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## Do small (6.6 Fr.) active and passive fixation defibrillation leads perform as well as larger sized leads? A multi-centre analysis

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### KEYWORDS

Defibrillation leads;  
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ICD;  
Lead handling;  
Safety;  
Electrical performance.

**Aims** The 6.6 Fr. Sprint Fidelis<sup>®</sup> lead family may allow multiple lead implantation procedures with reduced risk of venous obstruction.

**Methods and results** Two prospective, historically controlled, multi-centre studies were conducted in Europe (80 patients) and Canada (79 patients). The purpose was to assess the ventricular lead-related adverse events (LRAEs) and performance of the small Models 6948 and 6949 defibrillation leads, respectively, in patients with a standard indication for an ICD implant. Safety was assessed by demonstrating equivalence of the LRAE free rate at 1 month to comparable but larger leads (Models 6942, 6943, 6944, 6947 and 4074). Seventy-five of 80 patients with a 6948 lead (93.8%) remained free of LRAEs. Seventy-four out of 79 patients (93.7%) with the 6949 lead remained free of LRAEs. The 95% lower confidence bounds were above the critical difference limits. Thus, safety of the Sprint Fidelis<sup>®</sup> leads is similar to that of larger leads. Electrical performance through 1-month follow-up proved to be acceptable in comparison with other established leads.

**Conclusion** These multi-centre studies confirm that smaller defibrillation leads offer similar safety and efficacy features to widely used larger leads; they have low LRAE rates and defibrillation thresholds, while providing the advantage of a smaller introducer size and reduced venous obstruction.

### Introduction

Implantable-cardioverter defibrillator (ICD) therapy has become the standard of care for patients at risk of life-threatening ventricular arrhythmias.<sup>1–4</sup> Use of transvenous non-thoracotomy lead systems has substantially decreased perioperative mortality and morbidity.<sup>5</sup>

However, system functionality is critically dependent on high performance transvenous defibrillator leads which contribute to device longevity and allow appropriate arrhythmia detection and termination by the ICD. Various complications are associated with transvenous leads. These include venous occlusion, lead fractures, and isolation defects causing system malfunction. To facilitate cardiac resynchronization therapy and uptake of ICDs for primary prevention of sudden cardiac death, further ICD lead design development is necessary.<sup>6,7</sup> Small defibrillation

leads might facilitate multiple lead implantation procedures (when additional leads are required for multi-site pacing for diagnostic purposes) improve maintenance of venous blood flow and lead longevity by reducing the risk of subclavian crush syndrome.<sup>8</sup> The small Sprint Fidelis<sup>®</sup> defibrillation lead family (Medtronic), has a 6.6 Fr. isodiametric lead body, utilizing design features available in the Sprint and Sprint Quattro<sup>®</sup> 9,10 leads (Medtronic), including a multi-lumen cable lead body construction, passive fixation and extendable/retractable active fixation, dual- and single defibrillation coil electrodes, silicone backfilled shocking electrodes, and steroid elution. With a 23% reduction in lead diameter, these smaller Sprint Fidelis<sup>®</sup> leads, together with a right atrial and left ventricular lead, occupy up to 35% less of the venous lumen when compared with the existing lead systems. However, the consequences for lead clinical functionality and system longevity by reducing component size have not been assessed.

Therefore, two related studies were conducted to evaluate the safety, operative handling, and acute chronic electrical performance of the tined (Model 6948) and screw-in (Model 6949) 6.6 Fr. dual defibrillation coil leads.

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Table 1. Comparison of lead characteristics

General description	6949	6948	6947	6944	6943	6942	4074
Lead design	Multilumen, isodiametric	Multilumen, isodiametric	Multilumen, isodiametric	Multilumen, isodiametric	Multilumen, isodiametric	Multilumen	Coaxial
Lead body circumference/diameter	6.6 Fr. (2.1 mm)	6.6 Fr. (2.1 mm)	8.6 Fr. (2.8 mm)	8.2 Fr. (2.7 mm)	7.8 Fr. (2.5 mm)	7.8 Fr. (2.6 mm)	5.6 Fr. (1.88 mm)
Sensing	True bipolar	True bipolar	True bipolar	True bipolar	True bipolar	Integrated bipolar	Uni/bipolar
Fixation	Helix, screw-in	Passive tined	Helix, screw-in	Passive tined	Helix, screw-in	Passive tined	Passive tined
Tip surface area	4.2 mm <sup>2</sup>	2.5 mm <sup>2</sup>	5.7 mm <sup>2</sup>	1.6 mm <sup>2</sup>	6.5 mm <sup>2</sup>	5.8 mm <sup>2</sup>	2.5 mm <sup>2</sup>
Introducer	7 Fr.	7 Fr.	9 Fr.	9 Fr.	10.5 Fr.	10 Fr.	7 Fr.

