Current Accel™ ICDs and AnalyST Accel™ ICDs

Sales Reference Guide

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

How to Sell:
Current Accel™ ICDs and AnalyST Accel™ ICDs

Current Accel™ ICDs and AnalyST Accel™ ICDs are designed to minimise risk and provide clinicians with the control they require. Each device includes advancements to facilitate delivery of highly tailored patient therapies and to simplify patient management—all in the interest of patient safety and improved outcomes.

AnalyST Accel ICDs include all the features in the Current Accel devices, plus the ST Monitoring diagnostic algorithm. For more information on the ST Monitoring algorithm, please see the AnalyST Accel ICD marketing materials.

Current Accel™ and AnalyST Accel™ ICDs are all built upon the safety, control and convenience of the Current™ RF ICD. The following is a brief review of the previous features, as well as an overview of the new features.

Safety

Nothing is more important than patient safety. That's why, from design and engineering to manufacturing and clinical testing, Current Accel™ ICDs and AnalyST Accel™ ICDs feature exclusive advancements designed to reduce life-threatening risks. Capture Confirmation in both chambers, continuous ST segment monitoring, device self-integrity checks, multiple system safeguards, and daily lead tests help provide unparalleled therapy to patients—always with a critical focus on safety.

- Capture Confirmation in BOTH chambers **NEW**
- Continuous, high-fidelity ST segment monitoring **NEW** (AnalyST Accel ICDs only)
- Multiple hardware and software system safeguards
- VIP™ (Ventricular Intrinsic Preference) pacing extended to 450 ms **NEW**
- Automatic daily high-voltage lead integrity (HVLI) test
- Vibratory patient notifier

Control

If all patients were alike, pacemakers and ICDs would not have to be programmable. However, every patient presents unique treatment requirements and challenges. Current Accel and AnalyST Accel ICDs help clinicians detect, diagnose, and respond to individual patient needs using technologies that allow tailored patient therapy. Alerting patients/physicians on the AT/AF status, non-invasive DFT management, preferential EGM within storage capability, and access to trending diagnostics help clinicians manage variations within every patient with greater efficiency and accuracy than ever before.

- AF/AF Alerts **NEW**
- DeFT Response™ technology
- Sense*Ability*™ technology with Decay Delay and Threshold Start
- Multiple ATP schemes programming capability
- Morphology Discrimination plus AV Rate Branch
- Heart In Focus™ report with Exercise Trend Diagnostic
- Preferential EGM Storage
- AF Suppression™ algorithm

Convenience

Patient management is on the mind of every overworked physician and his or her staff. Current Accel and AnalyST Accel ICDs feature seamless remote monitoring and follow-up, wireless telemetry, leadless ECGs, and simplified timing cycle optimisation, helping to reduce implant time and streamline follow-up.

- Wireless Connectivity
  - Merlin.net™ Patient Care Network (PCN) **NEW**
  - Merlin@home™ wireless transmitter **NEW**
  - InvisiLink™ wireless telemetry and leadless ECGs
- QuickOpt™ timing cycle optimisation
- DC Fibber™ induction

Need | Problem | Solution

The best method of handling objections is to prevent them. By creating a belief in your customer's mind, then identifying the problem he or she has or may face, you set up your solution to be positively received. Conversely, when need is not established, objections to the offered solution are more likely to be raised.

The Need | Problem | Solution chart below provides an outline for promoting our features to your customers.

