Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	Surgilon™ Braided Nylon sutures Sofsilk™ Braided Silk sutures
Device Model	S-606 S606-12
Lot No.	D2D0961RY D2D0961RY
Manufacturer	Covidien-Medtronic
Country of Origin	USA
Reference	Attached
Reason of Recall	NHRA initiates this FSN due to over-sterilization with gamma rays of specific Surgilon™ and Sofsilk™ suture lots, potentially weakening tensile strength over time, which may lead to wound dehiscence and critical bleeding.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Yousuf Mahmood Husain W.L.L at me.regulatory@ymh.com.bh to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

Recall 2024 0006

19/Mar/2024

Medtronic

Urgent Field Safety Notice

Surgilon™ Braided Nylon Suture

Sofsilk™ Braided Silk Suture

Recall

December 2023

Medtronic Reference: FA1391

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 and Sofsilk™ Braided Silk sutures.

You are receiving this letter as Medtronic records indicate your facility may have received one of the potentially affected sutures listed attachment A below. 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 and Sofsilk™ Braided Silk sutures were sterilized with gamma doses that exceeded the range approved. The affected lots were released between September 2022 and March 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 6 December 2023, Medtronic has received no complaints or reports of serious patient injury related to this issue.

Risk to Health:
The extra gamma levels have the potential to decrease the strength of these sutures over time which could result in harms such as wound dehiscence and hemorrhage/blood loss/bleeding at a critical level.

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.

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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. Please contact your Customer Service contact for the Return Good Authorization (RGA).
    - Credit for the returned affected product will be issued based on the RGA number.
    - If purchased from a distributor, contact your distributor directly to arrange for the return of the product back to your distributor.
- In addition, please complete and return the Customer Confirmation Form enclosed with this letter, acknowledging that you have received this information.
- 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,

Rita Habash

Business Manager

Enclosures:
Attachment A: List of Impacted Lot Number
Attachment B: Identifying Affected Product
Customer Confirmation Form

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Attachment A: List of Impacted Lot Numbers

Sofsilk™ Braided Silk Suture Product Description	Model Number	GTIN/UDI	Lot Number
S-606 SOFSILK* 0 BLK 2X150CM PCT X36	S-606	20884521086637	D2D0961RY
S606-12 SOFSILK* 0 BLK 2X150CM PCT X12	S606-12	10884521637887	D2D0961RY

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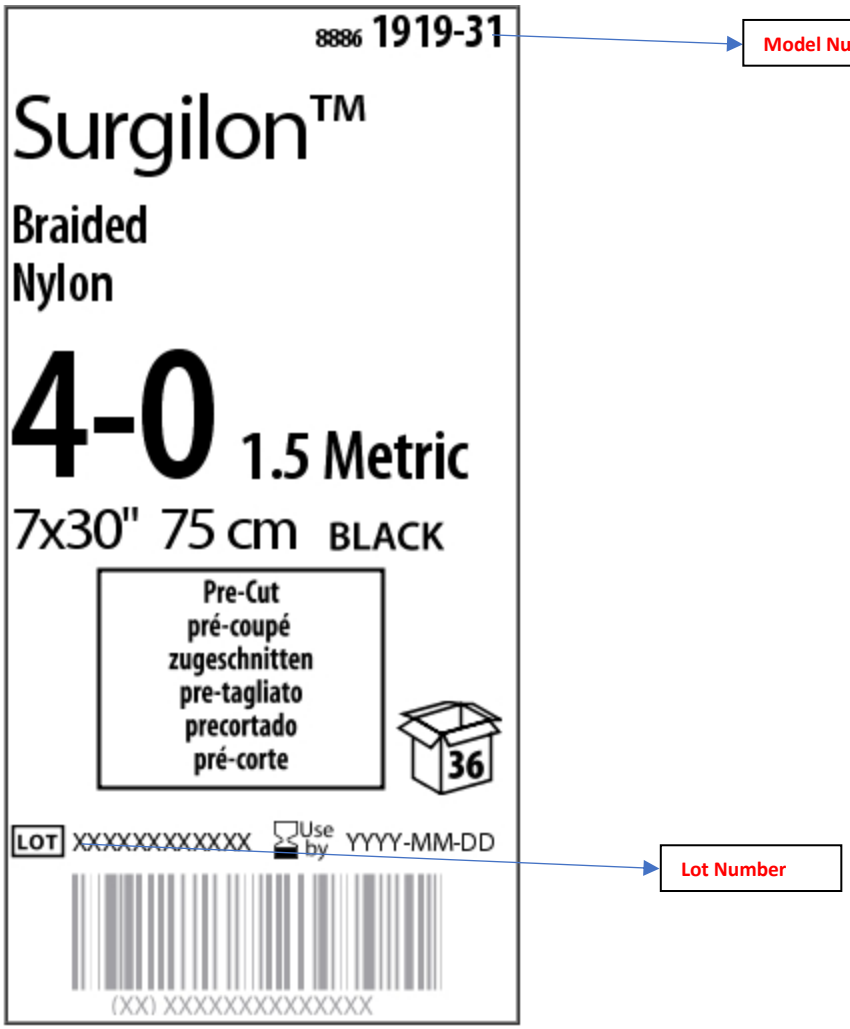
Attachment B:

IDENTIFYING AFFECTED PRODUCT

Locate product information on product labels in your inventory.



