### Important Cardiac Resynchronization Therapy Studies

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<th>STUDY</th>
<th>CO.</th>
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<th>PROJECTED PRODUCT IMPLICATIONS</th>
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</table>
| VENTAK CHF/CONTAK CD         | Guidant   | Completed 2001        | U.S.  | ▪ New York Heart Association (NYHA) class II-IV  
▪ QRS > 120 ms  
▪ LV ejection fraction (LVEF) < 35%  
▪ ICD indication  
▪ Normal sinus node function | 581      | Cardiac resynchronization therapy (CRT)  
▪ Composite index  
▪ EASYTRAK lead performance  
▪ Chronic left ventricular (LV) pacing threshold  
▪ Chronic biventricular (BiV) lead impedance and sensing  
▪ Safety | Efficacy  
▪ EASYTRAK lead placement success rate  
▪ Functional capacity  
▪ Quality of life (QOL)  
▪ Antitachycardia pacing (ATP) conversion efficacy  
▪ Safety of BiV pacing therapy | Indication  
CRT in ICD indicated + heart failure (HF)*  
Products  
CONTAK CD device  
EASYTRAK over-the-wire (OTW) lead |
| COMPANION                     | Guidant   | 2003                  | U.S.  | ▪ NYHA class III-IV  
▪ No indication for pacemaker or ICD  
▪ QRS > 120 ms  
▪ PR interval > 150 ms  
▪ EF < 35% | 2200     | Combined all-cause mortality and hospitalization | All-cause mortality  
▪ Cardiac morbidity  
▪ Chronic LV pacing threshold  
▪ Chronic BiV sensing and lead impedance  
▪ Safety of EASYTRAK lead  
▪ Sub-study: peak exercise performance | Indications  
CRT-only in HF** (CPx substudy)  
CRT-D in HF** (mortality and hospitalization)  
CRT in HF** (mortality and hospitalization) Products  
CONTAK TR device |
| MIRACLE                      | Medronic  | Completed 2000        | U.S.  | ▪ NYHA class III-IV  
▪ LVEDD > 60 mm  
▪ QRS > 130 ms  
▪ Stable 3 month regimen of beta-blocker and ACE inhibitor  
▪ EF < 35% | 300      | 6-minute walk distance  
▪ NYHA class  
▪ QOL  
▪ Device safety  
▪ Lead safety | Improvement in quality of life  
▪ Neurohormone levels  
▪ Echo indices  
▪ Peak VO2 | Indication  
CRT in HF*  
Product  
InSync device  
Attain LV (stylet driven) lead, Model 2187  
Attain CS (stylet driven) lead, Model 2188 |

