GALVANI
BIOELECTRONICS

MRI Guidelines
Galvani Neuromodulation System

Instructions for Use

Warning: **Do not conduct an MRI scan on a patient with any implanted Galvani System component until you read and fully understand all of the information in this manual. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including death.**

AW-1928 Rev B

℞ *Only*

Caution: Investigational device.

Limited by US Federal law to investigational use.

Exclusively for Clinical Investigation (UK/EU).

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PACKAGING SYMBOL DEFINITIONS

Symbol	Explanation
	Caution
	Consult Instructions for Use
	Magnetic Resonance (MR) Conditional
	Magnetic Resonance (MR) Unsafe
	Caution: Federal law restricts this device to sale by or on the order of a physician.

Chapter 1 INTRODUCTION

This manual is intended for use by physicians and other Healthcare Professionals (HCPs) involved in managing patients implanted with the Galvani Neuromodulation System (Galvani System), as well as radiologists and other HCPs involved in performing Magnetic Resonance Imaging (MRI) scans on such patients.

It is important to read the information in this manual in its entirety before conducting a magnetic resonance imaging (MRI) examination on a patient who has an implanted Galvani System.

Contact a Galvani representative if you have any questions about the information in this manual.

Caution: This manual focuses specifically on the use of 1.5T and 3T horizontal closed bore MRI systems for patients implanted with the Galvani System.

- MRI procedures should be performed using **ONLY 1.5T and 3T** horizontal closed bore MRI Systems. **DO NOT use MRI Systems that are open-sided, vertical-field, or are other static magnetic field strengths.** The risks of using these MRI systems have not been determined and could significantly affect the patients safety and/or device functionality.
- Refer to *Chapter 3 Warnings, Precautions and Potential Risks on page 10.*

OBTAIN THE LATEST MRI GUIDELINES

Always obtain the latest MRI guidelines the same day of the patient's MRI appointment. Make sure you have the most up-to-date version of the MRI guidelines which can be downloaded from the Galvani website: https://galvani.bio/mri or request this form from Galvani directly. See *Page 1* for Galvani contact information.

THE REQUIRED MRI ELIGIBILITY FORM

Physicians involved in managing Galvani patients are required to fill out an MRI Eligibility form to establish whether or not the Galvani patient is eligible for an MRI scan (as defined by the form). The physician provides the completed form to the patient's MRI facility before the scheduled MRI scan.

Warning: **It is critical that the MRI facility receives the MRI eligibility form before scheduling the MRI scan appointment. This form is available upon request from Galvani[1] and also at https://galvani.bio/mri. For instructions on completing the MRI Eligibility Form, see *Chapter 4 Instructions for Completing the MRI Eligibility Form on page 13*.**

[1] See *Page 1* for Galvani contact information.

MRI Preparation Steps

Clinician Prescribing an MRI

- **Request a Completed MRI Eligibility Form -** Organize a clinical visit for the patient with their treating physician who is knowledgeable about their implanted Galvani System and who has access to a Galvani programming system. This physician will fill out the MRI Eligibility form to determine if the patient is eligible for an MRI.

  Note: Check if the patient has any other medical device implants - The most restrictive MRI Exposure requirements must be used if the patient has multiple medical device implants.

- **Review the MRI Eligibility form**
  - **Review the MRI Eligibility form** to determine what type of MRI scan can be performed and review the required scan conditions.
  - Optionally, **consult with the Galvani representative in case any additional information is required**. See *Page 1* for Galvani contact information.

- **Patient preparation**
  - Advise the patients to bring the most up-to-date patient ID card to all MRI appointments. MRI personnel can then use the patient ID card to identify Galvani Bioelectronics as the manufacturer of the patient's Galvani System and to confirm the model number of the implanted IPG and Leads

    Note: If the patient cannot locate their Patient ID card, contact the treating physician or a Galvani representative for assistance.

  - Patients should consult with the treating physician prior to MR Imaging.
  - Tell the patient they will need to visit their treating physician before the MRI can be performed. Communicate the scheduled date for the clinical visit where the device checks will be performed.
  - Patients should charge their neurostimulator before their appointment with their treating physician.

Treating Physician - Determine Scan Eligibility

The physician or qualified staff member familiar with Galvani System should:

- Assess and record a patient's MRI scan-type eligibility by completing the MRI Eligibility form.
- For instructions on completing the MRI Eligibility form, see *Chapter 4 Instructions for Completing the MRI Eligibility Form on page 13*.
- Provide the MRI Eligibility form to the patient's MRI facility prior to the scheduled MRI scan.

PATIENT FLOW

An example sequence flow for a patient with a Galvani System who needs an MRI:

1 An MRI is recommended to the patient by a specialist (for example: orthopedist or oncologist).

2 The patient, or specialist, or radiologist contacts the treating physician (e.g. Rheumatologist) who manages the patient's Galvani System.

3 The treating physician determines patient eligibility for scan by completing the MRI Eligibility form and verifies if the system is functioning per specifications.

Note: The treating physician may delegate the responsibility for verifying the system functionality to a Galvani Field Clinical Engineer, see *Page 1* for Galvani contact information.

4 If the patient is eligible for an MRI, the treating physician programs the Galvani System OFF and returns this form to the appropriate Healthcare Providers involved in performing the MRI scan. (If the patient is not eligible for an MRI, the Galvani System is not programmed OFF.)

Note: Appropriate care must be taken to minimize the length of time that the therapy is programmed off. If required, consult with a Galvani representative, see *Page 1* for Galvani contact information.

Note: The ordering physician or specialist may discuss with the radiologist whether or not the MRI conducted as specified (see *Chapter 6 MRI Scanning Instructions for 1.5 Tesla and 3 Tesla, on page 16*) will provide the necessary clinical information. If not, other imaging modalities may be considered.

