Edwards Lifesciences

# Swan-Ganz

**Thermodilution Paceport Catheter: 931F75**
**Thermodilution A-V Paceport Catheter: 991F8**

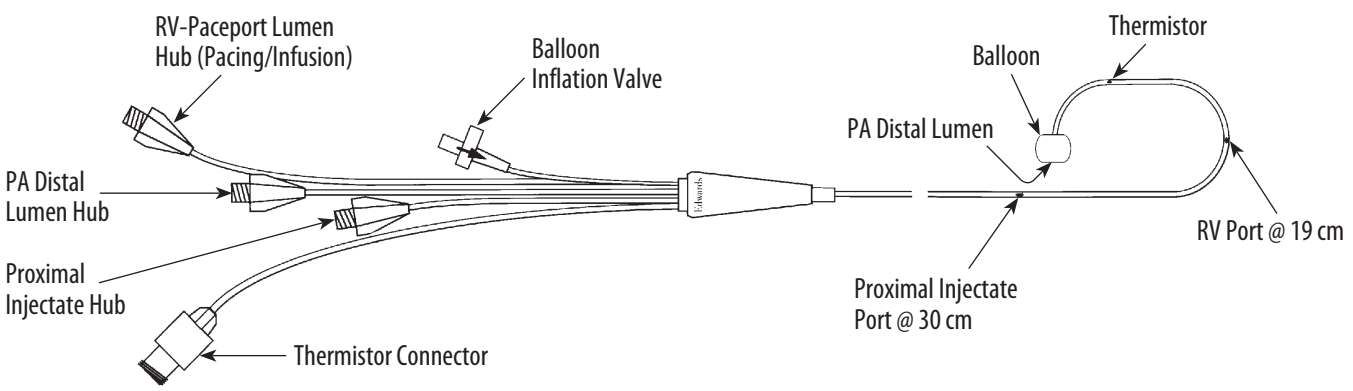


**Figure 1.** Swan-Ganz Thermodilution Paceport Catheter (Model 931F75)

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 2 and 3 please refer to page 9.

### Paceport Catheter Concept/ Description (Model 931F75)

The Swan-Ganz thermodilution Paceport catheter (Model 931F75) allows insertion and placement of the Chandler Transluminal V-pacing probe (Model D98100). The Swan-Ganz thermodilution Paceport catheters (Model 931F75) are intended for use in patients who require hemodynamic monitoring when the need for temporary transvenous pacing is anticipated.



The Paceport catheter (Model 931F75) right ventricular (RV) lumen terminates 19 cm from the tip, and is used for the insertion of Model D98100 Chandler Transluminal V-pacing probes into the right ventricle when the tip of the catheter is in the pulmonary artery. When the pacing probe is not inserted (in Model 931F75) the RV lumen may be used for infusing solutions. The proximal lumen may be used for pressure monitoring and bolus injection for cardiac output determinations by the thermodilution technique.

### A-V Paceport Catheter Concept/ Description (Model 991F8)

**The Swan-Ganz thermodilution A-V Paceport catheter (Model 991F8) allows insertion and placement of the Chandler Transluminal V-pacing probe (Model D98100) and Flex-Tip A-pacing probe (Model D98500).**

The Swan-Ganz thermodilution A-V Paceport catheter (Model 991F8) serves as a diagnostic tool for the physician to rapidly determine hemodynamic pressures and cardiac output when used with a compatible cardiac output computer. The A-V Paceport catheter (Model 991F8) is intended for use in patients who require hemodynamic monitoring when temporary transvenous pacing is anticipated.

The A-V Paceport catheter (Model 991F8) right ventricular (RV) lumen which terminates 19 cm from the tip is provided for the insertion of a Model D98100 Chandler Transluminal V-pacing probe into the right ventricle when the tip of the catheter is in the pulmonary artery. A right atrial (RA) lumen that terminates 30 cm from the tip is provided for the insertion of a Model D98500 Flex-Tip Transluminal A-pacing probe into the right atrium when the tip of the catheter is in the pulmonary artery. When the pacing probes are not inserted (in Model 991F8), the ventricular and atrial lumens may be used for right ventricular or atrial pressure monitoring, or infusing solutions.

