

February 14, 2017

To: Orthosize[®] Templating Users

Subject: **URGENT MEDICAL DEVICE CORRECTION**

Affected Product: Echo[®] Bi-Metric[®] Hip Stem Digital Templates

See Attachment 1 – Affected Template List

Zimmer Biomet is conducting a field correction for Echo[®] Bi-Metric[®] Hip Stem Digital Templates. Through a complaint investigation it was determined that the digital templates were created with the incorrect files. As seen in a comparison of Figure 1 and Figure 2 below, the correct stem has a different profile.

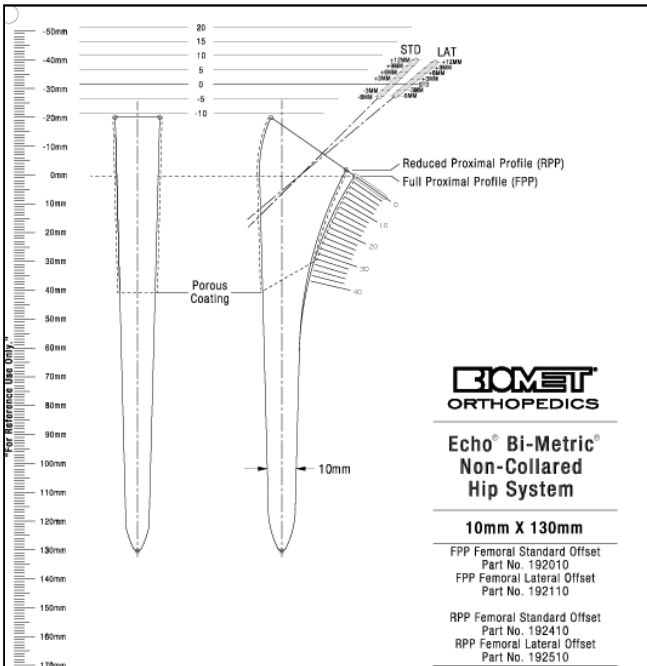


Figure 1 Example of Incorrect Template

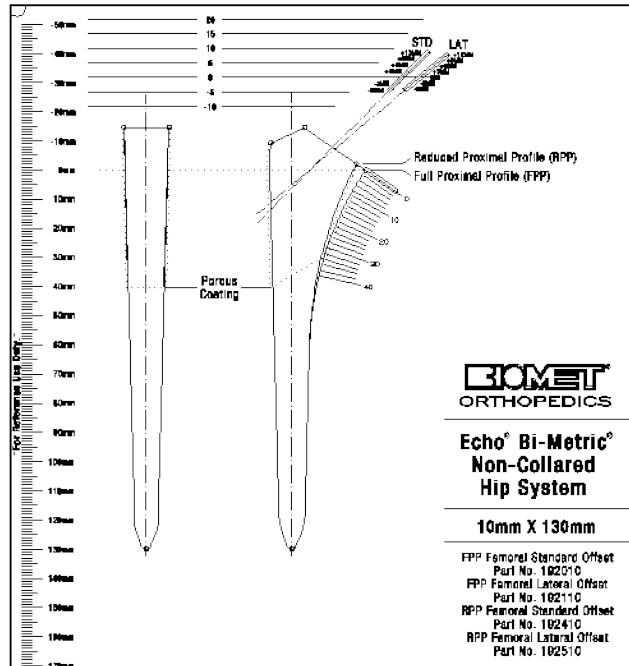


Figure 2 Example of Correct Template

As described below the use of an incorrect template may result in surgical delay and or stem subsidence.

<i>Risks</i>		
<i>Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.</i>	<i>Most Probable</i>	<i>Worst Case</i>
	<i>No immediate health consequences</i>	<i>Delay greater than 30 minutes</i>

<i>Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.</i>	<i>Most Probable</i>	<i>Worst Case</i>
	<i>No long range health consequences</i>	<i>Stem subsides over time</i>

Our records indicate you are an Orthosize[®] Templating user. In approximately 6 weeks you will receive a notice that an update is available for the Orthosize[®] Templating App. Upon selecting the app the screen seen in Figure 3 below, will be displayed requiring you to update the app in order to use it.

