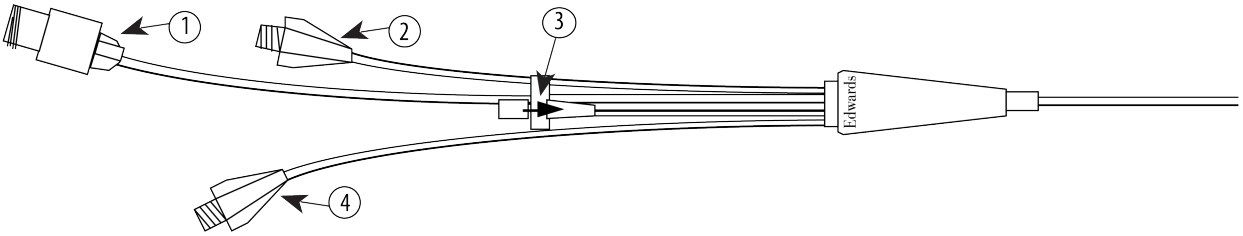
Edwards

Swan-Ganz True Size Thermodilution Catheters
Models 131F7, 131F7J, & 151F7

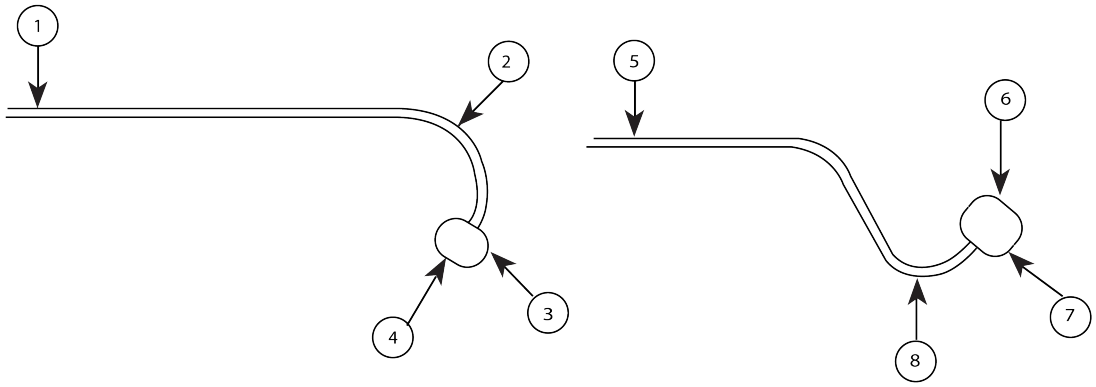
DC-2146-3



Swan-Ganz True Size Thermodilution Catheter

1. Thermistor Connector
2. Proximal Lumen Hub
3. Balloon Inflation Valve
4. Distal Lumen Hub

DC-2138-2
DC-2138-3



Standard Tip Models 131F7 and 131F7J

"S" Tip Model 151F7

1. Proximal Injectate Lumen Port @ 30 cm
2. Thermistor
3. Balloon
4. Distal Lumen Port
5. Proximal Injectate Lumen Port @ 30 cm
6. Distal Lumen Port
7. Balloon
8. Thermistor

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

1.0 Concept/Description

The Swan-Ganz True Size thermodilution catheter (Model 131F7 and 131F7J) provides a diagnostic tool for physicians to rapidly determine hemodynamic pressures and cardiac output when used with a compatible cardiac output computer. The Swan-Ganz True Size thermodilution catheter with "S-Tip" (Model 151F7) has the same design and functions as the standard Swan-Ganz thermodilution catheter with a tip specifically designed for femoral vein insertion.

2.0 Indications

Swan-Ganz thermodilution catheters are indicated for the 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.

3.0 Contraindications

There are no absolute contraindications to the use of flow-directed pulmonary artery catheters. 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, the capability for temporary transvenous pacing (or the use of a Swan-Ganz Paceport or Pacing-TD catheter) should be immediately available.

4.0 Preparation for Insertion

Swan-Ganz catheters can be inserted at the patient's bedside without the aid of fluoroscopy, guided by continuous pressure monitoring. Fluoroscopy is recommended for femoral vein insertion.

