Smith & Nephew Inc
1450 Brooks Road
Memphis, TN 38116

T +1 901-396-2121
www.smith-nephew.com

[Recipients Address]

November 15, 2016

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

Reference: R-2016-48
Concerned Devices: Modular Neck Hip Prostheses of the Modular SMF° and Modular REDAPT° Revision Femoral Hip Systems.

Please find the product details and affected lots attached.

Dear Sir or Madam

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary market removal for all lots of modular neck hip prostheses due to a higher than anticipated complaint and adverse event trend.
As a result of this voluntary market removal of the modular neck, which is a common component of the Modular SMF° and Modular REDAPT° Revision Femoral Hip Systems, the associated stems will also be removed from the market.
The affected devices were shipped: October 2008 through July 2016.

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

Risks to Health	In the worst case scenario implanted patients are symptomatic and exhibits adverse tissue reaction to metal debris which may lead to revision surgery.
Enclosure	Please find the associated Dear Doctor letter attached. Please ensure that each surgeon who has used the affected modular neck hip prostheses is provided a copy of the enclosed letter along with a copy of the product detail list.
Actions to be taken by the user	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 concerning the Modular Neck Hip Prostheses. 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	Lot Numbers	Qty. Returned	Product	Description	Lot Numbers	Qty. Returned
71352401	SMF STEM RSA SIZE 1			71352501	SMF STEM WITH STIKTITE SZ 1		
71352402	SMF STEM RSA SIZE 2			71352502	SMF STEM WITH STIKTITE SZ 2		
71352403	SMF STEM RSA SIZE 3			71352503	SMF STEM WITH STIKTITE SZ 3		
71352404	SMF STEM RSA SIZE 4			71352504	SMF STEM WITH STIKTITE SZ 4		
71352405	SMF STEM RSA SIZE 5			71352505	SMF STEM WITH STIKTITE SZ 5		
71352406	SMF STEM RSA SIZE 6			71352506	SMF STEM WITH STIKTITE SZ 6		
71352407	SMF STEM RSA SIZE 7			71352507	SMF STEM WITH STIKTITE SZ 7		
71352408	SMF STEM RSA SIZE 8			71352508	SMF STEM WITH STIKTITE SZ 8		
71352409	SMF STEM RSA SIZE 9			71352509	SMF STEM WITH STIKTITE SZ 9		
71354061	MOD NECK HO +10 NECK HEIGHT			71354362	REDAPT MODULAR SLVD STEM 240MM SZ 17		
71354312	REDAPT PF STEM 240MM SZ 12			71354363	REDAPT MODULAR SLVD STEM 240MM SZ 18		
71352111	STANDARD OFFSET NEUTRAL MODULAR NECK			71352112	HIGH OFFSET NEUTRAL MODULAR NECK		
71352116	LEFT ANTEVERTED MODULAR NECK			71352117	RIGHT ANTEVERTED MODULAR NECK		
71354313	REDAPT PF STEM 240MM SZ 13			71354364	REDAPT MODULAR SLVD STEM 240MM SZ 19		
71354314	REDAPT PF STEM-240MM SZ 14			71354365	REDAPT MODULAR SLVD STEM 240MM SZ 20		
71354315	REDAPT PF STEM-240MM SZ 15			71354366	REDAPT MOD SLVD STEM 240MM SZ 21		
71354316	REDAPT PF STEM-240MM SZ 16			71354367	REDAPT MOD SLVD STEM 240MM SZ 22		
71354317	REDAPT PF STEM 240MM SZ 17			71354368	REDAPT MOD SLVD STEM 240MM SZ 23		

Product	Description	Lot Numbers	Qty. Returned	Product	Description	Lot Numbers	Qty. Returned
71354318	REDAPT PF STEM-240MM SZ 18			71354369	REDAPT MOD SLVD STEM 240MM SZ 24		
71354319	REDAPT PF STEM-240MM SZ 19			71354370	REDAPT MOD SLVD STEM 240MM SZ 25		
71354320	REDAPT PF STEM-240MM SZ 20			71354371	REDAPT MOD SLVD STEM 240MM SZ 26		
71354321	REDAPT PF STEM-240MM SZ 21			71354372	REDAPT MOD SLVD STEM 240MM SZ 27		
71354322	REDAPT PF STEM-240MM SZ 22			71354374	REDAPT MOD SLVD STEM 300MM SZ 12		
71354323	REDAPT PF STEM-240MM SZ 23			71354375	REDAPT MOD SLVD STEM 300MM SZ 13		
71354324	REDAPT PF STEM-240MM SZ 24			71354376	REDAPT MOD SLVD STEM 300MM SZ 14		
71354325	REDAPT PF STEM-240MM SZ 25			71354377	REDAPT MOD SLVD STEM 300MM SZ 15		
71354326	REDAPT PF STEM-240MM SZ 26			71354378	REDAPT MOD SLVD STEM 300MM SZ 16		
71354327	REDAPT PF STEM-240MM SZ 27			71354379	REDAPT MOD SLVD STEM 300MM SZ 17		
71354328	REDAPT PF STEM-300MM SZ 12			71354380	REDAPT MOD SLVD STEM 300MM SZ 18		
71354329	REDAPT PF STEM-300MM SZ 13			71354381	REDAPT MOD SLVD STEM 300MM SZ 19		
71354330	REDAPT PF STEM-300MM SZ 14			71354382	REDAPT MOD SLVD STEM 300MM SZ 20		
71354331	REDAPT PF STEM-300MM SZ 15			71354383	REDAPT MOD SLVD STEM 300MM SZ 21		
71354332	REDAPT PF STEM-300MM SZ 16			71354384	REDAPT MOD SLVD STEM 300MM SZ 22		
71354333	REDAPT PF STEM-300MM SZ 17			71354385	REDAPT MOD SLVD STEM 300MM SZ 23		
71354334	REDAPT PF STEM-300MM SZ 18			71354386	REDAPT MOD SLVD STEM 300MM SZ 24		
71354335	REDAPT PF STEM-300MM SZ 19			71354387	REDAPT MOD SLVD STEM 300MM SZ 25		
71354336	REDAPT PF STEM-300MM SZ 20			71354388	REDAPT MOD SLVD STEM 300MM SZ 26		
71354337	REDAPT PF STEM-300MM SZ 21			71354389	REDAPT MOD SLVD STEM 300MM SZ 27		
71354338	REDAPT PF STEM-300MM SZ 22			71354404	REDAPT PF STEM 300MM SZ 26		
71354339	REDAPT PF STEM-300MM SZ 23			71354405	REDAPT PF STEM 300MM SZ 27		
71354340	REDAPT PF STEM-300MM SZ 24			71354407	REDAPT MOD SLEEVED STEM 240MM SZ 12		
71354341	REDAPT PF STEM 300MM SZ 25			71354408	REDAPT MOD SLVD STEM 240MM SZ 13		
71354001	MDF REV IMPLANT 240MM SZ 11			71354409	REDAPT MODULAR SLVD STEM 240MM SZ 14		
71354015	MDF REV IMPLANT 300MM SZ 11						
71354360	REDAPT MODULAR SLVD STEM 240MM SZ 15						
71354361	REDAPT MODULAR SLVD STEM 240MM SZ 16						

