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Cardiac Rhythm Management  
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Heart Failure Therapy  
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**Linux Leads**  
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## Linux Leads

### Technical Manual



**CAUTION**

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

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## 1. General

### 1.1 Description

The Linux Lead Systems are implantable, transvenous ICD leads for use with BIOTRONIK's implantable cardioverter defibrillators (ICDs). The Linux Lead Systems include

- Linux S
- Linux SD
- Linux T
- Linux TD

The Linux S and Linux T Lead Systems have two sensing and pacing electrodes and one defibrillation electrode, all of which are contained in one single-pass lead. The Linux SD and Linux TD Lead Systems have two sensing and pacing electrodes and two defibrillation electrodes. These lead systems, in conjunction with an ICD, perform the following functions:

- sense electrical signals from cardiac tissue and conduct those signals to the ICD;
- conduct bradycardia and antitachycardia pacing pulses emitted from the ICD to cardiac tissue;
- conduct defibrillation shocks of both high and low energies from the ICD to cardiac tissue.

The Linux Lead Systems are intended for placement in the right ventricle. The tip and ring electrodes form the most distal portion of the lead and provide dedicated bipolar sensing and pacing. All Linux Lead Systems have one shock electrode that is positioned in the right ventricle (RV). The Linux SD and Linux TD dual-coil ICD leads have an additional shock electrode for placement in the superior vena cava (SVC).

The Linux S, and Linux SD 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 (see [Section 6](#) of this manual for technical specifications). The fractal surface structure on the electrodes provides a larger effective tissue interface that is a major factor in determining a lead's sensing characteristics.

The Linux T and Linux TD leads feature a passive fixation tip coated with fractal iridium for use in lead placement. The fractal surface structure on the electrode provides a larger effective tissue interface that is a major factor in determining a lead's sensing characteristics.

The distal tip of all Linux ICD leads consists of a steroid-eluting collar which contains up to 1.3 mg of dexamethasone acetate (DXA). Upon exposure to body fluids, the steroid elutes from the collar. 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.

The Linux S and Linux T leads have one IS-1 bipolar sensing and pacing connector and one DF-1 defibrillation lead connector. The Linux SD and Linux TD leads have one IS-1 bipolar sensing and pacing connector and two DF-1 defibrillation lead connectors. The lead systems are designed for use in conjunction with an ICD that allows a defibrillation shock pathway to include the housing of the ICD.

IS-1 refers to the international standard whereby leads and generators from different manufacturers are assured a basic fit [Reference ISO 5841-3:1992]. DF-1 refers to the international standard for defibrillation lead connectors [Reference ISO-11318:1993].

### 1.2 Indications and Usage

The Linux<sup>smart</sup> 8F steroid-eluting, bipolar, IS-1 transvenous lead system is intended for use in the right ventricle of patients for whom implantable cardioverter defibrillators are indicated.

## 1.3 Contraindications

Do not use the Linux Lead System in patients with severe tricuspid valve disease or patients who have a mechanical tricuspid valve implanted.

### Active Fixation

The Linux steroid-eluting leads with active fixation are additionally contraindicated for patients who cannot tolerate a single systemic dose of up to 1.3 mg of dexamethasone acetate (DXA).

### Passive Fixation

The Linux steroid-eluting leads with passive fixation are additionally contraindicated for patients who cannot tolerate a single systemic dose of up to 1.0 mg of dexamethasone acetate (DXA).

## 1.4 Warnings

**MRI (Magnetic Resonance Imaging)**—Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

**Electrical Isolation**—Electrically isolate the patient from potentially hazardous leakage current to prevent inadvertent arrhythmia induction.

**Resuscitation Availability**—In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias. Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available.

**Defibrillation Threshold**—Be aware that changes in the patient's condition, drug regimen, and other factors may affect the defibrillation threshold (DFT) which may result in nonconversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

**Maximum Fixation Tool Rotations**—Under no circumstances should you exceed 30 turns to extend the fixation helix. (Linux S and Linux SD only).

## 1.5 Precautions

### 1.5.1 Sterilization, Storage, and Handling

**Lead Packaging**—Do not use the lead if the lead's packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the lead to BIOTRONIK.

**Resterilization**—Do not resterilize and re-implant explanted leads.

**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.

**Use Before Date**—Do not implant the lead after the USE BEFORE DATE.

### 1.5.2 Implantation and Evaluation

**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 dislodgment and protect the lead body from damage by the securing ligature.

**Blind Plug**—A blind plug must be inserted and firmly connected into any unused header port of the ICD to prevent chronic fluid influx and possible shunting of high-energy therapy.

**Capping Leads**—If a lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.

**Connector Compatibility**—ICD and lead system compatibility should be confirmed prior to the implant procedure. Consult your BIOTRONIK representative regarding lead/pulse generator compatibility prior to the implantation of an ICD system.

**Cross-Threading**—To prevent cross-threading the setscrew, do not back the setscrew completely out of the threaded hole. Leave the screwdriver in the slot of the setscrew while the lead is inserted.

**Gripping Leads**—Do not grip the lead with surgical instruments or use excessive force or surgical instruments to insert a stylet into a lead.

**Helix Extension**—Due to 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. (Linux S and Linux SD only)

**Helix Extension, Maximum Additional Turns**—If the fixation helix is not fully extended after 20 turns, continue to extend the fixation helix with a maximum of 10 additional turns. (Linux S and Linux SD only)

**Helix Mechanical Function Test**—Do not implant the lead if this function test is not successful. In this case, test a replacement lead in the same way, and if the test is successful, implant the replacement lead (Linux S and Linux SD only).

**Lead Handling**—Make sure that the lead is neither knotted, twisted, nor bent at a sharp angle.

**Liquid Immersion**—Do not immerse terminated pins in mineral oil, silicone oil, or any other liquid.

**Over-Tightening**—Do not over-tighten the setscrew(s). Use only a torque wrench which automatically prevents over-tightening. (Linux S and Linux SD only)

**Pacemaker/ICD Interaction**—In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or explanted if previously implanted). For more information, please refer to the appropriate ICD technical manual.

**Repositioning or Explanting**—Before repositioning or explanting the lead, use fluoroscopy to ensure that the fixation screw has been fully retracted. (Linux S and Linux SD only).

**Sealing System**—Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the sealing system and its self-sealing properties.

**Setscrew(s)**—Failure to back off the setscrew(s) may result in damage to the lead(s), and/or difficulty connecting the lead(s).

**Shock Impedance**—Never implant a device with a lead system that has a measured shock impedance that is less than what is recommended in the appropriate ICD technical manual. Damage to the device may result. If the shock impedance is less than the recommended value, reposition the lead system to allow a greater distance between the electrodes.

**Short Circuit**—Ensure that none of the lead electrodes are in contact (a short circuit) during delivery of shock therapy as this may cause current to bypass the heart or cause damage to the ICD system.

