The Swan-Ganz Continuous Cardiac Output (CCO) thermodilution catheter series is for use in patients who require hemodynamic monitoring. They are intended to be used in conjunction with compatible cardiac output computer equipment to continuously measure cardiac output. When used with a compatible cardiac output computer, models 177F75N, 744F75, and 774F75 also measure mixed venous oxygen saturation. When used with the compatible cardiac output computer, models 177F75N, 744F75, and 774F75 also measure volumetric parameters, including right ventricular ejection fraction and end diastolic volume.

**Indications**

The primary indications for the Swan-Ganz CCO thermodilution catheter include:

- Acute heart failure
- Severe hypovolemia
- Complex circulatory situations
- Medical emergencies
- Adult respiratory distress syndrome
- Gram negative sepsis
- Drug intoxication
- Acute renal failure
- Hemorrhagic pancreatitis
- Intracardiac and post-operative management of high risk patients
- History of pulmonary or cardiac disease
- Fluid shifts (e.g., extensive intra-abdominal operations)
- Management of high-risk obstetrical patients
- Diagnosed cardiac disease
- Torsion
- Premature Separation of placenta
- Cardiac output determinations
- Differential diagnosis of mitral regurgitation and ventricular septal rupture
- Diagnosis of cardiac tamponade

Models with CEDV capabilities are also indicated for volumetric determinations. Secondary indications include the following:

- Blood Sampling
- Infusion of saline and dextrose solutions

**Contraindications**

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

**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.

The CCO/CEDV thermodilution catheter series is for use in patients who require hemodynamic monitoring. They are intended to be used in conjunction with compatible cardiac output computer equipment to continuously measure cardiac output. When used with a compatible cardiac output computer, models 177F75N, 744F75, and 774F75 also measure mixed venous oxygen saturation.

When used with the compatible cardiac output computer, models 177F75N, 744F75, and 774F75 also measure volumetric parameters, including right ventricular ejection fraction and end diastolic volume.

**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 1 and 2 please refer to page 4.

**Description**

The Swan-Ganz Continuous Cardiac Output thermoregulator catheters are flow-directed pulmonary artery catheters designed to make the monitoring of hemodynamic pressures and to provide continuous cardiac output. The pulmonary artery (PA) distal lumen terminates at the distal tip. The proximal injectate lumen terminates at a port located 26 cm from the distal tip. When the distal tip is located in the pulmonary artery, the proximal injectate port will reside in the right atrium or vena cava, allowing for bolus cardiac output injections, right atrial pressure monitoring, blood sampling, or infusion of solutions.

When used with a compatible cardiac output computer, the Swan-Ganz Continuous Cardiac Output (CCO) thermodilution catheter (Models 139F75, 746F8, and 777F8) allows for continuous calculation and display of cardiac output. To measure cardiac output continuously, a compatible cardiac output computer uses thermal energy emitted by the thermal filament located on the catheter to calculate cardiac output using thermoregulation principles. Alternatively, cardiac output can be measured by the traditional bolus thermodilution method.

When used with a compatible cardiac output computer, the Swan-Ganz CCO/CEDV catheter (Models 744F75, 774F75) allows for continuous calculation and display of cardiac output and mixed venous oxygen saturation. The CCO catheter (Models 139F75, 746F8, and 777F8) is designed to enable continuous end diastolic volume (CEDV) when used with the compatible cardiac output computer. To measure end diastolic volume continuously, the compatible cardiac output computer uses thermal energy emitted by the thermal filament located on the catheter, and an ECG monitor (preferably in a lead II configuration) “sensed” into the compatible cardiac output computer (refer to the operator’s manual for information regarding “sensing” techniques) to calculate ejection fraction using thermoregulation principles. CEDV is then derived from the ejection fraction and cardiac output measurements.

**Used Intended**

The CCO/CEDV thermoregulation catheter series is for use in patients who require hemodynamic monitoring. They are intended to be used in combination with clinical pressure monitoring equipment to measure right heart and pulmonary artery pressures, and with a compatible cardiac output computer to continuously measure cardiac output. Models 744F75, 774F8, and 777F8 are also capable of calculating the pulmonary arteriogram or right ventricular angiogram. Models 139F75, 746F8, and 777F8 are intended for use in patients who require hemodynamic monitoring. They are intended to be used in conjunction with compatible cardiac output computer equipment to continuously measure cardiac output. Models 744F75, 774F8, 777F8, and 778F8 also measure mixed venous oxygen saturation.

