Medtronic
8200 Coral Sea St NE
Mounds View, MN 55112
www.medtronic.com

URGENT MEDICAL DEVICE RECALL

BIOCAL™ Temperature Controller

Model Numbers 370 and 370I

February 2018

Dear Risk Manager, Health Care Professional, or Distributor:

The purpose of this letter is to advise you that Medtronic is conducting a voluntary Urgent 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:

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

- **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/
- Acknowledge this Urgent Medical Device Recall by completing the enclosed Customer Confirmation Certificate, then scan and email to RS.CFQFCA@medtronic.com

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.

Medtronic is communicating this information to the appropriate Regulatory authority.

Adverse reactions or quality problems experienced with this product should be reported to FDA and Medtronic:
• Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
• Call FDA (800) FDA-1088
• Contact Medtronic at rs.cctcomplaints@medtronic.com

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,

Christopher D. Harrold
Vice President, Quality
Medtronic Coronary & Structural Heart