



**Urgent Medical Device Recall Notice**  
**R-2018-38**

December 13, 2018

<Insert Address>

Dear Customer,  
cc: Chairman Medical Board and relevant Head of Departments

This letter is to inform you that Smith & Nephew Inc., have voluntarily initiated a recall to remove a single lot of Lag Screw Guide Pin Sleeve Surgical Instruments due to a manufacturing error. The affected Lag Screw Guide Pin Sleeves are missing the detent ball used to secure the lag screw guide pin sleeve inside the lag screw drill sleeve.

Please see product details below:

Product Number	Description	Batch Number
71674032	LAG SCREW 3.2MM GUIDE PIN SLEEVE	17MM04909

Shipment Date: 6/8/2018 through 7/30/2018

**Potential Risk of Use of the Product**

In the event the affected device is presented for use, the lag screw guide pin will not remain secured in the lag screw drill sleeve. The surgeon would hold the guide pin in place to complete the procedure. Therefore, the use of or exposure to the affected device presents a low risk adverse health consequence.

**Required Actions:**

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form

