Sultanate of Oman
Ministry of Health
Drug Safety Center
Muscat

سلطنة عُمان
وزارة الصحة
مركز سلامة الدواء
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 88 **dated** 27/6/2024 **Regarding Recall of Sterile Percutaneous Reference Pin from (mfr: Medtronic).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DSC**
- **Director of Pharmacovigilance & Drug Information Dept, DSC**
- **Director of Drug Control Department, DSC**
- **Director of Pharmaceutical Licensing Department, DSC**
- **Director of Central Quality Control Lab., DSC**
- **Supdt. of Central Drug Information**

DSC
مركز سلامة الدواء
Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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Ministry of Health
Drug Safety Center
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سلطنة عُمان
وزارة الصحة
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Circular No. 88 / 2024

20-12-1445 H
27-06-2024

Recall of Sterile Percutaneous Reference Pin from Medtronic.

Source	Medtronic through their local agent Al Zahrawi Medical Supplies.
Product	Sterile Percutaneous Reference Pin.
Manufacturer	Medtronic.
Local agent	Al Zahrawi Medical Supplies LLC.
The affected products	Attached.
Reason	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.
Action	1. Immediately locate and quarantine all unused impacted product(s). Refer to the affected lot numbers identified in Table 1. 2. Return the impacted product(s) to Medtronic. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

DSC مركز سلامة الدواء Drug Safety Center

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
@DSCPHO Email: dscpho@moh.gov.om

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

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.

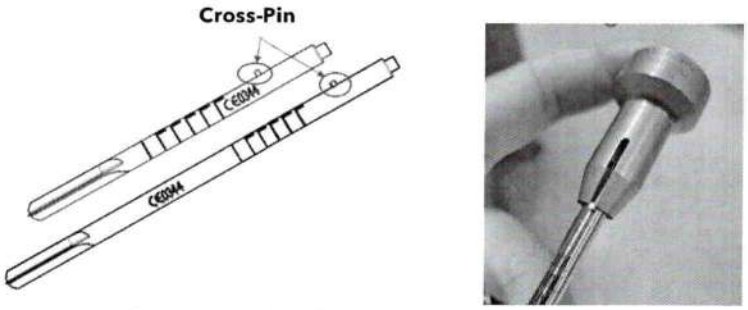

Figure 1. Percutaneous Pin Cross pin identification (left) and fit issue with Tap Cap (right)

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).

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.
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, 2023010551, 2023010840, 2023041134, 2023051137, 2023051138, 2023051139, 2023060368, 2023060369
Sterile Percutaneous Reference Pin, 150mm	9733236	00613994247865	2023041143, 2023051122, 2023051457, 2023051458, 2023060918, 2023051459

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,
Ibrahim Yassir
Neurosurgery Manger

Enclosures:

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

Medtronic

Attachment A:

IDENTIFYING AFFECTED PRODUCT

Locate product information on product labels in your inventory and compare to affected product information below.

Table 1			
Product Name	**Manufacturer's Catalog Number**	**GTIN**	**Lot Number**
Sterile Percutaneous Reference Pin, 100mm	9733235	00613994247872	2023010549, 2023010551, 2023010840, 2023041134, 2023051137, 2023051138, 2023051139, 2023060368, 2023060369
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