ACC/AHA/HRS 2008–2009 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities[1]

ACC/AHA/HRS CLASSIFICATION OF RECOMMENDATIONS (See details on back)	**SIGNS / SYMPTOMS**	**DEVICE THERAPY**
I	Ischemic: Post-MI ≥ 40 days, EF ≤ 30%, NYHA Class II/III Nonischemic: EF ≤ 30%, NYHA II/III, chronic OPT	**ICD**
I	Current/prior symptoms of HF and reduced EF with history of SCA, VF, or unstable VT	**ICD**
I	EF: 30–35% of any origin; NYHA Class II/III	**ICD**
I/II	Congenital heart disease such as Long QT, Brugada, HCM- *see guidelines for full clarification	**ICD**
IIa	Ischemic, EF ≤ 30%, post-MI ≥ 40 days NYHA Class I	**ICD**
Additional Pacing Consideration	Optimization of pacemaker programming to minimize unneeded RV pacing is encouraged.	
I	EF ≤ 35%, sinus rhythm, NYHA Class III or ambulatory NYHA Class IV, QRS ≥ 120 ms, OPT	**CRT-D** **CRT-P**
IIa	EF ≤ 35%, NYHA Class III, or ambulatory NYHA Class IV, OPT, frequent dependence on ventricular pacing	**CRT-D** **CRT-P**
IIa	EF ≤ 35%, NYHA Class III, or ambulatory NYHA Class IV, QRS ≥ 120 ms, OPT, atrial fibrillation	**CRT-D** **CRT-P**
IIb	EF ≤ 35%, NYHA Class I or II, OPT, device implant with anticipated frequent ventricular pacing	**CRT-D** **CRT-P**

Boston Scientific
Delivering what's next.™

ACC/AHA 2005 Heart Failure Guideline Update: Summary[2]

Classifications and Stages

ACC/AHA Classification of Recommendations

Class I — **Conditions for which there is evidence and/or general agreement that a given procedure/therapy is beneficial, useful, and/or effective.**

Class II — Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure/therapy.

- **IIa** **Weight of evidence/opinion is in favor of usefulness/efficacy.**
- **IIb** **Usefulness/efficacy is less well established by evidence/opinion.**

Class III — Conditions for which there is evidence and/or general agreement that a procedure/therapy is not useful/effective and in some cases may be harmful.

ACC/AHA HF Stage

- A — High risk for HF; no structural disease
- B — Structural heart disease; no HF symptoms
- C — Structural heart disease; prior/current HF symptoms
- D — Refractory end-stage HF requiring special interventions

NYHA Functional Class[3, 4]

- Class I — Asymptomatic
- Class II — Symptomatic with moderate exertion
- Class III — Symptomatic with minimal exertion
- Class IV — Symptomatic at rest

This piece is intended to be used in conjunction with the brief summaries provided with this material and as a complement to the ACC/AHA/HRS Updates for the Diagnosis and Management of Chronic Heart Failure in the Adult.

[1] Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2008;117(21):e350-e408.

[2] Hunt SA, Abraham WT, Chin, et al. ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult—Summary Article: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure). Journal of the American College of Cardiology. 2005;6(46):1116-1143.

[3] Jessup M and Brozena S. Heart Failure. The New England Journal of Medicine. 2003;348:2007-2018.

