**Urgent Safety Communication**

**Notice of Counterfeited Products (SURGICEL ABSORBABLE HEMOSTAT W1913T)**

<table>
<thead>
<tr>
<th>Device/ Product Name:</th>
<th>SURGICEL ABSORBABLE HEMOSTAT 5 X 7.5CM / PRODUCT CODE: W1913T</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot numbers/Serials:</td>
<td>Lot Number 8665956</td>
</tr>
<tr>
<td>Manufacturer:</td>
<td>ETHICON SARL, Neuchatel, Switzerland, 2000</td>
</tr>
</tbody>
</table>

**Problem:**

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. The safety of the product, sterility, biocompatibility and hemostatic efficacy of these counterfeit products cannot 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 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.
**Authorized Representative Details**

<table>
<thead>
<tr>
<th>Company name:</th>
<th>Johnson &amp; Johnson Medical Saudi Arabia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Person:</td>
<td>Ahmed Alabsi</td>
</tr>
<tr>
<td>Phone:</td>
<td>+966 564234000</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:aalabsi@its.jnj.com">aalabsi@its.jnj.com</a></td>
</tr>
</tbody>
</table>

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

SG-1805-12-H

05/08/2018