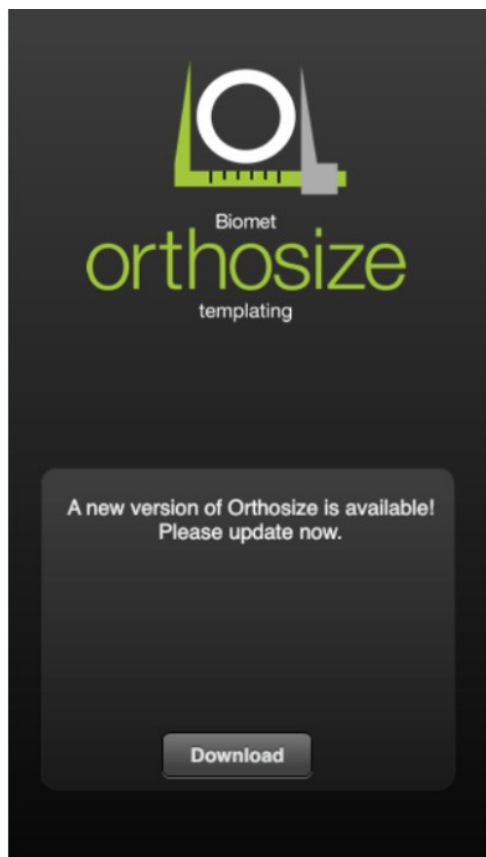


Figure 3 Orthosize Update Screen

Your Responsibilities

1. Review this notification and ensure affected personnel are aware its contents.
2. Immediately update the app when the update becomes available.
3. If after reviewing this notice you have further questions or concerns please call 411 Technical Services at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of the call center operating hours will receive a prompt to record a voicemail or



be transferred to an on-call representative in the case of an emergency. Alternatively, your questions may be sent by email to corporatequality.postmarket@zimmerbiomet.com

Other Information

This voluntary correction 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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- 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 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.

