tests were not passed at 36 months (real-time) aging.

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Risks:

- If the clinician places a ROX* Endobon product which indicates a remaining shelf life of fewer than 18 months, the patient may experience soft tissue irritation, up to and including infection.
- If the Endobon product was placed within 18 months of manufacture (i.e., has at least 18 months shelf life remaining, there is no increased risk.

All products listed in Attachment 1 are subject to recall.

Responsibilities:

1. Please review this notice.
2. Identify, remove from service and segregate all affected **Endobon ROX*** product in your inventory.
3. Complete the attached Business Reply Form (Attachment 2) and:
 - a. Fax it to **+34 93 371 78 49** or email it to Vigilance.EU@zimmerbiomet.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 2** 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 appropriate national health authorities. As the manufacturer, BIOMET **3i** is required to report any serious injury to the appropriate health authority if a product has contributed to or may have contributed to produce the incident. Please inform BIOMET **3i** 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 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 **+353 1 800 552 752**. 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 Affected Item and Batch # List

Item	Batch #	Expiration Date	Item	Batch #	Expiration Date
ROX05	S016303	1/31/2016	ROX20	T0074189	6/30/2016
ROX05	S016304	1/31/2016	ROX20	T0096191	6/30/2016
ROX05	S0163056	1/31/2016	ROX20	T0104217	7/31/2016
ROX05	S0163059	1/31/2016	ROX20	T0134261	8/31/2016
ROX05	S0171051	1/31/2016	ROX20	T0183280	9/30/2016
ROX05	S017105R	1/31/2016	ROX20	T0192311	10/31/2016
ROX05	S0171098	3/31/2016	ROX20	T0205297	9/30/2016
ROX05	T0001122	3/31/2016	ROX20	T0224338	11/30/2016
ROX05	T0001133	4/30/2016	ROX20	T0224346	11/30/2016
ROX05	T0001136	4/30/2016	ROX20	T0234357	11/30/2016
ROX05	T0001141	4/30/2016	ROX20	T0245006	12/31/2016
ROX05	T0001147	4/30/2016	ROX20	T0245009	12/31/2016
ROX05	T0025073	2/29/2016	ROX20	T0254015	12/31/2016
ROX05	T0034084	2/29/2016	ROX20	T0254024	12/31/2016
ROX05	T0045150	4/30/2016	ROX20	T0266030	12/31/2016
ROX05	T0045157	5/31/2016	ROX20	T0273037	1/31/2017
ROX05	T0052108	3/31/2016	ROX20	T0273051	1/31/2017
ROX05	T0064164	5/31/2016	ROX20	T0281043	1/31/2017
ROX05	T0064168	5/31/2016	ROX20	T0281065	2/28/2017
ROX05	T0064175	5/31/2016	ROX20	T0281078	2/28/2017
ROX05	T0096191	6/30/2016	ROX20	T0281093	3/31/2017
ROX05	T0104217	7/31/2016	ROX20	T0291099	3/31/2017
ROX05	T0104238	7/31/2016	ROX20	T0291106	3/31/2017
ROX05	T0114238	7/31/2016	ROX20	T0304125	4/30/2017
ROX05	T0122226	7/31/2016	ROX20	T0304155	5/31/2017
ROX05	T0122238	7/31/2016	ROX20	U0013142	4/30/2017
ROX05	T0134261	8/31/2016	ROX20	U0013170	5/31/2017
ROX05	T0134269	8/31/2016	ROX20	U0055142	4/30/2017
ROX05	T0142245	7/31/2016	ROX20	U0092189	6/30/2017
ROX05	T0142248	8/31/2016	ROX20	U0092202	6/30/2017
ROX05	T0162294	9/30/2016	ROX20	U0092254	8/31/2017
ROX05	T0183280	9/30/2016	ROX20	U0114279	9/30/2017
ROX05	T0192311	10/31/2016	ROX20	U0124265	8/31/2017
ROX05	T0192316	10/30/2016	ROX20	U0132307	9/30/2017
ROX05	T0205297	9/30/2016	ROX20	U0141251	8/31/2017
ROX05	T0214319	10/31/2016	ROX20	U0153300	9/30/2017
ROX05	T0224329	10/31/2016	ROX20	U0181316	10/31/2017
ROX05	T0224333	10/31/2016	ROX20	U0193328	10/31/2017
ROX05	T0224338	11/30/2016	ROX20	U0201349	11/30/2017
ROX05	T0224346	11/30/2016	ROX20	U0234061	2/28/2018