**Stylet**—A badly deformed stylet can damage the lead. Do not bend the stylet.

**Suturing the Lead**—Using the Linux S and Linux SD lead may involve an increased risk of perforation and rupture. This lead must be implanted in such a way that no tensile stress is exerted on the fixation screw during systole or diastole, or during other movements made by the patient. Suture the lead at the entry point into the vein in such a way that no tensile stresses occur and the tricuspid valve is not

obstructed. Do not suture directly over the lead body as this may cause structural damage. Use the appropriate suture sleeve to immobilize the lead and protect it against damage from ligatures. Make sure that there is no contact between shock and pacing/sensing electrodes inside the lead.

**Tricuspid Valve Bioprosthesis**—Use ventricular transvenous leads with caution in patients with a tricuspid valvular bioprosthesis.

### 1.5.3 Pulse Generator Explant and Disposal

**Device Incineration**—Never incinerate an ICD due to the potential for explosion. An ICD must be explanted prior to cremation.

**Explanted Devices**—Return all explanted devices to BIOTRONIK.

**Unwanted Shocks**—Prior to explanting the ICD, program the detection status of the device to OFF to prevent unwanted shocks.

### 1.5.4 Hospital and Medical Hazards

**Diathermy**—Diathermy therapy is not recommended for ICD patients due to possible heating effects at the implant site. If diathermy therapy must be used, it should not be applied in the immediate vicinity of the pulse generator or lead system. Following the procedure, proper ICD function should be checked and monitored.

**Electrocautery**—Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible.

**External Defibrillation**—External defibrillation may result in permanent myocardial damage at the electrode-tissue interface as well as temporarily or permanently elevated pacing thresholds. When possible, observe the following precautions:

- Position the adhesive electrodes or defibrillation paddles of the external defibrillator anterior-posterior or along a line perpendicular to the axis formed by the implanted ICD system and the heart.
- Set the energy to a level not higher than is required to achieve defibrillation.
- Place the paddles as far as possible away from the implanted device and lead system.
- After delivery of an external defibrillation shock, interrogate the ICD to confirm device status and proper function.

**MRI (Magnetic Resonance Imaging)**—Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

**Radio Frequency Ablation**—Prior to performing an ablation procedure, deactivate the ICD. Avoid applying ablation energy near the implanted lead system whenever possible. The ICD system should be checked for proper operation after the procedure.



## 1.6 Adverse Events

### 1.6.1 Potential Adverse Events

Adverse events (in alphabetical order) associated with ICD systems include, but are not limited to:

- Acceleration of arrhythmias
- Air embolism
- Arrhythmias
- Bleeding
- Body rejection phenomena
- Cardiac tamponade
- Chronic nerve damage
- Device migration
- Elevated pacing thresholds
- Erosion
- Fluid accumulation
- Formation of hematomas or cysts
- Heart valve damage
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration/dislodgment
- Lead fracture/insulation damage
- Muscle or Nerve Stimulation
- Myocardial damage
- Myopotential sensing
- Pacemaker mediated tachycardia
- Pneumothorax
- Potential mortality due to inability to defibrillate or pace
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Thromboembolism
- Undersensing of intrinsic signals
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while awake
- Fear that shocking ability may be lost
- Imagined shocking (phantom shock)

### 1.6.2 Observed Adverse Events

The Kentrox RV S Steroid and Kentrox SL S Steroid ICD leads clinical evaluation included a total of 64 patients implanted with 43 Kentrox RV S Steroid leads and 21 Kentrox SL S Steroid leads. All adverse events are classified into two types: observations and complications. Observations are defined as clinical events that do not require additional invasive intervention to resolve. Complications are defined as clinical events that require additional invasive intervention to resolve.

#### **NOTE:**

The Kentrox RV-S Steroid and Kentrox SL-S Steroid ICD leads are earlier generation of BIOTRONIK devices. The Linux<sup>smart</sup> family is based upon the Kentrox family and other BIOTRONIK ICD Leads (i.e., Linux and Kainox families of ICD leads).

[Table 1](#) provides a summary of the observed complications with the steroid version of the Kentrox ICD leads. Of the 64 patients, 35 were followed for at least 3 months and only 1 (1.6%) patient underwent a lead revision due to elevated pacing thresholds/loss of ventricular capture in this steroid lead registry.

**Table 1: Kentrox RV-S Steroid and Kentrox SL-S Steroid Lead Related Complication Rate**

Complication	Number of Patients with Complications	Percentage of Patients with Complications	Number of Complications
<b>Steroid (Total Number of Patients = 64, Followed for 3 months = 35)</b>			
Elevated Ventricular Pacing Threshold	1	1.6%	1
Lead Repositioning	1	1.6%	1
Total Steroid	2	3.2%	2

## 1.7 Clinical Studies

### 1.7.1 Linux ICD Leads

Because the Linux SD leads are based on BIOTRONIK's legally marketed Kentrox SL-S Steroid lead and Linux TD are based on BIOTRONIK's legally marketed Kentrox SL Steroid lead, extensive engineering tests and an animal study were performed in lieu of human clinical data.

### 1.7.2 Kentrox SL-S Steroid and Kentrox RV-S Steroid

BIOTRONIK conducted a prospective registry outside the United States (OUS) of the Kentrox RV-S Steroid and Kentrox SL-S Steroid ICD leads. Because no reasonable non-steroid control data from leads with the exact physical specifications was available, no comparison analysis was performed. However, data from this registry is presented in the following sections simply to support the efficacy of the Kentrox RV-S and Kentrox SL-S Steroid ICD leads including pacing threshold measurements that are within the normal range for steroid leads.

#### 1.7.2.1 Patients Studied

The Kentrox RV-S and Kentrox SL-S Steroid ICD leads clinical evaluation included a total of 64 patients implanted with 43 Kentrox RV-S Steroid leads and 21 Kentrox SL-S Steroid leads. The study population had a mean age of 65 years (range: 54 to 76 years) and included 59 males (92%) and 5 females (8%). Patients presented with ventricular fibrillation (52%–VF) and ventricular tachycardia (48%–VT). One month follow-up data for 49 patients and three month follow-up data for 35 patients was received and reviewed for this summary.

#### 1.7.2.2 Methods

Investigators were required to use the implanted ICD to obtain ventricular lead measurements including intrinsic sensing amplitudes, pacing thresholds and lead impedance values at the implant, pre-discharge, one-month, three-month, and subsequent routine follow-ups.