## Methods

### Patients

Both studies, one conducted in Europe (12 centres) and one in Canada (10 centres), were prospective, non-randomized, historically controlled, multi-centre studies. Both studies comply with the Declaration of Helsinki and the protocols were approved by the local ethics committees or institutional review boards. The leads were evaluated in a cohort of patients with a Class I or II<sup>1</sup> indication for a conventional ICD implant. All patients had given written informed consent. Patients were only to receive a commercially available Medtronic GEM<sup>®</sup> or Marquis<sup>®</sup> family ICD device together with the right ventricular (RV) investigational lead. In Europe all patients received the Model 6948, and in Canada patients were implanted with a Model 6949. An independent advisory committee reviewed all adverse events and patient deaths reported for both study populations.

### Description of the defibrillation leads studied

The Medtronic ICDs were implanted pectorally using Model 6948 or Model 6949 lead. Both leads are new true bipolar sensing, steroid-eluting, isodiametric, silicone leads with dual RV/SVC (superior vena cava) defibrillation coils. Model 6949 has a screw-in lead tip with an extendable/retractable helix. Model 6948 has a passive fixation tip with tines. Both leads have an isodiametric lead body of 6.6 Fr., with polyurethane overlay. They are designed to pace, sense, and deliver cardioversion and defibrillation therapies.

### Control groups

Data on the Sprint Quattro<sup>®</sup> Model 6944 and Sprint<sup>®</sup> Model 6942 defibrillation leads<sup>9</sup> and the CapSure Sense<sup>®</sup> Model 4074 pacing lead<sup>12,13</sup> were used as historical controls for the lead-related adverse events (LRAEs) rate comparison with the Model 6948. The Model 6944 lead is an (8.2 Fr.), true bipolar, steroid-eluting, isodiametric, tined, RV/SVC, silicone lead with a polyurethane overlay. The Model 6942 lead is a 7.8 Fr., integrated bipolar, steroid-eluting, tined, RV/SVC, silicone lead. Model 4074 is a steroid-eluting, passive fixation pacing lead. The lead is included in the safety comparison because of the similarity of the lead tip design (2.5 mm<sup>2</sup>) as the Model 6948.

Model 6949 is based on the technology of the commercially approved Sprint Quattro Secure<sup>®</sup> Model 6947 lead. This is a true bipolar, steroid-eluting, screw-in (extendable/retractable helix), RV/SVC silicone lead with 8.6 Fr. isodiametric lead body diameter. Model 6943 was found to be appropriate as control lead for evaluating the LRAE free rate of Model 6949 because of similarities in materials and design. Model 6943 lead is a bipolar sensing, steroid-eluting, screw-in (helix), and single coil lead with a 7.8 Fr. diameter. Table 1 shows the characteristics of the leads described above.

Table 2. Event rates in historical control studies through first month follow-up

	Study						
	6942	6944	4074	6943	6947	6948	6949
n	247	249	128	189	67	80	79
Patients with events	8	12	7	10	2	5	5
Patients free of events	239	237	121	179	65	75	74
% Free of events	96.8	95.2	94.5	94.7	97.0	93.8	93.7

### Data collection

Clinical data, electrical measurements, and adverse events/deaths were collected at enrolment, implant, 1-month, and at applicable 3- and 6-months follow-up visits. Electrical data were collected with a Medtronic programmer and included peak-to-peak R-wave amplitude sensing, ventricular pacing threshold (at 1 V), and ventricular pacing and defibrillation impedance. Defibrillation threshold (DFT) was determined at implant utilizing the Binary Search Protocol.<sup>14</sup> Data on handling characteristics of the lead were collected at implant by means of a questionnaire, in which the implanting physician rated 12 (Model 6948) or 14 (Model 6949) aspects of lead handling.

