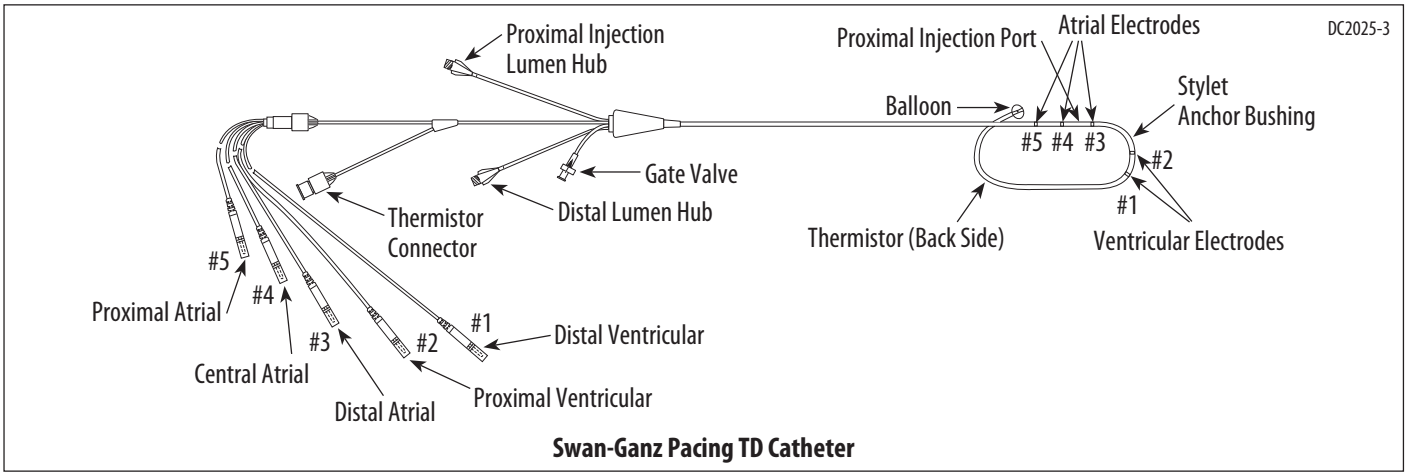
Edwards Lifesciences

Swan-Ganz Pacing-TD Catheter
D200F7, D205F7
D205F7 is not available in EU



Swan-Ganz Pacing TD Catheter

Carefully read these instructions for use and all contained warnings and precautions before using this product.

Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

For Single Use Only

For figures 1 through 6 please refer to page 7.

Concept/Description

Swan-Ganz Pacing-TD catheters serve as diagnostic and therapeutic tools in the management of critically ill patients. The Pacing-TD catheter can perform right atrial, pulmonary arterial, and pulmonary artery occlusion pressure (PAOP, also known as "wedge") measurements; blood sampling; solution infusion; and cardiac output measurements by thermodilution when used with a compatible cardiac output computer. In addition, the Pacing-TD catheter has three atrial and two ventricular electrodes for atrial and ventricular pacing and atrioventricular (A-V) sequential pacing.

The Pacing-TD catheter is available in two models: the standard Model D200F7 and the Model D205F7. For additional clinical flexibility in the smaller anatomy, the electrodes have been moved distally on the Model D205F7.

The Swan-Ganz pacing catheters are recommended for use *in situ* for up to 72 hours.

As part of the insertion procedure this product is used for ECG detection during placement, but is not intended for ECG monitoring.

Indications

The Swan-Ganz Pacing-TD catheter is indicated for atrial, ventricular, or A-V sequential pacing for hemodynamic reasons, overdrive suppression of atrial or ventricular arrhythmias, and diagnosis of complex arrhythmias. Additional indications are for assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions.

The distal (pulmonary artery) port also allows sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction.

Contraindications

Relative contraindications may include patients with either recurrent sepsis, or with hypercoagulable state where the catheter could serve as a focus for septic or bland thrombus formation.