### Indications (Model 931F75)

The Swan-Ganz thermodilution Paceport catheters (Model 931F75) are used for assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, and for infusing solutions. The Paceport catheter (Model 931F75) may also be used for standby temporary ventricular pacing.

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.

## Indications (Model 991F8)

The Swan-Ganz thermodilution A-V Paceport catheter (Model 991F8) is indicated for the assessment of a patient's hemodynamic condition through simultaneous right atrial, right ventricular, and pulmonary artery or wedge pressure monitoring, cardiac output determination, and for infusing solutions.

The A-V Paceport catheter (Model 991F8) is also indicated for standby temporary ventricular, atrial, or A-V sequential pacing using the Model D98100 Chandler Transluminal V-pacing probe and/or Model D98500 A-pacing probe.

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

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 modes should be immediately available.

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

Patients with either recurrent sepsis, or with hypercoagulopathy, in which the catheter could serve as a focal point for septic or bland thrombus formation, should not be considered candidates for a balloon flotation catheter.

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.

## Warnings

**Do not modify or alter the product in any way. Alteration or modification may affect product performance.**

**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. 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.**

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

## 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.

## 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.**

1. Swan-Ganz thermodilution A-V Paceport catheter (Model 991F8) or Swan-Ganz thermodilution Paceport catheter (Model 931F75)
2. Edwards Intro-Flex percutaneous sheath hemostasis valve introducer tray or kit, or single assembly.
3. Chandler Transluminal V-pacing probe (Model D98100)
4. Flex-Tip Transluminal A-pacing probe (Model D98500 - when using Model 991F8)
5. A-V sequential or ventricular demand external pacemaker
6. Any compatible cardiac output computer, compatible injectate probe, and connecting cable
7. Sterile flush system and pressure transducers
8. Bedside ECG and pressure monitor system
9. Percutaneous sheath introducer and contamination shield

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

## Catheter Preparation

**Use aseptic technique.**

**Note:** Use of a protective catheter sheath is recommended.

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

1. Flush catheter lumens with a sterile solution to ensure patency and to remove air.
2. Check balloon integrity by inflating it to the recommended volume. Check for major asymmetry and for leaks by submerging in sterile saline or water. Deflate balloon before insertion.
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 (refer to computer operations manual for detailed information).

## Insertion Procedure

**Warning: In some patients, the catheter may spontaneously wedge (with the balloon deflated) before positioning of the RV port in the right ventricle. Discontinue advancing the catheter. This pacing system is not suitable for use in these patients; however,**

**the catheter can still be used for pressure monitoring, blood sampling, fluid infusion and cardiac output determinations. Do not attempt to insert the probe if the RV port is in the RA. Damage to the tricuspid valve may result. Always make certain that the RV port is inside the ventricle before inserting the probe.**

Swan-Ganz catheters can be inserted at the patient's bedside, without the aid of fluoroscopy, guided by continuous pressure monitoring. For proper RV port positioning for placement of the pacing probes, simultaneous pressure monitoring from the distal and RV lumens is recommended.

**Note: The V-pacing and A-pacing probes (in Model 991F8) should be placed prophylactically into their respective lumens immediately after placement of the catheter. Severe difficulty in probe passage may be encountered if probe insertion is delayed.**

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

**Note:** The catheter should pass easily through the right ventricle and pulmonary artery and into a wedge position in less than a minute.

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

It is recommended that a contamination shield be used on the catheter because of the potential need to manipulate the catheter after initial insertion.

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

   **Note: The catheter can be inserted through a jugular, subclavian vein, or antecubital fossa. Femoral insertion is not recommended.**

   **Note: Femoral insertion should be used only when short-term pacing is recommended (e.g., catheterization lab procedures), because of the possible placement of the Chandler probe in the RV outflow tract.**

2. Under continuous pressure monitoring, with or without 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 3** (on page 9) 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, or 10 to 15 cm from the subclavian vein, or 30 cm from the femoral vein.