CAUTION: Damage to the catheter (i.e., melting) may occur during magnetic resonance imaging (MRI).

4.1 Equipment

- Swan-Ganz thermodilution catheter
- Any Edwards Lifesciences LLC cardiac output computer, compatible injectate probe, and connecting cable
- EKG recorder
- Strip-chart recorder or oscilloscope
- Pressure transducers and amplifiers
- Sterile flush system
- Contamination sheath

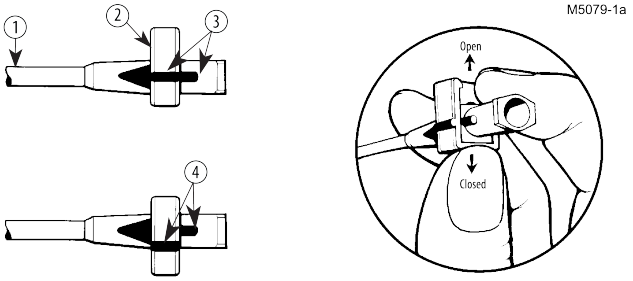
In addition, the following items should be immediately available if complications arise during catheter insertion: antiarrhythmic drugs, defibrillator, respiratory assist equipment, and a transvenous temporary pacing catheter.

4.2 Catheter Preparation

Use aseptic technique

Step	Procedure
1	Flush catheter lumens with a sterile solution to ensure patency and to remove air.
2	Using the volume-limited syringe provided in the catheter packaging, check balloon integrity by inflating the balloon to its 1.5 ml capacity, and checking for major asymmetry and for leaks by submerging in sterile saline or water. Figure 1 illustrates the operation of the gate valve on the balloon inflation lumen.
3	Connect the catheter's injectate and pressure monitoring lumens to the flush system and pressure transducers. Ensure that the lines and transducer domes are free of air.
4	Test the thermistor's electrical continuity before insertion by connecting the catheter to the cardiac output computer and checking for a "catheter fault" (CAT).

Precaution: It is possible to stretch the body of the catheter and cause the thermistor's internal wires to detach, thereby breaking the circuit. When testing and cleaning the catheter, do not forcefully wipe or stretch it.



1. Catheter
2. Sliding Gate Valve
3. Arrow Aligned Indicates "Open" Position
4. Arrow Offset Indicates "Closed" Position

Figure 1: Gate Valve Operation

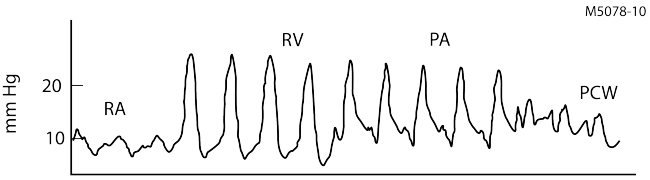


Figure 2: Standard Pressure Waveform showing RA-RV-PA-PCW progression

5.0 Insertion Procedure

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

Step	Procedure
1	Introduce the catheter into the vein by percutaneous insertion using a Seldinger-type guidewire, vein dilator, and catheter introducer sheath, or by venous cutdown.
2	Under continuous pressure monitoring, with or without the aid of fluoroscopy, gently advance the catheter into the right atrium. Entry of the catheter tip into the thorax is signaled by an increased respiratory fluctuation in pressure. Figure 2 shows the characteristic intracardiac and pulmonary pressure waveforms. **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 30 cm from the femoral vein.**
3	Using the volume-limited syringe provided in the catheter packaging, inflate the balloon with 1.5 ml of CO_2 or air. **Do not use liquid.**
4	Advance the catheter until pulmonary capillary wedge pressure (PAWP) is obtained, and passively 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.
5	Reduce or remove any excessive catheter length or loop in the right atrium or ventricle by slowly pulling the catheter back approximately 2 to 3 cm. **Precaution: Do not pull the catheter tip across the pulmonic valve while the balloon is inflated.**
6	Reinflate the balloon to determine the minimum inflation volume necessary to obtain a wedge tracing. Deflate the balloon. If a wedge is obtained with a volume less than 1.0 ml, the catheter must be withdrawn to a position where full or near full inflation volume (1.0 to 1.5 ml) produces a wedge tracing.

