What's new in the Device-Based Therapy Guidelines?

Summary of Device Indications (Adults)

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

These slides are a summary. A full version of the guidelines is available on the JACC Website:

http://content.onlinejacc.org/cgi/content/full/j.jacc.2008.02.032

1. Epstein et al. ACC/AHA/HRS Guidelines for Device-Based Therapy, JACC Vol. 51, No. 21, 2008

Abbreviations used

- 3rd, 2nd, 1st – AV block degree (unless specified otherwise)
- BB - beta blocking medication
- ARVD – arrhythmogenic right ventricular dysplasia
- AVB – atrio-ventricular block
- AVN – AV (atrio-ventricular) node
- CMP - cardiomyopathy
- DCM – dilated cardiomyopathy
- EPS – cardiac electrophysiology study
- FB – fascicular block
- HCM – hypertrophic cardiomyopathy
- HCSS – hypersensitive carotid sinus syndrome
- LQTS – long QT syndrome
- NCGS – neurocardiogenic syncope
- NSVT - non sustained ventricular Tachycardia
- Post-MI – after myocardial infarction
- RBBB, LBBB – right and left bundle branch block
- SCD – sudden cardiac death
- SHD - Structural Heart Disease
- SND – SN (sinus node) disease
- STEMI - ST-segment elevation myocardial infarction
- sVT – sustained ventricular tachycardia

