

Multi-Center Clinical Experience with a Lumenless, Catheter-Delivered, Bipolar, Permanent Pacemaker Lead: Implant Safety and Electrical Performance

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Purpose: *Reduced lead diameter and reliability can be designed into transvenous permanent pacing leads through use of redundant insulation and removal of the stylet lumen. The model 3830 lead (Medtronic Inc., Minneapolis, MN, USA) is a bipolar, fixed-screw, steroid-eluting, lumenless, 4.1-Fr pacing lead. Implantation can be performed in a variety of right heart sites using a deflectable catheter (Model 10600, Medtronic). Lead performance and safety were studied.*

Methods: *Two prospective trials of 338 implanted subjects from 56 global sites were conducted. Electrical and safety data were obtained at implant, pre-discharge, and up to 18 months post-implant. Leads were implanted at traditional and alternate right heart sites.*

Results: *The study enrolled 338 subjects (204 males, 70.6 ± 11.6 years) followed-up for a mean of 10.2 months (range, 0–21.6). Mean P-wave amplitudes ranged from 3.2 mV at 3 months to 2.9 mV at 18 months, while mean atrial pulse width thresholds at 2.5 V ranged from 0.07 ms at 3 months to 0.09 ms at 18 months. Mean R-wave amplitudes ranged from 11.3 mV to 11.1 mV and mean ventricular pulse width thresholds at 2.5 V ranged from 0.10 ms to 0.14 ms. There were 22 ventricular and 12 atrial lead complications within 3 months post-implant. Survival from lead-related complications improved to a clinically acceptable rate in the cohort of patients when revised implant techniques were employed.*

Conclusions: *With the use of recommended implant techniques, the study results support the electrical efficacy and safety of a catheter-delivered, lumenless lead in traditional or alternate right atrium or right ventricle sites through 18 months post-implant. (PACE 2006; 29:858–865)*

pacemaker leads, catheters, lead failure, cardiac function

Introduction

Current pacemaker lead designs incorporate a lumen that enables lead placement using a stylet at implant or use of a locking stylet during lead extraction. To satisfy clinical demands for reduced diameter in implantable pacemaker leads, manufacturers introduced co-radial or co-axial arrangement of conductor coils, as well as

different insulation materials that allow for reduction of insulation thickness.^{1–4} While these improvements did not require a change in the implant or extraction procedure, they exposed the vulnerability to electrical insulation failure at stress sites such as the first rib and clavicle junction, the suture tie-down area, where the lead is coiled in the generator pocket, and where the lead bends sharply.^{5–8}

A different approach to reducing lead diameter involves eliminating the stylet lumen, which contributes up to 40% of the diameter of a standard 7-Fr pacemaker lead. Other than facilitating lead implantation or extraction, the lumen provides no added clinical value. Lumen removal enables the use of cable-wound conductors for lead body tensile strength, extra electrical insulation for reliability, and extractability without the need for a locking stylet. The reliability of cable conductor

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designs in implantable cardioverter defibrillator leads (e.g., Medtronic Model 6932 lead) has been established.⁹ In a manner similar to catheter delivery of left heart leads, lumenless right heart leads can be delivered to any location in the right heart using either a fixed shape or a deflectable catheter. The purpose of two regional multi-center studies was to demonstrate the implant safety and performance of a lumenless lead implanted in traditional and alternate right heart pacing sites.

Methods

The two regional studies utilized a lumenless, bipolar, permanent pacing lead (SelectSecure™ lead model 3830, Medtronic, Inc.) (Fig. 1). This 4.1-Fr-diameter, active fixation, steroid-eluting lead is designed with an anode conductor that is helically wound around a cable cathode conductor with layered insulation of ethylene-tetrafluoroethylene with silicone (inner layer) and polyurethane 55D (outer layer).

The lead design includes:

1. 9 mm tip-to-ring spacing to minimize far-field R-wave detection,
2. Low electrode surface polarization enabling optimal ventricular capture detection,
3. Beclomethasone steroid-coated tip electrode to improve pacing thresholds,
4. Standard IS-1 connector.

Leads were delivered to the implant site using the deflectable model 10600 catheter (Medtronic, Inc.), which permits precise lead placement at selected sites within the right ventricle (RV) and the right atrium (RA).

