Medtronic News

FDA Classifies HeartWare(TM) HVAD(TM) Systems Unexpected Power Source Switching as Class I Recall

DUBLIN - June 1, 2018 - The United States Food and Drug Administration (FDA) has classified Medtronic plc's (NYSE: MDT) recent voluntary urgent field action related to the HeartWare(TM) HVAD(TM) System unexpected power source switching as a Class I recall. Class I recalls describe situations where there is reasonable risk of serious adverse health consequences or death.

There have been no confirmed reports of catastrophic harm associated with this issue. The per patient probability of serious adverse events due to this issue is approximately 0.003. This recall affects 16,399 HeartWare(TM) Ventricular Assist Device (HVAD) Systems implanted as of May 22, 2018.

In a notification letter distributed in May 2018, Medtronic alerted clinicians worldwide about a potential transient interruption of the electrical connection between a HeartWare HVAD System power source and the HVAD Controller, which results in unintended switching to the device's secondary power source and could cause the System to momentarily stop and restart. In addition, unintended power switching can result in unexpected audible tones ("beeping"). This beeping, which occurs when the electrical connection interruption automatically resolves, may confuse the patient or caregiver, as the Controller may display sufficient battery capacity or AC/DC connectivity at the time of the audible tone. Also, a Critical Battery Alarm may be momentarily incorrectly displayed due to this phenomenon.

In consultation with the Independent Practitioner Quality Panel, Medtronic has provided the following patient management recommendations to clinicians:

- Reinforce the importance of always ensuring TWO power sources (AC or DC adapter plus a battery, OR two batteries) are connected at all times (except when changing a power source).
- Reinforce best practice guidance for managing power sources when going to sleep and awakening:
    - When going to bed, connect a fully charged battery and then connect the AC adapter.
    - When getting out of bed in the morning, make sure to connect two fully charged batteries.
- Instruct patients to report any persistent, unexpected audible tones to the VAD team for additional instructions.

Patients do not need to take any action other than to follow patient management recommendations provided by their clinicians to effectively manage the HVAD System power source for this unexpected power switching issue.

In late May 2018, Medtronic made available a lubricant solution, which can be applied to HeartWare(TM) HVAD(TM) System power source connectors as a method for mitigating unexpected transient power switching. The lubricant is being distributed to Medtronic HeartWare Field Representatives.

Healthcare providers may report adverse reactions or quality problems experienced with the use of this device to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular mail or fax: Download form www.fda.gov/MedWatch/getforms.htm
- or call +1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to +1-800-FDA-0178

Clinicians with questions should contact their Medtronic HeartWare representative, call Medtronic HeartWare's 24-hour Clinical Support line at +1-888-494-6365, or email FSCA@heartware.com.

The HVAD System includes a ventricular assist device (VAD) that helps the heart pump and increases the amount of blood that flows through the body in patients with advanced heart failure and the HVAD(TM) Controller, which is a small computer that

monitors and manages the System. The HVAD System is powered by an AC Adapter or DC Adaptor and/or rechargeable Batteries.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

-end-

Contacts:
Kathleen Janasz
Public Relations
+1-763-526-3676

Ryan Weispfenning
Investor Relations
+1-763-505-4626

---

https://news.medtronic.com/2018-06-01-FDA-Classifies-HeartWare-TM-HVAD-TM-Systems-Unexpected-Power-Source-Switching-as-Class-I-Recall