

February x, 2010

URGENT FIELD SAFETY NOTICE

DePuy ASR™ Articular Surface Replacement and ASR™ XL Monoblock Metal-on-Metal System

Type of Action: New revision rate data / information regarding the use of the device

FSCA Identifier: DINT 12725

Dear Clinicians

Summary

As part of our ongoing post-market surveillance, DePuy is continually evaluating data from a variety of sources including national joint replacement registries, published literature, company sponsored clinical trials, internal complaints data and unpublished clinical research reports. Recent analysis of datasets from these sources suggests a higher than expected revision rate for the DePuy ASR™ Articular Surface Replacement and ASR® XL Monoblock Metal-on-Metal (MoM) System linked to usage of monoblock MoM cups with corresponding head sizes below 50 mm in diameter.

Actions

Adherence to the following is essential to achieve optimal implant performance and survivorship:

- Ensure that the cups are implanted with an inclination of between 40 to 45 degrees as recommended in the IFU. Optimal implant positioning is particularly important for femoral heads smaller than 50 mm in diameter (cup sizes 58 mm and smaller).
- Do not implant in contraindicated patients, including but not limited to females of childbearing age.
- When assessing patients for selection please give careful consideration to those with poor bone quality and to those needing head sizes smaller than 50 mm in diameter (cup sizes 58 mm and smaller).
- Ensure that the patients presenting post-operatively with pain/swelling/discomfort are appropriately assessed.

In the absence of symptoms, no additional measures are recommended apart from each individual surgeon's standard clinical follow-up.

Background

The Australian National Joint Replacement Registry reports a cumulative percentage revision rate of 5.4% at 3 years for the ASR® Cup and XL head used with DePuy stems in total hip replacement. Recent published and unpublished data suggests that this rate may be higher in cohorts where a

large proportion is female or has small acetabulae. These data suggest that smaller heads (less than 50 mm diameter) are associated with a higher rate of revision (up to 8-9 % at three years).

While the analysis does not demonstrate conclusive findings regarding the relationship between gender and implant head size, DePuy believes that the analysis of the collective dataset provides reasons to take special care in patient selection and cup placement when choosing to use the DePuy ASR™ Articular Surface Replacement and ASR® XL Monoblock Metal-on-Metal System with head sizes below 50 mm, (cup sizes 58 mm and smaller). This data is consistent with other published data for the use of the DePuy ASR monoblock metal-on-metal resurfacing system and other similar devices in the class.

Reasons for revision identified within the datasets are typical for the class of large diameter MoM monoblock cups and includes component loosening, component malalignment, infection, pain, fracture, dislocation and metal sensitivity.

As you know, the survivorship of any joint replacement implant system is dependent on a multitude of factors, including careful adherence to surgical technique, patient selection and rehabilitation. The importance of adherence to surgical technique was confirmed during the analysis of the available data. Excessive cup inclination (greater than 45 degrees) was associated with early revisions. Patient selection is also very important. Patients presenting with inferior bone quality such as osteoporosis are poor candidates for this type of procedure due to the possibility of migration of the prosthesis, fracture of the femoral shaft and/or the lack of adequate bone to support the implant(s). Furthermore, females of childbearing age are contraindicated due to the unknown effects of elevated levels of metal ions on the foetus.

DePuy will continue to monitor data from all available sources and will follow up if additional information becomes available that results in changes to our recommendations.

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

If you require additional information regarding this matter, please contact the DePuy Vigilance Manager on +44 (0)7771 971930.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has been made aware of this matter.

Sincerely,

Pamela L. Plouhar, Ph.D.
VP, Worldwide Clinical Affairs