Study Design

There were 338 patients enrolled from two regional studies. In Study Group A, 161 patients were enrolled from 25 European/South African

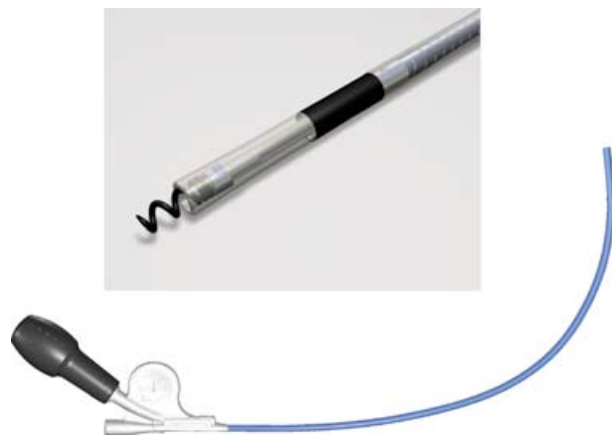


Figure 1. The SelectSecure™ Model 3830 lead and Model 10600 deflectable catheter.

centers; and 177 patients were enrolled from 31 North American/Australian centers in Study Group B (Appendix). Written patient consent was obtained under a common study protocol approved by the local institutional review board or the medical ethics committee.

Potential study candidates for *de novo* dual chamber permanent pacing systems were selected from the investigators' referral practice. Each patient had a Model 3830 lead implant attempted in both the atrium and the ventricle. In the Study Group A centers, lead implantation was randomly assigned to one of two non-RV apical sites (low septal or high anterior RV outflow tract (RVOT)) and one of two non-RA appendage sites (interatrial septum; coronary sinus ostium, CSOs) to prospectively assess the clinical utility of targeted pacing in selected sites. In the remaining centers, lead position was per investigator preference with initial focus on the traditional RA appendage (RAA) and RV apical sites.

Implant Procedure

Implant utilized a traditional percutaneous right or left subclavian and/or cephalic vein approach (at the discretion of the implanter) with placement of a long guidewire to the RA, over which the 10-Fr deflectable catheter was placed using a venous dilator. Dual puncture technique or retained guidewire approaches were allowed according to implanter preference; the catheter could also be inserted via a peel-away introducer sheath. For ventricular implant, the dilator was then removed, the catheter tip was deflected, and the catheter tracked over the guidewire across the tricuspid valve into the RV, following which the guidewire was removed and the lead advanced so that the fixed-screw cathode was proximal to the catheter tip. The catheter was then deflected to position the tip close to the myocardium at the desired implant site and the lead advanced to make contact with the myocardium. The lead was fixated by rotating the lead body 3–4 turns. The deflectable catheter was withdrawn to expose the lead anode and electrical/stability testing was performed. Once an adequate position was obtained, the catheter was removed using a standard slitting technique as used for implantation of left heart leads. Similar implant technique was used for the atrial lead with fixation achieved using 4–5 lead body turns (to effect torque transfer through the tighter catheter curve required to approach the septum). The implanted leads were anchored in the subcutaneous pocket and connected to the generator (IPG).

Data Collection

For the Study Group A cohort, data were collected at implant and during post-operative

follow-up (<24 hours), at pre-discharge, 1 month, and at 3 months. For Study Group B, data were additionally collected at the 6-month visit and every 6 months thereafter. Voltage and pacing pulse width thresholds were obtained via telemetry. Sensed electrogram amplitudes were measured from endocardial electrograms through pacemaker telemetry.

A lead-related complication was defined as an adverse event that resulted from the presence or performance of the lead which was resolved invasively or which directly resulted in the death of, or serious injury to, the patient, the explant of the device, or the termination of significant device function. Lead-related complications were monitored through the 3-month post-implant visit.

Data Analysis

Data from the two regional studies used identical lead systems and methodology for assessing both electrical efficacy and safety through the 3-month visit. Results from the pooled experience are presented. All analyses were performed using SAS (SAS Institute Inc., Cary, NC, USA, Proprietary Software Release 8.2) or S-PLUS (S-PLUS: Copyright (c) 1988, 2002 Insightful Corp. S: Copyright Lucent Technologies, Inc., Professional Edition Version 6.1.2 Release 1 for Microsoft Windows: 2002).

Pacing and sensing electrical results are presented at each follow-up visit as a mean value with a 95% confidence interval at the most recent visit associated with the administrative data cutoff.

