

AnalyST Accel™  
ICD with ST Monitoring

# CLINICAL COMPENDIUM

Publication and Abstract Summaries and Analyses

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## Continuous, High-Fidelity ST Segment Monitoring for Unprecedented Insight

The AnalyST Accel™ ICD from St. Jude Medical is the first ICD with a high-fidelity ST Monitoring diagnostic algorithm. This ST Monitoring diagnostic algorithm records important ST segment shifts and provides continuous and accurate information for unprecedented insight. An understanding of ST segment shifts can lead to more accurate correlation of specific clinical events including VT/VF episodes, enabling informed decision making. This new ST Monitoring diagnostic algorithm demonstrates the St. Jude Medical commitment to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient.

### *Disclaimer:*

Although the vast majority of research showing that intracardiac EGMs are more valuable compared to surface ECGs has centered around myocardial infarction (MI), it is important to ensure that the AnalyST Accel ICD is NOT positioned as an MI or ischaemia detector. Rather, the ST segment information provided by the AnalyST Accel ICD gives more control over clinical situations and better data for determining treatment options.



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## Burden of Disease: Medical and Economic Impact of Acute Coronary Syndromes

Turpie AGG. Am J Manag Care 2006; 12:S430-S434

### *Key Points:*

- Acute coronary syndromes (ACS) continue to be an enormous medical, social and economic burden despite advances in medical technology.
- Patients with ACS have a poor prognosis and tend to be at risk for further clinical events.
- Managing patients with ACS calls for an early invasive strategy.

### *Summary:*

Acute coronary syndromes (ACS) are ischaemic cardiovascular pathologies in which the blood flow (and thus oxygen) is restricted to a part of the body. ACS continues to be an enormous medical, social and economic burden at \$142,5 billion (U.S.) annually. ACS mainly consists of ST segment elevation myocardial infarction (STEMI), non-ST segment elevation myocardial infarction (NSTEMI) and unstable angina (UA).

Patients with ACS have a poor prognosis, and ACS, in the form of MI (STEMI and NSTEMI), are responsible for ~50% of all deaths related to cardiovascular disease. Further, one-third of STEMI patients (representing 30-45% of all ACS cases) die within 24 hours of onset of ischaemia. Additionally, 25% of men and 38% of women will die within one year of having an initial, recognised MI.

Patients with ACS have a high rate of recurrence post-treatment. Approximately 30% of discharged ACS patients require re-hospitalisation within the first six months. Additionally, 15% of UA/NSTEMI patients will experience re-infarction within 30 days. It is estimated that 30% of patients with UA will have an MI within three months. Finally, 18% of men and 35% of women experience a second MI within six years of having a recognised first attack.

The AnalyST Accel ICD provides a continuous high-fidelity ST Monitoring diagnostic to ensure ST segment shifts are captured.

## Real-Time Detection and Alerting for Acute ST-Segment Elevation Myocardial Ischemia Using an Implantable, High-Fidelity, Intracardiac Electrogram Monitoring System with Long-Range Telemetry in an Ambulatory Porcine Model

Fischell TA, Fishcell, DR, Fischell, RE, Virmani R, DeVries JJ, Krucoff MW. JACC 2006; 48:2306-2314.

### Key Points:

- The use of intracardiac electrograms for ST segment elevation detection could facilitate earlier and more reliable diagnosis of coronary occlusion, which can lead to acute myocardial infarction.

### Summary:

The authors investigated and confirmed the feasibility of early ischaemia detection using real-time, high-fidelity intracardiac electrograms to assist in the diagnosis of ST segment elevation myocardial infarction in eight copper-stented porcine subjects. The porcine coronary occlusion model closely mimicked the pathophysiology of coronary occlusion that precedes and leads to acute MI in patients with coronary artery disease. ST segment elevation events were well correlated to infarct age and location in the porcine subjects and were sufficient to trigger alerting thresholds from the left anterior descending (LAD), left circumflex (LCX) and right coronary (RCA) arteries. ST segment monitoring in the study was accomplished using a unipolar recording electrode from the RV apex (which is the same configuration as used in the AnalyST Accel™ ICD with ST Monitoring).

## Intrathoracic Far-Field Electrocardiogram Allows Continuous Monitoring of Ischemia after Total Coronary Occlusion

Asbach S, Weiss I, Wenzel B, Bode C, Zehender M. PACE 2006; 29:1334-1340.

