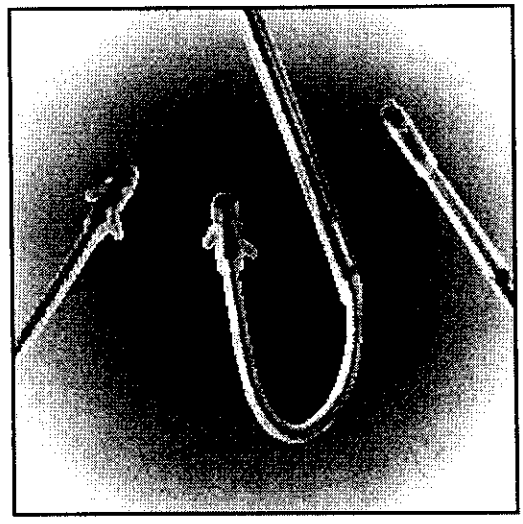

Stelid II, Stelix, and Stelix II Endocardial Steroid Eluting Pacing Leads Physician Manual

Caution: Federal law restricts this device to sale by or on the order of a physician

Table of Contents

INTENDED USE

The Stelid II, Stelix, and Stelix II steroid eluting endocardial pacing leads are designed to be used with an implantable pacemaker for pacing and sensing of the heart. The Stelid II models BTF25D/26D and UTF25D/26D are intended for permanent pacing and sensing of the ventricle. The Stelid II models BJF24D/25D, Stelix models BR45D/BR46D, and Stelix II models BRF25D/26D are intended for permanent pacing and sensing of the atrium.

CONTRAINDICATIONS

- Implantation of endocardial leads is generally contraindicated in patients with mechanical tricuspid valves.
- Do not implant in patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated.

DEVICE DESCRIPTION

Stelid II, Stelix and Stelix II leads use silicone insulation, a platinum-iridium proximal electrode, and a vitreous carbon distal electrode to provide permanent pacing and sensing between a pacemaker and the heart. A silicone elastomer collar containing a maximum of 1.0 mg. of dexamethasone sodium phosphate is located just behind the carbon distal electrode. Upon exposure to body fluids, the steroid elutes progressively to the cardiac tissue around the electrode.

The steroid aims to minimize the inflammatory response during the first weeks post-implantation.

The table below describes the technical specifications related to the lead models discussed in this manual.

	Stelid II BTF25D/26D	**Stelid II UTF25D/26D**	**Stelid II BJF24D/25D**	**Stelix BR45D/46D**	**Stelix II BRF25D/26D**
Chamber	Ventricle	Ventricle	Atrium	Atrium	Atrium
Lead shape	Straight	Straight	J-shaped	Straight	Straight
Length	52/59 cm	52/59 cm	45/52	52/59 cm	52/59 cm
Electrode material	Vitreous carbon	Vitreous carbon	Vitreous carbon	Vitreous carbon	Vitreous carbon
Electrode size	2 mm^2	2 mm^2	2 mm^2	4 mm^2	2 mm^2
Steroid	<1.0 mg of dexamethasone sodium phosphate	<1.0 mg of dexamethasone sodium phosphate	<1.0 mg of dexamethasone sodium phosphate	<1.0 mg of dexamethasone sodium phosphate	<1.0 mg of dexamethasone sodium phosphate
Fixation	Four silicone tines	Four silicone tines	Four silicone tines	Retractable helix	Retractable helix
Body diameter	2 mm	1.6 mm	2.5 mm	2.5 mm	2.5 mm
Introducer size	8 F (2.66 mm)	8 F (2.66 mm)	8 F (2.66 mm)	9 F (3.33 mm)	9 F (3.33 mm)
Connector	IS-1 bipolar	IS-1 unipolar	IS-1 bipolar	IS-1 bipolar	IS-1 bipolar

	Stelid II BTF25D/26D	Stelid II UTF25D/26D	Stelid II BJF24D/25D	Stelix BR45D/46D	Stelix II BRF25D/26D
Stylets furnished with lead	4 straight	4 straight	4 straight	2 straight 2 j-shaped 2 flat tip	2 straight 2 j-shaped 2 flat tip
Max pacing impedance	1000 Ω	1000 Ω	1000 Ω	900 Ω	1000 Ω
Max sensing impedance	1000 Ω	1000 Ω	1000 Ω	900 Ω	1000 Ω

CONTENTS OF THE PACKAGE

Sterile package:

- pacing lead with ligature sleeve,
- vein lifter,
- stylet guide (funnel),
- stylets.

