











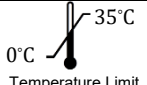


# Plato® 17 Microcatheter

## INTERNATIONAL SYMBOLS APPLICABLE TO PLATO® 17 MICROCATHETER

 REF Number Catalog	 Manufacturer	 LOT Batch Code	 Use By	 Non-pyrogenic	 Do not Reuse	 Do not use if package damaged
 Caution	 STERILE EO Sterilized using Ethylene Oxide	 Keep dry	 MR Unsafe	 Do not Resterilize	 0°C — 35°C Temperature Limit	

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

### Device Description:

The Scientia Vascular, Inc. Plato® 17 Microcatheter is a single lumen microcatheter constructed with a flexible polymer shaft of varying stiffness to aid in accessing the distal neuro and peripheral vasculature. The microcatheter has hydrophilic coating on the outer distal shaft to reduce friction during manipulation in vessels and has two radiopaque tip markers to facilitate fluoroscopic visualization. The Plato® 17 Microcatheter is not made with natural rubber latex. A peel-away introducer, ruler, and a steam shaping mandrel is included in the packaging.

	Dimensions		
	French	Inch	mm
Proximal O.D.	2.1	0.028	0.70
Distal O.D.	1.7	0.023	0.60
I.D.	---	0.017	0.43

**Contents:** One Plato® 17 Microcatheter with an introducer, ruler and tip shaping mandrel.

### Indications for Use:

The Plato 17 Microcatheter is intended for the introduction of therapeutic devices, infusion of diagnostic agents, such as contrast media, and delivery of embolization materials to the peripheral and neuro vasculature systems. The Plato 17 Microcatheter is not intended for use in the coronary vasculature.

### Contraindications:

None known.

### Potential Complications:

Potential complications include, but are not limited to: access site complications, allergic reaction, aneurysm rupture or perforation, death, emboli (air, foreign body, plaque, tissue, thrombus), hematoma, hemorrhage, infection, ischemia, nerve injury, neurological deficit, pain at insertion site, pseudoaneurysm, respiratory distress, seizure, stroke, transient ischemic attack, vessel dissection, vessel injury, vessel occlusion, vessel perforation, vessel rupture or perforation, vessel spasm, and vessel thrombosis.

### Adverse Events:

X-ray radiation exposure may cause adverse events including, but not limited to, alopecia, burns, cataracts, or delayed neoplasia (cancers).

### Warnings and Precautions

- The microcatheter system should be used only by physicians with a thorough understanding of angiography and/or percutaneous interventional procedures.
- Carefully inspect the microcatheter prior to use to verify the shape, size and condition are suitable for the specific procedure and for any damage such as kinks or bends. Any damage may decrease performance resulting in patient injury or death.
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- The Plato® 17 Microcatheter is supplied STERILE and non-pyrogenic for single use only. Inspect the pouch prior to use for any gaps in sterile barrier such as faulty seals or holes. Do not use if sterile barrier is damaged or package is opened. Do not reprocess or re-sterilize. Reprocessing or resterilizing increases the risks of patient infection and compromises device performance.
- Use only therapeutic/interventional devices, diagnostic agents, and embolization materials that have been cleared or approved for use in the intended target anatomy.
- Do not exceed the maximum injection pressure of 300 psi or the maximum allowable dynamic pressure of 300 psi.
- Use the microcatheter prior to the "Use By" date specified on the package.
- Avoid excessive wiping and wiping the device with dry gauze as this may damage the device coating.
- Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the coating, which could affect the device safety and performance.
- Avoid pre-soaking devices for longer than instructed, as this may impact the coating performance.
- Never advance or withdraw any device within the catheter against resistance until the cause of the resistance is determined.
- Discontinue use of microcatheter for infusion if increased resistance is noted. Resistance indicates possible blockage. Remove and replace blocked microcatheter immediately. Do not attempt to clear blockage by over-pressurization. Doing so may cause the microcatheter to rupture, resulting in vascular damage or patient injury.
- The Plato® 17 Microcatheter should be manipulated under fluoroscopy. Do not attempt to move the microcatheter without observing the resulting tip response. Movement of the microcatheter against resistance may result in damage to the microcatheter or injury to the patient.
- Limit exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors when possible.
- Exchange microcatheters frequently during lengthy procedures that require extensive guidewire manipulation or multiple guidewire exchanges.
- The Plato® 17 Microcatheter was evaluated for compatibility with agents that include contrast media, saline, dimethyl sulfoxide (DMSO), ethanol, and ethiodized oil (e.g. lipiodol). The use of these catheters for delivery of solutions other than the types that have been tested for compatibility has not been evaluated.
- The Plato® 17 Microcatheter was evaluated for the delivery of therapeutic devices, such as stents.
- The Plato® 17 Microcatheter is not compatible with stent retrievers. Use of these devices with the Plato® 17 Microcatheter could result in device damage that may lead to catheter failure and to enhance embolic risks.