3. Using the syringe provided, inflate the balloon with $CO_2$ or air to the recommended volume maximum. **Do not use liquid.** Note that an offset arrow on the gate valve indicates the "closed" position.

   **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.

   **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.**

4. Advance the catheter until pulmonary artery occlusion pressure (PAOP) is obtained, then passively deflate the balloon by removing the syringe from the gate valve. Do not forcefully aspirate as this may damage the balloon. After deflation, re-attach the syringe.

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

   **Note:** Before reinflation with $CO_2$ or air, completely deflate the balloon by removing the syringe and opening 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.

   **Precaution:** If a right ventricular pressure tracing is still observed after advancing the catheter several cm beyond the point where the initial right ventricular pressure was observed, the catheter may be looping in the 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.

   **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.

5. Reduce or remove any excessive 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 across the pulmonic valve while the balloon is inflated to avoid damage to the valve.

6. 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.

   **Warning: Do not advance the catheter beyond the wedge position to avoid pulmonary artery rupture.**

   **Precaution:** Overtightening the proximal Tuohy-Borst adapter of the contamination shield may impair catheter function by potentially compressing and occluding the lumens.

7. Confirm final catheter tip position with chest X-ray.

**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.

**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.

## Positioning the Paceport and A-V Paceport Catheters when Used for Pacing

For precautions and a detailed description of the insertion procedure for the pacing probe, consult the package insert provided with each probe.

**Note:** Ideal placement of the RV port of the Paceport or A-V Paceport catheter when the Chandler probe is to be inserted is 1 to 2 cm distal to the tricuspid valve.

1. During catheter insertion, it is recommended that the distal and RV lumen pressures be simultaneously monitored.
2. Advance the catheter into the pulmonary artery wedge position. Deflate the balloon.
3. Refer to the pacing probe (Models D98100 and D98500) package insert for detailed instructions on insertion.

**Warning: If the RV port is too distal, then the probe may exit the RV port pointed toward the RV outflow tract. This may result in poor thresholds, unstable pacing, and potential damage to the outflow tract and pulmonic valve.**

**Note:** A radiopaque marker is provided at the RV port to aid in port placement and identification by chest X-ray film or fluoroscopy.

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

## Guidelines for Femoral Insertion

**Precaution:** Femoral insertion should be used only when short-term pacing is recommended (e.g., catheterization lab procedures), because of the possible placement of the Chandler probe (Model D98100) in the RV outflow tract.

**Precaution:** Femoral insertion may lead to excessive catheter length in the right atrium and difficulties in obtaining a pulmonary artery wedge (occlusion) position.

**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.

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 flush twice after guidewire removal.
- The Paceport catheter, (Model 931F75) and A-V Paceport catheter (Model 991F8), Chandler probes (Model D98100), and A-pacing probes (Model D98500) can be inserted successfully under fluoroscopy using the right femoral vein. However, because of the characteristic shorter catheter loop in the right ventricle, the catheter RV port and Chandler probe (Model D98100) may become oriented towards the RV outflow tract (pulmonary artery) rather than the apex. This orientation may adversely affect stability of long term pacing. In addition, the shorter catheter loop may require advancing the catheter tip into the peripheral pulmonary artery in order to position the catheter RV port distal to the tricuspid valve, possibly resulting in permanent wedge or difficulties in measuring wedge pressure.

## Maintenance and Use *in situ*

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.

### Catheter Tip Position

Keep catheter tip centrally located in a main branch of the pulmonary artery near the hilum of the lungs. Do not advance tip too far peripherally. Tip should be kept where full or near full inflation volume is required to produce a wedge tracing. The tip migrates toward periphery during balloon inflation.

### Catheter Tip Migration

Anticipate spontaneous catheter tip migration towards periphery of pulmonary bed. Continuously monitor distal lumen pressure to verify tip position. If wedge tracing is observed when balloon is deflated, pull catheter back. Damage may be caused by prolonged occlusion or over-distension of vessel upon re-inflation of the balloon.

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-distention of the vessel upon reinflation of the balloon (see **Complications**).

PA pressures should be continuously monitored with the alarm parameter set to detect physiologic changes as well as spontaneous wedge.

