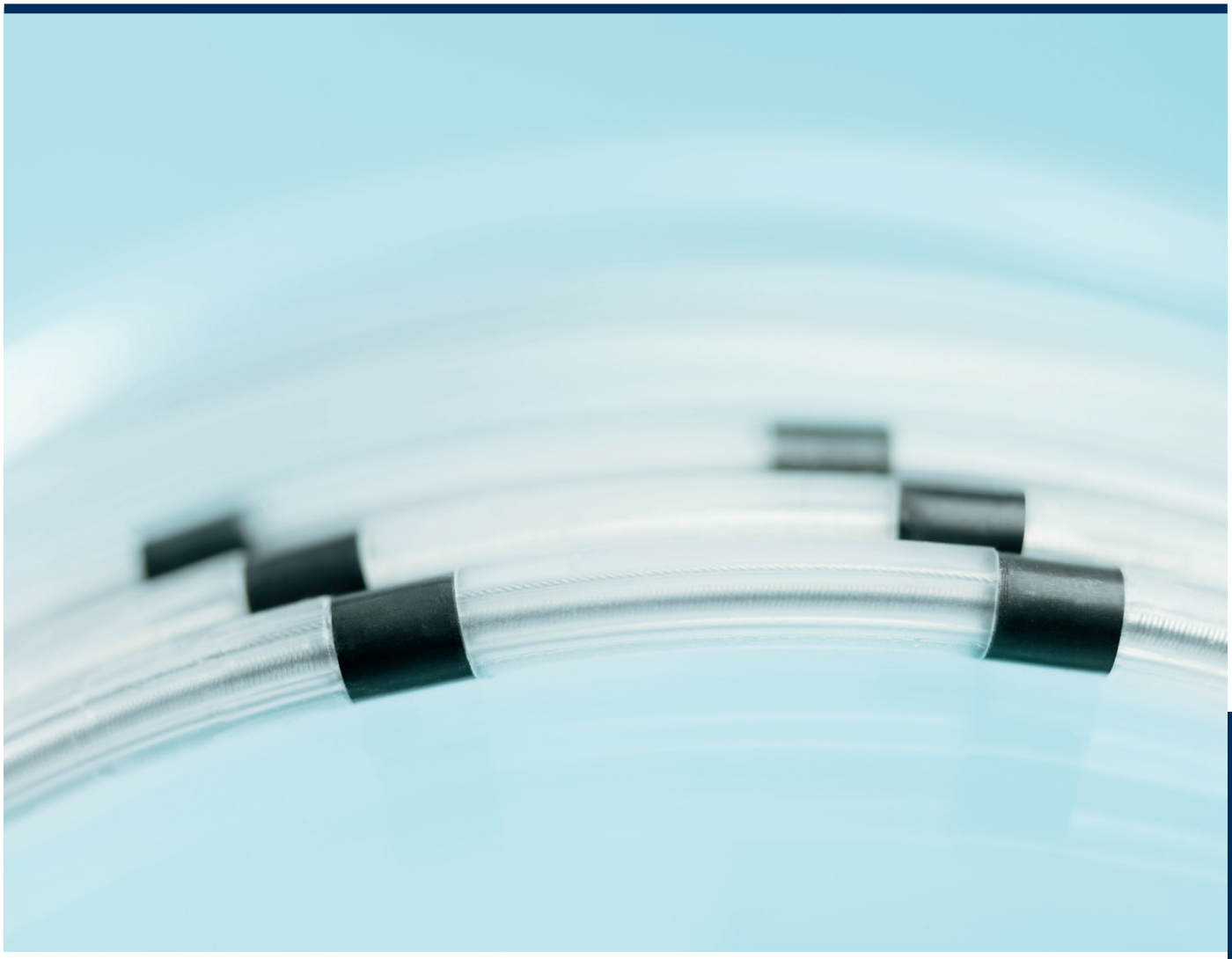
Linox^{smart} Steroid-Eluting ICD Leads

Technical Manual



BIOTRONIK
excellence for life

CAUTION

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

Contents

1. General

1.1 Description

The Linox^{smart} Lead Systems are implantable, transvenous ICD leads for use with BIOTRONIK's implantable cardioverter defibrillators (ICDs). The Linox^{smart} Lead Systems include

- Linox^{smart} T
- Linox^{smart} TD
- Linox^{smart} S
- Linox^{smart} SD
- Linox^{smart} S DX

The Linox^{smart} Leads Are Single-pass ICD Lead Systems with the following:

The Linox^{smart} S and Linox^{smart} T Lead Systems have two sensing and pacing electrodes (distal tip and ventricular ring electrode) and one defibrillation electrode (ventricular shock coil). The Linox^{smart} SD and Linox^{smart} TD Lead Systems have two sensing and pacing electrodes (distal tip and ventricular ring electrode) and two defibrillation electrodes (ventricular and superior vena cava shock coils). The Linox^{smart} S DX Lead System has two sensing and pacing electrodes (distal tip and ventricular ring electrode), two floating atrial sensing electrodes (atrial rings) and one defibrillation and cardioversion shock coil (ventricular shock coil).

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 Linox^{smart} 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 Linox^{smart} Lead Systems have one shock electrode that is positioned in the right ventricle (RV). The Linox^{smart} SD and Linox^{smart} TD dual-coil ICD leads have an additional shock electrode for placement in the superior vena cava (SVC). Additionally, the Linox^{smart} S DX Lead System replaces the SVC defibrillation coil with two floating electrode rings placed in the right atrium for bipolar sensing in the atrium.

These leads feature Silglide® surface treatment that differentiates them from earlier versions of the Linox ICD leads and is designed to reduce the force required to maneuver the lead during the implant procedure. This surface treatment provides a measurable difference between the force required to maneuver the Linox leads and the force required to maneuver the Linox^{smart} leads. Bench testing and physician survey results are consistent with this conclusion.

The Linox^{smart} S, Linox^{smart} SD and Linox^{smart} S DX 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 Linox^{smart} T and Linox^{smart} 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 Linox^{smart} ICD leads consists of a steroid eluting collar which contains the active ingredient 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 Linox^{smart} S and Linox^{smart} T leads have one IS-1 bipolar sensing and pacing connector and one DF-1 defibrillation lead connector. The Linox^{smart} SD and Linox^{smart} TD leads have one IS-1 bipolar sensing and pacing connector and two DF-1 defibrillation lead connectors. The Linox^{smart} S DX leads have two IS-1 bipolar sensing and pacing connectors and only one DF-1 defibrillation lead connector. 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 5841-3:2000-10]. DF-1 refers to the international standard for defibrillation lead connectors [Reference ISO 11318:2002-08].

1.2 ProMRI®

The following leads are part of BIOTRONIK's ProMRI® portfolio:

- Linox^{smart} S 65
- Linox^{smart} SD 65/18
- Linox^{smart} S DX 65/15
- Linox^{smart} S DX 65/17

For VR-T ICD models only:

- Linox^{smart} S 75
- Linox^{smart} SD 65/16
- Linox^{smart} SD 75/18

These ProMRI leads, when used in combination with a ProMRI cardiac device, make up a BIOTRONIK ProMRI system, which may be used in the MRI environment 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 leads are also identified on the packaging by the following MR Conditional symbol. 

1.3 Indications for Use

The Linox^{smart} 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.

The Linox^{smart} S DX lead is indicated for use as a system that includes both the Linox^{smart} S DX and a BIOTRONIK DX ICD.

1.4 Contraindications

Do not use the Linox^{smart} Lead System in patients with severe tricuspid valve disease or patients who have a mechanical tricuspid valve implanted.

Active Fixation

The Linox^{smart} 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 Linox^{smart} 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).

1.5 Linox^{smart} Lead Names

The Linox^{smart} lead names include both the lead type and the overall length of the lead in centimeters. The additional label “smart” indicates Linox leads which feature Silglide® surface treatment.

