Socrates® 38 Catheter

NOTE: This catheter has two separate indications for use. Read the Instructions for Use carefully.

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

Socrates® 38 Catheter for Use as part of the Socrates® Aspiration System

Device Description
The Scientia Vascular Socrates® Aspiration System features a single lumen catheter constructed with a flexible polymer shaft of varying stiffness to aid in accessing vasculature. The catheter has hydrophilic coating (90 cm) on the outer distal shaft to reduce friction during manipulation in vessels and has a radiopaque tip marker to facilitate fluoroscopic visualization. The system also includes Socrates® Aspiration Tubing to facilitate connection from the catheter to a compatible suction pump. The Socrates® 38 Catheter and Socrates® Aspiration Tubing are not made with natural rubber latex. A rotating hemostasis valve is included in the packaging.

	Outer Diameter			Inner Diameter		Length	
	French	Inch	mm	Inch	mm	Inch	cm
Socrates® 38 Catheter (156 cm)	**4**	**0.053**	**1.35**	**0.038**	**0.96**	**61.4**	**156**
Socrates® 38 Catheter (127cm)	**4**	**0.053**	**1.35**	**0.038**	**0.96**	**50**	**127**
Socrates® Aspiration Tubing	**N/A**	**0.188**	**4.78**	**0.110**	**2.79**	**100**	**254**

Indications for Use
Socrates® 38 Catheter
As part of the Socrates® Aspiration System, the Socrates® 38 Catheter with a compatible suction pump is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral -M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

Socrates® Aspiration Tubing
As part of the Socrates® Aspiration System, the Socrates® Aspiration Tubing is indicated to connect the Socrates® 38 Catheter to a compatible suction pump.

Contraindications
None known.

Potential Complications
Potential complications include, but are not limited to: access site complications, allergic reaction, dissection or perforation, death, emboli (air, foreign body, plaque, tissue, thrombus), inability to completely remove thrombus, hematoma, hemorrhage, infection, ischemia, neurological deficit, pain at insertion site, pseudoaneurysm, respiratory distress, seizure, stroke, transient ischemic attack, arteriovenous fistula, 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).

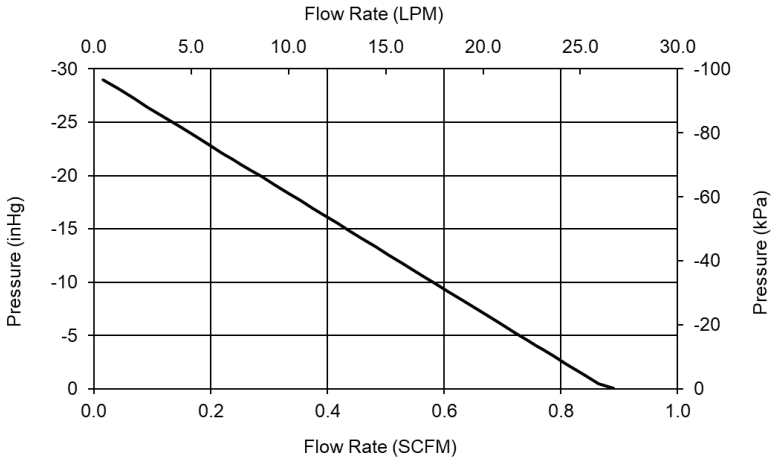
Warnings
- The Socrates® Aspiration System should be used only by physicians with a thorough understanding of angiography and/or percutaneous interventional procedures and treatment of acute ischemic stroke.
- Do not use in arteries with diameters smaller or equal to the outer diameter of the Socrates® 38 Catheter. Refer to the table above for dimensional information.
- Carefully inspect the catheter prior to use to verify the 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 Socrates® Aspiration System 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.
- The Socrates® 38 Catheter tips are not steam shapeable.
- Do not perform more than three (3) clot retrieval attempts with the Socrates® Aspiration System.
- Avoid wiping the device with gauze as this may damage the device coating.
- Avoid excessive wiping of the coated device.
- 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.
- Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- Never advance or withdraw any device within the catheter against resistance until the cause of the resistance is determined.
- Discontinue use of catheter for infusion if increased resistance is noted. Resistance indicates possible blockage. Remove and replace blocked catheter immediately. Do not attempt to clear blockage by over-pressurization. Doing so may cause the catheter to rupture, resulting in vascular damage or patient injury.
- The Socrates® 38 Catheter should be manipulated under fluoroscopy. Do not attempt to move the catheter without observing the resulting tip response. Movement of the catheter against resistance may result in damage to the catheter or injury to the patient.
- The Socrates® 38 Catheter should not be used with automated high-pressure contrast injection equipment as it may damage the device or injure the patient.
- The Socrates® 38 Catheter has not been evaluated for compatibility with stent retriever devices and should not be used in combination with stent retrievers, as the combined use could damage the catheter or result in patient injury.
- When performing aspiration, ensure that the Socrates® Aspiration Tubing clamp is open for only the minimum time needed to remove the thrombus. Do not aspirate for more than 300 continuous seconds (5 minutes) when no clot is engaged with the catheter. Excessive aspiration or failure to close the Socrates® Aspiration Tubing clamp when aspiration is complete can result in device malfunction.