Non sterile documentation:

- physician's manual,
- technical sheet.

The following ligature sleeves and stylets, packaged with the leads, are also available as separately packaged accessories:

- Ligature sleeve models XRL-430, XRL-432, and XRL-433
- Straight stylet models XRL-436, XRL-441, and XRL-446
- Flat tip yellow stylet models XRL-434 and XRL-435
- J-shaped stylet models XRL-437 and XRL-445

STORAGE

The lead must be stored at a temperature between 0° and 50°C.

OPENING THE PACKAGE

Before opening the package (Fig. 1):

- confirm that the lead is compatible with the pulse generator to be implanted
- check the use before date,
- make sure that the package has not been damaged or opened.

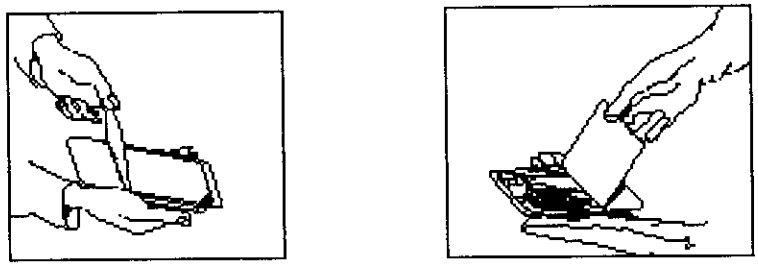

Fig. 1

STERILIZATION

All ELA Medical leads are sterilized with ethylene oxide before delivery.

On the use before date and in the event of alteration of the sterile package, please contact your local ELA Medical agent who will advise you what to do.

Note: *Never resterilize this lead.*

PRECAUTIONS

- A defibrillator must always be immediately available in the operating room throughout implantation of the lead. When implanted, the pacing lead is in direct electrical contact with the myocardium. Only battery-operated and CF class (low-leakage) electrical appliances should be used during the procedure.
- An AC electrical appliance that could accidentally be connected to the lead should not be placed in the vicinity of the patient.
- All operating room electrical appliances must be grounded.
- It is strongly advised not to use electrosurgical cautery appliances in the vicinity of an implanted lead.
- Do not immerse the lead in fluid prior to implantation as this may cause elution of some of the steroid and result in a reduction of the anti-inflammatory effect.
- Protect the carbon electrode from contact with powders, fibers and silicone oil lubricant. They may contaminate the electrode or clog the pores and therefore reduce the electrical performance.
- Therapeutic diathermy can cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator, due to induced currents.

ADVERSE EVENTS

Three separate clinical studies were performed on the leads. The adverse events from each one are listed separately.

Stelid II BTF25D/26D steroid eluting ventricular leads and Stelix BR45D/46D steroid eluting atrial leads

A randomized controlled study was performed to assess the safety and effectiveness of the Stelid II and Stelix steroid eluting leads. There were 218 patients implanted with Stelix steroid eluting atrial leads and 224 patients implanted with Stelid II steroid eluting ventricular leads. Patients were evaluated at pre-implant, implant, two weeks, one month, and three months post implant.

Table 1 summarizes the adverse events observed with the atrial leads and Table 2 summarizes the adverse events reported with the ventricular leads. No deaths were judged to be device related.

