Medtronic

Urgent Field Safety Notice

Medtronic Cardioblate™ CryoFlex™ Surgical Ablation Devices

Recall

October 2020

Medtronic reference: FA937

Dear Risk Manager or Healthcare Professional,

On October 14, 2020 Medtronic initiated a verbal Urgent Field Safety Notice of a subset of Cardioblate™ CryoFlex™ Surgical Ablation devices (hereafter referred to as CryoFlex devices). This notice is a follow-up to that verbal communication provided to your facility. Upon completion of the risk assessment, it has been determined that the scope of this recall includes all model and serial numbers listed in Table 1.

Model Number	Product Description	Serial Number
60SF3	**PROBE 60SF3 CRYOFLEX 10-S 26L**	**Refer to Table 1**

Medtronic's investigation process identified the above CryoFlex devices underwent a manufacturing process that may have resulted in a potential defect in the seals of the outer sterile barrier pouch used to package these CryoFlex devices. To mitigate patient safety risk, Medtronic took immediate action to quarantine all sold or consigned devices while the investigation into this issue is completed.

As of 19-OCT-2020, Medtronic has received zero (0) complaints related to this issue.

These CryoFlex devices have a double sterile barrier that consists of a sealed tray within a sealed pouch, to allow for the aseptic transfer of product into the sterile field. With the defect limited to the outer pouch, and since the sterile tray seal remains intact, the device itself remains sterile, reducing risk of patient exposure to non-sterile product.

Customer Instructions:

Medtronic records indicate that your facility has received one or more of the affected CryoFlex Surgical Ablation devices. As a result, Medtronic requests that you immediately take the following actions:

- Identify and quarantine all unused CryoFlex Surgical Ablation devices as listed in the table below.
- Return all unused affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you in the return of this product.
- Please forward this notice to all those who need to be aware within your organization.

There are no actions required for patients where the CryoFlex Surgical Ablation devices was used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols.

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 at <XXXX>.

Sincerely,

Local / BU Manager

Table 1: CryoFlex Surgical Ablation devices Affected Serial Numbers

CryoFlex Connector Probe Affected Model Numbers and Serial Numbers	
Model	**60SF3**
18420021,18420022,18420023,18420024,18420025,18420026,18420027, 19820016,19820017,19820018,19820019,19820020,19820021,19820022,19820023,19820024	