The letter “T” designates passive fixation (tines made of silicone rubber) and “S” designates active fixation (screw). The suffix “D” denotes leads with dual shock coils (Linox^{smart} SD and Linox^{smart} TD). Thus, the name “Linox^{smart} TD” is an ICD lead with dual shock coils and passive fixation and “Linox^{smart} S” is a single shock coil lead with an active fixation screw.

The number following the letter designation indicates the overall length of the lead in centimeters (60 (61.2), 65 or 75 cm). Thus, a “Linox^{smart} S 60” lead is a single shock coil ICD lead with an active fixation screw and an overall length of 61.2 cm.

For dual-coil Linox^{smart} leads (Linox^{smart} SD and Linox^{smart} TD), the number after the slash denotes the distance in centimeters between the superior vena cava shock coil and the lead tip. Thus, the name “Linox^{smart} TD 65/16” refers to a Linox^{smart} TD lead with a total length of 65 cm and a distance of 16 cm between the superior vena cava shock coil and the lead tip.

All Linox^{smart} leads are steroid-eluting and therefore this property is not specifically denoted for these leads.

1.6 Warnings

Use of Linox^{smart} S DX ICD lead-Linox^{smart} S DX leads are indicated for use only with BIOTRONIK DX ICDs. Use with ICDs from other manufacturers may cause undersensing, which can result in inappropriate detection or therapy.

MRI (Magnetic Resonance Imaging)-For non-MRI leads, do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. (Refer to Section 1.2 of this manual, the ProMRI System Technical Manual, or www.biotronikusa.com/promri to confirm which leads are MR Conditional.)

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.

Myocardial Perforation-Risk of myocardial perforation due to a disproportionate level of pressure on the lead tip. Use of excessive force with a preformed stylet can result in a significant level of pressure being placed on the ventricular myocardium via the lead tip. Do not place pressure on the lead in this way (Linox^{smart} S DX leads only).

1.7 Precautions

NOTE:

Please also observe the technical manuals and accompanying documents for devices combined with this lead (ICD, pacemaker, additional leads) and for devices and implant accessory used during implantation.

1.7.1 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-These leads are intended for single use. 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.

1.7.2 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 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 (Linox^{smart} S, Linox^{smart} SD and Linox^{smart} S DX leads only).

Lead Handling-Make sure that the lead is neither knotted, twisted, nor bent at a sharp angle. This could cause damage to the conductors or result in abrasion of the lead‘s insulation.

Lead Positioning-If the ICD is implanted underneath the pectoral muscle, ensure that no parts of the lead lie between the housing of the ICD and the ribs. Chafing and pressure on the lead between the housing of the ICD and the ribs could damage the lead‘s insulation and thus cause premature failure.

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.

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 (Linox^{smart} S, Linox^{smart} SD and Linox^{smart} S DX leads only).

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

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 excessively bend the stylet.

Suturing the Lead-Using the Linox^{smart} S, Linox^{smart} SD and Linox^{smart} S DX leads may involve an increased risk of perforation and rupture. These leads 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.

1.7.3 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.

1.7.4 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)-For non-MRI leads, do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. (Refer to Section 1.2 of this manual, the ProMRI System Technical Manual, or www.biotronikusa.com/promri to confirm which leads are MR Conditional.)

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.

1.8 Adverse Events

1.8.1 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
- Cardiac tamponade
- Chronic nerve damage
- Device migration
- Elevated pacing thresholds
- Erosion
- Fluid accumulation
- Foreign body rejection phenomena
- Formation of hematomas, cysts or fibrotic tissue
- 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
- Valvular damage
- 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)

1.8.2 Observed Adverse Events

Since the Linox^{smart} S and Linox^{smart} SD leads are based on BIOTRONIK's legally marketed Linox S, Linox SD and Kentrox SL-S Steroid ICD leads, the Linox^{smart} T and Linox^{smart} TD leads are based on BIOTRONIK's legally marketed Linox T, Linox TD and Kentrox SL Steroid ICD leads, and the Linox^{smart} S DX leads are based on BIOTRONIK's legally marketed Kainox A+ ICD leads, the observed adverse events for these predecessor leads have been included in this section of the manual.

1.8.2.1 Kentrox

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 Linox^{smart} family is based upon the Kentrox family and other BIOTRONIK ICD Leads (i.e., Linox 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
Steroid (Total Number of Patients = 64, Followed for 3 months = 35)			
Elevated Ventricular Pacing Threshold	1	1.6%	1
Lead Repositioning	1	1.6%	1
Total Steroid	2	3.2%	2

1.8.2.2 Kainox

NOTE:

The clinical study information included in this section was performed with the Kainox VDD ICD lead, which functions as a single lead system, comparable to the Kainox A+. Both leads have identical floating electrodes in the atrium and identical pacing electrode tip, ring and shock electrodes designed for placement in the right ventricle. The minor differences are in the ventricular shock coil (Kainox A+ coil has a slightly larger surface area, and the surface is not coated with fractal iridium).

Due to the structural and functional similarities between the Kainox A+ and Kainox VDD, a clinical study of Kainox A+ was determined to be unnecessary.

A clinical study of the Deikos A+ and Kainox VDD (Single-Lead ICD system) involved 9 devices implanted in 9 patients with a cumulative implant duration of 54.5 months (mean implant duration 6.1 months).

There was one patient death reported due to cerebral hemorrhage. The investigator determined the death was not related to the investigational device.

Table 2 provides a summary of the adverse events that were reported during the clinical study regardless of whether or not the event was related to the ICD system. A complication is defined as a clinical event that results in invasive intervention, injury, or death. An observation is defined as a clinical event that does not result in invasive intervention, injury, or death.

Table 2: Reported Adverse Events

	# of patients with AE's	% of patients with AE's	# of AE's	AE/pt-years
Complications (total)	1	11.1%	1	0.22
Lead Repositioning	1	11.1%	1	0.22
Observations (total)	3	33.3%	3	0.66
Sensing and Pacing	2	22.2%	2	0.44
Atrial Arrhythmias	1	11.1%	1	0.22

Number of Patients = 9, Number of Patient-Years = 4.5

1.8.2.3 Linox[smart] S DX

The Linox[smart] S DX Steroid ICD leads were evaluated in two clinical studies. 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. The adverse events from these studies are presented in the following sections.

1.8.2.3.1 Lumax DX / Linox DX Evaluation - European Clinical Study

In total, 6 adverse events were recorded within this clinical study. In Table 3 all adverse events are cross-tabulated by category according to the underlying causes and sorted by adverse events (AE) and serious adverse events (SAE). Of the 6 recorded adverse events, 5 (83.3 %) were classified as SAEs.

Table 3: Adverse events and serious adverse events, N (%)

Category	AE	SAE	Total
Patient Death – Cardiac	0 (0.0)	0 (0.0)	0 (0.0)
Patient Death – Non-cardiac	0 (0.0)	0 (0.0)	0 (0.0)
Lead related	0 (0.0)	0 (0.0)	0 (0.0)
ICD therapy related	0 (0.0)	2 (33.3)	2 (33.3)
Procedure related	1 (16.7)	2 (33.3)	3 (50.0)
Arrhythmias	0 (0.0)	0 (0.0)	0 (0.0)
Medical	0 (0.0)	1 (16.7)	1 (16.7)
Total	**1 (16.7)**	**5 (83.3)**	**6 (100)**

No lead related serious adverse device effects were reported and the SADE free-rate is 100% for the Linox[smart] S DX ICD leads.

1.8.2.3.2 Lumax 740 VR-T DX Subgroup of Lumax 740 Master Study

In total 11 adverse events have been recorded within this observation period and 8 events were classified as serious. In Table 4 all adverse events are cross-tabulated by category according to the underlying causes and sorted by adverse events (AE) and serious adverse events (SAE). Of the 11 recorded adverse events, 8 (72.7 %) were classified as SAEs.