### Key Points:

- Intrathoracic far-field electrocardiogram, or FF-ECG (also referred to as unipolar intracardiac electrocardiograms), provides earlier and more sensitive detection of ST segment changes from coronary artery occlusion, in addition to a larger maximum deviation from baseline, than surface ECG.

### Summary:

Reliable detection of ischaemia by ST segment analysis was possible in 38 out of 38 experiments involving seven porcine subjects. The subjects all received ICDs with

electrodes implanted in the right ventricle and superior vena cava. ST segment changes were measured using FF-ECG and surface ECG. FF-ECG showed larger deviations (1,21 mV) from the baseline than surface ECGs (0,23 mV,  $p < 0,01$ ) for all occlusion sites; developed earlier ( $p < 0,05$ ); and demonstrated a higher sensitivity (100% in the left anterior descending, 93% in the left circumflex, and 100% in the right coronary arteries) compared to surface ECG.

## Comparison of Electrocardiogram and Intrathoracic Electrogram Signals for Detection of Ischemic ST Segment Changes During Normal Sinus and Ventricular Paced Rhythms

Theres H, Stadler RW, Stylos L, Glos M, -Ing D, Leuthold T, Baumann G, Nelson S, Krucoff MW. J Cardiovasc Electrophysiol 2002; 13:990-995.

### Key Points:

- Ischaemic ST segment changes were significantly larger with EGM than with surface ECG during normal sinus and ventricular paced rhythms, apparently due to the larger amplitude of EGM signals.

### Summary:

Inconvenient and prone to false positives, surface ECGs have demonstrated limitations in the monitoring of ST segment deviations. Authors investigated the technical advantages of permanently implanted devices for long-term monitoring of ST segment shifts. ST deviations during normal sinus and ventricular pacing were significantly larger when detected by EGM vs. ECG. When normalised, however, the ST segment changes were comparable for normal sinus.

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## Real-Time Assessment of Acute Myocardial Ischaemia by an Intra-Thoracic 6-Lead ECG: Evaluation of a New Diagnostic Option in the Implantable Defibrillator

Baron TW, Faber TS, Grom A, Schwab T, Brunner M, Geibel A, Just H, Bode C, Zehender M. *Europace* 2006; 8:994-1001.

### Key Points:

- Intrathoracic ECG (IT-ECG) provides better diagnostic efficacy than surface ECG for ischaemia detection.
- Myocardial ischaemia monitoring would greatly increase the diagnostic impact of ICDs.

### Summary:

The feasibility and diagnostic accuracy of six IT-ECG leads to assess transient myocardial ischaemia—resulting from acute coronary artery occlusion—were evaluated in a prospective study of 22 patients. All patients had high-grade coronary artery stenosis and were indicated for PTCA (percutaneous transluminal coronary angioplasty). When compared to surface ECG, IT-ECG (derived from presently available ICD electrodes) proved more sensitive in detection of early and overall ischaemia. ST segment alterations were present 2,3 times more often at 30 seconds of coronary artery occlusion over surface ECG, and 1,4 times more often at 90 seconds. The authors conclude: “This study provides strong evidence that the ICD-based IT 6-lead ECG would provide a new and efficient means of assessing a patient’s daily ischaemic burden.”

## Potential of an Intracardiac Electrogram for the Rapid Detection of Coronary Artery Occlusion

Fischell TA, Fischell DR, Fischell RE, Baskerville S, Hendrick S, Moshier C, Harwood JP, Krucoff MW. *Cardiovascular Revascularization Medicine* 2005; 6:14-20.

### Key Points:

- A programmable, implantable device could provide assistance in the early detection and diagnosis of acute myocardial infarction.

### Summary:

To determine the feasibility of identifying early onset myocardial ischaemia or injury, 14 patients (17 lesions) were evaluated via intracardiac electrogram (RV to left upper chest) and ECG (V6 surface lead) while undergoing balloon occlusion during PTCA (percutaneous transluminal coronary angioplasty). The intracardiac electrogram detected a > 10% shift in ST segment in all

17 patients vs. 8 out of 17 for the surface ECG. Authors conclude: “The results of this study suggest that a simple implantable system resembling a ventricular pacemaker could be programmed to assist in the very early diagnosis of acute myocardial infarction.”

## Clinical Performance of the ST Monitoring Algorithm

TUV Submission.

### Summary:

Results from a clinical study conducted at the Dante Pazzanese Institute of Cardiology in Sao Paulo, Brazil, demonstrated the potential clinical benefit of early detection of rapidly progressive ST segment shifts using an investigational monitoring device. This investigational device and the St. Jude Medical™ AnalyST Accel™ ICD use the same algorithm for intracardiac electrogram-based ST segment monitoring.

