

[Recipients Address]

April 22, 2020

URGENT FIELD SAFETY NOTICE:
Medical Device Field Safety Notice for Recall

Reference: R-2020-04
Concerned Devices: R3[◊] Acetabular Shells

Product No.	Description	Batch No.
See appendix 1	R3 Acetabular Shells	See appendix 2

Dear Customer:

This letter is to inform you that Smith+Nephew has initiated a voluntary recall to remove specific lots of R3 Acetabular Shells due to a manufacturing error. Use of the affected devices, which may not have been manufactured to their design specifications, may result in an intraoperative locking failure.

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

Risks to Health	In the most likely scenario, the devices will function as intended. To date, we have received six complaints regarding intraoperative locking failure. In the 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.
Actions to be taken by the user	1. Locate and quarantine affected unused devices immediately. 2. Please provide a copy of the attached Physician Communication to the surgical staff. 3. Return quarantined product to your national Smith+Nephew agency/distributor. 4. Complete the return slip and e-mail or fax it to your national Smith+Nephew agency/distributor. 5. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 6. Please maintain awareness on this notice and resulting action until the Field Safety Notice for Recall 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.

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We hereby confirm that we are aware of this Field Safety Corrective Action and it has been communicated within our organization and surgical staff.

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

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

Institution: _____ Reference: R-2020-04

Name: _____ Date / Signature: _____

Enclosure:

- Product Number and Product Description List (Appendix 1)
- Product and Lot Number List (Appendix 2)
- Physician Communication

Appendix 1: Product Number and Product Description List

Product Number	Description	Product Number	Product Description
71331842	R3 0 HOLE ACETABULAR SHELL 42MM	71335540	R3 3 HOLE ACETABULAR SHELL 40MM
71331848	R3 0 HOLE ACETABULAR SHELL 48MM	71335542	R3 3 HOLE ACETABULAR SHELL 42MM
71331850	R3 0 HOLE ACETABULAR SHELL 50MM	71335544	R3 3 HOLE ACETABULAR SHELL 44MM
71331852	R3 0 HOLE ACETABULAR SHELL 52MM	71335546	R3 3 HOLE ACETABULAR SHELL 46MM
71331854	R3 0 HOLE ACETABULAR SHELL 54MM	71335548	R3 3 HOLE ACETABULAR SHELL 48MM
71331856	R3 0 HOLE ACETABULAR SHELL 56MM	71335550	R3 3 HOLE ACETABULAR SHELL 50MM
71331858	R3 0 HOLE ACETABULAR SHELL 58MM	71335552	R3 3 HOLE ACETABULAR SHELL 52MM
71331860	R3 0 HOLE ACETABULAR SHELL 60MM	71335553	R3 3 HOLE ACETABULAR SHELL 53MM
71331942	R3 3 HOLE HA COATED ACETABULAR SHELL 42MM	71335554	R3 3 HOLE ACETABULAR SHELL 54MM
71331946	R3 3 HOLE HA COATED ACETABULAR SHELL 46MM	71335556	R3 3 HOLE ACETABULAR SHELL 56MM
71331948	R3 3 HOLE HA COATED ACETABULAR SHELL 48MM	71335558	R3 3 HOLE ACETABULAR SHELL 58MM
71331950	R3 3 HOLE HA COATED ACETABULAR SHELL 50MM	71335560	R3 3 HOLE ACETABULAR SHELL 60MM
71331952	R3 3 HOLE HA COATED ACETABULAR SHELL 52MM	71338663	R3 MULTI HOLE ACET SHELL 48MM
71331954	R3 3 HOLE HA COATED ACETABULAR SHELL 54MM	71338664	R3 MULTI HOLE ACET SHELL 50MM
71331956	R3 3 HOLE HA COATED ACETABULAR SHELL 56MM	71338665	R3 MULTI HOLE ACET SHELL 52MM
71331958	R3 3 HOLE HA COATED ACETABULAR SHELL 58MM	71338666	R3 MULTI HOLE ACET SHELL 54MM
71331960	R3 3 HOLE HA COATED ACETABULAR SHELL 60MM	71338667	R3 MULTI HOLE ACET SHELL 56MM
71331962	R3 3 HOLE HA COATED ACETABULAR SHELL 62MM	71338668	R3 MULTI HOLE ACET SHELL 58MM
71331964	R3 3 HOLE HA COATED ACETABULAR SHELL 64MM	71338733	R3 HA MULTI-HOLE ACETABULAR SHELL 48MM
71331968	R3 3 HOLE HA COATED ACETABULAR SHELL 68MM	71338734	R3 HA MULTI-HOLE ACETABULAR SHELL 50MM
71332242	R3 0 HOLE HA COATED ACETABULAR SHELL 42MM	71338735	R3 HA MULTI-HOLE ACETABULAR SHELL 52MM
71332246	R3 0 HOLE HA COATED ACETABULAR SHELL 46MM	71338736	R3 HA MULTI-HOLE ACETABULAR SHELL 54MM
71332248	R3 0 HOLE HA COATED ACETABULAR SHELL 48MM	71338737	R3 HA MULTI-HOLE ACETABULAR SHELL 56MM
71332250	R3 0 HOLE HA COATED ACETABULAR SHELL 50MM	71338738	R3 HA MULTI-HOLE ACETABULAR SHELL 58MM
71332252	R3 0 HOLE HA COATED ACETABULAR SHELL 52MM	71338740	R3 HA MULTI-HOLE ACETABULAR SHELL 62MM
71332254	R3 0 HOLE HA COATED ACETABULAR SHELL 54MM	71338741	R3 HA MULTI-HOLE ACETABULAR SHELL 64MM
71332256	R3 0 HOLE HA COATED ACETABULAR SHELL 56MM		
71332258	R3 0 HOLE HA COATED ACETABULAR SHELL 58MM		
71332260	R3 0 HOLE HA COATED ACETABULAR SHELL 60MM		
71332262	R3 0 HOLE HA COATED ACETABULAR SHELL 62MM		
71332264	R3 0 HOLE HA COATED ACETABULAR SHELL 64MM		

Appendix 2: Product and Lot Number List

Product Number	Lot Number
71331842	18HM20691, 18KM15724, 18LM09819
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71338741	19AM22770, 19AM22770A

Physician Communication

Smith+Nephew Action: Voluntary Recall
Recall Reference: R-2020-04
Affected Product: R3 Acetabular Shells
Details of Affected Product: See attached

Dear Doctor,

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

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. In all six complaints received for the locking failure, a substitute device was used and the procedure was completed successfully. In the worst-case scenario, a ceramic liner, appearing to fully lock intraoperatively with the acetabular shell, may fracture post-operatively necessitating a revision procedure. However, there have been no reports of this occurring.

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. In addition, they are asked to manage affected devices per the associated Urgent Medical Device Recall Notice.

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,



Dr. Luca Orlandini MD
Vice President Medical Affairs

Smith+Nephew