

URGENT: MEDICAL DEVICE CORRECTION **Becker and Exacta External Drainage and Monitoring Systems** **Potential for Stopcock Cracking and Leaking**

13 November 2024

Dear Healthcare Professional:

The purpose of this letter is to notify you of a medical device correction 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.

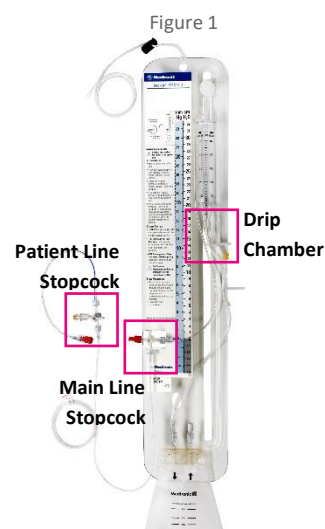
Issue Description:

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.



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

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.

Required Actions:

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

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. Adverse events or quality problems experienced with this product should be reported to Medtronic

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 representative

Sincerely,

Alison Webster
VP Quality CST
Medtronic, Inc.

Enclosure: Customer Confirmation Form

Appendix A Product Scope:

Product Names	Medtronic Product Number (REF)	GTIN
KIT 27581 EXACTA W/EDM VCATH 35CM	27581	00763000333478
EDMS 46128 BECKER II BLUE PT LN	46128	00763000333676
EDMS 46128 BECKER II BLUE PT LN	46128	00763000406073
SYSTEM 46700 EXACTA DISP. DRAINAGE	46700	00763000333690

Note: Kitted products may possess two CFNs, and the contents of the outer carton might have been removed and stored independently in the hospital inventory. The table above contains all CFNs (both outer carton and inner tray). Even if product is removed and stored outside of the outer carton, the listing above is inclusive of all impacted EDMS CFNs.

Below is an example of outer carton and inner tray labeling configurations:

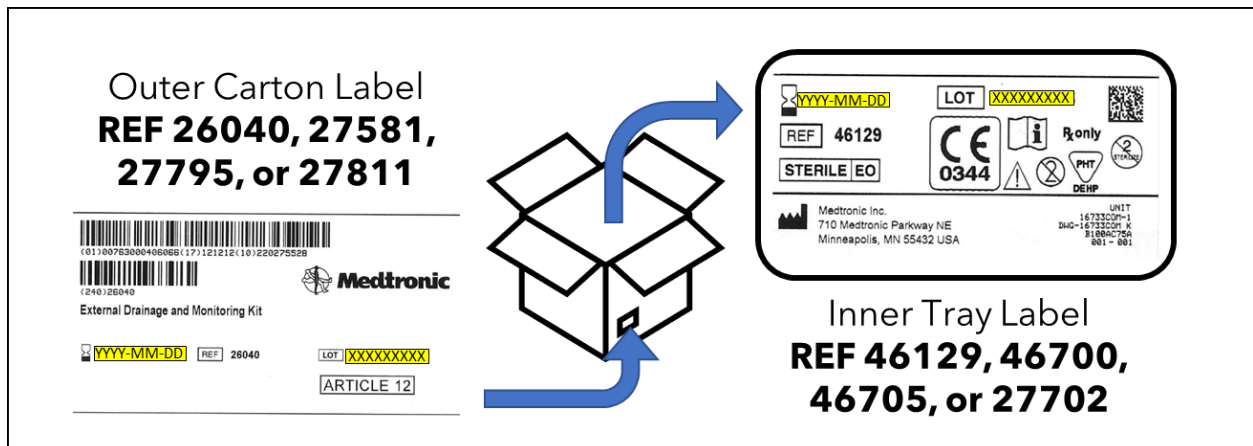


Figure 2 - Becker/Exacta EDMS Kit (outer carton) and Becker/Exacta EDMS Device (inner tray)