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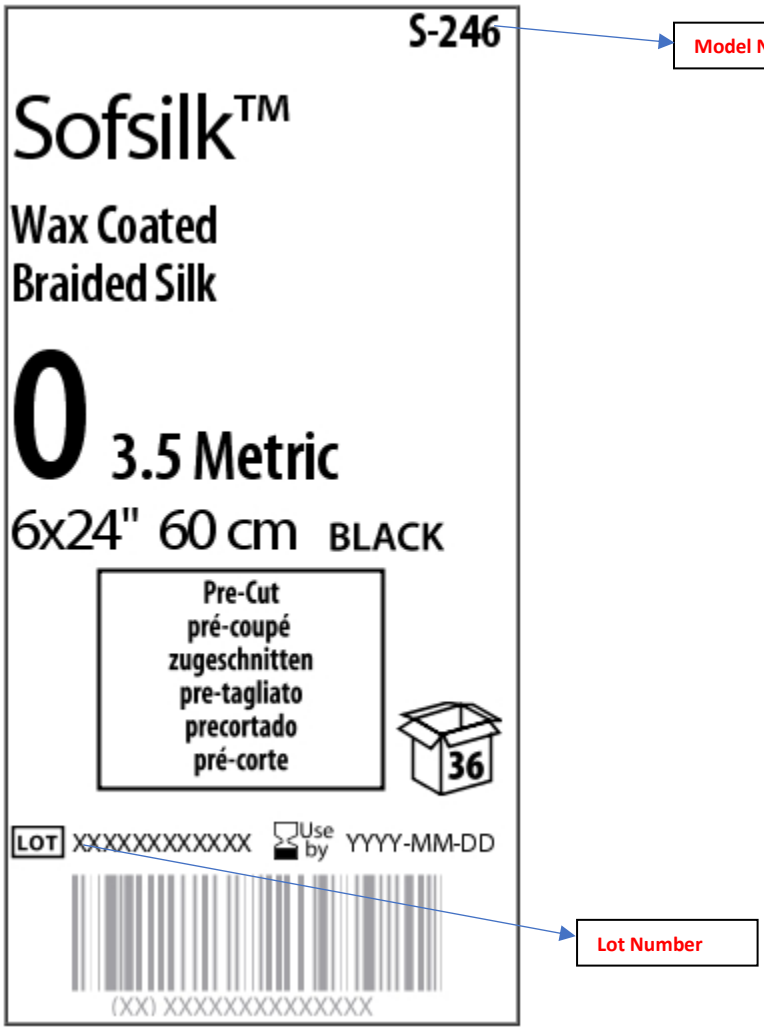

Model Number

Lot Number

Medtronic

CUSTOMER ACKNOWLEDGEMENT FORM

Please email this form back to Medtronic (even if you do not have affected inventory) to

nahar.s.alsurayi@medtronic.com

Urgent Field Safety Notice - Recall

FA1391: Gamma Sterilization Issue – Suture Products

Customer Contact Details			
Company name:		Account number (optional):	
Address:	City:		Country:

- I confirm that I have read and understood the Urgent Field Safety Notice
- I agree to pass on the Urgent Field Safety Notice to all those who need to be aware within our organization or to any organization where the potentially affected products have been transferred.
- I have reviewed our inventory, identified, and quarantined all unused affected products in our inventory, and I declare the following:

☐ No affected products are located at our facility.

☐ Affected products are located at our facility. See below table for details of affected products to be returned to Medtronic.

Name (print):	**Job title**:	**Date**:	**Signature**:

Please fill-in the section below only if you have affected stock:

Return Details			
Invoice or Delivery Note *(if available)*	**Item Code**	**Lot # / Serial #**	**Quantity** *(please count units inside of the box)*
☐ If you have more products to return, tick the box. Please create and send separate attachment with same data.			**Total**:

Contact Person at Point of Collection:		
Pick-up address / Department *(please provide location details. Eg: collection/accessible area):*		
City:		Post code:
Pick-up phone number:	Pick-up email:	
When the product will be ready for pick-up? *(Please allow 2 days for handling your request):*		
Opening hours of the pick-up location:		Dimension LxWxH (in cm): … x … x …
# Pallets:	# Parcels:	Number of parcels weighing over 45 KG:

- Customer Service will contact you directly to organise return of affected products and credit will be given for returned products.
- Please don't send the goods back before having received the return documentation.
- Please package goods according to packaging instructions that will be provided upon confirmation & remove all labels from the inbound shipment.