

Date: 13 April 2022
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Medical Devices Sector
National Center for Medical Devices Reporting




رسالة سلامة
Safety Communication

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| To: Healthcare providers | إلى: مقدمي الرعاية الصحية |
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| Title: | Recommendations for Healthcare Providers Regarding Surgical Staplers | العنوان: |
| Medical Device Description | Surgical Staplers | اسم ووصف الجهاز/المستلزم الطبي: |
| Manufacturer: | All | اسم المصنع: |

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| Medical Devices Marketing Authorization (MDMA) | All Authorized Surgical Staplers | إذن التسويق: |
| Potential /Associated Risks | <p>Based on the SFDA ongoing proactively activities, a post-market clinical evaluation study was conducted to analyze and evaluate multiple safety signals related to the surgical staplers for internal use. The study revealed the below complications associated with the surgical staplers :</p> <ol style="list-style-type: none"> 1- Misfiring. 2- Failure to form a staple/cutting but no staple forming or partially stapling. 3- Difficulty opening or closing/stapler jam. 4- Locked on the tissue and removed by excessive force. 5- Breaking/detachment of components. 6- Malformed staples/staple line. 7- Cartridge not loading/not adequately loaded. 8- Counterfeit staples. 9- Possibility of missing some parts. 10- Stapler fails to cut. <p>Note: Surgical staplers should be used carefully to avoid 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> | المخاطر المحتملة المرتبطة بالجهاز أو المستلزم الطبي |

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| <p>Recommendations</p> | <p>General Recommendations for Healthcare Providers and Users</p> <ul style="list-style-type: none"> - Users of surgical staplers must be specialized, trained, and qualified to use surgical staplers. - Healthcare providers and users must be aware that they are obligated to read, understand and follow the instructions 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 ensure that the components of the device and staples used with the stapler are all original and compatible. - Healthcare providers and users are highly advised to report any related incident /Adverse Event to SFDA. <p>Important Factors to be considered by the user:</p> <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 manufactures may use different color schemes on the cartridges to indicate different staple sizes. - 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. | <p>التوصيات</p> |
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| <p>For Reporting:</p> |  |  |  | <p>للإبلاغ:</p> |
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