

[Recipients Address]

May 04, 2017

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Corrective Action / Recall

Reference: R-2017-08

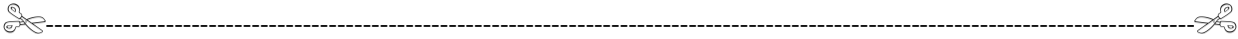
Concerned Devices: BHR Acetabular Cup

Product No.	Description	Batch No.
74120156	ACETABULAR CUP HAP 56MM W/ IMPTR	16FW05491 & 16FW06292
74122162	ACETABULAR CUP HAP SIZE 56/62	16FW07740; 16FW07750; 16FW07751

Dear Customer

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily remove several lots of BIRMINGHAM HIP Acetabular cups due to a manufacturing issue. The wire was assembled incorrectly; when a curved or offset introducer is used the wire will not assemble onto the introducer.

Risks to Health	In the event the affected device is presented for use, the user would have difficulty attaching the cup to the curved or offset introducer potentially resulting in a surgical delay.
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.



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 hereby confirm that we are aware of this Field Safety Notice. The Field Safety Notice was communicated within our organisation.

Please mark accordingly:

In our facility we do not have any of the affected product in stock
or

We will return the following products:

Product	Description	Qty. to be Returned / Lot Number				
74120156	ACETABULAR CUP HAP 56MM W/ IMPTR		16FW0549 1		16FW0629 2	
74122162	ACETABULAR CUP HAP SIZE 56/62		16FW0774 0		16FW0775 0	16FW0775 1

Institution

: _____ Reference: R-2017-08

Name: _____ Date / Signature: _____