**June 14, 2013**

**To:** **Surgeons**

**Subject:** **URGENT MEDICAL DEVICE RECALL**

**Affected Product:** **Zimmer Bigliani/Flatow® The Complete Shoulder Solution Fukuda Retractors**

| Item | Lot |
|---|---|
| 00-4305-019-30 | 61557761 |
| | 77000186 |
| | 61591732 |
| | 61612275 |
| | 61614764 |
| 00-4305-019-40 | 61588143 |
| | 61612276 |

In 2010, Zimmer initiated a recall of the Bigliani/Flatow® Fukuda Retractors due to fractures occurring at the grooves around the perimeter of the blades. Zimmer is expanding this recall to include seven lots that were not previously included. The devices are being recalled as they may have been manufactured with an increased grove depth. As a result, there is an increased potential for the retractor to fracture at the groves around the perimeter of the retractor. There have been fifteen reported complaints related to device fracture.

**Risks**

- Slight delay of surgery to replace the retractor.

**Your Responsibilities**

1. Review the notification and ensure affected personnel are aware of the contents.
2. If you find any product from these lots, quarantine the product and notify your Zimmer sales representative.
3. Please ensure the recalled devices are cleaned and sterilized prior to returning them to your Zimmer sales representative. Complete the Certificate of Sterilization (Attachment 2) when providing the units to them.
4. Your local Zimmer sales representative will remove the recalled product from your facility.

This voluntary notification will be reported to the U.S. Food and Drug Administration and local Competent Authority.

Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product.

Vigilance Reporting: Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 7 to the local health authority in your country.

Sincere regards

[redacted]
Post Market Surveillance & Regulatory Compliance Associate Director

# ATTACHMENT 1

## Notification Certification Form

**Zimmer Bigliani/Flatow® The Complete Shoulder Solution Fukuda Retractors**

Fax back to: Fax back to your respective Zimmer entity

Clinic Name: _____ Surgeon Name: _____

Place: _____

Country: _____

☐ The surgeon confirms having received and read the notification.

*Or*

☐ The Zimmer Representative confirms that the surgeon has received the confirmation of notification.

Printed Name:_____ Signature:_____

Title _____ Telephone: (  ) _____-_____ Date:____/____/____

Confirmed by local Quality Manager

Name: _____

Signature: _____

Date:____/____/____

# ATTACHMENT 2

## CERTIFICATE OF STERILIZATION

Zimmer Bigliani/Flatow® The Complete Shoulder Solution Fukuda Retractors

By signing below, I acknowledge that the instrumentation being returned to Zimmer, Inc. has been clean and sterilized prior to being returned.

Describe the method of disinfecting: _____

Printed Name_____ Signature_____

Title _____ Telephone: (  ) _____-_____

Date: ____/____/____

Territory Number: _____

Account Name: _____

Note: Please ensure this form is included with the returned parts.