URGENT: DEVICE REMOVAL

OF VARIOUS RECIPROCATING AND OSCILLATING SAW BLADES MANUFACTURED BY SYNVASIVE TECHNOLOGY, INC., EL DORADO HILLS, CA

APRIL 02, 2013

To	**Clinics/ Surgeons**	
PRODUCT	**Synvasive Technology, Inc. Oscillating Saw Blades: Affected REF numbers and lot numbers**	**Synvasive Technology, Inc. Reciprocating Saw Blades: Affected REF numbers and lot numbers**

Synvasive REF	Zimmer REF	Lot
11-2893-XX	19090127AF1	1X311
11-3289-XX	N/A	01251
11-3896-XX	09025038SMC	16325
11-3899-XX	05025060SMF	15023
11-3947-XX	14041060LMX	15024
11-3949-XX	N/A	1Y224
11-3960-XX	09025060AMF	23326
11-3964-XX	05025060AMF	0X401
11-3976-XX	N/A	26385
11-3978-XX	N/A	1Y174
11-4006-XX	08013060SMY	17151
11-4106-XX	19105137TGE	17150
11-4109-XX	25100147TB1	22028
11-4126-XX	N/A	28114
11-4325-XX	19110127AG1	23372
11-4386-XX	19090127AF1	23346
11-4516-XX	19105137LG1	25134

Synvasive REF	Zimmer REF	Lot
11-4019-XX	N/A	0Y280
11-4214-XX	N/A	19071
11-4397-XX	N/A	23504
		23505
11-4564-XX	12076100UR1	24348
		25304
		25333
		26068
		26165
		27015
		27016
11-4619-XX	12076100SRT	29392
11-4643-XX	N/A	PD4647
11-4543-XX	51KEELCMUR1	25341
		2W223
		2X105
11-4544-XX	47KEELCLUR1	26001
		2W573
		2W574

XX is the end of the REF number (-01, -10, -25)

REASON FOR REMOVAL	Zimmer Surgical is initiating a removal in response to a label review which was conducted after receipt of a labeling complaint. The label review revealed a number of labeling errors on products sold by Synvasive Technology, Inc. The labeling errors include: The pouch says oscillating saw blade when it actually contains a reciprocating saw blade (products 11-4019, 11-4214, 11-4397, 11-4564, 11-4619 and 11-4643).

	The box bar code date does not match the human readable expiration date (products 11-3899, 11-3947, 11-3964, 11-3976, 11-4106, 11-4126 and 11-4325). The box and/or pouch expiration date is incorrect (longer or shorter than the actual expiration date, but none of these products actually expire prior to the year 2015) (products 11-2893, 11-3289, 11-3896, 11-3949, 11-3960, 11-3978, 11-4006, 11-4109, 11-4386 and 11-4516). The label incorrectly states use with Zimmer/ Synthes handset and not the Zimmer Universal Power System (products 47KEELCLUR1 and 51KEELCMUR1).
CLINICAL IMPLICATIONS (Risks to Health)	It is possible that the incorrect name of the device on the label will delay or postpone the surgery due to the lack of appropriate intended product. Note: Reciprocating Blades incorrectly labeled "Oscillating" can be used only with the Reciprocating Attachment, since it has a specific hub that would not fit an Oscillating Attachment. If expired sterile product is used beyond its approved expiration date, there is a lack of assurance of sterility.
REQUIRED ACTIONS	1. **Review this notification.** 2. **Remove affected product from use.** 3. **Dispose of affected product immediately (per your facility's Sharps safety protocol) and document the activity on the response form attached to this notice OR send back the items to your Zimmer representative.** 4. **Complete the response form and return it via email to your Zimmer Representative.** 5. **Zimmer will credit your account for <u>unused</u> blades only.**
OTHER INFORMATION	Notifications of this removal are being sent to all affected direct accounts of Zimmer Surgical and Zimmer, Inc. Zimmer Surgical is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation, and we regret any inconvenience this action may cause your hospital and your staff. If you have any questions regarding this action, please contact your Zimmer Representative. ***This voluntary removal will be reported to the U.S. Food and Drug Administration and to the affected local Competent Authorities. The FDA will also receive from Zimmer progress reports on the implementation of this removal. Your urgent cooperation is requested.***

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

Kind regards

_____

[redacted]

_____

[redacted]
Vice President, QA/RA
Zimmer Surgical, Inc.

2 April 2013

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Date

OSCILLATING AND RECIPROCATING SAW BLADES REMOVAL RESPONSE FORM

IMMEDIATE RESPONSE REQUIRED

Send completed form via email to CorporateQuality.PostMarket@Zimmer.com

Or to your Zimmer Representative

Use the table below to record quantities of affected product (Synvasive Technology, Inc. Oscillating and Reciprocating Saw Blades) at your account (attach additional sheets as needed):

Part Number	Lot Number	Product Description	Qty on Hand	Disposition

Note: Zimmer will credit your account for unused blades only.

Clinic Name and Address: _____

_____

Signature of person completing this form _____

Printed name _____

Title _____ **Telephone ( ) _____-_____**

Date: _____

Important: If you have further distributed affected product(s), please provide the customer's information below, or on an attachment, so that we may notify them of this removal:

Facility Name: _____

Street Address: _____

City, Zip Code: _____

Phone number: _____

Date notified: _____