Create Belief | Develop Need	Identify Problem	Offer Solution
CAPTURE CONFIRMATION: AUTOCAPTURE™ PACING SYSTEM / ACAP™ CONFIRM		
Belief | Need: Patients' pacing thresholds can increase over time or due to medications. Discovery Question: Do you notice patients' pacing thresholds increase over time or with altered medications?	Problem: Loss of capture can lead to dropped beats, syncope and even asystole. Discovery Question: Do you want to risk loss of capture due to a patient's increased threshold?	Solution: Beat-by-Beat AutoCapture™ Pacing System and ACap™ Confirm technology ensure capture and conserve battery longevity in the Current Accel™ ICDs and the AnalyST Accel™ ICDs.
ST SEGMENT MONITORING		
Belief | Need: The majority of ICD patients are ischaemic and a large % of ischaemic attacks are silent. Additionally, the literature suggests that ischaemia who is related to VT/VF episodes and patients who receive a shock have a poor short-term prognosis, potentially requiring some form of medical intervention. Discovery Question: What information is helpful when your patient receives a shock? The AnalyST Accel ICD can provide information about ST segment changes associated with VT/VF events for improved insight and decision making. This is in addition to the functionality already provided by the Current™ RF device and with insignificant impact on battery longevity (i.e. 1% or ~3 weeks).	Problem: The majority of ICD patients are ischaemic and a large % of ischaemic attacks are silent. Additionally, receiving a shock may be a sign that the patient has a condition, potentially requiring further medical attention (such as an underlying ischaemic substrate). Discovery Question: How does the quality of surface ECGs compare to intracardiac EGM in your opinion? Would it be beneficial if you had the equivalent of a continuous patient stress test from an EGM? Discovery Question: Do you see advantages with being able to continuously monitor ST changes in ischaemic patients using highly sensitive unipolar intracardiac EGM?	Solution: Ischaemic ST segment changes on EGMs are proven to be significantly more sensitive than ECGs during normal sinus. Studies prove that intracardiac EGMs allow reliable and reproducible capture of induced ischaemia originating from all major coronary arteries. In fact, detection of ischaemia by ST segment analysis was possible in 100% of the experiments.[1] The information available from the AnalyST Accel device provides relevant ST segment information you can use to better treat your patients. AnalyST Accel ICDs should be especially considered as replacement devices in patients who are ischaemic or who have received multiple unexplained shocks in the past.
VIP™ (VENTRICULAR INTRINSIC PREFERENCE)		
Belief | Need: Unnecessary right-ventricular (RV) pacing can exacerbate heart failure and should be avoided. Discovery Question: Are you familiar with the results of the DAVID trial and the finding that unnecessary RV pacing can be harmful to patients?	Problem: Static programmed AV delays cannot adapt to changes in conduction patterns. Dropped beats may result in adverse patient events. Discovery Question: Are you aware that the Medtronic MVP™ algorithm allows dropped beats and can initiate VF in patients?	Solution: The VIP™ feature is designed to significantly reduce unnecessary RV pacing in select patients; this can minimise heart failure exacerbation (DAVID trial). The VIP window in the Current Accel and AnalyST Accel devices has now been extended to 450 ms to further reduce unnecessary RV pacing. VIP technology supports the ventricle for every non-conducted event.
AT/AF ALERTS		
Belief | Need: AT impacts many patients who receive an ICD. Additionally, AF is the most common cardiac arrhythmia encountered in clinical practice with a global prevalence of 7,34 million in 2007. AF causes up to a 30% reduction in cardiac output, leading to shortness of breath and fatigue. AF is also a major risk factor for stroke because blood pools form in the atria as a result of inefficient pumping, which then increases the likelihood of clot formation. Discovery Question: What percentage of your device patients have AT/AF episodes?	Problem: AT/AF can be asymptomatic, and patients may live for years without knowing that they suffer from the condition. Discovery Question: Would you provide different treatment for your patients if you knew they had sustained AT/AF episodes?	Solution: Both the Current Accel and AnalyST Accel devices allow the physician to program AT/AF thresholds and provide both vibratory patient alerts and/or messages through Merlin.net™ PCN to facilitate proper treatment and potentially avoid clinical complications associated with these disease states. The St. Jude Medical™ Accel family of ICDs allows improved medical decision making, especially when combined with the improved atrial measurements of the OptiSense™ Optim™ lead.

MVP is a trademark of Medtronic Inc.

Need | Problem | Solution

Create Belief I Develop Need	Identify Problem	Offer Solution
NEW PLATFORM		
Belief I Need: Minimising risk is important. Discovery Question: Do you know that the newest St. Jude Medical™ family of devices was designed with multiple system safeguards?	Problem: Previous device hardware and software lacked advanced system safeguards. Discovery Question: Do you know that the Boston Scientific Cognis™ and Teligen™ devices depend on new safety hardware?	Solution: The new St. Jude Medical device platform is designed to minimise risk through multiple hardware and software redundancies. These devices were built to be robust and should allay some clinical anxiety in the wake of the recent spate of device recalls.
DAILY MULTI-VECTOR HVLI CHECK AND TREND		
Belief I Need: I need the reassurance that my high-voltage lead system is functioning properly and is capable of delivering therapy. I need to be able to tune the defibrillation waveform BEFORE inducing fibrillation. Discovery Question: Doesn't it make sense to try to obtain the lowest possible DFT before inducing the patient?	Problem: Previous device hardware and software lacked advanced system safeguards. Not knowing the system impedance before shock prevents tuning the waveform. Discovery Question: Wouldn't you like more data to aid in diagnosing and addressing potential lead issues?	Solution: The daily test confirms that the high-voltage system is functioning properly and, in the event of an issue, can provide data to analyse and address it. By offering a sub-threshold HVLI test, we can determine impedance and tune the waveform before inducing the patient. A vibratory patient alert is also included to proactively alert patients to potential issues.
SENSE*ABILITY*™ AUTO SENSITIVITY CONTROL		
Belief I Need: Inappropriate shocks can be avoided. Discovery Question: Given that more patients are receiving devices prophylactically, wouldn't you like to help ensure that they don't receive inappropriate shocks?	Problem: T-wave oversensing can cause inappropriate therapy. Discovery Question: Are you aware that patients with Brugada syndrome or Long QT syndrome are more susceptible to T-wave oversensing?	Solution: Sense*Ability*™ sensitivity control offers the most programmable sensing options to program around T waves and avoid inappropriate therapy.
DEFT RESPONSE™ TECHNOLOGY		
Belief I Need: I need an adequate safety margin. High DFTs are a problem. Discovery Question: Did you know that some medications can increase DFTs? Did you know that disease state progression can result in higher DFTs post-implant?	Problem: Invasive methods for lowering DFTs add risk and time to procedures. Discovery Question: Wouldn't you rather avoid implanting an array?	Solution: DeFT Response™ technology offers the most non-invasive options for managing high DFTs. Programmable pulse widths allow the user to tailor the shock to the individual patient, making shocks more efficacious.

