



Expanded Indications for Medtronic CRT-D Devices

Sponsor Panel Briefing Package

Labeling: Indications for Use

Prepared for the Circulatory Systems Devices Panel Meeting, December 7, 2011

Labeling – Indications for Use

The following table provides a list of the most recent FDA approved Medtronic CRT-D devices. Medtronic's request to expand the indications for use includes all commercially available CRT-D devices and any future Medtronic CRT-D devices.

Medtronic CRT-D Devices

Name of Product	FDA Number	Date of FDA Approval
Concerto® CRT-D Model C154DWK	P010031/S031	05/12/2006
Consulta™ CRT-D Model D224TRK	P010031/S084	03/17/2008
Maximo® II CRT-D Model D284TRK	P010031/S084	03/17/2008
Concerto® II CRT-D Model D274TRK	P010031/S125	10/23/2008
Protecta XT CRT-D Model D314TRG	P010031/S171	03/25/2011
Protecta CRT-D Model D334TRG	P010031/S171	03/25/2011

The request to expand the indications for use requires an update to the product labeling. The only portion of the product labeling that requires updating is the *Indications and Usage* statement and in particular, the heart failure patient population.

For each of the products listed above, a red-lined version of the current *Indication and Usage* statement is provided; this is followed by an updated/clean version of the *Indication and Usage* statement that highlights the new heart failure patient population.



Medtronic

CONCERTO[®] C154DWK

Dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy (VVE/DDE¹-DDDR), atrial¹ and ventricular therapies, OptiVol[®] Fluid Monitoring, and Conexus[™] Telemetry

Implant Manual

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

¹ Atrial tachyarrhythmia (AT) therapies are available with appropriate software. Contact your Medtronic representative.

The Concerto CRT-D system is indicated for heart failure patients who meet any of the following classifications:
- New York Heart Association (NYHA) Functional Class III or IV who remain symptomatic despite stable, optimal medical therapy, and who have a left ventricular ejection fraction $\leq 35\%$ and a prolonged QRS duration.
- NYHA Functional Class II who remain symptomatic despite stable, optimal medical therapy, and who have a left bundle branch block (LBBB) with a QRS duration ≥ 120 ms, and left ventricular ejection fraction $\leq 30\%$.
In addition, Medtronic CRT-D systems are

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2 Indications and usage

~~The Concerto is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. In addition, the device is indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction $\leq 35\%$ and a prolonged QRS duration.~~

The system is also

for

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD-indicated patients with atrial septal lead placement and an ICD indication.

implantable cardioverter defibrillator (ICD)-indicated

3 Contraindications

Do not use the Concerto system in patients:

- Whose ventricular tachyarrhythmias may have transient or reversible causes, such as:
 - acute myocardial infarction
 - drug intoxication
 - drowning
 - electric shock
 - electrolyte imbalance
 - hypoxia
 - sepsis
- With incessant VT or VF
- Who have a unipolar pacemaker
- Whose primary disorder is bradyarrhythmias
- Whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF

4 Warnings and precautions

4.1 General

Anti-coagulation – Use of the device should not change the application of established anti-coagulation protocols.

Avoiding shock during handling – Disable tachyarrhythmia detection during implant, explant, or postmortem procedures. The device can deliver a high-voltage shock if the defibrillation terminals are touched.



Medtronic

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Dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy (VVE/DDE-DDDR), atrial and ventricular therapies, OptiVol[®] Fluid Monitoring, and Conexus[®] Telemetry

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- NYHA Functional Class II who remain symptomatic despite stable, optimal medical therapy, and who have left bundle branch block (LBBB) with a QRS duration ≥ 120 ms, and left ventricular ejection fraction $\leq 30\%$.

In addition, Medtronic CRT-D systems are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive (PMOP) are indicated for the suppression of atrial tachyarrhythmias in implantable cardioverter defibrillator (ICD)-indicated patients with atrial septal lead placement and an ICD indication

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4 Warnings and precautions

4.1 General

Anti-coagulation – Use of the device should not change the application of established anti-coagulation protocols.

Avoiding shock during handling – Disable tachyarrhythmia detection during implant, explant, or postmortem procedures. The device can deliver a high-voltage shock if the defibrillation terminals are touched.

