SUMMARY

This article includes general information about lead stylets and a guide to stylet model numbers.

Products Referenced

All referenced Boston Scientific stylets.

For comprehensive information on device operation, reference the full instructions for use or found at: **www.bostonscientific-elabeling.com**.

CAUTION: US Federal law restricts this device to sale by or on the order of a physician.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
S-ICD: Subcutaneous Implantable Defibrillator

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Boston Scientific Stylet Guide

Lead stylets aid in positioning a lead into the desired location within the heart. When using a stylet during lead placement, it is recommended to use a stylet model designed for use with the lead being implanted. Stylets of varying type and stiffness are available to accommodate various implant techniques and patient anatomy. Table 1, 2, and 3 below provide the recommended stylets to use with various Boston Scientific leads.

Stylet cap and knob colors provide a visual to differentiate between models. The stylet cap color indicates the stylet length (in centimeters) and the stylet knob color indicates the stiffness of the stylet, as shown in Figure 1.

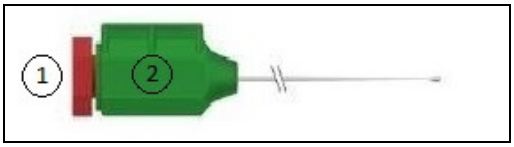

Figure 1. Stylet cap (1) and knob (2) color indicate stylet length and stiffness.

Additionally, the stylet length is imprinted on the stylet cap and the stylet type and/or stiffness is imprinted on the stylet knob, as identified in Figure 2. Note that stylets packaged with the lead are contained in a white hoop (straight stylets) or blue hoop (atrial J stylets).

Stylet Type	Knob Imprint	Hoop Color
Straight:		
Straight	S	White
Tapered	T	White
Long Tapered	LT	White
Atrial J:		
Atrial J	J	Blue
Wide Atrial J	W	Blue

Stylet Stiffness	Knob Imprint
Firm	Firm
Limber	Lmbr
Soft	Soft
Extra Soft	X-soft

Figure 2. Stylet Type and Stiffness Knob Imprints and Hoop Color

Boston Scientific Stylets

The following tables provide recommended stylets for use with Boston Scientific implantable transvenous leads. Ensure that an appropriate stylet length is selected for the lead being implanted. Please refer to specific product labeling for additional stylet information. Note that some lead models may not be approved in all geographies.

Table 1: RELIANCE 4-FRONT™, ENDOTAK RELIANCE 4-SITE™, and ENDOTAK RELIANCE™ Leads

Lead Models	Stylet Model	Stylet Type	Length (cm)	Stiffness	Diameter (in)	Knob W = White G = Green	Cap Y = Yellow G = Green B = Black
017X, 018X, 026X, 027X, 028X, 029X, 063X, 065X, 066X, 067X, 068X, 069X	6601	Straight	59	Soft	0.014	G	Y
	6602	Straight	59	Firm	0.016	W	Y
	6972	Straight	64	Soft	0.014	G	G
	6971	Straight	64	Firm	0.016	W	G
	6964	Straight	70	Soft	0.014	G	B
	6963	Straight	70	Firm	0.016	W	B

Table 2: INGEVITY™ MRI and INGEVITY™+

Lead Models	Stylet Model	Stylet Type	Length (cm)	Stiffness	Diameter (in)	Knob Y = Yellow G = Green	Cap Y = Yellow W = White R = Red
7735	5003	Straight	45	X-Soft	0.013	Y	W
	5012	Long Tapered	45	Soft	0.014	G	W
7740, 7840	5003	Straight	45	X-Soft	0.013	Y	W
	5012	Long Tapered	45	Soft	0.014	G	W
	6506	Atrial J	45	Soft	0.014	G	W
	6053	Wide Atrial J	45	Soft	0.014	G	W
7731	5004	Straight	52	X-Soft	0.013	Y	R
	5013	Long Tapered	52	Soft	0.014	G	R
7736	5004	Straight	52	X-Soft	0.013	Y	R
	5013	Long Tapered	52	Soft	0.014	G	R
7741, 7841	5004	Straight	52	X-Soft	0.013	Y	R
	5013	Long Tapered	52	Soft	0.014	G	R
	6586	Atrial J	52	Soft	0.014	G	R
	6054	Wide Atrial J	52	Soft	0.014	G	R
7732	5005	Straight	59	X-Soft	0.013	Y	Y
	5014	Long Tapered	59	Soft	0.014	G	Y
7742, 7842	5005	Straight	59	X-Soft	0.013	Y	Y
	5014	Long Tapered	59	Soft	0.014	G	Y
	6603	Atrial J	59	Soft	0.014	G	Y
	6055	Wide Atrial J	59	Soft	0.014	G	Y

