CRM PRODUCT CATALOG

DEFIBRILLATION LEADS

Abbott

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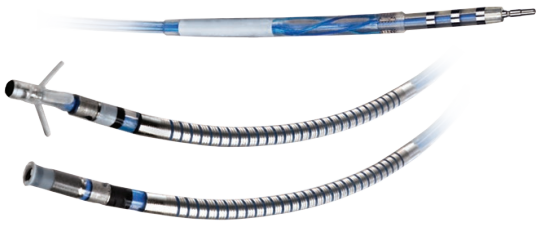
DEFIBRILLATION LEADS

Durata™

Defibrillation Lead



Product Highlights

- Allows patients to safely undergo an MRI scan when used in combination with an Abbott MRI Ready device.*,†
- Optim™ lead insulation is a chemical copolymer that offers superior handling and durability.[1]
- 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.[2]
- The DF4 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

REORDER NUMBER	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	SHOCK CONFIGURATION	SENSING	TIP-TO-PROXIMAL COIL (CM)	CONNECTOR§	LENGTH (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+
7121	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7121Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7122	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF1; IS-1	60; 65; 75
7122Q	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF4	52; 58+; 65+
7170	Optim	Tines	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65; 75
7170Q	Optim	Tines	7	Dual-coil	True bipolar	17	DF4	52; 58; 65
7171	Optim	Tines	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7171Q	Optim	Tines	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7172Q	Optim	Tines	7	Single-coil	True bipolar	N/A	DF4	52; 58; 65

Indications for Use: The Durata™ transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart. A transvenous lead system may offer the patient the benefit of avoiding a thoracotomy for lead implantation. If the initial lead configuration is not effective, repositioning of the lead or other lead configurations should be attempted. In some patients, a nonthoracotomy lead configuration may not provide reliable conversion of arrhythmias, and the use of subcutaneous or epicardial patch defibrillation leads should be considered.

Contraindications: Contraindications for use of the Durata leads with an implantable pulse generator include ventricular tachyarrhythmias resulting from transient or reversible factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Transvenous lead systems are contraindicated for patients with tricuspid valvular disease or a mechanical heart valve. Durata leads are contraindicated for patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. The Durata leads are contraindicated for extra firm (red color knob) stylets. The lead is not designed, sold, or intended for use other than as indicated.

Potential Complications: Possible complications of the use of transvenous lead systems include, but are not limited to, supraventricular or ventricular arrhythmias, conduction disturbances, cardiac perforation, cardiac tamponade, loss of contractility, air embolism, heart wall rupture, myocarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, hemothorax, infection, tissue necrosis and erosion of the skin. Specific events and effects are summarised below:

WARNING: Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the pulse generator, or other forces associated with cardiac contractions and patient physical activity, posture and anatomical influences. Cardiac leads' functional lifetimes can be affected by these and other factors.

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

Durata™

Defibrillation Lead

Product Specifications

TRUE BIPOLAR, ACTIVE-FIXATION DEFIBRILLATION LEADS

Models	**7120**	**7120Q**	**7121**	**7121Q**	**7122**	**7122Q**
Fixation	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65	52; 58; 65	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF1; IS-1	DF4
Body Diameter	6,8 F	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	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 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	6 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	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	588 mm^2	N/A	N/A
MRI Conditional	No	Yes, MRI Ready (lengths: 58 and 65 cm)	No	No	No	Yes, MRI Ready (lengths: 58 and 65 cm)
MRI Whole-body SAR	N/A	2 W/kg	N/A	N/A	N/A	58 cm = 2 W/kg 65 cm = 1.6 W/kg

TRUE BIPOLAR, PASSIVE-FIXATION DEFIBRILLATION LEADS

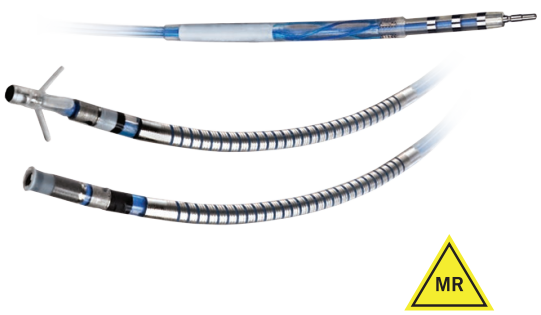
Models	**7170**	**7170Q**	**7171**	**7171Q**	**7171Q**
Fixation	Tines	Tines	Tines	Tines	Tines
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF4
Body 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	21 cm	N/A
Tip Electrode Area	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 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	588 mm^2	N/A
MRI Conditional	No	No	No	No	No
MRI Whole-body SAR	N/A	N/A	N/A	N/A	N/A

*MRI Conditional Field Strength, 1,5 Tesla.
†See MRI Procedure Information for approved MR Conditional Systems Device/Lead combinations and scan parameters
§Abbott DF1 lead connectors conform to the international connector standard ISO 11318/Amd. Abbott IS-1 lead connectors conform to the international connector standard ISO 5841. Abbott DF4 lead connectors conform to the international connector standard ISO 27186: 2010 (E).
+Indicates lead lengths that are MRI Conditional.*†

1. Jenney C, Tan J, Karicherla A, Burke J, Helland J. A New Insulation Material for Cardiac Leads with Potential for Improved Performance. *Heart Rhythm*. 2005;2:S318-S319.
2. Abbott. Engineering Report: Tension and Cable Shortening Comparison. Report 60032635.