Create Belief I Develop Need	Identify Problem	Offer Solution
MERLIN.NET™ PATIENT CARE NETWORK (PCN) AND MERLIN@HOME™ REMOTE MONITORING		
Belief I Need: Integration of device data with the patient's medical record allows for improved clinical decision making. Discovery Question: Don't you want the ability to integrate data interrogated from remote sessions, in-clinic sessions, as well a data captured from implant integrated into the patient's electronic medical record? Belief I Need: Interrogated device data is less meaningful without the patient's previous medical information. Discovery Question: Have you had to review device information on one system and a patient's other clinical information (i.e., meds, lab results) on another system, all to make a diagnosis?	Problem: Maintaining multiple management systems for devices and your practise's electronic health records (EHRs) is very costly.	Solution: View data from remote transmissions, implant procedures and in-clinic follow-ups in one central location. Seamlessly export data to most EHRs. Seamlessly export data to Paceart™, Cardiostation™, and other patient management systems.
INVISILINK™ WIRELESS TELEMETRY (RF)		
Belief I Need: Standard telemetry wands slow implant and follow-up. Discovery Question: Don't you want the convenience of wireless telemetry for all device configurations, including DR and VR?	Problem: Introducing the wand into the sterile field increases the risk of infection and prevents parallel programming. RF telemetry can have dead spots with poor signal. Discovery Question: Have you experienced telemetry issues on competitive wireless systems due to positioning of the programmer?	Solution: InvisiLink™ wireless telemetry provides convenience at implant and follow-up. The InvisiLink antenna can be repositioned without moving the programmer.
QUICKOPT™ TIMING CYCLE OPTIMISATION		
Belief I Need: Timing cycle optimisation can improve response to therapy. Discovery Question: Do you optimise your patients' AV delays?	Problem: Echocardiography echo is the standard method for optimisation. Echo is time-consuming and dependent on a technician for consistency. Discovery Question: Do you want to spend an hour in the echo lab? Did you know that QuickOpt™ optimisation correlates to echo?[2]	Solution: QuickOpt timing cycle optimisation allows optimisation for more patients, more often. QuickOpt optimisation showed a >96% correlation to echo.[3]

Key Features | Competitive Comparison

St. Jude Medical	Medtronic	Boston Scientific
CAPTURE CONFIRMATION		
SJM: AutoCapture™ Pacing System provides Beat-by-Beat™ RV capture verification. Enhanced ACap™ Confirm algorithm uses evoked response to determine capture and does not require a separate set-up test.	MDT: Checks thresholds only once daily. Capture confirmation not beat by beat. Atrial capture confirmation remains in high-output mode whether needed or not until reprogramming at next follow-up.	BSX: Has no capture management features in any of its ICDs.
ST SEGMENT MONITORING (ANALYST ACCEL™ ICDS ONLY)		
SJM: High-fidelity ST segment information to link VT/VF episodes with potential ischaemia. ST elevations and depressions are identified using a ventricular wide-band intracardiac EGM to detect acute voltage shifts in the ST segment relative to the isoelectric line (AnalyST Accel™ ICDs). Relevant ST-shift events are automatically recorded based on parameters selected by the physician (default and programmable setting available). – Correlating stored electrograms are available to view in the Episode Log during the device interrogation. – Trending and Histogram Diagnostics are also available to evaluate the ST information in the episode logs. Available in single- and dual-chamber ICDs.	MDT: No ST segment monitor available.	BSX: No ST segment monitor available.
INTRINSIC CONDUCTION		
SJM: VIP™ algorithm Up to 450 ms No dropped beats SJM supported DAVID trial Ventricular Intrinsic Preference (VIP) technology helps reduce unnecessary RV pacing in Current Accel and AnalyST Accel devices by automatically extending the AV delay.	MDT: MVP™ algorithm Allows intrinsic conduction longer than 450 ms Allows dropped beats Can be proarrhythmic	BSX: AV Hysteresis Up to 400 ms No dropped beats BSX supported Intrinsic RV trial
AT/AF ALERTS		
SJM: Programmable in vibratory patient notifier and transmitted through the Merlin.net™ Patient Care Network (PCN).	MDT: CareAlert capability transmitted through Medtronic CareLink network.	BSX: Yellow alert transmitted through Latitude™ programmer.
DEVICE PLATFORM		
SJM: Current Accel™ and AnalyST Accel ICDs are built on new, state-of-the-art, unified platform. Three operation levels for redundancy.	MDT: Consulta™ and Secura™ devices are built on the company's old platform.	BSX: Cognis™ and Teligen™ devices are built on a new platform with the the BSX Safety Core™ feature. Renewal™ and Vitality™ devices are built on old platforms.
HIGH-VOLTAGE LEAD INTEGRITY (HVLI) CHECKS		
SJM: Daily Automatic Multivector Trend data Sub-pacing threshold Correlates to shock impedance	MDT: Daily Automatic Trend data Sub-pacing threshold	BSX: Daily Automatic Trend data Sub-pacing threshold

Consulta, Secura, MVP, Conexus, Medtronic CareLink, and CareAlerts are trademarks of Medtronic Inc.
Latitude, Cognis, Teligen, Safety Core Renewal, Vitality, and Zip are trademarks of Boston Scientific Corporation.