Electrical isolation during implant – Do not allow the patient to have contact with grounded equipment that might produce electrical current leakage during implant. Electrical current leakage may induce arrhythmias that may result in the patient's death.

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use whenever arrhythmias are possible or intentionally induced during device testing, implant procedures, or post-implant testing.



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CONCERTO® C154DWK

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Reference Manual

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2.1.14 Treating bradycardia

The device provides rate responsive pacing to treat bradycardia. An internal accelerometer senses the patient's physical activity, allowing the device to increase and decrease the pacing rate in response to changes in the level of activity. The device provides dual chamber pacing and single chamber pacing modes.

2.1.15 Monitoring for real-time and stored data

The device and programmer provide real-time information on detection and therapy parameters and status during a patient session. The device also provides accumulated data on device operation, including stored electrograms, detected and treated tachyarrhythmia episodes, bradycardia interventions, and the efficacy of therapy. The Cardiac Compass report provides up to 14 months of clinically significant data, including arrhythmia episodes, shocks delivered, physical activity, heart rate, bradycardia pacing activities, and thoracic fluid trends. The Rate Histograms report shows the percent of time that cardiac events occurred at different heart rates. This report also shows the distribution of ventricular heart rates during AT/AF episodes.

All of this information can be printed and retained in the patient's file or saved in electronic format on a floppy diskette.

2.1.16 Conducting electrophysiologic tests

You can use the system to conduct non-invasive electrophysiologic studies, including manual delivery of therapies, to manage an

2.1.17 Alerting

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2.2 Indications and usage

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The system is also

threatening ventricular arrhythmias. In addition, the device is indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction $\leq 35\%$ and a prolonged QRS duration.

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Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD-indicated patients with atrial septal lead placement and an ICD indication.

2.3 Contraindications implantable cardioverter defibrillator (ICD)-indicated

Do not use the Concerto system in patients:

- Whose ventricular tachyarrhythmias may have transient or reversible causes, such as:
 - acute myocardial infarction
 - drug intoxication
 - drowning
 - electric shock
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- With incessant VT or VF
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- Whose primary disorder is bradyarrhythmias
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2.4 Patient screening

Before implant, patients should undergo a complete cardiac evaluation, including electrophysiologic testing. Also, electrophysiologic evaluation and testing of the safety and efficacy



Medtronic

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Dual chamber implantable cardioverter defibrillator with cardiac resynchronization therapy (VVE/DDE-DDDR), atrial and ventricular therapies, OptiVol[®] Fluid Monitoring, and Conexus[®] Telemetry

DRAFT

Reference Manual

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2.1.16 Conducting electrophysiologic tests

You can use the system to conduct non-invasive electrophysiologic studies, including manual delivery of therapies, to manage an induced or spontaneous tachyarrhythmia.

2.1.17 Alerting the patient to system events

You can use the programmable Medtronic CareAlert monitoring feature to notify the patient with audible tones if certain conditions occur that are related to the leads, battery, charge time, and therapies. The patient can then respond based on your prescribed instructions. The patient's monitor can then notify the patient or a family member of certain event conditions.

2.2 Indications and usage

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In addition, Medtronic CRT-D systems are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive (PMOP) are indicated for the suppression of atrial tachyarrhythmias in implantable cardioverter defibrillator (ICD)-indicated patients with atrial septal lead placement and an ICD indication

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 - electrolyte imbalance



Medtronic

CONSULTA™ CRT-D D224TRK

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)

Complete Capture Management™ Diagnostic (ACM, RVCM, LVCM), Detailed EGM™ Viewer, OptiVol® Fluid Status Monitoring, ATP During Charging™ Feature, TherapyGuide™ Feature, and Conexus® Wireless Telemetry

Clinician Manual

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Model 2696 InCheck Patient Assistant – Patients can use the Model 2696 InCheck Patient Assistant to perform the following tasks:

- Initiate recording of cardiac event data in the device memory. Cardiac event data can be viewed either on the programmer or using CareLink. In addition, when the InCheck Patient Assistant is activated, the EGM signals of the programmed EGM sources and markers are stored in the device and are available for review using CareLink. The CareLink monitor transmits the EGM data and markers from the patient’s device to the CareLink Network. You can identify patients who have new, not previously viewed patient-a EGM View
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 - Request patient-ac
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- NYHA Functional Class II who remain symptomatic despite stable, optimal medical therapy, and who have a left bundle branch block (LBBB) with a QRS duration ≥ 120 ms, and left ventricular ejection fraction $\leq 30\%$.