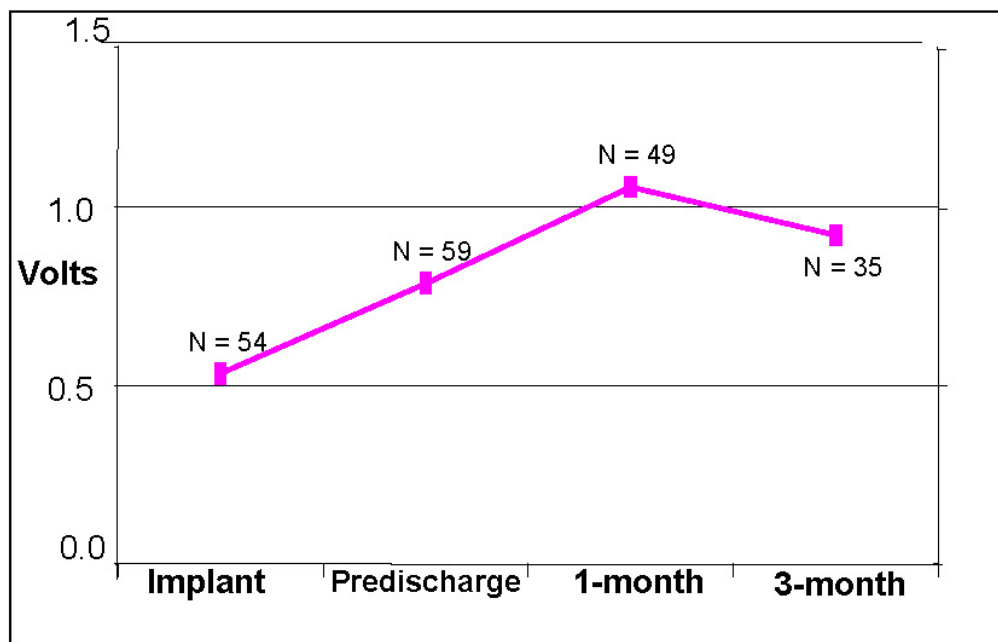
#### 1.7.2.3 Results

[Table 2](#), [Table 3](#) and [Table 4](#) provide summaries of measured ventricular pacing thresholds, R-waves, and ventricular pacing impedance measurements, respectively. Additionally, [Table 2](#) depicts the ventricular pacing thresholds over time. Both the Kentrox RV-S Steroid and the Kentrox SL-S Steroid ICD leads were pooled for presentation of this data because the leads are identical except for the second high energy shock coil embedded in the Kentrox SL-S Steroid ICD lead.

Sixty-one tests with two successful 20 J shocks or less demonstrated the ICD lead system's ability to convert VF and provide a minimum 10 J safety margin with BIOTRONIK ICDs.

**Table 2: Ventricular Pacing Threshold**

Pacing Threshold (Volts @ 0.5ms)	Results
<b>Implant</b>	
Number of Tests	64
Mean $\pm$ SE	$0.5 \pm 0.1$
Range	0.3 to 1.2
<b>Pre-discharge Follow-up</b>	
Number of Tests	59
Mean $\pm$ SE	$0.8 \pm 0.1$
Range	0.3 to 4.6
<b>One-Month Follow-up</b>	
Number of Tests	49
Mean $\pm$ SE	$1.1 \pm 0.2$
Range	0.3 to 5.2
<b>Three-Month Follow-up</b>	
Number of Tests	35
Mean $\pm$ SE	$0.9 \pm 0.2$
Range	0.3 to 4.6



**Figure 1: Ventricular Pacing Threshold**

**Table 3: R-Wave Amplitude**

R-Wave (mV)	Results
<b>Implant</b>	
Number of Tests	63
Mean $\pm$ SE	12.0 $\pm$ 0.4
Range	5.2 to 17.6
<b>Pre-discharge Follow-up</b>	
Number of Tests	58
Mean $\pm$ SE	11.5 $\pm$ 0.4
Range	4.1 to 17.5
<b>One-Month Follow-up</b>	
Number of Tests	49
Mean $\pm$ SE	11.7 $\pm$ 0.5
Range	6.3 to 17.3
<b>Three-Month Follow-up</b>	
Number of Tests	35
Mean $\pm$ SE	11.7 $\pm$ 0.5
Range	6.1 to 17.1

**Table 4: Ventricular Pacing Impedance**

Pacing Impedance (Ohms)	Results
<b>Implant</b>	
Number of Tests	42
Mean $\pm$ SE	573 $\pm$ 19
Range	400 to 1126
<b>Pre-discharge Follow-up</b>	
Number of Tests	40
Mean $\pm$ SE	468 $\pm$ 12
Range	339 to 871
<b>One-Month Follow-up</b>	
Number of Tests	34
Mean $\pm$ SE	507 $\pm$ 13
Range	377 to 829
<b>Three-Month Follow-up</b>	
Number of Tests	24
Mean $\pm$ SE	525 $\pm$ 23
Range	354 to 989

#### **1.7.2.4 Discussion and Conclusion**

There were a total of 64 patients implanted with 21 Kentrox SL-S Steroid leads and 43 Kentrox RV-S Steroid leads.

- Two of the 64 patients (3.125%) experienced lead related complications; patient #17 experienced an increase in pacing threshold and had an additional pace/sense lead added; patient #18 experienced a lead repositioning, an expected risk occurrence when using ICD leads, which was successfully revised.
- Sixty-one tests with two successful 20 J shocks or less demonstrated the ICD lead system's ability to convert VF and provide a minimum 10 J safety margin with BIOTRONIK ICDs.
- All pacing thresholds, R-wave amplitudes and pacing impedances are within clinically-acceptable normal ranges for single-coil and dual-coil, dedicated bipolar, ICD leads.

The data received and analyzed demonstrate that the Kentrox SL-S Steroid and Kentrox RV-S Steroid ICD leads are safe and effective for the implanted patients.



## 2. Sterilization and Storage

This lead is shipped in packaging equipped with a quality control seal and product information label. The label contains the model specifications, technical data, serial number, expiration date, sterilization, and storage information. The lead and its accessories have been sealed in a container and gas sterilized with ethylene oxide.





## 3. Implant Procedure

### 3.1 Implant Preparation

Prior to beginning an implant of the Linux Lead System, ensure that all of the necessary equipment is available. The implant procedure requires the ICD device, the lead system, a programmer, other external testing equipment, and the appropriate cabling and accessories. Additional sterile equipment and devices should be available in the event of accidental contamination or damage.

#### CAUTION

**Capping Leads**—If a lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.

**Gripping Leads**—Do not grip the lead with surgical instruments or use excessive force or surgical instruments to insert a stylet into a lead.

**Liquid Immersion**—Do not immerse leads in mineral oil, silicone oil, or any other liquid.

**Short Circuit**—Ensure that none of the lead electrodes are in contact (a short circuit) during delivery of shock therapy as this may cause current to bypass the heart or cause damage to the ICD system.

**Tricuspid Valve Bioprosthesis**—Use ventricular transvenous leads with caution in patients with a tricuspid valvular bioprosthesis.