Institution: _____ Reference: R-2016-48

Name: _____ Date / Signature: _____

Smith & Nephew Inc.
1450 Brooks Road
Memphis, TN 38116

T 901-396-2121

www.smith-nephew.com

Affected Product: **modular neck hip prostheses**
FSCA reference: R-2016-48
FSCA action: Voluntary Market Removal
Details of affected product: See below

Dear Dr.

This letter is to inform you of a voluntary market removal of modular neck hip prostheses manufactured by Smith & Nephew, Inc. USA. This letter provides an update concerning the ongoing performance of these prostheses in patients implanted with these devices.

As a result of this voluntary market removal of the modular neck, which is a common component to the Modular SMF® and Modular REDAPT® Revision Femoral Hip Systems, the associated stems will no longer be available and will also be removed from the market.

The Monolithic SMF and Monolithic REDAPT Revision Femoral Hip Systems are not affected by this field action.

Background
In compliance with post-marketing surveillance obligations, Smith & Nephew continually monitors the performance of its products. During a recent review of product complaints received by Smith & Nephew and clinical study data associated with the modular hip prostheses, we observed a rate of complaints higher than comparable monolithic hip prostheses.

Metal-related complaints are trending upward year-on-year with an overall complaint rate (number of complaints/total implantations) of 0.527% for Modular SMF and 0.25% for Modular REDAPT Revision Femoral Hip Systems. Overall, the metal-related Adverse Events accounted for the highest category of complaints in both products.

Context and reasons for this FSCA
Based on an analysis of available data sets, Smith & Nephew considers that patients implanted with the modular neck hip prostheses may be at greater risk of revision surgery than with comparable monolithic products. For this reason, on a precautionary basis Smith & Nephew is issuing a voluntary field safety corrective action for the modular neck hip prostheses. Please carefully review the information contained below as regards steps that need to be taken for the voluntary market removal. With this voluntary market removal of the modular neck, the Modular SMF® and Modular REDAPT® Revision Femoral Hip Systems will be removed as well from the market.

For avoidance of doubt, this voluntary measure does not affect the Monolithic SMF and Monolithic REDAPT Revision Femoral Hip Systems. Smith & Nephew has not received similar reports of metal-related complaints associated with these systems.

The voluntary market removal is being reported to the relevant regulatory authorities.

Information relating to patient safety
Physicians should maintain their routine follow-up protocol for patients who have undergone total hip arthroplasty and continue to monitor for pain, swelling, limited mobility and enlarged bursa.

For patients that exhibit these symptoms, physicians may consider additional clinical follow-up which includes the following:

- Cobalt/Chromium metal-ion level measurements in whole blood – metal ion levels in excess of 7ppb* may indicate the potential for soft tissue reaction; and
- Where appropriate and subject to the clinician's assessment, further active evaluation of the potential soft tissue reactions either through ultrasound or cross-sectional imaging might be indicated.

The need for any additional follow-up should be determined on an individual case-by-case basis following an assessment of patients' clinical circumstances.

Follow-up examinations should be repeated for symptomatic patients annually for the lifetime of the device to potentially help reduce the risk of complication and the need for additional surgery.

Smith & Nephew is not advising that physicians conduct pro-active revision surgery for patients implanted with the modular neck hip prostheses. If the blood metal ion level is above 7 ppb, a higher frequency of monitoring (e.g. every 3 months) might be considered. Revision surgery should only be considered after a comprehensive examination of all the clinical findings, including blood work, imaging and especially if an adverse soft-tissue reaction is confirmed.

---

* http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_042.pdf

Smith & Nephew is committed to distributing only products of the highest quality standards and to 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,

[redacted]

Smith & Nephew