### Statistics

The safety objective was to demonstrate equivalence of the LRAE free rate at 1-month to the historical controls. In Table 2, the LRAE free rates of the historical controls can be found. The mean LRAE was 95.6%; thus, 95% was taken as an expected value. For comparisons, a critical difference of 12% was adopted in the protocol, which is a conventional value used in similar studies. Statistical analysis of the safety objective was based on the proportion of patients free from LRAEs through the 1-month follow-up visit within the protocol defined visit window, or until the close of the 1-month window if no timely 1-month follow-up took place. The analysis used exact binomial methods with one-sided 95% confidence intervals. Equivalence was demonstrated if the lower limit of the one-sided 95% confidence bound for LRAE free rate at 1 month was at least 83%, which is the expected value minus the critical difference.

The leads were also evaluated with respect to DFT, R-wave sensing, pacing threshold, pacing impedance, and defibrillation impedance. The electrical parameters are observational and only descriptive statistics are reported, including mean, minimum, and maximum.

Lead handling was summarized by the results of a questionnaire and categorized as poor, fair, good, very good, or excellent.

## Results

### Patient population and lead implantation

In Europe 80 patients were enrolled between 26 January 2004 and 31 March 2004. All patients received the Model 6948. Mean follow-up time experience was 63.2 days, with a range from 29 to 98 days. In Canada 81 patients were enrolled between 16 December 2003 and 20 April 2004, with 80 patients receiving the Model 6949. One patient signed the informed consent, but did not receive the Model 6949 lead (refusing an investigational lead). One of the 80 Canadian patients did not meet the inclusion and exclusion criteria and was excluded from the statistical analysis. Mean follow-up duration was 6.1 months, range from 0.9 to 7.0 months. Patient characteristics did not differ significantly between the two study groups. The implantation success rate was 100% for both studies.

### Adverse events

Seventy-five out of 80 patients (93.8%) in the European Model 6948 lead study remained free of LRAEs 1 month post-implant. The 95% lower confidence bound is 87.3%. Five lead-related events, of which three required invasive intervention, were reported in five patients. No life-threatening situations were caused by the investigational lead.

In the first LRAE, progressive decrease of R-wave sensing and increasing pacing threshold was reported. The patient was known to have marked cardiac dilatation due to ischaemic heart disease. It was the implanting physician's view that the passive fixation lead was inappropriate given the patient's markedly dilated RV. The investigational lead was replaced by an active fixation lead Model 6947. In the second case, the DFT was too high, although normal pacing and sensing values were found. After repositioning of the lead in the RV apex, normal values were found for pacing, sensing, and DFT. In two other cases the investigational lead was explanted due to lead dislodgement and suspicion of lead malfunction. In these two cases the investigational leads were replaced by a Model 6943 and a new Model 6948 lead. For both cases inspection of the explanted leads revealed no anomalies and the mechanism of dislodgement/malfunction are unexplained. The last case of LRAE concerned micro-dislodgement. In this case the lead was successfully repositioned.

Two deaths were reported. One patient died, 92 days post-implant, of multiple organ failure as a result of progressive renal failure and hyperhydrosis, resulting in worsening myocardial function and pulmonary oedema. A second patient died, 168 days post-implant, of renal failure due to plasmocytoma. Both deaths were classified as non-system and non-procedure-related. The investigational leads were not explanted.

In the Canadian 6949 lead study, 74 of 79 implanted patients 93.7% were free of LRAEs at 1-month follow-up. The 95% lower confidence bound is 87.2%.

Six lead-related events were reported in five patients during the 1-month follow-up.

Four cases of swollen arm were reported. One patient reported chest pain during ventricular pacing. After repositioning of the 6949 lead, no further complaints were reported. In a sixth case lead dislodgement occurred but after repositioning no further complaints were recorded.

Two deaths were reported. One patient died of cardiac arrest and asystole caused by anoxic encephalopathy. A second patient died of sudden cardiac death as a result of acute respiratory failure. Both deaths were classified as non-system and non-procedure-related. The investigational leads were not explanted.

### Short-term electrical performance

The electrical parameters R-wave sensing, pulse width thresholds (PWT), DFTs, pacing impedance, and defibrillation impedance were measured at implant and at 1-month follow-up visits. Electrical measurements are summarized in Table 3.

### Operative lead handling

The overall ease of the 6948 lead placement was rated good to excellent on average. Difficulties experienced during lead placement were mainly associated with patient anatomy in relation to the lead fixation mechanism and repositioning of the lead due to unacceptable pacing and sensing parameters. These explain the lowest scores for the ability to traverse the tricuspid annulus, the lead placement time, and fluoroscopy time.