### 3.2 Product Inspection

The lead and its accessories have been sealed in a container and gas sterilized with ethylene oxide. To assure sterility, inspect the packaging and check for integrity prior to opening. Do not use products in which the lead or packaging appears damaged. Should a breach of sterility be suspected, return the lead to BIOTRONIK.

#### CAUTION

**Lead Packaging**—Do not use the lead if the lead's packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the lead to BIOTRONIK.

**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.

**Use Before Date**—Do not implant the lead after the USE BEFORE DATE.

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

## **WARNING**

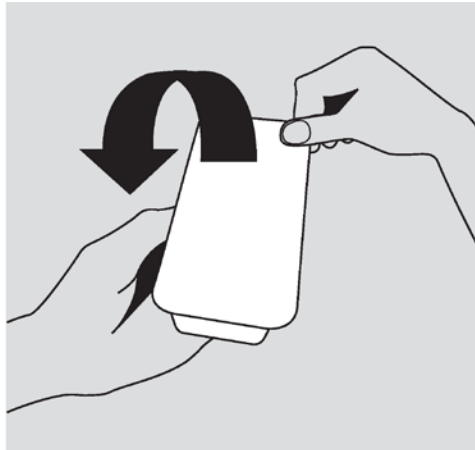
**Resuscitation Availability**—In order to implant the ICD system, it is necessary to induce and convert the patient's ventricular tachyarrhythmias. Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available.

### **3.3 Opening the Sterile Container**

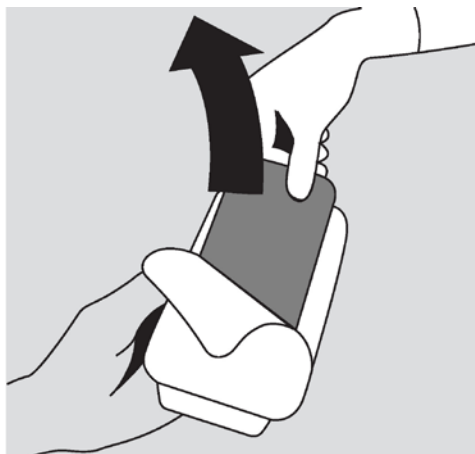
The lead is packaged in two plastic trays, one within the other. Each tray is individually sealed and sterilized with ethylene oxide.

The inner tray is sterile and can be removed from the outer tray using standard aseptic technique.

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



2. Carefully remove the inner sterile container by the gripping tab and open it by peeling the sealing paper as indicated by the arrow.



## 3.4 Package Content and Accessories

### Linux S Lead

The Linux S lead and contents of the inner blister package are sterile. Each Linux S Lead system package contains:

- 1 Linux S 65 or Linux S 75 lead with one silicone anchoring sleeve attached (EFH-30-8F), and a pre-inserted stylet (0.36 mm)
- 1 stylet (0.36 mm)
- 2 stylets (0.38 mm)
- 1 stylet introducer
- 1 fixation tool
- 1 vein lifter

### Linux T Lead

The Linux T lead and contents of the inner blister package are sterile. Each Linux T Lead system package contains:

- 1 Linux T 65 lead with one silicone anchoring sleeve attached (EFH-30-8F), and a pre-inserted stylet (0.36 mm)
- 1 stylet (0.36 mm)
- 2 stylets (0.40 mm)
- 1 stylet introducer
- 1 vein lifter

### Linux SD Lead

The Linux SD lead and contents of the inner blister package are sterile. Each Linux SD Lead system package contains:

- 1 Linux SD 60/xx, Linux SD 65/xx or Linux SD 75/xx lead with one silicone anchoring sleeve attached (EFH-30-8F), and a pre-inserted stylet (0.36 mm)
- 1 stylet (0.36 mm)
- 2 stylets (0.38 mm)
- 1 stylet introducer
- 1 fixation tool
- 1 vein lifter
- 1 vial of silicone oil (Optional)

### Linux TD Lead

The Linux TD lead and contents of the inner blister package are sterile. Each Linux TD Lead system package contains:

- 1 Linux TD 65/xx or Linux TD 75/xx lead with one silicone anchoring sleeve attached (EFH-30-8F), and a pre-inserted stylet (0.36 mm)
- 1 stylet (0.36 mm)
- 2 stylets (0.40 mm)
- 1 stylet introducer
- 1 vein lifter
- 1 vial of silicone oil (Optional)

**NOTE:**

Additional stylets also are available as separately packaged sterile accessories.

### 3.5 Linux T and Linux TD Lead Insertion

**NOTE:**

The Linux T and Linux TD Lead Systems are indicated for use in conjunction with a BIOTRONIK ICD. Currently, data is not available regarding the use of these lead systems with ICDs of other manufacturers. Use of other ICDs may adversely affect sensing and/or therapy delivery.

The following procedure is recommended for implanting of the Linux T and Linux TD leads.

1. Prior to lead placement, inspect the lead to ensure that the fixation sleeve is positioned close to the junction near the connector portion of the lead.
2. Venous access may be obtained through a standard cut-down or introducer technique. If the introducer method is used, select an appropriate introducer for the lead. A vein lifter is supplied inside the sterile packaging for use, if needed.

**NOTE:**

The recommended introducer size for the Linux T and Linux TD leads is 8 French.

3. The lead should be inserted into the vein and advanced into the ventricle under fluoroscopic guidance. Four stylets are included in the sterile package. Additional stylets are available in separate packaging, if required. Do not shape the stylet while it is inserted in the lead body. When changing stylets, care should be taken to keep the stylet free of blood to help ensure easy insertion and removal.
4. Advance the lead into the right ventricle. The tip should be placed in the apex of the right ventricle. Ensure the lead tip is stable within the ventricle and is in contact with the endocardium. Once adequate lead placement is achieved, the stylet should be carefully withdrawn under fluoroscopy so as not to dislodge the lead.