5 If the MRI eligibility is confirmed by the treating physician, the patient undergoes the MRI scan by the radiology department according to the conditions of use in this MRI Guidelines manual.

6 After the MRI scan is complete, the patient is instructed to return to their treating physician to have their Galvani System programmed ON.[1]

[1] Refer to the Galvani Clinician Programming manual for programing instructions. A clinician programming manual is provided with every clinician programmer. A copy of the manual is available upon request from Galvani. See *Page 1* for Galvani contact information.

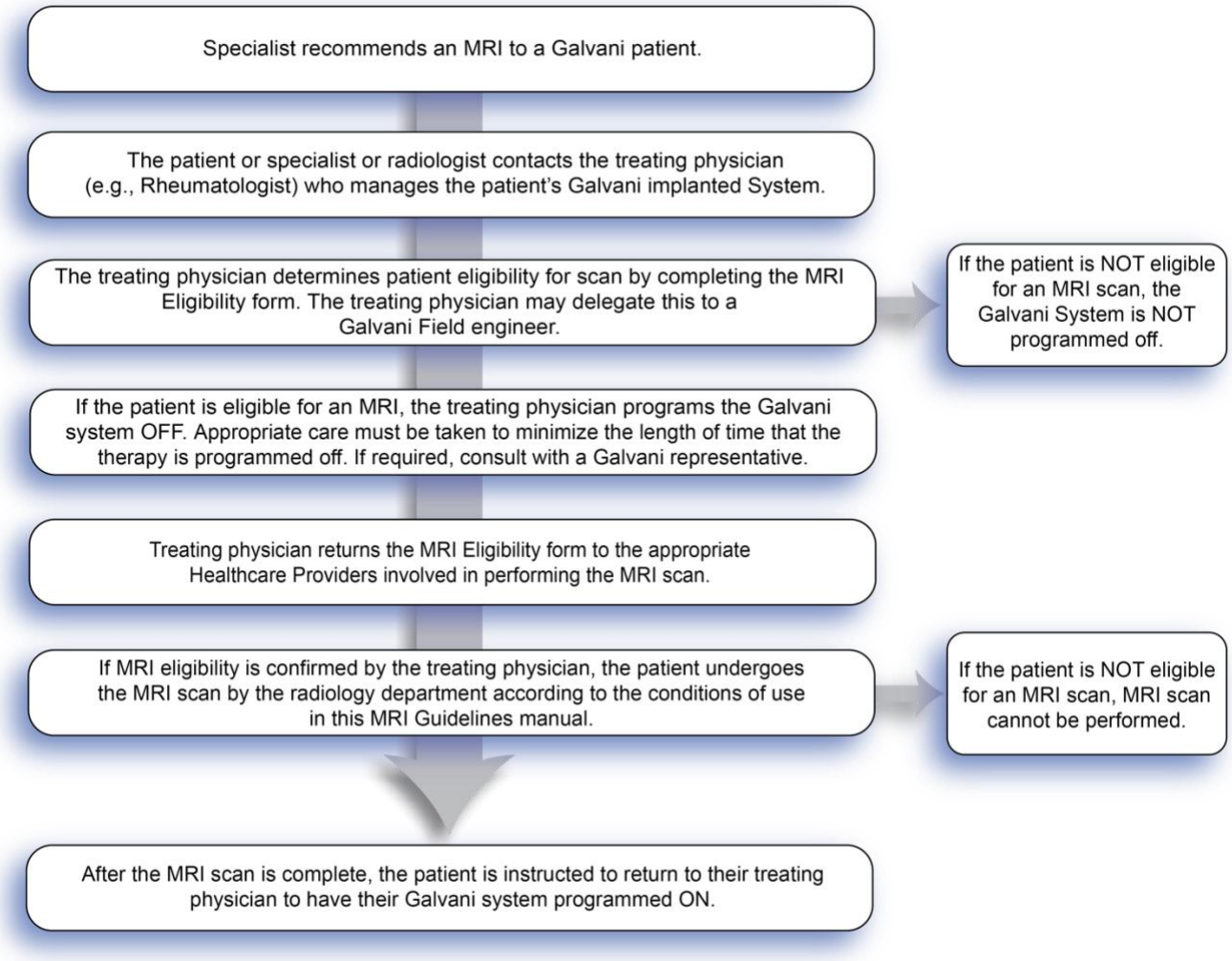


Figure 1-1 Example Patient Flow

Chapter 2 MR Conditional System Description

The Galvani system

The Galvani System is designed to provide therapy by delivering electrical stimulation to the splenic neurovascular bundle and is composed of implanted and external components.

Implanted Components

The implanted components consist of an Implantable Pulse Generator (IPG) and a Lead which delivers the electrical current used to stimulate the splenic neurovascular bundle. The IPG and Lead are implanted into the abdominal cavity using the laparoscopic procedure.

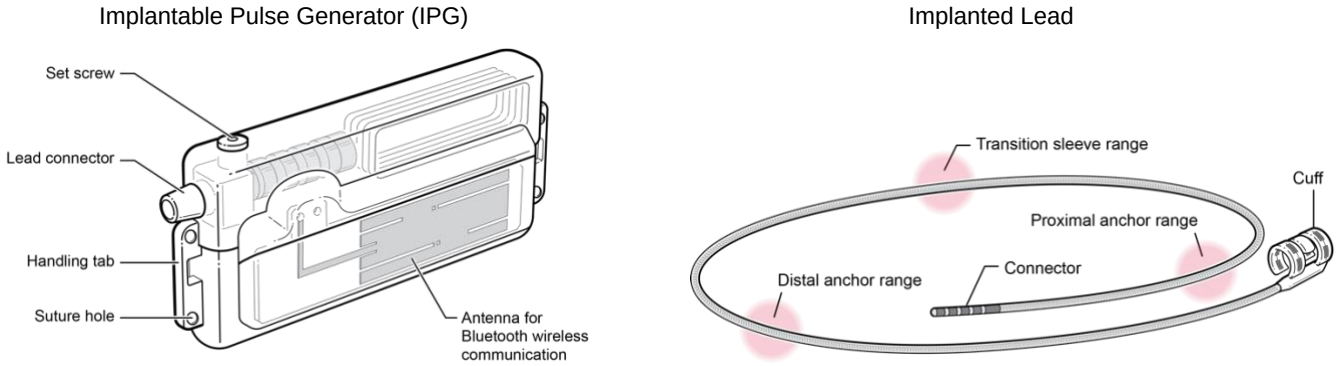


Figure 2-1 Galvani System Implanted Components:
IPG Model 21101, Lead Models 11303, 11305

