Algovita®

Spinal Cord Stimulation System

MRI Procedure Guidelines

Read this manual before performing an MRI scan on a patient implanted with an Algovita Spinal Cord Stimulation System.

NUVECTRA™

CE 0123

℞ ONLY 201x

This manual is a supplement to the Algovita Spinal Cord Stimulation System manuals which include detailed warnings, cautions, and instructions.

Contents

1. Introduction

Read this manual before performing a Magnetic Resonance Imaging (MRI) scan on a patient with an implanted Algovita Spinal Cord Stimulation (SCS) System. This manual is intended for use by physicians and other healthcare professionals managing patients with an Algovita SCS System, as well as radiologists and technicians performing MRI scans on these patients.

Cautions:

The instructions in this manual apply only to a complete and functional Algovita SCS System composed solely of components listed in Table 1 that are implanted in MR Conditionally safe locations within the body. Other configurations have not been evaluated.

This MRI manual focuses on patients implanted with MR Conditional Algovita SCS System components undergoing MRI procedures using a 1.5T, horizontal, closed bore MRI system. Do not use MRI systems that are open-sided, vertical field, or with static magnetic field strengths other than 1.5T.

2. MRI Symbol Description

The following is a description of the MRI symbols used in this manual and found on the Algovita SCS System packaging.

MR Conditional – an item that has been demonstrated to pose no known hazards in a specified Magnetic Resonance (MR) environment with specified conditions of use.

MR Unsafe – an item that is known to pose hazards in all MR environments.

3. MR Conditional Algovita SCS System Components

Many components of the Algovita SCS System are "MR Conditional" which means patients with these components may undergo MRI scans only if the conditions outlined in this manual are strictly followed. To meet MR Conditional requirements, the Algovita SCS System must be fully implanted and be composed of at least an implantable pulse generator (stimulator) that is connected to a lead.

MR Conditional Algovita SCS System components are listed in Table 1 below:

Table 1. MR Conditional[1] Algovita SCS System Components

Component	Model/Catalog Number	MR Conditionally Safe Implant Location
Stimulator 3 x 8	2408	Buttocks, abdomen, or flank
Stimulator 2 x 12	2412	Buttocks, abdomen, or flank
8 - Electrode Lead *1 mm or 4 mm spacings in 45, 60 or 75 cm lengths*	1081-45, 1081-60, and 1081-75 1084-45, 1084-60, and 1084-75	Epidural space[2]
12 - Electrode Lead *1 mm or 4 mm spacings in 45, 60 or 75 cm lengths*	1121-45, 1121-60, and 1121-75 1124-45, 1124-60, and 1124-75	Epidural space[2]
Paddle Lead *Lead with a 3-4-3-2 electrode configuration in 45 and 60 cm lengths*	3000-45 and 3000-60	Epidural space[2]
Paddle Lead *Lead with a 2 x 6 electrode configuration in 45 and 60 cm lengths*	3101-45 and 3101-60	Epidural space[2]
40 cm Lead Extension (1 x 8)	5208-40	Connected to the lead and stimulator[2]
40 cm Lead Extension (1 x 12)	5212-40	Connected to the lead and stimulator[2]
Lead Anchors	5400	Placed on the lead
Port Plugs	5510	In the stimulator connector port

[1]**Warnings:**
The above components are considered "MR Conditional" only when the specific MRI scanning conditions outlined in this manual are followed. All implanted components must be MR Conditional and implanted in approved locations in the body. If the implanted system contains any components not listed in the table above or are implanted in other locations, the system is considered untested for an MRI environment.

When performing a head scan, do not place any part of the transmit/receive coil over any implanted Algovita SCS System components. Doing so may cause serious patient injury due to potential excessive heating of the implanted components.

[2]**Note:** The placement of the leads, extension, and stimulator are conditionally safe if lateral placement is within 10 cm of the spinal axis. If placement is greater than 10 cm, the leads, extension, and anchor must follow an approximate diagonal pathway from the stimulator to the lead anchor as shown in Figures 1 and 2 on Page 3.