Table 4: Adverse Events and Serious Adverse Events, N (%)

Category	AE	SAE	Total
Patient Death – Cardiac	0	0	0
Patient Death – Non-Cardiac	0	0	0
Lead related	1 (50.0)	1 (50.0)	2 (100.0)
Arrhythmia	0	0	0
Medical	2 (22.2)	7 (77.8)	9 (100.0)
Medical procedure	0	0	0
Total	**3 (27.3)**	**8 (72.7)**	**11 (100.0)**

In Table 5 all adverse events are sorted by category and observation or complication. 2 events were classified as complication from which 1 was caused by the medical condition of the patient and 1 was caused by the implanted lead (complication is defined as adverse event that requires additional invasive intervention to resolve). For the lead related event, the lead was repositioned.

Table 5: AE category by observation/complication, N (%)

Category	Observation	Complication	Total
Patient Death – Cardiac	0	0	0
Patient Death – Non-cardiac	0	0	0
Lead related	1 (50.0)	1 (50.0)	2 (100.0)
ICD therapy related	0	0	0
Procedure related	0	0	0
Arrhythmias	0	0	0
Medical	8 (88.9)	1 (11.1)	9 (100.0)
Total	**9 (81.8)**	**2 (18.2)**	**11 (100.0)**

The reported AE/Observation from Table 4 and Table 5 was a single instance of decreased atrial sensing which required ICD reprogramming. The reported SAE/Complication from Table 4 and Table 5 was a single instance of increased threshold from a lead dislodgement that required lead repositioning.

1.9 Clinical Studies

1.9.1 Linox^{smart} ICD Leads

Because the Linox^{smart} S and Linox^{smart} SD leads are based on BIOTRONIK's legally marketed Linox S, Linox SD and Kentrox SL-S Steroid ICD leads, the Linox^{smart} T and Linox^{smart} TD leads are based on BIOTRONIK's legally marketed Linox T, Linox TD and Kentrox SL Steroid ICD leads, and the Linox^{smart} S DX leads are based on BIOTRONIK's legally marketed Kainox A+ ICD leads, engineering tests and an animal study were performed in lieu of extensive human clinical data.

The Linox^{smart} ICD leads feature Silglide® surface treatment that differentiates them from earlier versions of the Linox ICD leads and is designed to reduce the force required to maneuver the leads during the implant procedure. This surface treatment provides a measurable difference between the force required to maneuver the Linox leads and the force required to maneuver the Linox^{smart} leads. Bench testing and physician survey results are consistent with this conclusion.

1.9.2 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.

1.9.2.1 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.

1.9.2.2 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.

1.9.2.3 Results

Table 6, Table 7 and Table 8 provide summaries of measured ventricular pacing thresholds, R-waves, and ventricular pacing impedance measurements, respectively. Additionally, Table 6 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 6: Ventricular Pacing Threshold

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

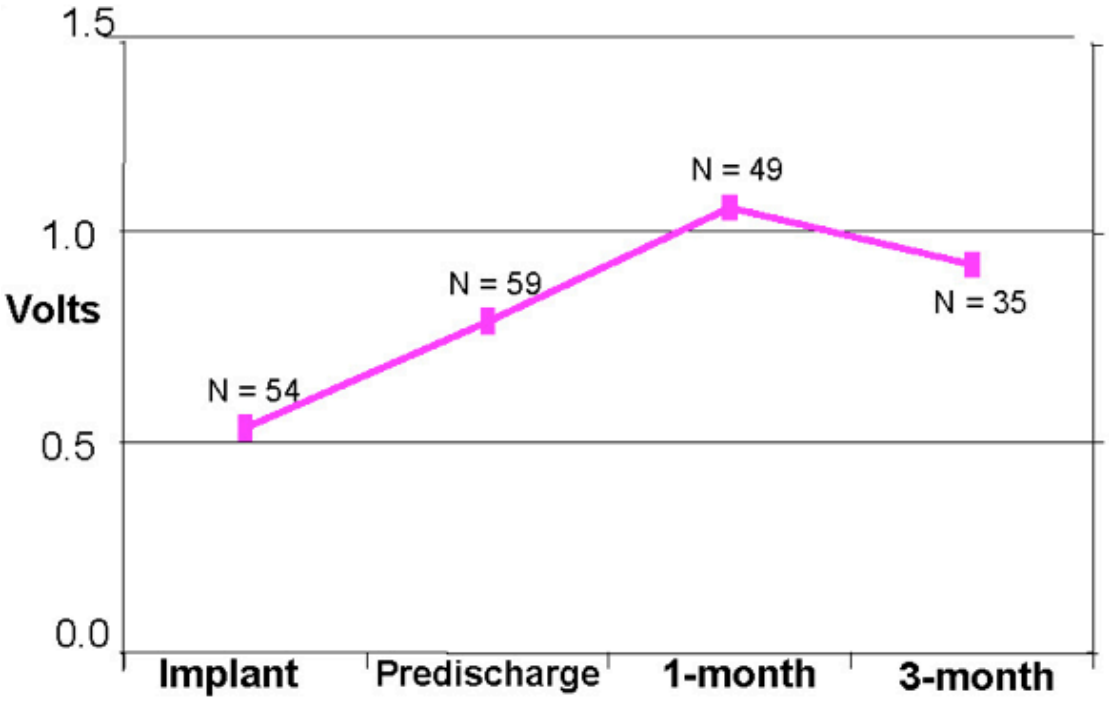


Figure 1: Ventricular Pacing Threshold

Table 7: R-Wave Amplitude

R-Wave (mV)	Results
Implant	
Number of Tests	63
Mean ± SE	12.0 ± 0.4
Range	5.2 to 17.6
Pre-discharge Follow-up	
Number of Tests	58
Mean ± SE	11.5 ± 0.4
Range	4.1 to 17.5
One-Month Follow-up	
Number of Tests	49
Mean ± SE	11.7 ± 0.5
Range	6.3 to 17.3
Three-Month Follow-up	
Number of Tests	35
Table 7: R-Wave Amplitude	
Mean ± SE	11.7 ± 0.5
Range	6.1 to 17.1

Table 8: Ventricular Pacing Impedance

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

1.9.2.4 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.

1.9.3 Kainox VDD and Deikos A+

1.9.3.1 U.S. Clinical Study

NOTE:

The clinical study information included in this section was performed with the Kainox VDD ICD lead, which functions as a single lead system, comparable to the Kainox A+. Both leads have identical floating electrodes in the atrium and identical pacing electrode tip, ring and shock electrodes designed for placement in the right ventricle. The minor differences are in the ventricular shock coil (Kainox A+ coil has a slightly larger surface area, and the surface is not coated with fractal iridium).

Due to the structural and functional similarities between the Kainox A+ and Kainox VDD, a clinical study of Kainox A+ was determined to be unnecessary.

1.9.3.1.1 Patients Studied

The Single-Lead ICD system clinical study involved 9 patients (7 males and 2 females) with a mean age of 58.8 years (range: 25 to 83 years). 66.7% presented with ventricular fibrillation/ polymorphic ventricular tachycardia as their primary tachycardia. The Single-Lead ICD system was selected for the diagnostic value of the atrial IEGMs in 88.9% of the patients.

1.9.3.1.2 Methods

The feasibility clinical investigation was designed to evaluate the quality of atrial signals obtained using the Single-Lead ICD. The study was also designed to evaluate the safety and effectiveness of the Single-Lead ICD system to detect and treat monomorphic ventricular tachycardia (MVT), polymorphic ventricular tachycardia (PVT), ventricular fibrillation (VF), and bradycardia. The specific predefined objectives of the investigation included UADE-free survival rate, appropriate bradycardia sensing and pacing, detection and treatment of ventricular tachyarrhythmias and appropriate atrial sensing during activities of daily living.

1.9.3.1.3 Results

The mean implant duration was 6.1 ± 9.4 months with a cumulative implant duration of 54.5 months. There were 5 patients followed for over six months and 2 patients followed for over three months. The patient follow-up compliance rate was 100%, 43 out of 43 required follow-ups. Table 9 provides a summary of the results of the study group.