* NYHA II-IV, interventricular conduction disorder (IVCD)  
** NYHA III-IV, IVCD

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<tr>
<td>MIRACLE ICD</td>
<td>Medtronic</td>
<td>2001</td>
<td>U.S. Canada</td>
<td>NYHA class II-IV</td>
<td>400</td>
<td>Safety and efficacy of CRT-D</td>
<td>Neurohormone levels</td>
<td>Indications CRT in ICD + HF*</td>
</tr>
<tr>
<td>Multi-center</td>
<td></td>
<td></td>
<td></td>
<td>LVEDD &gt; 55 mm</td>
<td></td>
<td>6-minute walk distance</td>
<td>Echo indices</td>
<td>Product InSync ICD device</td>
</tr>
<tr>
<td>InSync Randomized</td>
<td></td>
<td></td>
<td></td>
<td>QRS &gt; 130 ms</td>
<td></td>
<td>Device safety</td>
<td>Peak VO2</td>
<td></td>
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<tr>
<td>Clinical Evaluation - Implantable Cardioverter Defibrillator</td>
<td></td>
<td></td>
<td></td>
<td>EF &lt; 35%</td>
<td></td>
<td></td>
<td>Hospitalization</td>
<td></td>
</tr>
<tr>
<td>CHRONICLE</td>
<td>Medtronic</td>
<td>2001</td>
<td>U.S. Canada</td>
<td>Symptomatic HF</td>
<td>100</td>
<td>Safety and efficacy of the Chronicle device</td>
<td>Accuracy of pressure measurements</td>
<td>Indication IHM in HF**</td>
</tr>
<tr>
<td>(device name)</td>
<td></td>
<td></td>
<td>Europe</td>
<td></td>
<td></td>
<td></td>
<td>Therapeutic progress</td>
<td>Product Chronicle IHM device</td>
</tr>
<tr>
<td>Chronicle is an implantable hemodynamic monitor (IHM)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Healthcare utilization</td>
<td></td>
</tr>
<tr>
<td>The IHM does not provide pacing or ICD therapy. The IHM collects and transmits device data via telephone and Internet.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Exercise performance</td>
<td></td>
</tr>
<tr>
<td>InSync III</td>
<td>Medtronic</td>
<td>2002</td>
<td>U.S. Canada</td>
<td>NYHA class III-IV</td>
<td>NA</td>
<td>Safety and efficacy of the InSync III device and OTW lead performance</td>
<td>Healthcare utilization</td>
<td>Indication None - testing of features only</td>
</tr>
<tr>
<td>(device name)</td>
<td></td>
<td></td>
<td>Europe</td>
<td>LVEDD &gt; 60 mm</td>
<td></td>
<td></td>
<td>Exercise performance</td>
<td>Products InSync III device</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>QRS &gt; 150 ms</td>
<td></td>
<td></td>
<td>QOL</td>
<td>Attain OTW CS lead</td>
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<td></td>
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<td>Stable 3 month regimen of beta-blocker and ACE inhibitor</td>
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<td>NYHA class</td>
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| **SCD-HeFT***
Sudden Cardiac Death in Heart Failure Trial    | Medtronic        | 2003                 | World-wide | NYHA class II-III  
EF < 35%  
No record of VT/VF                                           | 2500    | Mortality                    | Morbidity  
QOL  
Medical cost                                      | *** This is not a CRT trial.  
Indication  
ICD in HF, NYHA II-III, EF< 35%  
Products  
All ICDs                                      |
| **MADIT II**
Multicenter Automatic Defibrillator Implantation Trial II | Guidant          | 2002                 | World-wide | ≥ 21 years of age  
MI ≥ 30 days prior to enrollment  
EF ≤ 30%                                           | 1200    | All-cause mortality        | QOL  
Cost-effectiveness  
Increased rate of ICD therapy delivery for EPS inducible vs. non-inducible at implant | *** This is not a CRT trial.  
Indication  
ICD in prior MI, EF ≥ 30%  
Product  
All ICDs, CRT-D                                   |
| **PATH-CHF II**
Pacing Therapies in Congestive Heart Failure II Study | Guidant          | Q4, 2001             | Europe | NYHA class ≥ II  
EF ≤ 30%  
Peak VO2 ≤ 18 ml/kg/min  
QRS ≥ 120 ms                                           | 100     | Improvement in functional capacity  
Peak VO2  
6-minute walk distance                                  | Improvement in quality of life  
Minnesota Living with Heart Failure Score  
NYHA class  
Hospitalization  
Improvement in prognostic and hemodynamic parameters | Indication  
Univentricular pacing in NYHA class ≥ II, EF ≤ 30%, Peak VO2 ≤ 18 ml/kg/min, QRS ≥ 120 ms  
Products  
CRT                                                      |
| **PACMAN**
Pacing for Cardiomyopathy, a EuropeAN Study      | Guidant          | Q3, 2002             | Europe | NYHA class III  
EF ≤ 35%  
QRS > 120 ms                                          | 328     | Improvement in functional capacity  
6-minute walk distance                                 | Improvement in quality of life  
Minnesota Living with Heart Failure Score  
NYHA class  
Hospitalization  
Incidence of ventricular arrhythmias                  | Indication  
CRT in NYHA class III, EF ≤ 35%, QRS > 120 ms  
Products  
CRT                                                      |