When used with the compatible cardiac output computer, models 177F75N, 744F75, and 774F75 also measure volumetric parameters, including right ventricular ejection fraction and end diastolic volume.
Specifications

<table>
<thead>
<tr>
<th>Models</th>
<th>139F75s</th>
<th>Models</th>
<th>744F75s</th>
<th>Models</th>
<th>746F8h, 771F7W</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Color</td>
<td>yellow</td>
<td>yellow</td>
<td>yellow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usable Length (cm)</td>
<td>110</td>
<td>110</td>
<td>110</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter Body</td>
<td>7.55 (2.3 mm)</td>
<td>7.55 (2.5 mm)</td>
<td>9 (2.7 mm)</td>
<td></td>
<td></td>
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<tr>
<td>Diameter of Inflated Balloon (mm)</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Required Introductory Size</td>
<td>8.55 (2.8 mm)</td>
<td>8.55 (2.8 mm)</td>
<td>9 (3.0 mm)</td>
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<tr>
<td>Balloon Inflation Capacity (ml)</td>
<td>1.5</td>
<td>1.5</td>
<td>1.5</td>
<td></td>
<td></td>
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<tr>
<td>Distance from Distal Tip to Thermistor</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<td></td>
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<tr>
<td>Distance from Distal Tip to Lumen Volumes (ml)</td>
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<td>10</td>
<td>10</td>
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<tr>
<td>Distal Lumen</td>
<td>0.96</td>
<td>0.96</td>
<td>0.96</td>
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<tr>
<td>Distal Portion of Lumen</td>
<td>0.8</td>
<td>0.95</td>
<td>0.85</td>
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<tr>
<td>Infusion Lumen</td>
<td>0.95</td>
<td>1.0</td>
<td>1.10</td>
<td></td>
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<tr>
<td>Balloon Inflation Syringe</td>
<td>3 ml</td>
<td>3 ml</td>
<td>3 ml</td>
<td></td>
<td></td>
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<tr>
<td>Frequency Response</td>
<td>0.025 in</td>
<td>0.018 in</td>
<td>0.018 in</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distortion at 10 Hz</td>
<td>(0.64 mm)</td>
<td>(0.46 mm)</td>
<td>(0.46 mm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal Lumen</td>
<td>&lt; 3 dB</td>
<td>&lt; 3 dB</td>
<td>&lt; 3 dB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usable Length (cm)</td>
<td>110</td>
<td>110</td>
<td>110</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catheter Looping might occur when excessive length has been inserted.</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</table>

Catheter Models and Functions

<table>
<thead>
<tr>
<th>Models</th>
<th>139F75s</th>
<th>744F75s</th>
<th>747F7W</th>
<th>774F8h</th>
<th>774F8h</th>
<th>777F8h</th>
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<tr>
<td>KCO</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>YCO</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>SeI</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>VIP</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>GEDV</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

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

Monitor Set-Up and Calibration for Mixed Venous Oxygen Saturation Monitoring

This section only applies to the following models: which have SVo2 capability: 744F75, 746F8h, 774F7W, and 777F8h.

The compatible cardiac output computer can be calibrated prior to catheter insertion by perfusing an in vitro calibration. When performing an in vitro calibration, do so before preparing the catheter (i.e., flushing the lumens). The catheter tip must not get wet before an in vitro calibration is performed. An in vivo calibration is required if an in vivo calibration is not done. In vivo calibration may be used to periodically recalibrate the monitor. Refer to the monitor operator’s manual for detailed calibration instructions.

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 to avoid breaking the thermistor wire. Deflate balloon before insertion.

Before the catheter is inserted, the following preparation procedure should be followed:

1. Perforate in vitro calibration (when measuring mixed venous oxygen saturation).
2. To open the catheter for calibration, peel back the top left perforated portion of the lid and fold diagonally according to the dotted fold line. In order to gain access to the catheter lumens for flushing, peel lid from the top right corner and fold according to the dotted fold line; otherwise, peel off the entire tray by peeling back the lid from the bottom right corner. Advance the catheter tip into the thorax is signaled by an increased respiratory fluctuation in pressure. Figure 2 (on page 4) shows the characteristic intracardiac and pulmonary waveform patterns.

