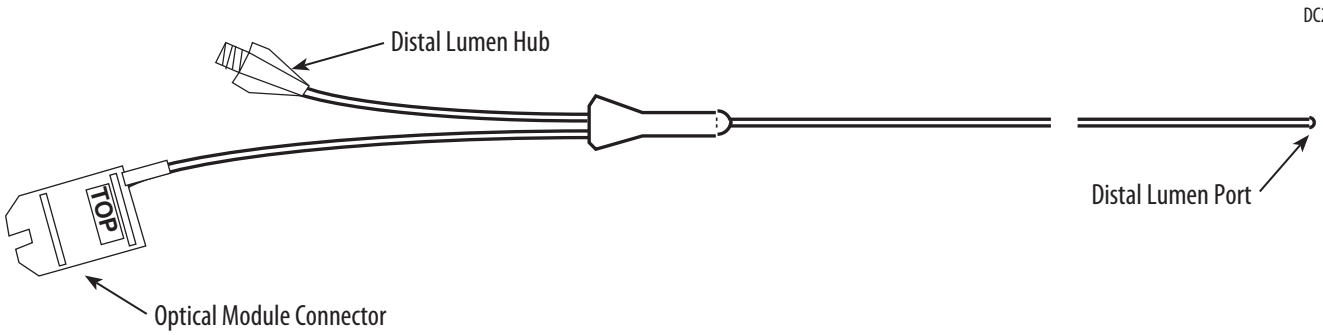
Edwards Lifesciences

Double Lumen Oximetry Catheters: 040F4 and 015F4



Double Lumen Oximetry Catheter

For Single Use Only

Description

Double Lumen oximetry catheters are non-balloon catheters that provide the means for monitoring hemodynamic pressures, taking blood samples, and for continuously monitoring venous oxygen saturation using an Edwards monitoring system and Model OM2 optical module.

Indications

Double Lumen oximetry catheters are indicated for the assessment of a patient's hemodynamic condition through blood sampling, hemodynamic pressure monitoring, and venous oxygen saturation measurement.

Contraindications

Although there are no absolute contraindications to the use of the Double Lumen oximetry catheters, relative contraindications may include patients with recurrent sepsis or a hyper-coagulable state where the catheter could serve as a focus for septic or bland thrombus formation. A patient with a left bundle branch block may develop a right bundle branch block during catheter insertion, resulting in complete heart block. In such patients, the ability for temporary transvenous pacing should be immediately available (or the use of a Swan-Ganz Paceport or Pacing-TD catheter). The use of this catheter is also not recommended in low birth weight infants due to the increased risk of intracranial bleeding.

Warnings

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.

Recommended Equipment

Warning: Compliance to IEC 60601-1 is only maintained when the catheter or probe (Type CF applied part, defibrillation proof) is connected to a patient monitor or equipment that has a Type CF defibrillation proof rated input connector. If attempting to use a third party monitor or equipment, check with the monitor or equipment manufacturer to ensure IEC 60601-1 compliance and compatibility with the catheter or probe. Failure to ensure monitor or equipment compliance to IEC 60601-1 and catheter or probe compatibility may increase the risk of electrical shock to the patient/operator.

Warning: Do not modify or alter the product in any way. Alteration or modification may affect patient/operator safety or product performance.

1. Double Lumen oximetry catheter
2. Edwards monitoring system
3. Model OM2 Optical Module
4. Sterile flush system and pressure transducers
5. Bedside ECG and pressure monitor system

In addition, the following items should be immediately available: antiarrhythmic drugs, defibrillator, and respiratory assist equipment.

Oximeter Setup

Refer to the appropriate operations manual for detailed setup procedures.

1. Connect the optical module to the Edwards monitoring system.
2. Turn on the power switch.
3. Connect the blue optical module connector to the optical module. Make certain that the side of the connector labelled "TOP" is up as it is placed into the optical module.