Table 9: Clinical Study Results

Description	Results
UADE-free Survival Rate	100% (9/9)
Complication Rate	11.1% (1/9)
Appropriate Atrial Sensing Rate*	97.6% (41/42)
Appropriate Atrial Sensing during 24-hour Holter Test	100% (9/9)
Appropriate Atrial Sensing during Exercise Treadmill Test	100% (6/6)
Detection and Conversion of Ventricular Tachyarrhythmias†	100% (68/68)

* The investigator determined the appropriateness of atrial sensing. The rate is determined by the number of appropriate atrial sensing evaluations divided by the total number of evaluations.

† Conversion data were collected in the clinical study for both induced and spontaneous ventricular tachyarrhythmia episodes. Therefore, both types of tachyarrhythmia episodes were included in the analysis.

1.9.3.2 European Clinical Study

1.9.3.2.1 Patients Studied

The European Deikos A+/Kainox VDD lead clinical study involved 82 patients (66 males and 16 females) with a mean age of 61.8 years (range: 29 to 84 years). 42.7% presented with monomorphic ventricular tachycardia as their primary tachycardia.

1.9.3.2.2 Study Objectives

This clinical investigation was designed to collect information on the performance and function of the Deikos A+/Kainox VDD ICD system. The specific predefined objectives of the investigation included the rate of inappropriate, i.e. unnecessary deliveries of antitachycardia therapy due to supraventricular tachycardia (SVT), the tachyarrhythmia conversion efficacy of the system with activated SMART Detection® algorithm, the rate of appropriate atrial sensing and the morbidity rate.

1.9.3.2.3 Results

The mean implant duration was 8.9 ± 4.4 months with a cumulative implant duration of 732 months. No unanticipated adverse events were reported during the study. There were two deaths reported, which were unrelated to the implanted device. A summary of the results obtained during the evaluation is provided in Table 10.

Table 10: OUS Clinical Study Results

Description	Results
UADE-free Survival Rate	100% (82/82)
Complication Rate	19.5% (16/82)
Inappropriate Therapies with SMART Detection® algorithm ON Rate	94.8% (234/250)
Inappropriate Therapies with SMART Detection® algorithm OFF Rate	84.7% (133/157)
Appropriate Atrial Sensing Rate*	92.6% (176/190)
Detection and Conversion of Ventricular Tachyarrhythmias†	100% (248/248)

* The investigator determined the appropriateness of atrial sensing. The rate is determined by the number of appropriate atrial sensing evaluations divided by the total number of evaluations.
† Conversion data were collected in the clinical study for both induced and spontaneous ventricular tachyarrhythmia episodes. Therefore, both types of tachyarrhythmia episodes were included in the analysis.

1.9.4 Lumax DX / Linox DX Evaluation – European Clinical Study

BIOTRONIK conducted a prospective study outside the United States (OUS) of the Linox^{smart} S DX leads to investigate the efficacy and safety of the Lumax DX / Linox DX system in a controlled clinical investigation. The results from this study are presented in the following sections.

1.9.4.1 Patients Studied

The study involved 38 patients from 5 clinical sites and involved 38 implant procedures and 116 follow-up procedures. The 38 patients were 31 males and 7 females with a mean age of 62.3 years (range: 35-72), a mean left ventricular ejection fraction (LVEF) of 38.8% (range: 17-87) and NYHA Class at enrollment (NHYA Class 1 (13.2%), Class II (52.6%), Class III (18.4%), Not evaluated (15.8%)).

1.9.4.2 Methods

The study was designed to demonstrate the effectiveness of the atrial sensing by evaluation the rate of appropriate atrial sensing in the leads, demonstrate the rate of successfully terminated tachyarrhythmia episodes and demonstrate the safety of the leads by evaluating the freedom from complications.

After successful enrollment, all patients were implanted with the Lumax 540 VR-T DX device and Linox^{smart} S DX ICD lead. Evaluations were performed at implant, pre-discharge, one- and three-month follow-ups.

1.9.4.3 Results

38 Linox^{smart} S DX leads were investigated in this DX Evaluation study. In total 430 atrial sensing assessments were performed, whereof 415 (96.5%) were classified as appropriate (refer to Table 11).

Table 11: Atrial sensing assessment

Atrial sensing assessment, N (%)	Procedure	Normal	Over sensing	Under sensing	Not evaluated*	Total evaluated
Lying dorsal	Implantation	37 (97.4)	0 (0.0)	1 (2.6)‡	0	38 (100.0)
	PHD	34 (97.1)	0 (0.0)	1 (2.9)§	1	35 (100.0)
	1 month FU	29 (93.6)	1 (3.2)†	1 (3.2)§	0	31 (100.0)
	3 month FU	31 (93.9)	0 (0.0)	2 (6.1)§	0	33 (100.0)
Sitting position	Implantation	n/a	n/a	n/a	n/a	n/a
	PHD	36 (100.0)	0 (0.0)	0 (0.0)	0	36 (100.0)
	1 month FU	28 (93.6)	1 (3.3)†	1 (3.3)§	0	30 (100.0)
	3 month FU	30 (96.8)	0 (0.0)	1 (3.2)§	2	31 (100.0)
Sitting position, palms together	Implantation	n/a	n/a	n/a	n/a	n/a
	PHD	35 (97.2)	0 (0.0)	1 (2.8)§	0	36 (100.0)
	1 month FU	29 (93.6)	1 (3.2)†	1 (3.2)§	0	31 (100.0)
	3 month FU	30 (96.8)	0 (0.0)	1 (3.2)§	2	31 (100.0)
Sitting position, Jendrassik's maneuver	Implantation	n/a	n/a	n/a	n/a	n/a
	PHD	35 (97.2)	0 (0.0)	1 (2.8)§	0	36 (100.0)
	1 month FU	30 (96.8)	1 (3.2)†	0 (0.0)	0	31 (100.0)
	3 month FU	31 (100.0)	0 (0.0)	0 (0.0)	2	31 (100.0)
Total		**415 (96.5)**	**4 (0.9)**	**11 (2.6)**	**7**	**430 (100.0)**

* Due to missing IEGM printout.
† 58-1-205-04: No more oversensing after reprogramming.
‡ 58-6-006-01: Atrial dipole has been positioned in the vena cava which caused no atrial sensing.
§ 58-1-205-08: patient was in atrial fibrillation in lying dorsal position at 3 month FU 58-1-205-09: Holter ECG confirmed undersensing.

61 analyzable tachyarrhythmia detections were documented (14 VF, 38 VT, 9 SVT) for 24 patients, 28 episodes were induced at implantation and/or pre-hospital discharge follow-up in 23 patients. In Table 12 the investigator-rated arrhythmias are listed with regard to the appropriateness of the delivery and inhibition of ICD therapy. All 49 delivered ICD therapies in VF and VT episodes were appropriate and successful. There were 3 inappropriate inhibitions of ICD therapy in VT episodes and 9 appropriate inhibitions in SVT episodes. Thus, 49 VF/VT episodes could be converted, 9 SVT were appropriately inhibited and 3 VT episodes that required therapy were not treated. Hence a rate of successfully terminated tachyarrhythmia episodes of 58/61=95.1%.

Table 12: Delivery and inhibition of ICD therapy in spontaneous and induced episodes, N

Outcome	VF	VT	SVT	Other	Total
Appropriate ICD therapy successful	14	35	0	0	49
Appropriate inhibition	0	0	9	0	9
VT/VF that required therapy was not treated	0	3*	0	0	3
Total	14	38	9	0	61

* Patient 58-1-078-05 had LAD stenosis caused numerous tachyarrhythmias which were appropriately detected and successfully treated. These mentioned three episodes were detected in the SVT zone. Due to the atrial undersensing single chamber discrimination algorithm was applied (onset, stability) As these 3 episodes did not show stable RR-intervals, they were detected as SVTs. Two of them were spontaneously terminated. Another episode was initially detected in the SVT zone, but correctly redetected in the VT zone and successfully terminated by an ATP. A successful stenting of LAD stenosis stopped this series of tachyarrhythmias.

