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Smith+Nephew

Physician Communication

Smith+Nephew Action: Voluntary Recall
Recall Reference: R-2020-04
Affected Product: R3 Acetabular Shells specific lots

Dear Doctor,

This letter is to update you regarding a voluntary recall for specific lots of R3 Acetabular Shells manufactured by Smith+Nephew, Inc. USA.

This update includes additional information included in the Health Hazard Evaluation assessment and potential risks associated with this device. The recommendation regarding routine patient follow up remains unchanged.

Background
Smith+Nephew has received six complaints related to intraoperative locking failure of R3 Acetabular Shells. A review of the manufacturing process identified that specific lots may not have been manufactured to their design specifications. While only some of the devices in the specified lots are potentially out of specification, Smith+Nephew is performing a voluntary recall of all the units from the specified lots.

Actions
In the most likely scenario, the devices will function as intended. To date, we have received six complaints regarding intraoperative locking failure with an XLPE liner and one of these complaints also reported a surgical delay of greater than 30 minutes. The following additional potential scenarios have been identified but there have been no reports of occurrence of these scenarios:

- Ceramic liner disassociation
- Polyethylene liner disassociation
- Polyethylene liner fracture

In the theoretical worst-case, a ceramic liner, appearing to fully lock intraoperatively with the acetabular shell, may fracture post-operatively necessitating a revision procedure. There have been no reports of occurrence of the worst-case scenario.

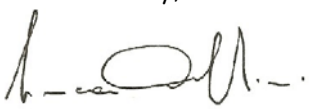
Smith+Nephew recommends that physicians maintain their routine patient follow-up protocol for implanted R3 Acetabular Shells identified in the scope of this voluntary recall.

As part of the execution of the voluntary recall, your facility manager is asked to acknowledge receipt and distribution of this letter, as applicable. All affected devices associated with this Urgent Medical Device Recall Notice have already been managed and returned to us as applicable.

Smith+Nephew is committed to distributing quality products that are safe and effective and providing support to surgeons who use those products.

If you have any questions, please contact me on the following email fieldactions@smith-nephew.com.

Yours sincerely,



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