Durata™

Defibrillation Lead

Product Highlights

- Allows patients to safely undergo an MRI scan when used in combination with an MRI-Ready device.*
- Optim™ insulation is a co-polymer that offers superior handling and durability.[1-3]
- Two innovative designs are intended to help prevent tissue ingrowth — flat-wire technology provides a low profile for the defibrillation coils, and silicone backfilling completely fills the shock coil space.
- Redundant conductors serve as a backup system in the unlikely event of a conductor failure.
- Symmetrically aligned cables within the lead body and centrally located coil provide for additional protection to the inner coil.[4]
- The DF-4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws.

Ordering Information

Contents: Defibrillation lead

MODEL NUMBER	INSULATION	FIXATION	MIN. INTRODUCER (F)	SHOCK CONFIGURATION	SENSING	TIP-TO-PROXIMAL COIL (CM)	CONNECTOR	LENGTHS (CM)
7120	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65
7120Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF4	52; 58; 65
7121Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF4	58; 65
7122	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF1; IS-1	60; 65
7122Q	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF4	52; 58; 65
7170Q	Optim	Tines	7	Dual-coil	True bipolar	17	DF4	58; 65

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Defibrillation Lead

Product Specifications

PHYSICAL SPECIFICATIONS

TRUE BIPOLAR, ACTIVE-FIXATION DEFIBRILLATION LEADS

Models	**7120**	**7120Q**	**7121Q**	**7122**	**7122Q**
Fixation	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65	52; 58; 65	58; 65	60; 65	52; 58; 65
Connector	DF1; IS-1	DF4	DF4	DF1; IS-1	DF4
Maximum Diameter	6,8 F	6,8 F	6,8 F	6,8 F	6,8 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	N/A	N/A
Tip Electrode Area	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	N/A	N/A
MR Conditional*	Yes, 60 and 65 cm only	Yes, 58 and 65 cm only	No	Yes, 60 and 65 cm only	Yes, 58 and 65 cm only

*For additional information about specific MR Conditional systems and lead model numbers, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the MRI Ready Systems Manual at manuals.eifu.abbott or check our MRI Ready resources at cardiovascular.abbott/mriready

TRUE BIPOLAR, PASSIVE-FIXATION DEFIBRILLATION LEADS

Models	**7170Q**
Fixation	Tines
Shock Configuration	Dual-Coil
Sensing Configuration	True Bipolar
Min. Size Introducer	7 F
Lengths (cm)	58; 65
Connector	DF4
Maximum Diameter	6,8 F
Tip-to-Anode Spacing	11 mm
Tip-to-Proximal Coil	17 cm
Tip Electrode Area	6 mm^2
Steroid Plug	Yes
Distal Shock Coil Area	367 mm^2
Proximal Shock Coil Area	588 mm^2
MR Conditional*	No

*For additional information about specific MR Conditional systems and lead model numbers, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the MRI Ready Systems Manual at manuals.eifu.abbott or check our MRI Ready resources at cardiovascular.abbott/mriready

References

1. Jenney, C., Tan, J., Karicherla, A., Burke, J., & Helland, J. (2005). A new insulation material for cardiac leads with potential for improved performance. Heart Rhythm, 2(5), S318-S319.
2. Wilkoff B, et al. The biostability of cardiac lead insulation materials as assessed from longterm human implants. J Biomed Mater Res B Appl Biomater. 2015 Apr 17. doi: 10.1002/jbm.b.33405.
3. Cosgriff-Hernandez E, Tkatchouk E, Touchet T, Sears N, Kishan A, Jenney C, Padsalgikar AD, Chen E. Comparison of clinical explants and accelerated hydrolytic aging to improve biostability assessment of silicone-based polyurethanes. J Biomed Mater Res A. 2016 Jul;104(7):1805-16.
4. St. Jude Medical Engineering Report: Tension and Cable Shortening Comparison. Report 60032635.

Rx Only

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.

Indications: The Durata™ defibrillation leads are indicated for use in combination with implantable cardioverter defibrillators (ICDs) or cardiac resynchronization therapydefibrillators (CRT-Ds) to provide sensing, pacing and cardioversion/defibrillation therapy for the treatment of bradyarrhythmia's and lifethreatening tachyarrhythmias in patients who are at risk from sudden cardiac death. They are implanted transvenously in the right ventricle.