External Components

The external components of the Galvani System (Clinician Programmer, Patient Remote, and IPG Charger) are **MR unsafe** and should not be taken into an MRI environment.

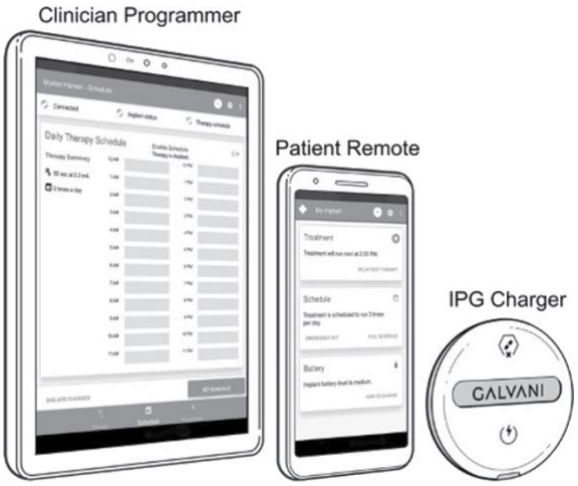


Figure 2-2 Galvani System External Components:
Clinician Programmer Model 41101, Patient Remote Model 31101, and IPG Charger Model 31102.

DETAILS ABOUT THE GALVANI SYSTEM

- For Galvani System component specifications, see the Galvani System Implant Manual which is available upon request from Galvani. See *Page 1* for Galvani contact information.
- For detailed system component and implant location information, see *Galvani System Components on page 23*.

Chapter 3 Warnings, Precautions and Potential Risks

Warnings and Cautions

- **Read and fully understand guidelines before conducting MRI scan** - Do not conduct an MRI examination on a patient with any implanted Galvani System component until you read and fully understand all the information in this manual. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including death. No claims of safety are made for MRI scans involving modified Galvani System or components or for non-Galvani components or accessories.
- **Verify all implanted devices** - Prior to an MRI scan, determine whether the patient has multiple medical device implants, either active medical device implants (such as chronic pain stimulation systems, implantable cardiac defibrillators, etc.) or passive medical device implants (such as spinal hardware, stents, etc.). Use the most restrictive MRI exposure requirements for the medical devices implanted. Contact the appropriate device manufacturers if you have questions. If you are unclear what implants may be present, perform an x-ray to determine implant type and location. Do not conduct an MRI scan if any conditions or implants that would prohibit or contraindicate an MRI are present
- **Abandoned Systems and Electromagnetic Interference (EMI) considerations** - MRI scan-type eligibility for patients with abandoned systems (i.e., abandoned components no longer providing therapy) cannot be determined for MRI scanning purposes. If any Galvani System components (neurostimulator, lead, or a lead fragment) remain implanted in the patient's body after a partial system explant, the patient is still susceptible to possible adverse effects from EMI. These effects include induced current and component heating, which may result in shocking or jolting the patient and tissue damage resulting in serious injury or death. Advise patients who have Galvani System components implanted in their body to notify all medical personnel that they have an implanted Galvani System.
- **Avoid exposure to unapproved MRI parameters** - In-vitro testing has shown that exposure of the Galvani System to MRI at parameters other than those described in this guideline can induce significant heating at the lead electrodes or malfunctioning of the device. Excessive heating may occur even if the lead and/or lead fragment are the only part of the Galvani System that is implanted. Excessive heating can result in serious and permanent injury including death.
- **Ensure appropriate supervision** - A responsible individual with expert knowledge about MRI, such as an MRI radiologist or MRI physicist, must ensure all procedures in this guideline are followed and that the MRI scan parameters, especially RF (Radiofrequency) specific absorption rate (SAR), and gradient parameters, comply with the recommended settings. The responsible individual must verify that parameters entered into the MRI system meet the guidelines in this manual.

PRECAUTIONS

- **External system components** are **MR Unsafe** in the scanner (magnet) room – Do not allow the following Galvani external control devices into the MRI scanner (magnet) room. These devices are MR Unsafe:
  - Patient Remote
  - Charger
  - Clinician Programmer
- **Confirmation of Model Number and Programmed Settings** – The Galvani System clinician programmer can be used to confirm the neurostimulator model number, check impedance, turn off therapy and/or change programming settings. A patient remote or a charger can also be used to turn off therapy. All clinician programmers can be used to match the therapy settings indicated on the MRI Eligibility form prior to an MRI scan.

  If a Galvani System clinician programmer cannot communicate with the neurostimulator, then MRI eligibility cannot be established. An MRI scan should not be conducted unless the implanted system configuration is known and it is determined to be safe to conduct an MRI scan under specific conditions.

  Note: Operating instructions for the clinician programmer are available in the Galvani Clinician Programming manual. For operation of a patient remote, refer to the Galvani System Patient Manual. These manuals are available upon request from Galvani, see *Page 1* for contact information.
- **Patient ID card:** Advise the patient to bring the most up-to-date patient identification (ID) cards to all MRI appointments. MRI personnel can then use the patient ID cards to identify Galvani Bioelectronics as the manufacturer of the patient's neurostimulation system and to confirm the model and serial number of the implanted neurostimulator.

