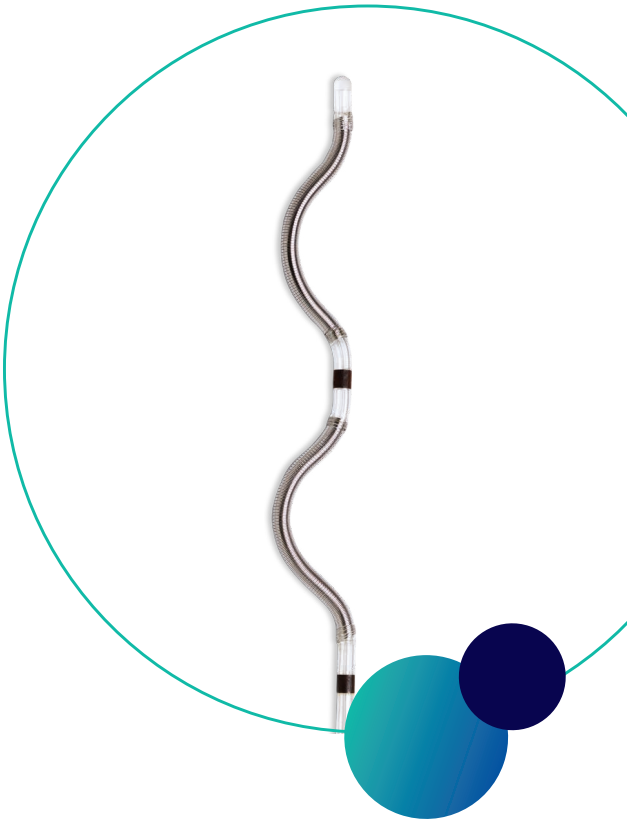
Medtronic

Epsila EV™ MRI SureScan™

Model EV2401



Extravascular quadripolar lead with shaped passive fixation, designed for sensing, cardioversion, defibrillation, and pacing therapies.

Product specifications

MR Conditional†

MR	1.5T 3T

†Refer to the MRI Technical manual for complete MR conditions for use.

Physical characteristics

Type	Quadripolar
Position	Anterior mediastinum
Fixation	Shaped passive fixation
Length	52 cm, 63 cm
Connector	
Type	EV4-LLHH
Length (distal end to proximal end)	24.3 mm
Diameter	3.2 mm
Materials	
Conductors	MP35N (silver cored) composite cables
Insulation	Polyurethane, ETFE
Overlay	Polyurethane
Ring electrodes (pace, sense)	Titanium nitride coated platinum iridium
Coil electrodes (defibrillation)	Platinum iridium, tantalum
Connector Pin	MP35N

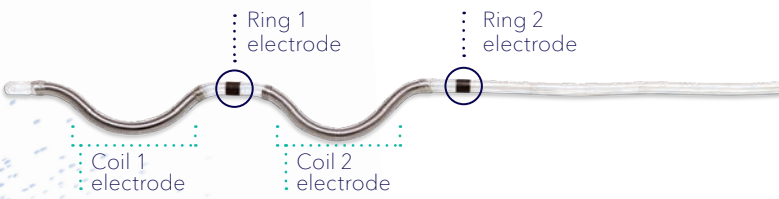
Conductor resistances	
Pacing (unipolar)	1.5 Ω (52 cm, 63 cm) (max)
Defibrillation	1.5 Ω (52 cm, 63 cm) (max)
Electrode Surface Areas	
Coil 1 and Coil 2	281 mm^2 each
Ring 1 and Ring 2	23.8 mm^2 each
Diameters	
Lead body	2.9 mm (8.7 Fr)
Tip	3.0 mm
Lead introducer (recommended size)	3.0 mm (9.0 Fr)

Respective electrode distances

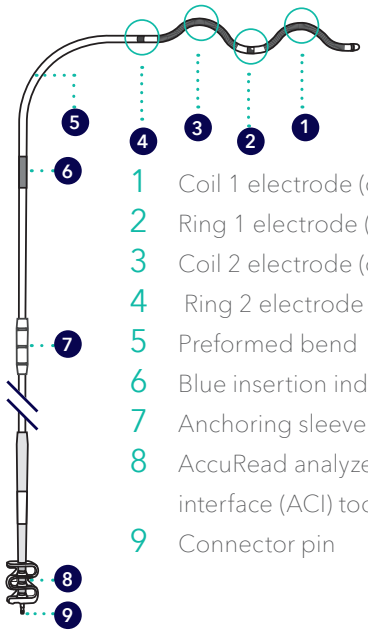
Coil 1 to Ring 1	4.3 mm
Ring 1 to Coil 2	4.3 mm
Coil 2 to Ring 2	5.0 mm

Pacing vectors

Cathode (-)	Anode (+)
Ring 1	Ring 2
Ring 1	Coil 2
Coil 2	Coil 1



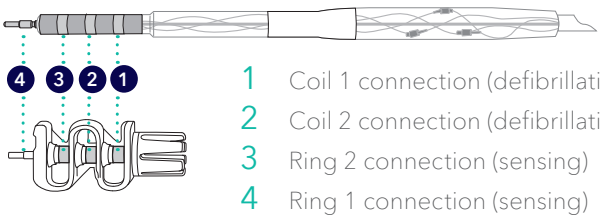
The Medtronic Epsila EV Model EV2401 lead is an extravascular quadripolar lead with shaped passive fixation, designed for sensing, cardioversion, defibrillation, and pacing therapies. The lead has been evaluated for use in the magnetic resonance imaging (MRI) environment. All lead lengths for this lead model are MR Conditional.