Aspiration Pump Compatibility

- The Socrates® Aspiration System is to be used with a portable vacuum pump designed for use in the hospital setting that is capable of providing a constant vacuum between -20 inHg and -29 inHg. Figure 1 represents a sample pressure-flow curve for a compatible suction pump. Review manufacturer's specific instructions and performance specifications to ensure pump compatibility with the Socrates® Aspiration System.

Figure 1 – Pump Pressure-Flow Performance Curve for Compatible Vacuum Pumps



Precautions

- Use the devices prior to the “Use By” date specified on the package.
- 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.
- Maintain a constant infusion of appropriate flush solution.
- Administration of anticoagulants and antiplatelets, medical management, and acute post stroke care should follow hospital guidelines. Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practices.

- The Socrates® 38 Catheter was evaluated for compatibility with solutions that include contrast media and heparinized saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility has not been evaluated.
- Socrates® catheters are not safe for use in or near Magnetic Resonance Imaging (MRI) equipment.

Adverse Event Reporting

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

Catheter Compatibility Information

Model	Working Length (cm)	Maximum Guidewire Diameter inch (mm)	Minimum Guiding Catheter ID inch (mm)
Socrates® 38 Catheter	127cm	0.035 in (0.89mm)	0.058 in (1.47mm)
Socrates® 38 Catheter	156cm	0.035 in (0.89mm)	0.058 in (1.47mm)

Instructions for Use

1. Remove packaging and rotating hemostasis valve, as applicable. Using a heparinized saline solution, flush the packing hoop using the attached luer. Next, flush the inner lumen of the Socrates® 38 Catheter through the hub of the device.
2. Gently remove the catheter from packaging hoop and inspect to verify that it is undamaged. Remove the Socrates® Aspiration Tubing from the packaging and inspect to verify that it is undamaged.
   Cautions: The accessories are not intended for use inside the human body.
3. Wet the hydrophilic outer shaft of the Socrates® 38 Catheter. Do not allow the hydrophilic coating on the catheter to dry.
4. Place an appropriate guiding catheter using standard technique. Attach Rotating Hemostasis Valve (RHV) to the guiding catheter luer connection and maintain a continuous flush.
5. Attach the RHV to the Socrates® 38 Catheter.
6. Carefully insert an appropriate guidewire into the Socrates® 38 Catheter.
7. Loosen RHV and carefully introduce Socrates® 38 Catheter and guidewire assembly through the guide catheter RHV. Tighten the RHV valve around the Socrates® 38 Catheter just enough to prevent back flow, but not so tightly as to inhibit catheter advancement.
8. Tighten the valve around the guidewire to prevent backflow, but not to inhibit advancement.
9. Advance the guidewire and the Socrates® 38 Catheter to the site of the thrombus by alternately advancing the neurovascular guidewire and then tracking the Socrates® 38 Catheter over the guidewire.
10. Once at the site of the thrombus, completely remove the guidewire.
11. Attach the aspiration tubing to a compatible aspiration pump. Ensure clamp on tubing is engaged and allow the aspiration pump to run for at least one minute prior to use and confirm that the aspiration gauge reads -20inHg to -29inHg [-67.7 kPa to -98.2 kPa].
12. Connect the Socrates® Aspiration Tubing to the side port on the RHV.
13. Open the clamp on the aspiration tubing and slowly retract the Socrates® 38 Catheter until completely removed from the patient. To stop aspiration, close the clamp on the Socrates® Aspiration Tubing.