For the 6949 Study, the lowest scores were found for the ease and visibility of helix extension, the torque ability,

Table 3 Electrical performance

Electrical parameters (mean $\pm$ SD) <sup>a</sup>	Implant		1-month	
	6948	6949	6948	6949
R-wave (mV)	8.7 $\pm$ 3.4 (n = 78)	8.9 $\pm$ 3.2 (n = 74)	10.5 $\pm$ 3.8 (n = 76)	10.9 $\pm$ 4.6 (n = 70)
PWT at 1.0 V (ms)	0.17 $\pm$ 0.13 (n = 79)	0.25 $\pm$ 0.19 (n = 73)	0.19 $\pm$ 0.16 (n = 74)	0.26 $\pm$ 0.11 (n = 69)
DFT (J) (mean)	8.1 (n = 63)	7.9 (n = 65)	NA	NA
Pacing impedance (Ohms)	747 $\pm$ 124 (n = 78)	644 $\pm$ 127 (n = 79)	693 $\pm$ 125 (n = 77)	541 $\pm$ 95 (n = 70)
Defibrillation impedance (Ohms) (GEM <sup>®</sup> devices)	15.6 $\pm$ 2.6 (n = 28)	NA	19.4 $\pm$ 1.9 (n = 28)	NA
Defibrillation impedance (Ohms) (Marquis <sup>®</sup> devices)	43.6 $\pm$ 5.9 (n = 50)	42.4 $\pm$ 6.4 (n = 79)	46.2 $\pm$ 5.4 (n = 49)	46.0 $\pm$ 5.5 (n = 70)

<sup>a</sup>Standard deviation.  
NA, not applicable.

and lead stiffness. However, overall, the handling scores rated good to excellent.

Both leads scored high for obtaining acceptable VF sensing, acceptable DFTs, and the ease of inserting the lead into the vein.

## Discussion

It is our view that the observed adverse events in these studies are compatible with the usual and accepted clinical experience of ICD lead implantation. The novel design features of the lead did not result in unacceptable procedural or follow-up complications. The studies showed that therapy and system safety is not compromised as the LRAE rates in these leads withstand the equivalence test to historical control leads.

With surface area reduction of the lead body, surface area of the shocking coil is reduced accordingly. Both the shocking coil surface area and the sealing of the spaces of the shock coil could influence electrical properties of the leads in a manner that might impact on defibrillation efficacy. In these studies, however, the shock impedance and clinically assessed DFTs were satisfactory for both leads. A mean DFT of 8 J for both lead types (75% of the patients had a DFT  $\leq$  9 J, and more than 95%  $\leq$  15 J), suggests that the defibrillation efficacy of these leads has an adequate safety margin.

The mean high voltage impedance values were between 15 and 20  $\Omega$  (as measured by a GEM<sup>®</sup> device) and approximately 45  $\Omega$  (as measured by a Marquis<sup>®</sup> device).

In line with the observations of Vollmann et al.,<sup>9,10</sup> Sprint Fidelis<sup>®</sup> pacing impedance measurements are highest at the time of implantation. At implant and at 1-month follow-up, there is a higher pacing impedance for the 6948 than for the 6949 lead. It is known that a smaller tip surface area (Table 1) increases the pacing impedance, reduces pacing current drain, and could extend battery longevity. How much the Sprint Fidelis<sup>®</sup> leads might contribute to prolonged battery longevity is the subject of further investigation.

Despite the reduced tip surface area of the passive fixation lead, there were no unacceptable R-wave sensing values. The results in the European 6948 Study match with values reported in the publication by Vollmann et al.<sup>9,10</sup> This publication showed that mean R-wave amplitudes in the 6944 group ( $9.1 \pm 3.1$  mV) were smaller than in the 6942 group ( $9.8 \pm 3.6$  mV), but remained constant for both lead models throughout the 12-month observation period. Both Vollmann and Sprint Fidelis<sup>®</sup> data do not support the idea that R-waves decrease with decreasing lead area. The active 6949 as well as the passive 6948 leads, with their small surface area and steroid-eluting depots, show a stable electrical performance.

Patients dropped out of the studies if the chosen lead's fixation mechanism proved to be suboptimal for the clinical scenarios encountered either during implantation or follow-up. It was apparent that some patients with ischaemic cardiomyopathy might have a similar reduction of trabecularity in the RV to that demonstrated in patients with idiopathic dilated cardiomyopathy. In these patients an active fixation mechanism not only allows selection of atypical lead positions but also facilitates more stable fixation.

The ease of lead handling was highly rated by implanting physicians. In particular, the slim lead design appeared to have clinical advantage at low volume implant centres.

