Systematic fluoroscopic and electrical assessment of implantable cardioverter-defibrillator patients implanted with silicone–polyurethane copolymer (Optim™) coated leads

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Received 22 April 2013; accepted after revision 1 July 2013; online publish-ahead-of-print 15 September 2013

Aims
Serious concerns have been recently raised about the reliability of the silicone–polyurethane copolymer (Optim™) lead insulation system. We sought to identify insulation defects and Optim-lead failures by systematic fluoroscopic and electrical assessment in a prospectively defined cohort of implantable cardioverter-defibrillator (ICD) patients.

Methods and results
Between July 2007 and December 2011, 234 patients were implanted with 413 optim-coated leads as part of an ICD system at a single centre. Fluoroscopic screening with high-resolution cine-fluoroscopy at 30 frames per second was offered to all patients. In addition, the electrical integrity of all implanted leads was assessed. Durata, Riata ST Optim, and low-voltage Optim leads were implanted in 199, 26, and 188 cases, respectively. During a total follow-up of 10 036 lead-months, there were 7 Optim-lead failures (defined as electrical malfunction resulting in lead replacement) and 31 deaths; no cases of electrical noises were encountered. The overall incidence of lead failure was 1.2 vs. 0.3 per 100 lead-years, for high- and low-voltage leads, respectively ($P = 0.1$). One hundred fifty-one patients agreed to undergo fluoroscopy screening; none of the 264 analysed Optim leads were found to have any fluoroscopically visible structural defects after an average of 31 months post-implant.

Conclusion
This study represents the first systematic screening of Optim-coated leads in a large unselected cohort of ICD patients. Over a 5-year period few lead failures were observed and normal fluoroscopic appearance was present in all patients.

Keywords
Durata • Implantable cardioverter-defibrillator • Insulation breach • Fluoroscopy • Lead failure • Riata

Introduction
Despite the positive effect in the secondary and primary prevention of sudden cardiac death in selected groups of patients,1,2 implantable cardioverter-defibrillator (ICD) therapy is also associated with potential malfunction of the implanted system. Leads are the most fragile and critical component of the ICD system and the insulation system represents an important site of ICD transvenous lead vulnerability.

Recently, Riata™ ICD family of silicone leads (St Jude Medical, Inc.) have been placed under a class I Food and Drug Administration (FDA) recall3 due to a unique insulation defect with externalization of conductors.4 The internal design of the recalled Riata leads, has caused insulation breaches originated by the movement of the conductor cables within their lumens. Some have raised concerns that St Jude Medical’s current-generation Durata™ ICD leads have certain similarities in structural design to the failed Riata and Riata ST ones. The high resistance to abrasions of the new silicone–polyurethane copolymer (Optim™) insulation of current-generation ICD leads from the same manufacturer is expected to confer greater protection against insulation failures than silicone-only leads.

Unexpectedly, a number of insulation failures in Optim leads have recently been reported.5,6 In addition, a recent paper suggested that

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What’s new?

- First study with systematic fluoroscopic and electrical assessment for screening of Optim-lead failures in a large unsolicited cohort of implantable cardioverter-defibrillator patients.
- Over a 5-year period, a low rate of Optim-lead failures was detected and normal fluoroscopic appearance was present in all patients.

Methods

This single-centre study was performed in a tertiary-care university hospital. All patients implanted with Optim-coated leads (Table 1) as part of an ICD or ICD-cardiac resynchronization therapy (CRT-D) system in our institution, were contacted to perform fluoroscopic screening of the lead. In addition, electrical integrity of the lead was assessed. Patients with a follow-up of at least 12 months after the implant were included in this analysis.

Data analysis and electrical measurements

Baseline data were collected on standardized implant forms and entered into the database prospectively at the time of device implantation. The implant procedure was conducted as per the usual procedure of our institution. Leads were inserted either through a cephalic or subclavian vein, usually with the aid of introducers. The defibrillation lead was positioned first, eventually followed by the atrial and the coronary sinus lead. The high-voltage lead was placed either in the right ventricular apex (73.3%) or in the interventricular septum (26.7%) according to conventional methods. A pacing threshold of ≤1 V and an R-wave ≥5 mV were required for a successful implantation. Final lead position was determined at the discretion of the operator based on acceptability of pacing thresholds and anatomical position.

