2012 ACCF/AHA/HRS Guidelines for Implantable Defibrillator and Cardiac Resynchronization Therapy for Cardiac Rhythm Abnormalities

Despite ICD and CRT being a Class I or IIa indication for treatment of patients, research confirms underutilization and variation of care in heart failure patients.
### Classification of Recommendations

<table>
<thead>
<tr>
<th>Class</th>
<th>Conditions</th>
<th>Example Classifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I</strong></td>
<td>Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.</td>
<td>Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.</td>
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<tr>
<td><strong>Class II</strong></td>
<td>Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.</td>
<td>Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy. Class IIb: Usefulness/efficacy is less well established by evidence/opinion.</td>
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<tr>
<td><strong>Class III</strong></td>
<td>Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.</td>
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### Level of Evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Level A</strong></td>
<td>Data derived from multiple randomized clinical trials or meta-analyses.</td>
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<tr>
<td><strong>Level B</strong></td>
<td>Data derived from a single randomized trial or nonrandomized studies.</td>
</tr>
<tr>
<td><strong>Level C</strong></td>
<td>Only consensus opinion of experts, case studies, or standard-of-care.</td>
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RECOMMENDATIONS FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS

Class I Recommendations

ICD therapy is indicated in patients*:

**Level of Evidence: A**

- With LVEF ≤ 35% due to prior MI who are at least 40 days post-MI and are in NYHA Functional Class II or III

- With LV dysfunction due to prior MI who are at least 40 days post-MI, have an LVEF ≤ 30%, and are in NYHA Functional Class I

- Who are survivors of cardiac arrest due to VF or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes

**Level of Evidence: B**

- With nonischemic DCM who have an LVEF ≤ 35% and who are in NYHA Functional Class II or III

- With nonsustained VT due to prior MI, LVEF < 40%, and inducible VF or sustained VT at electrophysiological study

- With structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable

- With syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VF induced at electrophysiological study

* Assuming patients are on chronic, optimal medical therapy and have a reasonable expectation of survival with good functional status for > 1 year.
Class IIa Recommendations

ICD implantation is reasonable for patients*:

* Assuming patients are on chronic, optimal medical therapy and have a reasonable expectation of survival with good functional status for > 1 year.

**Level of Evidence: B**
- To reduce SCD in patients with Long QT Syndrome who are experiencing syncope and/or VT while receiving beta blockers

**Level of Evidence: C**
- With unexplained syncope, significant LV dysfunction, and nonischemic DCM
- With sustained VT and normal or near-normal ventricular function
- With catecholaminergic polymorphic VT who have syncope and/or documented sustained VT while receiving beta blockers
- For the prevention of SCD in patients with ARVD/C who have one or more risk factors for SCD
- With HCM who have one or more major risk factors for SCD
- With Brugada syndrome who have had syncope or documented VT that has not resulted in cardiac arrest
- With cardiac sarcoidosis, giant cell myocarditis, or Chagas disease
- For nonhospitalized patients awaiting transplantation
RECOMMENDATIONS FOR CARDIAC RESYNCHRONIZATION THERAPY IN PATIENTS WITH SYSTOLIC HEART FAILURE

Class I Recommendations

**CRT is indicated for patients who have**

- LVEF ≤ 35%
- Left Bundle Branch Block (LBBB)
- Sinus rhythm
- QRS duration ≥ 150 ms
- NYHA class II, III, or ambulatory Class IV symptoms
- Guideline-Directed Medical Therapy

*(Level of Evidence: A for NYHA class III/IV; Level of Evidence: B for NYHA class II)*

Class IIa Recommendations

**CRT can be useful for patients who have:**

- LVEF ≤ 35%
- Sinus rhythm
- LBBB
- QRS duration 120 to 149 ms
- NYHA class II, III, or ambulatory Class IV symptoms
- Guideline-Directed Medical Therapy

*(Level of Evidence: B)*

**CRT can be useful for patients who have:**

- Atrial fibrillation
- LVEF ≤ 35%
- Guideline-Directed Medical Therapy

If a) the patient requires ventricular pacing or otherwise meets CRT criteria and b) AV nodal ablation or pharmacologic rate control will allow near 100% ventricular pacing with CRT.

*(Level of Evidence: B)*

**CRT can be useful for patients who have:**

- LVEF ≤ 35%
- Sinus rhythm
- Non-LBBB pattern
- QRS duration ≥ 150 ms
- NYHA class III, or ambulatory Class IV symptoms
- Guideline-Directed Medical Therapy

*(Level of Evidence: A)*

**CRT can be useful for patients who have:**

- LVEF ≤ 35%
- Guideline-Directed Medical Therapy
- Anticipated requirement for significant (> 40%) ventricular pacing

*(Level of Evidence: C)*
References


Brief Statement: Medtronic ICDs and IPGs

Indications
Medtronic implantable cardioverter defibrillators (ICDs) are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Medtronic pacemakers are indicated for chronic cardiac pacing, or rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity and/or minute ventilation. Medtronic pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output and VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm.

Contraindications
Medtronic ICDs are contraindicated in patients whose ventricular tachyarrhythmias may have transient or reversible causes, patients with incessant VT or VF, or in patients who have a unipolar pacemaker.

Medtronic pacemakers are contraindicated for the following applications:
• Dual chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias
• Asynchronous pacing in the presence (or likelihood) of competitive paced and intrinsic rhythms
• Unipolar pacing for patients with an implanted cardioverter defibrillator because it may cause unwanted delivery or inhibition of ICD therapy
• Medtronic Kappa® 400 Series pacemakers are contraindicated for use with epicardial leads and with abdominal implantation

Warnings and Precautions
Changes in a patient’s disease and/or medications may alter the efficacy of the device’s programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device.

Potential Complications
Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, and surgical complications such as hematoma, infection, inflammation, and thrombosis. An additional complication for ICDs is the acceleration of ventricular tachycardia.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic’s website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.