September 18, 2024

To: Surgeons

Subject: ZFA 2024-00121 Field Action Correction – Follow-up Notification

Affected Product: CPT® Hip System Femoral Stem 12/14 Neck Taper

Zimmer Biomet initiated a voluntary medical device field action correction on July 2, 2024, for the CPT Hip System Femoral Stem 12/14 Neck Taper products listed in **Attachment 2 – Affected Product List** due to an increased risk of postoperative periprosthetic femoral fracture (PFF)**.**

On September 17, 2024, the US Food and Drug Administration (FDA) issued a Medical Device Safety Communication related to the field action for the CPT Hip System Femoral 12/14 Neck Taper. The FDA-issued Safety Communication provides additional recommendations on the use of the CPT Hip System Femoral 12/14 Neck Taper during the phase out period. Below are excerpts from the Safety Communication and the full message can be found at: https://www.fda.gov/medical-devices/safety-communications/zimmer-biomet-cpt-hip-system-femoral-stem-and-increased-risk-thigh-bone-fracture-fda-safety?utm_medium=email&utm_source=govdelivery

For Health Care Providers and Facilities:

- Review and discuss the Recommendations for Patients and Caregivers from the Safety Communication with your patients.
- Surgeons should consider using an alternative prosthesis where possible.
- The CPT Hip System should only be implanted in new patients when the benefits of implanting the device outweigh the risks, and when appropriate alternative devices are not available.
- If no alternatives are possible, then inform the patient of the increased risk of postoperative PFF with the CPT Hip System and why it may be an appropriate treatment option
- Be aware of the increased risk of postoperative PFF in patients already implanted with the CPT Hip System

Although there are no specific patient monitoring instructions related to this field action correction, this follow-up notification provides a plain language description at **Appendix A – Post-Operative Patient Information** that may be provided to patients at your discretion. The plain language description of this communication is also available on the Zimmer Biomet website at https://www.zimmerbiomet.com/en/products-and-solutions/specialties/hip.html#cpt-info.

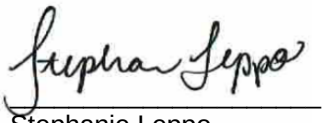
This follow-up notification additionally informs you that the instructions for use (IFU) has been updated to include PFF as a risk associated with the CPT Hip System Femoral Stem 12/14 Neck Taper. The updated IFU can be viewed electronically at labeling.zimmerbiomet.com by entering one of the part numbers from **Attachment 2 – Affected Product List** in the search field.

A few important points to know:

- This is follow-up notification to provide additional guidance published from the FDA and a plain language communication that may be provided to patients at your discretion.
- Zimmer Biomet initiated a field action correction on July 2, 2024, to ensure that you are aware of this risk and that the CPT Hip System Femoral Stem 12/14 Neck Taper displayed a rate of PFF at approximately 1.4% in the United Kingdom, which is more than twice the risk of PFF relative to a similar polished taper-slip (PTS) reference product that is stainless steel.
- In the July 2024 notice, Zimmer Biomet provided the phase out plan to transition users by the end of December 2024. Based on the current progress, all U.S. surgeons will be transitioned to alternative brands and the CPT Hip System Femoral Stem will be exited in the U.S. by the end of October 2024. At that time, the unconsumed products will be returned from the U.S. field to Zimmer Biomet through the standard discontinuation process.

Thank you for your assistance. We regret the inconvenience caused by this medical device correction.

Sincerely,



Stephanie Leppo
Quality Associate Director

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Appendix A - Post-Operative Patient Information Regarding the CPT Hip System Femoral Stem 12/14 Neck Taper