Table 3: FINELINE™ II Leads

Lead Models	Stylet Model	Stylet Type	Length (cm)	Stiffness	Diameter (in)	Knob Y = Yellow W = White G = Green	Cap Y = Yellow M = Mint P= Purple
4469	6061	Straight	45	Limber	0.014	G	Y
	6064	Straight	45	Firm	0.016	W	Y
	6032	Tapered	45	Limber	0.014	G	Y
	6038	Atrial J	45	Limber	0.014	G	Y
	6041	Atrial J	45	Firm	0.016	W	Y
4472	6061	Straight	45	Limber	0.014	G	Y
	6032	Tapered	45	Limber	0.014	G	Y
	6044	Tapered	45	Soft	0.013	Y	Y
	6038	Atrial J	45	Limber	0.014	G	Y
	6050	Atrial J	45	Soft	0.013	Y	Y

4479	6061	Straight	45	Limber	0.014	G	Y
	6064	Straight	45	Firm	0.016	W	Y
	6032	Tapered	45	Limber	0.014	G	Y
	6035	Tapered	45	Firm	0.016	W	Y
4456	6062	Straight	52	Limber	0.014	G	M
	6065	Straight	52	Firm	0.016	W	M
	6033	Tapered	52	Limber	0.014	G	M
	6036	Tapered	52	Firm	0.016	W	M
4458	6048	Straight	52	Soft	0.013	Y	M
	6062	Straight	52	Limber	0.014	G	M
	6033	Tapered	52	Limber	0.014	G	M
	6045	Tapered	52	Soft	0.013	Y	M
4470	6062	Straight	52	Limber	0.014	G	M
	6065	Straight	52	Firm	0.016	W	M
	6033	Tapered	52	Limber	0.014	G	M
	6039	Atrial J	52	Limber	0.014	G	M
	6042	Atrial J	52	Firm	0.016	W	M
4473	6062	Straight	52	Limber	0.014	G	M
	6033	Tapered	52	Limber	0.014	G	M
	6045	Tapered	52	Soft	0.013	Y	M
	6039	Atrial J	52	Limber	0.014	G	M
	6051	Atrial J	52	Soft	0.013	Y	M
4480	6062	Straight	52	Limber	0.014	G	M
	6065	Straight	52	Firm	0.016	W	M
	6033	Tapered	52	Limber	0.014	G	M
	6036	Tapered	52	Firm	0.016	W	M
4457	6063	Straight	58	Limber	0.014	G	P
	6066	Straight	58	Firm	0.016	W	P
	6034	Tapered	58	Limber	0.014	G	P
	6037	Tapered	58	Firm	0.016	W	P
4459	6049	Straight	58	Soft	0.013	Y	P
	6063	Straight	58	Limber	0.014	G	P
	6034	Tapered	58	Limber	0.014	G	P
	6046	Tapered	58	Soft	0.013	Y	P
4471	6063	Straight	58	Limber	0.014	G	P
	6066	Straight	58	Firm	0.016	W	P
	6034	Tapered	58	Limber	0.014	G	P
	6040	Atrial J	58	Limber	0.014	G	P
	6043	Atrial J	58	Firm	0.016	W	P
4474	6063	Straight	58	Limber	0.014	G	P
	6034	Tapered	58	Limber	0.014	G	P
	6046	Tapered	58	Soft	0.013	Y	P
	6040	Atrial J	58	Limber	0.014	G	P
	6052	Atrial J	58	Soft	0.013	Y	P

INGEVITY™ MRI and INGEVITY™+ Pace/Sense Lead

Indications

This Boston Scientific lead is indicated for use as follows:

- intended for chronic pacing and sensing in the right atrium and/or right ventricle when used with a compatible pulse generator (INGEVITY+ and INGEVITY MRI extendable/retractable fixation)
- intended for chronic pacing and sensing in the right atrium (Preformed Atrial J) or right ventricle (Straight) when used with a compatible pulse generator (INGEVITY MRI tined fixation)

Contraindications

Use of these leads are contraindicated for the following patients:

- Patients with a hypersensitivity to a nominal single dose of 0.91mg dexamethasone acetate (for INGEVITY+ and INGEVITY MRI extendable retractable fixation)
- Patients with a hypersensitivity to a nominal single dose of 0.61mg dexamethasone (for INGEVITY MRI tined fixation)
- Patients with mechanical tricuspid heart valves.

