Medtronic

ATTAIN STARFIX® 4195

Steroid eluting, transvenous, unipolar, left ventricular, over the wire, cardiac vein pacing lead with deployable lobes

Technical Manual

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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1 Device description

The Medtronic Attain StarFix Model 4195 steroid eluting, transvenous, unipolar, left ventricular, over the wire, cardiac vein pacing lead with deployable lobes is designed for pacing and sensing via a cardiac vein, when used in conjunction with a compatible implantable pulse generator or implantable cardiac defibrillator.

The lead features deployable lobes that are isodiametric with the lead body upon insertion and are deployable after the desired position is obtained (see Section 10.2, "Specifications drawing (nominal)", page 18). Each set of lobes is separated by radiopaque indicator rings. The lobes are deployed by advancing the push tubing. During the implant procedure, the lobes can be undeployed by withdrawing the push tubing. The push tubing has a hydrophilic coating on the inner surface. Upon exposure to body fluids, this coating is hydrated, minimizing friction between the push tubing and the insulation to allow easier deployment of the lobes.

The lead tip contains a tapered annular platinum alloy electrode tip. The electrode tip contains a molded silicone rubber seal. This molded tip seal provides a fluid seal that allows guide wire passage and reduces blood ingress. The lead also features nickel alloy conductors, polyurethane insulation and push tubing, and an IS-1[1] Unipolar (UNI) lead connector.

The distal tip of the lead contains a dose of 30 µg (micrograms) of beclomethasone dipropionate (BDP). Upon exposure to body fluids, the BDP elutes from the lead tip. The BDP is known to suppress the inflammatory response that is believed to cause threshold rises typically associated with implanted pacing electrodes.

The Model 4195 lead can be positioned with the aid of a guide wire or with a stylet. If a stylet is used, use only the stylets packaged with the lead or in a stylet kit (downsized knob). Always use a stylet that is 3 cm shorter than the lead length listed on the IS-1 connector label.

Note: To implant the Model 4195 lead in a cardiac vein, a compatible delivery system is required. A compatible delivery system includes a guide catheter and either a hemostasis valve or an introducer valve that can be removed or that allows passage over the IS-1 connector. Contact a Medtronic representative for further information regarding compatible delivery systems.

1.1 Package contents

Leads and accessories are supplied sterile. Each package contains the following items:

- 1 lead with stylet, anchoring sleeve, and retention sleeve
- 2 guide wire insertion tools
- 2 acute retention clips (one is on the lead)
- 1 guide wire clip
- 1 guide wire steering handle
- extra stylets
- product literature

1.2 Accessory descriptions

Stylet – A stylet provides additional stiffness and controlled flexibility for maneuvering the lead into position. Each stylet knob is labeled with the stylet diameter and length.

Guide wire insertion tool – A guide wire insertion tool provides additional control when inserting a guide wire into the lead connector pin or the lead tip.

Anchoring sleeve – An anchoring sleeve secures the lead to prevent it from moving and protects the lead insulation and conductors from damage caused by tight sutures.

Retention sleeve – A retention sleeve secures the push tubing with respect to the lead body when the acute retention clip is locked (acutely) or when sutures are tied (chronically).

Acute retention clip – An acute retention clip can be locked on the retention sleeve to retain push tubing and lobe position during lead positioning or repositioning.

Guide wire clip – A guide wire clip secures the excess guide wire and helps to protect and maintain the sterility of the guide wire.

Guide wire steering handle – A guide wire steering handle is used only with guide wires 0.46 mm (0.018 in) or less in diameter. The steering handle provides additional control and steerability of the guide wire.

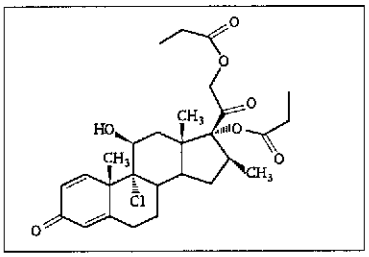
2 Drug component description

The drug substance present in the Model 4195 lead is beclomethasone 17,21-dipropionate, also known as beclomethasone dipropionate or BDP. The chemical name of

[1] IS-1 UNI refers to an international Connector Standard (ISO 5841-3) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

beclomethasone dipropionate is 9-chloro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20 dione 17,21-dipropionate. The structural formula for BDP is shown below:

Figure 1. Structural formula for BDP



BDP is a diester of beclomethasone, a synthetic halogenated corticosteroid. BDP is a white to creamy white, odorless powder with a molecular formula of $C_{28}H_{37}ClO_7$ and a molecular weight of 521.05. It is very slightly soluble in water, very soluble in chloroform, and freely soluble in acetone and alcohol.

The dosage of BDP per Model 4195 lead is 30 µg.

3 Indications

The Attain StarFix Model 4195 steroid eluting, transvenous lead with deployable lobe fixation is intended for chronic pacing and sensing of the left ventricle via a cardiac vein, when used in conjunction with a compatible implantable pulse generator or implantable cardiac defibrillator.

4 Contraindications

Coronary vasculature – This lead is contraindicated for patients with coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Steroid use – Do not use in patients for whom a single dose of 30 µg (micrograms) of beclomethasone dipropionate (BDP) cannot be tolerated.

5 Warnings and precautions

Removing the lead following long-term implant – The risk and difficulty of removing the Medtronic Attain StarFix Model 4195 lead following long-term implant will be characterized in a post-approval study. In light of the novel fixation mechanism of the Model 4195 lead, there may be unique risks and difficulty associated with late revision and removal of the Model 4195 lead. Therefore, referral to an experienced extraction center is recommended. Refer to "Chronic repositioning or removal", page 6.

Information on repositioning and removal experience from the Model 4195 clinical study is located in the Clinical Study Summary (section 5.7) posted on the Medtronic website. If you do not have web access, a printed copy of the Clinical Study Summary can be obtained from your Medtronic representative or call the toll-free number located on the back cover. When available, post-approval study data will be located on this website.

Single use – The lead is for single use only.

Inspecting the sterile package – Inspect the sterile package with care before opening it.

- Contact a Medtronic representative if the seal or package is damaged.
- Store at 25 °C (77 °F). Excursions from this storage temperature are permitted in the range of 15 to 30 °C (59 to 86 °F). (See USP Controlled Room Temperature.) According to USP excursion conditions, transient spikes up to 40 °C (104 °F) are permitted as long as they do not exceed 24 hours.
- Do not use the product after its expiration date.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment. This lead is for single use only and is not intended to be resterilized.

Necessary hospital equipment – Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during post-implant testing. Backup pacing should be readily available during implant. Use of the delivery system or leads may cause heart block.

Line-powered and battery-powered equipment – An implanted lead forms a direct current path to the myocardium. During lead implant and testing, use only battery-powered equipment or line-powered equipment specifically designed for this purpose to protect against fibrillation that may be caused by alternating currents. 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.

Magnetic resonance imaging (MRI) – Do not use magnetic resonance imaging (MRI) on patients who have this device implanted. MRI can induce currents on implanted leads, potentially causing tissue damage and the induction of tachyarrhythmias.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Drug interactions – Drug interactions of BDP with the Model 4195 lead have not been studied.

Use of multiple leads – Prior to implanting the Model 4195 lead, total patient exposure to BDP should be considered when implanting multiple leads.

Handling the distal tip – Avoid reducing the amount of steroid available before implanting the lead. Reducing the available amount of steroid may adversely affect low-threshold performance.

- Do not allow the electrode surface to come in contact with surface contaminants.
- Do not wipe or immerse the electrode in fluid, except blood or saline, at the time of implant.

Handling the lead – Handle the lead with care at all times.

- Always use an acute retention clip to reposition or to remove the lead.
- Always attempt to undeploy the lobes before repositioning or removing the lead.
- If a stylet is used for lead positioning, use only the stylets packaged with the lead or in a stylet kit (downsized knob). Always use a stylet that is 3 cm shorter than the lead length listed on the IS-1 connector label. Other stylets may extend beyond the lead tip causing lead tip seal damage or injury or perforation of the cardiac vein or heart.
- Verify that the stylet does not extend beyond the lead tip prior to inserting the lead into the delivery system. Implanting the lead with a stylet extending beyond the lead tip could cause injury or perforation of the cardiac vein or heart.
- Do not implant the lead if it is damaged. Return the lead to a Medtronic representative.
- Protect the lead from materials that shed small particles such as lint and dust. Lead insulators attract these particles.
- Handle the lead with sterile surgical gloves that have been rinsed in sterile water or a comparable substance.
- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pin.
- Do not immerse the lead in mineral oil, silicone oil, or any other liquid, except blood or saline, at the time of implant.
- Do not implant the acute retention clip.
- Use all 3 suture grooves on the retention sleeve.
- Use an anchoring sleeve with all leads. Ensure that the anchoring sleeve is positioned close to the lead retention sleeve, to prevent inadvertent passage of the anchoring sleeve into the vein. If wiping the lead is necessary before insertion, ensure that the anchoring sleeve remains in position.
- Do not force the guide catheter, leads, or lobe deployment if significant resistance is encountered. The use of guide catheters or leads may cause trauma to the heart.

Handling the guide wire – Handle the guide wire with care at all times.

- Damage to a guide wire may prevent the guide wire from performing with accurate torque response and control and may cause vessel damage. For additional information about vessel damage and other potential adverse events, refer to the technical manual packaged with the appropriate guide wire.
- If the distal end of the guide wire becomes severely kinked or twisted, it may be difficult to withdraw it back through the lead. Therefore, if there is an indication that the distal end of the guide wire has become damaged, or if there is significant resistance in guide wire passage, remove the lead and guide wire together as a unit. Remove the guide wire from the lead and re-insert a new guide wire into the lead. Do not use excessive force to retract the guide wire from the lead. Refer to the product literature packaged with the guide wire for additional information.

Handling the stylet – Handle the stylet with care at all times.

- To minimize the likelihood of trauma to the vein and to maintain lead flexibility while advancing the lead through the vein, keep the stylet withdrawn 1 to 2 cm.
- Always withdraw the stylet 2 to 3 cm before attempting to undeploy the lobes. Failure to withdraw the stylet may cause the stylet to extend beyond the lead tip, causing lead tip seal damage or injury or perforation of the cardiac vein or heart.
- Do not use excessive force or surgical instruments when inserting a stylet.
- Avoid overbending, kinking, or blood contact on stylets.
- Use a new stylet when blood or other fluids accumulate on the stylet. Accumulated fluids may cause damage to the lead or difficulty in passing the stylet through the lead.
- Curving the distal end of the stylet prior to insertion into the lead will achieve a curvature at the distal end of the lead. Do not use a sharp object to impart a curve to the distal end of the stylet.

Concurrent devices – Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference in the sensing capabilities of the devices. Previously implanted pulse generators and implantable cardioverter defibrillators should generally be explanted.

Chronic repositioning or removal – Chronic repositioning or removal of leads may be difficult because of fibrotic tissue development. The risk and difficulty of removing the Medtronic Attain StarFix Model 4195 lead following long-term implant will be characterized in a post-approval study. In light of the novel fixation mechanism of the Model 4195 lead, there may be unique risks and difficulty associated with late revision and removal of the Model 4195 lead. Therefore, referral to an experienced extraction center is recommended.

See the Clinical Study Summary for extraction experience from the clinical study. The use of extraction tools, including sheaths, within or beyond the coronary sinus has not been evaluated with the Model 4195 lead. If you do not have web access, a printed copy of the Clinical Study Summary can be obtained from your Medtronic representative or call the toll-free number located on the back cover.

When attempting to undeploy the lobes, proceed with extreme caution, particularly if difficulty undeploying the lobes or moving the lead body is encountered. If lobes cannot be undeployed, and simple traction does not result in lead removal, it is at the physician's discretion to try other removal techniques or cap the lead. Always use an acute retention clip when a lead must be removed or repositioned. Return all removed leads, unused leads, or lead sections to Medtronic for analysis.

