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Urgent Field Safety Notice

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

Notification

November 2024

Medtronic Reference: FA1452

Dear Healthcare Professional/ Risk Manager:

The purpose of this letter is to notify you of an Urgent Field Safety Notice 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 product GTINs listed in Appendix A, with remaining shelf life, are impacted. Medtronic will issue a follow-up notification when updated or alternative product is available.

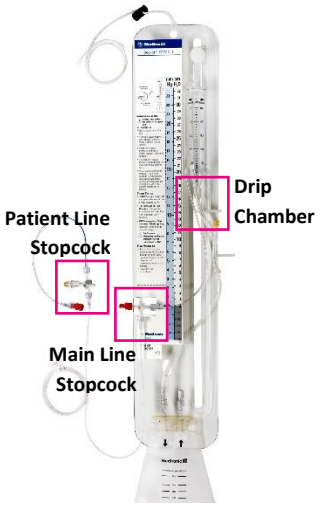

Figure 1

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.

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

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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 Acknowledgment 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 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,

Ibrahim Yassir
Neurosurgery OU Lead

Enclosure: Customer Acknowledgment Form
Appendix A Product Scope

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Appendix A Product Scope:

Product Names	Medtronic Product Number (REF)	GTIN
KIT 26040 BECKER EDMS II	26040	00763000333447
KIT 27581 EXACTA W/EDM VCATH 35CM	27581	00763000333478
EDMS 46128 BECKER II BLUE PT LN	46128	00763000333676

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:

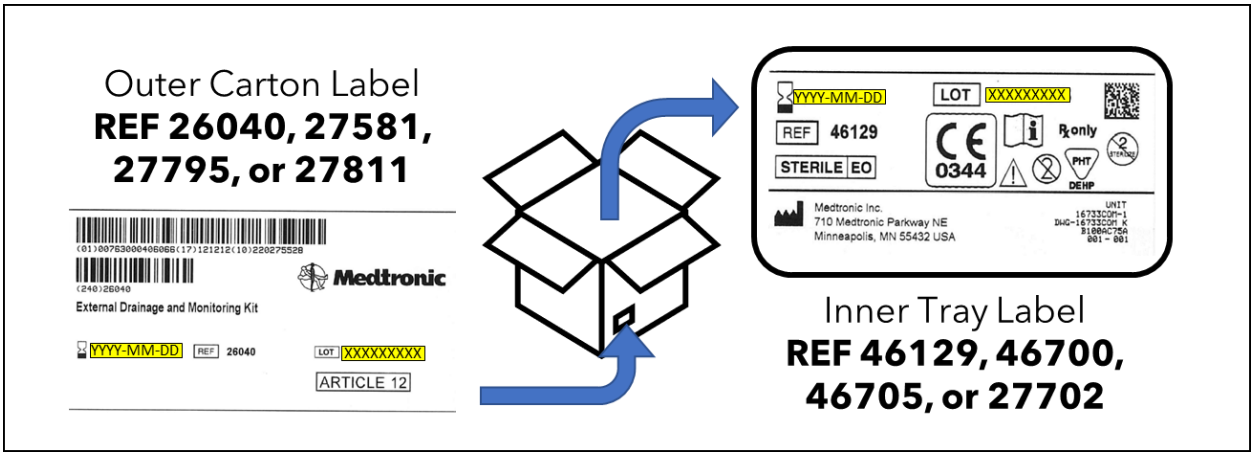

Figure 2 – Becker/Exacta EDMS Kit (outer carton) and Becker/Exacta EDMS Device (inner tray)

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FA1452 Customer Acknowledgement Form - Response is required

Becker and Exacta EDMS Stopcock Cracking and Leaking

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title:_____

Direct Phone #:_____

Email:_____

Account Name:_____

Account Number:_____

Account Address:_____

City: _____Zip Code:_____

Country:_____

I have read and understand the instructions provided and acknowledge receipt of the **notification** regarding the use of the **Becker and Exacta EDMS** by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed **Becker and Exacta EDMS** as required.

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

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

nahar.s.alsurayi@medtronic.com