AGILE DEVICES

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Agile Devices Angler®21 Steerable, Deflectable Microcatheter

Instructions for Use (IFU)

⚠ ***Important Information: Please read before use.***

Agile Devices Angler®21 Steerable, Deflectable Microcatheter

CAUTION

Federal law restricts this device to sale by or use under the order of a physician.

CONTENTS

One Agile Devices Angler®21 Steerable, Deflectable Microcatheter

WARNING

Do not use this device for any purpose other than the stated intended use.

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Agile Devices representative.

For single use only. Do not re-use, re-process or re-sterilize as this may lead to changes in material characteristics which may impact the strength of the device and compromise device performance which may result in patient injury, illness or death. Re-use of single use devices can also cause cross- contamination leading to patient infection or transmission of infectious disease(s) from on patient to another. Contamination of the device may also lead to patient injury, illness or death.

After use, dispose of product and packaging per institutional guidelines for biohazardous medical waste.

DEVICE DESCRIPTION

The Agile Devices Angler®21 Steerable, Deflectable Microcatheter is a variable stiffness, single lumen microcatheter designed to access small tortuous vasculature. It has a steerable articulating deflectable tip and as a hydrophilic polymer coating over the distal 80cm which gives lubricity when wet. Tip deflection is controlled using a manual steering mechanism / handle external to the body. On-plane bi-directional tip deflection is achieved via coaxial movement of the inner versus the outer shaft which bends a distal covered flat wire. Material injection is achieved via syringe connection to the luer at the proximal end of the catheter.

The Agile Devices Angler®21 Steerable, Deflectable microcatheter has a maximum outside diameter of 0.0394” (3F). It has an inside diameter of 0.021” and has two radiopaque marker bands on the distal tip and at the deflection point to facilitate fluoroscopic visualization.

It is compatible with guiding catheters with ID down to 0.043”. The microcatheter lumen is compatible with steerable guidewires up to 0.018”, and particles up to 500µm or embolic spheres up to 700µm, with a burst pressure rating up to 1000 psi.

The outer surface of the distal 80cm segment of these microcatheters has a hydrophilic coating. The proximal end of the steering mechanism / handle incorporates a standard luer which connects with either a rotating hemostatic valve (RHV) or Y-adapter.

Compatibility Information

Interface compatibility between any microcatheter, such as accessories and diagnostic, embolic or therapeutic agents for infusion, should be carefully considered before use. Consult table below.

Table 1. Agile Devices Angler®21 Steerable, Deflectable Microcatheter Compatibilities

				EMBOLICS for 0.021” I.D.	
Microcatheter	**Guidewire**	**Guide Catheter**	**Coils**	**Particles**	**Spherical**
Agile Devices Angler®21 Steerable, Deflectable Microcatheter	Max. Diam. 0.018 in (0.46 mm)	Min. I.D. 0.043 in (1.09 mm) ≥ 5F 0.038 in (0.97mm) (See Compatibility Sheet in Each Package)	0.018 in (0.47 mm)	≤ 500 Microns Emboli	≤ 700 Microns Microspheres

User Information

The intended users of Agile Devices Angler®21 Steerable, Deflectable Microcatheters are physicians trained in percutaneous, intravascular techniques and procedures. Operators should be trained in microcatheter and embolization procedures.

INTENDED USE / INDICATIONS FOR USE

The Agile Devices Angler®21 Steerable, Deflectable Microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the sub-selective region has been accessed, the microcatheter can be used for the controlled infusion of diagnostic agents and delivery of embolic or therapeutic devices. Use only contrast media and therapeutic devices that have been cleared or approved for use in the intended target area.

CONTRAINDICATIONS

- Patients in the acute phase of myocardial infarction
- Patients with serious serum electrolyte imbalance
- Patients who in prior procedures have developed an adverse reaction to the injection of contrast media
- Patients with coagulopathy or those whose blood has suffered a serious change in coagulation capability
- Patients who cannot lie on their back on the operating table because of congestive heart failure or some respiratory disorder
- Patients with mental disease or those who are not expected to lie quietly during angiography
- Pregnant, neonatal, or pediatric patients
- The Agile Devices Angler®21 Steerable, Deflectable Microcatheter is contraindicated for delivery of liquid embolic agents

NOTES

If package is opened or damaged when received, do not use. Visually inspect the device for damage, kinks, bends or breaks. If an abnormality is detected which could interfere with appropriate device use, do not use the device. Please notify your sales representative or contact Agile Devices directly.

Use of this device is restricted to trained healthcare professionals.

WARNINGS

THIS DEVICE IS INTENDED FOR ONE USE ONLY. Discard after each procedure.

Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance may result in damage or separation of the microcatheter or guidewire tip, or vessel perforation.

The infusion pressure with this microcatheter should not exceed 1000 psi (6895 kPa). Infusion pressure in excess of this maximum may result in microcatheter rupture, possibly resulting in patient injury. If flow through the microcatheter becomes restricted, do not attempt to clear the microcatheter lumen by infusion.

Use of excessive force to manipulate the microcatheter against resistance can cause a shaft fracture. Take care not to over-torque the microcatheter, and to relieve any tension before withdrawal by rotating the microcatheter in the opposite direction.

