THORATEC
CORPORATION

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URGENT: FIELD SAFETY NOTICE

Affected devices: All serial numbers of the HeartMate II® System Controller, Model No. 105109 (Pocket Controller™), provided within the following packaging configurations: HeartMate II LVAS Implant Kit with Sealed Grafts (Cat. Nos. 106015, 106016), HeartMate II System Controller (Cat. Nos. 106762, 106017) and HeartMate II LVAS Implant Kit (Cat. No. 107801).

Description of problem:

Thoratec has become aware of a recent trend in reports of serious injuries and deaths associated with the process of changing from a primary System Controller to their back-up System Controller in patients using the "Pocket" System Controller model. The System Controller is the external unit that controls the function of the implanted HeartMate II Left Ventricular Assist Device (LVAD, see Figure 1).

The HeartMate II LVAS Pocket System Controller has been prescribed for 2,142 patients, either at the time of the implantation of the HeartMate II LVAD, or as a replacement for an older controller model (EPC System Controller). As of February 4, 2014, Thoratec has received four (4) reports (0.2% of the patient population) of patient deaths that occurred during attempts to exchange one Pocket System Controller for another. Two (2) of the deaths occurred when patients attempted to exchange controllers while alone and, contrary to the labeling, without contacting the hospital first. Another five (5) patients (0.2% of the patient population) experienced temporary loss of consciousness or other symptoms of hypoperfusion while exchanging Pocket System Controllers. Thoratec's investigations of these reports have not revealed any failure of the devices to meet specifications or deficiencies in quality control procedures.

Thoratec's analysis has shown that eight out of nine (8/9) of the events occurred in patients who were converted to the Pocket System Controller after being originally trained on the EPC System Controller at the time of their HeartMate II LVAS implant. The risk of serious injury or death when exchanging Pocket System Controllers is likely associated with the inability of the patient and/or caregiver to make a complete connection between the driveline and the Pocket Controller in a timely manner. For newly implanted patients, training on the HeartMate II LVAS is quite intensive over the course of several weeks between implantation and discharge from the hospital. However, patients who are converted from the EPC System Controller to the Pocket System Controller typically have only a relatively short period of training on the new controller during outpatient clinic visits. These patients may not have received adequate training regarding the differences between the two controllers, especially differences related to connection of the driveline.