- Verify lead length on the IS-1 label on the connector to choose an appropriate stylet kit (downsized knob) length. Always use a stylet that is 3 cm shorter than the lead length listed on the IS-1 connector label. For example, choose a stylet kit (downsized knob) with stylets 75 cm long for a lead 78 cm long. Other stylets may extend beyond the lead tip, causing lead tip seal damage or injury or perforation of the cardiac vein or heart.
- Always withdraw the stylet 2 to 3 cm before attempting to undeploy the lobes. Failure to withdraw the stylet may cause the stylet to extend beyond the lead tip, causing lead tip seal damage or injury or perforation of the cardiac vein or heart.
- Lead removal or undeployment of the lobes may result in avulsion of the endocardium, valve, or vein.
- Lead junctions may separate, leaving the lead tip, lobe pieces, indicator rings, or bare wire in the heart or vein.
- Chronic repositioning of a lead may adversely affect a steroid lead's low-threshold performance.
- Cap abandoned leads to avoid transmitting electrical signals.
- For leads that have been severed, seal the remaining lead end and suture the lead to adjacent tissue.
- If a lead is removed during repositioning, inspect it carefully for insulator, conductor coil, or retention sleeve damage. Verify that the lobes are not damaged and remain deployable before repositioning. If any damage is observed or the lobes are undeployable, do not reuse the lead and return to Medtronic.

6 Drug information

6.1 Mechanism of action

Steroids suppress the inflammatory response that is believed to cause threshold rises typically associated with implanted pacing electrodes. Beclomethasone dipropionate (BDP) is a synthetic steroid of the glucocorticoid family. Glucocorticoid steroids have potent anti-inflammatory actions via direct and indirect effects on major inflammatory cells. While the mechanism of action of glucocorticoids is not fully understood, it is known that glucocorticosteroids bind to a cytoplasmic glucocorticoid receptor as well as to a membrane-bound receptor. Binding to the cytoplasmic receptor leads to receptor activation and translocation to the nucleus. The receptor interacts with specific DNA sequences (glucocorticoid responsive elements) within the regulatory regions of affected genes. Thus, glucocorticoids inhibit the production, by multiple cells, of transcription factors that are critical in generating the inflammatory response.

6.2 Pharmacokinetics and metabolism

Pharmacokinetics – The pharmacokinetics of BDP and its metabolites following implant of the Model 4195 lead was not evaluated in human clinical trials. However, pre-clinical intravenous dosing studies of BDP in canines showed that the original dose of BDP is rapidly eliminated, with plasma levels of BDP falling below the lowest level of quantitation within 2 hours. The primary active metabolite, beclomethasone-17-monopropionate (B-17-MP), was detected rapidly in the plasma, and remained at measurable levels for up to 8 hours. The metabolite beclomethasone (BOH) was formed at minimal levels, and was no longer detectable after 6 hours. After 24 hours, no measurable levels of BDP or any of its metabolites were observed in plasma.

Metabolism – BDP is a prodrug with weak glucocorticoid receptor binding affinity that is hydrolyzed via esterase enzymes to the active metabolite B-17-MP. Minor inactive metabolites, beclomethasone-21-monopropionate (B-21-MP) and beclomethasone (BOH), are also formed. The mean elimination half-life of B-17-MP is 2.7 hours. Irrespective of the route of administration (injection, oral, or inhalation), BDP and its metabolites are mainly excreted in the feces. Less than 10% of the drug and its metabolites are excreted in the urine.

6.3 Mutagenesis, carcinogenicity, and reproductive toxicity

The mutagenesis, carcinogenicity, and reproductive toxicity of the Model 4195 lead have not been evaluated. However, the mutagenesis, carcinogenicity, and reproductive toxicity of BDP have previously been evaluated.

Mutagenesis – BDP did not induce gene mutation in bacterial cells or mammalian Chinese Hamster ovary (CHO) cells in vitro or in the mouse micronucleus test in vivo.

Carcinogenicity – BDP was administered to rats for a total of 95 weeks (13 weeks inhalation: up to 0.4 mg / kg daily, 82 weeks oral administration: up to 2.4 mg / kg daily). These dosage levels represent approximately 40 times the maximum recommended human intranasal dosage on a mg / m^2 basis. There was no evidence of carcinogenic activity[2]. It is known that glucocorticoids are potent inhibitors of carcinogenesis[3]. Specifically, in a mouse model of benzypyrene-induced pulmonary adenoma formation, BDP inhalation reduced carcinoma formation by up to 60%[3].

Reproductive toxicity – Although there are no adequate and controlled studies that have been conducted to date in humans, subcutaneously administered BDP, at dosages that are approximately 1.2 times the maximum human intranasal dosage (on a mg / m^2 basis), have been shown to be teratogenic and embryocidal in rats and rabbits receiving 0.1 mg / kg and 0.025 mg / kg daily, respectively. Teratogenic effects in these animals include fetal resorption, cleft palate, agnathia, microstomia, aglossia, delayed ossification, and agenesis of the thymus gland. Teratogenic or embryocidal effects were not observed in rats following a combination of oral administration and inhalation of BDP at dosages of 10 and 0.1 mg / kg daily, respectively (approximately 250 times the maximum recommended human intranasal dosage [on a mg / m^2 basis][2]).

6.4 Pregnancy

Pregnancy category C – Like other corticosteroids, BDP was teratogenic and embryocidal in the mouse and rabbit at a subcutaneous dose of 0.1 mg / kg in mice or 0.025 mg / kg in rabbits. There are no adequate and well-controlled studies in pregnant women of BDP or the Model 4195 lead. The Model 4195 lead should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.

6.5 Lactation

Corticosteroids are secreted into human milk and there is a potential for serious adverse reactions. A decision should be made whether to nurse or to discontinue the drug, taking into account the importance of the drug to the mother. These potential risks of corticosteroids should also be considered along with any other steroidal therapy being received by the patient.

7 Potential adverse events

The potential clinical adverse events (listed in alphabetical order) resulting from the use of transvenous leads include, but are not limited to, the following:

- Air embolism
- Avulsion of the endocardium, valve, or vein
- Cardiac dissection
- Cardiac perforation
- Cardiac tamponade
- Coronary sinus dissection
- Death
- Endocarditis and pericarditis
- Erosion through the skin
- Extracardiac muscle or nerve stimulation
- Fibrillation or other arrhythmias
- Heart block
- Heart wall or vein wall rupture
- Hematoma/seroma
- Infection
- Myocardial irritability
- Myopotential sensing
- Pericardial effusion
- Pericardial rub
- Pneumothorax
- Rejection phenomena (local tissue reaction, fibrotic tissue formation, pulse generator migration)
- Threshold elevation
- Thrombosis
- Thrombotic embolism
- Valve damage (particularly in fragile hearts)

The risk and difficulty of removing the Medtronic Attain StarFix Model 4195 lead following long-term implant will be characterized in a post-approval study. In light of the novel fixation mechanism of the Model 4195 lead, there may be unique risks and difficulty associated with late revision and removal of the Model 4195 lead. Therefore, referral to an experienced extraction center is recommended.

When attempting to undeploy the lobes, proceed with extreme caution, particularly if difficulty undeploying the lobes or moving the lead body is encountered. Always use an acute retention clip when a lead must be removed or repositioned. Return all removed leads, unused leads, or lead sections to Medtronic for analysis.

Additional potential adverse events related to the lead and the programmed parameters include, but are not limited to, the following:

Potential adverse event	Indicator of potential adverse event	Corrective action to be considered
Lead dislodgement[a]	Intermittent or continuous loss of capture or sensing[a]	Reposition the lead.
Lead dislodgement[a]	Intermittent or continuous oversensing	Reposition the lead.

[2] AHFS Drug Information, 1999, ISBN 1-879907-91-7, pp 2420.
[3] Wattenberg, LW, et al., Chemoprevention of pulmonary carcinogenesis by brief exposures to aerosolized budesonide or beclomethasone dipropionate and by the combination of aerosolized budesonide and dietary myo-inositol. Carcinogenesis 2000; 21 (2): 179-182.

Potential adverse event	Indicator of potential adverse event	Corrective action to be considered
Lead conductor fracture or insulation failure	Intermittent or continuous loss of capture or sensing[a]	Replace the lead.
Threshold elevation or exit block	Loss of capture[a]	Adjust the implantable device output. Replace or reposition the lead.

[a] Transient loss of capture or sensing may occur following surgery until lead stabilization takes place. If stabilization does not occur, lead dislodgement may be suspected.

Implant techniques that may damage the lead include, but are not limited to, the following:

Implant techniques that may damage the lead	Possible effects on the lead	Corrective action to be considered
Forcing the lead through the introducer/delivery system	Electrode, conductor coil, indicator rings, lobe(s), push tubing, or insulation damage	Replace the lead.
Use of too medial of an approach with venous introducer resulting in clavicle and first rib binding	Conductor coil fracture; insulation damage	Replace the lead.
Puncturing the periosteum or tendon when using subclavian introducer approach	Conductor coil fracture; insulation or push tubing damage	Replace the lead.
Stretching the retention sleeve or push tubing with the acute retention clip	Retention sleeve or push tubing damage	Replace the lead.
Advancing the lead through the veins without the stylet or guide wire properly inserted	Tip distortion; insulation perforation; or damage to push tubing, lobes, or indicator rings	Replace the lead.
Forcing advancement of the push tubing	Buckling of push tubing; difficulty in lobe deployment	Replace or deploy distal to the buckled section.
Inserting the proximal end of the guide wire through the lead tip seal without using the guide wire insertion tool	Lead tip seal damage	Replace the lead.
Advancing a stylet tip beyond the distal end of the lead tip seal	Lead tip seal damage	Replace the lead.

8 Adverse events and clinical trial data

Information regarding the Model 4195 lead clinical study and adverse events is available at http://www.medtronic.com/manuals. To view, download, print, or order the clinical study from the Medtronic website:

1. Navigate your web browser to http://www.medtronic.com/manuals.
2. Set the "Your Location" option to United States and click [OK].
3. Select the "Model # or Name" field on the left side of the screen and type "4195."
4. Click [Search]. All technical literature for this lead will be listed.
5. Select the 4195 Clinical Study Summary from the technical literature.

If you do not have web access, a printed copy of the Model 4195 Clinical Study Summary can be obtained from your Medtronic representative or call the toll-free number located on the back cover.

9 Directions for use

Warning: Do not force the guide catheter, leads, or lobe deployment if significant resistance is encountered. The use of guide catheters or leads may cause trauma to the heart.

Note: To implant the Model 4195 lead in a cardiac vein, a compatible delivery system is required. A compatible delivery system includes a guide catheter and either a hemostasis valve or an introducer valve that can be removed or that allows passage over the IS-1 connector. Contact a Medtronic representative for further information regarding compatible delivery systems.

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. The implant procedures described in this manual are provided for information only. Each physician must apply the information in these instructions according to professional medical training and experience.

9.1 Placing the right ventricular lead

Note: When deciding which ventricular lead to place first, consider the ease of coronary sinus cannulation and the need for backup pacing.

- When a left ventricular lead is implanted first:
  - It may be easier to cannulate the coronary sinus without other leads already implanted.
  - Additional hospital equipment may be necessary to provide backup pacing.
- When a right ventricular lead is implanted first:
  - A right ventricular lead may be used to provide backup pacing.
  - It may be more difficult to cannulate the coronary sinus with a right ventricular lead already implanted.

9.2 Preparing the delivery system

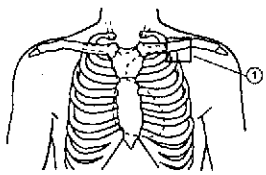
Prepare the delivery system for lead implant according to the instructions in the product literature packaged with the delivery system.

9.3 Accessing the subclavian vein

Access the subclavian vein:

1. Use a preferred method, based on professional experience, to access the subclavian vein.
   Caution: Certain anatomical abnormalities, such as thoracic outlet syndrome, may precipitate pinching and subsequent fracture of the lead.
   Caution: Insertion should be done as far lateral as possible to avoid clamping the lead body between the clavicle and the first rib (Figure 2).

Figure 2.



1 Suggested entry site

2. Introduce a J-shaped introducer guide wire and percutaneous introducer sheath.

9.4 Inserting the guide catheter assembly

Warning: Backup pacing should be readily available during implant. Use of the delivery system or leads may cause heart block.

Access the coronary sinus:

1. Insert the guide catheter assembly.
2. Advance the guide catheter to the right atrium.
3. Achieve entry into the coronary sinus by rotating the guide catheter tip posteriorly and to the patient's left.

See the delivery system product literature for additional information.

9.5 Obtaining venograms

Before placing a lead in the coronary sinus, obtain venograms. Venograms are recommended to assess a route for passage and a site for final placement based on the size, shape, location, and tortuosity of the veins. Also, venograms may be useful in identifying suspected coronary sinus trauma. For information on obtaining a venogram by using a venogram balloon catheter, see the product literature packaged with an appropriate venogram balloon catheter.

9.6 Locking and unlocking the acute retention clip

Warning: Do not implant the acute retention clip.

Note: If the acute retention clip is not attached to the lead, reattach it to the most proximal groove of the retention sleeve, as shown in Figure 3, position 1.

It is necessary to lock and unlock the acute retention clip during the implant procedure.

Note: The acute retention clip should remain attached to the lead (in either the locked or unlocked position) throughout the implant procedure, until the retention sleeve is secured to the lead with sutures.

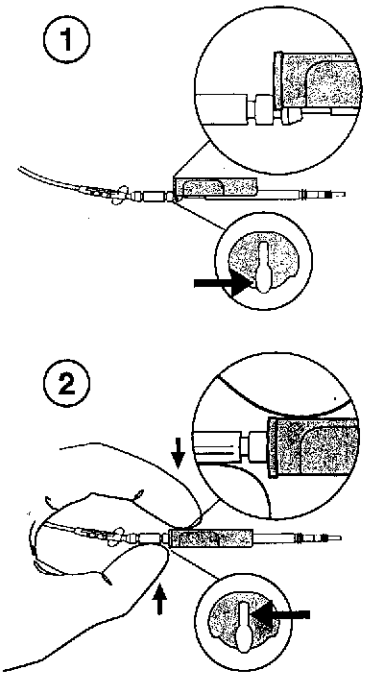
To lock the acute retention clip:

Press the proximal end of the retention sleeve into the smaller inner slot of the acute retention clip on the lead (Figure 3, position 2).

Note: The acute retention clip is shipped on the lead in the unlocked position (Figure 3, position 1).

Note: When the retention sleeve is in the innermost slot of the acute retention clip, the push tubing should not move freely.

Figure 3.



1 Acute retention clip not locked (allows push tubing movement and lobe deployment)
2 Acute retention clip locked (minimizes push tubing movement, lobe twisting, and lobe deployment)

To unlock the acute retention clip:

Push the distal end of the retention sleeve into the larger outer slot of the acute retention clip (Figure 3, position 1).

9.7 Preparing the lead for insertion

Warning: Always withdraw the stylet 2 to 3 cm before attempting to undeploy the lobes. Failure to withdraw the stylet may cause the stylet to extend beyond the lead tip, causing lead tip seal damage or injury or perforation of the cardiac vein or heart.

Caution: Stretching the retention sleeve or push tubing using the acute retention clip may damage the lead.

Prepare the lead for insertion by conditioning (flexing) the lobes:

1. Fully deploy the lobes by holding the IS-1 connector and lead body taut with one hand. With the other hand, grip the lead body distal of the retention sleeve and advance the push tubing while sliding your hand toward the distal end of the lead.
2. Undeploy the lobes by holding the IS-1 connector and lead body taut and then withdrawing the push tubing distal of the retention sleeve.

9.8 Inserting the lead into the delivery system

Warning: Use only the stylets packaged with the lead or in a stylet kit (downsized knob). Always use a stylet that is 3 cm shorter than the lead length listed on the IS-1 connector label. Other stylets may extend beyond the lead tip, causing lead tip seal damage or injury or perforation of the cardiac vein or heart.

Warning: Verify that the stylet does not extend beyond the lead tip prior to inserting the lead into the delivery system. Implanting the lead with a stylet extending beyond the lead tip could cause injury or perforation of the cardiac vein or heart.

Warning: Do not force the lead if significant resistance is encountered during lead passage. The use of guide catheters or leads may cause trauma to the heart.

Caution: Use care when handling the lead during insertion.

- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector pin.

Caution: Stretching the retention sleeve or push tubing using the acute retention clip may damage the lead.

Insert the lead:

1. Lock the acute retention clip with the lobes undeployed. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.
2. Insert the lead into the delivery system by grasping the lead on the lobed section.
   Note: If resistance is encountered during lead insertion, verify that the lobes are not deployed. Lobe deployment can be visualized by viewing the space between the indicator rings using fluoroscopy. See Figure 18, page 15 for fluoroscopic images. Minimal spacing or uneven spacing indicates lobe deployment. To undeploy the lobes, hold the IS-1 connector and lead body taut, and then withdraw the push tubing distal of the retention sleeve.
   Note: When the stylet is fully inserted, the distal tip of the stylet does not straighten the distal curve of the lead.

9.9 Selecting the lead placement method

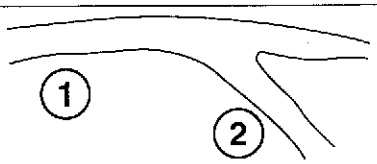
The Model 4195 lead can be placed in the cardiac vein with the aid of a stylet or with a guide wire.

Select a lead placement method:

Review the venogram to determine if stylet or guide wire delivery should be used.

Stylet delivery: If the patient's anatomy features gentle vein angulation off of the coronary sinus and the cardiac vein branch is less tortuous (Figure 4), use a stylet for lead delivery. Continue at Section 9.10, "Placing the lead using a stylet", page 11.

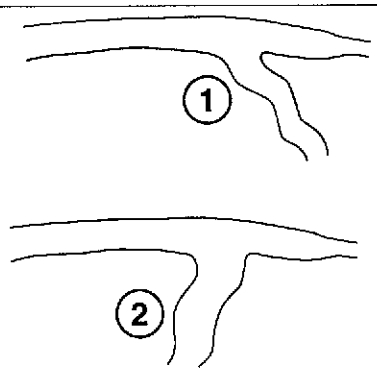
Figure 4.



1 Coronary sinus
2 Cardiac vein

Guide wire delivery: If the patient's anatomy features a more tortuous cardiac vein branch with gentle or acute angulation from the coronary sinus (Figure 5), use a guide wire for lead delivery. Continue at Section 9.11, "Preparing the guide wire", page 12.

Figure 5.



1 More tortuous cardiac vein branch with gentle angulation from the coronary sinus
2 More tortuous cardiac vein branch with acute angulation from the coronary sinus

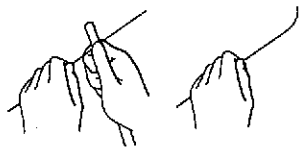
9.10 Placing the lead using a stylet

Warning: To minimize the likelihood of trauma to the vein and to maintain lead flexibility while advancing the lead through the vein, keep the stylet withdrawn 1 to 2 cm.

Warning: Do not force the lead if significant resistance is encountered during lead passage. The use of guide catheters or leads may cause trauma to the heart.

Caution: To avoid damage to the stylet, do not use a sharp object to impart a curve to the distal end of a stylet (Figure 6).

Figure 6.



Note: If resistance is encountered during lead placement, verify that the lobes are not deployed. Lobe deployment can be visualized by viewing the space between the indicator rings using fluoroscopy. See Figure 18, page 15, for fluoroscopic images. Minimal spacing or uneven spacing indicates lobe deployment.

To undeploy the lobes, see step 2 of Section 9.7, "Preparing the lead for insertion", page 10.

Note: If it is difficult to advance the stylet around a bend, consider changing the stylet. More flexible stylets are recommended for tortuous anatomies. Firmer stylets are recommended where additional support is needed.

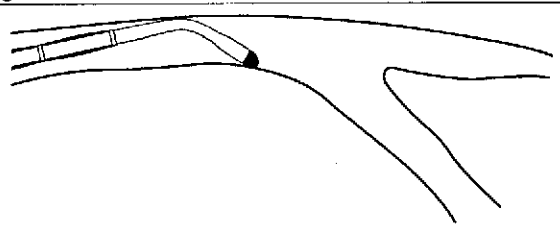
There are 2 techniques that may be used to advance the lead into a cardiac vein using a stylet. The choice of technique is left to the discretion of the physician.

9.10.1 First technique to advance the lead into a cardiac vein using a stylet

The lead may be advanced into a cardiac vein by following the steps in this section.

1. Ensure that the acute retention clip is locked. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.
2. Advance the lead up to, but not past, the ostium of the cardiac vein (Figure 7).
   Note: Hold the push tubing and the lead body together as a unit while advancing or torquing the lead. Rotation of the push tubing only or the lead body only can twist the lobes and impede lobe deployment. Locking the acute retention clip helps minimize twisting of the lobes.

Figure 7.

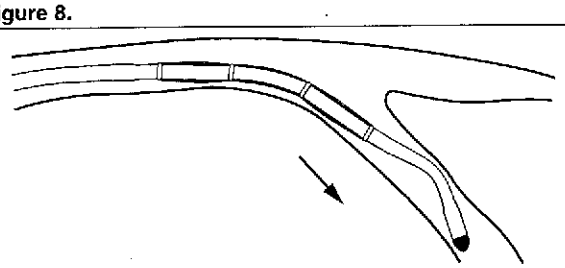


3. Use one or more of the following actions to direct the lead tip into the cardiac vein:
   - Withdraw the stylet.

- Advance the lead off of the stylet.
- Remove the straight stylet. Manually shape the stylet into a curve. Insert the curved stylet into the lead. Firmly grasp the lead body and the push tubing together as one unit, and rotate this unit together with the stylet.
- While holding the push tubing and the lead body together as a unit, rotate the curved tip of the lead into the vein.

4. Advance the lead into the cardiac vein to the desired position (Figure 8).

Figure 8.



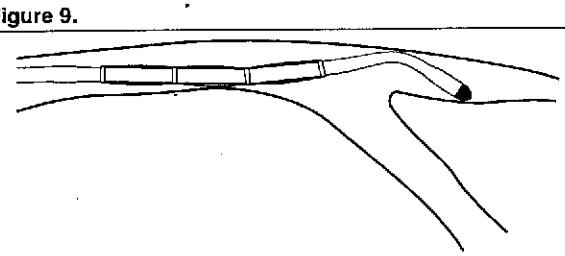
5. Fixate the lead with the acute retention clip. Continue at Section 9.13, "Fixating the lead acutely", page 14.

9.10.2 Second technique to advance the lead into a cardiac vein using a stylet

The lead may be advanced into a cardiac vein by following the steps in this section.

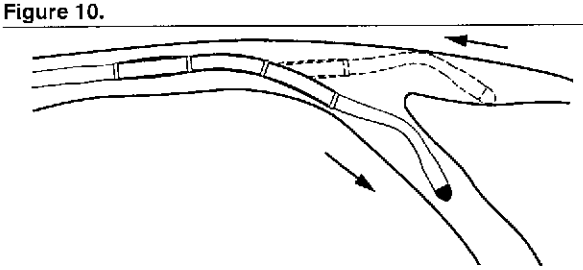
1. Ensure that the acute retention clip is locked. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.
2. Advance the lead past the ostium of the cardiac vein (Figure 9).
   Note: Hold the push tubing and the lead body together as a unit while advancing or torquing the lead. Rotation of the push tubing only or the lead body only can twist the lobes and impede lobe deployment. Locking the acute retention clip helps minimize twisting of the lobes.

Figure 9.



3. **Straight stylet:** If using a straight stylet, withdraw the stylet 1 to 2 cm and rotate the lead to align the curved lead tip with the ostium of the cardiac vein.
   Curved stylet: If using a curved stylet, withdraw the stylet 1 to 2 cm and rotate the stylet and lead body together to align the curved lead tip with the ostium of the cardiac vein.
4. Withdraw the lead and drag the curved lead tip over the ostium of the cardiac vein until the lead turns into the cardiac vein (Figure 10).

Figure 10.



5. Reinsert the stylet slightly to advance the lead into the cardiac vein to the desired position.
6. Fixate the lead with the acute retention clip. Continue at Section 9.13, "Fixating the lead acutely", page 14.

9.11 Preparing the guide wire

Warning: Damage to a guide wire may prevent the guide wire from performing with accurate torque response and control, and may cause vessel damage. For additional information about vessel damage and other potential adverse events, refer to the technical manual packaged with the appropriate guide wire.

Note: Be sure to remove the guide wire insertion tool before lead implant.

Note: Medtronic recommends using guide wires 0.36–0.46 mm (0.014–0.018 in) in diameter. Contact a Medtronic representative for further information about recommended guide wires.

Prepare the guide wire for use:

1. Select a guide wire. A more flexible guide wire is recommended if the patient has tortuous anatomy. If additional support is needed, use a firmer guide wire.
   Note: Guide wire firmness is determined by 2 factors: guide wire diameter and guide wire core design. A larger guide wire diameter may be firmer than a smaller guide wire diameter. However, guide wires with the same diameter may have different degrees of firmness.
   A "J" shaped guide wire or angled tip guide wire are recommended to aid in sub-selecting the cardiac vein and when more steerability is desired.
   Note: Consider soaking the guide wire in a heparin solution before insertion to minimize the risk of thrombus formation during use.
2. Remove the stylet.

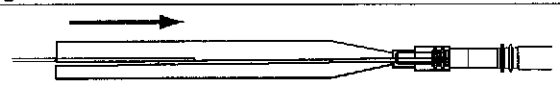
3. There are 2 techniques that may be used to load the guide wire into the lead. The choice of technique is left to the discretion of the physician.

9.11.1 First technique to load the guide wire into the lead

The guide wire may be loaded into the lead by following the steps in this section.

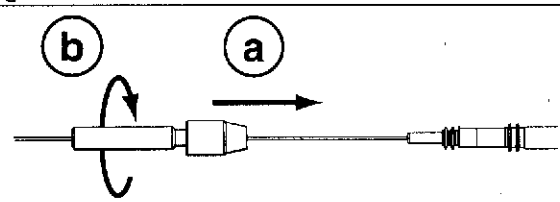
1. Ensure that the acute retention clip is locked. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.
2. Insert the guide wire into the lead by placing the distal (flexible) end of the guide wire into the lead connector pin using the guide wire insertion tool included in the package (Figure 11).

Figure 11.



3. Disengage the guide wire insertion tool from the lead connector pin.
   Caution: To minimize the risk of damaging the guide wire, be sure the flexible section of the guide wire is fully inserted into the lead before removing the guide wire insertion tool from the lead.
4. Remove the guide wire insertion tool by using the slit on the tool or by sliding the tool off the end of the guide wire.
5. Position the guide wire steering handle:
   a. Advance the guide wire steering handle over the proximal (rigid) end of the guide wire (Figure 12a).
   b. Tighten the guide wire steering handle onto the guide wire near the lead connector pin (Figure 12b).

Figure 12.



6. Attach the guide wire clip to the guide wire and secure it within the sterile field. Medtronic recommends securing the guide wire clip to the patient's sterile surgical drape.

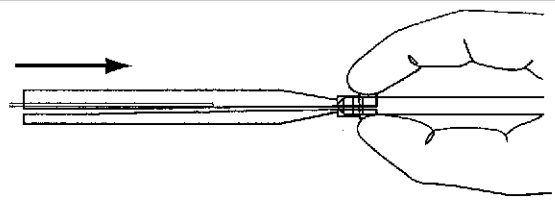
9.11.2 Second technique to load the guide wire into the lead

In situations where the guide wire is already in place, the lead can be loaded over the guide wire using the guide wire insertion tool.

Caution: Do not insert the proximal end of the guide wire through the lead tip seal without using the guide wire insertion tool.

1. Ensure that the acute retention clip is locked. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.
2. Insert the lead tip fully into the guide wire insertion tool (Figure 13).

Figure 13.



3. Insert the guide wire into the insertion tool while holding both the tool and lead tip together (Figure 13).
4. Advance the guide wire into the lead past the lead body curve.
   Note: There may be slight resistance as the guide wire passes through the lead tip seal and curve in the lead body. Manually flatten the curve in the lead body slightly to decrease the resistance.
5. Disengage the guide wire tool from the lead tip.
6. Remove the guide wire insertion tool using the slit on the tool.

9.12 Placing the lead using a guide wire

Warning: Do not force the lead if significant resistance is encountered during lead passage. The use of guide catheters or leads may cause trauma to the heart.

Caution: If the distal end of the guide wire becomes severely kinked or twisted, it may be difficult to withdraw it back through the lead. Therefore, if there is an indication that the distal end of the guide wire has become damaged, or if there is significant resistance in guide wire passage, remove the lead and guide wire together as a unit. Remove the guide wire from the lead and re-insert a new guide wire into the lead. Do not use excessive force to retract the guide wire from the lead.

Note: If resistance is encountered during lead placement, verify that the lobes are not deployed. Lobe deployment can be visualized by viewing the space between the indicator rings using fluoroscopy. See Figure 18, page 15, for fluoroscopic images. Minimal spacing or uneven spacing indicates lobe deployment. To undeploy the lobes, hold the IS-1 connector and lead body taut, and then withdraw the push tubing distal of the retention sleeve.

Note: If the lead is not advancing and the lobes are not deployed, or if the lead and guide wire seem to be sticking together, there may be thrombus on the guide wire at the lead tip. Remove and inspect the lead and guide wire. Consider using a new guide wire. Reinsert the lead and the guide wire as described in previous steps.

Note: If it is difficult to advance the guide wire around a bend, consider changing the guide wire. More flexible guide wires are recommended for tortuous anatomies. Firmer guide wires are recommended where additional support is needed.

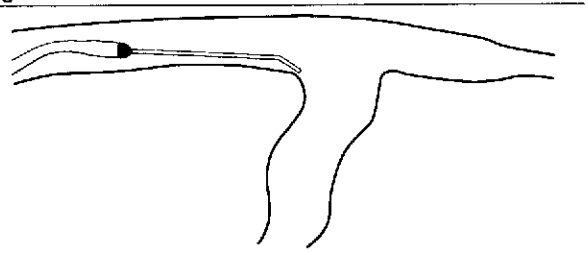
There are 2 techniques that may be used to advance the lead into a cardiac vein using a guide wire. The choice of technique is left to the discretion of the physician.

9.12.1 First technique to advance the lead into a cardiac vein using a guide wire

The lead may be advanced into a cardiac vein by following the steps in this section.

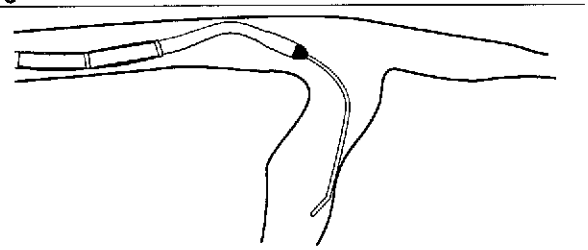
1. Using venogram images as a reference, advance the lead into the coronary sinus. Keep the distal tip of the guide wire beyond the distal tip of the lead during passage and placement (Figure 14).

Figure 14.



2. Rotate the guide wire and advance the guide wire into the cardiac vein (Figure 15.) Pass the lead over the guide wire and into the cardiac vein to the desired position.

Figure 15.

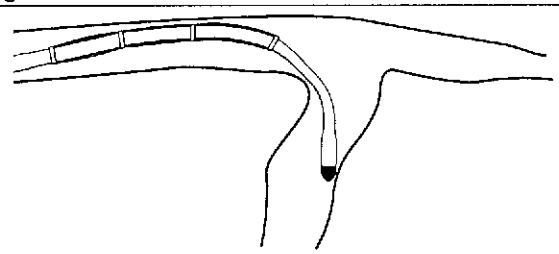


9.12.2 Second technique to advance the lead into a cardiac vein using a guide wire

The lead may be advanced into a cardiac vein by following the steps in this section.

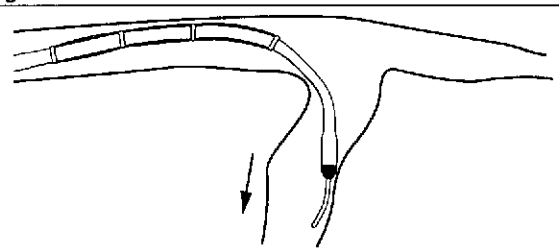
1. Using venogram images as a reference, advance the lead into the cardiac vein. The curved distal tip of the lead may be used to aid in subselecting cardiac veins within the coronary sinus by slightly retracting the guide wire inside the lead lumen (Figure 16).

Figure 16.



2. If the guide wire is retracted, reinsert the guide wire through the lead tip seal and further into the cardiac vein. Advance the lead over the guide wire into the cardiac vein to the desired position (Figure 17).

Figure 17.



9.13 Fixating the lead acutely

Warning: Do not force lobe deployment if resistance is encountered. The use of guide catheters or leads may cause trauma to the heart.

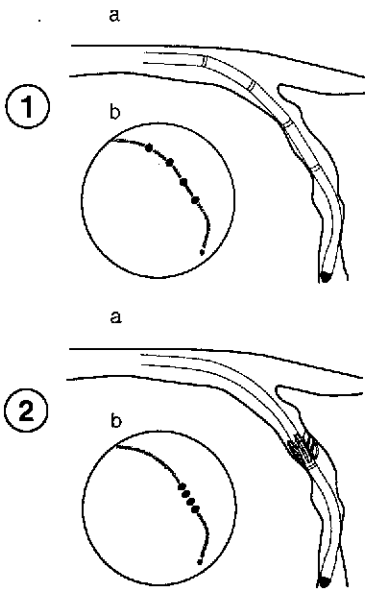
Caution: Forcing advancement of the push tubing may damage the lead.

Fixation is achieved the same way regardless of whether a stylet or a guide wire is used.

Fixate the lead with the acute retention clip:

1. Insert the stylet tip to the curve in the lead or extend the guide wire beyond the lead tip so that the stiff portion of the guide wire is past the most distal indicator ring.
2. Unlock the acute retention clip. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.
3. Using fluoroscopy for guidance, fixate the leads by deploying the lobes. Holding the IS-1 connector and lead body taut, advance the push tubing just proximal of the hemostasis valve or the introducer valve.
   Lobe deployment can be visualized under fluoroscopy as the space between the indicator rings is reduced (Figure 18).
   Note: Full lobe deployment is not always necessary in smaller veins.

Figure 18.



1 a. Lobes undeployed. b. Fluoroscopic image of lobes undeployed.
2 a. Lobes deployed. b. Fluoroscopic image of lobes deployed.

Note: If the cardiac vein is very large, it may be necessary to position the lead in a smaller cardiac vein to achieve lead fixation.

4. Verify fixation by applying slight traction to the lead. Ensure that the most proximal indicator ring is at least 1 cm beyond the ostium of the target vessel after the lobes are deployed.
5. Lock the acute retention clip to retain the lobe position. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.

9.14 Taking electrical measurements

Caution: Before taking electrical or defibrillation efficacy measurements, move objects made of conductive materials, such as guide wires or stylets, away from all electrodes.

Note: For the Model 4195, initial electrical measurements should be taken with the stylet or guide wire retracted a minimum of 4 cm inside the lead lumen.

Take electrical measurements:

1. Attach a surgical cable to the lead connector pin.
   Note: Testing the lead in a unipolar configuration requires the use of an indifferent electrode.
2. Use an implant support instrument, such as a pacing system analyzer, for obtaining electrical measurements (Table 1). For information on the use of the implant support instrument, consult the product literature for that device.

Satisfactory lead placement is indicated by low stimulation thresholds and adequate sensing of intracardiac signal amplitudes:

- A low stimulation threshold provides for a desirable safety margin, allowing for a possible rise in thresholds that may occur within 2 months following implant.
- Adequate sensing amplitudes ensure that the lead is properly sensing intrinsic cardiac signals. Minimum signal requirements depend on the sensitivity capabilities of the device. Acceptable acute signal amplitudes for the lead must be greater than the minimum device sensing capabilities including an adequate safety margin to account for lead maturity.

Table 1. Recommended implant values (Assumes 500 Ω resistance)

Measurements	Left Ventricle
Maximum acute stimulation thresholds[a]	3.0 V
Minimum acute sensing amplitudes	4.0 mV

[a] at pulse duration setting of 0.5 ms

3. If electrical measurements do not stabilize to acceptable levels, it may be necessary to reposition the lead and repeat the testing procedure. See Section 9.15, "Acutely repositioning the lead", page 15.
4. Check for diaphragmatic stimulation by pacing at 10 V and a pulse width setting greater than 0.5 ms. Then observe for diaphragmatic contracting either by fluoroscopy or direct abdominal palpitation. Further testing may include patient positional changes to simulate upright chronic conditions. If diaphragmatic pacing occurs, reduce the voltage until a diaphragmatic pacing threshold is determined. Diaphragmatic stimulation usually necessitates repositioning of the lead. See Section 9.15, "Acutely repositioning the lead", page 15.

9.15 Acutely repositioning the lead

Warning: Use care when withdrawing the push tubing. Applying excessive force when withdrawing the push tubing while a stylet is inserted may damage the lead or cause patient injury.

Warning: Always withdraw the stylet 2 to 3 cm before attempting to undeploy the lobes. Failure to withdraw the stylet may cause the stylet to extend beyond the lead tip, causing lead tip seal damage or injury or perforation of the cardiac vein or heart.

Caution: Stretching the retention sleeve or push tubing using the acute retention clip may damage the lead.

If necessary, the lead can be repositioned during the implant procedure:

1. Unlock the acute retention clip. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.

2. Undeploy the lobes by holding the IS-1 connector and lead body taut and then withdrawing the push tubing distal of the retention sleeve. This action should be completed in one of two ways:
   a. with a stylet withdrawn 2 to 3 cm
   b. with a guide wire inserted beyond the lead tip so that the stiff portion of the guide wire is past the most distal indicator ring
3. Lock the acute retention clip. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.
4. Reposition the lead. Refer to the appropriate method. See Section 9.10, "Placing the lead using a stylet", page 11 or Section 9.12, "Placing the lead using a guide wire", page 13.

9.16 Securing the lobes with the retention sleeve

Warning: Do not implant the acute retention clip.

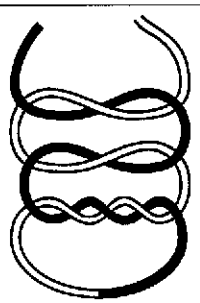
Caution: Use care when securing the retention sleeve.

- Use only nonabsorbable sutures.
- Do not attempt to remove or cut the retention sleeve.
- Take care to avoid dislodging the lead tip.
- Do not secure sutures so tightly that they damage the lead or retention sleeve.
- Do not tie a suture directly to the lead body or push tubing.

Fixate the lobes using all 3 grooves:

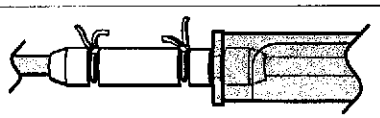
Note: To help retain the lobe position, Medtronic recommends using a surgeon's knot. A surgeon's knot provides added friction to hold the first knot until the additional crossings are made. One type of surgeon's knot is shown in Figure 19.

Figure 19.



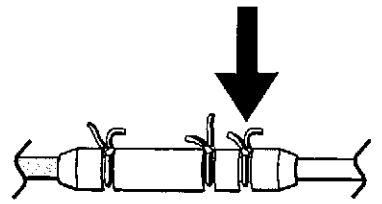
1. Secure the retention sleeve to the lead body by tying a suture firmly in each of the 2 distal grooves (Figure 20).

Figure 20.



2. Remove the acute retention clip completely from the lead.
3. Tie a suture in the third (most proximal) suture groove (Figure 21).
   Note: The third suture is the most important for retaining the lobe position.

Figure 21.



9.17 Removing the guide catheter from the lead

Once the lead is in the final position, remove the guide catheter from the lead:

1. If used, remove the guide wire and guide wire insertion tool. Replace the guide wire with a straight stylet (downsized knob). Insert the straight stylet into the lead to the mid-coronary sinus.
2. Remove the guide catheter from the lead. See the delivery system product literature for details.
   Note: For Medtronic slittable delivery systems, use a slitter compatible with a 1.7 mm (5 French) lead body.
3. Carefully and completely remove the stylet. When removing the stylet, grip the lead firmly just distal of the connector pin; this will help prevent possible lead tip dislodgement.
4. Repeat the electrical measurements. See Section 9.14, "Taking electrical measurements", page 15.

9.18 Anchoring the lead

Caution: Use care when anchoring the lead.

- Use only nonabsorbable sutures to anchor the lead.
- Do not attempt to remove or cut the anchoring sleeve.
- Do not use the anchoring sleeve tabs for suturing.
- During lead anchoring, take care to avoid dislodging the lead tip.
- Do not secure sutures so tightly that they damage the vein, lead, or anchoring sleeve (Figure 22).
- Do not tie a suture directly to the lead body (Figure 22).

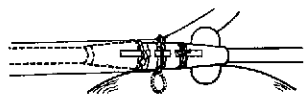
Figure 22.

Anchor the lead using all 3 grooves:

1. Position the anchoring sleeve against or near the vein.

2. Secure the anchoring sleeve to the lead body by tying a suture firmly in each of the 3 grooves (Figure 23).

Figure 23.



3. Use at least one additional suture in one of the grooves to secure the anchoring sleeve and lead body to the fascia.

9.19 Connecting the lead

Caution: Always remove the stylet before connecting the lead to the device. Failure to remove the stylet may result in lead failure.

Connect the lead to the device according to the instructions in the product literature supplied with the device.

Connect the lead to the device:

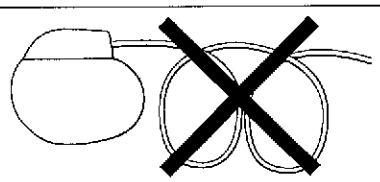
1. Take final electrical measurements.
2. Insert the lead connector into the connector block. Consult the product literature packaged with the implantable device for instructions on proper lead connections.

9.20 Placing the device and lead into the pocket

Caution: Use care when placing the device and lead into the pocket.

- Ensure that the lead does not leave the device at an acute angle.
- Do not grip the lead or device with surgical instruments.
- Do not coil the lead (Figure 24). Coiling the lead can twist the lead body and may result in lead dislodgement.

Figure 24.

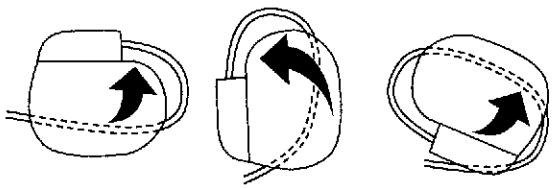


Caution: To prevent undesirable twisting of the lead body, wrap the excess lead length loosely under the device and place both the device and the lead into the subcutaneous pocket.

Place the device and lead into the pocket:

1. Rotate the device to loosely wrap the excess lead length under the device (Figure 25).

Figure 25.



2. Insert the device and lead into the pocket.
3. Suture the pocket closed.
4. Monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.

9.21 Chronic repositioning or removal of the lead

See Warnings and precautions, "Chronic repositioning or removal", page 6.

1. Remove sutures from anchoring sleeve and retention sleeve and attach acute retention clip to retention sleeve in unlocked position. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.
2. Undeploy the lobes by holding the IS-1 connector and lead body taut and then withdrawing the push tubing distal of the retention sleeve. This action should be completed in one of two ways:
   a. with a stylet withdrawn 2 to 3 cm
   b. with a guide wire inserted beyond the lead tip so that the stiff portion of the guide wire is past the most distal indicator ring
3. Lock the acute retention clip. See Section 9.6, "Locking and unlocking the acute retention clip", page 9.
4. Reposition or remove the lead. Refer to the appropriate method. See Section 9.10, "Placing the lead using a stylet", page 11 or Section 9.12, "Placing the lead using a guide wire", page 13.

10 Detailed device description

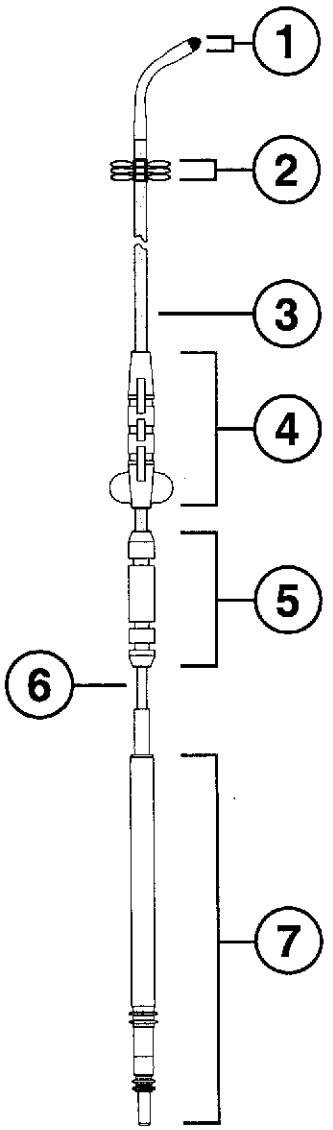
10.1 Specifications (nominal)

Parameter		Model 4195
Type		Unipolar
Chamber paced		Ventricle
Fixation		Deployable lobes
Length		20–110 cm
Connector		IS-1 UNI
Materials	Conductor:	MP35N
	Insulator:	Polyurethane
	Electrode tip:	Platinum alloy
	Push tubing:	Hydrophilic coated polyurethane
	Connector pin:	Titanium

Parameter		Model 4195
	Connector ring:	Titanium
	Indicator ring:	Platinum iridium
	Molded tip seal:	Silicone rubber
Electrode configuration		Tapered annular, platinized
Diameter	Lead body:	1.7 mm (5.0 French)
	Tip electrode:	1.8 mm (5.3 French)
Medtronic delivery system (recommended inner diameter)		2.3 mm (7 French)
Diagnostic guide wire (recommended diameter)		0.36–0.46 mm (0.014–0.018 in)
Tip electrode surface area		5.8 mm^2
Resistance	Unipolar:	52 Ω at 78 cm
Steroid		Beclomethasone dipropionate (BDP)
Amount of steroid		30 µg

10.2 Specifications drawing (nominal)

Figure 26.



1 Tip electrode diameter: 1.8 mm (5.3 French); surface area: 5.8 mm^2
2 Deployable lobes
3 Push tubing (shaded)
4 Anchoring sleeve
5 Retention sleeve

6 Lead body
7 IS-1 UNI connector

11 Medtronic warranty

For complete warranty information, see the accompanying warranty document.

12 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

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A15331001

Medtronic

ATTAIN® STARFIX™ MODEL 4195 LEFT VENTRICULAR LEAD

Clinical study information and adverse events

Clinical study summary

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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Please see the Technical Manual for a complete device description, indications for use, contraindications, warnings and precautions, drug information, potential adverse events, and directions for use.

The Technical Manual is available at www.Medtronic.com/manuals. To view, download, print, or order the Technical Manual from the Medtronic website:

1. *Navigate your web browser to http://www.Medtronic.com/manuals.*
2. *Set the "Your Location" option to United States and click [OK].*
3. *Select the "Model # or Name" field on the left side of the screen and type "4195".*
4. *Click [Search]. All technical literature for this lead will be listed.*
5. *Select the Technical Manual from the technical literature.*

Summary of Clinical Results

Study Title: The Attain® StarFix™ Model 4195 Left Ventricular Lead Clinical Study
Number of Centers: 20 US, 4 Canada, and 1 Italy
Number of Subjects: 440 subjects enrolled, 382 subjects implanted with a Medtronic Model 4195 lead

1 Study Purpose

The purpose of the clinical study was to assess the safety and efficacy of the Medtronic® Attain StarFix™ Model 4195 lead.

2 Study Scope, Design, and Methods

The Model 4195 lead study was a prospective, multi-center (20 US, 4 Canada, 1 Italy) clinical trial using objective performance criteria (OPC) to evaluate the safety and efficacy of the Model 4195 left ventricular (LV) lead. Data from a previous LV lead study were used to establish the Model 4195 lead OPC. Therefore, control subjects were not used in this study. Candidates for implant included subjects of both genders with heart failure who were classified as New York Heart Association (NYHA) functional class III and IV, and who met all inclusion and no exclusion criteria. All subjects with a successful Model 4195 lead implant were evaluated at pre-hospital discharge, 1 month, 3 months, 6 months, and every 6 months thereafter, until study completion.

3 Subject Inclusion and Exclusion Criteria

Subjects of both genders who were indicated for CRT and who met all inclusion and no exclusion criteria were eligible for a Model 4195 lead implant attempt.

3.1 *Inclusion Criteria*

- Demonstrated intrinsic QRS duration ≥ 130 ms (test documented within 6 months of baseline)
- Left Ventricular Ejection Fraction (EF) ≤ 35% (test documented within 12 months of baseline)
- Subject is diagnosed with NYHA Class III or IV despite optimal medical therapy which is defined as:
    - ACE inhibitor or Angiotensin Receptor Blocker (ARB), if tolerated, for at least one month prior to implant
    - Beta-blockers for at least three months preceding implant, if tolerated, and stable for one month. Stable is defined as no upward titration of beta-blockers

  OR

    - Subject has an urgent medical need for an ICD that precludes waiting the one or three months for medication requirement for ACE inhibitor, ARB or beta-blocker
- Subject is indicated for ICD implantation for the treatment of life-threatening ventricular arrhythmias[1] (required only if subject will receive an ICD)
- Subject has signed and dated the study Informed Consent
- Subject is 18 years of age or older
- Subject is expected to remain available for follow-up visits
- Subject is willing and able to comply with the protocol

3.2 *Exclusion Criteria*

- Subjects with a previous complete atrial based biventricular CRT system
- Subjects with a previous LV lead implanted or previous implant attempt within 30 days of implant or ongoing adverse events from previous unsuccessful attempt
- Subjects with unstable angina pectoris or who have had an acute MI within the past month
- Subjects that have had a CABG or PTCA within the past three months
- Subjects with chronic (permanent) atrial arrhythmias

[1] In accordance with Class I or II ICD indications as specified in the current ACC/AHA/HRS practice guidelines at the time of implant.

- Subjects with contraindications for standard transvenous cardiac pacing (e.g. mechanical right heart valves)
- Subjects contraindicated for < 100 micrograms beclomethasone dipropionate
- Post heart transplant subjects (subjects waiting for heart transplant are allowed in the study)
- Subjects enrolled in any concurrent drug and/or device study that may confound the results of this study
- Subjects with a terminal illness who are not expected to survive more than six months
- Women who are pregnant, or have a positive pregnancy test within 7 days before implant, or with child bearing potential and who are not on a reliable form of birth control. (All women of child bearing potential must undergo a pregnancy test within 7 days before implant.)
- Subjects unable to tolerate an urgent thoracotomy

4 Study Objectives

4.1 Primary Objectives

There were 2 primary study objectives for the Model 4195 lead clinical study.

4.1.1 Safety

The Model 4195 Lead will be considered safe if the complication-free survival from lead-related complications at three months is greater than or equal to 80%.

4.1.2 Efficacy

The Model 4195 Lead will be considered effective if the mean left ventricular (LV) voltage threshold (at 0.5 ms) at the three month visit is less than or equal to 2.5 volts (not including loss of capture values).

4.2 Secondary Objectives

- To evaluate the implant success rate of the Model 4195 Lead
- To evaluate the total implant, fluoroscopy, cannulation, and LV placement time for the Model 4195 lead
- To evaluate the handling characteristics and lobe deployment of the Model 4195 Lead
- To evaluate all adverse events (AEs) occurring during the clinical study (excluding unavoidable adverse events)
- To evaluate the electrical performance (sensing, LV pacing impedance, LV pulse width threshold, and phrenic nerve/diaphragmatic stimulation) of the Model 4195 Lead

5 Results

The clinical study for the Medtronic Attain StarFix Model 4195 lead was conditionally approved for 50 subjects at 10 centers on May 27, 2004 under G040036. The study approval was expanded to 20 centers and 250 US subjects on January 6, 2005. Medtronic also collected OUS data for up to 50 subjects at 5 centers in Canada and Europe. Per the Clinical Investigational Plan, the primary safety and effectiveness objectives were evaluated when the study's critical sample size was met. This analysis had a cut-off date of July 6, 2005 and all primary safety and efficacy objectives were met. Medtronic received approval for a Continued Access Phase (CAP) for the existing 20 US centers to enroll up to 175 additional subjects (425 total US subjects) on January 5, 2006. The original PMA was submitted on December 26, 2006 and included data for 296 IDE and CAP enrolled subjects as of a cut-off date of August 29, 2006. In the course of reviewing the PMA, additional safety data and confirmatory efficacy data were submitted for the 440 enrolled subjects (IDE & CAP cohorts) as of a cut-off date of March 5, 2007. The performance and efficacy of the Model 4195 lead was consistent between the July 6, 2005, August 29, 2006 and March 5, 2007 cut-off dates. The data presented in this summary are based on the 440 enrolled subjects as of a cut-off date of March 5, 2007 since this represents the most complete data set reviewed by FDA for approval of the Model 4195 lead.

5.1 Subject Demographics

The demographics for this cohort are presented in Table 1. Subjects ranged in age from 35.7 to 89.7 years, with a mean age of 68.6 years. 296 of the subjects (69.6%) were male and 129 of the subjects (30.4%) were female. The majority of subjects were NYHA Class III (408, 96.0%), and the remaining subjects were NYHA Class IV (17, 4.0%). The subject cohort had a mean intrinsic QRS width of 155.8 ms (SD = 19.6) and a mean LV ejection fraction of 23.3% (SD = 6.4).

Table 1: Subject Demographics
(As of March 5, 2007, N=425)

Category	Subjects with Implant Attempt
Gender, N (%)	
Male	296 (69.6%)
Female	129 (30.4%)
Age (years)	
Mean	68.6
Standard deviation	11.4
Range	35.7-89.7
NYHA functional classification, N (%)	
Class III	408 (96.0%)
Class IV	17 (4.0%)

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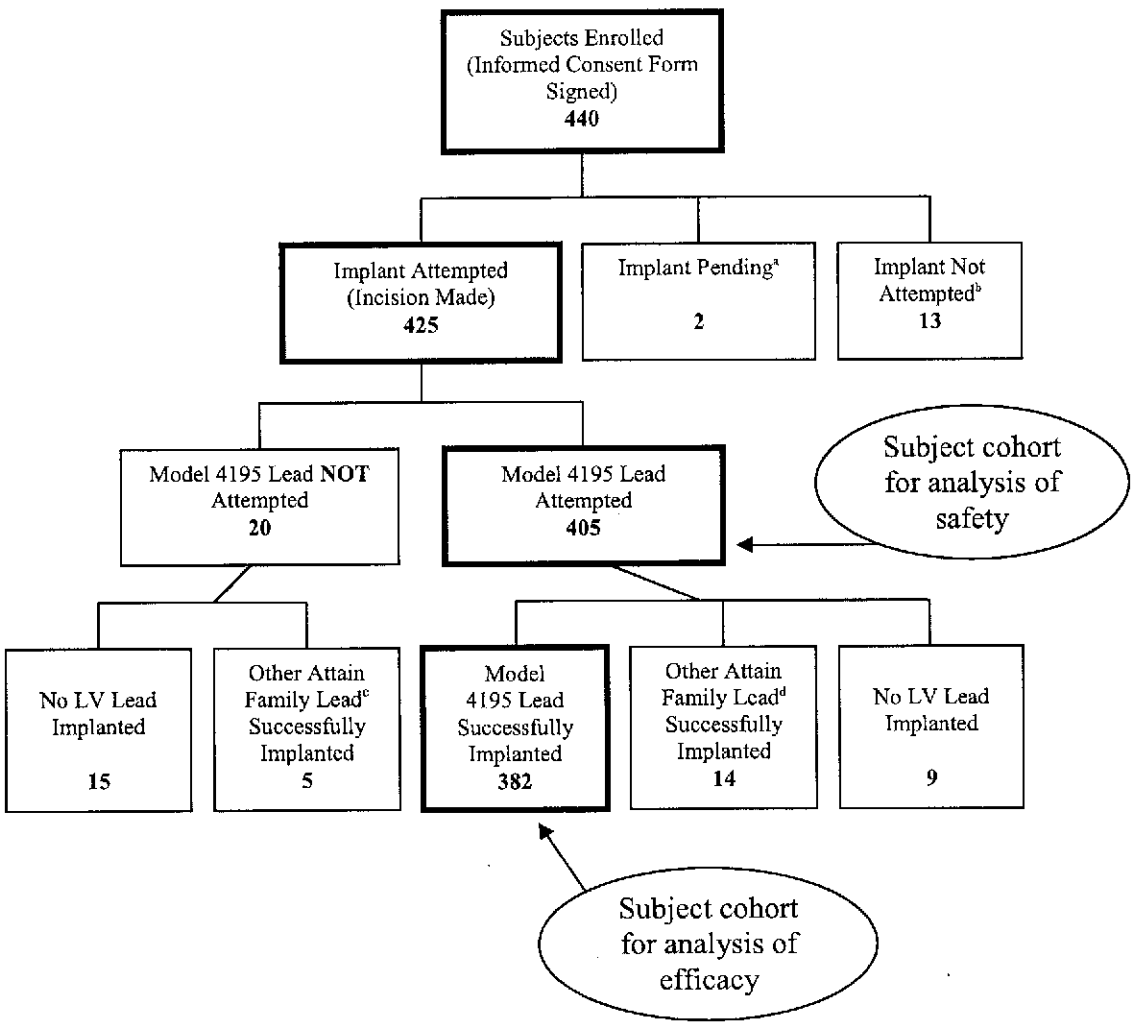
5.2 *Procedure Summary*

A summary of enrollment status is presented in Figure 1. Of the 440 subjects enrolled, 425 underwent an implant attempt, with 405 undergoing a Model 4195 lead implant attempt. Of the 405 subjects who had a Model 4195 lead implant attempt, 382 (94.3%) had a successful Model 4195 lead implant. All implant success rates were within the expected range for Medtronic LV lead implants.

Figure 1: Enrollment Status
(As of March 5, 2007, N=440)



[a] Two subjects were enrolled but pending implant at the time of data cut-off.
[b] Eleven subjects did not meet inclusion/exclusion criteria after consent and two subjects did not continue with an implant attempt (one subject had an increased BUN/creatinine level at the time of scheduled implant and the investigator chose not to proceed with an investigational implant, one subject's procedure was aborted after a venogram showed occlusion of the left subclavian vein).
[c] The "Other Medtronic Attain Family Leads" implanted in the subjects not attempted with the Model 4195 lead included three Model 4194 leads and two Model 4193 leads.
[d] The "Other Medtronic Attain Family Leads" implanted in the subjects attempted with the Model 4195 lead included 11 Model 4193 leads, two Model 4194 leads, and one Model 2187 lead.

After successful cannulation of the coronary sinus, 23 subjects who were attempted with a Model 4195 lead implant were not successfully implanted with a Model 4195 lead. Table 2 presents the reasons for the unsuccessful Model 4195 lead implant attempts.

Table 2: Unsuccessful Model 4195 Lead Implant Attempts
(As of March 5, 2007)

Reason	Number*
Unable to access coronary vein	8
Dislodgement/unstable location	7
Unacceptable pacing thresholds	7
Coronary vein too small	5
Unable to obtain adequate distal location	5
Extra-cardiac stimulation	3
Coronary sinus too small	1
Anterior location was the only vessel of suitable size	1
Lead would not fit in the catheter alongside heavy wire	1

* Reasons for unsuccessful attempts are not mutually exclusive.

5.3 Follow-up Experience

This summary includes 4759.9 device months of experience. Subject follow-ups ranged from 0 to 31.3 months and averaged 11.8 ± 9.4 months (median = 12.5 months).

5.4 Primary Objectives

A summary of primary objective results is presented in Table 3.

Table 3: Summary of Primary Objectives Results at Three Months (As of March 5, 2007)	
Primary Objective	**Results**
Safety: The Model 4195 Lead will be considered safe if the complication–free survival rate from lead related complications at three months is greater than or equal to 80%	Percent of Subjects Free of Complications = **96.8% (N=405)** 95% LCB = **94.4%** 13 lead related events in 12 subjects
Effectiveness: The Model 4195 Lead will be considered effective if the mean left ventricular (LV) voltage threshold (at 0.5 ms) at the three-month visit is less than or equal to 2.5 volts (not including loss of capture values)	Mean LV Voltage Threshold = **1.3 V (N=304)** 95% UCB = **1.4 V**

5.4.1 Safety Objective

The safety of the Model 4195 lead was evaluated by investigator documentation of all Model 4195 lead related adverse events. All subjects with a Model 4195 lead attempt were included in this evaluation. Table 4 presents the Kaplan-Meier estimate of freedom from lead related complications through 30 months. At 3 months, the primary objective end point, 12 subjects had experienced a total of 13 Model 4195 lead related complications (Table 5).

Table 4: Freedom from Model 4195 Lead Related Complications (As of March 5, 2007)			
Survival Interval	**Cumulative Number of Subjects with Events**	**Percent of Subjects Free of Complications**	**95% Lower Confidence Bound (1-Sided)**
1 month	10	97.4%	95.2%
3 month*	**12**	**96.8%**	**94.4%**
6 month	12	96.8%	94.4%
12 month	12	96.8%	94.4%
18 month	14	95.5%	92.3%
24 month	14	95.5%	92.3%
30 month	15	91.9%	92.3%

* Exceeds acceptance criteria of 80%.

Table 5 presents the thirteen Model 4195 lead related complications and treatments.

Table 5: Treatment of Model 4195 Lead Related Complications Through 3 Months
(As of March 5, 2007, N = 13)

Event	Treatment	N
Lead dislodgement	Lead replaced	2
	Lead repositioned	1
Failure to capture, loss of capture	Lead replaced	1
	Lead repositioned	1
Extra-cardiac stimulation	Lead removed	1
	Lead replaced	2
	Lead repositioned	2
	Lead capped	1
	Lead temporarily programmed Off	2

Section 5.6 includes a complete list of adverse events observed during the clinical study.

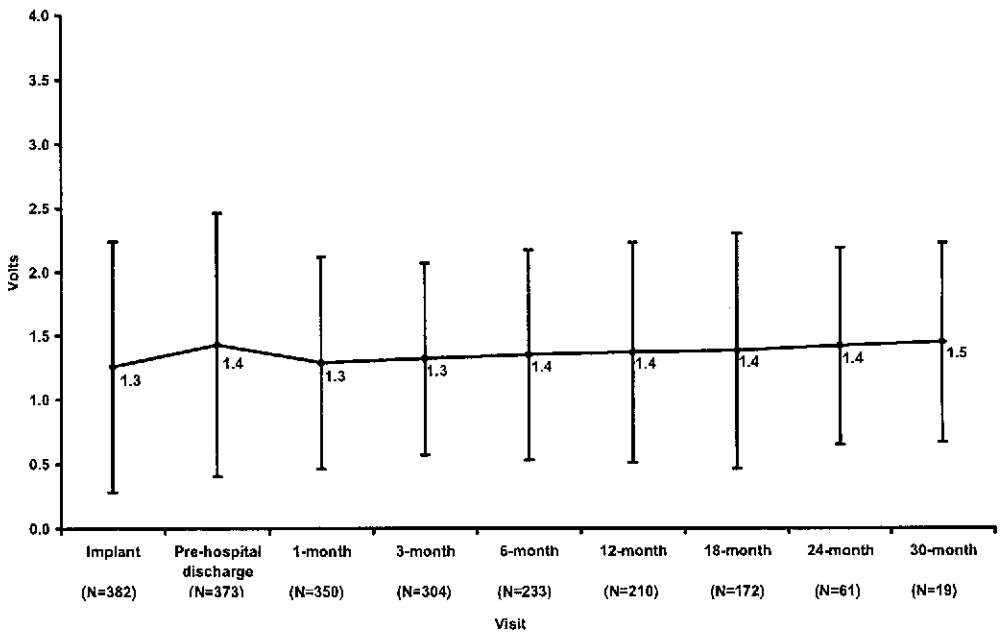
5.4.2 Efficacy Objective

Table 6 and Figure 2 summarize the voltage thresholds, measured at implant and at all protocol required follow-up visits. Only subjects with pacing thresholds captured at 0.5 ms were included in the analysis. Subjects with unable-to-capture (UTC) thresholds were not included in the efficacy analysis for the corresponding visit.

Table 6: Voltage Threshold at 0.5 ms (As of March 5, 2007)						
Visit	**N**	**Mean (volts)**	**Median**	**Std. Dev.**	**Range**	**95% UCB**
Implant	382	1.3	0.9	1.0	0.2 – 6.9	1.4
Pre-hospital discharge	373	1.4	1.0	1.0	0.5 – 6.0	1.5
1 month	350	1.3	1.0	0.8	0.5 – 6.0	1.4
3 month*	**304**	**1.3**	**1.0**	**0.8**	**0.5 – 6.0**	**1.4**
6 month	233	1.4	1.0	0.8	0.5 – 6.0	1.5
12 month	210	1.4	1.0	0.9	0.5 – 6.0	1.5
18 month	172	1.4	1.0	0.9	0.5 – 6.0	1.5
24 month	61	1.4	1.0	0.8	0.5 – 5.0	1.6
30 month	19	1.5	1.0	0.8	0.5 – 3.0	1.8

* Exceeds acceptance criteria of 2.5 V.

Figure 2. Model 4195 Lead Pacing Threshold Data at 0.5 ms
(As of March 5, 2007, Mean ± One Standard Deviation)



5.5 Secondary Objectives

The secondary objectives examined the Attain lead family and Model 4195 lead implant success, lead placement and procedure time, lead handling and lobe deployment, additional electrical performance, and all adverse events reported in the study. Table 7 and Figures 3, 4, and 5 present a summary of the secondary objectives results, with the exception of adverse events, which are presented in the *Adverse Events Summary* section.

Table 7: Summary of Secondary Objectives Results
(As of March 5, 2007)

Secondary Objective	Results
Evaluate the Attain leads implant success	All transvenous LV leads success = 94.4% (401/425) All transvenous LV leads success after cannulation = 95.9% (401/418) Attain family success = 94.4% (401/425) Model 4195 lead success = 94.3% (382/405)
Evaluate total implant, fluoroscopy, cannulation and Model 4195 lead placement time (mean ± standard deviation)	Cannulation time = 8.1 min ± 14.6 (N=382) Fluoroscopy time = 22.5 min ± 17.2 (N=377) Model 4195 lead placement time = 12.6 min ± 12.9 (N=382) Total implant time = 115.9 min ± 48.0 (N=382)
Evaluate lead handling and lobe deployment	Ability to Push (Good or Fair) = 97.4% (381/391) Ability to Navigate (Good or Fair) = 96.9% (379/391) Stability (Good or Fair) = 99.2% (383/386) Ability to Deploy/Undeploy (Good or Fair) = 96.6% (374/387) Acceptability = 98.3% (397/404) Number of deployments per unique lead = 1.9 ± 1.7
Model 4195 lead extra-cardiac stimulation threshold at implant (mean ± standard deviation)	Experienced extra-cardiac stimulation at implant = 8.6% (33/382) Mean stimulation threshold for the 33 subjects = 6.0 V ± 2.1

Figure 3. Model 4195 Lead R-wave Amplitude
(As of March 5, 2007, Mean ± One Standard Deviation)

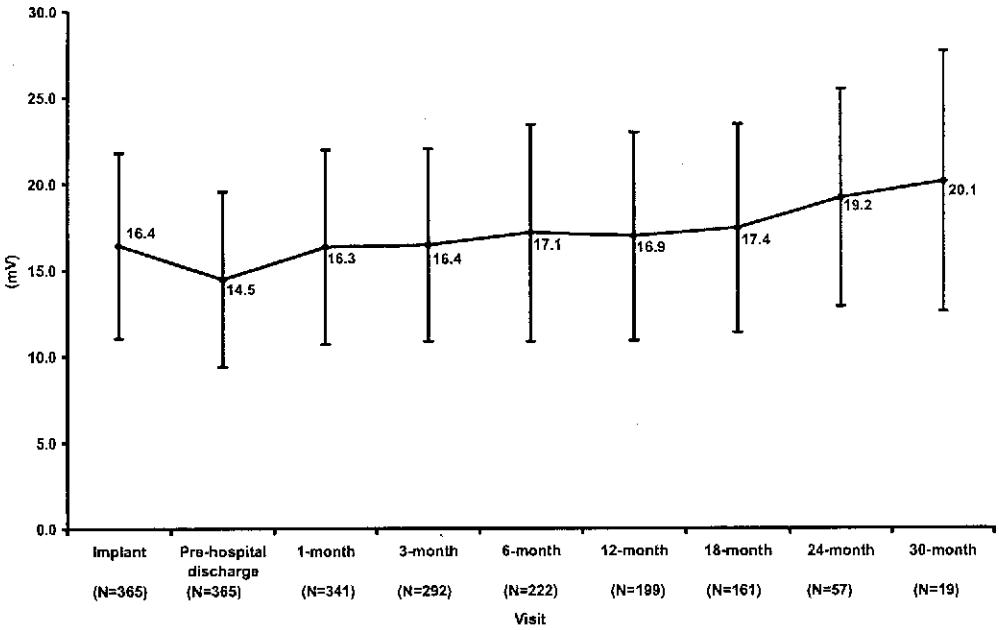


Figure 4. Model 4195 Lead Impedance
(As of March 5, 2007, Mean ± One Standard Deviation)

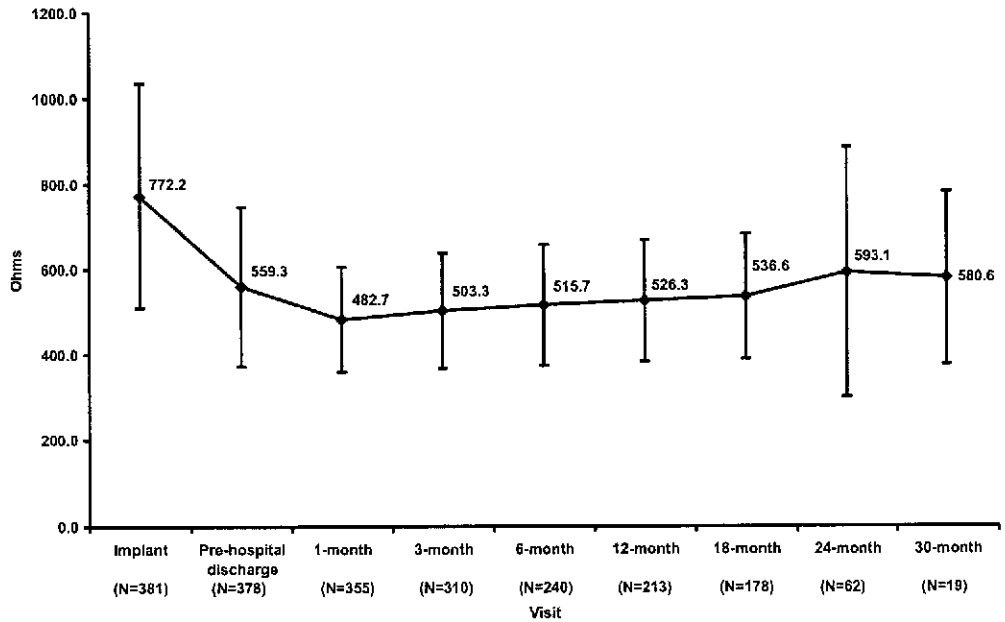


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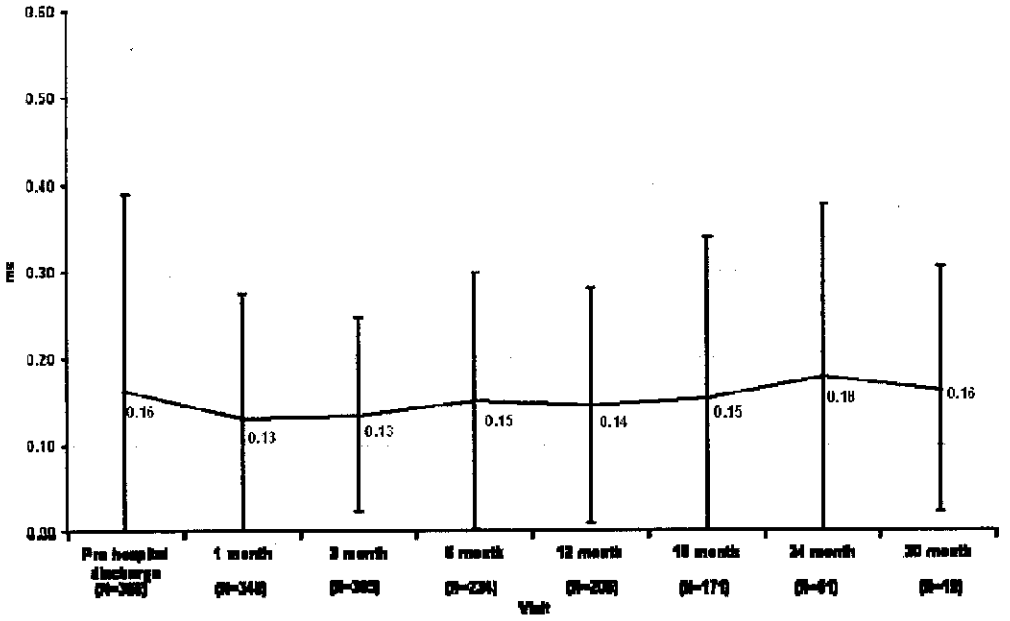
Figure 5. Model 4195 Lead Pulse Width Threshold
(As of March 5, 2007, Mean ± One Standard Deviation)



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5.6 Adverse Events Summary

For the purpose of the Model 4195 lead study, an adverse event was defined as any undesirable clinical occurrence in a subject, whether or not related to the investigational device. Adverse events were coded by the center and then further classified by relatedness. Medtronic reviewed each event and the treatment associated with the event to determine if the event was a complication or an observation. The Adverse Event Advisory Committee adjudicated this classification for every adverse event. The definition for each follows:

> **Complication:** An adverse event that results in invasive intervention, or the termination of significant device function regardless of other treatments. Intravenous (IV) and intramuscular (IM) therapies are considered invasive treatment.
>
> **Observation**: An adverse event that is not a complication.
>
> **Relatedness:** All adverse events were classified by their relatedness to the components, the CR system, implant tools, therapy, or procedure.

A total of 1217 adverse events in 296 subjects were reported in this subject cohort. Five hundred thirty-one of the events (in 202 subjects) were classified as complications and 686 (in 246 subjects) were classified as observations.

Table 8 provides a summary of all adverse events including incidence rates by complication and observation. Incidence rate is defined as the number of unique adverse events divided by subject months of exposure to the risk and normalized to 100 device months. The number of subjects at risk for each event can be found in the footnotes to Table 8. Tables 9 through 11 summarize all adverse events that were Model 4195 LV lead related (Table 9), implant / system modification / explant procedure related (Table 10), and implant tool related (Table 11). The percent of subjects with an event was calculated by dividing the total number of subjects experiencing an event by the number of subjects at risk (N) for that event.

Table 8: Summary of All Adverse Events (As of March 5, 2007)				
Relatedness	**Complications**		**Observations**	
	Number of Events	**Incidence Rate per 100 Device Months**	**Number of Events**	**Incidence Rate per 100 Device Months**
Model 4195 LV lead[1]	16	0.34	65	1.37
Model 4193 LV lead[2]	1	7.00	0	0
Right ventricular lead[3]	9	0.19	6	0.13
Right atrial lead[3]	7	0.15	12	0.25
Cardiac resynchronization device[4]	2	0.04	7	0.15
Cardiac resynchronization system[4]	4	0.08	5	0.10
Implant procedure[3]	32	0.67	51	1.07
Implant tool[3]	3	0.06	4	0.08
System modification / explant procedure[3]	2	0.04	0	0
Therapy[4]	4	0.08	0	0
Not related to cardiac resynchronization system[5]	451	9.38	536	11.14
Total	531	11.04	686	14.26

[1] 405 subjects experienced a Model 4195 lead implant attempt and were at risk for this event.
[2] 30 subjects experienced a Model 4193 lead implant attempt and were at risk for this event.
[3] 425 subjects experienced an implant attempt and were at risk for this event.
[4] 401 subjects received a cardiac resynchronization device and were at risk for this event.
[5] 440 subject were enrolled in the study and were at risk for this event.

Table 9: Left Ventricular Lead Related Adverse Events: Model 4195 Lead (As of March 5, 2007, N = 405)				
Event	**Complications**	**Observations**	**Number of Subjects**	**Percent of Subjects with Event**
Elevated pacing thresholds	0	7	7	1.73%
Failure to capture, loss of capture	3	3	5	1.23%
Lead conductor fracture*	1	0	1	0.25%
Lead dislodgement	3	0	3	0.74%
Muscle stimulation – chest wall	0	2	1	0.25%
Muscle stimulation – diaphragm	9	49	48	11.85%
Muscle stimulation - pectoral	0	1	1	0.25%
Unable to remove LV lead	0	3	3	0.74%
Total	**16**	**65**	**65**	**16.05%**

* One additional lead fracture was reported after the data cut-off.

Table 10: Procedure Related Adverse Events (As of March 5, 2007, N = 425)				
Event	**Complications**	**Observations**	**Number of Subjects**	**Percent of Subjects with Event**
Implant procedure				
Acute respiratory failure	1	0	1	0.24%
Anemia	2	0	2	0.47%
Arm/hand swelling	1	2	3	0.71%
Atelectasis	0	2	2	0.47%
Atrial fibrillation	0	1	1	0.24%
Atrial flutter	0	1	1	0.24%
Atrial standstill	0	1	1	0.24%
Back pain/discomfort	0	1	1	0.24%
Bacteremia	1	0	1	0.24%
Bleeding from pocket	1	0	1	0.24%
Coronary sinus dissection	0	1	1	0.24%
Diabetes	1	0	1	0.24%
Dressler's syndrome	1	0	1	0.24%

Table 10: Procedure Related Adverse Events (As of March 5, 2007, N = 425)				
Event	**Complications**	**Observations**	**Number of Subjects**	**Percent of Subjects with Event**
Extensive ecchymosis	0	1	1	0.24%
Heart failure decompensation	2	0	2	0.47%
Hemothorax/pneumothorax	1	2	3	0.71%
Hyperkalemia	0	1	1	0.24%
Hypertension	0	1	1	0.24%
Hypotension	4	0	4	0.94%
Inadequate electrical connection	1	0	1	0.24%
Pericardial effusion	1	0	1	0.24%
Phlebitis	0	1	1	0.24%
Pleural effusion	2	5	7	1.65%
Pocket infection	2	6	8	1.88%
Pocket seroma/hematoma	4	12	15	3.53%
Pocket site/incisional pain	0	5	5	1.18%
Pulmonary edema	0	1	1	0.24%
Rash	1	3	4	0.94%
Renal failure	2	1	3	0.71%
Sepsis	1	0	1	0.24%
Shoulder pain/discomfort	0	1	1	0.24%
Stitch abscess	0	1	1	0.24%
Stroke / CVA	1	0	1	0.24%
System infection	1	0	1	0.24%
Thrombosis	1	0	1	0.24%
Ventricular tachycardia	0	1	1	0.24%
Total	**32**	**51**	**65**	**15.29%**
System Modification Procedure				
Sepsis	1	0	1	0.24%
Total	**1**	**0**	**1**	**0.24%**
Explant Procedure				
Anemia	1	0	1	0.24%
Total	**1**	**0**	**1**	**0.24%**

Table 11: Implant Tool Related Adverse Events (As of March 5, 2007, N = 425)				
Event	**Complications**	**Observations**	**Number of subjects**	**Percent of Subjects with Event**
Asystolic episode	0	1	1	0.24%
Cardiac vein perforation	1	1	2	0.47%
Coronary sinus dissection*	1	2	3	0.71%
Hemothorax/pneumothorax	1	0	1	0.24%
Total	**3**	**4**	**7**	**1.65%**

* One event was attributed to the use of the Worley sheath, one event was attributed to the Pressure Products coronary sinus balloon venogram catheter, and one event was attributed to the Medtronic Attain Venogram Balloon Catheter Model 6215.

5.7 Summary of Model 4195 Modifications

Of the 382 subjects successfully implanted with a Model 4195 lead, 19 subjects underwent 21 Model 4195 lead modification attempts.

Fifteen of the 19 subjects (79%) had a Model 4195 lead successfully repositioned or removed. In the first 30 days following implant, 100% of the leads were successfully modified. A summary of the successful modification attempts from 0 to 910 days post-implant is outlined in Table 12.

Table 12: Summary of Successful Modifications by Time Post Implant (As of March 5, 2007, N=16)			
Reason for Modification	**Days Post Implant**	**Extraction Method Used**	**Outcome**
Failure to capture, loss of capture	0	Traction	Successfully removed
Dislodgement	1	Traction	Successfully removed
Dislodgement	1	Traction	Successfully removed
Dislodgement	1	Traction	Successfully repositioned
Extra-cardiac stimulation	1	Traction	Successfully repositioned
Extra-cardiac stimulation	8	Traction	Successfully removed
Extra-cardiac stimulation	16	Traction	Successfully repositioned
Infection	21	Traction	Successfully removed
Infection	22	Traction	Successfully removed
Failure to capture, loss of capture	23	Traction	Successfully repositioned
Extra-cardiac stimulation	37	Traction	Successfully removed
Infection	50	Traction	Successfully removed
Extra-cardiac stimulation	66	Traction	Successfully removed
Infection	92	Traction	Successfully removed
Extra-cardiac stimulation	581	Traction	Successfully repositioned
Infection	910	Laser in SVC, RA; counter-traction in CS with sheath	Successfully removed

The Model 4195 lead was capped in five cases after an unsuccessful modification attempt. The lead that was capped at 889 days post-implant was subsequently removed at 910 days using laser in the SVC and RA, and counter-traction in the CS. A summary of the five unsuccessful modification attempts is outlined in Table 13.

Table 13: Summary of Unsuccessful Modifications by Time Post Implant (As of March 5, 2007, N=5)			
Reason for Modification	**Days Post Implant**	**Extraction Method Used**	**Outcome**
RA lead reposition, non-response to CRT therapy	81	Traction	Capped, lead could not be removed by traction alone
Pocket erosion	478	Traction with locking stylet	Capped, with locking stylet, lead could not be removed by traction alone
Failure to capture, loss of capture	546	Traction	Distal segment of lead capped at clavicle
Lead fracture	795	Traction	Capped, lead could not be removed by traction alone
Sub-optimal LV lead placement	889	Traction	Capped, lead could not be removed by traction alone (later removed at 910 days)

Of the 21 modification attempts, no lead related complications were attributed to attempts at repositioning or removing the Model 4195 lead. One patient developed sepsis following an attempt to reposition the generator and Model 4195 lead (889 days post-implant). The same subject developed anemia following a second modification procedure (910 days post-implant) for complete removal of the CRT system.

The risk and difficulty of removing the Medtronic Attain StarFix Model 4195 lead following long-term implant is currently under post-approval study. In light of the novel fixation mechanism of the Model 4195 lead, there may be unique risks and difficulty associated with late revision and removal of the Model 4195 lead. Therefore, referral to an experienced extraction center is recommended.

5.8 Death Summary

As of March 5, 2007, 36 subjects had exited the Model 4195 LV lead study due to death. The AEAC categorized 18 deaths as cardiac related, 15 deaths as non-cardiac related, and 3 deaths as unknown cause. None of the subject deaths were thought to be LV lead related. One subject death, caused by a cerebrovascular accident, was considered to be related to the CRT system implant procedure.

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