Medicines & Healthcare products Regulatory Agency

DEVICE SAFETY INFORMATION (DSI)

Profemur Cobalt Chrome Modular Neck Hip Replacements: Higher than anticipated risk of revision surgery, metal-wear effects and component fracture.

DSI/2025/005

Specialisms: *Orthopaedics, General practice*

DEVICE DETAILS

- All hip replacement constructs using Profemur cobalt chrome (CoCr) modular neck components
- All Profemur Xm hip replacement stems (cobalt chrome) used with Profemur titanium or cobalt chrome modular neck components

PRODUCT CODES / AFFECTED LOT SERIAL NUMBERS

Profemur Cobalt Chrome Modular Necks:

PHAC1202, PHAC1204, PHAC1212, PHAC1214, PHAC1222, PHAC1224, PHAC1232, PHAC1234, PHAC1242, PHAC1244, PHAC1252, PHAC1254

Profemur Xm Cobalt Chrome Modular Stems:

PHA06000, PHA06002, PHA06004, PHA06006, PHA06008

All lots affected for all specified product codes.

MANUFACTURED BY

MicroPort Orthopedics Inc. (Please note the Profemur brand was formerly manufactured by Wright Medical)

Summary

An MHRA investigation has found increased risks of wear and corrosion, including an increased occurrence of device fracture and revision surgery associated with cobalt chrome-containing Profemur modular neck hip stem components. Patients implanted with affected Profemur devices are to be invited for a clinical review to inform them of the identified risks, assess their clinical presentation and discuss the need for continued follow-up.

Advice for Healthcare Professionals:

Clinical Follow-up Recommendation:

- trusts / hospitals should review local and national databases (e.g. the National Joint Registry) to identify patients implanted with the specified devices
- all identified patients should be contacted and invited to attend a virtual or face-to-face clinical review under the prioritised conditions recommended in Table 1

Table 1. Recommended risk prioritisation groupings for patients implanted with affected devices.

Risk Grouping*	Highest Risk Group	Moderate Risk Group	Lower Risk Group
Priority Condition	• All patients to be invited for clinical review as soon as practically possible.	• All patients to be invited for clinical review as soon as practically possible. • Priority is to be given to patients in the Highest Risk Group.	• Patients to be invited for clinical review only if they are concerned or have symptoms such as pain, loss of function or instability.

*Patient risk grouping is defined as follows:

- Highest Risk Group:

Patients implanted with the recalled CoCr modular neck product code PHAC1254

- Moderate Risk Group:

Patients implanted with a CoCr neck on either a Profemur or Ancafit titanium alloy or Profemur Xm CoCr stem. This group includes patients whose implant material combinations are unknown

- Lower Risk Group:

Patients implanted with a titanium alloy neck on a Profemur Xm CoCr stem

- all identified patients, regardless of risk grouping, should be informed of the risks provided within this Device Safety Information communication
- if symptoms or clinical findings suggest an adverse soft tissue reaction or other metal-related effects, the following follow-up is recommended:
  - perform a whole blood test for cobalt and chromium* using a laboratory associated with one of the following schemes:
    - in England, Northern Ireland, or Wales: laboratories participating in the UK National External Quality Assessment Service (UK NEQAS)
    - in Scotland: the Scottish Trace Element and Micronutrient Reference Laboratories
  - conduct cross-sectional imaging using MARS MRI or ultrasound, depending on local trust or hospital policy

    - each patient should be assessed on an individual basis
    - consider revision surgery if any of the following are present:
        - abnormal imaging findings
        - blood metal levels that are higher than expected and/or rising
        - deterioration in hip-related clinical function or Patient Reported Outcome Measures (PROMs)
- following this clinical review:
    - symptomatic patients should be followed up annually while the device remains in place
    - asymptomatic patients should be advised to return if they develop new or concerning symptoms

* There is no agreed threshold value for whole blood metal levels that either predicts outcome, or mandates revision. Decisions to revise are influenced by patient factors, blood metal levels, imaging findings, and implant type and position. Other patient specific factors may need to be considered when interpreting results for blood metal levels.