The Pacing-TD catheter is not recommended for use in pacemaker-dependent patients. No absolute contraindications for the use of flow-directed pulmonary artery catheters exist.

However, 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, temporary pacing modes should be immediately available.

Electrocardiographic monitoring during catheter passage is encouraged and is particularly important in the presence of either of the following conditions:

-Complete left bundle branch block, in which the risk of complete heart block is somewhat increased.

-Wolff-Parkinson-White syndrome and Ebstein's malformation, in which the risk of tachyarrhythmias is present.

These products contain metallic components. Do NOT use in a Magnetic Resonance (MR) environment.

Warnings

Air should never be used for balloon inflation in any situation where it may enter the arterial circulation, e.g. in all pediatric patients and adults with suspected right to left intracardiac intrapulmonary shunts.

Bacteria-filtered carbon dioxide is the recommended inflation medium because of its rapid absorption into the blood in the event of balloon rupture within the circulation. Carbon dioxide diffuses through the latex balloon, diminishing the balloon's flow-directed capability after 2 to 3 minutes of inflation.

Do not leave the catheter in a permanent wedge position. Furthermore, avoid lengthy balloon inflation while the catheter is in a wedge position; this occlusive maneuver may result in pulmonary infarction.

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.

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

Cleaning and resterilization will damage the integrity of the latex balloon. Damage may not be obvious during routine inspection.

As part of the insertion procedure this product is used for ECG detection during placement, but is not intended for ECG monitoring.

Precautions

Clinicians using the device should be familiar with the device and understand its applications prior to use.

When handling indwelling leads, the terminal pins or exposed metal (on the product) are not to be touched nor be allowed to contact electrically conductive or wet surfaces.

Failure of a balloon flotation catheter to enter the right ventricle or pulmonary artery is rare, but may occur in patients with an enlarged right atrium or ventricle particularly if the cardiac output is low or in the presence of tricuspid or pulmonic incompetence or pulmonary hypertension. Deep inspiration by the patient during advancement may also facilitate passage.

Insertion

Swan-Ganz catheters can be inserted at the patient's bedside, without the aid of fluoroscopy, guided by continuous pressure monitoring.

Precaution: Pacing TD Catheters are not suitable for placement through the inferior vena cava.

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.

1. Swan-Ganz Pacing-TD catheter
2. Percutaneous sheath introducer and contamination shield
3. Compatible cardiac output computer, injectate probe, and appropriate connecting cable
4. External pulse generator (ventricular demand or A-V sequential)
5. External pulse generator cable adapters
6. Sterile flush system and pressure transducers
7. Bedside pressure monitor system

In addition, the following items should be immediately available if complications arise during catheter insertion: antiarrhythmic drugs, defibrillator, respiratory assist equipment, and temporary pacing equipment.

Preparation

Use aseptic technique

Warning: This catheter requires special techniques for insertion and removal. Electrode dislodgment may result from pulling the catheter out through the percutaneous sheath.

Precaution: Avoid forceful wiping or stretching of the catheter during testing and cleaning as not to break the electrode or thermistor wire circuitry.

1. Flush catheter lumens with a sterile solution to ensure patency and to remove air.
2. Check balloon integrity. Inflate the balloon to the recommended volume and check for major asymmetry and for leaks by submerging in sterile saline or water.
3. Connect the catheter's injectate and pressure monitoring lumens to the flush system and pressure transducers. Ensure that the lines and transducers are free of air.
4. Test the thermistor's electrical continuity before insertion. Connect the catheter to the cardiac output computer and check for a "CATHETER FAULT".

Procedure

The following two procedures are offered as an aid to the physician. The first procedure requires fluoroscopy and the second procedure uses pressure monitoring.

Precaution: In a minority of patients, the possibility exists that adequate thresholds will not be obtained or that capture will be lost. If either occurs, the use of a conventional pacing catheter should be considered.