High-resolution fluoroscopy evaluation

Radiological evaluation of the entire lead was performed with high-resolution cine-fluoroscopy at 30 frames per second in at least two orthogonal views. Additional projections or other magnification settings to those areas known to be at greater risk of lead body failure were recorded as per the operator’s discretion. A careful fluoroscopic examination of the entire length of the lead was performed and particular attention was focused at the level of the tricuspid valve and at the points of contact of the lead with another device or anatomical structure. A lead was determined to have externalized conductors in the case of fluoroscopic evidence of conductors outside the lead body due to an abrasion-related breach of the outer insulation. Fluoroscopic images were evaluated independently by two electrophysiologists (G.B.F. and L.S.), who were experienced in ICD implantations, and the evidence of fluoroscopic abnormalities was classified as positive or negative. Disagreements were resolved by consensus.

All patients had either primary or secondary prevention indications according to the guidelines at the time of implantation. Implant data were prospectively collected in a dedicated database at the time of device implantation. The data were analysed retrospectively after a review of each patient’s medical record. Patients were included regardless of whether the implant was performed as a first-device implantation procedure or whether a high-voltage Optim lead was placed as part of an upgrade procedure in patients who already had a permanent pacemaker. The study was approved by our institutional review board and all patients gave written informed consent for fluoroscopic evaluation of the implanted leads as part of an investigational protocol.

Table 1

<table>
<thead>
<tr>
<th>Leads</th>
<th>Model numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defibrillation leads</td>
<td></td>
</tr>
<tr>
<td>Riata ST Optim</td>
<td>7020, 7022, 7070, 7071, 7030, 7031</td>
</tr>
<tr>
<td>Durata True Bipolar, active-fixation</td>
<td>7120, 7121, 7122, 7120Q, 7121Q</td>
</tr>
<tr>
<td>Durata Integrated Bipolar, active-fixation</td>
<td>7130, 7131</td>
</tr>
<tr>
<td>Durata True Bipolar, passive-fixation</td>
<td>7170, 7171</td>
</tr>
<tr>
<td>Pacing leads</td>
<td></td>
</tr>
<tr>
<td>Tendril ST Optim</td>
<td>1888TC, 1882TC</td>
</tr>
<tr>
<td>IsoFlex Optim, passive-fixation</td>
<td>1944, 1948</td>
</tr>
<tr>
<td>OptiSense Optim pacing lead</td>
<td>1999</td>
</tr>
<tr>
<td>Quickflex Micro Bipolar, left-ventricular lead</td>
<td>1258T</td>
</tr>
<tr>
<td>Quartet Quadripolar, left-ventricular lead</td>
<td>1458Q</td>
</tr>
</tbody>
</table>
Statistical analysis

Data were prospectively entered in a database and retrospectively ana-
ysed. Categorical data are summarized using absolute values (percent-
age). Continuous data are presented as mean (± SD). Non-continuous
variables expressed as proportions were compared using χ² analysis or
Fisher’s exact test. Inter-observer agreement was determined by the
overall proportion of agreement and the Kappa statistic. Survival
curves were constructed by the Kaplan–Meier method and differences
in the rate of lead failure were evaluated with the log-rank statistic.
All P-values were two-sided and a P-value of < 0.05 was considered to
indicate statistical significance.

Results

Between July 2007 and December 2011, 250 patients were implanted
with 444 Optim-coated leads as part of an ICD or CRT-D system at a
single centre (Tor Vergata University Hospital). Sixteen patients
(6.4%) were followed at other institutions, the remaining 234 patients
(413 Optim-coated leads) were included in the analysis (Figure 1). The
cohort was 83.8% male and ages ranged from 38 to 90 years. Reflect-
ing institutional use patterns during the time of implantation, majority
of implanted high-voltage leads (97%) were screw-in and 47% were
single coil. The leads were connected to a single-chamber device in
31.6% (n = 74), dual-chamber device in 19.2% (n = 45), or CRT-D
device in 49.1% (n = 115). Table 2 shows the baseline demographics
of screened patients and details of their ICD systems.