Advice for Healthcare Professionals to Provide to Patients:

- the majority of patients implanted with these hip replacements have well-functioning hips and are thought to be at a low risk of developing serious problems
- a small number of patients implanted with these hips may, however, develop soft tissue reactions or other metal-related effects resulting in the need for revision surgery
- patients with affected devices should expect to be contacted and, if in the highest or moderate patient risk groups, be invited for a clinical assessment to consider and discuss whether any action is required. Patients in the lowest risk group will be invited only if they are concerned or are symptomatic
- patients who have an affected hip replacement device implanted, should expect to be contacted by their surgeon or implanting hospital. There is no need for patients to contact their surgeon or implanting hospital directly.
- in the meantime, if patients experience any new or unexpected symptoms including pain, stiffness, or instability, they should speak to their implanting surgeon or the hospital where their surgery was performed in the first instance

Advice for Distributors:

There is no advice for distributors regarding this DSI.

Explanation of identified safety issue

In October 2024, the MHRA began investigating concerns about the safety and performance of dual taper/modular neck hip stems, particularly those composed of cobalt chrome alloy. Although broader concerns had been raised about modular neck devices in general, the Profemur modular hip system was selected for detailed review based on specific reports, its market share in the UK and supporting data indicating potential metal wear-related issues. Several adverse outcomes were observed at markedly higher rates than would be expected for alternative devices, such as hip stems with a fixed-neck design.

The investigation identified three key risks associated with these devices:

1. Complaint rates related to metal wear and corrosion, commonly associated with the modular neck junction, were significantly higher, approximately 6 in 1,000 patients, compared to fewer than 1 in 10,000 for fixed-neck alternatives from the same manufacturer.

2. There is an increasing risk of device fracture due to wear and corrosion at the modular neck junction. Worldwide complaint data held by the manufacturer shows the current risk of device fracture to be approximately 2 in 10,000 patients. Patients implanted with components subject to the manufacturer-led recall in 2015 (see previous FSCA section below) may have a higher risk of device fracture of approximately 1 in 100.

According to the UK National Joint Registry, for devices implanted in England, Wales, Northern Ireland, the Isle of Man and Guernsey, the likelihood of implant fracture for the affected devices differs between the risk groupings. The current fracture rates are shown in Table 2.

Table 2. Implant fracture rates by risk grouping for patients recorded in the UK National Joint Registry

Risk Grouping*	**Number of Implanted Devices**	**Number of Implant Fractures**	**Rate per 1,000 cases**
Highest Risk Group	204	8	39.2
Moderate Risk Group	1188	<5	1.6
Lowest Risk Group	833	0	0

* Risk groups are defined in Table 1 within the Advice for Healthcare Professionals section.

3. Long-term data from the UK National Joint Registry indicates a two-fold increase in revision surgery at 10 years, up to 9 in 100 patients, compared to 5 in 100 for other cementless hip stem designs.

MHRA's investigation also found that specific aspects of the manufacturer's Instructions for Use (IFU) are inappropriate for safe device use. The IFU advises users to consider cobalt chrome modular necks for patients over 230 lbs (104 kg) and those with high activity levels, despite these factors being known to increase wear and corrosion at the neck junction, thereby potentially increasing the risk of the adverse incidents described above.

The manufacturer has discontinued the supply of Profemur cobalt chrome and titanium modular neck components to the UK market.

Previous Field Safety Corrective Action (FSCA)

The Profemur modular neck range was previously subject to the following related Field Safety Corrective Action:

- 11 August 2015 (Manufacturer Reference: MP_FSCA150803): One cobalt chrome modular neck device product code (PHAC1254) had an unexpected rate of postoperative fractures of the femoral neck component.
- 10 July 2020 (Manufacturer Reference: MP_FSCA20030001): MicroPort Orthopedics Inc. continued to received reports of component fracture in all long titanium modular neck device product codes.

Note: This safety communication does not apply to Profemur fixed-neck hip stem products, nor to Profemur modular neck hip stems in which both the neck and stem components are composed of titanium alloy, with no cobalt chrome components present at the interface.

Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website 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 Yellow Card website in accordance with your organisations medical device policies and procedures.

Additional information:

You can sign up to receive email updates on alerts and device safety information from the MHRA.

You can sign up to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk

Stakeholder engagement:

- British Orthopaedic Association
- British Hip Society
- UK National Joint Registry
- NHS England National Patient Safety team
- Incident Reporting & Investigation Centre (IRIC) for Scotland
- NHS Wales
- Northern Ireland Adverse Incident Centre for Northern Ireland

An advance copy for review was sent to all the devolved administrations for stakeholder engagement.