

Important Medical Device Information



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Dear Doctor,

This letter provides important product performance information regarding a subset of seventy-two (72) Boston Scientific RELIANCE 4-FRONT™ single coil defibrillation leads distributed in Europe and Japan. Leads in this subset passed all manufacturing tests, but one lead exhibited intermittent high pacing impedance and oversensing at implant. The lead was explanted and returned to Boston Scientific. Laboratory analysis determined that the terminal ring for the distal shock electrode was not fully connected to the conductor cable. Further investigation determined that manufacturing equipment used to attach the terminal ring to the conductor cable was slightly offset from the intended position for a short period of time. The seventy-two leads (Table 1) were manufactured during this offset period, and may have a terminal ring that was not fully connected to the conductor cable.

Clinical Considerations

If the terminal ring is not securely connected to the conductor cable, potential clinical symptoms may include high or intermittently high pacing or shock lead impedance, noisy EGMs (particularly during pocket manipulation), or sensing anomalies that could affect either pacing pulses or shocks. An incomplete connection cannot be seen on X-ray.

Once securely inserted into the header of a pulse generator, the terminal ring is subject to less mechanical stress, and an incomplete ring-to-cable connection may operate properly. However, if the pulse generator were to be replaced, a terminal ring that is not fully connected to the conductor cable could cause clinical symptoms during the replacement procedure.

Patient Management Recommendations

Follow-up Testing and Schedule

We recommend normal follow-up testing on a three-month schedule, as described in Boston Scientific pulse generator labeling, to help identify symptoms of an incomplete terminal ring-to-cable connection if it were to occur. Boston Scientific Technical Services can help identify potential clinical symptoms that may be due to an incomplete ring-to-cable connection.

Audible Alerts

If audible alerts for out-of-range impedance are available in the attached pulse generator, confirm that the alerts are programmed ON and the patient is able to hear the alert/beeper if activated.

Remote Patient Monitoring

Boston Scientific recommends use of a remote/home monitoring system, such as the LATITUDE™ Patient Management System, which can supplement scheduled in-clinic visits with weekly and daily alerts for changes in lead-related performance.

Population

Table 1. Affected RELIANCE 4-FRONT single coil defibrillation leads (by model and serial number)

Model 0682		Model 0692				
121478	121502	121454	121466	121481	121516	121527
121485	121503	121455	121467	121482	121517	121528
121488	121504	121456	121468	121483	121519	121530
121489	121505	121458	121469	121484	121520	121531
121490	121506	121459	121470	121487	121521	121532
121491	121507	121460	121472	121492	121522	121533
121494	121509	121461	121473	121493	121523	121534
121495	121510	121462	121475	121496	121524	121538
121497	121511	121463	121476	121508	121525	121540
121501	121514	121464	121477	121515	121526	121541
		121465	121479			

Records indicate that these leads were distributed in France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, and United Kingdom. If an affected lead has not been implanted, our local representative will return it to Boston Scientific. No other Boston Scientific lead products are impacted.

Further information

We recognize the impact of this communication on you and your patient, and want to reassure you that patient safety remains our primary concern. If you have any questions or feel that an implanted lead system is not performing as expected, please contact your local Boston Scientific representative or Technical Services.

Sincerely,

[Redacted Signature]

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