SUMMARY

Radiofrequency identification (RFID) is a wireless technology that may potentially cause clinically significant events for patients. This article discusses different types of RFID technology and precautions for patients exposed to Electromagnetic Interference (EMI) from these devices.

Products Referenced

All referenced Boston Scientific pacemakers, ICDs, CRT-Ds, CRT-Ps, and S-ICDs

The following are trademarks of Cardiac Pacemakers Inc., a Boston Scientific company: PULSAR MAX, PULSAR MAX II, DISCOVERY, DISCOVERY II, MERIDIEN, INSIGNIA, ALTRUA, CONTAK RENEWALTR/TR2, ADVANTIO, INGENIO, VITALIO, FORMIO, INVIVE, INTUA, and INLIVEN, ALTRUA 2, ESSENTIO, PROPONENT, ACCOLADE, VALITUDE , and VISIONIST.

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the appropriate product labeling.

For comprehensive information on device operation, reference the full instructions for use or found at: **www.bostonscientific-elabeling.com**.

CAUTION: The law restricts this device to sale by or on the order of a physician.

Products referenced herein may not be approved in all geographies. Information is for the use in countries with applicable Health Authority product registrations.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
S-ICD: Subcutaneous Implantable Defibrillator

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Radiofrequency Identification and Implantable Pacemakers and Defibrillators

What is RFID?

Radiofrequency identification (RFID) is a wireless technology used to identify RFID tags mounted on objects or carried by/embedded in people or animals. Data stored in the RFID tag is read by RFID readers, wireless devices that contain one or more RF antennas. These antennas emit RF signals within a specified range; when an RFID tag enters the reader's RF signal field, information stored in the tag is captured by the reader (Figure 1). Each RFID tag relies on the reader to transmit information contained in the tag. Examples of RFID applications in public and occupational settings are provided in Figure 2.

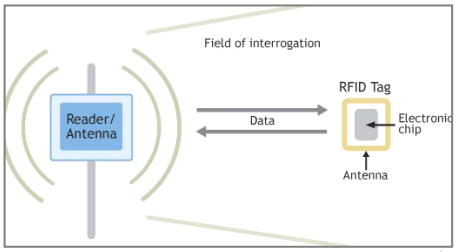

Figure 1. Example of RFID system operation.[1]

Figure 2. Examples of RFID Applications

Retail Tracking
(e.g., theft prevention, library book check-out, and pharmaceutical tracking)


Anti-theft RFID reader.[a]


Handheld RFID reader (inventory mgmt.[b])

Payment Processing
(e.g, toll booths and mass transit ticketing)


RFID toll collection.[c]


RFID subway ticketing [d]

Access Management
(e.g., buildings, parking lots, marinas, and international travel)


RFID access to community.[e]


Passport card RFID reader.[f]

RFID marina access control.[g]

Electromagnetic Interference

Electromagnetic interference (EMI) occurs when electromagnetic waves from one electronic device interfere with and cause an undesired response in another electronic device. When an electronic device interferes with the intended operation of an implanted pacemaker or defibrillator, the effects of the EMI are usually temporary and can typically be eliminated by moving away from the noise source.

Like most electronic devices, RFID systems generate electromagnetic waves, which can vary in amplitude and frequency. The operating frequency chosen for

a specific RFID system often depends on its application (Table 1). Some RFID readers may potentially produce electromagnetic fields of sufficient amplitude and/or frequency to interact with an implanted cardiac device. Whether or not an RFID reader will interfere with an implanted pacemaker or defibrillator depends on a number of technical parameters (e.g., frequency, power, pulse repetition rate, pulse width, modulation, distance/location/orientation), most of which are unknown to device patients in the vicinity of these systems.