  Note: Advise patients with multiple implanted neurostimulators to bring all current patient ID cards to their MRI appointments.

POTENTIAL RISKS

- **MRI-related heating effects** – The MRI RF field induces currents onto the lead system that can produce significant heating effects at the lead-electrode-tissue interface or at the location of any breaks in the neurostimulator lead system. Component heating from the MRI RF field is the most serious risk from MRI exposure. Failure to follow these MRI recommendations can result in thermal tissue damage, which could lead to serious and permanent injury including death.
- **Induced stimulation** – The gradient magnetic and RF fields produced by an MRI scanner induce currents onto implanted lead systems that could potentially cause unintended stimulation, which may result in unintended stimulation or unusual sensations.
- **Device Malfunction or Damage** – The static, gradient, and RF fields of the MRI may affect the neurostimulator operation and programming. For example, it may impact the telemetry, or stimulation pulses after the device is switched on.

- **Image Artifacts and Distortions** – Significant image distortion can result from the presence of the neurostimulator within the field of view. Image artifacts and distortion resulting from the presence of the neurostimulator or lead within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images. For details, see *Image Distortion on page 17*.
- **Magnetic field interactions** – The magnetic material in an implanted system may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. Patients may feel a mild tugging or vibration sensation at the site of the device implant. Patients with recent implant incisions should be monitored for any surgical wound discomfort during an MRI scan.

Chapter 4 Instructions for Completing the MRI Eligibility Form

It is critical that the MRI facility receives the MRI scan eligibility information before scheduling the MRI scan appointment. Use the MRI Eligibility Form to communicate this information to the MRI facility.

The MRI Eligibility form is available upon request from Galvani[1] and is also available at https://galvani.bio/mri.

Note: Communication between the treating physician and the MRI facility is always recommended prior to an MRI scan.

MRI Eligibility Factors

- No partial implanted device systems.
- Neurostimulator model number and implant location.
- System integrity.
- Head or whole body scan eligibility factors (1.5T or 3T).
- Galvani System programmed to Stimulation OFF or Hibernation mode.

Completing the MRI Eligibility Form

1 **Confirm that no partial device system is implanted.**
Use an x-ray or review of the patient record to confirm that there are no additional Galvani components implanted in the patient. The Galvani System is not intended to be scanned with abandoned leads. Confirm this information on the MRI Eligibility form.

2 **Interrogate the neurostimulator with a clinician programmer. For instructions, refer to the Galvani System Clinician Programming manual.[2]**

a Record the Galvani System model number, serial number, and the implant location on the MRI Eligibility form.

b Measure unipolar (monopolar) impedance between each electrode and the neurostimulator case, and bipolar impedance between electrode pairs.

i. Refer to Table 4-1 for passing impedance values.

Table 4-1 Impedance Passing Values Criteria

Monopolar Impedance Passing Criteria	Bipolar Impedance Passing criteria
Case to Distal: <1300 ohms	Distal to Proximal: <1300 ohms
Case to Proximal: <1300 ohms	

[1] See *Page 1* for Galvani contact information.

[2] A clinician programming manual is provided with every clinician programmer. A copy of the manual is available upon request from Galvani. See *Page 1* for Galvani contact information.

ii. Check the appropriate box based on the impedance values.

- Proceed to Step 3 if the Impedance values are in the passing range (the Galvani System is functioning properly and no open or short circuits are detected).
- If the impedance values are NOT in the passing range, then the MRI scan type eligibility cannot be determined and the safety of an MRI scan cannot be evaluated. These impedance values indicate that the system is compromised.

Warning: **An MRI procedure should not be performed on a patient with a Galvani System that has a broken conductor wire in the lead because higher than normal heating may occur at the lead break or the lead electrodes, which can cause thermal tissue damage. This tissue damage may result in death.**

Notes:

- If a programmer cannot communicate with the device, then MRI scan eligibility cannot be determined.
- If you cannot resolve an impedance issue or if you are unsure of system integrity after testing connections, contact Galvani representative, see *Page 1* for Galvani contact information.

3 **Program the device stimulation OFF or set the device to Hibernation mode.** For instructions, refer to the Galvani System Clinician Programming manual which is available upon request from Galvani. See *Page 1* for Galvani contact information.

Warning: **Abruptly ending stimulation for any reason may cause a return of disease symptoms. This can, in rare cases, become a medical emergency.**

Caution: The decision to turn off a patient's implanted neurostimulator for an MRI scan should be carefully considered based on the patient's underlying medical condition. Consultation with the appropriate medical professional (prescribing or implanting clinicians) is recommended.

4 **Select the type of MRI scan eligibility (Head and Whole Body) for the patient on the MRI form.** This step is used to select the appropriate scan conditions and MRI scanner (1.5 T or 3T) to perform the scan.

5 **Patient Preparation.** Instruct the patient to revisit the physician once the scan is complete so that the device stimulation can be turned ON.

Note: Therapy settings cannot be changed until the MRI scan is complete.

Note: In the event that the device malfunctions or a device event occurs during the MRI scan, contact a Galvani representative immediately using the contact information on *Page 1*.

6 **Send MRI Eligibility form** to the appropriate Healthcare provider performing the MRI scan.

Chapter 5 MRI Clinicians - Eligibility Confirmation

Before performing an MRI scan on a patient with a Galvani System, you should receive and review a completed MRI Eligibility form from the clinician managing the patient's Galvani System.

Note: Communication between the treating physician and the MRI facility is always recommended prior to an MRI scan.

