Medtronic
Medtronic Canada ULC
99 Hereford Street
Brampton, ON
L6Y 0R3

URGENT: MEDICAL DEVICE RECALL

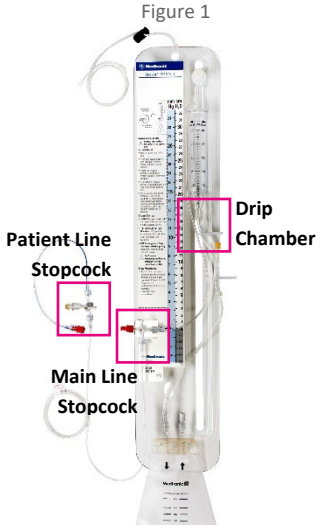
Becker and Exacta External Drainage and Monitoring Systems
Potential for Stopcock Cracking and Leaking

01-November-2024

Dear Risk Manager,

The purpose of this letter is to notify you of a medical device recall related to the Becker and Exacta external drainage and monitoring systems (EDMS). Specifically, there is the potential for cracking and leaking in the "stopcock" component on Becker and Exacta EDMS. Included in this notification are steps that can be taken to mitigate the issue. At this time, all lots of the products listed in Appendix A, with remaining shelf life, are impacted. Medtronic will issue a follow-up notification when updated or alternative product is available.

Figure 1



Issue Description:

Medtronic has received customer complaints reporting cracks and/or leaks on the stopcock of Becker and Exacta EDMS devices. On these devices, the stopcocks may be in three different locations in the EDMS, depending on the specific system configuration (see Figure 1 for an example Becker system).

Cracks or leaks of the stopcock can compromise line integrity and, as a result, present a potential for infection. Three adverse events associated with patient infection have been reported.

Recommended Mitigations*:

- Prior to use, inspect all stopcocks and connections to ensure that connections are secure and that there are no visible cracks in the stopcocks. If cracks or leaks are identified, do not use the device and return it to Medtronic.
- The system must be pre-filled with sterile isotonic saline solution prior to connecting to the patient.
- Check all connections to ensure that fittings (connections) are tight and leak-free.
- All connections should be finger tightened. Over tightening can cause cracks and leaks to occur.
- After cleaning with alcohol, or a disinfectant containing alcohol, allow to air dry completely prior to connecting the system.

Patient Management Recommendations:

- If the system develops cracks or leaks during use, replace it using sterile technique and return the damaged system to Medtronic. If the leak occurs with the Patient Line Stopcock (see Figure 1), consider application of a hemostat or other clamp to the proximal patient line while coordinating a replacement if occlusion of the patient line does not create a risk to the patient.
- As stated in the product labeling, all patients with EDMS should be monitored for evidence of infection. If a system is found to have cracks or leaks, the system should be replaced, and the patient should continue to be monitored for evidence of infection.

* The mitigations described are consistent with the instructions for use (IFU) for Becker and Exacta. Please refer to the IFU for full details.

Required Actions:

Please complete and return the enclosed customer confirmation form to acknowledge that you have read and understand this letter.

- Forms can be completed manually and emailed to rs.canfieldactions@medtronic.com including MDT Internal Reference #: FA 1452 Rev A in the subject line.
- A digital Customer Confirmation can be completed using the QR code provided below; or,
- Visit www.medtronic.ca/fieldactions and complete the form under: November 2024: *FA1452 Rev A Becker and Exacta External Drainage and Monitoring Systems, Potential for Stopcock Cracking and Leaking*

Please post a copy of this notification near impacted product as a reminder of the issue and recommended mitigating actions. Retain a copy of this letter and completed response form for your records.

Digital Customer Confirmation Form:

Additional Information:

Medtronic is working to address the potential for stopcock cracking and leaking. A follow-up notification will be issued when Medtronic is able to replace any unused Becker and Exacta products. Medtronic is communicating this information to the appropriate regulatory agencies. As is standard practice, adverse events or quality problems experienced with this product should be reported to Medtronic through your local Medtronic Sales 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 local Medtronic Sales Representative.

Sincerely,

Zachary Zoltek
Manager, Post-Market Vigilance
Medtronic Canada ULC

Enclosure:
Customer Confirmation Form

Appendix A Product Scope:

Product Names	Medtronic Product Number (REF)
KIT 27581 EXACTA W/EDM VCATH 35CM	27581
EDMS 27779 BECKER BC NDLESS BOND CONN	27779
EDMS 27785 EXACTA 50ML BC NDLESS INJ	27785
EDMS 46128 BECKER II BLUE PT LN	46128
SYSTEM 46700 EXACTA DISP. DRAINAGE	46700
SYSTEM 46705 EXACTA DRAINAGE 100ML	46705

Formulaire de confirmation du client
URGENT : RAPPEL DE DISPOSITIF MÉDICAL

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For completion by Medtronic Customers Only – Please complete all fields below and return immediately.

By signing this form I confirm that I have read the Urgent Medical Device Recall Notification Letter, dated 01 November 2024, from Medtronic regarding Becker and Exacta External Drainage and Monitoring Systems Potential for Stopcock Cracking and Leaking and taken appropriate action.

Please complete and sign the form as indicated below; if you are completing the form manually, please email it to rs.canfieldactions@medtronic.com.

_____	_____
Name of person completing form	Hospital/Account Name
_____	_____
Title/Department	Hospital/Account Address
_____	_____
Email	Hospital/Account City, Province, Postal Code
_____	
Phone number	
_____	_____
Signature (in ink)	Date (DD-MMM-YYYY)

Note: The addressee may continue to receive reminders of this notice until a response is received.