Medtronic

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

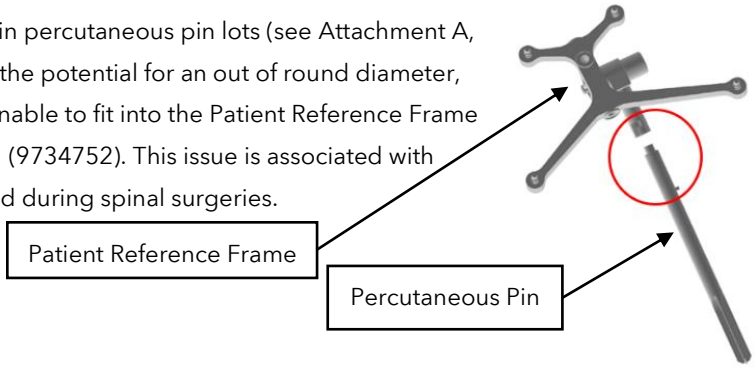
EU Manufacturer Single Registration Number (SRN): US-MF-000023263

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.

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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.
3. 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.

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 any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,

Local / OU manager

Enclosures:

- Attachment A: Product Identification

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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 00643169105676 (JAPAN)	2023091353	2023111491	2024051226
			2023101139	2024010332	2024060262
			2023101472	2024021011	N/A
			2023101473	2024021365	N/A
Sterile Percutaneous Reference Pin, 150mm	9733236	00613994247865 00643169105669 (JAPAN)	2023071144	2023120432	2024040325
			2023101142	2023121178	2024040897
			2023120041	2024010333	N/A

Figure 1. Product Label Information