California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Thoratec LLC HeartMate

Recall Date			
08/13/25	Brand Name: HeartMate Product Name: Mobile Power Unit, AC Power Cord Model/Catalog Number: 107760 Software Version: N/A Product Description: The HeartMate 3" Left Ventricular Assist System (LVAS) is a set of equipment and materials that together comprise a medical device designed to provide therapeutic benefit to those affected with advanced heart failure. In service, the LVAS assumes some or all of the workload of the left ventricle, thereby restoring the patient's systemic perfusion while palliating the underlying pathology. The LVAS features a Left Ventricular Assist Device (LVAD), a blood pump intended for long-term implantation in such patients, an extracorporeal Controller, plus all of the features, controls, attachments, interfaces, power sources, supporting equipment, labeling, and tools required to achieve the desired therapeutic benefit. The HeartMate II Left Ventricular Assist System is an axial-flow, rotary ventricular assist system that generates flows up to 10 liters per minute (lpm). One end of the Left Ventricular Assist Device is attached to the apex of the left ventricle; the other end of the device connects to the	Thoratec LLC	Due to misaligned V-Lock feature on the Mobile Power Unit power cords, which prevents the locking mechanism from properly engaging with the Mobile Power Unit and may cause unintended disconnect.

	ascending aorta. The Left Ventricular Assist Device diverts blood from the weakened left ventricle and propels it to the aorta. A small external computer, the System Controller, monitors system operation. A driveline, which passes through the patient s abdomen, connects the implanted pump to the System Controller. The system is powered by a Power Module or Mobile Power Unit (MPU) that is connected to an AC electrical outlet, or by two HeartMate 14 Volt Lithium-Ion batteries. The LVAS may be used in any of two configurations. First, line power may be utilized through the Power Module or the Mobile Power Unit (MPU) to run the LVAD indefinitely, convenient for sedentary or sleeping periods. Second, portable Battery power may be utilized for limited periods, convenient for active periods. The MPU AC power cord is distributed either as part of the complete MPU device package or as a standalone accessory. (Labeling - Attachments E1 to E6) Component: Yes, the AC Power Cord is a component of the Mobile Power Unit		
08/13/25	Brand Name: HeartMate Product Name: Mobile Power Unit Model/Catalog Number: 107754 Software Version: N/A Product Description: The HeartMate 3" Left Ventricular Assist System (LVAS) is a set of equipment and materials that together comprise a medical device designed to provide therapeutic benefit to those affected with advanced heart failure. In service, the LVAS assumes some or all of the workload of the left ventricle, thereby restoring the patient's systemic perfusion while palliating	Thoratec LLC	Due to misaligned V-Lock feature on the Mobile Power Unit power cords, which prevents the locking mechanism from properly engaging with the Mobile Power Unit and may cause unintended disconnect.

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	the underlying pathology. The LVAS features a Left Ventricular Assist Device (LVAD), a blood pump intended for long-term implantation in such patients, an extracorporeal Controller, plus all of the features, controls, attachments, interfaces, power sources, supporting equipment, labeling, and tools required to achieve the desired therapeutic benefit. The HeartMate II Left Ventricular Assist System is an axial-flow, rotary ventricular assist system that generates flows up to 10 liters per minute (lpm). One end of the Left Ventricular Assist Device is attached to the apex of the left ventricle; the other end of the device connects to the ascending aorta. The Left Ventricular Assist Device diverts blood from the weakened left ventricle and propels it to the aorta. A small external computer, the System Controller, monitors system operation. A driveline, which passes through the patient s abdomen, connects the implanted pump to the System Controller. The system is powered by a Power Module or Mobile Power Unit (MPU) that is connected to an AC electrical outlet, or by two HeartMate 14 Volt Lithium-Ion batteries. The LVAS may be used in any of two configurations. First, line power may be utilized through the Power Module or the Mobile Power Unit (MPU) to run the LVAD indefinitely, convenient for sedentary or sleeping periods. Second, portable Battery power may be utilized for limited periods, convenient for active periods. The MPU AC power cord is distributed either as part of the complete MPU device package or as a standalone		

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	accessory. Component: Yes, the MPU is a component of the HeartMate 3 and HeartMate II Left Ventricular Assist Systems.		

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot Code: US Model No 107760; UDI-DI 05415067038258,	53 Worldwide	June 2025 and prior.
I	Lot Code: US Model No 107754; UDI-DI 05415067038234	604 Worldwide	June 2025 and prior.

For additional information, please visit the FDA Website (Model No 107760) and (Model No 107754) .

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