Medtronic

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URGENT MEDICAL DEVICE RECALL
BIOCAL™ Temperature Controller
Model Numbers 370 and 370I

7 February 2018

Dear Risk Manager, Health Care Professional, or Distributor
CC: The Chairman Medical Board and relevant Head of Departments

The purpose of this letter is to advise you that Medtronic is conducting a voluntary medical device recall for all serial numbers of the BIO CAL Temperature Controller, Models 370 and 370I. We are requesting BIO CAL users to discontinue use and dispose of BIO CAL devices. No other Medtronic products are affected by this action.

Issue Description:

In recent years, safety issues have been raised by regulators, including FDA, regarding water system quality of temperature controllers, regardless of the manufacturer. The concern stems from the potential for bacterial growth in the water systems that can be transmitted to patients during surgery, and is likely related to the recommended water system cleaning practices and protocols employed. Medtronic distributed BIO CAL devices to the marketplace between 1989 and 2011. As of January 31, 2018, there have been two complaints received that suggest patients acquired a serious infection while undergoing surgery when a BIO CAL device was being utilized. These complaints were received from a single customer in 2015. Although a direct causal connection between the patient infection and the BIO CAL could not be confirmed, the infection type was consistent with a waterborne bacterium (*Mycobacterium abcessus*) and could have been attributed to the site's cleaning and disinfecting of the device prior to use.

Medtronic has collaborated with regulators to develop a revised cleaning protocol for the BIO CAL devices, but after significant efforts we have been unable to develop a cleaning protocol to satisfy current industry concerns and expectations. As a result, an updated cleaning protocol will not be developed by Medtronic and it has been determined that the best course of action is to request BIO CAL users to discontinue use and dispose of BIO CAL devices. Medtronic records indicate that you may have one or more remaining affected BIO CAL devices in your possession.

Customer Actions:

1. **Medtronic is recommending that BIO CAL Temperature Controllers Models 370 and 370I no longer be used for clinical procedures. An updated cleaning protocol will not be developed by Medtronic.**

2. **Dispose of any devices in your possession per your normal equipment obsolescence procedures. Do not resell for clinical use.**

3. For patients who were exposed to a BIO CAL device, there are no recommendations for additional follow-up, physician communication, or a change in patient management beyond routine practice. If infection and/or symptoms do develop after patients were exposed to a BIO CAL device, health care professionals should refer to the following communications on the topic for next steps: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/)

4. Please complete the attached Confirmation Form in its entirety and return it as directed to confirm your receipt and understanding of this information.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced quality problems or adverse events.

If you have any questions or concerns regarding this recall, please do not hesitate to contact your local Medtronic representative.

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 Sales Representative.

Sincerely,

[redacted]

Diana Teo
Quality System Lead SEA
Medtronic

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Customer Confirmation Form

BIOCAL™ Temperature Controller
Model Numbers 370

Customer Contact Details	Medtronic Contact Details
Hospital / HCP:	**E-mail:**
Address:	**Phone:**
Telephone no:	
Fax no:	
E-mail:	

Tick ☐ here: If the unit (s) have been obsoleted, and fill up the serial # of the affected unit(s) in below table

Indicate in the columns below all serial numbers you have in your facility. If you have forwarded affected BIOCAL 370 OR 370I to other persons or facilities, provide the serial numbers and the recipient's name and address, if known. Forward the notification to these facilities:

BIOCAL Product Code	BIOCAL Temperature Controller Serial Number	Sent to another facility Yes/No	Facility name and address (if different than above)

By signing this form, I confirm that I have read and understood the Urgent Medical Device Recall BIOCAL™ Temperature Controlled Model Numbers 370 and 370I Notification Letter, dated 7 February 2018, from Medtronic regarding the BIO CAL Temperature Controller. By signing this form, I confirm I understand that Medtronic is recommending that BIO CAL Temperature Controllers Models 370 and 370I no longer be used for clinical procedures; and to dispose of these devices if in possession per my facilities normal equipment obsolescence procedures. Do not resell for clinical use. I also agree to further distribute and communicate this import information within my facility as required.

Name: _____ (print) Signature (ink): _____ Stamp: _____ Date: _____