6.0 Warnings/Precautions

WARNING: 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.

WARNING: Pulmonary complications may result from improper inflation technique. To avoid damage to the pulmonary artery and possible balloon rupture, do not inflate the balloon above the recommended volume. Bacteria filtered carbon dioxide is the recommended inflation medium because of its rapid absorption into the blood in the event of a 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.

WARNING: 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 in adults with suspected right to left intracardiac or intrapulmonary shunts (Ref. 15).

Precaution: If a right ventricular pressure tracing is still observed after advancing the catheter 15 cm beyond the point where the initial right ventricular pressure tracing was observed, the catheter may be looping in the right ventricle, which can result in kinking or knotting of the catheter (see Complications). Deflate the balloon and withdraw the catheter into the right atrium. Reinflate the balloon and readvance the catheter to a pulmonary artery wedge position, then deflate the balloon.

Note: The catheter should pass easily through the right ventricle and pulmonary artery and into a wedge position in less than a minute. 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. Use of a Swan-Ganz guidewire thermodilution catheter or a Swan-Ganz Hi-Shore thermodilution catheter (Model 141F7) may be helpful in these patients. Deep inspiration by the patientduring advancement may also facilitate passage.

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

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.

7.0 Guidelines for Femoral Insertion

Precaution: The inferior vena cava approach may not be practical for a patient with a dilated right atrium. In such patients, femoral insertion may lead to excessive catheter length in the right atrium and difficulties in obtaining a pulmonary artery wedge position.

Insertion under fluoroscopy is recommended when using the femoral approach.

- When advancing the catheter into the inferior vena cava, the catheter may slip into the opposite iliac vein. Pull the catheter back into the ipsilateral iliac vein, inflate the balloon, and let the bloodstream carry the balloon into the inferior vena cava.
- If the catheter does not pass from the right atrium into the right ventricle, it may be necessary to change the orientation of the tip. Gently rotate the catheter and simultaneously withdraw it several centimeters. Care must be exercised so that the catheter is not kinked as it is rotated.
- If difficulty is encountered when positioning the catheter, a suitably sized guidewire may be inserted to stiffen the catheter.

Precaution: To avoid damage to intracardiac structures, do not advance the guidewire beyond the catheter tip. The tendency for thrombus formation will increase with prolonged guidewire use. Keep the period of time that the guidewire is used to a minimum. Aspirate 2 to 3 ml from the catheter lumen and double flush after guidewire removal.

8.0 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 (Ref. 20). 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. Damage may occur either by prolonged occlusion or by over-distension of the vessel upon re-inflation of the balloon (see Complications). 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. Daily chest X-ray films are also recommended to verify catheter position.

   Spontaneous catheter tip migration towards the periphery of the lung occurs during cardiopulmonary bypass (Ref. 19). 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 post bypass (Ref. 19). After termination of bypass, the catheter may require repositioning. Check the distal pulmonary artery tracing before inflating the balloon.
3. Re-inflation 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 into the balloon lumen.
4. Inflate the balloon slowly to the minimum volume needed to obtain PAWP (never exceeding the recommended volume). If PAWP 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 wedge 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 capillary wedge pressure if the pressures are nearly identical (Refs. 4 & 26), obviating the need for repeated balloon inflation.

   Note: Avoid prolonged maneuvers to obtain wedge pressure. If difficulties are encountered, discontinue wedge measurements.
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: 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 (Ref. 38).

9.0 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 (Ref. 16) and dye dilution technique (Ref. 43) for cardiac output determination.

Consult the references on the use of iced versus room temperature injectate (Refs. 13 & 29) or open versus closed injectate delivery systems (Refs. 30 & 44).

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*.

10.0 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.

The general risks and complications associated with indwelling catheters are described in the literature (see References). Strict adherence to the foregoing instructions and the awareness of possible complications have been the most significant factors in reducing the incidence of complications.

10.1 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 (Refs. 2 & 33), cardiac surgery with hypothermia and anticoagulation (Ref. 41), and distal catheter tip migration (Refs. 2 & 19).