It is recommended that clinicians familiar with the Galvani System assess their patients' MRI scan-type eligibility (i.e., Head only or whole body) before each patient receives an MRI scan. Clinicians determining MRI scan-type eligibility must record scan eligibility and system preparation information on a separate MRI eligibility form and provide that form to the patient's MRI facility before the scheduled MRI scan.

Note: The instructions and conditions to safely perform an MRI scan may extend the duration of the MRI appointment.

Caution: Only qualified MRI clinicians (i.e. the attending MR radiologist, MR medical director, or designated MR personnel) should use these procedures to make decisions about an MRI scan of a patient implanted with the Galvani System.

Review the MRI Eligibility Form

Review the MRI Eligibility form information to confirm the patient's MRI scan eligibility and that the Galvani System has been programmed for the MRI scan (i.e. stimulation turned off or set to Hibernation mode). If any required information is missing, contact the patient's treating physician prior to the MRI scan.

1 Confirm the patient's name and date of birth.

2 Review the MRI Eligibility determination date. The older the form, the greater the chance that changes to the Galvani System may have occurred.

3 Ask the patient if any of the following events have occurred since the MRI Eligibility form was generated:

- Has the patient had a fall, physical trauma, or revision surgery, which may have changed the MRI scan eligibility?
- Was the Galvani System turned back on, or the settings changed, which may affect patient safety during an MRI scan? If an event or therapy change is suspected, contact the treating physician before proceeding with the MRI scan.

4 Confirm that the neurostimulator and lead models listed on the form are correct by reviewing the Patient ID card.

5 Review the MR Conditional scan conditions and safety information found in *Chapter 6 MRI Scanning Instructions for 1.5 Tesla and 3 Tesla on page 16.*

Chapter 6 MRI Scanning Instructions for 1.5 Tesla and 3 Tesla

MRI Scan Procedure Overview

Before proceeding with an MRI scan, verify that the patient and the MRI scanner meet the MRI Conditions of Use.

See the following:

- *Chapter 5 MRI Clinicians - Eligibility Confirmation on page 15.*
- *Section: General requirements* on this page.

This verification must be performed prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MR Conditional scan.

Warning: Unless all of the MRI Conditions of Use are met, the patient is not eligible for an MRI scan and performing an MRI scan may cause significant harm to or death of the patient and/or damage to the implanted system.

Refer to *Chapter 3 Warnings, Precautions and Potential Risks on page 10,* for potential adverse events applicable when the Conditions of Use are not met.

General Requirements

Patient Body Temperature – If an integrated body coil is used (transmit only or transmit/receive), do not perform a scan if the patient's body temperature is greater than 37°C. Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which could cause tissue damage.

Note: Do not cover the patient with blankets or heated blankets. Blankets raise the patient's body temperature and increase the risk of tissue heating, which could cause tissue damage.

Patient Characteristics – See the MRI Eligibility Form for confirmation

- Patient position within the bore must be prone or supine.
- Scanning patients who have multiple MR Conditional items present is acceptable as long as the MR labeling conditions for all items can be satisfied.
- The patient has no abandoned leads and no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history.
- A complete Galvani System includes an implantable pulse generator (IPG) with one implantable Lead. The Galvani System is not intended to be scanned with lead extensions or different lead types or abandoned leads.
- The Galvani System is programmed to therapy OFF or the device is programmed to Hibernation mode.

- After the MRI scan, Instruct the patient to return to their treating clinician to have their Galvani System programmed ON.

CONFIRMING MRI SCANNER SETTINGS AND CONFIGURATION

Ensure that the MRI scanner equipment meets the requirements found in *Chapter 6 MRI Scanning Instructions for 1.5 Tesla and 3 Tesla on page 16.*

SCANNER REQUIREMENTS

Note: Do not use vertical field (open bore) MRI systems or systems operating at other static magnetic field strengths. The risk of using MRI systems operating at other static magnetic field strengths has not been evaluated.

- Only use static magnetic field strengths of 1.5T or 3T.
- Only use horizontal cylindrical (closed bore) MR scanners.
- Only use circular polarized (CP) mode coils to transmit.
- Only use MR scanners with maximum spatial field gradient of up to 1900 gauss/cm (19 T/m). Only use MR scanners which limit gradient slew rate to 200T/m/sec per axis or less.

IMAGE DISTORTION

Note: The presence of this implant may produce an image artifact of 67.7 mm for IPG and 11.53 mm for distal part of the lead with Cuff.

Image distortion must be considered when planning an MRI scan and when interpreting MRI images in proximity to the pulse generator and/or leads. Artifacts may include moderate spatial distortion beyond the boundaries of the visible artifact.

Table 6-1 Image Distortion

Galvani System IPG (3T MRI Testing) The MR image artifacts affect the object surrounding according to the below magnitudes		
Worst-Case artifacts of	**Spin Echo**	**Gradient Echo**
Length (Device Axis parallel to main magnetic field, B_0)	45.0 mm ± 6.7 mm	42.8 mm ± 6.4 mm
Width (Device Axis Perpendicular to main magnetic field, B_0)	39.3 mm ± 5.9 mm	52.3 mm ± 7.8 mm
Height (Device Axis Vertical to main magnetic field, B_0)	39.6 mm ± 5.9 mm	58.9 mm ± 8.8 mm
Test Object length (Cuff axis parallel to main magnetic field, B_0)	3.83 mm ± 2.9 mm	6.53 mm ± 5.0 mm
Test object diameter (Cuff axis parallel to main magnetic field, B_0)	4.83 mm ± 3.7 mm	6.18 mm ± 4.7 mm

MR SAFETY INFORMATION

Table 6-2 MRI Safety Information

MRI Safety Information

A patient with the "Galvani System" can be safely scanned under the following conditions. Failure to follow these conditions may result in serious and permanent injury, including death to the patient or item malfunction.

