Edwards Lifesciences

Swan-Ganz

Flow-Directed Monitoring Catheters
Double Lumen: 111F7, 111F7P, S111F7, T111F7, 123F6, 123F6P, T123F6, 110F5, 116F4
Triple Lumen: 114F7, 114F7P

111F7, 123F6 and 114F7 are not available in EU.

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 figure 1 please refer to page 3.

Description

The family of Swan-Ganz flow-directed monitoring catheters provides a rapid, simple, and effective method for monitoring right heart pressures, sampling mixed venous blood, and infusing solutions. "S-Tip" models (i.e. model S111F7) have the same design and functions as a standard Swan-Ganz monitoring catheter with a tip specifically designed for femoral vein insertion.

Monitoring catheters are available in both double and triple lumen models. In double lumen catheters, the larger lumen terminates at the distal tip of the catheter and is used to monitor pulmonary artery and wedge pressures; the distal lumen may also be used for sampling of mixed venous blood and infusing solutions. The smaller lumen permits balloon inflation and deflation. Triple lumen monitoring catheters have the same capabilities as double lumen catheters with the additional (proximal) lumen for central venous pressure monitoring. Refer to the Specifications for proximal lumen port location by model.

Indications

Swan-Ganz flow-directed monitoring catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Secondary indications are for sampling blood and infusing solutions.

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.

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.

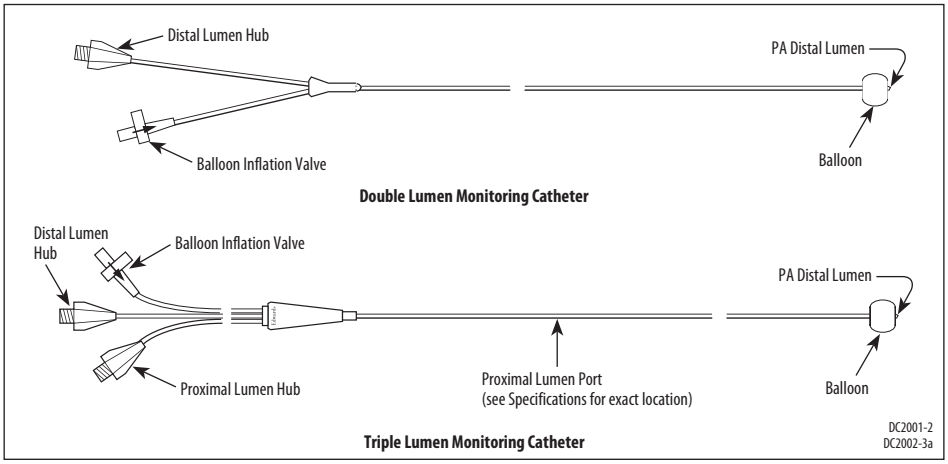
-Wolff-Parkinson-White syndrome and Ebstein's malformation, in which the risk of tachyarrhythmias is present.

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. 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

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

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 flow-directed monitoring catheter
2. Percutaneous sheath introducer and contamination shield
3. Sterile flush system and pressure transducers
4. 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 protective catheter sheath is recommended.

Precaution: Avoid forceful wiping or stretching of the catheter during testing and cleaning as not to break the optical fibers and/or 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 pressure monitoring lumens to the flush system and pressure transducers. Ensure that the lines and transducers are free of air.

Insertion Procedure

Swan-Ganz flow-directed 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: Should the catheter require stiffening during insertion, slowly perfuse the catheter with 5 ml to 10 ml of cold sterile solution 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:

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 3) 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 about 30 cm from the femoral vein.
3. Using the syringe provided, inflate the balloon with CO_2 or 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. 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 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.

   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.

   Precaution: Overtightening the proximal Tuohy-Borst adapter of the contamination shield may impair catheter function.

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

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

Note: Model S111F7 is designed for femoral vein insertion only.

Fluoroscopy is recommended for femoral vein insertion.

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

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.

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.

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.

Specifications

Swan-Ganz Monitoring Catheters	Triple Lumen 114F7, 114F7P	Double Lumen 111F7P, 111F7	S111F7	T111F7	123F6P, 123F6	110F5	116F4*	T123F6
Usable Length (cm)	110	110	110	110	110	110	60	110
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)	4F (1.3 mm)	6F (2.0 mm)
Body Color	Yellow	Yellow	Yellow	White	Blue	White	Pink	White
Depth Markings (cm)	10	10	10	10	10	10	10	10
Minimum Recommended 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)	5F (1.7 mm)	7F (2.3 mm)
Diameter of Inflated Balloon (mm)	13	13	13	13	10	11	8	13
Balloon Inflation Capacity (ml)	1.5	1.5	1.5	1.5	1.0	0.8	0.5	1.5
Distance from Proximal Port to Tip (cm)	30	–	–	–	–	–	–	–
Lumen Volume (ml)								
Distal Lumen	1.29	2.10	2.13	1.85	1.65	1.02	0.48	1.41
Proximal Lumen	1.03	–	–	–	–	–	–	–
Infusion Rate (ml/min)								
Distal Lumen	12	32	31	28	21	8	6	18
Proximal Lumen	16	–	–	–	–	–	–	–
Compatible Guidewire Distal Lumen								
(in.)	0.035	0.038	0.038	0.038	0.030	0.025	0.018	0.030
(mm)	0.89	0.97	0.97	0.97	0.76	0.64	0.46	0.76
Frequency Response Distortion at 10 Hz Distal Lumen	< 3 dB	< 3 dB	< 3 dB	< 3 dB	< 3 dB	< 3 dB	< 3 dB	< 3 dB

An "S" in the model number denotes an "S-Tip" configuration. A "T" in the model number denotes a "T-Tip" configuration.

MRI Information

MR **MR Safe**

The Swan-Ganz flow-directed monitoring catheter is made from non-metallic, non-conducting, and non-magnetic materials. Therefore, the Swan-Ganz flow-directed monitoring catheter is MR-safe, which is an item that poses no known hazards in all MR environments.

Precaution: The cables and transducers which connect the Swan-Ganz flow-directed monitoring catheters to monitors do contain metals and must be disconnected and removed from patient contact prior to performing the MRI procedure. Failure to do so may cause patient burns or unintentional removal of catheter from patient.

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 fatal pulmonary artery rupture include pulmonary hypertension, advanced age, cardiac surgery with hypothermia and anticoagulation, distal catheter tip migration, 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, cardiac arrhythmias may occur during insertion, withdrawal, or repositioning of the tip from the pulmonary artery into the right ventricle. 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.

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, nitroglycerin absorption, thrombophlebitis, thrombosis and heparin-induced thrombocytopenia.

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 non-pyrogenic 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.

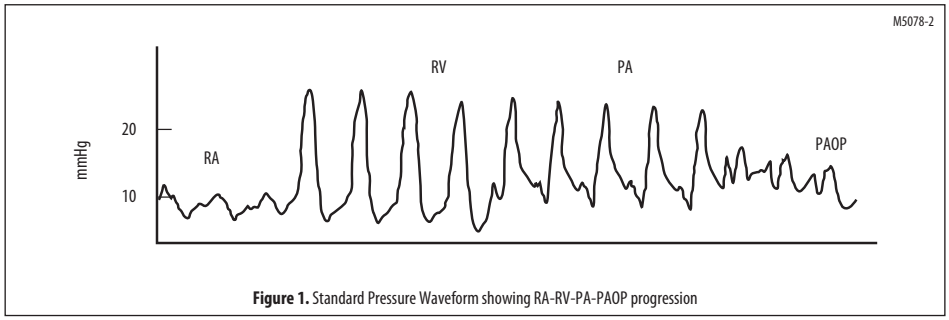


Figure 1. Standard Pressure Waveform showing RA-RV-PA-PAOP progression

Disposal

After patient contact, treat the device as biohazardous waste. Dispose of in accordance with hospital policy and local regulations.

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

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

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

Sterilized Using Ethylene Oxide

Symbol Legend

	English		English		English
	Number of Lumens	STERILE	Sterile		MR Unsafe
	Exterior Diameter	STERILE EO	Sterilized Using Ethylene Oxide	MR	MR Safe
cm	Usable Length	STERILE R	Sterilized Using Irradiation		MR Conditional
GW	Recommended Guidewire Size	STERILE	Sterile Using Steam or Dry Heat		Consult instructions for use
	Lumen Size	Rx only	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.		Consult instructions for use
REF	Catalogue Number		Manufacturer		Do not resterilize
I	Minimum Introducer Size		Date of Manufacture		Non-pyrogenic
	Caution	LATEX	Contains or presence of natural rubber latex		Type B Applied Part
	Single use	PHT	Contains phthalates		Type CF Applied Part
#	Quantity	SZ	Size		Do not use if package is opened or damaged.
LOT	Lot Number		No components of this package or the products it contains are made from natural rubber latex or dry natural rubber.		Open
	Use By		Temperature Limitation		Aspirate Balloon ~0.5 cc Before Introduction or Withdrawal.
	Inner Diameter		Humidity Limitation	EC REP	Authorized Representative in the European Community
BC	Balloon Capacity	eifu.edwards.com + 1 888 570 4016	Consult Instructions for use on the website eifu.edwards.com		CE conformity marking per European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
	Keep dry	eifu.edwards.com + 1 888 570 4016	Follow Instructions for use on the website eifu.edwards.com		

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

SGNHEMSL8x11.3

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