No lead related serious adverse device effects were reported and the SADE free-rate is 100% for the Linox^{smart} S DX ICD leads.

1.9.4.4 Discussion and Conclusion

There were a total of 38 patients implanted with 38 Linox^{smart} S DX ICD leads and a total of 116 follow-up procedures.

- The rate of atrial sensing assessments was 96.5%.
- The rate of successfully terminated tachyarrhythmia episodes was 95.1%. There were 3 VT episodes in one patient that required ICD therapy which was not performed. Two episodes were terminated spontaneously; one episode was converted due to ventricular re-detection which was successfully treated.
- No lead related serious adverse device effects were reported and the SADE free-rate is 100% for the Linox^{smart} S DX ICD leads.

The data received and analyzed demonstrate that the Linox^{smart} S DX ICD leads are safe and effective for the implanted patients.

1.9.5 Lumax 740 VR-T DX Subgroup of Lumax 740 Master Study – European Clinical Study

BIOTRONIK conducted a prospective study outside the United States (OUS) to investigate the efficacy and safety of the Lumax 740 ICD family in a controlled clinical investigation. A subset of devices used in the study is the VR T DX devices implanted with Linox^{smart} S DX ICD leads. The results from this subgroup of the study are presented in the following sections.

1.9.5.1 Patients Studied

The study involves 23 patients from 7 clinical sites and involved 23 implant procedures and 78 follow-up procedures. The 23 patients were 20 males and 3 females with a mean age of 57.0 years (range: 26-73), a mean left ventricular ejection fraction (LVEF) of 36.4% (range: 20.0-65.0) and NYHA Class at enrollment (NHYA Class 1 (26.1%), Class II (65.2%) and Class III (8.7%).

1.9.5.2 Methods

The study is designed to provide an objective evaluation of the Lumax 740 study devices to demonstrate the clinical efficacy and safety of the Lumax 740 ICD family. The assessment of the efficacy of the ICDs is supported by the collection of standard pacing and defibrillation measurements and the investigator's assessment of the system performance. For all Lumax 740 VR-T DX systems, the atrial sensing performance is evaluated in different body positions.

The safety of the Lumax 740 VR-T DX is assessed by asking the investigator to record any adverse event. All serious adverse device effects (SADE) possibly or securely causally related to the implanted ICD contribute to the calculation of the SADE free rate.

After successful enrollment, all patients were implanted with the Lumax 740 VR-T DX device and Linox[smart] S DX ICD lead. Evaluations were performed at implant, pre-discharge, one-, three and six-month follow-ups.

1.9.5.3 Results

23 Linox[smart] S DX leads were investigated in this Lumax 740 VR T DX study. In total 238 atrial sensing assessments were performed, whereof 236 (99.2%) were classified as appropriate (refer to Table 13).

Table 13: Atrial sensing assessments in different body positions

Atrial sensing assessment, N (%)	Procedure	Normal	Over sensing	Under-sensing	Not evaluated*	Total (evaluated)
Dorsal lying position	PHD	17 (100 %)	0 (0.0)	0 (0.0)	2	17 (100.0 %)
	1-Month FU	18 (100 %)	0 (0.0)	0 (0.0)	0	18 (100.0 %)
	3-Month FU	18 (100 %)	0 (0.0)	0 (0.0)	0	18 (100.0 %)
	6-Month FU	7 (100 %)	0 (0.0)	0 (0.0)	0	7 (100.0 %)
Sitting position	PHD	15 (100 %)	0 (0.0)	0 (0.0)	3	15 (100.0 %)
	1-Month FU	18 (100 %)	0 (0.0)	0 (0.0)	0	18 (100.0 %)
	3-Month FU	19 (100 %)	0 (0.0)	0 (0.0)	0	19 (100.0 %)
	6-Month FU	7 (100 %	0 (0.0)	0 (0.0)	0	7 (100.0 %)
Sitting position, palms together	PHD	16 (100 %)	0 (0.0)	0 (0.0)	3	16 (100.0 %)
	1-Month FU	18 (100 %)	0 (0.0)	0 (0.0)	0	18 (100.0 %)
	3-Month FU	17 (94.4 %)	0 (0.0)	1 (5.6 %)†	0	18 (100.0 %)
	6-Month FU	7 (100 %)	0 (0.0)	0 (0.0)	0	7 (100.0 %)
Sitting position, Jendassik manoeuvre	PHD	16 (100 %)	0 (0.0)	0 (0.0)	3	16 (100.0 %)
	1-Month FU	18 (100 %)	0 (0.0)	0 (0.0)	0	18 (100.0 %)
	3-Month FU	18 (94.7 %)	0 (0.0)	1 (5.3 %)†	0	19 (100.0 %)
	6-Month FU	7 (100 %)	0 (0.0)	0 (0.0)	0	7 (100.0 %)
Total		**236 (99.2 %)**	**0 (0.0)**	**2 (0.8 %)**	**11**	**238 (100.0 %)**

*** 55-1-017-01 had permanent AF during visit, 55-9-402-07 reason unknown, 55-6-027-20 was unable to sit**
† atrial undersensing due to ventricular extrasystole (one patient)

ICD therapy was delivered in 118 episodes (4 induced and 114 spontaneous episodes), in which 86 episodes were appropriate and the other 32 were due to atrial fibrillations. All 32 episodes occurred in the same patient. The patient suffered from recurrent atrial fibrillation with a temporarily very fast conduction (180 to 220 bpm). The programmed criteria were fulfilled for the detection of a VT1 episode. In Table 14 the invtestigator-rated arrhythmias are listed with regard to the appropriateness of the therapy. In 86 out of 86 cases (100%) the therapy was appropriate and successful.

Table 14: Delivered ICD therapy in spontaneous and induced episodes, N

Outcome	VF	VT	AF	Other	Total
Appropriate and successful	4	82	0		86
Appropriate, but not successful	0	0	0		0
Inappropriate therapy	0	0	32		32
Total	**4**	**82**	**32**		**118**

1.9.5.4 Discussion and Conclusion

There were a total of 23 patients implanted with 23 Linox^{smart} S DX ICD leads and a total of 78 follow-up procedures.

- The rate of atrial sensing assessments was 99.2%.
- According to the investigator-rated arrhythmias, in 86 out of 86 cases (100%) the therapy was appropriate and successful.

Although the Lumax 740 Master Study is still ongoing, the data received and analyzed thus far demonstrates that the Linox^{smart} S DX ICD leads are safe and effective for the indicated patients.

1.9.6 Linox^{smart} S DX Complication Rate

The Linox^{smart} S DX complication rate appears low based on voluntary/ non-mandatory reporting and limited clinical data, but has not been confirmed with mandatory reporting or long term clinical study results.

1.9.7 Home Monitoring Data from European Studies

In addition to the Lumax 740 Master Study and the Lumax DX/ Linox DX Evaluation, BIOTRONIK conducted a prospective study outside the United States (OUS) to evaluate the Linox^{smart} S DX leads prior to full market release. This study enrolled 116 patients at 25 sites in Europe and performed evaluations up to six-month follow-ups.

Since most of the patients enrolled in all three European studies have Home Monitoring® (HM), remote follow-up data was collected for the patients via the Home Monitoring Service Center. In addition, long-term remote follow-up HM data was collected for some patients beyond the planned 3- or 6- month study durations up to 21-months.

BIOTRONIK analyzed atrial sensing collected in the long-term HM dataset from enrollment out to 21-months from implantation. The data demonstrated that the atrial sensing values remained consistent over the 21-months; which demonstrates long-term atrial sensing is stable and within a clinically acceptable range. The following Figure 2 is a graph depicting the atrial P-waves recorded in the long-term HM dataset. Depicted are the means and standard deviations at each time interval.