Results

Patient Demographics

The global cohort consisted of 338 enrolled patients indicated for dual chamber pacemaker implantation between June 2002 and May 2003 (Table I). The mean age of the cohort was 70.6 ± 11.6 years and 60% were men. High grade (2nd or 3rd degree) atrioventricular block was present in 47% of patients at baseline. Nearly one-third of patients had a history of congestive heart failure and 17% had previous myocardial infarction.

Atrial and Ventricular Lead Implantation

The 338 enrolled patients resulted in a potential for 676 leads to be implanted. Of the 676 leads, implantation was abandoned in 8 leads (three patients with exclusion criteria, two patients with inability to attempt atrial lead implant), resulting in 668 leads attempted for implantation. Of the 668 leads attempted, 632 were successfully implanted (316 atrial, 316 ventricular). Lack of implant success for 36 leads was attributed to catheter use difficulties (curve reach too large for anatomy, catheter

Table I.

Patient Demographics

SelectSecure™ Lead Global Experience

Gender N (%)	
Male	204 (60%)
Female	134 (40%)
Age (years)	
Mean	70.6
SD	11.6
N	338
Indications N (%)	
Ventricular rhythm normal	273 (81%)
Non-sustained VT	18 (5%)
1 st degree block	58 (17%)
2 nd degree block	75 (22%)
3 rd degree block	83 (25%)
Atrial normal rhythm	67 (20%)
Atrial tachyarrhythmia	122 (36%)
Atrial sinus brady	161 (48%)
Cardiovascular status N (%)	
CHF	30 (9%)
Previous MI	58 (17%)
Previous cardiac surgery	48 (14%)
Pacemaker dependent	27 (8%)

kinking) associated with lead delivery to alternate sites.

RAA implant was performed in 38% of the 316 atrial leads. Right ventricular apex (RVA) implant was performed in 25% of the 316 ventricular leads (Fig. 2).

Atrial Lead Electrical Performance

Acute and chronic electrical performance of the Model 3830 lead in the RA is presented in Table II. For the Study Group A cohort (selected atrial pacing sites), lead position was achieved in the majority of cases within 17.5 minutes for the CSOs and 18 minutes for the inter-atrial septum (median implant time). Mean P-wave amplitude was 2.97 ± 1.56 mV at pre-hospital discharge, increased to 3.3 ± 1.71 mV at 1 month, and remained stable thereafter. Pacing pulse width threshold at 2.5 V was 0.062 ± 0.086 ms and rose at 2 weeks to 0.074 ± 0.073 ms. Pacing threshold reached a plateau at 0.085 ± 0.061 ms by the 6-month visit and represented an overall increase of 37% above implant values. Mean bipolar lead impedance was highest at discharge ($650.1 \pm 177.1 \Omega$) and gradually decreased over the first 6 months to $575.4 \pm 68.0 \Omega$ where it stabilized. Overall, the electrical performance of the atrial lead for the first 12 months post-implant appears to be at least comparable to stylet-based active fixation leads.

Table II.

Model 3830 Atrial Lead Electrical Parameters

Model 3830 Atrial Electrical Measurements						
Visit	Pulse Width Thresholds		P-wave Amplitudes		Bipolar Impedance	
	N	Mean ± SD (ms)	N	Mean ± SD (mV)	N	Mean ± SD (Ω)
Pre-discharge	280	0.062 ± 0.086	296	2.97 ± 1.56	302	650.1 ± 177.1
2 Weeks	274	0.074 ± 0.073	280	3.17 ± 1.59	288	585.9 ± 63.7
1 Month	281	0.062 ± 0.035	278	3.30 ± 1.71	282	587.0 ± 68.5
3 Months	279	0.071 ± 0.063	274	3.22 ± 1.66	281	579.8 ± 66.8
6 Months	214	0.085 ± 0.061	213	3.00 ± 1.50	225	574.2 ± 67.7
12 Months	161	0.085 ± 0.060	164	3.01 ± 1.37	185	575.4 ± 68.0
18 Months	62	0.086 ± 0.050	61	2.88 ± 1.44	67	570.9 ± 70.0

Results at 18 months are suggestive of stable electrical performance, albeit with a low sample size (N = 61).

