SYNCHROMED II PUMPS IN THE AFFECTED POPULATION

The graphs identified as Figure 1 and Figure 2 show cumulative survival probability for SynchroMed II pumps within the affected population of devices. These graphs were generated using US device registration and returned product analysis data.

Figure 1 shows the cumulative survival probability from this battery performance issue by length of implant time. As shown on the graph, within the affected population, SynchroMed II pumps show 99.7% survival from the battery performance issue 60 months post implant.

Figure 2 shows the cumulative survival probability from all failure modes by length of implant time. As shown on the graph, within the affected population, SynchroMed II pumps show 98.6% survival from all failure modes 60 months post implant.

SynchroMed® II pumps within the affected population continue to perform within reliability expectations.