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

Sincerely,

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ATTACHMENT 1

Affected Template List

Template Part Number	Associated Implant Part Number	Associated Implant Item Description
XR192007-1	192007	Full Proximal Profile (FPP) – Standard Size 7 mm
XR192008-1	192008	Full Proximal Profile (FPP) – Standard Size 8 mm
XR192009-1	192009	Full Proximal Profile (FPP) – Standard Size 9 mm
XR192010-1	192010	Full Proximal Profile (FPP) – Standard Size 10 mm
XR192011-1	192011	Full Proximal Profile (FPP) – Standard Size 11 mm
XR192012-1	192012	Full Proximal Profile (FPP) – Standard Size 12 mm
XR192013-1	192013	Full Proximal Profile (FPP) – Standard Size 13 mm
XR192014-1	192014	Full Proximal Profile (FPP) – Standard Size 14 mm
XR192015-1	192015	Full Proximal Profile (FPP) – Standard Size 15 mm
XR192016-1	192016	Full Proximal Profile (FPP) – Standard Size 16 mm
XR192017-1	192017	Full Proximal Profile (FPP) – Standard Size 17 mm
XR192018-1	192018	Full Proximal Profile (FPP) – Standard Size 18 mm
XR192019-1	192019	Full Proximal Profile (FPP) – Standard Size 19 mm
XR192020-1	192020	Full Proximal Profile (FPP) – Standard Size 20 mm
XR192021-1	192021	Full Proximal Profile (FPP) – Standard Size 21 mm
XR192107-1	192107	Full Proximal Profile (FPP) - High Offset Size 7 mm
XR192108-1	192108	Full Proximal Profile (FPP) - High Offset Size 8 mm
XR192109-1	192109	Full Proximal Profile (FPP) - High Offset Size 9 mm
XR192110-1	192110	Full Proximal Profile (FPP) - High Offset Size 10 mm
XR192111-1	192111	Full Proximal Profile (FPP) - High Offset Size 11 mm
XR192112-1	192112	Full Proximal Profile (FPP) - High Offset Size 12 mm
XR192113-1	192113	Full Proximal Profile (FPP) - High Offset Size 13 mm
XR192114-1	192114	Full Proximal Profile (FPP) - High Offset Size 14 mm
XR192115-1	192115	Full Proximal Profile (FPP) - High Offset Size 15 mm
XR192116-1	192116	Full Proximal Profile (FPP) - High Offset Size 16 mm
XR192117-1	192117	Full Proximal Profile (FPP) - High Offset Size 17 mm
XR192118-1	192118	Full Proximal Profile (FPP) - High Offset Size 18 mm
XR192119-1	192119	Full Proximal Profile (FPP) - High Offset Size 19 mm
XR192120-1	192120	Full Proximal Profile (FPP) - High Offset Size 20 mm
XR192121-1	192121	Full Proximal Profile (FPP) - High Offset Size 21 mm
XR192407-1	192407	Reduced Proximal Profile (RPP) – Standard Size 7 mm
XR192408-1	192408	Reduced Proximal Profile (RPP) – Standard Size 8 mm
XR192409-1	192409	Reduced Proximal Profile (RPP) – Standard Size 9 mm
XR192410-1	192410	Reduced Proximal Profile (RPP) – Standard Size 10 mm
XR192411-1	192411	Reduced Proximal Profile (RPP) – Standard Size 11 mm
XR192412-1	192412	Reduced Proximal Profile (RPP) – Standard Size 12 mm
XR192413-1	192413	Reduced Proximal Profile (RPP) – Standard Size 13 mm
XR192414-1	192414	Reduced Proximal Profile (RPP) – Standard Size 14 mm

ATTACHMENT 1 Continued

Affected Template List

Template Part Number	Associated Implant Part Number	Associated Implant Item Description
XR192415-1	192415	Reduced Proximal Profile (RPP) – Standard Size 15 mm
XR 192416-1	192416	Reduced Proximal Profile (RPP) – Standard Size 16 mm
XR192017-1	192417	Reduced Proximal Profile (RPP) – Standard Size 17 mm
XR192018-1	192418	Reduced Proximal Profile (RPP) – Standard Size 18 mm
XR192019-1	192419	Reduced Proximal Profile (RPP) – Standard Size 19 mm
XR192020-1	192420	Reduced Proximal Profile (RPP) – Standard Size 20 mm
XR192021-1	192421	Reduced Proximal Profile (RPP) – Standard Size 21 mm
XR192508-1	192508	Reduced Proximal Profile (RPP) - High Offset Size 8 mm
XR192509-1	192509	Reduced Proximal Profile (RPP) - High Offset Size 9 mm
XR192510-1	192510	Reduced Proximal Profile (RPP) - High Offset Size 10 mm
XR192511-1	192511	Reduced Proximal Profile (RPP) - High Offset Size 11 mm
XR192512-1	192512	Reduced Proximal Profile (RPP) - High Offset Size 12 mm
XR192513-1	192513	Reduced Proximal Profile (RPP) - High Offset Size 13 mm
XR192514-1	192514	Reduced Proximal Profile (RPP) - High Offset Size 14 mm
XR192515-1	192515	Reduced Proximal Profile (RPP) - High Offset Size 15 mm
XR192516-1	192516	Reduced Proximal Profile (RPP) - High Offset Size 16 mm
XR192517-1	192517	Reduced Proximal Profile (RPP) - High Offset Size 17 mm
XR192518-1	192518	Reduced Proximal Profile (RPP) - High Offset Size 18 mm
XR192519-1	192519	Reduced Proximal Profile (RPP) - High Offset Size 19 mm
XR192520-1	192520	Reduced Proximal Profile (RPP) - High Offset Size 20 mm
XR192521-1	192521	Reduced Proximal Profile (RPP) - High Offset Size 21 mm