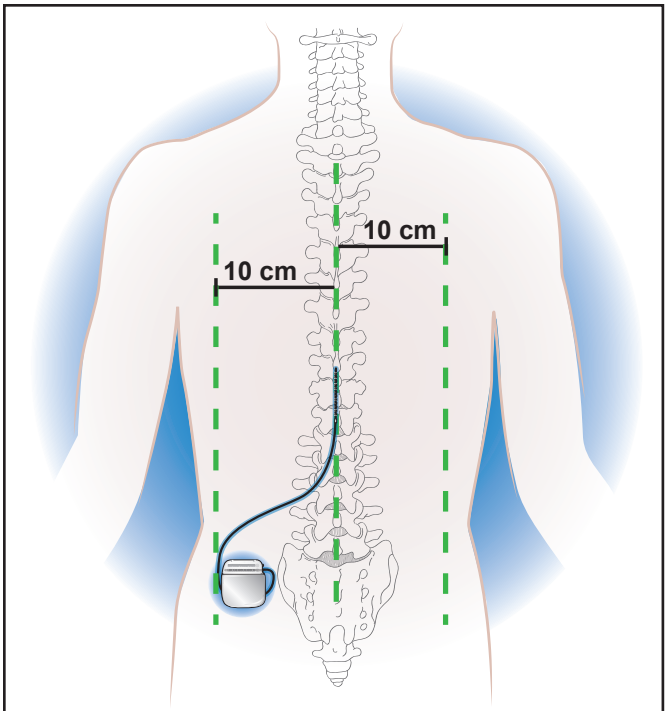


Figure 1. MR conditionally safe placement within 10 cm of the spinal axis

The leads and stimulator are MR conditionally safe if the lateral placement of the stimulator and leads are within 10 cm of the spinal axis.

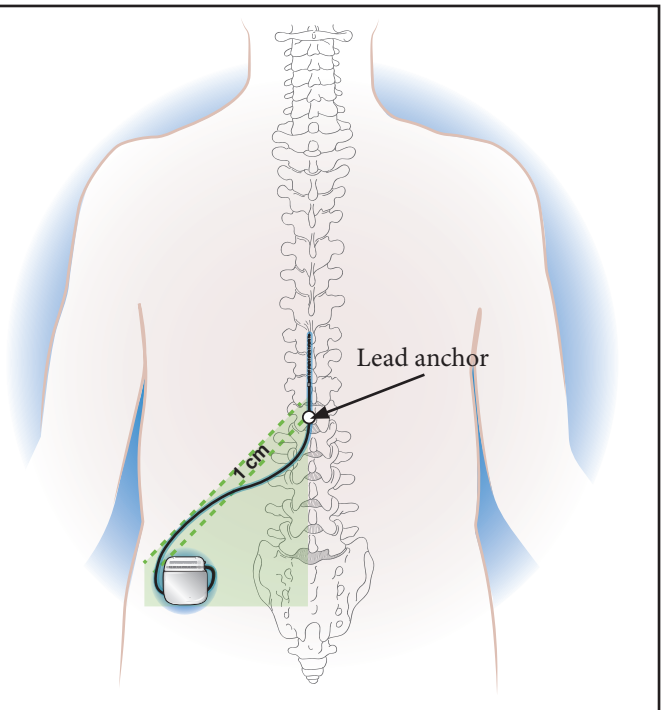


Figure 2. MR conditionally safe placement greater than 10 cm from the spinal axis

If the lateral placement of the leads and/or stimulator are greater than 10 cm from the spinal axis, the leads must follow an approximate diagonal pathway from the stimulator to lead anchor(s). The placement of the leads must not vary more than 1 cm above this diagonal but may be placed below the diagonal as illustrated by the green shading.

4. Safety Information

The MR Conditional Algovita SCS System has been shown through non-clinical testing to minimize the potential interactions with MRI when the appropriate conditions listed in this manual are followed. If an MRI scan is performed in a condition other than what is described in this manual, it may result in serious risks such as tissue damage or severe patient injury.

A person with expert MRI knowledge needs to check that all procedures and MRI scan parameters in this manual are followed.