The distribution of lead models in this analysis is shown in Table 3.
Riata ST Optim leads, Durata leads, and low-voltage Optim leads
were implanted in 26, 199, and 188 cases, respectively. Of the
enrolled patients, 33 (14.1%) were receiving a high-voltage lead as
an ICD replacement (for infection or lead dysfunction) or to
upgrade an existing pacemaker system and 51.3% of patients received
a remote home monitoring system. Majority of low-voltage Optim
leads were quadrupolar left ventricular leads (n = 86; Quartet™,
St Jude Medical).11

Follow-up

The total follow-up time was 501 patient-years with an overall
average of 25.7 ± 14.1 months of follow-up per patient. One
hundred and eighteen patients (50.4%) completed 24 months follow-
up evaluation and 61 patients (26.1%) completed 36 months of
follow-up. During this period there were 31 deaths from all causes
and four patients required device and leads extraction for infection.
Twenty-nine of the 31 deaths were confirmed to be unrelated to a
lead dysfunction; in the remaining two patients there were insufficient
data to confirm or refuse lead integrity.

Complete lead electrical performance data were available for all
patients. As expected, the follow-up time of the patients with Riata
ST Optim leads was significantly longer than that of patients with
Durata leads (P = 0.002). During a total follow-up of 10 036 lead-
months, there were seven Optim-lead failures. Electrical lead
failure occurred in six high-voltage (four Durata and two Riata ST
Optim) and in one low-voltage lead (Figure 2 and Table 3). Specifically,
the following causes for electrical lead failure were encountered:
threshold changes (n = 2), inadequate sensing (n = 2), pacing and
impedance abnormalities (n = 2), or sensing and pacing abnormalities
(n = 1); no cases of electrical noise were encountered. In the remain-
ing leads, electrical parameters remained within clinically acceptable
ranges throughout the follow-up period.

The time from implant to identification of an electrical lead failure
ranged from 12 to 52 months and in no cases the lead dysfunction
resulted in inappropriate shocks. The overall incidence of Optim-lead

Table 2 Baseline characteristics and outcome

<table>
<thead>
<tr>
<th>Variable</th>
<th>Patients, n</th>
<th>Male sex, n (%)</th>
<th>Leads with Optim insulation, n</th>
<th>Age at implantation, years</th>
<th>Coronary artery disease, n (%)</th>
<th>Left ventricular ejection fraction (%)</th>
<th>Primary prevention, n (%)</th>
<th>Remote monitoring, n (%)</th>
<th>Device characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>234</td>
<td>196 (83.8)</td>
<td>413</td>
<td>67.5 ± 10.6</td>
<td>140 (59.8)</td>
<td>28.4 ± 9.5</td>
<td>202 (86.3)</td>
<td>120 (51.3)</td>
<td>Single-chamber device, n (%)</td>
</tr>
<tr>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>74 (31.6)</td>
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<td></td>
<td></td>
<td></td>
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<td></td>
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<td>Dual-chamber device, n (%)</td>
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<td></td>
<td></td>
<td></td>
<td>45 (19.2)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Biventricular device, n (%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>115 (49.1)</td>
</tr>
<tr>
<td>Outcome</td>
<td>Follow-up duration</td>
<td>25.7 ± 14.1</td>
<td>Death, n (%)</td>
<td>31 (13.2)</td>
<td>Appropriate ICD therapy, n (%)</td>
<td>43 (18.4)</td>
<td>Inappropriate ICD therapy, n (%)</td>
<td>19 (8.1)</td>
<td>ICD lead dislodgement, n (%)</td>
</tr>
<tr>
<td></td>
<td>Optim-lead failure, n (%)</td>
<td>7 (3.0)</td>
<td>Fluoroscopic abnormalities, n (%)</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Values are mean ± SD unless specified.