St. Jude Medical	Medtronic	Boston Scientific
VT/VF THERAPY		
SJM: DeFT Response™ technology Offers programmable pulse width, programmable shocking vectors, and programmable tilt options plus the highest levels of delivered energy. Programmable pulse width is clinically proven to reduce DFTs. SVC ON/OFF 36 J delivered energy RV Anode Nominally (shown to be optimal polarity) Some customers see DeFT Response feature as difficult to program. Using the Daily HVLI impedance simplifies programming of the optimal pulse widths.	MDT: ATP during charging Auto reverse polarity for last shock Fixed tilt (not programmable) SVC NOT programmable 35 J delivered energy	BSX: Fixed tilt (not programmable) Reversed polarity SVC NOT programmable 35 J delivered energy
SENSING		
SJM: Sense*Ability*™ technology Threshold Start Decay Delay Allows programming around T-wave oversensing without decreasing sensitivity. For challenging cases, Sense*Ability* technology gives the clinician a lot of programming flexibility without sacrificing safety.	MDT: Must decrease sensitivity to avoid T-wave oversensing.	BSX: Must decrease sensitivity to avoid T-wave oversensing.
WIRELESS TELEMETRY		
SJM: InvisiLink™ wireless telemetry MICS (402-405 MHz) bandwidth Leadless ECG; no wand in the sterile field Faster telemetry speed Remote monitoring External antenna allows flexible configuration	MDT: Conexus™ telemetry MICS (402-405 MHz) bandwidth Remote monitoring	BSX: Zip™ telemetry 900 MHz common bandwidth Remote monitoring (blood pressure cuff and weight scale)
REMOTE MONITORING		
SJM: Merlin.net™ Patient Care Network (PCN) is the only such system that lets clinicians merge in-clinic and remote data for "the total picture," and the only one that allows data to be sent directly to the clinic's electronic health records system. Transmitter not tied to any one patient or clinic. Merlin@home™ monitor allows for seamless remote monitoring. Automatically transmits follow-up data wirelessly.	MDT: Medtronic CareLink™ network, etc. First Internet-based system Over 150,000 patients enrolled in the US. Brady support Must go through Paceart™ system to transfer data to electronic health records system. Transmitter tied to both patient and clinic.	BSX: Latitude™ programmer Approximately 50,000 patients in the US. Offers the option of adding a blood pressure cuff and weight scale (at additional cost). All communicators tied to device. Uses 914 MHz bandwidth for RF (off-the-shelf bandwidth used for common household appliances).
TIMING CYCLE OPTIMISATION		
SJM: QuickOpt™ timing cycle optimisation 96% correlation to echo Measures intrinsic and paced conduction Optimise AV timing in a simple programming step that takes about a minute Multiple published manuscripts support the QuickOpt timing cycle optimisation method. Some customers use QuickOpt optimisation regularly to optimise patients. Some customers still don't trust electrical measurement for estimating mechanical function.	MDT: Medtronic has been promoting M-mode for optimisation.	BSX: Some customers adopted COMPANION formula 70% of X if QRS > 150 ms. BSX has "Easy as 1-2-3" card based only on intrinsic measurement. Paced conduction is more important.
SAFETY FEATURES		
SJM: Painless multiple hardware and software system safeguards. Vibratory patient notifier Multivector subthreshold HVLI	MDT: Painless HVLI Audible patient alerts (CareAlert™) signals	BSX: Painless HVLI Audible patient alert (limited programming options)

Competing with Medtronic

No Medtronic device offers all of the benefits of Current Accel™ and AnalyST Accel™ devices.

Medtronic Customer Profile

Medtronic customers are often very responsive to advertising and promotional efforts, which explains why many of them will be quick to tout certain product features that they learned from their Medtronic representatives and their literature. Medtronic buyers appreciate good service, and they probably view the Medtronic brand as strong and the company's marketing materials as credible.

How to Approach a Die-Hard Medtronic Account

Make sure they have literature, e.g. manuals, sell sheets, proof sources, and anything else that you think might help them understand our products. Don't assume they know our product features. Many loyal Medtronic users do not know what St. Jude Medical has to offer. Or they might be comparing the latest and greatest product from Medtronic to a product St. Jude Medical introduced five years ago, simply because it's the last St. Jude Medical™ product they used.

Direct Competition | Medtronic

Device	Medtronic	St. Jude Medical
Single-chamber ICD	Secura™ VR ICD	Current Accel™ VR ICD
ST Monitoring device	None	AnalyST Accel™ VR ICD
Dual-chamber ICD	Secura™ DR ICD	Current Accel™ DR ICD
ST Monitoring device	None	AnalyST Accel™ DR ICD

First introduced in June 2008, these devices are probably best known by customers for patient management features including the OptiVol™ volume status monitor, exercise trend, and heart rate variability diagnostic data. They also feature the MVP™ algorithm (to limit unnecessary RV pacing), wireless connectivity, remote patient monitoring through the well-known Medtronic CareLink™ system, and 35 J delivered energy with good longevity. They also offer ATP during charging and patient notification (which has been around in other Medtronic systems). The dual-chamber system shows AF trends and will cardiovert atrial tachyarrhythmias either automatically or by patient activation.

