

Safety Communication

رسالة سلامة

Safe Use of Surgical Staplers and Staples-for internal use****

Device/ Product Description:	Surgical Staplers and Staples
Brand Name:	All
Lot numbers/Serials:	All
Manufacturer:	All
Problem:	<p>SFDA has studied the risks associated with using Surgical Staplers and Staples for internal use and would like to bring your attention to the following:</p> <p>Based on the study results, the most risk problems associated with the Surgical Staplers for internal use, that have been reported:</p> <ol style="list-style-type: none">1. Misfiring2. Failure to form a staple/cutting but no staple forming or partially stapling3. Difficulty opening or closing/stapler jam4. Locked on the tissue and removed by excessive force.5. Breaking/detachment of components6. Malformed staples/staple line7. Cartridge not loading/not properly loaded8. Counterfeit staples9. Possibility of missing some parts10. Stapler not cutting <p>Misusing the device or any cause of malfunction may lead to prolonged surgical operations or additional unplanned surgical interventions, which may lead to other complications, such as: bleeding, sepsis, fistula formation, tearing of internal tissues and organs, increased risk of cancer recurrence, and death.</p>

	<p>As per the study results, the risk factor, which causing the risk problems to happen, for Surgical Staplers for internal use are mostly associated either with:</p> <ul style="list-style-type: none"> - Users not complying to all necessary information that the manufacturers supposed to provide <p>And/or</p> <ul style="list-style-type: none"> - Manufacturers in the Labelling are not identifying clearly key technical characteristics and performance parameters of the Surgical Stapler and compatible staples and all information needed to assure the safety when using the device.
<p>Recommendation/Actions:</p>	<ul style="list-style-type: none"> ➤ General Recommendations for Healthcare Providers and Users <ul style="list-style-type: none"> • Healthcare providers must insure that the user and the surgeons must be specialized, trained, and qualified to use the Surgical Stapler device. • Healthcare providers and users must be aware that they are obligated to read, understand and follow the instruction for use, technical characteristics, performance parameters and any necessary information the manufacturer provides in which the device operates safely and effectively. • Healthcare providers and users must insure that the components of the device and staples used with stapler are all original and compatible. • Healthcare providers and users are highly advised to report any related Adverse Event to SFDA. ➤ Common Important Factors; to be Considered by the User: <ul style="list-style-type: none"> • Read and carefully follow the stapler manufacturer's instructions for use. • Have a range of staple sizes available and select the appropriate size cartridge for the tissue type and thickness. • If you have difficulty squeezing the handle of the stapler, you may need to select a different size staple. • Avoid using the stapler on tissue that is too thick or too thin for the selected staple size. • Be aware that different companies may use different color schemes on the cartridges to indicate different staple sizes.

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| | <ul style="list-style-type: none">• Consider other options if the patient's tissue is edematous, friable, or necrotic and delicate tissue.• Be familiar with the structures around the intended staple site.• If a malfunction of the stapler occurs while applying staples across a blood vessel, then clamp or ligate the vessel before releasing the stapler, while the stapler is still closed on the tissue.• Caution of using the fake staples. |
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