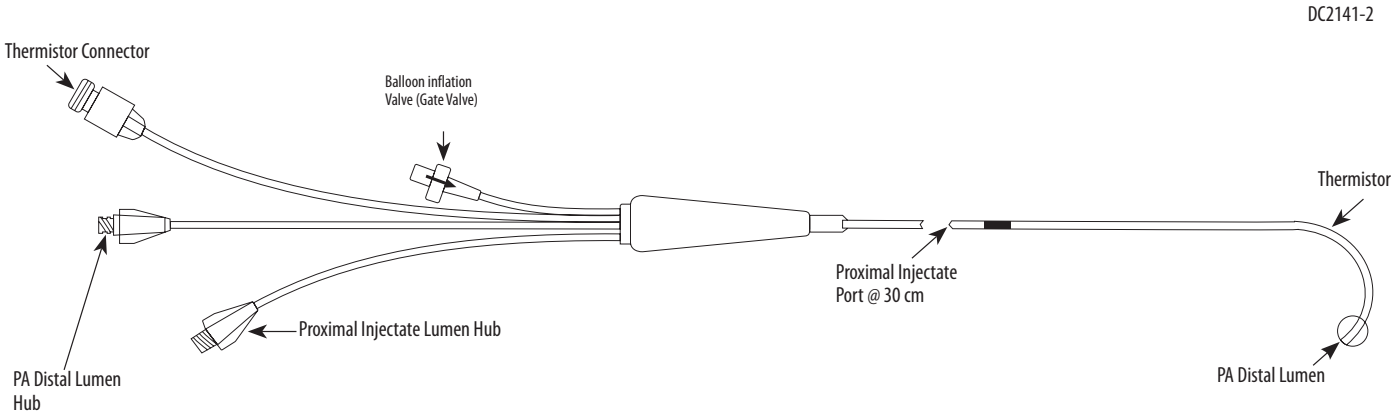
Edwards

Swan-Ganz

Thermodilution Catheters: 131NX7P, 131VNX7P, 141NX7P, 143TNX7 and 151NX7
True Size: 096NX6P, TS105NX5 and 132NX5



Swan-Ganz Thermodilution Catheter (Model 143TNX7)

Model 143TNX7 is illustrated. The models listed above contain some but not all of the features shown.

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

Not made with natural rubber latex.

For Single Use Only

For figure 1 please refer to page 5.

Description

The Swan-Ganz thermodilution catheters provide diagnostic information to rapidly determine hemodynamic pressures and cardiac output when used with a compatible cardiac output computer.

The Swan-Ganz Hi-Shore, CardioCath, and "S" Tip thermodilution catheters (Models 141NX7P and 151NX7 respectively) have the same functions as the standard Swan-Ganz thermodilution catheter (Models 131NX7P and 131VNX7P). The "S" Tip catheter (Model 151NX7) is designed for femoral vein insertion. The Swan-Ganz Hi-Shore thermodilution catheter (Model 141NX7P), is slightly stiffer than the standard Swan-Ganz catheter, and may be used when more torque control and maneuverability is needed (i.e., from the femoral approach). The CardioCath thermodilution catheter (Model 143TNX7) is made from the same material as the Swan-Ganz Hi-Shore TD catheter but is even stiffer due to the stiffening rod in one lumen. CardioCath catheter has a "C" tip bend.

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

Indications

Models: 131NX7P, 131VNX7P, 141NX7P, 143TNX7, 151NX7, 096NX6P, TS105NX5 and 132NX5

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.

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 intra-pulmonary 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.

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. Such action could lead to illness or an adverse event as the device may not function as originally intended.

Cleaning and resterilization will damage the integrity of the 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

Computation Constants

Model		131NX7P, 131VNX7P, 141NX7P and 151NX7	143TNX7	096NX6P	132NX5	TS105NX5
Injectate Temp (°C)	**Injectate Volume (ml)**	**Computation Constants (CC)*** **				
0 - 5	10	0.542	0.554	0.547	—	0.542
	5	0.247	0.259	0.259	0.270	0.255
	3	0.132	—	0.144	0.154	0.143
	1	—	—	—	0.037	—
19 - 22	10	0.578	0.587	0.582	—	—
	5	0.274	0.286	0.280	0.292	—
	3	0.154	—	0.161	0.170	—
	1	—	—	—	0.048	—
23 - 25	10	0.595	0.599	0.608	—	0.605
	5	0.287	0.291	0.305	0.307	0.297
	3	0.165	—	0.180	0.181	0.175
	1	—	—	—	0.055	—

Computation Constants for CO-Set+

Cold Injectate						
6 °C - 12 °C	10	0.561	0.569	0.558	—	0.552
8 °C - 16 °C	5	0.259	0.266	0.277	0.285	0.265
Room Temperature	10	0.608	0.589	0.607	—	0.589
18 °C - 25 °C	5	0.301	0.287	0.301	0.307	0.289

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

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 Hi-Shore thermodilution catheter (Model 141NX7P) may be helpful in these patients. 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 (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 catheter
2. Percutaneous sheath introducer and contamination shield
3. Compatible cardiac output computer, compatible injectate probe, and connecting cable or compatible computer
4. Sterile flush system and pressure transducers
5. Bedside ECG and 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 a means for temporary pacing.

Catheter Preparation

Use aseptic technique.

Note: Use of a contamination shield is recommended. Inflation of balloon prior to insertion into contamination shield may result in increased resistance through the contamination shield.

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

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

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

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.