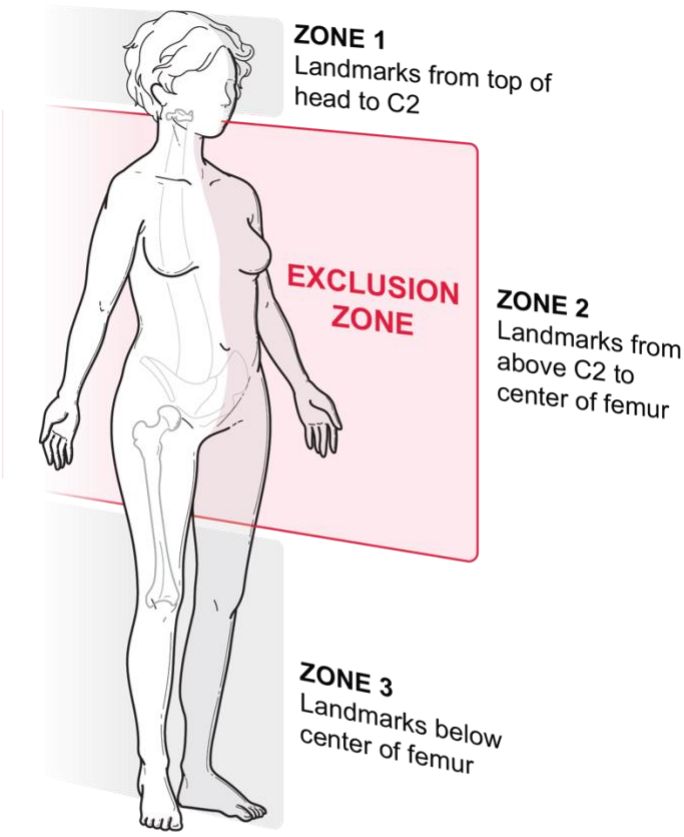
Additional Resources for MRI Safety Information	https://galvani.bio/mri
Parameter	Conditions of Use / Information
Item Name / Identification	Galvani System for MR conditional labeling consists of: Galvani Neuromodulation Implantable Pulse Generator (IPG) and Implantable Lead
Static Magnetic Field Strength (B0)	1.5 Tesla, 3 Tesla
Type of Nuclei	Hydrogen
Static Magnetic Field (B0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	19 T/m (1,900 gauss/cm)
Maximum switched gradient slew rate per axis	200 T/m/s
RF Polarization	Circular polarization (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit RF coil Detachable-Head Transmit/Receive RF coil Detachable-Knee Transmit/Receive RF coil
RF Receive Coil	Any receive-only RF coil may be used
MR System (RF) Operating Mode or Constraints	Device-Specific RF Operation Constraints
Patient Characteristics	Scanning patients who have multiple MR Conditional items present is acceptable as long as the MR labeling conditions for all items can be satisfied. The patient has no abandoned extension or adaptor leads. The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history.
Patient Position in Scanner	Any patient position is acceptable (prone or supine).

MRI Safety Information

A patient with the "Galvani System" can be safely scanned under the following conditions. Failure to follow these conditions may result in serious and permanent injury, including death to the patient or item malfunction.

Item Configuration	A complete and functional Galvani System is required for use in the MR environment. A complete Galvani System includes IPG with implantable Lead. The Galvani System is not intended to be scanned with lead extensions or different lead types or abandoned leads.
Scan Duration	Scan for 60 minutes with one or more MR imaging pulse sequences (scan or series).
MR Image Artifact	The presence of this implant may produce an image artifact of 67.7 mm for IPG and 11.53 mm for distal part of the lead with Cuff.
Required programming settings	Do not scan a patient without programming the therapy off, or placing the Galvani System in hibernation mode.
Instructions to be followed before, during and /or after the MRI exam	Patients are required to have the system programmed and checked before and after the MR exam by an appropriate expert / e.g., treating physician.
Maximum Head SAR	**1.5 T** Landmarks from the top of head to C2 (Zone 1): 1.0 W/kg Landmarks from C2 to middle of femur (Zone 2): Exclusion Zone **3 T** Landmarks from top of head to C2 (Zone 1): 2.0 W/kg Landmarks from C2 to C7 (Zone 2): 1.0 W/kg
Maximum Whole-Body SAR	**1.5 T** Landmarks from C2 to middle of femur (Zone 2): Exclusion Zone Landmarks from below middle of femur (Zone3): 1.0 W/kg **3 T** Landmarks from C2 to C7 (Zone 2): 1.0 W/kg Landmarks from C7 to middle of femur (Zone 3): 0.5 W/kg Landmarks from below of middle of femur (Zone 4): 2 W/kg

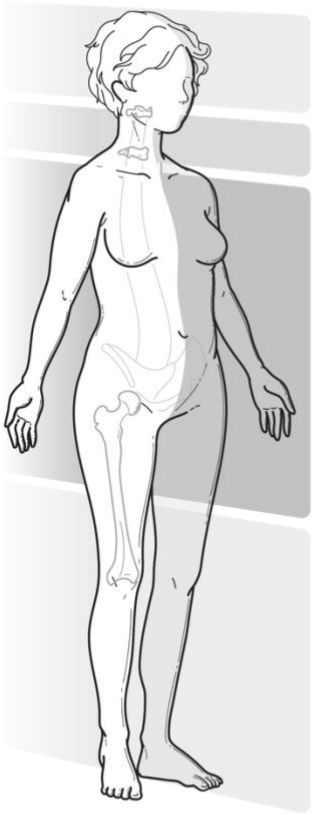
Table 6-3 Head and Whole Body SAR

Maximum Head and Whole Body SAR	
1.5 T **Head, Legs, and Feet Only MRI**	**1.5 T**  **ZONE 1** LIMIT: 1 W/kg SARwb/ha **ZONE 2** **EXCLUSION ZONE** **ZONE 3** LIMIT: 1 W/kg SARwb