### Balloon Inflation and Wedge Pressure Measurement

Re-inflation of the balloon should be performed gradually while monitoring pressures. Inflation is usually associated with a feeling of resistance. If no resistance is encountered, it should be assumed that the balloon has ruptured. Discontinue inflation at once. The catheter may still be used for hemodynamic monitoring, however, take precautions against infusion of air or liquids into the balloon lumen. During normal catheter use, keep inflation syringe attached to gate valve to prevent inadvertent injection of liquid into the balloon inflation lumen.

Measure wedge pressure only when necessary and only when tip is properly positioned (see above). Avoid prolonged maneuvers to obtain wedge pressure and keep wedge time to a minimum (two respiratory cycles or 10 - 15 seconds), especially in patients with pulmonary hypertension. If difficulties are encountered, discontinue wedge measurements. In some patients, pulmonary arterial end-diastolic pressure can often be substituted for pulmonary artery wedge pressure if the pressures are nearly identical, obviating the need for repeated balloon inflation.

### Spontaneous Tip Wedging

| Model | Indications | Probe Placement | Pacing Probe |
|---|---|---|---|
| 931F75 | Temporary Ventricular Pacing<br>Fluid Administration | Ventricle | D98100 |
| 991F8 | Temporary | Atrium and Ventricle | D98500 |
| | Atrial - Ventricular Pacing | | D98100 |
| | Temporary Atrial Pacing only | Atrium | D98500 |
| | Temporary Ventricular Pacing only | Ventricle | D98100 |
| | Fluid Administration | | |

## Specifications

| Swan-Ganz Thermodilution | Paceport Catheter (Model 931F75) | A-V Paceport Catheter (Model 991F8) |
|---|---|---|
| Usable Length (cm) | 110 | 110 |
| Catheter Body French Size | 7.5F (2.5 mm) | 8F (2.7 mm) |
| Balloon Inflation Capacity (ml-$CO_2$) | 1.5 | 1.5 |
| Diameter of Inflated Balloon (mm) | 13 | 13 |
| Minimum Recommended Introducer Size | 8.5F (2.8 mm) | 9F (3.0 mm) |
| Distance from Distal Tip (cm) | | |
| RA Port | – | 27 |
| RV Port | 19 | 19 |
| Proximal Injectate Port | 30 | 30 |
| Lumen Volume (ml) | | |
| Proximal Injectate | 0.89 | 0.70 |
| Distal | 0.88 | 0.93 |
| RA Lumen | – | 1.07 |
| RV Lumen | – | 1.13 |
| without probe | 1.10 | – |
| with T-B adapter attached and probe in lumen | 0.88 | – |
| Infusion Rates* (ml/min) | | |
| Distal | 5 | 6 |
| Proximal Injectate | 12 | 8 |
| RA Pacing/Infusion | | |
| with probe | – | 1 |
| without probe | – | 15 |
| RV Pacing/Infusion | | |
| with probe | 0.5 | 1 |
| without probe | 11 | 12 |
| Infusion Rate* (ml/min) using $D_{50}W$ | | |
| RV Lumen | | |
| without probe | 3 | – |
| with T-B adapter attached and probe in lumen | 0.2 | – |
| Radiopaque Marker | distal edge of RV port | at RA and RV port |
| Compatible Guidewire Diameter | | |
| Distal Lumen | 0.025 in. (0.64 mm) | 0.018 in. (0.46 mm) |
| Proximal Injectate Lumen | 0.035 in. (0.89 mm) | – |
| RV Lumen | 0.035 in. (0.89 mm) | 0.028 in. (0.71 mm) |
| RA Lumen | – | 0.028 in. (0.71 mm) |
| Frequency Response | | |
| Distortion at 10 Hz | | |
| Distal Lumen | < 3 dB | < 3 dB |

All specifications given are nominal values.
A 3 ml syringe volume-limited to 1.5 ml is provided with each catheter.
* Using normal saline at room temperature, 1 m above insertion site, gravity drip. Rates represent average values. Infusing blood products or hyperalimentation solutions through the RV lumen is not recommended if the RV lumen will be used for placement of the Chandler probe.

