October **, 2017

To: Clinicians

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: Hex Driver, 2.5 mm with GemLock® Retention

See Attachment 1 – Affected Product List

RHD2.5 Hex Driver

Zimmer Biomet is conducting a medical device recall for the 2.5 mm GemLock Hex Driver, RHD2.5. The RHD2.5 Hex Driver may contain a manufacturing condition affecting the geometry of the driver's hex feature, which prevents it from properly engaging with mating components.

The RHD2.5 Hex Driver is used to carry and drive the implant into the osteotomy by connecting to the Fixture Mount/Transfer or directly to the implant. This hex driver is compatible with all 2.5 mm platform sizes of Tapered Screw-Vent®, Trabecular Metal™, SwissPlus®, Tapered SwissPlus®, and Ad-Vent® Implants. Two instruments, RH2.5 and RHL2.5, may be utilized as alternatives to the RHD2.5. Please refer to the respective Surgical Manuals for proper instructions.

The RHD2.5 Hex Driver is distributed individually as well as in the instrument kits identified in **Attachment 1, Affected Product List**. However, it is not necessary to return the entire kit because only the RDH2.5 Driver is being recalled.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Delay in treatment	*Delay in treatment*
Describe long-range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	*None*

Our records indicate that you may have received one or more of the affected products. The affected units were sold between February 1, 2017 and August 15, 2017.

Clinician Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your normal follow-up schedule.
3. Review your inventory: Complete **Attachment 2 – Certificate of Acknowledgement** and send to Vigilance.EU@zimmerbiomet.com.
4. For each return, please contact customer service or send a copy of **Attachment 2 – Certificate of Acknowledgement** to: Vigilance.EU@zimmerbiomet.com.
5. Customer Service will organize the pick-up of the product and will provide you with an **RMA number**. Please include a copy of **Attachment 2** inside the package.
6. Replacement RHD2.5 hex drivers will be provided for returned hex drivers.
7. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
8. If you have further questions or concerns after reviewing this notice, please call (CS contact details) Alternatively, your questions may be emailed to Vigilance.EU@zimmerbiomet.com.

Other Information

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

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

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

ATTACHMENT 1
Affected Product List

NOTE: For Kit Items identified below, only the RHD2.5 driver is being recalled. It is not necessary to return the entire kit. The RH2.5 and RHL2.5 manual hex drivers are not affected.

Item Number	Lot Number	UDI Number	Item Description
RHD2.5	63563072	(01)00889024016705(10)63563072	Tool, Driver, Latchlock, Hex
RHD2.5	63572755	(01)00889024016705(10)63572755	Tool, Driver, Latchlock, Hex
RHD2.5	63583270	(01)00889024016705(10)63583270	Tool, Driver, Latchlock, Hex
RHD2.5	63755802	(01)00889024016705(10)63755802	Tool, Driver, Latchlock, Hex
OPCST	63666559	(01)00889024015890(10)63666559	Kit, Surgical, Complete
OPCST	63705907	(01)00889024015890(10)63705907	Kit, Surgical, Complete
STRKIT	63688941	(01)00889024017894(10)63688941	Surgical Kit, Starter
STRKIT	63698713	(01)00889024017894(10)63698713	Surgical Kit, Starter
STRKIT	63710867	(01)00889024017894(10)63710867	Surgical Kit, Starter
STRKIT	63726919	(01)00889024017894(10)63726919	Surgical Kit, Starter
STRKIT	63732673	(01)00889024017894(10)63732673	Surgical Kit, Starter
STRKIT	63759854	(01)00889024017894(10)63759854	Surgical Kit, Starter
TSVKIT	63581758	(01)00889024019614(10)63581758	Surgical Kit, Complete
TSVKIT	63583277	(01)00889024019614(10)63583277	Surgical Kit, Complete
TSVKIT	63587717	(01)00889024019614(10)63587717	Surgical Kit, Complete
TSVKIT	63623845	(01)00889024019614(10)63623845	Surgical Kit, Complete
TSVKIT	63632463	(01)00889024019614(10)63632463	Surgical Kit, Complete
TSVKIT	63632464	(01)00889024019614(10)63632464	Surgical Kit, Complete
TSVKIT	63666560	(01)00889024019614(10)63666560	Surgical Kit, Complete
TSVKIT	63669280	(01)00889024019614(10)63669280	Surgical Kit, Complete
TSVKIT	63676567	(01)00889024019614(10)63676567	Surgical Kit, Complete
TSVKIT	63676568	(01)00889024019614(10)63676568	Surgical Kit, Complete
TSVKIT	63693941	(01)00889024019614(10)63693941	Surgical Kit, Complete
TSVKIT	63694051	(01)00889024019614(10)63694051	Surgical Kit, Complete
TSVKIT	63715410	(01)00889024019614(10)63715410	Surgical Kit, Complete
TSVKIT	63716081	(01)00889024019614(10)63716081	Surgical Kit, Complete
TSVKIT	63724569	(01)00889024019614(10)63724569	Surgical Kit, Complete
TSVKIT	63724570	(01)00889024019614(10)63724570	Surgical Kit, Complete
TSVKIT	63728840	(01)00889024019614(10)63728840	Surgical Kit, Complete
TSVKIT	63735508	(01)00889024019614(10)63735508	Surgical Kit, Complete
TSVKIT	63735987	(01)00889024019614(10)63735987	Surgical Kit, Complete
TSVKIT	63739443	(01)00889024019614(10)63739443	Surgical Kit, Complete
TSVKIT	63743229	(01)00889024019614(10)63743229	Surgical Kit, Complete
TSVKIT	63748227	(01)00889024019614(10)63748227	Surgical Kit, Complete
TSVKIT	63750186	(01)00889024019614(10)63750186	Surgical Kit, Complete

ATTACHMENT 2
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: RHD2.5 Hex Driver **Field Action Reference:** ZFA 2017-351

Do you have affected product in your facility?

Please check one as applicable:

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

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 is closed for your account. It is important that you complete this form and email a copy to Vigilance.EU@zimmerbiomet.com or fax to +34 93 193 42 79.