

## SUMMARY

Patients with an implanted heart device such as a pacemaker or defibrillator may have questions about traveling with their device.

This article provides heart patients with valuable travel-related information.

### Products Referenced

All Boston Scientific ICDs, CRT-Ds, CRT-Ps, S-ICDs, Pacing Systems, and the LATITUDE® Patient Management System

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

**CAUTION:** Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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

### Contact Information

#### Americas

(Caribbean, and Central, North, and South America)

[www.bostonscientific.com](http://www.bostonscientific.com)

#### Technical Services

##### LATITUDE® Clinician Support

1.800.CARDIAC (227.3422)  
+1.651.582.4000

#### Patient Services

1.866.484.3268

#### Europe, Middle East, Africa

##### Technical Services

+32 2 416 7222

[eurtechservice@bsci.com](mailto:eurtechservice@bsci.com)

##### LATITUDE Clinician Support

[latitude.europe@bsci.com](mailto:latitude.europe@bsci.com)

#### Asia Pacific

##### Technical Services

+61 2 8063 8299

[aptechservice@bsci.com](mailto:aptechservice@bsci.com)

##### LATITUDE Clinician Support

[latitude.asiapacific@bsci.com](mailto:latitude.asiapacific@bsci.com)  
[japan.latitude@bsci.com](mailto:japan.latitude@bsci.com) (Japan)

© 2013 by Boston Scientific Corporation or its affiliates. All rights reserved.

## Information for the Traveling Pacemaker or Defibrillator Patient

### Preparing for Travel

Before traveling away from home, talk with your heart doctor and ask:

- *What should I do if I have a medical emergency?*
- *Who should I call if I receive a shock from my device?*
- *Do you want to see me in the clinic before I leave?*

Additional considerations if you use a LATITUDE® Patient Management System:

- *Should I continue with scheduled remote follow-up sessions while away?*
- *Will my LATITUDE Communicator work in the country where I am going?*
  - LATITUDE Communicators were designed for use in your home country. However, some versions may work in other countries. Please contact Boston Scientific Patient Services at the number in this article to find out if your Communicator will work at your destination. Contact your doctor or LATITUDE-following clinic to determine if any adjustments (for example, time zones and follow-up schedules) need to be made before you go.
  - If traveling to another country, a different style of telephone connector and power supply plug may be needed.
- *Will my Communicator work in my hotel?*
  - Call your hotel to find out if they have analog data ports, usually used to connect a computer or fax machine, in the rooms. Some hotels use digital PBX phone lines, which will not work with your Communicator. [Note that if you have a cellular phone plan with your LATITUDE NXT Communicator, you will not need a data port.]
- Pack your LATITUDE Communicator in carry-on luggage. If you use a blood pressure monitor and/or weight scale, you may pack them in your checked luggage.

### At the Airport

When traveling through airport security, have your **Medical Device ID Card** available. This card identifies you as a patient with an implanted pacemaker or defibrillator.

- **Handheld security wands** – Some wands contain strong magnets that may temporarily affect the function of your implanted device. If a handheld wand must be used, it should be passed over the device quickly. In general, a hand-search is preferred to wand use.
- **Security archways** – Walk through security archways at a normal pace (do not linger). Pacemakers and defibrillators may trigger airport security metal detector alarms. However, this will not harm you or your device.
- **Airport Body Scanners** – The Transportation Security Administration (TSA) currently uses two types of full-body “people scanners” — X-ray scans and millimeter wave scans. Neither type of scanner should affect your implanted pacemaker or defibrillator system. Step away from the scanner if you feel poorly.

## While Away From Home

### Emergency Information

Always carry emergency information with you. You should have the information both for local assistance at your destination as well as your home physician's contact information. Make this information readily available to your travel companions. If you are relocating for a longer period of time you may want to request a print-out from your most recent device interrogation. This will identify device settings and predicted longevity.

### LATITUDE Communicator

When you arrive, repeat the setup process following the on-screen instructions. This will verify successful communication between your implanted heart device, the Communicator, and the weight scale and blood pressure monitor (if used). This process will also allow you to change the time zone (US only), if necessary. If you are outside of your home country, contact Boston Scientific Patient Services or your doctor for additional Communicator setup information.

### Questions

For emergencies, you should contact local emergency personnel. For medical-related questions, contact your heart doctor. Patients with non-medical questions in regard to the device or Communicator are welcome to call the numbers in the following table.

Location	Question Regarding	Call
United States and Canada	LATITUDE Communicator	Boston Scientific Patient Services <b>1.866.484.3268</b>
United States and Canada	Device	Boston Scientific Technical Services <b>1.800.CARDIAC (227.3422)</b>
Europe, Middle East, Africa	LATITUDE Communicator OR Device	Boston Scientific Technical Services <b>+32 2 416 7222</b>
Asia Pacific	LATITUDE Communicator OR Device	Boston Scientific Technical Services <b>+61 2 8063 8299</b>

**NOTE:** The BSC CRM patient newsletter, LifeBeat<sup>SM</sup> Online lists clinic and hospital locations familiar with Boston Scientific products nearest to your travel destination. Go to The Traveling Patient section of [www.lifebeatonline.com](http://www.lifebeatonline.com), and click on the Travel with Your Device section. The clinics and hospitals on this list can help patients with matters related to their device.