Ventricular Lead Electrical Performance

Electrical performance of the lead in the RV is presented in Table III. For the Study Group A cohort (selected ventricular pacing sites), lead position was achieved in the majority of cases within 20 minutes for high anterior RVOT and 31 minutes for low septal RVOT (median implant time). At discharge, the mean R-wave amplitude was 9.8 ± 4.9 mV and climbed over the next 3 months by 15% to 11.3 ± 6.2 mV. The ventricular pacing threshold pulse width at discharge was 0.05 ± 0.07 ms. It nearly doubled to 0.096 ± 0.16 ms at 1-month and rose only by a small increment further at 12 months follow-up. Pacing threshold behavior beyond the first year could not be fully characterized because of the small number of patients followed-

up beyond 12 months. Bipolar lead impedance declined from 708.6 ± 146 Ω at discharge to 646.7 ± 102.5 Ω at 1-month and remained stable thereafter. In summary, ventricular sensing threshold of the lead improved over the first 12 months and pacing threshold increased by 157%, but remained well within the clinically acceptable range. Preliminary data at 18 months (N = 65) suggest consistent electrical performance.

Lead-Related Complications

A total of 12 atrial lead complications occurred in 10 (3%) patients during the first 3 months of follow-up (Table IV). Clinically relevant complications included atrial lead dislodgment (seven patients), micro-dislodgment causing increased pacing thresholds (one patient), cardiac perforation without hemodynamic consequences (one patient, confirmed by echocardiography), and atrial under-sensing (three patients).

Table III.

Model 3830 Ventricular Lead Electrical Parameters

Model 3830 Ventricular Electrical Measurements						
Visit	Pulse Width Thresholds		R-Wave Amplitudes		Bipolar Impedance	
	N	Mean ± SD (ms)	N	Mean ± SD (mV)	N	Mean ± SD (Ω)
Pre-discharge	290	0.049 ± 0.071	284	9.83 ± 4.92	303	708.6 ± 146.0
2 Weeks	281	0.085 ± 0.134	274	10.78 ± 5.35	287	644.2 ± 92.9
1 Month	290	0.096 ± 0.157	269	10.92 ± 5.67	286	646.7 ± 102.5
3 Months	284	0.096 ± 0.072	271	11.29 ± 6.20	280	640.9 ± 103.3
6 Months	224	0.110 ± 0.081	206	11.39 ± 5.64	224	635.0 ± 100.2
12 Months	174	0.126 ± 0.120	157	11.67 ± 5.46	187	631.1 ± 107.4
18 Months	65	0.140 ± 0.143	55	11.11 ± 4.70	65	629.5 ± 113.8

Table IV.
Lead-Related Complications at 3 Months

Adverse Event	Atrial Complications Number of Events	Ventricular Complications Number of Events
Elevated pacing thresholds	0	3
Pericardial effusion	0	4
Lead dislodgment	7	7
Failure to capture/Loss of capture	0	2
Cardiac perforation	1	3
Muscle stimulation	0	0
Tamponade	0	1
Other	0	1
Sinus bradycardia	0	1
Venous occlusion	0	0
Failure to sense/Under-sensing	3	0
Suspected micro-dislodgment	1	0
Number of leads with complication	12	22
Number (%) of patients with complication	10 (3.0%)	20 (5.9%)

All events displayed in this table occurred within 135 days post-implant with the majority occurring within 6 weeks of the implant.

There were 22 ventricular lead complications in 20 (5.9%) patients through 3 months of follow-up (Table IV). Lead dislodgment was the most common problem and was observed in seven patients. Other important complications confirmed by echocardiography in eight patients included myocardial perforation without effusion or tamponade (three patients), pericardial effusion (four patients), and cardiac tamponade (one patient). Elevated pacing threshold and failure of pacing capture were reported in five patients.

The study's scientific committee that monitored the early adverse events recommended modification of the lead implant technique and then convened educational sessions for all investigative centers to review optimal implant techniques for the Study Group A centers on October 25, 2002, and for Study Group B centers on November 9, 2002. Implant technique modifications are summarized (Table V).

To examine the factors that might have influenced the adverse events encountered with this right heart catheter delivery technology, we compared the rate of complications before and after

the educational sessions. Prior to the educational sessions, the observed rate of atrial and ventricular lead-related adverse events was 4.2% (N = 95) and 13.7% (N = 95), respectively. In patients enrolled after the sessions, these observed rates subsequently dropped to 3.3% (N = 242) and 3.7% (N = 243), respectively. No cardiac perforations occurred after the educational sessions, suggesting that instruction-based training was effective at minimizing lead-related complications.