- This information is for patients who received a specific type of total hip replacement that was manufactured by Zimmer Biomet.
- More specifically, Zimmer Biomet is conducting a voluntary medical device correction related to the **CPT Hip System Femoral Stem 12/14 Neck Tape**r (CPT Femoral Stem) due to an increased risk of postoperative periprosthetic femoral (thigh) bone fracture (PFF).
- All hip replacements have potential risks associated with their use, including fracture of the femoral bone after surgery. This is typically caused by a traumatic event, such as a fall. The CPT Femoral Stem did not list the risk of bone fracture around the implant in revision D of the instructions for use. The instructions for use have since been updated to revision E, which now reflects the risk of periprosthetic femoral (thigh) bone fracture.
- Based on a recent review of patients in the United Kingdom implanted with the CPT Femoral Stem, approximately 1.4% of patients experienced a femoral (thigh) bone fracture after surgery, and similar PTS Hip Stems have PFF rates ranging from approximately 0.6% to 1%. The full message from the United Kingdom health authority can be found at: https://www.gov.uk/drug-device-alerts/cpt-hip-system-femoral-stem-12-slash-14-neck-taper-increased-risk-of-postoperative-periprosthetic-femoral-fracture-dsi-slash-2024-slash-007.
- Patients should be aware of the increased risk of femoral (thigh) bone fracture after surgery with the CPT Hip System.
- If fracture of the femoral bone occurs, an additional surgery is typically required to repair the bone and potentially replace the femoral stem implant. If you have been experiencing any new pain, difficulty when walking, inability to bear weight, swelling or instability of the hip, it is recommended that you follow-up with your surgeon or another health care provider for further evaluation.
- Patients should continue normal follow-up with their surgeon or health care provider unless experiencing unexpected symptoms.
- The fact that a patient has a hip component within the scope of this notice does not necessarily mean that the hip component is not functioning well or needs to be replaced or removed.
- Removal of any hip arthroplasty when a patient is not experiencing any symptoms is not recommended.
- Questions regarding the CPT Femoral Stem or any other Zimmer Biomet's hip products should be directed to the Zimmer Biomet Customer Service Team at 574-371-3071.
- Complaints related to the CPT Femoral Stem or any other Zimmer Biomet hip products can be reported to Zimmer Biomet's Post-Market Surveillance Department at product.experience@zimmerbiomet.com for investigation, potential regulatory reporting and monitoring.
- For your reference, the item list for the affected CPT Femoral Stem products is provided in Table 1. You may refer to your health care provider or surgery center to obtain your operation implant information records to identify the item numbers.
- Patient health and safety are top priorities at Zimmer Biomet. We appreciate your time and attention in reading this important information.

Table 1 – CPT Femoral Stem Product List		
Item Number	**GTIN Number**	**Item Description**
00-8114-000-00	00889024145733	Size 0 105 mm Stem Length Standard Offset
00-8114-000-10	00889024145740	Size 0 105 mm Stem Length Extended Offset
00-8114-001-00	00889024145757	Size 1 130 mm Stem Length Standard Offset
00-8114-001-10	00889024145764	Size 1 130 mm Stem Length Extended Offset
00-8114-002-00	00889024145771	Size 2 130 mm Stem Length Standard Offset
00-8114-002-10	00889024145788	Size 2 130 mm Stem Length Extended Offset
00-8114-002-30	00889024145801	Size 2 130 mm Stem Length Extra Extended Offset
00-8114-003-00	00889024145818	Size 3 130 mm Stem Length Standard Offset
00-8114-003-10	00889024145825	Size 3 130 mm Stem Length Extended Offset
00-8114-003-30	00889024145849	Size 3 130 mm Stem Length Extra Extended Offset
00-8114-004-00	00889024145856	Size 4 130 mm Stem Length Standard Offset
00-8114-004-10	00889024145863	Size 4 130 mm Stem Length Extended Offset
00-8114-004-30	00889024145900	Size 4 130 mm Stem Length Extra Extended Offset
00-8114-005-00	00889024145917	Size 5 130 mm Stem Length Standard Offset
00-8114-005-10	00889024145924	Size 5 130 mm Stem Length Extended Offset
00-8114-005-30	00889024145931	Size 5 130 mm Stem Length Extra Extended Offset
00-8114-040-00	00889024145962	Extra Small 85 mm Stem Length
00-8114-050-00	00889024145979	Small 95 mm Stem Length
00-8114-002-18	00889024145795	Size 2 180 mm Stem Length Standard Offset
00-8114-003-18	00889024145832	Size 3 180 mm Stem Length Extended Offset
00-8114-004-20	00889024145870	Size 4 200 mm Stem Length Extended Offset
00-8114-004-23	00889024145887	Size 4 230 mm Stem Length Extended Offset
00-8114-004-26	00889024145894	Size 4 260 mm Stem Length Extended Offset
00-8114-012-18	00889024145948	Size 2 180 mm Stem Length Valgus Neck
00-8114-013-18	00889024145955	Size 3 180 mm Stem Length Valgus Neck

July 2, 2024

To: Risk Managers and Surgeons

Subject: **URGENT MEDICAL DEVICE CORRECTION**

Affected Product: CPT® Hip System Femoral Stem 12/14 Neck Taper (see **Attachment 2** for the **Affected Product List**)

Reason for Field Action Correction

Zimmer Biomet is voluntarily initiating a medical device field action correction for the CPT Hip System Femoral Stem 12/14 Neck Taper listed in **Attachment 2 – Affected Product List** due to an increased risk of postoperative periprosthetic femoral fracture (PFF)**.**

You are receiving this correction notice because our records indicate that you have implanted the CPT Hip System Femoral Stem 12/14 Neck Taper in the past 12 months, or your facility may currently have inventory of this product.

