

**Safety Communication**

**رسالة سلامة**

**Spinal Rod Cutters May Fracture during Use; Manufacturer Announces Discontinuation**

<b>Device/ Product Description:</b>	Spinal Rod Cutters
<b>Affected Lot Number:</b>	Spinal Rod Cutter Maximum Pin Diameter ¼ Inch (6.4M) Item Number: 00-3925-002-00
<b>Manufacturer:</b>	Zimmer Biomet
<b>Problem:</b>	There is a potential for fracture during use. The cutter is primarily used in spine procedures to cut stainless steel rods. If the pin cutter were to fracture during use, it would be easily recognized. The highest severity event may result if the cutters were to fracture intra-operatively in an internal fixation procedure and a fragment creates a puncture wound that resulted in permanent impairment of a body function or damage to a body structure.
<b>Recommendation /Actions:</b>	Identify and isolate any affected product in your inventory. Return affected product to Zimmer Biomet.  For more information, Please click <a href="#">here</a> .  If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through: <a href="#">NCMDR</a> <a href="#">Vigilance system</a> (19999) unified call center

<b>Devices/Products photo:</b>		
<b>Authorized Representative Details</b>	AR name:	Zimmer Biomet Asel Alarabia Limited
	Assigned Contact Person:	Mohammed AlThobaiti
	Mobile/Phone:	Telephone Number: +(966) 0112606436 Mobile Number: +(966) 506795069
	Email:	<a href="mailto:Mohammed.AlThobaiti@zimmerbiomet.com">Mohammed.AlThobaiti@zimmerbiomet.com</a>

