

May 30, 2018

To: Risk Managers

Subject: **URGENT MEDICAL DEVICE RECALL (JAPAN ONLY)**

Affected Product: M/L Taper Hip Prosthesis and M/L Taper Hip Prosthesis with Kinectiv® Technology (See Attachment 2 – Affected Product List)

Zimmer Biomet is conducting a medical device recall for M/L Taper Hip Prosthesis and M/L Taper Hip Prosthesis with Kinectiv® Technology manufactured prior to October 2015 due to the potential for black residue to be observed within the polyethylene bag containing the implant. The frequency of this occurrence based on complaint receipt is approximately 1 in 28,000 cases. The black residue has been identified as a combination of the titanium plasma spray used to create the porous surface of the implant and polyethylene bag containing the implant. The residue is biocompatible as the implant material demonstrates proven biocompatibility and the polyethylene bags are biocompatible.

A previous investigation determined that there is a correlation between the number of shipments and related transportation handling and the occurrence of residue in the polyethylene bag. As a result, certain devices in the United States and Canada were recalled in 2014, and the packaging design was updated in 2015 to further mitigate this type of event. Although there has never been a complaint for black residue in the updated packaging design, additional complaints emanating almost exclusively from Japan have been received involving the previous packaging design. Accordingly, the remaining devices in the previous packaging design are being recalled from Japan. All devices currently being distributed from Zimmer Biomet Global Distribution Centers are manufactured using the updated packaging design.



Figure 1: Example of Black Residue

Risks

| Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable | Highest Severity |
|---|--|---|
| | Delay of Surgery, less than 30 minutes due to replacement device being readily available | Delay of Surgery, greater than 30 minutes due to replacement device not being readily available |
| Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue. | Most Probable | Highest Severity |
| | None | Surgical intervention due to wear caused by debris |

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between September 2009 and April 2018.

Risk Manager Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

This 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.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch 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 Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing Zimmer.PER@zimmerbiomet.com.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,



Kevin W. Escapule
Post Market Surveillance and Regulatory Compliance Director



ATTACHMENT 1

Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: M/L Taper & M/L Taper w/ Kinectiv Field Action Reference: ZFA 2018-00052

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|--|
| <p>Do you have affected product in your facility? (Hospital Facility Only: Please mark the appropriate response.)</p> <p><input type="checkbox"/> Yes, we currently have one or more affected items in our facility.</p> <p><input type="checkbox"/> No, we currently have no affected items in our facility.</p> |
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By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** () _____ - _____ **Date:** ____/____/____

Facility Name: _____

Facility Address: _____

City: _____ **State:** _____ **ZIP:** _____

Note: This form must be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-372-4265.

ATTACHMENT 2

Affected Product List

| | | | |
|-------------------------|---------------------------------|-------------------|-------------------|
| Item Number | 00771100410 | | |
| Item Description | MONOBLOCK M/L TAPER ST4 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 62107667 | 62469393 | 62554172 | 62652981 |
| 62410983 | 62478848 | 62559999 | 62659334 |
| 62410984 | 62478852 | 62560152 | 62667678 |
| 62445410 | 62478855 | 62577929 | 62753395 |
| 62449677 | 62503181 | 62630007 | 62770876 |
| 62450635 | 62547038 | 62806022 | 62897465 |
| 62777941 | 62791158 | 62636746 | |
| Item Number | 00771100440 | | |
| Item Description | MONOBLOCK M/L TAPER EXT4 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 61967700 | 62450669 | 62601210 | 62797379 |
| 62114291R | 62458974 | 62615697 | 62797380 |
| 62386066 | 62472166 | 62622678 | 62882393 |
| 62386068 | 62484291 | 62636747 | 62917816 |
| 62410987 | 62503192 | 62665742 | 77003795R |
| 62416627 | 62515309 | 62681670 | |
| 62445412 | 62594187 | 62740032 | |

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|-------------------------|-------------------------|-------------------|-------------------|
| Item Number | 00771300500 | | |
| Item Description | MOD ML TAPER FEM ST 5 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 61930610 | 62460391 | 63034172 | 63081182 |
| 61967651 | 62503140 | 63034173 | 63128514 |
| 62010520 | 62794209 | 63034174 | 63128518 |
| 62053333 | 62876154 | 63038714 | 63161307 |
| 62430587 | 62927048 | 63076525 | |
| Item Number | 00771300600 | | |
| Item Description | MOD ML TAPER FEM ST 6 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 62044925 | 62831345 | 62953032 | 63081184 |
| 62571340 | 62869740 | 63068885 | 63089967 |
| Item Number | 00771300700 | | |
| Item Description | MOD ML TAPER FEM ST 7.5 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 62420821 | 62745221 | 63089985 | |
| 62647157R | 62848683 | 63161324 | |
| Item Number | 00771300900 | | |
| Item Description | MOD ML TAPER FEM ST 9 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 62350575 | 63044896 | 63076554 | 63174034 |
| 62647167 | 63044897 | 63120523 | |
| 62787292 | 63068905 | 63161387 | |
| Item Number | 00771301000 | | |
| Item Description | MOD ML TAPER FEM ST 10 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 62361460 | 62528141 | | |

