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Medtronic Statement on FDA Classification of Voluntary Action on Implantable Cardioverter Defibrillators, Cardiac Resynchronization Therapy Defibrillators

In May 2023, Medtronic began informing physicians of a potential risk for reduced-energy or no-energy high-voltage therapy in its implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) manufactured after July 2017. Medtronic provided physicians with comprehensive patient management recommendations in the communication. We have recommended that physicians non-invasively reprogram these devices to reduce the risk for this issue.

The FDA recently designated this voluntary action by Medtronic as a Class I recall. There have been no reports of permanent patient harm or deaths due to this issue in the affected population.

https://news.medtronic.com/Medtronic-Statement-on-FDA-Classification-of-Voluntary-Action-on-Implantable-Cardioverter-Defibrillators,-Cardiac-Resynchronization-Therapy-Defibrillators