## CRT-P Systems from Boston Scientific - INVIVE™

### Indications

The INVIVE cardiac resynchronization therapy pacemaker (CRT-Ps) is indicated for patients who have 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 pharmacologic therapy 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 devices are contraindicated in patients who have a separate implanted cardioverter-defibrillator (ICD). Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction. Atrial tracking modes are contraindicated for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

### Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only. Do not reuse, reprocess or resterilize. Always have external defibrillation protection available during implant and electrophysiologic testing. Do not use this pulse generator with another pulse generator. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversible to Safety Core operation. Do not kink, twist, or braid leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial only modes in patients with heart failure. In devices with the lead safety switch programmed to On, the lead polarity will switch to unipolar in the presence of a lead impedance of ≤ 200 or ≥ 2000 Ω. If programmed to a fixed atrial sensitivity value of 0.15 mV, 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. Left ventricular (LV) lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition.

### 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 electric or magnetic interference (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 (pacing/sensing), infection, lead tip deformation and/or breakage, procedure related, and component failure. 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-P System from Boston Scientific – CONTAK® RENEWAL™ TR

### Indications

The CONTAK RENEWAL TR pulse generator is indicated for patients who have 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 heart failure drug therapy (as defined in the clinical trials section in the System Guide). These devices provide atrial-ventricular tracking modes to help preserve AV synchrony and adaptive-rate pacing for patients who would benefit from adjusted pacing rates concurrent with physical activity.

### Contraindications

These devices are contraindicated in patients who have a separate implanted cardioverter-defibrillator (ICD). Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction. Atrial tracking modes are contraindicated for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

### Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only Do not reuse, reprocess, or resterilize. Such damage can result in patient injury or death. Do not expose a patient to MRI device scanning. Do not expose a patient with an activated implanted pulse generator to diathermy. Do not use atrial-only modes in patients with heart failure. The clinical outcomes for patients with chronic refractory atrial tachyarrhythmias are not fully known. Safety and effectiveness studies have not been conducted. If a chronic refractory atrial tachyarrhythmia develops in a patient with these devices, do not use dual-chamber or single-chamber atrial pacing. Left ventricular (LV) lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition.

### Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implantation and device programming; pulse generator explant and disposal; environmental and medical therapy hazards. Advise patients to avoid sources of electromagnetic interference (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 (pacing/sensing), infection, lead tip deformation and/or breakage, procedure related, and component failure. 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. M)*

## Pacing Systems from Boston Scientific – INGENIO™ and ADVANTIO™

### Indications

INGENIO and ADVANTIO indications include: 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; 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. Pacemakers' 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: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (eg, pacemaker syndrome) in the presence of persistent sinus rhythm or low cardiac output or congestive heart failure secondary to bradycardia.

### Contraindications

Pacemakers are contraindicated for the following patients under the circumstances listed: patients who have a separate implanted cardioverter-defibrillator (ICD); use of 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

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only. Do not reuse, reprocess or resterilize. Always have external defibrillation protection available during implant and electrophysiologic testing. Do not use this pulse generator with another pulse generator. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversible to Safety Core operation. Do not kink, twist, or braid leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. In devices with the lead safety switch programmed to On, the lead polarity will switch to unipolar in the presence of a lead impedance of ≤ 200 or ≥ 2000 Ω. If programmed to a fixed atrial sensitivity value of 0.15 mV, 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. Advise patients to avoid sources of electric or magnetic interference (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, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. 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)*

## Pacing Systems from Boston Scientific ALTRUA™ and INSGNIA™

### Indications

Pacemaker indications include: 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; 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 who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Pacemakers' 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: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (eg, pacemaker syndrome) in the presence of persistent sinus rhythm.

### Contraindications

Pacemakers are contraindicated for the following patients under the circumstances listed: patients with unipolar pacing leads or in MV mode with an implanted ICD because it may cause unwanted delivery or inhibition of ICD therapy; use of the MV sensor in patients with only unipolar leads, because a bipolar lead is required in either the atrium or the ventricle for MV detection (INSGNIA® Plus, ALTRUA® 20/40); MV mode in patients with both unipolar atrial and ventricular leads (INSGNIA® Ultra, ALTRUA® 60); single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias, 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

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only-do not resterilize devices. Inappropriate sustained high-rate pacing occurred in the PULSAR™ MAX clinical study in 5 out of 130 patients with MV ON, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming a reduced Max Sensor Rate or MV to Passive. These programming recommendations are intended to assure that MV calibration is evaluated and, if necessary, recalibrated (4 → ON) when the patient and pacing system have stabilized post implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred.