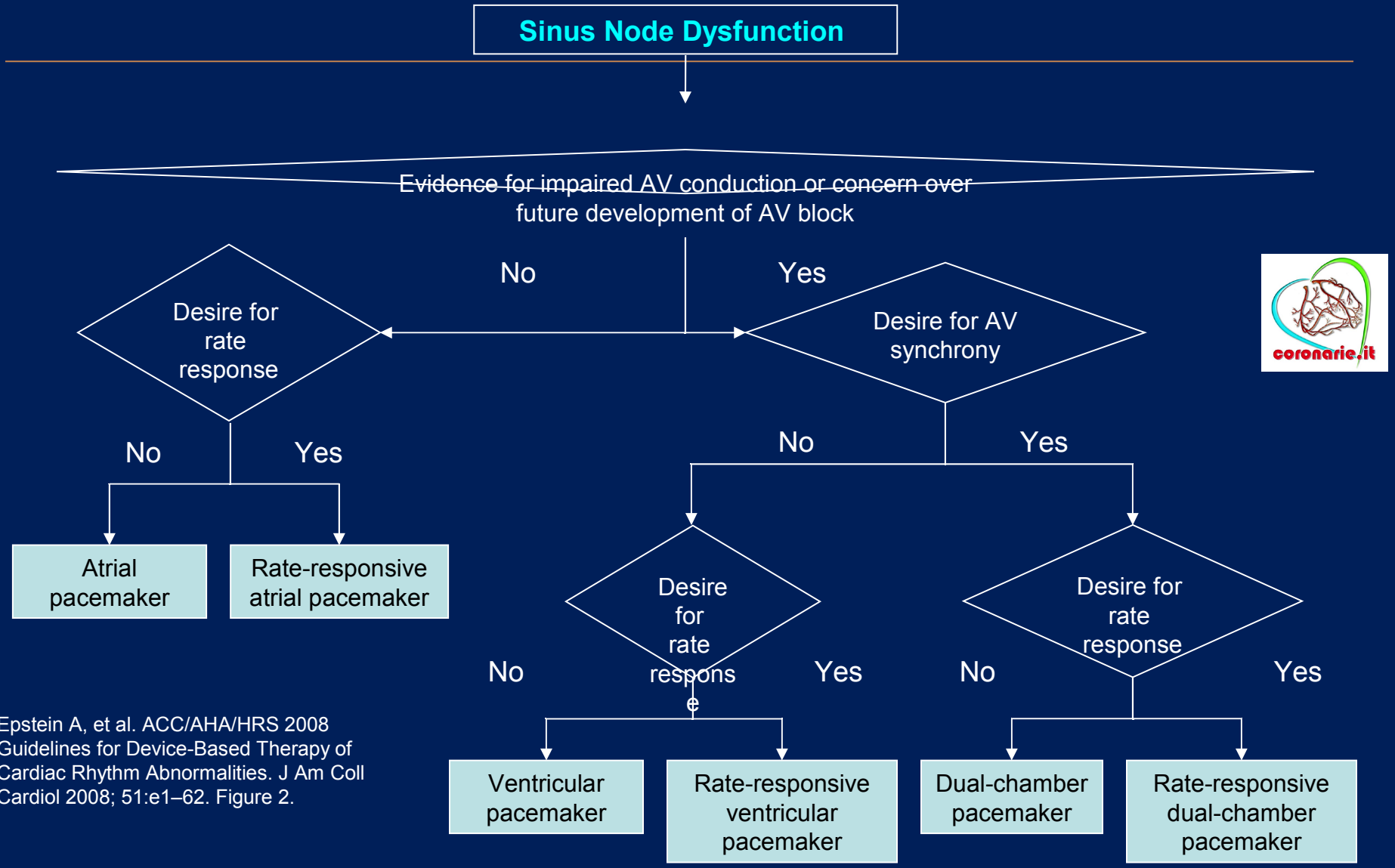
Pacemaker

Pacemaker

Sinus Node Dysfunction

- Class I – symptomatic:
  - bradycardia or pauses
  - chronotropic incompetence
  - due to required drug therapy
- Class IIa
  - unassociated symptoms (HR<40bpm)
  - unexplained syncope with SND (discovered or provoked)
- Class IIb
  - HR<40 bpm while awake
- Class III
  - Asymptomatic SND
  - unrelated symptoms (Symptoms occur also in absence of Bradycardia)
  - Drug related – Due to nonessential drug therapy

Selection of Pacemaker Systems for Patients With Sinus Node Dysfunction



Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008; 51:e1–62. Figure 2.

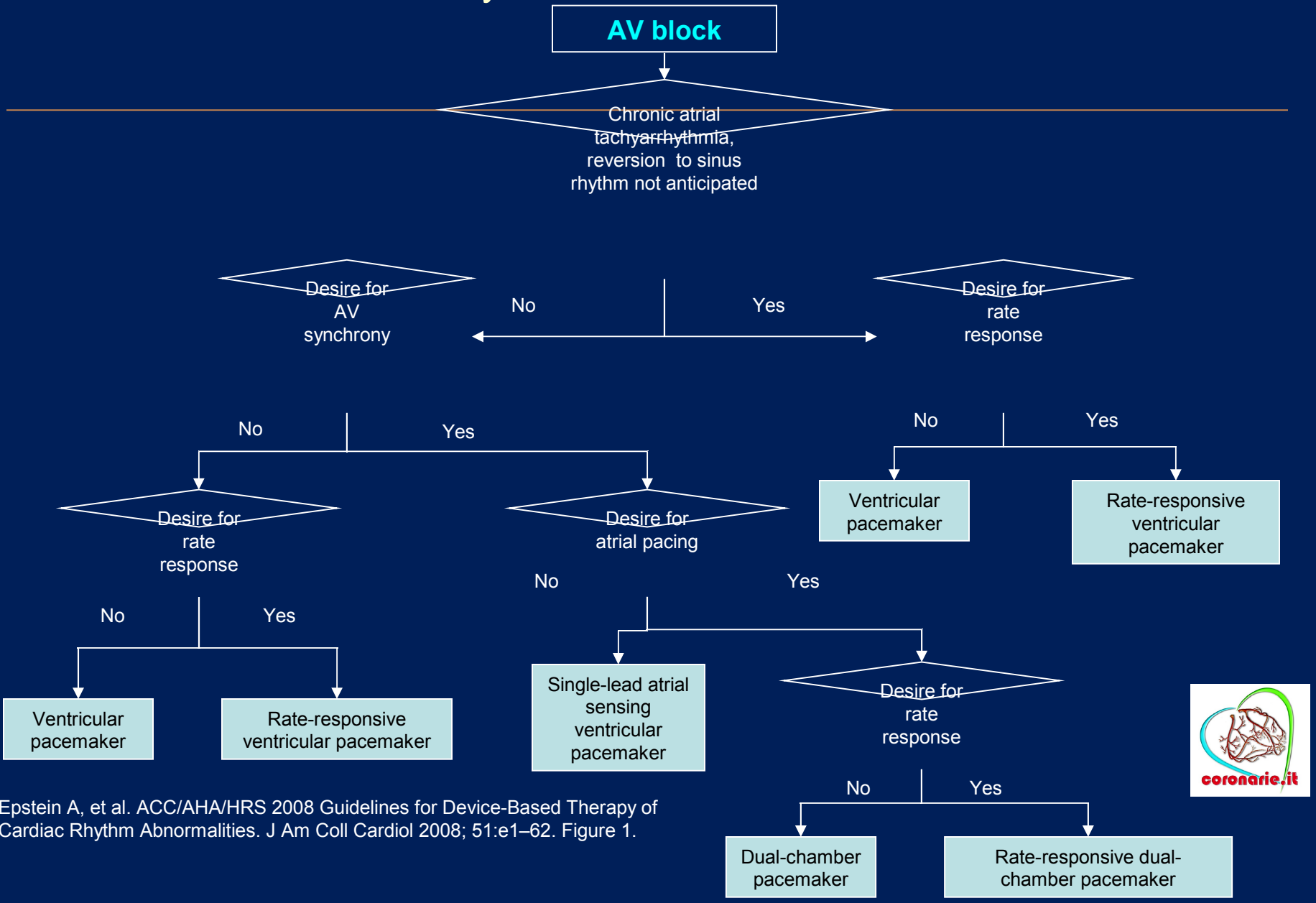
AV Block (adults)