### 3.6 Linux S, and Linux SD Lead Insertion

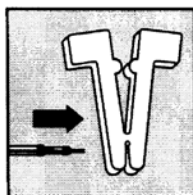
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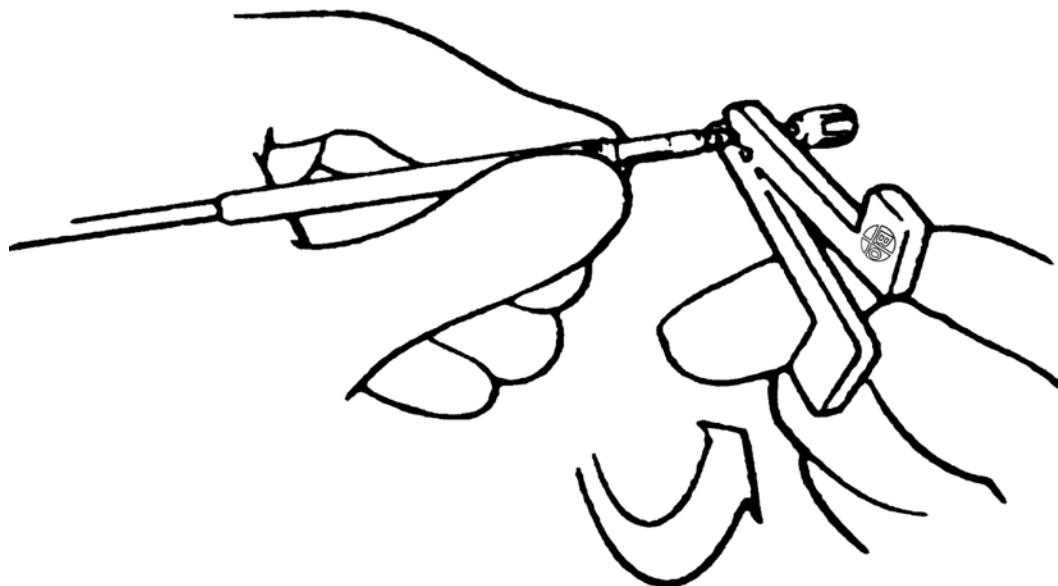
#### **Verifying the Mechanical Function of the Fixation Helix**

Prior to implantation, test the operation of the fixation helix with inserted stylet:

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



2. Practice extending the helix by rotating the tool clockwise until the helix is completely exposed (a minimum of 20 complete clockwise rotations of the fixation tool). The helix should fully extend 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 into the sheath (a minimum of 20 complete counterclockwise rotations of the fixation tool).

**NOTE:**

More than the recommended minimum of 20 rotations may be necessary to extend or retract the fixation helix.

**CAUTION**

**Helix Mechanical Function Test**—Do not implant the lead if this function test is not successful. In this case, test a replacement lead in the same way, and if the test is successful, implant the replacement lead.

**Beginning the Implantation**

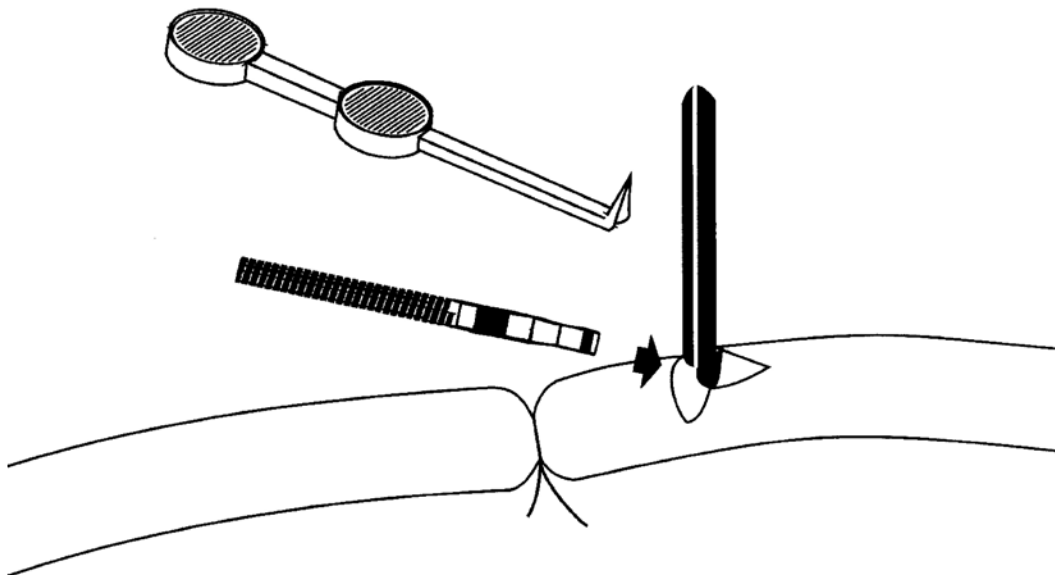
5. Begin implantation by positioning the lead fixation sleeve close to the lead's connector pin.
6. If the subclavian stick approach is used to gain venous access, select an appropriate introducer for the lead.

**NOTE:**

The recommended introducer size for the Linux S, and Linux SD leads is 8 French.

**Using the Vein Lifter**

7. If using the cephalic cutdown procedure for lead implant, 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 the following figure).



8. Advance the stylet into the lead. This will stiffen and straighten the lead, and prevent the lead from bending during advancement.

**NOTE:**

BIOTRONIK stylets are designed to be 1 to 2 cm longer than the stylet lumen of the lead body. Four stylets are included in the sterile package. Additional stylets are available in separate packaging for use, if required.

Do not shape the stylet while it is inserted in the lead body.

Avoid blood contact to the stylet, which may make its reinsertion and/or removal difficult. Spare stylets are provided in the inner tray.

**CAUTION**

**Stylet**—A badly deformed stylet can damage the lead. Do not bend the stylet.

9. Insert the lead into the right ventricle under fluoroscopic guidance.

**Securing the Electrode into the Endocardium**

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

**NOTE:**

A minimum of 20 rotations of the fixation tool is recommended to fully extend (or retract) the fixation helix.

To extend the helix, only use the fixation tool provided.

## WARNING

**Maximum Fixation Tool Rotations**—Under no circumstances should you exceed 30 turns to extend the fixation helix.

12. Use fluoroscopy to verify the position of the fixation helix. Both the helix and the tip are visible under fluoroscopy as noted in the X-rays below.

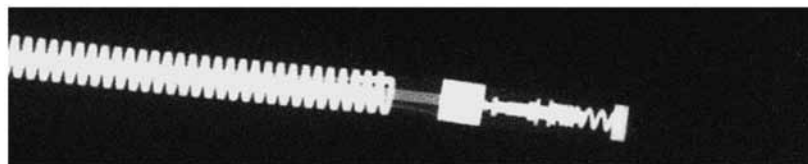


Figure 2: Helix Retracted

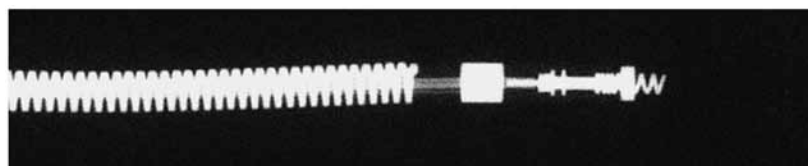


Figure 3: Helix Extended

## CAUTION

**Helix Extension**—Due to 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.

**Helix Extension, Maximum Additional Turns**—If the fixation helix is not fully extended after 20 turns, continue to extend the fixation helix with a maximum of 10 additional turns.

**Repositioning or Explanting**—Before repositioning or explanting the lead, use fluoroscopy to ensure that the fixation screw has been fully retracted.

