

## Urgent Field Safety Notice

### IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheters

#### Recall

March 2022

Medtronic reference: FA1239

Dear Risk Manager/Physician,

The purpose of this letter is to advise you that Medtronic is recalling a subset of IN.PACT™ Admiral™ Paclitaxel-coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheters due to the potential for pouch damage resulting in potential loss of sterility.

#### **Issue Description:**

During a routine inspection, Medtronic noted there was damage to the sterile pouch that contains the IN.PACT Admiral catheter. An investigation determined that there had been a change implemented to one manufacturing line which may cause pouch damage. All batches manufactured on this line after that change are being retrieved.

The affected units are limited to the lot numbers of IN.PACT Admiral catheters listed in Table 1. No other Medtronic products are affected by this issue. Damage to the pouch can cause a loss of sterility and may result in potential clinical harm of systemic reaction including infection. Through 11 MAR 2022, Medtronic has received zero (0) complaints or reports of patient injury related to this issue.

There are no additional actions required for patients where the affected IN.PACT Admiral catheter was used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols.

#### **Actions:**

Medtronic records indicate that your facility has received one or more of the affected IN.PACT Admiral catheters. As a result, Medtronic requests that you immediately take the following actions:

- Identify and quarantine all unused affected IN.PACT Admiral catheters as listed in Table 1.
- Return all unused affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you with the initiation of the return.

# Medtronic

This notice should 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 Field Representative.

Sincerely,

Local / OU manager

**Table 1: Product Scope - Denmark**

Product Information		
Product Name	Model #	Lot Serial #
IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter	<b>SBI04008008P</b>	0010735613
	<b>SBI05012008P</b>	0010742135
	<b>SBI06008008P</b>	0010885372