B|BRAUN
SHARING EXPERTISE

B. Braun Surgical, S.A.
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España
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Urgent Field Safety Notice
Several code-batches of STEELEX STE SET, STEELEX MONOFILAR and PACKS containing those products
Return of the Medical Device to the manufacturer
Att. Users of above products

July 27th, 2021

Dear Sir or Madam,

B. Braun Surgical, S.A. is voluntarily recalling some reference/batches of Steelex products. Steelex is a sterile, non-absorbable stainless-steel surgical suture material supplied as twisted multifilament or monofilament. Sternum Set is a special surgical suture set consisting of a stainless-steel wire monofilament for sternal closure.
Additionally, some Procedure Packs that contain Steelex product are affected.

Description of the medical device deficiency

Bioburden results of Steelex Sternum Set in Long Pack carboard were determined to be out of specification. Such finding was part of the Ethylene Oxide (EO) sterilization validation activities of Steelex Sternum Set.

Therefore, EO sterilization validation for products containing such cardboard failed.

Potential harms associated

The risk of remaining bioburden present on the cardboard inner part is considered "very low" as any viable bacteria should migrate from the inner part to the outer part of the sterilized support. The suture thread is made of steel, a material that does not facilitate the colonization, as it does not contain any component to feed bacteria. Therefore, the risk of colonization is considered low. Finally, any survival in the implantable parts could be introduced in the patient body and develop and infection. Such risk is minimized due to the antibiotic therapy applied in such cardiothoracic interventions.

Therefore, based on the qualitative rationale exposed above, the probability of occurrence of the harm (infection) is considered very low.

In those patients for whom the device has already been used, no additional follow-up is required. If the patient presents any of the complications described: wound infection (mediastinitis for sternal closure), dehiscence, post-operative pain and hyperthermia, allergic or foreign body reactions, the hospital protocol for such situations will be acted upon.

Identification of affected medical devices

Reference name:	STEELEX STE SET, STEELEX MONOFILAR and PACKS containing those products (Several references affected, see attachment)
Reference and batch number:	Detailed list in the attachment

Actions to be taken

Please identify and quarantine if you still have the listed product in your warehouse.

Please check with your customers if they still have the listed product in their warehouse. If yes, ask them to send the product back to you immediately.

Once you have all affected units for return contact us for the management of the material.

Please, fill out the attached "FSCA/Recall Confirmation Form" and send the completed form to us by August 19th, 2021.

This notice needs to be passed on all those who need to be aware within your organization and to any organization where the potentially affected devices have been transferred.

If you have any questions regarding this voluntary product recall, please contact us at the e-mail: vigilance_CT@bbraun.com.

We apologize the inconveniences we might have caused.

Thank you for your cooperation.

Yours faithfully,

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