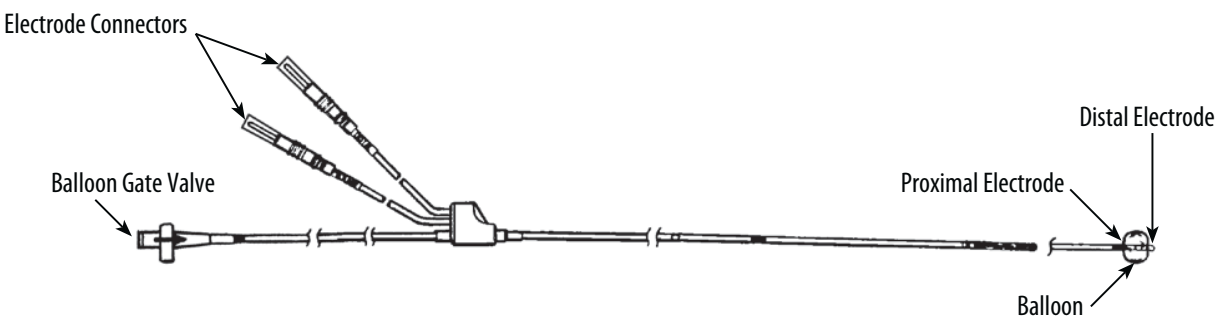
Edwards Lifesciences

Swan-Ganz Bipolar Pacing Catheters: D97120F5 and D97130F5



Swan-Ganz Bipolar Pacing Catheter (D97120F5)

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

For Single Use Only

For Figures 1 and 2 please refer to pages 5 and 6.

Concept/Description

The Swan-Ganz bipolar pacing catheters are designed for temporary right ventricular endocardial pacing. A distal balloon facilitates insertion by flow-direction. A pair of electrodes at the tip provides capabilities for bipolar pacing and electrocardiographic monitoring.

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

The kit provided with the catheter contains the components necessary for percutaneous insertion of the catheter.

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

Model D97130F5 features a "J"-tip configuration (3.5 cm radius) for femoral insertion to predispose the catheter to a stable pacing position in the apex of the right ventricle.

Indications

The Swan-Ganz bipolar pacing catheters are indicated for use in temporary, transvenous right ventricular pacing.

Contraindications

Endocardial pacing catheters are contraindicated in patients with a tricuspid valve prosthesis. Relative contraindications may include patients with recurrent sepsis or a hypercoagulable state where the catheter could serve as a focus for septic or bland thrombus formation.

No absolute contraindications to 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 models should be immediately available.

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

Warnings

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.

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.

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

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.

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

Warning: 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 to avoid electrical shock to patient or clinician.

Insertion

Rapid insertion of the catheter into the right ventricle can be accomplished at the patient's bedside, usually without fluoroscopy, by ECG monitoring.

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 Bipolar Pacing Catheter
2. External pulse generator
3. External pulse generator cable adapters
4. Electrocardiograph (properly isolated)

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

Preparation

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

1. For the VIP bipolar pacing catheter, flush the infusion lumen with a sterile solution to assure patency and to remove air. If the infusion lumen is not to be used immediately, a sterile heparinized D_5W or saline solution should be used intermittently to ensure patency.
2. For all bipolar pacing catheters, check balloon integrity. Inflate to the recommended volume and check for major asymmetry and leaks by submerging in sterile saline or water.

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

   Precaution: Since proper functioning of the pacing catheter depends on the electrical continuity of its electrodes and internal wires, care should be exercised when handling the catheter.

   Note: Use of a protective catheter sheath is recommended.

Procedure

Although a variety of techniques may be used for insertion, the following guidelines are provided as an aid to the physician.

Model D97120F5 is intended for antecubital insertion (or other superior vena cava approaches). Model D97130F5 is intended for femoral insertion.

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

   Model D97130F5 is intended for femoral insertion, in which the right femoral vein is preferred. For femoral insertion, inflation of the balloon will facilitate flotation of the catheter into the right atrium – see Step 4 for precautions on balloon inflation.

   Precaution: With femoral insertion, it is possible to transfix the femoral artery in some situations during percutaneous entry into the vein. Proper femoral vein puncture technique should be followed, including removal of the innermost occluding stylet when the insertion set needle is advanced toward the vein.

