

**URGENT: MEDICAL DEVICE RECALL (REMOVAL)**  
**STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices Size 1**  
**(Product Lot Number: LPH946; PAH360; PAH633; MMH401; PAH055; PAH073)**

September 4, 2019

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

Ethicon has initiated a voluntary recall (removal) of specific product codes and specific lots of **STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device**, as listed in the table below. Ethicon has identified that the product lots listed below do not meet certain internal testing specifications. No complaints or adverse events related to this issue have been received for the lot codes, and no impact to clinical performance or overall product risk/benefit is expected. Ethicon holds itself to high quality and compliance standards and has implemented immediate actions to ensure ongoing manufacturing of **STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device** conforms to all required specifications.

Healthcare practitioners who have treated patients using the **STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device affected** lots noted below should follow up with these patients post-operatively in the usual manner with no additional action required.

This voluntary recall does NOT affect any other product codes or lots for **STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices**.

**EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT LOTS BELONGING TO STRATAFIX™ Spiral PDS™ Plus Devices (ONLY SPECIFIC PRODUCT CODES AND LOTS BELOW). REFER TO ACTION REQUIRED FOR FURTHER INSTRUCTIONS:**

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	DESCRIPTION / SIZE
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device	SXPP1B430	LPH946	1 STRATAFIX™ Spiral PDS Plus Violet 18" (45cm) CT-1 Needle
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device	SXPP1B201	PAH360	STRATAFIX SPIRAL PDS+ 1 45CM OS-6
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device	SXPP1B204	PAH633	STRATAFIX SPIRAL PDS+ 1 70CM OS-8
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device	SXPP1B401	MMH401	1 STRATAFIX™ Spiral PDS Plus Violet 27" (70cm) CTX Needle
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device	SXPP1B402	PAH055	STRATAFIX SPIRAL PDS+ 1 90CM CTX
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device	SXPP1B402	PAH073	STRATAFIX SPIRAL PDS+ 1 90CM CTX

Our records indicate that you may have ordered or received the above listed product/s subject to this recall. The product families include **STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device**. **PLEASE DISTRIBUTE THIS INFORMATION TO ALL STAFF WITHIN YOUR FACILITY WHO USE STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices.**

Refer to Attachment 1 for assistance in identifying the product lot subject to this recall.

### IDENTIFICATION OF PRODUCT SUBJECT TO THIS RECALL (Removal):

**Product subject to the recall (removal) in your inventory can be identified by product code and lot number (see product code and lot listing above). All unused STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device products subject to this recall (removal) are required to be returned. The product code and lot number can be determined by using the Product Identification Tool attached at Attachment 1.**

### ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have product subject to this action on hand and quarantine such product(s).
2. Remove the products subject to this voluntary recall and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed. Do not open foil pouches to confirm contents.
3. If any product subject to this recall has been forwarded to another facility, contact that facility to arrange return.
4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and hand it to your Ethicon Sales Representative within three (3) business days. **Please return the BRF even if you do not have product subject to this recall (removal).**
5. Keep this notice visibly posted for awareness until all products subject to this recall has been returned to your Ethicon sales representative. While processing your returns, please maintain a copy of this notice with the products subject to this recall (removal) and keep a copy for your records.
6. Customers are required to return unused impacted **STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices** subject to this recall that are in their inventory immediately. To receive replacement product, customers must return products subject to this recall (removal) by November 30, 2019. **Any non-affected product or impacted products returned after the date specified will not be replaced.**
7. To return products subject to this action, please contact your Ethicon sales representative.

If you require any assistance with returning the impacted products, please contact your Ethicon sales representative.

We recognize the recall of the **STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device** may be disruptive to your facility and we apologize for any inconvenience this may cause.

If you have additional questions regarding this action or to report any customer complaints, please contact your Ethicon sales representative.

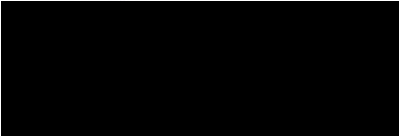


**Attachments:**

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form

Yours sincerely,



Lee Ching Hwee  
Manager, Regulatory Affairs

cc: Chairman Medical Board  
Relevant Head of Departments

## ATTACHMENT 1: Product Identification Tool for STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device

This tool will help customers identify the impacted product subject to this recall (removal). This tool will help customers identify product codes and lot codes of STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices subject to this recall by using the packaging labels. Please refer to table above for a list of all lot codes subject to this recall.

### FRONT OF SALES UNIT CARTON (Representative Sample)



**FOIL PACKAGE (Representative Sample)**



**Product  
Code**

**Lot  
Number**

## ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and hand it to your Ethicon Sales Representative **within 3 business days, even if you do not have product subject to this recall (removal) to return.**

If you have product lots subject to this recall (removal) to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

### Product Inventory – please check one

- We have **NO** STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices subject to this recall (removal).
- We have STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices subject to this recall (removal) and are returning the following products:

Device Name	Product Code	Lot Number	Quantity Returning (in "Eaches")
STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device	SXPP1B430	LPH946	
	SXPP1B201	PAH360	
	SXPP1B204	PAH633	
	SXPP1B401	MMH401	
	SXPP1B402	PAH055	
	SXPP1B402	PAH073	

Print Name of Person Completing Business Reply Form:	Sign & Date:
Customer Account Details (Name and Address)	