A Tailored Approach to CRT Optimization

The challenges of CRT Optimization

Reducing the risk of replacement

>60% of CRT-D patient survival at 5 years\(^1\), but not all battery technologies have the same performance over time

Maximizing CRT response

Non-Apical pacing is associated with better CRT outcome\(^2\) versus Apical pacing, but is harder to achieve without dedicated lead design

Longer RVS-LVS interval has shown improved CRT response\(^3\), but a measurement is needed for each patient due to conduction variability

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*Unmatched device longevity* shown in independent real-world studies

Maximizing CRT response

*Acuity X4 family of leads* for more non-apical pacing options

*VectorGuide™* one-click test to help you identify the longest RVS-LVS interval

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What is the need for long-lasting CRT-D devices?

- **What are the risks associated with device replacements?**

- What would be the **clinical benefit** of a CRT-D that lasts 8-10 years instead of a CRT-D that lasted 4-5 years?

  ✓ Compared to a first implant, the cumulative incidence of surgical re-intervention following device replacement is 2.5 times higher – and goes up to 7-9% (Borleffs 2010)

  ✓ 30% of device related infections could be avoided if device batteries lasted at least 9 years (Ramachandra 2010)

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1 Borleffs. Recurrent Implantable Cardioverter-Defibrillator Replacement Is Associated with an Increasing Risk of Pocket-Related Complications.


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ENDURALIFE™ Battery Technology

**Capacity**
High battery capacity is nearly double the standard capacity of other ICDs and CRT-Ds.\(^2\)

**Chemistry**
Li/MnO2 chemistry maintains stable operating voltage and internal resistance for more effective battery utilization.\(^3\)

**Efficiency**
Advanced manufacturing capabilities enable a device that is up to 11% smaller and 24% thinner with nearly twice the capacity than other manufacturers.\(^4\)

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1. EnduraLife™ Battery Technology is featured in X4 CRT-Ds and EL ICDs, as well as Cognis, Teligen, Puncture, Emergen, Incepta ICDs and CRT-Ds.
2. Boston Scientific ICDs and CRT-Ds with contemporary battery technology have 1.8 Ah. Medtronic ICDs and CRT-Ds have 1.8 Ah. 3. Data on file at Boston Scientific Corporation.
3. Boston Scientific ICDs and CRT-Ds with contemporary battery technology have 1.8 Ah. Medtronic ICDs and CRT-Ds have 1.0 Ah. 4. Data on file at Boston Scientific Corporation.

OVERVIEW CAPACITY CHEMISTRY EFFICIENCY

ENDURALIFE™ Battery Technology has the largest battery capacity in the industry.\(^2\)

High battery capacity is nearly 2x the standard capacity of Medtronic ICDs and CRT-Ds.\(^5\)

REFERENCES
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A Unique two-step approach for maximizing CRT response (1/2)

1. More effective pacing options in a non-apical location

   - MADIT CRT and other studies have shown that most patients benefit from non-apical pacing

   Acuity X4 Family of leads offers three options to select the most suitable LV lead

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**“Apical pacing should be avoided in CRT”**

Left Ventricular Lead Position and Clinical Outcome in MADIT-CRT Trial.
Singh J. et al., Circulation, 2011

<table>
<thead>
<tr>
<th>Probability of survival free of heart failure or death</th>
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</thead>
<tbody>
<tr>
<td>Years from randomization</td>
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<tr>
<td>Apical Pacing</td>
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<tr>
<td>Non-apical</td>
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</tbody>
</table>

72% Increased risk for HF/death with apical pacing


**“Position of the RV lead tip was indifferent”**

Sites of LV and RV lead implantation and response to CRT observations from REVERSE trial.
Thebault C et al., European Heart Journal, 2012

<table>
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</tbody>
</table>

73% Increased risk for HF/death with apical pacing

1. Thebault C et al. Sites of left and right ventricular lead implantation and response to cardiac resynchronization therapy observations: from the REVERSE trial. Eur Heart J 2012;33:2662–2671. *Defined as proportion of patients whose LVEF had decreased by ≥15% at 12 months
### The challenges of Non-Apical pacing

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Non-Apical</th>
<th>Apical</th>
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<tbody>
<tr>
<td>Threshold(^1)</td>
<td>Worse capture (poor electrode-myocardial contact)</td>
<td>Better capture (close electrode-myocardial contact)</td>
</tr>
<tr>
<td>Stability</td>
<td>Higher risk of dislodgement</td>
<td>Lower risk of dislodgement</td>
</tr>
<tr>
<td>PNS(^2)</td>
<td>Better</td>
<td>Worse</td>
</tr>
<tr>
<td>Patient Outcome(^3)</td>
<td>Better</td>
<td>Worse</td>
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**Non-Apical pacing locations**, which shown to have **better clinical outcomes**, may be harder to achieve in the implant setting.

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### More effective pacing options in a non-apical location

- **Long veins**
  - ACUITY™ X4 Spiral L

- **Short veins**
  - ACUITY™ X4 Spiral S

- **Narrow or tortuous veins**
  - ACUITY™ X4 Straight

The Acuity™ X4 family of LV leads offers different electrode spacing to accommodate individual anatomy and help you pace at your target location.

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2. Occurrence of phrenic nerve stimulation in cardiac resynchronization therapy patients: the role of left ventricular lead type and placement site.

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A Unique two-step approach for maximizing CRT response (2/2)

A one-click test to identify the longest RVS-LVS electrical delay

- Patients ventricular activation patterns may vary considerably
- Longer electrical delay at pacing site has shown to reduce HF hospitalization and increase the number of responders

VectorGuide™ tool offers a one-click test to target the most appropriate electrode

One additional click for a potential lifetime benefit

1. Khan FZ et al. Targeted left ventricular lead placement to guide cardiac resynchronization therapy: the TARGET study, a randomized, controlled trial. J Am Coll Cardiol 2012;59:1509–1518

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2

Longer RVS-LVS interval at pacing site: independent predictor of CRT response?

Gold M. et al. ESC 2014 (n=419)

Longer RVS-LVS was an independent predictor of structural responses to CRT

Response rates varies from 30% to 75% (quartiles 1 and 4 respectively)

Gold M. et al., ESC 2014 (n=1342)

Reduction of risk of HF hospitalization or death associated with longer RVS-LVS delay

30%

The changes in LVESV, LVEDV and LVEF responses from implant to 6 months for RV-LV quartiles

Gold M. et al. The Relationship Between RV-LV Delay and Left Ventricular Reverse Remodeling With Cardiac Resynchronization Therapy. ESC 2014. Patients were grouped by RV-LV quartiles with cutoffs at 40, 65, and 100 ms. Response rates by quartile were 90%, 49%, 53% and 75% respectively.

Gold M. et al. The Role RV-LV Delay to Predict Time to First Heart Failure Hospitalization and Mortality with Cardiac Resynchronization Therapy. ESC 2014.

Kaplan-Meier curves of HF-Free Survival for the short and long RV-LV groups

2. Gold M. et al. The Role RV-LV Delay to Predict Time to First Heart Failure Hospitalization and Mortality with Cardiac Resynchronization Therapy. ESC 2014.

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2. One click test to identify the longest RVS-LVS electrical interval

VectorGuide™ is designed to quickly identify the best of 17 vectors options based on clinically relevant tests including RVS-LVS delay

* Example of RVS-LVS delay test results from a Rally X4 Study patient. Data on file

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Acuity X4 family of leads for more non-apical pacing options

VectorGuide™ one-click test to help you identify the longest RVS-LVS interval

X4 CRT-D System

One Click for a Potential Lifetime Benefit

Now with VectorGuide™