   If the introducer assembly is used, the following procedure should be followed (modified Seldinger technique):

   a. After antiseptic skin preparation and infiltration with a local anesthetic, enter the vessel (internal jugular or subclavian) with the 22 gauge (0.7 mm) locating needle and attached 5 ml syringe.

   b. Upon aspiration of venous blood, remove the needle and syringe.

   c. Insert the 18 gauge (1.2 mm) needle and relocate the internal jugular or subclavian vein previously entered.

   d. Pass the guidewire through the 18 gauge (1.2 mm) needle into the lumen of the vein.

   e. Remove the 18 gauge (1.2 mm) needle from the vein. The guidewire remains in place.

   f. Enlarge the cutaneous puncture site with a Number 11 scalpel blade (optional).

   g. Advance the dilator sheath with a twisting motion over the guidewire and into the vein.

   h. Once the dilator and sheath are well within the vessel, remove the guidewire and dilator.

   i. Introduce the catheter without delay through the sheath into the vein.

2. During placement, a unipolar electrocardiogram can be monitored from the distal tip electrode by connection to the V lead of a properly isolated electrocardiograph (battery powered is preferred). An ECG adapter is provided for this purpose.

   Warning: To ensure patient safety, the incorporation of an isolation circuit is mandatory when intracavity electrocardiograms are recorded.

3. Under continuous distal tip electrode ECG monitoring, with or without fluoroscopy, advance the catheter into the right atrium. Entry of the catheter into the right atrium is indicated by a large atrial complex (P wave) as shown in Figure 1 (on page 5).

   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.

4. At this point, inflate the balloon with CO_2 or air to the recommended volume (1.3 ml) printed on the catheter body **(Do not use liquid)**. Note that an offset arrow on the gate valve indicates the "closed" position.

   Warning: To avoid 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.

   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. Be sure to take precautions to prevent infusion of air or liquid into the balloon lumen.

5. With the balloon inflated, continue to advance the catheter slowly through the right atrium and into the right ventricle. Entry of the catheter into the right ventricle is indicated by a marked decrease in the amplitude of the atrial complex and an increase in the ventricular complex (see page 5, Fig. 1).

   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 a neck vein with only the proximal shaft advancing into the heart. Deflate the balloon and withdraw the catheter until the 20 cm mark is visible. Reinflate the balloon and advance the catheter.

6. Once the catheter has entered the right ventricle, immediately deflate the balloon to avoid catheter flotation into the pulmonary outflow tract.

7. Advance the catheter a few centimeters until elevation of the ST segment of the distal electrode ECG is observed, indicating contact with the endocardium.

8. After establishing contact, connect the distal lead to the negative terminal and the proximal lead to the positive terminal of the pulse generator and determine the pacing threshold. A threshold less than 1.0 mA, together with a 2 or 3 mV ST elevation (contact potential) recorded from the tip electrode, is generally an indication of proper electrode placement.

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

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

9. Assess catheter stability. A chest X-ray film can be taken to verify catheter position.

10. After stable pacing has been confirmed, aseptically secure the proximal end of the catheter to the insertion site to prevent undue movement, which could result in tip dislodgment and loss of capture, or catheter migration. Take care not to kink the catheter body when securing it.

    Note: 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.

11. An IV line may now be attached to the catheter's infusion port hub. Keep the infusion lumen patent by intermittent flush, continuous, slow infusion with heparinized saline solution, or use of a heparin lock.

12. 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.

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 indwelling 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 Right Ventricle

Cases of myocardial perforation associated with the use of temporary transvenous pacing catheters have been reported. Careful repositioning and withdrawal of the catheter under ECG and fluoroscopic control is recommended.

Cardiac Arrhythmias

Although usually transient and self-limiting, arrhythmias may occur during insertion or removal. 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.

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.

Thrombosis

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

Thrombophlebitis

If definite evidence of thrombophlebitis appears, the catheter should be withdrawn.

Other Complications

Temporary transvenous pacing catheters in general have been associated with pulmonary embolization and diaphragmatic stimulation.

Swan-Ganz 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, and heparin-induced thrombocytopenia

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 and resterilize a used catheter.

Packaging

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.

This product is manufactured and sold under one or more of the following US patent(s): US Patent No. 6,036,654; 6,045,512; 6,371,923; 6,387,052; and corresponding foreign patents.