| | | | |
|-------------------------|--------------------------|-------------------|-------------------|
| Item Number | 00771301100 | | |
| Item Description | MOD ML TAPER FEM ST 11 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 62432961 | 62927105 | 63081264 | 63116798 |
| 62848695 | 62927112 | 63090024 | 63161432 |
| 62914651 | 63068929 | 63090028 | |
| Item Number | 00771301200 | | |
| Item Description | MOD ML TAPER FEM ST 12.5 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 61741690 | 62831371 | 63090038 | 63128589 |
| 62808128 | 63068944 | 63094522 | |
| Item Number | 00771301300 | | |
| Item Description | MOD ML TAPER FEM ST 13.5 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 61349197 | 62484285 | 62808130 | 63068955 |
| 61690629 | 62496087 | 62808133 | 63068957 |
| 61721526 | 62521418R | 62869767 | 63076577 |
| 61781828 | 62546976 | 62869769 | 63081279 |
| 62010553 | 62559966 | 62939011R | 63094534 |
| 62118873 | 62578405 | 62953079 | 63094538 |
| 62130040 | 62616562 | 62993667 | 63102051 |
| 62201735 | 62634733 | 62993703 | 63128592 |
| 62258067 | 62652960 | 63034232 | 63128592R |
| 62275219 | 62700955 | 63038804 | 63128593 |
| 62356222 | 62733912 | 63044938 | 77002646R |
| 62361475 | 62798024 | 63068954 | |

| Item Number | 00771301500 | | |
|------------------|------------------------|------------|------------|
| Item Description | MOD ML TAPER FEM ST 15 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 61288759 | 62191383 | 62578409 | 63063344 |
| 61429027R | 62225911 | 62652963 | 63063345 |
| 61542760 | 62270944 | 62659314 | 63063346 |
| 61710043 | 62273474 | 62659315 | 63063348 |
| 61729725 | 62275220 | 62667476 | 63068961 |
| 61735130 | 62275874 | 62700958 | 63068965 |
| 61768446 | 62316364 | 62721036 | 63068967 |
| 61805951 | 62329143 | 62739979 | 63068969 |
| 61843648 | 62335432R | 62761717 | 63076579 |
| 61874222 | 62356225 | 62776407 | 63076580 |
| 61950885 | 62418056 | 62787314 | 63081284 |
| 61957017 | 62420829 | 62787315 | 63081286 |
| 61967640 | 62420831 | 62794382 | 63090043 |
| 61967642 | 62420832 | 62815408 | 63090044 |
| 61985977 | 62432973 | 62836783 | 63094542 |
| 62010557 | 62472159 | 62836785 | 63102029 |
| 62014550 | 62503173 | 62836786R | 63102030 |
| 62059104 | 62521423 | 62885067 | 63108843 |
| 62066989R | 62521424 | 62939020 | 63174078 |
| 62124960 | 62521425 | 62939021 | 63174079 |
| 62134980 | 62521426 | 62939023 | 63174081 |
| 62153554 | 62540539 | 63044942 | 77004214 |
| 62163677 | 62571382 | 63051893 | |

| Item Number | 00771301600 | | |
|------------------|---------------------------|------------|------------|
| Item Description | MOD ML TAPER FEM ST 16.25 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 60936172 | 61757673 | 62432974 | 62939025 |
| 61002401 | 62014555 | 62503175 | 62953083 |
| 61150834 | 62014556 | 62521427 | 63063349 |
| 61326535 | 62014557 | 62560139 | 63063351 |
| 61332941 | 62059105 | 62578410 | 63063352 |
| 61359861 | 62071437 | 62586781 | 63068972 |
| 61375746 | 62071437R | 62616563 | 63090045 |
| 61403159 | 62118877 | 62647184 | 63090046 |
| 61409715 | 62130043 | 62659327 | 63090047 |
| 61459935 | 62163680 | 62694084 | 63116808 |
| 61479150 | 62207789 | 62707654 | 63116809 |
| 61559581 | 62282107 | 62721037 | 63116810 |
| 61590535R | 62323345 | 62782080 | 77004216 |
| 61729731 | 62356227 | 62803651 | |
| 61741696 | 62420836 | 62927127 | |
| Item Number | 00771301700 | | |
| Item Description | MOD ML TAPER FEM ST 17.5 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 11016141 | 62059106 | 62745241 | 63063358 |
| 60936173 | 62361479 | 62782081 | 77004218 |
| 60964158 | 62521429 | 63063354 | 77004219 |
| 61086272 | 62659329 | 63063356 | |
| 61991590R | 62694085 | 63063357 | |

| | | | |
|-------------------------|--------------------------|-------------------|-------------------|
| Item Number | 00771302000 | | |
| Item Description | MOD ML TAPER FEM ST 20.0 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 00114166 | 61294384 | 61985982 | 77004221 |
| 61068340 | 61308863 | 62225912 | |
| 61081252 | 61729730 | 62356231 | |
| 61269285 | 61774484 | 62478335 | |
| Item Number | 00771302200 | | |
| Item Description | MOD ML TAPER FEM ST 22.5 | | |
| Lot Number | Lot Number | Lot Number | Lot Number |
| 00111778 | 61063904 | 61134445 | 62798037 |
| 60940196 | 61097911 | 61619526 | |
| 61025425 | 61120383 | 62420837 | |