Note: Due to the unique bend at the location of the ventricular electrodes, the catheter cannot be inserted from the inferior vena cava approach (see **Specifications**). Insertion must be accomplished through the superior vena cava.

1. Insertion Under Fluoroscopy

a. Introduce the catheter into the vein through a sheath introducer using percutaneous insertion using modified Seldinger technique.

b. Gently advance the catheter into the right atrium. Note: When the catheter is near the junction of the right atrium and the superior vena cava of the typical adult patient, the tip has been advanced approximately 40 cm from the right or 50 cm from the left antecubital fossa, or 15 to 20 cm from the subclavian vein.

c. Should the catheter require stiffening during insertion, slowly perfuse the catheter with 5 to 10 ml cold sterile saline or 5% dextrose as the catheter is advanced through a peripheral vessel.

d. Using the syringe provided, inflate the balloon with CO_2 or air to the recommended volume (1.5 ml) printed on the catheter shaft (**Do not use liquid**). Note that an offset arrow on the gate valve indicates the "closed" position.

Warning: Pulmonary complications may result from improper inflation technique. To avoid damage to the pulmonary artery and possible balloon rupture, do not inflate above the recommended volume. Use the volume-limited syringe provided in the catheter package.

Before reinflation with CO_2 or air, completely deflate the balloon by removing the syringe and opening the gate valve. Do not forcefully aspirate with the syringe, as this may damage the balloon. After deflation, reattach the syringe to the gate valve.

Precaution: It is recommended that the provided syringe be re-attached to the gate valve after balloon deflation to prevent inadvertent injection of liquids into the balloon lumen.

e. Advance the catheter in the usual manner until the inflated balloon is wedged in a central pulmonary artery (See page 7, Fig. 2). Deflate the balloon and then pull the catheter back a few centimeters to remove any slack. Avoid lengthy balloon inflation while the catheter is in a wedge position; this is an occlusive maneuver and may result in pulmonary infarction.

Precaution: Catheter looping may occur when excessive length has been inserted, which could result in kinking or knotting (see **Complications**). If the right ventricle is not entered after advancing the catheter 15 cm beyond entry into the right atrium, the catheter may be looping, or the tip may be engaged in the neck of the vein with only the proximal shaft advancing into the heart. Deflate the balloon and withdraw the catheter until the 20 cm mark is visible. Re-inflate the balloon and advance the catheter.

f. Reinflate the balloon and advance the catheter until the ventricular electrodes contact the right ventricular wall, usually in the inflow tract. Deflate the balloon. Figure 3 (on page 7) shows the final catheter position.

g. Determine pacing thresholds. If necessary, manipulate the catheter slightly to obtain good ventricular thresholds (1 or 2 mA). Check for stability of pacing with respiration and adjust catheter position if necessary.

h. Attempt atrial, ventricular, or A-V sequential pacing as required.

2. Insertion Using Pressure Monitoring

a. Insert the catheter and advance to the "wedge" position in the usual manner under continuous pressure monitoring (see paragraphs 1a and 1b). Figure 1 (on page 7) illustrates the characteristic pressure waveforms.

Note: Use of a protective catheter sheath is recommended.

b. Deflate the balloon to verify the presence of a normal pulmonary artery pressure tracing.

c. Reinflate the balloon to determine the minimum inflation volume necessary to obtain a wedge tracing. If a wedge is obtained with less than the maximum recommended volume (see specifications table for balloon inflation capacity), the catheter must be withdrawn to a position where full inflation volume produces a wedge tracing.

Caution: Do not pull the catheter across the pulmonic valve while the balloon is inflated to avoid damage to the valve.

Note: When the catheter is near the junction of the right atrium and the superior or inferior vena cava of the typical adult patient, the tip has been advanced approximately 40 cm from the right or 50 cm from the left antecubital fossa, 15 to 20 cm from the jugular vein, 10 to 15 cm from the subclavian vein, or about 30 cm from the femoral vein.

Note: After deflation, the catheter tip may tend to recoil towards the pulmonic valve and slip back into the right ventricle, requiring that the catheter be repositioned.

