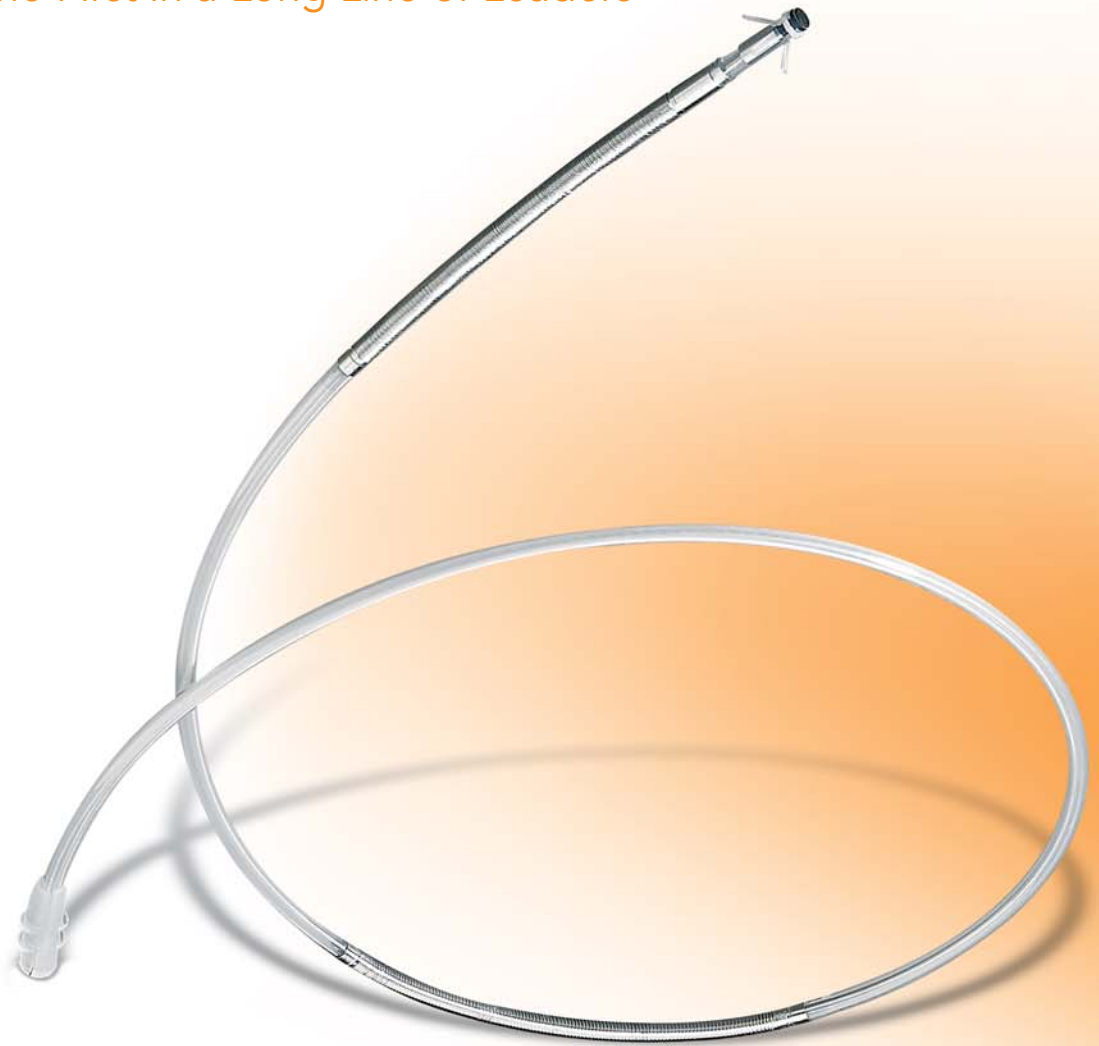


Isoline™ 2CT-5, 2CT-6

Tined Fixation Defibrillation Leads

The First in a Long Line of Leaders

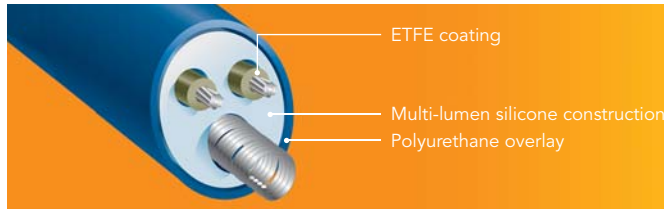


Isoline™ 2CT-5, 2CT-6

ISOLINE 2CT5 (58 CM) IJ26U
ISOLINE 2CT6 (65 CM) IJ23U

Tined Fixation, Dual Coil, Flexible Lead Body, Steroid

- Abrasion resistant¹
- Isodiametric structure
- 7.8F lead body diameter
- Dual Coil
- Steroid Eluting
- Two Lengths: 58 cm and 65 cm



Electrical Performance	Pacing			Defibrillation
	Pacing Threshold	Impedance	Sensing Threshold	Shock Impedance
	0.4 V	658Ω	13.7 mV	43Ω

Internal clinical validation ISOLINE 2CT, nominal values at implant

Model	2CT-5	2CT-6
General characteristics	Endocardial Defibrillation Lead	
Type	Endocardial Defibrillation Lead	
Length	58 cm	65 cm
Fixation	Tines (passive)	
Sensing	Integrated	
Electrode spacing	Tip to RV coil Tip to SVC coil	11 mm 180 mm
Pacing electrode	Material	Carbon
	Area	2 mm ²
Steroid collar	Material	Silicone + DSP**
	Quantity of steroid	< 1.0 mg of DSP**
Pacing conductor	Material	MP35N
	Distal resistance	< 120 ohms
Defibrillation electrode	Material	Platinum iridium
	Area	RV Coil : 600 mm ² SVC Coil : 770 mm ²
Defibrillation conductor	Material	Ag composite DFT
	Defibrillation resistance	< 10 ohms
Lead body	Diameter	7.8 F
	Insulation	Polyurethane / Silicone / ETFE*
Terminal pins	Standards	IS-1 and DF-1
	Material	Stainless steel
Introducer	Diameter without guidewire	9.5 F
	Diameter with guidewire	11 F

Nominal numeric values

¹Results in an internal study demonstrate that a similar lead with the same polyurethane overlay, UW28D is at least 201 times more resistant to abrasion in this model than the non-polyurethane coated UC28D lead (465179 / 2312 = 201).

* Ethylene Tetrafluoroethylene

** Dexamethasone Sodium Phosphate

Indications: ISOLINE 2CR-5/6 and 2CT-5/6 leads are indicated for use with ELA Medical implantable defibrillators. Indications for use of a defibrillator are included in the defibrillator physician's manual.

