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

WARNINGS

Limited testing has been performed with solutions such as contrast media, and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.

Not intended for use with power injectors.

If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace catheter.

Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could dislodge a clot, perforate a vessel wall, or damage the device.

PRECAUTIONS

Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Do not use a device that has been damaged in any way. Damaged device may cause complications.

To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.

Use the product prior to the “Use By” date printed on the label.

To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.

Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.

Table 1. Compatibility Information

<table>
<thead>
<tr>
<th>Catheter</th>
<th>Inner Diameter (mm) (in)</th>
<th>Outer Diameter F (mm) (in)</th>
<th>Effective Length (cm)</th>
<th>Overall Length (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AXS Catalyst 5</td>
<td>1.47 (0.058)</td>
<td>Prox: 5.6F (1.86) [0.073] Dist: 5.3F (1.76) [0.069]</td>
<td>115, 132</td>
<td>120, 137</td>
</tr>
<tr>
<td>AXS Catalyst 6</td>
<td>1.52 (0.060)</td>
<td>Prox: 6.0F (2.01) [0.079] Dist: 5.4F (1.81) [0.071]</td>
<td>132</td>
<td>137</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Accessory</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotating Hemostatic Valve (RHV)</td>
<td>7 cm</td>
</tr>
<tr>
<td>Tuohy Borst valve with sideport</td>
<td>3.5 cm</td>
</tr>
</tbody>
</table>

INTENDED USE/INDICATIONS FOR USE

The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.

CONTRAINDICATIONS

None known.
ADVERSE EVENTS
Potential adverse events associated with the use of catheters or with the endovascular procedures include, but are not limited to:
- Access site complications
- Allergic reaction
- Aneurysm perforation
- Aneurysm rupture
- Death
- Embolism (air, foreign body, plaque, thrombus)
- Hematoma
- Hemorrhage
- Infection
- Ischemia
- Neurological deficits
- Pseudoaneurysm
- Stroke
- Transient Ischemic Attack
- Vasospasm
- Vessel dissection
- Vessel occlusion
- Vessel perforation
- Vessel rupture
- Vessel thrombosis

Adverse Event Reporting
Please notify your Stryker Neurovascular representative immediately if a device malfunctions 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 Stryker Neurovascular.

HOW SUPPLIED
Stryker Neurovascular products are sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

Do not use if package is opened or damaged.
Do not use if labeling is incomplete or illegible.

Handling and Storage
Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS
Required Additional Items
- Continuous flush set up

PREPARATIONS FOR USE
1. Set-up continuous flush through sheath or guide catheter lumen.
2. Select an appropriately sized catheter based on intended procedure and anatomy.
3. Gently remove contents from pouch using standard sterile technique

Caution: Flush the packaging hoop prior to removal of product to activate the hydrophilic coating of the catheter. Once hydrated, do not allow to dry.

4. Gently remove the catheter and accessories from the hoop and inspect prior to use to verify that they are undamaged. If any damage, replace with a new device.
5. Attach compatible RHV or Tuohy Borst valve based on intended procedure and associated devices, then flush RHV/Tuohy Borst valve and catheter lumen.
6. Set up continuous flush through catheter.

DIRECTIONS FOR USE
1. Gently insert catheter tip through a compatible sheath or guide catheter and over an appropriately sized guidewire.

(Optional) Use the peel-away introducer sheath to assist in insertion of the catheter tip into the sheath/guide catheter valve. Once the catheter is inserted, retract and remove the peel-away introducer sheath.

2. Under fluoroscopic guidance, advance the catheter through the vasculature to the desired location.

Recommended Aspiration Procedure
1. Tighten the RHV/Tuohy Borst valve to prevent backflow.
2. Attach a partially filled 60mL syringe or aspiration system to catheter.
3. Apply aspiration to the catheter during withdrawal of the retrieval device.
4. If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove catheter under aspiration and flush catheter outside of patient. If flush is unsuccessful, replace catheter.
5. Continue aspirating until retriever and microcatheter are withdrawn from the catheter.

Note: If withdrawal of the retrieval device is difficult, simultaneously withdraw the catheter, microcatheter and retriever as a unit into the sheath/guide catheter under continuous aspiration. Remove sheath/guide catheter if necessary.

Table 2. Flow rate

<table>
<thead>
<tr>
<th>Media (100%)</th>
<th>Size</th>
<th>Approximate Average Flow Rate at 43.5 psi (300 kPa), (ml/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saline</td>
<td>0.058 x 115</td>
<td>438</td>
</tr>
<tr>
<td></td>
<td>0.058 x 132</td>
<td>405</td>
</tr>
<tr>
<td></td>
<td>0.060 x 132</td>
<td>445</td>
</tr>
<tr>
<td>Omnipaque®-300 (Non-Ionic Contrast)</td>
<td>0.058 x 115</td>
<td>158</td>
</tr>
<tr>
<td></td>
<td>0.058 x 132</td>
<td>141</td>
</tr>
<tr>
<td></td>
<td>0.060 x 132</td>
<td>156</td>
</tr>
<tr>
<td>MD-76R (Ionic Contrast)</td>
<td>0.058 x 115</td>
<td>103</td>
</tr>
<tr>
<td></td>
<td>0.058 x 132</td>
<td>91</td>
</tr>
<tr>
<td></td>
<td>0.060 x 132</td>
<td>102</td>
</tr>
</tbody>
</table>
WARRANTY

Stryker Neurovascular warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Stryker Neurovascular’s control directly affect the instrument and the results obtained from its use. Stryker Neurovascular’s obligation under this warranty is limited to the repair or replacement of this instrument and Stryker Neurovascular shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Stryker Neurovascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Stryker Neurovascular assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

Omnipaque is a trademark of GE Healthcare.