The CPT Hip System Femoral Stem 12/14 Neck Taper is a polished taper-slip (PTS) style stem. Though PTS stems demonstrate low rates of aseptic loosening, contributing to high rates of survivorship, registry-based analyses have indicated that all PTS stems are associated with increased risk of PFF compared to composite beam stems.[3,4] Within the PTS stem category, stems manufactured from cobalt chromium alloy are at increased risk for PFF in comparison to stainless steel.[5] The CPT Hip System Femoral Stem 12/14 Neck Taper is manufactured from cobalt chromium alloy.

While PFF is a generally recognized risk associated with all total hip arthroplasty, the current instructions for use (IFU) for the CPT Hip System Femoral Stem 12/14 Neck Taper do not identify post-operative bone fracture as a risk. As a result, Zimmer Biomet is initiating a field action correction to ensure that orthopaedic surgeons are aware of this risk and that the CPT Hip System Femoral Stem 12/14 Neck Taper displayed a rate of PFF at approximately 1.4% in the United Kingdom, which is more than twice the risk of PFF relative to a similar PTS reference product that is stainless steel.[6] The IFU is in the process of being updated to reflect the risk of PFF, with an anticipated release by the end of August 2024.

Risks

In the event that PFF occurs, which is often associated with a traumatic event, surgical intervention will likely be required. Surgical intervention typically involves either internal fixation of the fractured bone or the femoral stem implant is replaced with a new implant. Users should consider potential risk factors for PFF that are available in published literature when evaluating its use during this time, such as those presented by Lamb et al.[5] and ensure patients are informed appropriately on potential risks associated with the CPT Hip System Femoral Stem 12/14 Neck Taper. The potential modifiable risk factors include:

- Increasing age
- Intra-operative fracture
- Increasing stem offset
- Increasing head size
- Low viscosity bone cement

Additional Information on Affected Product

The CPT Hip System Femoral Stem 12/14 Neck Taper has been on the market for over 20 years. During this time, it achieved and has maintained the highest possible Orthopaedic Data Evaluation Panel (ODEP) rating of 15A*[1], as well as provided 96.4% all-cause survivorship at 10 years in the latest United Kingdom National Joint Registry (UK NJR) annual report.[2]

Product Phase Out

Zimmer Biomet has also made the decision to phase out the CPT Hip System Femoral Stem 12/14 Neck Taper, with a target of December 2024 to stop sales in your market. The product has successful long-term survivorship and may continue to be implanted during this phase out period.

Zimmer Biomet recognizes the importance of a well-planned phase out and transition when changing hip stem brands and has obtained feedback on preferred phase out periods and approaches from several surgeons who use the CPT Hip System Femoral Stem 12/14 Neck Taper. We will be taking actions to aid surgeons in transitioning to new hip stem brands, such as offering dedicated training opportunities in your market on alternative Zimmer Biomet brands and adjusting supply plans accordingly.

Hospital Responsibilities:

1. Review this correction notice and ensure that affected personnel, including surgeons, are aware of the contents.
   a. There are no specific patient monitoring instructions related to this field action correction that are recommended beyond your existing follow-up schedule.
2. If you currently use CPT Hip System Femoral Stem 12/14 Neck Taper, please coordinate with your local Zimmer Biomet representative on a transition plan for this product.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send it to CorporateQuality.PostMarket@zimmerbiomet.com. This form must be returned even if you no longer use CPT Hip System Femoral Stem 12/14 Neck Taper.
4. Retain a copy of **Attachment 1 – Certificate of Acknowledgement** with your field action correction records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this correction notice, please contact your local Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this correction notice for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action correction that are recommended beyond your existing follow-up schedule.
3. Consider the benefits and risks of implanting the CPT Hip System Femoral Stem 12/14 Neck Taper on an individual patient basis and ensure patients are informed appropriately on the increased risk of PFF.
4. To assist with communicating the increased risk of PFF to prospective patients during the phase out period, **Attachment 3 – Prospective Patient Information** may be provided to patients considering CPT Hip System Femoral Stem 12/14 Neck Taper.
5. Zimmer Biomet is in the process of updating the IFU to reflect the risk of PFF. The latest IFU can be viewed electronically at labeling.zimmerbiomet.com and entering one of the part numbers from **Attachment 2 – Affected Product List** in the search field**.**
6. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com.
7. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.