Contraindications: Use of ISOLINE 2CR-5/6 and 2CT-5/6 leads are contraindicated for those patients with tricuspid valvular disease or any type of tricuspid replacement heart valve (mechanical or tissue). Do not implant in patients for whom < 1.0 mg of dexamethasone sodium phosphate (DSP) is contraindicated. Contraindications relative to the use of a defibrillator are included in the defibrillator physician's manual.

Warnings: Properly ground any line-powered equipment used near the patient. Electrosurgical units (e.g. electrocautery) should not be used near an ICD or its associated leads. Currents generated from electrosurgical devices may cause permanent loss of output, induce ventricular fibrillation, or reset programmed parameters in the ICD. If using electrocautery is unavoidable, however, program the Therapy parameters to "Off" and be sure the electrocautery discharge does not make direct contact with the ICD or leads. Following electrocautery, determine the functional integrity of the circuitry and programming. Do not resterilize the lead if sterility is compromised. Return damaged packages to ELA Medical. The ISOLINE Models 2CR and 2CT series leads are for one-time use only. Do not implant an explanted lead in another patient. Do not kink the lead. Do not attempt to curve the stylet when it is in the lead. Do not immerse the lead in mineral oil prior to implant. Do not attempt to alter the lead in any way. Use only the appropriate stylets provided by the manufacturer.

Side Effects: Adverse events observed with Isoline 2CT were open RV continuity and suspicion of RV lead dislodgement or migration and open SVC continuity and oversensing. Adverse events observed with Isoline 2CR lead were lead dislodgement or migration, RV oversensing and pericardial effusion.

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