Medtronic

Urgent Field Safety Notice

Surgilon™ Braided Nylon Suture

Sofsilk™ Braided Silk Suture

Monosof™ Monofilament Nylon Sutures

Ti-Cron™ Coated Braided Polyester Sutures

Steel Monofilament Stainless Steel Sutures

Recall

January 2024

Medtronic Reference: FA1391

EU Manufacturer Single Registration Number (SRN): US-MF-000028763

Dear Healthcare Professional, Risk Manager,

The purpose of this letter is to advise you that Medtronic is initiating a recall for specific lots of Surgilon™ Braided Nylon sutures, Sofsilk™ Braided Silk sutures, Monosof™ Monofilament Nylon Sutures, Ti-Cron™ Coated Braided Polyester Sutures and Steel Monofilament Stainless Steel Sutures.

You are receiving this letter as Medtronic records indicate your facility may have received one of the potentially affected listed below in attachment A.

Medtronic is initiating this action to prevent the use of potentially affected sutures that may impact patients.

Issue Description:

Medtronic determined that specific lots of the Surgilon™ Braided Nylon sutures, Sofsilk™ Braided Silk sutures, Monosof™ Monofilament Nylon Sutures, Ti-Cron™ Coated Braided Polyester Sutures and Steel Monofilament Stainless Steel Sutures were sterilized with gamma doses that exceeded the range approved or were exposed to more than the approved number of Ethylene Oxide- (EO) sterilization cycles. The affected lots were distributed between May 2022 and November 2023. The expected impact on the tensile strength of these sutures will develop overtime throughout their labelled shelf life.

The issue was identified during a recent review of records. Through 10 January 2024, Medtronic has received no complaints or reports of serious patient injury related to this issue.

Risk to Health:

The extra gamma levels or additional Ethylene Oxide (EO) cycle have the potential to decrease the strength of these sutures over time which could result in harms such as wound dehiscence, hemorrhage/blood

Medtronic

loss/bleeding, tissue breakdown, peritonitis, unspecified infection, malunion of bone (Steel Suture), vision loss (when used in ophthalmic application), and/or prolonged surgery.

Patient Management Recommendations:

There are no additional patient management recommendations for patients where potentially affected sutures in scope of this recall were used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols with consideration to the specific use.

Customer Actions:

- Identify and quarantine all unused and non-expired affected sutures listed in Attachment A. See Attachment B for guidance on identifying potentially affected devices.
- Return all unused product from the affected lot in your inventory to Medtronic.
    - Credit for the returned affected product will be issued based on the RGA number.
- Pass on this notice to all those who need to be aware within your organization or to any organization where the potentially affected sutures have been transferred or distributed.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We are committed to patient safety and appreciate your prompt attention to this matter. We regret any inconvenience this may cause. If you have any questions regarding this communication, please contact your Medtronic Sales Representative.

Sincerely,

Local / BU Manager

Enclosures:

Attachment A: List of Impacted Lot Numbers

Attachment B: Identifying Affected Sutures

Medtronic

Attachment A: List of Impacted Lot Numbers distributed to Denmark

Monosof™ Monofilament Nylon Sutures* Product Description	Model Number	GTIN/UDI	Lot Number
N-63 MONOSOF 3-0 BLK 12X45CM PCT X36	N-63	20884521076607	D2A0862RY

Attachment B:

IDENTIFYING AFFECTED PRODUCT

Locate product information on product labels in your inventory.