

# Cost-Effectiveness of Cardiac Resynchronization Therapy in the COMPANION Trial

GuidePoint

Simplifying Reimbursement

Cardiac Rhythm Management  
and Electrophysiology

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Feldman, et al. retrospectively analyzed the incremental cost-effectiveness ratios (ICERs) for COMPANION patients who received cardiac resynchronization therapy (CRT) via a pacemaker (CRT-P) or a defibrillator (CRT-D) in combination with optimal pharmacological therapy (OPT) relative to patients with OPT alone. The results of the analysis demonstrate the following economic value of CRT in COMPANION patients<sup>1</sup>:

- The CRT-D ICER was \$43,000 per quality-adjusted-life-year (QALY) gained.
- The CRT-P ICER was \$19,000 per QALY gained.
- Over 2 years, all-cause follow-up hospitalization costs were reduced by 29% for patients with a CRT-D and 37% for patients with a CRT-P when compared with patients in the OPT arm.

Therapeutic interventions are considered to be cost-effective if they have a cost-effectiveness ratio below the generally accepted benchmarks, which range from \$50,000 to \$100,000 per QALY<sup>2</sup>. For COMPANION patients, the use of CRT-P and CRT-D was associated with an ICER well **below** those benchmarks. This analysis demonstrates that the clinical benefits of CRT-D and CRT-P are economically viable and can be achieved at a reasonable cost.

Results from the retrospective cost-effectiveness analysis of the COMPANION study data are published in the December 20, 2005 issue of *The Journal of the American College of Cardiology*.

## Available resources for the cost-effectiveness of CRTs and ICDs

Feldman AM, de Lissovoy G, Bristow MR, et al. Cost-effectiveness of Cardiac Resynchronization Therapy in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Trial. *Journal of the American College of Cardiology (JACC)*. 2005;46(12):2322-4.

Sanders GD, Hlatky MA, Owens DK. Cost-Effectiveness of Implantable Cardioverter-Defibrillators. *New England Journal of Medicine (NEJM)*. 2005;393(14):1471-80.

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<sup>1</sup> Feldman AM, de Lissovoy G, Bristow MR, et al. Cost-effectiveness of cardiac resynchronization therapy in the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial. *Journal of the American College of Cardiology (JACC)*. 2005;46(12):2322-4.

<sup>2</sup> Wilson LS, Ramsey JM, Koplowitz YB, et al. Cost-effectiveness of implementation methods for ELISA serology testing of *trypanosoma cruzi* in California blood banks. *The American Society of Tropical Medicine and Hygiene*. 2008;79(1):53-68.

## CRT-D Systems from Boston Scientific CRM

### Indications and Usage

Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with moderate to severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal heart failure drug therapy, and have left ventricular dysfunction ( $EF \leq 35\%$ ) and QRS duration  $\geq 120$  ms.

### 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. Such damage can result in patient injury or death. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. 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 device scanning. Strong magnetic fields may damage the device and cause injury to the patient. Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. Do not use atrial-only modes in patients with heart failure because such modes do not provide CRT. 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. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. Do not use defibrillation patch leads with the CRT-D system, or injury to the patient may occur. Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction.

### Precautions

For 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, 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. L)

## CRT-P Systems from Boston Scientific CRM

### Indications

Cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction ( $EF \leq 35\%$ ) and QRS duration  $\geq 120$  ms and remain symptomatic despite stable, optimal heart failure drug therapy (as defined in the clinical trials section in the System Guide). The 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. Such damage can result in patient injury or death. Do not kink the leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. Do not expose a patient with an activated implanted pulse generator to diathermy. Therapeutic diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pacemaker because of induced currents. Do not use atrial-only modes in patients with heart failure because such modes do not provide CRT. 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 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 from implantation of the CRT-P 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 (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. J)

## ICD Systems from Boston Scientific CRM

### ICD Indications and Usage

ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. ICDs 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. Such damage can result in patient injury or death. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue. 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 device scanning. Strong magnetic fields may damage the device and cause injury to the patient. Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. (Applies to dual-chamber devices only.) Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction.

### Precautions

For information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implantation and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; 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 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.

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### Cardiac Rhythm Management

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