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

1-901-396-2121
1-800-821-5700
www.smith-nephew.com

June 13, 2018

Urgent Field Safety Notice

NOTE: This notice does not affect the JOURNEY® II BCS Knee System

Affected Product: **First generation JOURNEY® BCS introduced 2005, phased-out 2013-14**
- **femoral component (voluntary removal)**
- **tibial insert (advisory notice)**

FSCA reference: R-2018-26
FSCA action: Advisory Notice and Voluntary Removal
Details of affected product: See below

Dear Customer,

This letter is to inform you of a voluntary Field Safety Corrective Action (FSCA) in relation to the first generation JOURNEY® BCS femoral and tibial insert components, manufactured by Smith & Nephew Inc. Memphis, TN ('Smith & Nephew'). For avoidance of doubt, **this field action does not affect the JOURNEY® II BCS Knee System**.

This field action is being reported to relevant regulatory authorities.

Please find the product details and affected lots attached.

Background

The first generation JOURNEY BCS femoral components were phased out globally in 2013-14 as part of Smith & Nephew's continuing development of its commercial strategy and innovative technologies and are no longer available for sale. Review of post-market surveillance data on this phased-out prosthetic knee construct prompted this action.

Potential Risk with the Use of the Product

Our analysis of available post-market surveillance data suggests that patients that have been implanted with a first generation JOURNEY® BCS Knee System may have a higher risk of requiring a revision earlier than they or their surgeon had expected. The reasons for revision of JOURNEY BCS are the same as those seen for other primary total knee systems, albeit at a rate higher than expected.

Context and reasons for this FSCA

As part of its post-market surveillance (PMS) and post-marketing clinical follow-up processes, Smith & Nephew has conducted an analysis of the National Joint Registry of England, Wales and Northern Ireland (NJREWNI) and Australian Orthopaedic Association National Joint Replacement Registry

(AOANJRR) data on the first generation JOURNEY® BCS Knee System. The data indicate that the system has a revision rate over 1.5 times the primary total knee arthroplasty device class average revision rates in the NJREWNI and AOANJRR.
We conducted a Health Hazard Evaluation (HHE) to review these analyses and as a result of its review of the available data, Smith & Nephew is taking the following actions:

- We are issuing this Field Safety Corrective Action in each jurisdiction where the first generation JOURNEY® BCS was used, to inform implanting surgeons of the higher than expected rate of revision for patients in whom the first generation JOURNEY BCS was implanted.
- We are contacting accounts where first generation JOURNEY BCS femoral components were supplied before the phase out of the product to ensure that no further inventory specific to first generation JOURNEY BCS (as listed below) remains at those facilities, and any such components remaining are not used but returned to Smith & Nephew.
- We are communicating that the first generation JOURNEY BCS tibial insert **remains available** for use but should only be used for polyethylene exchange revision of first generation JOURNEY BCS total knee constructs where the femoral component and tibial baseplate are well fixed. For avoidance of doubt, the first generation JOURNEY BCS tibial inserts are not subject to a voluntary removal.

Enclosure
Please find the associated surgeon letter attached. Please ensure that each surgeon who has used the first generation JOURNEY BCS Knee System is provided a copy of the enclosed letter along with a copy of the product detail list.

Information relating to patient safety
Physicians should maintain their routine follow-up protocol for patients who have undergone total knee arthroplasty with the first generation JOURNEY BCS Knee System.

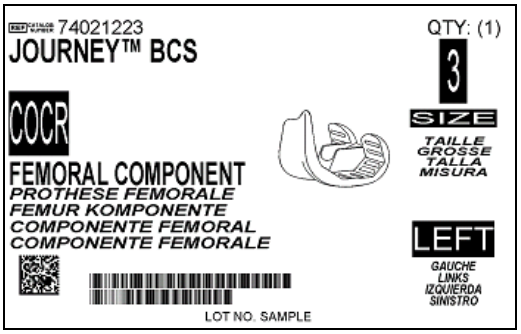
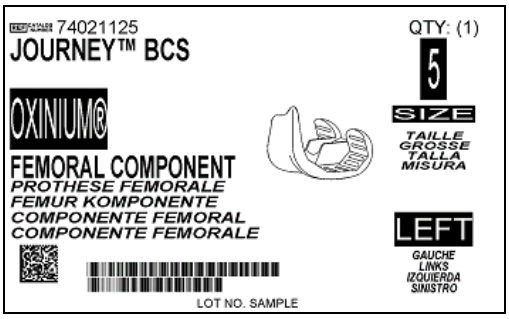
Signs and symptoms to consider for a potential revision are no different from those that might be reported by any patient having undergone primary total knee arthroplasty. The need for revision should be determined on a case-by-case basis following a detailed assessment of each patient's clinical circumstances. Smith & Nephew is not recommending pro-active revision surgeries for patients implanted with this device.

Please fill in the acknowledgment of receipt enclosed in this notice and make sure this safety information is passed on to all those who need to be aware of it within your organization.

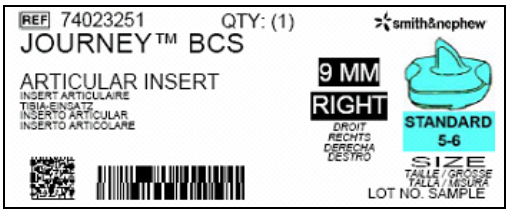
Actions to be taken by Hospital Representatives and Smith & Nephew Personnel
Please follow the instructions on the attached Response Form.

