Recommended MRI labeling based on the document, Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, Guidance for Industry and Food and Drug Administration Staff, Document issued on May 20, 2021.

MRI Safety Information

MR Conditional

The **VivoKey Spark 2** is MR Conditional. A patient with the **VivoKey Spark 2** may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name of the Device	VivoKey Spark 2
Nominal Values of Static Magnetic Field (T)	1.5-T and 3-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back to back sequences/series without breaks)
MR Image Artifact	The presence of this implant does produce an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

Important Note: The VivoKey Spark 2 is known to be magnetic (i.e., this implant has a ferrite core). However, during its intended use (i.e., implanted subcutaneously), it will not dislodge, displace, or move in association with a 3-Tesla or less, MRI environment. Importantly, the VivoKey Spark 2 becomes encapsulated by fibrous tissue within one month after implantation, thus, providing substantial stabilization of this implant.