



Dear Colleague,

You will have received an advisory notice from the MHRA regarding St Jude Riata and Riata ST ICD leads. HRUK would like to add some explanation and advice regarding the situation; you will appreciate that our information is limited and that the situation is fluid, so we are not able to be definitive in all areas.

The communication addressed lead abrasion, a well known issue with silicone leads, but includes a relatively new observation, externalized conductors. The potential problem affects only the pre-OPTIM Riata and Riata ST leads and results from externalisation of the conductors within the leads. The mechanism is not clearly understood at present, but results from abrasion or cut-through of the conductors such that they lie outside the body of the lead. This may occur within the circulation or in the generator pocket and can be difficult to detect.

These conductors are coated with ETFE (similar to Teflon) which provides some insulation and may hence protect the electrical integrity of the cables; ETFE has not, however, been proven to provide full electrical insulation under these circumstances. This externalisation may, however, produce no obvious electrical malfunction and so can be difficult to detect at follow up. When it has occurred, abnormal electrical function has been detected most often as excessive noise, but inappropriate shocks and sensing failures have also been noted.

The current rates of abrasion and conductor externalization worldwide on the basis of spontaneous reports to St Jude Medical have been < 0.5% and 0.05% respectively. The survival rate at 44 months for St. Jude Medical defibrillation leads using Optim insulation is 98.8% vs. 98.4% for the Riata and Riata ST silicone leads; the difference is attributable to the lower rate of abrasion reported for Optim leads.

Following the recent medical device alert issued by MHRA, HRUK consider that further clinical advice would be beneficial for its members. HRUK recommend:

1. Identification and early review of all patients with Riata and Riata ST ICD leads, followed by three (3) monthly review.
2. Undertaking of testing with provocative movements (eg deep respiration, movement of ipsilateral arm) to look for sensing/noise abnormalities).
3. If evidence exists for lead malfunction, consider fluoroscopy to examine for evidence of this process within the pocket or in the circulation; this may need magnified views.

4. As should be the case for any generator replacement, patients with a Riata or Riata ST leads requiring a generator replacement must have fluoroscopy performed to assess the lead prior to generator replacement.
5. There is no evidence at present that patients with these leads should be exposed to the risks of lead extraction unless the clinician considers that other indications exist for extraction/replacement.
6. Establish home monitoring (if available for the generator) to increase monitoring ability and frequency.
7. No new Riata or Riata ST (pre-Optim) leads should be implanted; although these leads have not been marketed for some time, Trusts may still have some in stock. These should be returned to St Jude.
8. Evidence to date indicates that St. Jude Medical Riata ST Optim and Durata leads are not subject to this issue.

We shall be very happy to receive any information or queries from colleagues about their own experiences and will provide updates as information becomes available.

HRUK Council, December 2010