Affected Products
This FSCA is applicable to the following products:

JOURNEY® BCS Femoral Components – subject to voluntary removal

Product Description	Catalogue Numbers	Batches/Lots
JOURNEY® BCS CoCr Femoral Component 	74021210, 74021211, 74021212, 74021213, 74021214, 74021215, 74021216, 74021217, 74021218, 74021219, 74021220, 74021221, 74021222, 74021223, 74021224, 74021225, 74021226, 74021227, 74021228, 74021229	All Batches
JOURNEY® BCS OXINIUM® Femoral Component 	74021110, 74021111, 74021112, 74021113, 74021114, 74021115, 74021116, 74021117, 74021118, 74021119, 74021120, 74021121, 74021122, 74021123, 74021124, 74021125, 74021126, 74021127, 74021128, 74021129, 74021130, 74021131, 74021132, 74021133, 74021134, 74021135, 74021136, 74021137, 74021138, 74021139, 74021140, 74021141, 74021142, 74021143, 74021144, 74021145, 74021146, 74021147, 74021148, 74021149	All Batches

JOURNEY° BCS Referenced Products - catalogue numbers subject to Advisory Notice (not for removal)

Product Description	Catalogue Numbers	Batches/Lots
JOURNEY° BCS Tibial Insert 	74023111, 74023112, 74023113, 74023114, 74023115, 74023116, 74023117, 74023118, 74023121, 74023122, 74023123, 74023124, 74023125, 74023126, 74023127, 74023128, 74023131, 74023132, 74023133, 74023134, 74023135, 74023136, 74023137, 74023138, 74023141, 74023142, 74023143, 74023144, 74023145, 74023146, 74023147, 74023148, 74023211, 74023212, 74023213, 74023214, 74023215, 74023216, 74023217, 74023218, 74023221, 74023222, 74023223, 74023224, 74023225, 74023226, 74023227, 74023228, 74023231, 74023232, 74023233, 74023234, 74023235, 74023236, 74023237, 74023238, 74023241, 74023242, 74023243, 74023244, 74023245, 74023246, 74023247, 74023248, 74023251, 74023252, 74023253, 74023254, 74023255, 74023256, 74023257, 74023258, 74023261, 74023262, 74023263, 74023264, 74023265, 74023266, 74023267, 74023268, 74023271, 74023272, 74023273, 74023274, 74023275, 74023276, 74023277, 74023278, 74023281, 74023282, 74023283, 74023284, 74023285, 74023286, 74023287, 74023288, 74023311, 74023312, 74023313, 74023314, 74023315, 74023316, 74023317, 74023318, 74023321, 74023322, 74023323, 74023324, 74023325, 74023326, 74023327, 74023328, 74023331, 74023332, 74023333, 74023334, 74023335, 74023336, 74023337, 74023338, 74023341,	All Batches

	74023342, 74023343, 74023344, 74023345, 74023346, 74023347, 74023348, 74023411, 74023412, 74023413, 74023414, 74023415, 74023416, 74023417, 74023418, 74023421, 74023422, 74023423, 74023424, 74023425, 74023426, 74023427, 74023428, 74023431, 74023432, 74023433, 74023434, 74023435, 74023436, 74023437, 74023438, 74023441, 74023442, 74023443, 74023444, 74023445, 74023446, 74023447, 74023448, 74023451, 74023452, 74023453, 74023454, 74023455, 74023456, 74023457, 74023458, 74023461, 74023462, 74023463, 74023464, 74023465, 74023466, 74023467, 74023468, 74023471, 74023472, 74023473, 74023474, 74023475, 74023476, 74023477, 74023478, 74023481, 74023482, 74023483, 74023484, 74023485, 74023486, 74023487, 74023488, 74023648, 74203326	

Urgent Medical Device Removal Notice
R-2018-26

June 13, 2018
<Insert Address>

PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Required Actions:

1. Please inspect your inventory and locate any devices from the listed product and batch numbers on the first page of this Field Action Notification, and quarantine them immediately.
    a. If you are a distributor, you must notify your customers of the field action and ensure that these actions are carried out.
2. If you have no product to return, please put an X in the appropriate location below.
3. If you have product to return, please list the batch numbers and quantities of each batch that you are returning in the appropriate boxes below.
4. Complete the remainders of the form sign and send to FieldActions@smith-nephew.com or fax to 901-566-7975.
   Please Note – even if you have no product to return, this form must be completed, signed and returned.
5. Once the form is received by Smith & Nephew, you will be sent a Return Authorization (RA) number.

If you have any questions or concerns regarding this voluntary removal please contact FieldActions@smith-nephew.com.

No Product to Be Returned ☐

Product Part Number	Batch Number (List Specific Batch #'s to be Returned)	Quantity of Units to be Returned

We hereby confirm that we are aware of this Medical Device Field Action and it has been communicated within our organization.

Printed Name (required): _____Title: _____

Signature (required):_____ Date (required):____/____/____

Email:_____ Telephone: (___) _____-_____

S&N Account Number: _____ RA Number (S&N use only):_____

Name of Organization(s) Covered by Response: _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | Building G, 1450 Brooks Rd. East| Memphis, TN 38116

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Required actions

Please fill in the acknowledgment of receipt enclosed in this notice and make sure this safety information is passed on to all those who need to be aware of it within your organization.

Smith & Nephew is committed to distributing only products of the highest quality and to providing support to surgeons and patients who use those products.

If you have any questions, please contact Debbie Phillips at +1 901-399-5635 or by e-mail: fieldactions@smith-nephew.com.

Yours sincerely,

Andy Weymann, MD
Chief Medical Officer
Smith & Nephew, Inc.

Smith & Nephew Inc
1450 Brooks Road
Memphis, TN 38116

T 901-396-2121

www.smith-nephew.com

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Return Slip

Please complete and return this acknowledgement form to fieldactions@smith-nephew.com.

☐ We confirm the receipt of this Advisory Notice

Institution: _____ Reference: R-2018-26

Name: _____ Date/Signature: _____