

September XX, 2016

To: Dentists and Health Care Professionals

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: Low Profile products listed in Attachment 2 – Affected Product List



Bags are unsealed



BIOMET **3i** is conducting a medical device recall for the Low Profile products listed in Attachment 2. Through investigation, it was determined that a limited number of product pouches may not have been sealed during packaging. In the event that a sterile product pouch is unsealed, the sterility of the product contained within the pouch cannot be assured. Also, the component(s) may be missing from the pouch if the seal is missing.

Note: The recall notice dated December 3, 2015 for a similar issue involved a different product scope. This notice identifies a new recall for the products defined in Attachment 2 – Affected Product List.

<i>Risks</i>		
<i>Immediate / Long-range</i>	<i>Most Probable</i>	<i>Worst Case</i>
<i>Immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.</i>	The most probable health consequences range from none to delay in treatment.	The worst case health consequences range from none to delay in treatment.
<i>Long-range health consequences (injuries or illness) that may result from use of or exposure to the product issue.</i>	None	Injuries reversible with medical/surgical intervention (to preclude permanent impairment / damage of a body function or to a body structure) For example, soft tissue irritation, inflammation, localized infection.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between the dates of November 2015 and August 2016.

Dentists and Health Care Professional's Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow up schedule.
3. Follow the instructions indicated in Attachment 1 – Inventory Return Certification Form
4. If after reviewing this notice you have further questions or concerns please call the customer call center at **(CS number for country)** during normal business hours, Monday through Friday. Alternatively, your questions may be sent by email to Vigilance.EU@zimmerbiomet.com.

Other Information

This voluntary 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.

- 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 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 BIOMET **3i** informed of any adverse events associated with this product or any other BIOMET **3i** product by emailing 3iEUComplaints@zimmerbiomet.com.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies. Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local health authority in your country.

We would like to thank you for your co-operation in advance and regret any inconveniences caused by this recall.

Sincerely,

[Redacted signature block]

ATTACHMENT 1 - Inventory Return Certification Form

Instructions:

1. ☐ **I have no product to return.** Fill in the customer details section, and e-mail a **signed copy** of this form to Vigilance.EU@zimmerbiomet.com or fax it to **+34 93 193 42 79**, to acknowledge receipt of this letter.
2. ☐ **I do have product to return.** Complete the full form below and email a copy to Vigilance.EU@zimmerbiomet.com or fax it to **+34 93 193 42 79**. Customer Service will send you an e-mail or fax with the **RMA number** within a few days and will organize the product return on our expense.
3. Please also ensure that the shipping container lists the **RMA number** for quick processing.

Product return information:

Item #	Lot #	Quantity On-Hand	Quantity Returning

Replacement product will be sent within a few days with an invoice. A credit note will be issued once we receive the returned product.



Customer Details:

Customer Name (doctor/clinic/lab):

Customer Number (if available):

Contact Name:

Telephone Number:

Billing Address:

Name:

Address (Street, Number):

Postal Code:

City:

Shipping Address (only needed in case it differs from the Billing address)

Name:

Address (Street, Number):

Postal Code:

City:

Please indicate below the pick-up address, if it differs from the Shipping Address:

Name:

Address (Street, Number):

Postal Code:

City:



Within a few days, Customer Service will send you an RMA number. Please indicate your e-mail address or fax number below:

E-mail address:

Fax number:

Please indicate your preferred date for product pick-up, within the next 7 days:.....

The product will be picked-up by our courier agency. Please include the RMA document within the product return package.

Signature:

ATTACHMENT 2 - Affected Product List

Item Number	Lot Number	UDI Number	Item Description
ILPAC3217	2015111777	(01)00844868037514(17)201101(10)2015111777	CERTAIN® LOW PROFILE 17° ABUTMENT 3.4MM(D) X 2MM(H)
ILPAC3417	2015111355	(01)00844868037545(17)201101(10)2015111355	CERTAIN® LOW PROFILE 17° ABUTMENT 3.4MM(D) X 4MM(H)
ILPAC3530	2016030311	(01)00844868037606(17)210301(10)2016030311	CERTAIN® LOW PROFILE 30° ABUTMENT 3.4MM(D) X 5MM(H)
ILPAC4217	2015112156	(01)00844868037552(17)201201(10)2015112156	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
ILPAC4217	2015112157	(01)00844868037552(17)201101(10)2015112157	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
ILPAC4217	2015112158	(01)00844868037552(17)201201(10)2015112158	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
ILPAC4217	2015112159	(01)00844868037552(17)201101(10)2015112159	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
ILPAC4217	2015120466	(01)00844868037552(17)201201(10)2015120466	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
ILPAC4217	2016010159	(01)00844868037552(17)210101(10)2016010159	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
ILPAC4217	2016031210	(01)00844868037552(17)210301(10)2016031210	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
ILPAC4217	2016040438	(01)00844868037552(17)210401(10)2016040438	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
ILPAC4217	2016061525	(01)00844868037552(17)210601(10)2016061525	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
ILPAC4330	2015111372	(01)00844868037613(17)201101(10)2015111372	CERTAIN® LOW PROFILE 30° ABUTMENT 4.1MM(D) X 3MM(H)
ILPAC4330	2016011713	(01)00844868037613(17)210201(10)2016011713	CERTAIN® LOW PROFILE 30° ABUTMENT 4.1MM(D) X 3MM(H)
ILPAC4330	2016020101	(01)00844868037613(17)210201(10)2016020101	CERTAIN® LOW PROFILE 30° ABUTMENT 4.1MM(D) X 3MM(H)
ILPAC4417	2016011141	(01)00844868037569(17)210101(10)2016011141	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 4MM(H)
ILPAC4417	2016030088	(01)00844868037569(17)210301(10)2016030088	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 4MM(H)
ILPAC4417	2016031214	(01)00844868037569(17)210301(10)2016031214	CERTAIN® LOW PROFILE 17° ABUTMENT 4.1MM(D) X 4MM(H)
ILPAC4530	2015111373	(01)00844868037620(17)201101(10)2015111373	CERTAIN® LOW PROFILE 30° ABUTMENT 4.1MM(D) X 5MM(H)
ILPAC4530	2015111778	(01)00844868037620(17)201101(10)2015111778	CERTAIN® LOW PROFILE 30° ABUTMENT 4.1MM(D) X 5MM(H)
ILPAC4530	2015120887	(01)00844868037620(17)201201(10)2015120887	CERTAIN® LOW PROFILE 30° ABUTMENT 4.1MM(D) X 5MM(H)
ILPAC4530	2016021477	(01)00844868037620(17)210201(10)2016021477	CERTAIN® LOW PROFILE 30° ABUTMENT 4.1MM(D) X 5MM(H)
ILPC342	2015121064	(01)00844868021179(17)210101(10)2015121064	CERTAIN® LOW PROFILE ABUTMENT 3.4MM(D) X 2MM(H)
ILPC342	2016030816	(01)00844868021179(17)210401(10)2016030816	CERTAIN® LOW PROFILE ABUTMENT 3.4MM(D) X 2MM(H)
ILPC342U	2016020057	(01)00844868021100(17)210201(10)2016020057	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 3.4MM(D) X 2MM(H)
ILPC344U	2016011182	(01)00844868021087(17)210201(10)2016011182	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 3.4MM(D) X 4MM(H)
ILPC344U	2016041553	(01)00844868021087(17)210501(10)2016041553	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 3.4MM(D) X 4MM(H)