- Class I
  - 3rd , advanced 2nd
    - with symptoms
    - drug-related
    - Escape rate < 40bpm or any rate below AV node
    - >3 sec pause
    - >5 sec pause and AF
    - AV junction ablation/surgery
    - neuromuscular diseases
    - exercise related (not ischemic)
  - 2nd type II
    - with wide QRS (RBBB incl.)
  - 3rd
    - with cardiomegaly or LV dysfunction
    - below the AV node

AV Block (adults)

- Class IIa
  - 3rd persistent
  - 2nd (intra- or infra-His) found during EPS
  - 1st and 2nd with symptoms (PM-syndrome-like or hemodynamic)
  - 2nd type II with narrow QRS
- Class IIb
  - Any AVB + neuromuscular disease
  - Any AVB due to drug use, expected to recur after drug withdrawal
- Class III
  - 1st asymptomatic
  - 2nd supra-His type I asymptomatic
  - any transient

Selection of Pacemaker Systems for Patients With Atrioventricular Block



Epstein A, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J Am Coll Cardiol 2008; 51:e1–62. Figure 1.

Chronic Bifascicular Block

- Class I
  - advanced 2nd
  - intermittent 3rd
  - 2nd type II
  - alternating BBB
- Class IIa
  - syncope with other reasons excluded
  - HV time during EPS>100ms
  - pacing-induced infra-His block
- Class IIb
  - neuromuscular diseases
- Class III
  - no AVB or symptoms
  - 1st AVB no symptoms

After the Acute Phase of MI

- Class I
  - 2nd with alternating BBB
  - 3rd after STEMI
  - 2nd or 3rd infranodal AVB and associated BBB
  - 2nd or 3rd with symptoms
- Class IIb
  - 2nd and 3rd at AVN level asymptomatic
- Class III
  - transient without intraventricular conduction defects
  - transient with isolated left anterior FB
  - new BBB or FB without AVB
  - 1st asymptomatic with BBB or FB

HCSS and NCGS

- Class I
  - recurrent syncope and inducible pause > 3 sec
- Class IIa
  - inducible pause longer than 3 sec
- Class IIb
  - symptomatic NCGS with bradycardia
- Class III
  - no symptoms
  - effective avoidance behavior

After transplant

- Class I
  - all other class I indications
- Class IIb
  - bradycardia, limiting rehabilitation
  - syncope

Devices with Automatic Detection and Pacing to Terminate Tachycardias

- Class IIa
  - Symptomatic recurrent SVT terminated by pacing when ablation and drugs fail
- Class III
  - rapid anterograde conducting accessory pathway is present

Hypertrophic Cardiomyopathy

- Class I
  - SND or AVB as described before
- Class IIb
  - medically refractory symptoms with LV outflow tract obstruction (check SCD risk)
- Class III
  - asymptomatic (or medically controllable)
  - no LV outflow tract obstruction

Pacing to prevent VT

- Class I
  - pause-dependent VT
- Class IIa
  - High risk congenital long-QT
- Class IIb
  - Recurrent drug refractory symptomatic AF & SND
- Class III
  - ectopic ventricular activity
  - torsade, reversible caused