1 Coil 1 electrode (defibrillation)
2 Ring 1 electrode (sensing)
3 Coil 2 electrode (defibrillation)
4 Ring 2 electrode (sensing)
5 Preformed bend
6 Blue insertion indicator
7 Anchoring sleeve
8 AccuRead analyzer cable interface (ACI) tool
9 Connector pin

Medtronic EV4 connector

The EV4 connector is a Medtronic proprietary design, not an industry standard. No claims of safety and efficacy can be made with regard to devices that are not labeled as EV4 by Medtronic.



1 Coil 1 connection (defibrillation)
2 Coil 2 connection (defibrillation)
3 Ring 2 connection (sensing)
4 Ring 1 connection (sensing)

Brief Statement
Epsila EV™ MRI SureScan™ Lead Model EV2401
Indications: The Epsila EV™ MRI SureScan™ Model EV2401 extravascular lead is indicated for use in the anterior mediastinum for pacing therapies, cardioversion, and defibrillation when an extravascular implantable cardioverter defibrillator is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias. For more information, refer to the product documentation supplied with the extravascular implantable cardioverter defibrillator, Aurora EV-ICD™ MRI SureScan™ Model DVEA3E4.
MR Conditions for Use: The Aurora EV-ICD MRI SureScan system is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MR conditions for use. A complete SureScan system is required for use in the MR environment. Before performing an MR scan, refer to the MRI technical manual for MRI-specific warnings and precautions. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned. A complete SureScan system includes a SureScan extravascular ICD device (Model DVEA3E4) with a SureScan extravascular lead (Model EV2401). To verify that components are part of a SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan.
Contraindications: The Epsila EV MRI SureScan Model EV2401 lead is contraindicated for any application that is not specified in the Indications.
Warnings and Precautions: It is important to read the Aurora EV-ICD MRI Technical Manual before conducting an MRI scan on a patient with an implanted SureScan system. The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine. When programmed to On, MRI SureScan operation disables arrhythmia detection and all user-defined diagnostics. Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan system.
Patients and their implanted systems must be screened to meet the following requirements for MRI: no implanted lead extenders, lead adaptors or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; and the Sure Scan device must be operating within the projected service life; the device does not provide pacing therapy when SureScan mode is programmed On. Do not scan pacemaker-dependent patients. MRI scans during the lead maturation period have not been prospectively studied by Medtronic and are not recommended. If scanning a patient with multiple devices, ensure all devices meet the MRI labeling conditions.
Use only the Epsila EV MRI SureScan Model EV2401 extravascular lead with a Medtronic EV4 implantable cardioverter defibrillator system. The known potential adverse consequences of using any other combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection. All can present serious risks for adverse events to the patient. The EV4 connector is a Medtronic proprietary design, not an industry standard. No claims of safety and efficacy can be made with regard to devices that are not labeled as EV4 by Medtronic.
Use of the EV2401 lead has not been evaluated in patients who have undergone a prior sternotomy. Performing a sternotomy on a patient with an implanted lead has not been evaluated.
Do not implant the EV2401 lead using any tools other than the Medtronic tunneling tools designed for implanting the extravascular ICD system.
Potential Adverse Events: Implant and usage of this lead may result in adverse events, which may lead to injury, death, or other serious adverse reactions. Potential adverse events include, but are not limited to, acute tissue trauma, allergic reaction, bradyarrhythmia, cardiac arrest, cardiac inflammation, cardiac perforation, cardiac tamponade, death, discomfort, dizziness, dyspnea, erosion, extracardiac stimulation, fever, hematoma, hemorrhage, hemothorax, hospitalization, inappropriate shock, infection, insulation failure, lead abrasion, lead fracture, lead migration or dislodgement, lethargy, mental anguish, organ damage (liver, mammary arteries, diaphragmatic arteries), palpitations, pericardial effusion, pneumothorax, return of cardiac symptoms, syncope, tachyarrhythmia, toxic reaction, and wound dehiscence.
Potential MRI adverse events include the following: lead electrode heating resulting in tissue damage near the lead electrodes or patient discomfort or both; spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan mode is programmed to On; device heating resulting in tissue damage in the implant pocket or patient discomfort or both; MR-induced muscle stimulation resulting in patient discomfort; damage to the device or lead causing the system to fail to detect or treat irregular heartbeats or causing the system to treat the patient's condition incorrectly; damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer; and movement or vibration of the device or leads resulting in dislodgment.
See the Aurora EV-ICD MRI SureScan Technical Manual before performing an MRI Scan and the Epsila EV lead manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. Refer to the Medtronic Manual Library website www.medtronic.com/manuals. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com or www.mrisurescan.com.
Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

Printed in USA.

UC202103594 EN 09/2023