

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

MicroPort Orthopedics Inc., PROFEMUR Neck Varus/Valgus CoCr 8 Degree, Part number PHAC 1254

Recall Class: Class I

Date Recall Initiated: August 7, 2015

Product: PROFEMUR Long Cobalt Chrome 8 Degree Varus/Valgus Modular Neck, Part 1254

- All lots are affected
- Manufactured from: June 15, 2009 to July 22, 2015
- Distributed from: June 15, 2009 to July 31, 2015
- Devices Recalled in the U.S.: 10,825

Use: MicroPort Orthopedics has a variety of hip joint replacement systems that allow the surgeon to fit the implant specifically to the patient. During total hip replacement surgery, the damaged portions of the hip joint are removed and replaced with prosthetic parts including a femoral head, femoral stem and modular neck. The PROFEMUR Neck Varus/Valgus CoCR, part number PHAC1254 is the modular neck being recalled.

Recalling Firm:

MicroPort Orthopedics, Inc.
5677 Airline Road
Arlington, TN 38002

Reason for Recall: MicroPort Orthopedics Inc. has received reports of an unexpected rate of fractures after surgery related to this specific modular neck. If the modular neck fractures, the patient may experience sudden pain, instability and difficulty walking and performing common task. An acute fracture will require revision surgery to remove and replace the neck and stem components. Acute fracture and emergency revision surgery is a serious adverse health consequence and could lead to neurovascular damage, hematoma, hemorrhage, and even death.

Public Contact: Questions should be directed to MicroPort Orthopedics Inc.'s Customer Experience Department at 1-866-872-0211, Monday through Friday, between the hours of 7:30 a.m. and 7:30 p.m. Central Standard Time.

FDA District: New Orleans District Office

More Information about this Recall:

On August 7, 2015, MicroPort Orthopedics Inc. informed distributors and hospital staff of a voluntary device product recall.

Instructions for distributors and hospital staff including risk managers and surgeons: The following instructions were provided:

1. Review the notification and ensure affected personnel are aware of the recall.
2. Locate all affected product identified in the recall letter.
3. Stop using and distributing the affected product.
4. Return the recalled product to MicroPort Orthopedics Inc. Distribution Center at 11481 Gulf Stream, Arlington, TN 38002. Mark all return shipping boxes with "RECALL" on several sides for better identification and processing.
5. Regardless of whether you have the affected product, complete and return the Verification Form/Effectiveness Check by fax to 901-451-6032 or by e-mail to cathy.park@ortho.microport.com (<mailto:cathy.park@ortho.microport.com>).

Instructions for patients:

- Patients should continue to follow up with their health care provider at regular intervals as prescribed by their surgeon.
- There is currently no evidence that modular neck fractures can be anticipated by patient history, physical exam, visual inspection or by using any imaging modality including X-ray, MRI, or CT scans.
- Patients not experiencing symptoms should not take any further action.
- Patients should seek immediate medical treatment if they experience any sudden onset of severe pain in their post-operative hip, difficulty or inability walking, significant trauma to their hip or leg (e.g. falling), or a tingling sensation or loss of feeling in their leg.

About Class I Recalls:

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm) (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>) either online, by regular mail or by FAX.

[More in Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/default.htm\)](/MedicalDevices/Safety/ListofRecalls/default.htm)

[2015 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm429489.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

[2014 Medical Device Recalls \(/MedicalDevices/Safety/ListofRecalls/ucm384921.htm\)](/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)