

***MEDICAL DEVICE CORRECTION NOTICE***  
***C-2017-28***

February 1, 2018

Smith & Nephew, Inc. has initiated a Field Correction for several lots of ORBIT INCISOR PLUS EP-1 due to a manufacturing error. The devices were manufactured as Tin-Nickle plate opposed to EP/Silver plate.

Please see product details below:

Product	Description	Lot	Shipment Date
7205687	ORBIT INCISOR PLUS EP-1 (6/BX)	50615767 ; 50616375 & 50599483	May 24, 2016 through December 9, 2016

**Potential Risk with Use of the Product**

In the event the affected device is presented for use, there is a potential that severing of the flex cut interface of the inner blade could occur. As a result, the inner blade tip ceases to spin and the blade ceases to resect. The inner blade tip remains contained with the outer tip facilitating removal. A backup blade can be used to complete the case; as such, there is no risk of dispersing parts into the surgical cavity and no associated risk to the patient.

**Actions for Hospital Representatives**

1. Please inspect your inventory and complete the attached Inventory Correction Certification Form.
2. If you have the affected products, please maintain awareness of this notice.



## Inventory Correction Certification Form

C-2017-28

February 1, 2018

**PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT**

### Acknowledgement of Correction Notification

By signing below, I acknowledge that I have received the notification and I have taken the appropriate actions.

Printed Name: \_\_\_\_\_ Title \_\_\_\_\_

Telephone: ( \_\_\_\_ ) \_\_\_\_\_ - \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Facility Name:

Account Number:

Signature \_\_\_\_\_

### Check One:

- ☐ I have checked my inventory and my facility no longer possesses any device from the affected lots.
- ☐ I have checked my inventory and my facility still possesses a device(s) from the affected lots and I acknowledge the correction notification.

**PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:**

Email: [FieldActions@smith-nephew.com](mailto:FieldActions@smith-nephew.com)

Fax: +1-901-566-7975