Contraindication

Do not perform an MRI scan on patients with abandoned neuromodulation components or with broken, intermittent, or fragmented leads.

Warnings

Do not perform an MRI scan on patients with

- Algovita SCS System components not listed in Table 1 or with components implanted in different locations than those listed in Table 1.
- An Algovita SCS trial stimulation system or with any Algovita SCS System components that are not fully implanted as heating of the lead electrodes could occur, resulting in tissue damage or serious patient injury.
- Lead impedance measurements that are coded red or indicate “high impedance”. Refer to the Clinician Programming Manual for instructions on conducting impedance tests.

Warnings Continued

Do not perform an MRI scan on patients with

- Body temperature greater than 37˚C (98.6˚F). Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of tissue heating, which could cause tissue damage.

Do not cover the patient with a blanket. Blankets raise the patient's body temperature and increase the risk of tissue heating, which could cause tissue damage.

Place the patient in the prone or supine position. Do not position the patient in other positions, e.g., on his or her side (called the lateral decubitus position) within the MRI bore. Scanning patients in positions other than prone or supine has not been evaluated and could cause excessive tissue heating during an MRI scan.

When performing a head scan, do not place any part of the transmit/receive coil over any implanted Algovita SCS System components. Doing so may cause serious patient injury due to potential excessive heating of the implanted components.

Do not use RF transmit coils other than a body transmit/receive (built-in) quadrature coil or a head transmit/receive quadrature coil. Other transmit/receive coils (e.g., linear coils) have not been tested and could cause excessive heating, which can result in tissue damage or serious patient injury.

Do not use gradient systems producing gradient slew rates greater than 200T/m/s because they have not been tested and could cause increased risk of induced stimulation (resulting in shocking or jolting sensations, discomfort, or pain for the patient) or warming of the stimulator.

Potential risks resulting from exposure to an MRI environment may include

- Damage to the Algovita SCS components causing the system to fail, potentially requiring components to be replaced.
- Warming of the stimulator and leads which may cause discomfort, pain, or burns.
- Energy induced into the leads potentially causing unintended or uncomfortable sensations such as tingling, shocking, or jolting.

The effect of scanning patients with other implantable devices in conjunction with the Algovita SCS System has not been evaluated. Contact the manufacturer of the additional medical device implants for questions about MR compatibility. Do not scan a patient with implantable devices known to be MR Unsafe.

Precautions

External components (e.g., external trial stimulators or cables) or devices (e.g., the Programmer Charger, Clinician Programmer, charging paddle, or Pocket Programmer) are MR Unsafe. They cannot be taken into any MR environment such as the MR scanner room.

The Algovita SCS System must be turned off. Ensure stimulation is turned off by checking that the stimulator icon located on the top left of the home screen of the Programmer Charger does NOT contain a check mark. Leaving stimulation on during the MRI scan could cause uncomfortable or unintended stimulation and could damage the Algovita SCS System.

The MRI magnetic field may exert force or torque on the Algovita SCS System causing patients to feel a tugging or vibration sensation. Patients with recent implant incisions may feel surgical wound discomfort.

Image Artifacts and Distortion

The Algovita SCS MR Conditional System has minimal image distortion when the stimulator and the leads are out of the field of view. Significant image distortion can result when the stimulator and/or leads are within the field of view. When selecting the field of view and imaging parameters, image artifacts and distortion resulting from the presence of the stimulator and/or leads within the field of view must be considered. These factors must also be considered when interpreting the MRI images.

5. Preparing for the MRI Procedure

Check the Most Recent MRI Guidelines

The most recent MRI Guidelines are on the Nuvectra website at nuvectramedical.com. They can also be obtained by calling +1-214-618-4980. It is important to check the most recent guidelines as this manual may be updated as needed.

Conditions to be Met Before an MRI Scan

The following conditions must be met before an MRI scan is performed on a patient with an MR Conditional Algovita SCS System. For additional information, please refer to the page numbers listed in Table 2 below.

