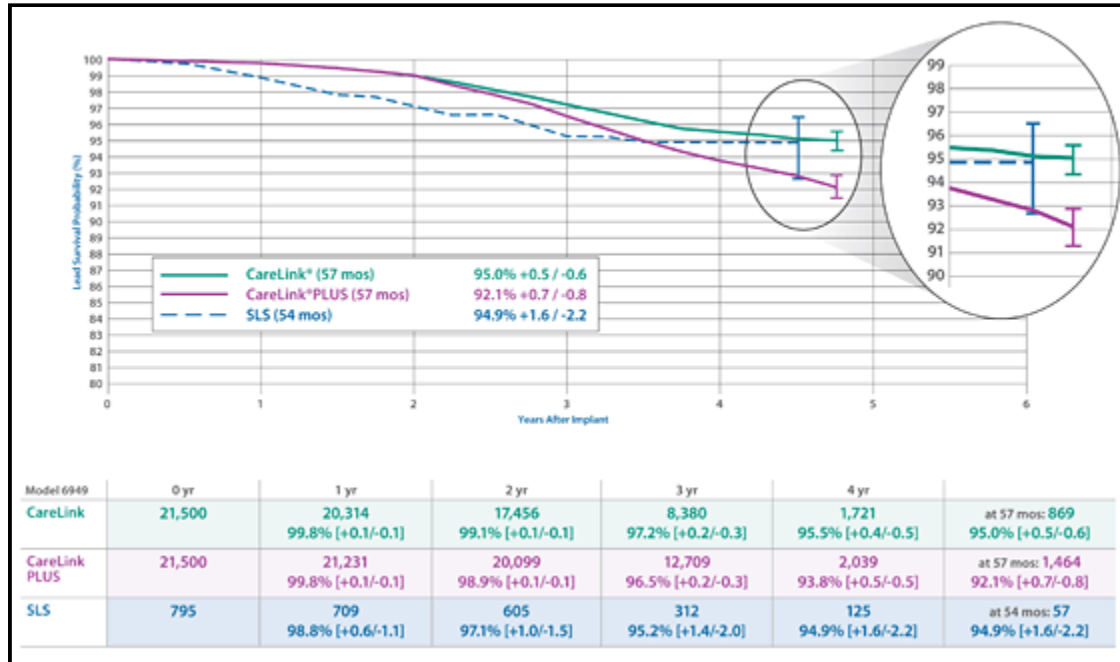




Register to receive periodic updates (<http://www.medtronic.com/product-advisories/physician/sprint-fidelis/SPRINTFIDELISOPTINFORM.htm>) on the performance of the Sprint Fidelis lead.

Sprint Fidelis® Model 6949 Lead Performance

February 2010 Website Update



(http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/documents/documents/sf-curve-57mo-htm.html?TB_iframe=true&height=650&width=840)

[Click to view larger image \(http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/documents/documents/sf-curve-57mo-htm.html?TB_iframe=true&height=650&width=840\)](http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/documents/documents/sf-curve-57mo-htm.html?TB_iframe=true&height=650&width=840)

Medtronic strives to monitor product performance as accurately as possible. Starting in November 2009, Medtronic added a third performance curve to our Fidelis 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.

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

- Availability of Lead Integrity Alert (LIA)
- 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. The impact of these factors can already been seen by looking at the difference between the CareLink and CareLink PLUS curves.

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**Numerator**

- Fractures determined by CareLink Transmissions (post indication of a fracture)

Denominator

- Number of Fidelis leads based on last CareLink transmission

CareLink PLUS

- 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
-
- Number of Fidelis leads based on Medtronic registry data



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

Last updated: 18 Feb 2010

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