Warnings

Read the manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads. Implant of the system cannot be performed in an MRI site Zone III (and higher). Take care to obtain appropriate electrode position. Failure to do so may result in suboptimal lead measurements. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements of the implanted system. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as a complete list of MRI related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.
For INGEVITY+ and INGEVITY MRI extendable/retractable fixation: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow-up testing.

Potential Adverse Events

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature: Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Pulse generator and/or lead migration; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion).
For a list of potential adverse events associated with MRI scanning, refer to the ImageReadyTM MR Conditional Pacing System or Defibrillation System MRI Technical Guide.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436283 Rev. B)*

FINELINE™ II STEROX

Indications

FINELINE™ II STEROX Leads are intended for chronic pacing and sensing of the ventricle (4456, 4457, 4458, 4459) or the atrium (4479, 4480) when used with a compatible pulse generator.

Contraindications

Do not use these leads in patients with: mechanical tricuspid heart valves; a hypersensitivity to a maximum single dose of a 0.94 mg of dexamethasone acetate.

Warnings

Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Implant of the system cannot be performed in an MRI site zone III (and higher). The use of battery-powered equipment is recommended during lead implantation and testing. Line-powered equipment used in the vicinity of the patient must be properly grounded. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. For single patient use only. Do not reuse, reprocess, or resterilize.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: general, handling, implanting. NOTE: Use of Boston Scientific MR Conditional pulse generators and leads is required for an implanted system to be considered MR Conditional. Refer to the appropriate ImageReady MR Conditional Pacing System or Defibrillation System MRI Technical Guide for model numbers of pulse generators, leads, accessories, and other system components needed to satisfy the Conditions of Use for MR Conditional scanning.
NOTE: Other implanted devices or patient conditions may cause a patient to be ineligible for an MRI scan, independent of the patient's ImageReady MR Conditional System.

Potential Adverse Events

Based on the literature and on pulse generator and/or lead implant experience, the following list includes the possible adverse events associated with implantation of products described in this literature: Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Pulse generator and/or lead migration; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion).
For a list of potential adverse events associated with MRI scanning, refer to the appropriate ImageReady MR Conditional Pacing System or Defibrillation System MRI Technical Guide.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436282 Rev. A)*

FINELINE™ II STEROX EZ™

Indications

The lead is intended for chronic pacing and sensing of the atrium or ventricle when used with a compatible pulse generator.

Contraindications

Do not use this lead in patients with: mechanical tricuspid heart valves; a hypersensitivity to a maximum single dose of approximately 0.94 mg of dexamethasone acetate; an allergy to mannitol.

Warnings

Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Implant of the system cannot be performed in an MRI site zone III (and higher). The use of battery-powered equipment is recommended during lead implantation and testing. Line-powered equipment used in the vicinity of the patient must be properly grounded. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not reuse, reprocess, or resterilize.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: general, handling, implanting.
NOTE: Use of Boston Scientific MR Conditional pulse generators and leads is required for an implanted system to be considered MR Conditional. Refer to the appropriate ImageReady MR Conditional Pacing System or Defibrillation System MRI Technical Guide for model numbers of pulse generators, leads, accessories, and other system components needed to satisfy the Conditions of Use for MR Conditional scanning. NOTE: Other implanted devices or patient conditions may cause a patient to be ineligible for an MRI scan, independent of the patient's ImageReady MR Conditional System.

Potential Adverse Events

Based on the literature and on pulse generator and/or lead implant experience, the following list includes the possible adverse events associated with implantation of products described in this literature: Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve

damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Pulse generator and/or lead migration; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion).
For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Pacing System or Defibrillation System MRI Technical Guide.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436282 Rev. A)*

ENDOTAK RELIANCE® IS-1 Extendable-Retractable

Indications

The ENDOTAK RELIANCE leads provide pacing and rate-sensing and deliver cardioversion and defibrillation shocks for ICD automatic implantable cardioverter defibrillator systems.