One primary endpoint of this study was to show the ability of the implanted system to accurately record ST segment shifts that occur without an associated heart rate elevation, from acute occlusion of a coronary artery during PCI (percutaneous coronary intervention). This is predictive of what the device would record from the acute closure of a coronary artery preceding a heart attack. Subjects enrolled in the study were implanted with an investigational device prior to undergoing a coronary artery stent implantation. Electrogram data were collected via the implanted system during balloon inflation either during stent delivery or pre-dilatation. Results from the study indicate that the implanted system was able to detect ST segment changes across multiple types of lesions within the three major epicardial arteries during PCI. These intracardiac ST changes were consistent with the ST segment changes typically seen on surface leads. A total of 20 subjects were enrolled and followed at one, three, and every six months post-implantation. Over 22 patient years of implantation data are available, with the average follow-up time of 12 months (range 3 to 18 months).

During the follow-up period, two subjects experienced ST shift events on their intracardiac electrograms. These were detected by the device and confirmed via angiography to be related to coronary occlusions requiring revascularisation.

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## Clinical Performance of the ST Monitoring Algorithm

TUV Submission.

### Summary:

With more than 100,000 electrogram segments monitored, the study also demonstrated that patients at high risk for AMI will have relatively stable ST shift levels over time. An algorithm update implemented after the fifth patient was enrolled in the study, resulted in observation of no false positive ST shift detections.

The study concluded that the implanted system can detect progressive ST shifts on the intracardiac electrogram due to coronary occlusions including early detection of those resulting from ruptured plaque events. There were no clinically significant device-related adverse events in the study.

## Association of Myocardial Ischemia with Mortality and Implantable Cardioverter-Defibrillator Therapy in Patients with Coronary Artery Disease at Risk of Arrhythmic Death

Ehrendy A. Journal of the American College of Cardiology 2005; 46:1721–6.

### Key Points:

- Detection and appropriate treatment of myocardial ischaemia might reduce the incidence or frequency of ICD therapy.

### Summary:

To shed light on the relationship between myocardial ischaemia, resulting therapy and mortality, 90 patients were studied. All had a history of coronary heart disease. Fifty-three patients received ICDs for primary prevention of sudden cardiac death (SCD); 37 patients received ICDs for secondary prevention of SCD. The patients were evaluated during stress echocardiography via exercise treadmill or dobutamine, with ischaemia being defined as “new or worsening wall motion abnormalities.” Twenty of 24 patients with subsequent events exhibited ischaemia, compared to 24 of 66 patients without subsequent events. Fifty-three percent of patients with inducible ventricular tachycardia and ischaemia experienced events on EP studies. The authors conclude: “Ischemia during stress echocardiography is an independent predictor of death and ICD therapy in patients with coronary heart disease at high risk of arrhythmic death. Patients without inducible ischemia

or VT on a previous EP study have a very low risk of events. A combination of ischemia and a positive EP study is associated with a very high risk of events.”

## Prognostic Importance of Defibrillator Shocks in Patients with Heart Failure

Poole JE et al. New England Journal of Medicine 2008; 359:1009-17.

### Key Points:

- Heart failure patients, meeting the SCD-HeFT criteria, who received a single-chamber ICD for primary prevention and receive shocks for arrhythmias (appropriate and inappropriate), are at higher risk of death than those who do not receive shocks.

### Summary:

Noting the limited information regarding long-term prognosis of heart failure patients who receive ICDs for primary prevention, the authors studied 829 heart failure patients who received ICDs for primary prevention over 45.5 months (median). Thirty-three percent (269 patients) received at least one ICD shock, (28 patients received appropriate shocks only, 87 received inappropriate shocks only, and 54 received both appropriate and inappropriate shocks). The authors relied on electrocardiograms recorded before arrhythmia detection and after administration of the shock. In addition, R-R intervals were plotted. Shocks triggered due to ventricular fibrillation (VF) or ventricular tachycardia (VT) were deemed appropriate, while inappropriate shocks were those triggered by supraventricular tachycardias (SVTs), oversensing, double counting lead fracture artifacts or electromagnetic interference (EMI). The authors found a marked increase in death in patients who received appropriate shocks, as well as an increase in death among patients who experienced inappropriate shocks. The most common cause of death was progressive heart failure, which other published literature suggests is typically caused by ischaemia.

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St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.

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