Operators should take all necessary precautions to limit X-radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible

PRECAUTIONS

- This device should only be used by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Diagnostic, embolic, or therapeutic agents are to be used in accordance with specifications outlined by the manufacturer.
- Do not use a product after the expiration date.
- Prior to use, carefully examine the unit to verify that the sterile package or products has not been damaged in the shipment.
- Take care not to damage or drop the product or accessories when removing them from the package.
- Prior to a procedure, all equipment to be used for the procedure should be carefully examined to verify proper function and integrity.
- Before removing the microcatheter from the carrier hoop, flush the hoop with 25cc of heparinized saline to aid in removal and activate the hydrophilic coating. Do not allow the microcatheter to dry once it has been hydrated.
- The following practices should be avoided during device preparation or use that could result in damage of the hydrophilic coating over the distal 80cm of the device: Avoid wiping the device with dry 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 maycause 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.
- Potential x-ray exposure complications include alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia. The probability of these complications increases as the procedure time and the number of procedures increase.
- Inspect the microcatheter and all accessory devices prior to use for any surface irregularities, bends or kinks. Also, exercise care in handling them during the procedure to reduce the possibility of accidental damage. Do not use any devices that are damaged.
- Do not introduce the microcatheter without guidewire support as this may cause damage to the catheter. Introduce the microcatheter and wire either directly through a fully opened Tuohy borst or, if placing directly through an introducer sheath, use a cheater device through the valve so as to not damage the distal tip.
- When the microcatheter and/or guidewire are in the body, they should be manipulated only under fluoroscopy. Do not attempt to move the microcatheter and/or guidewire without observing the resultant tip response.
- To avoid guidewire damage and possible shearing of plastic, do not withdraw or manipulate the guidewire through a metal needle cannula.
- Extensive guidewire manipulation during lengthy procedures and the use of embolic agents may require the exchange of new microcatheters in place of the used microcatheters.
- Because the microcatheter may be advanced into narrow sub-selective vasculature, repeatedly assure that the microcatheter has not be advanced so far as to interfere with its removal.
- Do not power inject through the hemostatic valve.
- Make sure to warm contrast media to 37ºC before use.

- Excessive tightening of the hemostatic valve onto the microcatheter shaft or guidewire may result in damage to the microcatheter and/or abrasion of the coating of the wire.
- Excessive tightening of the torque device onto the guidewire may result in abrasion of the coating of the wire.
- It is recommended that a continuous saline flush be maintained between the microcatheter and the guidewire during the procedure. Flushing prevents contrast crystal formation and/or clotting on the guidewire and in the catheter lumen.
- If other interventional devices are used with the microcatheter, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that device.
- Always verify tip response under fluoroscopy and the position of the proximal portion of the microcatheter, to avoid shaft coiling and/or fracture.
- If resistance is felt during rotations or deflection of the microcatheter and there is no visible tip response, stop and rotate / deflect in the opposite direction to release tension.
- Should the shaft fracture under too much tension, attempt to advance a guidewire through the fracture point and past the distal lumen, or retract the microcatheter into the guiding catheter. Then withdraw the system in a smooth motion, minimizing any rotation or torquing.

POTENTIAL COMPLICATIONS / ADVERSE EVENTS

The Adverse Events include, but are not limited to the following:

- Access Site Complications
- Allergic Reaction
- Aneurysm Perforation or Rupture
- Death
- Embolism or Air Embolism
- Hematoma / Hemorrhage
- Infection
- Ischemia
- Neurological Deficits
- Pseudoaneurysm
- Stroke
- Transient Ischemic Attack
- Vascular Thrombosis
- Vessel Occlusion
- Vasospasm
- Vessel Trauma (dissection, perforation, rupture)

STORAGE

Recommended storage conditions: Keep in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Preparation for Use

1. Verify that the device is suitable for use by checking the expiration date and ensuring the packaging and sterile barrier are still intact.
2. Using standard sterile technique, transfer the carrier hoop from the pouch into the sterile field.
3. Before removing the microcatheter from the carrier hoop, flush the carrier hoop with 25cc of heparinized saline to aid in the removal and activate the hydrophilic coating. The luer fitting attached to the carrier hoop should be used to facilitate flushing. Once the product is hydrated, do not allow it to dry.
4. Remove the microcatheter from the carrier hoop. First undock (pop-up) the proximal clear hub from the holder and then carefully pull the distal white part of the handle out of the tapered hoop connecting tube. If resistance is felt when removing the catheter, re-flush the carrier hoop with heparinized saline or place in a saline bath. Do not reinsert the product into the carrier hoop.
5. Connect a Y-Adapter to the microcatheter hub.
6. Test the tip deflection handle mechanism without a guidewire in place to make sure the mechanism is working properly outside of the patient.
7. Carefully remove the guidewire from its packaging and prepare it in accordance to the manufacturer's instructions. Carefully insert and advance the guidewire into the microcatheter. A guidewire introducer may be used to facilitate introduction of the guidewire.
8. Place the appropriate guiding catheter using standard technique. Refer to Table 1: Agile Devices Angler®21 Steerable, Deflectable Microcatheter Compatibilities.

