

URGENT: MEDICAL DEVICE CORRECTION

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

November 2024

Dear Healthcare Professional/ Risk Manager:

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.

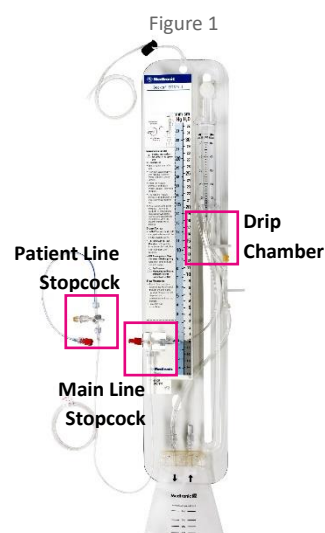
Issue Description:

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.

If you choose to return unused product, Medtronic will honor the return for a full credit. Contact Medtronic Customer Service via email: rs.jaxcustomerservice@medtronic.com, or Phone: 1-800-874-5797 Option 1, and mention FA1452, <Lot Number and Product Number> to initiate the returns process.

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 and the FDA MedWatch Adverse Event Reporting program via:

- Medtronic Customer Quality at rs.mnsprodexperiencehelp@medtronic.com. Please retain product associated with complaints for return to Medtronic for analysis.
- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>
- FDA telephone at 1-800-FDA-1088 (1-800-332-1088)

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 or Medtronic Technical Support (US) at 1-888-826-5603 and reference FA1452.

Sincerely,



Alison Webster
VP Quality CST
Medtronic, Inc.

Enclosure: Customer Confirmation Form

Appendix A Product Scope:

Product Names	Medtronic Product Number (REF)	GTIN
EDMS 24146 BECKER NO Y-SITE	24146	00763000333423
EDMS 24146 BECKER NO Y-SITE	24146	00763000572839
EDMS II 25120 BECKER W/1-WAY VALVE	25120	00763000333430
EDMS II 25120 BECKER W/1-WAY VALVE	25120	00763000431297
KIT 26040 BECKER EDMS II	26040	00763000333447
KIT 26040 BECKER EDMS II	26040	00763000406066
KIT 27581 EXACTA W/EDM VCATH 35CM	27581	00763000333478
BECKER 27609 W/NEEDLESLESS INJ. SITE	27609	00763000333485
BECKER 27609 W/NEEDLESLESS INJ. SITE	27609	00763000529307
EDM 27636 EXACTA W/BRAIDED CORD LOCK	27636	00763000333492
EDM 27666 EXCTA W GLUE STPCK GR PT LN	27666	00763000333515
BECKER 27670 STOP BELOW DC NDL-LS IN	27670	00763000333522
BECKER 27670 STOP BELOW DC NDL-LS IN	27670	00763000529314
BECKER 27672 ONEWAY VLV Y-SITE PT LN	27672	00763000333539
EDMS 27702 EURO BECKER II GR PT LN	27702	00763000333553
EDMS 27702 EURO BECKER II GR PT LN	27702	00763000467326
EDM 27732 EXACTA W/NDL-LS INJ. ST W/CAP	27732	00763000333560
BECKER 27761 STOP BCNDLESS PATLN 24	27761	00763000333577
BECKER 27761 STOP BCNDLESS PATLN 24	27761	00763000529338
BECKER 27767 NO STPCOCK ON PTLN 63	27767	00763000333584
EDMS 27779 BECKER BC NDLESS BOND CONN	27779	00763000333591
EDMS 27779 BECKER BC NDLESS BOND CONN	27779	00763000529345
EDMS 27785 EXACTA 50ML BC NDLESS INJ	27785	00763000333607
EDMS 27795 EXACTA 100ML CATH	27795	00763000333614
EDMS 27811 BECKER GRN PL VCATH	27811	00763000333638
EDMS 27861 EXACTA 50ML ANTIRFLUX GRNPL	27861	00763000333645
EDMS 27873 BECKR W/SC BLW DC W/NLESS INJ	27873	00763000333652
EDMS 27931 BECKER GS TUBING SMARTSITES	27931	00763000333669
EDMS 27931 BECKER GS TUBING SMARTSITES	27931	00763000467364
EDMS 46128 BECKER II BLUE PT LN	46128	00763000333676
EDMS 46128 BECKER II BLUE PT LN	46128	00763000406073
EDMS 46129 EURO BECKER II BLUE PT LN	46129	00763000333683
EDMS 46129 EURO BECKER II BLUE PT LN	46129	00763000431259
SYSTEM 46700 EXACTA DISP. DRAINAGE	46700	00763000333690
SYSTEM 46705 EXACTA DRAINAGE 100ML	46705	00763000333706

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:

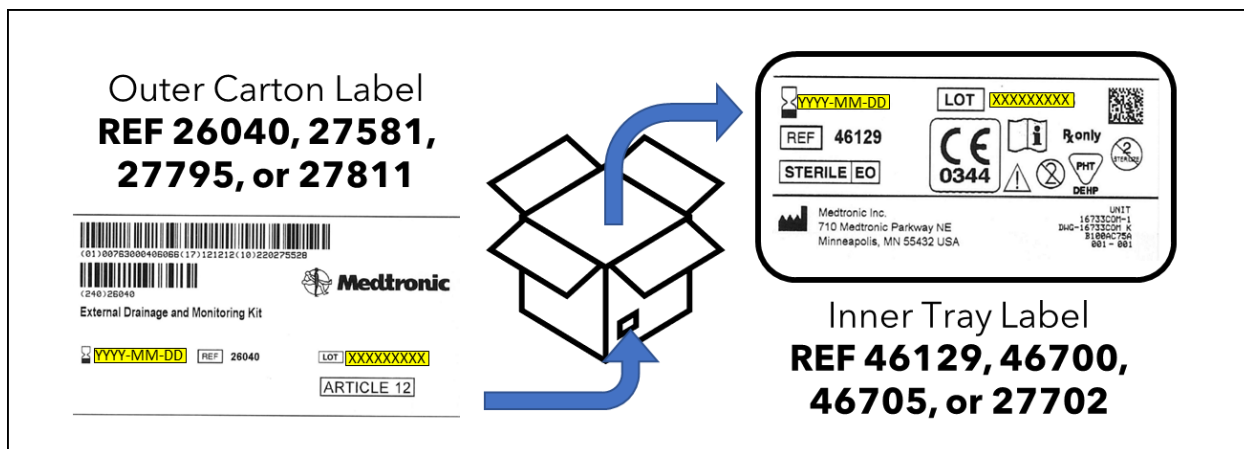


Figure 2 - Becker/Exacta EDMS Kit (outer carton) and Becker/Exacta EDMS Device (inner tray)