Discussion

The initial multi-center study results of the first right heart catheter-delivered lumenless lead demonstrate feasibility of the implant technique and acceptable electrical performance through 18 months post-implant. With limited follow-up at the time of data analysis, preliminary results at 18 months appear promising. Ventricular pulse width threshold results at the 18-month visit were higher than expected, as investigator expectations were based on experience with stylet-delivered leads implanted in the RVA. However, these study results were deemed to be clinically acceptable, as they permit delivery of pacing therapy at 2.0–2.5 V with an appropriate safety margin of pulse width (three-fold). In addition, numbers of patients followed-up to these time points remain relatively small; this potential trend will be followed further to determine whether or not it is a true phenomenon.

The lead-related complications with respect to acute lead dislodgment and cardiac perforation were evaluated shortly after trial initiation and found to be unacceptable in both regional studies. Root-cause analysis of each type of complication was discussed during investigator meetings, and this effort resulted in additional lead implant recommendations. Study results from the majority (71%) of patients enrolled into the regional studies were based on the use of these revised techniques, which are now part of the recommended implant procedure. The risk of cardiac perforation can be further minimized when leads are placed on the atrial or ventricular septum.^{10,11}

This instruction-based learning experience is similar to catheter-delivered cardiac resynchronization therapy leads, which initially had up to a 20% failure rate, and relatively high complication rate.¹² Based on current practice, it is now accepted that catheter-delivered LV leads can be implanted with high success and low complication rates that are comparable to non-catheter-delivered leads.

As evidence continues to build-up that pacing at traditional (RVA and RAA) sites can have a deleterious effect on synchronous ventricular

Table V.
Evolution of Lead Implant Procedure Recommendations

Description	Pre-meeting Recommendation	Post-meeting Recommendation
Catheter kinking during RA or RV	Deflect catheter without lead in place	Deflect catheter after lead is extended
Perforations from catheter during catheter positioning	Track catheter over a guide wire in the RA or RV	Reminder of the importance of this point
Perforations from catheter during lead positioning	Extend catheter to RV or RA wall, then fixate lead	Avoid touching wall with catheter. When distal tip of guide catheter is near desired location, gently advance the lead until outside the distal opening of the guide catheter
Perforations from coring during lead fixation	Rotate lead to fix to endocardium	To avoid lead over-rotation, use 3–4 turns to affix the ventricular helix; 4–5 turns to affix the atrial helix
Lead dislodgment during slitting of the catheter resulting in excessive forces on lead	Prior to slitting, establish final amount of slack on lead	Confirm helix fixation, then gently advance lead to provide lead slack. Slit catheter, then establish final amount of slack on lead

activation and potential for heart failure,^{13–17} exploration of new approaches to accessing pacing sites based on individualized patient needs that minimize left ventricular dysfunction is vital. Current stylet-delivered pacemaker leads are close to the limit of current technology with regard to further downsizing, and by their inherent design are limited in their ability to be accurately placed at alternate pacing sites.

Achieving alternate RA and RV pacing sites requires a change in practice from current traditional stylet delivery of pacing leads, the development of new tools to access alternate pacing sites, and validated definitions of the desired pacing site(s).^{18–20} A deflectable catheter has the potential to achieve this individually prescribed, site-selected pacing in the RA and RV. The time to achieve lead implant in the septal positions was evaluated in Study Group A. In the majority of cases, the implant duration was found to be clinically acceptable, demonstrating the feasibility to access selected pacing sites despite the fact that the Model 10600 catheter was designed with only one curve reach during the study.

Study Limitations

The two regional studies were designed to support lead performance and implant procedure safety. The major limitation of these studies was the lack of statistical power to differentiate evidence-based clinical outcomes between traditional and alternate pacing sites.

Independent of lead position (traditional or alternate), however, the global study results suggest

that there is no clinical difference in electrical or safety performance up to 18 months of follow-up in a *de novo* pacemaker population. Even if such differences existed, additional follow-up with a larger sample of patients would be needed to elucidate the chronic effects of pacing at selected sites. This study was neither designed nor powered to demonstrate long-term functional effects or potential benefits of selective site pacing, but to demonstrate the safety and efficacy of the equipment which will facilitate the performance of such studies.

