SPECIFICATIONS

- The CorVue Congestion Monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts.

- Unique 40 J Safety Shock option, delivered energy, provides a greater DFT safety margin and may minimise the need for multiple DFT tests at implant.

- The SJ4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws.

- QHR™ chemistry battery provides greater capacity for enhanced longevity and charge times.

- The addition of antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for converting tachyarrhythmias before or during charge.

- The % V-Pacing alert notifies patients and their clinics when percent ventricular pacing is greater than the programmed threshold.

- The Low Frequency Attenuation filter is designed to enhance sensing performance and may reduce the possibility of oversensing T waves.

- DfT Response™ technology tools provide more clinically proven, noninvasive options for managing high DFTs.
  - Programmable pulse widths allow the user to tailor the shock to the individual patient, making shocks more efficacious.¹
  - SVC shocking electrode can be quickly and noninvasively activated or deactivated with the touch of a button.
  - 40 J delivered energy provides unsurpassed energy for defibrillation.
  - Four programmable tilt options are available to accommodate variances among patients.²

- Unique SenseAbility™ feature, with Delay Cor and Threshold Shift, offers the flexibility to fine-tune sensing to individual patient needs.

- QuickOpt™ timing cycle optimisation provides quick and effective optimisation for more patients at the touch of a button.³

- Unique Morphology Discrimination plus AV Rate Branch SVT discrimination feature helps reduce the risk of inappropriate ICD shocks and is intended to promote fast, accurate diagnosis and delivery of therapy. Clinical data states that this combination resulted in a sensitivity of 100% with a specificity of 85%.⁴

- Unique AF Suppression™ algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF.
  - Studies show a 25% decrease in symptomatic AF burden.⁵

- AT/AF Alerts notify patients and their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode.

- Up to 45 minutes of continuous, fully annotated stored electrogamograms, including up to 60 seconds of pre-trigger information per electrogamogram.

- Unique Vibratory Patient Notifier allows even patients with hearing problems to be notified of paroxysmal and persistent AF.

- Automatic Daily High-Voltage (HV) Lead Integrity Test is designed to automatically test the HV lead on a daily basis to ensure therapy delivery for optimal patient safety.

- Multiple hardware and software system safeguards are included for added security and patient comfort.

- Decreased device footprint and volume with the most narrow (40 mm) design available for greater patient comfort and range of motion during activity.

- AutoCapture™ Pacing System offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ capture confirmation. The AutoCapture Pacing System automatically delivers a 5.0 V backup safety pulse when noncapture is detected.

- Designed to reduce unnecessary right ventricular pacing, the Ventricular Intrinsic Preference (VIP™) algorithm allows intrinsic conduction when possible and provides optimised ventricular support when needed.

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automatic treatment of life-threatening ventricular arrhythmias.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from treatment or controllable factors such as drug toxicity, electrolyte imbalance, or acute miscellaneous infection.

Warnings and Precautions: Implantation of a pulse generator system involves risks, some possibly life-threatening. These include:

- Device Storage. Store the pulse generator at temperatures between 10° and 45°C. Do not subject it to temperatures below -20° or over 60°C. After cold storage, allow the device to reach room temperature before charging the capacitors, programming, or implanting the device because cold temperature may affect initial device function.

- Device Replacement. Replace the pulse generator within three months of reaching the ERI indication. Replace the pulse generator immediately upon reaching a DFT if there is frequent high-voltage charging and/or noncapture of the pacing vectors is programmed.

- Battery Incineration. Do not incinerate pulse generators as they contain certain chemical power cells and capacitors that may explode. Refer unimplanted devices to SJM ElectroMedical.

- Magnetic Resonance Imaging (MRI). Avoid MRI devices because of the magnitude of the magnetic fields and the strength of the radiofrequency (RF) fields they produce.

- Device Testing. Turn off nearby electrical equipment or move it away from the patient and the programmer. If the problem persists, contact SJM ElectroMedical.

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- ACap™ Confirm Pacing System periodically completes a threshold search and automatically adjusts amplitude to address patients’ changing atrial thresholds.

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- Refer to the User’s Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.