OVERCOMING MEDTRONIC STRENGTHS

- The Medtronic CareLink patient monitoring system has strong name recognition and the virtue of being familiar to many clinicians; some will prefer to stick with the system just because it's familiar.
- Medtronic CareLink monitoring is older technology; some customers may prefer the newer face of Merlin.net™ PCN.
- ATP during Charging and AF Cardioversion may be important features to some physicians and no other devices on the market offer them. But neither ATP nor atrial cardioversion are new features. Earlier attempts at atrial defibrillators, such as the Boston Scientific Vitality™ AVT device, failed to gain patient acceptance.
- If ATP during Charging is important, this could be easily set up in St. Jude Medical devices by programming ATP therapy first with a rapid timeout limit. In other words, the very same effect can be achieved with a St. Jude Medical device with the advantage that it is under clinician control rather than device control.
- The St. Jude Medical™ AF Suppression™ algorithm was designed to suppress AF before it can start; the Medtronic AF cardioversion is a rescue option that patients may find distressing, even painful. What's better, to suppress high atrial rates or to shock them after they've occurred?

Secura and OptiVol are trademarks of Medtronic Inc.

MEDTRONIC PARITY WITH ST. JUDE MEDICAL

- In terms of footprint, size, and longevity, the devices are roughly equivalent. St. Jude Medical delivers 36 J of energy compared to 35 J the Secura™ device. The Secura device is slightly lighter but has slightly more volume, and longevity is slightly less or slightly more than St. Jude Medical depending on settings and models. (The VR models give Medtronic a bit more longevity than St. Jude Medical, but in DR models, St. Jude Medical has the edge.)
- Medtronic lost the 'wireless advantage' when St. Jude Medical launched both Current™ RF and Promote™ RF devices. This continues with the launch of Current Accel™ and AnalyST Accel™ ICDs.
- Both companies offer devices with
  - Capture confirmation in atrium and ventricle
  - AT/AF alerts and trends
  - Patient notification

MEDTRONIC VS. ST. JUDE MEDICAL ADVANTAGES

- Complete Capture Management:
  - There is no beat-by-beat capture verification in Medtronic devices.
  - The Medtronic atrial capture algorithm goes to high output in the case of a failed threshold test and stays there until the device can be reprogrammed, whether necessary or not.
- ST Monitoring:
  - Medtronic has no ST Monitoring capability in any of its devices.
- Managed Ventricular Pacing (MVP™) algorithm:
  - There have been reports in the literature of patients developing a pause-dependent ventricular tachyarrhythmia[4] or other symptomatic arrhythmia.[5]
  - The MVP algorithm works by skipping a beat (and essentially mode-switching to AAIR).
  - Since RV pacing is a hot-button issue right now, this may be a very important point to some physicians. But RV pacing is not bad per se; the evidence states only that unnecessary RV pacing can exacerbate systolic dysfunction. Optimal AV timing for improved hemodynamics may be crucial to the whole "RV debate" (that is, necessary and proper RV pacing is better than unnecessary and poorly timed RV pacing). For that, only St. Jude Medical offers the QuickOpt™ timing cycle optimisation.
- Stored EGM capacity is smaller:
  - There is no Preferred EGM algorithm to prioritise how memory is utilised.
  - EGMs cannot be "stitched" together for easier analysis.
  - Since stored EGMs are just about the single most important diagnostic in the arsenal, this is an important advantage for St. Jude Medical™ products and one that doctors might never ask about.
- Very little flexibility for managing high or rising DFTs:
  - No programmable pulse widths
  - No programmable tilt
  - No programmable shocking vectors
  - St. Jude Medical has leadership in this area, but needs to keep telling the story. Many clinicians do not appreciate the problem that DFTs represent, or they feel that all devices manage high DFTs the same way.
- Atrial tachyarrhythmia management:
  - No rate-responsive AMS mode options and no programmable AMS base rate.
  - Patient-activated AF cardioversion seems like a feature that most patients will not want.
  - St. Jude Medical offers a clinically proven algorithm designed to reduce AF burden[6] and improve quality of life.[7]
  - PR Logic and Wavelet Discrimination are features that have found some criticism among customers; this is anecdotal.
- Very little flexibility for troubleshooting sensitivity:
  - No programmable Threshold Start
  - No programmable Decay Delay
  - No separately programmable ventricular paced versus sensed refractory periods.
- No way to show both remote and in-clinic data on remote monitoring systems.
- No device-based timing algorithm comparable to our QuickOpt timing cycle optimisation algorithm.
- The Medtronic CareLink™ system cannot show remote information plus in-clinic data together.

Competing with Boston Scientific

No Boston Scientific devices offer all of the benefits of Current Accel™ and AnalyST Accel™ devices.

Boston Scientific Customer Profile

The Boston Scientific/Guidant organisation has definitely had a tumultuous time the past few years with an acquisition, re-branding efforts, and a series of product advisories. Who are the loyal Boston Scientific customers? They are clinicians who have had exemplary customer support from their sales reps and field teams and/or clinicians who have not had an unduly difficult time with the recent run of recalls.

Many former Guidant customers are changing loyalties in the wake of the company's recent troubles, and some fair-weather customers defected long ago. We strongly urge our field force in competitive selling situations not to make the product advisories an issue. Firstly, many customers feel that advisories can happen to any company. Secondly, your customers have already made up their minds about what they think of the recalls. Answer questions or listen to what they have to say, but keep steering the discussion back to our great products and features.

