Edwards

PERIPHERAL GUIDEWIRE

Instructions for Use

CAUTION: Federal law (U.S.A.) restricts this device to sale by, or on the order of, a physician.

1.0 DESCRIPTION

Edwards Lifesciences peripheral guidewires are J-Tip, .038 in (0.97 mm), stainless steel guidewires available in various lengths and diameters.

PIKV, VEN210: .038 in (0.97 mm) x 210 cm, (J-tip, 3 mm)

PIKA, ART100: .038 in (0.97 mm) x 100 cm, (J-tip, 3 mm)

Each Edwards Lifesciences device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

2.0 INTENDED USE

The Edwards Lifesciences guidewire is intended for use in surgical procedures which require a guidewire to access peripheral vessels.

3.0 CONTRAINDICATIONS FOR USE

This device is not intended for use other than as indicated and should not be used when any physical impairment would contraindicate its use.

4.0 WARNINGS AND PRECAUTIONS

Supplied sterile and non-pyrogenic in undamaged package. Do not use if device shows signs of damage (i.e., cuts, kinks, crushed areas, leakage), or if package is damaged or open as this may indicate compromised sterility and/or product damage.

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

Products are known to contain phthalates, which may be found in device materials containing plasticizers such as DEHP and BBP. High exposure to such phthalates during medical treatments in children and pregnant or nursing women may raise a concern. A review of available data and literature supports the conclusion that the benefits outweigh the overall residual risk.

The device is intended for transient use only (< 60 min). There are no data to support the function and performance of the device beyond six hours of use.

Proper surgical procedures and techniques are the responsibility of the medical profession. Described procedures are provided for informational purposes only. Each physician must determine the appropriate use of this device for each patient based on medical training, experience, the type of procedure employed, and the benefits and risks associated with device use.

Dispose of used product in accordance with established hospital protocols for biohazards to minimize risk of exposure.

Do not use the guidewire to navigate blood vessels in the central circulatory system.

5.0 DIRECTIONS FOR USE

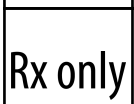
To insert, employ a cutdown, Seldinger, or other appropriate sterile technique.

Made in the U.S.A.

Symbol Legend

	English
	Single use
	Sterilized Using Ethylene Oxide
	Non-pyrogenic
	Do not use if package is damaged
	Lot Number

	English
	Use By
	Consult instructions for use
	Caution
	Quantity

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

Note: Not all symbols may be included in the labeling of this product.

EC REP

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