Medtronic

Medtronic Ireland Limited
Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
www.medtronic.ie
Tel: 01 511 1400
Fax: 01 807 7220

Urgent Field Safety Notice

Sterile Percutaneous Reference Pin (Model #9733235 and 9733236)

Percutaneous Pin Fit Issue with Patient Reference Frame and/or Percutaneous Pin Adapter

Recall

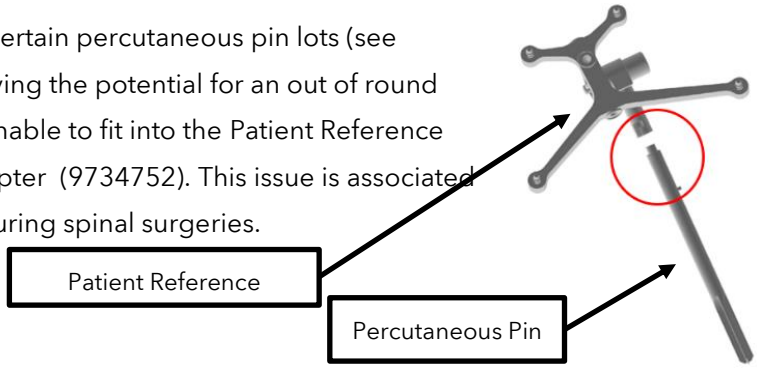
December 2024

Medtronic Reference: FA1459
EU Manufacturer Single Registration Number (SRN): US-MF-00002326>
Dear Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is recalling specific lots of the Sterile Percutaneous Pin due to the potential that the pin may be unable to fit into the Patient Reference Frame or Percutaneous Pin Adapter when attempting to attach the components that are used in image guided surgeries. The Sterile Percutaneous Reference Pin is a sterile, single-use disposable device used for rigid attachment of a patient reference frame which is commonly used in spine surgery.

Issue Description:

Medtronic has become aware that certain percutaneous pin lots (see Attachment A, Table 1) have been identified as having the potential for an out of round diameter, that may render the percutaneous pin unable to fit into the Patient Reference Frame (9732353) or Percutaneous Pin Adapter (9734752). This issue is associated with specific lots of the Percutaneous Pin used during spinal surgeries.



Potential Health Hazard:

If this issue occurs, the user will be unable to connect the frame or adapter onto the percutaneous pin. This could result in surgical delay, additional surgical intervention for removal and replacement of percutaneous pin, modification of the surgical approach using an alternative device (spinous process clamp) or abandonment of the use of navigation or the procedure.

As of October 10th, 2024, Medtronic has received twenty-nine (29) complaints of this issue, which correspond to an approximate observed failure rate of 0.09%. Of these complaints, sixteen (16) required an additional surgical intervention during the procedure, thirteen (13) resulted in a surgical delay, one (1) resulted in a non-navigated procedure, the remining complaints did not result in a health hazard. None of the complaints reported a serious adverse event.

Required Customer Actions:

Our records show that your facility has received the impacted product. Medtronic requests that you immediately take the following actions:

1. Immediately locate and quarantine all unused impacted product(s). See Attachment A for affected lot numbers and product identification.
2. Return unused impacted product(s) to Medtronic following the instructions in the enclosed Customer Acknowledgment Form.
3. Complete the Customer Acknowledgment Form enclosed with this letter, acknowledging that you have received this information
4. This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please maintain a copy of this notice in your records.
5.

Additional Information

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

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have questions related to this issue, please contact your local Medtronic representative at 01 511 1400.

Sincerely,

Bethany Moxon

Associate Regulatory Affairs Specialist – UK and Ireland

Enclosures:

- Attachment A: Product Identification
- Attachment B: Customer Acknowledgment Form

Attachment A: IDENTIFYING AFFECTED PRODUCT

Locate product information on product labels in your inventory and compare to affected product information below. Refer to Figure 1 below for the identifying product label information.

Table 1.

Product Name	Manufacturer's Catalog Number	GTIN	Lot Number		
Sterile Percutaneous Reference Pin, 100mm	9733235	00613994247872	2023071142	2023111489	2024040896
			2023080327	2023111490	2024050686
			2023080330	2023111491	2024050687
			2023091351	2023120008	2024050688
			2023091353	2023120009	2024051221
			2023091354	2023120434	2024051222
			2023091355	2023120834	2024051225
			2023091356	2023120835	2024051226
			2023100459	2023121177	2024060262
			2023100460	2024010330	2024060479
			2023101139	2024010332	2024060480
			2023101140	2024011153	2024060484
			2023101470	2024021011	2024070408
			2023101472	2024021014	2024070409
			2023101473	2024021015	2024070410
			2023110368	2024021016	2024070411
			2023110370	2024021100	2024070414
			2023110371	2024021103	2024070415
			2023110821	2024021365	2024080529
			2023110823	2024040327	2024080530
			2023110824	2024040895	N/A
Sterile Percutaneous Reference Pin, 150mm	9733236	00613994247865	2023071143	2023120042	2024021367
			2023071144	2023120431	2024040325
			2023091357	2023120432	2024040328
			2023091358	2023120433	2024040897
			2023091359	2023120831	2024040898
			2023091360	2023120832	2024050689
			2023101141	2023121178	2024051224
			2023101142	2024010333	2024060263
			2023101471	2024010334	2024060481
			2023110372	2024011154	2024060482
			2023110373	2024011155	2024060483
			2023110822	2024021012	2024070413
			2023111492	2024021013	2024070416
			2023120010	2024021101	2024070417
			2023120039	2024021102	2024080534

Product Name	Manufacturer's Catalog Number	GTIN	Lot Number		
			2023120040	2024021364	2024080535
			2023120041	2024021366	N/A

Figure 1. Product Label Information

Medtronic

Medtronic UK and Ireland

CUSTOMER ACKNOWLEDGEMENT FORM

Please email or fax this form back to Medtronic (even if you do not have affected inventory): rs.regulatoryuk-ire@medtronic.com

Urgent Field Safety Notice - Recall

FA1459: Percutaneous Pin Fit Issue

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. E.g.: 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.