## Computation Constants

| Model | | 931F75 | 991F8 |
|---|---|---|---|
| Injectate Temp. (°C) | Volume (ml) | Computation Constants (CC)*** | |
| 0 - 5 | 10 | 0.564 | 0.568 |
| | 5 | 0.262 | 0.268 |
| | 3 | 0.139 | 0.147 |
| 19 - 22 | 10 | 0.588 | ––– |
| | 5 | 0.283 | ––– |
| | 3 | 0.158 | ––– |
| 23 - 25 | 10 | 0.612 | 0.616 |
| | 5 | 0.301 | 0.302 |
| | 3 | 0.177 | 0.176 |
| **Computation Constants* for CO-Set+ Injectate Delivery System** | | | |
| **Cold Injectate** | | | |
| 6 °C - 12 °C | 10 | 0.578 | 0.553 |
| 8 °C - 12 °C | 5 | ––– | 0.277 |
| 8 °C - 16 °C | 5 | 0.272 | ––– |
| **Room Temperature Injectate** | | | |
| 18 °C - 25 °C | 10 | 0.592 | 0.607 |
| 18 °C - 25 °C | 5 | 0.290 | 0.295 |

* 3 ml injectate is not recommended.
*** $CC = (1.08)C_T(60)(V_I)$

The catheter may migrate into the distal pulmonary artery and spontaneous tip wedging may occur. To avoid this complication, pulmonary artery pressure should be monitored continuously with a pressure transducer and display monitor.

Forward advancement should never be forced if resistance is encountered.

### Patency

All pressure monitoring lumens should be filled with a sterile, heparinized saline solution (e.g. 500 I.U. heparin in 500 ml saline) and flushed at least once each half hour or by continuous slow infusion. If loss of patency occurs and cannot be corrected by flushing, the catheter should be removed.

### General

Keep pressure monitoring lumens patent by intermittent flush or continuous slow infusion with heparinized saline solution or use of a heparin lock using the provided injection caps with heparinized saline solution. Infusion of viscous solutions (e.g., whole blood or albumin) is not recommended, as they flow too slowly and may occlude the catheter lumen.

To use injection caps:

a. Disinfect injection caps before entry with syringe needle (see **Complications**).

b. Use a small bore needle (22 gauge (0.7 mm) or smaller) to puncture and inject through the injection caps.

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

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

## 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.

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

Invasive procedures involve some patient risks. Although serious complications are relatively uncommon, the physician is advised before deciding to use the catheter, to consider the potential benefits in relation to the possible complications.

The techniques for insertion, methods of using the catheter to obtain patient data information, and the occurrence of complications is well described in the literature.

Strict adherence to these instructions and awareness of risks reduces the incidence of complications.

Several known complications include:

**Perforation of the Pulmonary Artery**

Factors which are associated with the development of fatal pulmonary artery rupture are pulmonary hypertension, advanced age, cardiac surgery with hypothermia and anticoagulation, distal catheter tip migration, and arteriovenous fistula formation and other vascular traumas.

**Extreme care should therefore be exercised during the measurement of pulmonary artery wedge pressure in patients with pulmonary hypertension.**

**In all patients, balloon inflation should be limited to two respiratory cycles, or 10 to 15 seconds.**

**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 pulmonary artery infarction.

**Cardiac Arrhythmias**

Although usually transient and self-limiting, arrhythmias may occur during insertion, withdrawal, and repositioning of the tip from the pulmonary artery into the right ventricle. Whereas premature ventricular contractions are the most commonly observed 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. Use of prophylactic lidocaine should be considered to decrease 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**

Other complications include right bundle branch block and complete heart block, tricuspid and pulmonic valve damage, thrombocytopenia, pneumothorax, thrombophlebitis, nitroglycerin absorption, and thrombosis.

In addition, allergic reactions to latex have been reported. Physicians should identify latex sensitive patients and be prepared to treat allergic reactions promptly.

