[Physician / medical center contact information to be inserted]

January 28, 2013

Urgent Medical Device Field Safety Notice

ISOLINE defibrillation leads, model 2CR5, 2CR6 and 2CT6

Dear Doctor,

This information is related to ISOLINE defibrillation leads, models 2CR5, 2CR6 and 2CT6. As of December 31, 2012, Sorin has confirmed 30 cases out of 13500 units implanted worldwide (0.222%) where the analysis of the returned leads identified internal insulation breach under the right ventricular (RV) and/or Superior Vena Cava (SVC) defibrillation coil electrode, resulting in low pacing impedance, and/or ventricular oversensing and/or inappropriate therapies.

No permanent serious injury or death has been reported as a result of the confirmed malfunction.

Details about potentially affected leads

This information affects ISOLINE defibrillation leads, models 2CR5, 2CR6 and 2CT6[1]. The 2CR5 and 2CR6 models have a retractable screw fixation mechanism while the 2CT6 model has tined fixation.

ISOLINE leads are integrated bipolar leads with two defibrillation coils. The lead body contains three conductors, which are encased by a multi-lumen silicone tube: one pacing/sensing conductor and two defibrillation microcables. Both microcables are protected with an ETFE[2] polymer coating, except under each defibrillation coil.

Description of the issue

As of December 31, 2012, 30 cases of internal insulation breach under the RV or SVC defibrillation coil have been confirmed by the analysis conducted on returned products.

In each of the 30 identified cases, the internal insulation breach of the silicone lumen was observed under the RV and/or SVC defibrillation coil, i.e. where the microcables are not coated with ETFE, resulting in a contact between the conductors, thus leading to low pacing impedance and/or ventricular oversensing, and/or inappropriate therapy. It should be noted that in case of ventricular oversensing, pacing is inhibited.

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[1] Since the commercial release in 2005, these leads had been manufactured in France or in Italy by "ELA Medical" or "Sorin CRM". Although the manufacturer name changed over time (from ELA Medical to Sorin CRM), the commercial name of the product remained "ISOLINE".

[2] Ethylene tetrafluoroethylene (fluorine based plastic)

These leads had been implanted for a mean duration of 1.4 years (from 2 months to 4.5 years). No early indicator that could have warned of a potential issue has been identified in those cases.

Visual inspection of each of the 30 returned products revealed presence of abnormal torsion and/or compression. In depth investigation determined that the insulation abrasion by the microcable of the ISOLINE lead models under the RV or SVC defibrillation electrode may be attributed to particular and rare implant conditions that induce bending, compression and/or torsion on the lead, thus promoting internal abrasion of the silicone lumen by pushing the microcable against the lumen wall.

However, such torsion and/or compression are barely detectable through X-ray imaging. The insulation breach itself is not visible through X-ray imaging because of its position under the defibrillation coil.

It should be noted that no conductor externalization was observed and that no conductor externalization is possible since the conductor wires are secured within the lead by the defibrillation coil itself.

Patient Management Recommendations

After consultation with Sorin CRM's independent Product Performance Monitoring Board, Sorin CRM provides the following recommendations:

- Leads which are not implanted yet, shall not be used and should be returned to Sorin CRM.
- Considering the low occurrence rate of the issue, prophylactic replacement or removal of any ISOLINE lead is not recommended in patients whose ISOLINE lead has not shown any electrical malfunction.
- Physicians should continue to regularly monitor their patients implanted with ISOLINE leads. During follow up, standard checks should be conducted as recommended in the HRS/EHRA expert consensus on the monitoring of Cardiovascular Implantable Electronic Devices[3]: battery voltage, pacing & sensing operation, lead impedances, arrhythmias detected by the device, etc. Recorded treated and non-treated episodes should be carefully reviewed; examples of typical ventricular oversensing episodes associated to the issue are provided with this letter.
- In the absence of any evidence of malfunction, standard follow up intervals apply (3 months intervals, as recommended in the Sorin ICD labeling); reprogramming of VT/VF detection parameters could be evaluated (such as extending the persistence[4]); however, this should be weighed against delaying appropriate therapy. At the next routine follow up, patients should be informed to contact you should they experience shock therapy.
- In case of evidence of a lead issue (as shown in the appendix), physicians should consider replacing the lead, while weighing the risks and benefits of extracting the

[3] HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations - Bruce L. Wilkoff & al. – Europace 2008;10:707-25

[4] Refer to pulse generator IFUs, for non Sorin ICD's manufacturer.

lead compared to capping it and leaving it in place. The decision to remove a lead should be taken on an individual basis, as described in HRS guidelines[5]. Any event associated to a potentially defective ISOLINE lead should be reported to Sorin CRM; any extracted lead should be returned to Sorin CRM for analysis.

- When the ISOLINE lead is connected to a remote monitoring enabled ICD or CRT-D device, appropriate alert parameter(s) programming shall be considered. For Paradym RF family, physicians should consider programming the following alerts:
  - RF communication to "ON"
  - Alerts to "ON"

Type of Alerts	**Parameter**	**Programmable value**
Clinical Alerts	V oversensing	On
Tachy Therapy Alerts	Shock delivered	All shocks
Leads Alerts	Abnormal RV lead impedance	On Low Limit: 200 Ohm

- At the time of the device replacement, a remote enabled ICD or CRT-D should be considered.

