MRI SAFETY INFORMATION

OPTIMIZER Smart Mini Implantable Pulse Generator

	MR - Conditional

MR scans are permissible at 1.5 T and 3 T with <u>local RF transmit-receive head and extremity coils only</u>. The use of the RF Body coil can result in serious injury to the patient.

The OPTIMIZER Smart Mini IPG is Magnetic Resonance (MR) Conditional, and patients with this device may be scanned safely with magnetic resonance imaging (MRI) **<u>if all the requirements for the implanted components and for scanning are met</u>**.

Restrictions for the Patient and the Implanted System

- The OPTIMIZER Smart Mini IPG must be implanted with two ventricular leads (and one optional atrial lead) of the following models:

Model	Manufacturer	Lengths (cm)
CapSureFix Novus MRI™ SureScan™ 5076	Medtronic	52, 58
CapSureFix Novus MRI™ SureScan™ 5086	Medtronic	52, 58
SelectSecure MRI SureScan 3830	Medtronic	59
2088TC Tendril STS	Abbott (St Jude Medical)	52, 58
Solia S	Biotronik	53, 60
Ingevity 7741 and 7742	Boston Scientific	52, 59
Ingevity + 7841 and 7842	Boston Scientific	52, 59

When combined, the OPTIMIZER Smart Mini IPG and such leads constitute an MR conditional device system.

WARNING: Only the lead lengths above have been evaluated for MRI compatibility and individual scan parameters. The system is considered MR-Conditional only if used with the listed leads and lengths.

- There are no other active or abandoned cardiac implants (e.g., lead extensions, lead adapters or abandoned leads) in the patient's body.

  WARNING: Do not bring any system components that are not marked MR-safe or MR-conditional into the MRI suite.

- At least six (6) weeks have elapsed since the OPTIMIZER Smart Mini IPG and/or lead implantation and/or any electrode revision or surgical modification.

- The device system is implanted pectorally.
- The OPTIMIZER Smart Mini IPG is programmed to OOO mode before the MRI scan.
- Patient does not have elevated body temperature or compromised thermoregulation at time of scan.

  WARNING: Do not scan a patient with an elevated body temperature.

Requirements of the MRI Scanner

- Use of a clinical, hydrogen-atom MRI scanner with horizontal cylindrical closed-bore magnet, and a static magnetic field strength of **1.5 or 3 Tesla.**
- **Use only transmit-receive head and extremities local RF coils** that are not positioned over the implant location.
- Maximum spatial gradient of the magnetic field of 40 T/m or 4000 Gauss/cm.
- The slew rate of the MRI scanner's gradient fields must not exceed 200 T/m/s per axis.

  WARNING: scanning under other conditions may result in severe patient injury, death, or device malfunction.

Restrictions During the MRI scan

- The specific absorption rate must not exceed limits for local transmit-receive coils as defined in IEC 60601-2-33, for example 3.2 W/kg for the head.
- Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- Patient must be continuously monitored by pulse oximetry and electrocardiography (ECG).

Image Artifacts

In non-clinical testing, the maximum image artifact size was seen on the gradient echo pulse sequence at 1.5 T and extends by approximately 6.7 cm from the boundary of the implant.

In non-clinical testing, the maximum image artifact size was seen on the gradient echo pulse sequence at 3 T and extends by approximately 4.6 cm from the boundary of the implant.

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