**Long Term Monitoring**

The duration of catheterization should be the minimum required by the patient's clinical state since the risk of thromboembolic and infection complications increases with time. The incidence of complications increases significantly with indwelling periods longer than 72 hours. Prophylactic systemic anticoagulation and antibiotic protection should be considered when long-term catheterization (i.e. over 48 hours) is required, as well as in cases involving increased risk of clotting or infection.

## 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 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.

Because of continuing product improvements, prices, specifications, and model availability are subject to change without notice.

These products are 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**

## Summary Guidelines for Safe Use of Balloon-tipped Pulmonary Artery Catheters

1. **Keep catheter tip centrally located in a main branch of the pulmonary artery:**
   - During insertion, inflate the balloon to the full recommended volume (1.5 ml) and advance the catheter to a pulmonary artery wedge position. Deflate the balloon.
   - To reduce or remove any redundant length or loop in the right atrium or ventricle, slowly pull the catheter back 2 to 3 cm.
   - Do not advance the catheter tip too far peripherally. Ideally, the catheter tip should be located near the hilum of the lungs. Remember, the tip migrates towards the periphery of the lungs during balloon inflation. Therefore, a central location before inflation is important.
   - Keep the tip at all times 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 toward the periphery of the pulmonary bed:**
   - Reduce any redundant length or loop in the right atrium or ventricle **at the time of insertion** to prevent subsequent peripheral migration (see No. 1).
   - Monitor the distal tip pressure continuously to ensure that the catheter is not inadvertently wedged with the balloon deflated (this may induce pulmonary infarction).
   - Check catheter position daily by chest X-ray film to detect peripheral placement. If migration has occurred, pull the catheter back to a central pulmonary artery position, carefully avoiding contamination of the insertion site.
   - 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 withdrawal may help reduce the amount of distal migration and may prevent permanent catheter wedging in the postbypass period. After termination of bypass, the catheter may require repositioning. Check the distal pulmonary artery tracing **before** inflating the balloon.
3. **Exercise caution when inflating the balloon:**
   - If "wedge" is obtained at volumes less than 1.0 ml, pull the catheter back to a position where the full or near-full inflation volume (1.0 to 1.5 ml) produces a wedge pressure tracing.
   - Check the distal pressure waveform before inflating the balloon. If the waveform appears dampened or distorted, do not inflate the balloon. The catheter may be wedged with the balloon deflated. Check catheter position.
   - When the balloon is reinflated to record wedge pressure, add the inflation medium ($CO_2$ or air) **slowly** under continuous monitoring of the pulmonary artery pressure waveform. Stop inflating **immediately** when the pulmonary artery tracing is seen to change to pulmonary artery wedge pressure. Remove the syringe to allow rapid balloon deflation, then reattach the syringe to the balloon lumen. Air should never be used for balloon inflation in any situation where air may enter the arterial circulation (see **Insertion Procedure**).
   - Never over-inflate the balloon beyond the maximum volume printed on the catheter shaft (1.5 ml). Use the volume-limited syringe provided with the catheter.
   - Do not use liquids for balloon inflation; they may be irretrievable and may prevent balloon deflation.
   - Keep the syringe attached to the balloon lumen of the catheter to prevent accidental injection of liquids into the balloon.
4. **Obtain a pulmonary artery occlusion "wedge" pressure only when necessary:**
   - If the pulmonary artery diastolic (PAD) and the wedge (PAW) pressures are nearly identical, wedging the balloon may not be necessary: measure PAD pressure instead of PAW as long as the patient's heart rate, blood pressure, cardiac output and clinical state remain stable. However, in states of changing pulmonary arterial and pulmonary venous tone (i.e., sepsis, acute respiratory failure, shock), the relationship between PAD and "wedge" may change with the patient's clinical condition. PAW measurement may be necessary.
   - Keep "wedge" time to a minimum (two respiratory cycles or 10 to 15 seconds), especially in patients with pulmonary hypertension.
   - Avoid prolonged maneuvers to obtain wedge pressure. If difficulties are encountered, give up the "wedge.
   - Never flush the catheter when the balloon is wedged in the pulmonary artery.
5. **Patients at highest risk of pulmonary artery rupture or perforation are elderly patients with pulmonary hypertension.** These are usually elderly patients who are undergoing cardiac surgery with anticoagulation and hypothermia. Proximal catheter tip location near the hilum of the lungs may reduce the incidence of pulmonary artery perforation.

