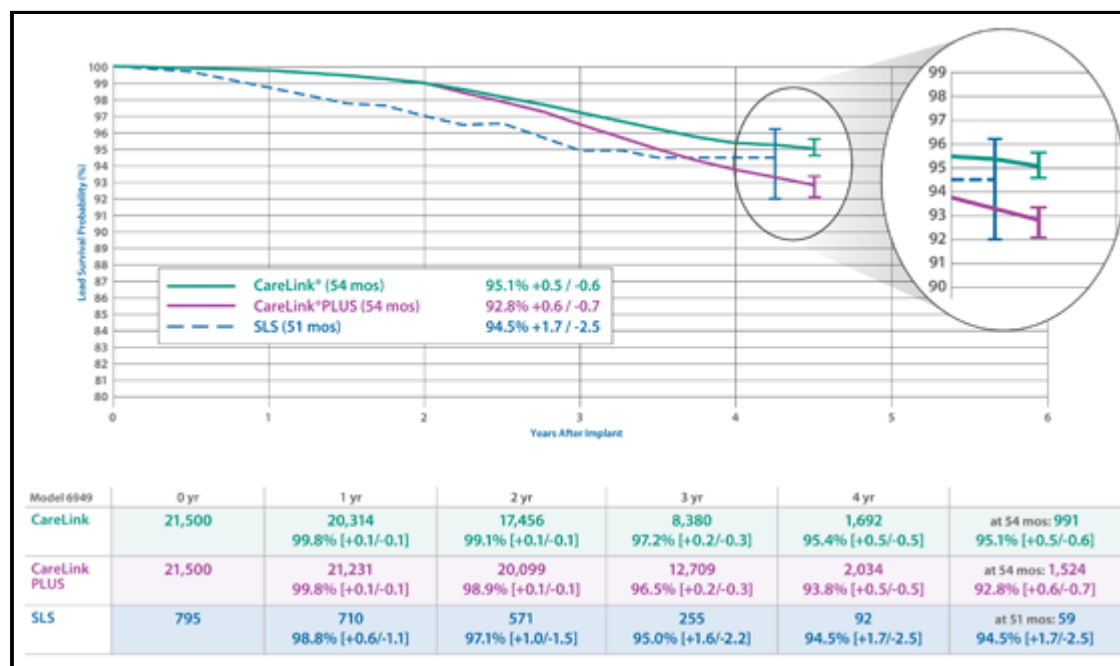




Register to receive periodic updates (<http://www.medtronic.com/product-advisories/physician/sprint-fidelis/SPRINTFIDELISOPTINFORM.htm>) on the performance of the Sprint Fidelis lead.

Sprint Fidelis® Model 6949 Lead Performance

November 2009 Website Update



(http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/documents/documents/sf-curve-54mo-htm.html?TB_iframe=true&height=650&width=840)

[Click to view larger image \(http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/documents/documents/sf-curve-54mo-htm.html?TB_iframe=true&height=650&width=840\)](http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/documents/documents/sf-curve-54mo-htm.html?TB_iframe=true&height=650&width=840)

Medtronic strives to monitor product performance as accurately as possible. As such, starting in November 2009, Medtronic has added a third performance curve to our lead performance update. This curve, called CareLink PLUS, includes fractures determined by CareLink transmissions PLUS fractures confirmed through returned product analysis and save-to-disk analysis.

Medtronic's traditional CareLink data analysis was designed to overcome the inherent limitations of determining lead survival based on Returned Product Analysis (under-reporting) and SLS (small sample size). The historical CareLink methodology requires that a CareLink transmission occur following indications of a lead fracture for the event to be included in the CareLink lead survival estimate.

However, the likelihood of a transmission occurring after a fracture may now increasingly be affected by new factors:

- The success of Lead Integrity Alert (LIA) in alerting patients to fractures
- Heightened monitoring of Fidelis patients
- Fidelis patients with devices near replacement date

Medtronic designed the new CareLink PLUS curve to compensate for these new factors, which are likely to increase in impact over time. Medtronic believes CareLink PLUS is the best representation of Fidelis lead fractures available. The chart below compares the historical CareLink presentation with the new CareLink PLUS.

Lead Survival Estimate = Numerator/Denominator

Historical CareLink

CareLink PLUS

Numerator

- Fractures determined by CareLink Transmissions (post indication of a fracture)
- Fractures determined by CareLink Transmissions
- Returned Product Analysis of explanted leads
- Analysis of Save-to-Disk files from returned devices that were associated with Fidelis leads

Denominator

- Number of Fidelis leads based on last CareLink transmission
- Number of Fidelis leads based registry data



(<http://www.medtronic.com/physician/LIA/index.html>)

Last updated: 22 Nov 2009

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