Table 1: Atrial lead adverse events

	Stelix steroid eluting atrial lead				Non steroidal atrial control lead+			
Nature of event	Number of patients	Percent of patients	Number of events	Events per device year	Number of patients	Percent of patients	Number of events	Events per device year
Non-device related death	20	9.2 %	20	0.11	12	15.6 %	12	0.205
Dislodgement	4	1.8 %	4	0.02	1	1.3 %	1	0.017
Increased atrial pacing threshold and dislodgement	1	0.5 %	1	0.006	--	--	--	--
Loss of capture	--	--	--	--	2	2.6 %	2	0.034
Extracardiac stimulation	1	0.5 %	1	0.006	--	--	--	--
Pulmonary embolism	1	0.5 %	1	0.006	--	--	--	--
Undersensing/loss of sensing	3	1.4 %	3	0.017	--	--	--	--
Oversensing	--	--		--	2	2.6 %	2	0.034
Hematoma of the pocket and pocket infection	1	0.5 %	1	*	--	--	--	--
Leads reversed in the header	2	2.6 %	2	*	--	--	--	--
Pleural effusion	1	0.5 %	1	*	--	--	--	--
Pneumothorax	1	0.5 %	1	*	1	1.3 %	1	*
Pocket infection	2	2.6 %	2	*	--	--	--	--
Loss of slack in leads	1	0.5 %	1	*	--	--	--	--
Accumulation of fluid	1	0.5 %	1	*	--	--	--	--
Hematoma of the pocket	3	1.4 %	3	*	1	1.3 %	1	*
Transient edema of left arm	1	0.5 %	1	0.006	--	--	--	--
Serious, not related	55	25.2 %	82	0.3	25	32.5 %	52	0.44

* Events are related to the implant procedure and involve both atrial and ventricular leads. Therefore, calculation of the number of events per device year is not appropriate.

+ Commercially available leads.

Table 2: Ventricular lead adverse events

	Stelid II steroid eluting ventricular lead				Non steroidal control ventricular lead+			
Nature of event	Number of patients	Percent of patients	Number of events	Events per device year	Number of patients	Percent of patients	Number of events	Events per device year
Non-device related death	21	9.4 %	21	0.11	12	15.6 %	12	0.21
Dislodgement	3	1.4 %	3	0.016	--	--	--	--
Extracardiac stimulation	2	0.9 %	2	0.011	--	--	--	--
Loss of capture	1	0.4 %	1	0.005	--	--	--	--
Pulmonary embolism	1	0.4 %	1	0.005	--	--	--	--
Undersensing/loss of sensing	1	0.4 %	1	0.005	--	--	--	--
High ventricular pacing threshold	1	0.4 %	1	0.005	1	1.3 %	1	0.017
Oversensing and undersensing/loss of sensing	--	--	--	--	1	1.3 %	1	0.017
Hematoma of the pocket and pocket infection	1	0.5 %	1	*	--	--	--	--
Leads reversed in the header	2	2.6 %	2	*	--	--	--	--
Pleural effusion	1	0.5 %	2	*	--	--	--	--
Pneumothorax	1	0.5 %	1	*	1	1.3 %	1	*
Pocket infection	2	0.5 %	2	*	--	--	--	--
Loss of slack in leads	1	0.5 %	1	*	--	--	--	--
Accumulation of fluid	1	0.5 %	1	*	--	--	--	--
Hematoma of the pocket	3	1.4 %	3	*	1	1.3 %	1	*
Transient edema of left arm	1	0.5 %	1	*	--	--	--	--
Serious, not related	56	25.0 %	83	0.44	25	32.5 %	52	0.44

* Events are related to the implant procedure and involve both atrial and ventricular leads. Therefore, calculation of the number of events per device year is not appropriate.

+ Commercially available leads.

Stelid II BJF25D and Stelix II BRF25D steroid eluting atrial leads

The Stelid II BJF25D steroid eluting atrial lead was evaluated in a 30-patient observational study; the Stelix II BRF25D steroid eluting atrial lead was evaluated in a 32-patient observational study. The Stelid II BJF25D and Stelix II BRF25D steroid eluting atrial leads are similar to the Stelid II BTF25D/26D steroid eluting ventricular leads and Stelix BR45D/46D steroid eluting atrial leads, respectively, in terms of design and materials of construction, which were evaluated in the randomized, controlled study described above. Therefore, two 30-patient observational studies were adequate to evaluate the safety and effectiveness of the Stelid II BJF24D/25D and the Stelix II BRF25D/26D steroid eluting atrial leads.