In addition, Medtronic CRT-D systems are

Contents of defibrillator, one torque wrench, and one DF-T pin plug.

1.3 Indications and usage

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~~The Consulta CRT-D system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. In addition, the device is indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction $\leq 35\%$ and a prolonged QRS duration.~~

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implantable cardioverter defibrillator (ICD)-indicated



Medtronic

CONSULTA[®] CRT-D D224TRK

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)

Complete Capture Management[™] Diagnostic (ACM, RVCM, LVCM), Detailed EGM[™] Viewer, OptiVol[®] Fluid Status Monitoring, ATP During Charging[™] Feature, TherapyGuide[™] Feature, and Conexus[®] Wireless Telemetry

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- Initiate recording of cardiac event data in the device memory. Cardiac event data can be viewed either on the programmer or using CareLink. In addition, when the InCheck Patient Assistant is activated, the EGM signals of the programmed EGM sources and markers are stored in the device and are available for review using CareLink. The CareLink monitor transmits the EGM data and markers from the patient's device to the CareLink Network. You can identify patients who have new, not previously viewed patient-activated episodes and then proceed to view their EGM data using the Detailed EGM Viewer on CareLink.
- Verify whether the implanted device has detected a suspected atrial tachyarrhythmia.
- Request delivery of atrial cardioversion therapy (if the device is programmed to allow patient-activated cardioversion).

Note: Patient-activated cardioversion is delivered only if the implanted device is currently detecting an AT/AF episode and the physician has programmed the device to allow patient-activated cardioversion.

Contents of sterile package – The package contains one implantable cardioverter defibrillator, one torque wrench, and one DF-1 pin plug.

1.3 Indications and usage

The Consulta CRT-D CRT-D system is indicated for heart failure patients who meet any of the following classifications:

- New York Heart Association (NYHA) Functional Class III or IV who remain symptomatic despite stable, optimal medical therapy, and who have a left ventricular ejection fraction $\leq 35\%$ and a prolonged QRS duration.
- NYHA Functional Class II who remain symptomatic despite stable, optimal medical therapy, and who have left bundle branch block (LBBB) with a QRS duration ≥ 120 ms, and left ventricular ejection fraction $\leq 30\%$.

In addition, Medtronic CRT-D systems are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive (PMOP) are indicated for the suppression of atrial tachyarrhythmias in implantable cardioverter defibrillator (ICD)-indicated patients with atrial septal lead placement and an ICD indication



Medtronic

MAXIMO[®] II CRT-D D284TRK

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (VVE-DDDR)

ATP During Charging[™] Feature, TherapyGuide[™] Feature, and Conexus[®] Wireless Telemetry

Clinician Manual

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1.3 Indications and usage

~~The Maximo II CRT-D system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction \leq 35% and a prolonged QRS duration.~~

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- New York Heart Association (NYHA) Functional Class III or IV who remain symptomatic despite stable, optimal medical therapy, and who have a left ventricular ejection fraction \leq 35% and a prolonged QRS duration.
- NYHA Functional Class II who remain symptomatic despite stable, optimal medical therapy, and who have left bundle branch block (LBBB) with a QRS duration \geq 120 ms, and left ventricular ejection fraction \leq 30%.

In addition, Medtronic CRT-D systems are



Medtronic

MAXIMO[®] II CRT-D D284TRK

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (VVE-DDDR)

ATP During Charging[™] Feature, TherapyGuide[™] Feature, and Conexus[®] Wireless Telemetry

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Clinician Manual

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Medtronic

MAXIMO® II CRT-D D284TRK

1.3 Indications and usage

The Maximo II CRT-D CRT-D system is indicated for heart failure patients who meet any of the following classifications:

- New York Heart Association (NYHA) Functional Class III or IV who remain symptomatic despite stable, optimal medical therapy, and who have a left ventricular ejection fraction $\leq 35\%$ and a prolonged QRS duration.
- NYHA Functional Class II who remain symptomatic despite stable, optimal medical therapy, and who have left bundle branch block (LBBB) with a QRS duration ≥ 120 ms, and left ventricular ejection fraction $\leq 30\%$.