Lead failure was defined as electrical malfunction resulting in lead replacement, excluding infections, dislodgements, or perforations.

ICD, implantable cardioverter-defibrillator; n, number of patients.

Figure 1 Flow diagram of the study.
failure was 1.2 vs. 0.3 per 100 lead-years, for high- and low-voltage leads, respectively \((P = 0.1)\). Previously acquired fluoroscopic images were available for all dysfunctioning leads: in no cases an insulation failure was suspected, nor other apparent lead body abnormalities were identified. Four leads were completely removed and replaced with a new defibrillation lead; in three of the seven cases of lead failure the approach after diagnosis was surgical revision with the failed lead abandoned and a new lead implanted. No major complications occurred with removal of these leads.

**Fluoroscopy screening in asymptomatic patients**

As of November 2012 to January 2013 and 151 patients agreed to participate. Among these patients, the mean time from implant to date of fluoroscopy was 31.3 ± 14.6 months. Normal fluoroscopic appearance was present in all patients. None of the 264 Optim leads analysed were found to have any fluoroscopically visible insulation defects or externalized conductors. There was an excellent agreement in the fluoroscopic evaluation with a \(k\) score of 1.

**Discussion**

To our knowledge, this is the first systematic fluoroscopic and electrical assessment of Optim-coated leads which has been reported. The main finding of this study is that no cases of externalized conductors were detected on fluoroscopic screening of 264 Optim leads. In addition, a low rate of Optim-lead failures was detected during a total follow-up of 10 036 lead-months (501 patient-years).

Since the introduction of pacemaker and ICD technology, a variety of problems with leads and pulse generators have been documented. In December 2011, the FDA issued a Class I recall of the Riata and Riata ST silicone endocardial defibrillation leads. Riata leads are subjected to inside-out abrasion which results in conductor cables becoming externalized, outside the lead body. This defect has been attributed to ethylene-tetrafluoroethylene-coated conductor cables exerting pressure on the inner luminal surface, leading to abrasion of the silicone insulation.

Some have raised concerns that St Jude Medical’s current-generation Durata™ ICD leads have certain similarities in structural design to the failed Riata and Riata ST one, with the exception of a novel silicone–polyurethane copolymer (Optim™) insulation system. This new hybrid material, manufactured by AorTech International (Elast-Eon™ E2A), has been reported to exhibit a better abrasion resistance than silicone and could help avoid or reduce the risk of insulation failures.12 Nevertheless, to date, these aspects are still controversial. Durata’s internal design shares many design elements with the Riata ST. Since Riata family leads have failed, some physicians are now facing the issue whether they should trust the new generation of Optim-coated leads. As a result, a serious

### Table 3 Study observational leads outcome

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Cephalic access (%)</th>
<th>Follow-up 95% confidence interval</th>
<th>Dislodgement (n) (%)</th>
<th>Electrical lead failure (n) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optim-coated leads (overall)</td>
<td>413</td>
<td>47.7</td>
<td>24.3 ± 13.4</td>
<td>4 (1.0)</td>
<td>7 (1.7)</td>
</tr>
<tr>
<td>High-voltage Optim leads</td>
<td>225</td>
<td>63.6</td>
<td>26.0 ± 14.2</td>
<td>2 (0.9)</td>
<td>6 (2.7)</td>
</tr>
<tr>
<td>Riata ST defibrillation lead</td>
<td>26</td>
<td>42.3</td>
<td>33.9 ± 19.2</td>
<td>0</td>
<td>2 (7.7)</td>
</tr>
<tr>
<td>Durata defibrillation leads</td>
<td>199</td>
<td>66.3</td>
<td>25.0 ± 13.1</td>
<td>2 (1.0)</td>
<td>4 (2.0)</td>
</tr>
<tr>
<td>Low-voltage Optim leads</td>
<td>188</td>
<td>28.2</td>
<td>22.2 ± 12.1</td>
<td>2 (1.1)</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Tendril ST pacing lead</td>
<td>37</td>
<td>67.6</td>
<td>35.0 ± 14.7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>OptiSense pacing lead</td>
<td>59</td>
<td>39.0</td>
<td>20.1 ± 9.1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Quickflex Micro Bipolar left-ventricular pacing lead</td>
<td>6</td>
<td>33.3</td>
<td>28.2 ± 14.9</td>
<td>1 (16.7)</td>
<td>1 (16.7)</td>
</tr>
<tr>
<td>Quartet Quadripolar left-ventricular pacing lead</td>
<td>86</td>
<td>4.7</td>
<td>17.8 ± 8.1</td>
<td>1 (1.2)</td>
<td>0</td>
</tr>
</tbody>
</table>