For both studies, the routine evaluation consisted of pre-implant screening, implant, and a follow-up at one month post implant. Table 3 summarizes the adverse events reported during these two studies. No deaths occurred during these studies and no serious events were judged to be device related.

Table 3: Adverse Events for Stelid II BJF25D and BRF25D

	Stelid II BJF25D steroid eluting atrial lead			Stelix II BRF25D steroid eluting atrial lead		
Nature of event	Number of patients	Percent of patients	Number of events	Number of patients	Percent of patients	Number of events
Non-device related death	--	--	--	--	--	--
Loss of atrial capture	2	6.67 %	2	--	--	--
Axillary vein thrombosis	1	3.3 %	1	--	--	--
Pneumothorax	1	3.3 %	1	--	--	--
Dislodgement	--	--	--	1	3.1 %	1
VA crosstalk	--	--	--	1	3.1 %	1
Atrial fibrillation at implant	--	--	--	1	3.1 %	1
Serious, not related	--	--	--	2	6.3 %	2

POTENTIAL ADVERSE EVENTS

Based on the literature and lead implant experience, the possible physical effects from implantation of Stelid II, Stelix, or Stelix II steroid eluting atrial or ventricular leads are listed below in alphabetical order:

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac perforation / tamponade
- Chronic nerve damage
- Death
- Elevated pacing thresholds
- Erosion / extrusion
- Excessive fibrotic tissue growth
- Formation of hematomas or cysts
- Inappropriate therapy
- Incomplete connection with pulse generator
- Induced atrial or ventricular arrhythmias
- Infection
- Keloid formation
- Lead abrasion
- Lead displacement / dislodgement
- Lead fracture, insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Myocardial injury
- Myocardial irritability
- Oversensing / undersensing
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with external paddles
- Threshold elevation
- Thrombosis / thromboemboli

CLINICAL STUDIES

STELID II BTF25D/26D STEROID ELUTING VENTRICULAR LEAD AND STELIX BR45D/46D STEROID ELUTING ATRIAL LEAD

To evaluate the safety and effectiveness of the Stelid II steroid eluting ventricular lead and Stelix steroid eluting atrial lead, a prospective randomized controlled study was conducted at 30 sites. Safety and effectiveness results for patients receiving an implantable pacemaker with Stelid II steroid eluting ventricular leads and Stelix steroid eluting atrial leads were compared to those receiving commercially available non-steroidal leads.

Methods

Patients were implanted with either a Stelix BR45D/46D steroid eluting atrial lead and Stelid II BTF25D/26D steroid eluting ventricular lead or non-steroidal control leads. The randomization ratio was 3:1 (test: control).

Time frame: The study's routine evaluation consisted of pre-implant screening, implant, and scheduled follow-up visits at two weeks, one month, and three months. Investigators also documented unscheduled follow-up visits, explants, and patients lost to follow-up.

Primary effectiveness objectives: To demonstrate that pacing thresholds are lower than controls, pacing impedance is higher than controls and sensing thresholds are no lower than controls.

Endpoints:
Pacing thresholds at 0.49 ms pulse width measured at implant, two weeks, one month, and three months.
Sensing thresholds measured at implant, two weeks, one month, and three months.
Pacing impedance at 5 V measured at implant, two weeks, one month, and three months.

Pass/fail criteria, individual follow-ups:
Pacing thresholds: At least 30 % lower than non-steroidal control leads
Sensing thresholds: Equivalent to non-steroidal control leads
Pacing impedance: At least 30 % greater than non-steroidal control leads

Primary safety objective: To demonstrate that the freedom from lead related complications with Stelid II and Stelix leads is no lower than controls.

Endpoint: Three-month complication-free rate.

Pass/fail criterion:
The three-month complication-free rate observed with steroid eluting leads must be equivalent to or better than that observed with non-steroidal control leads.