Atrial Pacing

d. Connect the "distal atrial" electrode (#3) to the negative pulse generator terminal. Connect the "central atrial" electrode (#4) to the positive terminal.

Note: To facilitate a connection between the catheter and pulse generator, a cable adapter may be required.

e. Adjust the pulse generator output to 0.1 milliamps and the rate to 15% above the patient's heart rate, or to a physiological rate. With the pulse generator turned on, slowly increase the output until atrial pacing occurs (See page 7, Fig. 5). A typical atrial pacing current threshold is 5 milliamps. If atrial pacing does not occur, slowly advance or withdraw the catheter 0.5 cm at a time with the pulse generator operating at 5 milliamps and the balloon deflated.

Note: Diaphragmatic pacing may occasionally occur; it can usually be alleviated by advancing the catheter 0.5 to 1 cm.

f. Check the catheter position once again to make sure it has not been advanced to a permanent wedge position.

Precaution: If atrial and ventricular pacing occur only with the catheter in a permanent wedge position, withdraw the catheter to a pulmonary artery position. In this situation, pacing should not be performed because of the likelihood of pulmonary infarction resulting from the catheter being permanently wedged (see **Complications**).

If using a contamination shield, extend the distal end towards the introducer valve. Extend the proximal end of the catheter contamination shield to desired length, and secure.

Ventricular Pacing

g. Connect the "distal ventricular" electrode (#1) to the negative pulse generator terminal. Connect the "proximal ventricular" electrode (#2) to the positive terminal.

Note: To facilitate a connection between the catheter and pulse generator, a cable adapter may be required.

h. Adjust the external generator R-wave sensitivity to approximately 3 millivolts to avoid competition between the pulse generator's rate and the patient's rate.

i. Repeat steps 2e and 2f to achieve ventricular pacing. Ventricular stimulation at 3 milliamps or less is generally obtainable. Check for adequate sensitivity once pacing is established. Successful ventricular capture is shown in Figure 4 (on page 7).

j. Unused electrode connectors must be capped to prevent their contact with a faulty ground.

A-V Sequential Pacing

k. After achieving atrial and ventricular pacing, connect the two ventricular electrodes to the A-V sequential pulse

generator; attempt pacing. Successful A-V sequential pacing is shown in Figure 6 (on page 7).

Note: To facilitate a connection between the catheter and pulse generator, a cable adapter may be required.

Maintenance and Use *in situ*

1. Keep the catheter tip centrally located in a main branch of the pulmonary artery. Ideally, the catheter tip should be located near the hilum of the lungs. The tip migrates towards the periphery of the lungs during balloon inflation. Therefore, a central location before inflation is important. Keep the tip in a position where a full or near full (1.0 to 1.5 ml) inflation volume is necessary to produce a "wedge" tracing.

2. Anticipate spontaneous catheter tip migration towards the periphery of the pulmonary bed. To avoid possible damage to the pulmonary artery, continuously monitor the catheter tip pressure while the catheter is in place. If a wedge pressure tracing is observed when the balloon is deflated, the catheter should be pulled back to a central pulmonary artery position.

   Spontaneous catheter tip migration towards the periphery of the lung occurs during cardiopulmonary bypass. Partial catheter withdrawal (3 to 5 cm) just before bypass should be considered, as it may help reduce distal migration and prevent permanent catheter wedging postbypass. After termination of bypass, the catheter may require repositioning. Check the distal pulmonary artery tracing before inflating the balloon.

   Precaution: Over a period of time, the catheter tip may migrate towards the periphery of the pulmonary bed and lodge in a small vessel. Damage may occur either by prolonged occlusion or by over-distension of the vessel upon reinflation of the balloon (see Complications).