Contraindications

Use of this Boston Scientific active fixation lead is contraindicated for the following patients:

- Patients who have a unipolar pacemaker
- Patients with a hypersensitivity to a maximum single dose of 1.1 mg dexamethasone acetate
- Patients with mechanical tricuspid heart valves

Warnings

Do not attempt to use the ENDOTAK lead system with any device other than a commercially available implantable defibrillator system with which it has been tested and demonstrated to be safe and effective. Do not implant in MRI site Zone III. The safety and efficacy of the tip electrode placement above midseptum has not been clinically established. Lead fracture, dislodgment, abrasion and/or an incomplete connection can cause a periodic or continual loss of rate-sensing, possibly resulting in arrhythmia non-detection; or over-sensing of rate, possibly resulting in inappropriate delivery of a pulse generator shock; or inadequate delivery of conversion energy. Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. Take care to obtain appropriate electrode position. In order to deliver defibrillation therapy, the single-coil ENDOTAK RELIANCE S or ENDOTAK RELIANCE SG lead must be implanted with a separate defibrillation electrode. When connecting the lead to the ICD pulse generator, it is very important that proper connections are made. Use of any component of the ENDOTAK lead system to assist in delivery of external-source rescue shocks could cause extensive tissue damage. Always have external defibrillation protection available during implant. Do not kink, twist, or braid the lead terminals as doing so could cause lead insulation abrasion damage. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. For single patient use only. Do not reuse, reprocess or resterilize. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Do not expose a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

Precautions

Refer to the Implant Information, Implantation, and Post-Implant Evaluation sections of the manual for cautions specific to handling, implanting, and testing the ENDOTAK RELIANCE lead family. Failure to observe these cautions could result in incorrect lead implantation, lead damage, and/or harm to the patient.

Potential Adverse Events

Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Coronary venous spasm; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Local tissue reaction; Low amplitude VF signals; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., irritability, injury, tissue damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Post-shock rhythm disturbances; Pulse generator and/or lead migration; Shunting current during defibrillation with internal or external paddles; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion).
For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation MRI Technical Guide.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436281 Rev. A)*

RELIANCE 4–FRONT™

Indications and Usage

This Boston Scientific lead is indicated for use as follows:

- Intended for pacing, rate-sensing, and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator

Contraindications

Use of this Boston Scientific lead is contraindicated for the following patients:

- Patients who have a unipolar pacemaker
- Patients with a hypersensitivity to a maximum single dose of 1.1 mg dexamethasone acetate
- Patients with mechanical tricuspid heart valves

Warnings

Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Do not use any component of the lead system to assist in delivery of external-source rescue shocks or extensive tissue damage could occur. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. The lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the lead terminal, other than the terminal pin, even when the lead cap is in place. Implant of the system cannot be performed in an MRI site Zone III (and higher). In order to deliver defibrillation therapy, the single-coil models must be implanted with an additional defibrillation electrode. For DF4-LLHH or DF4-LLHO leads, only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as for a complete list of MRI-related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

EXTENDABLE/RETRACTABLE models: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established. Use fluoroscopy to verify that the lead tip is directed toward the apex when implanted.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow up testing.

Potential Adverse Events

Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature: Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Local tissue reaction; Low amplitude VF signals; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., irritability, injury, tissue damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Post-shock rhythm disturbances; Pulse generator and/or lead migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion).
For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide.

CAUTION: *Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. (92436280 Rev. A)*

ENDOTAK™ RELIANCE™ IS-1 Tined

Indications

The ENDOTAK RELIANCE G lead, Models 0174/0175/0176/0177, and the ENDOTAK RELIANCE SG lead, Models 0170/0171, provide pacing and rate-sensing and deliver cardioversion and defibrillation shocks for ICD automatic implantable cardioverter defibrillator systems.