14. Carefully remove the stylet after the electrode has been fixed into a stable position.

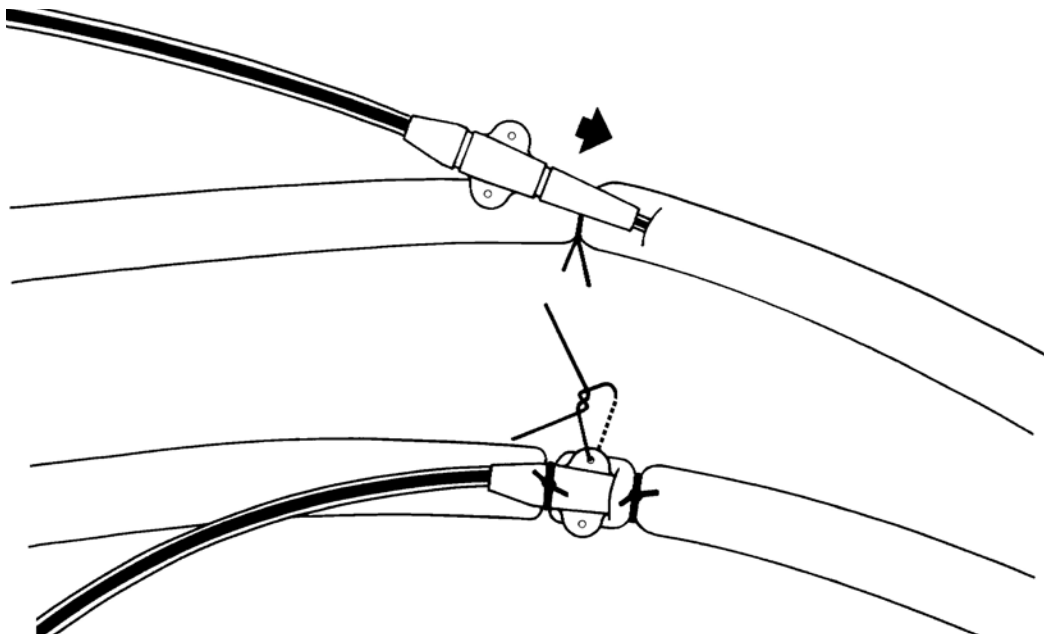
### 3.7 Baseline Measurements

Standard baseline lead measurements should be performed before connecting the lead to a BIOTRONIK ICD. Medical judgment should be used in cases where optimal lead signals cannot be reliably obtained.

If tunneling is required, baseline R wave and capture threshold measurements are recommended after the tunneling procedure to confirm lead performance and ensure system integrity. Refer to the appropriate BIOTRONIK ICD manual for the configuration of the ports prior to connecting the leads.

### 3.8 Anchoring the Lead

To lessen the possibility of dislodgment, 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 anchoring sleeve 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 dislodgment and protect the lead body from damage by a securing ligature.

**Suturing the Lead**—Using the Linux S or Linux SD lead may involve an increased risk of perforation and rupture. This lead must be implanted in such a way that no tensile stress is exerted on the fixation screw during systole or diastole, or during other movements made by the patient. Suture the lead at the entry point into the vein in such a way that no tensile stresses occur and the tricuspid valve is not obstructed. Do not suture directly over the lead body as this may cause structural damage. Use the appropriate suture sleeve to immobilize the lead and protect it against damage from ligatures. Make sure that there is no contact between shock and pacing/sensing electrodes inside the lead.

### 3.9 Lead to Device Connection

The Linux Lead System may only be connected to a BIOTRONIK ICD. (See Table 1)

The Linux S and Linux T leads have one IS-1 bipolar sensing and pacing connector and one DF-1 defibrillation connector. The connectors are marked as "IS-1 BI" for the sensing and pacing connector and "Ventricle HV1" for the distal coil defibrillation connector.



The Linux SD and Linux TD leads have one IS-1 bipolar sensing and pacing connector and two DF-1 defibrillation connectors. The connectors are marked as "IS-1 BI" for the sensing and pacing connector, "Ventricle HV1" with the internal conductor coated white for the distal coil defibrillation connector, and "Atrium HV2" with a blue coated conductor for the proximal coil defibrillation connector. The colors aid in easy identification.

BIOTRONIK ICDs have self-sealing setscrew sealing covers. Refer to the following steps when connecting the lead to the ICD.

1. Withdraw the stylet and stylet guide before connecting the lead to the ICD.
2. To retract a setscrew, insert the enclosed torque wrench through the perforation in the self-sealing plug at a 90° angle to the lead connector until it is firmly placed in the setscrew. Rotate the wrench counterclockwise until the receptacle is clear of obstructions.
3. Insert the lead connector into the receptacle of the ICD header, without bending the lead, until the connector pin becomes visible beyond the connector block. Hold the connector in this position.
4. Insert the enclosed torque wrench and securely tighten the setscrew by rotating the wrench in a clockwise direction until torque transmission is limited by the wrench.
5. After removing the torque wrench, the silicone sealing plug will self-seal.

## CAUTION

**Blind Plug**—A blind plug must be inserted and firmly connected into any unused header port of the ICD to prevent chronic fluid influx and possible shunting of high-energy therapy.

**Setscrew(s)**—Failure to back off the setscrew(s) may result in damage to the lead(s), and/or difficulty connecting the lead(s).

**Cross-Threading**—To prevent cross-threading the setscrew, do not back the setscrew completely out of the threaded hole. Leave the screwdriver in the slot of the setscrew while the lead is inserted.

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

**Sealing System**—Failure to properly insert the torque wrench into the perforation at an angle perpendicular to the connector receptacle may result in damage to the sealing system and its self-sealing properties.

**Table 5: Active Housing ICD with a Linux lead**

Port	Connector pin
HV 1	DF-1 pin of the Linux ventricular shock coil
HV 2	DF-1 pin of the Linux SD lead SVC shock coil or DF-1 pin of the Linux TD lead SVC shock coil or separate SVC lead or blind plug
P/S	IS-1 pin of the Linux leads

### 3.10 Final Implant Steps and Defibrillation Testing

The ICD and/or lead system may be placed in the pocket at this time. The following steps will help ensure appropriate chronic Linux Lead System function:

- BIOTRONIK ICD leads are made of highly flexible materials. Depending on where the lead is implanted and the patient's anatomy, the lead may be longer than required. If this is the case, during implantation carefully observe the following guidelines:
  - To protect the lead from excessive tensile stress or pressure, spare lead length should be wound around the ICD in loose loops (see figure below).
  - Ensure that the lead does not become knotted or contorted and is not bent at a sharp angle, as this could result in damage to the conductors or abrasion of the lead's insulation.
- If you are implanting the ICD under the pectoral muscle, ensure that no portion of the lead becomes lodged between the ICD housing and the patient bone structure.



#### **CAUTION**

**Lead Handling**—Make sure that the lead is neither knotted, twisted, nor bent at a sharp angle.

- Place the device into the pocket with the etched side facing anteriorly.
- Evaluate the pacing and sensing functions of the device.

