Medtronic

Urgent Field Safety Notice

Sterile Percutaneous Reference Pin (Model #9733235 and 9733236)

Percutaneous Pin Cross-Pin Fit Issue

Recall

December 2023

Medtronic Reference: FA1384

EU Manufacturer Single Registration Number (SRN): US-MF-0000023263

Dear Healthcare Professional,

The purpose of this letter is to advise you that Medtronic is recalling recent lots of the Sterile Percutaneous Reference Pin due to the potential that the cross-pin will be unable to fit into the Tap Cap when attempting to place the pin percutaneously into the pelvis for attachment of a reference frame for 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 Table 1) have been identified as having a cross-pin that may render the percutaneous pin unable to fit into the Tap Cap, or too tight to remove the Tap Cap from the percutaneous pin once placed in the pelvis. This issue is associated with recently manufactured lots of the Percutaneous Pin used during spinal surgeries.

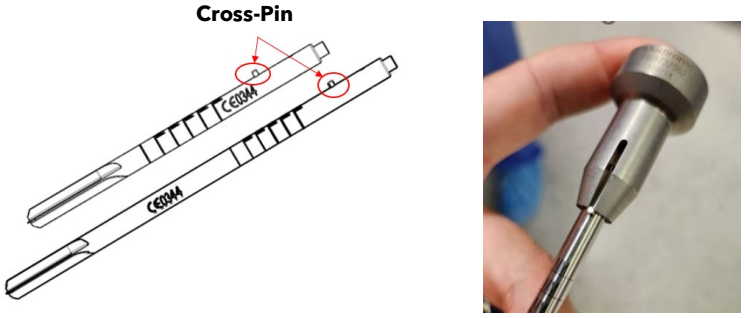

Figure 1. Percutaneous Pin Cross pin identification (left) and fit issue with Tap Cap (right)

Potential Health Hazard:

If this issue occurs, either prior to or after placement within the intended anatomy, the user may be unable to remove a Tap Cap from the percutaneous pin. This could result in surgical delay, additional intervention for removal and replacement of percutaneous pin, or modification of the surgical approach using an alternative device (spinous process clamp).

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From June 2020 through November 12th, 2023, Medtronic has received 131 complaints of this issue. Of these, thirty (30) requiring an additional intervention during the procedure, forty-nine (49) resulting in a surgical delay and the rest did not result in more than negligible patient impact. All complaint events were resolved by utilizing an available alternative device; 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). Refer to the affected lot numbers identified in Table 1 below.
2. Return the impacted product(s) to Medtronic following the Return Instruction.
3. Complete the Customer Confirmation Form enclosed with this letter, acknowledging that you have received this information.
   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.
4. This notice should be distributed to all others in your organization who should be aware, or to any organization where the potentially affected devices have been transferred. Please maintain a copy of this notice in your records.

Table 1

Product Name	Manufacturer's Catalog Number	GTIN	Lot Number
Sterile Percutaneous Reference Pin, 100mm	9733235	00613994247872	2023010549, 2023041134, 2023051138,
Sterile Percutaneous Reference Pin, 150mm	9733236	00613994247865	2022030438, 2023041141, 2023051457

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,
Medtronic

Enclosures:

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

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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.

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Sterile Percutaneous Reference Pin, 150mm	9733236	00613994247865	2022030438, 2023041141, 2023051457