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

1. Introduce the catheter into the vein through a sheath introducer using percutaneous insertion using modified Seldinger technique.
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 1 (on page 5) 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

Specifications

Function	Thermodilution				True Size		
Model Number	**131NX7P, 131VNX7P (Standard)**	**141NX7P (Hi-Shore)**	**143TNX7 (CardioCath)**	**151NX7 ("S" Tip)**	**096NX6P**	**132NX5****	**TS105NX5**
Usable Length (cm)	110	110	110	110	110	75	100
Catheter Body French Size	7F (2.3 mm)	7F (2.3 mm)	7F (2.3 mm)	7F (2.3 mm)	6F (2.0 mm)	5F (1.7 mm)	5F (1.7 mm)
Minimum Introducer Size	8F (2.7 mm)	8F (2.7 mm)	8F (2.7 mm)	8F (2.7 mm)	7F (2.3 mm)	6F (2.0 mm)	6F (2.0 mm)
Minimum Contamination Shield Size	7.5F (2.5 mm)	7.5F (2.5 mm)	7.5F (2.5 mm)	7.5F (2.5 mm)	6.5F (2.2 mm)	5.5F (1.8 mm)	5.5F (1.8 mm)
Diameter of Inflated Balloon (mm)	13	13	13	13	11	8	8
Balloon Inflation Capacity (ml)	1.5	1.5	1.5	1.5	1.1	0.7	0.7
Distance from Tip (cm)							
Injectate Port	30	30	30	30	30	15	24
Thermistor	4	4	4	4	4	1.5	-
Lumen Volume (ml)							
Distal Lumen	1.02	1.01	0.89	1.02	0.92	0.64	0.67
Injectate Lumen	0.81	0.81	0.73	0.81	0.74	0.57	0.58
Infusion Rate* (ml/min)							
Infusion (VIP) Lumen	-	-	-	-	5 (distal)	-	-
RV Infusion (VIP+) Lumen	-	-	-	-	7 (injectate)	-	-
Distal Lumen	-	-	-	-	-	-	1.7
Proximal Injectate Lumen	-	-	-	-	-	-	2.6
Recommended Guidewire Size							
Distal Lumen	0.025 in (0.64 mm)	0.025 in (0.64 mm)	0.025 in (0.64 mm)	0.025 in (0.64 mm)	0.025 in (0.64 mm)	0.020 in (0.51 mm)	0.018 in (0.46 mm)
Frequency Response Distortion at 10 Hz							
Distal Lumen	< 3 dB	< 3 dB	< 3 dB	< 3 dB	< 3 dB	< 3 dB	<3 dB

All specifications given are nominal values. A syringe is provided with each catheter.
* Using normal saline at room temperature, 1 m above insertion site, gravity drip.
**In situations where the insertion site or patient physiology requires a larger insertion distance, a longer catheter model or larger introducer size should be selected.

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.

3. Using the syringe provided, inflate the balloon with air to the maximum recommended volume. **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. After deflation, re-attach the syringe.

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

   Note: Immediately after inflation and prior to removing the syringe, the balloon may be manually aspirated to remove air after the syringe plunger has been pushed back by pressure from the balloon.

   Note: Before reinflation with 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 centimeters 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.

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.

   Precaution: Overtightening the proximal Tuohy-Borst adaptor 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.

Guidelines for Femoral Insertion

Fluoroscopy is recommended for femoral vein insertion.

Note: The "S" Tip catheter is designed for femoral vein insertion only.

Precaution: Femoral insertion may lead to a redundancy of the 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.

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 in positioning the catheter, a suitable 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 the duration of 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.

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-distension 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

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.

Catheter Contamination Shield

Secure distal Tuohy-Borst adapter to the catheter.

Extend the proximal end of the catheter contamination shield to desired length, and secure proximal Tuohy-Borst adapter to the catheter.

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. 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.

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

Invasive procedures involve some patient risks. Although serious complications are relatively uncommon, the physician is advised, before deciding to insert or 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 include 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-limited, 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 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.

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.

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 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

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

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

M5078-12

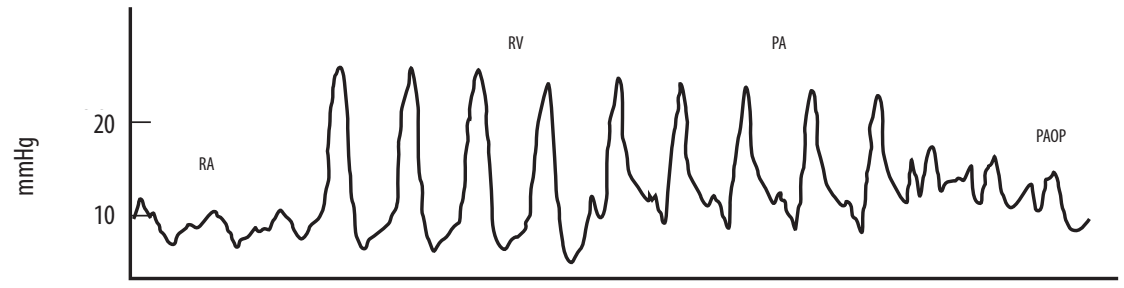


Figure 1. Standard Pressure Waveform showing RA-RV-PA-PAOP progression

Symbol Legend

	English		English		English
	Exterior Diameter		Sterilized Using Ethylene Oxide		MR Unsafe
	Usable Length		Sterilized Using Irradiation		MR Safe
	Recommended Guidewire Size	Rx only	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.		Do not resterilize
	Minimum Introducer Size		Manufacturer		Non-pyrogenic
	Minimum Contamination Shield Size				
	Catalogue Number		Date of Manufacture		Do not use if package is opened or damaged.
	Caution		Temperature Limitation		Authorized Representative in the European Community
	Single use		Humidity Limitation		Keep dry
	Quantity		Follow 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.
	Lot Number		Use By		

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

SGNLTXEMSL6x8.1

Edwards

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA
Made in USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

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10027425002 A
DOC-0123871 A