



State of California—Health and Human Services Agency
California Department of Public Health



Food and Drug Branch – Device Recalls

California Device Recall Information Sheet

Thoratec Corp. Recalls Heartmate Ventricular Assist System For Extrinsic Outflow Graft Obstruction

Recall Date	Product Description	Recalling Firm	Recall Reason
3/27/2024	<p>Heartmate 3 Left Ventricular Assist System (Lvas)</p> <p>1. HeartMate 3 Sealed Outflow Graft with Bend Relief, Investigational Device Exemption (IDE) 2. HeartMate 3 Sealed Outflow Graft with Bend Relief, US 3. HeartMate 3 Sealed Outflow Graft with Bend Relief, OUS 4. HeartMate 3 LVAS Implant Kit, IDE 5. HeartMate 3 LVAS Implant Kit, US 6. HeartMate 3 LVAS Implant Kit, OUS</p> <p>HeartMate 3 Left Ventricular Assist System: The HeartMate 3 LVAS is designed to provide therapeutic benefit to those affected with advanced heart failure. The LVAS assumes some or all of the workload of the left ventricle. The LVAS features a Left Ventricular Assist Device (LVAD), a blood pump intended for long-term implantation in such patients, an extracorporeal Controller, plus supporting equipment.</p>	<p>THORATEC CORP. Pleasanton, California</p>	<p>Observed outflow graft deformation known as Extrinsic Outflow Graft Obstruction (EOGO) associated with Left Ventricular Assist System.</p>

<p>3/27/2024</p>	<p>Heartmate II Left Ventricular Assist System (Lvas)</p> <p>1. HeartMate II Sealed Outflow Graft with Bend Relief REF 103393 2. HeartMate II LVAS Implant Kit, US REF 106015 3. HeartMate II LVAS Implant Kit, OUS REF 106016 Update (February 14, 2024) HeartMate II Left Ventricular Assist System (LVAS): 1. HeartMate II LVAS Implant Kit, OUS REF 102139 2. HeartMate II LVAS Implant Kit, US REF 1355 3. HeartMate II LVAS Implant Kit (with RSOC Controller), US REF 103695 4. HeartMate II LVAS Implant Kit (with RSOC Controller), OUS REF 103693 5. HeartMate II LVAS Implant Kit (with Sealed Graft), US REF 104911 6. HeartMate II LVAS Implant Kit (with Sealed Graft), OUS REF 104912 7. HeartMate II LVAS Implant Kit (Used for pump exchange, No Graft) REF 107801 8. HeartMate II LVAS Implant Kit, (EPC), CANADA REF 103695-CAN 9. HeartMate II LVAS Implant Kit (with Sealed Graft), JAPAN REF 104911JPN 10. HeartMate II LVAS Implant Kit (with Pocket System Controller and Sealed Grafts), for geographies outside of US & EU REF 106515OUS</p> <p>HeartMate II Left Ventricular Assist System: The HeartMate II LVAS is an axial-flow, rotary ventricular assist system. 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.</p>	<p>THORATEC CORP. Pleasanton, California</p>	<p>Observed outflow graft deformation known as Extrinsic Outflow Graft Obstruction (EOGO) associated with Left Ventricular Assist System.</p>
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Recall Class	Product Identification	Distribution	Affected Dates
I	<p>Heartmate 3 Left Ventricular Assist System (Lvas) HeartMate 3 LVAS Model Numbers: 1. 105581 (IDE, cannot be implanted without a Left Ventricular Assist Device (LVAD)) 2. 105581US (cannot be implanted without a LVAD) 3. 105581INT (cannot be implanted without a LVAD) 4. 106524 (IDE) 5. 106524US 6. 106524INT UDI-DI codes: HeartMate 3 LVAS: 1. N/A (IDE) 2. 00813024013266 3. 00813024011675 4. N/A (IDE) 5. 00813024013297 6. 00813024011712 Serial Numbers: For Model 106524 US MLP-000991 to MLP-0187</p>	22663 Units Worldwide	February, 2024 and prior
I	<p>Heartmate II Left Ventricular Assist System (Lvas) HeartMate II LVAS Model Numbers: 1. 103393 (cannot be implanted without a LVAD) 2. 106015 (US) 3. 106016 (OUS) Update (February 14, 2024) HeartMate II LVAS: 1. 102139 (OUS), includes Unsealed Outflow Graft with Bend Relief 2. 1355 (US), includes Unsealed Outflow Graft with Bend Relief 3. 103695 (US), includes Unsealed Outflow Graft with Bend Relief 4. 103693 (OUS), includes Unsealed Outflow Graft with Bend Relief 5. 104911 (US) 6. 104912 (OUS) 7. 107801 (US), does not include Outflow Graft 8. 103695-CAN, includes Unsealed Outflow Graft with Bend Relief 9. 104911JPN 10. 106515OUS UDI-DI codes: HeartMate II LVAS: 1. 00813024010807 2. 00813024011224 3. 00813024011231 Update (February 14, 2024) HeartMate II LVAS: 1. N/A 2.</p>	2240 Units Worldwide	February, 2024 and prior

	00813024010005 3. 00813024010616 4. 00813024010623 5. 00813024011170 6. 00813024010821 7. 00813024011996 8. N/A 9. 00813024011682 10. 00813024011682 Serial Numbers: US VAD-0357 to VAD-9940		
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For additional information, please visit the FDA website [HeartMate 3](#), [HeartMate II](#)

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