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January 12, 2017

To: Surgeons, Health Care Professionals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE / INFORMATION**

Reference: **FA 2017-01 (ZFA 2016-164)**

Affected Product: **Revitan® Straight and Curved Distal Stems (List in attachment 2)**

Dear Sir or Madam/ Dear Health Care Professional,

This notice is to inform you that Zimmer GmbH is conducting a voluntary medical device Field Safety Notice for the Revitan Revision System. This Field Safety Notice is to provide information on the use of the Revitan Revision System and is jointly provided with the latest updated surgical techniques with references 06.01169.012X - Ed 2016.11 – rev. 03 for the Revitan Curved and 06.01109.012X - Ed 2016.11 – rev. 04 for the Revitan Straight [1].

Zimmer GmbH would like to emphasize that patient selection for modular hip revision systems, such as the Revitan system, is a key parameter. Modular stems have been used in revision surgery for many years and provide advantages for issues that are frequently encountered in a revision setting.[2] However, a modular system also comes with the risk for potential stem fractures.[3] This is a rare complication of modular revision stems caused, most commonly, by large stresses to the modular junction when the proximal component lacks medial bone contact at the calcar.[4,5] The risk of stem failure is not unique to any one modular system. [6,7,8,9,10] Bone stock of adequate quality must be present and appraised at the time of surgery. For patients with severe proximal deficiency, a surgeon should consider surgical options to ensure proximal bone support (such as medial and/or lateral strut grafts) or switching to a monobloc revision stem, such as the Wagner SL Revision® Hip Stem. Please review the indications and contra indications in the associated surgical techniques and Instructions for Use of the Revitan Revision System.

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[1] *English version, other languages available.*
[2] *Murray, et al. Modularity in Revision Total Hips: The Use of the Distally-Fixed Stem. Seminars in Arthroplasy, 2008*
[3] *Sekundiak, T., A Modular Hip System for Simplification of Revision Hip Arthroplasty. American Journal of Orthopedics, 2010; 39:7-12*
[4] *Fink, B., Urbansky, K., & Schuster, P. (2014). Midterm results with the curved modular tapered, fluted titanium Revitan stem in revision hip replacement. Bone Joint J, 96-B(7), 889-895*
[5] *Buttaro, M.A., Mayor, M.B., Van Citters, D. et al. Fatigue fracture of a proximally modular, distally tapered fluted implant with diaphyseal fixation. Journal of Arthroplasty, 22(2007), 780.*
[6] *Kwong, L.M, Miller, A.J, Lubinus, P. A modular distal fixation option for proximal bone loss in revision total hip arthroplasty: a 2-to-6 year follow-up study. Journal of Arthroplasty, 18 (3 Suppl 1) (2003), S22.*
[7] *Rodriguez, J., Fada, R. Murphy, S.B., et al. Two year to five year follow-up on femoral defects in femoral revision treaded with the Link MP modular stem. Journal of Arthroplasty, 24 (2009), 94.*
[8] *Slover, James, et al. "Fatigue failure of newer generation modular revision femoral stem following fracture healing: a case report." Bulletin of the NYU Hospital for Joint Diseases 73.1 (2015): 54.*
[9] *Ele, T., Schmitt, J. Analyses of prosthesis stem failures in noncemented modular hip revisin prostheses. Journal of Arthroplasty (2011); 665-667.*
[10] *Skytta, E.T., Eskelinen, A., Remes, V. Successful femoral reconstruction with a fluted and tapered modular distal fixatin stem in revisin total hip arthroplasty. Scandinavian Journal of Surgery (2012): 101; 222-226.*

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Potential Risks associated with the issue:

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	Pain	Revision surgery due to breakage of the stem. Additional possible complications in order to achieve the removal of the broken prosthesis: Transfemoral approach necessary to remove fractured implant which leads to a significant prolongation of initial surgery time. An additional damage of tissue and bone quantity may be expected.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	Pain	Potential increased infection risk due to prolongation of surgery time and additionally a potential prolongation of healing time. The mobility phase of the patient will be decreased due to the fact that an immediate loading after a transfemoral approach is not applicable. An additional damage of tissue and bone quantity may be expected.

Please note that the latest revision rates for the Revitan Revision System due to breakages, as monitored on regular basis by Zimmer GmbH are within acceptable rates.

Our records indicate that you are using the Revitan Revision System.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall Field Safety Notice that are recommended beyond your existing follow up schedule.
3. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to uk.fieldaction@zimmerbiomet.com or to your local Zimmer Biomet contact
    b. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your documentation.

4. If after reviewing the notice you have further questions or concerns please discuss them with your Zimmer Biomet sales representative.

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Other Information

This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.uk@zimmerbiomet.com or to your local Zimmer Biomet contact.

Specific to Canada only: Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. This action is being taken with the knowledge of Health Canada and is in compliance with regulations set forth by Health Canada. Your urgent cooperation is needed.

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

We would like to thank you for your co-operation in advance.

Sincerely,

Matthias Bürger

Zimmer Biomet Vice President QARC EMEA

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ATTACHMENT 1
Certificate of Acknowledgement

By signing below, I acknowledge that the required actions have been taken in accordance with the Field Safety Notice.

[ ] **Hospital Facility** [ ] **Surgeon** (Please check one as applicable)

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date:**____/____/____

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to:

Uk.fieldaction@zimmerbiomet.com or to your local Zimmer Biomet contact.

ATTACHMENT 2- Affected Product List

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Description	Material
REVITAN dist. straight 14/120	01.00405.014
REVITAN dist. straight 14/140	01.00405.114
REVITAN dist. straight 16/140	01.00405.116
REVITAN dist. straight 18/140	01.00405.118
REVITAN dist. straight 20/140	01.00405.120
REVITAN dist. straight 22/140	01.00405.122
REVITAN dist. straight 24/140	01.00405.124
REVITAN dist. straight 14/200	01.00405.214
REVITAN dist. straight 16/200	01.00405.216
REVITAN dist. straight 18/200	01.00405.218
REVITAN dist. straight 20/200	01.00405.220
REVITAN dist. straight 22/200	01.00405.222
REVITAN dist. straight 24/200	01.00405.224
REVITAN dist. straight 26/200	01.00405.226
REVITAN dist. straight 28/200	01.00405.228
REVITAN dist. straight 16/260	01.00405.316
REVITAN dist. straight 18/260	01.00405.318
REVITAN dist. straight 20/260	01.00405.320
REVITAN dist. straight 22/260	01.00405.322
REVITAN dist. straight 24/260	01.00405.324
REVITAN dist. straight 26/260	01.00405.326
REVITAN dist. straight 28/260	01.00405.328
REVITAN dist. curved 14/140	01.00406.114
REVITAN dist. curved 16/140	01.00406.116
REVITAN dist. curved 18/140	01.00406.118
REVITAN dist. curved 20/140	01.00406.120
REVITAN dist. curved 22/140	01.00406.122
REVITAN dist. curved 24/140	01.00406.124
REVITAN dist. curved 14/200	01.00406.214
REVITAN dist. curved 16/200	01.00406.216
REVITAN dist. curved 18/200	01.00406.218
REVITAN dist. curved 20/200	01.00406.220
REVITAN dist. curved 22/200	01.00406.222
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REVITAN dist. curved 26/260	01.00406.326
REVITAN dist. curved 28/260	01.00406.328