Class 2 Device Recall Vanguard Knee

**Date Initiated by Firm**: December 15, 2016

**Create Date**: February 16, 2017

**Recall Status**: Open, Classified

**Recall Number**: Z-1219-2017

**Recall Event ID**: 76178

**510(K)Number**: K142933

**Product Classification**: Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer


**Code Information**: Vanguard Total Knee, PUNCH THRU TRL PLATES, 63 MM Item No: 32-487261, 67 MM Item No: 32-487262, 71 MM Item No: 32-487263, 75 MM Item No: 32-487264, and 79 MM Item No: 32-487265; Lot No's: ZB160701, ZB160702, ZB160703, ZB160701, ZB160702, ZB160701, ZB160703, ZB160801, ZB160802, ZB160803, ZB160801, ZB160802

**Recalling Firm/Manufacturer**: Zimmer Biomet, Inc. 55 E Bell Dr Warsaw IN 46582-6989

**For Additional Information Contact**: Customer Service 800-348-2759

**Manufacturer Reason for Recall**: Zimmer Biomet is conducting a medical device recall for ARCOS & TPRLC broaches and rasps due to potential alumina inclusions in the raw material batch used to produce the affected products. Inclusions contained within the finished product could lead to the cracking and separation of the instrument.

**FDA Determined Cause**: Material/Component Contamination

**Action**: Zimmer Biomet is conducting a medical device recall for ARCOS & TPRLC broaches and rasps due to potential alumina inclusions in the raw material batch used to produce the affected products. Inclusions contained within the finished product could lead to the cracking and separation of the instrument.

**Quantity in Commerce**: 26

**Distribution**: Domestic: 0 Foreign: Singapore & Malaysia

**Total Product Life Cycle**: TPLC Device Report

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1. 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 it is updated for a final time when the recall is terminated.