


Safety Communication

incomplete staple formation due to missing of the alignment pin

Device/ Product Description:	Automated Surgical Stapling, Single Use
Brand Name:	Endo GIA, Tri-Staple 2.0
Lot numbers/Serials:	Check the link
Manufacturer:	Medtronic ltd.
Problem:	Potential for a device to be missing one of two pin components that maintain alignment of the device jaws. Use of a product without a pin may result in incomplete staple formation, potentially leading to bleeding, anastomotic leak, peritonitis, or pneumothorax, which can result in the potential for infection and/or sepsis.
Recommendation/Actions:	<ul style="list-style-type: none"> - Ensure that affected product is removed from use, quarantined and returned to the supplier/ manufacturer. <p>You can find more information and recommendations from (HERE).</p>
Devices/Products photo:	

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product 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

4904 northern ring branch rd - Hitteen Dist.

RIYADH 13513 - 7148

Tel: +966 (11) 2038222 Ext: 2995, 2952

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Or

Saudi Vigilance

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Sincerely,

NCMDR Team