Finally, it must be acknowledged that the reported clinical experience was based on use of the Model 10600 deflectable catheter, which offered only one curve reach for both atrial and ventricular lead placement. The lack of optimized catheter sizes/shapes for atrial and ventricular anatomy contributed to the 5% rate of failed implantations. With the recent availability of additional deflectable catheter designs, the failed implantations and early unacceptable safety results reported from this series may no longer be applicable to the broader patient population. Additional prospective studies to further characterize the implant procedure using these new tools and advanced techniques may be warranted.

Conclusion

This is the first multi-center study to prospectively demonstrate that implantation of pacing leads in traditional and alternate right atrial and right ventricular pacing sites is not compromised by a 4.1-Fr lumenless lead design. This study also demonstrates that catheter delivery of such a lead

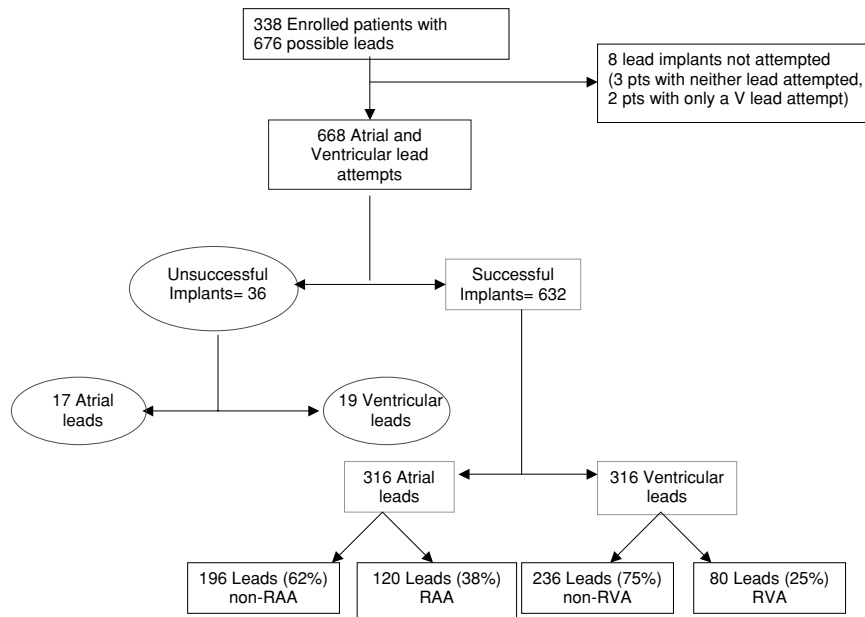


Figure 2. Model 3830 lead disposition.

to a variety of sites within the right heart is feasible and appears safe and efficacious with instruction-based learning. Future modifications of equipment and technique will, however, be likely in view of the experiences with this new system.

Further follow-up data beyond 18 months are clearly needed to confirm the reliability of this approach and long-term performance data are currently being collected. The availability of the deflectable catheter tool for site-specific delivery of pacemaker leads should facilitate the studies required to address the need for evidence-based clinical outcomes of alternate pacing sites over traditional pacing sites within the right heart.²¹

Appendix

The following principal investigators and centers participated in the two regional studies:

Dr. Bowes, Northern General Hospital, Sheffield, UK; Dr. Gammage, University of Birmingham Queen Elizabeth Hospital, Birmingham, UK; Dr. Brandt, University Hospital Lund, Lund, Sweden; Prof. Goethals, H. Hart Ziekenhuis, Roeselare, Belgium; Dr. Curnis, Spedali Civili, Brescia, Italy; Dr. Grabenwöger, AKH Vienna, Vienna, Austria; Prof. Dokumaci, Eskisehir SSK Hospital, Eskisehir, Turkey; Dr. Hanksy, Klinik für Thorax und Kardiovaskular Chirurgie, Oeynhausen, Germany; Dr. Forzani, Ospedale di Circolo, Castellanza, Italy; Dr. Kautzner, IKEM, Praha, Czech Republic; Prof. Fröhlig, Universitätskliniken des Saarlandes, Homburg, Germany; Dr. Lemke, Bergmannsheil Kardiologie, Bochum, Germany;

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