Safety Communication

Safety Information Warning about Essure Permanent Birth Control Device Manufactured by Bayer

Device/ Product Name:	**Essure Permanent Birth Control**
Manufacturer:	**Bayer**
Problem:	Saudi FDA would like to bring your attention a warning Safety Information about **Essure Permanent Birth Control** manufactured by Bayer. Some patients implanted Permanent Birth Control - the Essure System and they have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions.
Recommendation/Actions for Healthcare providers:	SFDA would like to recommend the following : • Make sure that Essure is to be used only by physicians who are knowledgeable hysteroscopists; have read and understood the Instructions for Use manual and Physician have successfully completed the Essure training program, including pre-ceptoring in placement until competency is established, typically 5 cases. • Essure is contraindicated in patients who: ○ are uncertain about their desire to end fertility ○ would be able to have only one micro-insert placed due to their anatomy (including patients with apparent contralateral proximal tubal occlusion or suspected unicornuate uterus) ○ have previously undergone tubal ligation ○ are pregnant or suspect pregnancy ○ have delivered or terminated a pregnancy less than 6 weeks prior to the Essure placement procedure ○ have an active upper or lower genital tract infection ○ have a known allergy to contrast media

	○ have suspected or known cancer of the female reproductive organs ○ have unexplained vaginal bleeding • The Essure inserts contain metals, including nickel, titanium, iron, chromium, silver-tin, platinum and a material called polyethylene terephthalate (PET). Patients who are allergic or sensitive to any of these materials may have a reaction to this device following implantation. Typical symptoms may include rash, itching, and hives but may also include other symptoms not reported in the clinical trials such as chest pain, breathing difficulties and intestinal discomfort such as nausea, diarrhea or vomiting. Physicians should ask whether patients have an allergy to nickel or other metals and materials when discussing their sterilization options. ○ While some patients with nickel sensitivity can tolerate Essure, physicians should discuss with their patients the potential for a reaction to the nickel component as they weigh the benefits and the risks of Essure in each individual case. • When discussing Essure and the procedure, make sure the patient understands: ○ Essure benefits and risks ○ Essure is a permanent form of birth control ○ Importance of the Essure Confirmation Test If the device needs to be removed to address such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the Essure System of Permanent Birth Control during discussion of the benefits and risks of the device.

Devices/Products photo:		
Authorized Representative Details	**Company name:**	**Bayer.**
	Contact Person:	**AL-KAMAL Import**
	Phone:	**(011) 2181122 / (011) 4141778**
	Email:	**akio@alkamal-sa.com**

For further information, please **Click Here** **and** **Click Here.**

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