October 16, 2017

To: Risk Managers and Surgeons

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: TunneLoc Tibial Fixation Devices

Item Description	Item Number	Lot(s)
TUNNELOC TIBIAL FIXATION 8MM	906512	All
TUNNELOC TIBIAL FIXATION 9MM	906513	All
TUNNELOC TIBIAL FIXATION 10MM	906514	All
TUNNELOC TIBIAL FIXATION 11MM	906515	All
8MM ACL IN A BOX	906532	All
9MM ACL IN A BOX	906533	All
10MM ACL IN A BOX	906534	All
11MM ACL IN A BOX	906535	All

Figure 1: TunneLoc Tibial Fixation Device

Zimmer Biomet is conducting a medical device recall for TunneLoc Tibial Fixation Device Family due to gamma sterilization validation testing associated with external pack vendors that indicates the sterilization dose may not be adequate.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	None
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Infection which is treatable with antibiotic therapy.	Revision due to infection, additional surgery with associated surgical risks.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between August 2011 and December 2016.

Risk Manager Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to [redacted]. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to [redacted].

Surgeon 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 existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to [redacted]
4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls

received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to [redacted].

Other Information
This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing product.experience@zimmerbiomet.com.

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

Sincerely,

[redacted]
Post Market Surveillance and Regulatory Compliance Director

ZIMMER BIOMET

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: TunneLoc Tibial Fixation Family

Field Action Reference: ZFA 2017-426

Please check one as applicable:

☐ Hospital Facility ☐ Surgeon

Do you have affected product in your facility?
(Hospital Facility Only: Please mark the appropriate response.)

☐ **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 CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-372-4265.