Extreme care should therefore be exercised during the measurement of pulmonary artery wedge 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 (3 cm to 5 cm) just before bypass should be considered, as it may help reduce distal migration and prevent permanent catheter wedging postbypass (Ref. 19). 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 (Ref. 21).

10.2 Pulmonary Infarction

Tip migration with spontaneous wedging, air embolism, and thromboembolism can lead to this complication (Refs. 14 & 31).

10.3 Cardiac Arrhythmias

Although usually transient and self-limiting, arrhythmias may occur during insertion (Refs. 11, 34, & 39), 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 (Ref. 38). EKG 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 (Ref. 37).

10.4 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 (Refs. 8 & 28) and manipulation of the catheter under fluoroscopy. If the knot does not include any intracardiac structures (Ref. 27), the knot may be gently tightened and the catheter withdrawn through the site of entry (Ref. 24).

10.5 Sepsis/Infection

Positive catheter-tip cultures resulting from contamination and colonization have been reported (Ref. 14), as well as incidences of septic and aseptic vegetation in the right heart (Ref. 17). 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 (e.g., use of sterile technique, application of topical, antibiotic ointment, and frequent changing of sterile dressings), as well as the frequent assessment of the continued need for invasive hemodynamic monitoring.

10.6 Other Complications

Pulmonary artery catheters have also been associated with right bundle branch block and complete heart block (Ref. 42), tricuspid and pulmonic valve damage (Refs. 3 & 32), thrombocytopenia (Refs. 22 & 23), pneumothorax (Refs. 6 & 38), thrombophlebitis (Ref. 6), nitroglycerin absorption (Ref. 45) and thrombosis (Refs. 7 & 12).

11.0 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.

Sterilized, using ethylene oxide.

12.0 Packaging and Sterility

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 and to protect the balloon from exposure to the atmosphere. It is therefore recommended that the catheter remain inside the package until use.

Store in a cool, dry place.

13.0 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. Also, the heparin coating may no longer be effective beyond the recommended shelf life.

Note: Resterilization will not extend the shelf life.

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

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

14.0 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

15.0 Specifications

Models 131F7, 131F7J, & 151F7

Usable Length (cm)	110
Catheter Body Size	7F
Balloon Specifications	
Diameter of Deflated Balloon	7F
Diameter of Inflated Balloon (mm)	13
Inflation Capacity (ml)	1.5
Required Introducer Size	8F
Distance from Tip (cm)	
Proximal Injectate Port	30
Lumen Volume (ml)	
Distal Lumen	1.02
Proximal Injectate Lumen	0.81
Infusion Rates* (ml/hr)	
Distal Lumen	425
Proximal Injectate Lumen	568
Compatible Guidewire Diameter (in)	
Distal Lumen	0.028
Proximal Injectate Lumen	0.031
Natural Frequency/Amplitude Ratio	
Distal Lumen	37 Hz/3.0:1
Proximal Injectate Lumen	48 Hz/3.3:1
Thermistor Data	
Nominal Resistance at 37 °C (Ω) Resistance	14,004
Rate Change at 37 °C (Ω/°C) Blood Temp.	520
Measurement Accuracy** (°C)	17- 31 ± 0.5
	31- 41 ± 0.3

All specifications are nominal values.

* At room temperature, 40" above insertion site, gravity drip. Rates represent average values.

** With COM-2 connected to catheter.

†Indicates "S-Tip" configuration.

16.0 Computation Constants (CC)[1]

for use with bath temperature probes

Injectate Temperature	Computation Constant at indicated injectate volumes		
°C	**3 ml**	**5 ml**	**10 ml**
0-5	0.132	0.247	0.542
19-22	0.154	0.274	0.578
23-25	0.165	0.287	0.595

for use with CO-Set+ Injectate Delivery System

Injectate Temp. & Volume	Computation Constant at indicated injectate volumes
Iced Injectate	
10 ml: 6-12 °C	0.561
5 ml: 8-16 °C	0.259
Room Temperature Injectate	
10 ml: 18-25 °C	0.608
5 ml: 18-25 °C	0.301

[1] $CC = (1.08)C_T(60)V_I$

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