## Studies' limitations

The limitation of both studies is the relatively small number of patients and the short post-implant (1 month) follow-up period. Long-term performance of both leads clearly requires a longer follow-up to assess the impact of smaller lead size on system longevity.

Although the inline slim body design of the leads is likely to reduce ingrowths on the defibrillation coils and insulation, so facilitating lead explantation when necessary, there was no assessment of this in the studies' design.

## Summary

We report the initial clinical experience of a smaller size (6.6 Fr.) defibrillation (active and passive fixation) leads intended to facilitate multiple lead implantation.

These smaller defibrillation leads offered good performance characteristics when compared with other established leads. The slimmer lead body did not compromise sensing, pacing, or defibrillation performance. Both leads show good pacing performance and their DFT was reproducibly low. Active fixation leads seem to be a better choice for patients with cardiomyopathy and therefore reduced trabecularity in the RV. In these patients an active fixation mechanism not only allows selection of atypical lead positions but also facilitates more stable fixation.

The time corridor of this study was short. It will be left to future studies to contribute to the questions of long-term electrical performance, lead endurance, handling of the lead while being extracted, and ICD longevity.

**Conflict of interest:** C. S. S. received honoraria from Medtronic for speaking engagements. M. W. is a Clinical Research Specialist for Medtronic. M. H. holds stock in Medtronic, and is currently conducting research sponsored by Medtronic.

## References

1. The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. *N Engl J Med* 1997;337:1576-83.
2. Moss AJ, Zareba W, Hall WJ, Klein H, Wilber DJ, Cannom DS et al. for the Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002;346:877-83.
3. Bardy GH, Lee KL, Mark DB, Poole JE, Packer DL, Boineau R et al. for the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005;352:225-37.
4. Buxton AE, Lee KL, DiCarlo L, Gold MR, Greer GS, Prystowsky EN et al. for the Multicenter Unsustained Tachycardia Trial Investigators. Electrophysiologic testing to identify patients with coronary artery disease who are at risk for sudden cardiac death. *N Engl J Med* 2000;342:1937-45.
5. Saksena S, The PCD Investigator Group. Clinical outcome of patients with malignant ventricular tachyarrhythmias and a multiprogrammable implantable cardioverter defibrillator implanted with or without thoracotomy: an international multicenter study. *J Am Coll Cardiol* 1994;23:1521-30.
6. Jones GK, Bardy GH, Kudenchuk PJ, Poole JE, Dolack GL, Troutman C et al. Mechanical complications after implantation of multiple-lead non-thoracotomy defibrillator systems: Implications for management and future system design. *Am Heart J* 1995;130:327-32.

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7. Dorwarth U, Frey B, Dugas M, Matz T, Fiek M, Schmoeckel M *et al.* Transvenous defibrillation leads: high incidence of failure during long-term follow-up. *J Cardiovasc Electrophysiol* 2003;14:38-43.
8. Roelke M, O'Nunain SS, Osswald S, Garan H, Harthorne JW, Ruskin JN. Subclavian crush syndrome complicating transvenous cardioverter defibrillator systems. *Pacing Clin Electrophysiol* 1995;18:973-9.
9. Vollmann D, Ahern T, Gerritse B, Canby RC, Zenker D, Binner L *et al.* for the Worldwide Medtronic Model 6944 Investigators Group. Worldwide evaluation of a defibrillation lead with a small geometric electrode surface for high-impedance pacing. *Am Heart J* 2003;146:1066-70.
10. Vollmann D, Stevens J, Zenker D, Kriegelstein H, Unterberg C. 1-year performance of a defibrillation lead with a small electrode surface for high impedance pacing: a randomized, controlled study. *Pacing Clin Electrophysiol* 2002;25:1577-82.
11. Gregoratos G, Abrams J, Epstein A *et al.* ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines). *Circulation* 2002;106:2145-61.
12. Model 4074/4574 bipolar steroid eluting passive pacing leads. Medtronic PMA-S Clinical Section, Version 1.0, 28 January 2002.
13. Final Clinical Report, Version 1.0, 26 November 2002 (IDE G010090, Investigational Plan, Version 1.4).
14. Hursel TM, Kilat H, Stertmann WA *et al.* Binary search algorithm versus 'step down' protocol to assess the intraoperative defibrillation threshold: can the implantation procedure be shortened? (Abstract). *Circulation* 1996;94(Suppl.):I-131.