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

Sterilized Using Ethylene Oxide

Specifications

Swan-Ganz Bipolar Pacing Catheter Kits

Bipolar Pacing Catheter Model	**D97120F5/D97130F5**
Body French Size	5F (1.67 mm)
Usable Length (cm)	90
Balloon Inflation Capacity (ml) CO_2 or Air	1.3
Body Color	White
Lumens	1
Diameter of Inflated Balloon (mm)	10
Electrode Location	At catheter tip and 1 cm proximal
Electrode Connections	0.080 inch (2.0 mm) diameter standard pin connections that terminate at the proximal end of the catheter
Bipolar Electrical Resistance	36 ohms
Frequency Response Distortion at 10 Hz	< 3 dB

*Using normal saline at room temperature, 1 m above insertion site, gravity drip.

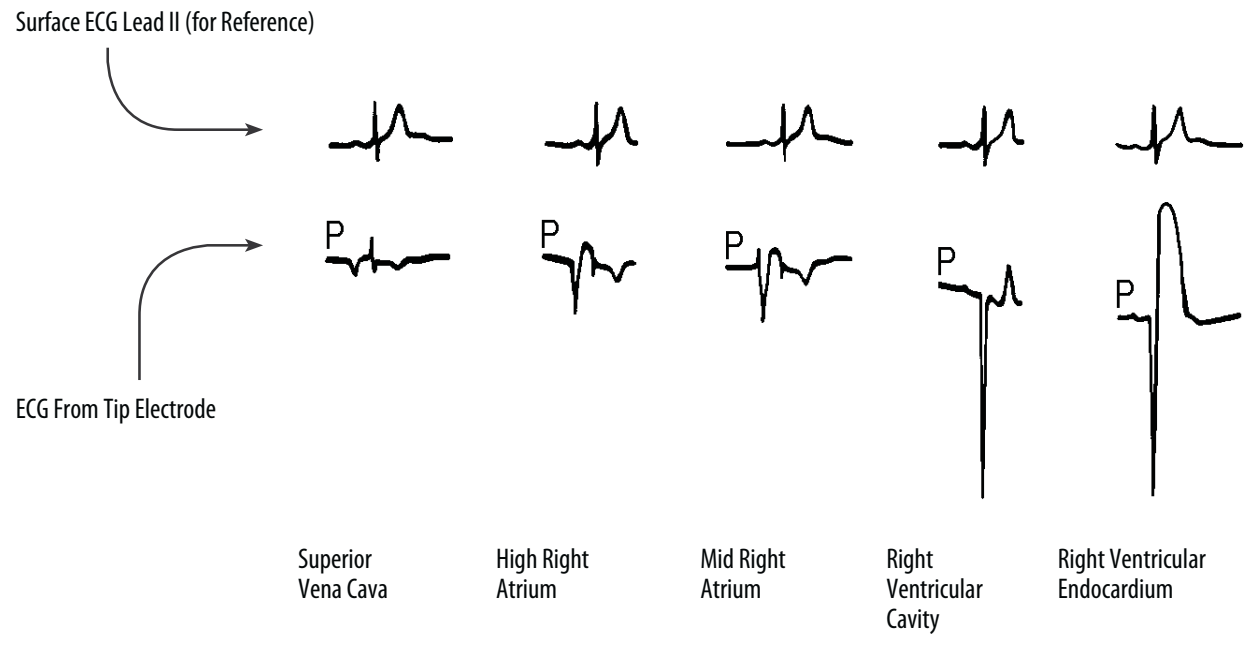


Figure 1.

Figure 2.

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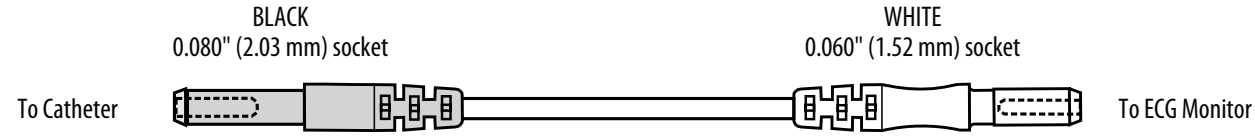
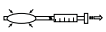
PACING PRODUCTS KITS (Models D98100, D98500)

ECG adapter used to facilitate the use of modified shrouded pin connectors with ECG monitor patient cables is available with pacing product kits.



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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