Patients studied

A total of 218 patients were implanted with Stelix BR45D/46D steroid eluting atrial leads and 77 patients received atrial non-steroidal control leads. Stelid II BTF25D/26D steroid eluting ventricular leads were implanted in 224 patients and 77 patients received

ventricular non-steroidal control leads. Of these, 171 (56.6 %) patients were male with 124 (55.1 %) of them implanted with steroid eluting leads and 131 (43.4 %) patients were female with 101 (44.9 %) of them implanted with steroid eluting leads. Patient age ranged from 37 to 98 with a mean age of 75.7 years.

Primary indications for pacemaker implant were the following: may benefit from rate-adaptive pacing (3.3 %), symptomatic or paroxysmal second or third degree AV block (30.8 %), symptomatic bilateral bundle branch block (1.3 %), transient sinus node dysfunctions (32.5 %), brady-tachy syndrome (24.5 %), vaso-vagal syndromes or hypersensitive carotid sinus syndromes (1.3 %), and may benefit from maintenance of AV synchrony (6.3 %).

Effectiveness results

To compare the electrical performance of the Stelid II and Stelix steroid eluting leads, measurements were taken at implant and scheduled follow-ups at two weeks, one month, and three months. The Stelid II and Stelix steroid eluting leads were to have pacing thresholds lower than non-steroidal control leads, pacing impedances higher than non-steroidal control leads, and sensing thresholds no lower than non-steroidal control leads, at all follow-ups.

The tables below present the mean electrical measurements for steroid and non-steroidal control leads across all visits.

Pacing threshold

Visit	Pacing threshold, Stelix BR45D/46D steroid eluting atrial lead	Pacing threshold, non-steroidal atrial control lead	Percentage difference[a]	Pacing threshold, Stelid II BTF25D/26D steroid eluting ventricular lead	Pacing threshold, non steroidal ventricular control lead	Percentage difference[a]
Implant	0.55 V	0.72 V	24 %	0.4 V	0.38 V	-5 %
Two weeks	0.65 V	1.47 V	56 %	0.64 V	0.94 V	32 %
One month	0.61 V	1.46 V	58 %	0.68 V	0.93 V	26 %
Three months	0.63 V	1.25 V	49 %	0.71 V	0.83 V	15 %

[a] (Mean control – Mean steroid)/Mean control

Stelix steroid eluting atrial leads had significantly lower pacing thresholds than non-steroidal atrial control leads at two weeks, one month and three months post implant ($p<0.001$). Therefore, the primary effectiveness objective was met. The primary effectiveness objective was not met at implant. However, pacing thresholds were equivalent for Stelix steroid eluting atrial leads and non-steroidal atrial control leads at implant ($p< 0.001$).

Stelid II steroid eluting ventricular leads did not have significantly lower pacing thresholds than non-steroidal ventricular control leads at implant or any follow-up. Therefore, the primary effectiveness objective was not met at implant or any of the follow-ups.

Pacing impedance

Visit	Pacing impedance, Stelix BR45D/46D steroid eluting atrial lead	Pacing impedance, non-steroidal atrial control lead	Percentage difference[b]	Pacing impedance, Stelid II BTF25D/26D steroid eluting ventricular lead	Pacing impedance, non-steroidal ventricular control lead	Percentage difference[b]
Implant	541 Ω	604 Ω	- 10 %	773 Ω	680 Ω	14 %
Two weeks	493 Ω	583 Ω	- 16 %	706 Ω	574 Ω	23 %
One month	496 Ω	607 Ω	- 18 %	743 Ω	653 Ω	14 %
Three months	499 Ω	636 Ω	- 22 %	751 Ω	685 Ω	10 %

[b] (Mean steroid- Mean Control)/Mean control

Stelix steroid eluting atrial leads did not have significantly higher pacing impedance compared to non-steroidal atrial control leads ($p>0.05$). Stelid II steroid eluting ventricular leads did not have significantly higher pacing impedance compared to non-steroidal ventricular control leads ($p>0.05$). Therefore, the primary effectiveness objectives were not met for both Stelix and Stelid II steroid eluting leads. However, pacing impedances for Stelix and Stelid II steroid eluting leads were equivalent to non steroidal control leads at implant and all follow-ups ($p<0.001$).

