



Edwards Dilator Kit

Instructions for Use

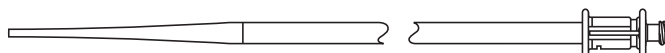
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Please verify that you have the latest version of the instructions for use prior to using the device by visiting <http://THVIFU.edwards.com> or by calling 1.800.822.9837. In order to access the instructions for use, an IFU Code will be required.

1.0 Device Description

The Edwards Dilator Kit is a set of flexible, atraumatic dilators to allow for smooth vessel dilation. The kit contains multiple stepped dilators with hydrophilic coating and tapered distal segments. Each dilator is 0.035" (0.89 mm) guidewire compatible.

THV113



Model	Dilators
9100DKS	16F (5.3 mm), 18F (6.0 mm), 20F (6.7 mm), and 22F (7.3 mm)

2.0 Indications

The Edwards Dilator Kit is intended for use in dilation of the peripheral vasculature.

3.0 Contraindications

This product is contraindicated for tortuous or calcified vessels that would prevent safe entry of a dilator.

4.0 Warnings

The devices are designed, intended, and distributed for single use only. **Do not re-sterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

The Edwards Dilator Kit must be used with a compatible 0.035" (0.89 mm) guidewire to prevent vessel injury.

5.0 Precautions

Do not use the dilator kit if the packaging sterile barriers and any components have been opened or damaged.

6.0 Potential Adverse Events

Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, stroke, infection, and/or death.

7.0 Directions for Use

1. Prime and flush the guidewire lumen of the dilators with heparinized saline. Hydrate the length of each dilator.
2. Using standard catheterization techniques, gain access to the vessel and insert an exchange length 0.035" (0.89 mm) guidewire.
3. Dilate the vessel using the Edwards Dilator Kit by advancing increasing sized dilators over the guidewire until the appropriate diameter is reached. Advance the dilator over the guidewire while following its progression on fluoroscopy.

8.0 How Supplied

The Edwards Dilator Kit is supplied pouched and sterilized by ethylene oxide.

9.0 Storage

The Edwards Dilator Kit should be stored in a cool, dry place.

10.0 Device Disposal

Used dilators may be handled and disposed of in the same manner as hospital waste and biohazardous materials. There are no special risks related to the disposal of these devices.



Edwards

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