



Dual-Functioning Implantable Cardioverter Pacemaker/Defibrillator Devices:- Cardiac Resynchronization Therapy + Defibrillation (CRT-D)

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Overview

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FOCUSED REPORT: Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy (CRT)

Implications for Driving a Commercial Motor Vehicle (CMV)

The use of pacemakers and implantable cardiac defibrillators (ICDs) in the treatment of heart failure and cardiac arrhythmias has advanced substantially over the last decade. Reimbursable indications have expanded to include prophylactic treatment or primary prevention of various cardiovascular diseases (CVDs). Similarly, the use of pacemakers combined with an ICD (cardiac resynchronization therapy-CRT) for the treatment of various stages of heart failure has become a growing option. The Federal Motor Carrier Safety Administration (FMCSA) has commissioned this focused report to inform its position on the use of ICDs—in particular dual-functioning ICD-pacemaker devices—in interstate CMV drivers.

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- ▶ Full report will be available at the National Transportation Library
Web site: <http://ntl.bts.gov>

Current Cardiovascular Regulations

§391.41(b)(4) & (6)

A person is physically qualified to drive a commercial motor vehicle if that person:

(4) Has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive cardiac failure;

(6) Has no current clinical diagnosis of high blood pressure likely to interfere with his/her ability to operate a commercial motor vehicle safely;

Do not specifically address use of ICDs in regulations



Summary of FMCSA Guidance

Implantable Cardiac Defibrillators

Diagnosis	Physiology/Functional	Recommendations to Medical Examiners for Certification	Re-certification
Primary Prevention	Patient has high risk of death or sudden incapacitation	No	NA
Secondary Prevention	Patient demonstrated to have high risk of death or sudden incapacitation	No	NA



International Guidance

Country	Address use of ICD (Yes of No)	General Rule (Yes of No)	Conditional License Granted (Yes of No)
Australia (2003)	Yes	Yes	No
Canada (2006)	Yes	Yes	No*
New Zealand (2002)	Yes	Yes	No
United Kingdom (2008)	Yes	Yes**	No

*Conditional license issued for personal or general license

**Considers multiple reasons for implantation of ICD, including prophylactic or primary prevention, and secondary prevention. License permanently barred in all instances of ICD implant.



Pacemakers and ICDs

- ▶ Pacemakers traditionally used for arrhythmias resulting from sinus node dysfunction or atrial-ventricular (AV) block
 - Single-chamber, dual-chamber, and biventricular-pacemakers (CRTs)
- ▶ ICDs indicated for a prior cardiac arrest, ventricular tachycardia (VT), ventricular fibrillation (VF), ejection fractions of less than 30% to 40%
 - Single-chamber, dual-chamber, and biventricular-ICDs (CRT-Ds)



Cardiac Resynchronization Therapy without ICD (CRT)

Relatively new therapy:

- ▶ Indicated for patients with symptomatic heart failure
 - Moderate-to-severe CHF symptoms, despite lifestyle changes and medication
 - A weakened and enlarged heart muscle
 - A significant electrical delay in the lower pumping chambers (bundle branch block)
- ▶ Intended to reduce cardiac deterioration and/or lessen the progressive consequences of heart failure



Cardiac Resynchronization Therapy with ICD (CRT-D)

- ▶ **Combines CRT with an ICD** for patients with moderate to severe heart failure who also have indications for an ICD.
 - Indicated for patients with symptomatic heart failure and ventricular tachyarrhythmia who are at increased risk of sudden cardiac arrest