Pacing to prevent AF

- Class III
  - if no other pacing indication

Cardiac Resynchronization Therapy

CRT

CRT

- Class I
  - LV EF<35%, QRS>120ms, NYHA III-IV, SR
- Class IIa
  - LV EF<35%, QRS>120ms, NYHA III-IV, AF
  - LV EF<35%, NYHA III-IV, VP dependent
- Class IIb
  - LV EF<35%, NYHA I-II, VP% high
- Class III
  - reduced LV EF only
  - limited life expectancy (non-cardiac)

ICD

ICD

- Class I
  - VT/VF survivors with irreversible etiology
  - sustained VT with structural heart disease
  - syncope + VT/VF at EPS
  - NYHA II-III, LV EF<35%
  - NYHA I, post-MI, LV EF<30%
  - NSVT, post-MI, LV EF<40%, VT/VF at EPS

ICD

- Class IIa
  - syncope, LV dysfunction, non-ischemic DCM
  - Sustained VT
  - HCM with major risk factors
  - ARVD with major risk factors
  - LQTS with syncope while on BB therapy
  - transplant bridge
  - Brugada syndrome with syncope or VT
  - Catecholaminergic polymorphic VT with syncope
  - VT while on BB therapy
  - sarcoidosis, giant cell myocarditis, Chagas-disease

ICD

- Class IIb
  - NYHA I, LV EF<35%
  - LQTS and SCD risk factors
  - idiopathic syncope and advanced SHD
  - familial CMP & SCD
  - LV noncompaction

ICD

- Class III
  - expected survival less than 1 year (other cause)
  - incessant VT/VF
  - significant psychiatric illness
  - NYHA IV without transplant or CRT indication
  - idiopathic syncope with no inducible VT/VF and SHD
  - VT/VF amenable with ablation
  - VT/VF with reversible cause

Notable Changes in 2008 ACC/AHA/HRS Guidelines

1. ICD recommendations are combined into a single list because of overlap between primary and secondary indications.
2. Primary prevention ICD indications in nonischemic cardiomyopathy are clarified using data from SCD-HeFT (i.e., ischemic and nonischemic cardiomyopathies and LVEF ≤35%, NYHA II-III) for support.
3. Indications for ICD therapy in inherited arrhythmia syndromes and selected nonischemic cardiomyopathies are listed.
4. MADIT II indication (i.e., ischemic cardiomypathy and LVEF ≤30%, NYHA I) is now Class I, elevated from Class IIa.
5. EF criteria for primary prevention ICD indications are based on entry criteria for trials on which the recommendations are based.

Notable Changes in 2008 ACC/AHA/HRS Guidelines

6. The need for optimization of medical therapy before CRT implantation is emphasized.
7. Independent risk assessment preceding ICD implantation is emphasized, including consideration of patient preference.
8. Optimization of pacemaker programming to minimize unneeded RV pacing is encouraged.
9. Pacemaker insertion is discouraged for asymptomatic bradycardia, particularly at night.
10. A section has been added that addresses ICD and pacemaker programming at end of life.
11. Emphasized primary SCD prevention ICD recommendations apply only to patients
    receiving optimal medical therapy and reasonable expectation of survival with good functional capacity for >1 year.

Brief Statement

Indications

Implantable Pulse Generators (IPGs) are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity and increases in activity and/or minute ventilation. 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.

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

Cardiac Resynchronization Therapy (CRT) ICDs are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and 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 less than or equal to 35% and a prolonged QRS duration.

CRT IPGs are 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 less than or equal to 35% and a prolonged QRS duration.

Contraindications

IPGs and CRT IPGs are contraindicated for 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; and certain IPGs are contraindicated for use with epicardial leads and with abdominal implantation.

ICDs and CRT ICDs are contraindicated in patients whose ventricular tachyarrhythmias may have transient or reversible causes, patients with incessant VT or VF, and for patients who have a unipolar pacemaker. ICDs are also contraindicated for patients whose primary disorder is bradyarrhythmia.

Warnings/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. Additionally, for CRT ICDs and CRT IPGs, certain programming and device operations may not provide cardiac resynchronization. Also for CRT IPGs, Elective Replacement Indicator (ERI) results in the device switching to VVI pacing at 65 ppm. In this mode, patients may experience loss of cardiac resynchronization therapy and / or loss of AV synchrony. For this reason, the device should be replaced prior to ERI being set.

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 and CRT 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.

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