How to Approach a Die-Hard Boston Scientific Account

Most customers who started using and liking Boston Scientific products did so because of the technology. Not so long ago, the Boston Scientific franchise had innovative, first-to-market technology. The company has lost that focus recently, but that doesn't mean its customers are not still impressed by technology. This group needs to know about "only from St. Jude Medical" innovations (e.g., ST Monitoring, DeFT Response™ technology, Sense*Ability*™ technology, QuickOpt™ timing cycle optimisation, AF Suppression™ algorithm, etc.). The classic Boston Scientific customer also appreciates innovation, and could be considered an "early adopter" of new features. Many Boston Scientific loyalists are avid Latitude™ system users—wireless connectivity and remote patient monitoring pioneers. Make sure they know that St. Jude Medical has come to the party!

Direct Competition | Boston Scientific

Device	Boston Scientific	St. Jude Medical
Single-chamber ICD	Teligen™ VR ICD	Current Accel™ VR ICD
ST Monitoring device	None	AnalyST Accel™ VR ICD
Dual-chamber ICD	Teligen™ DR ICD	Current Accel™ DR ICD
ST Monitoring device	None	AnalyST Accel™ DR ICD

Teligen Devices

When the Teligen devices hit the market in February 2008, the biggest drawing card they had was size, new battery technology and safety architecture. These device families offer several models and are all high-energy devices, delivering 35 J of energy. Disease state management features (AT/AF trends, and weight and blood pressure management) are still strong, but other device features are the basics (SVT discrimination algorithms, mode switching, stored EGMs).

OVERCOMING BOSTON SCIENTIFIC STRENGTHS

- The Latitude™ system has loyalists and the company and its devices have been wireless pioneers.
- Disease state management reports have been part of the devices for many years; Boston Scientific users are used to exercise trends, heart rate variability reports, an autonomic balance monitor, and the ability to set up weight and blood pressure monitoring to feed into the Latitude system.
- The Teligen™ device is thin, which may be advantageous in certain patient niches; however, the unique St. Jude Medical approach—focused on "More Control. Less Risk."—overcomes any thickness comparisons and proves the thickness story isn't worth two nickels. (The 5 mm thickness difference vs. Current Accel™ and AnalyST Accel™ ICDs is roughly the equivalent of two U.S. nickels stacked together.)

BOSTON SCIENTIFIC PARITY WITH ST. JUDE MEDICAL

- InvisiLink™ wireless technology, the Merlin.net™ PCN and the Merlin@home™ transmitter give St. Jude Medical parity with Boston Scientific wireless technology—something that once set the company's offerings apart in a class by themselves.
- Boston Scientific has offered SMARTSensing™ in its devices; St. Jude Medical™ Sense*Ability*™ technology provides even more programming flexibility. This is an area of "pseudo-parity," that is parity some doctors may feel exists but which, in fact, is a myth. Boston Scientific customers may think SMARTSensing technology is equal to Sense*Ability* technology, but the Sense*Ability* algorithm is more flexible.
- Both companies offer AT/AF alerts and trend monitoring and an algorithm for high intrinsic atrial rates (however, only the AF Suppression™ algorithm from St. Jude Medical has been clinically proven to reduce AT/AF burden).

BOSTON SCIENTIFIC VS. ST. JUDE MEDICAL ADVANTAGES

- Capture Confirmation:
  - — Boston Scientific has no capture confirmation features in any of its ICDs.
- Boston Scientific offers mode switching, but there are no options to program to a rate-responsive mode or to an interim mode switch base rate. Add this to the fact that there is no clinically proven algorithm to manage high atrial rates and you have devices that may not be the best choice for patients with AF or other high intrinsic atrial rates. Since AF is one of the most common rhythm disorders, doctors must know that selecting a Boston Scientific device means foregoing important features for patients with atrial tachyarrhythmias or those who might develop them in the future (that's everybody).
- ST Monitoring:
  - — Boston Scientific has no ST Monitoring capability in any of its devices.
- Boston Scientific has very little programming flexibility to improve defibrillation efficacy in the face of high or rising DFTs:
  - — No programmable pulse width
  - — No programmable tilt
  - — No programmable shocking vectors
  - — No wonder this company is famous for the "array"!
- SMARTSensing technology is not as flexible in managing sensitivity troubleshooting issues as Sense*Ability* technology:
  - — No programmable Threshold Start
  - — No programmable Decay Delay
  - — No separately programmable ventricular paced versus sensed refractory periods
- There are no device-based timing algorithms for AV delay or VV timing optimisation.
- EGM storage capacity is limited.
- There have been reported issues with the new port plugs, in which the physicians could not engage the lead into the header due to air pressure. The wrench had to be placed into the header to relieve this air pressure from the sealing rings before the lead could be inserted and screwed in.
- There has been one reported incident of a device being stuck in a DFT mode that required external defibrillation of a patient. During the case, after the physician directed the induction of a patient into VF, the device continued to induce the patient regardless of the Boston Scientific representative's efforts to stop induction.