Item Number	Lot Number	UDI Number	Item Description
ILPC441	2016021500	(01)00844868021209(17)210301(10)2016021500	CERTAIN® LOW PROFILE ABUTMENT 4.1MM(D) X 1MM(H)
ILPC441U	2015112073	(01)00844868021070(17)201201(10)2015112073	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 1MM(H)
ILPC441U	2016040049	(01)00844868021070(17)210401(10)2016040049	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 1MM(H)
ILPC441U	2016040914	(01)00844868021070(17)210501(10)2016040914	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 1MM(H)
ILPC441U	2016042048	(01)00844868021070(17)210501(10)2016042048	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 1MM(H)
ILPC442	2016030811	(01)00844868021216(17)210401(10)2016030811	CERTAIN® LOW PROFILE ABUTMENT 4.1MM(D) X 2MM(H)
ILPC442U	2015111460	(01)00844868021063(17)201201(10)2015111460	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 2MM(H)
ILPC442U	2015121066	(01)00844868021063(17)210101(10)2015121066	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 2MM(H)
ILPC442U	2016042047	(01)00844868021063(17)210501(10)2016042047	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 2MM(H)
ILPC443U	2015120624	(01)00844868021056(17)210101(10)2015120624	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 3MM(H)
ILPC444U	2016020511	(01)00844868021049(17)210201(10)2016020511	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 4MM(H)
ILPC444U	2016040048	(01)00844868021049(17)210401(10)2016040048	CERTAIN® LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 4MM(H)
LPAC3330	2015120640	(01)00844868036234(17)210201(10)2015120640	LOW PROFILE 30° ABUTMENT 3.4MM(D) X 3MM(H)
LPAC3530	2015110514	(01)00844868036210(17)210101(10)2015110514	LOW PROFILE 30° ABUTMENT 3.4MM(D) X 5MM(H)
LPAC4217	2015110506	(01)00844868036203(17)201201(10)2015110506	LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
LPAC4217	2016030834	(01)00844868036203(17)210501(10)2016030834	LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
LPAC4217	2016042066	(01)00844868036203(17)210601(10)2016042066	LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
LPAC4217	2016042068	(01)00844868036203(17)210601(10)2016042068	LOW PROFILE 17° ABUTMENT 4.1MM(D) X 2MM(H)
LPAC4330	2016010803	(01)00844868036197(17)210201(10)2016010803	LOW PROFILE 30° ABUTMENT 4.1MM(D) X 3MM(H)
LPAC4330	2016030830	(01)00844868036197(17)210401(10)2016030830	LOW PROFILE 30° ABUTMENT 4.1MM(D) X 3MM(H)
LPAC4417	2015110513	(01)00844868036180(17)210101(10)2015110513	LOW PROFILE 17° ABUTMENT 4.1MM(D) X 4MM(H)
LPAC4417	2016010805	(01)00844868036180(17)210301(10)2016010805	LOW PROFILE 17° ABUTMENT 4.1MM(D) X 4MM(H)
LPAC4417	2016050344	(01)00844868036180(17)210601(10)2016050344	LOW PROFILE 17° ABUTMENT 4.1MM(D) X 4MM(H)
LPC441	2015110365	(01)00844868021322(17)201101(10)2015110365	LOW PROFILE ABUTMENT 4.1MM(D) X 1MM(H)
LPC441U	2015120620	(01)00844868020950(17)201201(10)2015120620	LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 1MM(H)
LPC442U	2015101819	(01)00844868020943(17)201101(10)2015101819	LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 2MM(H)
LPC443	2016011726	(01)00844868021346(17)210301(10)2016011726	LOW PROFILE ABUTMENT 4.1MM(D) X 3MM(H)
LPC443U	2015120622	(01)00844868020936(17)201201(10)2015120622	LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 3MM(H)
LPC444U	2016030294	(01)00844868020929(17)210301(10)2016030294	LOW PROFILE ONE-PIECE ABUTMENT 4.1MM(D) X 4MM(H)