Note: The maximum number of times to engage and retrieve the thrombus by the Socrates® 38 Catheter should not exceed three (3) attempts.

14. Obtain a post-treatment angiogram by injecting contrast media through the guide catheter.
15. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

Note: If injection through the Socrates® 38 Catheter is necessary, remove the support catheter and guidewire and aspirate the Socrates® 38 Catheter lumen prior to injection. Do not use automated high-pressure injection equipment with the Socrates® 38 Catheter as it may damage the device or injure the patient.

Socrates® 38 Catheter for Use as a Neuro and Peripheral Vascular Access Catheter

Device Description

The Scientia Vascular Socrates® 38 Catheter is a single lumen catheter constructed with a flexible polymer shaft of varying stiffness to aid in accessing vasculature. The catheter has hydrophilic coating (90 cm) on the outer distal shaft to reduce friction during manipulation in vessels and has a radiopaque tip marker to facilitate fluoroscopic visualization. The Socrates® 38 Catheter is not made with natural rubber latex. A rotating hemostasis valve is included in the packaging.

	Outer Diameter			Inner Diameter		Length	
	French	Inch	mm	Inch	mm	Inch	cm
Socrates® 38 Catheter (156 cm)	**4**	**0.053**	**1.35**	**0.038**	**0.96**	**61.4**	**156**
Socrates® 38 Catheter (127cm)	**4**	**0.053**	**1.35**	**0.038**	**0.96**	**50**	**127**

Indications for Use
The Socrates® 38 Catheter is indicated for use in facilitating the insertion and guidance of an appropriate microcatheter or diagnostic agents into a selected blood vessel in the peripheral or neuro vasculature. The Socrates® 38 Catheter 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, dissection or perforation, death, emboli (air, foreign body, plaque, tissue, thrombus), inability to completely remove thrombus, hematoma, hemorrhage, infection, ischemia, neurological deficit, pain at insertion site, pseudoaneurysm, respiratory distress, seizure, stroke, transient ischemic attack, arteriovenous fistula, 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
- The Socrates® 38 Catheter should be used only by physicians with a thorough understanding of angiography and/or percutaneous interventional procedures.
- Do not use in arteries with diameters smaller or equal to the outer diameter of the Socrates® 38 Catheter. Refer to the table above for dimensional information.
- Carefully inspect the catheter prior to use to verify the 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 Socrates® 38 Catheter 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.
- The Socrates® 38 Catheter tips are not steam shapeable.
- Use only compatible microcatheters/guidewires and diagnostic agents that have been cleared or approved for use in the intended target anatomy.
- Avoid wiping the device with gauze as this may damage the device coating.
- Avoid excessive wiping of the coated device.
- 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.
- Failure to abide by the warnings in this labeling might result in damage to the device coating, which may necessitate intervention or result in serious adverse events.
- Never advance or withdraw any device within the catheter against resistance until the cause of the resistance is determined.
- Discontinue use of catheter for infusion if increased resistance is noted. Resistance indicates possible blockage. Remove and replace blocked catheter immediately. Do not attempt to clear blockage by over-pressurization. Doing so may cause the catheter to rupture, resulting in vascular damage or patient injury.
- The Socrates® 38 Catheter should be manipulated under fluoroscopy. Do not attempt to move the catheter without observing the resulting tip response. Movement of the catheter against resistance may result in damage to the catheter or injury to the patient.
- The Socrates® 38 Catheter should not be used with automated high-pressure contrast injection equipment as it may damage the device or injure the patient.
- The Socrates® 38 Catheter has not been evaluated for compatibility with therapeutic devices and should not be used in direct combination with therapeutic devices, as the combined use could damage the catheter or result in patient injury.

Precautions
- Use the devices prior to the “Use By” date specified on the package.
- 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.
- Maintain a constant infusion of appropriate flush solution.
- Administration of anticoagulants and antiplatelets, medical management, and acute post stroke care should follow hospital guidelines. Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practices.
- The Socrates® 38 Catheter was evaluated for compatibility with solutions that include contrast media and heparinized saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility has not been evaluated.
- Socrates® catheters are not safe for use in or near Magnetic Resonance Imaging (MRI) equipment.