ITU Designation Frequency	LF 30 kHz – 300 kHz	HF 3000 kHz – 30 MHz	UHF 300 MHz – 3000 MHz	Microwave 30 GHz – 300 GHz
Range	125–134 kHz	13.56 MHz	860-930 MHz	2.4 GHz
Read Range	0 to 1.5 ft*	0 to 3 ft*	10-20 ft*	0-30 ft*
Used for:	Access control Animal tracking Product Authorization	Smart cards Clothing ID Library books	Electronic tolls Animal tracking Pallet/carton tracking	Airline baggage Electronic tolls Fleet vehicle ID
Pros	Works well around water and metal objects	Low cost of tags Penetrates water	Long-read range Base of EPC Standard	Long-range read Fastest read rates High data transfer rate
Cons	Slow Short read range	Can't penetrate metal	Can't penetrate metal Can't penetrate water	Can't penetrate metal Can't penetrate water

Table 1. Examples of RFID applications in various frequency bands.

Evaluation of RFID

The Food and Drug Administration Center for Device and Radiological Health evaluated electromagnetic compatibility between RFID systems and implantable cardiac pacemakers and defibrillators.[2] The study was developed with support of the Association for the Advancement of Medical Instrumentation Cardiac Rhythm Management Devices Electromagnetic Compatibility Task Force and investigated in-vitro (simulated) interaction between RFID readers[3] and implantable pacemakers and defibrillators.

Thirty implantable cardiac devices from various manufacturers and thirteen RFID readers were tested. The RFID readers tested operated in three commonly used frequency bands—low-frequency (LF), high-frequency (HF), and ultra-high-frequency (UHF). Potential interactions were classified as follows:

- Class I: Temporary ventricular inhibition ≥ 3 seconds, any permanent change in programmed settings, or inappropriate tachycardia therapy
- Class II: Temporary ventricular inhibition for > 2 seconds, but < 3 seconds
- Class III: Inappropriate pacing, atrial inhibition, ventricular inhibition for ≤ 2 seconds, noise reversion mode, and all other types of device reactions not in Class I or Class II

Interactions were not observed in the UHF band, while Class I and III interactions were observed in both the LF and HF bands, with interactions most prevalent at LF. The separation distances where interactions occurred in the study ranged from 2.5 to 60 cm. For Boston Scientific devices, Class I interactions ranged from 2.5 to 40 cm for pacemakers and from 2.5 to 7.5 cm for ICDs, CRT-Ds and CRT-Ps. Table 2 lists suggested separation distances for patients implanted with a Boston Scientific cardiac device. The data in Table 2 reflects currently marketed Boston Scientific implantable devices based on testing evidence obtained after the completion of the referenced study.

Separation Distances Suggested for Patients Implanted with Boston Scientific Devices		
Device Type	**Device Family**	**Separation Distance**
Pacemakers	PULSAR MAX®, PULSAR MAX® II, DISCOVERY®, DISCOVERY®II, MERIDIEN®	60 cm (2 ft)
	INSIGNIA® , ALTRUA™	40 cm (1.5 ft)
	CONTAK RENEWAL® TR/TR2, ADVANTIO™, INGENIO™, VITALIO™, FORMIO™, INVIVE™, INTUA™, INLIVEN™, ALTRUA™ 2, ESSENTIO™, PROPONENT™, ACCOLADE™, VALITUDE™ , VISIONIST™	15 cm (6 in)
Defibrillators	All ICD, CRT-D, and S-ICD Device Families	15 cm (6 in)

Table 2. Suggested separation distance between RFID source (transmit antenna) and implanted device.

IMPORTANT NOTES:

- *The study authors cited many study limitations including programmable device sensitivity, lead configurations, RFID reader antenna orientation relative to the implant, and in-vitro as opposed to in-vivo testing. For this reason, test results may not be predictive of the actual clinical experience of a patient with an implanted pacemaker or defibrillator. It is possible that an individual patient may not encounter any interference at distances closer than those shown above; similarly, the above distances cannot be guaranteed as safe for all patients in all situations.*
- *The authors reported that although they believe the study did not reveal an urgent public health risk, they were concerned that the continued proliferation of RFID technology without considering implantable pacemaker and ICD electromagnetic compatibility could potentially cause clinically significant events for patients. Additionally, the authors believe that further testing is warranted.*

Precautions for Patients in the Presence of EMI

Although implanted cardiac pacemakers and defibrillators are designed to function normally around most appliances and equipment, patients and their cardiologists should be aware that RFID readers may be a potential source of EMI and could have temporary effects on implanted cardiac devices. Because the presence of RFID systems may not always be apparent in public and occupational settings, patients who feel symptomatic (e.g., light-headed, fast heart rate) should move away from nearby electrical equipment (or the identifiable RFID system), and call their physician to report the episode.