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Item	Batch #	Expiration Date	Item	Batch #	Expiration Date
ROX05	T0224357	11/30/2016	ROX20	U0253082	2/28/2018
ROX05	T0234357	11/30/2016	ROX20	U0261106	3/31/2018
ROX05	T0245006	12/31/2016	ROX20	U0261138	4/30/2018
ROX05	T0245009	12/31/2016	ROX20	V0021148	4/30/2018
ROX05	T0254015	12/31/2016	ROX20	V0034187	6/30/2018
ROX05	T0266030	12/31/2016	ROX20	V0034194	6/30/2018
ROX05	T0273037	1/31/2017	ROX20	V0044208	6/30/2018
ROX05	T0273051	1/31/2017	ROX20	V0051239	7/31/2018
ROX05	T0281043	1/31/2017	ROX20	V0051278	9/30/2018
ROX05	T0281065	2/28/2017	ROX20	V0063288	9/30/2018
ROX05	T0281078	2/28/2017	ROXLG20	T0002136	4/30/2016
ROX05	T0291099	3/31/2017	ROXLG20	T0002141	4/30/2016
ROX05	T0291106	3/31/2017	ROXLG20	T0002150	4/30/2016
ROX05	T0291118	3/31/2017	ROXLG20	T0002157	5/31/2016
ROX05	T0291125	4/30/2017	ROXLG20	T0002164	5/31/2016
ROX05	T0291134	4/30/2017	ROXLG20	T0035065	2/29/2016
ROX05	U0013175	5/31/2017	ROXLG20	T0035073	2/29/2016
ROX05	U0025142	4/30/2017	ROXLG20	T0035084	2/29/2016
ROX05	U0025170	5/31/2017	ROXLG20	T0035098	3/31/2016
ROX05	U0035175	5/31/2017	ROXLG20	T0065191	6/30/2016
ROX05	U0055155	5/31/2017	ROXLG20	T0085238	7/31/2016
ROX05	U0055170	5/31/2017	ROXLG20	T0135294	9/30/2016
ROX05	U0084189	6/30/2017	ROXLG20	T0143259	8/31/2016
ROX05	U0084209	6/30/2017	ROXLG20	T0143308	10/31/2016
ROX05	U0092202	6/30/2017	ROXLG20	T0143319	10/31/2016
ROX05	U0092237	7/31/2017	ROXLG20	T0215006	12/31/2016
ROX05	U0102265	8/31/2017	ROXLG20	T0215015	12/31/2016
ROX05	U0114279	9/30/2017	ROXLG20	T0235357	11/30/2016
ROX05	U0124272	8/31/2017	ROXLG20	T0274024	12/31/2016
ROX05	U0132289	9/30/2017	ROXLG20	T0282051	1/31/2017
ROX05	U0132307	9/30/2017	ROXLG20	T0292062	2/28/2017
ROX05	U0132316	10/31/2017	ROXLG20	T0305093	3/31/2017
ROX05	U0141251	8/31/2017	ROXLG20	U0014099	3/31/2017
ROX05	U0141254	8/31/2017	ROXLG20	U0014125	4/30/2017
ROX05	U0141265	8/31/2017	ROXLG20	U0024106	3/31/2017
ROX05	U0153300	9/30/2017	ROXLG20	U0034142	4/30/2017
ROX05	U0171316	10/31/2017	ROXLG20	U0044134	4/30/2017
ROX05	U0181349	11/30/2017	ROXLG20	U0044155	5/31/2017
ROX05	U0193328	10/31/2017	ROXLG20	U0103202	6/30/2017
ROX05	U0193349	11/30/2017	ROXLG20	U0125260	8/31/2017
ROX05	U0201005	12/31/2017	ROXLG20	U0125265	8/31/2017
ROX05	U0201019	12/31/2017	ROXLG20	U0142209	6/30/2017
ROX05	U0201337	11/30/2017	ROXLG20	U0194330	10/31/2017
ROX05	U0201349	11/30/2017	ROXLG20	U0262075	2/28/2018
ROX05	U0213019	12/31/2017	ROXLG20	V0035097	3/31/2018
ROX05	U0213040	1/31/2018	ROXLG20	V0045120	3/31/2018