3. **Reinflation of the balloon while in the pulmonary artery should be performed gradually and with caution while observing the pressure tracing.**

   Note: Inflation is usually associated with a feeling of resistance. On release, the syringe plunger should usually spring back. If no resistance to inflation is encountered, it should be assumed that the balloon has ruptured. Discontinue inflation at once. The catheter may continue to be used for hemodynamic monitoring. However, be sure to take precautions to prevent infusion of air or liquid into the balloon lumen.

4. Inflate the balloon slowly to the **minimum** volume needed to obtain PAOP (never exceeding the recommended volume). If PAOP is obtained at volumes less than 1.0 ml, pull the catheter back to a position at which the full or near full inflation volume (1.0 to 1.5 ml) produces a wedge pressure tracing.

5. Measure pulmonary artery occlusion pressure only when necessary and keep the number of wedge pressure measurements and wedge time to a minimum (two respiratory cycles or 10 to 15 seconds), especially in patients with pulmonary hypertension.

   In some patients, pulmonary arterial end-diastolic pressure can often be substituted for pulmonary artery occlusion pressure if the pressures are nearly identical, obviating the need for repeated balloon inflation.

   Note: Avoid prolonged maneuvers to obtain wedge pressure. If difficulties are encountered, give up the "wedge".

6. Keep the inflation syringe attached to the gate valve to prevent inadvertent injection of liquid into the balloon inflation lumen.

7. Keep pressure monitoring lumens patent by intermittent flush or continuous slow infusion with heparinized saline solution.

   Warning: To avoid pulmonary artery rupture, never flush the catheter when the balloon is wedged in the pulmonary artery.

8. Periodically check IV lines, pressure lines, and transducer domes to keep them free of air. Also ensure that connecting lines and stopcocks remain tightly fitted.

9. Infusion of viscous solutions (e.g., whole blood or albumin) is not recommended, as they flow too slowly and may occlude the catheter lumen.

10. The catheter should remain indwelling only as long as is required by the patient's condition.

    Precaution: The incidence of complications increases significantly with indwelling periods longer than 72 hours.

Cardiac Output Determination

To determine cardiac output by thermodilution, a known amount of sterile solution of known temperature is injected into the right atrium or vena cava, and the resultant change in blood temperature is measured in the pulmonary artery by the catheter thermistor. Cardiac output is inversely proportional to the integrated area under the resulting curve. This method has been shown to provide good correlation with the direct Fick method and dye dilution technique for cardiac output determination.

Consult the references on the use of iced versus room temperature injectate or open versus closed injectate delivery systems.

Refer to the appropriate cardiac output computer manual for specific instructions in the use of thermodilution catheters for cardiac output determination. Correction factors or computation constants needed to correct for indicator heat transfer are given in the specifications.

Edwards cardiac output computers require that a computation constant be used to correct for injectate temperature rise as it passes through the catheter. The computation constant is a function of injectate volume, temperature, and catheter dimensions. The computation constants listed in the specifications have been determined *in vitro.*

MRI Information

MR Unsafe

The Swan-Ganz device is MR unsafe as the result of the device containing metallic components, which experience RF-induced heating in the MRI environment; therefore the device poses hazards in all MRI environments.

Complications

All invasive procedures inherently involve some patient risks. Although serious complications associated with pulmonary artery catheters are relatively uncommon, the physician is advised before deciding to use the catheter to consider and weigh the potential benefits and risks associated with the use of the catheter against alternative procedures. Strict adherence to the foregoing instructions and the awareness of possible complications have been the most significant factors in reducing the incidence of complications.

Perforation of the Pulmonary Artery

Factors associated with the development of fatal pulmonary artery rupture during the use of flow-directed balloon-tipped catheters are pulmonary hypertension, advanced age, cardiac surgery with hypothermia and anti-coagulation, and distal catheter tip migration.

Extreme care should therefore be exercised during the measurement of pulmonary artery occlusion pressure in patients with pulmonary hypertension. The period of time during which the balloon remains inflated and wedged in these patients should be minimal and limited to two respiratory cycles, or 10 to 15 seconds.