In addition, Medtronic CRT-D systems are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias.

1.4 Contraindications

The Maximo II CRT-D system is contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis.

The device is contraindicated for patients who have a unipolar pacemaker implanted.

The device is contraindicated for patients with incessant VT or VF.



Medtronic

CONCERTO[®] II CRT-D D274TRK

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)

OptiVol[®] Fluid Status Monitoring, ATP During Charging[™] Feature, TherapyGuide[™] Feature, and Conexus[®] Wireless Telemetry

Clinician Manual

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The Concerto II CRT-D system is indicated for heart failure patients who meet any of the following classifications:

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Contents of system: defibrillator, one

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Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD-indicated patients with atrial septal lead placement and an ICD indication.

implantable cardioverter defibrillator (ICD)-indicated

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The device is contraindicated for patients who have a unipolar pacemaker implanted.

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The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.



Medtronic

CONCERTO® II CRT-D D274TRK

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)

OptiVol® Fluid Status Monitoring, ATP During Charging™ Feature, TherapyGuide™ Feature, and Conexus® Wireless Telemetry

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Clinician Manual

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Medtronic

CONCERTO® II CRT-D D274TRK

Note: Patient-activated cardioversion is delivered only if the implanted device is currently detecting an AT/AF episode and the physician has programmed the device to allow patient-activated cardioversion.

Contents of sterile package – The package contains one implantable cardioverter defibrillator, one torque wrench, and one DF-1 pin plug.

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The device is contraindicated for patients who have a unipolar pacemaker implanted.

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The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.



Medtronic

PROTECTA™ XT CRT-D D314TRG

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)

SmartShock™ Technology (RV Lead Noise Discrimination, RV Lead Integrity Alert, TWave Discrimination, Confirmation+, Wavelet, PR Logic®), OptiVol® 2.0 Fluid Status Monitoring, Complete Capture Management™ Diagnostic (ACM, RVCM, LVCM), and ATP During Charging™ Feature

Clinician Manual

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Medtronic PROTE

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The device is contraindicated for patients who have a unipolar pacemaker implanted.

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Contents of steri defibrillator, one to

1.3 Indications and usage

~~The Protecta CRT-D system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. In addition, the device is indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction $\leq 35\%$ and a prolonged QRS duration.~~

The system is also

for

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ~~ICD-indicated~~ patients with atrial septal lead placement and an ICD indication.

implantable cardioverter defibrillator (ICD)-indicated

1.4 Contraindications

The Protecta CRT-D system is contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis.

The device is contraindicated for patients who have a unipolar pacemaker implanted.

The device is contraindicated for patients with incessant VT or VF.

The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.



Medtronic

PROTECTA™ CRT-D D334TRG

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy (DDE-DDDR)

SmartShock™ Technology (RV Lead Noise Discrimination, RV Lead Integrity Alert, TWave Discrimination, Confirmation+, Wavelet, PR Logic®), and ATP During Charging™ Feature

DRAFT

Clinician Manual

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Medtronic

PROTECTA™ CRT-D D334TRG

Note: Patient-activated cardioversion is delivered only if the implanted device is currently detecting an AT/AF episode and the physician has programmed the device to allow patient-activated cardioversion.

Contents of sterile package – The package contains one implantable cardioverter defibrillator, one torque wrench, and one DF-1 pin plug.

1.3 Indications and usage

The Protecta CRT-D CRT-D system is indicated for heart failure patients who meet any of the following classifications:

- New York Heart Association (NYHA) Functional Class III or IV who remain symptomatic despite stable, optimal medical therapy, and who have a left ventricular ejection fraction $\leq 35\%$ and a prolonged QRS duration.
- NYHA Functional Class II who remain symptomatic despite stable, optimal medical therapy, and who have left bundle branch block (LBBB) with a QRS duration ≥ 120 ms, and left ventricular ejection fraction $\leq 30\%$.

In addition, Medtronic CRT-D systems are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive (PMOP) are indicated for the suppression of atrial tachyarrhythmias in implantable cardioverter defibrillator (ICD)-indicated patients with atrial septal lead placement and an ICD indication

1.4 Contraindications

The Protecta CRT-D system is contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis.

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The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.