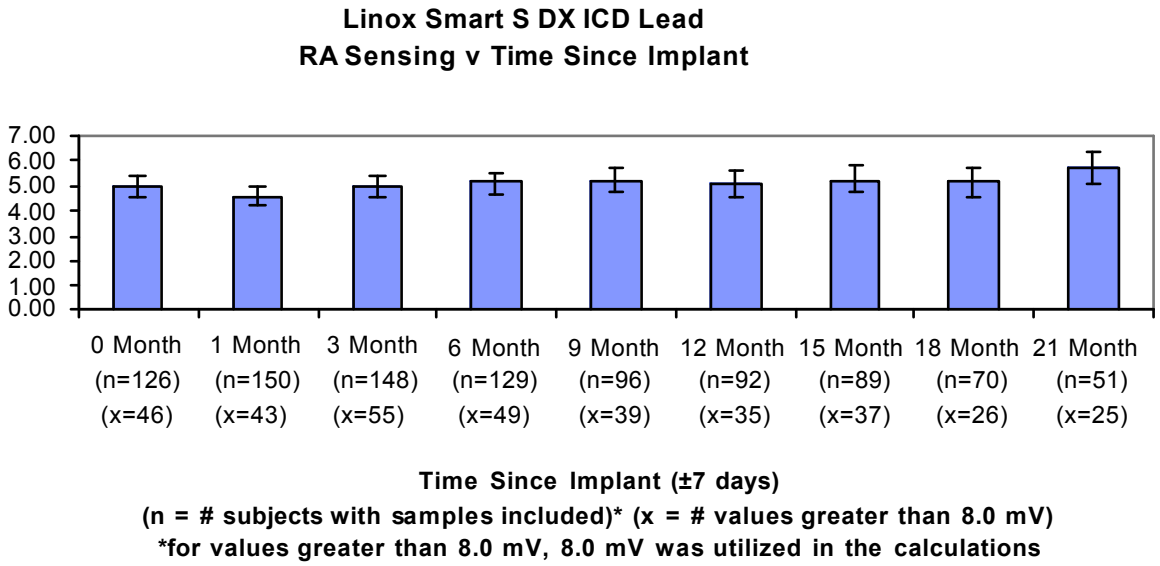


Figure 2: Home Monitoring Atrial Sensing Data

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

NOTE:

Please also observe the technical manuals and accompanying documents for devices combined with this lead (ICD, pacemaker, additional leads) and for devices and implant accessory used during implantation.

3.1 Implant Preparation

Prior to beginning an implant of the Linox^{smart} Lead System, ensure that all of the necessary equipment is available. The implant procedure requires the ICD, 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 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 no 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 25º C (77º F); excursions permitted from 5º to 55º C (41º to 131º 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

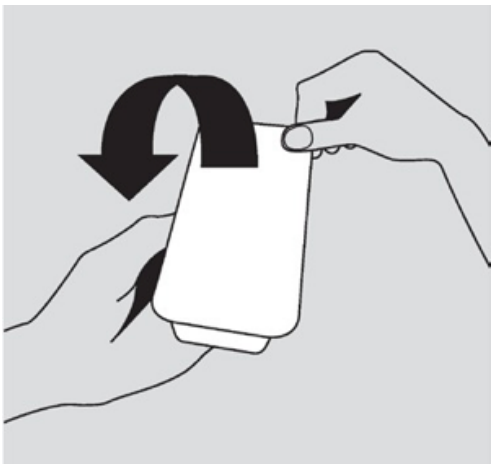
Resuscitation Availability - In order to implant the IDC system, it is necessary to induce and convert the patient‘s ventricular tachyarrhythmias. Do not perform induction testing unless an alternate source of patient defibrillation such as an external defibrillator is readily available.

3.3 Opening the Sterile Container

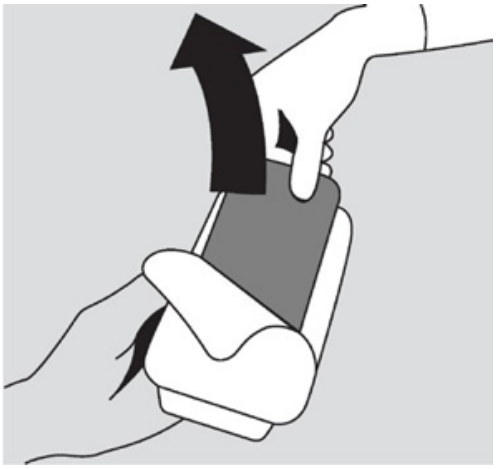
The lead is packaged in two plastic trays, one within the other. Each tray is individually sealed and sterilized with ethylene oxide.

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

Linox^{smart} S Lead

The Linox^{smart} S lead and contents of the inner blister package are sterile. Each Linox^{smart} S Lead system package contains:

- **1** - Linox^{smart} S 60, Linox^{smart} S 65 or Linox^{smart} 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
- **2** - fixation tools
- **1** - vein lifter

Linox^{smart} T Lead

The Linox^{smart} T lead and contents of the inner blister package are sterile. Each Linox^{smart} T Lead system package contains:

- **1** - Linox^{smart} 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

Linox^{smart} SD Lead

The Linox^{smart} SD lead and contents of the inner blister package are sterile. Each Linox^{smart} SD Lead system package contains:

- **1** - Linox^{smart} SD 60/xx, Linox^{smart} SD 65/xx or Linox^{smart} 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
- **2** - fixation tools
- **1** - vein lifter

Linox^{smart} TD Lead

The Linox^{smart} TD lead and contents of the inner blister package are sterile. Each Linox^{smart} TD Lead system package contains:

- **1** - Linox^{smart} TD 65/xx or Linox^{smart} 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

Linox^{smart} S DX Lead

The Linox^{smart} S DX lead and contents of the inner blister package are sterile. Each Linox^{smart} S DX Lead system package contains:

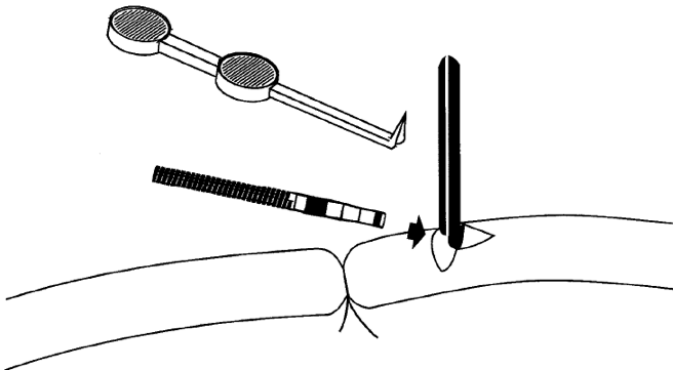
1 - Linox^{smart} S DX 65/15 or Linox^{smart} S DX 65/17 lead with one silicone anchoring sleeve attached (EFH-30-8F), and a pre inserted stylet (0.36 mm)
1 - stylet (0.36 mm)
2 - stylets (0.38 mm)
1 - stylet introducer
2 - fixation tools
1 - vein lifter

NOTE:
Additional stylets also are available as separately packaged sterile accessories.

3.5 Linox^{smart} T and Linox^{smart} TD Lead Insertion

The following procedure is recommended for implanting of the Linox^{smart} T and Linox^{smart} 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. 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).



NOTE:
The recommended introducer size for the Linox^{smart} T and Linox^{smart} TD leads is 8 French.