Table 2. Required Conditions for Scanning a Patient with MR Conditional Algovita SCS Components

Algovita SCS Implant System Conditions	Page
The patient is implanted only with components listed in Table 1.	2,6
All components are implanted in locations listed in Table 1.	2,6
The patient has no leads or stimulators that are not connected to the Algovita SCS System.	6
The patient has no lead fragments or abandoned components.	6
There is no evidence of fractured or compromised stimulator-lead integrity.	6
An impedance check was performed and the results were in the normal range.	6
The lateral placement of the leads, extension, and stimulator are within 10 cm of the spinal axis. If placement is greater than 10 cm, the leads, extension, and anchor follow an approximate diagonal pathway from the stimulator to the lead anchor as shown in Figures 1 and 2.	2,6
If performing a head scan, all Algovita SCS System components are outside of the transmit/receive coil.	6

Patient Conditions	Page
The patient charged their stimulator so that at least two bars (50 – 100% charged) show on the Programmer Charger or Pocket Programmer stimulator battery icon.	7
The patient has their Programmer Charger and charging paddle. The Programmer Charger has a charge level of 50% or more (2 or more bars).	7
The patient turned stimulation OFF with their Programmer Charger or Pocket Programmer.	7
The Programmer Charger, Clinician Programmer, charging paddle, Pocket Programmer, or any other external Algovita SCS devices are NOT present in the strictly controlled MR environment (Zones III and IV).	7
The patient is aware of the potential risks of undergoing an MRI scan with an Algovita SCS System.	7

MRI System Conditions		Page
MRI system type	1.5T horizontal closed bore with a maximum spatial gradient of 20 T/m (2000 gauss/cm)	8
RF coils	Body transmit/receive (built-in), quadrature only Head transmit/receive, quadrature only	8
RF power	Normal operating mode	8
Specific absorption rate (SAR)	For full body scans, SAR must be ≤ 2.0 W/kg (0.91 W/lb) For head only scans, SAR must be ≤ 3.2 W/kg (0.91 W/lb)	8
Gradients	Maximum slew rate performance per axis ≤ 200 T/m/s	8
Patient position	Prone or supine in the MRI bore	8
Scan time limits	Do not exceed 30 minutes of continuous scan time.	8
Patient monitoring	The patient must be monitored (visually and audibly) continuously during the scan. The scan must be terminated if the patient experiences pain or discomfort from unexpected device stimulation, device heating, or device displacement force.	8

6. MRI Scan Procedure

1. MRI Scan Eligibility

Table 3 lists the patient eligibility conditions that must be met before performing an MRI scan on patients implanted with an MR Conditional Algovita SCS System. The table includes suggested methods to confirm each condition. Any or a combination of the suggested methods may be used. Appendix B includes a patient eligibility checklist that the referring physician may fill out and give to the patient to bring to the scanning appointment. The checklist is designed to confirm that the patient's Algovita SCS System is MR Conditional.

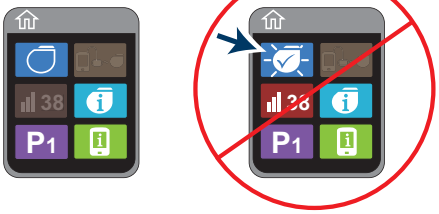
Table 3. Patient Eligibility Conditions

MRI Scanning Condition	Suggested Methods to Confirm
Confirm that the patient's Algovita SCS System components are MR Conditional as listed in Table 1 on page 2.	Look at the Patient Checklist (Appendix B) Check patient records Check with the physician responsible for managing the patient's Algovita SCS System.
The leads are implanted in the epidural space. The lateral placement of the leads, extension, and stimulator are within 10 cm of the spinal axis. If placement is greater than 10 cm, the leads, extension, and anchor follow a diagonal pathway from the stimulator to the lead anchor as shown in Figures 1 and 2.	Verify by x-ray.
If performing a head scan, all Algovita SCS System components are outside of the transmit/receive coil.	Check patient records Verify by x-ray
The stimulator is implanted in the buttock, abdomen or flank.	Examine the patient to determine the location of the stimulator. Ask the patient where they place the charging paddle. Check patient records Verify by x-ray
The patient has no abandoned neuromodulation components.	Check patient records Verify by x-ray
There is no evidence of fractured or compromised stimulator-lead integrity.	Impedance values as measured by the Clinician Programmer must be in the normal range (green). This is recorded on the Patient Checklist (Appendix B).

