

**Indications for Use:** ILUMIEN Therapy Guidance System is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. ILUMIEN System will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

## PRODUCT BENEFITS

- Combine the functional and anatomical modalities of Fractional Flow Reserve (FFR) and Optical Coherence Tomography (OCT)
- Move between FFR and OCT modalities with one touch
- Wireless FFR setup in one or multiple labs
- Easy on-screen guide simplifies ILUMIEN FFR and OCT procedures with a new seamless user interface
- The flexibility and cost efficiency of a mobile unit
- Integrated case storage and easy patient ID retrieval
- Ability to perform FFR measurements with optional wireless Wi-Box™, PressureWire™ Aeris™ and cables

## GENERAL PRODUCT INFORMATION

The compact, mobile console contains all the working elements of the ILUMIEN Therapy Guidance System, including:

- ILUMIEN proprietary imaging engine, custom PC software and wireless receivers to perform FFR measurements
- Two monitors (17" and 19") plus remote video output for multiple sightlines
- Keyboard or mouse click control of system and catheter
- 22x CD/DVD±RW dual layer DVD-RAM drive for faster image management
- Large hard drive for ample data storage
- Integrated drive-motor and optical controller (DOC)

## TECHNICAL SPECIFICATIONS

### ILUMIEN

Size mm/in: 1430 (h) x 471 (w) x 683 (d)/56.3 (h) x 18.5 (w) x 27 (d)

### DRAGONFLY

Usable length: 135 cm  
Outer diameter: 2.7 F (distal)  
Wire lumen: 0.014"

### PRESSUREWIRE AERIS

#### PressureWire Aeris

Operating pressure: -30 to +300mmHg  
Accuracy: ±1 mmHg plus ±1% of reading (-30 to 50mmHg)  
±3% of reading (50 to 300mmHg)

#### AO pressure via Wi-Box to Ilumien

Operating pressure: -30 to +300mmHg  
Accuracy: ±1 mmHg or ±1% of reading whichever greatest

#### AO pressure via Wi-Box to hemodynamic recording system

Direct galvanic connection  
Max Pressure shift: <2mmHg

#### Radio specification

Frequency range: 2.4000-2.4835GHz  
Type: Frequency hopping spread spectrum (FHSS)  
Range: 0-4m  
Delay time: <20ms

## IMAGING PARAMETERS

Maximum frame rate: 100 fps  
Nominal pullback speed: 20 mm/sec  
# of lines per frame: 500  
Scan diameter: 10 mm  
Axial resolution: 15 µm



# Ordering Information

## Ilumien Therapy Guidance System

Contents: OCT Imaging Engine, St. Jude Medical Cardiology Application Software Package, Drive-motor & Optical Controller, ILUMIEN Custom Computer, Operator's Monitor - High Resolution LED 17", Physician's Monitor - High Resolution LED 19", Integrated Mobile Console, Keyboard & Mouse, Accessory Tools, Operator's Manual, and Essential's Guide (1 unit per box).

Reorder Number	Description
900-700-00	ILUMIEN Therapy Guidance System



## PressureWire Aeris

(5 units per box)

Reorder Number	Product
12056	PressureWire Aeris, 175 cm



## Wireless Wi-Box\*

(1 unit per box)

Reorder Number	Product
C12783	Wireless Wi-Box interface unit

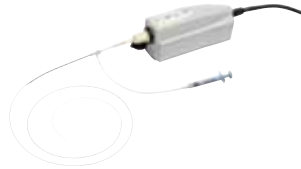
\*Cables (for initial installation) are available separately. Please refer to your St. Jude Medical product catalog. Note: One wireless Wi-Box is needed for each cath lab where ILUMIEN is used.



## Dragonfly™ Imaging Catheter

Kit Contains: Dragonfly Imaging Catheter, Sterile DOC Cover, Sterile 3 ml Syringe (1 unit per box)

Reorder Number	Length (cm)	Outer Diameter (distal)	Wire Lumen (in)	Coating
100-100-KT	135	2.7 F	0.014	Hydrophilic



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## For more information visit [www.SJMknowledge.com](http://www.SJMknowledge.com)

An online resource for more detailed information for FFR and OCT clinical information.



**ST. JUDE MEDICAL™**

MORE CONTROL. LESS RISK.

Pending CE mark

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EuroPCR IPN 1436-11