Medicines & Healthcare products Regulatory Agency

Device Safety Information (DSI)

CPT Hip System Femoral Stem 12/14 Neck Taper: Increased Risk of Postoperative Periprosthetic Femoral Fracture, DSI/2024/007

Devices Details

Device Name:
CPT Hip System Femoral Stem 12/14 Neck Taper

Product Code: Refer to the Field Safety Notice (FSN) issued by the manufacturer for details on the affected devices.

Manufactured by:
Zimmer Inc.

Summary

Recent research has found that the CPT Hip System Femoral Stem 12/14 Neck Taper, cobalt chromium, (a type of hip implant) carries a higher risk of postoperative periprosthetic femoral fracture (PFF) compared to hips of a similar design but made of a different material. The device will be phased out in the UK by December 2024.

Background

The CPT Hip System Femoral Stem 12/14 Neck Taper (a type of hip implant) is manufactured from cobalt chromium alloy and follows a polished-taper slip (PTS) design philosophy. PTS hip stems have a well-established track record and are the most common type used in total hip arthroplasty (also known as total hip replacement) in the UK. However, recent, currently unpublished research[1] combining registry data with other healthcare data, namely Hospital Episode Statistics, indicates that the risk of postoperative periprosthetic femoral fracture (PFF) (fracture around the femur (thigh bone) near the site of the hip implant) is higher for cobalt chromium PTS hip stems

compared to hip stems designed with a different philosophy (e.g. composite beam stems) and PTS stems made from a different material.

From an analysis of the most commonly implanted PTS Hip Stems (>1000 implantations in the UK), the research indicated that patients with the CPT Hip System have the highest risk of periprosthetic fracture, approximately 1.4% in the UK. Similar PTS Hip Stems have PFF rates ranging from approximately 0.6% to 1%[1].

The manufacturer Zimmer Inc. issued a Field Safety Notice notifying users of this increased risk, an upcoming change to the instructions for use (IFU), and the phase-out (discontinuation) of the product in the UK by December 2024. Due to the high number of UK hospitals using the CPT Hip System, a phase-out was deemed appropriate by the MHRA to ensure continuity of care while the healthcare system adapts to new product lines.

The MHRA has been working with the British Hip Society (BHS), the British Orthopaedic Association (BOA), and the National Joint Registry (NJR) with regard to the provision of additional clinical advice during the phase-out of the CPT Hip System. As an output of these discussions, a joint statement, from the BHS, the BOA and NJR, has been issued advising against the use of the CPT Hip System for elective surgery except in certain circumstances. Surgeons should consider using an alternative prosthesis where possible. There may be certain indications such as fracture neck of femur where the benefit of using the CPT Hip System may outweigh the risk of delaying treatment. The needs of each patient should be assessed individually and the decision to use the device should be determined between the surgeon and patient.

Risk involved with using affected product

In the event that PFF occurs, which is often associated with a traumatic event, surgical intervention will likely be required. For patients implanted with the CPT Hip System Femoral Stem 12/14 Neck Taper, the risk of PFF is approximately 1.4% in the UK. While the risk of this fracture occurring is low, this is more than twice the risk of PFF compared to similar PTS stems that are not made of cobalt chromium.

The risk of PFF is approximately equivalent to other common risks associated with total hip arthroplasty, such as infection, dislocation and implant loosening. Also, the long-term survivorship of the CPT Hip System Femoral Stem is 96.4% at 10 years[2] which is above the expected performance rate of 95% at 10 years.

For patients already implanted with a CPT Hip System, there are currently no known modifiable behaviours (such as lifestyle changes or exercises) that are known to reduce the risk of PFF.

Actions

Actions for healthcare professionals (particularly surgeons)

- Follow the actions set out in the Field Safety Notice.
- Do not use CPT Hip System for elective surgery except in certain circumstances.
    - The CPT Hip System should only be implanted in new patients when the benefits of implanting the device outweigh the risks. A patient-centered consultation should consider the risks of implanting the affected device alongside the management needs of their condition. This discussion should be documented in the patient's records.
- For situations where it is in the patient's interest to receive urgent treatment, only use the CPT Hip System when appropriate alternative devices are not available.
- There are no specific patient monitoring instructions that are recommended beyond your existing follow-up schedule.
- There are specific reporting arrangements for healthcare professionals to follow in each region. Healthcare professionals should report incidents:
    - in England and Wales to the Yellow Card scheme or via the Yellow Card app
    - in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
    - in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

Actions for hospitals

- Hospitals with exclusive access or use of the CPT stem should engage with their supply chain management to seek alternative products and arrange suitable training for staff in their use.

Actions for patients

- There are no specific actions for patients already implanted with a CPT Hip System. Continue to follow the guidance and advice of your surgeon.
- If you experience any new or unexpected symptoms including pain, stiffness, or instability, please speak to your implanting surgeon or the hospital where your surgery was performed in the first instance.
- Report any suspected or actual adverse incidents to the MHRA using the Yellow Card scheme website.

Stakeholder engagement

- National Joint Registry (NJR)
- British Orthopaedic Association (BOA)
- British Hip Society (BHS)
- Incident Reporting and Investigation Centre (IRIC), NHS National Services Scotland
- NHS England - National Patient Safety Team
- Welsh Government
- Northern Ireland Adverse Incident Centre

Relevant medical specialties.

- General practice
- Orthopaedics

References

1. 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.
2. National Joint Registry. 20th Annual Report. 2023. www.njrcentre.org.uk

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