Instructions for Use

1. Flush the microcatheter I.D. fully through the luer (Figure 1) and flush the carrier hoop through the luer (Figure 2) to wet the outer hydrophilic coating with 25cc of heparinized saline before insertion, Be sure to keep the microcatheter and other devices sufficiently flushed and hydrated throughout the procedure.

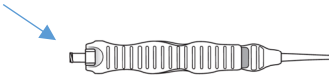


Figure 1 Handle Luer

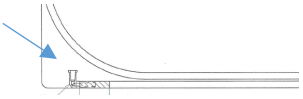


Figure 2 Hoop Flush Luer

2. Insert the guidewire into the handle luer then align the distal tip of the guidewire to the distal tip of the microcatheter.

   Caution: Do not introduce the microcatheter without guidewire support as this may cause damage to the proximal shaft of the catheter.

3. Carefully insert the microcatheter-guidewire assembly into the fully opened guiding catheter Tuohy Borst or directly into the introducer sheath using a cheater to open the valve, so as not to damage the microcatheter tip in the valve.
4. If desired, install a torque device by slipping it over the proximal end of the guidewire. When it is positioned over the desired location on the guidewire, secure it in place by tightening the cap. The torque device may be repositioned or removed by loosening the re-tightening the cap.
5. Advance the microcatheter-guidewire assembly to the selected vascular site by alternately advancing the guidewire and then tracking the microcatheter over the guidewire. The microcatheter can be tracked over a guidewire in order to access distal tortuous vasculature or advanced independently using the tip deflection mechanism to select target vessels.
6. The tip of the microcatheter can be deflected in vivo and torqued into the target vessel using the handle on the proximal end of the device. The Agile Devices Angler®21 Steerable, Deflectable microcatheter is packaged with the grteen handle thumbpad in the neutral position with a straight tip. The user can push the thumbpad forward or back to deflect tip distal tip in both directions. Then the guidewire can be pushed further into the target site, and the catheter can be straightened and tracked over it.

   Caution: When manipulating or deflecting the microcatheter, always do so under fluoroscopy to observe the resultant tip response.
7. Before infusing, completely remove the guidewire from the microcatheter.
8. Connect a syringe with infusate or introduce embolic materials to the microcatheter luer and infuse as required. For all agents, refer to the manufacturer's instructions for use.
9. If during the procedure additional treatment sites are necessary, the microcatheter can be repositioned by reinserting the guidewire, or by deflecting, torquing and maneuvering the microcatheter.

   Caution: Always verify tip response under fluoroscopy and the position of the proximal portion of the microcatheter, to avoid shaft coiling and/or fracture.

   Caution: If resistance is felt during rotation of the microcatheter and there is no visible tip response, stop and rotate in the opposite direction to release tension.

   Caution: Should the shaft fracture under too much tension, attempt to advance a guidewire through the fracture point and past the distal lumen, or retract the microcatheter into the guiding catheter. Then withdraw the system in a smooth motion, minimizing any rotation and torquing.
10. Repeat steps 7-9 as necessary until the procedure is complete.

ADVERSE EVENT REPORTING

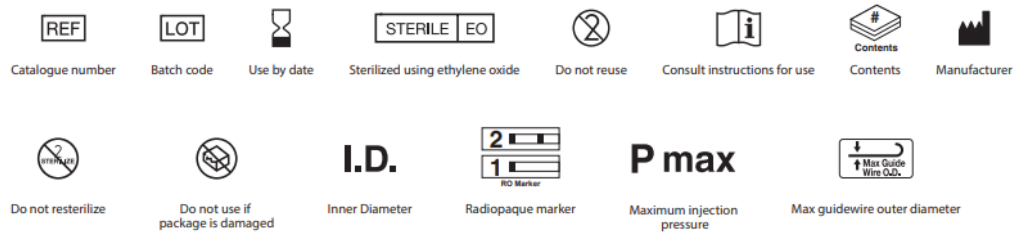
Please notify your Agile Devices representative immediately if a device malfunction or patient complication or injury is experienced or suspected. Please make every attempt to retain any suspect device, its associated components, and their packaging for return to Agile Devices.

Table 2. Operational Information

Microcatheter: 3F Max O.D. and 0.021" I.D. (distal 80cm hydrophilic coated)	Useable Length (cm)	Tip Deflection Length (cm)	Max Infusion Pressure (psi [KPa])	Distance Between 1st and 2nd Marker Band (cm)	Dead Space / Fill Volume
Agile Devices Angler®21 Steerable, Deflectable Microcatheter	130	1.7	1000 (6895)	1.4	0.40cc
	147	1.7	1000 (6895)	1.4	0.45cc

Microcatheter:	Flow Rate Distilled Water 1cP at 300psi	Flow Rate 37°C ISOVUE300 Contrast 4.7cP at 300psi	Average Pull Deflection Angle (Straight)	Average Push Deflection Angle (Straight)
Agile Devices Angler®21 Steerable, Deflectable Microcatheter	1.52 ml/sec	0.53 ml/sec	180 degrees	180 degrees

Symbols:



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