Medtronic
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URGENT: MEDICAL DEVICE RECALL

Sterile Percutaneous Reference Pin (Model #9733235 and 9733236)

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

05 December 2024 | 13:41 SGT

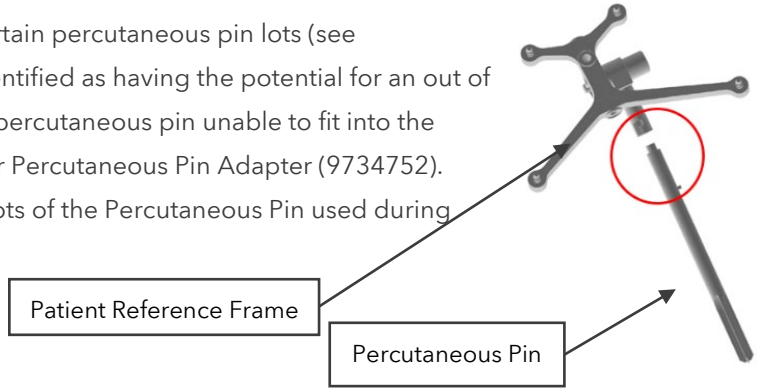
Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Healthcare Professional:

The purpose of this letter is to advise you that Medtronic is voluntarily 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. Your local Medtronic field representative can assist you in the return of unused affected product(s) as necessary.
3. Complete the Customer Confirmation Form enclosed with this letter, acknowledging that you have received this information, then send the completed form back to your local Medtronic field representative.
4. If the affected devices have already been utilized and/or discarded, we still ask that you complete and return the Customer Confirmation Form detailing that information.
5. 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 is communicating this information to the appropriate regulatory agencies.

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 local Medtronic field representative.

Sincerely,

Signed by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 05 December 2024 | 13:41 SGT

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Quality and Regulatory Affairs Director

Mainland and Island Southeast Asia

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)	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 00643169105669 (JAPAN)	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

Product Name	Manufacturer's Catalog Number	GTIN	Lot Number		
			2023110822	2024021012	2024070413
			2023111492	2024021013	2024070416
			2023120010	2024021101	2024070417
			2023120039	2024021102	2024080534
			2023120040	2024021364	2024080535
			2023120041	2024021366	N/A

Figure 1. Product Label Information

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Customer Confirmation Form

Urgent: Medical Device Recall

Sterile Percutaneous Reference Pin (Model #9733235 and 9733236)

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

For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately even if you do not have any product to return.

Customer Contact Details		Medtronic Contact Details
Distributor/Hospital/Clinic/Patient name:		**Name:**
		Contact:
Address:		**Email:**
Phone no:	**Email:**	

If you have no affected stock to be returned, please tick the appropriate box, and sign off the form.

Do you have remaining inventory of the affected units? (Please select only ONE):

☐ no, **NONE** of the affected inventory to be returned. I have examined our inventory for product/s covered by this and confirm that all affected was/were previously consumed.

☐ YES, affected inventory to be returned. I have examined our inventory and have the affected product/s listed in the following table that remain/s unconsumed and is to be returned.

Product Number	Lot Number	Quantity to be returned (in units)

By signing this form, I confirm that I have read the Urgent Medical Device Recall Notification Letter, dated 05 December 2024 | 13:41 SGT , **from Medtronic regarding the Sterile Percutaneous Reference Pin (Model #9733235 and 9733236) and taken appropriate action.**

Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic representative.

Name (print): _____ Signature: _____ Stamp: _____ Date: ☐☐ ☐☐☐ ☐☐☐☐

Note: The addressee may continue to receive reminders of this notice until a response is received.

****Please fill out the previous table first** and list the remaining on this page.
This page must also be signed and dated.**

Product Number	Lot Number	Quantity to be returned (in units)

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy