Solia S Steroid-Eluting Leads

Active Fixation Pacing Endocardial Leads IS-1 Connector

Technical Manual

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CAUTION

Federal (U.S.A) law restricts this device to sale by, or on the order of, a physician.

Contents

1. Device Description

The BIOTRONIK Solia S transvenous, steroid-eluting, active fixation endocardial lead family is designed for permanent pacing and sensing. Active fixation pacing leads with a bipolar (BP) IS-1 connector configuration are designed for use in conjunction with implantable pulse generators with IS-1 compatible headers. The leads may be used with single- or dual-chamber pulse generators, dual chamber ICDs, CRT-P and D-devices.

Solia S leads feature an electrically active extendable/retractable fixation helix for use in lead placement. The helix is extended and retracted by rotating the connector pin with a fixation tool. Both the fixation helix and ring electrode are comprised of a platinum/iridium alloy base with a fractal iridium surface. The fractal surface of the lead electrodes creates a larger effective surface area, as a result maximizes the myocardial interface, which is a major factor in determining a lead's sensing characteristics. All leads are multifilar and insulated with medical grade silicone.

The distal tip of the Solia S lead consists of a steroid-eluting collar, containing 0.85 mg of dexamethasone acetate (DXA). Upon exposure to body fluids, the steroid elutes from the collar into the body tissue by diffusion. Release of the steroid is intended to decrease the inflammatory response at the contact site between the lead tip and the endocardium, thereby decreasing the elevated pacing thresholds of the endocardial lead that often occur after lead implantation.

Solia S leads have straight distal ends (Solia S xx) and are intended for placement in either the right atrium or right ventricle. The "xx" represents the lead length in centimeters. The Solia S leads are available in the following configurations: Solia S 45, Solia S 53, and Solia S 60.

CAUTION

Because of the numerous available 3.2 mm configurations, e.g., the IS-1 and VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

NOTE:

IS-1, wherever stated in this manual, refers to the international standard, whereby leads and generators from different manufacturers are assured a basic fit. [Reference ISO 5841-3:1992(E)].

See Section 11 for the technical specifications of the Solia S leads.

The leads referenced in this manual are MR Conditional devices. Therefore, MR scans are permissible under certain conditions. Refer to the ProMRI® System Technical Manual or www.biotronikusa.com/promri for specific MR conditions for use and to confirm the approved ProMRI device-lead combination. The ProMRI® device is also identified on the packaging by the following MR Conditional symbol.

2. Indications for Use

The BIOTRONIK Solia S lead is a 5.6 French (6F introducer), transvenous, steroid-eluting (0.85 mg DXA), bipolar, IS-1 compatible, active fixation lead intended for permanent sensing and pacing in either the right atrium or right ventricle when used with a compatible pulse generators with IS-1 headers. The leads may be used with single of dual chamber pacing systems, dual chamber ICDs, CRT-P and CRT-D.

3. Contraindications

Transvenous endocardial pacing leads are contraindicated in the presence of severe tricuspid valvular disease and in patients with mechanical heart valves. The Solia S lead is additionally contraindicated for patients who cannot tolerate a single systemic dose of up to 1.0 mg of dexamethasone acetate (DXA).

4. Warnings and Precautions

The performance of a cardiac pacing system depends on proper interaction of its three components: the pulse generator, the lead(s), and the patient. Abnormalities or changes in the electrical properties of any of the three components, or their interfaces with each other, may directly affect function of the entire system. Correct lead implantation is critical to safe and effective performance of the pacing system.

The pacing system may cease to function at any time due to medical and/or technical complications:

Medical Complications

Medical complications of the pacemaker treatment may include, but are not limited to: fibrotic tissue formation, thrombosis, embolism, elevated thresholds, body rejection phenomena, cardiac tamponade, muscle and nerve stimulation, myocardial perforation, erosion of the pulse generator/lead through the skin, infection and pacemaker-induced dysrhythmia (some of which could be life-threatening such as ventricular fibrillation).

Technical Complications

Incorrect operation of the pacing system may be caused by but is not limited to: improper lead placement, lead dislodgement, lead fracture, loss of insulation integrity, battery depletion, or electrical component failure.

Potentially Harmful Therapeutic and Diagnostic Procedures

As an implanted pacing lead is a direct, low resistance path to the myocardium for electrical current, the observance of high standards of electrical safety is required. Electrosurgical instruments, for example, could generate voltages of such amplitude that a direct coupling between the tip of the electrocautery device and the implanted lead may result, possibly inducing myocardial lesions or serious cardiac arrhythmias (e.g., fibrillation).

Some therapeutic and diagnostic procedures (e.g., diathermy, MRI, electrocautery) may result in latent damage to the pacing system. This damage may not be detected when testing the pulse generator function immediately after the procedure, but may become evident at a later time, resulting in pacing system malfunction or failure.

Lithotripsy- Lithotripsy treatment should be avoided since electrical and/or mechanical interference with the pacemaker or ICD is possible. If this procedure must be used, the greatest possible distance from the point of electrical and mechanical strain should be chosed in order to minimize a potential interference with the implant.

Medical Procedures- For any medical procedures that may affect the device (e.g., therapeutic ultrasound, external defibrillation, electrophysiological ablation, HF surger, lithotripsy), perform a complete follow-up after the procedure.

Therapeutic Ultrasound- Therapeutic ultrasound is not recommended due to possible heating effects of the device at the implant site. If therapeutic ultrasound must be considered, it should not be applied in the immediate vicinity of the implant.

Transcutaneous Electrical Nerve Stimulation (TENS)- Transcutaneous Electrical Nerve Stimulation should be avoided, as it may lead to uninteded heart stimulation.

Prevention of Leakage Current Conduction

Pulse generators and testing equipment connected to the lead must be battery-powered. Proper grounding of line-powered devices in the vicinity of the patient is essential to prevent leakage currents arising from such devices to be conducted via the lead’s terminal or any other non-insulated part.

Excessuve Pressure

Excessive pressure and hyperbaric oxygen therapy should be avoided as it may cause damage to the implant.

Previously Implanted Leads

It is generally recommended that a chronically implanted endocardial lead not be explanted. If it becomes necessary to abandon a lead, the connector pin should be capped to prevent the transmission of electrical signals to the heart.

Storage Temperature

Storage at temperatures up to 25° C (77° F); excursions permitted from 5° to 55° C (41° to 131° F). Exposure to temperatures outside this range may result in lead malfunction.

Necessary Equipment for Implantation

During implantation the ECG should be recorded; a pacing system analyzer (PSA) and defibrillation equipment should always be readily available.

Handling the Lead

The lead should be handled very carefully at all times. Any severe application of force (bending, stretching, crimping, etc.) may permanently damage the lead. The metal portion of the lead connector should not be touched.

Intrusion of Blood

Avoid intrusion of blood into the lead lumen.

Lead Positioning

If the ICD or pacemaker is implanted underneath the pectoral muscle, ensure that no parts of the lead lie between the ribs and the clavicle or between the housing of the implant and the ribs/clavicle. Chafing and pressure on the lead between the housing of the implant and the ribs/clavicle could damage the lead's insulation and thus cause premature failure.

Stylet Compatibility

To ensure compatibility, use only the stylets that are packages with the lead or approved for use with the lead. Unapproved stylet types may result in damage to the lead and/or patient injury.

Stylet Insertion

To avoid damage to the lead, do not insert the stylet too rapidly nor use excessive force when inserting the stylet into the lead.

Lead/Pulse Generator Compatibility

Because of the numerous available 3.2 mm configurations, e.g., the IS-1 and VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

NOTE:

IS-1, wherever stated in this manual, refers to the international standard, whereby leads and generators from different manufacturers are assured a basic fit. [Reference ISO 5841-3:1992(E)].

Extending/Retracting the Fixation Helix

In the event of previous handling or repositioning of the lead, more than the minimum number of rotations may be necessary to fully extend or retract the helix. Full helix extension should always be verified through fluoroscopy.

If the screw mechanism becomes difficult to handle or if it or the stylet sticks due to repeated extension and retraction of the fixation screw (from repositioning of the lead tip), the lead should be removed and replaced with a new one by the following measures:

- No longer use the screw mechanism
- Rotate the entire lead with inserted stylet counterclockwise in order to unscrew the lead from the myocardium without using the screw mechanism

Anchoring Sleeve

Always use an anchoring sleeve (lead fixation sleeve) when implanting a lead. Use of the anchoring sleeve, which is provided with the lead, will lessen the possibility of lead dislodgement and protect the lead body from damage by a securing ligature.

Complications due to the usage of multiple lead fixation sleeves- if a separately packaged lead fixation sleeve is used, it should be used as a replacement to the existing lead fixation sleeve on the lead and should not be used in conjunction with the existing lead fixation sleeve. The use of multiple lead fixation sleeves to sever the lead is not recommended as it may result in damage to the lead.

Measuring Intracardiac Signals

Depending on the PSA used, pacing may be interrupted during the measurement of the intracardiac signals. BIOTRONIK's ERA 300 or Reliaty Pacing System Analyzer has back-up VVI pacing at a rate of 30 ppm during the intracardiac measurements.

Chronic Repositioning

It is generally recommended that a chronically implanted endocardial lead not be explanted. Chronic repositioning or removal of active fixation leads may be difficult due to the presence of blood or fibrotic tissue in the helix. If it becomes necessary to remove the lead without successfully retracting the fixation helix, the lead should be rotated counter-clockwise during withdrawal in order to minimize the risk of endothelial laceration. If it becomes necessary to abandon a lead, the connector pin should be capped to prevent the transmission of electrical signals to the heart.

Setscrew Adjustment

The pulse generator's setscrew(s) must be retracted prior to inserting the lead connector. Failure to back off the pulse generator's setscrew(s) may result in damage to the lead(s), and/or difficulty connecting the lead(s).

Cross-Threading Setscrew

To prevent cross-threading the setscrew, do not back the setscrew completely out of the threaded hole. Leave the torque wrench in the slot of the setscrew while the lead is inserted.

Tightening Setscrew

Do not over-tighten the setscrew(s). Use only a torque wrench, which automatically prevents over-tightening.

Sealing Caps

For pacemakers requiring sealing caps, secure a sealing cap over the setscrew(s) to prevent pacemaker malfunction.

5. Potential Adverse Events

Potential complications resulting from the use of endocardial leads include, but are not limited to: thrombosis, embolism, body rejection phenomena, cardiac tamponade, pneumothorax, muscle/nerve stimulation, valve damage, fibrillation, infection, skin erosion and ventricular ectopy. Lead perforation through the myocardium has been rarely observed. The table below summarizes some of the potential symptoms indicating a complication and possible corrective actions:

Table 1: Potential Complications and Corrective Actions

Symptom	Potential Complication	Potential Corrective Action
Loss of pacing or sensing	Lead dislodgement	Reposition lead
	Lead fracture	Replace lead
	Lead insulation defect	Replace lead
	Improper lead / pulse generator connection	Reconnect lead to pulse generator
Increase/ decrease in threshold	Fibrotic tissue formation	Adjust pulse generator output; Replace/reposition lead

6. Clinical Study

6.1 SIELLO*

6.1.1 Primary Objectives

This clinical investigation is a multi-center, prospective, non-randomized, combined Pre-Market Study and Post-Approval Registry. The completed Pre-Market Study was designed to demonstrate the safety and effectiveness of the BIOTRONIK Siello S pacing lead and included three primary endpoints, which condense into two main objectives:

- Primary safety endpoints 1 & 2 – Evaluation of the atrial and ventricular adverse event-free rates (AEFRs) at 12 months post-implant for Siello leads implanted with a BIOTRONIK pacemaker device
- Primary effectiveness endpoint 3 – Evaluation of the rate of successful sensing and pacing at 12 months post-implant for Siello leads implanted with a BIOTRONIK pacemaker device

6.1.2 Methods

This study enrolled subjects implanted with any market-released BIOTRONIK pacemaker system including one or two Siello S leads.

The subjects selected for participation were from the investigator's general patient population, met the indications for use of a BIOTRONIK pacemaker system including one or two Siello S pacing leads, and also satisfied study inclusion and exclusion criteria.

Subjects were consented, underwent an implant procedure, and had follow-ups completed at 3 months, 6 months, and 12 months post-implant. During follow-up visits a device interrogation was performed, electrical parameters of the implanted leads were recorded, all device and electrical parameters were evaluated to ensure the device was correctly pacing and sensing, and an assessment of the incidence of any adverse events (AEs) was completed. If an implanted system was planned to include a Siello lead, but the subject could not be implanted with a lead, the subject was exited from the study after being followed for a period of 30 days in order to capture any AEs.

All protocol defined AEs were adjudicated by an independent Clinical Events Committee (CEC) and classified as implant procedure, implanted pulse generator or lead related. For each AE, the CEC also indicated the relatedness to the Siello lead as: unrelated, related, possibly related, or unknown.

6.1.3 Results

At the conclusion of the Pre-Market Study, a total of 1515 subjects had been implanted (or attempted to be implanted) between March 13, 2013 and April 3, 2015 with 2767 Siello S leads (1280 atrial, 1487 ventricular) at 60 US investigational centers, with a cumulative implant duration of 1240.5 years (mean of 0.82 ± 0.48 years). Mean subject age was 74.3 years with a range of 20.0 to 98.6, and 804 (53.1%) subjects were male. The most common primary reasons for implant were sinus node dysfunction (65.4%) and acquired atrioventricular block in adults (29.8%).

The observed sensing, pacing threshold, and impedance measurements for all originally implanted leads at implant and all follow-up visits were as follows:

- Mean RV lead pacing threshold at pulse width of 0.4 or 0.5 ms was 0.74 ± 0.30 V (n = 4195), mean RV lead sensing was 12.25 ± 4.56 mV (n = 3858); and mean RV lead impedance was 630.0 ± 104.3 ohms (n = 4258)
- Mean RA lead pacing threshold at pulse width of 0.4 or 0.5 ms was 0.83 ± 0.36 V (n = 3313); mean RA lead sensing was 3.56 ± 1.90 mV (n = 3607); and mean RA lead impedance was 515.1 ± 71.9 ohms (n = 3662)

* The leads studied as Siello are marketed under the name Solia S ProMRI in the U.S.

The observed sensing, pacing threshold, and impedance measurements for all originally implanted leads at 12 months post-implant were as follows:

- Mean RV lead pacing threshold at pulse width of 0.4 or 0.5 ms was 0.86 ± 0.29 V (n = 505), mean RV lead sensing was 12.68 ± 5.02 mV (n = 446); and mean RV lead impedance was 595.7 ± 89.1ohms (n = 515)
- Mean RA lead pacing threshold at pulse width of 0.4 or 0.5 ms was 0.85 ± 0.35 V (n = 389); mean RA lead sensing was 3.66 ± 1.92 mV (n = 429); and mean RA lead impedance was 524.0 ± 66.7 ohms (n = 441)

Primary Endpoints 1 & 2

The purpose of primary safety endpoints 1 and 2 was to evaluate the 12-month AEFRs of the Siello leads implanted in the atrium and ventricle respectively. AEs meeting the primary endpoint definitions and adjudicated by the CEC as related to the Siello lead qualified for inclusion in calculations of primary endpoint 1 and 2 AEFRs. For the purposes of AEFR calculations, evaluable subjects were those who had an implanted atrial/ventricular Siello lead reach the 12-month follow-up time point and/or experienced a qualifying AE.

Analysis

Primary safety endpoints 1 and 2 were evaluated by performing an exact, binomial test comparing a binomial proportion (AEFR at 12 months) to 94.0%.

Of the 450 evaluable subjects for primary endpoint 1, there were no subjects with a qualifying event, resulting in an AEFR of 100% (450/450), 95% CI (99.2%, 100%), $p < 0.0001$. Of the 525 evaluable subjects for primary endpoint 2, there were two subjects with a qualifying event, resulting in an AEFR of 99.62% (523/525), 95% CI (98.6%, 100%), $p < 0.0001$.

Table 2 provides a summary of primary endpoint 2 AEs related to the Siello lead implanted in the right ventricle, as adjudicated by the independent CEC.

Table 2: Primary Endpoint 2 Adverse Event Summary for Ventricular Siello Leads

Adverse Event	Subjects with Adverse Event, n	Subjects with Adverse Event, %	Adverse Events, n	Adverse Events per Subject-Year
Extracardiac stimulation	1	0.19%	1	0.0019
High pacing threshold	1	0.19%	1	0.0019
Intermittent capture, no lead capture	1	0.19%	1	0.0019
Total	2	0.38%	3	0.0058

Total number of evaluable subjects = 525; Number of subject years= 521.3

Conclusion

These results indicate the 12-month AEFRs of the Siello leads implanted in the atrium and ventricle are greater than 94.0%, and primary endpoints 1 and 2 are met.

Primary Endpoint 3

The purpose of primary effectiveness endpoint 3 was to evaluate the rate of successful sensing and pacing of the implanted system including one or two Siello leads, at 12 months post-implant. Only AEs unresolved at the time of the 12-month follow-up that were adjudicated as either lead undersensing or loss of sensing, or intermittent capture, no lead capture and adjudicated as related to the Siello lead

qualified for inclusion in the calculation of the primary endpoint 3 rate of successful sensing and pacing. For the purposes of this rate calculation, evaluable subjects were those who had an implanted Siello lead reach the 12-month follow-up time point and/or experienced a qualifying primary endpoint 3 AE.

Analysis

Primary effectiveness endpoint 3 was evaluated by performing an exact, binomial test comparing a binomial proportion (rate of successful sensing and pacing at 12 months) to 97.0%.

Of the 538 evaluable subjects for this endpoint, there were no subjects with a qualifying event, resulting in a rate of successful sensing and pacing of 100% (538/538), 95% CI (99.3%, 100%), $p < 0.0001$.

Conclusion

These results indicate the rate of successful sensing and pacing of the implanted system including one or two Siello leads at 12 months post-implant is greater than 97%, and primary endpoint 3 is met.

6.1.4 Clinical Study Conclusions

The purpose of the Siello Pre-Market Study was to confirm the safety and effectiveness of the Siello S pacing lead as used in conjunction with any market-released BIOTRONIK pacemaker device.

Overall Results

- There were no primary endpoint 1 AEs adjudicated as related to the atrial Siello lead, resulting in a per-protocol atrial Siello AEFR at 12 months of 100% (450/450), 95% CI (99.2%, 100%), $p < 0.0001$. Primary endpoint 1 was met.
- There were three primary endpoint 2 AEs for two subjects adjudicated as related to the ventricular Siello lead, resulting in a per-protocol ventricular Siello AEFR at 12 months of 99.62% (523/525), 95% CI (98.6%, 100%), $p < 0.0001$. Primary endpoint 2 was met.
- There were no primary endpoint 3 AEs adjudicated as related to the Siello lead, resulting in a per-protocol rate of successful sensing and pacing at 12 months of 100% (538/538), 95% CI (99.3%, 100%), $p < 0.0001$. Primary endpoint 3 was met.

All Pre-Market Study primary endpoints were met. The data received and analyzed represented the IDE experience of the Siello S pacing leads and confirmed the clinical safety and effectiveness of the Siello lead as used in conjunction with any market-released BIOTRONIK pacemaker device.

7. Adverse Events

7.1 Observed Adverse Events

7.1.1 SIELLO

The SIELLO Pre-Market Study included adverse event (AE) information for 582 subjects with a cumulative number of subject years of 570.6.

Investigators were required to assess and classify each reported AE as related to the implant procedure, implanted pulse generator, or implanted lead. For each AE, the investigator indicated whether the AE relatedness to the Siello lead was: not related, related, possibly related or unknown.

All protocol defined AEs were adjudicated by the independent Clinical Events Committee (CEC) and classified as implant procedure, implanted pulse generator, or lead related. For each AE, the CEC indicated the relatedness to the Siello lead as: unrelated, related, possibly related, or unknown.

Table 3 provides a summary of all 135 AEs in 108 subjects reported for the Pre-Market Study. The total number of subjects includes all subjects from the Pre-Market Study cohort who experienced an AE and/or reached the 12-month follow-up time point.

The CEC adjudicated 4 events as related to the Siello lead, 61 events as possibly related to the Siello lead, 68 events as unrelated to the Siello lead, and 2 events as having unknown relation to the Siello lead. Of the 4 AEs in 3 subjects adjudicated as related to the Siello lead implanted in the right ventricle, 3 AEs in 2 subjects met the primary endpoint 2 definition, and were included in the endpoint analysis. The remaining AE for high pacing threshold adjudicated by the CEC as related to the Siello lead implanted in the right ventricle, was not included in the analysis of primary endpoint 2 as this AE was resolved without any of the protocol specified additional actions required to meet the primary endpoint 2 definition.

Table 3: Summary of Pre-Market Study Adverse Events

Adverse Event	Subjects with Adverse Event, n	Subjects with Adverse Event, %	Adverse Events, n	Adverse Events per Subject-Year
Adverse Events Related to Siello Lead				
Related to RV Siello Lead				
Primary Endpoint 2 Adverse Events				
Extracardiac stimulation	1	0.17%	1	0.0018
Intermittent capture, no lead capture	1	0.17%	1	0.0018
High pacing threshold	1	0.17%	1	0.0018
Total Primary Endpoint 2 Adverse Events	2	0.34%	3	0.0053
Resolved Without Required Action				
High pacing threshold	1	0.17%	1	0.0018
Total Resolved Without Required Action	1	0.17%	1	0.0018
Total Related to RV Siello Lead	**3**	**0.52%**	**4**	**0.0070**
Adverse Events Possibly Related to Siello Lead				
Possibly Related to RA Siello Lead				
Lead dislodgement	22	3.78%	23	0.0403
Lead undersensing or loss of sensing	8	1.37%	8	0.0140
High pacing threshold	5	0.86%	5	0.0088
Cardiac perforation associated with the lead	2	0.34%	2	0.0035
Total Possibly Related to RA Siello Lead	**37**	**6.36%**	**38**	**0.0666**

Adverse Event	Subjects with Adverse Event, n	Subjects with Adverse Event, %	Adverse Events, n	Adverse Events per Subject-Year
Possibly Related to RV Siello Lead				
Lead dislodgement	10	1.72%	10	0.0175
High pacing threshold	5	0.86%	5	0.0088
Lead undersensing or loss of sensing	4	0.69%	4	0.0070
Cardiac perforation associated with the lead	2	0.34%	2	0.0035
Extracardiac stimulation	1	0.17%	1	0.0018
Lead impedance out of range, high impedance	1	0.17%	1	0.0018
Total Possibly Related to RV Siello Lead	**23**	**3.95%**	**23**	**0.0403**
Total Possibly Related to Siello Lead	**52**	**8.93%**	**61**	**0.1069**
Adverse Events Unrelated to Siello Lead				
Procedure Related				
Infection	11	1.89%	12	0.0210
Hematoma	8	1.37%	8	0.0140
Pneumothorax	7	1.20%	7	0.0123
Damage to lead during procedure	4	0.69%	4	0.0070
Loose set-screw	3	0.52%	3	0.0053
Pocket pain	2	0.34%	3	0.0053
Inability to place lead	3	0.52%	3	0.0053
Other procedure related	2	0.34%	2	0.0035
Venous occlusion	2	0.34%	2	0.0035
Lead dislodgement during a procedure	2	0.34%	2	0.0035
Pulmonary embolism	1	0.17%	1	0.0018
Lead reversed in header	1	0.17%	1	0.0018
Total Procedure Related	**43**	**7.39%**	**48**	**0.0841**
Pulse Generator Related				
Twiddler's syndrome	2	0.34%	2	0.0035
Other pulse generator related	1	0.17%	1	0.0018
Total Pulse Generator Related	**3**	**0.52%**	**3**	**0.0053**
RV Lead Related (Non-Siello)				
Lead dislodgement	1	0.17%	1	0.0018
Total RV Lead Related (Non-Siello)	**1**	**0.17%**	**1**	**0.0018**
LV Lead Related				
Extracardiac stimulation	6	1.03%	6	0.0105
High pacing threshold	4	0.69%	4	0.0070
Lead dislodgement	3	0.52%	3	0.0053
Intermittent capture, no lead capture	1	0.17%	1	0.0018
Lead impedance out of range, high impedance	1	0.17%	1	0.0018
Other RA/RV/LV (Inability to place LV lead)	1	0.17%	1	0.0018
Total LV Lead Related	**12**	**2.06%**	**16**	**0.0280**
Total Unrelated to Siello Lead	**57**	**9.79%**	**68**	**0.1192**
Adverse Events with Unknown Relation to Siello Lead				
Coincidental finding of endocarditis after PPM placement-Infection	1	0.17%	1	0.0018
Lead dislodgement during Afib ablation	1	0.17%	1	0.0018
Total Unknown Relation to Siello Lead	**2**	**0.34%**	**2**	**0.0035**
Total	**108**	**18.56%**	**135**	**0.2366**

Total Number of Subjects = 582, Number of Subject Years = 570.6

8. General Information on Product Handling

The following information generally applies to all transvenous implantable leads, but does not attempt to describe all procedures to be followed, precautions to be taken, or contraindications to be considered.

8.1 Sterilization and Storage

The lead and its accessories have been sealed in a double blister plastic container and gas sterilized with ethylene oxide. To assure sterility, the container should be checked for integrity prior to opening. Should a breach of sterility be suspected, return the lead to BIOTRONIK.

The blister package is shipped in an outer box, equipped with a quality control seal and product information label. The label contains the model specifications, technical data, serial number, shelf-life expiration date, sterilization and storage information of the lead.

CAUTION

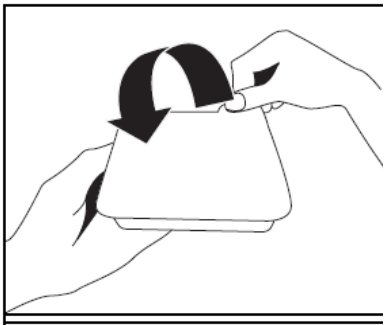
Storage Temperature – Storage at temperatures up to 25° C (77° F); excursions permitted from 5° to 55° C (41° to 131° F). Exposure to temperatures outside this range may result in lead malfunction.

Handling the Lead – The lead should be handled very carefully at all times. Any severe application of force (bending, stretching, crimping, etc.) may permanently damage the lead. The metal portion of the lead connector should not be touched.

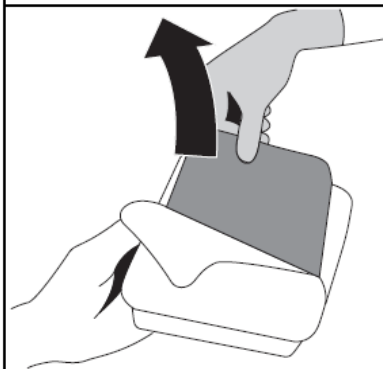
Should a replacement lead be required, contact your local BIOTRONIK representative.

8.2 Opening the Sterile Container

The lead is packaged in two plastic containers, one within the other. The two packages are individually sealed and then sterilized with ethylene oxide gas. Due to the double packaging, the outside of the inner container is sterile and can be removed using standard aseptic technique and placed in the sterile field.



Peel off the sealing paper of the outer unsterile container as indicated by the arrow.



Take out the inner sterile container by the gripping tab and open it by peeling the sealing paper as indicated by the arrow.

8.3 Package Content and Accessories

The Solia S leads and the accessories provided in the inner blister package with each lead are delivered sterile.

Each Solia S (available in 45, 53, and 60 cm lengths) package contains the following:

Solia S (available in 45, 53, and 60 cm lengths)

- external fixation tool(s)
- lead fixation sleeve – mounted on lead
- additional stylets

Table 4: Number of Stylets for Solia S

	Solia S 45	Solia S 53	Solia S 60
S xx-K stylet (straight) (one of which is pre-inserted)	2	2	2
S xx-J stylet (J-shaped)	1	1	N/A
S xx-JL stylet (J-shaped)	1	1	N/A
Total	4	4	2

- stylet guide
- vein lifter

NOTE:

The fixation tool and all stylets are also available as separately packaged accessories.

9. Implantation

The lead tip consists of a silicone rubber collar that contains a steroid agent. The steroid is used to reduce inflammation after the implantation and decrease the postoperative threshold increase caused by inflammation.

9.1 General Guidelines

Solia S leads come with a regular straight ball-tipped stylet already inserted.

Verifying the Mechanical Function of the Fixation Helix

Prior to implantation, test the operation of the fixation helix:

1. Press both legs of the fixation tool together and place the most distal hole of the fixation tool on the connector pin.

Note: Only empoy the screws mechanism using the provided
fixation tool, which is clamped to the connector pin.
Do not use any other tools or accessories.

2. Practice extending the helix by rotating the tool clockwise until the helix is completely exposed (5-10 complete clockwise rotations of the fixation tool). This number of rotations of the fixation tool should fully extend the helix to approximately 1.8 mm. (See following figure).
3. Remove the fixation tool from the connector pin and release the proximal end of the lead body. Allow the residual torque in the lead to be relieved.
4. Reattach the fixation tool. Practice retracting the helix by rotating the tool counterclockwise until the helix is retracted in the sheath (6-9 complete counterclockwise rotations of the fixation tool).

NOTE:
More than the recommended 6-9 rotations may be necessary to extend or retract the fixation helix.

Venous Access

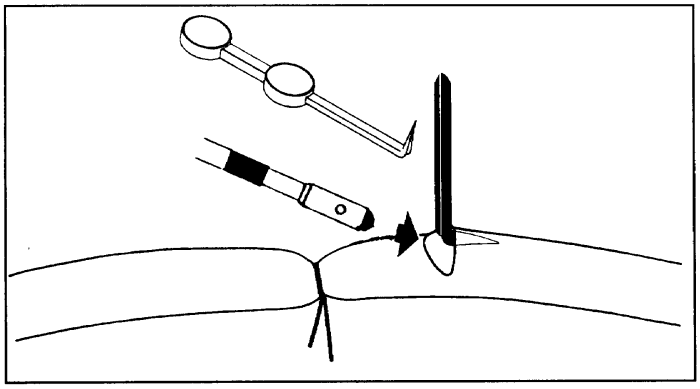
A number of venous routes are available for implanting an endocardial lead, including the cephalic, subclavian, and external or internal jugular veins. Venous access can be gained by using either the cutdown or subclavian puncture technique.

CAUTION

Lead/Pulse Generator Compatibility Because of the numerous available 3.2 mm configurations, e.g., the IS-1 and VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

NOTE:
IS-1, wherever stated in this manual, refers to the international standard, whereby leads and generators from different manufacturers are assured a basic fit. [Reference ISO 5841-3:1992(E)].

5. Position the lead fixation sleeve close to the lead's connector pin.
6. To employ the cephalic cutdown technique, carefully insert the pointed end of the disposable vein lifter into the lumen after opening the vein, and then lift the vein to permit easy lead insertion. (see following figure)



7. If the subclavian route is selected and access by subclavian puncture is preferred, a percutaneous lead introducer should be used. Perform a subclavian puncture and insert a lead introducer into the vein. Remove the introducer guidewire and dilator, leaving the sheath in place in the vein to receive the lead.
8. Advance the stylet all the way into the lead. This will stiffen and straighten the lead, and prevent lead bending or perforation.
9. Excessive lead slack can potentially lead to perforation.

NOTE:

Avoid blood contact to the stylet which may make its reinsertion and/or removal difficult. A spare stylet is provided in the inner tray.

NOTE:

BIOTRONIK stylets are designed to be 1 to 2 cm longer than the stylet lumen of the lead body.

CAUTION

Stylet Compatibility To ensure compatility use only the stylets that are packaged with their lead or approved for use with the lead. Unapproved stylet types may result in damage to the lead and/or patient injury.

Stylet Insertion To avoid damage to the lead, do not insert the stylet too rapidly nor use excessive force when inserting the stylet into the lead.

Securing the Electrode into the Endocardium

9. After the electrode has been advanced into a stable position within the atrium or ventricle, leave the stylet to the lead and attach the fixation tool to the connector pin.
10. Achieve permanent lead fixation by rotating the fixation tool clockwise until the helix is completely exposed.

NOTE:

A minimum of 6-9 rotations of the fixation tool are recommended to fully extend (or retract) the fixation helix.

> **CAUTION**
>
> In the event of previous handling or repositioning of the lead, more than the minimum number of rotations may be necessary to fully extend or retract the helix. Full helix extension should always be verified through fluoroscopy.

11. Use fluoroscopy to verify the position of the fixation helix. Both the helix and the tip are visible under fluoroscopy as noted in the figure below.

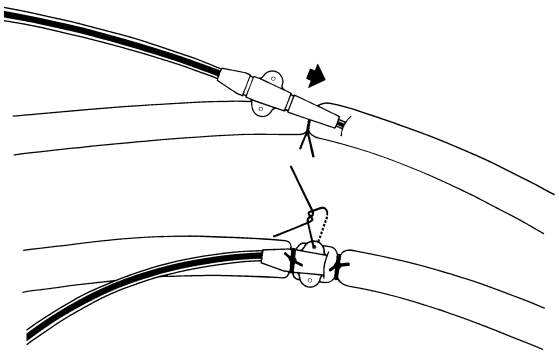
Helix retracted

Helix extended

12. Carefully remove the stylet after the electrode has been positioned and fixed into a stable position.

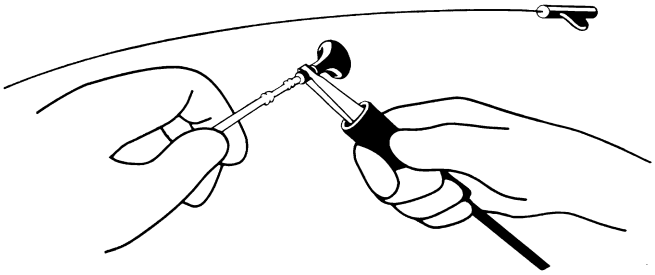
To lessen the possibility of dislodgement, it is recommended to anchor the lead at the incision site where it enters the vein. To facilitate anchoring without damaging the lead insulation or the conductor coil, BIOTRONIK leads are supplied with a silicone rubber fixation sleeve designed with ligature grooves and anchoring tabs.

> **CAUTION**
>
> **Anchoring Sleeve** Always use an anchoring sleeve (lead fixation sleeve) when implanting a lead. Use of the anchoring sleeve, which is provided with the lead, will lessen the possibility of lead dislodgement and protect the lead body from damage by a securing ligature.



Care should be taken to avoid perforating or otherwise damaging the lead with the stylet, clamps or other surgical instruments. The white marker clamp available separately may be used for identification during a dual lead implantation procedure.

The notch at the side of the stylet guide permits connection of a surgical cable alligator clip to the lead connector pin for measurement of the capture threshold and the intracardiac signal. After this, the pacemaker is connected to the lead as described in Section 9.3 and in the appropriate technical manual for pacemaker implantation.



NOTE:

Special care should be taken not to damage the sealing rings of the lead connector, particularly when making contact with the ring electrode of a bipolar lead with an IS-1 connector (letter designation “BP”) by means of an alligator clip.

9.2 Measurement of the CaptureThreshold and Intracardiac Signals

Low capture thresholds and adequate sensing of intracardiac signal amplitudes indicate appropriate lead placement. The BIOTRONIK Pacing System Analyzer or a comparable device may be used to accurately determine pacing capture thresholds, as well as intracardiac signals, in accordance with implant characteristics of implantable pulse generators.

WARNING

Prevention of Leakage Current Conduction – Pulse generators and testing equipment connected to the lead must be battery-powered. Proper grounding of line-powered devices in the vicinity of the patient is essential to prevent leakage currents arising from such devices to be conducted via the lead’s terminal or any other non-insulated part.

Previously Implanted Leads – It is generally recommended that a chronically implanted endocardial lead not be explanted. If it becomes necessary to abandon a lead, the connector pin should be capped to prevent the transmission of electrical signals to the heart.

Generally, the electrode position is regarded acceptable if the values for capture and sensing threshold meet the following industry-recommended values:

Measurement	Atrial	Ventricular
Maximum acute capture threshold at pulse duration setting ≤0.5 ms	1.5 V	3.0 V
Minimum acute sensing amplitudes	2.0 mV	5.0 mV
Impedance range (0.5 ms, 4.8 V)	500 to 2000 Ω	

9.3 Lead Connection to the Pulse Generator

1. Withdraw the stylet and stylet guide before connecting the lead to the pulse generator.
2. Using the pulse generator torque wrench, retract the setscrew(s) counterclockwise far enough to ensure unimpeded insertion of the lead connector(s) into the port(s).

> **CAUTION**
>
> **Setscrew Adjustment** The pulse generator's setscrew(s) must be retracted prior to inserting the lead connector. Failure to back off the pulse generator's setscrew(s) may result in damage to the lead(s), and/or difficulty connecting the lead(s).

3. Insert the lead connector into the pulse generator's header receptacle following the manufacturer's directions for lead insertion. The method of insertion depends upon the header configuration of the pulse generator.
4. Securely tighten the setscrew(s) of the pulse generator connector.

> **CAUTION**
>
> **Tightening Setscrew** Do not over-tighten the setscrew(s). Use only a torque wrench, which automatically prevents over-tightening.

5. Assure correct insertion of the connector pin by verifying that the tip of the pin is visible past the header connector block.
6. Visually and mechanically check the integrity of the connection after tightening the setscrew(s).

CAUTION

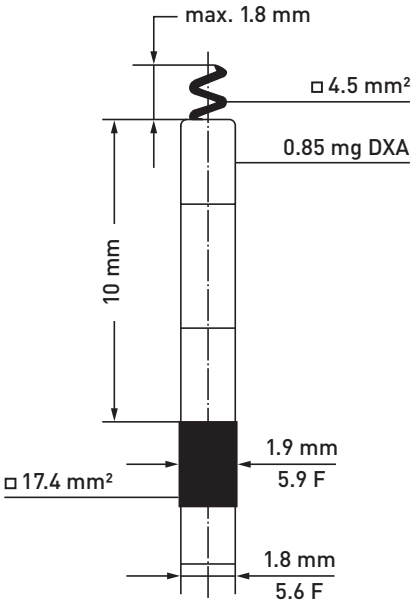
Sealing Caps For pacemakers requiring sealing caps, secure a sealing cap over the setscrew(s) to prevent pacemaker malfunction.

10. Disclaimer

BIOTRONIK leads, lead extensions, adapters and accessories used in connection with these devices (referred to as: leads and accessories) have been qualified, manufactured and tested in accordance with well-proven and accepted standards and procedures. The physician should be aware, however, that leads and accessories may be easily damaged by improper handling or use. Except as set forth in BIOTRONIK's Lead Limited Warranty, BIOTRONIK makes no express or implied warranties for its leads and accessories.

11. Technical Specifications

Solia S Steroid-Eluting, Bipolar Implantable Endocardial Leads with Active Fixation



Model (xx = length in cm)	Order Number
Solia S 45	377 176
Solia S 53	377 177
Solia S 60	377 179

Solia S xxTechnical Parameters	
Connection	IS-1
Polarity	Bipolar
Configuration	Straight
Fixation Helix	
Fixation	Electrically active helix, retractable
Extended	max. 1.8 mm
Surface Area	4.5 mm²
Material	70% Pt/30% Ir
Surface Structure	Iridium, Fractal
Steroid	
Steroid	Dexamethasone acetate (DXA)
Steroid Amount	0.85 mg
Steroid Carrier	Silicone Rubber
Ring Electrode	
Surface Area	17.4 mm²
Material	90% Pt / 10% Ir
Surface Structure	Iridium, Fractal
Tip to Ring Distance	10 mm
Lead Body	
Insulation	Silicone Rubber / Polyurethane
Conductor	MP35N
Lead Body Diameter	1.8 mm (5.6 F)
Maximum Diameter	1.9 mm (5.9 F)
Number of Wire Filaments	4
Lengths	45 / 53 / 60 cm
Wire Resistance (Tip)	0.65 Ω/cm
Wire Resistance (Ring)	2.45 Ω/cm
Recommended Lead Introducer	6 F

12. Solia S Compatible Accessories and Stylets

Solia S Compatible Accessories	
Compatible but not separately available	
Name	**Model Number**
Stylet Guide SG-UP	---
Compatible & separately available	
VL-6	371805
VL (5-pack)	206157
VL (single pack)	395084
Fixation Tool (DH) (5-pack)	331668
Fixation Tool (DH) (single pack)	395111
DH IS-1/DF4 (10 pack)	401298
DH IS-1/DF4 (2 pieces)	401297
EFH-6F-W (5 pieces)	433306
EFH-6F-W (single pack)	433307
EFH-22 (5 pieces)	330489
EFH-22 (single pack)	395114
BK-IS (5-pack)	109185
BK-IS (single pack)	395079

Solia S Compatible & Separately Available Stylets		
Stylet	**Model Number (10-pack)**	**Model Number (single pack)**
S 45-F	130091	395085
S 45-J	113395	395086
S 45-JL	353385	395087
S 45-K	113588	395088
S 53-F	130093	395090
S 53-J	107237	395091
S 53-JL	353235	395092
S 53-K	107235	395093
S 53-S	130013	395094
S 60-F	124697	395102
S 60-J	106164	395103
S 60-K	106162	395104
S 60-S	119291	395105

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Solia S Leads
Technical Manual

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MN072 11/21/17

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035-5369

(800) 547-0394 (24-hour)
(800) 291-0470 (fax)
www.biotronik.com

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excellence for life