Medtronic

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.
- Please complete the enclosed Customer Acknowledgement Form and email to: rs.dusregulatory@medtronic.com.

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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

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Table 1: Product Scope

Product Information		
Product Name	**Model #**	**Lot Serial #**
IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter	**SBI04004013P**	0011018180
	SBI04008008P	0010735613
	SBI04012013P	0010915831
	SBI04015013P	0010947014
	SBI05004008P	0010947013
	SBI05006013P	0010982240
	SBI05012008P	0010742135
		0010947011
	SBI05012013P	0010902109
	SBI05015013P	0010863859
	SBI06004008P	0010735615
		0010885373
	SBI06004013P	0010894506
		0011018170
	SBI06006008P	0010755363
		0010982241
	SBI06008008P	0010885372
		0011018176
	SBI06012013P	0011029688
	SBI06015013P	0010745656
	SBI07004013P	0010926502
	SBI08004013P	0010742136
	SBI10004008P	0010915833