Competitive Comparison ICD VR

Cardiac Rhythm Management Industry

	Biotronik Lumax™ 540 VR-T	Boston Scientific Teligen™ VR HE	Sorin Ovatio™ VR	Medtronic Secura™ VR	St. Jude Medical Current Accel™ VR	St. Jude Medical AnalyST Accel™ VR
Model Number		F102	6250	D224VRC	1215-36	1219-36
Volume (cc)	37,2	31,5	29	37	41	41
Weight (g)	92	71	85	68	79	79
Thickness (mm)	13	9,9	10,9	15	14	14
Max Delivered Energy (J)	35	35	29,3	35	36	36
Charge Time to Max Delivered Energy (sec)		8,8		7,7	9,2	9,2
Longevity (year)	9,8@2,5 V; 0,4 ms; 60 min^{-1}; 700 ohms; 15% VVI pacing	8,4@2,5 V; 0,4 ms; 60 min^{-1}; 500 ohms; 15% RV pacing	6,9@2,5 V; 0,35 ms; 60 min^{-1}; 500 ohms; 15% VVI pacing	7,2@2,5 V; 0,5 ms; 500 ohms; 60 min^{-1}; 15% VVI pacing	8,9@1,0 V; 0,5 ms; 25% VVI pacing; 500 ohms; AC=On	8,9@1,0 V; 0,5 ms; 25% VVI pacing; 500 ohms; AC=On
ST Segment Monitoring	No	No	No	No	No	Yes
HV Therapy - ATP	Yes	Yes	Yes	Yes	Yes	Yes
HV Therapy - Reverse Last Therapy	Yes	Yes	Yes	Yes	No - RV Anode Nominal	No - RV Anode Nominal
HV Therapy - Shock Vector Programmability	Yes	Yes - SVC On/Off	Yes	Yes - Can On/Off	Yes - SVC On/Off	Yes - SVC On/Off
HV Therapy - Waveform Programmability	Yes - Polarity	Yes - Polarity	Yes - Polarity	Yes - Polarity	Yes - Pulse Width, Polarity, Tilt	Yes - Pulse Width, Polarity, Tilt
Induction - DC Fibber™	No	No	No	No	Yes	Yes
Capture Confirmation - RV	No	No	No	Yes	Yes - AutoCapture™ Pacing System	Yes - AutoCapture Pacing System
Capture Confirmation - Follow-up EGMs	No	No	No	No	Yes	Yes
Auto Sensitivity	Yes	Yes - Dynamic	No	No	Yes - Dynamic	Yes - Dynamic
Sensing - T-wave Oversensing	Yes - Enhanced T-wave Suppression	No	No	No	Yes	Yes
Discrimination - Morphology Discrimination	No	No	No	No	Yes	Yes
IEGM Storage - Capacity (min)	32	19	19	23,5	45	45
System Diagnostics - HV Lead Impedance	Yes	Yes	No	Yes	Yes - Multi-vector, Daily	Yes - Multi-vector, Daily
Remote Management - Remote Monitoring	Yes	Yes	No	Yes	Yes	Yes
Battery		MnO2	SVO	SVO	SVO	SVO
Wireless Telemetry	Yes	Yes	No	Yes	Yes	Yes
Patient Alert	No	Yes - Audible	No	Yes - Audible	Yes - Vibratory	Yes - Vibratory
Safety Platform	No	Yes	No	Yes	Yes	Yes
Full Page 8-1/2" x 11" Printouts	No	No	No	No	Yes	Yes

Competitive Comparison ICD DR

Cardiac Rhythm Management Industry

	Biotronik Lumax™ 540 DR-T	Boston Scientific Teligen™ DR HE	Sorin Ovatio™ DR	Medtronic Secura™ DR	St. Jude Medical Current Accel™ DR	St. Jude Medical AnalyST Accel™ DR
Model Number		F110	6550	D224DRG	2215-36	2219-36
Volume (cc)	37,2	31,5	29	37	42	42
Weight (g)	92	71	86	68	80	80
Thickness (mm)	13	9,9	10,9	15	14	14
Max Delivered Energy (J)	35	35	29,3	35	36	36
Charge Time to Max Delivered Energy (sec)		8,8		7,7	9,2	9,2
Longevity (year)	8,8@2,5 V; 0,4 ms; 60 min^{-1}; 50% RA and 15% RV pacing; 700 ohms	7,8@2,5 V; 0,4 ms; 60 min^{-1}; 500 ohms; 15% A&V pacing	6,5@2,5 V; 0,35 ms; 60 min^{-1}; 500 ohms; 15% DDD pacing; 4 max energy shocks/ year; EGM pre-storage unknown	6,2@2,5 V; 500 ohms; 0,5 ms; 60 min; 15% A&V pacing	7,7@RV 1,0 V; A 2,0 V; 0,5 ms; 60 min^{-1}; 25% DDD pacing; 500 ohms; AC=On	7,7@RV 1,0 V; A 2,0 V; 0,5 ms; 60 min^{-1}; 25% DDD pacing; 500 ohms; AC=On
ST Segment Monitoring	No	No	No	No	No	Yes
HV Therapy - ATP	Yes	Yes	Yes - RV	Yes - RV	Yes	Yes
HV Therapy - Reverse Last	Yes	Yes	Yes	Yes	No - RV Anode Nominal	No - RV Anode Nominal
HV Therapy - Shock Vector Programmability	Yes	Yes - SVC On/Off	Yes	Yes - Can On/Off	Yes - SVC On/Off	Yes - SVC On/Off
HV Therapy - Waveform Programmability	Yes - Polarity	Yes - Polarity	Yes - Polarity	Yes - Polarity	Yes - Pulse Width, Polarity, Tilt	Yes - Pulse Width, Polarity, Tilt
Induction - DC Fibber™	No	No	No	No	Yes	Yes
Pacing Options - Reduced V-Pacing	Yes - IOPT	Yes - AV Hysteresis (US), Reverse Mode Switch (OUS)	Yes - AAIsafeR™	Yes - MVP™	Yes - VIP™ algorithm	Yes - VIP algorithm
Pacing Options - AV Optimisation	No	Yes - SmartDelay™	No	No	Yes - QuickOpt™ optimisation	Yes - QuickOpt optimisation
AF Management - Prevention	No	No	Yes	No	Yes - AF Suppression™ algorithm	Yes - AF Suppression algorithm
Capture Confirmation - RV	No	No	No	Yes	Yes - AutoCapture™ Pacing System	Yes - AutoCapture Pacing System
Capture Confirmation - Atrial	No	No	No	Yes	Yes - ACap™ Confirm	Yes - ACap Confirm
Capture Confirmation - Follow-up	No	No	No	No	Yes	Yes
Auto Sensitivity	Dynamic	Dynamic	No	No	Dynamic	Dynamic
Sensing - T-wave Oversensing	Yes - Enhanced T-wave Suppression	No	No	No	Yes	Yes
Discrimination - Morphology Discrimination	No	No	No	No	Yes	Yes
Discrimination - A-V Rate Branch	Yes	Yes	Yes	Yes - PR Logic™	Yes	Yes
Rhythm Diagnostic - AT/AF Burden Trend	Yes	Yes	No	Yes	Yes	Yes
IEGM Storage - Capacity (min)	32	19	19	23,5	45	45
System Diagnostics - HV Lead Impedance	Yes	Yes	No	Yes	Yes - Multi-vector, Daily	Yes - Multi-vector, Daily
Remote Management - Remote Monitoring	Yes	Yes	No	Yes	Yes	Yes
Battery		MnO2	SVO	SVO	SVO	SVO
Wireless Telemetry	Yes	Yes	No	Yes	Yes	Yes
Patient Alert	No	Yes - Audible	No	Yes - Audible	Yes - Vibratory	Yes - Vibratory
Safety Platform	No	Yes	No	Yes	Yes	Yes
Full Page 8-1/2" x 11" Printouts	No	No	No	No	Yes	Yes

