

**Urgent Field Safety Notice****Becker and Exacta External Drainage and Monitoring Systems  
Potential for Stopcock Cracking and Leaking**

Follow-up notification to November 2024 communication

June 2025

Medtronic Reference: FA1452

EU Manufacturer Single Registration Number (SRN): US-MF-000023270

Dear Healthcare Professional/ Risk Manager:

This letter is a follow-up notification to Medtronic's November 2024 communication regarding Becker and Exacta External Drainage and Monitoring systems (EDMS) potential for stopcock cracking and leaking. Within that notification Medtronic committed to informing customers when alternative product was available. At this time, the Duet EDMS system is available as an alternative to the Becker and Exacta EDMS.

Duet EDMS products available for order:

- 46913 - Duet™ EDMS with Interlink™ needleless injection site
- 46914 - Duet™ EDMS with SmartSite™ needleless injection site

Medtronic is ceasing production of Becker and Exacta products. The existing Becker and Exacta unused inventory may continue to be used according to the previously communicated mitigations in the November 2024 Urgent Field Safety Notice (included as an enclosure to this letter).

**Customer Actions:**

The November 2024 Urgent Field Safety Notice has been included for your reference. 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 communicating this updated 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 issue may have caused. We are committed to patient safety. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Local / OU manager

Enclosure: November 2024 Urgent Field Safety Notice