Calibration

Precaution: *In vitro* calibration cannot be performed with these catheters. For proper calibration, the catheter must be inserted into the patient and an *in vivo* calibration performed (see appropriate operations manual for *in vivo* calibration procedures).

Catheter Preparation

Use aseptic technique.

1. Flush catheter lumen with a sterile solution to assure patency and to avoid introduction of air into the circulation.
2. Connect the catheter distal lumen to the flush system and/or pressure transducers. Ensure that the lines and transducers are free of air.

   Warning: Positioning the distal tip of the catheter in the right atrium or ventricle is NOT recommended (see Complications: Cardiac Perforation).

Insertion Procedure

Double Lumen oximetry catheters can only be introduced through a suitable 4.5F (1.50 mm) introducer (minimum size) with or without the aid of fluoroscopy. Continuous pressure monitoring is recommended during catheter insertion.

Note: Due to decreased pulsatility in the superior vena cava, the Signal Quality Indicator should not be used to assess tip position of these catheters.

1. Under continuous pressure monitoring and fluoroscopy (if desired), gently advance the catheter. Use the depth markings on the catheter body to ensure correct catheter tip position.
2. Verify that the catheter is correctly positioned by X-ray film immediately after insertion.

   Note: The X-ray film should confirm that the catheter tip is parallel to the vessel wall.

Maintenance and Use *in situ*

Note: Infusion of viscous solutions such as whole blood or albumin is not recommended, as they flow too slowly and may occlude the catheter lumen.

1. Keep lumen patent by intermittent flush or continuous, slow infusion with heparinized saline solution or use of a heparin lock.
2. Periodically check lines and transducer domes for air bubbles. Ensure that connecting lines and stopcocks remain tightly fitted.
3. The catheter should remain indwelling only as long as is required by the patient's condition.

   Warning: The incidence of complications increases significantly with indwelling periods greater than 72 hours. Prophylactic anticoagulation and antibiotic protection should be considered in cases with increased risks and long-term catheterization (more than 48 hours).

Specifications

Double Lumen Oximetry Catheter	**040F4**	**015F4**
Usable length (cm)***	40	25
Catheter Body Size	4F (1.33 mm)	4F (1.33 mm)
Minimum Recommended Introducer Size***	4.5F (1.50 mm)	4.5F (1.50 mm)
Lumen Volume		
Distal Lumen (cc)	0.6	0.5
Infusion Rate*		
Distal Lumen (ml/min)	8.5	13
Compatible Guidewire Diameter		
Distal Lumen (in)	0.016	0.016
Distal Lumen (mm)	0.41	0.41
Frequency Response Distortion at 10 Hz		
Distal Lumen	< 3 dB	< 3 dB

All specifications given are nominal values.
* Using normal saline at room temperature, 1 meter (100 cm) above insertion site, gravity drip.
*** Catheter usable length is decreased by 5 cm when used with a 4.5F (1.50 mm) introducer.

MRI Information

MR **MR Safe**

The Double Lumen oximetry catheter is made from nonmetallic, non-conducting, and nonmagnetic materials. Therefore, the Double Lumen oximetry catheter is MR-safe, which is an item that poses no known hazards in all MR environments.

Precaution: The cables which connect the Double Lumen oximetry catheters to monitors do contain metals and must be disconnected prior to performing the MRI procedure. Failure to do so may cause unintentional removal of catheter from patient.

Complications

Thrombosis

Thrombi have been shown to form on the surface of catheters after their insertion into the central circulation. Complications associated with thrombosis may include pulmonary emboli and infarction, and septic phlebitis.

Sepsis/Infection

Positive catheter-tip cultures resulting from contamination and colonization have been reported, as well as incidences of septic and aseptic vegetation in the right heart. Increased risks of septicemia and bacteremia have been associated with blood sampling, infusion of fluids, and catheter-related thrombosis. Preventive measures should be taken to guard against infection (e.g., use of sterile technique, application of topical antibiotic ointment, changing of sterile dressings as indicated by institutional policy, and disinfecting the injection caps before entry with syringe needle), as well as the frequent assessment of the continued need for invasive hemodynamic monitoring.