PR Logic is a trademark of Medtronic Inc.; Ovatio and AAIsafeR are trademarks of Sorin; Lumax is a trademark of Biotronik; SmartDelay is a trademark of Boston Scientific Corporation.

NOTES

Current Accel™ ICDs and AnalyST Accel™ ICDs

Sales Reference Guide

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.

[1] Baron TW et al. Real-time assessment of acute myocardial ischaemia by an intra-thoracic 6-lead ECG: evaluation of a new diagnostic option in the implantable defibrillator. Europace 2006; 8:994-1001.

[2] Porciani MC et al. A real-time three-dimensional echocardiographic validation of intracardiac electrogram based method for optimizing cardiac resynchronization, PACE 2008; 31: 56-63

[3] Baker JH et al. Acute evaluation of programmer-guided AV/PV and VV Delay optimization comparing an IEGM method and echocardiogram for cardiac resynchronization therapy in heart failure patients and dual-chamber ICD implants. Journal of Cardiovascular Electrophysiology 2007; 18:185-191.

[4] Gray J et al. Inappropriate application of managed ventricular pacing in a patient with Brugada syndrome leading to polymorphic ventricular tachycardia, ventricular fibrillation and implantable cardioverter defibrillator shocks. Heart Rhythm 2006; 3(1):S137.

[5] Mansor F et al. Pacemaker troubleshooting: when MVP is not the most valuable parameter. Heart Rhythm 2006; 3(5):612-4.

[6] Carlson M et al. A new pacemaker algorithm for the treatment of atrial fibrillation, results of the Atrial Dynamic Overdrive Pacing Trial (ADOPT-A). JACC 2003; 42:627-33.

[7] Attuel P et al., and the INOVA Study Group. Quality of life in permanently paced AF patients. The INOVA Study. Europace 2003; Abstract A42-6.

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIAC SURGERY CARDIOLOGY NEUROMODULATION

Global Headquarters
One Lillehei Plaza
St. Paul, Minnesota 55117
USA
+1 651 483 2000
+1 651 490 4310 Fax

Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, California 91342
USA
+1 818 362 6822
+1 818 364 5814 Fax

St. Jude Medical Sweden AB
Veddestavägen 19
175 84 Järfälla
Sweden
+46 8 474 4000
+46 8 760 3855 Fax

St. Jude Medical Europe, Inc.
The Corporate Village
Figueras Building
Avenue Da Vinci Iaan, 11 Box F1
B-1935 Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brasil Ltda.
Rua Frei Caneca, 1380
7º ao 9º andares
01307-002 - São Paulo (SP)
Brazil
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Ltd.
Unit 2701-07 27/F, COSCO Tower
Grand Millennium Plaza
183 Queen's Road
Central, Hong Kong
+852 2996 7688
+852 2956 0622 Fax

St. Jude Medical Japan Co., Ltd.
3-1-30, Minami-Aoyama
Minato-ku
Tokyo 107 0062
Japan
+81 3 3423 6450
+81 3 3402 5586 Fax

www.sjm.com

ST. JUDE MEDICAL™
MORE CONTROL. LESS RISK.