Sensing threshold

Visit	Sensing threshold, Stelix BR45D/46D steroid eluting atrial lead	Sensing threshold, non-steroidal atrial control	Percentage difference[c]	Sensing threshold, Stelid II BTF25D/26D steroid eluting ventricular lead	Sensing threshold, non-steroidal ventricular control	Percentage difference
Implant	2.52 mV	2.52 mV	0 %	9.15 mV	8.73 mV	5 %
Two weeks	2.78 mV	2.13 mV	31 %	9.43 mV	9.03 mV	4 %
One month	2.84 mV	2.19 mV	29 %	9.84 mV	9.65 mV	2 %
Three months	2.85 mV	2.42 mV	18 %	9.98 mV	9.93	1 %

[c] (Mean steroid- Mean control)/Mean control

Sensing thresholds were equivalent for Stelix steroid eluting atrial leads and non-steroidal control leads at implant and all follow-ups ($p < 0.001$). Stelid II steroid eluting ventricular leads also provided sensing thresholds equivalent to non-steroidal control leads ($p< 0.001$). Therefore, the primary effectiveness objectives were met.

STELID II BJF25D STEROID ELUTING ATRIAL LEAD

The Stelid II BJF25D steroid eluting atrial lead uses the same silicone insulation, vitreous carbon distal electrode, platinum-iridium proximal electrode, steroid collar, and IS-1 bipolar connector as the Stelid II BTF25D steroid eluting ventricular lead. The only differences between the two leads are that the Stelid II BJF25D steroid eluting atrial lead is j-shaped and implanted in the atrium. The Stelid II BTF25D steroid eluting ventricular lead was evaluated in a prospective randomized controlled study. Because the Stelid II BJF25D steroid eluting atrial lead is similar to the Stelid II BTF25D steroid eluting ventricular lead, a 30-patient observational study was adequate to evaluate the safety and effectiveness of the Stelid II BJF25D steroid eluting atrial lead. Clinical data gathered on the Stelid II BJF25D steroid eluting atrial lead are applicable to the Stelid II BJF24D steroid eluting atrial lead because the only difference between the two leads is length.

Methods

Patients were implanted with a Stelid II BJF25D steroid eluting atrial lead.

Time frame: The study's routine evaluation consisted of pre-implant screening, implant, and a follow-up at one month post implant.

At implant and follow-up, pacing threshold (0.49 ms pulse width), pacing impedance at 5 V, p-wave amplitude (peak to peak), and sensing threshold were recorded.

Primary effectiveness objectives: To report pacing thresholds, pacing impedance, p-wave amplitude, and sensing thresholds for the BJF25D steroid eluting atrial lead.

> *Endpoints:*
> Pacing threshold at 0.49 ms pulse width measured at pre-discharge and one month.
> Pacing impedance at 5V, measured at pre-discharge and one month.
> P-wave amplitude (peak to peak) measured at pre-discharge and one month.

Primary safety objective: To report the incidence and nature of adverse events for the BJF25D steroid eluting atrial lead.

> *Endpoint:* Adverse events

Patients studied

A total of 30 patients were implanted with Stelid II BJF25D steroid eluting atrial leads. Average patient age was 73 (± 9) years.

Primary indications for pacemaker implant were the following: AV block or bundle branch block (37 %), Sinus node dysfunction (53 %), other (7 %), or unknown (3 %).

Effectiveness results

To observe the electrical performance of the Stelid II BJF25D steroid eluting atrial lead, measurements were taken at implant and one month following implant.

The table below presents mean (± SD) electrical measurements for the BJF25D steroid eluting atrial lead.

	PRE-DISCHARGE		ONE MONTH		PASS/FAIL CRITERIA
PACING THRESHOLD	0.55 (± 0.28) V	(n= 28)	0.82 (± 0.74) V	(n= 29)	≤ 1.46 (± 0.66) V
PACING IMPEDANCE	682 (± 82) Ω	(n= 29)	685 (± 83) Ω	(n= 30)	≥ 607 (± 51) Ω
P-WAVE AMPLITUDE	1.8 (± 0.91) mV	(n= 26)	1.72 (± 0.83) mV	(n= 28)	--
SENSING THRESHOLD	3.1 (± 1.2) mV	(n= 19)	3.15 (± 0.85) mV	(n= 16)	≥ 2.19 (± 1.07) mV

Electrical measurements observed in this study were better than or comparable at one month to non-steroidal atrial control leads in the Stelid II/Stelix randomized, controlled study.