Boston Scientific's evidence suggests that maintaining the Table 2 separation distances (measured between an RFID reader and an implanted Boston Scientific cardiac pacemaker or defibrillator) should minimize the likelihood of encountering interaction. This expectation is based on the study's sample size and test methodology. As always, it is best to maintain the furthest distance possible from a suspected source of EMI.

Frequently Asked Questions

Q1. What is the potential for RFID to interact with an implanted device?

A1. Interaction is unlikely, unless the patient is in close proximity to an RFID reader. See Table 2 for suggested separation distances.

Q2. Is RFID utilized in bar code readers?

A2. No. Bar code readers use visible light to perform their designed function and are not a source of EMI to implantable pacemakers or defibrillators.

Q3. Should patients be concerned with RFID Tags?

A3. To date, RFID tags have not been identified as sources of EMI to implanted cardiac devices.

Q4. Who should patients talk to regarding potential EMI and their implanted device?

A4. Patients should talk to their physician if they have any questions specific to their implanted device, including EMI-related topics.

Q5. Is there information available to patients regarding other potential sources of EMI to their implanted device?

A5. Boston Scientific's *Living with Your Implanted Device* web page includes an overview of some common items that create EMI. The page can be accessed by going to our website, www.bostonscientific.com, and searching "living with your implanted device".

Q6. Are there industry standards that reduce the likelihood of EMI to implantable devices?

A6. While medical device standards are intended to address device susceptibility to EMI, they cannot encompass every piece of technology. Therefore, there may be a need to review and/or test a specific or new piece of technology to understand if there are potential interactions. While individual technologies meet their respective standards, this does not guarantee compatibility when the two are brought together. The ANSI/AAMI/ISO 14117:2012 (formerly AAMI PC-69) standard includes an informative *Annex M* that provides manufacturers of electromagnetic emitters with information about the level of immunity to be expected from active implantable pacemakers and defibrillators.

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[1] How does it work? web page. Trevise-Consulting web site. Available at http://www.trevise-consulting.com/index_uk.php?page=page2 Accessed September 23, 2009.

[2] Current Issue web page. Heart*Rhythm* Journal web site. In Vitro Tests Reveal Sample Radio Frequency Identification Readers Inducing Clinically Significant Electromagnetic Interference to Implantable Pacemakers and Implantable Cardioverter Defibrillators. Full-text PDF available for registered users. Abstract available at http://www.heartrhythmjournal.com/article/S1547-5271(09)01146-1/abstract. Accessed July 26, 2017.

[3] RFID readers from passive tag systems were used in the study, as their readers are generally known to emit stronger electromagnetic fields than those from active tag systems.

a http://www.rfid-library.com/e_rf06.htmlhttp://www.rfid-library.com/e_rf06.html. Accessed September 29, 2009.
b http://www.gaorfid.com/index.php?main_page=index&cPath=97. Accessed July 26, 2017.
c http://www.phaisan.com/toll-collection-system. Accessed July 26, 2017.
d http://embeddedsystemnews.com/seoul-subway-uses-rfid-technology-from-stmicroelectronics-for-ticketing-in-mass-transportation.html. Accessed September 29, 2009.
e http://www.archiexpo.com/prod/vingcard/rfid-reader-for-access-control-10481-34254.html. Accessed July 26, 2017.
f http://www.economist.com/sciencetechnology/displaystory.cfm?story_id=14066895. Accessed July 26, 2017.
g http://www.maritimetrackingsystems.org.uk/id2.html. Accessed September 29, 2009.