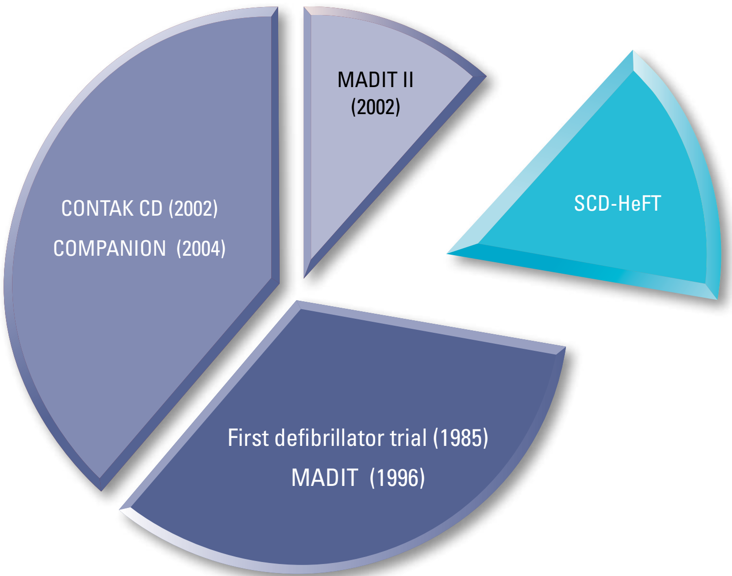
[4] Farrell MH, Foody JM, Krumholz HM. Blockers in Heart Failure: Clinical Applications. The Journal of the American Medical Association 2002;287:890-897.

Primary Prevention

No history of cardiac arrest or sustained VT, but at risk for an event. All primary prevention indications include chronic OPT and reasonable expectation of survival with good functional status > 1 year.

Secondary Prevention

Prior cardiac arrest or sustained VT regardless of the underlying type of structural heart disease.



More than 80% of U.S. patients who receive an ICD or CRT-D were first indicated for this therapy by a landmark Boston Scientific-sponsored clinical trial.[5]

[5] ICD and CRT-D implant estimates using full-year 2007 data as of 8/08/08, including Boston Scientific CRM implant data, third-party implant data, and publically available industry information including analyst calls and earnings releases. Data on file at Boston Scientific. All calculations include indicated, on-label uses only. **Primary prevention:** First indication calculation for MADIT II (2002) assumes ischemic primary prevention patients with EF ≤ 30%. Available data suggest 58% of primary prevention patients are ischemic and 71% of those patients have an EF ≤ 30%. Of the primary prevention implants, 42% were first indicated by MADIT II. **Secondary prevention:** Of these total implants, 100% were first indicated by either MADIT (1996) or the trial that led to approval of the first defibrillator (1985) *[Mirowski M, Mower MM, Veltri EP, Juanteguy JM, Reid PR: Recent clinical experience with the automatic implantable cardioverter defibrillator. Cardiol Clin 1985;3(4):623-30]*. **Heart failure:** Of these CRT-D implants, 100% were first indicated by either COMPANION (2004) or CONTAK CD (2002).

First Indications Due to Boston Scientific-Sponsored Clinical Trials

Heart Failure/CRT-D

CRT-D devices first received FDA approval based on the CONTAK CD Trial (2002). The COMPANION trial (2004) was the first to expand CRT-D to a primary prevention population. 100% of CRT-D patients were first indicated on the basis of one of these two trials.

Secondary Prevention

For patients with a history of ventricular arrhythmias, approvals were based on the first defibrillator trial (1985) and later expanded with MADIT (1996) to post-MI patients with EF ≤ 35% and inducible VT. 100% of patients who currently meet a secondary prevention indication were first indicated on the basis of one of these two trials.

Primary Prevention *(Ischemic, EF ≤ 30%)*

For patients at risk of ventricular arrhythmias, approval for ischemic patients with EF ≤ 30% but without prior inducibility was first received as a result of the MADIT II trial (2002). Patients meeting the MADIT II criteria make up 42% of the primary prevention indication population.

First Indications Due to Other Clinical Trials

Primary Prevention (Ischemic, EF > 30% and nonischemic)

The remaining 58% of the primary prevention indication population was first indicated for ICD therapy based on the SCD-HeFT trial[6], which extended ICD therapy to patients with a non-ischemic etiology and to patients with an ischemic etiology with an EF between 30–35%.

[6] sponsored by the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH), Wyeth-Ayerst, and Medtronic.

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 /IV) who remain symptomatic despite stable, optimal heart failure drug therapy, and have left ventricular dysfunction (EF ≤ 35%) and QRS duration ≥ 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 CRM 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. K)

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 ≤ 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). 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; 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-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. I)

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 area protected by a warnng 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.

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

(Rev. L)

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C3-528-0509