Maximum Head and Whole Body SAR

3 T
Head and Whole Body MRI

3 T

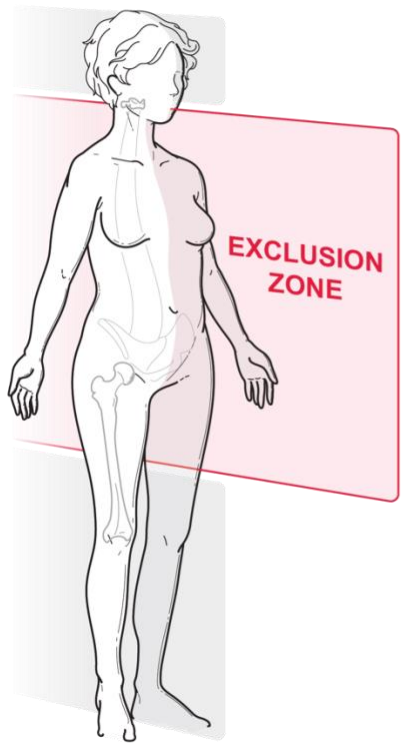


ZONE 1	LIMIT: 2 W/kg SARha
ZONE 2	LIMIT: 1 W/kg SARwb/ha
ZONE 3	LIMIT: 0.5 W/kg SARwb
ZONE 4	LIMIT: 2 W/kg SARwb

Table 6-4 1.5 T and 3 T Exclusion Zones

1.5 T and 3 T Exclusion Zones	
1.5 T Scans: Exclusion Zone	**3 T scans: There is no exclusion zone.**

1.5 T

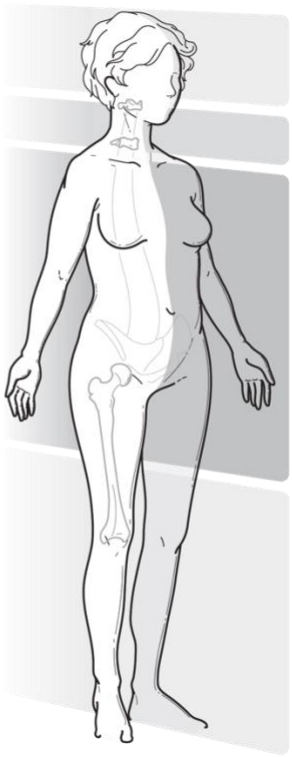


ZONE 1
Landmarks from top of head to C2

ZONE 2
Landmarks from above C2 to center of femur

ZONE 3
Landmarks below center of femur

3 T



ZONE 1
Landmarks from top of head to C2

ZONE 2
Landmarks from C2 to C7

ZONE 3
Landmarks from C7 to center of femur

ZONE 4
Landmarks below center of femur

Appendix A Galvani System Components

Implantable Pulse Generator Model 21101

The Galvani System Implantable Pulse Generator (IPG) is the source of neurostimulation for the Galvani System, see *Figure* 6-1. It is connected directly to the lead to supply one single channel of bipolar stimulation to the splenic neurovascular bundle.

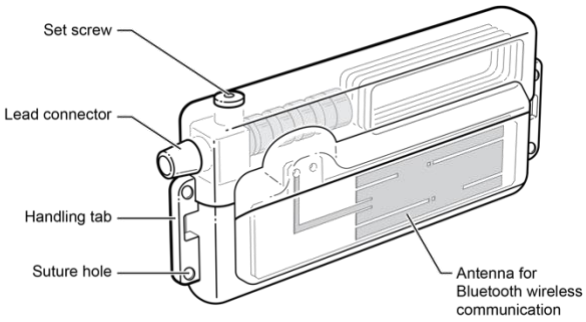


Figure 6-1 IPG consisting of a main body with a lead connector, set screw and an antenna for Bluetooth® wireless communication. Each end has a handling tab with suture holes for fixation. When implanted, the antenna must face towards the skin to ensure communication.

The Lead Models 11303, 11305

The implantable lead is used to deliver the stimulation generated by the IPG to the splenic neurovascular bundle, see *Figure* 6-2.

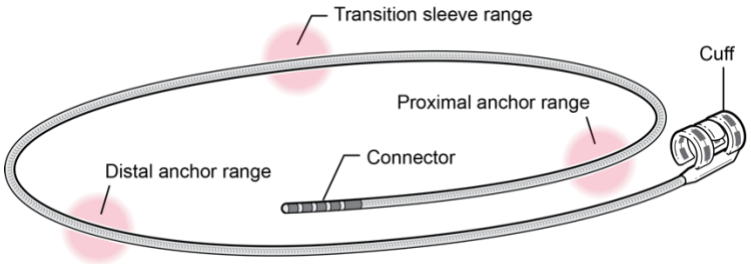


Figure 6-2 Lead detail with cuff, proximal and distal anchors, transition sleeve and connector. The cuff is composed of two electrode arms, a middle arm, and a spine.

The lead is composed of a cuff on the distal end, designed to interface with the nerves located within the splenic neurovascular bundle (defined as the splenic artery and the surrounding plexus of nerves), and a connector on the proximal end used for connecting to the IPG.

The lead body contains two conductors which are individually insulated with the conductors helically wound. The lead body is 65 cm in length and consists of three segments: proximal, distal, and transition sleeve, see *Figure* 6-2.

Galvani Implant Location

Unlike conventional neuromodulation systems, the lead and IPG of the Galvani System are designed to be implanted into the abdominal cavity. However, for some implants, the IPG is implanted in the subcutaneous tissues similar to other neuromodulation systems.

The Galvani System implants are implanted in the abdominal cavity or subcutaneous tissues. This section briefly describes the location of the implanted components in each scenario (intra-abdominal and subcutaneous IPG placement).