2. Prepare the Patient

Table 4 lists the patient preparation conditions that must be met before performing the MRI scan. The table includes suggested methods to confirm each condition. Any or a combination of the suggested methods may be used.

Table 4. Patient Preparation Conditions

MRI Scanning Condition	Suggested Methods to Confirm	Picture
The patient charged their Algovita SCS stimulator to a level of at least 50%.	Ensure that two or more bars are displayed on the stimulator battery icon located at the bottom right of the Programmer Charger home screen. If the patient does not have their Programmer Charger, they can still be scanned (if they can turn stimulation off with their Pocket Programmer) but will not be able to bring their stimulator out of storage mode until they can use their Programmer Charger and charging paddle.	
The Programmer Charger has a charge level of 50% or more.	Ensure that two or more bars are displayed on the Programmer Charger battery icon located close to the center of the bottom of the home screen.	
The patient turned stimulation OFF.	Ensure that the stimulator icon located on the top left of the home screen of the Programmer Charger does NOT contain a check mark. If the patient only brought their Pocket Programmer, the stimulator icon is located on the top right of the home screen.	
The Programmer Charger, Clinician Programmer, charging paddle, Pocket Programmer, or any other external Algovita SCS devices are NOT present in the strictly controlled MR environment (Zones III and IV).	Check with the patient before they enter the strictly controlled MR environment (Zones III and IV) that they do not have their Programmer Charger, charging paddle, Pocket Programmer, or any other external Algovita SCS devices.	

3. Inform the Patient

In addition to the requirements in Table 4, inform the patient of the perceptible effects of undergoing an MRI scan with the MR Conditional Algovita SCS System. These effects include vibration, a tugging motion, or warming of the stimulator. If unintended induced electrical stimulation occurs, the patient could experience a tingling or jolting sensation. Instruct the patient to inform the technician if any of these effects become uncomfortable.

Discuss the potential risks of undergoing an MRI scan with an Algovita SCS System (found on pages 3 - 4) before performing the MRI scan.

Remind the patient that exposure to the MR environment will place their stimulator in storage mode. After their procedure, the patient will need to charge their stimulator briefly (less than a minute) to bring it out of storage mode.

4. Verify MRI System Conditions

Table 5 lists the MRI System conditions that must be met before performing the MRI scan. The table includes suggested methods to confirm each condition. Any or a combination of the suggested methods may be used.

Table 5. MRI System Conditions

MRI System Condition	Suggested Methods to Confirm
MRI scanner: 1.5T horizontal closed bore with a maximum spatial gradient of 20 T/m (2000gauss/cm)	Check the specifications of the MRI scanner.
RF coils: Body transmit/receive (built-in), quadrature only Head transmit/receive, quadrature only	Check the specifications of the coils.
RF power: Normal operating mode Whole body SAR must be ≤ 2.0 W/kg (0.91 W/lb) Head only SAR must be ≤ 3.2 W/kg (0.91 W/lb)	Ensure that normal operating mode is used and that SAR limits are not exceeded.
Gradients: Maximum slew rate performance per axis ≤ 200 T/m/s	Ensure that gradient systems do not produce gradient slew rates greater than 200 T/m/s.
Patient is in a supine or prone position during the scan	Monitor the patient's position continually during the scan.

5. Perform the MRI Scan

Table 6 lists the conditions that must be met when performing the MRI scan. The table includes suggested methods to confirm each condition. Any or a combination of the suggested methods may be used.

Table 6. MRI Scan Conditions

MRI Scan Condition	Suggested Methods to Confirm
Minimize artifact	Minimal image distortion may occur around an implanted lead or stimulator. Consider these factors when selecting imaging parameters and the field of view.
Continuous scan time must not exceed 30 minutes	Monitor continuous scan time and ensure it does not exceed 30 minutes.
Monitor the patient (visually and audibly) continuously during the scan. Terminate the scan if the patient experiences pain or discomfort from unexpected device stimulation, device heating, or device displacement force.	Periodically check that the patient is able to provide immediate feedback in the event of any problems during the scan.