Sorin is communicating this information to the MHRA. Sorin CRM encourages health care professionals to continue to report any serious adverse events with the use of our products to their Sorin CRM representative.

Please make sure that all personnel involved in the management of patients implanted with ISOLINE defibrillation leads (models 2CR5, 2CR6 or 2CT6) in your organisation are aware of the information described in this letter.

We regret the inconvenience this could cause you and your patients. If you have any questions, please contact your local Sorin representative or contact Sorin Group at 01452 638500

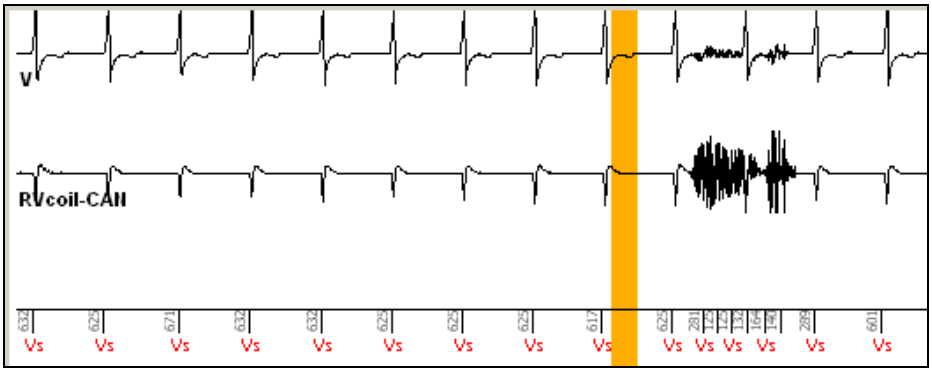
Sincerely,

[5] Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management - Bruce L. Wilkoff and al. Heart Rhythm July 2009; 6 :7 : 1085-1104

Appendix

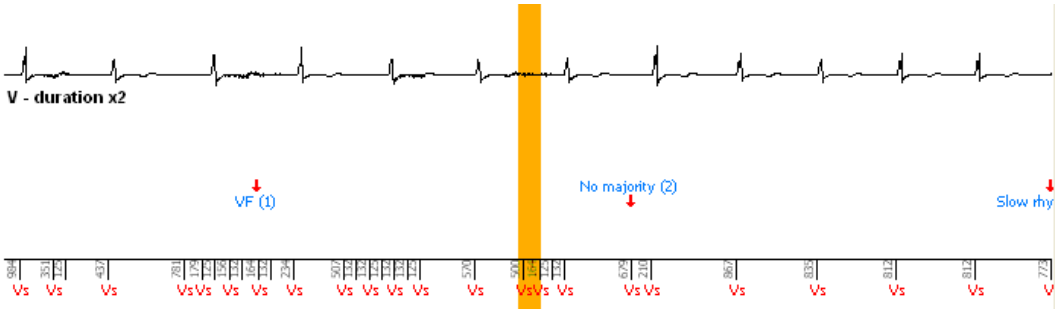
Ventricular oversensing is a well known complication of implanted defibrillation systems[6]. It is not necessarily related to a lead issue. It can also be caused by T-wave oversensing, myopotentials, interference with electromagnetic fields, etc. In most cases, ventricular oversensing could be avoided by reprogramming ICD settings or preventing the initiating trigger. Examples of some typical episodes recorded by Sorin ICDs are provided below.

Ventricular oversensing caused by external signals (such as 50 Hz Electro Magnetic Interferences):



Such episodes are not related to lead malfunction. If such an episode is recurrent, avoidance of the source of interference is recommended.

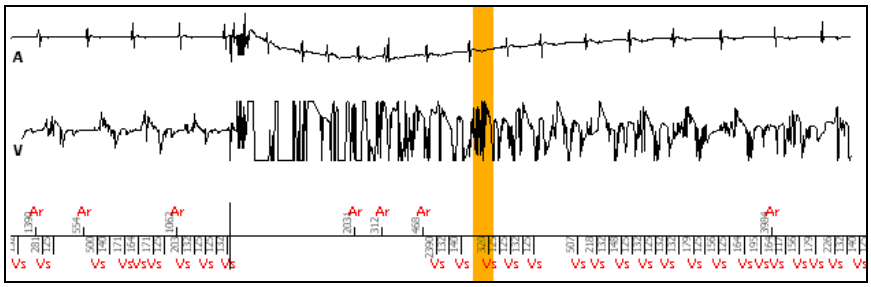
Ventricular oversensing caused by myopotentials:



Such episodes are not related to lead malfunction. If such an episode is recurrent, sensitivity should be adjusted.

Ventricular oversensing caused by lead issue:

[6] Ventricular oversensing in 518 patients with implanted cardiac defibrillators: incidence, complications, and solutions - T. Rauwolf*†, M. Guenther†, N. Hass, A. Schnabel, M. Bock, M.U. Braun, and R.H. Strasser – Europace (2007) 9, 1041–1047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