8. 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 field action 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
- Call: 1-800-332-1088 to request a reporting form
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

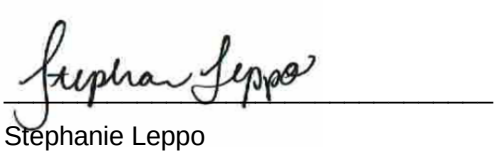
Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing product.experience@zimmerbiomet.com.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. Your urgent cooperation is needed. The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

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

Sincerely,

Sincerely,



Stephanie Leppo
Quality Associate Director

References

[1]Orthopaedic Data Evaluation Panel. www.odep.org.uk/product/cpt-stem-cocr/
[2]National Joint Registry. 20th Annual Report. 2023. www.njrcentre.org.uk
[3]Palan J, Smith MC, Gregg P et al. The influence of cemented femoral stem choice on the incidence of revision for periprosthetic fracture after primary total hip arthroplasty. Bone Joint J. 2016;98-B:1347-54. doi: 10.1302/0301-620X.98B10. PMID: 27694588.
[4]Jain S, Lamb JN, Pandit H. Cemented femoral stem design and postoperative periprosthetic fracture risk following total hip arthroplasty. Bone Joint J. 2024 Jan 1;106-B(1):11-15. doi: 10.1302/0301-620X.106B1.BJJ-2023-0587.R1. PMID: 38160687.
[5]Lamb JN, Jain S, King SW, West RM, Pandit HG. Risk Factors for Revision of Polished Taper-Slip Cemented Stems for Periprosthetic Femoral Fracture After Primary Total Hip Replacement: A Registry-Based Cohort Study from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. J Bone Joint Surg Am. 2020 Sep 16;102(18):1600-1608. doi: 10.2106/JBJS.19.01242. PMID: 32604382.
[6]Pandit HG et al. Postoperative periprosthetic femoral fracture is the leading cause of major reoperation in the United Kingdom following primary total hip replacement: A study using national health data linked to National Joint Registry. Unpublished.

ATTACHMENT 1- Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: CPT Hip System Femoral Stem 12/14 Neck Taper

Field Action Reference Number: ZFA 2024-00121

Please check one as applicable:

☐ Hospital Facility ☐ Surgeon

Do you have affected product in your facility?
(Hospital Facility Only: Please mark the appropriate response.)

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this correction notice.

Printed Name: _____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

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

Note: This form will 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 574-373-3589 or 574-372-4011.

ATTACHMENT 2 - Affected Product List

Item Number	GTIN Number	Item Description
00-8114-000-00	00889024145733	Size 0 105 mm Stem Length Standard Offset
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00-8114-012-18	00889024145948	Size 2 180 mm Stem Length Valgus Neck
00-8114-013-18	00889024145955	Size 3 180 mm Stem Length Valgus Neck

ATTACHMENT 3 – Prospective Patient Information

Your surgeon may be considering the CPT Femoral Stem for your hip replacement surgery. This additional information is being provided to communicate a risk that is not identified in the current instructions for use for the CPT Femoral Stem.

All hip replacements have potential risks associated with their use, including fracture of the femoral bone after surgery. This is typically caused by a traumatic event, such as a fall. The CPT Femoral Stem does not list the risk of bone fracture around the implant in the current instructions for use.

Based on a review of patients in the United Kingdom implanted with the CPT Femoral Stem, approximately 1.4% of patients experienced a femoral bone fracture after surgery. This rate of occurrence is higher than that of similar femoral stem implants.

If fracture of the femoral bone occurs, an additional surgery is typically required to repair the bone and potentially replace the femoral stem implant.

The CPT Femoral Stem has been on the market for over 20 years and has strong long-term survivorship. More than 96% of patients receiving a CPT Femoral Stem still have the implant after 10 years.

As with any surgery, you are encouraged to discuss the risk benefit of using the CPT Femoral Stem with your surgeon.