

[Recipients Address]

Device Field Safety Corrective Action / Recall

Reference: R-2017-25

Concerned Devices: 12 14 CoCr Femoral Head

| Product No. | Description | Batch No. / UDI No. |
|-------------|--|---------------------|
| 71303604 | COBALT CHROME 12/14 TAPER FEMORAL HEAD 36MM +4 | 16FM08275 |
| 71303603 | COBALT CHROME 12/14 TAPER FEMORAL HEAD 36MM -3 | 16FM08268 |

Dear Customer

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily remove two lots of 12/14 CoCr Femoral Head due to a manufacturing error. The head offset did not match the product labeling. The head was incorrectly laser etched and packaged as a 36MM + 4 offset femoral head but the package contained a 36 MM -3 offset femoral head.

This field action has been reported to the relevant competent authorities.

| | |
|--|--|
| Risks to Health | In the event the surgical team does not immediately notice the error and a replacement device is not available, the failure could potentially lead to adjustments to make use of available components. |
| Actions to be taken by the user | <ol style="list-style-type: none"> 1. Locate and quarantine affected unused devices immediately. 2. Return quarantined product to your national Smith & Nephew agency/distributor. 3. Complete the return slip and fax it to your national Smith & Nephew agency/distributor. 4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 5. Please maintain awareness on this notice and resulting action until the Field Safety Corrective Action is terminated to ensure effectiveness of the action. |

Smith & Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.

If you have any questions please feel free to contact us under the following contact details:

Contact Details of Subsidiary / Distributor

Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.

We confirm the receipt of this Field Safety Notice.

In our facility we have _____ [Qty] concerned devices which we will return.

_____ [Qty] concerned devices have been discarded in our facility.

Institution: _____ Reference: R-2017-25

Name: _____ Date / Signature: _____