6. Post MRI Procedure

Confirm that the patient did not experience any Algovita SCS System related adverse effects as a result of the MRI procedure. Report adverse events to Nuvectra by calling customer service at +1-214-618-4980.

After the patient has left the strictly controlled MR environment, remind the patient to briefly charge their stimulator to bring it out of storage mode. Instructions are included in Appendix A.

If the patient has their Programmer Charger and charges their system briefly to bring it out of storage mode, verify that the Algovita SCS System is operational. If the Algovita SCS System displays error messages or does not turn on, ask the patient to contact Nuvectra customer service at +1-214-618-4980.

Appendix A – Turning the Stimulator On After an MRI Scan

Exposure to the MR environment will place the stimulator in storage mode. When it is in storage mode, the stimulator will not deliver stimulation and will not establish a connection to the Programmer Charger or Pocket Programmer. To bring the stimulator out of storage mode, follow the instructions below.

To Bring Your Stimulator Out of Storage Mode

1. Make sure your Programmer Charger is within 1 meter (3 feet) of your stimulator.
2. Turn your Programmer Charger on.
3. When the Not Able to Connect to Stimulator Notification screen appears, tap Cancel (Figure 1).

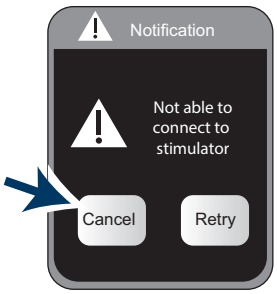


Figure 1. Notification screen

4. Connect the charging paddle to the Programmer Charger (Figure 2). The  icon becomes available.

Figure 2. Attaching the charging paddle

5. Tap  on the Home screen (Figure 3). The Charge Status Screen appears.

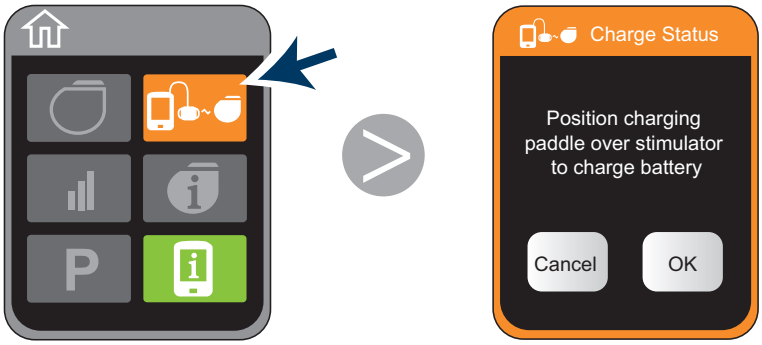


Figure 3. Displaying the Charge Status screen

6. Tap OK on the Charge Status screen (Figure 4). The Charging in Progress screen appears.

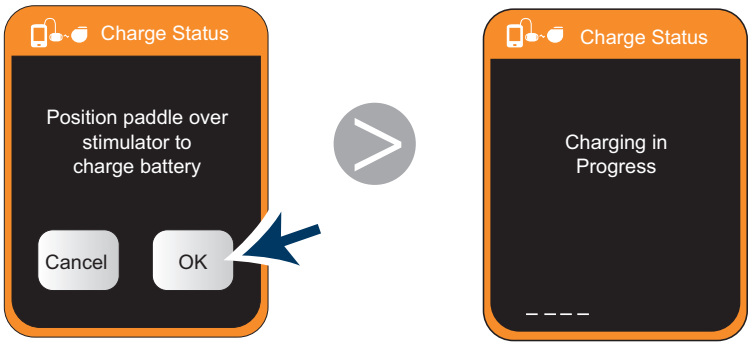


Figure 4. Charging In Progress Screen

7. Slowly move the charging paddle over your stimulator, crossing the location of the stimulator at least twice before centering the paddle over the stimulator.

8. After the stimulator exits storage mode, the Programmer Charger automatically establishes communication with your stimulator and the Communication icon appears (Figure 5).