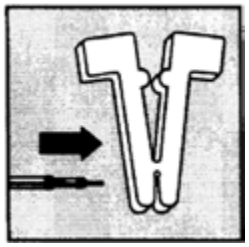
3. The lead should be inserted into the vein and advanced into the ventricle under fluoroscopic guidance. Four stylets are included in the sterile package. Additional stylets are available in separate packaging, if required. Do not shape the stylet while it is inserted in the lead body. When changing 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 Linox^{smart} S, Linox^{smart} SD and Linox^{smart} S DX Lead Insertion

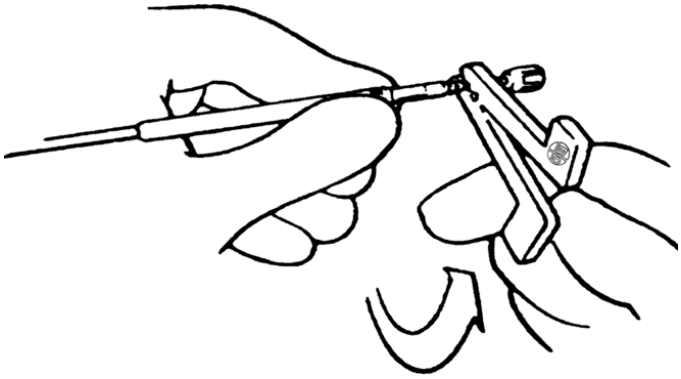
Verifying the Mechanical Function of the Fixation Helix

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 (see the following figure). Typically 5-14 complete clockwise rotations of the fixation tool are required to fully extend the helix; however, it can take up to a maximum of 20 complete clockwise rotations of the fixation tool. The helix should fully extend to approximately 1.8 mm.



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.

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

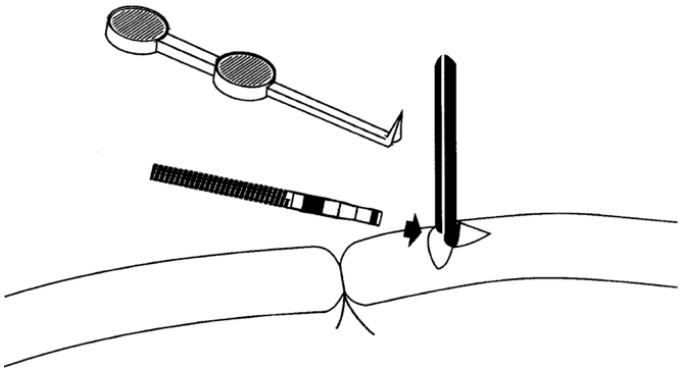
5. Ensure that the fixation screw is completely retracted.
6. Begin implantation by positioning the lead fixation sleeve close to the lead's connector pin.
7. If the subclavian stick approach is used to gain venous access, select an appropriate introducer for the lead.

NOTE:

The recommended introducer size for the Linox^{smart} S, Linox^{smart} SD and Linox^{smart} S DX leads is 8 French.

Using the Vein Lifter

8. 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).



9. 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 excessively bend the stylet

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

Positioning the Linox^{smart} S DX Lead Atrial Ring Electrodes:

While using fluoroscopy to monitor the position of the lead, position the atrial ring electrodes approximately at the middle third of the lateral atrium wall. In general, the 17 cm length is preferable for most patients with a dilated heart/large RV. The 15 cm spacing may be used in smaller patients or patients with a small heart/small RV to allow the atrial electrodes to be positioned in the mid atrium.

NOTE:

The atrial ring electrodes are radiopaque. Check that the atrial signal amplitudes are stable. Positioning on the lower lateral wall poses the risk of far-field sensing (sensing of ventricular signals in the atrial channel). Positioning on the upper lateral wall poses the risk of insufficient atrial signal amplitude.

WARNING

Risk of myocardial perforation due to a disproportionate level of pressure on the lead tip.

Use of excessive force with a preformed stylet can result in a significant level of pressure being placed on the ventricular myocardium via the lead tip.

Do not place pressure on the lead in this way.

Securing the Electrode into the Endocardium

11. 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.
12. Achieve permanent lead fixation by rotating the fixation tool clockwise until the helix is completely exposed.

NOTE:

Up to a maximum of 20 complete clockwise rotations of the fixation tool may be necessary to fully extend the fixation helix. While extending the helix, use fluoroscopy as described in Step #13, to verify that the helix is fully extended.

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

13. 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 3: Helix Retracted

Figure 4: Helix Extended

CAUTION

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

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

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

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

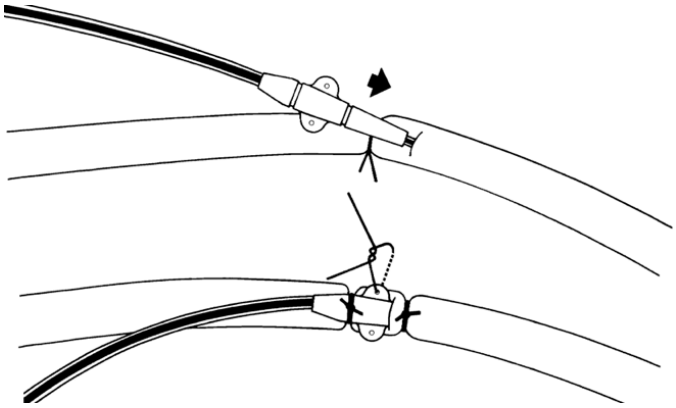
3.7 Baseline Measurements

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 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 Linox^{smart} S, Linox^{smart} SD or Linox^{smart} S DX 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 the 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 Linox^{smart} S and Linox^{smart} 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 DF-1” for the distal coil defibrillation connector.

The Linox^{smart} SD and Linox^{smart} 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 DF-1” with the internal conductor coated white for the distal coil defibrillation connector, and “Atrium DF-1” with a blue coated conductor for the proximal coil defibrillation connector. The colors aid in easy identification.

The Linox^{smart} S DX leads have two IS-1 bipolar sensing and pacing connectors and one DF-1 defibrillation connector. The connectors are marked as “IS-1 BI” for the ventricular sensing and pacing connector, “Atrium DF-1” for the atrial sensing connector, and “Ventricle DF-1” for the distal coil defibrillation connector.

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 90º 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 15: Active Housing ICD with a Linox^{smart} lead

Port	Connector pin
RV / HV 1	DF-1 pin of the Linox^{smart} ventricular shock coil
SVC / HV 2	DF-1 pin of the Linox^{smart}SD lead SVC shock coil or DF-1 pin of the Linox^{smart}TD lead SVC shock coil or separate SVC lead or blind plug
SA / P/S A	IS-1 pin of the Linox^{smart}S DX atrial sense electrodes or separate atrial pace/sense lead
P/S V	IS-1 pin of the Linox^{smart} leads ventricular pace/sense electrode

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 Linox^{smart} 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. This could cause damage to the conductors or result in abrasion of the lead's insulation.

Lead Positioning-If the ICD is implanted underneath the pectoral muscle, ensure that no parts of the lead lie between the housing of the ICD and

the ribs. Chafing and pressure on the lead between the housing of the ICD and the ribs could damage the lead's insulation and thus cause premature failure.