Item Number	Lot Number	UDI Number	Item Description
LPCHC	2016030791	(01)00844868036364(17)210301(10)2016030791	LOW PROFILE ABUTMENT HEALING CAP
LPCHC	2016030792	(01)00844868036364(17)210401(10)2016030792	LOW PROFILE ABUTMENT HEALING CAP
LPCHC	2016030793	(01)00844868036364(17)210301(10)2016030793	LOW PROFILE ABUTMENT HEALING CAP
LPCPIC1	2015110454	(01)00844868025160(17)201201(10)2015110454	LOW PROFILE ABUTMENT (HEXED) PICK-UP IMPRESSION COPING
LPCPIC2	2015112084	(01)00844868036388(17)201201(10)2015112084	LOW PROFILE ABUTMENT (NON-HEXED) PICK-UP IMPRESSION COPING
LPCPIC2	2016031299	(01)00844868036388(17)210401(10)2016031299	LOW PROFILE ABUTMENT (NON-HEXED) PICK-UP IMPRESSION COPING
LPCPIC2	2016041629	(01)00844868036388(17)210501(10)2016041629	LOW PROFILE ABUTMENT (NON-HEXED) PICK-UP IMPRESSION COPING
LPCPIC2	2016042021	(01)00844868036388(17)210501(10)2016042021	LOW PROFILE ABUTMENT (NON-HEXED) PICK-UP IMPRESSION COPING
LPCPTC2	2016011174	(01)00844868021414(17)210201(10)2016011174	LOW PROFILE ABUTMENT NON-HEXED PREFORMANCE® TEMPORARY CYLINDER
LPCPTC2	2016011175	(01)00844868021414(17)210201(10)2016011175	LOW PROFILE ABUTMENT NON-HEXED PREFORMANCE® TEMPORARY CYLINDER
LPCPTC2	2016011178	(01)00844868021414(17)210301(10)2016011178	LOW PROFILE ABUTMENT NON-HEXED PREFORMANCE® TEMPORARY CYLINDER
LPCQB	2016040022	(01)00844868036395(17)210401(10)2016040022	LOW PROFILE ABUTMENT QUICKBRIDGE®
LPCTC1	2016030247	(01)00844868025177(17)210301(10)2016030247	LOW PROFILE ABUTMENT HEXED TEMPORARY CYLINDER
LPCTC2	2015111121	(01)00844868036401(17)201101(10)2015111121	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTC2	2015120495	(01)00844868036401(17)201201(10)2015120495	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTC2	2015120497	(01)00844868036401(17)201201(10)2015120497	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTC2	2016031197	(01)00844868036401(17)210301(10)2016031197	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTC2	2016031875	(01)00844868036401(17)210301(10)2016031875	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTC2	2016031878	(01)00844868036401(17)210301(10)2016031878	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTC2	2016050008	(01)00844868036401(17)210501(10)2016050008	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTC2	2016060232	(01)00844868036401(17)210601(10)2016060232	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTC2	2016060233	(01)00844868036401(17)210601(10)2016060233	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTC2	2016062347	(01)00844868036401(17)210601(10)2016062347	LOW PROFILE ABUTMENT NON-HEXED TEMPORARY CYLINDER
LPCTIC2	2015110389	(01)00844868036418(17)201101(10)2015110389	LOW PROFILE ABUTMENT (NON-HEXED) TRANSFER IMPRESSION COPING
LPCTIC2	2015110452	(01)00844868036418(17)201101(10)2015110452	LOW PROFILE ABUTMENT (NON-HEXED) TRANSFER IMPRESSION COPING
LPCTIC2	2016021488	(01)00844868036418(17)210301(10)2016021488	LOW PROFILE ABUTMENT (NON-HEXED) TRANSFER IMPRESSION COPING
LPCTIC2	2016021490	(01)00844868036418(17)210301(10)2016021490	LOW PROFILE ABUTMENT (NON-HEXED) TRANSFER IMPRESSION COPING
LPCTIC2	2016040888	(01)00844868036418(17)210401(10)2016040888	LOW PROFILE ABUTMENT (NON-HEXED) TRANSFER IMPRESSION COPING
LPCTSH	2016021930	(01)00844868021155(17)210301(10)2016021930	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW

Item Number	Lot Number	UDI Number	Item Description
LPCTSH	2016022074	(01)00844868021155(17)210301(10)2016022074	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW
LPCTSH	2016031247	(01)00844868021155(17)210301(10)2016031247	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW
LPCTSH	2016031248	(01)00844868021155(17)210401(10)2016031248	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW
LPCTSH	2016040024	(01)00844868021155(17)210401(10)2016040024	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW
LPCTSH	2016040025	(01)00844868021155(17)210401(10)2016040025	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW
LPCTSH	2016040064	(01)00844868021155(17)210401(10)2016040064	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW
LPCTSH	2016040898	(01)00844868021155(17)210401(10)2016040898	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW
LPCTSH	2016041632	(01)00844868021155(17)210501(10)2016041632	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW
LPCTSH	2016041635	(01)00844868021155(17)210501(10)2016041635	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW
LPCTSH	2016042030	(01)00844868021155(17)210501(10)2016042030	LOW PROFILE ABUTMENT TITANIUM RETAINING SCREW