Values are mean ± SD unless specified.

Electrical lead failure was defined as electrical malfunction resulting in lead replacement, excluding infections, dislodgements, or perforations.

### Figure 2

**Kaplan–Meier estimates of event-free outcome for high- and low-voltage Optim leads (log-rank \(P = \text{NS}\)).**
consideration should be given to monitoring the performance and survivability of these high-voltage leads.

Hauser et al. using data taken from the FDA Manufacturers and User Facility Device Experience (MAUDE) database analysed 52 reports of lead insulation abrasions for Riata ST Optim and Durata leads after a mean of 29 and 22 months, respectively, after the implant. Insulation defects were mainly the result of ‘outside-in abrasions’, or abrasions which were caused when the lead came into contact with another device or anatomical structure and the investigators concluded that the Optim does not prevent lead insulation failures which are caused by friction with the can or another device. It is noteworthy to emphasize that the main limitation of this analysis is that the MAUDE database is not a controlled, audited database and the government site prominently states that it ‘is not intended to be used either to evaluate rates of adverse events or to compare adverse-event occurrence rates across devices’. Furthermore, since lead abrasions might occur with any lead regardless of the insulation type, the absence of a control group in the study by Hauser et al. has precluded a direct comparison with a group of non-Optim leads.

Additional concerns about the reliability of the Optim-coated leads arise from a work by Chaffin et al., who tested the long-term performance of this copolymer after immersion in buffered water for up to 52 weeks at temperatures ranging from 37 to 85 °C. Although this study was strictly limited by the absence of a control group of currently available non-Optim lead insulation materials, the treatment at 85 °C resulted in a steady reduction of the molecular mass with concomitant degradation of the ultimate tensile properties, suggesting that this copolymer might not be reliable over the long term.

These studies have raised several concerns about the reliability of Optim-coated leads. The possibility of insulation failures highlights the need for careful examination of implanted patients. Lead defects can be detected during routine ICD control by electrical parameters mainly represented by sensing abnormalities, whereas in one-third of patients the defect is recognized only after the occurrence of inappropriate shocks. Fluoroscopic screening can identify early stages of insulation failure before the occurrence of electrical abnormalities. Of note, the majority of inside-out insulation defects reported in patients with Riata and Riata ST leads were not associated with electrical abnormalities, and lead evaluation with high-resolution fluoroscopic imaging might be helpful to identify this defect.

By contrast, two recent single-centre retrospective analyses evaluated the electrical performance of St Jude’s high-voltage Optim-coated leads and both these studies found a low rate of adverse lead events. In the first study by Liu et al., the failure-free lead survival rates of the Optim-coated leads were significantly better than that of the Riata 8F lead and similar to that of the Medtronic Quattro lead (Medtronic). In a second study by Rodorff et al., no cases of lead failure were recorded in 99 Optim ICD leads (Riata Optim/Durata) after a median follow-up of 22 months. A significant limitation of these two studies is the lack of fluoroscopy data of the implanted leads; this precludes the assessment of electrically silent insulation failure. Furthermore, insulation damage is more likely to proceed slowly over time and to be recognized in the early stages only with fluoroscopy, without significant changes in electrical parameters impedance. These aspects introduce a potential bias for a higher rate of lead insulation failure. Conversely, the present study population was systematically screened with device interrogation and high-density cine-fluoroscopy, adding important evidence that corroborates the findings of the two aforementioned studies.