### Precautions

For specific information on precautions, refer to the following sections of the product labeling: MV sensor calibration at implant; clinical considerations; sterilization, storage and handling; lead evaluation and connection; implantation; programming and pacemaker operation; MV initialization; environmental and medical therapy hazards; elevated pressure; explanted pacemakers. Advise patients to avoid sources of electric or magnetic interference (EMI). If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of the EMI, moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

### Potential Adverse Events

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. 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. Q)

## CRT-D System from Boston Scientific – COGNIS®

### 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
- Left bundle branch block (LBBB) with QRS ≥ 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 the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have sterile external and internal defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. 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 to diathermy. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is 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, storage and handling; implant and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

### Potential Adverse Events

Potential adverse events from implantation of the CRT-D system 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. R)

## CRT-D Systems from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™

### Indications and Usage

The PUNCTUA™, ENERGEN™, and INCEPTA™ 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
- Left bundle branch block (LBBB) with QRS ≥ 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 the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. 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 to diathermy. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Do not kink, twist or braid the lead with other leads. Do not use defibrillation patch leads with the CRT-D system. Do not use this pulse generator with another pulse generator. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet. For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and 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.

### Precautions

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

### Potential Adverse Events

Potential adverse events from implantation of the CRT-D system 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.

ADDENDUM TO: 002-1604, Rev. B, US

Most Current Brief Summaries found @ [www.http://www.bostonscientific.com/](http://www.bostonscientific.com/)

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 from Boston Scientific – PUNCTUA™, ENERGEN™, and INCEPTA™

#### ICD Indications and Usage

PUNCTUA™, ENERGEN™, and INCEPTA™ ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

#### Contraindications

Use of these ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

#### Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. Patients should 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 to diathermy. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is set to inhibit therapy, the patient should not reapply the magnet.

For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and 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.

#### 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 electromagnetic interference (EMI).

#### Potential Adverse Events

Potential adverse events from implantation of the ICD system 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, psychologic intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. 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 from Boston Scientific –TELIGEN®

#### ICD Indications and Usage

ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. ICDs (i.e. Vitality AVT) with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have or are at risk of developing atrial tachyarrhythmias.

#### Contraindications

Use of ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

#### Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. For single patient use only. Do not reuse, reprocess, or resterilize. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures. Always have external defibrillator protection available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing. Patients should 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 to diathermy. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias. Do not use this pulse generator with another pulse generator. Do not kink, twist or braid lead with other leads. For Patient Triggered Monitor (PTM) feature, make sure the feature is enabled prior to sending the patient home with a magnet. Once the PTM feature has been triggered and the magnet response programming is 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 electromagnetic interference (EMI).

#### Potential Adverse Events

Potential adverse events from implantation of the ICD system 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, psychologic intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. 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. Q)

---

### LATITUDE® Patient Management System from BostonScientific

#### Intended Use

The LATITUDE Patient Management system is intended for use to remotely communicate with a compatible pulse generator from Guidant or Boston Scientific CRM and transfer data to a central database. The LATITUDE system provides patient data that can be used as part of the clinical evaluation of the patient.

#### Contraindications

The LATITUDE system is contraindicated for use with any pulse generator other than a compatible pulse generator from Guidant or Boston Scientific CRM. Not all Guidant or Boston Scientific pulse generators are compatible with the LATITUDE system. For contraindications for use related to the pulse generator, refer to the System Guide for the pulse generator being interrogated.

#### Precautions

The LATITUDE system is designed to notify clinicians within 24 hours if new red alert conditions are detected by the Communicator. Alert notifications are based on clinician configured alert settings. Pulse generator data is typically available for review on the LATITUDE system within 15 minutes of a successful interrogation. However, data availability and alert notification can take up to 24 hours or the next business day. Note that pulse generator data will not be available and alert notification cannot occur if:

- The Communicator is unplugged or is not able to connect to the LATITUDE system through an active phone line.
- The pulse generator and the Communicator cannot complete a telemetry session. This session must be initiated by the patient if he or she has a pulse generator that uses inductive telemetry.
- The Communicator is damaged or malfunctions.
- The patient is not compliant with prescribed use or is not using the LATITUDE system as described in the patient manual.
- Up to two weeks may elapse before LATITUDE first detects the conditions mentioned above. Additional time may be required for clinic notification and resolution of the condition. During this time, no new patient data, device data, or alert notifications since the last successful data transmission are available.

#### Adverse Effects

None known.

Refer to the product labeling for specific instructions for use. Rx only. (Rev. L)

---

## ADDENDUM TO: 002-1604, Rev. B, US

Most Current Brief Summaries found @ [www.http://www.bostonscientific.com/](http://www.bostonscientific.com/)