PRODUCT RECALL NOTIFICATION

Advantus Health Partners

Ethicon Urgent Medical Device Recall: STRATAFIX™ Spiral MONOCRYL™ Plus Bidirectional Knotless Tissue Control Device

RECALL DATE: 3/8/2024
NOTIFICATION DATE: 4/9/2024
LAST REVISED ON: 4/9/2024
SUPPLIER/CATEGORY: SUTURE PRODUCTS

SITUATION

- Ethicon has initiated a voluntary medical device recall (removal) of one (1) lot of STRATAFIX™ Spiral MONOCRYL TM Plus Bidirectional Knotless Tissue Control Device, Product Code SXMP2B412, Lot SHBAEC.

BACKGROUND

- Ethicon received complaints for one lot of STRATAFIX™ Spiral MONOCRYL TM Plus Sutures regarding suture degradation. Internal testing on returned product confirmed that some STRATAFIX™ Spiral MONOCRYL™ Plus Sutures from this lot were degraded and unusable upon removal from the foil pouch. Ethicon has identified the root cause as a packaging/seal defect that allowed some STRATAFIX™ Spiral MONOCRYLTM Plus Sutures from lot SHBAEC to be exposed to environmental conditions during transit and storage.

ASSESSMENT

- Based on complaint information and investigation, the issue is likely detectable by the user prior to suture use due to the packaging defect and/or level of suture degradation. Therefore, the impacted product would be either unusable or unlikely to be used once detected, which would lead to user inconvenience to obtain a new or alternative device for surgery but cause no harms for the patient.
- In the unlikely event that the user does not detect the open seal and/or suture degradation or, despite detecting the issue, opts to use the impacted product, potential harms include wound infection resulting from the loss of sterility, and treatment failure/ wound dehiscence due to reduced suture tensile performance, as well as impaired healing if wound separation is untreated.
- The health risk is limited to those products with compromised foil packaging. Other products in the field with no seal issues are unaffected.
- **Ethicon has not received any reports of injuries related to this issue.** Health care practitioners who have treated patients using this product should follow those patients post-operatively in the usual manner with no additional action required.
- Ethicon has determined the root cause of this issue, identified the specific lot impacted, and is implementing corrective actions to address the issue and prevent reoccurrence.

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PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	EXP DATE	DISTRIBUTION DATES	GTIN / PRIMARY DI NUMBER	DESCRIPTION / SIZE
STRATAFIX™ Spiral MONOCRYLTM Plus Bidirectional Knotless Tissue Control Device	SXMP28412	SHBAEC	June 30, 2024	December 20, 2023- December 21, 2023	30705031464289 (box) 10705031464285 (pouch)	STRATAFIX SPIRAL MONOCRYL PLUS BI UD 12+12IN(30+30 CM) USP3-0(M2) D/A PS PRM

- This recall (removal) does NOT affect any other STRATAFIX™ Spiral MONOCRYL™ Plus Suture codes or lots.

RECOMMENDATIONS

- Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s). If you have product subject to this recall, please maintain a copy of this notice with the quarantined product and keep a copy for your records.
- Distributors are required to return unused STRATAFIX™ Spiral MONOCRYL™ Plus Sutures subject to this recall that are in inventory immediately. To receive credit, distributors must return product subject to this recall no later than June 30, 2024. Any non-affected product and any product returned after the date specified will not receive credit.
- To return product subject to this recall, photocopy the completed BRF, place it in the box with the product, and affix the pre-paid authorized shipping label included with the recall notification letter. Ethicon will pay for the shipping charges only if the authorized label is used. Extra shipping labels may be obtained by calling Sedgwick at 855-215-5702. Your account number and mailing address have been pre-populated on the BRF.
- Keep this notice visibly posted for awareness until all product subject to this recall has been returned to Sedgwick.
- If any product subject to this recall has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.
- If you require any assistance with returning product, please contact Sedgwick at 855-215-5702 and reference Event # 7775.