



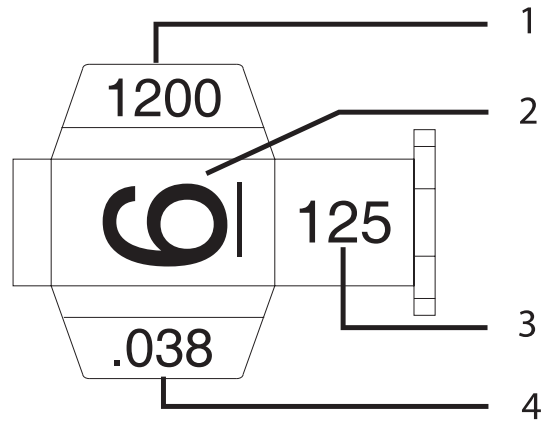
***Cordis***<sup>TM</sup>

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Instructions for Use









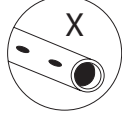
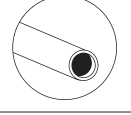



**INFINITI™ Ambi  
Angiographic Catheter**

Figure 1



**Explanation of symbols on labels and packaging:**

	<p><b>Lot number</b></p>
	<p><b>Caution</b></p>
	<p><b>Do not re-use</b></p>
	<p><b>Manufacturer</b></p>
	<p><b>Sterilized using ethylene oxide</b></p>
	<p><b>Consult instructions for use or consult electronic instructions for use</b></p>
	<p><b>Upper limit of temperature</b></p>
	<p><b>n units per box</b></p>
	<p><b>Caution: Federal (USA) law restricts this device to sale by or on order of a physician.</b></p>
	<p><b>Catalogue number</b></p>

	<p><b>Non-Pyrogenic</b></p>
	<p><b>Do not resterilize</b></p>
	<p><b>Use-by date</b></p>
	<p><b>Keep away from sunlight</b></p>
	<p><b>Keep dry</b></p>
	<p><b>Do not use if package is damaged and consult instructions for use</b></p>
	<p><b>Catheter with side holes</b></p>
	<p><b>Closed End with side holes</b></p>
	<p><b>Open End with side holes</b></p>
	<p><b>Open end, no side holes</b></p>
	<p><b>Single sterile barrier system; Sterilized using Ethylene Oxide</b></p>
	<p><b>Medical Device</b></p>
	<p><b>Maximum Pressure</b></p>

**STERILE. Sterilized with ethylene oxide gas. Non-pyrogenic. For one use only. Do not resterilize.**

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

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### **Description**

Cordis catheters are available in a broad variety of French sizes and configurations. These catheters combine an atraumatic tip with either a braided or nonbraided body.

### **Specifications**

The following specifications are identified on the catheter hub (refer to Figure 1):

1. maximum pressure rating (psi)
2. catheter outer diameter (F)
3. catheter length (cm)
4. maximum guidewire diameter (in.)

The color of the hub printing indicates the catheter French size as follows:

- |    |           |       |
|----|-----------|-------|
| 5F | (1.65 mm) | Grey  |
| 6F | (2.0 mm)  | Green |

### **Intended Purpose**

Cordis catheters are intended to deliver radiopaque contrast medium to selected sites in the vascular system.

### **Indications for Use**

Cordis catheters are indicated for enabling diagnosis of various pathologies by facilitating the positioning of diagnostic devices within the coronary and peripheral vasculature.

### **Patient Target Group**

The patient target group includes individuals that require diagnosis of various pathologies in the cardiac and peripheral vasculature. The patient target group of this device is based on the patient's anatomy and compatibility with the device.

### **Performance Characteristics**

The following characteristics are included on the hub of the device (See Figure 1):

- Maximum pressure rating (psi), catheter outer diameter (F), catheter length (cm), maximum guidewire diameter (in.).
- The information regarding the maximum pressure rating (psi), catheter tip shape, number of side holes, tip end shape (closed or open) are provided on the product label.

### **Contraindications**

None known.

### **Warnings**

- This product is designed and intended for single use. It is not designed to undergo reprocessing and re-sterilization after initial use.
- Reuse of this product, including after reprocessing and/or re-sterilization, may cause a loss of structural integrity which could lead to a failure of the device to perform as intended and may lead to a loss of critical labeling/use information all of which present a potential risk to patient safety.
- Do not expose to organic solvents.
- Do not use with Ethiodol™ or Lipiodol™ contrast media, or other such contrast media which incorporates the components of these agents.
- Do not exceed maximum pressure rating printed on product label and hub.

### **Precautions**

- This product is intended for use by professionals who have been trained to perform diagnostic and interventional catheterization procedures.
- Store in a cool, dark, dry place.
- Do not use if package is open or damaged.
- Do not use the catheter if the "Use By" date on the package label has expired.
- Do not resterilize.
- Exposure to temperatures above 54°C (130°F) may damage the catheter.
- To prevent damage to the catheter tip during removal from the package, grasp the hub and withdraw the catheter.
- Exercise care when removing guidewires from multiple-curve catheters.

- To prevent kinking of 5F (1.65 mm), use a guidewire when introducing the catheter through the catheter sheath introducer (CSI) and into the vasculature.
- Before use, flush all devices entering a blood vessel with sterile heparinized saline or a similar isotonic solution.
- Keep the catheter filled with either flushing solution or contrast medium while the catheter is in the vascular system and consider the use of systemic heparinization.
- Forcibly aspirate and flush the catheter with heparinized saline solution at least once every two minutes.
- The safety and effectiveness have not been demonstrated in patients who are pregnant or lactating and/or pediatric patients.

### **Complications**

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications. Complications may occur at any time during or after the procedure.

Possible complications include, but are not limited to the following:

- air embolism
- hematoma at the puncture site
- infection
- perforation of the vessel wall

### **Clinical Benefits**

Aid in successful cardiac and peripheral vasculature visualization during diagnostic catheter-based procedures.

### **Device Related Adverse Event Reporting**

Any adverse event (clinical incident) involving the Cordis INFINITI Ambi Angiographic Catheters should be reported to Cordis immediately. To report an incident in the U.S.A., call the Product Quality services Department at 1-800-327-7714.

### **Recommended Procedure**

Introduce the catheter into the blood vessel using a vascular entry technique of choice.

PTFE (Polytetrafluoroethylene) coated guidewires are recommended for use with Cordis angiographic catheters.

After use, all components used and packaging materials may be a potential biohazard. Handle and dispose of in accordance with the accepted medical practice and with applicable local, state and federal laws and regulations.

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