المركز الوطني للبلاغات عن الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Urgent Safety Communication

Notice of Counterfeited Products (SURGICEL SNoW JGB5361 and HPB0451)

Device/ Product Name:	SURGICEL SNoW™ (4 inch x 4 inch); PRODUCT CODE: 2083
Lot numbers/Serials:	Lot Number JGB5361 and Lot Number HPB0451
Manufacturer:	ETHICON, LLC San Lorenzo, Puerto Rico 00754
Problem:	Saudi FDA would like to bring to your attention that Johnson & Johnson become aware of existence of a counterfeit of the following product: SURGICEL SNoW, product code 2083 with lot numbers JGB5361 and HPB0451. These two products were confirmed to be counterfeit and were neither manufactured nor distributed by Johnson & Johnson nor their authorized distributors in the Kingdom of Saudi Arabia. The safety of the product, sterility, biocompatibility and hemostatic efficacy of these counterfeit products can't be guaranteed. Johnson & Johnson cannot be held responsible for issues arising from the use of these counterfeit products on patients.
Recommendation/Actions:	• The above-mentioned products with the designated codes and lot numbers should not be used on patients. • Hospitals should immediately inform the Saudi FDA and Johnson & Johnson about medical devices products that were purchased from non-authorized distributors in the Kingdom of Saudi Arabia. • Healthcare providers advised to purchase medical devices products only with obtained Medical Devices Market Authorization - MDMA to guarantee patient safety, product quality and compliance with Saudi FDA regulations.

Devices/Products photo:	  

Authorized Representative Details		
	Company name:	**Johnson & Johnson Medical Saudi Arabia**
	Contact Person:	**Ahmed Alabsi**
	Phone:	**+966 564234000**
	Email:	**aalabsi@its.jnj.com**

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

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Sincerely,
NCMDR Team