#### **Defibrillation Testing**

1. It is recommended that at least one induction and device conversion be done prior to closing the pocket. This will ensure that the lead system has been properly connected to the ICD.
2. Before induction testing, a synchronized low energy test shock into sinus rhythm is recommended to confirm the defibrillator electrode integrity. Normal shock impedance is 30-100 Ohms.
3. Between fibrillation inductions, sufficient time should be allocated for recovery of hemodynamic status.

#### **CAUTION**

**Shock Impedance**—Never implant a device with a lead system that has a measured shock impedance that is less than what is recommended in the appropriate ICD technical manual. Damage to the device may result. If the shock impedance is less than the recommended value, reposition the lead system to allow a greater distance between the electrodes.

## **WARNING**

**Defibrillation Threshold**—Be aware that changes in the patient's condition, drug regimen, and other factors may affect the defibrillation threshold (DFT) which may result in nonconversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

- Close the device pocket using standard surgical technique. Ensure the ICD detection status has been deactivated prior to using electrocautery.
- If a Linux Lead System is being implanted without an ICD at this time, each of the lead connectors must be capped with an appropriate lead cap and carefully laid in the subcutaneous pocket. Ensure that the lead system is carefully coiled and not twisted.
- Complete the implant form provided with the Linux Lead System and return it to BIOTRONIK for patient and device registration.
- This manual is intended to be used in conjunction with other appropriate BIOTRONIK technical manuals (i.e., BIOTRONIK ICD technical manual).



## 4. Follow-Up Procedures

### 4.1 ICD Patient Follow-Up

Follow the instructions described in the appropriate BIOTRONIK ICD technical manual.

### 4.2 Explantation

To explant the Linux S or Linux SD lead, the fixation helix must be fully retracted. An explanted lead may not be reused. Please complete the appropriate explant form and return the form to BIOTRONIK with the explanted lead system. Explanted devices should be sent to BIOTRONIK for analysis and/or disposal. Contact BIOTRONIK if you are in need of assistance with returning any explanted devices. If possible, the explanted devices should be cleaned with a sodium hypochlorite solution of at least 1% chlorine and, thereafter, washed with water prior to shipping.

#### **CAUTION**

**Resteralization**—These devices are intended for single use. Do not resterilize and re-implant explanted leads.



## **5. 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.





## 6. Technical Data (Linux Passive Fixation Leads)

General Specifications		
	Linux T	Linux TD
Leads, Length (cm)	65, 75	65, 75, 100
Polarity	Tripolar	Quadripolar
Insulation	Silicone tubing	Silicone tubing
Connectors	1 x IS-1 bipolar 1 x DF-1	1 x IS-1 bipolar 2 x DF-1
Connector Material	Surgical Steel; 1.4435	Surgical Steel; 1.4435
Lead Diameter (Including Insulation)	2.6 mm (7.8 F)	2.6 mm (7.8 F)
Diameter of Recommended Introducer	8 F	8 F
Fixation	Passive fixation, with four silicone tines	Passive fixation, with four silicone tines

Tip Electrode		
	Linux T	Linux TD
Electrode Surface Area	1.8 mm <sup>2</sup>	1.8 mm <sup>2</sup>
Electrode Surface	Iridium, fractal	Iridium, fractal
Electrode Material	Pt / Ir (90% / 10%)	Pt / Ir (90% / 10%)
Conductor Style	Coil	Coil
Conductor Material	MP35N*	MP35N
Number Of Filaments (to Helix)	4	4
Conduction Resistance	≤ 85 Ω (65 cm length) ≤ 100 Ω (75 cm length)	≤ 85 Ω (65 cm length) ≤ 100 Ω (75 cm length) ≤ 130 Ω (100 cm length)

Steroid Reservoir (Collar)		
	Linux T	Linux TD
Active Agent	Dexamethasone Acetate	Dexamethasone Acetate
Steroid amount	0.75 mg	0.75 mg
Steroid binding agent	Silicone rubber	Silicone rubber

\* MP35N®, MP and Multiphase are registered trademarks of the Standard Pressed Steel Co.

Ring Electrode		
	Linux T	Linux TD
Surface Area	24.5 mm <sup>2</sup>	24.5 mm <sup>2</sup>
Surface: Material, Structure	Iridium, fractal	Iridium, fractal
Basic Material	Pt / Ir (80% / 20%)	Pt / Ir (80% / 20%)
Distance from Lead Tip	9 mm	9 mm
Conductor Style*	Cable	Cable
Conduction Material	MP35N	MP35N
Number of Filaments	4 (coil)/7*7(cable)	4 (coil)/7*7(cable)
Resistance: IS-1 Connector, Ring Electrode	$\leq 50 \Omega$ (65 cm length) $\leq 60 \Omega$ (75 cm length)	$\leq 50 \Omega$ (65 cm length) $\leq 60 \Omega$ (75 cm length) $\leq 75 \Omega$ (100 cm length)
*The ring electrode utilizes a different conductor style and material and has a different number of filaments before and after the bifurcation / trifurcation where the lead divides into separate conductors for defibrillation and sensing/pacing.		

Ventricular Shock Coil (RV)		
	Linux T	Linux TD
Geometric Surface	2.9 cm <sup>2</sup>	2.9 cm <sup>2</sup>
Diameter	2.6 mm (7.8F)	2.6 mm (7.8F)
Length:	5.0 cm	5.0 cm
Distance From Lead Tip	15 mm	15 mm
Basic Material	Pt / Ir (90% / 10%) with a Tantalum core (no special surface treatment)	Pt / Ir (90% / 10%) with a Tantalum core (no special surface treatment)
Conductor Style	Cable	Cable
Conduction Material	MP35N/DFT (41% Ag)	MP35N/DFT (41% Ag)
Number Of Filaments	7*7	7*7
Resistance (Connector—Lead)	$\leq 1.6 \Omega$ (65 cm length) $\leq 1.9 \Omega$ (75 cm length)	$\leq 1.6 \Omega$ (65 cm length) $\leq 1.9 \Omega$ (75 cm length) $\leq 2.4 \Omega$ (100 cm length)

Superior Vena Cava Shock Coil (SVC)		
	Linux T	Linux TD
Geometric Surface	N/A	4.1 cm <sup>2</sup>
Diameter	N/A	2.6 mm
Length:	N/A	7.0 cm
Basic Material	N/A	Pt / Ir (90% / 10%) with a Tantalum core (no special surface treatment)
Distance From Lead Tip	N/A	16, 18 cm
Conductor Style	N/A	Cable
Conduction Material	N/A	MP35N/DFT (41% Ag)
Number Of Filaments	N/A	7*7
Resistance (Connector—Lead)	N/A	$\leq 1.2 \Omega$ (65 cm length) $\leq 1.4 \Omega$ (75 cm length) $\leq 1.8 \Omega$ (100 cm length)