Note: The catheter tip 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 left fibula from the left antecubital focus, 15 to 20 cm from the jugular vein, 10 to 15 cm from the subclavian vein, or about 30 cm from the femoral vein.

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 maximum recommended volume. Do not use liquid. Note that an effort 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. Note that an effort arrow on the gate valve indicates the “closed” position.

Compensation Constants for CO-Set+ Delivery System

<table>
<thead>
<tr>
<th>Injectate</th>
<th>Injectate</th>
<th>Volume (ml)</th>
<th>Computation Constants (CC)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 5</td>
<td>10</td>
<td>0.564</td>
<td>0.550</td>
</tr>
<tr>
<td>5 - 10</td>
<td>5</td>
<td>0.257</td>
<td>0.256</td>
</tr>
<tr>
<td>10 - 15</td>
<td>3</td>
<td>0.148</td>
<td>0.138</td>
</tr>
<tr>
<td>15 - 20</td>
<td>2</td>
<td>0.087</td>
<td>0.081</td>
</tr>
<tr>
<td>20 - 25</td>
<td>1</td>
<td>0.053</td>
<td>0.050</td>
</tr>
</tbody>
</table>

* Use normal saline at room temperature, 1 m above insertion site, limited to 1.5 ml limited to 1.5 ml limited to 1.5 ml.

**CC = (1.08)CT(60)(VI)
III = 0 - 5
III = 5 - 10
III = 10 - 15
III = 15 - 20
III = 20 - 25

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 2 (on page 4) shows the characteristic intracardiac and pulmonary waveform patterns.

Note: When the catheter tip 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 left fibula from the left antecubital focus, 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. Flushing before inflation with CO2 or air to the maximum recommended volume. Do not use liquid. Note that an effort arrow on the gate valve indicates the “closed” position.

Note: Inflation is usually associated with a feeling of resistance. Note that an effort arrow on the gate valve indicates the “closed” position.

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 maximum recommended volume.

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

Note: Avoid prolonged maneuvers to operate wedge pressure. If difficulties are encountered, give up the “wedge”.

5. Before removal with CO2 or air, completely deflate the balloon by removing the syringe and opening the gate valve.
Precaution: Do not pull the catheter across the pulmonary 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: Overinflating 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 recalc to the pulmonary artery valve and sink into the right ventricle, requiring that the catheter be repositioned.

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.

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 too far to prevent perforation. 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.

Insertion of the thermal filament beyond the pulmonary valve may result in erroneous continuous cardiac output measurements.

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 cardiodiaphysial bypass. Partial catheter withdrawal (2 to 5 cm) just before bypass should be considered, as it may help reduce distal migration and prevent permanent catheter wedge pathology. 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 re-inflation of the balloon (see Complications).

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 resonance. If no resonance 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 inflation of air or liquids into the balloon lumen.

Difficulties encountered, discontinue wedge measurements. In some cases involvement, pulmonary arterial end-diastolic pressure can often be substituted for pulmonary artery wedge pressure if the pressures are nearly identical, especially in patients with pulmonary hypertension. 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 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., 100 I.U. heparin in 500 ml saline) and flushed at least once every 8 hours or by continuous slow infusion. If loss of patency occurs and cannot be corrected by flushing, the catheter should be removed.

Continuous Cardiac Output Measurement
Continuous Cardiac output measurement is made by periodically warming the blood in the right atrium or ventricle with a known quantity of heat. The catheter thermodilutor detects the small change in blood temperature downstrom, and the compatible cardiac output computer makes a dilution curve via a modified Stewart-Hamilton indicator dilution equation. This measurement technique is used without additional instrument calibration, material preparation, or operator intervention. If confirmation of the displayed continuous cardiac output value is deemed necessary, perform an additional 15 second cardiac output measurement is recommended. Refer to the compatible cardiac output computer operator's manual for more information.

Bolus Thermodilution Method
Continuous thermodilution method is made by injecting an exact amount of physiological solution (saline or dextrose) of known temperature into the right atrium or superior vena cava and by using the thermistor in the pulmonary artery to detect the resultant change in blood temperature. Continuous cardiac output is inversely proportional to the area under the temperature-time curve. The accuracy of this method depends on the accuracy with which the quantity and temperature of the injectate are known. The accuracy of the thermodilution method correlates well with the dye dilution technique and with the direct Fick method.

