ZIMMER BIOMET

January XX, 2017

To: Dentists and Health Care Professionals

Subject: **URGENT MEDICAL DEVICE REMOVAL**

Affected Product: Hexagonal Driver – Medium- 1.2

Item Number	Lot Number
131011	032887

Zimmer Biomet is conducting a medical device lot specific recall for the Hexagonal Driver - Medium-size 1.2. Through investigation, it was determined that when the clinician torques an abutment or abutment screw with the prosthetic driver, it could deform resulting in an inconvenience, annoyance, temporary discomfort and/or compromised product performance. A new driver would be required to complete the procedure.

Risks		
Immediate / Long-range	Most Probable	Worst Case
Immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Inconvenience, annoyance, temporary discomfort and/or compromised product performance.	Inconvenience, annoyance, temporary discomfort and/or compromised product performance.
Long-range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	None	None

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of 13OCT2015 and 30OCT2015.

Dentists and Health Care Professional's Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow up schedule.
3. Complete Attachment 1 – Inventory Return Certification Form
    a. Return a digital copy to Vigilance.EU@zimmerbiomet.com or fax to **+34 93 193 42 79**
    b. Retain a copy of the Inventory Return Certification Form with your recall records in the event of a compliance audit of your facilities documentation.
4. Immediately return all affected product within your control along with a completed Attachment 1 – Inventory Return Certification Form to Zimmer Biomet.

a. Customer Service will send you an e-mail or fax with the **RMA number** within a few days.
b. The product will be picked up by a courier agency. Please include Attachment 1 and the RMA document with the product return package. Provide the pickup address and preferred product pick up date within one week on Attachment 1.
c. Upon receipt of the returned affected product, replacement product will be ordered by Zimmer Biomet customer service and immediately shipped.

5. If after reviewing this notice you have further questions or concerns please call the customer call center at **+44 (0) 800 652 1233** during normal business hours, Monday through Friday. Alternatively, your questions may be sent by email to Vigilance.EU@zimmerbiomet.com.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing 3iEUComplaints@zimmerbiomet.com.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies. Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local health authority in your country.

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this recall.

Sincerely,

_____

<Printed Name and Title>

ATTACHMENT 1
Inventory Return Certification Form

Return Authorization _____

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

An exhaustive search for the affected lots has been performed and all available affected product is being returned to Zimmer Biomet; any product not returned or found in inventory are considered consumed/lost and unavailable for use.	**Check one of the following:**			
	Yes		**No**	

☐ **Credit My Account**

Item Number	Lot Number	Quantity Returned

Complete this table for all affected items returned. If additional space is needed, please enter the above information on a spreadsheet and return with this form via email to Vigilance.EU@zimmerbiomet.com or via fax to **+34 93 371 78 49.**

Customer Information

Customer Name: _____ Customer Number: _____

Facility Name: _____

Facility Address: _____

Postal Code: _____ City: _____

Product Pickup Information

Facility Name: _____

Facility Address: _____

Postal Code: _____ City: _____

Preferred Pickup Date (within 7 days): _____

Certificate of Acknowledgement:

By signing below, I acknowledge that received, read, and understand the contents of this recall communication. All required activities are complete or are being completed.

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** ( ) ____-_____ x _____ **Date:** ___/___/_____

Note: This form and affected product 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: Vigilance.EU@zimmerbiomet.com **in addition to including a copy with your product returns.**

Please do not return recalled product with other returns.