Optisure™

Defibrillation Lead



The Optisure™ lead expands on the Abbott high-voltage product portfolio, providing an additional system enhancement for addressing lead complications and improving system reliability.

Product Highlights

- Allows patients to safely undergo a magnetic resonance imaging (MRI) scan when used in combination with an Abbott MRI Ready device*,†
- Building on the proven 7 F Durata™ defibrillation lead design, the Optisure lead features additional Optim™ lead insulation at the proximal end of the lead and under the superior vena cava coil, resulting in an 8 F lead body.
  - Optim™ lead insulation is a chemical copolymer that offers superior handling and durability.[1]
- 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.[2]
- The DF4 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

REORDER NUMBER	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	SHOCK CONFIGURATION	SENSING	TIP-TO-PROXIMAL COIL (CM)	CONNECTOR§	LENGTHS (CM)
LDA220Q	Optim	Ext/Ret Helix	8	Dual-coil	True bipolar	17	DF4	52; 58+; 65+
LDA210Q	Optim	Ext/Ret Helix	8	Single-coil	True bipolar	N/A	DF4	52; 58+;65+
LDP220Q	Optim	Tines	8	Dual-coil	True bipolar	17	DF4	52; 58; 65
LDP210Q	Optim	Tines	8	Single-coil	True bipolar	N/A	DF4	52; 58; 65

Indications for Use: The Optisure™ transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart.

A transvenous lead system may offer the patient the benefit of avoiding a thoracotomy for lead implantation. If the initial lead configuration is not effective, repositioning of the lead or other lead configurations should be attempted. In some patients, a nonthoracotomy lead configuration may not provide reliable conversion of arrhythmias, and the use of subcutaneous or epicardial patch defibrillation leads should be considered.

Contraindications: Contraindications for use of the Optisure™ leads with an implantable pulse generator include ventricular tachyarrhythmias resulting from transient or reversible factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Transvenous lead systems are contraindicated for patients with tricuspid valvular disease or a mechanical heart valve. Optisure™ leads are contraindicated for patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. Optisure™ leads are contraindicated for use with extra firm (red color knob) stylets for active fixation lead models. The lead is not designed, sold, or intended for use other than as indicated.

Potential Adverse Events: Possible complications of the use of transvenous lead systems include, but are not limited to, supraventricular or ventricular arrhythmias, conduction disturbances, cardiac perforation, cardiac tamponade, loss of contractility, air embolism, heart wall rupture, myocarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, hemothorax, infection, tissue necrosis, and erosion of the skin.

Warning: Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the pulse generator, or other forces associated with cardiac contractions and patient physical activity, posture, and anatomical influences. Cardiac leads' functional lifetimes can be affected by these and other factors.

Refer to the defibrillator manual for additional system complications and precautions as well as those specific to the pulse generator.

Optisure™

Defibrillation Lead

PRODUCT SPECIFICATIONS

True Bipolar, Active-fixation Defibrillation Leads

Models	**LDA220Q**	**LDA210Q**
Fixation	Ext/Ret Helix	Ext/Ret Helix
Shock Configuration	Dual-coil	Single-coil
Sensing Configuration	True Bipolar	True Bipolar
Min. Size Introducer	8 F	8 F
Lengths (cm)	52; 58; 65	52; 58; 65
Connector[§]	DF4	DF4
Maximum Diameter	7,6 F	7,3 F
Tip-to-Anode Spacing	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	N/A
Tip Electrode Area	6 mm^2	6 mm^2
Steroid Plug	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2
Proximal Shock Coil Area	642 mm^2	N/A
MR Conditional	Yes, MRI Ready (lengths: 58 and 65 cm)	Yes, MRI Ready (lengths: 58 and 65 cm)
MRI Whole-body SAR	≤ 2 W/kg	≤ 2 W/kg

True Bipolar, Passive-fixation Defibrillation Leads

Models	**LDP220Q**	**LDP210Q**
Fixation	Tines	Tines
Shock Configuration	Dual-coil	Single-coil
Sensing Configuration	True Bipolar	True Bipolar
Min. Size Introducer	8 F	8 F
Lengths (cm)	52; 58; 65	52; 58; 65
Connector[§]	DF4	DF4
Maximum Diameter	7,6 F	7,3 F
Tip-to-Anode Spacing	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	N/A
Tip Electrode Area	3.5 mm^2	3.5 mm^2
Steroid Plug	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2
Proximal Shock Coil Area	642 mm^2	N/A
MR Conditional	No	No
MRI Whole-body SAR	N/A	N/A

*MR Conditional Field Strength, 1,5 Tesla.
[†]See MRI procedure information for approved MR Conditional systems device/lead combinations and scan parameters.
[§]Abbott DF1 lead connectors conform to the international connector standard ISO 11318/Amd. Abbott IS-1 lead connectors conform to the international connector standard ISO 5841. Abbott DF4 lead connectors conform to the international connector standard ISO 27186: 2010 (E).
+Indicates lead lengths that are MR Conditional.[*,†]

1. Jenney C, Tan J, Karicherla A, Burke J, Helland J. A New Insulation Material for Cardiac Leads with Potential for Improved Performance. *Heart Rhythm*. 2005;2:S318-S319.
2. Abbott. Engineering Report: Tension and Cable Shortening Comparison. Report 60032635.

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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.

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