- The Plato® 17 Microcatheter was evaluated for the delivery of embolization materials, such as embolic coils, embolic particles, and liquid embolic agents, including Onyx. The use of these catheters for delivery of other embolization materials has not been evaluated.
- The Plato® 17 Microcatheter has not been evaluated for compatibility with embolization materials containing n-BCA, such as Trufill. Use of these devices with the Plato® 17 Microcatheter could result in device damage that may lead to

- catheter failure and patient injury.
- Plato® 17 Microcatheters are not safe for use in or near Magnetic Resonance Imaging (MRI) equipment.

**Adverse Event Reporting:**

Please notify Scientia Vascular, Inc. immediately if a device malfunctions, patient complication or patient injury is experienced. Please retain any suspect device with its associated components and packaging. Please return all items to Scientia Vascular, Inc.

**Microcatheter Compatibility Information:**

Diagnostic agents, therapeutic devices, and embolization materials should be used in accordance with information provided by their respective manufacturer and labeling. The Plato® 17 Microcatheter should only be used with devices that are compatible with 0.017-inch inner diameter microcatheters per the manufacturer’s instructions. The Plato® 17 Microcatheter should only be used with large bore catheters that are compatible with 0.028-inch (2.1F) outer diameter microcatheters. Interface compatibility with the catheter should be carefully considered before use. The Plato® 17 Microcatheter has been verified to be compatible for use with polyvinyl alcohol (PVA) embolic particles up to 300µm-500µm in size. Consult table below.

Model	Working Length (cm)	Maximum Guidewire Diameter inch (mm)	Minimum Guiding Catheter ID inch (mm)
Plato 17	160	0.014 in (0.36mm)	0.038 in (1.00mm)

**Instructions for Use:**

1. For straight tip Plato® 17 Microcatheters,
  - Before removing the microcatheter from the packaging hoop, flush the hoop with a heparinized saline solution through the luer fitting connected to the end of the packaging hoop. Repeat if friction is felt when attempting to remove the catheter.
2. For pre-shaped tip Plato® 17 Microcatheters,
  - Remove packaging and tip shape retention mandrel from microcatheter tip and discard. Gently remove the catheter from packaging hoop and inspect to verify that it is undamaged.

**Cautions:** The tip shape retention mandrel is for packaging only and not intended for use inside the human body. The accessories are not intended for use inside the human body.

3. Wet the hydrophilic outer shaft of the microcatheter. Do not allow the hydrophilic coating on the catheter to dry. Flush the lumen of the microcatheter with a heparinized saline solution.
4. Steam Shaping Mandrel Instructions (if necessary)
  - Remove the steam shaping mandrel from card and insert the straight length into the distal tip of the microcatheter.
  - Bend the shaping mandrel to an exaggerated shape to allow for relaxation.
  - Hold shaping mandrel/tip directly over a steam source for approximately 30 seconds to set the shape.
  - Remove from heat source and allow the catheter tip to cool in either air or liquid prior to removing the shaping mandrel.
  - Remove shaping mandrel from the microcatheter tip and discard; multiple shaping is not recommended.
  - Carefully inspect the microcatheter prior to use to verify the shaping did not damage the tip. If any damage is identified, do not use the microcatheter.
5. Place an appropriate guiding catheter using standard technique. Attach Rotating Hemostasis Valve (RHV) to the guiding catheter luer connection and maintain a continuous flush.
6. Carefully insert an appropriate guidewire into the microcatheter.
7. Loosen RHV and carefully introduce microcatheter and guidewire assembly through the guide catheter RHV using the peel away introducer. Tighten the RHV valve around the microcatheter just enough to prevent back flow, but not so tightly as to inhibit microcatheter advancement. Remove the peel away introducer from the microcatheter shaft by retracting the introducer from the RHV and pulling the tab.
8. Tighten the valve around the microcatheter to prevent backflow, but not to inhibit microcatheter advancement.
9. Advance the guidewire and the microcatheter to the selected target site by alternately advancing the guidewire and then tracking the microcatheter over the guidewire.
10. To infuse through the microcatheter, remove the guidewire from the microcatheter, connect a 3cc (3cm<sup>3</sup>) or larger syringe and infuse as required.
11. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

**Microcatheter Flow Rates:**

Catheter	Working Length (cm)	Dead Space Volume [cm <sup>3</sup> ]	Injection Pressure	Approximate Flow rate [ml/sec.]			
				Saline	76% Contrast / Saline (50/50) Viscosity @ 20°C: 2.9 cP	61% Contrast Viscosity @ 20°C: 8.8 cP	76% Nonionic Contrast Viscosity @ 20°C: 20.9 cP
Plato 17	160	0.38	100psi	0.33	0.12	0.04	0.02
			300psi	0.81	0.37	0.14	0.06



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