## 7. Technical Data (Linux Active Fixation Leads)

General Specifications		
	Linux S	Linux SD
Leads, Length (cm)	65, 75	61.2, 65, 75
Polarity	Tripolar	Quadripolar
Insulation	Silicone tubing	Silicone tubing
Connectors	1 x IS-1 bipolar 1 x DF-1	1 x IS-1 bipolar 2 x DF-1
Connector Material	Surgical Steel; 1.4435	
Lead Diameter (Including Insulation)	2.6 mm (7.8 F)	
Diameter of Recommended Introducer	8 F	
Fixation	Electrically active, extendable/retractable helix	

Steroid Reservoir (Collar)		
	Linux S	Linux SD
Active Agent	Dexamethasone Acetate	
Steroid amount	1.0 mg	
Steroid binding agent	Silicone rubber	

Tip Electrode		
	Linux S	Linux SD
Length of Extended Helix (max)	1.8 mm	
Electrode Surface Area	4.5 mm <sup>2</sup> (Surface Area of Extended Screw)	
Number of Turns for Helix Extension (max)	20	
Electrode Surface	Iridium, fractal	
Electrode Material	Pt / Ir (70% / 30%)	
Conductor Style	Coil	
Conductor Material	MP35N*	
Number Of Filaments (to Helix)	4	
Conduction Resistance	$\leq 50 \Omega$ (61.2, 65 cm length) $\leq 60 \Omega$ (75 cm length)	

\* MP35N®, MP and Multiphase are registered trademarks of the Standard Pressed Steel Co.

## Chapter 7 Technical Data (Linux Active Fixation Leads)

### Linux Leads Technical Manual

Ring Electrode		
	Linux S	Linux SD
Surface Area	24.5 mm <sup>2</sup>	
Surface: Material, Structure	Iridium, fractal	
Basic Material	Pt / Ir (80% / 20%)	
Distance from Tip to Ring	11 mm	
Conductor Style* between ring and trifurcation & between trifurcation and connector	Cable	
Conduction Material	MP35N	
Number of Filaments	7*7(cable)	
Resistance: IS-1 Connector, Ring Electrode	$\leq 50 \Omega$ (65 cm length) $\leq 60 \Omega$ (75 cm length)	$\leq 50 \Omega$ (61.2, 65 cm length) $\leq 60 \Omega$ (65 cm length)
<small>*The ring electrode utilizes a different conductor style and material and has a different number of filaments before and after the bifurcation / trifurcation where the lead divides into separate conductors for defibrillation and sensing/pacing.</small>		

Ventricular Shock Coil (RV)		
	Linux S	Linux SD
Geometric Surface	2.9 cm <sup>2</sup>	
Diameter	2.6 mm (7.8F)	
Length	5.0 cm	
Distance From Lead Tip	17 mm	
Basic Material	Pt / Ir (90% / 10%) with a Tantalum core (no special surface treatment)	
Conductor Style	Cable	
Conduction Material	MP35N/DFT (41% Ag)	
Number Of Filaments	7*7	
Resistance (Connector – Lead)	$\leq 1.6 \Omega$ (65 cm length) $\leq 1.9 \Omega$ (75 cm length)	$\leq 1.6 \Omega$ (61.2, 65 cm length) $\leq 1.9 \Omega$ (75 cm length)

Superior Vena Cava Shock Coil (SVC)		
	Linux S	Linux SD
Geometric Surface	N/A	4.1 cm <sup>2</sup>
Diameter		2.6 mm
Length:		7.0 cm
Basic Material		Pt / Ir (90% / 10%) with Tantalum core (no special surface treatment)
Distance From Lead Tip		16, 18 cm
Conductor Style		Cable
Conduction Material		MP35N/DFT (41% Ag)
Number Of Filaments		7*7
Resistance (Connector – Lead)		$\leq 1.2 \Omega$ (61.2, 65 cm length) $\leq 1.4 \Omega$ (75 cm length)





## 8. Glossary

**Arrhythmia.** Any abnormality of the cardiac rhythm. The heart rhythm may be too fast, too slow, or irregular in its pattern. Also known as dysrhythmia.

**Atria.** The upper chambers of the heart. These act as receiving chambers for blood from the body. The sinus node is found in the right atrium.

**Bradycardia.** Refers to a slow heart rate, usually below 60 bpm. Bradycardia normal may be caused by the sinus node not functioning properly, heart block, or medications.

**Cardioversion.** The use of minimally necessary shock energy to convert the arrhythmia to a rhythm. This energy is delivered at the same time as the heart beat.

**Defibrillation.** The delivery of a high energy shock to restore a normal heart beat.

**Defibrillator.** An external or internal device used to terminate an extremely fast or irregular rhythm.

**Electrocardiogram (ECG, EKG).** A picture of the electrical activity of the heart that shows the heart rate and the rhythm. This is recorded using surface electrodes.

**Electromagnetic Interference (EMI).** Produced by invisible line of force called an electromagnetic field. If the force is strong enough, it may interfere with the ICD system. This happens on rare occasions.

**Heart Rhythm.** Another term for heart beat. Refers to the rate and regularity of the heart beat.

**Implantable Cardiac Defibrillator (ICD).** A device used to treat arrhythmias that is implanted in the body. The ICD consists of a battery and electronic circuitry.

**Implanted.** To be placed inside the body. The ICD is a system that is implanted.

**Lead.** An insulated wire that is used both to receive signals from the heart and to send electrical impulses to the heart. The lead is connected to the ICD.

**Myocardium.** Refers to the muscle of the heart.

**Noise.** Current or voltage that can interfere with an electrical device or system.

**Programmer.** A computerized device that allows the physician to communicate with the ICD. With the programmer, the doctor can reprogram the device to fit your needs and to help determine when the device needs to be replaced.

**Steroid.** Dexamethasone Acetate (DXA) is a synthetic adrenocortical steroid primarily used for its powerful anti-inflammatory effect.

**Tachycardia.** An abnormal, fast heart rate, inappropriate for the tissue involved. Tachycardia rates are usually faster than 100 bpm.

**Transvenous.** Placed in the heart through a vein.

**Ventricle.** One of the two lower chambers of the heart. Blood from the right ventricle is pumped to the lungs to receive oxygen. Blood from the left ventricle is pumped to the body.

**Ventricular Fibrillation.** Chaotic contraction of the ventricles that results in little or no blood being pumped to the body. This is a life-threatening rhythm if left untreated.

**Ventricular Pacing.** Pacing in the ventricle to prevent the heart rate from becoming too slow.

**Ventricular Tachycardia.** A fast heart beat that originates in a single area in the ventricle. The rate is usually faster than 120 bpm.





# Linux Leads

## Technical Manual



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