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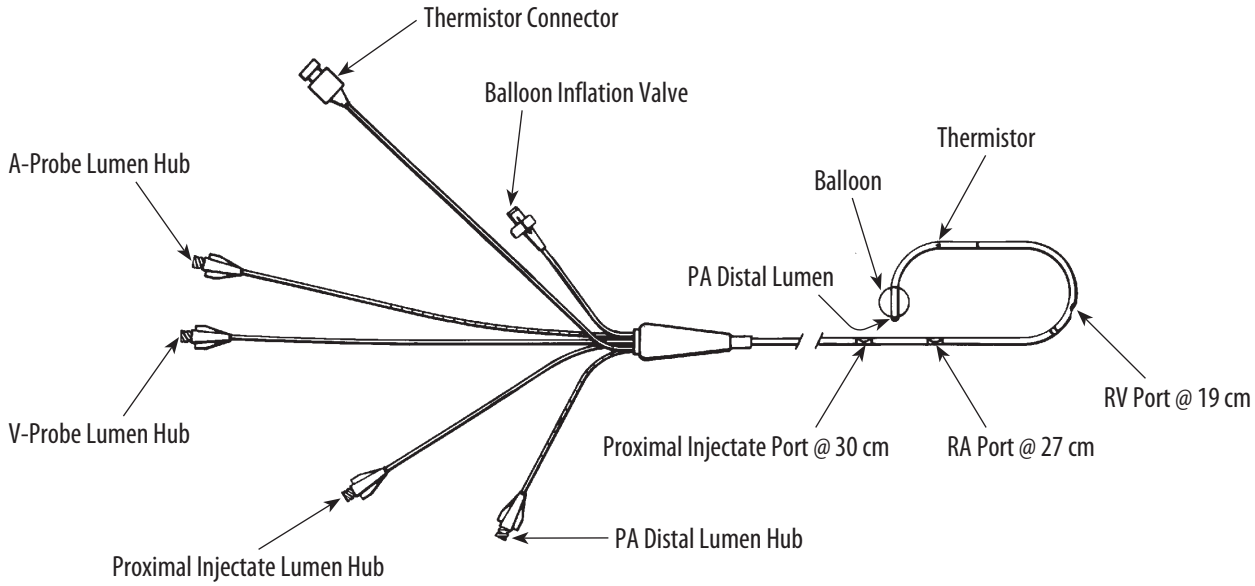


**Figure 2.** Swan-Ganz Thermodilution A-V Paceport Catheter (Model 991F8)

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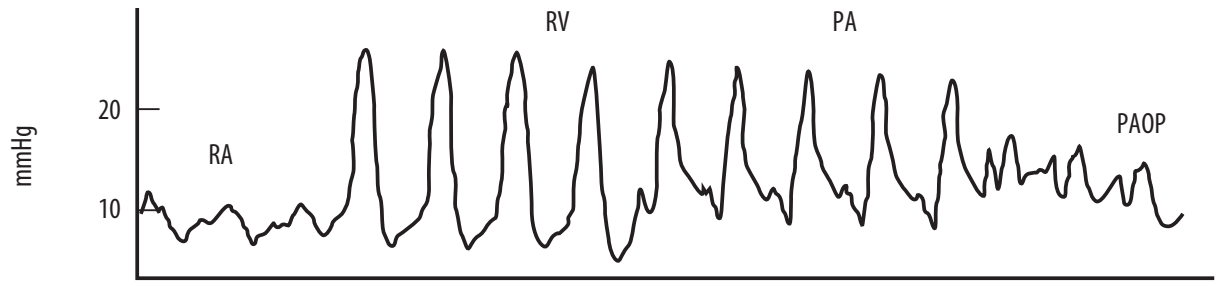


**Figure 3**

## 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 |  | CE conformity marking per European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. |
| | | eifu.edwards.com + 1 888 570 4016 | Follow Instructions for use on the website | | |

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

SGNHEMSL8x11.2

Edwards

EC REP

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