Pacing Systems - ACCOLADE™MRI, ESSENTIO™MRI, VITALIO™MRI, INGENIO™MRI, ADVANTIO™

INDICATIONS AND USAGE

Boston Scientific pacemakers are indicated for treatment of the following conditions:
• Symptomatic paroxysmal or permanent second- or third-degree AV block
• Symptomatic bilateral bundle branch block
• Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block)
• Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
• Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes
Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity.
Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.
Dual chamber modes are specifically indicated for treatment of the following:
• Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block
• VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm
• Low cardiac output or congestive heart failure secondary to bradycardia

CONTRAINDICATIONS

These Boston Scientific pacemakers are contraindicated in patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads.
Use of certain pacing modes and/or features available in these Boston Scientific pacemakers is contraindicated for the following patients under the circumstances listed:
• Unipolar pacing or use of the MV Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy.
• Minute Ventilation in patients with both unipolar atrial and ventricular leads
• Single-chamber atrial pacing in patients with impaired AV nodal conduction
• Atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing
• Dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias
• Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms

WARNINGS

General

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of EMI. The pulse generator may inhibit pacing due to oversensing, or may switch to asynchronous pacing at the programmed pacing rate or at the magnet rate in the presence of EMI. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev.C)

CRT-P Systems – VISIONIST™, VISIONIST™ X4, VALITUDE™, VALITUDE™ X4, INTUA™, INVIVE™

Indications and Usage

Boston Scientific cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients with moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF <=35%) and QRS duration >= 120 ms and remain symptomatic despite stable optimal pharmacological therapy (OPT) for heart failure.
Atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.
Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in physical activity.

Contraindications

These Boston Scientific pulse generators have the following contraindications:
• In patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads;
• Unipolar pacing or use of the Respiratory Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) is contraindicated because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy;
• Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction;
• Atrial tracking modes are contraindicated in patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing;
• And asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Such damage may result in patient injury, illness, or death. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage; implantation; device programming; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments; follow-up testing; explant and disposal; supplemental precautionary information These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

Potential Adverse Events

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined s hocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev C)

ICD Systems – DYNAGEN™ EL, DYNAGEN™ MINI, INOGEN™ EL, INOGEN™ MINI, ORIGEN™ EL, ORIGEN™ MINI, INCEPTA™, ENERGEN™, PUNCTUA™, TELIGEN™100

INDICATIONS AND USAGE

Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS

Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

WARNINGS

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to

avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

PRECAUTIONS
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information

POTENTIAL ADVERSE EVENTS
Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev B)

ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL

INDICATIONS AND USAGE
Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS
Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

WARNINGS
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

PRECAUTIONS
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information

POTENTIAL ADVERSE EVENTS
Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev A)

CRT-D Systems –AUTOGEN™, AUTOGEN™X4, DYNAGEN™, DYNAGEN™X4, INOGEN™, INOGEN™ X4, ORIGEN™, ORIGEN™X4, INCEPTA™, ENERGEN™, PUNCTUA™. COGNIS™ 100-D CRT-D

INDICATIONS AND USAGE
These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms; or left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

CONTRAINDICATIONS
There are no contraindications for this device.

WARNINGS
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response set to Inhibit therapy the patient should not reapply the magnet.

PRECAUTIONS
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

POTENTIAL ADVERSE EVENTS
Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev C)

CRT-D Systems –RESONATE™HF, RESONATE™, RESONATE™X4, VIGILANT™, VIGILANT™X4, MOMENTUM™, MOMENTUM™ X4

INDICATIONS AND USAGE
These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications: Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms; or left bundle branch block (LBBB) with QRS duration ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

CONTRAINDICATIONS
There are no contraindications for this device.

WARNINGS
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use defibrillation patch leads with the pulse generator system. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures. Do not kink, twist, or braid the lead with other leads. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO lead terminal, other than the terminal pin, even when the lead cap is in place. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. When implant a system that uses both a DF4–LLHH or DF4–LLHO and IS4–LLLL

lead, ensure that the leads are inserted and secured in the appropriate ports. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. If desired, ensure that Patient Triggered Monitor (PTM) is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. Once the PTM feature has been triggered and the magnet response set to Inhibit therapy the patient should not reapply the magnet.