STELIX II BRF25D STEROID ELUTING ATRIAL LEAD

The Stelix II BRF25D steroid eluting atrial lead uses the same silicone insulation, platinum-iridium proximal electrode, steroid collar, and IS-1 bipolar connector as the Stelix BR45D steroid eluting atrial lead. The only difference between the two leads is that the BRF25D steroid eluting atrial lead has a 2 mm^2 distal electrode, which has the same active surface area as the BTF25D steroid eluting ventricular leads. The Stelix BR45D steroid eluting atrial lead and Stelid II BTF25D steroid eluting ventricular lead were evaluated in a prospective randomized, controlled study. Because the Stelix II BRF25D steroid eluting atrial lead is similar to the Stelix BR45D steroid eluting atrial lead and Stelid II BTF25D steroid eluting ventricular lead, a 30-patient observational study was adequate to evaluate the safety and effectiveness of the Stelix II BRF25D steroid eluting atrial leads. Clinical data gathered on the Stelix II BRF25D steroid eluting atrial lead are applicable to the Stelix II BRF26D steroid eluting atrial lead because the only difference between the two leads is length.

Methods

Patients were implanted with Stelix II BRF25D steroid eluting atrial leads.

Time frame: The study's routine evaluation consisted of pre-implant screening, implant, and follow-up at one month post implant.

At implant and follow-up, pacing threshold (0.49 ms pulse width), pacing impedance at 5 V, and p-wave amplitude (peak to peak) measurements were recorded.

Primary effectiveness objectives: To report pacing thresholds, pacing impedance and p-wave amplitude for the Stelix II BRF25D steroid eluting atrial lead.

Endpoints:
Pacing threshold at 0.49 ms pulse width measured at pre-discharge and one month.
Pacing impedance at 5 V, measured at pre-discharge and one month.
P-wave amplitude (peak to peak) measured at pre-discharge and one month.

Primary safety objective: To report the incidence and nature of adverse events with the Stelix II BRF25D steroid eluting atrial lead.

Endpoint: Adverse events

Patients studied

A total of 32 patients were implanted with Stelix II BRF25D steroid eluting atrial leads. Average patient age was 78 (± 9) years.

Primary indications for pacemaker implant were the following: AV block or bundle branch block (34 %), Sinus node dysfunction (40 %), both (19 %), or other (7 %).

Effectiveness results

To observe electrical performance of the Stelix II BRF25D steroid eluting atrial leads, measurements were taken at implant and one month following implant.

The table below presents mean (± SD) electrical measurements for the BRF25D atrial lead.

	PRE-DISCHARGE	ONE MONTH	PASS/FAIL CRITERIA
PACING THRESHOLD	0.59 (± 0.26) V (n= 30)	0.72 (± 0.33) V (n=30)	≤ 1.46 (± 0.66) V
PACING IMPEDANCE	572 (± 62) Ω (n= 29)	577 (± 44) Ω (n= 31)	≥ 607 (± 51) Ω
P-WAVE AMPLITUDE	2.29 (± 1.1) mV (n= 19)	2.0 (± 0.7) mV (n= 24)	--

Electrical measurements observed in this study were better than or comparable at one month to non-steroidal atrial control leads in the Stelid II/Stelix randomized, controlled study.

STELID II UTF25D/26D STEROID ELUTING VENTRICULAR LEAD

The UTF25D/26D leads use the same insulation material and conductor coil material, and have the same number of filars, as ELA's marketed Stela UT46 lead (K000029). The only difference between the leads is that the UTF25D/26D leads have a reduced electrode surface area and a steroid-eluting collar. The electrode and steroid-eluting collar are the same as those on the BTF26D lead, for which a multicenter, prospective, randomized clinical trial was conducted (reported herein). Therefore, clinical evaluation of the Stelid II UTF25D/26D steroid eluting ventricular lead was not required.