SUMMARY

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

Products Referenced

All referenced Boston Scientific stylets.

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.

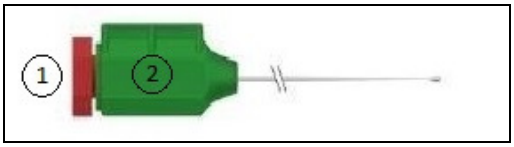

Figure 1. Stylet cap (1) and knob (2) color indicate stylet length and stiffness.

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

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	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	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	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 Extendable/Retractable Fixation and Tined Fixation

Indications

INGEVITY™ MRI Leads are intended for chronic pacing and sensing in the right atrium (only preformed atrial J with the Tined Fixation) and/or right ventricle (only straight with the tined fixation) when used with a compatible pulse generator.

Contraindications

Use of these leads are contraindicated in: patients with a hypersensitivity to a nominal single dose dexamethasone acetate: 0.61 mg for Tined Fixation, 0.91 mg for Extendable Retractable Fixation; and patients with mechanical tricuspid heart valves.

Warnings

Refer to the product labeling before implanting the lead 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 Extendable/Retractable Fixation: The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established.

Precautions

Refer to the implant product labeling for cautions specific to clinical considerations, sterilization and storage, handling, implantation, hospital and medical environments, and follow up testing of the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient. Prior to implantation of this lead, confirm lead/pulse generator compatibility. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. Defibrillation equipment should be kept nearby during the implant procedure. Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted.
For Extendable/Retractable Fixation: Avoid creating sharp bends while extending or retracting the helix. Sharp bends can increase the risk of breaking the conductor coil or fixation mechanism during helix extension or retraction. Do not rotate the terminal pin clockwise or counterclockwise more than the recommended maximum number of turns indicated in the specifications. Continuing to rotate the terminal pin once the helix is fully extended or retracted (as indicated by fluoroscopy) can damage the lead, cause a conductor coil break during fixation, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise.

Potential Adverse Events

Potential adverse events include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure-related, and component failure. In rare cases severe complications or device failures can occur.
For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Refer to the physician's manual(s) for specific indications, contraindications, warning/precautions and adverse events. Rx only. (Rev. A)

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 approximately 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

Use of Boston Scientific MR Conditional pulse generators and leads is required for an implanted system to be considered MR Conditional. 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 Pacing System.. Prior to implantation of this lead, confirm lead/pulse generator compatibility. Defibrillating equipment should be kept nearby during the implant procedure. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this lead. Refer to the PDR for potential adverse effects. Refer to the lead product labeling for cautions specific to handling and implanting the lead.

Potential Adverse Events

Potential adverse events include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure-related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the physician's manual(s) for specific indications, contraindications, warning/precautions and adverse events. Rx only.
(Rev. E)

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

Use of Boston Scientific MR Conditional pulse generators and leads is required for an implanted system to be considered MR Conditional. 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 Pacing System. Refer to the implant product labeling for cautions specific to handling and implanting the lead. Prior to implantation of this lead, confirm lead/pulse generator compatibility. Defibrillating equipment should be kept nearby during the implant procedure. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this lead. Refer to the PDR for potential adverse effects. Refer to the lead product labeling for cautions specific to handling and implanting the lead.

Potential Adverse Events

Potential adverse events include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure-related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the physician's manual(s) for specific indications, contraindications, warning/precautions and adverse events. Rx only.
(Rev. A)

ENDOTAK RELIANCE™ G/SG Leads with DF4-LLHH and DF4-LLHO connectors

Indications

This Boston Scientific lead is 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, and 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, follow-up testing

Potential Adverse Events
Potential adverse events from implantation of the ICD lead system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/ precautions and adverse events. Rx only.
(Rev. D)