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Item	Batch #	Expiration Date	Item	Batch #	Expiration Date
ROX05	U0242047	1/31/2018	ROXLG20	V0052106	3/31/2018
ROX05	U0253061	2/3/2018	ROXLG20	V0064138	4/30/2018
ROX05	U0253068	2/28/2018	ROXLG20	V0073176	5/31/2018
ROX05	U0253075	2/28/2018	ROXLG20	V0091159	5/31/2018
ROX05	U0253082	2/28/2018	ROXLG20	V0104194	6/30/2018
ROX05	U0253089	2/28/2018	ROXLG20	V0112168	5/31/2018
ROX05	U0253138	4/30/2018	ROXLG20	V0123201	6/30/2018
ROX05	U0261131	4/30/2018	ROXLG20	V0134208	6/30/2018
ROX05	U0261148	4/30/2018	ROXLG20	V0203299	9/30/2018
ROX05	U0261159	5/31/2018	ROXLG50	S017204	1/31/2016
ROX05	V0021138	4/30/2018	ROXLG50	T0026056	1/31/2016
ROX05	V0021176	5/31/2018	ROXLG50	T0044179	5/31/2016
ROX05	V0034194	6/30/2018	ROXLG50	T0044189	6/30/2016
ROX05	V0044201	6/30/2018	ROXLG50	T0044259	8/31/2016
ROX05	V0044208	6/30/2018	ROXLG50	T0044287	9/30/2016
ROX05	V0044239	7/31/2018	ROXLG50	T0053133	4/30/2016
ROX05	V0051267	8/31/2018	ROXLG50	T0065238	7/31/2016
ROX05	V0051273	8/31/2018	ROXLG50	T0075191	6/30/2016
ROX05	V0051278	9/30/2018	ROXLG50	T0075287	9/30/2016
ROX05	V0063299	9/30/2018	ROXLG50	T0143311	10/31/2016
ROX05	V0082187	6/30/2018	ROXLG50	T0193333	11/30/2016
ROX10	S0171056	1/31/2016	ROXLG50	T0193357	11/30/2016
ROX10	S0171065	2/29/2016	ROXLG50	T0206338	11/30/2016
ROX10	S0171108	3/31/2016	ROXLG50	T0215037	1/31/2017
ROX10	T0001119	3/31/2016	ROXLG50	T0235346	11/30/2016
ROX10	T0001122	3/31/2016	ROXLG50	T0274024	12/31/2016
ROX10	T0001133	4/30/2016	ROXLG50	T0282034	12/31/2016
ROX10	T0001141	4/30/2016	ROXLG50	T0282043	1/31/2017
ROX10	T0001147	4/30/2016	ROXLG50	T0282051	1/31/2017
ROX10	T0025073	2/29/2016	ROXLG50	U0014125	4/30/2017
ROX10	T0025098	3/31/2016	ROXLG50	U0014134	4/30/2017
ROX10	T0034084	2/29/2016	ROXLG50	U0034155	5/31/2017
ROX10	T0045150	4/30/2016	ROXLG50	U0044142	4/30/2017
ROX10	T0045157	5/31/2016	ROXLG50	U0044155	5/31/2017
ROX10	T0052108	3/31/2016	ROXLG50	U0091189	6/30/2017
ROX10	T0064168	5/31/2016	ROXLG50	U0115260	8/31/2017
ROX10	T0074175	5/31/2016	ROXLG50	U0142209	6/30/2017
ROX10	T0074179	5/31/2016	ROXLG50	U0172286	9/30/2017
ROX10	T0084189	6/30/2016	ROXLG50	U0182307	9/30/2017
ROX10	T0096191	6/30/2016	ROXLG50	U0224005	12/31/2017
ROX10	T0104217	7/31/2016	ROXLG50	U0262075	2/28/2018
ROX10	T0114238	7/31/2016	ROXLG50	V0045120	3/31/2018
ROX10	T0134261	8/31/2016	ROXLG50	V0052106	3/31/2018
ROX10	T0142248	8/31/2016	ROXLG50	V0052131	4/30/2018
ROX10	T0142254	8/31/2016	ROXLG50	V0064141	4/30/2018
ROX10	T0162294	9/30/2016	ROXLG50	V0091159	5/31/2018