- The Socrates® 38 Catheter may remain in situ for no longer than 24 hours.

Adverse Event Reporting

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

Catheter Compatibility Information

Model	Working Length (cm)	Maximum Microcatheter/Guidewire Device OD inch (mm)	Minimum Guiding Catheter ID inch (mm)
Socrates® 38 Catheter	127cm	0.035 in (0.89mm)	0.058 in (1.47mm)
Socrates® 38 Catheter	156cm	0.035 in (0.89mm)	0.058 in (1.47mm)

Catheter Dead Space Volume

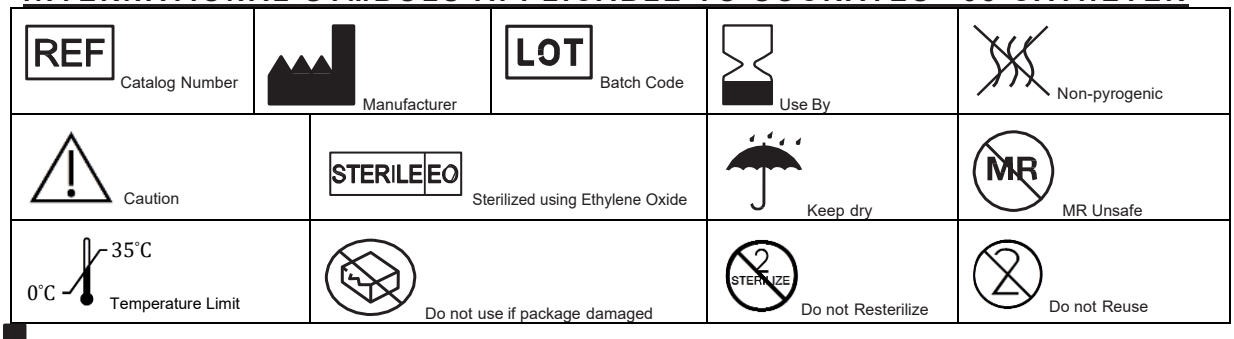
Catheter	Working Length (cm)	Dead Space Volume (cm^3)
Socrates® 38 Catheter	156	1.21
Socrates® 38 Catheter	127	1.03

Instructions for Use

1. Remove packaging and rotating hemostasis valve, as applicable. Using a heparinized saline solution, flush the packing hoop using the attached luer. Next, flush the inner lumen of the Socrates® 38 Catheter through the hub of the device.
2. Gently remove the catheter from packaging hoop and inspect to verify that it is undamaged.
   Cautions: The accessories are not intended for use inside the human body.
3. Wet the hydrophilic outer shaft of the catheter. Do not allow the hydrophilic coating on the catheter to dry.
4. Place an appropriate guiding catheter using standard technique. Attach Rotating Hemostasis Valve (RHV) to the guiding catheter luer connection and maintain a continuous flush.
5. Attach the RHV to the Socrates® 38 Catheter.
6. Carefully insert an appropriate guidewire or compatible microcatheter and guidewire assembly into the Socrates® 38 Catheter.
7. Loosen RHV and carefully introduce Socrates® 38 Catheter and microcatheter and/or guidewire assembly through the guide catheter RHV. Tighten the RHV valve around the Socrates® 38 Catheter just enough to prevent back flow, but not so tightly as to inhibit catheter advancement.
8. Tighten the valve around the microcatheter and/or guidewire to prevent backflow, but not to inhibit advancement.
9. Advance the microcatheter and/or guidewire and the Socrates® 38 Catheter through the vasculature to the desired location. by alternately advancing the neurovascular microcatheter and/or guidewire and then tracking the Socrates® 38 Catheter over the microcatheter and/or guidewire.
10. Remove the microcatheter and/or guidewire prior to the introduction of diagnostic agents.
11. To infuse through the catheter, connect a 3cc ($3cm^3$) or larger syringe and infuse as required.
12. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

Note: Do not use automated high-pressure injection equipment with the Socrates® 38 Catheter as it may damage the device or injure the patient.

INTERNATIONAL SYMBOLS APPLICABLE TO SOCRATES® 38 CATHETER



Manufacturer

Scientia Vascular, INC
2460 South 3270 West
West Valley City, Utah 84119 USA
Tel: +1 (888) 385-9016

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