

## MEDICAL DEVICE CORRECTION

### InPen™ smart insulin pen Cartridge Holder Assembly Issue

Model/CFN	Impacted lot numbers
MMT-105NNBLNA	D0020, D0034, D0036, D0038, D0045, D0046, D0050, D0057
MMT-105NNGYNA	D0026, D0037, D0039, D0041, D0042, D0043, D0049
MMT-105NNPKNA	D0029, D0030, D0040, D0051, D0062
MMT-105ELBLNA	D0021, D0033, D0035, D0044, D0059, D0060, D0061
MMT-105ELGYNA	D0031, D0032, D0047, D0068
MMT105ELPKNA	D0027, D0028, D0048

March 2025

Medtronic is contacting you with a medical device correction regarding InPen smart insulin pen. Some InPens have been identified with an issue that can cause difficulty in removing the cartridge holder or installing the insulin cartridge into the cartridge holder.

#### **Issue Description:**

Some InPens from certain lots may have been incorrectly assembled. For affected InPens, users could potentially experience either one of two issues: either the insulin cartridge will not fit into the cartridge holder; or the cartridge holder may be difficult to remove from the insulin pen, requiring a significant amount of force.

#### **Risk to Health:**


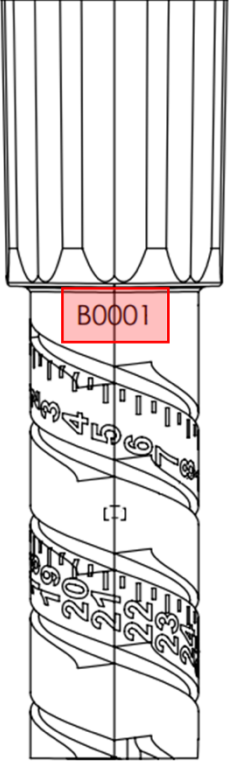
An InPen with an insulin cartridge that will not fit into the cartridge holder cannot be used. An InPen with a cartridge holder that is difficult to remove should not be used even if you are able to do so. If you do not have backup insulin when you need it, you may experience temporary hyperglycemia.

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Between May 2024 and November 2024, Medtronic received 31 complaints potentially related to this issue. There have not been any serious adverse events associated with these complaints.

## Actions Required:

1. If you have already inserted your insulin cartridge into your InPen and are using your InPen without difficulty removing the cartridge holder, then your InPen is not affected by this issue, and you can continue to use your InPen as normal.
2. Locate the lot number for your InPen. You can find the lot number in the two locations indicated in the sample images below.

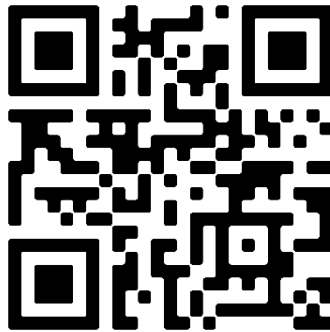
The first location is the fold-over label that is affixed to the InPen box/carton	The second location is on the dose knob portion of the InPen
	

3. Verify if your lot number matches one of the impacted lot numbers listed at the top of this letter.
4. If you have an InPen from one of the affected lot numbers listed at the top of this letter and have not yet started using it or have had difficulty in removing the cartridge holder or

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inserting the insulin cartridge, please call 1-800-646-4633, option 1, or go to <https://info.medtronicdiabetes.com/ICH-replacement-form> to request a replacement. **Do not use this InPen** and dispose of it according to local regulations.

**Regardless if your InPen is affected, please acknowledge that you have read and understood this notification and have followed the actions listed in this letter** by either completing and returning the confirmation form, scanning the QR code below with your phone or tablet, or by visiting <https://info.medtronicdiabetes.com/cartridge-holder>



**Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.**

- Complete and submit the report online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm).
- Regular mail or fax: Download the form at [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

As always, we are here to support you and ensure we are delivering the highest quality products possible. If you have further questions or need assistance, please call the Medtronic 24-Hour Technical Support line at 1-800-646-4633, option 1.

Sincerely,

# Medtronic

## **Julio Salwen**

Vice President, Quality

Medtronic Diabetes