Continuous Volumetric Measurement
Continuous thermodilution measurements are made by periodically warming the blood in the right atrium or ventricle with a known quantity of heat, and by sensing heat rate by a "scaled" ECG signal (see the appropriate operator's manual for information regarding "scaling" techniques). The catheter thermodilutor detects the small change in blood temperature downstream, and the compatible cardiac output computer makes an ejection fraction based on thermodilution principles. Subsequently, continuous stroke, end systolic and end diastolic volumetric measurements are derived from the ejection fraction and cardiac output measurements as follows:

\[
\text{ CESV = CEDV - CSV } \\
\text{ CSV = CCO/HR } \\
\text{ Where: } \\
\text{ CESV = Continuous Stroke Volume } \\
\text{ CCO = Continuous Cardiac Output } \\
\text{ HR = Heart Rate } \\
\text{ CESF = Continuous Ejection Fraction } \\
\text{ CEDV = Continuous End Diastolic Volume } \\
\text{ CSV = Continuous End Systolic Volume } \\
\]

This measurement technique is conducted without additional instrument calibration, material preparation or operator intervention. Refer to the compatible cardiac output computer operator's manual for more information.

MRI Information
MRI Unsafe

The Swan-Ganz device is MR unsafe as the result of the device containing latex rubber in the balloon is acted upon and deteriorated by the environment; therefore the device poses hazards in all MRI environments. The Swan-Ganz device is MR unsafe as the result of the device containing latex rubber in the balloon is acted upon and deteriorated by the environment; therefore the device poses hazards in all MRI environments.

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 package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize.

The packaging within is designed to avoid crushing of the catheter and to protect the balloon from exposure to the atmosphere. It is 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:

In the U.S. and Canada: (24 hours): 800 822 9837

Outside the U.S. and Canada: (24 hours): 949 250 2222

In the UK: (24 hours): 0870 606 2040 - Option 4

In Ireland:

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.
Sterilized Using Ethylene Oxide

Figure 1.

Figure 2. Standard Pressure waveform showing RA-RV-PA-PAOP progression
### Symbol Legend

<table>
<thead>
<tr>
<th>English</th>
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<th>English</th>
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</thead>
<tbody>
<tr>
<td>Number of Lumens</td>
<td>Sterile</td>
<td>MR Unsafe</td>
</tr>
<tr>
<td>Exterior Diameter</td>
<td>Sterilized Using Ethylene Oxide</td>
<td>MR Safe</td>
</tr>
<tr>
<td>Usable Length</td>
<td>Sterilized Using Irradiation</td>
<td>MR Conditional</td>
</tr>
<tr>
<td>Recommended Guidewire Size</td>
<td>Sterile Using Steam or Dry Heat</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>Lumen Size</td>
<td>Rx only</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>Catalogue Number</td>
<td>Manufacturer</td>
<td>Do not re-sterilize</td>
</tr>
<tr>
<td>Minimum Introducer Size</td>
<td>Date of Manufacture</td>
<td>Non-pyrogenic</td>
</tr>
<tr>
<td>Caution</td>
<td>Contains or presence of natural rubber latex</td>
<td>Type B Applied Part</td>
</tr>
<tr>
<td>Single use</td>
<td>Contains phthalates</td>
<td>Type CF Applied Part</td>
</tr>
<tr>
<td>Quantity</td>
<td>Size</td>
<td>Do not use if package is opened or damaged.</td>
</tr>
<tr>
<td>Lot Number</td>
<td>No components of this package or the products it contains are made from natural rubber latex or dry natural rubber.</td>
<td>Open</td>
</tr>
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<td>Use By</td>
<td>Temperature Limitation</td>
<td>Aspirate Balloon -0.5 cc Before Introduction or Withdrawal.</td>
</tr>
<tr>
<td>Inner Diameter</td>
<td>Humidity Limitation</td>
<td>Authorized Representative in the European Community</td>
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<td></td>
<td>Follow Instructions for use on the website</td>
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</table>

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

---

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DOC-0029495 B

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