Primary Data Sources

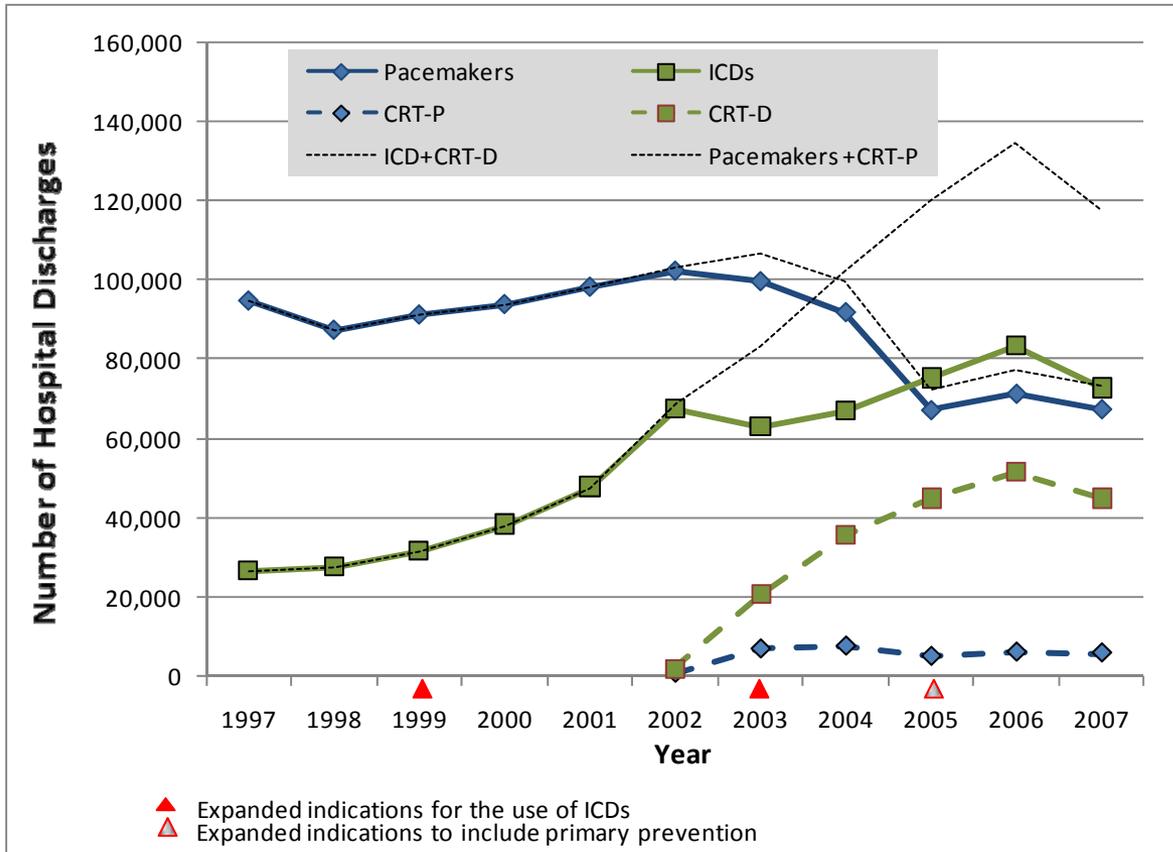
- ▶ Clinical trials of these devices
- ▶ Clinical practice guidelines (*ACC/AHA/HRS 2008*)
- ▶ FDA approved devices and indications
- ▶ Medicare coverage policies for use of devices



FDA Approved CRT-D Devices

Device Name, Company, and Date Approved
OVATIO CRT SYSTEM ELA MEDICAL, INC. May 15, 2008
TUPOS LV/ATX & KRONOS LV-T CRT-D & COROX OWT STERIOD PACING LEAD; BIOTRONIK, INC. Aug. 10, 2006
ST JUDE MEDICAL EPIC HF SYSTEM ST. JUDE MEDICAL, INC. June 30, 2004
INSYNC(TM) ICD MODEL 7272 MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT June 26, 2002
CONTAK CD/EASYTRAK LEAD SYSTEM GUIDANT CORP. May 02, 2002

Hospital Discharge Data



ICD and CRT-Ds more common than pacemakers and CRT-Ps

CRT-P not used as widely as CRT-D.



Current Standard of Care – CRT

- ▶ **Indicated for patients meeting the following criteria:**
 - Moderate to severe chronic heart failure (NYHA Functional Class III or IV);
 - Symptomatic despite stable, optimal heart failure drug therapy;
 - Left ventricular ejection fraction $\leq 35\%$; and
 - QRS duration $\geq 120\text{ms}$.



Current Standard of Care – CRT-D

Indicated for patients meeting the criteria for a CRT (previous slide), plus:

▶ ***Primary prevention SCA***

- Recurrent, poorly tolerated sustained ventricular tachycardia, *or*
- Prior myocardial infarction and a documented episode of non-sustained VT, with an inducible ventricular tachyarrhythmia, *or*
- Prior myocardial infarction and a LVEF $\leq 30\%$.

▶ ***Secondary prevention SCA***

- Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) caused by a ventricular tachyarrhythmia



Summary

- ▶ Individuals indicated for CRT, regardless of whether an ICD is included in the device (CRT-D) do not meet FMCSA's current guidance for qualifying CMV drivers

Thus, whether the ICD component is turned on or off, is irrelevant

- ▶ Furthermore, individuals who are indicated for a CRT-D device have additional CVD symptoms (e.g., VT) that are disqualifying by FMCSA's current guidance