**Date Initiated by Firm**: August 15, 2019  
**Create Date**: September 12, 2019  
**Recall Status**: Open, Classified  
**Recall Number**: Z-2518-2019  
**Recall Event ID**: 83594  
**510(K)Number**: K132873  
**Product Classification**: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer  
**Product Code**: JWH  
**Product**: XP-XP Tibial Tray - Interlok 83 mm  
**Lot Number**: 559070 527660 677630 191210 219890 677620 758460 089950 283100 358850 283080 374620 321750 321770 358830 374580 374590 420310  
**Recalling Firm/Manufacturer**: Zimmer Biomet, Inc.  
56 E Bell Dr  
Warsaw IN 46582-6989  
**For Additional Information Contact**:  
411 Technical Services  
574-371-3071  
**Manufacturer Reason for Recall**: The locking bar not fully engaging  
**FDA Determined Cause**: Manufacturing material removal  
**Action**:  
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 provide instructions regarding return instructions.  
3. Complete Attachment 1 Certificate of Acknowledgement and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form will be returned even if you have no affected product. This form will be returned even if you have no affected product.  
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 5:00 pm EST, Mo-Sur.  
**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. A visual and audible confirmation should be made to ensure complete locking bar insertion.  
5. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility’s documentation.  
6. If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00 pm EST, Mo-Sur.  
**Quantity in Commerce**: 384 units  
**Distribution**:  
State  
NY  

![Class 2 Device Recall Vanguard XP](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=175837)
A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and recall cause determinations are subject to modification up to the point of termination of the recall.

The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

510(K)s with Product Code = JWH and Original Applicant = BIOMET, INC.