PRECAUTIONS

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal, supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks /pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.(Rev A)

EMBLEM™ MRI S-ICD System

Indications for Use

The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications

Unipolar pacing and impedance-based features are contraindicated for use with the S-ICD System.

Warnings

Read the manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific S-ICD System only. Connection of any S-ICD System components to a non-compatible component will result in failure to deliver life-saving defibrillation therapy. Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Concomitant use of the S-ICD System and implanted electromechanical devices (for example a ventricular assist device, VAD; or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. Electromagnetic (EMI) or therapy delivery from the co-implanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the co-implanted device and compromise it's functionality. To help prevent undesirable interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Handle the components of the SICD System with care at all times and maintain proper sterile technique. Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Do not implant in MRI site Zone III. Use caution when placing a magnet over the SICD pulse generator because it suspends arrhythmia detection and therapy response. In patients with a deep implant placement (greater distance between the magnet and the pulse generator) magnet application may fail to elicit the magnet response. Do not expose a patient with an implanted S-ICD System to diathermy. EMBLEM S-ICD devices are considered MR Conditional. Unless all MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. The Programmer is MR Unsafe and must remain outside the MRI site Zone III. During MRI Protection Mode the Tachycardia therapy is suspended. MRI scanning after ERI status has been reach may lead to premature batter depletion, a shortened device replacement window, or sudden loss of therapy. The Beeper may no longer be usable following an MRI scan. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal and supplemental precautionary information. Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following: Acceleration/induction of atrial or ventricular arrhythmia, adverse reaction to induction testing, allergic/adverse reaction to system or medication, bleeding, conductor fracture, cyst formation, death, delayed therapy delivery, discomfort or prolonged healing of incision, electrode deformation and/or breakage, electrode insulation failure, erosion/extrusion, failure to deliver therapy, fever, hematoma/seroma, hemothorax, improper electrode connection to the device, inability to communicate with the device, inability to defibrillate or pace, inappropriate post shock pacing, inappropriate shock delivery, infection, keloid formation, migration or dislodgement, muscle/nerve stimulation, nerve damage, pneumothorax, post-shock/post-pace discomfort, premature battery depletion, random component failures, stroke, subcutaneous emphysema, surgical revision or replacement of the system, syncope, tissue redness, irritation, numbness or necrosis. Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. C)

S-ICD™ System

Indications for Use

The S-ICD™ System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Contraindications

Unipolar pacemakers are contraindicated for use with the S-ICD System.

Warnings and Cautions

The S-ICD System contains sterile products for single use only. Do not resterilize. Handle the components of the SICD System with care at all times and maintain proper sterile technique. All implantable components are designed for use with the S-ICD System only. Connection of any S-ICD System components to any other ICD system will result in failure to deliver lifesaving defibrillation therapy.

General

- External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up.
- Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response.
- Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.
- The S-ICD System has not been evaluated for pediatric use.
- The S-ICD System does not provide long-term bradycardia pacing, Cardiac Resynchronization Therapy (CRT) or Anti-Tachycardia Pacing (ATP).

Potential Adverse Events related to implantation of the S-ICD System may include, but are not limited to, the following:

Acceleration/induction of atrial or ventricular arrhythmia; Adverse reaction to induction testing; Allergic/adverse reaction to system or medication; Bleeding; Conductor fracture; Cyst formation; Death; Delayed therapy delivery; Discomfort or prolonged healing of incision; Electrode deformation and/or breakage; Electrode insulation failure; Erosion/extrusion; Failure to deliver therapy; Fever; Hematoma; Hemothorax; Improper electrode connection to the device; Inability to communicate with the device; Inability to defibrillate or pace; Inappropriate post-shock pacing; Inappropriate shock delivery; Infection; Keloid formation; Migration or dislodgement; Muscle stimulation; Nerve damage; Pneumothorax; Post-shock/post-pace discomfort; Premature battery depletion; Random component failures; Stroke; Subcutaneous emphysema; Surgical revision or replacement of the system; Syncope; Tissue redness, irritation, numbness or necrosis.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. E)