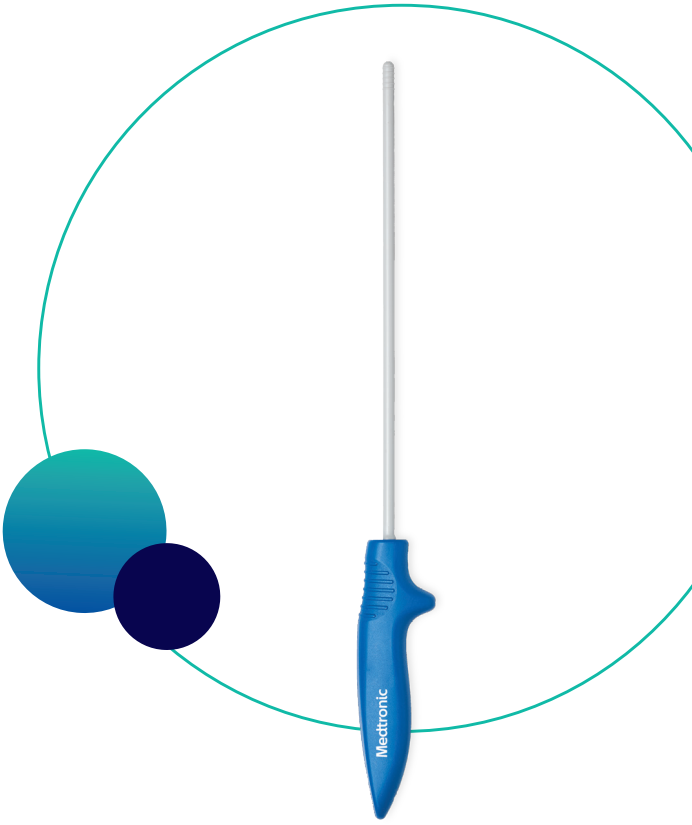
Medtronic

Epsila EV™ transverse tunneling tool

Model EAZ201

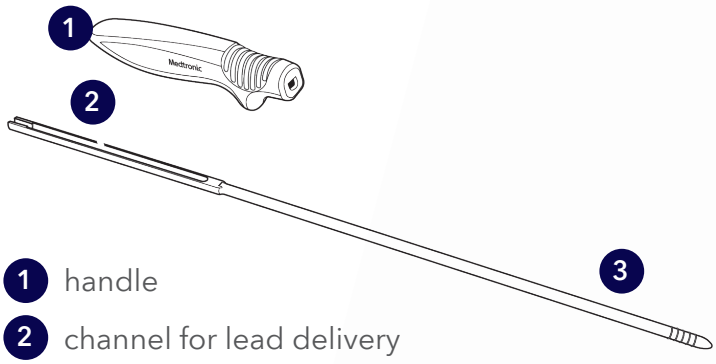


The Medtronic Epsila EV Model EAZ201 transverse tunneling tool is designed to deliver the proximal portion of an extravascular lead to the device pocket during implant of an extravascular implantable device system.

Product specifications

The transverse tunneling tool consists of the following components:

1 handle
1 tunneling rod



1. handle
2. channel for lead delivery
3. tunneling rod

Physical characteristics

Length	
Overall length	36.1 cm
Tunneling length	22.9 cm
Material	
Handle	Polycarbonate
Tunneling rod	Polyetherimide

This tool is for single use only.

Brief Statement
Epsila EV™ EAZ101 Sternal and Epsila EV™ EAZ201 Transverse Tunneling Tools for implanting the Aurora EV-ICD™ System

Indications
The Epsila EV™ Model EAZ101 sternal tunneling tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.
The Epsila EV™ Model EAZ201 transverse tunneling tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

Contraindications
The Epsila EV Model EAZ101 sternal tunneling tool is contraindicated for use in patients with a prior sternotomy.
The Epsila EV Model EAZ201 transverse tunneling tool is contraindicated for any application that is not specified in the Indications.

Warnings and Precautions
The tunneling tools have not been tested for use with non-Medtronic products or for pediatric use.
Use of the EAZ201 transverse tunneling tool has not been evaluated in patients who have undergone a prior sternotomy.

Potential Adverse Events or Potential Complications
Potential adverse events associated with the use of these tunneling tools include, but are not limited to, acute tissue trauma, allergic reaction, cardiac perforation, cardiac tamponade, death, discomfort, hematoma, hemorrhage, hemothorax, infection, organ damage (liver, mammary arteries, diaphragmatic arteries, pain, pericardial effusion, pericarditis, pneumothorax, and seroma.

See the device manuals 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

UC202103596 EN 09/2023