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Item	Batch #	Expiration Date	Item	Batch #	Expiration Date
ROX10	T0183280	9/30/2016	ROXLG50	V0104194	6/30/2018
ROX10	T0192311	10/31/2016	ROXLG50	V0112194	6/30/2018
ROX10	T0192316	10/30/2016	ROXLG50	V0161208	6/30/2018
ROX10	T0205297	9/30/2016	ROXLG80	S017204	1/31/2016
ROX10	T0214319	10/31/2016	ROXLG80	T0002150	4/30/2016
ROX10	T0234357	11/30/2016	ROXLG80	T0002157	5/31/2016
ROX10	T0245006	12/31/2016	ROXLG80	T0002164	5/31/2016
ROX10	T0245020	12/31/2016	ROXLG80	T0026056	1/31/2016
ROX10	T0254015	12/31/2016	ROXLG80	T0044175	5/31/2016
ROX10	T0254051	1/31/2017	ROXLG80	T0053108	3/31/2016
ROX10	T0266030	12/31/2016	ROXLG80	T0053122	4/30/2016
ROX10	T0273037	1/31/2017	ROXLG80	T0065238	7/31/2016
ROX10	T0281043	1/31/2017	ROXLG80	T0097191	6/30/2016
ROX10	T0281062	2/28/2017	ROXLG80	T0097238	7/31/2016
ROX10	T0281065	2/28/2017	ROXLG80	T0115238	7/31/2016
ROX10	T0281071	2/28/2017	ROXLG80	T0125261	8/31/2016
ROX10	T0291078	2/28/2017	ROXLG80	T0135269	8/31/2016
ROX10	T0291125	4/30/2017	ROXLG80	T0135294	9/30/2016
ROX10	T0291170	5/31/2017	ROXLG80	T0163316	10/31/2016
ROX10	T0304134	4/30/2017	ROXLG80	T0193333	11/30/2016
ROX10	T0304170	5/31/2017	ROXLG80	T0206338	11/30/2016
ROX10	TOOO1136	4/30/2016	ROXLG80	T0215006	12/31/2016
ROX10	U0035142	4/30/2017	ROXLG80	T0215346	11/30/2016
ROX10	U0035155	5/31/2017	ROXLG80	T0255006	12/31/2016
ROX10	U0035237	7/31/2017	ROXLG80	T0264020	12/31/2016
ROX10	U0073170	5/31/2017	ROXLG80	T0274024	12/31/2016
ROX10	U0084189	6/30/2017	ROXLG80	T0282034	12/31/2016
ROX10	U0092202	6/30/2017	ROXLG80	T0292043	1/31/2017
ROX10	U0102251	8/31/2017	ROXLG80	T0292065	2/28/2017
ROX10	U0114279	9/30/2017	ROXLG80	T0292085	2/28/2017
ROX10	U0114286	9/30/2017	ROXLG80	T0305071	2/28/2017
ROX10	U0114307	9/30/2017	ROXLG80	T0305078	2/28/2017
ROX10	U0124265	8/31/2017	ROXLG80	T0305093	3/31/2017
ROX10	U0124272	8/31/2017	ROXLG80	U0024106	3/31/2017
ROX10	U0141254	8/31/2017	ROXLG80	U0034125	4/30/2017
ROX10	U0153300	9/30/2017	ROXLG80	U0054142	4/30/2017
ROX10	U0171316	10/31/2017	ROXLG80	U0054155	5/31/2017
ROX10	U0193328	10/31/2017	ROXLG80	U0074170	5/31/2017
ROX10	U0201005	12/31/2017	ROXLG80	U0085189	6/30/2017
ROX10	U0201337	11/30/2017	ROXLG80	U0091189	6/30/2017
ROX10	U0201349	11/30/2017	ROXLG80	U0115260	8/31/2017
ROX10	U0213026	12/22/2017	ROXLG80	U0142209	6/30/2017
ROX10	U0223026	12/31/2017	ROXLG80	U0154286	9/30/2017
ROX10	U0234054	1/31/2018	ROXLG80	U0172289	9/30/2017
ROX10	U0234061	2/28/2018	ROXLG80	U0182307	9/30/2017
ROX10	U0242040	1/31/2018	ROXLG80	U0202337	11/30/2017