9. Your stimulator is out of storage mode and the battery is charging.

Figure 5. Communication with stimulator established

10. Tap the Home button  to return to the Home screen.

11. The communication icon on the left side of the bottom of the home screen will have an exclamation mark (!)  by it. Tap the communication icon and the exclamation mark (!)  will disappear. Communication with your stimulator has been reestablished.

12. Grasp the charging paddle connector where it connects to the Programmer Charger and remove the paddle from the Programmer Charger. Do not pull on the cable below the connector when disconnecting the paddle or you may damage the cable.

If you have any concerns or questions, please contact Nuvectra customer service at +1-214-618-4980.

Appendix B – Algovita SCS MRI Patient Eligibility Checklist

Use this checklist to help determine if a patient implanted with Algovita SCS System components is eligible for an MRI scan under the conditions described in the Algovita SCS MRI Procedure Guidelines. Give this checklist to the patient to bring to their imaging appointment.

Patient and Physician Information

Patient Name	Date
Physician Name	Phone

Impedance Check Results

Impedance check performed by	Date
Results (circle one):	GREEN YELLOW RED

Algovita SCS System Information

Algovita SCS System Component	Model/Catalog Numbers	MRI Eligible	MRI NOT Eligible
Stimulator	2408 or 2412	☐	
8 or 12 Electrode Lead 1 or 4 mm spacings 45, 60, or 75 cm length	1081-45, 1081-60, 1081-75, or 1084-45, 1084-60, 1084-75, or 1121-45, 1121-60, 1021-75, or 1124-45, 1124-60, 1124-75	☐	
8 or 12 Electrode Lead 6 mm spacings Any spacings, 90 cm length	XXX6-XX or XXXX-90		☐
Paddle leads	3000-45, 3000-60, 3101-45, or 3101-60	☐	
Lead Extensions: 40 cm	5208-40 or 5212-40	☐	
Lead Extensions: 20 or 60 cm	5208-20, 5208-60, 5212-20, or 5212-60		☐
Anchor	5400	☐	
Port Plug	5510	☐	

Summary Information

Condition	MRI Eligible	MRI NOT Eligible
The patient's Algovita SCS components are all MRI eligible as documented in the Algovita SCS System Information Table above.	YES	NO
The stimulator is implanted in the buttock, flank, or abdomen	YES	NO
The lead(s) are implanted in the epidural space.	YES	NO
The patient has no abandoned neuromodulation components or broken, intermittent, or fragmented leads.	YES	NO
An impedance check was performed using the Clinician Programmer with results in the normal range (green) as documented above.	YES	NO
The lateral placement of the leads, extension, and stimulator are within 10 cm of the spinal axis. If placement is greater than 10 cm, the leads, extension, and anchor follow an approximate diagonal pathway from the stimulator to the lead anchor as shown in Figures 1 and 2 on Page 3.	YES	NO
If a head scan is planned, all Algovita SCS System components are outside of the transmit/receive coil.	YES	NO

Patient Instructions

Inform the patient of the potential risks of undergoing an MRI scan with the MR Conditional Algovita SCS System.

Ask the patient to charge their stimulator so that two or more bars (50 – 100% charged) are present next to the stimulator icon on their Programmer Charger. They must also charge their Programmer Charger so that at least two bars are present next to the Programmer Charger icon.

The patient needs to bring their Programmer Charger and charging paddle to their imaging appointment. Inform the patient that exposure to the MR environment will automatically place their stimulator in storage mode. To bring their stimulator out of storage mode, the patient will need to charge their stimulator briefly (less than one minute).

If the patient does not bring their Programmer Charger but has their Pocket Programmer, they can still be scanned but will not be able to bring their stimulator out of storage mode until they can use their Programmer Charger and their charging paddle.

The Programmer Charger, Pocket Programmer, and charging paddle are MR Unsafe and must not be brought into the strictly controlled MR environment (Zones III and IV) MRI procedure room.

Prior to performing the MRI procedure, the patient must turn the stimulation OFF.

Questions?

Call Nuvectra customer service at +1-214-618-4980.

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