

Urgent Safety Communication

Notice of Counterfeited Products (SURGICEL ABSORBABLE HEMOSTAT W1913T

Device/ Product Name:	SURGICEL ABSORBABLE HEMOSTAT 5 X 7.5CM / PRODUCT CODE: W1913T
Lot numbers/Serials:	Lot Number 8665956
Manufacturer:	ETHICON SARL, Neuchatel, Switzerland, 2000
Problem:	<p>Saudi FDA would like to bring to your attention that Johnson & Johnson become aware of existence of a counterfeit of the following product: Surgical Absorbable Hemostat product code W1913T with lot number 8665956. 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.</p> <p>The safety of the product, sterility, biocompatibility and hemostatic efficacy of these counterfeit products cannot be guaranteed.</p> <p style="color: red;">Johnson & Johnson cannot be held responsible for issues arising from the use of these counterfeit products on patients.</p>
Recommendation/Actions:	<ul style="list-style-type: none"> • The above-mentioned products with the designated code and lot number 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. • Hospitals are 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.

<p>Devices/Products photo:</p>		
<p>Authorized Representative Details</p>	<p>Company name:</p>	<p>Johnson & Johnson Medical Saudi Arabia</p>
	<p>Contact Person:</p>	<p>Ahmed Alabsi</p>
	<p>Phone:</p>	<p>+966 564234000</p>
	<p>Email:</p>	<p>aalabsi@its.jnj.com</p>

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