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Item	Batch #	Expiration Date	Item	Batch #	Expiration Date
ROX10	U0253082	2/28/2018	ROXLG80	U0202349	11/30/2017
ROX10	U0253089	2/28/2018	ROXLG80	U0214342	11/30/2017
ROX10	U0261124	3/31/2018	ROXLG80	U0214349	11/30/2017
ROX10	U0261187	6/30/2018	ROXLG80	U0224026	12/22/2017
ROX10	V0021138	4/30/2018	ROXLG80	U0233047	1/31/2018
ROX10	V0021148	4/30/2018	ROXLG80	U0243040	1/31/2018
ROX10	V0021168	5/31/2018	ROXLG80	U0254061	2/28/2018
ROX10	V0021176	5/31/2018	ROXLG80	U0262075	2/28/2018
ROX10	V0044194	6/30/2018	ROXLG80	V0022082	2/28/2018
ROX10	V0044208	6/30/2018	ROXLG80	V0035097	3/31/2018
ROX10	V0044230	7/31/2018	ROXLG80	V0045120	3/31/2018
ROX10	V0044239	7/31/2018	ROXLG80	V0052117	3/31/2018
ROX10	V0051260	8/31/2018	ROXLG80	V0073176	5/31/2018
ROX10	V0051267	8/31/2018	ROXLG80	V0083141	4/30/2018
ROX10	V0063299	9/30/2018	ROXLG80	V0091159	5/31/2018
ROX10	V0082187	6/30/2018	ROXLG80	V0112194	6/30/2018
ROX20	T0001119	3/31/2016	ROXLG80	V0123201	6/30/2018
ROX20	T0001133	4/30/2016	ROXLG80	V0134208	6/30/2018
ROX20	T0001150	4/30/2016	ROXLG80	V0143230	7/31/2018
ROX20	T0025098	3/31/2016	ROXLG80	V0154273	8/31/2018
ROX20	T0052108	3/31/2016	ROXLG80	V0161208	6/30/2018
ROX20	T0064164	5/31/2016	ROXLG80	V0172239	7/31/2018
ROX20	T0074157	5/31/2016	ROXLG80	V0182272	8/31/2018
ROX20	T0074175	5/31/2016	ROXLG80	V0194278	9/30/2018

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ATTACHMENT 2 BUSINESS REPLY FORM / PACKING SLIP, Endobon® Xenograft

Instructions:

1. Complete the form below and fax to **+34 93 371 78 49** or email a copy to Vigilance.EU@zimmerbiomet.com
2. If you have product to return, contact BIOMET **3i** at **+353 1 800 552 752** 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 UK Ltd.
1 Bell Street
SL6 1BU Maidenhead, Berkshire

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 – +34 93 371 78 49 Email – Vigilance.EU@zimmerbiomet.com**