

Fortify Assura™ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- ShockGuard™ technology with DecisionTx™ programming, designed to reduce inappropriate therapy and minimize the need for programming adjustments at implant
- SecureSense™ RV lead noise discrimination detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
- Far Field MD morphology and Chamber Onset discrimination improve SVT and VT discrimination for reduced inappropriate therapies
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high-voltage shock
- The Low Frequency Attenuation filter is designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- The SenseAbility™ feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST-segment as a diagnostic tool to help guide appropriate clinical action
- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- Unique 40 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response™ technology offers the most noninvasive options for managing high DFTs
- QHR™* chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- 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
- Ventricular Intrinsic Preference (VIP™) algorithm automatically searches for intrinsic conduction



Ordering Information

Contents: Cardiac pulse generator

Reorder Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD2259-40	74 x 40 x 14	76	35	DF1	IS-1
CD2259-40Q	71 x 40 x 14	75	35	DF4	IS-1; DF4

DRAFT SPECIFICATIONS; CE MARK PENDING

*QHR is a trademark of Greatbatch Medical

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country.

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

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Adverse Events: Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

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

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Item GMCRM910EN

Last Updated: 19 April 2013