Since concerns have been recently raised about the reliability of the Optim insulation system, we also evaluated the performance of low-voltage Optim-covered pacing leads. Of note, fluoroscopic screening of Optim-coated leads was performed only in ICD patients. The main reason was that there has been much concern about the safety of Durata leads, since insulation failure of high-voltage leads has resulted in multiple deaths; therefore, the most serious consequences related to the dysfunction of high-voltage lead, might justify the extra radiation exposure.

Follow-up in our study was relatively short and the mean time from implant to date of fluoroscopy screening was 31.3 ± 14.6 months. However, it should be stressed that in other studies a similar follow-up was sufficient to demonstrate an increased risk of lead insulation failures. Two studies reported lead structural failure in Riata family after a mean of 18 months and 22 months following implantation. More importantly, Hauser et al. reported lead insulation abrasions for Riata ST Optim and Durata leads after a mean of 29 and 22 months, respectively, after the implant. In recent years, the two largest recalls occurred with the Sprint Fidelis (Medtronic) and the St Jude Medical Riata lead families; a follow-up similar to that of the present study has been sufficient to prove an increased risk of lead insulation failure in Riata and Sprint Fidelis leads. The Sprint Fidelis lead was introduced in 2004, and concerns of an early failure rate were first raised in 2007. In 2008, the first concerns regarding insulation defects of Riata ICD leads were raised; later confirmed in 2011. St Jude Medical’s data suggest that the majority of Riata abrasions occur in the first 27 months after implant. In our study, seven patients had Optim-lead failure requiring lead replacement over a mean of 25.7 months of follow-up and abnormal fluoroscopic findings were not detected among Optim-coated leads evaluated only for ‘screening’ purposes. Durata and Riata ST Optim leads have been distributed for over 5 years and a total of > 300 000 leads were implanted worldwide. Based on these considerations and in the view of recent concerns about reliability of the Optim-covered leads, data obtained with high-density fluoroscopy screening after a mean follow-up of 31 months provides important information about the reliability of these widely implanted leads.

**Limitations**

This is a single-centre retrospective study and has the inherent limitations of this design. However, to minimize the possibility of referral or selection biases, we included all consecutive ICD patients with Optim-covered leads implanted in our centre. While we were aware that a direct comparison with a control group would have added significant information, the absence of lead abnormalities detectable with fluoroscopy has precluded a direct comparison with a group of ICD patients implanted with non-Optim leads.

About 47.7% of the leads were implanted with the cephalic vein. As subclavian puncture has been demonstrated to significantly increase the risk of lead failure in Riata leads, these results may not be extended to leads which are implanted via a non-cephalic approach.
Finally, lead extraction was not performed routinely. Therefore, the precise cause of lead failure could not be clarified in all cases.

Conclusions

This study represents the first systematic fluoroscopic and electrical assessment of Optim-coated leads in a large unselected cohort of ICD patients. Leads evaluated in this study proved to be safe and were associated with a reliable long-term performance. Over a 5-year period, few lead-related adverse events were observed and a normal fluoroscopic appearance was present in all patients. Lead durability with this copolymer seems promising, nevertheless additional supporting clinical studies with longer surveillance data may be necessary to make a definitive statement about its reliability and chronic performance characteristics.

Acknowledgements

The authors thank Cecilia Rubaudo for her assistance in the preparation of this manuscript.

Conflict of interest: G.B.F. has received Lecture fees from St Jude Medical. L.D.B. is a consultant for Hansen Medical, Biosense Webster, and St Jude Medical. L.S. received lecture fees from St Jude Medical. A.N. received speaker honorariums from Boston Scientific, Biosense Webster, St Jude Medical, Biotronik and Life Watch.

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