Contraindications
Use of the ENDOTAK RELIANCE G lead and ENDOTAK RELIANCE SG lead is contraindicated for the following patients;

- Patients who have a unipolar pacemaker
- Patients with a hypersensitivity to a maximum single dose of 1.1 mg dexamethasone acetate
- Patients with mechanical tricuspid heart valves

Warnings
Do not attempt to use the ENDOTAK lead system with any device other than a commercially available implantable defibrillator system with which it has been tested and demonstrated to be safe and effective. Do not implant in MRI site Zone III. Lead fracture, dislodgment, abrasion and/or an incomplete connection can cause a periodic or continual loss of rate-sensing, possibly resulting in arrhythmia non-detection; or over-sensing of rate, possibly resulting in inappropriate delivery of a pulse generator shock; or inadequate delivery of conversion energy. Although pliable, the lead body is not designed to tolerate excessive flexing, bending, or tension. Take care to obtain appropriate electrode position. In order to deliver defibrillation therapy, the single-coil ENDOTAK RELIANCE SG lead must be implanted with a separate defibrillation electrode. When connecting the lead to the ICD pulse generator, it is very important that proper connections are made. Use of any component of the ENDOTAK lead system to assist in delivery of external-source rescue shocks could cause extensive tissue damage. Do not kink, twist, or braid the lead terminals as doing so could cause lead insulation abrasion damage. For single patient use only. Do not reuse, reprocess or resterilize. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Do not expose a patient with an implanted pulse generator and/or lead to diathermy treatment since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

Precautions
Refer to the General Precaution section of the manual for cautions specific to the ENDOTAK RELIANCE lead family. Failure to observe these cautions could result in incorrect lead implantation, lead damage, and/or harm to the patient.

Potential Adverse Events
Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Breakage/failure of the implant instruments; Cardiac perforation/tamponade; Chronic nerve damage; Component failures; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Erosion/extrusion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or cysts; Heart block; Hemorrhage; Hemothorax; Inability to provide therapy; Inappropriate therapy/shocks; Incisional pain; Incomplete connection with pulse generator; Infection; Keloid formation; Lead abrasion; Lead displacement/dislodgment; Lead fracture, insulation break; Lead tip deformation and/or breakage; Local tissue reaction; Low amplitude VF signals; Malignancy or skin burn due to fluoroscopic radiation; Myocardial injury; Myocardial irritability; Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Post-shock rhythm disturbances; Pulse generator and/or lead migration; Shunting of current or insulation of myocardium during defibrillation with internal or external paddles; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Threshold elevation; Thrombosis/thromboemboli; Valve damage; Venous occlusion; Venous perforation/erosion For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation MRI Technical Guide.

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ENDOTAK RELIANCE™ Leads

Indications
This Boston Scientific lead is indicated for use as follows: Intended for pacing, rate-sensing and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator.

Contraindications
Use of this lead is contraindicated for the following patients: Patients who have a unipolar pacemaker, Patients with a hypersensitivity to a maximum single dose of 1.1 mg dexamethasone acetate, Patients with mechanical tricuspid heart valves.

Warnings
Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation protection available during implant. Do not use any component of the lead system to assist in delivery of external-source rescue shocks. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. The lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads. Use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the lead terminal, other than the terminal pin even when the lead cap is in place. Implant of the system cannot be performed in an MRI site zone III (and higher). The safety and efficacy of the tip electrode placement above midseptum has not been clinically established. In order to deliver defibrillation therapy, the single-coil models must be implanted with an additional defibrillation electrode. Use fluoroscopy to verify that the lead tip is directed toward the apex when implanted. For DF4-LLHH or DF4-LLHO leads, only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

Precautions
For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow up testing.

Potential Adverse Events
Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature: Air embolism; Allergic reaction; Arterial damage with subsequent stenosis; Bleeding; Bradycardia; Breakage/failure of the implant instruments; Cardiac perforation; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Hemorrhage; Hemothorax; Inability to defibrillate or pace; Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing); Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgment; Lead fracture; Lead insulation breakage or abrasion; Lead tip deformation and/or breakage; Local tissue reaction; Low amplitude VF signals; Malignancy or skin burn due to fluoroscopic radiation; Myocardial trauma (e.g., irritability, injury, tissue damage); Myopotential sensing; Oversensing/undersensing; Pericardial rub, effusion; Pneumothorax; Post-shock rhythm disturbances; Pulse generator and/or lead migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion) For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide.

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