The Durata™ Models 7120Q, 7121Q, and 7122Q leads are 7 French, transvenous, steroid eluting, bipolar, DF4 compatible (single connector with four electrical terminals), active fixation leads intended for permanent sensing and pacing of the right ventricle and the delivery of cardioversion/defibrillation therapy when used with a compatible Abbott Medical pulse generator with a DF4-LLHH lead receptacle designation.

Contraindications: Durata™ Models 7120, 7121, and 7122 leads are contraindicated in the following: Patients with tricuspid valvular disease or a mechanical tricuspid valve. Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. Durata™ Models 7120Q, 7121Q, and 7122Q leads, please add "For use with extra firm (red color knob) stylets.".

Potential Adverse Events: The following lists potential adverse effects and their categories as applicable when using a high voltage lead. Arrhythmia (Arrhythmia acceleration, Induced atrial ectopy or arrhythmias, Induced atrioventricular or bundle branch block, Induced ventricular ectopy or arrhythmias, Myocardial irritability), Cardiac perforation (Cardiac tamponade, Perforation of the myocardium, Pericardial effusion), Death, Embolism (Air embolism, Intravascular foreign body, Dislodgement of intracardiac thrombus), Extra-cardiac stimulation (Diaphragmatic stimulation, Stimulation of phrenic nerve), Heart failure (Cardiogenic shock, Right ventricular decompensation, Pacing-induced cardiomyopathy, Tricuspid valve dysfunction), Hemorrhage, (Acute hemorrhage/bleeding), Hypersensitivity (Hypersensitivity, including local tissue reaction or allergic reaction), Infection (Endocarditis, Pericarditis), Lead revision or reprogramming (Electrical malfunction of the lead, Lead dislodgement, Lead dysfunction (sensing/threshold issue), Mechanical malfunction of the lead, Inappropriate defibrillation therapy), Pleural perforation (Hemothorax, Pneumothorax), Pocket Erosion (Erosion of the skin, Extrusion), Prolonged exposure to fluoroscopic radiation, Seroma (Fluid accumulation), Tissue necrosis, Tricuspid valve perforation, Vascular perforation (Arteriovenous fistula, Arterial perforation, Coronary sinus or coronary vein perforation, Hematoma, Venous perforation), Vascular Thrombosis (Venous thrombosis and/or obstruction, Venous occlusion). The physician should discuss the patient's potential adverse events with them.

Possible adverse events associated with the use of transvenous lead systems include, but are not limited to, those summarized in as follows. Refer to the appropriate pulse generator manual for additional complications and precautions specific to the pulse generator. Dislodgement, breaching of the lead insulation, connector fracture, poor connection to the pulse generator, electrode fracture, or conductor is continuity (Intermittent or continuous loss of sensing, possibly resulting immunodetection of arrhythmia; oversensing of artifact, possibly causing inappropriate delivery of therapy from the pulse generator; intermittent or continuous loss of defibrillation, cardioversion, or pacing therapy; possible muscle or nerve stimulation in the pocket area; intermittent or continuous loss of cardioversion/defibrillation therapy, sensing, or pacing therapies.), Cardiac perforation (Intermittent or continuous loss of sensing, cardiac tamponade, hemorrhage, pneumothorax, or loss of contractility), Venous perforation (Acute hemorrhage (may not be readily apparent), hemothorax, pneumothorax, or cardiac tamponade), Myocardial irritability (Premature ventricular contractions, supraventricular and ventricular tachyarrhythmias, postoperative heart failure), Transvenous implantation procedure (Air embolism), Chronic(> 3 months) implantation (Venous thrombosis and/or obstruction, tissue necrosis, skin erosion, tricuspid valve dysfunction, chronic mechanical stimulation of the heart), Contamination (Infection requiring removal of lead system, pulse generator, or both), Post-shock rhythm disturbances (Post-shock bradycardia or supraventricular arrhythmias, conduction disturbances), Threshold elevation or exit block (Loss of efficacy of defibrillation, cardioversion, or pacing therapy), Shunting or insulating of current during defibrillation with internal or external paddles (Increased external defibrillation energy and/or repositioning of paddles required).

Refer to the defibrillator manual for additional complications and precautions specific to the pulse generator.

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