Cardiac Perforation

Atrial perforation and subsequent pericardial tamponade have been reported. Preventive measures should include verification of catheter tip position by chest X-ray film and noting insertion depth immediately following insertion. Ideally, the catheter tip should be positioned parallel to the vessel wall and no farther than the junction of the superior vena cava and right atrium.

Vessel Perforation

Venous perforation and necrosis of the wall of the vein which can lead to perforation, due to a malpositioned catheter, have been reported. Preventive measures should include verification

of the catheter tip position by chest X-ray film, noting insertion depth immediately following insertion. Ideally, the catheter tip should be positioned parallel to the vessel wall and no farther than the junction of the superior vena cava and right atrium.

Warning: If there is any doubt that the catheter tip may not be intravascular, further steps should be taken to identify the exact location of the catheter tip, see Complications for cardiac perforation and vessel perforation.

Hemorrhage

The use of heparin infusions to maintain the patency of vascular catheters has been associated with germinal matrix-intraventricular hemorrhage in infants with birth weights under 2000 grams.

Other Complications

Central venous pressure catheters have also been associated with pneumothorax, air embolism, catheter embolism, nitroglycerin absorption, hemomediastinum/hydromediastinum, thoraces, and heparin induced thrombocytopenia.

How Supplied

Contents sterile and nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize.

The packaging is designed to avoid crushing of the catheter. It is therefore recommended that the catheter remain inside the package until use.

Storage

Store in a cool, dry place.

Temperature/Humidity Limitations:
0° - 40 °C, 5% - 90% RH

Operating Conditions

Intended to operate under physiological conditions of the human body.

Shelf Life

The recommended shelf life is marked on each package. Storage beyond the recommended time may result in catheter deterioration.

Note: Resterilization will not extend the shelf life.

Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada
(24 hours): 949.250.2222
In the UK: . . . . . 0870 606 2040 - Option 4
In Ireland: . . . . . 01 8211012 Option 4

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

Disposal

After patient contact, treat the device as biohazardous waste. Dispose of in accordance with hospital policy and local regulations.

Prices, specifications, and model availability are subject to change without notice.

Refer to the symbol legend at the end of this document.

Sterilized Using Ethylene Oxide

Symbol Legend

	English		English		English
	Number of Lumens	STERILE	Sterile		MR Unsafe
	Exterior Diameter	STERILE EO	Sterilized Using Ethylene Oxide	MR	MR Safe
cm	Usable Length	STERILE R	Sterilized Using Irradiation		MR Conditional
GW	Recommended Guidewire Size	STERILE	Sterile Using Steam or Dry Heat		Consult instructions for use
	Lumen Size	Rx only	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.		Consult instructions for use
REF	Catalogue Number		Manufacturer		Do not resterilize
I	Minimum Introducer Size		Date of Manufacture		Non-pyrogenic
	Caution	LATEX	Contains or presence of natural rubber latex		Type B Applied Part
	Single use	PHT	Contains phthalates		Type CF Applied Part
#	Quantity	SZ	Size		Do not use if package is opened or damaged.
LOT	Lot Number		No components of this package or the products it contains are made from natural rubber latex or dry natural rubber.		Open
	Use By		Temperature Limitation		Aspirate Balloon -0.5 cc Before Introduction or Withdrawal.
	Inner Diameter		Humidity Limitation	EC REP	Authorized Representative in the European Community
BC	Balloon Capacity	eifu.edwards.com + 1 888 570 4016	Consult Instructions for use on the website eifu.edwards.com		CE conformity marking per European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
	Keep dry	eifu.edwards.com + 1 888 570 4016	Follow Instructions for use on the website eifu.edwards.com		

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

SGNHEMSL8x11.3

Edwards

EC REP

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