- Intra-abdominal Implant Location: The lead cuff is placed around the splenic neurovascular bundle.

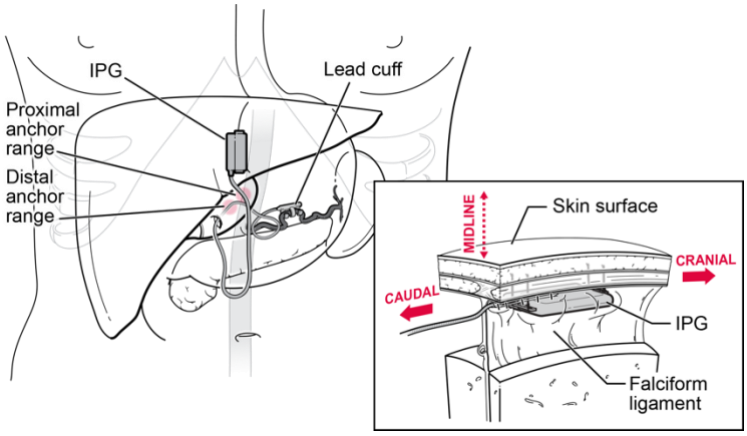


Figure 6-3 Complete system placement with intra-abdominal IPG placement.

- Subcutaneous pocket Implant Location: The lead body, including the proximal anchor, is externalized through the abdominal wall at the midline (linea alba), and the IPG placed into a pocket formed along the costal margin. The IPG is fixed in the pocket, see *Figure* 6-4.

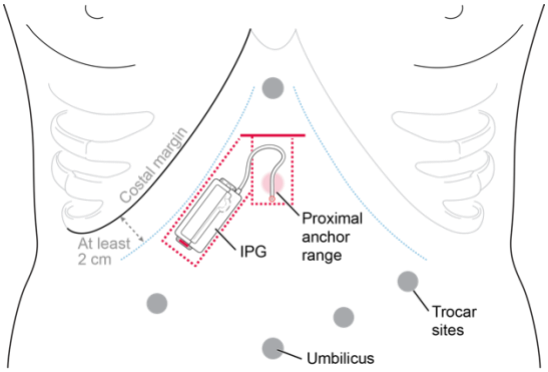


Figure 6-4 Subcutaneous IPG and proximal anchor placement. Placement may be a mirror image of this, depending on the patient's body wall anatomy.

Note: The exact location of the IPG pocket in the cranial-caudal extent, will depend in large part on the degree of angulation of the patient's costal margin as well as the position of the trocars used during the implantation. Likewise, the patient's body wall anatomy may determine IPG placement on the patients left or right side. If on the patient's left side, the placement would be a mirror image of placement shown in *Figure* 6-4.

The scar from the cranial end of the IPG pocket as well as palpation of the device should inform which side the IPG is placed on.

Appendix B MRI Basic Concepts, Terms, and Definitions

An MRI system produces 3 types of electromagnetic fields that may interact with implanted device systems. All 3 of these fields are necessary to produce an MRI image. The 3 fields are defined below.

- **Static magnetic field (B_0)** – This is a steady state non-varying magnetic field that is always present around an MRI machine, even when no scan is underway.
- **Gradient magnetic fields** – These low-frequency pulsed magnetic fields are present only during a scan. MRI equipment uses 3 orthogonal gradient magnetic fields to construct the 3-dimensional image.
- **RF field** – This is a pulsed radio-frequency (RF) field that is present only during a scan. The RF field can be produced by a variety of transmission RF coils, such as a whole body transmit coil (that is integrated into the scanner) or an extremity coil (for example, a head transmit/receive coil).
- **G** – magnetic field gradient expressed in units of T/m.
- **MR Conditional** – item with demonstrated safety in the MR environment within defined conditions, including conditions for the static magnetic field, the switched gradient magnetic field and the radiofrequency fields.
- **SAR** – Specific Absorption Rate radio frequency power absorbed per unit of mass (W/kg).
- **Whole Body SAR** – SAR averaged over the total mass of the body and over a specified time.
- **Head SAR** – SAR averaged over the mass of the head and over a specified time.
- **Maximum Gradient Slew Rate** – rate of change of the gradient obtained by switching the gradient unit between its maximum specified gradient strengths G_{+max} and G_{-max} in the shortest possible ramp time obtainable under normal scan conditions.

Appendix C GALVANI SYSTEM MRI ELIGIBILITY FORM

FOR REFERENCE ONLY – REFER TO AW-1946 FOR LATEST FORM

GALVANI SYSTEM MRI ELIGIBILITY FORM

At the Time of the MRI Appointment:

- Review MRI Instructions for Use found at https://galvani.bio/mri
- Refer to the information below for MRI Scan Eligibility

Patient Name _____ **Date of Birth** _____

Physician name and office _____

Address, phone number _____

Galvani System IPG **Model Number:** _____ **Serial Number:** _____

Galvani System Lead **Model Number:** _____ **Serial Number:** _____

Date Eligibility was determined: _____

Patient and Galvani System Confirmation

☐ This patient does not have any additional Galvani components implanted other than the Galvani system being assessed for this MRI scan eligibility.

Has the Galvani System integrity been tested?

☐ Galvani System Integrity confirms that the system is functioning nominally.

☐ Galvani System Integrity did not pass. MRI cannot not be performed.

Has Galvani System been programmed OFF?

☐ The Galvani system stimulation is programmed OFF or set to Hibernation mode.

MRI Eligibility Mode

☐	MR Conditional Head and Whole Body Scan Eligible (**3 T)**	
☐	MR Conditional Head, Legs, and Feet Scan Eligible **(1.5 T)**	
☐	The neurostimulation system MRI scan-type eligibility cannot be determined or is MR Unsafe