**Class 2 Device Recall Tibial Alignment Guide**

**Date Posted**: June 02, 2015  
**Recall Status**: Open  
**Recall Number**: Z-1701-2015  
**Recall Event ID**: 7120224  
**Premarket Notification 510(K) Number**: K12232625  
**Product Classification**: Orthopedic Stereotactic Instrument26 - Product Code OLO27  
**Product**: Tibial Alignment Guide; Orthopedic Stereotactic Instrument;  
**Code Information**: Item Number: 20-8011-013-00; Lot Numbers: 120265; 110623; 120659; 120794; 120659-1; 130134; 120793; 130135  
**Recalling Firm/Manufacturer**: Zimmer CAS  
75 Queen St #3300  
Montreal  
**Manufacturer Reason for Recall**: Zimmer CAS has determined that the potential exists for the spikes on the iASSIST Tibial Alignment Guide to bend or break during insertion or extraction from the tibia during use.  
**FDA Determined Cause**: DESIGN: Device Design  
**Action**: Zimmer distributed notices via certified mail on May 14, 2015. Zimmer is removing affected Tibial Alignment Guide iAssist Knee System product from distribution in a two-phase process. Based upon complaint investigation, Zimmer CAS has determined that the potential exists for the spikes on the iASSIST Tibial Alignment Guide to bend or break during insertion or extraction from the tibia during use. Customers were asked to return the notification. For further notice, the iASSIST Surgical Knee Technique provided, further distribute the notice for any distributed product, inspect devices in use before and after procedures, report any adverse events, and complete the certificate of acknowledgment and return it to CorporateQuality PostMarket@zimmer.com. For questions regarding this recall, please contact Customer Service at the following address/phone number. Customer Service / Zimmer CAS 75 Queen Street, Suite 3300 Montreal, Quebec, Canada H3C 2N6 Email: cas-support@zimmercas.com, Telephone: 1-514-395-8883, toll free for North America 1-866-336-7848, Fax: 1-866-978-3801. For questions regarding this recall 574-372-4487.  
**Quantity in Commerce**: 78 devices  
**Distribution**: Nationwide Distribution including AL, AZ, CA, CO, FL, IN, MI, NJ, NY, OH, OR, PA, TX, VA, and WI.  
**Total Product Life Cycle**: TPLC Device Report28

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §455

2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.