- 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 Linox^{smart} 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 Linox^{smart} 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 Linox^{smart} S, Linox^{smart} SD and Linox^{smart} S DX 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

Resterilization-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 (Linox^{smart} Passive Fixation Leads)

General Specifications		
	Linox^{smart} T	**Linox^{smart} TD**
Leads, Length (cm)	65	65, 75
Polarity	Tripolar	Quadripolar
Insulation	Silicone tubing with Silglide® surface treatment	Silicone tubing, with Silglide® surface treatment
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		
	Linox^{smart} T	**Linox^{smart} TD**
Electrode Surface Area	1.8 mm^2	1.8 mm^2
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)	≤ 85 Ω (65 cm length) ≤ 100 Ω (75 cm length)

Steroid Reservoir (Collar)		
	Linox^{smart} T	**Linox^{smart} 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		
	Linox^{smart} T	**Linox^{smart} TD**
Surface Area	24.5 mm^2	24.5 mm^2
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	≤ 50 Ω (65 cm length)	≤ 50 Ω (65 cm length) ≤ 60 Ω (75 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)		
	Linox^{smart} T	**Linox^{smart} TD**
Geometric Surface	2.9 cm^2	2.9 cm^2
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)	≤ 1.6 Ω (65 cm length)	≤ 1.6 Ω (65 cm length) ≤ 1.9 Ω (75 cm length)

Superior Vena Cava Shock Coil (SVC)		
	Linox^{smart} T	**Linox^{smart} TD**
Geometric Surface	N/A	4.1 cm^2
Diameter	N/A	2.6 mm (7.8F)
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	≤ 1.2 Ω (65 cm length) ≤ 1.4 Ω (75 cm length)

7. Technical Data (Linox^{smart} Active Fixation Leads)

General Specifications			
	Linox^{smart} S	**Linox^{smart} SD**	**Linox^{smart} S DX**
Leads, Length (cm)	61.2, 65, 75	61.2, 65, 75	65
Polarity	Tripolar	Quadripolar	Pentapolar
Insulation	Silicone tubing, with Silglide® surface treatment		
Connectors	1 x IS-1 bipolar 1 x DF-1	1 x IS-1 bipolar 2 x DF-1	2 x IS-1 bipolar 1 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)			
	Linox^{smart} S	**Linox^{smart} SD**	**Linox^{smart} S DX**
Active Agent	Dexamethasone Acetate		
Steroid amount	1.0 mg		
Steroid binding agent	Silicone rubber		

Tip Electrode			
	Linox^{smart} S	**Linox^{smart} SD**	**Linox^{smart} S DX**
Length of Extended Helix (max)	1.8 mm		
Electrode Surface Area	4.5 mm^2 (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	≤ 50 Ω (61.2, 65 cm length) ≤ 60 Ω (75 cm length)		≤ 50 Ω

Atrial Ring Electrode			
	Linox^{smart} S	**Linox^{smart} SD**	**Linox^{smart} S DX**
Surface Area	N/A		24.5 mm^2
Surface: Material, Structure			Iridium, fractal
Basic Material			Pt / Ir (80% / 20%)
Distance from Tip to Ring			15 cm / 17 cm
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			≤ 40 Ω

*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 Ring Electrode			
	Linox^{smart} S	**Linox^{smart} SD**	**Linox^{smart} S DX**
Surface Area	24.5 mm^2		
Surface: Material, Structure	Iridium, fractal		
Basic Material	Pt / Ir (80% / 20%)		
Distance from Lead Tip to Ring	11 mm		
Conductor Style*	Cable		
Conduction Material	MP35N		
Number of Filaments	4 (coil)/7*7(cable)		
Resistance: IS-1 Connector, Ring Electrode	≤ 50 Ω (61.2, 65 cm length) ≤ 60 Ω (75 cm length)		≤ 40 Ω

*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)			
	Linox^{smart} S	**Linox^{smart} SD**	**Linox^{smart} S DX**
Geometric Surface	2.9 cm^2		
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		

Ventricular Shock Coil (RV)			
	Linox^{smart} S	**Linox^{smart} SD**	**Linox^{smart} S DX**
Conduction Material	MP35N/DFT (41% Ag)		
Number Of Filaments	7*7		
Resistance (Connector – Lead)	≤ 1.6 Ω (61.2, 65 cm length) ≤ 1.9 Ω (75 cm length)		≤ 1.6 Ω

Superior Vena Cava Shock Coil (SVC)			
	Linox^{smart} S	**Linox^{smart} SD**	**Linox^{smart} S DX**
Geometric Surface	N/A	4.1 cm^2	N/A
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)		≤ 1.2 Ω (61.2, 65 cm length) ≤ 1.4 Ω (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.

Silglide®. A surface treatment to the silicone insulation to improve gliding properties.

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.

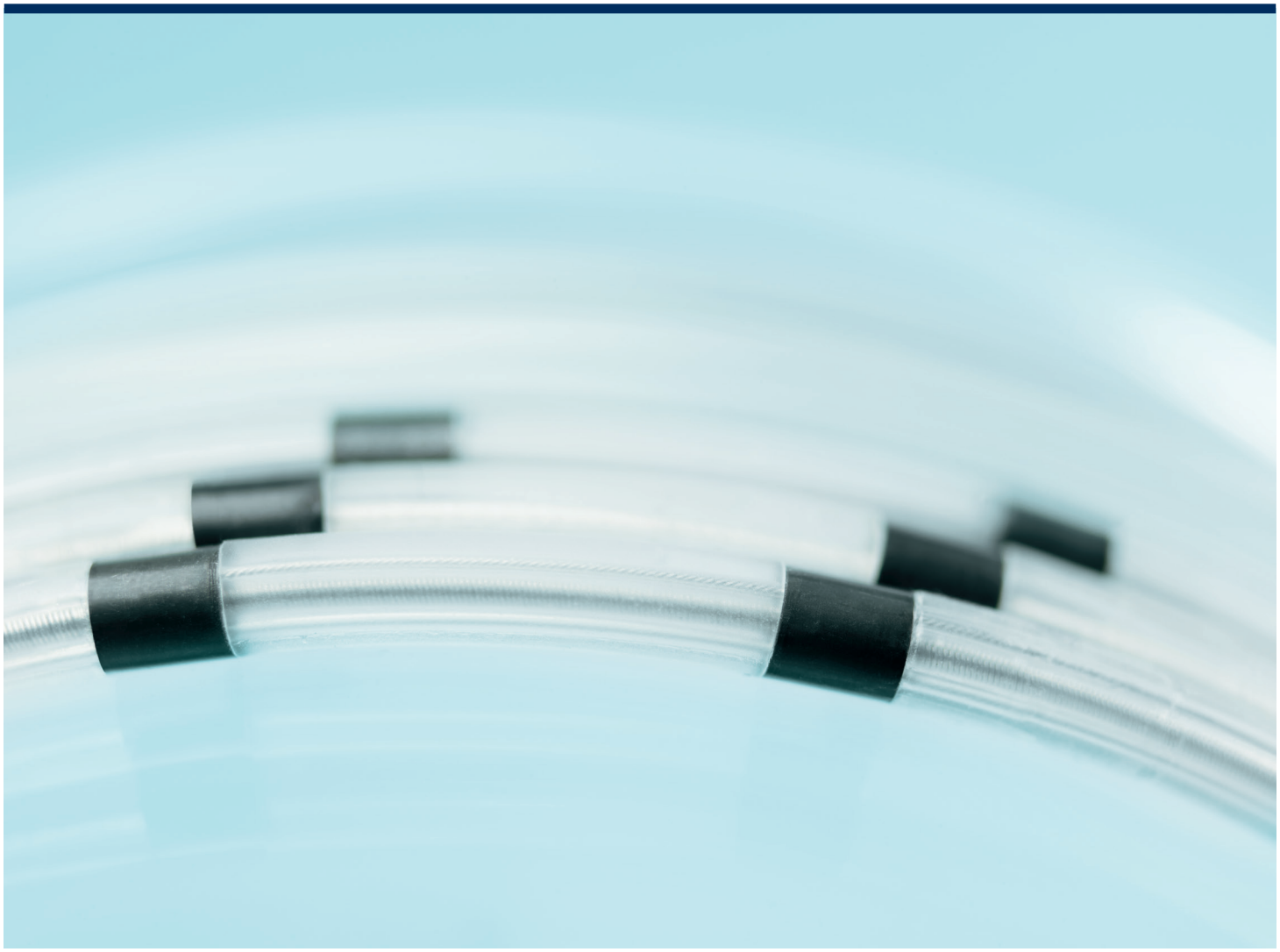
Ventricular Fibrillation. Chaotic contraction of the ventricles that results in little or no blood being pumped to the body. This is a life-threatening rhythm if left untreated.

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.

Linox^{smart} Steroid-Eluting ICD Leads

Technical Manual



Manufactured by:

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin Germany

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

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

M4133-I 05/16

MN041r3 5/4/16

BIOTRONIK
excellence for life