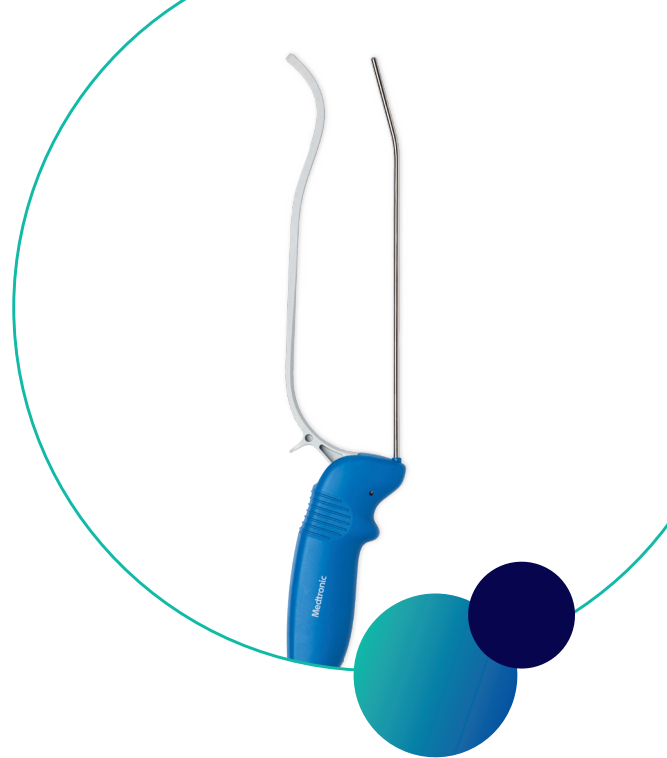


# Medtronic

## Epsila EV™ sternal tunneling tool

Model EAZ101

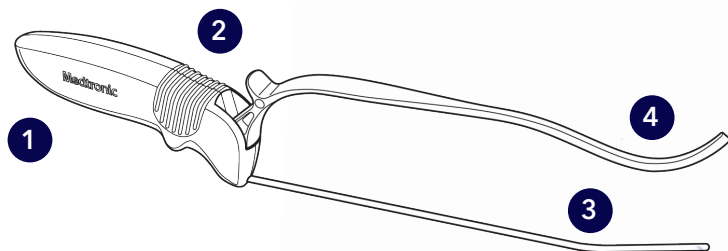
The Medtronic Epsila EV Model EAZ101 sternal tunneling tool is designed to deliver an introducer to place an extravascular lead into the anterior mediastinum during implant of an extravascular implantable device system.



### Product specifications

The sternal tunneling tool consists of the following components:

- 1 A **handle**.
- 2 A **thumb tab** that can be used to raise and lower the external guide.
- 3 A **stainless-steel tunneling rod** that delivers an introducer to the anterior mediastinum. The tunneling rod has a preformed bend and is malleable to accommodate patient anatomy.
- 4 An **external guide** that remains above the skin and indicates the distance and direction of the tunneling rod. The external guide is hinged and removable to accommodate physician preference and patient anatomy.



### Physical characteristics

#### Length

Overall length 35.5 cm

Tunneling length 22.3 cm

Tunneling rod diameter 3.0 mm (9 Fr)

#### Material

Handle Polycarbonate

Tunneling rod 304 stainless steel

External guide Acrylonitrile butadiene styrene (ABS)

#### Recommended introducer

Diameter 3.0 mm (9 Fr)

Length 19.13 cm

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](http://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](http://www.medtronic.com) or [www.mrisurescan.com](http://www.mrisurescan.com).

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

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UC202103595 EN 09/2023