Spontaneous catheter tip migration towards the periphery of the lung occurs during cardiopulmonary bypass. Partial catheter withdrawal just before bypass should be considered, as it may help reduce distal migration and prevent permanent catheter wedging postbypass. After termination of bypass, the catheter may require repositioning. Check the distal pulmonary artery tracing before inflating the balloon. **A central location of the catheter tip near the hilum of the lung may prevent pulmonary artery perforation.**

Pulmonary Infarction

Tip migration with spontaneous wedging, air embolism, and thromboembolism can lead to this complication.

Cardiac Arrhythmias

Although usually transient and self-limiting, arrhythmias may occur during insertion, removal, or following displacement of the tip from the pulmonary artery into the right ventricle. Whereas premature ventricular contractions are the most commonly encountered arrhythmias, ventricular tachycardia and atrial and ventricular fibrillation have also been reported. ECG monitoring and the immediate availability of antiarrhythmic drugs and defibrillating equipment are recommended. Prophylactic lidocaine may be helpful in decreasing the incidence of ventricular arrhythmias during catheterization.

Knotting

Flexible catheters have been reported to form knots, most often as a result of looping in the right ventricle. Sometimes the knot can be resolved by insertion of a suitable guidewire and manipulation of the catheter under fluoroscopy. If the knot does not include any intracardiac structures, the knot may be gently tightened and the catheter withdrawn through the site of entry.

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, the infusing of fluids, and catheter-related thrombosis. Preventive measures should be taken to guard against infection.

Other Complications

Pulmonary artery catheters have also been associated with right bundle branch block and complete heart block, tricuspid and pulmonic valve damage, thrombocytopenia, pneumothorax, thrombophlebitis, nitroglycerin absorption, and thrombosis.

How Supplied

Swan-Ganz catheters are supplied sterile, unless otherwise stated. Do not use if package has been previously opened or damaged.

Catheters are for single use only. Do not clean or resterilize a used catheter.

The packaging is designed to avoid crushing of the catheter and to protect the balloon from exposure to the atmosphere. 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 balloon deterioration, since the natural latex rubber in the balloon is acted upon and deteriorated by the atmosphere.

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

Computation Constants

Model Number		D200F7, D205F7
Temp (°C)	Volume (ml)	Computation Constants (cc)*
0 - 5	10	0.542
	5	0.247
	3	0.132
19 - 22	10	0.578
	5	0.274
	3	0.154

Computation Constants for CO-Set+

Cold Injectate	10	0.561
10 ml: 6-12 °C	5	0.259
5 ml: 8-16 °C	3	---
Room Temperature	10	0.608
Injectate	5	0.301
5 or 10 ml: 18-25 °C	3	---

*$CC = (1.08)C_T(60)V_I$

Specifications

Function	Atrio-Ventricular Pacing and Thermodilution	
Model Number	D200F7	D205F7
COC Compatibility	Edwards	Edwards
Usable Length (cm)	110	110
Catheter Body French Size	7F (2.3 mm)	7F (2.3 mm)
Required Introducer Size	8F (2.7 mm)	8F (2.7 mm)
Body Color	Yellow	Yellow
Diameter of Inflated Balloon (mm)	13	13
Balloon Inflation Capacity (ml)	1.5	1.5
Injectate Port (cm from tip)	30	29.5
Injectate Lumen Volume (ml)	1.20	0.93
Electrode Connector	0.40" x 0.080" (10.16 mm x 2.03 mm) dia pin plugs	0.40" x 0.080" (10.16 mm x 2.03 mm) dia pin plugs
Atrial Electrodes (cm from tip)	28.5, 31.0, 33.5	25.5, 28.0, 30.5
Ventricular Electrodes (cm from tip)	18.5, 19.5	16.5, 17.5
Compatible Guidewire Diameter (in)	0.020 (0.51 mm)	0.020 (0.51 mm)
Frequency Response Distortion at 10 Hz	< 3 dB	< 3 dB
Thermistor Location (cm from tip)	4	4

All specifications given are nominal values.

M5078-2

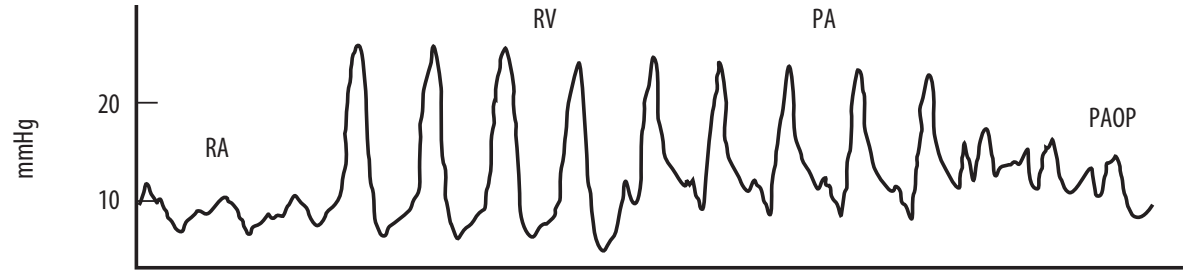


Figure 1. Standard Pressure Waveform showing RA-RV-PA-PAOP progression

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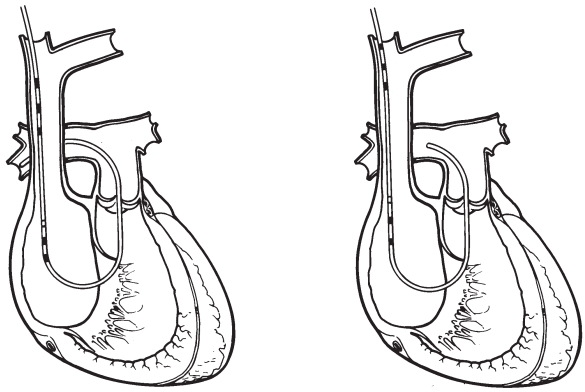

A. Before B. After

Figure 2. Catheter position before and after pulling back from initial wedge position

DC2026-5

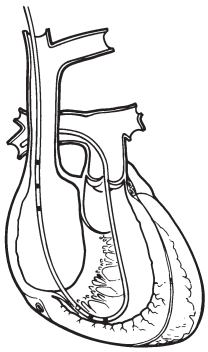

Figure 3. Final Catheter Position

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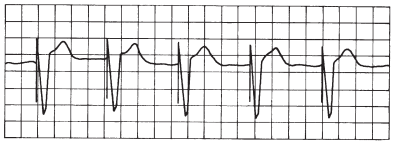

Figure 4. Surface ECG showing ventricular pacing

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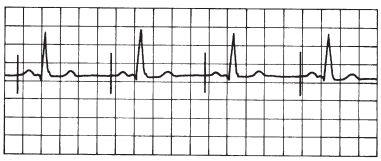

Figure 5. Surface ECG showing atrial pacing

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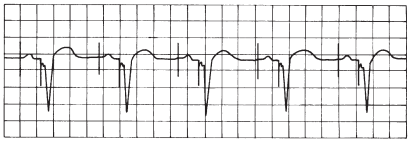
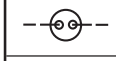


Figure 6. Surface ECG showing A-V sequential pacing

Symbol Legend

	English		English		English
	Number of Lumens		Sterile		MR Unsafe
	Exterior Diameter		Sterilized Using Ethylene Oxide		MR Safe
	Usable Length		Sterilized Using Irradiation		MR Conditional
	Recommended Guidewire Size		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
	Catalogue Number		Manufacturer		Do not resterilize
	Minimum Introducer Size		Date of Manufacture		Non-pyrogenic
	Caution		Contains or presence of natural rubber latex		Type B Applied Part
	Single use		Contains phthalates		Type CF Applied Part
	Quantity		Size		Do not use if package is opened or damaged.
	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		Authorized Representative in the European Community
	Balloon Capacity		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		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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