Urgent Safety Communication

Warning Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures

Device/ Product Name:	Energy-based devices
Purpose:	Energy-based devices - commonly radiofrequency or laser - have been approved for general gynecologic tool indications, including, but not limited to, the destruction of abnormal or pre-cancerous cervical or vaginal tissue and condylomas (genital warts).
The issue:	Saudi FDA would like to bring your attention to the published Safety communication on FDA website about Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures. Certain device manufacturers may be marketing their energy-based medical device for vaginal "rejuvenation" and/or cosmetic vaginal procedures. If these devices used **to perform vaginal "rejuvenation," cosmetic vaginal procedures, or non-surgical vaginal procedures** to treat symptoms related to menopause, urinary incontinence, or sexual function, it **may be associated with serious adverse events,** including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain. **The safety and effectiveness of energy-based devices for treatment of these conditions has not been established.** Vaginal "rejuvenation" is an ill-defined term; however, it is sometimes used to describe non-surgical procedures intended to treat vaginal symptoms and/or conditions including, but not limited to: Vaginal laxity, Vaginal atrophy, dryness, or itching, Pain during sexual intercourse, Pain during urination and Decreased sexual sensation.

Recommendation/Actions:	**Recommendations for Health Care Providers:** • Be aware that the safety and effectiveness of energy-based devices to perform vaginal "rejuvenation" or cosmetic vaginal procedures has not been established. • Discuss the benefits and risks of all available treatment options for vaginal symptoms with your patients. • If any patients experience adverse effects from procedures that involved the use of energy-based devices to perform vaginal "rejuvenation", cosmetic procedures, or treat genitourinary symptoms of menopause, sexual dysfunction, or urinary incontinence, please submit a report through The National Center for Medical Devices Reporting

For further information, please **see** **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